(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 November 2016 (24.11.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/186880 A1

(51) International Patent Classification:
*A61M 25/00* (2006.01) *A61B 18/00* (2006.01)
*A61B 17/00* (2006.01)

(21) International Application Number:
PCT/US2016/031461

(22) International Filing Date:
9 May 2016 (09.05.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/162,453 15 May 2015 (15.05.2015) US

(71) Applicants: **THE UNITED STATES OF AMERICA, as represented by THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES** [US/US]; National Institutes of Health, Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, MSC 7660, Bethesda, MD 20852-7660 (US). **HENRY FORD HEALTH SYSTEM** [US/US]; 1 Ford Place, Detroit, MI 48202 (US).

(72) Inventors: **LEDERMAN, Robert, J.**; NIH/NHL BI, Building 10, Room 2C713, 10 Center Drive, Bethesda, MD 20814 (US). **ROGERS, Toby**; NHLBI, Building 10, Room B1D219, 10 Center Drive, Bethesda, MD 20814 (US). **RAFIEE, Nasser**; Mehr Medical, 39 Abbot Street, Andover, MA 01810 (US). **GREENBAUM, Adam, B.**; One Ford Place, Detroit, MI 48202 (US). **O'NEILL, William, W.**; 2799 West Grand Boulevard, Detroit, MI 48202 (US).

(74) Agent: **DUNCAN, Sandon, M.**; Klarquist Sparkman, LLP, One World Trade Center, Suite 1600, 121 SW Salmon Street, Portland, OR 97204 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17**:

— *of inventorship (Rule 4.17(iv))*

**Published**:

— *with international search report (Art. 21(3))*

WO 2016/186880 A1

(54) **Title**: THREE-DIMENSIONAL RIGHT ATRIAL APPENDAGE CURVE CATHETER

(57) **Abstract**: Disclosed delivery catheters have a three-dimensional curvature that facilitates reaching the RAA from the inferior vena cava, positioning the distal end of the catheter generally parallel to the plane of the pericardial space at the puncture location within the RAA, orienting the puncturing device in a direction that avoids the right coronary artery, aorta, pulmonary artery, and other structures to prevent bystander injury to such structures, and provides sufficient rigidity to puncture through a wall of the RAA into the pericardial space.

# THREE-DIMENSIONAL RIGHT ATRIAL APPENDAGE CURVE CATHETER

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application No. 62/162,453, filed May 15, 2015, which is entirely incorporated by reference herein.

## FIELD

The present disclosure relates to catheters and other devices for accessing the pericardial space through the right atrium and right atrial appendage.

## BACKGROUND

Some procedures require access to the pericardial space, such as for left atrial appendage ligation, circumferential tricuspid annuloplasty, or epicardial ablation for rhythm disorders. One way to access the pericardial space is by advancing a transvascular catheter through the right atrium and into the right atrial appendage, and passing the catheter through a puncture in the right atrial appendage into the pericardial space. However, such procedures can risk myocardial or coronary laceration, along with other risks.

## SUMMARY

Described herein are curved catheters that are shaped and configured to more safely guide traversal of the right atrial appendage (RAA) and more effectively exit through the superior left sulcus wall of the RAA into the pericardial space in a desired orientation that reduces the risks of injuring bystander tissues and increases the success rate of procedures requiring access to the pericardial space.

Disclosed catheters can comprise a proximal segment, a transition segment extending distally from the proximal segment, a distal segment extending distally from the transition segment, and a distal end, wherein the transition segment and/or the distal segment are adapted to extend from the proximal segment with a clockwise spiral curvature when the catheter is positioned within a patient. When inserted into a patient, the proximal segment is positioned within the inferior vena cava, the transition segment extends across the caval-atrial junction and curves rightward, forward, and upward such that the catheter abuts a right lateral wall of the right atrium, and the distal segment curves leftward, forward, and upward from the transition segment through the right atrium such that the catheter abuts an anterior wall of the right atrium adjacent to the RAA, and the distal

segment continues to curve leftward, rearward, and upward from the anterior wall of the right atrium along an anterior-superior wall of the RAA such that distal end of the catheter contacts a cephalad wall of the RAA. The catheter is configured to guide a coaxial puncturing device to extend from the distal end of the catheter and puncture through the superior left sulcal wall of the RAA into the pericardial space safely cephalad and away from critical structures such as coronary artery. The curvature of the catheter orients the distal end of the catheter pointing generally leftward and parallel with the pericardium such that the puncturing device passes through the cephalad wall of the RAA and into the pericardial space without damaging the pericardium and at a location spaced apart from the right coronary artery, the pulmonary artery, and the aorta to minimize the risk of damage such bystander structures. The catheter can be configured to deliver and/or be used with an inflatable balloon catheter that is inflated within the RAA to separate or flatten trabeculations within the RAA to facilitate advancing the distal end of the catheter against the left sulcal wall of the RAA.

The foregoing and other features and advantages of the disclosed technology will become more apparent from the following detailed description of several embodiments, which proceeds with reference to the accompanying figures.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a model representing the interior volume of a heart, as viewed from the right side. The right atrial appendage is in the foreground.

FIG. 2 shows a model representing the interior volume of only the venous structures of the heart.

FIG. 3 illustrates an exemplary curved catheter extending through the inferior vena cava, through the right atrium, and into to the right atrial appendage abutting the cephalad left sulcal wall.

FIG. 4 illustrates the curved catheter of FIG. 3 in isolation.

FIGS. 5A-5H show various side views of the curved catheter of FIG. 4 as the catheter is rotated about a vertical axis.

FIGS. 6 and 7 illustrate another exemplary curved catheter.

FIGS. 8A-8D are radiographic images illustrating an exemplary procedure using a curved catheter to engage the right atrial appendage from the inferior vena cava (FIG. 8A) and then aligning with and engaging against the outer or anterior wall of the right atrial appendage with the tip purchased against the cephalad left sulcus wall of the right atrial appendage (FIG. 8B). In FIG. 8C, a guidewire exits the curved catheter to traverse the wall of the right atrial appendage and enter

the pericardial space, and in FIG. 8D a microcatheter is delivered through the curved catheter over the guidewire from the right atrium into the pericardial space.

FIGS. 9A-9D are radiographic images illustrating another exemplary procedure using a curved catheter to access the pericardial space through the right atrial appendage.

FIG. 10 is a contrast pericardiogram illustrating two alternative exit trajectories from the right atrial appendage.

## DETAILED DESCRIPTION

The catheters, systems, and methods described herein can be used for performing various intrapericardial procedures, such as left atrial appendage suture ligation, epicardial ablation for rhythm disorders, and tricuspid annuloplasty. More information regarding such procedures as well as related systems and devices can be found in International Publication Number WO 2014/015842 A1, published October 2, 2014, and entitled "DEVICES AND METHODS FOR TREATING FUNCTIONAL TRICUSPID VALVE REGURGITATION"; International Publication Number WO 2014/200764 A1, published December 18, 2014, and entitled "ENCIRCLING IMPLANT DELIVERY SYSTEMS AND METHODS"; and International Publication Number WO 2015/061775 A1, published April 30, 2015, and entitled "ATRIAL APPENDAGE LIGATION"; all of which are incorporated by reference herein in their entireties.

As used herein, the direction "right" refers to the right lateral side of a patient and the term "left" refers to the left lateral side of a patient. Similarly, the terms front and rear refer to the anterior and posterior sides of a patient. Terms such as "up" and "top" refer to the superior direction of a patient, and terms such as "down" and "bottom" refer to the inferior direction of a patient. The terms "distal" and "proximal" as used herein refer to proximal and distal ends of a catheter or other transvascular device, with the proximal direction being toward the point of insertion into the patient and the distal direction being toward the free end of the device.

FIGS. 1 and 2 show models of the interior volume of the heart, and in particular illustrate the geometry and orientation of the right atrium (RA) and the right atrial appendage (RAA). In FIG. 1, the entire interior of the heart is shown from the right side, while FIG. 2 shows only the de-oxygenated blood regions of the heart (e.g., the right side of the heart, vena cavas, pulmonary artery, etc.). As shown, the RA and RAA include irregular interior wall surfaces that form many small folds, flaps and crevices that can obstruct the delivery of the catheter device.

Disclosed delivery catheters have a three-dimensional curvature that facilitates reaching the RAA from the femoral vein via the inferior vena cava, positioning the distal end of the catheter

generally parallel to the plane of the pericardial space at the puncture location within the RAA, orienting the puncturing device in a direction that avoids the right coronary artery, aorta, pulmonary artery, and left atrial appendage to prevent bystander injury to such structures, and provides sufficient rigidity to puncture through the cephalad wall of the RAA into the pericardial space.

FIG. 3 illustrates an exemplary curved catheter 10 extending through the IVC, through the RA, and into the RAA. The disclosed catheters include three segments, as illustrated in FIG. 4. A first, proximal segment 12 is generally straight or slightly curved and can project generally vertically through the IVC. A second, transitional segment 13 can be positioned in the vicinity of the caval-atrial junction to curve toward the right and front sides of the patient. As shown in FIG. 4, the catheter 10 passes behind a vertical z-axis at the transitional segment 13 and then curves around and passes in front of the z-axis at a third, distal segment 14, which curves more sharply toward the left side of the patient to the distal end 18 of the catheter when the catheter is positioned for use. The distal segment 10 can also include a substantially straight portion 16 at the distal end, which can extend generally transversely within the patient.

The transition segment 13 and distal segment 14 spiral clockwise from the proximal segment 12 toward to the straight distal portion 16. The spiral or helical curvature is illustrated in FIG. 4 with reference to a straight vertical z-axis. The terms “spiral” and “helix” are used interchangeably herein and are defined broadly herein to mean any three-dimensional curvature that curves around a central axis as the curvature also extends in the direction of the central axis, and such terms do not require the curvature to have a constant radius from the central axis (as in a circular helix), a constant pitch or tangent angle relative to the central axis (as in some helixes), a continuously increasing or decreasing radius from the central axis (as in some spirals), a straight central axis, or any minimum arc length around the central axis, though all such species are included within the definition. The term “clockwise” means that the catheter curves with a right-handed chirality such that a catheter with a clockwise curvature appears to curve in a generally clockwise path when viewing the catheter from the proximal segment looking upward/distally along the vertical z-axis.

