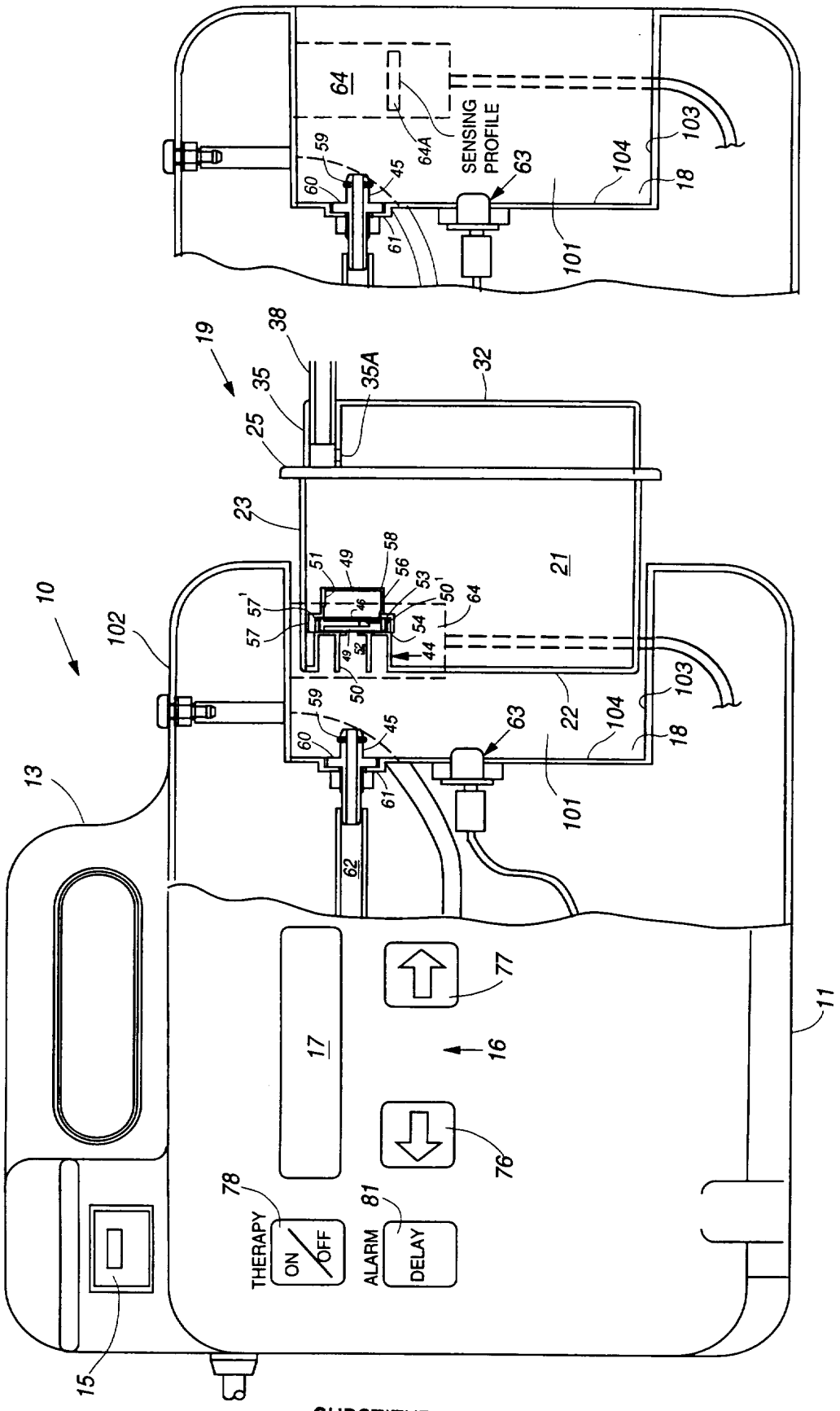


FIG.6A

FIG.6

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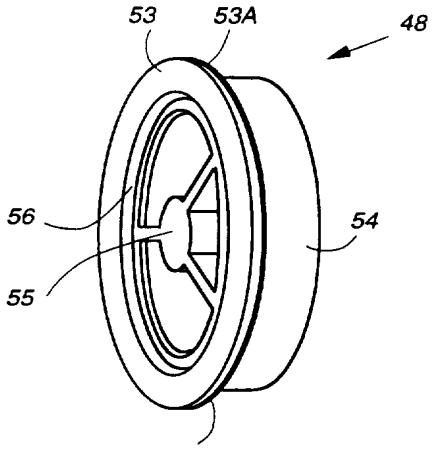


FIG.7

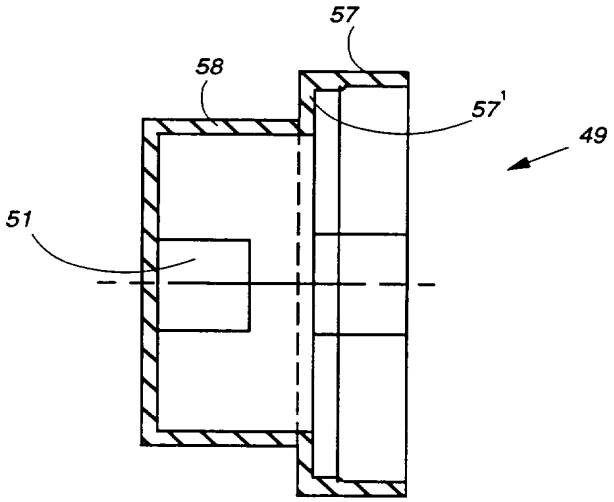


FIG.8

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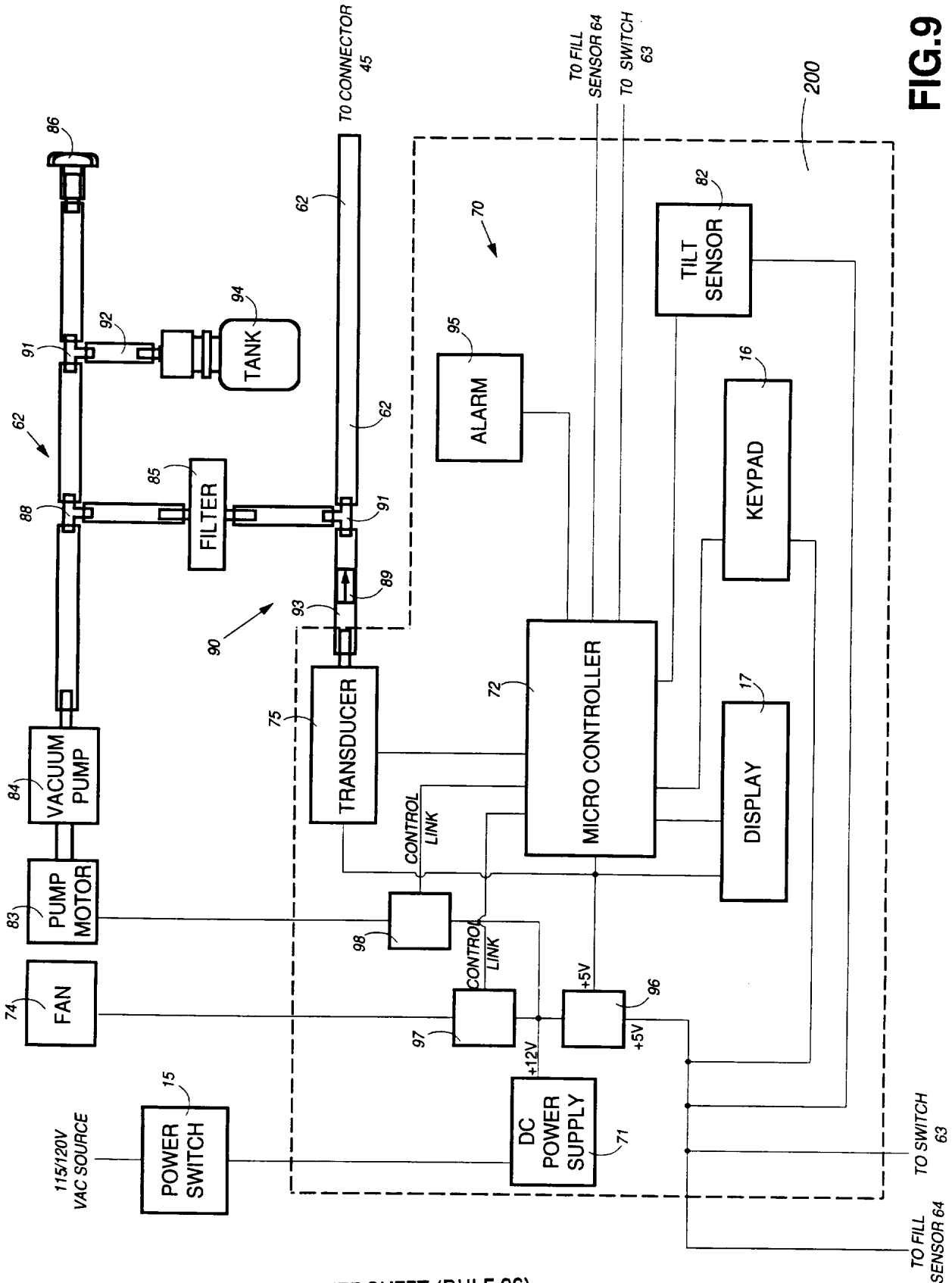


FIG.9

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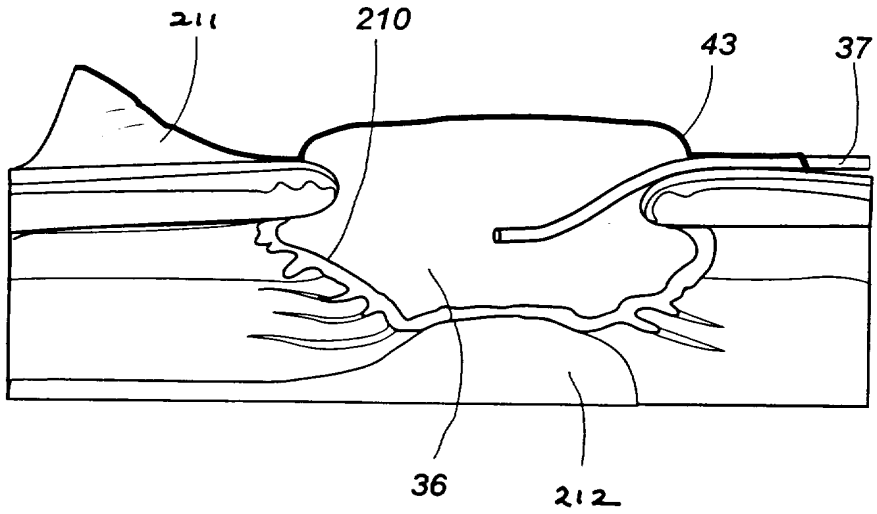


FIG.10

Solventum-Exhibit 1002-0335

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/GB 95/01983

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,3 520 300 (FLOWER GUILES JR) 14 July 1970 see column 2, line 10 - column 3, line 16; figures ---	1,7-13, 16-19 2-6,14, 15,22-24
Y A	US,A,4 758 220 (SUNDBLOM LEIF J ET AL) 19 July 1988 see abstract; figures 3,6A see column 5, line 3 - line 34 see column 12, line 48 - line 50 ---	3,4,14, 15 5
Y	DE,A,26 40 413 (WOLF GMBH RICHARD) 9 March 1978 see claims 1,6,7; figure 1 ---	5,6
A	US,A,5 279 550 (HABIB MAGDI F ET AL) 18 January 1994 see abstract; figures 1,3 ---	15
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
9 November 1995	23. 11. 95
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	**Authorized officer** Zeinstra, H

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Sopharma Exhibit 1002-0336

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/GB 95/01983

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 215 522 (PAGE ET AL.) 1 June 1993 see abstract; figures 1-3 see column 1, line 55 - line 68	16
X	EP,A,0 358 302 (SMITHS INDUSTRIES PLC) 14 March 1990	20,21
Y	see abstract; figures 1,4	2,22,23
A	see column 2, line 26 - column 4, line 34	1
Y	GB,A,2 197 789 (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY) 2 June 1988 see abstract; figures see page 5, line 1 - line 13	22
Y	US,A,5 092 858 (BENSON C DAVID ET AL) 3 March 1992 see abstract; figures 1-6 see column 4, line 33 - column 5, line 27	23
Y	PATENT ABSTRACTS OF JAPAN vol. 016 no. 394 (C-0976) ,21 August 1992 & JP,A,04 129536 (TERUMO CORP) 30 April 1992, see abstract	24
A	WO,A,93 09727 (WAKE FOREST UNIVERSITY) 27 May 1993 cited in the application	

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Solventum Exhibit 1002-0337

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ..onal Application No
PCT/GB 95/01983

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-3520300	14-07-70	NONE		
US-A-4758220	19-07-88	US-A-	4790816	13-12-88
		US-A-	4810242	07-03-89
DE-A-2640413	09-03-78	FR-A,B	2364036	07-04-78
		GB-A-	1574066	03-09-80
US-A-5279550	18-01-94	NONE		
US-A-5215522	01-06-93	US-A-	4569344	11-02-86
		US-A-	4638539	27-01-87
		US-A-	4696296	29-09-87
		US-A-	5277177	11-01-94
		US-A-	4836199	06-06-89
		US-A-	4872579	10-10-89
EP-A-0358302	14-03-90	GB-A-	2220357	10-01-90
GB-A-2197789	02-06-88	NONE		
US-A-5092858	03-03-92	NONE		
WO-A-9309727	27-05-93	AU-A-	3130393	15-06-93
		CA-A-	2121688	27-05-93
		EP-A-	0620720	26-10-94
		JP-T-	7501958	02-03-95

Solventum-Exhibit 1002-0338

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(43) Date of A Publication 19.02.2003

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(51) INT CL[7]
F04B 17/00 // A61M 1/00

(52) UK CL (Edition V)
F1W WCA WDX
A5R RCEB

(56) Documents Cited
GB 2124712 A
EP 0494375 A
US 4798589 A
EP 1045146 A
US 4842584 A
US 4639245 A

(58) Field of Search
UK CL (Edition T) A5R RCEB, F1W WCA WDL WDM WDX
INT CL[7] A61M 1/00, F04B 9/02 17/00 17/03 35/00 39/16 53/22
Other: ONLINE: WPI; EPODOC; JAPIO

(54) Abstract Title
Disposable pump with detachable motor

(57) A vacuum pump comprises a drive 40 and a manually disengageable, disposable pumping system connected thereto. The pumping system comprises a two or three chambered cannister 1, 18, 21 in which solids liquids and gases can be separated from one another. A pumping means such as a diaphragm 24 is attached to the cannister and sealed against it cicumferentially. Activation of the drive means causes reciprocation of the pumping means to produce the pumping action.

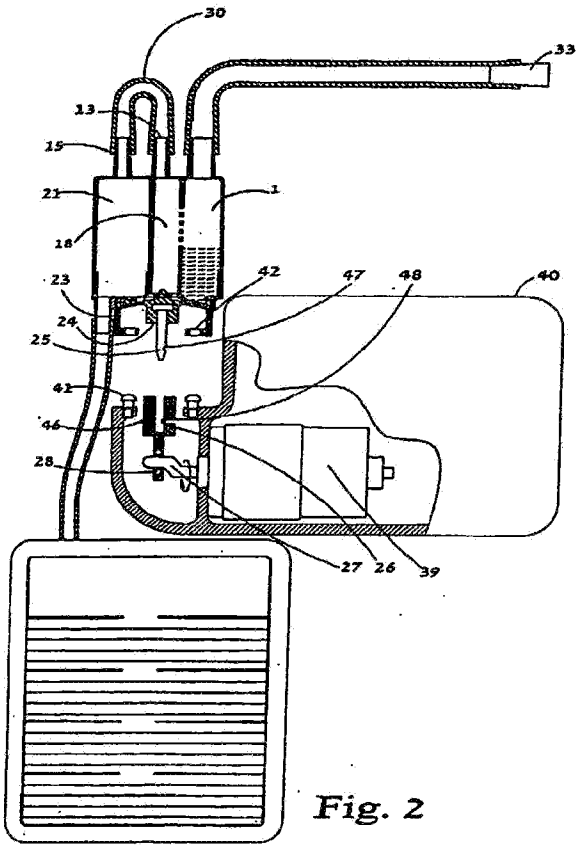


Fig. 2

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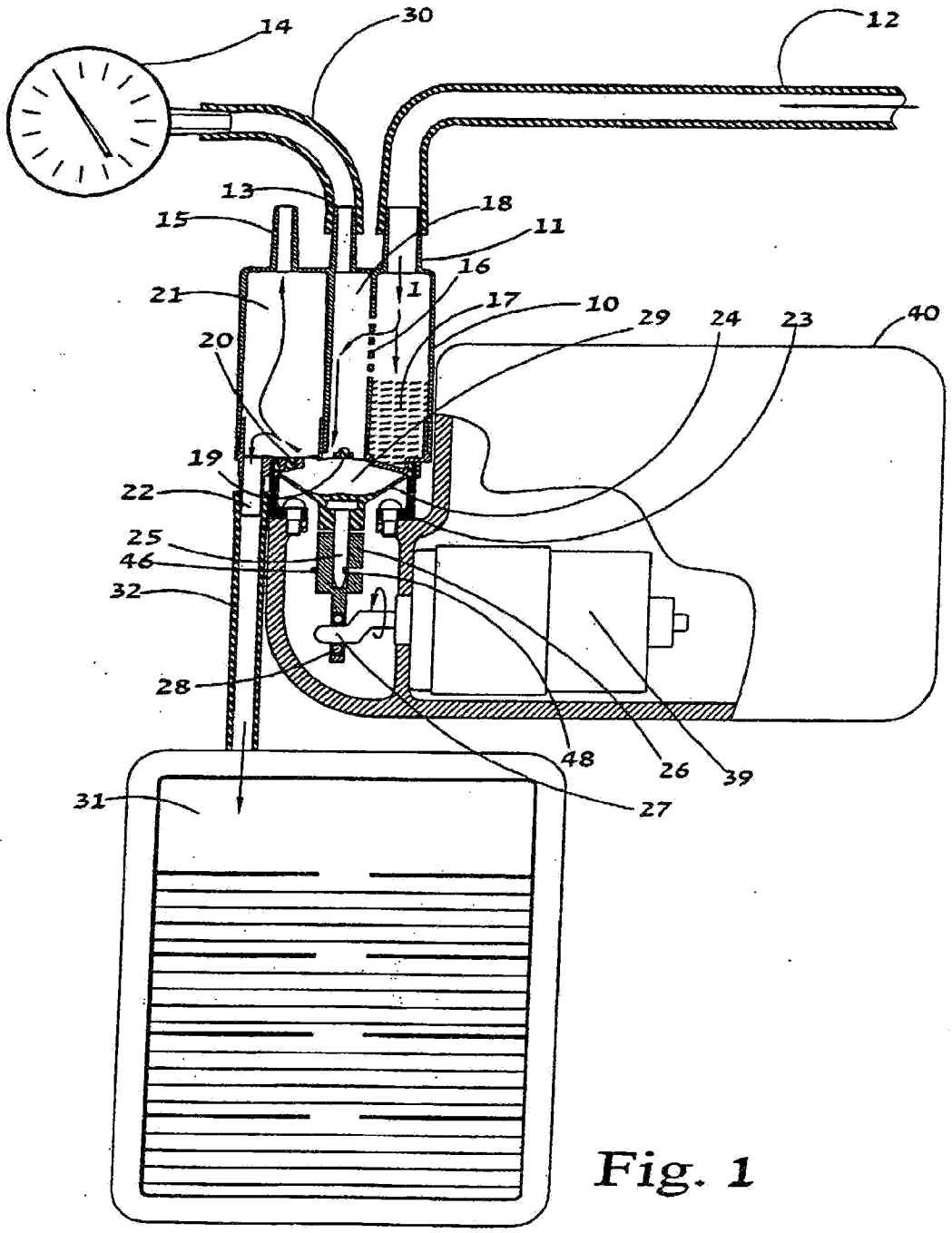

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Fig. 1

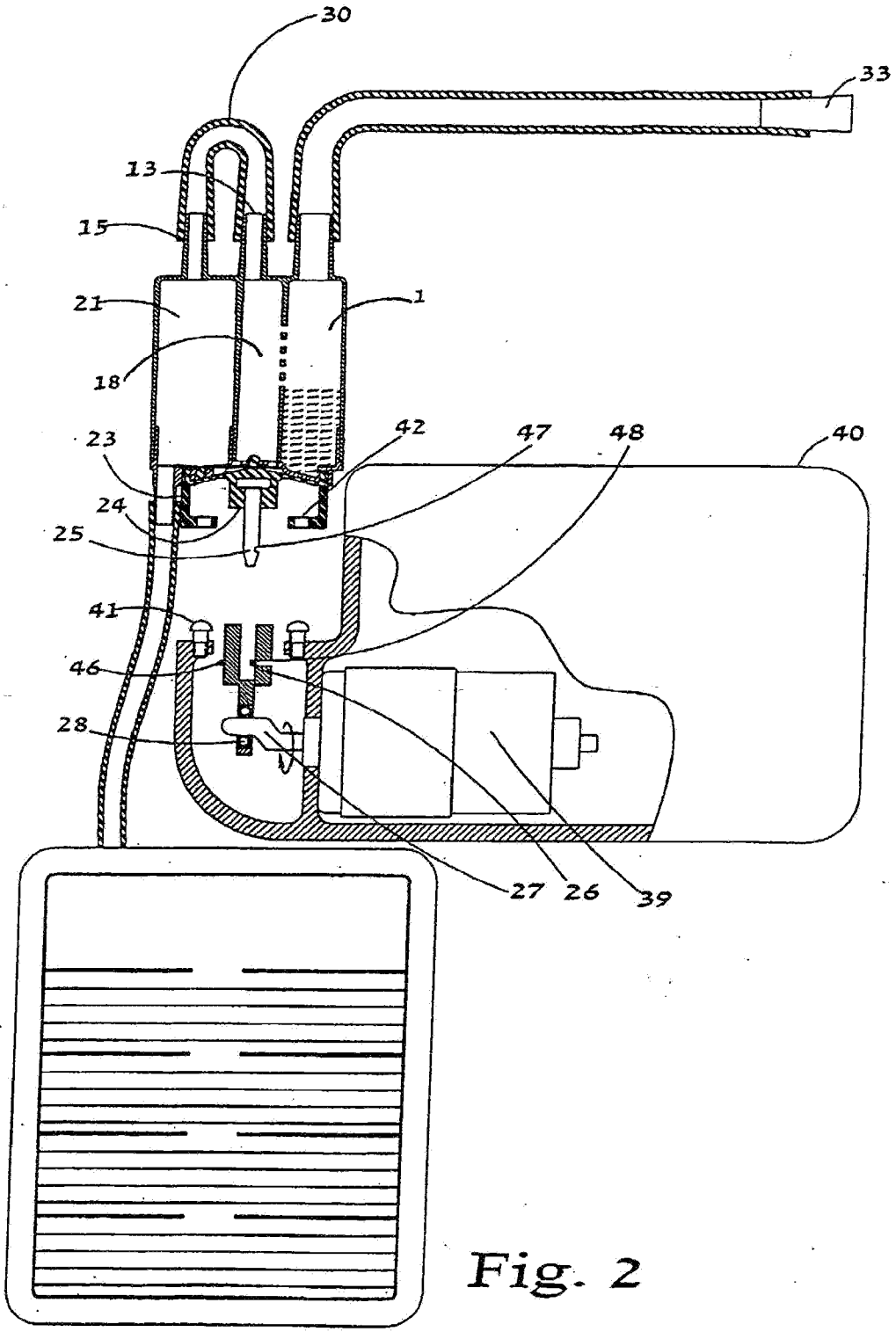


Fig. 2

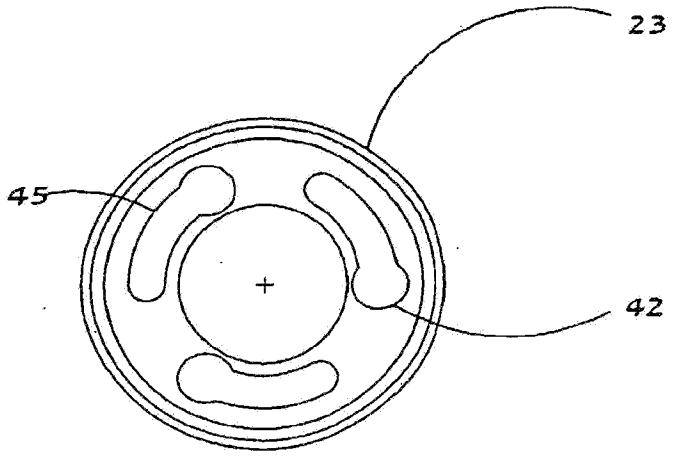


Fig. 3

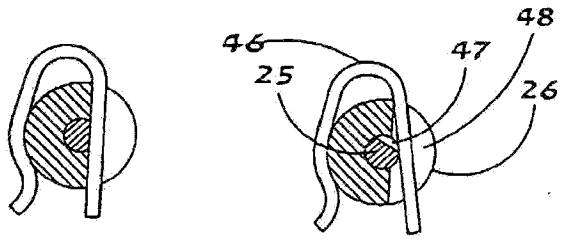


Fig.4

A COMPACT VACUUM PUMP

The present invention relates to a vacuum pump, especially useful in the field of medicine. More specifically, the pump disclosed herein comprises a drive, and a disposable pumping system that can be easily disengaged from the drive after use, to allow for easy disposal of all pump components which come in contact with the matter being sucked, together with the contained matter. The pump should not be limited in the volume of matter it is capable of sucking, while maintaining uninterrupted vacuum pressure.

During medical surgery or emergency airway clearing, body fluids such as blood, or emesis, are subjected to suction. Vacuum pumps are utilized to generate vacuum inside a suction canister, into which the body fluids are drawn through a tube, called a "suction catheter". Conventional vacuum pumps, also termed "aspirators" in medicine, contain rigid vacuum canisters into which the suctioned fluids are collected, which maintain their shape and stiffness under high vacuum pressure. Some suction canisters are disposable and others can be removed for cleaning, disinfection, and re-use.

Aspirators of the type described above are characterized by a number of disadvantages, including the following:

1. When a large volume of fluid is collected, the suction canisters have to be relatively large in volume. Most commonly, a canister of up to five liters in volume is used. Large canisters slow the vacuum rise rate, because of the large air volume to be removed from the canister before a vacuum is created in the canister strong enough to draw the suctioned

matter.

2. Since the air in the suction canister is drawn through the pump, it is very difficult to prevent contamination of the non-disposable pump components, such as the diaphragm, valves, cylinder or piston, even when the suction canister is disposed of after use. Contaminated pumps are a health hazard, as the air flowing through them is exhausted to the atmosphere.

3. Aspirators are used for drawing body fluids and emesis, which may contain solids. Air is also drawn into the pump, during aspiration. Vacuum pumps are generally efficient in pumping either air or fluids, but most pumps are inefficient in pumping all three types of matter.

Thus, conventional vacuum devices are large, bulky, costly and inefficient in performing their function.

In the present invention, the term "pumping system" generally refers to a system having at least the following components: a suction canister, a suction inlet, a waste outlet, and integral means for creating suction. The term "disposable vacuum pump" generally refers to a pump in which all components other than the drive are inexpensive, and therefore may be disposed of. One wishing to re-use the disposable components (or use similar, non-disposable components) may, however do so. The term "drive" generally refers to a pump component comprising of an electric motor, or other means by which a pump piston, or a diaphragm, may be caused to reciprocate, contained within a housing. The term "body fluids" refers typically to blood, emesis or mucus. The terms "three types of matter", "three types of media", and "three states of matter", refer to liquid, solid and gas. The terms "matter",

"media", and "material" are used interchangeably to refer to the material being suctioned. The term "load", or "high load", refers to the quantity and weight of the material being suctioned or pumped.

Embodiments of the invention may provide an improved vacuum pump, capable of pumping air or gas, liquid and solids, and capable of separating the three types of matter, to allow efficient pumping, while collecting the liquid in a low cost bag.

Further embodiments may provide a pump in which all components that come in contact with body matter, or any other pumped media, can be easily disconnected and removed from the pump's drive means, to be sterilized or disposed of. This leaves the non-disposable drive free from contamination. In prior-art pumps that have disposable canisters, the suctioned air is drawn through the pump, bringing the inside of the pump in contact with air which may be contaminated. The inside of the pump is traditionally not accessible for cleaning.

Embodiments of the present invention may further provide a vacuum pump which is extremely fast in generating a high vacuum or suction pressure, yet doing so with a relatively small vacuum canister and a low-capacity pump.

It is further desirable to provide a physically compact vacuum pump, with performance and capacity which are independent of its dimensions, and are significantly higher than those of physically larger vacuum pumps and moreover to provide a vacuum pump which generates uninterrupted vacuum, independent of the volume of the vacuum canister, which does not fill up as do conventional vacuum canisters.

The vacuum pump comprises a drive, and a disposable pumping system connected to this drive (but designed to

be manually disengaged therefrom), wherein the disposable pumping system comprises:

a) a three-chambered canister, wherein an inlet leads into the first chamber, and the first chamber has means for retaining solids and preventing their passage from said first chamber to the second chamber; and the second chamber has a one-way valve at its exit, said valve allowing passage of liquid and gas out of said second chamber; and the third chamber has an outlet for the discharge of air, and an additional outlet for the discharge of liquid; and said third chamber further has a one-way valve, at its inlet, allowing entry of liquid and gas through said valve, while preventing exit of matter through said valve;

b) a highly flexible diaphragm, attached to said three-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said three-chambered canister, in which said valves are installed;

c) a drive member attached to said diaphragm, wherein reciprocation of said drive member induces reciprocation of said diaphragm; and

d) means for mounting and engaging said disposable pumping system to the housing of a drive, wherein said means are capable of simultaneously coupling the pump drive member to said drive.

The drive is coupled to the drive member, and the drive includes an electric motor rotating a crank, said crank being connected to reciprocating means, in such a way that activation of the drive induces reciprocation of the crank and of the drive member. The pumping

system is capable of being attached to or detached from the drive in a rapid and facile manner (in the preferred embodiment, accomplished by a single, simple, wrist twist motion).

According to a preferred embodiment of the present invention, the three-chambered canister has a volume of approximately 100 cc.

Further according to a preferred embodiment of the present invention, the pump includes a vacuum port outlet present in the second chamber, said outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside the first and second chambers.

Additionally according to preferred embodiment of the present invention, the means for retaining solids in the first chamber includes a sieve.

Moreover according to preferred embodiment of the present invention, the highly flexible diaphragm is capable of yielding or stretching when large quantities of fluid are contained within it. When subjected to high loads, the diaphragm is capable of stretching to effectively reciprocate only a fraction of its area (such as 50%) while the remainder of its surface remains stationary.

Still further according to preferred embodiments of the present invention, the vacuum pump additionally comprises means for sealing said three-chambered canister and preventing leakage of air or materials into or out of said canister; and further preventing loss of vacuum in first and second chambers.

According to embodiments of the present invention, the pump additionally comprises a disposable waste container, for collection of discharged liquid, attached to the liquid outlet of said third chamber. In a preferred embodiment, the disposable waste

container is a waste bag, having any appropriate size. In some preferred embodiments, the capacity of said waste bag is between 500 cc and 5 liters. The waste-collection bag is a low cost waste container, at ambient pressure, which is easily disposed of along with the body fluids it contains, together with the pumping system.

Furthermore, according to the preferred embodiment of the present invention, the means for mounting and engaging the pumping system to the drive housing comprise a mounting base protruding from the lower portion of the three-chambered canister, said mounting base adapted for mating and attaching to the drive housing. In the preferred embodiment, twisting of the mounting base against the drive housing or mating portion thereof couples the two physically.

Still further yet, according to the preferred embodiment of the present invention, the drive rotates a crank, and a reciprocating rod receptacle is connected to said crank, and said rod receptacle is adapted to mate with said drive member. In the preferred embodiment, a lock clip secures the drive member to the rod receptacle. Coupling said mounting base to said drive housing is affected simultaneously with the securing of said drive member to the rod receptacle, in a single operation.

Additionally, the pumping system and the drive may be portable and may be operated on battery power. Moreover, the pumping system may additionally comprise means for sealing said pumping system, for facilitating disposal of said pumping system, with all pumped matter contained.

Further according to preferred embodiments of the present invention, the pump is capable of generating continuous unlimited flow of matter therethrough, while maintaining uninterrupted vacuum pressure. The

pump may be capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in the first and second chambers.

Additionally, in a preferred embodiment, the pump further comprises suction catheter tubing attached to the inlet present in said first chamber, allowing entry of matter into the three-chambered canister.

Unlike common diaphragm pumps, the diaphragm in this invention is flexible and not restrained by a rigid piston. The flexibility of the diaphragm allows it to stretch and conform to the pumped matter, irrespective of the reciprocal motion of the rigid drive member. Thus, when the diaphragm encounters resistance it stretches and yields, allowing uninterrupted motion of the reciprocating drive member.

The three-chambered canister, the diaphragm and the one-way valves advantageously comprise an integral pumping system, which can easily be attached to a drive, which causes the drive member to reciprocate. Such a drive, as described, may be an electric motor, whose output shaft has a crank to which the drive member is connected. The electric motor will thus, when powered, affect pumping from one chamber of the canister to the other. The pumping system can easily be disengaged from the drive after use, and be sterilized or disposed of. The ability to completely separate the heart of the pump and its associated chambers and tubing conduits, from the drive motor allows disposal or sterilization of all pump components that come in contact with pumped matter. It would be obvious to those skilled in the art that means other than an electric motor may be utilized to induce the reciprocal motion of the drive member.

The three-chambered canister is constructed in a manner such that the solids entering the chamber are

trapped and prevented from entering further into the pump and affecting its performance by blocking the valves and tubing. It would be obvious to those skilled in the art that when the pumped matter is not likely to include solids, there would be no need to prevent them from reaching the pump one-way valves, and thus the pumping system hereby described would function equally well without the first chamber. A pump having only two chambers, to be used in such case, is thus described below as well. Additionally, the pumped air is separated from the fluid, and released to the atmosphere, so that liquid, and not air, is collected in the waste bag, thereby utilizing the volume of the waste bag efficiently. Thus, the capacity of the pump to suck or collect fluids is not limited by the size of the chamber into which the fluid is drawn, and even a small chamber can be utilized to pump large volumes of fluid, limited only by the capacity of the waste bag. This is in contrast to pumps of the prior art, in which the canister or chamber size limits the amount of matter that may be suctioned, and when large canisters are used to overcome this limitation, evacuating the large canister by the pump becomes a slow process.

The present invention can be utilized in the field of medicine, to aspirate body fluids, emesis and mucus; however, the scope of the invention is not limited to medical use alone, and the vacuum pump may be utilized in other fields as well. An important feature of the pump is the ability easily and economically to remove and replace all components that come in contact with the materials being pumped, preventing any harmful contamination. The pump can therefore, find application in the field of chemistry as well, where prior art pumps are difficult to clean after use.

In addition, there is thus provided in an alternative aspect of the present invention, a vacuum

pump for the pumping of liquid and gas, (preferably not for use in pumping of solids), comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:

a) a dual-chambered canister, wherein the first chamber has an inlet and a one-way valve at the exit of said first chamber, said valve allowing passage of liquid and gas out of said first chamber; and the second chamber has an outlet for the discharge of air, and an additional outlet for the discharge of liquid; and said second chamber is further connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

b) a highly flexible diaphragm, attached to said dual-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said dual-chambered canister in which said valves are installed;

c) a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

d) means for mounting and engaging said disposable pumping system to the housing of a drive, wherein said means are capable of simultaneously coupling the drive member to said drive.

In the vacuum pump the drive is coupled to the pumping system so that activation of said drive induces reciprocation of said flexible diaphragm; and the pumping system is capable of being

attached to or detached from said drive in a rapid and facile manner.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention embodiments of it will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a cross-sectional view of a preferred disposable vacuum pump having a three-chambered canister connected to a waste bag, wherein the suction is created by reciprocating a diaphragm by an electric motor drive;

Fig. 2 is a cross-sectional view of the "pumping system" disengaged from the "drive", to be disposed of as one integral unit;

Fig. 3 is a view of a mounting base, with a bayonet arrangement for quick - twist engagement and disengagement of the disposable components; and

Fig. 4 is a cross-sectional view of the locking mechanism, utilized to attach the pump drive member to the receptacle rod of the electric motor.

DETAILED DESCRIPTION OF THE INVENTION

It is appreciated that the detailed description that follows is intended only to illustrate certain preferred embodiments of the present invention. It is in no way intended to limit the scope of the invention, as set out in the claims.

Referring now to **Fig. 1**, there is provided a vacuum pump containing a three-chambered canister 10, which is employed for the performance of several different functions. The three-chambered canister 10 has an inlet 11 in its first chamber 1. A suction tube

catheter 12 is connected to the inlet 11. In the second chamber 18 a vacuum outlet port 13 is connected to a vacuum gauge 14. In the third chamber 21 an air discharge outlet 15 is present, which is open to the atmosphere. The first chamber 1 contains a sieve 16, utilized to prevent solids 17 from entering the second chamber 18, also termed the "liquid chamber". Two one-way umbrella valves 19 and 20 are present in the bottom of the second chamber 18 and the third chamber 21, respectively. The third chamber 21 is at ambient pressure, and has a liquid outlet 22. To the bottom of the three-chambered canister 10 there is attached a mounting base 23, used to mount the canister and its associated tubing 12 on the drive housing 40 or on a docking means connected to the drive housing. The mounting base 23 is also utilized to secure a diaphragm 24 to the underside of the three-chambered canister 10. The diaphragm 24 has an integral rod-shaped drive member 25, which is inserted into a corresponding cavity in a receptacle rod 26, pivotally attached to a drive 40, via a crank 27 coupled to a bearing 28. Upon activation of the motor 39, the crank 28 is rotated by the motor 39, which reciprocates the receptacle rod 26, causing the diaphragm 24 to increase and decrease the volume of the cavity 29 it forms. This creates a vacuum therein, capable of drawing towards it, and thus pumping, air or fluid that pass through the one-way umbrella valves 19 and 20.

While the preferred embodiment describes a motor-crank combination as the means by which to reciprocate diaphragm 24, it would be apparent that other drive means may be used to create the reciprocal movement of the diaphragm.

Air, liquid and solids may enter the three-chambered canister 10 through a suction tube 12, which may, by way of example, be inserted into a patient's

mouth, for the removal of emesis. The three states of matter being pumped enter the three-chambered canister 10 through the inlet 11. Solids 17 are prevented from moving further than the first chamber 1, by sieve 16. Liquids and air enter the second chamber (liquid chamber) 18, which is under vacuum when diaphragm 24 reciprocates, driving them past one-way umbrella valve 20, into the third chamber 21. The vacuum level in the liquid chamber 18 is monitored by a vacuum gauge 14, connected to the vacuum outlet port 13 via a conduit 30. The air and liquid entering the third chamber 21 are separated, whereupon the liquid is drained into a waste bag 31 through a drain tube 32, and the air is driven out to atmosphere through an air discharge outlet 15.

From the description above, it is clear that the three-chambered canister 10 is the heart of the pump, to which the diaphragm 24 is attached to perform the pumping function together with the one-way umbrella valves 19 and 20. Out of the three chambers that make up the three-chambered canister, only one, the liquid chamber 18, is under vacuum. The three-chambered canister is partitioned by the sieve 16; the first chamber 1 and the third chamber 21 are essentially at ambient pressure.

The pump hereby described is distinct in its capability to suck liquid, solids and air or any mixture of the three, and to direct each of the three matter types to their respective destination while separating them. The three types of matter are separated in order to prevent clogging of the pump by solids suctioned, and in order to collect only fluid to dispose of, and not gas, and thus minimize the volume of the waste material for disposal, and of the canister which holds this waste material. It is also of particular importance to note that air and liquid can

be pumped through the pump continuously, at any volume, limited only by the volume of the waste bag 31 to contain the pumped liquids.

The pump's ability to pump air and liquid, unlike conventional pumps, which are efficient in pumping only one type of matter, is enhanced by the flexibility of the diaphragm 24. Unlike conventional pump diaphragms, which are rigidified by a piston or ribbing, to prevent them from excessive flexing, which reduces displacement, the diaphragm 24 described in this embodiment is particularly flexible, so it can yield when encountering heavy loads, such as those present when pumping liquid. This diaphragm flexibility also provides an additional substantial advantage: when the vacuum in the pumping cavity 29 is high, the diaphragm 24 stretches to allow the reciprocation of the receptacle rod 26 to occur, at minimal burden to the "drive", which in the preferred embodiment comprises an electric motor 39.

Referring to **Figure 2**, to obtain high vacuum levels it is necessary to extract all air from the pumping cavity 29 when the diaphragm 24 is at its upper travel extremity, as illustrated in Fig. 2. This function, in a conventional vacuum pump, will cause damage to the pump when liquid or solids enter the pumping chamber, as they cannot be expelled through the pump's outlet valve fast enough. In the disclosed invention, the flexibility of the diaphragm 24 will allow it to yield, or bulge, when encountering resistance as a result of liquid or solid presence, preventing excessive forces and the ensuing damage.

An additional important function of the flexibility of the diaphragm 24 is its ability to stretch and yield, so that when the vacuum level in the pumping cavity 29 is high, only a smaller effective area of the diaphragm 24 reciprocates, and stretches,

requiring less power from the motor 39 to effect reciprocation.

In Figure 2, the drive 40, which contains the motor 39, crank 27 and reciprocating receptacle rod 26, is shown disengaged from all other parts, since the drive will be re-used, while all other parts, which have directly contacted the matter being pumped, are slated for disposal, and are termed the "disposable pumping system". The disposable pumping system, essentially comprising the canister, the diaphragm, associated valves, the disposable waste bag, and associated tubing, are shown in Figure 2 after all outlets have been sealed for disposal. The suction tube 12 is plugged with a plug 33 to prevent any liquid from leaking out of it. The conduit 30 is disengaged from the vacuum gauge 14 and attached to the air discharge outlet 15, sealing all possible leak paths from three-chambered canister 10.

It will be appreciated by persons skilled in the art that the drive 40, which is the only non-disposable hardware in the preferred embodiment, does not come in contact with any of the pumped media, unlike conventional aspirators or suction pumps, which pass the suctioned air through them, and may thus be contaminated by infectious air.

The method and means for attachment and mounting of the disposable pumping system to drive 40 is illustrated in **Figs. 2 and 3**, whereby the mounting base 23 is placed on top of retainers 41, shown in Fig. 2. The retainers 41 protrude from a shelf- or step-like part of the drive 40 and have a large mushroom-shaped head, which passes through large openings 42 in a flange of the base 23, as shown in Fig. 3. When the three-chambered canister 10 is rotated clockwise, with its mounting base 23, the large heads of the retainers 41 engage slots 45, attaching the mounting

base 23 to the drive 40, in a bayonet-type fastening action using a 45-degree twist. This action is similar to attaching a cap to a glass jar. The drive member 25, shown in Figs. 1, 2, is inserted into the receptacle rod 26, simultaneously with the attachment of the mounting base 23 to the housing of the drive 40.

Referring to **Figure 4**, a spring-loaded lock-clip 46 keys and locks the drive member 25 to the receptacle rod 26, when the lock clip engages pre-aligned slots 48 present in the drive member 25 and the receptacle rod 26. The disengagement of the mounting base 23 from the drive 40 is effected, simultaneously with disengagement of the drive member 25 from the receptacle rod 26, when both are rotated counterclockwise, as illustrated in Fig. 4, by drive member 25 pushing lock clip 46 out of its slot 47, eliminating the keying between drive member 25 and receptacle rod 26. This action is similar to the removal of a cap from a jar, by twisting counterclockwise and lifting.

While only one form of engagement of canister 10 to drive 40 was described in the preferred embodiment of this invention, it would be clear to those skilled in the art, that other similar methods for quick fastening of these parts, can be utilized effectively.

The above-described method of engagement has, however, an important feature that should be noted. Since the receptacle rod 26 may be at its lower position at the time when the drive member 25 is inserted into it, slots 47 and 48 may come into alignment only when motor 39 is powered and crank 27 raises receptacle rod 26 allowing lock clip 46 to key slots 47 and 48. Thus, the insertion of the drive member 25 into the receptacle rod 26 enables engagement, rather than fastening the two together.

CLAIMS

1. A vacuum pump capable of pumping solid, liquid and gas, or any combination thereof, especially useful for suctioning body liquids, comprising a drive and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:

a three-chambered canister, wherein the first chamber has an inlet, and means are provided for retaining solids and preventing their passage from said first chamber to the second chamber; the second chamber having a one-way valve at its exit, said valve allowing passage of liquid and gas out of said second chamber; the third chamber having an outlet for the discharge of air, and having an additional outlet for the discharge of liquid; and said third chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

a highly flexible diaphragm, attached to said three-chambered canister, sealing against it circumferentially, said flexible diaphragm being attached to a partition with said three-chambered canister in which said valves are installed;

a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

means for mounting and engaging said disposable pumping system to the housing of a drive, these means being capable of simultaneously

coupling the drive member to the drive;

wherein, in the assembled vacuum pump, the drive is coupled to the pumping system in such a way that activation of the drive induces reciprocation of said flexible diaphragm, and the pumping system is capable of being attached or detached from drive in a rapid and facile manner.

2. A vacuum pump according to claim 1, wherein the three-chambered canister has a volume of approximately 100 cc.

3. A vacuum pump according to claim 1 or 2, additionally comprising a vacuum outlet port, present in said second chamber, said outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside the first and second chambers.

4. A vacuum pump according to any preceding claim, wherein said means for retaining solids in the first chamber are comprised of a sieve.

5. A vacuum pump according to any preceding claim, wherein said highly flexible diaphragm is capable of yielding or stretching when exposed to high load or resistance.

6. A vacuum pump according to any preceding claim, wherein said highly flexible diaphragm, when subjected to high loads, is capable of stretching to effectively reciprocate only a fraction of its area while the remainder of its surface remains stationary.

7. A vacuum pump according to any preceding

claim, additionally comprising a disposable waste container, for collection of discharged liquid, attached to the liquid discharge outlet of said third chamber;

8. A vacuum pump according to claim 7, wherein said disposable waste container is a waste bag, having any appropriate size.

9. A vacuum pump according to claim 8, wherein the capacity of said waste bag is between 500 cc and 5 liters.

10. The vacuum pump according to any preceding claim, wherein the means for mounting and engaging said pumping system to said drive comprise a mounting base protruding from the lower portion of the three-chambered canister, said mounting base adapted for mating and attaching to said drive housing.

11. A vacuum pump according to any preceding claim, wherein said drive rotates a crank, and said drive is coupled to said drive member via a reciprocating rod receptacle connected to said crank, and said rod receptacle is adapted to mate with said drive member.

12. A vacuum pump according to claim 11, wherein coupling said mounting base to said drive housing, is affected simultaneously with the securing of said drive member to the rod receptacle, in a single operation.

13. A vacuum pump according to claim 11 or 12, additionally comprising a lock clip, capable of securing the drive member to the rod receptacle.

14. A vacuum pump according to any preceding claim, wherein said pumping system and said drive are portable and may be operated on battery power.

15. A vacuum pump according to any preceding claim, wherein said pumping system additionally comprising means for sealing said disposable pumping system, for facilitating disposal of said pumping system, while containing the pumped waste.

16. A vacuum pump according to any preceding claim, wherein said pump is capable of maintaining an unlimited flow of matter therethrough, while maintaining uninterrupted vacuum pressure.

17. A vacuum pump according to any preceding claim, wherein said pump is capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in the first and second chambers.

18. A vacuum pump according to any preceding claim, wherein said pump is capable of suctioning, continuously, an unlimited volume of matter therethrough.

19. A vacuum pump according to any preceding claim, additionally comprising a suction catheter tube attached to the inlet present in said first chamber, for allowing entry of matter into said three-chambered canister.

20. A vacuum pump capable of pumping liquid and gas,comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:
a dual-chambered canister, wherein the first chamber

has an inlet and a one-way valve at the exit of the first chamber, said valve allowing passage of liquid and gas out of said first chamber; and the second chamber having an outlet for the discharge of air and an additional outlet for the discharge of liquid; said second chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

a highly flexible diaphragm, attached to said dual-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said dual-chambered canister in which said valves are installed;

a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

means for mounting and engaging said disposable pumping system on the housing of a drive, wherein said means are capable of simultaneously coupling the drive member to said drive;

wherein in the assembled vacuum pump, said drive is coupled to said pumping system, such that activation of said drive induces reciprocation of said flexible diaphragm; and wherein said pumping system is capable of being attached or detached from said drive in a rapid and facile manner.

21. A vacuum pump capable of pumping liquid and gas, comprising a drive and a disengageable disposable pumping system connected to the drive, wherein the disposable pumping system comprises:

a first chamber having an inlet and a first one-way

valve at its exit, allowing passage of liquid and gas out of the first chamber; and a second chamber having an outlet for the discharge of air and an outlet for the discharge of liquid; and an inlet via a second one-way valve, allowing entrance of liquid or gas through the valve while preventing exit of liquid or gas through the valve;

a flexible diaphragm sealing against the exterior of the chambers so as to define a pump cavity whose inlet is the first one-way valve and whose outlet is the second one-way valve; and

a drive member attached to the diaphragm, reciprocation of which induces reciprocation of the diaphragm;

the pump further comprising means for mounting the disposable pumping system on the housing of the drive, and for coupling the drive member to the drive.

22. A pump system substantially as described herein with reference to the attached drawings.

Amendments to the claims have been filed as follows

CLAIMS

1. A vacuum pump capable of pumping solid, liquid and gas, or any combination thereof, comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system is comprised:

a three-chambered canister, wherein the first chamber has an inlet, and means are provided for retaining solids and preventing their passage from said first chamber to the second chamber; and the second chamber having a one-way valve at its exit, said valve allowing passage of liquid or gas out of said second chamber; and the third chamber having an outlet for the discharge of air, and having an additional outlet for the discharge of liquid; and said third chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

a highly flexible diaphragm, attached to said three chambered canister, sealing it circumferentially, said flexible diagram being attached to a partition with said three-chambered canister, in which said valves are installed;

a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

a bayonet arrangement for selectably simultaneously coupling said disposable pumping system to the housing of a drive and said drive member to the drive, and for selectably simultaneously decoupling said disposable pumping system from the housing of said drive and said drive member from said drive.

2. A vacuum pump according to claim 1, wherein the three-chambered canister has a volume of approximately 100 cc.

3. A vacuum pump according to claim 1 or 2, additionally comprising a vacuum outlet port, present in said second chamber, said outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside the first and second chambers.

4. A vacuum pump according to any of the preceding claims, wherein said means for retaining solids in the first chamber are comprised of a sieve.

5. A vacuum pump according to any of the preceding claims, wherein said highly flexible diaphragm is capable of yielding or stretching when exposed to high load or resistance.

6. A vacuum pump according to any of the preceding claims, wherein said highly flexible diaphragm, when subjected to high loads, is capable of stretching to effectively reciprocate only a fraction of its area while the remainder of its surface remains stationary.

7. A vacuum pump according to any of the preceding claims, additionally comprising a disposable waste container, for collection of discharged liquid, attached to the liquid discharge outlet of said third chamber.

8. A vacuum pump, according to claim 7, wherein said disposable waste container is a waste bag, having any appropriate size.

9. A vacuum pump according to claim 8, wherein the capacity of said waste bag is between 500 cc and 5 liters.

10. The vacuum pump according to any of the preceding claims, wherein the means for mounting and engaging said pumping system to drive comprise a mounting base protruding from the lower portion of the three-chambered canister, said mounting base adapted for mating and attaching to said drive housing.

11. A vacuum pump according to any of the preceding claims, wherein said drive rotates a crank, and said drive is coupled to said drive member via a reciprocating member connected to said crank, and said member is adapted to be coupled with said drive member.

12. A vacuum pump according to claim 11, wherein coupling said mounting base to said drive housing, is effected simultaneously with the securing of said drive member to the reciprocating member, in a single operation.

13. A vacuum pump according to claim 11 or 12, additionally comprising a lock clip, capable of securing the drive member to the reciprocating member.

14. A vacuum pump according to any of the preceding claims, wherein said pumping system additionally comprising means for sealing said pumping system, for facilitating disposal of said pumping system, while containing the pumped waste.

15. A vacuum pump according to any of the preceding claims, wherein said pump is capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in the first and second chambers.

16. A vacuum pump according to any of the preceding claims, additionally comprising a suction catheter tube attached to the inlet present in said first chamber, for allowing entry of matter into said three-chambered canister.

17. A vacuum pump capable of pumping liquid and gas, comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:

a dual-chambered canister, wherein the first chamber has an inlet and a one-way valve at the exit of the first chamber, said valve allowing passage of liquid and gas out of said first chamber; and the second chamber having an outlet for the discharge of air and an additional outlet for the discharge of liquid, said chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;
a highly flexible diaphragm, attached to said dual-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said dual-chambered canister in which said valves are installed;
a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said flexible diaphragm; and

a bayonet arrangement for selectably simultaneously coupling said disposable pumping system to the housing of a drive and said drive member to the drive, and for selectably simultaneously decoupling said disposable pumping system from the housing of said drive and said drive member from said drive.

18. A vacuum pump capable of pumping liquid and gas, comprising a drive and a disengageable disposable pumping system connected to the drive, wherein the disposable pumping system comprises:

a first chamber having an inlet and a first one-way valve at its exit, allowing passage of liquid and gas through the first chamber; and a second chamber having an outlet for the discharge of air and an outlet for the discharge of liquid; and an inlet via a second one-way valve, allowing entrance of liquid or gas through the valve while preventing exit of liquid or gas through the valve;

a flexible diaphragm sealing against the exterior of the chambers so as to define a pump cavity whose inlet is the first one-way valve and whose outlet is the second one-way valve; and

a drive member attached to the diaphragm, reciprocation of which induces reciprocation of the diaphragm;

the pump further comprising means for mounting the disposable pumping system on the housing of the drive, and for coupling the drive member to the drive.

19. A pump system substantially as described herein with reference to the attached drawings.

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Application No: GB 0119811.8 **Examiner:** David Hotchkiss
Claims searched: 1 - 20 **Date of search:** 4 April 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): F1W (WCA, WDX, WDL, WDM); A5R (RCEB)

Int Cl (Ed.7): F04B (9/02, 17/00, 17/03, 35/00, 39/16, 53/22); A61M (1/00)

Other: Online: WPI; EPODOC;JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2124712 A	(MEDTRONIC INC) See especially screws 30 & 32 in figures 1 and 2, which could be unscrewed to detach the motor	
A	EP 1045146 A2	(CLEMENS MICHELER) See English abstract	
A	EP 0494375 A1	(IWAKI CO LTD) See especially column 4 lines 45 - 46	
A	US 4842584	(ABBOTT LAB) See especially column 1, paragraph 2 and chambers 90, 82 & 22	
A	US 4798589	(FISHER SCIENT GROUP INC) See especially column 2 line 35 - column 4 line 59	
A	US 4639245	(OXIMETRIX) See especially figure 1	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

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(21) Application No 9623743.3

(22) Date of Filing 14.11.1996

(30) Priority Data
(31) 9523253 (32) 14.11.1995 (33) GB

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(51) INT CL[6]
A61M 1/00

(52) UK CL (Edition O)
A5R RCEB

(56) Documents Cited
GB 2277035 A EP 0080179 A1 WO 96/05873 A1
WO 93/09727 A1 WO 80/02182 A1 US 4392858 A

(58) Field of Search
UK CL (Edition O) A5R RCEA RCEB RCED RCEX
INT CL[6] A61B 19/00 , A61F 13/00 , A61M 1/00
ONLINE: WPI

(54) Portable pump for draining fluid from a wound dressing

(57) Wound healing is stimulated by applying a porous dressing from which fluid is drawn into canister 100 via a catheter using portable suction pump 6 which is contained in housing 210 and is worn on a harness or belt. Overfilling of canister 100 is prevented by a filter contained in the canister and a pressure sensor which detects pressure reductions in tube 103 between canister 100 and pump 6 which occur when drainage liquid covers the filter. Contamination of pump 6 is prevented by a further filter placed between pump 6 and canister 100 and pressure at the wound site is monitored by a conduit connected to the porous dressing.

