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Flexible cryoprobe

Abstract

A cryoablation tool may include a catheter. The catheter may have a shaft having: a proximal end, a distal end, a shaft wall extending between the proximal end and the distal end, the shaft wall having an outer surface and an inner surface and a vacuum gap defined therebetween that forms a vacuum chamber, the inner surface of the shaft wall being gas permeable, a shaft lumen bounded by the inner surface of the shaft wall, the shaft lumen for carrying a cryogen gas, and the vacuum chamber having a proximal opening connectable to a vacuum source, the proximal opening establishing vacuum communication between the vacuum chamber and the vacuum source.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATION (1) This application is a Continuation of U.S. patent application Ser. No. 16/994,145, filed Aug. 14, 2020, now U.S. Pat. No. 12,016,608

which claims priority to Provisional Application No. 62/886,858, filed Aug. 14, 2019, which is herein incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

(1) This disclosure relates to a cryoprobe for use in cryoablation and a system for cryoablation.
(2) During cryosurgery, a surgeon may deploy one or more cryoprobes to ablate a target area of a patient anatomy by freezing and thawing the tissue. In one example, a cryoprobe uses the Joule-Thomson effect to produce cooling or heating of the probe tip. In such cases, the expansion of a cryofluid in the cryoprobe from a higher pressure to a lower pressure leads to cooling of the device tip to temperatures at or below those corresponding to cryoablating a tissue in the vicinity of the tip. Heat transfer between the expanded cryofluid and the outer walls of the cryoprobe leads to formation of an ice ball, in the tissue around the tip and consequent cryoablation the tissue.
(3) Some cryoprobes may be useful for ablating lesions in a human lung. In such cases, the cryoprobes may have to navigate tortuous passageways. Cryoprobes with rigid shafts may not be suitable for such applications.

SUMMARY OF THE INVENTION

(4) In general, various embodiments relating to devices, systems, and methods for a cryoprobe, an insulated sheath, and an insulated catheter. Such devices, systems, and methods can be used in an exemplary application in medical technology. These embodiments can be useful in such an exemplary application, for instance, when providing cryoablation. Yet, at the same time, these embodiments may solve some of the problems noted above.
(5) One aspect of the invention relates to a cryoablation tool comprising a shaft. The shaft may comprise a proximal end, a distal end, a shaft wall. The shaft wall may extend between the proximal end and the distal end and also have an outer surface, an inner surface, and a gap defined there-between that forms a chamber. In some aspects the shaft wall can be gas permeable. The shaft may further comprise a shaft lumen bounded by the inner surface of the shaft wall as well as a cryogen supply conduit. The cryogen supply conduit may be housed within the shaft lumen and may be further configured to carry a cryogen from a cryogen source to a distal portion of the cryoablation tool. The shaft lumen may additionally provide a return flow passage configured to carry the cryogen gas away from the distal end of the cryoablation tool. The chamber, defined between the outer surface and the inner surface of the shaft wall, may have a proximal opening connectable to a vacuum source. The proximal opening may establish vacuum communication between the chamber and the vacuum source. The chamber may also have a chamber fluid pressure therein and the chamber fluid pressure may regulatable via the vacuum source.
(6) Another aspect of the invention relates to an insulated sheath suitable for use with a cryoablation tool. The sheath may comprise a shaft having a proximal end, a distal end, and a shaft wall. The shaft wall may extend between the proximal end and the distal end and also have an outer surface, an inner surface, and a gap defined there-between that forms a chamber. In some aspects the shaft wall can be gas permeable. The shaft may further comprise a shaft lumen bounded by the inner surface of the shaft wall. The shaft lumen may be configured for receiving a cryoablation tool and may also be open at the proximal end and the distal end. The chamber, defined between the outer surface and the inner surface of the shaft wall, may be sealed at the distal end and have a proximal opening connectable to a vacuum source. The proximal opening may be used to establish vacuum communication between the chamber and the vacuum source. The chamber may also have a chamber fluid pressure therein and the chamber fluid pressure may regulatable via the vacuum source.
(7) An additional aspect of the invention relates to an insulated catheter. The insulated catheter may comprise a tubular shaft having a proximal end, a distal end, and a shaft wall. The shaft wall may extend between the proximal end and the distal end and also have an outer surface, an inner surface, and a gap defined there-between that forms a chamber. In some aspects the shaft wall can

be gas permeable. The shaft may further comprise a shaft lumen open at the proximal end and distal end and bounded by the inner surface of the shaft wall. The chamber, defined between the outer surface and the inner surface of the shaft wall, may have a proximal opening connectable to a vacuum source. The proximal opening may establish vacuum communication between the chamber and the vacuum source. The chamber may also have a chamber fluid pressure therein and the chamber fluid pressure may regulatable via the vacuum source.

(8) An additional aspect of the invention relates to a cryoablation system. The system may comprise an endoscope, a vacuum source, a sheath, and a cryoablation tool. The endoscope may have a working channel. The cryoablation tool may be of any type disclosed herein. The cryoablation tool may be extendible from and retractable within the sheath. The cryoablation tool and the sheath may be insertable in the working channel. The cryoablation tool may have a shaft and a chamber of any type disclosed herein. The shaft may be sufficiently flexible to form a curve along an extent of the chamber having a smallest radius of 20 mm. The vacuum source may be connectable to the proximal opening of the chamber for actively regulating fluid pressure in the chamber, including reducing the chamber fluid pressure.

(9) Another aspect of the invention relates to a cryoablation system having an endoscope, a vacuum source, an insulated sheath, and a cryoablation tool. The insulated sheath may be of any type disclosed herein. The cryoablation tool may be insertable within the insulated sheath. The cryoablation tool may have a shaft and a cryogen supply conduit. The shaft may have a proximal end, a distal end, and a shaft wall. The shaft wall may extend between the proximal end and the distal end, and may have an inner surface and an outer surface, and a shaft lumen bounded by the inner surface of the shaft wall. The cryogen supply conduit may be housed within the shaft lumen and be configured to carry a cryogen from a cryogen source to a distal portion of the cryoablation tool. The cryoablation tool may be extendible from and retractable within the insulated sheath. The cryoablation tool and the sheath may be insertable in the working channel. The shaft of the cryoablation tool being sufficiently flexible to form a curve along the shaft having a smallest radius of 20 mm. The vacuum source may be connectable to the proximal opening of the chamber for actively regulating the chamber fluid pressure, including reducing the chamber fluid pressure.

(10) The details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings.

