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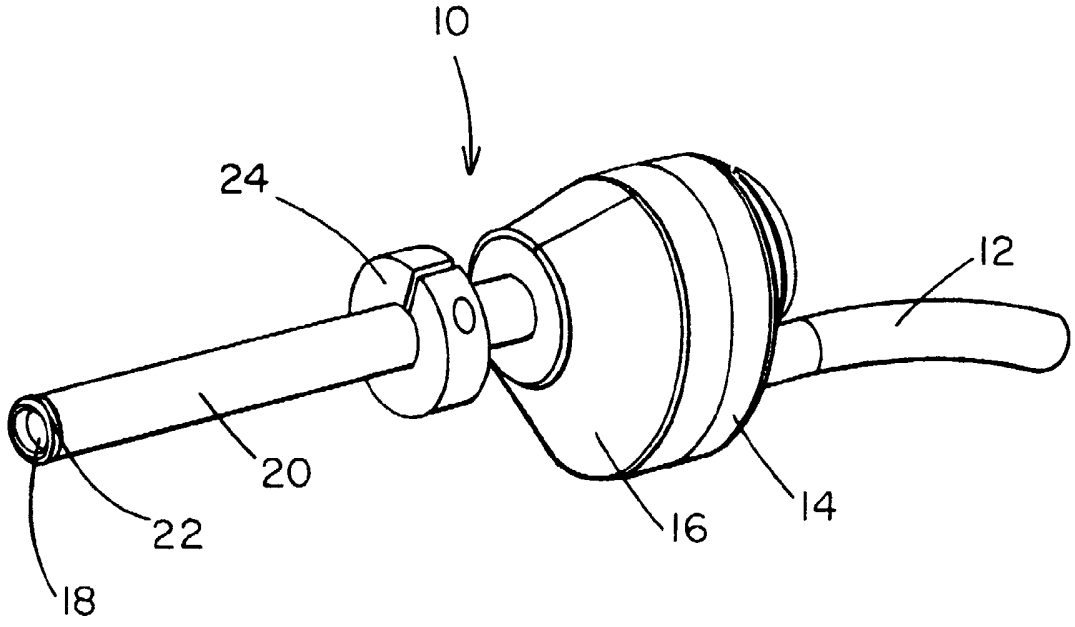
(54) Title: NOZZLE FOR STOMA CLEANSING SYSTEM



(57) Abstract: A cleansing system for the intestine of a patient includes a pumping system adapted to provide pulses of a cleansing fluid at a controlled rate and an annular fluid channel in fluid communication with the pumping system. The annular fluid channel serves as a fluid conduit between the body cavity to be cleansed and the exterior of the body. A delivery system includes a nozzle assembly (10), the nozzle assembly having at least two lumens (54, 154, 254, 56, 156, 256) through which the cleansing fluid exits the nozzle assembly, the at least two lumens being arranged at an angle relative to the annular fluid channel (18).

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NOZZLE FOR STOMA CLEANSING SYSTEM

FIELD OF THE INVENTION

The present invention relates generally to a system and method for cleansing An internal body cavity, and, more particularly, to a system for an irrigating a colon through a to remove fecal material.

BACKGROUND OF INVENTION

It is well known that individuals having surgically created stomas have some special needs associated with evacuation of bowel contents through the stoma. The need for a gentle irrigation method that aggressively breaks up intestinal contents without damaging the fragile intestinal lining has prevented prior devices from being able to successfully and safely facilitate rapid bowl evacuation. Irrigation, especially on a repeated basis, can compromise mucous linings, resulting in actinic changes to mucous membrane tissue. Use of known systems for irrigation of a body cavity, typically a colon, takes a long time, which can be very disruptive of the user's life-style. It is therefore desirable to provide a system that produces gentle irrigation, while at the same time permitting aggressive break up of the matter to be removed.

Attempts to develop systems that are considered to be gentle on tissue typically consist of gravity feed bags with a single lumen and steady flow rate nozzle. These systems are very slow and generally used by caregivers, rather than by the patient for irrigation.

A known electro-mechanical system, Pulsed Irrigation and Evacuation (PIE), pumps a very large volume of water (such as about 11.5 – to about 19 liters) at a flow rate of two to three liters per minute. The water is pumped into the colon through a specula inserted into the rectum or stoma. The water is pumped in in aliquots (25 – 1—ml) that repeatedly fill and empty the colon at a very rapid rate (e.g. one to four second cycles). This system is far too aggressive to be used on a regular basis, except in sever cases of chronic bowel impaction, where alternatives are limited. These cases include patients with chronic neurogenic bowel due to spinal chord injury or disease. Thus, the PIE system is too aggressive for widespread use, and is limited to cases where other, less aggressive or less invasive alternatives do not exist. The present invention provides a mechanism for addressing the above problems.

SUMMARY OF INVENTION

An aspect of the present invention, briefly, is a cleansing system for the intestine of a patient. The system includes a pumping system adapted to provide pulses of a cleansing fluid at a controlled rate and an annular fluid channel in fluid communication with the pumping system. The annular fluid channel serves as a fluid conduit between the body cavity to be cleansed and the exterior of the body. A delivery system includes a nozzle assembly, the nozzle assembly having at least two lumens through which the cleansing fluid exits the nozzle assembly, the at least two lumens being arranged at an angle relative to the annular fluid channel.

Another aspect of the present invention is to provide a nozzle assembly comprising a nozzle body housing a nozzle body cavity; an inlet port in fluid communication with the nozzle body cavity; an annular fluid channel in fluid communication with the nozzle body cavity; and a nozzle tip having at least two lumens in fluid communication with the fluid channel.

