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(54) Title: A SUTURING DEVICE

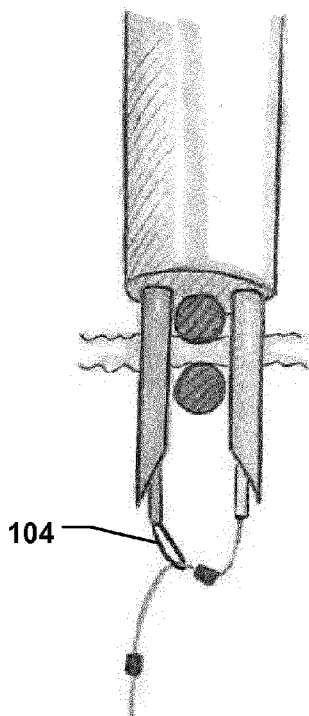


Fig. 1e

(57) Abstract: A suturing device is disclosed, comprising a sheath extending in a longitudinal direction, a retrieval catheter having a retrieval unit at a distal end thereof, said retrieval catheter extending from said sheath, a suture delivery catheter extending from said sheath, a suture being deliverable from a distal opening of said suture delivery catheter at a distal end thereof, a distal end of said sheath being positionable towards a proximal part of an implant in said longitudinal direction, said retrieval unit and said suture being positionable to extend beyond a distal part of said implant in said longitudinal direction, said retrieval unit is configured to capture said suture, whereby said suture can be pulled towards said retrieval catheter to form a bridge with said suture across said distal part of said implant between said suture delivery catheter and said retrieval catheter. A method of suturing an implant to a target site is also disclosed.



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:**Declarations under Rule 4.17:**

— *of inventorship (Rule 4.17(iv))*

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

A suturing device

Technical Field

5 The present invention generally relates to the field of attaching implants to tissue. More particularly, the invention relates to a suturing device for fixating an annuloplasty implant to a heart valve annulus, and a related method.

10 Background

Diseased mitral valves frequently need repair to function properly. The mitral valve leaflets or supporting chordae may degenerate and weaken or the annulus may dilate leading to valve
15 leak (valve insufficiency). Mitral valve repair is frequently performed with aid of an annuloplasty ring or helix, used to reduce the diameter of the annulus, or modify the geometry of the annulus in any other way. In some procedures the annuloplasty ring is fixated around the annulus of the valve.

20 Previous suturing devices for implants, such as annuloplasty implants, have disadvantages that makes it difficult to suture in the correct position, thereby resulting insufficient suturing strength, and also in a very time consuming procedure, which increases the risks for the patient. Previous suturing devices
25 are also not sufficiently compact for catheter based procedures.

Further, devices and clips in the prior art are not suitable for annuloplasty implants such as helix rings that are to be positioned on either side of a heart valve. Such device would not provide sufficient fixation of such implant and lead to traumatic
30 effects since the fixation structure must ensure the correct position of the device over time.

The above problems may have dire consequences for the patient and the health care system. Patient risk is increased.

Hence, an improved device for attaching annuloplasty implants
35 such as helix rings would be advantageous and in particular

allowing for avoiding more of the above mentioned problems and compromises, and in particular allowing for ensuring long-term functioning, a less complex procedure, and increased patient safety. A related method would also be advantageous.

5

Summary

Accordingly, examples of the present invention preferably seeks to mitigate, alleviate or eliminate one or more
10 deficiencies, disadvantages or issues in the art, such as the above-identified, singly or in any combination by providing a device according to the appended patent claims.

According to a first aspect a suturing device is provided, comprising a sheath extending in a longitudinal direction, a
15 retrieval catheter having a retrieval unit at a distal end thereof, said retrieval catheter extending from said sheath, a suture delivery catheter extending from said sheath, a suture being deliverable from a distal opening of said suture delivery catheter at a distal end thereof, a distal end of said sheath
20 being positionable towards a proximal part of an implant in said longitudinal direction, said retrieval unit and said suture being positionable to extend beyond a distal part of said implant in said longitudinal direction, said retrieval unit is configured to capture said suture, whereby said suture can be pulled towards
25 said retrieval catheter to form a bridge with said suture across said distal part of said implant between said suture delivery catheter and said retrieval catheter.

According to a second aspect a method of suturing an implant to a target site is provided, comprising; positioning a retrieval
30 catheter at a first side of said implant, said retrieval catheter having a retrieval unit; positioning a suture delivery catheter at a second side of said implant, opposite said first side; delivering a suture from said suture delivery catheter; capturing said suture with said retrieval unit beyond a distal portion of
35 said implant, to form a bridge with said suture across said distal part of said implant between said suture delivery catheter

and said retrieval catheter; withdrawing said retrieval unit and said suture delivery catheter to suture said implant to tissue.

Further examples of the invention are defined in the dependent claims, wherein features for the second aspect of the disclosure are as for the first aspect mutatis mutandis.

Some examples of the disclosure provide for securing long-term functioning and position of an annuloplasty implant.

Some examples of the disclosure provide for less complex fixation procedures of an annuloplasty implant.

Some examples of the disclosure provide for a reduced risk of damaging the anatomy such as the CS.

Some examples of the disclosure provide for secure fixation of annuloplasty implants while ensuring an atraumatic procedure.

Some examples of the disclosure provide for secure fixation of an annuloplasty implant on either side of a heart valve.

Some examples of the disclosure provide for increased accuracy when attaching a suture to a beating heart.

Some examples of the disclosure provide for a more secure attachment with a suture and improved fixation of annuloplasty rings having different diameters.

Some examples of the disclosure provide for a more compact suturing device.

Some examples of the disclosure facilitates placing the sutures at the correct position.

