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(54) Title: SYSTEM OF MEDICAL DEVICES AND METHOD FOR PERICARDIAL PUNCTURE

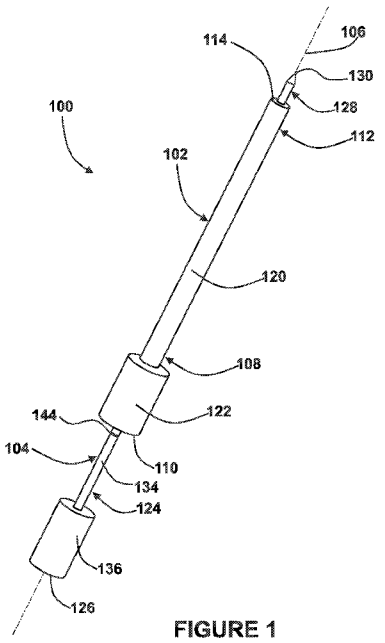

FIGURE 1

(57) Abstract: A system of medical devices includes an introducer and a needle. The introducer has an introducer proximal portion and an introducer distal portion. The introducer proximal portion defines an introducer proximal end and the introducer distal portion defines an introducer distal end. The introducer has a lumen extending therethrough from the introducer proximal end to the introducer distal end. The needle is receivable in the introducer and has a needle proximal portion and a needle distal portion. The needle proximal portion defines a needle proximal end and the needle distal portion defines a sharp needle distal end. The needle proximal portion comprises at least a first depth marker that, when aligned with a feature of the introducer, indicates a first relative position of the needle distal end and the introducer distal end.

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SYSTEM OF MEDICAL DEVICES AND METHOD FOR PERICARDIAL PUNCTURE

FIELD:

[0001] This document relates to medical devices. More specifically, this document relates to medical devices that can be used in pericardial puncture, and related methods.

SUMMARY:

[0002] The following summary is intended to introduce the reader to various aspects of the detailed description, but not to define or delimit any invention.

[0003] Systems of medical devices are disclosed. According to some aspects, a system of medical devices includes an introducer having an introducer proximal portion and an introducer distal portion. The introducer proximal portion defines an introducer proximal end and the introducer distal portion defines an introducer distal end. The introducer has a lumen extending therethrough from the introducer proximal end to the introducer distal end. A needle is receivable in the introducer. The needle has a needle proximal portion and a needle distal portion. The needle proximal portion defines a needle proximal end and the needle distal portion defines a sharp needle distal end. The needle proximal portion includes at least a first depth marker that, when aligned with a feature of the introducer, indicates a first relative position of the needle distal end and the introducer distal end.

[0004] In some examples, the feature of the introducer is the introducer proximal end.

[0005] In some examples, when the first depth marker is aligned with the feature of the introducer, the needle distal end is flush with the introducer distal end. In some examples, when the first depth marker is aligned with the feature of the introducer, the needle distal end is proud of the introducer distal end by a predetermined distance. The predetermined distance can be approximately 1 mm.

[0006] In some examples, the needle further includes a second depth marker that when aligned with the feature of the introducer, indicates a second relative position of the needle

distal end and the introducer distal end. When the first depth marker is aligned with the feature of the introducer, the needle distal end can flush with the introducer distal end, and when the second depth marker is aligned with the feature of the introducer, the needle distal end can be proud of the introducer distal end by a predetermined distance.

[0007] In some examples, the introducer distal end is blunt. In some examples, the introducer includes an introducer shaft and an introducer hub, and the introducer hub defines the introducer proximal end. The introducer shaft can include a metallic hypotube embedded in a polymeric coating. In some examples, the introducer distal portion includes a radiopaque marker.

[0008] In some examples, the needle includes a needle shaft and a needle hub, and the first depth marker includes a band applied to the needle shaft. The needle shaft can be metallic, and the band can be polymeric. The band can be polytetrafluoroethylene.

[0009] Methods for pericardial puncture are also disclosed. According to some aspects, a method for pericardial puncture includes: a. advancing an introducer towards a pericardium until a distal end of the introducer contacts the pericardium; and b. advancing a needle through the introducer towards the pericardium until a first depth marker of the needle is aligned with a feature of the introducer to indicate a first relative position of the distal end of the needle and the distal end of the introducer.

[0010] In some examples, in the first relative position, the distal end of the needle is flush with the distal end of the introducer. In some examples, in the first relative position, the distal end of the needle is proud of the distal end of the introducer by a predetermined distance. The predetermined distance can be approximately 1 mm.