The curvature of the catheter 10 is further illustrated in FIGS. 5A-5H, which show eight side elevation views taken at 45° increments around the z-axis. FIGS. 5A is front view, FIG. 5B is a front-left view (similar to the views of FIGS. 3 and 4), FIG. 5C is a left side view, FIG. 5D is a rear-left view, FIG. 5E is a rear view, FIG. 5F is a rear-right view, FIG. 5G is a right side view, and FIG. 5H is a front-left view. As shown in FIGS. 5A-5H, the catheter 10 curves rightward and forward at the transitional segment 13. The catheter 10 then curves leftward and rearward at the distal

segment 14, such that the distal end 18 projects leftward and slightly upward and rearward. This trajectory is configured to allow the distal end of the catheter and/or a puncturing device deploying from within the catheter, to be desirably oriented within the RAA such that it passes through the cephalad wall of the RAA and into the pericardial space with minimal risk of bystander injury.

The rightward curvature of the transition segment 13 (FIG. 5A) can cause the transition segment to abut the right lateral wall of the RA. The frontward curvature of the transition segment 13 and distal segment 14 (see FIG. 5C) is configured to increase apposition of the distal segment 14 of the catheter to the anterior and/or superior walls of the RA and the RAA, and also serves as a smooth transition from the generally vertical orientation of the proximal segment 12 to the more horizontal orientation of the distal segment 14. In some examples, the distal segment 14 can be oriented in a plane that is generally perpendicular to the proximal segment 12. The distal segment 14 can have a sharper curvature (i.e., smaller radius of curvature) at the anterior aspect of the catheter where the catheter abuts the anterior and/or superior walls of the RA and RAA, relative to the more gently curving transition segment 13 that passes through the caval-atrial junction and the generally straight distal portion 16 that extends into the RAA. The apposition of the distal segment 14 to the anterior and/or superior walls of the RA and RAA cause the distal end 18 to align along the crest of the RAA parallel with the tangential plane of the visceral pericardium and abut the cephalad wall of the RAA, where the distal end 18 is positioned far from the right coronary artery and its branches.

In some examples, the distal segment 14 of the curved catheter can have a radius of curvature of between about 2 inches and about 4 inches, between about 2.5 inches and about 3 inches, and/or about 2.8 inches. In some examples, the distal segment 14 of the curved catheter can have an arc length of between about 90° and about 180°, between about 120° and about 150°, and/or about 135°.

FIGS. 6 and 7 show another exemplary curved catheter 20 that is similar to the catheter 10. FIG. 6 shows a rear view (similar to FIG. 5E) and FIG. 7 shows a right side view (similar to FIG. 5G). The catheter 20 includes a proximal segment 22, a transition segment 24, and a distal segment 26 that terminates in distal end 30. The proximal segment 22 and transition segment 24 are joined at point 32, and the transition segment 24 and distal segment 26 are joined at point 34. FIGS. 6 and 7 include exemplary dimensions for the transition segment 24 and the distal segment 26. For example, the direct distance from the point 32 to the distal end 30 can be about 6 inches.

FIGS. 8A-8D are radiographic images showing four stages in an exemplary procedure wherein the pericardial space is accessed via the RAA. In FIG. 8A, an exemplary curved catheter

40 is positioned extending through the IVC with its distal end 50 within the RA. In FIG. 8B, the distal end 50 has advanced into the RAA and abuts a cephalad wall or crest 52 of the RAA. In this position, a proximal segment 42 is within the IVC, a transition segment 44 passes through the caval-atrial junction into the RA, a distal segment 46 abuts the anterior and/or superior walls of the RA and RAA as it curves leftward into the RAA with a straight distal portion 48 projecting through the RAA. In FIG. 8C, a puncturing device 54 is deployed from the distal end of the catheter 50 and punctures through the wall 52 of the RAA in generally horizontal plane and passes into the pericardial space. The puncture device 54 can extend coaxially from within the catheter 40, for example. In some examples, the puncture device can comprise a 0.014 inch wire. FIG. 8D shows an exemplary therapeutic device 56 extending from the catheter 40, through the puncture in the RAA, and into the pericardial space. The device 56 can include a microcatheter that extends over the puncture device/guidewire 54. The device 56 can comprise any of a variety of device for performing a procedure within the pericardial space.

FIGS. 9A-9D are radiographic images showing four stages in another exemplary procedure wherein the pericardial space is accessed via the RAA. In FIG. 9A, an exemplary curved catheter 70 is positioned extending through the IVC with its distal end 80 within the RA. In FIG. 9B, the distal end 80 has advanced into the RAA and abuts a cephalad wall or crest of the RAA. In this position, a proximal segment 72 is within the IVC, a transition segment 74 passes through the caval-atrial junction into the RA, a distal segment 76 abuts the anterior and/or superior wall of the RA and RAA as it curves leftward into the RAA with a straight distal portion 78 projecting through the RAA. In FIG. 9C, a puncturing device 84 is deployed from the distal end of the catheter 70 and punctures through the wall of the RAA in generally horizontal plane and passes into the pericardial space. The puncturing device 84 can include a guidewire. FIG. 9D shows an exemplary therapeutic device 86 extending from the catheter 50, through the puncture in the RAA, and into the pericardial space. The device 86 can include a microcatheter that extends over the puncture device/guidewire 84. The device 86 can comprise any of a variety of devices for performing a procedure within the pericardial space.

FIG. 10 illustrates how the disclosed curved catheters can provide a more desirable crossing trajectory when puncturing through the cephalad wall 102 of the RAA 100. With a conventional catheter projecting relatively straight through RA and the RAA, the crossing trajectory is more vertically oriented, as shown by arrow 104. The orientation of the RAA illustrated further in FIGS. 1 and 2, which show the RAA projecting from the RA with a significant vertical tilt. Without the disclosed curved catheter, the crossing trajectory 104 can have an analogous vertical tilt. The

trajectory 104 is undesirable as it is transverse to the plane of the pericardium, such that the RAA puncturing device can easily extend too far and also puncture the pericardium. By contrast, the disclosed curved catheters abut the anterior and/or superior walls of the RA and RAA can such that the distal end gives the puncturing device the trajectory 106 that is more horizontal and parallel with the plane of the pericardium, reducing the risk of puncturing the pericardium. The trajectory 106 also helps to avoid other adjacent bystander structures, such as the right coronary artery, pulmonary artery, and aorta. The trajectory 106 also helps direct a therapeutic device more smoothly into the pericardial space without having to make a sharp turn after crossing the wall of the RAA, as is the case with trajectory 104.

A conventional trajectory 104 can be about 36° to about 72° from horizontal, while the disclosed trajectory 106 can be less that 36° from horizontal, less that 30° from horizontal, and/or less than 25° from horizontal. As used here, "horizontal" means in a transverse plane defined by the front, rear, left, and right directions of a patient.

Any of the catheter embodiments disclosed herein can further include, can be used with, or can coaxially deliver, an inflatable balloon catheter that can be inflated at or near the distal end of the catheter to separate and/or flatten the trabeculated walls of the RAA (see FIGS 1 and 2) to allow distal apposition of the puncturing device against the crest and cephalad wall of the RAA. This can help avoid obstruction by the trabeculations inside the RAA while advancing the catheter along the crest of the RAA to the cephalad wall. Such a balloon catheter can be inflated and deflated any number of times while the curved catheter is advanced through the RAA.

In any of the disclosed embodiments, the curved catheter can be constructed to provide sufficient column strength so that the catheter can provide counter-resistance against the puncturing force applied to the puncturing device while puncturing the RAA wall.

For any of the catheters, systems, and methods disclosed herein, analogous embodiments can be configured for use in a delivery from the superior vena cava (SVC). In such devices the catheter can curve slightly rightward, forward, and downward at the juncture of the SVC and the RA so that it abuts the right lateral wall of the RA, then curve back upward, forward and leftward toward and against the anterior and superior walls of the RA/RAA, then curve slightly rearward, leftward and upward through the RAA.

For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatuses, and systems should not be construed as limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone

and in various combinations and sub-combinations with one another. The methods, apparatuses, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

Features, integers, groups, dimensions, materials, compounds, or other characteristics described in conjunction with a particular aspect, embodiment or example of the disclosed invention are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The invention is not restricted to the details of any foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

Although the operations of some of the disclosed methods are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. As used herein, the terms “a”, “an”, and “at least one” encompass one or more of the specified element. That is, if two of a particular element are present, one of these elements is also present and thus “an” element is present. The terms “a plurality of” and “plural” mean two or more of the specified element.

As used herein, the term “and/or” used between the last two of a list of elements means any one or more of the listed elements. For example, the phrase “A, B, and/or C” means “A”, “B,”, “C”, “A and B”, “A and C”, “B and C”, or “A, B, and C.”

As used herein, the term “coupled” generally means physically, magnetically, chemically, electrically, or otherwise coupled or linked and does not exclude the presence of intermediate elements between the coupled elements absent specific contrary language.

In view of the many possible embodiments to which the principles disclosed herein may be applied, it should be recognized that illustrated embodiments are only examples and should not be

considered a limitation on the scope of the disclosure. Rather, the scope of this disclosure is at least as broad as the following claims and their equivalents.

