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(54) **CRYOABLATION CATHETER FOR DUODENAL PAPILLA INSERTION AND A CRYOABLATION CATHETER SYSTEM**

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(57) **ABSTRACT**

A cryoablation catheter for a duodenal papilla insertion including an outer tube, a first inner tube disposed in an inner cavity of the outer tube, and a first discharge flow path, is provided. The first inner tube has a guide wire lumen and a plurality of supply lumens. The first discharge flow path is located between an inner surface of the outer tube and an outer surface of the first inner tube. The first inner tube includes a hole located in a distal portion of the first inner tube. Any of the supply lumens and the first discharge flow path are in communication with each other through the hole.

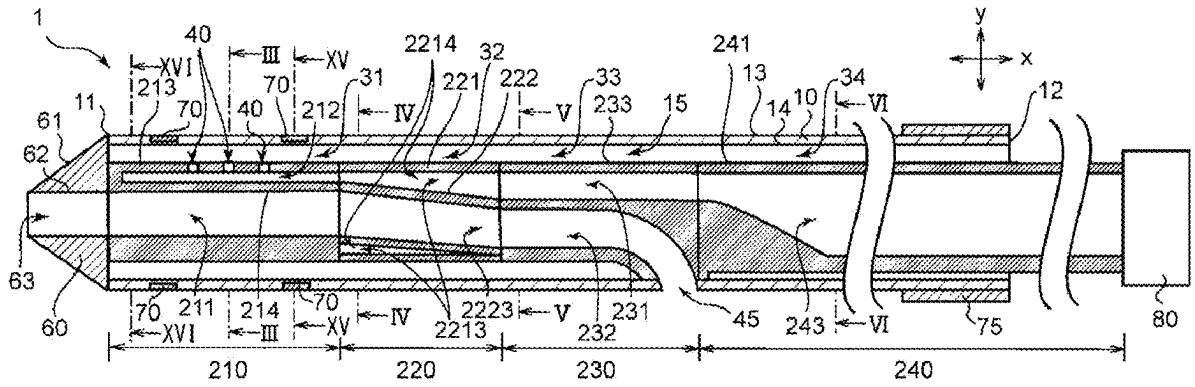

FIG. 1

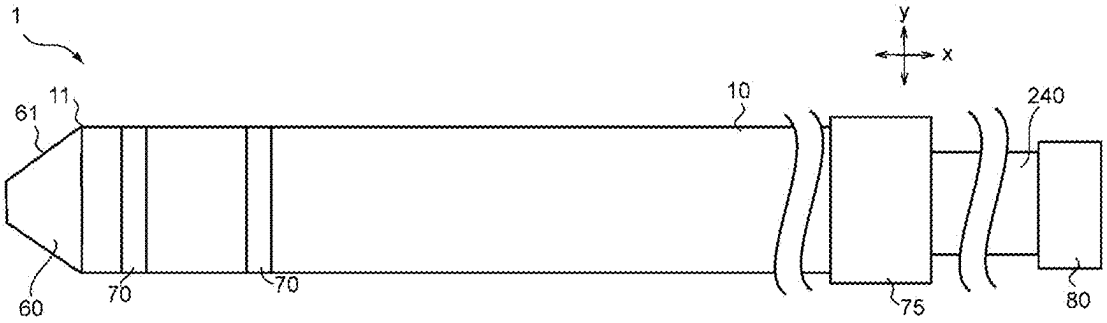
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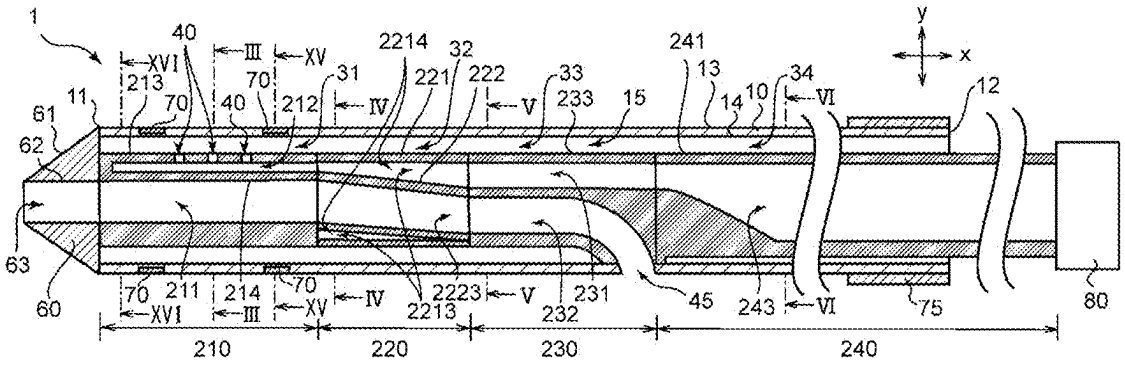
FIG. 2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V
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VI
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63
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70
211
214
III
XVI
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FIG. 3

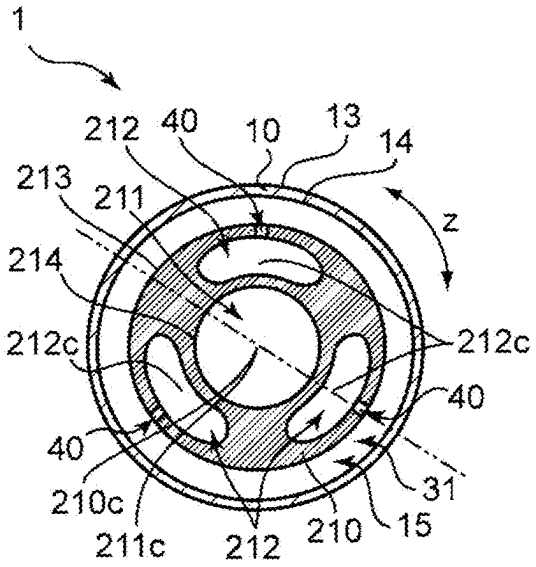
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FIG. 4

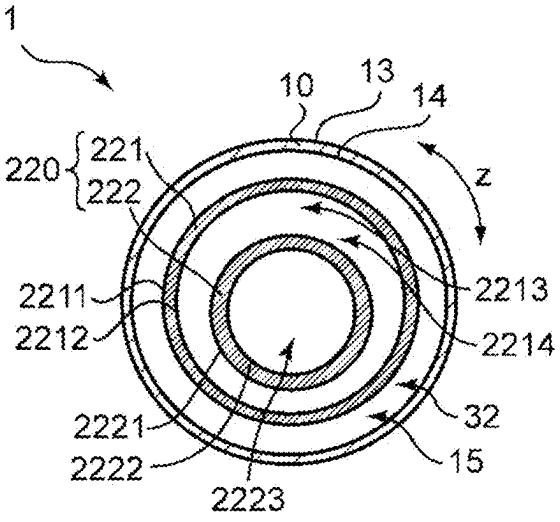
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FIG. 5

