ENDOSCOPIC METHODS AND DEVICES FOR TRANSNASAL PROCEDURES

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Abstract

Medical devices, systems and methods that are useable to facilitate transnasal insertion and positioning of guidewires and various other devices and instruments at desired locations within the ear, nose, throat, paranasal sinuses or cranium.
Fig. 4 A

Fig. 4 B

Fig. 4 C
Fig. 11 A

Fig. 11 B

Fig. 11 C
Fig. 39 A

Fig. 39 B

Fig. 39 C

Fig. 39 D
Fig. 40 A

Fig. 40 B

Fig. 40 C

Fig. 40 D

Fig. 40 E
ENDOSCOPIC METHODS AND DEVICES FOR TRANSNASAL PROCEDURES

CROSS-REFERENCE


[0002] This application also claims the benefit of U.S. Provisional Application No. 60/844,874, filed Sep. 15, 2006, which application is expressly incorporated herein, in its entirety, by reference thereto and to which we claim priority under 35 USC §119.

FIELD OF THE INVENTION

[0003] The present invention relates generally to medical apparatus and methods and more particularly to devices and methods that are to be used to facilitate transnasal insertion and positioning of guidewires and various other apparatus at desired locations within the ear, nose, throat, paranasal sinuses or cranium.

BACKGROUND OF THE INVENTION

[0004] Functional endoscopic sinus surgery (FESS) is currently the most common type of surgery used to treat chronic sinusitis. In a typical FESS procedure, an endoscope is inserted into the nostril along with one or more surgical instruments. The surgical instruments are then used to cut tissue and/or bone, cauterize, suction, etc. In most FESS procedures, the natural ostium (e.g., opening) of at least one paranasal sinus is surgically enlarged to improve drainage from the sinus cavity. The endoscope provides a direct line-of-sight view whereby the surgeon is typically able to visualize some but not all anatomical structures within the surgical field. Under visualization through the endoscope, the surgeon may remove diseased or hypertrophic tissue or bone and may enlarge the ostia of the sinuses to restore normal drainage of the sinuses. FESS procedures can be effective in the treatment of sinusitis and for the removal of tumors, polyps and other aberrant growths from the nose.

[0005] The surgical instruments used in the prior art FESS procedures have included: applicators, chisels, curettes, elevators, forceps, gouges, hooks, knives, saws, mallets, morsetizers, needle holders, osteotomes, ostium seekers, probes, punches, backbiters, rasps, retractors, rongeurs, scissors, snare, specula, suction cannulae and trocars. The majority of such instruments are of substantially rigid design.

[0006] In order to adequately view the operative field through the endoscope and/or to allow insertion and use of rigid instruments, many FESS procedures of the prior art have included the surgical removal or modification of normal anatomical structures. For example, in many prior art FESS procedures, a total uncinectomy (e.g., removal of the unciante process) is performed at the beginning of the procedure to allow visualization and access of the maxillary sinus ostium and/or ethmoid bulla and to permit the subsequent insertion of the rigid surgical instruments. Indeed, in most traditional FESS procedures, if the unciante process is allowed to remain, such can interfere with endoscopic visualization of the maxillary sinus ostium and ethmoid bulla, as well as subsequent dissection of deep structures using the available rigid instrumentation.

[0007] More recently, new devices, systems and methods have been devised to enable the performance of FESS procedures and other ENT surgeries with minimal or no removal or modification of normal anatomical structures. Such new methods include, but are not limited to, unciante-sparing procedures using Balloon Sinuplasty™ tools and unciante-sparing ethmoidectomy procedures using catheters, non-rigid instruments and advanced imaging techniques (Acclarent, Inc., Menlo Park, Calif.). Examples of these new devices, systems and methods are described in incorporated U.S. patent application Ser. Nos. 10/829,917 entitled Devices, Systems and Methods for Diagnosing and Treating Sinusitis and Other Disorders of the Ears, Nose and/or Throat; Ser. No. 10/944,270 entitled Apparatus and Methods for Dilating and Modifying Ostia of Paranasal Sinuses and Other Intranasal or Paranasal Structures; Ser. No. 11/116,118 entitled Methods and Devices for Performing Procedures Within the Ear, Nose, Throat and Paranasal Sinuses filed Apr. 26, 2005 and Ser. No. 11/150,847 filed Jun. 10, 2005, each of which is hereby incorporated herein, in its entirety. Procedures using Balloon Sinuplasty™ tools such as those described in the above-noted applications, for example, are performable using various types of guidance including but not limited to C-arm fluoroscopy, transnasal endoscopy, optical image guidance and/or electromagnetic image guidance.

[0008] In FESS procedures, the surgeon typically holds or navigates the endoscope with one hand while using the other hand to handle the surgical instruments. Recognizing the desirability of integrating an endoscope with an operative device so that both could be moved with a single hand, application Ser. No. 11/234,395 filed Sep. 23, 2005 describes a number of transnasally insertable sinus guides that have endoscopes attached thereto or integrated therewith.

[0009] There remains a need for further development of new devices and methodology to facilitate the integration of endoscopes with sinus guides and/or other instruments to facilitate endoscopic viewing of guidewires and/or other devices/instruments as they are transnasally inserted, positioned and used to treat disorders of the ear, nose, throat, paranasal sinuses or other intracranial disorders that are transnasally accessible.

SUMMARY OF THE INVENTION

[0010] A beneficial aspect of the present invention is to allow a user to be able to see an adjustable view, with an endoscope, that is generally aligned with the same axis of movement of the user’s working device. This is particularly useful when the axis of movement is at an angle with respect to the axis of entry into the patient. This aspect allows the user to see “around the corner” of anatomy that ordinarily would block his/her view and which would therefore require removal in a traditional FESS procedure to allow visualiza-
tion. This aspect of the invention allows the user to also verify the location of his/her Balloon Sinuplasty™ tools without having to use fluoroscopy or image guidance sys-
tems, so that the procedure does not have to be performed in an operating room. Another beneficial aspect of the present invention is that it enables a reduction in the amount of fluoroscopy that needs to be performed by the user doing the procedure, resulting in a reduction in radiation exposure to the user and the patient.

[0011] Another beneficial aspect of the present invention is that it allows a user to hold a tool with an endoscope attached or incorporated therein, such that both can be held with one hand while allowing the user to manipulate another tool with the other hand, thereby eliminating the need for an assistant.

[0012] Another aspect of the invention is a disposable, flexible endoscope that is inexpensive enough for the user to dispose of after ten uses or less, or even after a single use, because the expensive optics that are normally present in the proximal end portion of a conventional flexible (or rigid) endoscope have been relocated in the present embodiments to a re-usable coupler. Also, steerable elements that are normally present in a conventional flexible endoscope have been removed in the present embodiments. Importantly, in at least one embodiment, the entire diameter of the flexible endoscope has an outer diameter of about 0.035 inches or less, so that interventional devices such as a dilatation catheter can be loaded onto and passed over the flexible endoscope. At least one embodiment of the present invention allows the user to load and remove the flexible endoscope from a curved tool, even one having an acute angle bend therein, without breaking or damaging the lens and/or fibers in the endoscope.

[0013] In accordance with the present invention, there is provided a method for positioning a working device (e.g., a guidewire, catheter, instrument or other device usable to perform or facilitate a therapeutic or diagnostic task) at a desired location within the ear, nose, throat or cranium of a human or animal subject. In general, this method includes the steps of: (A) providing a guide device that comprises an elongate shaft, a distal end, a second channel into which a working device may be inserted and an first channel into which an endoscope may be inserted; (B) providing an endoscope sized to be received within the endoscope channel; (C) providing a working device sized to be received within the second channel; (D) positioning the endoscope in the endoscope channel; (E) inserting the guide device through a nostril of the subject; (F) using the endoscope to guide or visually verify the positioning of the guide device at the desired location; (G) inserting a working device into the second channel; and (H) advancing the working device to the desired location.

[0014] Further in accordance with the present invention, there is provided an endoscope/sinus guide device that is usable to position a working device at a desired location within the ear, nose, throat or cranium of a human or animal subject. In general, this device comprises a transnasally insertable elongate shaft (e.g., a rigid or flexible catheter, cannula or tube) having a proximal end, a distal end, a working channel through which the working device may be advanced and an endoscope channel, a portion of which is angled relative to the elongate shaft, and into which an endoscope may be inserted such that the endoscope may be used to view at least an area beyond the distal end of the shaft. After the endoscope has been used to facilitate placement of the distal end of the guide device to or near the desired location, a working device (e.g., a guidewire, catheter, instrument or other device usable to perform or facilitate a therapeutic or diagnostic task) is then advanced through the working channel and to the desired location. The elongate shaft of the endoscope/sinus guide device may be straight, curved, malleable or steerable.

[0015] Still further in accordance with the present invention, there is provided a transnasally insertable guide system and method for positioning a guidewire at a desired location within the ear, nose, throat or cranium of a human or animal subject. In general, this system comprises a tubular guide (e.g., a sinus guide) that has an elongate shaft and a lumen. At least a portion of the elongate shaft has a predetermined shape, and may be straight, curved, malleable or steerable. A sheath is sized to be inserted into the lumen of the tubular guide. Such sheath comprises an elongate flexible body having a distal end, a scope lumen and a guidewire lumen. An endoscope is advanceable through the scope lumen of the sheath and a guidewire is advanceable through the guidewire lumen such that a distal portion of the guidewire extends out of the distal end of the sheath. The endoscope is usable to view at least a portion of the guidewire as it advances out of the distal end of the sheath. In this manner, the endoscope may be used to guide the advancement of the guidewire to or near the desired location. Thereafter, the sheath and endoscope may be removed leaving the tubular guide and guidewire in place. A working device (e.g., a guidewire, catheter, instrument or other device usable to perform or facilitate a therapeutic or diagnostic task) may then be advanced through the tubular guide and over the guidewire to the desired location where it is usable to perform or facilitate a therapeutic or diagnostic task. In some embodiments, a distal portion of the sheath may be advanceable out of and beyond the distal end of the tubular guide and such distal portion of the sheath may be deflectable (e.g., steerable) in situ. In such deflectable (e.g., steerable) embodiments, a handpiece may be attached to the proximal end of the sheath and such handpiece may include an actuator or other control that is usable to cause the distal portion of the sheath to deflect (e.g., steer) when so desired.

[0016] Still further in accordance with the present invention, there is provided a guidewire system and method wherein a translucent body (e.g., a flexible guidewire tip) is mounted on the distal end of a guide member. An elongate scope is engageable with the translucent body such that light will be cast from the scope, through the translucent body and images will be received by the scope through the translucent body. In this manner, the scope is usable to view an area adjacent to the elongate guide tip, thereby facilitating advancement of the elongate guide tip to a desired location within the body of a human or animal subject. After the elongate guide tip has been advanced to or near the desired location, a working device (e.g., a catheter or other device usable to perform a diagnostic or therapeutic task) is then advanced over the endoscope, translucent member and guide tip. In this manner, the endoscope, translucent member and guide tip combine to perform a function of a continuous guidewire.
Still further in accordance with the present invention, there is provided another guide system and method wherein an elongate guide member (e.g., a flexible guidewire tip) is attached to and extends from the distal end of a rigid or flexible catheter having a side opening. An endoscope is advanceable out of the side opening of the elongate catheter and useable, when so advanced, to view an area adjacent to the elongate guide tip, thereby facilitating advancement of the elongate guide tip to a desired location within the body of a human or animal subject. Thereafter, the endoscope may be retracted back into the catheter and a working device (e.g., a catheter or other device useable to perform a diagnostic or therapeutic task) is then advanceable over the catheter and guide member. In this manner, the catheter and the guide member combine to perform the function of a continuous guidewire.

Further aspects, elements and advantages of the present invention will be understood by those of skill in the art upon reading of the detailed description set forth herebelow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of one embodiment of a guide system of the present invention.

FIG. 2 is a perspective view of the guide system of the present invention in use on a human subject.

FIG. 3A is a side view of the guide catheter of the system of FIG. 1.

FIG. 3B is a cross sectional view through line 3B-3B of FIG. 3A.

