UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., and WAKE FOREST UNIVERSITY HEALTH SCIENCES	§	
Plaintiffs,	§	
VS.	§	**CIVIL ACTION NO. SA-03-CA-0832-RF**
BLUESKY MEDICAL CORPORATION, MEDELA AG, MEDELA, INC., and PATIENT CARE SYSTEMS, INC.	§	
Defendants.	§	

PLAINTIFFS' FIFTH AMENDED COMPLAINT

Plaintiffs, Kinetic Concepts, Inc., KCI Licensing, Inc., and KCI USA, Inc. (collectively, "KCI"), and Wake Forest University Health Sciences (individually, "Wake Forest") and (collectively, "Plaintiffs") file this Fifth Amended Complaint for damages and injunctive relief against BlueSky Medical Corporation ("BlueSky"), Richard S. Weston, Medela AG, Medela, Inc. and Patient Care Systems, Inc. ("PCS") (collectively, "Defendants"). In support of their Fifth Amended Complaint, Plaintiffs allege as follows:

I. PARTIES

1. Plaintiff Kinetic Concepts, Inc. is a Texas corporation with its principal place of business in San Antonio, Texas. Kinetic Concepts, Inc., by and through its subsidiaries, is a leader in the development, manufacture and distribution of specialty therapeutic medical devices.

2. Plaintiff KCI USA, Inc. ("KCI USA") is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. KCI USA is a wholly owned subsidiary of Kinetic Concepts, Inc.

3. Plaintiff KCI Licensing, Inc. ("KCI Licensing") is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. KCI Licensing is a wholly owned subsidiary of Kinetic Concepts, Inc.

4. Plaintiff Wake Forest is a non-profit corporation organized under the laws of the State of North Carolina having its principal place of business at Medical Center Boulevard, Winston-Salem, North Carolina 27157-1023. Wake Forest is a wholly-controlled subsidiary of Wake Forest University.

5. Defendant BlueSky is a California corporation, incorporated in April of 2002, with its principal place of business in La Costa, California. BlueSky has been served with process and has filed an answer.

6. Defendant Richard S. Weston is the president of BlueSky and served as president and director of BlueSky during the relevant time period in this lawsuit. Weston has been served with process and has filed an answer.

7. Defendant Medela AG is a Swiss company having its principal place of business at Lattchstrasse 4, 6341 Baar/Switzerland. Medela AG has been served with process and has filed an answer.

8. Defendant Medela, Inc. is a Delaware corporation with its principal place of business at 1101 Corporate Dr., McHenry, Illinois 60050. Medela, Inc. has been served with process and has filed an answer. Defendants Medela AG and Medela, Inc. are wholly owned

subsidiaries of Medela Holding AG, such that Medela AG and Medela, Inc. (collectively "Medela") are affiliates of one another.

9. Defendant PCS is a Texas corporation having its principal place of business at 5802 Gardendale Dr., Houston, Texas 77092. PCS is a distributor of BlueSky's products and has an office in San Antonio, Texas. PCS has been served with process and has filed an answer.

II. JURISDICTION AND VENUE

10. This case arises under the federal patent, trademark and unfair competition laws, 35 U.S.C. § 1 *et seq.* and 15 U.S.C. § 1050 *et seq.*, and therefore this Court has jurisdiction under 28 U.S.C. §§ 1331, 1338(a)(b). This Court has subject matter jurisdiction over the state law claims pursuant to the doctrine of supplemental jurisdiction.

11. This Court has personal jurisdiction over the Defendants. Defendants regularly conduct business in this District and have committed acts of infringement and other torts alleged herein within the state of Texas and within this judicial district.

12. Venue is proper in this district under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and 1400(b) because the acts and transactions constituting the violations alleged herein, occurred in part in this judicial district and because the Defendants transact business in this judicial district. Venue is also proper in this district under 28 U.S.C. § 1391(c) because Defendants BlueSky, Medela and PCS are corporations that are subject to personal jurisdiction in this district.

III. BACKGROUND

13. Kinetic Concepts, Inc., by and through its subsidiaries KCI USA and KCI Licensing (collectively, "KCI"), is a leader in the development, manufacture and distribution of

specialty therapeutic medical devices. KCI is a Medicare participating supplier, providing medical equipment to Medicare beneficiaries throughout the Untied States.

14. Several of KCI's product lines feature products that provide wound care benefits for patients. KCI's wound care product lines include variations of the Vacuum Assisted Closure® System ("V.A.C.® System"). The designations "V.A.C." and "Vacuum Assisted Closure" are federally registered trademarks of KCI Licensing, Inc. A true and correct copy of U.S. Trademark Reg. No. 1,982,349 for the mark "V.A.C." is attached hereto as **Exhibit "A"**. A true and correct copy of U.S. Trademark Reg. No. 2,657,666 for the mark "VACUUM ASSISTED CLOSURE" is attached hereto as **Exhibit "B"**. The V.A.C. System is marketed and sold by KCI under both the registered V.A.C.® mark and the registered Vacuum Assisted Closure® mark.

15. The V.A.C. System is comprised of a negative pressure wound therapy pump unit, a porous dressing for application over an open wound, an occlusive adhesive drape placed over the dressing and sealed to the skin around the wound, and a disposable canister. The V.A.C. System has been very effective and represents a significant technological advance in wound healing.

16. The commercialization of the V.A.C. System marked a drastic departure from the simple application of suction that has long been used to facilitate the removal of excessive fluid that naturally pools in wounds. The unique V.A.C. System dramatically revolutionized wound care by providing effective treatment for difficult-to-treat and chronic wounds.

17. The V.A.C. System incorporates certain novel features and characteristics invented by researchers working on behalf of Wake Forest University Health Sciences in Winston-Salem, North Carolina. In recognition of the technological advances made by these

researchers, the U.S. Patent and Trademark Office issued U.S. Patent No. 5,636,643 ("'643 patent") and 5,645,081 ("'081 patent"), which were subsequently assigned to Wake Forest. A true and correct copy of the '643 patent is attached hereto as **Exhibit "C"**. A true and correct copy of the '081 patent is attached hereto as **Exhibit "J"**.

18. The '643 patent, entitled "Wound Treatment Employing Reduced Pressure," was duly and lawfully issued on June 10, 1997, and is extant and enforceable until its expiration date of June 10, 2014. Wake Forest is the true and record owner of the '643 patent.

19. The '081 patent, entitled "Method of Treating Tissue Damage and Apparatus for Same," was duly and lawfully issued on July 8, 1997, and is extant and enforceable until its expiration date of June 10, 2014. Wake Forest is the true and record owner of the '081 patent.

20. Kinetic Concepts, Inc. is the exclusive licensee of the '643 and '081 patents, by virtue of a written license agreement effective October 6, 1993 with Wake Forest. Pursuant to that license agreement, KCI has the exclusive worldwide right to make, have made, use, lease and sell products incorporating the inventions covered by the '643 and '081 patents.

21. In recognition of additional technological advances, the U.S. Patent and Trademark Office has also issued U.S. Patent No. 4,969,880 (the "'880 patent"). The '880 patent, entitled "Wound Dressing and Treatment Method," was duly and lawfully issued on November 13, 1990. A true and correct copy of the '880 patent is attached hereto as **Exhibit "D"**.

22. All right, title and interest in and to the '880 patent was assigned to Kinetic Concepts, Inc. by written assignment dated August 16, 1994 and recorded in the Patent and Trademark Office on June 10, 1996 at Reel 8119 and Frame 0119. KCI subsequently assigned all right, title and interest in and to the '880 patent to KCI Licensing by written assignment dated

September 19, 2001 and recorded in the Patent and Trademark Office on September 25, 2001 at Reel 0122190 and Frame 0150. The '880 patent is extant and enforceable. At all times relevant to the acts complained of herein, KCI Licensing has been the true and record owner of the '880 patent.

23. Medela is a manufacturer of suction pumps used in the medical field. On multiple occasions, Medela AG and its subsidiaries and distributors have improperly attempted to commercialize their suction pumps for use with specialized dressings to promote wound healing, and KCI has taken steps to resolve such improper commercialization attempts.

24. On March 23, 2001, in the course of appealing an injunction that prohibited Medela's German subsidiary from distributing Medela's VARIO pump for applications like those of the V.A.C. System, Medela's German subsidiary agreed to a written settlement agreement (the "German Agreement"), which in part states that it would "refrain from offering, distributing, selling, renting out and/or promoting (or causing to be offered, distributed, sold, and/or promoted) in the competitive marketplace the VARIO-type suction pump for use in the vacuum-sealing of wounds…Medela, for its part, shall warn users against such misapplication and – as far as possible – see to it that no misuse occurs in [the] future." A true and correct certified English translation of the German Agreement is attached hereto as **Exhibit "E"**.

25. On October 1, 2001, subsequent to the execution of the German Agreement, Medela AG executed another settlement agreement in resolution of a patent protection action filed by KCI in Zurich, Switzerland (the "Swiss Agreement"). Under the terms of the Swiss Agreement, Medela AG "affirms to KCI that it will desist from offering, distributing, selling, leasing and/or advertising the suction pump of the VARIO type for competitive purposes and/or causing the suction pump of the VARIO type to be thus offered, distributed, sold and/or

advertised for the purpose of the vacuum-assisted closure of wounds." A true and correct copy of the English translation of the Swiss Agreement is attached hereto as **Exhibit "F"**.

26. In addition to the German and Swiss Agreements, Medela AG executed another Agreement on December 16, 2002 (the "2002 Agreement"). A true and correct copy of the 2002 Agreement is attached hereto as **Exhibit "G"**. In the 2002 Agreement, as in the German and Swiss Agreements, Medela AG admits that the VARIO is not suitable and should not be used as a wound healing system like the V.A.C. System. Medela AG again agreed to immediately "cease and desist from marketing, advertisement [sic], selling or offering to sell or leasing" the Vario as suitable for such purposes, rather than for the purpose of suctioning secretions out of wounds. In addition, Medela also agrees in the 2002 Agreement to make it known to third parties that they should not use or commercialize the Vario pump as a wound healing system for vacuum assisted closure of wounds. An example of one such notification is attached as Schedule A to the 2002 Agreement. A true and correct copy of the notification is attached hereto as **Exhibit "H"**. In furtherance of the German, Swiss and 2002 Agreements, Medela's Dutch subsidiary signed a similar Agreement on February 4, 2003 (the "Dutch Agreement"). A true and correct copy the Dutch Agreement is attached hereto as **Exhibit "I"**.

27. Weston was an employee of Medela for over twenty years and was employed by Medela at the time Medela agreed to the German and Swiss Agreements. Consequently, Weston knew or should have known about the contents and prohibitions contained in those Agreements.

28. In April 2002, two months after Weston left Medela, he founded and incorporated BlueSky. Weston was the sole founder, shareholder and director of the company. Weston has complete control over the operations of BlueSky, including product development, design, packaging, marketing, and distribution. In addition to having sole control and authority over

BlueSky's operations, company purchases and expenditures are made using Weston's personal cash and credit cards.

29. It appears that Weston formed BlueSky solely for his own personal benefit and to avoid personal liability for any obligations incurred and wrongdoing committed in the course of his business dealings. It also appears that Weston created BlueSky for the express purpose of trading on the goodwill of KCI and causing injury to KCI. In his capacity as president and director of BlueSky, Weston has the authority to control and direct and does control and direct BlueSky's packaging, marketing and distribution of a "Versatile 1" pump that is manufactured by Medela. The Versatile 1 pump is substantially similar to the Vario pump that was the subject of the German, Swiss, 2002 and Dutch Agreements (the "Agreements") referenced above. Weston also controls and directs the packaging, marketing and distribution of BlueSky disposable dressing kits (the "Blue Sky Dressings") that are commercialized for use with the Versatile 1 pump (collectively the "Versatile 1 System"). The BlueSky Dressings are labeled as either "Chariker-Jeter" wound drainage kit, "Wooding-Scott" wound drainage kit or "Kremlin" wound drainage kit. BlueSky's "Chariker-Jeter" kit contains specific instructions on how to use the dressing with the Versatile 1 pump.

30. Following requests from KCI, Medela AG has affirmed its obligations under the Agreements but has failed and/or refused to take any remedial action in relation to the distribution and marketing of the Versatile 1 System by Weston and BlueSky.

31. On or about January 8, 2003, Weston and BlueSky were notified of KCI's complaints concerning BlueSky's use of the Versatile 1 System as a negative pressure wound treatment device and KCI's request that BlueSky cease and desist such usage. Weston and BlueSky ignored KCI's notice and have continued to distribute and market the Versatile 1

System. Accordingly, Weston has knowingly and intentionally aided and abetted BlueSky's misconduct.

32. In addition to the improper distribution and marketing of the Versatile 1 System, Weston, individually and as the president of BlueSky, has engaged in and continues to engage in a disparaging public marketing campaign through which he, BlueSky and BlueSky's distributors, have made false claims in connection with its Versatile 1 System. Weston has had and continues to have the sole control and authority to make decisions at BlueSky and to direct BlueSky's distributors in relation to the marketing campaign of the Versatile 1 System.

33. Weston, BlueSky, PCS and others under the control and direction of Weston and BlueSky have knowingly and intentionally participated in false advertising of the Versatile 1 System. They have promoted, described, and represented the Versatile 1 System in ways that, directly and by implication, were false and misleading, such as representing that the V.A.C. and the Versatile 1 System offer patients and health care professionals identical services and therapy or that the V.A.C. is more costly to operate than the Versatile 1 System and/or causes patient injuries and deaths.

34. Weston, individually and through his position as president of BlueSky, has attempted and continues to attempt to knowingly and maliciously damage KCI by disparaging KCI and its products through the distribution of malicious and misleading marketing material, from which prospective and existing customers of KCI will perceive that the V.A.C. discourages or prevents wound healing and/or causes patient injuries and deaths.

35. Defendants have promoted and are promoting the Versatile 1 System under the designations "Negative Pressure Wound Therapy," "Vacuum Assisted Wound Therapy," "V.A.C.," "VAC", "wound vacuum" and other confusingly similar designations.

36. Weston, individually and as the president of BlueSky, has knowingly and recklessly made public statements and representations and has directed and caused others to knowingly and recklessly make public statements and representations that falsely and maliciously mischaracterize KCI and its products.

37. In addition to his individual liability, Weston is jointly and severally liable for the wrongful conduct of BlueSky because BlueSky is the alter ego of Weston.

IV. CAUSES OF ACTION

COUNT ONE: BREACH OF CONTRACT

38. Paragraphs 1 through 37 are repeated and realleged as if fully set forth herein.

39. The Agreements executed by Medela and its subsidiaries constitute valid, subsisting and enforceable contracts. KCI is a party, third-party beneficiary and/or assignee of the Agreements. KCI has not breached the Agreements and has fulfilled all obligations under the Agreements. Any and all conditions precedent to the Agreements have been satisfied.

40. Medela has breached the Agreements in various ways, including the re-labeling and sale of the Vario model suction pump as the Versatile 1 pump for use in negative pressure wound therapy, with dressing kits including Wooding-Scott and Chariker-Jeter wound drainage kits.

41. Medela's breaches of the Agreements have been material and have not been cured, and have caused KCI actual damages, all without legal justification or excuse.

42. Medela's breaches of the Agreements entitle KCI to recover its actual damages resulting from those breaches.

43. Pursuant to Section 38.001 of the Texas Civil Practice and Remedies Code, or other applicable law, KCI is entitled to recover its attorney's fees and costs incurred in prosecuting its claim for breach of contract against Medela.

COUNT TWO: FEDERAL PATENT INFRINGEMENT

44. Paragraphs 1 through 43 are repeated and realleged as if fully set forth herein.

45. Defendants' Versatile 1 System, in whole or in part, incorporates the invention of the '643 patent and/or the '081 patent exclusively licensed to KCI and/or the '880 patent owned by KCI Licensing. Manufacture, sale and use of the Versatile 1 System infringes the '643 and/or '880 and/or '081 patents either literally or under the doctrine of equivalents.

46. Defendants are knowingly and directly infringing, inducing infringement or contributorily infringing the '643 and/or '880 and/or '081 patents within this District and elsewhere, without leave or license from KCI, all to KCI's substantial damage. Defendants will continue to do so unless enjoined from it by this Court.

47. Said direct or contributory infringement of the '643 and/or '880 and/or '081 patents, or the active inducement of others to infringe the '643 and/or '880 and/or '081 patents, is willful and is damaging KCI, and KCI will suffer additional and irreparable damage unless this Court enjoins Defendants from continuing to directly or contributorily infringe or induce others to infringe the '643 and/or '880 and/or '081 patents.

48. Unless enjoined by this Court, Defendants will continue to deliberately and willfully infringe or contributorily infringe or induce others to infringe the '643 and/or '880 and/or '081 patents, making this an exceptional case and justifying the assessment of increased damages pursuant to 35 U.S.C. §284 and the award of attorneys' fees pursuant to 35 U.S.C. §285.

COUNT THREE: FEDERAL TRADEMARK DILUTION

49. Paragraphs 1 through 48 are repeated and realleged as if fully set forth herein.

50. KCI's V.A.C. and Vacuum Assisted Closure trademarks are famous marks within the meaning of 15 U.S.C. § 1125(c)(1).

51. Defendants' use of V.A.C. and/or Vacuum Assisted Closure and confusingly similar designations is likely to dilute the distinctive quality of KCI's trademarks.

52. The actions of Defendants constitute trademark dilution in violation of federal Lanham Act, 15 U.S.C. § 1125(c).

53. Said trademark dilution is irreparably injuring the goodwill of KCI.

54. Defendants' direct and contributory dilution of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks has been willful with intent to trade on KCI's reputation or to cause dilution of KCI's trademarks.

55. Pursuant to 15 U.S.C. §§ 1125(c)(2) and 1117(a), KCI is entitled to damages for Defendants' trademark dilution, an accounting for profits made by Defendants on sales of the Versatile 1 System, and recovery of KCI's costs of this action.

56. The acts of Defendants make this an exceptional case entitling Plaintiffs to recover their reasonable attorneys' fees pursuant to 15 U.S.C. §§ 1125(c)(2) and 1117(a).

57. Defendants' direct and contributory dilution of KCI's trademarks has irreparably injured KCI's goodwill and diluted its share of the wound therapy market, and unless enjoined by this Court, will continue to do so.

58. Pursuant to 15 U.S.C. § 1125(c)(1), Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing dilution of the V.A.C. and/or Vacuum Assisted Closure trademarks.

COUNT FOUR: VIOLATION OF TEXAS ANTI-DILUTION STATUTE

59. Paragraphs 1 through 58 are repeated and realleged as if fully set forth herein.

60. KCI's V.A.C. and Vacuum Assisted Closure trademarks are famous marks within the meaning of 15 U.S.C. § 1125(c)(1).

61. Defendants' use of V.A.C. and/or Vacuum Assisted Closure, and confusingly similar designations, has diluted the distinctive quality of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks and has injured KCI's business reputation.

62. Defendants' use of V.A.C. and/or Vacuum Assisted Closure and confusingly similar designations is likely to dilute the distinctive quality of KCI's trademarks.

63. The actions of Defendants constitute trademark dilution in violation of Texas Business and Commerce Code § 16.29.

64. Said trademark dilution is irreparably injuring the goodwill of KCI.

65. Defendants' dilution of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks has been willful with intent to trade on KCI's reputation or to cause dilution of KCI's trademarks.

66. Defendants' dilution of KCI's trademarks has irreparably injured KCI's goodwill and diluted its share of the wound therapy market, and unless enjoined by this Court, will continue to do so.

67. Pursuant to Texas Business and Commerce Code § 16.29, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing dilution of the V.A.C. and/or Vacuum Assisted Closure trademarks and from injuring KCI's business reputation.

COUNT FIVE: FEDERAL FALSE ADVERTISING

68. Paragraphs 1 through 67 are repeated and realleged as if fully set forth herein.

69. The Defendants' public statements and false representations, including but not limited to numerous emails, letters, banners and other communications characterizing negative

pressure wound therapy systems, like the V.A.C. System, as being no different that the general purpose suction pumps such as BlueSky's Versatile 1 System and/or as causing patient injuries and deaths constitute false statements.

70. Said representations, whether express or implied, are false.

71. Said representations, whether express or implied, have a tendency to deceive health care providers, group purchasing organizations, the United States government and others (collectively herein, "Health Care Providers").

72. Said false or deceptive representations are material to the purchasing and/or reimbursement practices of Health Care Providers in that the representations are causing Health Care Providers to purchase the Versatile 1 System.

73. Said false or deceptive representations are injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to the V.A.C. System, when in fact it is not.

74. The actions of Defendants constitute false or misleading representations of fact in commercial advertising or promotion concerning the nature, characteristics, or qualities of the Versatile 1 System in violation of federal Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

75. Pursuant to 15 U.S.C. § 1117(a), Plaintiffs are entitled to damages for Defendants' false advertisements and an accounting of profits made by Defendants on the sale of the Versatile 1 System, and recovery of Plaintiffs' costs of this action.

76. Defendants' false advertisement of the Versatile 1 System have been made willfully and wantonly for the purpose of deceiving Health Care Providers, the United States government and others, inducing them to utilize the Versatile 1 System in the mistaken belief that it is identical or equivalent to the V.A.C. System, and injuring the goodwill of KCI.

77. The acts of Defendants make this an exceptional case entitling Plaintiffs to recover their attorneys' fees pursuant to 15 U.S.C. § 1117(a).

78. Defendants' false advertisements are irreparably injuring Plaintiffs' goodwill and eroding Plaintiffs' share of the wound therapy market, and unless enjoined by this Court, will continue to do so.

79. Pursuant to 15 U.S.C. § 1116(a), Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing false advertisements.

COUNT SIX: FEDERAL UNFAIR COMPETITION

80. Paragraphs 1 through 79 are repeated and realleged as if fully set forth herein.

81. The actions of Defendants constitute unfair competition with KCI in violation of federal Lanham Act, 15 U.S.C. § 1125(a).

82. Pursuant to 15 U.S.C. § 1117(a), KCI is entitled to damages for Defendants' unfair competition, an accounting of profits made by Defendants on sales of the Versatile 1 System, and recovery of KCI's costs of this action.

83. Defendants' false or misleading representations and descriptions and other acts complained of herein, are likely to cause confusion, or association of Defendants with KCI, or as to the origin, sponsorship, or approval of Defendants' goods, services, or commercial activities.

84. Defendants' false or misleading representations and descriptions and other acts complained of herein, misrepresent the nature, characteristics, qualities, or origin of Defendants' goods, services, or commercial activities.

85. Defendants' unfair competition with KCI has been willful and wanton for the purpose of deceiving others and injuring the goodwill of KCI.

86. Defendants' acts of unfair competition make this an exceptional case entitling Plaintiffs to recover their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a).

87. Defendants' acts of unfair competition are irreparably injuring KCI's goodwill and eroding KCI's share of the wound therapy market, and unless enjoined by this Court, will continue to do so.

88. Pursuant to 15 U.S.C. § 1116(a), KCI is entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts of unfair competition.

COUNT SEVEN: FEDERAL TRADEMARK INFRINGEMENT

89. Paragraphs 1 through 88 are repeated and realleged as if fully set forth herein.

90. KCI's V.A.C. and Vacuum Assisted Closure trademarks are distinctive of KCI's patented V.A.C. System, and indicate to hospitals, group purchasing organizations and the United States government that every system used for reduced pressure wound treatment comes from a single source, KCI.

91. KCI's distinctive V.A.C. and Vacuum Assisted Closure trademarks symbolize the goodwill of KCI, which is the result of its significant promotion and distribution of the high quality V.A.C. System.

92. Defendants are knowingly and directly infringing, inducing infringement or contributorily infringing on KCI's V.A.C. and Vacuum Assisted Closure trademarks. Defendants' direct and contributory use in commerce of the V.A.C. and Vacuum Assisted Closure trademarks and the phrase "Vacuum Assisted Wound Therapy" or other confusingly similar designations is likely to cause confusion, or to cause mistake, or to deceive as to the origin of the Versatile 1 System. Such use is likely to cause Health Care Providers to believe that the Versatile 1 System and the V.A.C. System come from the same source, or that KCI or Defendants sponsor or approve

the pump of the other, or that KCI and Defendants are somehow affiliated, connected or associated with one another when in fact they are not.

93. Defendants' use in commerce of the V.A.C. and/or Vacuum Assisted Closure trademarks, and/or confusingly similar designations, in connection with the Versatile 1 System is injuring the goodwill of KCI and its high quality V.A.C. System.

94. The actions of Defendants constitute trademark infringement in violation of the federal Lanham Act, 15 U.S.C. § 1117(a)(1)(A).

95. Pursuant to 15 U.S.C. § 1117(a), KCI is entitled to damages for Defendants' trademark infringement, an accounting of profits made by Defendants on sales of the Versatile 1 System, and recovery of KCI's costs of this action.

96. Defendants have willfully and wantonly infringed on KCI's V.A.C. and/or Vacuum Assisted Closure trademarks, and their actions have been calculated to confuse, mislead or deceive Health Care Providers, and to injure the goodwill of KCI.

97. The acts of Defendants make this an exceptional case, entitling Plaintiffs to recover their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a).

98. Defendants' infringement of KCI's trademarks is irreparably injuring KCI's goodwill and eroding KCI's share of the wound therapy market, and unless enjoined by this Court, will continue to do so.

99. Pursuant to 15 U.S.C. § 1116(a), KCI is entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing trademark infringement.

COUNT EIGHT: COMMON LAW TRADEMARK INFRINGEMENT

100. Paragraphs 1 through 99 are repeated and realleged as if fully set forth herein.

101. Defendants' acts constitute trademark infringement under the applicable common law.

102. Defendants' acts of trademark infringement entitle KCI to recover damages and costs of this action, together with an accounting of profits made by Defendants on sales of the Versatile 1 System.

103. The acts of Defendants have been malicious and calculated to injure KCI. The willful, wanton and malicious nature of Defendants' conduct entitles Plaintiffs to an award of their reasonable attorneys' fees and punitive damages against Defendants.

104. Defendants' infringement of KCI's trademarks is irreparably injuring KCI's goodwill and eroding KCI's share of the wound therapy market, and unless enjoined by this Court, will continue to do so.

105. Under the applicable common law, KCI is entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing trademark infringement.

COUNT NINE: COMMON LAW NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC RELATIONS

106. Paragraphs 1 through 105 are repeated and realleged as if fully set forth herein.

107. An economic relationship exists between Plaintiff KCI and third parties; specifically between KCI and Health Care Providers. Furthermore, economic relationships exist between KCI and the United States government by virtue of KCI's status as a participating Medicare distributor.

108. There is a significant probability of future economic benefit to Plaintiff KCI by virtue of these relationships.

109. Defendants at all relevant times knew or should have known of these economic relationships as exhibited by their objectively false statements to the United States government, Health Care Providers, the public, and other third parties.

110. Defendants' negligent and wrongful acts were designed to induce breach or disruption of these contractual relationships. Moreover, Defendants' acts were compelled by an improper motive. Therefore, Defendants' conduct falls outside the realm of legitimate business transactions.

111. Moreover, actual disruptions of these economic relationships have occurred as a result of Defendants' negligent, unlawful and wrongful acts.

112. Plaintiff KCI has suffered economic harm proximately caused by the acts of Defendants because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to the V.A.C. System.

COUNT TEN: COMMON LAW TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC RELATIONS

113. Paragraphs 1 through 112 are repeated and realleged as if fully set forth herein.

114. An economic relationship between Plaintiff KCI and third parties; specifically between KCI and Health Care Providers. Furthermore, economic relationships exist between KCI and the United States government by virtue of KCI's status as a participating Medicare provider. In addition, economic relationships exist between KCI and the United States government by virtue of the fact that KCI is a third party beneficiary of economic relationships between the government and the users of negative pressure wound therapy equipment.

115. There is a significant probability of future economic benefit to Plaintiff KCI by virtue of these relationships.

116. Defendants at all relevant times knew or should have known of these economic relationships as exhibited by their objectively false statements to the United States government, Health Care Providers, the public, and other third parties.

117. Defendants' intentional, malicious and wrongful acts were designed to induce breach or disruption of these economic relationships. Moreover, Defendants' acts were compelled by an improper motive. Therefore, Defendants' conduct falls outside the realm of legitimate business transactions.

118. Moreover, actual disruptions of these economic relationships have occurred as a result of Defendants' unlawful and wrongful acts.

119. Plaintiff KCI has suffered economic harm proximately caused by the acts of Defendants because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to The V.A.C. System.

COUNT ELEVEN: COMMON LAW TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONS

120. Paragraphs 1 through 119 are repeated and realleged as if fully set forth herein.

121. Valid contracts exist between Plaintiff KCI and third parties; specifically between KCI and Health Care Providers. Furthermore, valid contract and relationships exist between KCI and the United States government by virtue of KCI's status as a participating Medicare provider. In the alternative, KCI is a third party beneficiary of contracts between the United States government and purchasers and users of negative pressure wound therapy equipment.

122. Defendants have and at all relevant times had knowledge of these contracts as exhibited by their statements to the United States government, Health Care Providers, the public, and other third parties.

123. Defendants' intentional and malicious acts were designed to induce breach or disruption of these contractual relationships.

124. Moreover, actual breaches and/or disruptions of these contractual relationships have occurred as a result of Defendants' unlawful acts.

125. Defendants' intentional and malicious acts are resulting in pecuniary loss to KCI and injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to the V.A.C. System.

COUNT TWELVE: COMMON LAW BUSINESS DISPARAGEMENT

126. Paragraphs 1 through 125 are repeated and realleged as if fully set forth herein.

127. Weston, individually and as president of BlueSky, has published and has caused to be published false and misleading statements about KCI and its products on the BlueSky website, and in numerous emails, letters, banners and other communications. These statements characterize negative pressure wound therapy systems, like the V.A.C. System, as being no different than the general purpose suction pumps, such as BlueSky's Versatile 1 System. The statements also suggest that the V.A.C. System is not cost efficient and that the V.A.C. System does not promote healthy wound healing and/or causes patient injuries and deaths.

128. The statements infer that the quality of the V.A.C. System is not worthy of reimbursement or federal trademark and/or patent protection or that the V.A.C. System does not have effective patent protection.

129. These statements when viewed in their broad context, which includes the general tenor of the work, the subject of the statements, the setting, and the format of the work are misleading and objectively factual.

130. The specific context and content of the statements, analyzing the extent of figurative or hyperbolic language used and the reasonable expectations of the audience in these particular situations, is deceptive and misleading.

