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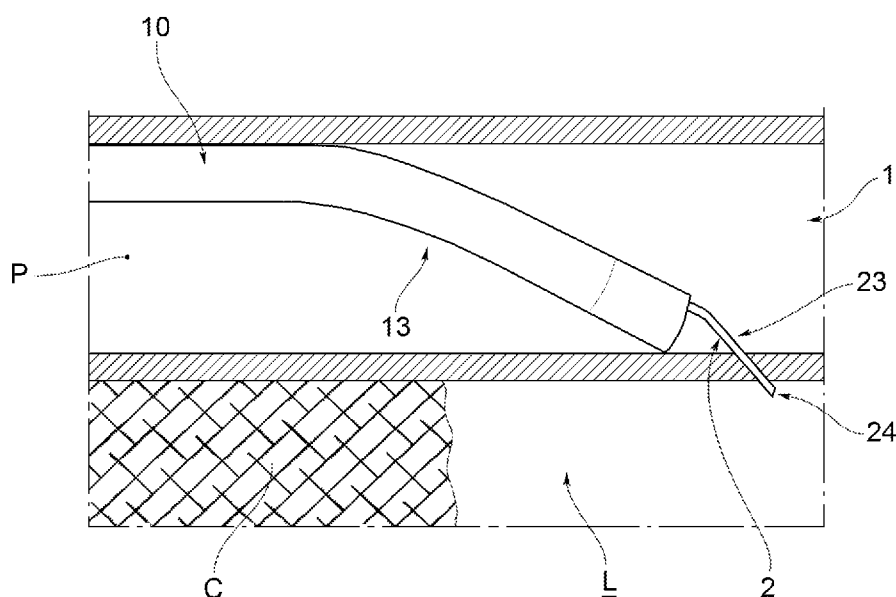


FIG. 5a

(57) Abstract: A re-entry device (1) for recanalization procedures of an arterial vessel by an intraluminal or subintimal technique comprises a catheter (10) having a distal end (12) with a curved tip (13) by an angle (α) of between 30° and 90°, and an angled-tip stylet (2) intended to be inserted into the inner lumen of the catheter (10) to exit from a distal opening (14) thereof. The angled-tip stylet (2) is made of a metal material and has a distal end (22) with a curved tip (23) ending in a sharpened apex (24). In particular, the distal end (22) of the an angled-tip stylet (2) is tapered and has a length of between 3cm and 5cm, and the curved tip (23) is bent by an angle (β) of between 30° and 50°: such a structure makes the apex (24) adjustable also outside the two-dimensional plane defined by the curved tip (13) of the catheter (10) to facilitate the penetration of the arterial wall.

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**"Re-entry device for peripheral arterial recanalization
procedures"**

DESCRIPTION

5 [0001] The present invention refers to a medical device for the recanalization of occluded arterial vessels, especially in lower peripheral districts.

[0002] The present invention can be used in surgery and particularly in minimally invasive procedures, such as
10 endovascular recanalization in challenging areas where the space of manoeuvre is significantly reduced and reaching the target area requires specific skills.

[0003] In particular, the device object of the invention, is intended for use in revascularization procedures in
15 peripheral districts through intraluminal or subintimal technique.

[0004] As well known in the medical field, a chronic total occlusion (CTO) is an obstruction within an arterial lumen, reduces the blood flow within the vessel itself.
20 In some cases it may be difficult if not impossible to pass through such occlusion with a medical device, from an anterograde or retrograde direction, in order to recanalize the vessel. The nature of the occlusion may be markedly calcified making the use of normal guide wires
25 having a diameter of 0.014; 0.018 or 0.035 ineffective.

If direct crossing is impossible, special guide wire techniques have been developed for the creation of a subintimal path (that is, a path through the medial-intimal layer of the arterial vessel wall) that passes
5 outside the occlusion, then returns into the true lumen of the vessel in a point distal to the occlusion, so creating a path suitable to restore the normal blood flow.

[0005] In some cases, also the re-entry in the true lumen
10 from the subintimal space can be difficult without the use of a recanalization devices so making easier and safer the re-entry.

[0006] The aim of the present invention is to solve the problems related to the current state-of-the-art devices
15 also considering specific safety requirements.

[0007] This goal is achieved by using a recanalization device according to claim 1. The dependent claims describe preferred embodiments of the invention.

[0008] Further features and advantages of the invention
20 will appear more clearly from the detailed description of a preferred, non-exclusive embodiment, shown by way of a non-limiting example with the aid of the accompanying drawings, in which:

- figure 1 shows a perspective view of the distal portion
25 of an angled-tip stylet as part the re-entry or,

alternatively, intraluminal crossing device according to the present invention;

- figure 2 shows a perspective view of the distal portion of a guide catheter as part of the re-entry device
5 according to the present invention;

- figures 3a and 3b show the re-entry device during use for a re-entry and particularly the direction of the guide catheter curved tip as function of the needle retraction inside it;

10 - figure 4 shows the re-entry device during an occlusion (CTO) crossing;

- figures 5a and 5b show the re-entry device during use, particularly the re-entry of stylet tip into the true lumen of the arterial vessel, beyond the occlusion;

15 - figure 6 shows the angled-tip stylet 2 inserted into the inner lumen of the catheter 10.

[0009] As shown in the above figures, reference numeral 1 indicates as a whole a re-entry device for recanalization procedures of an arterial vessel through subintimal
20 technique according to the present invention.

