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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DR. SHAUN L.W. SAMUELS,

Plaintiff,

v.

TRIVASCULAR, INC.,

Defendant.

Case No. C 05

COMPLAINT FOR THREATENED AND ACTUAL PATENT INFRINGEMENT, MISAPPROPRIATION OF TRADE SECRETS, UNFAIR COMPETITION, BREACH OF FIDUCIARY DUTY AND UNJUST ENRICHMENT

DEMAND FOR JURY TRIAL

Plaintiff Dr. Shaun L.W. Samuels ("Dr. Samuels") for his Complaint against Defendant TriVascular, Inc. ("TriVascular"), alleges as follows:

NATURE OF THE ACTION

1. In this Complaint, Plaintiff Dr. Samuels seeks injunctive relief and monetary damages against Defendant TriVascular for their threatened and actual infringement of Dr. Samuels' patent rights in inflatable intraluminal stents, and their misappropriation of Dr. Samuels' trade secrets in such technology, unfair competition and unjust enrichment.

JURISDICTION AND VENUE

2. This action arises under the United States patent laws, 35 U.S.C. §§271 and 281-285.

3. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331, 1338(a), and 2201-2202.

4. Venue is proper in this district under 28 U.S.C. §§1391(b) and (c) and 1400(b).

INTRADISTRICT ASSIGNMENT

5. This is an Intellectual Property Action assigned on a district-wide basis pursuant to Civil L.R. 3-2(c).

PARTIES

6. Plaintiff Dr. Samuels is a doctor of medicine currently residing at 1111 Brickell Bay Drive, Apt. 611, Miami, Florida 33131.

7. Based on information and belief, Defendant TriVascular is a corporation organized under the laws of the State of California and has a principal place of business located at 3660 North Laughlin Road, Santa Rosa, California 95403.

ALLEGATIONS OF FACT

I. DR. SAMUELS' PROPRIETARY INFLATABLE INTRALUMINAL STENT TECHNOLOGY

8. Plaintiff Dr. Samuels is an active investigator and inventor in the field of interventional radiology. He currently holds six (6) patents issued by the United States Patent and Trademark Office related to medical devices that incorporate proprietary expandable cuff technology. Two of Dr. Samuels' patents specifically address the development of stent grafts designed to repair abdominal aortic aneurysms ("AAA"), a weakening and swelling of the abdominal section of the body's largest artery.

9. An untreated AAA has a mortality rate of more than 50% if left untreated. With about one out of every 250 persons over the age of 50 dying of such aneurysms, rupture of an AAA is a leading cause of death in the United States.

10. Angioplasty balloons and stents are two of the most successful devices used to enable therapeutic interventions to treat AAA. Both start out with low profiles, are introduced via minimally invasive procedures, and are expanded at the site where therapy is required; however, there are key differences when the two devices are used.

11. The inflated angioplasty balloon remains integral to a catheter and exerts significant force against the walls in which it is contained. The balloon is a solid structure when inflated, and does not allow passage of blood, for example, beyond it. A deployed metallic stent, on the other hand, is a rigid, implantable object used to open blockages in blood vessels.

12. Plaintiff Dr. Samuels is the inventor of a new inflatable intraluminal stent that combines into a single device the features of an angioplasty balloon's radial force with the stent's ability to affix to the inner wall of a vessel while providing access through a central lumen.

II. DR. SAMUELS' '575 PATENT

13. Plaintiff Dr. Samuels' new inflatable intraluminal stent is the subject of United States Patent No. 6,007,575, entitled "Inflatable Intraluminal Stent And Method For Affixing Same Within The Human Body," which was duly and legally issued from the United States Patent and Trademark Office on December 28, 1999 naming Dr. Samuels as the sole inventor (hereinafter "the '575 patent"). A copy of the '575 patent is attached as Exhibit A.

14. Plaintiff Dr. Samuels is the lawful owner of all right, title and interest in and to the '575 patent, including the right to sue and to recover for past infringement thereof.

III. DEFENDANT TRIVASCULAR'S THEFT OF DR. SAMUEL'S TRADE SECRETS

15. Based on information and belief, Defendant TriVascular is currently manufacturing a AAA stent known as the Enovus™ AAA stent and that device is undergoing clinical trials in the United States.

16. Based on information and belief, Defendant TriVascular misappropriated Plaintiff Dr. Samuels' trade secrets and used those trade secrets to develop TriVascular's Enovus™ AAA stent.

17. In November 1997, Plaintiff Dr. Samuels, with his business partner, Peter Yorke, drafted a business plan for their proposed new company, EndoVention. The business plan included Dr. Samuels' plans for the development and commercialization of an AAA stent. Dr. Samuels distributed copies of the business plan in confidence to only those people who were approached with regard to establishing a partnership or seeking capital to fund the partnership.

18. In early December 1997, Plaintiff Dr. Samuels met with Dr. Michael D. Dake, one of his partners in Interventional Radiology at Stanford University, and specifically discussed the inflatable cuff portion of the business plan for the proposed EndoVention company which was the first of many subsequent meetings on the proprietary AAA stent designs of the proposed EndoVention company.

19. During these meetings, Plaintiff Dr. Samuels disclosed in confidence to Dr. Dake the inflatable intraluminal stent technology disclosed in his pending patent application that later issued as the '575 patent.

20. At a meeting with Plaintiff Dr. Samuels and Peter Yorke, Dr. Dake agreed to serve on the Scientific Advisory Board ("SAB") of the proposed EndoVention company.

21. Subsequent to his appointment to the SAB of the proposed EndoVention company, Dr. Dake was asked by Plaintiff Dr. Samuels on several occasions if he was considering becoming

an SAB member (or serving as an advisor in any capacity) to Triad Vascular, the predecessor to Defendant TriVascular. Dr. Dake repeatedly stated that he had no intention of joining TriVascular's SAB and was not serving as an advisor/consultant to TriVascular.

22. Plaintiff Dr. Samuels further explained to Dr. Dake that serving as a consultant to a competing start-up developing an AAA device would result in a conflict of interest and be damaging to the proposed EndoVention company both in terms of maintaining trade secrets and causing confusion with potential investors. Dr. Dake acknowledged and agreed that it would be improper to serve on the Scientific Advisory Boards of both companies and stated that he would not assist Defendant TriVascular.

23. Having received Dr. Dake's repeated assurances, Plaintiff Dr. Samuels continued to provide confidential information to Dr. Dake in his capacity as a member of the SAB of the proposed EndoVention company.

24. Despite his repeated pledges not to do so, Dr. Dake did join Defendant TriVascular's SAB. Dr. Dake did not promptly or directly notify Plaintiff Dr. Samuels that he had joined a competitor's SAB. In fact, Dr. Dake never advised Dr. Samuels that he had joined TriVascular's SAB. Dr. Dake's agreement to join TriVascular's SAB was only revealed to Dr. Samuels through a conversation with a third party.

25. By simultaneously serving on the Scientific Advisory Boards for the proposed EndoVention company and Defendant TriVascular, Dr. Dake was in a unique position to advise TriVascular as to Plaintiff Dr. Samuels' trade secrets.

26. Based on information and belief, Defendant TriVascular knew or should have known that Dr. Dake was a member of the SAB of the proposed EndoVention company when it retained Dr. Dake to serve on TriVascular's SAB and that his appointment would inevitably lead to the misappropriation of Plaintiff Dr. Samuels' trade secrets.

27. Based on information and belief, Plaintiff Dr. Samuels believes that Defendant TriVascular's President and CEO, Dr. Michael Chobotov, and other employees of TriVascular improperly learned of Dr. Samuels' proprietary inflatable intraluminal stent technology directly or indirectly through Dr. Dake.

28. Based on information and belief, after learning of Plaintiff Dr. Samuels' stent technology, Dr. Chobotov, then applied for and obtained U.S. Patent No. 6,395,019B2 which incorporates technology stolen from Dr. Samuels.

29. Based on information and belief, Dr. Chobotov has assigned the right to his patent incorporating Dr. Samuels' proprietary technology to Defendant TriVascular.

30. Based on information and belief, Defendant TriVascular subsequently developed the Enovus™ AAA stent using the same proprietary technology described and claimed in Dr. Samuels' patent application that later issued as the '575 patent.

31. Based on information and belief, Defendant TriVascular has filed an application with the United States Food and Drug Administration ("FDA") seeking approval to market its Enovus™ AAA stent and has represented in public disclosures that FDA approval of its application is imminent.

32. Based on information and belief, Defendant TriVascular has undertaken substantial activities to commercialize its Enovus™ AAA stent by expanding its manufacturing workforce and facilities.

33. Based on information and belief, Defendant TriVascular has partnered with Boston Scientific Corporation for the purpose of facilitating the international commercialization of the Enovus™ AAA stent.

34. Based on information and belief, Defendant TriVascular has undertaken various activities, including clinical trials, of its Enovus™ AAA stent for the purpose of obtaining approval to market that product in Europe.

35. Based on information and belief, Defendant TriVascular has already earned revenues in the United States, prior to obtaining pre-market approval status from regulatory agencies for the Enovus™ AAA stent, by charging prices higher than that necessary to recover its cost. TriVascular's President and CEO, Dr. Michael Chobotov, was quoted by the North Bay Business Journal as stating "The revenue initially will not be significant, but we have a unique strategy to improve them." A copy of the North Bay Business Journal article is attached as Exhibit B.

36. Defendant TriVascular's misappropriation of Plaintiff Dr. Samuels' proprietary trade secrets has hindered Dr. Samuels' ability to raise financing from venture capital sources. In particular, Dr. Samuels has been unable to obtain funding from venture capital groups who chose to finance the development of TriVascular's Enovus™ AAA stent design rather than Dr. Samuels' AAA stent design -- not knowing that the TriVascular Enovus™ AAA stent had been developed based on the trade secrets misappropriated from Dr. Samuels.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(Threatened Infringement Of The '575 Patent)

37. Plaintiff Dr. Samuels hereby incorporates the allegations set forth in Paragraphs 8 through 36 above as if fully set forth herein.

