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(54) **CRYOABLATION CATHETER AND A CRYOABLATION CATHETER SYSTEM**

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(57) **ABSTRACT**

A cryoablation catheter including an outer tube, an inner tube whose external shape is an irregular shape and a discharge flow path, is provided. The inner tube includes a guide wire lumen and a plurality of supply lumens. The discharge flow path is located between an inner surface of the outer tube and an outer surface of the inner tube, and allows the fluid to pass therethrough from a distal side to a proximal side of the outer tube. The inner tube includes a hole located in a distal portion of the inner tube. Any of the supply lumens and the discharge flow path are in communication with each other through the hole.

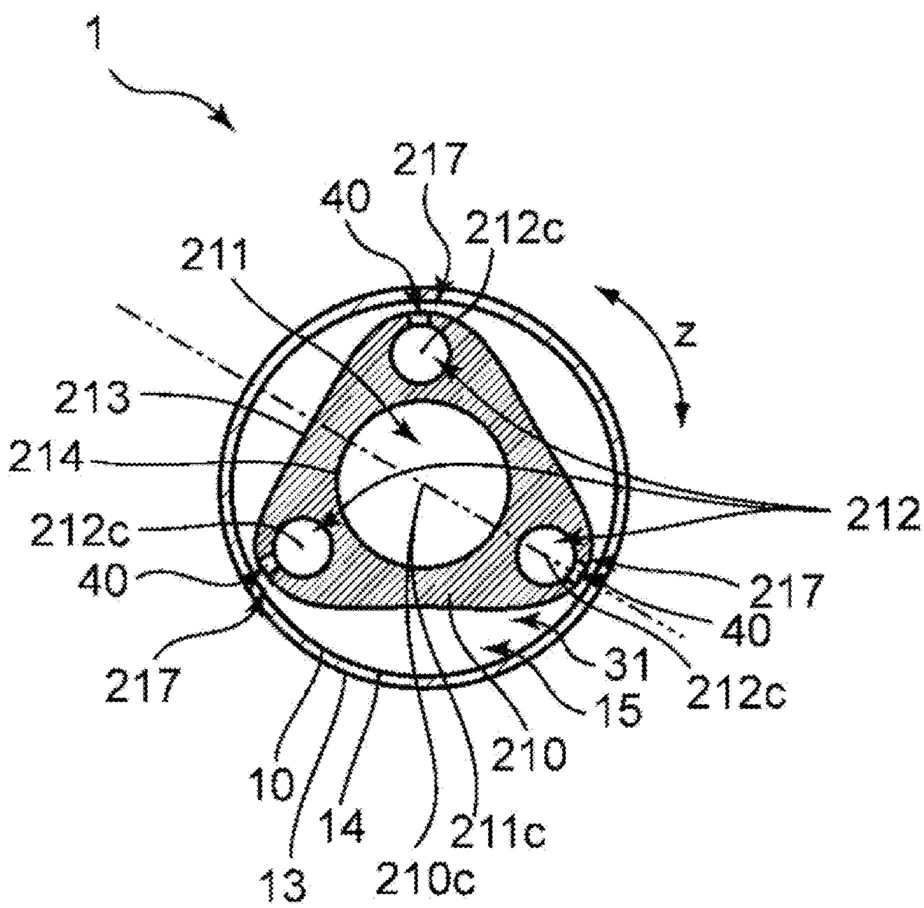


FIG. 1

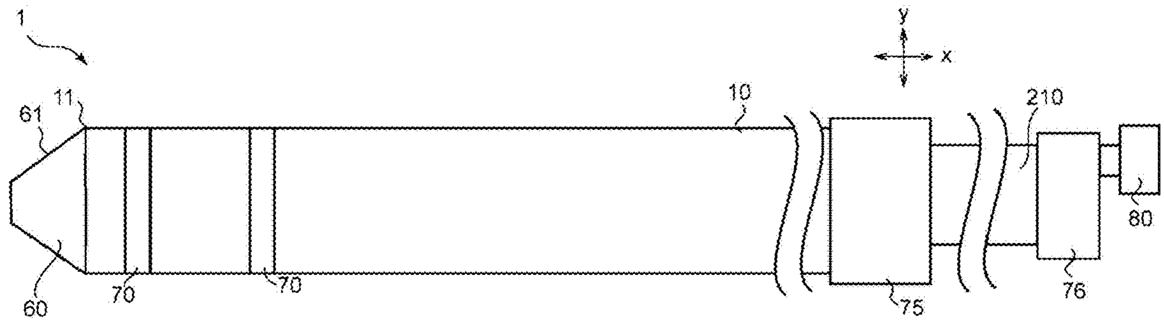



FIG. 2

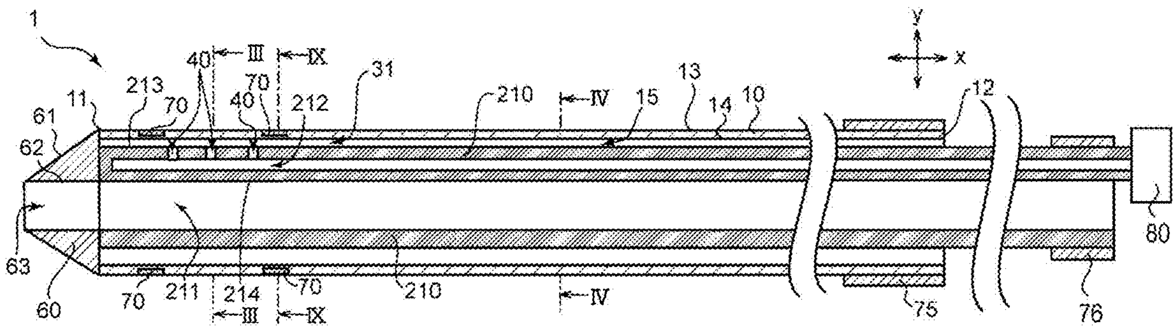



FIG. 3

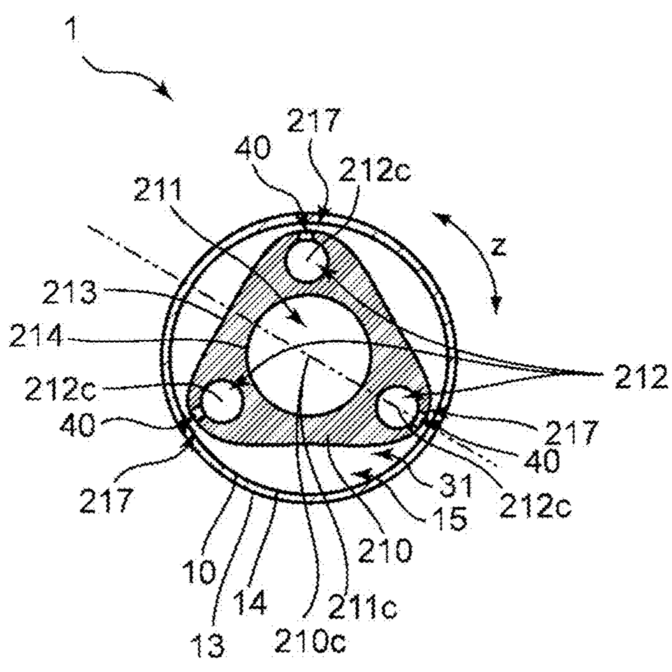


FIG. 4

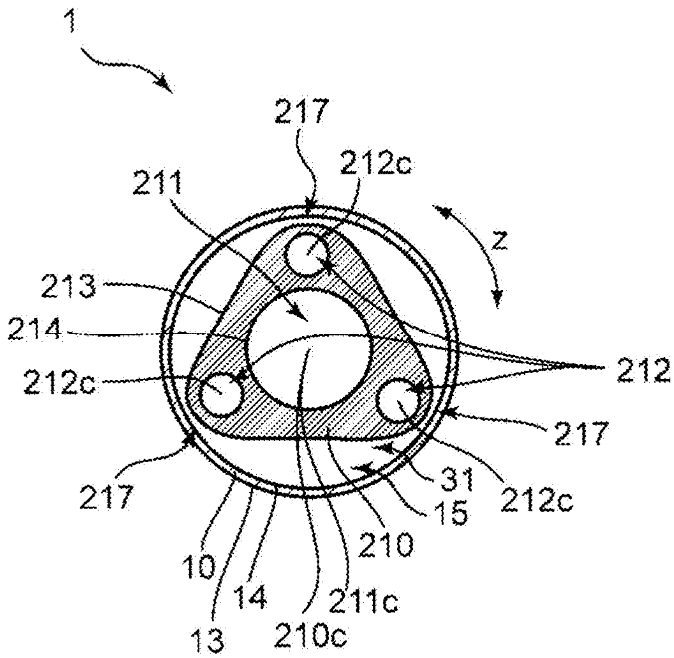
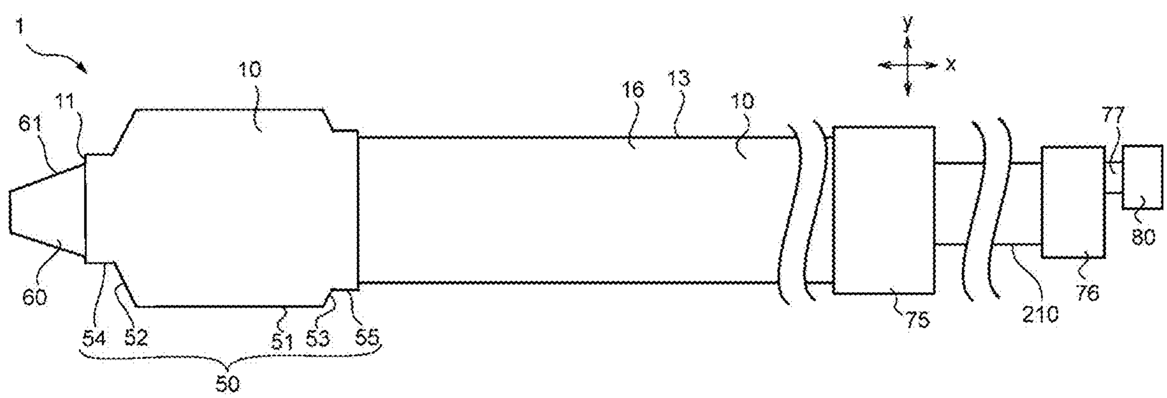