[0010] The re-entry device 1 comprises a catheter 10, shown in figure 2 and 4.

[0011] Catheter 10 is configured to be advanced on a traditional guide wire (not shown) to reach the site of
25 intervention that needs to be re-vascularized.

Preferably, the catheter 10 is an OTW (over-the-wire) type having an inner lumen 17 extending across the entire length of catheter 10.

[0012] Catheter 10 comprises a body 11 extending from a proximal portion (not shown) to a distal end 12.

[0013] Body 11, or a portion thereof, is a braided polyamide extruded body having one or more internal inner lumens and preferably one or more side holes.

[0014] The distal end 12 of catheter 10, well illustrated in figure 2, comprises a curved tip 13 ending in a distal opening 14 through which an angled-tip stylet 2 is intended to protrude.

[0015] Catheter 10 is in fact internally provided with an inner lumen 17, extending from the proximal portion to the distal end 12, up to the distal opening 14. A angled-tip stylet 2 is then intended to be inserted into catheter 10, slide along the inner lumen 17 of said catheter 10, up to exit from the distal opening 14, as shown in figures 5a and 5b.

[0016] Preferably, the curved tip 13 is bent by an angle α with respect to the longitudinal axis of catheter 10. Preferably, at rest, or in the absence of an angled-tip stylet 2 inserted into the curved tip 13, angle α is of between 30° and 90° , preferably 60° .

[0017] The distal end 12 is partially flexible, i.e. able to deform. In particular, the curved tip 13 changes its bending degree when an angled-tip stylet 2 is advanced therein.

5 [0018] Advantageously, the curved tip 13 of catheter 10 still retains a minimum angle of curvature (i.e. it does not straightens up completely) also in the presence of an angled-tip stylet 2 inserted therein. Preferably, the minimum angle α is about 30° (figure 5a and 5b). This
10 technical feature allows guiding the angled-tip stylet 2 in the correct direction, i.e. facing towards the vessel wall to be penetrated to return into the true lumen of the vessel.

[0019] As shown in figures 3a and 3b (where the distal end
15 of the angled-tip stylet 2 is indicated with a circle), the advancement of the angled-tip stylet 2 causes a partial straightening of the curved tip 13. Preferably, the advancement of the angled-tip stylet 2 in the curved tip 13 causes a variation of angle α of about 30° .

20 [0020] In an embodiment example, angle α measures at rest (figure 2) about 60° ; advancing the angled-tip stylet 2, the angle α decreases to 50° (figure 3a) and gradually up to about 30° (figure 3b).

[0021] The re-entry device 1 further comprises an angled-
25 tip stylet e 2, whose distal end 22 is shown in figure 1.

[0022] The angled-tip stylet 2 is configured to be advanced within catheter 10 to reach the site of intervention that needs to be revascularized.

[0023] The angled-tip stylet 2 comprises a body 21
5 extending from a proximal portion (not shown) to a distal end 22 (figure 1). The body 21 has a circular section.

[0024] Body 21 is a solid body made of metal. The angled-tip stylet 2 is made of stainless steel, preferably austenitic in an alloy with chromium-nickel. For example,
10 the metal alloy of which the angled-tip stylet is made of about 70% Iron, 20% Chromium, 8% Nickel, 1% Silicon and 1% Manganese. Since the material used to make body 21 determines the flexibility, support and manoeuvrability of the angled-tip stylet 2, the choice to use steel
15 (stainless steel) allows achieving a more easily manoeuvrable and stiffer stylet.

[0025] Preferably, body 21 of the angled-tip stylet 21 has a Teflon (PTFE) coating.

[0026] Body 21 of the angled-tip stylet 2 has an outer
20 diameter in inches of 0.018in or in millimeters of 0.45mm or 0.014in, i.e. 0.35mm. Considering that the larger the diameter, the greater the support provided, a 0.018in body 21 ensures better rotation capability (torquability) of the angled-tip stylet 2.

[0027] Preferably, the angled-tip stylet 2 has an overall length of about 200.

[0028] The distal end 22 of the angled-tip stylet 2 is tapered, i.e. the diameter is reduced towards the distal tip. In particular, the outer diameter decreases by about 45%. For example, in the case of a 0.018in body 21, the outer diameter changes from 0.45mm to 0.20mm at apex 24. Considering that the penetration capacity of the distal end 22 of the angled-tip stylet 2 is a function of its rigidity and its cross sectional area, a minimum diameter of 0.20mm imparts greater thrust force to traverse the vessel wall and to return into the true lumen.

[0029] Moreover, the tapered distal end 22 has a length of between 3cm and 5cm, preferably 4 cm. Considering that the distal end of the angled-tip stylet 2 is the most flexible portion that affects the maneuverability thereof, a shortened distal end increases the transmission of force and makes the angled-tip stylet 2 more manoeuvrable.

[0030] The distal end 22 of the angled-tip stylet 2, well illustrated in figure 1, comprises a curved tip 23 ending in an apex 24.

[0031] Preferably, the curved tip 23 is bent by an angle β with respect to the longitudinal axis of the angled-tip stylet 2. Preferably, angle β is of between 30° and 50°,

preferably between 40° and 45°. This technical feature allows easily directing apex 24 of the angled-tip stylet 2 in the desired direction, i.e. facing towards the vessel wall to be penetrated in order to return into the
5 true lumen of the vessel.