131. The statements are sufficiently factual to be susceptible to being proven true or false. The statements made by Weston and by BlueSky and its distributors, including PCS, at Weston's direction and with his approval are clearly factual and, as such, are easily disproved.

132. Said representations, whether express or implied, are false.

133. Said representations, whether express or implied, have a tendency to deceive doctors, group purchasing organizations, hospitals and others.

134. Said false or deceptive representations are material to the purchasing practices and/or reimbursement practices of hospitals and group purchasing organizations in that the representations are causing Health Care Providers, to purchase the Versatile 1 System in place of the V.A.C. System.

135. Said false or deceptive representations are injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers, to believe that the Versatile 1 System is an effective alternative to the V.A.C. System.

136. Said false or deceptive representations have caused KCI to suffer pecuniary loss because they are causing Health Care Providers to purchase the Versatile 1 System for use in negative pressure wound therapy.

137. The actions of Weston, BlueSky and PCS are likely to deceive and have deceived the reasonable wound therapy consumer, and KCI has suffered and continues to suffer pecuniary loss as a direct and proximate result of these Defendants. As such, Defendants' conduct constitutes business disparagement under the applicable common law.

COUNT THIRTEEN: COMMON LAW TRADE LIBEL

138. Paragraphs 1 through 137 are repeated and realleged as if fully set forth herein.

139. The posting of press releases on the BlueSky website and the numerous emails, letters, banners and other communications, characterizing negative pressure wound therapy systems, like the V.A.C. System, as being no different that the general purpose suction pumps such as BlueSky's Versatile 1 System constitute false statements.

140. The statements infer that the quality of the V.A.C. System is not worthy of reimbursement levels or the price charged by KCI, or worthy of federal trademark and/or patent protection and that the V.A.C. System does not have effective patent protection and/or causes patient injuries and deaths.

141. These statements when viewed in their broad context, which includes the general tenor of the work, the subject of the statements, the setting and the format of the work, are misleading and objectively factual.

142. The specific context and content of the statements, analyzing the extent of figurative or hyperbolic language used and the reasonable expectations of the audience in that particular situation, is deceptive and misleading.

143. The statements are sufficiently factual to be susceptible to being proved true or false.

144. Said representations, whether express or implied, are false.

145. Said representations, whether express or implied, have a tendency to deceive doctors, group purchasing organizations, hospitals and others.

146. Said false or deceptive representations are material to the purchasing practices and/or reimbursement practices of Health Care Providers.

147. Said false or deceptive representations are injuring the goodwill of KCI and its high quality V.A.C. System because they are causing Health Care Providers to believe that the Versatile 1 System is an effective alternative to The V.A.C. System.

148. Said false or deceptive representations have caused KCI to suffer pecuniary loss because they are causing Health Care Providers to purchase the Versatile 1 System for use in negative pressure wound therapy.

149. The actions of Weston, BlueSky and its distributors, including PCS, are likely to deceive and have deceived the reasonable wound therapy consumer, and KCI has suffered and continues to suffer pecuniary loss. Accordingly, the Defendants' conduct constitutes trade libel under applicable common law.

COUNT FOURTEEN: COMMON LAW UNFAIR COMPETITION

150. Paragraphs 1 through 149 are repeated and realleged as if fully set forth herein.

151. Defendants' illegal acts constitute unfair competition under the common law of the State of Texas.

152. As set forth elsewhere in this complaint, Defendants' acts interfered with Plaintiffs' ability to conduct its business.

153. Furthermore, through its acts, Defendants have appropriated and used, in competition with the Plaintiffs, several unique pecuniary interests created by the Plaintiffs through the expenditure of Plaintiffs' labor, skill and money.

154. Plaintiffs' pecuniary interests, which Defendants have appropriated and used, include, but are not limited to, Plaintiffs' patents and trademarks, the goodwill Plaintiffs have developed for themselves and for their products, and the health care market's appreciation of the value and therapeutic benefit of Plaintiffs' V.A.C. System.

155. Defendants' misappropriation has been without Plaintiffs' permission or authority and in competition with Plaintiffs' own licensing programs.

156. Defendants' acts of unfair competition entitle Plaintiffs to recover its damages and costs of this action, together with an accounting of profits made by Defendants on sales of their pumps, dressings, and other accessories.

157. Defendants' acts of unfair competition have been malicious and calculated to injure Plaintiffs.

158. The willful, wanton and malicious nature of Defendants' conduct entitles Plaintiffs to an award of their reasonable attorney's fees and punitive damages against Defendants.

159. Defendants' acts of unfair competition are irreparably injuring Plaintiffs' goodwill and eroding Plaintiffs' share of the wound healing market, and unless enjoined by this Court, will continue to do so and cause damage to Plaintiffs.

160. Under the common law of the State of Texas, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts of unfair competition.

COUNT FIFTEEN: CONSPIRACY

161. Paragraphs 1 through 160 are repeated and realleged as if fully set forth herein.

162. Defendants acted together in a combination and conspiracy to carry out the acts alleged in this complaint, including the infringement and dilution of KCI's patents and trademarks, the unfair competitive conduct and the publication of false advertisements and statements.

163. In carrying out the conspiracy, the Defendants committed a number of unlawful, overt acts, including:

a. Breaching the Agreements executed by Medela;

b. Infringing and diluting KCI's patents;

c. Infringing and diluting KCI's trademarks;

d. False advertisement;

e. Unfair competition;

f. Tortious Interference;

g. Business disparagement; and

h. Trade libel.

164. As a direct and proximate result of the Defendants' unlawful combination and conspiracy, Plaintiffs have suffered and will continue to suffer damages.

165. The Defendants' conspiracy was willful and intentional and was carried out with the intent to benefit from their wrongful conduct, and they are jointly and severally liable for all acts done by any of them in furtherance of the unlawful combination.

166. Under all applicable laws, Plaintiffs are entitled to recover actual and exemplary damages.

V. JURY DEMAND

Plaintiffs hereby request a **trial by jury**.

VI. PRAYER

For these reasons, Plaintiffs ask for judgment against Defendants for the following:

A. Defendants, their officers, agents, servants, employees, successors, assigns and attorneys, and all persons in active concert or participation with any of them, be preliminarily and permanently enjoined from the following:

1. Any further acts of infringement or contributory infringement or inducing others to infringe U.S. Patent Nos. 5,636,643, 4,969,880 and 5,645,081;

2. Any further acts of infringement or contributory infringement or inducing others to infringe on KCI's V.A.C. and Vacuum Assisted Closure trademarks;

3. Imitating, copying or making unauthorized use of KCI's V.A.C. and Vacuum Assisted Closure trademarks;

4. Manufacturing, producing, distributing, circulating, selling, offering for sale, advertising, promoting or displaying any product bearing any simulation, reproduction, counterfeit, copy or colorable imitation of KCI's V.A.C. or Vacuum Assisted Closure trademarks, including but not limited to the Versatile 1 System;

5. Using any simulation, reproduction, counterfeit, copy or colorable imitation of KCI's V.A.C. or Vacuum Assisted Closure trademarks in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of any product in such a fashion as to relate or connect, or tend to relate or connect, such product in any way to KCI, or to the goods, including the V.A.C. System, sold or manufactured or sponsored by, or connected with, KCI;

6. Making any statement or representation whatsoever, or using any false designation of origin or false description (including without limitation, any letters or symbols), or performing any act in commerce, which can be or is likely to lead to the trade or public or individual members thereof to believe that any products manufactured, distributed or sold by Defendants are in any manner associated or connected with KCI or the V.A.C. System, or are sold, manufactured, licensed, sponsored, approved or authorized by KCI;

7. Directly or indirectly falsely advertising or promoting or selling the Versatile 1 System;

8. Making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of the Versatile 1 System or of any product in such a fashion as to suggest that such product is equivalent to or a substitute for, or has the same qualities or characteristics as, Plaintiffs' V.A.C. System;

9. Diluting the distinctive quality of KCI's V.A.C. and/or Vacuum Assisted Closure trademarks; and

10. Unfairly competing with KCI.

B. Defendants, their officers, agents, servants, employees, successors, assigns and attorneys, and all persons in active concert or participation with any of them, be

ordered to deliver up for destruction, and recall from their suppliers and distributors for like delivery and destruction, all products, labels, signs, plates, packages, dies, wrappers, receptacles and advertisements in their possession or under their control bearing the following:

1. any words, terms, names, symbols, devices, or any combination thereof, which misrepresent the nature, characteristics or qualities of the Versatile 1 System, and all plates, molds, matrices and other means of making the same;

2. any markings similar to KCI's V.A.C. or Vacuum Assisted Closure trademarks or any simulation, reproduction, counterfeit, copy or colorable imitation thereof, and all plates, molds, matrices and other means of making the same; and/or

3. any words, terms, names, symbols, devices, or any combination thereof, which are similar to, or dilute the distinctive quality of, KCI's V.A.C. and/or Vacuum Assisted Closure trademarks and all plates, molds, matrices and other means of making the same.

C. Plaintiffs be granted such other relief as the court may deem appropriate to correct and to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics or qualities of Defendants' Versatile 1 System.

D. Defendants be ordered to take corrective action to correct any erroneous impression the public may have derived concerning the nature, characteristics or qualities of Defendants' Versatile 1 System, including without limitation the placement of corrective advertising.

E. Plaintiffs recover all damages they have sustained as a result of Defendants' infringement, unfair competition and other illegal acts.

F. Plaintiffs be awarded increased damages under 15 U.S.C. § 1117(a), 15 U.S.C. §§ 1125(c)(2) and 35 U.S.C. §284.

G. Plaintiffs be awarded punitive damages for Defendants' willful and malicious infringement, unfair competition and other illegal acts.

H. The court declare that this is an exceptional case pursuant to 35 U.S.C. §285 and 15 U.S.C. §§ 1125(c)(2) and 1117(a) and award Plaintiffs their reasonable attorney fees, costs, and increased damages.

I. Plaintiffs recover their costs and expenses for prosecuting this action and prejudgment and postjudgment interest.

J. Plaintiffs recover all other relief the court deems appropriate.

Respectfully submitted,

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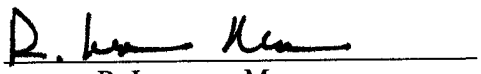


R. Laurence Macon

The United States of America

CERTIFICATE OF REGISTRATION

This is to certify that the records of the Patent and Trademark Office show that an application was filed in said Office for registration of the Mark shown herein, a copy of said Mark and pertinent data from the Application being annexed hereto and made a part hereof,

And there having been due compliance with the requirements of the law and with the regulations prescribed by the Commissioner of Patents and Trademarks,

Upon examination, it appeared that the applicant was entitled to have said Mark registered under the Trademark Act of 1946, as amended, and the said Mark has been duly registered this day in the Patent and Trademark Office on the

PRINCIPAL REGISTER

to the registrant named herein.

This registration shall remain in force for TEN years unless sooner terminated as provided by law.

In Testimony whereof I have hereunto set my hand and caused the seal of the Patent and Trademark Office to be affixed this twenty-fifth day of June 1996.

Bruce Lehman

Commissioner of Patents and Trademarks

PTO-130
(Rev. 8-89)

Int. Cl.: 10

Prior U.S. Cls.: 26, 39 and 44

United States Patent and Trademark Office

Reg. No. 1,982,349

Registered June 25, 1996

TRADEMARK
PRINCIPAL REGISTER

V.A.C.

KINETIC CONCEPTS, INC. (TEXAS CORPORATION)
3440 E. HOUSTON STREET
SAN ANTONIO, TX 78219

FOR: MEDICAL DEVICES, NAMELY PUMP UNITS FOR PROMOTING WOUND HEALING, RECEPTACLES FOR COLLECTING WOUND DRAINAGE, AND PARTS AND ACCESSORIES FOR THE FOREGOING, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 4-1-1995; IN COMMERCE 4-1-1995.

SER. NO. 74-676,320, FILED 5-1-1995.

JOYCE A. WARD, EXAMINING ATTORNEY

The United States of America

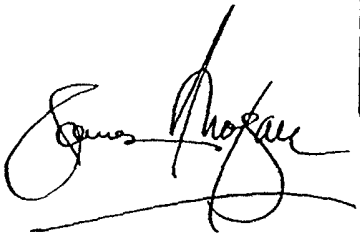
CERTIFICATE OF REGISTRATION
PRINCIPAL REGISTER

The Mark shown in this certificate has been registered in the United States Patent and Trademark Office to the named registrant.

The records of the United States Patent and Trademark Office show that an application for registration of the Mark shown in this Certificate was filed in the Office; that the application was examined and determined to be in compliance with the requirements of the law and with the regulations prescribed by the Director of the United States Patent and Trademark Office; and that the Applicant is entitled to registration of the Mark under the Trademark Act of 1946, as Amended.

A copy of the Mark and pertinent data from the application are part of this certificate.

This registration shall remain in force for TEN (10) years, unless terminated earlier as provided by law, and subject to compliance with the provisions of Section 8 of the Trademark Act of 1946, as Amended.



Director of the United States Patent and Trademark Office

Int. Cl.: 10

Prior U.S. Cls.: 26, 39 and 44

United States Patent and Trademark Office

Reg. No. 2,657,666

Registered Dec. 10, 2002

TRADEMARK
PRINCIPAL REGISTER

VACUUM ASSISTED CLOSURE

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FOR: MEDICAL DEVICES, NAMELY PUMP UNITS FOR PROMOTING WOUND HEALING, RECEPTACLES FOR COLLECTING WOUND DRAINAGE, AND PARTS AND ACCESSORIES FOR THE FOREGOING, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 4-1-1995; IN COMMERCE 4-1-1995.

NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "VACUUM ASSISTED", APART FROM THE MARK AS SHOWN.

SER. NO. 75-874,141, FILED 12-15-1999.

TINA L. SNAPP, EXAMINING ATTORNEY

US005636643A

United States Patent [19]

Argenta et al.

[11] Patent Number: 5,636,643

[45] Date of Patent: Jun. 10, 1997

[54] **WOUND TREATMENT EMPLOYING REDUCED PRESSURE**

[75] Inventors: **Louis C. Argenta**, Winston-Salem; **Michael J. Morykwas**, Pfafftown, both of N.C.

[73] Assignee: **Wake Forest University**, Winston-Salem, N.C.

[21] Appl. No.: 28,677

[22] Filed: Mar. 9, 1993

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 792,001, Nov. 14, 1991.

[51] **Int. Cl.**[6] **A61B 19/00**

[52] **U.S. Cl.** **128/897**; 602/42

[58] **Field of Search** 128/897–898; 602/42–53

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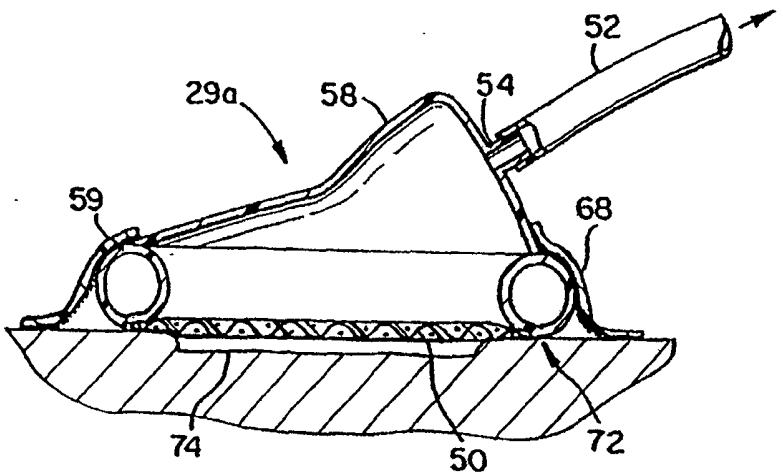
[57] **ABSTRACT**

A method of treating tissue damage comprises applying a negative pressure to a wound sufficient in time and magnitude to promote tissue migration and thus facilitate closure of the wound. The method is applicable to wounds, burns, infected wounds, and live tissue attachments. A wound treatment apparatus is provided in which a fluid impermeable wound cover is sealed over a wound site. A screen in the form of an open-cell foam screen or a rigid porous screen is placed beneath the wound cover over the wound. A vacuum pump supplies suction within the wound cover over the treatment site.

40 Claims, 5 Drawing Sheets



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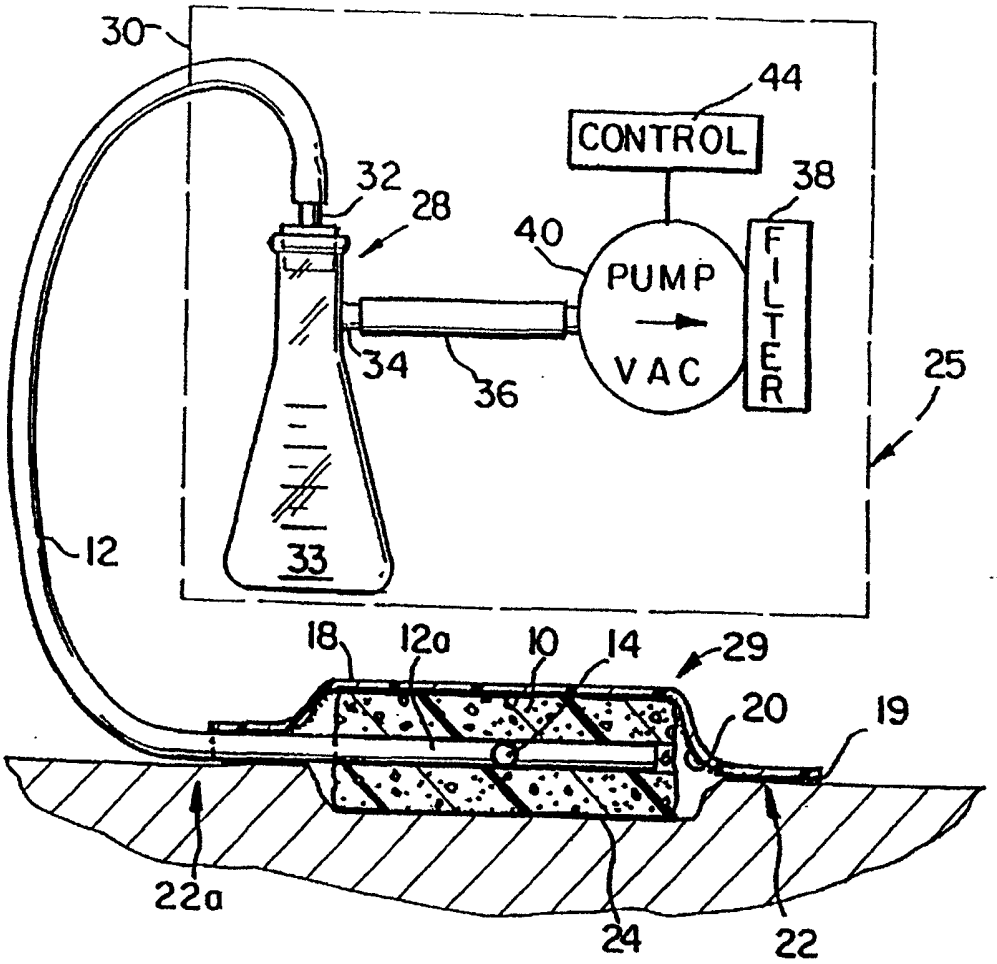
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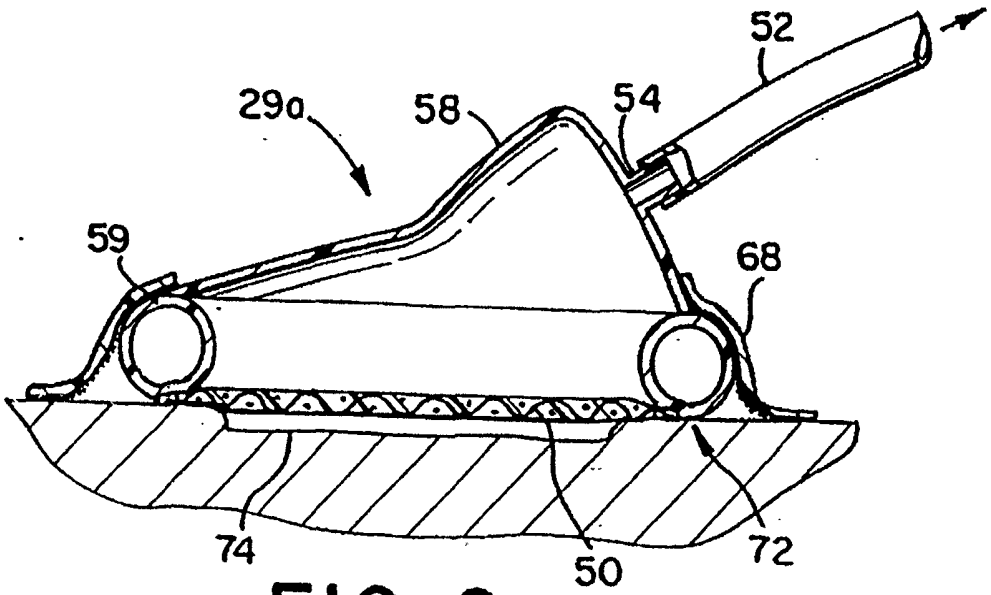
32
28
40
PUMP
VAC
FILTER
34
36
25
12
33
18
12a
10
14
29
20
19
22a
24
22

FIG. 1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29a
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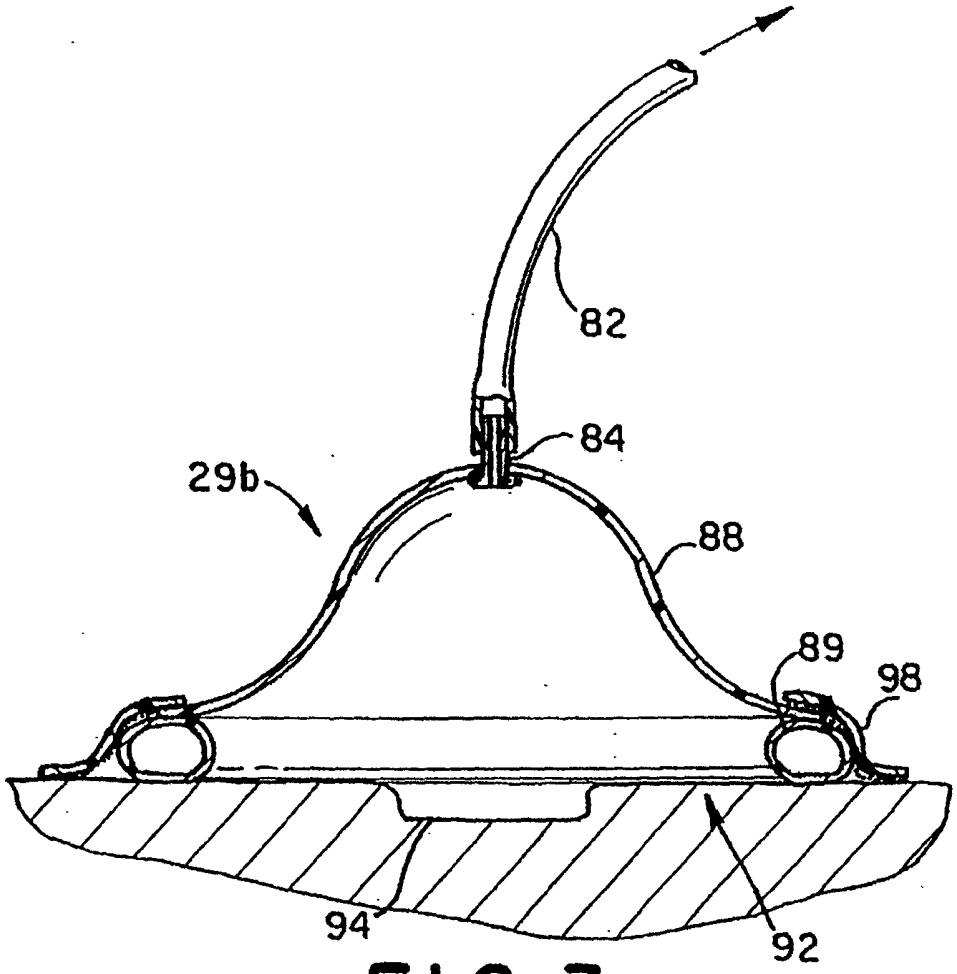
54
59
68
74
50
72

FIG. 2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29b
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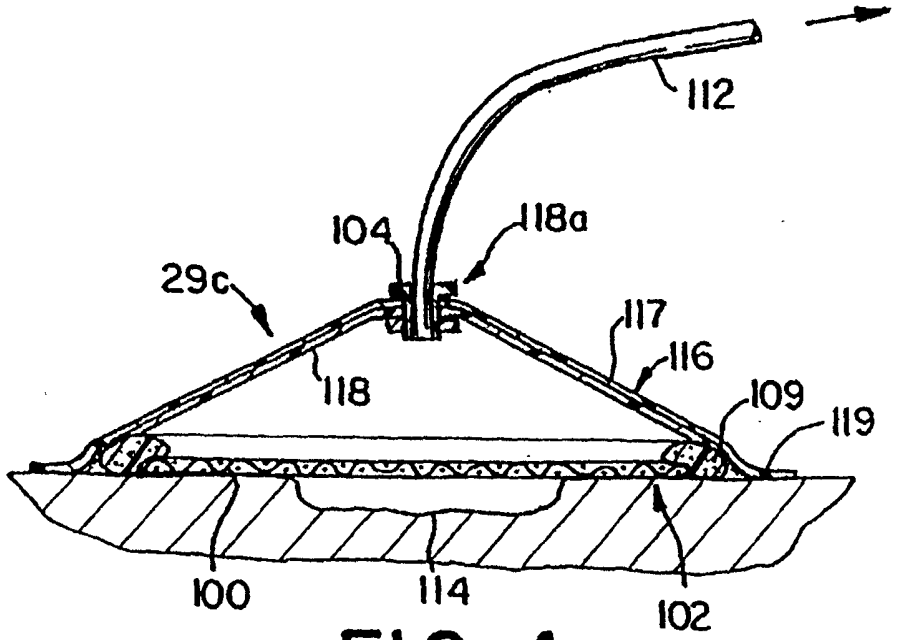
98
94
92

FIG. 3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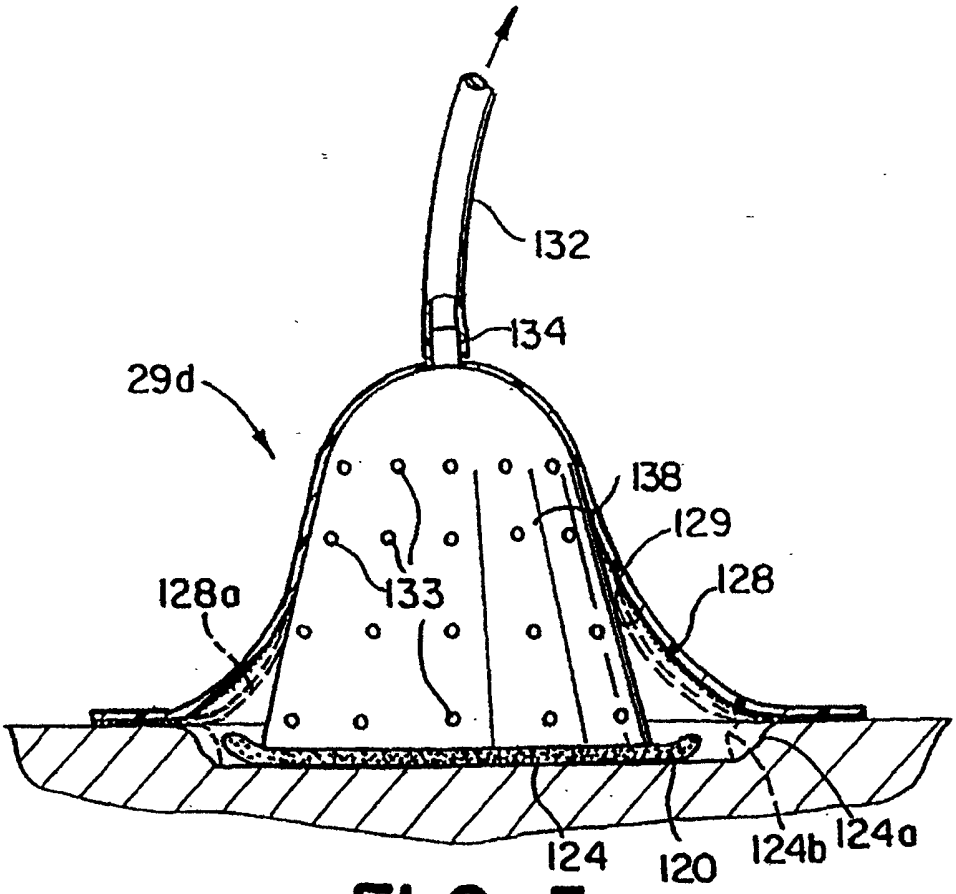
29c
117
116
118
109
119
100
114
102

FIG. 4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29d
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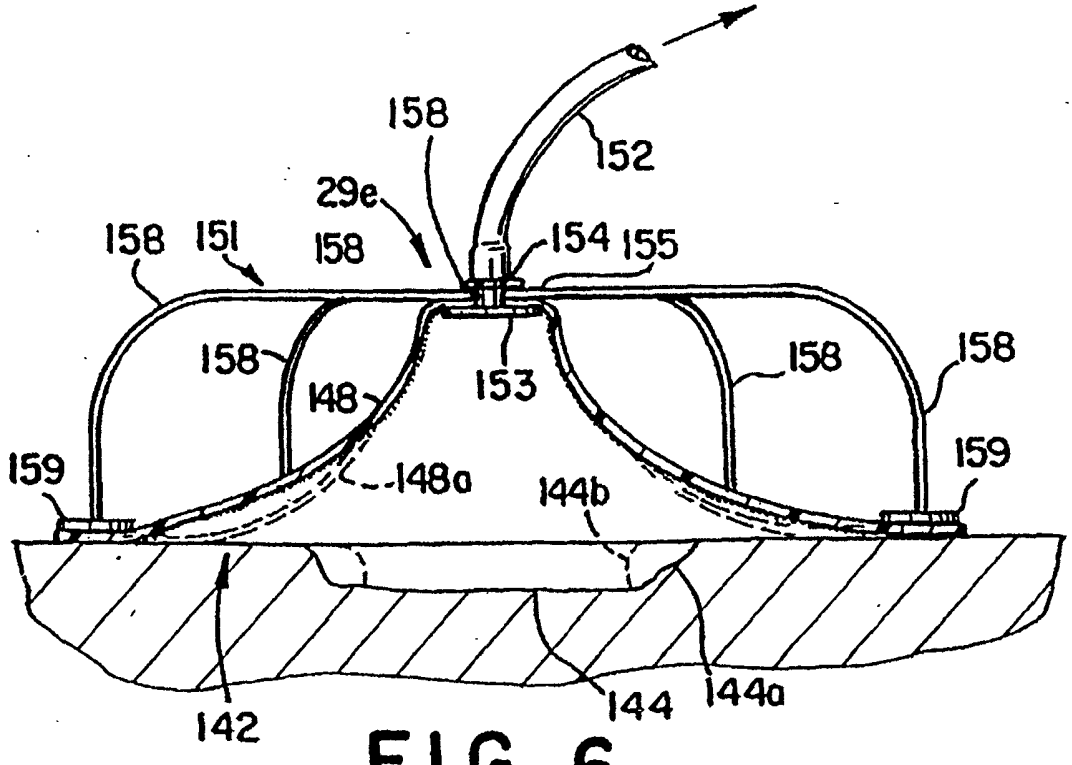
129
128
133
128a
124
120
124b
124a