1
217
212c
211
z
213
214
212
212c
217
31
217
15
212c
210
10
14
211c
13
210c

FIG. 5


1
y
x
10
16
13
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61
77
80
60
54
52
51
53
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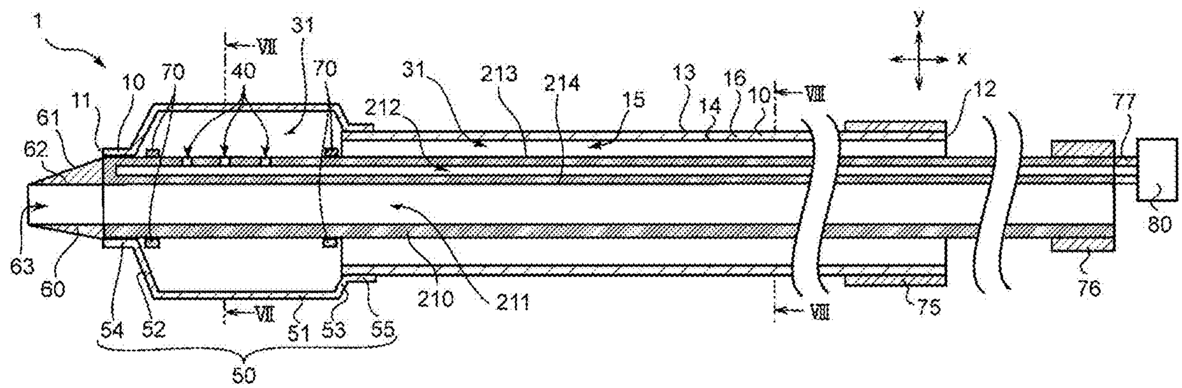
75
210
76
50

FIG. 6


1
10
11
61
62
63
60
70
40
31
VII
213
214
212
15
13
16
14
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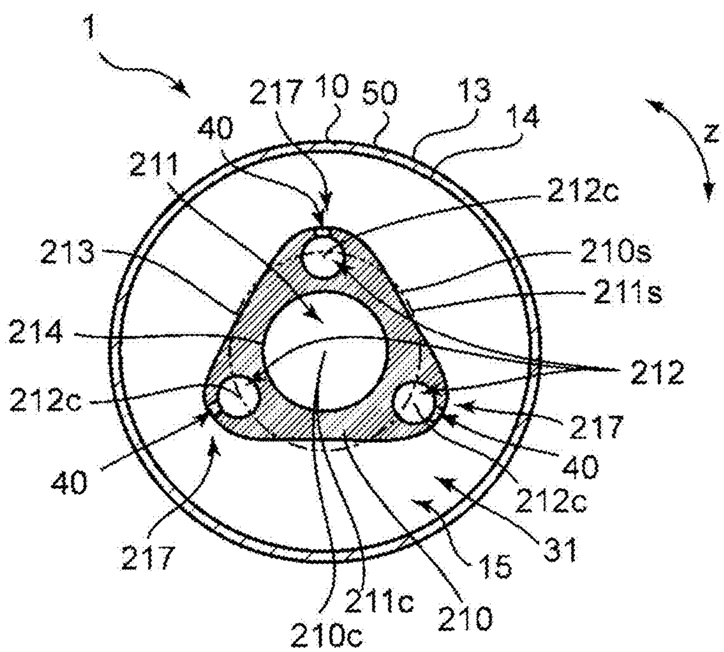
VIII
y
x
12
77
80
76
75
210
211
54
52
51
53
55
50

FIG. 7


1
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211
212c
213
210s
211s
214
212
212c
217
40
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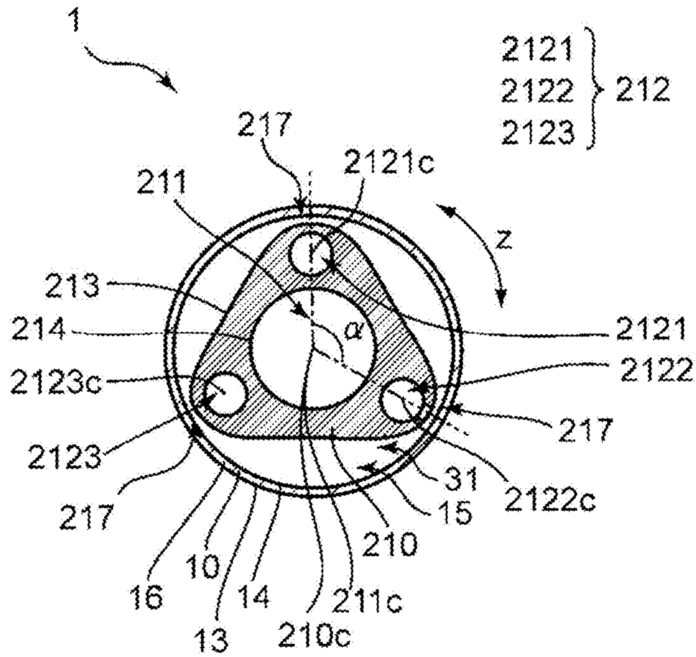
212c
217
31
15
211c
210
210c

FIG. 8


1
2121
2122
2123
212
217
2121c
211
z
213
214
α
2121
2122
2123c
217
2123
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2122c
217
15
210
10
16
14
211c
13
210c

FIG. 9

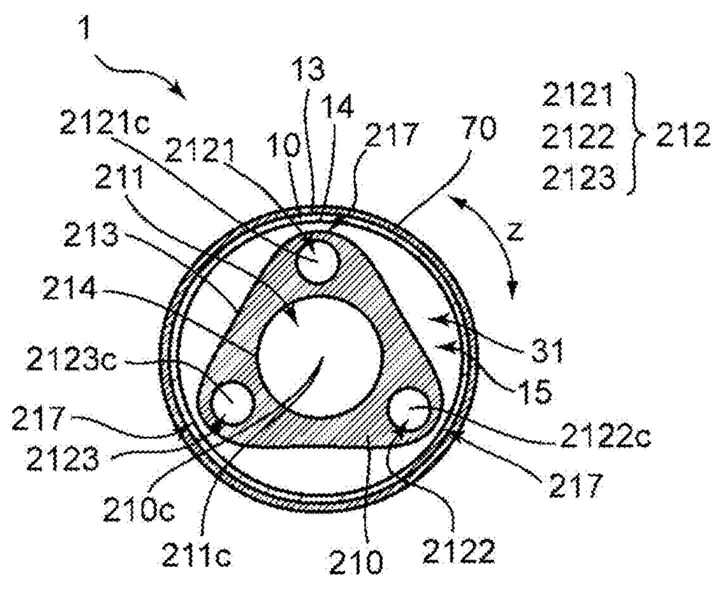
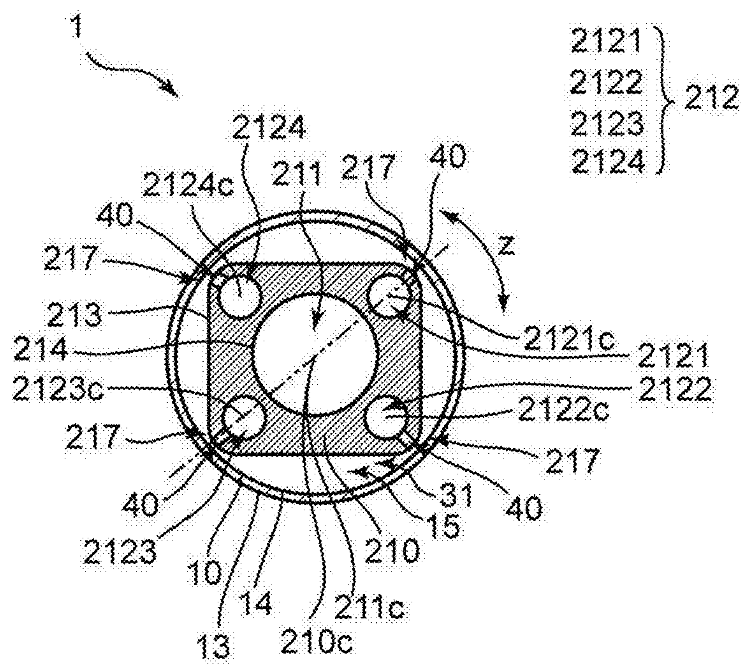

1
13
14
2121
2122
2123
212
2121c
2121
10
217
70
211
213
z
214
31
2123c
15
217
2122c
2123
217
210c
211c
210
2122

FIG. 10


1
2121
2122
2123
2124
212
2124
2124c
211
217
40
40
z
217
213
214
2123c
217
2121c
2121
2122
2122c
217
31
40
15
40
2123
10
14
13
210
211c
210c

# CRYOABLATION CATHETER AND A CRYOABLATION CATHETER SYSTEM

## TECHNICAL FIELD

**[0001]** One or more embodiments of the present invention relate to a cryoablation catheter and a cryoablation catheter system.

## BACKGROUND

**[0002]** Cryoablation techniques are medical techniques that involve bringing a device having been set to have a low temperature into contact with a target tissue so as to freeze and necrose cells forming the target tissue. The cryoablation techniques are used for therapies for cardiac muscle tissues and against tumor tissues. As methods for setting a device to have a low temperature, there are a method in which liquid nitrogen is used and a method in which the Joule-Thomson effect based on high-pressure gas is utilized.

