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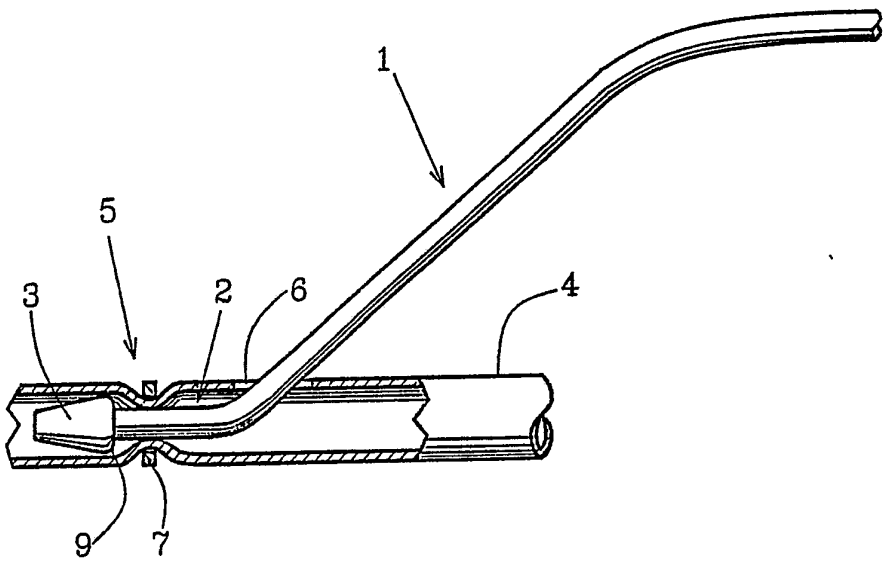
(54) Title: UNCOLLAPSIBLE CATHETER AND METHODS



(57) Abstract

An uncollapsible catheter (1) is formed with a collapse inhibitor (8) positioned within it in select proximity to its tip or head (3) to form an uncollapsible section. The collapse inhibitor (8) can be metallic, preferably a stainless steel or titanium alloy. The collapse inhibitor (8) can be short enough to allow bending of the catheter (1) at a select distance from the tip or head (3). There can be a plurality of short, flat or round collapse inhibitors (8) with bending flexibility of the catheter (1) between them. The collapse inhibitors (8) can also be a continuous linear coil. A use method includes tightly positioning a clip (7) around an anatomical duct (4) in which an uncollapsible catheter (1) is inserted without peril of squeezing the catheter (1) and the duct (4) together.

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Description

UNCOLLAPSIBLE CATHETER AND METHODS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to catheters and use methods. In particular, it relates to catheters used in association with relatively tight clamping means for preventing escape of dyes and other substances around outside surfaces of the catheters when in use.

Description of the Related Art

In current endoscopic procedures and relates use of dyes in association with catheters for examining and treating such hollow anatomical organs as the gallbladder through the cystic duct, there exists a very serious problem of inadvertently including the duct and a catheter inserted into it with clamping pressure of clipping tools for positioning and fastening ligation clips to seal fluid flow around the catheter. One U.S. surgical product used, for instance, is known as a Sutiate Titanium Clip. It is held and position around the duct by a very thin-bodied special clipping instrument. Its use resembles that of a staple in a stapler. The jaws of the clipping instrument are very small in proportion to length and size of its handle. This causes high leverage and mechanical advantage that make it difficult to determine how tightly the clip is being fastened around a duct in which a catheter is inserted. Consequently, in a lot of cases, inclusion results from squeezing the duct and the catheter together.

In the medical field where lives are at risk and losses from errors are immense, this is a very serious problem. It has gone unsolved for decades. Now with the use of endoscopic equipment and associated treatment procedures, the problem has become increasingly acute, owing to related incision confinement. A wide variety of similar problems have lead to this invention.

