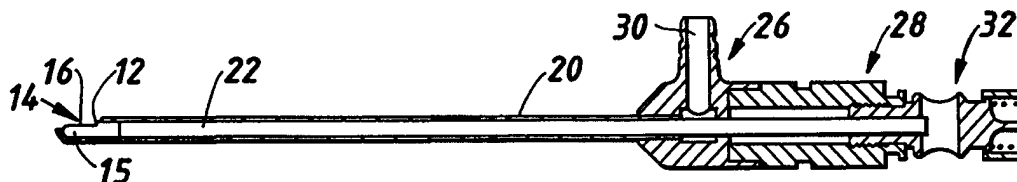




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US98/03333 (22) International Filing Date: 20 February 1998 (20.02.98) (30) Priority Data: 08/805,143 24 February 1997 (24.02.97) US (71) Applicant: SMITH &amp; NEPHEW, INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US). (72) Inventor: SMITH, Graham; 68 Forrest Street U3B, Plaistow, NH 03865 (US). (74) Agents: STACEY, George, K. et al.; Smith &amp; Nephew, Inc., 1450 Brooks Road, Memphis, TN 38116 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: ENDOSCOPIC SURGICAL INSTRUMENT



## (57) Abstract

An endoscopic surgical instrument is provided that includes a surgical implement, e.g., a cutting tool, and an irrigation device that supplies fluid to the surgical implement during use of the device. The endoscopic surgical instrument includes a surgical implement disposed at a distal region of the surgical instrument, and an irrigation device associated with the surgical implement in a manner to define a path for conveying irrigation fluid from a proximal region of the surgical instrument to the surgical implement.

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## ENDOSCOPIC SURGICAL INSTRUMENT

The present invention relates to endoscopic surgical  
5 instruments.

Several different kinds of surgical instruments have been developed for performing arthroscopic and other endoscopic surgical procedures. Some of these surgical instruments are  
10 powered, that is, operated by a motor; others are manual. Motor-driven instruments typically are received by a handpiece which houses the motor. Manual instruments are operated with a trigger-like handle. Examples of powered endoscopic surgical instruments are described in U.S. Patent Nos. 4,203,444, 4,274,414, 4,834,729,  
15 4,842,578, and 4,705,038; examples of manual endoscopic surgical instruments are described in U.S. Patent Nos. 4,522,206 and 4,662,371. All of these patents are assigned to the present assignee and are incorporated herein by reference.

20 The instruments may include a wide variety of surgical implements for performing different types of surgical operations on body tissue. For example, some instruments are equipped with blades for cutting soft tissue, while others have burrs for abrading bone tissue. Still other implements (such as forceps and graspers)  
25 grip, rather than cut, tissue.

A typical cutting or abrading endoscopic, e.g., arthroscopic, surgical instrument includes a stationary outer tube within which an inner tube is moved (either manually or driven by a motor) during  
30 operation. The surgical implement is mounted to the distal end of the inner tube. Tissue or bone is exposed to the surgical implement through an opening in the distal end of the outer tube, and tissue

and/or bone is cut by the moving implement. The cut tissue and bone fragments are drawn through the interior of the inner tube by suction applied at the proximal end of the instrument.

5           Endoscopic instruments are, whenever possible, used with irrigation devices, such as fluid pumps, which supply irrigating fluid to and suction fluid from the surgical site, as this improves cutting and transport of excised tissue and bone fragments from the surgical site.

10

          Knee arthroscopy, which is performed in a closed capsule, where little danger exists of extravasation of fluid into adjacent anatomical structures, is carried out with the joint infused with saline. The use of fluid in this manner increases the cutting efficiency of  
15   powered resectors, and the transport of resected material from the joint. Some other areas of the body where tissue is routinely resected, however, are not generally amenable to infusion of saline. For example, in sinus surgery infusion of the sinuses with saline could potentially result in dangerous extravasation of fluid into the  
20   patient's airway.