FIG. 5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152
29e
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148a
144b
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144
144a

FIG. 6

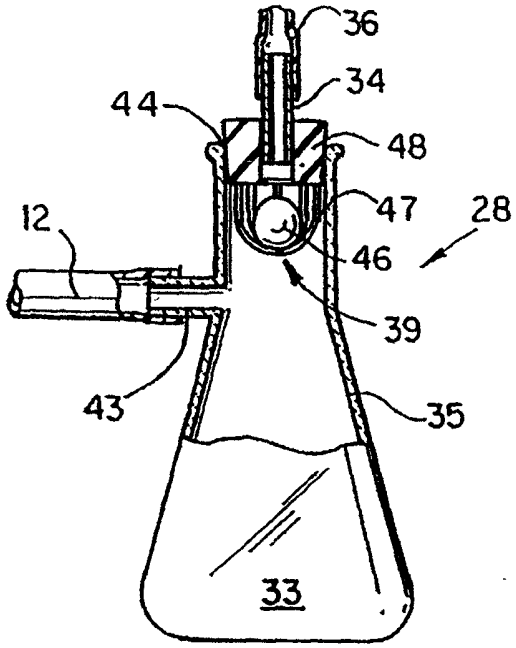

FIG. 7

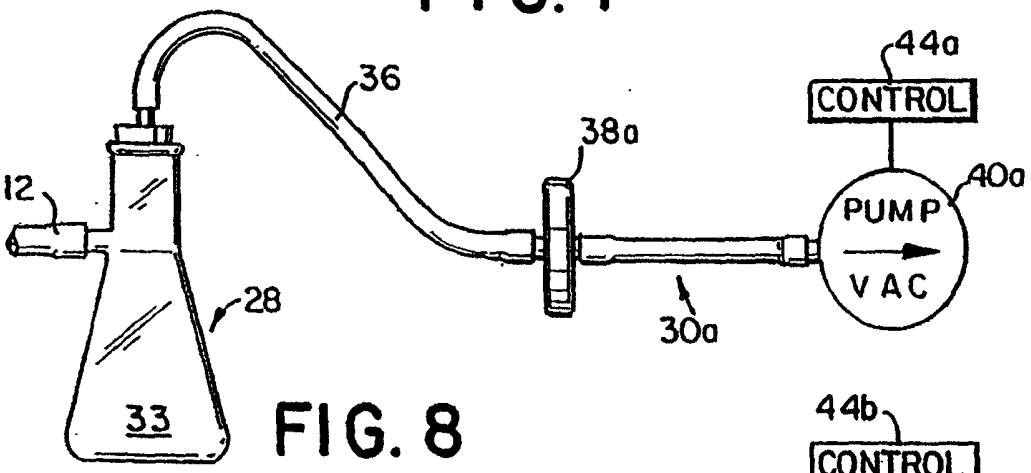

FIG. 8

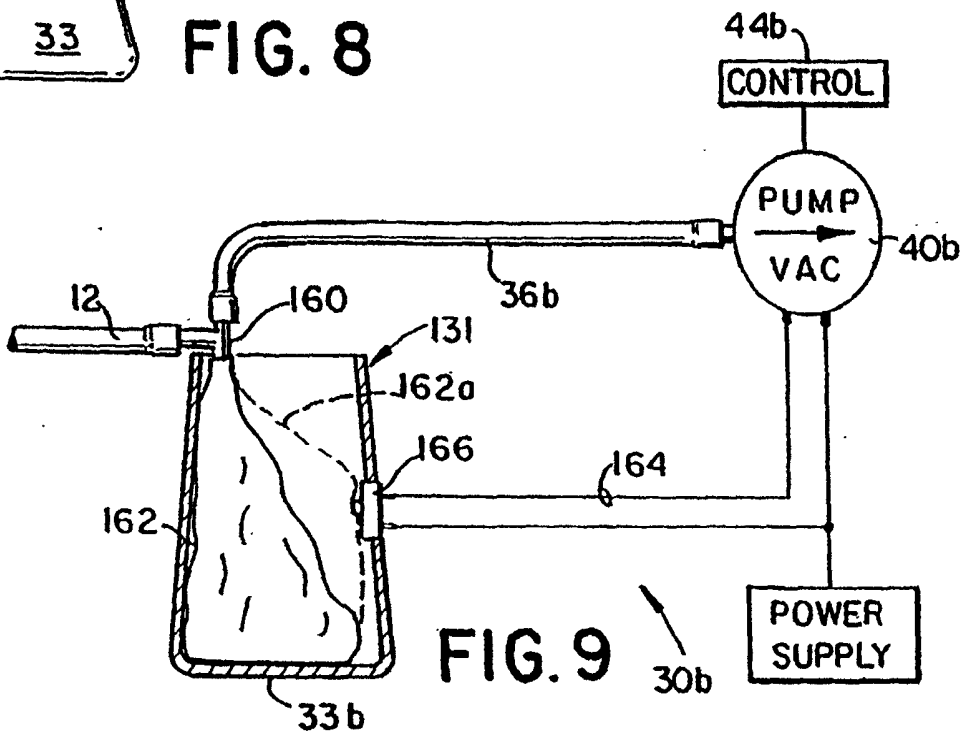

FIG. 9

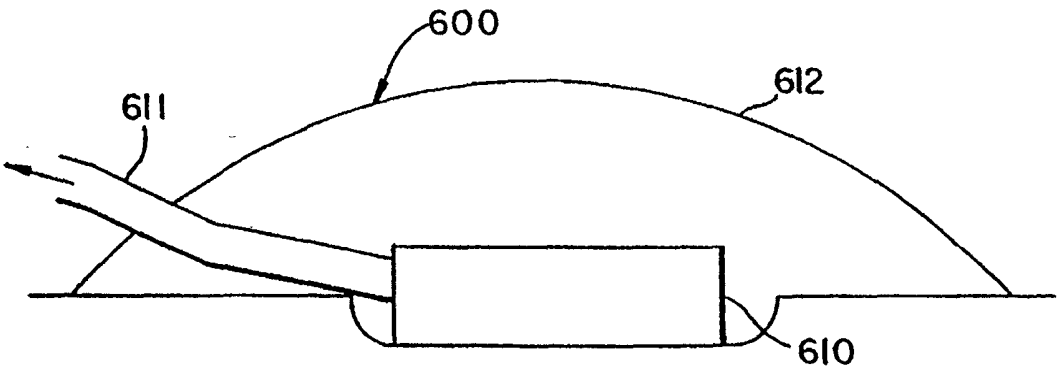

FIG. 10

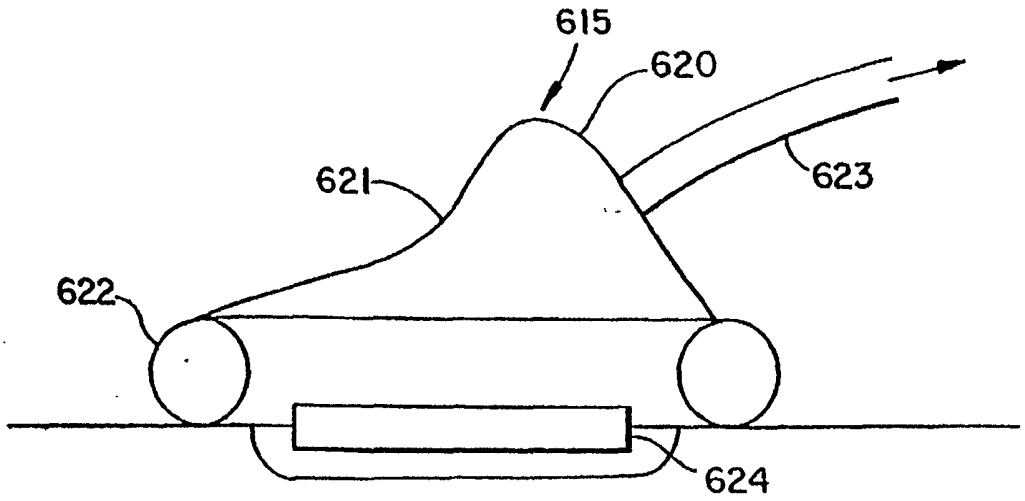

FIG. 11

WOUND TREATMENT EMPLOYING REDUCED PRESSURE

This application is a continuation-in-part of co-pending application Ser. No. 07/792,001, entitled "Method of Treating Tissue Damage and Apparatus for Same," filed on Nov. 14, 1991.

FIELD OF THE INVENTION

The present invention relates to an apparatus and method for treating a wound by applying reduced pressure to the wound.

BACKGROUND OF THE INVENTION

The treatment of open wounds that are too large to spontaneously close has long been a troublesome area of medical practice. Closure of an open wound requires inward migration of surrounding epithelial and subcutaneous tissue. Some wounds, however, are sufficiently large or infected that they are unable to heal spontaneously. In such instances, a zone of stasis in which localized edema restricts the flow of blood to the epithelial and subcutaneous tissue forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and is accordingly unable to close spontaneously.

An initial stage of wound healing is characterized by the formation of granulation tissue which is a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that forms the basis for subsequent epithelialization of the wound. Infection and poor vascularization hinder the formation of granulation tissue within wounded tissue, thereby inhibiting wound healing. It therefore becomes desirable to provide a technique for increasing blood circulation within wounded tissue to promote spontaneous healing and to reduce infection.

Poor blood circulation and infection at the wound may also hinder attachment of skin grafts or flaps upon wounded tissue. Skin grafts and flaps will not attach to tissue that is poorly vascularized, infected or necrotic. However, grafts and flaps can be used with much greater success on tissue that, although wounded, is able to form granulation tissue. Accordingly, a technique for promoting blood circulation at the wounded tissue would also promote successful attachment, or "take," of skin grafts or flaps to the wounded tissue as a consequence of increased blood circulation within the grafts or flaps.

Another problem encountered during the treatment of wounds is the selection of an appropriate technique for wound closure during the healing process. Sutures are often used to apply force to adjacent viable tissue in order to induce the edges of a wound to migrate together and heal. However, sutures apply a closure force to only a very small percentage of the area surrounding a wound. When there is scarring, edema, or insufficient tissue, the tension produced by the sutures can become great causing excessive pressure to be exerted by the sutures upon the tissue adjacent to each suture. As a result, the adjacent tissue often becomes ischemic thereby rendering suturing of large wounds counterproductive. If the quantity or size of the sutures is increased to reduce the tension required of any single suture, the quantity of foreign material within the wound is concomitantly increased and the wound is more apt to become infected. Additionally, the size or type of a particular wound may prevent the use of sutures to promote wound closure. It therefore becomes desirable to provide an apparatus and method for closing a large wound that distributes a closure force evenly about the periphery of the wound.

Wounds resulting from ischemia, or lack of blood flow, are also often difficult to heal since decreased blood flow to a wound may inhibit normal immune reaction to fight infection. Patients that are bedridden or otherwise non-ambulatory are susceptible to such ischemic wounds as decubitus ulcers or pressure sores. Decubitus ulcers form as a result of constant compression of the skin surface and underlying tissue thus restricting circulation. Since the patient is often unable to feel the wound or to move sufficiently to relieve the pressure, such wounds can become self-perpetuating. Although it is common to treat such wounds with flaps, the conditions that initially caused the wound may also work against successful flap attachment. Wheelchair-bound paraplegics, for example, must still remain seated after treatment of pelvic pressure sores. It therefore becomes desirable to provide a treatment procedure for ischemic wounds that can be conducted in situ upon an immobile or partially mobile patient.

Other types of wounds in which ischemia leads to progressive deterioration include partial thickness burns. A partial thickness burn is a burn in which the cell death due to thermal trauma does not extend below the deepest epidermal structures such as hair follicles, sweat glands, or sebaceous glands. The progression of partial thickness burns to deeper burns is a major problem in burn therapy. The ability to control or diminish the depth of burns greatly enhances the prognosis for burn patients and decreases morbidity resulting from burns. Partial thickness burns are formed of a zone of coagulation, which encompasses tissue killed by thermal injury, and a zone of stasis. The zone of stasis is a layer of tissue immediately beneath the zone of coagulation. Cells within the zone of stasis are viable, but the blood flow is static because of collapse of vascular structures due to localized edema. Unless blood flow is re-established within the zone of stasis soon after injury, the tissue within the zone of stasis also dies. The death of tissue within the zone of stasis is caused by lack of oxygen and nutrients, reperfusion injury (re-establishment of blood flow after prolonged ischemia), and decreased migration of white blood cells to the zone resulting in bacterial proliferation. Again, it becomes desirable to provide a technique for treating burn wounds by enhancing blood circulation to the wounded tissue to inhibit burn penetration.

SUMMARY OF THE INVENTION

In accordance with the present invention a wound treatment apparatus is provided for treating a wound by applying reduced pressure (i.e. pressure that is below ambient atmospheric pressure) to the wound in a controlled manner for a selected time period. The application of reduced pressure to a wound provides such benefits as faster healing, increased formation of granulation tissue, closure of chronic open wounds, reduction of bacterial density within wounds, inhibition of burn penetration, and enhancement of flap and graft attachment. Wounds that have exhibited positive response to treatment by the application of negative pressure include infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached.

The wound treatment apparatus in accordance with the present invention includes a reduced pressure application appliance which is applied to a treatment site at which there is a wound and normal tissue surrounding the wound. The reduced pressure application appliance includes a fluid

impermeable wound cover for covering and enclosing the wound. The appliance also includes sealing means for sealing the wound cover to the surrounding tissue of the wound in order to maintain reduced pressure in the vicinity of the wound during wound treatment. When the wound cover is sealed in position over the wound site, a generally fluid-tight or gas-tight sealed enclosure is formed over the wound site. The sealing means may be in the form of an adhesive applied to the underside of the wound cover for sealing the wound cover around the periphery of the wound. The sealing means may also include a separate sealing member such as an adhesive strip or a sealing ring in the form of a tubular pad or inflatable cuff secured to the wound cover for positioning around the periphery of the wound. In selected embodiments, the reduced pressure within the sealed enclosure under the wound cover may serve to seal the wound cover in position at the wound site. The reduced pressure appliance also includes a suction port for supplying reduced pressure within the sealed volume enclosed beneath the wound cover. The suction port may be in the form of a nipple on the wound cover. Alternatively, the suction port may be in the form of a tube attached to the wound cover or provided as a feedthrough beneath the wound cover. The appliance may also include a porous wound screen for placement in the wound or in position overlying the wound in order to prevent overgrowth of wound tissue during treatment. The wound screen is sufficiently porous to permit gas flow to the wound. The porous wound screen may be in the form of a sponge or opencell foam material for placement in the wound. The porous screen may also include a rigid or semi-rigid screen for overlying the wound.

A vacuum system is connected with the reduced pressure appliance in order to provide suction or reduced pressure to the appliance. For this purpose, the vacuum system includes a suction pump or suction device for connection with the suction port of the appliance for producing the reduced pressure over the wound site. The vacuum system may include a section of hose or tube, such as a vacuum hose, that interconnects the suction device with the suction port of the appliance to provide the reduced pressure at the wound site. A collection device in the form of a fluid trap may be provided intermediate the vacuum hose of the suction device and the suction port of the appliance to trap any exudate which may be aspirated from the wound by the negative pressure appliance. A stop mechanism may also be provided for the vacuum system to halt production of the reduced pressure at the wound site in the event that an excessive quantity of exudate has been collected. The apparatus may also include a control device for controlling the pump and for providing intermittent or cyclic production of reduced pressure.

In a particular embodiment of the invention, the wound cover for the reduced pressure appliance may be in the form of a gas impermeable covering sheet of flexible polymer material, such as polyethylene, having an adhesive backing that provides the seal for securing the sheet over the wound site to provide an gas-tight or fluid-tight sealed enclosure over the wound site. The vacuum system of the wound treatment apparatus may include a suction pump having a vacuum hose that is connected with a suction tube serving as a suction port for the appliance. The suction tube for the appliance runs beneath the cover sheet that is sealed in position over the wound site and into the fluid-tight enclosure provided under the cover sheet. An adhesive backing on the cover sheet is used to provide a fluid-tight seal around the feedthrough for the suction tube at the wound site. Within the enclosure, the suction tube is connected with a piece of open-cell foam for placement in the wound. The open-cell foam functions to more uniformly apply reduced pressure or suction over the wound site while holding the cover sheet substantially out of the wound during the application of reduced pressure at the enclosed wound site.

In operation, a method of treating tissue damage is provided which comprises applying a negative or reduced pressure to a wound over an area sufficient to promote the migration of epithelial and subcutaneous tissue toward the wound and for a time period sufficient to facilitate closure of the wound. The method is useful for treating pressure sores.

A method of treating a burn wound is also provided which comprises applying a negative or reduced pressure to the burn over an area and for a time sufficient to inhibit progression in the depth of the burn. The method is useful on a partial thickness burn soon after its infliction.

A method of treating tissue damage is also provided which comprises applying a negative or reduced pressure to a wound for a time sufficient to reduce bacterial density in the wound. One use of this method is its application to a wound for a selected time period such as at least three days to reduce the bacterial density of an infected wound to the point at which surgical closure can be attempted.

Another aspect of the invention is a method of enhancing the attachment of adjacent tissue to a wound which comprises applying negative or reduced pressure to a joined complex of the adjacent living tissue and the wound at a sufficient magnitude of reduced pressure and for a sufficient time duration to promote the migration of epithelial and subcutaneous tissue toward the complex. This method enhances attachment of adjacent tissue to tissues of the wound edges. Another use of this method is to enhance attachment of an open skin graft to the wound tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of the preferred embodiments of the present invention, will be better understood when read in conjunction with the appended drawings, in which:

FIG. 1 is a schematic elevational view of a wound treatment apparatus in accordance with the present invention in which a reduced pressure appliance, shown in partial section, includes a flexible, fluid impermeable wound cover sealed over the wound and a foam wound screen positioned in the wound, and in which a vacuum system provides reduced pressure within the wound cover of the appliance;

FIG. 2 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention having a rigid, fluid impermeable wound cover sealed over a wound and a rigid or semi-rigid screen overlying the wound;

FIG. 3 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention having a rigid, fluid impermeable wound cover sealed over a wound;

FIG. 4 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention having a semi-rigid, fluid impermeable cover enclosing a wound and a rigid or semi-rigid screen overlying the wound, with an overlying flexible fluid impermeable cover sheet sealing the enclosure over the wound;

FIG. 5 is a schematic elevational view of a reduced pressure appliance, shown in partial section, in accordance with another embodiment of the present invention having a

flexible, fluid impermeable wound cover over an inner rigid porous support cup;

FIG. 6 is a schematic elevational view of a reduced pressure appliance, shown in partial section, having a rigid outer frame with support legs for supporting a flexible, fluid impermeable sealing cover over a wound;

FIG. 7 is a schematic elevational view in partial section of an alternative fluid collection device having a float valve for use in the vacuum system of FIG. 1;

FIG. 8 is a schematic view of an alternative vacuum system;

FIG. 9 is a schematic view of an alternative vacuum system incorporating a fluid collection device having an actuator for de-activating the vacuum system upon collection of a predetermined quantity of fluid;

FIG. 10 is a schematic cross-sectional view of a reduced or negative pressure appliance comprising an open-cell polymer foam screen, a flexible hose for connecting the foam screen with a vacuum system, and an adhesive-backed flexible polymer sheet overlying the foam-hose assembly to provide a seal over a wound; and

FIG. 11 is a schematic cross-sectional view of a reduced or negative pressure appliance comprising a rigid porous screen for a wound, a rigid or semi-rigid cup for covering the wound having an inflatable cuff attached about the base of the cup, and a flexible hose extending from the cup for connection with a vacuum system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In accordance with the present invention, a wound treatment apparatus is provided for treating a wound by application of reduced pressure (i.e., below atmospheric pressure) so that suction may be applied to a wound site in a controlled manner for a selected time period. As schematically shown in FIG. 10, a wound treatment apparatus includes a reduced pressure appliance, generally designated 600, which is applied to a wound site to treat the wound through the application of reduced pressure. The appliance 600 is sealed in position over the wound site to create a generally fluid-tight or gas-tight enclosure over the wound site.

The appliance 600 includes a substantially flat section of open cell polyester foam section 610 (Fischer Scientific, Pittsburgh, Pa. 15219) sufficiently large to cover the wound and thus prevent wound overgrowth, a flexible hollow tube 611 (Fischer Scientific) inserted into the open cell foam section 610 and joined thereto with an adhesive and extending to attach at its opposite end with a Gast Vacuum pump (Fischer Scientific), and an Ioban adhesive sheet 612 (Minnesota Mining and Manufacturing, St. Paul, Minn. 55144) overlying the foam section 610 and tubing 611 and adhered to the skin surrounding the wound, thus forming a seal that allows creation of a vacuum when the suction pump operates. Such an appliance 600 would most preferably be packaged in a sterile condition to ameliorate the need for sterilization of the apparatus prior to use. The adhesive sheet 612 may be packaged separately from the foam-tube assembly 610 and 611. A particular advantage of this configuration is its use with pressure sores because the device can be placed in the depths of the wound and the patient can lie upon the device without either affecting the utility of the device or further damaging the wound. This becomes critical if the patient cannot be moved from this posture for medical or other reasons.

As shown in FIG. 11, a reduced pressure appliance, generally designated 615, in accordance with another embodiment of the present invention, is schematically depicted. The reduced pressure appliance 615 includes an adult CPR mask 620 (Doug Brown and Associates, Huntington Beach, Calif. 92648) comprising a rigid or semi-rigid fluid impermeable cup 621 having an inflatable cuff 622 mounted around the periphery of the base of the cup 622 for contact with the skin, an open cell polyester screen 624 overlying the wound, and a flexible ¼ inch diameter hose 623 (Fischer Scientific) connected by a Nalgene tubing connector extending through a sealed hole in the cup for connection with a vacuum pump (Fischer Scientific). The hose 623 is connected with the pump 40 of a vacuum system 30 of the type shown in FIG. 1 to provide reduced pressure within the cup 621. The vacuum created within the cup 621 by the vacuum system may be sufficient to seal the cup in position over the wound site. Alternatively, fluid impermeable adhesive covering or strips may also be used to seal the appliance 615 in proper position.

Referring to FIG. 1, a wound treatment apparatus, generally designated 25, is depicted having a reduced pressure appliance 29 for enclosing a wound site to provide a fluid-tight or gas-tight enclosure over the wound site to effect treatment of a wound 24 with reduced or negative pressure. The wound treatment apparatus 25 includes a reduced pressure appliance, generally designated 29, which is applied to and sealed over a wound site in order to enclose the wound site for treatment with suction or reduced pressure within a sealed generally fluid-tight or gas-tight enclosure. For the purpose of creating suction within the appliance 29, the appliance 29 is connected with a vacuum system, generally designed 30, to provide a source of suction or reduced pressure for the sealed appliance 29 at the wound site. The appliance 29 includes a fluid-impermeable wound cover 18 in the form of a flexible, adhesive, fluid impermeable polymer sheet for covering and enclosing the wound 24 and the surrounding normal skin 22 at the wound site. The wound cover 18 includes an adhesive backing 20 which functions to seal the wound cover to the normal skin 22 around the periphery of wound 24 to provide a generally gas-tight or fluid-tight enclosure over the wound 24. The adhesive cover sheet 18 must have sufficient adhesion to form a fluid-tight or gas-tight seal 19 around the periphery of the wound and to hold the sheet 18 in sealed contact with the skin during the application of suction or reduced or negative pressure.

The appliance 29 also includes a porous wound screen 10 which is placed within the wound 24. The wound screen 10 is placed over substantially the expanse of the wound to prevent its overgrowth. The size and configuration of the wound screen 10 can be adjusted to fit the individual wound. It can be formed from a variety of porous materials. The material should be sufficiently porous to allow oxygen to reach the wound. The wound screen 610 may be in the form of an open-cell polymer foam, such as a polyurethane foam, which is sufficiently porous to allow gas flow to and/or from the wound 24. Foams may be used that vary in thickness and rigidity, although it may be desirable to use a spongy material for the patient's comfort if the patient must lie upon the appliance during treatment. The foam may also be perforated to enhance gas flow and to reduce the weight of the appliance. As shown in FIG. 1, the screen 10 is cut to an appropriate shape and size to fit within the wound 24. Alternatively, the screen may be sufficiently large to overlap the surrounding skin 22.

The appliance 29 also includes a suction port in the form of a hollow suction tube 12 that connects with the vacuum system 30 to provide suction within the sealed enclosure.

The suction tubing **12** serves as a suction port for appliance **29**. An end segment **12***a* of the tubing **12** is embedded within the foam screen **10** for providing suction or reduced pressure within the enclosure provided under the wound cover **18**. Embedding the open end of segment **12***a* of tubing **12** within the interior of the foam screen **10** permits the foam screen **10** to function as a shield to help prevent the wound cover **18** from being inadvertently sucked into sealing engagement with the open end of the tube thereby plugging the tube **12** and restricting gas flow. The tube segment **12***a* embedded within the foam screen **10** preferably has at least one side port **14** for positioning within the interior of the foam screen **10** to promote substantially uniform application of reduced pressure throughout the enclosure. Positioning the side port **14** of tube segment **12***a* within the interior of the foam screen **10** permits the foam screen **10** to function as a shield for the side port to thereby prevent the wound cover **18** from being sucked into the side port **14** and thereby restricting gas flow. The open cells of the foam screen **10** facilitate gas flow throughout the enclosure. In addition, the foam screen **10** functions to prevent wound overgrowth and to hold the wound cover **18** generally out of contact with the wound **24** during the application of suction within the enclosure.

Tubing **12** and tube segment **12***a* are sufficiently flexible to permit movement of the tubing but are sufficiently rigid to resist constriction when reduced pressure is supplied to the appliance **29** or when the location of the wound is such that the patient must sit or lie upon the tubing **12** or upon the reduced pressure appliance **29**. The screen-tube assembly comprising the foam screen **10** and the tube **12** may be fabricated by snaking the end of the tube segment **12***a* through an internal passageway in the foam screen **10** such as by pulling the end of the tube segment **12***a* through the passageway using forceps. Alternatively, fabrication of the screen-tube assembly may be accomplished by suspending the end of the tube segment **12***a* into a suitable mold or form and then blowing foam into the mold or form to embed the tube end segment **12***a* within the blow-molded foam screen. The screen-tube assembly **12** and **10** is preferably prepared prior to use under sterile conditions and then stored in an aseptic package.

In order to use the reduced pressure appliance **29** at the site of the wound **24**, the flexible, gas-impermeable, adhesive wound cover sheet **18** is secured in position at the wound site overlying the foam screen **10** disposed within the wound **24**. The wound cover sheet **18** is secured and sealed to the surrounding normal skin **22** by an adhesive layer **20** on the under surface of the wound cover **18** to form a gas-tight seal **19** around the periphery of the wound **24**. The wound cover **18** also provides a gas-tight seal around the tubing **12** at the feedthrough location **22***a* where the tubing **12** emerges from beneath the wound cover **18**. The wound cover **18** is preferably formed of a fluid impermeable or gas impermeable flexible adhesive sheet such as Ioban, a product of the 3M corporation of Minneapolis, Minn.

The vacuum system **30** includes a suction pump **40** that produces a source of reduced pressure or suction which is supplied to the reduced pressure appliance **29** by suction tubing **12**. As shown in FIG. **1**, a fluid trap, generally designated **28**, is interconnected between the suction pump **40** and the appliance **29** to remove and collect any exudate which may be aspirated from the wound **24** by the reduced pressure appliance. The appliance **29** functions to actively draw fluid or exudate from the wound **24**. Collection of exudate in a fluid trap **28** intermediate the pump **40** and the appliance **29** is desirable to prevent clogging of the pump **40**. A suitable fluid trap **28** may be assembled from an Erlenmeyer or side-arm flask **31** having a top opening and a side-arm opening. The fluid trap **28** includes a first port **32** at the top opening of the flask for sealed connection to suction tubing **12**. The first port **32** enables suction to be applied to the reduced pressure appliance **29** through the tubing **12** and also enables exudate from the wound covered by reduced pressure appliance **29** to be drained into the flask **31**. The flask **31** provides a collecting vessel **33** for the fluid trap for containing and temporarily storing the collected exudate. A suction port **34** is provided at the side-arm opening of the flask to enable the application of suction from vacuum pump **40**. The suction port **34** of the fluid trap **28** is connected to the vacuum pump **40** by vacuum line **36**. The fluid trap **28** is sealed generally gas-tight to enable the suction pump **40** to supply suction to the appliance **29** through the fluid trap **28**. A filter **38** such as micropore filter is preferably attached to the exhaust of the pump **40** to prevent potentially pathogenic microbes or aerosols from being vented to atmosphere by the vacuum pump **40**.

Predetermined amounts of suction or reduced pressure are produced by the vacuum pump **40**. The vacuum pump **40** is preferably controlled by a control device **44** such as a switch or a timer which may be set to provide cyclic on/off operation of the vacuum pump **40** according to user-selected intervals. Alternatively, the vacuum pump **40** may be operated continuously without the use of a cyclical timer.