CLAIMS:

1. A transvascular catheter for accessing a pericardial space from within a right atrial appendage (RAA) of a heart, the catheter comprising:

a proximal segment, a transition segment extending distally from the proximal segment, a distal segment extending distally from the transition segment, and a distal end, wherein the transition segment and the distal segment are adapted to extend from the proximal segment with a clockwise spiral curvature when the catheter is positioned within a patient such that:

the proximal segment is positioned within the inferior vena cava;

the transition segment extends across the caval-atrial junction and curves rightward, forward, and upward such that the catheter abuts a right lateral wall of the right atrium; and

the distal segment curves leftward, forward, and upward from the transition segment through the right atrium such that the catheter abuts an anterior wall of the right atrium adjacent to the RAA, and the distal segment continues to curve leftward, rearward, and upward from the anterior wall of the right atrium along an anterior-superior wall of the RAA such that distal end of the catheter contacts a cephalad wall of the RAA;

wherein the catheter is configured to guide a coaxial puncturing device to extend from the distal end of the catheter and puncture through the cephalad wall of the RAA into the pericardial space; and

wherein the curvature of the catheter orients the distal end of the catheter pointing generally leftward and parallel with the pericardium such that the puncturing device passes through the cephalad wall of the RAA and into the pericardial space without damaging the pericardium and at a location spaced apart from the right coronary artery, the pulmonary artery, and the aorta.

2. The catheter of claim 1, wherein the curvature of the catheter orients the distal end of the catheter with a trajectory that is less than 36° from horizontal.

3. The catheter of claim 1, wherein the curvature of the catheter orients the distal end of the catheter with a trajectory that is less than 25° from horizontal.

4. The catheter of any one of claims 1-3, wherein the spiral curvature of the catheter is adapted to have a minimum radius of curvature of less than 3 inches and an arc length of at least about 120° about the vertical z-axis when the catheter is positioned within a patient.

5. The catheter of any one of claims 1-4, further comprising an inflatable balloon catheter that is configured to be inflated within the RAA to separate or flatten trabeculations within the RAA to facilitate advancing the distal end of the catheter against the cephalad wall of the RAA.

6. The catheter of any one of claims 1-5, wherein the catheter is configured to deliver a therapeutic device through the puncture in the cephalad wall of the RAA and into the pericardial space without damaging the pericardium and at a location spaced apart from the right coronary artery, the pulmonary artery, and the aorta.

7. The catheter of any one of claims 1-6, wherein the distal segment includes a straight portion at the distal end of the catheter.

8. A method of accessing a pericardial space from within a right atrial appendage (RAA) of a heart of a patient, the method comprising:

positioning a catheter within a patient, the catheter comprising a proximal segment, a transition segment extending distally from the proximal segment, a distal segment extending distally from the transition segment, and a distal end, wherein the transition segment and the distal segment extend from the proximal segment with a clockwise spiral curvature such that:

the proximal segment is positioned within the inferior vena cava;

the transition segment extends across the caval-atrial junction and curves rightward, forward, and upward such that the catheter abuts a right lateral wall of the right atrium; and

the distal segment curves leftward, forward, and upward from the transition segment through the right atrium such that the catheter abuts an anterior wall of the right atrium adjacent to the RAA, and the distal segment continues to curve leftward, rearward, and upward from the anterior wall of the right atrium along an anterior-superior wall of the RAA such that distal end of the catheter contacts a cephalad wall of the RAA; and

delivering a coaxial puncturing device through the catheter and out of the distal end of the catheter so that the puncturing device punctures through a cephalad wall of the RAA into the pericardial space;

wherein the curvature of the catheter orients the distal end of the catheter pointing generally leftward and parallel with the pericardium such that the puncturing device passes through the

cephalad wall of the RAA and into the pericardial space without damaging the pericardium and at a location spaced apart from the right coronary artery, the pulmonary artery, and the aorta.

9. The method of claim 8, further comprising:

delivering a balloon catheter through the catheter;

inflating the balloon catheter within the RAA to separate or flatten trabeculations within the RAA; and

advancing the distal end of the catheter past the separated or flattened trabeculations to the cephalad wall of the RAA.

10. The method of claim 8 or claim 9, further comprising delivering a therapeutic device through the catheter and over the puncturing device into the pericardial space at a location spaced apart from the right coronary artery, the pulmonary artery, and the aorta.

11. The method of any one of claims 8-10, wherein the distal end of the catheter is oriented such that the puncturing device has a trajectory that is less than 36° from horizontal.

12. The method of any one of claims 8-10, wherein the distal end of the catheter is oriented such that the puncturing device has a trajectory that is less than 25° from horizontal.

13. The method of any one of claims 8-12, wherein the spiral curvature of the catheter has a minimum radius of curvature of less than 3 inches and an arc length of at least about 120° about the vertical z-axis when the catheter is positioned within the patient.

14. The method of any one of claims 8-13, wherein the distal segment includes a straight portion at the distal end of the catheter that is positioned within the RAA.

15. The method of any one of claims 8-14, further comprising insufflating the pericardial space with a gas prior to puncturing the RAA.

16. The method of any one of claims 8-15, wherein the therapeutic device comprises a left atrial appendage ligation device or a circumferential tricuspid annuloplasty device.

17. A catheter of any one of claims 1-7 for use in a method of accessing a pericardial space from within a right atrial appendage (RAA) of a heart of a patient, the method comprising:

positioning the catheter within a patient, the catheter comprising a proximal segment, a transition segment extending distally from the proximal segment, a distal segment extending distally from the transition segment, and a distal end, wherein the transition segment and the distal segment extend from the proximal segment with a clockwise spiral curvature such that:

the proximal segment is positioned within the inferior vena cava;

the transition segment extends across the caval-atrial junction and curves rightward, forward, and upward such that the catheter abuts a right lateral wall of the right atrium; and

the distal segment curves leftward, forward, and upward from the transition segment through the right atrium such that the catheter abuts an anterior wall of the right atrium adjacent to the RAA, and the distal segment continues to curve leftward, rearward, and upward from the anterior wall of the right atrium along an anterior-superior wall of the RAA such that distal end of the catheter contacts a cephalad wall of the RAA; and

delivering a coaxial puncturing device through the catheter and out of the distal end of the catheter so that the puncturing device punctures through a cephalad wall of the RAA into the pericardial space;

wherein the curvature of the catheter orients the distal end of the catheter pointing generally leftward and parallel with the pericardium such that the puncturing device passes through the cephalad wall of the RAA and into the pericardial space without damaging the pericardium and at a location spaced apart from the right coronary artery, the pulmonary artery, and the aorta.

18. The catheter of claim 17, further comprising:

delivering a balloon catheter through the catheter;

inflating the balloon catheter within the RAA to separate or flatten trabeculations within the RAA; and

advancing the distal end of the catheter past the separated or flattened trabeculations to the cephalad wall of the RAA.

19. The catheter of claim 17 or claim 18, wherein the method further comprises delivering a therapeutic device through the catheter and over the puncturing device into the pericardial space at a location spaced apart from the right coronary artery, the pulmonary artery, and the aorta.

20. The catheter of any one of claims 17-19, wherein the distal end of the catheter is oriented such that the puncturing device has a trajectory that is less than 36° from horizontal.

21. The catheter of any one of claims 17-19, wherein the distal end of the catheter is oriented such that the puncturing device has a trajectory that is less than 25° from horizontal.

22. The catheter of any one of claims 17-21, wherein the spiral curvature of the catheter has a minimum radius of curvature of less than 3 inches and an arc length of at least about 120° about the vertical z-axis when the catheter is positioned within the patient.

23. The catheter of any one of claims 17-22, wherein the distal segment includes a straight portion at the distal end of the catheter that is positioned within the RAA.

24. The catheter of any one of claims 17-23, the method further comprising insufflating the pericardial space with a gas prior to puncturing the RAA.

25. The catheter of any one of claims 17-24, wherein the therapeutic device comprises a left atrial appendage ligation device or a circumferential tricuspid annuloplasty device.

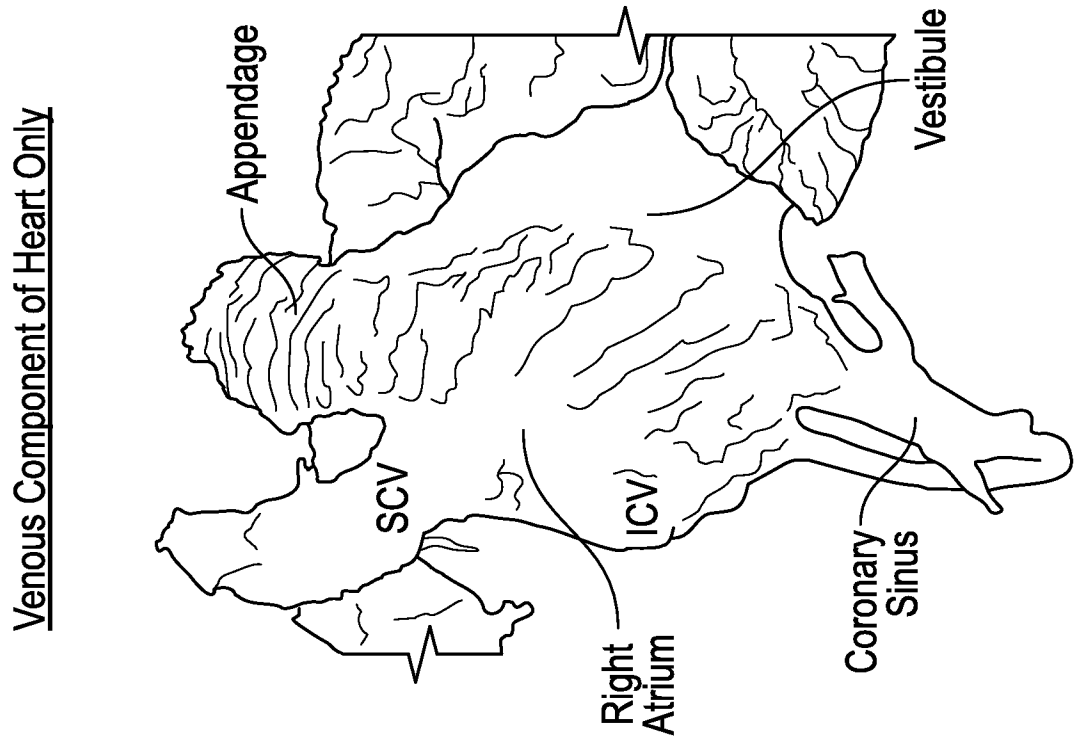
Venous Component of Heart Only
Appendage
Vestibule
SCV
ICV
Right Atrium
Coronary Sinus