**[0003]** Patent Document 1 describes a cryosurgical therapy catheter having a catheter body including a proximal end portion, a distal end portion, and a main lumen penetrating the proximal end portion and the distal end portion. A balloon for accommodating a low-temperature fluid supplied through the main lumen is placed over an orifice in the catheter body forming the cryosurgical therapy catheter, and the low-temperature fluid is supplied through the catheter body into the balloon. Consequently, the balloon is bulged, and the lesion is cooled.

## Patent Document

**[0004]** Patent Document 1: Japanese Translation of PCT International Application Publication No. JP-T-2001-524345

**[0005]** The catheter needs to be inserted into a duodenal papilla in order to freeze a luminal tissue located on the liver side, the gallbladder side, or the pancreas side relative to the duodenal papilla. For example, in order to insert the catheter into a bile duct via the duodenal papilla, the catheter needs to be significantly bent when being moved from the duodenum side to the bile duct side. The catheter for the cryoablation techniques described in Patent Document 1 is designed such that the area of contact between the fluid as a coolant and a wall surface that is located in the catheter and that defines the lumen is set to be as small as possible in order to make it less likely for the temperature of the coolant to increase before the coolant is carried to a target tissue. Accordingly, it is common to form only one lumen for supplying the fluid. Another purpose of forming only one lumen for supplying the fluid is to make it easy to decrease the diameter of the catheter in order to enable insertion into a narrower body cavity. However, such a conventional catheter in which only one lumen for supplying the fluid is formed is bent while passing through a bent body cavity. Consequently, the lumen for supplying the low-temperature fluid is closed, whereby the catheter cannot stably send the fluid.

## SUMMARY

**[0006]** One or more embodiments of the present invention have been made in view of the aforementioned circumstances, and a cryoablation catheter and a cryoablation catheter system, the diameters of which are easily decreased and which can stably send a fluid from a proximal side to a distal side, are provided.

**[0007]** One embodiment of a cryoablation catheter is as follows.

**[0008]** [1] A cryoablation catheter comprising:

**[0009]** an outer tube having a distal end and a proximal end and extending in a longitudinal direction;

**[0010]** an inner tube extending in the longitudinal direction and disposed in an inner cavity of the outer tube; and

**[0011]** a discharge flow path, wherein,

**[0012]** in a cross section perpendicular to the longitudinal direction, an external shape of the inner tube is an irregular shape,

**[0013]** in the cross section perpendicular to the longitudinal direction, the inner tube has a guide wire lumen into which a guide wire is inserted and a plurality of supply lumens which allow a fluid to pass therethrough from a proximal side to a distal side of the inner tube and which are formed in regions different from a region in which the guide wire lumen is formed,

**[0014]** the discharge flow path is located between an inner surface of the outer tube and an outer surface of the inner tube and allows the fluid to pass therethrough from a distal side to a proximal side of the outer tube, and

**[0015]** the inner tube has a distal portion in which a hole through which any of the supply lumens and the discharge flow path are in communication with each other is formed.

**[0016]** The fluid for cooling a lesion is carried from a proximal side to a distal side of the catheter through the supply lumens. The carried fluid is jetted from the hole to the outer side in the radial direction of the outer tube, and a lesion located on the outer side in the radial direction relative to the outer tube is cooled. The fluid that has come to have an increased temperature as a result of cooling the lesion is carried from the distal side to the proximal side of the catheter through the discharge flow path. In the cryoablation catheter according to one or more embodiments of the present invention, the external shape of the inner tube is an irregular shape, whereby the distance in the radial direction of the outer tube between the inner surface of the outer tube and the outer surface of the inner tube varies depending on the position. Consequently, even in a case where the distance between the inner surface of the outer tube and the outermost surface of the inner tube is shortened by decreasing the outer diameter of the outer tube, the fluid can move from the distal side to the proximal side by passing through positions at each of which the distance in the radial direction of the outer tube between the inner surface of the outer tube and the outer surface of the inner tube is comparatively long. Therefore, the passage capability of the cryoablation catheter according to one or more embodiments of the present invention can be improved by decreasing the diameter thereof, and the cryoablation catheter allows the fluid to stably move from the distal side to the proximal side. In addition, in the inner tube of the cryoablation catheter according to one or more embodiments of the present invention, the plurality of supply lumens are formed. Thus, even when one of the supply lumens is closed owing to bending of the cryoablation catheter which is passing through a bent body cavity, the fluid can be sent through the remaining supply lumens.

Consequently, the fluid can be stably sent from the proximal side to the distal side. Furthermore, in the cryoablation catheter according to one or more embodiments of the present invention, the external shape of the inner tube is an irregular shape in the cross section perpendicular to the longitudinal direction of the outer tube, whereby stabilization of the position of the inner tube in the inner cavity of the outer tube can be facilitated.

**[0017]** Other aspects of the cryoablation catheter are as shown in the following [2] to [10]:

**[0018]** [2] The cryoablation catheter according to above [1], wherein, in the cross section perpendicular to the longitudinal direction, the external shape of the inner tube is a polygonal shape.

**[0019]** [3] The cryoablation catheter according to above [1], wherein, in the cross section perpendicular to the longitudinal direction, the external shape of the inner tube is a triangular shape.

**[0020]** [4] The cryoablation catheter according to any one of above [1] to [3], wherein,

**[0021]** in the cross section perpendicular to the longitudinal direction, the inner tube has a vertex portion protruding outward in a radial direction of the outer tube, and

**[0022]** the hole is formed in the vertex portion.

**[0023]** [5] The cryoablation catheter according to any one of above [1] to [4], wherein,

**[0024]** in the cross section perpendicular to the longitudinal direction, a roundness of an external shape of the outer tube obtained according to the following formula is higher than a roundness of the external shape of the inner tube obtained according to the following formula,

$$(Rmax-Rmin)/Rmin, \text{ where} \qquad \text{[Formula]}$$

**[0025]** Rmax represents a radius of a circumscribed circle, and Rmin represents a radius of an inscribed circle.

**[0026]** [6] The cryoablation catheter according to any one of above [1] to [5], wherein, in the cross section perpendicular to the longitudinal direction, the guide wire lumen is formed at a position that overlaps with a centroid of the inner tube, and each of the supply lumens is formed at a position that does not overlap with the centroid of the inner tube.

**[0027]** [7] The cryoablation catheter according to any one of above [1] to [6], wherein, in the cross section perpendicular to the longitudinal direction, the plurality of supply lumens are located on an imaginary circle having a center at a centroid of the guide wire lumen.

**[0028]** [8] The cryoablation catheter according to any one of above [1] to [7], wherein, in the cross section perpendicular to the longitudinal direction, a maximum width of each of the supply lumens is smaller than a maximum width of the guide wire lumen.

**[0029]** [9] The cryoablation catheter according to any one of above [1] to [8], wherein the outer tube has, on a distal portion thereof, a balloon expandable and shrinkable in a radial direction of the outer tube.

**[0030]** [10] The cryoablation catheter according to any one of above [1] to [9], wherein

**[0031]** the cryoablation catheter further comprises a distal tip in which a lumen extending in the longitudinal direction is formed and which has an outer diameter decreasing from a proximal side toward a distal side, and

**[0032]** a distal end portion of the outer tube and a distal end portion of the inner tube are fixed to a proximal end portion of the distal tip.

**[0033]** One or more embodiments of the present invention also provide the following.

**[0034]** [11] A cryoablation catheter system comprising:

**[0035]** the cryoablation catheter according to any one of above [1] to [10]; and

**[0036]** a fluid supply device configured to supply the fluid to the supply lumens, wherein

**[0037]** the inner tube is connected to the fluid supply device.

**[0038]** In the cryoablation catheter according to one or more embodiments of the present invention, the external shape of the inner tube is an irregular shape, whereby the distance in the radial direction of the outer tube between the inner surface of the outer tube and the outer surface of the inner tube varies depending on the position. Consequently, even in a case where the distance between the inner surface of the outer tube and the outermost surface of the inner tube is shortened by decreasing the outer diameter of the outer tube, the fluid can move from the distal side to the proximal side by passing through positions at each of which the distance in the radial direction of the outer tube between the inner surface of the outer tube and the outer surface of the inner tube is comparatively long. Therefore, the passage capability of the cryoablation catheter according to one or more embodiments of the present invention can be improved by decreasing the diameter thereof, and the cryoablation catheter allows the fluid to stably move from the distal side to the proximal side. In addition, in the inner tube of the cryoablation catheter according to one or more embodiments of the present invention, the plurality of supply lumens are formed. Thus, even when one of the supply lumens is closed owing to bending of the cryoablation catheter which is passing through a bent body cavity, the fluid can be sent through the remaining supply lumens. Consequently, the fluid can be stably sent from the proximal side to the distal side. Furthermore, in the cryoablation catheter according to one or more embodiments of the present invention, the external shape of the inner tube is an irregular shape in the cross section perpendicular to the longitudinal direction of the outer tube, whereby stabilization of the position of the inner tube in the inner cavity of the outer tube can be facilitated. The cryoablation catheter system according to one or more embodiments of the present invention including the above cryoablation catheter also has the same advantageous effect.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0039]** FIG. **1** is a side view showing an example of the cryoablation catheter according to one or more embodiments of the present invention.

**[0040]** FIG. **2** is a cross-sectional view of the cryoablation catheter shown in FIG. **1**.

**[0041]** FIG. **3** is a cross-sectional view, at the line III-III, of the cryoablation catheter shown in FIG. **2**.

**[0042]** FIG. **4** is a cross-sectional view, at the line IV-IV, of the cryoablation catheter shown in FIG. **2**.

**[0043]** FIG. **5** is a side view showing a modification of the cryoablation catheter according to one or more embodiments of the present invention.

**[0044]** FIG. **6** is a cross-sectional view of the cryoablation catheter shown in FIG. **5**.

**[0045]** FIG. **7** is a cross-sectional view, at the line VII-VII, of the cryoablation catheter shown in FIG. **6**.

**[0046]** FIG. **8** is a cross-sectional view, at the line VIII-VIII, of the cryoablation catheter shown in FIG. **6**.

