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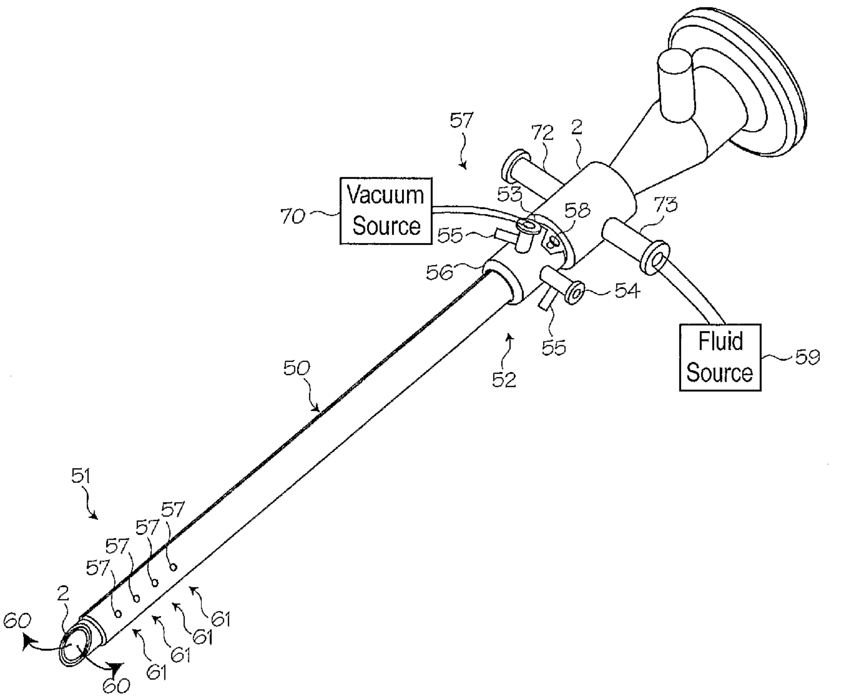
(54) Title: ATRAUMATIC ARTHROSCOPIC INSTRUMENT SHEATH



(57) Abstract: A removable, resilient atraumatic sheath for arthroscopic instruments. The sheath covers sharp edges on the arthroscopic instrument, particularly the distal tip of the rigid cannula, and thereby protects tissue and objects near a surgical site from accidental trauma. The sheath may be provided in the form of an inflow/outflow sheath that allows a surgeon to irrigate and drain a surgical field without the use of a separate irrigation instrument.

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ATRAUMATIC ARTHROSCOPIC INSTRUMENT SHEATH

Field of the Inventions

The inventions described below relate the field of arthroscopic surgical instruments.

Background of the Inventions

Arthroscopic surgery involves using optical instruments, such as an arthroscope, to visualize an operating field inside or near a joint of a patient. The same instrument or other instruments may be used to perform a surgical procedure in the operating field. Common instruments used in addition to the arthroscope include a trimming instrument for cutting tissue and an irrigation instrument for irrigating the surgical field. Each of the instruments requires its own incision to be introduced into the surgical field; thus, many surgeons prefer to use only a trimming instrument and an arthroscope during arthroscopic surgical procedures.

Arthroscopes are fragile in relation to the forces applied during arthroscopic surgery, so a rigid cannula is placed over the arthroscope to reinforce it. The distal end of the rigid cannula is pointed, usually sharp, and so the rigid cannula can scratch or gouge soft tissue within the operating field. The rigid cannula can also become stuck between bones or cartilage during a procedure. A rigid cannula can also damage metal prosthetics used to replace joints, resulting in a shortening of the useful life of the prosthetic and forcing the patient to undergo additional, painful surgeries to correct the problem.

An additional problem associated with arthroscopic surgery is maintaining a clear surgical field during surgery.

Blood and debris can cloud the field, impairing a surgeon's ability to visualize tissue. One method of solving this problem is to use the irrigation instrument to clear the surgical field with saline; however, many surgeons strongly prefer to avoid the additional trauma caused by inserting a third instrument. These surgeons will perform arthroscopic surgeries despite problems with visualizing the surgical field. Thus, devices and methods are needed both to maintain a clear surgical field and reduce accidental injury to the patient while only using two instruments.

Summary

The devices and methods shown below provide for a soft plastic, disposable atraumatic sheath that slides over the rigid cannula of an arthroscope. The distal end of the atraumatic sheath extends slightly past the distal end of the rigid cannula, thereby providing a soft, blunt cushion over the distal end of the rigid cannula. The atraumatic sheath thereby protects any surrounding tissue or objects from accidental injury or damage while the arthroscope is manipulated inside the operating field.

The atraumatic sheath may also be provided as an inflow/outflow sheath that allows a surgeon to drain fluids from or introduce fluids into the surgical field, thereby keeping the surgical field clear. The inflow/outflow sheath is a multi-lumen tube into which the arthroscope is inserted. The proximal portion of the sheath is provided with fluid ports, a manifold and other means of controlling the flow of fluid inside the sheath. The distal portion of the inflow/outflow sheath is provided with a plurality of holes. Each hole communicates with one or more of the lumens inside the tube, thereby allowing fluid to flow between the surgical field and sources or sinks located outside the patient. The

inflow/outflow sheath thereby allows the surgeon to maintain a clear surgical field and protect the patient from accidental injury while eliminating the need for a third irrigation instrument.

Brief Description of The Drawings

Figure 1 shows a method of performing arthroscopic surgery on a patient.

Figure 2 shows an atraumatic sheath for use with arthroscopic instruments.

Figure 2a shows an atruamatic sheath having two tabs.

Figure 3 shows an atraumatic sheath for use with arthroscopic instruments and an arthroscope disposed inside the atraumatic sheath.

Figure 4 shows an atraumatic sheath for use with arthroscopic instruments, an arthroscope disposed inside the atraumatic sheath and an irrigation tube disposed on the sheath.

Figure 5 shows a cross section of the atraumatic sheath shown in Figure 2 and an arthroscopic instrument disposed inside the atraumatic sheath.

Figure 6 shows an inflow/outflow atraumatic sheath for use with arthroscopic instruments.

Figure 7 shows an inflow/outflow atraumatic sheath for use with arthroscopic instruments and an arthroscope disposed inside the atraumatic sheath.

Figure 8 shows a cross section of the distal portion of the inflow/outflow atraumatic sheath of Figure 7.

Figure 9 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 10 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 11 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 12 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 13 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 14 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 15 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 16 shows a cross section of the distal portion of an inflow/outflow atraumatic sheath.

Figure 17 shows an inflow/outflow atraumatic sheath for use with arthroscopic instruments.

Figure 18 shows a cross section of the distal portion of the inflow/outflow sheath shown in Figure 17.

Figure 19 shows an inflow/outflow sheath having a distal portion that has an inner diameter that closely conforms to the outer diameter of the distal portion of an arthroscope.

Figure 20 shows an atraumatic sheath and an elastic grip disposed on the proximal portion of the sheath.

Figure 21 shows a cross section of an atraumatic sheath disposed over an arthroscope and an elastic grip disposed on the proximal portion of the sheath.

Figure 22 shows a cross section of an atraumatic sheath disposed over an arthroscope, an elastic grip and levers disposed inside the grip.

Figure 23 shows the distal end of the grip.

Figure 24 shows the distal end of the grip and levers extending distally from the openings in the grip.

Figure 25 shows the distal portion of an atraumatic sheath and an arthroscope extending distally of the distal end of the sheath.

Figure 26 shows the distal portion of an atraumatic sheath and an arthroscope extending distally of the distal end of the sheath.

Figure 27 shows a continuous inflow/outflow atramatic sheath with a tissue retention feature in the shape of radially extending ridges.

Figure 28 shows a continuous inflow/outflow atramatic sheath with a tissue retention feature in the shape of a threaded screw.

Figure 29 shows a tissue retention module disposed over an atraumatic sheath.

Figure 30 shows a tissue retention collar.

Detailed Description of the Inventions

Figure 1 shows a method of performing arthroscopic surgery on a patient by using an arthroscopic instrument **2** sheathed in an atraumatic introducer sheath **3**. An arthroscopic instrument may be an athroscope, endoscope, awl, pick, shaver, etc. In figure 1, the arthroscopic instrument 2 shown is an arthroscope. (The various parts of the arthroscope are shown in phantom to indicate their positions inside the sheath.) Various anatomical landmarks in the patient's knee **4** are shown for reference, including the femur **5**, patella **6**, posterior cruciate ligament **7**, anterior cruciate ligament **8**, meniscus **9**, tibia **10** and fibula **11**. During surgery, the surgeon introduces the arthroscope **2** into the knee via a first incision **12** in order to visualize the surgical field. A trimming instrument **13** is introduced through a second incision **14** to remove or trim tissue that the surgeon determines should be removed or trimmed. Optionally, an irrigating instrument **15** may be introduced through a third incision **16** in order to irrigate the surgical field and thereby maintain a clear view. As provided below, the irrigating instrument may be replaced by a combined arthroscope and inflow/outflow atraumatic sheath, thus reducing the number on incisions required to perform the surgery.

The arthroscope **2** is an optical instrument **17** surrounded by a rigid cannula **18** having a distal edge that typically is cut at an angle. To protect the patient from unintended injury or trauma during the procedure, the arthroscope has been inserted into a resilient, outer introducer sheath or atraumatic sheath **3** that extends over the rigid cannula. The distal tip **19** of the atraumatic sheath extends distally just past the distal end of the arthroscope and rigid cannula to further protect the patient.

Figures 2 through 4 illustrate the atraumatic sheath **3**. The atraumatic sheath is a tube of a resilient material, such as a soft plastic or rubber. The inner diameter of the atraumatic sheath is sized and dimensioned to closely fit over the outer diameter of an arthroscopic instrument. The distal tip **19** of the atraumatic sheath is provided with a shape that closely approximates the shape of the distal tip of the arthroscope and/or the rigid cannula. A flange **30** disposed around the distal end of the sheath prevents the distal tip of the rigid cannula from gouging the patient. The flange is integral with the walls of the sheath and extends inwardly towards the axis of the sheath. The flange is sized and dimensioned to prevent the distal tip of the rigid cannula from accidentally slipping distally during a surgical procedure. An opening **36** is provided in some atraumatic sheaths so that the surgeon may insert the endoscope or other instruments through the opening and into the surgical space. The distal lens **31** of an optical instrument is shown for reference in Figures 3 and 4.

The proximal end **32** of the atraumatic sheath is provided with a tab **33** to allow medical personnel to easily pull the atraumatic sheath over the rigid cannula, arthroscope and/or arthroscopic instrument. The proximal end of the atraumatic sheath may also be provided with fittings, such as a locking hub or snap latches, that attach to fittings or openings disposed on the arthroscope or other instrument, thereby securing the atraumatic sheath.