FIG. 2

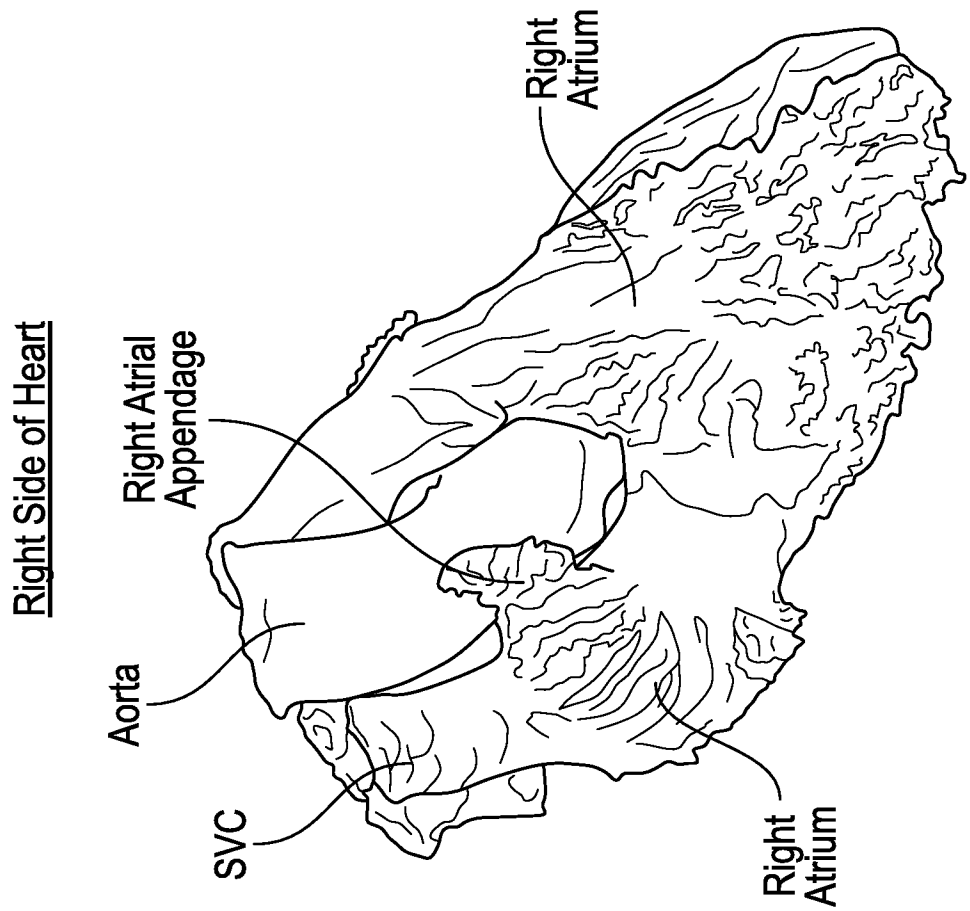
Right Side of Heart
Right Atrial Appendage
Right Atrium
Aorta
SVC
Right Atrium

