



(51) International Patent Classification:

A61B 17/32 (2006.01) A61B 18/00 (2006.01)  
A61B 17/00 (2006.01) A61F 2/24 (2006.01)

(21) International Application Number:

PCT/IL2021/050844

(22) International Filing Date:

11 July 2021 (11.07.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/051,479 14 July 2020 (14.07.2020) US

(71) Applicant: **RAMBAM MEDTECH LTD.** [IL/IL]; 8 Second Aliyah Street, P.O. Box 9664, 3109601 Haifa (IL).

(72) Inventors: **FELD, Yair**; 57C Disraeli Street, 3433335 Haifa (IL). **KERNER, Arthur**; 21 Albert Schweitzer Street, Haifa (IL). **TREYSTMAN, Alexander**; 6 HaTikshoret Street, 2307045 Migdal HaEmek (IL). **ALMUZNINO, Gdaliahu**; 52 HaKitzanit Street, 2350751

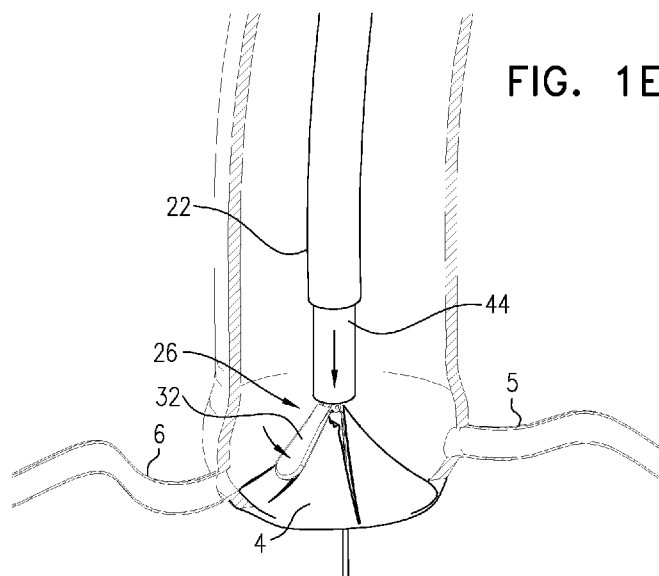
Migdal HaEmek (IL). **TSEFADIA, Issac**; Ein-Harod Ihud, 189600 Gilboa (IL).

(74) Agent: **COLB, Sanford T.** et al.; SANFORD T. COLB & CO., 4 Shaar Hagai Street, P.O. Box 1653, 7611502 Rehovot (IL).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) Title: DEVICES FOR VALVE SPLITTING



(57) Abstract: A valve-splitting device (20, 120) for splitting a native or prosthetic valve cusp (4) is provided. The valve-splitting device (20, 120) includes a cover sheath (22) and a splitter (26, 126), which is removably disposed inside the cover sheath (22). The splitter (26, 126) includes a first over-the-wire cutter (30), which is shaped so as to define a guidewire lumen (40) that is configured to accept and slide over a guidewire (3); and a second opposing cutter (32, 132). The splitter (26, 126) is configured, upon distal advancement of the splitter (26, 126) out of a distal end of the cover sheath (22), to be opened such that the first over-the-wire cutter (30) and the second opposing cutter (32, 132) are separated from each other and are disposable on opposite sides of the cusp (4), such that closing the splitter (26, 126) by bringing the first over-the-wire cutter (30) and the second opposing cutter (32, 132) together cuts the cusp (4). Other embodiments are also described.



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).

**Published:**

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

## DEVICES FOR VALVE SPLITTING

### **CROSS-REFERENCE TO RELATED APPLICATIONS**

The present patent application claims priority from US Provisional Application 63/051,479, filed July 14, 2020, which is assigned to the assignee of the present application  
5 and incorporated herein by reference.

### **BACKGROUND OF THE APPLICATION**

Transcatheter Aortic Valve Implantation (TAVI) has become common practice for aortic valve replacement for severe aortic stenosis (AS) and valve-in-valve procedures for biological prosthetic valve degeneration (see, for example, "Five-Year Outcomes of  
10 Transcatheter or Surgical Aortic-Valve Replacement," Makkar RR, et al., N Engl J Med. 2020).

A rare catastrophic complication of TAVI is coronary artery obstruction, specifically in the case of prosthetic valves ("Assessing the Risk for Coronary Obstruction After Transcatheter Aortic Valve Implantation and the Need to Perform BASILICA: The  
15 VIVID Classification," Gilbert H L Tang, Ikki Komatsu, Liron Tzemach, Matheus Simonato, Arik Wolak, Philipp Blanke, Danny Dvir EuroIntervention. 2020 May 4) and TAVI-in-TAVI ("Feasibility of Repeat TAVR After SAPIEN 3 TAVR A Novel Classification Scheme and Pilot Angiographic Study," Gilbert H.L. Tang, Syed Zaid, Eisha Gupta, Hasan Ahmad, Asaad Khan, Jason C. Kovacic, Steven L. Lansman, George D.  
20 Dangas, Samin K. Sharma and Annapoorna Kini. JACC: Cardiovascular Interventions Volume 12, Issue 13, July 2019).

### **SUMMARY OF THE APPLICATION**

Some embodiments of the present invention provide a dedicated device for intentional splitting of a native or prosthetic valve cusp before performing TAVI, in order  
25 to prevent coronary artery obstruction.

There is therefore provided, in accordance with an application of the present invention, a valve-splitting device for splitting a native or prosthetic valve cusp, the valve-splitting device for use with a guidewire, the valve-splitting device including:

a cover sheath; and

a splitter, which is removably disposed inside the cover sheath, and which includes:  
a first over-the-wire cutter, which is shaped so as to define a guidewire lumen that is configured to accept and slide over the guidewire; and  
a second opposing cutter,

5 wherein the splitter is configured, upon distal advancement of the splitter out of a distal end of the cover sheath, to be opened such that the first over-the-wire cutter and the second opposing cutter are separated from each other and are disposable on opposite sides of the cusp, such that closing the splitter by bringing the first over-the-wire cutter and the second opposing cutter together cuts the cusp.

10 For some applications, at least one of the first over-the-wire cutter and the second opposing cutter includes one or more cutting protrusions, which are configured to cut the cusp by lacerating the cusp.

For some applications, the second opposing cutter includes the one or more cutting protrusions.

15 For some applications, at least one of first over-the-wire cutter and the second opposing cutter includes an elongate cutting blade, which is configured to cut the cusp by excising a piece of material of the cusp.

For some applications, the second opposing cutter includes the elongate cutting blade.

20 For some applications, the elongate cutting blade is located along at least a portion of an edge of the second opposing cutter.

For some applications, the splitter further includes a cutting sleeve, which is configured to be distally advanced toward and then over the open splitter, thereby closing the splitter by bringing the first over-the-wire cutter and the second opposing cutter  
25 together, and cutting the cusp when the first over-the-wire cutter and the second opposing cutter are disposed on the opposite sides of the cusp.

For some applications, the cutting sleeve is configured to be advanced out of the distal end of the cover sheath in order to reach the splitter.

For some applications, the splitter further includes a spring that is configured to  
30 open the splitter by separating the first over-the-wire cutter and the second opposing cutter from each other.

For some applications, the valve-splitting device is configured to apply energy during cutting.

There is further provided, in accordance with an application of the present invention, a method for splitting a native or prosthetic valve cusp of a patient, the method including:

5 inserting a guidewire into a left ventricle of the patient;

advancing a valve-splitting device over the guidewire to a location above an aortic root, while a splitter of the valve-splitting device is removably disposed inside a cover sheath of the valve-splitting device, while the guidewire slides through a guidewire lumen defined by a first over-the-wire cutter of the splitter, and while the splitter is closed;

10 advancing the splitter out of a distal end of the cover sheath toward the native or prosthetic valve cusp;

while the splitter is open such that the first over-the-wire cutter and a second opposing cutter of the splitter are separated from each other, disposing the first over-the-wire cutter and the second opposing cutter on opposite sides of the cusp;

15 cutting the cusp by closing the splitter by bringing the first over-the-wire cutter and the second opposing cutter together;

proximally retracting the splitter from the cusp into the cover sheath; and

withdrawing the cover sheath, including the splitter, from a body of the patient.