It should be emphasized that the term "comprises/comprising" when used in this specification is taken to specify the presence of stated features, integers, steps or components but does not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

Brief Description of the Drawings

These and other aspects, features and advantages of which examples of the invention are capable of will be apparent and elucidated from the following description of examples of the

present invention, reference being made to the accompanying drawings, in which

Figs. 1a-g are a schematic illustrations of an example of a suturing device;

5 Figs. 2a-b are a schematic illustrations of an example of a suturing device;

Figs. 3a-c are a schematic illustrations of an example of a suturing device;

10 Figs. 4a-f are a schematic illustrations of an example of a suturing device; and

Fig. 5 is a flow-chart illustrating a method of suturing an implant according to one example.

Detailed description

15

Specific examples of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the examples set forth herein; rather, 20 these examples are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the examples illustrated in the accompanying drawings is not intended to be limiting of the 25 invention. In the drawings, like numbers refer to like elements.

The following description focuses on embodiments of the present invention applicable to fixation of annuloplasty implants to valve tissue. However, it will be appreciated that the invention is not limited to this application but may be applied 30 to many other procedures involving attachment of sutures to tissue, including for example fixation of other medical implantable devices or suturing parts of tissue together, in any medical procedure.

Figs. 1a-g, 2a-b, 3a-c, 4a-4 show a suturing device (100) according to one example. Fig. 5 show a flow-chart of a method according to one example.

The suturing device (100) comprises a sheath (101) extending
5 in a longitudinal direction, and a retrieval catheter (102)
having a retrieval unit (104) at a distal end thereof, which is
shown in Fig. 1b. The retrieval catheter extends from said
sheath. The device (100) comprises a suture delivery catheter
10 (103) extending from said sheath. A suture (105) is deliverable
from a distal opening of said suture delivery catheter at a
distal end thereof, which is shown in Figs. 1c-d. The distal end
of said sheath is positionable towards a proximal part of an
implant (400, 400') in said longitudinal direction, which is
shown in Fig. 1a. The retrieval unit and said suture are
15 positionable to extend beyond a distal part of said implant in
said longitudinal direction, which is also shown in e.g. Fig. 1a.
The retrieval unit is configured to capture said suture, whereby
said suture can be pulled towards said retrieval catheter to form
a bridge with said suture across said distal part of said implant
20 between said suture delivery catheter and said retrieval
catheter, which is shown in Fig. 1e-g. This provides for a
compact suturing device that facilitates suturing and fixation of
an implant such as an annuloplasty implant to tissue. It is
particularly easy to suture beneath a tissue wall, such as the
25 annulus of a heart valve, from the opposite side facing the
operator, which otherwise is very cumbersome due to the limited
visibility. The compact suturing device (100) allows it to be
catheter deliverable for a minimally invasive procedure.

The retrieval catheter and/or the suture delivery catheter
30 may comprise a tip portion (108, 109) configured for penetrating
into tissue, which is illustrated in e.g. Fig. 1a. This further
facilitates the positioning of the retrieval catheter and/or the
suture delivery catheter.

The retrieval catheter and said suture delivery catheter may
35 be separated by a radial distance (110), substantially
perpendicular to said longitudinal direction, corresponding at
least to a width of said implant, whereby said retrieval catheter

and said suture delivery catheter are being positionable on either side of said implant in said radial direction, which is illustrated in e.g. Fig. 1a. This advantageously provides for easy positioning of the device 100 in the correct position over the implant.

The retrieval unit may comprise a loop 104 for circumflexing said suture, which is illustrated in Figs. 1b-f. In these examples, the loop 104 is positioned around the suture delivery catheter before the suture is delivered, which facilitates the procedure.

The retrieval unit may comprise a magnet, and said suture may comprise a metal portion to be attracted by said magnet. This is also a possible and convenient method of retrieving the suture.

The retrieval unit, and/or said retrieval catheter may be movable towards said suture delivery catheter across said distal part of the implant, after having pierced tissue. This facilitates retrieving or capturing elements, such as a suture, delivered from the suturing catheter.

The suture delivery catheter may alternatively, or in addition, be movable towards said retrieval unit and/or said retrieval catheter across said distal part of the implant, after having pierced tissue. This also facilitates retrieving or capturing elements delivered from the opposite catheter.

The retrieval unit may comprise a shape memory material being resiliently biased to move towards said suture delivery catheter when being pushed out from said retrieval catheter, which is illustrated in e.g. Fig. 1b. The material may be NiTiNol or any other material that can be heat-set to a predefined shape. This facilitates positioning of the retrieval unit.

The retrieval catheter and said suturing catheter may be independently movable in said longitudinal direction. This allows for accurate control of the suturing procedure.

The suture may comprise a distal increased diameter portion (107) to be captured by said retrieval unit, shown in Fig. 1c.

The retrieval unit can thereby easily pull in the suture, without having to rely on friction.

The suture may comprise a proximal increased diameter portion (107') to be engaged by a pusher (106) movable inside said suture delivery catheter, for pushing said suture distally from said suture delivery catheter, shown in Figs. 1c-d. Thus the suture
5 can be easily pushed out of the catheter.

The retrieval catheter and said suture delivery catheter may extend at least a distance from said sheath corresponding to the length of said implant between said proximal and distal portions thereof. Fig. 1a show as an example an annuloplasty ring having
10 two rings 400, 400' on either side of the tissue wall (cross-sectional view of a section of the ring). The two rings can thereby be provided in a coiled configuration, i.e. helix configuration. The suture delivery catheter and retrieval catheter penetrate the tissue wall and extend past the ring on
15 the opposite side of the wall, as illustrated, for suturing from this opposite side. Other types of annuloplasty implants can also be sutured, such as single rings, i.e. having only the ring on one side of the tissue wall of the valve, or even other types of implants where space is limited and suturing must be done with a
20 high degree of control.