Summary of the Invention

An uncollapsible catheter is formed with a collapse resistor ring positioned within it in select proximity to its tip or head. A collapse resistor can be metallic, preferably a stainless steel or titanium alloy. It can be short enough to allow bending of the catheter at a select distance from the tip or head. There can be a plurality of short, flat or round collapse resistors with bending flexibility of the catheter between them. The collapse resistor can also be a continuous linear coil. A use method includes tightly positioning a clip around an anatomical duct in which an uncollapsible catheter is inserted without peril of squeezing the catheter and the duct together.

Brief Description of the Drawings

This invention is described in appended claims in relation to description of a preferred embodiment with reference to the following drawings wherein:

Figure 1 is a cutaway side view of the invention being used in a cystic duct to prevent catheter and duct inclusion by clamping pressure of a duct clip.

Figure 2 is a front elevation view of a convention Sutiate Titanium Clip used with special insertion tools to seal ducts around inserted catheters.

Figure 3 is a cutaway side view of an embodiment of this invention with a solid tube positioned in a section of catheter adjacent to a tip portion of the catheter.

Figure 4 is a cutaway side view of the invention with a plurality of solid tubes, some with optional rounded edges for facilitating movement against each other.

Figure 5 is a cutaway side view of the invention using a series of square-walled rings positioned in the catheter to prevent its collapse while allowing it to bend.

Figure 6 is a cutaway side view of the invention using a series of round-walled rings positioned in the catheter to prevent its collapse while allowing it to bend.

Figure 7 is a cutaway side view of the invention using a square-walled metal coil positioned in the catheter to prevent its collapse when used in conjunction with a sutiate clip.

Figure 8 is a cutaway side view of the invention using a round-walled metal coil positioned in the catheter to prevents its collapse and having a smooth tubular base in which the coil is embedded to prevent entrapment of material in the catheter.

Description of the Preferred Embodiment

Referring to Figure 1 of the drawings, a catheter 1 with an uncollapsible section 2 in close proximity to a catheter head 3 is positionable in an anatomical duct 4, such as a cystic duct, at a sealing section 5 of the duct 4. For inserting a catheter in an anatomical duct 4 such as cystic duct without a natural outside entrance, an incision 6 is made and the catheter 1 is bent as necessary after insertion to

allow the catheter 1 to be a different attitudinal angle at the head 3 than the remaining portion of the catheter 1.

Current procedures in the use of catheters include insertion of dyes in anatomical ducts 4 through the catheters 1. Distribution of the dyes in body organs is then observed with endoscopic instruments which are often inserted through the catheter. This endoscopic procedure is in lieu of observation with more open surgery and with other equipment such as X-rays. Objectives usually are to determine the existence, nature and extent of cystic calculus, adenomas, Morgagnian cataracts, degeneration, malignancy, adenoma destruens and other dysfunctions.

In order to achieve an effective level of disbursement of dyes and other agents in body organs, it is helpful to employ a select level of pressure against them through the catheter 1. To prevent escape and passage of fluids past the catheter 1 and the catheter head 3 as a result of the pressure, a clamping or sealing device in the form of a clip 7, shown separately from a face view in Figure 2, is inserted around the duct 4 and bent or otherwise fastened. Clamping pressure of a tool used to insert the clip 7 often closes the duct 4 and the catheter 1 inadvertently. Collapse or closure of the catheter 1 can impair its use and effectiveness for fully achieving objectives of an operational procedure.

In Figure 3, a relatively solid collapse inhibitor 8 is shown inside the catheter 1 which may include an internal, smooth, non-porous base, wherein the collapse inhibitor 8 is positioned in select proximity to the catheter head 3. The collapse inhibitor 8 can be in the form of a hollow metallic

cylinder approximately the length of an average conventional catheter head and may include a non-metallic coating thereon to minimize possible corrosion of the metal. The term "uncollapsible" used in relation to this invention is relative to resistance of pressure application to a fastening clip 7.

