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Notice Of Entitlement

660010

I, John G. Hinde, of 31 Market Street, Sydney, New South Wales, 2000, Australia, being the Patent Attorney for the Applicant/Nominated Person in respect of Application No. 11898/92, state the following:-

The Applicant/Nominated person has entitlement from the actual inventor as follows:-

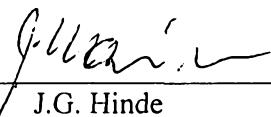
The Applicant/Nominated Person has entitlement from the actual inventors by way of assignment.

The Applicant/Nominated Person is entitled to rely on the application listed in the Declaration under Article 8 of the PCT as follows:

Roger R. Hill, one of the basic applicants, assigned his rights in the invention to the Applicant/Nominated Person. John A. Stevens, the other basic applicant, assigned his rights in the invention to Tahoe Pro Instruments, who subsequently assigned their rights in the invention to the Applicant/Nominated Person.

The basic application listed on the Declaration under Article 8 of the PCT is the first application made in a Convention country in respect of the invention.

DATED this Twenty-eighth Day of March 1995



J.G. Hinde

IRN: 244428

Instructor Code: 057440



AU9211898

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SUCTION IRRIGATOR VALVE APPARATUS

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(56) Prior Art Documents
**US 3993099
AU 458487 42277/72 F16K 11/07 3/26 A61M 1/00
US 2633324**

(57) Claim

1. An apparatus operable from an off condition to allow passage of an irrigating fluid therethrough, and operable alternately from the off condition to apply a vacuum therethrough, the apparatus comprising:

(1) a body having an internal cavity defining a longitudinal axis;
(2) a vacuum inlet opening passing from the exterior of the body to the cavity;

(3) an irrigation inlet opening passing from the exterior of the body to the cavity;

(4) a vacuum and irrigation outlet opening passing from the exterior of the body to the cavity, the outlet being positioned along the longitudinal axis between the vacuum inlet opening and the irrigation inlet opening;

(5) a piston disposed within the cavity and along the longitudinal axis, the piston comprising:

(a) a first sealing portion, a central sealing portion, and a second sealing portion disposed along the longitudinal axis,

(b) a first waisted portion disposed between the first sealing portion and the central sealing portion, and

(c) a second waisted portion disposed between the central sealing portion and the second sealing portion,
the piston being slideable along the longitudinal axis from a central off position, whereat the central sealing portion seals the vacuum and irrigation outlet opening, to one of an irrigate position and a vacuum position, the first sealing portion, the central sealing portion, the second sealing portion, the first waisted portion, and the second waisted portion being disposed along the longitudinal axis relative to the irrigation inlet opening, the vacuum inlet opening, and the irrigation and vacuum outlet opening such that:

the first waisted portion, the first sealing portion, and the central sealing portion together provide a sealed passage between the irrigation inlet opening and the irrigation and vacuum outlet opening only when the piston is slid to the irrigate position, and seal the irrigation inlet opening when the piston is in the off position,

the second waisted portion, the second sealing portion, and the central sealing portion together provide a sealed passage between the vacuum inlet opening and the irrigation and vacuum outlet opening only when the piston is slid to the vacuum position, and seal the vacuum inlet opening when the piston is in the off position, and

the central sealing portion:

seals the vacuum inlet opening when the piston is slid to the irrigate position; and

seals the irrigate inlet opening when the piston is slid to the vacuum position, and

(6) biassing means for biassing the piston to the off position.

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(21) International Application Number: PCT/US92/00142 (22) International Filing Date: 9 January 1992 (09.01.92)		(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KR, LU (European patent), MC (European patent), NL (European patent), NO, RU, SE (European patent).	
(30) Priority data: 640,242 11 January 1991 (11.01.91) US		Published <i>With international search report.</i>	
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(74) Agents: BENGSSON, W., Patrick et al.; Limbach & Limbach, 2001 Ferry Building, San Francisco, CA 94111 (US).		(54) Title: SUCTION IRRIGATOR VALVE APPARATUS	
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(57) Abstract		<p>A device for irrigation and suction removal of blood, bodily fluids and debris from a body cavity primarily during laparoscopic procedures and surgery. The device contains a single piston (5) slidably disposed in a passage (2) contained in a housing (1) having two inlets (29, 30) and a single outlet (31). The piston (5) includes a central seal with two valve portions positioned on each side of the central seal (6, 7, 8, 9 and 15, 16, 17). Piston positioning means (25, 26) are provided to move the piston (5) to align the valve portions (39, 40) within the housing (2) with the outlet (31) and one of the inlets (29, 30), while the other inlet is simultaneously sealed off. Thus, the piston (5) may be moved from a neutral or shut-off position to an open irrigation position, or, alternately, moved from the neutral or shut-off position to an open vacuum position. The valve may also contain automatic biasing means (27, 28) for returning the valve from either the open-irrigation position or the open-vacuum position to the central shut-off position.</p>	

