IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MEDTRONIC, INC.,

Plaintiff,

vs.

THEREX LIMITED PARTNERSHIP, and

ARROW-THEREX CORPORATION,
General Partner of Therex Limited Partnership,

Defendants.

Hon. Patti B. Saris

Case No.: 00-CV-11271 PBS

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

(Demand for Jury Included)

Plaintiff, Medtronic, Inc., by its attorneys, brings this action against Defendants Therex Limited Partnership and Arrow-Therex Corporation (collectively referred to as "Therex") for a judgment declaring that United States Patent No. 4,978,338 ("Therex Patent-in-Suit") is unenforceable and that the claims are not infringed or are invalid and states as follows:

PARTIES

1. Plaintiff Medtronic, Inc. ("Medtronic") is a corporation organized under the laws of the State of Minnesota and has a principal place of business at 7000 Central Avenue N.E., Minneapolis, Minnesota 55432.

2. On information and belief, Therex Limited Partnership ("Therex LP") is a partnership organized under the laws of the State of Delaware, having a principal place of

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business at 1600 Providence Highway, Walpole, Massachusetts. Therex LP is qualified to do business in Massachusetts, having registered under Mass. Gen. L. ch. 109, §49.

3. On information and belief, Arrow-Therex Corporation ("Arrow-Therex") is a corporation organized under the laws of the State of Delaware, having a principal place of business at 1600 Providence Highway, Walpole, Massachusetts. Arrow-Therex is qualified to do business in Massachusetts, having registered under Mass. Gen. L. ch. 181, §4. Arrow-Therex is the General Partner of Therex LP. On information and belief, Arrow-Therex, as General Partner of Therex LP, controls the decisions and activities of Therex LP, including any actions Therex LP has taken and may take with respect to the issue of alleged patent infringement set forth below, and is therefore a necessary party to this action.

JURISDICTION AND VENUE

4. Based on paragraphs 1-3 above, paragraphs 8-30 below, and the facts set forth herein, this action arises under the Acts of Congress relating to patents, 35 U.S.C. §§ 1 *et seq.*, and for a declaratory judgment and further relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. This Court has subject matter jurisdiction over this complaint in accordance with the provisions of 28 U.S.C. §§ 1331 and 1338 (a).

5. On information and belief, Therex LP and Arrow-Therex, directly, by an agent or both, have transacted business within the Commonwealth, from which the below-described causes of action arise.

6. Based on paragraphs 1-5 above, paragraphs 8-30 below, and the facts set forth herein, this Court has personal jurisdiction over Therex LP and Arrow-Therex by virtue of Mass. Gen. L. ch. 223A, §§1-3 and federal law.

7. Venue is proper under 28 U.S.C. §§ 1391(b, c).

FACTUAL BACKGROUND

8. Medtronic incorporates by reference paragraphs 1-7 of this Complaint as though fully and completely set forth herein.

Therex Patent-in-Suit

9. On information and belief, Therex LP is the owner, by assignment, of United States Patent No. 4,978,338 ("Therex Patent-in-Suit"), issued on December 18, 1990 in the names of Gerald S. Melsky and Frank R. Prosl, and originally assigned to Therex Corporation (a Massachusetts corporation now dissolved). Therex Corporation assigned the Therex Patent-in-Suit to Therex LP. A copy of the Therex Patent-in-Suit is attached hereto as Exhibit A.

10. On information and belief, the Therex Patent-in-Suit describes and claims, *inter alia*, an implantable pump for delivering medication to a site within a patient. The pump includes two ports: one for filling a reservoir with medication for metered release to the site, and the other for direct release to the site.

11. On information and belief, the Therex Patent-in-Suit issued from U.S. Application No. 184,244 ("Therex U.S. Application"). Therex originally attempted to file the Therex U.S. Application with the United States Patent and Trademark Office ("USPTO") on April 21, 1998, but was denied that filing date because Therex did not comply with all necessary legal requirements. The USPTO accorded the Therex U.S. Application a filing date of June 20, 1988.

12. On information and belief, Therex requested that the Therex U.S. Application be accorded the earlier April 1998 date. When that request was not granted, Therex petitioned the Commissioner of Patents and Trademarks ("Commissioner") for the earlier filing date. Therex's petition was denied by the Commissioner. June 20, 1988 remains the official USPTO filing date of the Therex Patent-in-Suit.

Therex Concealed Prior Art from the U.S. Patent and Trademark Office

Undisclosed Material Prior Art Application

13. On information and belief, Therex filed U.S. Application No. 184,352 ("Therex's Earlier Related Application," attached hereto as Exhibit B) on April 21, 1998. This was the same day on which Therex attempted to file the Therex U.S. Application. Therex's Earlier Related Application has since issued as U.S. Patent No. 4,955,861. Because Therex's Earlier Related Application was filed prior to the Therex Patent-in-Suit, it is prior art to the Therex Patent-in-Suit. Further, because of its teachings, Therex's Earlier Related Application was non-cumulative and material to the USPTO examination of the Therex Patent-in-Suit.

14. On information and belief, even after the multiple decisions resulting in the Therex Patent-in-Suit having a filing date later than that of Therex's Earlier Related Application, Therex still intentionally withheld disclosing, in the Therex Patent-in-Suit prosecution, this prior art. The USPTO examiner in the Therex Patent-in-Suit prosecution never considered Therex's Earlier Related Application before the Therex Patent-in-Suit issued.

Additional Undisclosed Material Prior Art

15. On information and belief, at least fifteen (15) U.S. patent references and four (4) foreign patent references ("Therex Known References") were cited during prosecution of Therex's Earlier Related Application while prosecution was still pending on the Therex Patent-in-Suit. These Therex Known References were non-cumulative and material to the patentability of the Therex Patent-in-Suit. Therefore, Therex was legally required to disclose each of these Therex Known References to the USPTO. However, Therex intentionally withheld disclosing, in the Therex Patent-in-Suit prosecution, at least eleven (11) of the Therex Known References. These Therex Known References were never considered by the examiner before the Therex Patent-in-Suit issued.

Foreign Filings Based on the Improper U.S. Filing Date

16. On information and belief, in 1989 Therex LP filed PCT patent application number PCT/US89/01719 ("Therex's PCT Application"). Therex's PCT Application claimed subject matter that allegedly related to the Therex Patent-in-Suit. Therex claimed the priority date of April 21, 1988 for Therex's PCT Application, even though Therex knew that the official USPTO filing date of the allegedly related Therex Patent-in-Suit was June 20, 1988.

17. On information and belief, Therex LP owns European Patent No. 0 612 535 ("Therex's European Patent"). Therex's European Patent derives from Therex's PCT Application. Therex's European Patent includes subject matter that allegedly relates to the Therex Patent-in-Suit. During prosecution of Therex's European Patent, Therex claimed priority from the Therex Patent-in-Suit and again fraudulently claimed a priority date of April 21, 1988, even though Therex knew that the official USPTO filing date of the allegedly related Therex Patent-in-Suit was June 20, 1988.

18. On information and belief, Therex LP owns German Patent No. DE 689 28 626 ("Therex's German Patent"). Therex's German Patent claims priority to Therex's European Patent. Therex's German Patent includes subject matter that allegedly relates to the Therex Patent-in-Suit. Once again, Therex fraudulently claimed a priority date of April 21, 1988, even though Therex knew that the official USPTO filing date of the allegedly related Therex Patent-in-Suit was June 20, 1988.

19. On information and belief, Therex LP owns Belgian Patent No. BE 0 612 535 ("Therex's Belgian Patent"). Therex's Belgian Patent claims priority to Therex's European Patent. Therex's Belgian Patent includes subject matter that allegedly relates to the Therex Patent-in-Suit. Once again, Therex fraudulently claimed a priority date of April 21, 1988, even though Therex knew that the official USPTO filing date of the allegedly related Therex Patent-in-Suit was June 20, 1988.

20. On information and belief, Therex LP owns Dutch Patent No. NL 0 612 535 ("Therex's Dutch Patent"). Therex's Dutch Patent claims priority to Therex's European Patent. Therex's Dutch Patent includes subject matter that allegedly relates to the Therex Patent-in-Suit. Once again, Therex fraudulently claimed a priority date of April 21, 1988, even though Therex knew that the official USPTO filing date of the allegedly related Therex Patent-in-Suit was June 20, 1988.

Therex Threatens Medtronic with Domestic and Foreign Litigation Using Therex's Fraudulently Obtained Patent Portfolio

21. An affiliate of Medtronic manufactures Medtronic's IsoMed® implantable drug infusion pump ("IsoMed Pump") in The Netherlands. Subsidiaries and affiliates of Medtronic market the IsoMed Pump throughout Europe.

22. As reported in an October 9, 1997 article of Clinica (attached hereto as Exhibit C), on information and belief, Arrow International, Inc., the parent corporation of Arrow-Therex, "complained to Medtronic that the new German pump violates its existing patent on the system in both Germany *and the US*" and that "Arrow is prepared to sue for patent infringement" (emphasis added). The Clinica article quotes Marlin Miller, then CEO and President of Arrow, as saying that such lawsuits "could slow the introduction of the product to Arrow's advantage." On information and belief, the Clinica article references to "the new German pump" and Mr. Miller's quoted reference to "the product" refer to the IsoMed Pump.

23. On information and belief, on August 17, 1998, Therex LP filed an infringement suit ("German suit") in Germany against Medtronic's German subsidiary

(Medtronic GmbH). Therex alleged that the IsoMed Pump infringed Therex's German Patent. In accordance with the German judicial procedure related to patent cases, the court hearing the German suit allegedly had jurisdiction to consider only the issue of infringement. Therefore, the court did not fully consider whether or not Therex's German Patent was valid. On July 22, 1999, the German court ruled that the IsoMed Pump infringed Therex's German Patent, without evaluating the validity of the patent. Since the German court ruling, the EPO has found that the claims of Therex's European Patent, which were identical to those of Therex's German Patent, have been found to be invalid, requiring claim modifications by Therex. Thus, the German court decision was based on claims that the EPO determined to be invalid. Medtronic has appealed the German court trial infringement decision, which appeal is currently pending.

24. On information and belief, on March 21, 2000, purporting to represent Therex LP, Prof. Willem A. Hoyng, sent a letter (attached hereto as Exhibit D) to Medtronic's subsidiary in The Netherlands (Medtronic B.V.). Prof. Hoyng explained a continuing series of actions Therex LP had taken and would take in the future in Europe using the fraudulently obtained patents to halt Medtronic's manufacture and sale of the IsoMed Pump. In the March 21 letter, Prof. Hoyng expressed Therex LP's intention to obtain a court injunction to halt Medtronic's manufacture of the IsoMed Pump in the Netherlands, which could be tantamount to an attempt to shut down Medtronic's worldwide production of the IsoMed Pump. Prof. Hoyng reiterated Therex LP's contention that the IsoMed Pump infringes Therex's European Patent.

25. On information and belief, on August 4, 2000, Therex LP served a request for preliminary injunction in the Netherlands to recall and destroy all existing IsoMed Pumps in

stock or which were previously distributed by Medtronic's Dutch subsidiary. Therex also requested halting of the manufacture, use and export of the IsoMed Pump. On information and belief, Therex has requested that all IsoMed Pumps that were manufactured in the Netherlands, including IsoMed Pumps that are presently implanted in U.S. patients, be destroyed.

26. On information and belief, in January and February 2000, U.S. counsel for Therex LP and Medtronic engaged in communications regarding a possible business solution between Therex LP and Medtronic involving Therex LP's patents and the Medtronic IsoMed Pump. Therex stated that Therex LP has patents around the world, and indicated that such solution would require a seven-figure payment (*i.e.*, at least $1 million) and a double-digit royalty (*i.e.*, at least 10%). On information and belief, such figures are greater than those customary in licensing agreements in the medical device industry for comparable markets. On information and belief, Therex knew its suggested royalty rate would be unreasonable for any industry member, including Medtronic, to pay.

27. On information and belief, Medtronic, through its affiliates and subsidiaries, currently have other adversarial proceedings pending with Therex LP involving the IsoMed Pump and Therex's other patents in Europe. In Belgium, Therex LP has alleged that the IsoMed Pump infringes Therex's fraudulently obtained Belgian Patent, in response to a petition brought by Medtronic. Medtronic claims that Therex's Belgian Patent is not infringed by the IsoMed Pump and is otherwise invalid. In addition, Medtronic and Therex LP are involved in (1) an action brought in The Netherlands on June 6, 2000 by Medtronic seeking a determination

that Therex's Dutch patent is invalid; and (2) an appeal by Medtronic contesting a European Patent Office decision that found Therex's European Patent, in an amended form, to be valid.

Further Therex Threats of Litigation Directed at Medtronic's U.S. Success

28. Medtronic applied to the United States Food and Drug Administration ("FDA") for approval to market the IsoMed Pump in the United States. At the time this declaratory judgment action was initiated, the FDA was scheduled to decide whether to grant marketing approval for the IsoMed Pump in July 2000 and Medtronic expected the FDA to grant approval at that time. Also prior to initiating this declaratory judgment action, Medtronic had made substantial investments in designing and manufacturing the IsoMed Pump, in seeking FDA approval for the IsoMed Pump, and in preparing marketing, sales, and distribution means to provide the IsoMed Pump to United States customers. In preparation for such sales in the United States, Medtronic had also imported multiple IsoMed Pumps into the United States prior to initiating the present action. On July 21, 2000, the United States Food and Drug Administration ("FDA") granted approval for marketing of the IsoMed Pump in the United States. On July 24, 2000, Medtronic began offering the IsoMed Pump for sale in the United States and continues to do so today.

29. On information and belief, on July 31, 2000 Arrow International, Inc., ("Arrow") issued a press release ("July 31, 2000 Press Release," a true copy of which is attached hereto as Exhibit E) which discussed various above-described adversarial proceedings in Europe between Medtronic and Therex. In the July 31, 2000 Press Release, Arrow Chairman and CEO Marlin Miller, responding specifically to the instant declaratory judgment action, was quoted as

saying: "We intend to protect our technology and our competitive position by enforcing our intellectual property rights. Arrow has made a significant investment in research and development to bring its own constant flow implantable pump to market, and has also made a considerable investment in obtaining patent protection covering its innovative technology." By these statements, Arrow, Arrow-Therex, and Therex LP have admitted the existence of an actual controversy between Medtronic and Therex regarding the Therex Patent-in-Suit and the IsoMed Pump.