Conventional catheter heads often have abrupt flash shoulders at their major diameter ends. This aids in providing a seal without applying enough clamping pressure on the clip 7 to close the conventional catheter. But it is difficult and highly user-dependent to be able to apply only enough clamping pressure on the clip 7 for preventing leakage around the conventional catheter without closing it and rendering it useless for achieving desired objectives. Often an entire operation fails when a conventional catheter collapses from this clamping pressure. A patient's life may be imperiled and observations may be misleading or incomplete. Further, when the conventional catheter with abrupt seal-inducing shoulders is removed, it can injure linings of anatomical ducts and organs. With this invention, however, it is not necessary to achieve sealing with a sharp-edged catheter head. Instead, a selectively rounded catheter shoulder 9 is used because the uncollapsible section 2 of the catheter 1 will not collapse when a clip 7 is tightened on the duct 4 sufficiently tight to prevent leakage from an upstream portion of the duct 4.

Reference is made now to Figure 4. In order to provide an uncollapsible section 2 of a catheter 1 close to and also further removed from a catheter head 3, a plurality of short collapse inhibitors 10 can be employed. This increases flexibility in that a clip

7 can be positioned without probability of failure of the catheter function. Rounded corners 11 can be provided on the short collapse inhibitors 10 in order for them to allow bending of the uncollapsible section 2 when they may be positioned relatively close together. These short collapse inhibitors 10 have walls with rectangular cross sections 12.

In Figure 5, a plurality of square-walled rings 13 are employed as a collapse inhibitor for construction of the uncollapsible section 2. Each square-walled ring 13 has an effectively square cross section 14. These increase further yet the flexibility of where the uncollapsible section 2 can be bent for fitting a catheter into a duct 4 from an attitudinal angle different from linear axis of the duct 4.

In Figure 6, a plurality of round-walled rings 15 with substantially round cross sections 16 are employed to add flexibility of the uncollapsible section 2. Roundness of edges allows the rings 16 to be positioned closer yet together while allowing ease of bending without collapse from sealing pressure on the uncollapsible section 2.

Figure 7 shows use of a square-walled coil 17 with square cross sections 18 embedded in the inside periphery 19 of the uncollapsible section 2.

Figure 8 is a round-walled coil 20 with round cross sections 21 employed to provide uncollapsibility. The round cross sections 21 are embedded in a smooth base 22 to avoid areas for accumulation of contaminants around surfaces of the round-walled coil 20.

The smooth base 22 can be employed with any of the collapse inhibitors 8, 10, 13, 15, 17 or 20. To avoid conditions for contamination further, material

for construction of the collapse inhibitors 8, 10, 13, 15, 17 or 20 can be stainless steel with either of a wide variety of alloys of nickel and chromium. Titanium and its alloys also are particularly noncorrosive. Alloys of palladium and titanium are relatively inexpensive and easily formable and machinable in comparison to other titanium metals. In addition to avoiding contamination conditions by being stainless and noncorrosive, titanium alloys are only about a third as heavy per strength of collapse resistance for this invention.

In selecting between square-walled coils 17 and round-walled coils 20, tradeoff factors are greater strength with less diameter per strength of the square cross sections 18 and greater catheter-bending characteristics with the round cross sections 21. These same tradeoff factors apply for square-walled rings 13 and round-walled rings 15.

An entire length of catheter 1 can be constructed with either collapse inhibitors 13, 15, 17 or 20. Most convenient for construction would be square-walled coils 17 or round-walled coils 18.

A new and useful uncollapsible catheter has been described. All such modifications, adaptations, applications and forms of the catheter as described by the following claims are included in this invention.

Claims

1. An uncollapsible catheter having a distal section comprising:

an elongate, resilient tube section having a generally uniform interior and exterior diameter,

a head portion, said head portion being of a generally larger exterior diameter than said tube section, and being integrally formed therewith so as to form a rounded shoulder therebetween, and

an internally positioned collapse inhibitor, said collapse inhibitor being a select length so as to define an uncollapsible section extending generally from said head and in said tube section.