The vacuum system **30** preferably includes a shutoff mechanism for halting or inhibiting the supply of the reduced pressure to the appliance **29** in the event that the exudate aspirated from the wound **24** exceeds a predetermined quantity. Interrupting the application of suction to the appliance **29** is desirable to prevent exsanguination in the unlikely event a blood vessel ruptures under the wound cover **18** during treatment. If, for example, a blood vessel ruptures in the vicinity of the wound **24**, a shut-off mechanism would be useful to prevent the vacuum system **30** from aspirating any significant quantity of blood from the patient. As a safety feature, various mechanical or electrical detection mechanisms may be employed to detect the level of exudate in the fluid trap **28**.

As shown in FIG. **7**, a fluid trap **28** employing a collection bottle or flask **35** is provided for connection intermediate the pump **40** and the appliance **29** for collecting exudate from the wound site. The flask **35** has a side-arm port **43** connected to suction tube **12** leading to the reduced pressure appliance **29** and a suction port **34** located at the top **44** of the flask **35** connected to the vacuum hose **36** leading to the vacuum pump **40**. For the purpose of detecting liquid level within the flask **35**, a float valve assembly, generally designated **39**, is provided. The float-valve assembly **39** functions to close and seal off the suction port **34** of the fluid trap **28** when the quantity of exudate in the collecting vessel **33** exceeds a predetermined quantity. The float valve assembly **39** is provided in the form of a ball **46** which is held and suspended within a cage **47** positioned below a valve seat **48** disposed within the opening at the top **44** of the flask **35**. The ball **46** has a specific gravity below that of the exudate so that the ball **46** will float upon the exudate and will be lifted against the valve seat **48** as the vessel **33** fills with exudate. When the ball **46** is firmly seated against the valve seat **48**, the float valve **39** blocks suction port **34** and thereby shuts off the source of suction from vacuum line **36**. The suction within the appliance **29** at the wound site arrests thus halting the aspiration of exudate from the wound.

Other types of mechanisms may be employed to detect the liquid level within the fluid trap **28** in order to arrest operation of the vacuum source. An alternative vacuum

system 30*a* is shown in FIG. 8 in which a filter 38*a* is employed in vacuum line 36 for filtering the fluid or gas flow through the vacuum line 36 and for detecting the level of liquid in fluid trap 28. Exudate from the wound is collected in vessel 33. When the vessel 33 becomes full, aspiration of further exudate from the wound causes the vacuum line 36 to begin to collect exudate which eventually reaches the in-line filter 38a positioned in the vacuum line 36 intermediate the fluid trap 28 and the pump 40*a* having operational control 44*a*. The filter 38*a* contains a filter element that is selected to clog when exposed to sufficient amounts of moisture to thereby halt the supply of suction through the fluid trap 28 to the appliance 29. The filter 38*a* is preferably an in-line, disc-shaped submicron filter having a nitrocellulose or PTFE filtration element for filtering particles larger than about 0.1 μm from the vacuum line 36. In addition to preventing excess fluid aspiration, the filter 38*a* in the vacuum line 36 prevents contamination of the vacuum pump 40 by filtering potentially pathogenic microbes and aerosols.

Other types of detection devices may also be employed to detect a predetermined level of liquid collected in collection vessel 33. For example, collection of exudate in excess of a predetermined quantity may enable actuation of an electronic switch which turns off the vacuum pump or otherwise halts the supply of suction to the reduced pressure appliance 29. Referring to FIG. 9, the suction tubing 12 from the reduced pressure appliance 29 is connected to a three-port coupling device 160 that interconnects suction tube 12, vacuum line 36*b* and fluid collecting apparatus 131. The coupling device 160 permits transmission of suction from the vacuum line 36*b* of the pump 40*b* to the suction tubing 12. The coupling device 160 also permits aspirated exudate from tubing 12 to be collected in an expandable container, such as an intravenous fluid bag 162, housed beneath the coupling device 160 in a rigid housing vessel 33*b*. As exudate is collected, the bag 162 expands to conform to the shape of the interior surface of the surrounding rigid vessel 33*b*. An actuator 166, such as a spring-loaded actuator switch, is located within the side wall of the rigid vessel 33*b* and functions to shut off the pump 40*b* upon actuation of the switch 166. When the bag 162 expands sufficiently to contact and actuate switch 166 as shown in dashed lines at 162*a* in FIG. 9, the switch 166 is opened and the supply of power to the pump 40*b* along power line 164 is interrupted and the supply of suction to the appliance 29 is stopped. The actuator switch 166 may also cooperate with control 44*b* for the pump 40*b* to stop operation of the pump 40*b*. Other types of devices may also be employed to detect fluid levels in fluid trap 28. For example, weight detectors may be employed to detect a predetermined weight limit as the fluid trap fills with exudate or other liquid. Alternatively, optical sensors or detectors may also be employed.

For the purpose of protecting the site of a wound from impact or abrasion during treatment, a reduced pressure appliance employing a rigid or semi-rigid wound cover may be utilized over the site of the wound. As shown in FIG. 2, a reduced pressure appliance 29*a* includes a CPR mask 58 that provides a rigid wound cover for enclosing an appropriately-sized wound 74. The mask 59 is impermeable to fluids or gases so that a fluid-tight or gas-tight enclosure is effected over the wound site. The mask 59 is sufficiently rigid to support itself away from the wound during the application of suction or reduced pressure so that the mask 59 does not collapse into the wound 74. The CPR mask 58 is of the type having an inflatable air cuff 59 around the base of the mask. The cuff 59 may be inflated via an external valve for sealing the mask 59 against the normal skin 72 around the periphery of the wound 74. The air cuff 59 also prevents the base of the mask from digging into the skin 72 during application of reduced pressure. An optional screen 50 for preventing overgrowth of the wound 74 may be positioned to overlie the wound 74. The screen 50 may be formed of a rigid or semi-rigid perforated polymer surgical mesh such as Prolene mesh. Alternatively, a section of honeycombed polyethylene sheet may be cut to a suitable size and shape to overlie the wound 74. The screen 50 is held against the surrounding normal skin 72 in position overlying wound 74 by the cuff 59 which overlaps at least a portion of the periphery of the screen 50. The CPR mask 58 also includes a suction port in the form of a hose connector 54 to which one end of a suction tube 52 is attached. The other end of tube 52 is connected with a vacuum system 30 of the type previously described to provide a source of suction or reduced pressure for the appliance 29*a*. Suction produced within the appliance 29*a* may be sufficient to seal the cuff 59 to the skin and to thereby seal the appliance 29*a* in position over the wound site. However, in order to ensure a gas-tight seal between the reduced pressure appliance 29*a* and the surrounding skin 72, the mask 58 may also be secured to the treatment site with a fluid impermeable adhesive seal 68. The adhesive seal 68 may be formed of a flexible adhesive material such as an adhesive tape or an adhesive sheet that has been cut to surround and at least partially overlie the cuff 59. As shown in FIG. 2, the adhesive seal is secured to the base portion of the rigid mask 58 and to the normal skin 72 around the periphery of the air cuff 59 to seal the mask in position over the wound site.

As shown in FIG. 3, a reduced pressure appliance 29*b* is depicted having a rigid, fluid impermeable, cup-shaped wound cover 88 overlying a wound site. The appliance 29*b* is used to treat a wound 114 without any screen either in the wound or overlying the wound. The cover cup 88 can be formed of a polymer such as polystyrene, HDPE, or other suitably rigid material. The cup 88 must be sufficiently rigid to support itself out of contact with the wound 114 during the application of suction or negative pressure so that the cup 88 does not collapse into the wound. Reduced pressure is supplied to the interior of the cup 88 through the suction tubing 82 connected to suction port 84 in the form of a nipple sealed in position on the cup 88. The tubing 82 is also connected with a suitable vacuum system 30 of the type previously described to provide a source of suction or negative pressure within the appliance 29*b*. The base of the cup 88 supports an inflatable air cuff 89 to seal the cup 88 to the skin and to prevent the cup 88 from digging into the skin 92 and causing discomfort when reduced pressure is applied. The cuff 89 is positioned upon the normal skin 92 surrounding the wound 94. While the suction created within the cup 88 may be sufficient to hold the appliance in position by causing the air cuff to seal to the skin, more effective attachment of the appliance to the surrounding skin 92 may be obtained by the use of a strip of fluid impermeable, adhesive material secured to the skin 102 and to the base of the cup 88 over the air cuff 89 around the periphery of the base of the cup 88. The layer of adhesive material 98 helps to ensure that a fluid-tight or gas-tight seal is maintained between the cup 88 and the surrounding skin 92 so that a fluid-tight enclosure is formed over the wound site.

Referring to FIG. 4, a reduced pressure appliance 29*c* is depicted for enclosing a wound site for the treatment of wound 114 with suction or reduced pressure. The reduced pressure appliance 29c includes a fluid-impermeable wound covering, generally designated 116, having an outer flexible, adhesive polymer sheet 117 applied over an inner, generally

circular, semi-rigid shield **118**, such as a polystyrene shield, for covering and enclosing the wound site. The base of the shield **118** is positioned over a circular pad **109** which may be formed from flexible tubing to prevent the base of the cup from digging into the skin **102** and causing discomfort when suction is applied to the appliance **29***c*. The pad **109** may also facilitate sealing of the cover shield **118** in position over the wound site to form a fluid-tight or gas-tight enclosure over the wound site. The pad **109** may be positioned directly onto the normal skin **102** surrounding the wound **114** or, as shown in FIG. **4**, the pad **109** may overlie an outer peripheral portion of a rigid screen **100** in order to hold the screen **100** in a position overlying the wound to prevent wound overgrowth. A suction port **104** is provided at the top of the shield **118** to permit gas-tight connection to suction tube **112**. The suction port **104** may be in the form of a removable connector that is screwed into position at the top of the shield **118**. Suction tube **112** functions to connect the appliance **29***c* to a suitable vacuum system **30** of the type previously described. For the purpose of enhancing the sealing of the appliance **29***c* in position over the wound site, an over-sized, generally circular, adhesive, fluid impermeable polymer sheet **117** is adhered and secured to the top surface of the shield **118**. The oversized adhesive sheet **117** extends beyond the outer periphery of the shield **118** so that the adhesive sheet **117** provides a sealing ring **119** of material around the periphery of the shield. The sealing ring **119** is sealed and adhered to the normal skin **102** around the outer periphery of pad **109**. When sealed in position overlying wound **114**, the appliance **29***c* provides a generally fluid-tight or gas-tight enclosure over the wound site.

Referring to FIG. **5**, a reduced pressure appliance **29***d* is depicted for enclosing and treating a wound **124** with suction or reduced pressure. A rigid or semirigid porous cup **138** is placed rim side down upon a porous screen or pad **120** located within a wound **124**. The cup **138** has perforations **133** for equalizing pressure inside and outside of the cup **138**. A flexible, fluid impermeable adhesive polymer cover sheet **128** is draped over the cup **138** to enclose the wound **124**. The adhesive cover sheet **128** is adhered and sealed to the top portion of the cup **138** and to the surrounding normal skin **122** by adhesive layer **129** on the underside of the cover sheet **128** to provide a fluid-tight enclosure beneath the sheet **128**. The cup **138** provides a generally central support beneath the cover sheet **128** to hold the cover sheet **128** out of contact with the wound **124** during application of suction. The cup **138** has a central suction port **134** sealed in position at the top of the cup **128** to permit connection by suction tube **132** to a vacuum system **30** of the type previously described. When reduced pressure is supplied to the appliance **29***d*, the cover sheet **128** is deformed downward and inward to position **128***a* as shown in phantom in FIG. **5**. Tension developed within the deformed sheet **128***a* by virtue of the suction is exerted upon the surrounding skin by the sheet at position **128***a*. The outer periphery **124***a* of the wound **124** is pulled inward by virtue of such tension to the position shown in phantom at **124***b* to promote closure of the wound. The tension within the sheet at position **128***a* also exerts a downward force upon the cup **138** which more firmly presses the cup **138** onto the wound **124**. Such downward force on the cup **138** may be desired in such applications as flap or graft attachment to promote contact between the flap or graft and the underlying tissue. The pad **124** under the cup **138** helps to alleviate discomfort caused by the downward force on the cup **138**.

For applications where a downward pressure of the appliance into a wound is not desired, a reduced pressure appliance **29***e*, as shown in FIG. **6**, may be utilized having a support structure, generally designated **151**, which is positioned external to a flexible sealing sheet **148** for covering a wound **144**. The flexible cover sheet **148** is in the form of a flexible, fluid impermeable, adhesive polymer sheet. The reduced pressure appliance **29***e* shown in FIG. **6** includes an external support frame **151** in the form of a series of spider-like legs **158** radiating outwardly from a central support hub **155**. The legs **158** hold the central hub **159** directly over the wound **144**. A connector **153** is removably mounted to the hub **155** to permit a suction tube **152** to be connected with the flexible cover sheet **148**. The connector **153** may screw together and apart to permit the connector to be removably mounted relative to the hub **155**. The flexible adhesive sheet **148** is adhered to the connector **153** at hub **155** and to the surrounding normal skin **142** so that the sheet is suspended over the wound **144** from the hub **155** in tentlike fashion. The flexible sheet is adhesively sealed to the connector **153** at the hub **155** and is also adhesively sealed to the skin **142** around the periphery of the wound **144** to form a fluid-tight or gas-tight enclosure over the wound site. The legs **158** of the frame **153** extend radially outward from the hub **153** and stand upon feet members **159** which may rest upon the outer periphery of the sheet **148** to help hold the cover sheet **148** in a position from being sucked together during the application of suction. Alternatively, the feet members **159** may extend beyond the cover sheet **148** and may rest upon the surrounding tissue beyond the periphery of the cover sheet **148**. The connector **153** supported on the hub **155** provides a suction port **154** through which suction is supplied to the appliance **29***e* via suction tube **152**. Tube **152** is connected to a vacuum system **30** of the type previously described for supplying reduced pressure within the cover sheet **148**. When suction or reduced pressure is introduced via port **154**, the sheet **148** deforms inwardly and downwardly to the position shown in phantom at **148***a* thus developing tension which is exerted upon the surrounding skin **142**. The deformed sheet in position at **148***a* pulls the edges of the wound **144** inwardly to the position indicated in phantom at **144***b* hence promoting closure of the wound **144**.

Negative pressure appliances are useful for treating a variety of wounds. Treatment of a wound can be carried out by securing a negative pressure appliance to the treatment site as previously shown and described, and then maintaining a substantially continuous or cyclical reduced pressure within the appliance until the wound has reached a desired improved condition. A selected state of improved condition may include formation of granulation tissue sufficient for the attachment of a flap or graft, reduction of microbial infection in the wound, arrest or reversal of burn penetration, closure of the wound, integration of a flap or graft with the underlying wounded tissue, complete healing of the wound, or other stages of improvement or healing appropriate to a given type of wound or wound complex. It may be preferable to change the appliance periodically, such as at 48 hour intervals, during treatment, particularly when using appliances incorporating a screen on or in the wound. The method is preferably practiced using a negative or reduced pressure ranging from 0.01 to 0.99 atmospheres, and more preferably practiced using a negative or reduced pressure ranging between 0.5 to 0.8 atmospheres. The time period for use of the method on a wound may preferably be at least 12 hours, but can be, for example, extended for one or more days. There is no upper limit beyond which use of the method is no longer beneficial; the method increases the rate of closure up to the time the wound actually closes. Satisfactory treatment of various types of wounds has been obtained via

the use of reduced pressures equivalent to about 2 to 7 in. Hg below atmospheric pressure.

Supplying reduced pressure to the appliance in an intermittent or cyclic manner has also been demonstrated to be useful for treating wounds. Intermittent or cyclic supply of reduced pressure to an appliance may be achieved by manual or automatic control of the vacuum system. A cycle ratio, the ratio of "on" time to "off" time, in such an intermittent reduced pressure treatment may be as low as 1:10 or as high as 10:1. The preferred ratio is approximately 1:1 which is usually accomplished in alternating 5 minute intervals of reduced pressure supply and non-supply.

A suitable vacuum system includes any suction pump capable of providing at least 0.1 pounds of suction to the wound, and preferably up to three pounds suction, and most preferably up to fourteen (14) pounds suction. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the necessary suction. The dimension of the tubing interconnecting the pump and the reduced pressure appliance is controlled by the pump's ability to provide the suction level needed for operation. A ¼ inch diameter tube may be suitable.

The present invention also includes a method of treating damaged tissue which comprises the steps of applying negative pressure to a wound for a selected time and at a selected magnitude sufficient to reduce bacterial density in the wound. Open wounds are almost always contaminated with harmful bacteria. Generally a bacterial density of 10^5 bacterial organisms per gram of tissue is regarded as infected. It is generally accepted that at this level of infection, grafted tissue will not adhere to a wound. These bacteria must be killed, either through the wound host's natural immune response or through some external method, before a wound will close. The application of negative pressure to a wound appears to reduce the bacterial density of the wound. It is believed that this effect is due to either the bacteria's incompatibility with a negative pressure environment or the increased blood flow to the wound area, as blood brings with it cells and enzymes to destroy the bacteria. The method can be used to reduce bacterial density in a wound by at least half. More preferably, it can be used to reduce bacterial density by at least 1,000 fold. Most preferably, the method can be used to reduce bacterial density by at least 1,000,000 fold.

The present invention also includes a method of treating a burn which comprises the steps of applying negative pressure to the burn over an area with predetermined reduced pressure and for a time sufficient to inhibit formation of a full thickness burn. A partial thickness burn, one which has a surface layer of dead tissue and an underlying zone of stasis, is often sufficiently infected so that it will transform within 24–48 hours into a full thickness burn, one in which all epidermal structures are destroyed. The application of negative pressure to the wound prevents the infection from becoming sufficiently severe to cause destruction of the underlying epidermal structures. The magnitude, pattern, and duration of pressure application can vary with the individual wound.

The present invention also provides a method for enhancing the attachment of living tissue to a wound which comprises the steps of first joining the living tissue to the wound to form a wound-tissue complex, then applying a negative or reduced pressure of selected magnitude to the wound-tissue complex over an area sufficient to promote migration of epithelia and subcutaneous tissue toward the complex, with the negative pressure being maintained for a selected time period sufficient to facilitate closure of the wound. Attachment of living tissue to a wound is a common procedure that can take many forms. For example, one common technique is the use of a "flap," a technique in which skin tissue from an area adjacent to the wound is detached on three sides but remains attached on the fourth, then is moved onto the wound. Another frequently used technique is an open skin graft in which skin is fully detached from another skin surface and grafted onto the wound. The application of negative pressure to the wound-graft complex reduces bacterial density in the complex and improves blood flow to the wound, thereby improving the attachment of the grafted tissue. Further features of the apparatus and methods for the use thereof shall be made apparent in the following examples.

EXAMPLE 1

Treatment of Open Wounds

In order to demonstrate the use of a negative pressure appliance in the treatment of open wounds, an animal study was conducted using pigs as subjects. Pigs are frequently used as subjects in wound healing studies since they have essentially the same skin and subcutaneous tissue structure as humans.

Five 15 kg Chester pigs were obtained and acclimated for 1 week prior to use. The animals were sedated with an intramuscular injection of ketamine (25 mg/kg): xylazine (2.5 mg/kg): acepromazine (5 mg/kg). The backs and sides of the animals were shaved and scrubbed for surgery. One percent halothane was administered by endotracheal tube for maintenance of anesthesia. Two circular wounds were created on the midline of the animals. The wounds were 2.5 cm in diameter having a depth reaching, but not including, the deep fascia over the spine (approximately 1 cm). Wounds in pigs in this site do not contract during healing. Alginate impressions were made of each wound to determine the volumes of the wounds.

A reduced pressure appliance of the type discussed in connection with FIGS. 2 and 11 was positioned over each wound, and the cups were sealed to the skin with an Ioban sheet. A non-compressible silicone tube was attached to the anterior appliance of each pig and a reduced pressure of 5 in. Hg below atmospheric pressure was supplied to the anterior appliances. No reduced pressure was applied to the posterior wounds. The animals were allowed to recover from anesthesia and given food and water ad libitum. The tubes were suspended from a pulley system over the top of each pen arranged to provide each animal with full, unrestricted access to its pen.

The animals were sedated 48 hours after surgery as described above, and then daily thereafter, so that alginate impressions could be made of each wound. This routine was continued until the wounded areas were filled with granulation tissue until coplanar with the surrounding tissue. The results of this experiment, including time to complete filling of the wound space by granulation tissue and the rate of granulation tissue formation, are presented in Table 1. The data in the third column of Table 1 shows the number of days needed for the treated and non-treated wounds to heal. In order to allow comparisons between the healing rate of variously-sized wounds, the data in the fourth column is expressed as a healing rate in terms of cc granulation tissue per day. As can be seen, the treated wounds exhibited higher rates of healing than did the non-treated wounds. The wounds treated with reduced pressure filled with granulation

tissue at an average rate that was 52.3% greater than the rate of granulation of the control wounds. Animals numbered 1 and 2 experienced intermittent loss of reduced pressure throughout the experiment, yet the treated wounds of these animals also healed significantly faster than their control wounds.

TABLE 1

Animal	Wound	Initial Wound Volume (cm^3)	Days to Full Granulation	Fill Rate (cm^3/day)	% Rate Increase Due to Treatment
#1	Control	4.9	13	0.38	
	Treated	5.3	11	0.48	26.3
#2	Control	7.2	8	0.90	
	Treated	9.3	8	1.16	28.9
#3	Control	4.0	12	0.33	
	Treated	3.5	6	0.58	75.8
#4	Control	4.7	11	0.43	
	Treated	5.0	7	0.71	65.1
#5	Control	4.7	11	0.43	
	Treated	5.1	7	0.71	65.1
Average	—	—	—	—	52.3

EXAMPLE 2

Reduction of Infection

During the course of the experiment described as Example 1 above, it was observed that the reduced pressure-treated wounds were much cleaner and bled more spontaneously than non-treated wounds. It was therefore undertaken to determine the relative rates of clearance of a known bacterial inoculum from treated and non-treated wounds.

Five 15 kg pigs were obtained and wounds created as set forth in Example 1. Two 2.5 cm diameter defects were created on the dorsum of each pig using a sterile technique, with a 7.5 cm interval retained between the edges of the defects. Hemostasis was obtained by electrocautery. Prior to placement of the reduced pressure appliances, 10^8 organisms of *Staphylococcus aureus* in 1 ml saline solution were injected into each wound. The reduced pressure appliances of the type shown in FIGS. 2 and 11 were then attached as in Example 1, and a reduced pressure of 5 in. Hg below atmospheric pressure was applied to one of the wounds upon each animal. Reduced pressure was not applied to the other wound upon each animal. T-shirts were placed over the animals and no antibiotics were given during the course of the study. The animals were sedated as in Example 1 at 24 hour intervals, and a 3 mm diameter full thickness biopsy was taken from each wound site daily. The devices were then reattached and reduced pressure re-applied. This routine was continued for one week.

The biopsy samples were weighed and sterile saline (99×biopsy weight) added. The tissue samples were homogenized in a tissue grinder and serial dilutions were made in triplicate. 100 microliters of each dilution was plated on a blood agar plate and incubated overnight. The number of colonies were counted on each plate and thus the number of organisms per gram of tissue was calculated. The data was recorded as the common logarithm of the number of organisms/gram tissue and is shown in Table 2.

TABLE 2

	Average Log_{10}(organisms/gm)						
	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 7
Control	8.44	8.04	8.17	7.13	7.13	8.82	7.08
Treated	7.69	7.36	7.37	6.79	6.43	3.98	4.32

As can be seen in Table 2, the common logarithm of the average number of organisms per gram of tissue present in the treated and non-treated wounds decreased slightly for all five animals over the first 4 days. In the treated wounds, the mean log of organisms/gm decreased dramatically between days 4 and 5. The mean log of organisms/gm within the non-treated wounds increased during the same period. Using the traditional baseline of 10^5 organisms/gm to define infection, the data of Table 2 shows that the average treated wound was disinfected after four days of treatment while the average non-treated wound was still infected after 7 days.

EXAMPLE 3

Treatment of Burns

Use of reduced pressure appliances upon burns has been found to retard the progression of partial thickness burns into full thickness burns. A partial thickness burn is a burn in which the depth of cell death due to thermal trauma does not extend below the level of the deepest epidermal structures (i.e., the base of hair follicles, sweat glands, sebaceous glands, etc.). A burn that is initially a partial thickness burn will often deepen and progress into a full thickness burn due to insufficient blood circulation to the epidermal cells beneath the partial burn.

EXAMPLE 3A

The backs of five 15 kg pigs were shaved and scrubbed for surgery. A 1.5 inch diameter brass rod was heated to 190° C. in an oil bath. The rod was pressed onto the pig's skin for 15 seconds following a well-known technique of relating depth of burn to time and temperature. Three burns were created over the spine of each pig, separated by 5 cm intervals. Suction apparatus cups of the configuration shown in FIGS. 2 and 11 were placed over two of the burns, with silver sulphadiazine (Silvadine) cream, the standard antibiotic cream applied to human burns prior to excision of burned tissue, applied to the third. Cefaxolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). Suction (2–6 pounds vacuum) was applied to one of the cups. A small (2 mm) punch biopsy was taken of the wounded area and examined histologically for depth of burn.

Biopsies were analyzed by a dermatopathologist who was not told the nature of the study. It was concluded that the suctioned tissue specimens were healthier and healing more quickly than non-suctioned specimens.

EXAMPLE 3B

A set of 2 cm diameter standardized depth partial thickness burns were created by pressing a heated metal rod to each side of five anesthetized pigs to create 16 burns on each side of each pig. Reduced pressure appliances of the type shown in FIGS. 2 and 11 were secured over each of the burns on the left side of each animal and a continuous pressure of 6 in. Hg was supplied to the reduced pressure appliances. The animals were anesthetized daily, and elliptical full-

thickness biopsies extending from non-injured tissue, through the center of each burn, and into non-injured tissue were harvested, fixed in formalin, processed for histological analysis and stained with Hematoxylin/eosin and Gomori's trichrome. The histologic slides were then given to a Dermatopathologist for blind determination of burn depth according to the Breslow Local Scale of maximum depth of cell death below the surface of the skin.

The Breslow Level (maximum total depth) for the burns treated by reduced pressure was 0.095 mm. The maximum depth of the burns which were not treated by reduced pressure was 0.885 mm. The use of reduced pressure appliances thus resulted in a 112% reduction in the maximum depth of burn progression.

EXAMPLE 3C

Treatment of Burn With Negative Pressure

Patient B. is admitted with second and third degree burns over the face and upper extremities, including both hands, as a result of a house fire. A large mitten-shaped reduced pressure appliance of the general type shown in FIGS. **1** and **10** is placed over the patient's right hand, with open cell foam inserts placed between the fingers to apply reduced pressure to the interdigit spaces. Three pounds of vacuum is applied cyclically in a pattern of five minutes on, 5 minutes off. The appliance is changed on a three times per week schedule. Treatment is continued until the necrotic tissue sloughs off or is excised, followed by split thickness skin graft placement.

EXAMPLE 4

Treatment of Flaps

In order to determine the effect of reduced pressure application upon skin flap survival, five 15 kg Chester pigs were obtained and acclimated for 1 week as described previously. Two dorsally-based 3 cm by 12 cm flap outlines were drawn using indelible ink on each side of the pigs, leaving 6 cm between each flap. The flaps were assigned to one of four groups as follows:

(1) Dual-treated flaps are flaps that were exposed to reduced pressure both prior to and following surgery;

(2) Pre-treated flaps are flaps that were exposed to reduced pressure prior to surgery, but were not exposed to reduced pressure after surgery;

(3) Post-treated flaps are flaps that were exposed to reduced pressure following surgery; and

(4) Control flaps are flaps that were not exposed to reduced pressure either pre- or post-surgery.

The pre-treated flaps were initially treated by covering an area surrounding one of the flap outlines on the left side of each animal with a reduced pressure appliance of the type shown in FIGS. **1** and **10** having a large piece of open cell foam into which a tube was inserted. The foam was covered and sealed to the flap area with impermeable adherent sheeting. A reduced pressure of 7 pounds was then continuously applied to the area for 7 days.

On the day of surgery, each pig was sedated as previously described and anesthesia was maintained by 1% halothane. Two 3 cm by 12 cm dorsally based flaps were created on each side of the pig following the flap outlines. The flaps were created at a depth immediately below the panniculus carnosus (a subcutaneous muscle layer). The flaps were raised and then sutured back in place with single, interrupted sutures of 3–0 nylon. The reduced pressure appliances were then placed over the anterior flaps on each side of the animal. A reduced pressure of 5–7 pounds was continuously applied to the anterior flaps. Each suction tube ran from the appliances on the animals upward through a pulley suspended over the pens and down to a vacuum trap bottle to collect any liquid exudate. A hose was connected from each vacuum trap bottle to a vacuum pump to supply the reduced pressure to the appliances. The animals had free access to all areas of the pen.

The animals were anesthetized 72 hours after surgery and the appliances were removed. Photographs of each side of the animals were taken, and tracings of the flaps (and encompassing any discolored areas) were made on acetate to allow for planimetric calculation of percent survival. The appliances were then replaced and reduced pressure re-applied. This routine was continued at 48 hour intervals until no further necrosis or healing of the flaps was observed.

The distal portions of all flaps were discolored 72 hours post surgery, with the flaps exposed to reduced pressure being lighter in color. The distal ends of all flaps appeared to necrose and an eschar formed over the distal portion of each flap. Over time the eschar spontaneously desquamated, exposing the outline of the original flap. The eschar over the control and pre-treated flaps consistently desquamated sooner than the post-treated and the dual-treated flaps. The control flaps had contracted to a Y shape which was evident after the eschar had desquamated. The dual-treated flaps had contracted slightly and appeared as long, thin rectangles after dislodgement of the eschar. The pre-treated flaps and post-treated flaps were intermediate between the control and dual-treated flaps in regard to flap contraction.

Dual-treated flaps exhibited the greatest survival in terms of percent retention (72.2%) of the original flap size. The post-treated flaps had the second greatest survival (67.4%). The pretreated flaps had the third most flap survival (64.8%). The control flaps had the least flap survival (51.2%). All treated flaps (dual-treated; pre-treated; and post-treated) exhibited significantly greater surface area survival than the control flaps. The dual-treated flaps had significantly greater surface area survival than either the pre-treated or post-treated flaps. The pre-treated flaps were not significantly different than post-treated flaps in regard to flap survival.