[0032] Apex 24 of the curved tip 23 of the angled-tip stylet 2 is sharp to facilitate the penetration of the vessel wall.

[0033] Apex 24 of the curved tip 23 of the angled-tip
10 stylet 2 may have different geometries: conical, rounded, pyramid.

[0034] Preferably, the sharpened angle of apex 24 is oriented parallel to the longitudinal axis of body 21 of the angled-tip stylet 2 (as shown in figure 6), to do not
15 penetrate into the wall of the inner lumen 17 of the catheter during the advancement.

[0035] Preferably, the curved tip 23 of the angled-tip stylet 2 has a Teflon (PTFE) coating, an extension of the coating applied on body 21.

20 [0036] Preferably, the curved tip 23 of the angled-tip stylet 2 has a coating of a radiopaque, abrasion-resistant metal material, such as platinum or gold.

[0037] Preferably, the distal end 22 of the angled-tip stylet is devoid of radiopaque hydrophilic polymer

coating so preventing such a coating from detachment when directing apex 24 to reach the lumen of the vessel.

[0038] The re-entry device 1 can therefore operate along a two-dimensional plane (2D) if the curved tip 23 of the
5 angled-tip stylet 2 is in the same plane as the curved tip 13 of catheter 10 (as shown in figures 5a and 5b).

[0039] However, unlike known devices, since the angled-tip stylet 2 is provided with its own torquability even when inserted within lumen 17 of catheter 10, the curved tip
10 23 provided with sharpened apex 24 may be in turn directed towards the desired direction, also outside the two-dimensional plane in which the curved tip 13 of catheter 10 is. The re-entry device 1 is therefore a three-dimensional system (3D) in which catheter 10 imparts to
15 the angled-tip stylet 2 a first direction in the plane, but in which the angled-tip stylet 2 itself can be oriented taking three-dimensional advancement properties. This technical feature, absent in the known and commercially available re-entry systems, greatly
20 increases the direction possibilities and facilitates the re-entry into the true vessel lumen beyond the occlusion.

[0040] This capability is further improved by the crossability (ability to cross the stenosis) and pushability (ability to transmit thrust) features of the

angled-tip stylet 2, along with its great penetration capability provided by the stiff sharpened curved tip 23.

[0041] It is noted that the angled-tip stylet 2 is designed in particular for peripheral revascularization procedures: it is provided with a larger diameter that ensures greater capacity of rotation; it is made of a material (stainless steel) making it easily manoeuvrable; it has a short distal end that increases the transmission of force and has a high penetration capacity.

10 [0042] In an embodiment example, the re-entry device 1 comprises:

- a catheter 10 having outer diameter 4Fr (i.e. 1.35mm), inner diameter 0.042in (i.e. 1mm), length 100cm, with curved tip 13 with angle α of between 45° and 90° , with
15 braided body 11;

- an angled-tip stylet 2 having a body 21 with 0.018in or 0.014in outer (0.45mm or 0.35mm), made of stainless steel (preferably austenitic in alloy with chromium-nickel), with tapered distal end 22 for a length of 4cm, curved
20 tip 23 with angle β of 45° , sharpened apex 24.

[0043] The re-entry technique is now described in the peripheral arterial recanalization with subintimal technique, through antegrade homolateral femoral route using a re-entry device 1 comprising a catheter 10 and an
25 angled-tip stylet 2 as described above.

[0044] The recanalization technique of a peripheral arterial vessel by sub-intimal route is routinely used in extended occlusions, also with varying degrees of calcification.

5 [0045] Through antegrade femoral route, a catheter 10 is advanced towards the beginning of occlusion C as described above and depicted in figure 2 and 4 (i.e., an angiographic catheter, provided with support, angled tip, 4F or 1.35 mm), on a first guide wire (i.e. steel, with
10 outer Teflon-coated coil, flexible straight tip, gauge 0.035in or 0.89mm).

[0046] The occlusion is tested using short advancing movements of the traditional guide wire until resistance is encountered that prevents the correct advancement
15 thereof.

[0047] The first guide wire is then replaced with a second guide wire (made of nitinol, with hydrophilic polymer coating, flexible J-curved tip, preferably of 1.5 mm radius, gauge 0.035in; or for tibial arteries, with stiff
20 guide wire, 0.014in gauge with hydrophilic polymer tip).

[0048] The advancement of the second guide wire in the occlusion leads to the bending of the distal floppy end of the guide wire itself, so forming a loop due to the increased flexibility of the distal segment thereof.

[0049] The loop of the distal end of the second guide wire travels into the thickness of the arterial wall of the occluded vessel tract, virtually between the intimae and the adventitia, ideally beneath the intima.

5 [0050] During the advancement, if at the end of the occluded vessel has a large lumen without significant calcification of the arterial wall, the loop of the second guide wire is usually able to spontaneously jump into the true lumen.

10 [0051] Unfortunately this lucky event cannot be predicted with certainty, depending on the degree of fibrosis and calcification of the vessel segment at the end of the occlusion which prevents the immediate return.

[0052] In this case, the loop of the second guide wire is
15 advanced up to the level where the lumen is reconstituted, followed by the support catheter 10.

[0053] The second guide wire is then removed and an angled-tip stylet 2 according to the invention is inserted into the catheter 10 (gauge 0.018in or 0.014in).

20 [0054] The tip of catheter 10 is then oriented towards the vessel lumen with the distal opening 14 facing the arterial wall to be punctured in order to return into the lumen L.