The suture delivery catheter may comprise radially displaceable arms (110, 110') holding said suture in a looped shape when in a displaced state outside said suture delivery catheter, shown in Figs. 4b-f. This is another way of providing
25 for a facilitated procedure to capture the suture and form a bridge across the implant.

The retrieval unit may comprise a hook-shaped portion (111) that can engage said looped shape suture to capture a portion thereof, seen in Figs. 4b-e.

30 A method (500) of suturing an implant (400, 400') to a target site according to embodiment is provided. The method (500) is illustrated in Fig. 5. The order in which the steps are described should not be construed as limiting, and the order of the steps may vary depending on the procedure. The method (500) comprises;
35 positioning (501) a retrieval catheter (102) at a first side of said implant, said retrieval catheter having a retrieval unit (104), positioning (502) a suture delivery catheter (103) at a

second side of said implant, opposite said first side, delivering (503) a suture from said suture delivery catheter, capturing (504) said suture with said retrieval unit beyond a distal portion of said implant, which is illustrated in Fig. 3a, to form
5 a bridge with said suture across said distal part of said implant between said suture delivery catheter and said retrieval catheter, which is shown in Fig. 3b, and withdrawing (505) said retrieval unit and said suture delivery catheter to suture said implant to tissue, which is shown in Fig. 3c.

10 The present invention has been described above with reference to specific embodiments. However, other embodiments than the above described are equally possible within the scope of the invention. The different features and steps of the invention may be combined in other combinations than those described. The scope
15 of the invention is only limited by the appended patent claims. More generally, those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will
20 depend upon the specific application or applications for which the teachings of the present invention is/are used.

Claims

1. A suturing device (100) comprising
a sheath (101) extending in a longitudinal direction,
5 a retrieval catheter (102) having a retrieval unit (104) at a
distal end thereof, said retrieval catheter extending from said
sheath,
a suture delivery catheter (103) extending from said sheath,
a suture (105) being deliverable from a distal opening of
10 said suture delivery catheter at a distal end thereof,
a distal end of said sheath being positionable towards a
proximal part of an implant (400, 400') in said longitudinal
direction, said retrieval unit and said suture being positionable
to extend beyond a distal part of said implant in said
15 longitudinal direction,
said retrieval unit is configured to capture said suture,
whereby said suture can be pulled towards said retrieval catheter
to form a bridge with said suture across said distal part of said
implant between said suture delivery catheter and said retrieval
20 catheter.

2. Suturing device according to claim 1, wherein said
retrieval catheter and/or said suture delivery catheter comprises
a tip portion (108, 109) configured for penetrating into tissue,
25

3. Suturing device according to claim 1 or 2, wherein said
retrieval catheter and said suture delivery catheter are
separated by a radial distance (110), substantially perpendicular
to said longitudinal direction, corresponding at least to a width
30 of said implant, whereby said retrieval catheter and said suture
delivery catheter are being positionable on either side of said
implant in said radial direction.

4. Suturing device according to any of claims 1 - 3, wherein
35 said retrieval unit comprises a loop for circumflexing said
suture.

5. Suturing device according to any of claims 1 - 3, wherein said retrieval unit comprises a magnet, and said suture comprising a metal portion to be attracted by said magnet.

5 6. Suturing device according to any of claims 1 - 5, wherein said retrieval unit, and/or said retrieval catheter is movable towards said suture delivery catheter across said distal part, after having pierced tissue.

10 7. Suturing device according to any of claims 1 - 7, wherein said suture delivery catheter is movable towards said retrieval unit and/or said retrieval catheter across said distal part, after having pierced tissue.

15 8. Suturing device according to any of claims 1 - 7, wherein said retrieval unit comprises a shape memory material being resiliently biased to move towards said suture delivery catheter when being pushed out from said retrieval catheter.

20 9. Suturing device according to any of claims 1 - 8, wherein said retrieval catheter and said suturing catheter are independently movable in said longitudinal direction.

25 10. Suturing device according to any of claims 1 - 9, wherein said suture comprises a distal increased diameter portion (107) to be captured by said retrieval unit.

30 11. Suturing device according to any of claims 1 - 10, wherein said suture comprises a proximal increased diameter portion (107') to be engaged by a pusher (106) movable inside said suture delivery catheter, for pushing said suture distally from said suture delivery catheter.

35 12. Suturing device according to any of claims 1 - 11, wherein said retrieval catheter and said suture delivery catheter extend at least a distance from said sheath corresponding to the

length of said implant between said proximal and distal portions thereof.

13. Suturing device according to any of claims 1 - 3, wherein
5 said suture delivery catheter comprises radially displaceable arms (110, 110') holding said suture in a looped shape when in a displaced state outside said suture delivery catheter.

14. Suturing device according to claim 13, wherein said
10 retrieval unit comprises a hook-shaped portion (111) that can engage said looped shape suture to capture a portion thereof.

15. Method (500) of suturing an implant (400, 400') to a target site comprising;
15 positioning (501) a retrieval catheter (102) at a first side of said implant, said retrieval catheter having a retrieval unit (104),
positioning (502) a suture delivery catheter (103) at a second side of said implant, opposite said first side,
20 delivering (503) a suture from said suture delivery catheter, capturing (504) said suture with said retrieval unit beyond a distal portion of said implant, to form a bridge with said suture across said distal part of said implant between said suture delivery catheter and said retrieval catheter,
25 withdrawing (505) said retrieval unit and said suture delivery catheter to suture said implant to tissue.