FIG. 1

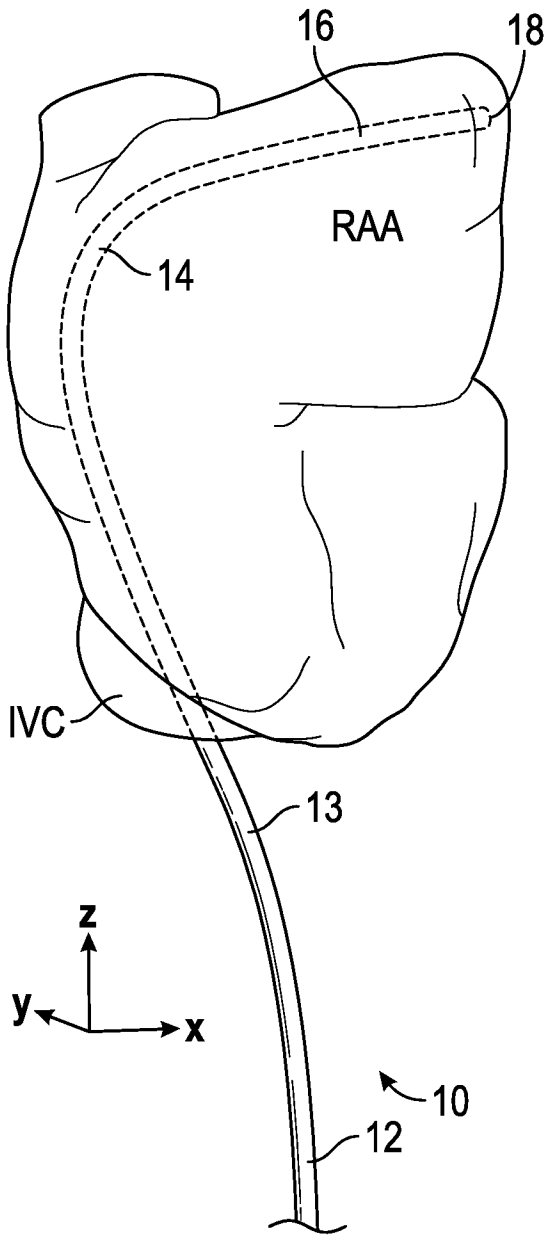


FIG. 3

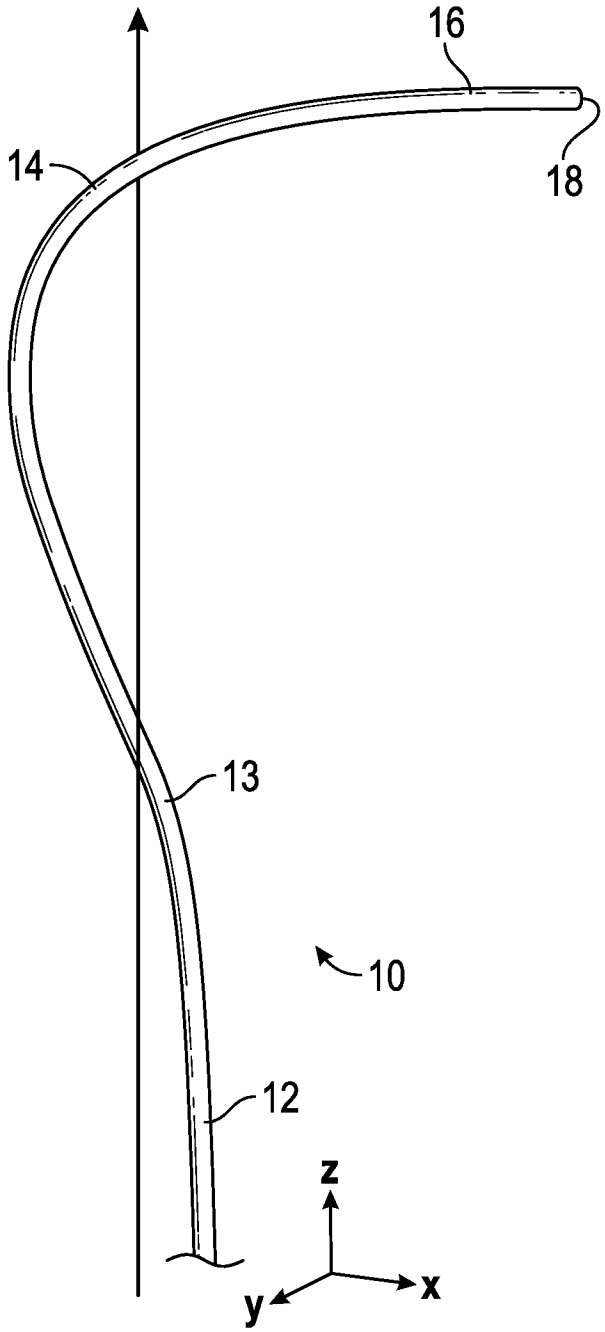


FIG. 4

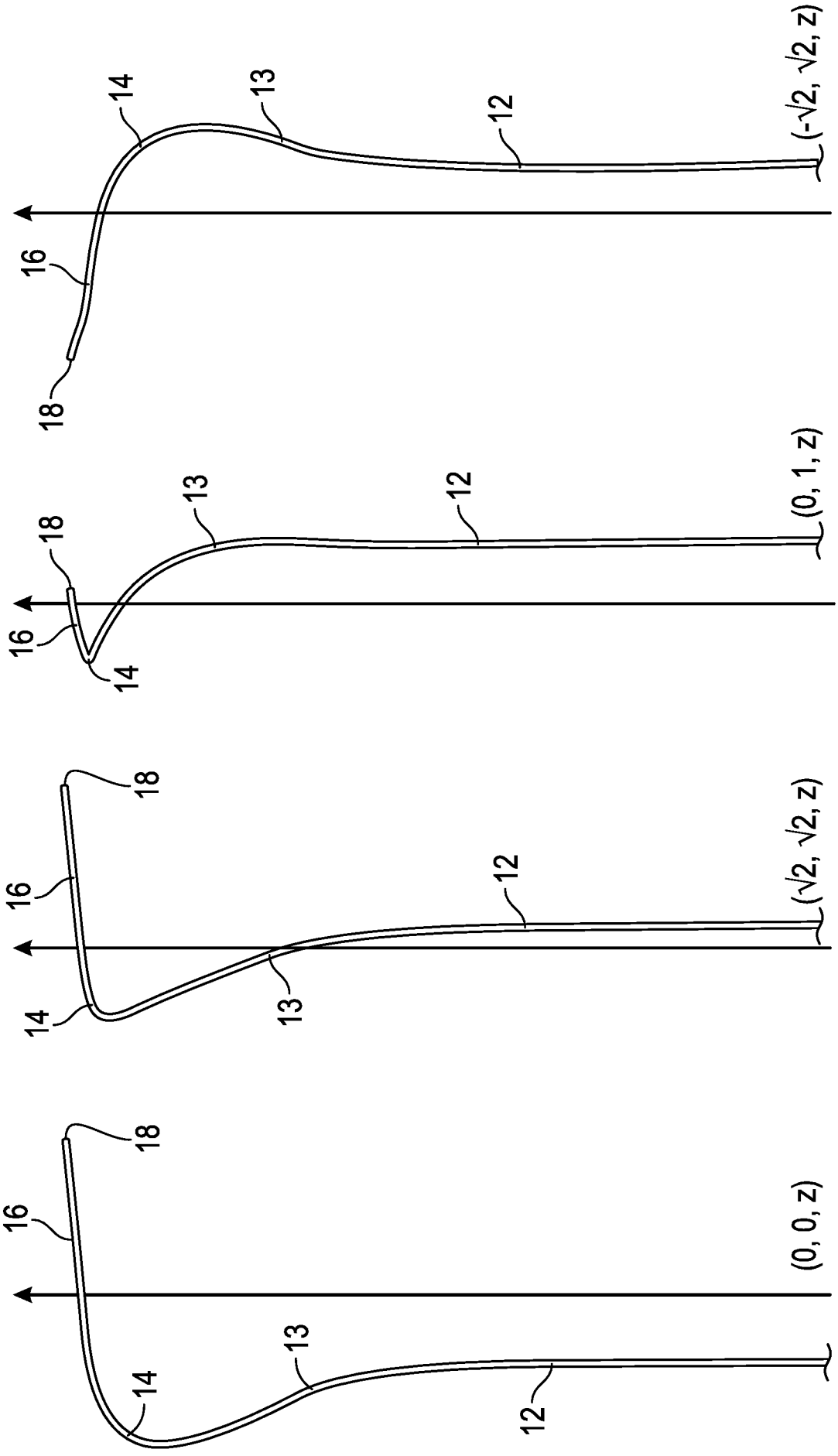


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

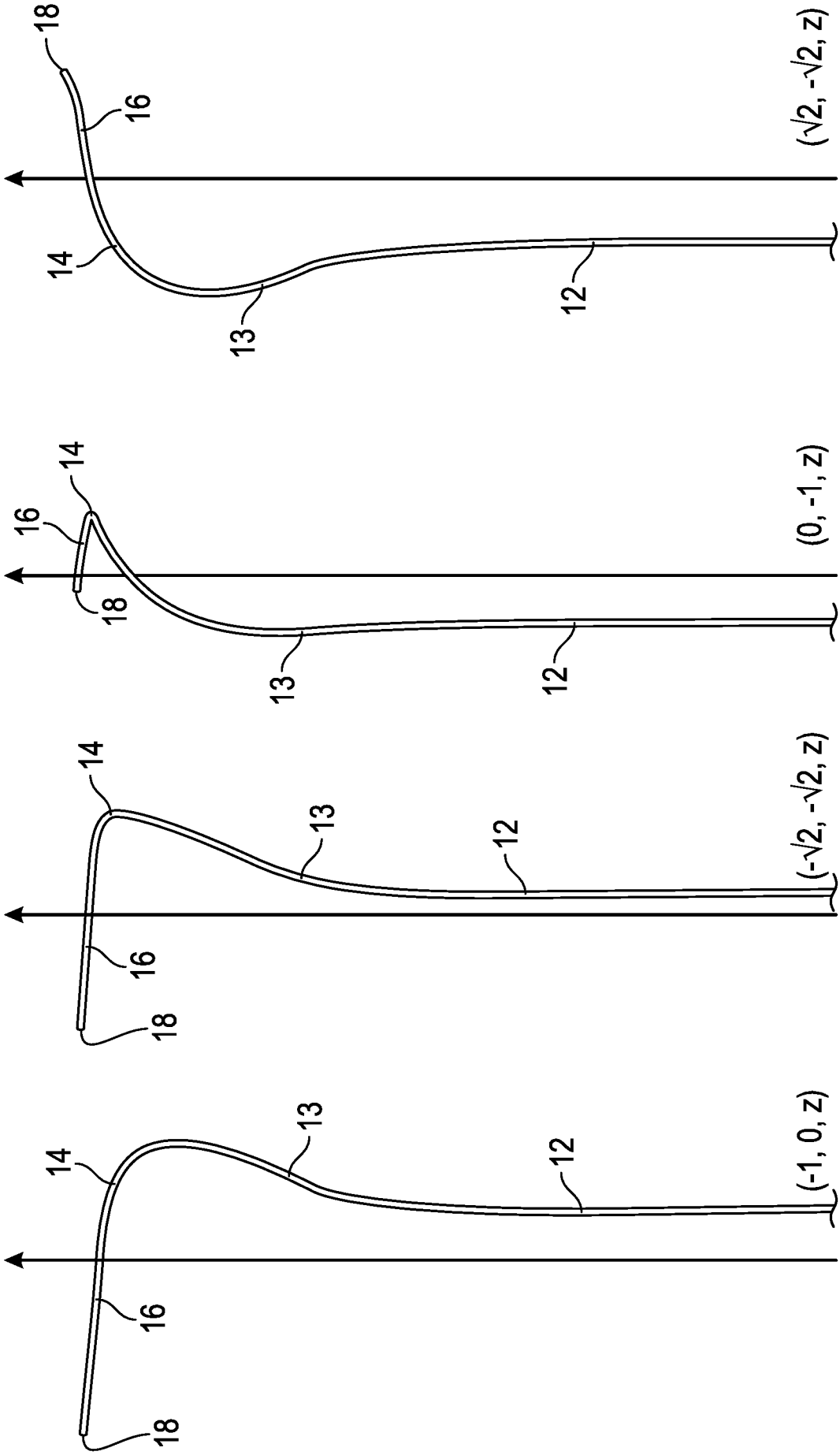


FIG. 5H

FIG. 5G

FIG. 5F

FIG. 5E

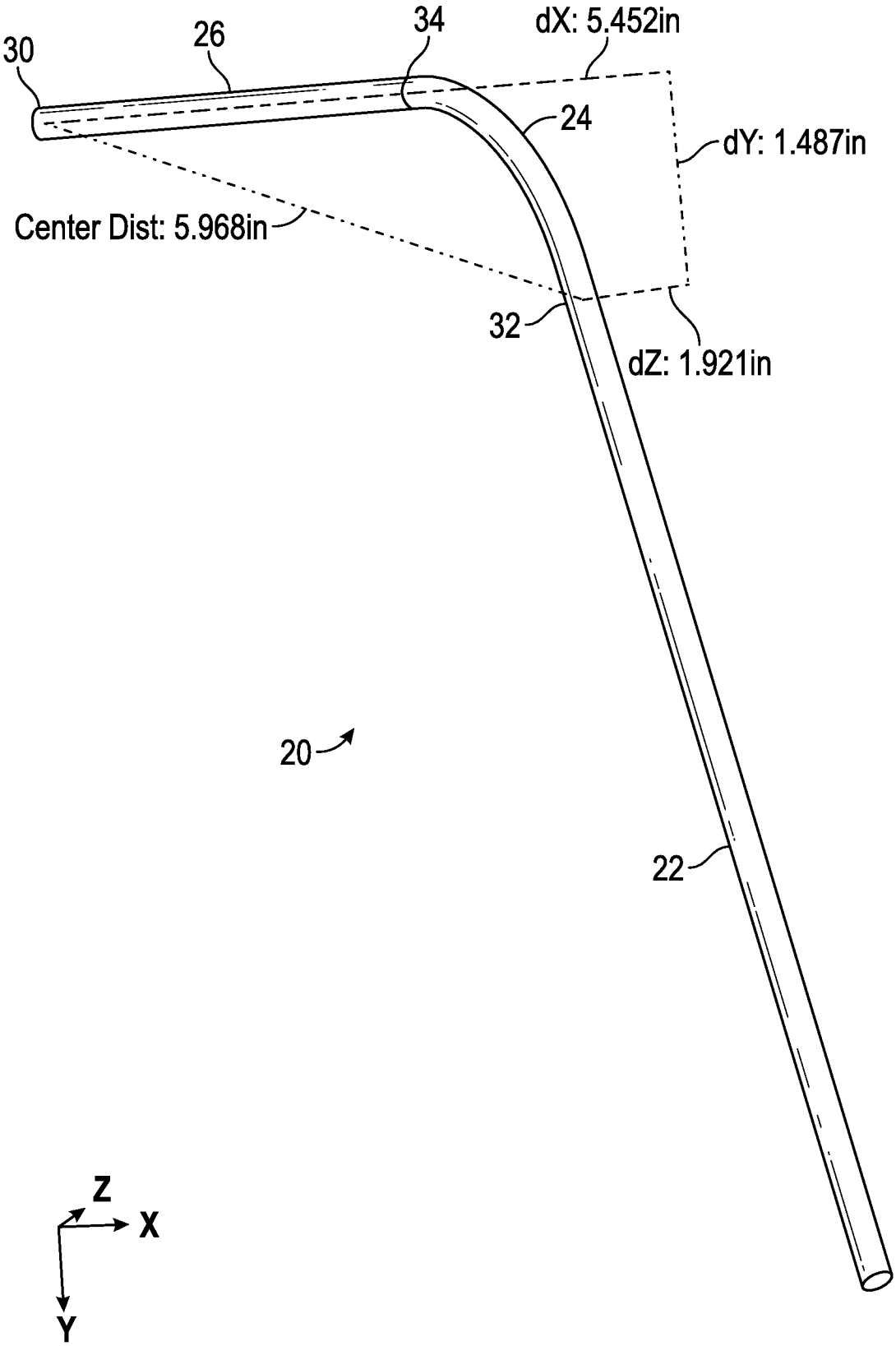
30
26
34
dX: 5.452in
24
dY: 1.487in
Center Dist: 5.968in
32
dZ: 1.921in
20
22
Z
X
Y

