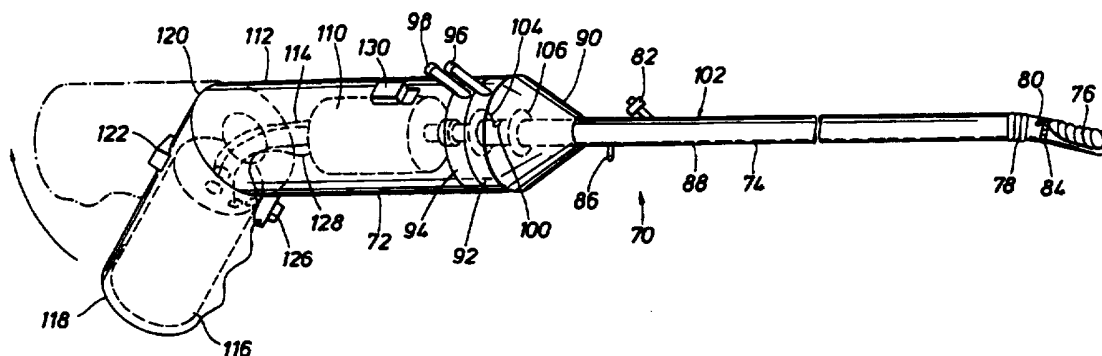


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(54) Title: SPINAL DISC SURGICAL INSTRUMENT



(57) Abstract

The surgical instrument of the present invention includes a cannula shaft terminating in a cutting window at the distal end of the cannula shaft. The proximal end of the cannula shaft is supported by a handle having an axial bore extending therethrough. A flexible drive shaft, connected at one end to an external drive mechanism, extends through the handle and the cannula shaft. A cutting head is mounted to the distal end of the drive shaft and positioned for cooperative cutting action with the cutting window of the cannula shaft. A non-rotating idler shaft is journaled about the drive shaft. Severed tissue is removed or evacuated from the surgical site through an annular passage formed by the cannula and idler shafts. An irrigation tube through the cannula shaft provides a clean surgical site. The irrigation tube is preferably large enough to accept a fiberoptic element that may then be directed to the surgical site. The instrument further includes an ultrasonic array on the tip of the instrument to assist in directing the cutting element and to view tissue around the tip of the instrument. The handle of the instrument contains the power means, including a motor and a battery pack, and provides a swivel means to give a clear view of the surgical site.

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SPINAL DISC SURGICAL INSTRUMENT

This is a Continuation-in-Part of co-pending U.S. Application Serial No. 07/985,329, now U.S. Patent No. 5,383,884, issued January 24, 1995

FIELD OF THE INVENTION

- 5 The present invention generally relates to the field of surgical instruments and, more particularly, to a surgical instrument for performing intervertebral surgery for stabilizing the spine.

BACKGROUND OF THE DISCLOSURE

- 10 A common medical condition is chronic low back pain due to spinal disc problems. Low back pain is the most frequent cause of disability in persons under age 45 years, and the third most frequent cause in the 45-64 age group. Currently, there are 2.6 million Americans temporarily disabled and another 2.6 million
15 Americans permanently disabled by chronic low back pain. Approximately 2 percent of all workers injure their back annually.

- The need to rehabilitate these patients quickly and return them to a productive life style is obvious as studies indicate the
20 ability to ever work again decays rapidly after six months. If an injured worker has not returned to work within two years, chances are very high that he or she will never work again.

- Low back pain can be avoided if relative motion between spinal vertebra can be prevented. Intervertebral stabilization is
25 sought in a variety of treatment methods. To abate low back pain, stabilization is directed to stabilizing contiguous vertebra in the lumbar region of the spine. A common non-surgical procedures is the use of a back brace. The brace is worn externally by the patient to restrict lumbar movement. The brace however is bulky
30 and uncomfortable and limited in its effectiveness.

 Laminotomy with discectomy is the standard treatment for patients with disc protrusion producing sciatica. The procedure is performed under general anesthesia. A surgical incision is made

and the surgeon directly visualizes the posterior disc and nerve root. The disc extrusion or free fragments are excised and removed. However, this direct approach necessitates entry into the spinal canal, thereby putting the patient at risk for epidural
5 bleeding, perineural fibrosis and reherniation from the site of the annular fenestration.

Low back pain is associated with the degeneration of the intervertebral disc which commonly occurs with age. Surgical stabilization seeks to rigidly join the lumbar vertebra which are
10 separated by the degenerated disc. Ideally, the surgery effectively replaces the vertebra-disc-vertebra combination with a single rigid vertebra. That is, adjacent vertebra are fused together to form a single vertebra.

Various surgical techniques have been developed for
15 alleviating lower back pain. One surgical approach is directed to a total disc removal through a partial hemilaminectomy. This is a major surgical procedure; it is costly and the in-hospital convalescence is long.

Another procedure, chemonucleolysis, has been developed
20 to avoid the problems associated with major surgery. The intradiscal pressure is decreased by the percutaneous introduction of chymopapain entered into the intravertebral disc to dissolve it. Such an approach is effective in the majority of patients but does have some side effects, as some patients are hypersensitive to the
25 drug.

Arthroscopic discectomy offers an alternative method treatment for lumbar radiculopathy due to herniated disc. Several such devices are described in U.S. Patent No. 4,203,444; U.S. Patent No. 4,598,710; U.S. Patent No. 4,603,694; U.S. Patent No.
30 4,834,729; and U.S. Patent No. 5,062,845. However, each of these devices suffer limitations. For example known devices require time consuming removal of very small amounts of tissue via the guillotine cutting approach, the clogging of cutters and cannula due to adherent tissue fragments and, with the use of lasers, very
35 slow canalization of the nucleus pulposus, time consuming ablation with considerable heat and char at the operative site.

Recent clinical studies have shown that patients can benefit from minimal invasive surgery utilizing the percutaneous approach. Removal of nucleus pulposus from lumbar disc, utilizing small cannula and cannulated surgical instruments, with
5 or without endoscopic aids, thereby reducing surgical trauma, can result in immediate relief of symptoms, low morbidity and cost efficiencies.

It is therefore an object of the present invention to provide a surgical instrument for removing all or part of a intervertebrate
10 disc employing a minimal invasive surgical technique.

It is another object of the present invention to provide a surgical instrument that eliminates all of the aforesaid problems, does not compromise future surgical procedures and offers a number of advantages including: avoidance of epidural bleeding
15 and perineural fibrosis, elimination of reherniation through intraoperatively induced annular fenestration, preservation of spinal stability, and the establishment of a portal space for fusion.

SUMMARY OF THE INVENTION

20 The surgical instrument of the present invention includes a cannula shaft terminating in a cutting window at the distal end of the cannula shaft. The proximal end of the cannula shaft is mounted to a handle. A flexible drive shaft, connected at one end to a drive mechanism, extends through the handle and the
25 cannula shaft. A cutting head is mounted to the distal end of the drive shaft and positioned for cooperative cutting action with the cutting window at the distal end of the cannula shaft. The drive shaft extends through a non-rotating idler shaft. Severed tissue is removed or evacuated from the surgical site through an annular
30 passage defined between the cannula and idler shaft.

A flexible joint in the cannula shaft near the cutting window is provided to permit the operator to adjust the angle at which the cutting action is performed. Adjacent the flexible joint, an irrigation port flushes the surgical site, allowing the operator to
35 keep the surgical site free of removed tissue. The distal end of

the instrument is also provided with two means of viewing, an ultrasonic array for viewing through tissue and a fiberoptic viewing means for a clear view of the surgical site.

5 The handle of the instrument is also provided with a swivel joint to provide the operator with a clear view. Similarly, the cannula shaft may be rotated about a 360 degree angle so that the operator may cut on the underside of a vertebra as easily as the upper side.

10 The instrument of the present invention is a fully contained unit, other than the fiberoptic and ultrasonic viewing features. That is, the cutting element is driven by a motor that is powered by a battery pack contained within the handle of the instrument.