2. An uncollapsible catheter as recited in claim 1 wherein said separate rings include rounded exterior surfaces.

3. An uncollapsible catheter according to claim 1 wherein the uncollapsible section is provided with a metallic-tube collapse inhibitor fixably positionable in the uncollapsible section of the catheter.

4. An uncollapsible catheter according to claim 3 and further comprising non-metallic material coating on the interior and end surfaces of the metallic-tube collapse inhibitor.

5. An uncollapsible catheter according to claim 1 wherein the uncollapsible section is positioned at a select distance from the catheter head to allow bending of the catheter at both ends of the uncollapsible section.

6. An uncollapsible catheter according to claim 1 and further comprising a plurality of short collapse inhibitors of select lengths fixably positionable at select distances from each other within a catheter.

7. An uncollapsible catheter according to claim

6 wherein the plurality of short collapse inhibitors are separate rings with rigid bores of select lengths.

8. An uncollapsible catheter according to claim 7 wherein the separate rings are of substantially equivalent dimensions.

9. An uncollapsible catheter according to claim 8 wherein the separate rings are positionable with a distance between them which allows select bending of the catheter.

10. An uncollapsible catheter according to claim 1 including a truncated-cone head having selectively rounded edges on a major-diameter thereof.

11. An uncollapsible catheter as recited in claim 1 wherein said collapse inhibitor includes a linear resilient coil fixably positionable within the catheter and linear to its axial walls.

12. An uncollapsible catheter according to claim 11 wherein the resilient linear coil is a metallic coil spring.

13. An uncollapsible catheter according to claim 12 wherein a cross-section of a coiled wire forming the metallic coil spring is rectangular.

14. An uncollapsible catheter according to claim 12 wherein a cross-section of a coiled wire forming the coil spring is round.

15. An uncollapsible catheter according to claim 11 wherein the resilient linear coil is positionable in select proximity to said head of the catheter and extended a select distance therefrom within the catheter.

16. An uncollapsible catheter according to claim 1 and further comprising:

a plurality of collapse inhibiting members of select dimension linear to the catheter extended a select distance throughout the catheter from the

catheter head; and

a smooth, non-porous base in which the plurality of collapse inhibitors are positioned to prevent accumulation of contamination around the collapse inhibitors.

17. A method for using an uncollapsible catheter comprising the following steps:

inserting the uncollapsible catheter a select distance inside of an anatomical duct;

fastening a sealing member selectively tight against an outside periphery of a portion of the anatomical duct in which an uncollapsible section of the uncollapsible catheter is inserted, and substantially abutting a head of the catheter so as to prevent sliding of the catheter outwardly through the sealing member,

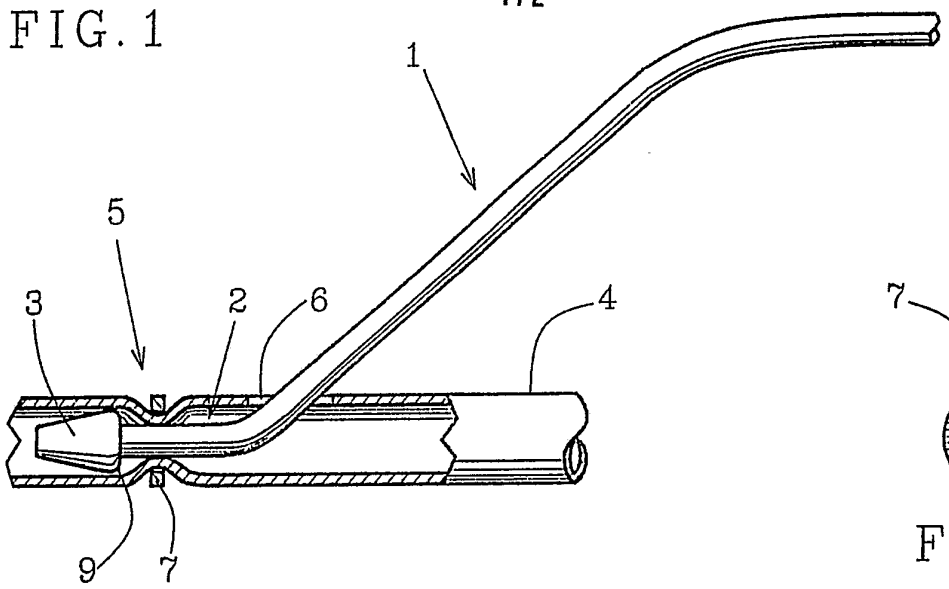
inserting into and withdrawing from within the anatomical duct such material and instrumentation as desired;