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Suction Irrigator Valve Apparatus

Technical Field of the Invention

This invention relates generally to an apparatus for the flushing of an internal body cavity and, alternately vacuuming excess fluid or body tissue primarily during surgery. The apparatus has the capability of providing a vacuum force to remove blood, tissue, and liquid from a body cavity and alternately providing an irrigation flow, such as a sterile cleansing solution, into the body cavity. An attachment for the access of a flexible instrument such as fiber optic bundle is also provided.

Background of the Invention

It is necessary during certain surgical procedures, such as, but not limited to, laparoscopic or surgical procedures, to provide a source of irrigation fluid and, alternately, a suction or vacuum force to a body cavity. It is also common during the above described procedures to provide a flexible instrument such as a fiber optic bundle or endoscope into the body cavity. The procedure may be carried out with the use of instruments that may provide all three functions.

The use of presently available devices have certain drawbacks. For example, a device that provides a suction force and an irrigation stream to a body cavity utilizes two independent button activated valves which are independently operated. The described device has the undesirable drawback in that both valves can be inadvertently depressed creating flow of irrigation stream into the vacuum line thereby resulting in wasted time and energy in order to clean and flush the line.

Another drawback of the above described invention is the gradual buildup of blood and tissue in a common cavity joining the irrigation and vacuum passages. The result is that the blood and tissue are eventually mixed into the irrigation stream and carried back into the body cavity. The specific drawback is the potential of 5 contamination of the irrigation solution and the waste of valuable time and irrigation solution in having to further suction out the blood and tissue that was flushed back into the body cavity.

Another example of a device presently available is the invention described in U.S. Patent Number 4,881,523, which utilizes a single valve and a single plunger in 10 providing an irrigation stream and a suction force. But, as with the above described invention, the device has the drawback of an intermediate position which allows a common passage between the irrigation flow and the suction passage, thus, having the same critical problems as the above described device.

SUMMARY OF THE INVENTION

15 It is the object of the present invention to overcome or substantially ameliorate the above disadvantages.

There is disclosed herein an apparatus operable from an off condition to allow passage of an irrigating fluid therethrough, and operable alternately from the off condition to apply a vacuum therethrough, the apparatus comprising:

20 (1) a body having an internal cavity defining a longitudinal axis;
(2) a vacuum inlet opening passing from the exterior of the body to the cavity;
(3) an irrigation inlet opening passing from the exterior of the body to the cavity;
25 (4) a vacuum and irrigation outlet opening passing from the exterior of the body to the cavity, the outlet being positioned along the longitudinal axis between the vacuum inlet opening and the irrigation inlet opening;

....



(5) a piston disposed within the cavity and along the longitudinal axis, the piston comprising:

- (a) a first sealing portion, a central sealing portion, and a second sealing portion disposed along the longitudinal axis,
- 5 (b) a first waisted portion disposed between the first sealing portion and the central sealing portion, and
- (c) a second waisted portion disposed between the central sealing portion and the second sealing portion,

the piston being slidable along the longitudinal axis from a central off position, whereat
10 the central sealing portion seals the vacuum and irrigation outlet opening, to one of an irrigate position and a vacuum position, the first sealing portion, the central sealing portion, the second sealing portion, the first waisted portion, and the second waisted portion being disposed along the longitudinal axis relative to the irrigation inlet opening, the vacuum inlet opening, and the irrigation and vacuum outlet opening such
15 that:

20 the first waisted portion, the first sealing portion, and the central sealing portion together provide a sealed passage between the irrigation inlet opening and the irrigation and vacuum outlet opening only when the piston is slid to the irrigate position, and seal the irrigation inlet opening when the piston is in the off position,

25 the second waisted portion, the second sealing portion, and the central sealing portion together provide a sealed passage between the vacuum inlet opening and the irrigation and vacuum outlet opening only when the piston is slid to the vacuum position, and seal the vacuum inlet opening when the piston is in the off position, and

30 the central sealing portion:

- seals the vacuum inlet opening when the piston is slid to the irrigate position; and
- seals the irrigate inlet opening when the piston is slid to the vacuum position, and

(6) biassing means for biassing the piston to the off position.