A further aspect of the present invention is a method for cleansing a stoma comprising providing a cleansing fluid stream to a nozzle assembly, the nozzle assembly having a central axis; pulsing the cleansing fluid stream; and discharging the pulsed fluid stream from the nozzle assembly through at least two lumens at an angle to the axis of the nozzle.

These and other aspects and advantages of the invention will be in part apparent and in part pointed out herein below. These are merely illustrative aspects of the present invention and should not be deemed an all-inclusive listing of the innumerable aspects associated with the present invention.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of the nozzle assembly of the present invention.

FIG. 2 is a cross-sectional view taken along line 2-2 of FIG. 1.

FIG. 3 is a perspective view of the interior of transition hub of the nozzle assembly of FIG. 1.

FIG. 4 is a perspective view of the exterior of the transition hub of FIG. 3.

FIG. 5 is a perspective view of the interior of the hubcap of the nozzle assembly of FIG. 1.

FIG. 6 is a perspective view of the exterior of the hubcap of FIG. 5.

FIG. 7 is a perspective view of the distal end of the nozzle assembly of FIG. 1 illustrating an embodiment having three lumens.

FIG. 8 is a perspective view of the distal end of the nozzle assembly of FIG. 1 illustrating an embodiment having two lumens.

FIG. 9 is a perspective view of the distal end of the nozzle assembly of FIG. 1 illustrating an embodiment having four lumens.

FIG. 10 is a cross-sectional view illustrating the angular projection of the lumen in a preferred embodiment.

FIG. 11 is a perspective view of the irrigation tubing assembly of the present invention.

FIG. 12 is an exploded view of the irrigation tubing assembly of FIG. 11.

FIG. 13 is a cross-sectional view along line 13-13 of FIG. 11.

DETAILED DESCRIPTION

The present invention is a cleansing system method and apparatus for irrigation of a cavity for the removal of solid and colloidal matter. This invention has utility to a wide variety of industrial, medical and cosmetic applications. Without straying from the broad intent of this invention, a medical application of the technology will be used for illustration.

A nozzle assembly, generally designated 10, is shown in FIGS. 1 and 2. Nozzle assembly 10 comprises the main component of a delivery system. Nozzle assembly 10 is connected to a pumping system, not shown, by a polyethylene tube, 12. Assembly 10 further includes a transition hubcap 14 and a transition hub 16, shown in more detail in FIGS. 3 through 6, discussed below. Inner and outer nozzle tubes 18, 20 respectively, nozzle tip 22 and location collar 24 complete the basic nozzle assembly 10.

FIGS. 3 and 4 illustrate the transition hub 16 in detail. Transition hub 16 includes a central aperture 26, threaded screw acceptors 28 and 30 and a shoulder 32. FIGS. 5 and 6 illustrate transition hubcap 14, including a central aperture 34 and associated projecting shoulder 35, and screw apertures 36 and 38. Transition hubcap 14 further includes a cleansing fluid inlet port 42, an opposing projection 40, and a shoulder 44.

Nozzle tip 22 includes a front face 48, an inner projecting portion 52 and an outer projecting portion 50, best seen in FIGS. 7 through 10. A variety of nozzle assemblies have been devised that demonstrate varying levels of performance and can be selected from for use, depending upon the particular application. In a first embodiment, illustrated in FIG. 7, the front face 48 includes three apertures, or lumens 54, 56 and 58, formed as a result of cutting or machining fluid lumens in the nozzle body. The angle of the lumens relative the axis of the nozzle tubes 18, 20, is shown in FIG. 10. This angle results in discharge of the fluid stream from nozzle tip 22 at a preferred 60° angle relative to the axis of the nozzle tubes 18, 20. An acceptable range for the angle of the discharge of fluid stream relative to the axis of the nozzle tubes is within about 30° to about 60°. The purpose of this angle is to impart a swirling action to the fluid as it exits the nozzle assembly, and may be varied depending on the particular application. The fluid discharging lumens are fed pulses intermittently in sequence or simultaneously, as preferred. This provides a swirling ("vortex") action that imparts a shearing action to the matter to be broken up, which causes it to break into clumps. Elements which are particularly critical in creating this vortex effect are: 1) the angulation of the orifices, combined with 2) pulsatile (sequential) flow and 3) a plurality of angled lumens and 4) the energy of the fluid streams. The intermittent action of the pulse provides a "jack hammer" action to further break up the clumps. Similarly, with only simultaneous flow out of the same nozzle design there is created only the "jack hammer" action, which has not proven to be as effective in breaking up clumps if all other parameters (i.e. orifice angle, number of orifices and energy of fluid streams) remain constant.

Another factor which importantly affects the effectiveness of the fluid stream in breaking up fecal clumps is the size of the lumen orifices. In order for the proper nozzle stream velocity to be obtained the orifices should be in the range of about 1.0 mm to about 0.5 mm in diameter. The overall construction of the transition hub and hubcap (the "manifold" system) is designed to provide equivalent flow out of each orifice. The integration of the nozzle with the manifold is constructed to provide such equivalent flow.

In an alternative embodiment, this nozzle assembly may be fitted with an additional lumen to provide access to the body cavity into which the nozzle is placed

for the purpose of facilitating the monitoring pressure or temperature. Particularly the monitoring of pressure within the body cavity as necessary for safety reasons, to prevent the possible rupture of the body cavity.