38. Based on information and belief, Defendant TriVascular has undertaken substantial activities directed toward engaging in infringement, contributory infringement and active inducement of infringement of the '575 patent by making, using and undertaking substantial preparations for offering to sell, without authority from Plaintiff Dr. Samuels, the Enovus™ AAA stent, whose device is covered by one or more claims of the '575 patent.

39. Based on information and belief, Defendant TriVascular is aware of the existence of the '575 patent, but nevertheless has engaged in substantial activities directed toward infringing, contributorily infringing and actively inducing infringement of the '575 patent. The substantial activities engaged in by Defendant TriVascular toward infringement, contributory infringement and active inducement of infringement of the '575 patent have been willful and deliberate and in total disregard for Plaintiff Dr. Samuels' lawful rights under the '575 patent, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. §285.

40. The substantial activities engaged in by Defendant TriVascular directed toward infringement, contributory infringement and active inducement of infringement as set forth above demonstrate the existence of an actual and justiciable controversy, and if allowed to continue and progress, will inevitably constitute infringement, contributory infringement and active inducement of infringement of the '575 patent, will cause Plaintiff Dr. Samuels irreparable harm, including irreparable harm within the State of California and this Judicial District, for which he has no adequate remedy at law, and will continue unless preliminarily and permanently enjoined by this Court.

SECOND CLAIM FOR RELIEF
(Infringement Of The '575 Patent)

41. Plaintiff Dr. Samuels hereby incorporates the allegations set forth in Paragraphs 8 through 36 above as if fully set forth herein.

42. Based on information and belief, based on the acts of Defendant TriVascular set forth above which are not exempt under 35 U.S.C. §271(e)(1), TriVascular has been and is now infringing, contributorily infringing and actively inducing others to infringe the '575 patent by

making, using, offering to sell or selling, without authority from Plaintiff Dr. Samuels, the Enovus™ AAA stent, whose device is covered by one or more claims of the '575 patent.

43. Based on information and belief, Defendant TriVascular is aware of the existence of the '575 patent, but nevertheless has been and is now infringing, contributorily infringing and actively inducing infringement of the '575 patent. The infringement, contributory infringement and active inducement of infringement of the '575 patent by Defendant TriVascular has been willful and deliberate and in total disregard for Plaintiff Dr. Samuels' lawful rights under the '575 patent, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. §285.

44. The acts of infringement, contributory infringement and active inducement of infringement by Defendant TriVascular set forth above have damaged Plaintiff Dr. Samuels, will continue to cause Plaintiff irreparable harm for which he has no adequate remedy at law, including damage and irreparable harm within the State of California and this Judicial District, and will continue unless preliminarily and permanently enjoined by this Court.

THIRD CLAIM FOR RELIEF
(Misappropriation Of Trade Secrets (Cal. Civ. Code §3426))

45. Plaintiff Dr. Samuels hereby incorporates the allegations set forth in Paragraphs 8 through 36 above as if fully set forth herein.

46. The information misappropriated from Plaintiff Dr. Samuels consisted of confidential, proprietary and trade secret information that Dr. Samuels had incorporated into his inflatable intraluminal stent, including technical features such as stent design, function and/or methods of use.

47. The technology developed by Plaintiff Dr. Samuels was confidential and a trade secret at the time in that the technology was not generally known or readily ascertainable through proper means and had independent economic value due to its novel technical features.

48. Plaintiff Dr. Samuels exercised reasonable care under the circumstances to maintain his technology as a trade secret.

49. Based on information and belief, Defendant TriVascular knew, or had reason to know, that the information it received concerning Dr. Samuels' inflatable intraluminal stent technology was confidential, trade secret information belonging to and misappropriated from Plaintiff Dr. Samuels.

50. As a direct and proximate result of Defendant TriVascular's misappropriation of Plaintiff Dr. Samuels' trade secret technology, Dr. Samuels has suffered and will continue to suffer damages.

51. Plaintiff Dr. Samuels is entitled to actual damages and unjust enrichment damages caused by Defendant TriVascular's misappropriation pursuant to Section 3426.3 of the California Business and Professions Code.

52. Plaintiff Dr. Samuels is also entitled to exemplary damages for Defendant TriVascular's willful and malicious misappropriation pursuant to Section 3426.3 of the California Business and Professions Code.

53. Plaintiff Dr. Samuels is further entitled to an injunction against Defendant TriVascular in order to eliminate commercial advantage, including such advantage obtained from financing, sale of business and/or sale of intellectual property rights, that otherwise would be derived from the misappropriation pursuant to Section 3426.2 of the California Business and Professions Code.

FOURTH CLAIM FOR RELIEF
(Unfair Competition/Unfair Business Practices (Cal. Civ. Code §17200 *et seq.*))

54. Plaintiff Dr. Samuels hereby incorporates the allegations set forth in Paragraphs 8 through 36 above as if fully set forth herein.

55. Defendant TriVascular, by the acts alleged herein, has engaged in unfair, unlawful and fraudulent business practices in violation of Section 17200 *et seq.* of the California Business and Professions Code.

56. Plaintiff Dr. Samuels is entitled to preliminary and injunctive relief and restitution of all benefits received by Defendant TriVascular as a result of this unlawful conduct, pursuant to Section 17203 of the California Business and Professions Code.

57. Plaintiff Dr. Samuels is further entitled to reasonable attorneys' fees and costs of suit.

FIFTH CLAIM FOR RELIEF
(Unjust Enrichment)

58. Plaintiff Dr. Samuels hereby incorporates the allegations set forth in Paragraphs 8 through 36 above as if fully set forth herein.

59. Defendant TriVascular improperly obtained confidential and trade secret information belonging to Plaintiff Dr. Samuels. As a result, Defendant TriVascular improperly obtained the

ability to develop, test, patent or otherwise derive value from inflatable intraluminal stent technology owned by Dr. Samuels.

60. Defendant TriVascular improperly incorporated misappropriated technology into the TriVascular Enovus™ AAA stent, thereby depriving Plaintiff Dr. Samuels of the opportunity to obtain funding from investors who chose to finance the development of the TriVascular Enovus™ AAA stent design rather than Dr. Samuels' AAA stent design -- not knowing that the TriVascular Enovus™ AAA stent had been developed based on trade secrets misappropriated from Dr. Samuels.

61. Defendant TriVascular has improperly obtained significant commercial value from the Enovus™ AAA stent.

62. The circumstances as described herein are such that it is inequitable for Defendant TriVascular to retain the value of Plaintiff Dr. Samuels' confidential and trade secret information and yet fail to compensate Dr. Samuels for his contribution.

RELIEF REQUESTED

WHEREFORE, Plaintiff Dr. Samuels prays for judgment as follows:

A. Adjudging that the '575 patent is valid and enforceable;

B. Declaring that the manufacture, use and substantial preparations for offering for sale of Defendant TriVascular's Enovus™ AAA stent, as complained of in the First Claim For Relief, if allowed to continue and progress, will constitute infringement, contributory infringement and active inducement of infringement of the '575 patent;

C. Alternatively, adjudging that Defendant TriVascular has infringed, contributorily infringed and actively induced others to infringe the '575 patent and that such infringement, contributory infringement and active inducement of infringement have been willful and deliberate;

D. Preliminarily and permanently enjoining Defendant TriVascular, their officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation or in privity with them, and their successors and assigns, from infringing, contributorily infringing or inducing others to infringe the '575 patent;

E. Preliminarily and permanently enjoining Defendant TriVascular, their officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation or in privity with them, and their successors and assigns, in order to eliminate commercial advantage, including such advantage

obtained from financing, sale of business and/or sale of intellectual property rights, that otherwise would be derived from their misappropriation;

F. Awarding Plaintiff Dr. Samuels all damages as described in the claims for relief above;

G. Awarding Plaintiff Dr. Samuels his costs as provided by 35 U.S.C. §284;

H. Declaring this an exceptional case and awarding Plaintiff Dr. Samuels attorneys' fees as provided by 35 U.S.C. §285; and

I. Awarding Plaintiff Dr. Samuels such fees and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Dr. Samuels demands a trial by jury of all issues properly triable to a jury in this case.

Dated: April 8, 2005

Respectfully submitted,

By: 

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Attorneys for Plaintiff
Dr. Shaun L.W. Samuels

Exhibit A

US006007575A

United States Patent [19]

Samuels

[11] Patent Number: 6,007,575

[45] Date of Patent: Dec. 28, 1999

[54] INFLATABLE INTRALUMINAL STENT AND METHOD FOR AFFIXING SAME WITHIN THE HUMAN BODY

[76] Inventor: Shaun Laurence Wilkie Samuels, 1055 Sonoma Ave., Menlo Park, Calif. 94025

[21] Appl. No.: 08/870,745

[22] Filed: Jun. 6, 1997

[51] Int. Cl.[6] A61F 2/02; A61F 2/04; A61F 2/06; A61M 39/00

[52] U.S. Cl. 623/1; 623/11; 623/12; 606/192; 606/194; 606/195; 606/198

[58] Field of Search 623/1, 12, 11; 606/192, 194, 195, 198

[56] References Cited

U.S. PATENT DOCUMENTS

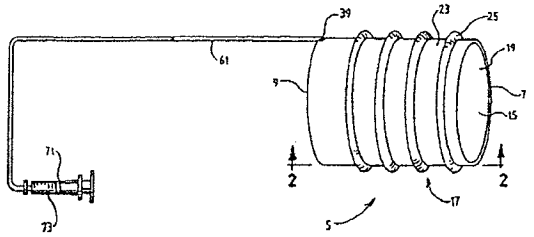
5,156,620	10/1992	Pigott	623/1
5,370,691	12/1994	Samson	623/12
5,494,029	2/1996	Lane et al.	128/207.15
5,554,180	9/1996	Turk	623/1
5,554,185	9/1996	Block et al.	623/2
5,649,978	7/1997	Samson	623/12