removing the sealing member; and

withdrawing the uncollapsible catheter.

18. A method according to claim 17 wherein the anatomical duct, such as a cystic duct, has no existing outside entrance and further comprising the steps of first incising a select opening in the cystic duct and in obstructive covering organs for insertion of the uncollapsible catheter and lastly suturing the incision.

FIG. 1



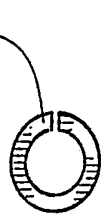


FIG. 2

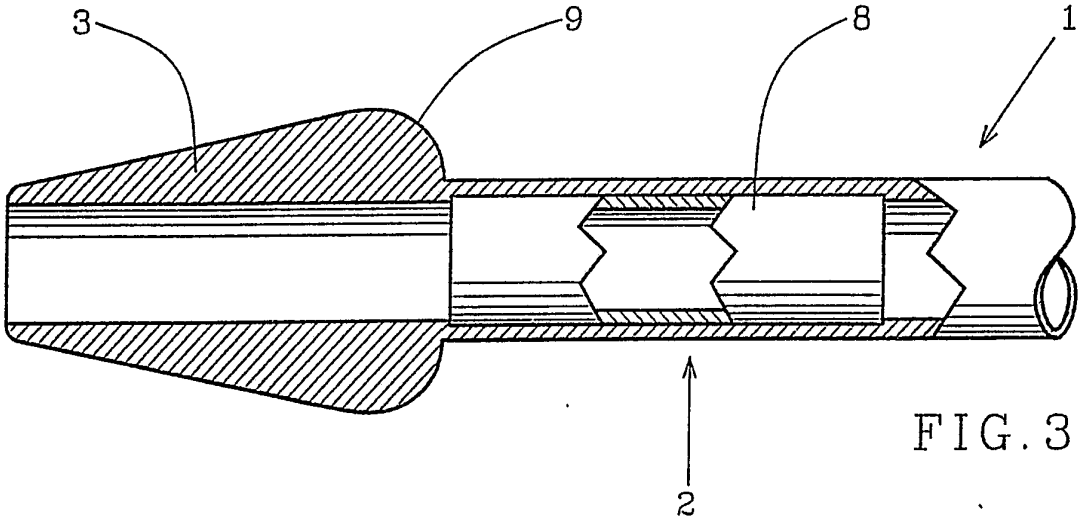


FIG. 3

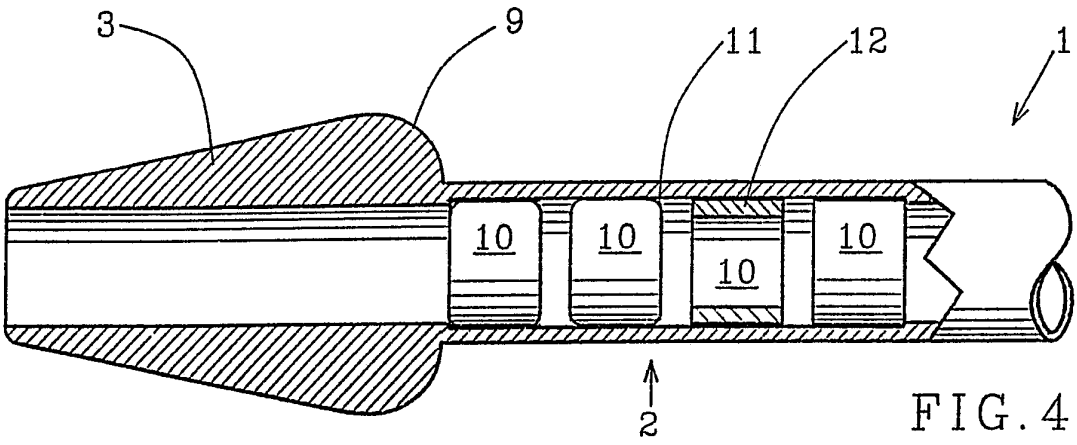


FIG. 4

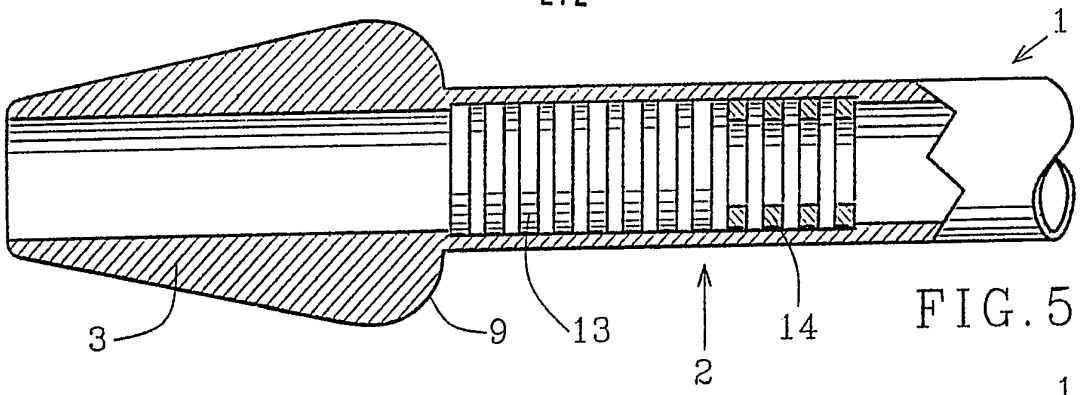


FIG. 5

