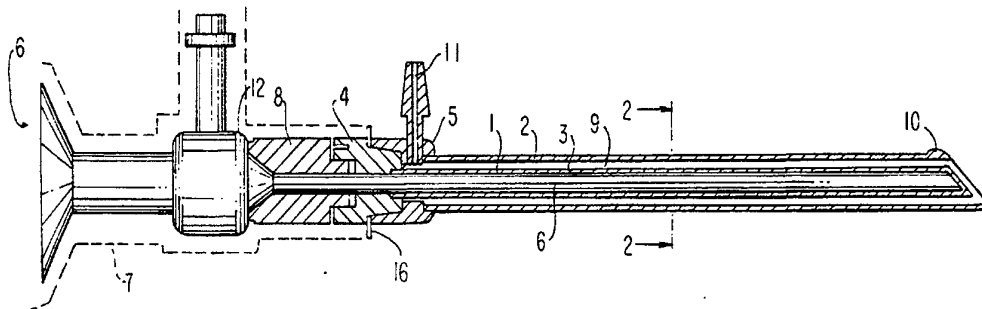




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US94/09816 (22) International Filing Date: 1 September 1994 (01.09.94) (30) Priority Data: 106868 2 September 1993 (02.09.93) IL (71)(72) Applicant and Inventor: SOHN, Zeev [US/IL]; Neve Tsuf, 71945 D.N. Modiin (IL). (74) Agents: DIPPERT, William, H. et al.; Cowan, Liebowitz & Latman, P.C., 605 Third Avenue, New York, NY 10158 (US).</p>		<p>(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p>

(54) Title: DISPOSABLE CYSTOSCOPE



(57) Abstract

This invention provides a flexible or rigid endoscopy and/or cystoscopy apparatus comprising at least two tubes (1, 2) running one inside the other and having a space (3) between them for water and/or air irrigation, the inner tube (1) being closed with transparent material at its distal tip, and the inner tube having an internal lumen to enable an optics tube (6) to slide in and out before, during and after the surgical procedure.

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DISPOSABLE CYSTOSCOPE

FIELD OF THE INVENTION

This invention is directed to a novel cystoscope. More particularly, this invention is directed to a disposable cystoscope having a removable sheath.

5

BACKGROUND OF THE INVENTION

Cystoscopy and endoscopy are common daily practices of physicians. These short time procedures require substantial time intervals between procedures for cleaning the parts, such as disinfection with liquids (for example, "Cidex") or heat and gas disinfection or sterilization techniques which may take even longer. The problem with cleaning or sterili-zation is not limited just to the time required, but also involves the fact that cystoscope and endoscope lumens and valves do not always sterilize effectively, leaving the possibility of cross-contamination.

There is a need for a disposable, low-cost cysto-scope/endoscope apparatus which permits the use of most cystoscopic accessories, having the optics of a multi-use product, but need not be sterilized. Also, such a system should have a large inner lumen for rapid water and particle removal from the body.

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25

OBJECTS OF THE INVENTION

It is an object of the invention to provide a novel cystoscope and endoscope sheath.

It is also an object of the invention to provide a disposable cystoscope and endoscope having a removable interchangeable sheath.

5 It is a further object of the invention to provide a disposable cystoscope or endoscope sheath used to perform procedures inside the body, which has no communication between the multi-use optics and the external environment. The system has a large lumen for water irrigation and evacuation, and the device has a rigid
10 structure to support rigid optics or a flexible structures for flexible optics.

These and other objects of the invention will become more apparent in the discussion below.

15

SUMMARY OF THE INVENTION

Applicants have developed a novel disposable cystoscope and endoscope meeting the requirement for single use sterile procedures and function required by cystoscopes to be used in modern-day urological
20 procedures. The cystoscope and endoscope of the invention comprises a rigid, elongate, substantially cylindrical, external tube and an inner semi-rigid tube into which the multi-use optics is inserted. Concentrically fitting around the outer surface of said
25 inner tube is an outer cylindrical rigid sheath open at at least its distal end and having one or more ports for infusion or withdrawal of liquid. The distal end of the multi-use optics member has a standard slant of 0°, 30°, 70°, etc., and the inner tube has a transparent distal
30 tip that is spatially compatible with the slant of the multi-use optics member. Potentially one inner tube fits optics of 0° and 30° slant.