FIG. 3C is a cross sectional view through line 3C-3C of FIG. 3A.

FIG. 3D is a side view of the endoscope of the system of FIG. 1.

FIG. 3E is a cross sectional view through line 3D-3D of FIG. 3C.

FIG. 3F is a side view of the connector/camera/light cable assembly of the system of FIG. 1.

FIG. 4A is a side view of another embodiment of a guide catheter device useable in the guide catheter systems of the present invention.

FIG. 4B is a cross sectional view through line 4B-4B of FIG. 4A.

FIG. 4C is a cross sectional view through line 4C-4C of FIG. 4A.

FIGS. 5A-5C show steps in a method for using a flexible endoscope in conjunction with the guide catheter component of FIG. 4A.

FIGS. 5D shows one embodiment of a fixture apparatus that is useable to facilitate passage of a flexible endoscope through the distal endoscope guide lumen of the guide catheter of FIG. 4A.

FIGS. 5E shows another embodiment of a fixture apparatus that is useable to facilitate passage of a flexible endoscope through the distal endoscope guide lumen of the guide catheter of FIG. 4A.

FIG. 6 is a partial perspective view of a guide catheter of the present invention with an optional linking apparatus for linking the endoscope to a guidewire to deter divergence of the endoscope away from the path of the guidewire.

FIG. 7A shows another embodiment of a guide catheter device useable in the guide catheter systems of the present invention during insertion of a flexible endoscope into a dynamic endoscope lumen.

FIG. 7B shows the guide catheter device of FIG. 7A after the endoscope has been fully advanced through the dynamic endoscope lumen.

FIG. 8A shows the guide catheter device of FIG. 7A with an optional endoscope lumen retractor, during insertion of a flexible endoscope into a dynamic endoscope lumen.

FIG. 8B shows the guide catheter device of FIG. 8A after the endoscope has been fully advanced through the dynamic endoscope lumen.

FIG. 9A shows an embodiment of a guide catheter of the present invention having a pivoting arm apparatus in an extended position to facilitate loading of an endoscope into the endoscope lumen.

FIG. 9B shows the guide catheter of FIG. 9A with the pivoting arm apparatus in a non-extended position after the endoscope has been loaded into the endoscope lumen.

FIG. 10 is a side view of a prior art guidewire having an angled distal tip.

FIG. 10A shows a step in a method for using a guide catheter system of the present invention in conjunction with the guidewire of FIG. 10.

FIG. 10B shows another step in a method for using a guide catheter system of the present invention in conjunction with the guidewire of FIG. 10.

FIG. 11A is a perspective view of the distal portion of a guide catheter device of the present invention having its endoscope lumen disposed on top of the curvature of the guide catheter.

FIG. 11B is a perspective view of the distal portion of a guide catheter device of the present invention having its endoscope lumen disposed along side of the curvature of the guide catheter.

FIG. 11C is a perspective view of the distal portion of a guide catheter device of the present invention having its endoscope lumen disposed below the curvature of the guide catheter.

FIGS. 12A through 12D are illustrations of partial sagittal sectional views through a human head showing various steps of a method of gaining access to a paranasal sinus using a sinus guide.

FIG. 13 illustrates a scope introduced on the side of the sinus guide.

FIG. 14 shows an illuminating guidewire according to one embodiment of the present invention.

FIG. 15 shows a distal end portion of a guidewire having a bent shape.
FIG. 16 is a cross-sectional illustration of a distal end portion of a guidewire device showing a core support fixed to the coil.

FIG. 17 shows a cross-sectional view of a guidewire device that includes a fiber optic bundle of light fibers.

FIG. 18 shows an illuminating guidewire according to another embodiment of the present invention.

FIG. 19 is a cross-sectional illustration of a distal end portion of the guidewire shown in FIG. 18.

FIG. 20 shows an illuminating guidewire according to another embodiment of the present invention.

FIG. 21 illustrates an alternative transparent portion that may be included in a device shown in FIG. 20.

FIG. 22 illustrates another alternative transparent portion that may be included in a device shown in FIG. 20.

FIG. 23A illustrates an illuminating guidewire device including a quick release connector that is optically coupled to a light source.

FIG. 23B is a view of the arrangement of FIG. 23A in which the quick release locking mechanism is in the locked position.

FIG. 24A illustrates an alternative quick release connector.

FIG. 24B illustrates the connector of FIG. 24A mounted over a proximal end portion of an illuminating guidewire.

FIG. 25 illustrates another alternative quick release connector.

FIG. 26 illustrates another alternative quick release connector.

FIGS. 27A-27E are illustrations of partial coronal sectional views through a human head showing various steps of a method for treating an ostium that opens to a frontal sinus.

FIG. 28 illustrates a situation, like that described with regard to FIG. 13, where a scope has been inserted as far as possible without causing significant trauma to the patient. Additionally, FIG. 28 shows an illuminating guidewire having been extended distally of the limit of illumination of the scope, to effectively extend the illumination distance viewable by the scope.

FIG. 29 illustrates non-limiting examples of where one or more filters may be placed in an illuminating guidewire device.

FIG. 30A schematically illustrates a connector having a rotating shutter rotatably mounted therein.

FIG. 30B is an illustration of a plan view of the shutter of FIG. 30A.

FIG. 31 shows a frontal ostium seeker instrument that can be used to access a sinus ostium.

FIG. 32 shows a suction sinus instrument that is configured to evacuate blood and/or other fluids from a target surgical site, such as the frontal sinus.

FIG. 33 shows an integrated wire dilatation catheter 120 that includes an elongate, flexible catheter shaft having a balloon mounted thereon.

FIG. 34 is a perspective view of another guide catheter system of the present invention incorporating the guide catheter component of FIG. 4A in combination with a long flexible endoscope and camera assembly.

FIG. 35 is a side view of a transnasal guide catheter.

FIG. 36 is a side view of a sheath that is insertable through the guide catheter of FIG. 7 to facilitate endoscopically guided advancement of a guidewire through the guide catheter of FIG. 35.

FIG. 37 is an enlarged view of a distal portion of the guide catheter of FIG. 35 having the sheath of FIG. 36, an endoscope and a guidewire operatively inserted there-through.

FIG. 37A is a cross sectional view through line 15A-15A of FIG. 15.

FIGS. 38A-38E show steps in a method for using the guide catheter of FIG. 35 in combination with the sheath device of FIG. 36 to facilitate endoscopically guided placement of a guidewire.

FIG. 39A is a perspective view of a deflectable (e.g., steerable) sheath device of the present invention in combination with a transnasally insertable guide catheter, a guidewire and an endoscope.

FIGS. 39B and 39C show steps in a method for using the deflectable sheath device of FIG. 39A to facilitate placement of a guidewire.

FIG. 39D shows the guidewire and guide catheter after removal of the steerable sheath and endoscope.

FIG. 40A is a partial exploded view of a guide system having an elongate guide tip, a translucent body and an endoscope that is engageable with the translucent guide body.

FIG. 40B shows the guide system of FIG. 40A in an assembled, operative state.

FIG. 40C is a schematic diagram of an endoscope monitor showing a view received by the endoscope component of the system shown in FIGS. 40A and 40B.

FIG. 40D is a partial perspective view of a guide system having an elongate guide member attached to and extending from the distal end of a catheter that has a side opening out of which an endoscope advances to view an area adjacent to the guide member.

FIG. 40E is a schematic diagram of an endoscope monitor showing a view received by the endoscope component of the system shown in FIG. 40D.

FIG. 41A is a sectional view of a proximal connector device of the present invention positioned adjacent to the device of FIG. 40A.

FIG. 41A' is a sectional view of a proximal connector device of the present invention operatively attached to the proximal end of the device of FIG. 40A.
FIG. 41B is a sectional view of a proximal connector device of the present invention positioned adjacent to the device of FIG. 40D.

FIG. 41B' is a sectional view of a proximal connector device of the present invention operatively attached to the proximal end of the device of FIG. 40D.

FIGS. 42A-42C are partial perspective views of the distal ends of curved guide catheters of the present invention having an endoscope with a distal end for cleaning a flexible endoscope translatable in the channel.

DETAILED DESCRIPTION OF THE INVENTION

Before the present devices and methods are described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural references unless the context clearly dictates otherwise. Thus, for example, reference to "a channel" includes a plurality of such channels and reference to "the endoscope" includes reference to one or more endoscopes and equivalents thereof known to those skilled in the art, and so forth.

The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to anticipate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

FIG. 1 shows one embodiment of a sinus guide system 10 of the present invention. This sinus guide system 10 comprises a sinus guide 12 and a camera/transmission/endocone assembly 14. This embodiment of the sinus guide 12 is shown in more detail in FIGS. 3A-3C. As shown, this sinus guide 12 comprises a sinus guide body 26 and an endoscope channel 28 in generally side-by-side arrangement. The sinus guide body 26 comprises a tube 44 having a lumen 45 (e.g., see FIG. 3B), such as a polymer tube made of biocompatible polymeric material. Optionally, a liner 46 (FIG. 3B) may be disposed within the lumen 45 of the tube 44. Such liner may be formed of lumbricius or smooth material such as polyethylene terephthalate/PETE). Also, optionally, a proximal portion of the tube 44 may be surrounded by an outer tube member 42 formed of material such as stainless steel hypotube. In the embodiment shown, a distal portion of tube 44 extends out of and beyond the distal end of outer tube 42. This protruding distal portion of tube 44 may be straight or curved. Also, it may be preformed at the time of manufacture or malleable to a desired shape at the time of use. When intended for use in accessing the ostium of a paranasal sinus, the proxial portion of tube 44 may be curved to form an angle A from about 0 degrees to about 120 degrees. For example, a series of sinus guides 12 having angles A of 0, 30, 70, 90 and 110 degrees may be provided thereby allowing the physician to select the sinus guide angle A that is most appropriate for the particular paranasal sinus ostium to be accessed. Additionally, in some embodiments, a rotation grip 60 may be positioned about a proximal portion of the sinus guide 10, as seen in FIGS. 1, 3A and 3B. This rotation grip 60 may have a smooth or textured round outer surface (e.g., it may be a cylindrical tube) that may be grasped between the fingers of the operator's hand and easily rotated, thereby facilitating rotation (e.g., rolling) of the sinus guide 12 as it is being used. Such rotation of the sinus guide 12 may be desirable for a number of reasons including but not limited to positioning of the distal end of the sinus guide 12 at a desired location and/or maneuvering the location of an endoscope 30 that is inserted through the endoscope channel 28.

The endoscope channel 28 may comprise any structure (e.g., tube, track, groove, rail, etc.) capable of guiding the advancement of a flexible endoscope. In the particular examples shown in these figures, the endoscope channel 28 comprises a tube (e.g., a polymer tube) having a lumen 29 extending therethrough. In the embodiment seen in FIGS. 1-3C, the endoscope channel 28 is attached to and extends along substantially the entire length of the sinus guide body 26. In another embodiment, the endoscope channel 28 can be inside the sinus guide body 26. In other embodiments, such as that shown in FIGS. 4A-4C and described herebelow, the endoscope channel 28 may be interrupted, non-continuous or may extend over less than the entire length of the sinus guide body 26. An outer skin 40 may be heat shrunk or otherwise disposed around the sinus guide body 26 and endoscope channel 28 to hold the
endoscope channel 28 at a desired position on the outer surface of the sinus guide body 26. Alternatively, the endoscope channel 28 may be attached to the sinus guide body 26 at one or more locations by any other suitable attachment substance, apparatus or technique, including but not limited to adhesive, soldering, welding, heat fusion, coextrusion, banding, clipping, etc. The particular circumferential location of the endoscope channel 28 can be important in some applications, particularly when the sinus guide body 26 includes a curve formed in its distal portion 44. In this regard, for some applications, the endoscope channel 28 may be affixed at a particular circumferential location on the sinus guide body 26 to allow a flexible fiber endoscope 30 inserted through the endoscope channel 28 to provide a view from a desired or optimal vantage point, without obstruction from adjacent anatomical structures. For example, FIGS. 11A, 11B and 11C show embodiments where the endoscope channel 28, 28p, 28s and 28u is attached to the sinus guide body 26 at alternative locations and wherein a curve is formed in the distal portion of tube 44.

