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<p>(54) Title: DEVICE AND METHOD FOR EVACUATING REFUSE FROM TISSUES OF THE BODY</p>		
<p>(57) Abstract</p> <p>This invention is a device (10), and a method for evacuating pathologic material from body cavities, and organs. The device (10) includes a sheath (14) defining a suction route internally, a means of providing suction connected to the suction route, a rotor (12) internally disposed with the sheath (14), a suction outlet (22) continuous with the suction route, and connectable to the means for providing suction, and at least one cutting knife (13), connected to the rotor (12), for cutting the pathological material, the pathological material being removed via the suction outlet (22).</p>		

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DEVICE AND METHOD FOR EVACUATING REFUSE FROM TISSUES OF THE BODY

FIELD OF THE INVENTION

The present invention relates to aspirating devices. Particularly, the
5 invention relates to a method for the production of such devices for use in surgery.

BACKGROUND OF THE INVENTION

In order to drain fluids and other matter from the human body cavities,
suction devices are often used. These are effective for non-viscous fluids such as
non-clotted blood. However, the effectiveness is diminished when more viscous
10 fluids are involved, such as contents of cysts, thick secretions, blood clots, viscid
forms of pus and other hard pathologic materials. Suction activity is insufficient for
the evacuation of such solid and semi-solid types of refuse, rather direct
mechanical intervention is needed.

US patents 5,275,609 and 5,290,303 describe devices for removing
15 target objects from a body passageway. The devices employ a rotating spiral
woven coil as a mechanical fragmenting agent, and the evacuation of the
fragments of the target object is carried out by suction force.

The article "The development of a new surgical device – the Endoscopic
Liquidiser and Surgical Aspirator (ELSA)" (Journal of Medical Engineering and
20 Technology – November/December 1989) describes an Endoscopic Liquidiser
and Surgical Aspirator (ELSA). ELSA can liquify solid pathologic tissues by
employing a rotating knife in the form of a drill or a propeller as a mechanical

fragmenting agent and evacuation of tissue fragments with aspiration (suction) force.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an improved device for the
5 evacuation of refuse consisting of solid and semi-solid material from organs of a body, the refuse having different levels of viscosity and fluidity.

There is thus provided, in accordance with a preferred embodiment of the invention, a device for evacuating pathologic material from body cavities and organs. The device includes a sheath defining a suction route internally; a means
10 of providing suction connected to the suction route; a rotor internally disposed with the sheath; a suction outlet continuous with the suction route and connectable to the means for providing suction, and at least one cutting knife, connected to the rotor, for cutting the pathological material, the pathological material being removed via the suction outlet.

15 Furthermore, in accordance with a preferred embodiment of the invention the device further includes a ribbed cutting cage disposed around the at least one cutting knife.

Furthermore, in accordance with a preferred embodiment of the invention the knife is located outside of the sheath. At least a part of the sheath is flexible
20 and/or disposable.

In addition, in accordance with a preferred embodiment of the invention, the knife may be loop shaped. The knife comprises two concave blades radially disposed in the direction of the suction outlet.

Furthermore in accordance with a preferred embodiment of the invention the device further includes means for incising the pathological material.

Furthermore in accordance with a preferred embodiment of the invention the cutting means further includes correspondingly configured articulating jaws.

5 In addition, there is also provided, in accordance with a preferred embodiment of the invention a method for evacuating pathologic material from body cavities and organs. The method includes:

subjecting at least a portion of the pathologic material to a suction force;
and

10 concomitantly applying a cutting action on the pathologic material by at least one knife.

Furthermore in accordance with a preferred embodiment of the invention the method further includes the step of the at least one cutting knife pushing the cut pathologic material away from the body cavities and organs.

15 Furthermore in accordance with a preferred embodiment of the invention the step of applying a cutting action is performed manually.

Furthermore in accordance with a preferred embodiment of the invention the method further includes the step of:

grinding the cut pathologic material.

20 Furthermore in accordance with a preferred embodiment of the invention the method also includes a second step of:

applying suction following the step of grinding.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

5 Fig. 1A is a sectional elevational illustration of a suction device (or aspirator), constructed and operated in accordance with a preferred embodiment of the invention;

 Fig. 1B is an illustration of spacers used with the suction device of Fig. 1A;

10 Figs. 1C-1E are detailed elevational views of the blade arrangement of the aspirator of Fig. 1A;

 Fig. 2A-C are isometric, side and front elevations of the cage-like stable knife for covering the end of the aspirator device of Fig. 1A;

 Fig. 3 is an illustration of an aspirator device constructed and operated in
15 accordance with a further preferred embodiment of the invention;

 Fig. 4 is a detailed illustration of the knife of Fig. 3;

 Fig. 5A is an illustration of an aspirator device constructed and operated in accordance with a further preferred embodiment of the invention;

 Fig. 5B is a detailed illustration of a knife used with the aspirator of Fig.
20 5A;

 Fig. 5C is an illustration of an alternative arrangement of knives used with aspirator of Fig. 5A;

 Fig. 6 is an illustration of an aspirator device constructed and operated in accordance with a further preferred embodiment of the invention;

Fig. 7 is an illustration of an aspirator device constructed and operated in accordance with a further preferred embodiment of the invention; and

Figs. 8A-8D are illustrations of an aspirator device constructed and operated in accordance with a further preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

Reference is now made to Fig. 1A, which illustrates a suction device 10 (or aspirator), constructed and operated in accordance with a preferred embodiment of the invention. Suction device 10 comprises a cylindrical sheath 14 connected to a suction outlet 22. A rotor 12 is inserted within cylindrical sheath 14. The rotor 12 is connected to a rotatable half-loop type knife 13, the blades of which are completely enclosed by a knife head 40 composed of a cage-like structure (best seen in Figs. 2A-2C). The sheath 14 connects the suction outlet 22 with the orifice 11 of the aspirator 10, meaning that it performs a second task of channeling the suction into the site of cutting. A motor 24, typically electric or pneumatic, functionally connected to the rotor 12, is disposed at the one end of the device, opposite to the knife 13. The rotor 12 is centered within the sheath 14 via a radial spacer 20 located proximally to the external orifice 11, and a second spacer 18 which is located proximal to suction outlet 22 (distal from orifice 11).