Description

BRIEF DESCRIPTION OF THE FIGURES

(1) FIG. **1** is an exemplary schematic of a cryoablation system that includes a cryoablation tool according to a non-limiting exemplary embodiment;

(2) FIG. **2** is an end view of an outer tubular member with an outer surface of a shaft wall according to a non-limiting exemplary embodiment;

(3) FIG. **3** is dimensioned view of the cryoablation tool of FIG. **1**;

(4) FIG. **3**A is an exemplary schematic of a system that includes an insulated sheath according to a non-limiting exemplary embodiment;

(5) FIG. **4** is an enlarged view of a proximal end of the shaft wall along with components that may be part of a cryoablation system, an insulated sheath system, or an insulated catheter system; and

(6) FIG. **5** is a plot illustrating the details of a three-point bend test of components of an illustrative cryoablation tool.

DETAILED DESCRIPTION

(7) FIG. **1** illustrates a schematic of an exemplary schematic of a cryoablation system that includes a cryoablation tool **100** according to an embodiment. According to some embodiments, the

cryoablation tool **100** may include a catheter **102**. In advantageous aspects, the catheter **102** may be inserted into a working channel of an endoscope such as a bronchoscope **104**, and may, therefore be, generally flexible. In some aspects the cryoablation tool is used in conjunction with a sheath. The sheath may be disposed over the shaft of the tool. In some aspects the outer surface of the shaft of the cryoablation tool may be thermally insulated from the inner surface of the shaft. In some aspects, the outer surface of the shaft of the sheath is thermally insulated from the inner surface. One approach to such aspects is discussed with illustrative reference to FIG. **3**A. In some aspects the cryoablation tool **100** may be part of a cryoablation system that may include a vacuum source connectible to the cryoablation tool. In some aspects the cryoablation tool **100** may be part of a cryoablation system that includes a sheath **160** and an endoscope, such as a bronchoscope **104**, where the cryoablation tool is insertable into the working channel of the endoscope.

(8) With continued reference to FIG. **1**, the catheter **102** may include a tubular shaft **200** having a shaft wall **106**. The shaft wall **106** may extend between a proximal end **108** and a distal end **110**. The shaft wall **106** may include an outer surface **112** forming an exterior of the shaft wall **106**, and an inner surface **114** forming an interior of the shaft wall **106** that defines a shaft lumen **150**. In some aspects of the design, the shaft wall **106** may include an inner shaft wall **201** and may include an outer shaft wall **202**. The outer surface **112** may be the outer surface of the outer shaft wall **202**. The inner surface **114** may be the inner surface of the inner shaft wall **201**. The outer shaft wall **202** may have an outer shaft wall inner surface **203** and the inner shaft wall **201** may have an inner shaft wall outer surface **204**. A gap **206** between the outer shaft wall and the inner shaft wall forms a chamber **180**, which may be annular in shape. The chamber **180** may be bounded by the outer shaft wall inner surface **203** and the inner shaft wall outer surface **204**.

(9) In one approach, the inner shaft wall **201** may be formed by an inner tubular member. The outer shaft wall **202** may likewise be formed by an outer tubular member. The outer tubular member may be radially displaced from the inner tubular member. The outer tubular member may surround the inner tubular member. A gap **206** is defined between the outer tubular member and inner tubular member. In this approach, this gap **206** forms the chamber **180**.

(10) The outer surface **112** and the inner surface **114** may each extend between the proximal end **108** and the distal end **110** of the cryoablation tool **100**. Likewise, the inner shaft wall **201** and the outer shaft wall **202** may each extend between the proximal end **108** and the distal end **110** of the cryoablation tool **100**. The distal end **110** of the shaft may terminate in a distal operating tip **116**. The distal operating tip **116** may be surrounded by a tissue and may cryogenically ablate the tissue in some instances. The distal operating tip **116** may be advantageously configured to pierce tissue in some instances. For example, the distal operating tip **116** may include a sharp tip, such as a trocar tip. Alternatively, the distal operating tip **116** may not be a sharp tip.

(11) In certain optional aspects referencing FIG. **1**, certain portions of the shaft may be flexible. For instance, in an aspect, an entire length of the shaft extending between the proximal end **108** and the distal end **110** may be flexible. For instance, the shaft may be bendable about its longitudinal axis **118** shown by dotted lines in FIG. **1**. In some such embodiments, the shaft may have a shaft diameter configured such that the shaft may be sufficiently flexible to form a curve having a desired radius of curvature. Further, in certain illustrative aspects, an entire length of the shaft may be equally flexible. In such embodiments, the curve radius of different portions of the shaft may be different.

(12) In advantageous aspects, materials and dimensions of the shaft may be configured to provide sufficient degree of flexibility to be bendable about its longitudinal axis **118**. According to an aspect, the catheter shaft may include a polymer. For instance, the inner shaft wall **201** may include a polymer. In one example, the polymer may include polyimide. In additional aspects, the outer shaft wall **202** may also include a polymer. According to one embodiment, the outer shaft wall **202** may include polyimide. Further, the outer shaft wall **202** may include polytetrafluoroethylene (“PTFE”), and/or one or more Polyether block amides (known under the tradename Pebax®,