[0055] The angled-tip stylet 2 is then advanced within
25 catheter 10 to reach the distal end 12 thereof. The

further advancement of the angled-tip stylet 2 inside the curved tip 13 of catheter 10 modifies the bending thereof up to reach the minimum angle α (e.g. 30°). The correct position of the tip is verified using angiograms at a
5 mutual angle of 90° .

[0056] Keeping catheter 10 in place, the angled-tip stylet 2 is advanced (in the plane of the curved tip 13) up to exit from the distal opening 14 of catheter 10.

[0057] Due to its high torqueability, the angled-tip stylet
10 2 can be oriented along three dimensions (also outside the plane of the curved tip 13) so as to be easily directed towards the wall of the vessel to be pierced to return into lumen L (figure 5a). The angled-tip stylet 2 is then rotated to direct the tip 23 thereof along
15 different planes than those of catheter 10 so as to cross the subintimal space, reach the vessel lumen and advance by a few centimeters along the same.

[0058] The angled-tip stylet 2 easily pierces, due to the short, hard curved tip 23 provided with sharp apex 24,
20 the part of the vessel and penetrates lumen L of the vessel.

[0059] At this point, once the access to lumen L of the vessel has been achieved, catheter 10 can be removed, and a dilatation catheter (over-the-wire or rapid exchange
25 type) with short balloon (for example with a diameter of

between 2mm and 4mm and length of about 3-6cm) is fitted on the angled-tip stylet 2 (from the proximal direction) and advanced up to reach the tip of the angled-tip stylet 2. If the advance thereof is too difficult, the balloon is inflated to expand the path towards the lumen of the vessel.

[0060] At this point, the angled-tip stylet 2 is replaced with a support guide wire (such as coronary, with soft tip, gauge 0.014in or 0.018in) to reach the Popliteal or Tibial tract and used for a greater dilatation of the path with a balloon catheter having greater length and diameter.

[0061] If the artery to be treated is femoral or popliteal, catheter 10 according to the invention is again fitted onto this guide wire, then the support guide wire is replaced with an exchange guide wire (0.035in). At this point, catheter 10 is again removed and a dilatation catheter (such as over-the-wire type) with long balloon (for example, with a diameter of about 5-6mm and length of 20cm) is inserted in its place and inflated to complete the procedure according to the operator's choices.

[0062] The present invention also relates to a peripheral arterial vessel recanalization method by sub-intimal route using a re-entry device 1 as described and

represented above. This method involves the following steps:

- advancing catheter 10 into the thickness of the arterial wall of the occluded vessel tract, up to the level where the lumen is reconstituted and adjusting the tip of catheter 10 so that the distal opening 14 is facing the arterial wall to be pierced to return into lumen L;
- advancing an angled-tip stylet 2 into lumen 17 of catheter 10 up to the distal tip 12 thereof;
- changing the bending of the curved tip 13 of catheter 10 up to reach the minimum angle α ;
- making the angled-tip stylet 2 exit from the distal opening 14 of catheter 10 and directing it three-dimensionally towards the vessel wall up to pierce, through the curved tip 23 provided with sharpened apex 24, the part of the vessel and penetrate into lumen L of the vessel;
- completing the recanalization of the vessel.

[0063] Moreover, such a recanalization method, in order to advance catheter 10 into the thickness of the arterial wall of the occluded vessel tract, provides for the following steps:

- advancing catheter 10 through anterograde femoral route towards the beginning of occlusion C on a first guide

wire (steel, Teflon-coated outside, flexible straight tip, gauge 0.035in);

- replacing the first guide wire with a second guide wire (nitinol, hydrophilic polymer coating, flexible J-curve

5 tip, gauge 0.035 in);

- advancing the second guide wire into the occlusion until its distal end bends, thus forming a loop which travels into the thickness of the arterial wall of the occluded tract of the vessel up to the level where the

10 lumen is reconstituted.

- removing the second guide wire.

[0064] Moreover, such a recanalization method, in order to complete the recanalization of the vessel, provides for the following steps:

15 - removing catheter 10 and fitting a short balloon dilatation catheter on the angled-tip stylet 2;

- inflating the balloon to expand the path towards the lumen of the vessel;

- replacing the angled-tip stylet 2 with a support guide wire (soft tip, gauge 0.014in or 0.018in) to reach the

20 popliteal or tibial tract.

[0065] Moreover, if the artery to treat is femoral or popliteal, the method finally provides for:

- removing the dilatation catheter and fitting catheter

25 10 according to the invention on the support guide;

- replacing the support guide wire with a change guide wire (0.035 in);
- removing catheter 10 and fitting a long balloon dilatation catheter on the support guide wire 2;
- 5 - inflating the balloon to complete the vessel recanalization.

[0066] It is noted that in order to meet the safety requirements, it is important that prior to each advancement of the angled-tip stylet 2, the correct
10 direction of the curved tip 23 must be checked by two orthogonal projections (90°) with contrast medium injection from the femoral introducer sheath.

[0067] It is also noted that the use of the re-entry technique through contralateral femoral route (crossover)
15 is not recommended due to the numerous curves that the system would have, which does not allow a safe and predictable directionality thereof, thus exposing to the risk of complications. The latter, which would possibly be determined by an instrument having a diameter slightly
20 greater (0.35mm) or less than twice (0.45mm) than an insulin needle (0.27mm), which is the smallest needle available, would obviously be very little, if non-existing.