30. On information and belief, Therex's actions with respect to Medtronic and the IsoMed Pump are part of an ongoing pattern directed to keeping Medtronic out of the global market for fixed-rate implantable infusion pumps, including the U.S. sector of that market. To date, Therex has taken actions that Therex knew, if successful, will affect sales of IsoMed Pumps in the U.S. The threatened U.S. patent infringement suit by Therex is another mechanism by Therex to attempt to affect sales of IsoMed Pumps in the worldwide implantable pump market. Based upon all of the above facts, Medtronic has a reasonable apprehension that it will be sued in the United States by Therex LP for alleged infringement of the Therex Patent-in-Suit by the IsoMed Pump, such that an actual controversy now exists between the parties hereto with respect to the validity of the Therex Patent-in-Suit and with respect to Medtronic's alleged infringement of this patent.

COUNT I - DECLARATORY JUDGMENT OF NON-INFRINGEMENT

31. Medtronic incorporates by reference paragraphs 1-30 of this Complaint as though fully and completely set forth herein.

32. Medtronic's IsoMed Pump does not infringe any valid and enforceable claim of the Therex Patent-in-Suit. Therefore, Medtronic is entitled to a declaratory judgment that Medtronic does not infringe the Therex Patent-in-Suit.

COUNT II - DECLARATORY JUDGMENT OF INVALIDITY

33. Medtronic incorporates by reference paragraphs 1-32 of this Complaint as though fully and completely set forth herein.

34. Therex's Therex Patent-in-Suit, and each and every claim thereof, is invalid for failure to meet the requirements of one or more of 35 U.S.C. §§ 102, 103, and/or 112. Therefore, Medtronic is entitled to a declaratory judgment that the Therex Patent-in-Suit is invalid.

COUNT III - DECLARATORY JUDGMENT OF UNENFORCEABILITY

35. Medtronic incorporates by reference paragraphs 1-34 of this Complaint as though fully and completely set forth herein.

36. The Therex Patent-in-Suit is unenforceable due to Therex's inequitable conduct before the USPTO. In particular, Therex, with intent to deceive the USPTO, failed to

disclose material prior art made known to it during the prosecution of a co-pending Therex patent application in violation of 37 C.F.R. § 1.56. Therex's failure to disclose material prior art includes, but is not limited to, the failure to disclose one or more material prior art references, including Therex's Earlier Related Application (U.S. Patent Application No. 4,955,861), as well as one or more references cited in Therex's Earlier Related Application ("Therex Known References"). The Therex Patent-in-Suit was still pending in the USPTO when Therex's Earlier Related Application and the Therex Known References became known to Therex. Therefore, Medtronic is entitled to a declaratory judgment that the Therex Patent-in-Suit is unenforceable based upon Therex's inequitable conduct.

REQUESTED RELIEF

WHEREFORE, Plaintiff Medtronic, Inc. prays that this Court:

A. Declare United States Patent No. 4,978,338 has not been infringed by Medtronic, Inc., and would not be infringed by the making, using, selling, offering to sell, or importing in the United States of the Medtronic IsoMed Pump;

B. Declare all claims of United States Patent No. 4,978,338 are invalid;

C. Declare that United States Patent No. 4,978,338 is unenforceable;

D. Declare this is an exceptional case within the meaning of 35 U.S.C. § 285 and award Medtronic, Inc. its costs and reasonable attorney's fees expended in this action; and

E. Award Medtronic, Inc. such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff Medtronic, Inc. demands a jury trial on all issues triable to a jury in this matter.

Dated: 8/9/2000

MEDTRONIC, INC.
By its Attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that on this day a true copy of the above document was served upon the attorney of record for each party ~~by mail~~/by facsimile/~~by hand.~~

Dated: 8/9/2000

James J. Marcellino (BBO# 318840)

Exhibit A

United States Patent [19]

Melsky et al.

[11] **Patent Number: 4,978,338**

[45] **Date of Patent: Dec. 18, 1990**

[54] **IMPLANTABLE INFUSION APPARATUS**

[75] Inventors: **Gerald S. Melsky**, Lexington; **Frank R. Prosl**, Duxbury, both of Mass.

[73] Assignee: **Therex Corp.**, Walpole, Mass.

[21] Appl. No.: **184,244**

[22] Filed: **Jun. 20, 1988**

[51] Int. Cl.[5] A61M 5/00

[52] U.S. Cl. 604/93; 604/132; 604/86

[58] Field of Search 604/93, 175, 131, 132, 604/140, 141, 86, 83, 82, 43

[56] **References Cited**

U.S. PATENT DOCUMENTS

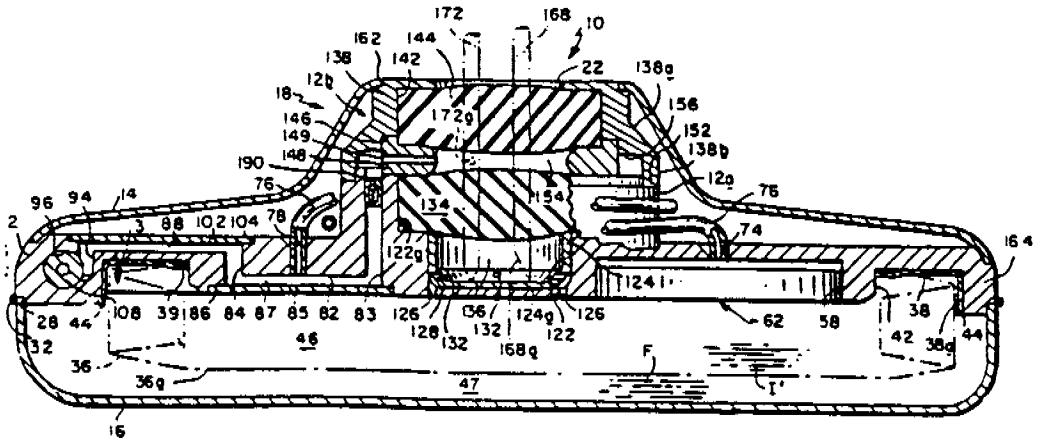
3,552,441	1/1971	Luhleich .	
3,730,170	5/1973	Michael .	
3,731,681	5/1973	Blackshear et al. .	
4,193,397	3/1980	Tucker .	
4,258,711	3/1981	Tucker .	
4,496,343	1/1985	Prosl .	
4,525,165	6/1985	Fischell .	
4,692,146	9/1987	Hilger	604/175

Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Denise W. DeFranco
Attorney, Agent, or Firm—Nutter, McClennen & Fish

[57] **ABSTRACT**

Implantable infusion apparatus includes a housing with an inlet passage extending into the housing at a pronounced promontory on the housing wall. The passage has an outer end at the top of the promontory and an inner end defined by a needle stop positioned inside the housing. Self-sealing septa mounted in the passage at selected spacings from the needle stop divide the passage into a plurality of aligned inlet ports each of which has its own fluid outlet. One of the outlets leads to a pumpable infusate reservoir having an outlet conduit connected to a catheter that extends outside the housing; another leads directly to the outlet conduit so that while a first fluid is being pumped from the reservoir to the catheter, a second fluid can be introduced into the other inlet port for mixing with the first fluid flowing to the catheter. Several different infusate flow configurations are also disclosed.

45 Claims, 2 Drawing Sheets



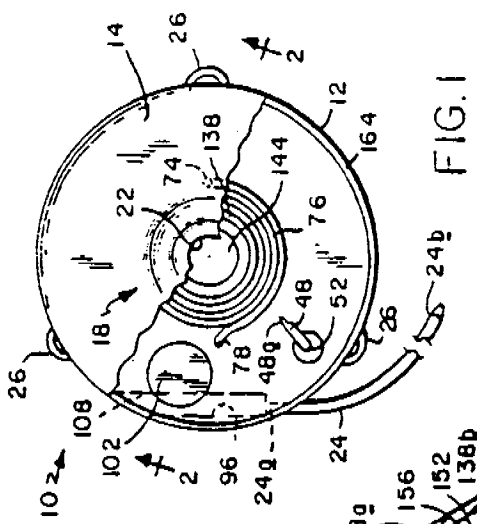


FIG. 1

FIG. 2

FIG. 3

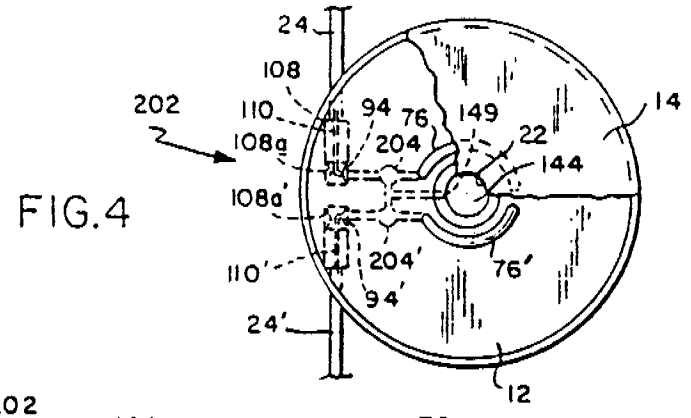


FIG.4

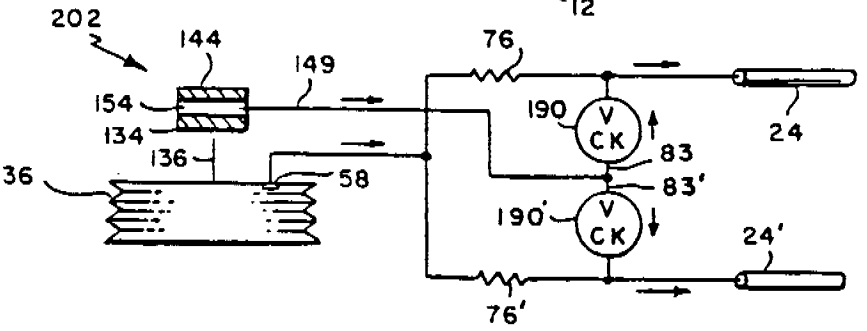


FIG.5

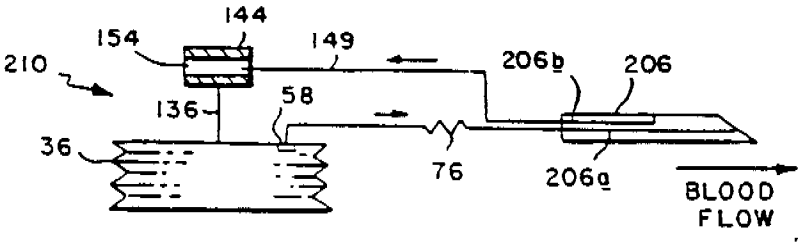


FIG.6

IMPLANTABLE INFUSION APPARATUS

This invention relates to implantable infusion apparatus. It relates more particularly to an implantable self-powered infusate pump which is capable of dispensing a measured dose of infusate to a patient over the long term and which is refillable and rechargeable by trancutaneous injection.

BACKGROUND OF THE INVENTION

Implantable infusion apparatus of the general type with which we are concerned has been in use for a number of years to treat diabetes, Alzheimer's disease, certain types of cancer and other chronic diseases. Basically, the apparatus includes a housing which contains a collapsible infusate reservoir. An inlet port through a wall of the housing communicates with the interior of the reservoir and that passage is closed by a needle-penetrable septum mounted in the housing wall. An outlet passage from the reservoir containing a flow restrictor extends to the housing exterior where it is connected to the proximal end of a flexible catheter.

In use, the apparatus is implanted at a selected location in the body so that the inlet septum is situated directly underneath the patient's skin and the distal end of the catheter is positioned at a selected infusion site. Infusate is delivered to the infusion site by forcing that fluid from the apparatus reservoir through the catheter to the infusion site. The flow restrictor in the reservoir outlet determines the flow rate from the reservoir. When the infusate reservoir becomes empty, it may be refilled by injecting fresh infusate through the apparatus' inlet septum. As noted previously, the inlet is accessible readily by transcutaneous injection using a hypodermic needle or cannula.

In the infusion apparatus of interest here, infusate is expelled from the reservoir to the infusion site by collapsing the reservoir. This collapsing force is provided by a two-phase fluid which is situated in a fluid-tight space outside the reservoir. The fluid is both a liquid and a vapor at physiological temperatures, e.g. 98.6° F., and it exerts a positive and constant pressure over the full volume change of the reservoir. On the other hand, when the infusate reservoir is expanded upon being refilled with fresh infusate during the refilling process described above, the two-phase fluid is compressed with a portion of it reverting to its liquid phase thereby recharging that vapor pressure power source. The construction and operation of inplantable infusate apparatus and pumps of this general type are described in detail, for example, in U.S. Pat. Nos. 3,731,681 and 3,951,147 and in the article entitled "Liquid Dispensers" by B. M. Wright in the *Quarterly Bulletin and Review*, Vol. 16, No. 3, Sept. 1, 1964 and in the *Journal of Physiology*, Vol. 177, (1965). See also the September 1964 Masters Thesis of P. D. W. Soden to be found at Victoria University of Manchester, England.

While the prior art pumps operate satisfactorily, they are relatively expensive to manufacture and to assemble. Also, they are relatively large. For example, one such pump of which we are aware is in the order of 3.3 inches in diameter, one inch thick and weighs about 220 grams. When that prior prosthesis is implanted in a patient's body, the patient is obviously well aware of its presence and may, as a result, suffer considerable discomfort and anxiety.

Some known implantable pumps are difficult to refill in that it is difficult to locate their septa in order to insert needles into their inlet ports to refill or otherwise service the apparatus. This may be due to a combination of factors, including the use of an inlet septum having a small surface area and the inability to distinguish the septum from the remainder of the implanted apparatus. Even if the spot on the patient's skin directly above the septum is marked by a tattoo when the pump is implanted initially, over the course of time, the relative positions of the mark and the underlying septum may change due to patient movements and weight changes. In those known pumps whose catheters exit the housing close to the septum, a mispositioned needle can actually damage the pump by puncturing the rubber catheter. Such damage would, of course, necessitate surgical removal of the pump.

In this connection, we should mention that when refilling an implanted pump, the normal procedure is to insert a hollow needle into the pump's inlet port and allow any remaining volume of the original infusate in the reservoir served by that inlet port to back-flow out through the needle. Then, a fixed volume of the fresh infusate is injected into the reservoir through the needle, after which the needle is withdrawn. It is apparent, therefore, that each emptying and refilling procedure is a time-consuming process that involves skin penetrations and requires the patient to remain still while the needle fixed to his body introduces and/or removes fluid from the infusion device implanted in his body. In many instances, this procedure is performed in a clinic or physician's office or on a hospital out-patient basis. Therefore, each office visit for servicing the pump can be quite expensive.