**[0047]** FIG. **9** is a cross-sectional view, at the line IX-IX, of the cryoablation catheter shown in FIG. **2**.

**[0048]** FIG. **10** is a cross-sectional view showing a modification of the cryoablation catheter shown in FIG. **3**.

## DETAILED DESCRIPTION

**[0049]** One or more embodiments of the present invention will be specifically explained below based on the following embodiments, however, the present invention is not restricted by the embodiments described below of course, and can be certainly put into practice after appropriate modifications within in a range meeting the gist of the above and the below, all of which are included in the technical scope of the present invention. In the drawings, hatching, a reference sign for a member may be omitted for convenience, and in such a case, the description and other drawings should be referred to. In addition, sizes of various members in the drawings may differ from the actual sizes thereof, since priority is given to understanding the features of one or more embodiments of the present invention.

**[0050]** A cryoablation catheter according to one or more embodiments of the present invention is a cryoablation catheter having the following gist. That is, the cryoablation catheter includes: an outer tube having a distal end and a proximal end and extending in a longitudinal direction; an inner tube extending in the longitudinal direction of the outer tube and disposed in an inner cavity of the outer tube; and a discharge flow path. In a cross section perpendicular to the longitudinal direction of the outer tube, an external shape of the inner tube is an irregular shape. In the cross section perpendicular to the longitudinal direction of the outer tube, the inner tube has a guide wire lumen into which a guide wire is inserted and a plurality of supply lumens which allow a fluid to pass therethrough from a proximal side to a distal side of the inner tube and which are formed in regions different from a region in which the guide wire lumen is formed. The discharge flow path is located between an inner surface of the outer tube and an outer surface of the inner tube and allows the fluid to pass therethrough from a distal side to a proximal side of the outer tube. The inner tube has a distal portion in which a hole through which any of the supply lumens and the discharge flow path are in communication with each other is formed.

**[0051]** An overall configuration of a cryoablation catheter **1** according to one or more embodiments of the present invention will be described with reference to FIG. **1** to FIG. **10**. The cryoablation catheter **1** shown in FIG. **1** to FIG. **10** includes an outer tube **10** and an inner tube **210**. In these drawings, the longitudinal direction and the radial direction of the outer tube **10** are respectively indicated by x and y. The radial direction y is a direction perpendicular to the longitudinal direction x. In addition, the circumferential direction of the outer tube **10** is indicated by z. Hereinafter, the cryoablation catheter **1** is sometimes simply referred to as the catheter **1**.

**[0052]** In the present description, the proximal side refers to the hand side of a user in an extension direction of the outer tube, and the distal side refers to the side opposite to the proximal side, i.e., a treatment target side. A distal portion of each member refers to the distal half of the member, and a proximal portion of each member refers to the proximal half of the member.

**[0053]** FIG. **1** is a side view showing an example of the cryoablation catheter according to one or more embodiments of the present invention. FIG. **2** is a cross-sectional view of the cryoablation catheter shown in FIG. **1**. FIG. **3** is a cross-sectional view, at the line III-III, of the cryoablation catheter shown in FIG. **2**. FIG. **4** is a cross-sectional view, at the line IV-IV, of the cryoablation catheter shown in FIG. **2**. FIG. **5** is a side view showing a modification of the cryoablation catheter according to one or more embodiments of the present invention. FIG. **6** is a cross-sectional view of the cryoablation catheter shown in FIG. **5**. FIG. **7** is a cross-sectional view, at the line VII-VII, of the cryoablation catheter shown in FIG. **6**. FIG. **8** is a cross-sectional view, at the line VIII-VIII, of the cryoablation catheter shown in FIG. **6**. FIG. **9** is a cross-sectional view, at the line IX-IX, of the cryoablation catheter shown in FIG. **2**. FIG. **10** is a cross-sectional view showing a modification of the cryoablation catheter shown in FIG. **3**.

**[0054]** As shown in FIG. **1** to FIG. **10**, the outer tube **10** provided to the catheter **1** has a distal end **11** and a proximal end **12** and extends in the longitudinal direction x. The outer tube **10** has an inner cavity **15**. The inner cavity **15** may extend in the longitudinal direction x of the outer tube **10**. The outer tube **10** has an outer surface **13** facing the outside of the outer tube **10** and an inner surface **14** facing the inner cavity **15** of the outer tube **10**.

**[0055]** As shown in FIG. **1** to FIG. **10**, the inner tube **210** provided to the catheter **1** extends in the longitudinal direction x of the outer tube **10** and is disposed in the inner cavity **15** of the outer tube **10**. As shown in FIG. **3**, FIG. **4**, FIG. **7** and FIG. **8**, the inner tube **210** has, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, a guide wire lumen **211** into which a guide wire is inserted and a plurality of supply lumens **212** which allow a fluid to pass therethrough from the proximal side to the distal side of the inner tube **210** and which are formed in regions different from a region in which the guide wire lumen **211** is formed.

**[0056]** As shown in FIG. **3** and FIG. **10**, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the external shape of the inner tube **210** is an irregular shape. The irregular shape means a shape other than perfect circular shapes, and the perfect circular shapes do not include elliptical shapes or oval shapes. In a case where, for example, the term "circular shape" is used in the present description, the circular shape encompasses shapes such as perfect circular shapes, elliptical shapes, and oval shapes.

**[0057]** As shown in FIG. **2** to FIG. **4** and FIG. **6** to FIG. **10**, the catheter **1** has a discharge flow path **31** which is located between the inner surface **14** of the outer tube **10** and an outer surface **213** of the inner tube **210** and which allows the fluid to pass therethrough from the distal side to the proximal side of the outer tube **10**. The discharge flow path **31** is a space provided between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210**. The fluid having passed through the supply lumens **212** so as to be carried from the proximal side to the distal side of the catheter **1** is discharged to the outside of the catheter **1** via the discharge flow path **31** which is a space provided between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210**.

**[0058]** As shown in FIG. **2**, FIG. **3**, FIG. **6**, FIG. **7**, and FIG. **10**, the inner tube **210** has a distal portion in which holes **40** through which the respective supply lumens **212** and the discharge flow path **31** are in communication with each other are formed. The fluid having passed through the supply lumens **212** so as to be carried from the proximal side to the distal side of the catheter **1** is jetted to the discharge flow path **31** via the holes **40**.

**[0059]** The fluid passes through the supply lumens **212** so as to be carried from the proximal side to the distal side of the catheter **1**. Then, the fluid is jetted from the holes **40** of the inner tube **210** to the outer side in the radial direction of the outer tube **10** and passes through the discharge flow path **31** so as to be carried from the distal side to the proximal side. Then, the fluid is discharged to the outside of the catheter **1**.

**[0060]** In the catheter **1** according to one or more embodiments of the present invention, the external shape of the inner tube **210** is an irregular shape, whereby the distance in the radial direction y of the outer tube **10** between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210** varies depending on the position. Consequently, even in a case where the distance between the inner surface **14** of the outer tube **10** and the outermost surface of the inner tube **210** is shortened by decreasing the outer diameter of the outer tube **10**, the fluid can move from the distal side to the proximal side by passing through positions at each of which the distance in the radial direction y of the outer tube **10** between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210** is comparatively long. Therefore, the passage capability of the catheter **1** according to one or more embodiments of the present invention can be improved by decreasing the diameter thereof, and the catheter **1** allows the fluid to stably move from the distal side to the proximal side. In addition, in the inner tube **210** of the catheter **1** according to one or more embodiments of the present invention, the plurality of supply lumens **212** are formed. Thus, even when one of the supply lumens **212** is closed owing to bending of the cryoablation catheter **1** which is passing through a bent body cavity, the fluid can be sent through the remaining supply lumens **212**. Consequently, the fluid can be stably sent from the proximal side to the distal side. Furthermore, in the catheter **1** according to one or more embodiments of the present invention, the external shape of the inner tube **210** is an irregular shape in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, whereby stabilization of the position of the inner tube **210** in the inner cavity **15** of the outer tube **10** can be facilitated.

**[0061]** The catheter **1** may be a cryoablation catheter for duodenal papilla insertion. The cryoablation catheter for duodenal papilla insertion means a cryoablation catheter to be inserted into a duodenal papilla in order to freeze a luminal tissue that leads to the opening of the duodenal papilla and that is located on the liver side, the gallbladder side, or the pancreas side relative to the duodenal papilla.

**[0062]** The outer tube **10** may have flexibility so as to be inserted into a body. Consequently, the outer tube **10** can be deformed according to the shape of the body cavity. In addition, the outer tube **10** may have elasticity in order to retain the shape thereof.

**[0063]** Examples of the outer tube **10** include: a hollow member formed by arranging one or more wire materials in a predetermined pattern; a member formed by coating at least one of an inner surface or an outer surface of the above hollow member with a resin; a resin tube; and a member formed by a combination thereof, e.g., a member formed by connecting these outer tubes in a longitudinal axis direction. The hollow member formed by arranging a wire material in a predetermined pattern is exemplified by: a tubular member having a network structure as a result of simple intersection or weaving of the wire material; and a coil formed by winding the wire material. The wire material may be one or more single wires or may be one or more twisted wires. The resin tube may be produced through, for example, extrusion molding. In a case where the outer tube **10** is the resin tube, the outer tube **10** may be composed of a single layer or a plurality of layers. The outer tube **10** may be such that: one portion thereof extending in the longitudinal direction x or the circumferential direction z is composed of a single layer; and another portion thereof extending in the longitudinal direction x or the circumferential direction z is composed of a plurality of layers.

**[0064]** The outer tube **10** may be formed from, for example: a synthetic resin such as a polyolefin resin (e.g., polyethylene or polypropylene), a polyamide resin (e.g., nylon), a polyester resin (e.g., PET), an aromatic polyether ketone resin (e.g., PEEK), a polyether polyamide resin, a polyurethane resin, a polyimide resin, or a fluorine resin (e.g., PTFE, PFA, or ETFE); or a metal such as stainless steel, carbon steel, or a nickel-titanium alloy. These types of materials may be used singly, or two or more of these types of materials may be used in combination.