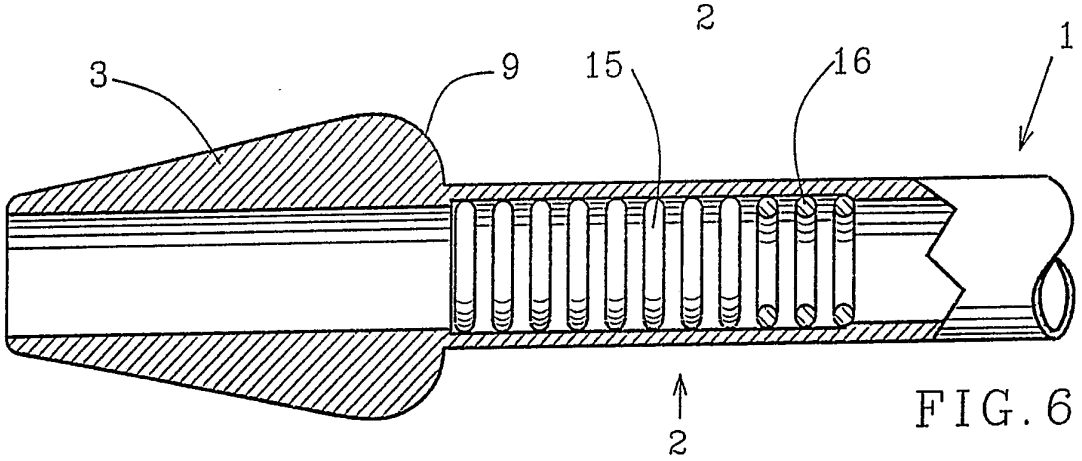


FIG. 6

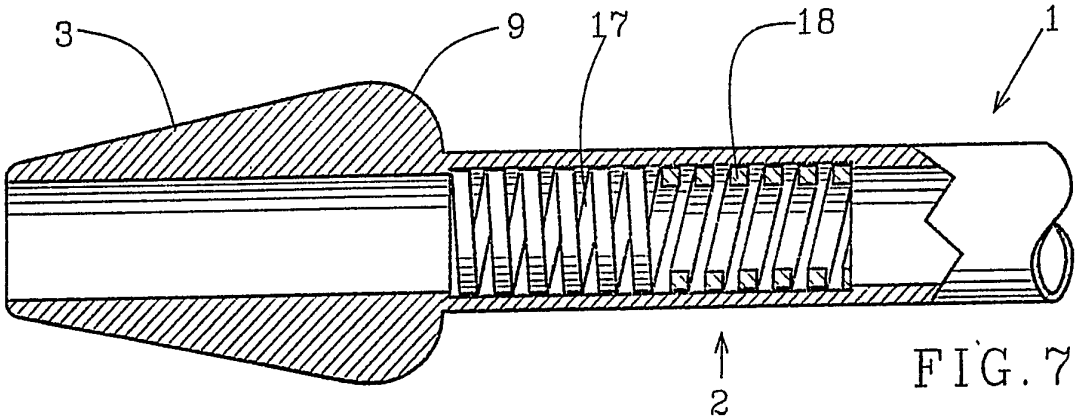


FIG. 7

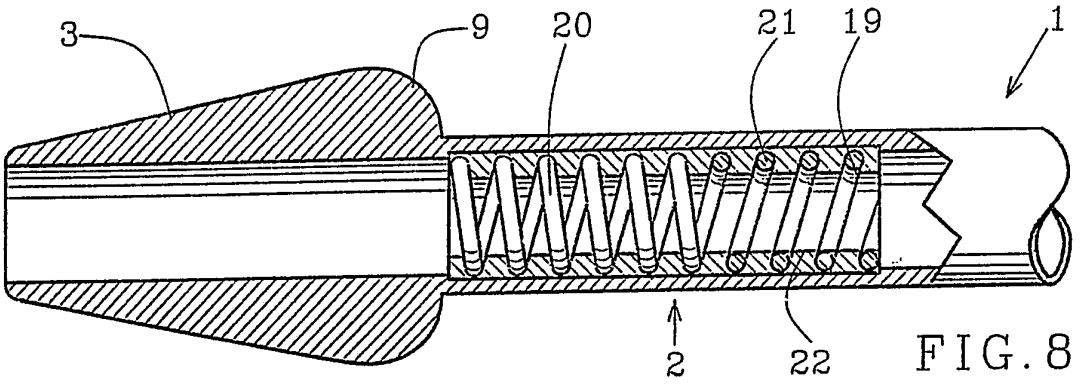


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/04669

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 25/00
US CL :604/282

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. : 604/54,270,280,95;606/157;128/656-658,772;138/172

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	SU,A, 940,777 (Kish Medic Inst.) 07 July 1982 Refer to abstract.	1-3,5-10
Y	US,A, 3,780,740 (Rhea) 25 December 1973 Refer to figure 3.	1-3,5-16
Y	US,A, 5,017,193 (Fields) 21 May 1991 Refer to figure 3.	1-3,5-16
Y	US,A, 3,757,768 (Kline) 11 September 1973 Refer to figure 1.	1,11-16
Y	US,A, 4,547,192 (Brodsky et al.) 15 October 1985 Refer to figure 6.	1,11-16
Y	US,A, 4,737,153 (Shimamura et al.) 12 April 1988 Refer to figure 3.	1,11-16
Y	US,A, 4,719,924 (Crittenden et al.) 19 January 1988 Refer to figure 7.	13
Y	US,A, 5,069,217 (Fleischhacker, Jr. 03 December 1991 Refer to figure 1.	13
X	US,A, 4,306,566 (Sinko) 22 December 1981 Refer to column 4, lines 1-28.	17-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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