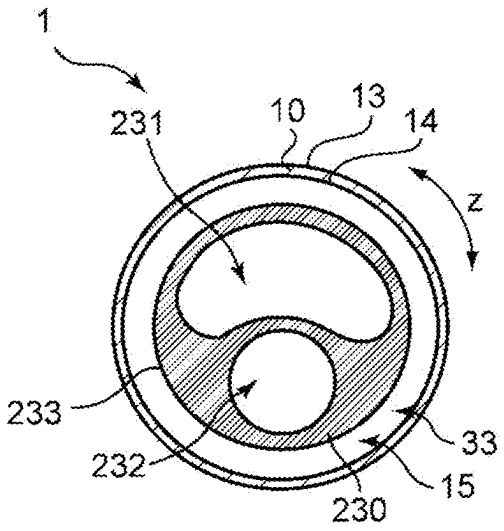

FIG. 6

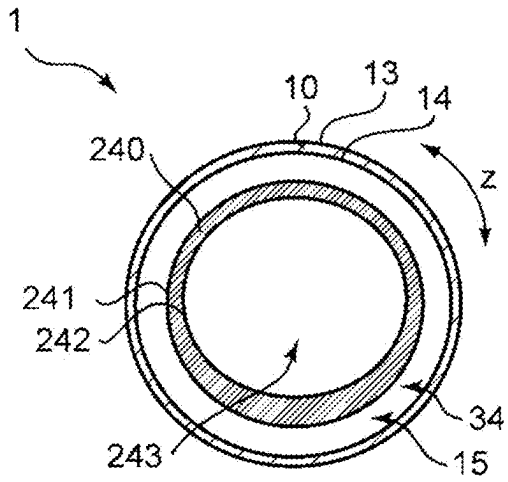

FIG. 7

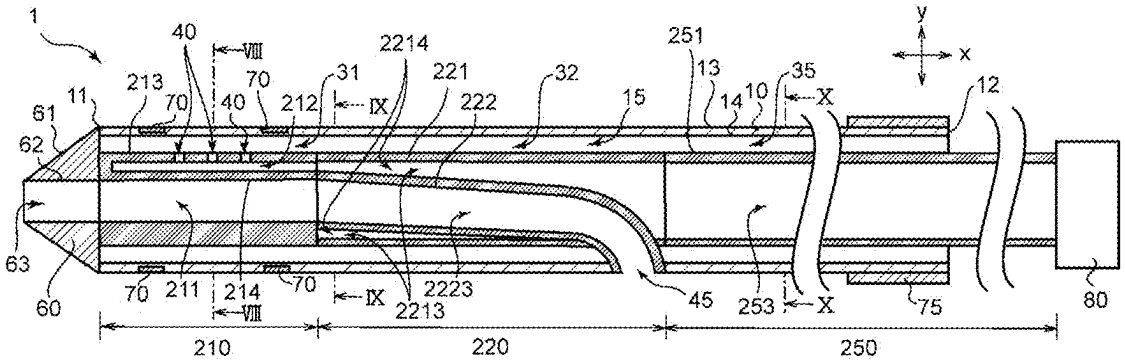
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FIG. 8

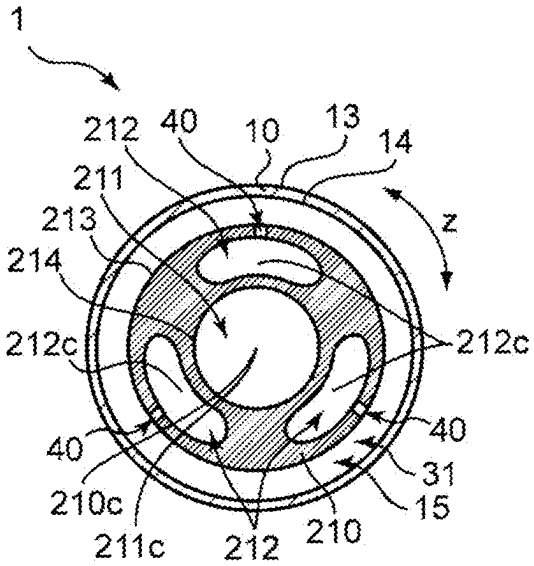
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FIG. 9

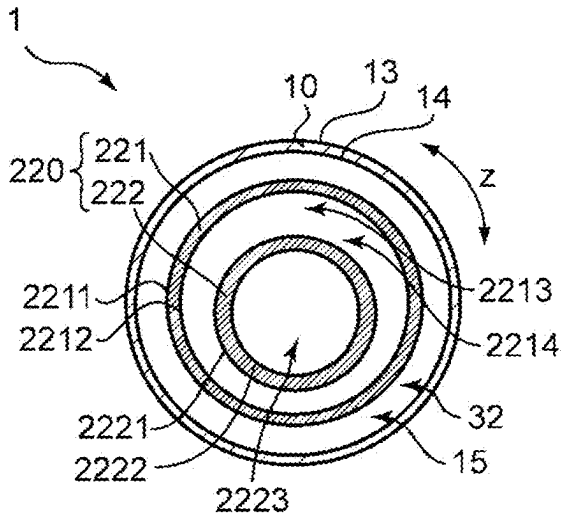
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FIG. 10

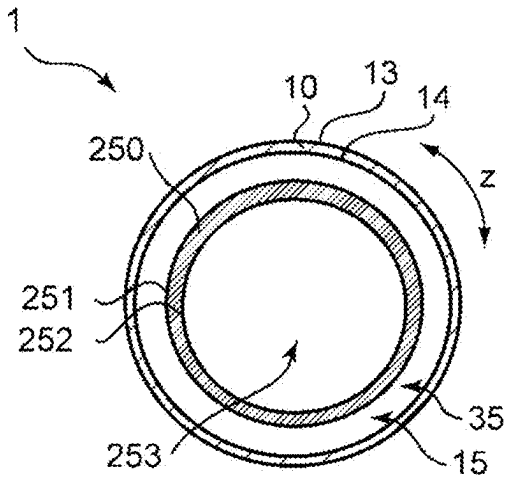
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FIG. 11

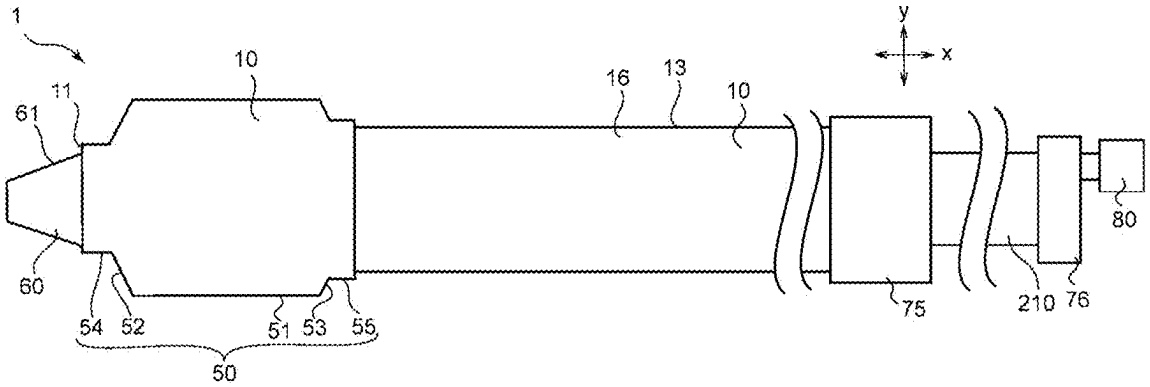
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FIG. 12