In the example of FIG. 11A, the endoscope channel 28 is on the lower side of the sinus guide body 26 (e.g., the 6 o'clock position adjacent to the lesser aspect of the curve). This construction provides an endoscopic vantage point that is desirable for applications where the ostium of a sphenoid sinus is to be accessed.

In the example of FIG. 11B, the endoscope channel 28 is on the right side of the sinus guide body 26 (e.g., the 3 o'clock position adjacent to the greater aspect of the curve). This construction provides an endoscopic vantage point that is desirable for applications where the ostium of a maxillary sinus is to be accessed. Alternatively, the maxillary lumen may terminate before the distal end of the guide, then it can be located on the outside or on the side of the sinus guide body 26.

In FIG. 11C, the endoscope channel 28 is on the upper side of the sinus guide body 26 (e.g., the 12 o'clock position adjacent to the greater aspect of the curve). This construction provides an endoscopic vantage point that is desirable for applications where the ostium of a frontal sinus is to be accessed.

Again referring to FIGS. 1-3C, a proximal Y connector 41 may be attached to the proximal end of the sinus guide 12. A first arm 43f of this Y connector comprises a female Luer fitting that is connected to the lumen 45 of the sinus guide body 26. The other arm 43f is a female Luer fitting that is connected to the lumen 29 of the endoscope channel 26.

A camera/cable/endoscope assembly 14 is attachable to arm 43a. In the particular embodiment shown in FIGS. 1 and 3F, the camera/cable/endoscope assembly 14 comprises an adjustable scope/lock extension 16, an endoscope 18 having an elongate flexible scope body 30 and integrated light cable 50, a camera 20 and a monitor cable 24. The scope body 30 is advanced through the scope/lock extension 16 and through the lumen 29 of the endoscope channel 28. As shown in FIG. 2, the light cable 50 and monitor cable 24 may be connected to console 34 that houses a monitor 36, light source 38 and video recorder 40.

FIGS. 3D and 3E show a flexible endoscope 30 attached to a proximal body member 52 that engages and attaches to the adjustable scope/lock extension 16. As seen in the cross section of FIG. 3E, the scope 30 comprises a flexible shaft having an image fiber bundle 54 that extends coaxially through the center with light transmitting fibers 56 disposed about the periphery. In one preferred embodiment, the flexible shaft is a braided polyimide sheathing that has a maximum outer diameter of 0.0375 inches and a length of two feet. Preferably, the image fiber bundle is made up of 10,000 thin image fibers and the light transmitting fibers are illumination fibers with a diameter of between about 0.008 and 0.020 inches, with a minimum lumen of about 10,000. Preferably, the distal end of the flexible shaft has a lens with a minimum field of view of about seventy degrees.

**Sinus Guide With Proximal and Distal Endoscope Channel**

FIGS. 4A-5E show another embodiment of a sinus guide 12a which differs from the above-described sinus guide 12 of FIGS. 1 and 3A only in that it does not have a single continuous endoscope channel 28 that extends over its entire length, but rather a proximal endoscope channel 28p that is spaced apart from a distal endoscope channel 28d. These proximal and distal endoscope channels 28p and 28d may comprise any structure (e.g., tube, track, groove, rail, etc.) capable of guiding the advancement of an endoscope.

The proximal endoscope channel 28p extends along a proximal portion of the sinus guide body 26 and the distal endoscope channel 28d extends along a distal portion of the sinus guide body 26. The proximal channel 28p and distal channel 28d are oriented at an angle relative to one another such that there is an angle A between the respective longitudinal axes of the two channels. Also, this sinus guide 12a may optionally include a longitudinally moveable sheath 61 which is moveable from a retracted position (shown in FIGS. 5A and 5D described below) and an extended position (shown in FIG. 5C described below). In the FIGures, this embodiment of the sinus guide 12a is shown without a rotation grip 60. However, such a rotation grip 60 may be included in this and all other embodiments. If a rotation grip 60 is included, the moveable sheath 61 will be positioned over such rotation grip 60, or located distally of the distal edge of the rotation grip 60, when the sheath 61 is in its retracted position.

FIGS. 5A-5C show a method for loading the flexible fiber endoscope 30 into this embodiment. As seen in FIG. 5A, with the optional moveable sheath 61 in a retracted position, the flexible fiber endoscope 30 is advanced through the proximal endoscope channel 28p such that its distal end emerges out of the distal end of the proximal endoscope channel 28p. Thereafter, as seen in FIG. 5B, the direction and orientation at an angle with a gentle curve in the flexible endoscope and the distal most portion of the flexible endoscope being straight so that the fragile lens in the distal most portion of the flexible endoscope is not broken or damaged, but will facilitate insertion of the distal end of the flexible fiber endoscope 30 into or through the distal endoscope channel 28d. With the flexible fiber endoscope 30 so oriented, it is inserted into or through the distal endoscope channel 28d, as shown. Then, as seen in FIG. 5C, the optional moveable sheath 61 (if present) is moved to its advanced position so as to compress any slack in the flexible endoscope 30 and to hold a portion of the flexible endoscope 30 between the proximal endoscope channel 28p and the distal endoscope channel 28d in juxtaposition to the adjacent sinus guide body 26.
FIGS. 5D and 5E show fixture devices 240, 240a that may be used during loading of the flexible endoscope 30 to ensure that the distal end of the flexible endoscope 30 is oriented at an angle that will facilitate insertion into or through the distal endoscope channel 28d, while at the same time protecting the lens in the distal most portion of the flexible endoscope 30.

In FIG. 5D, the fixture device 240 comprises a rigid body formed of suitable material, such as molded plastic. A groove 242, shaped to correspond to a distal portion of the sinus guide device 12, is formed in the upper surface of the fixture device 240. The outer edge 243 of the fixture device 240 is shaped such that, when the endoscope 30 is extended along and in contact with such edge 243, the distal end of the endoscope 30 will be in an orientation that facilitates its passage into or through the distal endoscope channel 28d. After the distal end of the endoscope 30 has been successfully passed into or through the distal endoscope channel 28d, the sinus guide 12a and endoscope 30 are removed from the fixture device 240, the loading of the endoscope 30 is completed in accordance with FIG. 5C described above.

FIG. 5E shows another fixture device 240a which is substantially same as the fixture device 240 shown in FIG. 5D, but wherein an endoscope receiving groove 244 is also formed in the upper surface of the fixture device 240. This endoscope receiving groove 244 is shaped such that, when the endoscope 30 is placed in groove 244, the distal end of the endoscope 30 will be in an orientation that facilitates its passage into or through the distal endoscope channel 28d.

Optional Linkage of Endoscope to Working Device

In some applications, it may be desirable to advance the flexible endoscope 30 out of and beyond the distal end of the endoscope channel 28, 28a. For example, as shown in FIG. 6, the endoscope 30 may sometimes be advanced along side a working device, such as a guidewire 110, so as to view the advancement, positioning and/or use of the working device. In such instances, it is desirable to prevent the endoscope from diverging away from the working device and/or to maintain the endoscope 30 at a specific spaced distance away from the working device. To accomplish this, an optional linkage device 62 may be used to link (e.g., couple, connect or attach) the endoscope 30 to the guidewire 110 or other working device.

Sinus Guide With Dynamic Endoscope Channel

FIGS. 7A-7B show another embodiment of a sinus guide 12b which incorporates a spring loaded curved sinus guide body 26a and a dynamic endoscope channel 28a. In this example, the endoscope channel 28a comprises a flexible tube, wherein only the distal end of the dynamic endoscope channel 28a is attached to the sinus guide body 26a. A spring 64 is mounted between stop 47 and proximal sleeve 49 such that spring 64 may be compressed in the distal direction. As shown in FIG. 7A, the flexible endoscope 30 is inserted into the dynamic endoscope lumen 28a and advanced until the distal end of the endoscope begins to navigate the curve near the distal end of the device. This causes the endoscope channel 28a to deform or move outwardly and exerts distally directed pressure on spring 64, thereby compressing spring 64. As seen in FIG. 7B, as the distal end of the endoscope navigates the curve and advances to a position where it is flush with or extended out of the distal end of the endoscope channel 28a, the spring 64 will relax and the dynamic endoscope lumen 28a will return to a position where it extends along side of the sinus guide body 26, as shown.

FIGS. 8A and 8B show the sinus guide 12b as shown in FIGS. 7A and 7B with the inclusion of an optional retraction member 260, such as an elastic band, to assist the dynamic endoscope channel 28a in returning to its position along side the sinus guide body 26a after the distal end of the endoscope has successfully navigated the curve.

FIGS. 9A and 9B show another embodiment of a sinus guide 12c which is the same as the first embodiment 12 shown in FIG. 1 except that only a distal portion of the endoscope channel 28b is attached to the sinus guide body 26, a single female Luer hub 45 is on the proximal end of the sinus guide body and a separate single Luer hub 47 is on the proximal end of the endoscope channel 28b. A pivot arm 262 is pivotally attached to the sinus guide body 26, as shown. The proximal hub 47 of the endoscope channel 28b is slidably engaged within a spring loaded track 264 on the pivot arm. During loading of the endoscope 30, the pivot arm 262 is placed in an extended position and a spring within spring loaded track 264 causes the proximal proximal hub 47 to be located at the outer end of the spring loaded track 264, as shown in FIG. 9A. This causes the endoscope channel 28b to be held in a position that facilitates passage of the endoscope 30 through the endoscope channel and around the curve formed near its distal end. After the endoscope 30 has been advanced around the curve, the pivot arm 262 is moved to the collapsed position shown in FIG. 9b, thereby causing the spring within the spring loaded track 264 to compress and proximal hub 47 to move to the opposite end of spring loaded track 262. In this manner, the endoscope channel 28b extends along side of the sinus guide body 26 and the proximal hub 47 of the endoscope channel 28b is held in an accessible position adjacent to the proximal hub 45 of the sinus guide body 26.

Operation and Positioning of the Endoscope and Working Device

In the examples of sinus guides 12, 12a, 12b, 12c described above, the flexible fiber endoscope 30 may be freedly advanced to or beyond the end of the sinus guide and retracted during use, in order to facilitate endoscopic viewing of the desired anatomical structures and/or to view, guide and/or verify the positioning of the sinus guide device or a working device that has been inserted through the sinus guide. The ability to advance the tip of the flexible fiber endoscope 30 beyond the end of the sinus guide allows the tip to be positioned closer to anatomy or to reach spaces in the paranasal sinuses that the sinus guide tip cannot travel to due to size constraints.

In some instances, it may be desired to advance a guidewire 110 into or through a specific body opening, such as an opening of a paranasal sinus. In such applications, as shown in FIG. 10, it is sometimes desirable to form a bend in the guidewire 110 near its distal end DE so that rotation of the guidewire in situ will redirect its distal end DE. The guidewire may be maneuvered into the opening by simply rotating the guidewire 110. FIGS. 10A and 10B show an example of such a procedure, wherein the guide device 12 is advanced to a position where its distal end is a spaced distance D from the opening O into which the guidewire 110...
is to be inserted. In some instances, the user may use fluoroscopy and/or a surgical navigation system to position the guide device as described in previous applications to which this application claims priority and which have been incorporated herein by reference. With the guide device 12 so positioned, an endoscope inserted through the endoscope channel 28 may be used to view the distal end DE of the guidewire 110 as it advances out of the distal end of the sinus guide body 26. With the flexible endoscope 30 so positioned, the user has a view generally along the same axis as the distal opening of the guide device, rather than the proximal axis of the guide device. Furthermore the view can be from behind anatomy that normally would block a conventional endoscope view. In FIG. 10A, the view provided by the endoscope allows the operator to see that the distal end of the guidewire 110 is not directed into the opening O. As a result, the operator may rotate the guidewire 110 causing its distal end DE to be directed into the opening O as verified by the view provided from the endoscope. Thus, in these sorts of applications, it is desirable to place the distal end of the sinus guide device 12 at a spaced distance D back from the opening O rather than advancing it to a point where the distal end of the sinus guide body is immediately adjacent to or within the opening O. In an alternative embodiment, the guidewire can be an illuminating guidewire as described in co-pending application Ser. No. 11/522,497, titled “Methods and Devices for Facilitating Visualization in a Surgical Environment”, filed Sep. 15, 2006, which was incorporated by reference above, in its entirety, and/or as described in the following section.