For some applications, cutting the cusp includes lacerating the cusp using one or  
20 more cutting protrusions of at least one of first over-the-wire cutter and the second opposing cutter.

For some applications, the second opposing cutter includes the one or more cutting protrusions, and cutting the cusp includes lacerating the cusp using the one or more cutting protrusions of the second opposing cutter.

25 For some applications, cutting the cusp includes excising a piece of material of the cusp using an elongate cutting blade of at least one of first over-the-wire cutter and the second opposing cutter.

For some applications, the second opposing cutter includes the elongate cutting blade, and cutting the cusp includes excising the piece of material of the cusp using the  
30 elongate cutting blade of the second opposing cutter.

For some applications, the elongate cutting blade is located along at least a portion of an edge of the second opposing cutter.

For some applications, cutting the cusp includes distally advancing a cutting sleeve toward and then over the open splitter, thereby closing the splitter by bringing the first over-  
5 the-wire cutter and the second opposing cutter together.

For some applications, distally advancing the cutting sleeve toward the open splitter includes distally advancing the cutting sleeve out of the distal end of the cover sheath toward the open splitter.

For some applications, the splitter further includes a spring that is configured to  
10 open the splitter by separating the first over-the-wire cutter and the second opposing cutter from each other.

For some applications, the method further includes subsequently implanting a prosthetic aortic valve.

For some applications, cutting the cusp further includes applying energy during  
15 cutting.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

### **BRIEF DESCRIPTION OF THE DRAWINGS**

Figs. 1A-F are schematic illustrations a method for splitting a native or prosthetic  
20 valve cusp before performing a Transcatheter Aortic Valve Implantation (TAVI), in accordance with an application of the present invention;

Figs. 2A-B are schematic illustrations of the cusp after it has been lacerated using a valve-splitting device described with reference to Figs. 1A-F, in accordance with an application of the present invention;

25 Figs. 3A-F are schematic illustrations another method for splitting a native or prosthetic valve cusp before performing TAVI, in accordance with an application of the present invention;

Figs. 4A-B are schematic illustration of the cusp after a piece of material has been removed using a valve-splitting device described with reference to Figs. 3A-F, in accordance with an application of the present invention; and

Fig. 5 is a schematic illustration of an operating handle positioned at a distal end of the valve-splitting device of Figs. 1A-F or Figs. 3A-F, in accordance with an application of the present invention.

### DETAILED DESCRIPTION OF THE APPLICATION

Reference is made to Figs. 1A-F, which are schematic illustrations a method for splitting a native or prosthetic valve cusp 4 before performing a Transcatheter Aortic Valve Implantation (TAVI), in accordance with an application of the present invention. Figs. 1A-F also show a valve-splitting device 20 used to perform the method. Fig. 1A shows aortic valve cusp 4, a left coronary artery 5, and a right coronary artery 6.

As shown in Fig. 1A, a guidewire 3 is inserted into the left ventricle, e.g., via the femoral artery. Guidewire 3 is typically not an element of valve-splitting device 20. For example, first a sheath may be inserted into the femoral artery. The aortic valve may be crossed with a straight wire over a catheter (e.g., an AL1 catheter) and an exchange wire may be introduced to the left ventricle. Then a pigtail catheter may be introduced, and the guidewire 3 is inserted to the apex of the left ventricle.

Also as shown in Fig. 1A, valve-splitting device 20 is then advanced over guidewire 3 to a location above the aortic root. Valve-splitting device 20 typically comprises a cover sheath 22 and/or a nosecone 24.

As shown in Fig. 1B, optionally, after nosecone 24 of valve-splitting device 20 has been advanced into the left ventricle, cover sheath 22 is proximally retracted.

Valve-splitting device 20 further comprises a splitter 26, which is removably disposed inside cover sheath 22 at the stage of the procedure shown in Fig. 1B. Splitter 26 comprises a first over-the-wire cutter 30 and a second opposing cutter 32 that comprises one or more cutting protrusions 34 (e.g., a single cutting protrusion 34, as shown), such as one or more needles or spikes. Splitter 26 is shaped so as to define a guidewire lumen 40, configured to accept and slide over guidewire 3. Typically, first over-the-wire cutter 30 of splitter 26 is shaped to define guidewire lumen 40. Alternatively, first over-the-wire cutter 30 comprises the one or more cutting protrusions 34, or both second opposing cutter 32 and

first over-the-wire cutter 30 comprise respective one or more cutting protrusions 34 (configurations not shown). Even in configurations in which only one of cutters 30 and 32 comprises the one or more cutting protrusions 34, such as shown in the figures, both cutters 30 and 32 are considered cutters, because the cutter without cutting protrusions assists in the cutting by providing a surface against which the cutting protrusions press during cutting. Cutters 30 and 32 may also be considered jaws of splitter 26.

Typically, guidewire lumen 40 has a diameter of between 0.035' and 0.042', in order to accommodate a standard guidewire having a diameter of 0.035' - 0.038'.

As shown in Fig. 1C, splitter 26 is advanced out of a distal end of cover sheath 22 toward cusp 4 of the aortic valve. Although the aortic valve is shown in the figures as a native aortic valve, the aortic valve may also be a prosthetic valve of a previously implanted prosthetic aortic valve, e.g., implanted in a TAVI procedure.

As shown in Fig. 1D, after confirmation of proper positioning, splitter 26 is opened by separating first over-the-wire cutter 30 and second opposing cutter 32 from each other. For some applications, splitter 26 comprises a spring 42 that is configured to separate the cutters 30 and 32 from each other (as shown, for example, in Fig. 1D); alternatively, splitter 26 is opened using other techniques, such as using one or more control wires (configuration not shown). Splitter 26 is oriented towards the cusp 4 that needs laceration. As also shown in Fig. 1D, splitter 26 is advanced into contact with cusp 4, such that cutters 30 and 32 are disposed on opposite surfaces of cusp 4. For example, first over-the-wire cutter 30 may be disposed on a ventricular side of cusp 4 and second opposing cutter 32 may be disposed on an aortic side of cusp 4, or *vice versa*.

As shown in Fig. 1E, a cutting sleeve 44 of valve-splitting device 20 is distally advanced toward and then over splitter 26, thereby closing splitter 26 by bringing first over-the-wire cutter 30 and second opposing cutter 32 together, and cutting cusp 4. Typically, cutting sleeve 44 is advanced out of the distal end of cover sheath 22 in order to reach splitter 26.

For some applications, splitter 26 is configured to cut cusp 4 by lacerating cusp 4, typically substantially without removing any material (e.g., tissue) of cusp 4.

Optionally, during cutting, heat is applied, such as by a diathermia device, for improving cutting efficiency. Alternatively, optionally, during cutting, energy, such as RF ablation energy, is applied, for improving cutting efficiency.

As shown in Fig. 1F, splitter 26 and cutting sleeve 44 are proximally retracted from lacerated cusp 4 into cover sheath 22. Cover sheath 22, including splitter 26 and cutting sleeve 44, is withdrawn from the patient's body.

Subsequently, a prosthetic aortic valve is implanted, such as in a TAVI procedure.

Reference is made to Figs. 2A-B, which are schematic illustrations of cusp 4 after it has been lacerated using valve-splitting device 20 as described with reference to Figs. 1A-F, in accordance with an application of the present invention. As can be seen, the ostium of right coronary artery 6 is not obstructed when cusp 4 is pushed toward the aorta, such as during implantation of a prosthetic valve, e.g., during a TAVI procedure.

Reference is now made to Figs. 3A-F, which are schematic illustrations another method for splitting a native or prosthetic valve cusp 4 before performing TAVI, in accordance with an application of the present invention. Figs. 3A-F also show a valve-splitting device 120 used to perform the method. Other than as described below, the method is identical to the method described hereinabove with reference to Figs. 1A-F, and valve-splitting device 120 is identical to valve-splitting device 20, described hereinabove with reference to Figs. 1A-F. Valve-splitting device 120 comprises a splitter 126, which, other than as described hereinbelow, is generally similar to splitter 26 of valve-splitting device 20, described hereinabove with reference to Figs. 1A-F, and may implement any of the features of splitter 26, *mutatis mutandis*.