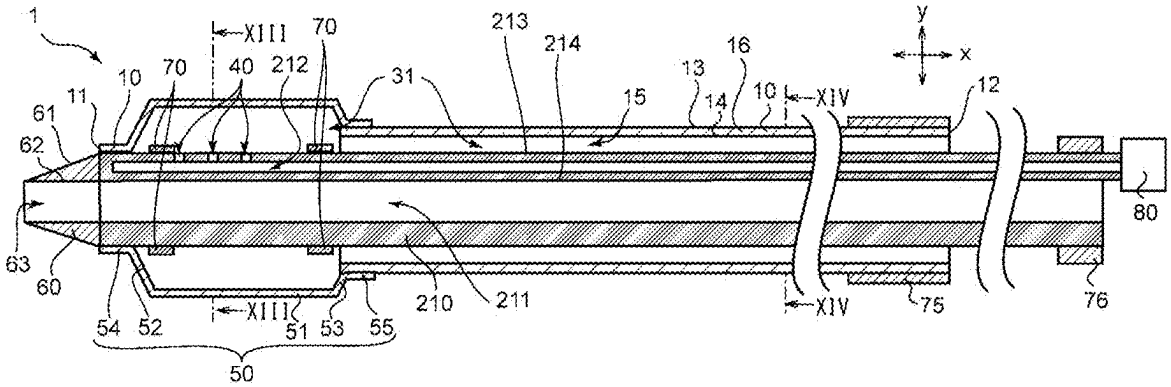
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FIG. 13

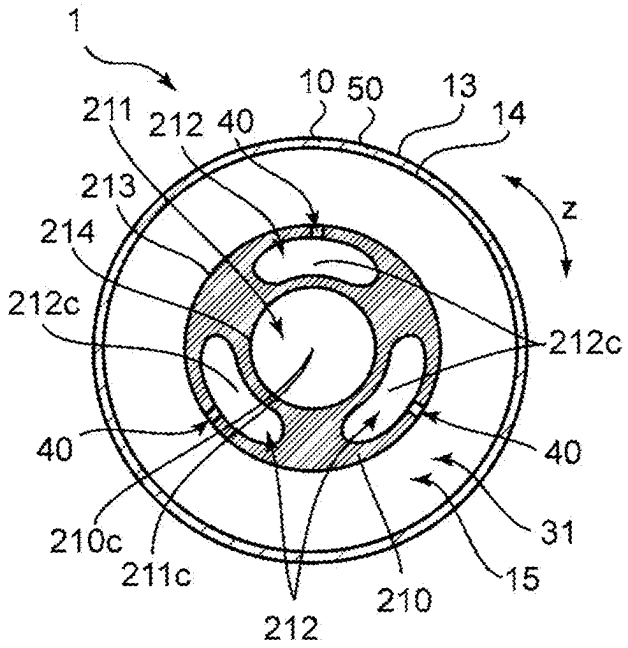
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FIG. 14

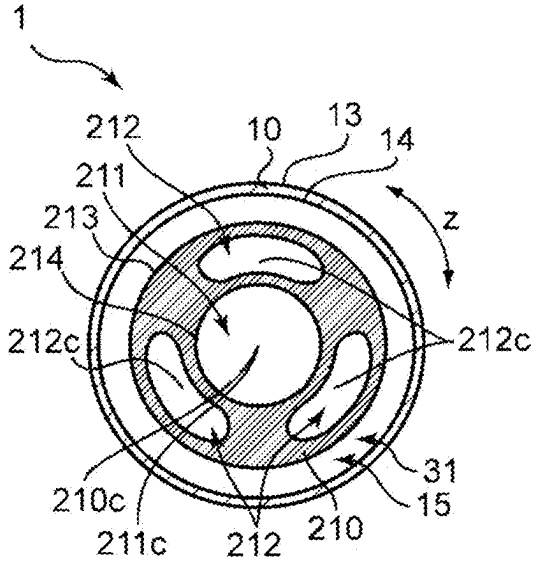
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Fig. 15

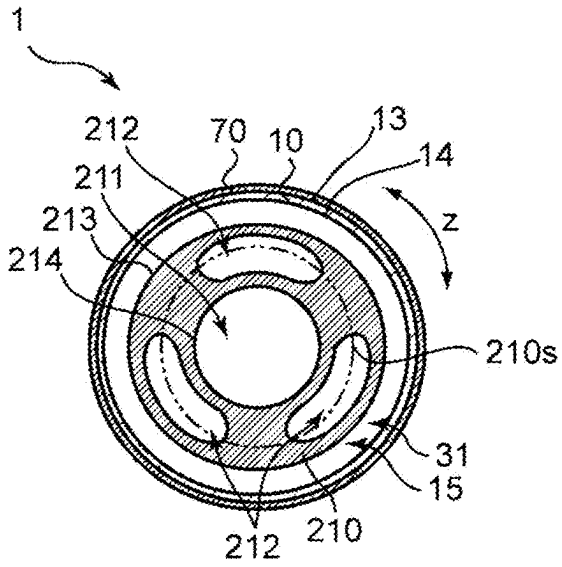
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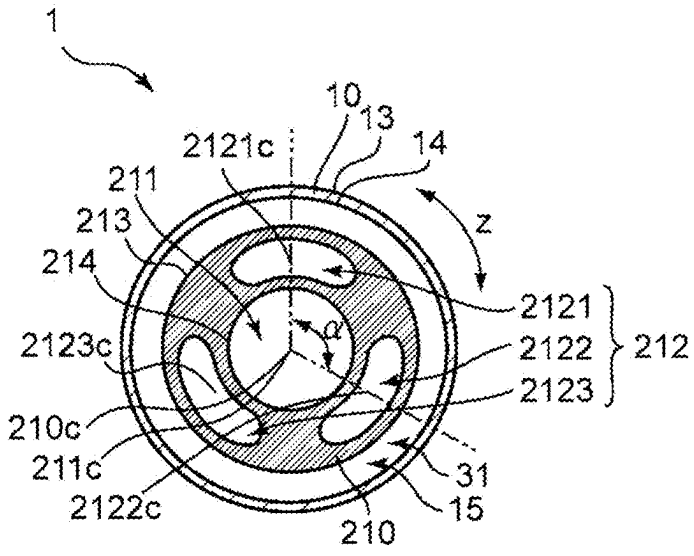
FIG. 16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CRYOABLATION CATHETER FOR DUODENAL PAPILLA INSERTION AND A CRYOABLATION CATHETER SYSTEM

TECHNICAL FIELD

[0001] One or more embodiments of the present invention relate to a cryoablation catheter for duodenal papilla insertion 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 portion having a large bending angle such as the duodenal papilla. 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 for duodenal papilla insertion and a cryoablation catheter system, capable of stably sending a fluid from a proximal side to a distal side, are provided.

[0007] One embodiment of a cryoablation catheter for duodenal papilla insertion is as follows.

[0008] [1] A cryoablation catheter for duodenal papilla insertion comprising:

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

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

[0011] a first discharge flow path, wherein,

[0012] in a cross section perpendicular to the longitudinal direction, the first 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 first inner tube and which are formed in regions different from a region in which the guide wire lumen is formed,

[0013] the first discharge flow path is located between an inner surface of the outer tube and an outer surface of the first inner tube and allows the fluid to pass therethrough from a distal side to a proximal side of the outer tube, and

[0014] the first inner tube has a distal portion in which a hole through which any of the supply lumens and the first discharge flow path are in communication with each other is formed.