          In accordance with the present invention, there is provided an endoscopic surgical instrument comprising a surgical implement disposed at a distal region of the surgical instrument, and an  
25   irrigation device associated with the surgical implement in a manner to define a path for conveying irrigation fluid from a proximal region of the surgical instrument to said surgical implement.

30           The present invention provides an endoscopic surgical instrument which includes an irrigating device, eliminating the need

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for a separate irrigating device. This is particularly advantageous in applications, such as sinus surgery, where there is typically insufficient room at the surgical site for the placement of a separate irrigation device.

5

The invention, in one general aspect, features an improved endoscopic surgical instrument that includes a surgical implement disposed at a distal region of the surgical instrument, and an irrigation device associated with the surgical implement in a manner to define a path for conveying irrigating fluid from a proximal region of the surgical instrument to the surgical implement. The invention also features methods of using the instrument for endoscopic surgery, e.g., for sinus surgery.

15 Among other advantages, the invention allows the surgical instrument and the irrigation device to be introduced into the body together as a single surgical device (for example, through the same cannula during endoscopy). In addition to simplifying the surgical procedure, the invention reduces the trauma to the patient that  
20 accompanies the insertion of two separate instruments, and, as noted above, allows irrigating fluid to be introduced during surgery in very small areas, e.g., the patient's sinuses, where irrigation was hitherto typically difficult.

25 Moreover, in preferred embodiments the instrument of the invention delivers fluid directly to the surgical implement while simultaneously and continuously suctioning the fluid away at a sufficient rate so that fluid does not infuse the surgical site. Because fluid is delivered at the cutting blade, there is no need to  
30 infuse the entire surgical site. By reducing or eliminating the potential for extravasation, this feature advantageously allows the

instrument to be used in applications, such as sinus surgery, in which the surgical site cannot safely be infused with saline.

In preferred embodiments, the endoscopic surgical instrument includes an outer tube with an opening at its distal region, an inner tube that rotates or otherwise moves within the outer tube, and a cutting implement, carried by the inner tube. Preferably, the irrigation device includes an irrigation sheath surrounding the outer tube to define a passage for fluid flow between the sheath and the outer tube. It is preferred that the irrigation sheath surround the surgical implement and have an opening at its distal region that is in communication with the opening in the outer tube. The irrigation sheath further includes a port, disposed in a proximal region of the sheath, for receiving irrigating fluid into the passage.

Other preferred embodiments include one or more of the following features. The endoscopic surgical instrument further includes a hub mounted at the proximal end of the outer tube, and the irrigation sheath includes an adaptor constructed to allow the irrigation sheath to be mounted onto the hub. The adaptor is bonded to the hub, e.g., by welding or adhesive. The adaptor includes a port for receiving fluid into the irrigation sheath. The port includes a valve to control fluid flow. The irrigation sheath is constructed of stainless steel or plastic. The outer diameter of the irrigation sheath in the region of the surgical implement is less than about 0.200", more preferably less than about 0.130". The clearance between the irrigation sheath and outer tube is less than 0.010", more preferably from about 0.008" to 0.010". The endoscopic surgical instrument is constructed to allow suction to be

5

applied at the proximal end of the surgical instrument to remove fluid from the surgical site. Suction is applied through the inner tube.

The invention also features methods of using the surgical  
5 instrument.

Other features and advantages of the invention will become apparent from the following detailed description, and from the claims.

10 Fig. 1 is a perspective view of an endoscopic surgical instrument with an outer irrigation sheath. Fig. 1a is an exploded view of the endoscopic surgical instrument of Fig. 1.

Figs. 2 and 3 are top and side views, respectively, of the endoscopic surgical instrument shown in Fig. 1.

15 Fig. 4 is a side cross-sectional view of the endoscopic surgical instrument shown in Fig. 1, taken along line 4-4 in Fig. 2.

Fig. 5 is a perspective view of an endoscopic surgical instrument with an outer irrigation sheath and a stopcock to control fluid flow.