[0011] In some examples, the method further includes advancing the needle into pericardium until a second depth marker of the needle is aligned the feature of the introducer to indicate a second relative position of the distal end of the needle and the distal end of the introducer. In the second relative position, the distal end of the needle can be proud of the distal end of the introducer by a predetermined distance. The predetermined distance can be approximately 1 mm.

BRIEF DESCRIPTION OF THE DRAWINGS:

[0012] The accompanying drawings are for illustrating examples of articles, methods, and apparatuses of the present disclosure and are not intended to be limiting. In the drawings:

[0013] Figure 1 is a perspective view of a system of medical devices, in an assembled state;

[0014] Figure 2 is a perspective view of the system of medical devices of Figure 1, in an unassembled state.

[0015] Figure 3 is a cutaway view of the system of Figure 1, showing a first depth marker of the needle aligned with a proximal end of the introducer, and a distal end of the needle flush with a distal end of the introducer;

[0016] Figure 4 is a cutaway view similar to that of Figure 3, showing a second depth marker of the needle aligned with the proximal end of the introducer, and the distal end of the needle proud of the distal end of the introducer by a predetermined distance;

[0017] Figure 5 is a cutaway view similar to that of Figures 3 and 4, showing a fourth depth marker of the needle aligned with the proximal end of the introducer, and the distal end of the needle flush proud of the distal end of the introducer by another predetermined distance.

DETAILED DESCRIPTION:

[0018] Various apparatuses or processes or compositions will be described below to provide an example of an embodiment of the claimed subject matter. No example described below limits any claim and any claim may cover processes or apparatuses or compositions that differ from those described below. The claims are not limited to apparatuses or processes or compositions having all of the features of any one apparatus or process or composition described below or to features common to multiple or all of the apparatuses or processes or compositions described below. It is possible that an apparatus or process or composition described below is not an embodiment of any exclusive right granted by issuance of this patent application. Any subject matter

described below and for which an exclusive right is not granted by issuance of this patent application may be the subject matter of another protective instrument, for example, a continuing patent application, and the applicants, inventors or owners do not intend to abandon, disclaim or dedicate to the public any such subject matter by its disclosure in this document.

[0019] Generally disclosed herein is a system of medical devices that includes an introducer and a needle. The system is configured to provide the user with an indication of the relative position of the distal end of the needle and the distal end of the introducer, even if the distal end of the needle and the distal end of the introducer are not within view. For example, the system can provide the user with an indication that the distal end of the needle is flush with the distal end of the introducer, or an indication that the distal end of the needle is proud of the distal end of the introducer by a predetermined distance (e.g. approximately 1 mm, or approximately 3 mm). This may be particularly beneficial where the needle and introducer are being used for pericardial puncture. In such procedures, due to the relatively thin nature of the pericardium, it may be desirable to advance the needle only a small distance proud of the introducer (e.g. up to approximately 3 mm, or about 1 mm), in order to puncture the pericardium without puncturing the epicardium. By providing the user with an indication of the relative position of the distal end of the needle and the distal end of the introducer, patient safety can be enhanced.

[0020] Referring now to Figure 1, an example system 100 of medical devices is shown. The system 100 generally includes an introducer 102 and a needle 104, which is receivable in and advanceable through the introducer 102. The introducer 102 can serve to atraumatically guide the needle 104 towards a target location in a patient's body (e.g. the heart), and the needle 104 can then puncture the target location (e.g. the pericardium).

[0021] Referring to Figure 2, the introducer 102 extends along a longitudinal axis 106 and has a proximal portion 108 (also referred to herein as an 'introducer proximal portion'), which defines a proximal end 110 (also referred to herein as an 'introducer distal end'), and a distal portion 112 (also referred to herein as an 'introducer distal portion'), which defines a distal end 114 (also referred to herein as an 'introducer proximal end. The

introducer has a length (also referred to herein as an 'introducer length') between the proximal end 110 and the distal end 114. A lumen 118 extends through the introducer 102 from the proximal end 110 to the distal end 114, for receiving the needle 104. In the example shown, the introducer 102 includes a shaft 120 (also referred to herein as an 'introducer shaft') and a hub 122 (also referred to herein as an 'introducer hub), and the hub 122 defines the introducer proximal end 110 while the shaft defines the introducer distal end 114. The hub 122 may include various features, such as fluid ports and hemostatic valves, etc. (not shown). In use, the hub 122 may be grasped and manipulated by the user, while the distal portion 112 is directed to a target site within a patient's body (e.g. the heart). The distal end 114 is blunt, to avoid damaging tissue in contact with the distal end 114.