Unlike in splitter 26 of valve-splitting device 20 described hereinabove with reference to Figs. 1A-F, a second opposing cutter 132 of splitter 126 of valve-splitting device 120 comprises an elongate cutting blade 134, which is configured to cut cusp 4 by excising a piece of material of cusp 4, such as shown in the transition between Figs. 3D and 3E. The excised piece of cusp material is trapped between first over-the-wire cutter 30 and second opposing cutter 132, and removed from the patient's body using splitter 126 as splitter 126 is proximally retracted into cover sheath 22, such as shown in Fig. 3F. (The piece of material is tissue if the cusp is a native cusp, and is material, e.g., graft material, if the cusp is a prosthetic cusp.) Alternatively, first over-the-wire cutter 30 comprises elongate cutting blade 134, or both second opposing cutter 132 and first over-the-wire cutter

30 comprise respective elongate cutting blades 134 (configurations not shown). Even in configurations in which only one of cutters 30 and 132 comprises elongate cutting blade 134, such as shown in the figures, both cutters 30 and 132 are considered cutters, because the cutter without the elongate cutting blade assists in the cutting by providing a surface  
5 against which the elongate cutting blade presses during cutting. Cutters 30 and 132 may also be considered jaws of splitter 126.

Optionally, elongate cutting blade 134 is generally U-shaped (as shown in Fig. 3D) or generally V-shaped (configuration not shown). Alternatively, elongate cutting blade 134 is shaped so as to form a closed loop (configuration not shown).

10 Optionally, elongate cutting blade 134 is located along at least a portion of an edge of second opposing cutter 132.

Reference is made to Figs. 4A-B, which are schematic illustration of cusp 4 after the piece of material has been removed using valve-splitting device 120 as described with reference to Figs. 3A-F, in accordance with an application of the present invention. As can  
15 be seen, the ostium of right coronary artery 6 is not obstructed when cusp 4 is pushed toward the aorta, such as during implantation of a prosthetic valve, e.g., during a TAVI procedure.

Reference is made to Fig. 5, which is a schematic illustration of an operating handle 212 positioned at a distal end of valve-splitting device 20 or valve-splitting device 120, in accordance with an application of the present invention. Although operating handle 212 is  
20 shown in Fig. 5 as positioned at the distal end of valve-splitting device 20, the operating handle may also be positioned at the distal end of valve-splitting device 120, *mutatis mutandis*.

Operating handle 212 comprises one or more of the following elements: a knob 214 for retracting cover sheath 22, a port 216 for guidewire 3, a knob 218 for advancing cutting sleeve 44, a port 220 for diathermia input to cutting sleeve 44 and/or one or both of the  
25 splitter cutters, and/or a flushing port 222.

In an embodiment, techniques and apparatus described herein are combined with techniques and apparatus described in US Provisional Application 63/051,479, filed July 14, 2020, which is assigned to the assignee of the present application and incorporated  
30 herein by reference.

It will be appreciated by persons skilled in the art that the present invention is not

limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing  
5 description.

## CLAIMS

1. A valve-splitting device for splitting a native or prosthetic valve cusp, the valve-splitting device for use with a guidewire, the valve-splitting device comprising:  
a cover sheath; and  
5 a splitter, which is removably disposed inside the cover sheath, and which comprises:  
a first over-the-wire cutter, which is shaped so as to define a guidewire lumen that is configured to accept and slide over the guidewire; and  
a second opposing cutter,  
10 wherein the splitter is configured, upon distal advancement of the splitter out of a distal end of the cover sheath, to be opened such that the first over-the-wire cutter and the second opposing cutter are separated from each other and are disposable on opposite sides of the cusp, such that closing the splitter by bringing the first over-the-wire cutter and the second opposing cutter together cuts the cusp.
- 15 2. The valve-splitting device according to claim 1, wherein at least one of the first over-the-wire cutter and the second opposing cutter comprises one or more cutting protrusions, which are configured to cut the cusp by lacerating the cusp.
3. The valve-splitting device according to claim 2, wherein the second opposing cutter comprises the one or more cutting protrusions.
- 20 4. The valve-splitting device according to claim 1, wherein at least one of first over-the-wire cutter and the second opposing cutter comprises an elongate cutting blade, which is configured to cut the cusp by excising a piece of material of the cusp.
5. The valve-splitting device according to claim 4, wherein the second opposing cutter comprises the elongate cutting blade.
- 25 6. The valve-splitting device according to claim 5, wherein the elongate cutting blade is located along at least a portion of an edge of the second opposing cutter.
7. The valve-splitting device according to any one of claims 1-6, wherein the splitter further comprises a cutting sleeve, which is configured to be distally advanced toward and then over the open splitter, thereby closing the splitter by bringing the first over-the-wire cutter and the second opposing cutter together, and cutting the cusp when the first over-the-wire cutter and the second opposing cutter are disposed on the opposite sides of the cusp.
- 30

8. The valve-splitting device according to claim 7, wherein the cutting sleeve is configured to be advanced out of the distal end of the cover sheath in order to reach the splitter.
9. The valve-splitting device according to any one of claims 1-6, wherein the splitter  
5 further comprises a spring that is configured to open the splitter by separating the first over-the-wire cutter and the second opposing cutter from each other.
10. The valve-splitting device according to any one of claims 1-6, wherein the valve-splitting device is configured to apply energy during cutting.
11. A method for splitting a native or prosthetic valve cusp of a patient, the method  
10 comprising:  
inserting a guidewire into a left ventricle of the patient;  
advancing a valve-splitting device over the guidewire to a location above an aortic root, while a splitter of the valve-splitting device is removably disposed inside a cover sheath of the valve-splitting device, while the guidewire slides through a guidewire lumen  
15 defined by a first over-the-wire cutter of the splitter, and while the splitter is closed;  
advancing the splitter out of a distal end of the cover sheath toward the native or prosthetic valve cusp;  
while the splitter is open such that the first over-the-wire cutter and a second opposing cutter of the splitter are separated from each other, disposing the first over-the-  
20 wire cutter and the second opposing cutter on opposite sides of the cusp;  
cutting the cusp by closing the splitter by bringing the first over-the-wire cutter and the second opposing cutter together;  
proximally retracting the splitter from the cusp into the cover sheath; and  
withdrawing the cover sheath, including the splitter, from a body of the patient.
- 25 12. The method according to claim 11, wherein cutting the cusp comprises lacerating the cusp using one or more cutting protrusions of at least one of first over-the-wire cutter and the second opposing cutter.
13. The method according to claim 12, wherein the second opposing cutter includes the one or more cutting protrusions, and wherein cutting the cusp comprises lacerating the cusp  
30 using the one or more cutting protrusions of the second opposing cutter.

14. The method according to claim 11, wherein cutting the cusp comprises excising a piece of material of the cusp using an elongate cutting blade of at least one of first over-the-wire cutter and the second opposing cutter.
15. The method according to claim 14, wherein the second opposing cutter includes the  
5 elongate cutting blade, and wherein cutting the cusp comprises excising the piece of material of the cusp using the elongate cutting blade of the second opposing cutter.
16. The method according to claim 15, wherein the elongate cutting blade is located along at least a portion of an edge of the second opposing cutter.
17. The method according to claim 11, wherein cutting the cusp comprises distally  
10 advancing a cutting sleeve toward and then over the open splitter, thereby closing the splitter by bringing the first over-the-wire cutter and the second opposing cutter together.
18. The method according to claim 17, wherein distally advancing the cutting sleeve toward the open splitter comprises distally advancing the cutting sleeve out of the distal end of the cover sheath toward the open splitter.
- 15 19. The method according to claim 11, wherein the splitter further includes a spring that is configured to open the splitter by separating the first over-the-wire cutter and the second opposing cutter from each other.
20. The method according to claim 11, further comprising subsequently implanting a prosthetic aortic valve.
- 20 21. The method according to claim 11, wherein cutting the cusp further comprises applying energy during cutting.