The tab **33** is sized and dimensioned to divert liquids away from any device proximal the atraumatic sheath, such as cameras, optics, motors and other equipment that may be sensitive to liquids or moisture. Liquids that escapes the surgical site and that travel along the outer surface of the sheath will be deflected by the tab, which has a radial dimension greater than that of the lumen of the sheath.

Figure 2a shows an atraumatic sheath **3** having two tabs **33** disposed along the longitudinal length of the sheath. If the flow of liquids is expected to be heavy for a surgical procedure, then the additional tab ensure that liquids do not reach sensitive devices located proximally of the sheath. Additional tabs may be provided along the longitudinal length of the sheath.

The outer surface of the atraumatic sheath may be provided with a smooth coating to allow the arthroscope and rigid cannula to more easily move within an operating site. For example, the sheath may be provided with a Teflon® (PTFE or expanded polytetrafluoroethylene) coating or covered with a water-activated lubricant. In contrast, the inner surface of the atraumatic sheath (the walls that define the lumen of the tube) may be provided with a non-slip coating or other high coefficient of friction coating. For example, the inner surface of the atraumatic sheath may be coated with a co-extruded tacky thermoplastic elastomer (TPE). The non-slip coating prevents the sheath from easily slipping over the outer surface of the rigid cannula or arthroscope, thereby helping to prevent the atraumatic sheath from twisting or slipping around the arthroscope.

Figures 3 and 4 show an atraumatic sheath **3** for use with arthroscopic instruments and an endoscope or arthroscope **2** disposed inside the atraumatic sheath. The atraumatic sheath shown in Figure 3 is provided with a balloon **34** on the distal portion of the sheath. (The balloon may be integrally formed with the sheath.) The balloon allows a surgeon to open a space within tissue, thereby dissecting the surgical field. The arthroscope may then be extended distally out of the opening

36 and the surgical space visualized. In addition, the distal end of the sheath may be provided with a distally projecting spoon or other distally projecting object to prop open a space in front of the arthroscope. The balloon and the distally projecting spoon thus provide a means for dissecting or retracting tissue to form a small surgical space.

Figure 4 shows an atraumatic sheath **3** having a second, working tube **35**. The working tube allows irrigation, fiber optics, sutures, needles, probes or surgical tools through the lumen. The atraumatic sheath shown in Figure 4 may be combined with the atraumatic sheath shown in Figure 3 to provide an atraumatic sheath with both a balloon and a working tube.

Figure 5 shows a cross section of the atraumatic sheath **3** shown in Figure 2 and an arthroscopic instrument **2** disposed inside the sheath. The atraumatic sheath is provided with a tab **33** on the proximal end of the sheath in order to increase the ease of pulling the sheath over the arthroscope. The distal end of the sheath is provided with an opening **36** to allow light to pass between the arthroscope and the operating space and, optionally, to allow additional instruments to pass through or alongside the arthroscope and into the surgical field. The walls **37** of the sheath at the distal end **19** of the sheath are thicker than the rest of the sheath walls to form a flange **30** at the distal end of the sheath. (The flange may be a separate ring of material attached to the inside of the sheath.) The flange covers the sharp distal tip of the arthroscopic instrument and prevents the instrument from slipping distally through opening **36**. The rest of the walls of the atraumatic sheath are thin in order to minimize the overall thickness of the combined sheath and arthroscopic instrument.

In use, the atraumatic sheath is provided and pulled over an arthroscopic instrument. (The instrument may also be thought of as being inserted into the sheath.) The sheathed arthroscopic instrument is then inserted into the surgical site and the surgeon performs a medical procedure therein. If a balloon is provided, the balloon is used to dissect tissue so that the arthroscope may be extended distally out of the opening **36** and the surgical space visualized.

Figures 6 and 7 show an inflow/outflow atraumatic sheath **50** and an arthroscope 2 disposed inside the sheath. Like the sheath shown in Figure 2, the inflow/outflow atraumatic sheath **50** is formed of a resilient material that protects the patient from accidental injury should the arthroscope poke at or scrape along tissue. The sheath material may also be radiopaque. A preferred durometer hardness of the sheath material is in the range of about 40 Shore D to about 90 Shore D. In this hardness range the sheath is sufficiently resilient that the sheath protects the patient from accidental injury but is sufficiently hard to prevent the lumens within sheath from collapsing.

The inflow/outflow sheath **50** is a multi-lumen tube into which an arthroscope is inserted. Each lumen extends from the distal portion **51** of the sheath to the proximal portion **52** of the sheath. The proximal portion of the sheath is provided with one or more fluid ports, such as first port **53** or second port **54**; one or more stopcocks **55** or fluid switches; one or more valves, such as a check valve; a manifold **56**; or other means of controlling the flow of fluid inside the sheath. The distal portion **51** of the inflow/outflow sheath is provided with a plurality of holes **57**. Each hole communicates with one or more of the lumens inside the tube, thereby allowing fluid to flow between the surgical field and the lumens inside the sheath.

Prior to surgery, medical personnel or the device manufacturer inserts the arthroscope into the inflow/outflow atraumatic sheath and secures the sheath to the arthroscope via a set-screw, snap-on attachment, other releasable attachments or other means **58** for securing the sheath to the arthroscope. During use, a surgeon may cause a fluid, preferably saline, to flow from a fluid source **59**, through the arthroscope and into the surgical field, as shown by inflow arrows **60**. (The arthroscope is provided with one or more lumens, ports or working tubes that allow fluid to flow through the arthroscope and into the surgical field.) In turn, blood, other fluids and debris are drained from the surgical field through the holes **57**, as shown by outflow arrows **61**, and flow through one or more lumens in the sheath. The inflow of clear saline and the outflow of cloudy fluid and debris allow the surgeon to maintain a clear surgical field using a single instrument. In turn, this capability eliminates the need to use an irrigating instrument. Thus, the surgeon may have a clear field of view while using only a two-incision arthroscopic procedure.

Figure 7 also shows that fluids are drained through the inflow/outflow atraumatic sheath by using a vacuum source **70** or gravity drain operatively attached to a fluid port, such as port **53**, connected to the sheath manifold **56**. Fluids are provided through the arthroscope **2** from a fluid source **59** (by using a pump or gravity feed) operatively attached to a fluid port, such as third port **72** or fourth port **73** connected to the arthroscope. Depending on the capabilities of the arthroscope and the surgeon's needs, the vacuum source and fluid source may be connected to different combinations of ports provided with the inflow/outflow sheath or the arthroscope. For example, the vacuum source may be attached to port **73** and the fluid source may be attached to port **72** on the inflow/outflow sheath. In this case, the surgeon may both introduce fluids into and drain fluids from the surgical site using only the inflow/outflow sheath. Thus, even if the arthroscope is incapable of introducing fluids to or draining fluids from the surgical site, the inflow/outflow sheath allows the surgeon to eliminate the need for the irrigation instrument. In any case, a pressure sensor, and flow rate control system and feedback control system may be provided to automatically monitor and control the rate of fluid flow into and out of the surgical site.

Figure 8 shows a cross section of the distal portion of the inflow/outflow sheath **3** shown in Figure 6. The inflow/outflow sheath **50** has a central lumen **80**, bounded by inner wall **81**, through which the arthroscope is inserted. The sheath has four outer lumens, including a first outer lumen **82**, a second outer lumen **83**, a third outer lumen **84** and a fourth outer lumen **85** bounded by the inner wall **81**, the outer wall **86** and four relatively stiff ribs **87** that extend between the inner and outer walls and that run along the length of the sheath. The outer lumens are annular. The distal end of the sheath in the area of the outer lumens **82**, **83**, **84** and **85** is sealed closed and provided with a rounded shape to help prevent injury to the patient (the central lumen remains open to accommodate the arthroscopic instrument). Holes **57** or apertures disposed in the outer wall allow fluids to flow into or out of the outer lumens. For example, lumens **82** and **84** could serve as passages through which fluids are introduced into the surgical site and lumens **83** and **85** could serve as passages through which fluids are drained from the surgical site. During another surgical procedure, all four lumens could be used to either drain or introduce fluids. Thus, the surgeon has the option of using the inflow/outflow atraumatic sheath in many different modes. (In addition, the sheath may be formed with more than or fewer than the four ribs shown, so long as at least one outer lumen remains open to fluid flow after the sheath and scope have been inserted into the surgical site.)

Figures 9 through 16 show cross sections of the distal portion of various inflow/outflow atraumatic sheaths. Figure 9 shows an inflow/outflow sheath having a second set of inner lumens, including a first inner lumen **100**, a second inner lumen **101**, a third inner lumen **102** and a fourth inner lumen **103**. With this design, the surgeon can increase the rate of fluid exchange by using all of the inner lumens to introduce fluids into the surgical site and by using all of the outer lumens **82**, **83**, **84** and **85** to drain fluid from the surgical site (or visa versa).

Figure 10 shows an inflow/outflow sheath 50 without an inner wall 81. Instead, the outer surface of the arthroscope **2** serves as the inner wall of the sheath once the arthroscope has been inserted into the sheath. The four, relatively stiff ribs **87** form a seal with the outer surface 88 of the arthroscope, thereby creating the four outer lumens **82**, **83**, **84** and **85**. The ends **104** of the ribs may be provided with elastic flanges or extensions to enhance the seal made between the ribs and the arthroscope. This configuration reduces the overall size of the combined inflow/outflow sheath and arthroscope. (If the outer wall **86** is made of an elastomeric material, then the tube can stretch radially to accommodate a variety of sizes of arthroscopes.)

As depicted in Figure 10, the arthroscope **2** is inserted into the sheath 50 through the central lumen 80. The arthroscope **2** may or may not be covered by a secondary protective sheath prior to insertion. Once inserted, the outer surface 88 of the arthroscope **2** comes in contact with the flanges or extensions of the ribs **87**. The land of a rib may also be used to contact the outer surface of the arthroscope **2** when the ribs **87** do not have flanges or extensions. The force of the outer surface 88 of the arthroscope **2** pushing against the ribs **87** and the rib flanges or rib extensions forms a seal between the ribs **87** and the outer surface 88 of the arthroscope **2**. Outer lumens **82, 83, 84** and **85** are created by the ribs, the outer surface of the endoscope 88, and inner surface 89 of the outer wall 86 of the inflow/outflow sheath. The ribs act as longitudinal struts that prevent the sheath from collapsing as they support the sheath under compression. The ribs reduce the unsupported span of the thin outer wall in the traverse axis, further preventing the collapse of the sheath. The seals formed by the contact between the ribs **87** and the outer surface 88 of the arthroscope prevent fluids from flowing between the outer lumens **82, 83, 84** and **85**. The outer lumens **82, 83, 84** and **85** facilitate the continuous inflow and outflow of fluids to and from a surgical site from outside the patient 1. Check valves or gates may also be coupled to the inner wall of the inflow/outflow sheath 50 within the outer lumens **82, 83, 84** and **85** to prevent outflow fluids from flowing back towards the surgical site and to prevent inflow fluids from flowing out the proximal end of the sheath.