BRIEF DESCRIPTION OF THE DRAWINGS

15 So that the manner in which the above recited features, advantages and objects of the present invention are attained and can be understood in detail, a more particular description of the invention, briefly summarized above, may be had by reference to the embodiments thereof which are illustrated in the appended
20 drawings.

It is to be noted, however, that the appended drawings illustrate only typical embodiments of this invention and are therefore not to be considered limiting of its scope, for the invention may admit to other equally effective embodiments.

25 Figure 1 is a partially broken away, sectional view of a preferred embodiment of the invention;

Figure 2 is a partial, sectional view showing the distal end of the surgical instrument of a preferred embodiment of the invention;

30 Figure 3 is a partial, sectional view showing an alternate embodiment of the distal end of the surgical instrument of a preferred embodiment of the invention; and

Figure 4 is a partial, sectional view of the distal end of the surgical instrument of the invention showing a guide wire extending through the drive shaft and cutting head of a preferred embodiment of the invention.

5 Figure 5A is a perspective view of a complete dissector instrument, including the cutting head and the power/drive system, of a preferred embodiment of the invention.

Figure 5B is a detail view of an articulated section of the cutting head of the invention. Figure 5C is a detail view of the articulated section of Figure 5C, shown in an actuated position.
10

Figure 6A is a side view of the cutter head of the invention; Figures 6B through 6E are detail views of the cutter head of Figure 6A.

Figure 7A is a side view of the cutter head of the invention; Figures 7B through 7D are detail view of the cutter head of Figure 7A.
15

Figure 8A is a side view of the cutter head of the invention; Figure 8B is partially a section view and partly a detail view of the cutter head of Figure 8A.

20 Figure 9A is a side view of the cutter head, including a scope port. Figure 9B is a top view of the cutter head of Figure 9A and Figure 9C is a bottom view.

Figure 10A is an enlarged view of a cutting element or bit of the invention; Figure 10B is a left-end view of the cutting element and Figure 10C is a right-end view.
25

Figure 11 is a further enlarged view of a cutting element within its enclosure, particularly preferred assembly relationships of the various parts of the cutter head.

Figures 12A through 12D are detail views of cutters with varying blade pitch and window angles.
30

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Figure 1 depicts the surgical instrument 10 of the present invention. The surgical instrument 10 comprises a handle 12, a cannula shaft 14 and an external drive mechanism (Figure 5A, for example). The cannula shaft 14 of Figures 1-4 is a substantially rigid, hollow tubular member approximately 10 to 12 inches in length. However, the cannula shaft preferably includes a malleable or articulated section near an end or tip 20, as described below in greater detail.

10 The cannula shaft 14 is mounted to the end 16 of the handle 12. The proximal end of the cannula shaft 14 is received in a bore formed in the handle 12 which terminates at a shoulder 18. The cannula shaft 14 is press fit into the end 16 of the handle 12 so that the proximal end thereof engages the shoulder 15 18 formed in the handle 12.

The distal end of the cannula shaft 14 terminates in an end 20. The end 20 is slotted to form a cutting window. The end 20 may be integrally formed with the cannula shaft 14, however, for ease of manufacture, the end 20 is preferably formed as a separate component and is welded or otherwise secured to the distal end of the cannula shaft 14 as shown in greater detail in Figure 2.

The handle 12 includes a through-bore 22 axially extending through the handle 12. The proximal end of the bore 22 is closed by an end cap 24 which is press fit into the end 26 of the handle 25 12. An evacuation port 28 angularly extends through the body of the handle 12. The port 28 opens into the bore 22 thereby forming an evacuation passage for tissue removed at the surgical site. The port 28 provides a connection for connecting an aspirating device to the handle 12. Alternatively, the port 28 30 may be utilized as an injection port for delivery of medication to the surgical site.

Referring now to Figure 2, the cutting end of the surgical instrument 10 is shown in greater detail. The end 20 is slotted on one side to provide a cutting window for progressively shaving 35

away the herniated disc. The cutter 30 is mounted on the drive shaft 32. It is welded or otherwise secured to the end of the drive shaft 32 and positioned within the end 20 of the surgical instrument 10 so that each rotation of the cutter 30 shaves off a segment of the herniated disc. The auger-like profile of the cutter 30 transports the shaved segments backward to the annulus 34. The shavings are then aspirated to a collection vessel connected to the evacuation port 28. Alternatively, the drive shaft 32 may be hollow, as shown in Figure 4. The hollow shaft 32 extends through cutter 30 and cannula end 20, allowing a guide wire 64 to pass through the entire assembly, as best shown in Figure 3 and Figure 4, to facilitate passage and positioning of the cannula shaft 14 for removal of tissue at the surgical site.

Removal of the herniated disc is accomplished by shaving away bits of the disc. Each pass of the cutter 30, however, does not always sever and separate discrete portions of the disc. In addition, the suction of the aspirating device may draw tissue into the cutting chamber which will be severed by the cutter 30. Therefore, relatively long and stringy shavings or cuttings may be cut by the cutter 30. Long and stringy shavings have a tendency to wrap around a rotating drive shaft and thereby tend to block the evacuation passage. The present surgical instrument avoids this problem by incorporating an idler shaft 36 about the drive shaft 32. The idler shaft 36 does not rotate with the drive shaft 32. However, it does tend to vibrate slightly in response to the rotating action of the drive shaft 32. The vibrating action of the idler shaft 36 agitates and dislodges shavings which might otherwise adhere to the surface of the idler shaft 36. Thus, shavings removed by the cutter 30 are quickly aspirated from the surgical site through the annulus 34 and into a collection receptacle.

Referring again to Figure 1, it will be observed that the idler shaft 36 terminates at a coupling 38 located in the passage 22 of the handle 12. The idler shaft 36 is secured to the coupling 38 by a set screw 40 or the like. A seal 42 is journaled about the idler shaft 30 for sealing the evacuation passage. The seal 42 seals the passage 22 extending through the handle 12 so that

shavings are directed through the evacuation port 28 to a collection vessel (not shown in the drawings).

5 The drive cable 32 extends through the end cap 24 and connects to a drive motor (Figure 5A). Stabilization of the flexible drive shaft 32 is provided by a stabilizer 44 which extends from the coupler 38 and into the end cap 24. The stabilizer 44 is secured to the coupler 38 by a set screw 46. The stabilizer 44 confines the flexible drive shaft 32 so that it does not whip about within the handle 12 thereby causing severe vibration of the
10 handle 12.

Referring now to Figures 3 and 4, alternate embodiments of the cutting head of the surgical instrument 10 are shown. As shown in Figure 3, the cutter 50 defines a substantially cylindrical cutting element. The cutter 50 is open at the proximal end
15 thereof. The forwardmost or distal end of the cutter 50 is closed and defines a rounded profile substantially corresponding to the profile of the tip 52 of the cutter housing 54 which is mounted on the end of the cannula shaft 14. The cutter 50 is provided with a pair of slots 56 formed in the sidewall thereof. The slots 56
20 substantially correspond to the size of the cutting window 58 formed in one side of the cutter housing 54. The slots 56 are diametrically opposite each other and extend longitudinally along the sidewall of the cutter 50. The drive shaft 32 extends to the distal end of the cutter 50 and is welded or otherwise fixedly
25 secured to the cutter 50. Likewise, the idler shaft 36 extends into the cutter 50 terminating adjacent the distal end thereof. To aid in the positioning and stabilization of the cutter 50, a guide wire 64 extends through the drive shaft 32 and the cutter 50.

The alternate embodiment of Figure 4 depicts a cutter 60
30 defining a substantially conical profile. The cutter 60 includes a plurality of blades 62 spaced about the conical body of the cutter 60. The blades 62 of the cutter 60 are particularly suited for boring through or chipping away calcified matter. To aid in the positioning and stabilization of the cutter 60, a guide wire 64
35 extends through the drive shaft 32 and the cutter 60.