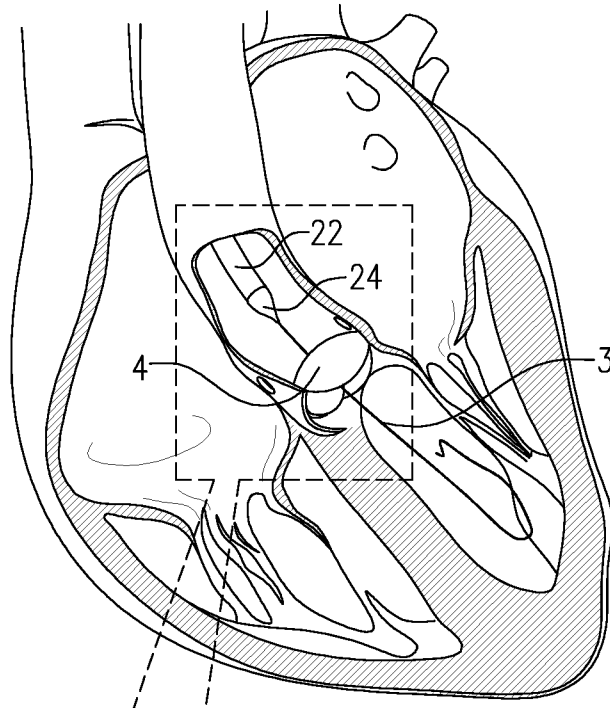
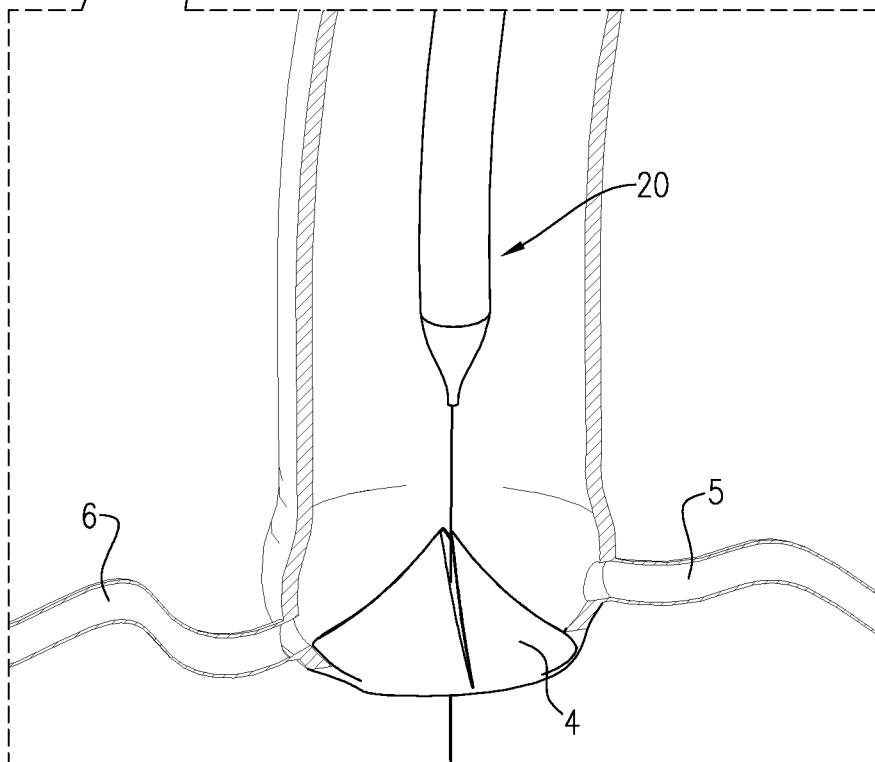