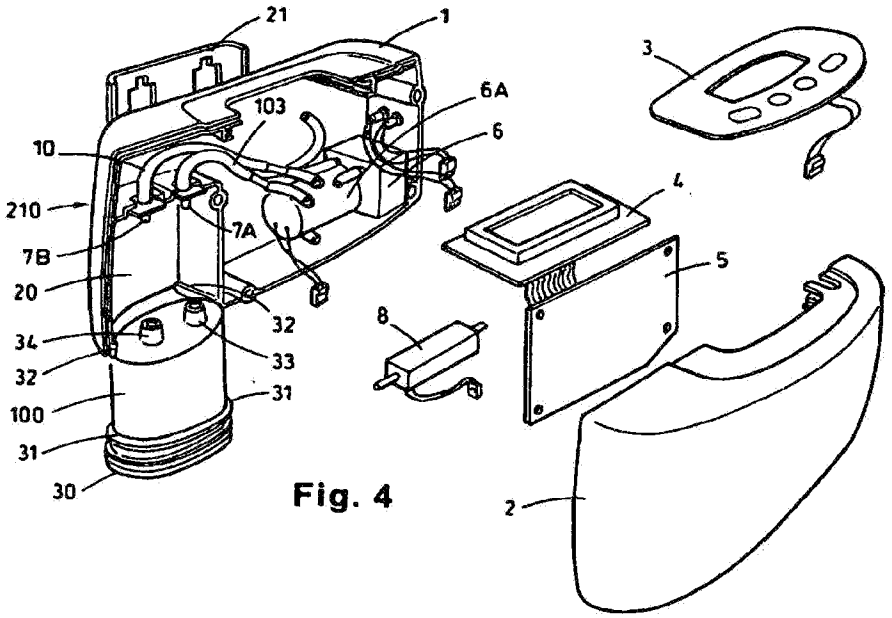


Fig. 4

GB 2 307 180 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

Solventum-Exhibit 1002-0370

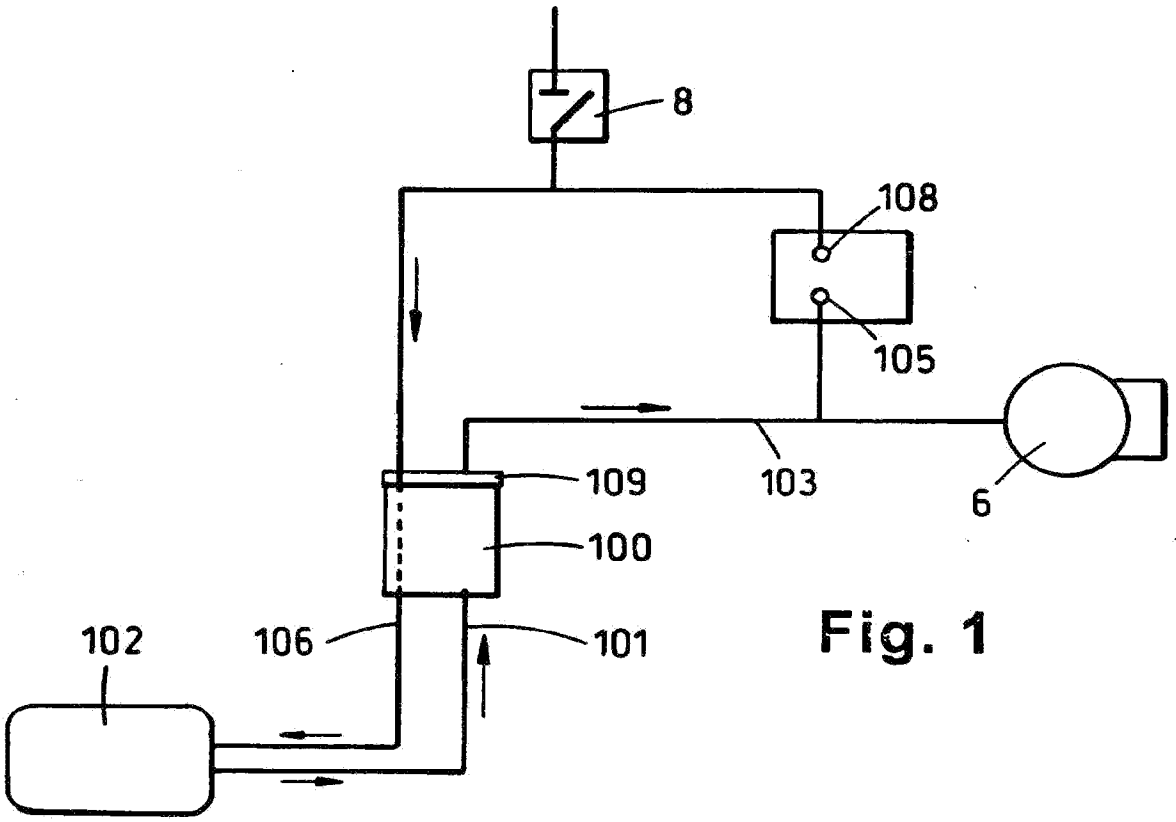


Fig. 1

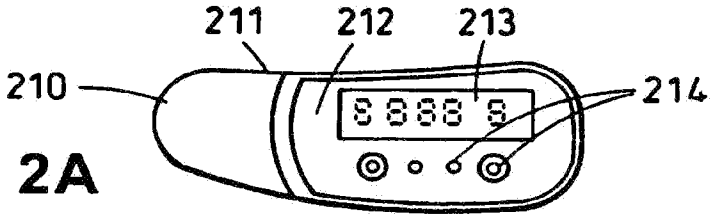


Fig. 2A

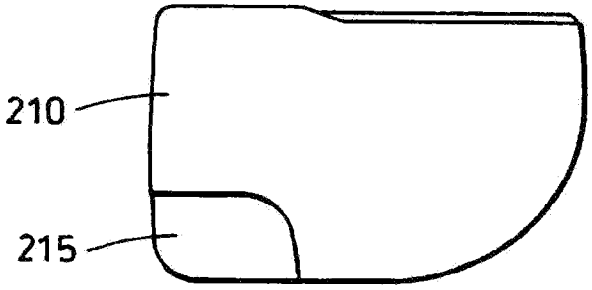


Fig. 2B

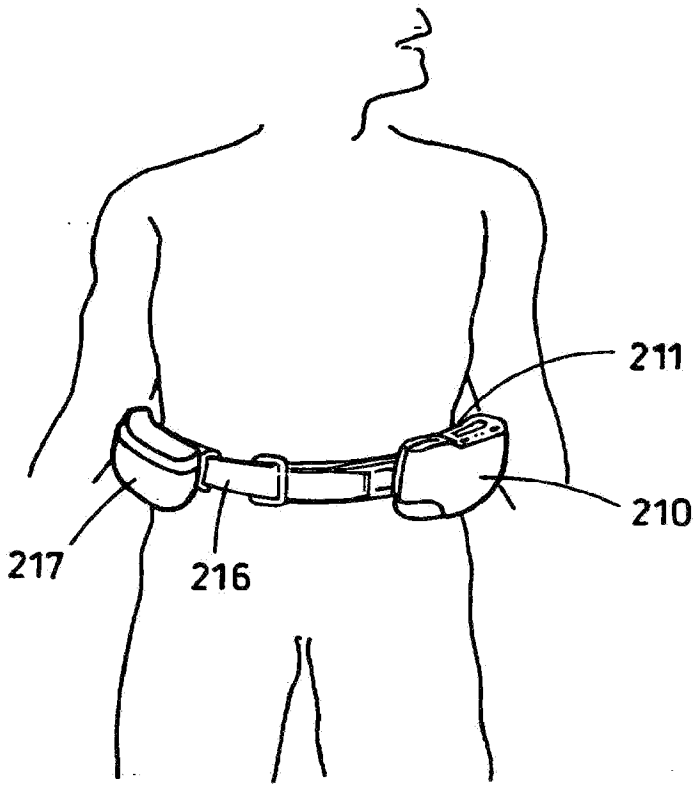


Fig. 3A

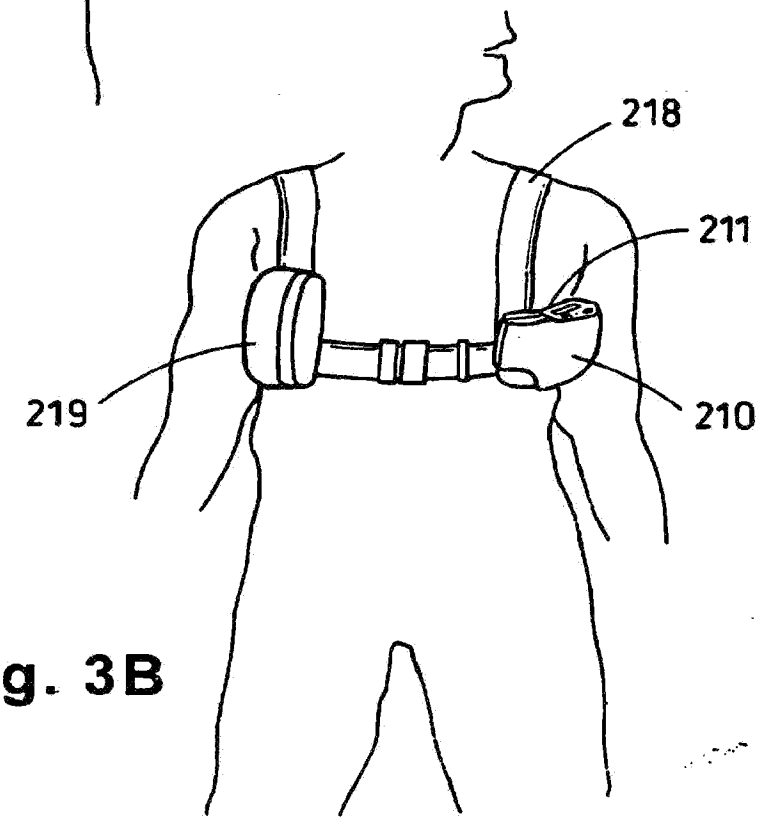


Fig. 3B

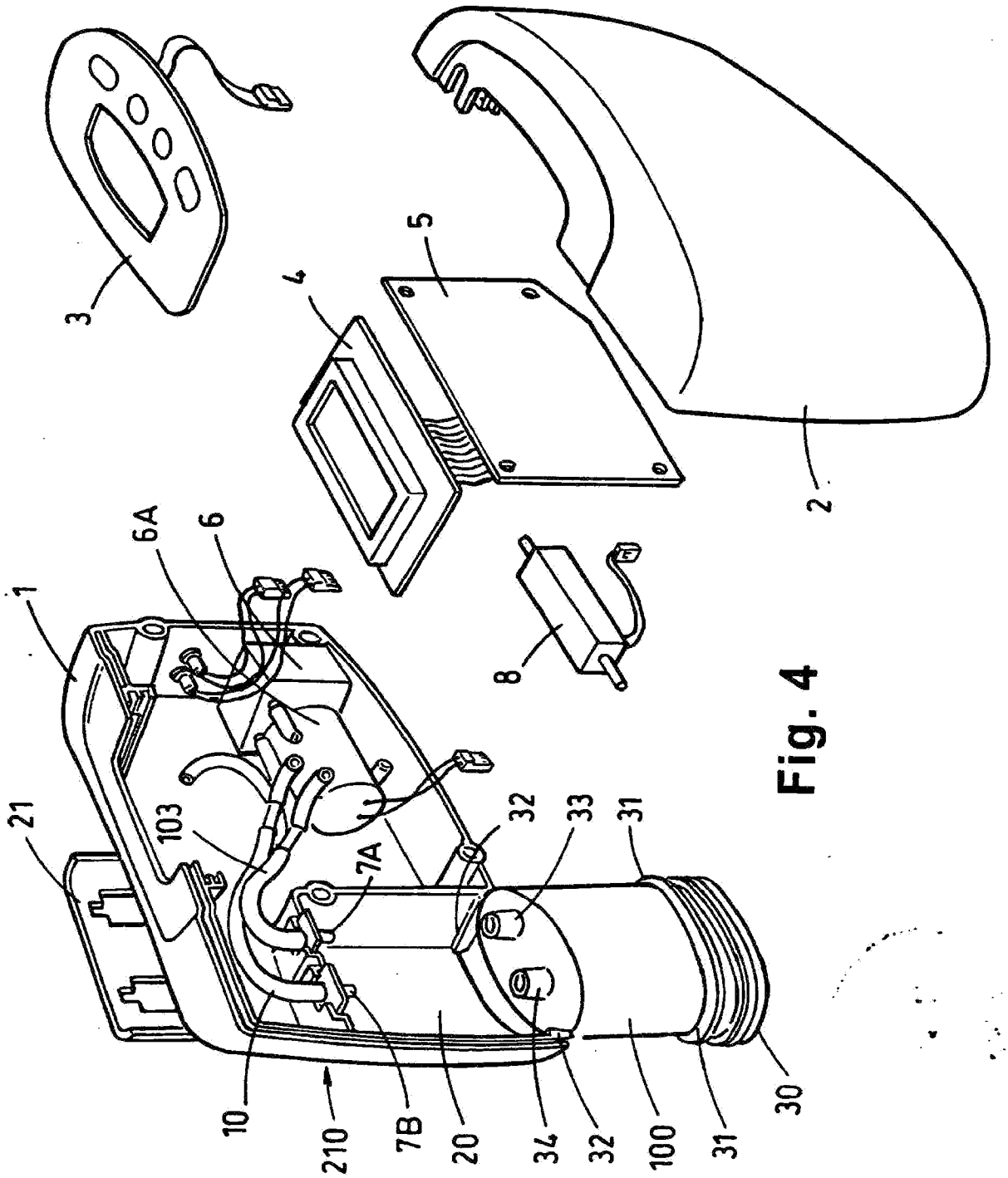


Fig. 4

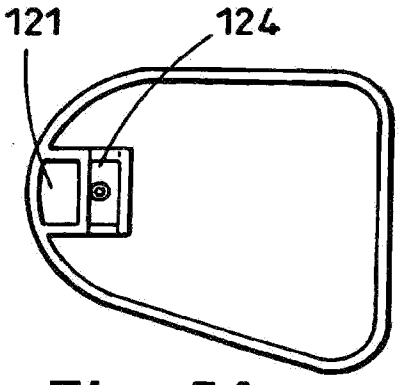


Fig. 5A

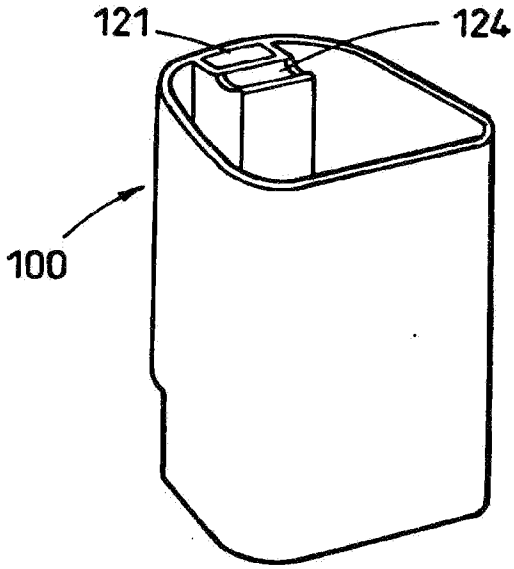


Fig. 5D

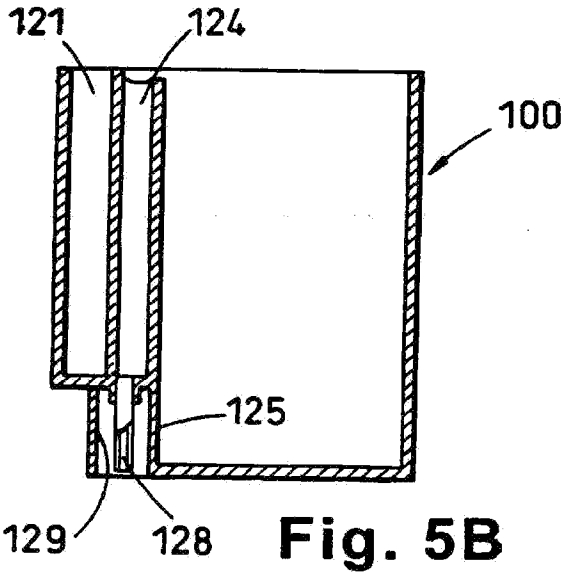


Fig. 5B

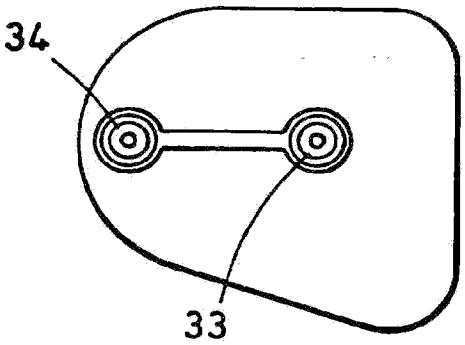


Fig. 5E

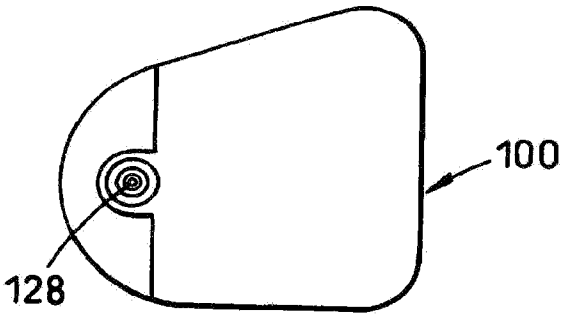


Fig. 5C

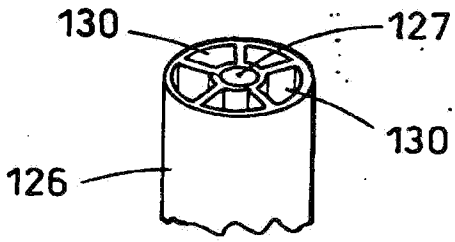


Fig. 5F

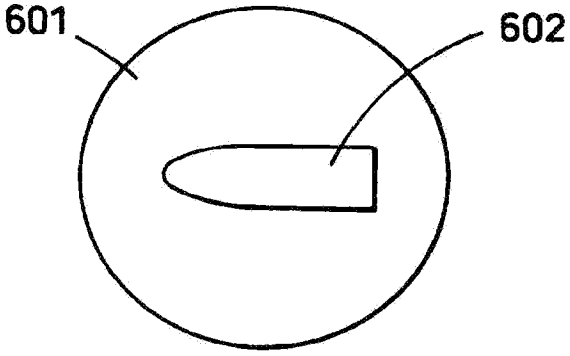


Fig. 6A

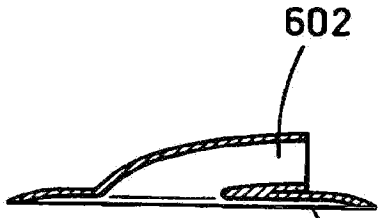


Fig. 6B



Fig. 6C

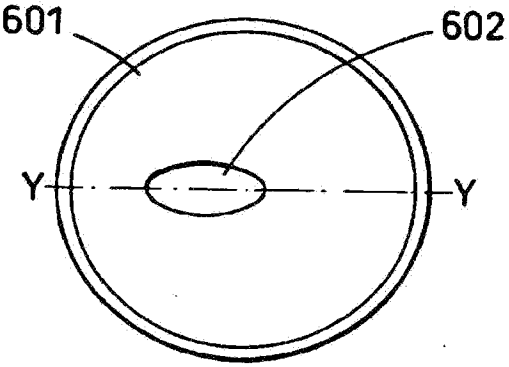


Fig. 6D

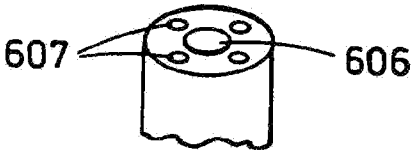


Fig. 6E

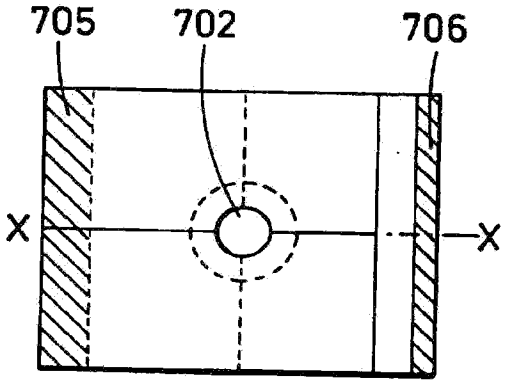


Fig. 7A

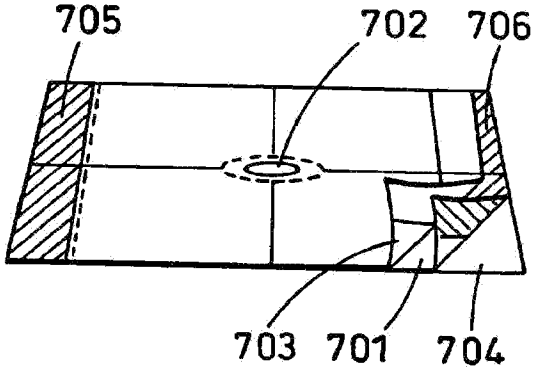


Fig. 7B

2307180

PORTABLE WOUND TREATMENT APPARATUS

This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile it means that he or she would be confined for long periods while the treatment takes place.

An object of this invention is therefore to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

According to one aspect of the present invention there is provided a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including

Solventum-Exhibit 1002-0376

means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

Typically, the housing will have a curved surface on the side intended to be supported against the person's body so as to make the apparatus more comfortable to wear. In addition, controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above PCT application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a

predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of the apparatus in accordance with the invention,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

Figures 6A to D show various views of a foam dressing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube,

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig in to the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A the housing 210 is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister

spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in manner to be described later. By means of tube 106 and transducer 108 the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the

canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lypophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by

an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

In an alternative embodiment, the multi-lumen tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

Figure 5E is a plan view of the top of a preferred shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with respectively conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5F. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for

a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

Figures 6A~6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity is formed around the wound.

In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed

by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705,706, which are not coated with adhesive, to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound re-sutured. This therapy improves the rate of granulation and healing of wounds after surgery.

CLAIMS:-

1. A portable therapeutic apparatus for stimulating the healing of a superficial wound in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

2. Apparatus as claimed in claim 1 wherein the housing has a curved surface on the side intended to be supported against the person's body, and controls located on an upper side of the housing.

3. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and a filter barrier located in the canister at the outlet side, and pressure detecting means arranged to detect pressure changes in the tube between the canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

4. Apparatus as claimed in claim 3 wherein the filter barrier covers the entire outlet from the canister and the dimensions of the pores in said barrier are such that when liquid covers substantially the whole of the filter barrier, said pressure detecting means signals a sharp increase in negative pressure in the tube connecting the canister with the pump.

5. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and at least one filter interposed between the canister and the pump, said apparatus including an additional conduit connecting the porous pad to pressure detecting means whereby the pressure substantially at the wound site can be monitored.

6. Apparatus as claimed in claim 5 which includes a relief valve for admitting air to the additional conduit and means for controlling the operation of the valve so that intermittent suction can be applied to the wound site.

7. Apparatus as claimed in claim 5 or 6 in which a single tube links the porous pad with the housing, said tube being longitudinally partitioned to provide a conduit for applying suction and an additional conduit for connection to said pressure detecting means.

The Patent Office

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Application No: GB 9623743.3 **Examiner:** Mr S J Pilling
Claims searched: 1 and 2 **Date of search:** 11 February 1997

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RCEA, RCEB, RCED, RCEX)

Int Cl (Ed.6): A61B 19/00, A61F 13/00, A61M 1/00,

Other: ONLINE: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	GB 2277035 A	(UNITED SURGICAL SERVICES) see page 6 lines 8 to 18 and the figures, particularly Figure 1.	1
Y	EP 0080179 A1	(INTERMEDICAT) 01.06.83 (see the figures and also WPI Abstract Accession No. 83-54112K/23)	1
P,A	WO 96/05873 A1	(MEDISCUS PRODUCTS) see page 4 line 27 to page 12 line 9 and the figures.	-
Y	WO 93/09727 A1	(WAKE FOREST UNIVERSITY) see the examples, particularly Examples 4 to 8 and the figures.	1
Y	WO 80/02182 A1	(MOSS) see page 2 lines 18 to 33, page 4 lines 16 to 31 and the figures, particularly Figure 1.	1
Y	US 4392858	(GEORGE & DI PALMA) see column 2 lines 24 to 36 and the figures, particularly Figure 1	1

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.
& Member of the same patent family

A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.

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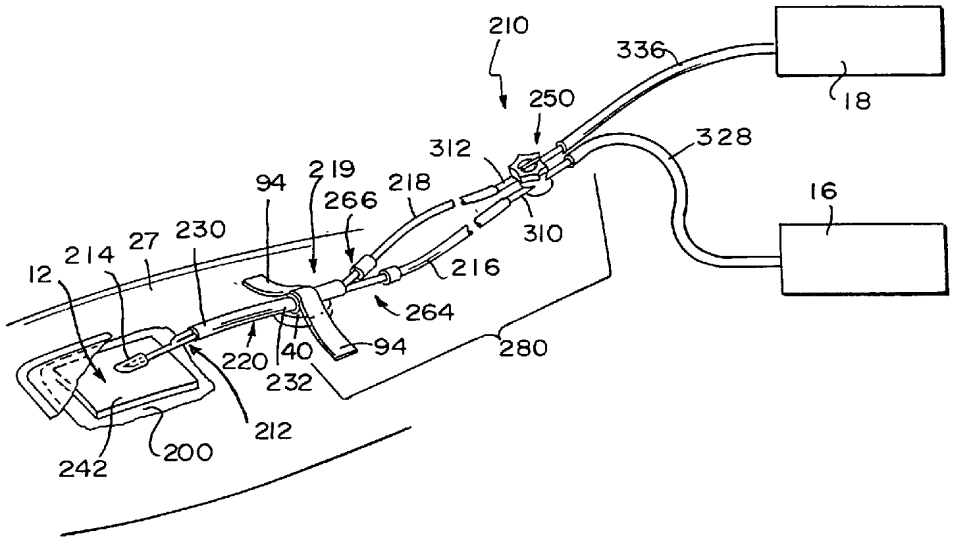
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[Continued on next page]

(54) Title: VENTED VACUUM BANDAGE AND METHOD



(57) Abstract: A ventilated bandage system (10, 210, 400) is provided for use with a wound (200). The system (10, 210, 400) includes a bandage (14, 410) positioned adjacent the wound (200) to create a sealed environment around the wound (200). A vacuum source (16) of the system (10, 210, 400) is in communication with the bandage (14, 410) to create negative pressure between the bandage (14, 410) and the wound (200). The system (10, 210, 400) may also include a first passageway or vent (19, 119, 219, 460) in communication with the bandage (14, 410) and with the surrounding atmosphere, and a second passageway in communication with the bandage and with the vacuum source (16).

WO 03/057070 A2

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

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VENTED VACUUM BANDAGE AND METHOD

BACKGROUND OF THE INVENTION

The present disclosure relates to vacuum therapy wound treatment systems including a vacuum bandage coupled to a vacuum source and an irrigation source.

The prior art contemplates that chronic wounds may be treated by providing a vacuum in the space above the wound to promote healing. A number of prior art references teach the value of the vacuum bandage or the provision of vacuum in the space above the surface of a chronic wound.

A vacuum bandage is a bandage having a cover for sealing about the outer perimeter of the wound and under which a vacuum is established to act on the wound surface. Applying vacuum to the wound surface promotes healing of chronic wounds. Typically, suction tubes are provided for drawing exudate away from the wound and for creating a vacuum under the cover. The following U.S. Patents establish the nature of vacuum treatment bandages and devices: 6,095,992; 6,080,189; 6,071,304; 5,645,081; 5,636,643; 5,358,494; 5,298,015; 4,969,880; 4,655,754; 4,569,674; 4,382,441; and 4,112,947. All of such references are incorporated herein by reference.

Further, the prior art contemplates that wounds may be treated by providing irrigation in the space above the wound. Typically, a tube is provided in communication with the wound surface of the wound at one end and with an irrigation source an another end. The fluid from the irrigation source travels through the tube to the wound surface.

The prior art further contemplates the use of stopcocks for use in intravenous injections and infusions. Stopcocks may be designed to include multiple ports for directing fluid flow along various paths or channels. The following U.S. Patents establish the nature of stopcocks: 6,158,467; 3,586,049; 2,485,842; 2,842,124; and U.S. Patent Application Publication No. US 2001/00 13370 A1.

SUMMARY OF THE INVENTION

The present invention comprises one or more of the following features or combinations thereof:

A wound care bandage system is provided for use with a wound. The system, among other things, may be capable of ventilating the wound. The system may include a vacuum source, an irrigation source, a vent in communication with the surrounding atmosphere and with the wound, and a bandage. The vacuum source creates negative pressure above the wound and the irrigation source irrigates the wound. As is herein defined, the term "vent" is or includes any passageway to the atmosphere, unless noted otherwise.

The bandage is configured to lie adjacent the wound to create a sealed environment about the wound. The vent may be positioned between the bandage and the vacuum source. A vacuum passageway of the system may extend between the bandage and the vacuum source, and a vent passageway of the system may extend from the bandage to the vent in communication with the surrounding atmosphere. The vacuum passageway may extend through the vent to the vacuum source.

The system may also include a multi-lumen tube which forms the vacuum passageway and the vent passageway, and a wound dressing member coupled to the multi-lumen tube configured to lie adjacent the wound. The multi-lumen tube may be configured to couple to the vacuum bandage and may include a venting lumen in communication with the surrounding atmosphere and another vacuum/irrigation lumen in communication with either or both of the vacuum source and the irrigation source. Further, the multi-lumen tube may include a vacuum lumen and a separate irrigation lumen distinct from the vacuum lumen.

The system may also include a vent-valve apparatus having the vent or a portion of the vent passageway formed therein. The apparatus provides selective communication between the wound and either the vacuum source or the irrigation source. The apparatus may include a multi-lumen connector configured to communicate with the bandage. The multi-lumen connector may include at least one inner conduit in communication with the vacuum source and/or the irrigation source and at least one outer conduit in communication with the atmosphere. The apparatus may further include a vacuum connector coupled to the vacuum source and an irrigation connector coupled to the irrigation source. An opening of the apparatus may be provided to communicate with the atmosphere and with the outer conduit of the multi-lumen connector.

In one embodiment, the apparatus may include a vent having the multi-

lumen connector, and a stopcock coupled to the vent and including the vacuum connector and the irrigation connector. The vent may include a single-lumen connector coupled to the inner conduit of the multi-lumen connector. The vent may further include a housing and a filter housed within the housing. The filter may be in communication with the surrounding atmosphere and with the outer conduit of the multi-lumen connector through the opening.

The stopcock may include a single-lumen connector coupled to the single-lumen connector of the vent and a diverter to selectively couple the single-lumen connector of the stopcock with either the vacuum connector or with the irrigation connector. The stopcock may further include a body and the diverter may be coupled to the body for rotational movement relative to the body. The diverter may include a cut-out portion to selectively communicate the vacuum connector or the irrigation connector with the vent.

In another embodiment, the apparatus may include a body or outer shell defining an aperture and a diverter or inner barrel received within the aperture. The diverter may rotate relative to the outer shell to selectively communicate with the vacuum source or the irrigation source. The outer shell may include the multi-lumen connector, the vacuum connector, and the irrigation connector. The diverter may include a first set of passageways and a second set of passageways formed therethrough. The first set of passageways communicates with the inner conduit of the multi-lumen connector, the vacuum connector, and the irrigation connector. The second set of passageways may communicate with the outer conduit of the multi-lumen connector through a groove or channel formed in the outer shell between the outer conduit and the second set of passageways. The outer shell illustratively includes the opening of the apparatus and the second set of passageways is in selective communication with the opening. A filter may be coupled to the opening.

In yet another embodiment, the apparatus may include a vent and a stopcock coupled to the vent. The vent may include a multi-lumen connector and a first and second single-lumen connector. The stopcock may include a vacuum connector and an irrigation connector. The vacuum connector may include a first portion coupled to the first single-lumen connector of the vent and a second portion coupled to the vacuum source. The irrigation connector may include a first portion coupled to the second single-lumen connector of the vent and a second portion

coupled to the irrigation source.

The inner conduit of the multi-lumen connector may be a vacuum conduit and the multi-lumen connector may further include an irrigation conduit. Each of the vacuum and irrigation conduits may be positioned within the outer conduit. The vacuum conduit may be coupled to the first single-lumen connector of the vent and the irrigation conduit may be coupled to the second single-lumen connector of the vent. The vent further may include a housing coupled to the multi-lumen connector and a filter within the housing. The filter may be in communication with the surrounding atmosphere and with the opening through a passageway of the housing.

The stopcock may include a body coupled to the vacuum and irrigation connectors and a diverter received within an aperture of the body. Each of the first and second portions of the vacuum and irrigation connectors may communicate with the aperture of the body. The vacuum connector may illustratively lie in a first horizontal plane and the irrigation connector may illustratively lie in a second horizontal plane.

The diverter may include a first cut-out portion for communication with the vacuum connector and a second cut-out portion for communication with the irrigation connector. The diverter may rotate relative to the body to connect the first and second portions of the vacuum connector with each other and to connect the first and second portions of the irrigation connector with each other to selectively communicate the vacuum source and the irrigation source to the wound.

Other features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of the preferred embodiments exemplifying the best mode of carrying out the invention as presently perceived.

BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description particularly refers to the accompanying figures in which:

Figs. 1-8 illustrate components of a wound care bandage system of the present disclosure which provides suction, irrigation, and ventilation to a wound;

Fig. 1 is a part perspective, part diagrammatic view of the wound care

bandage system located on the leg of a patient and coupled to a vent and to vacuum and irrigation sources through the use of a stopcock or a switch valve;

Fig. 2 is a perspective view of the vent of the system showing a multi-lumen connector for communication with the wound via a multi-lumen tube, a single-lumen connector for communication with the switch valve, and a circular housing holding a filter (in phantom) in communication with the surrounding atmosphere;

Fig. 3 is a side view of the vent, with portions broken away, showing the multi-lumen connector aligned for coupling to the multi-lumen tube, the single-lumen connector aligned for coupling to a single lumen tube, a passageway of the vent extending between outer lumens of the multi-lumen tube and the filter of the vent, and further showing a thin, flexible wound dressing member of the bandage coupled to the multi-lumen tube by a barbed coupler;

Fig. 4 is a sectional view of the multi-lumen tube taken along line 4-4 of Fig. 3 showing an inner lumen of the tube for communication with the vacuum source and the irrigation source of the system and four outer lumens of the tube for communication with the filter and surrounding atmosphere to aspirate an area above the wound;

Fig. 5 is an exploded perspective view of the switch valve and vent of the system showing a vent connector of the valve aligned for coupling to the single-lumen connector of the vent, a vacuum connector for communication with the vacuum source, an irrigation connector for communication with the irrigation source, and a handle or diverter for providing selective communication between the vent connector and either the vacuum source or the irrigation source;

Figs. 6a and 6b are perspective views of the handle of the switch valve showing a grip and a stem of the handle and further showing a cut-out portion of the stem for selective communication between the vent, vacuum, and irrigation connectors of the switch valve;

Fig. 7 is a sectional view taken along line 7-7 of Fig. 5 showing the handle of the switch valve in an irrigation position so that the cut-out portion provides a passageway between the irrigation connector and the vent connector to permit fluid from the irrigation source to run through the switch valve to the wound;

Fig. 8 is a sectional view similar to Fig. 7 showing the handle of the switch valve in a vacuum position so that the cut-out portion provides a passageway

between the vacuum connector and the vent connector to permit the vacuum source to draw fluid and exudate from the wound;

Figs. 9-16 illustrate components of another wound care bandage system in accordance with the present disclosure which also provides suction, irrigation, and ventilation to the wound;

Fig. 9 is a part perspective, part diagrammatic view similar to Fig. 1 showing the wound care bandage system of Figs. 9-16 including a two-level stopcock or switch valve in selective communication with the bandage, vacuum source, and irrigation source of the system, and further showing the two-level stopcock including a vent coupled to a filter;

Fig. 10 is an exploded view of the two-level stopcock showing an inner barrel or handle and an outer shell, with portions broken away, and further showing the inner barrel having a grip and a stem including an upper level of ports for communication with either the vacuum source or the irrigation source, depending on the position of the inner barrel relative to the outer shell, and a lower level of ports for communication with the vent, and further showing an inner vent groove of the outer shell for providing communication between the outer lumens of the multi-lumen tube and the lower level ports of the barrel;

Figs. 11-16 show three positions of the two-level stopcock provided by moving the inner barrel relative to the outer shell to selectively align certain upper level ports of the inner barrel with the vacuum and irrigation connectors of the outer shell and to selectively align certain lower level ports with the vent of the outer shell;

Figs. 11 and 12 show the two-level stopcock in a vented vacuum position so that the vacuum source and vent are in communication with the wound to create a negative pressure adjacent the wound while drawing air into the system through the vent and over the wound to aspirate the passageways of the system;

Fig. 11 is a top view of the two-level stopcock in the vented vacuum position showing a passageway (in phantom) connecting the vacuum connector and the multi-lumen tube connector;

Fig. 12 is a sectional view taken along line 13-13 of Fig. 9 when the two-level stopcock is in the vented vacuum position showing venting passageways of the inner barrel and showing one passageway connecting the vent groove of the outer shell with the vent;

Figs. 13 and 14 show the two-level stopcock in a vacuum position where only the vacuum source is in communication with the wound to create a negative pressure adjacent the wound;

Fig. 13 is a top view similar to Fig. 11 of the stopcock in the vacuum position after the handle has been turned clockwise from the vented vacuum position shown in Fig. 11, and showing a passageway (in phantom) between the vacuum connector and the multi-lumen tube connector;

Fig. 14 is a sectional view similar to Fig. 12 showing the two-level stopcock in the vacuum position where none of the venting passageways of the inner barrel connect the vent groove of the outer shell with the vent;

Figs. 15 and 16 show the two-level stopcock in a vented irrigation position where the irrigation source and the vent are in communication with the wound;

Fig. 15 is a top view similar to Figs. 11 and 13 showing the two-level stopcock in the vented irrigation position after the handle has been turned clockwise from the vacuum position shown in Fig. 13, and showing a passageway (in phantom) between the irrigation connector and the multi-lumen connector;

Fig. 16 is a sectional view similar to Figs. 12 and 14 showing the two-level stopcock in the vented irrigation position and showing a passageway of the inner barrel connecting the vent groove of the outer shell with the vent;

Figs. 17-19 show a multi-lumen tube coupler according to the present disclosure for use with either of the systems illustrated in Figs. 1-8 and Figs. 9-16 described above for coupling two multi-lumen tubes together;

Fig. 17 is a part perspective, part diagrammatic view of the multi-lumen tube coupler in use with the system shown in Figs. 9-16;

Fig. 18 is a perspective view of the multi-lumen tube coupler showing an inner passageway for communication with each inner lumen of the multi-lumen tubes and an outer passageway for communication with each outer lumen of the multi-lumen tubes, and also showing a contoured upper surface and a flat bottom surface of the tube coupler;

Fig. 19 is a sectional view of the multi-lumen tube coupler coupled to two multi-lumen tubes showing a flow path of fluids through the multi-lumen tubes and the coupler;

Figs. 20 -28 illustrate components of yet another wound care bandage system in accordance with the present disclosure for providing suction, irrigation, and ventilation to the wound;

Fig. 20 is a part perspective, part diagrammatic view similar to Fig. 1 showing the wound care bandage system of Figs. 20-28 including a vent coupled to the bandage via a multi-lumen tube (shown in Fig. 21) and a stopcock or switch valve coupled to the vent (via two single-lumen tubes) to provide selective communication between the bandage and the irrigation and vacuum sources;

Fig. 21 is an end view of the multi-lumen tube of the system shown in Figs. 20-28 showing the tube including a vacuum lumen, an irrigation lumen, and four outer vent lumens formed within a body of the tube;

Fig. 22 is a perspective view of a "Y-connecter" of the system shown in Figs. 20-28 for coupling the wound dressing member of the bandage with the multi-lumen tube shown in Fig. 21 showing a bandage portion of the connector for insertion within a connector of the member, a vacuum portion for insertion within the vacuum lumen of the multi-lumen tube, and an irrigation portion for insertion within the irrigation lumen of the multi-lumen tube;

Fig. 23 is a perspective view of the vent of the system shown in Fig. 20 showing a multi-lumen connector for coupling with the multi-lumen tube of Fig. 21, a vacuum connector for communication with the vacuum source via a single-lumen tube, an irrigation connector for communication with the irrigation source via a separate single-lumen tube, and also showing a filter housing coupled to the multi-lumen connector for communication with the venting lumens of the multi-lumen tube and with the atmosphere;

Fig. 24 is a sectional view of the vent coupled to the multi-lumen tube and the two single-lumen tubes showing a filter of the vent (in phantom), the separate vacuum, irrigation, and vent passageways formed through the vent, and also showing the Y-connecter of the system coupled to the multi-lumen tube and to the member;

Fig. 25 is an exploded perspective view of the stopcock or switch valve of the system shown in Figs. 20-28 showing two separate passageways through a body of the stopcock for separate communication with the vacuum source and the irrigation source, and showing a handle or diverter, having two cut-out portions, to be received within the body of the stopcock;

Figs. 26-28 are sectional views showing the stopcock in an irrigation position, a vacuum position, and an off position;

Fig. 26 is a sectional view of the stopcock showing the stopcock in the vacuum position so that a first cut-out portion of the handle creates a passageway between first and second portions of a vacuum conduit of the stopcock;

Fig. 27 is a sectional view similar to Fig. 26 showing the stopcock in the irrigation position where the handle has been rotated in a clockwise direction from that shown in Fig. 26 so that a second cut-out portion (shown in phantom) connects first and second portions of an irrigation conduit with each other;

Fig. 28 is a sectional view similar to Figs. 26 and 27 showing the stopcock in the off position where the handle has been rotated 180 degrees from that shown in Fig. 27 so that neither the first nor the second cut-out portions connect the first and second portions of either of the vacuum conduit or the irrigation conduit;

Figs. 29-31 illustrate components of still another vacuum bandage system of the present disclosure which provides suction, irrigation, and ventilation to a wound;

Fig. 29 is a part perspective and part diagrammatic view of a vacuum bandage system of the present disclosure showing a wound dressing member of the bandage including a cover having a port and a wound contacting layer having a wound contacting surface and channels formed in an opposite surface to cooperate with the cover and form passageways of the member in communication with the port and a vacuum source and/or an irrigation source, and also showing a vent line or tube having a first end for communication with the passageways and a second end in communication with the surrounding atmosphere through a filter and a cap;

Fig. 30 is a sectional view of the bandage of Fig. 29 positioned within a wound and showing a sealing film of the bandage providing a sealed vacuum space above the wound, the first end of the vent line in communication with the vacuum space, and the second end of the vent line coupled to the filter and to the cap outside of the vacuum space;

Fig. 31 is a sectional view taken along line 31-31 of Fig. 30 showing the vent line and a vacuum tube coupled to each other by a coupler;

Fig. 32 is a sectional view of an alternative vent line and vacuum tube showing a multi-lumen tube having a vent passageway and a vacuum tube

passageway formed therein and separated by a partition; and

Fig. 33 is a sectional view of yet another vent line and vacuum tube combination showing an outer wall of the vent line and an outer wall of the vacuum tube integrally coupled to one another to form a single multi-lumen tube.

DETAILED DESCRIPTION OF THE DRAWINGS

A wound care bandage system is provided which has the capability to create negative pressure adjacent the wound, to irrigate the wound, and to ventilate the wound. A vent of the system is provided to communicate with the wound and with the surrounding atmosphere. In some embodiments, a vent-valve apparatus or a vent and valve combination of the system is in communication with the wound and with a vacuum source and an irrigation source of the wound. The vent-valve apparatus includes the vent which is in communication with the surrounding atmosphere and a diverter to provide selective communication between the wound and the irrigation source or between the wound and the vacuum source, as is described in greater detail below.

One embodiment of a wound care bandage system 10 is shown in Figs. 1-8 and is provided to allow a caregiver to create a negative pressure above a wound surface (not shown) of a wound 200 (see Fig. 20) through the use of an illustrative vacuum bandage 14 and a vacuum source 16, as shown in Fig. 1. System 10 further allows a caregiver to irrigate the wound surface through the use of an irrigation source 18. Additionally, system 10 ventilates the wound during the application of negative pressure to the wound and irrigation of the wound through use of a vent 19 in communication with the surrounding atmosphere.

The system 10 further includes a stopcock or switch valve 50 coupled to vent 19. Switch valve 50 allows a caregiver to selectively provide communication between the wound and either vacuum source 16 or irrigation source 18. As is herein defined, the terms switch valve and stopcock are used interchangeably to describe an apparatus for selectively controlling and/or diverting fluid flow therethrough. As shown in Fig. 1, switch valve 50 is coupled to vent 19 via a single-lumen tube 52. However, switch valve 50 may also be coupled directly to vent 19, as shown in Fig. 5 and described in more detail below. The vent 19 and switch valve 50 (and tube 52, if used) cooperate to create a vent-valve assembly 80 to allow a caregiver to toggle

between different modes such as vented vacuum therapy and vented irrigation therapy. The system 10 incorporates two separate fluid lines. One fluid line selectively provides vacuum suction or irrigation to the wound while the other fluid line vents the system 10 by providing communication between the wound and the surrounding atmosphere to create air flow above the wound.

Vacuum bandage 14, as shown in Fig. 1, is provided for use with the wound and is sealed about the wound by a cover or sealing film 13 of bandage 14 to create a sealed environment between the wound and sealing film 13 in which a negative pressure can be established. Bandage 14 is selectively coupled to both vacuum source 16 and irrigation source 18 through the use of switch valve 50, as is described in more detail below.

Bandage 14 promotes the healing of the wound by providing vacuum therapy to the wound to promote blood flow and remove exudate from the wound surface and by providing for irrigation of the wound with fluids such as saline, for example. An illustrative wound treatment apparatus having a wound temperature control system, a medicine delivery system, and a drainage system is disclosed in U.S. Patent No. 6,458,109. An illustrative vacuum and irrigation system is disclosed in U.S. Patent Publication No. US 2002/0161317 A1. Additionally, an illustrative vacuum bandage is disclosed in U.S. Patent Publication No. US 2002/0065494 A1. Alternative vacuum bandages are disclosed in U.S. Patent Publication No. US 2002/0082567 A1. Further, a vacuum bandage system including a controller of the system is disclosed in U.S. Patent Application No. 10/159,583 filed on May 31, 2002, titled WOUND TREATMENT APPARATUS and in U.S. Patent Application No. 10/159,720 filed on May 31, 2002, titled WOUND TREATMENT APPARATUS. All of these applications are hereby incorporated herein by reference.

As mentioned above, system 10 incorporates two separate fluid lines to provide vented vacuum therapy and vented irrigation therapy to the wound. Venting of bandage 14 is disclosed in U.S. Patent Application Serial No. 60/344,588 filed on December 26, 2001. This application is hereby incorporated herein by reference. Venting provides for increased air flow through bandage 14 and above or adjacent the wound while vacuum source 16 applies suction to the wound. System 10 is also vented while irrigation source 18 provides fluid to the wound. Without providing for ventilation of the system 10 during operation of vacuum source 16, a generally closed

system is created between vacuum bandage 14 and vacuum source 16. For example, in bandages without a ventilation system, once the requisite amount of air has been removed by the vacuum source 16 to create a predetermined negative pressure at the wound surface, it is possible for the system to become generally static, inhibiting much, if any, fluid flow from the wound surface. In some embodiments disclosed herein, static conditions may be created at the wound surface.

Ventilation of the system 10, while drawing a negative pressure over the wound, acts to prevent the system 10 from becoming static by drawing air in from the surrounding atmosphere through vent 19, to bandage 14 to create air flow above the wound, and out through a vacuum tube in communication with vacuum source 14. Therefore, venting the system 10 increases air flow above the wound while vacuum source 16 applies suction to the wound.

The two fluid lines for ventilation and vacuum/irrigation of the wound are provided in multi-lumen tube 20, shown in cross-section in Fig. 4. As shown in Fig. 3, tube 20 is coupled to a connector 15 of bandage 14, and is therefore in communication with the wound at one end 21 and is coupled to vent 19 at the other end 23. Tube 20 includes an inner lumen 22 for selective communication with the vacuum source 16 and the irrigation source 18 and outer lumens 24 formed in a body or outer wall 25 of tube 20 for communication with the surrounding atmosphere through vent 19. Inner lumen 22 thus defines a portion of a vacuum/irrigation passageway 42 and outer lumens 24 each define a portion of a ventilation passageway 44.

As shown in Fig. 4, tube 20 includes four outer lumens 24 spaced about inner lumen 22. It is within the scope of this disclosure, however, to include a multi-lumen tube having one or more outer lumens in communication with the surrounding atmosphere and one or more inner lumens in selective communication with the vacuum source 16 and the irrigation source 18. Illustratively, the outer diameter 26 of tube 20 is 0.250 inch (6.300 mm), the inner diameter 28 of tube 20 (the diameter of inner lumen 22) is 0.125 inch (3.150 mm), and the diameter 29 of each outer or peripheral lumen is 0.014 inch (0.353 mm). Although tube 20 includes the above dimensions, it is within the scope of this disclosure to provide any suitable multi-lumen tube having lumens of any suitable size.

As shown in Fig. 3, bandage 14 illustratively includes a thin, flexible

wound dressing member 12 having connector 15 coupled to tube 20 by a barbed tube coupler 11. Member 12 lies adjacent to and generally conforms to the wound surface. Sealing film 13 is placed over member 12 and sealed around tube 20 to the patient's healthy skin 27 surrounding the wound, as shown in Fig. 1. Illustratively, connector 15 is in communication with the wound by a plurality of passageways 66 of member 12 and a plurality of holes 67, each in communication with one of the passageways 66, formed in a bottom surface 68 of member 19. Tube coupler 11 connects inner lumen 22 of tube 20 with connector 15. Each outer lumen 24 is open at an end 21 of tube 20. This allows air to be drawn in from the atmosphere through vent 19, to flow through outer lumens 24 and exit tube 20 at end 21, to circulate around member 12 to the wound surface, and to flow through the holes 67 and passageways 66 of member 12 into a vacuum/irrigation passageway 42 formed in part by lumen 22. The negative pressure created by vacuum source 16 causes air to flow through system 10 in this manner.

Although bandage 14 is described above, it is within the scope of this disclosure for the system 10, and other alternative systems described below, to include any suitable bandage or wound dressing member coupled to the vacuum source 16 to communicate negative pressure from the vacuum source 16 to the wound. Bandage 14, therefore, is merely an illustrative bandage of the wound care bandage systems disclosed herein.

As mentioned above, system 10 further includes vent 19. Vent 19 is coupled to end 23 of tube 20, as shown in Fig. 1, and is illustratively shown to be coupled to patient's healthy skin 27 by tape 94, for example. As shown in Figs. 2 and 3, vent 19 includes a multi-lumen or wound connector 30 for coupling with multi-lumen tube 20 and a single-lumen connector 32 for coupling with single-lumen tube 52 or for coupling directly to switch valve 50, as shown in Fig. 5. Vent 19 further includes a filter 34, shown in phantom in Figs. 2 and 3, housed within a filter housing 40. Multi-lumen connector 30 includes an inner conduit 36 and an outer conduit 38 concentric and coaxial with inner conduit 36 along an axis 39, as shown in Fig. 3. An edge 41 of inner conduit 36 is substantially coplanar with an edge 43 of outer conduit 38. An annular space 45 is defined between a cylindrical inner surface 47 of outer conduit 38 and a cylindrical outer surface 53 of inner conduit 36.

Inner conduit 36 is in communication with vacuum source 16 and

irrigation source 18 through stopcock 50 and defines a portion of the vacuum/irrigation passageway 42. The vacuum/irrigation passageway 42 extends through inner lumen 22, a portion of vent 19 and stopcock 50. Outer conduit 38, or annular space 45, is in communication with the surrounding atmosphere and defines a portion of vent passageway 44. The vent passageway 44 extends through outer lumens 24 and a portion of vent 19 to the surrounding atmosphere.

As shown in Fig. 3, a ridge or stop 59 is coupled to inner surface 47 of outer conduit 38 to prevent tube 20 from being inserted too far within connector 30 and thus sealing off outer lumens 24. Stop 59 prevents vent passageway 44 from becoming closed off and keeps vent passageway 44 open to receive air from the surrounding atmosphere. Vent 19 includes three evenly spaced stops 59 coupled to inner surface 47. It is within the scope of this disclosure, however, to include a vent having any number of stops 59 or the like to prevent vent passageway 44 from becoming closed off.

When connecting multi-lumen tube 20 with vent 19, inner conduit 36 is received within inner lumen 22 of tube 20. Wall 25 of tube 20, which includes outer lumens 24, is received within annular space 45 of connecter 30. Tube 20 is, therefore, press fit into connector 30 and, if desired, may be permanently coupled to connecter 30 through the use of adhesives applied to the appropriate surfaces of connecter 30 and/or tube 20.

Connector 32 is received within single-lumen tube 52 when connecting vent 19 to tube 52. Tube 52 is press fit onto connector 32 so that an end 65 of single-lumen tube 52 abuts an annular shoulder surface 69 of conduit 30. As noted above, vent 19 may also be coupled directly to switch valve 50 through the use of a luer lock connection shown in Fig. 5 and discussed further below.

As shown in Fig. 3, vent 19 includes an opening or passageway 46 leading between outer conduit 38 and filter 34 to connect annular space 45 with the surrounding atmosphere. Opening 46 extends radially away from conduit 30 and is generally perpendicular to axis 39. Opening 46 is defined by cylindrical wall 27. Illustratively, opening 46 has a diameter of 0.100 inch (2.54 mm), however, it is within the scope of this disclosure to include a vent having any suitably sized opening for receiving air from the surrounding atmosphere.

Further illustratively, filter 34, is a 0.2 micron anti-microbial filter for

preventing bacteria and other microorganisms in the atmosphere from entering the vent 19 and traveling along vent passageway 44 below sealing film 13 of bandage 14 to the wound. Such an air filter, for example, is made by W.L. Gore & Associates, Inc. of Elkton, MD. As mentioned above, filter 34 is housed within housing 40. Housing 40 has a circular top wall 31, a cylindrical sidewall 33, and a circular bottom wall (not shown). Filter 34 is a generally circular dish of material sandwiched between top wall 31 and the bottom wall. The bottom wall has apertures, openings, or the like so that filter 34 is in communication with the surrounding atmosphere. Further, the bottom wall is removable so that filter 34 may be replaced if needed. Vent 19 further includes reinforcement ribs 35 appended to top wall 31 of housing 40 and wall 27 defining passageway 46.

In operation, vent 19 is used during both vacuum and irrigation modes of the system. As mentioned before, vent 19 provides increased air flow through bandage 14 and above the wound. Vent 19 also creates an open system and prevents the system from becoming static. The air flow path while vacuuming the system begins as air is drawn in from the surrounding atmosphere into filter housing 40 of vent 19 and through filter 34. The air then travels through opening 46 into annular space 45 defined by outer conduit 38 and through outer lumens 24 of multi-lumen tube 20. The air travels through the outer lumens 24 from vent end 23 of tube 20 to end 21 of tube 20, a portion of which is positioned under sealing film 13, to communicate with the wound. Vacuum source 16 then draws the air around wound dressing member 12 through passageways 66 at an open peripheral edge of member 12 and through holes 67 into passageways 66. Air is then drawn from passageways 66 into connector 15 of member 12, through barb 11, and through inner lumen 22 of multi-lumen tube 20 toward vacuum source 14.

It is also within the scope of the disclosure for the caregiver to close off vent 19 while vacuuming or irrigating the wound. Vent 19 may be closed in a number of ways. For example, a cap or valve (not shown) may be coupled to filter 34 or filter housing 40 to prevent air flow through filter 40. It is within the scope of this disclosure to include a vent having other suitable means of preventing air flow therethrough.

As shown in Fig. 3 and mentioned above, inner conduit 36 and outer conduit 38 form separate passageways through vent 19. Inner conduit 36 is in

communication with and forms a portion of vacuum/irrigation passageway 42 which extends through inner lumen 22, a portion of vent 19 and on to switch valve 50. Outer conduit 38 is in communication with and forms a portion of vent passageway 44, which extends through outer lumens 24 and a portion of vent 19. Vent passageway 44 is in communication with the atmosphere through filter 34.

As shown in Fig. 1, system 10 further includes switch valve 50. Switch valve 50 is positioned between vent 19 and vacuum and irrigation sources 16, 18. Single-lumen tube 52 is coupled to and extends between single-lumen connector 32 of vent 19 and switch valve 50 and forms a portion of vacuum/irrigation passageway 42. Switch valve 50, includes a vent connector 54 which can be coupled either to single-lumen tube 52, as shown in Fig. 1, or directly to connecter 32 of vent 19, as shown in Fig. 5, through the use of a luer lock. Single-lumen connector 32 includes a female thread portion 55 of the luer lock, and vent connector 54 of switch valve 50 includes a male portion 57 of the luer lock so that the two can be coupled together.

As shown in Fig. 5, switch valve 50 includes a body 60 and a handle or diverter 51 coupled to body 60. Body 60 includes vent connector 54, a vacuum connector 56 in communication with vacuum source 16, and an irrigation connector 58 in communication with irrigation source 18. Vent connector 54 forms another portion of vacuum/irrigation passageway 42 and is in selective communication with vacuum source 16 and irrigation source 18. Vacuum/irrigation passageway 42 therefore extends from end 21 of inner lumen 22 of multi-lumen tube 20 to multi-lumen connector 30 of vent 19, through inner conduit 36 of vent 19, out connector 32 of vent 19, to vent connector 54 of switch valve 50 and partially through switch valve 50 to diverter 51 of switch valve 50.

Switch valve 50 includes diverter 51 for selectively providing communication between vacuum source 16 and bandage 14 and between irrigation source 18 and bandage 14. Diverter 51 includes a grip 62 and a stem 64 coupled to grip 62, as show in Figs. 6a and 6b. Diverter 51 is rotatably movable relative to body 60 to selectively provide communication between either vent connector 54 and irrigation connector 58 or between vent connector 54 and vacuum connector 56. A caregiver rotates diverter 51 between an irrigation position shown in Fig. 7 and a vacuum position shown in Fig. 8 depending on whether the wound is to receive

vacuum or irrigation treatment, respectively. Switch valve 50 allows the caregiver to easily switch between communication with vacuum source 16 and irrigation source 18 without the need to disconnect or reconnect various tubes from each of the vacuum source 16 and/or irrigation source 18, for example.

As shown in Figs. 7 and 8, body 60 includes an aperture 61 for receiving stem 64 of diverter 51. Vent connector 54, vacuum connector 56, and irrigation connector 58 each form a respective opening 82, 84, 86 in communication with aperture 61. As diverter 51 is rotated, a cut-out portion 63 of stem 64 provides a passageway between vent connector 54 and vacuum connector 56 when diverter 51 is in the vacuum position, for example. When diverter 51 is in the irrigation position, cut-out portion 63 provides a passageway between vent connector 54 and irrigation connector 64. Diverter 51 is also movable to an off position where cut-out portion 63 does not provide any communication between the connectors 54, 56, 58.

In addition to vacuum/irrigation passageway 42 and vent passageway 44, system 10 further includes a separate vacuum passageway 70 and a separate irrigation passageway 72. Vacuum connector 56 defines a portion of vacuum passageway 70 and irrigation connector 58 defines a portion of irrigation passageway 72. As shown in Fig. 1, vacuum connector 56 is coupled to a vacuum tube 74 which is, in turn, coupled to vacuum source 16. The vacuum passageway 70, therefore, extends from opening 84 of body 60 through vacuum connector 56 and vacuum tube 74 to vacuum source 16.

As shown in Fig. 1, irrigation connector 58 is coupled to an irrigation tube 76 which is, in turn, coupled to irrigation source 18. The irrigation passageway 72, therefore, extends from opening 86 of body 60 through irrigation connector 58 and irrigation tube 76 to irrigation source 18. Thus, at opening 82 of body 60, vacuum/irrigation passageway 42 ends and is split into separate vacuum and irrigation passageways 70, 72.

As shown in Fig. 5, an attachment 88 is coupled to irrigation connector 58. Attachment 88 includes a first inlet 90 for communication with irrigation tube 76 and irrigation source 18 and a second inlet 92 for communication with a hand-held syringe (not shown). Attachment 88 provides two means of introducing fluids into system 10. Second inlet 92 allows a caregiver to manually introduce fluids into system 10 while irrigation source 18 includes automatic controls for introducing

fluids into system 10 through first inlet 90. A slot 96 of irrigation connector 58 receives a portion of second inlet 92 to secure attachment 88 within irrigation connector 58.

As mentioned above, system 10 allows a caregiver to treat the wound using vented vacuum therapy through the use of vent 19 with vacuum source 16 and using vented irrigation therapy through the use of irrigation source 18 and vent 19. To provide vented vacuum therapy to the wound, the caregiver moves diverter 51 to the vacuum position, shown in Fig. 8, so that cut-out portion 63 of stem 64 connects opening 82 of vent connector 54 with opening 84 of vacuum connector 56. Therefore, irrigation connector 58 and irrigation passageway 72 are closed off and vacuum/irrigation passageway 42 is connected with vacuum connector 56 and vacuum passageway 70. Vent passageway 44 is kept open to the surrounding atmosphere. The negative pressure provided by vacuum source 16 above wound 12 acts to draw air in from the atmosphere through filter 34 of vent 19 and outer lumens 24. As mentioned above, vent 19 is provided to aspirate the system 10 by creating an air flow path from the atmosphere to the bandage 14, over the wound, and out through inner lumen 22 in communication with vacuum source 16.

To create vented irrigation of wound 12, a caregiver moves diverter 51 to the irrigation position so that cut-out portion 63 of stem 64 connects opening 82 of vent connector 54 with opening 56 of irrigation connector 58. Therefore, irrigation passageway 72 of the irrigation connector 58 is in communication with the vacuum/irrigation passageway 42 of the vent connector 54. The vacuum passageway 70 is thus cut off from communication with the vacuum/irrigation passageway 42. Irrigation fluid is then dispensed from irrigation source 18 through irrigation passageway 72 of tube 76 and switch valve 50 to the vacuum/irrigation passageway 42 through vent connector 54, tube 52, vent 19, and inner lumen 22 of multi-lumen tube 20 to wound 12. Vent 19 is left in an open position to allow air to flow out of bandage 14 while fluid from irrigation source 18 is channeled to the wound. As mentioned above, it is also within the scope of this disclosure to provide non-vented irrigation of the wound by closing off vent 19 from the surrounding atmosphere while providing fluid to the wound through irrigation source 18.

As mentioned above, the combination of vent 19, and switch valve 50 is defined as vent-valve assembly 80. If desired, assembly 80 may also include tube

52 or another conduit or passageway between vent 19 and switch valve 50. Assembly 80 provides a caregiver with the ability to toggle or selectively switch between the vented vacuum mode of therapy and the vented irrigation mode of therapy for the treatment of the wound. As mentioned above, it is within the scope of this disclosure to include a vent which is able to be closed off from communication with the surrounding atmosphere so that vacuum only and/or irrigation only therapy may be provided as well.