[0022] Referring still to Figure 2, the needle 104 has a proximal portion 124 (also referred to herein as a 'needle proximal portion'), which defines a proximal end 126 (also referred to herein as a 'needle distal end'), and a distal portion 128 (also referred to herein as a 'needle distal portion'), which defines a distal end 130 (also referred to herein as a 'needle proximal end). The needle 104 has a length (also referred to herein as a 'length length') between the proximal end 126 and the distal end 130, and the needle length is greater than the introducer length. In the example shown, the needle 104 includes a shaft 134 (also referred to herein as a 'needle shaft') and a hub 136 (also referred to herein as an 'needle hub), and the hub 136 defines the needle proximal end 126 while the shaft 134 defines the needle distal end 130. In use, the hub 136 is grasped or manipulated by the user, while the distal portion 128 is directed to a target site within a patient's body (e.g. the heart). The distal end 130 is sharp, in order to puncture tissue. For example, the distal end 130 can be beveled or conical.

[0023] In alternative examples, the needle hub can be omitted.

[0024] The term "needle" as used herein refers to any generally elongate and sharp-tipped device that is intended for use in puncturing tissue. The term "needle" can refer to a device in which the needle shaft is relatively stiff, as in the example shown. Alternatively,

the term “needle” can refer to a device in which the needle shaft is relatively flexible. For example, a needle can be in the form of a sharp-tipped guidewire.

[0025] Referring now to Figures 3 to 5 the needle 104 is advanceable through the introducer 102 from the proximal end 110 of the introducer 102 towards and beyond the distal end 114 of the introducer 102. In use, when the needle 104 is received in the introducer 102, the distal end 130 of the needle 104 can be shy of the distal end 114 of the introducer 102, flush with the distal end 114 of the introducer 102 (as shown in Figure 3), or proud of the distal end 114 of the introducer 102 (e.g. proud of the distal end 114 of the introducer 102 by about 1 mm, as shown in Figure 4, or proud of the distal end 114 of the introducer 102 by about 3 mm, as shown in Figure 5). In order to provide the user with an indication (i.e. a visual indication) of the relative position of the distal end 130 of the needle 104 and the distal end 114 of the introducer 102, particularly when the distal end 130 of the needle 104 and distal end 114 of the introducer 102 are not visible (e.g. when they are within the body), the needle proximal portion 124 includes a set of depth markers 138-144. Alignment of a given depth marker with the introducer proximal end 110 provides an indication of the relative position of the needle distal end 130 and the introducer distal end 114. More specifically, in the example shown, the needle includes a first 138, a second 140, a third 142, and a fourth depth marker 144. Referring to Figure 3, when the first depth marker 138 is aligned with the introducer proximal end 110, the needle distal end 130 is flush with the introducer distal end 114. Referring to Figure 4, when the second depth marker 140 is aligned with the introducer proximal end 110, the needle distal end 130 is proud of the introducer distal end 114 by a predetermined distance (e.g. approximately 1 mm). When the third depth marker 142 is aligned with the introducer proximal end 110 (not shown), the needle distal end 130 is proud of the introducer distal end 114 by another predetermined distance (e.g. approximately 2 mm). As shown in Figure 5, when the fourth depth marker 144 is aligned with the introducer proximal end 110, the needle distal end 130 is proud of the introducer distal end 114 by another predetermined distance (e.g. approximately 3 mm).

[0026] While the depth markers 138-144 may be positioned to indicate various relative positions of the needle distal end 130 and the introducer distal end 114, the positions

shown in Figures 3 to 5 may be particularly useful for pericardial puncture procedures (as described in further detail below), as the pericardium is typically approximately 1 mm thick, but may be as thick as approximately 3 mm.

[0027] In alternative examples, the needle 104 may include another number of depth markers (i.e. at least one depth marker). For example, the needle 104 may include only a single depth marker, which when aligned with the introducer proximal end 110, can indicate that the needle distal end 130 is flush with the introducer distal end 114, or that the needle distal end 130 is proud of the introducer distal end 114 by a predetermined distance.