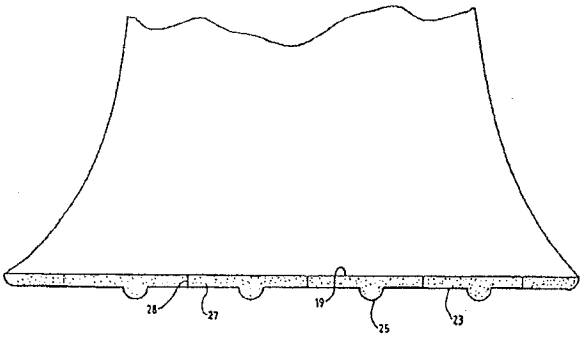
Primary Examiner—Paul B. Prebilic
Assistant Examiner—Choon P. Koh
Attorney, Agent, or Firm—Rudnick & Wolfe

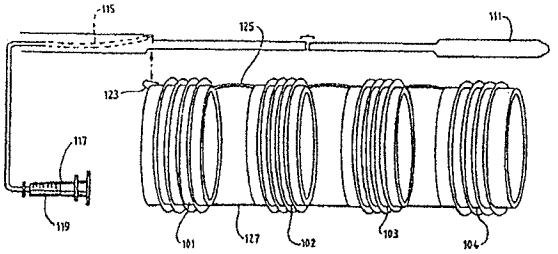
[57] ABSTRACT

An inflatable intraluminal stent for attachment to the interior surface of a tubular structure within the human body is disclosed. The stent features a cuff having an inflatable chamber and a friction-enhancing outer surface. The friction-enhancing outer surface engages the interior surface of the tubular structure without penetration when the inflatable cuff is in an inflated condition. An intraluminal medical device may be attached to the inner surface of the stent. A valve is integral with the inflatable cuff and allows for the inflation, deflation and sealing of the inflatable cuff.

24 Claims, 10 Drawing Sheets







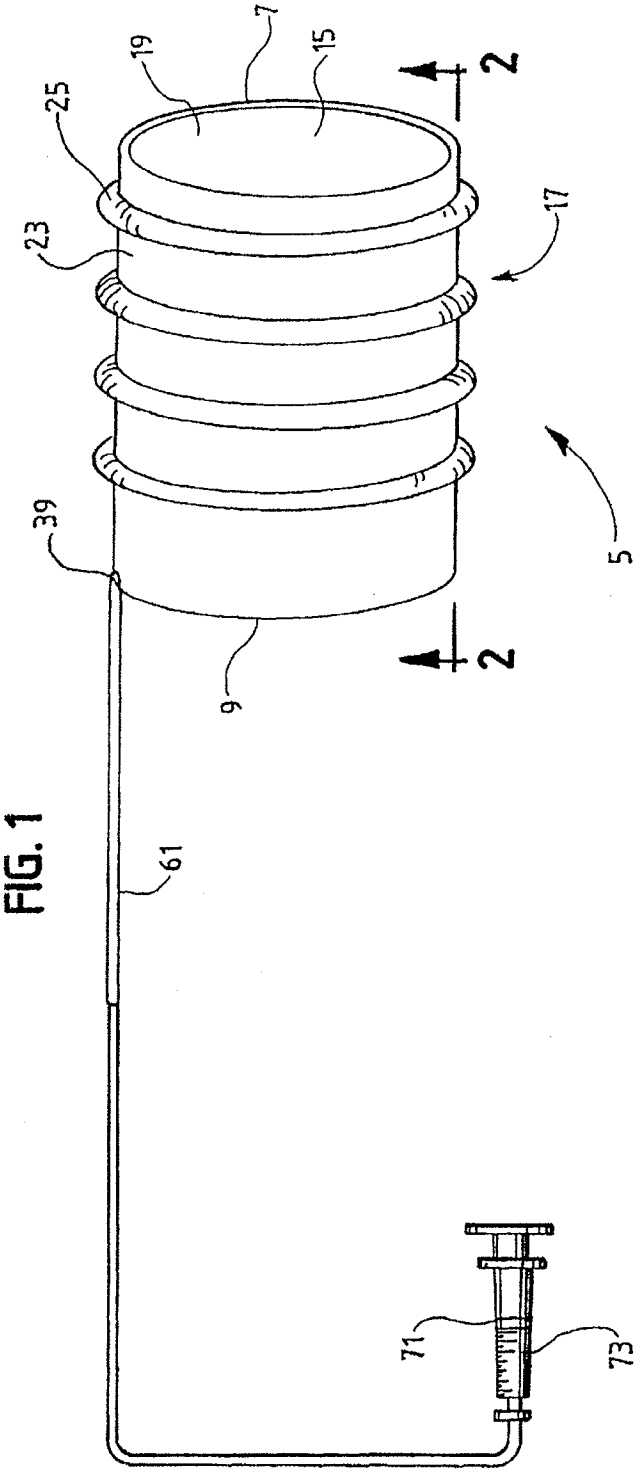


FIG. 1

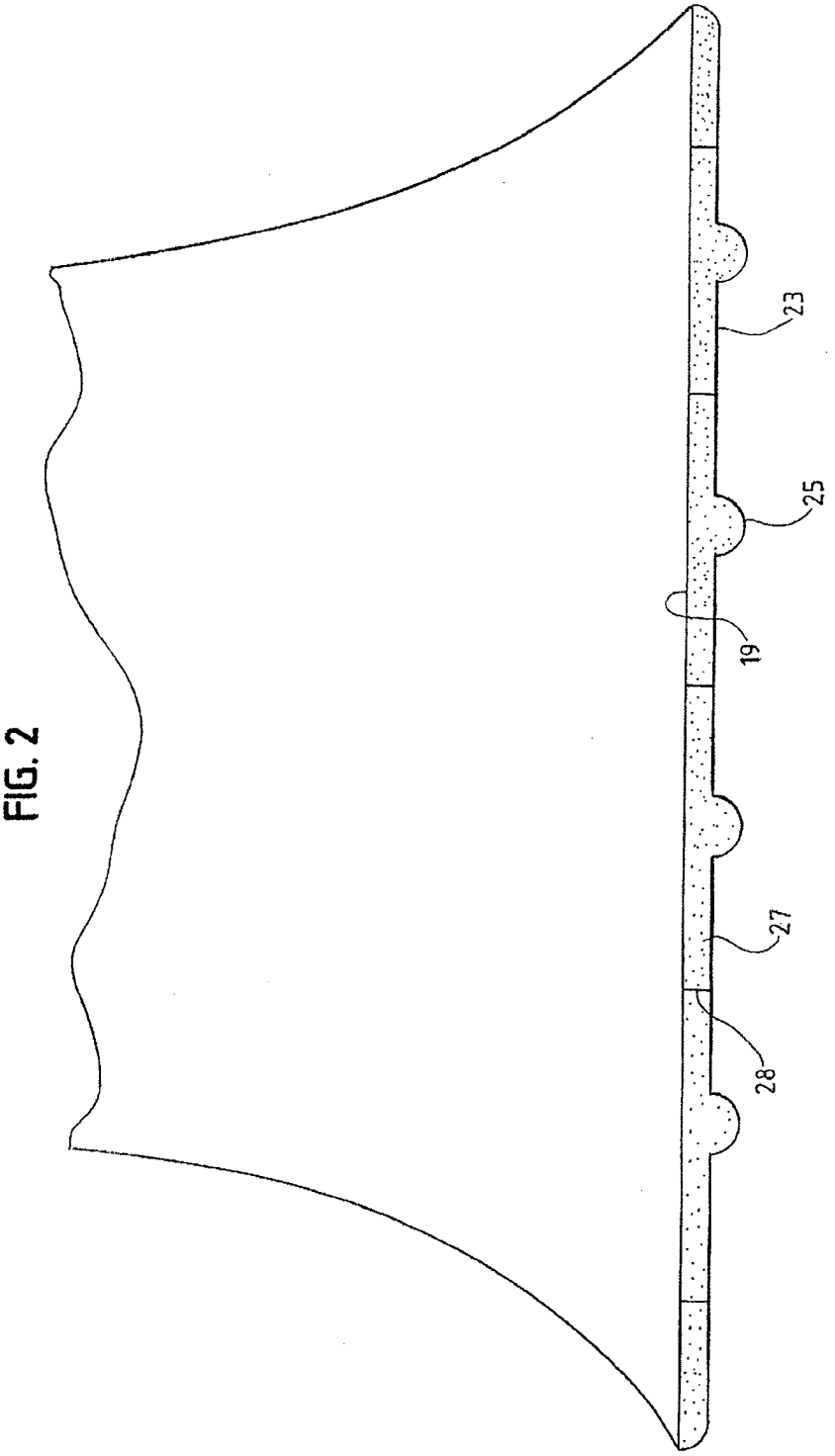


FIG. 2

FIG. 4a

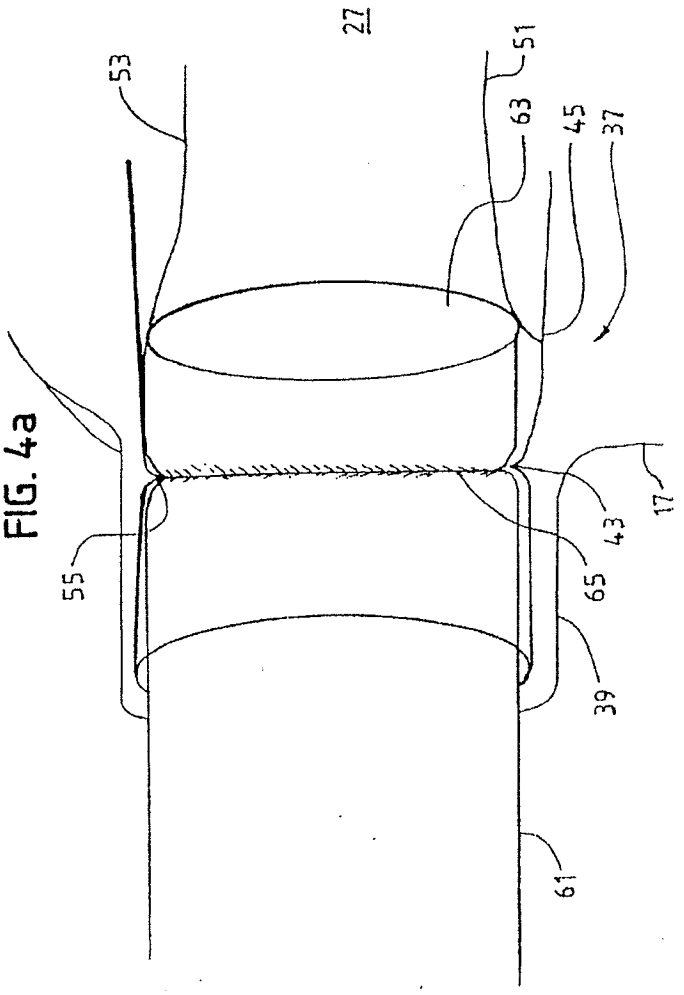
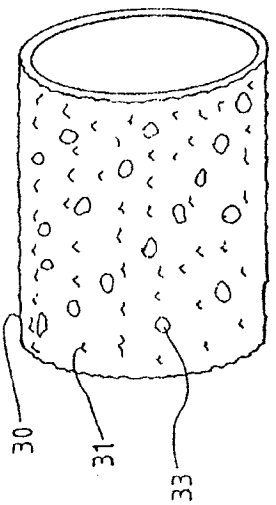


