

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
2 June 2005 (02.06.2005)

PCT

(10) International Publication Number
WO 2005/048827 A1

(51) International Patent Classification⁷: **A61B 1/307**, 1/07

(21) International Application Number:
PCT/US2004/012364

(22) International Filing Date: 22 April 2004 (22.04.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/464,602 22 April 2003 (22.04.2003) US

(71) Applicant and

(72) Inventor: **CAMPOS, Jorge, A.** [MX/US]; 1878 Coral
Way, Miami, FL 33145 (US).

(74) Agent: **TOBOR, Ben, D.**; Bracewell & Patterson, L.L.P.,
P.O. Box 61389, Houston, TX 77208-1389 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

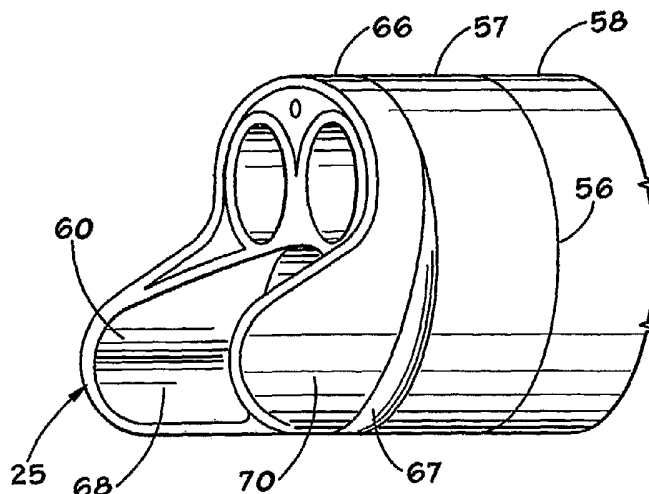
(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), Euro-
pean (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,
GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: SYSTEM, APPARATUS, AND METHOD FOR VIEWING A VISUALLY OBSCURED PORTION OF A CAVITY



(57) Abstract: A system, apparatus, and method for viewing a visually obscured portion of a body cavity. The system includes an endoscopic-type instrument (10), an imaging apparatus, and a human interface apparatus. The endoscopic-type instrument includes a face tip assembly (11) connected to a shaft assembly (12), the shaft assembly (12) being connected to a handle and viewing assembly (13). The face tip assembly (11) includes a plurality of input/output ports (21, 22, 23, 24) and a working channel extension (25) to protect an optical image collector. The shaft assembly includes an actively flexible shaft segment and a passively flexible shaft. The method for viewing a visually obscured portion of a cavity includes the steps of providing an instrument having an actively flexible shaft segment and manipulating the actively flexible shaft segment to a desired angular deflection.

WO 2005/048827 A1

SYSTEM, APPARATUS, AND METHOD FOR VIEWING A VISUALLY OBSCURED PORTION OF A CAVITY

BACKGROUND OF THE INVENTION

1. Related Applications

[0001] This application claims the benefit of U.S. Provisional Patent Application
10 Serial No. 60/464,602, filed April 22, 2003.

2. Field of the Invention

[0002] The invention relates to exploratory instruments and, more particularly, to
endoscopic type instruments.

3. Description of the Related Art

[0003] Endoscopic type instruments have been developed to allow physicians and
surgeons to view within a visually obscured portion of a body cavity. Physicians and
surgeons in particular use endoscopic type instruments in a body to perform certain
surgical procedures with limited trauma, disfiguration, expense, and hazards usually
20 associated with conventional types of surgery performed through relatively large
incisions.

[0004] Endoscopic type instruments may be constructed as rigid, semi-rigid, or
flexible. Before the 1980's, segments of the urinary system such as the urethra,
prostate and bladder were the anatomical areas that could only be examined and
operated upon using substantially rigid endoscopes and/or conventional surgical
procedure requiring large incisions. During the early 1980's, the introduction of new
slimmer and longer endoscopes presented the field of urology with a major revolution
by allowing the exploration of the ureter (the hollow tubular structure that leads the
urine from the kidney to the urinary bladder) and upper urinary system within the
30 kidney. These revolutionary instruments negated the need for a surgical procedure

requiring a large incision. These new devices were named ureteroscopes and nephroscopes. Thus, the era of minimally invasive surgery had begun. These instruments were particularly helpful in removing kidney stones. Also, the advent of Extracorporeal Shock Wave Lithotripsy (stone fragmentation from outside of the body) made it necessary to dislodge and remove stone fragments from the kidney using an endoscopic type device in the ureter. During this time, the endoscopes were substantially rigid and their diameters were rather large, which had several limitations when entering and exploring a soft and curved conduit, such as the ureter.

10 [0005] Subsequently and towards the end of the 1980's, the incorporation of fiber optics into endoscopes permitted the reduction of the instrument's diameter and rendered the instrument's shaft some flexibility, thus overcoming "some" of the limitations of rigid endoscopes. This new generation of instruments were named "semi-rigid" miniscopes and made rigid scopes obsolete for most surgical procedures in the ureter and upper urinary tract, with the exception of percutaneous procedures in which rigid scopes are still used. These endoscopic type instruments, however, had many design and functionality limitations that do not facilitate diagnosis and surgery of body cavities, such as those in the upper urinary system. For example, rigid and semi-rigid endoscopes could not explore the upper urinary system within the kidney, thus, there was a risk of missing some pathology during diagnosis that might not be
20 apparent by other imaging techniques such as x-rays, MRI, and CT scans, etc. Also, rigid and semi-rigid endoscopes were further inherently limited when performing surgical procedures that require flexibility.

[0006] By the end of the 1980's, "flexible" endoscopes were created to provide an opportunity to examine and operate on the upper urinary system. Currently, the semi-rigid and flexible endoscopes are the devices most commonly utilized for the ureter and upper urinary tract. The advantages of the flexible endoscopes are adaptability and finesse, or control of the device. The rigid, or even the semi-rigid, endoscopes do not permit exploration and intervention of the upper urinary tract within the kidney due to their inherent lack of adaptability and flexibility. For example, use of a rigid
30 endoscope required penetration of the kidney during examination, or if entrance through the natural channels, then excessive rotation and maneuvering of the device is required, whereas the flexible endoscope has the versatility to maneuver through the

urinary tract and directly into the kidney. Specifically, the rigid and semi-rigid endoscopes cannot properly explore the upper urinary system within the kidney; thus a diagnosis might be missed. Use of nonflexible endoscopes requires the surgeon to rotate the instrument to negotiate the passageways. The rigid and semi-rigid endoscopes are typically made of a hard material that can injure or lacerate the urinary system, if not used properly, especially during the rotating maneuver. Therefore, examination within the natural anatomical curves of the urinary system ideally requires use of flexible instruments that can adapt and maneuver through, and to, the ureter passage instead of forcing the ureter passage to adapt to the shape of the instrument.

[0007] Flexible endoscopes, however, are typically very difficult to use since their flexibility makes insertion of the instrument difficult, and proper use in such anatomical sections such as the upper urinary system is beyond the typical user's experience level. Most urologists do not have the skill, sensitivity, dexterity, or expertise to operate with fully flexible endoscopes. Fully flexible endoscopic type instruments are difficult to insert due to their lower consistency and firmness because they are typically made from a soft plastic, or polymer like material formed around the fiber optics, which material bends easily. Also, in addition to where the insertion end of the instrument bends, the flexible instruments are easily breakable at the union of the handle area and the instrument's shaft. The instrument's excessive flexibility makes handling difficult and often results in the need for an extra pair of trained hands, such as those of a nurse or physician, for its introduction. Because of its difficulty of use, most urologists prefer the rigid or semi-rigid endoscopes in spite of their limitations. Therefore, urologists have sought an endoscopic type instrument that: is surgically friendly; has reduced difficulty of use; should increase the probability of success, while minimizing the risks during surgery. Therefore, the art has also sought a new generation of endoscopes that will improve and facilitate surgery upon the urinary system (including the upper urinary tract within the kidney, bladder, prostate and urethra) and minimize the risk of laceration and injury during surgical procedures. More specifically, the art has sought an instrument design that: can facilitate the insertion of the instrument into, and through, a delicate non-linear cavity such as a urinary tract; facilitate the exploration of the upper urinary tract in

order to diagnose and surgically intervene anywhere in the urinary system; provides stability to avoid breakage during the procedure; provides easier mobility within the upper urinary system; and facilitates the introduction of different accessories with more precision.

[0008] The design and elements of a traditional face tip of an endoscopic type instrument, either rigid, semi-rigid or flexible, has changed very little since the first one was introduced. Basically they all include one or more of the following input/output ports: a working channel port to introduce operating accessories to perform a procedure; an optical image collector-conductor port, for example, a telescope port for viewing; a luminous conductor port, for example, an illumination fiberoptics port; and sometimes an irrigation & suction channel port. It is believed that with conventional endoscopes, the accessories are introduced before they can actually be observed within the urinary system. The conventional operating accessories exit port is located behind the optics created a "blind spot"; thus they enter the urinary system before the surgeon has visual control. In the medical setting, the exit of the accessories on the instrument's side is typically very close to the urinary tract wall. The surgeon's lack of view of the natural curves of the ureter, caused by the blind spot, can produce an inadvertent tear or perforation of the ureteral wall. Also, by exiting the operating tools on the side of the instrument, it obligates the surgeon to rotate the instrument in order to appropriately target the lesion, or the foreign body, to achieve the purpose of the exploration or the intervention. This maneuver, or "frequent rotation" may increase the risk of perforation and/or the inherent trauma by the instrument's insertion or pressure creating inflammation of the structures under exploration. Therefore, the art has sought an endoscopic type instrument wherein the working tool or accessories exit at the face tip, coincident with or in front of the viewing device to reduce the risk of laceration by allowing the surgeon to view the instrumental accessories as they exit either in front of the optics, lenses, or from the midsection of the instrument face tip

[0009] Endoscopic type instruments have typically ranged in complexity from simple viewing scopes which employ a light source and an ocular system, to relatively complex instruments having a light source, an image collection system, fluid channels, and a surgical or working tool channel. The required features employed in

an endoscopic type instrument are determined in part by the requirements of the type of examination or surgery in which the instrument is used.

[0010] The light source for illuminating the site of interest is usually positioned outside the cavity. The light is communicated through the instrument by an illumination, or light conductor, usually formed of a fiber optic bundle. It is conceivable that the light conductor could be separate from the instrument itself. This would allow for use of an endoscope with a reduced diameter or would allow additional functions in a scope of a given diameter. No matter what additional use endoscopic type instruments have been put to, their examination properties remain their staple use. Conventional lenses for image collection and transmission generally require that the instrument be rigid or semi-rigid. Flexible endoscopic type instruments typically employ coherent optical fiber bundles wherein the opposite ends of the fibers are identically ordered. The image quality of lens based image collection and transmission is generally superior to image collection and transmission formed of fiber optics or fiber optics alone.

