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Method and Articles for Treating the Sinus System

Abstract

A method of treating a sinus cavity of a subject includes advancing a distal portion of a light source through a drainage pathway of a sinus cavity and into the sinus cavity and visually observing a transdermal light emitted from the light source. A distal portion of a substantially rigid inner guide member of a balloon dilation catheter is advanced into the drainage pathway, the balloon dilation catheter including a movable shaft including a balloon that is slidably mounted on the substantially rigid inner guide member. The movable shaft and balloon are advanced distally over the substantially rigid inner guide member to place a portion of the balloon in the drainage pathway whereby the balloon is inflated.

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Background/Summary

RELATED APPLICATIONS [0001] This application is a continuation of U.S. application Ser. No. 18/761,293 filed on Jul. 1, 2024, which is a continuation of U.S. application Ser. No. 17/072,879 filed on Oct. 16, 2020, which is a continuation of U.S. application Ser. No. 16/011,397 filed on Jun. 18, 2018, which is a continuation of U.S. application Ser. No. 14/918,468 filed on Oct. 20, 2015, which is a continuation of U.S. application Ser. No. 14/468,617 filed on Aug. 26, 2014, which is a continuation of U.S. application Ser. No. 13/277,885 filed on Oct. 20, 2011, which is a continuation-in-part of U.S. application Ser. No. 12/479,521 filed on Jun. 5, 2009 and claims priority to U.S. Provisional Patent Application No. 61/405,035 filed on Oct. 20, 2010. Priority is claimed pursuant to 35 U.S.C. §§ 119 and 120. The above-noted patent applications are incorporated by reference as if set forth fully herein.

FIELD OF THE INVENTION
[0002] The field of the invention relates to balloon dilation devices, devices for illuminating nasal and sinus cavities, and methods for the treatment of sinusitis.
BACKGROUND OF THE INVENTION
[0003] Sinusitis is a condition affecting over 35 million Americans, and similarly large populations in the rest of the developed world. Sinusitis occurs when one or more of the four paired sinus cavities (i.e., maxillary, ethmoid, frontal, sphenoid) becomes obstructed, or otherwise has compromised drainage. Normally the sinus cavities, each of which are lined by mucosa, produce mucous which is then moved by beating cilia from the sinus cavity out to the nasal cavity and down the throat. The combined sinuses produce approximately one liter of mucous daily, so the effective transport of this mucous is important to sinus health.
[0004] Each sinus cavity has a drainage pathway or outflow tract opening into the nasal passage. This drainage passageway can include an ostium, as well as a “transition space” in the region of the ostia, such as the “frontal recess,” in the case of the frontal sinus, or an “ethmoidal infundibulum,” in the case of the maxillary sinus. When the mucosa of one or more of the ostia or regions near the

ostia become inflamed, the egress of mucous is interrupted, setting the stage for an infection and/or inflammation of the sinus cavity, i.e., sinusitis. Though many instances of sinusitis may be treatable with appropriate medicates, in some cases sinusitis persists for months or more, a condition called chronic sinusitis, and may not respond to medical therapy. Some patients are also prone to multiple episodes of sinusitis in a given period of time, a condition called recurrent sinusitis.

[0005] Balloon dilation has been applied to treat constricted sinus passageways for the treatment of sinusitis. These balloon dilation devices typically involve the use of an inflatable balloon located at the distal end of a catheter such as a balloon catheter. Generally, the inflatable balloon is inserted into the constricted sinus passageway in a deflated state. The balloon is then expanded to open or reduce the degree of constriction in the sinus passageway being treated to facilitate better sinus drainage and ventilation.

[0006] Exemplary devices and methods particularly suited for the dilation of anatomic structures associated with the maxillary and anterior ethmoid sinuses are disclosed, for example, in U.S. Pat. No. 7,520,876 and U.S. Patent Application Publication No. 2008-0172033. Other systems have been described for the treatment of various other sinuses including the frontal sinus. For example, U.S. Patent Application Publication No. 2008-0097295 discloses a frontal sinus guide catheter (FIG. **6**B) and method of treating the frontal sinuses (e.g., FIGS. **8**B-**8**C). U.S. Patent Application Publication No. 2008-0125626 discloses another guide device (e.g., FIGS. **10**C and **10**C′) for transnasal access to the frontal sinuses for treatment.

SUMMARY OF THE INVENTION

[0007] In a first embodiment of the invention, a balloon dilation catheter includes a substantially rigid inner guide member and a movable shaft coupled to a balloon that is slidably mounted on the substantially rigid inner guide member. To treat a drainage pathway of a sinus cavity (e.g., frontal sinus cavity) of a subject using the balloon dilation catheter, the substantially rigid inner guide member is advanced into a drainage pathway of the subject via a nasal passageway. The shaft and balloon are then advanced in a distal direction over the substantially rigid inner guide member to place the balloon in the drainage pathway. This enables the balloon to track over the inner guide member. The balloon is inflated to expand or otherwise remodel the drainage pathway. Where the sinus cavity is the frontal sinus cavity the drainage pathway is the frontal recess.

[0008] In another aspect of the invention, a device for dilating the outflow tract of a sinus cavity includes a substantially rigid inner guide member having a proximal end and a distal end and a shaft coupled to a balloon, the shaft having a first lumen along at least a portion thereof containing the substantially rigid inner guide member, the shaft having a second lumen operatively coupled to the interior of the balloon. A handle is disposed along a proximal portion of the substantially rigid inner guide member, the handle including a moveable knob operatively coupled to the shaft, wherein distal advancement of the knob advances the shaft and balloon over the substantially rigid inner guide in a distal direction.

[0009] In further aspects of the invention, taught herein are methods of treating a sinus cavity of a subject. In some embodiments the method includes advancing a distal portion of a light source through a drainage pathway of a frontal sinus cavity of a subject and into the frontal sinus cavity; visually observing a transdermal light emitted from the distal portion of the light source in the frontal sinus cavity; advancing a distal portion of a substantially rigid inner guide member of a balloon dilation catheter into the drainage pathway of the frontal sinus cavity, the balloon dilation catheter including a movable shaft slidably mounted on the substantially rigid inner guide member, the movable shaft including a balloon; advancing the movable shaft and balloon distally over the substantially rigid inner guide member to place a portion of the balloon in the drainage pathway; and inflating the balloon.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. **1** illustrates a perspective view of a balloon dilation catheter according to one embodiment.

[0011] FIG. **2**A illustrates a side view of a balloon dilation catheter of FIG. **1**. The advancer knob is illustrated in the retracted, proximal position.