FIG. 3



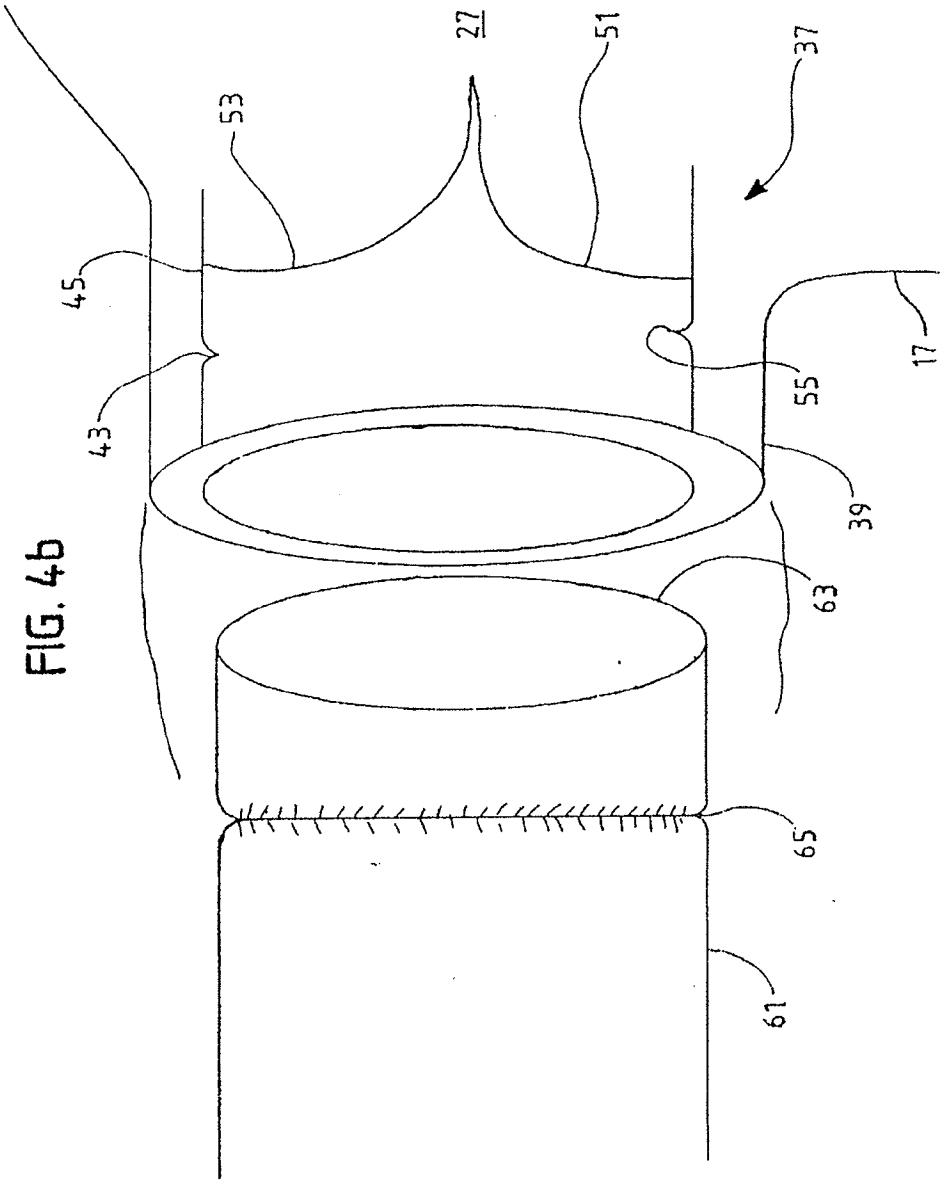


FIG. 4b

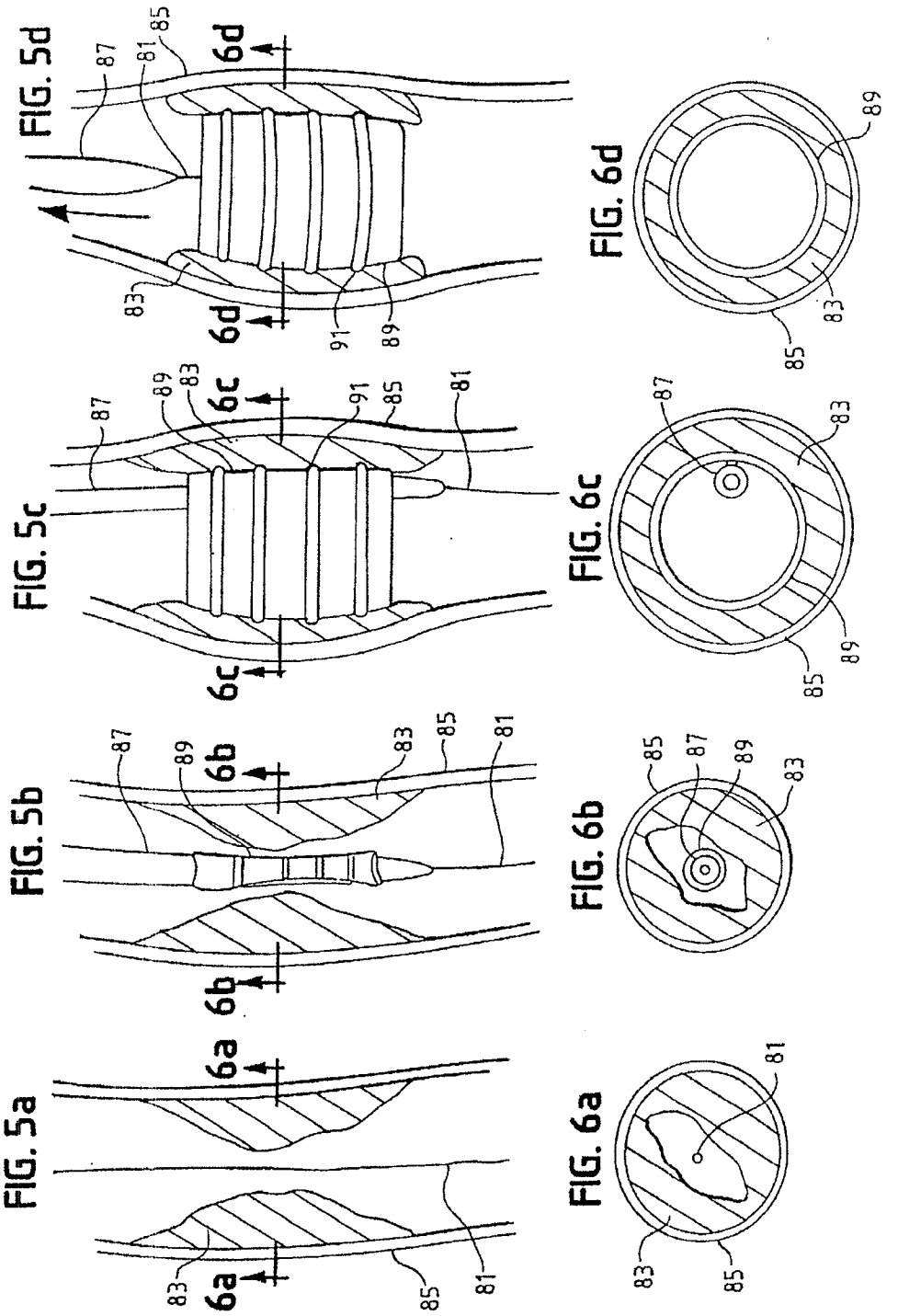


FIG. 5d
FIG. 6d
FIG. 5c
FIG. 6c
FIG. 5b
FIG. 6b
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FIG. 6a
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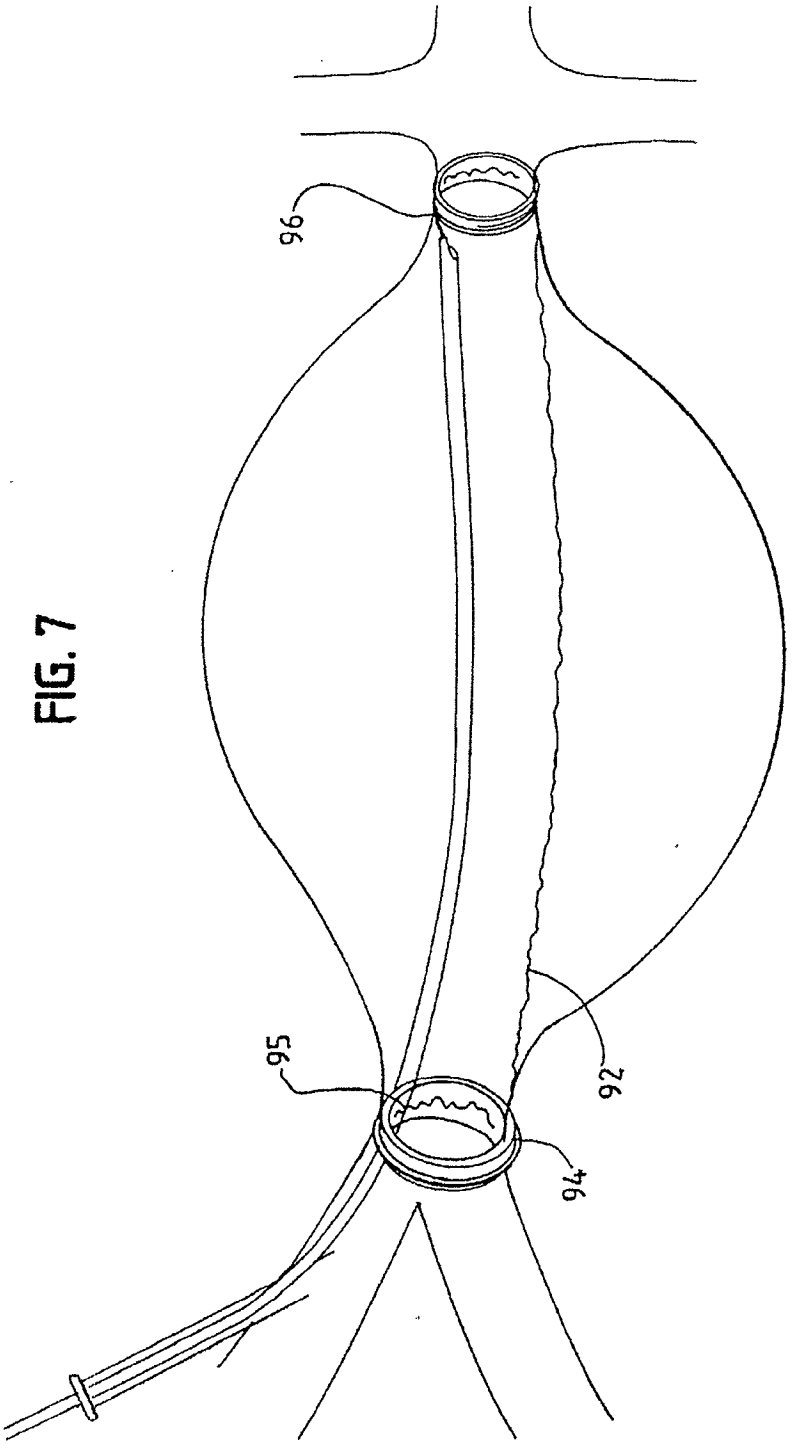