hereinafter “Pebax”).
(13) In one such example illustrated in FIG. **2**, the outer shaft wall **202** may be formed from a generally cylindrical outer tubular member **210**. In aspects of the design of the outer shaft wall, the outer surface **112** may be formed on an outer layer of the outer shaft wall **202**. The outer shaft wall **202** may be formed integrally with the shaft wall **106** (FIG. **1**) or it may be assembled together from separate components. The outer shaft wall **202** may include one or more layers. Accordingly, a first layer **120** of the outer shaft wall **202** may include Pebax. A second layer **122** of the outer surface **112** may include a PTFE and/or polyimide. A third layer **124** of the outer shaft wall **202** may include polyimide. The first layer **120** may be an outermost layer of the outer shaft wall. The second layer **122** may be positioned between the first layer **120** and the third layer **124**. The third layer **124** may form an innermost layer of the outer shaft wall. The outer shaft wall **202** may include a hollow interior portion **126** bounded by the third layer **124** of the outer shaft wall **202** and specifically by the outer shaft wall inner surface **203**.
(14) According to an example construction, the shaft may have a shaft diameter of less than about 5 millimeters (hereinafter “mm”). Accordingly, the dimensions of the shaft wall may be configured to result in a shaft diameter of less than about 5 mm. In this example, an outer diameter **130** of the outer surface **112** (that may be formed by a tubular member) may be less than about 5 mm. In certain preferred embodiments, the outer diameter **130** of the outer surface **112** may be between about 1 mm and about 2 mm (for example, about 1.75 mm). With continued reference to FIG. **2**, an inner diameter **132** of the outer shaft wall **202** may be between about 1 mm and about 1.8 mm (for example, about 1.6 mm). The outer shaft wall **202** (comprising one or more layers), may have a radial thickness **134** defined radially between the inner surface **203** and the outer surface **112**. In such embodiments, the radial thickness **134** of the outer shaft wall **202** may be between about 0.01 mm and about 0.5 mm thick (e.g., about 0.07 mm).
(15) FIG. **3** illustrates a dimensioned view of the cryoablation tool **100** of FIG. **1**. According to illustrative embodiments of FIG. **3**, the inner shaft wall **201** of the shaft wall **106** may be formed from a generally cylindrical inner tubular member which may be a polymer tube. The inner tubular member may be inserted within the outer shaft wall **202**, that may also be a generally cylindrical outer tubular member and may also be a polymer tube. In aspects of the design the inner surface **114** may be formed on an inner layer of the inner shaft wall and the outer surface **112** may be formed on an outer layer, of the outer shaft wall. The inner shaft wall **201** and the outer shaft wall **202** may be formed integrally with the shaft wall **106** or they may be assembled together from separate components
(16) In an exemplary construction, the inner shaft wall **201** may be generally coaxial with the outer shaft wall **202**. The inner shaft wall **201** may have an outer diameter **136**, an inner diameter **138** and a radial thickness **140** defined therebetween in the radial direction. The outer diameter **136** of the inner shaft wall may be less than the inner diameter **132** of the shaft wall **202**, such that the inner shaft wall may be inserted or contained within the hollow interior of the outer shaft wall.
(17) With reference to FIG. **3**, in illustrative embodiments, the outer diameter **136** of the inner polymer may be between about 0.5 mm and about 1.5 mm (e.g., 1.4 mm). The inner diameter **138** of the inner shaft wall **201** may be between about 0.5 mm and about 1.4 mm (e.g., about 1.3 mm). The radial thickness **140** of the inner shaft wall may be about 0.01 mm and about 0.2 mm (e.g., about 0.1 mm).
(18) In certain optional embodiments, the shaft wall **106** may include at least one reinforcement layer for mechanical strength. With reference to FIG. **2**, this reinforcement layer **142** may particularly be present in the outer shaft wall **202**. In the outer shaft wall, the reinforcement layer may be interposed between the first layer **120** comprising Pebax and the second layer **122** comprising polyimide. In certain examples, the reinforcement layer may include a metal (e.g., stainless steel). Further, in advantageous optional embodiments, the reinforcement layer may include a braided structure, such as a braided stainless steel.

(19) The reinforcement layer may be generally radially outward of the inner shaft wall **201**, and thus radially outward of the chamber **180**, and particularly radially outward of the inner surface **203** of the outer shaft wall **202**. The reinforcement layer may provide sufficient mechanical strength for withstanding pressures such as the pressure of the cryogen in the cryogen supply conduit **152** or the pressure in the cryogen return conduit **158**, which functions as a shaft lumen pressure in the shaft lumen **150** defined by the inner surface **114**. With reference to FIG. **2**, the reinforcement layer may be generally radially outward of the second layer **122** and the third layer **124**. Further, the reinforcement layer may be generally radially inward of the first layer **120**.
(20) Materials and dimensions of the shaft such as those described above may provide adequate degree of flexibility to be bendable about its longitudinal axis **118**. For instance, the shaft may be sufficiently flexible, particularly along the extent of the chamber **180**, such that the shaft may form a curve having a smallest radius of curvature of 20 mm, measured between a center of curvature of the bent shaft and the longitudinal axis **118**. The shaft may form a curve having a smallest radius of curvature of 10 mm or even 5 mm.
(21) Referring back to FIG. **1**, according to certain aspects of the disclosure, the interior of the shaft includes a shaft lumen **150**. The shaft lumen **150** may be bounded by the inner surface **114** of the shaft wall. The shaft lumen **150** may receive a cryogen. For example, in an embodiment, a cryogen supply conduit **152** may be housed (e.g., annularly) within the shaft lumen **150**. The cryogen supply conduit **152** may be configured to supply a cryogen from a cryogen source to a distal portion (e.g., distal end **110** or distal operating tip **116**) of the cryoablation tool **100**. The cryogen supply conduit **152** may be, in some illustrative examples, a capillary tube. In optional embodiments, the cryogen supply conduit **152** may be coaxial with the shaft. The shaft lumen **150** may provide a return flow passage **158** configured to carry the cryogen gas away from the distal end of the cryoablation tool. The return flow passage **158** may be at least partially peripherally surrounded by the inner shaft wall **201**, and more particularly the inner surface of the shaft **114**. The return flow passage may be co-extensive with the shaft lumen **150**.
(22) In certain aspects described further below, the cryogen may pass through a cryocooler **154** and reach cryogenic temperatures. At cryogenic temperatures, the cryogen may be suitable for cooling a surface of a distal portion of the shaft. For instance, the cryogen may cool the outer surface **112** of the distal end **110** (and/or distal operating tip **116**) of the shaft, and thereby remove heat (e.g., and advantageously, ablating) from tissue surrounding the distal end **110** (and/or distal operating tip **116**) of the shaft.
(23) In one arrangement, the cryogen supply conduit may terminate distally in a Joule-Thomson ("J-T") orifice **154**. Accordingly, the cryocooler **154** can be an open loop cryocooler, such as the J-T orifice **154**. The cryogen can be a cooling fluid (e.g., nitrogen, air, argon, krypton, xenon, N.sub.2O, CO.sub.2, and CF4) in embodiments. In such cases, the cryogen may be at a pressure such that expansion via the J-T orifice **154** may result in the cryogen cooling to temperatures for cryogenically ablating tissue surrounding the distal operating tip **116**. In certain aspects, the pressure of the cryogen upstream of the J-T orifice **154** can be between about 7 Megapascal (hereinafter, "MPa") and about 15 MPa (e.g., about 12 MPa). Accordingly, in the embodiments where the cryogen may be a cooling fluid, the temperature of the cryogen after expansion from the J-T orifice **154** can be less than about 190 Kelvin.
(24) Alternatively, the cryogen can be a heating fluid (e.g., helium, hydrogen). In such cases, the cryogen may be at a pressure such that expansion via the J-T orifice **154** may result in a temperature increase of the cryogen, correspondingly resulting in heating of tissue surrounding the distal operating fluid. Such embodiments may be useful for thawing frozen tissue.
(25) With continued reference to FIG. **1**, in embodiments where the cryocooler **154** may be a J-T orifice **154**, the distal end of the shaft may also include a distal expansion chamber **156**, which may be in fluid communication with the return flow passage. The cryogen supply conduit may terminate in a J-T orifice which opens into the expansion chamber. As the cryogen leaves the cryogen supply

conduit **152** via the J-T orifice **154**, the cryogen may undergo J-T expansion and expand into the distal expansion chamber **156**. The distal expansion chamber **156** may be disposed within the flexible portions of the shaft and may particularly be disposed within the active region **172** of the shaft and particularly within a metallic portion thereof as this improves heat exchange with tissue as explained further elsewhere herein.