The details of the spacers 18,20 are shown in Fig. 1B to which reference is now made. Fig. 1B is a cross-sectional view of the spacer 18 within sheath 14. Spacers 18, 20 ensure that the rotor 12 is equi-distant from the circumference of the sheath 14 while allowing free passage (void 15) for the material being suctioned..

Further properties of this embodiment of the invention showing the blade arrangement of the suction device (aspirator) 10 are described in Figs. 1C-1F, to which reference is now made, showing the blade arrangement of the aspirator 10. The knife 13 is half-loop-shaped, having two blades, 19 and 21 each having a sharp cutting edge in a forward direction of movement. Thus, the cutting direction

for each blade is on the opposite edge of each blade 19 and 21. The cutting edge 23 of blade 21 is positioned in the direction of rotation.. Arrow 27 indicates the direction of the rotation around rotor 12.

In operation, a medical team uses the device of the invention to disrupt,
5 dislocate and evacuate chunks of refuse. During the work of the medical team, the apparatus of the invention uses both the mechanical power and the suction power to evacuate refuse. At times the refuse is located very close to healthy tissue or to tissue which should be left untouched. Therefore, using a stable knife head 40 (or cage) to protect from physical harm to healthy tissue and tissue which
10 is to be left unharmed is very important.

The stable knife head 40 is shown in Figs. 2A, 2B and 2C which are an isometric, sectional and front view of knife head 40 respectively and which are now referred to herein. In Figs. 2A-2C, the knife head 40 is shown to comprise a cage made up of ribs 41 and has a base ring 45 which is screwed to the sheath
15 14, thus covering the orifice 11 of the aspirator (not shown). This allows for material to reach the vicinity of the half-loop-type knife 13, without placing body tissues at risk due to knife action. This cage has a dual function in that it protects the tissue from potential knife injuries on the one hand and on the other hand it dissects the refuse by way of the cutting action on tissue or refuse of the manually
20 pushed cage ribs. This cutting action assists in the evacuation of refuse, especially for semi-solid refuse.

According to another preferred embodiment of the invention, a different disposition of the knife is provided. In Fig. 3, to which reference is now made, a straight knife 30 is protected by a cylindrical sheath 14 and by knife head 40.

Elements of this embodiment of the invention which are similar to elements which have been previously described with respect to the preferred embodiment hereinabove, are similarly designated and will not be further described.

5 A rotor 12 turning the knife 30 is centered by a proximal spacer 20 and a distal spacer 18, and driven by a motor 24. A suction outlet 22 facilitates connection to a vacuum generator (not shown).

The structure of knife 30 is elaborated in Fig. 4 to which reference is now made. The knife 30 is composed of at least two radially disposed blades 32 and 33, having the rotor 12 connected at location 55, which overlaps the center of radial symmetry of the knife, marked by axis 56. The direction of rotation of the rotor is indicated by three arrows. The knife is viewed indicating opposite cutting edges 31 and 29, each of a different blade. The flank of each blade facing the direction of the rotor 12 is curved, with the sharp, cutting edges 31 and 33 facing the direction of radial movement respectively, as indicated by the straight arrows 10 51 and 52. Arrow 53 indicates the direction of the radial movement around the rotor 12.

The shape of the blades in this embodiment promotes the parallel functionality of the knife 30. The cutting and mincing action on the one hand, and the backward pushing of the minced suspension on the other hand as marked by 20 arrow 57 are the two parallel functions of the knife. The pushing action is provided due to the shape of the progressing blade flank. When a refuse chunk has been cut off by the blade, it is subjected to the constant pushing action of the blade flank. One component of that force is in the circular direction, whereas the other component, exerted simultaneously, results from the backward pushing

component of the progressing blade. Such a backward pushing force is exerted in addition to the suction force provided through the suction outlet.

A further embodiment of an aspirator is shown in Figs. 5A and 5B to which reference is now made. Elements of this embodiment of the invention which
5 are similar to elements which have been previously described with respect to the preferred embodiment hereinabove, are similarly designated and will not be further described.

A sectional elevational view of the aspirator shown in Fig. 5A comprises a proximal spacer 20 and a distal spacer 18 to keep the rotor 13 centralized. The
10 rotor is powered by a motor 24, and the torque is conveyed by rotor 13 to a first knife 30 (proximal to cage 40) and a second knife 35 (distal to cage 40).