[0012] FIG. **2**B illustrates a cross-sectional view of the balloon dilation catheter of FIG. **2**A.

[0013] FIG. **3**A illustrates a side view of a balloon dilation catheter of FIG. **1**. The advancer knob is illustrated in the advanced, distal position.

[0014] FIG. **3**B illustrates a cross-sectional view of the balloon dilation catheter of FIG. **3**A.

[0015] FIG. **4** is a cross-sectional view of the handle portion (dashed line portion) of FIG. **3**B.

[0016] FIG. **5**A is a cross-sectional view of the balloon dilation catheter taken along the line A-A′ of FIG. **2**B.

[0017] FIG. **5**B is a cross-sectional view of the balloon dilation catheter taken along the line B-B′ of FIG. **4**.

[0018] FIG. **6**A is a side view of an inner guide member according to one embodiment.

[0019] FIG. **6**B is a side view of an inner guide member according to another embodiment.

[0020] FIG. **6**C is a side view of an inner guide member according to another embodiment.

[0021] FIG. **7** illustrates a perspective view of a balloon dilation catheter according to another embodiment.

[0022] FIG. **8** illustrates a cross-sectional view of the frontal sinus of a subject with the inner guide member of the balloon dilation catheter being advanced into the subject's frontal recess.

[0023] FIG. **9** illustrates a cross-sectional view of the frontal sinus of a subject with the inner guide member of the balloon dilation catheter being positioned in the subject's frontal recess. A guide wire is shown advanced through the catheter and into the subject's frontal sinus cavity.

[0024] FIG. **10** illustrates a cross-sectional view of the frontal sinus of a subject with the balloon (in a deflated state) and shaft being advanced into the subject's frontal recess.

[0025] FIG. **11** illustrates a cross-sectional view of the frontal sinus of a subject with the balloon of FIG. **10** in an inflated state to thereby widen and remodel the frontal recess.

[0026] FIG. **12** illustrates a cross-sectional view of the frontal sinus of a subject after the frontal sinus has been widened and the balloon inflation catheter withdrawn.

[0027] FIG. **13** illustrates a perspective view of a lighted probe device.

[0028] FIG. **14** illustrates a top view of a lighted probe device.

[0029] FIG. **15** illustrates a side view of a lighted probe device.

[0030] FIG. **16** illustrates a cross-sectional view of the lighted probe device taken along line A-A of FIG. **14**.

[0031] FIG. **17** illustrates an exploded side view of a light source.

[0032] FIG. **18** illustrates a cross-sectional side view of a connector.

[0033] FIG. **19**A illustrates a perspective view of a guide catheter.

[0034] FIG. **19**B illustrates a photographic view of a removable light-fiber light source and tuohy-borst connector.

[0035] FIG. **19**C illustrate a perspective side view of portions of a removable light-fiber light source.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0036] FIG. **1** illustrates one embodiment of a balloon dilation catheter **10** that is particularly suited for treatment of the outflow tract (frontal sinus ostium and frontal recess) of the frontal sinus of a subject. The balloon dilation catheter **10** includes a handle **12** that is configured to be gripped or otherwise manipulated by the operator. An elongate-shaped inner guide member **14** extends longitudinally from the handle **12** in a distal direction. The inner guide member **14** is formed of a suitably rigid material such as stainless steel hypotube. The inner guide member **14** projects or otherwise extends distally from the handle **12** for a pre-determined distance. The inner guide member **14** may be pre-shaped to have a curved distal portion **16** as is illustrated in FIGS. **1**, **2**A, **2**B, **3**A, **3**B, **6**A, **6**B, **7**, **8**, and **9**. For example, the nature and degree of the curved distal portion **16** may be configured to match with the frontal sinus outflow tract or frontal recess.

[0037] Alternatively, the inner guide member **14** may have some degree of malleability such that the user may bend or impart some desired shape or configuration to the distal end of the inner guide member **14**. As explained herein in more detail, the inner guide member **14** may include an optional lumen **18** (best illustrated in FIG. **5**A) that extends the length of the inner guide member **14**. In particular, the inner guide member **14** and the contained lumen **18** may extend from a distal end **20** to a proximal end **21** (best seen in FIGS. **2**B and **3**B) that interfaces with a sealed arrangement with a port **22** disposed at a proximal end **24** of the handle **12**. The port **22** may be configured with a conventional interface such as a Luer connector. The port **22** may be used as an aspiration port or a delivery port for fluids and/or medicaments, or for introduction of a guide wire.

[0038] Still referring to FIG. **1**, a shaft **30** is mounted about the periphery of the inner guide member **14**. In particular, the shaft **30** is dimensioned to slide over the inner guide member **14** in response to actuation of an advancer knob **32** located on the handle **12**. The advancer knob **32** is moveable along a slot **42** contained in a surface of the handle **12**. A distal end **34** of the shaft **30** includes a balloon **36** that is configured to be selectively inflated or deflated as explained herein. During use, the inner guide member **14** is manipulated and advanced across or into the anatomical space of interest. The shaft **30** as well as the attached balloon **36** is illustrated in a retracted state in FIG. **1**. While FIG. **1** illustrates the balloon **36** in an inflated state for better illustration, the balloon **36** is typically in a deflated state when the shaft **30** is in the proximal position as illustrated in FIGS. **2**A and **2**B. After the inner guide member **14** is properly positioned, the user actuates the advancer knob **32** by sliding the same in the distal direction which, in turn, advances the shaft **30** and balloon **36** in a distal direction over the pre-placed inner guide member **14**. Once the balloon **36** is properly placed, the balloon **36** is inflated. Inflation of the balloon **36** is accomplished using an inflation device (not shown) that is coupled to a port **38** located at the proximal end **24** of the handle **12**. One exemplary inflation device that may be used in connection with the balloon dilation catheter **10** is described in U.S. patent application Ser. No. 12/372,691, which was filed on 17 Feb. 2009, published as U.S. Pat. App. Pub. No. 2010/0211007, and is incorporated by reference as if set forth fully herein. Of course, other inflation devices may also be used. An inflation lumen **48** contained within the shaft **30** (described in more detail below), fluidically couples the port **38** to an interior portion of the balloon **36**.

[0039] Still referring to FIG. **1**, an optional support member **40** in the form of a tube may be located about the external periphery of a portion of the shaft **30** to impart further stiffness to the balloon dilation catheter **10**. The particular length of the support member **40** may vary depending on the application and may extend along some or all or the shaft **30**. The support member **40** may be made of a metallic material such as stainless steel hypotube that is secured to the shaft **30**. The support member **40** may be welded or bonded along a length of the shaft **30**. Generally, the support member **40** does not cover the helical portion (described in detail below) of the shaft **30** that is contained within the handle **12**.