[0011] Endoscopic type instruments may be constructed to have fluid channels which may serve a variety of different purposes. For example, in certain procedures on the lungs, the fluid channel provides an air passage to allow the lung to breathe. In other procedures, the fluid channel may be used to insufflate, or inflate, a cavity in the body for better access to obtain a better view. In other procedures, a supply of cleansing fluid, such as water, may be used to clear away undesirable contaminant fluid, such as blood, from a location to facilitate inspection or to clean the image collector. A suction line is often used for removing fluids from the site. A working tool channel provides for the insertion of various working implements, or accessories, through the instrument such as forceps, scissors, punches, electrodes, lasers, and the like.

[0012] An endoscopic type instrument may include a typically tubular shaped shaft connected to a handle and viewing assembly which typically provide a mechanical coupling to which a viewing apparatus is connected. The typical endoscopic type instrument may include fluid channels extending through the shaft which communicate with external fluid connections on the handle and the assembly. A working tool port on the handle and viewing assembly typically communicates with a

working tool channel in the shaft and may include a clamp or other support device to hold the working tool in place. An illumination port typically communicates with a light source. The light is normally transmitted from the viewing end or proximal end of the instrument to a light directing lens, or lenses, at the distal end. An optical collector including an objective lens is positioned at the distal end and passes the image through the image conductor to the handle and viewing apparatus through which the operator views the section of the cavity of interest. The objective lens, if used, is typically fixed and may be oriented along the longitudinal axis of the shaft or be angled off-axis for a view to the side. Some endoscopic type instruments have a fixed combination of functions, while others may be adapted to allow a selection of functions from a variety of working tools and viewing methodologies.

[0013] The handle and viewing apparatus of endoscopic type instruments usually accommodate various adapters for connecting various types of video, or other imaging, devices. In some cases, an image multiplexer is utilized to separate the image for simultaneous display on an optical viewer used for direct viewing and a video imager to televise or record the procedure.

[0014] An endoscopic type instrument having only a single optical collector-optical conductor or single telescope, alone, creates only a two-dimensional, or monoscopic, view of the region under inspection. This often results in a lack of depth perception for the user of the instrument, making it difficult to perform an accurate inspection or surgery. Three dimensional, or 3-D, viewing would allow for more precise viewing when maneuvering inside such anatomical features as the urinary tract, and would allow for better identification and perception of dimensions and distances from the instrument tip to the object in question, especially where the instrument is being used in a cavity containing a fluid. Although, three-dimensional, or stereoscopic, laproscopic type instruments, such as steromicroscopes, have been developed for creating a three-dimensional view of the object or region under inspection these are not suited for use in endoscopies. These instruments are provided with a pair of optical pathways or channels for transmitting a plurality of simultaneously gathered images of the object of interest to a stereoscopic viewer. Traditionally, the stereoscopic viewer has had microscope-like eyepieces through which the viewer views the respective images. The eyepieces are arranged so that the

viewer's eyes provide the necessary convergence to combine the images into a stereoscopic view. Convergence of right eye and left eye images of an object is done in normal stereopsis by converging the optical axes with the eyes or optical/mechanical means to accomplish convergence of the right and left images so that the brain receives and perceives the images as sufficiently close together for the brain to combine the images as a single three-dimensional image. The stereomicroscope is an example of such an optical/mechanical device. Although the human brain can converge and "fuse" two separate views if the separation between the images is not too great, this is not easy or comfortable to achieve in practice. In
10 typical stereo-microscopes, the problem is solved by using two converging optical systems. However, this is not a practical solution in endoscopic type systems where the necessary convergence at very short focal lengths is compounded by the need to keep the overall diameter of the system as small as possible so that the endoscope tube can be inserted through a single minimum size surgical incision, minimizing invasive procedures. Also, traditionally, where a video viewing system is used, the two parallel optical systems used in such arrangements do not converge the images and provide two separate images or video pictures.

[0015] Accordingly, prior to the development of the present invention, it is believed that there has been no endoscopic type instrument which: has the versatility
20 of a flexible endoscope, while retaining the controllability of a semi-rigid or rigid endoscope; has an instrument shaft which is both rigid for a portion of its length and flexible for a portion of its length; which avoids, or reduces, the necessity for rotation of the instrument when targeting is required and while working inside delicate cavities; provides three dimensional imaging; does not have a blind spot associated with the instrument when working tools or accessories exit the instrument. Therefore, the art has sought an endoscopic instrument, or endoscope, which has the versatility of a flexible endoscope, while retaining the controllability of a semi-rigid or rigid endoscope; has an instrument shaft which has a rigid portion and a flexible portion; prevents, or reduces, the necessity for rotation of the instrument when
30 targeting is required and while working inside delicate cavities; provides three dimensional imaging in the viewing system; and does not have a blind spot at the point where the working tools or accessories exit the instrument.

SUMMARY OF THE INVENTION

- [0016] In accordance with the invention the foregoing advantages have been believed to be achieved through the endoscope, endoscope system, and method for viewing a portion of a body cavity of the present invention. The endoscope system of the present invention for viewing a visually obscured portion of a body cavity may include: an endoscope have a face tip assembly, having a plurality of input/output ports, associated with a shaft assembly, the shaft assembly being associated with a handle and viewing assembly; the shaft assembly including a shaft having a distal end
10 and an actively flexible shaft segment disposed at the distal end of the shaft for insertion into the cavity; a least one optical image collector adapted to gather an image from within the body cavity; at least one optical conductor, associated with the at least one optical image collector, and adapted to transmit the image to the handle and viewing assembly; at least one luminous conductor adapted to provide illumination to the body cavity; at least one working channel disposed within the shaft assembly adapted to permit a working instrument entry into the body cavity; and an imaging apparatus, associated with the at least one optical conductor, and adapted to capture the image to send it to a human interface apparatus adapted to permit viewing of the image.
- 20 [0017] Another feature of this aspect of the invention is that the endoscope system may include a working channel extension, associated with the face tip assembly, which includes at least one protrusion adapted to guide the working instrument and to prevent impact of foreign matter located within the body cavity upon the at least one optical collector. An additional feature of this aspect of the present invention is that there may be two optical conductors for producing a three-dimensional image. A further feature of this aspect of the present invention is that the actively flexible shaft segment may be disposed adjacent a passively flexible shaft segment. An additional feature is that the passively flexible shaft segment may be disposed adjacent a semi-rigid shaft segment.
- 30 [0018] In accordance with the invention, the foregoing advantages have also been achieved through the present endoscope for viewing a portion of a body cavity. This aspect of the present invention may include: a face tip assembly, have a plurality of

input/output ports, associated with a shaft assembly, the shaft assembly being associated with a handle and viewing assembly; the shaft assembly may include a longitudinal axis, a shaft having a distal end and an actively flexible shaft segment disposed at the distal end of the shaft for insertion into the body cavity; at least one optical image collector adapted to gather an image from within the body cavity; at least one optical conductor, associated with the at least one optical image collector, and adapted to transmit the image to the handle and viewing assembly; at least one luminous conductor adapted to provide illumination to the body cavity; and at least one working channel disposed within the shaft assembly and adapted to permit a
10 working instrument entry into the body cavity.

[0019] An additional feature of this aspect of the present invention is that the endoscope may include a working channel extension associated with the face tip assembly, which includes at least one protrusion to guide the working instrument and to prevent impact of foreign matter upon the at least one optical image collector. A further feature of this aspect of the present invention is that the shaft assembly may have a longitudinal axis and the at least one optical image collector may lie in a first plane which is disposed substantially perpendicular to the longitudinal axis of the shaft assembly; and the at least one protrusion is disposed at the distal end of the shaft forward of the first plane in which the at least one optical image collector lies,
20 whereby the at least one optical image collector may view an operating tool passing forwardly beyond the at least one protrusion.

[0020] Another feature of this aspect of the present invention is that the plurality of input/output ports may include at least one operating tool port, and the operating tool port lies in a second plane which is disposed substantially parallel with the first plane in which the at least one optical collector lies. The first plane and the second plane may be substantially coplanar or the second plane be disposed in a spaced relationship from the first plane, toward the distal end of the shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

30 [0021] While some of the features, advantages, and benefits of the present invention, having been stated, others will become apparent as the description proceeds when taken in conjunction with the accompanying drawings in which:

- [0022] FIG. 1 is a side view of an endoscope, such as a ureterscope, in accordance with the present invention;
- [0023] FIG. 2 is a front view of a face tip assembly for use with the endoscope of FIG. 1;
- [0024] FIG. 3 is a side view of the face tip assembly of FIG. 2;
- [0025] FIG. 4 is a perspective view of the face tip assembly of FIGS. 2 and 3;
- [0026] FIG. 5 is a front view of another embodiment of a face tip assembly for use with the endoscope of FIG. 1;
- [0027] FIG. 6 is a side view of the face tip assembly of FIG. 5;
- 10 [0028] FIG. 7 is a front view of another embodiment of a face tip assembly for use with the endoscope of FIG. 1;
- [0029] FIG. 8 is a front view of another embodiment of a face tip assembly for use with the endoscope of FIG. 1;
- [0030] FIG. 9 is a partial cross-sectional view of the endoscope of FIG. 1, taken along line 9-9 in FIG. 1;
- [0031] FIG. 10 is a partial cross-sectional view of the endoscope of FIG. 1, taken along line 10-10 in FIG. 1; and
- [0032] FIG. 11 is a schematic diagram of a system for viewing a visually obscured portion of a cavity.
- 20 [0033] While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0034] The present invention will now be described more fully hereinafter with reference to the accompanying drawings which illustrate embodiments of the invention. This invention may, however, be embodied in many different forms and should not be construed as limited to the illustrated embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like reference numbers refer to like elements throughout, and the prime notation, if
10 used, indicates similar elements in alternative embodiments. The preferred embodiment of the present invention implements an endoscopic type instrument, or endoscope, which may be in the form of a ureteroscope.

[0035] Referring now to the drawings, a first embodiment of the present invention in the form of a ureteroscope **10** is illustrated in **FIGS. 1-4**. This ureteroscope **10** is only one of many variations of endoscopes, or endoscopic type instruments, that can be produced using the teachings of the present invention. The preferred embodiment of a ureteroscope **10** of the present invention generally comprises: a face tip assembly **11** connected to a shaft, or shaft assembly **12**, the shaft assembly **12** being connected to, or associated with, a handle and viewing assembly **13**. In conjunction with the face
20 tip assembly **11**, the shaft assembly **12** provides for a reduced risk of laceration of a cavity by allowing the use, or viewing, of conventional, instrument accessories, or "operating tools" (not shown), by providing a tool exit, or port **21**, in front of an optical image collector **61**, **FIGS. 2** and **5**, or an exit, or port **21'**, in the center of the face tip assembly **11**, **FIG. 7**. The shaft assembly **12** also: provides for simultaneous usage of both the viewing apparatus and an operating tool; facilitates exploration in such cavities as the upper urinary tract; and avoids the necessity for excessive rotation of instruments when targeting, or viewing, is required while working inside such sensitive cavities such as the ureter.