An alternative vent-valve assembly 180 is provided for use with system 10, as shown in Figs. 9-16. Assembly 180 includes a stopcock or valve portion in selective communication with vacuum source 16 and irrigation source 18 and a vent portion in communication with the surrounding atmosphere. Assembly 180 is configured to selectively provide three modes of therapy: vacuum therapy, vented vacuum therapy, and vented irrigation therapy.

As shown in Fig. 9, vent-valve assembly 180 is positioned between illustrative bandage 14 of system 10 and vacuum and irrigation sources 16, 18. Assembly 180 serves a similar function as assembly 80, including vent 19 and stopcock 50, shown in Figs. 1-8. Similar to assembly 80, assembly 180 is in communication with bandage 14, vacuum source 16, and irrigation source 18 of system 10. Assembly 180 is operated by a caregiver during the treatment of a patient to change from mode to mode as desired.

As shown in Fig. 10, assembly 180 includes an outer shell or body 110 and a diverter or inner barrel 112. Inner barrel 112 is normally positioned within outer shell 110, as shown in Fig. 9, and is rotatable relative to outer shell 110 between three different positions which correlate with the three available modes: vacuum, vented vacuum, vented irrigation. Outer shell 110 includes a cylindrical hub 114 having an outer surface 116 and in inner surface 118, shown in Fig. 10. Outer shell 110 further includes a multi-lumen or wound connector 130, a vent 119, a vacuum connector 156, and an irrigation connector 158. Suitable coupling means such as a C-clip (not shown) to fit around inner barrel 112, a pin (not shown) through outer shell 110 and inner barrel 112, for example, are provided to prevent inner barrel or diverter 112 from being inadvertently separated from body 110. Such coupling means are also provided for use with stopcocks 50 and 250 (discussed below) to prevent the handle of each from being inadvertently decoupled from the body of each.

Similar to multi-lumen connector 30 of vent 19, multi-lumen connector 130 of assembly 180 includes inner conduit 36 and outer conduit 38 spaced apart from and concentric with inner conduit 36. Inner conduit 36 defines a portion of vacuum/irrigation passageway 42 and outer conduit 38 defines a portion of vent passageway 44 of system 10. Inner conduit 36 is received within inner lumen 22 of tube 20. Wall 25 of tube 20, which includes outer lumens 24, is received within outer conduit 38 of multi-lumen connector 130. As shown in Fig. 9, inner conduit 36 is coupled to a barb 37. Barb 37 is received within inner lumen 22 as well and helps maintain the connection between tube 20 and multi-lumen connector 130. It is within the scope of this disclosure for multi-lumen connector 30 of vent 19 to have barb 37 formed integrally with inner conduit 36.

As shown in Fig. 10, outer conduit 38 includes a partition 48 having multiple vent holes 49 formed therethrough. Air traveling through lumens 24 also travels through the holes 49 to a vent grove 122 formed in inner surface 118 of hub 114. It is not necessary for outer lumens 24 of tube 20 to align directly with one of the vent holes 49. A stop (not shown), similar to stop 59, is coupled to inner surface 47 of outer conduit 38 to prevent tube 20 from being inserted too far within connecter 130. Vent groove 122 connects outer conduit 38 with vent 119, as is described in more detail below.

Vacuum connector 156 communicates with vacuum source 16 through vacuum tube 74. Vacuum connector 156 includes barb 37 received within tube 74. Vacuum connector 156 and vacuum tube 74 form vacuum passageway 70 of system 10. Irrigation connector 158 communicates with irrigation source 18 through irrigation tube 76, as shown in Fig. 17. Irrigation connector 158 and irrigation tube 76 form the irrigation passageway 72 of system 10. Vacuum connector 156 and irrigation connector 158 are each in selective communication with multi-lumen connector 130, as is described below. As shown in Fig. 9, air filter 34, contained within a housing 124, is coupled to vent 119 and is received within an aperture 120 (shown in Fig. 10) of vent 119. Housing 124 includes an air inlet tube 126 and a connector tube 128 coupled to vent 119 and in communication with aperture 120 of vent 119.

Diverter 112, as shown in Fig. 10, includes a grip 162 and a cylinder or stem 164 coupled to grip 162. Cylinder 164 includes an upper level of holes and a

lower level of holes, as shown in Fig. 10. As shown in phantom in Figs. 11, 13, and 15, the upper level of holes includes first, second, third, fourth, and fifth holes 166, 168, 170, 172, 174, respectively. As shown in Figs. 12, 14, and 16, the lower level of holes includes first, second, third, and fourth holes 182, 184, 186, and 188, respectively. The upper level of holes communicate with inner conduit 36 of multi-lumen connector 130 and with each of the vacuum and irrigation connectors 156, 158. The lower level of holes communicate with outer conduit 38 and aperture 120 of vent 119. The upper holes of cylinder 164 form interconnecting passageways through cylinder 164 to selectively connect inner conduit 36 with vacuum conduit 156 and irrigation conduit 158 and the lower holes form passageways through cylinder 164 to selectively connect outer conduit 38 with vent 119, as is described in more detail below.

As shown in Figs. 11 and 12, assembly 180 is in the vented vacuum position. As shown in Fig. 11, the upper holes are positioned so that hole 166 is in communication with inner conduit 36 and hole 170 is in communication with vacuum connector 156 to provide a passageway between inner conduit 36 and vacuum connector 156. The other holes 168, 172 and 174 are not in communication with any of the connectors 130, 156, 158 of outer shell 110. Looking now to the lower level of holes shown in Fig. 12, hole 182 is in communication with vent groove 122 and hole 186 is in communication with aperture 120 of vent 119 to provide a passageway between vent groove 122 and vent 119 so that outer lumens 24 of tube 20 are in communication with the surrounding atmosphere.

By rotating grip 162 clockwise (as viewed from the top of apparatus 180), a caregiver rotates inner barrel 112 relative to outer shell 110 to move assembly 180 to the vacuum position shown in Figs. 13 and 14. In the vacuum position, upper level hole 174 is in communication with inner conduit 36 of multi-lumen connector 130 and hole 168 is in communication with vacuum connector 156 to provide a passageway between inner conduit 36 and vacuum connector 156. In the vacuum position, however, vent passageway 44 of system 10 is prevented from communicating with the surrounding atmosphere through vent 119. As shown in Fig. 14, for example, none of the lower level holes are in communication with either vent groove 122 or aperture 120 of vent 119.

By rotating grip 162 still further clockwise, a caregiver rotates inner

barrel 112 relative to outer shell 110 to move assembly 180 to the vented irrigation position shown in Figs. 15 and 16. Fig. 15 shows the orientation of the upper level holes of the inner barrel 112 while assembly 180 is in the vented irrigation position. Hole 172 is in communication with inner conduit 36 of multi-lumen connector 130 and hole 166 is in communication with irrigation connector 158 to provide communication between inner conduit 36 and irrigation connector 158. Fig. 16 shows the orientation of the lower level holes when stopcock 180 is in the vented irrigation position. Hole 188 is in communication with vent groove 122 and hole 184 is in communication with aperture 120 of vent 119 so that outer conduit 38 is in communication with vent 119 to allow air from the surrounding atmosphere to enter system 10. It is also within the scope of this disclosure for assembly 180 to be in an "off" position where none of the upper level passageways connect any of the connecters 130, 158, 156 with each other, and where none of the lower level passageways connect the vent grove 122 with the vent 119.

Referring now to Figs. 17-19, a tube coupler 140 is provided for use with system 10. As shown in Fig. 17, coupler 140 is positioned between bandage 14 and assembly 180. It is within the scope of this disclosure, however, to position a tube coupler between bandage 14 and assembly 80 shown in Fig. 1. Coupler 140 connects or couples two multi-lumen tubes together. Coupler 140 allows a caregiver to disconnect a portion of system 10 between bandage 14 and assemblies 80 or 180. As shown in Figs. 17-19, coupler 140 couples multi-lumen tube 20 to another multi-lumen tube 17.

Coupler 140 includes an outer body 142 having a curved upper surface 144 and a generally flat bottom surface 146. Outer body 142 defines a passageway 148 therethrough for receiving a portion of a multi-lumen tube at a first end 136 and at a second end 138. Passageway 148 is defined by an inner surface 149 of body 142. Coupler 140 further includes an inner conduit 150 which defines a portion of vacuum/irrigation passageway 42. Inner conduit 150 is positioned within passageway 148. A portion of vent passageway 44 is annular and is defined between inner surface 149 of body 142 and an outer surface 151 of inner conduit 150. Coupler 140 further includes a central partition 152 formed around conduit 150 and connected to inner surface 149. Partition 152 includes three generally evenly spaced holes 154 for the vented air to flow through.

An end of tube 20 is inserted into first end 136 of coupler 140 and an end of tube 17 is inserted into second end 138 of coupler 140, as shown in Fig. 19, so that inner conduit 150 is received within the inner lumen 22 of each tube 20, 17. As mentioned above, multi-lumen tubes 20, 17 include four outer lumens 24 formed in wall 25. As shown in Fig. 19, tubes 20, 17 are inserted into coupler 140 and are generally spaced-apart from partition 152 so that air flowing through the four outer lumens 24 of tube 17 flows into an open space 155 on the right side of partition 152, as shown in Fig. 19, through holes 154 of partition 152 and into an open space 157 located on the left side of partition 152 into outer lumens 24 of tube 20.

Tube coupler 140 may also be used to aide in effectively securing sealing film 13 of bandage 14 over or around tube 20. For example, coupler 140 may be placed on the patient's healthy skin adjacent the wound. The film 13 may then be placed over curved upper surface 144 of coupler 140 and effect a seal around coupler 140 to create a sealed environment between film 13 and the wound. Coupler 140, therefore, may also act to prevent leaks in the vacuum space created below film 13. Coupler 140 further includes a ridge or stop 153 coupled to inner surface 149 to each of the right and left sides of partition 152 to prevent each respective tube 20, 17 from abutting partition 152 and closing off vent lumens 24 from communication with the surrounding atmosphere. Each open space 155, 157, therefore, is defined between a respective stop 153 and partition 152, as shown in Fig. 19.

Referring now to Figs. 20-28, another illustrative wound care bandage system 210 is provided. System 210 operates similarly to system 10 described above and includes a vent-valve apparatus 280 to provide ventilation while allowing a user to toggle between a vacuum therapy mode and an irrigation therapy mode. As shown in Fig. 20, bandage 14 is coupled to a vent 219 via an alternative multi-lumen tube 220. Specifically, member 12 of bandage 14 is coupled to a "Y-connector" 212 of the system 210 which is coupled to tube 220. Y-connector 212 is shown in more detail in Figs. 22 and 24 and is discussed in more detail below.

Vent-valve apparatus 280 includes a stopcock or switch valve 250 coupled to vent 219 via two single-lumen tubes 216, 218. Switch valve 250 is coupled to both vacuum source 16 and irrigation source 18 to provide selective communication between either the bandage 14 and vacuum source 16 or between bandage 14 and irrigation source 18, as described below.

Vent 219, similar to vent 19, is spaced apart from bandage 14 and is illustratively shown to be coupled to patient's healthy skin 27 by tape 94, for example. Vent 219 is able to provide ventilation to wound 200 (shown in Fig. 20) during the application of negative pressure to wound 200 and during irrigation of wound 200 because vent 219, similar to vents 19 and 119 are in communication with the surrounding atmosphere and with the wound 200.

The wound care bandage system 210 shown in Figs. 20-28 incorporates three separate fluid paths. One fluid path is used exclusively for the purpose of venting the wound 200 with air from the surrounding atmosphere. A second fluid path is used to create a negative pressure adjacent the wound 200, while the third fluid path is used to irrigate the wound 200. Switch valve 250 acts to selectively communicate either the vacuum path or the irrigation path with the wound 200. The three fluid paths for ventilation, vacuum, and irrigation of wound 200 are provided by multi-lumen tube 220.

Multi-lumen tube 220 includes a vacuum lumen 222, an irrigation lumen 224, and four outer venting lumens 226 formed within and defined by a body 228, as shown in Fig. 21. Vacuum lumen 222 is in communication with vacuum source 16, irrigation lumen 224 is in communication with irrigation source 18, and each venting lumen 226 is in communication with the atmosphere through vent 219, as is described below. As shown in Figs. 20 and 24, multi-lumen tube 220 is coupled to an alternative connector 214 of member 12 by Y-connecter 212, and is therefore in communication with the wound 200 at one end 230 and is coupled to vent 260 at another end 232.

Although tube 200 is shown to include four venting lumens 214, it is within the scope of this disclosure to include a multi-lumen tube having one or more venting lumens in communication with the surrounding atmosphere, one or more vacuum lumens in communication with the vacuum source 16, and one or more irrigation lumens in communication with the irrigation source 18. Illustratively, an outer diameter 234 of tube 220 is 0.375 inch (9.53 mm), a diameter 236 of vacuum lumen 222 is 0.125 inch (3.175 mm), a diameter 238 of irrigation lumen 224 is 0.125 inch (3.175 mm), and a diameter 240 of each outer venting lumen 226 is 0.020 inch (0.508 mm). Although tube 220 includes the above dimensions, it is within the scope of this disclosure to provide any suitable multi-lumen tube having lumens of any

suitable size.

As mentioned above, Y-connecter 212 is provided for coupling with alternative connector 214 of vacuum bandage 14. Connector 214 is similar to connector 15 and is in communication with wound 200 through channels 66 and holes 67 of member 12. Connector 214 is different from connector 15 in that connector 214 is positioned at an angle relative to a top surface 242 of member 12 and includes a single angled passageway 244 (as shown in Fig. 24) rather than a vertical passageway connected to a horizontal passageway of connector 15 (as shown in Fig. 3). In the illustrative embodiment, the included angle between an axis along passageway 244 and the top surface 242 of member 12, when member 12 is in a flat configuration, is about 30 degrees.

Illustratively, Y-connecter 212 includes a bandage portion 246, an irrigation portion 248, and a vacuum portion 252, as shown in Fig. 22. Irrigation portion 248 includes a passageway 254 forming a section of the irrigation passageway, vacuum portion 252 includes a passageway 256 forming a section of the vacuum passageway, and bandage portion 246 includes a passageway 258 forming a section of the vacuum/irrigation passageway. The passageway 254 of irrigation portion 248 and the passageway 256 of vacuum portion 252 each merge into passageway 258 of the bandage portion 246. Once bandage portion 246 of Y-connecter 212 splits into the irrigation portion 248 and the vacuum portion 252, the irrigation and vacuum passageways remain separate and distinct passageways through multi-lumen tube 220, vent 219, and switch valve 250 to the respective irrigation source 18 and vacuum source 16.

Bandage portion 246 is press fit into connector 214, as shown in Fig. 24, and includes an angled end 260 to lie adjacent to the top surface 242 of member 12. Irrigation portion 248 is similarly press fit into irrigation lumen 224 of tube 220 and vacuum portion 252 is press fit into vacuum lumen 222 of tube 220. In some embodiments, adhesive or sealant is applied to either or all of portions 246, 248, 252 to further enhance the connection between bandage portion 246 and connector 214 between irrigation portion 248 and tube 220, and between vacuum portion 252 and tube 220. Y-connecter 212 is provided to connect bandage 14 with multi-lumen tube 220 and vent 219.

Referring now to Fig. 23, vent 219 includes a multi-lumen connector

262 for coupling with multi-lumen tube 220, a single-lumen vacuum connector 264 for coupling with a single-lumen tube, such as tube 216, and a single-lumen irrigation connector 266 for coupling with a single-lumen tube, such as tube 218 (as shown in Fig. 20). Tubes 216 and 218 are also coupled to switch valve 250 as shown in Fig. 20 and described in more detail below. It is also within the scope of this disclosure to eliminate the use of tubes 216 and 218 so that vent 219 is coupled directly to switch valve 250. Similar to vents 19, 119, vent 219 further includes filter 34 (shown in phantom), housed within filter housing 40, in communication with multi-lumen connector 262.

Multi-lumen connector 262 includes an outer conduit 272, an inner vacuum conduit 274, and an inner irrigation conduit 276, as shown in Fig. 23. Both vacuum conduit 274 and irrigation conduit 276 are located within outer conduit 272. An edge 278 of outer conduit 272 is substantially coplanar with an edge 281 of vacuum conduit 274 and an edge 282 of irrigation conduit 276. Vacuum conduit 274 is in communication with vacuum source 16 through switch valve 250 and defines a portion of the vacuum passageway. Irrigation conduit 276 is in communication with the irrigation source 18 through switch valve 250 and defines a portion of the irrigation passageway. Outer conduit 252 is in communication with the surrounding atmosphere and defines a portion of the vent passageway.

As shown in Fig. 24, vacuum conduit 274 is received within vacuum lumen 222 of tube 220. Body 228 of tube 220, which includes outer venting lumens 226, is received within a space 284 defined between a cylindrical inner surface 286 of outer conduit 272 and cylindrical outer surfaces 288, 290 of vacuum and irrigation conduits 274, 276, respectively (as shown in Fig. 23). Tube 220 is press fit into the space 284 so that the outer surface of tube 220 abuts cylindrical inner surface 286 of outer conduit 272, so that an inner surface of vacuum lumen 220 abuts the cylindrical outer surface 288 of the vacuum conduit 274, and so that the inner surface of irrigation lumen 224 abuts the cylindrical outer surface 290 of the irrigation conduit 276. In some embodiments, an adhesive material or sealant is applied to the appropriate surfaces of tube 220 and multi-lumen connector 262 to enhance the connection between tube 220 and vent 219.

As shown in Fig. 23, a ridge or stop (not shown) is coupled to and positioned between outer surface 288 of vacuum conduit 274 and outer surface 290 of

irrigation conduit 276 to prevent tube 220 from being inserted too far within connector 262 and thus sealing off outer lumens 226. The stop prevents vent passageway from becoming closed off and keeps vent passageway open to receive air from the surrounding atmosphere. Illustratively, vent 219 includes one stop, however, it is within the scope of this disclosure to include a vent having any number of stops or the like to prevent the vent passageway from becoming closed off from the surrounding atmosphere.

Vacuum connector 264 of vent 219 includes an inner surface 292 defining a portion of the vacuum passageway and an outer surface 294. Vacuum connector 264 is in communication with vacuum conduit 274 of multi-lumen connector 262, as shown in phantom in Figs. 23 and 24. Illustratively, single-lumen tube 216, coupled to vacuum source 16, is press fit into vacuum connector 264, as shown in Fig. 24. Tube 216 may further be permanently or temporarily bonded to vacuum connecter 264 through the use of an adhesive material applied to the appropriate surfaces of tube 216 and connecter 264.

Irrigation connector 266 of vent 219 similarly includes an inner surface 296 defining a portion of the irrigation passageway and an outer surface 298 including a shoulder 300. Irrigation connector 266 is in communication with irrigation conduit 276 of multi-lumen connector 262, also shown in Figs. 23 and 24. Illustratively, single-lumen tube 218 is press-fit into irrigation connector 266, as shown in Fig. 24. Tube 218 may further be permanently or temporarily bonded to irrigation connector 266 through the use of an adhesive material applied to the appropriate surfaces of tube 218 and connector 266. It is within the scope of this disclosure, however, to connect tubes 216 and 218 to the respective irrigation and vacuum connectors 266, 264 through the use of a barb or a luer lock connection, for example.

Outer conduit 272 of multi-lumen connector 262 further includes an opening or aperture 302 in communication with the surrounding atmosphere. Housing 40 for filter 34 is coupled to multi-lumen connector 262 so that a passageway 46 of housing 40 connects space 284 with the filter 34 and the surrounding atmosphere. Passageway 46 extends radially away from outer conduit 272 and is generally perpendicular to an axis running through vacuum conduit 274. Passageway 46 is defined by cylindrical wall 27.

In operation, vent 219 is used during both vacuum and irrigation

modes of the system. As mentioned before with respect to vents 19 and 119, vent 219 provides increased air flow through bandage 14 and above wound 200. Vent 219 also creates an open system and prevents the system from becoming static. Vent 219 further maintains separate vacuum and irrigation passageways. As mentioned before with respect to vents 19, 119, it is within the scope of the disclosure for the caregiver to close off vent 160 while vacuuming or irrigating wound 200. Vent 219 may also be closed in a number of ways. For example, a cap or a valve (not shown) may be coupled to filter 34 or filter housing 40 to prevent air flow through filter 34. It is within the scope of this disclosure to include a vent having other suitable means of preventing air flow therethrough.

Referring now to Figs. 25-28, the stopcock 250 of system 210 includes a diverter or handle 314 and a body 316 defining an aperture 318 for receiving at least a portion of the handle 314. Handle 314 includes a grip 320 and a hub or stem 322 coupled to the grip 320. Hub 322 is received within aperture 318 of body 316. Stopcock or switch valve 250 further includes a vacuum conduit 310 having a first portion 324 coupled to tube 216 and a second portion 326 coupled to a single-lumen tube 328, as shown in Fig. 20. Tube 328, is coupled to vacuum source 16, as shown in Fig. 20. As shown in Figs. 25-28, vacuum conduit 310 defines a portion of the vacuum passageway through body 316. Each single-lumen tube 216, 328 is coupled to the respective first portion 324 and second portion 326 of the stopcock 250 through the use of luer locks (not shown). It is within the scope of this disclosure, however, to connect tubes 216, 328 to stopcock 250 in another suitable manner such as through the use of a barb, by press-fitting each tube 216, 328 onto conduit 310 of stopcock 250, or by slip-fitting each tube 216, 328 into conduit 310, and including the use of adhesive material to permanently or temporarily bond each tube 216, 328 to conduit 310.

Stopcock 250 further includes an irrigation conduit 330 having a first portion 332 coupled to tube 218 and a second portion 334 coupled to a single-lumen tube 336. Tube 336 is coupled to irrigation source 18, as shown in Fig. 20. Irrigation conduit 330 defines a portion of the irrigation passageway through body 316 of stopcock 250. As shown in Fig. 25, irrigation conduit 330 lies below vacuum conduit 310 as indicated by a distance 311 so that the irrigation conduit 330 and vacuum conduit 310 are positioned to lie in separate horizontal planes. Tubes 218, 336 may

be coupled to irrigation conduit 330 by the same or similar means as those discussed above with respect to tubes 216, 328 and vacuum conduit 310.

Hub 322 of handle 314 includes a first or vacuum cut-out portion 340 and a second or irrigation cut-out portion 342. Similar to conduits 310 and 330, cut-out portions 340, 342 do not lie in the same horizontal plane. When hub 322 is received within aperture 318 of body 316, vacuum cut-out portion 340 lies in the same horizontal plane as vacuum conduit 310 and irrigation cut-out portion 342 lies in the same horizontal plane as irrigation conduit 330.

Handle 314, and thus hub 322, is rotatable relative to body 316. Handle 314 is able to be positioned by a caregiver to align the vacuum cut-out portion 340 with the vacuum conduit 310, as shown in Fig. 26, or to align the irrigation cut-out portion 342 with the irrigation conduit 330, as shown in Fig. 27. Further, handle 314 may be rotated to an "off" position where neither cut-out portion 340, 342 is aligned with either of the conduits 310, 330, as shown in Fig. 28. Thus, passageways 344, 346 through conduits 310, 330 each communicate with aperture 318 of body 316.

Referring to Fig. 26, the stopcock 250 is in a vacuum position where vacuum cut-out portion 340 is aligned with vacuum conduit 310, as mentioned above. Vacuum cut-out portion 340 connects first portion 324 of vacuum conduit 310 with second 326 of vacuum conduit 310 so that vacuum source 16 is able to create a negative pressure adjacent the wound 200. When stopcock 250 is in the vacuum position, irrigation cut-out portion 342 is not in communication with the irrigation conduit 330.

Rotating handle 314 about 90 degrees clockwise from the vacuum position aligns irrigation cut-out portion 342 with irrigation conduit 330 in an irrigation position shown in phantom in Fig. 27. Irrigation cut-out portion 342 connects first end 332 of irrigation conduit 330 with second end 334 of irrigation conduit 330 so that the irrigation source 18 is able to send fluids through stopcock 250 to wound 200. When stopcock 250 is in the irrigation position, vacuum cut-out portion 340 is not in communication with the vacuum conduit 310.

To move the stopcock 250 to the "off" position (shown in Fig. 28), the caregiver may either rotate the handle 180 degrees in either direction from the irrigation position (shown in Fig. 27) or the caregiver may rotate the handle 90

degrees in the counter-clockwise direction from the vacuum position (shown in Fig. 26). As mentioned above, neither cut-out portion 340, 342 communicates with either conduit 310, 330 when stopcock 250 is in the "off" position.

As shown in Fig. 25, grip 320 of handle 314 includes an indicator 350 to indicate to the caregiver whether the stopcock 250 is in the vacuum position, irrigation position, or off position. It is within the scope of this disclosure to include a seal, gasket, or o-ring (not shown) between hub 322 and body 316 of stopcock 250 to create a seal between the two components.

Looking now to Figs. 29 and 30, yet another wound care bandage system 400 is provided which has the capability to create negative pressure adjacent wound 200, to irrigate wound 200, and to ventilate wound 200. Ventilated vacuum bandage system 400 is provided for use with wound 200 having a wound surface 413. The system 400 includes a wound dressing member 419 similar to wound dressing member 12, shown in Fig. 24, a vacuum source 16, an irrigation source 18, and a vent 460 in communication with the member 419. The vent 460 is also in communication with the surrounding atmosphere to provide increased air flow above the wound surface 413 and through the member 419 particularly when the vacuum source 16 is operating to create a negative pressure above the wound 200. As is herein defined with respect to all embodiments disclosed herein, the term "vent" is or includes any passageway to the atmosphere, unless noted otherwise.

In one illustrative embodiment, a vacuum bandage 410 is provided for use with wound 200 having wound surface 413, shown in Fig. 30. Bandage 410 includes the wound dressing member 419 and a vent 460 in communication with member 419 as shown in Figs. 29 and 30. Member 419 is illustratively thin and flexible and includes a wound contacting layer 420 and a cover 422 coupled to the layer 420. Member 419 also includes a connector 423 coupled to cover 422 for communication with vacuum source 16 and/or irrigation source 18.

Vacuum bandage 410 is coupled to vacuum source 16 and irrigation source 18 through the use of a switch valve 455, as shown diagrammatically in Fig. 29. Switch valve 455 may be the same as or similar to stopcock 50 and/or assemblies 80, 180, described above, for example. Similar to bandage 14, bandage 410 also promotes the healing of large wound 200 by providing vacuum therapy to the wound 200 to promote blood flow and remove exudate from wound surface 413 and by

providing for irrigation of the wound 200 with fluids such as saline, for example.

Vent 460 of system 400 is provided for increased air flow through bandage 410 and above wound 200 while vacuum source 16 applies suction to wound 200. Without vent 460, a generally closed system is created between vacuum bandage 10 and vacuum source 14. Vent 460, similar to vents 19, 119, 219 discussed above, acts to prevent the system 400 from becoming static by drawing air in from the surrounding atmosphere around bandage 410. Air is drawn through vent 460 to bandage 410 to create airflow above wound 200, through member 419, and out through a vacuum tube 441 coupled to vacuum source 16. A wound care technique disclosing ventilation of the wound is provided in the article "No wound is too big for resourceful nurses" by Margaret Wooding-Scott, RN, CCRN, Barbara Ann Montgomery, RN, ET, and Deborah Coleman, RN, MS, CS as published in the December 1988 edition of the magazine RN.

Referring now to member 419, layer 420, cover 422, and connecter 423 are each made of a medical grade silicone or other type of pliable elastomer. Two companies, for example, which manufacture such medical grade silicone are GE Silicones and NuSil Technology. It is within the scope of this disclosure, however, to include a member made of any suitable type of material. Illustratively, member 419 is made of material that is non-porous and non-foam-like. This thin, flexible material is also generally non-absorptive. For example, materials such as polyvinylchloride (PVC), PVC free of diethylhexyl phthalate (DEHP-free PVC), polyurethane, or polyethylene may be used in the manufacture of member 419. However, as mentioned above, it is within the scope of this disclosure to include a bandage having a member made of any suitable material to communicate the negative pressure from the vacuum source to the wound. Further, layer 420, cover 422, and connecter 423 may each be molded to include anti-microbial constituents. For example, it is within the scope of this disclosure to impregnate member 419 with silver ions which are known anti-microbials.

Illustratively, member 419, including layer 420, cover 422, and connecter 423, is also made of a generally non-adhesive material. Therefore, wound contacting layer 420, which lies generally adjacent to the wound surface 413, does not adhere to the wound surface 413. Further, member 419 is illustratively solid in nature and generally non-compressible. Member 419 is also illustratively transparent.

Therefore, a caregiver or user is able to see the wound 200 through member 419 when member 419 is placed adjacent to wound surface 413. This transparency allows the caregiver to view the progress of the healing of the wound 200.

Layer 420 includes a wound facing surface 424 and an upper or opposite surface 426. Wound facing surface 424, or portions thereof, contact and conform to the wound surface 413. Opposite surface 426 includes a central area 428 and a plurality of channels 430 spaced-apart from and extending radially away from central area 428. Central area 428 is recessed relative to the portions of upper surface 426 between channels 430. As shown in Fig. 29, channels 430 are open at the sides and ends of member 419. Opposite surface 426 further includes concentric channels 431. Illustratively, each channel 430, 431 is 0.030 inch (0.762 mm) wide and 0.030 inch (0.762 mm) deep. It is within the scope of this disclosure, however, to include channels 430, 431 of opposite surface 426 having other suitable widths and depths suitable for the present application. Central area 428 of layer 420 is provided to communicate with the vacuum source 16 and irrigation source 18 through a port 440 of cover 422, as will be described below.

Illustratively, a plurality of radially extending protrusions or bosses 432 are positioned around central area 428. Bosses 432 are positioned between central area 428 and channels 430, 431, as shown in Fig. 29. Bosses 432 are provided to prevent central area 428 from collapsing in on port 440 of cover 422 to form a seal and effectively block air flow through port 440 while suction is applied to the bandage 410. Port 440 communicates with the vacuum source 16 and/or the irrigation source 18 via connecter 423 and tube 441, as shown in Figs. 29 and 30. Tube 441 is coupled to connecter 423 by a barbed tube coupler 498, similar to tube coupler 11 described above. Tube 441 may also be coupled directly to connecter 423.

As mentioned above, port 440 is in communication with central area 428 of layer 420. Illustratively, four bosses 432 are shown in Fig. 29. However, it is within the scope of this disclosure to provide any number of bosses 423 or the like around central area 428 of layer 420 to prevent central area 428 from sealing off port 440 of cover 422 as suction is applied to bandage 410. Further, it is within the scope of this disclosure to include a boss or bosses having any shape in order to prevent central area 428 from sealing off port 440 when vacuum source 16 is running.

Connecter 423, as shown in Figs. 29 and 30 is a tubal port coupled to a

top surface 436 of cover 422 and in communication with port 440 of cover 422. As mentioned before, it is within the scope of this disclosure for connector 423 to be a separate component of member 419 which is coupled to cover 422 or for connecter 423 to be coupled to cover 422 by being molded integrally with cover 422.

Connector 423 includes a passageway formed at a right-angle. Thus, the passageway in connecter 423 has a vertical portion 425 that communicates with port 440 and a horizontal portion 427 that communicates with vertical portion 425. Connector 423 connects with tube 441 through the coupler 498 to provide a horizontal tube attachment for tube 441. Cover 422 includes a bottom surface 434 and top surface 436, as shown in Fig. 29. Bottom surface 434 engages opposite surface 426 of layer 420, as shown in Fig. 30.

In some embodiments, member 419 is formed by heat sealing opposite surface 426 of layer 420 and bottom surface 434 of cover 422 together and by heat sealing connecter 423 to top surface 436 of cover 422. For example, each of connecter 423, cover 422 (or the combination of cover 422 and connecter 423), and layer 420 may be pre-shaped and formed from semi-cured silicone. Once the connecter 423, cover 422, and layer 420 are placed together appropriately, the entire member 419 may be heated to heat seal and cure each of the three components to one another. Alternatively, for example, the cover 422 only may be made from semi-cured silicone while the connecter 423 and layer 420 may be made from fully cured silicone. Once placed together and heated, connecter 423 and layer 420 will heat seal to cover 422. Semi-cured silicone may be bought and pre-molded from a manufacturer such as NuSil Technology, for example.

Although the method of heat sealing the cover 422, connecter, and layer 420 to each other is disclosed, it is within the scope of this disclosure to form member 419 by coupling layer 420, cover 422, and connector 423 together by any other suitable means such as through the use of adhesives, for example. Further, it is within the scope of this disclosure to provide a member 419 where cover 422 lies adjacent to, but is not coupled to, layer 420.

As mentioned above, cover 422 is coupled to layer 420 and connecter 423 is coupled to cover 422 to form member 419. Cover 422 and layer 420 cooperate to form distinct passageways 442 of member 419 defined by channels 430, 431 of layer 420 and lower surface 434 of cover 422. Passageways 442 extend from the

outer edges of member 419 and are in communication with central area 428 of layer 420. Central area 428 of layer 420 is in communication with port 440 of cover 422 which is in communication with the vacuum and/or irrigation sources 16, 18, via connecter 423, and tube 441. Therefore, passageways 442 are in communication with the vacuum and/or irrigation sources 16, 18.

Layer 420 includes through holes 446 which extend from channels 430, 431 to wound facing surface 424, as shown in Fig. 30. Illustratively, holes 446 are distinct and are provided to communicate with channels 430, 431 of layer 420. Holes 446 therefore communicate with passageways 442 of member 419 and the vacuum and/or irrigation sources 16, 18 as well to allow the suction from the vacuum source 16 and/or the fluid from the irrigation source 18 to reach the wound bed surface 413 via the holes 446. Illustratively, holes 46 are 0.020 inch (0.508 mm) in diameter and are spaced approximately 0.500 inch (12.700 mm) apart along channels 430, 431 of layer 420. It is, however, within the scope of the disclosure to include holes having other suitable sized diameters and/or other suitable spacing that allow for the removal of exudate without clogging.

Bandage 410 further includes a sealing layer or film 450 that is placed over cover 422 and around tube 441, as shown in Fig. 30. Film 450 acts as an outer cover of the bandage 410 and covers the entire wound 412 by extending over wound 412 and attaching to the patient's healthy skin 452, also as shown in Fig. 30. Preferably, film 450 is an occlusive or semi-occlusive material which allows water vapor to permeate through. Because of this characteristic, the film 450 is referred to as Moisture Vapor Transmission Rate film or MVTR film. The products TEGADERM® brand sealing film made by 3M Corporation, and OPSITE FLEXIGRID® semi-permeable dressing made by Smith & Nephew can be used for film 450, for example. Film 450 is approximately 0.003 inch (0.076 mm) thick. However, it is within the scope of this disclosure to include any occlusive or semi-occlusive film 450 having another thickness. Film 450 is provided to create a sealed environment below the film 450 and around the wound 200 in which a vacuum or negative pressure can be maintained as provided by vacuum source 16. Film 450 therefore creates a vacuum space 453 below film 450 and above wound surface 413.

As shown in Fig. 30, sealing film 450 is positioned adjacent to top surface 436 of cover 422. It is within the scope of this disclosure, however, for

bandage 410 to further include a packing material or filler such as gauze, for example, positioned between film 450 and member 419.

It is also within the scope of this disclosure to provide a bandage (not shown) having a self-sealing member which seals about the wound 412 to the patient's healthy skin 27 to provide a vacuum space between the member and the wound surface 413. In other words, it is within the scope of this disclosure to include a bandage having a sealing means without the use of sealing film 450. For example, it is within the scope of this disclosure to include a wound contacting layer of the member having an adhesive positioned about the outer perimeter of the wound contacting surface of the layer. The adhesive perimeter would be provided to seal to the patient's healthy skin 27 surrounding wound 200. The adhesive would, therefore, permit the member to be self-sealing such that a vacuum or negative pressure can be created and maintained above wound surface 413 without the use of sealing film 450. It is also within the scope of this disclosure to provide any member having an adhesive for attachment to the patient's healthy skin surrounding the wound so that the member is self-sealing and able to maintain a negative pressure above the wound without the use of a sealing film. For example, the wound contacting layer may be sized smaller than the cover and the bottom surface of the cover may include an outer adhesive perimeter for coupling with the patient's surrounding healthy skin.

As shown in Fig. 30, member 419 of bandage 410 has a smooth wound facing surface 424. Wound facing surface 424 may also be textured or roughened and/or may include ribs, protrusions, channels, or spacers, or a single rib, protrusion, channel or spacer design. By providing member 419 with one or more ribs, protrusions, channels, spacers, etc., a space is created between surface 424 of layer 420 and wound surface 413. Through holes 446 communicate with this space to permit vacuum source 16 to establish a generally uniformly distributed vacuum or negative pressure to the wound surface 413 to draw blood from the body to the wound surface 413 and to draw exudate from the wound 412 through holes 446, into channels 430, 431 and passageways 442, and out port 440 of cover 422.

Although bandage 410 is described above, it is within the scope of this disclosure for the ventilated vacuum bandage system to include any suitable bandage or wound dressing member coupled to the vacuum source 16 to communicate negative pressure from the vacuum source 16 to the wound 412. Bandage 410,

therefore, is merely an illustrative bandage for use with the wound care bandage systems disclosed herein.

The vacuum or negative pressure which draws blood from the body to the wound surface 413 and draws exudate from the wound 200 up through member 419 promotes the healing of wound 200. As wound 200 heals, granulations form along the wound surface 413. Granulations, therefore, are the replacement within the wound bed of tissue lost. As the granulations fill in the wound bed causing the wound 200 to heal, member 419 rides up on the wound surface 413 on top of the granulations which are formed.

As mentioned above, port 440 of cover 422 communicates with vacuum source 16 and/or irrigation source 18 via connecter 423 and tube 441. As shown in Fig. 29, switch valve 455 is provided which allows the caretaker to switch between the use of the vacuum source 16 and the irrigation source 18. It will be appreciated that a mechanism other than the switch valve 455 may be used to selectively couple the vacuum source 16 or the irrigation source 18 to the bandage 410. Simple tube clamps, for example, may be used selectively to open and close the tube set provided with bandage 410. When valve 455 is switched to operate the vacuum source 16, the vacuum suction draws exudate up through holes 446 and radially inwardly through passageways 442 toward port 440 and finally through connecter 423 and tube 441. Although tube 441 has been referred to as vacuum tube 441, tube 441 may also be used as an irrigation tube carrying liquid to the wound 200 from irrigation source 18, as described above.

As mentioned above, bandage 410 includes vent 460 similar to vents 19, 119, 219 described above. Vent 460 also operates to increase air flow through the wound 200 and the passageways 442 of member 419 while vacuum source 16 applies suction to wound 200. Without vent 460 a generally closed system is created between vacuum bandage 410 and vacuum source 414. For example, in bandages without vent 460, once the requisite amount of air in the tubing 441 and below sealing film 450 within vacuum space 453 has been removed by the vacuum source 16 to create a predetermined negative pressure at wound surface 413, it is possible for the system to become generally static inhibiting much, if any, fluid flow from wound surface 413 through passageways 442 and out port 440 and connector 423. Vent 460, however, opens the system to aspirate the passageways 442 and tube 41 of the system which

promotes removal of debris that may be clogging the system.

Vent 60 acts as a first port of bandage 410 and port 440 of member 419 acts as a second port of bandage 410. Bandage 410 , therefore, includes a first port in communication with the surrounding atmosphere above or around bandage 410 and a second port in communication with the vacuum source 16. When vacuum source 16 is running, a pressure differential is initially created as vacuum source 16 draws more air out from beneath sealing film 450 than is drawn in from the surrounding atmosphere through vent 460. Therefore, a negative pressure is created above wound 200. Once a desired negative pressure above wound 200 is reached, that negative pressure may be maintained so that the amount of air flow into the bandage through vent 460 is generally equal to the amount of air flow out of the bandage 410 through connecter 423 and tube 441 by vacuum source 16. The two ports of bandage 410 allow an air flow current to be created beneath the film 450 to generally prevent the bandage 410 and vacuum source 16 system from becoming static.

As shown in Figs. 29 and 30, vent 460 comprises a vent line or tube 462 having a first end 464 and an opposite second end 466. Illustrative vent line 462 runs parallel to tube 441 and is coupled to tube 441 by one or more couplers 468, as shown in Figs. 30 and 31. First end 464 is positioned to lie below sealing film 450 and above member 419. As shown in Fig. 30, first end 464 is adjacent top surface 436 of cover 422 and second end 466 of vent line 462 is positioned outside the vacuum space 453 defined between wound surface 413 and sealing film 450. Thus, second end 466 communicates with the surrounding atmosphere to draw air from the surrounding atmosphere into the system and through passageways 442 of member 419. Although vent 460 is illustrated as a tube, it is within the scope of this disclosure for vent 460 to include any type of conduit or passage which provides communication between the atmosphere surrounding the bandage 410 and the passageways 442 of the bandage 410.

An air filter 470 similar to filter 34, described above, is coupled to second end 466 of vent line 462 as shown in Figs. 29 and 30. Illustratively, air filter 470 is a 0.2 micron anti-microbial filter for preventing bacteria and other microorganisms in the atmosphere from entering the wound space below film 450. Filter 470 is also hydrophobic. Such an air filter, for example, is made by W.L. Gore & Associates, Inc. of Elkton, MD. A cap or a valve 472 is also coupled to

second end 466 of vent line 462. As shown in Figs. 29 and 30, filter 470 is positioned between end 466 and valve 472. Valve 472 allows a user to manually control and adjust the amount of air flow into vent line 462. For example, valve 472 is movable between a fully closed position and a fully opened position. In the fully closed position, no air flow is permitted through valve 472 and the system operates as a closed system. In the fully open position, a maximum amount of air is drawn in through the valve 472 and vent line 462 so that the system operates as an open system to aspirate the passageways 442 of member 419 and create fluid flow throughout the system. The valve 472 is also adjustable to any desired partially open position between the fully closed position and the fully open position. Therefore, the amount of air flow through vent line 462 is adjustable by the caregiver.

While the valve 472 is open or partially open and air is being drawn in through vent line 462, vacuum source 16 will maintain a negative pressure under sealing film 450 while vacuum source 16 is operating. In other words, the vacuum bandage 410 and vacuum source 16 act to initially vent less air into the system than is vacuumed out of the system to create a negative pressure above the wound 200. Once created, the negative pressure above the wound 200 is maintained by vacuum source 16 when vent line 462 is open. For example, even though vent line 462 is open, vacuum source 16 is still able to create a negative pressure above wound 200 as a result of the pneumatic resistance provided by the vent 460. The vent line 462 and air filter 470 create pneumatic resistance to the entry of air from the surrounding atmosphere into the space 453 above the wound 200 when the valve 472 is open, thus enabling the net effect to be a negative pressure above the wound 200 created by the vacuum source 16. In preferred embodiments, vent 460 is open or partially open while the vacuum source 16 is operating. It is within the scope of the disclosure, however, to close the vent 460 while the vacuum source is running.

Although vent line 462 is shown to run parallel to tube 441, it is within the scope of this disclosure to position vent line 462 anywhere so long as first end 464 is positioned below sealing film 450 and second end 466 communicates with the surrounding atmosphere. Vent line 462 of the embodiment of Figs. 29-31 comprises a separate tube formed independently from tube 441 and coupled to tube 441 by couplers 468, such as medical tape wrapped around tube 441 and vent line 462. Figs. 32-33, as well as Fig. 4, described above, illustrate the cross sections of various

alternative vent lines and vacuum/irrigation tube combinations.

The embodiments shown in Figs. 32 and 33 as well as Fig. 4 illustrate parallel vent lines and vacuum/irrigation tubes which do not require a coupler 68, for example, to maintain their parallel relationship. A vent line and vacuum tube combination 480 is shown in Fig. 32. Combination 480 includes vent line passageway 482 and vacuum/irrigation passageway 484 separated from vent line passageway 482 by a partition 486. As shown in Fig. 32, combination 480 has a circular cross-section defined by an outer wall 488. Combination 480 is extruded or manufactured as a single tube having two passages or lumens, whereas vent line 462 and tube 441 of Fig. 31 are extruded or manufactured separately.

Another illustrative vent line and vacuum/irrigation tube combination 490 is shown in Fig. 33. In combination 490, vent line 462 and tube 441 are integrally coupled to each other. As illustrated, vent line 462 includes an outer wall 492 and tube 441 includes an outer wall 494. A portion of outer wall 492 is integrally coupled to a portion of outer wall 494. An external coupler 468, for example, is not required to maintain the parallel relationship of vent line 462 and tube 441 of combination 490. Further, combination 490 is extruded or manufactured as a single tube having two passages or lumens.

Yet another illustrative vent line and vacuum/irrigation tube combination is shown in Fig. 4 as multi-lumen tube 20 and was discussed above with reference to system 10. Multi-lumen tube is a single multi-lumen tube having outer wall 25 and a central, inner lumen or vacuum passageway 22. Passageway 22 may be coupled at one end to either the vacuum source 16 or the irrigation source 18 of system 410 and may be coupled at the other end to connecter 423 of member 419 via the barbed coupler 498, as shown in Fig. 3, and described in more detail below. As mentioned above with respect to system 10, multi-lumen tube 20 further includes four outer lumens or air vent passageways 24. Passageways 24 are formed within outer wall 25 and around central passageway 22. Passageways 24 are in communication with the atmosphere surrounding bandage 410 at one end and are in communication with the vacuum space 453 below sealing film 450. Combination 500 is also extruded or manufactured as a single tube.

As shown in Figs. 29 and 30, barbed tube coupler 498 is received within tube 441 and horizontal passageway 427 of connector 423. Coupler 498

includes ridges 499 for preventing coupler 498 from separating from either tube 441 or connector 423. The vent line and vacuum tube combinations 480, 490 of Figs. 32 and 33 as well as multi-lumen tube 20 of Fig. 4, are also coupled to connector 423 via coupler 498. For example, coupler 498 is received within tube passageway 484 of vent line and vacuum tube combination 480 leaving vent line passageway 482 free to draw air into the bandage 410 from the surrounding atmosphere. Coupler 498 is also received within tube 441 of combination 490 and vacuum passageway 22 of multi-lumen tube 20. It is within the scope of this disclosure to further include combinations 480, 490 where vent line passageway 482 and vent line 462 respectively, extend beyond tube passageway 484 and tube 441 to space first end 464 of vent line passageway 482 and vent line 462 away from tube passageway 484 and tube 441.

Vent 460, shown in Figs. 29 and 30, comprises vent line 462, filter 470, and valve 472 as mentioned above. However, it is within the scope of this disclosure to provide any vent in communication with both vacuum space 453 and passageways 442 and with the surrounding atmosphere. In other words, a vent is provided for communication between an area outside bandage 410 and an area within bandage 410 below film 450 or any other sealing means to permit air to flow through the system to aspirate the passageways 442 of the system and to allow the system to operate as an open system. The vent 460 is provided to create a fluid flow path from outside the sealing means, through the sealing means to the member 419 and finally through the holes 446 and passageways 442 of the member 419 and out port 440 of member 419.

The air from vent 460 flows within the wound space 453 below film 450, or a similar sealing means, and above wound surface 413 of wound 200. For example, some air from the surrounding atmosphere reaches passageways 442 through openings at the peripheral edges of member 419 and some reaches passageways 442 through holes 446 via various gaps which may exist between wound surface 413 of wound 200 and wound facing surface 424 of member 419. Further, ribs, protrusions, nubs, or texturing on wound facing surface 424 act to promote air flow through holes 446 by providing a space between wound surface 413 and wound facing surface 424.

Although vent 460 is provided to create a fluid flow path from the

surrounding atmosphere through the passageways 442 of member 419 and out port 440 of member 419, it is within the scope of this disclosure for vent line 462 of vent 460 to also be used as a separate irrigation line after filter 420 and valve 472 are detached from line 462. This second line may be connected to the irrigation source 18, for example, rather than be exposed to the surrounding atmosphere. It is therefore within the scope of this disclosure to connect second end 466 of vent line 462 to irrigation source 18 to permit irrigation of bandage 410 and wound surface 413 simultaneously with the operation of the vacuum source 16.

Although this invention has been described in detail with reference to certain embodiments, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.

CLAIMS:

1. A vacuum bandage connectable to a vacuum source and provided for use with a wound having a wound surface, the bandage comprising:

a wound contacting surface adapted to be in contact with and generally conform to the wound surface,

a plurality of discrete passageways defined by a non-porous material, the passageways being configured for communication with the wound surface and with the vacuum source, and

a vent in communication with the passageways and configured for communication with the atmosphere surrounding the bandage.

2. The bandage of claim 1, wherein the vent comprises a tube and a filter coupled to the vent tube.

3. The bandage of claim 2, wherein the vent comprises a removable cap coupled to the filter.

4. The bandage of claim 2, wherein the vent comprises a tube and a valve coupled to the tube, the valve being movable between a closed position prohibiting air flow through the tube and an open position allowing air flow through the tube.

5. The bandage of claim 1, further including a sealing means to seal about the wound and provide a sealed space above the wound and below the sealing means, and wherein the vent comprises a tube having a first end in communication with the space above the wound and a second end in communication with the air above the sealing means.

6. The bandage of claim 5, wherein the vent includes an air filter and a valve each coupled to the second end of the tube.

7. The bandage of claim 5, wherein the first end of the tube is positioned adjacent to a top surface of the member.

8. A vacuum bandage connectable to a vacuum source and provided for use with a wound having a wound surface, the bandage comprising,

a non-porous member having a wound contacting surface adapted to be in contact with and generally conform to the wound surface, the member further including distinct passageways configured for communication with the wound surface

and configured for communication with the vacuum source,

an outer cover adjacent to the member to create a vacuum space between the cover and the wound surface, the passageways of the member being positioned within the vacuum space, and

a port in communication with the vacuum space and configured to communicate with an area outside the vacuum space to create a fluid flow path from the area outside the vacuum space to the vacuum space.

9. The bandage of claim 8, wherein the port is configured for communication with an irrigation source to pass fluid through the port and into the vacuum space.

10. The bandage of claim 9, further including a second port in communication with the passageways and configured for communication with the vacuum source.

11. The bandage of claim 8, wherein the port includes a first end in communication with the passageways and a second end in communication with the area outside the sealing means, and further including a valve coupled to the second end of the port, the valve being movable between a fully closed and fully opened position.

12. A tubing set for use with a vacuum bandage coupled to a vacuum source, the vacuum bandage having a member including a wound contacting surface adapted to be in contact with and conform to a wound surface, a port in communication with the vacuum source, and a plurality of passageways in communication with the wound surface and the port, the tubing set comprising:

a first tube configured to communicate with the port and the vacuum source,

a second tube configured to communicate with the passageways and the atmosphere surrounding the vacuum bandage to provide air flow from the surrounding atmosphere to the passageways of the vacuum bandage,

an air filter coupled to the second tube, and

a valve coupled to the second tube, the valve being operable between a closed position preventing air flow from the atmosphere to the vacuum bandage and an open position permitting air flow from the atmosphere through the filter to the vacuum bandage.

13. A bandage for use with a wound comprising:

a wound contacting member adapted to be in contact with and generally conform to the surface of the wound,

a vent in communication with the member and with the atmosphere surrounding the bandage to provide a passageway from the atmosphere to the member, and

a filter coupled to the vent and configured to filter the air passing through the vent from the atmosphere to the member.

14. The bandage of claim 13, wherein the passageway is a tube having a first end configured for in communication with the atmosphere and a second end in communication with the member.

15. The bandage of claim 14, wherein the bandage further includes a filter coupled to the first end of the tube.

16. The bandage of claim 13, wherein the member includes a port configured for communication with a vacuum source, holes configured for communication with the wound surface, and a passageway between each hole and the port, and wherein the vent is in communication with the passageways.

17. The bandage of claim 16, wherein the member is generally non-compressible.

18. The bandage of claim 16, wherein the member is generally non-porous.

19. A vacuum bandage for use with a wound and a vacuum source, the bandage comprising:

a wound contacting member adapted to be in contact with and generally conform to a wound surface of the wound,

a cover positioned over the member and configured to seal to the patient's healthy skin surrounding the wound to create a space below the cover and above the wound,

a vent in communication with the space and configured for communication with the atmosphere surrounding the bandage, and

a port in communication with the space and configured for communication with the vacuum source.

20. A method for creating continuous air flow above a wound

surface while maintaining a continuous negative atmosphere above the surface comprising the steps of:

placing a bandage over the wound surface and the bandage having a vacuum port and a vent,

creating a sealed environment above the wound,

connecting the port to a vacuum source, the vent being in communication with the atmosphere surrounding the bandage, and

drawing air in from the atmosphere through the vent of the bandage, over the wound surface, and out the port of the bandage by operation of the vacuum source.

21. A method for applying a negative pressure therapy to a wound surface comprising the steps of:

applying a wound dressing member to the wound surface, the member including a port for communication with a vacuum source, a wound contacting surface having holes formed therein, and passageways communicating between the holes and the port,

applying a cover to establish a vacuum space between the cover and the wound surface,

providing a passageway communicating between the vacuum space and the atmosphere to create an air flow path from the atmosphere to the vacuum space, through the holes and passageways, and out the port of the member, and

operating the vacuum source to create a negative pressure above the wound.

22. The method of claim 21, wherein the passageway is open when the vacuum source is operating

23. A system for ventilating a vacuum bandage covering a wound having a wound surface, and the bandage being connectable to a vacuum source and an irrigation source, the system comprising:

a multi-lumen tube configured to couple to the vacuum bandage, the multi-lumen tube including a first lumen configured to communicate with the vacuum source, a second lumen in communication with the surrounding atmosphere, and a third lumen in communication with the irrigation source, and

a wound dressing member coupled to the multi-lumen tube, the wound

dressing member being provided to communicate negative pressure from the vacuum source to the wound.

24. The system of claim 23, wherein the multi-lumen tube includes four lumens to communicate with the surrounding atmosphere.

25. The system of claim 23, wherein a diameter of each of the first lumen in communication with the vacuum source of the third lumen in communication with the irrigation source is approximately 3.175 mm, and wherein a diameter of the second lumen in communication with the surrounding atmosphere is approximately 0.508 mm.

26. The system of claim 23 wherein the multi-lumen tube includes an outer wall defining the first lumen, and the second and third lumens are formed in the outer wall of the multi-lumen tube.

27. The system of claim 26, wherein the multi-lumen tube further includes four outer lumens formed in the outer wall of the multi-lumen tube and in communication with the surrounding atmosphere.

28. The system of claim 23, further including a vent coupled to the multi-lumen tube and including a passageway between the second lumen and the surrounding atmosphere.

29. The system of claim 28, wherein the vent includes a multi-lumen connector coupled to the multi-lumen tube and a single-lumen connector configured to be coupled to the vacuum source.

30. The system of claim 29, wherein the vent further includes another single-lumen connector configured to be coupled to the irrigation source.

31. The system of claim 30, wherein the multi-lumen connector includes an irrigation conduit coupled to the single-lumen connector configured to be coupled to the irrigation source and a vacuum conduit coupled to the single-lumen connector configured to be coupled to the vacuum source.

32. The system of claim 31, wherein the multi-lumen connector further includes an outer conduit positioned around and spaced-apart from the vacuum and irrigation conduits to create a space in communication with the second lumen and with the surrounding atmosphere.

33. The system of claim 29, wherein the multi-lumen connector includes a vacuum conduit, an irrigation conduit, and an outer conduit positioned

around and spaced-apart from the vacuum and irrigation conduits to create a space, and further wherein the vent includes a filter in communication with the annular space and with the surrounding atmosphere.

34. The system of claim 29, wherein the multi-lumen connector includes an inner conduit in communication with the single-lumen connector and an outer conduit in communication with the passageway and the surrounding atmosphere.

35. The system of claim 34, wherein the vent further includes a filter in communication with the outer conduit.

36. The system of claim 23, wherein the vent includes a multi-lumen connector coupled to the multi-lumen tube, a single lumen connector in communication with the first lumen and configured to communicate with the vacuum source, and a filter in communication with the second lumen.

37. The system of claim 36, wherein the multi-lumen connector includes an inner conduit in communication with the first lumen of the multi-lumen tube, and an outer conduit in communication with the second lumen, and wherein the filter is in communication with the outer conduit.

38. A vent for use with a vacuum bandage in communication with a wound and a vacuum source, the vent comprising:

a multi-lumen connector configured to communicate with the bandage, the multi-lumen connector having an inner conduit defining a vacuum passageway in communication with the vacuum source, and an outer conduit defining a vent passageway in communication with the surrounding atmosphere, and

a single-lumen connector coupled to the vacuum passageway and configured to communicate with the vacuum source.

39. The vent of claim 38, further including an anti-microbial filter in communication with the atmosphere and with the vent passageway.

40. The vent of claim 39, further including a housing for the filter, the housing being coupled to the multi-lumen connector.

41. The vent of claim 39, further including an opening connecting the outer conduit with the filter.

42. The vent of claim 38, wherein the multi-lumen connector further including a second inner conduit defining an irrigation passageway in

communication with the irrigation source, and the vent further including a second single-lumen connector in communication with the second inner conduit.

43. A vented vacuum bandage system for use with a wound and a vacuum source, comprising:

a bandage configured to lie adjacent the wound to create a sealed environment about the wound,

a vent positioned between the bandage and the vacuum source,

a vacuum passageway extending from the bandage, through the vent, to the vacuum source, and

a vent passageway extending from the bandage to the vent in communication with the surrounding atmosphere.

44. The system of claim 43, further including a tube having a first end coupled to the bandage and a second end coupled to the vent, the tube including the vent passageway and a portion of the vacuum passageway from the bandage to the vent.

45. The system of claim 44, wherein the tube further includes an irrigation passageway from the bandage to the vent.

46. The system of claim 44, wherein the tube has an outer body forming an inner lumen defining the vacuum passageway and an outer lumen formed in the outer wall defining the vent passageway.

47. The system of claim 46, wherein the tube has four outer lumens formed in the outer body.

48. The system of claim 44, wherein the vent includes a multi-lumen connector coupled to the tube and a single-lumen connector configured to communicate with the vacuum source.

49. The system of claim 48, wherein the multi-lumen connector includes an inner conduit and an outer conduit around the inner conduit, and further wherein the vacuum passageway is in communication with the inner conduit and the vent passageway is in communication with the outer conduit.

50. The system of claim 49, wherein the vent further includes an opening between the outer conduit and the surrounding atmosphere.

51. The system of claim 49, wherein the inner conduit is in communication with the single-lumen connector and the outer conduit is in

communication with the surrounding atmosphere.

52. The system of claim 50, wherein the vent further includes a filter housing coupled to the outer conduit, and a filter housed within the filter housing and positioned between the opening of the vent and the surrounding atmosphere.

53. The system of claim 52, wherein the filter is a 0.2 micron filter.

54. The system of claim 44, wherein the bandage includes a member having distinct passageways formed therein and distinct holes in communication with the passageways and configured to communicate with the wound, and wherein the second lumen of the tube is in communication with the holes and passageways.

55. A vented vacuum bandage system for use with a wound, a vacuum source, and an irrigation source, the system comprising:

a bandage positioned adjacent the wound to create a sealed environment around the wound,

a vacuum source in communication with the bandage to create a negative pressure between the bandage and the wound,

a first passageway in communication with the bandage and with the surrounding atmosphere,

a second passageway in communication with the bandage and with the vacuum source, and

a third passageway in communication with the bandage and with the irrigation source.

56. The system of claim 55, further including an irrigation source and a third passageway in communication with the bandage and with the irrigation source.

57. The system of claim 56, further including a vent including the first, second, and third passageways.

58. A wound bandage system for use with a wound, a negative pressure source, and an irrigation source, comprising:

a wound bandage, and

a vent apparatus through which ambient atmosphere vents to the wound bandage, through which irrigation fluid flows from the irrigation source to the

wound bandage, and through which negative pressure is communicated to the wound bandage.

59. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

a vent in communication with the atmosphere and configured to communicate with the wound, and

a stopcock coupled to the vent and in selective communication with the vacuum source and the irrigation source, the stopcock being movable between a vacuum position connecting the wound with the vacuum source and an irrigation position connecting the wound with the irrigation source.

60. The apparatus of claim 59, further including a multi-lumen connector having a first conduit coupled to the vent and a second conduit configured to communicate with one of the vacuum source and the irrigation source.

61. The apparatus of claim 60, wherein the multi-lumen connector further includes a third conduit and wherein the second conduit is configured to communicate with the vacuum source and the third conduit is configured to communicate with the irrigation source.

62. The apparatus of claim 61, wherein the vent includes the multi-lumen connector and a first single-lumen connector coupled to the second conduit of the multi-lumen connector and a second single-lumen connector coupled to the third conduit of the multi-lumen connector.

63. The apparatus of claim 61, wherein the stopcock includes a vacuum connector coupled to the first conduit and an irrigation connector coupled to the second conduit.

64. The apparatus of claim 60, further including a filter coupled to the multi-lumen connector and in communication with the first conduit of the multi-lumen connector.

65. The apparatus of claim 59, wherein the stopcock includes a handle having a first cut-out portion and a second cut-out portion.

66. The apparatus of claim 65, wherein the stopcock includes a vacuum conduit in communication with the first cut-out portion and configured to be coupled to the vacuum source and an irrigation conduit in communication with the

second cut-out portion and configured to be coupled to the irrigation source.

67. The apparatus of claim 66, wherein the stopcock defines an aperture for receiving a portion of the handle, and wherein the vacuum conduit includes a first portion in communication with the aperture and a second portion in communication with the aperture and the irrigation conduit includes a first portion in communication with the aperture and a second portion in communication with the aperture, and further wherein the handle is rotatable within the aperture to selectively align the first cut-out portion with the first and second portions of the vacuum conduit when the stopcock is in the vacuum position and to selectively align the second cut-out portion with the first and second portions of the irrigation conduit when the stopcock is in the irrigation position.

68. The apparatus of claim 66, wherein the first cut-out portion lies in a first plane and the second cut-out portion lies in a second plane parallel to the first plane.

69. A wound bandage system for use with a vacuum bandage on a wound, comprising:

a multi-lumen tube having a first lumen configured to be coupled to a vacuum source, a second lumen configured to be coupled to an irrigation source, and a third lumen in communication with the surrounding atmosphere,

a vent-valve apparatus coupled to the multi-lumen tube, the apparatus having a vent coupled to the third lumen, a filter coupled to the vent, and a valve coupled to the first and second lumens, the vent-valve apparatus provided to selectively communicate negative pressure and irrigation fluids to the wound while exposing the wound to the surrounding atmosphere through the vent,

a first single-lumen tube coupled to the vent-valve apparatus and configured to be coupled to the vacuum source, and

a second single-lumen tube coupled to the vent-valve apparatus and configured to be coupled to the irrigation source.

70. A vent-valve apparatus for use with a vacuum bandage coupled to a wound, a vacuum source coupled to the bandage, and an irrigation source coupled to the bandage, the vent-valve apparatus comprising:

a vacuum conduit configured to be coupled to the vacuum source,

an irrigation conduit configured to be coupled to the irrigation source,

a body having an aperture in communication with the vacuum conduit and the irrigation conduit,

a rotatable handle received in part within the aperture and including a passageway configured to selectively communicate the vacuum conduit and the irrigation conduit with the wound,

a vent in communication with the atmosphere and configured to communicate with the wound.

71. A wound care bandage system for use with a vacuum bandage coupled to a wound, a vacuum source coupled to the bandage, and an irrigation source coupled to the bandage, the system comprising:

a vacuum passageway in communication with the wound and the vacuum source,

an irrigation passageway in communication with the wound and the vacuum source,

a ventilation passageway in communication with the wound and the surrounding atmosphere, and

a valve coupled to the vacuum passageway and the irrigation passageway to selectively communicate the wound with either the vacuum source or the irrigation source.

72. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

a stopcock having a body including a wound connector configured to communicate with the wound, a vacuum connector configured to communicate with the vacuum source, and an irrigation connector configured to communicate with the irrigation source, and a handle rotatably coupled to the body and movable between a vacuum position connecting the wound connector with the vacuum connector and an irrigation position connecting the wound connector and the irrigation connector, and

a passageway in communication with the surrounding atmosphere and configured to communicate with the wound.

73. The apparatus of claim 72, wherein the apparatus further includes a multi-lumen connector having an outer conduit and an inner conduit.

74. The apparatus of claim 73, wherein the inner conduit is in

communication with the single-lumen connector and the outer conduit is configured to communicate with the surrounding atmosphere.

75. The apparatus of claim 74, further including a filter coupled to the passageway, and wherein the passageway connects the outer conduit with the filter.

76. The apparatus of claim 73, wherein the handle includes a grip and a stem coupled to the grip, and wherein the stem includes a cut-out portion forming a passageway to selectively connect the wound connector with either the vacuum connector or the irrigation connector.

77. The apparatus of claim 76, wherein the body of the stopcock includes an aperture and the stem is received within the aperture.

78. The apparatus of claim 76, wherein the cut-out portion is semi-circular in shape.

79. The apparatus of claim 73, wherein the apparatus includes a vent comprising the passageway and the multi-lumen connector, and wherein the vent further includes a single-lumen connector coupled to the wound connector of the stopcock..

80. The apparatus of claim 72, wherein the wound connector includes an outer conduit in communication with the passageway and an inner conduit in selective communication with the vacuum connector and the irrigation connector.

81. The apparatus of claim 80, wherein the handle includes a grip and a stem coupled to the handle, and wherein the stem includes a passageway to selectively connect the wound connector with either the vacuum connector or the irrigation connector.

82. The apparatus of claim 80, wherein the apparatus further includes a filter and the passageway connects the outer conduit with the filter.

83. The apparatus of claim 72, wherein the stopcock includes an outer shell and an inner barrel rotatably coupled to the outer shell and received within an aperture of the outer shell, and wherein the outer shell includes the wound connector, the vacuum connector, the irrigation connector, and the passageway.

84. The apparatus of claim 83, wherein the wound connector includes an inner conduit in selective communication with vacuum connector and the irrigation connector and an outer conduit in communication with the vent.

85. The apparatus of claim 84, wherein the vent includes a filter.

86. The apparatus of claim 84, wherein the inner barrel includes an upper set of passageways to selectively connect the wound connector with either the vacuum connector or the irrigation connector, and a lower set of passageways to selectively connect the outer conduit with the vent.

87. The apparatus of claim 86, wherein the outer shell includes a groove extending between the outer conduit and the lower set of passageways.

88. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

a multi-lumen connector configured to communicate with the bandage, the multi-lumen connector including an inner conduit and an outer conduit,

a vacuum connector in selective communication with the inner conduit of the multi-lumen connector and configured to communicate with the vacuum source,

an irrigation connector in selective communication with the inner conduit of the multi-lumen connector and configured to communicate with the irrigation source, and

an opening in communication with the atmosphere and with the outer conduit of the multi-lumen connector.

89. The apparatus of claim 88, further including a handle in communication with and movable relative to the vacuum connector, the irrigation connector, and the multi-lumen connector between a vacuum position where the vacuum connector is in communication with the inner conduit and an irrigation position where the irrigation connector is in communication with the inner conduit.

90. The apparatus of claim 89, wherein the handle includes a grip, a stem, and a passageway through the stem configured to selectively connect the inner conduit with either the vacuum connector or the irrigation connector.

91. The apparatus of claim 90, wherein the handle includes a second passageway in selective communication with the outer conduit and the vent.

92. The apparatus of claim 89, further including a filter coupled to the vent.

93. The apparatus of claim 88, wherein the outer conduit defines a

vent passageway in communication with the surrounding atmosphere and the inner conduit defines a vacuum/irrigation passageway configured to selectively communicate with the vacuum source and the irrigation source.

94. The apparatus of claim 93, further including a vent comprising the multi-lumen connector and the passageway and a stopcock coupled to the vent including the vacuum connector and the irrigation connector.

95. A vent-valve apparatus coupled to a vacuum bandage for providing selective communication between the bandage and either a vacuum source or an irrigation source, comprising:

a vent in communication with the atmosphere and the vacuum bandage,

a valve coupled to the vent,

a vacuum passageway in communication with vacuum source and the valve,

an irrigation passageway in communication with the irrigation source and the valve, and

a vacuum/irrigation passageway in communication with the vacuum bandage and the valve, and in selective communication with the vacuum passageway and the irrigation passageway.

96. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

an outer body including a central aperture, a vacuum connector in communication with the vacuum source and the aperture, and an irrigation connector in communication with the irrigation source and the aperture,

a handle rotatably received within the aperture, the handle having a passageway formed therein, and

a multi-lumen connector in communication with the wound having an inner conduit in communication with the wound and the handle, and an outer conduit in communication with the wound and the surrounding atmosphere.

97. The apparatus of claim 96, wherein the inner conduit is in selective communication with the vacuum connector and the irrigation connector.

98. The apparatus of claim 97, wherein the handle is rotatable

between a vacuum position wherein the passageway provides communication between the inner conduit and the vacuum connector, and an irrigation position wherein the passageway provides communication between the inner conduit and the irrigation connector.

99. A wound care bandage system provided for use with a wound having a wound surface, a vacuum source, and an irrigation source, comprising:

a bandage configured to lie adjacent the wound surface and seal about the wound surface to provide a sealed environment below the wound surface,

a multi-lumen tube coupled to the bandage and configured for communication with the wound surface, the tube including an inner lumen configured to selectively communicate with the vacuum source and the irrigation source, and an outer lumen in communication with the surrounding atmosphere, and

a vent-valve assembly coupled to the multi-lumen tube and movable between a vacuum position connecting the inner lumen with the vacuum source, and an irrigation position connecting the inner lumen with the irrigation source.

100. The system of claim 99, wherein the multi-lumen tube includes an outer wall and a plurality of outer lumens formed in the outer wall.

101. The system of claim 100, wherein the vent-valve assembly includes a vent in communication with the outer lumens of the multi-lumen tube.

102. The system of claim 101, wherein the vent includes a filter.

103. The system of claim 100, wherein the vent valve assembly includes a multi-lumen connector coupled to the multi-lumen tube, and wherein the multi-lumen connector includes an inner conduit to be received within the inner lumen of the multi-lumen tube and an outer conduit to receive the outer wall of the multi-lumen tube.

104. The system of claim 103 wherein the outer conduit is in communication with the vent.

105. The system of claim 99, wherein the vent-valve assembly includes a body having a vacuum connector, an irrigation connector, and an aperture in communication with the vacuum connector and the irrigation connector.

106. The system of claim 105, wherein the vent-valve assembly further includes a handle rotatably received within the aperture, the handle includes a passageway to selectively connect the vacuum connector with the inner conduit and

the irrigation connector with the inner conduit.

107. The system of claim 106, wherein the handle includes another passageway to selectively connect the vent with the outer conduit of the multi-lumen connector.

108. A method of wound care therapy is provided for wound having a wound surface, comprising the steps of:

applying a bandage over the wound surface to seal about the wound surface,

coupling a multi-lumen tube to the bandage to communication with the wound surface, the multi-lumen tube including an inner lumen and an outer lumen,

coupling the inner lumen of the multi-lumen tube to a multi-lumen connector of an apparatus in selective communication with a vacuum source and an irrigation source,

coupling an outer lumen of the multi-lumen tube to a vent in communication with the atmosphere,

coupling a single lumen tube to an irrigation connector of the apparatus for communication with the irrigation source,

coupling a single lumen tube to a vacuum connector of the apparatus for communication with the vacuum source, and

moving the apparatus between a vacuum position where the vacuum connector is in communication with the inner lumen of the multi-lumen tube and an irrigation position where the vacuum connector is in communication with the inner lumen of the multi-lumen tube.

109. A method of wound care therapy is provided for wound having a wound surface, comprising the steps of:

coupling a bandage to a first fluid line and a second fluid line,

coupling the first fluid line to a vent in communication with the surrounding atmosphere,

coupling the second fluid line to a valve in selective communication with a vacuum source and an irrigation source, and

switching the valve between a vacuum position where the second fluid line is in communication with the vacuum source, and an irrigation position where the second fluid line is in communication with the irrigation source.

110. A wound bandage system for use with a wound, comprising:

a bandage,

an irrigation source,

a negative pressure source,

a vent-valve apparatus,

a first single lumen tube coupled to the irrigation source and the vent-valve apparatus,

a second single lumen tube coupled to the vacuum source and the vent-valve apparatus, and

a multi-lumen tube coupled to the vent-valve apparatus and the bandage.

111. A wound bandage system for use with a wound, a negative pressure source, and an irrigation source, comprising:

a wound bandage, and

a vent-valve apparatus through which ambient atmosphere vents to the wound bandage, through which irrigation fluid flows from the irrigation source, and through which negative pressure is communicated to the wound bandage.

112. The system of claim 111, further including a multi-lumen tube coupled to the wound bandage at a first end and coupled to the vent-valve apparatus at a second end.

113. The system of claim 112, wherein the multi-lumen tube includes an irrigation lumen, a vacuum lumen, and a vent lumen.

114. The system of claim 113, wherein the multi-lumen tube four vent lumens.

115. The system of claim 111, wherein the vent-valve apparatus includes a multi-lumen connector coupled to the multi-lumen tube, and wherein the multi-lumen connector includes an outer conduit formed to receive a portion of a vent lumen of the multi-lumen tube, a vacuum conduit positioned within the outer conduit and received within a vacuum lumen of the multi-lumen tube, and an irrigation conduit positioned within the outer conduit and received within an irrigation lumen of the multi-lumen tube.

116. The system of claim 115, wherein the vent-valve apparatus further includes a passageway from the outer conduit to the surrounding atmosphere,

a filter coupled to the passageway.

117. The system of claim 111, wherein the vent-valve apparatus includes a vacuum conduit configured to be coupled to the vacuum source, an irrigation conduit configured to be coupled to the irrigation source, an aperture defined by a body of the apparatus in communication with the vacuum conduit and the irrigation conduit, and a handle rotatably received within the aperture to selectively provide communication between the wound and the irrigation source or between the wound and the vacuum source.

118. The system of claim 117, wherein the handle includes a first cut-out portion and a second cut-out portion, and wherein the first cut-out portion is aligned with the vacuum conduit when the handle is in a first, vacuum position and wherein the second cut-out portion is aligned with the irrigation conduit when the handle is in the second, irrigation position.

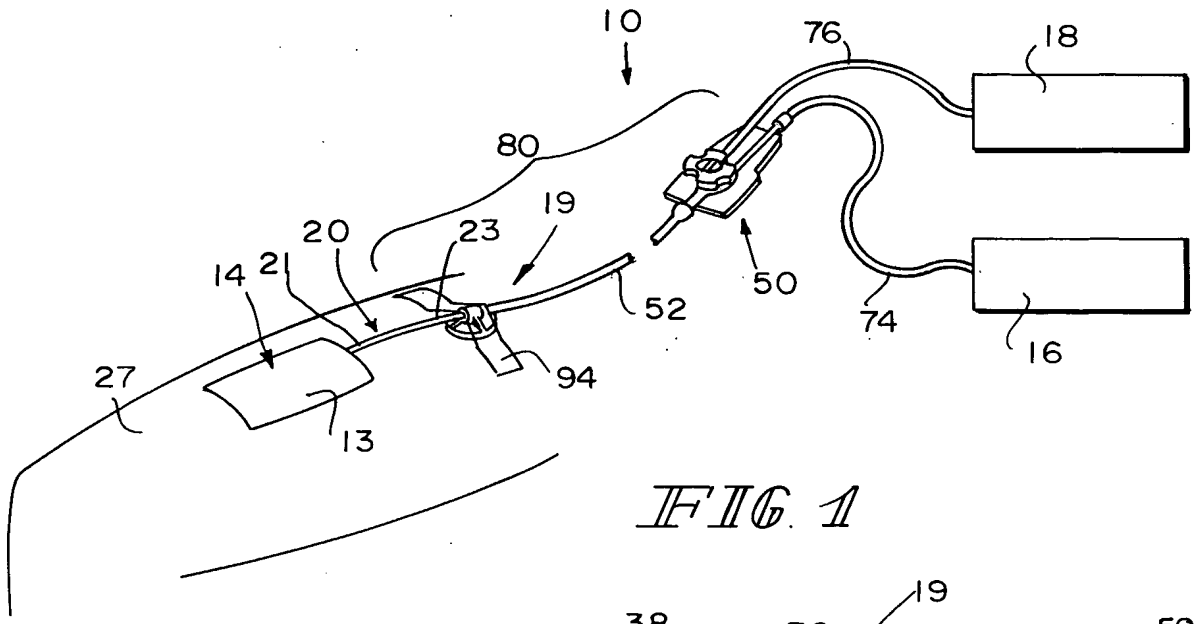


FIG. 1

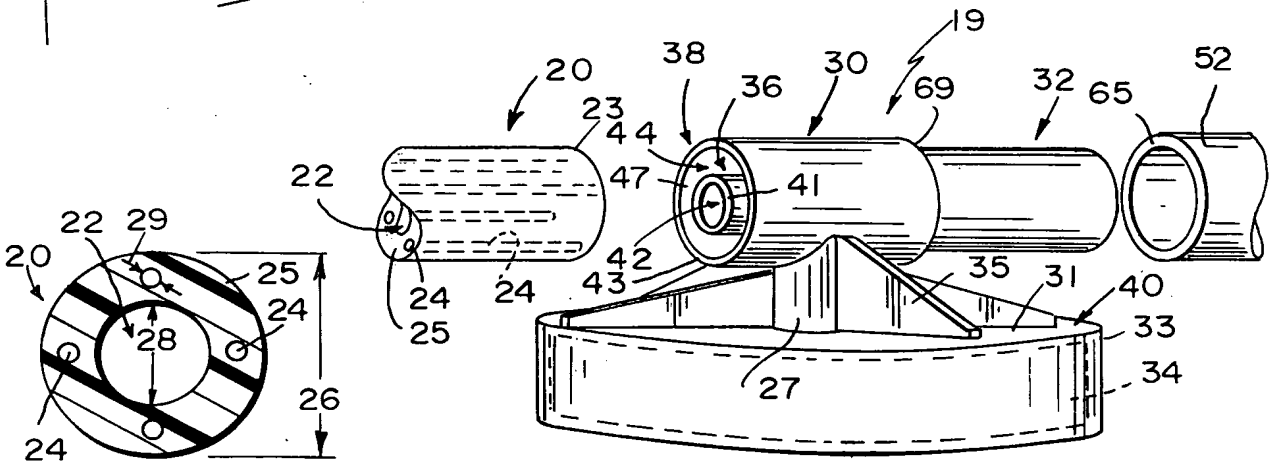


FIG. 4

FIG. 2

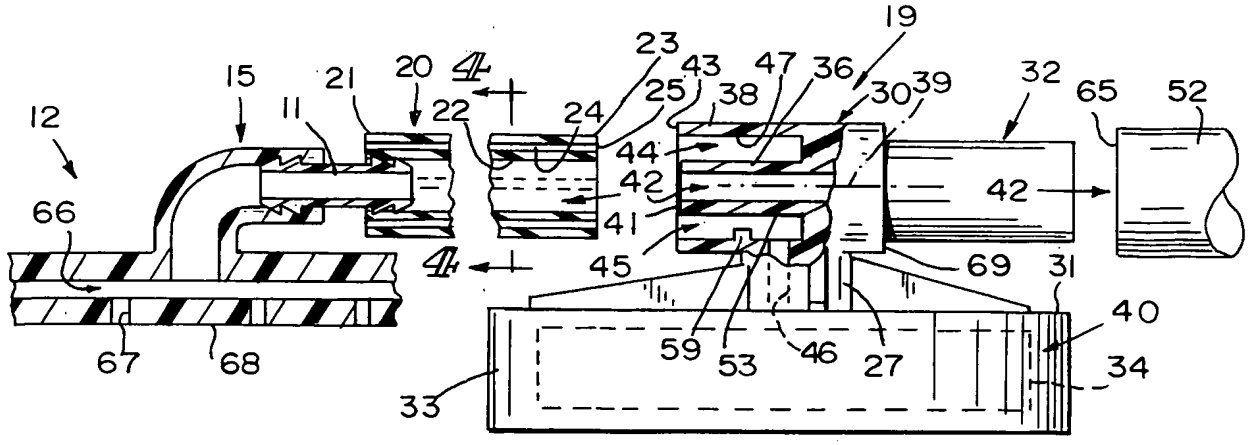


FIG. 3

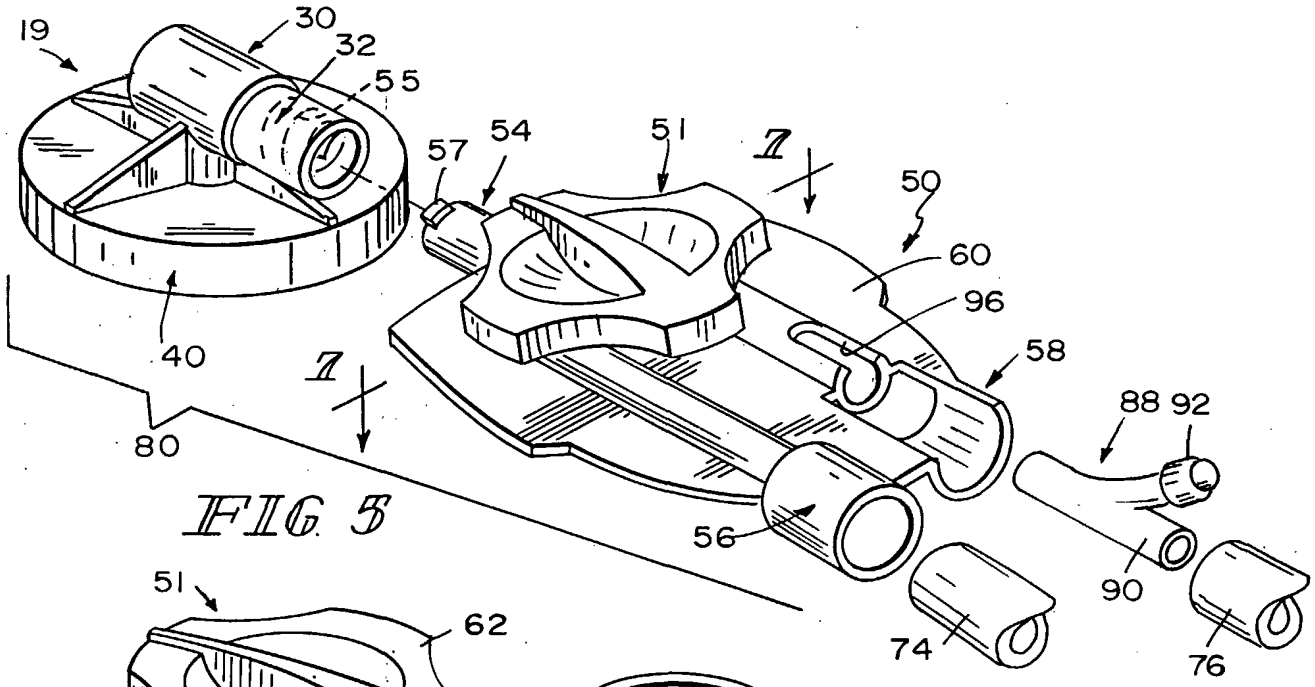


FIG. 5

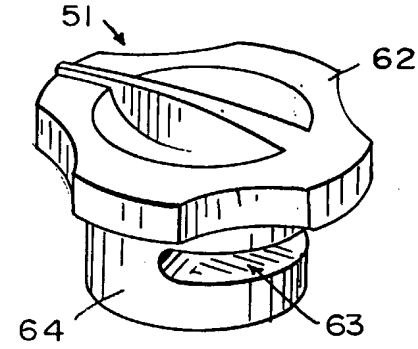


FIG. 6a

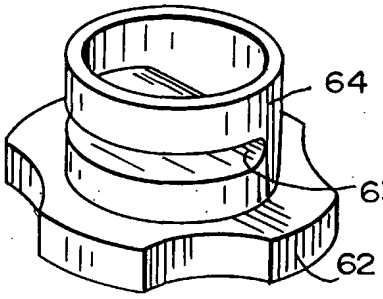


FIG. 6b

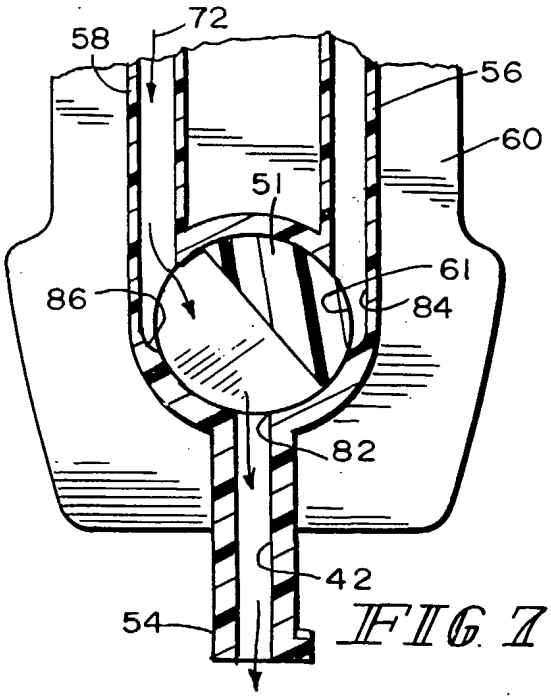


FIG. 7

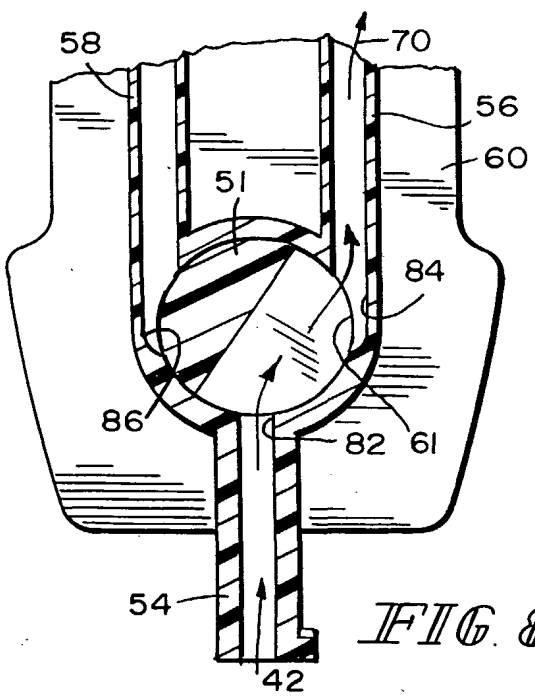


FIG. 8

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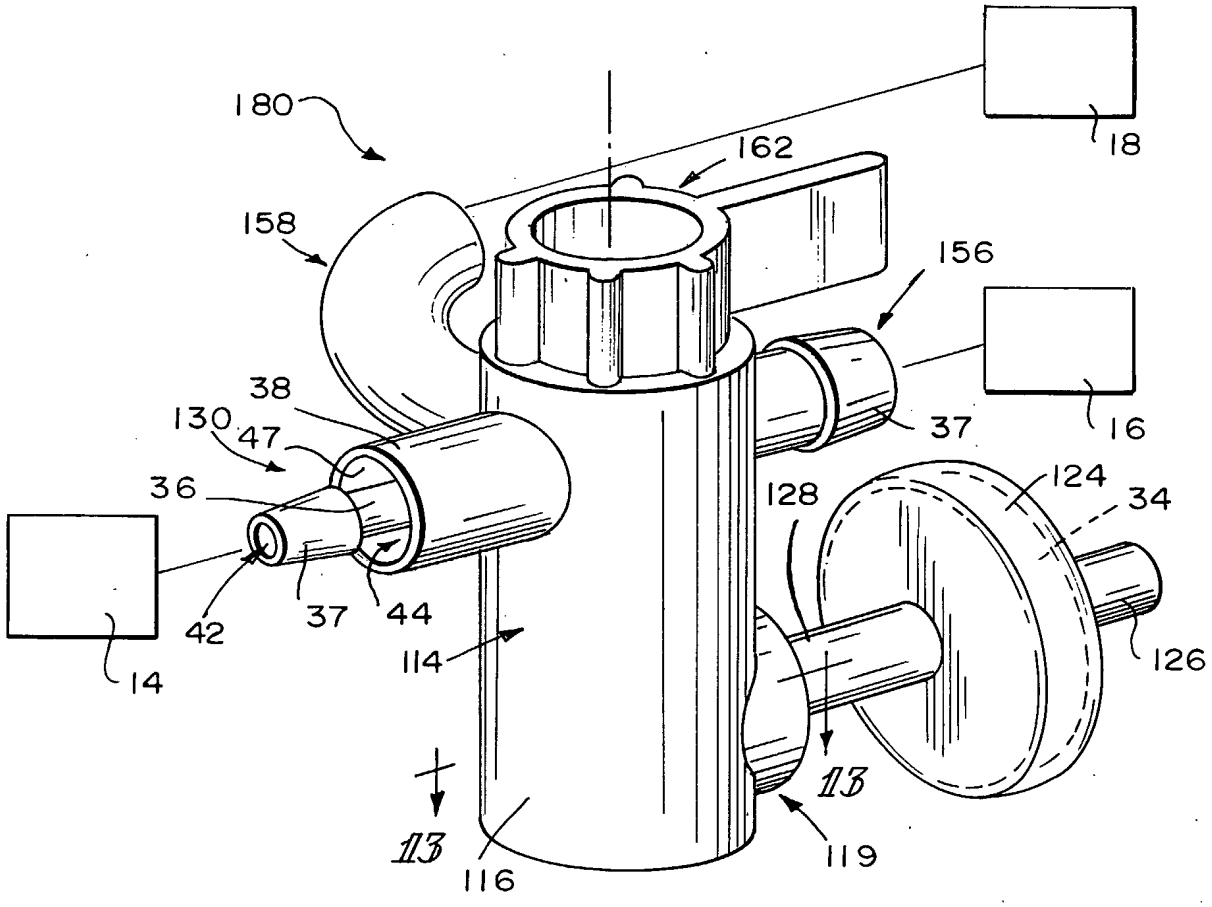

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FIG. 9

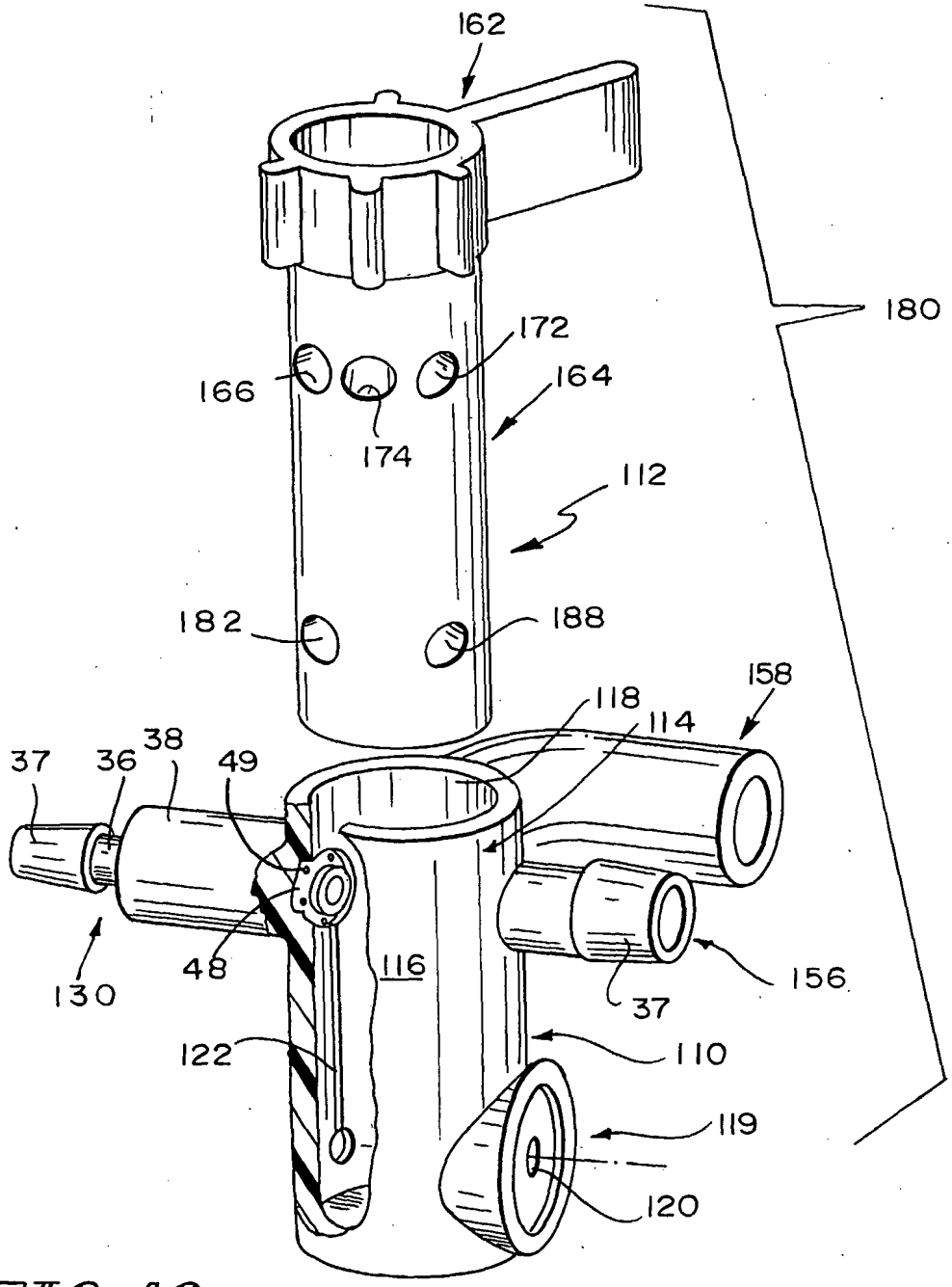

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FIG. 10

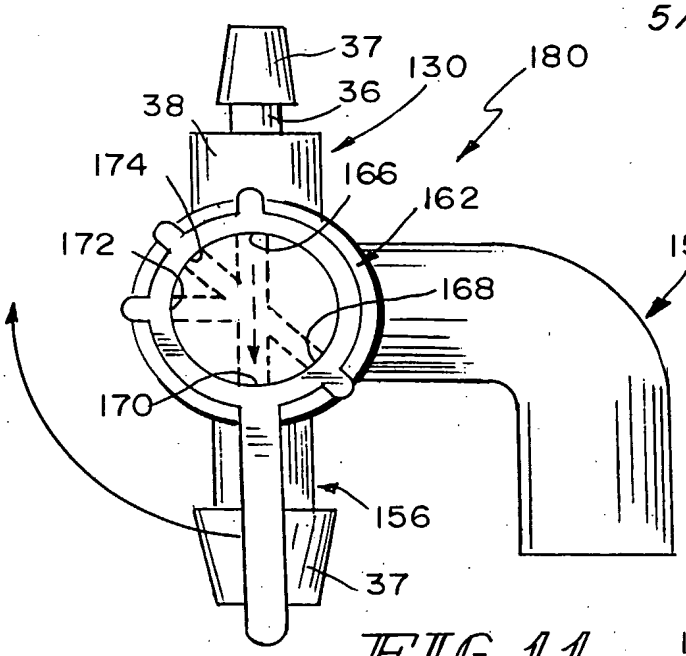


FIG. 11

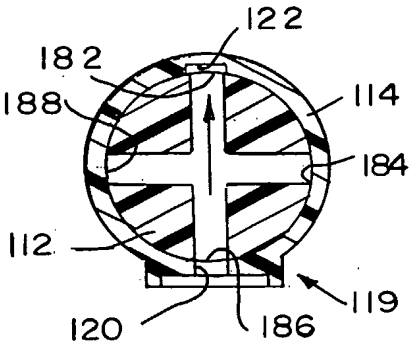


FIG. 12

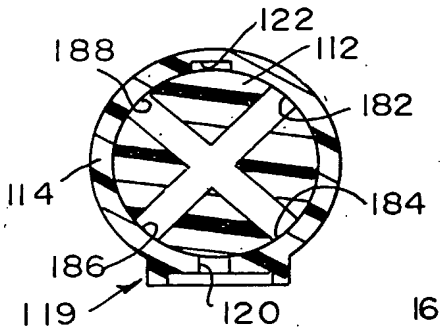


FIG. 14

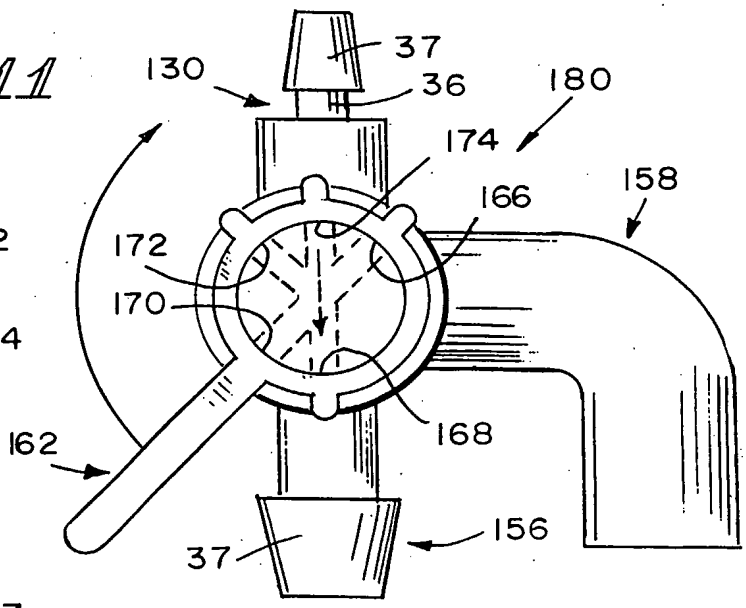


FIG. 13

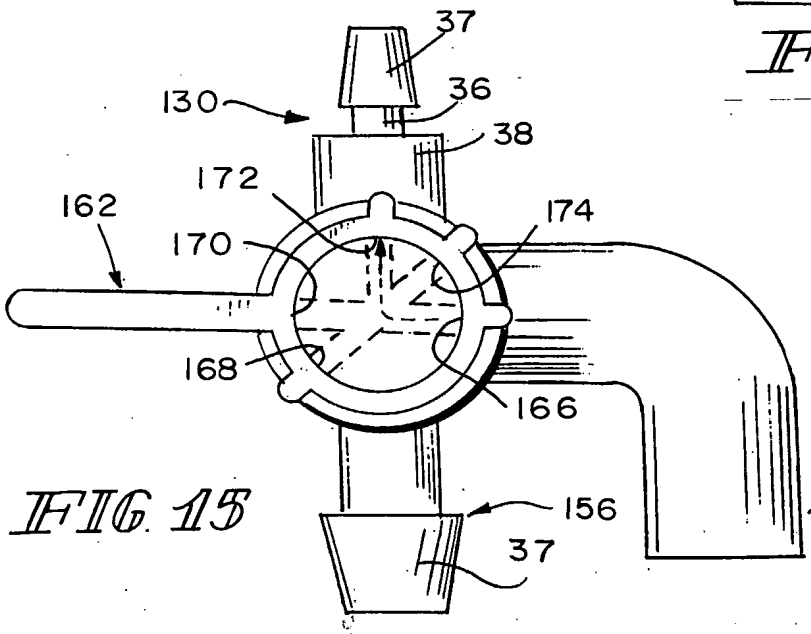


FIG. 15

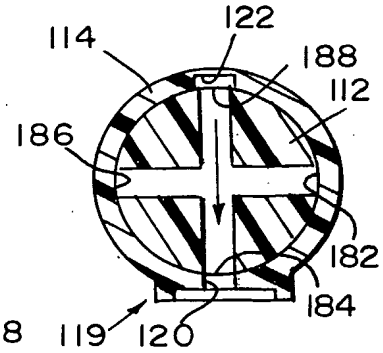


FIG. 16

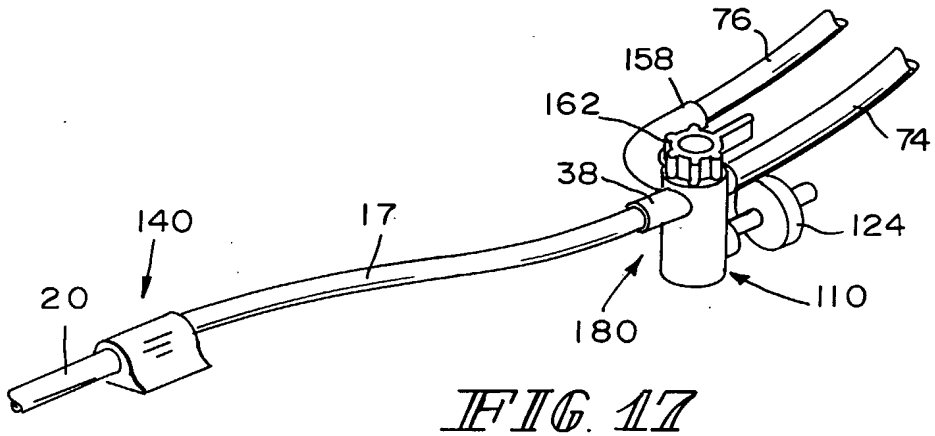


FIG. 17

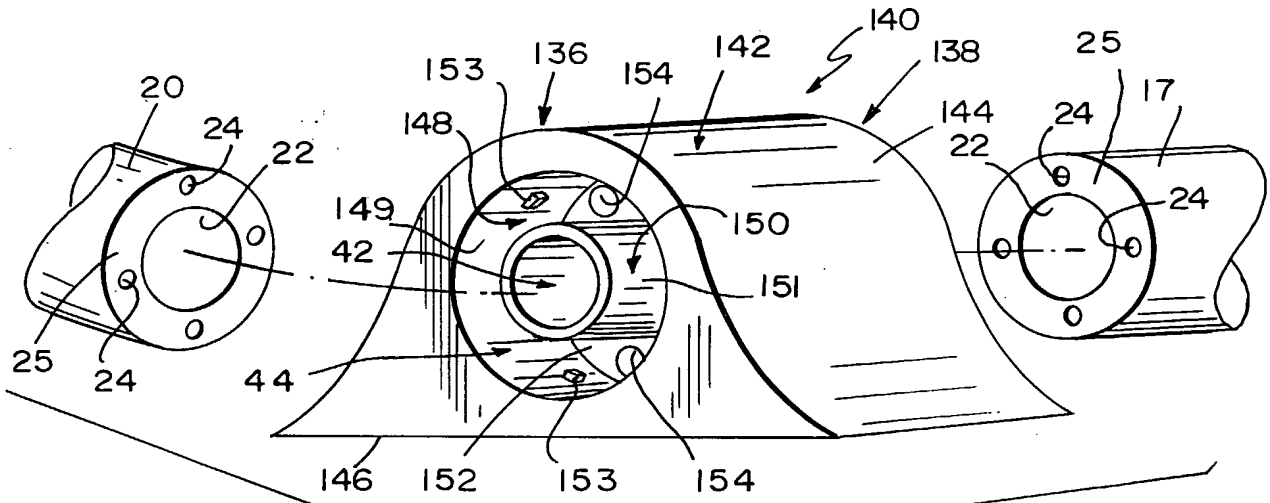


FIG. 18

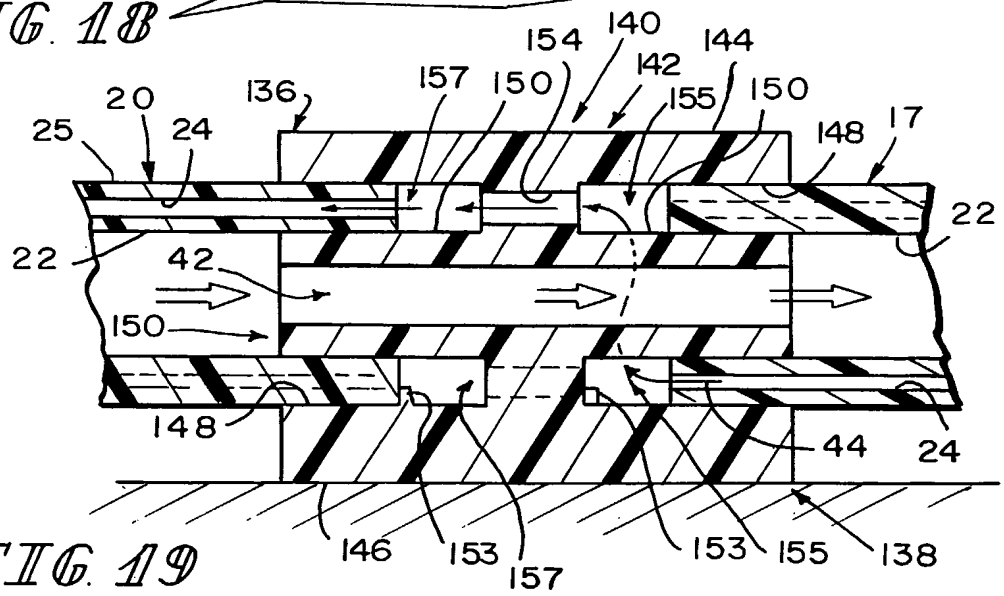


FIG. 19

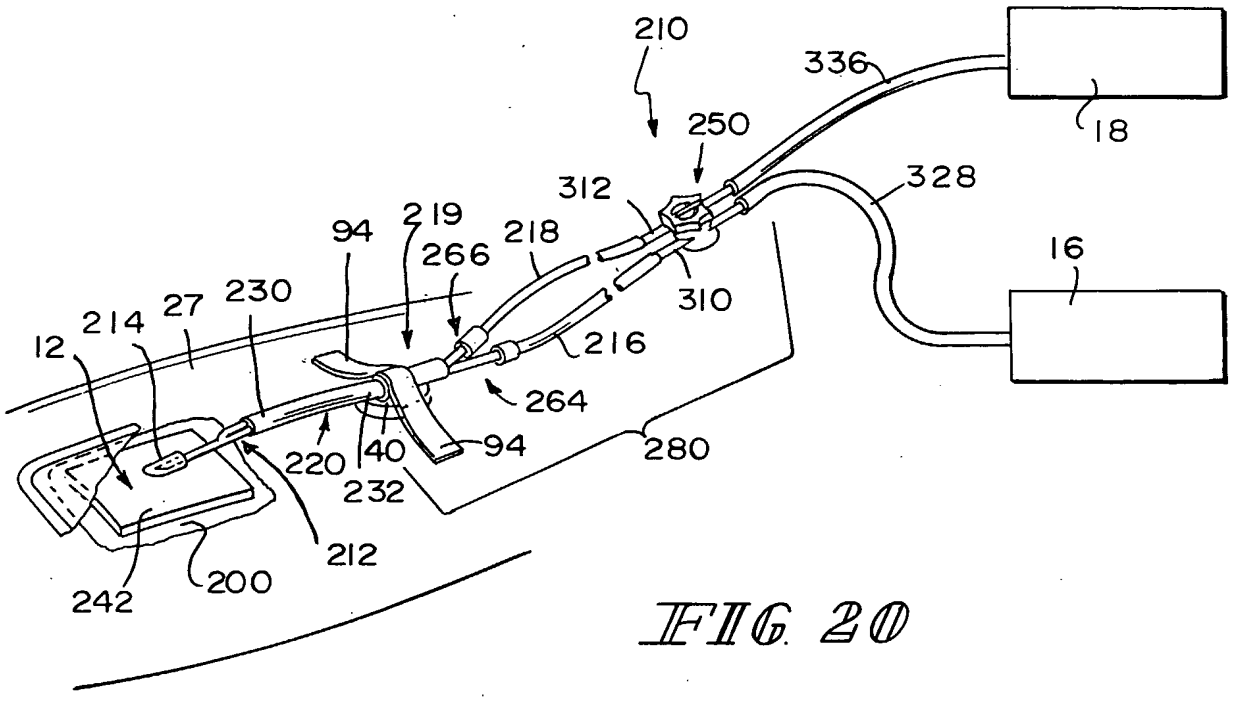
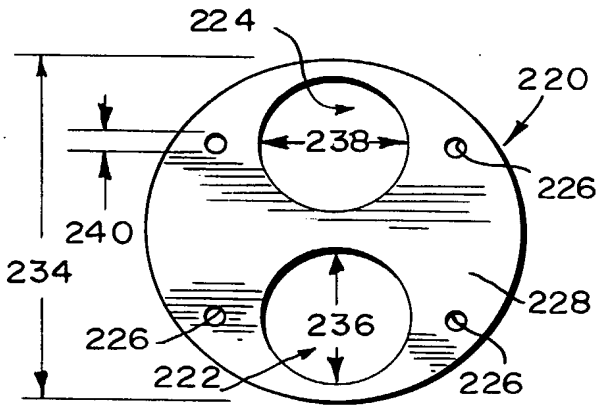


FIG. 20

FIG. 21



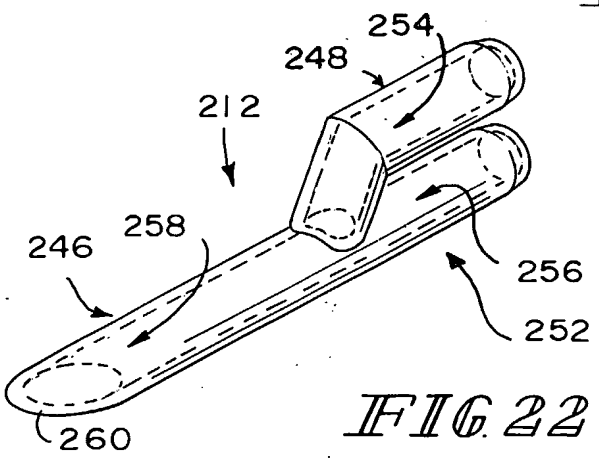


FIG. 22

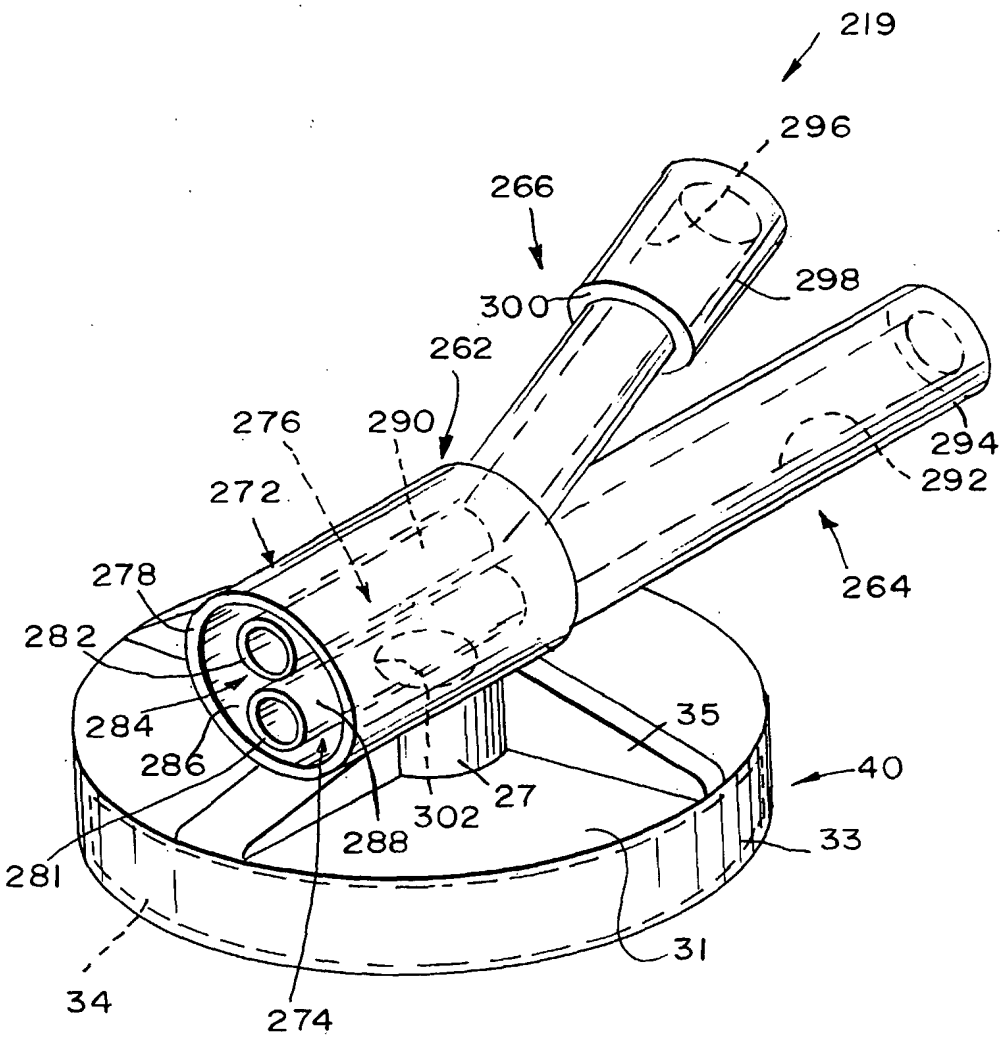

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FIG. 23

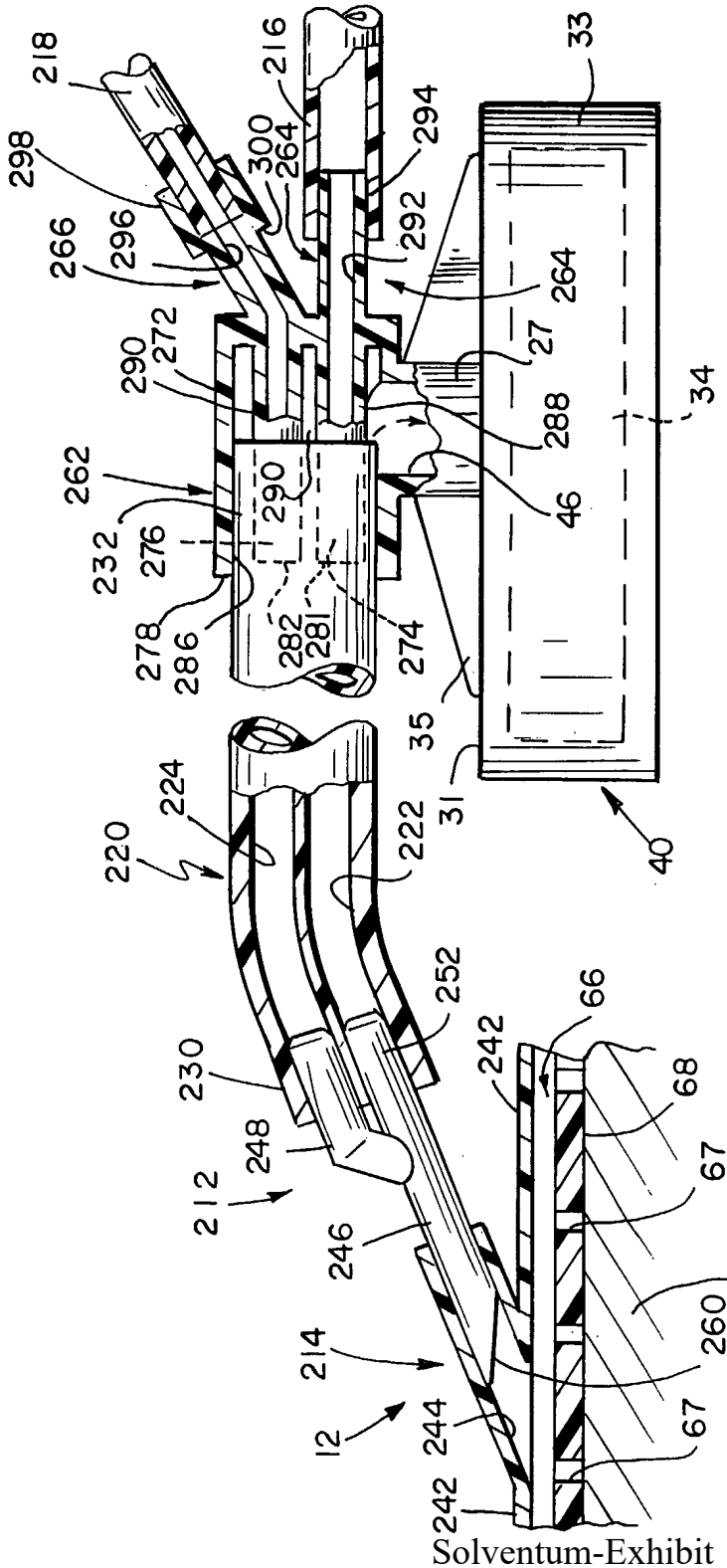


FIG. 24

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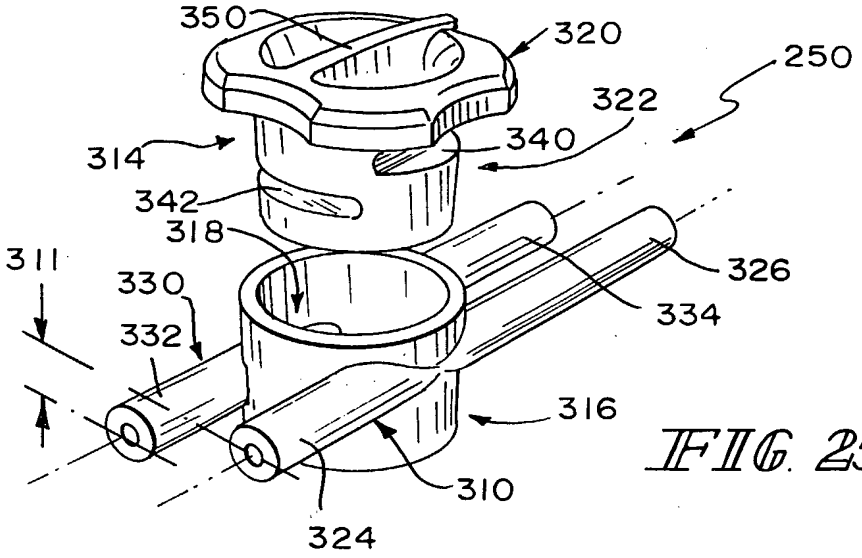