[0040] FIGS. **2**A and **2**B illustrate, respectively, side and cross-sectional views of the balloon dilation catheter **10** with the advancer knob **32** and thus balloon **36** in the proximal position. In actual use, as explained herein, the balloon **36** is typically in a deflated state when the advancer knob **32** is the proximal position as illustrated in FIGS. **2**A and **2**B. As best seen in FIG. **1**, the advancer knob **32** is slidably disposed along a length of the handle **12** inside a slot **42**. The advancer knob **32** is thus able to slide back and forth in the distal/proximal direction along the length of the slot **42**. The slot **42** may incorporate a stop or the like (not shown) to prevent the balloon **36** from being advance too far along the length of the inner guide member **14**. The length of the slot **42** may be varied in different devices to adjust the length at which the balloon **36** may be advanced. Generally, the slot **42** has a length within the range of about 1 inch to about 2 inches although other dimensions may fall within the scope of the invention.

[0041] As seen in FIG. **2**B, the advancer knob **32** may be directly coupled to the support member **40** that is mounted on the shaft **30**. Alternatively, the advancer knob **32** may be coupled directly to the shaft **30**. The advancer knob **32** may be configured or otherwise shaped to enable a finger of the user (e.g., index finger or thumb) to easily advance or retract the knob **32** along the slot **42** contained in the handle **12**.

[0042] FIGS. **3**A and **3**B illustrate, respectively, side and cross-sectional views of the balloon dilation catheter **10** with the advancer knob **32** and thus balloon **36** in the distal position. Thus, unlike the configurations of FIGS. **2**A and **2**B, the advancer knob **32** is located at or near the distal end **26** of the handle **12**. Advancement of the advancer knob **32** also slides the shaft **30** and attached balloon **36** in a distal direction (arrow A in FIG. **3**A) along the inner guide member **14**. The balloon **36** thus is positioned at or adjacent to the distal end **20** of the inner guide member **14**. The balloon dilation catheter **10** may be designed such that the advancer knob **32** may be positioned at either the proximal or distal extremes as illustrated in FIGS. **2**A, **2**B, **3**A, **3**B. Alternatively, the advancer knob **32** may be positioned somewhere in between the two extremes. For example, the optimal position of the balloon **36** may be accomplished by sliding the advancer knob **32** some fraction (e.g., ¾) of the full distance of the slot **42**.

[0043] Referring to FIGS. **2**B and **3**B, the inner guide member **14** of the balloon dilation catheter **10** extends from a distal end **20** to a proximal end **21** that terminates in a sealed interface with a port **22** disposed at a proximal end **24** of the handle **12**. The inner guide member **14** optionally includes a lumen **18** disposed therein that may be used to provide aspiration functionality via an aspiration device (not shown) coupled to port **22**. Aspiration functionality permits the removal of blood and other secretions. This makes it easier to visualize the placement of the balloon dilation catheter **10**. The inner guide member **14** is advantageously rigid to enable the balloon dilation catheter **10** to be positioned without the need of a separate guiding catheter or guide wire in most, if not all, instances.

[0044] The inner guide member **14** may have a length of about 7 inches to about 11 inches from the distal end **20** to the proximal end **21** when loaded into the handle **12**, although other dimensions may be used. The inner guide member **14** may be formed from stainless steel hypotube having an inner diameter in the range of about 0.019 inch to about 0.050 inch, and more preferably between about 0.036 inch and 0.040 inch, with a wall thickness within the range of about 0.005 inch to about 0.020 inch, and more preferably between about 0.008 inch to about 0.012 inch. The curved distal portion **16** of the inner guide member **14** may be formed right to the distal end **20** and may have a radius of curvature of about 0.25 inch to about 1.5 inch, and more preferably about 0.75 to about 1.25 inch.

[0045] The length of the inner guide member **14** that projects distally from the distal-most portion of the balloon **36** is about 0.5 inch to about 2.0 inch, and more preferably, about 0.8 inch to about 1.2 inch when the balloon **36** is in the fully retracted state (e.g., illustrated in FIGS. **2**A and **2**B). As seen in FIGS. **1**, **2**A, **2**B, **3**A, **3**B, **6**A-**6**C, **7**-**11**, the distal end **20** of the inner guide member **14** may incorporate an optional bulbous tip **44** in order to make the distal end **20** more atraumatic. The bulbous tip **44** further serves to limit forward movement of the balloon **36** and attached shaft **30** when they are advanced distally. The outer diameter of the tip **44** is preferably between about 1 mm and about 3 mm.

[0046] The balloon **36** is mounted on the shaft **30** so as to form a fluidic seal between the two components. The balloon **36** may be bonded to the shaft using a weld, adhesive, or the like. Alternately, the balloon **36** may be secured to the shaft using a mechanical connection. Generally, any technique known to those skilled in the art may be used to secure to the balloon **36** to the shaft **30**. Given that the balloon **36** is secured directly to the shaft **30**, both structures are slidably mounted over the inner guide member **14**. The balloon **36** generally takes on a cylindrical-shape when inflated. While not limited to specific dimensions, the inflated balloon **36** has a diameter within the range of about 3 mm to about 9 mm, and more preferably a diameter within the range of about 5 to about 7 mm when inflated. The length of the balloon **36** may generally fall within the range of about 10 mm to 25 mm although other lengths may be used. Both the shaft **30** and the balloon **36** are preferably formed of high strength but flexible polymeric materials such as polyamides (e.g., Nylon), PEBAX or the like. The balloon **36** may be "blow molded" to a relatively thin wall thickness, and capable of holding relatively high pressures from about 6 atmospheres to about 20 atmospheres of inflation pressure. The balloon **36** is inflated using a fluid which is typically a liquid such as water or saline.

[0047] Referring now to FIG. **4**, a magnified, cross-sectional view of a portion of the handle **12** is illustrated. At the proximal end **24** of the handle **12** are located ports **22**, **38**. The port **22** may be configured with a conventional interface such as a Luer connector or any other connector known to those skilled in the art. The port **22** may be integrally formed with the handle **12** or, alternatively, the port **22** may be a separate structure that is secured to the handle **12** during assembly. As seen in FIG. **4**, the proximal end **21** of the inner guide member **14** forms a sealing arrangement with the port **22**. As explained herein, the port **22** may be used as an aspiration port or a delivery port for fluids and/or medicaments.