[0028] In further alternative examples, the depth marker(s) 138-144 may align with another feature of the introducer 102 (i.e. a feature other than the introducer proximal end 110) to indicate the relative position of the distal end 130 of the needle 104 and the distal end 114 of the introducer 102. For example, the introducer 102 may include its own marker with which the depth markers 138-144 of the needle 104 can align.

[0029] The introducer 102, needle 104, and depth markers 138-144 may be of various constructions. In the example shown, the introducer shaft 120 includes a metallic hypotube 146 embedded in a polymeric coating 148 (e.g. a lubricious coating such as high-density polyethylene). The introducer distal portion 112 may optionally include a radiopaque marker (not shown), to facilitate visualization of the introducer 102 under fluoroscopy. Furthermore, in the example shown, the needle shaft 134 includes a metallic rod (e.g. a stainless-steel rod), and the depth markers 138-144 are in the form of polymeric bands applied to the metallic rod. The polymeric bands may be, for example, polytetrafluorethylene (PTFE) bands. In alternative examples, the depth markers 138-144 may be of another construction, for example the depth markers 138-144 may be etched into the needle shaft 134. Furthermore, the needle may optionally include a lumen, for delivery of fluids (e.g. contrast solution).

[0030] In use, the introducer 102 may be percutaneously advanced towards a target location in a patient's body, until the introducer distal end 114 contacts the target location.

For example, the introducer 102 may be percutaneously advanced via the subxiphoid process towards the heart until the introducer distal end 114 contacts the pericardium.

[0031] The needle 104 may then be advanced through the introducer 102 towards the target location until the first depth marker 138 of the needle 104 is aligned with a proximal end 110 of the introducer 102, to indicate a first relative position of the distal end 130 of the needle 104 and the distal end 114 of the introducer 102. More specifically, the needle 104 may be advanced through the introducer 102 towards the target location until the first depth marker 138 is aligned with the proximal end 110 of the introducer 102, to indicate to the user that the distal end 130 of the needle 104 is flush with the distal end 114 of the introducer 102, as shown in Figure 3. Stopping advancement of the needle 104 when the first depth marker 138 is aligned with the proximal end 110 of the introducer 102 can help to ensure that the distal end 130 of the needle 104 is not advanced out of the introducer 102 until the user is ready to puncture tissue, which can enhance patient safety.

[0032] At this point, various optional procedure may be carried out. For example, fluoroscopy or ultrasound may be used to confirm the position of the distal end 114 of the introducer 102.

[0033] When the user is ready, the needle 104 may be advanced to puncture the target location. In examples where the target location is a relatively thin tissue such as the pericardium, it may be desired to advance the needle 104 only a small distance (e.g. a predetermined distance of up to about 3 mm, or about 1 mm), in order to puncture the target tissue without puncturing other tissue (e.g. in order to puncture the pericardium without puncturing the epicardium). The depth markers 138-144 can be used to ensure that the needle 104 is advanced by only a small amount. For example, the needle 104 can be advanced until the second depth marker 140 is aligned with the proximal end 110 of the introducer 102, to indicate that the distal end 130 of the needle 104 is proud of the distal end 114 of the introducer 102 by approximately 1 mm, as shown in Figure 4. If further advancement is needed to puncture the pericardium (e.g. if the pericardium is relatively thick), the needle 104 can be advanced until the third depth marker 142 is aligned with the proximal end 110 of the introducer 102, to indicate that the distal end 130

of the needle 104 is proud of the distal end 114 of the introducer 102 by approximately 2 mm, or until the fourth depth marker 144 is aligned with the proximal end 110 of the introducer 102, to indicate that the distal end 114 of the needle 104 is proud of the distal end 114 of the introducer 102 by approximately 3 mm, as shown in Figure 5.

[0034] Once the target tissue has been punctured, the needle 104 can be withdrawn from the introducer 102, and the medical procedure can proceed (e.g. a guidewire or another device can be advanced through the introducer 102 into the pericardium).

[0035] While the above description provides examples of one or more processes or apparatuses or compositions, it will be appreciated that other processes or apparatuses or compositions may be within the scope of the accompanying claims.

[0036] To the extent any amendments, characterizations, or other assertions previously made (in this or in any related patent applications or patents, including any parent, sibling, or child) with respect to any art, prior or otherwise, could be construed as a disclaimer of any subject matter supported by the present disclosure of this application, Applicant hereby rescinds and retracts such disclaimer. Applicant also respectfully submits that any prior art previously considered in any related patent applications or patents, including any parent, sibling, or child, may need to be re-visited.