FIG. 6

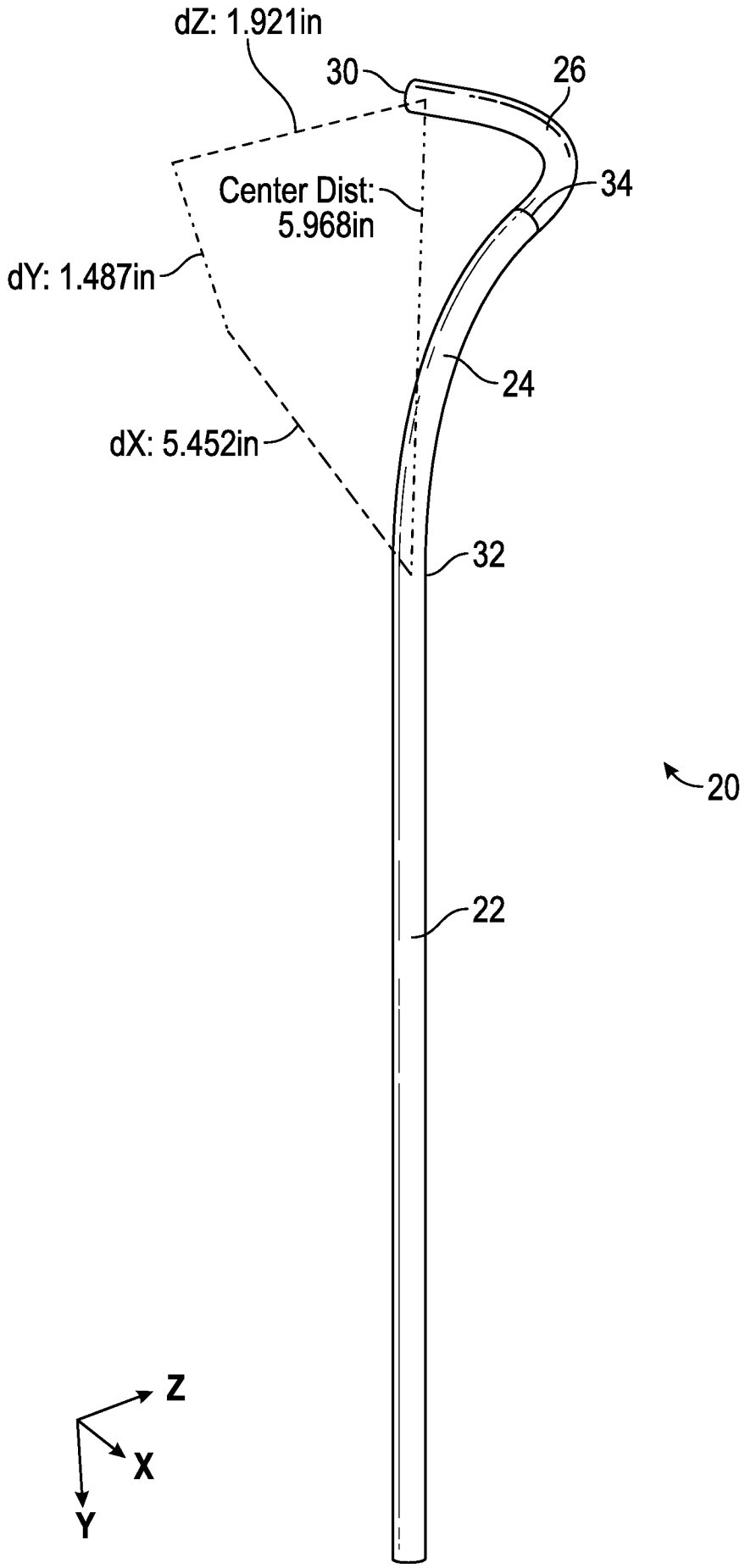
dZ: 1.921in
30
26
Center Dist:
5.968in
34
dY: 1.487in
24
dX: 5.452in
32
20
22
Z
X
Y

FIG. 7

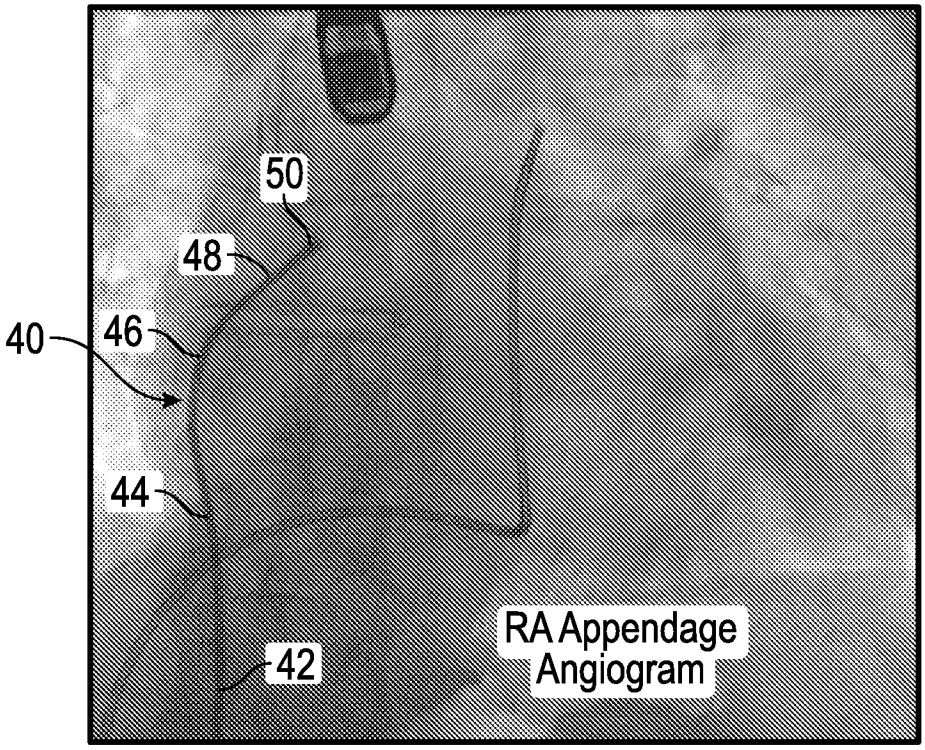
50
48
46
40
44
42
RA Appendage
Angiogram

FIG. 8A

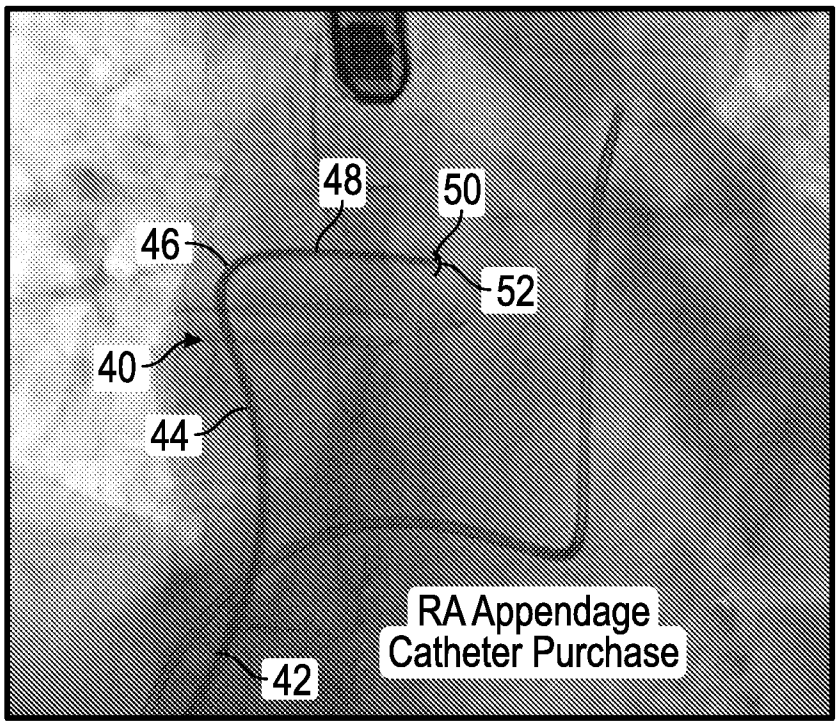
48
50
46
52
40
44
42
RA Appendage
Catheter Purchase

FIG. 8B

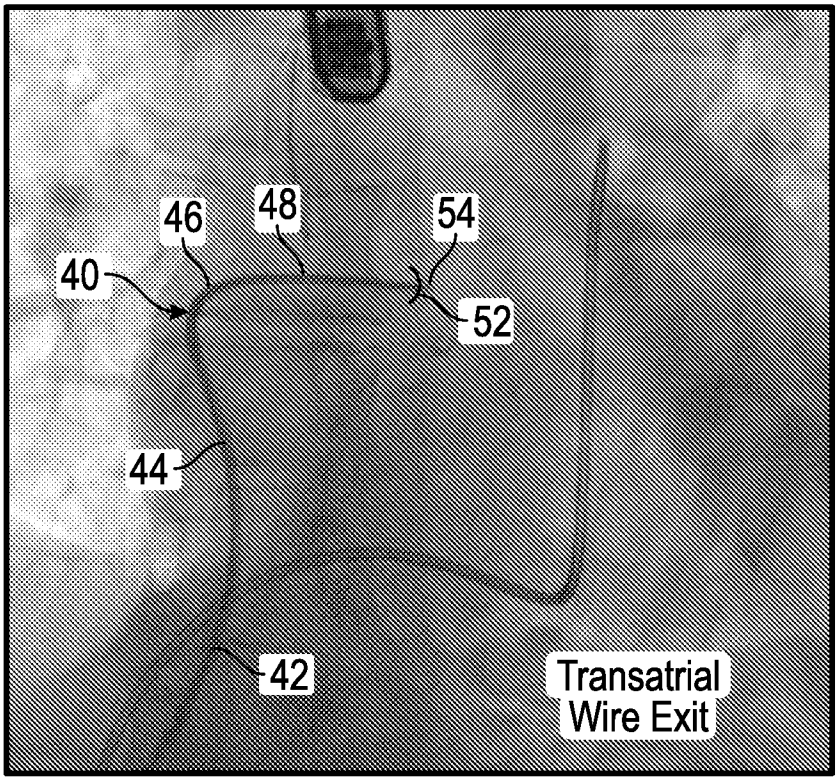
46
48
54
40
52
44
42
Transatrial
Wire Exit