Removal of a herniated disc is accomplished with the present surgical instrument by making a small incision in the back of the patient to access the spine. The cannula shaft 14 is inserted through the incision and the cutting tip of the instrument 5 10 is positioned to engage the herniated disc. The cutter is rotated and by contacting the disc with the cutting tip, the surgeon may progressively shave away the herniated disc. The process is repeated until the herniated disc is completely removed.

Figure 5A depicts a currently preferred embodiment of the 10 surgical instrument 70 of the present invention. Generally, the instrument 70 comprises a handle 72, a cannula shaft 74, and a cutter 76. The cutter 76 may comprise any of the previously described cutter elements.

Adjacent the cutter 76, and near the distal end of the 15 cannula shaft 74, the instrument 70 includes a flexible joint 78. The flexible joint 78 may be constructed by any of a number of techniques, but is preferably malleable or articulated. The flexible joint enables the operator of the instrument to deflect the cutter 76. This deflection directs the cutter to cut on a different 20 plane and provides greater functionality to the surgeon.

Also adjacent the cutter, and preferably between the cutter and the joint 78, the instrument includes an irrigation port 80. The irrigation provides a means of irrigating the region that is being cut, thereby flushing removed tissue and assisting in the 25 removal of the material through aspiration. The irrigation port 80 further serves as an exit port for a fiber optic viewing system, as described below, to enable the surgeon to directly view the area being cut. The fiber optic viewing system may be coupled to a fiberoptic port 82 or any appropriate means.

30 Also adjacent the cutter, and preferably between the irrigation port 80 and the cutter, is an ultrasonic array 84. The ultrasonic array 84 may be built into the cannula shaft 74, or it too may be fed by wire through the irrigation port 80.

Attached to and protruding from the cannula shaft is a 35 deflector lever 86. The deflector lever 86 is attached to the distal

end of the cannula shaft by a wire or rod 88 to permit the operator to adjust the precise angle of deflection of the flex joint 78.

5 The handle 72 joins to the cannula shaft 74 at a shoulder 90, as previously described with regard to Figures 1-4. Immediately behind the shoulder 90 the handle includes an irrigation chamber 92 and immediately behind the irrigation chamber 92 is an aspiration chamber 94. The irrigation chamber 92 is provided with a supply port 96 and the aspiration chamber 10 94 communicates with a suction port 98. Each of the ports 96 and 98 is provided with a connector means of any appropriate type, preferably to enable quick connect and disconnect.

Within the irrigation chamber 92 is an irrigation orifice 100. The irrigation orifice 100 provides communication between 15 the chamber 92 and an irrigation tube 102. Aspiration from the aspiration chamber 94 through the suction port 98 is carried out as previously described. Furthermore, the chambers 92 and 94 are sealed off between the handle and the cannula shaft by O-ring seals 104 and 106 in a conventional manner.

20 The drive shaft of the instrument 70, like the drive shaft 32 of Figure 1, is coupled via a coupling 108 like the coupling 38 as previously described. The coupling 108 couples to a drive means 110, preferably a 4.5 volt DC motor. The motor 110 is firmly mounted within a motor shell 112 and is powered through power 25 cables 114. Power is provided by a battery pack 116 and the cables 114 provide the electrical connection to the motor 110. The battery pack 116 is firmly mounted within a battery shell 118.

Referring to Figures 5B and 5C, a handle swivel feature of 30 the present invention is disclosed. Between the battery shell 118 and the motor shell 112 is a swivel joint 120. Rotation of the swivel joint 120 is enabled by a swivel lock 122. The swivel lock 112 also serves to lock the shells in place in the swivelled position. When the swivel lock 122 is depressed, a latch is 35 released permitting rotation of the battery shell 118 relative to the motor shell 112. The shells are coupled to one another

through a rotating flange 124 and the rotating flange also encloses the cables 114 which connect the battery pack to the motor. This feature of the present invention permits adjustment of the handle to improve the field of view for the operator when
5 he is operating from an anterior approach.

Mounted on the battery shell is a control switch 126. The control switch 126 controls operation of the motor through connecting wires 128.

The present invention also permits rotation of the cannula
10 shaft through a key lock 130.

Figures 6A through 6E provide details of the construction of the flex joint 78 and its controls. It should be understood that the side view of Figure 6A is turned over from the perspective view of Figure 5A. Figure 6B provides details of the flex joint 78 itself.
15 As shown, the flex joint is preferably formed of an accordion-like construction, to give flexibility while remaining sealed. Figures 6A to 6E also show the structural relationship between the irrigation tube 102 and an aspiration tube, as previously described, and shown in section in Figure 8B. Also, Figure 6E
20 illustrates that the end of the irrigation tube 102 is sealed at one end within the cannula shaft and is penetrated by the orifice 100.

Figures 7A through 7D depict details of the ultrasonic array feature of the present invention. An array 84 of piezoelectric crystals is placed about the tip 20 of the cannula shaft 74 to
25 provide as assembly of ultrasonic transmitters and receivers which may be serially activated to ultrasonically scan a preselected pattern about the surgical field. The ultrasonic signal is generated by a set of transducers and receivers, typically operating at a frequency range of 5 to 50 megahertz. The
30 transmitted and received signals are preferably conducted through a set of leads 132. The electric wire leads are embedded or encapsulated in the length of the cannula to transmit the signal to and from the ultrasonic transducer crystals. These crystals act in response to excitation of an external voltage pulse (typically 5-
35 50 volt range) or in response to sonic vibration return from body

tissue onto a receiver crystal and thereby converted to an electric signal.

Figures 8A and 8B illustrate the structural relationship between various elements within the cannula shaft 74. Coaxial within the cannula shaft 74 are a drive shaft 134 which rotates within an idler shaft 136. These shaft elements operate in a manner as previously described. Within the cannula shaft 74 and running axially parallel with the shaft is the irrigation tube 102. Recall that the irrigation tube 102 also serves as the access tube for a fiber optic instrument that may be inserted through the instrument. The tube 102 may be attached to an inner wall 138 of the cannula shaft by any appropriate means, preferably by spot welding.

Also within the cannula shaft, and perhaps opposite the tube 102, is the deflector wire or rod 88. The wire or rod 88 is attached to the deflector lever 86. The lever 86 may be mounted upon a pedestal 140 which provides a pivot axis 142, as through a pin 144.

Figure 9A depicts a side view of the cannula shaft 74 of the invention. Figure 9B provides a top view and Figure 9C provides a bottom view. These figures depict the preferred structural relationship of the cannula shaft, the deflection wire 88 (*i.e.*, preferably on the upper portion of the cannula shaft 74), and the irrigation and scope tube 102 (*i.e.*, preferably on the bottom portion of the cannula shaft).

Finally, Figures 10A through 10C, 11, and 12A through 12D depict another feature of the present invention. It has been found that the cutter element and the window through which the cutter element have two parameters that may be varied to tailor specific performance of the instrument, depending on the application and the type of tissue that is to be removed. Specifically, the operator should have the option to select a particular cutter window angle β , the angle being determined from the centerline at the tip, for example, depending on the tissue of interest. An angle of 5° as defined by Figure 11, has been found to be more aggressive in drawing desired tissue into the instrument because more of the

blade is exposed. Thus, where the particular tissue of interest is, for example, hard calcified deposits, a greater angle β is preferred because a steeper window angle has been found to provide greater "bite" for the cutter element. Thus, the window angle is preferably from about 5° to about 10° .

The other parameter that may be varied is referred to herein as the blade pitch α . Conceptually, the blade pitch α may be thought of as the angle between the edge of the blade and the axis of rotation of the cutter element, as viewed from the side.

10 The blade pitch α is preferably between about 14° and about 20° . Angles significantly less than about 14° present too flat an aspect to the tissue being cut and the blades lose the shear force in the cutting motion. On the other hand, angles significantly greater than about 20° tend to pull the instrument and such blades

15 introduce an unnecessary instability in the operation.