[0036] Referring now to **FIGS. 2-4**, an embodiment of face tip assembly **11**
30 includes a plurality of input/output ports. The ports may include: an operating tool port, or tool exit, **21** where conventional operating accessories (not shown) may exit and are introduced; at least one optical image channel port **22**, and at least one

luminous channel port 23. The face tip assembly 11 may also include at least one fluid and/or suction channel port 24. The face tip assembly 11 also includes at least one optical image collector 61 interfaced with the at least one optical image channel port 22 of face tip assembly 11, for gathering an image from within the interior body cavity. The type of optical image collector 61 corresponds with the type of optical conductor 62 utilized in ureteroscope 10. For example, selection of an optical waveguide to implement the optical conductor 62 may result in the requirement for a lens, or prism, as an optical image collector 61. If the means for implementing the optical conductor 62 utilized is fiber optics, such as a fiber optics bundle or array, the face of the fiber-optics array may, in turn, be the only means required to collect the optical image for transmission through the optical conductor 62 through to the handle and viewing assembly 13, albeit, with reduced visual acuity. The face tip assembly design, of FIGS. 2-4, as well as other designs hereinafter described, provide the mobility to access the upper urinary system within the kidney and incorporate improved visibility so as to avoid the "blind spot" inherent in many systems comprising the state-of-the-art.

[0037] A preferred embodiment of the face tip assembly 11 is best shown in FIGS. 2-4, as a three-dimensional viewing face tip design. In this embodiment, the face tip assembly 11 is a separate unit associated with, or connected to, the distal end 32 of a first flexible shaft segment 31 of shaft assembly 12. In this embodiment, where the distal end 32 has a substantially circular cross-sectional shape, the face tip assembly 11 is "face shaped", or appears as having two eyes and a mouth, as shown in FIG. 2. The face tip assembly 11 includes a plurality of optical image collectors 61, which, in this embodiment take the form of a pair of lenses 55 which provide for a three-dimensional view. The lenses 55 are preferably positioned in a plane P disposed substantially perpendicular to the longitudinal L axis of shaft segment 31 and shaft assembly 12 and face assembly 11 (as shown in FIG. 3). Plane P may also be considered to be disposed substantially parallel to the interface 56 between face tip assembly 11 and the distal end 32 of flexible segment 31 of shaft assembly 12. As illustrated, the two lenses are preferably spaced upwardly of the longitudinal axis L. In this embodiment, face tip assembly 11 also includes an operating tool port 21 which is preferably offset from the center of the face tip assembly 11, or longitudinal

axis L, away from the lenses 55, toward the outer perimeter 57, of face tip assembly 11. In this embodiment, the face tip assembly's 11 outer perimeter 57 may be partially congruent with the outer perimeter 58 of the distal end 32 of the first flexible shaft segment 31. In this embodiment, luminous conductors 63 for light conduction and illumination, in the form of a fiber optics bundle, array, or a single fiber optic strand is located in a portion of the spaces between the lenses 55 and operating tool port 21, as shown in FIG. 2.

[0038] As shown in FIGS. 3 and 4, face tip assembly 11 may have a working channel port extension 25 which may be in the form of at least one protrusion 65
10 which functions as an operating tool guide that tends to restrict movement of the operating tool to movement generally along longitudinal axis L. As an operating tool (not shown) exits from operating tool, or tool, port 21, the protrusion 65 may act as a guide to prevent the operating tool from moving outwardly toward the adjacent wall surface of an adjacent body passageway (not shown) until after the end of tool is visible to the operator via lenses 55. Additionally, protrusion 65 provides protection of the lenses 55 from impact with particulate matter (stone fragments, etc.). The protrusion 65 may be formed integrally as a unitary structure with the outer perimeter 57 of face tip assembly 11. The protrusion 65 may have two spaced apart peaks 60, 70
20 extending forwardly toward a distal end of the face tip assembly and from a smooth rounded outer distal surface 66. The peaks 60, 70 may preferably be disposed adjacent each side of the tool port 21, as shown in FIGS. 2-4. In this embodiment, where the protrusion 65 is formed as a unitary structure, the protrusion 65 has a concave proximal deflection 67 adjacent outer perimeter 57 in a spaced relationship from interface 56. Alternatively, the working channel port extension 25 may be a separate structure connected to the front of face tip assembly 11. Although the working channel port extension 25 shown in FIGS. 3-4 is a unitary structure with a smooth rounded outer distal surface 66 and a smooth inner surface 68 smoothly contoured and tapering toward operating tool port 21, one of ordinary skill in the art would understand there are many variations of positioning the working channel port
30 extension 25 within the spirit and scope of the present invention. Preferably, as shown in FIGS. 3, 4, and 6, the peaks 60, 70 are disposed offset from the center of the

face tip assemblies **11**, **11'**, or longitudinal axis **L**, and are disposed with a substantial portion of peaks **60**, **70** disposed below longitudinal axis **L**.

[0039] Additionally, although the operating tool port **21**, lenses **55**, and the distal end **32** of first flexible segment **31** are depicted as having generally, circular cross-sectional configurations for the preferred embodiment, it is important to note that in variations of this embodiment, other geometric shapes as known by those of ordinary skill in the art, are within the spirit of the disclosure, such as elliptical, oval, or other shapes. Also, still within the spirit of the preferred embodiment, the distal end **32** of first flexible segment **31** may have a smaller circumference, or diameter, than the main shaft body **34** of first flexible shaft segment **31**, whereby the outer perimeter **57** of face tip assembly **11** may be at least partially received around, and connected to, the smaller outer circumference of distal end **32**. Still referring to **FIGS. 2-4**, face tip assembly **11**, may include variations in the shape of outer perimeter **57**, variations in the positioning, or location, of lenses **55**, operating tool port **21**, and optical conductor **62**. Additionally, in other embodiments of the face tip assembly **11** structure depicted in **FIGS. 2-4**, the optical image collector **61** may be in another form such as prisms or a substantially flush bundle of fiber optics or other methodologies as known by those of ordinary skill in the art. The optical conductor **62** and luminous conductors **63** may also be in any acceptable form as known by those of ordinary skill in the art that can perform substantially the same function as fiber optics.

[0040] Referring now to **FIGS. 5-6**, a monoptic face-tip assembly embodiment is illustrated. In this face tip assembly **11'**, the general shape of the outer circumference **57** and protrusion **65** are substantially similar to those described in connection with **FIGS. 2-4**. In this embodiment, the face tip assembly **11'** is a separate unit connected to the distal end **32** of first flexible shaft segment **31**. In this embodiment, when the distal end **32** has a substantially circular cross-sectional configuration, the face tip assembly **11'** may have a corresponding generally, circular cross-sectional configuration shown in **FIG. 5**. The face tip assembly **11** includes a single optical image collector **61**, which, in this embodiment takes the form of a single lens **55** which provides for a view to help those users with difficulty in adapting to three-dimensional viewing. The lens **55** is positioned, or disposed, on plane **P** and spaced from longitudinal axis **L**, and offset toward the outer perimeter **57**. In this

embodiment, the face tip assembly 11' also includes an operating tool port 21 which is offset from the center, or longitudinal axis L, of the face tip assembly 11', away from the lens 55, toward the outer perimeter 57 opposite that of lens 55. In this embodiment, outer perimeter 57 of face top assembly 11', is partially congruent with the outer perimeter 58 of the distal end 32 of the first flexible segment 31. Luminous conductors 63 for light conduction and illumination in the form of fiber optics may be located on opposite sides of the lens 55. In this embodiment, face tip assembly 11' also has a working channel port extension 25 in the form of the protrusion 65, previously described, which may function as an operating tool guide as previously described, and provides protection of the lens 55 from impact with particulate matter (stone fragments, etc.). In this embodiment, the protrusion 65 is again formed integrally as a unitary structure with the outer perimeter 57 of face tip assembly 11'. The protrusion 65 has two peaks 69, 70, formed by smooth rounded outer distal surface 66. In this embodiment, when the protrusion 65 is formed of a unitary structure, the protrusion 65 also may have a concave proximal deflection 67, spaced from interface 56. The working channel port extension 25 may be a separate structure connected to the front of face tip assembly 11'.

[0041] Although the working channel port extension 25 is shown in FIGS. 5-6 as a unitary structure extending forwardly from a smooth rounded outer distal surface 66 and a smooth inner surface 68 smoothly contoured and tapering toward operating tool port 21. One of ordinary skill in the art would understand there are many variations of positioning the working channel port extension 25 within the spirit of the disclosure. Additionally, although the operating tool port 21, lens 55, and the distal end 32 of first flexible shaft segment 31 are depicted as having generally circular shapes for this embodiment, in variations of this embodiment, other geometric designs, or shapes, as known by those of ordinary skill in the art, are within the scope of the present invention. Again, the distal end 32 of first flexible segment 31 may have a smaller circumference than the main shaft body 34 of first flexible shaft segment 31, whereby the outer perimeter 57 of face tip assembly 11 may be at least partially received around, and connected to the smaller outer circumference of distal end 32. Still referring to FIGS. 5-6, there may be variations in the shape of outer perimeter 57, variations in the positioning of lens 55, operating tool port 21, and

optical conductors 62. Again, the optical image collector 61 may be in another form such as prisms or a substantially flush bundle of fiber optics or other methodologies as known by those of ordinary skill in the art. The optical conductor 62 and luminous conductors 63 may also be in any acceptable form as known by those of ordinary skill in the art that can perform substantially the same function as fiber optics. The protrusion 65 in the embodiments discussed regarding FIGS. 2-4 and FIGS. 5-6 may be in more of a form similar to a semicircular hollow cylinder of a more equal distal height as opposed to a form similar to peaks and valleys as described above, as well as may have the other shapes which provide the desired tool guiding functions.

10 [0042] With reference to FIG. 7, an alternative three-dimensional viewing face-tip assembly 11" is shown. The face tip assembly 11", generally has the shape of the face of face tip assemblies 11 and 11', but is generally flatter in appearance, and lacks substantial protrusions 65. In other words, the front face 78 of face tip assembly 11" generally lies in a plane substantially parallel with plane P previously described. The face tip assembly 11" may also include a generally elliptical shaped operating tool port 21' which is substantially centered between the lenses 55. Disposed on either side of port 21' plurality of optical image collectors 61, which, in this embodiment may take the form of a pair of lenses 55 which provide for a three-dimensional view. The lenses 55 are generally positioned on a plane substantially parallel with plane P
20 previously described.