In another embodiment, illustrated in FIG. 8, front face 148 includes two apertures, or lumens, 154, 156, located opposite each other on the periphery of the nozzle tube. These are fed fluid by the pumping system in either alternating intermittent or simultaneous pulses. Use of this nozzle permits matter to be broken up by "batting" it back and forth with the pulses of fluid. In an alternate embodiment, not shown, this nozzle assembly may also include a lumen to provide access to the body cavity into which the nozzle is placed for the purpose of facilitating the monitoring pressure or temperature, as described above.

In yet another embodiment, illustrated in FIG. 9, front face 248 includes four apertures or lumens 254, 256, 258 and 260 equally spaced apart around the periphery of the nozzle exit. This nozzle configuration permits aggressive pulsating application of fluid to permit effective break up of the contents of a body cavity without damage to the neighboring tissue. In an alternative embodiment, not shown, the nozzles are preferably arranged in two pairs, each pair being operated in sequence with the opposite pair. The first pair imparts a clockwise swirl to the fluid, while the second pair imparts a counterclockwise flow to the fluid. The resultant action of operating these pairs of pulsejets in and out of phase sequence is to impart additional shear to the target matter resulting in rapid breakup of the target material. This assembly can also be fitted with pressure/temperature sensing/communicating lumens and a central drain tube as in the other nozzle assemblies. Other constructions and variation of the described nozzles and pumping systems can be conceived which are considered to be within the scope of the invention, such as varying the number of lumens in each set.

As is best seen in the cross-sectional view FIG. 2, the irrigation tube 12 is connected to transition hubcap 14 through projection 40. Transition hub 16 and hubcap 14 are attached to each other along shoulders 32 and 44, respectively, by a silicon seal, not shown, and are held in place by screws extending through screw apertures 36, 38 into screw acceptors 28, 30. Transition hub 16 and hubcap 14 form a nozzle body that houses a cavity 44, the cavity being is in fluid communication with irrigation tubing 12 through projection 40.

Central apertures 26, 34 accept the inner nozzle tube 18, which is open to the atmosphere through central aperture 34. The interior of inner nozzle tube 18 and central aperture 34 may be adapted to provide a relatively large central drain hole in the middle of the nozzle assembly that can be gravity fed, pressure fed or vacuum evacuated, as desired. The purpose of such adaptation is to drain the matter broken up by the nozzle along with the irrigation fluid from the body cavity. Outer nozzle tube is located coaxially around inner nozzle tube, and is sealed at the projecting shoulder 35 of hubcap 14. The coaxial arrangement of inner and outer nozzle tubes 18, 20 forms an annular space 46, that is in fluid communication with cavity 44. Nozzle tubes 18, 20 are connected to nozzle tip projecting portion 50, seen in FIG. 10, by any suitable means, for example by silver solder bonding when the components are formed from metal.

In operation, a cleansing fluid stream is provided to the nozzle assembly through irrigation tubing 12 and into cavity 46 through projection 40. The fluid fills cavity 46 and is then forced into annular flow channel 48 and discharged through nozzle tip lumens 54, 56, 58. This nozzle system also provides for the draining of the irrigated area through a relatively large drain tube that can be inserted into inner tube 18 through central aperture 34. The drain tube can be left open or intermittently closed as conditions warrant.

Attached downstream of irrigation tubing 12 is an irrigation tubing assembly generally designated 50, shown in FIGS. 11 through 13. Tubing assembly 50 allows the internal pressure to be monitored in order to detect flow blockage or leakage.

Tubing 52 is attached to connector 54, pressure sensor housing 56, connectors 58, 60, circuit board 62 and pressure sensor 64. The electronic pressure monitor and associated circuit board may be of any conventional design, as is well known by those in the art.

Nozzle assembly 10 is connected to a pumping system, not shown, through irrigation tubing assembly 50. In one embodiment, the new system utilizes a peristaltic pumping mechanism, which insures hygienic fluid delivery. This system may provide a motor controller capable of on/off temperature control of the pump mechanism and an internal pressure monitoring system for pump flow blockage or leakage detection. This monitoring system may be coupled with an intra-lumenal

pressure sensor referenced to atmospheric pressure for the purpose of monitoring the anatomical cavity pressures associated with the nozzle portion of the device. An example of this type of pumping system is described in U.S. Patent Ser. No. 09/362,638, filed July 28, 1999.

Suitable pumping systems provide for independent adjustment of pressure and flow rate as well as adjustment of pulse rate. Other adjustments may include flow rate, pulse duration, pulse volume, total volume, time between pulses or dwell time. Preset parameters may include pressure of fluid delivery, fluid velocity as dictated by number, size and orifice geometry of flow lumens at any given flow rate, and temperature of liquid being delivered.

An alternate embodiment of the pumping system generates fluid pressure, which is stored in a bladder type tank. In this case the pump is controlled by an adjustable pressure-sensing switch. The fluid is directed from the bladder storage tank to a motor operated pulsing mechanism. One embodiment includes a series of cam operated valves, the inputs of which are connected by a fluid bus to the bladder tank. The output from each valve is independently directed to the fluid delivery nozzle assembly through separate tubes. The duty cycle of each pulse is controlled by a combination of the cam design and the location of the valves relative to the cam. One embodiment has two separate cams and sets of valves, provided to allow the use of any of the nozzle assemblies. The cams of this embodiment are motor-operated with a motor the speed of which is user controllable. This embodiment also includes a tachometer to measure and display the rotational speed of the cam, thus allowing the user to precisely adjust the speed of the pulses. An additional feature is the ability to provide a steady flow to all of the fluid conduits simultaneously. Additionally, this embodiment also provides the ability to have a user-selectable off-dwell period during which no pumping occurs.