Both of the knives are similar to the knife of Fig. 4. The knives 30, 35 therefore perform two tasks, one, of cutting and the other of pushing material away from the cage 40. At the head of the aspirator, the knife 30 is again
15 protected by a cage 40 which has a base ring 45 screwed to the sheath 14, thus covering the orifice of the aspirator (not shown). In Fig. 5B, the cage 40 is shown to comprise ribs 41. This specific embodiment allows for material to reach the vicinity of the front knife 30, without risking body tissues, which are not to be touched, due to knife action as discussed hereinabove in relation to other
20 embodiments. As described earlier, the cage has a dual function in that it protects the tissue from potential knife injuries on the one hand and on the other hand it possibly dissects the refuse by way of the cutting action of the manually pushed cage ribs. As in the other embodiments, a vacuum outlet 22 induces a suction in the sheath 14. In addition, this embodiment provides extra drawing

power for minced material, by applying the mechanical suction provided by the distal knife 35. Fig. 5C shows an alternative knife configuration for this embodiment, where the knife 30 is a half-loop shaped knife (similar to knife 13 of Fig. 1A) and the knife 35 is a straight knife (similar to knife 30 of Fig. 3). In practice, any combination of types of knives may be used and also any number of knives may be used, and the combinations above are given by way of examples only. The above embodiments are characterized by a cutting action (C) of the knife head, a grinding action (G) of the rotating blade and a suction action (S) of the device. Thus, we can characterize these embodiments by the abbreviation (C.G.S).

In Fig. 6 to which reference is now made, another embodiment of a suction device is shown in which a knife 30 is distal to the orifice 11 of the aspirator. The motor 24, the rotor 13, the sheath 14 and two spacers 18 and 20 are similar to those in the previous embodiments.

Another embodiment in which a single knife 13 is distal from the orifice is shown in Fig. 7A to which reference is now made. In this embodiment, the knife 13 is loop shaped with the axis of rotation vertical, perpendicular to the axis of the sheath 14. The knife is disposed substantially at the outlet 22 of the vacuum and the driving motor 24 is disposed in line with the knife rotation axis and the rotor 12. The motor is encased in a handle 11 which is grasped in the hands of the physician wielding the aspirator. Fig. 7B to which reference is now also made shows the loop shaped knife 13 and the shaft 19 by which it is attached to driving motor 24. The above two embodiments are termed Cutting, Suction, Grinding, Suction (C.S.G.S) as they are characterized by that sequence of events.

Figs. 8A, 8B, 8C and 8D to which reference is now made, illustrate a further embodiment of the present invention. In the present embodiment similar items to those in previous figures have similar numerals and will not be described further. In addition to the features of the previous embodiment, which include a loop-shaped knife 13 positioned substantially at the outlet 22 of the vacuum, the present embodiment features a pair of jaws 50 situated in front of orifice 11. Jaws 50 open and close in a pincer-like movement to trap and cut pieces of tissue in a pincer-like fashion. Jaws 50 are hollow, forming a hollow conical-like shape with a curved front, when closed. The closed position is shown best in Fig. 8C.

The mechanism for opening and closing of jaws 50, best illustrated in Figs. 8B and 8C, comprises a handle 53 connected to a shaft 55 which is anchored to the body of suction device 10 via a pivot 57 which allows the end of shaft 55 to articulate via a second pivot 59 with a plate 61. Plate 61 is attached to an outer cylinder 63 surrounding sheath 14 which moves in the direction of the external orifice 11 of the aspirator against the action of a spring 65 when handle 53 is pulled in the direction of arrow 69. Tabs 71 and 73 are attached to the top and the bottom of outer cylinder 63 via pivots 75 and 77, respectively. Tabs 71 and 73 push against tabs 79 and 81, respectively attached to jaws 50 at a fixed angle, via pivots 83 and 85. Tabs 79 and 81 are anchored to sheath 14 at pivots 89 and 87, respectively. Thus, jaws 51 close when handle 53 is squeezed in the direction of arrow 69 and open when handle 53 is released, facilitating a cutting action.

The cutting action of jaws 51 aids in the process of removing and evacuating certain types of tissue which it would be difficult to remove in their

absence. These difficult tissues include Fibrin peels, Pus, Tumor tissue and wall of Hydatid cysts. The invention thus facilitates minimal invasive surgery for removal of these types of tissues in that the tissue is cut and evacuated simultaneously. This embodiment may be termed B.G.S or Biting, Grinding and

5 Suction illustrating the actions which occur.

Some exemplary uses of the features of each embodiment of the present invention for various procedures and for dealing with different types of tissue are now described hereinbelow with respect to the table.

Name of Instrument	Pathology	Substances
Cutting, grinding, suction C.G.S	Hemothorax, Hydatid Cysts Dermoid Cysts Fibrinopurulent phase of empyema thoracis Hematoma Abscess	Blood clots Cyst's contents Cyst's contents Pus, Fibrin Blood Clots Pus
Cutting, suction, grinding, suction C.S.G.S	Hemothorax Exudative Empyema Thoracis Abscess Ileus	Blood Clots Pus Pus Bowel contents
Biting, grinding, suction B.G.S (D.D.)	Loculatid Empyema Thoracis Benign tumors Hydatid cysts	Peels Tumor's tissue Cyst's contents

It will be appreciated that, in the present invention, the cutting knife having the first contact with the refuse to be evacuated may be positioned in various locations with respect to the sheath of the rotor. The sheath also functions as a conduit of suction power. In the first embodiment, the knife is a curved knife
5 disposed at the open end of the sheath, in the second embodiment it is a straight knife, in the third embodiment two consecutive knives are disposed inside of the sheath, and in the fourth and fifth embodiments the knives are disposed deep inside the sheath.

The fourth and fifth embodiments enable the sheath to be made of
10 flexible tubing so that the sheath can be manipulated by the physician to reach unexposed or inaccessible niches in the body cavities. In order to guard against collapse of the sheath if a flexible tubing is used, it can be prefabricated using a metal coil of the appropriate parameter as reinforcement for the flexible tubing and manipulators.

15 The sixth embodiment utilizes a knife deep within the sheath and a cutting implement at the orifice to cut tough tissues prior to evacuating them. It should be noted that combinations of any of the above configurations may be made, thus gaining combinations of the advantages of each of them. Thus, the number and type of knives and their positions may be varied.