FIG. 8C

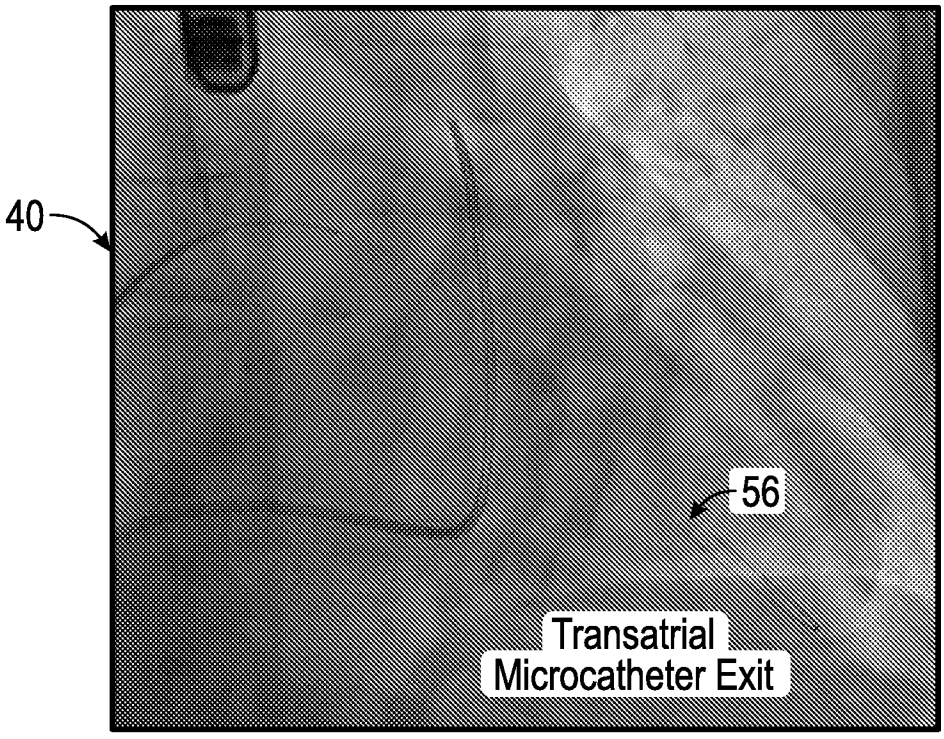
40
56
Transatrial
Microcatheter Exit

FIG. 8D

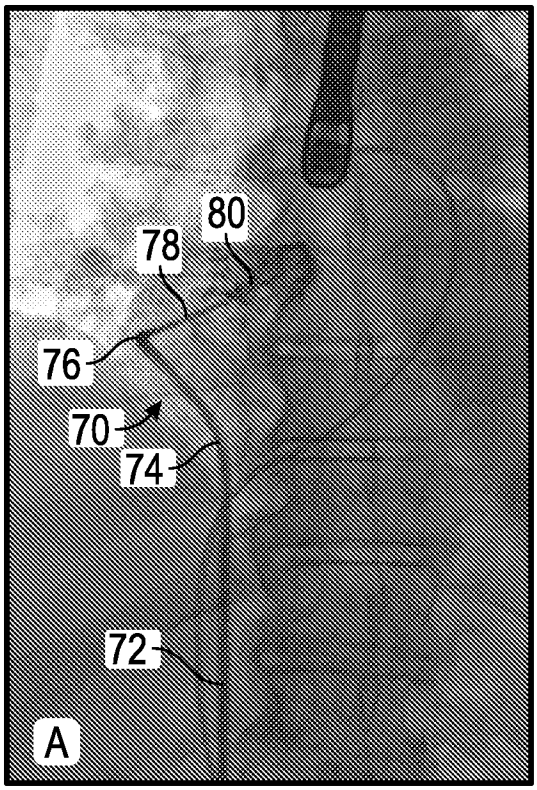


FIG. 9A

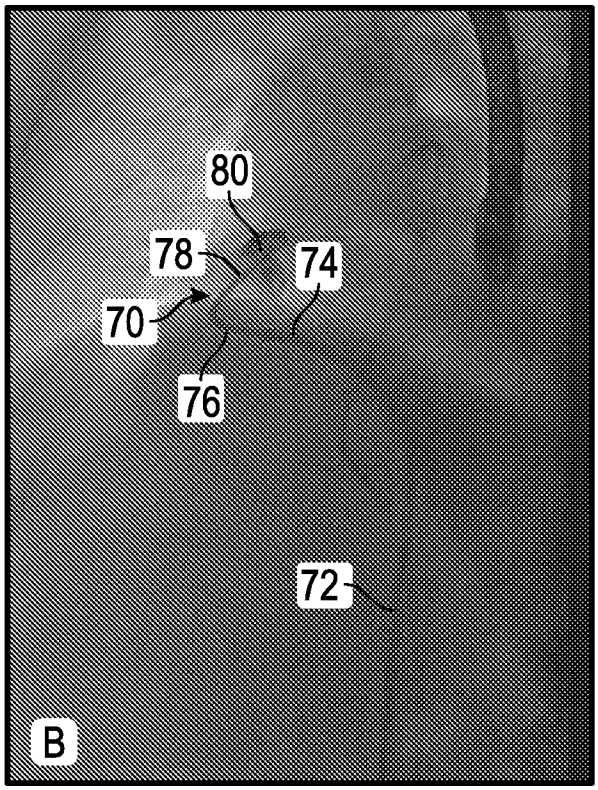


FIG. 9B

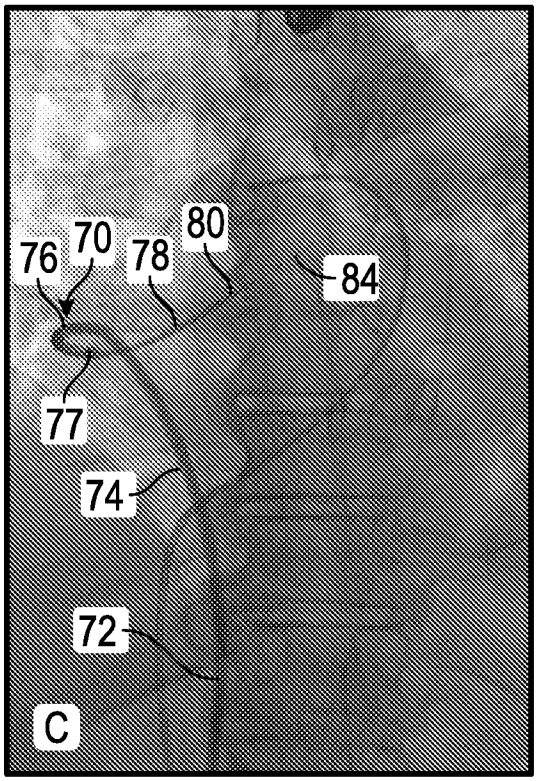


FIG. 9C

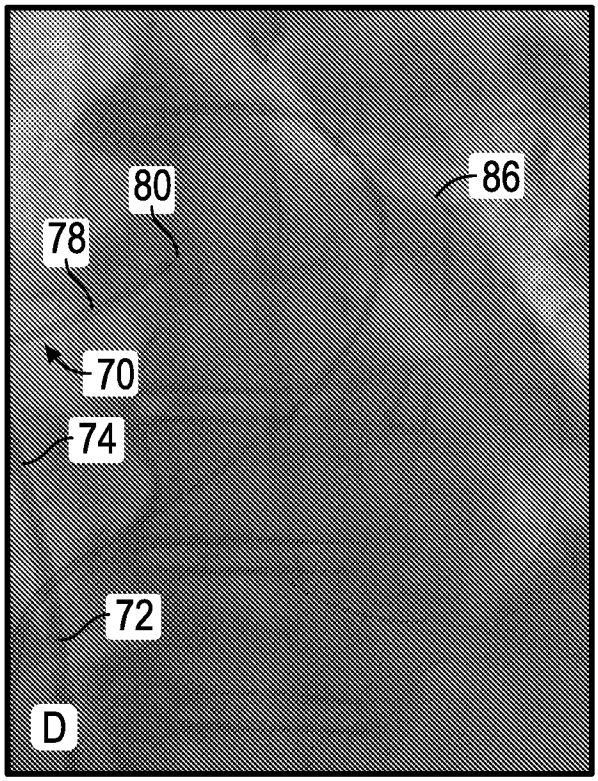


FIG. 9D

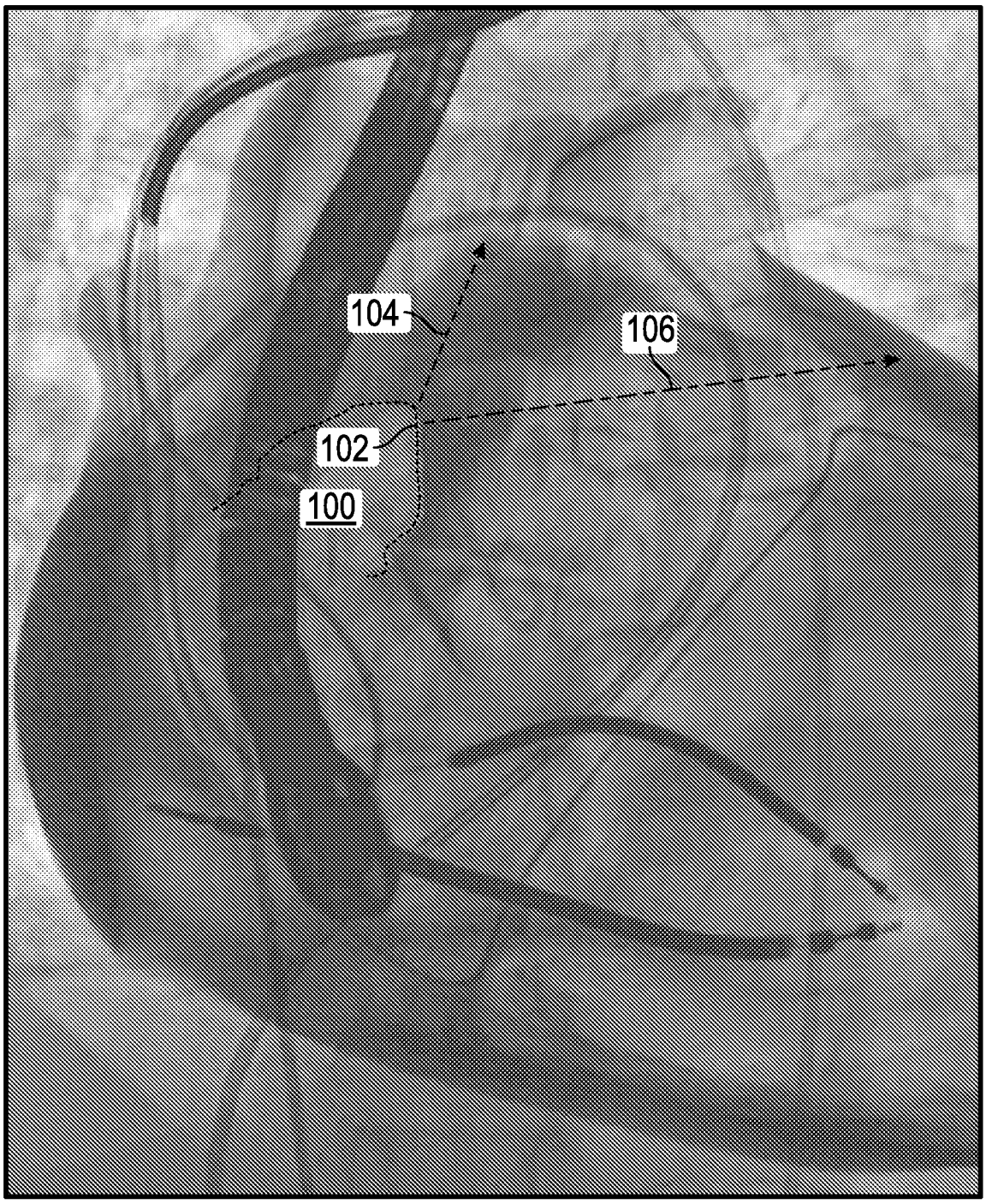


FIG. 10

**INTERNATIONAL SEARCH REPORT**

International application No.
**PCT/US2016/031461**

**A. CLASSIFICATION OF SUBJECT MATTER**

**A61M 25/00(2006.01)I, A61B 17/00(2006.01)I, A61B 18/00(2006.01)I**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
A61M 25/00; A61M 29/00; A61M 31/00; A61N 1/02; A61B 18/18; A61B 5/00; A61B 17/00; A61B 18/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: catheter, pericardial, right atrial appendage, RAA, curvature, inferior vena cava, right atrium

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 2005-0234436 A1 (BAXTER, LINCOLN S. et al.) 20 October 2005<br>See abstract; paragraphs [0017], [0030], [0091], [0103], [0108]; claim 1; and figures 1-2. | 1-4 |
| Y | US 5269326 A (VERRIER, RICHARD L.) 14 December 1993<br>See abstract; column 4, lines 3-35; claims 1, 5; and figures 3, 5. | 1-4 |
| A | US 7226440 B2 (GELFAND, MARK et al.) 5 June 2007<br>See the whole document. | 1-4 |
| A | MICKELSEN, STEVEN R. et al., Transvenous Access to the Pericardial Space: An Approach to Epicardial Lead Implantation for Cardiac Resynchronization Therapy. Pacing and Clinical Electrophysiology. October 2005, Volume 28, Issue 10, pages 1018-1024.<br>See the whole document. | 1-4 |
| A | WO 2008-112870 A2<br>(UNIVERSITY OF VIRGINIA PATENT FOUNDATION et al.) 18 September 2008<br>See the whole document. | 1-4 |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 August 2016 (10.08.2016) | **16 August 2016 (16.08.2016)** |


Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea
Facsimile No. +82-42-481-8578

Authorized officer
Han, Inho
Telephone No. +82-42-481-3362

# INTERNATIONAL SEARCH REPORT

International application No.
**PCT/US2016/031461**

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 8-16
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 8-16 pertain to methods for treatment of the human body and thus relate to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.

2. ☒ Claims Nos.: 18
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claim 18 directly or indirectly refers to one of the unsearchable claims which do not comply with PCT Rule 6.4(a).

3. ☒ Claims Nos.: 5-7,11-17, 19-25
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2016/031461**

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 2005-0234436 A1 | 20/10/2005 | EP 0781154 A2 | 30/03/2005 |
| | | EP 1200002 A2 | 02/05/2002 |
| | | EP 1200002 B1 | 12/04/2006 |
| | | EP 1301139 A1 | 16/04/2003 |
| | | EP 1527798 A2 | 04/05/2005 |
| | | EP 1527798 A3 | 04/04/2007 |
| | | EP 1592358 A2 | 09/11/2005 |
| | | EP 1679045 A2 | 12/07/2006 |
| | | EP 1679045 A3 | 30/09/2009 |
| | | EP 1679045 B1 | 27/03/2013 |
| | | EP 1866019 A1 | 19/12/2007 |