[0015] In the first inner tube of the cryoablation catheter for duodenal papilla insertion 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 portion having a large bending angle such as a duodenal papilla, 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.

[0016] Other aspects of the cryoablation catheter for duodenal papilla insertion are as shown in the following [2] to [15]:

[0017] [2] The cryoablation catheter according to above [1], wherein, in the cross section perpendicular to the longitudinal direction, an eccentric distance from a centroid of the first inner tube to a centroid of each of the supply lumens is longer than an eccentric distance from the centroid of the first inner tube to a centroid of the guide wire lumen.

[0018] [3] The cryoablation catheter according to above [1] or [2], 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 first inner tube, and each of the supply lumens is formed at a position that does not overlap with the centroid of the first inner tube.

[0019] [4] The cryoablation catheter according to any one of above [1] to [3], wherein the first inner tube is molded as one piece from a predetermined material.

[0020] [5] The cryoablation catheter according to any one of above [1] to [4], wherein a plurality of the holes are formed, and, in the cross section perpendicular to the longitudinal direction, only one of the holes is present on one straight line passing through a centroid of the first inner tube.

[0021] [6] The cryoablation catheter according to any one of above [1] to [5], wherein, in the cross section perpendicular to the longitudinal direction, only one of the supply lumens is present on one straight line passing through a centroid of the first inner tube and the hole. [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 first inner tube.

[0022] [8] The cryoablation catheter according to any one of above [1] to [7], wherein the outer tube has, on a distal portion thereof, a balloon expandable and shrinkable in a radial direction of the outer tube.

[0023] [9] The cryoablation catheter according to above [8], wherein a material forming the balloon has a higher thermal conductivity than a material forming a portion of the outer tube other than the balloon.

[0024] [10] The cryoablation catheter according to any one of above [1] to [9], wherein the fluid is gas.

[0025] [11] The cryoablation catheter according to any one of above [1] to [10], wherein,

[0026] in the cross section perpendicular to the longitudinal direction, the first inner tube has a first supply lumen and a second supply lumen formed to be adjacent to the first supply lumen in a circumferential direction of the first inner tube, and,

[0027] in the cross section perpendicular to the longitudinal direction, an angle a formed between a half-line that has one end at a centroid of the first inner tube and that passes through a centroid of the first supply lumen and a half-line that has one end at the centroid of the first inner tube and that passes through a centroid of the second supply lumen is 105 degrees or larger and **135** degrees or smaller.

[0028] [12] The cryoablation catheter according to any one of above [1] to [11], wherein

[0029] the cryoablation catheter further comprises a second inner tube extending in the longitudinal direction and disposed, in the inner cavity of the outer tube, on a proximal side relative to the first inner tube,

[0030] the second inner tube has a $(2\text{-}1)^{th}$ inner tube extending in the longitudinal direction and a $(2\text{-}2)^{th}$ inner tube disposed in an inner cavity of the $(2\text{-}1)^{th}$ inner tube and extending in the longitudinal direction,

[0031] a $(2\text{-}1)^{th}$ flow path in communication with the plurality of supply lumens formed in the first inner tube is present between an inner surface of the $(2\text{-}1)^{th}$ inner tube and an outer surface of the $(2\text{-}2)^{th}$ inner tube, and

[0032] the $(2\text{-}2)^{th}$ inner tube has an inner cavity in communication with the guide wire lumen formed in the first inner tube.

[0033] [13] The cryoablation catheter according to above [12], wherein

[0034] the cryoablation catheter further comprises a third inner tube extending in the longitudinal direction and disposed, in the inner cavity of the outer tube, on the proximal side relative to the second inner tube, and,

[0035] in the cross section perpendicular to the longitudinal direction, the third inner tube has a $(3\text{-}1)^{th}$ lumen which extends in the longitudinal direction and which is in communication with the $(2\text{-}1)^{th}$ flow path and a $(3\text{-}2)^{th}$ lumen which is in communication with the inner cavity of the $(2\text{-}2)^{th}$ inner tube and which is formed in a region different from a region in which the $(3\text{-}1)^{th}$ lumen is formed.

[0036] [14] The cryoablation catheter according to above [13], wherein

[0037] the cryoablation catheter further comprises a fourth inner tube extending in the longitudinal direction and disposed, in the inner cavity of the outer tube, on the proximal side relative to the third inner tube, and

[0038] the fourth inner tube has an inner cavity in communication with the $(3\text{-}1)^{th}$ lumen.

[0039] [15] The cryoablation catheter according to any one of above [1] to [14], wherein

[0040] 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

[0041] a distal end portion of the outer tube and a distal end portion of the first inner tube are fixed to a proximal end portion of the distal tip.

[0042] One or more embodiments of the present invention also provide the following.

[0043] [16] A cryoablation catheter system comprising:

[0044] the cryoablation catheter according to any one of above [1] to [15]; and

[0045] a fluid supply device configured to supply the fluid to the supply lumens, wherein

[0046] the first inner tube is connected to the fluid supply device.

[0047] In the first inner tube of the cryoablation catheter for duodenal papilla insertion 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 portion having a large bending angle such as a duodenal papilla, 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. The cryoablation catheter system according to one or more embodiments of the present invention including the above cryoablation catheter for duodenal papilla insertion also has the same advantageous effect.

BRIEF DESCRIPTION OF THE DRAWINGS

[0048] FIG. **1** is a side view showing an example of the cryoablation catheter according to one or more embodiments of the present invention.

[0049] FIG. **2** is a cross-sectional view of the cryoablation catheter shown in FIG. **1**.

[0050] FIG. **3** is a cross-sectional view, at the line III-III, of the cryoablation catheter shown in FIG. **2**.

[0051] FIG. **4** is an end surface view of a cut portion, at the line IV-IV, of the cryoablation catheter shown in FIG. **2**.

[0052] FIG. **5** is an end surface view of a cut portion, at the line V-V, of the cryoablation catheter shown in FIG. **2**.

[0053] FIG. **6** is an end surface view of a cut portion, at the line VI-VI, of the cryoablation catheter shown in FIG. **2**.

[0054] FIG. **7** is a cross-sectional view showing a modification of the cryoablation catheter shown in FIG. **2**.

[0055] FIG. **8** is a cross-sectional view, at the line VIII-VIII, of the cryoablation catheter shown in FIG. **7**.

[0056] FIG. **9** is an end surface view of a cut portion, at the line IX-IX, of the cryoablation catheter shown in FIG. **7**.

[0057] FIG. **10** is an end surface view of a cut portion, at the line X-X, of the cryoablation catheter shown in FIG. **7**.

[0058] FIG. **11** is a side view showing a modification of the cryoablation catheter according to one or more embodiments of the present invention.

[0059] FIG. **12** is a cross-sectional view of the cryoablation catheter shown in FIG. **11**.

[0060] FIG. **13** is a cross-sectional view, at the line XIII-XIII, of the cryoablation catheter shown in FIG. **12**.

[0061] FIG. **14** is an end surface view of a cut portion, at the line XIV-XIV, of the cryoablation catheter shown in FIG. **12**.

[0062] FIG. **15** is a cross-sectional view, at the line XV-XV, of the cryoablation catheter shown in FIG. **2**.

[0063] FIG. **16** is a cross-sectional view, at the line XVI-XVI, of the cryoablation catheter shown in FIG. **2**.