Also, some implantable apparatus such as those described in U.S. Pat. Nos. 4,193,397 and 4,258,711 have two-pumping chambers or reservoirs enabling them to dispense two different infusate concentrations or infusates. The two pumping chambers are purged and refilled independently by way of separate inlet ports positioned at different locations on the pump housing, each port having its own needle-penetrable septum located underneath the patient's skin.

Another known implantable infusate dispenser disclosed in U.S. Pat. No. 4,496,343 for example, has, instead of a second pumping chamber, an injection portal on the housing wall. This portal is basically a small chamber with an outlet leading to the catheter and an inlet port closed by a self-sealing septum located underneath the patient's skin. Infusate injected transcutaneously into the portal flows directly to the catheter and, therefore, to the infusion site. In other words, the injection process provides the pumping force to deliver the infusate. Such a device can also be used for blood withdrawal.

It is apparent that the proper servicing and utilization of such dual port devices may require many more skin penetrations than are needed to service a pump with a single inlet port. As noted above, once the device is implanted, the positions of the inlet ports and their septa are more or less fixed with respect to the overlying skin area of the patient. Therefore, over the period of implantation, the patient's skin may be punctured many times at the two septa locations resulting in inconvenience and pain for the patient.

Another disadvantage of the prior plural-port implantable pumps is their propensity for being refilled with the wrong fluid. More particularly, after the de-

vice is implanted, as noted above, its position may change somewhat relative to a fixed spot on the patient's skin surface. Also, the septa are quite small and indistinguishable. Therefore, when refilling or purging the implanted device, it is quite easy for a nurse to insert a needle into the wrong inlet port if she is not very careful. In the case of a two chamber insulin pump, for example, this could result in the basal reservoir of the pump being refilled with bolus infusate and the bolus reservoir being charged with lower concentration basal infusate, or it could result in one reservoir of that pump being emptied or filled twice and the other reservoir not being serviced at all.

It would be desirable, therefore, if the number and duration of the transcutaneous injections required to access or to service an implanted pump could be minimized, along with the potential for servicing errors. This would not only reduce the risk of infection to the patient, it would also reduce the incidence of epidermal problems associated with implanted refillable infusate pumps of this type, and it would certainly reduce the physical and emotional stress on a patient required to wear such an implanted device.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide improved implantable, refillable, self-powered infusion apparatus.

Another object of the invention is to provide such apparatus which is smaller and more compact than conventional implantable apparatus of this general type.

A further object of the invention is to provide an implantable, refillable infusion pump which is relatively lightweight.

Still another object is to provide such a pump which is relatively easy to manufacture and to assemble as compared to existing devices of this general type.

Yet another object of the invention is to provide an implantable, refillable infusion pump whose refill port or ports can be located easily after the pump is implanted in the patient's body.

A further object of the invention is to provide an implantable, refillable, dual-port infusion device which minimizes the number and duration of skin penetrations required to properly service the device by transcutaneous injection into the device.

Another object of the invention is to provide an implantable, refillable, dual-port infusion apparatus whose inlet ports can be accessed simultaneously with a single penetration of the patient's skin.

Still another object is to provide a dual-port, refillable infusion device which prevents a surgeon or physician from accessing the wrong inlet port when servicing the device after it is implanted.

Still another object is to provide such an infusion device which has sealing redundancy to prevent leakage of infusate within the patient.

Another object of the invention is to provide a device of the type which has a smoothly rounded outer surface which minimizes dead spaces in the implantation area at which infection can occur.

Still another object is to provide an implantable infusion device which has a minimum number of separate tubes and plumbing joints.

Other objects will be, in part, be obvious and will, in part, appear hereinafter.

The invention accordingly comprises the features of construction, combination of elements and arrangement of parts which will be exemplified in the following detailed description, and the scope of the invention will be indicated in the claims.

In general, our infusion apparatus operates on the same basic principles as the implantable infusion pump described in the aforementioned U.S. Pat. No. 3,731,681. Our apparatus can also deliver at least two different infusates to the same infusion site or to different sites in the body of the patient in which the apparatus is implanted. In this, it is similar to the device described in the above-mentioned U.S. Pat. No. 4,496,343. However, our apparatus is constructed in such a way as to materially reduce the overall size and weight of the apparatus as compared to those prior implantable pumps, and additionally, to minimize discomfort and danger to the patient in which the device is implanted by reducing the number of skin penetrations required to service the apparatus after it is implanted, by reducing the incidence of errors in accessing the apparatus and by minimizing patient trauma caused generally by the implantation of the device.

Our infusion apparatus is generally cylindrical having the overall shape of a large pocketwatch. All of the major components and fluid pathways of the apparatus are incorporated in or mounted to a single rigid discoid header or manifold structure. Upper and lower shells mounted to the top and bottom of the header structure are shaped to define internal spaces which enclose various apparatus parts and to give the apparatus a smooth, uninterrupted, gently contoured exterior shape or profile.

A collapsible bellows capsule is positioned in the space between the header and the lower shell. One end of the bellows capsule is open and specially secured in an annular groove present in the underside of the header to facilitate assembly of the capsule as will be described in more detail later. The opposite end of the bellows capsule is closed so that the capsule separates the space between the header and the lower shell into two fluid-tight variable volume compartments. One of these compartments, say, the one inside the capsule, constitutes an infusate reservoir; the other compartment, i.e. the one between the capsule and the lower shell normally contains a two-phase fluid which, at physiological temperatures, produces sufficient vapor pressure to collapse the bellows capsule as described in the above-identified prior art.

When the bellows capsule is collapsed by the driving fluid, infusate inside the capsule flows along a fluid pathway provided in the header to the periphery of the apparatus. That fluid pathway includes an outlet filter recessed into the underside of the header and a flow restrictor to maintain a constant fluid flow from the capsule. Provision is made at the periphery of the apparatus for connecting the proximal end of a flexible catheter so that the catheter lumen is in fluid communication with the fluid pathway in the header. The connection is removed from the surface of the device that faces the skin and is arranged so that the catheter extends tangentially from the apparatus shell so that the catheter will not be punctured when the apparatus is being serviced.

The bellows capsule is located eccentric to the outer diameter of the header thereby providing room on one side of the periphery of the device where the catheter may be connected while keeping the header diameter as small as possible. The catheter may be of any selected length so that when the apparatus is implanted in a patient, it will conduct infusate from the apparatus to a

selected infusion site in the patient's body. As will be described in greater detail later, the fluid pathways in the header that conduct infusate from the bellows capsule through the filter and flow restrictor to the catheter can all be formed by simple drilling and/or surface milling operations so that precise manufacturing and defect-free assembly of the apparatus are facilitated.

The present apparatus also includes at least two inlet or access ports by which two different infusates or liquids may be introduced into the apparatus after it is implanted. One of these inlet ports leads to the interior of the bellows capsule, the other inlet port is connected by a passage in the apparatus header to the outlet from the bellows capsule that leads to the catheter. As with prior implantable pumps of the dual-port type, each of the inlet ports is closed by a needle-penetrable, self-sealing septum, which when the pump is implanted in the body, is accessible by transcutaneous injection. Thus, one infusate can be injected into the one inlet port to refill the bellows capsule and to recharge the pump and a second or different infusate may be injected into the other inlet port from which it will flow directly to the catheter so as to supplement the infusate flow thereto from the bellows capsule.

However, whereas prior dual-access devices of this general type have their two inlet ports located at two different locations on the pump housing, in the present apparatus, the two ports are stacked one on top of the other at a pronounced promontory or mesa that projects up at the center of the apparatus. The two ports are isolated from one another and from the outside environment by a pair of septa spaced one on top of the other in a passage that extends down through the header, the inner end of the passage being closed by a permeable needle stop. Thus, the passage segment between the needle stop and the inner septum constitutes the one inlet port which leads to the interior of the bellows capsule and the passage segment between the two septa constitutes the other inlet port which leads directly to the apparatus outlet and the catheter. Thus, when the apparatus is implanted, both of its inlet ports are located at different levels underneath the very same area of the patient's skin.

It should be appreciated that the locating of the common entrance to the inlet ports at a raised rounded promontory or mesa on the apparatus facilitates servicing same. This is because, after implantation, the physician or surgeon can readily locate that promontory and distinguish it from the apparatus housing generally by feeling or pressing against the patient's skin area overlying the general vicinity of the apparatus. When he finds that promontory, it can serve as a target for the needle or cannula. That, coupled with the fact that septa being penetrated have surface areas about four times larger than those on conventional devices of this type means that the servicing of the apparatus can be carried out expeditiously and with minimum discomfort and inconvenience to the patient.

The apparatus is accessed by different needles or cannulae or, more preferably, by a single needle unit which has two parallel fluid paths or lumens. The lumens have separate inlets which permit fluid to be introduced into or withdrawn from each lumen independently. The lumens also have separate outlets which are located at different elevations on the needle unit, as measured from the unit's tip. Moreover, the spacing of the outlets is related to the spacing of the stacked inlet ports of the infusion apparatus so that when the apparatus is implanted and the needle unit is punctured through the patient's skin into the apparatus through the latter's septa until its tip contacts the needle stop, the outlet of each needle unit lumen will automatically be in fluid communication only with the corresponding inlet port of the implanted prosthesis.

Thus, with a single needle penetration, both ports of the implanted device can be accessed independently at the same time. For example, while the infusate reservoir constituted by the bellows capsule is being emptied or filled by way of the needle unit lumen communicating with the one inlet port, a bolus dose of infusate can be infused into the patient via the other lumen which communicates with the other inlet port. It should be understood, however, that although our apparatus allows simultaneous access to both inlet ports of the implanted device, one does not necessarily have to perform the flow operations simultaneously. The point is that our arrangement reduces the number of skin punctures necessary to service an implanted infusion pump or other such device of the dual-port type. It also reduces the length of time that the patient has to be inconvenienced by needles or cannulae penetrating his epidermis. This should, of course, make the wearing of such an implanted device much more bearable to the patient.

It is also important to note that since the fluid paths through the needle unit are keyed or matched to the inlet ports of the implanted apparatus by the corresponding placements of the respective needle outlets and apparatus inlet ports, there is no possibility of a needle accessing the wrong internal port or chamber of the implanted apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description, taken in connection with the accompanying drawings, in which:

FIG. 1 is a plan view with parts broken away of implantable infusion apparatus incorporating our invention;

FIG. 2 is a vertical sectional view on a much larger scale showing the FIG. 1 apparatus in greater detail;

FIG. 3 is a sectional view taken along line 3—3 of FIG. 2;

FIG. 4 is a view similar to FIG. 1 of apparatus incorporating our invention which dispenses infusate to two different infusion sites in the body;

FIG. 5 is a diagrammatic view of the FIG. 4 apparatus; and

FIG. 6 is a similar view of an apparatus embodiment having a dual lumen outlet catheter.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Drawing FIG. 1 shows our infusion apparatus generally at 10. The overall size and shape of apparatus 10 are determined by a rigid discoid header or manifold 12, an upper annular shell 14 and a lower cup-like shell 16 (FIG. 2). The shells are secured at their edges to the periphery of the header to form a housing or enclosure which has a more or less continuous, smoothly-contoured outer surface devoid of sharp edges and corners. The header and shells are all made of stainless steel, titanium or other strong biocompatible material. Typically, apparatus 10 has an overall diameter of about three inches and a thickness of about one-half inch except at a central raised mesa or promontory 18 where its

thickness is about one inch. The weight of apparatus 10 is only in the order of 120 grams. Actually, apparatus 10 is about one-half as heavy as, and occupies about one-half the volume of, conventional infusion apparatus of this type.

Infusate is introduced into apparatus 10 through an opening 22 at the promontory 18. It leaves the apparatus 10 by way of a flexible catheter 24, the proximal end 24a of which is connected to header 12 at the very edge of the apparatus. In use, apparatus 10 is implanted at a suitable location in the patient's body, e.g. in a subcutaneous pocket in the patient's abdominal wall and it is positioned so that opening 22 is located directly underneath the patient's skin. Small wire loops 26 are welded to the periphery of the header at spaced-apart locations around the apparatus. These can be sutured to body tissue at the implantation site to anchor the apparatus. The distal end 24b of catheter 24 is also sutured in place at a selected infusion site, e.g. a blood vessel or a ventricle space, whose location depends upon the particular patient's physical problem so that the infusate introduced into opening 22 will be conducted via catheter 24 only to that selected site.

Referring now to FIG. 2, the lower edge of header 12 has a circumferential notch 28 that forms a seat for the edge of the lower shell 16 and those two parts are welded all around at 32 so that the header and lower shell together define a fluid-tight space in which is positioned a collapsible bellows capsule 36 preferably of the welded type. The lower end of capsule 36 is closed by an end wall 36a. The upper end of the capsule is open and connected to the underside of header 12.

To effect this connection, a special annular bracket or plate 38 is welded all around at 39 to the inner edge of the uppermost diaphragm 36b of capsule 36 prior to mounting the capsule to the header. The bracket or plate 38 has a slightly larger diameter than that of capsule 36 and its edge margin is bent down to form a peripheral flange 38a that surrounds the uppermost convolutions of the bellows capsule.

The open end of capsule 36, including the bracket 38, seats in a circular groove or channel 42 formed in the underside of header 12 adjacent to the outer edge thereof.

The groove 42 is formed eccentric to the circular perimeter of manifold or header 12 so that capsule 42 is displaced away from the catheter to provide room in the housing for the catheter connection to be described. This keeps the header diameter quite small so that the overall volume of the device is minimized.

Preferably, bracket 38 is shaped so as to space its inner edge, where the weld connection 39 to the bellows is made, from the bottom of the groove 42 to minimize stresses on the weld seam. Groove 42 is deep enough so that when the capsule is fully collapsed, its convolutions nest in groove 42 to a degree that positions the bellows end wall 36a above the lower edge of the bracket flange 38a. This clearance allows a weld bead 44 to be made between that flange edge and the outer edge of the header groove 42 all around the flange without any likelihood of the heat from the welding operation damaging bellows capsule 36. Thus, manufacture of apparatus 10 is facilitated because the bellows capsule can be completely fabricated and attached to bracket 38 outside the apparatus and then the open end of that assembly can be welded to the header reliably all around the bellows capsule at 44 without adversely affecting the bellows capsule. The nesting of the bellows capsule in the header groove 42 also minimizes the compressed volume of the bellows which, in turn, minimizes the bellows extension or stroke required to expel a given volume of infusate from the capsule 36, and thus, the overall thickness of the apparatus.