20

Referring to the figures, surgical instrument 10 includes a stationary outer tube 12 (Fig. 4) with a tissue-receiving opening 14 at its tip 15, an inner tube 16 that rotates or otherwise moves within outer tube 12, and a surgical implement 17 (Fig. 2) that cuts tissue  
25 admitted through the opening 14 in the outer tube. In this embodiment, the surgical implement consists of the sharp edges 19 of the inner tube 16, shown in Fig. 2.

Surgical instrument 10 further includes an irrigation sheath  
30 20, surrounding outer tube 12. Irrigation sheath 20 defines an annular passage 22 for fluid flow between irrigation sheath 20 and

outer tube 12. Irrigation sheath 20 includes an opening 23 (Fig. 1) at its distal tip 24 that is in communication with opening 14 in the stationary outer tube. Irrigation sheath 20 further includes an adaptor 26 at its proximal end. Adaptor 26 includes a side-facing port 30 for receiving irrigating fluid into the passage 22. Irrigating fluid is conveyed from port 30 to the distal tip 24 by passage 22, and is removed by suction (along with tissue and bone debris) through the interior of inner tube 16.

Adaptor 26 is dimensioned to be permanently attached onto the hub 28 of the surgical instrument, e.g., by ultrasonic welding, adhesive, or by being insert molded onto the hub. Hub 28 is typically formed of plastic, and is rigidly mounted at the proximal end of outer tube 12. Hub 28 rotatably receives drive shaft 32, which is rigidly mounted at the proximal end of inner tube 16.

15

The irrigation sheath 20 is constructed of stainless steel or plastic for strength and inertness. When surgical instrument 10 is to be used in a surgical application in which space is severely limited, e.g., sinus surgery, the distal end 11 of surgical instrument 10 has an outer diameter of less than about 0.130". To achieve this small outer diameter, irrigation sheath 20 has a wall thickness of less than 0.005", and the clearance between the inner wall of the irrigation sheath and the outer wall of the outer tube is less than 0.010", more preferably from about 0.008" to 0.010".

25

As shown in Fig. 5, port 30 may include a stopcock 34, to allow control of the flow of fluid into irrigation sheath 20.

Alternatively, other types of fluid-control valves may be used.

30

In operation, the surgical instrument is first assembled by placing inner tube 16 within outer tube 12, thereby moveably



mounting drive shaft 32 in hub 28. Next, hub 28 is mounted in a handpiece (not shown) that includes a motor to turn drive shaft 32 and a device for applying suction through inner tube 16 to remove irrigation fluid and debris. The distal region 11 of surgical instrument 10 is then placed at the surgical site. When the surgeon wishes to use the surgical instrument, irrigation fluid is supplied through port 30 and removed by suction through inner tube 16, and the motor of the handpiece is activated to drive inner tube 16 and thus surgical implement 17.

10

Other embodiments are within the claims.

For example, adaptor 26 could be removably attached to hub 28. Hub 28 may be provided with a collar that extends distally and has a threaded interior surface that is spaced from the outer surface of outer tube 12. In this case, the proximal region 27 of the adaptor is compatibly threaded to engage the threads of the threaded collar, and is constructed to fit radially between the threaded collar of hub 28 and the outer surface of outer tube 12. Surgical instruments having a threaded hub are commercially available from Smith & Nephew Endoscopy Inc. of Andover, Massachusetts.

20

Moreover, while the surgical instrument described above is a powered arthroscopic surgical instrument (that is, an instrument constructed to be driven by a motor, rather than by hand), the invention may also be used with manual instruments, as well as with other types of surgical instruments.

25

Additionally, while the surgical implement shown in the figures is a tissue-cutting tool, other surgical implements, e.g., other cutting tools, abrading tools, grasping tools, and the like, can also be used.