While specific embodiments have been shown and described, many variations are possible. Additional variations within the scope of the invention are as follows. Nozzle bodies can be formed of rigid fabrication or flexible material fabrication, or combinations thereof to achieve conformance to passages (such as a stoma tract) used for nozzle insertion, drain configurations and fluid lumen geometry. Fluid lumens

may be of separate tubing configurations, further defined as a nozzle by jacketing, joining or insert molding such tubing sections into nozzle forms.

Additionally, the nozzle body can be integral to a catheter, stint or port structure (see, e.g., U.S. Patent 6,033,390) wherein the catheter, stint or port provides a permanent or semi-permanent fluid communication between the body cavity and the atmosphere and is connected to the pumping device via the irrigation set when it is desired to irrigate the body cavity.

Nozzle orifices have been defined as being formed as a result of cutting or machining fluid lumens in a nozzle body material and exposing lumen openings for fluid escapement. However, lumens may also be formed from separate components inserted into nozzle lumens to effect a defined orifice and pattern of fluid escapement. Such orifice articles are easily built in plastics and metals.

Pump sequences can include the continuous or intermittent delivery of fluids with uninterrupted drain flow, periodic drain flow, or no drain flow until delivery of fluids is complete. Dwell periods may be utilized for further dissolution and wetting of effected masses at any stage of the pump sequence wherein pulsation or supply flow is not occurring.

While suitable materials for constructing the present invention have been disclosed, the components may be made of any suitable, medically acceptable material.

In view of the foregoing, it will be seen that the several aspects of the invention are achieved and other advantages are attained. Thus, there has been shown and described several embodiments of a system a system and method for cleaning a stoma, which system and method fulfill all of the aspects and advantages sought therefore. As is evident from the foregoing description, certain aspects of the present invention are not limited by the particular details of the examples illustrated herein, and it is therefore contemplated that many changes, modifications, variations and other uses and applications of the present invention, including equivalents thereof, will become apparent to those skilled in the art after considering this specification and the accompanying figures. All such changes, modifications, various and other uses and applications which do not depart from the spirit and scope of the invention are

deemed to be covered by the invention which is limited only by the claims which follow.

Claims:

1. A cleansing system for the intestine of a patient, the system comprising:

a pumping system adapted to provide pulses of a cleansing fluid at a controlled rate;

an annular fluid channel in fluid communication with the pumping system, the annular fluid channel serving as a fluid conduit between the body cavity to be cleansed and the exterior of the body; and

a delivery system including a nozzle assembly, the nozzle assembly having at least two lumens through which the cleansing fluid exits the nozzle assembly, the at least two lumens being arranged at an angle relative to the annular fluid channel.

2. The cleansing system of claim 1 wherein the pumping system comprises a peristaltic pump.

3. The cleansing system of claim 1, and further comprising an additional lumen within the nozzle to act as a condui9t through which to monitor the internal pressure of the body cavity of the patient.

4. The cleansing system of claim 1 wherein the nozzle assembly comprises

a nozzle body housing a nozzle body cavity ;

an inlet port in fluid communication with the nozzle body cavity;

an annular fluid channel in fluid communication with the nozzle body cavity; and

a nozzle tip having at least two lumens in fluid communication with the fluid channel.

5. The cleansing system of claim 4 wherein the at least two lumens comprises three lumens arranged at an angle relative the annular fluid channel.

6. The cleansing system of claim 4 wherein the at least two lumens comprises two lumens arranged at an angle relative the annular fluid channel.

7. The cleansing system of claim 4 wherein the at least two lumens comprises four lumens arranged at an angle relative the annular fluid channel.

8. The cleansing system of claim 4 wherein the nozzle body and nozzle body cavity are formed by the interconnection of a transition hub and a transition hub cap.

9. The cleansing system of claim 4 wherein the annular fluid channel is formed between an inner nozzle tube and an outer nozzle tube in coaxial arrangement.

10. A nozzle assembly comprising

a nozzle body housing a nozzle body cavity ;

an inlet port in fluid communication with the nozzle body cavity;

an annular fluid channel in fluid communication with the nozzle body cavity;

a nozzle tip having at least two lumens in fluid communication with the fluid channel and arranged at an angle relative the annular fluid channel.

11. The nozzle assembly of claim 10 wherein the at least two lumen comprises three lumens.

12. The nozzle assembly of claim 10 wherein the at least two lumens comprises two lumens.

13. The nozzle assembly of claim 10 wherein the at least two lumens comprises four lumens.

14. The nozzle assembly of claim 10 wherein the nozzle body and nozzle body cavity are formed by the interconnection of a transition hub and a transition hubcap.

15. The nozzle assembly of claim 10 wherein the annular fluid channel is formed between an inner nozzle tube and an outer nozzle tube in coaxial arrangement.

16. A nozzle assembly comprising

a nozzle body housing comprising a transition hub and a transition hubcap connected to form a nozzle body cavity ;

an inlet port in fluid communication with the nozzle body cavity;

an annular fluid channel in fluid communication with the nozzle body cavity, the annular fluid channel being formed between an inner nozzle tube and an outer nozzle tube in coaxial arrangement; and

a nozzle tip having at least two lumens in fluid communication with the fluid channel, and arranged at an angle relative to the annular fluid channel..