FIG. 25

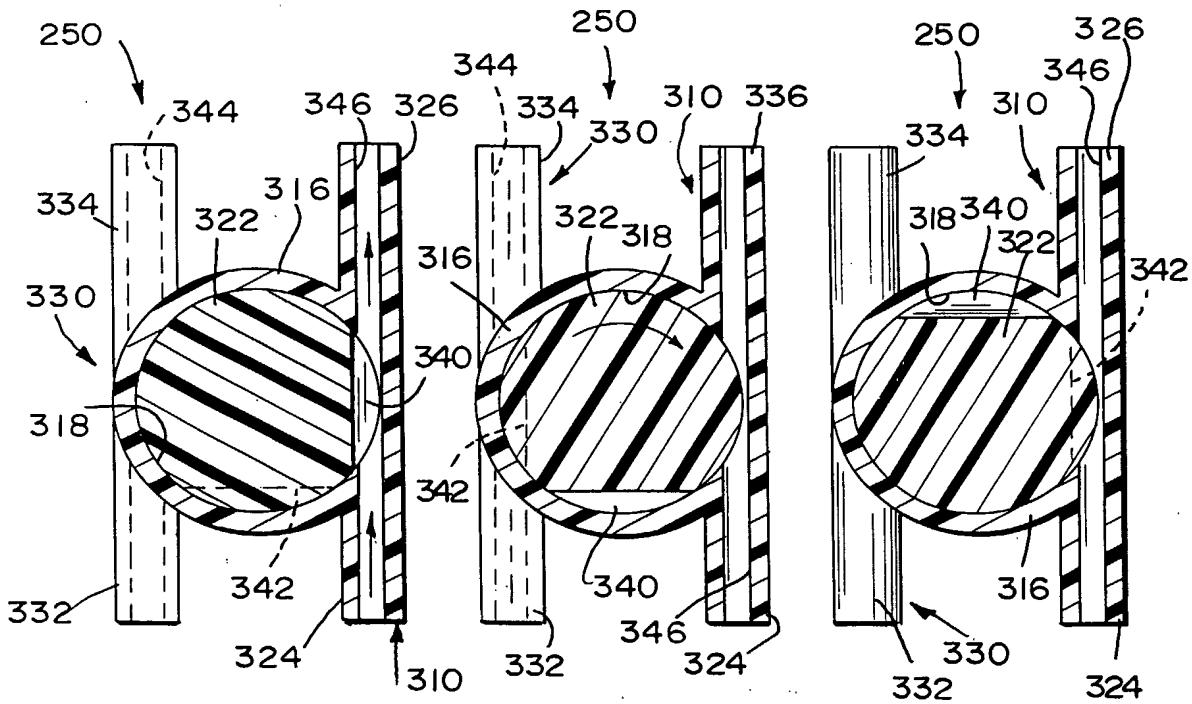


FIG. 26 FIG. 27 FIG. 28

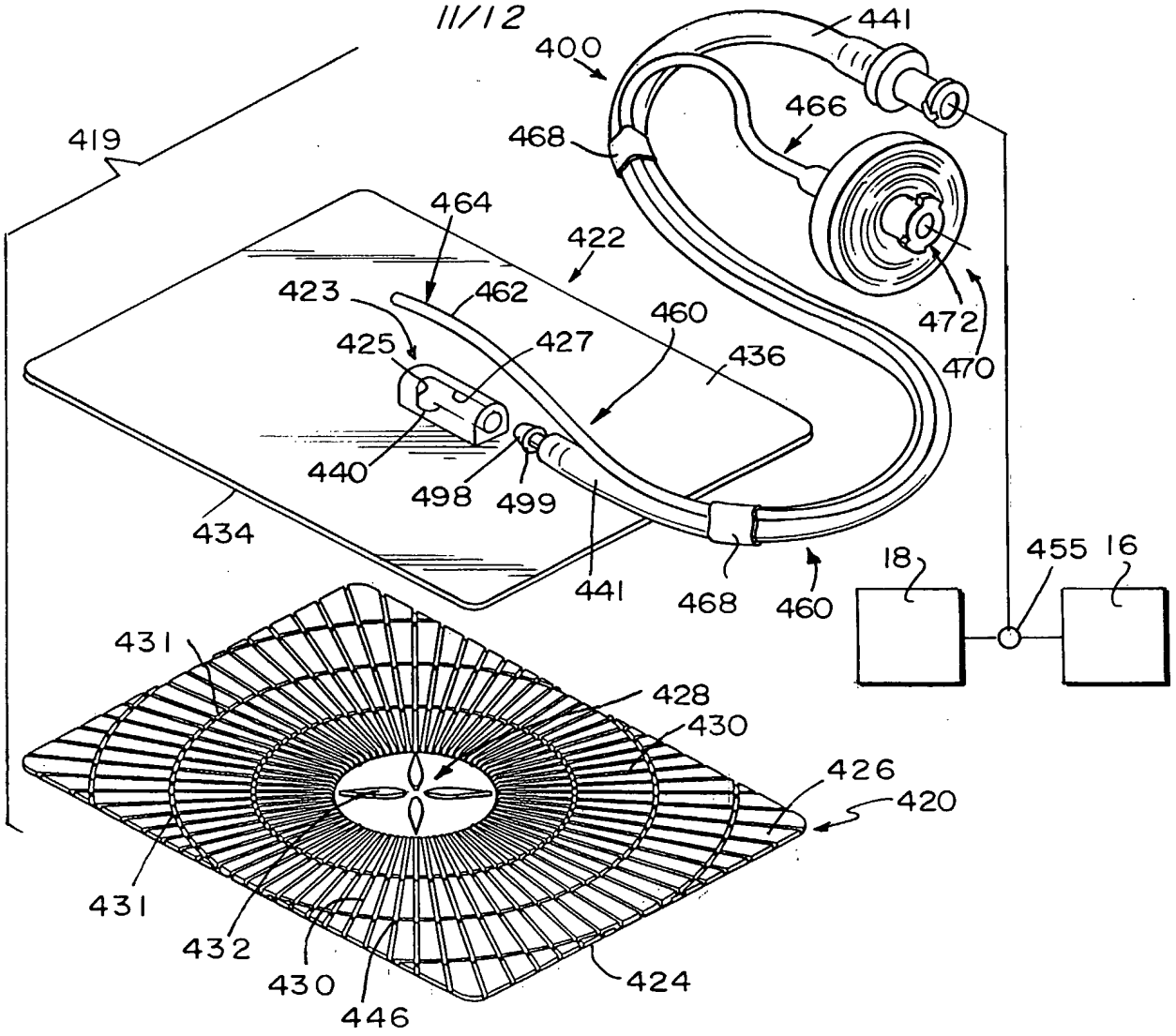

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FIG. 29

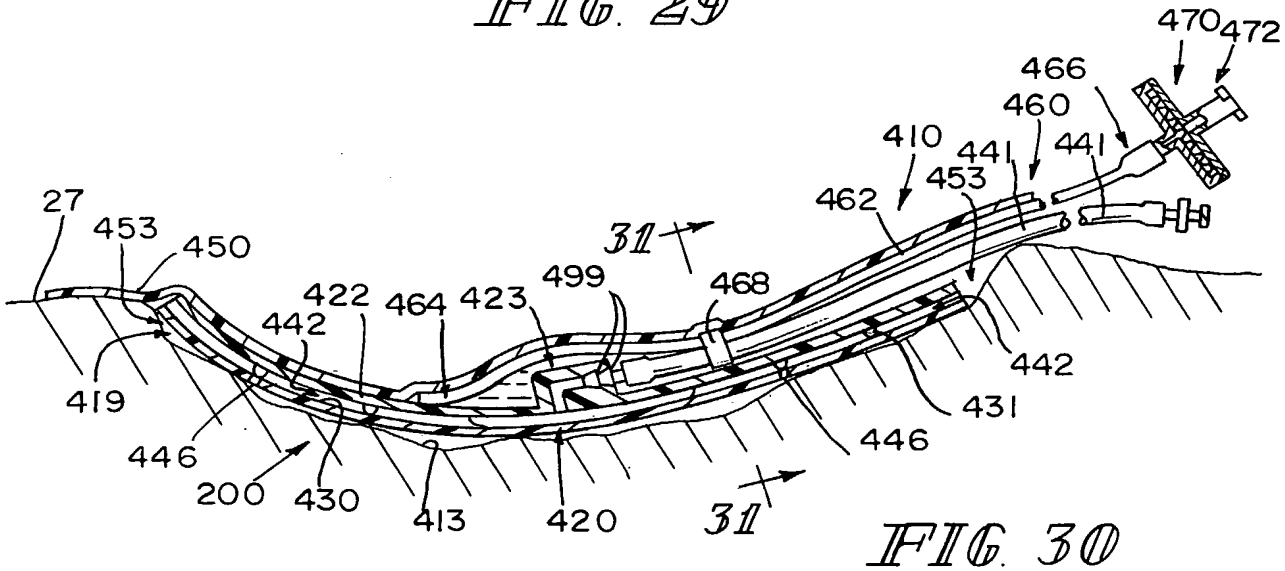

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FIG. 30

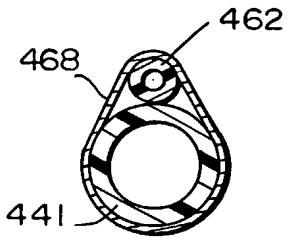


FIG. 31

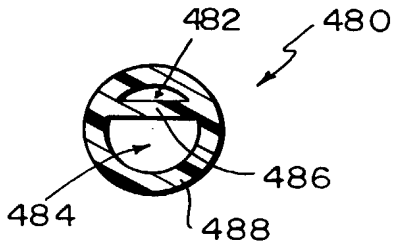


FIG. 32

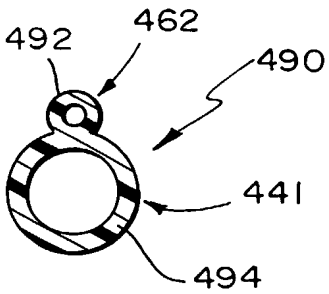


FIG. 33

Electronic Acknowledgement Receipt

EFS ID:	8846114
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	16-NOV-2010
Filing Date:	24-JAN-2008
Time Stamp:	13:46:47
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	Letter_Examiner_reIDSpreviouslysubmitted.pdf	69882 da03a6c993c38863c02723e98cc3ca1f6f56f7cb	no	2

Warnings:	
Information:	

Solventum-Exhibit 1002-0461

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Information:					
13	Foreign Reference	GB_2307180_A.pdf	8865647 03bf7de7776ae900ed7e7301171da3140f24a851	no	18
Warnings:					
Information:					
14	Foreign Reference	WO_03057070_A2.pdf	3510815 d908a2b9f2e018a7e01be072335aef09ab16597b	no	73
Warnings:					
Information:					
		Total Files Size (in bytes):	57246878		

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ADAHAN		Conf. No.:	4766
Appl. No.:	11/989,297	Examiner:	TREYGER
Appl. Filing Date:	January 24, 2008	Art Unit:	3761
Title:	**WOUND CLOSURE AND DRAINAGE SYSTEM**		

LETTER TO THE EXAMINER

ATTN: EXAMINER TREYGER
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner:

The IDS is being filed herewith is to replace the IDS filed on June 5, 2008, of which the 1449 and the references were misplaced within the USPTO.

Evidence of the filing is submitted herewith as the stamped filing receipt, dated June 5, 2008.

As provided in MPEP § 503, a stamped Filing Receipt/Return Postcard is prima facie evidence that the United States Patent and Trademark Office has received all of the items listed on the Filing Receipt. MPEP § 503, provides, in relevant parts that:

> The USPTO will stamp the receipt date on the filing receipt. A filing receipt which itemizes and properly identifies the items which are being filed serves as *prima facie* evidence of receipt in the USPTO of all the items listed thereon on the date stamped thereon by the USPTO. (Emphasis Added).

Applicants respectfully submit that the filing receipt stamped by the United States Patent and Trademark Office on June 5, 2008, clearly and properly identifies all of the items submitted in the filing. Additionally, none of the items were noted as not being received. Accordingly, the stamped Filing Receipt submitted herewith serves as *prima facie* evidence that the Office received the 1449 and references with the filing of June 5, 2008.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO/SB/08 in the next Official Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO/SB/08, and return a copy of the initialed Form PTO/SB/08 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

The Examiner is invited to contact the undersigned attorney at the below-listed telephone number, with regard to any questions that may arise.

Respectfully submitted,

THE NATH LAW GROUP

/Susanne M. Hopkins/

_____

Susanne M. Hopkins
Registration No. 33,247
Customer No. 20529

Date: November 16, 2010

THE NATH LAW GROUP
112 S. West Street, Alexandria, Virginia 22314
Tel: (703) 548-6284; Fax: (703) 683-8396
SMH/le

Attorney Docket No. 29068U

FILING RECEIPT

Date: June 5, 2008

Fees: $ 0.00 Attorney: GMN/JLM/DR

In re Application of:

ADAHAN

Serial No.:	11/989,297	Intl. Appl. No.:	PCT/IL2005/000784
Filed:	January 24, 2008	Intl. Filing Date:	July 24, 2005

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

DOCUMENTS BEING FILED:
THE PTO STAMP HEREON ACKNOWLEDGES RECEIPT OF:

(1) Transmittal Letter;
(2) Information Disclosure Statement (2 pages); and
(3) PTO Form-1449 (2 pages) with forty-four (44) references cited, and copies of eleven (11) of the forty-four (44) references cited.

THE NATH LAW GROUP
112 S. West Street
Alexandria, VA 22314
(703) 548-6284

FILE CHECK

Prepared by: le
Approved by:
Copy reviewed:
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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5116206	A	1992-05-26	ADAHAN	
	2	7503910	B2	2009-03-17	ADAHAN	

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Solventum-Exhibit 1002-0467

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Solventum-Exhibit 1002-0468

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-01-03
Name/Print	Susanne M. Hopkins	Registration Number	33247

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Solventum-Exhibit 1002-0469

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Solventum-Exhibit 1002-0470

Electronic Acknowledgement Receipt

EFS ID:	9147955
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	03-JAN-2011
Filing Date:	24-JAN-2008
Time Stamp:	17:13:12
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	sb0008-IDS.pdf	611757 e1cfaa48f51cb09bdcce025a520c78f55e442483	no	4

Warnings:	
Information:	

Solventum-Exhibit 1002-0471

Total Files Size (in bytes):	611757

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Mail Stop AMENDMENT
Attorney Docket No. 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli Adahan	Conf. No.: 4766
Application No.: 11/989,297	Examiner: TREYGER, ILYA Y.
Filed: January 24, 2008	Group Art Unit: 3761

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

AMENDMENT AND RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This paper is submitted responsive to the non-final Official Action dated October 14, 2010, along with a Petition for a one (1) month extension of time to extend the period to respond to February 14, 2011. Accordingly, this paper is timely filed.

A **Listing of the Claims** begins on page **2** of this paper.

Remarks begin on page **10** of this paper.

A **Conclusion** appears at page **20** of this paper.

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows. This listing of claims replaces all prior version of the claims in this application.

Claims 1-10 (Canceled)

11. (currently amended) An enclosure for applying negative pressure to ~~draining an open~~ a wound ~~from liquids exuded therefrom~~ , the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable ~~by means of a tube~~ to ~~an inlet of~~ a vacuum ~~pump~~ source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, ~~wherein one or more bleeding holes are provided in the enclosure or adjacent to its outlet~~ outside said enclosure, such that ambient air can enter said tube via said venting arrangement ~~and flow together with the exuded liquids under the action of the negative pressure, and the ambient pressure may be restored in said confined volume when said vacuum pump is not operating~~.

12. (Currently amended) The enclosure ~~of Claim~~ according to claim 11, ~~having a nipple for connecting to said tube~~ wherein ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.

13. (Currently amended) The enclosure ~~of Claim~~ according to claim 11, wherein said venting arrangement comprises ~~a plurality of~~ one or more bleeding holes ~~is provided in the form of a porous body mounted in said enclosure~~.

14. (Currently amended) The enclosure ~~of Claim~~ according to claim of claim 11, ~~completed with a tube connected to said outlet, for connection to said vacuum pump inlet, wherein said one or more bleeding holes are provided in the tube, adjacent to said outlet~~ wherein said venting arrangement is provided in the form of a porous body.

Claims 15-33 (Canceled)

34. (New) The enclosure according to claim 11, wherein said venting arrangement acts as a flow restrictor to provide, under the action of the vacuum source, a restricted flow of ambient air therethrough and along said tube.

35. (New) The enclosure according to claim 11, wherein said enclosure facilitates drainage of fluids exuded from the wound, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure.

36. (New) The enclosure according to claim 11, wherein said venting arrangement provides for ambient air to enter said enclosure via said tube and for ambient pressure to be restored in said confined volume when the vacuum source is not operating.

37. (New) The enclosure according to claim 11, wherein in operation of the enclosure, ambient air enters the tube directly via said venting arrangement without entering said enclosure when negative pressure is being applied to the wound via said enclosure.

38. (New) A disposable assembly for applying negative pressure to a wound, the assembly comprising an enclosure as defined in claim 11 attachable to the wound circumference so as to define a confined volume, a vacuum pump unit of the vacuum pump connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit being configured for being detachably attached to a drive unit of the vacuum pump for operating the pump unit, and a waste container connected to said vacuum pump unit, wherein said enclosure is connected to an inlet of said vacuum pump unit via said tube and said waste container is connected to an outlet of said vacuum pump unit.

39. (New) A disposable assembly according to claim 38, wherein said assembly further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

40. (New) The disposable assembly according to claim 38, wherein said venting arrangement comprises one or more bleeding holes.

41. (New) The disposable assembly according to claim 38, wherein said venting arrangement is provided in the form of a porous body.

42. (New) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside

said enclosure, such that ambient air can enter said tube via said venting arrangement, and further comprising a waste container in fluid communication with said vacuum source.

43. (New) The vacuum system of claim 42, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

44. (New) The vacuum system according to claim 42, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

45. (New) The vacuum system according to claim 44, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

46. (New) The vacuum system according to claim 42, wherein said venting arrangement comprises one or more bleeding holes.

47. (New) The vacuum system according to claim 42, wherein said venting arrangement is provided in the form of a porous body.

48. (New) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

49. (New) The vacuum system of claim 48, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

50. (New) The vacuum system according to claim 48, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said collection chamber being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

51. (New) The vacuum system according to claim 50, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

52. (New) The vacuum system according to claim 48, wherein said venting arrangement comprises one or more bleeding holes.

53. (New) The vacuum system according to claim 48, wherein said venting arrangement is provided in the form of a porous body.

REMARKS

Claims 1-33 are pending in the application, claims 1-10 and 15-33 are withdrawn from consideration, and claims 11-14 are rejected in the outstanding Official Action.

After entry of the above amendments, claims 1–10, and 15-33 are canceled without prejudice or disclaimer of the subject matter contained therein, and claims 11-14 are amended.

Support for the above amendments appears throughout the originally filed specification, claims, and drawings.

Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert any of the claims canceled or the original scope of any claim amended herein, in a continuing application.

It is respectfully submitted that the above amendments to the claims introduce no new matter within the meaning of 35 U.S.C. §132. Accordingly, Applicant requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

I. Claims 11 and 12 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lerman (U.S. Patent No. 5,941,859)as set forth in paragraph 4 on page 2 of the Official Action.

The Examiner asserts that claims 11 and12 are anticipated under 35 U.S.C. §102(b) by Lerman. This rejection is respectfully traversed.

Applicants respectfully submit that the rejection of claims 11 and 12 must be withdrawn because the cited reference to Lerman does not disclose, teach, and/or suggest all of the features of the currently claimed subject matter.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. V. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Further, "when evaluating the scope of a claim, every limitation in the claim must be considered. U.S.P.T.O. personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered." *U.S.P.T.O. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, page 9, October 26, 2005. As the Federal Circuit stated, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Col.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

Lerman discloses a wound irrigation shield with fluid scavenging. Lerman describes that the "perimeter of the shield has a group of cutouts or vacuum breaks 22, shown as three in number, but fewer or more can be used. Vacuum breaks 22 and suction tube 16 are disposed approximately 180 degrees opposite each other around an imaginary

symmetrical axis which passes through the apex of the shield." *See column 4, lines 13-18.*

Further, Lerman describes the "[V]acuum breaks 22 prevent excessive suction from being applied to the wound itself and allow air to enter the shield so that there is greater air flow directed toward the suction tube." *See column 4, lines 43-46.*

Independent claim 11 currently recites:

> An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement.

Lerman does ***not*** describe the claimed combination comprising "said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement."

In view of the above, it is submitted that Lerman does not teach each and every element of the claims as required for anticipation under 35 U.S. C. §102. Thus, Applicant respectfully requests the Examiner to withdraw this rejection.

It is noted that claim 12 depends on independent claim 11, thus claim 12 is also not anticipated by Lerman.

II. Claims 13 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lerman (U.S. Patent No. 5,941,859) in paragraph 7 on page 6 of the Official Action.

The Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice." Further, the Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide bleeding holes on the vacuum tubing in order convenience the treatment procedure, since it has been held that rearranging parts of an invention involves only routine skill in the art." These rejections are respectfully traversed.

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Lerman discloses a wound irrigation shield with fluid scavenging. Lerman describes that the "perimeter of the shield has a group of cutouts or vacuum breaks 22, shown as three in number, but fewer or more can be used. Vacuum breaks 22 and suction tube 16 are disposed approximately 180 degrees opposite each other around an imaginary symmetrical axis which passes through the apex of the shield." *See column 4, lines 13-18.*

Further, Lerman describes the "[V]acuum breaks 22 prevent excessive suction from being applied to the wound itself and allow air to enter the shield so that there is greater air flow directed toward the suction tube." *See column 4, lines 43-46.*

Independent claim 11 currently recites:

> *An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement.*

Lerman does ***not*** describe the claimed combination comprising ***"said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement."***

The Examiner agrees that such a venting arrangement is novel and not disclosed in Lerman, but argues that it would have been obvious to provide the "bleeding holes" of Lerman in the tubing 26, since:

1. tubing 26 and enclosure 10 form a common confined volume;

2. shifting the position of the holes would not have modified operation of the device; and

3. re-arranging parts of an invention involves only routine skill in the art.

The Examiner suggests that it would have been obvious to provide the bleeding holes in the suction tube "*to convenience the procedure since it has been held that rearranging parts of an invention involves only routine skill in the art*". It is not entirely clear what the Examiner means by "convenience", and how this would be an improvement over the disclosed position of the holes in the shield.

Lerman is directed to a wound irrigation device for use with a standard syringe and suction trap comprises a shield 10 which incorporates an irrigation tube 12 and nozzle 14 to deliver fluid at high pressure to a wound.

As clearly stated in the Abstract and elsewhere in Lerman, the intended purpose of the shield in Lerman is to ***protect the operator from splashback***, and includes a suction tube 16 to scavenge effluent, thus preventing spillage back into the wound or onto the patient and environs.

Regarding item 1 above, the tubing 26 is connected to the shield 10, and the internal volume of the tube is nominally in fluid communication with the internal volume of the shield. However, it is the ***other*** end of the tube that is connected to the pump, and thus, in operation of the pump, fluid is meant to flow only in one direction, i.e. from the shield to the tube, but not vice versa.

Furthermore, if the position of the holes is changed, then the fluid dynamics changes from a situation in which the flow through the holes and the shield and to the suction tube are essentially "in series" when the holes are in shield, to a situation in which the flow through the holes and the shield and to the suction tube are essentially "in parallel" when the holes are in the suction tube.

Regarding item 3, it is clear from the figures of Lerman, that the sum total of cross-sectional flow areas through the vacuum breaks in each of the illustrated embodiments could easily exceed the cross-sectional flow area of the suction tube. In such case, it is not entirely clear how one skilled in the art would go about transferring these "holes" to the suction tube, and still ensure that there is still a fluid flow from the shield to the suction tube.

Regarding item 2, it is respectfully submitted that the position of the holes 22 in Lerman ***does*** affect the operation of the device, particularly when shifting the position of the holes from being on the shield to being on the tube, as suggested by the Examiner.

Vacuum breaks 22, referred to by the Examiner (and thus herein as well) as "holes" are provided to "*prevent excessive suction from being applied to the wound itself **and** allow air to **enter the shield** so that there is greater air flow **toward** the suction tube*" (column 4, lines 44-46).

Thus, when, as actually disclosed in Lerman, the holes 22 are provided ***on the shield 10 itself***, the effect is to provide greater air flow ***towards*** the suction tube, ***through*** the enclosed volume of the shield. This forces the ambient air to pass over the wound, and the flow of air over the wound enhances drainage of the wound.

Placing ***any*** of the "holes" on tube 26 instead of on the shield would ***not*** "*allow air to* ***enter the shield***" through these holes, contrary to the stated purpose of the "holes" in column 4, lines 44-46 of Lerman, since the tube is downstream of the shield and the suction provided by the vacuum pump would result in ambient air entering the tube via these holes and going straight to the pump, bypassing the shield. This is self evident.

It is also to be noted that operation of the device 28 in Lerman would be substantially different in at least some circumstances, according to the position of the holes, for example where the suction port of the suction tube to the shield were to be blocked during pumping. In such circumstances, and with the "holes" located on the shield, the device 28 would increase suction significantly due to the blockage, and the user may be easily alerted to this (the motor would sound strained, for example), enabling the user to check the shield and to unblock the suction opening, and then continue as normal. On the other hand, with the holes transferred to the suction tube, such a blockage at the suction tube port would result in more ambient air being sucked through the holes and the suction tube, but no significant increase in suction. The operator would not realize that there is a blockage as the device would continue to work at the more or less normal suction levels, and moreover the collection reservoir would show that no fluid is being collected. This could give the wrong indication to the user that there is no more wound fluid to collect, while the reality would be that more and more fluid is being deposited in the shield. Thus, when the shield is removed, the fluids therein would, unexpected by the user, splash and contaminate the environment, contrary to the purpose of the device.

Furthermore, having the holes in the shield, as disclosed in Lerman, induces entrainment of fluids in the shield and increases the air flow ***through*** the shield and ***towards*** the suction tube (column 4, lines 44-46). However, placing the holes in the suction tube instead of on the shield can actually have the ***opposite*** effect, since the direct suction of ambient air through the suction tube hole actually results in there being less suction available for the shield itself (since now the suction is being shared by the fluid flow coming from the shield and the fluid flow coming from the holes (these two flows now being "in parallel" rather than "in series")), and thus less air and fluids are actually sucked through the shield and towards the suction tube via the shield. In fact, if the total flow area through the holes is close to or exceeds the cross-sectional flow area through the suction tube itself, then effectively no suction is applied to the shield at all, and there is only direct fluid flow from ambient to the suction tube via these holes.

Thus, by having the "holes" on the tube rather than on the shield this modification can actually render the Lerman device unsatisfactory for its intended purpose, contrary to the principle established in *In re Gordon* (733 F.2d 900, 221 USPQ 1125 (Fed Cir 1984)).

Moreover, and given that in Fig. 2 the tube 26 is gravitationally below the shield 10 (it makes sense to use the device in this manner to enhance drainage of fluids), it is not inconceivable that if the device is switched off while there are still wound fluids in the tube (for example due to a power shortage, malfunction, overfull reservoir, etc), these fluids could easily leak out and contaminate the environment via the suction tube holes (this

would not happen with the vacuum breaks 22 in their disclosed positions on the shield). This is of course contrary to the purpose of the device in Lerman, and also contrary to In re Gordon.

In fact, the intention in Lerman is to place the holes ***as far away as possible from the suction tube***, and mentions over and over again that the "*vacuum breaks 22 and the suction tube 16 are disposed approximately 180 degrees from one another with respect to the shield*" (see column 4, lines 15-18; column 6, lines 6-9 and 24-29). Thus, Lerman clearly ***teaches away*** from claim 11.

In view of the foregoing, it is submitted that nothing in the applied reference, renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

The above arguments apply to newly submitted independent claims 42, and 48, and it is similarly respectfully submitted that these claims are patentable over the cited reference.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

/William L. Klima/
Susanne M. Hopkins
Registration No. 33,247
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Registration No. 32,422
Customer No. 20529

Date: February 14, 2011

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PTO/SB/22 (07-09)
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** (*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*)	Docket Number (Optional) 29068U
Application Number 11/989,297	Filed January 24, 2008
For WOUND CLOSURE AND DRAINAGE SYSTEM	
Art Unit 3761	Examiner TREYGER, ILYA Y.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☑	One month (37 CFR 1.17(a)(1))	$130	$65	$ 65
☐	Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐	Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐	Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐	Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 14-0112.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 32,422

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/William L. Klima/ — Signature

February 14, 2011 — Date

William L. Klima — Typed or printed name

703-548-6284 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of one (1) forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/William Klima
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	65	65

Solventum-Exhibit 1002-0495

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**65**

Electronic Acknowledgement Receipt

EFS ID:	9443966
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/William Klima
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	14-FEB-2011
Filing Date:	24-JAN-2008
Time Stamp:	23:05:39
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$65
RAM confirmation Number	6954
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

Solvente Exhibit 1002-0497

1		2011_02_14_ROA.pdf	142665 41a7b9a5154daac591c1169cbec46b524ac6facd	yes	20

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	9
Applicant Arguments/Remarks Made in an Amendment	10	20

Warnings:					
Information:					
2	Extension of Time	sb0022.pdf	312922 26f237393ff912b7037c93ac8989bcd1e704501b	no	2
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30036 8882fe1ee43eee5d52f75ee57fe017976af8596f	no	2
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/989,297	01/24/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 02/14/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 24	Minus	** 33	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***5	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

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The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/RUTH M. LLOYD/

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	Adahan
Art Unit	3761
Examiner Name	Treyger
Attorney Docket Number	29068U

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	1	2002035111	JP	A	2002-02-05	Pigeon Corp	With English Abstract	☒

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

Solventum-Exhibit 1002-0500

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Adahan
	Art Unit	3761
	Examiner Name	Treyger
	Attorney Docket Number	29068U

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Solventum-Exhibit 1002-0501

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Adahan
	Art Unit	3761
	Examiner Name	Treyger
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-02-25
Name/Print	Susanne M. Hopkins	Registration Number	33,247

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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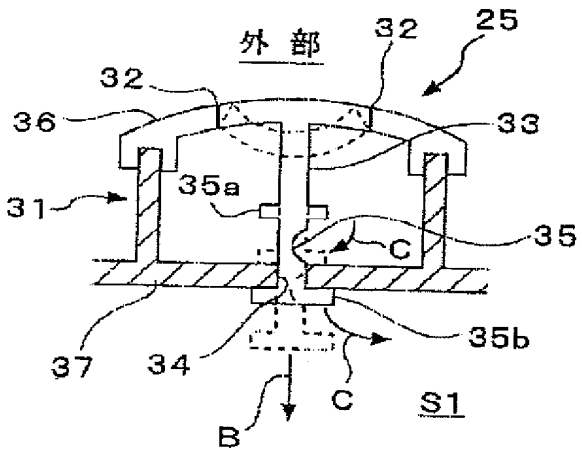
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(54)【発明の名称】　脈動搾乳器

(57)【要約】
【課題】　脈動における圧力変化を小さくして、使用に無理のない圧力変化を実現できる脈動搾乳器を提供すること。
【解決手段】　フードの開口を塞いだ状態で真空引き手段により陰圧が形成される陰圧形成空間を備える脈動型搾乳器１０であって、この陰圧形成空間と外部空間との間に設けられる小部屋３１と、前記外部空間と前記小部屋とを開閉する小部屋開閉手段３２及びこの小部屋３１と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋３１内の空気を前記陰圧形成空間に導く構成とした陰圧調整手段２５を有する。



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【特許請求の範囲】

【請求項１】　フードの開口を塞いだ状態で真空引き手段により陰圧が形成される陰圧形成空間を備える脈動型搾乳器であって、

この陰圧形成空間と外部空間との間に設けられる小部屋と、

前記外部空間と前記小部屋とを開閉する小部屋開閉手段及びこの小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、

前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とした陰圧調整手段を有することを特徴とする、脈動搾乳器。

【請求項２】　前記フードの内部空間が前記陰圧形成空間と連通しており、

前記フードに前記陰圧調整手段を設けたことを特徴とする、請求項１に記載の脈動搾乳器。

【請求項３】　前記弁手段の小部屋開閉手段と内部開閉手段とが択一的に開閉される構成としたことを特徴とする、請求項１または２のいずれかに記載の脈動搾乳器。

【請求項４】　前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記内部開閉手段を開いて小部屋内の空気を前記陰圧形成空間に導き、陰圧形成空間の陰圧が小さくなると、小部屋開閉手段を開いて小部屋内に外部の空気を導入することを特徴とする、請求項１ないし３のいずれかに記載の脈動搾乳器。

【請求項５】　一端が開放されたフード部と、

このフード部の他端が接続され、前記フード部の内部空間と連続した空間を有する本体部と、

この本体部に設けられ、本体の空間を陰圧形成空間とする真空引き手段と、

この本体部もしくは前記フード部に設けられる陰圧調整手段と

を有しており、

前記陰圧調整手段が、

前記陰圧形成空間と外部空間との間に設けられる小部屋と、

前記外部空間と前記小部屋とを開閉する小部屋開閉手段と、

この小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、

前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とされており、

かつ前記本体部には、母乳の収容容器が接続され、

前記本体部と前記母乳の収容容器の間を開閉する陰圧空間の限定手段を備えることを特徴とする、脈動搾乳器。

【請求項６】　前記小部屋が、フード部の側面から一体に起立される壁部と、

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この壁部の上端を塞ぐ柔軟な材料で形成した蓋部と、

この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通して貫通孔を開閉する拡径部を有するタクト部とを備えることを特徴とする、請求項５に記載の脈動搾乳器。

【請求項７】　前記小部屋が、フード部の側面から一体に起立される壁部と、

この壁部の上端を塞ぐ蓋部と、

この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通し、他端が前記蓋部を貫通するタクト部とを有しており、

前記内部空間の陰圧の大きさに対応して、前記タクト部が移動することにより、タクト部の前記各端部が前記内部開閉手段と小部屋開閉手段を択一的に開閉することを特徴とする、請求項５に記載の脈動搾乳器。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】この発明は、母乳を搾乳するための搾乳器に係り、特に、簡単な構成で脈動動作を行うことができる脈動搾乳器に関するものである。

【０００２】

【従来の技術】従来、この種の脈動搾乳器としては、例えば、本出願人による特公平３－６２１０６号に記載のものが知られている。すなわち、この搾乳器は、乳房を当てる開口を備えたフードに往復運動する弁手段を備えた圧力調整手段が設けられている。

【０００３】そして、フード内を真空引きすることで、フード内の陰圧が大きくなると、上記弁体の動作により、フード内が大気開放されるのようになっている。この動作を繰り返し行うことにより、脈動的に母乳を吸引することができるようにされているとともに、上記弁体の動作トルクを調整することで、脈動の圧力を変化させることができるようにされたものである。

【０００４】

【発明が解決しようとする課題】しかしながら、このような従来の脈動搾乳器においては、フード内の空間と外部の空間の直接的に開閉する弁手段を用いていることから、大気開放した時に流入する空気量が一定せず、精密な圧力調整が困難であるという問題がある。すなわち、フード内等の陰圧空間へ流入する空気量は、脈動における負圧の大きさの変化と関係し、脈動時の負圧の変化幅が大きいと、搾乳器を使用する母親の乳房への刺激が大きくなってしまう。

【０００５】また、従来の搾乳器において、圧力調整手段の弁体の動作トルクを調整する機構を設けることは、圧力調整手段の構造を複雑にし、故障の原因となるとともに、使い慣れない母親等にとっては、自分で自己に適する圧力に調整することは困難があるという欠点があった。

【０００６】本発明は、このような問題を解決するため

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になされたもので、脈動における圧力変化を小さくして、使用に無理のない圧力変化を実現できる脈動搾乳器を提供すること目的としている。

【０００７】

【課題を解決するための手段】上記目的は、請求項１の発明によれば、フードの開口を塞いだ状態で真空引き手段により陰圧が形成される陰圧形成空間を備える脈動型搾乳器であって、この陰圧形成空間と外部空間との間に設けられる小部屋と、前記外部空間と前記小部屋とを開閉する小部屋開閉手段及びこの小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とした陰圧調整手段を有する、脈動搾乳器により、達成される。

【０００８】請求項１の構成によれば、陰圧形成空間と外部空間との間に小部屋を設けて、陰圧形成空間内には、この小部屋を介して空気が流れこむようにされている。これにより、脈動動作における圧力変化の際に、陰圧形成空間へ流れ込む空気量を小部屋の大きさにより制限することができる。このため、陰圧が増大した状態から、外部に直接大気開放される場合と比べて、空気が流れ込む量が少なくしかも一定しているので、脈動動作における圧力変化を小さくすることができるとともに、安定させることができる。したがって、従来のように、大きな圧力変化により使用者が痛みを覚えることがなく、また、圧力変化も一定しているので、この点においても、不安定な圧力変化による不意の痛みや不快感を防止することができる。

【０００９】請求項２の発明は、請求項１の構成において、前記フードの内部空間が前記陰圧形成空間と連通しており、前記フードに前記陰圧調整手段を設けたことを特徴とする。請求項２の構成によれば、陰圧調整手段を例えば、真空引き手段等を内蔵する本体内でなくフード部に設けることから、構成が簡単になり、故障を起こしにくく、さらに、動作不良の際等にもフードを交換することにより修理できる利点がある。

【００１０】請求項３の発明は、請求項１または２の構成において、前記弁手段の小部屋開閉手段と内部開閉手段とが択一的に開閉される構成としたことを特徴とする。

【００１１】請求項３の構成によれば、前記陰圧形成空間に、正確に小部屋の容積分だけの空気を送り込むことができるので、圧力変化をより正確に一定に保つことができる。

【００１２】請求項４の発明は、請求項１ないし３のいずれかの構成において、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記内部開閉手段を開いて小部屋内の空気を前記陰圧形成空間に導き、陰圧形成空間の陰圧が小さくなると、小部屋開閉手段を開いて小部屋内に外部の空気を導入することを特徴とする。

【００１３】請求項４の構成によれば、真空引き手段は、連続動作するだけで、正確な脈動を行うことができる。

【００１４】また、上記目的は、請求項５の発明によれば、一端が開放されたフード部と、このフード部の他端が接続され、前記フード部の内部空間と連続した空間を有する本体部と、この本体部に設けられ、本体の空間を陰圧形成空間とする真空引き手段と、この本体部もしくは前記フード部に設けられる陰圧調整手段とを有しており、前記陰圧調整手段が、前記陰圧形成空間と外部空間との間に設けられる小部屋と、前記外部空間と前記小部屋とを開閉する小部屋開閉手段と、この小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とされており、かつ前記本体部には、母乳の収容容器が接続され、前記本体部と前記母乳の収容容器の間を開閉する陰圧空間の限定手段を備える、脈動搾乳器により、達成される。

【００１５】請求項５の構成によれば、脈動動作における圧力変化の際に、フード部の内部空間へ流れ込む空気量を小部屋の大きさにより制限することができる。このため、陰圧が増大した状態から、外部に直接大気開放される場合と比べて、空気が流れ込む量が少なく、しかも一定しているので、脈動動作における圧力変化を小さくすることができるとともに、安定させることができる。しかも、本体部の真空引き手段は、連続動作するだけで、正確な脈動を行うことができる。そして、この脈動動作が開始されるに際して、陰圧空間の限定手段により、陰圧を形成すべき空間が小さく限定されることで、脈動の立ち上がりが速やかに行われる。

【００１６】請求項６の発明は、請求項５の構成において、前記小部屋が、フード部の側面から一体に起立される壁部と、この壁部の上端を塞ぐ柔軟な材料で形成した蓋部と、この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通して貫通孔を開閉する拡径部を有するタクト部とを備えることを特徴とする。

【００１７】請求項７の発明は、請求項５の構成において、前記小部屋が、フード部の側面から一体に起立される壁部と、この壁部の上端を塞ぐ蓋部と、この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通し、他端が前記蓋部を貫通するタクト部とを有しており、前記内部空間の陰圧の大きさに対応して、前記タクト部が移動することにより、タクト部の前記各端部が前記内部開閉手段と小部屋開閉手段を択一的に開閉することを特徴とする。

【００１８】

【発明の実施の形態】以下、この発明の好適な実施形態

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を添付図面を参照しながら、詳細に説明する。尚、以下に述べる実施形態は、本発明の好適な具体例であるから、技術的に好ましい種々の限定が付されているが、本発明の範囲は、以下の説明において特に本発明を限定する旨の記載がない限り、これらの態様に限られるものではない。

【００１９】図１は、本発明の実施形態による脈動搾乳器の全体構成を示す概略断面図である。図において、脈動搾乳器１０（以下、「搾乳器１０」と略称する）は、母乳の収容容器として、例えば、哺乳瓶の瓶本体１５に取り付けた状態が示されている。すなわち、搾乳器１０は、本体部１１とフード部１２とを有している。フード部１２は一端が拡径された広口の開口１２ａを備えており、斜めに延びる筒状の内部空間Ｓ１を備えている。フード部１２の他端側は、容器の方向へ向かうように曲げられた通路１２ｂを備えている。

【００２０】フード部１２の下端はリング状の蓋体１３とされており、この蓋体１３の内周に形成されたメネジが、瓶本体１５の上端開口の周囲に形成されたオネジと螺合されている。尚、この搾乳器１０は、哺乳瓶だけでなく、蓋体１３と接続できるあらゆる形態の容器に取り付けることができる。また、瓶本体１５の上端開口内側には、短い筒状の部材１９が配置されており、この部材は後述する陰圧空間の限定手段を構成している。この筒状の部材１９は、その上端のフランジ部１９ａがフード部１２の段部と瓶本体１５の上端との間に挟み込まれるようにして着脱自在に取付けられてる。この陰圧空間限定手段１９の下端は、開閉蓋１８が形成されており、この開閉蓋１８を図示の実線のように閉めた状態では、瓶本体１５の内部空間Ｓ４との間に仕切りとなって内部空間Ｓ３を閉じることになる。

【００２１】フード部１２の通路１２ｂに隣接して、垂直な筒状の接合部１４が一体に設けられており、内部空間Ｓ２が形成された本体１１がこの接合部１４に取り付けられている。本体１１の図において上部の筐体には、図示しないバッテリや、このバッテリにより駆動されるモータ等と、これにより駆動されるダイヤフラム等の電動部が収容されており、内部空間Ｓ２を真空引きするための手段１１ａを構成している。この真空引き手段１１ａは、連結部２２を介して、空気通路となった接続部２３に接続されており、上記内部空間Ｓ２に連通している。

【００２２】また、真空引き手段１１ａの下には、上記内部空間Ｓ２に接続された圧力開放ボタン１６が配置されている。圧力開放ボタン１６は、頭部１６と頭部１６の裏側中心部から貫通孔１６ｃを通って内部空間Ｓ２に入り込む弁体１６ａと、弁体１６ａの先端に形成され、内部空間Ｓ２に位置する閉止部１６ｂを有している。

【００２３】また、圧力開放ボタン１６は、頭部１６の裏側周縁に沿って複数設けられ、頭部１６の裏側周縁と本体側との間に配置された付勢手段１７，１７を有している。付勢手段１７，１７は例えば、弾性を有するバネ状の部材で、頭部１６が、使用者の手指等により、矢印Ａの方向に押し込まれると変形して弁体１６ａを内部空間Ｓ２の方向に移動させて、その閉止部１６ｂが外気と連通した上記貫通孔１６ｃを開放する。これにより、内部空間Ｓ２には外部の空気が入り込む。また、手指を離すと、付勢手段１７，１７はその弾性に基づいて、図示されているように延びるから、弁体１６ａを内部空間Ｓ２から離れる方向に移動させ、図示されているように閉止部１６ｂは貫通孔１６ｃを塞いで、内部空間Ｓ２を密閉するようになっている。

【００２４】かくして、搾乳器１０では、フード部１２の開口に、例えば母親等が乳房（図示せず）を当てて、本体１１の電動部の図示しないスイッチをオンさせることにより、真空引き手段１１ａが作動して、内部空間Ｓ２と、この内部空間Ｓ２が連通している内部空間Ｓ３と、この内部空間Ｓ３が連通しているフード部１２の内部空間Ｓ１内の空気を吸引して陰圧空間とするようになっている。この陰圧により母親の乳房から絞られた母乳は、フード部１２の内部空間Ｓ１を通り、通路１２ｂから下に導かれて、筒状の部材１９（陰圧空間の限定手段）内に一時貯留される。そして、開閉蓋１８を図示の点線のように開くと、母乳は瓶本体１５内に落下して貯留されるようになっている。すなわち、陰圧空間の限定手段１９は、瓶本体１５の内側に図示するように装着される有底筒体でなっており、この底部が開閉蓋１８となっている。この底部は、例えば、ある程度弾性を備えた筒体の底部をその周方向に沿って、一部を残して切り離した構成であり、この切り離されていない一部がヒンジとして機能する。これにより、開閉蓋１８は構造的には、その剛性に基づいて閉じており、内部空間Ｓ３内の陰圧が高まると、開閉蓋１８を閉じる力は大きくなる。しかしながら、開閉蓋１８が閉じた状態で、搾乳された母乳が筒状の部材１９内にある程度貯留されると、その重さにより、開閉蓋１８は開かれる。尚、陰圧空間の限定手段の開閉蓋１８が開かれていると、真空引き手段１１ａは、瓶本体１５の内部空間Ｓ４を含む広い容積の空間を真空引きする必要がある。

【００２５】ここで、搾乳器１０では、フード部１２の側面に陰圧調整手段２５を備えることにより、上記陰圧が一定周期で変化する脈動をつくり出すことができる。次に、この陰圧調整手段２５の構成を説明する。ここで、陰圧調整手段は、フード部１２の側面だけでなく、陰圧を形成する空間であるＳ２，Ｓ３のいずれの箇所に対応して設けてもよい。しかしながら、この実施形態では、フード部１２が搾乳器１０の本体１１と取り外しができることや、フード部１２が外部に大きく突出して、広い側面を持つので、陰圧調整手段はの取り付けが簡単であること等から、構成が簡単となり、故障の際の修理

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等も容易となる。

【００２６】図２及び図３は、陰圧調整手段の第１の実施形態を示しており、図２はその上面図、図３は図２のＢ－Ｂ線概略断面図である。図において陰圧調整手段２５は、外部空間に突出するように設けられた小部屋３１を有している。小部屋３１は、比較的小さな容積の部屋であって、外部空間と陰圧形成空間であるフード１２の内部空間Ｓ１との間に設けられる。小部屋の容積は、搾乳器１０の構造によって変わるが、この実施形態では、例えば、小部屋３１は、陰圧が形成される空間の２０パーセントである程度の容量とされている。

【００２７】小部屋３１を形成する円筒状の壁の上端は、柔軟な屋根状の蓋部３６により塞がれている。この蓋部３６は、合成ゴム材料等により上方に凸となるようなドーム状の形成でなり、柔軟な性質を備えている。蓋部３６には、図２に示されているように、例えば２箇所の十字状の切り込み部３２，３２が設けられており、図示の状態では、切り込み部３２，３２は閉じている。この実施形態では、この切り込み部３２，３２が、外部空間と前記小部屋とを開閉する小部屋開閉手段を構成している。蓋部３６の裏面の切り込み部３２，３２の間のほぼ中心付近には、図３に示されているように、小部屋３１の内部空間に向かって、柱状のロッドもしくはタクト部３３が一体に延びている。タクト部３３の下端は、フード部１２の壁３７を貫通する貫通孔３４を通って内部空間Ｓ１と連通している。タクト部３３の下端には、第１の拡径部３５ｂが形成されており貫通孔３４の内部空間Ｓ１側周縁に対して、この第１の拡径部３５ｂが当接することにより、貫通孔３４を塞ぐとともに、タクト部３３の下端も貫通孔３４から外側に抜けないようになっている。

【００２８】タクト部３３の第１の拡径部３５ｂよりも上の位置で、少なくともフード部１２の壁３７の厚み分よりも離れた箇所には、タクト部３３の軸状の側面を切り欠いて形成された縮径部３５が設けられている。この縮径部３５よりも上方には、第２の拡径部３５ａが形成されている。この実施形態では、この縮径部３５と貫通孔３４とで、小部屋と陰圧形成空間とを開閉する内部開閉手段を構成している。

【００２９】陰圧調整手段の第１の実施形態は以上のように構成されており、図１で説明したように、真空引き手段１１ａの動作により、フード１２の内部空間Ｓ１の空気が連続的に吸引されて陰圧とされる。この陰圧が一定以上大きくなると、タクト部３３が矢印Ｂの方向に引かれる。これにより、第１の拡径部３５ｂが下に引かれて、貫通孔３４の周縁から離れると同時に、この貫通孔３４の位置には、タクト部３３の縮径部３５が移動してくるので、貫通孔３４は開放される。これにより、小部屋３１内の空気は、矢印Ｃに示すように、内部空間Ｓ１に導入される。そして、貫通孔３４にタクト部３３に設けられた第２の拡径部３５ａが当たり、縮径部３５が内部空間Ｓ１内に入り込んで、貫通孔３４が閉じると、蓋部３３の切り込み部３２，３２との間の領域がタクト部３３に引っ張られて点線で示すように変形する。このため、切り込み部３２，３２は開いて、外部の空気が小部屋３１内に侵入する。

【００３０】この動作により、フード１２内の内部空間Ｓ１へは、小部屋３１の収容していた空気が流れ込むことから、陰圧が小さくなり、タクト部３３を下に引く力が弱まるから、蓋部３６の弾性に基づいて、図３の実線の状態に戻る。そして、真空引き手段１１ａが、再び内部空間Ｓ１の陰圧を大きくすると、上記の動作を繰り返すことになり、後述するような脈動が生じて、フード部１２内の陰圧は周期的に変化し、この周期的変化に基づいて、母乳が吸引される。

【００３１】図４ないし図７は、陰圧調整手段の第２の実施形態を示しており、図４はその外部空間と前記小部屋とを開閉する小部屋開閉手段を開いた状態の上面図、図５は図４のＣ－Ｃ線概略断面図、図６はその外部空間と前記小部屋とを開閉する小部屋開閉手段を閉じた状態の上面図、図７は図６のＣ－－Ｃ線概略断面図である。これらの図において陰圧調整手段４０は、外部空間に突出するように設けられた小部屋４１を有している。小部屋４１は比較的小さな容積の部屋であって、外部空間と陰圧形成空間であるフード１２の内部空間Ｓ１との間に設けられる。

【００３２】小部屋４１を形成する円筒状の壁の上端は、柔軟な屋根状の蓋部４６により塞がれている。この蓋部４６は、合成ゴム材料等により上方に凸となるようなドーム状の形成でなり、柔軟な性質を備えている。蓋部４６には、図４に示されているように、やや偏心した位置に湾曲した切り込み部４２が設けられており、図４の状態では、切り込み部４２は開いており、図６の状態では、切り込み部４２は閉じている。

【００３３】この実施形態では、この切り込み部４２が、外部空間と前記小部屋とを開閉する小部屋開閉手段を構成している。蓋部４６の裏面の切り込み部４２よりも中心によった位置には、図５に示されているように、小部屋４１の内部空間に向かって、柱状のロッドもしくはタクト部４３が一体に延びている。タクト部４３の下端は、フード部１２の壁３７を貫通する貫通孔３４を通って内部空間Ｓ１と連通している。タクト部４３の下端には、拡径部４７が形成されており貫通孔３４の内部空間Ｓ１側周縁に対して、この拡径部４７が当接することにより、貫通孔３４を塞ぐとともに、タクト部４３の下端も貫通孔３４から外側に抜けないようになっている。

【００３４】タクト部４３の拡径部４７より上には、少なくともフード部１２の壁３７の厚み分より離れて、タクト部４３の軸状の側面を切り欠いて形成された縮径部４５が設けられている。この実施形態では、この縮径部

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４５と貫通孔３４とで、小部屋と陰圧形成空間とを開閉する内部開閉手段を構成している。

【００３５】陰圧調整手段の第２の実施形態は以上のように構成されており、図１で説明したように、真空引き手段１１ａの動作により、フード１２の内部空間Ｓ１の空気が連続的に吸引されて陰圧とされる。この陰圧が一定以上大きくなると、図７に示されているように、タクト部４３が矢印Ｆの方向に引かれる。これにより、拡径部４７が下に引かれて、貫通孔３４の周縁から離れると同時に、この貫通孔３４の位置には、タクト部４３の縮径部４５が移動してくるので、貫通孔３４は開放される。これにより、小部屋４１内の空気は、矢印Ｅに示すように、内部空間Ｓ１に導入される。これと同時に、蓋部４３の切り込み部４２のある領域はタクト部４３に引っ張られて、図７に示されているように内側に凸となるような変形が生じる。このため、切り込み部４２は閉じていて外部部の空気は小部屋４１内に侵入しない。

【００３６】この動作により、フード１２内の内部空間Ｓ１へは、小部屋４１の収容していた空気が流れ込むことから、陰圧が小さくなり、タクト部４３を下に引く力が弱まるから、蓋部４６の弾性に基づいて、図５の状態に戻る。これにより、切り込み部４２は開いて、矢印Ｄに示されているように、外部の空気が小部屋４１内に導入される。そして、真空引き手段１１ａが、再び内部空間Ｓ１の陰圧を大きくすると、上記の動作を繰り返すことになり、後述するような脈動が生じて、フード部１２内の陰圧は周期的に変化し、この周期的変化に基づいて、母乳が吸引される。

【００３７】図８ないし図１１は、陰圧調整手段の第３の実施形態を示しており、図８はその上面図、図９ないし図１１は、図８のＤ－Ｄ線概略断面図を示しており、この図９ないし図１１は動作の各段階を示している。これらの図において陰圧調整手段５０は、外部空間に突出するように設けられた小部屋５１を有している。小部屋５１は比較的小さな容積の部屋であって、外部空間と陰圧形成空間であるフード１２の内部空間Ｓ１との間に設けられる。

【００３８】小部屋５１を形成する筒状の壁の上端は、蓋部５６により塞がれている。この蓋部５６は、下面の小部屋５１内に突起５６ｂを備えており、他の実施形態のように変形しない。蓋部５６の図８に示されているやや端部によった位置に貫通孔５６ａが形成されおり、この貫通孔５６ａの真下には、フード部１２の壁面（側面）３７に貫通孔５４が形成されている。

【００３９】上記各貫通孔５６ａと５４を貫通するように、柱状のロッドもしくはタクト部５３が挿通されている。タクト部５３は、小部屋５１の壁面３７ａに沿って上下に摺動されるように設けられている。小部屋５１内の空間内において、タクト部５３の途中からは水平に一体に延びる掛止片５７が設けられており、掛止片５７とフード部１２の壁面（側面）３７の間には、付勢手段として例えばコイルスプリングが挿入されている。また、タクト部５３の上部には、上端よりやや下の位置から上記掛止片５７の上面までの間に第１の切り欠き部５９が形成されており、この第１の切り欠き部５９は上段部５９ａと下段部５９ｂを備えている。この第１の切り欠き部５９の上下方向の大きさは、少なくとも蓋部５６の厚みより大きくされている。この実施形態では、貫通孔５６ａと第１の切り欠き部５９が、外部空間と前記小部屋とを開閉する小部屋開閉手段を構成している。

【００４０】上記タクト部５３の下部には、下端部よりやや上の位置に第２の切り欠き部５５が形成されており、この第２の切り欠き部５５は上段部５５ａと下段部５５ｂを備えている。この第２の切り欠き部５５の上下方向の大きさは、少なくともフード部１２の側面３７の厚みよりも大きく設定されている。さらに、第１に切り欠き部５９の上段部５９ａと第２の切り欠き部５５の下段部５５ｂまでの距離は、各貫通孔５６ａと５４の外縁部の間の距離を越えないように設定されている。そして、この実施形態では、貫通孔５４とタクト部５３の第２の切り欠き部５５が、小部屋と陰圧形成空間とを開閉する内部開閉手段を構成している。

【００４１】陰圧調整手段の第３の実施形態は以上のように構成されており、搾乳器１０の使用を開始する時には、フード部１２の内部空間Ｓ１は大気圧で、陰圧を生じてでいない。このため、図９に示すように、タクト部５３は上端に位置しており、掛止片５７の上面が蓋部５６の突起５６ｂと当接されている。タクト部５３の第１の切り欠き部５９の上段部５９ａは、貫通孔５６ａの上端よりも上に位置して、外部空間と小部屋５１の内部とは連通しており、外部空間から矢印Ｇに示すように、小部屋５１内に空気が導入される。

【００４２】次いで、図１で説明したように、真空引き手段１１ａの動作により、フード１２の内部空間Ｓ１の空気が連続的に吸引されて陰圧とされる。この陰圧が一定以上大きくなると、図１０に示されているように、タクト部５３がコイルスプリング５８の付勢力に抗して、矢印の方向に次第に引かれる。これにより、タクト部５３の第１の切り欠き部５９の上段部５９ａが貫通孔５６ａの上端を越えて下に位置して貫通孔５６ａを塞ぐ。同時に、タクト部５３の第２の切り欠き部５５の下段部５５ｂも、貫通孔５４の下端を越えて下降していないので、図１０の状態では、貫通孔５６ａも貫通孔５４も塞がれている。

【００４３】次いで、内部空間Ｓ１の陰圧がさらに大きくなると、タクト部５３がコイルスプリング５８の付勢力に抗して、矢印の方向にさらに引かれる。これにより、タクト部５３の第１の切り欠き部５９の上段部５９ａが貫通孔５６ａの下端を越えて下に位置して貫通孔５６ａを塞ぐ状態を継続する。一方、タクト部５３の第２

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の切り欠き部５５の下段部５５ｂは、貫通孔５４の下端を越えて下降する。これにより、図１１の状態では、貫通孔５６ａは塞がれているが、貫通孔５４は第２の切り欠き部５５により、小部屋５１の内部と連通するので、小部屋５１内の空気だけが、性格に内部空間Ｓ１に導入される。

【００４４】この動作により、フード１２内の内部空間Ｓ１へは、小部屋５１の収容していた空気だけが流れ込むことから、陰圧が小部屋５１の容積の空気分だけ正確に小さくなり、タクト部５３を下に引く力が弱まるから、コイルスプリング５８の付勢力に抗しきれなくなり、タクト部５３は上昇されて図９の状態に戻り、外部の空気が小部屋５１内に導入される。そして、真空引き手段１１ａが、再び内部空間Ｓ１の陰圧を大きくすると、上記の動作を繰り返すことになり、後述するような脈動が生じて、フード部１２内の陰圧は周期的に変化し、この周期的変化に基づいて、母乳が吸引される。

【００４５】かくして、この第３の実施形態は、他の実施形態と比べて、図１０で説明したように、第１の切り欠き部５９と第２の切り欠き部５５とが、それぞれ外部空間と内部空間Ｓ１とに確実に択一的に開放されるから、上記脈動の振幅がきわめて正確になされることになる。

【００４６】図１２は、本実施形態の搾乳器１０の全体の動作の一例を簡単に説明するためのフローチャートと、各ステップにおける陰圧の関係を示している。図において、使用者である授乳者が自己の乳房にフード部１２の開口１２ａを当てる（ＳＩ１）。ここで、通常は、図１の陰圧空間の限定手段１９の開閉蓋１８を実線のように閉じられている。次に、図示しないスイッチをオンして電動部を作動させ（ＳＴ２）、真空引き手段の一部であるダイヤフラム（図示せず）を作動させると、真空引き手段１１ａが陰圧形成空間である内部空間Ｓ２、Ｓ３、Ｓ１の空気を吸引することで、これらの空間を真空引きして陰圧を生じさせる（ＳＴ３）。この状態では、陰圧は形成されたばかりであり、弱い（小さい）。

【００４７】真空引き手段１１ａの動作が継続して、この陰圧が一定以上大きくなると（ＳＴ４，）、ここから、脈動による搾乳動作に入る。上述の各実施形態で説明したように、各陰圧形成手段が動作されて、小部屋と内部空間との間の内部開閉手段が開くと、小部屋の空気が内部空間に入り込むので、陰圧は弱まる（ＳＴ５）。ここで、搾乳動作により、搾乳された母乳が内部空間Ｓ１からＳ３に導かれて、筒状の部材である陰圧空間の限定手段１９内に一時貯留され、ある程度の量が溜まったら、開閉蓋１８が開かれる（ＳＴ６，ＳＴ７）。これに対して、母乳が一定量溜まらない間は、ＳＴ８に進む（ＳＴ６，ＳＴ８）。すなわち、陰圧空間の限定手段１９内で、母乳が一定量に到達しない間は、開閉蓋１８を開くことができないので、ＳＴ８に進んで、内部開閉手段が閉じられ、陰圧が大きくなる（ＳＴ８）。また、ＳＴ６で母乳が一定量溜まって、開閉蓋１８が開かれると、母乳は直ちに瓶本体１５内に落下して貯留され、開閉蓋１８は直ぐに閉じられて、ＳＴ８に進む。次いで、搾乳作業が終了しない限りは、ＳＴ５に戻って、作業者が瓶本体１５に貯留された母乳の量や出方を見ながら、搾乳作業が終了しないうちは、上記の動作が繰り返される。また、作業者が瓶本体１５に貯留された母乳の量を見ながら、母乳が目的の量だけ貯留されたり、あるいは母乳が出なくなって、搾乳作業が終了したと判断したら（ＳＴ９）、ＳＴ１０に進んで、圧力開放ボタン１６の頭部１６ａを図１の矢印Ａの方向に押し込んで、各内部空間Ｓ２，Ｓ３，Ｓ１を大気圧とし（ＳＴ１０）、図示しない電源スイッチをオフにして、使用を終了する（ＳＴ１１）。