FIG. 7

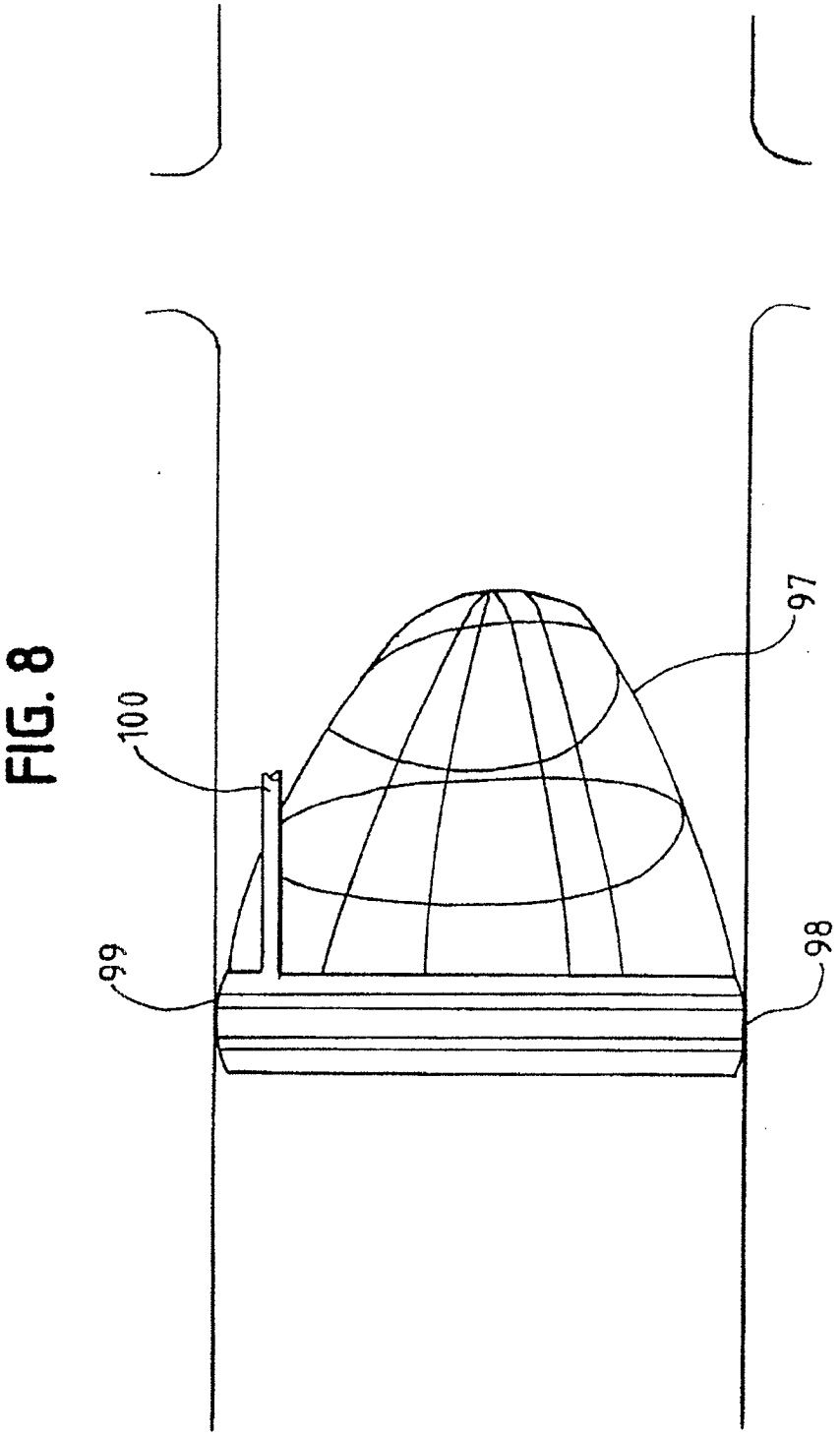

FIG. 8

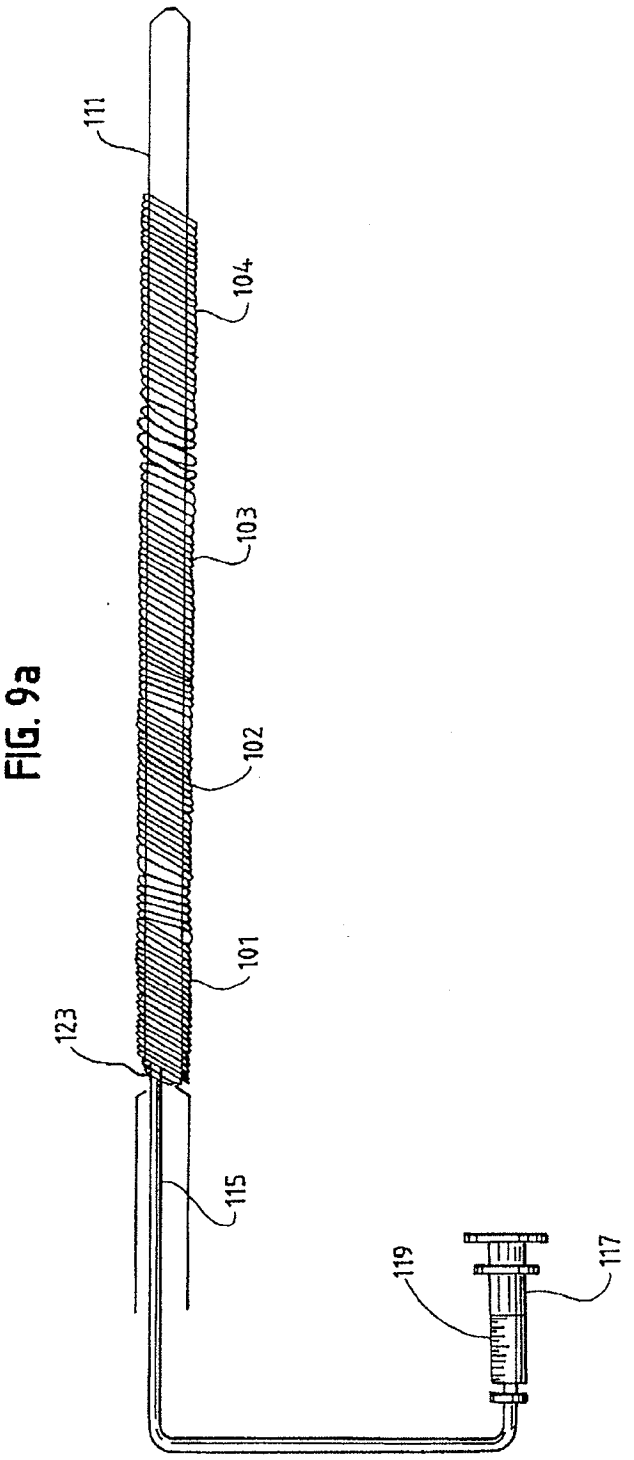

FIG. 9a

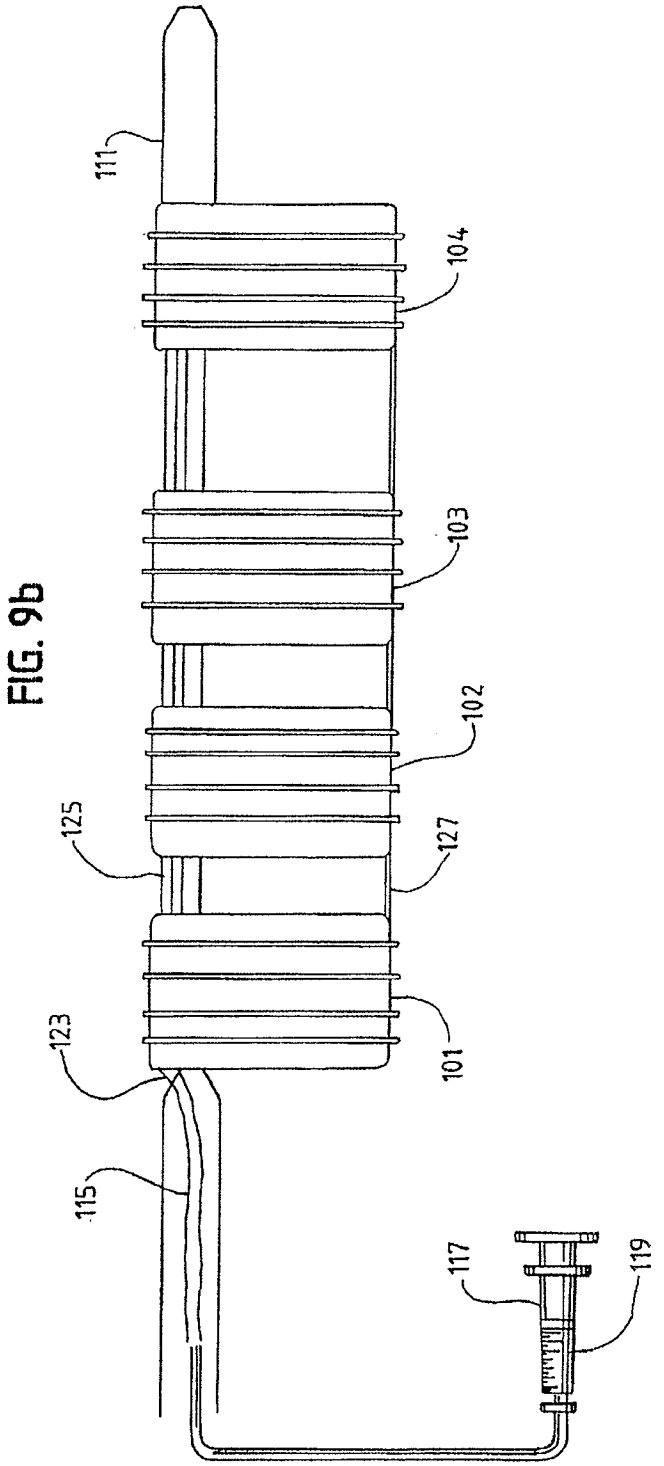

FIG. 9b

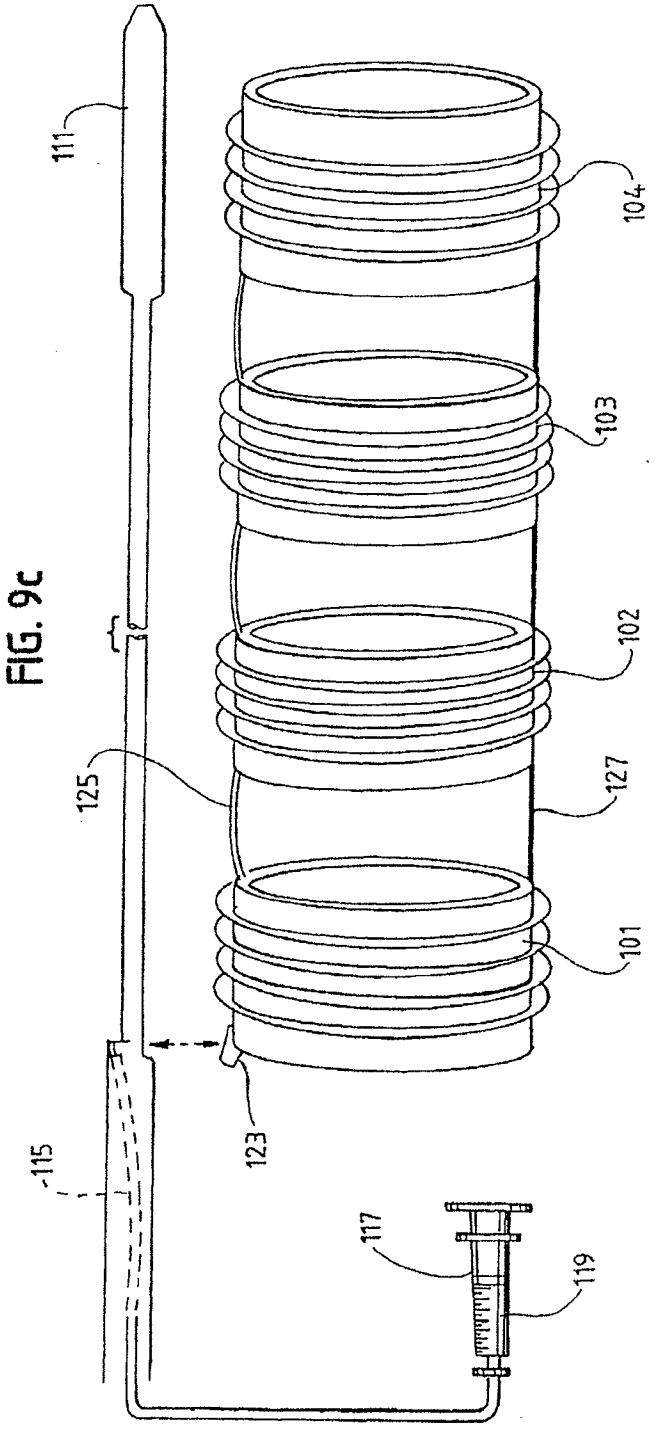

FIG. 9c

INFLATABLE INTRALUMINAL STENT AND METHOD FOR AFFIXING SAME WITHIN THE HUMAN BODY

BACKGROUND

Various tubular structures within the human body, such as the biliary duct system, excretory system and vascular system, may deteriorate so that medical repair is necessary. For example, weaknesses in the walls of the tubular structures or deteriorative diseases may affect the ability of the tubular structures to conduct fluids and, in turn, may be life threatening. Surgical and interventional radiological techniques have been a primary means of providing treatment for such problems. Such surgical and interventional radiological techniques involve inserting a catheter and other medical devices into the tubular structures through an incision in the patient's skin.

As an example, degenerative effects on blood vessels may cause a narrowing or constriction of the lumen of the vessel so that blood flow is restricted. Such a condition is known as "stenosis". Treatment of stenosis involves the use a stent to permanently widen the portion of the vessel that is obstructed.

The use of stents in the treatment of stenosis is well known. Stents are tubular bodies having a diameter which may be increased once they are properly positioned within the tubular structure. There are a variety of different stent designs, but by far most are made of metal wire or ribbon. The most widely used method of deploying a stent involves the use of a dilation catheter having an inflatable balloon at its distal end. The stent, its diameter at a minimum, is positioned over the uninflated balloon portion of the dilation catheter. With the aid of fluoroscopy, the physician then positions the catheter and stent at the proper location within the tubular structure. The balloon is then expanded which in turn expands the stent in a radial fashion so that the stent, now having an enlarged diameter, supports the wall of the tubular structure. Next, the balloon is deflated and the catheter is removed. By virtue of its deformable metal construction, the stent remains positioned in tension against, and in support of the tubular structure wall upon removal of the balloon and catheter.

Problems exist with such an arrangement, however, in that the irregular surfaces of most metallic stents are likely to damage the endothelial walls of healthy arteries during delivery. Furthermore, once the stent is positioned, repositioning is difficult if not impossible. To further complicate matters, misplacement of the stent can lead to catastrophic results such as the complete occlusion of the tubular structure. Finally, the stent may ultimately loose its tension against the wall and migrate to an undesired location.

Some stent designs feature anchoring pins, surgical staple-like clips or exposed barbs to secure the stent to the tube walls via penetration of the walls. Damage to the tubular wall may occur when a such device is being positioned within the tube. Furthermore, repositioning of such stents cannot be accomplished without damaging the tube walls.