20 The fourth and fifth embodiments, with a knife disposed deep within the sheath, lend themselves easily to the use of disposable sheath tubing. Such an application removes the need for cleaning and sterilizing the sheath and may thus be of further advantage.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

CLAIMS

1. A device for evacuating pathologic material from body cavities and organs, the device comprising:
- 5 a sheath defining a suction route internally;
- a means of providing suction connected to said suction route;
- a rotor internally disposed with said sheath;
- a suction outlet continuous with said suction route and connectable to said means for providing suction, and
- 10 at least one cutting knife, connected to said rotor, for cutting said pathalogical material, said pathalogical material being removed via said suction outlet.
2. A device according to claim 1 further comprising a ribbed cutting cage disposed around said at least one cutting knife.
3. A device according to any of Claims 1-2, wherein one of said at least one
- 15 knife is located outside of said sheath.
4. A device according to any of claims 1-3, wherein at least a part of said sheath is flexible.
5. A device according to any of claims 1-4, wherein at least a part of said sheath is disposable.
- 20 6. A device according to any of claims 1-5, wherein said at least one knife is loop shaped.

7. A device according to any of claims 1-6, wherein said at least one knife comprises two concave blades radially disposed in the direction of said suction outlet.

8. A device according to any of claims 1-7, further comprising a means for
5 incising said pathological material.

9. A device according to claim 8, wherein said means for cutting comprises correspondingly configured articulating jaws.

10. A method for evacuating pathologic material from body cavities and organs, the method comprising:

10 subjecting at least a portion of said pathologic material to a suction force; and
 concomitantly applying a cutting action on said pathologic material by at least one knife.

11. A method according to claim 10, further comprising the step of said at
15 least one cutting knife pushing the cut pathologic material away from said body cavities and organs.

12. A method according to claim 10, wherein said step of applying a cutting action performed manually.

13. A method according to claim 10, further comprising the step of:
20 grinding said cut pathologic material.

14. A method according to claim 10, further comprising a second step of:
 applying suction following said step of grinding.