**[0065]** The shape of the outer tube **10** is a tubular shape and may be a shape such as the shape of a hollow column or a hollow polygonal prism.

**[0066]** Specifically, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the external shape of the outer tube **10** may be any of circular shapes, polygonal shapes including triangular shapes and quadrangular shapes, semi-circular shapes, fan shapes, wedge shapes, protruding shapes, a combination of these shapes, and the like, but may differ from the external shape of the inner tube **210**. Since the inner tube **210** has an irregular shape other than perfect circular shapes, the external shape of the outer tube **10** may be a circular shape or a perfect circular shape, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**. By employing the above configuration, the distance in the radial direction y of the outer tube **10** between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210** varies depending on the position. Consequently, even in a case where the distance between the inner surface **14** of the outer tube **10** and the outermost surface of the inner tube **210** is shortened by decreasing the outer diameter of the outer tube **10**, the fluid can move from the distal side to the proximal side by passing through positions at each of which the distance in the radial direction y of the outer tube **10** between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210** is comparatively long. Although not shown, the external shape of the outer tube **10** and the external shape of the inner tube **210** may be congruent with each other in the cross section perpendicular to the longitudinal direction x of the outer tube **10**. For example, in a case where the external shape of the outer tube **10** and the external shape of the inner tube **210** are triangular shapes congruent with each other, each vertex portion of one of the triangular shapes and each vertex portion of the other triangular shape are located at different positions in the circumferential direction z of the outer tube **10**. By doing so, the distance in the radial direction y of the outer tube **10** between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210** varies depending on the position, whereby the above advantageous effects can be obtained.

**[0067]** As shown in FIG. **1**, FIG. **2**, FIG. **6**, and FIG. **9**, radiopaque markers **70** may be provided on the distal portion of the outer tube **10**. In this configuration, use of an X-ray imaging device makes it possible to visually recognize the position of the distal portion of the catheter **1**. As shown in FIG. **1**, FIG. **2**, and FIG. **9**, each of the radiopaque markers **70** may be provided on, for example, the outer surface **13** of the outer tube **10**.

**[0068]** As shown in FIG. **6**, the radiopaque markers **70** may be provided on the distal portion of the inner tube **210**. In this configuration, use of an X-ray imaging device makes it possible to visually recognize the position of the distal portion of the catheter **1**.

**[0069]** The shape of each of the above radiopaque markers **70** may be a tubular shape as shown in FIG. **1**, FIG. **2**, and FIG. **9**. Other examples of the shape include the shape of a hollow column, the shape of a hollow polygonal prism, a shape obtained by forming a slit in a tube so as to have a C-shaped cross section, the shape of a coil obtained by winding a wire material, and the like.

**[0070]** As a material forming the above radiopaque marker **70**, a radiopaque substance such as lead, barium, iodine, tungsten, gold, platinum, iridium, stainless steel, titanium, or a cobalt-chromium alloy may be used, for example. The radiopaque marker **70** may be obtained in such a manner that radiopaque particles made from barium sulfate or the like are dispersed in the outer tube **10**, the inner tube **210**, or a separately provided resin member.

**[0071]** As shown in FIG. **5** to FIG. **7**, the outer tube **10** may have, on the distal portion thereof, a balloon **50** expandable and shrinkable in the radial direction y of the outer tube **10**. FIG. **5** to FIG. **7** show states where the diameter of the balloon **50** is increased. The balloon **50** may be configured such that the diameter thereof is increased by supplying the fluid into the balloon **50** and is decreased by removing the fluid.

**[0072]** In a case where the outer tube **10** has the balloon **50**, a portion of the outer tube **10** formed as the balloon **50** and a portion of the outer tube **10** other than the balloon **50** may be different components and may compose the outer tube **10** by being connected to each other. For example, as shown in FIG. **5** and FIG. **6**, the outer tube **10** may be configured to have the balloon **50** and a tubular member **16**. Alternatively, in a case where the outer tube **10** has the balloon **50**, the portion of the outer tube **10** formed as the balloon **50** and the portion of the outer tube **10** other than the balloon **50** may be molded to be integrated with each other.

**[0073]** In the case where the catheter **1** has the balloon **50**, the fluid passes through the supply lumens **212** so as to be carried from the proximal side to the distal side of the catheter **1** and is jetted from the holes **40** of the inner tube **210** to the outer side in the radial direction of the outer tube **10** so as to increase the diameter of the balloon **50**. Then, the fluid passes through the discharge flow path **31** so as to be carried from the distal side to the proximal side and is discharged to the outside of the catheter **1**. When the diameter of the balloon **50** is increased, the outer surface of the balloon **50** comes into contact with a biological tube wall of a blood vessel, a gastrointestinal tract, or the like, whereby the position of the catheter **1** in the body cavity can be stabilized. In addition, since the outer surface of the balloon **50** comes into contact with a biological tube wall of a blood vessel, a gastrointestinal tract, or the like, local freezing of a tissue with which the outer surface of the balloon **50** is in contact can be facilitated.

**[0074]** The diameter of the balloon **50** is increased by the fluid jetted from the holes **40** to the outer side in the radial direction of the outer tube **10** and is decreased by discharging the fluid. As shown in FIG. **5** and FIG. **6**, in a state where the diameter of the balloon **50** is increased, the balloon **50** may have: a straight tube portion **51** having a substantially cylindrical shape; a distal-side tapered portion **52** located on the distal side relative to the straight tube portion **51** and having an outer diameter decreasing toward the distal side; and a proximal-side tapered portion **53** located on the proximal side relative to the straight tube portion **51** and having an outer diameter decreasing toward the proximal side. Furthermore, the balloon **50** may have: a distal-side sleeve portion **54** located on the distal side relative to the distal-side tapered portion **52** and fixed to the outer surface **213** of the inner tube **210**, the distal-side sleeve portion **54** having a diameter that is not increased by the fluid jetted from the holes **40** to the outer side in the radial direction of the outer tube **10**; and a proximal-side sleeve portion **55** located on the proximal side relative to the proximal-side tapered portion **53** and fixed to the outer surface of the tubular member **16**, the proximal-side sleeve portion **55** having a diameter that is not increased by the fluid jetted from the holes **40** to the outer side in the radial direction of the outer tube **10**.

**[0075]** Although a material forming the portion of the outer tube **10** formed as the balloon **50** and a material forming the portion of the outer tube **10** other than the balloon **50** may be identical to or different from each other, the material forming the balloon **50** may have a higher thermal conductivity than the material forming the portion of the outer tube **10** other than the balloon **50**. Consequently, the temperature of the portion of the outer tube **10** formed as the balloon **50** is more easily decreased than the temperature of the portion of the outer tube **10** other than the balloon **50**, whereby the tissue freezing efficiency at the location at which the balloon **50** is disposed is easily increased.

**[0076]** As shown in FIG. **6**, the holes **40** may be located inside the balloon **50**. That is, the holes **40** may be formed in portions of the inner tube **210** that are located inside the balloon **50**. Although the holes **40** may be formed also in portions of the inner tube **210** that are not located inside the balloon **50**, the holes **40** may be formed only in the portions of the inner tube **210** that are located inside the balloon **50**. Consequently, the temperature of the portion of the outer tube **10** formed as the balloon **50** easily becomes lower than the temperature of the portion of the outer tube **10** other than the balloon **50**, whereby the tissue freezing efficiency at the location at which the balloon **50** is disposed is easily increased.

**[0077]** As shown in FIG. **2** and FIG. **6**, it may be preferable that, in the longitudinal direction x of the outer tube **10**, a plurality of the radiopaque markers **70** are provided, one of the radiopaque markers **70** is located on the distal side relative to the holes **40**, and another one of the radiopaque markers **70** is located on the proximal side relative to the holes **40**. Consequently, use of an X-ray imaging device makes it possible to facilitate recognition of the positions of the holes **40**.

**[0078]** As shown in FIG. **6**, the radiopaque markers **70** may be provided on the outer surface **213** of the inner tube **210** so as to be located at positions corresponding, in the longitudinal direction x of the outer tube **10**, to the positions of the distal end and the proximal end of the straight tube portion **51** of the balloon **50**. Alternatively, although not shown in FIG. **6**, the radiopaque markers **70** may each be provided on the outer surface **213** of the inner tube **210** so as to be located at a position corresponding, in the longitudinal direction x of the outer tube **10**, to the position of the center of the straight tube portion **51** of the balloon **50**. In this configuration, use of an X-ray imaging device makes it possible to visually recognize the position of the straight tube portion **51** of the balloon **50**.

**[0079]** The inner tube **210** has the guide wire lumen **211** and the supply lumens **212**. The guide wire lumen **211** and the supply lumens **212** may extend in the longitudinal direction x of the outer tube **10**. The inner tube **210** has: the outer surface **213** facing the outside of the inner tube **210**, i.e., facing the outer tube **10** side; and an inner surface **214** facing the guide wire lumen **211**. As shown in FIG. **2**, the guide wire lumen **211** may be in communication with a lumen **63** of a distal tip **60** described later.

**[0080]** As a material forming the inner tube **210**, a synthetic resin, a metal, or the like which are the same as those for the outer tube **10** may be used. The material forming the inner tube **210** and the material forming the outer tube **10** may be identical to or different from each other.

**[0081]** The inner tube **210** may be molded as one piece from a predetermined material. The predetermined material includes a material obtained by mixing a plurality of substances or a material formed from only a single substance. The inner tube **210** can be molded as one piece through, for example, extrusion molding by using the predetermined material. By molding the inner tube **210** as one piece from the predetermined material, there is no seam between components, whereby portions having high and low rigidities are less likely to be generated. Consequently, it is possible to facilitate, when passing through a portion having a large bending angle such as a duodenal papilla, suppression of bending of the inner tube **210** and suppression of closure of the supply lumens **212**. In addition, by molding the inner tube **210** as one piece from the predetermined material, it is unnecessary to manufacture a plurality of components, whereby a manufacturing process for the inner tube **210** can be simplified, and the time and cost required for the manufacturing can be decreased.