The inflow/outflow sheath 50 depicted in figure 10 typically has an outer diameter measuring about 5 to 7 millimeters when the sheath is manufactured for use with arthroscopic instruments in larger joints, though this size may vary depending on the diameter of the arthroscopic instrument. When the inflow/outflow sheath is manufactured for use with arthroscopic instruments in smaller joints, the sheath 50 has an outer diameter measuring about 2 to 3 millimeters. The outer wall thickness 86 of the inflow/outflow sheath 50 is typically 1 millimeter or less depending on the extrusion and material comprising the tube. The inflow/outflow sheath 50 can fit a range of arthroscopes

+/- 10% of the sheath's nominal diameter. The ribs 87 extend from the inner surface of the inflow/outflow sheath inwardly and make a tight fit when the arthroscope is inserted.

A smaller outer diameter inflow/outflow sheath 50 is particularly useful in arthroscopic surgery. Due to the unique, the inflow/outflow sheath 50 has been able to achieve a 30% reduction in diameter when compared to multi-lume cannula devices requiring an inner wall of a cannula contacting the outer wall of the arthroscope. Presently, arthroscopic surgical techniques use a standard three-incision technique. A first incision is made and used to insert an inflow cannula to distend the joint. The inflow cannula is used to fill the joint with a sterile fluid to expand the joint and make room for the surgeon to see and work. A second incision is made in the patient and used to insert an arthroscope to view the surgical site. A third incision is created by the surgeon to insert a specialized surgical instrument to correct the injury or abnormality. After the procedure, the joint is washed out with a stream of fluid, the instruments are removed, and the portals are closed with stitches, staples, or Steri-strips. Recently, surgeons have begun to shift to a two-incision technique during arthroscopic. Surgeons use one incision for inserting the arthroscope and a second incision for inserting the specialized surgical instrument. This technique eliminates a third portal by using an arthroscope with an inflow and outflow sheath. Sheaths currently used for inflow and outflow, however, do not facilitate the continuous and simultaneous inflow and outflow of fluids to and from a surgical site with a sheath having a reduced diameter. Present sheaths only facilitate alternating inflow and outflow of fluids to the surgical site and these sheaths are of a larger diameter requiring the incision to be larger. When in use, the Applicant's inflow/outflow sheath 50 can facilitate the substanially simultaneous flow of fluids to and from a surgical site through the outer lumens **82, 83, 84** and **85** while requiring a smaller size incision. Substanially simultaneous inflow and outflow allows the surgeon to keep the surgical site clean and the field of view clear.

A unique feature of the Applicant's inflow/outflow sheath 50 is the allowance of outflow to exceed inflow in the sheath 50. Higher outflow capacity facilitates the removal of debris and bodily fluids from the surgical site. Fluid pressure supplied to the inflow/outlow sheath 50 is usually standard arthroscopic distension pressure at a pressure head of approximately 6 feet to 8 feet of water, but this may vary depending on the surgical application. Suction for use with the inflow/outflow sheath 50 ranges from approximately 0 to 250 mm/Hg depending on the sheath size and surgical application. When the inflow/outflow sheath is used in conjunction with a 5.7 mm arthroscope, the inflow of fluid to a surgical site can be performed at the rate of 800 ml/min at 6 feet of water while outflow from the surgical site can be accomplished at the rate of 850 ml/min at 21 mm/Hg suction. The higher outflow capacity is able to remove both the irrigation fluid and the additional debris and bodily fluid coming from the patient during surgery.

Figure 11 shows an inflow/outflow atraumatic sheath **50** similar to that shown in Figure 10. The relatively hard ribs **87** are pleated, but still form a seal with the outer wall of the arthroscope **2**, thereby forming the outer lumens **82, 83, 84** and **85** once the arthroscope is inserted into the sheath. The sheath of Figure 11 accommodates a variety of sizes of arthroscopes since the pleated ribs will bend to a degree necessary to accommodate larger sizes of arthroscopes, as shown in Figure 12.

Figure 13 shows an inflow/outflow atraumatic sheath **50** similar to that shown in Figure 11. The ribs **87** of this sheath are elastic tubes that form a seal with the outer wall of the arthroscope **2**, thereby forming the outer lumens **82**, **83**, **84** and **85** once the arthroscope is inserted into the sheath. The sheath of Figure 13 accommodates a variety of sizes of arthroscopes since the tubes will compress to a degree necessary to accommodate larger sizes of arthroscopes, as shown in Figure 14.

Figure 15 shows a "C"-shaped or slit inflow/outflow sheath **50**. Like the sheath of Figure 8, four outer lumens **82**, **83**, **84** and **85** are provided, with the outer lumens bounded by three ribs **87**, the inner wall **81** and the outer wall **86**. When the arthroscope **2** is inserted into the sheath, a small gap **105** may form between the respective tips of the first arcuate segment **106** and the second arcuate segment **107**. (As the arthroscope is inserted into the surgical space, tissue **108** will seal the gap and prevent fluids from leaking from the surgical space to outside the body.) The sheath of Figure 15 accommodates a variety of sizes of arthroscopes since the arcuate segments will move radially outwardly as a larger arthroscope is inserted into the sheath, as shown in Figure 16.

Optionally, a protrusion or a guide rail **109** may extend from either the arthroscope or the sheath. The guide rail helps the user align the sheath on the arthroscope while inserting the arthroscope into the sheath. The guide rail also prevents unwanted rotation or twisting of the sheath over the arthroscope during a surgical procedure.

Figures 17 and 18 show an inflow/outflow atraumatic sheath **50** and an arthroscope **2** inserted into the sheath. In contrast to the inflow/outflow sheaths shown in Figures 6 through 16, the outer wall **86** of the distal portion **51** of the sheath is made from a continuous tube (the distal portion of the sheath is not provided with holes). Nevertheless, like the sheath of Figure 8 the sheath of Figure 17 has an inner lumen to accommodate the arthroscope and four outer lumens to accommodate fluid inflow and outflow, including a first outer lumen **82**, a second outer lumen **83**, a third outer lumen **84**, and a fourth outer lumen **85**. The outer lumens are bounded by the inner wall **81**, outer wall **86** and supporting ribs **87**. The instrument shown in Figure 17 provides fluid inflow and outflow out of the distal end **110** of the sheath.

Figure 19 shows an inflow/outflow atraumatic sheath **50** having a closely-conforming distal portion **111** that has an inner diameter that closely conforms to the outer diameter of the distal portion of an arthroscope **2**. The fluid-conducting portion **112** of the sheath is set proximally from the closely conforming distal portion **111** of the sheath. The outer diameter of the fluid conducting portion **112** and the outer diameter of the closely conforming distal portion **111** may be formed integrally with each other such that both portions are part of the same sheath. Holes **57** disposed in the fluid-conducting portion **112** just proximally of the distal portion **111** of the sheath communicate with one or more lumens inside the sheath, thereby allowing a surgeon to either introduce or drain fluids from a surgical site. The sheath shown in Figure 19 has a distal portion **111** with a relatively small radius, since the sheath closely conforms to the arthroscope at the distal portion of the arthroscope. This provides the surgeon with the capability of inserting the arthroscope into narrow surgical sites. In addition, the fluid-conduction portion still allows a surgeon to irrigate the surgical field with the combined sheath/arthroscope instrument.

Figures 20 and 21 show an atraumatic sheath **3** disposed over an arthroscope **2** and an elastic grip **120** disposed on the proximal portion **121** of the sheath. The grip **120** is preferably a hollow, ergonomic cylinder of elastic material (such as a thermoplastic elastomer) that is sized and dimensioned to allow a surgeon to manipulate the arthroscope and sheath easily, even if the surgeon's hands become wet. The grip extends proximally of the proximal end **32** of the sheath so that the proximal portion **122** of the grip will extend over an arthroscope **2** disposed within the sheath **3**. (The proximal portion **121** of the sheath in Figure 20 is shown in phantom to indicate its position inside the grip.) The grip is designed such that the grip is biased to assume a shape having an inner diameter less than the outer diameter of the arthroscopic instrument and preferably less than the inner diameter of the sheath's inner lumen. Thus, the grip will exert an inwardly directed radial force, as indicated by arrows **123** in Figure 21, against an instrument disposed within the sheath.

In use, the proximal portion **122** of the grip **120** will squeeze down on and grasp an arthroscope **2** disposed within the sheath **3**. If the proximal portion of the grip is peeled back and released, the grip is biased to spring back to its original shape. Thus, the arthroscope will remain secure within the sheath as the arthroscope or sheath is manipulated during surgery.

Figure 22 shows a cross section of an atraumatic sheath **3** disposed over an arthroscope **2**, an elastic grip **120** and levers **124** and **125** disposed inside the grip for widening the proximal opening of the grip. The grip shown in Figure 22 is provided with a first channel **126** and a second channel **127** into which a corresponding first lever **124** and second lever **125** have been inserted. The levers are provided with barbs, tangs or other means for securing the levers within their respective channels. The distal portions of the levers are provided with an arcuate shape such that the levers bend away from the sheath.

In use, a user presses on the distal portions of the levers. As the distal portions of the levers move radially inwardly, the proximal portions of the levers will exert a force directed radially outwardly against a corresponding segment of the proximal portion of the grip, thereby bending the proximal portion of the grip radially outwardly. This action widens the proximal opening of the grip. With the proximal opening of the grip widened, the user may easily insert or remove the arthroscope from the sheath. Fulcrums **128** disposed on the distal portions of the levers prevent the levers from moving radially inwardly by more than a pre-determined amount. The fulcrums also allow a user to apply more outward force to corresponding segments in the proximal portion of the grip, thereby making the insertion of instruments easier.

Figures 23 and 24 show the distal end of the grip **120** and levers **124** and **125** extending from the distal end of the grip. A portion of the sheath **3** is shown extending distally from the grip in Figure 23 for reference. Channels **126** and **127** disposed in the grip extend longitudinally through (or partially through) the grip to accommodate the levers. In use, a user presses on the levers to peel back the proximal portion of the grip. The user then slides the arthroscope into or out of the sheath as desired.

Figure 25 shows the distal portion of an atraumatic sheath **3** and an arthroscope **2** extending distally of the distal end **140** of the sheath **3**. Holes **57** are provided in the distal portion of the sheath. The holes communicate with one or more lumens in the sheath. The lumen or lumens communicate with a vacuum source, fluid source, therapeutic agent source or a combination of sources. Thus, the holes provide for the inflow and outflow of fluids during a procedure.