(26) Referring to FIG. **1**, a cryogen return conduit **158** carry the cryogen away from the distal portion of the shaft. As illustrated, in some embodiments, the cryogen return conduit **158** may be in fluid communication with the expansion chamber. Accordingly, after expanding in the distal expansion chamber **156** the cryogen may flow via the cryogen return conduit **158**. In the illustrated embodiment, the cryogen return conduit **158** may be formed by the inner surface **114** of the shaft wall **106**, and may, therefore, be co-extensive with the shaft lumen **150** defined by the interior wall **114**. Alternatively, the cryogen return conduit **158** may be a separate physical conduit. In an exemplary aspect, the cryogen return conduit **158** may be coaxial with the cryogen supply conduit **152**. Additionally, in advantageous aspects, the cryogen return conduit **158** may annularly surround the cryogen supply conduit **152**, thereby facilitating precooling (e.g., for instance, when the cryogen may be a cooling fluid) or preheating (e.g., for instance, when the cryogen may be a heating fluid) of the cryogen in the cryogen supply conduit **152** with the expanded cryogen in the cryogen return conduit **158**.

(27) Referring back to FIG. **1**, the cryoablation tool **100** may include a sheath **160** which may be disposed over the shaft. The sheath **160** may, in certain embodiments, surround the shaft wall **106**. For example, the sheath **160** may be disposed generally coaxially with the shaft, and may annularly surround the shaft. In advantageous aspects, the sheath **160** and the shaft wall **106** may be displaceable relative to one another. For instance, the sheath **160** and the shaft wall **106** may be displaceable as illustrated by the arrows **161** (parallel to the longitudinal axis **118**) in FIG. **1**. In one example, the distal portion of the shaft may be extendable beyond the sheath **160** and retractable into the sheath **160**. The displacement of the sheath **160** relative to the shaft may be controllable from the proximal end **108** of the cryoablation tool **100**. The sheath **160** may advantageously house and enclose the distal (e.g., sharp) operating tip of the cryoablation tool **100**. Such embodiments may be advantageous, for instance, when the cryoablation tool **100** includes a sharp tip and when the cryoablation tool **100** may be inserted into the working channel of an endoscope such as a bronchoscope **104**. In such instances, the sheath **160** may protect the distal (e.g., sharp) operating tip from protruding out of the sheath **160** and inadvertently damaging the working channel. Further, advantageously, the sheath **160** may protect the outer surface **112** of the shaft from mechanical damage (e.g., abrasions) when inserted into the working channel of the bronchoscope **104**.

(28) Materials of the sheath **160** may be configured to provide desired degree of flexibility and other mechanical properties. According to an aspect, the sheath **160** may include a polymer. In one embodiment, the polymer may include Pebax for sufficient flexibility and kink resistance. The polymer may also include PTFE that may offer ease of engagement of the sheath **160** with respect to the catheter **102**. Additional polymer additives may be added to the materials of the sheath **160** to decrease friction on the outer surface **112** of the sheath **160**. Further, optionally, the sheath **160** may be constructed as a layered arrangement of one or more polymers.

(29) Dimensions of the sheath **160** may be configured to provide desired degree of flexibility and other mechanical properties. In an example construction, referencing FIG. **3**, the sheath **160** may be sufficiently large to receive the catheter **102** there within, and yet have sufficient degree of flexibility and kink resistance. The sheath **160** may have an outer diameter **162** of between about 1 mm and about 3 mm (e.g., about 2 mm) and an inner diameter **164** of between about 1 mm and about 2 mm (e.g., about 1.8 mm).

(30) Referring again to FIGS. **1** and **3**, the shaft may include a thermally insulated region **170**. When a vacuum is actively drawn in the chamber **180**, at least a portion of the chamber forms a thermally insulated region that provides thermal insulation around the shaft lumen. Within the

thermally insulated region **170**, the surface of the shaft **112** is thermally insulated from the cryogen in the return conduit **158**. The thermally insulated region may be co-extensive with the chamber **180**. In the illustrated example, the thermally insulated region **170** extends for a substantial length of the shaft. The thermally insulated region **170** may thermally insulate the shaft from the sheath **160** and/or the working channel of the bronchoscope **104**. Such embodiments may be advantageous in thermally insulating portions other than desired areas of the shaft from areas exterior to the shaft. For instance, the thermally insulating region may thermally insulate the shaft from portions of the patient other than a target site where a cryoablation procedure may be performed.

(31) According to an aspect, the thermally insulated region **170** may extend over a substantial length of the shaft. In the embodiment of FIG. **3**, for instance, the thermally insulated region **170** extends substantially between the proximal end **108** and distal end **110**, except an active region **172** near the distal end **110**. The thermally insulated region **170** may extend at least partially circumferentially around the outer diameter **136** of the inner surface **114** of the shaft. In certain advantageous aspects, the thermally insulated region **170** may provide a thermal insulation to the outer surface **112** of the shaft entirely around the diameter of the shaft.

(32) As described previously, materials and dimensions of the shaft may be chosen so as to provide a desired degree of flexibility. Accordingly, in such embodiments, materials of the shaft wall may be gas permeable. For instance, the inner surface **114** of the shaft wall, the outer surface **112** of the shaft wall or both may be gas permeable. The inner shaft wall **201**, the outer shaft wall **202** or both shaft walls may be gas permeable. The surfaces and shaft walls may be gas permeable particularly when the fluid pressure in the chamber **180** is below atmospheric pressure, such as when a partial vacuum is applied e.g. at 0.1 torr. In one arrangement, the shaft wall **106** (e.g. features such as the inner shaft wall, the outer shaft wall, the outer surface the inner surface) is configured such that, when the chamber fluid pressure is reduced to 0.1 torr, the chamber fluid pressure would increase to 0.9 torr within 30 minutes due to gas permeating through the gas permeable shaft wall, in the absence of continued evacuation.

(33) For instance, the inner surface **114** of the shaft wall may permit expanded cryogen from the cryogen return conduit **158** to flow through the inner surface **114**, and enter the annular space between the inner surface **114** and the outer surface **112** of the shaft wall. Entry of expanded cryogen may reduce thermal insulation between the inner surface **114** and the outer surface **112**, thereby resulting in unintentional heat transfer between cryogen in the cryogen return conduit **158** of the shaft lumen **150** and portions of the outer surface **112** of the shaft wall and exterior areas surrounding the outer surface **112** of the shaft wall. The chamber fluid pressure being at a vacuum pressure, may lead to the cryogen gas carried in the shaft lumen **158** permeating through the shaft wall **106** into the chamber. The permeation of the cryogen through the inner shaft wall **201** may be due at least in part to shaft lumen fluid pressure being greater than the chamber **180** fluid pressure. The chamber fluid pressure will therefore increase unless the chamber fluid pressure is regulated via the vacuum source.