In the apparatus 10 specifically illustrated herein, the region inside capsule 36 constitutes a reservoir 46 for a first infusate I_1. The space or compartment 47 between capsule 36 and shell 16 contains a two-phase fluid F, such as a Freon which is in a two phase state at physiological temperatures with a suitable vapor pressure. Fluid F is introduced into compartment 47 by means of a small tube 48 (FIG. 1) whose lower end is connected to the upper end of a vertical passage 52 in header 12 which leads to that compartment. After that space is charged with fluid F, the upper end of tube 48 is crimped and sealed by a weld 48a. It is important to note that when the apparatus is fully assembled, tube 48 is completely covered and protected by the upper shell 14. However, even if a leak should occur in the tube, the escaping fluid F will be confined in the space under shell 14 and will not be released into the patient.

Still referring to FIG. 2, a shallow generally cylindrical recess 58 is formed in the underside of header 12 at the righthand side thereof, as viewed in that figure. Press fit in that recess is a disk-like filter member 62 consisting of, for example, a 0.2 micron membrane filter.

A small vertical passage 74 is formed in header 12 directly opposite recess 58 for receiving one end of a glass capillary tube 76. The tube end may be anchored and sealed in passage 74 by suitable means such as an epoxy cement. Tube 76 constitutes a fluid flow restrictor and to obtain the necessary degree of restriction for a flow rate of 1 ml/day, for example, the tube must be relatively long. Therefore, the tube is wrapped around a raised header section 12a at the center of the header. The opposite end of tube 76 is received and sealed into a vertical passage 78 extending down through header 12 at a location spaced from passage 74 therein.

A radial groove 82 inscribed in the undersurface of header 12 intercepts the lower end of passage 78. The radially inner end of groove 82 joins the lower end of a vertical passage 83 that extends down from the top of header section 12a. The radially outer end of groove 82, on the other hand, intercepts the lower end of a vertical hole 84 that extends to the upper surface of header 12. Groove 82 is covered by a thin discoid plate 85 seated in a shallow recess 86 provided in the underside of header 12. Thus, a straight fluid conduit (e.g. $0.01 \times 0.05 \times 1.25$ inch) exists between passage 83 and hole 84 that functions as a mixing chamber 87 as will be described in detail later.

A similar radial groove 88 is formed in the upper surface of header 12. Groove 88 leads from the upper end of hole 84 to a second hole 94 that extends vertically from the header upper surface part way down through a thickened marginal sector of header 12 where it intercepts a much larger diameter orthogonal passage 96. As best seen in FIG. 3, passage 96 extends horizontally following a chord line through the header that leads into a slightly smaller diameter collinear passage 98, with each passage exiting the header at spaced-apart locations around the perimeter thereof.

Groove 88 is covered by a thin plate 102 which is similar to plate 85 and which seats in a shallow recess 104 in the upper surface of the header. Both plates are held in place by epoxy cement, welding or other suitable means. Thus, a fluid flowing from tube 76 into

mixing chamber 87 is conducted via hole 84, groove 88 and hole 94 to passage 96.

Still referring to FIG. 3, passage 96 is arranged to snugly receive a cylindrical plug 108 made of the same material as header 12, the outer end of the plug being flush with the outer surface of the header. Plug 108 is formed with a reduced diameter waist segment 108*a* which, when the plug has bottomed in its passage 96 as shown in FIG. 3, is situated directly opposite the hole 94 that intercepts passage 96. Plug 108 has an axial passage 110 that extends from the inner end of the plug at least to the plug segment 108*a* where it joins a short branch passage 110*a* leading to the surface of plug segment 108*a*. Further, that plug inner end is counterbored at 110*b*, the counterbore having the same diameter as passage 98. Both the passage and the counterbore snugly receive the proximal end 24*a* of catheter 24 which, along with plug 108, is secured and sealed in place by a cement or other suitable means. Thus, the fluid flowing into hole 94 as described above is conducted via plug passages 110 and 110*a* into the lumen of catheter 24.

It is noteworthy that the catheter 24 exits apparatus 10 well below the rounded edge of the periphery of the upper shell 14 and more or less tangentially. This ensures that there are no sharp bends in the catheter where it leaves the apparatus that could obstruct fluid flow or project into tissue at the implantation site in the patient's body. The catheter is also positioned well away from the upper surface of the apparatus that faces the patient's skin area after the apparatus is implanted. Consequently, there is little likelihood of the catheter being pinched off by tissue ingrowth or being punctured or damaged by an errant needle ostensibly being aimed at opening 22 in order to service the apparatus.

Referring again to FIG. 2, as stated previously, apparatus 10 has a central promontory 18 at the top of the apparatus. This promontory is formed by two header sections and the raised central portion of shell 14. One header section is the aforementioned integral raised section 12*a* at the center of the header 12. The other is a separate header section 12*b* that sits on top of section 12*a*. A relatively large diameter vertical bore or passage 122 is provided in header section 12*a* for snugly seating a cup-shaped needle stop 124. Bore 122 does not extend to the underside of header 12. However, small holes 126 do pass through the bottom wall of bore 122 to the header undersurface inside capsule 36. Needle stop 124 may be made of metal or, more preferably, of a suitable rigid plastic which does not interact with the infusate in apparatus 10 and which is of a hardness to stop a needle or cannula inserted into passage 122 without unduly damaging the tip of the needle or cannula. The bottom wall 124*a* of the needle stop is shaped to leave an annular clearance space 128 between the needle stop and holes 126. Also, that wall is provided with a circular array of tiny holes 132 to conduct infusate from passage 122 and the inside of the needle stop to the clearance space 128, whence it will flow through holes 126 into the bellows capsule 36.

Header section 12*a* also has a counterbore 122*a* that extends down from the top of that section collinearly with passage 122. Seated in the counterbore is a discoid, needle-penetrable, self-sealing septum 134 made of medical grade rubber or the like. The septum 134 seats snugly in counterbore 122*a* so that its upper surface is more or less flush with the upper surface of section 12*a*. Thus, the space inside passage 122 and needle stop 124 below septum 134 constitutes an inlet port 136 for bellows capsule 36, i.e. for infusate reservoir 46 inside the capsule.

The header section 12*b* that seats on section 12*a* is a generally cylindrical annular member 138 having an axial bore or passage 142 extending from the underside of that member almost to the top thereof. A smaller diameter bore extends down from the top of member 138 to form the opening 22 at the top of the apparatus that was described at the outset. Typically, that opening is about one-half inch in diameter. A second discoid septum 144 similar to septum 134 is seated in passage 142 so that it completely fills opening 22. Passage 142 is counterbored from below at 146 to receive an annular spacer 148 which engages under septum 144 and holds the septum in place in member 138. Spacer 148 may be made of the same plastic material as needle stop 124 and for reasons to become apparent shortly, a radial hole or passage 149 is provided through that spacer.

As noted previously, header section 12*b* is designed to seat on header section 12*a*. Accordingly, it is provided with a shoulder 138*a* and a cylindrical skirt 138*b* that extends down and seats in a circumferential notch 152 at the top of section 12*a*. When the two sections are stacked as shown, the spacer 148 separates the two septa 134 and 144 so that a short, generally cylindrical space exists between the two septa which constitutes the second inlet port 154 of apparatus 10. As shown in FIG. 2, inlet port 154 is located directly over inlet port 136 and both ports are accessible through the single opening 22 at the top of the apparatus.

Also as seen from FIG. 2, the underside of the spacer shoulder 138*a* is flared so as to leave an annular clearance space 156 between the shoulder and the top of header section 12*a* which space intercepts both the radial hole 149 in spacer 148 and the passage 83 that extends down through header section 12*a* to the mixing chamber 87. Accordingly, infusate introduced through opening 22 into inlet port 154 is free to flow directly through passage 83 into mixing chamber 87 where it can mix with the infusate from reservoir 46 that enters that chamber by way of capillary tube 76.

After header section 12*b* is secured to section 12*a* by epoxy cement, welding or other suitable means, the upper shell 14 of the apparatus is engaged over the top of the header so that its inner edge seats in a circumferential notch 162 at the top of header section 12*b* and so that its outer edge rests in a circumferential groove 164 at the upper edge of the header periphery. When that shell is secured in place by welding, epoxy cement or the like, the shell protectively encloses the capillary tube 76 and, as noted above, the fill tube 48. It also gives the upper half of apparatus 10, including its promontory 18, a smooth uninterrupted surface and a gently curved contour. In the same manner, the lower shell 16, connected at its edge to the lower edge of the header periphery by weld 32 as described above, protectively encloses bellows capsule 36 and gives the underside of apparatus 10 a similar smooth, gently curved contour so that when the apparatus is implanted, there will be minimal dead spaces created at the exterior surfaces of the apparatus in which body fluids can collect and create potential sites for infections.

The shells 14 and 16 also have a sealing function. As noted above, shell 14 provides sealing redundancy to prevent fluid F leakage through tube 48 from reaching the patient. Both shells minimize the likelihood of leakage of infusate from the apparatus into the patient after

the device has been implanted. That is, the shells are impervious and the welded connections of the shells to the manifold at 32, 162 and 164 are all fluid tight. Therefore, if an infusate leak should develop in the glass tube 76 or in the relatively high pressure bolus flow path, i.e. at plates 102 or header notch 152, the leakage would be contained within the space under shell 14. Similarly, a leak in bellows capsule 36 would only result in infusate flowing into the fluid tight chamber 47. In no event would there be uncontrolled fluid flow from apparatus 10 into the patient at the implantation site.

It is apparent from the above description and from the drawings that all of the vertical fluid pathways in the header 12 consist of vertical holes or passages, e.g. 72, 74, 78, 83, 96, 98 and 122, that can be formed easily and precisely by simple drilling operations. On the other hand, the horizontal pathways through the header are formed by surface grooves and recesses, e.g. 58, 82, 86, 88 and 104, which can be inscribed in the header using standard milling or surface grinding processes. Thus the design lends itself to automated manufacture of the apparatus. Indeed, for some applications, it is even possible to mold header 12 (sans section 12*b*), with all of its various passages and recesses in a single molding operation.

It is worthy of note also that all of the other apparatus 10 parts, such as bellows capsule 36, filter member 62, the glass capillary tube 76, and cover plates 85 and 102 are all mounted directly to the header 12 at precisely defined locations so that there is no possibility of mispositioning those parts during assembly. This helps to insure that infusion apparatus 10 can be produced in quantity on a reliable basis and with few rejects.

After apparatus 10 is implanted in the body with its opening 22 located directly under the patient's skin and the distal end 24*b* of catheter 24 positioned at the selected infusion site, the apparatus' infusate reservoir 46 may be filled with infusate by inserting a hollow needle (Huber tip), such as the needle shown in phantom at 168 in FIG. 2, through the patient's skin over opening 22 and through septa 144 and 134, in turn, until the needle tip bottoms against the needle stop 124. The needle is provided with an outlet opening 168*a* adjacent to the tip so that when the needle bottoms against the needle stop as shown in FIG. 2, the opening 168*a* is level with inlet port 136. Accordingly, infusate flowed into needle 168 will enter port 136 and flow into capsule 36, i.e. reservoir 46, by way of holes 132 and 126.

During the filling operation, a predetermined volume of infusate is injected under pressure into the bellows capsule. This causes the capsule to extend and, in the process to compress the two-phase fluid F in the compartment 47 inside shell 16 so that that fluid assumes its liquid phase, thereby recharging the apparatus' pumping power source in a manner well known in this art. A similar needle 168 can be used to empty fluid from bellows capsule 36 or to refill the capsule with fresh infusate. At the body temperature of the patient, the two-phase fluid F will exert sufficient vapor pressure to collapse capsule 36, thereby forcing infusate I_1 from reservoir 46 through the filter member 62 and capillary tube 76 to mixing chamber 87 and thence to catheter 24 as described above.

In order to access the apparatus' second inlet port 154, a needle shown in phantom at 172 in FIG. 2 is inserted through the patient's skin and through septa 144 and 134 until the tip of that needle bottoms against the needle stop 124. Needle 172 has a side opening 172*a* that is aligned with inlet port 154 when the needle is fully inserted into the apparatus as shown in FIG. 2. Thus the needle 172 can be used to inject a second infusate I_2 into the inlet port 154 whence that liquid will flow directly to mixing chamber 87 where it will mix with the infusate I_1 being pumped from capsule 36 so that a selected mixture of infusates I_1 and I_2 will be delivered to the infusion site by way of catheter 24. Since mixing chamber 87 is downstream from the flow restricting capillary tube 76 and the fluid pathway from the mixing chamber to catheter 24 is comparatively large, there is minimal possibility of the infusate I_2 being conveyed back into bellows capsule 36 containing infusate I_1.

In some instances, it may be desirable to provide a check valve in the flow path from the second inlet port 154. Such a valve is shown at 190 in FIG. 2. It ensures that if a leak should occur in the inner septum 134, the infusate leaking from reservoir 46 into port 154 would not be able to follow the unrestricted flow path through passages 83, 87, 88, etc. to catheter 24. Such a valve 190, e.g. a conventional spring-loaded ball valve, is arranged to open or unseat under a pressure in port 154 that is greater than the vapor pressure of the fluid in compartment 47. In other words, the valve opens only when infusate is being forceably injected into port 154 via needle 172 under a pressure appreciably greater than that exerted by the two phase fluid in compartment 47. Also, if a leak should develop in the outer septum 144, valve 190 will prevent infusate outflow from passage 83.

In actual practice, the needles 168 and 172 may be separate needles or they may be incorporated into a single needle unit having two flow paths or lumens whose outlet openings are spaced apart on the needle unit so that they open into the inlet ports 136 and 154 respectively, as described above. Thus apparatus 10 can be used, for example, to deliver a basal dose of insulin at a controlled, very low flow rate to a patient, with such basal dose being supplemented from time to time by a bolus dose of infusate injected into inlet port 154. If a dual lumen needle unit is used, liquids may be introduced into or withdrawn from inlet ports 136 and 154 independently and simultaneously after only a single puncture of the patient's skin.

Because opening 22 is quite large and is centered in the raised promontory 18 whose location can be determined readily by pressing against the patient's skin, apparatus 10 can be accessed quite quickly and with minimum discomfort to the patient in whom the apparatus is implanted. Since apparatus 10 controls such access so as to prevent each lumen of the needle unit from conducting liquid into the wrong inlet port of the apparatus, there is little likelihood of the patient being given the wrong medication.