The distal tip **141** of the sheath is made of an elastic material having a higher modulus of elasticity than the modulus of elasticity found in the material of the proximal portion of the sheath. In another embodiment, the sheath and the distal tip 141 may be manufactured from a single flexible sterilizeable polymer.The distal tip of the sheath also has an inner diameter that is slightly smaller than the outer diameter of most arthroscopes. In another embodiment, the sheath and the distal tip 141 may be manufactured from a single flexible sterilizeable polymer.

In use, a user inserts the arthroscope into the sheath. The distal tip expands as the distal end of the arthroscope slides past the distal tip of the sheath. Because the inner diameter of the tip is less than the outer diameter of the arthroscope, the tip will form a fluid-proof seal with the arthroscope.

Figure 26 shows the distal portion of an atraumatic sheath **3** and an arthroscope **2** extending distally of the distal end **140** of the sheath. Holes **57** are provided in the sheath to allow the inflow and outflow of fluids during a surgical procedure. The distal tip **141** of the sheath is made of an elastic material having a hardness that is less than the hardness of the proximal portion of the sheath. A slit **142** is provided in the tip and may extend into the distal portion of the sheath. In use, the slit and tip expand as a user slides an arthroscope through the tip. Thus, the slit allows the sheath to accommodate larger arthroscopes or other medical instruments.

Figure 27 and 28 shows a continuous inflow/outflow atramatic sheath 50 with a tissue retention feature 113. The outer surface of the proximal portion 52 of the sheath is corrugated or provided with ridges 114 to help prevent the sheath or instrument from being unintentionally forced out of the operating field. The ridges 114 of the tissue retention feature 113 are circumferentially disposed around the sheath and may be in the shape of straight ridges extending radially outward as illustrated in Figure 27. The ridges 114 of the tissue retention feature 113 may also be in the shape of a threaded screw as illustrated in figure 28.

Figure 29 and 30 illustrate how the tissue retention feature is incorporated into a separate tissue retention sleeve 115 for use over an atraumatic sheath **50** without tissue retention feature 113. In this embodiment, the tissue retention sleeve has an inner diameter so sized and dimensioned to fit over an atraumatic sheath. The tissue retention sleeve is manufactured from an elastomer having a coefficient of friction that prevents the module from moving easily once the module has been forcibly slid into position over the outer surface of the atraumatic sheath. The sleeve friction fits over the surgical instrument or atraumatic sheath. The elastomer is sterilizeable for use in a patient. The outer surface of the tissue retention sleeve is corrugated or disposed with ridges to help prevent the sheath or instrument from being unintentionally forced out of the operating field when the sheath or instrument is provided with the tissue retention sleeve. The ridges 114 disposed on the sleeve are circumferentially disposed around the outer surface of the sleeve 115 and may be in the shape of straight ridges extending radially outward. The ridges 114 may also be in the shape of a threaded screw.

The atraumatic sheath configurations may be designed or sized and dimensioned to conform to differently shaped instruments, the sheath is also useful with other medical instruments and other surgical procedures in which it is desirable to protect surrounding tissue from accidental trauma. For example, the atraumatic sheath may be disposed over a trimming instrument for use during arthroscopic surgery or over an energy-delivering medical instrument, such as a laser or RF energy instrument. Other procedures in which the atraumatic sheath is useful include laparoscopic surgery and other kinds of endoscopic surgery. In addition, the various sheath configurations shown herein may be combined to form additional types of instrument sheaths. Thus, while the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims.

We claim:

1. A system for performing arthroscopic surgery, said system comprising:

an arthroscopic instrument suitable for performing an arthroscopic surgical procedure;

an atraumatic sheath comprising a tube characterized by a proximal portion and a proximal end, said sheath having an inner diameter sized and dimensioned to closely conform to an outer diameter of the arthroscopic instrument, wherein the atraumatic sheath is adapted to be removably disposed over the arthroscopic instrument;

a cylindrical grip disposed on the proximal portion of the sheath, said grip characterized by a proximal portion;

wherein the proximal portion of the grip extends proximally past the proximal end of the sheath;

wherein the material of the proximal portion of the grip and the size and dimensions of the proximal portion of the grip are selected such that the proximal portion of the grip is biased to assume a shape having an inner diameter less than the outer diameter of the arthroscopic instrument, whereby the proximal portion of the grip may squeeze the arthroscopic instrument.

2. The system of claim 1 further comprising a first lever operably attached to the grip, said first lever operable to move a first segment of the proximal portion of the grip in a radially outwardly direction.

3. The system of claim 2 further comprising a second lever operably attached to the grip, said second lever operable to

move a second segment of the proximal portion of the grip in a radially outwardly direction.

4. The system of claim 3 wherein:

the first lever and the second lever extend distally from the grip;

the first lever and the second lever are characterized by a distal portion; and

the distal portions of the first lever and second lever comprise arcuate segments that extend radially outwardly from the sheath.

5. The system of claim 4 further comprising a first fulcrum disposed on the distal portion of the first lever and a second fulcrum disposed on the distal portion of the second lever.

6. The system of claim 1 further comprising a first tab disposed on the sheath, said tab adapted to prevent fluids disposed outside the sheath from moving proximally of the tab.

7. The system of claim 6 further comprising a second tab disposed on the sheath and distally of the first tab, said second tab adapted to prevent fluids disposed outside the sheath from moving proximally of the second tab.

8. The system of claim 1 wherein the sheath is characterized by a distal tip and wherein:

the distal tip comprises a material having a hardness less than the hardness of the material of the sheath; and

the distal tip has an inner diameter less than the inner diameter of the sheath.

9. The system of claim 8 wherein the tip is split in at least one location on the tip.

10. The system of claim 1 wherein the sheath is further characterized by a distal portion and wherein the sheath further comprises a hole disposed in the distal portion of the sheath, said hole communicating from the outer diameter of the sheath to a lumen disposed within the sheath, whereby fluids may be introduced into and suctioned from a surgical site through the hole.

11. The system of claim 6 wherein the sheath is further characterized by a distal portion and wherein the sheath further comprises a hole disposed in the distal portion of the sheath, said hole communicating from the outer diameter of the sheath to a lumen disposed within the sheath, whereby fluids may be introduced into and suctioned from a surgical site through the hole.

12. The system of claim 8 wherein the sheath is further characterized by a distal portion and wherein the sheath further comprises a hole disposed in the distal portion of the sheath, said hole communicating from the outer diameter of the sheath to a lumen disposed within the sheath, whereby fluids may be introduced into and suctioned from a surgical site through the hole.

13. An atraumatic sheath comprising:

a tube having a distal tip, said tube characterized by a distal portion, an inner surface, and an inner diameter;

wherein the inner diameter of said tube is sized and dimensioned to permit fluid flow between the inner surface of the tube and an outer surface of an arthroscopic instrument when the arthroscopic instrument is disposed within the tube;

wherein the distal tip expands to form a seal around the outer surface of the arthroscopic instrument when the arthroscopic instrument is disposed within the tube; and

a plurality of ribs extending inwardly from the inner surface of the tube and running longitudinally along the tube;

wherein said ribs further define outer lumens between the outer surface of the arthroscopic instrument and the inner surface of the tube.

14. The atraumatic sheath of claim 13 wherein the distal tip and the tube are comprised of the same flexible material.

15. The atraumatic sheath of claim 13 wherein the distal tip is comprised of a dissimilar material from material comprising the tube, said dissimilar material having a higher modulus of elasticity than the material comprising the tube.

16. The atraumatic sheath of claim 13 wherein the distal tip is split in at least one location on the tip.

17. The atraumatic sheath of claims 13, 14, or 15 wherein the distal portion of the tube further comprises a plurality of holes in fluid communication with one or more outer lumens and a surgical site.

18. The atraumatic sheath of claim 13 further comprising one or more check valves coupled to one or more outer lumens.

19. The atraumatic sheath of claim 17 wherein a distal end of the arthroscopic instrument may extend distally from the

distal tip of the atraumatic sheath when the arthroscopic instrument is disposed within the atraumatic sheath.

20. A method of performing arthroscopic surgery, said method comprising the steps of:

providing a system for performing arthroscopic surgery, said system comprising:

an arthroscopic instrument suitable for performing an arthroscopic surgical procedure;

an atraumatic sheath comprising a distal tip, a distal portion, and an inner diameter sized and dimensioned to permit fluid flow between the inner surface of the sheath and an outer surface of the arthroscopic instrument disposed within the sheath, said sheath further comprising a plurality of ribs extending inwardly from an inner surface of said sheath and running longitudinally along said sheath;

wherein said ribs define outer lumens between an outer surface of the arthroscopic instrument and the inner surface of the sheath, said lumens facilitating the inflow and outflow of fluid to and from a surgical site;

wherein the atraumatic sheath is adapted to be removably disposed over the arthroscopic instrument;

wherein the distal tip expands to form a seal around the outer surface of the arthroscopic instrument when the arthroscopic instrument is disposed within the atraumatic sheath and extends distally from the distal tip;

placing the arthroscopic instrument inside the sheath; and

performing an arthroscopic surgical procedure with the system for performing arthroscopic surgery.

21. The method of claim 20 wherein the distal tip comprises a material having a different modulus of elasticity than the rest of the atraumatic sheath.

22. The method of claim 20 wherein the distal tip and the rest of the atraumatic sheath comprise the same material.

23. The method of claim 20 wherein the distal portion of the sheath further comprises a plurality of holes in fluid communication with one or more outer lumens and a surgical site.

24. The method of claim 20 or 23 further comprising the step of providing substantially simultaneous inflow and outflow of fluid to an arthroscopic surgical site.

25. The method of claim 24 further comprising the step of providing outflow of fluid at a rate equal to or exceeding the inflow rate of fluid to the arthroscopic surgical site.

26. A device for use with an arthroscopic sheath comprising:

a sleeve having an outer surface and a bore extending therethrough, said bore having an inner diameter so sized and dimensioned as to frictionally fit over an outer diameter of an arthroscopic surgical instrument; and

a ridge disposed on the outer surface of the sleeve to prevent the surgical instrument from being easily removed from a surgical site.

27. A tissue retention device of claim 26 wherein said ridge is helical and shaped as a thread.

28. A tissue retention device of claim 26 wherein said ridge is circumferential.

29. A tissue retention device of claim 26 further comprising a plurality of circumferential ridges disposed on the outer surface of the sleeve.