BRIEF DESCRIPTION OF THE DRAWINGS

A preferred form of the present invention will now be described by way of example with reference to the accompanying drawings, wherein:

5 Figure 1 is an external view of the preferred embodiment of the present invention held within a practitioner's hand;

Figure 2 is a cross sectional top view of the valve housing wherein the piston is shown in a central sealed position;

10 Figure 3 is a cross sectional view of the present invention wherein the piston is shown in an open irrigation position;

Figure 4 is a cross sectional view of the present invention wherein the piston is shown in an open vacuum position;

15 Figure 5 is an external side cross sectional view of the present invention wherein an integral side port attachment is shown.

DETAILED DESCRIPTION OF THE INVENTION

15 The present invention will be described with reference to the preferred embodiment shown in the figures.

Figure 1 shows a device according to the invention held within a human hand during operation. Generally, each of Figures 1-4 show a valve housing 1, which housing may be formed from any suitable inert



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material such as stainless steel. In the preferred form of the invention body 1 is formed of a plastic material such as polyphthalate carbonate (such as Lexan PPC) and is therefore inexpensively
5 manufactured and disposable. It will be appreciated that many parts of the invention can be formed from such materials, i.e. stainless steel or plastic, or other materials, the choice depending on the cost of manufacture and the intended market. If the product
10 is intended to be reusable the material must be sufficiently stable to be routinely subjected to sterilizing conditions, for example in an autoclave. On the other hand, disposable products need only meet
15 the requirement that they be stable and inert with respect to the conditions under which they will be used.

Figures 2-4 show valve housing 1 having a cylindrical cavity 2 extending longitudinally through the housing from a first end 3 to the second end 4. A piston 5 is positioned within the passage 2. Like body 1, piston 5 may be constructed of a metal or
20 plastic, and in the preferred case will be polyphthalate carbonate, i.e Lexan PPC. Piston 5 is configured with four circular flanges 6-9 located at the center of the piston. Piston 5 is further
25 configured with four additional flanges 10-13, i.e. two each located at each end of the piston 5. "O" rings 14-18 are placed between the flanges in use. "O" rings 14-18 are made from any suitable material
30 which will provide a satisfactory seal along the inner surface of cavity 2.

In the preferred embodiment actuating buttons 25 and 26 are positioned on the end most portions of piston 5, separately numbered 19 and 20 in Figure 2. Locking interfaces 21 and 22 are formed on end most
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portions 19 and 20 respectively such that buttons 25 and 26 can snap fit on either end of the piston. Flanged sleeve stops 23 and 24, constructed of either plastic or stainless steel, as well as compression springs 27 and 28 are positioned before buttons 25 and 26 are snapped into position. In the preferred embodiment springs 27 and 28 are double action equalizing springs of stainless steel, which may be obtained for example from the Smalley company of Illinois. Such springs provide for an especially smooth feel when buttons 25 and 26 are pressed in use, and therefore provide a better tool for the practitioner. Springs 27 and 28 are respectively set against the flanged sleeve stops 23 and 24. Those skilled in the art will appreciate that other means for biasing the piston in the manner obtained by using springs 27 and 28 could be used, again depending on the requirements for a given application, i.e. disposable or reusable.

Figures 2-4 show inlet tubes 29 and 30 located at openings on one side of the housing 1. Tube 31 is located at an opening on the opposite side of the housing, the opening being longitudinally located between the opening for tubes 29 and 30. Naturally these openings could be positioned in a number of orientations other than that shown in this preferred embodiment, limited only by the need to ensure that there are at least two inlet ports and one outlet port, and that the configuration of the openings allows for alternative communication between either of the tubes acting as an inlet with the tube acting as an outlet. The arrangement must not allow direct communication between the two inlet ports regardless of the piston position within the communication passage.