Due to the above problems, extensive fluoroscopic examination is required to ensure the correct placement of existing stent designs to minimize the risk of misplacement and tissue damage.

Accordingly, it is an objective of the present invention to provide a stent, and a method of placing it, that allows for repositioning of the stent within a tubular structure of the body. It is also an object of the present invention to provide a stent, and a method of placing it, that allows for the stent to be affixed to the tubular structure inner walls in a manner that prevents both damage to the walls and migration of the stent after it has been affixed.

A further problem with existing stent designs is that they do not allow for the stent to be used to secure other medical devices to the tube walls. Many interventional radiology procedures require the insertion of medical devices, other than a stent, into the lumen of the tubular structures of a patient.

As an example, aneurysms may occur in blood vessels having weakened walls. An aneurysm is a ballooning of the wall of an artery. Left untreated, the aneurysm will frequently rupture resulting in a loss of blood through the rupture. Aneurysm repair involves inserting a vascular prosthesis, also known as a graft or stent-graft, into the lumen of the damaged vessel to reconstruct the section that is in need of repair. Such grafts must be anchored within the lumen of the blood vessel at the location of the aneurysm. The utility of a stent would be greatly increased if it could be used for such a purpose.

As such, it is also an object of the present invention to provide a stent that may be utilized to secure other medical devices to the inner walls of the tubular structure.

SUMMARY

The present invention is directed to an inflatable intraluminal stent and a method of among it to the interior surface of a tubular structure within the human body as a means of treating conditions such as stenosis. Intraluminal medical devices may also be attached to the inner surface of the stent. The stent of the present invention features an inflatable cuff having an inner surface, an outer surface, and an inlet and an outlet with a lumen extending therebetween. The outer surface has a friction-enhancing face that engages the interior surface of the tubular structure, without penetrating it, when the inflatable cuff is deployed.

If the initial placement of the stent within the tubular structure is not optimal, it may be deflated, repositioned to the optimal position and reinflated so as to again be affixed to the tubular walls via its outer surface. The tissue of the walls is not damaged or harmed by its exposure to the friction-enhancing face of the stent outer surface.

The stent is inflated with an inflation material that may contain a hardening agent. A valve, which is integral with the stent, allows it to be sealed in an inflated condition after it is placed in the proper position.