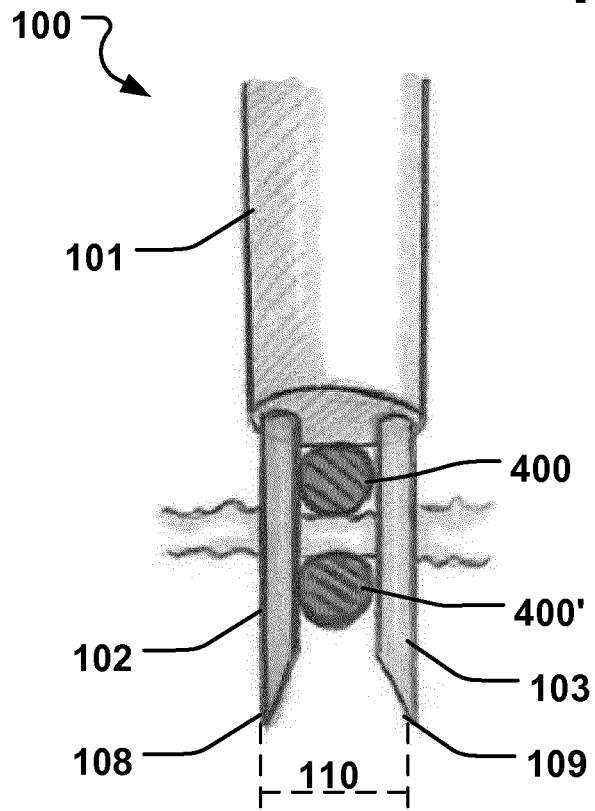


Fig. 1a

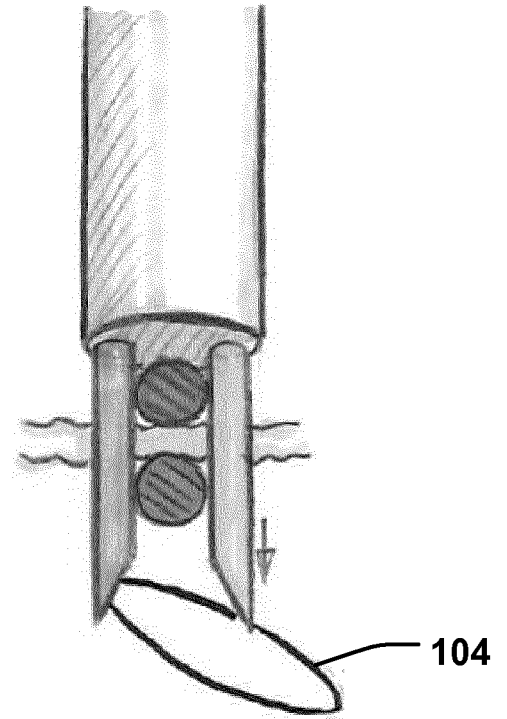


Fig. 1b

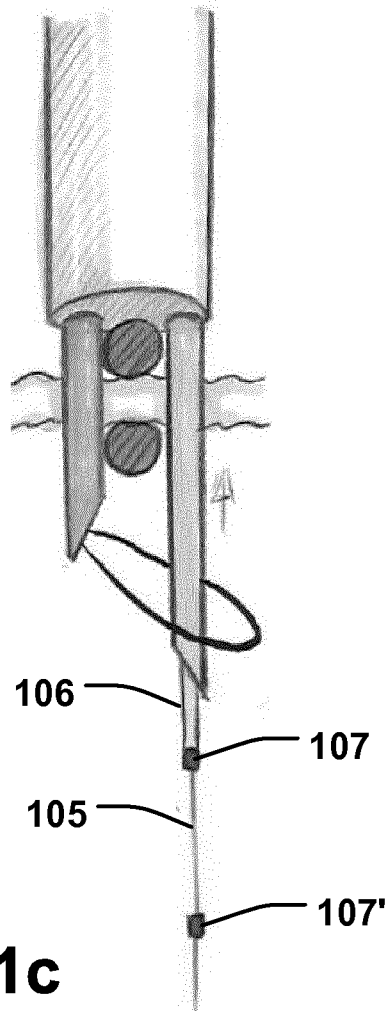


Fig. 1c

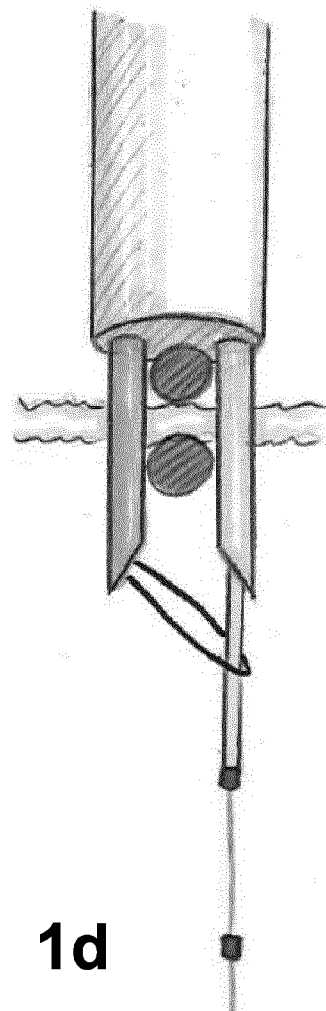