**[0082]** As shown in FIG. **1**, FIG. **2**, FIG. **5** and FIG. **6**, the inner tube **210** may extend over the entire length of the outer tube **10**. The catheter **1** shown in FIG. **1**, FIG. **2**, FIG. **5** and FIG. **6** is of a so-called over-the-wire type.

**[0083]** As described above, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the external shape of the inner tube **210** is an irregular shape. Specifically, the external shape of the inner tube **210** may be any of polygonal shapes including triangular shapes and quadrangular shapes, semi-circular shapes, fan shapes, wedge shapes, protruding shapes, a combination of these shapes, and the like. However, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the external shape of the inner tube **210** may be a polygonal shape as shown in FIG. **3** and FIG. **10** or a triangular shape as shown in FIG. **3**. The polygonal shapes including triangular shapes and quadrangular shapes not only include polygonal shapes having definite vertices and having straight sides but also include: so-called rounded-corner polygonal shapes such as rounded-corner triangular shapes and rounded-corner quadrangular shapes having rounded corners; and polygonal shapes having sides that are at least partially curved. Alternatively, the external shape of the inner tube **210** may be an indefinite shape having a recess/protrusion, a chip, or the like.

**[0084]** As shown in FIG. **3**, FIG. **7**, and FIG. **10**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the inner tube **210** has vertex portions **217** protruding outward in the radial direction of the outer tube **10**, and the holes **40** are formed in the vertex portions **217**. Each of the vertex portions **217** is a portion protruding outward in the radial direction of the outer tube **10** in the cross section perpendicular to the longitudinal direction x of the outer tube **10**. For example, a vertex portion of any of polygonal shapes including triangular shapes and quadrangular shapes, a rounded-corner portion of any of rounded-corner polygonal shapes such as rounded-corner triangular shapes and rounded-corner quadrangular shapes, and the like correspond to each of the vertex portions **217**. Thus, the distance between the corresponding hole **40** and the inner surface **14** of the outer tube **10** can be shortened. Consequently, it is possible to suppress increase, in the temperature of the fluid jetted from the hole **40**, that occurs before said fluid reaches the inner surface **14** of the outer tube **10**. Therefore, the lesion can be efficiently cooled. Although not shown, the hole **40** may be formed in a portion of the inner tube **210** other than the vertex portion **217** in the cross section perpendicular to the longitudinal direction x of the outer tube **10**. For example, in a case where the external shape of the inner tube **210** in the cross section perpendicular to the longitudinal direction x of the outer tube **10** is a triangular shape, the holes **40** may be formed at portions other than the vertices.

**[0085]** As shown in FIG. **3**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, an eccentric distance from a centroid **210***c* of the inner tube **210** to a centroid **212***c* of each of the supply lumens **212** is longer than an eccentric distance from the centroid **210***c* of the inner tube **210** to a centroid **211***c* of the guide wire lumen **211**. The eccentric distance from the centroid **210***c* of the inner tube **210** to the centroid **212***c* of each of the supply lumens **212** refers to the distance to the centroid **212***c* of the supply lumen **212** with the centroid **210***c* of the inner tube **210** being regarded as the center. The eccentric distance from the centroid **210***c* of the inner tube **210** to the centroid **211***c* of the guide wire lumen **211** refers to the distance to the centroid **211***c* of the guide wire lumen **211** with the centroid **210***c* of the inner tube **210** being regarded as the center. By setting the eccentric distance from the centroid **210***c* of the inner tube **210** to the centroid **212***c* of each of the supply lumens **212** to be longer than the eccentric distance from the centroid **210***c* of the inner tube

**210** to the centroid **211***c* of the guide wire lumen **211**, the supply lumen **212** is formed on the outer side in the radial direction of the inner tube **210** relative to the guide wire lumen **211**. Consequently, the fluid carried to the distal side through the supply lumens **212** can be jetted via the holes **40** to the discharge flow path **31** comparatively early, whereby efficient cooling of a tissue as a therapy target can be facilitated.

**[0086]** As shown in FIG. **3**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the guide wire lumen **211** is formed at a position that overlaps with the centroid **210***c* of the inner tube **210**, and each of the supply lumens **212** is formed at a position that does not overlap with the centroid **210***c* of the inner tube **210**. By forming the guide wire lumen **211** at a position that overlaps with the centroid **210***c* of the inner tube **210** and by forming each of the supply lumens **212** at a position that does not overlap with the centroid **210***c* of the inner tube **210**, the supply lumen **212** is formed on the outer side in the radial direction of the inner tube **210** relative to the guide wire lumen **211**. Consequently, the fluid carried to the distal side through the supply lumens **212** can be jetted via the holes **40** to the discharge flow path **31** comparatively early, whereby efficient cooling of a tissue as a therapy target can be facilitated. In addition, by forming the guide wire lumen **211** at a position that overlaps with the centroid **210***c* of the inner tube **210**, the guide wire is easily located at the axis of the inner tube **210**, whereby improvement of the operability of the catheter **1** can be facilitated.

**[0087]** As shown in FIG. **3**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, a roundness of the external shape of the outer tube **10** obtained according to the following formula is higher than a roundness of the external shape of the inner tube **210** obtained according to the following formula. In the present description, each roundness is obtained according to the following formula.

$$(R_{max}-R_{min})/R_{min}, \text{ where} \qquad \text{[Formula]}$$

**[0088]** Rmax represents a radius of a circumscribed circle, and Rmin represents a radius of an inscribed circle.

**[0089]** By the above configuration, the distance in the radial direction of the outer tube **10** between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210** varies depending on the position. Consequently, even in a case where the distance between the inner surface **14** of the outer tube **10** and the outermost surface of the inner tube **210** is shortened by decreasing the outer diameter of the outer tube **10**, the fluid can move from the distal side to the proximal side by passing through positions at each of which the distance in the radial direction of the outer tube **10** between the inner surface **14** of the outer tube **10** and the outer surface **213** of the inner tube **210** is comparatively long. Therefore, the passage capability of the catheter **1** according to one or more embodiments of the present invention can be improved by decreasing the diameter thereof, and the catheter **1** allows the fluid to stably move from the distal side to the proximal side. In addition, employment of the above configuration makes it possible to facilitate stabilization of the position of the inner tube **210** in the inner cavity **15** of the outer tube **10**.

**[0090]** The shape of each of the holes **40** may be set to a shape such as a circular shape, an oval shape, or a polygonal shape. The number of the formed holes **40** may be one or may be two or more. All of a plurality of the holes **40** may have the same shape, or the holes **40** may have mutually different shapes.

**[0091]** As shown in FIG. **3**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, one of the holes **40** is formed in one of the supply lumens **212**. Although not shown, it is also allowed to employ a configuration in which, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, a plurality of the holes **40** are formed in one of the supply lumens **212**.

**[0092]** As shown in FIG. **3**, it may be preferable that: a plurality of the holes **40** are formed; and, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, only one of the holes **40** is present on the one straight line passing through the centroid **210***c* of the inner tube **210**. In FIG. **3**, the one straight line passing through the centroid **210***c* of the inner tube **210** is indicated by an alternate long and two short dashes line. When the catheter **1** is bent, a force is applied particularly to a portion that is located on the outer peripheral edge of the inner tube **210** and that intersects the one straight line passing through the centroid **210***c* of the inner tube **210**. There are two such portions that are located on the outer peripheral edge of the inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the inner tube **210**. One of the two portions receives a force that causes elongation in the longitudinal direction x of the outer tube **10**, and the other one of the two portions receives a force that causes contraction in the longitudinal direction x of the outer tube **10**. In particular, the portion in which each of the holes **40** is formed tends to have a lower rigidity and tends to be more easily bent than the other portion. Employment of a configuration in which, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, only one of the holes **40** is present on the one straight line passing through the centroid **210***c* of the inner tube **210** makes it possible to facilitate retention of the rigidity of each of the portions that are located on the outer peripheral edge of the inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the inner tube **210**. Thus, improvement of the resistance to bending can be facilitated. Consequently, suppression of closure of the supply lumens **212** due to bending of the catheter **1** can be facilitated. Alternatively, as shown in FIG. **10**, it is also allowed to employ a configuration in which, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, two of the holes **40** are present on the one straight line passing through the centroid **210***c* of the inner tube **210**. In FIG. **10**, the one straight line passing through the centroid **210***c* of the inner tube **210** is indicated by an alternate long and two short dashes line.

**[0093]** As shown in FIG. **3**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, only one of the supply lumens **212** is present on one straight line passing through the centroid **210***c* of the inner tube **210** and any of the holes **40**. In FIG. **3**, the one straight line passing through the centroid **210***c* of the inner tube **210** and the hole **40** is indicated by the alternate long and two short dashes line. When the catheter **1** is bent, a force is applied particularly to a portion that is located on the outer peripheral edge of the inner tube **210** and that intersects the one straight line passing through the centroid **210***c* of the inner tube **210**. There are two such portions that are located on the outer peripheral edge of the inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the inner tube **210**. One of the two portions receives a force that causes elongation in the longitudinal direction x of the outer tube **10**, and the other one of the two portions receives a force that causes contraction in the longitudinal direction x of the outer tube **10**. In particular, the portion in which each of the holes **40** is formed tends to have a lower rigidity and tends to be more easily bent than the other portion. Employment of a configuration in which, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, only one of the supply lumens **212** is present on the one straight line passing through the centroid **210***c* of the inner tube **210** and the hole **40** makes it possible to facilitate retention of the rigidity of each of the portions that are located on the outer peripheral edge of the inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the inner tube **210**. Thus, improvement of the resistance to bending can be facilitated. Consequently, suppression of closure of the supply lumens **212** due to bending of the catheter **1** can be facilitated. Alternatively, as shown in FIG. **10**, it is also allowed to employ a configuration in which, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, two of the supply lumens **212** are present on the one straight line passing through the centroid **210***c* of the inner tube **210** and the hole **40**. In FIG. **10**, the one straight line passing through the centroid **210***c* of the inner tube **210** and the hole **40** is indicated by the alternate long and two short dashes line.