A number of the stents may be joined together so as to form a multi-ring stent. Such an arrangement may be used to affix medical devices which require more support due to their length or in situations requiring a stent of a length greater than the length of a single stent.

For a more complete understanding of the nature and scope of the invention, reference may now be had to the following detailed description of embodiments thereof taken in conjunction with the appended claims and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of an embodiment of the stent of the present invention;

FIG. 2 shows a vertical sectional view of the stent of FIG. 1 taken along line 1—1;

FIG. 3 shows a perspective view of another embodiment of the stent of the present invention;

FIGS. 4*a* and 4*b* are enlarged partially broken away perspective views showing the detail of the mitre valve and breakaway valve connections of the stent of FIG. 1 in engaged and disengaged positions, respectively;

FIGS. 5*a* through 5*d* show in cross-section a constricted blood vessel with an elevational view of the stent of FIG. 1 being deployed therein in accordance with the method of the present invention;

FIGS. 6*a* through 6*d* show cross-sectional views corresponding to FIGS. 5*a* through 5*b* taken along line 2—2;

FIG. 7 shows a cross-sectional view of a blood vessel with an aneurysm and a stent-graft utilizing the stent of the present invention;

FIG. 8 shows a cross sectional view of an inferior vena cava with a filter disposed therein via the stent of the present invention;

FIGS. 9*a* through 9*c* show partial section, elevation and perspective views of another embodiment of the stent of the present invention, and the method of deploying the stent in accordance with the present invention, wherein multiple stents of the type of FIG. 1 are connected in a gang arrangement.

DESCRIPTION

Referring to FIG. 1, an embodiment of the inflatable intraluminal stent of the present invention is indicated generally at **5**. The stent **5**, shown in its inflated and deployed configuration, is a hollow cylinder and features an inlet **7**, an outlet **9** and a lumen **15** extending between inlet **7** and outlet **9**. The lumen of the stent is defined by an inflatable cuff; indicated generally at **17**, having an inner surface **19** and an outer surface **23**.

As shown in FIG. 1, outer surface **23** features a number of inflatable ridges **25** disposed about its circumference. While inflatable ridges are shown in the FIGS., any friction-enhancing outer surface, that would secure the inflated stent to the interior wall of a tubular structure without penetrating it, could be used. For example, the surface could feature nubs, bumps, indentations, etc.. As will be shown later, medical device may be secured to inner surface **19** of cuff **17** by way of biologically inert adhesives.

Inflatable cuff **17** is manufactured to the appropriate diameter and width to support or simulate the wall of, or to support a medical device within, the desired tubular structure of the patient. Inflatable cuff **17** is preferably constructed by extrusion and is drawn so as to have a low profile when viewed down the axis of the center of the ring defining cuff **17**. Also, inflatable cuff **17** and its outer surface **23** are preferably composed of a polymeric plastic which is biologically inert. The material of cuff **17** must be able to withstand high inflation pressures and must be of sufficient durability to provide for decades of effective use within the body.

As illustrated in FIG. 2, circumferential ridges **25** are in fluid communication with the inflatable chamber **27** of cuff **17**. Spot welds **28**, positioned incrementally about the circumference and parallel with the longitudinal axis of cuff **17**, prevent distention of the flat portions of the outer surface **23** of cuff **17**.

As an example of an alternative friction-enhancing surface, another embodiment of the stent of the invention is shown in FIG. 3. As illustrated in FIG. **3**, the outer surface **30** of the cuff is made coarse by a combination of raised portions **31** and lowered portions **33**. These surface features allow the inflated stent to grip the interior walls of a tubular structure with a force that is sufficient to prevent its migration.

In addition, it may be desirable in some applications to provide the cuff with an outer surface that promotes tissue ingrowth. This would allow the stent to become more integrated, and thus more firmly affixed, within the tubular structure as time progresses. Such a surface could be provided by combining a friction-enhancing surface, as discussed above, with a surface material such as TEFLON.

The cuff **17** is inflated and deflated by means of a valve, indicated generally at **37** in FIGS. 4*a* and 4*b*, which is integral with inflation port **39** of cuff **17**. Preferably, valve **37** combines a breakaway valve **43** with a "duck bill" or "mitre" valve **45**. Mitre valve **45** features opposing leaflets **51** and **53** which are constructed of a non-elastomeric, biologically inert material. Breakaway valve **43** features a circumferential rim **55** formed upon the interior surface of inflation port **39**. Inflation tubing **61** features mating end **63** and circumferential notch **65**. As shown in FIG. 4*a*, when inflation tubing **61** is in an engaged configuration with valve **37**, mating end **63** separates opposing leaflets **51** and **53** so that cuff **17** may be inflated or deflated. When in this configuration, circumferential notch **65** engages circumferential rim **55** so as to secure inflation tubing **61** within inflation port **39**.

Referring to FIG. 4*b*, once cuff **17** has been inflated (or deflated) to the desired level, a sharp tug on inflation tubing **61** in a direction away from inflation port **39** causes circumferential notch **65** and circumferential rim **55** to disengage. This allows easy withdrawal of mating end **63** from mitre valve **45** and inflation port **39**. Upon withdrawal of the mating end **63** of inflation tubing **61**, as shown in FIG. 3*b*, opposing leaflets **51** and **53** of mitre valve **45** close to seal the inflated cuff **17**.

Referring back to FIG. **1**, cuff **17** is inflated by way of an inflation syringe **71** with an inflation material **73**. The inflation material could be a saline-based fluid or a material that contains a photo-activated or heat-activated hardening agent or any hardening agent that hardens over time. Typically, the inflation syringe **71** is mounted in a screw-feed pressure generating device provided with a manometer in order to accurately gauge inflation pressures. After cuff **17** has been installed and inflated, the material **73** hardens over time to permanently affix stent **5** within the tubular structure of the body via circumferential ridges **25**.

FIGS. 5*a* through 5*d*, and corresponding FIGS. 6*a* through 6*d*, illustrate the steps to be performed in deploying the stent of the present invention in accordance with the method of the present invention. Referring to FIGS. 5*a* and 6*a*, a guide wire **81** is initially fed from outside of the patient's body, through an incision and finally, through the constricted portion **83** of a blood vessel **85**.

Once guide wire **81** is in place, catheter **87**, with stent **89** collapsed over it, is advanced along guide wire **81** so as to become positioned at the constricted portion **83** of blood vessel **85**, as shown in FIGS. 5*b* and 6*b*. Inflation tubing, not shown in this view, is located within catheter **87** and is connected to stent **89** by the valve arrangement described in connection with FIGS. 4*a* and 4*b*. Stent **89** is then inflated using the technique described above. As shown in FIGS. 5*c* and 6*c*, stent **89** is inflated so that the size of the lumen of stent **89** approximates the lumen size of the original, unconstricted blood vessel. By doing so, constricted portion **83** is compressed between blood vessel wall **85** and stent **89**, the latter of which is fixed in place by way of protruding ridges **91**.

A unique feature of the present invention is its capability of being optimally positioned within a tubular structure in

the body (in this case, a blood vessel) without causing damage to the surrounding tissue. Specifically, after stent **89** has been inflated so that ridges **91** affix the stent to the tubular walls without penetration, the position of the stent is examined fluoroscopically to determine if it is optimal. If not, stent **89** may be deflated, repositioned and then reinflated. It is important to note that the tissue of the vessel walls is not damaged by exposure to ridges **91** of the stent.

As the final step of the procedure, as shown in FIGS. *5d* and *6d*, catheter **87** is removed from stent **89** so that the former may be removed from the blood vessel. As discussed in reference to FIGS. *4a* and *4b*, breakaway and mitre valves allow the inflation tubing within catheter **87** to be removed from the stent so that the stent may be sealed in an inflated condition. Finally, guidewire **81** is removed from the blood vessel.

Note that utilization of the stent and method of the present invention for the treatment of stenosis is presented only as an example of its potential applications. A non-exhaustive list of other applications includes: placing filters in the inferior vena cava, use of the stent in the vascular or biliary system to maintain the patency of the respective tubular structures and endoarterial grafts via a percutaneous approach. In order to accommodate some of these applications, as stated earlier, an intraluminal medical device may be attached to the interior surface of the stent of the present invention.

As an illustration, FIG. **7** shows a stent-graft utilizing the stent of the present invention to treat an aneurysm. A graft **92** is held by its end portions to the interior surfaces of stents **94**, shown in an inflated condition, by biologically inert adhesive **95**. The stent-graft is secured to the vessel walls via ridges **96** so that blood passes through graft **92**.

As another example, FIG. **8** shows a filter **97** disposed within the inferior vena cava via the stent of the present invention. Filter **97** is attached to the interior surface of stent **98**. Stent **98**, shown in an inflated condition, is held within the inferior vena cava by ridges **99**. In some applications, it may be desirable to temporarily place filter **98** in the inferior vena cave The stent of the present invention is perfectly suited to such an application in that it can be deflated for retrieval without damaging the interior walls of the inferior vena cava. In such instances, stent **98** is inflated with a saline-based material that does not contain a hardening agent. This allows for easy deflation of stent **98** for retrieval. During the retrieval process, stent **98** is deflated and the inflation stalk **100** is snared with a separate device. The stent and attached filter may then removed from the inferior vena cava.

Referring to FIGS. *9a* through *9c*, a ganged arrangement of four inflatable stents, **101** through **104**, is shown. Each of the stents is similar in construction to stent **5** of FIG. **1**. Such an arrangement preferably is used to affix medical devices which require more support due to their length, such as long tubes or endo-arterial grafts. Alternatively, the ganged arrangement may be utilized in situations requiring a stent of a length greater than the length a single cuff. Examples include colonic or esophageal stents. FIGS. *9a* through *9c* also show how such a ganged arrangement may be deployed in accordance with the method of the present invention.

FIG. *9a* shows the multi-ring stent collapsed over deployment catheter **111**. FIG. *9a* also illustrates that, via a partial sectional view of catheter **111**, inflation tubing **115** is located within catheter **111** and connected at one end to stent **101** via port **123**. Stent **101** features breakaway and mitre valves (not shown) of the type illustrated in FIGS. *4a* and *4b* within its port **123**. As will be shown below, stents **101** through **104** are in fluid communication with one another. The opposing end of inflation tubing **115** is connected to inflation syringe **117** which is filled with inflation material **119**.