【００４８】図１３は、本実施形態の搾乳器１０と従来の脈動型搾乳器の搾乳動作における脈動の様子を示すグラフである。図示のＡは、本実施形態の搾乳器１０によるもの、Ｂは図１の構成中において、限定手段１８を設けないか、開閉蓋１８ａを開いて使用したもの、Ｃは従来の脈動型搾乳器である。

【００４９】図示されているように、本実施形態の搾乳器１０は、陰圧調整手段を備えているので、使用開始からの陰圧形成において、一定の大きさの陰圧になるまでの立ち上がりのスピードが早く、しかも、従来と比べて、小さな振幅による正確な脈動を実現できる。これにより、使用者の乳房に与える刺激がきわめて少なく、不快感のない使用が可能であるとともに、乳幼児の授乳動作における脈動にきわめて近似した搾乳動作を実現することができる。しかも、陰圧調整手段は、このような脈動を行う陰圧を自動的に実現することができ、構成が簡単で、その分故障もすくなく、確実な動作を行うことができる。

【００５０】本発明は、上述の実施形態に限定されるものではなく、上記しない構成を付加することもできる。また、上記実施形態の各構成は、その一部を省略することができるし、相互に組み合わせてもよい。

【００５１】

【発明の効果】以上述べたように、本発明によれば、脈動における圧力変化を小さくして、使用に無理のない圧力変化を実現できる脈動搾乳器を提供することができる。

【図面の簡単な説明】

【図１】本発明の実施形態に係る脈動搾乳器の構成を示す概略断面図である。

【図２】図１の脈動搾乳器の陰圧調整手段の第１の実施形態を示す上面図である。

【図３】図２のＢ－Ｂ線概略断面図である。

【図４】図１の脈動搾乳器の陰圧調整手段の第２の実施形態の外部空間と前記小部屋とを開閉する小部屋開閉手

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段を開いた状態の上面図である。

【図５】図４のＣ－Ｃ線概略断面図である。

【図６】図４の陰圧調整手段の外部空間と小部屋とを開閉する小部屋開閉手段を閉じた状態の上面図である。

【図７】図６のＣ－Ｃ線概略断面図である。

【図８】図１の脈動搾乳器の陰圧調整手段の第３の実施形態を示す上面図である。

【図９】図８のＤ－Ｄ線概略断面図であり、外部空間と前記小部屋とを開閉する小部屋開閉手段を開いた状態の上面図である。

【図１０】図８のＤ－Ｄ線概略断面図であり、外部空間と前記小部屋とを開閉する小部屋開閉手段を閉じ、小部屋と陰圧形成空間とを開閉する内部開閉手段も閉じた状態の図である。

【図１１】図８のＤ－Ｄ線概略断面図であり、外部空間と前記小部屋とを開閉する小部屋開閉手段を開いた状態＊

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＊の図である。

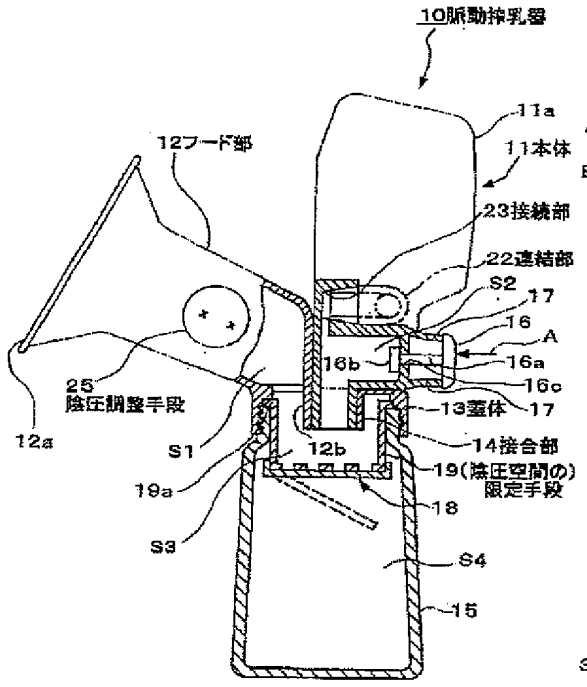
【図１２】図１の脈動搾乳器の動作の一例を示すフローチャートである。

【図１３】図１の脈動搾乳器の脈動動作と従来の脈動搾乳の脈動動作を比較したグラフである。

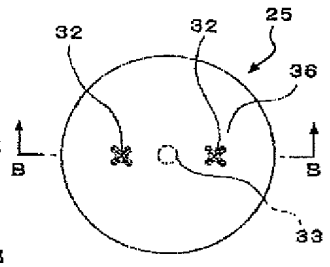
【符号の説明】

１０・・・脈動搾乳器、１１・・・本体、１２・・・本体、１３・・・蓋体、１５・・・瓶本体、１６・・・圧力開放ボタン、１８・・・開閉蓋、１９・・・（陰圧空間の）限定手段、２５・・・陰圧調整手段、３１・・・小部屋、３２・・・切り込み、３５・・・タクト部、３６・・・蓋部、４０・・・陰圧調整手段、４１・・・小部屋、４２・・・切り込み、４３・・・タクト部、４６・・・蓋部、５０・・・陰圧調整手段、５１・・・小部屋、５３・・・タクト部、５６・・・蓋部、Ｓ１，Ｓ２，Ｓ３，Ｓ４・・・内部空間

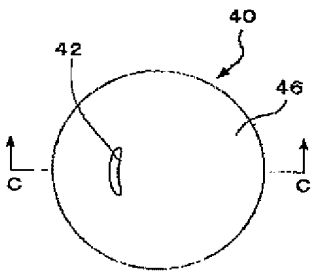
【図１】



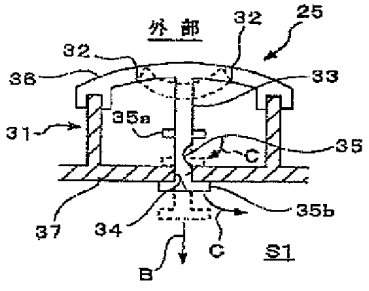
【図２】



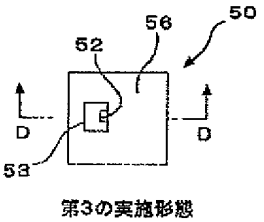
【図４】



【図３】

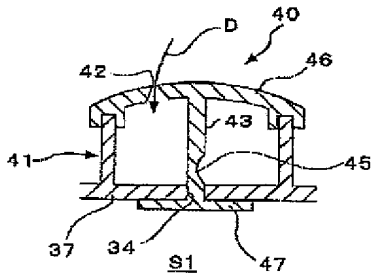


【図８】

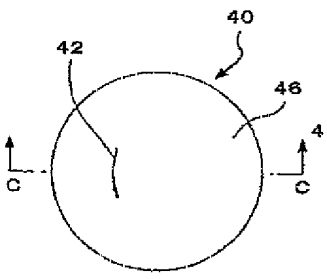


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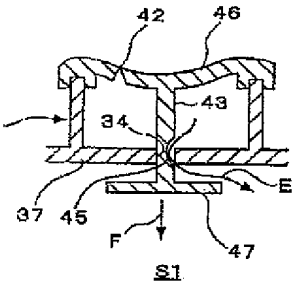
【図５】



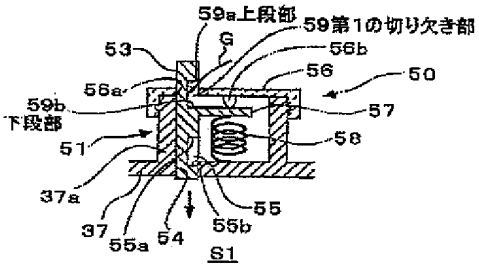
【図６】



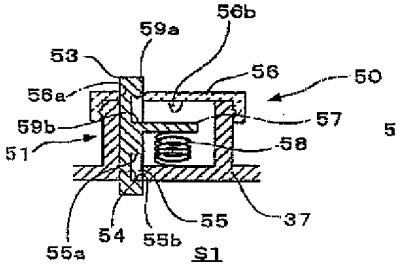
【図７】



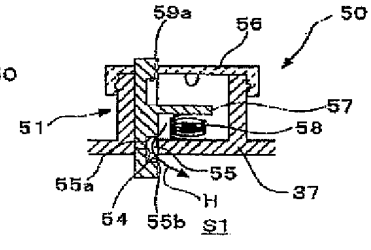
【図９】



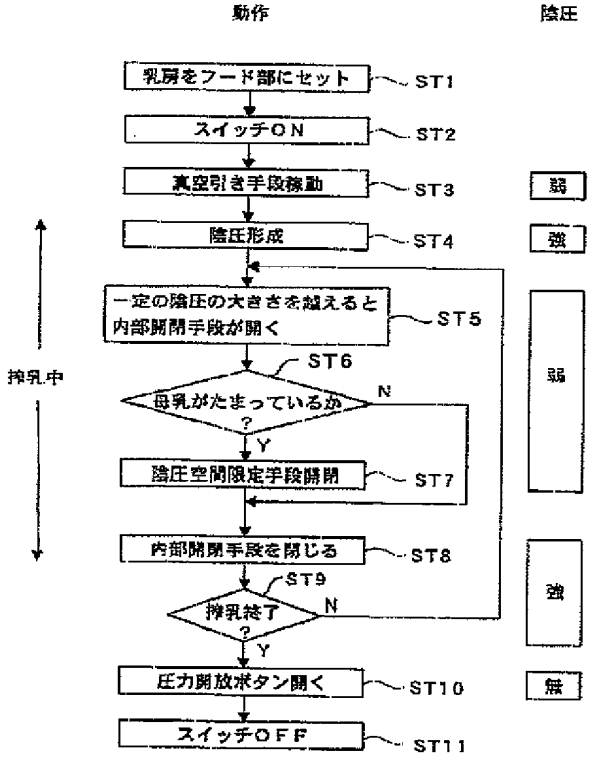
【図１０】



【図１１】

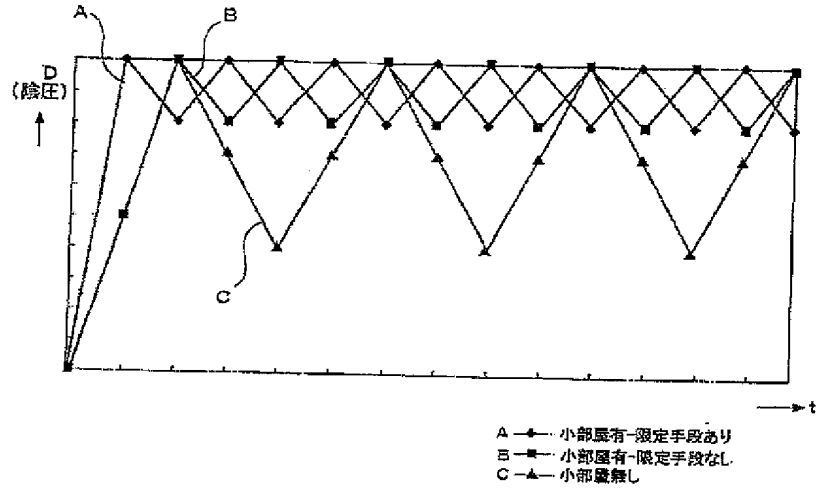


【図１２】



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【図１３】



Solventum-Exhibit 1002-0513

(19) JAPANESE PATENT OFFICE

PATENT ABSTRACTS OF JAPAN

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(71) Applicant: **PIGEON CORP**

(72) Inventor: **OMURA KENJI**
OOUSHI YOSHIYUKI

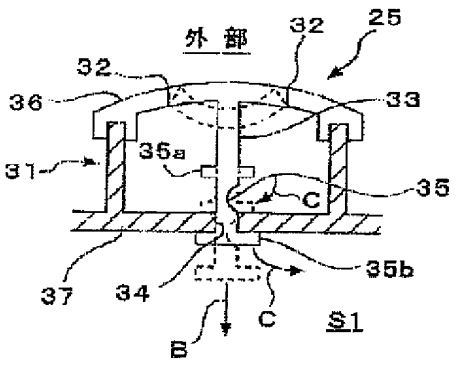
(54) PULSATIVE BREAST PUMP

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(57) Abstract:

PROBLEM TO BE SOLVED: To provide a pulsative breast pump which can realize such a pressure change that allows the pump to be used reasonably by making the pressure change in pulsation smaller

SOLUTION: This pulsative breast pump 10 provided with a negative pressure forming space in which a negative pressure is formed by means of an evacuating means in a state where the opening of a hood is closed is also provided with a small room 31 between the negative pressure forming space and an external space, a small room opening/closing means 32 which opens and closes the external space and room 31, and an internal opening/closing means which opens and closes the room 31 and negative pressure forming space. In addition, the pump 10 is also provided with a negative pressure adjusting means 25 which guides the air in the room 31 to the negative pressure forming space when the negative pressure in the space becomes a fixed value or higher after the evacuating means continuously evacuates the space



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Electronic Acknowledgement Receipt

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Application Number:	11989297
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Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Howard Kline
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Attorney Docket Number:	29068U
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Filing Date:	24-JAN-2008
Time Stamp:	09:02:32
Application Type:	U.S. National Stage under 35 USC 371

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	updated_IDS.pdf	612249 2c4f528adc5369097e0896e489f354054ffd5581	no	4

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	29068U	4766

20529 7590 04/20/2011

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
04/20/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Solventum-Exhibit 1002-0517

Office Action Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA Y. TREYGER	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 15-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14 and 34-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/2010; 01/03/2011; 02/25/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Solventum-Exhibit 1002-0518

DETAILED ACTION

1. Claims 11-14 are amended representing new limitations.

2. Claims 34-53 are new representing new limitations.

3. Claims 11-14 and 34-53 are examined on the merits.

Response to Arguments

4. Applicant's arguments with respect to claims 11-14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 11-13 and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Lockwood et al. (US 2005/0004534).

7. In Re claims 11, 12, and 35-37, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6). The tube 20 comprises a venting arrangement 19 (Abstract, lines 7-8); page 5, [0069]; fig. 1) such that ambient air can enter said tube via the venting arrangement, wherein the ambient air

necessarily enters the tube 20 via the venting arrangement and flow to the vacuum source without entering the enclosure if the negative pressure is applied, and wherein the ambient air can flow together with the exuded liquids under the action of the negative pressure.

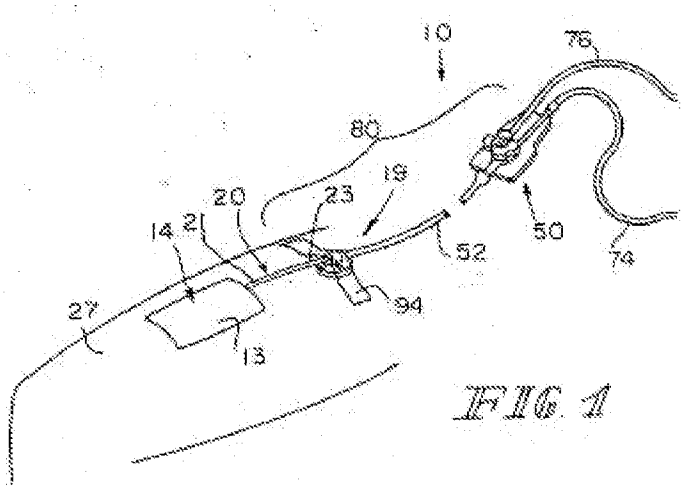


FIG. 1

8. In Re claim 13, Lockwood discloses the venting arrangement 19 (fig. 1) necessarily comprising a bleeding hole, since it has been disclosed as communicating with the surrounding atmosphere (Abstract, lines 7-8).

9. In Re claim 34, since the vent arrangement has been disclosed as being in communication with the ambient air, Lockwood discloses the vent arrangement that necessarily provides a restricted flow of ambient air therethrough and along the tube 20.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534)

Lockwood discloses the invention discussed above, but does not expressly disclose the structure, wherein the bleeding holes are provided in the form of a porous body.

Since the porous body is a material comprising plurality of holes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

13. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534) in view of Argenta et al. (US 2001/0029956).

14. In Re claim 38, Lockwood discloses the invention discussed above but does not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Lockwood with the collection vessel, as taught by Argenta in order to store the exudate, as motivated by Argenta (page 4, [0036], lines 21-22).

Lockwood in view of Argenta do not expressly disclose the apparatus wherein the waste container is connected to an outlet of the vacuum pomp unit.

Since shifting the position of the container would not have modified the operation of the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the waste container to the outlet of the pump in order to position the container remotely from the patient, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

15. In Re claims 39, 43 and 49, Lockwood discloses the assembly wherein the apparatus operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, a wherein the exuded fluid is fully capable of being stored in the waste container (Abstract, lines 1-10).

16. In Re claims 40, 44, 46 and 52, Lockwood discloses the venting arrangement necessarily comprising a bleeding hole, since it has been disclosed as communicating with the surrounding atmosphere (Abstract, lines 7-8).

17. In Re claims 41, 47 and 53, Lockwood in view of Argenta disclose the invention discussed above, as applied to claim 38, but do not expressly disclose the apparatus, wherein the bleeding holes are provided in the form of a porous body.

The rationale of obviousness rejection discussed above in claim 14 is incorporated herein in its entirety.

18. In Re claims 42 and 45, Lockwood discloses a vacuum system comprising an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6). The tube 20 comprises a venting arrangement 19 (Abstract, lines 7-8); page 5, [0069]; fig. 1) such that ambient air can enter said tube via the venting arrangement, wherein the ambient air necessarily enters the tube 20 via the venting arrangement and flow to the vacuum source without entering the enclosure if the negative pressure is applied, wherein the ambient air can flow together with the exuded liquids under the action of the negative pressure, and wherein the vacuum source is fully capable of being detached from the system.

Lockwood does not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

The rationale of obviousness rejection discussed above in claim 38 is incorporated herein in its entirety.

19. In Re claims 48, 50 and 51, Lockwood discloses a vacuum system comprising an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6). The tube 20 comprises a venting arrangement 19 (Abstract, lines 7-8); page 5, [0069]; fig. 1) such that ambient air can enter said tube via the venting arrangement, wherein the ambient air necessarily enters the tube 20 via the venting arrangement and flow to the vacuum source without entering the enclosure if the negative pressure is applied, wherein the ambient air can flow together with the exuded liquids under the action of the negative pressure, and wherein the vacuum source is fully capable of being detached from the system.

Lockwood does not expressly disclose the system wherein the vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

Argenta teaches an apparatus wherein the vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber (page 4, [0036]; fig. 1).

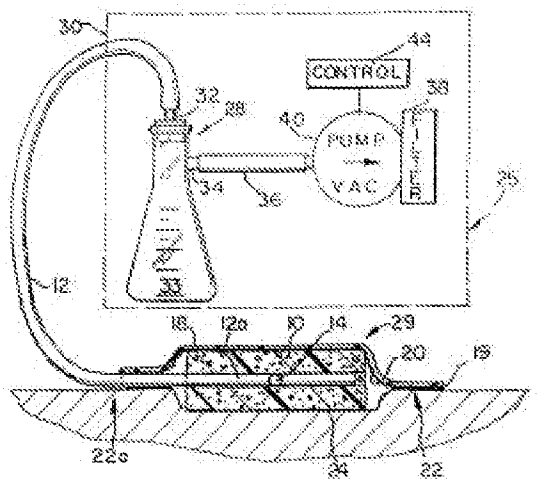


FIG. 1

The rationale of obviousness rejection discussed above in claim 14 is incorporated herein in its entirety.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Michele Kidwell/
Primary Examiner, Art Unit 3761

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BIB DATA SHEET

CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************* I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Solventum-Exhibit 1002-0527

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	54	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L2	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L3	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L4	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L5	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L6	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L7	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L8	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L9	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L10	18	L2 and L3	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L11	135	L2 and L4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L12	149	L2 and L5	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54

L13	169	L2 and L6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L14	125	L2 and L7	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L15	7	L2 and L8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L16	4	L2 and L9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L17	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L18	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L19	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L20	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" |	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54

		"4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.					

EAST Search History (Interference)

< This search history is empty>

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA Y TREYGER	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011							
	1	-	-							
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	3	-	-							
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	10	-	-							
	11	✓	✓							
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	32	-	-							
	33	-	-							
	34		✓							
	35		✓							
	36		✓							

Solventum-Exhibit 1002-0532

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA Y TREYGER	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011							
	37		✓							
	38		✓							
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	48		✓							
	49		✓							
	50		✓							
	51		✓							
	52		✓							
	53		✓							

Solventum-Exhibit 1002-0533

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA Y TREYGER	3761

SEARCHED

Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES

Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.
Search updated	4/15/2011	I. T.

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5116206	A	1992-05-26	ADAHAN	
	2	7503910	B2	2009-03-17	ADAHAN	

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	1							☐

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Solventum-Exhibit 1002-0535

Receipt date: 01/03/2011	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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Examiner Signature	/Ilya Treyger/	Date Considered	04/15/2011

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Solventum-Exhibit-1002-0536

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	Adahan
Art Unit	3761
Examiner Name	Treyger
Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2002035111	JP	A	2002-02-05	Pigeon Corp	With English Abstract	☒

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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Solventum-Exhibit 1002-0537

Receipt date: 02/25/2011	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	Adahan	
	Art Unit	3761	
	Examiner Name	Treyger	
	Attorney Docket Number	29068U	

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Examiner Signature	/Ilya Treyger/	Date Considered	04/15/2011

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Solventum Exhibit 1002-0538

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5370610	A	1994-12-06	REYNOLDS	
	2	5662599	A	1997-09-02	REICH, et al.	
	3	6471982	B1	2002-10-29	LYDON, et al.	
	4	5636643	A	1997-06-10	ARGENTA, et al.	
	5	7128735	B2	2006-10-31	WESTON	
	6	6824533	B2	2004-11-30	RISK, JR., et al.	
	7	6562013	B1	2003-05-13	MARASCO, JR.	
	8	4447226		1984-05-08	MAYORAL	

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Solventum-Exhibit-1002-0539

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	9	4611627		1986-09-16	EIDSVOOG, et al.	
	10	1599899		1926-09-14	KETTERING, et al.	
	11	6071267	A	2000-06-06	ZAMICROWSKI	
	12	0599333		1898-02-22	HULSE	
	13	3416461		1968-12-17	McFARLAND	
	14	5419687	A	1995-05-30	ADAHAN	
	15	6042560	A	2000-03-28	NIEDERBERGER	
	16	6648862	B2	2003-11-18	WATSON	
	17	4739791		1988-04-26	ADAHAN	
	18	4930997		1990-06-05	BENNETT	
	19	4661093		1987-04-28	BECK, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Solventum-Exhibit-1002-0540

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2008-01-24	
(Not for submission under 37 CFR 1.99)	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	20	5645081	A	1997-07-08	ARGENTA, et al.	
	21	5776119	A	1998-07-07	BILBO, et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050004534	A1	2005-01-06	LOCKWOOD, et al.	
	2	20040039243	A1	2004-02-26	BEARNSON, et al.	
	3	20030014022	A1	2003-01-16	LOCKWOOD, et al.	
	4	20010029956	A1	2001-10-18	ARGENTA, et al.	
	5	20040199840	A1	2004-10-07	TAKEOKA, et al.	
	6	20050192548	A1	2005-09-01	DOLLIVER, et al.	
	7	20040064132	A1	2004-04-01	BOCHRINGER, et al.	

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Solventum-Exhibit-1002-0541

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2008-01-24	
(Not for submission under 37 CFR 1.99)	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	8	20020151826	A1	2002-10-17	RAMEY, et al.	
	9	20040059284	A1	2004-03-25	NASH, et al.	
	10	20030097100	A1	2003-05-22	WATSON	
	11	20030040687	A1	2003-02-27	BOYNTON, et al.	
	12	20030050594	A1	2003-03-13	ZAMICROWSKI	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	03/030966	WO	A1	2003-04-17	HILL-ROM SERVICES, INC.		☐
	2	97/18007	WO	A1	1997-05-22	KCI MEDICAL LIMITED		☐
	3	102 15 896	DE	A1	2003-10-23	LEYBOLD VAKUUM GMBH	ABSTRACT	☒
	4	03/016719	WO	A1	2003-02-27	ADAHAN		☐

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Solventum Exhibit 1002-0542

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	5	24 01 643	DT	A1	1975-07-17	TUCHENHAGEN	ABSTRACT	☒
	6	0 156 211	EP	A2	1985-10-02	FRESENIUS AG	ABSTRACT	☒
	7	00/02016	WO	A1	2000-01-13	DEKA PRODUCTS LIMITED PARTNERSHIP		☐
	8	96/05873	WO	A1	1996-02-29	MEDISCUS PRODUCTS LIMITED		☐
	9	2 378 734	GB	A	2003-02-19	ADAHAN		☐
	10	2 307 180	GB	A	1997-05-21	KCI MEDICAL LIMITED		☐
	11	03/057070	WO	A2	2003-07-17	HILL-ROM SERVICES INC.		☐

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Solventum Exhibit 1002-0543

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

EXAMINER SIGNATURE			
Examiner Signature	/Ilya Treyger/	Date Considered	04/15/2011

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4552552		1985-11-12	POLASCHEGG, et al.	corresponds to DE 32 05 449 C2

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	32 05 445	DE	A1	1983-08-25	Fa. Wilhelm Schade	English Abstract attached separately	☒
	2	32 05 449	DE	C2	1983-09-01	Fresenius AG	corresponds to US 4,552,552	☐

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Solventum-Exhibit 1002-0545

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Solventum-Exhibit 1002-0546

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-05-04
Name/Print	Susanne M. Hopkins	Registration Number	33247

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Solventum-Exhibit 1002-0547

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Solventum-Exhibit 1002-0548

ABSTRACT

Source: DE3205445A [EN]

The invention relates to a tilt and slide cover in a vehicle roof. The tilt and slide cover comprises a cover and a frame, which is supported in lateral guides of a roof opening. The special feature of the tilt and slide cover lies in the fact that the cover is arranged relatively moveable in relation to the frame and can be locked to and released from this. The frame comprises a plastic section, into which the slide guide and other fittings such as slide cheek holders or the like can be integrated in one piece. It is also possible to fix the rear water collection channel directly on the frame.

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENTAMT

(12) **Offenlegungsschrift**

(11) **DE 3205445 A1**

(51) Int. Cl. 3: B60G 7/04

(21) Aktenzeichen: P 32 05 445.9
(22) Anmeldetag: 16. 2. 82
(43) Offenlegungstag: 25. 8. 83

DE 3205445 A1

(71) Anmelder:
Fa. Wilhelm Schade, 5970 Plettenberg, DE

(72) Erfinder:
Strunk, Harald, 5970 Plettenberg, DE

Gebührenfreiexemplar

(54) **Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel**

Die Erfindung betrifft einen Hebe-Schiebedeckel bei einem Fahrzeugdach. Der Hebe-Schiebedeckel besteht aus einer Abdeckung und einem Rahmen, der in Seitenführungen einer Dachöffnung gelagert ist. Das besondere des Hebe-Schiebedeckels besteht darin, daß die Abdeckung gegenüber dem Rahmen relativ beweglich angeordnet und mit diesem ver- und entriegelbar ist. Der Rahmen besteht aus einem Kunststoffteil, in das die Kulissenführung und sonstige Beschlagteile, wie Gleitbackenhalter o.dgl., einstückig integriert werden können. Auch ist es möglich, die hintere Wasserauffangrinne unmittelbar am Rahmen zu befestigen. (32 05 445)

DE 3205445 A1

BUNDESDRUCKEREI 07. 83 308 034/306 15/50

Solventum-Exhibit 1002-0550

Ansprüche

1. Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel, der eine Abdeckung und einen in Seitenführungen der Dachöffnung beweglich gelagerten Rahmen aufweist, dadurch gekennzeichnet, daß die Abdeckung (4) gegenüber dem Rahmen (5) relativ beweglich angeordnet und mit diesem ver- und entriegelbar ist.

2. Fahrzeugdach nach Anspruch 1, dadurch gekennzeichnet, daß die Abdeckung am Rahmen verschwenkbar angeordnet ist.

3. Fahrzeugdach nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Schwenklagergelenke (6) in dem Bereich zwischen der Unterseite (7) der Abdeckung nahe deren Vorderkante (8) und der zu der Unterseite parallelen Ebene des tiefsten dem Fahrzeuginneren (9) zugewandten Punktes des Rahmens angeordnet sind.

4. Fahrzeugdach nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Schwenklagergelenke (6) als gesonderte Teile an den Rändern der Abdeckung (4) befestigt sind.

5. Fahrzeugdach nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Schwenklagergelenke einstückig an die Abdeckung angeformt sind.

Solventum-Exhibit 1002-0551

6. Fahrzeugdach nacn den Ansprüchen 1 bis 5, dadurch gekennzeichnet, daß die Abdeckung mit einer zumindest bereichsweise deren Ränder übergreifenden Einfassung (11) versehen ist, an der die Lagergelenke (6) befestigt bzw. einstückig angeformt sind.

7. Fahrzeugdach nach Anspruch 6, dadurch gekennzeichnet, daß die Einfassung (11) einen die Ränder der Abdeckung umfassenden etwa U-förmigen Querschnitt besitzt und Versteifungsrippen (12) aufweist.

8. Fahrzeugdach nach den Ansprüchen 4 bis 6, dadurch gekennzeichnet, daß die Einfassung mit der Abdeckung verklebt ist.

9. Fahrzeugdach nach den Ansprüchen 1 bis 8, dadurch gekennzeichnet, daß der Rahmen als gespritztes, gegossenes oder gepreßtes Element ausgebildet ist und daß zu beiden Längsseiten des Rahmens je eine die Hebe- und Verschiebebewegung ermöglichende Kulissenführung (15) und / oder sonstige Beschlagteile, wie Gleitbackenhalter (16) o. dgl., einstückig an den Rahmen angeformt ist.

10. Fahrzeugdach nach dem Anspruch 9, dadurch gekenn-

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zeichnet, daß der Rahmen durch nach dessen Montage in der Dachöffnung in Kulissenführungen (15,25) einsetzbare Bolzen (17) an einem am Fahrzeugdach (3) verschiebbar in Seitenführungen (20) gelagerten Gleitstück (18) befestigbar ist und daß die Kulissenführungen (15,25) und das Gleitstück im Querschnitt gesehen parallel nebeneinander angeordnet sind.

11. Fahrzeugdach nach den Ansprüchen 1 bis 10, dadurch gekennzeichnet, daß dem Hebe-Schiebedeckel (4,5) an seinem im Bereich der Dachöffnungs-Hinterkante gelegenen Ende eine sich quer zur Fahrzeuglängsachse erstreckende Wasserauffangrinne (31) zugeordnet ist und daß die Wasserauffangrinne im Bereich dessen hinteren Endes am Rahmen (4) befestigt ist.

12. Fahrzeugdach nach Anspruch 11, dadurch gekennzeichnet, daß die Wasserauffangrinne an den Rahmen angeschraubt, angeklebt und angeschweißt ist.

13. Fahrzeugdach nach Anspruch 11, dadurch gekennzeichnet, daß die Wasserauffangrinne und der Rahmen als einstückige Einheit hergestellt sind.

14. Fahrzeugdach nach den Ansprüchen 1 bis 13, dadurch

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gekennzeichnet, daß der Rahmen (5) eine umlaufende Spaltdichtung (13) aufweist, auf der die Ränder der Abdeckung in der Schließstellung des Hebe-Schiebedeckels derart aufliegen, daß einerseits die Abdeckung gegenüber dem Rahmen und andererseits die Deckeleinheit (4,5) gegenüber dem Dachausschnitt abgedichtet ist.

15. Fahrzeugdach nach den Ansprüchen 1 bis 14, dadurch gekennzeichnet, daß an den beiden Längsseiten der Abdeckung (4) je eine die Hebe- und Verschiebebewegung der Abdeckung ermöglichende Kulissenführung (25) angeordnet ist, die in der Zusammenbaustellung des Hebe-Schiebedeckels eine Stellung zwischen den einander zugewandten Gleitflächen (30) der Kulissenführung (15) für den Rahmen (5) und der Gleitfläche (28) des Gleitstücks (18) einnimmt.

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Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel.

Die Erfindung bezieht sich auf ein Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel, der eine Abdeckung und einen in Seitenführungen der Dachöffnung beweglich gelagerten Rahmen aufweist.

Bei einem aus der Praxis bekannten Hebe-Schiebedeckel dieser Art ist die als transparente Scheibe ausgebildete Abdeckung mit dem die Scheibe tragenden Rahmen an ihren Rändern verklebt, so daß Abdeckung und Rahmen eine untereinander fest verbundene Einheit bilden. In seinem in Fahrtrichtung vorderen Bereich ist der Rahmen an seinen beiden Längsseiten durch einen an der Rahmenunterseite befestigten Hebel abgestützt, dessen der Rahmenunterseite abgewandtes Ende in einem Gleitschuh verschwenkbar gelagert ist. Der Gleitschuh dient einerseits als Lagerstelle für die Deckeleinheit zum Ausstellen aus ihrer Geschlossenstellung in die Hebestellung und zum anderen als Gleitführung beim Verschieben der Deckeleinheit. Außerdem ist der Hebe-Schiebedeckel über Gleit-

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bolzen in Kulissenführungen gelagert, die als von dem Deckel getrennte Einzelteile an seitlichen Führungsschienen angeschraubt sind. Die Führungsschienen sind im Bereich der Dachöffnung an der Karosserie befestigt. Bei der Montage werden zunächst die Kulissenführungen mit mehreren Schrauben an die seitlichen Führungsschienen angeschraubt und die Gleitbolzen in den Kulissenführungen vormontiert, bevor die Deckeleinheit in die Dachöffnung eingesetzt und an den Beschlagteilen befestigt wird.

Im Bereich der in Fahrtrichtung hinteren Dacheinschnittkante ist bei der bekannten Ausführung zusätzlich eine sich quer zur Dachöffnung erstreckende, verfahrbare Wasserauffangrinne vorgesehen, die in der Geschlossenstellung des Hebe-Schiebedeckels auf der Fahrzeuginnenseite den Dichtungsspalt zwischen der Hinterkante des Deckels und der dieser gegenüberliegenden Anschlagkante der Dachöffnung überbrückt. Wird der Deckel in die hintere Schiebestellung geschoben, nimmt er über besondere Mitnehmerteile die Wasserauffangrinne während seiner gesamten Öffnungsbewegung unterhalb der Dachhaut mit, so daß Wasser oder Feuchtigkeitsrückstände in jeder beliebigen Stellung vom Deckel über dessen Hinterkante in die Auffangrinne gelangen. Entsprechendes gilt für die entgegengesetzte Deckelbewegung beim Zurückfahren aus der Öffnungsstellung

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in die Geschlossenstellung.

Bei dieser bekannten Hebe-Schiebedach-Konstruktion ist es nachteilig, daß der den Schwenkpunkt für den Deckel enthaltende Gleitschuh einen relativ großen Abstand sowohl von der Längsmittelebene des Hebe-Schiebedeckels als auch von der Vorderkante der Dachöffnung haben muß, um einen genügend großen Bewegungsspielraum für den Deckel zuzulassen. Dies führt dazu, daß der Querspalt zwischen der Deckel-Vorderkante und der Vorderkante der Dachöffnung unverhältnismäßig breit sein muß und dadurch die den Querspalt abdeckende Dichtungsleiste durch die relativ weit ausladende Kippbewegung überbeanprucht wird. Dadurch besteht die Gefahr einer frühzeitigen Materialermüdung, die die Bildung von Leckstellen nach sich zieht. Außerdem unterstützt der breite Dichtungsspalt die Erhöhung von Windgeräuschen. Ein weiterer wichtiger Nachteil besteht bei der bekannten Ausführung darin, daß beim Ausstellen des Deckels in die Hebestellung die die Deckelränder umlaufend eng umfassenden Dichtungsleisten an den Rändern des Dachausschnittes entlangschleifen und diese nach außen, oder beim Schließen des Deckels nach innen zu drücken suchen. Durch diese ständig wechselnden Kräfteeinwirkungen ist es in der Praxis unvermeidbar, daß sich das relativ dünne, instabile Karosserieblech der Dachhaut besonders im Be-

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reich der Hinterkante leicht ausbeult und über längere Zeit sogar bleibend verformt.

Dadurch, daß die bekannte Hebe-Schiebedach-Konstruktion aus zahlreichen Einzelteilen besteht, wie gesonderten Kulissenführungen, vorzumontierenden Gleitbolzen, Befestigungsschrauben zum Anschrauben der Kulissenführungen an Seiten-Führungsschienen, eine getrennte verschiebbare Wasserauffangrinne u.s.w., stellt sich die Montage sehr zeitaufwendig und kostspielig. Zudem kann die Montage nur von ausgebildeten Fachkräften vorgenommen werden.

Aufgabe der Erfindung ist es, unter Vermeidung der genannten Nachteile ein baulich einfaches und funktionssicheres Hebe-Schiebedach der eingangs genannten Art, vorzuschlagen, das außerdem eine wesentliche Montageerleichterung ermöglicht.

Dies wird nach der Erfindung dadurch erreicht, daß die Abdeckung gegenüber dem Rahmen relativ beweglich angeordnet und mit diesem ver- und entriegelbar ist. Durch die erfindungsgemäße Trennung der Abdeckung von dem Rahmen ist es möglich, die Dichtungsspalte zwischen dem Hebe-Schiebedeckel und den Rändern des Dachausschnittes sehr eng zu halten, so daß neben einer Verringerung der

Solventum-Exhibit 1002-0558

Windgeräusche eine durchlaufend gute Abdichtung der Spalte erreicht wird. Dadurch, daß nicht der gesamte Rahmen nach oben aus der Dachöffnung ausgehoben zu werden braucht - die Hebefunktion wird bei dem Erfindungsgegenstand allein von der Abdeckung übernommen - tritt eine Überbelastung und damit eine unerwünschte Ausbeulung der Karosserieränder nicht auf. Vielmehr wird die Dachhaut im Bereich der Ränder des Dachausschnittes umlaufend gleichmäßig stabilisiert. Durch den Vorschlag nach der Erfindung wurden außerdem die Voraussetzungen dafür geschaffen, daß die Zahl der einzelnen Beschlagteile sehr gering gehalten werden kann und damit eine wesentliche Montageerleichterung erzielt wird. Zudem ist es nun erstmalig auch bei Hebe-Schiebedeckeln möglich, die Wasserauffangrinne an dem Rahmen starr zu befestigen, so daß jegliche bisher notwendige Beschlagteile zur Sicherung des Bewegungsablaufes der Auffangrinne entfallen können.

Zweckmäßig ist die Abdeckung am Rahmen schwenkbar angeordnet. Vorzugsweise sind die Schwenklagergelenke in dem Bereich zwischen der Unterseite der Abdeckung nahe deren Vorderkante und der zu der Unterseite parallelen Ebene des tiefsten dem Fahrzeuginneren zugewandten Umrißpunktes des Rahmens angeordnet. Auf einen besonderen Abstand der Lagerachsen von der Dachfläche oder von der Vorderkante

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der Dachöffnung braucht keine Rücksicht genommen zu werden, so daß die Gefahr einer Überbeanspruchung der Dichtungsleisten beim Ausstellen der Abdeckung nicht besteht. Die Schwenklagergelenke können nach der Erfindung dabei als gesonderte Teile an den Kändern der Abdeckung befestigt sein. Alternativ dazu können sie auch einstückig an die Abdeckung angeformt sein.

In vorteilhafter Weiterentwicklung des Erfindungsgegenstandes ist die Abdeckung mit einer zumindest bereichsweise deren Ränder übergreifenden Einfassung versehen, an der die Lagergelenke befestigt bzw. einstückig angeformt sind. Vorzugsweise besitzt die Einfassung einen die Ränder der Abdeckung umfassenden etwa U-förmigen Querschnitt und weist Versteifungsrippen auf. Vorteilhaft ist die Einfassung mit der Abdeckung verklebt.

In weiterer bevorzugter Ausgestaltung des Erfindungsgegenstandes ist der Rahmen als gespritztes, gegossenes oder gepreßtes Element ausgebildet, wobei die die Hebe- und Verschiebebewegung ermöglichende Kulissenführung und/oder sonstige Beschlagteile, wie Gleitbackenhalter o.dgl. einstückig an den Rahmen angeformt sind. Da nach diesem Vorschlag die Kulissenführungen und dgl. als Einzelteile fortfallen, weil sie bei dem Erfindungsgegenstand aufgrund der vernachlässigbaren Toleranzprobleme durch die Trennung der Abdeckung von den Rahmen unmittelbar in den Rah-

Solventum-Exhibit 1002-0560

men integriert werden können, sind durch die Erfindung nunmehr die Voraussetzungen gegeben, den Hebe-Schiebedeckel mit wenigen Handgriffen auch von ungelernten Kräften in die Dachöffnung einzusetzen und dort zu lagern. Zweckmäßig ist dazu der Rahmen durch vorzugsweise zwei, nach dessen Montage in der Dachöffnung, in die Kulissenführung einsetzbare Bolzen an einem am Fahrzeugdach verschiebbar in Seitenführungen gelagerten Gleitstück befestigbar, wobei die Bolzen gleichzeitig als Kulissenbolzen dienen. Auf diese Weise ist es möglich, daß der gesamte Hebe-Schiebedeckel allein von den Kulissenbolzen getragen wird.

In Weiterentwicklung der Erfindung ist dem Hebe-Schiebedeckel an seinem im Bereich der Dachöffnungs-Hinterkante gelegenen Ende eine sich quer zur Fahrzeuglängsachse erstreckende Wasserauffangrinne zugeordnet, die im Bereich des hinteren Endes des Rahmens befestigt ist. Die Wasserauffangrinne kann an den Rahmen angeschraubt, angeklebt, angeschweißt oder sonstwie befestigt werden. Alternativ dazu kann sie in bevorzugter Weise auch mit dem Rahmen als einstückige Einheit hergestellt sein. Die Entscheidung, ob eine mit dem Rahmen einstückige oder getrennte Ausführung der Wasserauffangrinne gewählt wird, ist in der Praxis jeweils davon abhängig, aus welchem Material der Rahmen und die Rinne hergestellt werden.

Solventum-Exhibit 1002-0561

Die Erfindung ist nachstehend anhand mehrerer in der Zeichnung dargestellter Ausführungsbeispiele näher beschrieben.

In der Zeichnung zeigen:

Fig. 1: eine teilweise geschnittene Draufsicht auf den in einen Dachausschnitt eingebauten Hebe-Schiebedeckel,

Fig. 2: einen Schnitt nach der Linie II-II in Figur 1,

Fig. 3: einen Schnitt entsprechend Figur 2, jedoch mit ausgestellter Abdeckung,

Fig. 4: einen Schnitt nach der Linie IV-IV in Figur 1 mit einem an eine Einfassung der Abdeckung angeformten Schwenklagergelenk,

Fig. 4a: einen Schnitt entsprechend Figur 4, jedoch mit einem unmittelbar an die Abdeckung angeformten Schwenklagergelenk,

Fig. 4b: einen Schnitt entsprechend Figur 4, bei dem das Schwenklagergelenk als gesondertes Beschlagteil an der Einfassung befestigt ist,

Fig. 5: einen Schnitt entsprechend Fig. 4 mit ausgestellter Abdeckung,

Fig. 6: einen Schnitt nach der Linie VI-VI in Fig. 1,

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Fig. 7: einen Schnitt entsprechend Fig. 6, mit teilweise nach hinten eingeschobenem Hebe-Schiebedeckel,

Fig. 8: einen Schnitt nach der Linie VIII-VIII in Fig. 1,

Fig. 9: einen Schnitt nach der Linie IX-IX in Fig. 1, mit geschlossenem Hebe-Schiebedeckel,

Fig. 10: einen Schnitt entsprechend Fig. 9 mit ausgestellter Abdeckung,

Fig. 11: einen Schnitt nach der Linie XI-XI in Fig. 1,

Fig. 12,12a, 12b: eine vereinfachte Schnittansicht nach der Linie XII-XII in Fig. 1, jeweils in verschiedenen Öffnungsstellungen des Hebe-Schiebedeckels.

Der Hebe-Schiebedeckel 1 ist in einem Dachausschnitt 2 eines Kraftfahrzeugdaches 3 montiert. Er weist eine Abdeckung 4 und einen Rahmen 5 auf. Die Abdeckung besteht vorzugsweise aus einer transparenten Scheibe, kann aber auch als eine undurchsichtige Metall- oder Kunststofftafel ausgebildet sein. Sie ist gegenüber dem Rahmen relativ beweglich angeordnet und mit diesem ver- und entriegelbar. Bei dem gewählten Beispiel ist die Abdeckung am Rahmen verschwenkbar angelenkt. Dazu besitzt sie Schwenk-

Solventum-Exhibit 1002-0563

lagergelenke 6, die im Bereich zwischen der Unterseite 7 der Abdeckung nahe deren Vorderkante 8 und der zu der Unterseite parallelen Ebene des tiefsten dem Fahrzeuginnern 9 zugewandten Punktes des Rahmens 5 angeordnet ist. Da bei dem gezeigten Ausführungsbeispiel der tiefste Punkt der Rahmenquerholme von deren ebener Unterseite gebildet ist, liegen die Schwenklagergelenke 6 in dem Abstandsraum zwischen der Ebene der Holmunterseite 5' und der dazu parallelen Unterseite 7 der Abdeckung 4. Die Schwenklagergelenke 6 können als gesonderte Teile 10 (Fig. 4b) an dem Rand der Abdeckung befestigt, z. B. angeschraubt oder angeklebt sein. Auch können sie einstückig (Fig. 4a) an den Rand der Abdeckung angeformt werden. Alternativ dazu ist auch eine getrennte Befestigung oder einstückige Anformung an einer Einfassung 11 möglich, wie aus Figur 4 ersichtlich.

Die Einfassung 11 übergreift die Ränder der Abdeckung 4 und besteht aus einem um die Abdeckung durchgehend umlaufenden, profilierten Blechstreifen. Die Einfassung 11 besitzt einen die Ränder ober- und unterseitig umfassenden U-förmigen Querschnitt, der durch Versteifungsrippen 12 (Fig. 4) verstärkt ist. Sie ist mit dem Rand der Abdeckung verklebt und kann z.B. aus einem Metall- oder einem Kunststoffteil bestehen. Statt der umlaufenden Ausführung ist es auch möglich, im Abstand voneinander auf

Solventum-Exhibit 1002-0564

die Ränder der Abdeckung aufgesetzte Teilstücke zu verwenden. Das entsprechende, über je einen auf beiden Seiten des Deckels vorgesehenen Lagerbolzen 6' verbundene Gegenstück für die an der Abdeckung befestigten Lagergelenke befindet sich jeweils am Rahmen selbst, der zusätzlich noch besonders profilierte Dichtungsleisten 13 trägt, die auf Vorsprünge 13' der Rahmenholme 4 aufgesteckt sind und die den Spalt 14 zwischen den Rändern des Dachausschnittes 2 und den diesen zugewandten Rändern der Abdeckung 4 und des Rahmens 5 umlaufend abdichten.

Dadurch, daß der Rahmen als von der Abdeckung getrenntes Teil ausgebildet ist und damit die bei den bisher bekannten Hebe-Schiebedeckeln auftretenden Toleranzprobleme nicht mehr gegeben sind, ist es bei dem dargestellten Ausführungsbeispiel möglich, den Rahmen 5 als einstückig gespritztes, gegossenes oder gepreßtes Kunststoffteil auszubilden und die Kulissenführungen 15 (Fig. 9,10) beidseits des Rahmens in den Rahmen einzuformen, so daß Rahmen und Kulissenführungen eine einstückige Einheit bilden. In gleicher Weise sind die Gleitbackenhalter 16 (Fig. 11) an den Rahmen unmittelbar angeformt. Die Aufhängung des kompletten Hebe-Schiebedeckels in der Dachöffnung erfolgt über zwei Bolzen 17, die beidseits des Rahmens jeweils durch eine in zugeordneten Gleitstücken 18 vorgesehene Bohrung 19 gesteckt werden.

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Die Gleitstücke 18 sind über in Seitenführungen 20 des Daches eingreifende Gleitfüße 21,22 parallel zur Ebene des Dachausschnittes verschiebbar gelagert. Die Bohrungen 19 in dem Gleitstück 18 decken sich mit länglichen Führungsausnehmungen 23,24, von denen die Führungsausnehmungen 23 in den in den Rahmen integrierten, jeweils zugeordneten Kulissenführungen 15 und die Ausnehmungen 24 in Kulissenführungen 25 vorgesehen sind, die mit der Einfassung 11 an der Unterseite 7 der Abdeckung 4 mittels Schrauben 26 starr verbunden sind. Die Kulissenführungen 25 sind im Querschnitt gesehen jeweils zwischen den Kulissenführungen 15 des Rahmens und den Gleitstücken 18 so angeordnet, daß die Seitenflächen 27 der Kulisse 25 die ihnen jeweils zugewandte Seitenfläche 28 des Gleitstückes 18 und die Seitenfläche 29 der Kulisse 25 die Seitenfläche 30 der Kulissenführung 15 des Rahmens mit Gleitsitz berührt. Wie ersichtlich, wird der gesamte Hebe-Schiebedeckel von den Bolzen 17 getragen, über die der Kraftfluß von den Kulissenführungen 15, 25 auf die Gleitstücke 18 übertragen wird.

Wie in den Figuren 6 und 7 verdeutlicht, ist an der Unterseite des hinteren Rahmenholmes eine sich quer zur Fahrzeug-Längsachse erstreckende Wasserauffangrinne 31 befestigt, z.B. angeschraubt, angeklebt oder angeschweißt.

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Ist der Rahmen als ein Kunststoffteil ausgebildet, bietet sich ebenfalls die Herstellung der Wasserauffangrinne als einstückige Einheit mit dem Rahmen an.

Wie aus Figur 12a ersichtlich, in der der Hebe-Schiebedeckel die Schließstellung entsprechend der Darstellung in Figur 9 einnimmt, befindet sich der Bolzen 17 in einer mittleren Anschlagstellung, in der er mit seinem die Ausnehmungen 23, 24 der Kulissenführungen 15,25 durchgreifenden Schaftende an Übergängen 32,33 der Ausnehmungen 23,24 anliegt. Bei der über einen nicht dargestellten Getriebemechanismus auf das Gleitstück 18 ausgeübten Bewegung in Pfeilrichtung 34 bleiben die Kulissenführungen 15,25 solange in Ruhestellung, bis die Bolzen den Übergang 35 der im wesentlichen horizontal verlaufenden Teilstrecke 36 der Ausnehmung 24 erreicht haben, weil sich auf dem Weg zwischen den Übergängen 32,35 der Verlauf der Teilstrecke 36 mit einer entsprechenden Teilstrecke 37 der Ausnehmung 23 in der Kulissenführung 15 des Rahmens 4 deckt. Überschreitet der Bolzen während der Bewegung des Gleitstücks 18 in Pfeilrichtung 34 den Übergang 35 der Ausnehmung 24, so bewirkt er zwangsläufig eine Auslenkbewegung der die Abdeckung 4 tragenden Kulissenführung 25 nach oben (Pfeil 38), weil die an den Übergang 35 anschließende Teilstrecke 39 der

Solventum-Exhibit 1002-0567

Ausnehmung 24 aus der horizontalen Ebene bis zum äußeren Auslaufende 40 schräg nach unten abgewinkelt ist, während die Teilstrecke 37 der Ausnehmung 23 der Kulissenführung 15 bis zu ihrem Auslaufende 41 hin geradlinig weiterverläuft. Gleichzeitig mit der Auslenkung wird die Abdeckung um die Achsen 6' der Lager 6 verschwenkt. In Figur 12 b ist die Öffnungsstellung der Abdeckung 4 dargestellt, die der Öffnungsstellung in Figur 10 entspricht, aus der deutlich wird, daß sich die Kulissenführung 25 gegenüber der in ihrer Grundstellung (Fig.9) unverändert gebliebenen Kulissenführung 15 in Pfeilrichtung 38 nach oben verlagert hat.

Bei einer dem Pfeil 34 entgegengesetzten Bewegung des Gleitwagens 18 überführen die Bolzen 17 im umgekehrten Bewegungsablauf die Abdeckung 4 zunächst in die Schließstellung (Fig. 9 und 12a). Nach Überschreiten der Übergänge 32,33 der Ausnehmungen 24,23 durch die Bolzen 17 werden sowohl die Kulissenführungen 25 der Abdeckung 4 als auch die Kulissenführungen 15 des Rahmens 5 gleichzeitig entgegen dem Pfeil 38 nach unten verlagert, weil die sich an die Übergänge 32,33 anschließenden Teilstrecken 43 bzw. 44 der Ausnehmungen 24 bzw. 23 aus der Horizontalen schräg nach oben abgewinkelt sind und sich bis zu den Auslaufenden 45,46 hin decken. Hierdurch wird der Rahmen 5 zusammen mit der Abdeckung 4 zwangsläufig in eine Stellung unterhalb der Dachhaut, wie in Figur 7 angedeutet, verlagert, in der der Hebe-Schiebedeckel bei seiner weiteren

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Bewegung nach hinten in eine nicht dargestellte Öffnungsstellung ausgefahren werden kann.

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Leerseite

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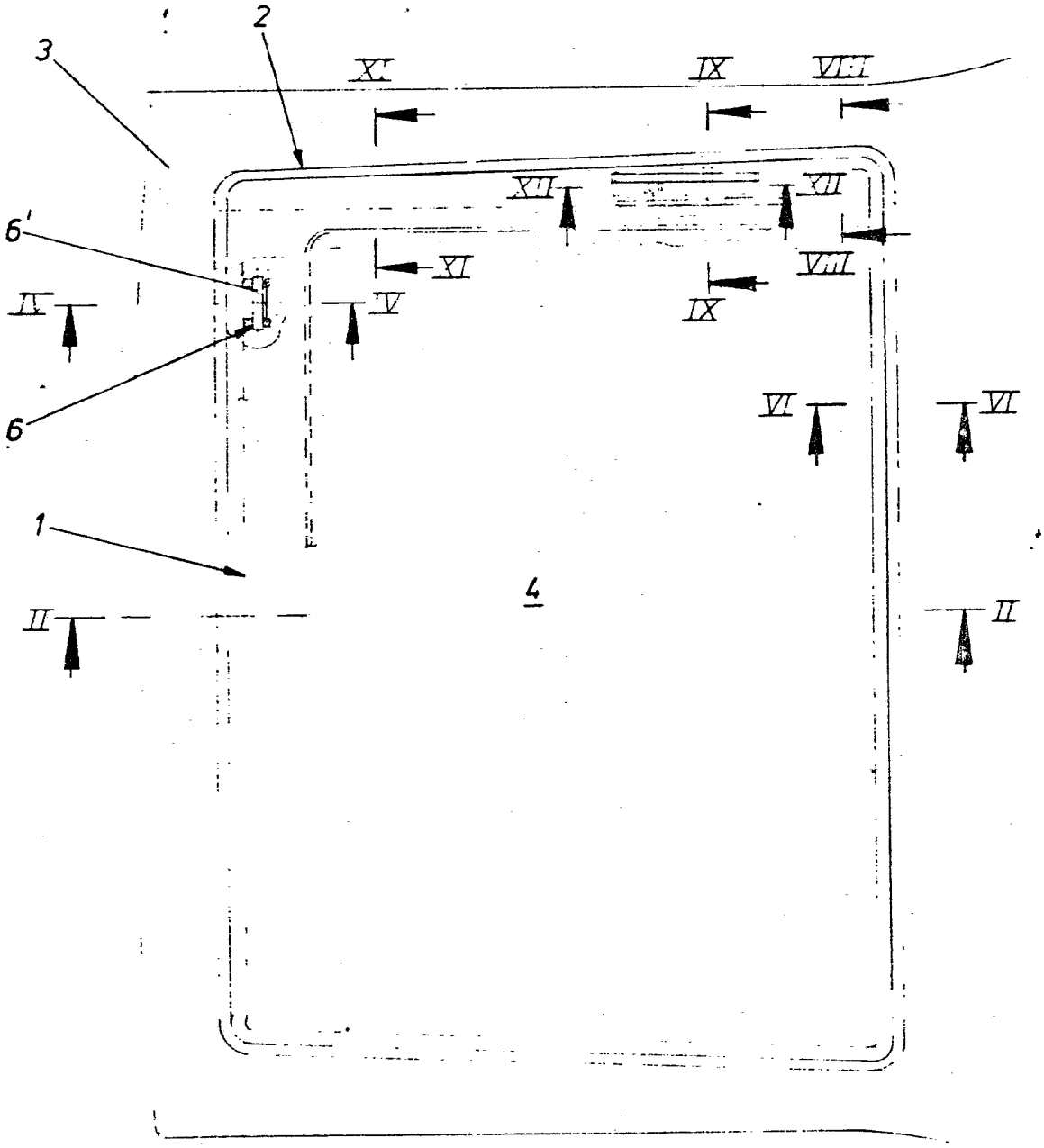


Fig. 1

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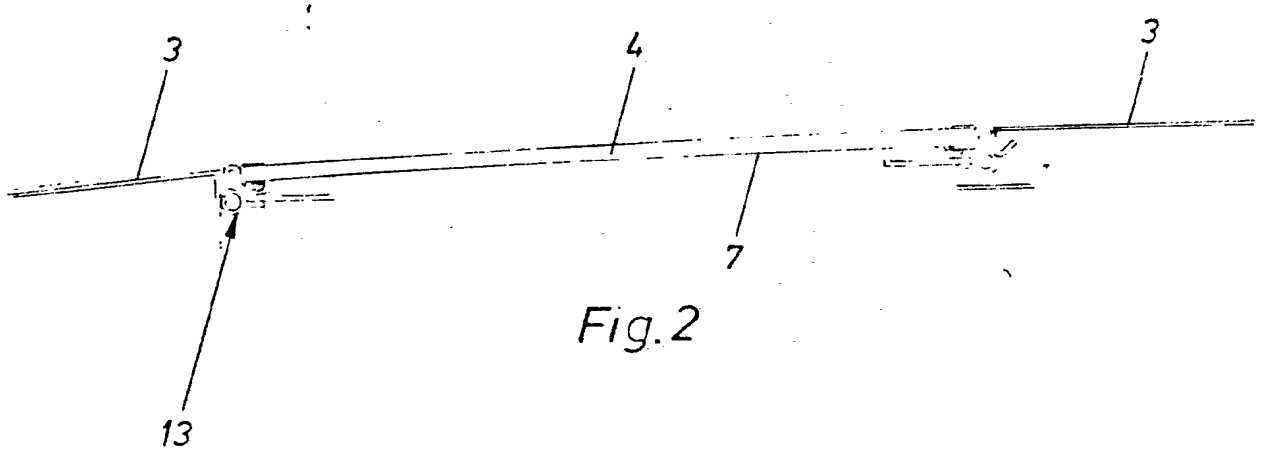


Fig. 2

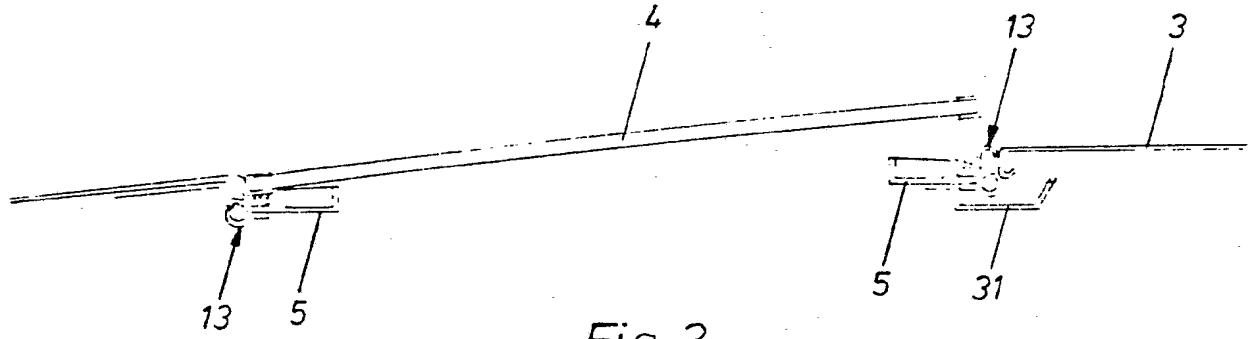
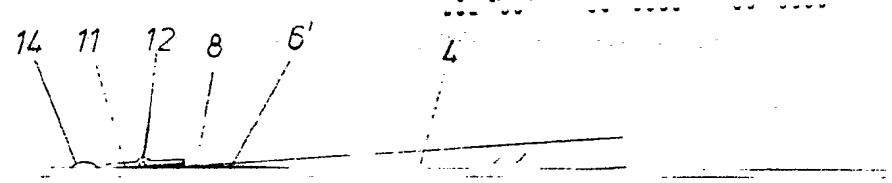


Fig. 3



Durchschreibung ausgefahren werden kann.