EXAMPLE 5

Treatment of Decubitus Ulcers

Application of reduced pressure was tested upon chronic decubitus ulcers and was found to be effective in the treatment thereof. Necrotic soft tissue was removed from the ulcers prior to placement upon the treatment site of a reduced pressure appliance of the type described in connection with FIGS. **1** and **10**. Treatment of decubitus ulcers was tested using both continuous and cyclic application of reduced pressure. It was found that cyclic application of reduced pressure was both more effective and produced less discomfort for the patients than continuous application. Cyclic application of reduced pressure was conducted according to an application schedule of 5 minutes of suction followed by 5 minutes of non-suction. In 15 patients tested, successful treatment required from 2 to 13 weeks. Thirteen of the ulcers healed completely and every ulcer treated demonstrated progressive decrease in size during treatment. The following case histories demonstrate the manner in which various pressure sores were treated:

Case 1—A 39 year-old male T4 paraplegic had suffered from multiple recurrent pressure sores over a period of 8 years. He had been treated for a trochanteric decubitus with

a tensor fascia lata flap which had developed a recurrent ulcer in the center of the flap 4 months prior to presentation. The ulcer was debrided of necrotic tissue to non-involved periosteum resulting in a wound measuring 12 cm by 5 cm with a depth of 5 cm. During the course of 4 weeks of cyclic reduced pressure application, the wound progressively closed and spontaneously re-epithelialized. Reduced pressure of 5 in. Hg below atmospheric pressure was applied cyclically with 5 minute intervals of applied pressure followed by 5 minute intervals with no applied pressure. The wound remained healed more than 5 months after treatment.

Case 2—A 45 year old male paraplegic suffered from a recurrent right ischial fossa pressure sore and abscess prior to treatment. Debridement of the wound was carried out with partial ischial resection. A week later, a re-advancement of the V-Y biceps femoris flap and rotation gluteus flap was performed. Six days later, the wound dehisced and the patient developed bilateral pneumonia requiring ventilatory support. The flap became progressively edematous and firm and resisted all efforts at mobilization. At this point, reduced pressure treatment providing continuous, non-cyclic suction or a vacuum at approximately five 5 in. Hg below atmospheric pressure was initiated. A total of 2 liters of fluid was removed by the reduced pressure appliance during the first 72 hours of treatment. Intravenous fluids were administered to replace the fluid removed from the wound. The appliance was replaced and the wound was examined three times each week. Treatment was continued for a total of six weeks during which the flap became progressively less indurated, granulation tissue formation rapidly progressed, the edges of the wound came into approximation, and the wound was healed completely.

Case 3—A 51 year-old T1 paraplegic had multiple previous pressure sores culminating in bilateral asynchronous hip disarticulations and bilateral total thigh flaps. Seven months prior to admission, he developed a 7 cm by 23 cm pressure sore over the remnants of both ischia. Bone was exposed and no tissue was available for wound closure. Dressing changes over a period of three months had failed to improve the wound. A reduced pressure appliance was then secured to the wound. During the first 3 weeks of treatment, reduced pressure of 5 in. Hg below atmospheric pressure was continuously applied. For the following 9 weeks, reduced pressure was applied cyclically in 5 minute intervals. The appliance was replaced every three days during treatment. In the course of the treatment, the wound first granulated to cover the bone completely and then the wound re-epithelialized from the margins. After 12 weeks of the treatment, a 2 cm by 5 cm scrotal flap was used to cover the midline area of the wound. The wound has remained stable beyond 6 months after treatment.

EXAMPLE 6

Treatment of Dehisced Incisions

A 50 year old debilitated white male who had undergone a colostomy through a midline laparotomy was re-admitted to the hospital for wound dehiscence and evisceration following an upper respiratory infection. He was taken immediately to the operating room and the abdominal wall was closed with Prolene mesh. Six weeks after placement of the Prolene mesh, the wound was still open and measured 28 cm by 23 cm. Only sparse granulation tissue had grown through the Prolene mesh during the six weeks. At this time a large reduced pressure appliance of the type shown in FIG. 5 was placed on an underlying porous aquaplast sheet (WFR/Aquaplast Corp., Wycoff, N.J. 07481) over top of the Prolene mesh/wound surface and the space closed with a covering tent of Ioban. A continuous vacuum of 5 in. Hg below atmospheric pressure was applied. The appliance was changed three times per week. After 8 days of treatment, granulation tissue had grown through and totally covered the Prolene mesh. Two days later, the patient was taken to the operating room, where the surrounding tissue was undermined and used to close 75% of the wound. Split thickness skin grafts were used to cover the remainder of the wound, and were placed on the bed of granulation tissue. There was 80% take of the grafts, and the remaining areas healed spontaneously with wet to dry dressing changes. The wound has remained stable 16 months after surgery.

EXAMPLE 7

Treatment of Infected Wound

Infected wounds have been successfully treated via application of reduced pressure as described in the following cases:

Case 1—A 39 year old white male sustained severe avulsive trauma to his left lower extremity in a motor vehicle accident 10 years prior to presentation. He presented with a ten year history of chronic osteomyelitis and a 3 cm diameter open ulcer with exposure of bone of his left lateral malleolus. He had previously undergone 7 local surgical procedures to attempt closure of the wound. An arteriogram demonstrated a one vessel foot with diffuse atherosclerosis and post traumatic changes. The extremity was debrided of necrotic soft tissue and all involved bone saucerized. The patient was placed on a five week course of antibiotics. The day after debridement, a reduced pressure device of the type shown in FIGS. 2 and 11 was applied over the wound and a reduced pressure of 5 in. Hg below atmospheric pressure was applied. The device was changed on a three times per week schedule. After 14 days of treatment, the wound was smaller and filled with granulation tissue which completely covered the previously exposed bone. A split thickness skin graft was placed over the wound and healed primarily. The wound has been stable for 13 months with no recurrence of osteomyelitis or tissue breakdown.

Case 2—A 51 year old white male T8 paraplegic was admitted to the hospital for an infected left trochanteric pressure sore which had been present for one year and measured 4 cm by 6 cm. The patient had previously undergone multiple procedures for treatment of this condition including a V-Y advancement flap 4 months prior to presentation. A scan revealed possible chronic osteomyelitis of the left femur. It was decided to treat the potential osteomyelitis with a five week course of IV antibiotics. The wound was debrided, then treated using a reduced pressure appliance of the type shown in FIGS. 1 and 10 for 6 weeks with cyclical reduced pressure (5 in. Hg below atmospheric pressure; 5 minutes on/5 minutes off). The wound rapidly granulated and decreased in size. After 6 weeks the wound had closed and the patient discharged. The patient was readmitted 1 month later with a draining sinus tract to the bone. The previously scanned head of the left femur was resected and the wound closed primarily over drains. The wound healed without further problems.

EXAMPLE 8

Chronic Open Wound Secondary to Stasis Ulcers

A 45 year old black female patient with a 10 year history of bilateral stasis ulcers of the pretibial area was presented

with bilateral 10 cm by 15 cm infected ulcers with exposed fascia. Two previous attempts at skin grafting in the previous year had failed. The patient was treated using a reduced pressure appliance of the type shown in FIGS. 1 and 10 for 14 days with cyclical (5 minutes on/5 minutes off) reduced pressure of approximately 5 in. Hg below atmospheric pressure. After 14 days treatment, quantitative bacterial counts of both ulcers were below 102 bacteria/gram tissue, and both ulcers appeared as healthy granulating beds. Split thickness skin grafts were then applied and exhibited 100% take. The patient is ambulating, and the wounds have remained healed for 2 months, which is the longest the wounds had been healed in the last 10 years.

EXAMPLE 9

Enhancement of Blood Flow

It is believed that the efficacy of reduced pressure appliances in such treatments as have been described is due at least in part to enhancement of blood circulation within the treated wounds. In order to determine the effect of pressure application upon blood flow, a laser doppler needle probe was inserted into tissue adjacent to a pressure sore. A baseline flow level was recorded for thirty minutes. Then, the relative blood flow level was measured while a reduced pressure corresponding to 5 in. Hg below atmospheric pressure was continuously applied to the wound for 30 minutes using a reduced pressure appliance of the type shown in FIGS. 1 and 10. During continuous reduced pressure application, the relative blood flow level was only slightly higher than the baseline level.

Then the supply of reduced pressure to the appliance was cycled on and off at equal 5 minute intervals. During the "off" portions of the cycle, the relative blood flow level was twice as high as the baseline level. It is postulated that the increased blood flow during the off cycle is likely due to a "rebound" phenomenon. During the "on" cycle, blood is drawn toward the wounded tissue from both the venous and arterial branches of the vascular network in the vicinity of the wound. During the "off" cycle, this blood is transported toward the venous branch of the vascular network at a rate that is greater than would have been observed in the absence of the preceding "on" cycle.

The terms and expressions which have been employed are used as terms of description and not of limitation and there is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described, or portions thereof, but it is recognized that various modifications are possible within the scope of the claimed invention.

What is claimed is:

1. An appliance for administering a reduced pressure treatment to a would comprising:

(a) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;

(b) a seal adapted to seal said cover to tissue surrounding the wound;

(c) reduced pressure supply means for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath said cover; and

(d) a screen adapted to prevent overgrowth of wound tissue, said screen being located between said wound and said cover.

2. The appliance as recited in claim 1 wherein said screen comprises a porous sheet.

3. The appliance as recited in claim 1 wherein said seal includes an adhesive material on the cover adapted to secure said cover to the tissue surrounding the wound.

4. The appliance as recited in claim 1 wherein said screen comprises a foam screen.

5. An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;

(b) a seal adapted to seal said cover to tissue surrounding the wound; and

(c) reduced pressure supply means for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath said cover, wherein said reduced pressure supply means comprises a screen having an open cell foam and said reduced pressure supply means includes a segment of tubing embedded within said screen.

6. An apparatus for treating a wound comprising:

(a) a vacuum system adapted to produce a reduced pressure, wherein said vacuum system includes a collection device for collecting fluid aspirated from the wound, wherein said collection device includes means for halting said application of reduced pressure to the wound when said fluid exceeds a predetermined quantity; and

(b) a reduced pressure appliance operably connected with said vacuum system adapted to apply said reduced pressure to the wound, the appliance including:

(i) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;

(ii) a seal adapted to seal said cover to tissue surrounding the wound; and

(iii) reduced pressure supply means for connection with the vacuum system adapted to supply said reduced pressure within said cover to the wound.

7. The apparatus as recited in claim 6 wherein said reduced pressure is from about 2 in. Hg below atmospheric pressure to about 7 in. Hg below atmospheric pressure.

8. The apparatus of claim 6 wherein said reduced pressure supply means comprises a length of tubing, said collection device comprises an aspirating container connected along said length of tubing between said vacuum system and cover, and said halting means comprises a flotation valve within said aspirating container for blocking said tubing when a predetermined amount of fluid is collected within said container.

9. The apparatus of claim 6 wherein said collection device comprises an expandable chamber and said means for halting said application of reduced pressure comprises sensing means for sensing expansion of said expandable chamber, said sensing means operatively connected with said vacuum system so that said reduced pressure is halted when a predetermined expansion of said expandable chamber is sensed by said sensing means.

10. The apparatus of claim 6 wherein said reduced pressure supply means comprises a length of tubing and said halting means comprises a filter along said tubing, said filter having pores that block the supply of reduced pressure via said tubing when said pores are filled with said fluid.

11. A method treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound, wherein said applying step comprises the steps of:

(i) placing a porous screen over the wound;
(ii) locating an impermeable cover over the wound, said cover having a suction port;
(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and
(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing.

12. The method as recited in claim 11 wherein said reduced pressure is from about 2 in. Hg below atmospheric pressure to about 7 in. Hg below atmospheric pressure.

13. A method of treating a wound comprising the steps of:

(a) securing an appliance for applying reduced pressure to the wound; and

(b) providing reduced pressure to said appliance in alternating intervals of application and non-application.

14. The method as recited in claim 13 wherein said reduced pressure is from about 2 in. Hg below atmospheric pressure to about 7 in. Hg below atmospheric pressure.

15. A method of pretreating a skin flap to promote attachment of the flap to a wound comprising the step of applying reduced pressure to a region of skin tissue adjacent to the wound prior to detachment of said skin tissue adjacent to the wound to form the flap from said region of skin.

16. An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound, wherein said cover comprises a flexible sheet;

(b) a seal adapted to seal said cover to tissue surrounding the wound; and

(c) reduced pressure supply means for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath said cover.

17. The appliance of claim 16 comprising support means for supporting said sheet outward from the wound.

18. The appliance of claim 17 wherein said support means comprises a support member located between said sheet and the wound.

19. The appliance of claim 18 wherein said support member includes a porous cup member having attachment means for connecting with said reduced pressure supply means.

20. The appliance of claim 18 further comprising a pad between the wound and said support member for alleviating discomfort caused in the wound by said support member.

21. The appliance of claim 17 wherein said support means comprises a support member extending outwardly over the wound and external to said sheet.

22. The appliance of claim 21 wherein said support means comprises attachment means for attaching said sheet to said support means, said attachment means having a connecting member for connecting with said reduced pressure supply means for providing said reduced pressure beneath said sheet, and said support member comprising a plurality of leg members attached to said attachment means for holding said attachment means and said sheet outward from the wound.

23. An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound, wherein said cover is sufficiently rigid to support said cover out of contact with the wound;

(b) a seal adapted to seal said cover to tissue surrounding the wound;

(c) reduced pressure supply means for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath said cover, wherein said reduced pressure supply means comprises a suction port on said cover; and

(d) a screen adapted to prevent overgrowth of the wound for placement at a location between the wound and said cover and secured in said location by the periphery of said cover.

24. The appliance of claim 23 wherein said screen comprises a sheet-like mesh.

25. The appliance of claim 23 wherein said seal includes an adhesive material on the cover adapted to adhere to tissue surrounding the wound and a seal member at least partially overlying said cover.

26. An apparatus for treating a wound comprising:

(a) a vacuum system adapted to produce a reduced pressure, wherein said vacuum system comprises:
(i) a vacuum pump; and
(ii) a filter for preventing said pump from venting micro-organisms aspirated from the wound; and

(b) a reduced pressure appliance operably connected with said vacuum system adapted to apply said reduced pressure to the wound, the appliance including:
(i) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;
(ii) a seal adapted to seal said cover to tissue surrounding the wound; and
(iii) reduced pressure supply means for connection with the vacuum system adapted to supply said reduced pressure to the wound, wherein said reduced pressure supply means comprises a length of tubing connected between said vacuum system and said cover.

27. The apparatus of claim 26 wherein said filter is connected along said tubing between said pump and said cover for preventing contamination of said pump.

28. An apparatus for treating a wound comprising:

(a) a vacuum system adapted to produce a reduced pressure, wherein said vacuum system comprises control means for cyclically controlling said production of reduced pressure in alternating periods of production and non-production of reduced pressure; and

(b) a reduced pressure appliance operably connected with said vacuum system adapted to apply said reduced pressure to the wound, the appliance including:
(i) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;
(ii) a seal adapted to seal said cover to tissue surrounding the wound; and
(iii) reduced pressure supply means for connection with the vacuum system adapted to supply said reduced pressure to the wound.

29. A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing, wherein said maintaining of said reduced pressure is conducted in alternating periods of application and non-application of the reduced pressure.

30. The method of claim 29 wherein each of said alternating periods is about 5 minutes.

31. A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing, wherein said selected stage of healing is cessation of partial thickness burn progression.

32. A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing, wherein said selected stage of healing is a reduction in bacterial density in the wound by at least 50%.

33. A device for promoting closure of a wound comprising:

(a) an impermeable deformable cover adapted to be placed over the wound;

(b) an adhesive layer on the cover adapted to form a seal between said cover and tissue surrounding the wound;

(c) support means for supporting said cover outward from the wound forming an enclosed volume bounded by said cover and the wound and tissue surrounding the wound; and

(d) supply means for supplying reduced pressure to said enclosed volume and for deforming said cover so as to exert tension upon the tissue surrounding the wound.

34. The device of claim 33 wherein said support means comprises a support member located within said enclosed volume.

35. The device of claim 34 wherein said support member comprises a porous cup member.

36. The device of claim 33 wherein said support means comprises a support member located external to said enclosed volume.

37. The appliance of claim 36 wherein said support means comprises attachment means for attaching said cover to said support means, and said support means comprises a plurality of leg members for supporting said cover out of contact with the wound.

38. A method of promoting attachment of a skin graft onto a wound comprising steps of:

(a) attaching the graft to the wound, and

(b) applying reduced pressure to the graft to promote blood circulation within the graft.

39. The method of claim 38 wherein the graft is a skin flap, the method further comprising steps of:

(a) applying reduced pressure to a region of skin adjacent to the wound, and

(b) forming the flap by detaching skin from said region prior to said attaching step.

40. The method of claim 38 comprising steps of:

(a) applying reduced pressure to a region of skin for use as the skin graft; and

(b) forming the graft by detaching skin from said region.

* * * * *

United States Patent [19]

Zamierowski

[11] **Patent Number: 4,969,880**

[45] **Date of Patent: Nov. 13, 1990**

[54] **WOUND DRESSING AND TREATMENT METHOD**

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[21] Appl. No.: 332,699

[22] Filed: Apr. 3, 1989

[51] Int. Cl.[5] A61F 13/00

[52] U.S. Cl. 604/305; 604/180

[58] Field of Search 604/174, 175, 176, 179, 604/180, 304, 305, 307, 313, 26, 49; 128/DIG. 26, 156, 155

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Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Kathleen A. Daley
Attorney, Agent, or Firm—Litman McMahon & Brown

[57] **ABSTRACT**

A wound dressing includes a cover membrane comprising a semi-permeable material with an adhesive-coated skin contact surface. An opening is formed in an interior portion of the membrane. An intermediate layer of material may be placed between the wound and the membrane contact surface for either absorbing fluids from the wound, e.g. with a hydrocolloid or hydrophilic material, or for passing such fluids to the opening with a synthetic material, e.g. rayon. A tube includes a proximate end fluidically communicating with the wound through the membrane opening. A distal end of the tube is adapted for connection to a suction source for draining the wound or fluid source for introducing liquid medication to the wound. Both evacuation and introduction can be either active or passive. A wound treatment method is also disclosed.

21 Claims, 2 Drawing Sheets

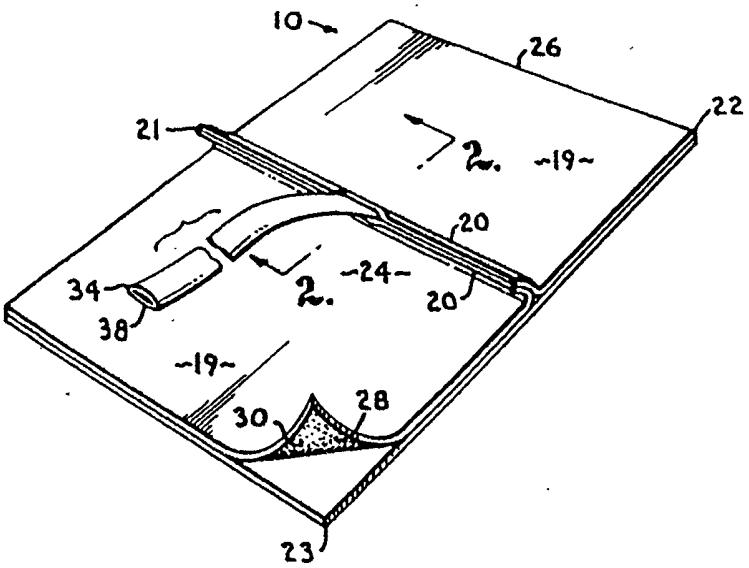
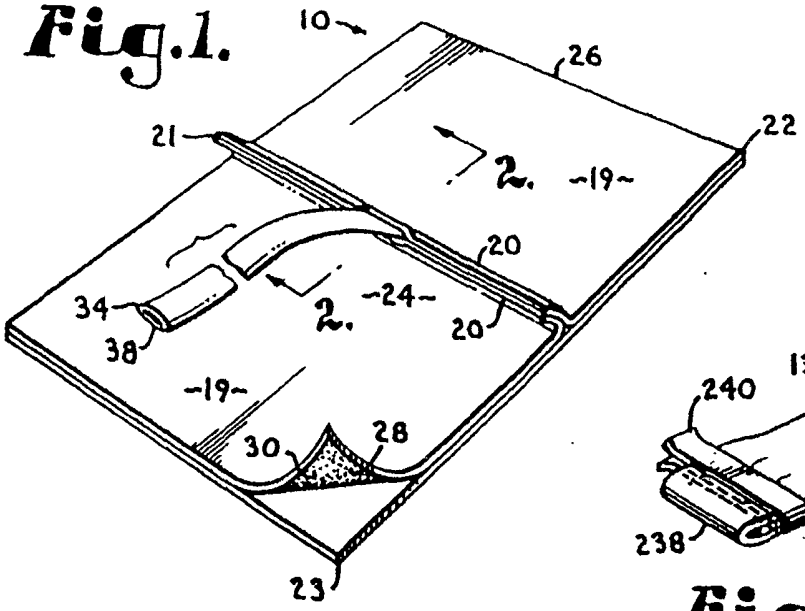


EXHIBIT D

SENGAD-Bayonne, N. J.

Fig.1.



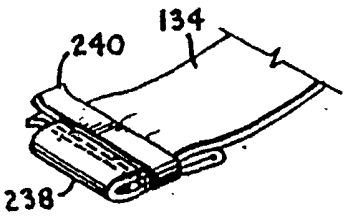


Fig.5.

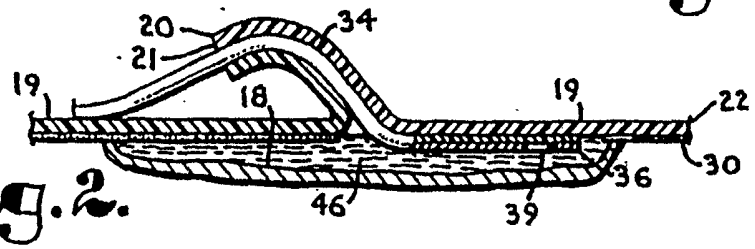


Fig.2.

Fig.3.

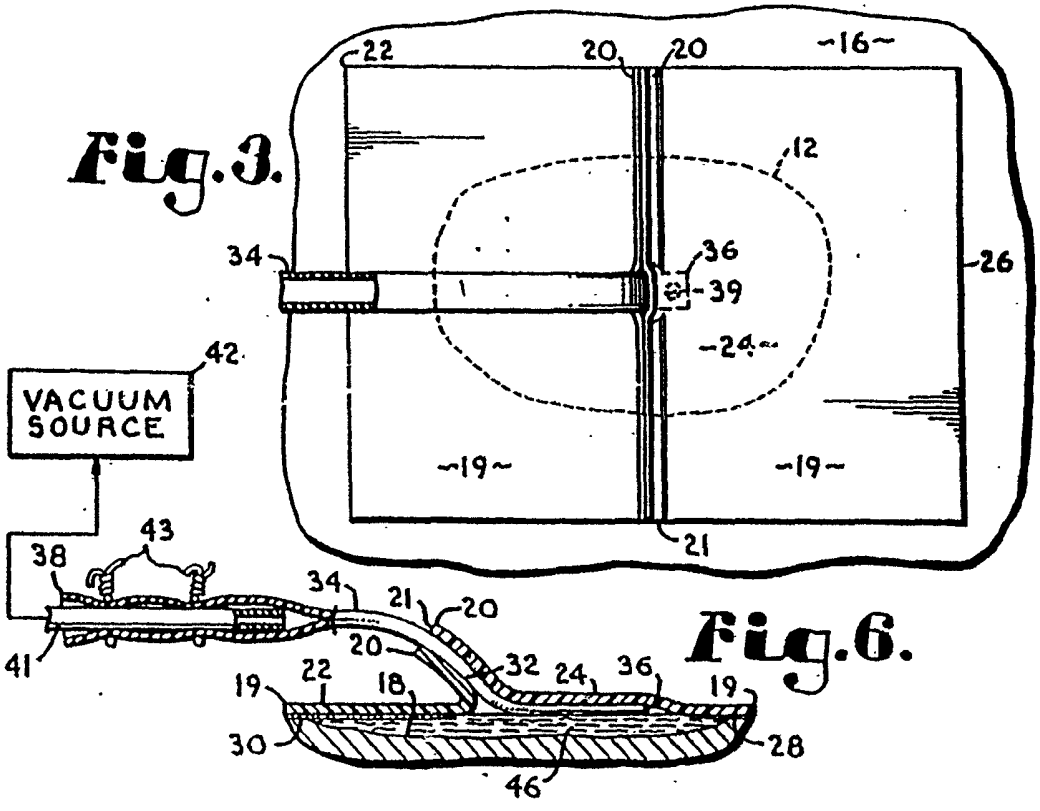


Fig.6.

Fig.8.

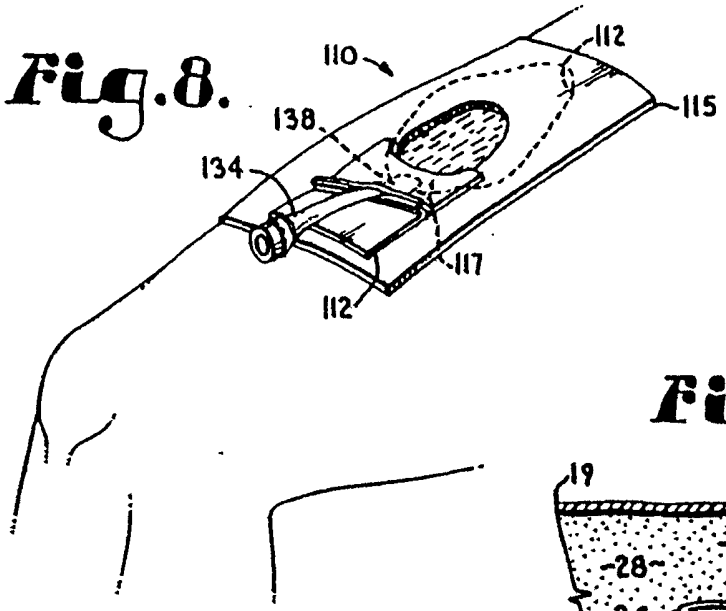
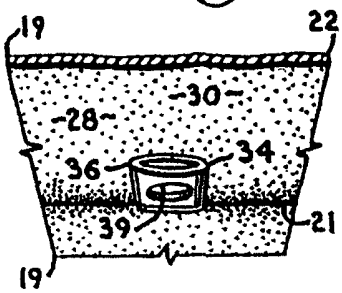


Fig.4.



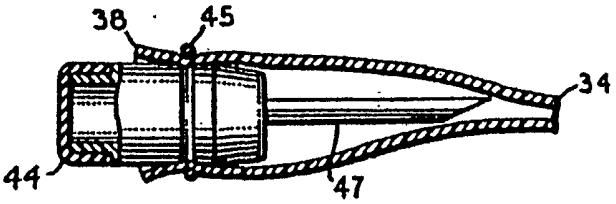


Fig.7.

Fig.9.

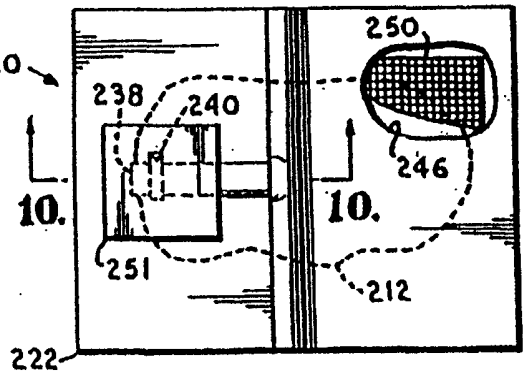
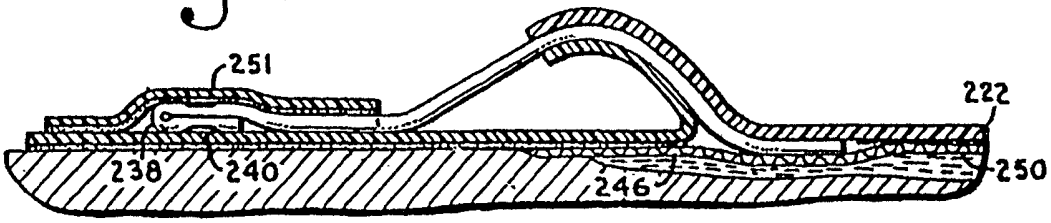


Fig.10.



WOUND DRESSING AND TREATMENT METHOD

BACKGROUND OF THE INVENTION.

1. Field of the Invention

The present invention relates generally to wound dressings and treatment methods, and in particular to a wound dressing adapted for both introducing and evacuating fluids.

2. Description of the Prior Art.

Wound dressings are typically applied over various types of wounds to promote healing and to reduce the risk of infection. Although various types of dressing materials have been successfully employed, membranes comprising semi-permeable materials are often preferred because they can increase patient comfort and lower the risk of infection. Semi-permeable membranes generally pass moisture vapors, but are generally impervious to liquids. Thus, they can promote healing by permitting a wound site to "breathe".

However, a problem can arise with semi-permeable membranes when they are placed over draining wounds because they tend to retain fluid. For example, surgical wounds often tend to drain for a post-operative period of about forty-eight hours. The fluid that can accumulate under such a semi-permeable membrane during a draining period can macerate the underlying tissue, cause infection and otherwise inhibit healing. A procedure for alleviating this problem involves periodically piercing the membrane, draining the accumulated fluids and resealing the membrane opening. However, such a procedure is time-consuming for health care professionals and, unless it is conducted at relatively frequent intervals, can be relatively ineffective in dealing with the problems associated with trapped fluid accumulation. Other procedures which involve opening or changing wound dressings tend to have problems associated with exposing a wound to a greater risk of infection and can be uncomfortable for patients.

Another disadvantage with many previous wound dressings is that they are not designed to accommodate the introduction of various liquid medications, such as antibiotics and growth factor solutions. The application of growth factor solutions may be particularly important in the regeneration of skin graft donor sites.

Heretofore there has not been available a wound dressing apparatus and method with the advantages and features of the present invention.

Summary of the Invention

In the practice of the present invention, a wound dressing is provided which includes a semi-permeable membrane for covering a wound site. The membrane may include an interior portion with an opening and a skin contact surface with an adhesive coating. A tube or sheath is adapted for fluidically communicating with the wound site through the membrane opening and includes a proximate end which extends through the membrane opening and a distal end. The tube distal end is adapted for connection to a liquid medication source for introducing liquid medication to the wound site or a suction source for evacuating fluid therefrom. An intermediate layer of material can be applied between the wound and an interior portion of the cover membrane.