FIG. *9b* illustrates the multi-ring stent in an inflated condition, such as would be desired once the stent is properly positioned within the tubular structure of a patient. Connecting inflation tubing **125** interconnects stents **101** through **104** so that all four stents can be simultaneously inflated. The inflation tubing **125** and stents **101** through **104** are formed into an integral construction by fastening the stents to the inflation tubing, the latter of which is initially provided with apertures (not shown) for conveying fluid into the cuffs. Fastening may be performed using a biologically inert adhesive, thermal welding or any other suitable fastening method. In the configuration shown in FIG. *9b*, inflation material **119** has been injected into stents **101** through **104** by manipulation of inflation syringe **117**. Stents **101** through **104** are also secured together by stabilizing bridging wire **127** so as the enhance the integrity of the multi-ring stent. Note that tape may be used in place of wire **127**.

FIG. *9c* shows the inflated multi-ring stent after catheter **111** has been pulled away so that catheter **111** may be removed from the tubular structure of the patient. As the catheter is pulled away, the breakaway valve within port **123** releases inflation tubing **115** and the mitre valve seals port **123** in a manner similar to the one illustrated in FIG. *4b*. As a result, inflation material **119** cannot escape from the multi-ring stent.

The present invention can be constructed in many different sizes and shapes. The only criterion which must be met is that the stent must be of an appropriate width and diameter so that the tubular wall may be simulated or supported by the stent or the medical device to be used can be fully supported within the tubular structure by the stent. Not only can the invention be practiced in small structures such as the vascular system, but also, the stent may be affixed within much larger structures such as the excretory system.

While the preferred embodiments of the invention have been shown and described, it will be apparent to those skilled in the art that changes and modifications may be made therein without departing from the spirit of the invention, the scope of which is defined by the appended claims.

What is claimed is:

1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:

a) an inflatable and deflatable cuff of generally hollow cylindrical continuation having a collapsible lumen, an inner surface, an inlet, an outlet and a friction enhancing outer surface, said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff, said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving in a longitudinal direction with respect to the tubular structure when said cuff is in a fully inflated condition;

b) means for injecting an inflation material into said cuff to inflate it; and

c) a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.

2. The inflatable intraluminal stent of claim 1 wherein the friction-enhancing outer surface is a coarse surface.

3. The inflatable intraluminal stent of claim 1 further comprising a plurality of spot welds between the inner surface and the friction-enhancing outer surface of the inflatable cuff in staggered relationship with the inflatable protrusion(s) to limit distention between the inner surface and the friction-enhancing outer surface.

4. The inflatable intraluminal stent of claim 1 wherein the friction-enhancing outer surface is constructed of a material that promotes tissue ingrowth.

5. The inflatable intraluminal stent of claim 4 wherein the material that promotes tissue ingrowth is TEFLON.

6. The inflatable intraluminal stent of claim 1 wherein the inflatable cuff is composed of a polymeric plastic which is biologically inert.

7. The inflatable intraluminal stent of claim 1 wherein the inflation material includes a hardening agent.

8. The inflatable intraluminal stent of claim 1 wherein the valve is a mitre valve.

9. The inflatable intraluminal stent of claim 1 wherein the valve is of a breakaway design to permit separation from the means for injecting.

10. The inflatable intraluminal stent of claim 1 further comprising means for securing an intraluminal medical device to the inner surface of the inflatable cuff.

11. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a graft for repairing aneurysms.

12. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a vena cava filter.

13. The inflatable intraluminal stent of claim 1 wherein the means for injecting an inflation material into said inflatable cuff to inflate it includes an inflation syringe and inflation tubing.

14. An apparatus for disposition within the lumen of a tubular structure within the human body comprising:

a) a cuff having a collapsible lumen, an inner surface and a friction-enhancing outer surface with an inflatable and deflatable chamber disposed therebetween, the cuff also having an inflation port in fluid communication with the inflatable chamber,

b) said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff and affixing the cuff with the lumen of the tubular structure without penetration of the tubular structure when the cuff is fully inflated so that movement of the cuff in a longitudinal direction with respect to the tubular structure is prevented;

c) means for inflating the cuff with inflation material in fluid communication with said inflation port; and

d) a valve integral with sad inflation port for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.

15. The apparatus of claim 14 wherein the friction-enhancing outer surface is a coarse surface.

16. The inflatable intraluminal stent of claim 14 wherein the friction-enhancing outer surface is constructed of a material that promotes tissue ingrowth.

17. The inflatable intraluminal stent of claim 10 wherein the material that promotes tissue ingrowth is TEFLON.

18. The apparatus of claim 14 wherein the valve is a mitre valve.

19. The apparatus of claim 14 wherein the valve is of a breakaway design to permit separation from the means for inflating.

20. The apparatus of claim 14 further comprising means for securing an intraluminal medical device to the inner surface of the cuff.

21. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical device is a graft for repairing aneurysms.

22. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical device is a vena cava filter.

23. An apparatus for disposition within the lumen of a tubular structure within the lumen body comprising:

a) a plurality of cuffs, each of said plurality of cuffs having an inner surface and a friction enhancing outer surface with an inflatable chamber disposed therebetween, the inflatable chambers of said plurality of cuffs being in fluid communication with one another;

b) said friction-enhancing outer surfaces featuring inflatable protrusion(s including at least one circumferential ridge disposed about the inflatable cuff and affixing the plurality of cuffs within the lumen of the tubular structure without penetration of the tubular structure when the plurality of cuffs are inflated;

c) means for inflating the plurality of cuffs with inflation material; and

d) a valve integral with one of the plurality of cuffs for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.

24. The apparatus of claim 22 further comprising means for securing an intraluminal medical device to the inner surfaces of the cuffs.

* * * * *

Exhibit B

North Bay Business Journal
NORTH SAN FRANCISCO BAY AREA SONOMA NAPA AND MARIN COUNTIES

Business Journal Article - Issue Number: 119

TriVascular readies for production

BY LORALEE STEVENS
STAFF REPORTER

SANTA ROSA -- Events are moving at a giddy pace for TriVascular Inc. since medical device giant Boston Scientific took an interest in the company's next-generation stent grafts. During one short year, TriVascular is moving from development stage, through a flurry of clinical trials, toward the goal of shipping products to Europe as early as the end of 2003.

In the U.S., TriVascular's tiny, durable, metal/polymer stent grafts and their percutaneous (through the skin) delivery platform are in Phase I clinical testing, moving into Phase II later in the year. Full FDA approval will take several more years. Without the support of Boston Scientific, TriVascular would have had a difficult slog, according to president and CEO Michael Chobotov, PhD.

In Europe, trials are more advanced. Once the company has received its CE mark, a European certification of quality, Boston Scientific will begin rolling out the product abroad. The Massachusetts-based device maker and marketer has a worldwide distribution network and exclusive distribution rights outside the U.S. for TriVascular's stent graft and other products. TriVascular retains the rights to the domestic market.

"Boston Scientific will probably go slowly at first," says Dr. Chobotov. "They'll want to test the market and see how the product performs early on. I expect that in a year sales might be a single-digit million figure, but that could escalate substantially in 2004 and reach tens of millions in 2005.

"By the time we receive FDA approval, in 2006 or 2007, the market for stent grafts is projected to reach $750 million, up from the $250 million-$275 million spent on products last year. The real increase is waiting for next-generation devices, so we expect to command a large share of that market," says Dr. Chobotov.

40 more staff this year

Revenues for the upcoming two years are difficult to project, he says, because ongoing clinical trials in the U.S. and the need to enroll patients in them will absorb many of the company's resources.

However, TriVascular will be earning revenues in the U.S., prior to obtaining pre-market approval status from regulatory agencies.

"The revenues initially will not be significant, but we have a unique strategy to improve them," says Dr. Chobotov, declining to elaborate. He and his local co-founders Robert Whirley, PhD and Joseph Humphrey, PhD are extremely protective of their intellectual property, including business plans and proprietary manufacturing equipment.

Sum

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Web: http://www.trivasc

Founded: 1998

Facilities: 36,000

Staff: 62

Customers: Phy abdominal aortic

That equipment will be going into an additional 15,000sf the company has leased for manufacturing processes, bringing TriVascular's total space on North Laughlin Road in Santa Rosa to 36,000sf. Manufacturing will not be outsourced, assuring more jobs for the county as the company grows. By the end of the year, 62-employee TriVascular will have filled another 40 positions in quality assurance, manufacturing, purchasing, testing, and regulatory and clinical support.

"Future growth of the staff depends on the sales numbers," says Dr. Chobotov. "Again, we'll move fairly slowly at first, and then ramp up rapidly in 2005 and 2006, as we approach FDA approval to sell in the U.S., which offers the biggest market for our devices."

FDA requirements are stringent when a device has life-or-death consequences, as the TriVascular product does. Abdominal aortic aneurysms, a weakening and swelling of the abdominal section of the body's largest artery, have a mortality rate of over 50% if left untreated. Estimates show that one of every 250 people over the age of 50 will die of a ruptured abdominal aortic aneurysm, making it a leading cause of death in the U.S.

All coming together

Stent grafts, delivered by a catheter through an incision in the patient's leg, have largely replaced the invasive and traumatic open abdominal surgery during which physicians place a graft in the aorta. Johnson & Johnson, Boston Scientific, Guidant, Cook, and Medtronic AVE manufacture stents.

The challenge for TriVascular was to build a stent graft that offered the least invasive delivery combined with the greatest durability, characteristics that are often at odds with each other.

"Our architecture and unique polymer support lend themselves to durability and low profile," says Dr. Chobotov. "We're also in the early development stage of a stent and delivery platform for thoracic aortic aneurysms.

"Boston Scientific's investment validated our technology, and now it's up to us to move forward toward giving physicians a next-generation, life-saving product. This is an exciting year for TriVascular, when development, clinical trials, and sales all come together."

For more information, visit www.trivascular.com.

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