DETAILED DESCRIPTION

[0064] 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.

[0065] A cryoablation catheter according to one or more embodiments of the present invention is a cryoablation catheter for duodenal papilla insertion 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; a first inner tube extending in the longitudinal direction of the outer tube and disposed in an inner cavity of the outer tube; and a first discharge flow path. In a cross section perpendicular to the longitudinal direction of the outer tube, the first 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 first inner tube and which are formed in regions different from a region in which the guide wire lumen is formed. The first discharge flow path is located between an inner surface of the outer tube and an outer surface of the first inner tube and allows the fluid to pass therethrough from a distal side to a proximal side of the outer tube. The first inner tube has a distal portion in which a hole through which any of the supply lumens and the first discharge flow path are in communication with each other is formed.

[0066] 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. **16**. The cryoablation catheter **1** shown in FIG. **2**, FIG. **3**, FIG. **7**, FIG. **8**, and FIG. **12** to FIG. **14** includes an outer tube **10** and a first 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**.

[0067] 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.

[0068] 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 an end surface view of a cut portion, at the line IV-IV, of the cryoablation catheter shown in FIG. **2**. FIG. **5** is an end surface view of a cut portion, at the line V-V, of the cryoablation catheter shown in FIG. **2**. FIG. **6** is an end surface view of a cut portion, at the line VI-VI, of the cryoablation catheter shown in FIG. **2**. FIG. **7** is a cross-sectional view showing a modification of the cryoablation catheter shown in FIG. **2**. FIG. **8** is a cross-sectional view, at the line VIII-VIII, of the cryoablation catheter shown in FIG. **7**. FIG. **9** is an end surface view of a cut portion, at the line IX-IX, of the cryoablation catheter shown in FIG. **7**. FIG. **10** is an end surface view of a cut portion, at the line X-X, of the cryoablation catheter shown in FIG. **7**. FIG. **11** is a side view showing a modification of the cryoablation catheter according to one or more embodiments of the present invention. FIG. **12** is a cross-sectional view of the cryoablation catheter shown in FIG. **11**. FIG. **13** is a cross-sectional view, at the line XIII-XIII, of the cryoablation catheter shown in FIG. **12**. FIG. **14** is an end surface view of a cut portion, at the line XIV-XIV, of the cryoablation catheter shown in FIG. **12**. FIG. **15** is a cross-sectional view, at the line XV-XV, of the cryoablation catheter shown in FIG. **2**. FIG. **16** is a cross-sectional view, at the line XVI-XVI, of the cryoablation catheter shown in FIG. **2**.

[0069] The cryoablation catheter according to one or more embodiments of the present invention is 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.

[0070] As shown in FIG. **1** to FIG. **3**, FIG. **7**, and FIG. **8**, 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**.

[0071] As shown in FIG. **1** to FIG. **3**, FIG. **7**, and FIG. **8**, the first 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** and FIG. **8**, the first 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 first inner tube **210** and which are formed in regions different from a region in which the guide wire lumen **211** is formed.

[0072] As shown in FIG. **2**, FIG. **3**, FIG. **7**, and FIG. **8**, the catheter **1** has a first discharge flow path **31** which is located between the inner surface **14** of the outer tube **10** and an outer surface **213** of the first 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 first 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 first 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 first 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 first inner tube **210**.

[0073] As shown in FIG. **2**, FIG. **3**, FIG. **7**, and FIG. **8**, the first inner tube **210** has a distal portion in which holes **40** through which the respective supply lumens **212** and the first 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 first discharge flow path **31** via the holes **40**. As shown in FIG. **2** and FIG. **7**, the holes **40** may be formed not only in the distal portion of the first inner tube **210** but also in the proximal portion of the first inner tube **210**. As shown in FIG. **12**, the holes **40** may be formed in the distal portion of the first inner tube **210** alone.

[0074] 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 first inner tube **210** to the outer side in the radial direction of the outer tube **10** and passes through the first 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**.

[0075] In the first inner tube **210** of the cryoablation catheter **1** for duodenal papilla insertion 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 portion having a large bending angle such as a duodenal papilla, 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.

[0076] 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.

[0077] 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.

[0078] 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.

[0079] 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.

[0080] As shown in FIG. **1**, FIG. **2**, FIG. **7**, and FIG. **15**, 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. **15**, each of the radiopaque markers **70** may be provided on, for example, the outer surface **13** of the outer tube **10**.

[0081] As shown in FIG. **12**, the radiopaque markers **70** may be provided on the distal portion of the first 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**. The shape of each of the above radiopaque markers **70** may be a tubular shape as shown in FIG. **1**, FIG. **2**, and FIG. **15**. 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.

[0082] 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 first inner tube **210**, or a separately provided resin member. As shown in FIG. **11** to FIG. **13**, 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. **11** to FIG. **13** 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.

[0083] 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. **11** and FIG. **12**, 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.

[0084] 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 first 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 first 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.

[0085] 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. **11** and FIG. **12**, 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 first 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**.

[0086] 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.

[0087] As shown in FIG. **12**, the holes **40** may be located inside the balloon **50**. That is, the holes **40** may be formed in portions of the first inner tube **210** that are located inside the balloon **50**. Although the holes **40** may be formed also in portions of the first inner tube **210** that are not located inside the balloon **50**, the holes **40** may be formed only in the portions of the first 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.

[0088] As shown in FIG. **2**, FIG. **7**, and FIG. **12**, 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**.

[0089] As shown in FIG. **12**, the radiopaque markers **70** may be provided on the outer surface **213** of the first 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. **12**, the radiopaque markers **70** may each be provided on the outer surface **213** of the first 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**.

[0090] The first 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 first inner tube **210** has: the outer surface **213** facing the outside of the first 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.

[0091] As a material forming the first 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 first inner tube **210** and the material forming the outer tube **10** may be identical to or different from each other.

[0092] The first 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 first inner tube **210** can be molded as one piece through, for example, extrusion molding by using the predetermined material. By molding the first 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 first inner tube **210** and suppression of closure of the supply lumens **212**. In addition, by molding the first inner tube **210** as one piece from the predetermined material, it is unnecessary to manu-

facture a plurality of components, whereby a manufacturing process for the first inner tube **210** can be simplified, and the time and cost required for the manufacturing can be decreased.

[0093] As shown in FIG. **1**, FIG. **2**, and FIG. **7**, the first inner tube **210** may extend only on the distal side relative to the proximal end **12** of the outer tube **10**. The catheter **1** shown in FIG. **1**, FIG. **2**, and FIG. **7** is of a so-called rapid exchange type.

[0094] As shown in FIG. **11** and FIG. **12**, the first inner tube **210** may extend over the entire length of the outer tube **10**. The catheter **1** shown in FIG. **11** and FIG. **12** is of a so-called over-the-wire type.

[0095] 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 first 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 first inner tube **210** to a centroid **211***c* of the guide wire lumen **211**. The eccentric distance from the centroid **210***c* of the first 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 first inner tube **210** being regarded as the center. The eccentric distance from the centroid **210***c* of the first 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 first inner tube **210** being regarded as the center. By setting the eccentric distance from the centroid **210***c* of the first 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 first 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 first 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 first discharge flow path **31** comparatively early, whereby efficient cooling of a tissue as a therapy target can be facilitated.