(34) Optionally, the outer surface **112** of the shaft wall and or the outer shaft wall itself, may likewise be gas permeable and may permit gases from the air surrounding the shaft, such as nitrogen or oxygen, to flow through the outer surface **112**, and/or the outer wall and enter the chamber **180** particularly if the fluid pressure in the chamber is less that of the air surrounding the shaft.

(35) Gas permeating through the inner surface **114** and/or the outer surface **112** and the inner and outer shaft walls may reduce the thermal insulation capability of the shaft wall and may degrade the vacuum condition within the chamber if an active vacuum is not maintained. Accordingly, illustrative embodiments may establish an active vacuum between the inner surface **114** and the outer surface **112** of the shaft wall or the inner and outer shaft walls. For example within the chamber **180**.

(36) FIG. **4** illustrates an enlarged view of the shaft wall. Referencing FIGS. **3** and **4**, the thermally

insulated region **170** may be formed by (e.g., and insulated by) a chamber **180** which may be located between the outer surface **112** and the inner surface **114**. The pressure within the chamber **180**, sometimes referred to as the chamber fluid pressure, may be regulatable. For example, chamber fluid pressure of the chamber **180** may be maintained at a vacuum so as to provide the thermally insulated region **170**. With continued reference to FIG. **4**, in certain illustrative aspects, the chamber **180** may be defined between the inner shaft outer surface **203** (e.g., radially outermost layer of the inner tubular member) and the inner surface **204** of the outer shaft **202** (e.g., radially innermost layer of the outer tubular member **112**) of the shaft. The inner shaft **201** and the outer shaft **202** may be spaced apart from each other in the radial direction such that an annular gap **206** exists therebetween and forms the chamber **180**. If a vacuum is applied to the chamber (as will be described further below), the chamber **180** may provide thermal insulation between the inner surface **114** of the shaft and the outer surface **112** such that the inner surface **114** is thermally insulated from the outer surface **112** and the outer surface **112** is thermally insulated from the inner surface **114**.

(37) According to aspects, the chamber **180** may at least partially circumferentially extend around the shaft lumen **150**. For instance, in an embodiment, the chamber may extend entirely around the shaft lumen **150** in the circumferential direction. The chamber **180** may, as illustrated in FIG. **4**, extend annularly around the shaft lumen **150** and may be coaxial therewith, in the thermally insulated region **170** of the shaft.

(38) The cryoablation tool **100** may be configured proximally for establishing vacuum communication between the chamber **180** and a vacuum source **182**. According to an embodiment illustrated in FIG. **4**, the cryoablation tool **100** may be configured proximally for connection to a vacuum source **182**. For instance, the chamber **180** may have a proximal opening **184** which may connect to a vacuum source **182**. The opening **184** is the only opening to the chamber **180**. The chamber is closed distally. In an aspect, the vacuum source **182** may be a vacuum pump **182**. The vacuum pump **182** may be in operative communication with the chamber **180** (e.g., via the proximal opening **184**), and may withdraw gas in the chamber **180**. Except for the proximal opening **184**, the chamber **180** may be sealed. If the chamber is sealed other than at the proximal opening, **184**, the withdrawal of gas by the vacuum source **182** may result in the chamber fluid pressure reducing to a value below atmospheric pressure, thereby resulting in a partial vacuum. According to illustrative aspects, the partial vacuum may be actively maintained in the chamber **180**. The vacuum pump **182** may continue to actively withdraw gas from the chamber **180**, thereby maintaining the pressure in the chamber **180** to a value below atmospheric pressure.

(39) The chamber **180** may have a radial thickness **190** of between about 0.01 mm and about 0.1 mm (e.g., 0.05 mm). According to an embodiment, the vacuum source **182** may maintain a chamber fluid pressure of about 0.05 torr (about 6.6 Pascals). In advantageous aspects, at such deep vacuum pressures, fluid may migrate through the inner surface **114** and/or the outer surface **112** and pass through the outer shaft and/or inner shaft into the chamber **180** due to one or more of the relatively high pressure the cryogen in the cryogen supply conduit **152**, the deep vacuum in the chamber **180**, a permeability of the inner surface **114**, the outer surface **112**, the outer shaft. The permeability of the inner surface **114** the inner shaft **201** the outer surface **112** and the outer shaft may be the result of the materials and dimensions of these features. As noted herein, in advantageous aspect of the shaft wall **106**, the shaft wall **106** has an adequate degree of flexibility to be bendable about its longitudinal axis **118** in a manner as described herein. The materials (e.g., the polymers described elsewhere herein) and dimensions (the millimeter thicknesses described elsewhere herein) of the inner shaft **201** and the outer shaft **202** may be selected, in part, to provide the shaft wall **106** with such degree of flexibility. As a result, fluid (e.g., shaft lumen pressure due to expanded cryogen in the cryogen return conduit **158**) may migrate into the chamber **180** due to one or more of the relatively high pressure the cryogen in the cryogen supply conduit **152**, the deep vacuum in the chamber **180**, the permeability of the inner shaft **201** and inner surface **114**, and the

permeability of the outer shaft **202** and outer surface **112**. The vacuum source **182** operates actively to suction such migrated fluid out of the chamber **180** and actively maintain the chamber fluid pressure at vacuum pressures as described elsewhere herein.

(40) With continued reference to FIG. **4**, the shaft may include structures for improving mechanical strength should a vacuum be actively maintained in the chamber **180**. In one embodiment, the shaft may include one or more support elements **192**. The support elements **192** may, in advantageous aspects, maintain the annular spacing between the inner shaft wall **201** (which may be an inner tubular member) and the outer shaft wall **202** (which may be an outer tubular member). The support elements **192** may be disposed within the chamber. Advantageously, they may not occupy an entire volume of the chamber **180**, and may partially occupy the space available in the chamber **180**, which may be annular. Such embodiments may be configured to facilitate the prevention of collapse of the chamber **180** should gas be withdrawn from the chamber **180**.

(41) According to an aspect, the support elements **192** may include a supporting filament **192**. The supporting filament **192** may include a polymer. In one embodiment, the polymer may include polyether ether ketone ("PEEK"). The supporting filament **192** may be formed by winding a filament, e.g. a polymer filament (e.g., PEEK) **192** in a series of turns about the inner shaft wall, more specifically about the outer face **204** of the inner shaft wall **20**. According to some embodiments, the filament **192** may have a diameter between about 0.01 mm and about 0.1 mm (e.g., about 0.05 mm). The winding of a supporting filament **192** may advantageously maintain the inner shaft wall **201** in a coaxial arrangement with the outer shaft wall. The filament **192** may, advantageously prevent direct contact between the inner surface **203** of the outer shaft wall **202** (e.g. the outer tubular member) and the outer surface **204** of the inner shaft wall (e.g. the inner tubular member) and counteract the forces due to vacuum pressure and thereby improve mechanical strength of the catheter **102**.