FIG. 1A





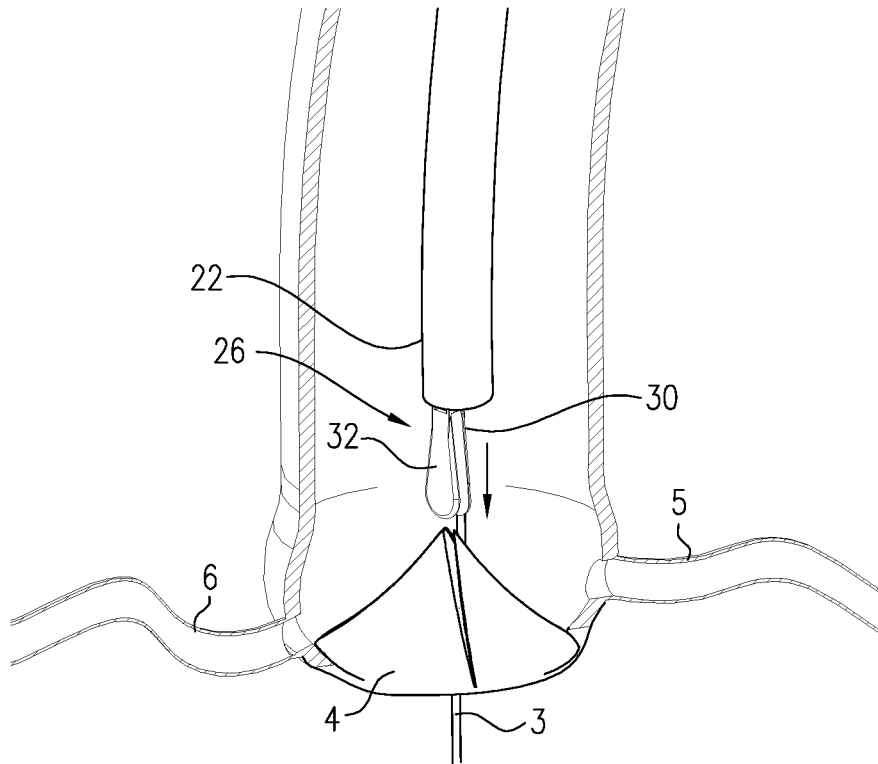


FIG. 1C

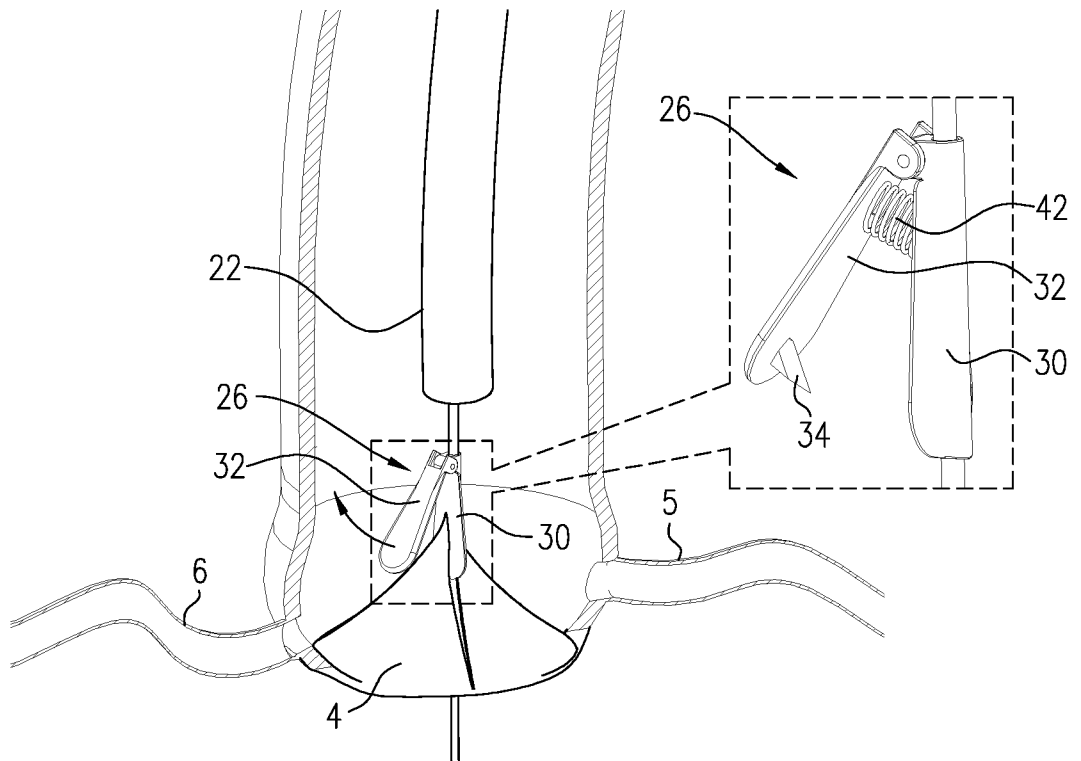


FIG. 1D

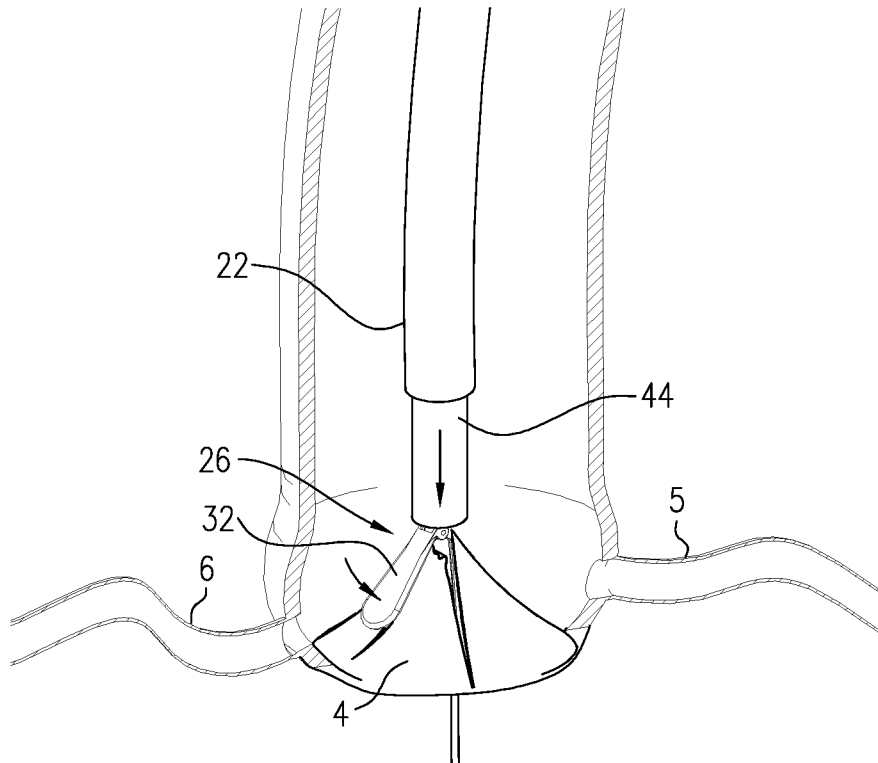


FIG. 1E

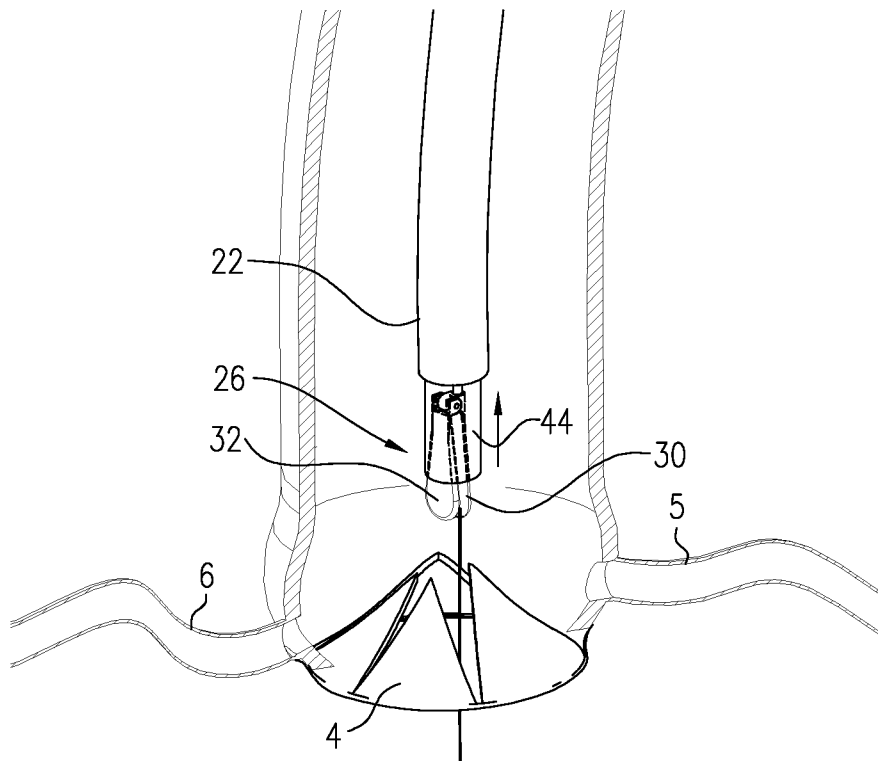


FIG. 1F