The principles, preferred embodiments, and modes of operation of the present invention have been described in the foregoing specification. This invention is not to be construed as limited to the particular forms disclosed, since these are regarded

20 as illustrative rather than restrictive. Moreover, variations and changes may be made by those skilled in the art without departing from the scope of the invention, as defined in the following claims.

I claim:

1 1. A surgical instrument comprising:
2 a cannula shaft, the cannula shaft including a lateral cutting
3 port formed on the distal end thereof;
4 a handle supporting the cannula shaft at one end thereof,
5 the handle including an axial bore extending
6 therethrough;
7 a drive shaft extending through the handle and the cannula
8 shaft, the drive shaft including a cutter mounted on
9 the distal end thereof, the cutter cooperating with the
10 cutting port for severing body tissue;
11 an idler shaft journaled about the drive shaft and enclosing
12 the drive shaft within the cannula shaft, the idler shaft
13 providing a non-rotating surface for evacuation of
14 severed tissue from the surgical site; and
15 power means within the handle, the power means connected
16 to the drive shaft for rotating the cutter means.

1 2. A surgical instrument comprising:
2 a cannula shaft, the cannula shaft including a lateral cutting
3 port formed on the distal end thereof;
4 an articulated swivel handle supporting the cannula shaft at
5 one end thereof, the handle including an axial bore
6 extending therethrough;
7 a drive shaft extending through the handle and the cannula
8 shaft, the drive shaft including a cutter mounted on
9 the distal end thereof, the cutter cooperating with the
10 cutting port for severing body tissue;

11 an idler shaft journaled about the drive shaft and enclosing
12 the drive shaft within the cannula shaft, the idler shaft
13 providing a non-rotating surface for evacuation of
14 severed tissue from the surgical site; and

15 means connected to the drive shaft for rotating the cutter
16 means.

1 3. A surgical instrument comprising:

2 a cannula shaft, the cannula shaft including a lateral cutting
3 port formed on the distal end thereof;

4 a handle supporting the cannula shaft at one end thereof,
5 the handle including an axial bore extending
6 therethrough;

7 a drive shaft extending through the handle and the cannula
8 shaft, the drive shaft including a cutter mounted on
9 the distal end thereof, the cutter cooperating with the
10 cutting port for severing body tissue;

11 an idler shaft journaled about the drive shaft and enclosing
12 the drive shaft within the cannula shaft, the idler shaft
13 providing a non-rotating surface for evacuation of
14 severed tissue from the surgical site;

15 means connected to the drive shaft for rotating the cutter
16 means; and

17 an irrigation tube within the cannula shaft.

1 4. The surgical instrument of Claim 3 wherein the
2 irrigation tube provides a means for directing a fiberoptic viewing
3 means adjacent the cutting port.

1 5. A surgical instrument comprising:
2 a cannula shaft, the cannula shaft including a lateral cutting
3 port formed on the distal end thereof;
4 a user operable flexible joint on the cannula shaft;
5 a handle supporting the cannula shaft at one end thereof,
6 the handle including an axial bore extending
7 therethrough;
8 a drive shaft extending through the handle and the cannula
9 shaft, the drive shaft including a cutter mounted on
10 the distal end thereof, the cutter cooperating with the
11 cutting port for severing body tissue;
12 an idler shaft journaled about the drive shaft and enclosing
13 the drive shaft within the cannula shaft, the idler shaft
14 providing a non-rotating surface for evacuation of
15 severed tissue from the surgical site; and
16 means connected to the drive shaft for rotating the cutter
17 means.

1 6. The surgical instrument of Claim 5 further comprising
2 a lever mounted on the cannula shaft and connected to the
3 flexible joint for directing the cutter at a user selectable angle.

1 7. A surgical instrument comprising:
2 a cannula shaft, the cannula shaft including a lateral cutting
3 port formed on the distal end thereof;
4 a handle supporting the cannula shaft at one end thereof,
5 the handle including an axial bore extending
6 therethrough;

7 a drive shaft extending through the handle and the cannula
8 shaft, the drive shaft including a cutter mounted on
9 the distal end thereof, the cutter cooperating with the
10 cutting port for severing body tissue;

11 an idler shaft journaled about the drive shaft and enclosing
12 the drive shaft within the cannula shaft, the idler shaft
13 providing a non-rotating surface for evacuation of
14 severed tissue from the surgical site;

15 means connected to the drive shaft for rotating the cutter
16 means; and

17 an ultrasonic array mounted on the cannula shaft.

1 8. A surgical instrument comprising:

2 a cannula shaft;

3 a handle supporting the cannula shaft at one end thereof,
4 the handle including an axial bore extending
5 therethrough;

6 a drive shaft extending through the handle and the cannula
7 shaft, the drive shaft including a cutter mounted on
8 the distal end thereof, the cutter comprising a dual-
9 fluted helical blade having a pitch of between about
10 14 degrees and about 20 degrees;

11 an idler shaft journaled about the drive shaft and enclosing
12 the drive shaft within the cannula shaft, the idler shaft
13 providing a non-rotating surface for evacuation of
14 severed tissue from the surgical site;

15 means within the axial bore in the handle and connected to
16 the drive shaft for rotating the cutter; and

17 wherein the cannula shaft and the idler shaft define an
18 annular evacuation passage therebetween for
19 evacuation of severed tissue from the surgical site.

1 9. A surgical instrument comprising:
2 a cannula shaft, the cannula shaft including a lateral cutting
3 port formed on the distal end thereof;
4 a first handle portion supporting the cannula shaft at one
5 end thereof, the first handle portion including an axial
6 bore therethrough;
7 a second handle portion, the second handle portion including
8 an axial bore therethrough;
9 a flexible joint between the first and second handle portions;
10 a drive shaft extending through the first handle portion and
11 the cannula shaft, the drive shaft including a cutter
12 mounted on the distal end thereof, the cutter
13 cooperating with the cannula shaft port for severing
14 body tissue;
15 an idler shaft journaled about the drive shaft and enclosing
16 the drive shaft within the cannula shaft, the idler shaft
17 providing a non-rotating surface for evacuation of
18 severed tissue from the surgical site; and
19 power means within the handle, the power means connected
20 to the drive shaft for rotating the cutter means.

1 10. A surgical instrument comprising:
2 a cannula shaft, the cannula shaft including a lateral cutting
3 port formed on the distal end thereof;
4 a user operable flexible joint on the cannula shaft;
5 a lever mounted on the cannula shaft and connected to the
6 flexible joint for directing the distal end of the cannula
7 shaft at a user selectable angle;

- 8 an ultrasonic array mounted on the cannula shaft;
- 9 an articulated swivel handle supporting the cannula shaft at
10 one end thereof, the handle including an axial bore
11 extending therethrough;
- 12 a drive shaft extending through the handle and the cannula
13 shaft, the drive shaft including a cutter mounted on
14 the distal end thereof, the cutter cooperating with the
15 cutting port for severing body tissue, the cutter
16 comprising a dual-fluted helical blade having a pitch
17 of between about 14 degrees and about 20 degrees;
- 18 an idler shaft journaled about the drive shaft and enclosing
19 the drive shaft within the cannula shaft, the idler shaft
20 providing a non-rotating surface for evacuation of
21 severed tissue from the surgical site;
- 22 power means within the handle and connected to the drive
23 shaft for rotating the cutter means;
- 24 an irrigation tube within the cannula, the irrigation tube
25 further providing means for directing a fiberoptic
26 viewing means adjacent the cutting port.