WE CLAIM:

1. A system of medical devices, comprising:
   an introducer having an introducer proximal portion and an introducer distal portion, wherein the introducer proximal portion defines an introducer proximal end and the introducer distal portion defines an introducer distal end, and wherein the introducer has a lumen extending therethrough from the introducer proximal end to the introducer distal end;
   a needle having a needle proximal portion and a needle distal portion, wherein the needle proximal portion defines a needle proximal end and the needle distal portion defines a sharp needle distal end, wherein the needle is receivable in the introducer, and wherein the needle proximal portion comprises at least a first depth marker that, when aligned with a feature of the introducer proximal end, indicates a first relative position of the needle distal end and the introducer distal end.

2. The system of claim 1, wherein the feature of the introducer is the introducer proximal end.

3. The system of claim 1, wherein when the first depth marker is aligned with the feature of the introducer, the needle distal end is flush with the introducer distal end.

4. The system of claim 1, wherein when the first depth marker is aligned with the feature of the introducer, the needle distal end is proud of the introducer distal end by a predetermined distance.

5. The system of claim 4, wherein the predetermined distance is approximately 1 mm.

6. The system of claim 1, wherein the needle further comprises a second depth marker that when aligned with the feature of the introducer, indicates a second relative position of the needle distal end and the introducer distal end.

7. The system of claim 6, wherein when the first depth marker is aligned with the feature of the introducer, the needle distal end is flush with the introducer distal end, and when the second depth marker is aligned with the feature of the introducer, the needle distal end is proud of the introducer distal end by a predetermined distance.

8. The system of claim 1, wherein the introducer distal end is blunt.

9. The system of claim 1, wherein the introducer comprises an introducer shaft and an introducer hub, and the introducer hub defines the introducer proximal end.

10. The system of claim 9, wherein the introducer shaft comprises a metallic hypotube embedded in a polymeric coating.

11. The system of claim 1, wherein the introducer distal portion comprises a radiopaque marker.

12. The system of claim 1, wherein the needle comprises a needle shaft and a needle hub, and the first depth marker comprises a band applied to the needle shaft.

13. The system of claim 12, wherein the needle shaft is metallic, and the band is polymeric.

14. The system of claim 13, wherein the band is polytetrafluoroethylene.

15. A method for pericardial puncture, comprising:
    a. advancing an introducer towards a pericardium until a distal end of the introducer contacts the pericardium;
    b. advancing a needle through the introducer towards the pericardium until a first depth marker of the needle is aligned with a feature of the introducer to indicate a first relative position of the distal end of the needle and the distal end of the introducer.

16. The method of claim 15, wherein in the first relative position, the distal end of the needle is flush with the distal end of the introducer.

17. The method of claim 15, wherein in the first relative position, the distal end of the needle is proud of the distal end of the introducer by a predetermined distance.

18. The method of claim 16, wherein the predetermined distance is approximately 1 mm.

19. The method of claim 15, further comprising: c. further advancing the needle into the pericardium until a second depth marker of the needle is aligned with the feature of the introducer to indicate a second relative position of the distal end of the needle and the distal end of the introducer.

20. The method of claim 19, wherein in the second relative position, the distal end of the needle is proud of the distal end of the introducer by a predetermined distance.