30. A tissue retention device of claim 26 wherein the sleeve of the device comprises a sterilizeable elastomer.

31. A system for performing arthroscopic surgery, said system comprising:

an arthroscopic instrument suitable for performing an arthroscopic surgical procedure, said arthroscopic instrument characterized by a distal tip;

an atraumatic sheath comprising a tube of resilient material having a distal end, said sheath having an inner diameter sized and dimensioned to closely conform to an outer diameter of the arthroscopic instrument and said sheath having a flange disposed at the distal end of the sheath, wherein the flange is disposed, sized and dimensioned to prevent the distal tip of the arthroscope from extending distally from the sheath;

wherein the atraumatic sheath is adapted to be removably disposed over the arthroscopic instrument.

32. The system of claim 31 wherein the sheath is characterized by an outer surface and an inner surface and wherein the outer surface is provided with a smooth coating.

33. The system of claim 32 wherein the inner surface of the sheath is provided with a non-slip coating.

34. The system of claim 31 wherein the sheath is provided with a tab disposed on the proximal end of the sheath, said tab sized and dimensioned to allow the sheath to be pulled onto and off of the arthroscopic instrument.

35. The system of claim 31 further comprising a first set of fittings disposed on the proximal end of the sheath and a second set of fittings disposed on the arthroscopic instrument, wherein the first and second sets of fittings are adapted for releasable coupling, whereby the sheath is secured to the arthroscopic instrument when the first and second sets of fittings are secured together.

36. The system of claim 31 wherein the atraumatic sheath is characterized by a distal portion and wherein the atraumatic sheath further comprises a balloon disposed on the distal portion of the sheath.

37. The system of claim 31 wherein the sheath further comprises a working tube, said working tube sized, dimensioned and disposed to allow fluid communication between a surgical site and the lumen of the working tube.

38. An atraumatic sheath comprising:

a tube of resilient material having a distal end, an outer surface, an inner surface, an inner diameter and an outer diameter;

wherein the inner diameter of said tube is sized and dimensioned to closely conform to an outer diameter of an arthroscopic instrument;

wherein the tube is provided with an inwardly directed flange disposed at the distal end of the sheath, wherein the flange is disposed, sized and dimensioned to prevent the distal tip of the arthroscope from extending distally from the sheath;

wherein the outer surface of the tube is provided with a smooth coating; and

wherein the inner surface of the tube is provided with a non-slip coating.

39. A system for performing arthroscopic surgery, said system comprising:

an arthroscopic instrument suitable for performing an arthroscopic surgical procedure, said arthroscopic instrument characterized by a distal tip;

a rigid cannula, said rigid cannula characterized by a lumen and a distal tip, said rigid cannula sized and dimensioned such that the arthroscopic instrument may be extended through the lumen and distally of the distal tip of the rigid cannula;

an atraumatic sheath comprising a tube of resilient material having a distal end, said sheath having an inner diameter sized and dimensioned to closely conform to an outer diameter of the arthroscopic instrument;

wherein the atraumatic sheath is adapted to be removably disposed over the arthroscopic instrument.

40. The system of claim 39 wherein the sheath is characterized by an outer surface and an inner surface and wherein the outer surface is provided with a smooth coating.

41. The system of claim 40 wherein the inner surface of the sheath is provided with a non-slip coating.

42. The system of claim 39 wherein the sheath is provided with a tab disposed on the proximal end of the sheath, said tab sized and dimensioned to allow the sheath to be pulled onto and off of the arthroscopic instrument.

43. The system of claim 39 further comprising a first set fittings disposed on the proximal end of the sheath and a second set of fittings disposed on the arthroscopic instrument, wherein the first and second sets of fittings are adapted for releasable coupling, whereby the sheath is secured to the arthroscopic instrument when the first and second sets of fittings are secured together.

44. The system of claim 39 wherein the sheath is characterized by a distal portion and wherein the sheath further comprises a balloon disposed on the distal portion of the sheath.

45. The system of claim 39 wherein the sheath further comprises a working tube, said working tube sized, dimensioned and disposed to allow fluid communication between a surgical site and the lumen of the working tube.

46. A method of performing arthroscopic surgery, said method comprising the steps of:

providing a system for performing arthroscopic surgery, said system comprising:

an arthroscopic instrument suitable for performing an arthroscopic surgical procedure, said arthroscopic instrument characterized by a distal tip;

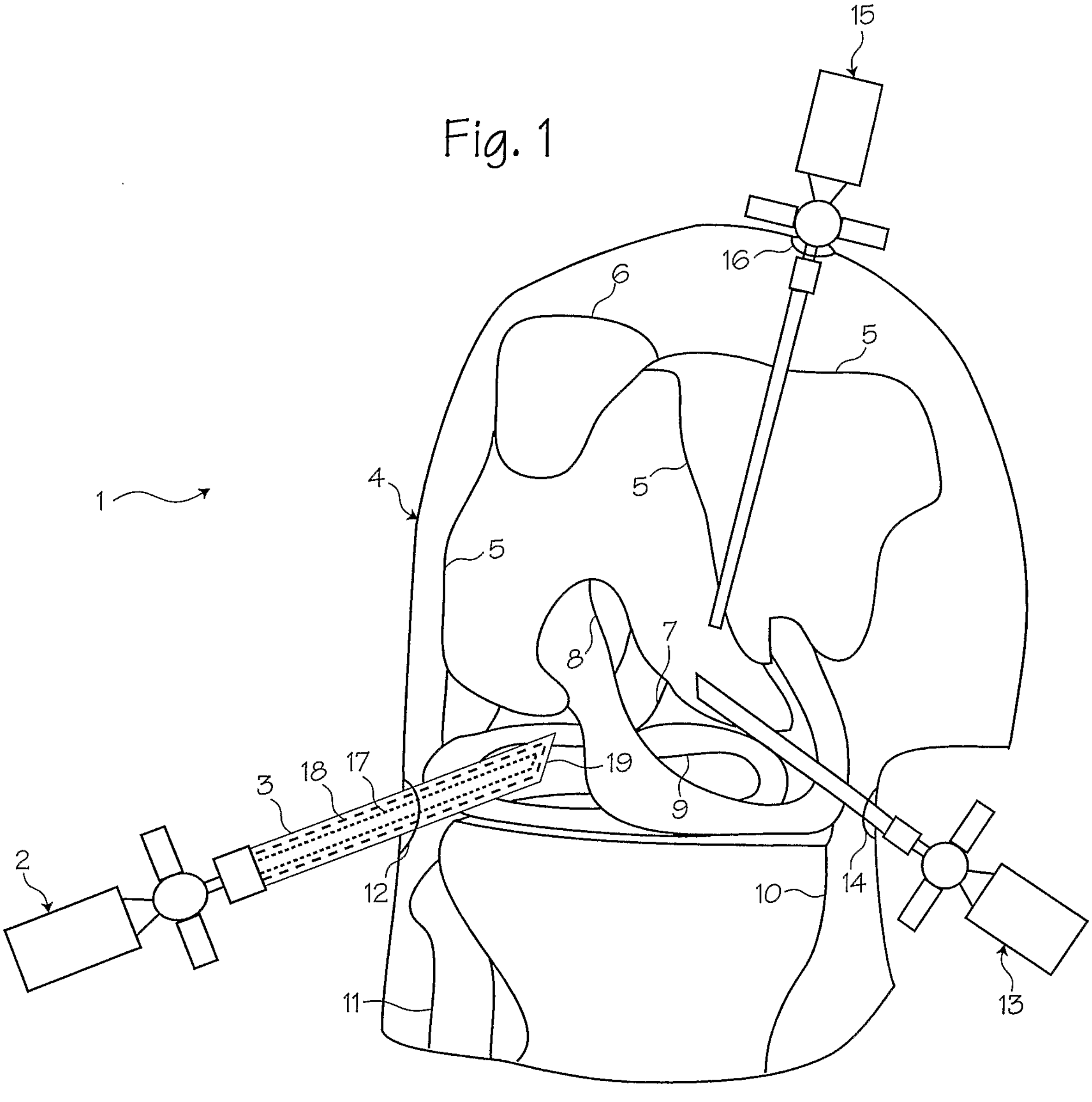
an atraumatic sheath comprising a tube of resilient material having a distal end, said sheath having an inner diameter sized and dimensioned to closely conform to an outer diameter of the arthroscopic instrument and said sheath having a flange disposed at the distal end of the sheath, wherein the flange is disposed, sized and dimensioned to prevent the distal tip of the arthroscope from extending distally from the sheath;

wherein the atraumatic sheath is adapted to be removably disposed over the arthroscopic instrument;

placing the arthroscopic instrument inside the sheath; and

performing an arthroscopic surgical procedure with the system for performing arthroscopic surgery.