While we have depicted and described in detail infusion apparatus having a single infusate reservoir served by an inlet port 136 and with a second inlet port 154 for conducting a second infusate directly to the same infusion site, it is obvious that the principles disclosed here can be extended to other implantable infusion devices.

Our apparatus design also lends itself to the incorporation of a second outlet catheter leading from housing 12. FIGS. 4 and 5 illustrate implantable infusion apparatus 202 which has two outlet catheters 24 and 24' for conducting infusate simultaneously to two different sites in the body, e.g. an artery and a vein. Apparatus 202 is similar to apparatus 10 described above except that it has two capillary tubes 76, 76' leading from filter

recess 58 via separate flow paths 204, 204' in manifold 12 to separate vertical holes 94, 94' communicating with two separate passages 110, 110' extending from opposite ends of plug 108 to two different plug waist segments 108a, 108a'. Note that both catheters exit housing 12 tangentially and below the edge of shell 14 for the reasons discussed above.

The outlet passage 149 from the bolus inlet port 154 leads to separate vertical passages 83, 83' in header 12, containing separate check valves 190, 190'. With this arrangement, infusate will flow from capsule 36 to catheters 24 and 24'. Because arterial pressure is higher than venous pressure, the tubes 76, 76' have different high resistance flow restrictions to equalize infusate flow to the artery and vein. These regulated infusate flows may be supplemented when necessary by bolus injections into port 154. The bolus flow to the catheters may also be proportioned by downstream flow restrictors (not shown). The two check valves 190, 190' prevent unwanted blood flow from the artery to the vein due to the blood pressure differential in those blood vessels.

Apparatus 202 may also be modified easily to have a single dual lumen outlet catheter such as catheter 206 in FIG. 6. In this event, plug 108 would have parallel passages 110 and 110' connecting plug waists 108a, 108a' to the catheter lumens 206a, 206b.

Of course, if in apparatus 202 a bolus capability is needed at only one of the catheters or only one of the catheter lumens, e.g. 24, 206a, the passage 83' and its valve 190' may be eliminated.

FIG. 6 shows an implantable device 210 similar to apparatus 10 but fitted with a single dual lumen catheter 206. When the catheter is placed at a selected infusion site, i.e. a blood vessel, infusate from capsule 37 may be flowed to that vessel through catheter lumen 206a, while at the same time, blood may be withdrawn from the vessel via catheter lumen 206b by a suction needle inserted into inlet port 154. As shown in FIG. 6, the outlets of the two lumens may be spaced apart along the catheter so that the blood is withdrawn from the blood vessel upstream from the infusion site.

A similar arrangement using either a dual lumen catheter or two separate catheters may be used to infuse a patient while having the capability of monitoring the patient's blood pressure. For this, a standing column of saline or other biocompatible liquid is maintained in the fluid path from inlet port 154 to its catheter lumen and a needle-like pressure transducer is inserted into port 154 to transmit the blood pressure variations coupled to it by the liquid column to an external pressure monitor.

This invention can also be incorporated into a dual-chamber pump of the type described in the aforementioned U.S. Pat. No. 4,193,397. In this event, the inlet port 154 would be connected by fluid pathways in the header 12 to a second bellows capsule inside shell 16 constituting the reservoir for a second infusate. Indeed, implantable pumping or portal apparatus may be provided with three or more inlet ports stacked in the manner described, with those ports being accessed independently by a needle unit having a corresponding number of flow paths or lumens, each one of which opens into a different one of the inlet ports.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained, and since certain changes may be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.

What is claimed as new and desired to be secured by Letters Patent of the United States is:

1. Implantable infusion apparatus comprising

a hermetically sealed housing, said housing including a pronounced outwardly projecting promontory positioned at or near the center of the housing away from the periphery thereof;

a passage into said housing at said promontory;

needle stop means at the end of said passage inside said housing;

a first needle-penetrable, self-sealing septum mounted in said passage at a selected spacing from said needle stop means, said first septum being located at the outer surface of said housing at the top of said promontory;

a second septum mounted in said passage at a selected spacing from said first septum thereby to divide said passage into a first segment extending between said needle stop means and said first septum and a second aligned segment extending between said first septum and said second septum;

first and second fluid outlets from said first and second passage segments;

a pumpable infusate reservoir inside said housing in fluid communication with one of said fluid outlets, the other of said fluid outlets being in fluid communication with fluid flow means extending within said housing;

a catheter extending from the housing for conducting fluid from said apparatus to an infusion site; and

a conduit in said housing for conducting fluid from said reservoir to said catheter.

2. The apparatus defined in claim 1 wherein the other of said fluid outlets is also in fluid communication with said catheter.

3. The apparatus defined in claim 2 wherein

A. said catheter is a dual lumen catheter;

B. said conduit is in fluid communication with one lumen of said catheter; and

C. said other of said outlets conducts fluid to the other lumen of said catheter.

4. The infusion apparatus defined in claim 2 wherein said conduit from said reservoir to said catheter includes a filter and a fluid flow restrictor.

5. The infusion apparatus defined in claim 4 wherein the flow restrictor comprises a length of glass capillary tubing.

6. The infusion apparatus defined in claim 4 wherein

A. said conduit also includes a mixing chamber downstream from said flow restrictor; and

B. the other of said fluid outlets leads to said mixing chamber, so that while a first fluid is being expelled from said pumpable reservoir to said mixing chamber, a second fluid introduced into said second passage segment will flow to and be mixed in said mixing chamber with said first fluid so that a fluid mixture will be conducted to the catheter.

7. The apparatus defined in claim 7 wherein said pumpable infusate reservoir includes

A. a collapsible infusate chamber; and

B. means for collapsing the chamber to force infusate from the chamber through said conduit to said catheter.

8. The apparatus defined in claim 7 wherein the collapsing means comprise a two-phase fluid confined inside said housing adjacent to said chamber, said fluid

exerting sufficient vapor pressure at physiological temperatures to collapse said chamber.

9. The apparatus defined in claim 1 wherein said housing is generally circular and said catheter exits said housing substantially tangentially.

10. The apparatus defined in claim 1 and further including

A. a second catheter, said second catheter exiting said housing substantially tangentially and collinearly to said catheter; and

B. means for conducting fluid from the other of said fluid outlets to said second catheter.

11. The apparatus defined in claim 1 wherein said pumpable infusate reservoir comprises

A. rigid manifold means inside the housing;

B. a collapsible metal bellows capsule having an open end mounted to the manifold means, the opposite end of the capsule being closed; and

C. means in the housing for collapsing the bellows capsule.

12. The apparatus defined in claim 1 wherein

A. said passage, said outlets and at least a portion of said conduit are formed in said manifold means; and

B. said needle stop, septa and catheter are all mounted to said manifold means adjacent to the open end of said bellows capsule.

13. The apparatus defined in claim 12 wherein the open end of the bellows capsule is recessed into a circular groove with an open edge formed in said manifold means.

14. Implantable infusion apparatus comprising:

a hermetically sealed housing;

a passage into said housing;

needle stop means at the end of said passage inside said housing;

a first needle-penetrable, self-sealing septum mounted in said passage at a selected spacing from said needle stop means;

a second septum mounted in said passage at a selected spacing from said first septum thereby to divide said passage into a first segment extending between said needle stop means and said first septum and a second aligned segment extending between said first septum and said second septum;

first and second fluid outlets from said first and second passage segments;

a pumpable infusate reservoir inside said housing in fluid communication with one of said fluid outlets, said reservoir including rigid manifold means inside the housing, means defining a circular groove with an open edge in said manifold means, a collapsible metal bellows capsule having an open end recessed into said groove, the opposite end of said capsule being closed, and means for mounting said bellows open end to said manifold means, said mounting means comprising a

bracket including an annular body having an inner edge seated in said groove and a cylindrical flange having a free edge extending from the periphery of said body to the open edge of said groove,

the inner edge of said body being connected by a continuous weld to the open end of said bellows capsule and

the free edge of said flange being connected by a continuous weld to said open edge of said groove in the manifold means,

means in said housing for collapsing the bellows capsule;

a catheter extending from the housing for conducting fluid from said apparatus to an infusion site, and

a conduit in said housing for conducting fluid from said reservoir to said catheter, said passage, said outlets and at least a portion of said conduit being formed in said manifold means, and said needle stop, septa and catheter all being mounted to said manifold means adjacent to the open end of said bellows capsule.

15. Implantable infusion apparatus comprising:

a hermetically sealed housing;

a passage into said housing;

needle stop means at the end of said passage inside said housing;

a first needle-penetrable, self-sealing septum mounted in said passage at a selected spacing from said needle stop means;

a second septum mounted in said passage at a selected spacing from said first septum thereby to divide said passage into a first segment extending between said needle stop means and said first septum and a second aligned segment extending between said first septum and said second septum;

first and second fluid outlets from said first and second passage segments;

a pumpable infusate reservoir inside said housing in fluid communication with one of said fluid outlets, said reservoir including rigid manifold means inside the housing, means defining a circular groove with one open edge in said manifold means, a collapsible metal bellows capsule having an open end recessed into said groove, the opposite end of the capsule being closed, and means for mounting said bellows open end to said manifold means at said groove;

means in the housing for collapsing the bellows capsule;

a catheter extending from the housing for conducting fluid from said apparatus to an infusion site,

said manifold means being disk-shaped and

said circular groove being located eccentric to the circular periphery of said manifold means so that the groove is displaced away from said catheter,

and a conduit in said housing for conducting fluid from said reservoir to said catheter, said passage, said outlets and at least a portion of said conduit being formed in said manifold means and said needle stop, septa and catheter all being mounted to said manifold means adjacent to the open end of said bellows capsule.

16. The apparatus defined in claim 1 and further including flow check means for preventing fluid flow from said other of said fluid outlets to said second passage segment.

17. Implantable infusion apparatus comprising:

a rigid discoid header having opposite first and second surfaces;

A circular groove in said header second surface;

a collapsible bellows capsule having a closed end and an open end;

mounting means for mounting said bellows open end to said header second surface, said mounting means including an annular bracket having a peripheral flange and radially inner and outer edges, the inner edge of said bracket being connected along its entire circular length to the capsule open end, said

bracket and said capsule open end being seated in said groove so that said flange extends adjacent to the radially outer wall of said groove and connecting means connecting said bracket outer edge along its entire circular length to said header all around said groove;

a first passage in said header extending between said header surfaces opposite the bellows capsule;

a second passage extending into said header from the periphery thereof;

a liquid conduit extending from said first passage to said second passage;

a self-sealing inlet port in said header opposite the bellows capsule, said inlet port being accessible from said header first surface, and fluid conduit means extending between said inlet port and the interior of said capsule.

18. The apparatus defined in claim 17 wherein said capsule is made of a biocompatible metal and said connections are welds.

19. The apparatus defined in claim 17 wherein said liquid conduit includes a length of flow-restricting glass tubing.

20. The apparatus defined in claim 17

A. wherein said second passage extends along a chord of said header; and

B. further including a flexible catheter having one end secured in a fluid-tight manner in said passage so that the catheter extends from the periphery of the apparatus more or less tangentially.

21. The apparatus defined in claim 17 wherein

A. said header includes a central mesa at said header first surface, said mesa having a central perpendicular axis; and

B. said inlet port is located in said mesa.

22. The apparatus defined in claim 21 further including

A. a smoothly contoured cup-like first shell mounted to said header second surface at the periphery thereof, said first shell defining with said header a first fluid-tight compartment that contains said capsule; and

B. a second smoothly contoured annular shell mounted to said header first surface, said second shell covering said second surface except at said inlet port and defining with said header a second fluid-tight compartment that overlies said first and second passages and said conduit.

23. The apparatus defined in claim 22 wherein said liquid conduit includes a length of flow restricting glass tubing wound around said mesa in said second compartment.

24. The apparatus defined in claim 23 wherein

A. said liquid conduit also includes a third passage in said header extending between said second passage and a location at said header first surface in said second compartment; and

B. said tubing is connected between said first and said third passages.

25. The apparatus defined claim 22

A. wherein said second passage extends along a chord of said header spaced from the outer edge of said second shell and has opposite ends spaced apart on the header periphery; and

B. further including a first catheter having one end in fluid-tight communication with one end of said second passage and a second catheter having one end in fluid-tight communication with the other end of said second passage so that said catheters extend more or less tangentially from the apparatus in opposite directions.

26. The apparatus defined in claim 22 and further including

A. a second self-sealing inlet port in said header, said second port being aligned along said axis in said mesa with said first port; and

B. liquid conducting means in said header extending from said second inlet port to said liquid conduit.

27. The apparatus defined in claim 26 wherein

A. said conduit includes a liquid flow restriction; and

B. said conducting means join said liquid conduit downstream from said flow restriction.

28. The apparatus defined in claim 27 and further including a check valve in said conducting means to prevent back flow into said second inlet port.

29. The apparatus defined in claim 26 and further including a check valve in said conducting means to prevent back flow into said second inlet port.

30. The apparatus defined in claim 22 and further including means accessible at said header second surface for flowing a two-phase fluid that vaporizes at physiological temperatures into said second compartment.

31. The apparatus defined in claim 22 and further including a plurality of suture loops attached to the outside of said header periphery at spaced apart locations therearound.

32. The apparatus defined in claim 17 and further including

A. a second self-sealing inlet port in said header, said second port being vertically aligned with said first port and accessible from the header second surface;

B. a liquid passage in said header extending from said second inlet port to the periphery of the header;

C. a first catheter having one end in fluid tight communication with said second passage at the header periphery; and

D. a second catheter having one end in fluid tight communication with said liquid passage at the header periphery.

33. The apparatus defined in claim 32 and further including a standing column of a biocompatible liquid filling said second inlet port, said liquid passage and said second catheter for transmitting pressure pulses from the opposite end of said catheter to said second inlet port for sensing by a needle-like pressure transducer inserted into said second inlet port.

34. Implantable infusion apparatus comprising

a rigid manifold having opposite first and second surfaces and a pronounced outwardly projecting mesa positioned at or near the center of said second surface away from the periphery thereof, said mesa having a central perpendicular axis;

a collapsible fluid-tight infusate chamber having a closed end and an open end;

means for mounting the chamber open end in a fluid-tight manner to the manifold first surface opposite said mesa;

a self-sealing inlet port in said manifold mesa, said inlet port being accessible from the manifold second surface at the top of said mesa; fluid conduit means extending between said inlet port and the interior of said chamber; and

a first outlet conduit communicating between said manifold first surface inside said chamber and the manifold periphery.