30

8  
**CLAIMS**

1. An endoscopic surgical instrument comprising a surgical implement disposed at a distal region of the surgical instrument, and an irrigation device associated with the surgical implement in a  
5 manner to define a path for conveying irrigation fluid from a proximal region of the surgical instrument to said surgical implement.
2. The endoscopic surgical instrument of claim 1 further comprising an outer tube with an opening at the distal region of the surgical  
10 instrument and wherein said surgical implement is constructed to move within the outer tube.
3. The endoscopic surgical instrument of claim 1 wherein said irrigation device comprises an irrigation sheath, surrounding said  
15 surgical implement to define a passage for fluid flow between said irrigation sheath and said surgical implement, said irrigation sheath having an opening at its distal region.
4. The endoscopic surgical instrument of claim 3 further comprising  
20 an outer tube, disposed within said irrigation sheath, with an opening at the distal region of the surgical instrument, wherein said surgical implement is constructed to move within the outer tube and said opening in said irrigation sheath is in communication with the opening in said outer tube.  
25
5. The endoscopic surgical instrument of claim 1 wherein said irrigation device includes a port, disposed in a proximal region of the irrigation device, for receiving fluid into the passage.
- 30 6. The endoscopic surgical instrument of claim 5 wherein said port includes a valve for controlling flow of fluid through said port.

7. The endoscopic surgical instrument of claim 3 further comprising a hub disposed at the proximal end of said outer tube, and an adaptor constructed to allow the irrigation sheath to be mounted  
5 onto said hub.

8. The endoscopic surgical instrument of claim 7 wherein said adaptor includes a port constructed to receive fluid into the passage defined by said irrigation sheath.  
10

9. The endoscopic surgical instrument of claim 1 wherein the irrigation device comprises stainless steel.

10. The endoscopic surgical instrument of claim 1 wherein the irrigation device comprises plastic.  
15

11. The endoscopic surgical instrument of claim 3 wherein the distal region of said irrigation sheath has an outer diameter of less than about 0.200".  
20

12. The endoscopic surgical instrument of claim 11 wherein said distal region has an outer diameter of less than about 0.130".

13. The endoscopic surgical instrument of claim 3 wherein there is a clearance between said irrigation sheath and said outer tube, and said clearance is less than 0.010".  
25

14. The endoscopic surgical instrument of claim 13 wherein said clearance is from about 0.008" to 0.010".  
30

15. A method of performing endoscopic surgery comprising:

- 5 (a) providing an endoscopic surgical instrument comprising a surgical implement disposed at a distal region of said surgical instrument, and an irrigation device associated with the surgical implement in a manner to define a path for conveying fluid from a proximal region of said surgical instrument to said surgical implement;
- (b) introducing said distal region of the surgical device into an area of the body of a patient;
- 10 (c) conveying an irrigating fluid from the proximal region of the surgical instrument through the path for fluid to the surgical implement; and
- (d) using the surgical implement to perform a surgical technique on said patient.

15 16. The method of claim 15 further comprising suctioning the fluid from the area of the body of the patient at a sufficient rate so that the area is not infused with the fluid.

20 17. The method of claim 16 wherein said area of the patient's body is the sinus cavity.

25 18. An endoscopic surgical instrument comprising a surgical implement disposed at a distal region of the surgical instrument, and an irrigation device associated with the surgical implement in a manner to define a path for conveying irrigation fluid from a proximal region of the surgical instrument to said surgical implement;

an outer tube with an opening at the distal region of the surgical instrument, said surgical implement being constructed to move within the outer tube;

30 said irrigation device comprising an irrigation sheath, surrounding said outer tube to define a passage for fluid flow

between said irrigation sheath and said outer tube, said irrigation sheath having an opening at its distal region in communication with said opening in said outer tube.

- 5 19. An irrigation device for use with an endoscopic surgical instrument that includes a surgical implement disposed at a distal region of the surgical instrument, comprising an irrigation device associated with the surgical implement in a manner to define a path for conveying irrigation fluid from a proximal region of the surgical  
10 instrument to said surgical implement.
20. A method of irrigating a surgical site at the distal end of an endoscopic surgical instrument comprising:  
    flowing irrigation fluid in a closed path from the proximal end  
15 of the surgical instrument to the surgical site and back to the proximal end of the surgical instrument via a pair of coaxial lumens that both have open ends at the surgical site.