**[0094]** As shown in FIG. **7**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the plurality of supply lumens **212** are located on an imaginary circle **210***s* having a center at the centroid **210***c* of the inner tube **210**. In FIG. **7**, one such imaginary circle **210***s* having a center at the centroid **210***c* of the inner tube **210** is indicated by an alternate long and two short dashes line. It may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, all of the plurality of supply lumens **212** formed in the inner tube **210** are located on the one imaginary circle **210***s* having a center at the centroid **210***c* of the inner tube **210**. Since portions of the inner tube **210** that have the supply lumens **212** formed therein are hollow, the portions each tend to easily have a decreased resistance to bending. However, employment of the above configuration leads to arrangement of the supply lumens **212** in the circumferential direction of the inner tube **210** as shown in FIG. **7**. Consequently, the portions each of which easily has a decreased resistance to bending are present in a scattered manner in the circumferential direction of the inner tube **210**. By doing so, retention of the resistance to bending can be facilitated regardless of the bending direction of the inner tube **210**. Although not shown, it may be also preferable, for the same reason as the reason described above, that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, each of the centroids **212***c* of the plurality of supply lumens **212** is located on the one imaginary circle **210***s* having a center at the centroid **210***c* of the inner tube **210**.

**[0095]** As shown in FIG. **7**, it may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the plurality of supply lumens **212** are located on an imaginary circle **211***s* having a center at the centroid **211***c* of the guide wire lumen **211**. In FIG. **7**, the imaginary circle **211***s* having a center at the centroid **211***c* of the guide wire lumen **211** is indicated by an alternate long and two short dashes line. It may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, all of the plurality of supply lumens **212** formed in the inner tube **210** are located on the imaginary circle **211***s* having a center at the centroid **211***c* of the guide wire lumen **211**. Since portions of the inner tube **210** that have the supply lumens **212** formed therein are hollow, the portions each tend to easily have a decreased resistance to bending. However, employment of the above configuration leads to arrangement of the supply lumens **212** around the guide wire lumen **211** so that the supply lumens **212** are easily arranged in the circumferential direction of the inner tube **210**, as shown in FIG. **7**. Consequently, the portions each of which easily has a decreased resistance to bending are present in a scattered manner in the circumferential direction of the inner tube **210**. By doing so, retention of the resistance to bending can be facilitated regardless of the bending direction of the inner tube **210**. Although not shown, it may be also preferable, for the same reason as the reason described above, that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, each of the centroids **212***c* of the plurality of supply lumens **212** is located on one such imaginary circle **211***s* having a center at the centroid **211***c* of the guide wire lumen **211**.

**[0096]** The fluid used for the above catheter **1** may be a liquid or a gaseous body. In a case where the fluid is a liquid, nitrogen or fluorocarbon may be used as the fluid. In a case where the fluid is a gaseous body, gas may be used as the fluid. Examples of the gas include argon, carbon dioxide, and nitrous oxide. The fluid used for the catheter **1** may be gas.

**[0097]** It may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, a maximum width of each of the supply lumens **212** is smaller than a maximum width of the guide wire lumen **211**. Consequently, it is possible to facilitate suppression of decrease, in the rigidity of the inner tube **210**, that occurs owing to formation of the plurality of supply lumens **212** in the inner tube **210**. It is also allowed to employ a configuration in which, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the maximum width of the supply lumen **212** is larger than the maximum width of the guide wire lumen **211**, or the maximum width of the supply lumen **212** is equal to the maximum width of the guide wire lumen **211**.

**[0098]** As shown in FIG. **9**, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the inner tube **210** may have: a first supply lumen **2121**; a second supply lumen **2122** formed to be adjacent to the first supply lumen **2121** in the circumferential direction of the inner tube **210**; and a third supply lumen **2123** formed to be adjacent to the first supply lumen **2121** and the second supply lumen **2122** in the circumferential direction of the inner tube **210**. In addition, the inner tube **210** may further have, in addition to the first supply lumen **2121**, the second supply lumen **2122**, and the third supply lumen **2123**, one or more supply lumens which allow the fluid to pass therethrough from the proximal side to the distal side of the inner tube **210**. For example, as shown in FIG. **10**, the inner tube **210** may have the first supply lumen **2121**, the second supply lumen **2122**, the third supply lumen **2123**, and a fourth supply lumen **2124**. In the present description, one of or a combination of two or more of the first supply lumen **2121**, the second supply lumen **2122**, the third supply lumen **2123**, and the fourth and larger-ordinal-number supply lumens which allow the fluid to pass therethrough from the proximal side to the distal side of the inner tube **210** are sometimes referred to as a supply lumen **212** or a plurality of supply lumens **212**. As described above, employment of a configuration provided with the three or more supply lumens **212** makes it possible to, even when two of the supply lumens **212** are closed owing to bending of the catheter **1** which is passing through a bent body cavity, send the fluid through the remaining supply lumen(s) **212**. Consequently, the fluid can be stably sent from the proximal side to the distal side.

**[0099]** As shown in FIG. **8**, it may be preferable that: in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the inner tube **210** has the first supply lumen **2121** and the second supply lumen **2122** formed to be adjacent to the first supply lumen **2121** in the circumferential direction of the inner tube **210**; and, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, an angle a formed between a half-line that has one end at the centroid **210***c* of the inner tube **210** and that passes through a centroid **2121***c* of the first supply lumen **2121** and a half-line that has one end at the centroid **210***c* of the inner tube **210** and that passes through the centroid **2122***c* of the second supply lumen **2122** is 105 degrees or larger and 135 degrees or smaller. In FIG. **8**, the half-line having one end at the centroid **210***c* of the inner tube **210** and passing through the centroid **2121***c* of the first supply lumen **2121** and the half-line having one end at the centroid **210***c* of the inner tube **210** and passing through the centroid **2122***c* of the second supply lumen **2122** are indicated by alternate long and two short dashes lines.

**[0100]** The above angle a may be 105 degrees or larger, 110 degrees or larger, or 115 degrees or larger. The above angle a may be 135 degrees or smaller, 130 degrees or smaller, or 125 degrees or smaller. The above angle a may be 120 degrees.

**[0101]** As shown in FIG. **3**, it may be preferable that the discharge flow path **31** is, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, present so as to cover the entirety of the outer surface **213** of the inner tube **210**. Although not shown, the discharge flow path **31** may be, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, present so as to cover only a part of the outer surface **213** of the inner tube **210**.

**[0102]** As shown in FIG. **1**, FIG. **2**, FIG. **5**, and FIG. **6**, the catheter **1** may further include a distal tip **60** in which a lumen **63** extending in the longitudinal direction x is formed. As shown in FIG. **1** and FIG. **2**, a distal end portion of the outer tube **10** and a distal end portion of the inner tube **210** may be fixed to a proximal end portion of the distal tip **60**.

**[0103]** The distal side of the discharge flow path **31** of the catheter **1** may be closed by fixing the distal end portion of the outer tube **10** and the distal end portion of the inner tube **210**. A configuration in which the distal side of the discharge flow path **31** in the longitudinal direction x of the outer tube **10** is closed can be obtained by, for example, fixing the distal end portion of the outer tube **10** and the distal end portion of the inner tube **210** via the distal tip **60** as shown in FIG. **1** and FIG. **2**. Although not shown, the distal end portion of the outer tube **10** and the distal end portion of the inner tube **210** may be welded and fixed to each other so as to close the distal side of the discharge flow path **31** without providing the distal tip **60**. As shown in FIG. **5** and FIG. **6**, in a case where the outer tube **10** has the balloon **50**, the configuration in which the distal side of the discharge flow path **31** of the catheter **1** is closed can be obtained by fixing a distal end portion of the balloon **50** and the distal end portion of the inner tube **210**. Consequently, a main direction in which the fluid jetted from the holes **40** to the outer side in the radial direction of the outer tube **10** moves can be set to be a direction toward the proximal side of the discharge flow path **31**.

**[0104]** As shown in FIG. **1**, FIG. **2**, FIG. **5**, and FIG. **6**, it may be preferable that: the catheter **1** further includes a distal tip **60** in which a lumen **63** extending in the longitudinal direction x of the outer tube **10** is formed and which has an outer diameter decreasing from the proximal side toward the distal side; and the distal end portion of the outer tube **10** and the distal end portion of the inner tube **210** are fixed to a proximal end portion of the distal tip **60**. By providing the distal tip **60** having an outer diameter decreasing from the proximal side toward the distal side, insertion of a distal end portion of the catheter **1** into a body cavity can be facilitated.

**[0105]** The shape of the distal tip **60** may be, for example, the shape of a hollow column, a hollow polygonal prism, a hollow truncated cone, or the like and may be the shape of a hollow truncated cone as shown in FIG. **1** and FIG. **2**.

**[0106]** As a material forming the distal tip **60**, a synthetic resin, a metal, or the like which are the same as those for the outer tube **10** may be used. The material forming the distal tip **60** and the material forming the outer tube **10** may be identical to or different from each other.

**[0107]** As shown in FIG. **1**, FIG. **2**, FIG. **5**, and FIG. **6**, a configuration may be employed in which a first handle **75** to be gripped by a user is connected to the proximal portion of the outer tube **10**. In FIG. **2** and FIG. **6**, the first handle **75** has a hollow portion extending in the longitudinal direction x of the outer tube **10**. The shape of the first handle **75** may be, for example, a tubular shape. In FIG. **1**, FIG. **2**, FIG. **5** and FIG. **6**, the outer tube **10** and the inner tube **210** are inserted into the hollow portion of the first handle **75**.