[0068] Innovatively, a re-entry device 1 according to the
25 present invention is a system orientable three-

dimensionally that allows rapid advance towards the true lumen of the vessel.

[0069] Advantageously, a re-entry device 1 according to the present invention can be used in revascularization
5 procedures in peripheral districts through subintimal technique, thus facilitating the penetration step of the vessel wall for a correct return into the true lumen beyond the occlusion and making it safer.

[0070] It is clear that a man skilled in the art might make
10 changes and variations to the re-entry system described above, all falling within the scope of protection as defined in the following claims.

Claims

1. Re-entry device (1) for arterial vessel recanalization procedures by an intraluminal or subintimal technique, comprising:

5 - a catheter (10) provided with a body (11) extending from a proximal portion to a distal end (12); said body (11) having an inner lumen ending distally in a distal opening (14); said distal end (12) being provided with a curved tip (13) bent by an angle (α) of between 30° and
10 90° with respect to the longitudinal axis of the body (11);

- an angled-tip stylet (2), intended to be inserted into the inner lumen of the catheter (10) to exit from the distal opening (14), having a body (21) of a metal
15 material, extending from a proximal portion to a distal end (22); said distal end (22) comprising a curved tip (23) ending in a sharpened apex (24);

wherein said distal end (22) of the angled-tip stylet (2) is tapered and has a length of between 3 cm and 5 cm, and
20 the curved tip (23) is bent by an angle (β) of between 30° and 50° with respect to the longitudinal axis of the body (21) so that the apex (24) of the angled-tip stylet (2) is also adjustable outside the two-dimensional plane defined by the curved tip (13) of the catheter (10) in
25 order to facilitate the penetration of the arterial wall.

2. Re-entry device (1) according to claim 1, wherein the body (21) of the angled-tip stylet (2) is a solid body, made of stainless steel, preferably austenitic in an alloy with chromium-nickel.

5 3. Re-entry device (1) according to claim 1 or 2, wherein the body (21) of the angled-tip stylet (2) has an outer diameter of 0.45mm, or 0.35mm.

4. Re-entry device (1) according to any of the previous claims, wherein the outer diameter of the distal end (22)
10 of the angled-tip stylet (2) decreases by about 45%.

5. Re-entry device (1) according to any of the previous claims, wherein the outer diameter of the distal end (22) of the angled-tip stylet (2) decreases from 0.45mm to 0.20mm at the apex (24).

15 6. Re-entry device (1) according to any of the previous claims, wherein the tapered distal end (22) of the angled-tip stylet (2) has a length of about 4cm.

7. Re-entry device (1) according to any of the previous claims, wherein the angle (β) of the curved tip (23) of
20 the angled-tip stylet (2) is of between 40° and 45°.

8. Re-entry device (1) according to any of the previous claims, wherein the advance of the angled-tip stylet (2) into the curved tip (13) of the catheter (10) causes a reduction of the angle (α) by about 30°.

25 9. Re-entry device (1) according to any of the previous

claims, wherein the curved tip (13) of the catheter (10) retains a minimum angle (α) of about 30° also in the presence of the angled-tip stylet (2) inserted therein.

10. Re-entry device (1) according to any of the previous
5 claims, wherein the angle (α) of the curved tip (13) of the catheter (10) is about 60° .

11. Peripheral arterial vessel recanalization method by sub-intimal route by means of a re-entry device (1) according to claim 1, comprising the steps of:

- 10 - advancing the catheter (10) into the thickness of the arterial wall of the occluded vessel tract, up to the level where the lumen is reconstituted and adjusting the curved tip (13) so that the distal opening (14) is facing the arterial wall to be pierced to return into lumen L;
- 15 - advancing an angled-tip stylet (2) into the lumen (17) of the catheter (10) up to the distal tip (12) thereof;
- changing the bending of the curved tip (13) of the catheter (10) up to reach the minimum angle (α);
- making the curved tip (23) of the angled-tip stylet (2)
20 exit from the distal opening (14) of the catheter (10) and directing it three-dimensionally towards the vessel wall up to pierce through the sharpened apex (24) the part of the vessel and penetrate into lumen L of the vessel;
- completing the recanalization of the vessel.

25 12. Recanalization method according to claim 11, wherein

in order to advance the catheter (10) into the thickness of the arterial wall of the occluded vessel tract, the following steps are provided:

- advancing on a first guide wire (steel, Teflon-coated, flexible straight tip, gauge 0.035 in), the catheter (10) through anterograde femoral route towards the beginning of occlusion;
- replacing the first guide wire with a second guide wire (nitinol, hydrophilic polymer coating, flexible J-curve tip, gauge 0.035 in);
- advancing the second guide wire into the occlusion until its distal end bends, thus forming a loop which travels into the thickness of the arterial wall of the occluded tract of the vessel up to the level where the lumen is reconstituted.
- removing the second guide wire.

13. Recanalization method according to claim 11, wherein in order to complete the vessel recanalization, the following steps are provided:

- removing the catheter (10) and fitting a short balloon dilatation catheter on the angled-tip stylet (2);
- inflating the balloon to expand the path towards the lumen of the vessel;
- replacing the angled-tip stylet (2) with a support guide wire (soft tip, gauge 0.014in or 0.018in) to reach

the popliteal or tibial tract.