The optics are isolated from the outside by the thin wall semi-rigid tube having its distal end closed with a transparent material so that the optics has no contact with the outside environment, eliminating the need to sterilize the optics from one patient to another. The optics proximal part can optionally be covered by a flexible (nylon) bag to isolate it from contact with the physician or optionally the patient. The fiber optic light cable source can be covered with the same system.

The invention relates also to a small, rechargeable, battery-operated light source, which is mounted directly on the optics preventing the need for an external fiber optic light source.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a longitudinal cross-sectional view of an embodiment of the invention;

Fig. 2 is a cross-sectional view along the line 2-2 in the embodiment shown in Fig. 1;

Fig. 3 is a longitudinal cross-sectional view of the blind insertion phase of the invention; and

Fig. 4 is a view of the rechargeable small light source.

DETAILED DESCRIPTION OF THE INVENTION

The invention can perhaps be better understood by making reference to the drawings. As shown in Fig. 1, the cystoscope of the invention comprises two disposable parts: inner tube 1 and outer tube 2. Inner tube 1 is a semi-rigid thin wall tube that is closed at its distal end. The internal diameter of inner tube 1 is slightly

larger than the external diameter of the distal portion of optics member 6, to permit insertion and removal of optics member 6 without creating significant vacuum or pressure within the annular space 3 between inner tube 1 and optics member 6.

The outer tube 2 is a rigid tube that supports the rigid optics member 6 against bending and breaking. It allows water irrigation and instrumentation required of medical procedures to be carried out through the annular space created between the two disposable tubes 1 and 2. The outer tube 2 can optionally have an elliptical cross-section to permit more space for instrumentation, if needed.

The distal tip of outer tube 2 has a preferably rounded projection 10 to ensure smooth passage through the urethra, with minimal trauma to the urethral wall. Also, the distal end of inner tube 1 should have an angular slant to match the slant of the distal end of optics member 6. Such angles are usually 0°, 30°, or 70°.

The proximal portions of tubes 1 and 2 are sealingly attached to locking members 4 and 5, respectively, which seal the lumens of tubes 1 and 2 from water or air leakage and which form a passageway to port 11 for annular space 9. The system here enables (1) sliding of inner tube 1 out with optics member 6, leaving outer tube 2 in the body, or (2) sliding optics member 6 out, leaving tubes 1 and 2 in the body (for the changing of the optics without changing the inner tube). When only outer tube 2 is left in a body cavity (for example, a urinary bladder), its large inner diameter enables fast bladder removal of urine, blood or stones.

Adapter 8 fits into the proximal surface of locking member 4 and is intended to cooperate with the proximal portion 12 of optics member 6. Adapter 8 varies according to the optics member 6 being used, which permits
5 the scope of the invention to be compatible with the optics of different companies, such as STORZ, OLYMPUS, CIRCON, and the like.

In Figure 2 outer tube 2 is shown with an oval cross-section, where portions of the annular space 9
10 between the inner tube 1 and outer tube 2 will be large. This will enable insertion of additional instrumentation during cystoscopy or endoscopy (such as ureter catheter insertion, biopsy forceps procedures, etc.).

The disposable mandrel 19 shown in Fig. 3 fits into
15 the internal lumen of outer tube 2 for easy blind insertion of the cystoscope. Then, once outer tube 2 is in position, mandrel 19 would be removed and inner tube 1 followed by optics member 6, or inner tube 1 and optics member 6 together, would be inserted. In this way the
20 optics member with the inner tube is inserted after the outer tube is inside the body.

It should be emphasized that the invention described herein is not limited to cystoscopies. The invention can be used in devices for transurethral resection of
25 prostate as well as any endoscopy using rigid or flexible optics and/or a camera.