Illuminating Guidewire

[0116] FIGS. 12A through 12D are illustrations of partial sagittal sectional views through a human head showing various steps of a method of gaining access to a parasanagal sinus using a sinus guide. In FIG. 12A, a first introducing device in the form of a sinus guide 12 is introduced through a nostril and through a nasal cavity 1012 to a location close to an ostium 1014 of a sphenoid sinus 1016. Sinus guide 12 may be strait, malicale, or it may incorporate one or more curved wires or bends as further described above, as well as in U.S. Patent Application Nos. 2006/004323; 2006/005973; and 2006/009506, for example, each of which are incorporated herein, in their entirety, by reference thereto. In embodiments where a sinus guide 12 is curved or bent, the deflection angle of the curve or bend may be in the range of up to about 135 degrees.

[0117] In FIG. 12B, a second introduction device comprising a guidewire 110 is introduced through the first introduction device (i.e., sinus guide 12) and advanced so that the distal end portion of guidewire 110 enters the sphenoid sinus 1016 through the ostium 1014.

[0118] In FIG. 12C, a working device 1006, for example a balloon catheter 100, is introduced over guidewire 110 and advanced to extend the distal end portion of device 1006, 100 into the sphenoid sinus 1016. Thereafter, in FIG. 12D, working device 1006, 100 is used to perform a diagnostic or therapeutic procedure. In this particular example, the procedure is dilatation of the sphenoid sinus ostium 1014, as is illustrated in FIG. 12D, where the balloon of device 1006 is expanded to enlarge the opening of the ostium 1014. After completion of the procedure, sinus guide 12, guidewire 110 and working device 1006, 100 are withdrawn and removed. It will be appreciated that the present invention may also be used to dilate or modify any sinus ostium or other man-made or naturally occurring anatomical opening or passageway within the nose, paranasal sinuses, nasopharynx or adjacent areas. As will also be appreciated by those of ordinary skill in the art, in this or any of the procedures described in this patent application, the operator may additionally advance other types of catheters, and that guidewire 110 may be steerable (e.g. torqueable, actively deformable) or shapeable or malleable.

[0119] FIGS. 12B-12D show an optional scope 30 in dotted lines, that may be inserted to provide visualization of advancement of sinus guide 12 and/or inserted alongside sinus guide 12 to provide visualization of all or at least a portion of working tool 1006, 100. It is to be appreciated that optional scope 30 may comprise any suitable types of rigid or flexible endoscope and such optional scope may be separate from or incorporated into the working devices and/or introduction devices of the present invention, as further described herein. In one preferred embodiment, endoscope 30 is a flexible fiber endoscope 30 as described herein.

[0120] Although scope 30 may be useful to reduce or eliminate the need for fluoroscopic visualization during placement of sinus guide 12 and/or for visualization of the procedure performed by working device 1006, 100, it does not provide stand-alone capability to see inside the sinus (e.g., sphenoid sinus 1016 or other sinus of interest), and therefore cannot provide sufficient visual feedback for use in guiding guidewire 110 into the desired sinus (e.g., frontal sinus, or some other sinus of interest) or sufficient visual image confirmation of correct placement of guidewire 110 into the desired sinus.

[0121] Further, depending upon the particular configuration of the sinus passageways to be traversed to gain access to a target ostium, the scope 30, due to physical limitations (e.g., outside diameter, degree of rigidity, etc.) may be unable to visualize as deep as the location of the ostium of interest. For example, FIG. 13 illustrates a situation where scope 30 has been inserted as far as possible without causing significant trauma to the patient. The range of adequately illuminated visibility in this case does not extend all the way to ostium 1020, as indicated schematically by the rays 1009 shown extending distally from scope 30. In this case, adequately illuminated visualization of guidewire 110 into ostium 1020 would not be possible via scope 30. Additionally, if sinus guide 12 is physically capable of being extended further distally to place the distal end thereof at the approach to ostium 1020, scope 30 would also not be capable of adequately visualizing this. Thus, prior to the provision of an illuminated guidewire 11 as described herein, fluoroscopic or other x-ray visualization of these procedures was required, in order to ensure that the devices approach (and extend through) the appropriate ostium 1020 and not another adjacent opening, such as opening 1024.

[0122] In order to overcome these and other problems, the guidewire devices 110 of the present invention include their own light emitting capability. By illuminating a distal end portion of guidewire 110, a process known as transillumination occurs as guidewire 110 traverses through the sinus passageways, passes through an ostium and enters a sinus cavity. Transillumination refers to the passing of light
through the walls of a body part or organ. Thus, when guidewire 110 is located in a sinus, the light emitted from guidewire 110 passes through the facial structures and appears as a glowing region on the skin (e.g., face) of the patient. It is noted that the light emitted from scope 30, such as positioned in FIG. 13, for example, results in transillumination as well, but the resultant glow is much more diffuse and larger in area. As the light source in guidewire 110 gets closer to the surface of the structure that it is inserted into (e.g., the surface of the sinus), the transillumination effect becomes brighter and more focused (i.e., smaller in area). Additionally, the movements of the guidewire 110 can be tracked by following the movements of the transillumination spot produced on the skin of the patient.

[0123] FIG. 14 shows an illuminating guidewire 110 according to one embodiment of the present invention. Device 110 includes a flexible distal end portion 110p that provides a similar degree of flexibility to a standard, non-illuminating type of guidewire. Distal end portion 110p may include a coil 110c as an exterior portion thereof, to help provide the desired flexibility to this portion. The proximal end portion 110p of device 110 extends the device to provide a sufficient length so that device 110 extends proximally outward of the patient (and, when inserted through another device, such as a sinus guide, proximally outward of the device into which guidewire 110 is inserted), at all times, including the deepest location into which the distal end of device 110 is placed. The proximal end portion 110p can have visible markings, preferably spaced at equal intervals, that can be observed by the user to confirm how far the guidewire 110 has been placed in the patient. Proximal end portion 110p also provides the necessary mechanical properties required to make the guidewire function properly. These mechanical properties include torqueability, i.e., the ability to torque the proximal end portion 110p from a location outside of the patient and have that torque transmitted to the distal end portion 110p; pushability, i.e., sufficient rigidity, so that when an operator pushes on the proximal end portion 110p from a location outside of the patient, the pushing force transmits to the distal end portion 110p to advance the distal portion 110p without buckling the device 110; and tensile strength so that an operator can pull on the proximal end portion 110p from a location outside of the patient and withdraw device 110 from the patient without significant plastic deformation or any disintegration of the device.

[0124] Coil 110c may be formed from a stainless steel wire, for example. The diameter of the coil wire can be between about 0.004 and about 0.008 inches, typically about 0.006 inches. Alternative materials from which coil 110c may be formed include, but are not limited to: ELGILOY®, CONICHIROME® or other biocompatible cobalt-chromium-nickel alloy; nickel-titanium alloys, or other known biocompatible metal alloys having similar characteristics. Further alternatively, distal end portion may comprise a braided metallic construction of any of the aforementioned materials in lieu of a coil.

[0125] The external casing of the proximal portion 110p may be made from a polyamide sheath, a continuous coil (optionally embedded in polymer or having polymer laminated thereon), a hypotube (e.g., stainless steel hypotube), a laser-cut hypotube, a cable tube, or a tube made from PEBAX® (nylon resin) or other medical grade resin. In any of these cases the construction needs to meet the required torqueability, pushability and tensile requirements of the device.

[0126] In the example shown, coil 110c is joined to proximal portion 110p by solder, epoxy or other adhesive or mechanical joint. One or more illumination channels 110i are provided in device 110 and extend the length thereof. Illumination channels 110i are configured to transport light from the proximal end of device 110 to and out of the distal end of device 110. In the example shown, two illumination channels are provided, each comprising a plastic illumination fiber. The plastic used to make the illumination fibers is compounded for light transmission properties according to techniques known and available in the art. As one example, ESKA™ (Mitsubishi Rayon), a high performance plastic optical fiber may be used, which has a concentric double-layer structure with high-purity polymethyl methacrylate (PMMA) core and a thin layer of specially selected transparent fluorine polymer cladding. In one example, illumination fibers each have an outside diameter of about 0.010". The inches to about 0.010 inches. Alternatively, a single plastic illumination fiber 110i may be used that has an outside diameter of about 0.020". Further alternatively, glass illumination fibers may be substituted which are much smaller in outside diameter, e.g., about 0.002". In this case, more illumination fibers may be provided in a bundle, e.g., about six to fifty glass fibers 110i may be provided.

[0127] The distal end of device 110 is sealed by a transparent (or translucent) seal 110w which may be in the form of epoxy or other transparent or translucent adhesive or sealing material. Seal 110w maintains the distal ends of illumination fibers 110i coincident with the distal end of device 110 and also provides an atraumatic tip of the device 110. Further, seal 110w prevents entrance of foreign materials into the device. The distal end can be designed to either focus or distribute the light as it emanates therefrom, to achieve maximum transillumination effects. In this regard, the distal end can include a lens, prism or diffracting element.

[0128] The proximal end of device 110 is also sealed by a transparent (or translucent) seal 110w which may be in the form of epoxy or other transparent or translucent adhesive or sealing material. Seal 110w maintains the proximal ends of illumination fibers 110i coincident with the proximal end of device 110. The proximal end of device 110 maybe further prepared by grinding and polishing to improve the optical properties at the interface of the proximal end of device 110 with a light source. The illumination fibers 110i at locations intermediate of the proximal and distal ends need not be, and typically are not fixed, since no mapping of these fibers is required, as device 110 provides only illumination, not a visualization function like that provided by an endoscope. Further, by leaving illumination fibers free to move at locations between the proximal and distal ends, this increases the overall flexibility and bendability of device 110 relative to a similar arrangement, but where the illumination fibers 110i are internally fixed.

[0129] The outside diameter of device 110 may be in the range of about 0.025 inches to about 0.040 inches, typically about 0.030 to 0.036 inches, and in at least one embodiment, is about 0.035±0.005". At least the distal portion 110p of device 110 is provided with a core support 110c that is
contained therein. In the example shown in FIG. 14, core support 110cw is a wire that is fixed to proximal section 110p such as by laser welding, epoxy or other adhesive or mechanical fixture. Core support 110cw may extend substantially the full length of device 110. In any case, core support 110cw is typically formed from stainless steel NITINOL (nickel-titanium alloy) or other biocompatible nickel-titanium alloys, cobalt-chromium alloys, or other metal alloys that are biocompatible and provide the necessary rigidity and torquability. Core support 110cw may be formed as a wire, as in the example shown in FIG. 14, or alternatively, may be braided from any of the same materials or combination of materials mentioned above. Core support 110cw, when formed as a wire can be ground to different diameters to provide varying amounts of rigidity and torquability. When formed as a braid, the braid can be formed to have varying amounts of rigidity and torquability along the length thereof. For example, core wire 110cw has a larger outside diameter at the proximal end portion than at the distal end portion so that it is more rigid and transfers more torque from the proximal portion of device 110, whereas at the distal end portion, core 110cw is relatively more flexible and twistable. For core supports 110cw that extend through proximal portion 110p, the portion of core support near the proximal end of device 110 may have an even larger outside diameter.