FIG. 1.

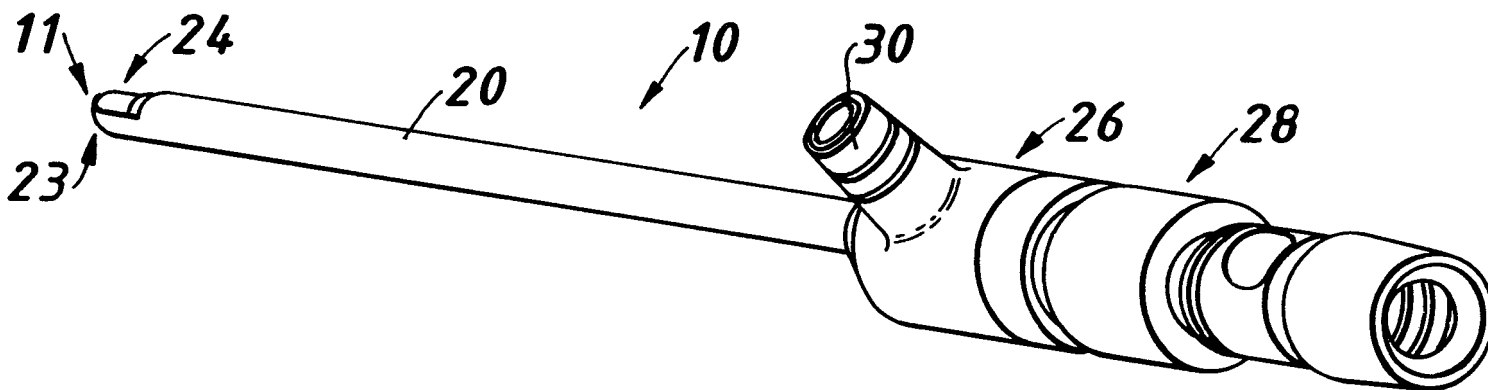
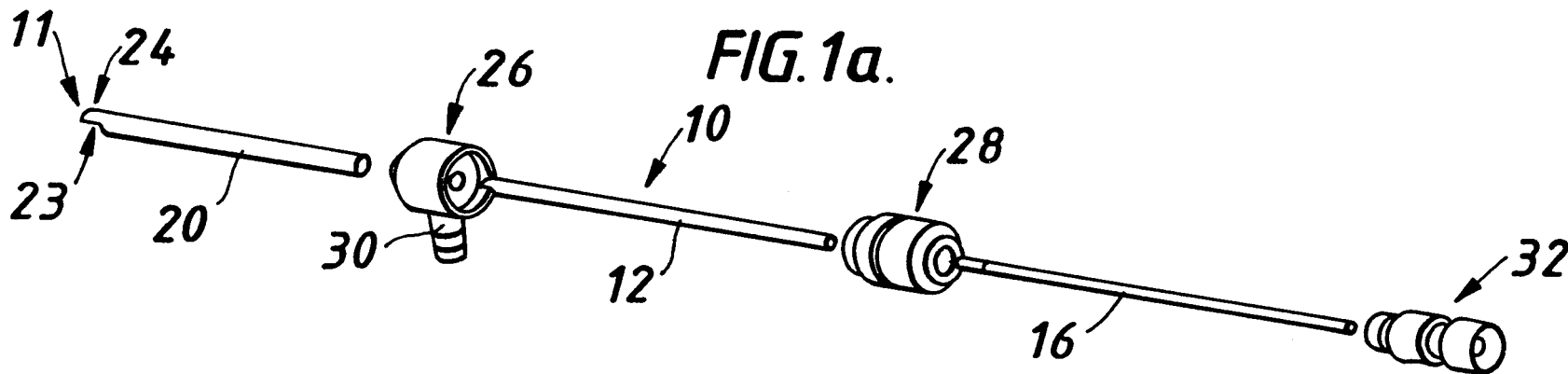


FIG. 1a.