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Probe 32 is shown inserted into tube 31. In the preferred embodiment probe 32 is held in place by an epoxy seal, indicated at 34. Alternatively, an internal push-in snap ring may be used. An "O" ring seal 35 is shown where the base of probe 32 rests against housing 1. Supply tubing 36 is shown placed over hollow tube 29 and is configured to be attached to an irrigation line. Supply tubing 37 is shown placed over hollow tube 30 and is configured to be attached to a vacuum line.

Figure 1 shows the preferred embodiment of the invention in a neutral or central shut-off position. Piston 5 is in a "rest" position, situated so that the central flanges 6-9 and the "O" rings held therein seal-off outlet hole 38 from communication with cavity 2. Valve portions 39 and 40 are formed on the piston on each side of the central seal formed by flanges 6-9. Outer seals are formed by flanges 10-13 and "O" rings 14 and 18.

Figure 3 shows the preferred embodiment of the invention in the open-irrigation position. The practitioner, when desiring an irrigation flow, depresses button 25 (arrow) transmitting longitudinal motion to piston 5 in the direction of the second end 4, thereby compressing spring 27. Valve portion 39 (figure 2) moves in the direction of the second end 4 until it allows irrigation fluid to flow from tube 29 into probe 32. When the practitioner releases button 25, the stored energy in the compressed spring 27 forces piston 5 back towards first end 3. The piston's motion is interrupted upon contact with flange sleeve 23 or flange sleeve 24 or both to reach the intermediate shut-off position illustrated in Figure 2.

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Figure 4 shows the preferred embodiment of the invention in the open-vacuum position. During use the practitioner may alternately desire a suction force. To achieve this, the practitioner would 5 depress button 26 (arrow), transmitting longitudinal motion to piston 5 in the direction of first end 3, compressing spring 28. Valve portion 40 (figure 2) moves in the direction of the first end 3 until it allows a suction force to flow through probe 32. 10 When the practitioner releases button 26, the stored energy in compressed spring 28 forces piston 5 back towards second end 4. The piston's motion is interrupted upon contact with flange sleeve 24 or flange sleeve 23 or both to reach the intermediate 15 shut-off position as illustrated in Figure 2.

Figure 5 shows an additional preferred embodiment of the invention which includes a side port configured to allow access of a flexible instrument through the valve body without 20 interrupting the function of the suction irrigation device. In this embodiment the valve body housing is shaped to form a side port 45 containing a narrow passage 46. A rubber dam seal 47 is placed over the outerpost portion of passage 46. A flexible 25 instrument such as a fiber optic bundle 49 is inserted through seal 47, continuing through the side port 45 and into hollow tube 31, finally extending into the hollow probe 32. A standard one-way medical on-off valve stopcock 48 available from the 30 Malenkrodt company, is shown permanently bonded to the side port 45, using an acrylic adhesive or solvent bonding technology. Valve 48 is turned off to prevent fluids from flowing through the narrow passage 46 when side port 45 is not being used to 35 hold a flexible instrument.

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In use the suction irrigation device of the present invention affords the practitioner substantial advantages over those devices of prior art. The invention allows for the practitioner to 5 operate the suction irrigation device with one hand. When not in use the device is designed to automatically return to a central fully sealed position. No by-pass of irrigation solution directly to the vacuum line is possible.

10 While the preferred embodiment shown in the figures is depicted as having particular shapes for its external and internal surfaces, skilled artisans will appreciate that other functional and cosmetic changes are possible without departing from the true 15 spirit of the invention. For example, the shapes and/or colors of buttons 25 and 26 might be varied to provide the practitioner with improved grip, or to color code the vacuum and irrigation functions. Naturally, the single piston could also be positioned 20 from one side, by pushing and pulling the piston from that side rather than utilizing the to and fro action of the preferred embodiment. While the spring loaded self centering feature of the invention is considered 25 advantageous, it would also be possible to utilize such to and fro action, but have the piston rest in any of the three desired positions, i.e. vacuum open/irrigation closed, fully closed, or irrigation open/vacuum closed. We believe, however, that the 30 embodiment shown in the figures provides the greatest ease of use.