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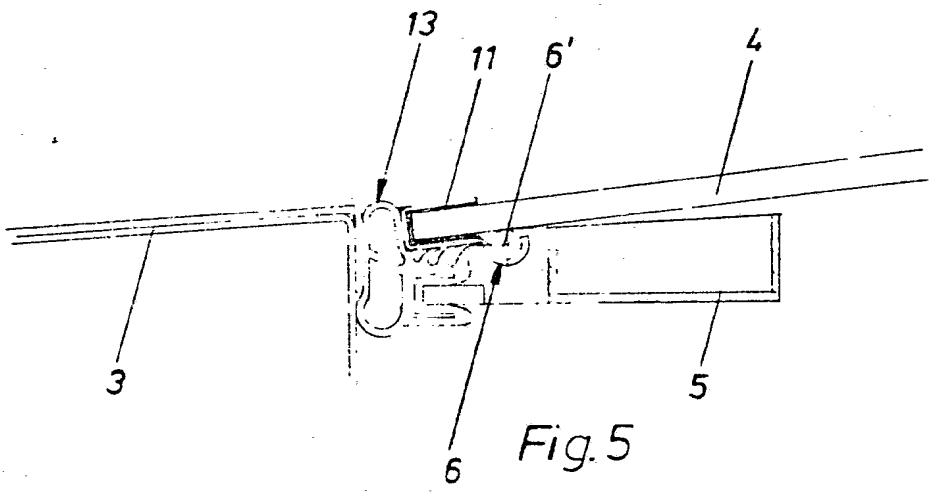


Fig. 5

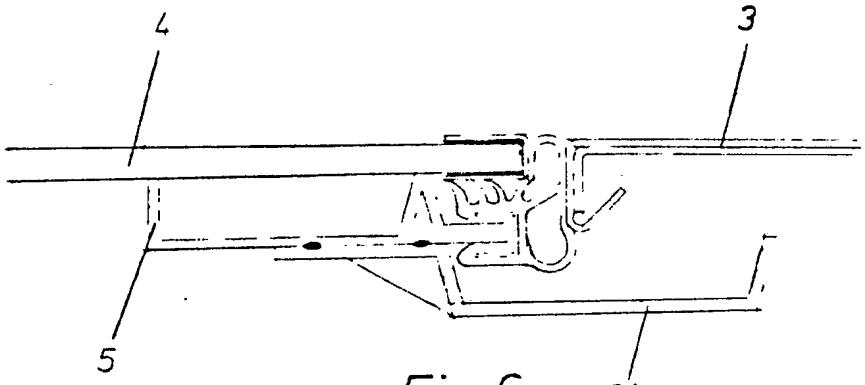


Fig. 6

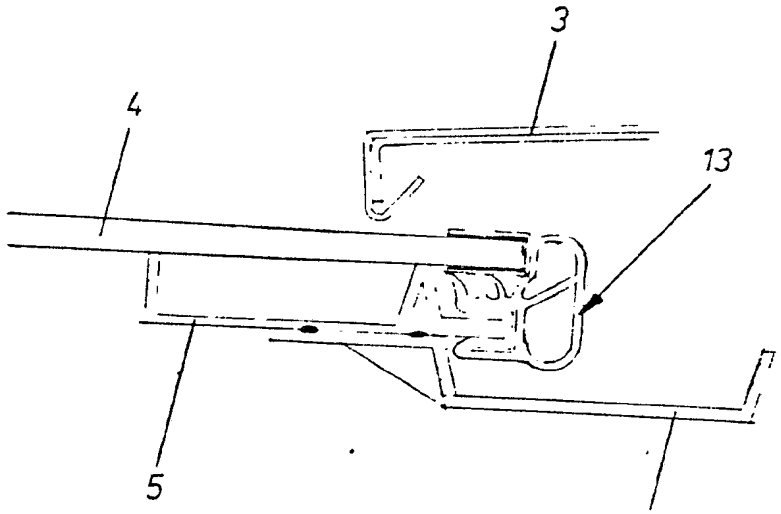


Fig. 7

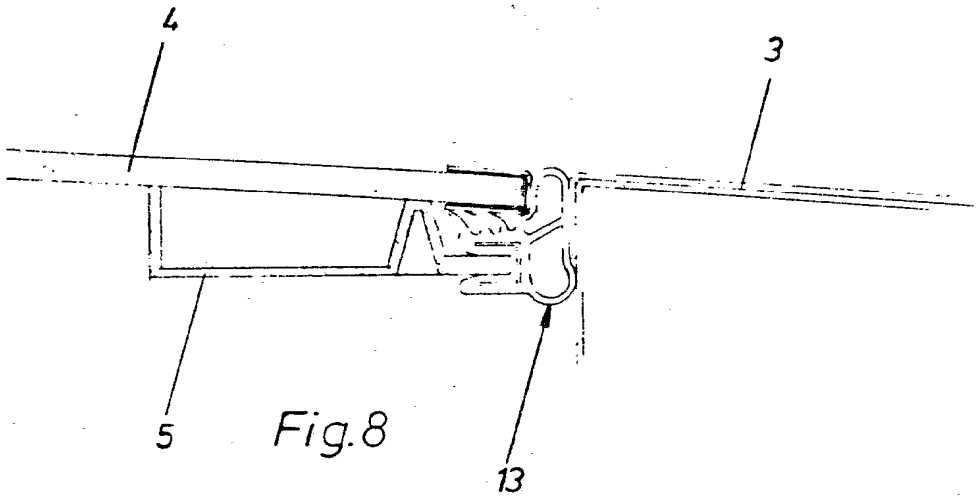


Fig.8

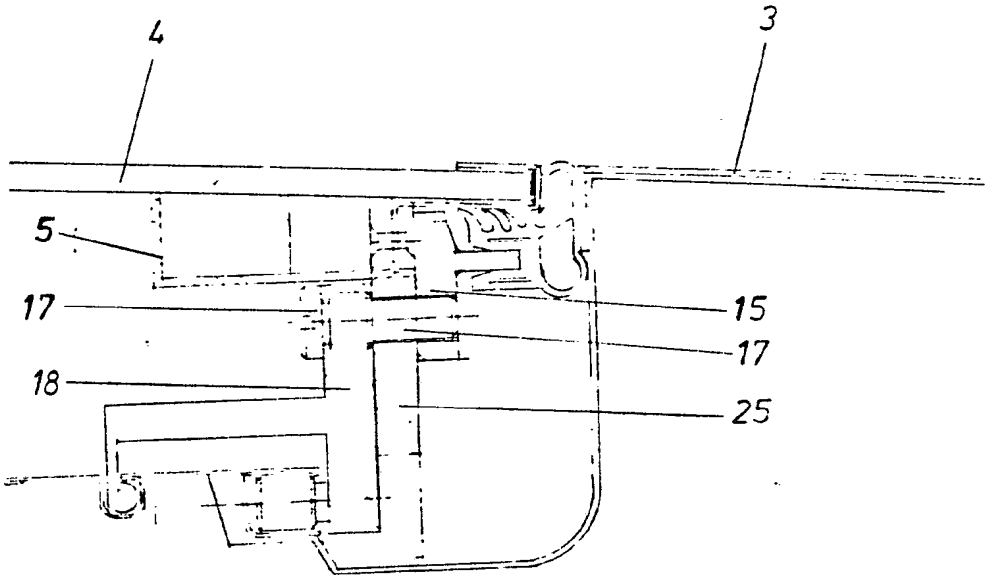


Fig. 9

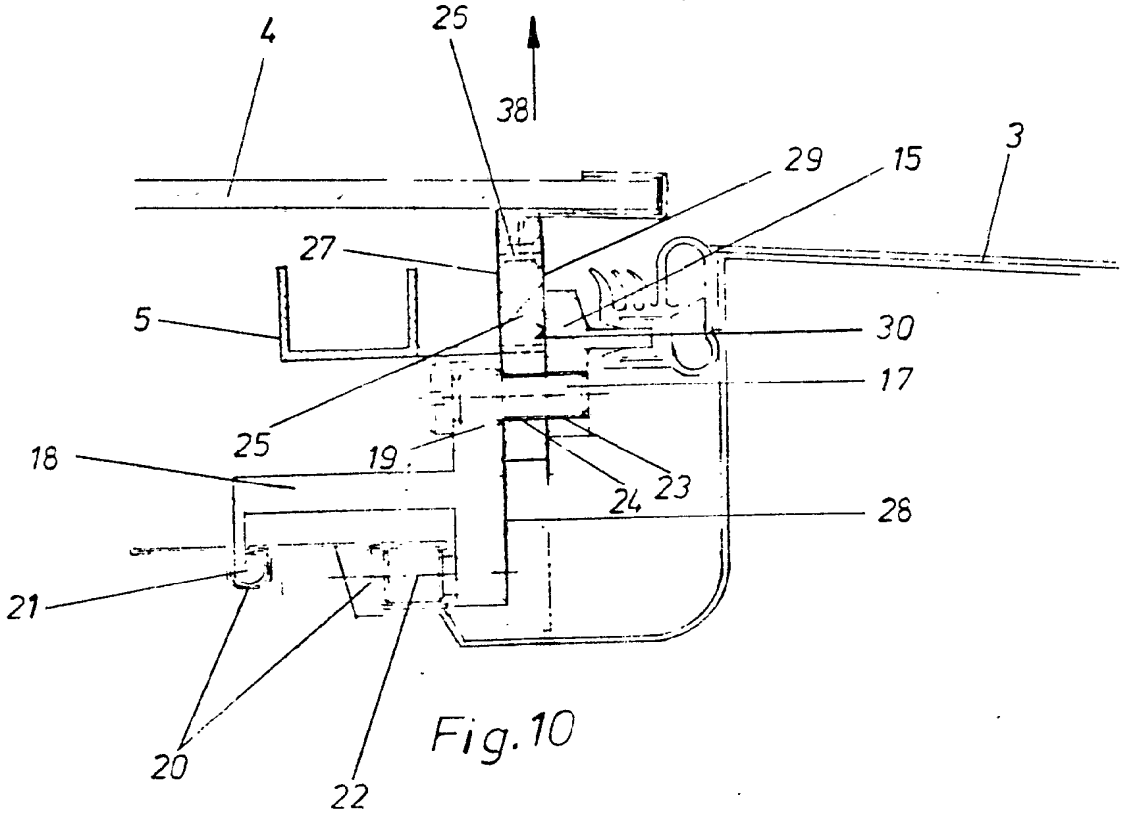


Fig. 10

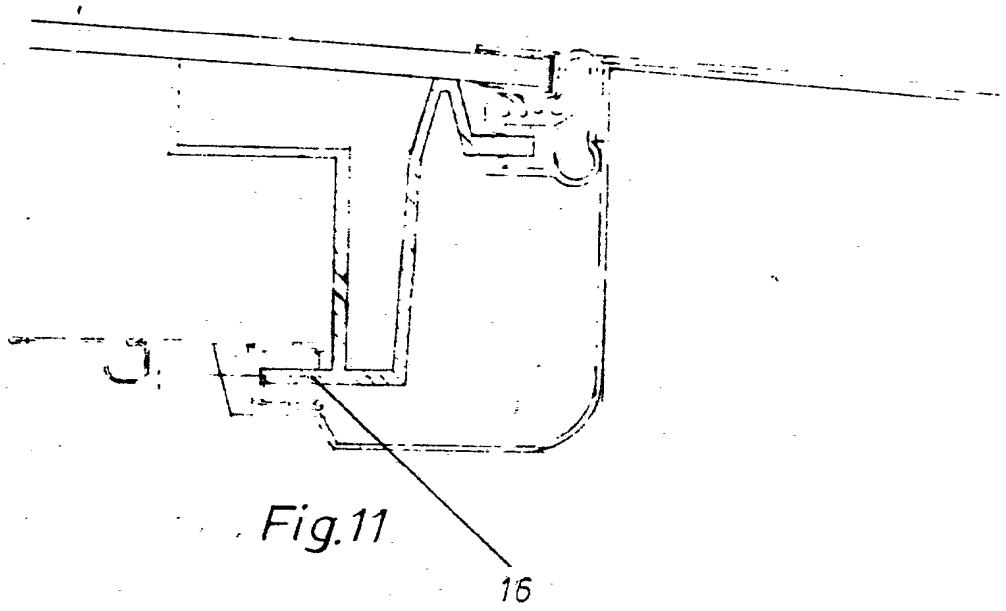


Fig.11

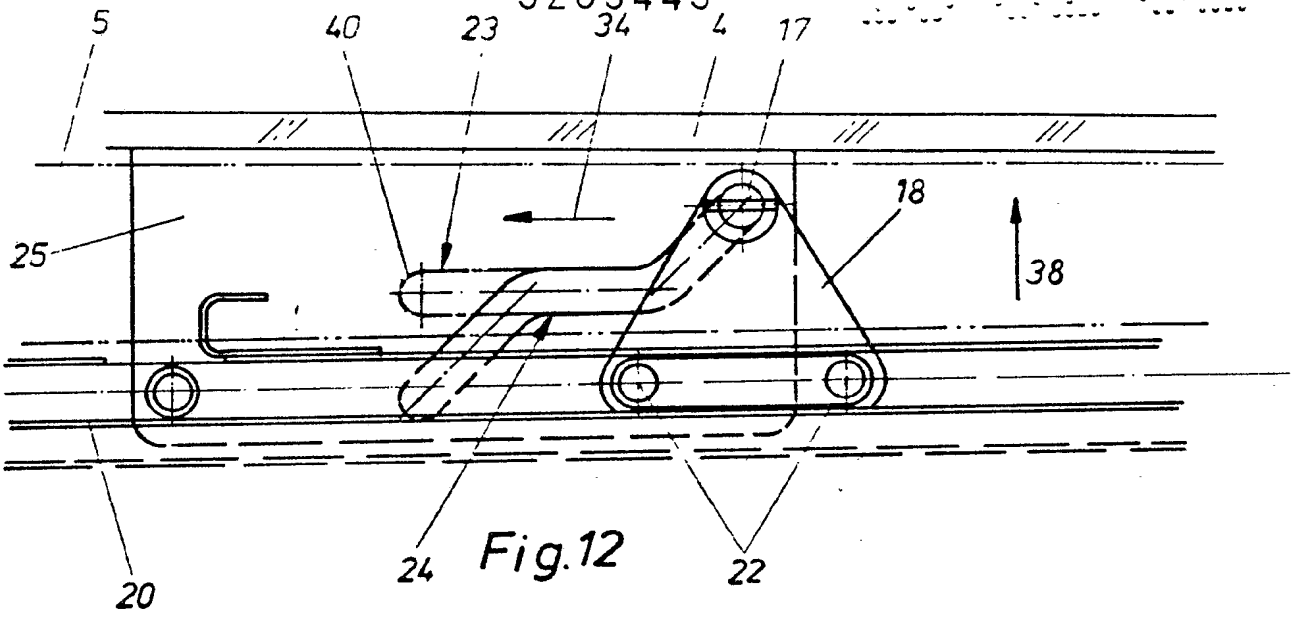


Fig.12

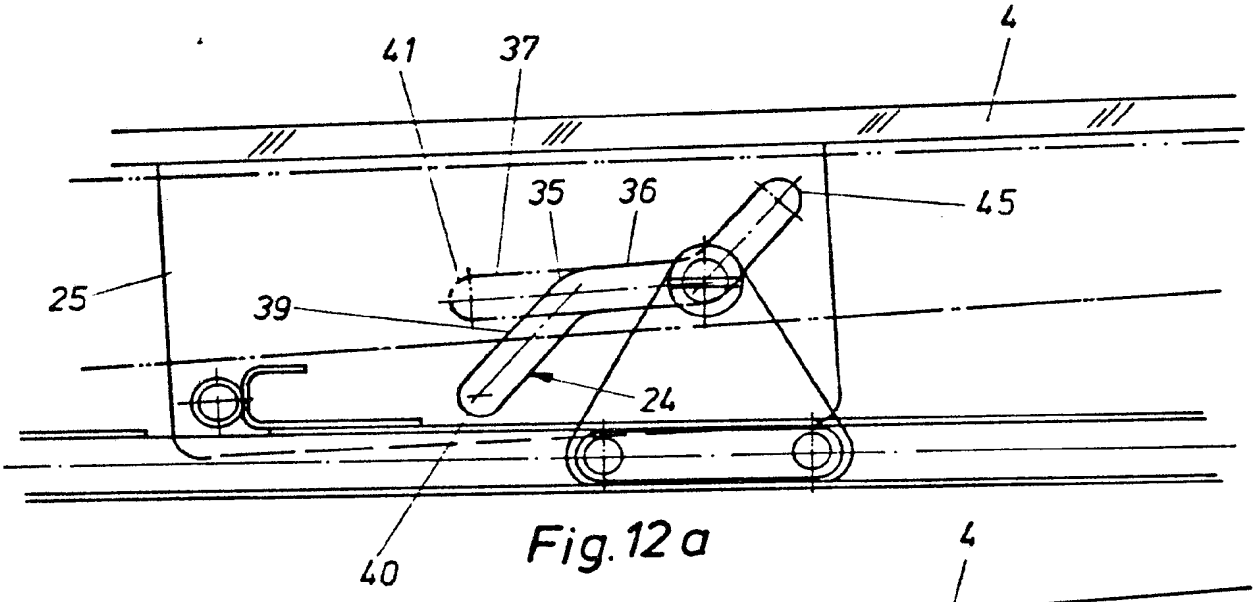


Fig.12a

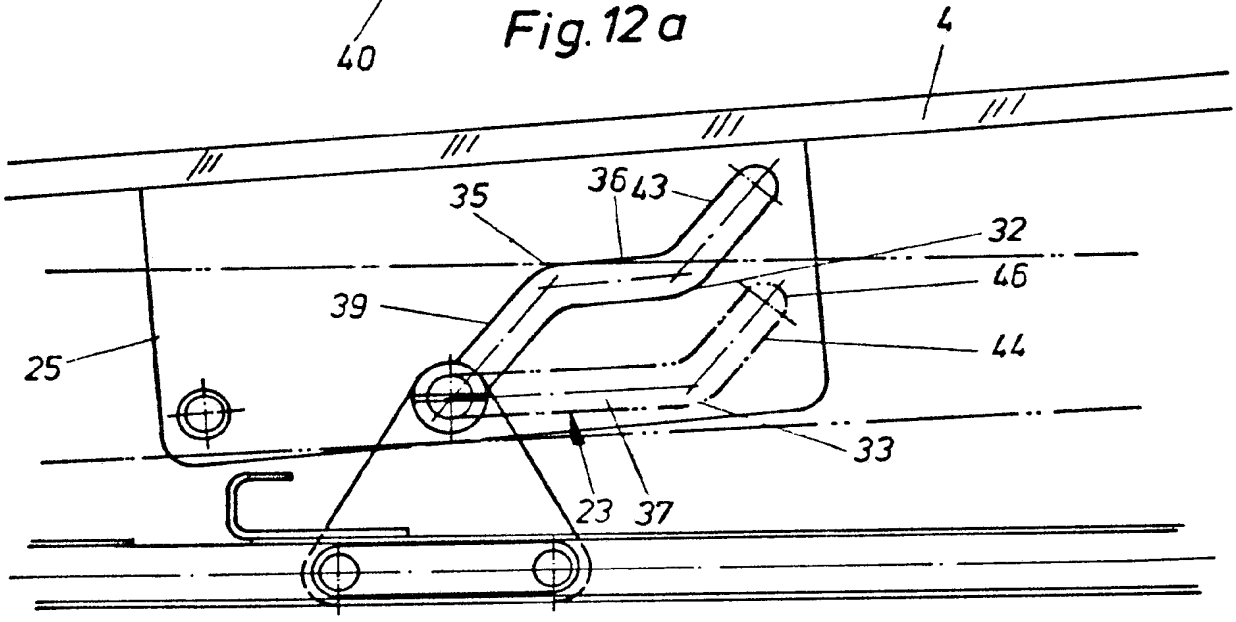


Fig.12b

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(56) Im Prüfungsverfahren entgegengehaltene Druckschriften nach § 44 PatG:

DE-OS 26 19 324
DE-OS 24 55 917
DE-OS 21 49 026
US 38 11 800
US 37 91 787
DE-Z.: Medizinal-Markt/Acta Mediotechnica 26 (1978) 12, S.381-383;

(54) Vorrichtung zum Reinigen des Blutes von Stoffwechselprodukten

DE 3205449 C2

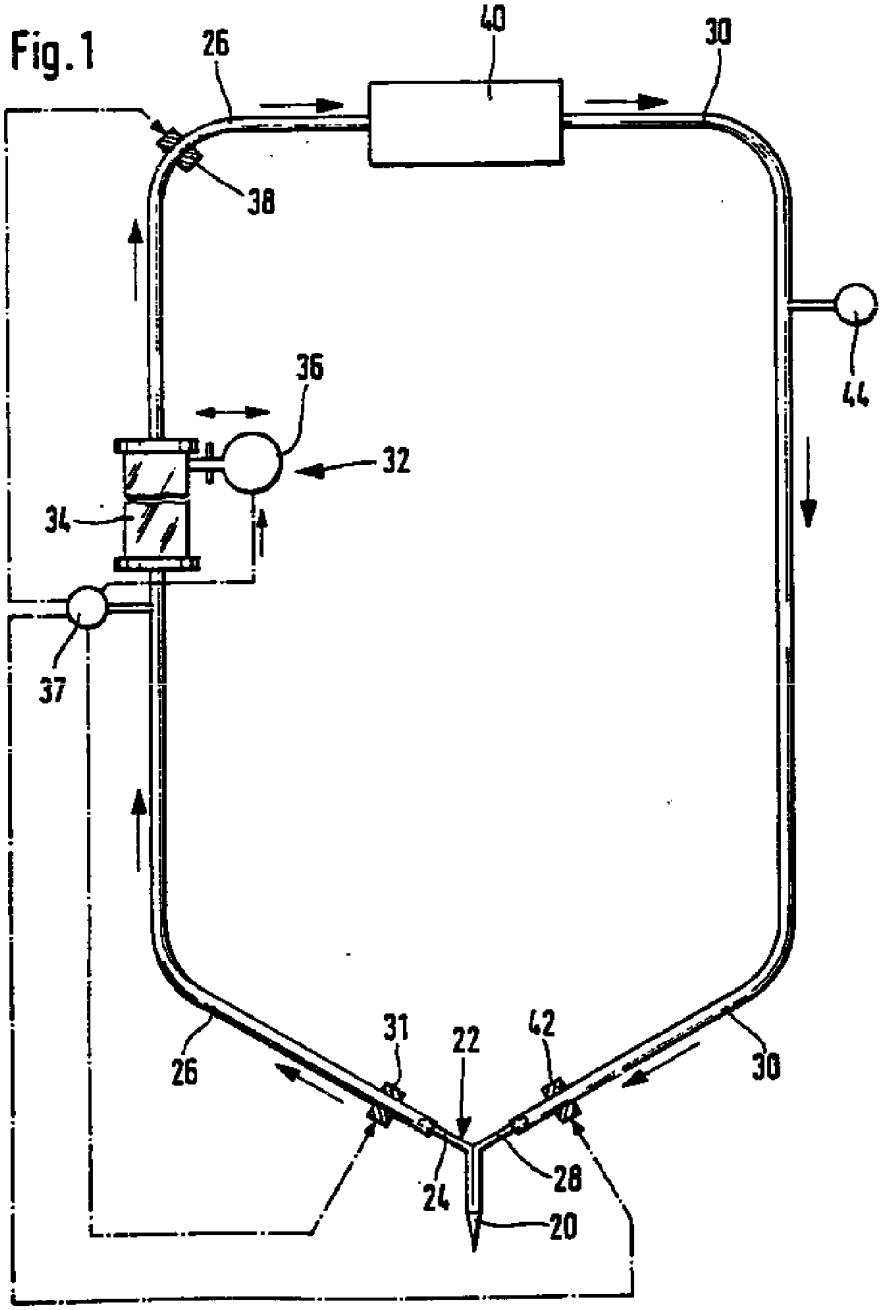
BUNDESDRUCKEREI 08. 85 508 142/251

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ZEICHNUNGEN BLATT 1

Nummer: 32 05 449
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Fig. 1



Solventum-Exhibit 1002-0581

Patentansprüche:

1. Vorrichtung zum Reinigen des Blutes von Stoffwechselprodukten, insbesondere Single-Needle-Dialysevorrichtung, mit einem Dialysator mit einem Dialysatkreislauf und einem Blutkreislauf, der bluteingangs- und blutausgangsseitig über eine Zuleitung und eine Ableitung mit wenigstens einem Blutanschluß verbunden ist, bei der die Zuleitung eine Pumpe und jeweils ein stromauf und stromab der Pumpe angeordnetes Absperrorgan aufweist, wobei die Pumpe ein im wesentlichen starres Gehäuse und eine flexible, innerhalb des Gehäuses angeordnete Membran aufweist, die den Innenraum des Gehäuses in eine erste mit Blut beaufschlagbare Kammer und eine zweite Kammer trennt, die über eine Leitung mit einer als Antrieb dienenden Hubkolbenpumpe verbunden ist, dadurch gekennzeichnet, daß das Antriebsmedium ein Gas ist und der Gasraum mittels Überdruck- und Unterdruckventilen (128, 132) mit der Umgebung in Verbindung steht.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das Hubvolumen der Hubkolbenpumpe (124) größer ist als das Speichervolumen der Pumpe (34).

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß das Hubvolumen bis zu 20% größer ist als das Speichervolumen.

4. Vorrichtung nach einem der Ansprüche 1—3, dadurch gekennzeichnet, daß in der die Pumpe (34) und die Hubkolbenpumpe (36, 124) verbindenden Leitung (116) eine hydrophobe, gasdurchlässige Membran (132) vorgesehen ist, die den Innenquerschnitt der Leitung (116) abdeckt.

5. Vorrichtung nach einem der Ansprüche 1—4, dadurch gekennzeichnet, daß die Hubkolbenpumpe (36, 124) zwangsgesteuert ist und an ihren Umkehrpunkten die Absperrorgane (31, 38, 42) umgeschaltet werden.

6. Vorrichtung nach einem der Ansprüche 1—5, dadurch gekennzeichnet, daß die Ventile (128, 132) und die Hubkolbenpumpe (36, 124) mit einer Überwachungseinrichtung (131) verbunden sind.

7. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, daß mit der Überwachungseinrichtung (131) die Pumpgeschwindigkeit gesteuert, die zeitliche oder phasengebundene Abfolge der Ventilzustände registriert oder ein Alarmsignal abgegeben wird.

8. Vorrichtung nach einem der Ansprüche 1—7, dadurch gekennzeichnet, daß in der Pumpleitung (122) ein Drucksensor angeordnet ist, mit dem über die Überwachungseinrichtung (131) die Änderung der Druckabfolge registriert wird.

Die Erfindung betrifft eine Vorrichtung zum Reinigen des Blutes von Stoffwechselprodukten, insbesondere Single-Needle-Dialysevorrichtung, mit einem Dialysator mit einem Dialysatkreislauf und einem Blutkreislauf, der bluteingangs- und blutausgangsseitig über eine Zuleitung und eine Ableitung mit wenigstens einem Blutanschluß verbunden ist, bei der die Zuleitung eine Pumpe und jeweils ein stromauf und stromab der Pumpe

angeordnetes Absperrorgan aufweist, wobei die Pumpe ein im wesentlichen starres Gehäuse und eine flexible, innerhalb des Gehäuses angeordnete Membran aufweist, die den Innenraum des Gehäuses in eine erste mit Blut beaufschlagbare Kammer und eine zweite Kammer trennt, die über eine Leitung mit einer als Antrieb dienenden Hubkolbenpumpe verbunden ist.

Die US-PS 37 91 767 beschreibt eine Vorrichtung der eingangs erwähnten Art, die eine Pumpanordnung in einem Single-Needle-Dialysesystem aufweist. Bei dieser Pumpanordnung wird das Blut in eine schlauchförmige, flexible Speicherkammer in einem ersten Schritt eingepumpt und aus dieser im nächsten Schritt abgepumpt. Diese flexible Speicherkammer ist in einem starren Gehäuse angeordnet und bildet in diesem einen Ringraum, in den durch Pumpen eine Flüssigkeit als Pumpfluid gefördert wird.

Die Pumpe gemäß US-PS weist einen mit einem Balg verbundenen Kolben auf, der gegen die Kraft einer Feder bewegt wird. Da sich das Balginnenvolumen verändert und hierdurch ein Unterdruck erzeugt wird, erfolgt ein Ansaugen der Flüssigkeit aus dem Ringraum des Speichers. Das Blut wird dabei solange angesaugt, bis sich der Schlauch an die Speicherwand angelegt hat, ohne daß er jedoch erweitert worden wäre.

Das Blutvolumen ist durch die in der Pumpanordnung befindliche Flüssigkeitsmenge und das Innenvolumen des nicht elastisch erweiterbaren Schlauchs begrenzt.

Um das Blut aus dem Schlauch abzupumpen, wird der Solenoid, der den Balg bewegt, abgeschaltet. Durch die Rückschnellkraft der Feder wird der Balg anschließend zusammengepreßt, so daß die Pumpflüssigkeit in den Speicher zurückgepumpt wird.

Da dieses System volumenkonstant ist, ergeben sich einige schwerwiegende Nachteile.

Zunächst sind die auf das Blut einwirkenden Unter- und Überdrücke nicht beliebig einstellbar, da sie weitgehend von der Auslegung der einzelnen Pumpelemente festgelegt sind. So stellt die Feder infolge ihrer konstanten Federkraft grundsätzlich den Balg und somit die Pumpflüssigkeit mit konstantem Druck zurück, die wegen der Inkompressibilität diesen Druck an das Blut weitergibt. Da für den Solenoid ähnliche Betriebsbedingungen gelten, ist davon auszugehen, daß keine Drucksteuerung vorliegt. Dies führt dazu, daß das zu pumpende Flüssigkeitsvolumen relativ genau eingestellt werden muß, um die Pumpe effektiv auszunutzen.

Weiterhin fördert der Balg zwar die Pumpflüssigkeit zurück, erzeugt jedoch keinen steuerbaren Unterdruck im Pumpsystem, da das Blut ohne einen Strömungswiderstand in den Schlauch nachströmt und der Schlauch selbst aus seinem kollabierten Zustand ohne Unterdruck in den expandierten, jedoch immer noch drucklosen Zustand, überführt wird.

Ein bedeutender Nachteil dieser Pumpanordnung besteht darin, daß bei Betriebsbeginn die Phasenlage zwischen dem Speicher einerseits und der Balgpumpe andererseits übereinstimmen muß, damit die Pumpanordnung überhaupt funktionieren kann. Eine solche Übereinstimmung läßt sich jedoch regelmäßig nicht oder nur schwer erzielen, mit der Folge, daß nur noch eine unvollständige Füllung der Speicherkammer mit Blut stattfindet. Dies gilt insbesondere bei der Verwendung eines inkompressiblen Mediums als Pumpfluid. Da sich weiterhin die Pumpverhältnisse während des Betriebs ändern können, beispielsweise die Phasenlage zwischen der Speicherkammer und der Pumpe verschoben wird, variiert in entsprechender Weise das Pumpergebnis, das

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regelmäßig nicht zufriedenstellend ist.

Diese bekannte Pumpanordnung weist also weder in der Anlaufphase noch während der normalen Betriebsphase ein völlig zufriedenstellendes Pumpergebnis auf, was darauf zurückzuführen ist, daß außer der Menge der Pumpflüssigkeit sämtliche Betriebsparameter praktisch konstant und somit nicht mehr steuerbar sind.

Die US-PS 36 11 800 beschreibt ein weitgehend ähnliches System, bei dem wiederum ein sich nach dem Zusammendrücken in die Ausgangslage zurückstellender, jedoch nicht erweiterbarer Schlauch als Speicherelement eingesetzt wird. Auf diesen Schlauch wirkt ein weiterer Schlauch ein, der mit einem hydraulischen Pumpfluid gefüllt ist. Durch eine Erweiterung dieses Schlauchs wird der mit Blut gefüllte Schlauch zusammengedrückt und das im Schlauch befindliche Blut abgepumpt. Der Blutschlauch wird anschließend beim Zurückziehen der Pumpflüssigkeit zurückgestellt und füllt sich somit bei entsprechender Steuerung der Klemmen, die den Blutschlauch abschließen und öffnen.

Es wird also mit einer hydraulisch angetriebenen Pumpe gepumpt, die innerhalb eines starren Gehäuses untergebracht ist. Das Volumen dieses Gehäuses ist dabei geringer als das Volumen der beiden Schläuche. So kommt es daher ständig zu einer Kollabierung eines der beiden Schläuche.

Derartige hydraulische Systeme weisen Probleme bei der Drucksteuerung auf, da der Kompressionsdruck nicht durch eine einfach zu gewährleistende Sicherheitsmaßnahme begrenzt werden kann.

Weiterhin kann die Blutansauggeschwindigkeit nicht geregelt werden, da sie durch die Rückschnellkraft des Blutschlauchs sowie die Eigenschaften des Pumpschlauches und des angeschlossenen Systems bestimmt ist. Eine weitere Regelung ist nicht möglich.

Die DE-OS 24 55 917 beschreibt einen extrakorporalen Kreislauf in Form eines Single-Needle-Dialysesystems, das wiederum eine Pumpe zum Umpumpen von Blut mit einem veränderlichen Innenvolumen aufweist. Zum Einsatz kommen die bereits als nachteilig beschriebenen Schlauchpumpen oder eine rohrförmige Membran und Ventile aufweisende Membranpumpen, die ein gesteuertes Einlaß- und Auslaßventil aufweisen. Derartige Pumpen sind als Ventrikelpumpen bekannt, die grundsätzlich selbstansaugend sind und den Blutfluß in eine Richtung steuern.

Ähnliche Pumpsysteme sind weiterhin aus den DE-OS 21 49 026 und 26 19 234 bekannt, die als Blutpumpen eingesetzt werden sollen. Dabei handelt es sich um passiv betriebene Ausdehnungsgefäße, die sich regelmäßig selbsttätig füllen, ohne daß eine optimale Pumpleistung durch das Antriebselement erreicht werden kann.

Weiterhin ist ein solches balgartiges Ausdehnungsgefäß, das unmittelbar mit Blut beaufschlagt wird, in Medizinalmarkt/Acta Medicotechnica 26, (1978) Bd. 12, S. 381–383 beschrieben. Eine solche mechanisch angetriebene Balgpumpe hat den Nachteil, daß sie nicht per se den Überdruck oder Unterdruck einschränkt. Sie benötigt daher einen zusätzlichen, in das Blutzuführungssystem integrierten Druckaufnehmer, der wiederum die externe Pumpe bzw. die Vorschubgeschwindigkeit steuert, mit der der Balg zusammen- oder auseinandergezogen wird.

Demgemäß kann also nur festgehalten werden, daß die vorstehend erläuterten Pumpsysteme entweder einer volumenkonstanten Zwangssteuerung unterzogen sind oder aber eine mit der Pumpkammer gekoppelte Drucksteuerung aufweisen. Darüber hinaus können solche Blutpumpen zu Beginn ihrer Tätigkeit bei unbestimmter Phasenlage nur schwierig und mit einem speziellen Füllprogramm oder speziellen Einrichtungen hierfür betrieben werden.

Der Erfindung liegt daher die Aufgabe zugrunde, eine Vorrichtung der eingangs erwähnten Art zur Verfügung zu stellen, bei der die Pumpe in jeder Betriebsart sicher gefüllt und entleert werden kann, ohne daß die Hubkolbenpumpe über mit der Pumpe oder dem Blutzuführungssystem verbundene Druckaufnehmer geregelt werden muß.

Die Lösung der Aufgabe erfolgt dadurch, daß das Antriebsmedium ein Gas ist und der Gasraum mittels Überdruck- und Unterdruckventilen mit der Umgebung in Verbindung steht.

Erfindungsgemäß erfolgt die Regelung der Hubkolbenpumpe unabhängig von einer mit der Pumpe in Verbindung stehenden Regeleinrichtung, d. h. die Pumpe regelt sich selbsttätig, wenn ein bestimmter an die Pumpe angelegter Überdruck oder Unterdruck erreicht wird. Dabei öffnen sich die Ventile, so daß der auf die Pumpe einwirkende Druck nicht mehr erhöht oder abgesenkt wird.

Eine derartige Betriebsweise ist mit den eingangs erwähnten hydraulischen Pumpen nur schwierig durchzuführen, da die Pumpflüssigkeiten infolge ihres inkompressiblen Charakters regelmäßig in Pumpanordnungen mit konstantem Volumen untergebracht sind, d. h. Pumpe und Antrieb werden regelmäßig zwangsgesteuert.

Erfindungsgemäß kann jeder beliebige Über- und Unterdruck in der pneumatisch betriebenen Pumpe eingestellt werden, ohne daß diese beschädigt wird.

Weiterhin ist es vorteilhaft, daß die erfindungsgemäße Pumpanordnung zu Beginn ohne jegliche Schwierigkeit gefüllt werden kann, da sie von der Phasenlage unabhängig ist. Die Pumpe saugt nämlich Blut solange an, bis sich die elastische Membran an das starre Pumpgehäuse angelegt hat und dadurch der Druck abfällt. Wenn ein bestimmter Unterdruck erreicht ist, öffnet sich das Unterdruckventil und hält diesen Unterdruck solange konstant, bis die Pumpe den Umkehrpunkt erreicht. Ist dieser Umkehrpunkt erreicht, so schließt sich das Unterdruckventil und es wird die Pumpe entleert. Nach dem Entleeren steigt der Überdruck an und wird bei einem bestimmten Wert dadurch konstant gehalten, daß das Überdruckventil sich öffnet.

Die Pumpe arbeitet jedoch weiter und kehrt erst an ihrem anderen Umkehrpunkt zum Saugbetrieb zurück. An diesem Punkt hat sie nun die richtige Phasenlage erreicht.

Sie benötigt daher lediglich einen Zyklus, um zu der jeweils angestrebten Phasenlage zu kommen, die einen optimalen Pumpbetrieb garantiert.

In einer besonders bevorzugten Ausführungsform ist das Innenvolumen der Pumpe und der Hubkolbenpumpe korreliert und somit das Verhältnis dieser Volumina begrenzt. Demzufolge unterliegt auch der Druck einer bestimmten Begrenzung in diesem pneumatisch betriebenen System, so daß u. U. auch der Ausfall der Druckbegrenzungsventile toleriert werden kann.

Weitere Einzelheiten, Vorteile und Ausführungsformen sind in der nachfolgenden Beschreibung unter Bezugnahme auf die Zeichnung erläutert. Es zeigt

Fig. 1 schematisch eine Single-Needle-Dialysenanordnung mit dem erfindungsgemäßen Pumpsystem,

Fig. 2 einen Längsschnitt durch eine erste Ausführungsform des erfindungsgemäßen Pumpspeichers,

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Fig. 3 einen Längsschnitt durch eine zweite Ausführungsform des erfindungsgemäßen Pumpspeichers,

Fig. 4 eine Druck/Volumen-Charakteristik der in Fig. 2 gezeigten Ausführungsform beim Befüllen,

Fig. 5 eine Membranpumpe für das in Fig. 1 gezeigten Pumpsystem,

Fig. 6—8 jeweils den Endabschnitt weiterer Ausführungsformen von Pumpspeichern im Längsschnitt, wobei eine weitere zylindrische Außenwand des Pumpspeichers skizziert angedeutet ist und

Fig. 9 eine schematische Darstellung eines kontinuierlich pumpenden Systems mit zwei Pumpspeichern.

Gemäß Fig. 1 wird einem Patienten über eine Hohlkanüle 20 Blut entnommen, die in ein Blutgefäß eingeschoben wird. Diese Hohlkanüle 20 weist an ihrem Ende einen y-förmigen Anschluß 22 auf, bei dem der eine Anschluß 24 mit der Arterienleitung 26 verbunden ist, während der andere Ast 28 mit der Venenleitung 30 verbunden ist. Die Hohlkanüle kann als Biflownadel ausgebildet sein, d. h. sie besteht aus zwei ineinander koaxial angeordneten Kanülen, bei denen die äußere Kanüle um wenige Millimeter zurückgesetzt ist, um einen Vermischungseffekt zu vermeiden. Andererseits kann jedoch auch der geringe Vermischungseffekt bei der vorzugsweise eingesetzten y-förmigen Nadel 20 hingenommen werden.

In der Arterienleitung 26 ist im Anschluß an die y-förmige Hohlnadel 20 ein Absperrorgan 31 vorgesehen, mit der die Arterienleitung geöffnet und abgeschlossen werden kann. An dieses Absperrorgan 31 schließt sich ein Pumpsystem 32 an, das mit der Arterienleitung 26 in Verbindung steht und im wesentlichen die Pumpe 34 und die damit in Verbindung stehende Hubkolbenpumpe 36 aufweist. Stromab des Pumpsystems 32 ist in der Arterienleitung 26 ein weiteres Absperrorgan 38 angeordnet, das vorteilhafterweise entweder als Klemme oder aber als Rückschlagventil ausgebildet ist.

Stromab des Absperrorgans 38 ist die Arterienleitung 26 mit dem Dialysator 40 verbunden, in dem das zu reinigende Blut von den Stoffwechselprodukten und überschüssiger Flüssigkeit befreit wird. Dieser Dialysator 40 ist mit einer nicht gezeigten Dialysemanordnung verbunden, die die Dialyseflüssigkeit mit ebenfalls nicht gezeigten Zu- und Ableitungen durch den Dialysator 40 fördert.

An diesen Dialysator 40 schließt sich die Venenleitung 30 mit dem Leitungsast 28 an, der zur y-förmigen Kanüle 20 geführt ist. Vor der Kanüle 20 ist ein weiteres Absperrorgan 42 vorgesehen, mit der die Venenleitung 30 geöffnet und geschlossen werden kann.

Weiterhin kann vorteilhafterweise in der Venenleitung 30 ein Drucksensor 44 angeordnet sein, der den Druck anzeigt, der sich in dem Leitungsabschnitt zwischen dem Schließorgan 38 und der Klemme 42 aufbaut.

Die in Fig. 1 gezeigte erste Ausführungsform wird folgendermaßen betrieben:

Das Blut wird über die Hohlkanüle 20 mittels des in Fig. 5 näher gezeigten und nachstehend beschriebenen Pumpsystems 32 angesaugt, wobei das Organ 38 und die Klemme 42 geschlossen und das Absperrorgan geöffnet sind. Über die Arterienleitung 26 wird das Blut in die Pumpe 34 mittels der Hubkolbenpumpe 36 gepumpt, wobei die anhand Fig. 2 nachstehend näher erläuterte schlauchförmig ausgebildete Pumpe 34 zunächst drucklos aufgefüllt wird. Anschließend erweitern sich unter sprunghaftem Druckanstieg die Außenwände, ähnlich dem Zustand, in dem ein Ballon aufgeblasen wird. Bereits eine geringe Menge zusätzliches Blut reicht aus, um diesen sprunghaften Druckanstieg in ein nur noch geringfügig ansteigendes Druckplateau umzuwandeln, d. h. daß bei der weiteren Einspeisung von Blut in die Pumpe 34 der Druck in der Pumpe 34 im wesentlichen nur noch geringfügig ansteigt oder sogar konstant bleibt, ohne zunächst wieder sprunghaft anzusteigen. Dieser Anstieg erfolgt dann, wenn ein Grenzzustand erreicht wird, bei dem sich die elastischen Eigenschaften der Speicherwand verändern. Diese Druckcharakteristik ist in der Fig. 4 gezeigt.

In Fig. 2 ist die erste Ausführungsform der erfindungsgemäßen Pumpe 34 im Längsschnitt gezeigt. Diese Pumpe 34 weist im wesentlichen kreisförmige Endplatten 46 und 48 auf, in die ringförmige Nuten 50, 52, 54 und 56 eingelassen sind. Beide Endplatten 46 und 48 weisen weiterhin eine Öffnung 58 und 60 auf, die jeweils von den Anschlußstutzen 62 und 64 umgeben sind. Auf diese Anschlußstutzen 62 und 64 sind die Leitungen 26 aufgesteckt oder aufgeklebt.

Beide Endplatten 46 und 48 sind miteinander über den erweiterbaren Schlauch 66 und die zylinderförmige Speicherwand 68 verbunden. Der Schlauch 66 ist in seinem Endbereich 70 und 72 quergespannt und in die ringförmigen Nuten 50 und 54 der Endplatten 46 und 48 eingelassen und dort befestigt. In seinem mittleren Bereich ist er jedoch nicht quergespannt, sondern allenfalls vorteilhafterweise in Längsrichtung etwas vorgespannt. In die zweiten ringförmigen Nuten 52 und 56 der Endplatten 46 und 48 ist die Speicherwand 68 fest eingesetzt, was beispielsweise durch Kleben oder mechanisches Klemmen vorgenommen werden kann.

Wie aus Fig. 2 ersichtlich, ist der Innenraum 74 des Schlauchs 66 mit der Öffnung 58 und somit der Arterienleitung 26 in Verbindung und wird beim Betrieb mit Blut gefüllt. Hierdurch erfolgt eine Erweiterung der Wand des elastischen Schlauchs 66 solange, bis sich dieser an die Speicherwand 68 vollständig angelegt hat, wie dies durch die strichpunktierte Linie 76 angedeutet ist.

Um eine derartige elastische Erweiterung des Schlauchs 66 zu erreichen, muß natürlich auf die Außenwand des Schlauchs 66 ein Unterdruck ausgeübt werden, der in dem im wesentlichen ringförmigen Raum 78 angelegt wird, der zwischen dem Schlauch 66 und der Speicherwand 68 gebildet wird. Hierzu ist in der Speicherwand 68 wenigstens eine Öffnung 80 vorgesehen, die über eine Zuleitung 82 mit der Hubkolbenpumpe 36 in Verbindung steht, die in Fig. 5 näher dargestellt und erläutert ist. Diese Hubkolbenpumpe 36 pumpt über die Zuleitung 82 und die Öffnung 80 Luft aus bzw. in den ringförmigen Raum 78, was entweder zur Erweiterung oder zum Kollabieren des Schlauchs 66 führt.

Infolge seiner hochelastischen Eigenschaften kollabiert der Schlauch 66 in seinem in Fig. 2 gezeigten aufgespannten Zustand nicht vollständig, so daß zum völligen Abpumpen von Blut aus dem Innenraum 74 ein zusätzlicher Überdruck durch die Hubkolbenpumpe 36 erzeugt werden muß.

Für die Zuführung von Blut ist ein Unterdruck von etwa 150 und max. 500 mm Hg-Säule notwendig, der mit den Sensoren 37, 44, 84 oder 88 gemessen werden kann, wobei letztere mit dem ringförmigen Raum 78 und/oder der Zuleitung 82 über die Leitung 86 bzw. 90 in Verbindung stehen.

Als Material für diesen Schlauch 66 werden hochelastische Materialien eingesetzt, beispielsweise organische Polymere und deren Gemische, wie Polyurethane Kautschuke, Silikonkautschuke, Latex, Gummi, regenerierter Gummi u. dgl. Vorzugsweise wird Latex einge-

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setzt, das ggf. übliche Zusatz- und die Elastizität verbessernde Mittel aufweist. Ein derartiger Schlauch 66 kann wenigstens um das Fünffache seines Lumens, insbesondere um das Zehnfache ausgedehnt werden, so daß er also — wenigstens in der bevorzugten Ausführungsform — das Zehnfache seines Innenvolumens zusätzlich aufnehmen kann.

Die Wandstärke eines derartigen Schlauches 66 liegt in einem Bereich von etwa 0,05—0,5, vorzugsweise 0,1—0,4 mm. Sie wird in Abhängigkeit von der gewünschten Druckcharakteristik und der Volumenerweiterung der einzusetzenden Pumpe 34 gewählt. Je dicker die Wandstärke des Schlauches 66 ist, desto höher ist der Anfangsdruck, der aufzuwenden ist, um zu dem über einen weiten Volumenbereich führenden Druckplateau zu kommen. Vorzugsweise wird die Wandstärke so gewählt, daß das Druckplateau oberhalb des in der Vene herrschenden Druckes, vorzugsweise über 20 mm Hg liegt. Dieser Druck muß also in der Venenleitung vorliegen, um überhaupt Blut in die Vene überführen zu können.

Das Schlauchvolumen und die Länge des Schlauches 66 richten sich nach dem Einsatzzweck sowie der Auslegung der Dialysevorrichtung. Üblicherweise wird der Durchmesser eines Schlauchs 66 in einem Bereich von 5—15, vorzugsweise etwa 8 mm liegen, während die Länge des Schlauchs 10—20, vorzugsweise ca. 15 cm betragen kann. Es sind jedoch aber auch kürzere oder längere Abmessungen denkbar, sofern dies der Einsatzzweck erfordert. Wenn nur geringe Blutvolumina befördert werden, wird man eine entsprechend geringer dimensionierte Pumpe mit einem entsprechend kleineren Schlauch einsetzen als bei größeren Blutumsätzen.

Bei der ersten in Fig. 2 gezeigten Ausführungsform weist der Schlauch 66 eine von der einen Endplatte 48 zur anderen Endplatte 46 abnehmende Wandstärke auf. Vorzugsweise nimmt die Wandstärke über die Gesamtlänge der Pumpe 34 um bis zu 50% ab. Ein derartig über seine Gesamtlänge im wesentlichen stetig in seiner Wanddicke abnehmender Schlauch kann dadurch erzeugt werden, daß man einen Stab in eine flüssige Latexmasse eintaucht und diesen Stab anschließend aus der flüssigen Latexmasse herauszieht. Durch den flüssigen Zustand dieser Latexmasse fließt ein Teil der an dem Schlauch hängenden Masse herunter, so daß die Wandstärke des dadurch hergestellten Schlauchs von einem Schlauchende zum anderen Schlauchende stetig zunimmt. Hierdurch steigt das Druckplateau, das sich beim Aufblähen des Schlauches 66 ergibt, nach dem abrupten Anstieg, wie aus Fig. 4 ersichtlich, ebenfalls stetig an.

Eine derartige in Fig. 2 dargestellte Anordnung eines Schlauches 66 mit abnehmender Wanddicke zieht die Anordnung der Öffnung 80, die mit der Hubkolbenpumpe 36 über die Zuleitung 82 in Verbindung steht, in der Nähe des Schlauchbereichs 72 nach sich, in dem der Schlauch 66 seine größte Wandstärke besitzt. Der Schlauch wird sich nämlich dort zuerst aufblähen, wo die Wandstärke des Schlauchs am geringsten ist, d. h. im Bereich der Endplatte 46. Dabei legt sich dieser Endbereich an die Speicherwand 68 an und füllt sich unter Bildung einer Wellenfront in Richtung auf das die größte Wandstärke aufweisende Schlauchende.

In Fig. 3 ist eine weitere Ausführungsform gezeigt, wobei für gleiche Teile die gleichen in Fig. 2 verwendeten Bezugszeichen eingesetzt werden. In dieser Ausführungsform kommt vorzugsweise ein Schlauch 66 zum Einsatz, dessen Wandstärke über seine Gesamtlänge im wesentlichen gleich ist. Die Verwendung dieser Ausführungsform ist jedoch nicht auf einen Schlauch mit im wesentlichen gleicher Wandstärke beschränkt, so daß auch Schläuche mit abnehmender Wandstärke, wie in Fig. 2 gezeigt, eingesetzt werden können.

Die Ausführungsform gem. Fig. 3 unterscheidet sich von der in Fig. 2 gezeigten Ausführungsform im wesentlichen dadurch, daß die Speicherwand 68 eine Vielzahl von Öffnungen 92 aufweist, die beliebig über dem Umfang und die Länge dieser Speicherwand 68 vorgesehen sind. Über diese Öffnungen 92 kann die Luft, die von der Hubkolbenpumpe 36 ab- oder zugepumpt wird, entweder entweichen oder aber zufließen.

Weiterhin ist bei der zweiten Ausführungsform eine weitere Außenwand 94 vorgesehen, deren Durchmesser größer ist als der Durchmesser der Speicherwand 68 und die im wesentlichen die gleiche Form wie die Speicherwand besitzt. Somit wird bei einer Zylinderform der beiden Wände 68 und 94 ein ringförmiger Raum 96 zwischen diesen beiden Wänden gebildet, der über die Öffnungen 92 mit dem ringförmigen Raum 78 in Verbindung steht. Die Außenwand 94 ist jeweils in ihrem Endbereich 98 und 100 mit den Endplatten 46 und 48 fest verbunden, wobei die gesamte Anordnung bis auf die in der Außenwand 94 vorgesehene Öffnung 102 als gasdicht anzusehen ist. Diese Öffnung 102 kann an beliebiger Stelle in der Außenwand 94 vorliegen, da sich der Schlauch 66 nur an die Speicherwand 68 anlegen kann und durch die Vielzahl der Öffnungen 92 sichergestellt ist, daß der Schlauch 66 beim Abpumpen der Luft nicht die Abströmöffnung zusetzt und dadurch ein weiteres Abpumpen von Luft verhindert.

Eine solche Ausführungsform ist insbesondere bei einem Schlauch mit gleichbleibender Wandstärke zweckdienlich, da dieser in aller Regel keine von einem Schlauchende zum anderen Schlauchende ablaufende Wellenbewegung mitmacht, sondern sich beim Füllen mit Blut an einer beliebigen Stelle erweitern kann. Durch diese Anordnung wird sichergestellt, daß auch hier eine gleichmäßige Füllung des Schlauches 66 bis zum Anlegen an die Speicherwand 68 erfolgt, wobei sich der Schlauch 66 über seine gesamte Länge an die Speicherwand 68 anlegen kann.

Die Öffnung 102 ist wiederum über die Leitung 104 mit der Hubkolbenpumpe 36 in Verbindung. Weiterhin sind ebenfalls wie in der ersten Ausführungsform Sensoren 84 und 88 vorgesehen, die über Leitungen 106 und 108 und entsprechende Öffnungen in der Außenwand 94 mit dem ringförmigen Raum 96 in Verbindung stehen.

Zweckmäßigerweise werden die Abmessungen des Schlauchs 66 so gewählt, daß der Raum 74 etwa 50—80 ml beträgt, während der elastische Schlauch 66 im drucklosen Zustand etwa 10—15 ml faßt.

Hinzuzufügen ist, daß als Material für den elastischen Schlauch 66 alle wasserundurchlässigen Materialien in Frage kommen, die eine entsprechend große Bruchdehnung (> 200%) aufweisen, wozu die vorstehend genannten Materialien gehören.

Als Material für die Speicherwand 68 und die Außenwand 94 kommen Materialien in Frage, die im wesentlichen starr sind. So sind beispielsweise Polymerisate, wie Polyethylen, Acrylglas, PVC u. dgl. einsetzbar.

Als Fluid für die ringförmigen Räume 78 und 96 setzt man üblicherweise Luft ein.

Wenn bei den vorstehend geschilderten Ausführungsformen Blut in den Schlauch 66 durch Erzeugung von Unterdruck mittels der Hubkolbenpumpe 36 eingepumpt wird, steigt der Druck anfangs nur geringfügig

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an, da der Schlauch 66 sich unter geringer Dehnung füllt und dabei das Volumen nur geringfügig zunimmt. Danach bläht sich der Schlauch 66 zunächst an der Stelle auf, die die geringste Wandstärke besitzt. Er legt sich dabei an die Speicherwand 68 solange an, bis die Luft aus dem gesamten Raum 78 verdrängt ist. Während bei der ersten Ausführungsform mit der abnehmenden Wandstärke des Schlauchs 66 die Dehnungsfronten sich in axialer Richtung ausbreiten und der aufzuwendende Unterdruck im wesentlichen gleich bleibt, verändert sich dieser stetig mit dem gemäß der zweiten Ausführungsform eingesetzten Schlauch 66, der eine im wesentlichen gleiche Wandstärke besitzt.

Wenn die Luft vollständig aus dem Raum 78 verdrängt ist, so daß der Schlauch 66 entsprechend der Linie 76 an der Speicherwand 68 anliegt, steigt der Druck sehr rasch an, da sich der Schlauch 66 nicht mehr verformen läßt.

In Fig. 4 ist die Druck/Volumen-Charakteristik eines Beispiels des ersten Druckspeichers in durchgezogener Linie gezeigt, während in gestrichelter Linie das Idealverhalten eines Druckspeichers mit gleichbleibender Wandstärke dargestellt ist. Das Diagramm bezieht sich natürlich auf das Blutvolumen, das bereits einem bei Normaldruck gefüllten Schlauch 66 zugeführt wird. Der gemäß der ersten Ausführungsform eingesetzte Schlauch ist durch Tauchen eines Stabes in ein Latexbad und langsames Herausziehen dieses Stabes hergestellt worden, was aus der stetig ansteigenden Druckcharakteristik in Abhängigkeit von zugeführten Blutvolumen zu ersehen ist.

Da sich im elastischen Schlauch 66 sowohl die Druck- als auch die Volumenverhältnisse verändern, können beide Parameter zur Steuerung der Pumpe 34 unabhängig voneinander oder zusammen eingesetzt werden.

In Fig. 5 ist eine spezielle Pumpanordnung mit 110 bezeichnet, die sowohl für die erste als auch die zweite Ausführungsform einsetzbar ist. Dabei ist die Wand 112, die der Speicherwand 68 bzw. der Außenwand 94 entspricht, mit einer Öffnung 114 durchsetzt, an die sich auf der Innenseite der Wand 112 der ringförmige Raum 78 bzw. 96 anschließt. Auf der Außenseite der Wand 112 steht die Öffnung 114 mit der Leitung 116 in Verbindung, die der Leitung 82 bzw. 104 entspricht.

Diese Leitung 116 weist an ihrem anderen Ende ein Paßstück 118, beispielsweise einen Flansch oder einen Luer-Konus auf, mit dem die Pumpe 34 mit einem weiteren Paßstück 120 gasdicht verbunden werden kann. An dieses weitere Paßstück schließt sich die Leitung 122 an, die mit der Balgpumpe 124 verbunden ist.

Unter Balgpumpe wird eine Pumpe mit konstantem Hubvolumen verstanden. Bevorzugt ist eine Balgpumpe 124, deren Hubvolumen größer ist als das Speichervolumen der Pumpe 34. Besonders bevorzugt ist eine Balgpumpe 124, deren Volumen bis zu 20% größer ist als das Speichervolumen der Pumpe 34.