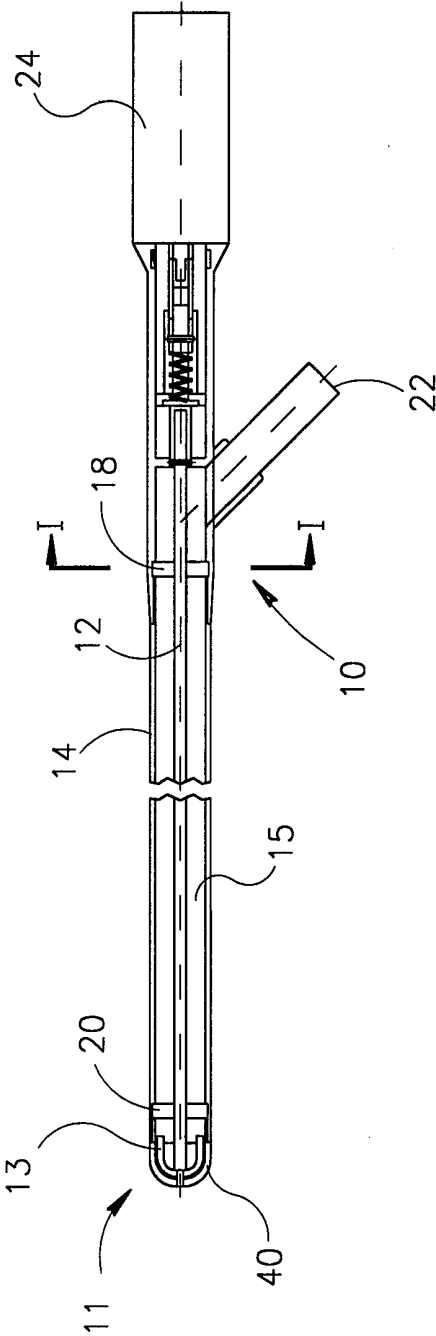


FIG. 1A

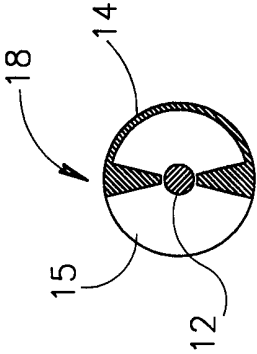


FIG. 1B

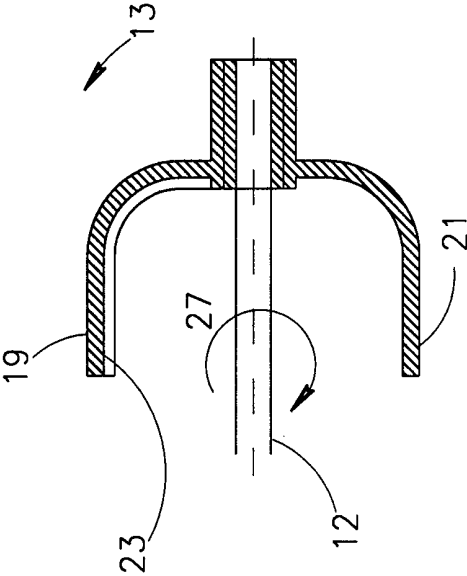


FIG. 1C

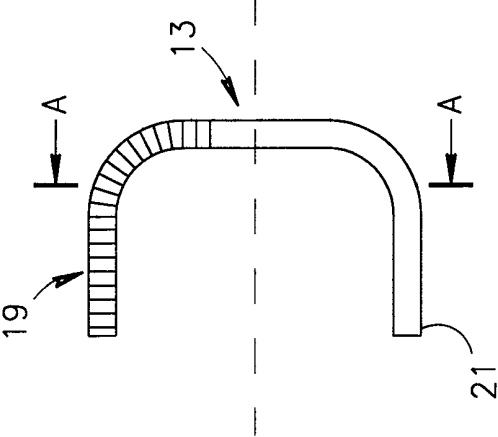


FIG. 1D

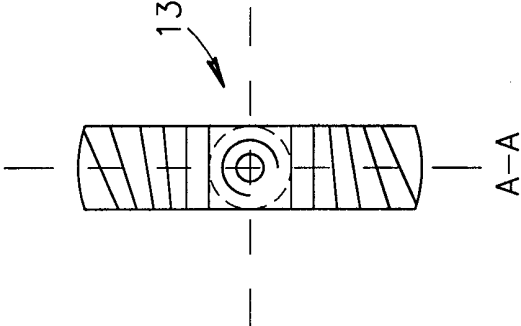


FIG. 1E

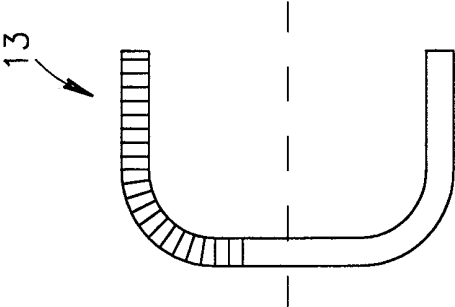


FIG. 1F

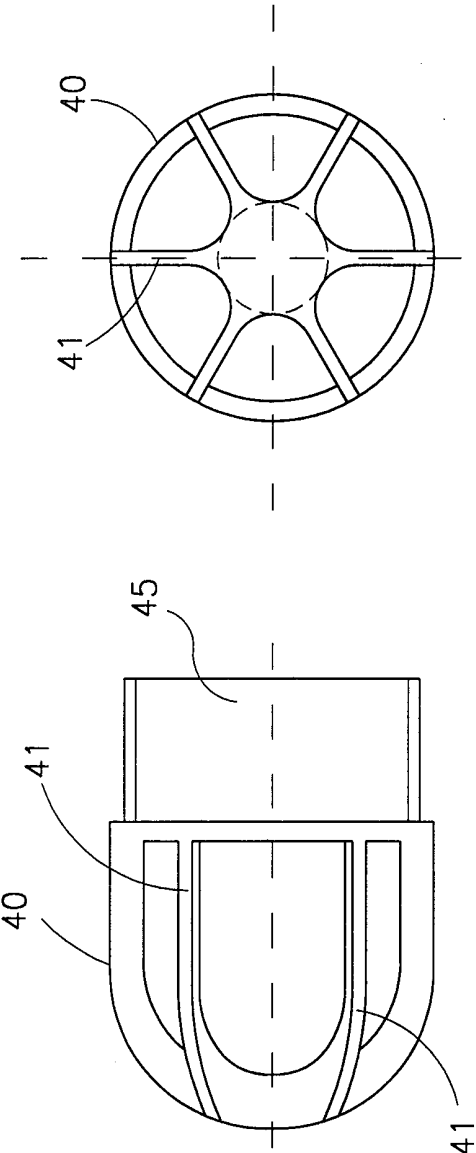


FIG. 2A

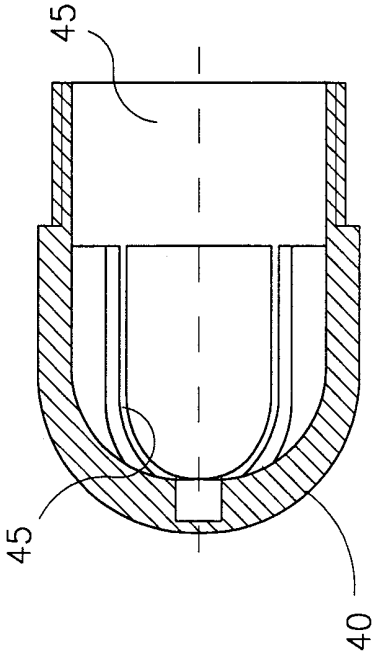


FIG. 2B

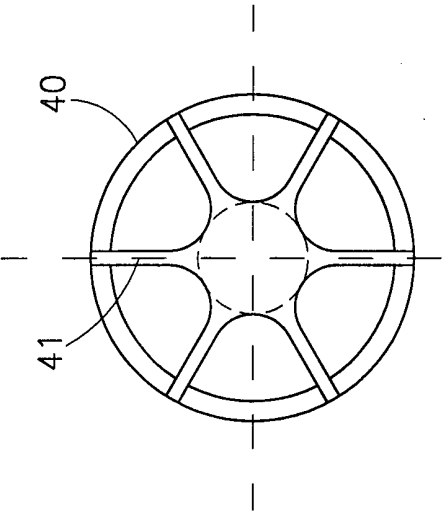


FIG. 2C

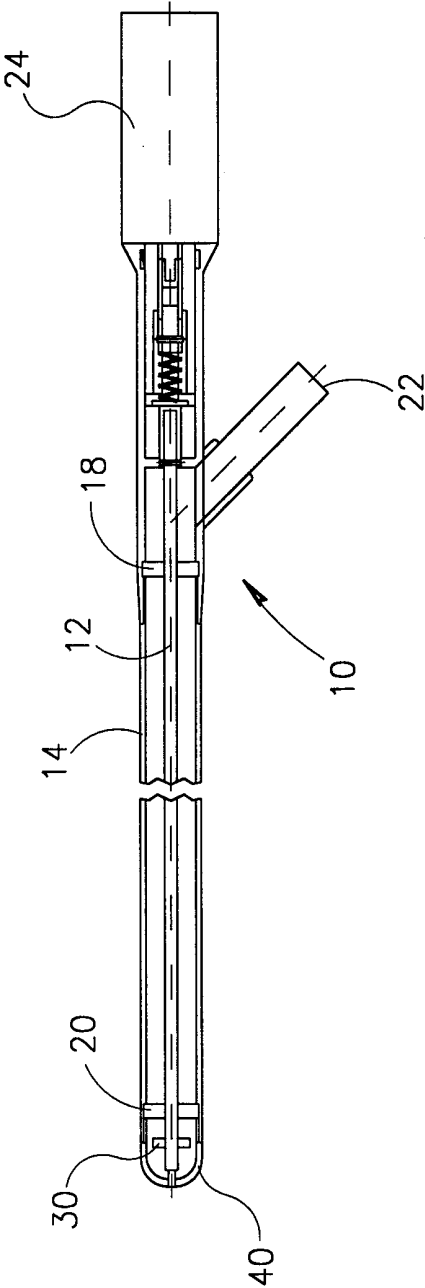