[0048] FIG. **4** also illustrates port **38** which may be constructed in the same or similar manner as port **22** as described above. The port **38** is fluidically coupled to the inflation lumen **48** in the shaft **30**. In this regard, inflation fluid from an inflation device (not shown) is able to pass through the port **38** and into the inflation lumen **48** of the shaft **30**. The port **38** may be configured with a conventional interface such as a Luer connector. The fluid then is able to travel along the length of the shaft **30** via the lumen **48** where the fluid enters the interior of the balloon **36**. The inflation fluid is thus able to inflate the balloon **36** upon actuation of the inflation device.

[0049] As best seen in FIG. **4**, a portion of the handle **12** includes a recessed region **50** that receives both the inner guide member **14** and the shaft **30**. In the recessed region **50** of the handle **12**, the shaft **30** is helically wrapped around the outer periphery of the inner guide member **14** forming a helical portion **52**. The helical portion **52** facilitates the distal advancement and proximal retraction of the shaft **30** and attached balloon **36** along the inner guide member **14** yet still maintains fluid communication with the port **38**. The helical portion **52** of the shaft **30**, which is located proximal to the advancer knob **32** is in the shape of a helix that wraps around the inner guide member **14** and is configured to elongate and contract upon movement of the advancer knob **32**. FIG. **4** illustrates the state of the helical portion **52** after the advancer knob **32** has been advanced distally. Thus, in the extended state, the length of the helical portion **52** traverses much if not all of the recessed region **50**. Contrast this with FIG. **2**B which illustrates the helical portion **52** compressed to the proximal portion of the recessed region **50** because the advancer knob **32** is the in proximal position. Thus, the helical portion **52** is thus able to expand or compress much in the way that a spring does in response to a tensile or compressive load. One or both of the inner guide member **14** and the helical portion **52** of the shaft **30** may be optionally coated or lined with a lubricious coating to prevent the contact surfaces from any unwanted frictional binding or the like.

[0050] The helical portion **52** of the shaft **30** may be formed by "skiving" away a portion of the shaft **30**. FIG. **5**A illustrates a cross-sectional view of the shaft **30**, inner support guide **14**, and support member **40** along the line A-A′ of FIG. **2**B. As seen in FIG. **2**B, this area is distal to where the helical portion **52** of the shaft **30** is located. Referring now to FIG. **5**A, the shaft **30** includes a rider lumen **54** that is dimensioned to have a diameter that is slightly larger than the outer diameter of the inner support guide **14**. The rider lumen **54** thus enables the shaft **30** to advance and retract over the inner support guide **14** in a close-fit arrangement. The outer diameter of the shaft **30** may generally fall within the range of about 0.050 inch to about 0.110 inch or within the range of about 0.070 inch to about 0.100 inch. One or both of the exterior surface of the inner guide member **14** and the interior surface of the rider lumen **54** may be optionally coated with a lubricious coating to reduce frictional contact forces. FIG. **5**B illustrates a cross-sectional view of the inner support guide **14** and the helical portion **52** of the shaft taken along the line B-B′ of FIG. **4**. As seen in FIG. **5**B, a portion of the shaft **30** that includes the rider lumen **54** is skived away. The result is that a single lumen (inflation lumen **48**) remains in the shaft **30** that is helically wrapped about the inner support guide **14**.

[0051] FIGS. **6**A-**6**C illustrate various embodiments of an inner guide member **14**. The inner guide member **14** may have a variety of shapes and configurations depending on the particular application or patient. The different shapes of the inner guide member **14** may be factory-formed in a particular shape and offered as a different model as fully assembled or, alternatively, the inner guide member **14** may be replaceable or modular elements that could slide inside the rider lumen **54** and inserted into the port **22** in a press-fit type sealing arrangement. In yet another alternative, the shapes could represent desirable shapes that a malleable inner guide member **14** could be formed into by the user to better fit a particular application or subject's anatomy.

[0052] FIG. **6**A illustrates an inner guide member **14** that includes a curved distal portion **16** that terminates in a straight segment **46**. In the embodiment of FIG. **6**A, the curve in the curved distal portion **16** is pronounced and turns back on itself in the shape of a “U” in which the distal end **20** turns back in retrograde fashion. This embodiment may be useful to treat hard to reach ostia or other structures, e.g., the maxillary ostium or the infundibulum via a transnasal route, if the nasal anatomy will allow for a transnasal approach. While FIG. **6**A illustrates a “U” shaped curve, other degrees of curvature are contemplated. FIG. **6**B illustrates an inner guide member **14** according to another embodiment. In this embodiment, the curved distal portion **16** also terminates in a straight segment **46** although the radius of curvature is less pronounced. In this embodiment, the straight segment **46** may have a length within the range of about 8 mm to about 10 mm although other lengths may be used. It is believed that this embodiment is particularly suited for most frontal recess anatomy. FIG. **6**C illustrates an embodiment in which the inner guide member **14** is substantially straight. This later embodiment may be particularly suited for treating the sphenoids of the subject, or straightforward frontal recess anatomy.

[0053] FIG. **7** illustrates a balloon dilation catheter **10** according to another embodiment. In this embodiment, a tracking element **60** is located on the handle **12** of the balloon dilation catheter **10**. The tracking element **60** may include an antenna, transmitter, optical reflectors, or the like that communicates a wireless signal that is then received and processed to determine the orientation and/or positioning of the balloon dilation catheter **10**. In certain embodiments, more than one tracking element **60** may be disposed on the balloon dilation catheter **10**. Data regarding the orientation and/or positioning of the balloon dilation catheter **10** may then be processed and displayed on the display for viewing by the physician. For example, image guided surgery is becoming increasingly commonplace, permitting physicians to review real time actual or virtual images of a particular device within a subject during a surgical procedure.

[0054] For example, U.S. Pat. Nos. 5,391,199 and 5,443,489, which are incorporated by reference, describe a system wherein coordinates of an intrabody probe are determined using one or more field sensors such as, Hall effect devices, coils, or antennas that are carried on the probe. U.S. Patent Application Publication No. 2002-0065455, which is also incorporated by reference, describes a system that is capable of generating a six-dimensional position and orientation representation of the tip of a catheter using a combination of sensor and radiation coils. U.S. Patent Application Publication No. 2008-0269596, which is also incorporated by reference, describes yet another monitoring system that has particular applications in orthopedic procedures. Commercial systems such as the LANDMARX Element (Medtronic Xomed Products, Inc., Jacksonville, FL) are available for use in conjunction with ENT procedures.