21. The method of claim 20, wherein the predetermined distance is approximately 1 mm.

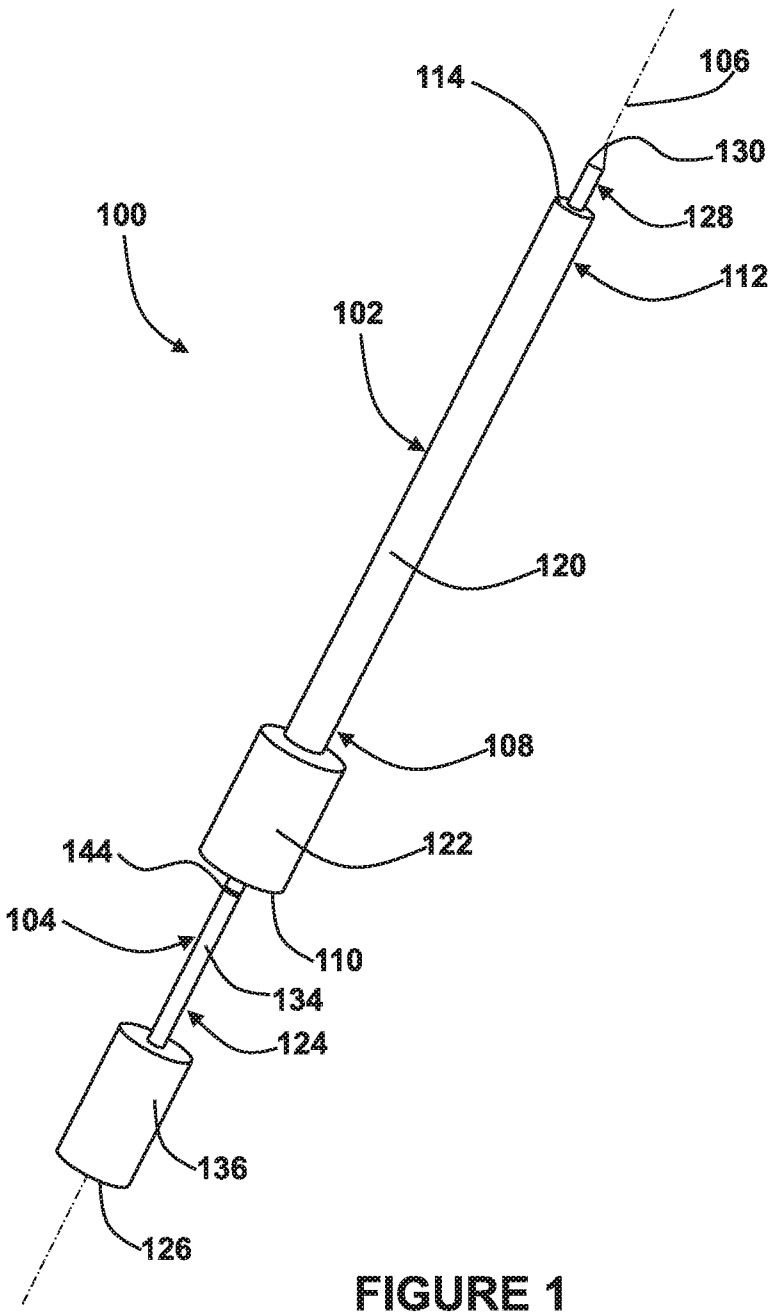