[0096] 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 first 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 first inner tube **210**. By forming the guide wire lumen **211** at a position that overlaps with the centroid **210***c* of the first 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 first inner tube **210**, the supply lumen **212** is formed on the outer side in the radial direction of the first 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 first 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 first inner tube **210**, the guide wire is easily located at the axis of the first inner tube **210**, whereby improvement of the operability of the catheter **1** can be facilitated.

[0097] 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.

[0098] 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**.

[0099] 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 first inner tube **210**. In FIG. **3**, the one straight line passing through the centroid **210***c* of the first 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 first inner tube **210** and that intersects the one straight line passing through the centroid **210***c* of the first inner tube **210**. There are two such portions that are located on the outer peripheral edge of the first inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the first 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 first 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 first inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the first 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.

[0100] 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 first inner tube **210** and any of the holes **40**. In FIG. **3**, the one straight line passing through the centroid **210***c* of the first 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 first inner tube **210** and that intersects the one straight line passing through the centroid **210***c* of the first inner tube **210**. There are two such portions that are located on the outer peripheral edge of the first inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the first 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 first 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 first inner tube **210** and that intersect the one straight line passing through the centroid **210***c* of the first 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.

[0101] As shown in FIG. **15**, 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 first inner tube **210**. In FIG. **15**, one such imaginary circle **210***s* having a center at the centroid **210***c* of the first 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 first inner tube **210** are located on the one imaginary circle **210***s* having a center at the centroid **210***c* of the first inner tube **210**. Since portions of the first 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 first inner tube **210** as shown in FIG. **15**. 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 first inner tube **210**. By doing so, retention of the resistance to bending can be facilitated regardless of the bending direction of the first 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 first inner tube **210**.

[0102] 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.

[0103] As shown in FIG. **16**, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the first 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 first 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 first inner tube **210**. Although not shown, the first 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 first inner tube **210**. 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.

[0104] As shown in FIG. **16**, it may be preferable that: in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the first 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 first 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 first 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 first 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. **16**, the half-line having one end at the centroid **210***c* of the first 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 first 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.

[0105] 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.

[0106] As shown in FIG. **3**, it may be preferable that the first 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 first inner tube **210**. Although not shown, the first 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 first inner tube **210**.

[0107] As shown in FIG. **2**, FIG. **4**, FIG. **7**, and FIG. **9**, it may be preferable that: the catheter **1** further includes a second inner tube **220** extending in the longitudinal direction x of the outer tube **10** and disposed, in the inner cavity **15** of the outer tube **10**, on the proximal side relative to the first inner tube **210**; the second inner tube **220** has a $(2\text{-}1)^{th}$ inner tube **221** extending in the longitudinal direction x of the outer tube **10** and a $(2\text{-}2)^{th}$ inner tube **222** disposed in an inner cavity **2213** of the $(2\text{-}1)^{th}$ inner tube **221** and extending in the longitudinal direction x of the outer tube **10**; a $(2\text{-}1)^{th}$ flow path **2214** in communication with the plurality of supply lumens **212** formed in the first inner tube **210** is

present between an inner surface **2212** of the (2-1)th inner tube **221** and an outer surface **2221** of the (2-2)th inner tube **222**; and the (2-2)th inner tube **222** has an inner cavity **2223** in communication with the guide wire lumen **211** formed in the first inner tube **210**.

[0108] As a material forming the second inner tube **220**, 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 second inner tube **220** and the material forming the outer tube **10** may be identical to or different from each other. The material forming the second inner tube **220** and the material forming the first inner tube **210** may be identical to or different from each other.

[0109] The shape of the (2-1)th inner tube **221** is a tubular shape and may be a shape such as the shape of a hollow column or a hollow polygonal prism. The shape of the (2-2)th inner tube **222** is a tubular shape and may be a shape such as the shape of a hollow column or a hollow polygonal prism.

[0110] As shown in FIG. **2**, the entirety of the (2-2)th inner tube **222** may be disposed in the inner cavity **2213** of the (2-1)th inner tube **221**. As shown in FIG. **7**, a part of the (2-2)th inner tube **222** may be located in the inner cavity **2213** of the (2-1)th inner tube **221**, and another part of the (2-2)th inner tube **222** may be located on the outer side in the radial direction of the (2-1)th inner tube **221** relative to the (2-1)th inner tube **221**.

[0111] In a case where the catheter **1** further includes the second inner tube **220**, it may be preferable that: the catheter **1** has a second discharge flow path **32** which is located between the inner surface **14** of the outer tube **10** and an outer surface **2211** of the (2-1)th inner tube **221** and which allows the fluid to pass therethrough from the distal side to the proximal side of the outer tube **10**; and the second discharge flow path **32** is in communication with the first discharge flow path **31**.

[0112] As shown in FIG. **2** and FIG. **5**, it may be preferable that: the catheter **1** further includes a third inner tube **230** extending in the longitudinal direction x of the outer tube **10** and disposed, in the inner cavity **15** of the outer tube **10**, on the proximal side relative to the second inner tube **220**; and, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, the third inner tube **230** has a (3-1)th lumen **231** which extends in the longitudinal direction x of the outer tube **10** and which is in communication with the (2-1)th flow path **2214** and a (3-2)th lumen **232** which is in communication with the inner cavity **2223** of the (2-2)th inner tube **222** and which is formed in a region different from a region in which the (3-1)th lumen **231** is formed.

[0113] It may be preferable that, in the cross section perpendicular to the longitudinal direction x of the outer tube **10**, a centroid of the (3-1)th lumen **231** does not overlap with the (3-2)th lumen **232**, and a centroid of the (3-2)th lumen **232** does not overlap with the (3-1)th lumen **231**. Consequently, formation of the (3-2)th lumen **232** near the outer edge of the third inner tube **230** can be facilitated, whereby formation of an opening **45** (guide wire port) described later in the catheter **1** can be facilitated.

[0114] As a material forming the third inner tube **230**, 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 third inner tube **230** and the material forming the outer tube **10** may be identical to or different from each other. The material forming the third inner tube **230** and the material forming the first inner tube **210** may be identical to or different from each other. The material forming the third inner tube **230** and the material forming the second inner tube **220** may be identical to or different from each other.

[0115] The catheter **1** may have an opening **45** into which a guide wire is inserted and through which the (3-2)th lumen **232** and a space located on the outer side in the radial direction of the outer tube **10** relative to the outer tube **10** are in communication with each other. For example, as shown in FIG. **2**, it may be preferable that: at least a part of an outer surface **233** of the third inner tube **230** is connected to the inner surface **14** of the outer tube **10**; the (3-2)th lumen **232** is configured to, at a position thereof closer to the connected part, be closer to the outer tube **10**; and the provided opening **45** is configured to allow this (3-2)th lumen **232** to be in communication with the space located on the outer side in the radial direction of the outer tube **10** relative to the outer tube **10**. The opening **45** of the catheter **1** shown in FIG. **2** is a so-called guide wire port.

[0116] In a case where the catheter **1** further includes the third inner tube **230**, it may be preferable that: the catheter **1** has a third discharge flow path **33** which is located between the inner surface **14** of the outer tube **10** and the outer surface **233** of the third inner tube **230** and which allows the fluid to pass therethrough from the distal side to the proximal side of the outer tube **10**; and the third discharge flow path **33** is in communication with the first discharge flow path **31** and the second discharge flow path **32**.