[0055] In the embodiment of FIG. **7**, the tracking element **60** permits accurate tracking of the distal end **20** of the balloon dilation catheter **10** such that an image of distal portion of the balloon dilation catheter **10** may be superimposed on a patient's anatomical imagery. For example, a previously conducted computed tomography (CT) scan of the patient may be used to generate a visual image of the patient's anatomical regions of interest. Based on the location of the tracking element **60**, an image guided surgery (IGS) system can then superimpose an image of the balloon dilation catheter **10** onto the image to better enable the physician to manipulate and orient the balloon dilation catheter **10**.

[0056] Other commercial systems may also be used in connection with the balloon dilation catheter **10** illustrated in FIG. **7**. For example, the INSTATRAK 3500 Plus—ENT from GE Healthcare, Chalfont St. Giles, United Kingdom may be integrated and/or used with the balloon dilation catheter **10**. The use of CT guidance to position the balloon dilation catheter **10** is preferred because the device may be positioned by the operator with just a single hand, while viewing the CT image interface (e.g., display) at the same time the handle **12** is manipulated. Optionally, the balloon dilation catheter **10** may be initially positioned using an endoscope or other visualization tool. For instance, a conventional “Hopkins rod” endoscope (not shown) may be manipulated alongside the balloon dilation catheter **10** to aid in placement.

[0057] FIGS. **8-12** illustrate various cross-sectional views (sagittal plane) of the frontal sinus of a subject undergoing treatment with a balloon dilation catheter **10**. The cross-sectional views illustrate the nasal passageway **100**, the frontal recess **102**, and the frontal sinus cavity **104**. Referring to FIG. **8**, the balloon dilation catheter **10** is inserted into the nasal passageway **100** with the advancer knob **32** in the retracted position (e.g., as illustrated in FIG. **1**, **2**A, **2**B) such that the shaft **30** and balloon **36** are also retracted proximally. In addition, the balloon **36** is in a deflated state as seen in FIG. **8**. The curved portion **16** of the inner guide member **14** is then positioned within the frontal recess **102** of the subject as seen in FIG. **8**. This positioning of the inner guide member **14** may be accomplished under endoscopic visualization using a conventional endoscope such as a Hopkins rod-type endoscope that is positioned alongside the balloon dilation catheter **10**. Alternatively, the inner guide member **14** may be positioned using IGS techniques that track the position of the balloon dilation catheter using one or more tracking elements **60** as illustrated, for instance, in the embodiment of FIG. **7**. For instance, the inner guide member **14** may be advanced under guidance from CT imaging.

[0058] Referring now to FIG. **9**, confirmation of accurate positioning of the inner guide member **14** within the frontal recess **102** may be accomplished by placement of a fluoroscopically visible guide wire **64** through the lumen **18** of the inner guide member **14**. The guide wire **64** may be inserted into the lumen **18** via the port **22**. Under fluoroscopic visualization, the guide wire **64** can be seen to advance into the frontal sinus cavity **104** once the inner guide member **14** is positioned properly within the frontal recess **102**. If the guide wire **64** does not advance into the frontal sinus cavity **104**, the balloon dilation catheter **10** is re-positioned and confirmation is subsequently attempted. As an alternative to a fluoroscopically visible guide wire **64**, the guide wire **64** could be a light emitting guide wire such as that disclosed in U.S. Patent Application Publication No. 2007-0249896, which is incorporated by reference herein. Of course, the guide wire **64** is optional as the inner guide member **14** may be placed without the aid or need for the same. Alternatively, the guide wire **64** could be positioned in the frontal sinus initially, prior to placement of the balloon catheter **10**.

[0059] Now referring to FIG. **10**, once the curved portion **16** of the inner guide member **14** is properly positioned, the advancer knob **32** is advanced in the distal direction (arrow A of FIG. **3**A) thereby advancing the shaft **30** and attached balloon **36** into the frontal recess **102**. This is illustrated in FIG. **10**. After the balloon **36** is positioned in the frontal recess **102**, the balloon **36** is inflated as illustrated in FIG. **11**. Inflation is accomplished by coupling an inflation device (not shown) to the port **38**. The inflation device may include a syringe or the like that is depressed to infuse a fluid into the inflation lumen **48** which then passes into the interior of the balloon **36** to effectuate expansion of the balloon **36** to the state illustrated in FIG. **11**. Pressures typically used to accomplish widening or remodeling of the frontal recess **102** are within the range of about 3 atmospheres to about 12 atmospheres. The balloon **36** may be inflated only a single time or, alternatively, the balloon **36** may be inflated, deflated, and inflated again a plurality of times in order to achieve the desired degree of widening. Each inflation step may be performed after positioning the balloon **36** in a different position within the frontal recess **102**.

[0060] After the frontal recess **102** has been widened or otherwise remodeled, the balloon **36** is deflated and removed as illustrated in FIG. **12**. The widened frontal recess **102** illustrated in FIG. **12** is believed to restore the drainage and aeration function and health of the frontal sinus cavity **104**. Deflation of the balloon **36** is accomplished by reducing the fluid pressure within the interior of the balloon **36**. For example, the plunger of a syringe or the like that is fluidically coupled to the port **38** may be withdrawn to remove fluid from the interior of the balloon **36**. The balloon dilation catheter **10** can then be withdrawn proximally from the nasal passageway **100**.

[0061] In certain patients, treatment of one or both frontal sinuses **104** as described above may be adequate. In other patients, additional sinuses may need to be treated, particularly the maxillary and/or anterior ethmoid sinuses. In such patients, a combination procedure may be well suited. The maxillary and/or anterior ethmoid sinuses can be treated with a system such as described in U.S. Pat. No. 7,520,876 and U.S. Patent Application Publication No. 2008-0172033, commercially available as the FinESS system by Entellus Medical, Inc. of Maple Grove, MN. Alternatively, other sinuses could be treated more conventionally using surgical techniques such as, for instance, functional endoscopic sinus surgery (FESS).

[0062] Also, the sphenoid and/or maxillary sinus outflow tracts could be dilated with the embodiment of the balloon catheter **10** described above. It is also contemplated that the balloon catheter **10**, particularly the embodiment of FIG. **7** with a suitable IGS device is incorporated, and with an appropriate shape for the inner support member **14**, preferably straight as illustrated in FIG. **6**C, could be used to dilate the maxillary sinus outflow tract via the canine fossa route. Suitable access tools are described in co-pending U.S. patent application Ser. No. 12/038,719, which was published as U.S. Patent Publication 2009-0216196 and is incorporated by reference herein. This could be performed without need for additional endoscopic visualization, permitting treatment through a relatively small diameter access passageway into the sinus cavity in the region of the canine fossa. A small endoscope (not shown) could be utilized, if desired, through the lumen **18** of the inner support member **14** to further aid in visualization of the maxillary sinus outflow tract.