17. The nozzle assembly of claim 16 wherein the at least two lumens comprises three lumens.

18. The nozzle assembly of claim 16 wherein the at least two lumens comprises two lumens.

19. The nozzle assembly of claim 16 wherein the at least two lumens comprises four lumens.

20. A method for cleansing a stoma comprising:

providing a cleansing fluid stream to a nozzle assembly, the nozzle assembly having a central axis;

pulsing the cleansing fluid stream; and

discharging the pulsed fluid stream from the nozzle assembly through at least two lumens being arranged at an angle to the axis of the nozzle, to discharge the pulsed fluid stream at an angle relative to the annular fluid channel.

21. The method of claim 20 further including monitoring the cleansing fluid stream pressure.

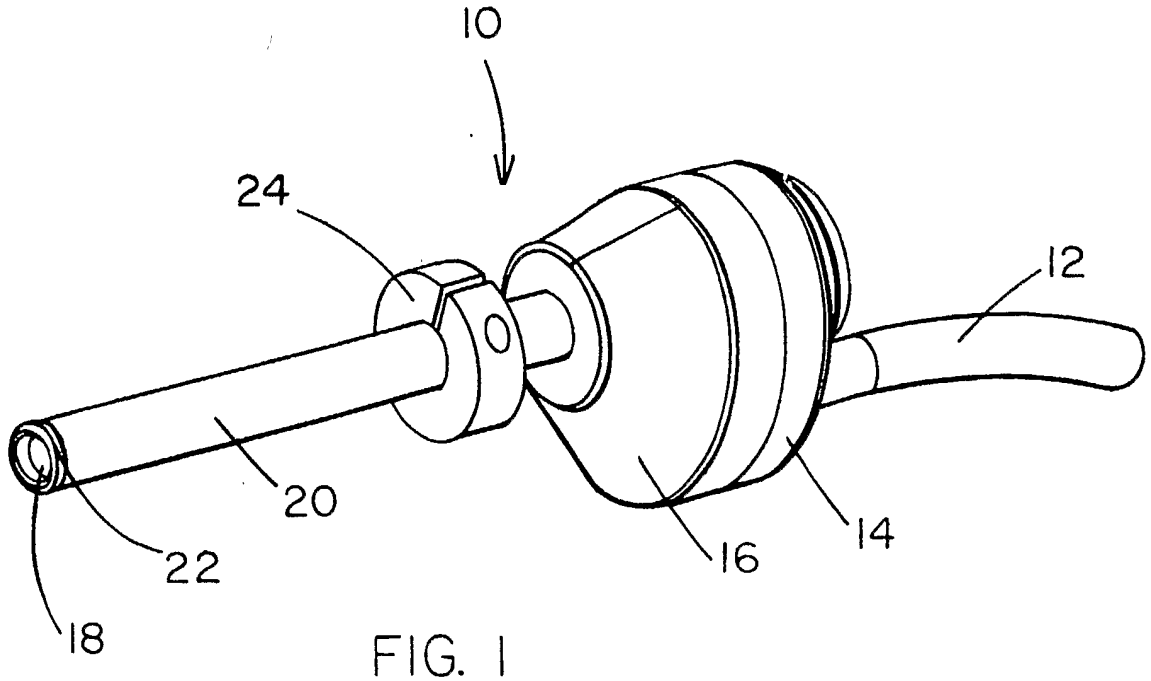

FIG. 1

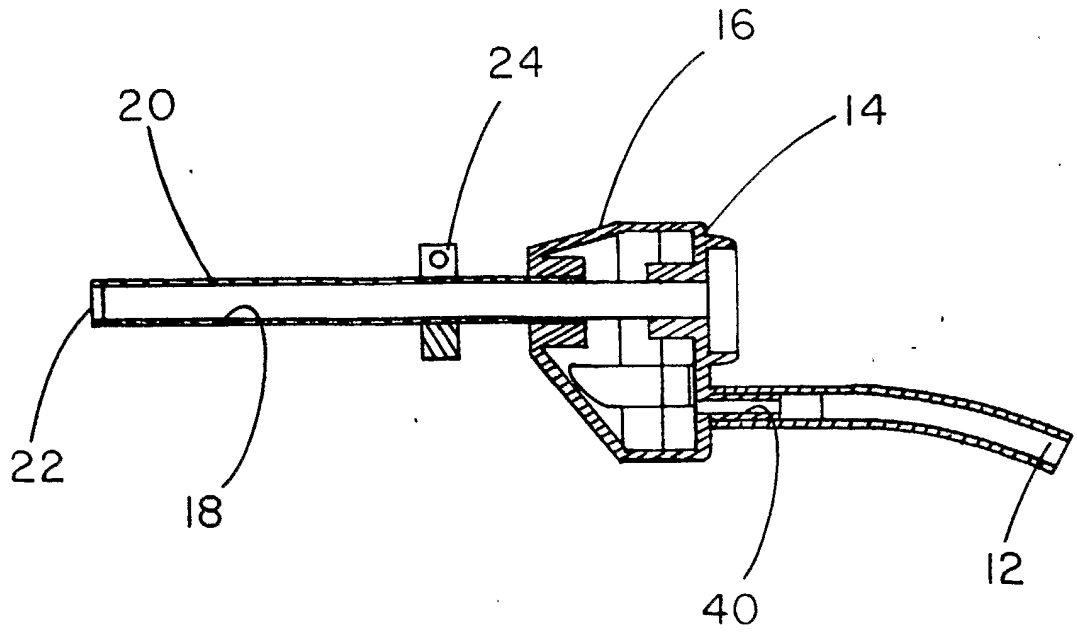

FIG. 2

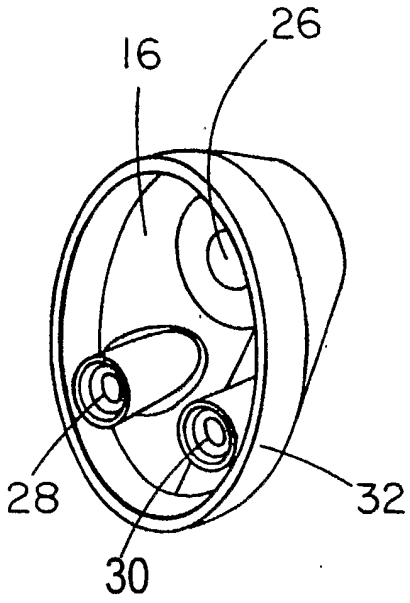

FIG. 3