Fig. 1d

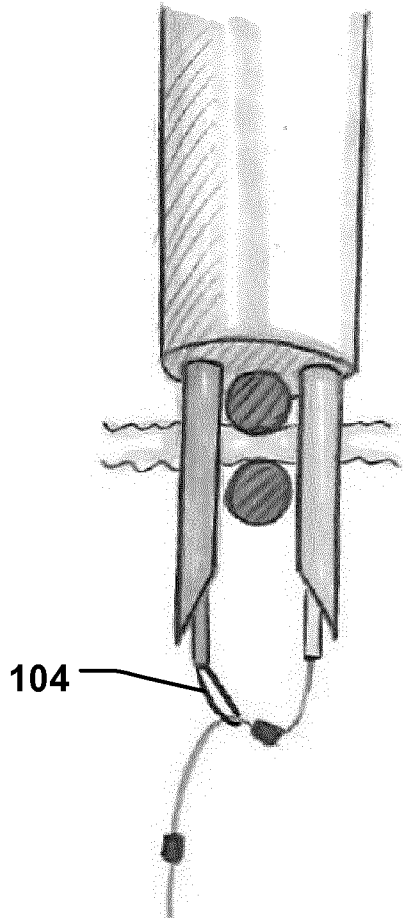


Fig. 1e

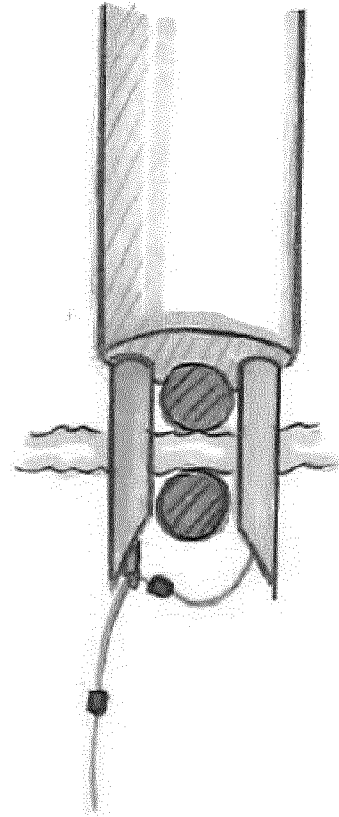


Fig. 1f

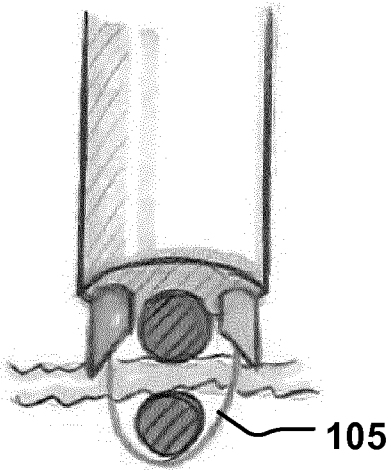


Fig. 1g