[0130] Core support 110cw particularly increases the pushability and the torquability of coil 110c which, by itself, is quite flexible and twistable. Combined with the core support 110cw, the distal portion is much more effective at transferring pushing and torque forces without buckling or twisting. Additionally, core support 110cw may be plastically deformed or memory set into a bent shape, an example of which is shown in FIG. 5. Bend 110a provides a steerable function, allowing an operator to direct the distal end of device 110 in different directions by torquing device about the longitudinal axis of the device, as indicated by the arrows in FIG. 15. In some embodiments this bending can be performed by an operator in the midst of a procedure, which can be particularly useful in combination with a scope 30, as viewing through the scope may make it apparent to the operator that the guidewire 110 needs to be inserted or directed at an angle offset from where the straight direction along the longitudinal axis of the device would direct it to. In some embodiments, the guidewire 110 does not have a core support or core wire. In these embodiments, the outer jacket (e.g., a coil, cable tube, laser-cut hypotube, braided polymer tube, etc.) provides the support for torque, pushability and tension. An advantage of not having a core wire/core support is that the full inner diameter of the guidewire is then available to be filled with illumination fibers.

[0131] The illumination fibers, as noted above, can be free to move about radially within the device. Further, there is no need to center the illumination fibers 110i with respect to device 110 even at the distal and proximal ends of the device. FIG. 16 is a sectional illustration of a distal end portion of device 110 showing core support 110cw fixed to coil 110c, with illumination fibers 110i residing adjacent to core support 110cw, but not fixed to either core support 110cw or coil 110c.

[0132] The plastic or glass illumination fibers 110i of the device shown in FIG. 14 are typically used to transmit light from a light source such as one provided in an operating room for use by endoscopes, e.g., xenon light source, halogen light source, metal halide light source, etc. Alternatively, device 110 may be configured to transmit light from other light sources, such as a laser light source, wherein laser fibers 110f would be substituted for the illumination fibers described above, and extend through device 110 in a fiber optic bundle as illustrated in the cross-sectional view of FIG. 17. The fiber optic bundle, like the illumination fibers 110i, contributes to stiffness (in both bending and torquing motions) of device 110, thereby enhancing trackability, steering and other torquing.

[0133] FIG. 18 illustrates another embodiment of an illuminating guidewire 110. In this example, proximal end portion of device 110 is formed externally by a coil with a polymer layer laminated thereon, but any of the other arrangements described above may be substituted. In this example, illumination is provided by a high intensity light emitting diode (LED) 110id fitted at the distal end of device 110. The proximal end of device 110 may be sealed such as with epoxy, or any of the other alternatives mentioned above with regard to the proximal end of device 110 in FIG. 14, in order to prevent pulling on the wires 110iw at the connections with LED 110id, as well as to seal the proximal end of the device. Grinding and polishing are not necessary, as the proximal end of device 110 in FIG. 18 does not transmit light.

[0134] Device 110 in FIG. 18 performs substantially similar to the device 110 of FIG. 14 with regard to the properties of pushability, torquability and tensile properties. Device 110 of FIG. 18, however, does not require illumination fibers or laser fibers. Instead, a pair of insulated lead wires are electrically connected to the terminals of LED 110id (not shown) and then extend within device 110 over the length of device 110 to extend proximally from the proximal end of device 110. The free ends of wires 110w are configured to be connected to a power source that functions as the source of electrical power, to deliver electrical energy to LED 110id to illuminate it. FIG. 19 illustrates a cross-sectional view of a distal end portion of device 110 of FIG. 18. In this example, core support 110cw is in the form of a flattened distal end core wire or shaping ribbon as known in the art, that extends between the two wires 110w. FIG. 19 also illustrates the insulation layer 110iw over each wire.

[0135] Any of the devices 110 described herein may optionally include one or more radiopaque markers and/or electromagnetic coils on the tip of the device 110 and/or elsewhere along the device for enhancing visibility by fluoroscopy systems, image guided surgery (IGS) systems, or other visualization systems.

[0136] FIG. 20 shows an alternative design of device 110 in which light is emitted proximally of the distal end of the device. This configuration may employ any of the various light transmission means described above (e.g., illumination fibers, laser fibers, LED). The proximal portion 110p may be constructed in any of the manners described above with regard to other embodiments of device 110. The distal portion 110d includes a transparent proximal end portion 110dp that mounts over the distal end of proximal end portion 110p of the device 110. The transparent portion 110dp permits the illumination emitted from illumination member 110i or 110id to pass out of the device 110 at the
location of transparent portion 110dp. The illumination member(s) 110i or 110id thus terminate at the proximal end portion 110dp of the distal end portion of device 110. Distally of this transparent portion 110dp, the distal portion 110dd of distal end portion 110d of device 110 extends as a floppy guidewire leader or tip. This floppy guidewire leader or tip 110dd may include a coiled section 110c and may optionally include a core support 110sw in the manner described above with regard to FIG. 14. The light emitted from illumination fibers 110i or 110id will disperse naturally through the transparent portion 110dp. Optionally, a deflector 111, such as a convex mirror (e.g., parabolic or other convex) shape or other reflective surface may be provided distally of illumination fibers/light emitting portion 110i, 110id of device 110 to deflect light rays out of the transparent portion. Additionally, or further alternatively, illumination fibers 110i may be angled at the distal end portions thereof to direct the emitted light out through the transparent portion.

[0137] This configuration may be beneficial in further protecting the illumination emitter(s) 110i, 110id from foreign materials inside the body, as well as from trauma that may be induced by bumping the illumination emitter up against structures within the body. Further, a floppy guidewire leader 110dd of this type may provide more flexibility and maneuverability than a device in which the illumination emitter is located on the distal tip of the device.

[0138] Transparent portion 110dp may be provided as a clear plastic or glass integral tube, or may have openings or windows 110e provided therein (see the partial view of FIG. 21). Further alternatively, transparent portion may be formed by a plurality of struts 110st circumferentially arranged to interconnect the distal floppy tip 110dd with the proximal end portion 110p of device 110 as shown in the partial illustration of FIG. 22. Alternatively members 110st may be intersecting in a criss-crossing cage like configuration or other cage configuration. In any of these alternative configurations, members 110st may be transparent, but need not be and could be formed of non-transparent materials, such as metals or opaque plastics, for example.

[0139] Device 110 should be readily connectable to and disconnectable from a power source to enable attachment for providing illumination for positioning the guidewire 110 and/or other devices during a procedure, to allow another device to be slid onto the guidewire 110 from a free proximal end thereof, and reattachment to again provide illumination, to assist in guidance/visualization of the device being passed over the guidewire 110, for example.

[0140] FIGS. 23A and 23B illustrate one example of a coupler or connector 1120 that is configured for quick connection and disconnection of an illumination guidewire 110 that employs illumination fibers 110i or laser fibers 110f. Coupler 1120 is connected to a light source 1030, such as a conventional endoscope light source, for example, or other light source capable of delivering preferably at least 10,000 lux through coupler 1120. Light cable 1032 optically connects connector 1120 with light source 1030 to deliver light from the light source 1030 to connector 1120. Light cable 1032 can optionally be a fluid-filled light cable, such as the type provided with DYMAX BlueWave™ 200 and ADAC Systems Cure Spot™ light cables, for example. A liquid filled light cable comprises a light conducting liquid core within plastic tubing. The liquid is non-toxic, non-flammable and transparent from 270 to 720 nm. The ends of a liquid filled light cable can be sealed with high quality quartz glass and metal spiral tubing surrounded by a plastic sleeve for exterior protection.

[0141] Connector 1120 includes a proximal channel, slot or bore 1122 that has an inside dimension or circumference that is slightly greater than the outside diameter or circumference of device 110 at the proximal end portion 110p. A quick release locking mechanism 1124 is provided for locking and unlocking device 110 within connector 1120. Quick release locking mechanism is biased toward the locking position shown in FIG. 23B, in which the locking portion 1124 of mechanism 1124 is driven into channel slot or bore 1122 and may even abut against the opposite wall of the channel, slot or bore 1122, when no guidewire 110 has been inserted. Locking mechanism 1124 may be spring-biased toward the locked position, for example. Additionally, locking mechanism 1124 may include a ball and detent arrangement, or other temporary locking means to maintain the mechanism 1124 in the locked configuration. An additional, similar mechanism may be provided to temporarily fix locking mechanism 1124 in the unlocked configuration as shown in FIG. 23A. Alternative locking mechanisms may be employed, such as a pivoting lock arm, for example, that is manually pivotable between the locked and unlocked orientations, or other mechanism that would be apparent to one of ordinary skill in the mechanical arts, such as a collapsible silicone valve that grips the device, for example.

[0142] Light cable 1032 generally has a much larger inside diameter than the inside diameter or combined inside diameters of the illumination fibers 110f. Accordingly, the proximal end portion of connector 1120 provides a tapering or funnel shaped pathway 1126 having a proximal inside diameter that is substantially equivalent to the inside diameter of cable 1032 or greater, and which tapers to a distal inside diameter that is about the same or only slightly greater than the inside diameter or combined inside diameters of the illumination fiber(s), or alternatively, that is about the same or only slightly greater than the outside diameter of the proximal end of device 110. The light cable 1032 generally has a larger diameter bundle of illumination fibers than that contained within the illuminating guidewire 110. Accordingly, the taper 1126 is used to transition between the larger bundle in the light cable 1032 and the smaller bundle in the guide wire 110. With this arrangement, light delivered through light cable 1032 is concentrated or focused down to a pathway where most of the light can be transmitted through the illumination fibers.

[0143] To insert device 110 into connector 1120, an operator retracts quick connect locking mechanism 1124 to the open position shown in FIG. 23A. If quick connect mechanism 1124 is provided with a temporary locking mechanism as referred to above, then quick connect locking mechanism 1124 can be temporarily fixed in the orientation shown in FIG. 23A, without the operator having to hold it open. Otherwise, the operator will hold connector 1124 open in the position shown in FIG. 23A. The proximal end of device 110 is next inserted into the open channel, slot or bore 1122 and slid proximally with respect to connector 1120 until the proximal end of device 110 abuts against the proximal end of channel, slot or bore 1122. Quick release mechanism is next released by the operator (in embodiments when there is
no temporary locking mechanism to maintain the quick release in the open configuration) or released from the temporary locked open configuration, so that the locking arm 1124a is advanced toward the proximal end portion 110p of device 110, by the biasing of quick connect locking mechanism 1124 described above. Locking arm 1124a contacts device 110 and holds device 110 under compression between locking arm 1124a and the opposite inner wall of channel, slot or bore 1122, with sufficient force to prevent device 110 from sliding out of connector 1120 even if the distal tip of device 110 is pointed straight down in a vertical direction. Optionally, locking arm 1124a may be additionally temporarily locked in place by a ball and detent mechanism, or other temporary locking mechanism, as mentioned above. To remove device 110 from connector 120, quick connect locking mechanism 1124 is repositioned to the open or unlocked orientation shown in FIG. 23A and the device is slid distally with respect to the connector until it is free from the connector 1120.

[0144] FIGS. 24A-24B illustrate an alternative connector 1120 that includes a quick release locking mechanism 1124. In this example, two or more locking arms 1124 are provided circumferentially about the distal end of connector 1120. Arms 1124 are biased to the closed or locked configuration as shown in FIG. 24A. For example, arms 1124 may be made from resilient spring steel, nickel-titanium alloy or resilient plastic and formed to assume the configuration shown in 24A when mounted to connector 1120 and when in an unbiased state. Installation of device 110 into connector 1120 is simplified by the automatic grasping and temporary locking functions provided by quick release locking mechanism 1124. The proximal end of device 110 is simply inserted between the two or more arms 1124. Arms 1124 included ramped or cammed surfaces 1124b that guide the proximal end of device 110 into connector 1120, and, as device 110 is pushed against these surfaces 1124b, arms 1124 are deflected into the opened, biased configuration shown in FIG. 24B. The biasing/resiliency of arms 1124 imparts compressive forces to the shaft of device 110 via temporary locking surfaces 1124a, so that device 110 is gripped and held in position as shown in FIG. 24B. To remove device 110, the operator need simply pull on device 110, while holding connector 1120 relatively immobile, with a force sufficient to overcome the compressive and frictional forces imparted by surfaces 1124a. The resilient arms 1124 then return to the unbiased configuration shown in FIG. 24B. Optionally, surfaces 1124a may be coated with, or include a friction enhancing surface, such as rubber or other elastomer, and/or be roughened, such as by knurling or other surface roughening technique.