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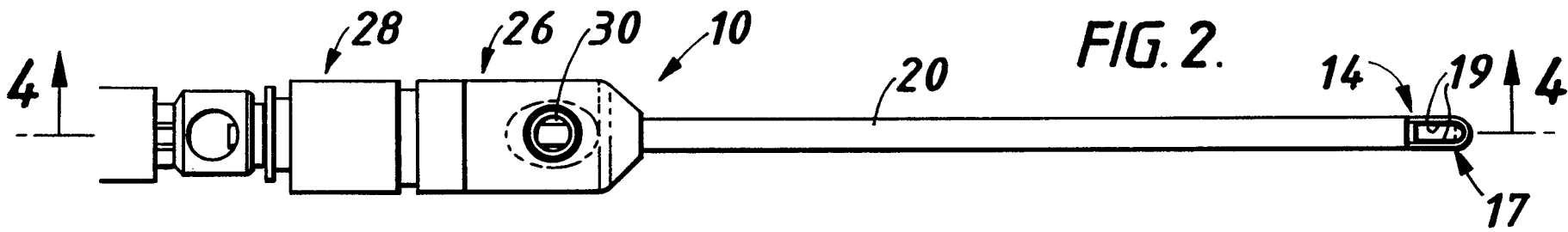


FIG. 2.

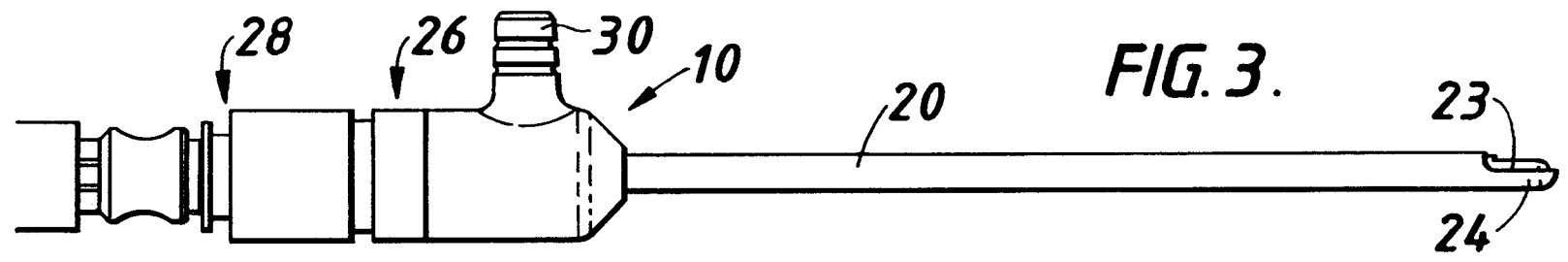


FIG. 3.