Mittels dieser Balgpumpe 124 wird die Luft aus dem Innenbereich der Pumpe 34 abgesaugt und in den Balg 126 überführt.

Bei der Zwangssteuerung, bei der die Hubkolbenpumpe zwischen einem oberen und unteren Totpunkt, d. h. einem Höchst- und Tiefstdruckwert pendelt, sind diese Sensoren 84 und 88 nicht zwangsläufig notwendig. Setzt man nämlich eine Balgpumpe 124 mit konstantem Fördervolumen und konstanter, zuvor bestimmter Pumpgeschwindigkeit ein, so kann in der Leitung 122 ein Unterdruckventil 128 vorgesehen sein, das sich öffnet, wenn ein bestimmter Unterdruck in dieser Leitung erreicht ist. Vorzugsweise wird man dieses Unterdruckventil 128 so einstellen, daß dieses umschaltet, wenn sich der Schlauch 66 vollständig mit Blut angefüllt hat und sich an die Speicherwand 68 angelegt hat. Die Balgpumpe 124 schaltet dann selbsttätig am Totpunkt in ihrer Pumpfunktion um und schaltet zugleich an diesem Punkt die Klemmen 31, 38 und 42.

Es erfolgt darauf das Abpumpen von Blut aus dem Schlauch 66 entweder mittels der Balgpumpe 124 selbst oder aber durch Belüften der Leitung 122 durch ein nicht gezeigtes Ventil, wobei sich der Schlauch 66 infolge seiner elastischen Eigenschaften selbst entlädt.

Ist der Schlauch 66 völlig zusammengedrückt, so steigt der Druck in der Außenkammer stark an, sofern die Pumpe 126 weiterhin komprimiert, was der Fall ist, wenn das Hubvolumen der Pumpe größer ist als das Speichervolumen der Pumpe 34. In diesem Fall ist vorteilhafterweise ein Überdruckventil 132 in der Leitung 122 vorgesehen, über das die überschüssige Luft entweichen kann, so daß ein bestimmter Höchstdruckwert im System nicht überschritten wird. Am unteren Totpunkt der Balgpumpe 124 wird dann die Klemme 38 sowie die Venenklemme 42 geschlossen und die Arterienklemme 31 geöffnet.

Aus der vorstehenden Ausführung ist ersichtlich, daß kein Sensor zum Umsteuern der Hubkolbenpumpe benötigt wird. Dabei kann im Fehlerfall, d. h. bei Versagen einer Klemme oder beim Verstopfen der Leitungen kein Druck im Blutsystem auftreten, der größer ist als der durch das Überdruckventil 132 in der Pumpleistung bestimmte Maximaldruck. Da die Balgpumpe 124, sofern deren Hubvolumen größer ist als das Füllvolumen der Pumpe 34, immer mit einem Überschuß an Luft arbeitet, wird auch bei einer Undichtigkeit in der Pumpleitung 122 zwischen Balg 126 und dem Ausdehnungsraum 78 immer das volle Füllvolumen des Ausdehnungsraumes 78 gepumpt. Auf diese Weise erreicht man ein Pumpvolumen, das pro Hub dem Füllvolumen der Pumpe 34 entspricht. Aus der Zahl der Hübe, die man mittels eines nicht gezeigten Zählgeräts bestimmen kann, läßt sich direkt durch Multiplikation mit dem Pumpvolumen die durchgesetzte Menge bestimmen und anzeigen sowie aus derem zeitlichen Differential auch die Pumprate.

Bei der gesamten Anordnung ist es wenigstens nützlich festzustellen, ob eine Unterbrechung, beispielsweise ein Verstopfen oder Lösen der Leitung, an irgendeiner Stelle aufgetreten ist. Dies kann einerseits durch Überprüfung des Druckes in der Venen- oder Arterienleitung mittels der Drucksensoren 37 oder 44 erfolgen. Dieser Druck wird nämlich Schwankungen unterliegen, die aufgrund des Strömungswiderstandes der Leitung 26 bzw. 30 und der Nadel 20 unter Förderung von Blut in den entsprechenden Leitungen 26 und 30 auftreten. Diese Drucksensoren 37 und 44 sind mit einer nicht gezeigten zeitgesteuerten Überwachungseinrichtung in Verbindung, die bei einem unerwünschten Druckwert die gesamte Anlage ausschaltet.

Eine entsprechende Überwachungseinrichtung 131 kann jedoch auch bei dem gemäß Fig. 5 gezeigten Pumpsystem angeordnet sein. Diese Überwachungseinrichtung ist sowohl mit den Ventilen 128 und 132 als auch mit der Balg-Pumpe 124 verbunden. Dabei ersetzt diese Überwachungseinrichtung eine nicht gezeigte Einrichtung, die das Öffnen der Ventile 128 und 132 anzeigen kann. Ist beispielsweise eine der Leitungen 26 oder 30 blockiert, so wird der Ausdehnungsraum 78 nur mit einem bestimmten Blutvolumen gefüllt sein und sich ansonsten jedoch inkompressibel verhalten, da ja auf-

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grund der Blockierung Blut weder zu- noch abgeführt werden kann. Infolgedessen wird sich das Über- bzw. Unterdruckventil 128 bzw. 132 nicht bei dem vorgesehenen Bruchteil der Hubbewegung des Balges 126 bzw. nicht zum dafür vorgesehenen Zeitintervall in Abhängigkeit vom Zeitpunkt des Umschaltvorganges öffnen, sondern schon weit früher. In einem solchen Fall schaltet die Überwachungseinrichtung 131 die gesamte Anlage ab.

In einer weiteren Ausführungsform können die Drucksensoren 37 und 44 zu einem einzigen Drucksensor zusammengefaßt sein, der vorteilhafterweise in der Nähe des Y-Stücks 22 zwischen den Klemmen 31 und 42 liegt. Dieser Sensor kann wiederum mit der Überwachungseinrichtung 131 verbunden sein, wobei man in der Ansaugphase den dadurch hervorgerufenen negativen Druck ablesen kann, andererseits in der Druckphase den Überdruck bestimmen kann.

Die vorstehend erläuterte Anordnung läßt weiterhin die folgende Überwachungsautomatik für das Einregulieren der Pumpengeschwindigkeit zu: Ist die Ergiebigkeit des Shunts oder der Nadel 20 nicht groß genug im Vergleich zur eingestellten Pumpgeschwindigkeit, so wird bei der Expansion des Balges 126 ein Unterdruck auftreten, der wesentlich über einem für die Kombination aus Schlauchsystem und Nadel charakteristischen Wert liegt. Dies kann durch einen Drucksensor, beispielsweise den Sensor 37 oder 84 detektiert werden. Dieser Wert kann jedoch aber auch bei Vorhandensein eines Unterdruckventiles 128 durch den Öffnungszeitpunkt dieses Ventiles detektiert werden. Vorteilhafterweise kann man schließlich aber auch auf eine Detektion dieses Zustandes völlig verzichten, wobei man das Unterdruckventil bzw. den Umsteuerungssensor auf einen Wert stellt, der aufgrund der Daten des Schlauchsystems und der Nadel berechnet bzw. zuvor empirisch bestimmt werden kann. Ist die Ergiebigkeit des Shunts groß genug, so wird der Unterdruck diesen Wert erst überschreiten, wenn der Ausdehnungsraum 78 vollgefüllt ist. Ist dies nicht der Fall, so wird der Unterdruck diesen Wert bereits vorher überschreiten, wobei das Unterdruckventil 128 geöffnet und dadurch das Pumpvolumen und die Pumprate beschränkt werden. Somit erhält man eine Pumpvorrichtung, die mit einfachen Mitteln verfahrenstechnisch sicher ist, wobei die Pumpgeschwindigkeit optimal der Leistungsfähigkeit des Shunts angebracht ist. In diesem Fall wird man die Balgpumpe 124 mit hoher Geschwindigkeit arbeiten lassen und auf eine vollständige Füllung des Ausdehnungsraums 78 verzichten. Ein Ablesen der geförderten Blutmenge aus der Zahl der Pumphübe ist dann allerdings nicht mehr möglich.

Im übrigen ist zu bemerken, daß die Anordnung eines Drucksensors in der Blutleitung wesentlich kritischer ist als im Pumpensystem selbst. An der Pumpleitung 122 kann der Drucksensor fest angeschlossen werden, wobei die Gefahr von Undichtigkeiten im wesentlichen vernachlässigbar ist. Im übrigen kann der Sensor mit Umgebungsluft beaufschlagt werden, ohne daß hierdurch Kontaminationsgefahren entstehen. Insofern kann natürlich ein ungeschützter Sensor verwendet werden.

Um sicherzustellen, daß bei einem Platzen des Schlauchs 66 kein Blut in die Hubkolbenpumpe 36 dringt, weist in einer bevorzugten Ausführungsform jede von der Wand 68 und 94 abzweigende Leitung eine hydrophobierte Membran 136 auf, wie dies in Fig. 5 dargestellt ist. Eine derartige hydrophobierte Membran, beispielsweise auf der Basis von PTFE mit einer Dicke von 10—50 µm und einem Porendurchmesser von unterhalb 1 µm, hält das Blut bei den verwendeten Drükken von einem Ausströmen aus der Pumpe 34 zurück gestattet jedoch den ungehinderten Durchtritt von Luft.

Über eine derartige Drucksteuerung läßt sich natürlich die in der Pumpe 34 gespeicherte Blutmenge beliebig feststellen, sofern die eingesetzten Sensoren vorher entsprechend justiert und geeicht wurden. Weiterhin kann hierdurch eine bestimmte Blutmenge zyklisch durch den Dialysator 40 gepumpt werden, wobei die Pumpe 34 nicht vollgepumpt werden muß.

Das in Fig. 1 gezeigte Absperrorgan 38 kann wahlweise einen konstanten Öffnungsquerschnitt oder aber auch einen variablen Öffnungsquerschnitt aufweisen, was von der durchzulassenden Blutmenge abhängt. Bei im wesentlichen konstanten Druckplateau wird man ein Absperrorgan 38 mit konstantem Öffnungsquerschnitt einsetzen, um gleiche Förder- und Druckverhältnisse in der Venenleitung 30 herzustellen. Andererseits wird man bei einem ansteigenden Druckplateau, also bei über die Öffnungszeit der Absperrorgane 38 variierenden Druck- und Förderverhältnissen eine Klemme mit variierbarem Öffnungsquerschnitt einsetzen, um die durch die Venenleitung 30 geförderten Mengen im wesentlichen konstant zu halten. Dieser Öffnungsquerschnitt wird durch eine nicht gezeigte Steuerungseinrichtung, die druck- oder volumengesteuert sein kann, variiert.

Eine derartige Anordnung hat den Vorteil, daß der an dem Dialysator anliegende Druck nicht identisch ist mit dem Pumpdruck in der Pumpe 34, so daß der Dialysator mit erheblich niedrigeren, beliebig gegenüber dem Speicherdruck einstellbaren Drücken betrieben werden kann.

Die Pumpe 34 kann natürlich auch hinter dem Dialysator 40, d. h. in der Venenleitung 30 angeordnet sein, wobei natürlich das Absperrorgan 38 entfällt.

Weiterhin kann auch stromab des Dialysators eine zusätzliche Klemme angeordnet sein, die vorzugsweise einen variierbaren Öffnungsquerschnitt besitzt. In Verbindung mit dem Absperrorgan 38 kann somit in diesem Zweig, der den Dialysator umfaßt, ein beliebiger unterhalb dem sonstigen Betriebsdruck liegender Druck eingestellt werden.

In Fig. 6—8 sind weitere Ausführungsformen der erfindungsgemäßen Pumpe 34 gezeigt, in denen speziell die Befestigung des aufblähbaren Schlauchs 66 an den Endplatten 46 und 48 erläutert ist. Gemäß Fig. 6 ist der Innenschlauch 66 an der Endplatte 46 mit Hilfe eines Klemmrings 160 befestigt, der vorzugsweise eine konusförmige Gestalt zum leichteren Einschieben dieser Anordnung in die Ausnehmung 162 der Endplatte 46 aufweist. Der Durchmesser des Klemmrings 160 ist dabei so bemessen, daß der aufgeweitete Schlauch 66 sicher in der Ausnehmung 162 gehalten wird.

Beim Einsetzen wird zunächst der Schlauch 66 geweitet und über den Klemmring 160 gezogen. Anschließend wird diese Anordnung in der Endplatte 46 festgeklemmt. Die Speicherwand 68 läßt sich dann in die entsprechende ringförmige Nut 52 einsetzen. Danach wird der Schlauch 66 durch die Speicherwand 68 durchgezogen und mit einem entsprechenden Klemmring in die Endplatte 48 eingesetzt.

In Fig. 7 ist eine weitere Befestigungsart des Innenschlauchs 66 gezeigt. Dabei weist die Platte 46 auf ihrer Innenseite eine weite ringförmige Nut 164 auf, während die ringförmige Nut 52 für die Speicherwand 68 beibe-

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halten wird. Auf den durch die ringförmige Nut 164 in der Endplatte 46 gebildeten Rohransatz 166 wird der Schlauch 66 mit Hilfe eines Klemmrings 168 befestigt, wobei wiederum die aus dem Schlauch 66 und dem Klemmring 168 bestehende Anordnung auf diesen Rohransatz 166 formschlüssig aufgeschoben wird.

In Fig. 8 ist eine Abwandlung der in Fig. 7 erläuterten Ausführungsform dargestellt. Dabei weist der Rohransatz 166 an seinem unteren Ende einen olivenförmigen Wulst 170 auf, dessen Außenumfang etwas größer ist als der Innenumfang des Klemmrings 168. Dieser Klemmring 168 ist jedoch so elastisch, daß er zusammen mit dem Schlauch 66 über den Wulst 170 geschoben werden kann und durch den Wulst 170 fest in Stellung gehalten wird.

Die in Fig. 6—8 gezeigte Pumpe 34 kann natürlich auch die in Fig. 3 gezeigte Außenwand 94 aufweisen, was durch die strichpunktierten Linien angedeutet ist.

Weiterhin ist es bevorzugt, daß der Schlauch 66 axial in der Pumpe 34 vorliegt. Vorteilhafterweise wird der Schlauch 66 um mindestens etwa 10% seiner Gesamtlänge in Axialrichtung gedehnt, um ein Zusammenfallen zu verhindern. In Verbindung mit der vorstehend beschriebenen Querdehnung im Endbereich wird dadurch ein voll aufgespannter Schlauch 66 in der Pumpe 34 erhalten. Hierdurch erreicht man eine bessere Aufblähbarkeit des Schlauchs 66 im Betrieb. Zugleich wird ein Zusammenkleben der Schlauchwände durch fortschreitende Vulkanisierung im Lagerzustand vermieden.

Die erfindungsgemäße Pumpe 34 läßt sich ohne Probleme sterilisieren und wird bereits in Verbindung mit dem Schlauchsystem einsatzbereit dem Patienten zur Verfügung gestellt. Bettseitig muß lediglich noch die Hubkolbenpumpe an die Pumpe 34 angeschlossen werden.

In Fig. 9 ist schematisch ein Pumpensystem 180 gezeigt, das für eine übliche Vorrichtung zur Hämodialyse eingesetzt werden kann, die mit zwei Nadeln arbeitet. In einem solchen System wird kontinuierlich Blut aus der Arterie über die Leitung 26 abgepumpt und über die Leitung 30 wieder der Vene zugeführt. Da jedoch die Pumpe 34 nicht kontinuierlich beladen und zugleich entladen werden kann, sind entsprechend der in Fig. 10 gezeigten Ausführungsform wenigstens zwei Pumpen 182 und 184 vorgesehen, die durch die Pumpen 186 und 188 angetrieben werden.

Dabei können die Pumpen 182 und 184 den Pumpen gemäß Fig. 2 oder Fig. 3 entsprechen, während die zum Einsatz kommenden Pumpen 186 und 188 in Form der vorstehend beschriebenen Hubkolbenpumpen vorliegen können.

Die Zuführungsleitung 26 verzweigt sich stromauf der beiden Pumpen 182 und 184 in wenigstens zwei Leitungsäste 190 und 192 und führt stromab der Pumpen 182 und 184 über zwei Leitungsäste 194 und 196 in die Leitung 30 zurück. An den Verzweigungspunkten ist jeweils eine Schalteinrichtung 200 und 202 vorgesehen mit der wechselweise die Leitungen 26 bzw. 30 mit einer der Leitungen 190 oder 192 bzw. 194 oder 196 verbunden werden können. Vorzugsweise sind die Schalteinrichtungen gegenläufig geschaltet, d. h., daß beim Füllen des einen Zweiges der andere Zweig geleert werden kann und umgekehrt.

Als Schalteinrichtungen 200 und 202 können Drei-Wege-Ventile, Doppelklemmen usw. in Frage kommen, die mit dem Umsteuerungszeitpunkt der Pumpen 186 und 188 synchronisiert sind. So können diese Schalteinrichtungen entweder durch Sensoren umgeschaltet werden, die zugleich die Pumpen umschalten, oder aber zwangsläufig am Totpunkt der Balgpumpen geschaltet werden.

Weiterhin kann es vorteilhaft sein, daß die Pumpen 186 und 188 zu einer Pumpe zusammengefaßt sind, beispielsweise zu einer Balgpumpe, die mit einer Kolbenstange zwei Bälge gegenläufig betätigt.

Es muß nicht hinzugefügt werden, daß bei dem in Fig. 9 gezeigten Pumpensystem eine Druck- und Zwangssteuerung möglich sind.

Die Ventile oder Absperrorgane 128 und 132 können in einer weiteren Ausführungsform auch ohne elektrische Verbindung mit der Balgpumpe 124 allein durch eine mechanische Betätigung, beispielsweise durch nicht gezeigte Nocken, die auf dem Balg oder vorteilhafterweise auf dem Kolben der Balgpumpe angebracht sind, gesteuert werden. Durch eine entsprechende Verschiebbarkeit dieser Nocken kann der zweckmäßige Öffnungszeitpunkt und damit der Druckwert in der Leitung 122 eingestellt werden.

Besonders zu beachten ist weiterhin, daß bei Alarm, insbesondere beim Lösen der Förderleitung 26, neben dem Abschalten der wichtigsten Organe auch die Arterienklemme 31 geschlossen wird, so daß die vollständige Sicherheit des Patienten hergestellt ist.

Hierzu 5 Blatt Zeichnungen

Solventum-Exhibit 1002-0588

ZEICHNUNGEN BLATT 2

Nummer: 32 05 449
Int. Cl.³: A 61 M 1/30
Veröffentlichungstag: 17. Oktober 1985

Fig. 2

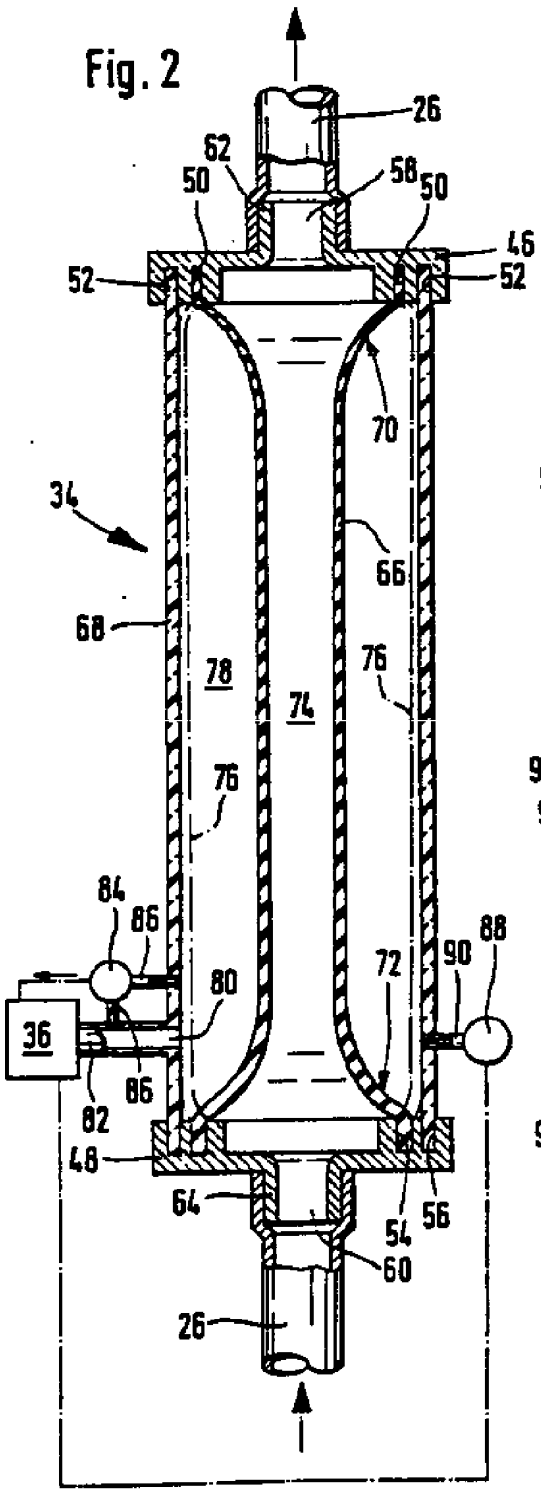
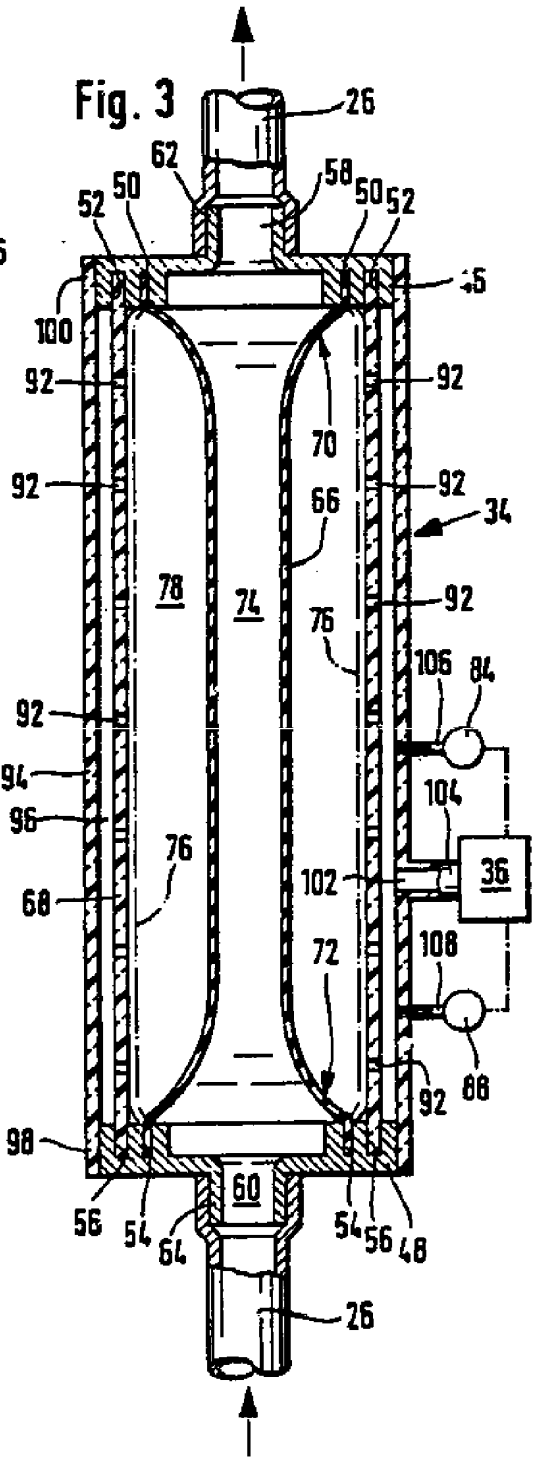


Fig. 3



Solventum-Exhibit 1002-0589

ZEICHNUNGEN BLATT 3

Nummer: 32 05 449
Int. Cl.³: A 61 M 1/30
Veröffentlichungstag: 17. Oktober 1985

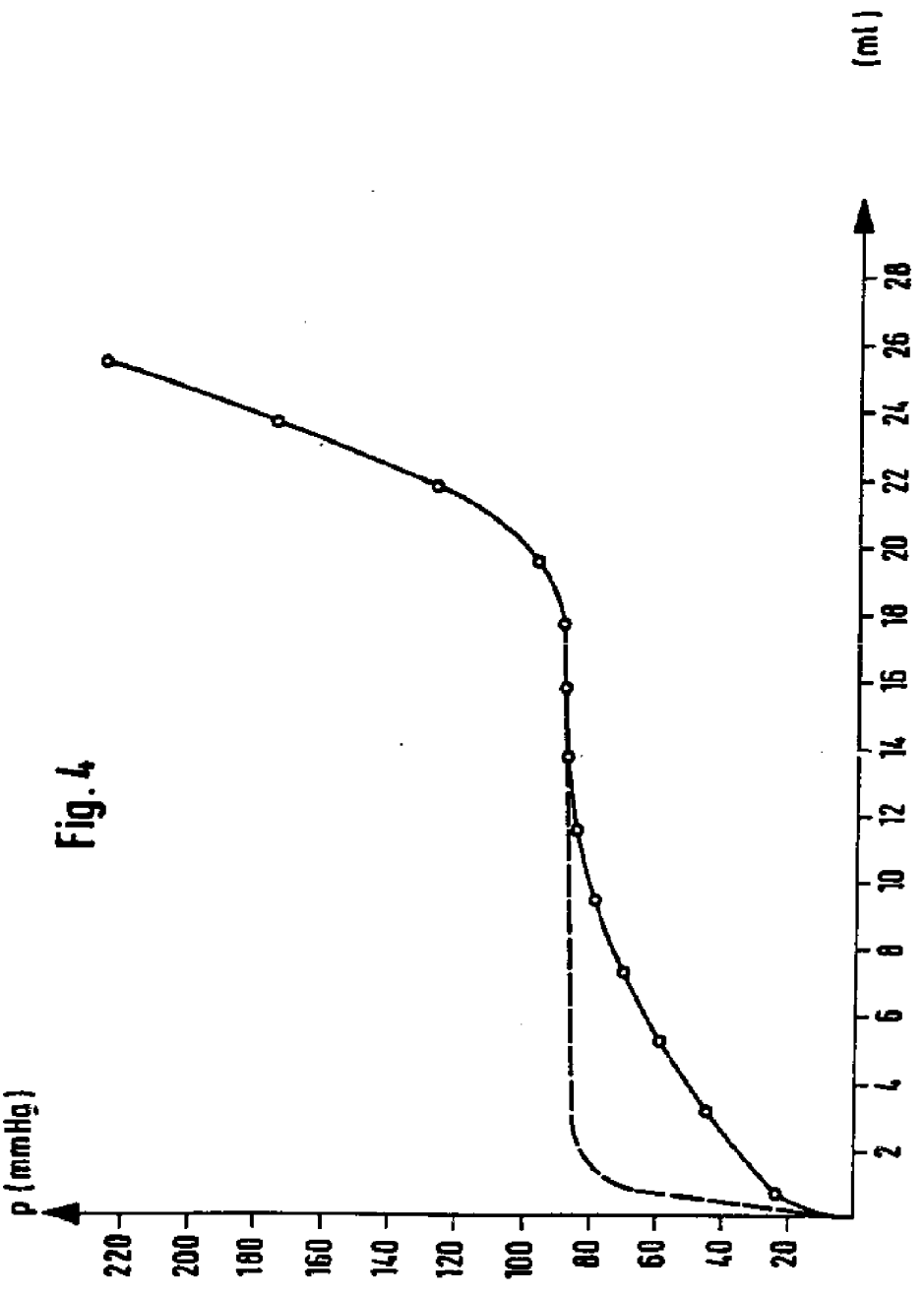


Fig. 4

Nummer: 32 05 449
Int. Cl.³: A 61 M 1/30
Veröffentlichungstag: 17. Oktober 1985

Fig. 5

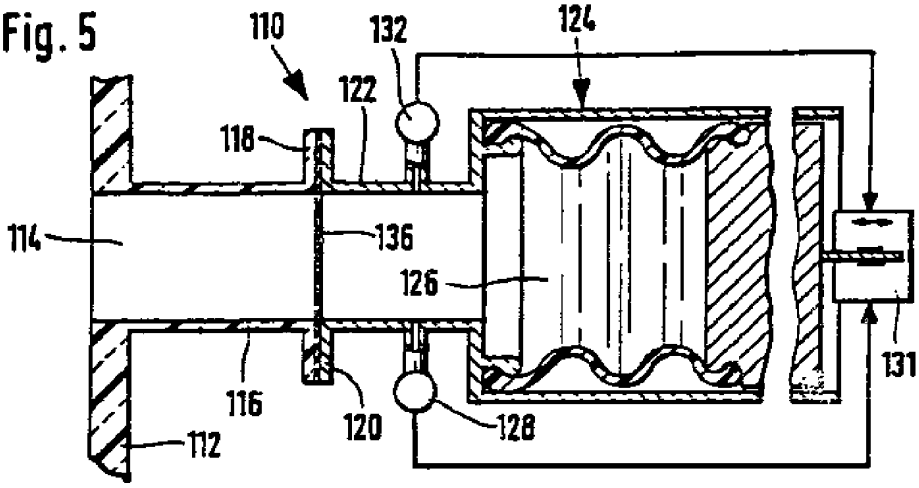


Fig. 6

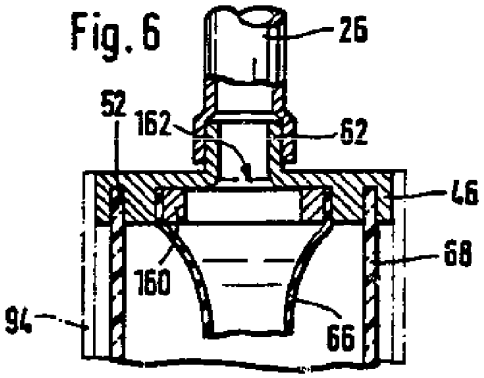


Fig. 7

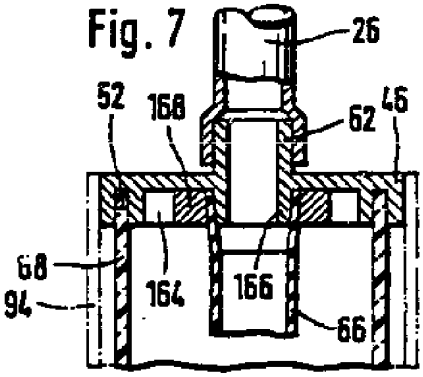
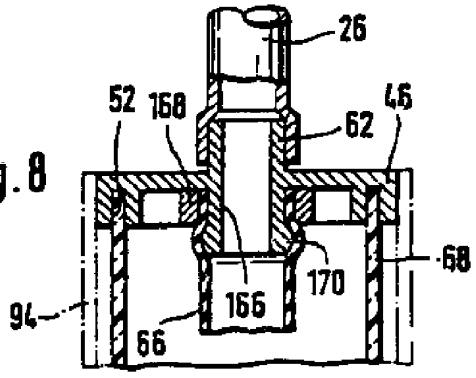


Fig. 8

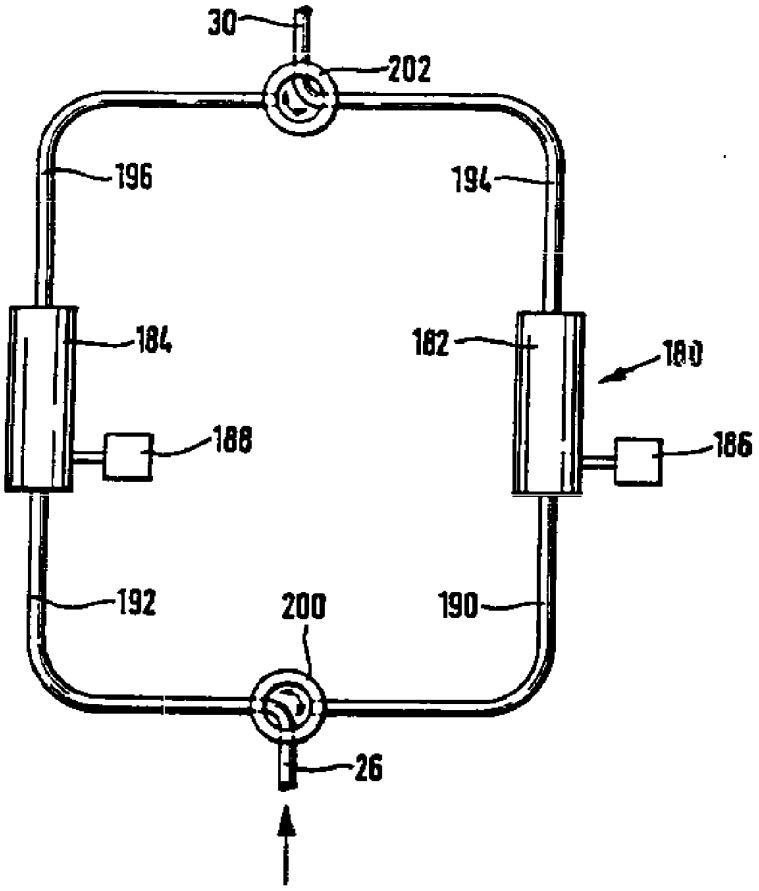


Solventum-Exhibit 1002-0591

ZEICHNUNGEN BLATT 5

Nummer: 32 05 449
Int. Cl.³: A 61 M 1/30
Veröffentlichungstag: 17. Oktober 1985

Fig. 9



Solventum-Exhibit 1002-0592

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/Lisa Elliott
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	10015761
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	04-MAY-2011
Filing Date:	24-JAN-2008
Time Stamp:	16:12:04
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	2879
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

Solventum Exhibit 1002-0593

1	Information Disclosure Statement (IDS) Filed (SB/08)	sb0008.pdf	611796 0134ec3887bffa207ee473d57ca0043c3d066a66	no	4
Warnings:					
Information:					
2	Abstract	ABSTRACT_DE3205445.pdf	64563 261c47698b07950d1bf35ea243ed9265d8b4d1b0	no	1
Warnings:					
Information:					
3	Foreign Reference	DE3205445.pdf	881229 8dc2f6215d2ee6b7f84f5710cd105319999845f8	no	30
Warnings:					
Information:					
4	Foreign Reference	DE3205449.pdf	800451 2d550117f6fdd9af02dc022321238d9ea23e4544	no	13
Warnings:					
Information:					
5	Fee Worksheet (PTO-875)	fee-info.pdf	29989 f1d17b6c4de87f21be2a552678ff08ad6490c754	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2388028		

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4108574		1978-08-22	BARTLEY, et al.	
	2	4208171		1980-06-17	JONSSON	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040015042	A1	2004-01-22	VINCENT, et al.	
	2	20050180868	A1	2005-08-18	MILLER	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

Solventum-Exhibit 1002-0597

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐
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EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Solventum-Exhibit 1002-0598

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-05-16
Name/Print	Susanne M. Hopkins	Registration Number	33247

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Solventum-Exhibit 1002-0599

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Solventum-Exhibit 1002-0600

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/Lisa Elliott
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	10092022
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	16-MAY-2011
Filing Date:	24-JAN-2008
Time Stamp:	15:04:07
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	1293
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /	Pages (if appl.)

Solvent Exhibit 1002-0603

1	Information Disclosure Statement (IDS) Filed (SB/08)	sb0008.pdf	611789 84bd40b6f41fc018528b3351d8de25c0b36d60cc	no	4
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29990 3185e502da8559101343c1b172128d59dc084e3d	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	641779	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11/989,297	Filing Date	2008-01-24	Docket Number (if applicable)	29068U	Art Unit	3761
First Named Inventor	Carmeli ADAHAN			Examiner Name	TREYGER, ILYA Y.		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☐ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No _____

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Solventum-Exhibit 1002-0605

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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Name	William L. Klima	Registration Number	32422

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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Solventum-Exhibit 1002-0606

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Solventum-Exhibit 1002-0607

Mail Stop AFTER FINAL
Attorney Docket No. 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli Adahan — Conf. No.: 4766

Application No.: 11/989,297 — Examiner: TREYGER, ILYA Y.

Filed: January 24, 2008 — Group Art Unit: 3761

For: WOUND CLOSURE AND DRAINAGE SYSTEM

AMENDMENT AND RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This paper is submitted responsive to the final Official Action dated April 20, 2011, along with a Request for Continued Examination (RCE) and a Petition for a one (1) month extension of time to extend the period to respond to August 22, 2011. Accordingly, this paper is timely filed.

Amendments to the Claims begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

A **Conclusion** appears at page 19 of this paper.

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows. This listing of claims replaces all prior version of the claims in this application.

1-10. (Canceled)

11. (Currently amended) An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.

12. (Canceled)

13. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement comprises one or more bleeding holes.

14. (Previously presented) The enclosure according to claim of claim 11, wherein said venting arrangement is provided in the form of a porous body.

15-33. (Canceled)

34. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement acts as a flow restrictor to provide, under the action of the vacuum source, a restricted flow of ambient air therethrough and along said tube.

35. (Previously presented) The enclosure according to claim 11, wherein said enclosure facilitates drainage of fluids exuded from the wound, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure.

36. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement provides for ambient air to enter said enclosure via said tube and for ambient pressure to be restored in said confined volume when the vacuum source is not operating.

37. (Previously presented) The enclosure according to claim 11, wherein in operation of the enclosure, ambient air enters the tube directly via said venting arrangement without entering said enclosure when negative pressure is being applied to the wound via said enclosure.

38. (Previously presented) A disposable assembly for applying negative pressure to a wound, the assembly comprising an enclosure as defined in claim 11 attachable to the wound circumference so as to define a confined volume, a vacuum pump unit of the vacuum pump connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit being configured for being detachably attached to a drive unit of the vacuum pump for operating the pump unit, and a waste container connected to said vacuum pump unit, wherein said enclosure is connected to an inlet of said vacuum pump unit via said tube and said waste container is connected to an outlet of said vacuum pump unit.

39. (Previously presented) A disposable assembly according to claim 38, wherein said assembly further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

40. (Previously presented) The disposable assembly according to claim 38, wherein said venting arrangement comprises one or more bleeding holes.

41. (Previously presented) The disposable assembly according to claim 38, wherein said venting arrangement is provided in the form of a porous body.

42. (Previously presented) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement, and further comprising a waste container in fluid communication with said vacuum source.

43. (Previously presented) The vacuum system of claim 42, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

44. (Previously presented) The vacuum system according to claim 42, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

45. (Previously presented) The vacuum system according to claim 44, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

46. (Previously presented) The vacuum system according to claim 42, wherein said venting arrangement comprises one or more bleeding holes.

47. (Previously presented) The vacuum system according to claim 42, wherein said venting arrangement is provided in the form of a porous body.

48. (Currently amended) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

49. (Previously presented) The vacuum system of claim 48, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

50. (Previously presented) The vacuum system according to claim 48, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said collection chamber being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

51. (Previously presented) The vacuum system according to claim 50, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

52. (Previously presented) The vacuum system according to claim 48, wherein said venting arrangement comprises one or more bleeding holes.

53. (Previously presented) The vacuum system according to claim 48, wherein said venting arrangement is provided in the form of a porous body.

REMARKS

Claims 11-13, 14, and 34-53 are pending in the application. Claims 11-14, and 34-53 are rejected.

Claim 12 is canceled above without prejudice or disclaimer of the subject matter contained therein. Claims 1–10, and 15-33 were previously canceled without prejudice or disclaimer of the subject matter contained therein. Claims 11 and 48 are amended above.

Support for the above amendments appears throughout the originally filed specification, claims, and drawings. Specifically, claims 11 and 48 have been amended to incorporate the subject matter of claim 12.

Applicant, by amending any claims herein, makes no admission as to the validity of any rejection made by the Examiner against any claim. Applicant reserves the right to reassert any of the claims canceled or the original scope of any claim amended herein, in a continuing application.

It is respectfully submitted that the above amendments to the claims introduce no new matter within the meaning of 35 U.S.C. §132. Accordingly, Applicant requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

I. Claims 11-13, and 35-37 stand rejected under 35 U.S.C. §102(e) as being anticipated by Lockwood et al. ("Lockwood", US 2005/0004534)as set forth in paragraph 7 on page 2 of the Official Action.

The Examiner asserts that claims 11-13, and 35-37 are anticipated under 35 U.S.C. §102(e) by Lockwood. This rejection is respectfully traversed.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. V. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Further, "when evaluating the scope of a claim, every limitation in the claim must be considered. U.S.P.T.O. personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered." *U.S.P.T.O. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, page 9, October 26, 2005. As the Federal Circuit stated, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Col.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

Claim 11 currently recites the limitation of the venting arrangement (which is outside of the enclosure) is such that "*ambient air can enter said tube via said venting arrangement and flow to said vacuum source* ***without entering said enclosure***."

Thus air sucked in through the venting arrangement goes **directly** to the pump under suction ***without passing through the enclosure***, and tends to dislodge any blockage in the tube, if present there.

The Examiner contends on page 3 of the Official Action that in Lockwood (US 2005/00045534) "*ambient air necessarily enters the tube 20 via the venting arrangement and flows to the vacuum source without entering the enclosure if negative pressure is applied…*".

Applicant respectfully submits that this is a fundamental misreading of Lockwood, which does not disclose or suggest such a feature at all.

Quite the contrary, Lockwood ***teaches away*** from the claimed subject matter recited in claim 11, the disclosed apparatus in Lockwood being structurally and functionally configured for ensuring that the ambient air is drawn in via vent 19 **has to flow over the wound** via the bandage 14 before flowing to the vacuum source, as supported by at least the following sections of Lockwood:

Paragraph [0068], lines 6 to 9:

> *"Venting provides for increased air **flow through bandage 14 and above or adjacent the wound** while vacuum source 16 applies suction to the wound"*

Paragraph [0069], lines 1 to 8:

"*Ventilation of the system 10, while drawing a negative pressure over the wound, acts to prevent the system 10 from becoming static by drawing air in from the surrounding atmosphere through vent 19, to bandage 14* ***to create air flow above the wound, and out through a vacuum tube*** *in communication with vacuum source 14. Therefore, venting the system 10* ***increases air flow above the wound while vacuum source 16 applies suction to the wound.***"

Paragraph [0081], lines 2 to 4:

"*As mentioned before, vent 19 provides increased air flow* ***through bandage 14 and above the wound***."

Paragraph [0124], lines 2 to 5:

"*As mentioned before with respect to vents 19 and 119, vent 219 provides increased* ***air flow through bandage 14 and above wound 200***."

Structurally, and referring to paragraph [0072] and Fig. 3 in particular, the bandage 14 includes a wound dressing member 12 having connector 15 coupled to tube 20 by a barbed tube coupler 11. Member 12 lies adjacent to and generally conforms to the wound

surface. Sealing film 13 is placed over member 12 and sealed around tube 20 to the patient's healthy skin 27 surrounding the wound, as shown in FIG. 1. Connector 15 is in communication with the wound by a plurality of passageways 66 of member 12 and a plurality of holes 67, each in communication with one of the passageways 66, formed in a bottom surface 68 of member 19. Tube coupler 11 connects inner lumen 22 of tube 20 with connector 15.

Each outer lumen 24 is open at an end 21 of tube 20, **this end 21 being positioned under sealing film 13 to communicate the end 21 with the wound** (paragraph [0081], lines 13 to 13). This allows air to be drawn in from the atmosphere through vent 19, to flow through outer lumens 24 and exit tube 20 at end 21, to circulate around member 12 to the wound surface, and to flow through the holes 67 and passageways 66 of member 12 into a vacuum/irrigation passageway 42 formed in part by lumen 22. The negative pressure created by vacuum source 16 causes air to flow through system 10 in this manner.

The flow path from the vent to the vacuum source is explicitly disclosed as follows in paragraph [0081], lines 5 to 19:

> *"The air flow path while vacuuming the system begins as **air is drawn in from the surrounding atmosphere into filter housing 40 of vent 19** and through filter 34. The air then travels through opening 46 into annular space 45 defined by outer conduit 38 and through outer lumens 24 of multi-lumen tube 20. The **air travels through the outer lumens 24 from vent end 23 of tube 20 to end 21 of tube 20, a portion of which is positioned under sealing film 13, to communicate with***

the wound. ***Vacuum source 16 then draws the air around wound dressing member 12*** *through passageways 66 at an open peripheral edge of member 12 and through holes 67 into passageways 66. Air is then drawn from passageways 66 into connector 15 of member 12, through barb 11, and through inner lumen 22 of multi-lumen tube 20* ***toward vacuum source 14.*** *"*

Thus, it is abundantly clear Lockwood teaches away from claim 11, which in contrast requires the ambient air to enter the tube via the venting arrangement and flow to the vacuum source ***without entering the enclosure***.

It is therefore respectfully submitted that claim 11 is not anticipated by Lockwood. For at least the reason that claim 11 is not anticipated by Lockwood, all claims depending from claim 11, directly or indirectly, are also submitted to be novel and inventive over this reference.

In view of the above, it is submitted that Lockwood does not teach each and every element of claims 11-13, and 35-37 are required for anticipation under 35 U.S.C. §102. Thus, the Examiner is respectfully requested to withdraw this rejection.

II. Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. ("Lockwood", US 2001/0004534), as set forth in paragraph 12 on page 4 of the Official Action.

The Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125USPQ416.*" This rejection is respectfully traversed.

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Lockwood is discussed in detail in the response set forth in paragraph 1 above.

Again, Lockwood does not teach or suggest the claimed subject matter, and teaches away therefrom.

In view of the foregoing, it is submitted that nothing in Lockwood renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

III. Claims 38-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. ("Lockwood", US 2001/0004534) in view of Argenta et al. ("Argenta", US 2001/0029956), as set forth in paragraph 13 on page 4 of the Official Action.

The Examiner asserts that "[It] would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Lockwood with the collection vessel, as taught by Argenta in order to store the exudates, as motivated by Argenta (page 4, [0036), lines 21-22).

The Examiner further asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the waste container to the outlet of the pump in order to position the container remotely from the patient, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70 (MPEP 2144.04 (VI-C)). These rejections are respectfully traversed.

Lockwood is discussed in detail in the response set forth in paragraph 1 above.

Argenta was cited, in combination with Lockwood, for obviousness in some of the claims that depend from claim11, and such rejections are therefore moot in view of the above. While not addressing whether or not such a combination is proper, it is to be noted that, as de facto agreed to by the Examiner, Argenta does ***not*** cure the deficiencies in Lockwood regarding claim 11.

Claim 48 has been amended in a similar manner to claim 11, and therefore the arguments above apply, *mutatis mutandis*, to claim 48 as well. It is therefore respectfully submitted that claim 48 is novel and inventive over Lockwood.

The combination of Lockwood and Argenta was also cited for obviousness in original claim 48. Argenta is relied on by the Examiner as disclosing a collection chamber, but as discussed above, Argenta does not cure the deficiencies in Lockwood regarding the feature that the "*ambient air can enter said tube via said venting arrangement and flow to said vacuum source* ***without entering said enclosure***".

It is therefore respectfully submitted that claims 38-53, in particular independent claim 48, are ***not*** taught or suggested by the combination of Lockwood and Argenta.

In view of the foregoing, it is submitted that nothing in Lockwood and Argenta, taken alone or together, render the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

GENERAL COMMENTS

It is to be noted that the feature "*ambient air can enter said tube via said venting arrangement and flow to said vacuum source* ***without entering said enclosure***" was already present in the claims (i.e. claim 12) and therefore was already considered and searched by the Examiner. In view of the above the application should now be in condition for allowance, and no further searching or consideration is required.

CONCLUSION

Applicant asserts that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicant's undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

/William L. Klima/
Susanne M. Hopkins
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Date: August 22, 2011
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PTO/SB/22 (07-09)
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** (*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*)	Docket Number (Optional) 29068U
Application Number 11/989,297	Filed January 24, 2008
For WOUND CLOSURE AND DRAINAGE SYSTEM	
Art Unit 3761	Examiner TREYGER, ILYA Y.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	
☑	One month (37 CFR 1.17(a)(1))	$130	$65	$ 65
☐	Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐	Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐	Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐	Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☑ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 14-0112.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 32,422

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/William L. Klima/ — Signature

August 22, 2011 — Date

William L. Klima — Typed or printed name

703-548-6284 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of one (1) forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/William Klima
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	65	65

Solventum-Exhibit 1002-0629

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**470**

Electronic Acknowledgement Receipt

EFS ID:	10787143
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/William Klima
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	22-AUG-2011
Filing Date:	24-JAN-2008
Time Stamp:	17:01:37
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$470
RAM confirmation Number	3697
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part / .zip	Pages (if appl.)

Solvent Exhibit 1002-063

1	Request for Continued Examination (RCE)	sb0030e_fill.pdf	797962 d2481f38b203dd9126873101803b823f6bed85b4	no	3
Warnings:					
Information:					
2		2011_08_22_ROA.pdf	139466 73794b4c7f7bcd1570b1818f6620bc611deb3ceb	yes	19

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Claims	2	8
	Applicant Arguments/Remarks Made in an Amendment	9	19

Warnings:					
Information:					
3	Extension of Time	sb0022.pdf	312959 368fe43b79bf1538d9b93aa05b27d747a5bfd824	no	2
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	31923 a2381abf12002e3efea18fa71335216da55238a0	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1282310	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6257847	B1	2001-07-10	SILVER, et al.	
	2	7255681	B1	2007-08-14	SILVER, et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Solventum-Exhibit 1002-0634

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Solventum-Exhibit 1002-0635

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-08-23
Name/Print	Susanne M. Hopkins	Registration Number	33247

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Solventum-Exhibit 1002-0636

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Solventum-Exhibit 1002-0637

Electronic Acknowledgement Receipt

EFS ID:	10792150
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	23-AUG-2011
Filing Date:	24-JAN-2008
Time Stamp:	12:17:43
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	SB08.pdf	611628 a738ee10e3e97c585b5339185077803d14e9f7d0	no	4

Warnings:	
Information:	

Solventum-Exhibit 1002-0638

Total Files Size (in bytes):	611628

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/989,297	01/24/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	08/22/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 23	Minus	** 33	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***5	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LYNNELL JOHNSON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Solventum-Exhibit 1002-0640

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	29068U	4766

20529 7590 10/11/2011

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
10/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Solventum-Exhibit 1002-0641

Office Action Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA TREYGER	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-10,12 and 15-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13,14 and 34-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Solventum-Exhibit 1002-0642

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 11/16/2010; 08/23/2011; 05/16/2011; 05/04/2011.

Solventum-Exhibit 1002-0643

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/24/2008 has been entered.

2. Claims 11 and 48 are amended.

3. Claim 12 is canceled.

4. Claims 11, 13, 14 and 34-53 are examined on the merits.

Response to Arguments

5. Applicant's arguments are substantially based on the fact that the reference of Lockwood does not disclose the venting arrangement capable of performing claimed functions.

This argument is found persuasive and rejection under 35 U.S.C. 102(b) has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Leffler (US 3,516,160).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11, 13 and 14 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534) in view of Leffler (US 3,516,160).

9. In Re claims 11, 14 and 35-37, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6).

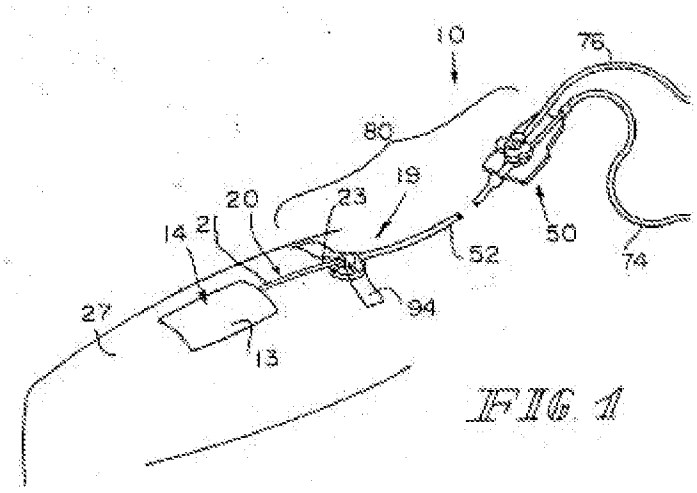


FIG 1

Lockwood does not expressly disclose the system, wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter the tube via the venting arrangement and flow to the vacuum source without entering the enclosure.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement outside of the wound area allowing the flow to the vacuum source without entering the wound area.

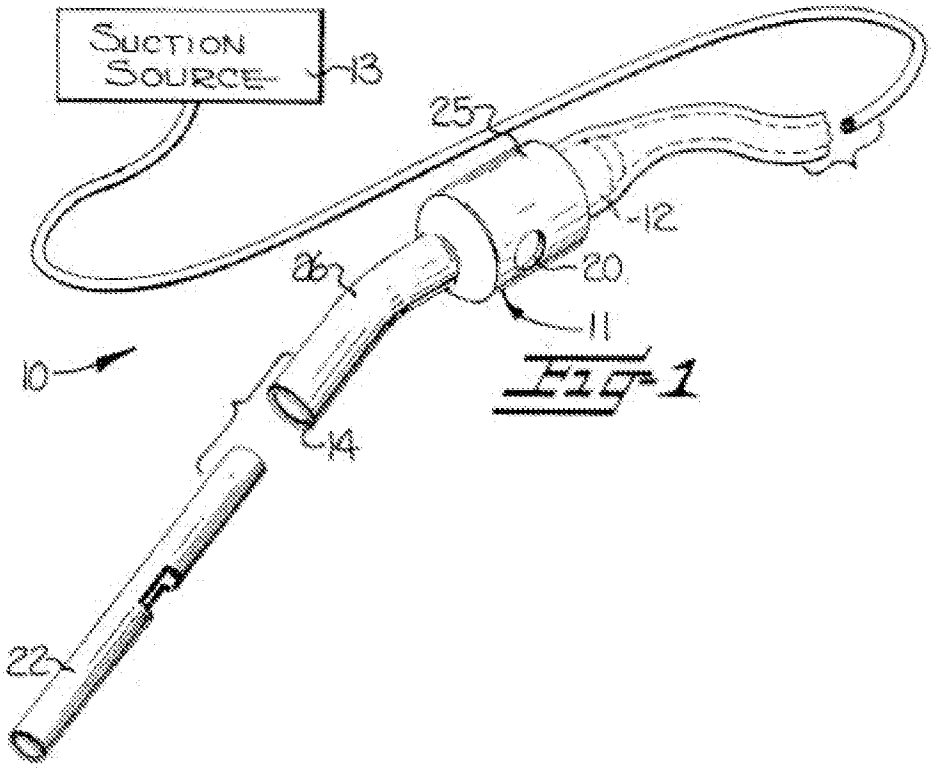


Fig. 1

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the suction tube of Lockwood with the venting arrangement, as taught by Leffler in order to control the flow in the tube, as motivated by Leffler (col. 4, lines 35-40).

10. In Re claim 13, Lockwood discloses the venting arrangement 19 (fig. 1) necessarily comprising a bleeding hole, since it has been disclosed as communicating with the surrounding atmosphere (Abstract, lines 7-8).

In Re claim 14, Lockwood discloses the invention discussed above, but does not expressly disclose the structure, wherein the bleeding holes are provided in the form of a porous body.

Since the porous body is a material comprising plurality of holes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process by using the material known in the art.

11. In Re claim 34, since the vent arrangement has been disclosed as being in communication with the ambient air, Lockwood discloses the vent arrangement that necessarily provides a restricted flow of ambient air therethrough and along the tube 20.

12. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534) in view of Leffler (US 3,516,160), as applied to claim 11 above, and further in view of Argenta et al. (US 2001/0029956).

13. In Re claim 38, 39, 43 and 49, Lockwood in view of Leffler disclose the invention discussed above but do not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Lockwood/ Leffler with the

collection vessel, as taught by Argenta in order to store the exudate, as motivated by Argenta (page 4, [0036], lines 21-22).

Lockwood in view of Argenta do not expressly disclose the apparatus wherein the waste container is connected to an outlet of the vacuum pomp unit.

Since shifting the position of the container would not have modified the operation of the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the waste container to the outlet of the pump in order to position the container remotely from the patient, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

14. In Re claims 40, 44, 46 and 52, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6).

Lockwood does not expressly disclose the assembly, wherein the venting arrangement comprises one or more bleeding holes.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement made in the form of bleeding hole.

The rationale of obviousness rejection discussed above in claim 11 is incorporated herein in its entirety.

In Re claims 41, 47 and 53, Lockwood in view of Leffler, and further in view of Argenta disclose the invention discussed above, as applied to claim 38, but do not expressly disclose the apparatus, wherein the bleeding holes are provided in the form of a porous body.

The rationale of obviousness rejection discussed above in claim 14 is incorporated herein in its entirety.

15. In Re claims 42, 45, 48 and 51, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6).

Lockwood does not expressly disclose the system, wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter the tube via the venting arrangement and flow to the vacuum source without entering the enclosure.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement outside of the wound area allowing the flow to the vacuum source without entering the wound area.

The rationale of obviousness rejection discussed above in claim 11 is incorporated herein in its entirety.

Lockwood in view of Leffler do not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

The rationale of obviousness rejection discussed above in claim 38 is incorporated herein in its entirety.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

Notice of References Cited	Application/Control No. 11/989,297	Applicant(s)/Patent Under Reexamination ADAHAN, CARMELI	
	Examiner ILYA TREYGER	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-3,516,160	06-1970	LEFFLER DENNIS F	433/95
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	Q					
	R					
	S					
	T					

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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Solventum-Exhibit 1002-0651

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

SEARCHED

Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES

Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.
Search updated	4/15/2011	I. T.
Search updated	9/26/2011	I. T.

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

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CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE / RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************ I.T. 06/22/2010**

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07/08/2009

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☑ Yes ☐ No	☐ Yes ☐ No	/ILYA Y TREYGER/ Examiner's Signature	☐ Initials	ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Solventum-Exhibit 1002-0653

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4552552		1985-11-12	POLASCHEGG, et al.	corresponds to DE 32 05 449 C2

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	1	32 05 445	DE	A1	1983-08-25	Fa. Wilhelm Schade	English Abstract attached separately	☒
	2	32 05 449	DE	C2	1983-09-01	Fresenius AG	corresponds to US 4,552,552	☐

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Solventum Exhibit 1002-0654

Receipt date: 05/04/2011	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Examiner Signature	/Ilya Treyger/	Date Considered	09/26/2011

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Solventum Exhibit 1002-0655

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(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4108574		1978-08-22	BARTLEY, et al.	
	2	4208171		1980-06-17	JONSSON	

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	1	20040015042	A1	2004-01-22	VINCENT, et al.	
	2	20050180868	A1	2005-08-18	MILLER	

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Solventum-Exhibit-1002-0636

Receipt date: 05/16/2011	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

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Solventum Exhibit 1002-0657

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6257847	B1	2001-07-10	SILVER, et al.	
	2	7255681	B1	2007-08-14	SILVER, et al.	

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Solventum-Exhibit 1002-0658

Receipt date: 08/23/2011	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Examiner Signature	/Ilya Treyger/	Date Considered	09/26/2011

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Solventum-Exhibit-1002-0659

Receipt date: 08/23/2011			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Application Number	11989297	11989297 - GAU: 3761
	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-08-23
Name/Print	Susanne M. Hopkins	Registration Number	33247

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Solventum Exhibit 1002-0660

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Solventum Exhibit 1002-0661

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011	09/26/2011						
	1	-	-	-						
	2	-	-	-						
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	9	-	-	-						
	10	-	-	-						
	11	✓	✓	✓						
	12	✓	✓	-						
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	23	-	-	-						
	24	-	-	-						
	25	-	-	-						
	26	-	-	-						
	27	-	-	-						
	28	-	-	-						
	29	-	-	-						
	30	-	-	-						
	31	-	-	-						
	32	-	-	-						
	33	-	-	-						
	34		✓	✓						
	35		✓	✓						
	36		✓	✓						

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