35. Implantable infusion apparatus comprising

a rigid manifold having opposite first and second surfaces and a central mesa at said second surface, said mesa having a central perpendicular axis;

a collapsible fluid-tight infusate chamber having a closed end and an open end;

means for mounting the chamber open end in a fluid-tight manner to the manifold first surface opposite said mesa;

a self-sealing inlet port in said manifold mesa, said inlet port being accessible from the header second surface at the top of said mesa;

fluid conduit means extending between said inlet port and the interior of said chamber;

a first outlet conduit communicating between said manifold first surface inside said chamber and the manifold periphery;

a second self-sealing inlet port in said manifold mesa, said second inlet port being in alignment along said axis with said first inlet port and accessible from the manifold second surface at the top of said mesa; and

a second outlet conduit in said manifold communicating between said second inlet port and the periphery of said manifold.

36. The apparatus defined in claim 35 wherein first and second outlet conduits join in said manifold to form a Y-conduit that has a single outlet at the periphery of the manifold and which receives fluid from both said chamber and said second inlet port.

37. The apparatus defined in claim 36 and further including a check valve in said Y-conduit downstream from the joint with said first outlet conduit to prevent fluid back flow into said second inlet port.

38. The apparatus defined in claim 37 and further including a fluid flow restrictor in said Y-conduit upstream from the joint with said second outlet conduit.

39. The apparatus defined in claim 38 wherein said Y-conduit includes

A. a first manifold passage extending into said chamber;

B. a second manifold passage extending into the manifold from the periphery thereof; and

C. a flow-restricting glass capillary tube wound around said mesa and connected between said first and second passages.

40. The apparatus defined in claim 35

A. wherein first and second outlet conduits have separate outlets located adjacent to the periphery of said manifold; and

B. further including first and second catheters having corresponding first ends connected to said first and second conduits respectively.

41. The apparatus defined in claim 35 and further including a dual-lumen catheter having a first end connected to the periphery of said manifold, the two lumens of said catheter being in fluid communication with different ones of said outlet conduits.

42. The apparatus defined in claim 35

A. wherein said first outlet conduit branches to form a Y-conduit that has first and second outlets at spaced-apart locations on the periphery of said manifold; and

B. further including a pair of catheters having corresponding first ends connected to said header periphery and being in fluid communication with said first and second outlets respectively; a first check valve connected between said second outlet conduit and one branch of said Y-conduit, and a second check valve connected between said second outlet conduit and the other branch of said Y-conduit, both of said valves preventing back flow from the Y-conduit into said second conduit.

43. The apparatus defined in claim 42 and further including a flow restrictor in each branch of said Y-conduit upstream from the said check valve connected thereto.

44. The apparatus defined in claim 42 wherein said catheters are connected to the header so that they extend more or less tangentially from the apparatus.

45. The apparatus defined in claim 33 and further including

A. a smoothly contoured cup-like first shell mounted to said header first surface at the periphery thereof, said first shell defining with said header a first fluid-tight compartment that contains said infusate chamber; and

B. a second smoothly contoured annular shell covering said manifold second surface except that the access to said inlet ports, said second shell being connected to said manifold periphery and said mesa so that the second shell defines with said manifold a second fluid-tight compartment that overlies said first and second outlet conduits.

* * * * *

Exhibit

B

United States Patent [19]
Enegren et al.

[11] **Patent Number: 4,955,861**
[45] **Date of Patent: Sep. 11, 1990**

[54] **DUAL ACCESS INFUSION AND MONITORING SYSTEM**

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[73] Assignee: **Therex Corp., Walpole, Mass.**

[21] Appl. No.: **184,352**

[22] Filed: **Apr. 21, 1988**

[51] **Int. Cl.**[5] **A61M 1/00**
[52] **U.S. Cl.** **604/141**; 604/411; 604/93; 604/175
[58] **Field of Search** 604/93, 175, 48, 131, 604/140, 141, 891.1, 44, 45, 411, 414; 141/329, 330

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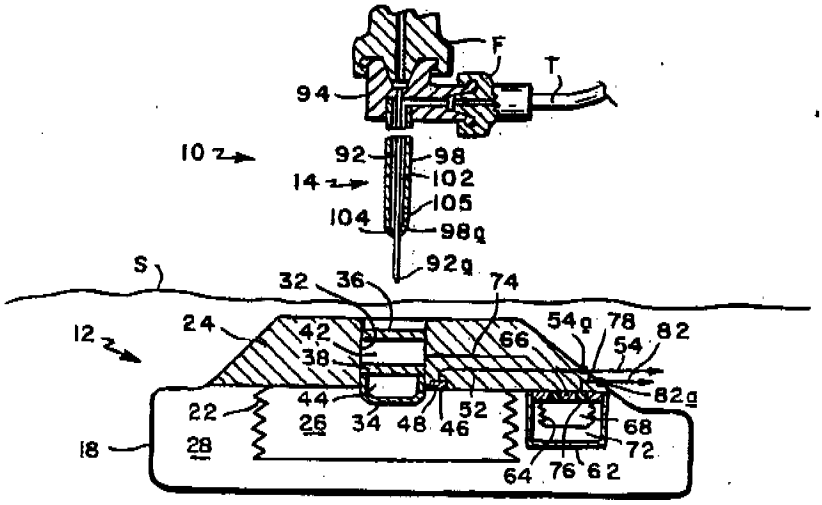
Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Kathleen A. Daley
Attorney, Agent, or Firm—Nutter, McClennen & Fish

[57] **ABSTRACT**

A dual access infusion or monitoring system comprises implantable apparatus and an injection needle. This system enables one to introduce into or withdraw from the apparatus, after it is implanted, a plurality of fluids simultaneously with only a single penetration of the patient's skin. The implantable apparatus includes a sealed housing with an inlet passage extending into the housing which passage has an outer end adjacent to the housing surface and an inner end located inside the housing. A needle stop is positioned at the inner end of that passage and self-sealing septa are mounted at different locations along the passage at selected spacings from the needle stop so as to divide the passage into aligned compartments or segments each of which has its own fluid outlet. The injection needle includes a plurality of lumens, the number of same corresponding to the number of different compartments in the apparatus housing. The proximal ends of the lumens are connected to different passages in a hub and the lumens have outlet openings spaced at different locations along the needle from the needle tip in correspondence with the spacings of the housing passage compartments so that when the needle is inserted into the housing passage through the septa until the needle bottoms on the needle stop, each outlet opening in the needle will be positioned in a different compartment in the housing passage, with all of the needle openings being isolated in a fluid-tight manner from one another and from the atmosphere by at least one septum.

11 Claims, 1 Drawing Sheet



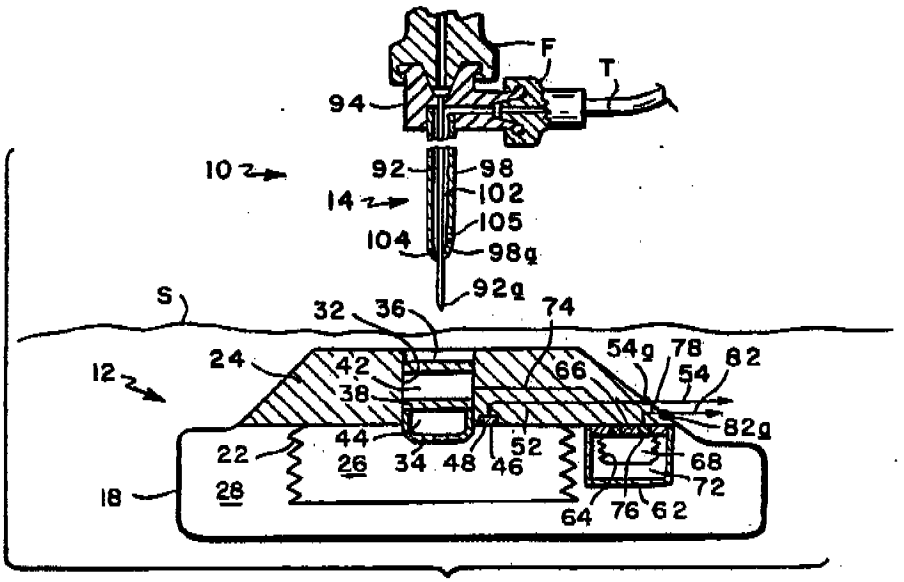


FIG. 1

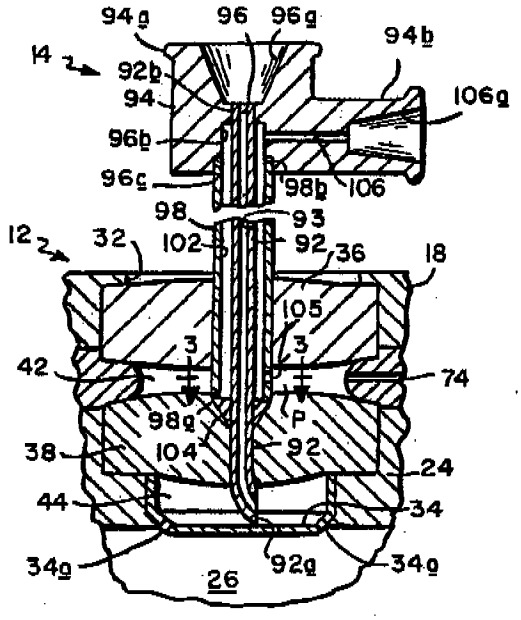


FIG. 2

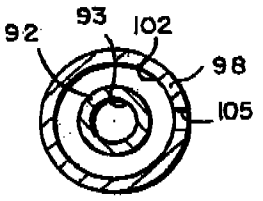


FIG. 3

DUAL ACCESS INFUSION AND MONITORING SYSTEM

This invention relates to an implantable infusion or monitoring system. It relates more particularly to means for accessing simultaneously from outside the body two or more inlet ports of an implanted infusate pump or portal and thereby two or more infusion or monitoring sites within the body.

BACKGROUND OF THE INVENTION

Over the last ten years or so, drug infusion pumps have been developed which can be implanted in the body and remain there for a relatively long period of time to dispense small measured doses of medication to a selected infusion site in the body. The pump chamber can be refilled with infusate without having to remove the pump from the body by injecting additional infusate transcutaneously through a penetrable septum in the pump wall which septum is located directly under the patient's skin. In some pumps, the refilling of the device also recharges the device's power source. The main advantage of dosing devices of this type is that medication can be routed to the site where it is needed, rather being injected into the bloodstream so that it spreads throughout the body.

Some implantable infusion apparatus have dual pumping chambers enabling them to dispense different infusate concentrations or even different infusates to the same or different infusion sites in the patient's body. The two pumping chambers are purged and refilled independently by way of separate inlet ports at different locations on the pump wall, each port having its own needle-penetrable septum located underneath the patient's skin. An example of this type of pump is disclosed in U.S. Pat. No. 4,258,711.

Another known implantable infusate-dispensing apparatus has, instead of a second pumping chamber, an injection portal incorporated into the pump wall. This portal is basically a chamber with an outlet tube leading to an infusion site in the patient's body and an inlet port closed by a needle-penetrable septum located underneath the patient's skin and which is accessible by transcutaneous injection. This type of device dispenses a continuous flow of infusate to the patient. Then, if a bolus dose or supplemental medication is required, this is administered by percutaneous injection into the portal. Such a device can also be used for blood withdrawal. Apparatus of this type is shown, for example, in U.S. Pat. No. 4,496,343.

In some cases, a patient's drug protocol may call for periodic injection of two different drugs over a long period of time. In this event, such a patient might be fitted with two or more implanted injection portals so that a particular infusate can be supplied to two different sites in the body or so that different drugs can be routed to the same infusion site.

It is apparent from the foregoing that once these implantable pumps and portals have been surgically implanted in the patient's body, the positions of their various inlet ports are more or less fixed with respect to the overlying skin area of the patient. Therefore, each time the physician must inject additional infusate into a particular inlet port in the implanted apparatus, he must penetrate or puncture the skin at substantially the same location. Over a period of time, then, a patient may

receive many such needle penetrations in order to service the implanted device.

In this connection, we should mention that when introducing infusate into an implanted pump or portal, the normal procedure is to insert a cannula or needle into that device's inlet port and allow the drug in the reservoir to flow out (i.e. the reservoir is at a higher pressure than the needle or cannula lumen). Then, when the reservoir is empty, a fixed volume of the fresh infusate is injected into the pump or portal through the needle, after which the needle is withdrawn. It is apparent, therefore, that this refilling procedure is a time consuming process that requires the patient to remain still while the needles penetrating his body introduce and/or drain the various fluids from the infusion device implanted in his body. In many instances this procedure is performed in a clinic or physician's office or on a hospital outpatient basis. Therefore, each office visit can be quite time consuming and expensive.

Another disadvantage of the prior techniques for servicing plural port implantable devices of this general type is their propensity for being refilled with the wrong fluid. More particularly, after the device is implanted, its position may change somewhat relative to a fixed spot on the patient's skin surface due to changes in the patient's body weight, for example. Therefore, when refilling or purging the device, it is quite easy for a nurse to insert a needle into the wrong inlet port if she is not very careful. In a dual-chamber infusate pump, for example, this could result in the basal reservoir of the pump being refilled with bolus infusate and the bolus reservoir being charged with lower concentration basal infusate, or it could result in one reservoir of that pump being emptied and filled twice and the other reservoir not being serviced at all.

It would be desirable, therefore, if the number and duration of transcutaneous injections required to access or to service an implanted pump or portal could be minimized, along with the potential for servicing errors. This would not only reduce the risk of infection to the patient, it would also reduce the incidence of epidermal problems associated with implanted access or drug infusion devices of this type, and it would certainly reduce the physical and emotional stress on a patient required to have such an implanted device.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide an improved implantable dual-access infusion or monitoring system.

Another object of the invention is to provide improved means for accessing simultaneously two or more internal infusate chambers of an implantable infusion device.

A further object of the invention is to provide a needle or cannula for accessing simultaneously at least two internal chambers of an implantable infusion apparatus.

Another object is to provide apparatus for enabling individual access from without simultaneously to a plurality of sites inside a patient's body.

Still another object is to provide apparatus of this type which prevents a nurse or physician from accessing the wrong internal chamber of the implanted apparatus when servicing the apparatus.

Yet another object of the invention is to provide apparatus which minimizes the number and duration of skin penetrations or punctures required to properly

service a plural-chamber implantable infusion device by transcutaneous injection into the device.

Other objects will, in part, be obvious and will, in part, appear hereinafter.