(42) In advantageous embodiments, returning to FIG. **1**, the distal end **110** of the catheter shaft may include an active region **172**, over which the expanded cryogen may exchange heat with regions exterior to the shaft (e.g., tissue). The active region **172** may, accordingly, not have thermal insulation. The thermally insulated region **170** may extended over a substantial length of the catheter shaft except at the active region **172**. The active region **172** may include a metallic portion disposed distally of the thermally insulated region **170**. The active region **172** may facilitate heat exchange between the expanded cryogen flowing in the cryogen return conduit **158** and regions exterior to the shaft (e.g., tissue).

(43) In accordance with certain aspects of the present disclosure, the active region **172** may also be substantially flexible. The active region **172** may be flexible substantially to the same degree as the thermally insulated region **170**. The active region **172** may be include one or more bellows, grooves, and the like, and may offer satisfactory degree of bendability without kinking within the metallic region. The shaft may thus comprise a flexible metallic region, disposed at the distal end **110** of the shaft **200**. The flexible metallic region may terminate in a distal tip operating tip **116** which may be configured for penetration of tissue.

(44) Referring back to FIGS. **1** and **3**, according to certain embodiments, the catheter **102** may include a heat-exchange spiral **194** wound around at least distally over the cryogen supply conduit **152**. The heat-exchange spring **194** may enhance circulation and/or residence time of the cryogen (e.g., upon expansion) and may, additionally help maintain the coaxial arrangement between the cryogen supply conduit **152** and the active metal region. In an embodiment, the heat-exchange spiral **194** may be formed from a metallic (e.g. tin-coated copper) wire wound around the distal end **110** of the cryogen supply conduit **152** (e.g., capillary tube). The heat-exchange spiral **194** may have a desired pitch (e.g., between about 1 mm and about 10 mm, for instance, about 4 mm).

(45) In a further embodiment, the shaft walls of the thermally insulated region of the cryoablation tool may be used as the shaft wall of an insulated sheath, or may be further used as the shaft walls of an insulated catheter. The insulated sheath may be used with a cryoablation tool as described

further herein.
(46) Cryoablation tools may lack a thermally insulated region, but may never the less be used in conjunction with an endoscope, such as a bronchoscope or similar device. In one approach, cryoablation tools may be used in conjunction with an insulated sheath in order to provide protection for the working channel of an endoscope from the cryogenic temperatures that may be found in the cryoablation tool. The sheath may also provide protection for tissue that is not intended to be ablated.
(47) With reference to FIG. **3**A a sheath (or catheter) has a shaft wall **106**, which is generally tubular and has a proximal end **108** and a distal end **230**. The shaft is provided with the same features as the shaft of cryoablation tools described elsewhere herein.
(48) A shaft wall **106** extends between the proximal end and the distal end. The shaft wall has an outer surface **112** and an inner surface **114**. A gap **206** may be defined between the outer surface of the shaft **112** and the inner surface of the shaft **114**. This gap **206** may define a chamber **180** between the two surfaces. The chamber may be sealed at the distal end **230** such as by a closure **231**.
(49) The shaft may comprise an inner shaft wall **201** and may also comprise an outer shaft wall **202**. The outer surface of the outer shaft wall **202** may provide the outer surface **112** of the shaft. The inner surface of the inner shaft wall **201** may provide the inner surface **114** of the shaft. The chamber **180** may be defined between outer shaft wall **202** and the inner shaft wall **201**. More specifically the chamber **180** may be defined between the outer shaft wall inner surface **203** and the inner shaft wall outer surface **204**.
(50) The components, construction, materials and gas permeability properties of the shaft wall are as per those of the cryoablation tool described in detail elsewhere herein.
(51) The sheath or catheter has a shaft lumen **232** bounded by the inner surface of the shaft wall **114**, the shaft lumen of a sheath may be configured for receiving a cryoablation tool **300**, The lumen of a sheath or catheter may be open at the distal end **230** and may be open at the proximal end. With reference to FIG. **4** and analogously, the chamber defined between the inner surface **114** and outer surface **112** of the shaft may have a proximal opening **184** connectable to a vacuum source **182**, the proximal opening **184** being configured to establish vacuum communication between the chamber **180** and the vacuum source, the chamber having a chamber fluid pressure therein. Connection of the chamber **180** to the vacuum source **182** allows the chamber fluid pressure to be regulated by the vacuum source analogously to the approach discussed elsewhere herein in relation to a cryoablation tool.
(52) With continued reference to FIG. **3***a*, a cryoablation tool **300** has a shaft **340** having **108** and a distal end **110**. A shaft wall **341** extends between the proximal end and **108** and the distal end **110**. The shaft wall having an inner surface **342** and an outer surface **343**. The shaft wall is typically of a polymeric nature and may in some approaches, be constructed of a series of layers in the same manner as the outer shaft wall of cryoablation tools described elsewhere herein and with reference to FIG. **2**. In particular the shaft wall may comprise a reinforcing layer **142**, which may comprise a braided layer, particularly a stainless steel braid as described elsewhere herein. The tool may have a shaft lumen **158** bounded by the inner surface **342** of the shaft wall. A cryogen supply conduit **152** may be housed within the shaft lumen, the cryogen supply conduit configured to carry a cryogen from a cryogen source to a distal portion **110** of the cryoablation tool. The tool may be provided with a cryogen return passage for evacuation of the cryogen, which, as for the devices discussed elsewhere herein, typically evacuates proximally or may be recycled. The return flow passageway may be provided by the shaft lumen, which may be configured to carry the cryogen gas away from the distal end of the cryoablation tool.
(53) The distal end **110** of the cryoablation tool may terminate in a distal operating tip **116**. The distal operating tip **116** may be advantageously configured to pierce tissue. For example, the distal operating tip **116** may include a sharp tip, such as a trocar tip. Alternatively, the distal operating tip