As shown in Fig. 4, optics member 6 can optionally comprise a proximally positioned, rechargeable, battery-operated, small light source with no externally-
30 connecting wire or fiber optics. Lamp body 12 has a shape to fit the optics connector to the fiberoptic. Switch 15 opens lamp 14 which gets its energy from batteries 13. This would make the cystoscope/endoscope

operation easier to perform since there would not be a fiber optic cable to disturb the physician's maneuvers. A small battery-operated light source could thus replace the conventional external high-intensity light source.

5 Also, when a rechargeable, optics-mounted light source is used, there is no need for fiber optics to transmit the light from an external light source, resulting in less light dispersion, and less energy needed for the optic mounted light source.

10 Optional protective flexible sleeve 7 is comprised of a polymer bag extending from an annular ring 16 located in a space or groove between locking members 4 and 5. Also sleeve 7 permits a sterile field when no sterile optics, fiber optic cable, small mounted light
15 source or camera are used.

Inner tube 1 and outer tube 2 are comprised of sterilizable, physiologically acceptable rigid or semi-rigid materials. Preferably polymeric material such as polymers or co-polymers of polyethylene, polybutylene,
20 polypropylene, polyurethane or even fiberglass-epoxy composite materials are used. Locking members 4 and 5, which should be rigid, could be comprised of similar material. Inner tube 2 may be continuously one material or even two materials, so long as the distal end of inner
25 tube 2 is optically clear. The interior space between the distal end of inner tube 2 and the optics member 6 blunt can be filled potentially with an optical gel to minimize the reflection of light between the two components.

30 The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed

without departing from the spirit of the invention or the scope of the appended claims.

I CLAIM:

1. A disposable scope system for film optics, comprising

a disposable inner tubular member having a lumen extending therethrough and proximal and distal ends, the distal end of the inner tubular member being closed and being comprised of optically clear material and the proximal end of the inner tubular member comprising a first locking means

a disposable outer tubular member having proximal and distal ends, the distal end of the outer tubular member being open and the proximal end of the outer tubular member comprising a second locking means and a port,

wherein the inner tubular member fits slidingly within the outer tubular member, wherein the first locking means and the second locking means fit together, and wherein there is a space between the inner tubular member and the outer tubular member that is in fluid communication with the port and provides a passage for water and/or air irrigation, and wherein a fiber optics member fits slidingly within the lumen of the inner tubular member.

2. The scope system of Claim 1, wherein a protective, flexible sleeve extends proximally from the proximal part of the scope system along the proximal part of the fiber optics and over any TV cable and/or external light source.

3. The scope system of Claim 1, wherein the distal end of the inner tubular member is angled to facilitate insertion of different fiber optics.

4. The scope system of Claim 1, wherein the fiber optics is capable of sliding easily in and out of the inner tubular member during a procedure without the need to remove the system from the body, which enables the use of the large lumen for the procedure.

5. The scope system of Claim 1, wherein one or both of the disposable tubular members are rigid to resist bending and breaking of the rigid multi-use optics.

6. The scope system of Claim 1, wherein one or both of the disposable tubular members are flexible.

7. The scope system of Claim 1, which is useful in laparoscopic surgery to eliminate the need for optics sterilization.

8. The scope system of Claim 1, wherein an adaptor enables the same system to fit different fiber optics.

9. The scope system of Claim 1, which also comprises a disposable mandrel that fits within either of the inner and outer members for blind insertion of the tubular member or members inside the body.

10. The scope system of Claim 1, wherein the space between the tubular members functions for the insertion of instrumentation or for irrigation or for optics/lens cleaning.

11. The scope system of Claim 1 for a trans-urethral resection in which the inner tubular member is connected to an axially moving cutting knife.