**[0108]** As shown in FIG. **1**, FIG. **2**, FIG. **5**, and FIG. **6**, a configuration may be employed in which a second handle **76** is connected to the proximal portion of the inner tube **210**. In FIG. **2** and FIG. **6**, the second handle **76** has a hollow portion extending in the longitudinal direction x of the outer tube **10**. The shape of the second handle **76** may be, for example, a tubular shape. In FIG. **2** and FIG. **6**, the inner tube **210** is inserted into the hollow portion of the second handle **76**. The second handle **76** may have a guide wire port as an opening into which a guide wire is inserted. Also, the second handle **76** may be connected to a fluid supply device **80** described later. As shown in FIG. **2**, the proximal end of the inner tube **210** and the fluid supply device **80** may be directly connected to each other such that the fluid can be supplied to the supply lumens **212** of the inner tube **210**.

**[0109]** Materials forming the first handle **75** and the second handle **76** are not particularly limited, and, for example, a synthetic resin such as a polyolefin resin such as polypropylene (PP) or polyethylene (PE), a polyester resin such as polyethylene terephthalate (PET), a polycarbonate resin, an ABS resin, or a polyurethane resin may be used.

**[0110]** A coating may be provided on the outer surface **13** of the outer tube **10**. The coating may be provided on only a part of the outer surface **13** of the outer tube **10** or on the entirety of the outer surface **13** of the outer tube **10**.

**[0111]** The coating to be provided on the outer surface **13** of the outer tube **10** may be a hydrophilic coating or a hydrophobic coating and may be selected according to the purpose. The coating can be provided on the outer surface **13** of the outer tube **10** by: immersing the outer tube **10** in a hydrophilic coating agent or a hydrophobic coating agent; applying the hydrophilic coating agent or the hydrophobic coating agent onto the outer surface **13** of the outer tube **10**; or coating the outer surface **13** of the outer tube **10** with the hydrophilic coating agent or the hydrophobic coating agent. The coating agent may contain a drug and an additive.

**[0112]** Examples of the hydrophilic coating agent include: hydrophilic polymers such as polyvinyl alcohol, polyethylene glycol, polyacrylamide, polyvinylpyrrolidone, and methyl vinyl ether-maleic anhydride copolymers; hydrophilic coating agents made from a combination of any of these hydrophilic polymers; and the like.

**[0113]** Examples of the hydrophobic coating agent include polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), perfluoroalkoxy alkanes (PFA), silicone oil, hydrophobic urethane resins, carbon coatings, diamond coatings, diamond-like carbon (DLC) coatings, ceramic coatings, substances each having an alkyl group or a perfluoro alkyl group at a terminal thereof and each having a low surface free energy, and the like.

**[0114]** The above coating may be provided also on an outer surface **61** of the distal tip **60**. The coating may be provided on only a part of the outer surface **61** of the distal tip **60** or on the entirety of the outer surface **61** of the distal tip **60**.

**[0115]** A cryoablation catheter system according to one or more embodiments of the present invention has the following gist. That is, the cryoablation catheter system includes the above catheter **1** and a fluid supply device **80** which supplies the fluid to the supply lumens **212**, and the inner tube **210** is connected to the fluid supply device **80**.

**[0116]** The fluid supply device **80** is not particularly limited as long as the fluid supply device **80** can supply the fluid to the inner tube **210**. Examples of the fluid supply device **80** include a regulator, a flow rate controller, a pump, or the like connected to a fluid-storing container.

**[0117]** The inner tube **210** may be directly connected to the fluid supply device **80**. For example, in the case of the catheter **1** shown in FIG. **2**, FIG. **3**, and FIG. **4**, the three supply lumens **212** may converge into one lumen on the proximal side, and the proximal end of the inner tube **210** may be directly connected to the fluid supply device **80**.

**[0118]** The inner tube **210** may be indirectly connected to the fluid supply device **80**. For example, as shown in FIG. **6**, a proximal end portion of the inner tube **210** may be connected to a distal end portion of a tubular member **77**, and a proximal end portion of the tubular member **77** may be connected to the fluid supply device **80**.

**[0119]** This application claims the benefit of the priority date of Japanese patent application No. 2022-179429 filed on Nov. 9, 2022. All of the contents of the Japanese patent application No. 2022-179429 filed on Nov. 9, 2022 are incorporated by reference herein.

**[0120]** Although only a few example embodiments have been described in detail above, those skilled in the art will readily appreciate that many modifications are possible in the example embodiments without materially departing from this invention. Accordingly, all such modifications are intended to be included within the scope of this disclosure as defined in the following claims.

REFERENCE SIGNS LIST

**[0121]** **1**: cryoablation catheter
**[0122]** **10**: outer tube
**[0123]** **11**: distal end of the outer tube
**[0124]** **12**: proximal end of the outer tube
**[0125]** **13**: outer surface of the outer tube
**[0126]** **14**: inner surface of the outer tube
**[0127]** **15**: inner cavity of the outer tube
**[0128]** **16**: tubular member
**[0129]** **210**: inner tube
**[0130]** **210***c:* centroid of the inner tube
**[0131]** **210***s:* imaginary circle having a center at the centroid of the inner tube
**[0132]** **211**: guide wire lumen
**[0133]** **211***c:* centroid of the guide wire lumen
**[0134]** **211***s:* imaginary circle having a center at the centroid of the guide wire lumen
**[0135]** **212**: supply lumen
**[0136]** **212***c:* centroid of the supply lumen
**[0137]** **2121**: first supply lumen
**[0138]** **2121***c:* centroid of the first supply lumen
**[0139]** **2122**: second supply lumen
**[0140]** **2122***c:* centroid of the second supply lumen
**[0141]** **2123**: third supply lumen
**[0142]** **2123***c:* centroid of the third supply lumen
**[0143]** **2124**: fourth supply lumen
**[0144]** **2124***c:* centroid of the fourth supply lumen
**[0145]** **213**: outer surface of the inner tube
**[0146]** **214**: inner surface the inner tube
**[0147]** **217**: vertex portion
**[0148]** **31**: discharge flow path
**[0149]** **40**: hole
**[0150]** **50**: balloon
**[0151]** **51**: straight tube portion
**[0152]** **52**: distal-side tapered portion
**[0153]** **53**: proximal-side tapered portion
**[0154]** **54**: distal-side sleeve portion
**[0155]** **55**: proximal-side sleeve portion
**[0156]** **60**: distal tip
**[0157]** **61**: outer surface of the distal tip
**[0158]** **62**: inner surface of the distal tip
**[0159]** **63**: lumen of the distal tip
**[0160]** **70**: radiopaque marker
**[0161]** **75**: first handle
**[0162]** **76**: second handle
**[0163]** **77**: tubular member
**[0164]** **80**: fluid supply device

**1**. A cryoablation catheter comprising:

an outer tube having a distal end and a proximal end and extending in a longitudinal direction;

an inner tube extending in the longitudinal direction and disposed in an inner cavity of the outer tube; and

a discharge flow path, wherein:

in a cross section perpendicular to the longitudinal direction, an external shape of the inner tube is an irregular shape;

the inner tube comprises a guide wire lumen and a plurality of supply lumens, wherein, in the cross section perpendicular to the longitudinal direction, the plurality of supply lumens are formed in regions different from a region in which the guide wire lumen is formed, wherein:

the guide wire lumen is configured to have a guide wire inserted; and

the plurality of supply lumens are configured to allow a fluid to pass therethrough from a proximal side to a distal side of the inner tube;

the discharge flow path is located between an inner surface of the outer tube and an outer surface of the inner tube and is configured to allow the fluid to pass therethrough from a distal side to a proximal side of the outer tube; and

the inner tube comprises a hole located in a distal portion of the inner tube, wherein any of the supply lumens and the discharge flow path are in communication with each other through the hole.

**2**. The cryoablation catheter according to claim **1**, wherein, in the cross section perpendicular to the longitudinal direction, the external shape of the inner tube is a polygonal shape.

**3**. The cryoablation catheter according to claim **1**, wherein, in the cross section perpendicular to the longitudinal direction, the external shape of the inner tube is a triangular shape.

**4**. The cryoablation catheter according to claim **1**, wherein:

in the cross section perpendicular to the longitudinal direction, the inner tube has a vertex portion protruding outward in a radial direction of the outer tube; and

the hole is formed in the vertex portion.

**5**. The cryoablation catheter according to claim **1**, wherein:

in the cross section perpendicular to the longitudinal direction, a roundness of an external shape of the outer tube obtained according to the following formula is higher than a roundness of the external shape of the inner tube obtained according to the following formula:

$(Rmax-Rmin)/Rmin$, where:

R max represents a radius of a circumscribed circle, and R min represents a radius of an inscribed circle.

**6**. The cryoablation catheter according to claim **1**, wherein, in the cross section perpendicular to the longitudinal direction, the guide wire lumen is formed at a position that overlaps with a centroid of the inner tube, and each of the supply lumens is formed at a position that does not overlap with the centroid of the inner tube.

**7**. The cryoablation catheter according to claim **1**, wherein, in the cross section perpendicular to the longitudinal direction, the plurality of supply lumens are located on an imaginary circle having a center at a centroid of the guide wire lumen.

**8**. The cryoablation catheter according to claim **1**, wherein, in the cross section perpendicular to the longitudinal direction, a maximum width of each of the supply lumens is smaller than a maximum width of the guide wire lumen.

**9**. The cryoablation catheter according to claim **1**, wherein the outer tube comprises, on a distal portion thereof, a balloon which is expandable and shrinkable in a radial direction of the outer tube.

**10**. The cryoablation catheter according to claim **1**, further comprising a distal tip comprising a lumen extending in the longitudinal direction, wherein: the distal tip has an outer diameter decreasing from a proximal side toward a distal side; and

a distal end portion of the outer tube and a distal end portion of the inner tube are fixed to a proximal end portion of the distal tip.

**11**. A cryoablation catheter system comprising:

the cryoablation catheter according to claim **1**; and

a fluid supply device configured to supply the fluid to the supply lumens, wherein the inner tube is connected to the fluid supply device.

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