[0043] Still with reference to FIG. 7, the outer perimeter 57 of face tip assembly 11" is generally congruent with the outer perimeter 58 of the distal end 32 of the first flexible shaft segment 31. In this embodiment, luminous conductors 63 for light conduction and illumination in the form of fiber optics as previously described, may be positioned above and below the elliptical shaped port 21'. Although the operating tool port 21' is depicted as generally elliptical, and lenses 55 and the distal end 32 of first flexible segment 31 are depicted as circular for this embodiment, it is important to note that in variations of this embodiment, other geometric designs and shapes, as known by those of ordinary skill in the art, are within the scope of the present
30 invention. Also, still within the spirit of this embodiment, the distal end 32 of first flexible shaft segment 31 may have a smaller circumference than the main shaft body 34 of first flexible shaft segment 31, whereby the outer perimeter 57 of face tip

assembly 11 may be at least partially received around, and connected to, the smaller outer circumference of distal end 32. Still referring to FIG. 7, another embodiment may include variations in the shape of outer perimeter 57, variations in the positioning of lenses 55, operating tool port 21', and optical conductor 63. Additionally, in other embodiments of the face tip assembly 11' structure depicted in FIG. 7, the optical image collector 61 may be in another form such as prisms or a substantially flush bundle of fiber optics or other methodologies as known by those of ordinary skill in the art. The optical conductor 62 and luminous conductors 63 may also be in any acceptable form as known by those of ordinary skill in the art that can perform substantially the same function as fiber optics.

[0044] Referring now to FIG. 8, another alternative three-dimensional viewing face-tip assembly 11''' is shown. In this face tip assembly 11''', the general shape of the face 78' of face tip assembly 11''' is flatter in appearance than those described in FIGS. 2-4 and FIGS. 5-6 and thus lacks a substantial protrusion 25 formed by peaks 69, 70. Front face 78' also generally lies in a plane substantially parallel with plane P previously described. The face tip assembly 11''' may include a pair of optical image collectors 61', which, in this embodiment take the form of a plurality of hexagonal shaped lenses 55' which provide for a three-dimensional view. The lenses 55' are positioned in plane P, as previously described and are offset toward the outer perimeter 57. In this embodiment, the face tip assembly 11''' also includes an operating tool port 21'' which is offset from the center, or longitudinal axis L, of the face tip assembly 11''', away from the lenses 55', toward the outer perimeter 57. In this embodiment, luminous conductors 63 for light conduction and illumination in the form of fiber optics are disposed in luminous channel ports 23'' located circumferentially between the lenses 55' and between lenses 55' and operating tool port 21'' and form a generally triangular shaped array wherein each port 23'' is located at the tips of the triangle. In this embodiment, face tip assembly 11 has a hexagonal shape and connects with, or alternatively is a part of, the first flexible shaft segment 31. Although the operating tool port 21'' and lenses 55' are hexagonal shaped, luminous channel ports 23'' is diamond shaped, and the distal end 32 of first flexible shaft segment 31 is depicted as circular, it is important to note that variations of this embodiment, would permit other geometric designs as known by those of

ordinary skill in the art, within the scope of the invention. Also, the distal end 32 of first flexible shaft segment 31 may be in the shape of a hexagon and have a smaller circumference than the main body 34 of first flexible shaft segment 31 whereby the outer perimeter 57 of face tip assembly 11''' may be at least partially received around, and connected to, the smaller outer perimeter of distal end 32. Still referring to FIG. 8, another embodiment may include variations in the shape of outer perimeter 57, variations in the positioning of lenses 55'', operating tool port 21'', and fiber-optic optical conductor 62. Additionally, in other embodiments of the face tip assembly 11''' depicted in FIG. 8, the optical image collector 61' may be in another form such as a prism or a substantially flush bundle of fiber optics or other methodologies as known by those of ordinary skill in the art. The optical conductor 62 and luminous conductors 63 may also be in any acceptable form as known by those of ordinary skill in the art that can perform substantially the same function as fiber optics.

[0045] Referring to FIGS. 1 and 9, the shaft assembly 12 of ureteroscope, or endoscope, 10 includes a shaft 27 having at least one longitudinally extending passageway 28 and handle and viewing assembly interface 29. Preferably, there is a passageway 28 which corresponds to, and is in communication with, each operating tool port 21-21'', optical image channel port 22, 22', and luminous channel port 22-23''. The shaft 27 is preferably constructed of a suitable nontoxic material, such as a plastic or polymer material and includes a first flexible shaft segment 31 having distal end 32 adapted for insertion into the cavity and interfaced with the face tip assembly 11 at interface 56; a second flexible shaft segment 41 having a distal end 42 connected to a proximal end 33 of the first flexible shaft segment 31; and a third shaft segment 51 having a distal end 52 connected to a proximal end 43 of the second flexible shaft segment 41.

[0046] Preferably, the shaft 27 is constructed so that it has a substantially smooth, continuous outer surface, and its preferred cross-sectional configuration is circular. Preferably the length of the third shaft segment 51 is approximately 50 cm long. The first flexible shaft section 31 is preferably approximately 4 cm long, and the second flexible shaft section 41 is preferably approximately 20 cm long. The first and second flexible shaft sections 31, 41 preferably have cross-sectional configurations that are substantially uniform along their lengths, but they may taper downwardly toward the

face tip assembly 11. The third section 51 of shaft 27 is constructed so that it has sufficient strength and rigidity to permit use within the bladder and to support the entry of the first and second flexible sections 31, 41 into the ureter and may be described as rigid or semi-rigid in construction. The first and second flexible shaft sections 31, 41 are constructed in order to follow the contours of the ureter. Also, as is known by those of ordinary skill in the art of endoscopes, the lengths of the first segment 31, second segment 41, and third segment 51 of the shaft 27 may vary according to the intended use of the endoscope 10.

[0047] The third shaft segment 51 is dimensioned to be received in a human body so that it extends through the urethra and substantially through the bladder, The distal end 52 of segment 51 is tapered to receive the proximal end 43 of the second flexible segment 41 and is formed to provide a smooth, gradual transition between the second flexible segment 41 and the third segment 51, to permit the non-traumatic passage of the shaft 27 through the urethra and into the bladder. Preferably, the third section 51, preferably, has sufficient strength and rigidity to enable both axial and rotational translation with the maneuvering of the handle and viewing assembly 13, without excessive twisting of the shaft 27. Additionally, the connection 14 between shaft segment 51 and the handle and viewing assembly 13 has sufficient strength and rigidity to avoid breaking during use and handling of endoscope 10. Thus, the user is able to insert the shaft 27, leading with face tip assembly 11, into the urethra and maneuver the instrument through the bladder in order to position the first flexible section 31 and thus the face tip assembly 11 into the opening of the ureter. The first flexible segment 31 having distal end 32 adapted for insertion into the cavity is dimensioned to be received in the ureter of a patient.

[0048] The second flexible shaft segment 41 having a distal end 42, like first flexible shaft t 31 is correspondingly also dimensioned to be received in the ureter of a patient and is sufficiently flexible along its length to follow various canals of the human body, such as the ureter. In order to optimize the versatility of a flexible endoscope while retaining the controllability of a rigid endoscope, the second flexible segment 41 is "passively flexible". The term "passively flexible" is intended to mean that shaft segment 41 may be moved, flexed, or bent, to assume a curved configuration, in response to forces exerted upon the shaft 27 as it passes through a

cavity or body passageway, but the movement, flexing, or bending is not substantially controllable by the operator of the instrument. While the third shaft segment 51 provides the user with sufficient feel and control of the instrument 10, the second flexible segment 41 has the ability to readily flex and follow the contours of a cavity or passageway, such as the ureter, without excessive deformation of its cavity or passageway, in order to minimize any traumatic effects.

[0049] In contrast, the first flexible shaft segment 31 is "actively flexible". The term "actively flexible" is intended to mean that shaft segment 31 may be moved, flexed, or bent to assume a curved configuration, such as shown in phantom lines 15 in FIG. 1, or an angular disposition with respect to longitudinal axis L, and such movement, flexing or bending is substantially controlled by the operator, who can cause and control the desired movement, flexing, and/or bending. The deflection of face tip assembly 11 upon operator, or user, command, or control, aids the user in the detection and penetration of the opening of the ureter. Additionally, the relatively small diameters of face tip assembly 11 and first flexible shaft segment 31 allow the user to insert the shaft 27 into the narrow opening of the ureter to gain access to the ureter and kidney. The active flexibility of the first flexible shaft segment 31 also provides for non-traumatic use of the instrument 10 and precise positioning of the face tip assembly 11 adjacent to items of interest such as a lesion or kidney stone. Most significantly, the actively flexible first flexible segment 31 enables the user to view and, along with other features of the present invention, non-traumatically deliver a working tool via the working channel 71 and operating tool port 21 to the item of interest. The flexibility of the first flexible segment 31 generally negates the need for rotating the instrument when targeting or advancing the instrument as required.

[0050] The first flexible shaft segment 31 may be made actively flexible using various methodologies. In the preferred embodiment, the first flexible segment 31 is made actively flexible through use of operating, or guide, wires 30 guided through individual conduits which pass longitudinally through shaft segment 31 or a through passageway 28 within shaft 27 toward the distal end 32, which wire, or wires, may be manipulated, or pulled, so as to bend, move, or flex, the shaft segment 31 in a desired direction. The distal ends of the wires 30 may be suitably anchored adjacent the distal end 32 of shaft segment 31, whereby upon pulling on the wire, or wires 30, the

desired controlled flexing, moving, or bending will occur. Alternatively, the first flexible shaft segment **31** may be comprised of a connected string of body members consisting of semicircular disc-like ring elements forming selectively controllable expandable bodies, whereby upon controlled expansion of selected ring elements, the shaft segment **31** moves or flexes in the desired direction, similar to the manner in which a snake moves. Other methodologies for providing the requisite flexibility could include the use of springs, separate wire guides, or the working tool itself, among others. If desired, the cross-sectional shape of first flexible shaft segment **31** could be varied in order to provide varying inherent flexibility characteristics. In other words, one or more portions, or sides, of the first flexible shaft segment **31** can be made to be more pliable, or flexible, than other portions, or sides, of the same first flexible shaft segment in order to make a shaft segment that more readily flexes in a first direction and is more rigid in a second direction.

[0051] Alternatively, the first flexible shaft segment **31** can be made from a composite material that has differing properties that will result in having a first flexible segment **31** predisposed to more readily bend, or flex, in a first direction, for example, upwardly and downwardly, rather than from side to side. Alternatively, the active desired flexibility of the first flexible shaft segment **31** could be obtained by use of a longitudinally disposed tension cable with a distal spring deflection recovery member, whereby increased tension or compression on the tension cable initiated through a suitable control causes the flexible shaft segment **31** to deflect or flex in a desired direction.