Fig. 1



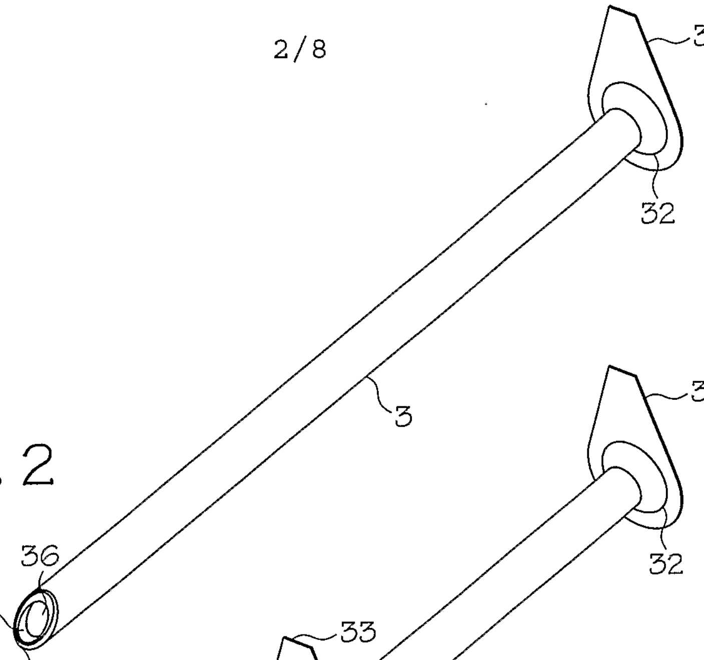


Fig. 2

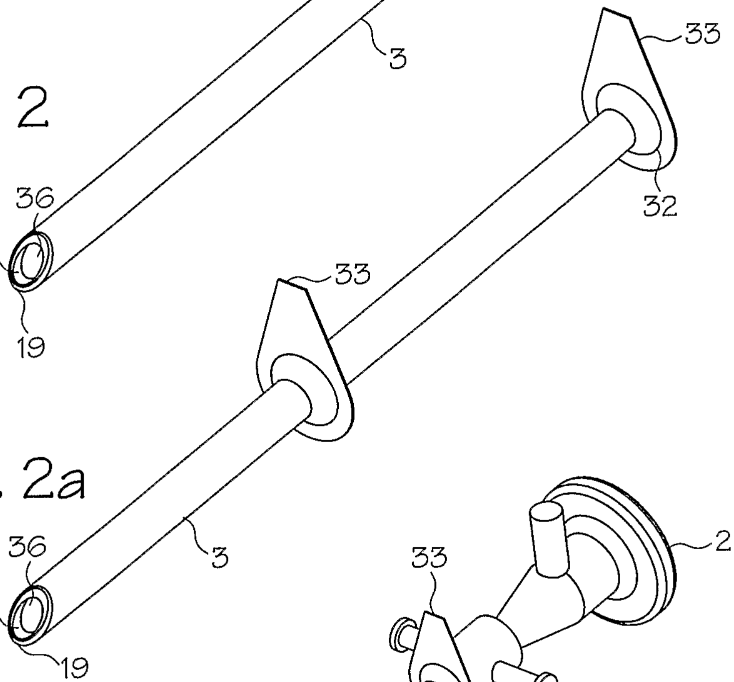


Fig. 2a

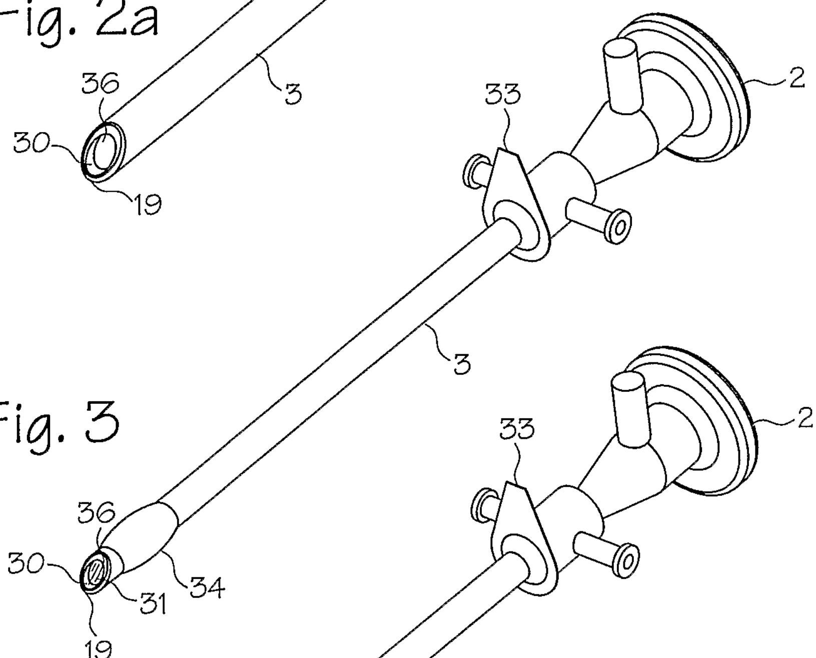


Fig. 3

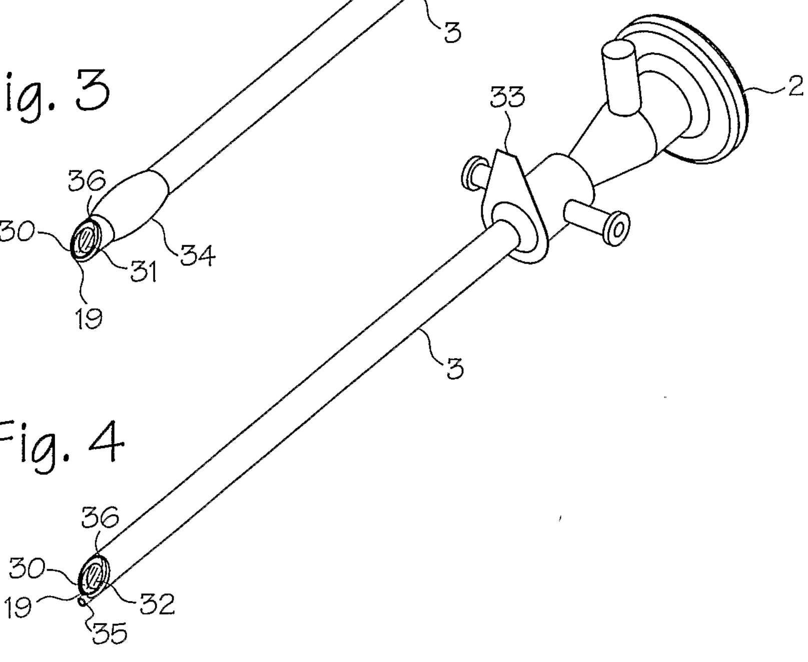


Fig. 4

Fig. 5

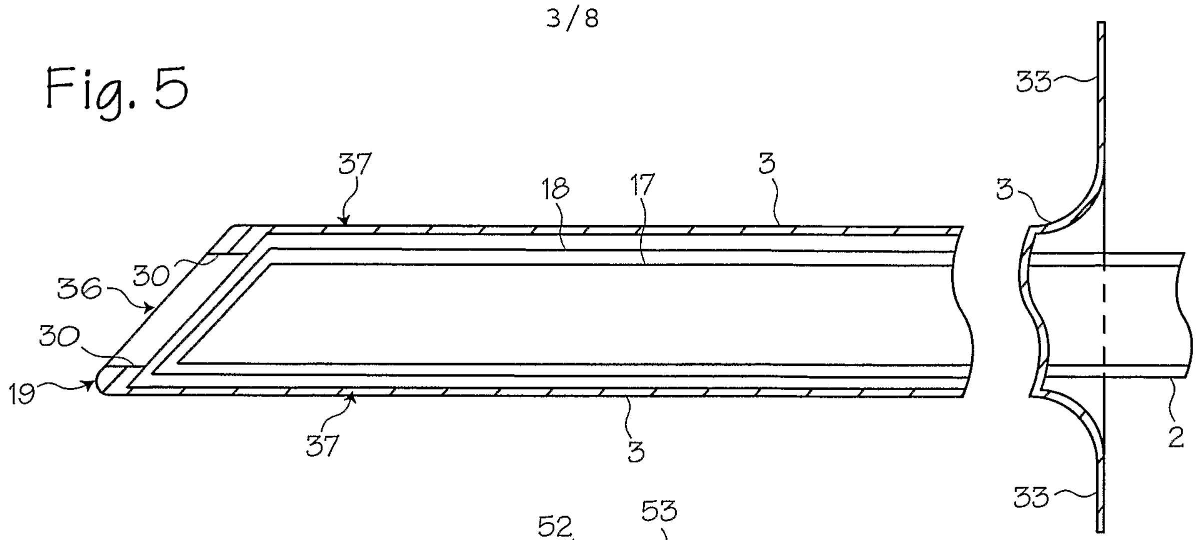

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Fig. 6

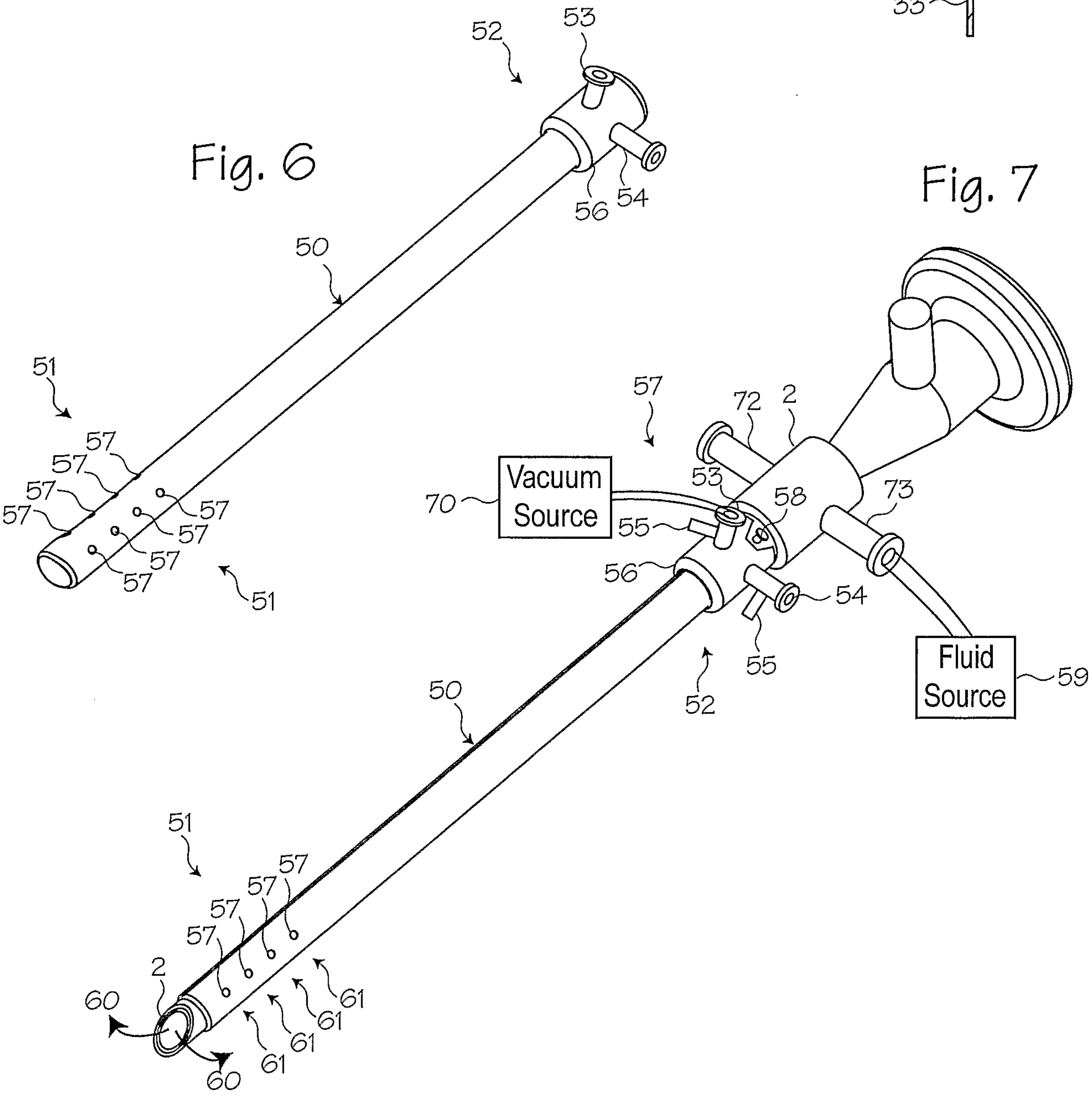
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Fig. 7
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Vacuum Source
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Fluid Source
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Fig. 8