| | | JP 10-504989 A | 19/05/1998 |
| | | JP 2003-518395 A | 10/06/2003 |
| | | JP 2004-503326 A | 05/02/2004 |
| | | JP 2006-516465 A | 06/07/2006 |
| | | JP 2008-531086 A | 14/08/2008 |
| | | JP 3675482 B2 | 27/07/2005 |
| | | JP 4261101 B2 | 30/04/2009 |
| | | JP 4732330 B2 | 27/07/2011 |
| | | JP 5065052 B2 | 31/10/2012 |
| | | KR 10-1997-0706039 A | 03/11/1997 |
| | | US 2002-0068924 A1 | 06/06/2002 |
| | | US 2002-0077623 A1 | 20/06/2002 |
| | | US 2002-0183729 A1 | 05/12/2002 |
| | | US 2004-0006333 A1 | 08/01/2004 |
| | | US 2004-0059397 A1 | 25/03/2004 |
| | | US 2004-0147911 A1 | 29/07/2004 |
| | | US 2004-0147912 A1 | 29/07/2004 |
| | | US 2004-0147913 A1 | 29/07/2004 |
| | | US 2004-0167503 A1 | 26/08/2004 |
| | | US 2005-0065504 A1 | 24/03/2005 |
| | | US 2005-0171520 A1 | 04/08/2005 |
| | | US 2005-0222557 A1 | 06/10/2005 |
| | | US 2005-0222558 A1 | 06/10/2005 |
| | | US 2005-0234437 A1 | 20/10/2005 |
| | | US 2005-0267452 A1 | 01/12/2005 |
| | | US 2006-0253113 A1 | 09/11/2006 |
| | | US 2008-0195088 A1 | 14/08/2008 |
| | | US 2009-0221997 A1 | 03/09/2009 |
| | | US 2009-0275934 A1 | 05/11/2009 |
| | | US 2009-0299354 A1 | 03/12/2009 |
| | | US 2009-0326320 A1 | 31/12/2009 |
| | | US 5632767 A | 27/05/1997 |
| | | US 5637877 A | 10/06/1997 |
| | | US 5643253 A | 01/07/1997 |
| | | US 5908415 A | 01/06/1999 |
| | | US 5947959 A | 07/09/1999 |
| | | US 6102905 A | 15/08/2000 |
| | | US 6168591 B1 | 02/01/2001 |

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.
**PCT/US2016/031461**

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| | | US 6270492 B1 | 07/08/2001 |
| | | US 6423055 B1 | 23/07/2002 |
| | | US 6558375 B1 | 06/05/2003 |
| | | US 6572609 B1 | 03/06/2003 |
| | | US 6579285 B2 | 17/06/2003 |
| | | US 6626900 B1 | 30/09/2003 |
| | | US 6676656 B2 | 13/01/2004 |
| | | US 6942657 B2 | 13/09/2005 |
| | | US 6953457 B2 | 11/10/2005 |
| | | US 7207984 B2 | 24/04/2007 |
| | | US 7357796 B2 | 15/04/2008 |
| | | US 7935108 B2 | 03/05/2011 |
| | | US 8025661 B2 | 27/09/2011 |
| | | US 8152795 B2 | 10/04/2012 |
| | | US 8241272 B2 | 14/08/2012 |
| | | US 8366705 B2 | 05/02/2013 |
| | | US 8540704 B2 | 24/09/2013 |
| | | US 8900219 B2 | 02/12/2014 |
| | | US 9033961 B2 | 19/05/2015 |
| | | WO 01-03599 A2 | 18/01/2001 |
| | | WO 01-03599 A3 | 17/05/2001 |
| | | WO 01-13812 A1 | 01/03/2001 |
| | | WO 02-05722 A1 | 24/01/2002 |
| | | WO 2004-069072 A2 | 19/08/2004 |
| | | WO 2004-069072 A3 | 07/10/2004 |
| | | WO 2004-110258 A2 | 23/12/2004 |
| | | WO 2004-110258 A3 | 25/08/2005 |
| | | WO 2006-091597 A1 | 31/08/2006 |
| | | WO 2010-120881 A2 | 21/10/2010 |
| | | WO 2010-120881 A3 | 10/02/2011 |
| | | WO 2010-120883 A2 | 21/10/2010 |
| | | WO 2010-120883 A3 | 24/03/2011 |
| US 5269326 A | 14/12/1993 | EP 0746376 A1 | 29/03/2000 |
| | | EP 0882452 A1 | 09/12/1998 |
| | | WO 93-07931 A1 | 29/04/1993 |
| US 7226440 B2 | 05/06/2007 | US 2006-0173441 A1 | 03/08/2006 |
| | | US 2007-0219525 A1 | 20/09/2007 |
| WO 2008-112870 A2 | 18/09/2008 | US 2010-0114093 A1 | 06/05/2010 |
| | | WO 2008-112870 A3 | 13/11/2008 |