1/7

FIG. 1

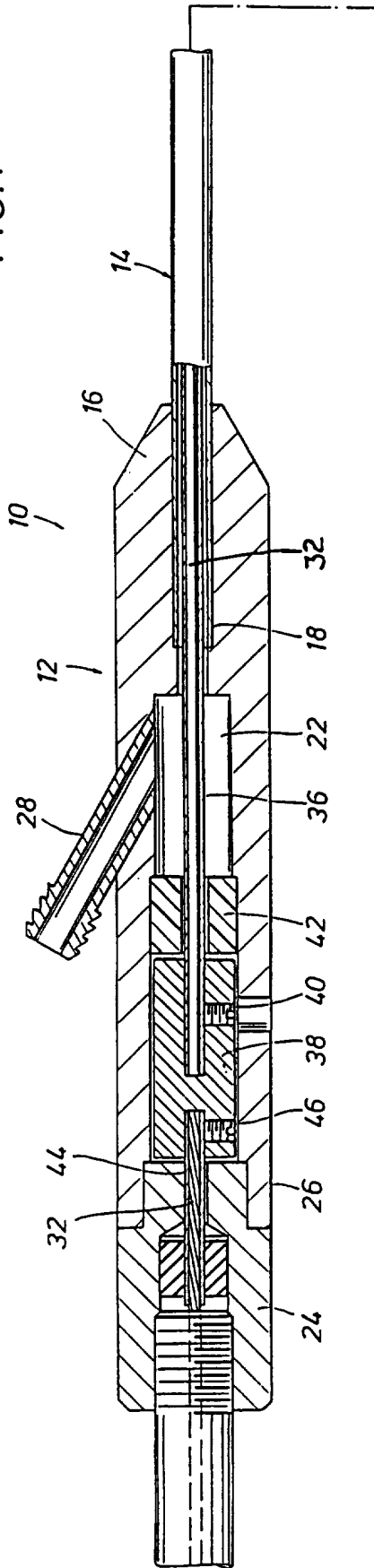


FIG. 2

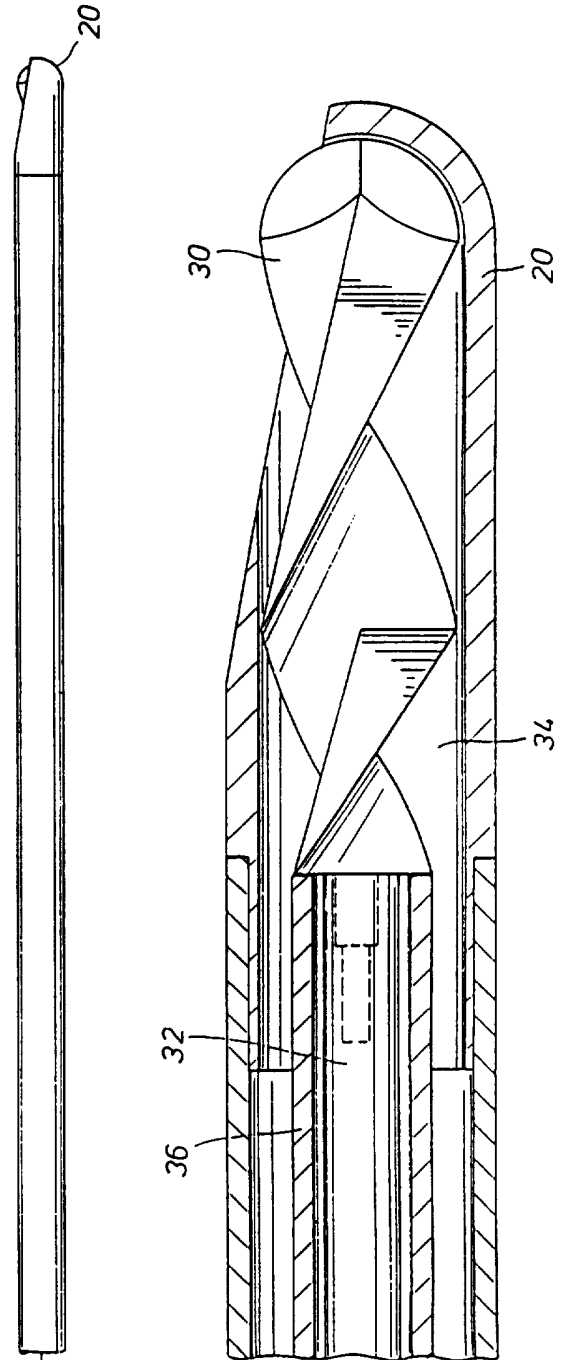


FIG. 3

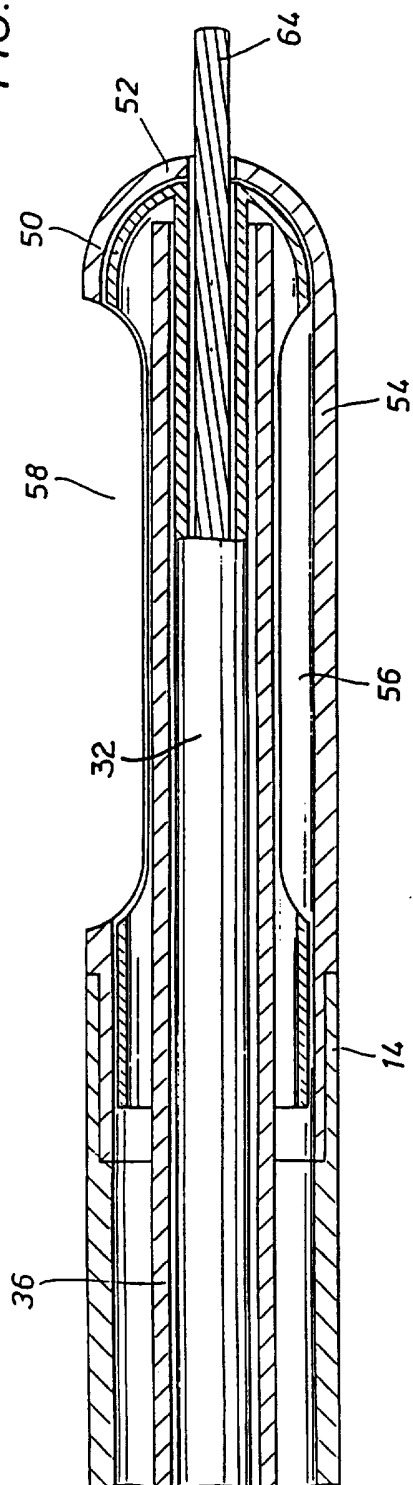


FIG. 4