[0063] In some embodiments, the invention includes the use of a light source to help a practitioner identify portions of, or confirm a location within, a sinus cavity or sinus cavity drainage pathway. For example, in some embodiments, a distal portion of a lighted instrument (e.g., a lighted guidewire, a lighted endoscope, or a lighted probe) is inserted into a subject via a transnasal route and directed into a space or body lumen that a practitioner suspects is a part of the frontal drainage pathway that leads to a frontal sinus cavity. The practitioner directs the lighted distal end of the instrument into the suspected pathway and gently advances the instrument further into the body lumen. If the lumen leads to a frontal sinus cavity, the light from the distal tip will travel through the bone and tissue walls of the cavity and provide a transdermal or transcutaneous illumination pattern visible to the practitioner. In this way, the practitioner can confirm that the suspected body lumen is a part of the frontal drainage pathway and does in fact lead to a frontal sinus cavity. Manipulation of the instrument (e.g., rotation) will move the illumination pattern, further confirming the positioning the instrument in the frontal recess. Once confirmed as part of the drainage pathway, the practitioner can use the other embodiments of this invention discussed above to dilate all or parts of the pathway. Typically, the lighted instrument would be removed from the frontal recess prior to the placement of any embodiment of the invention used to dilate all or parts of the pathway.

[0064] In another example, in some embodiments of the invention, a distal portion of a lighted instrument is used to confirm that a given location is within the maxillary sinus cavity. The practitioner directs the lighted distal end of the instrument to the location and looks for a visible

transdermal or transcutaneous illumination pattern (e.g., an illumination pattern on the roof of the mouth or through the skin near the cheekbone). Once the pattern is observed, the practitioner then knows the given location is within the maxillary sinus cavity. If the pattern is not observed, the practitioner then knows the given location is unlikely to be within the maxillary sinus cavity.
[0065] In some embodiments, the lighted instrument is a lighted probe, such as device **1300** as illustrated in FIGS. **13-16**. FIG. **13** illustrates a perspective view of the entire length of device **1300**, while FIGS. **14** and **15** illustrate top and side views of device **1300**, respectively. FIG. **16** illustrates a cut-away side view of device **1300** along lines C-C of FIG. **14**.
[0066] Lighted probe device **1300** includes a handle portion **1302** forming a proximal portion of device **1300**. Handle portion **1302** is configured to be gripped or otherwise manipulated by the operator. Attached to handle portion **1302** is an elongate-shaped probe member **1304** formed from a suitably rigid material such as a stainless steel hypotube. Probe member **1304** projects or otherwise extends distally from handle **1302**. Probe member **1304** is pre-shaped to have a curved distal portion **1306**. The nature and degree of curvature of probe member **1304** can be configured to match with the frontal sinus outflow tract or frontal recess. In some embodiments, probe member **1304** has some degree of malleability such that a user may bend or impart some desired shape or configuration to the distal end of probe member **1304**.
[0067] Device **1300** defines a light-fiber bundle lumen **1312** that extends along its length, from proximal end **1308** to distal tip **1310**. Lumen **1312** contains a light-fiber bundle that, during use, directs light from a light source connected at proximal end **1308** and out through distal tip **1310** of device **1300**. In some embodiments, lumen **1312** contains a single light-fiber (e.g., a 30 micron 0.44 NA illumination fiber or a 0.55-0.66 NA light fiber) while in other embodiment lumen **1312** contains multiple light-fibers. The light fiber may, for example, be able to conduct a light powerful enough to produce a 15,000 lux or greater illuminance at distal tip **1310**.
[0068] In some embodiments, the light-fiber or fiber bundle may be adhered to the inside walls of lumen **1312** using an epoxy (e.g., EP42HT-CLEAR available from Master Bond, Inc. of Hackensack, New Jersey). In other embodiments, the light-fiber or fiber bundle may be removably inserted or removably secured within lumen **1312** such that the light-fiber or fiber bundle can be removed from device **1300** at some point during use. For example, during use, a practitioner of the invention can insert the light fiber or fiber bundle into lumen **1312**, use the lighted probe device to identify portions of the sinus cavity or sinus cavity drainage pathway or to confirm a location within the nasal or sinus system, remove the light-fiber or fiber bundle while leaving the body portion of device **1300** in place, and then use the lumen of device **1300** to guide other devices to a desired location. Alternatively, or in addition, the lumen of device **1300** could be attached to a vacuum source or a fluid could be directed through the lumen **1300** (thereby allowing a practitioner to apply suction or deliver water and/or a medicament to a desired location within a sinus system before, during, or after use of the light-fiber or fiber bundle). In a further example, the light-fiber or fiber bundle can be removed while leaving the remainder of device **1300** in a desired or confirmed location, thereby providing a visual guide along side of which a practitioner can guide other devices (e.g., a balloon dilation device) to the desired or confirmed location. In some embodiments, the invention includes a removable light-fiber or fiber bundle that includes an atraumatic tip (e.g., a spherical ball tip).
[0069] In some embodiments, device **1300** may be attached or connected to a light source at proximal end **1308** and the light source directs light into and through the fiber bundle in lumen **1312** and out distal tip **1310**. Distal tip **1310** can include an atraumatic tip (as best illustrated in FIG. **13**). The specific size and dimensions of the lighted probe can be varied in order to adapt the device for specific indications or uses. FIG. **15** illustrates some of the dimensions of lighted probe **1300**, including overall length L.sub.1; lengths L.sub.2, L.sub.3, L.sub.4, and L.sub.5; angle α, and radius of curvature R.
[0070] The below Table 1 lists the numeric range of values that those dimensions can take

depending upon the specific design parameters for a given embodiment of a lighted probe. TABLE-US-00001 TABLE 1 Dimension Quantitative Value Length L.sub.1 ~6 to ~8.5 inches Length L.sub.2 ~1.5 to ~4 inches Length L.sub.3 ~0.750 to ~3 inches Length L.sub.4 ~0.1 to ~1.2 inches Length L.sub.5 ~0.170 to ~0.250 inches Angle α ~0 to ~120 degrees Radius of curvature R 0.125 and 0.850 inches