FIG.3

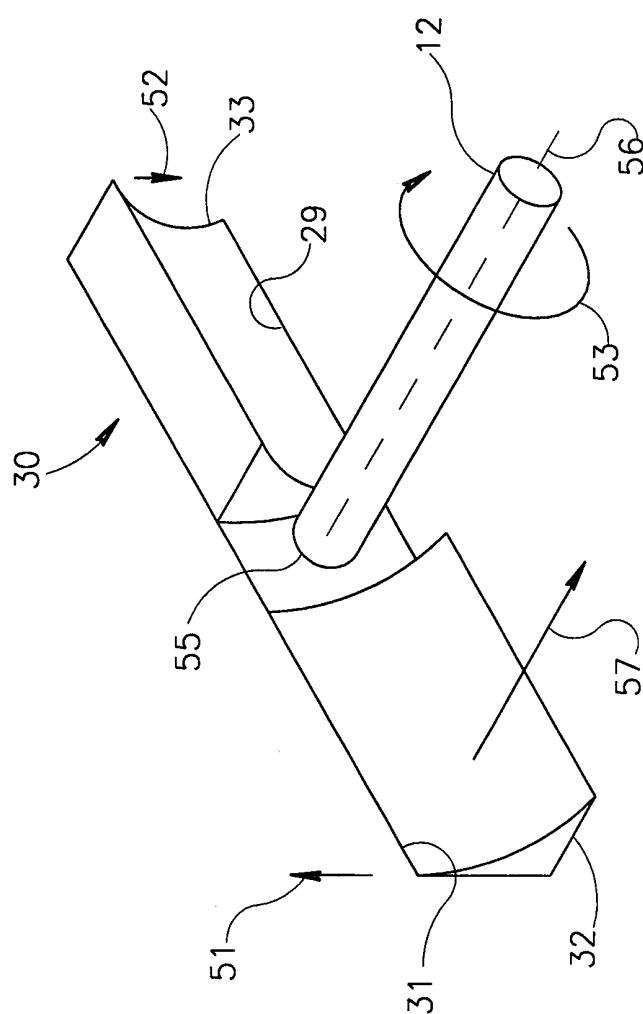


FIG. 4

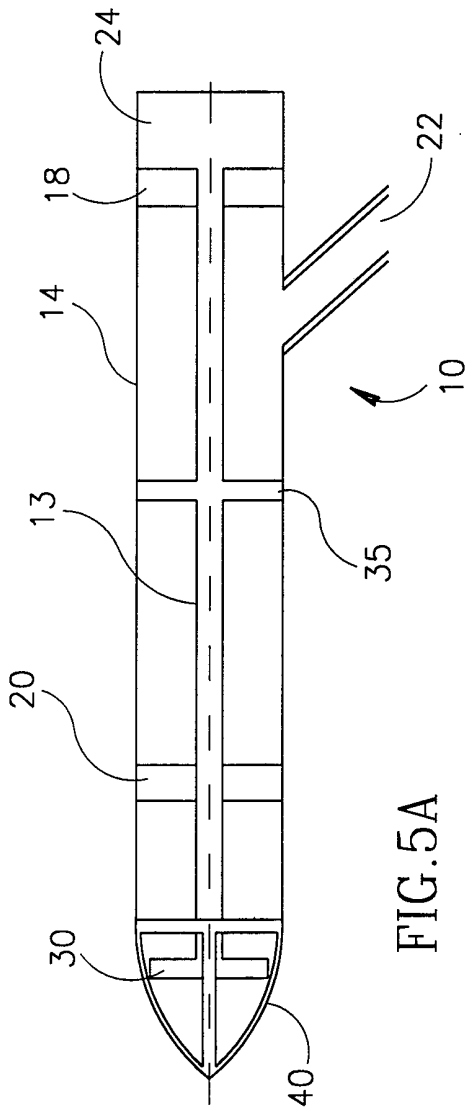


FIG. 5A

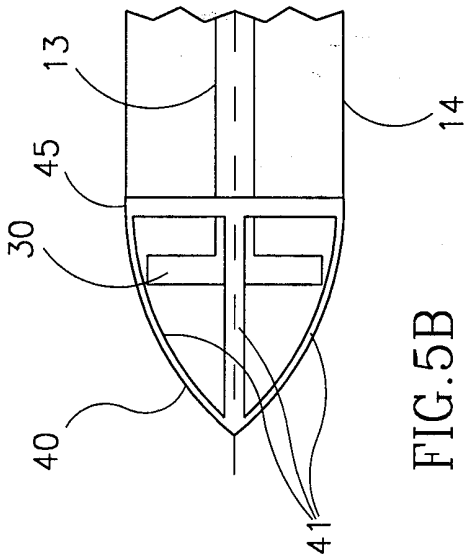


FIG. 5B

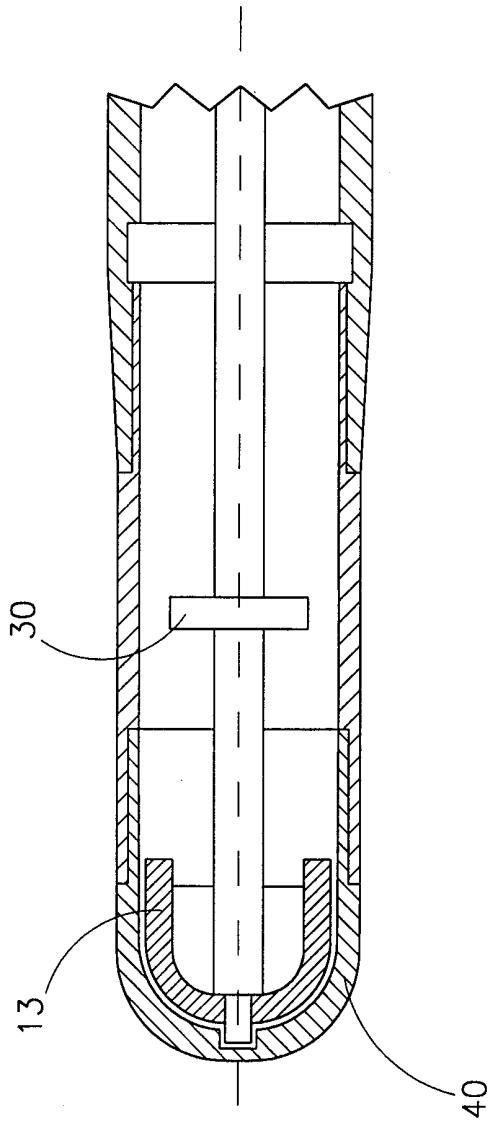


FIG.5C

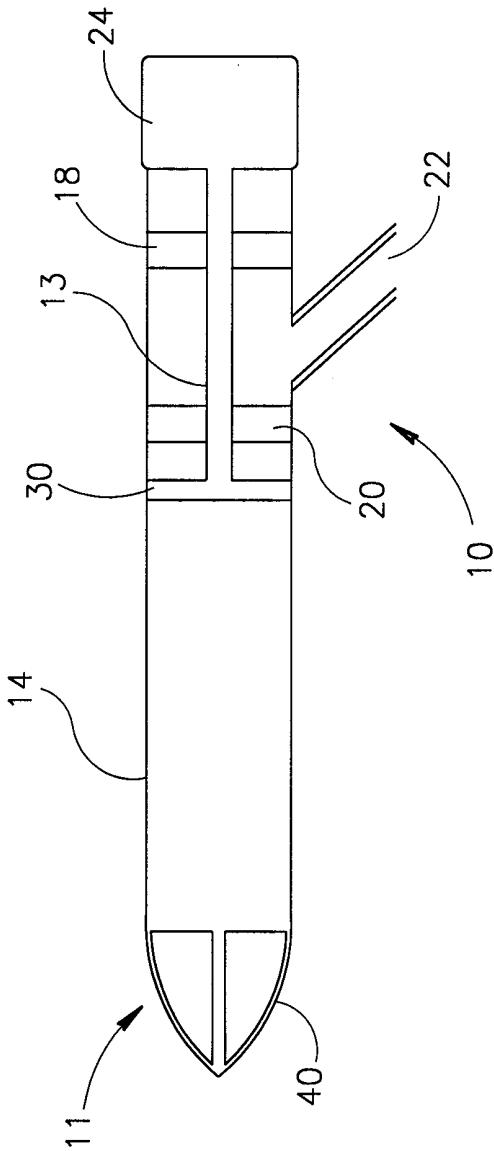


FIG. 6

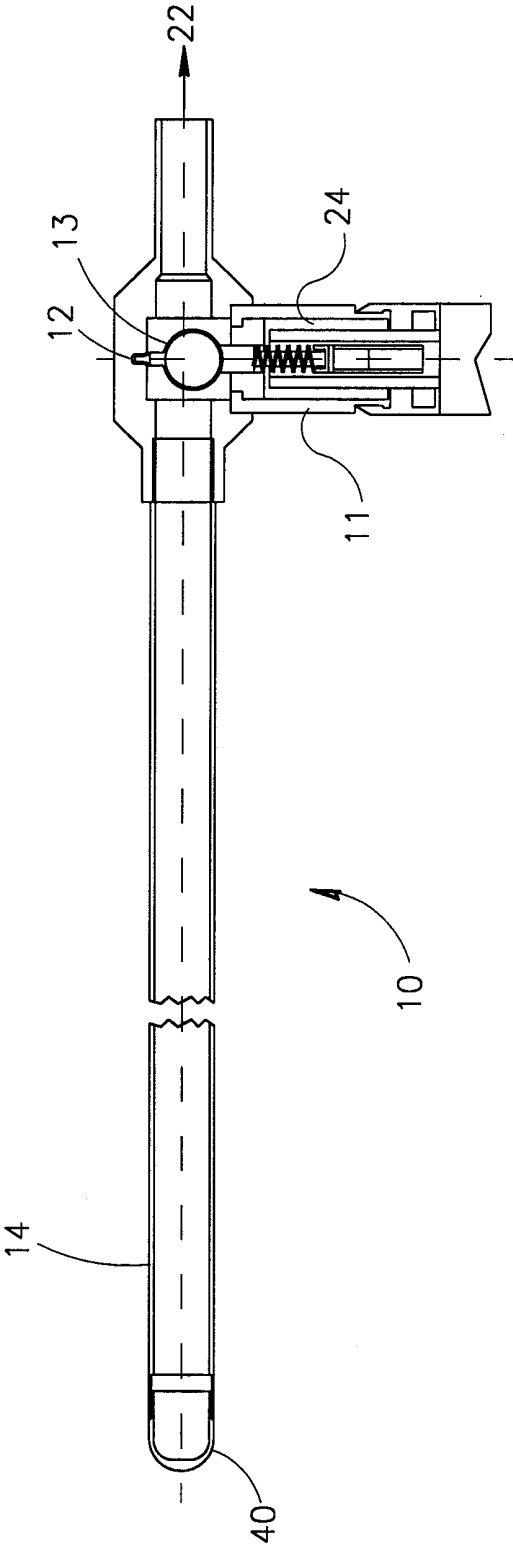


FIG. 7A

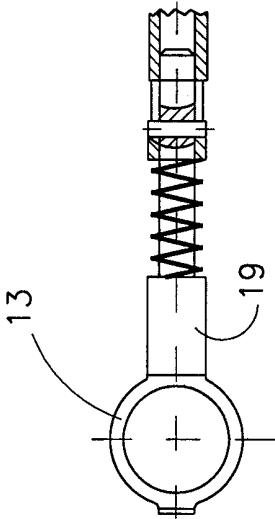


FIG. 7B

11/11

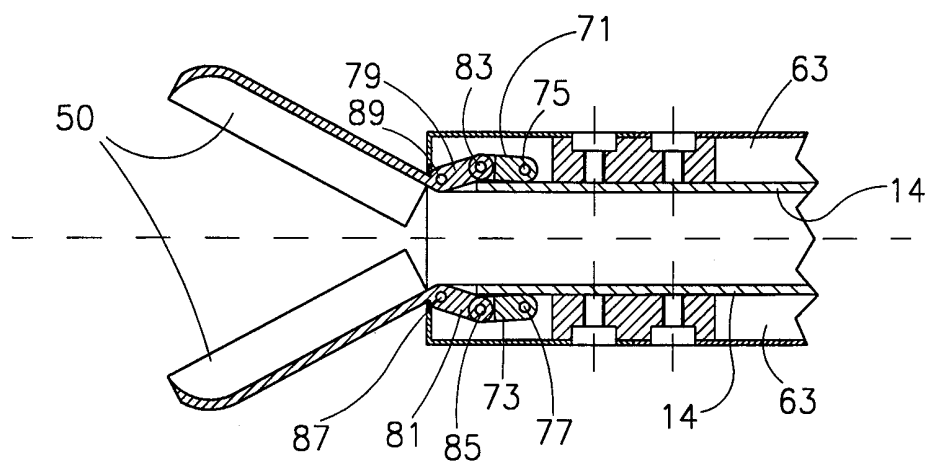


FIG. 8B

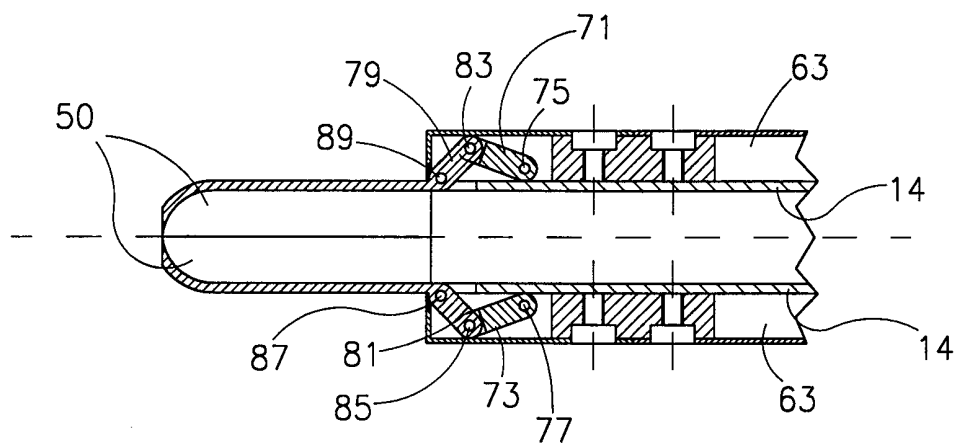


FIG. 8C

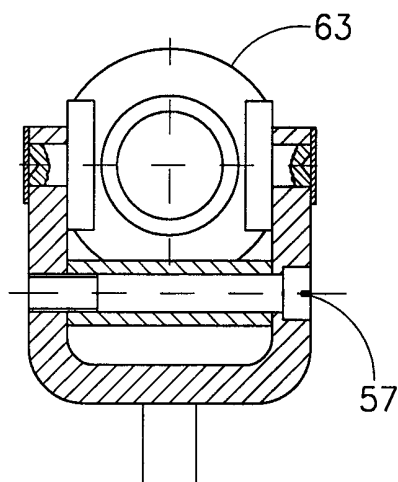


FIG. 8D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL99/00253

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/14, 32

US CL :606/170, 174, 180

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)

U.S. : 606/170, 174, 180

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 practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,100,426 A (NIXON) 31 March 1992, Abstract, col. 1 lines 42-62, col. 2 lines 1-11, and col. 3 lines 1-32.	1-6
X	US 4,857,045 A (RYDELL) 15 August 1989, Figs. 1-4, and Abstract.	1, 7, 8

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Further documents are listed in the continuation of Box C.

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See patent family annex.

* Special categories of cited documents:	"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
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"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

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