14. Recanalization method according to claim 13, wherein if the artery to treat is femoral or popliteal, the method finally provides for:

- 5 - removing the dilatation catheter and fitting the catheter (10) on the support guide;
- replacing the support guide wire with a change guide wire (0.035 in);
- removing the catheter (10) and fitting a long balloon
- 10 dilatation catheter on the support guide wire (2);
- inflating the balloon to complete the vessel recanalization.

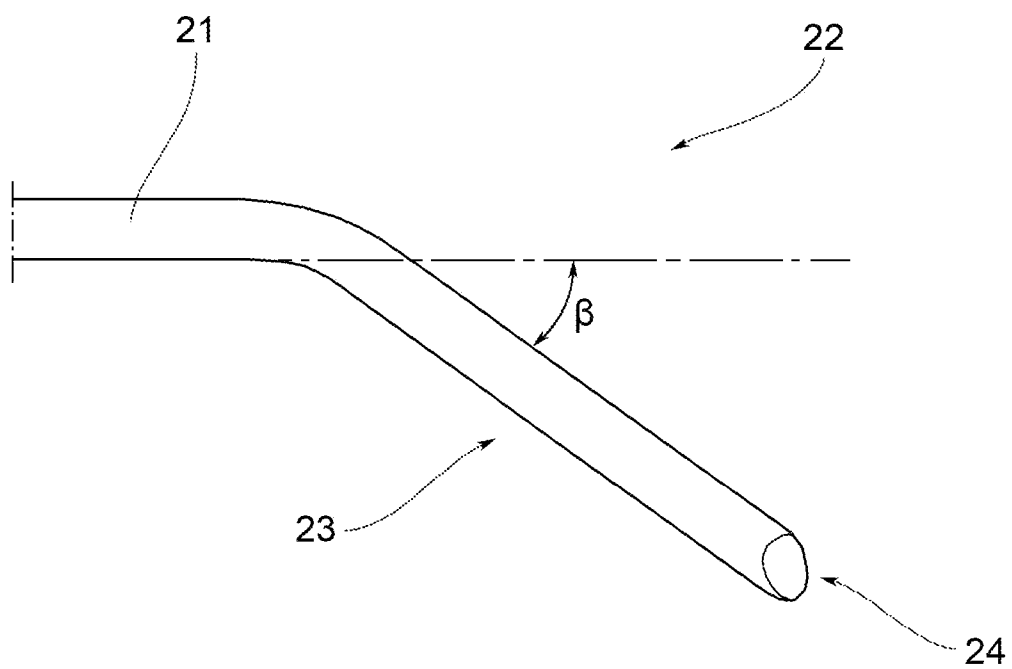


FIG.1

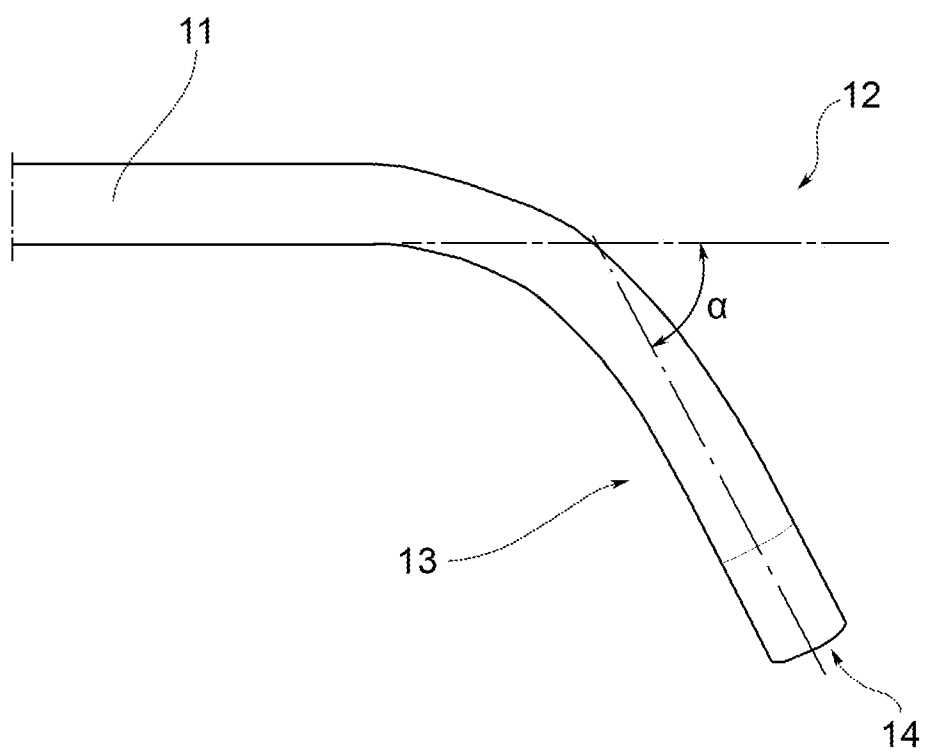
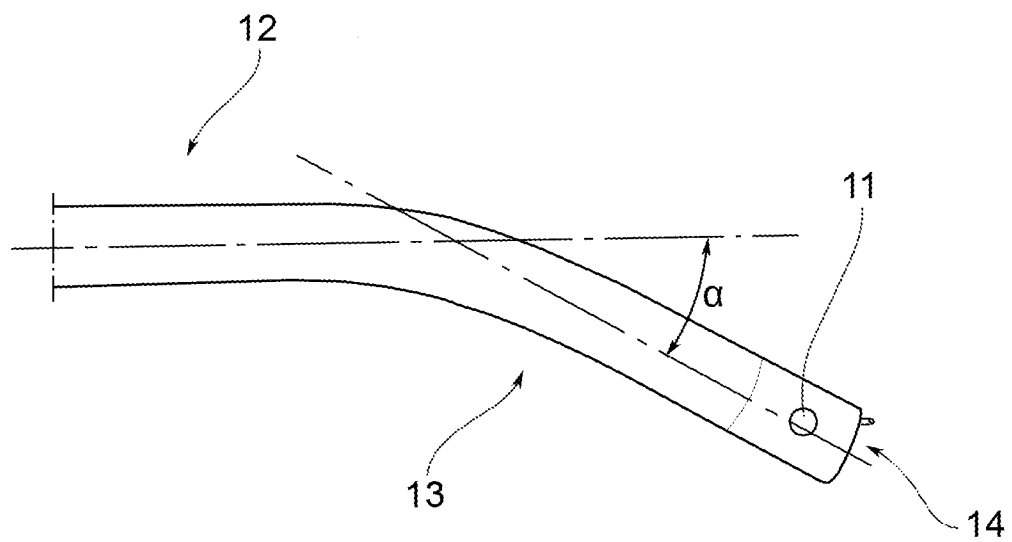
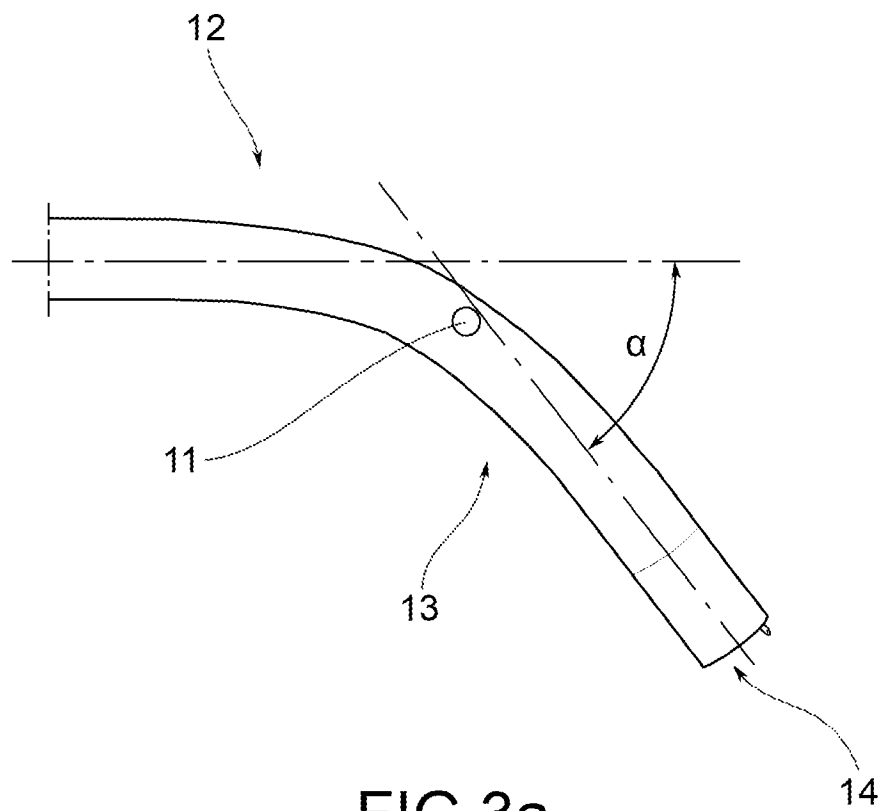