[0071] In some embodiments of the invention, the lighted probe is sized and dimensioned to match or access the frontal sinus outflow tract or frontal recess of a typical patient population, while in other embodiments the probe is sized and dimensioned to match or access the maxillary and/or sphenoid sinus outflow tracts and/or cavities. For example, a lighted probe having an Angle α of about zero degrees (essentially a straight probe) would be particularly useful for accessing the sphenoid sinus spaces. In some preferred embodiments, angle α is in a range of from about 28 degrees to about 88 degrees while the other dimensions angle α fall within the ranges listed in Table 1. In an especially preferred embodiment, length L.sub.1 is about 7.067 inches, length L.sub.2 is about 2.777 inches, length L.sub.3 is about 1.930 inches, length L.sub.4 is about 0.639 inches, length L.sub.5 is about 0.210 inches, an angle α is about 58 degrees, and a radius of curvature R of about 0.850 inches. In another especially preferred embodiment, length L.sub.1 is about 6.886 inches, length L.sub.2 is about 2.616 inches, length L.sub.3 is about 1.931 inches, length L.sub.4 is about 0.763 inches, length L.sub.5 is about 0.210 inches, an angle α is about 78 degrees, and a radius of curvature R of about 0.630 inches. In another especially preferred embodiment, particularly suited for use in the maxillary sinus cavities and outflow tract, angle α is between about 60 and about 120 degrees, the radius of curvature R is between 0.125 and 0.50 inches, and length L.sub.4 is between about 0.150 and 0.750 inches.

[0072] In some embodiments, the atraumatic ball tip of distal tip **1310** has a diameter in the range of between about 0.5 millimeters to about 2.5 millimeters, while in some specific embodiments the atraumatic ball tip has as diameter of about 0.060 inches.

[0073] In some embodiments, probe member **1304** has an inner wall diameter of between 0.0195 inches and 0.0225 inches and an outer wall diameter of between 0.1089 inches and 0.1092 inches. In some embodiments, the distal portion of probe member **1304** has an outer wall diameter that tapers gradually to a narrowed distal tip.

[0074] Prior or after use, the lighted probe can be sterilized via autoclaving, EtOH sterilization, or gamma irradiation.

[0075] In some embodiments, the invention includes the use of a light source having a distal portion that can be detached. FIG. **17** illustrates such an embodiment as light source **1700**. Light source **1700** includes handle portion **1702** and detachable distal portion **1704**. In some embodiments, one of the two portions (e.g., the handle portion) can be made of relatively resilient materials so that it can be sterilized and reused many times while the other portion is made of more economical materials so that it can be disposed of after one use. In further embodiments, the handle portion can be made to accommodate a wide variety of different second portions (e.g., differently shaped detachable distal portions).

[0076] Frequently, whenever two light-conducting elements join at a juncture, heat is generated when light crosses the juncture due to imperfections in the juncture. This is especially true when the juncture is between light-conducting elements made of disparate materials (e.g., one made of glass fiber and a second made of a polymeric fiber). In some cases, the heat generated can be quite substantial and can damage the light-conducting elements or burn an operator. In some embodiments, this invention includes a connector used to connect a light source of the invention with a light cable. The connector provides a juncture between the light source and the light cable that can reduce the amount of heat generated, and/or dissipates generated heat, more effectively and safely than if the light source and light cable were joined without the connector.

[0077] FIG. **18** illustrates such an embodiment as connector **1800**. Connector **1800** can be attached on one side to light cable **1802** to form juncture **1806** and on the other side to proximal end **1804** of the light fiber or fiber bundle of a light source of the invention to form juncture **1808** (for clarity, only the fiber bundle of a light source of the invention is illustrated in FIG. **18**). Connector **1800** includes housing **1810** that can be formed of a material that dissipates heat quickly (e.g., aluminum). Housing **1810** defines an inner lumen portion that contains a light-conducting element **1812** (e.g., a glass fiber or fiber bundle) and light taper **1814**. Light taper **1814**, together with light cable **1802**, forms juncture **1806**. Light-conducting element **1812**, together with proximal end **1804**, forms junction **1808**.

[0078] In use, light is transmitted across junction **1806** from light cable **1802** to light taper **1814**, where it is concentrated and focused into glass fiber **1812**. The light then travels along glass fiber **1812**, across junction **1806**, and into proximal end **1804**. While some amount of heat may be generated at junctions **1806** and **1808**, the heat is easily dissipated by housing **1810**, thereby preventing a undesirable amount of heat from building up in the assembly components.

[0079] FIGS. **19**A-**19**C illustrate various aspects of an embodiment of the invention that includes a light source device that have a removable light-fiber **1900** and guide catheter **1902**.

[0080] Guide catheter **1902** includes hypotube **1906** having malleable distal end **1904** and rigid distal portion **1910**. Hypotube **1906** extends through handle **1908**, with malleable distal end **1906** and a distal portion of rigid distal portion **1910** extending from distal end **1912** of handle **1908**. Hypotube **1906** defines a lumen extending from proximal portion **1914** to distal tip of malleable distal end **1912**. Second proximal portion **1916** defines a second lumen that joins together and is in fluid communication with the lumen defined by hypotube **1906**.

[0081] Removable light-fiber **1900** is illustrated in FIGS. **19**B and **19**C, with portions of the length of light-fiber **1900** omitted from FIG. **19**C for clarity. Light-fiber **1900** includes a length of single light-conducting fiber **1920** that extends from distal tip **1922** to proximal light connector **1924**. A proximal portion of light-fiber **1900** includes protective sheath **1926** of polymeric material overlying light-fiber **1920** and protective sheath **1928** of polymeric or metallic material overlying a proximal portion of protective sheath **1926**. FIG. **19**B also illustrates tuohy-borst connector **1930**.

[0082] In use, distal tip **1922** of light-fiber **1900** is directed into proximal portion **1914** of catheter **1902**, through the lumen defined by hypotube **1906**, and to the distal tip of malleable distal end **1904**. A light source is connected to proximal light connector **1924** so that light is conducted along light-fiber **1920** and projected out from distal tip **1922**. Light-fiber **1900** can be secured to catheter **1902** using connector **1930**. In this way, the light conducting light-fiber **1900** is mounted within catheter **1902** such that the light from distal tip **1922** emanates from the distal end of catheter **1902**. Once assembled to light-fiber **1900**, catheter **1902** can be used to probe a sinus system and confirm, via transdermal illumination, when the position of the distal end of catheter **1902** is within a maxillary or frontal sinus structure. Catheter **1902** can also be used light a flashlight to illuminate sinus structures for viewing structures within the sinus system with an endoscope. Once viewing or transdermal confirmation has been completed, a user may withdraw both catheter **1902** and light-fiber **1900** from the sinus system or, alternatively, may remove light-fiber **1900** leaving catheter **1902** within the sinus system. Fluid (e.g., saline) or suction sources may be secured to second proximal portion **1916** in order to direct fluid from the distal end of malleable distal end **1904** or suction material into and through catheter **1902**.