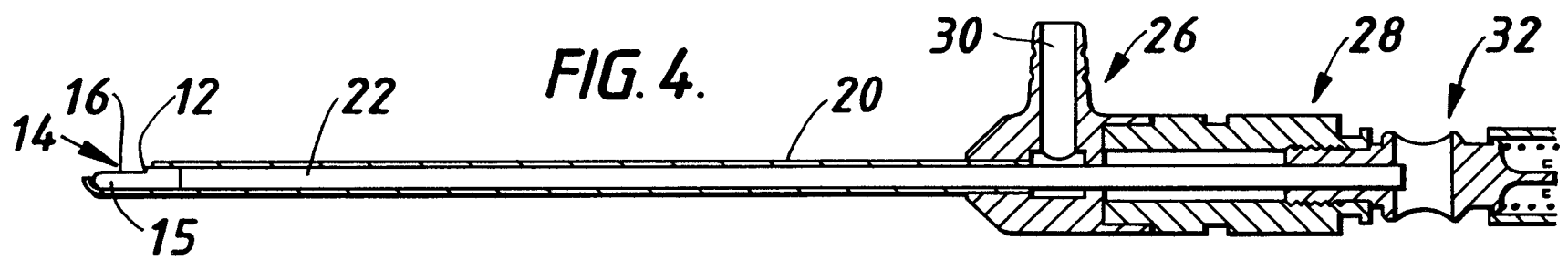
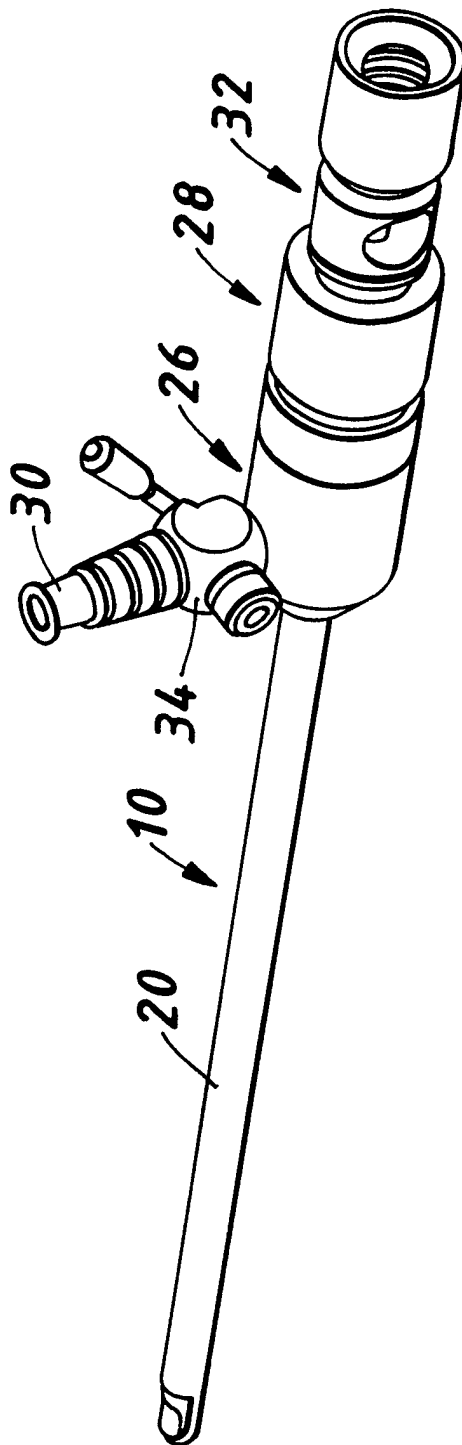


FIG. 4.

FIG. 5.





# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/03333

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 6 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 32894 A (XOMED INC) 24 October 1996 see page 11, line 22 - page 12, line 4 see page 5, line 4 - line 19; figure 3 ---	1-14, 18, 19
X A	US 4 678 459 A (ONIK GARY ET AL) 7 July 1987 see column 4, line 48 - line 55; figures 3-7 ---	1-10, 18, 19 11-14
X	EP 0 286 415 A (COPTCOAT MALCOLM JOHN ;WICKHAM JOHN EWART ALFRED (GB); CARTER SIMON) 12 October 1988 see column 3, line 47 - column 5, line 38; figures 3,4 --- -/--	1-10, 18, 19

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

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Date of the actual completion of the international search

9 June 1998

Date of mailing of the international search report

25.06.98

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/03333

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 312 327 A (BALES THOMAS O ET AL) 17 May 1994 see column 13, line 26 - column 15, line 9; figure 6 ---	1-10,18, 19
X	US 5 403 276 A (STAVE FREDERICK R ET AL) 4 April 1995 see column 9, line 15 - column 10, line 57; figures 1,3 ---	1-10,18, 19
A	WO 92 03099 A (SASTRI SURI A) 5 March 1992  see page 3, line 3 - line 6; figures 1-3 -----	1,9, 11-14, 18,19

# INTERNATIONAL SEARCH REPORT

Int. l. application No  
PCT/US 98/03333

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

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

1.  Claims Nos.: 15-17,20  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/03333

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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