[0117] As shown in FIG. **2** and FIG. **6**, it may be preferable that: the catheter **1** further includes a fourth inner tube **240** extending in the longitudinal direction x of the outer tube **10** and disposed, in the inner cavity **15** of the outer tube **10**, on the proximal side relative to the third inner tube **230**; and the fourth inner tube **240** has an inner cavity **243** in communication with the (3-1)th lumen **231**.

[0118] The shape of the fourth inner tube **240** is a tubular shape and may be a shape such as the shape of a hollow column or a hollow polygonal prism.

[0119] As a material forming the fourth inner tube **240**, 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 fourth inner tube **240** and the material forming the outer tube **10** may be identical to or different from each other. The material forming the fourth inner tube **240** and the material forming the first inner tube **210** may be identical to or different from each other. The material forming the fourth inner tube **240** and the material forming the second inner tube **220** may be identical to or different from each other. The material forming the fourth inner tube **240** and the material forming the third inner tube **230** may be identical to or different from each other.

[0120] In a case where the catheter **1** further includes the fourth inner tube **240**, it may be preferable that: the catheter **1** has a fourth discharge flow path **34** which is located between the inner surface **14** of the outer tube **10** and an outer surface **241** of the fourth inner tube **240** and which allows the fluid to pass therethrough from the distal side to the proximal side of the outer tube **10**; and the fourth discharge flow path **34** is in communication with the first discharge flow path **31**, the second discharge flow path **32**, and the third discharge flow path **33**.

[0121] In another embodiment, as shown in FIG. **7** and FIG. **10**, it may be also preferable that: the catheter **1**

includes a fifth inner tube **250** extending in the longitudinal direction x and disposed, in the inner cavity **15** of the outer tube **10**, on the proximal side relative to the second inner tube **220**; and the fifth inner tube **250** has an inner cavity **253** in communication with the $(2\text{-}1)^{th}$ flow path **2214**.

[0122] As shown in FIG. **7** to FIG. **10**, in a case where the catheter **1** includes the first inner tube **210**, the second inner tube **220**, and the fifth inner tube **250**, it may be preferable that the above third inner tube **230** is not provided.

[0123] As shown in FIG. **7**, the catheter **1** may have an opening **45** into which a guide wire is inserted and through which the space located on the outer side in the radial direction of the outer tube **10** relative to the outer tube **10** and the inner cavity **2223** of the $(2\text{-}2)^{th}$ inner tube **222** are in communication with each other. The opening **45** can be provided by, for example, employing a configuration in which, as shown in FIG. **7**, the distal portion of the $(2\text{-}2)^{th}$ inner tube **222** penetrates a side wall of the $(2\text{-}1)^{th}$ inner tube **221** and a side wall of the outer tube **10**. The opening **45** of the catheter **1** shown in FIG. **7** is a so-called guide wire port.

[0124] The shape of the fifth inner tube **250** is a tubular shape and may be a shape such as the shape of a hollow column or a hollow polygonal prism.

[0125] As a material forming the fifth inner tube **250**, 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 fifth inner tube **250** and the material forming the outer tube **10** may be identical to or different from each other. The material forming the fifth inner tube **250** and the material forming the first inner tube **210** may be identical to or different from each other. The material forming the fifth inner tube **250** and the material forming the second inner tube **220** may be identical to or different from each other.

[0126] In a case where the catheter **1** includes the fifth inner tube **250**, it may be preferable that: the catheter **1** has a fifth discharge flow path **35** which is located between the inner surface **14** of the outer tube **10** and an outer surface **251** of the fifth inner tube **250** and which allows the fluid to pass therethrough from the distal side to the proximal side of the outer tube **10**; and the fifth discharge flow path **35** is in communication with the first discharge flow path **31** and the second discharge flow path **32**.

[0127] As shown in FIG. **1**, FIG. **2**, FIG. **7**, FIG. **11**, and FIG. **12**, 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**, FIG. **2**, and FIG. **7**, a distal end portion of the outer tube **10** and a distal end portion of the first inner tube **210** may be fixed to a proximal end portion of the distal tip **60**.

[0128] The distal side of the first 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 first inner tube **210**. A configuration in which the distal side of the first 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 first 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 first inner tube **210** may be welded and fixed to each other so as to close the distal side of the first discharge flow path **31** without providing the distal tip **60**. As shown in FIG. **11** and FIG. **12**, in a case where the outer tube **10** has the balloon **50**, the configuration in which the distal side of the first 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 first 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 first discharge flow path **31**.

[0129] As shown in FIG. **1**, FIG. **2**, FIG. **7**, FIG. **11**, and FIG. **12**, 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 first 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.

[0130] 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 preferably the shape of a hollow truncated cone as shown in FIG. **1** and FIG. **2**.

[0131] 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.

[0132] As shown in FIG. **1**, FIG. **2**, FIG. **7**, FIG. **11**, and FIG. **12**, 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**, FIG. **7**, and FIG. **12**, 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. **12**, the outer tube **10** and the first inner tube **210** are inserted into the hollow portion of the first handle **75**. In FIG. **2**, the outer tube **10** and the fourth inner tube **240** are inserted into the hollow portion of the first handle **75**. In FIG. **7**, the outer tube **10** and the fifth inner tube **250** are inserted into the hollow portion of the first handle **75**.

[0133] As shown in FIG. **11** and FIG. **12**, a configuration may be employed in which a second handle **76** is connected to the proximal portion of the first inner tube **210**. In FIG. **12**, 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. **12**, the first 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. **12**, the proximal end of the first 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 first inner tube **210**.

[0134] 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.

[0135] 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**.

[0136] 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. 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.

[0137] 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.

[0138] 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**.

[0139] 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 first inner tube **210** is connected to the fluid supply device **80**.

[0140] The fluid supply device **80** is not particularly limited as long as the fluid supply device **80** can supply the fluid to the first 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.

[0141] The first 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. **12**, FIG. **13**, and FIG. **14**, the three supply lumens **212** may converge into one lumen on the proximal side, and the proximal end of the first inner tube **210** may be directly connected to the fluid supply device **80**.

[0142] The first inner tube **210** may be indirectly connected to the fluid supply device **80**. For example, as shown in FIG. **2**, the second inner tube **220**, the third inner tube **230**, and the fourth inner tube **240** may be present between the first inner tube **210** and the fluid supply device **80**, and the first inner tube **210** and the fluid supply device **80** may be indirectly connected to each other via the second inner tube **220**, the third inner tube **230**, and the fourth inner tube **240**. Alternatively, as shown in FIG. **7**, the second inner tube **220** and the fifth inner tube **250** may be present between the first inner tube **210** and the fluid supply device **80**, and the first inner tube **210** and the fluid supply device **80** may be indirectly connected to each other via the second inner tube **220** and the fifth inner tube **250**.

[0143] This application claims the benefit of the priority date of Japanese patent application No. 2022-176154 filed on Nov. 2, 2022. All of the contents of the Japanese patent application No. 2022-176154 filed on Nov. 2, 2022 are incorporated by reference herein.