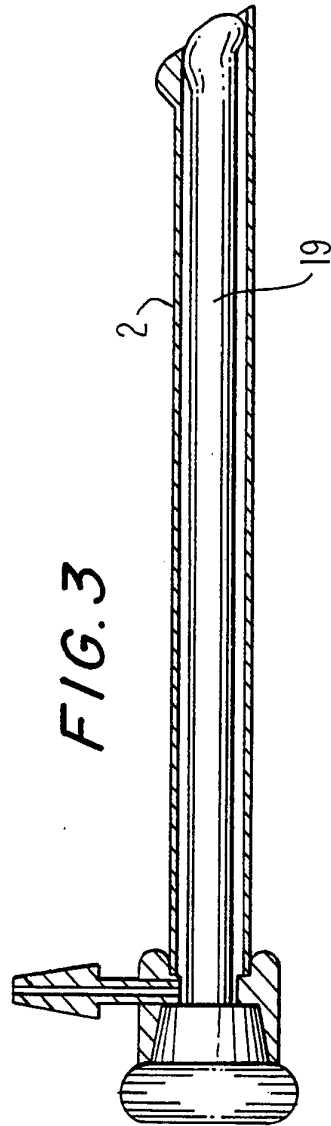
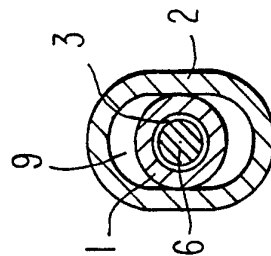
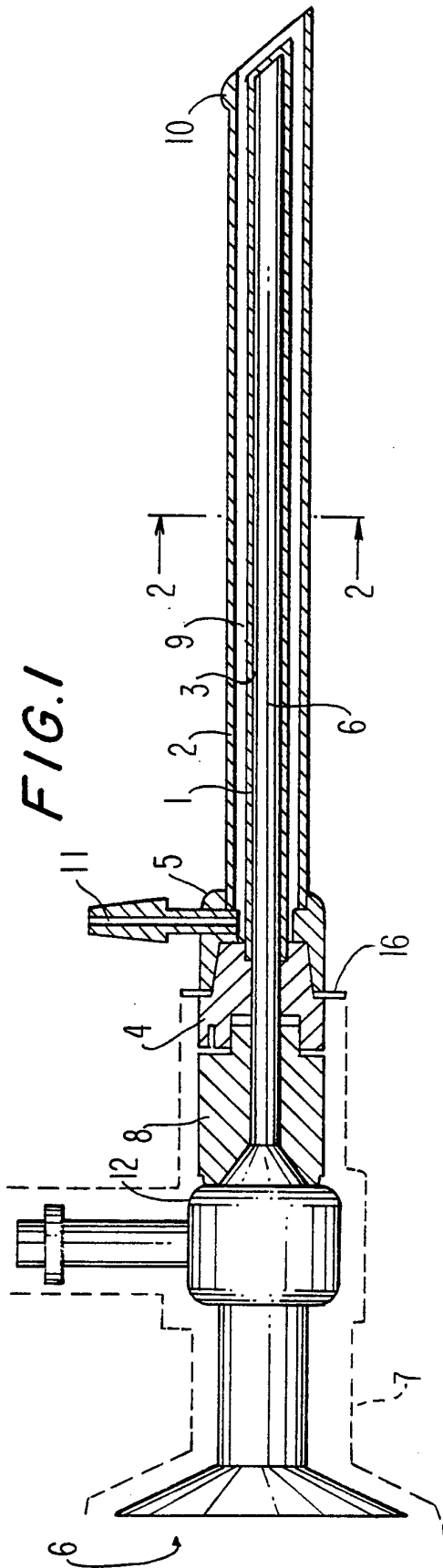
12. The scope system of Claim 1, for a T.U.R. apparatus, wherein the inner tube has three lumens, a

cutting knife slides in two of them and the third lumen has a clear closed end for the insertion of optics.