In the practice of the treatment method of the present invention, the intermediate layer of material can be applied to the wound site and the cover membrane is placed thereover. The cover membrane can be releasably, adhesively fastened to the skin around a periphery thereof. A tube fluidically communicates with the wound through an opening in the membrane. Fluids from a draining wound can be evacuated through the tube and liquid medication can be introduced through the tube to the wound site. The fluid evacuation and the medication introduction steps of the method can each be accomplished both actively and passively.

Objects of the Invention

The principle objects of the present invention include: to provide a wound dressing; to provide such a dressing which promotes the evacuation of drained fluids; to provide such a dressing which permits the introduction of liquid medications; to provide such a dressing which includes a semi-permeable membrane for releaseable, adhesive attachment to the skin surface surrounding a wound; to provide such a dressing which protects against infection; to provide such a dressing which promotes healing; to provide such a dressing which is economical to manufacture, efficient in operation, capable of a long operating life and particularly well adapted for the proposed usage thereof; and to provide a wound treatment method.

Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

Brief Description of the Drawings

FIG. 1 is a top perspective view of a wound dressing embodying the present invention.

FIG. 2 is an enlarged, vertical, cross-sectional view of the dressing taken generally along line 2-2 in FIG. 1.

FIG. 3 is a top plan view of the dressing.

FIG. 4 is an enlarged, fragmentary, bottom perspective view of the dressing, particularly showing a proximate end of the tube.

FIG. 5 is an enlarged, fragmentary, top perspective view of the dressing, particularly showing a tube closure clip.

FIG. 6 is an enlarged, fragmentary, vertical, cross-sectional view of the dressing, particularly showing the tube connected to a vacuum source.

FIG. 7 is an enlarged, fragmentary, vertical, cross-sectional view of the dressing, particularly showing a resealable injection port mounted on a distal end of the tube.

FIG. 8 is a top perspective view of a wound dressing comprising a first modified embodiment of the present invention.

FIG. 9 is a top plan view of a wound dressing comprising a second modified embodiment of the present invention with an intermediate material layer between the wound site and a cover membrane.

FIG. 10 is an enlarged, fragmentary, vertical, cross-sectional view of the second modified wound dressing embodiment, taken generally along line 10-10 in FIG. 9.

Detailed Description of the Preferred Embodiments

I. Introduction and Environment.

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

Referring to the drawings in more detail, the reference numeral 10 generally designates a wound dressing embodying the present invention. The dressing 10 is adapted for protecting and treating a variety of wounds, such as that shown at 12. Without limitation on the generality of the useful applications of the present invention, the dressing 10 may be applied over burns, cuts, scrapes and ulcers of various types, e.g. diabetic, decubitus, peripheral vascular disease, venous stasis and trauma ulcers.

Skin ulcers are a common problem among many diabetics, and are often brought on by poor blood circulation and nerve damage associated with diabetes. The treatment of such ulcers often involves grafting skin from a relatively healthy donor site to an ulcerous wound site. Split thickness surgical skin graft techniques may be employed to obtain skin grafts from donor sites that can then heal spontaneously. Full thickness skin grafts, on the other hand, generally require closure of the donor site. It will be appreciated from the following description that the wound dressing and treatment method of the present invention is particularly well adapted for the protection and regeneration of skin graft donor sites by providing a single dressing which facilitates both fluid drainage and growth factor introduction.

The wound site 12 is surrounded by healthy skin 16. A fibrin layer 18 forms at the wound site 12 from fibrinogen by the action of thrombin and the clotting of blood (FIGS. 2 and 6). Surgical wounds, including those associated with skin grafts, normally drain fluid. The fluid drainage from a surgical wound is generally heaviest during a post-operative period of about forty-eight hours.

II. Wound Dressing 10.

The wound dressing 10 generally comprises a cover membrane 22 with an interior portion 24 surrounded by a perimeter 26. The membrane 22 includes a skin contact surface 28 with an adhesive coating 30. The membrane 22 preferably comprises a breathable semi-permeable material characterized by an ability to pass moisture vapors and an imperviousness to liquids. The adhesive coating 30 should likewise be semi-permeable. Such membrane materials are commercially available, an example being material referred to as "Tagoderm", which is available from the 3M (Minnesota Mining and Manufacturing) Company of St. Paul, Minn. Other semi-permeable materials are available and can be successfully employed with the present invention. A protective backing 23 is placed over the adhesive coating 30 on the membrane skin contact surface 28 until the membrane 22 is ready for application.

The membrane 22 comprises a pair of panels 19 with inner, upturned edges 20 which can be adhesively joined together to form a seam 21 which extends transversely across the membrane 22 and projects generally upwardly therefrom. The panels 19 can be secured together at the seam 21 by the adhesive coating 30 to form the seam 21.

A tube or sheath 34 includes a proximate end 36 located under the membrane 22 and a distal or free end 38. The tube 34 can be inserted through the seam 21 which forms an opening 32 between the panel edge strips 20 at approximately the center of the membrane 22. A relatively short length of the tube 34 adjacent to its proximate end 36 is shown under the membrane 22, but greater lengths of the tube 34 could be placed under the membrane 22. As shown in FIG. 5, the tube proximate end 36 is open, and adjacent to the proximate end 36 an opening is formed. Preferably the tube opening 39 projects downwardly, i.e. away from the membrane skin contact surface 28. The short length of the tube 34 which is located under the membrane 22 can be releaseably secured to the skin contact surface 28 by the adhesive coating 30, preferably with the tube opening 39 facing downwardly.

The tube 34 can comprise, for example, a flexible, plastic tube of the type that is commonly used as a percutaneous sheath for intravenous treatments. Such sheaths are commercially available from Aero International, Inc. of Reading, Pa.

At its distal end 38, the tube 34 is adapted for: (1) closure with a variety of suitable closure devices; (2) connection to various active and passive fluid collection devices for draining and evacuating fluid from the wound site; and (3) connection to various fluid source devices for actively and passively introducing fluid to the wound site.

FIG. 5 shows a bifurcated clip 40 for releaseably closing and sealing the tube distal end 38, which is folded upon itself as shown.

FIG. 6 shows a vacuum tube end 41 inserted in the tube distal end 38 and secured therein by ties or ligatures 43. The vacuum tube 41 fluidically communicates with a suction or vacuum source 42 for actively draining fluid from the wound site. The suction or vacuum source 42 may comprise a relatively simple, hand-actuated bulb or bellows, or it may comprise a more sophisticated motorized pump which can be actuated at predetermined time intervals or in response to wound site conditions such as an accumulation of fluid under the membrane 22.

FIG. 7 shows an injection port 44 sealed to the tube distal end 38 by a band 45. The injection port 44 includes a sleeve 47 which can extend into the tube 34 to protect it from needle puncture. The injection port 44 can be of the type which is designed for reuse and which automatically reseals after being punctured by a syringe needle. It will be appreciated that a wide variety of devices can be employed for connecting the tube distal end 38 to various liquid medication sources.

III. Treatment Method.

According to the treatment method of the present invention, the protective backing 23 is removed from the membrane contact surface 28 to expose the adhesive coating 30 and the membrane 22 is placed over a wound site 12 with its contact surface 28 down. The membrane perimeter 26 is pressed against the healthy skin 16 surrounding the wound site 12 to preferably form a relatively liquid-tight adhesive bond therebetween. Various

adhesive preparations are commercially available for supplementing the bonding action of the adhesive coating 30 in bonding the membrane contact surface 28 to the healthy skin 16. The membranes 22 may be provided in various sizes to accomodate wounds of different sizes. A sufficiently large membrane 22 should normally be selected to provide ample overlap of the perimeter 26 over the healthy skin 16 to insure a good bond therebetween.

The tube distal end opening 39 may be placed directly over the approximate center of the wound site 12, or it may be placed eccentrically or at a depending location with respect to the wound site 12. A dependent or lower position for the opening 39 with respect to the wound site 12 may be preferred to facilitate fluid drainage. The dressing 10 may be applied promptly after a wound is inflicted, e.g. immediately after the graft removal procedure and a skin graft operation. To reduce the risk of infection, it may be advisable to promptly cover the open wound site 12. The wound dressing 10 may be kept in a sterile package until it is needed. Such sterile packages and packaging techniques are well known. For example, ethylene oxide may be used to sterilize the dressing 10 prior to placement in a suitable sterile package. The protective backing 23 is removed from the membrane 22, thereby exposing its adhesive-coated contact surface 28.

With the membrane 22 thus secured, a chamber 46 is formed between the wound site 12 and the membrane contact surface 28, and is surround by the membrane perimeter 26. The chamber 46 fluidically communicates with the membrane opening 32. In an evacuation mode of operation, such as might be desirable for forty-eight hours or so after removal of a split-thickness skin graft at a donor site, fluid 20 which accummulates in the chamber 46 is communicated through the opening 32 and thence through the tube 34 for collection and disposal. In a passive evacuation mode of operation, the fluid 20 is evacuated through capillary action, or by gravity with the opening 32 at a dependent, lower location in relation to the wound site 12. Such a capillary, passive drainage action may be sufficient for draining the wound site 12 in many situations. Alternatively, an active evacuation mode of operation involves attaching the tube 34 to the suction/vacuum source 42 whereby the fluid 20 is positively drawn from the wound site 12 and the chamber 46. Such an active evacuation mode of operation may be preferred when the dressing 10 is used in connection with a hydrophilic colloidal material (hydrocolloid), as will be explained in more detail hereinafter.

It may be desirable to operate the wound dressing 10 in an introduction mode of operation whereby medications such as antibiotics and growth factor solutions are introduced to the wound site 12. In this mode of operation, the tube distal end 38 is connected to a liquid solution source, which may comprise a syringe or any of various liquid containers for passive, gravity-induced introduction. Various adaptors, valves and injection needle ports are available for fluidically coupling the tube 34 to a wide variety of liquid solution sources. For example, many such connectors and adaptors are available from Aero International, Inc. of Reading, Pa. Such connecting devices are commonly used in connection with the intravenous introduction of various liquid solutions.

In an active introduction mode of operation, solutions may be pumped through the tube 34 into the chamber 46 for application to the wound site 12.

The evacuation and introduction treatment steps can be timed and sequenced as necessary to achieve the treatment objectives. For example, treatment of a skin graft donor site may involve fluid withdrawal and drainage for about two days immediately following the skin graft operation, followed by treatment steps comprising the introduction of antibiotics and/or growth factor solutions to the wound site. The evacuation and introduction steps can be alternated, and the intervals between such steps can be progressively increased or decreased as necessary to facilitate healing. As the wound heals, progressively smaller amounts of fluid will ooze therefrom and the frequency and duration of the drainage operations can be correspondingly reduced and finally discontinued altogether.

It will be appreciated that the wound dressing and treatment method of the present invention are broadly concerned with introducing fluid to wound sites and evacuating fluid therefrom. The fluid introduction and evacuation procedures described herein can be performed indefinitely without having to change the dressing 10. The tube 34 cooperates with the membrane 22 to permit the same dressing 10 to be used for both procedures, which may be alternated as often as necessary. Infection risks and patient discomfort can be reduced by minimizing wound dressing changes.

The removal of toxins and bacteria from wounds is an important aspect of the fluid drainage phase of the healing process. The wound dressing of the present invention facilitates removal of serum and other secretions to minimize the risk of infecting the wound site and macerating the tissue thereat. Growth factor solutions can be important in promoting healing, and antibiotics can be important in preventing and treating infection. Hence, a comprehensive wound treatment can be implemented with the wound dressing and treatment method of the present invention.

The wound dressing 10 can be employed to irrigate a wound whereby fluid is introduced and then removed.

The operation of the wound dressing 10 is largely a matter of fluid mechanics, and the function of the wound dressing 10 would probably be determined by such factors and variables as: (1) fluid viscosity; (2) permeability of the membrane 22; (3) cross-sectional area of the tube 34 and the area of its opening 39; (4) the integrity of the seal around the membrane perimeter 26; (5) the drawing power of the suction or vacuum source 42; (6) coagulation of the serum or other fluid; (7) the area of the fluid collection chamber 46; (8) the length of the tube 34; and (9) gravity and the relative positions of various components. Naturally, varying one or more of these factors or variables could change the operation of the system. It is anticipated that, applying such well-known principles of fluid mechanics, all of the wound dressing components could be properly sized and designed. For example, the tube opening 39 could be enlarged, or multiple openings could be provided to increase the rate of fluid flow into the tube 34. The rate of fluid flow can further be increased by locating the tube distal end 38 at a lower area within the chamber 46, i.e. below the level of most of the wound site 12. The tube 34 can extend downwardly to a collection site below the level of the wound site 12 to facilitate gravity drainage.

It is further anticipated that some fluids will resist drainage because of their viscosities or because they tend to coagulate. Drainage of such fluids can be effected by irrigating the wound site 12.

IV. First Modified Embodiment 110.

FIG. 8 shows a wound dressing 110 comprising a first modified embodiment of the present invention wherein a relatively small membrane 122 is provided and functions as a patch for a larger wound cover 115 with an opening 117 for receiving a distal end 138 of a tube 134. The primary wound cover 115 is selected to cover a wound site 112, and is placed thereover in the normal fashion. The wound dressing 110 can be placed on the primary wound cover 115 in a location chosen to enhance fluid introduction and/or evacuation. For example, to enhance the evacuation of fluid by gravity, it may be desirable to form the opening 117 at a relatively low position of the wound site 112. Thus, fluid will tend to flow to the tube 134 by gravity. To facility the introduction and distribution of fluid, it may be desirable to locate the wound dressing 110 at a relatively high position on the wound cover 115. In fact, two or more wound dressings 110 could be placed on a single, primary wound cover 115, with a lower wound dressing 110 being provided for fluid evacuation and an upper wound dressing 110 being provided for fluid introduction.

In the practice of the treatment method of the present invention, the wound dressing 110 provides for considerable flexibility in locating the wound dressing 110 in an appropriate location on the wound site 112. After the primary wound cover 115 is positioned, the opening 117 is formed at the chosen location and the wound dressing 110 may be applied; much like a patch, with the tube distal end 138 extending through the primary wound covery opening 117. It will be appreciated that wound dressings 110 may be changed as needed without changing the primary wound cover 115.

V. Second Modified Embodiment 210.

A wound dressing 210 comprising a second modified embodiment of the present invention is shown in FIGS. 9 and 10 and includes an intermediate layer of material 250 between a wound site 212 and a cover membrane 222. The intermediate material layer 250 can comprise a variety of materials with varying properties such as: (1) absorbency; (2) wicking or capillary action; and (3) surface contact action. The intermediate material layer is primarily located in a chamber 146 formed between the wound 212 and the membrane 222.

As a first example of an intermediate material layer 250, several hydrophilic colloid materials (i.e. hydrocolloids) are available which would tend to absorb fluids. For example, Envisan wound cleaning pads and paste are available from Marion Laboratories, Inc. of Kansas City, Mo. and comiprise: spherical, hydrophilic Beads of Dextranomer, 0.1 to 0.3 mm in diameter; polyethylene glycol 3000 in the pad; polyethylene glycol 600; and water QS enclosed in a polyamide net bag in the pad or available in a metal foil packet for the paste. The Envisan dextraminer beads function to absorb fluid and facilitate healing by drawing fluid from the wound. Excess fluid can be drained from the intermediate material layer 250 to prolong its effectiveness. Other hydrocolloids are commercially available and may be employed with the wound dressing 210 of the present invention, e.g. dextranimers available under the trademark "Debrisan".

Alternatively, the intermediate material layer 250 can comprise a mesh or sheet of synthetic material which is generally nonabsorbent and would tend to wick fluid from the wound site 212 to a tube distal end 238. For example, rayon could be used to form such an intermediate material layer 250, and material available from Marion Laboratories, Inc. under the trademark "Envinet" could also be employed. Such materials may be referred to as "surface active", i.e. promoting fibrin sealing on the wound surface. Such materials can also satisfy a capillary purpose whereby fluid is wicked from the wound for collection in the chamber 246 and ultimately for drainage. With many such materials, a balance is struck between surface action and capillary action, i.e. one such function is often maximized at the expense of the other. For example, Owens rayon is generally considered to be relatively surface active, but may provide less capillary action than other materials. Envinet mesh, on the other hand, provides greater capillary action, but may provide less surface action as compared to the rayon material.

Other materials that can be used for the intermediate material layer 250 include polyurethane foam and polyurethane mesh.

The wound dressing 210 can be used according to methods for use with the other wound dressings 10 and 110, and includes the additional step of placing the intermediate material layer 250 over the wound site 212. It will be appreciated that there may be a number of materials suitable for the intermediate layer 250 to achieve various objectives.

A closure patch 251 is provided for placement over the tube distal end 238 and is adapted for securing it in a folded configuration to the membrane 222. The closure patch 251 can be used in conjunction with a bifurcated clip 240 as shown in FIGS. 9 and 10, and permits convenient access to the tube distal end 238 for coupling it to various devices such as those described herein.

It is to be understood that while certain forms of the present invention have been illustrated and described herein, it is not to be limited to the specific forms or arrangement of parts described and shown.

I claim:

1. A wound dressing, which includes:

(a) wound covering means with a skin contact surface and an outer surface;

(b) means for releaseably attaching said wound covering means to a patient in covering relation over a wound;

(c) said wound covering means having an interior portion with an opening extending between and open at the skin contact and outer surfaces thereof;

(d) said wound covering means comprising a semipermeable material; and

(e) tube means having a proximate end extending through said opening and terminating adjacent said skin contact surface and a distal end located outwardly from said outer surface, said tube means fluidically communicating with said skin contact surface.

2. The dressing according to claim 1 wherein:

(a) said tube proximate end is connected to said covering means at said opening thereof.

3. The dressing according to claim 1 wherein:

(a) said fastening means comprises adhesive on said skin contact surface at said perimeter portion.

4. The dressing according to claim 1 wherein:

(a) said wound covering means comprises semi-permeable plastic.

5. The dressing according to claim 1, which includes:

(a) an intermediate material layer adapted for placement between said cover means interior portion and said wound.

6. The dressing according to claim 5 wherein:

(a) said intermediate material is hydrocoloid.

7. The dressing according to claim 5 wherein:

(a) said intermediate material is nonabsorbant.

8. The dressing according to claim 5 wherein:

(a) said intermediate material includes a fibrin coating adapted for contacting the wound.

9. The dressing according to claim 5, wherein:

(a) said intermediate material includes a hydrocolloid and a nonabsorbant fabric sheet.

10. The dressing according to claim 1, which includes:

(a) means for closing said tube means distal end.

11. The dressing according to claim 10 wherein:

(a) said tube closing means comprises a clip.

12. The dressing according to claim 10, wherein said tube closing means comprises:

(a) a needle vent adapted for puncturing by an injection needle and adapted for resealing after the withdrawal thereof.

13. The dressing according to claim 10, which includes:

(a) suction means connected to said tube distal end.

14. The dressing according to claim 10 wherein:

(a) said tube proximate end is closed; and

(b) said tube includes an opening in spaced proximity to its proximate end.

15. The dressing according to claim 10, which includes:

(a) introduction means adapted for introducing liquid medication into said tube through its distal end.

16. A wound dressing, which includes:

(a) wound covering means including:

(1) first and second panels each having a perimeter and an edge;

(2) each said panel having an inner contact surface and an outer surface;

(3) a seam extending transversely across said dressing and extending outwardly from said outer surface of said panels, said seam comprising said panels being connected together at their respective contact surfaces adjacent to their respective edges, said seam having opposite ends; and

(4) a tube opening through said seam between said panel contact surfaces and intermediate said seam ends, said tube opening extending between and open at said adjacent perimeter edges and said contact surface;

(b) an adhesive coating on said panel contact surfaces; and

(c) a tube including proximate and distal ends, said tube extending through said tube opening and terminating adjacent said skin contact surface adjacent to its proximate end with said tube proximate end being positioned adjacent to said contact surface.

17. A wound dressing, which includes:

(a) wound covering means with a skin contact surface and an outer surface;

(b) means for releaseably attaching said wound covering means to a patient in covering relation over a wound;

(c) said wound covering means having an interior portion with an opening extending between and open at the skin contact and outer surfaces thereof;

(d) said wound covering means comprising a semi-permeable material; and

(e) tubular connector means having a proximate end extending through said opening and terminating adjacent said skin contact surface and a distal end located outwardly from said outer surface, said tubular connector means fluidically communicating with said skin contact surface and comprising a flexible, collapsible material.

18. A wound dressing, which includes:

(a) wound covering means including:

(1) first and second panels each having a perimeter and an edge strip demarcated by a fold line, each said edge strip being folded outwardly from a remainder of a respective panel;

(2) each said panel having an inner contact surface and an outer surface;

(3) a seam extending transversely across dressing and extending outwardly from said outer surfaces of said panels, said seam comprising said edge strips being connected together at their respective contact surfaces, said seam having opposite ends; and

(4) a tube opening extending through said seam between said edge strips and intermediate said seam ends, said tube opening extending between and open at said panel perimeters adjacent to said edge strips and said contact surface;

(b) an adhesive coating on said panel contact surfaces; and

(c) a tubular connector including proximate and distal ends, said tubular connector extending through said tube opening adjacent to its proximate end with said tube proximate end being positioned and terminating adjacent to said contact surface, said tubular connector comprising a flexible, collapsible material.

19. A method of dressing a wound surrounded by unwounded skin, which comprises the steps of:

(a) applying a semi-permeable covering comprising first and second panels each including a skin contact surface, an outer surface, and a perimeter with an edge over the wound.

(b) releaseably and adhesively attaching said skin contact surfaces of said panels to said unwounded skin around said wound;

(c) forming a seam with opposite ends and extending transversely across said covering by adhesively engaging said panel contact surfaces along respective strips adjacent to said edges thereof;

(d) providing an opening open at said perimeter edges and at said contact surface between said interconnected strips and intermediate said seam opposite ends;

(e) extending a tube with open proximate and distal ends through said tube opening;

(f) positioning said tube proximate end adjacent to said seam and said skin contact surface; and

(g) alternately introducing a liquid to and draining said wound through said tube.

20. The method of claim 19 wherein said step of introducing a liquid to said wound includes introducing liquid medication to said wound.

21. The method of claim 19 wherein said step of introducing a liquid to said wound includes irrigating said wound.

* * * * *

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December 20, 2004

To whom it may concern:

This is to certify that the attached translation from German into English is an accurate representation of the document received by this office. This document is designated as:

KCI Medical Documents

George Alves, the Supervisor of Translation Services, certifies that Allan Edward, who translated this document, is fluent in German and standard North American English and is qualified to translate.

He attests to the following:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document."

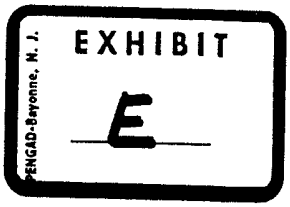
Signature of George Alves

Subscribed and sworn to before me this 20th day of December 2004.

Rosemary Brito
Notary Public, State of New York
No. 01BR6077317
Certificate filed in New York County
Qualified in Kings County
Commission Expires July 8, 2006

Sincerely,

Victor J. Hertz
President



[logo]

CLIFFORD CHANCE PUNDER
Düsseldorf
27 March 2001
[illegible handwritten entry]
Fax Received

File No.:
3HK O 2112/01

MINUTES

of a public hearing held in the State Court of Munich I's 3rd Chamber for Commercial Cases on March 23, 2001.

Present:

Presiding Judge:	Presiding Judge of the State Court Seifert
Panel Judge:	Commercial Court Judge Finger
Panel Judge:	Commercial Court Judge Konopka
Clerk of the Court:	Court Employee Eppert

In the matter of

KCI Medizingruppe GmbH, represented by its General Managers Andreas Marquardt and Frank DiLazzaro, Lappacher Weg 30, 91315 Höchstadt

-- Plaintiff in the proceeding regarding a court order –

Trial Attorney:
Clifford, Chance, Pünder, Atty's at Law, Cecilienallee 6, 40474
Dusseldorf, Gz.: 04162/schbi/KCI/50005068 A(3)

versus

Medela Medizintechnik GmbH & Co. Handels KG, represented by its General Manager Hans Schmidtner, Korbinianstr. 2, 85386 Eching

-- Respondent in the proceeding regarding a court order --

Trial Attorney:
Hermann Käbisch and Colleagues, Gymnasiumstr. 25,
85049 Ingolstadt, Gz.: HK/ebD 0341

seeking a temporary restraining order

the following appeared when the case was called

[cont'd]

for the plaintiff in the proceeding regarding a court order (hereinafter: Plaintiff)
Attorney Dr. Dieners

For the respondent in the proceeding regarding a court order (hereinafter: Respondent)
Attorney Käbisch
General Manager Mr. Schmidtner

The following also appeared: Ms. Sabine Rössler, witness for Plaintiff. The witnesses are instructed, as required by law, regarding their obligation to tell the truth and are then asked to leave the courtroom temporarily.

Plaintiff's attorney states that his party is en route from the airport.

The Court notes that a temporary restraining order was issued on February 2, 2001, which was served on the parties on February 12, 2001.

Plaintiff's attorney asks the Court to grant the temporary restraining order for which a petition was submitted on March 7, 2001.

Respondent's attorney asks the Court to lift the temporary restraining order and to nonsuit the petition.

Respondent's attorney is given photocopies of the writ dated March 21, 2001, which had been sent to him in advance by fax.

Respondent's attorney submits a writ dated March 22, 2001, of which Plaintiff's attorney has received photocopies.

The Court turns to the merits and current status of the case.

[cont'd]

Respondent's General Manager states:

The patent law dispute has not yet been engaged in court. The opposing attorney is Attorney Dr.Popp, of the law firm of Maissner, Bolte & Partners, of Ottobrunn.

Plaintiff's attorney states:

We obtained the instruction manual only as we were preparing our petition for a temporary restraining order. I am informed that prior to that time Plaintiff's firm was unaware of the instruction manual, notably when it drafted its letter dated November 28, 2000.

Respondent's attorney states that he contests the Court Marshal's legal authority, since his signature does not meet the statutory signature requirement.

Respondent's attorney states:

If Plaintiff's attorney is attempting to claim that Plaintiff was not in possession of an instruction manual in November of the year 2000, that claim is contested.

The parties then come to the following – revocable –

Compromise:

Respondent makes the following concluding statement:

I. Respondent promises Plaintiff

to refrain from offering, distributing, selling, renting out and/or promoting (or causing to be offered, distributed, sold, and/or promoted) in the competitive

[cont'd]

marketplace the VARIO-type suction pump for use in the vacuum-sealing of wounds, (in cases where users might in future unknowingly, or without being induced to do so by Medela, apply the VARIO-type suction pump for use in the vacuum-sealing of wounds, contrary to its prescribed use, KCI Medizinprodukte GmbH shall lodge no claim against Medela for damages); Medela, for its part, shall warn users against such misapplication and – as far as possible – see to it that no misuse occurs in future.)

II. to report to KCI Medizinprodukte GmbH by April 23, 2001 regarding the type and extent of actions taken pursuant to the foregoing paragraph I.

III. to pay KCI Medizinprodukte a contractual penalty of DM 10,100.00 (in words: ten thousand one hundred German Marks) for each violation of the obligations assumed in paragraph I, notwithstanding any claim to be excused on grounds of continuity of business relationships.

IV. to withdraw, immediately upon expiry of the waiting period for withdrawal, its objection of Feburary 15, 2001 to the State Court of Munich I's temporary restraining order of February 2, 2001 (File No.: 3 HK O 2112/01), as supplemented by the drawing like the one on page 3 (appendix to the Compromise), and to waive the legal recourse afforded by §§ 926 et seq. ZPO [Code of Civil Procedure].

V. To bear the costs of the temporary restraining order (each party shall bear its own attorneys' fees, both in -court and out-of-court)

[cont'd]

VI Plaintiff may revoke the present Compromise by filing a writ with the Court by no later than March 30, 2001.

-- read out and approved --

In case of revocation of the Compromise, Respondent's General Manager declares as follows: I certify the accuracy of the information contained in the writ dated March 22, 2001, and specify that the instruction manual referred to in section 2 has not yet been published and has not yet been used.

Plaintiff's attorney proposes that the witness in attendance be heard, who will testify that the instruction manual was requested on the open market by Plaintiff only in connection with the letter of information that was drawn up in preparation for the temporary restraining order.

Respondent's attorney submits, in this connection, the original of the affidavit of January 27 and March 13, 2001.

The Court thereupon observes that one may gather from the writ of March 22, 2001 that the earlier instruction manual did not contain any indicated use for vacuum-sealing of wounds.

Respondent's General Manager declares:

That is correct. All that it contained was an instruction as to how to drain a wound.

Respondent's attorney submits the original of the temporary restraining order that was served upon him, along with the record of service.

[cont'd]

After the panel of judges conferred privately, **the Presiding Judge** announced the following

Ruling:

The motion to hear the witness is granted.

The witness is then called and testifies as follows:

Personal data:

Sabine Rössler; date of birth: October 20, 1964; employed in Plaintiff's sales department; address: Buchenstr. 31a, 85716 Unterschleissheim;
no relation to the parties, no children.

Regarding the matter at issue:

I only know that Mr. Appelt is in possession of an instruction manual that he was given by a fellow employee. That must have been in January. I know nothing about any patent law dispute. The sales department is not informed of such things.

In response to a question by Respondent's attorney:

I was present at "Medica 2000", but while I was there I didn't pick up any informational material about the pump in question. The trade fair took place in late November. Mr. Appelt was there for a few hours.

I have no idea whether the concession stand was supposed to be photographed or was in fact photographed.

[cont'd]

Transcript approved.
The parties waived the opportunity
to hear same read out.

The attorneys for the two sides make no request to have the witness sworn.

After the panel of judges confer privately, the **Presiding Judge** announces the following

Ruling:

The witness need not be sworn.

The witness is then released by general consent.

In case of revocation of the Compromise, the parties are given the opportunity to make motions regarding the results of the hearing of evidence.

In addition, they reiterate the petitions lodged at the outset..

After the panel of judges confers privately, **the Presiding Judge** announces the following

Ruling:

In case of revocation of the Compromise, the date
of the hearing at which a decision will be handed down
is set for:

[cont'd]

Friday, April 20, 2001, at 1:00 p.m.
In Court Room 103/I. Courthouse
Building Lenbachplatz 7.