[0145] In the example shown in FIGS. 24A-24B, the light cable 1032 that is provided has an inside diameter that is about the same as the diameter of the proximal end of device 110 and thus, no tapering channel 1126 is required. However, for arrangements where the light cable 1032 is much larger, as is usually the case when using a conventional endoscope light source 1030, connector 1120 may be provided with a tapering light channel 1126 in the same manner as described above with regard to the embodiment of FIGS. 23A-23B.

[0146] FIG. 25 illustrates a longitudinal sectional view of a connector 1120 that is quickly connectable and releasable from a guidewire device 110 and is also connectable to and releasable from standard light source cables that are typically found in operating rooms. Thus, this connector 1120 functions both as an adapter to connect to a conventional endoscope light source channel or cable, and as a quick release locking connector to connect to and release from a proximal end portion of guidewire 110.

[0147] The proximal end of connector 1120 is provided with a light post 1128 that is configured to mate with a connector on the distal end of a light cable extending from a conventional endoscope light source. For example, light post 1128 may be an ACM light post (ACMI Corporation) or other standard connector typically used to connect endoscopes to operating room light sources. Because the cable extending from an operating room light source generally has a much larger inside diameter than the inside diameter or combined inside diameters of the illumination fibers of device 110, and larger than the diameter of the proximal end of guidewire 110, the proximal end portion of connector 1120 includes a light tapering or funnel-shaped pathway 1126 like that described above with regard to FIG. 23A.

[0148] The quick release locking mechanism 1124 in this example includes a collet 1124c that is configured to center the proximal end of device 110 with the distal end of tapering pathway 1126A. A threaded cap 1124d is threaded over mating threads 1124a on the body of connector 1120, so that when cap 1124d is torqued in a direction to advance cap 1124d proximally with respect to the body of connector 1120, inner ramped or cammed surfaces 1124e of cap 1124d ride over outer ramped or cammed surfaces 1124f of collet 1124c, thereby functioning as a pin vise and clamping collet 1124c against the proximal end portion of device 110 to clamp and maintain device 110 in its current position relative to connector 1120. To insert device 110, cap 1124d is rotated in a reverse direction from that described above to open the distal opening of the inner channel 1124g of collet 1124c to a dimension larger than the outside diameter of the proximal end of device 110, so that device 110 can be easily slid through the channel 1124g until the proximal end of device 110 abuts the proximal end portion of collet 1124c, or approximates the same. The cap 1124d is then turned with respect to the body of connector 1120 to clamp device 110 into position, as described above. Removal of device 110 can be performed by turning cap 1124d in a reverse direction relative to connector body 1120, thereby loosening the grip of collet 1124c on device 110, after which device 110 can be easily slid out from connection with connector 1120. Components of connector 1120 may be made from metal, such as stainless steel or other biocompatible metals, or temperature-resistant thermosetting polymer, for example.

[0149] Light post 1128 is rotatable with respect to the light cable 1032 of the light source 1030 when connector 1120 is connected to the distal end connector of the light cable 1032. This allows device 110, when connected to connector 1120 in this arrangement, to be rotated during use without building up significant twisting or rotational counter forces within the light cable 1032. For example, in the light post 1128 shown, the female receptacle (not shown) of the light cable 1032 couples over light post 1128 and engages in groove 1128a, about which the female receptacle is then rotatable relative to light post 1128. FIG. 26 is a longitudinal sectional view of a connector 1120 that is similar to the connector 1120 described with regard to FIG. 25 above. One difference in the example of FIG. 26 is that the tapered light guide 1126
is provided in the light post 1128, as contrasted with being provided in the proximal end portion of the main body of connector 1120 in FIG. 25. However, in both cases, the function is the same.

[0150] Turning now to FIGS. 27A-27E, illustrations of partial coronal sectional views through a human head showing various steps of a method for treating an ostium that opens to a frontal sinus are shown. The methods described here, and all other methods disclosed herein may also comprise a step of cleaning or lavaging anatomy within the nose, paranasal sinus, nasopharynx or nearby structures including but not limited to irrigating and suctioning. The step of cleaning the target anatomy can be performed before and/or after a diagnostic or therapeutic procedure. The methods of the present invention may also include one or more preparatory steps for preparing the nose, paranasal sinus, nasopharynx or nearby structures for the procedure, such as spraying or lavaging with a vasoconstricting agent (e.g., 0.025-0.5% phenylephrine or Oxymetazoline hydrochloride (Neoynephrine or Afinin) to cause shrinkage of the nasal tissues, an antibacterial agent (e.g., providine iodine (Betadine), etc. to cleanse the tissues, etc.

[0151] In FIG. 27A, a first introducing device in the form of a sinus guide 12 is introduced through a nostril and through a nasal cavity 1012 to a location close to an ostium 1034 of a frontal sinus 1036. Sinus guide 12 may be as described previously herein, or as described in the applications incorporated herein by reference. The advancement of sinus guide 12 can be visualized with a scope inserted into the nasal cavity 1012 and advanced as close to the ostium 1034 as possible without causing significant trauma to the tissues therein.

[0152] Once the surgeon is satisfied that the distal end of the sinus guide 12 is positioned close enough to the appropriate ostium 1034, illuminating guidewire 110, connected to a light source as described by any of the techniques mentioned above, is inserted through sinus guide 12 and advanced therethrough, see FIG. 27B. There may be some transillumination from the light emitted from the scope which can be used to confirm that the sinus guide 12 is positioned in the correct general area, which confirmation can be made even before the distal tip of guidewire 110 exits the distal end of sinus guide 12. However, much more specific transillumination effects are produced when the tip of guidewire 110 exits the distal end of guide 12 and especially when the light emitting portion of guidewire 110 touches or approximates an intended target surface, such as an inner wall of a sinus, for example. As the guidewire 110 is advanced, transillumination on the face of the patient can be observed as a glowing spot that moves as the distal end portion of device 110 moves, thereby making it possible to visibly track the location of the light emitting portion of device 110 without the need to use radiographic imaging, such as by fluoroscopy, for example.

[0153] While there may be some diffuse transillumination on the forehead of the patient overlying the frontal sinus 1036 as the light emitting portion of device 110 approaches the ostium 1034, the glow on the forehead becomes brighter and smaller in dimension (more focused) as the light emitting portion passes through the ostium 1034 and enters the frontal sinus 1036, FIG. 27C. As device 110 is further advanced, the glowing spot becomes most defined and brightest as the light emitting portion approaches and contacts a wall of the frontal sinus 1036. Further, as noted, the movement of the transilluminated spot can be visibly followed to confirm that the guidewire 110 is indeed moving within the location of the frontal sinus, as can be confirmed by the surgeon's knowledge of the particular anatomy of the patient being treated. In this regard, a CAT scan or other image of the sinus anatomy can be performed prior to this procedure and studied by the surgeon, to apprise the surgeon of any distinctive or unusual patterns in the individual patient's sinus anatomy which might be useful in tracking and confirmation of where the guidewire is located, as indicated by the transillumination.

[0154] Once properly positioned, the proximal end of device 110 is disconnected from connector 1120, while leaving guidewire 110 in its current position. A working device 1006, for example a balloon catheter 100, is the introduced over guidewire 110 and advanced thereover so that the proximal end of device 110 extends proximally beyond a proximal end of device 1006, 100. Device 110 is then reconnected to connector 1120 so that light is again emitted from the light emission portion of the distal end portion of device 110. Thus it can be visually confirmed, without radiography, that the distal end portion of the guidewire 110 remains properly in the frontal sinus 1036 as the working device 1006, 100 is advanced toward ostium 1034 and the balloon of balloon catheter 100 is extended across the ostium, FIG. 27D. The proper positioning of the working end (distal end portion) of working device 1006, 100 can be visualized with the scope and/or fluoroscopy.

[0155] Once proper placement of the working device 1006, 100 has been confirmed, working device 1006, 100 is used to perform a diagnostic or therapeutic procedure. In this particular example, the procedure is dilatation of the frontal sinus ostium 1034 by expansion of the balloon of balloon catheter 100 thereagainst, to enlarge the opening of the ostium 1034. However, it will be appreciated that the present invention may also be used to dilate or modify any sinus ostium or other man-made or naturally occurring anatomical opening or passageway within the nose, paranasal sinuses, nasopharynx or adjacent areas. Further, other working tools 1006 may be inserted and used according to these same techniques. After the completion of the procedure, sinus guide 12, guidewire 110 and working device 1006, 100 are withdrawn and removed, completing the procedure, see FIG. 27E.

[0156] Illuminating guidewire device 110 can also be used to facilitate visualization and placement of the sinus guide 12 in the procedure described above with regard to FIGS. 27A-27E, or in another procedure in which a sinus guide, sinus guide or guide tube is placed in the sinus pathways. FIG. 28 illustrates a situation, like that described above with regard to FIG. 13, where scope 30 has been inserted as far as possible without causing significant trauma to the patient. The range of visibility in this case does not extend all the way to ostium 1034, as indicated schematically by the rays 1009 shown extending distally from scope 30. In this case, adequate visualization of sinus guide 12 by scope 30 is possible only up to the extent of the rays 1009 shown. Thus, if sinus guide 12 is flexible enough to be advanced more closely to ostium 1034, then adequate visualization of this movement would not be possible via scope 30. That is, if sinus guide 12 is physically capable of being extended
further distally to place the distal end thereof at the approach to ostium 1034, scope 30 would not be capable of adequately visualizing this. However, by inserting illuminating guidewire 110 through sinus guide 12 as shown in FIG. 28, additional illumination can be provided distally of the illuminating range of scope 30. This additional illumination can be received by scope 30 to enable visualization up to the illumination portion of device 110 and potentially even extending to illumination range of device 110, as long as there is a straight pathway of the field of view. Thus, advancement of the sinus guide 12 can be visualized further distally by the scope 30 using this technique, and potentially all the way up to the ostium 1034.

[0157] Additionally, this technique can be used to visualize placement of the guidewire 110 up to and into the desired ostium 1034. Alternatively, this can be carried out without the sinus guide 12, wherein the guidewire 110 is inserted and the scope 30 can be used to visualize placement of guidewire 110 into the target ostium with the assistance of the light emitted by the scope 30 in addition to the light emitted by guidewire 110.

[0158] In any of these procedures where a scope 30 is used for visualization and an illuminating guidewire 110 is inserted, some transillumination of the target sinus may occur from the light emitted by the scope 30 alone. However, this transillumination will be diffuse and show a rather dim, large area of transillumination on the patient’s skin. When the illumination guidewire 110 is inserted and advanced, as noted earlier, a smaller, brighter transillumination spot will be visible when the illuminating portion of the guidewire has entered the sinus. Additionally, even before entering the sinus, the light emitted from the guidewire 110 will produce a moving transillumination spot as guidewire 110 is advanced, which also helps distinguish the location of the distal portion of the guidewire 110, relative to any diffuse transillumination produced by the scope light.

[0159] If the guidewire 110 is advanced into an ostium other than the target ostium (e.g., ostium 1035 shown in FIG. 28), this may be possible to be viewed by scope 30, depending upon the line of sight. However, even if it is not, the transillumination resulting from entrance into a different sinus than the target sinus will be evident by the different location on the patient’s face. Also, in the example shown, guidewire 110 would not be able to be advanced very far through ostium 135 before it was diverted and curled by the relatively small sinus space that ostium 135 lends into. Thus, by tracking the movement of the illumination spot produced by guidewire 110, the surgeon could confirm that guidewire 110 was misplaced as the guidewire would be diverted by a much smaller space than that characterized by the target frontal sinus 1036.

[0160] Thus, by using an illuminating guidewire device 110 in the methods as described above, the use of fluoroscopy or other X-ray visualization can be reduced as it is not required to confirm proper placement of the guidewire in some cases.