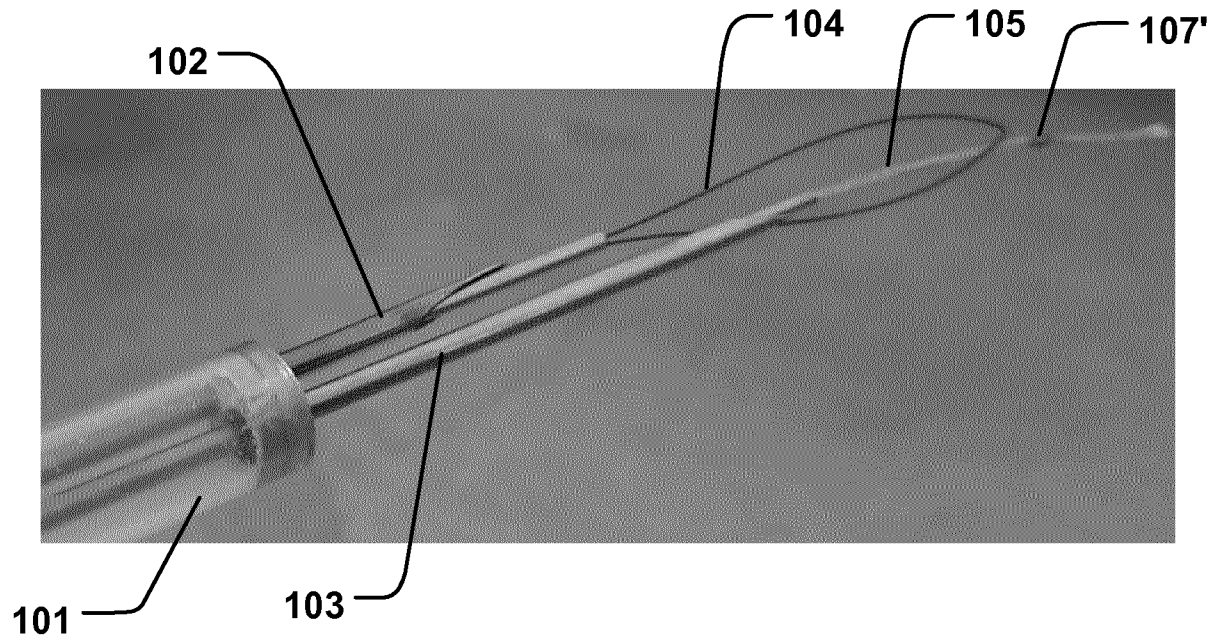


Fig. 2a

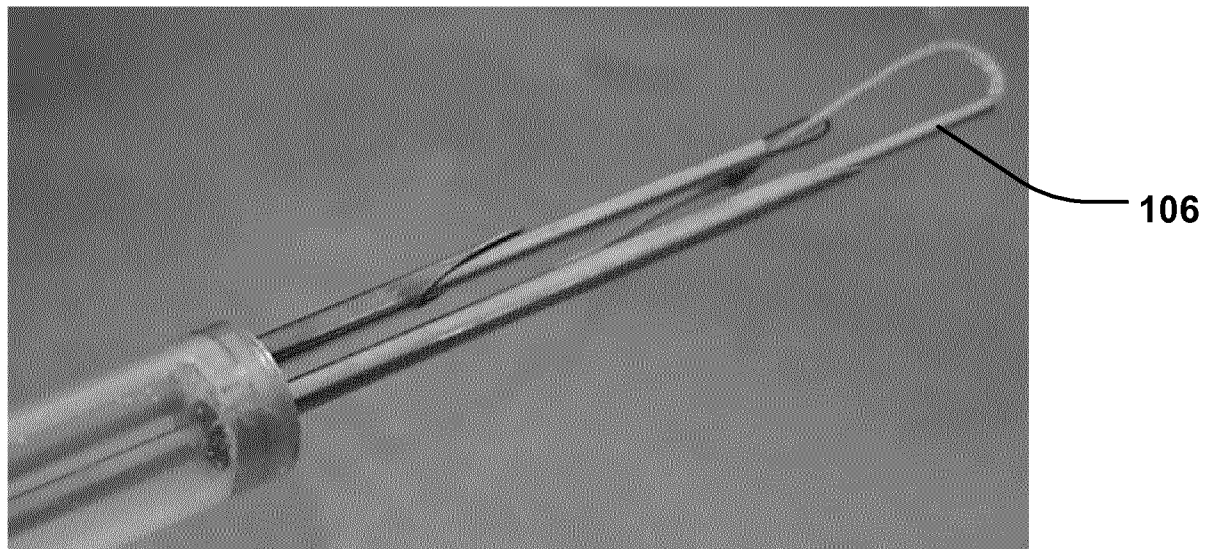


Fig. 2b

Fig. 3a

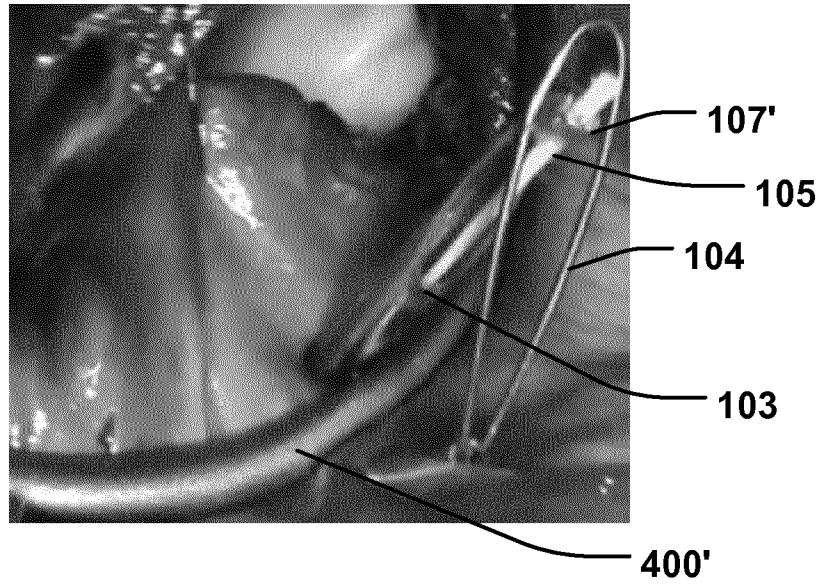


Fig. 3b

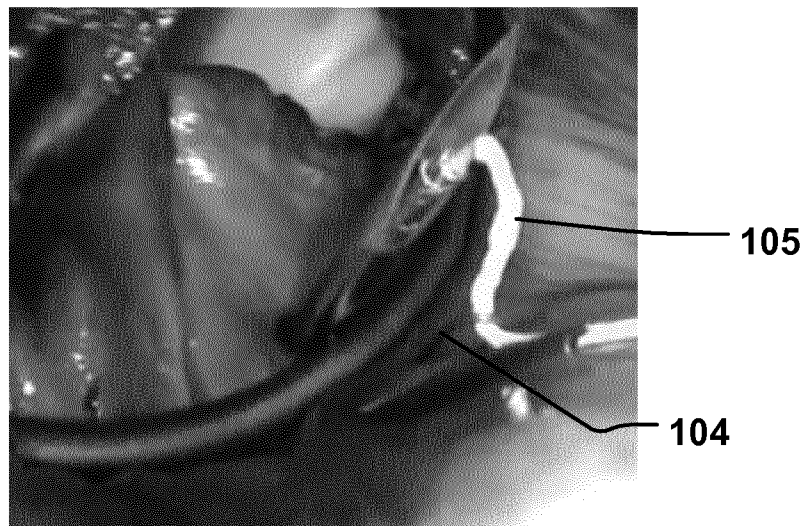