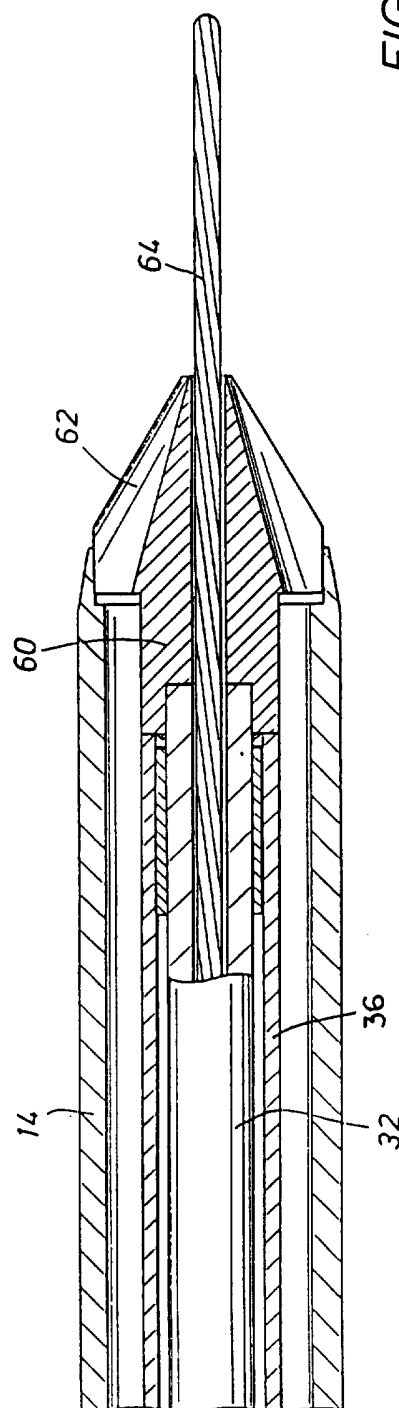
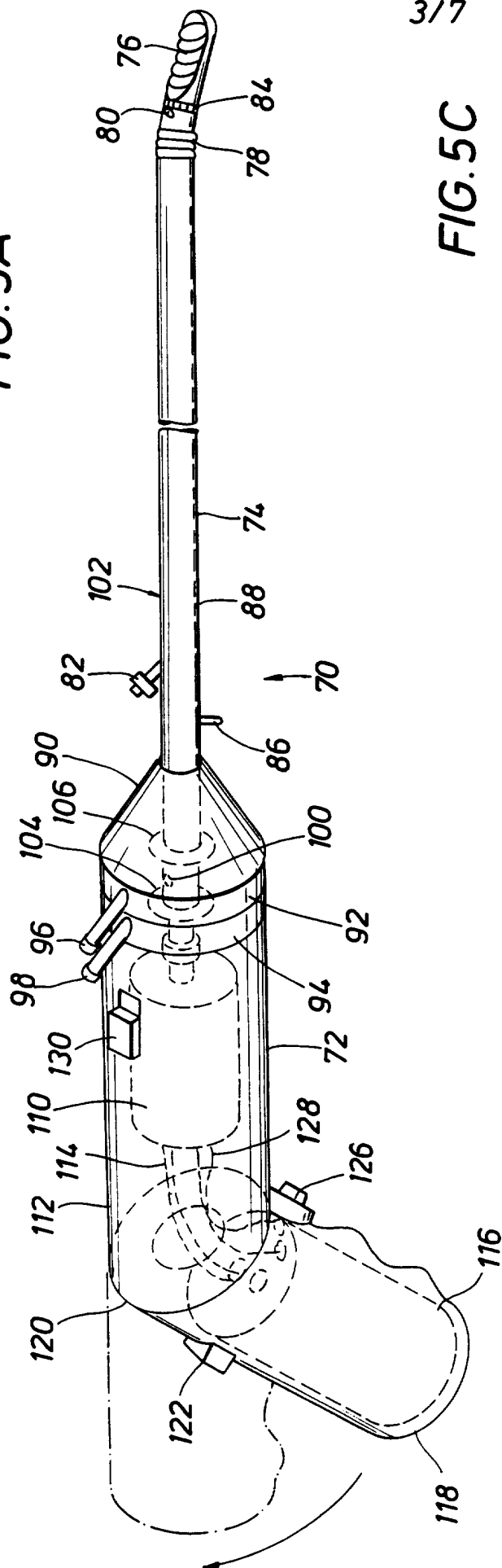


FIG. 5A



3/7

FIG. 5C

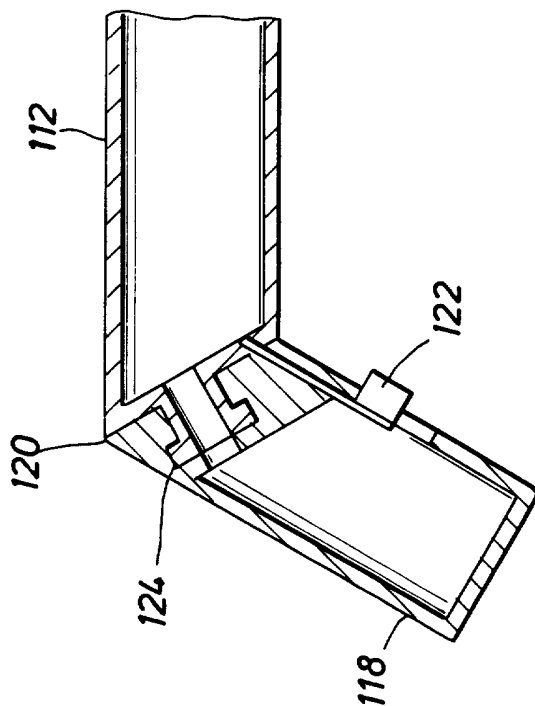
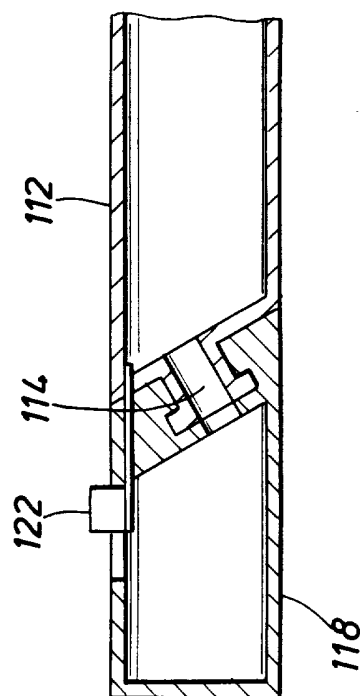