The claims defining the invention are as follows:

1. An apparatus operable from an off condition to allow passage of an irrigating fluid therethrough, and operable alternately from the off condition to apply a vacuum therethrough, the apparatus comprising:

(1) a body having an internal cavity defining a longitudinal axis;

5 (2) a vacuum inlet opening passing from the exterior of the body to the cavity;

(3) an irrigation inlet opening passing from the exterior of the body to the cavity;

10 (4) a vacuum and irrigation outlet opening passing from the exterior of the body to the cavity, the outlet being positioned along the longitudinal axis between the vacuum inlet opening and the irrigation inlet opening;

(5) a piston disposed within the cavity and along the longitudinal axis, the piston comprising:

15 (a) a first sealing portion, a central sealing portion, and a second sealing portion disposed along the longitudinal axis,

(b) a first waisted portion disposed between the first sealing portion and the central sealing portion, and

(c) a second waisted portion disposed between the central sealing portion and the second sealing portion,

20 the piston being slidable along the longitudinal axis from a central off position, whereat the central sealing portion seals the vacuum and irrigation outlet opening, to one of an irrigate position and a vacuum position, the first sealing portion, the central sealing portion, the second sealing portion, the first waisted portion, and the second waisted portion being disposed along the longitudinal axis relative to the irrigation inlet opening, the vacuum inlet opening, and the irrigation and vacuum outlet opening such that:

25 the first waisted portion, the first sealing portion, and the central sealing portion together provide a sealed passage between the irrigation



inlet opening and the irrigation and vacuum outlet opening only when the piston is slid to the irrigate position, and seal the irrigation inlet opening when the piston is in the off position,

5 the second waisted portion, the second sealing portion, and the central sealing portion together provide a sealed passage between the vacuum inlet opening and the irrigation and vacuum outlet opening only when the piston is slid to the vacuum position, and seal the vacuum inlet opening when the piston is in the off position, and

the central sealing portion:

10 seals the vacuum inlet opening when the piston is slid to the irrigate position; and

seals the irrigate inlet opening when the piston is slid to the vacuum position, and

(6) biassing means for biassing the piston to the off position.

2. The apparatus of claim 1, further comprising longitudinal positioning means for longitudinally positioning the piston within the cavity in each of the irrigating, vacuum, and off positions.

3. The apparatus of claim 2, wherein the piston additionally comprises a rod having first and second ends and the longitudinal positioning means comprises first and second buttons positioned at the first and second ends of the rod and adapted for manual actuation.

4. The apparatus of claim 3, wherein the biassing means comprises a pair of compression springs positioned adjacent to each of the actuating buttons.

5. The apparatus of claim 1 further comprising a side port hole integral with the body, the side port hole being configured to provide access for a flexible instrument without interfering with movement of the piston.



6. An apparatus operable from an off condition to allow passage of an irrigating fluid therethrough, and operable alternately from "off condition to apply a vacuum therethrough, said apparatus being substantially as hereinbefore described with reference to the accompanying drawings.

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DATED this Twenty-eighth Day of March 1995
Tahoe Surgical Instruments - Puerto Rico, Inc.