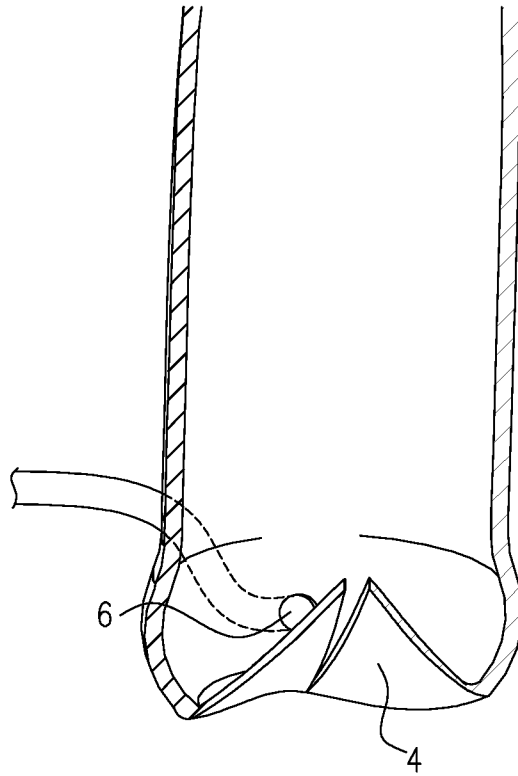


FIG. 2A

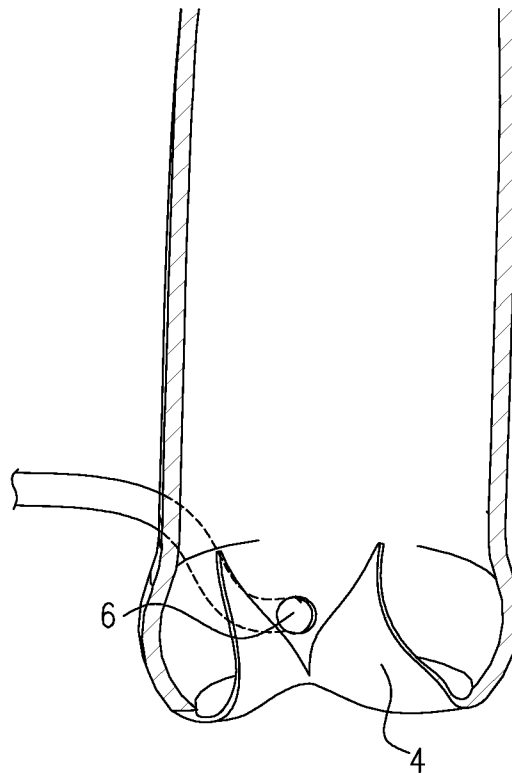


FIG. 2B

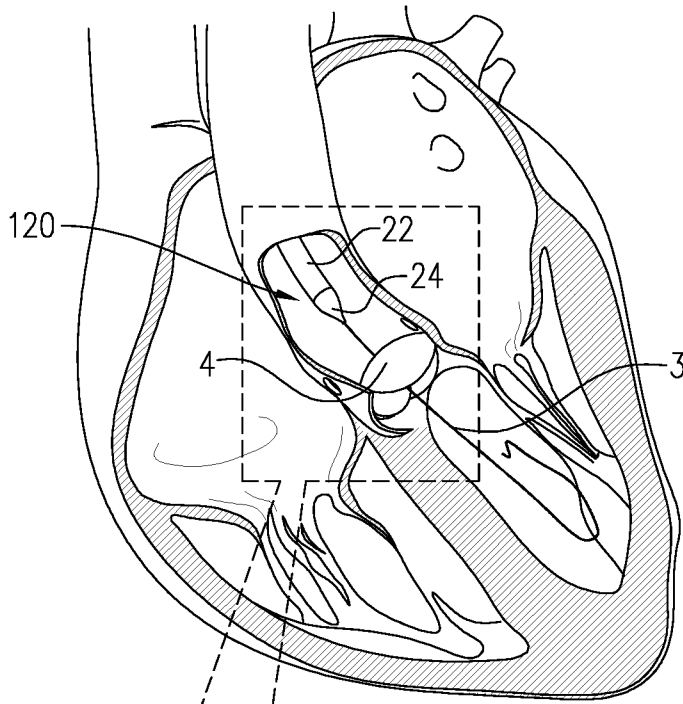
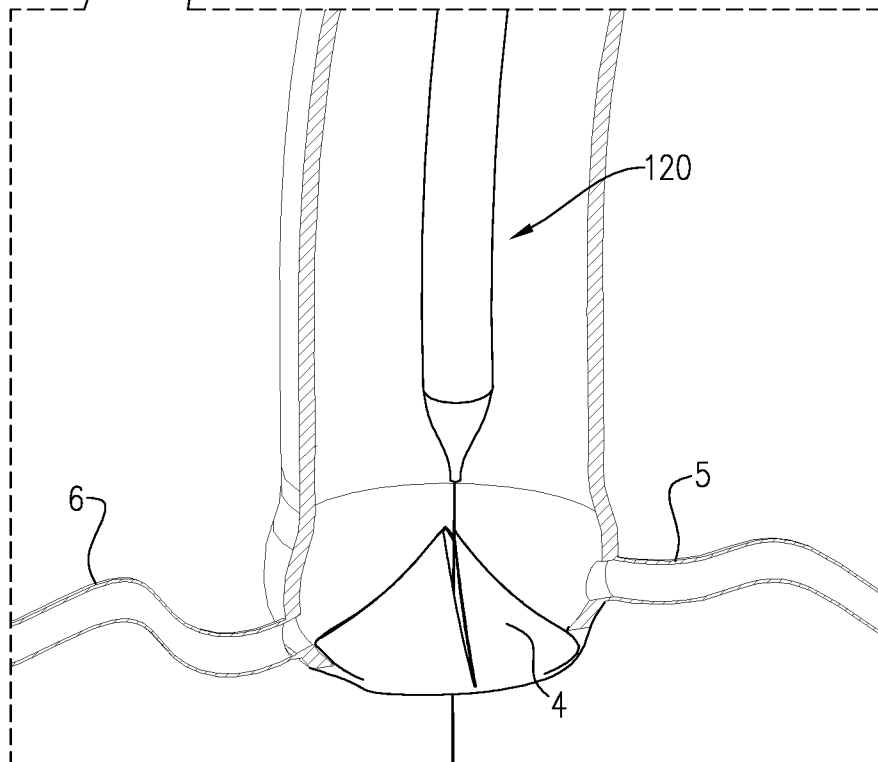
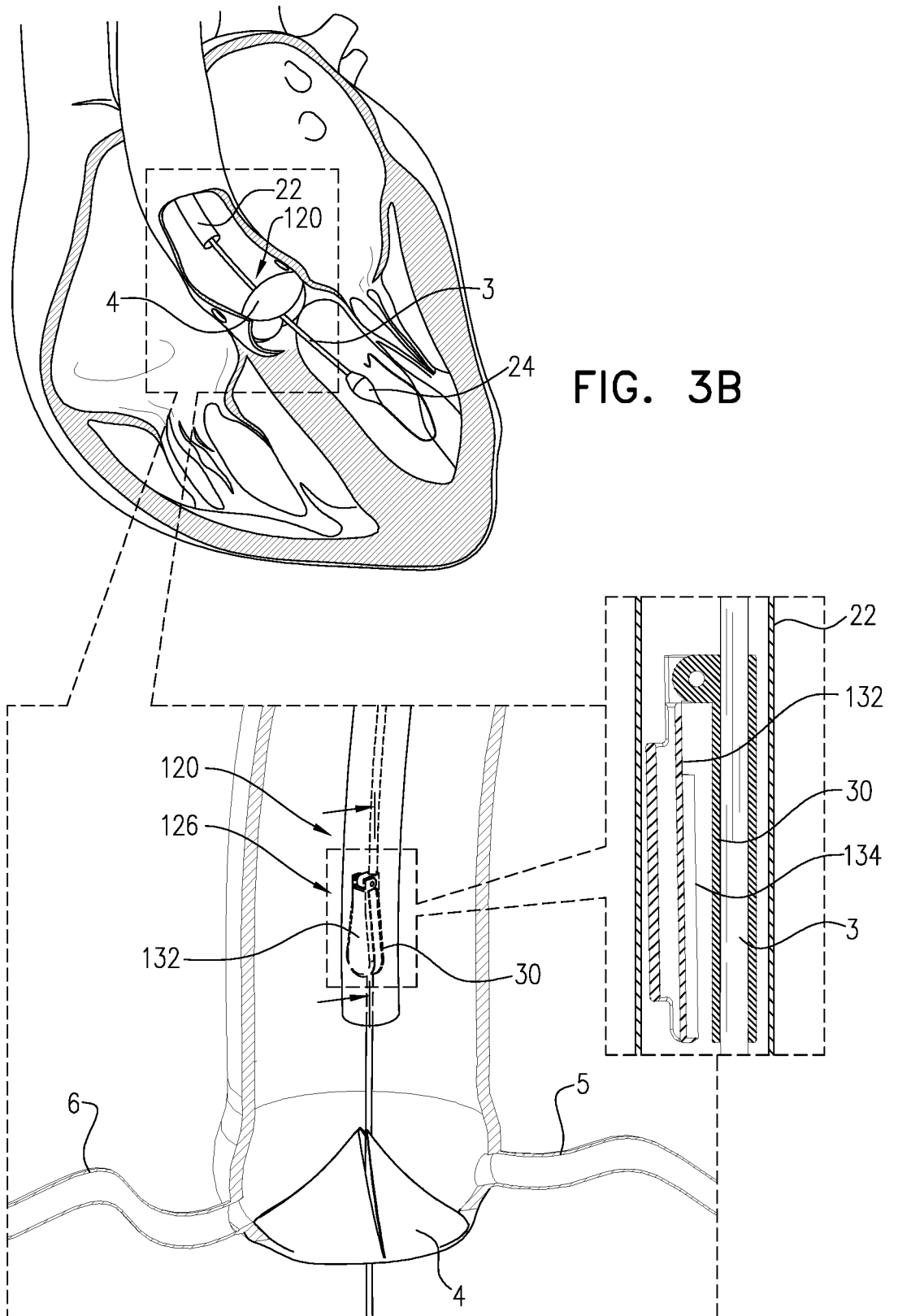