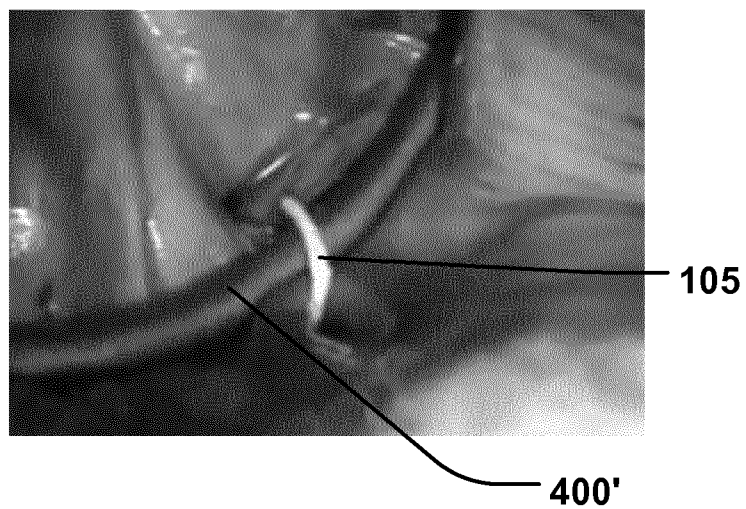
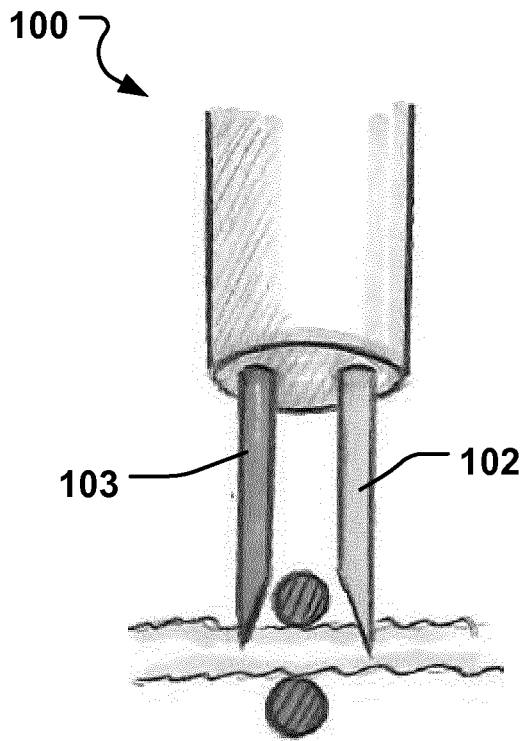
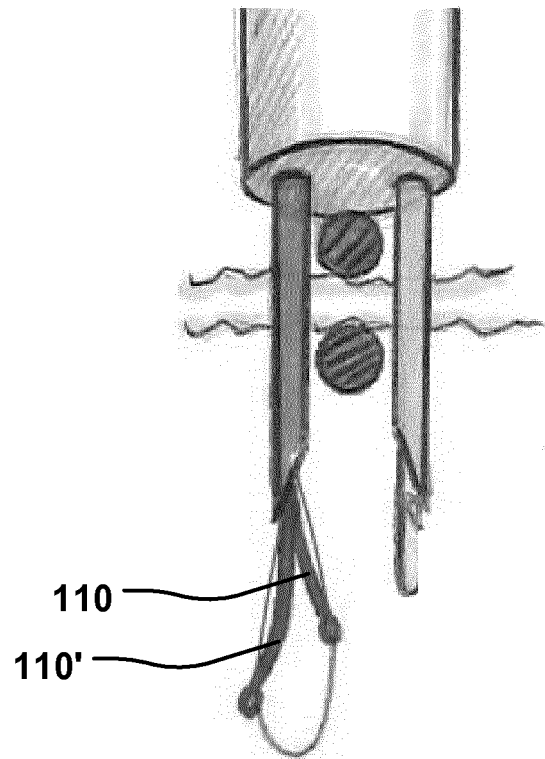
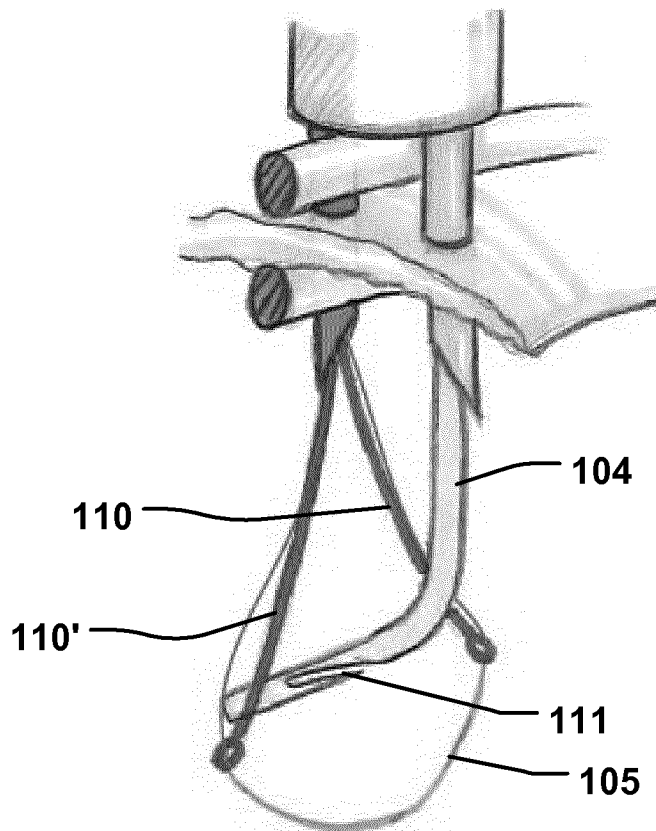