[0161] Similar procedures may be carried out in other sinuses. For example, a similar procedure to that described above with regard to FIGS. 27A-27E may be carried out to open or expand an opening of an ostium leading to a maxillary sinus. In this case, when illuminating guidewire device 110 passes through the ostium that opens to the target maxillary sinus and enters the maxillary sinus, a relatively bright, relatively small, defined transillumination spot can be observed to move across the cheek region of the patient. As guidewire 110 is advanced further distally along the maxillary sinus, the maxillary sinus typically tends to track in an inferior direction relative to the skull, and the bottom wall of the maxillary sinus is very close to the palate of the patient. Therefore as the illuminating portion of guidewire approaches and/or touches the bottom wall of the maxillary sinus, a transillumination spot can be observed on the roof of the patient’s mouth by looking into the mouth of the patient. At the same time, the transillumination spot on the cheek that was caused by the guidewire will diminish, or not be visible at all at this time. This viewability on the roof of the mouth is further confirmation that the guidewire has entered the maxillary sinus. Movement of the transillumination spot on the roof of the mouth can also be observed as the guidewire 110 is advanced and/or retracted.

[0162] It is further noted that some wavelengths of light may be more effective in producing the transillumination effects described herein, for the purpose of locating the position of the guidewire. In this regard, particular wavelengths of visible light can be selected for this purpose. Alternatively, or in addition, infrared wavelengths may be particularly effective. In this regard, guidewires that employ illuminating fibers may be provided with a filter 1112 to define the color/wavelength of the light emitted by device 110. As schematically shown in FIG. 29, filter 1112 may be provided distally of the illumination fibers, such as at the distal tip of device 110, proximally of the illumination fibers, such as at the proximal end of device 110, or in the light pathway at a location within connector 1120, for example. Multiple filters may be placed at one or more of these locations. For devices 110 that employ an LED light emitting component, different color LEDs may be employed to emit different wavelengths of light. For devices 110 that employ laser fibers, different types of lasers may be used that emit different wavelengths of light.

[0163] Another optional feature that guidewire 110 may be provided with is the ability to emit strobed, flashing or flickering light. The transillumination produced by a flashing light can be further distinguished from diffuse transillumination produced by other light sources, such as endoscopes, for example, since the transillumination produced by the guidewire 110 in this case will flicker or vary in intensity between bright and dim. To produce this type of light, either a light source having strobing capability could be connected to the device 110, or connector 1120 may be provided with this capability. When using a laser light source or an LED as the light emitter, as described in embodiments above, a blinking or strobing effect can be electronically generated according to techniques known in the electronics and lighting arts. FIG. 30A schematically illustrates a connector 1120 having a rotating shutter 1127 rotatably mounted therein so that the vanes 1127a and gaps 1127b between the vanes (see plane view in FIG. 30B) become successively aligned with the light pathway through the connector 1120 to alternate emission and blocking of light transmission out of the connector 1120 and ultimately through device 110 when a device 110 is connected thereto. Shutter 1127 can be powered by a motor 1129 that is either battery powered or connectable to an operating room power source, and motor can be operated by the user via actuator 1134, which can be configured to turn the motor on and off, and optionally can
be configured to vary the speed of rotation. Alternatively, shutter can be configured so that vanes extend through a slot in connector whereby a user can manually rotate the shutter to cause the light emitted from device to flicker.

[0164] Other instruments that are designed to be inserted into a sinus, or at least to be positioned at the ostium of a sinus can also be provided with illumination capability according to any or all of the features described above with regard to illumination guidewires. FIG. 31 shows a frontal ostium seeker instrument that can be used to access a sinus ostium. For example, seeker may be provided with a length of about 175 mm to about 250 mm (about 208 mm in the example shown) and a ball tip at one or both ends of the instrument. In FIG. 31, seeker includes a light emitter at one or both ends of the device that can be used to locate an end of device as it is being advanced to seek an ostium, by the transillumination effects as discussed above. Light emitter may be provided by LED, light illumination fibers or laser illumination fibers, for example. One or both end portions of the instrument may include a light fiber bundle or electrical wires for connection to a light source or power source in a manner as described above.

[0165] FIG. 32 shows a suction sinus instrument that is configured to evacuate blood and/or other fluids from a target surgical site, such as the frontal sinus, sphenoid sinus or other sinus, to improve visibility of a surgical procedure. Instrument includes an elongated shaft with a distal end that opens to deliver suction via a suction lumen end. Additionally, a light emitter is provided at the distal end of shaft, which may be an LED or one or more illumination fibers configured to transmit light in a manner as described above. Shafts are configured and dimensioned to be inserted into the sinus passageways and sinuses. The proximal end portion of instrument includes a light fiber bundle or electrical wires for connection to a light source or power source in a manner as described above.

[0166] FIG. 33 shows an integrated wire dilatation catheter having a balloon mounted thereon. A proximal Luer hub is attached to the proximal end of the catheter shaft. An inflation device (not shown) may be attached to the Luer hub and used to inflate and deflate the balloon. A non-removable, integrated guide member extends out of and beyond the distal end of the catheter shaft. Guide member can extend through the length of catheter shaft and extend proximally thereof as shown in FIG. 33. The proximal end portion may be configured with a polished proximal end containing illumination fibers, as described previously, or may have one or more electrical wires extending proximally thereof for connection with an electrical power source to deliver electrical power to an LED, for example. A light emitter may be provided at the distal tip of integrated guide member, as shown in FIG. 33 and may be one or more LEDs or one or more illumination fibers, according to any of the different embodiments described above. Alternatively, light emitter may be provided proximally of the distal tip of guide member, in a manner like that described with regard to FIG. 20, for example. Further alternatively, guide member may not extend through the entire length of catheter or may not extend proximally of balloon member at all. In these examples, light emitter may be an LED, wherein wires can be threaded through or alongside of catheter and into guide member to connect with the LED. Further alternatively, if light emitter comprises one or more illumination fibers, the illumination fibers may extend proximally of the proximal end of the guide member, and proximally through catheter where they are not surrounded by an external sheath in a guidewire formation.

[0167] In one preferred embodiment for adult applications, balloon catheter has an overall length of approximately 43.5 cm and its shaft has an outer diameter of approximately 0.058 inches. Further details about integrated wire dilatation catheters that may be configured with a light emitter in a manner as described herein can be found in co-pending application Ser. No. 11/438,090 filed May 18, 2006 and titled “Catheters with Non-Removable Guide Members Useable for Treatment of Sinusitis” application Ser. No. 11/438,090 is hereby incorporated herein, in its entirety, by reference thereto.

Extralong Endoscope

[0168] As seen in FIG. 2, when the system shown in FIG. 1 is used, the camera/transmission/endoscope assembly is attached to the proximal end of the sinus guide device and must be held or supported a spaced distance above the subject’s chest during performance of the procedure. FIG. 34 shows an alternative system which incorporates a long flexible endoscope and a different camera/transmission/endoscope assembly. FIG. 34 shows an alternative system which incorporates a long flexible endoscope and a different camera/transmission/endoscope assembly.

[0169] The long flexible endoscope has an extended length, preferably at least about two feet long, such that a portion of the flexible endoscope extends between the proximal end of the sinus guide device and the camera/transmission/endoscope assembly, thereby allowing the camera/transmission/endoscope assembly to rest upon the subject’s chest or on a nearby structure (e.g., a tray, clip, clamp, on the adjacent surface of the operating table, etc.). This eliminates the need for the operator to hold or support the weight of the camera/transmission/endoscope assembly in addition to that of the sinus guide. Rather, with the camera/transmission/endoscope assembly resting upon the subject’s chest or on a nearby structure, the operator need only hold or support the sinus guide thereby enabling the operator to potentially handle or operate other secondary devices, such as a second endoscope that may be inserted separately and in addition to the endoscope that passes through the sinus guide. The long flexible endoscope has utility in both therapeutic and diagnostic uses.

[0170] The modified camera/transmission/endoscope assembly shown in FIG. 34 need not include a connector for rigidly attaching it to the proximal hub of the sinus guide device. Rather, this camera/transmission/endoscope assembly comprises an eyepiece and a light post, preferably an ACMI light post with an integrated light taper, to which a light cable may be attached. A length of the flexible endoscope extends from this eyepiece to the proximal hub of the sinus guide and beyond through the guide. A camera has a coupler on its distal end to connect to a monitor where the image is displayed. The flexible
endoscope 30a has a coherent bundle of extremely small and highly packed fiber optic fibers with light fibers around the image fibers. For example, the flexible endoscope 30a can be a fiber scope having about 6,000 thin image fibers in a bundle, preferably at least about 10,000 thin image fibers for better resolution of the image. The light fibers are preferably illumination fibers with a diameter between about 0.008 and 0.020 inches and a minimum length of about 10,000. The diameter of the flexible endoscope 30a ranges from about 0.25 mm to about 1 mm and is preferably about 0.5 mm in diameter, and has a flexible outer sheathing of braided polyimide. The field of view is preferably about 70 degrees. The field of view could also be "straight ahead" (i.e., zero degrees) or at other angles (e.g., 30, 45 or 60 degrees) as is available in commercial endoscopes.

Guide Systems With Removable Endoscope/ Guidewire Sheaths

[0171] FIGS. 35-38D show another transnasal insertable guide system usable to position a guidewire at a desired location within the ear, nose, throat or cranium of a human or animal subject. This guide system comprises a straight or curved transnasal sinus guide 80 and a sheath 90 that is insertable through the sinus guide 80. The sheath 90 has an endoscope lumen 85 through which a flexible endoscope 30 may be inserted and a guidewire lumen 87 through which a guidewire 110 may be inserted. An endoscope 30 inserted through the endoscope lumen 85 may be advanced substantially parallel to the guidewire 110 inserted through the guidewire lumen 87 so as to view, guide or verify the positioning of the guidewire 110. As noted earlier, guidewire 110 can also be used to extend the viewing range of endoscope 30 when the guidewire used is an illuminating guidewire 110 and the illuminating portion of the guidewire 110 is distally beyond the viewing portion of endoscope 30.


[0173] The details of the sheath 90 are shown in FIG. 36. The sheath 90 comprises an elongate flexible shaft 92 through which the endoscope lumen 85 and guidewire lumen 87 extend. A proximal hub 94 having three arms 96, 98, 100 is mounted on the proximal end of the flexible shaft. Arm 96 leads into the endoscope lumen 85 and arm 100 leads into the guidewire lumen 87.

[0174] FIGS. 37 and 37A show the sheath 90 inserted through one type of sinus guide 80 with an endoscope 30 and guidewire 110 inserted through the respective lumens 85, 87 of the sheath. The sinus guide comprises a tube 44 having a lumen 45, such as a polyester tube made of biocompatible polymer. Optionally, a liner (not shown in FIG. 15A) may be disposed within the lumen 45 of the tube 44. Such liner may be formed of lubricious or smooth material such as polytetrafluoroethylene (PTFE). Also, optionally, a proximal portion of the tube 44 may be surrounded by an outer tube member 42 formed of material such as stainless steel hypotube. In the embodiment shown, a curved distal portion of tube 44 extends out of and beyond the distal end of outer tube 42. Additionally, a radiographically visible marker 86 may optionally be formed on or attached to the distal end of the sinus guide 80. The flexible shaft 92 of the sheath 90 is advanceable through lumen 45 of tube 44. As seen in FIG. 35, a distal portion of the sheath shaft 92 may extend out of and beyond the distal end of the sinus guide 80. Also, as seen in FIG. 37, distal portions of the endoscope 30 and guidewire 110 may advance out of and beyond the distal end of shaft 92.

[0175] FIGS. 38A-38D show an example of steps in a method for using the guide catheter 80 and sheath 90 shown in FIGS. 35-37A to perform a procedure wherein a balloon catheter is used to dilate an anatomical structure such as the ostium of a paranasal sinus.

[0176] Initially, as seen in FIG. 38A, the sinus guide 80 is inserted transnasally and advanced to a position where the distal end of the sinus guide is substantially aligned with but a spaced distance away from the anatomical structure to be dilated (see an example of such spacing in FIGS. 10A and 10B). Thereafter, the shaft 92 of sheath 90 is advanced through the lumen 45 of the sinus guide such that a distal portion of the sheath is flush with or protrudes out of the distal end of the sinus guide 80. The guidewire 110 is then advanced out of the end of sheath 90 while the endoscope 30 is used to view, guide and/or verify the position of the guidewire. In some instances, it may be desirable to advance the endoscope 30 along with the guidewire 110 so that the distal end of the scope remains within an optimal distance behind the distal end of the guidewire, as seen in FIG. 38B. Such positioning of the endoscope 30 may allow the operator to observe the distal end of the guidewire 110 as it is advanced into or through the anatomical structure to be dilated.