[0052] Face tip assemblies **11**, **11'**, **11''**, **11'''** may be a separate multi-port piece which is connected to the distal end **32** of first flexible shaft segment **31** of shaft **27** as previously described. In an alternative embodiment, the face tip assemblies **11-11'''** may be a unitary piece formed integral with first flexible segment **31** as previously described. If desired, the same material used to form the first flexible shaft segment **31** may also be used for the second flexible shaft segment **41**. The first flexible shaft segment **31** may have approximately the same diameter as the second flexible shaft segment **41**, and the two segments may be formed integral with each other or formed separately and connected by any suitable connection. If desired, as seen in **FIGS. 1** and **9**, the first shaft segment **31** could extend along the longitudinal axis **L** of the

shaft 27 from its distal end 32 to the handle and viewing assembly, whereby shaft segment 31 is concentrically disposed within the second shaft segment 41 and third shaft segment 51. In turn, the second shaft segment could also extend along the longitudinal axis L of shaft 27 to the handle and viewing assembly 13, whereby shaft segment 41 is concentrically disposed within the third shaft segment 51. Where the first shaft segment 31 enters the second shaft segment 41, and where the second shaft segment 41 enters the third shaft segment 51, define transition zones, or transition locations, 39, 49, and preferably at these zones the larger diameter shaft segment as shown at zone 49 in FIG. 1. These tapering transition zones 39, 49 provide increased durability of the shaft 27 to bending fatigue and ease the insertion of the shaft 27 into the desired body cavity. The second flexible segment 41 may have a different diameter than the third segment 51, and the second flexible segment 41 may be disposed inside the third segment 51. In the preferred embodiment, the first and second flexible section 31, 41 have a diameter of approximately 7.2 French equal to approximately 2.16 millimeters, wherein the third segment 51 has a diameter of approximately 8.2 French equal to approximately 2.46 millimeters.

[0053] With reference to FIGS. 1, 9, and 10 the handle and viewing assembly 13 has a plurality of passageways, or channels, 88 in communication with corresponding passageways, or channels, 28 of shaft 27 and longitudinally extend to the first flexible shaft segment 31 to the input/output ports of the face tip assemblies 11-11''. The passageways, or channels, between face tip assembly 11 and handle and viewing assembly 13 may be of equal diameter, or of differing diameter sizes, whereby they taper from one end to another to provide a smooth continuation of the passageways or channels.

[0054] With reference to FIGS. 1, 9, and 10, the handle and viewing assembly 13 includes: a distal section 81 which connects, or interfaces, with shaft 27, a working channel interface section 82 including a working channel interface assembly 72 which provides access for various operating tools through the instrument 10; a luminous conductor interface assembly 73 which provides for connecting, or interfacing, a light source such as a lamp box, for example, with the luminous conductor 63; and a proximal section 83 including proximal section assembly 84, including optical channel interface assembly 74, and which provides either an interface, or an

intermediate connection, to a conventional imaging apparatus (not shown). The handle and viewing assembly 13 may include, if desired, any one or more of the following connection components: a handhold or pistol-type grip; a telescopic viewing assembly; an eyepiece adjustment; an optical tap for transmission of the optical image to an imaging apparatus; an electronic image enhancer/transmitter; and/or valve(s) for irrigation/suction.

[0055] The instrument 10 includes a working channel 71 for providing a pathway into the internal cavity for a conventional working instrument. Referring now to FIGS. 1, 2, 9 and 10, in the preferred embodiment, the working channel 71 is formed via passageways 28, 88 and provides working tool access to the interior cavity, the channel 71 extending from the working channel interface assembly 72 through to the operating tool port 21. In an embodiment, the working channel 71 has a substantially smooth interior surface to provide smooth movement of a working tool through instrument 10. The working channel 71 may have a substantially circular cross-sectional configuration, and may be coaxially surrounded by shaft segments 31, 41, and 51 of shaft 27. The interior wall surface 75 of working channel 71 may be coated with, or formed of, a material having a reduced coefficient of friction to facilitate easy passage and use of working accessories, or tools, in the working channel 71.

[0056] The instrument 10 includes at least one luminous conductor 63 for providing illumination within the interior cavity. The luminous conductor 63 extends from the luminous conductor interface assembly 73 of handle and viewing assembly 13, through shaft 27, to distal end 32 of first flexible shaft segment 31 to face assembly 11-11'''. The luminous conductor 63 is in the form of a fiber optic light carrying bundle. The luminous conductor interface assembly 73 provides a connector, as understood by those skilled in the art, between the luminous conductor 63 (light guide) and a conventional light source (not shown). Light travels through the luminous conductor interface assembly 73 and through the handle and viewing assembly housing 87 and shaft 27 to the interior cavity in a manner depending upon the configuration of the face tip assembly 11-11'''. For example, in one of the embodiments described with regard to FIG. 2, the luminous conductor 63 is a single fiber-optic bundle and may be interspersed among the optical conductor 62 in working channel 71. However, in one of the embodiments of FIGS. 3, 4, or 5, the

implementation may be best had through a plurality of independent fiber-optic bundles or a single fiber-optic bundle divided prior to or upon reaching luminous channel port 23. Also, in an embodiment, the luminous conductor interface assembly 73 may include an adjustable light valve (not shown) for selectively adjusting the intensity of the light. In another embodiment, the handle and viewing assembly 13 may include a plurality of the luminous conductor interface assemblies 73.

[0057] Referring again to FIGS. 1 and 9, an embodiment of the present invention also comprises at least one optical conductor 62 optically interfaced with the optical collector 61 for transmitting the gathered interior cavity image to the handle and viewing assembly 13. In the preferred embodiment, the optical conductor 62 is in the form of a fiber-optic bundle 64. In this embodiment, the instrument 10 includes an optical conductor channel 92 which encloses and receives the optical conductor 62, 64. The optical conductor 62, 64 may be located within the instrument 10, such as by disposing it in the working channel 71, or it may be formed as a separate channel. A luminous conductor channel 93 may be provided to carry light to the face tip assembly 11-11'" and correspondingly the internal cavity and thus, the area of interest. A fused fiber optic image bundle 62 would extend through shaft 27 to the face tip assembly 11-11'" and correspondingly to the optical image collector 61. In an embodiment, the optical conductor 62 is supported within handle and viewing assembly housing 87 by means known by those skilled in the art. For example, the optical conductor 62 would be supported within the handle and viewing assembly housing 87. The handle and viewing assembly 13 of endoscope 10 may be equipped to interface with an imaging apparatus 91 (FIG. 11) having an imaging processor 93 in order to capture the image gathered by optical image collector 61 in order to process the image for transmission to a human interface apparatus 101, such as a monitor and/or to video capable glasses. In an alternative embodiment, the handle and viewing assembly 13 is used as a form of telescope as known by those skilled in the art, whereby an ocular lens and lens support would cooperate with a spring means to permit relative movement between the optical conductor 62 and the housing 87 to provide direct, adjustable, visual imaging. In an embodiment, an optical wedge (not shown) is included, the optical wedge can be located near the distal end 32 of the first flexible segment 31 to provide a direction of view compensation of about 5-10

degrees when viewed under water, as would be the case if implemented as a ureteroscope.

[0058] Referring now to **FIGS. 1, 2, and 11**, a system to view a visually obscured portion of a body cavity will be described. The system may include an endoscope **10** as previously described. The system may further include an imaging apparatus **91** coupled with the at least one optical conductor **62** via the handle and viewing assembly **13**, for capturing the image to send it to a human interface apparatus **101**. In an embodiment, instead of the user strictly viewing the image gathered by the optical image collector **61** through a telescope or eye piece portion of a viewing assembly as
10 is the case with much of the state-of-the-art, the handle and viewing assembly **13** of the present invention may include a proximal section assembly **84** which provides an interface for the imaging apparatus **91** as known by those skilled in the art. In an embodiment, the imaging apparatus **91** is an image transceiver **92** including an image processor **93** capable of providing video output to a human interface apparatus **101**. In another embodiment, the imaging apparatus **91** is a pair of cameras optically coupled with a plurality of optical conductors **62**. The preferred function of the imaging apparatus **91** is to render a three-dimensional image of the area of interest as selected by the user. Typically this is accomplished using individual "optical feeds." Additionally, in the preferred embodiment utilizing a pair of optical conductors **62**
20 and optical image collectors **61**, the imaging apparatus **91** captures each half of the image to render a complete and broader view of the area of interest.

[0059] The system may include a human-interface apparatus **101**, as shown in **FIG. 11**. The human interface apparatus **101** is electrically or optically coupled with the imaging apparatus **91**. In various embodiments, the human interface apparatus **101** may include such display/interface devices including a first image display device **94** such as a CRT, HDTV, for example, and in the preferred embodiment, a second image display device **94** including a video stereoscopic viewer unit **95** as known and understood by those skilled in the art. Although visual clarity is an important feature of the human interface apparatus **101**, the invention is not limited to, or to the quality
30 of, the examples provided above.

[0060] An embodiment of the present invention includes a method of performing a procedure in a visually obscured portion of a body cavity while under direct visual

control. Specifically, the method of the present invention comprises the steps of: providing an endoscopic type instrument **10**, having a face tip assembly, such as face tip assembly **11-11'''** connected to a shaft assembly **12** having an actively flexible shaft segment **31** at its distal end, the shaft assembly **12** being connected to a handle and viewing assembly **13**; providing an illumination source, such as luminous conductor **62**; inserting the distal end of the shaft assembly into a body cavity; manipulating the actively flexible shaft segment to a desired angular deflection in order to properly target, or view, the area of interest to allow both diagnosis and operative procedures. Another step may be advancing a working tool through the

10 working channel **71**, into the body cavity, while simultaneously monitoring its exit through the face tip assembly **11-11'''**. The user can view the inner portion of a cavity such as, for example, the ureter or kidneys, and simultaneously view the insertion of a working/operating tool. Thus, various procedures can be carried out within the cavity while under direct visual control. The method may include the steps of irrigating the area of interest and suctioning particulate matter from the body cavity. Note, that one skilled in the art would know that some of the above steps do not need to be accomplished in the order provided in this embodiment. The method may also include the step of viewing during insertion, the relative location of the face tip assembly to properly position the assembly with respect to an area of interest **114**;

20 **[0061]** In the drawings and specification, there have been disclosed a typical preferred embodiment of the invention, and although specific terms are employed, the terms are used in a descriptive sense only and not for purposes of limitation. The invention has been described in considerable detail with specific reference to these illustrated embodiments. It will be apparent, however, that various modifications and changes can be made within the spirit and scope of the invention as described in the foregoing specification. It is understood that other materials and dimensions may be used for the endoscopic type instrument of the present invention keeping in mind the dimensions of the affected body parts. Further, the number and dimensions of the channels or passageways employed are variable depending on the accessories (i.e. dye

30 laser, fiber optics, etc.) used in conjunction with the instrument. Additionally, the actively flexible shaft segment could be used with other shaft segments which are all rigid, all semi-rigid, all flexible, or combinations thereof. Further, the face tip

assemblies may be used with any type of endoscopic instrument or shaft assembly. Also, other shaped handles and handles of other designs may be used. Accordingly, the invention is to be limited only by the scope of the appended claims.