FIG. 5B



4/7

FIG. 6A

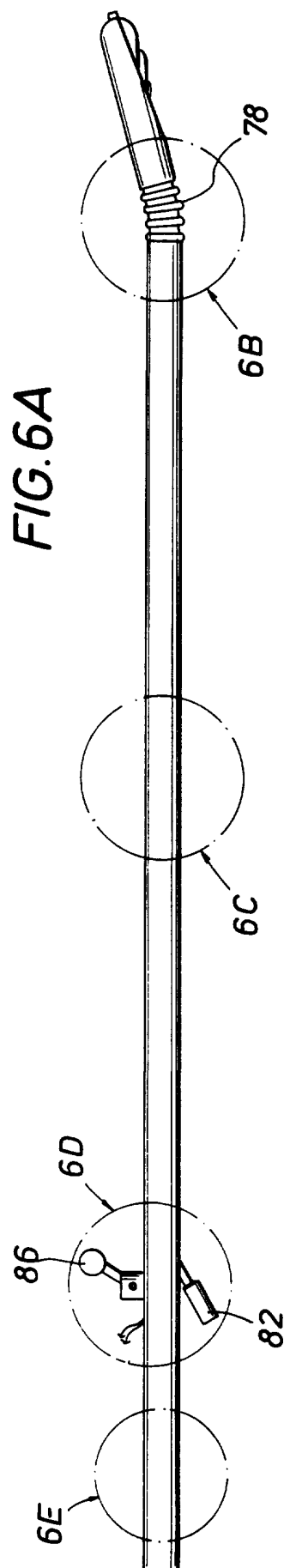


FIG. 6C

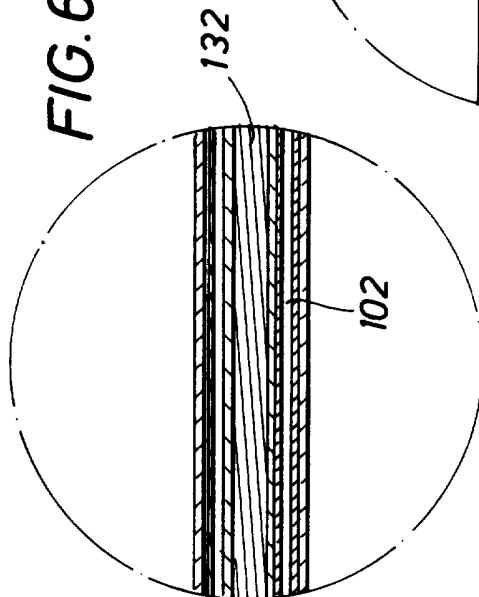


FIG. 6E

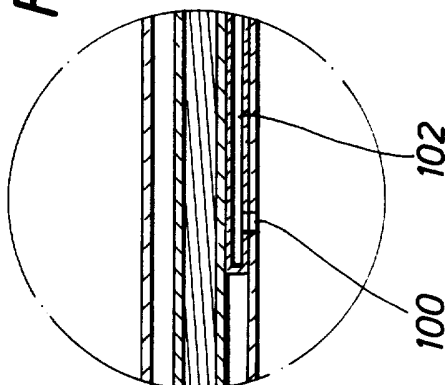


FIG. 6B

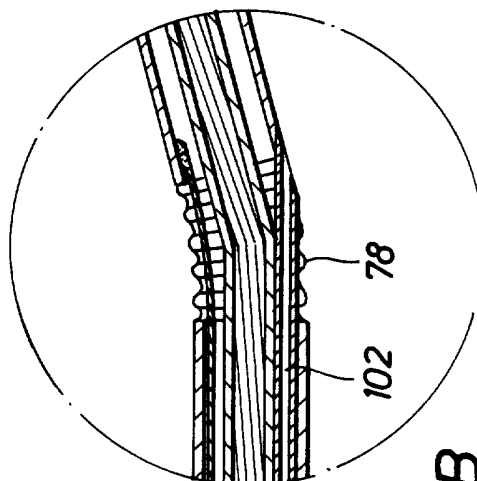
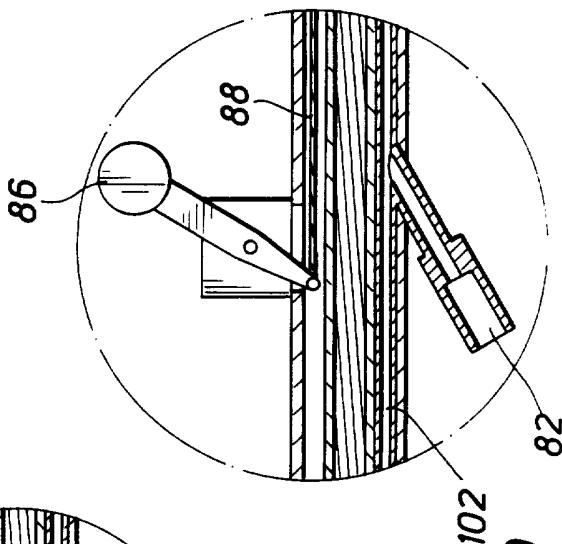
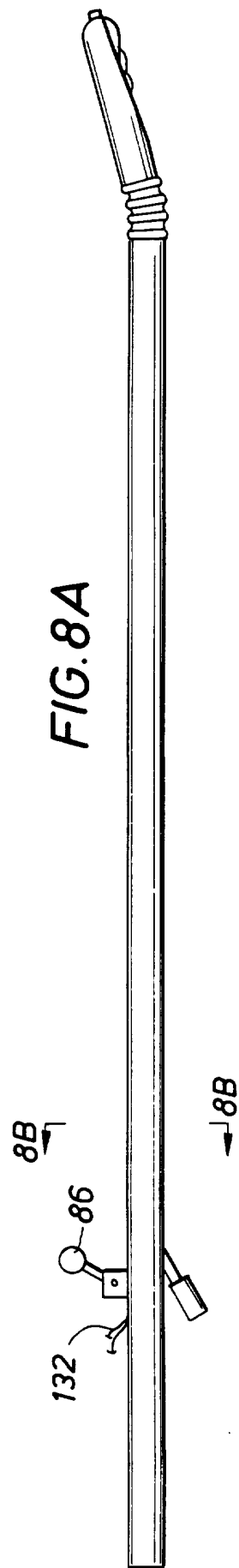
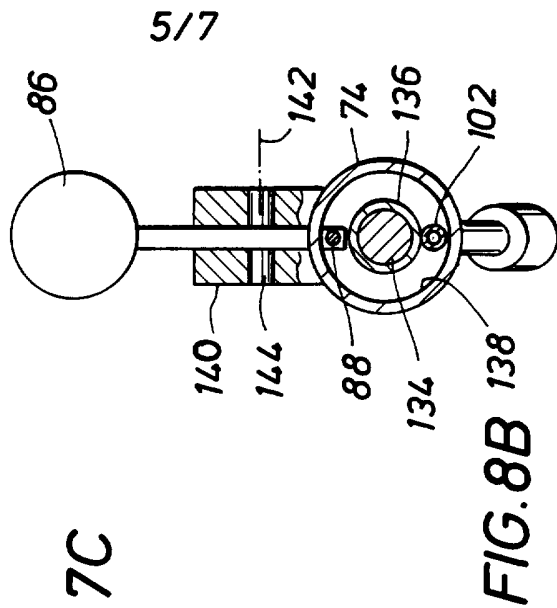
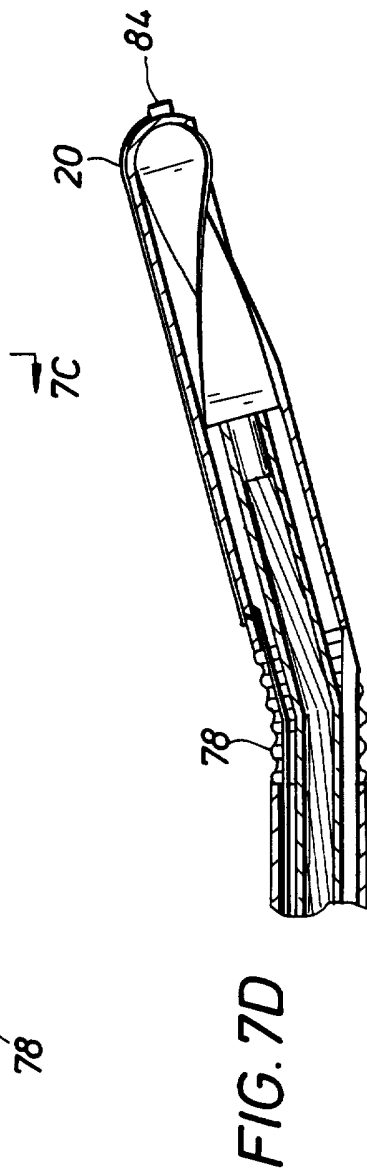
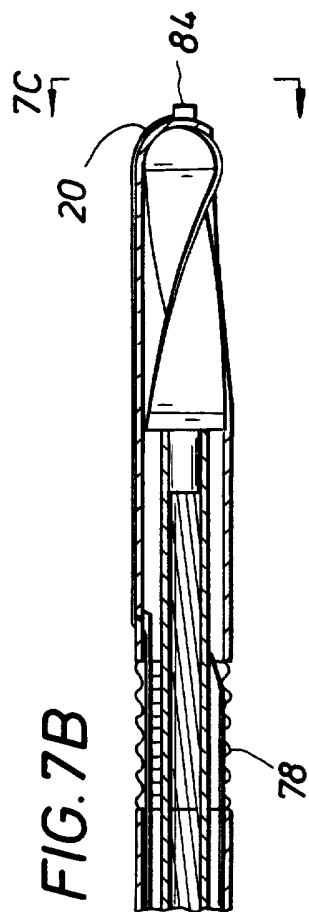
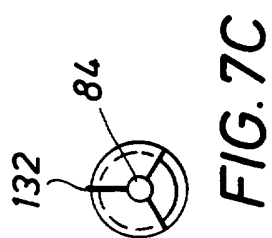
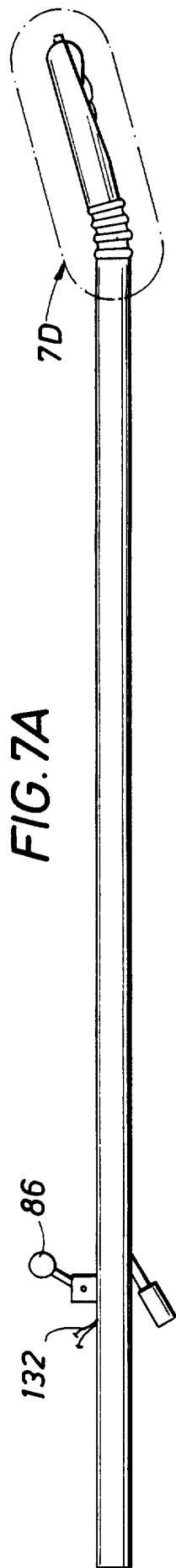