[0083] In some embodiments of the invention, a portable light source may be used and attached to the light-conducting devices described herein (e.g., device **1300** or light-fiber **1900**). The portable light source may include a battery-powered LED light source.

[0084] In some embodiments of the invention, light of various wavelengths may be directed through the light-conducting devices described herein (e.g., device **1300** or light-fiber **1900**). Red or infrared light tends to pass through blood and tissue more easily than light of other spectrums, so use of red light can be desirable when performing transdermal illumination. Hence, in some embodiments of the invention, a red light may be used with the light-conducting devices described herein when the devices are used to illuminate transdermally while a white light may be used when the devices are used to view structures with an endoscope. In some embodiments of the invention, a portable light source having two dissimilar colors of light (e.g., white and red) is used with the light-conducting devices described herein, with the user toggling the light source between the two colors as desired during use.

[0085] While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. The invention, therefore, should not be limited, except to the following claims, and their equivalents.

Claims

1. A balloon dilation device comprising: a handle having a proximal end and a distal end, wherein the handle comprises a first port at the proximal end of the handle and a second port at the proximal end of the handle; an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member, wherein the first port is in fluid communication with the lumen at the proximal end of the inner guide member; a shaft mounted about a periphery of the inner guide member; an inflatable balloon coupled to the shaft and disposed about the inner guide member; and an inflation lumen extending from the second port of the handle to the inflatable balloon, wherein a center axis of the first port is coaxial with a longitudinal axis of the proximal portion of the inner guide member in the handle, wherein a center axis of the second port and the longitudinal axis define an acute angle on a proximal side, wherein the handle comprises a recessed region that receives the inner guide member, the shaft, the first port, and the second port, wherein the recessed region has a Y-shape, wherein the handle comprises a web structure that extends between the first port and the second port, and wherein the web structure defines a portion of the Y-shape of the recessed region.

2. The balloon dilation device of claim 1, wherein a cross-sectional shape of the web structure along the longitudinal axis is triangular.

3. The balloon dilation device of claim 1, wherein the handle comprises a distal portion, a proximal portion, and an intermediate portion between the distal portion and the proximal portion, wherein the distal portion is tapered inwardly from the intermediate portion to the distal end of the handle, and wherein the proximal portion is tapered outwardly from the intermediate portion to the proximal end of the handle.

4. The balloon dilation device of claim 3, wherein the recessed region comprises a first segment, a second segment, and a third segment that define the Y-shape of the recessed region, wherein a junction between the first segment, the second segment, and third segment is at an interface between the intermediate portion and the proximal portion of the handle.

5. The balloon dilation device of claim 1, wherein the handle comprises a top side, a bottom side, a first lateral side, and a second lateral side that extend between the proximal end and the distal end of the handle, wherein the top side is opposite of the bottom side, wherein the first lateral side is opposite of the second lateral side, wherein the first port and the second port are centered between the first lateral side and the second lateral side, wherein the first port is above the second port such that the first port is closer to the top side and the second port is closer to the bottom side.

6. The balloon dilation device of claim 1, further comprising a light fiber that extends from a distal tip to a proximal light connector, wherein the light fiber is configured to be disposed in the lumen of the inner guide member, wherein the proximal light connector is configured to receive light from a light source, and wherein the distal tip is configured to emit the light received by the proximal light connector.

7. The balloon dilation device of claim 6, further comprising a portable light source coupled to the proximal light connector, wherein the portable light source is configured to generate the light received by the proximal light connector.

8. The balloon dilation device of claim 7, wherein the portable light source is elongated along the longitudinal axis.

9. The balloon dilation device of claim 7, wherein a center axis of the portable light source is coaxial with the center axis of the first port.

10. The balloon dilation device of claim 7, wherein the portable light source comprises a battery-powered light emitting diode (LED) light source.

11. The balloon dilation device of claim 7, wherein the portable light source is configured to generate the light as a red light.

12. The balloon dilation device of claim 6, wherein the light fiber is a lighted guide wire that is configured to be advanced through the lumen of the inner guide member to a position at which the distal tip of the light fiber is distal of a distal-most end of the inner guide member.

13. The balloon dilation device of claim 12, wherein the light fiber is removable from the lumen of the inner guide member.

14. A balloon dilation device comprising: a handle having a proximal end and a distal end, wherein the handle comprises a first port at the proximal end of the handle and a second port at the proximal end of the handle; an inner guide member comprising a proximal portion and a distal portion, wherein the proximal portion of the inner guide member is in the handle, wherein the distal portion of the inner guide member extends distally from the distal end of the handle, wherein the inner guide member comprises a lumen extending from a proximal end of the inner guide member to a distal end of the inner guide member, wherein the first port is in fluid communication with the lumen at the proximal end of the inner guide member, wherein a center axis of the first port is coaxial with a longitudinal axis of the proximal portion of the inner guide member in the handle; a shaft mounted about a periphery of the inner guide member; an inflatable balloon coupled to the shaft and disposed about the inner guide member; and an inflation lumen extending from the second port of the handle to the inflatable balloon, a light fiber that extends from a proximal end to a distal tip, wherein the light fiber is configured to be inserted into the first port and extend in the lumen of the inner guide member; and a portable light source coupled to the proximal end of the light fiber, wherein the light fiber is configured to emit, at the distal tip, light that is generated by the portable light source.

15. The balloon dilation device of claim 14, wherein the portable light source is elongated along the longitudinal axis.

16. The balloon dilation device of claim 14, wherein a center axis of the portable light source is coaxial with the center axis of the first port.

17. The balloon dilation device of claim 14, wherein the portable light source comprises a battery-powered light emitting diode (LED) light source.

18. The balloon dilation device of claim 14, wherein the portable light source is configured to generate the light as a red light.

19. The balloon dilation device of claim 14, wherein the light fiber is a lighted guide wire that is configured to be advanced through the lumen of the inner guide member to a position at which the distal tip of the light fiber is distal of a distal-most end of the inner guide member.

20. The balloon dilation device of claim 14, wherein the light fiber is removable from the lumen of the inner guide member.