[0144] 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

[0145] **1**: cryoablation catheter
[0146] **10**: outer tube
[0147] **11**: distal end of the outer tube
[0148] **12**: proximal end of the outer tube
[0149] **13**: outer surface of the outer tube
[0150] **14**: inner surface of the outer tube
[0151] **15**: inner cavity of the outer tube
[0152] **16**: tubular member
[0153] **210**: first inner tube
[0154] **210***c*: centroid of the first inner tube
[0155] **210***s*: imaginary circle having a center at the centroid of the first inner tube
[0156] **211**: guide wire lumen
[0157] **211***c*: centroid of the guide wire lumen
[0158] **212**: supply lumen
[0159] **212***c*: centroid of the supply lumen
[0160] **2121**: first supply lumen
[0161] **2121***c*: centroid of the first supply lumen
[0162] **2122**: second supply lumen
[0163] **2122***c*: centroid of the second supply lumen
[0164] **2123**: third supply lumen
[0165] **2123***c*: centroid of the third supply lumen
[0166] **213**: outer surface of the first inner tube
[0167] **214**: inner surface the first inner tube
[0168] **220**: second inner tube
[0169] **221**: $(2\text{-}1)^{th}$ inner tube
[0170] **2211**: outer surface of the $(2\text{-}1)^{th}$ inner tube
[0171] **2212**: inner surface of the $(2\text{-}1)^{th}$ inner tube
[0172] **2213**: inner cavity of the $(2\text{-}1)^{th}$ inner tube
[0173] **2214**: $(2\text{-}1)^{th}$ flow path
[0174] **222**: $(2\text{-}2)^{th}$ inner tub
[0175] **2221**: outer surface of the $(2\text{-}2)^{th}$ inner tube
[0176] **2222**: inner surface of the $(2\text{-}2)^{th}$ inner tube
[0177] **2223**: inner cavity of the $(2\text{-}2)^{th}$ inner tube
[0178] **230**: third inner tube
[0179] **231**: $(3\text{-}1)^{th}$ lumen
[0180] **232**: $(3\text{-}2)^{th}$ lumen
[0181] **233**: outer surface of the third inner tube
[0182] **240**: fourth inner tube
[0183] **241**: outer surface of the fourth inner tube
[0184] **242**: inner surface of the fourth inner tube
[0185] **243**: inner cavity of the fourth inner tube
[0186] **250**: fifth inner tube
[0187] **251**: outer surface of the fifth inner tube
[0188] **252**: inner surface of the fifth inner tube
[0189] **253**: inner cavity of the fifth inner tube
[0190] **31**: first discharge flow path
[0191] **32**: second discharge flow path

[0192] **33**: third discharge flow path
[0193] **34**: fourth discharge flow path
[0194] **35**: fifth discharge flow path
[0195] **40**: hole
[0196] **45**: opening
[0197] **50**: balloon
[0198] **51**: straight tube portion
[0199] **52**: distal-side tapered portion
[0200] **53**: proximal-side tapered portion
[0201] **54**: distal-side sleeve portion
[0202] **55**: proximal-side sleeve portion
[0203] **60**: distal tip
[0204] **61**: outer surface of the distal tip
[0205] **62**: inner surface of the distal tip
[0206] **63**: lumen of the distal tip
[0207] **70**: radiopaque marker
[0208] **75**: first handle
[0209] **76**: second handle
[0210] **80**: fluid supply device

1. A cryoablation catheter for a duodenal papilla insertion comprising:
- an outer tube having a distal end and a proximal end and extending in a longitudinal direction;
- a first inner tube extending in the longitudinal direction and disposed in an inner cavity of the outer tube; and
- a first discharge flow path, wherein:
  - the first inner tube comprises a guide wire lumen and a plurality of supply lumens, wherein, in a cross section perpendicular to the longitudinal direction, a 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
    - a plurality of supply lumens are configured to allow a fluid to pass therethrough from a proximal side to a distal side of the first inner tube;
  - the first discharge flow path is located between an inner surface of the outer tube and an outer surface of the first 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 first inner tube comprises a hole located in a distal portion of the first inner tube, wherein any of the supply lumens and the first 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, an eccentric distance from a centroid of the first inner tube to a centroid of each of the supply lumens is longer than an eccentric distance from the centroid of the first inner tube to a centroid of the guide wire lumen.

3. 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 first inner tube, and each of the supply lumens is formed at a position that does not overlap with the centroid of the first inner tube.

4. The cryoablation catheter according to claim **1**, wherein the first inner tube is molded as one piece from a predetermined material.

5. The cryoablation catheter according to claim **1**, wherein:
- a plurality of the holes are formed; and
- in the cross section perpendicular to the longitudinal direction, only one of the holes is present on one straight line passing through a centroid of the first inner tube.

6. The cryoablation catheter according to claim **1**, wherein, in the cross section perpendicular to the longitudinal direction, only one of the supply lumens is present on one straight line passing through a centroid of the first inner tube and the hole.

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 first inner tube.

8. 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.

9. The cryoablation catheter according to claim **8**, wherein a material forming the balloon has a higher thermal conductivity than a material forming a portion of the outer tube other than the balloon.

10. The cryoablation catheter according to claim **1**, wherein the fluid is gas.

11. The cryoablation catheter according to claim **1**, wherein:
- in the cross section perpendicular to the longitudinal direction, the first inner tube comprises a first supply lumen and a second supply lumen formed to be adjacent to the first supply lumen in a circumferential direction of the first inner tube; and
- in the cross section perpendicular to the longitudinal direction, an angle a formed between a half-line that has one end at a centroid of the first inner tube and that passes through a centroid of the first supply lumen and a half-line that has one end at the centroid of the first inner tube and that passes through a centroid of the second supply lumen is 105 degrees or larger and 135 degrees or smaller.

12. The cryoablation catheter according to claim **1**, further comprising a second inner tube extending in the longitudinal direction and disposed, in the inner cavity of the outer tube, on a proximal side relative to the first inner tube, wherein:
- the second inner tube comprises a $(2\text{-}1)^{th}$ inner tube extending in the longitudinal direction and a $(2\text{-}2)^{th}$ inner tube disposed in an inner cavity of the $(2\text{-}1)^{th}$ inner tube and extending in the longitudinal direction;
- a $(2\text{-}1)^{th}$ flow path in communication with the plurality of supply lumens formed in the first inner tube is present between an inner surface of the $(2\text{-}1)^{th}$ inner tube and an outer surface of the $(2\text{-}2)^{th}$ inner tube; and
- the $(2\text{-}2)^{th}$ inner tube comprises an inner cavity in communication with the guide wire lumen formed in the first inner tube.

13. The cryoablation catheter according to claim **12**, further comprising a third inner tube extending in the longitudinal direction and disposed, in the inner cavity of the outer tube, on the proximal side relative to the second inner tube, wherein, in the cross section perpendicular to the longitudinal direction, the third inner tube comprises:
- a $(3\text{-}1)^{th}$ lumen which extends in the longitudinal direction and which is in communication with the $(2\text{-}1)^{th}$ flow path; and

a (3-2)th lumen which is in communication with the inner cavity of the (2-2)th inner tube and which is formed in a region different from a region in which the (3-1)th lumen is formed.

14. The cryoablation catheter according to claim **13**, further comprising a fourth inner tube extending in the longitudinal direction and disposed, in the inner cavity of the outer tube, on the proximal side relative to the third inner tube; and

the fourth inner tube comprises an inner cavity in communication with the (3-1)th lumen.

15. 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 first inner tube are fixed to a proximal end portion of the distal tip.

16. 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 first inner tube is connected to the fluid supply device.

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