Patent Attorneys for the Applicant
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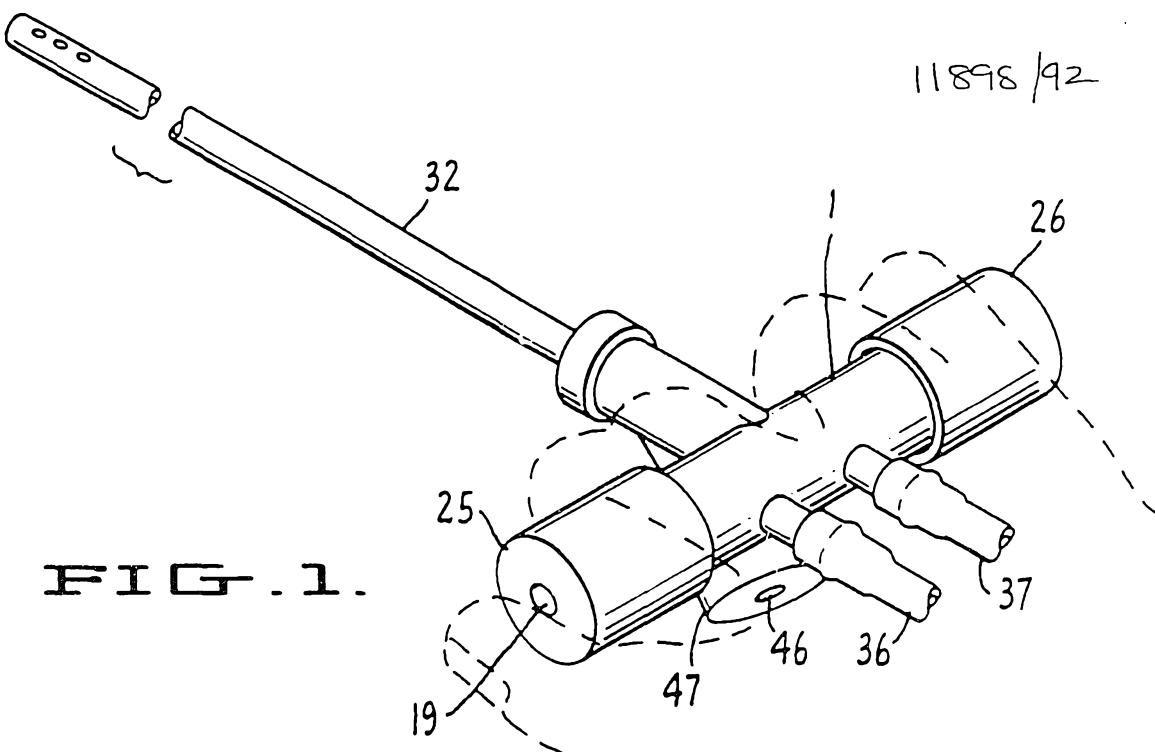


FIG. 1.