116 may not be a sharp tip.
(54) In one arrangement, the cryogen supply conduit may terminate distally in a Joule-Thomson ("J-T") orifice **154**. The distal end of the shaft may also include a distal expansion chamber **156**, which may be in fluid communication with the return flow passage. The cryogen supply conduit may terminate in a J-T orifice which opens into the expansion chamber.
Illustrative Examples
(55) FIG. **5** illustrates the flexibility of various components of the catheter **102** according to an embodiment. The flexibility of the components may be quantified by a three-point bend test. The tested components were supported between two points at a distance of about 25 mm apart. The force (in pounds) required to deflect the tested component by about 3 mm is plotted in FIG. **5**.
(56) With continued reference to FIG. **5**, in an embodiment, the outer shaft wall **202** is constructed to have an inner diameter **132** of about 1.6 mm, an outer diameter **130** of about 1.75 mm, a first layer **120** comprising Pebax® 72D, a reinforcement layer **142** having a stainless steel wire braiding, a second layer **122** comprising a polyimide-PTFE blend, and a third layer **124** comprising polyimide. The force for deflecting the outer surface **112** by 3 mm is about 0.375 pounds (about 1.668 N). The outer shaft wall **202** according to this embodiment may have a bend radius of about 12.7 mm and a burst pressure of about 27 MPa.
(57) Referencing FIG. **5**, in another embodiment, the inner shaft wall **201** is constructed to have an inner diameter **138** of about 1.32 mm, an outer diameter **136** of about 1.45 mm, and includes polyimide. The force for deflecting the inner shaft wall **201** by about 3 mm is about 0.14 pounds (about 0.6228 N).
(58) Referring again to FIG. **5**, in another embodiment, the sheath **160** is constructed to have an inner diameter **164** of 1.8 mm and an outer diameter **162** of about 2 mm. The sheath **160** includes a plurality of layers, with a first layer **120** of the sheath **160** including PTFE, a second layer **122** of the sheath **160** including stainless steel, a third layer **124** of the sheath **160** including Pebax 63D®. The bend radius of the sheath **160** was about 12.7 mm. The force for deflecting the sheath **160** by about 3 mm is about 0.3 pounds (about 1.334 N).
(59) In a further embodiment, the cryogen supply conduit **152** includes a nitinol capillary tube having an outer diameter of about 0.57 mm. According to this embodiment, the force for deflecting the capillary tube by 3 mm is about 0.38 pounds (about 1.69 N). The combined force for deflecting the sheath **160**, the outer surface **112**, the inner surface **114**, and the capillary tube by about 3 mm may be about 0.954 pounds (about 4.244 N).
(60) A further embodiment provides an insulated sheath. The insulated sheath may be used with a cryoablation tool as described further herein, or it may be adapted as an insulated catheter.
(61) Cryoablation tools may lack a thermally insulated region, but may never the less be used in conjunction with an endoscope, such as a bronchoscope or similar device. In one approach, cryoablation tools may be used in conjunction with an insulated sheath in order to provide protection for the working channel of an endoscope from the cryogenic temperatures that may be found in the cryoablation tool. The sheath may also provide protection for tissue that is not intended to be ablated.
(62) With reference to FIG. **3**A a sheath or catheter has a shaft wall **106**, which is generally tubular and has a proximal end **108** and a distal end **230**. The shaft is provided with the same features as the shaft of cryoablation tools described elsewhere herein.
(63) A shaft wall **106** extends between the proximal end and the distal end. The shaft wall **106** has an outer surface **112** and an inner surface **114**. A gap **206** may be defined between the outer surface of the shaft **112** and the inner surface of the shaft **114**. This gap **206** may define a chamber **180** between the two surfaces. The chamber may be sealed at the distal end **230** such as by a closure **231**.
(64) The shaft may comprise an inner shaft wall **201** and may also comprise an outer shaft wall **202**. The outer surface of the outer shaft wall **202** may provide the outer surface **112** of the shaft.

The inner surface of the inner shaft wall **201** may provide the inner surface **114** of the shaft. The chamber **180** may be defined between outer shaft wall **202** and the inner shaft wall **201**. More specifically the chamber **180** may be defined between the outer shaft wall inner surface **203** and the inner shaft wall outer surface **204**.
(65) The components, construction, materials and gas permeability properties of the shaft wall are as per those of the cryoablation tool described in detail elsewhere herein.
(66) The sheath or catheter has a shaft lumen **232** bounded by the inner surface of the shaft wall **114**, the shaft lumen of a sheath may be configured for receiving a cryoablation tool **300**, The lumen of a sheath or catheter may be open at the distal end **230** and may be open at the proximal end. With reference to FIG. **4** and analogously, the chamber defined between the inner surface **114** and outer surface **112** of the shaft may have a proximal opening **184** connectable to a vacuum source **182**, the proximal opening **184** being configured to establish vacuum communication between the chamber **180** and the vacuum source, the chamber having a chamber fluid pressure therein. Connection of the chamber **180** to the vacuum source **182** allows the chamber fluid pressure to be regulated by the vacuum source analogously to the approach discussed elsewhere herein in relation to a cryoablation tool.
(67) With continued reference to FIG. **3**A, a cryoablation tool **300** has a shaft **340** having **108** and a distal end **110**. A shaft wall **341** extends between the proximal end and **108** and the distal end **110**. The shaft wall having an inner surface **342** and an outer surface **343**. The shaft wall is typically of a polymeric nature and may in some approaches, be constructed of a series of layers in the same manner as the outer shaft wall of cryoablation tools described elsewhere herein and with reference to FIG. **2**. In particular the shaft wall may comprise a reinforcing layer **142**, which may comprise a braided layer, particularly a stainless steel braid as described elsewhere herein. The tool may have a shaft lumen **158** bounded by the inner surface **342** of the shaft wall. A cryogen supply conduit **152** may be housed within the shaft lumen, the cryogen supply conduit configured to carry a cryogen from a cryogen source to a distal portion **110** of the cryoablation tool. The tool may be provided with a cryogen return passage for evacuation of the cryogen, which, as for the devices discussed elsewhere herein, typically evacuates proximally or may be recycled. The return flow passageway may be provided by the shaft lumen, which may be configured to carry the cryogen gas away from the distal end of the cryoablation tool.
(68) The distal end **110** of the cryoablation tool may terminate in a distal operating tip **116**. The distal operating tip **116** may be advantageously configured to pierce tissue. For example, the distal operating tip **116** may include a sharp tip, such as a trocar tip. Alternatively, the distal operating tip **116** may not be a sharp tip.
(69) In one arrangement, the cryogen supply conduit may terminate distally in a Joule-Thomson ("J-T") orifice **154**. The distal end of the shaft may also include a distal expansion chamber **156**, which may be in fluid communication with the return flow passage. The cryogen supply conduit may terminate in a J-T orifice which opens into the expansion chamber.

Claims

1. A cryoablation tool, comprising: a shaft having: a proximal end, a distal end, a shaft wall extending between the proximal end and the distal end, the shaft wall having an outer surface and an inner surface and a gap defined therebetween that forms a chamber, the shaft wall being gas permeable, a shaft lumen open at the proximal end and the distal end and bounded by the inner surface of the shaft wall; and wherein the chamber sealed at the distal and comprises a proximal opening connectable to a vacuum source, wherein the proximal opening establishes vacuum communication between the chamber and the vacuum source, and the chamber has a chamber fluid pressure therein, the chamber fluid pressure being regulatable via the vacuum source that is configured to actively maintain the chamber fluid pressure at vacuum pressures such that a shaft

lumen fluid pressure is greater than the chamber fluid pressure; and wherein the gas permeable shaft wall is configured such that a cryogen carried in the shaft lumen is configured to permeate through the inner surface of the shaft wall into the chamber when the shaft lumen fluid pressure is greater than the chamber fluid pressure.