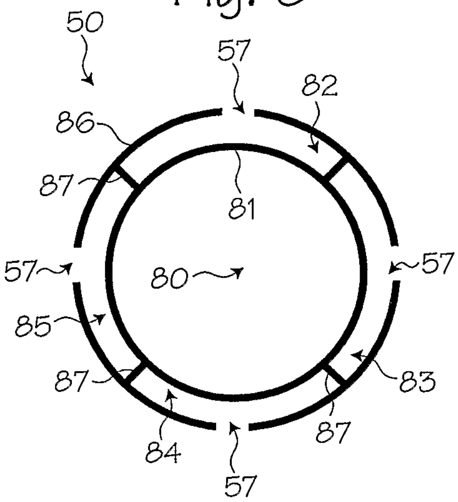

Fig. 9

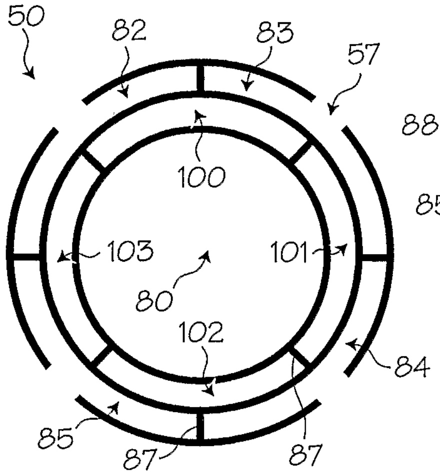

Fig. 10

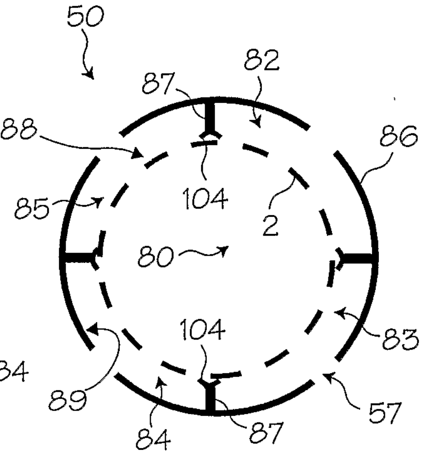

Fig. 11

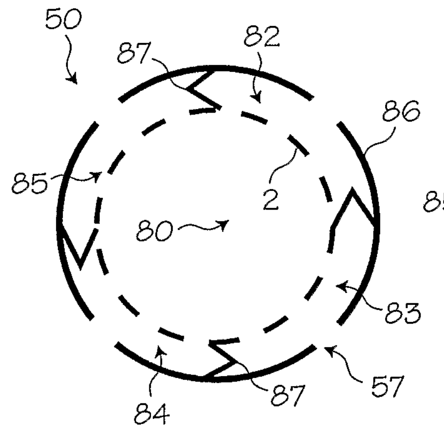

Fig. 13

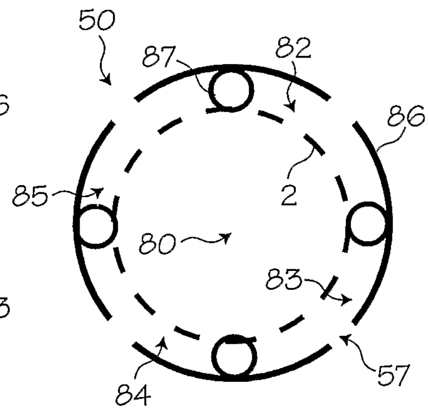

Fig. 15

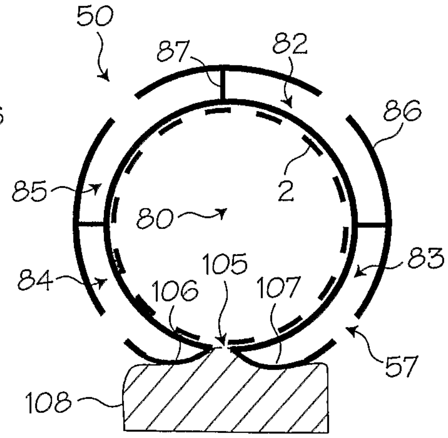

Fig. 12

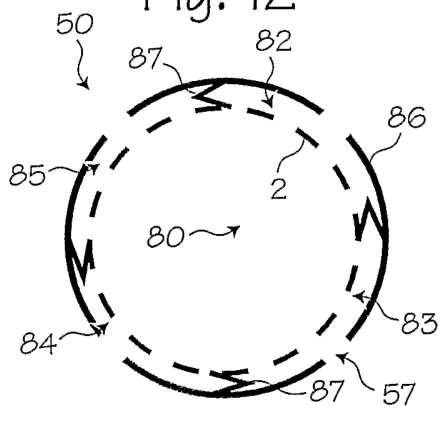

Fig. 14

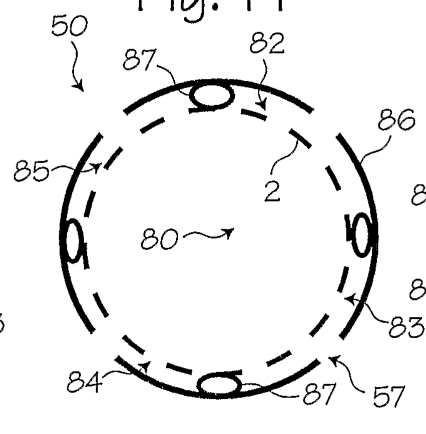

Fig. 16

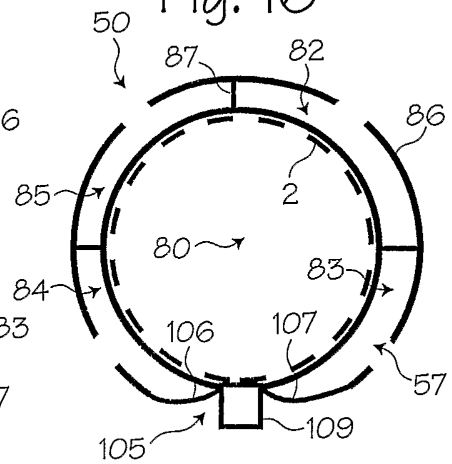

Fig. 17

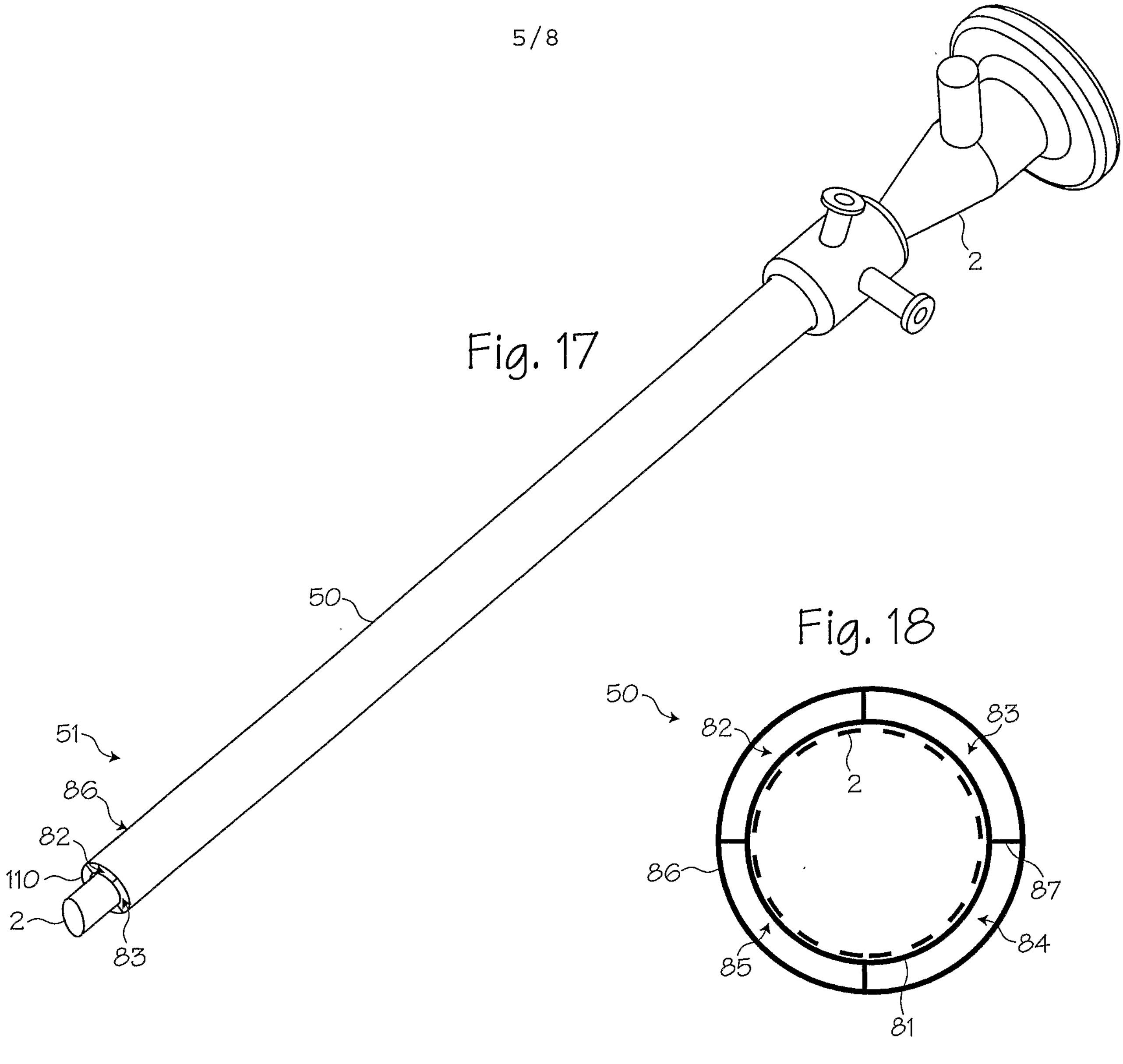
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Fig. 18
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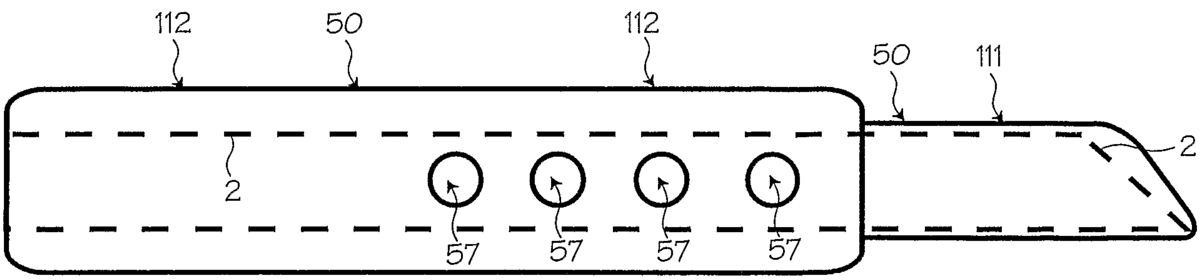
Fig. 19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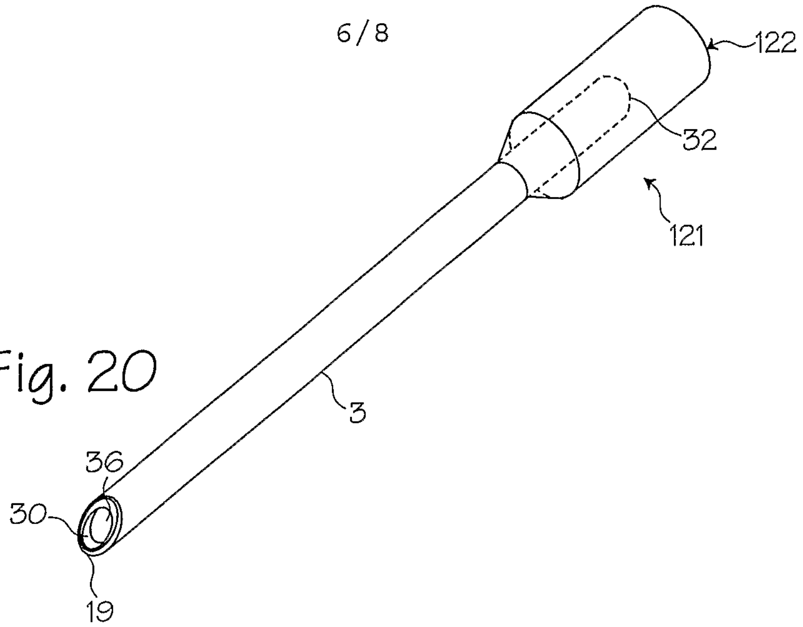