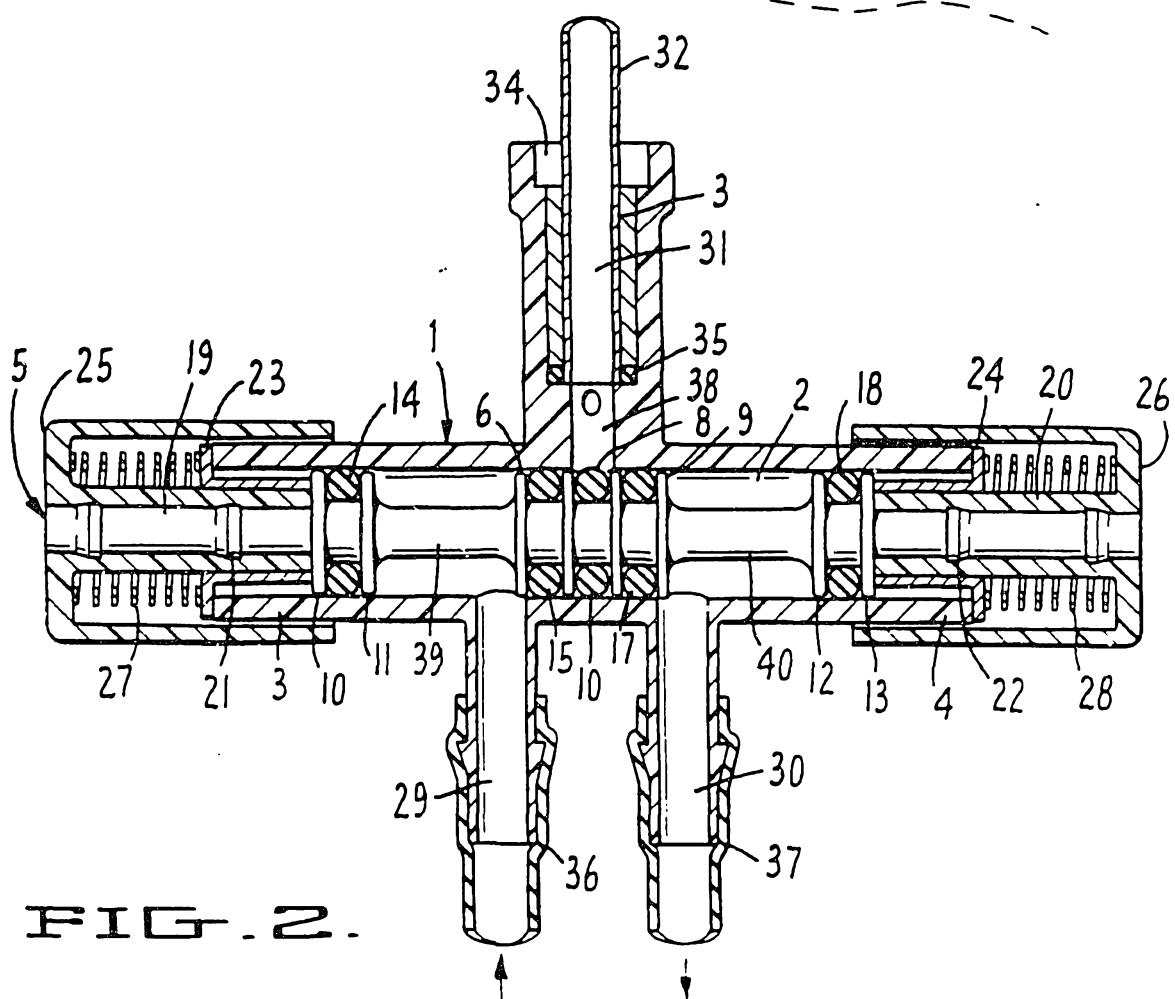


FIG. 2.

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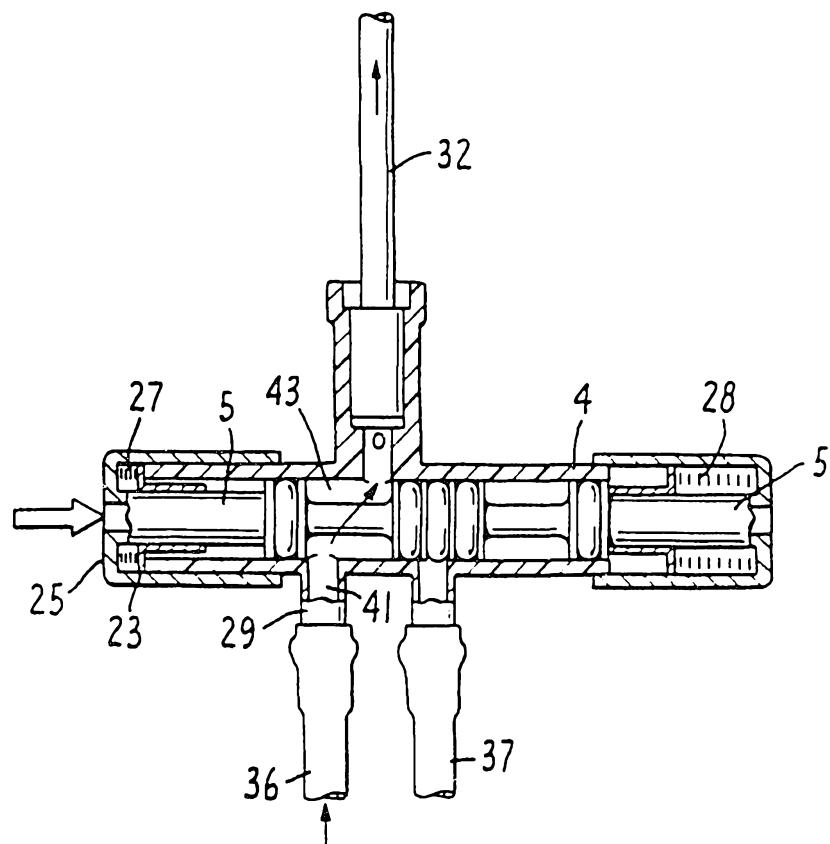


FIG. 3.