The Presiding Judge

Seifert
Presiding Judge of the
State Court

The Document Clerk

Eppert
Court Employee

CLIFFORD
CHANCE
PÜNDER

Medela Medizintechnik
GmbH & Co. Handels KG
Tel. 089 / 3 19 75 9 – 0
E-mail: [illegible]

Postfach 11 48, 85278 Eching
Korbinianstr. 2, 85386 Eching
Fax 039 / 3 19 75 999
[illegible]

[logo] **medela**

Information

Test of a suction pump and its accessories for use in the vacuum-sealing of wounds

- **As described in the delivery note, we are sending you for testing a complete suction system for use in the vacuum-sealing of wounds.**
- **The conditions of delivery and an itemization of contents are provided in the enclosure.**
- **We are making the VARIO-type suction pump and its accessories available to you at no charge.**
- **The period available for testing – at no charge – is 2 weeks.**
- **After expiry of the agreed period, the system is to be**
  - ف **purchased**
  - ف **leased**
  - ف **returned.**

The Medela employee named below is available to answer any questions you may have.

Medela employee: _____

Telephone: _____

[illegible bottom of letterhead information]

Geschäftsnummer:
3HK O 2112/01

P R O T O K O L L

aufgenommen in öffentlicher Sitzung der 3. Kammer für Handelssachen des Landgerichts München I am 23.3.2001.

Gegenwärtig:

Vorsitzende:	Vors. Richterin am LG Seifert
Beisitzer:	Handelsrichter Finger
Beisitzer:	Handelsrichter Konopka
Urk.B. der Geschäftsstelle:	Justizangestellte Eppert

In Sachen

KCI Medizinprodukte GmbH, vertr. durch den Geschäftsführer Andreas Marquardt und Frank DiLazzaro, Lappacher Weg 30, 91315 Höchstadt

- Verfügungsklägerin -

Prozeßbevollmächtigte:
Rechtsanwälte Clifford, Chance, Pünder, Cecilienallee 6, 40474 Düsseldorf, Gz.: 04162/schbi/KCI/50005068 A(3)

gegen

Medela Medizintechnik GmbH & Co. Handels KG, vertr. durch den Geschäftsführer Hans Schmidtner, Korbinianstr. 2, 85386 Eching

- Verfügungsbeklagte -

Prozeßbevollmächtigte:
Rechtsanwälte Hermann Käbisch u. Koll., Gymnasiumstr. 25, 85049 Ingolstadt, Gz.: HK/ebD 0341

wegen einstweiliger Verfügung

erschienen nach Aufruf der Sache

...

für die Verfügungsklägerin (im folgenden: Klägerin)
Rechtsanwalt Dr. Dieners

für die Verfügungsbeklagte (im folgenden: Beklagte)
Rechtsanwalt Käbisch
der Geschäftsführer,
Herr Schmidtner

Ferner ist erschienen Frau Sabine Rössler als mitgebrachte Zeugin der Klagepartei. Die Zeugin werden nach den gesetzlichen Bestimmungen belehrt, auf ihre Wahrheitspflicht hingewiesen und gebeten, einstweilen den Sitzungssaal zu verlassen.

Klägervertreter erklärt, seine Partei sei vom Flugplatz unterwegs.

Es wird festgestellt, daß am 02.02.01 eine einstweilige Verfügung erlassen wurde, die am 12.02.2001 zugestellt wurde.

Klägervertreter stellt Antrag zum einstweiligen Verfügungsantrag gemäß Schriftsatz vom 07.03.2001.

Beklagtenvertreter beantragt, die einstweilige Verfügung aufzuheben und den Antrag zurückzuweisen.

Beklagtenvertreter erhält Abschriften des Schriftsatzes vom 21.03.2001, den er per Fax vorab erhalten hat.

Beklagtenvertreter übergibt Schriftsatz vom 22.03.01, von dem Klägervertreter Abschriften erhalten hat.

Das Gericht führt in den Sach- und Streitstand ein.

...

Der Geschäftsführer der Beklagten erklärt:

Die patenrechtliche Auseinandersetzung ist noch nicht bei Gericht. Der gegnerische Anwalt ist Herr Rechtsanwalt Dr. Popp aus der Kanzlei Meissner, Bolte & Partner, Ottobrunn.

Klägervertreter erklärt:

Die Gebrauchsanweisung haben wir erst im Vorfeld der Beantragung der einstweiligen Verfügung erlangt. Ich bin informiert worden, daß die Gebrauchsanweisung zuvor, insbesondere bei dem Schreiben vom 28.11.2000, im Hause der Klägerin nicht bekannt war.

Beklagtenvertreter erklärt, er rüge die ordnungsgemäße Zuständigkeit durch den Gerichtsvollzieher, weil dessen Unterschrift die Anforderungen an eine Unterschrift nicht erfülle.

Beklagtenvertreter erklärt:

Sollte der Klägervertreter so zu verstehen sein, daß eine Gebrauchsanweisung im November 2000 der Klägerin nicht vorgelegen hat, wird dieser Sachvortrag bestritten.

Die Parteien schließen sodann folgenden - widerruflichen -

Vergleich:

Die Beklagte gibt folgende Abschlußerklärung ab:

I. Die Beklagte verpflichtet sich, gegenüber der Klägerin

es zu unterlassen, im geschäftlichen Verkehr zu Wettbewerbszwecken die Absaugpumpe vom Typ VARIO zum Zwecke der Wund-/Vakuumversiegelung anzubieten, zu vertreiben, zu verkaufen, zu vermieten und/oder

...

zu bewerben und/oder anbieten zu lassen, vertreiben zu lassen, verkaufen zu lassen und/oder bewerben zu lassen, (für den Fall, daß Anwender die Absaugpumpe vom Typ VARIO zukünftig ohne Kenntnis bzw. Veranlassung von Medela zweckwidrig zur Wund-Vakuumversiegelung einsetzen, wird die Fa. KCI Medizinprodukte GmbH ihr hierdurch entstehende mögliche Schadensersatzansprüche gegenüber Medela nicht geltend machen; Medela wird ihrerseits die entsprechenden Anwender auf die zweckwidrige Verwendung aufmerksam machen und - soweit möglich - dafür sorgen, daß dies zukünftig unterbleibt)

II. der Fa. KCI Medizinprodukte GmbH bis 23.04.01 Auskunft zu erteilen über Art und Umfang der Handlungen gemäß Ziffer I.

III. für jeden Fall der Zuwiderhandlung gegen die Verpflichtung aus vorstehender Ziffer I unter Ausschluß der Einrede des Fortsetzungszusammenhangs zur Zahlung einer Vertragsstrafe in Höhe von DM 10.100,-- (i.W. zehntausendeinhundert Deutsche Mark) an die KCI Medizinprodukte.

IV. den Widerspruch vom 15. Februar 2001 gegen die am 2. Februar 2001 ergangene einstweilige Verfügung des Landgerichts München I (Aktenzeichen: 3 HK O 2112/01, die um die Abbildung wie Seite 3) (Anlage zu dem Vergleich) ergänzt wird), unverzüglich nach Ablauf der Widerrufsfrist zurückzunehmen und auf die Rechtsbehelfe der §§ 926 *f.* ZPO zu verzichten.

V. die Gerichtskosten des einstweiligen Verfügungsverfahrens zu tragen (die Rechtsanwaltskosten - gerichtlich und außergerichtlich - trägt jede Partei selbst).

...

VI. Die Klagepartei kann diesen Vergleich durch Einreichung eines Schriftsatzes, der bis spättestens 30.03.2001 bei Gericht eingegangen sein muß, widerrufen.

- vorgelesen und genehmigt -

Für den Fall des Vergleichswiderrufs erklärt der Geschäftsführer der Beklagten: Ich versichere die Richtigkeit der Angaben im Schriftsatz vom 22.03.01 an Eides Statt mit der Maßgabe, daß die Gebrauchsanleitung, auf die in Ziff. 2 Bezug genommen ist, noch nicht veröffentlicht ist und noch nicht verwendet wird.

Klägervertreter bietet die Einvernahme der präsenten Zeugin dazu an, daß die Gebrauchsanweisung von Seiten der Klägerin erst im Zusammenhang mit dem Informationsschreiben zur Vorbereitung der einstweiligen Verfügung auf dem freien Markt verlangt wurde.

Beklagtenvertreter übergibt dazu eidesstattl. Versicherungen vom 27.01. und 15.03.2001 im Original.

Das Gericht weist darauf hin, daß dem Schriftsatz vom 22.03.2001 entnommen werden kann, daß in der früheren Gebrauchsanweisung die Zweckbestimmung für die Wundvakuum-Versiegelung nicht enthalten war.

Der Geschäftsführer der Beklagten erklärt:

Dies ist richtig. Es war lediglich enthalten, wie man in der Wunde eine Drainage legt.

Beklagtenvertreter übergibt Original der ihm zugestellten einstweiligen Verfügung mit Zustellurkunde.

...

Nach geheimer Beratung des Gerichts verkündet **die Vorsitzende** folgenden

Beschluss:

Die Zeugin ist antragsgemäß zu vernehmen.

Die Zeugin wird sodann vorgerufen und vernommen wie folgt:

Zur Person:

Sabine Rössler, geb. 20.10.1964, tätig in der Vertriebsleitung der Klägerin
Buchenstr. 31a, 85716 Unterschleißheim
mit den Parteien nicht verwandt und nicht verschwägert.

Zur Sache:

Ich weiß nur, daß Herr Appelt im Besitz einer Gebrauchsanweisung ist, die er über einen Mitarbeiter bekommen hat. Das muß im Januar gewesen sein. Von einer patentrechtlichen Auseinandersetzung weiß ich nichts. Das ist dem Vertrieb nicht mitgeteilt worden.

Auf Frage des Beklagtenvertreters:

Auf der "Medica 2000" war ich, habe mir dort aber kein Informationsmaterial über diese Pumpe beschafft. Die Messe war Ende November 2000. Herr Appelt war stundenweise zugegen.

Davon, daß der Stand fotografiert werden sollte oder wurde, weiß ich nichts.

...

Auf Diktat genehmigt
Auf Verlesen wird allseits
verzichtet

Die Parteivertreter stellen keinen Antrag zur Beeidigung der Zeugin.

Nach geheimer Beratung des Gerichts verkündet die Vorsitzende folgenden

Beschluss:

Die Zeugiin bleibt unbeeidigt.

Die Zeugin wird sodann im allseitigen Einverständnis entlassen.

Für den Fall des Vergleichswiderrufs wird den Parteien Gelegenheit gegeben, zum Beweisergebnis Stellung zu nehmen.

Sie wiederholen im übrigen die eingangs gestellten Anträge.

Nach geheimer Beratung des Gerichts verkündet die Vorsitzende folgenden

Beschluss:

Für den Fall des Vergleichswiderrufs wird
Termin zur Verkündung einer Entscheidung
bestimmt auf

...

Freitag, 20.04.2001, 13.00 Uhr,
Sitzungssaal 103/I, Justizgebäude Lenbachplatz 7.

Die Vorsitzende	Die Urkundsbeamtin
Seifert Vors. Richterin am Landgericht	Eppert Justizangestellte

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www.medela.de

medela

Information

Erprobung einer Absaugpumpe mit Zubehör für die Wund-Vakuumversiegelung

- Gemäß Lieferschein stellen wir Ihnen ein komplettes Absaugsystem für die Wund-Vakuumversiegelung zum Test zur Verfügung.
- Bedingungen und Lieferumfang ergeben sich gemäß Anlage.
- Wir stellen Ihnen die Absaugpumpe vom Typ VARIQ sowie das aufgeführte Zubehör ohne Berechnung zur Verfügung.
- Der Zeitraum für die Testung - ohne Berechnung - beträgt 2 Wochen.
- Nach dem vereinbarten Zeitraum wird das System
  - ☐ gekauft
  - ☐ gemietet
  - ☐ zurückgegeben

Für Fragen steht Ihnen unser Mitarbeiter gerne zur Verfügung.

Medela Mitarbeiter [redacted]

Telefon-Nr. [redacted]

VERGLEICH

zwischen

KCI Medical GmbH,
Grindlenstrasse 5, 8954 Geroldswil,

(nachfolgend "KCI")

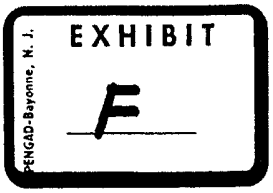
und

Medela AG,
Lättichstrasse 4b, 6340 Baar,

(nachfolgend "Medela")

Zur aussergerichtlichen Erledigung des vor dem Audienzrichteramt des Bezirksgerichtes Zürich hängigen Verfahrens Prozess Nr. EU010729 vereinbaren die Parteien was folgt:

1. Medela verpflichtet sich gegenüber KCI, es zu unterlassen, im geschäftlichen Verkehr die Absaugpumpe vom Typ VARIO zum Zwecke der Wund-/Vakuumversiegelung anzubieten, zu vertreiben, zu verkaufen, zu vermieten und/oder zu bewerben und/oder anbieten zu lassen, vertreiben zu lassen, verkaufen zu lassen und/oder bewerben zu lassen. Für den Fall, dass Anwender die Absaugpumpe vom Typ VARIO zukünftig ohne Kenntnis bzw. Veranlassung von Medela zweckwidrig zur Wund-/Vakuumversiegelung einsetzen sollten, wird Medela die entsprechenden Anwender



auf die zweckwidrige Verwendung aufmerksam machen und - soweit möglich - dafür besorgt sein, dass dies zukünftig unterbleibt.

2. Für den Fall, dass Anwender die Absaugpumpe vom Typ VARIO zukünftig ohne Kenntnis bzw. Veranlassung von Medela zweckwidrig zur Wund-/Vakuumversiegelung einsetzen, wird KCI ihre hierdurch entstehenden möglichen Schadenersatzansprüche gegenüber Medela nicht geltend machen.

3. Medela verpflichtet sich, KCI innert 10 Tagen nach rechtskräftiger Abschreibung des beim Bezirksgericht Zürich pendenten Prozesses Nr. EU010729 Auskunft über die Art und den Umfang allfälliger bisheriger Handlungen zu erteilen, für welche die eingegangene Unterlassungsverpflichtung gemäss obiger Ziff. 1 gilt.

4. Für jeden Fall der Zuwiderhandlung gegen die Verpflichtung gemäss vorstehender Ziff. 1 hat Medela der KCI eine Konventionalstrafe in der Höhe von DEM 11'000.00 zu bezahlen. KCI ist berechtigt, nebst der Konventionalstrafe den Ersatz des weiteren Schadens zu verlangen. Überdies kann KCI neben der Konventionalstrafe und dem Schadenersatz die Beseitigung des vertragswidrigen Zustandes verlangen.

5. KCI verpflichtet sich, mit Unterzeichnung des vorliegenden Vergleichs das Bezirksgericht Zürich unter Einreichung dieses Vergleichs zu ersuchen, den pendenten Prozess Nr. EU010729 infolge aussergerichtlichen Vergleichs abzuschreiben, wobei die Gerichtskosten den Parteien je zur Hälfte aufzuerlegen sind und vom gegenseitigen Verzicht auf Partei- bzw. Prozessentschädigung Vormerk zu nehmen ist.

6. Aussergerichtliche Parteikosten werden wettgeschlagen.

Gerlingen, den 28.9. 2001

KCI MEDICAL GmbH

Baar, den 1.10. 2001

Medela AG

-Translation for convenience only -

SETTLEMENT

between

KCI Medical GmbH,

Grindlenstrasse 5, 8954 Geroldswill

(hereinafter "KCI")

and

Medela AG,

Lättichstrasse 4b, 6340 Baar

(hereinafter „Medela")

The parties agree on the following out-of-court Settlement for the purpose of terminating the matter No. EU010729 pending before the audience judge ("*Audienzrichteramt*") of the Zurich District Court:

1. Medela affirms to KCI that it will desist from offering, distributing, selling, leasing and/or advertising the suction pump of the VARIO type for competitive purposes and/or causing the suction pump of the VARIO type to be thus offered, distributed, sold and/or advertised for the purpose of the vacuum-assisted closure of wounds. In the event that users in the future use the suction pump of the VARIO type inappropriately for vacuum-assisted closure of wounds without the knowledge or permission of Medela, Medela shall for its part draw the users' attention to such inappropriate use and will, as far as possible, make sure that this does not recur.

2. In the event that users in the future use the suction pump of the VARIO type inappropriately for vacuum-assisted closure of wounds without the knowledge or permission of Medela, KCI shall not assert against Medela any claims for damages thereby incurred.

3. Medela undertakes, that it will within 10 days after the termination of the case No. EU010729 pending with the Zurich District Court has become legally binding provide/disclose information on the manner/kind and the extent of all possible (previous) actions hitherto, which the obligation of omission entered into is valid for according to the above para. 1.

4. Medela will pay a penalty for breach of contract amounting to DEM 11'000.00 to KCI for each violation of the obligation under No. 1 above. Apart from a penalty for breach of contract, KCI can also claim damages. Moreover, apart from being entitled to a penalty for breach of contract as well as damages, Medela can claim to have conditions in breach of contract removed.

5. By signing this settlement, KCI undertakes that it will - submitting the present settlement - request the Zurich District Court to terminate the pending case No. EU010729 by way of an out-of-court Settlement. Each party will bear fifty per cent of the court fees. The parties will notify the court of mutually waving possible claims for a party's compensation against each other concerning legal fees resulting from the trial proceedings.

6. Each party shall bear its own legal fees including judicial and extra judicial fees.

Geroldswill, 28 September 2001

KCI MEDICAL GmbH

Baar, 1 October 2001

Medela AG

Medela AG · Medical Technology
Lättichstrasse 4 · 6341 Baar/Switzerland
http://www.medela.ch

Phone ++41 (0)41 769 51 41
Fax ++41 (0)41 769 51 01
ism@medela.ch

medela®

Telefax ISBD

To:	CLIFFORD CHANCE / Amsterdam, The Netherlands Fax-No.: +31 (0) 20 711 99 99
Attn.:	Th. C.J.A. van Engelen

STATEMENT

To KCI Medical B.V.

Dear Sirs,

Medela AG (Lättichstrasse 4b, 6341, Baar Switzerland) declares that:

1. Medela will, with immediate effect cease and desist from marketing, advertisement, selling, offering to sell or leasing Medela Suction pump model type VARIO as suitable for a wound healing system for vacuum assisted closure of wounds, rather than the purpose of suctioning secretions out of wounds.

2. Medela will inform both Mediprof B.V. and Welcare B.V. (the company from which Mediprof B.V. purchased Medela pumps), by sending them a written statement in accordance with the Schedule A hereto, that the Medela Suction pump model type VARIO are not suitable and not to be used as wound healing system for vacuum assisted closure of wounds, rather than the purpose of suctioning secretions out of wounds.

3. With regards to future sales of Medela Suction pump model type VARIO, Medela will clearly indicate and draw the potential buyers attention to the fact that Medela Suction pump model type VARIO are not suitable and not to be used for the purpose of a wound healing system for vacuum assisted closure of wounds, rather than the purpose of suctioning secretions out of wounds.

4. In the event that third parties use or commercialize Medela Suction pump model type VARIO for wound healing system for vacuum assisted closure of wounds, Medela shall draw such third party's attention to such inappropriate use.

5. Medela will pay a penalty for breach of contract of EURO 7'000 to KCI for each violation of their obligations to KCI mentioned in this statement. Apart from a penalty for each breach of contract, KCI may in its sole discretion also claim damages.

Baar, 16th December 2002

MEDELA AG

Urs Tanner
CEO of the Medela Group

Peter Høst
Manager International Sales & New Business Development

EXHIBIT G

PENGAD-Bayonne, N. J.

Medela AG · Medical Tec gy
Lättichstrasse 4 · 6341 B witzerland
http://www.medela.ch

Phone ++41 (0)41 769 51 41
Fax ++41 (0)41 769 51 01
ism@medela.ch

medela

SCHEDULE A

To Welcare B.V.
To Mediprof B.V.

Baar, 16th December 2002

Dear Sirs,

Hereby we ask your attention for the following:

It has been brought to our attention by KCI Medical B.V. that Mediprof BV is marketing Medela Suction pump model type VARIO for the purpose of a wound healing system for vacuum assisted closure of wounds, rather than the purpose of suctioning secretions out of wounds.

Please be advised that Medela Suction pump model type VARIO is not suitable and not to be used for the purpose of a wound healing system for vacuum assisted closure of wounds.

We kindly ask you to cease and desist from marketing Medela Suction pump model type VARIO for that purpose and to inform any third parties that either use or commercialize Medela Suction pump model type VARIO as wound healing system for vacuum assisted closure of wounds is not suitable.

Sincerely yours,

MEDELA AG

Urs Tanner
CEO of the Medela Group

Peter Høst
Manager International Sales & New Business Development

EXHIBIT
H

Telefax

To:	CLIFFORD CHANCE / Amsterdam, The Netherlands Fax-No.: +31 (0) 20 711 99 99
Attn.:	Th. C.J.A. van Engelen

Naar aanleiding van uw brief van 3 februari 2003, ontvangt u onderstaand dezelfde verklaring als Medela AG reeds heeft gedaan, door ons ondertekend.

STATEMENT

To KCI Medical B.V.

Dear Sirs,

Medela Benelux BV (Dintel 4, 5422 VT Gemert, the Netherlands) declares that:

1. Medela Benelux BV will, with immediate effect cease and desist from marketing, advertisement, selling, offering to sell or leasing Medela Suction pump model type VARIO as suitable for a wound healing system for vacuum assisted closure of wounds, rather than the purpose of suctioning secretions out of wounds.

2. Medela Benelux BV will inform Mediprof B.V. by sending them a written statement in accordance with the Schedule A hereto, that the Medela Suction pump model type VARIO are not suitable and not to be used as wound healing system for vacuum assisted closure of wounds, rather than the purpose of suctioning secretions out of wounds.

3. With regards to future sales of Medela Suction pump model type VARIO, Medela will clearly indicate and draw the potential buyers attention to the fact that Medela Suction pump model type VARIO are not suitable and not to be used for the purpose of a wound healing system for vacuum assisted closure of wounds, rather than the purpose of suctioning secretions out of wounds.

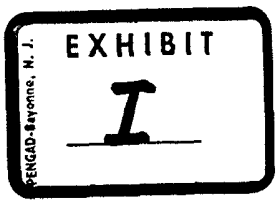
4. In the event that third parties use or commercialize Medela Suction pump model type VARIO for wound healing system for vacuum assisted closure of wounds, Medela shall draw such third party's attention to such inappropriate use.

5. Medela will pay a penalty for breach of contract of EURO 7'000 to KCI for each violation of their obligations to KCI mentioned in this statement. Apart from a penalty for each breach of contract, KCI may in its sole discretion also claim damages.

Gemert, February 4, 2003

Medela Benelux BV

F. van Wel
Directeur



LEGAL LANGUAGE SERVICES

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New York, NY 10038

Telephone (212) 766-4111
Toll Free (800) 788-0450
Telefax (212) 349-0964
www.legallanguage.com

December 20, 2004

To whom it may concern:

This is to certify that the attached translation from Dutch into English is an accurate representation of the document received by this office. This document is designated as:

KCI Medical Documents

George Alves, the Supervisor of Translation Services, certifies that Renee Vankeulen, who translated this document, is fluent in Dutch and standard North American English and is qualified to translate.

He attests to the following:

"To the best of my knowledge, the accompanying text is a true, full and accurate translation of the specified document."

Signature of George Alves

Subscribed and sworn to before me this 20th day of December 2004.

Rosemary Brito
Notary Public, State of New York
No. 01BR6077317
Certificate filed in New York County
Qualified in Kings County
Commission Expires July 8, 2006

Sincerely,

Victor J. Hertz
President

In reply to your letter dated February 3 2003, below you hereby receive the same declaration that Medela AG has already issued, signed by us.

US005645081A

United States Patent [19]

Argenta et al.

[11] Patent Number: 5,645,081

[45] Date of Patent: *Jul. 8, 1997

[54] **METHOD OF TREATING TISSUE DAMAGE AND APPARATUS FOR SAME**

[75] Inventors: **Louis C. Argenta**, Winston-Salem; **Michael J. Morykwas**, Pfafftown, both of N.C.

[73] Assignee: **Wake Forest University**, Winston-Salem, N.C.

[*] Notice: The portion of the term of this patent subsequent to Mar. 9, 2013, has been disclaimed.

[21] Appl. No.: **792,001**

[22] Filed: **Nov. 14, 1991**

[51] **Int. Cl.**[6] **A61B 19/00**

[52] **U.S. Cl.** **128/897**; 602/42

[58] **Field of Search** 128/897–8; 602/42–53

[56] **References Cited**

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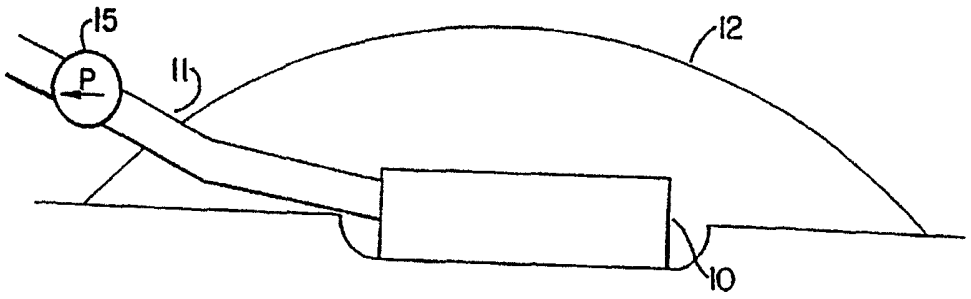
[57] **ABSTRACT**

The invention disclosed is a method of treating tissue damage comprising applying a negative pressure to a wound sufficient in time and magnitude to promote tissue migration and thus facilitate closure of the wound. The method is applicable to wounds, burns, infected wounds, and live tissue attachments. Configurations of apparatus for carrying out the method are also disclosed.

82 Claims, 1 Drawing Sheet



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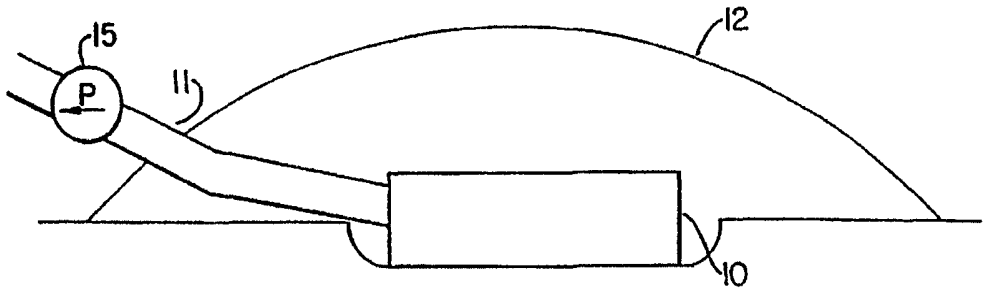

FIG. 1.

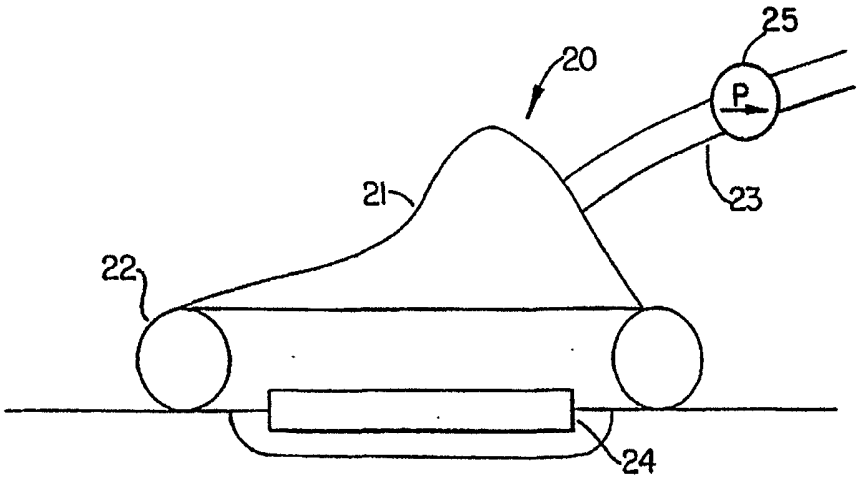

FIG. 2.

METHOD OF TREATING TISSUE DAMAGE AND APPARATUS FOR SAME

FIELD OF THE INVENTION

This invention relates generally to wound healing, and more specifically is directed at wounds that are unlikely to heal completely under conventional methods.

BACKGROUND OF THE INVENTION

The treatment of open wounds that are too large to spontaneously close has been a troublesome area for many years. Wound closure requires that epithelial and subcutaneous tissue adjacent to the wound migrate toward and eventually close the wound. Some wounds are sufficiently large or infected that they are unable to close spontaneously. In such instances, a zone of stasis, an area in which localized swelling of tissues restricts the flow of blood to these tissues, forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and accordingly is unable to close spontaneously.

The most common technique for closure of open wounds has long been the use of sutures or staples. These mechanical closure methods provide tension on the skin tissue at the wound border that encourages epithelial tissue to migrate toward the wound and cover it. While suturing and stapling of wounds is widely practiced, it has a major drawback: the tensile force required to achieve closure with sutures or staples causes very high localized stresses at the suture insertion points, resulting in the rupture of the tissue at these points. Substantial rupture will eventually cause dehiscence in some wounds, which results in additional tissue loss. Moreover, some infected wounds harden and inflame to such a degree that closure by suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high costs, and major surgical procedures, such as grafts of surrounding tissue. Examples of such wounds include large, deep, open wounds, pressure sores resulting from prolonged pressure, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

To date, there has been no consistently satisfactory method for treating such wounds. What is needed is a method of closing the wound without the localized stresses that accompany suturing while at the same time treating any infection present in the wound along with a simple apparatus to carry out the method. Such a method and apparatus would reduce hospitalization and increase the probability of wound closure.

SUMMARY OF THE INVENTION

A first aspect of the invention is a method of treating tissue damage which comprises applying a negative pressure to a wound over an area sufficient to promote the migration of epithelial and subcutaneous tissue toward the wound and for a time period sufficient to facilitate closure of the wound. The method is particularly useful for treating pressure sores.

A second aspect of the invention is a method of treating a burn wound which comprises applying a negative pressure to the burn over an area and for a time sufficient to inhibit progression in the depth of the burn. The method is preferably used on a partial thickness burn soon after its infliction.

A third aspect of the invention is a method of treating tissue damage which comprises applying a negative pressure to a wound for a time sufficient to reduce bacterial density in a wound. A preferred use of this method is its application to a wound for at least 3 days to reduce the bacterial density of an infected wound to the point at which surgical closure can be attempted.