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FIGURE 1

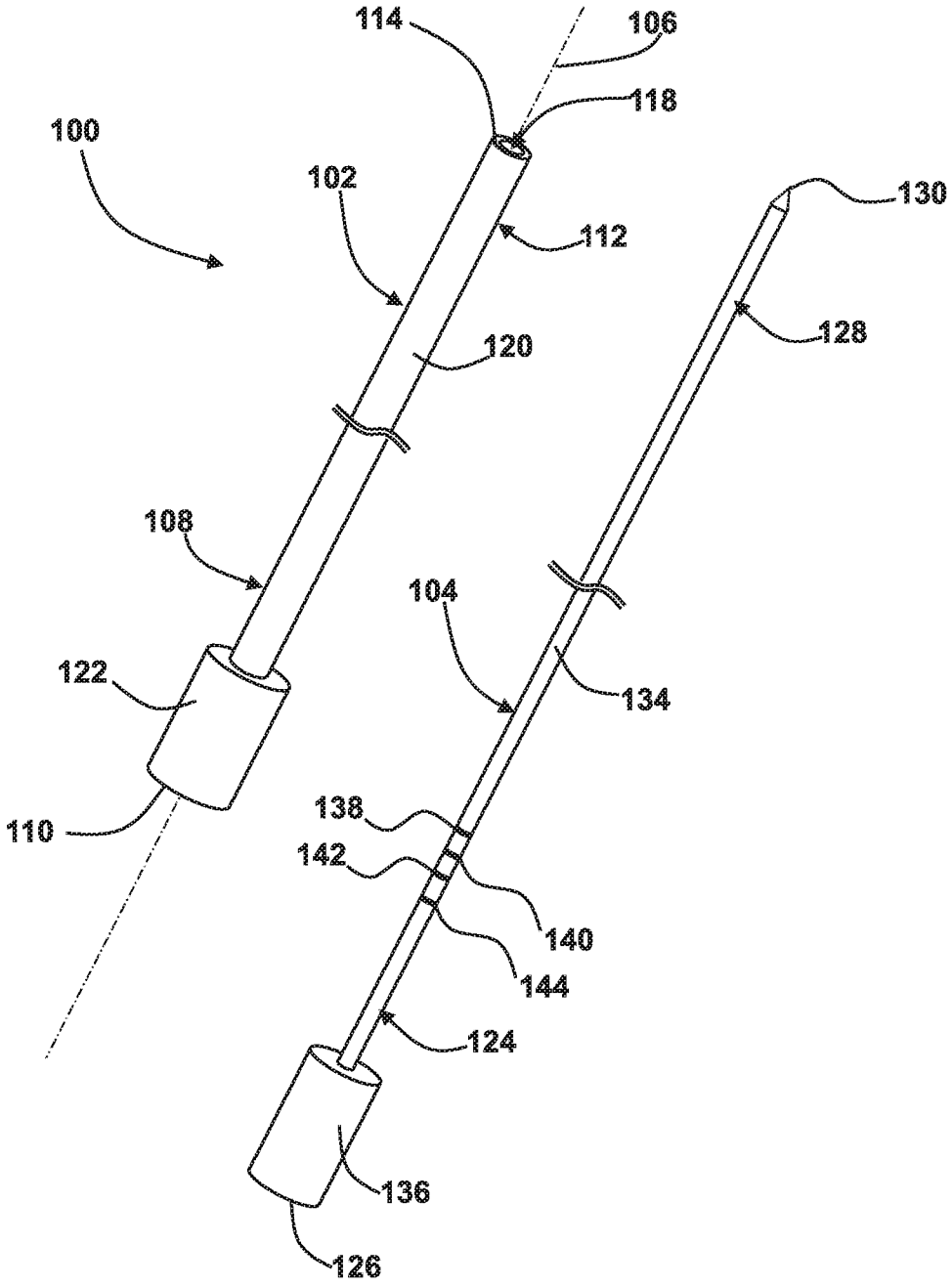
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FIGURE 2