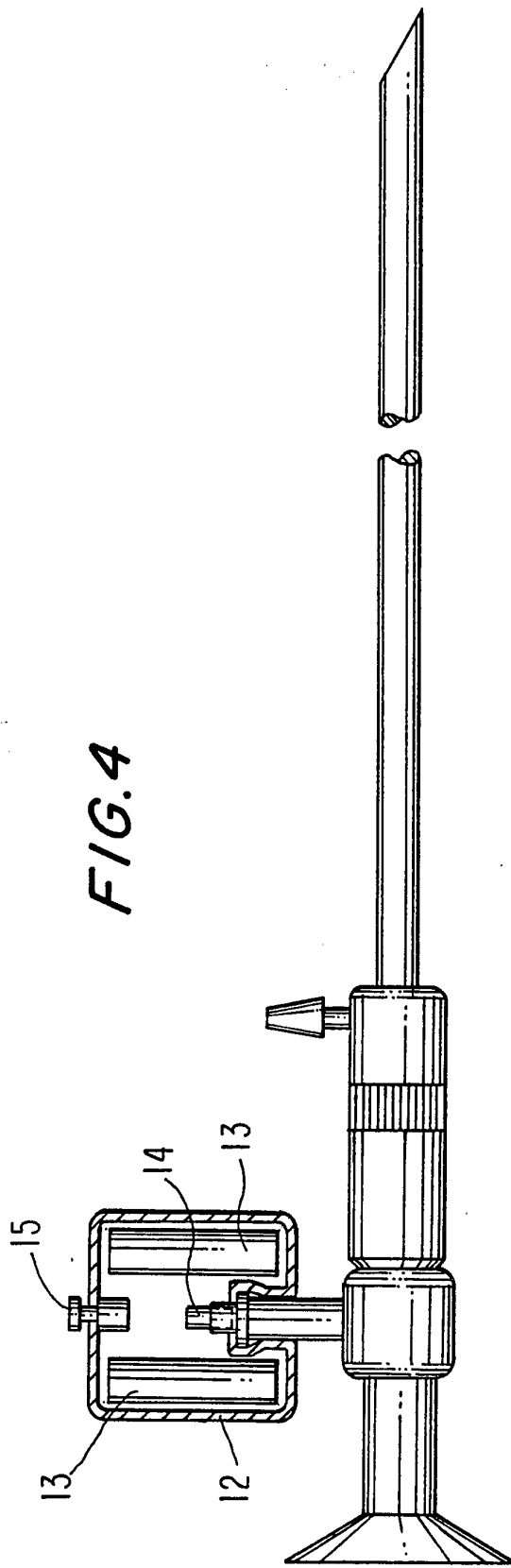
13. A system for performing sterile endoscopy procedures using a disposable endoscope/cystoscope sheath having two longitudinal lumens, one for water/air or instrumentation and the other with a closed optically clear distal end to fit the multi-use optics and isolate it from the surrounding environment.

14. The system of claim 13, for a transurethral resection in which the inner tubular member is connected as the working element of a T.U.R. apparatus.

15. The system of Claim 13, for a T.U.R. apparatus, wherein the inner tube has three lumens, a cutting knife slides in two of them, and the third lumen has a clear closed end for insertion of optics.



1/2



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/09816

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(5) :A61B 1/00, 1/30
 US CL :128/4, 7
 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. : 128/4, 7

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,254,762, (YOON), 10 March 1981. See column 3, lines 66-68; column 4, lines 36-46; column 5, lines 3-12; column 6, lines 43-62; Abstract; and Figs. 7 and 8.	1, 3-5, 7, 8, 10, 13 ----- 2, 6, 9, 11, 12, 14, 15
Y	US, A, 4,878,485, (ADAIR), 07 November 1989. See column 5, lines 11-15; and Fig. 7.	2
Y	US, A, 4,712,536, (HAWKS), 15 December 1987. See Figs. 4 and 5.	9
Y, P	US, A, 5,320,091, (GROSSI ET AL.), 14 June 1994. See column 4, lines 3-7 and 17-20; column 7, lines 55-66; column 8, lines 50-61; and Figs. 9 and 16.	11, 12, 14, 15

Further documents are listed in the continuation of Box C. 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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Date of the actual completion of the international search 21 NOVEMBER 1994	Date of mailing of the international search report DEC 14 1994
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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,567,880, (GOODMAN), 04 February 1986. See Fig. 1.	1, 4, 7, 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/09816

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

APS

Search Terms: cystoscope(s), cystoscopies, endoscope(s), disposable, optics, and tube or tubular