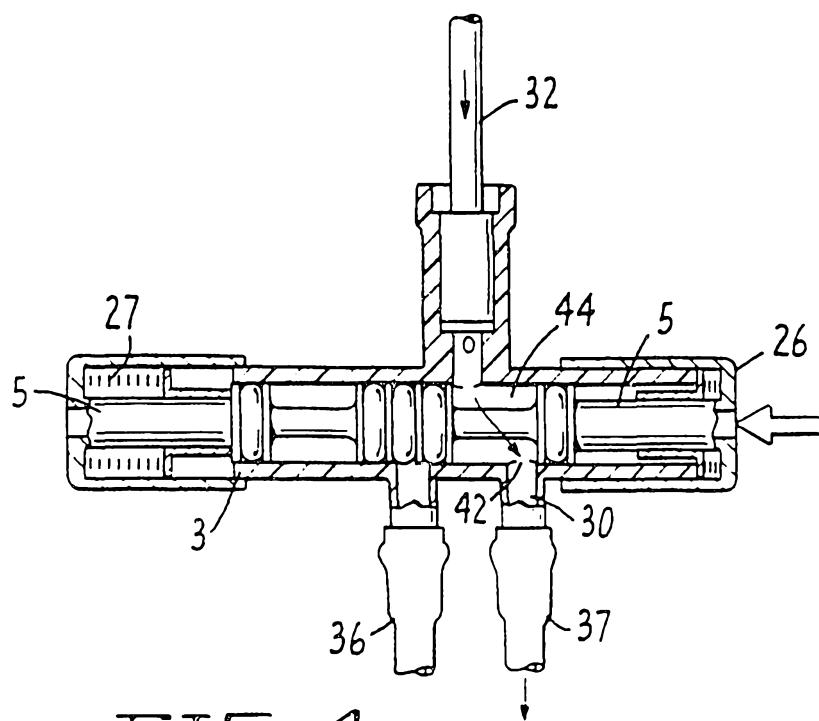


FIG. 4.

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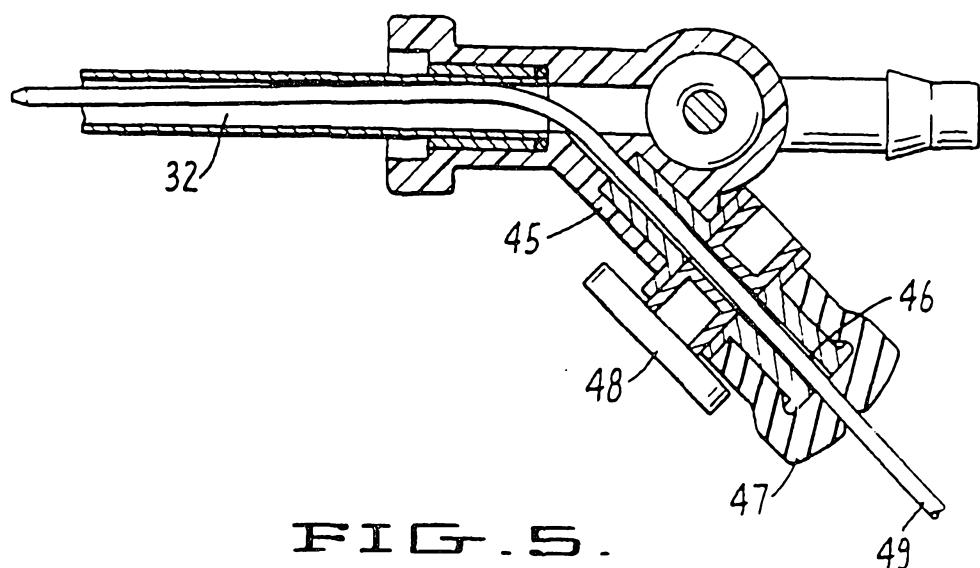


FIG. 5.

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/00142

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁸

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): F16K 11/065

U.S. CL.: 137/625.69

II. FIELDS SEARCHED

Minimum Documentation Searched ⁷

Classification System	Classification Symbols
U.S.	137/625.48, 625.69 251/900 604/33,249

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹

Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X Y	US, A, 4,502,508 (LESTER) 05 March 1985, See Figs. 5a-5c.	1-2 3-7
Y	US, A, 3,678,959 (LIPOSKY) 25 July 1972, See Figs. 3-4.	3-5
Y	US, A, 2,633,324 (BIERMAN) 31 March 1953, See Fig. 1.	6
A	US, A, 3,993,099 (NIGHTINGALE) 23 November 1976, See Fig. 1.	
A	US, A, 3,951,166 (WHITENER) 20 April 1976, See Fig. 1.	
A	US, A, 3,722,800 (SHAMES) 27 March 1973, See Figs. 6-7.	

* Special categories of cited documents: ¹⁰

"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, i.e. 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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search

11 MARCH 1992

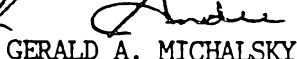
Date of Mailing of this International Search Report

23 APR 1992

International Searching Authority

ISA/US

Signature of Authorized Officer


GERALD A. MICHALSKY