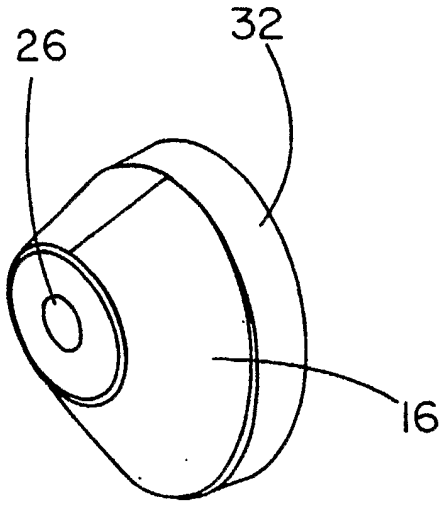

FIG. 4

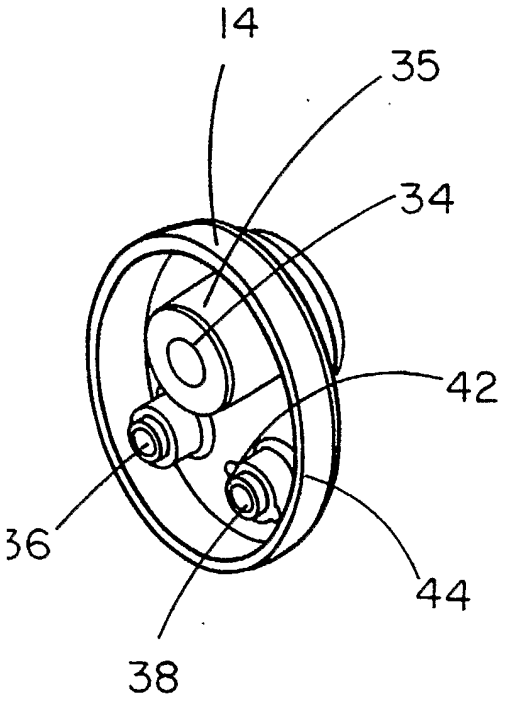

FIG. 5

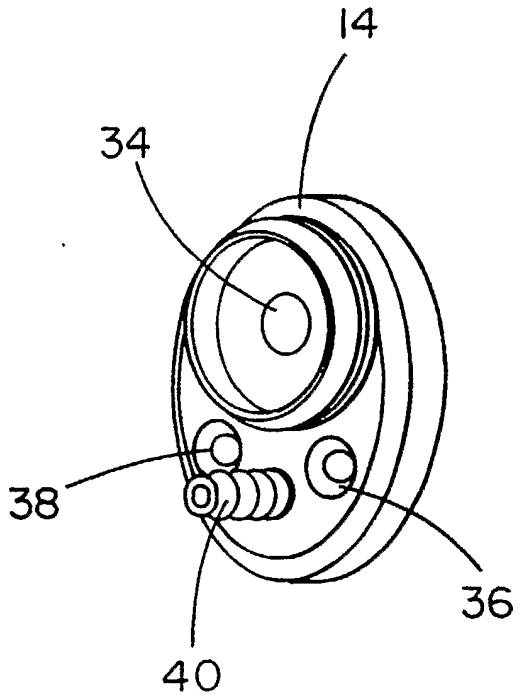

FIG. 6

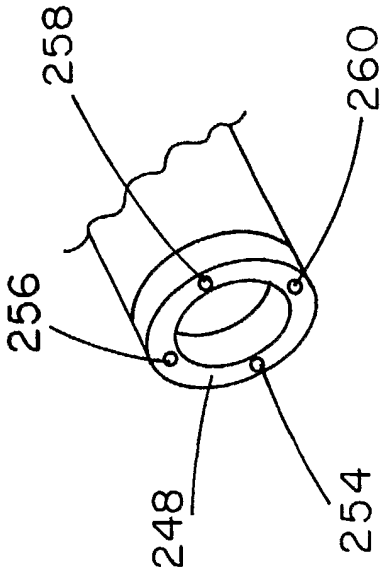

FIG. 9

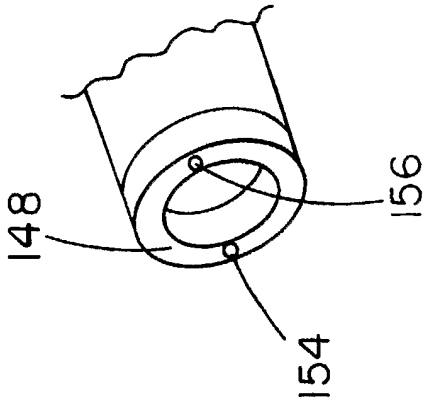

FIG. 8

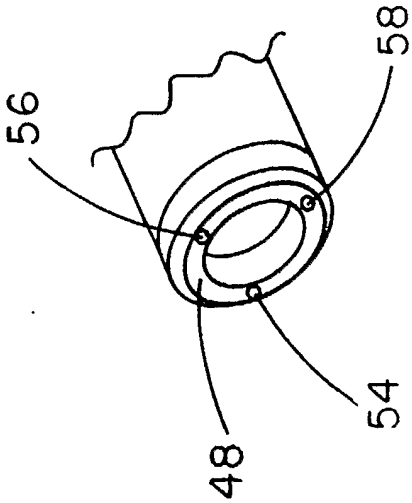

FIG. 7

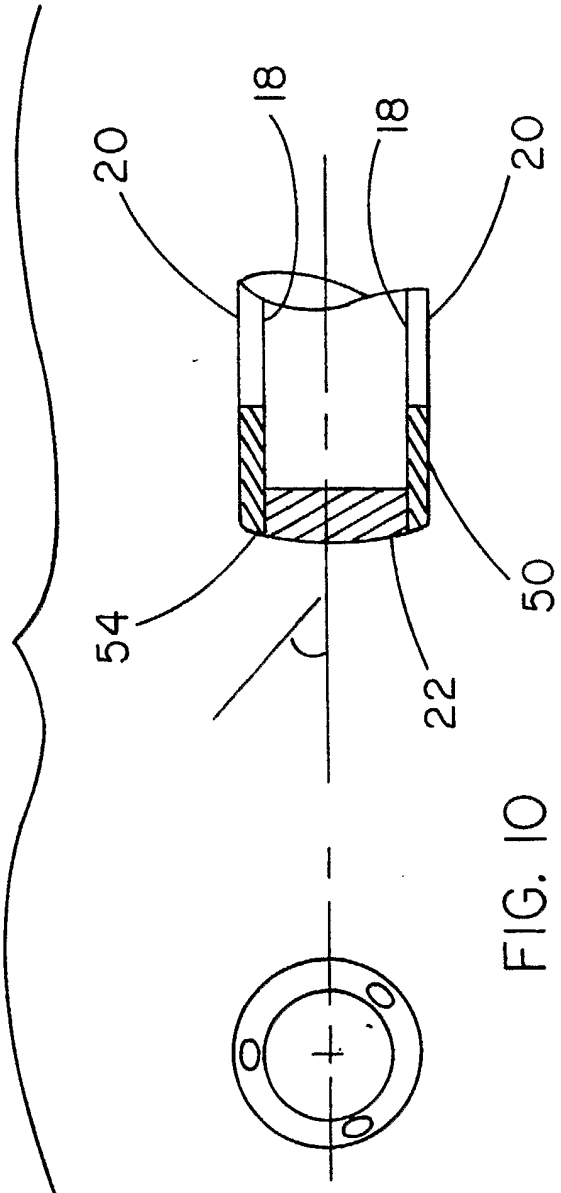

FIG. 10

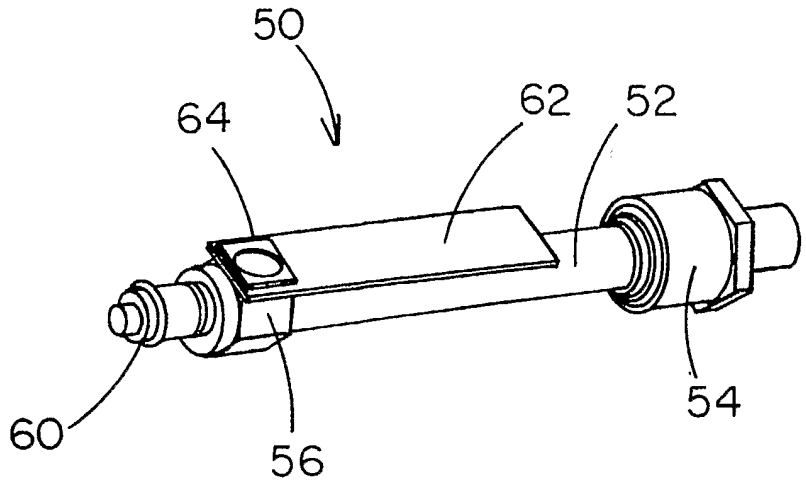

FIG. 11

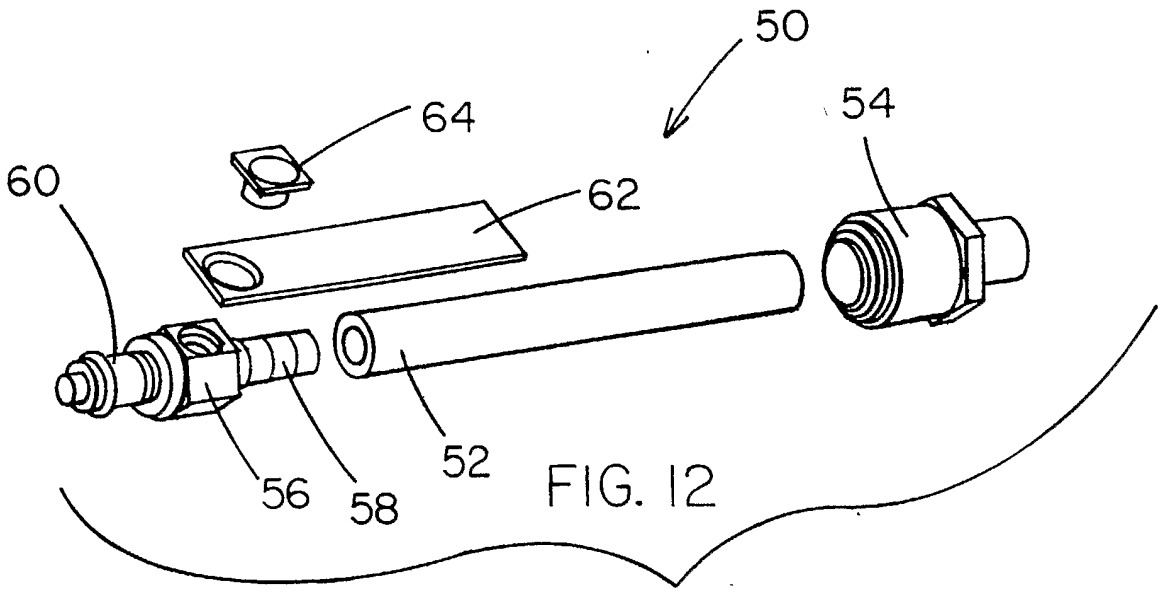

FIG. 12

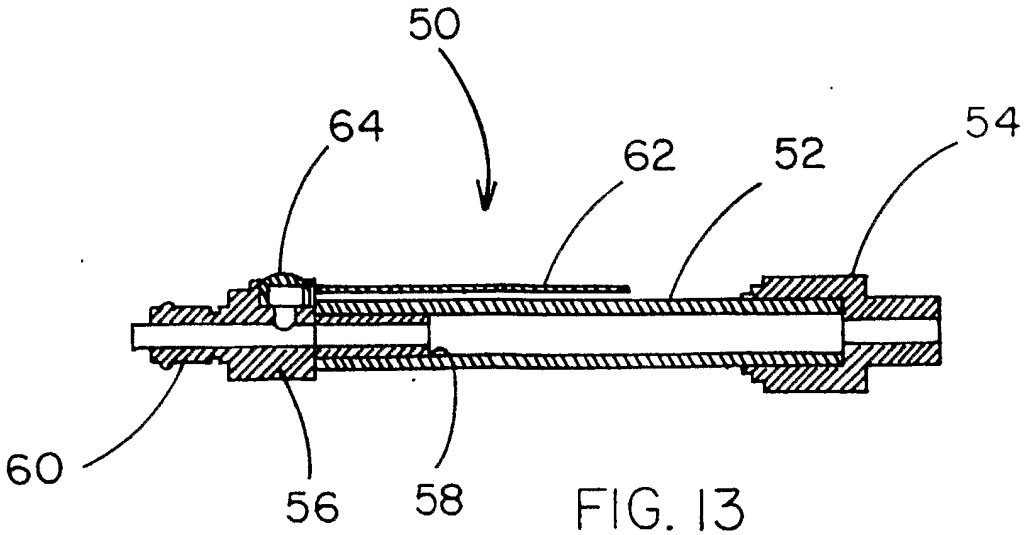

FIG. 13

INTERNATIONAL SEARCH REPORT

ıtional Application No
PCT/US 03/23609

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M3/02 A61M1/00 A61F5/44

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 7 A61M A61F

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 294 251 A (GEIGER JACK M ET AL) 13 October 1981 (1981-10-13) column 2, line 9-21; figures 1-3	1,2,4,7, 9,10,13, 15,16,19