[0177] After the guidewire 110 has been advanced into or through the anatomical structure to be dilated, the sheath 90 and endoscope 30 are withdrawn and removed, leaving the sinus guide 80 and guidewire 110 in place, as seen in FIG. 38C.

[0178] Thereafter, as shown in FIG. 38D, a balloon catheter 100 is advanced over the guidewire 110 and through the sinus guide 80 to a position where its balloon 102 is positioned within the ostium or other anatomical structure to be dilated. The balloon 102 is then inflated, thereby performing the desired dilation.

[0179] In the example of FIGS. 38A-38C, a flexible sheath 90 is advanced through a straight or curved sinus guide 80. However, in some applications, it may be desirable to steer the sheath 90 within the body, thereby allowing the sheath 90 to be navigated through tortuous anatomical regions and/or around anatomical structures. In this regard, FIGS. 39A through 39D show another system which utilizes a straight sinus guide 80a in conjunction with a steerable sheath 122 that has endoscope and guidewire lumens extending therethrough. A handpiece 124 on the proximal end of the sheath 122 has an actuator 126 that moves a pull wire or otherwise causes a distal portion 128 of the sheath 122 to deflect or bend. The distal portion 128 of the sheath 122 may be slightly deflected as seen in FIG. 39A, severely deflected as seen in FIG. 39B, not deflected (straight) as seen in FIG. 39C, or any variations therebetween.

[0180] In operation, the sinus guide 80a is inserted into or through a nostril and the sheath 122 is inserted through the sinus guide and is advanced to a desired location. During such advancement of the sheath 122, the endoscope 30 may...
be used to view the area immediately ahead of the sheath 122 and the operator may use actuator 126 to steer or deflect the sheath 122 as needed to navigate the sheath 122 to the desired location. After the sheath 122 has been navigated to a desired position, the guidewire 110 may be advanced, under endoscopic guidance, as described above with respect to the example of FIGS. 38A-38D. After the guidewire 110 has been advanced to the desired location, the steerable sheath 122 and endoscope 30 are withdrawn and removed, leaving the sinus guide 80 and guidewire 110 in place, as seen in FIG. 39D. Thereafter, a working device (e.g., a balloon catheter or other diagnostic or therapeutic apparatus) may be advanced over the 110 and used to perform a therapeutic or diagnostic function.

Guide Systems Having Small Diameter Endoscopes Attached to Guidewire Tips

[0181] Referring specifically to FIGS. 40A-40C, there is provided in some embodiments of the present invention a flexible guidewire 126 which is advanced through the sheath 122 and the proximal end of the endoscope 30a. In this embodiment, the guidewire 110 is advanced through the distal end of the endoscope 30a, and the proximal end of the guidewire 110 is used to guide the endoscope into the desired location. The guidewire 110 is then used to navigate the endoscope into the desired location, with the guidewire 110 being used to guide the endoscope into the desired location. The guidewire 110 is used to guide the endoscope into the desired location, with the guidewire 110 being used to guide the endoscope into the desired location.

[0182] Referring specifically to FIGS. 40A-40C, there is provided in some embodiments of the present invention a flexible guidewire 126 which is advanced through the sheath 122 and the proximal end of the endoscope 30a. In this embodiment, the guidewire 110 is advanced through the distal end of the endoscope 30a, and the proximal end of the guidewire 110 is used to guide the endoscope into the desired location. The guidewire 110 is then used to navigate the endoscope into the desired location, with the guidewire 110 being used to guide the endoscope into the desired location. The guidewire 110 is used to guide the endoscope into the desired location, with the guidewire 110 being used to guide the endoscope into the desired location.

[0183] After the endoscope guidewire 110 has been advanced to a desired location (e.g., into or through the ostium of a paranasal sinus) as working device (e.g., a catheter such as a balloon catheter or other diagnostic or therapeutic device) is advanced over the endoscope 30a, over the transverse body member 134 and over the endoscope guidewire 110. This may require detachment of any large diameter or bulky hub or other component from the proximal end of the endoscope. The detachability configuration described in regard to FIGS. 41A and 41A' applies to other scope embodiments herein and helps to keep the cost of the disposable elements to a minimum. FIGS. 41A and 41A' show a detachable hub 224 that may be attached to and detached from the proximal end of the endoscope 30a. This hub 224 comprises a body 226 having a scope-receiving channel 227 in its distal end, a light input cable 230 and an image output cable 256. As seen in FIG. 41A', the proximal end of the endoscope 30a is inserted into scope-receiving channel 227, thereby causing a light fiber contact on the proximal end of the endoscope 30a to optically couple to a corresponding contact at the proximal end of scope-receiving channel 227 so that light from light cable 230 will be transmitted in the distal direction through the light fibers of the endoscope 30a. Also, this will cause an image contact formed on the endoscope 30a to be optically coupled to a corresponding contact on the inner wall of the scope-receiving channel 227 such that images from the scope’s image fibers will be transmitted through image cable 256 to a camera monitor, eyepiece or other image viewing apparatus known in the art of endoscopy. After the detachable hub 224 has been placed in the desired position, the proximal end of the endoscope 30a may be pulled out of scope-receiving channel 227 and the hub 224 may be removed, thereby allowing the working device to advance over and be guided by the body of the endoscope 126, through the transverse member 134 and the detachable hub 132.

[0184] Referring specifically to FIGS. 40D-40E, there is provided in some embodiments of the present invention a flexible guidewire 126 which is advanced through the sheath 122 and the proximal end of the endoscope 30a. In this embodiment, the endoscope 30a comprises a outer tube having a side opening 144 and a flexible guidewire tip 146 that is advanceable out of and retractable into the side opening 144. When advanced out of the side opening 144, the endoscope tip 146 is used to view an area adjacent to the elongate guide tip 132a to a desired location. When the endoscope tip is advanced out of the side opening 144, it may provide a view along one side of the guide tip 132a, as shown in the diagram of FIG. 40E. After the endoscope tip 132a has been advanced to the desired location, the endoscope 30a is retracted back into the endoscope's outer tube through side opening 144 and a working device (e.g., a catheter such as a balloon catheter or other diagnostic or therapeutic device) is advanceable out of the endoscope 30a and over the elongate guide tip 132a. To facilitate this, the above-described detachable hub 224 may be used in conjunction with this endoscope 30a, as shown in FIGS. 41B and 41B'.

Self Cleaning Endoscope Feature

[0185] Any of the sinus guides 12, 12a, 12b, 12c, 12d, 12e, 12f of this invention may incorporate apparatus, such as a drip line, mist, suction or feature on the sinus guide, for cleaning debris from the endoscope without requiring the device to be removed from the subject’s body. In this regard, FIGS. 42A-42C show one example of an endoscope sinus guide 12d having a scope cleaning member 260 at the distal end of its scope-receiving channel 28. In this example, the scope cleaning member 260 comprises an elastomeric diaphragm disposed transversely over the distal end of the scope-receiving channel 28 and having a self-closing slit through which the endoscope 30 passes. It will be appreciated, however, that such scope cleaning member 260 need not necessarily be a slit elastomeric diaphragm, but may comprise various other types of members that wipe or frictionally clear the distal end of the endoscope 30 as the endoscope is advanced or retracted.

[0186] In the example shown, the endoscope is advanced through the slit and out of the endoscope channel 28, where it is used to observe the advancement of a guidewire 110 from the adjacent sinus guide body 26. During such procedure, a quantity of debris 262 (e.g., blood, mucus, etc.)
accumulates on the distal end of the endoscope, thus interfering with obtaining of a suitable quality image from the endoscope. To remedy this, the endoscope is briefly retracted back through the scope cleaning member such that the slit rides over the outer surface of the endoscope and closes over the distal tip of the endoscope as it is retracted. This removes the debris from the endoscope, as shown in FIG. 42C. Thereafter, the endoscope may be re-advanced through scope cleaning member and may once again be used to obtain an endoscope image of the sinus guide device.

[0187] It is to be appreciated that the invention has been described hereinafore with reference to certain examples or embodiments of the invention but that various additions, deletions, alterations and modifications may be made to these examples and embodiments and or equivalents may be substituted without departing from the intended spirit and scope of the invention. For example, any element or attribute of one embodiment or example may be incorporated into or used with another embodiment or example, unless to do so would render the embodiment or example unsuitable for its intended use. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

1-26. (canceled)
27. A guide device useable to position a working device at a desired location within the ear, nose, throat or cranium of a human or animal subject, said device comprising:
   a transnasally insertable elongate shaft having a proximal end and a distal end;
   a first channel into which an endoscope may be inserted so that the endoscope may be used to view at least an area beyond the distal end of the shaft; and
   a second channel through which the working device may be advanced.
28. The device of claim 27, wherein at least a distal portion of the shaft is bendable to a desired shape.
29. The device of claim 27, wherein the shaft is substantially straight.
30. The device of claim 27, wherein a curve of less than about 30 degrees is formed in a distal portion of the shaft.
31. The device of claim 27, wherein a curve of about 30 degrees is formed in a distal portion of the shaft.
32. The device of claim 27, wherein a curve of about 70 degrees is formed in a distal portion of the shaft.
33. The device of claim 27, wherein a curve of about 90 degrees is formed in a distal portion of the shaft.
34. The device of claim 27, wherein a curve of about 110 degrees is formed in a distal portion of the shaft.
35. The device of claim 27, wherein a distal portion of the shaft is more flexible than a proximal portion of the shaft.
36. The device of claim 27, wherein a distal portion of the shaft is substantially transparent.
37. The device of claim 27, wherein a distal portion of the shaft is curved, and wherein the first channel is positioned along the outside of the curve of the second channel.
38. The device of claim 27, wherein a distal portion of the shaft is curved, and wherein the first channel is positioned along the inside of the curve of the second channel.
39. The device of claim 27, wherein a distal portion of the shaft is curved, and wherein the first channel is positioned side by side with the second channel.
40. The device of claim 27, wherein the first channel is formed by a metal tube having a distal end and a plastic tube that extends through the metal tube, a distal portion of the plastic tube protruding out of and beyond the distal end of the metal tube, and the first channel comprises a lumen of the plastic tube.
41. The device of claim 40, wherein the plastic tube is formed substantially of a material selected from the group consisting essentially of nylon, nylon 11, nylon 12, Pebax, Pebax 722D, polyimide, poly(etheretherketone) (PEEK), poly(butylene terephthalate) (PBT) and combinations or blends thereof.
42. The device of claim 40, wherein a tubular liner is disposed within the lumen of the plastic tube, and wherein the first channel comprises the lumen of the liner.
43. The device of claim 42, wherein the liner is formed substantially of material selected from the group consisting of polytetrafluoroethylene, poly(vinylidene fluoride) (PVDF) and high density polyethylene (HDPE).
44. The device of claim 27, wherein said first channel comprises a dynamic endoscope channel, comprising a flexible tube, wherein a distal end of the flexible tube is attached to a distal end of a tube defining the second channel and a proximal end of the dynamic endoscope channel is slidable with respect to the second channel.
45. The device of claim 44, further comprising a retraction member configured to facilitate movement of the dynamic endoscope channel toward the tube defining the second channel.
46. The device of claim 44, wherein a proximal end portion of the dynamic endoscope channel is mounted to a proximal sleeve that is slidable over the tube defining the second channel, a stop is mounted distally of said proximal sleeve and a biasing member is positioned between said stop and said proximal sleeve.
47. The device of claim 27, further comprising a pivot arm interconnecting a proximal end portion of said first channel to a proximal end portion of said second channel, wherein said pivot arm is actuable to pivot the proximal end portion of said first channel away from said second channel to facilitate insertion of an endoscope into said first channel.
48-95. (canceled)

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