A fourth aspect of the invention is a method of enhancing the attachment of adjacent tissue to a wound which comprises applying a negative pressure to a joined complex of wound and adjacent living tissue at a sufficient magnitude and for a sufficient time to promote the migration of epithelial and subcutaneous tissue toward the complex. A preferred use of this method is enhanced attachment of adjacent tissue to tissues of the wound edges. Another use is enhanced attachment of an open skin graft.

A fifth aspect of the invention is an apparatus for facilitating the healing of wounds which comprises vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain the negative pressure on the wound, and screen means for preventing overgrowth of tissue in the wound area. A preferred embodiment of the invention comprises a section of open-cell foam configured to be placed over a wound, a flexible tube inserted into the foam section for attachment to a suction pump, and a flexible polymer sheet overlying the foam section and tubing and configured to be adhered to the skin surrounding the wound.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a cross-sectional view of a negative pressure device comprising a open-cell polymer screen, a flexible hose connecting the foam section to a suction pump, and a flexible polymer sheet overlying the foam-hose assembly to provide the necessary seal; and

FIG. **2** shows a cross-sectional view of a negative pressure device comprising a porous screen, an inflatible cuff attached to a semi-rigid cup, and a flexible hose extending from a suction pump to a point within the sealed volume of the cup-cuff assembly.

DETAILED DESCRIPTION OF THE INVENTION

The present invention includes a method of treating tissue damage which comprises the stages of applying a negative pressure to a wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound, with the negative pressure being maintained for a time sufficient to facilitate closure of the wound. Wound closure requires that epithelial and subcutaneous tissue migrate from the wound border toward the wound. The use of negative pressure provides tension on this border tissue that causes accelerated tissue migration. It has been observed that the use of the method also causes within the wound increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing.

The method is particularly suited for use on pressure sores. A pressure sore is a wound that develops due to constant compressive pressure on the skin surface and underlying tissue. Blood flow to the compressed tissue is restricted to the extent that the overlying tissue dies and subsequently allows the underlying tissue to become infected. The decrease of blood flow to the wound prevents a normal immune reaction to fight the infection, the presence of which prevents tissue migration from the wound border.

Pressure sores often occur on bedridden patients who are unable to feel the sore or to move sufficiently to relieve the contact pressure. Such wounds can become very serious, requiring extensive and repeated skin grafts; some are even fatal. As described above, application of negative pressure to the sore permits migration of wound border tissue to occur and thus allows sores to heal without these more drastic procedures.

The method can be practiced with the application of substantially continuous negative pressure, where the pressure is relieved only to change the dressing on the wound, or it can be practiced with the use of a cyclic application of pressure in alternate periods of application and non-application. The ratio of duration of application period to non-application period can be as low as 1:10 or as high as 10:1, but is most preferably 1:1. A preferred pattern is 5 minutes of pressure application followed by 5 minutes of relief.

The method is preferably practiced using a negative pressure ranging from 0.01 to 0.99 atmospheres, and more preferably practiced using a negative pressure ranging between 0.5 to 0.8 atmospheres. The time period for use of the method on a wound is preferably at least 12 hours, but can be, for example, 1 day, 2 days, 5 days, 7 days, 14 days, 30 days, or even longer. There is no upper limit beyond which use of the method is no longer beneficial; the method increases the rate of closure up to the time the wound actually closes.

The present invention also includes a method of treating damaged tissue which comprises the steps of applying a negative pressure to a wound for a time and at a magnitude sufficient to reduce bacterial density in the wound. Open wounds are almost always contaminated with harmful bacteria. Generally a bacterial density of 10^5 bacterial organisms per gram of tissue is regarded as infected. (It is generally accepted that at this level of infection, grafted tissue will not adhere to a wound).

These bacteria must be killed, either through the wound host's natural immune response or through some external method, before a wound will close. We have observed that application of negative pressure to a wound will reduce the bacterial density of the wound; it is believed that this effect is due to either the bacteria's incompatibility with a negative pressure environment or the increased blood flow to the wound area, as blood brings with it cells and enzymes to destroy the bacteria.

The method can be used to reduce bacterial density in a wound by at least half. More preferably, it can be used to reduce bacterial density by at least 1,000 fold. Most preferably, the method can be used to reduce bacterial density by at least 1,000,000 fold. The ranges of pressure magnitude and application duration are as described above, although Example 3 demonstrates dramatic reduction in wound contamination after a 4-day application of negative pressure. Pressure can be applied continuously or cyclically in the application/nonapplication ratios described above.

The present invention also includes a method of treating a burn which comprises the steps of applying a negative pressure to the burn over an area and for a time sufficient to inhibit formation of a full thickness burn. A partial thickness burn, one which has a surface layer of dead tissue and an underlying zone of stasis, is often sufficiently infected that it will transform within 24–48 hours into a full thickness burn, one in which all epidermal structures are destroyed. As explained above, the application of a negative pressure to the wound prevents the infection from becoming sufficiently severe to cause destruction of the underlying epidermal structures. As above, the magnitude, pattern, and duration of pressure application can vary with the individual wound.

The present invention also provides a method for enhancing the attachment of living tissue to a wound which comprises the steps of first joining the living tissue to the wound to form a wound-tissue complex, then applying a negative pressure to the wound-tissue complex over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the complex, with the negative pressure being maintained for a time period sufficient to facilitate closure of the wound. Attachment of living tissue to a wound is a common procedure that can take many forms. For example, one common technique is the use of a "flap", a technique in which skin tissue from an area adjacent to the wound is detached on three sides but remains attached on the fourth, then is moved onto the wound. Another frequently used technique is an open skin graft in which skin is fully detached from another skin surface and grafted onto the wound. The application of negative pressure to the wound-graft complex reduces bacterial density in the complex and improves blood flow to the wound, thereby improving the attachment of the grafted tissue.

The acceptable ranges of time, magnitude, and application/non-application ratio are as described above. Each of these variables is affected by the size and type of wound.

The present invention also includes an apparatus for facilitating the healing of wounds. In general, an apparatus is provided for facilitating the healing of wounds comprising vacuum means for creating a negative pressure on the area of skin including and surrounding the wound and sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound. More specifically, an apparatus comprises vacuum means such as a pump for creating a negative pressure on the area of skin surrounding the wound, sealing means such as an adhesive sheet operatively associated with the vacuum means for maintaining negative pressure on the wound by contacting the skin surrounding the wound, and screen means such as an open-cell foam section located within the sealing means for preventing the overgrowth of tissue in the wound area.

The screen means is placed over substantially the expanse of the wound to prevent its overgrowth. The size and configuration of the screen can be adjusted to fit the individual wound. It can be formed from a variety of porous semi-rigid materials. The material must be sufficiently porous to allow oxygen to reach the wound, and sufficiently rigid to prevent wound overgrowth. Most preferred is the use of an open-cell polymer foam, which permits direct connection of the screen means to the vacuum means through a flexible hose inserted into the foam. Such foam can vary in thickness and rigidity, although it is preferred that a spongy material be used for the patient's comfort if the patient must lay upon the device during its operation. It can also be perforated to reduce its weight. Another embodiment comprises a section of honeycombed polyethylene sheet cut to the shape of the wound.

Possible sealing means include a flexible sealing rim contacting the skin surrounding the wound, a flexible polymer sheet overlying the screen means and the vacuum means and attached to the skin through an adhesive applied to the sheet surface facing the skin, and an inflatable sealing cuff that conforms to the skin when inflated and that is held in place by the suction of the vacuum means. If an adhesive

sheet is used, it must have sufficient adhesion to remain in contact with the skin and form a seal under the negative pressure. Additionally, it must be sufficiently flexible to overlay the screen means and still conform to the skin around the wound. The sealing means also can include a semi-rigid cup that protects the wound from external contact. For example, a suitable cup-cuff assembly is provided by an adult CPR mask with an inflatable sleeve.

Suitable vacuum means includes any suction pump capable of providing at least 0.1 pound suction to the wound, and preferably up to 3 pounds suction, and most preferably up to 14 pounds suction, and a flexible hose that leads from the pump to a point within the pressurized volume created by the sealing means. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the necessary suction. The dimension of the tubing are limited only by the pump's ability to provide the suction level needed for operation. A ¼ inch diameter tube has proven suitable. The vacuum means may operate substantially continuously, or may operate cyclically with alternate periods of application and nonapplication of pressure to the wound.

A preferred embodiment of the invention, shown in FIG. 1, comprises a substantially flat section of open cell polyester foam section **10** (Fischer Scientific, Pittsburgh, Pa. 15219) sufficiently large to cover the wound and thus prevent wound overgrowth, a flexible hollow tube **11** (Fischer Scientific) inserted into the open cell foam section **10** and joined thereto with an adhesive and extending to attach at its opposite end to a Gast Vacuum pump **15** (Fischer Scientific), and an Ioban adhesive sheet **12** (Minnesota Mining and Manufacturing, St. Paul, Minn. 55144) overlying the foam section **10** and tubing **11** and adhered to the skin surrounding the wound, thus forming a seal that allows creation of a vacuum when the suction pump operates. Such an apparatus would most preferably be packaged in a sterile condition to ameliorate the need for sterilization of the apparatus prior to use (note that the adhesive sheet **12** could be packaged separately from the foam-tube assembly). A particular advantage of this configuration is its use with pressure sores: the device can be placed in the depths of the wound and the patient can lie upon it without either affecting the utility of the device or further damaging the wound. This becomes critical if the patient cannot be moved from this posture for other medical reasons.

The present invention is explained further in the following examples. These examples are provided for illustrative purposes only and are not to be taken as limiting.

EXAMPLE 1

Rate of Wound Healing under Negative Pressure

This example demonstrates the use of negative pressure to increase the rate of healing of full thickness defects by increasing vascularity and the amount of granulation tissue present.

Fifteen-kilogram pigs were obtained and conditioned for 1 week prior to use. The backs of the pigs were shaved and scrubbed for surgery. Two full thickness circular defects were created on the midline of the animals, 2.5 cm in diameter and 1 cm thick. Alginate impressions were taken of each defect to determine its volume. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). The suction devices used, shown in FIG. **2**, comprised an adult CPR mask **20** (Doug Brown and Associates, Huntington Beach, Calif. 92648) comprising a semi-rigid cup **21** and inflatible cuff **22** in contact with the skin, an open cell polyester screen **24** overlying the wound, and a flexible ¼ inch diameter hose **23** (Fischer Scientific) connected by a Nalgene tubing connector to a vacuum pump **25** (Fischer Scientific) and extending through a sealed hole in the cup. Each device was configured such that the suction hose ran from the cup on the animal up through a pulley suspended over the center of the pen and down to a vacuum trap bottle to collect any liquid exudate, then down to the vacuum pump. A suction device was attached over each defect, and suction (2–6 pounds vacuum) was applied to one of the devices. The devices were removed only so that impressions could be made of each defect. This procedure was continued until the volume of both defects was zero.

Table 1 shows data expressed as the amount of granulation tissue formed per day and as the percent difference in rate of granulation tissue formation. The data shows that in all cases the use of negative pressure increased the rate of wound closure and the formation of granulation tissue at a statistically significant rate.

EXAMPLE 2

Rate of Burn Healing under Negative pressure

This example was designed to demonstrate the use of continuous closed suction for the treatment of deep, partial thickness thermal burns (second degree burns).

The backs of 15 kg pigs were shaved and scrubbed for surgery. A 1.5 inch diameter brass rod was heated to 190° C. in an oil bath. The rod was pressed onto the pig's skin for 15 seconds following a well-known technique of relating depth of burn to time and temperature. Three burns were created over the spine of each pig, separated by 5 cm intervals. Suction apparatus cups of the configuration described above were placed over two of the burns, with silver sulphadiazine (Silvadine) cream, the standard antibiotic cream applied to human burns prior to excision of burned tissue, applied to the third. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). Suction (2–6 pounds vacuum) was applied to one of the cups. A small (2 mm) punch biopsy was taken of the wounded area and examined histologically for depth of burn.

TABLE 1

Rate of granulation tissue formation for control and reduced pressure treated full thickness defects in pigs.

Animal	Granulated Treatment	Tissue/Day(cc)	% Increase*
1	Suction	0.48	26.3
	Control	0.38	
2	Suction	1.16	28.9
	Control	0.90	
3	Suction	0.58	75.8
	Control	0.33	
4	Suction	0.71	65.1
	Control	0.43	
5	Suction	0.71	65.1
	Control	0.43	

*(Suction-Control)/Control

TABLE 2

Rate of reduction in bacterial density for control and reduce and pressure treated pigs (n = 5).
Log Organisms Per Gram Tissue

Treatment		Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 7
Control	Mean	8.44	8.04	8.17	7.13	7.13	8.82	7.08
	SD	+ .38	± .13	± .98	± .15	± .24	± 1.12	± .52
Vacuum	Mean	7.69	7.36	7.37	6.79	6.43	3.98	4.32
	SD	± .83	± .84	± 1.40	± .55	± .45	± 3.46	± 3.74

Biopsies were analyzed by a dermatopathologist who was not told the nature of the study. It was concluded that the suctioned tissue specimens were healthier and healing more quickly than non-suctioned specimens.

EXAMPLE 3

Reduction of Bacterial Density under Negative Pressure

This example illustrates the effects of continuous closed suction on the bacterial density of infected tissue.

Fifteen-kilogram pigs were shaved and prepared for surgery. Two 2.5 cm diameter defects were created on the dorsum of each pig using sterile technique, with a 7.5 cm interval retained between the edges of the defects. Hemostasis was obtained by electrocautery. One ml of culture broth containing 10^8 *Staph. aureus* organisms was injected just beneath the surface tissue in the center of each wound. Suction cups of the configuration described above were placed over each defect, and a T-shirt was placed over the animal. Suction (2–6 pounds vacuum) was applied 24 hours after surgery to only one of the defects, allowing each animal to act as its own control. No antibiotics were given during the course of the study.

Each day, a small (3 mm biopsy punch) piece of granulation tissue was removed from the center of each defect. The number of organisms present in the tissue was determined by weighing the tissue, homogenizing the tissue, serially diluting the supernatant, and plating the diluted supernatant on blood agar plates. Samples of the original broth were treated in an identical manner to determine effects of mechanical manipulations on bacteria viability. The procedure was performed until the wounds were healed.

Table 2 compares the bacterial density of treated wounds and control wounds over time. The data is expressed as the mean log of the number of viable organisms per gram of tissue as a function of time. Clearly, the application of negative pressure increases the rate at which bacteria are destroyed. Using 10^5 organisms per gram of tissue as a baseline for infection, the data show that on average a suctioned wound was disinfected after 4 days of treatment, while the average non-treated wound was still infected after 7 days.

EXAMPLE 4

Treatment of Pressure Sore With Negative Pressure

Mr. L. J. is a 45-year-old diabetic male who has been a paraplegic as the result of a gunshot wound for 12 years. He has a history of recurrent right ischeal fossa pressure sore and right trochanteric pressure ulcer. L. J. was admitted to the hospital for treatment and closure of the pressure sores. A flap was placed onto the wound and secured with sutures and staples.

The incisions of the flap dehisced, resulting in a large, open wound. The tissues of the flap were very edematous and indurated. Nine days after the flap was detached, a negative pressure device was placed over the wound. The device comprised an open-cell polyester foam section (Fischer Scientific) approximately ½ inch in thickness attached to a suction pump by a flexible hose (Fischer Scientific) and covered and sealed by Ioban polymer sheet (Minnesota Mining and Manufacturing, St. Paul, Minn. 55144). A continuous vacuum of 5 psi was applied to the wound. The design of the device allowed the patient to lay comfortably on the device during operation.

The depth of the wound decreased dramatically. The devices were changed and the wound examined on a three times per week basis. Reduced pressure treatment was continued for 6 weeks, at which time the wound was healed.

EXAMPLE 5

Treatment of Pressure Sore With Negative Pressure

Mr. W. E. is a 51-year-old male who had both legs amputated at the hip approximately 20 years ago. He was afflicted with a large pressure sore in the buttocks region. The pressure sore had been present 7 months and measured 8 inches laterally and 3 in its greatest width. An open cell foam reduced pressure device as described in Example 4 was placed over the wound and a negative pressure of 5 psi was applied cyclically in alternate periods of 5 minutes on, 5 minutes off. The open cell foam device was used as the patient was lying on the device. The device was changed on a three times per week schedule.

After 5 weeks of treatment, the wound measured 3 inches laterally and 1.5 inches at its greatest width. At that point the wound was essentially healthy granulation tissue that accepted a cultured keratinocyte allograft and healed completely.

EXAMPLE 6

Treatment of Wound Dehiscence With Negative Pressure

Mr. C. L. is a 50-year-old male who had undergone a colostomy revision through a midline laparotomy. He was readmitted to the hospital for wound dehiscence and evisceration following forceful coughing. The abdominal wall was closed with Prolene mesh coverage. Six weeks after placement of the Prolene mesh, the wound was still open and measured 28 cm by 23 cm with sparse granulation tissue grown through the Prolene mesh. A large reduced pressure cup device of the type described in Example 1 with an underlying porous Aquaplast sheet (WFR/Aquaplast Corp., Wyckoff, N.J. 07481) was placed on the Prolene mesh/

wound surface and the space closed with a tent of Ioban. Five psi of continuous negative pressure was applied. The device was changed three times per week.

After 6 days, granulation tissue had grown through the Prolene mesh, totally covering the mesh. The patient was taken to the operating room where the surrounding tissue was undermined and grafted onto the wound to partially close the defect. Split thickness skin grafts were used to cover the remainder of the defect, and were placed on the bed of granulation tissue. The wound accepted 80% of the grafts, and the remaining areas closed with dressing changes alone.

EXAMPLE 7

Treatment of Ankle Osteomyelitic Ulcer With Negative Pressure

Mr. R. F. is a 39-year-old white male who had severe trauma to his left lower extremity secondary to a motor vehicle accident 10 years ago. He had contracted chronic osteomyelitis and an open ulcer with exposed bone of his left lateral ankle (lateral malleolar ulcer). Necrotic soft tissue and bone were surgically removed from the ankle. The patient was placed on a 2½ week course of antibiotics. The day after surgery, a reduced pressure device of the type described in Example 1 was placed over the wound, and a negative pressure of 5 psi was applied. The device was changed on a three times per week schedule. After 14 days of treatment, the wound was smaller and filled with granulation tissue. A split thickness skin graft was placed over the center of the defect and healed primarily.

EXAMPLE 8

Treatment of Burn With Negative Pressure

Patient B. is admitted with second and third degree burns over the face and upper extremities, including both hands, as a result of a house fire. A large mitten-shaped reduced pressure device of the type described in Example 4 is placed over the patient's right hand, with open cell foam inserts placed between the fingers to apply reduced pressure to the interdigit spaces. Three pounds of vacuum is applied cyclically in a pattern of 5 minutes on, 5 minutes off. The device is changed on a three times per week schedule. Treatment is continued until the necrotic tissue sloughs off or is excised, followed by split thickness skin graft placement.

The foregoing examples are illustrative of the present invention, and are not to be construed as limiting thereof. The invention is defined by the following claims, with equivalents of the claims to be included therein.

That which is claimed is:

1. An apparatus for facilitating the healing of wounds, comprising:

vacuum means for creating a negative pressure between about 0.1 and 0.99 atmospheres on the area of skin including and surrounding the wound;

sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound; and

screen means for positioning at the wound within the sealing means for preventing the overgrowth of tissue in the wound.

2. An apparatus according to claim 1, in which said screen means comprises an open-cell polymer foam.

3. An apparatus according to claim 1, in which said screen means comprises a flat, porous, semi-rigid member.

4. An apparatus according to claim 1, in which said sealing means includes a flexible sealing rim in contact with said skin surrounding said wound.

5. An apparatus according to claim 1, in which said sealing means includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin.

6. An apparatus according to claim 1, in which said sealing means includes a sealing cuff in contact with said skin surrounding the wound.

7. An apparatus according to claim 6, in which said sealing cuff is inflatable.

8. An apparatus according to claim 1, in which said vacuum means includes pump means for providing at least 0.1 pounds suction.

9. An apparatus according to claim 1, in which said vacuum means includes a pump means for providing at least 3 pounds suction.

10. An apparatus according to claim 1, in which said vacuum means includes a pump means for providing at least 14 pounds suction.

11. An apparatus according to claim 1, in which said vacuum means operates continuously.

12. An apparatus according to claim 1, in which said vacuum means operates cyclically to provide periods of application and non-application of suction.

13. An apparatus according to claim 1 wherein said vacuum means supplies a negative pressure between about 0.3 and 0.99 atmospheres to the wound.

14. An apparatus according to claim 1 wherein said vacuum means supplies a negative pressure between about 0.5 and 0.99 atmospheres to the wound.

15. An apparatus according to claim 1 wherein said vacuum means supplies a negative pressure between about 0.5 and 0.8 atmospheres to the wound.

16. An apparatus for facilitating the healing of wounds, comprising:

vacuum means for creating a negative pressure on the area of skin including and surrounding the wound;

sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound, wherein said sealing means includes a semi-rigid cup configured to protect said wound from external contact; and

screen means for positioning at the wound within the sealing means for preventing the overgrowth of tissue in the wound.

17. An apparatus for applying negative pressure to a wound beneath a fluid-impermeable seal comprising:

an open cell polymer foam section for positioning beneath said seal configured to overlie the wound such that said negative pressure is maintained within said foam and applied to the wound; and

a flexible tube having an inlet end inserted into said open cell polymer foam section and an outlet end for extending from beneath said seal and for supplying said negative pressure; and

wherein said apparatus is in an aseptic package.

18. An apparatus for treating a wound, comprising:

an open-cell foam section configured to overlie the wound;

a fluid-impermeable cover overlying said foam section, said cover adapted to form a seal with skin surrounding the wound for maintaining negative pressure beneath said cover; and

a single tubular member having a first end inserted beneath at least a portion of the foam section and having a second end extending from beneath said cover to a location external to said cover for supplying negative pressure beneath the cover.

19. The apparatus of claim **18** wherein said open-cell foam section is configured to overlie only a region of said wound within the margin of said wound.

20. The apparatus of claim **18** wherein said first end of the tubular member is embedded within the foam section.

21. An apparatus according to claim **18** wherein said vacuum source supplies a negative pressure between about 0.3 and 0.99 atmospheres to the wound.

22. An apparatus according to claim **18** wherein said vacuum source supplies a negative pressure between about 0.5 and 0.99 atmospheres to the wound.

23. An apparatus according to claim **18** wherein said vacuum source supplies a negative pressure between about 0.5 and 0.8 atmospheres to the wound.

24. An apparatus for treating a wound, comprising:

a semi-rigid, fluid-impermeable cup for positioning over the wound and for maintaining a negative pressure upon said wound, said cup having only a single external fluid communication port;

sealing means for sealing said cup about the wound, said sealing means including a cuff for inflating and conforming to the surrounding skin to seal said cup in place by said negative pressure;

tubular means extending from said fluid communication port of said cup for supplying said negative pressure; and

screen means for positioning beneath the cup at the wound for preventing overgrowth of the wound.

25. The apparatus of claim **24** wherein said screen means is a porous sheet.

26. The apparatus of claim **24** wherein said screen means is an open-cell foam.

27. An apparatus for facilitating the healing of wounds, comprising:

vacuum means for creating a negative pressure on the area of skin including and surrounding the wound, wherein said vacuum means operates cyclically to provide periods of application and non-application of suction with the ratio of duration of application period to non-application period between about 1:10 and 10:1;

sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound; and

screen means for positioning at the wound within the sealing means for preventing the overgrowth of tissue in the wound.

28. An apparatus according to claim **27** in which the duration of said application period is about 5 minutes.

29. An apparatus according to claim **28** in which the duration of said non-application period is about 5 minutes.

30. An apparatus according to claim **23**, in which said screen means comprises an open-cell polymer foam.

31. An apparatus according to claim **24**, in which said screen means comprises a flat, porous, semi-rigid member.

32. An apparatus according to claim **27**, in which said sealing means includes a flexible sealing rim in contact with said skin surrounding said wound.

33. An apparatus according to claim **27**, in which said sealing means includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin.

34. An apparatus according to claim **27**, in which said sealing means includes a sealing cuff in contact with said skin surrounding the wound.

35. An apparatus according to claim **34**, in which said sealing cuff is inflatable.

36. An apparatus according to claim **27**, in which said vacuum means includes pump means for providing at least 0.1 pounds suction.

37. An apparatus according to claim **27**, in which said vacuum means includes a pump means for providing at least 3 pounds suction.

38. An apparatus according to claim **27**, in which said vacuum means includes a pump means for providing at least 14 pounds suction.

39. An apparatus for facilitating the healing of wounds, comprising:

vacuum means for creating a negative pressure on the area of skin including and surrounding the wound;

sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound, wherein said sealing means comprises a fluid-impermeable cover; and

screen means for positioning at the wound within the sealing means for preventing the overgrowth of tissue in the wound.

40. An apparatus according to claim **39**, in which said screen means comprises an open-cell polymer foam.

41. An apparatus according to claim **39**, in which said screen means comprises a flat, porous, semi-rigid member.

42. An apparatus according to claim **39**, in which said sealing means includes a flexible sealing rim in contact with said skin surrounding said wound.

43. An apparatus according to claim **39**, in which said cover includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin.

44. An apparatus according to claim **39**, in which said sealing means includes a sealing cuff in contact with said skin surrounding the wound.

45. An apparatus according to claim **44**, in which said sealing cuff is inflatable.

46. An apparatus according to claim **39**, in which said vacuum means includes pump means for providing at least 0.1 pounds suction.

47. An apparatus according to claim **39**, in which said vacuum means includes a pump means for providing at least 3 pounds suction.

48. An apparatus according to claim **39**, in which said vacuum means includes a pump means for providing at least 14 pounds suction.

49. An apparatus according to claim **39**, in which said vacuum means operates continuously.

50. An apparatus according to claim **39**, in which said vacuum means operates cyclically to provide periods of application and non-application of suction.

51. An apparatus according to claim **50** in which said vacuum means provides periods of application and non-application of suction with the ratio of duration of application period to non-application period between about 1:10 and 10:1.

52. An apparatus according to claim **51** in which the duration of said application period is about 5 minutes.

53. An apparatus according to claim **52** in which the duration of said non-application period is about 5 minutes.

54. An apparatus for facilitating the healing of wounds, comprising:

vacuum means for creating a negative pressure on the area of skin including and surrounding the wound;

sealing means operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound; and

screen means for positioning at the wound within the sealing means, said screen means having a pore size sufficiently large to prevent the overgrowth of tissue in the wound.

55. An apparatus according to claim 54, in which said screen means comprises an open-cell polymer foam.

56. An apparatus according to claim 54, in which said screen means comprises a flat, porous, semi-rigid member.

57. An apparatus according to claim 54, in which said sealing means includes a flexible sealing rim in contact with said skin surrounding said wound.

58. An apparatus according to claim 54, in which said cover includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin.

59. An apparatus according to claim 54, in which said sealing means includes a sealing cuff in contact with said skin surrounding the wound.

60. An apparatus according to claim 59, in which said sealing cuff is inflatable.

61. An apparatus according to claim 54, in which said vacuum means includes pump means for providing at least 0.1 pounds suction.

62. An apparatus according to claim 54, in which said vacuum means includes a pump means for providing at least 3 pounds suction.

63. An apparatus according to claim 54, in which said vacuum means includes a pump means for providing at least 14 pounds suction.

64. An apparatus according to claim 54, in which said vacuum means operates continuously.

65. An apparatus according to claim 54, in which said vacuum means operates cyclically to provide periods of application and non-application of suction.

66. An apparatus according to claim 65, in which said vacuum means operates cyclically to provide periods of application and non-application of suction with the ratio of duration of application period to non-application period between about 1:10 and 10:1.

67. An apparatus according to claim 66 in which the duration of said application period is about 5 minutes.

68. An apparatus according to claim 67 in which the duration of said non-application period is about 5 minutes.

69. An apparatus for treating a wound comprising:

an open-cell foam section configured to overlie the wound;

a cover overlying said foam section, said cover adapted to form a seal with skin surrounding the wound for maintaining a negative pressure beneath said cover;

a single tubular member having a first end inserted beneath at least a portion of the foam section and having a second end extending from beneath said cover to a location external to said cover; and

a vacuum source connected with the second end of the tubular member for supplying said negative pressure between about 0.1 and 0.99 atmospheres to the wound.

70. An apparatus according to claim 69 wherein said vacuum source supplies a negative pressure between about 0.3 and 0.99 atmospheres to the wound.

71. An apparatus according to claim 69 wherein said vacuum source supplies a negative pressure between about 0.5 and 0.99 atmospheres to the wound.

72. An apparatus according to claim 69 wherein said vacuum source supplies a negative pressure between about 0.5 and 0.8 atmospheres to the wound.

73. An apparatus according to claim 69 wherein said open-cell foam section is configured to overlie only a region of said wound within the margin of said wound.

74. An apparatus according to claim 69 wherein said first end of the tubular member is embedded within the foam section.

75. An apparatus for treating a wound comprising:

an open-cell foam section configured to overlie the wound, said foam section having a pore size sufficiently large to prevent overgrowth of the wound;

a cover overlying said foam section, said cover adapted to form a seal with skin surrounding the wound for maintaining a negative pressure beneath said cover; and

a single tubular member having a first end inserted beneath at least a portion of the foam section and having a second end extending from beneath said cover to a location external to said cover for supplying said negative pressure beneath the cover.

76. An apparatus according to claim 75 wherein said open-cell foam section is configured to overlie only a region of said wound within the margin of said wound.

77. An apparatus according to claim 75 wherein said first end of the tubular member is embedded within the foam section.

78. An apparatus for treating a wound comprising:

an open-cell foam section configured to overlie the wound;

a cover overlying said foam section, said cover adapted to form a seal with skin surrounding the wound for maintaining a negative pressure beneath said cover;

a single tubular member having a first end inserted beneath at least a portion of the foam section and having a second end extending from beneath said cover to a location external to said cover; and

a vacuum source for supplying a negative pressure on the area of skin including and surrounding the wound, wherein said vacuum source operates cyclically to provide periods of application and non-application of suction with the ratio of duration of application period to non-application period between about 1:10 and 10:1.

79. An apparatus according to claim 78 in which the duration of said application period is about 5 minutes.

80. An apparatus according to claim 79 in which the duration of said non-application period is about 5 minutes.

81. An apparatus according to claim 78 wherein said open-cell foam section is configured to overlie only a region of said wound within the margin of said wound.

82. An apparatus according to claim 78 wherein said first end of the tubular member is embedded within the foam section.

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