X A	US 5 441 482 A (BLACKSHEAR JR PERRY L ET AL) 15 August 1995 (1995-08-15) abstract column 10, line 1 -column 11, line 54; figures 4-10	10, 13-16,19 4,7-9
A	US 4 682 979 A (GIROUARD JIMMY J) 28 July 1987 (1987-07-28) column 4, line 55 -column 6, line 30; figures 1,4-6	1,4,6, 10,12, 16,18

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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 :

"A" document defining the general state of the art which is not considered to be of particular relevance

"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

Date of the actual completion of the international search	Date of mailing of the international search report
27 November 2003	04/12/2003

Name and mailing address of the ISA	Authorized officer
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	Jameson, P

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INTERNATIONAL SEARCH REPORT

ıtional Application No
PCT/US 03/23609

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 2 243 299 A (ELLIS TRAVERS) 27 May 1941 (1941-05-27) the whole document	1,4,9, 10,15,16
A	US 1 845 343 A (SALERNI NICHOLAS B) 16 February 1932 (1932-02-16) page 1, line 53 -page 2, line 58; figures 1-4	1,4,7, 10,13, 16,19
A	WO 96 29044 A (MEZZOLI GIORGIO) 26 September 1996 (1996-09-26) page 5, line 22-27; figures 2A,2C,3A,3C	5,11,17
A	DE 34 30 095 A (SCHUBERT WERNER) 27 February 1986 (1986-02-27) page 21, line 4 -page 25, line 7; figures 1-5	1-19
A	US 4 804 373 A (BLOXOM JR INGRID B) 14 February 1989 (1989-02-14) abstract; figures 1-5	1-19
A	EP 0 456 470 A (SUMITOMO BAKELITE CO) 13 November 1991 (1991-11-13) column 2, line 5 -column 4, line 36; figures 1-7	1-19

INTERNATIONAL SEARCH REPORT

nternational application No.
PCT/US 03/23609

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20, 21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

ıational Application No
PCT/US 03/23609

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