Fig. 3c



**Fig. 4a****Fig. 4b****Fig. 4c**

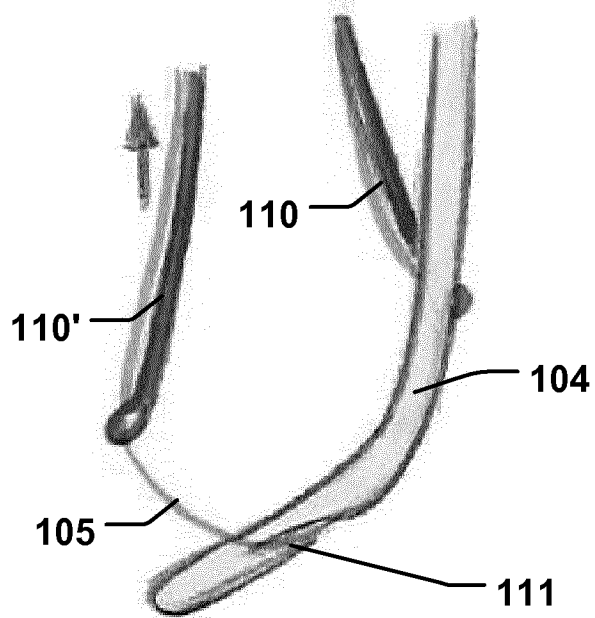


Fig. 4d

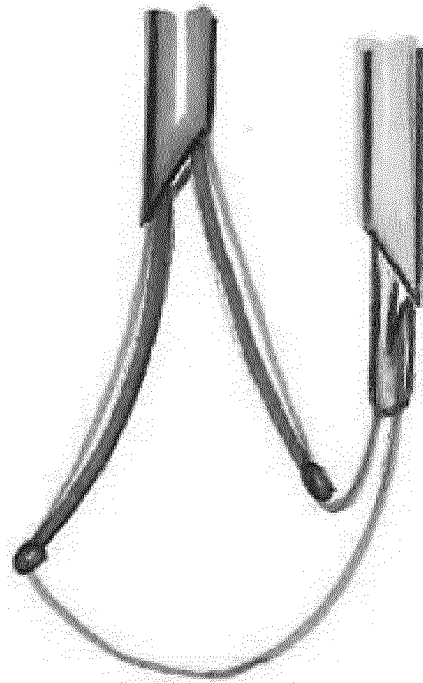


Fig. 4e

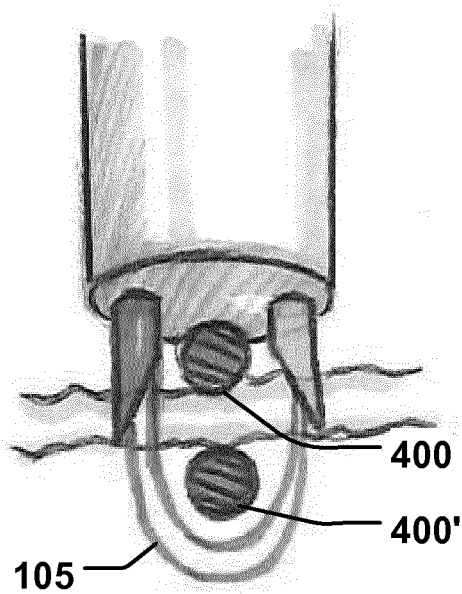
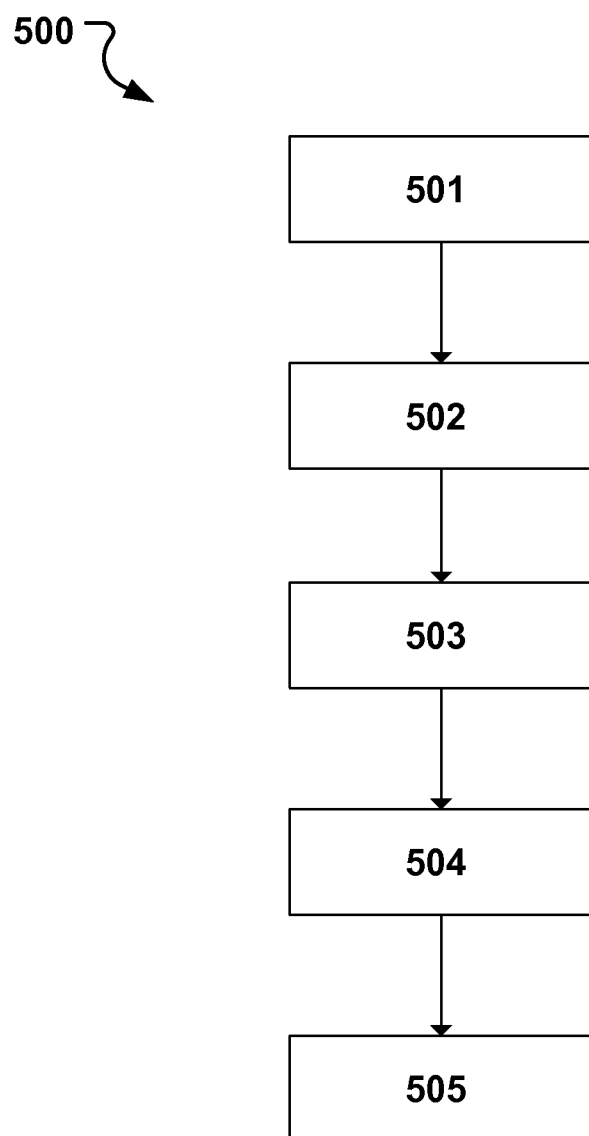


Fig. 4f

**Fig. 5**

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/082509

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04 A61F2/24
ADD.

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 A61F

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/198235 A1 (PIERCE JAVIN CEDRIC [US] ET AL) 5 August 2010 (2010-08-05) the whole document -----	1-14
X	US 2014/275757 A1 (GOODWIN JONATHAN [US] ET AL) 18 September 2014 (2014-09-18) paragraph [0068]; figures 4-9 -----	1-14
X	WO 2013/131925 A1 (HIGHLIFE SAS [FR]) 12 September 2013 (2013-09-12) figures -----	1



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

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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

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Date of the actual completion of the international search

10 April 2017

Date of mailing of the international search report

21/04/2017

Name and mailing address of the ISA/

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Authorized officer

Held, Günter

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2016/082509

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.: 15
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
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:
3. ☐ Claims Nos.:
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 additional 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 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.

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