FIG. 6D





6/7

FIG. 9B

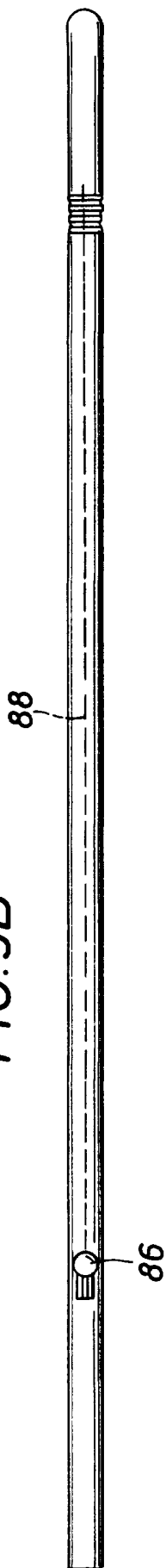


FIG. 9A

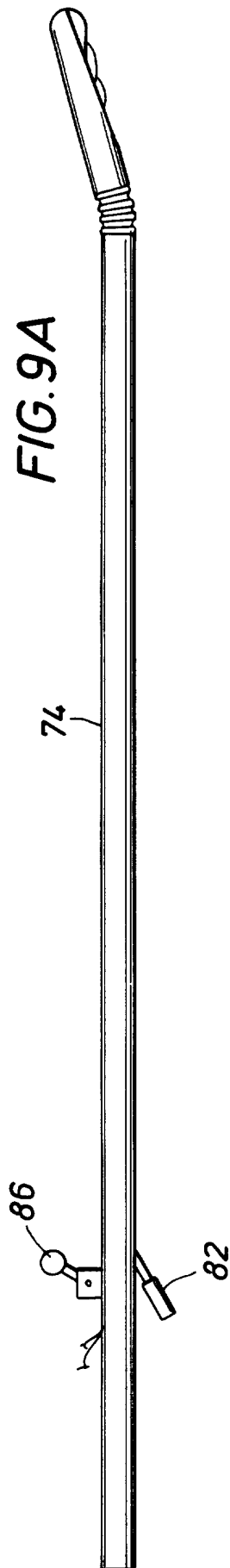


FIG. 9C



FIG. 10A



FIG. 10B



FIG. 10C

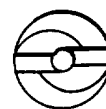


FIG. 11

7/7

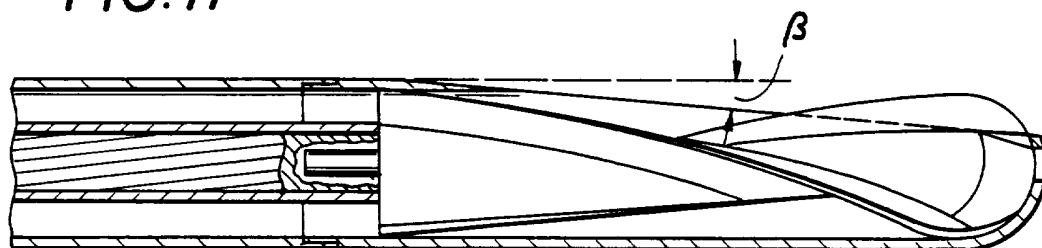


FIG. 12A

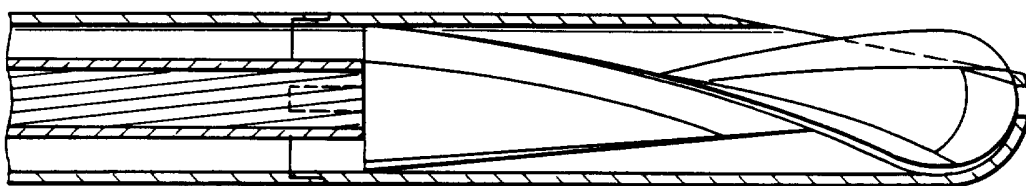


FIG. 12B

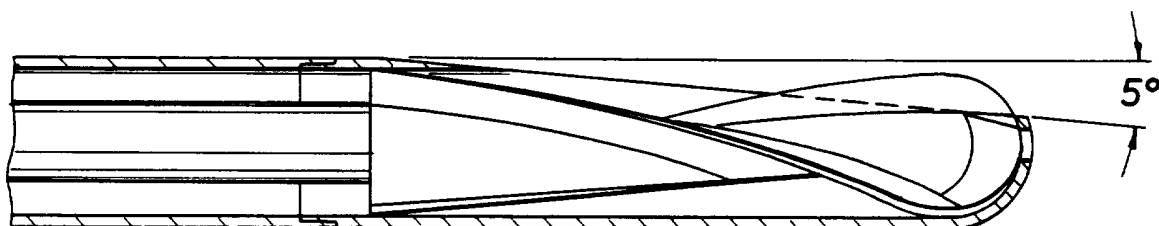


FIG. 12C

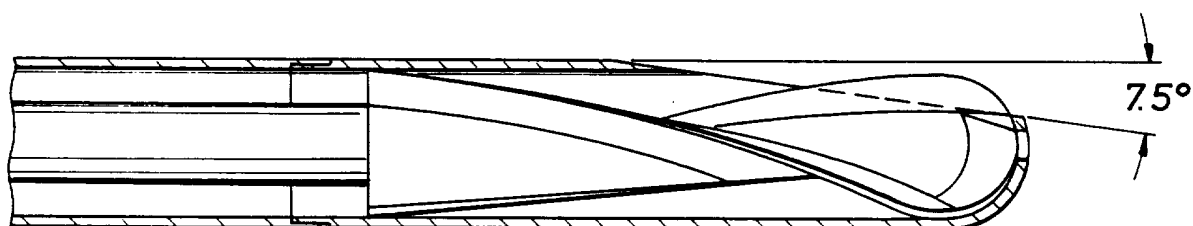
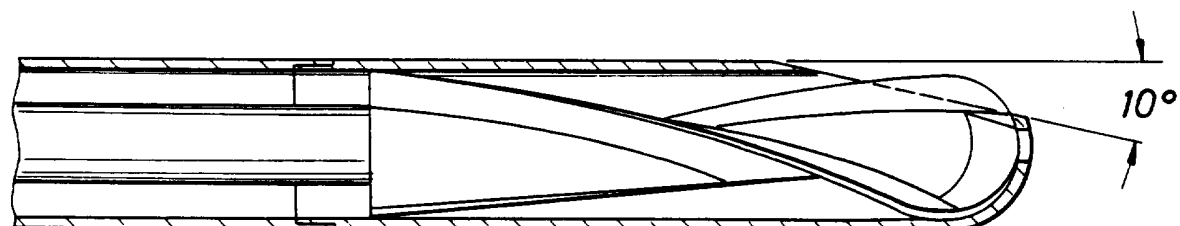


FIG. 12D



INTERNATIONAL SEARCH REPORT

Inter national Application No
PCT/US 95/00915

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 A61F

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.
A	EP,A,0 582 533 (LABORATOIRES DOMILENS S.A.) 9 February 1994 see abstract; claims; figures ---	1,8
A	US,A,4 955 882 (HAKKY) 11 September 1990 see abstract; claims; figures 1-4,13-17 ---	1,3,4,8
A	EP,A,0 442 263 (MICROCISION INC.) 21 August 1991 see claims; figures ---	1,3,8
A	US,A,5 226 909 (EVANS ET AL.) 13 July 1993 see column 6, line 29-46; claims; figures ---	1
A	US,A,3 976 077 (KERFOOT, JR.) 24 August 1976 see abstract; figures -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- * & * document member of the same patent family

Date of the actual completion of the international search

25 October 1995

Date of mailing of the international search report

07-11-95

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Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/00915

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0582533	09-02-94	FR-A- 2696924	22-04-94
US-A-4955882	11-09-90	US-A- 5061266 US-A- 5201731	29-10-91 13-04-93
EP-A-0442263	21-08-91	US-A- 5074841 AU-B- 6943891	24-12-91 01-08-91
US-A-5226909	13-07-93	US-A- 5312425 US-A- 5403334	17-05-94 04-04-95
US-A-3976077	24-08-76	NONE	