2. The cryoablation tool of claim 1, wherein the shaft wall comprises an inner shaft wall and an outer shaft wall, wherein the inner surface is the inner surface of the inner shaft wall and the outer surface is the outer surface of the outer shaft wall and wherein a gap defined between the outer shaft wall and the inner shaft wall forms the chamber.

3. The cryoablation tool of claim 2, wherein the inner shaft wall is formed by an inner tubular member and the outer shaft wall is formed by an outer tubular member, wherein the outer tubular member surrounds the inner tubular member, and wherein the gap is defined between the outer tubular member and inner tubular member to form the chamber.

4. The cryoablation tool of claim 1, wherein the gas permeable shaft wall is configured such that, gases from the air surrounding the outside of the shaft permeates through the shaft wall into the chamber to increase the chamber fluid pressure unless the chamber fluid pressure is regulated via the vacuum source.

5. The cryoablation tool of claim 1, comprising one or more support elements configured to prevent collapse of the chamber when gas is withdrawn from the chamber.

6. The cryoablation tool of claim 1, wherein when a vacuum is actively drawn in the chamber, at least a portion of the chamber forms a thermally insulated region that provides thermal insulation around the shaft lumen.

7. The cryoablation tool of claim 1, further comprising a cryogen supply conduit housed within the shaft lumen, the cryogen supply conduit configured to carry a cryogen from a cryogen source to a distal portion of the cryoablation tool and terminating in a Joule-Thomson orifice that opens into a distal expansion chamber of the shaft lumen so as to form an open loop cryogen supply system.

8. The cryoablation tool of claim 7, wherein the cryogen carried in the shaft lumen permeating through the inner surface of the shaft wall into the chamber when the shaft lumen fluid pressure is greater than the chamber fluid pressure causes the chamber fluid pressure to increase towards the shaft lumen fluid pressure over time, unless the chamber fluid pressure is regulated via the vacuum source.

9. A cryoablation system, comprising: an endoscope having a working channel; a vacuum source that is configured to actively maintain a chamber fluid pressure at vacuum pressures such that a shaft lumen fluid pressure is greater than the chamber fluid pressure; and a cryoablation tool insertable in the working channel comprising, a shaft having: a proximal end, a distal end, a shaft wall extending between the proximal end and the distal end, the shaft wall having an outer surface and an inner surface and a gap defined therebetween that forms a chamber, the shaft wall being gas permeable, a shaft lumen bounded by the inner surface of the shaft wall, wherein the chamber has a proximal opening connectable to the vacuum source, the proximal opening establishes vacuum communication between the chamber and the vacuum source, and the chamber is at the chamber fluid pressure therein, the chamber fluid pressure being regulatable via the vacuum source; and wherein the gas permeable shaft wall is configured such that the cryogen carried in the shaft lumen is configured to permeate through the inner surface of the shaft wall into the chamber when the shaft lumen fluid pressure is greater than the chamber fluid pressure.

10. The cryoablation system of claim 9, wherein a fluid pressure of the shaft lumen due to expanded cryogen in the shaft lumen is greater than the chamber fluid pressure due to the vacuum source such that the chamber fluid pressure is increased unless the chamber fluid pressure is regulated via the vacuum source.

11. The cryoablation system of claim 9, wherein the chamber fluid pressure is regulatable from a high pressure at the cryogen supply conduit to a deep vacuum at the chamber via the vacuum source.

12. The cryoablation system of claim 11, wherein the shaft wall is fluid permeable when the chamber fluid pressure is at deep vacuum pressures such that fluid is allowed to migrate into the chamber, and the vacuum source is configured to operate to actively suction migrated fluid out of the chamber while actively maintaining the chamber fluid pressure at the vacuum pressures.
13. The cryoablation system of claim 9, wherein the chamber is sealed other than at the proximal opening such that withdrawal of cryogen by the vacuum source reduces the chamber fluid pressure to a value below atmospheric pressure to thereby establish a partial vacuum.
14. A cryoablation tool, comprising: a shaft having: a proximal end, a distal end, a shaft wall extending between the proximal end and the distal end, the shaft wall having an outer surface and an inner surface and a gap defined therebetween that forms a chamber, the shaft wall being gas permeable, a shaft lumen bounded by the inner surface of the shaft wall, and a cryogen supply conduit housed within the shaft lumen, the cryogen supply conduit configured to carry a cryogen from a cryogen source to a distal portion of the cryoablation tool, wherein the shaft lumen provides a return flow passage configured to carry the cryogen away from the distal end of the cryoablation tool, the chamber has a proximal opening connectable to a vacuum source, the proximal opening establishes vacuum communication between the chamber and the vacuum source, and the chamber has a chamber fluid pressure therein, the chamber fluid pressure being regulatable from a high pressure at the cryogen supply conduit to a deep vacuum at the chamber via the vacuum source that is configured to actively maintain the chamber fluid pressure at vacuum pressures such that a shaft lumen fluid pressure is greater than the chamber fluid pressure, wherein a portion of the shaft wall includes polyimide; and wherein the gas permeable shaft wall is configured such that the cryogen carried in the return flow passage of the shaft lumen is configured to permeate through the inner surface of the shaft wall into the chamber when the shaft lumen fluid pressure is greater than the chamber fluid pressure, causing the chamber fluid pressure to increase towards the shaft lumen fluid pressure over time, unless the chamber fluid pressure is regulated via the vacuum source.
15. The cryoablation tool of claim 14, wherein the outer surface of the shaft wall is a multilayered material comprising a first layer and a second layer, wherein the first layer is different from the second layer.
16. The cryoablation tool of claim 15, wherein the first layer includes one or more Polyether block amides, and wherein the second layer includes polyimide.
17. The cryoablation tool of claim 16, further comprising a third layer, wherein the first layer is an outermost layer of the outer surface, and wherein the second layer is positioned between the first layer and the third layer such that the third layer is an innermost layer of the outer surface, wherein the third layer includes at least one of polytetrafluoroethylene and polyimide.
18. The cryoablation tool of claim 14, wherein fluid is allowed to migrate into the chamber due to one or more of the high pressure at the cryogen supply conduit, the deep vacuum in the chamber, a permeability of the inner surface, and a permeability of the outer surface.
19. The cryoablation tool of claim 14, wherein the high pressure is between 7 megapascal and 15 megapascal, and the chamber fluid pressure is between 0.01 torr and 0.05 torr.
20. The cryoablation tool of claim 14, wherein the cryogen carried in the return flow passage of the shaft lumen permeating through the inner surface of the shaft wall into the chamber when the shaft lumen fluid pressure is greater than the chamber fluid pressure causes the chamber fluid pressure to increase towards the shaft lumen fluid pressure over time, unless the chamber fluid pressure is regulated via the vacuum source.