FIG. 3A





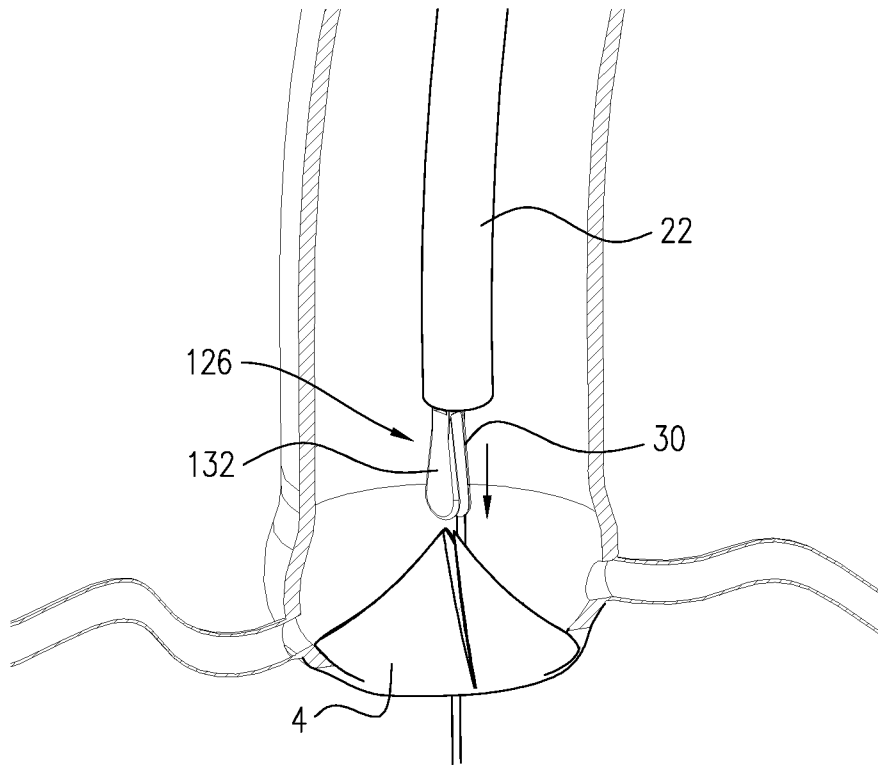


FIG. 3C

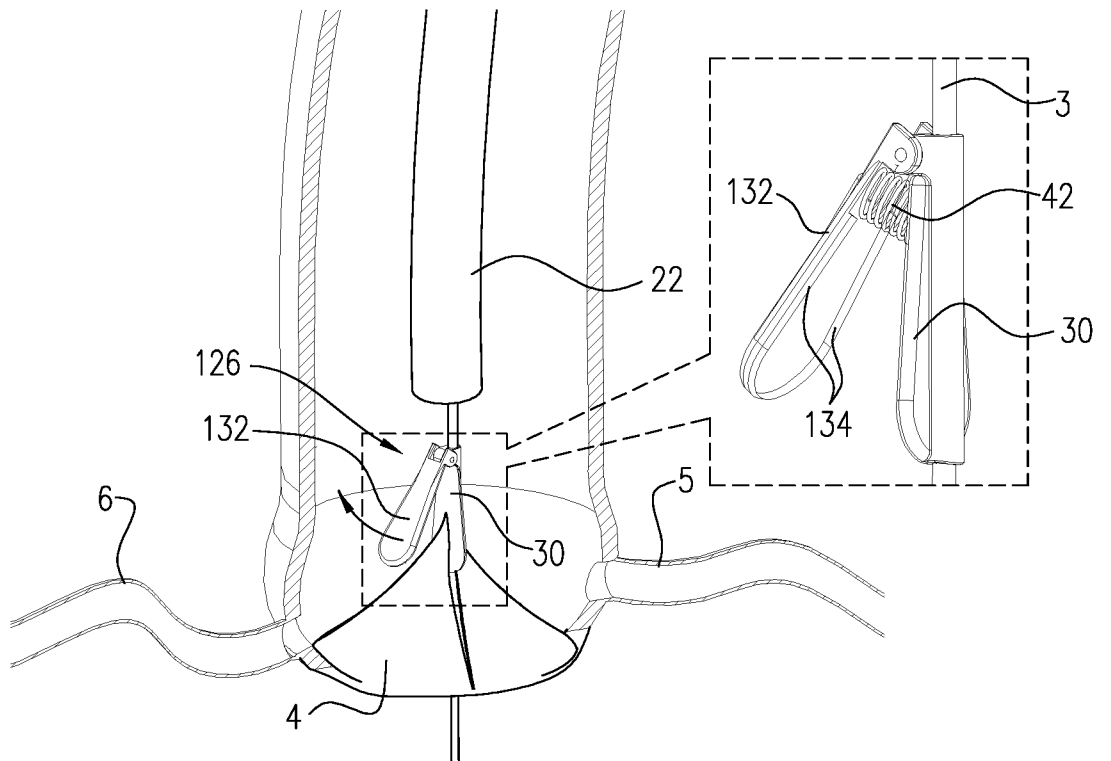


FIG. 3D

9/11

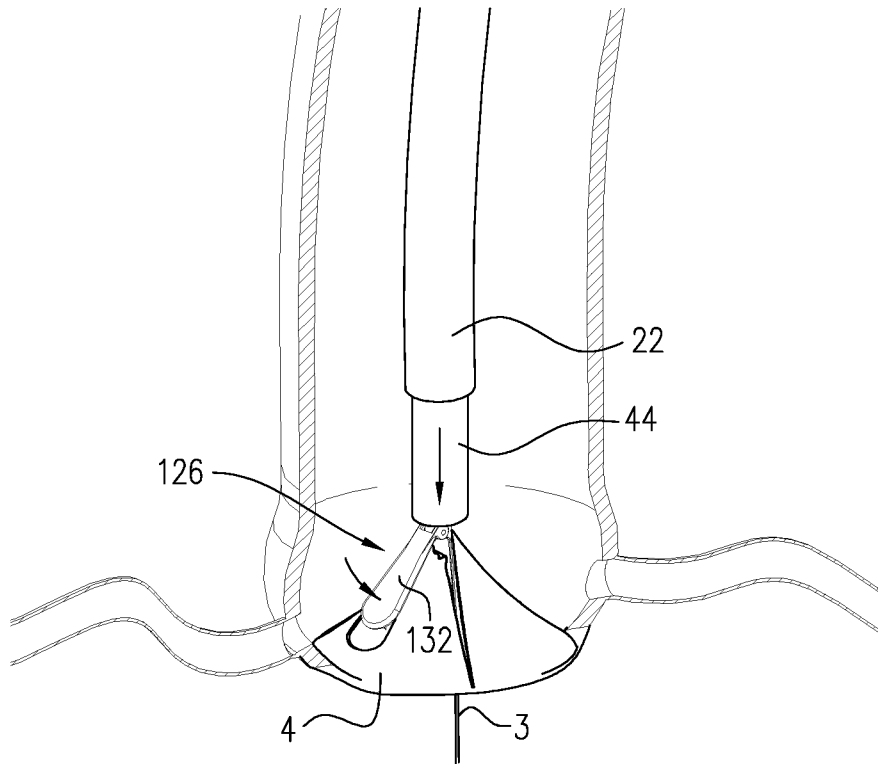


FIG. 3E

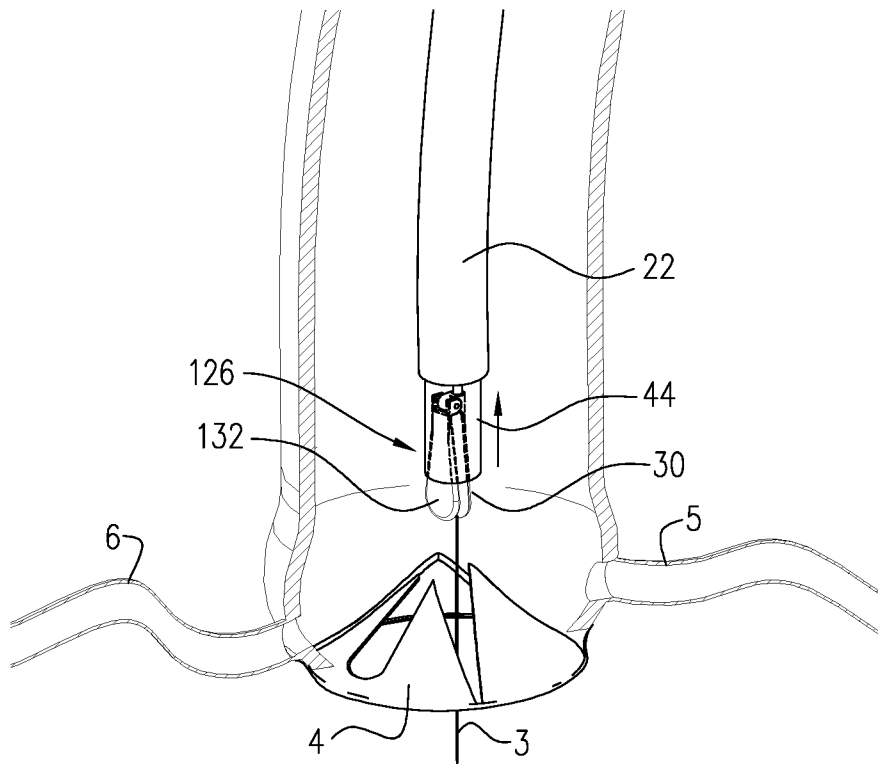


FIG. 3F

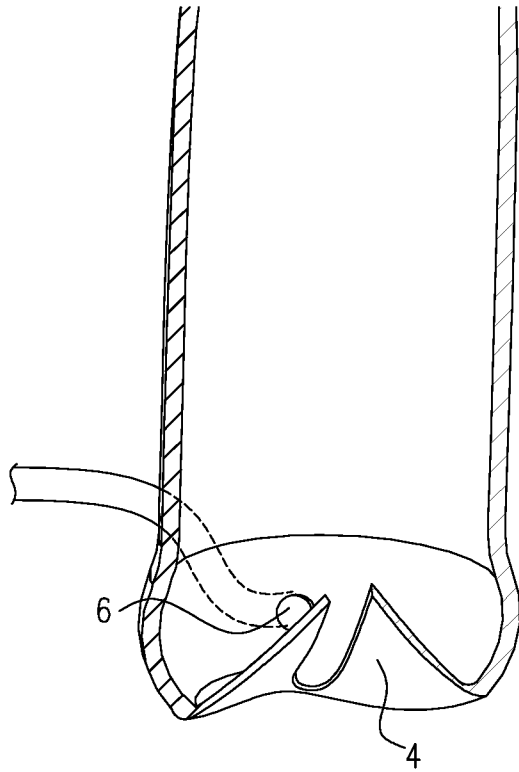


FIG. 4A

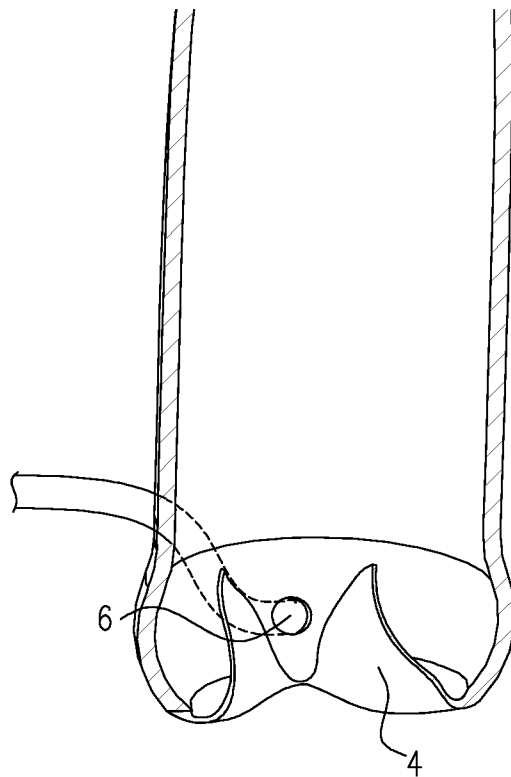


FIG. 4B

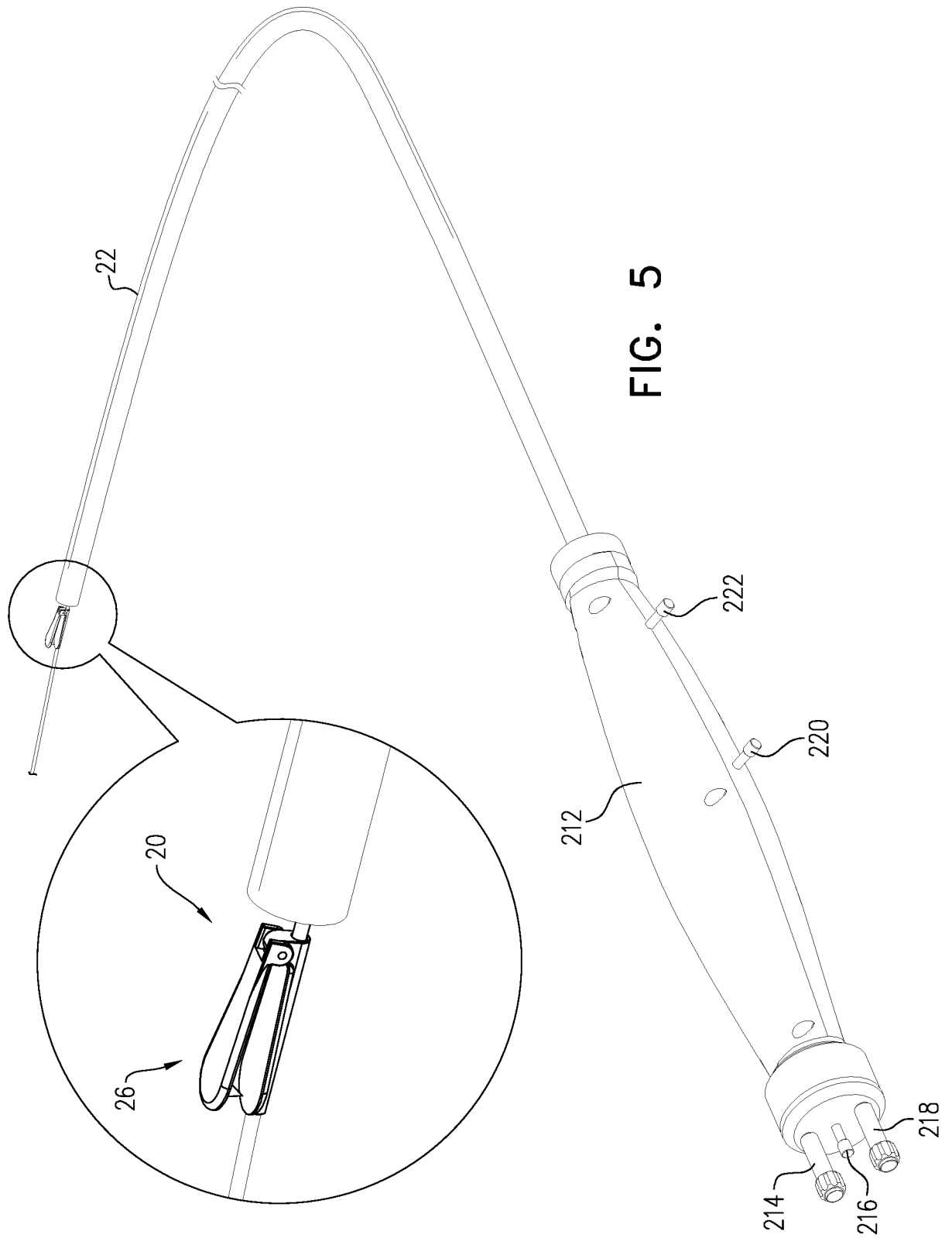


FIG. 5

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2021/050844

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC (20210101) A61B 17/32, A61B 17/00, A61B 18/00, A61F 2/24 CPC (20210501) A61B 17/32, A61B 2017/00243, A61B 2018/00369, A61F 2/2463, A61F 2/2466 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC (20210101) A61B 17/32, A61B 17/00, A61B 18/00, A61F 2/24 CPC (20210501) A61B 17/32, A61B 2017/00243, A61B 2018/00369, A61F 2/2463, A61F 2/2466 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Databases consulted: Esp@cenet, Google Patents, Orbit, Similari (AI-based)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2020146690 A1 MEDTRONIC INC 14 May 2020 (2020/05/14) The whole document	1-21
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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 "D" document cited by the applicant in the international application "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 06 Oct 2021		Date of mailing of the international search report 10 Oct 2021
Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Email address: pctoffice@justice.gov.il		Authorized officer BERGIG Keren Telephone No. 972-73-3927236

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
PCT/IL2021/050844

Patent document cited search report	Publication date	Patent family member(s)	Publication Date
US 2020146690 A1	14 May 2020	US 2020146690 A1	14 May 2020
<hr/>			
		CN 112969426 A	15 Jun 2021
		EP 3880101 A2	22 Sep 2021
		US 2020146691 A1	14 May 2020
		WO 2020102320 A2	22 May 2020
		WO 2020102320 A3	06 Aug 2020