The invention accordingly comprises the features of construction, combination of elements and arrangement of parts which will be exemplified in the following detailed description, and the scope of the invention will be indicated in the claims.

Briefly, in accordance with this invention, the two or more inlet ports of a plural-chamber infusion pump or access portal are stacked one over the other and are isolated from one another by spaced-apart, needle-penetrable septa so that all of the ports in the implanted device are located at different levels underneath the same spot on the patient's skin.

In addition, injection means are provided which have at least two parallel fluid paths or lumens. The lumens have separate inlets which permit fluid to be introduced into or withdrawn from each needle flow path or lumen independently or to be monitored independently. The injection means lumens also have separate outlets which are located at different elevations on the injection means. Moreover, the spacing along the injection means between the outlets is related to the spacings of the stacked inlet ports in the implanted device so that when the injection means are punctured through the patient's skin into the device through the latter's penetrable septa, the outlet of each lumen will automatically be in fluid communication only with the proper one of the implanted device's inlet ports.

Thus, with a single puncture of a patient's skin, all chambers of a plural-chamber implanted device or portal can be accessed independently at the same time. For example, if the implanted device is a dual chamber infusion pump, the two injection needle inlets can be connected to two different infusate sources so that the two chambers of the implanted device can be filled simultaneously with different drugs. Alternatively, if one needle inlet is connected to an infusate source and the other inlet is connected to a source of negative pressure, one apparatus chamber can be filled with fresh infusate while old infusate is being withdrawn from the other chamber. As still another example, for an implanted device in which one inlet port leads to an infusate chamber and the other inlet port constitutes an injection portal leading to an infusate site in the patient's body, a bolus dose of infusate can be infused into the patient via the injection needle and the portal, while the pump chamber is being flushed out or refilled.

In all of these examples, the combination of the dual channel injection means and the implanted dual chamber infusion apparatus with stacked inlet ports permits two independent operations to be performed simultaneously on the implanted device with a single needle penetration. Although our apparatus allows simultaneous access to all of the internal chambers of the implanted device, one does not, of course, have to perform the flow operations simultaneously. The point is that our apparatus reduces the number of skin punctures necessary to service the implanted apparatus, it also reduces the length of time that the patient has to be inconvenienced by needles or cannulae penetrating his epidermis. This should, in turn, make the wearing of such an implanted device much more bearable to the patient.

It is important to note also that since the injection means or needle fluid paths are "keyed" to the stack of inlet ports in the implanted apparatus by the unique placement of each one of the corresponding needle opening-port pairs, there is no possibility of the injection means accessing the wrong chamber of the apparatus.

The needle-apparatus combination comprising our invention also allows individual access from outside the body simultaneously to a plurality of monitoring sites inside the body for monitoring the same or different variables at those sites, e.g. pressure, temperature, sugar level, etc.

BRIEF DESCRIPTION OF THE DRAWING

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description, taken in connection with the accompanying drawing, in which:

FIG. 1 is a diagrammatic view of a dual-access infusion system embodying the invention; and

FIG. 2 is a view in vertical section and on a much larger scale, showing the FIG. 1 apparatus in greater detail.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1 of the drawing, the present system, shown generally at 10, comprises an implantable dual-chamber infusion or pumping apparatus 12 and a dual-channel injection needle or cannula unit 14 for servicing apparatus 12 after the apparatus is implanted. Apparatus 12 includes a generally cylindrical housing 18 which is in the order of two inches in diameter and one-half inch thick and is made of a biocompatible material such as titanium. Positioned within the container is a bellows capsule 22 having an open end mounted to a header 24 constituting the upper wall of housing 18, the opposite end of the capsule being closed. Thus the capsule defines an infusate chamber 26 inside the capsule and a second chamber 28 outside the capsule, but inside housing 18 which contains a known two-phase fluid which vaporizes at physiological temperatures, e.g. 98.6°.

As shown in FIG. 2, formed in the upper wall of the housing and extending down into the header is a passage 32 which communicates with chamber 26 by way of holes 34*a* in a needle stop 34 at the lower end of the passage. The outer or upper end of passage 32 is closed by a needle-penetrable septum 36. A second septum 38 is positioned midway along the passage thereby dividing it into an upper or outer compartment 42 and a lower or inner compartment 44. Thus, the lower compartment 44 is in fluid communication with chamber 26 by way of the needle stop holes 34*a*, but it is isolated from the other compartment 42 by the fluid-tight septum 38. The outer compartment 42, on the other hand, is isolated by septa 38 and 36 from compartment 44 and the region outside housing 18, respectively. Referring again to FIG. 1, formed in header 24 is an outlet port 46 from capsule 22 which contains a filter 48. In the illustrated apparatus 12, the port 46 communicates with an outlet conduit or passage 52 in header 24 which leads to the outer surface of the housing where it is connected to one end 54*a* of a catheter 54. Usually passage 52 includes a fluid restriction to regulate the flow of fluid through the catheter.

The apparatus 12 specifically illustrated herein also has a separate compartment 62 inside housing 18 which contains a second bellows capsule 64 having an open

end mounted to a header 66 at the top of compartment 62, with the opposite end of capsule 64 being closed. Thus, capsule 64 defines an infusate chamber 68 inside the capsule and a second chamber 72 outside the capsule, but inside compartment 62 for containing a two-phase fluid similar to that in chamber 28. Fluid communication is established between the compartment 42 located between septa 36 and 38 and chamber 68 inside bellows capsule 64 by a passage 74 in housing header 24. Also, an outlet port 76 in header 66, which port may include a filter similar to filter 48 and a flow restriction communicates with a conduit or passage 78 in header 24, which leads to the outside surface of housing 18 where it connects to one end 82a of a catheter 82.

Thus, in the illustrated apparatus 12, the passage compartment 42 between septa 36 and 38 constitutes an inlet port for bellows capsule 64, while the inner compartment 44 below septum 38 constitutes an inlet port for bellows capsule 22.

In use, apparatus 12 is implanted in the patient's body, e.g. in a subcutaneous pocket in the patient's abdominal wall and it is positioned so that its septum 36 is located directly underneath the patient's skin S. Catheters 54 and 82 may lead to the same infusion site in the patient or to different sites depending upon the particular patient's physical problems. Bellows chambers 26 and 68 may be filled with the same infusates in different concentrations or with different drugs. Chambers 28 and 72 are filled with two-phase fluids which vaporize at physiological temperatures so that they exert a pressure on bellows capsules 22 and 64, respectively, tending to collapse them. These forces tend to expell the infusates from the capsules through their respective outlet passages 52 and 78 to catheters 54 and 82 respectively. The operation of such pumps with fluid power cells is well known from U.S. Pat. No. 3,731,681, as well as from the patents identified above. Also, although catheters 54 and 82 are shown separately in the drawing, they could just as well be the two lumens of a double lumen catheter of the type sold, for example, by HDC Corporation, Mountain View, California (Stock No. 330-12).

When the supply of infusate in chamber 26 is exhausted, the chamber can be refilled by injecting fresh infusate transcutaneously into passage compartment 44 using needle or cannula unit 14. The extension of the bellows capsule 22 that occurs during the refilling operation exerts a pressure on the two-phase fluid in chamber 28 causing that fluid to condense thereby recharging the fluid power cell that collapses capsule 22 as described in the above patents.

In like manner, when the bellows capsule 64 is empty of infusate, it can be refilled and its power cell recharged using needle unit 14 by injecting fresh infusate into passage compartment 42 which constitutes the inlet port for the bellows chamber 68.

The implantable apparatus 12 specifically depicted herein is a dual-chamber pump with two outlet catheters which enables the apparatus to independently pump the same infusate to different infusion sites in the patient's body or different infusates to the same infusion site, with the bellows capsules 22 and 64 being emptied and refilled independently of one another. Apparatus 12 may also be of the type described in the above-mentioned U.S. Pat. No. 4,258,711 which has only a single outlet catheter that delivers the infusates from both pump chambers 26 and 68 to the same infusion site. In this event, the outlet passage 78 from chamber 68 would join outlet passage 74 from chamber 26 at a Y-connection so that fluids flowing along both of those paths would be routed to the single catheter 54. Alternatively, the outlets from the two chambers may be routed to a double lumen catheter of the type described above.

Still another apparatus enbodiment may be arranged to dispense basal and bolus infusate doses in the manner of the device described in the aforementioned U.S. Pat. No. 4,496,343. That apparatus pumps a basal dose of infusate in a controlled manner to the patient, with such basal dose being supplemented from time to time by a bolus dose injected directly into a portal leading to the infusion site. To modify apparatus 12 to operate in this fashion, compartment 62, capsule 64 and the outlet catheter 82 would be eliminated and passage 74 leading from passage compartment 42 would be connected by a Y-connection to passage 52 so that a bolus infusate dose injected into compartment 42 would be conducted directly to the infusion site. As described in that patent, passage 74 should include a check valve (not shown) to prevent reverse flow of infusate from compartment 42 back into bellows capsule 22 during a bolus injection.

Also, of course, the implanted apparatus 12 may consist simply of a stack of independent injection portals similar to compartments 42 and 44, each portal being isolated from its neighbors by a septum similar to septum 36 and having its own outlet passage leading exteriorly of the housing for connection to a catheter. In this way, individual portals may be dedicated to carry to a particular infusate to a selected infusion site in the patient's body, access to each portal being had by transcutaneous injection into that portal of the portal stack.

As a further application, the portal unit may be used to provide access for pressure monitoring at different points in the body. In this event, the catheters leading from each portal of the unit would extend to a different arterial or venous monitoring site and be filled with fluid. The plural lumen needle inserted into the portal unit would be connected by tubing, also filled with fluid, to different channels of a pressure recorder or monitor.

Referring now particularly to FIGS. 2 and 3 of the drawing, after apparatus 12, in one of its aforesaid versions, is implanted under the skin S as shown, its infusate chambers 26 and 68 are accessed by inserting the needle or cannula unit 14 through septa 36 and 38 into passage 32 until it bottoms on the needle stop 34 at the inner end of passage 32. Unit 14 comprises a more or less conventional hypodermic needle 92 having a tip 92a which is preferably of the Huber-type and a lumen 93 extending the length of the needle.

The upper end 92b of needle 92 is joined to a metal or plastic hub 94 where the needle lumen 93 communicates with a collinear passage 96 in the hub. The hub upper end 94a and a flared upper end 96a of passage 96 are configured as a female Luer-type connector so that as shown in FIG. 1, the hub end 94a can be releasably coupled to a mating fitting F on a tube T leading from a standard infusate source such as a syringe or to a source of negative pressure.

Surrounding needle 92 partway along its length is a length of hypodermic tubing 98 whose inner diameter is slightly larger than the outer diameter of needle 92 thereby leaving an annular channel or gap 102 between the needle and the tube. The lower end 98a of tubing 98 is connected to the outside wall of needle 92 by an annular weld or brazing fillet 104 so that there is a fluid-tight seal at that location. Also, a small hole 105 is present in the wall of tubing 98 just above fillet 104.

The hub passage **96** has a relatively deep counterbore **96***b* extending in from the underside of the hub and a larger diameter, shallower counterbore **96***c*. The upper end **98***b* of tube **98** is secured in counterbore **98***c* by a suitable epoxy cement, with counterbore **96***b* being essentially an extension of gap **102**. Hub **94** is provided also with a lateral extension **94***b* which contains a lateral passage **106**. The passage inner end intercepts counterbore **96***b* above tubing **98**, while the flared passage outer end **106***a* and extension **94***b* are shaped to form a female Luer-type connector. This allows hub section **94***b* to be coupled to a mating Luer-lock fitting F at the end of a tube T leading to a second infusate source or to a negative pressure source as seen in FIG. **1**.

Referring to FIG. **2**, in accordance with the invention, the spacing of the tubing hole **105** above the needle tip **92***a* where the lower end of the needle lumen **93** is located corresponds to the spacing between the needle stop **34** in apparatus **12** and a point P midway along the passage compartment **42** therein. Resultantly, when needle unit **14** is inserted into passage **32** so that its needle tip **92***a* engages or bottoms on needle stop **34**, the lower end of the needle lumen **93** will automatically be located in passage compartment **44**, while the tubing hole **105** will be located in passage compartment **42**. Therefore, due to the presence of septa **36** and **38** in that passage, and the above described fluid paths in apparatus **12**, the needle lumen **93** will be in fluid communication only with bellows chamber **26**, whereas tubing passage **102** will be in fluid communication only with infusate chamber **68**. Resultantly, if hub sections **94***a* and **94***b* are both connected to sources of negative pressure, the liquids in bellows chambers **26** and **68** can be withdrawn independently from those chambers at the same time. By the same token, if the hub sections are coupled to different infusate sources, the two pump chambers in apparatus **12** can be recharged and refilled with different infusates simultaneously. Still further, if one of the passage compartments, say compartment **42**, constitutes an injection portal communicating directly with the catheter **54**, the hub section **96***b* can be connected to a syringe so that while the pump chamber **26** is being emptied or refilled with infusate via hub section **94***a*, needle **92** and passage compartment **44**, a bolus dose of infusate can be administered to the patient via hub section **94***b*, passage **102** and passage compartment **42**.

It is apparent from the foregoing, then, that using an implantable apparatus with stacked inlet ports, such as apparatus **12**, and a plural channel needle unit such as unit **14**, different fluids may be introduced into or withdrawn from the various chambers of the apparatus **12** independently and simultaneously after only a single puncture of the patient's skin to insert unit **14** into passage **32** of the implanted apparatus. The invention thus allows individual access simultaneously to a plurality of sites in a patient's body for purposes of introducing fluids into or withdrawing them from the body, or for measuring or monitoring pressure or other functions or variables at those sites. Moreover, the invention provides access in such a way as to prevent establishment of fluid communication between any flow path in the needle or cannula and the incorrect inlet port of the implanted device.

While there is shown infusion apparatus having a dual chamber capability and a needle unit **14** with two fluid channels, it is obvious that the principles disclosed here can be extended to implantable apparatus with a stack of three or more inlet ports or compartments which can be accessed simultaneously in a single penetration of the patient by a needle unit having a corresponding number of flow channels whose outlets are spaced from the unit's tip to correspond to the positions of the ports in the stack. Also, of course, the implanted apparatus may be accessed by separate needles or cannulae each one having its lumen outlet positioned along the needle to align with only one of the apparatus inlet ports or passages when the needle is inserted into the implanted apparatus.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawing be interpreted as illustrative and not in a limiting sense.