CLAIMS

What is claimed is:

1. An endoscope system for viewing a visually obscured portion of a body cavity comprising:

an endoscope having,

a face tip assembly, having a plurality of input/output ports associated

10 with a shaft assembly, the shaft assembly being associated with

a handle and viewing assembly;
the shaft assembly including a shaft having a distal end and an actively

flexible shaft segment disposed at the distal end of the shaft for insertion into the cavity;
at least one optical image collector adapted to gather an image from within the body cavity;

at least one optical conductor, associated with the at least one optical

20 image collector, and adapted to transmit the image to the handle

and viewing assembly;
at least one luminous conductor adapted to provide illumination to the

body cavity;
at least one working channel disposed within the shaft assembly adapted to permit a working instrument entry into the body cavity; and

30 an imaging apparatus, associated with the at least one optical conductor, and

adapted to capture the image to send it to a human interface
apparatus
adapted to permit viewing of the image.

2. The endoscope system of claim 1, including a working channel extension, associated with the face tip assembly, which includes at least one protrusion adapted to guide the working instrument and to prevent impact of foreign matter upon the at least one optical image collector.
- 10 3. The endoscope system of claim 1 wherein there are two optical conductors for producing a three-dimensional image.
4. The endoscope system of claim 3, including an image processor capable of capturing the image to render it three-dimensional for display by the human interface apparatus.
5. The endoscope system of claim 1 wherein there are two image collectors for producing a three-dimensional image.
- 20 6. The endoscope system of claim 1, wherein the actively flexible shaft segment is disposed adjacent a passively flexible shaft segment.
7. The endoscope system of claim 1, wherein the passively flexible shaft segment is disposed adjacent a semi-rigid shaft segment.
8. An endoscope for viewing a portion of a body cavity, comprising:
a face tip assembly, having a plurality of input/output ports, associated
with a
shaft assembly, the shaft assembly being associated with a
30 handle and
viewing assembly;

the shaft assembly including a longitudinal axis, a shaft having a distal end, and

an actively flexible shaft segment disposed at the distal end of the shaft

for insertion into the body cavity;

at least one optical image collector adapted to gather an image from within the

body cavity;

10 at least one optical conductor, associated with the at least one optical image

collector, and adapted to transmit the image to the handle and viewing

assembly;

at least one luminous conductor adapted to provide illumination to the body

cavity; and

at least one working channel disposed within the shaft assembly and adapted to

permit a working instrument entry into the body cavity.

20

9. The endoscope of claim 8, including a working channel extension, associated with the face tip assembly which includes at least one protrusion to guide the working instrument and to prevent impact of foreign matter upon the at least one optical image collector.

10. The endoscope of claim 9, wherein the at least one optical image collector lies in a first plane which is disposed substantially perpendicular to the longitudinal axis of the shaft assembly; and the at least one protrusion is disposed at the distal end of the shaft forward of the first plane in which the at least one optical image collector
30 lies, whereby the at least one optical image collector may view an operating tool passing forwardly beyond the at least one protrusion.

11. The endoscope of claim 10, wherein the plurality of input/output ports include at least one operating tool port, and the operating tool port lies in a second plane which is disposed substantially parallel with the first plane in which the at least one optical collector lies.
12. The endoscope of claim 11, wherein the first plane and the second plane are substantially coplanar.
13. The endoscope of claim 11, wherein the second plane is disposed in a spaced
10 relationship from the first plane, toward the distal end of the shaft.
14. The endoscope of claim 9, wherein the at least one protrusion has two peaks which extend forwardly toward a distal end of the face tip assembly.
15. The endoscope of claim 14, wherein the plurality of input/output ports include at least one operating tool port, having two sides, and the two peaks are spaced apart from each other, with a peak disposed adjacent each side of the operating tool port.
16. The endoscope of claim 15, wherein the peaks are disposed offset from the
20 longitudinal axis, with a substantial portion of each peak disposed below the longitudinal axis.
17. The endoscope of claim 8, wherein the plurality of input/output ports include at least one operating tool port, at least one optical image channel port, and at least one luminous channel port.
18. The endoscope of claim 8, wherein the face tip assembly includes at least two optical image collectors, each optical image collector being disposed in a first plane which is disposed substantially perpendicular to the longitudinal axis of the shaft
30 assembly.

19. The endoscope of claim 8, wherein the actively flexible shaft segment is disposed adjacent a passively flexible shaft segment.
20. The endoscope of claim 19, wherein the passively flexible shaft segment is disposed adjacent a semi-rigid shaft segment.
21. The endoscope of claim 8, wherein the actively flexible shaft segment is disposed adjacent a semi-rigid shaft segment.
- 10 22. An endoscope for viewing a portion of a body cavity, comprising:
a face tip assembly, having a plurality of input/output ports, associated with a
shaft assembly, the shaft assembly being associated with a handle and
viewing assembly;
the shaft assembly including a longitudinal axis, a shaft having a distal end, and
a shaft segment disposed at the distal end of the shaft for insertion into the body cavity;
20 at least two optical image collectors which produce a three dimensional image
from within the body cavity;
at least one optical conductor, associated with the at least two optical image
collectors, and adapted to transmit the three dimensional image to the handle and viewing assembly;
at least one luminous conductor adapted to provide illumination to the body
cavity; and
30 at least one working channel disposed within the shaft assembly and adapted to
permit a working instrument entry into the body cavity.

23. The endoscope of claim 22, wherein the shaft segment at the distal end of the shaft is actively flexible.

24. The endoscope of claim 22, including a working channel extension, associated with the face tip assembly which includes at least one protrusion to guide the working instrument and to prevent impact of foreign matter upon the at least one optical image collector.

10 25. The endoscope of claim 24, wherein the at least two optical image collectors lie in a first plane which is disposed substantially perpendicular to the longitudinal axis of the shaft assembly; and the at least one protrusion is disposed at the distal end of the shaft forward of the first plane in which the at least two optical image collectors lie, whereby the at least two optical image collectors may view an operating tool passing forwardly beyond the at least one protrusion.

26. The endoscope of claim 25, wherein the plurality of input/output ports include at least one operating tool port, and the operating tool port lies in a second plane which is disposed substantially parallel with the first plane in which the at least one
20 optical collector lies.

27. The endoscope of claim 26, wherein the first plane and the second plane are substantially coplanar.

28. The endoscope of claim 26, wherein the second plane is disposed in a spaced relationship from the first plane, toward the distal end of the shaft.

29. The endoscope of claim 25, wherein the at least one protrusion has two peaks which extend forwardly toward a distal end of the face tip assembly.

30

30. The endoscope of claim 29, wherein the plurality of input/output ports include at least one operating tool port, having two sides, and the two peaks are spaced apart from each other, with a peak disposed adjacent each side of the operating tool port.
31. The endoscope of claim 30, wherein the peaks are disposed offset from the longitudinal axis, with a substantial portion of each peak disposed below the longitudinal axis.
32. An endoscope for viewing a portion of a body cavity, comprising:
- 10 a face tip assembly, having a plurality of input/output ports, associated with a shaft assembly, the shaft assembly being associated with a handle and viewing assembly;
- the shaft assembly including a longitudinal axis, a shaft having a distal end, and
- a shaft segment disposed at the distal end of the shaft for insertion into the body cavity;
- 20 at least two optical image collectors which produce a three dimensional image from within the body cavity;
- at least one optical conductor, associated with the at least two optical image collectors, and adapted to transmit the three dimensional image to the handle and viewing assembly;
- at least one luminous conductor adapted to provide illumination to the body cavity;
- 30 at least one working channel disposed within the shaft assembly and adapted to permit a working instrument entry into the body cavity; and

a working channel extension, associated with the face tip assembly
which
includes at least one protrusion to guide the working instrument
and to
prevent impact of foreign matter upon the at least one optical
image
collector.

33. The endoscope of claim 32, wherein the at least one optical image collector
10 lies in a first plane which is disposed substantially perpendicular to the longitudinal
axis of the shaft assembly; and the at least one protrusion is disposed at the distal end
of the shaft forward of the first plane in which the at least one optical image collector
lies, whereby the at least one optical image collector may view an operating tool
passing forwardly beyond the at least one protrusion.

34. The endoscope of claim 33, wherein the plurality of input/output ports include
at least one operating tool port, and the operating tool port lies in a second plane
which is disposed substantially parallel with the first plane in which the at least one
optical collector lies.

20

35. The endoscope of claim 34, wherein the first plane and the second plane are
substantially coplanar.

36. The endoscope of claim 34, wherein the second plane is disposed in a spaced
relationship from the first plane, toward the distal end of the shaft.

37. The endoscope of claim 32, wherein the face tip assembly includes at least two
optical image collectors, each optical image collector being disposed in a first plane
which is disposed substantially perpendicular to the longitudinal axis of the shaft
30 assembly.

38. The endoscope of claim 33, wherein the at least one protrusion has two peaks which extend forwardly toward a distal end of the face tip assembly.
39. The endoscope of claim 38, wherein the plurality of input/output ports include at least one operating tool port, having two sides, and the two peaks are spaced apart from each other, with a peak disposed adjacent each side of the operating tool port.
40. The endoscope of claim 39, wherein the peaks are disposed offset from the longitudinal axis, with a substantial portion of each peak disposed below the longitudinal axis.
41. The endoscope of claim 32, wherein the shaft segment disposed at the distal end of the shaft is actively flexible.
42. The endoscope of claim 41, wherein the actively flexible shaft segment is disposed adjacent a passively flexible shaft segment.
43. A method for viewing a portion of a body cavity, comprising the steps of:
providing an endoscopic type instrument having a face tip assembly
associated
with a shaft assembly having a distal end and a proximal end,
the shaft
assembly having an actively flexible shaft segment at its distal
end, and
the proximal end of the shaft assembly is associated with a
handle and
viewing assembly;
providing an illumination source;
inserting the distal end of the shaft assembly into a body cavity; and
manipulating the actively flexible shaft segment to a desired angular
deflection in
order to properly view an area of interest in the body cavity.

44. The method of claim 43, including the step of: advancing a working tool through the endoscopic instrument, into the cavity, while substantially, simultaneously viewing its exit through the face tip assembly.
45. The method of claim 43, including the steps of:
irrigating the area of interest; and
suctioning particulate matter from the body cavity.
46. The method of claim 43, including the step of viewing the relative location of the face tip assembly during insertion of the distal end of the shaft assembly to properly position the shaft assembly with respect to the area of interest.
47. An endoscope for viewing a portion of a body cavity, comprising:
a face tip assembly, having a plurality of input/output ports, associated with a
shaft assembly, the shaft assembly being associated with a handle and
viewing assembly;
the shaft assembly including a longitudinal axis, a shaft having a distal end, and
a shaft segment disposed at the distal end of the shaft for insertion into the body cavity;
one optical image collector to gather an image from within the body cavity;
one optical conductor, associated with the optical image collector, and adapted to
transmit the image to the handle and viewing assembly;
at least one luminous conductor adapted to provide illumination to the body cavity;

at least one working channel disposed within the shaft assembly and adapted to permit a working instrument entry into the body cavity; and a working channel extension, associated with the face tip assembly which includes at least one protrusion to guide the working instrument and to prevent impact of foreign matter upon the optical image collector.