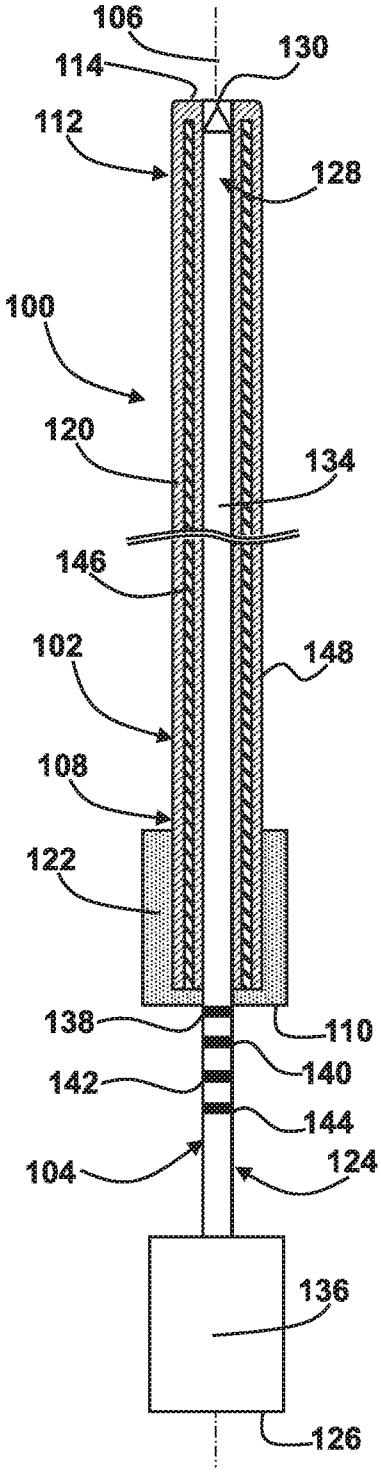

FIGURE 3

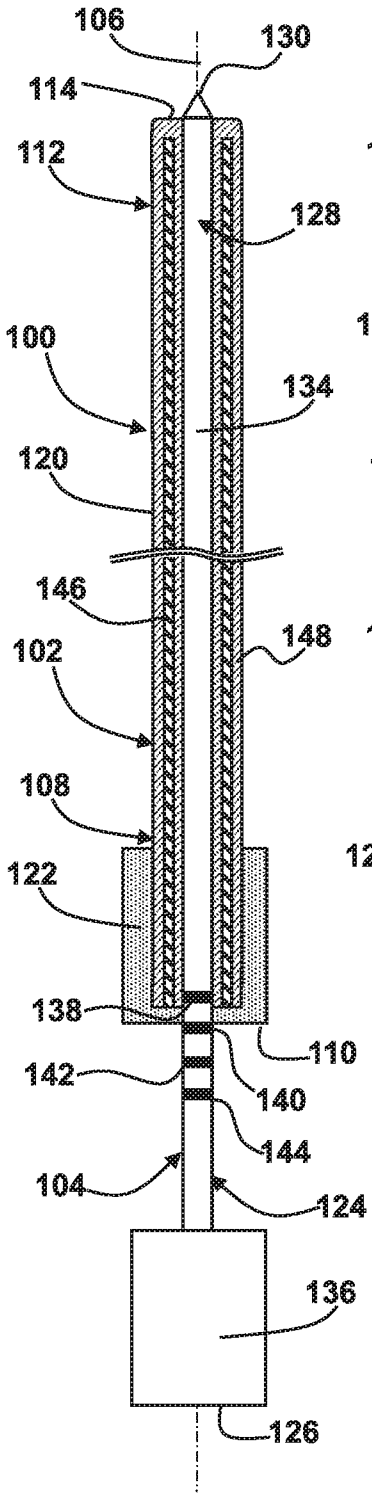

FIGURE 4

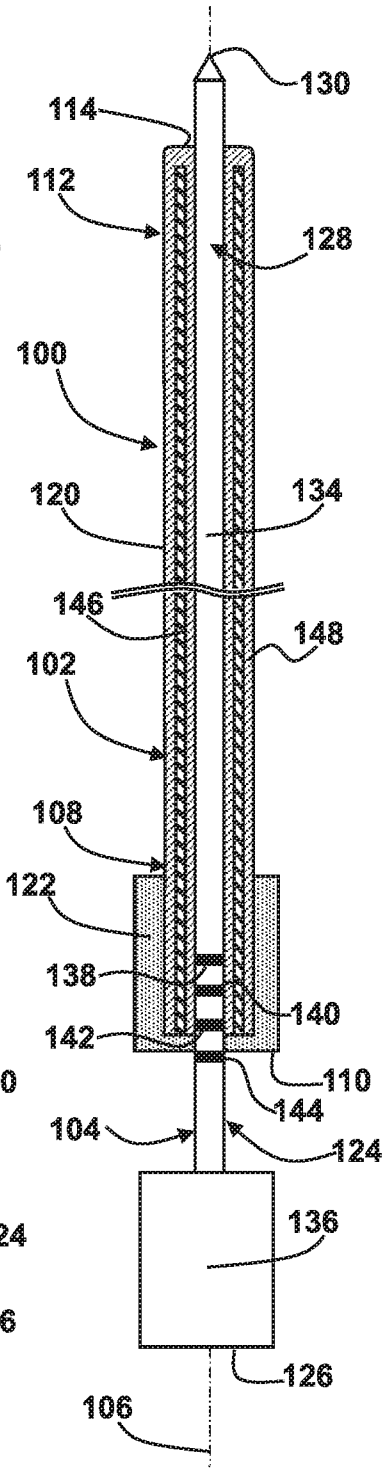

FIGURE 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2021/056361

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/34(2006.01)i; **A61B 90/00**(2016.01)i; **A61B 17/00**(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)

A61B 17/34(2006.01); A61B 17/00(2006.01); A61B 17/32(2006.01); A61B 90/00(2016.01)

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: pericardial puncture, introducer, needle, medical device, depth marker, metallic hypotube, polymeric coating

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008-0275481 A1 (SCARPONE, MICHAEL A.) 06 November 2008 (2008-11-06) paragraphs [0013], [0034]-[0045] and figures 1-4	1-4,6-7,9,11-12
Y		5,8,10,13-21
Y	CN 107095708 A (PIZHOU DONGDA HOSPITAL) 29 August 2017 (2017-08-29) paragraphs [0001], [0030] and figures 1, 6	5,15-21
Y	EP 3403603 A1 (CONTRACT MEDICAL INTERNATIONAL G.M.B.H.) 21 November 2018 (2018-11-21) paragraph [0034] and figure 5	8
Y	US 10278725 B2 (ZELTZER et al.) 07 May 2019 (2019-05-07) column 7, lines 13-19 and figure 7	10,13-14
A	CN 210931724 U (MIN, JIE) 07 July 2020 (2020-07-07) paragraph [0044] and figures 2-3	1-21

☐ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

* Special categories of cited documents:
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"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
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