What is claimed as new and desired to be secured by Letters Patent of the United States is:

1. A dual access infusion or monitoring system comprising in combination

A. implantable apparatus having

1. a biocompatible hermetically sealed housing,
2. an inlet passage extending into said housing from an exterior surface thereof, said passage having an outer end adjacent to said housing surface and an inner end located inside the housing,
3. needle stop means at the inner end of said passage;
4. a plurality of needle-penetrable, self-sealing septa mounted in said passage at selected different spacings from said needle stop thereby to divide said passage into a plurality of aligned segments; and
5. means defining separate fluid outlets from said passage segments,
6. an infusate pump inside the housing in fluid communication with one of said housing passage segment fluid outlets,
7. a catheter extending out of said housing, said catheter having at least one lumen for conducting fluid from said pump to an infusion site, and
8. a first fluid outlet in the housing for conducting fluid from said pump to said catheter, and

B. fluid injection means including

1. a plurality of tubes having proximal and distal ends and separate axial lumens therebetween, the number of tubes in the injection means corresponding to the number of passage segments in the implantable apparatus housing,
2. hub means mounted to the proximal ends of said tubes,
3. means defining separate fluid passages in said hub means extending from different surface locations on the hub means to the lumens of different ones of said tubes, and
4. means in said tubes defining outlets from said tube lumens, the axial spacings of said outlets along said injection means corresponding substantially to the spacings of said housing passage segments in said implantable apparatus so that when the injection means are inserted through said septa into said housing passage until the injection means bottom on said needle stop means, said tube outlets are positioned in different ones of said passage segments so that they are

isolated from one another and from the atmosphere by at least one septum whereby separate fluid-tight fluid paths exist between said hub means surface locations and said housing passage segment outlets.

2. The system defined in claim 1 and further including a second outlet conduit in said housing for conducting fluid from another one of said housing passage segment outlets to said catheter so that while the pump is being filled with or emptied of fluid via one of said injection means tubes, a fluid can be flowed directly to an infusion site via another one of said injection means tubes.

3. The system defined in claim 2 wherein

A. the catheter is a dual lumen catheter; and

B. said first and second outlet conduits are in fluid communication with different lumens of said catheter.

4. The system defined in claim 1 wherein said implantable apparatus also includes

A. a second infusate pump inside the housing;

B. a second outlet conduit for conducting fluid from another one of said housing passage segment outlets to said second pump; and

C. a third outlet conduit in said housing for conducting fluid from said second pump to said catheter.

5. The system defined in claim 1 wherein at least two of said housing passage segment fluid outlets lead to different locations on said housing exterior surface.

6. The system defined in claim 1 wherein

A. the injection means comprise a pair of concentric inner and outer tubes;

B. a fluid tight seal extends between the distal end of the outer tube and the outside surface of the inner tube; and

C. the outlets in said inner and outer tubes are located adjacent to the distal ends of those tubes.

7. The system defined in claim 6 wherein the distal end of said inner tube is formed with a Huber-type tip.

8. The system defined in claim 1 and further including fluid coupling means on the injection means hub exterior for releasably connecting said hub passages in a fluid-tight manner to different fluid paths exterior to said injection means.

9. A dual access infusion or monitoring system comprising injection needle means having a longitudinal axis and a tip, said means including

A. concentric inner and outer tubes permanently fixed to one another, said inner tube being longer than said outer tube and each tube having proximal and distal ends and an unobstructed axial lumen therebetween;

B. a hub mounted to the proximal end of said tubes;

C. first and second fluid passages in said hub extending from different surface locations on the hub exterior surface to different ones of said tube lumens;

D. a fluid-tight seal extending from the distal end of said outer tube and the outside wall of said inner tube, and

E. means defining openings in said tubes that provide outlets from the corresponding lumens of those tubes, said openings being located at selected fixed different axial spacings from said needle means tip so that fluids introduced into said first and second passages can flow simultaneously along said needle means and exit therefrom at said selected different spacings from said tip.

10. The system defined in claim 9 wherein the distal end of said inner cannula is formed with a Huber-type tip.

11. The system defined in claim 9 and further including fluid coupling means on the hub exterior for releasably connecting said hub passages in a fluid-tight manner to different fluid paths exterior to said needle means.

* * * * *

Exhibit

C

00555240
Arrow aims a shot at infusion pump leader
Clinica 778 p13, October 09, 1997 (19971009)
STORY TYPE: F WORD COUNT: 523

Arrow *International* is positioning itself for head-on competition against industry giant Medtronic in the $100 million market for implantable infusion pumps in both the specialists' office and the patent courts, according to Arrow's CEO and President Marlin Miller.

Arrow , with sales of $229.9 million last year, specialises in a broad range of clinically advanced disposable catheters and related products, entered the infusion pump business in 1995 with the purchase of *Therex*. In July, Arrow completed the purchase of Pfizer's Strato/Infusaid implantable infusion pump business.

Mr Miller acknowledges that Medtronic dominates infusion pump sales. "We are the only alternative to Medtronic, it gives us a growth position," he told the third annual UBS Securities Life Science conference in New York.

The FDA has approved the use of Arrow's Model 3000 constant flow implantable infusion pump to treat benign pain with morphine. Arrow was already marketing the pump to treat liver cancer with the chemotherapy drug FUDR and the treatment of malignant pain with morphine.

Medtronic has estimated that only 15 per cent of the potential market for infusion pumps has been penetrated. Currently 40% of the market is in chronic pain management and another 40% in baclofen, used to control spasticity. Medtronic has the exclusive licence to use baclofen until January 1. Arrow expects to offer the drug in its own pump sometime next year.

"Other drugs are coming on the market that could be very effectively delivered through implanted infusion pumps," Mr Miller said. "This is a really interesting expanding market with fairly lengthy room for two companies."

. . . several advantages

Arrow contends that its line of pumps offer several advantages over the programmable pumps sold by Medtronic. The Model 3000 is smaller than the Medtronic line but its drug reservoir has a larger capacity. The Arrow model runs on rechargeable batteries.

Medtronic's batteries last three to five years and the process of replacing them is costly.

In some cases the Medtronic pump is being replaced with an Arrow model, Mr Miller said. The Arrow models deliver a constant amount of the same drug which many doctors say is a lot more convenient than a programmable pump once a patient is at the proper dose. To further compete, Arrow sells its pump for $5,000, Medtronic for $8,000.

Medtronic has recognised the advantages of a constant dose pump in many circumstances and has begun clinical trials in the United States for a model made by the German company, Tricumed Medizintechnik.

Recently Arrow complained to Medtronic that the new German pump violates its existing patent on the system in both Germany and the US. Since Medtronic was not responded so Arrow is prepared to sue for patent infringement. This could slow the introduction of the product to Arrow's advantage, said Mr Miller.

While Arrow is moving on infusion pumps, its number one research priority remains the future-looking Left Ventricular Assist Device, intended to provide long-term cardiac assist to people with end-stage congestive heart failure who are not good candidates for a heart transplant (primarily people over age 65. Mr Miller said Arrow intends to begin international clinical trials next year and US clinical trials in 1999

Exhibit D

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22 MRT 2000

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Amsterdam, 21 March 2000
Your ref.:
Our ref.: f:\263\therex\b004.doc\lvB

Dear Sirs,

Re: Therex/Medtronic

Therex Limited Partnership has asked my assistance in the abovementioned matter. As you know my client has started proceedings in the District Court of Düsseldorf in order to obtain a decision about the infringement of my client's European patent no. 0612535 B1. The court of Düsseldorf has been chosen as it is one of the courts in Europe with the best reputation in patent matters. The court has ruled that your client is indeed infringing upon my clients European patent. Furthermore the Opposition Division of the European Patent Office has rejected the lodged oppositions.

Contrary to the expectation of my client these decisions have not lead to the cessation of the infringing activities in the designated countries. On the contrary my client has noted that you have launched a so-called Belgian Torpedo in an apparent attempt to be able to continue the infringing activities. From the

writ of summons in the Belgian proceedings my client has learned the acknowledgement that all infringing products are produced at your facilities at Kerkrade.

Your legal advisors must have informed you that my client has an urgent interest (certainly) after the decision of the Opposition Division to obtain a preliminary injunction to put to an end to the (willful) infringement in The Netherlands. The Belgian Torpedo is apparently designed to avoid such preliminary injunction. This is to inform you that my client is of the opinion that the Belgian court in both proceedings you have initiated has no jurisdiction with respect to other countries than Belgium. With respect to the preliminary injunction proceedings which you started in Belgium client accepts that there is an urgent interest for a decision of course - as the court has no jurisdiction for the other countries - to Belgium. My client will in the preliminary injunction proceedings file a cross complaint for an injunction for Belgium. Only in case the Belgian court would accept jurisdiction for the countries outside Belgium in the principal case my client - which in our view would be wrong - will also ask the Belgian court to grant a preliminary injunction for other countries than Belgium.

This is to inform you that if the Belgian court refuses jurisdiction or for any other reason no preliminary relief for The Netherlands will be obtained my client reserves the right to file for such relief in the District Court of The Hague. Although my client was planning to ask for such relief around the time the Belgian Torpedo was launched, my client now will therefor first await the outcome of the Belgian preliminary injunction proceedings in first instance as my client has understoond that a decision is to be expected in June. You will appreciate that this waiting period is caused by you choosing to institute proceedings in Belgium and that such waiting period is not taking away the urgency which my client according to Dutch law has with respect to preliminary relief in The Netherlands. You should also be aware of the fact that my client accepts this waiting period because if the Belgian court would grant relief for The Netherlands before the end of June no purpose is served to burden the Dutch court and parties with preliminary injunction proceedings in The Netherlands.

In order to avoid any misunderstanding I repeat that my client could start preliminary injunction proceedings and is entitled to a preliminary injunction for the Netherlands at any time but will only start such proceedings and seek such injunction if before June 30, 1999 the Court in Brussels has not granted such injunction.

Finally: if you are willing to accept that the court in Brussels has no jurisdiction for (among other countries) The Netherlands or for any other reason want the President of the Court of The Hague to deal with the question whether or not my client is entitled to a preliminary injunction for The Netherlands, my client is gladly prepared to ask the President for a date for a hearing during the coming weeks convenient to both parties.

You receive this letter by registered and ordinary mail.

Very truly yours,

Willem A. Hoyng

Exhibit E

today's news

Arrow International Announces Series of Victories for Its State-Of-The-Art Constant Flow Implantable Infusion Pump Technology

Website

READING, Pa., July 31 /PRNewswire/ -- Arrow International Chairman and Chief Executive Officer Marlin Miller today announced a series of international legal victories against Medtronic, Inc. in defense of Arrow's patented constant flow implantable infusion pump technology. Arrow's Model 3000 Series Constant Flow Implantable Infusion Pump is considered the state-of-the-art.

In Germany, a court determined on July 22, 1999 that Medtronic had infringed Arrow's European patent and as a result, Medtronic had to cease selling and withdraw its IsoMed(R) pumps from the market in Germany.

The European Patent Office upheld the validity of Arrow's European patent against another Medtronic challenge on December 23, 1999.

In Belgium, on June 23, 2000, a court effectively threw out Medtronic's challenge to Arrow's European Patent (No. 0612535) by denying Medtronic's request for a judgment of non-infringement.

Having failed to make a case in Europe, Medtronic challenged Arrow's U.S. patent (No. 4,978,338) in a suit filed on June 28, 2000 in Massachusetts, asserting that Medtronic's IsoMed(R) pump does not infringe Arrow's patent.

Responding to this most recent challenge, Arrow Chairman and CEO Miller said, "We intend to protect our technology and our competitive position by enforcing our intellectual property rights. Arrow has made a significant investment in research and development to bring its own constant flow implantable pump to market, and has also made a considerable investment in obtaining patent protection covering its innovative technology."

Arrow International, Inc.(Nasdaq: ARRO), through its subsidiary Arrow-Therex Corp., produces the state-of-the-art Arrow Model 3000 Series Constant Flow Implantable Infusion Pumps. The Model 3000 infusion pumps contain a unique design allowing for more accurate infusion of drugs and safer bolus dose injection than any other implantable pump on the market. Arrow's Model 3000 implantable drug delivery systems are used to significantly improve the quality of life for patients requiring chemotherapy for colorectal cancer metastasized to the liver, for chronic pain management, and for the treatment of spasticity. Arrow is making important strides in identifying additional drugs that can show improved therapeutic results with continuous infusion rather than intermittent or bolus injections.

More information about Arrow's Model 3000 Series implantable drug delivery systems can be found online at http://www.arrowintl.com.

Arrow International, Inc., headquartered in Reading, Pennsylvania, develops, manufactures and markets a broad range of clinically advanced, disposable catheters and related products for critical and cardiac care. The Company's products are used primarily by anesthesiologists, critical care specialists, surgeons, emergency and trauma physicians, cardiologists, interventional radiologists, electrophysiologists, pain management specialists and other health care providers.

Arrow International's news releases and other company information can be found on the World Wide Web at http://www.arrowintl.com.

The Company's common stock trades on The Nasdaq Stock Market(R) under the symbol ARRO.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: This news release provides historical information and includes forward-looking statements. Although the Company believes that the expectations in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to have been correct. The forward-looking statements are based upon a number of assumptions that,

while considered reasonable by the Company, are inherently subject to significant business, economic and competitive risks, uncertainties and contingencies which are beyond the control of the Company, and upon assumptions with respect to future business decisions which are subject to change. Accordingly, actual results will vary from the forward-looking statements, and these variations may be material. Consequently, the inclusion of the forward-looking statements should not be regarded as a representation by the Company of results that actually will be achieved. Forward-looking statements are necessarily speculative in nature, and it is usually the case that one or more of the assumptions in the forward-looking statements do not materialize. Investors are cautioned not to place undue reliance on the forward-looking statements. In connection with the "Safe Harbor" provisions of the Private Securities Litigation Reform Act of 1995, the Company wishes to caution the reader that the factors below and those in Exhibit 99.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended May 31, 2000 and in its other filings with the Securities and Exchange Commission could cause the Company's results to differ materially from those stated in the forward-looking statements. These factors include: (i) regulation of the Company's products by the U.S. Food and Drug Administration and, in some jurisdictions, by state, local and foreign governmental authorities; (ii) the highly competitive market for medical devices; (iii) pressures imposed by the health care industry to reduce the cost or usage of medical products and services; (iv) dependence on patents and proprietary rights; (v) risks associated with international operations; (vi) potential product liability; (vii) risks associated with derivative financial instruments; and (viii) dependence on key management.

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