10

48. The endoscope of claim 47, wherein the optical image collector lies in a first plane which is disposed substantially perpendicular to the longitudinal axis of the shaft assembly; and the at least one protrusion is disposed at the distal end of the shaft forward of the first plane in which the optical image collector lies, whereby the optical image collector may view an operating tool passing forwardly beyond the at least one protrusion.

20

49. The endoscope of claim 48, wherein the plurality of input/output ports include at least one operating tool port, and the operating tool port lies in a second plane which is disposed substantially parallel with the first plane in which the optical collector lies.

50. The endoscope of claim 49, wherein the first plane and the second plane are substantially coplanar.

51. The endoscope of claim 49, wherein the second plane is disposed in a spaced relationship from the first plane, toward the distal end of the shaft.

30

52. The endoscope of claim 47, wherein the optical image collector is disposed in a first plane which is disposed substantially perpendicular to the longitudinal axis of the shaft assembly.

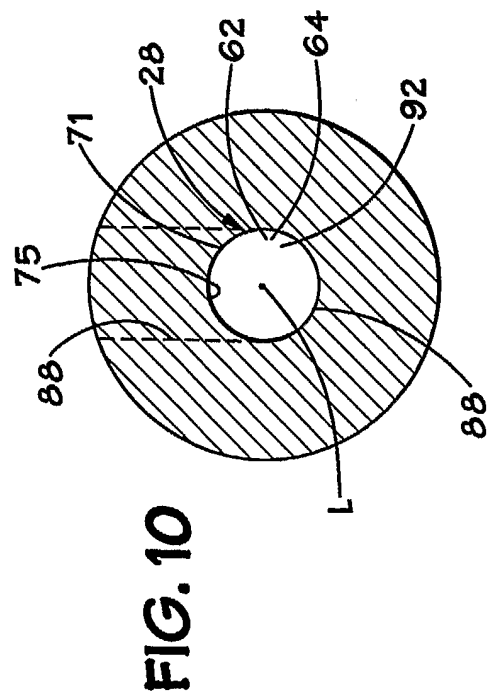
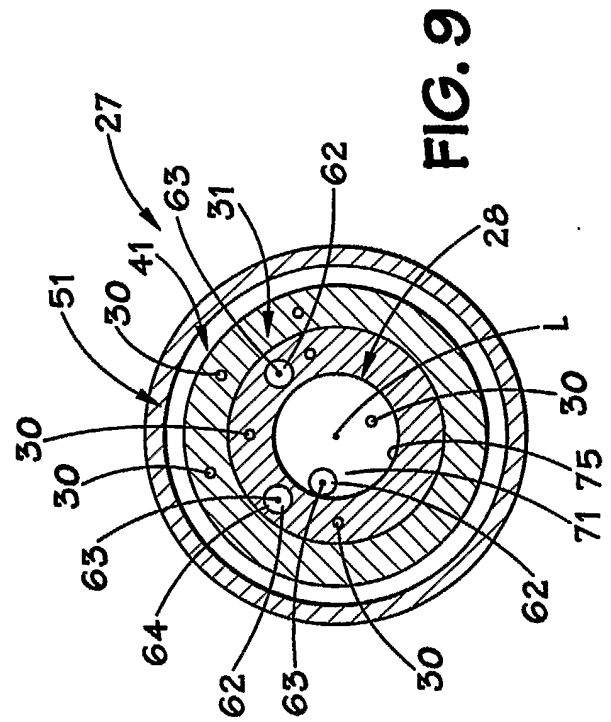
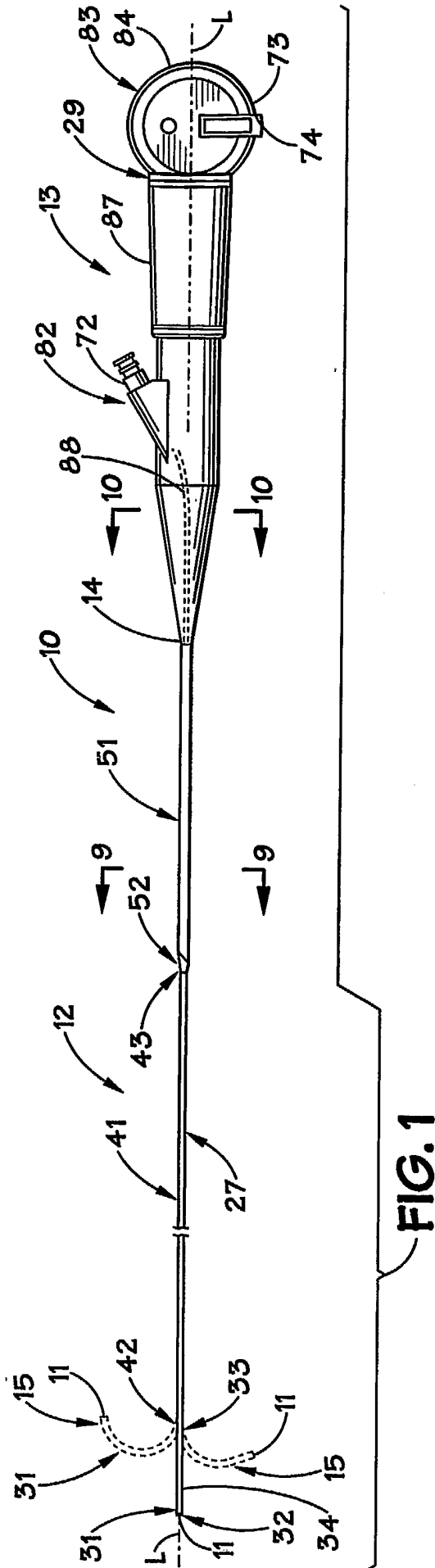
53. The endoscope of claim 48, wherein the at least one protrusion has two peaks which extend forwardly toward a distal end of the face tip assembly.

54. The endoscope of claim 53, wherein the plurality of input/output ports include at least one operating tool port, having two sides, and the two peaks are spaced apart from each other, with a peak disposed adjacent each side of the operating tool port.

55. The endoscope of claim 54, wherein the peaks are disposed offset from the longitudinal axis, with a substantial portion of each peak disposed below the
10 longitudinal axis.

56. The endoscope of claim 47, wherein the shaft segment disposed at the distal end of the shaft is actively flexible.

57. The endoscope of claim 56, wherein the actively flexible shaft segment is disposed adjacent a passively flexible shaft segment.



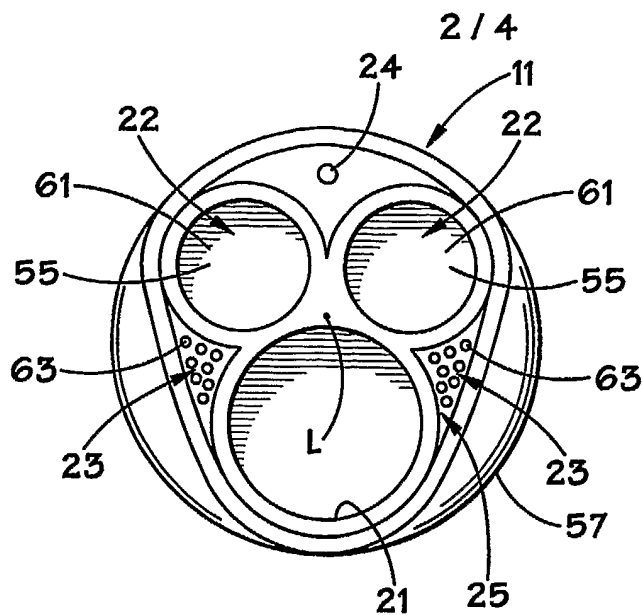


FIG. 2

FIG. 3

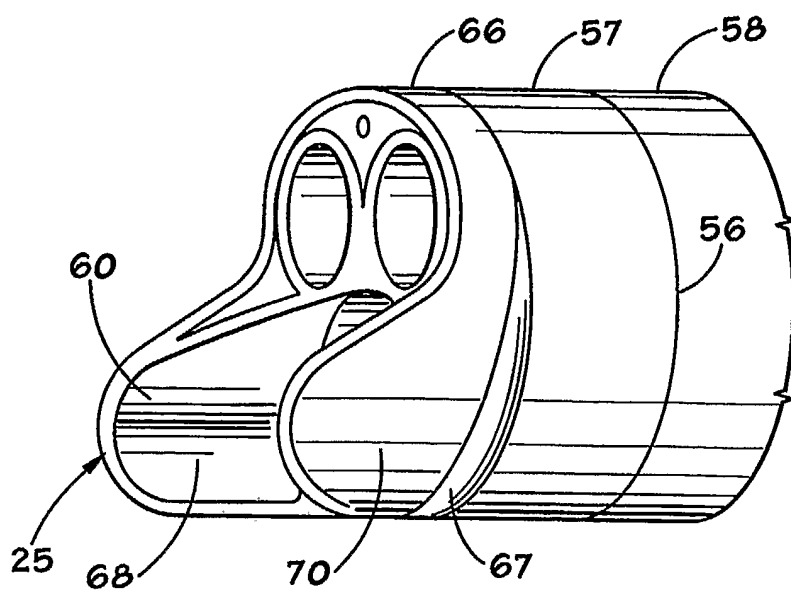
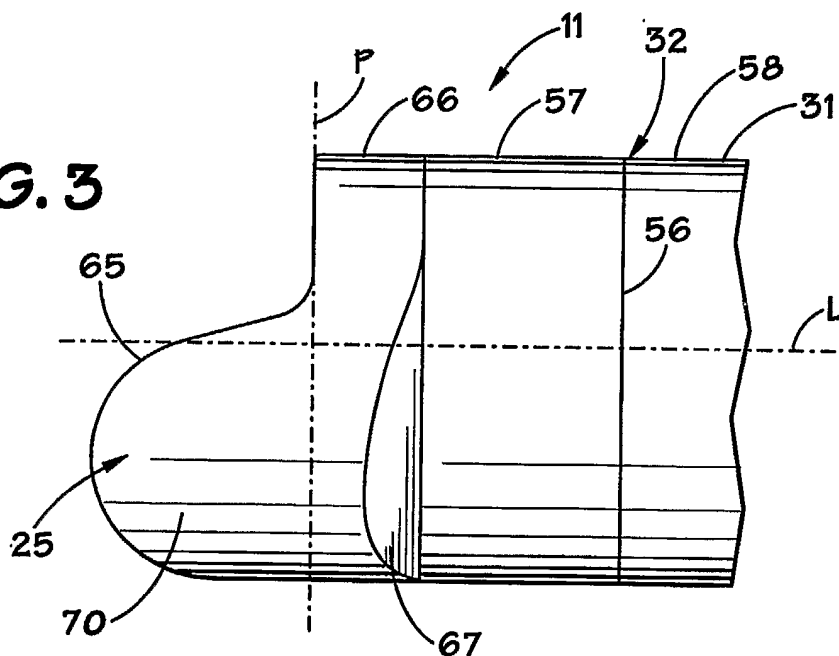