Fig. 20

Fig. 21

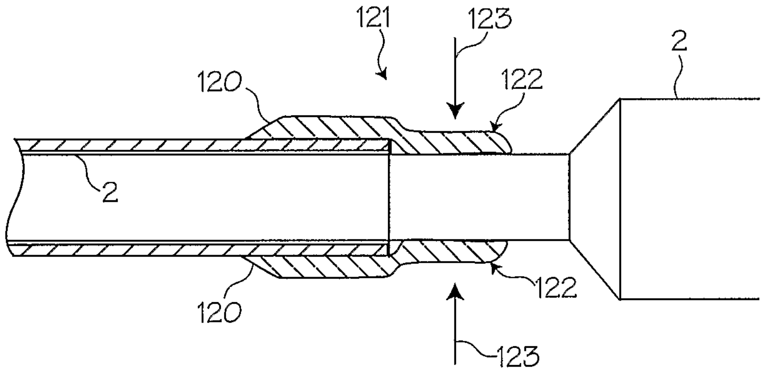


Fig. 22

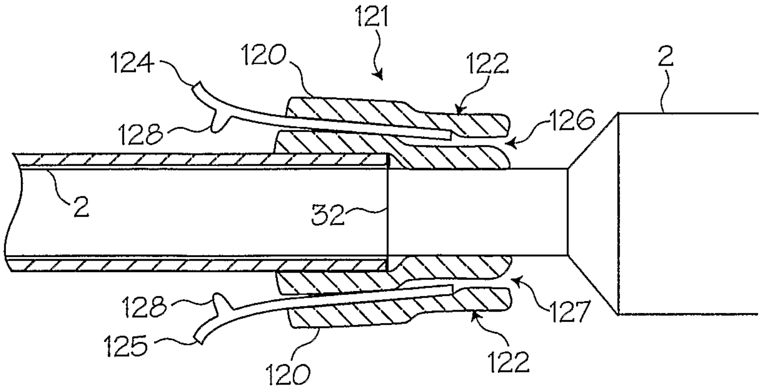


Fig. 23

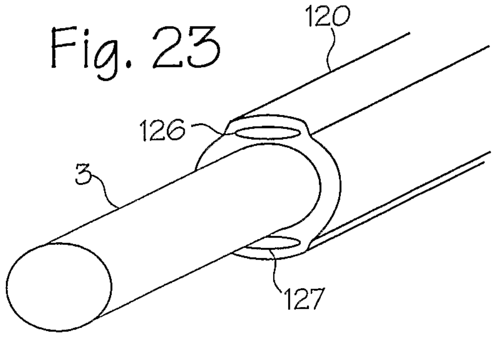


Fig. 24

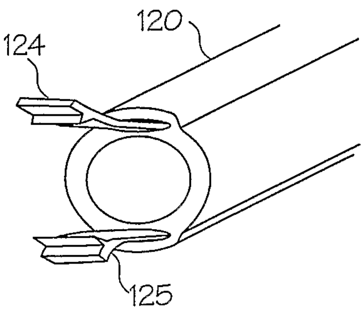


Fig. 25

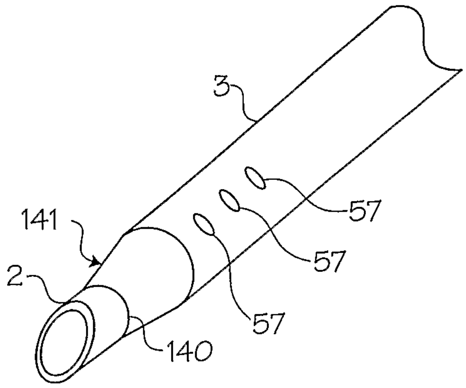
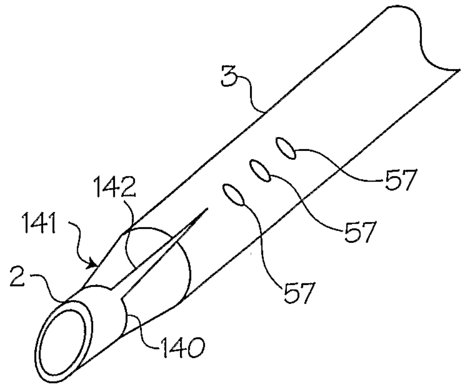


Fig. 26



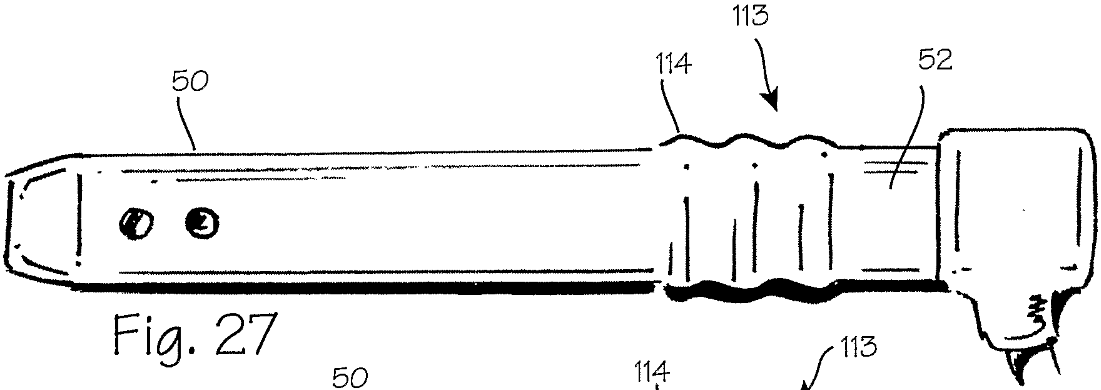


Fig. 27

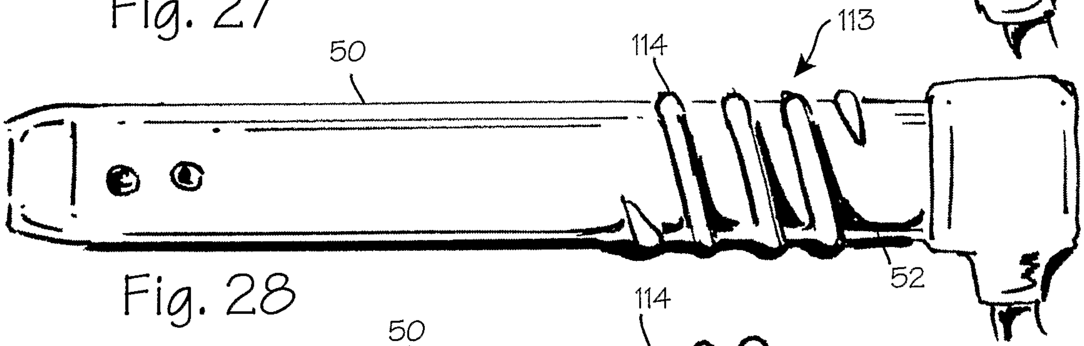


Fig. 28

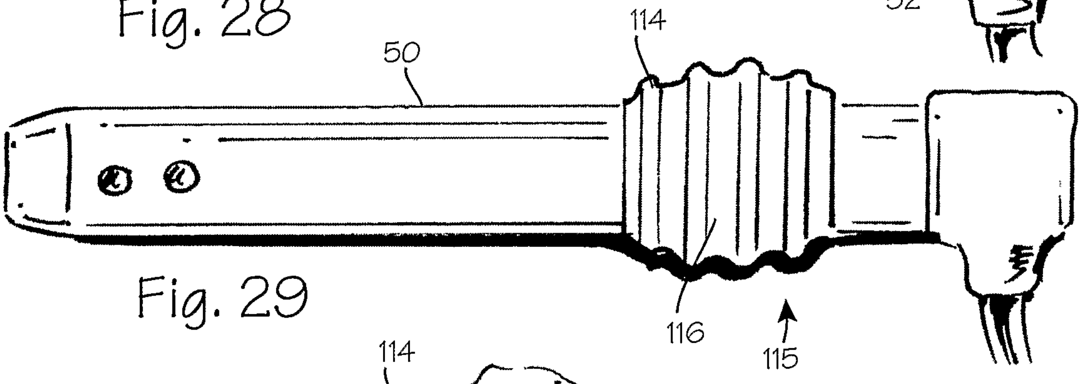


Fig. 29

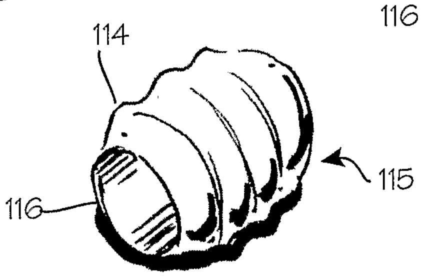


Fig. 30