FIG. 4

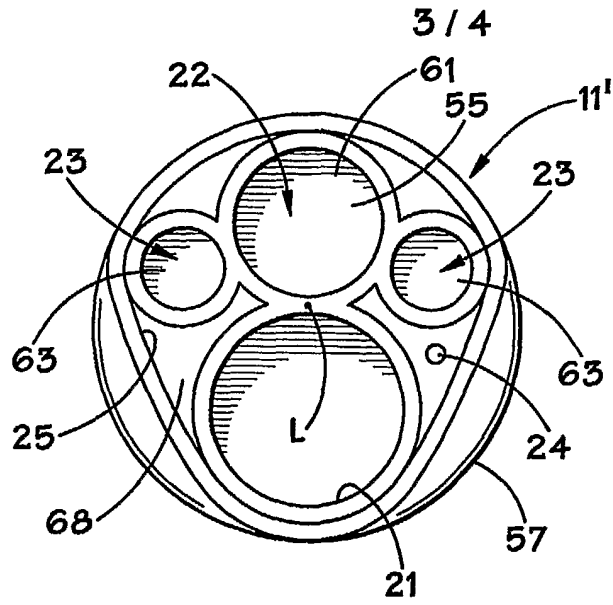


FIG. 5

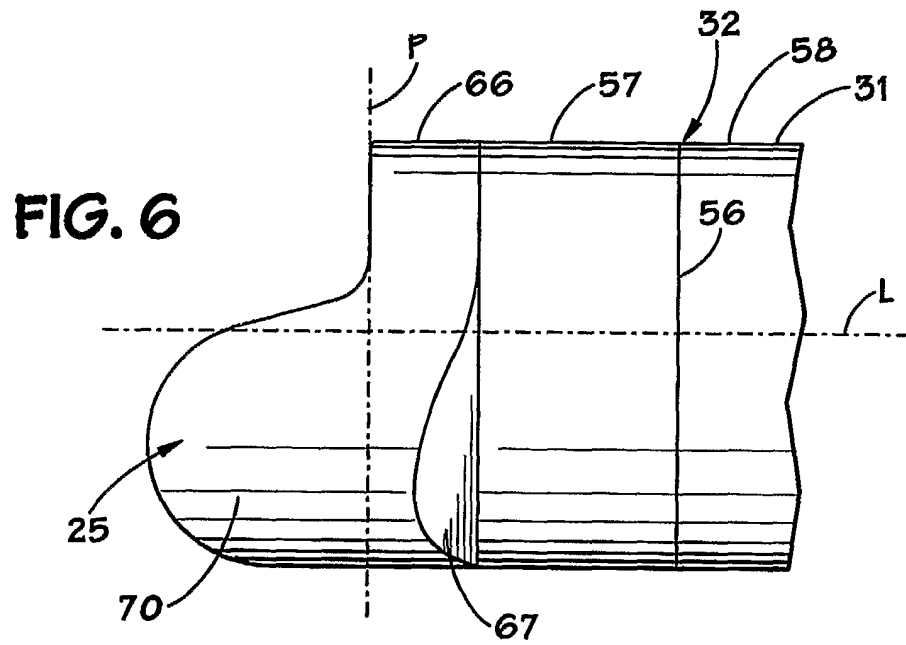


FIG. 6

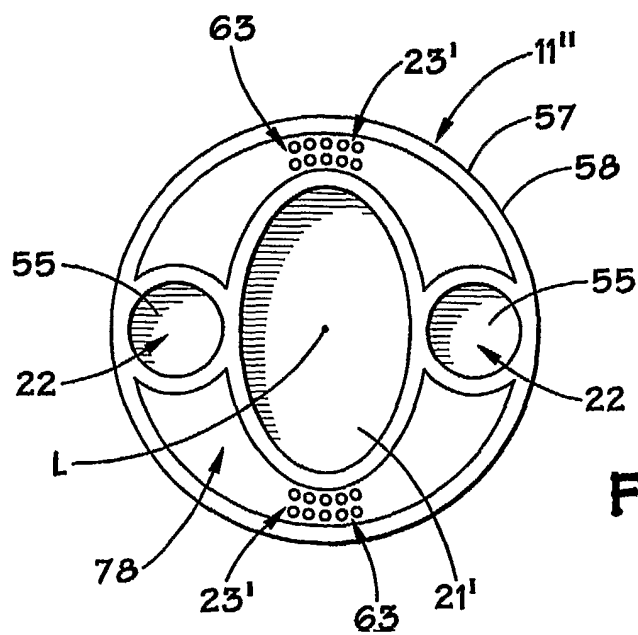
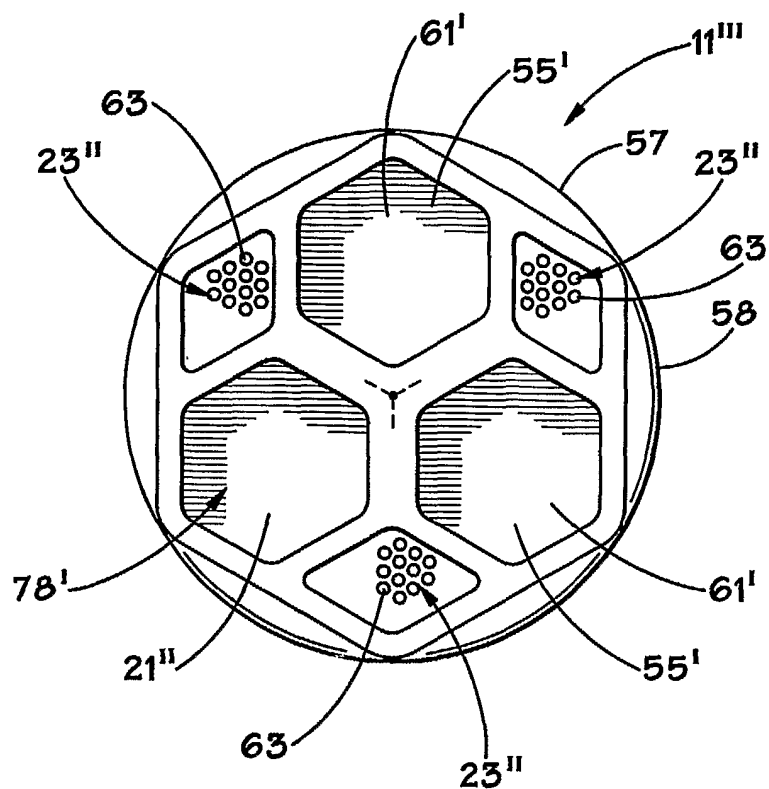
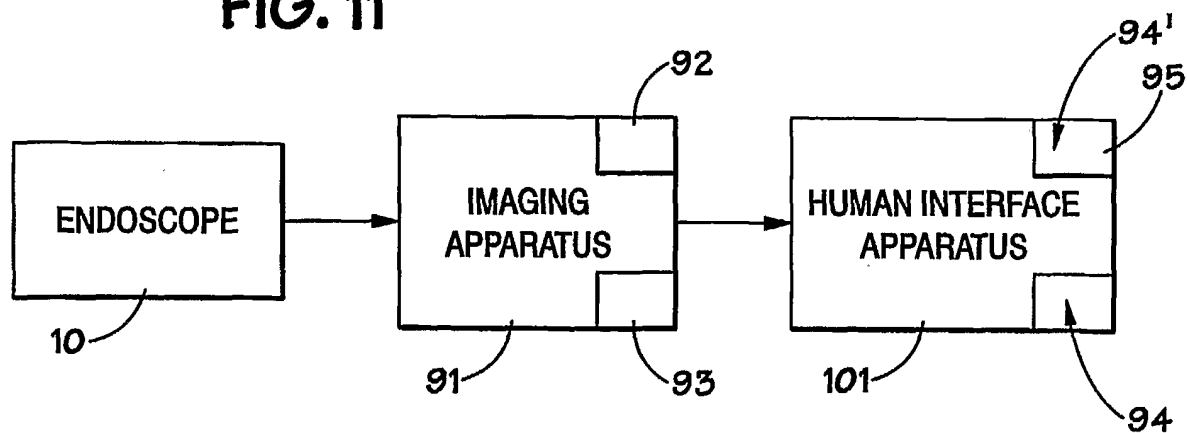


FIG. 7

FIG. 8**FIG. 11**

INTERNATIONAL SEARCH REPORT

International Application No
/US2004/012364

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B1/307 A61B1/07

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 7 A61B

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

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

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/24058 A (SONNENSCHNEIDER ELAZAR ; SONNENSCHNEIDER MINELU (IL); MEDIGUS LTD (IL); CHIN) 28 March 2002 (2002-03-28)	1,3-8, 17-23
A	page 3, line 24 - page 4, line 24	2,9-16, 24-42, 47-57
	page 5, line 14 - page 11, line 22	
X	US 6 165 123 A (THOMPSON ROBERT LEE) 26 December 2000 (2000-12-26) column 5, line 29 - line 50 column 6, line 66 - column 8, line 13 column 9, line 14 - column 10, line 4 figures 1,3,6,7	1,6,8
	----- -/--	

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

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

19 October 2004

Date of mailing of the international search report

27/10/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Hooper, M

INTERNATIONAL SEARCH REPORT

International Application No
/US2004/012364

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 2003, no. 08, 6 August 2003 (2003-08-06) & JP 2003 093325 A (OLYMPUS OPTICAL CO LTD), 2 April 2003 (2003-04-02) abstract -----	2, 9, 24, 32, 47

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/012364

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☒ Claims Nos.: 43-46
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery as the method claims the insertion of an endoscope into the human or animal body.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

tional Application No

/US2004/012364

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0224058	A	28-03-2002	AU 3952501 A	24-09-2001
			AU 8802901 A	02-04-2002
			CA 2403013 A1	20-09-2001
			CA 2422525 A1	28-03-2002
			EP 1265537 A2	18-12-2002
			EP 1322214 A2	02-07-2003
			EP 1452125 A2	01-09-2004
			WO 0167964 A2	20-09-2001
			WO 0224058 A2	28-03-2002
			JP 2003526439 T	09-09-2003
			JP 2004508868 T	25-03-2004
			NZ 524728 A	28-05-2004
			US 2003163029 A1	28-08-2003
			US 2001056282 A1	27-12-2001
			ZA 200302136 A	16-02-2004
US 6165123	A	26-12-2000	AU 9207398 A	16-03-1999
			EP 1009277 A1	21-06-2000
			WO 9909879 A1	04-03-1999
JP 2003093325	A	02-04-2003	US 2003088154 A1	08-05-2003