FIG.2



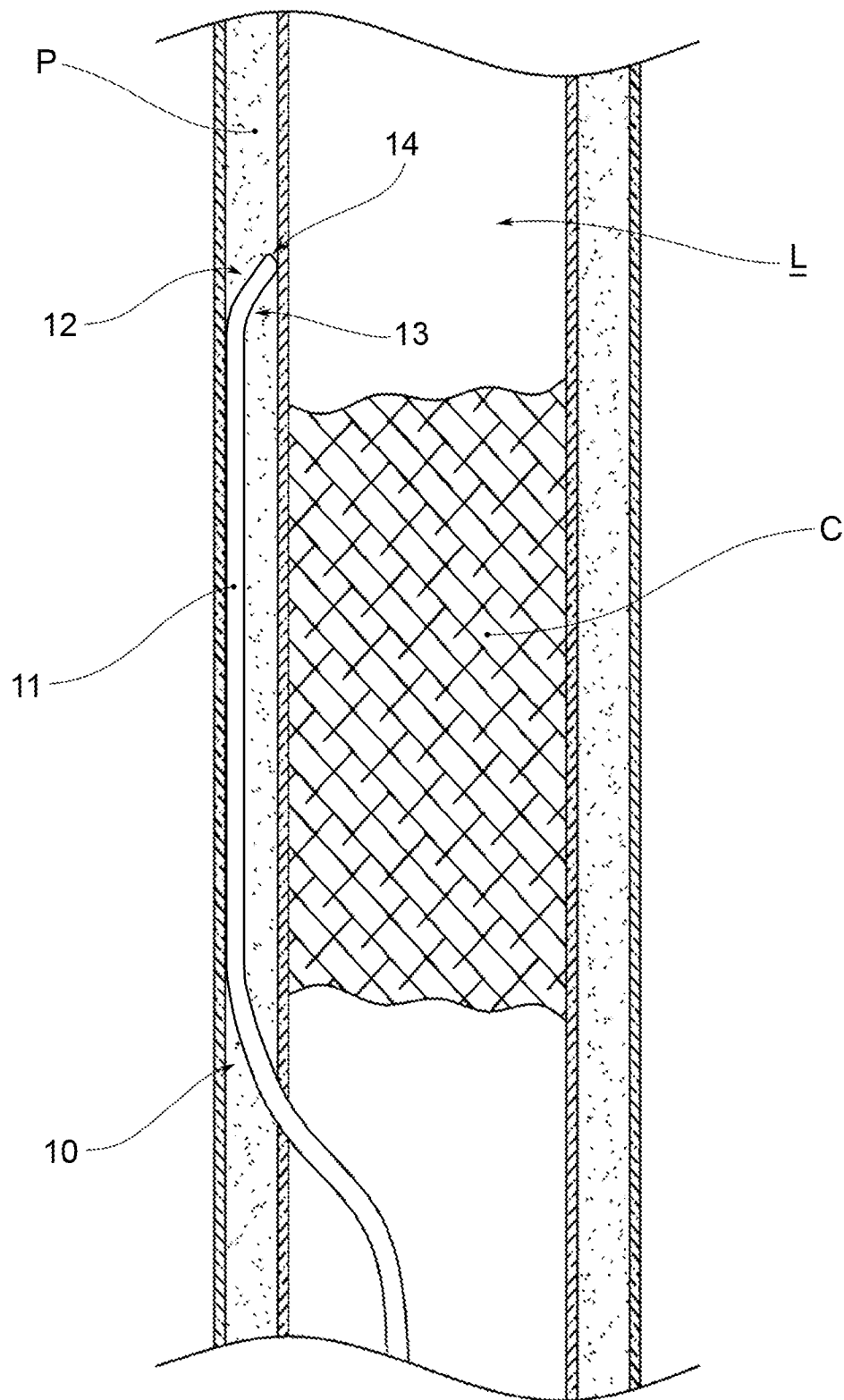


FIG.4

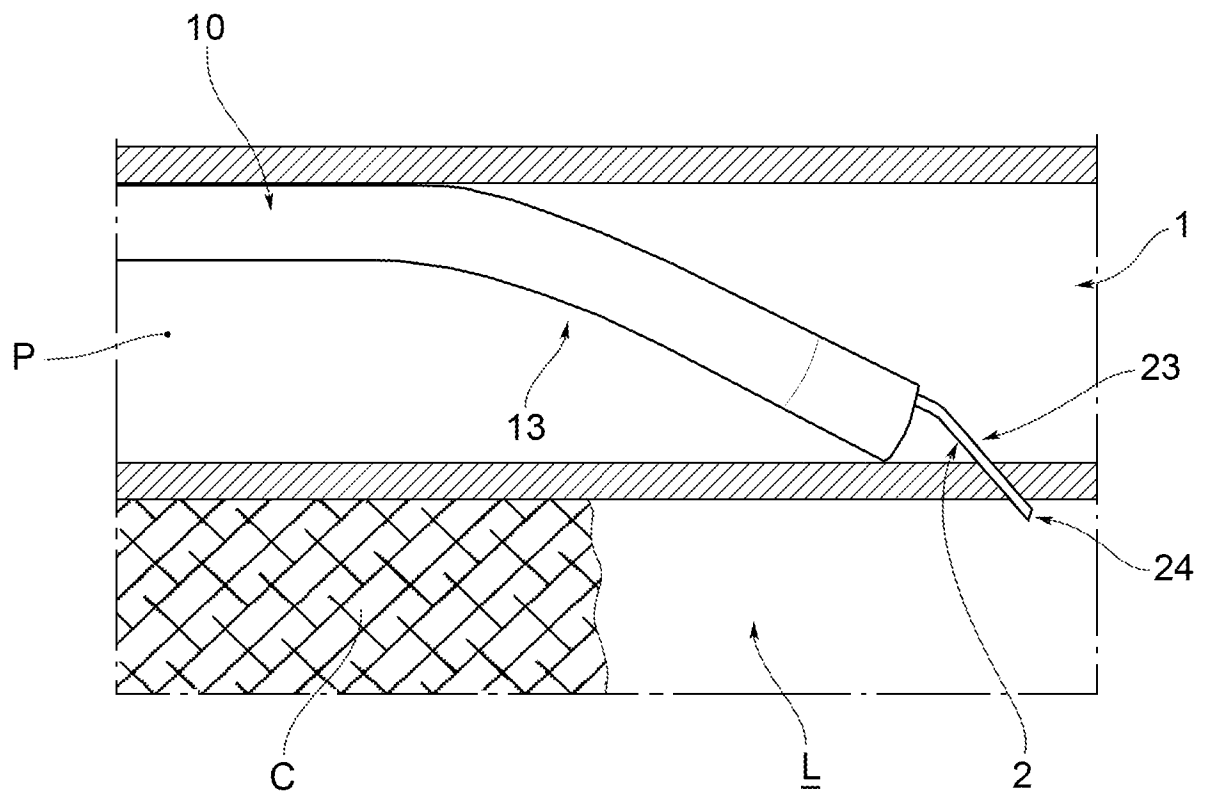


FIG.5a

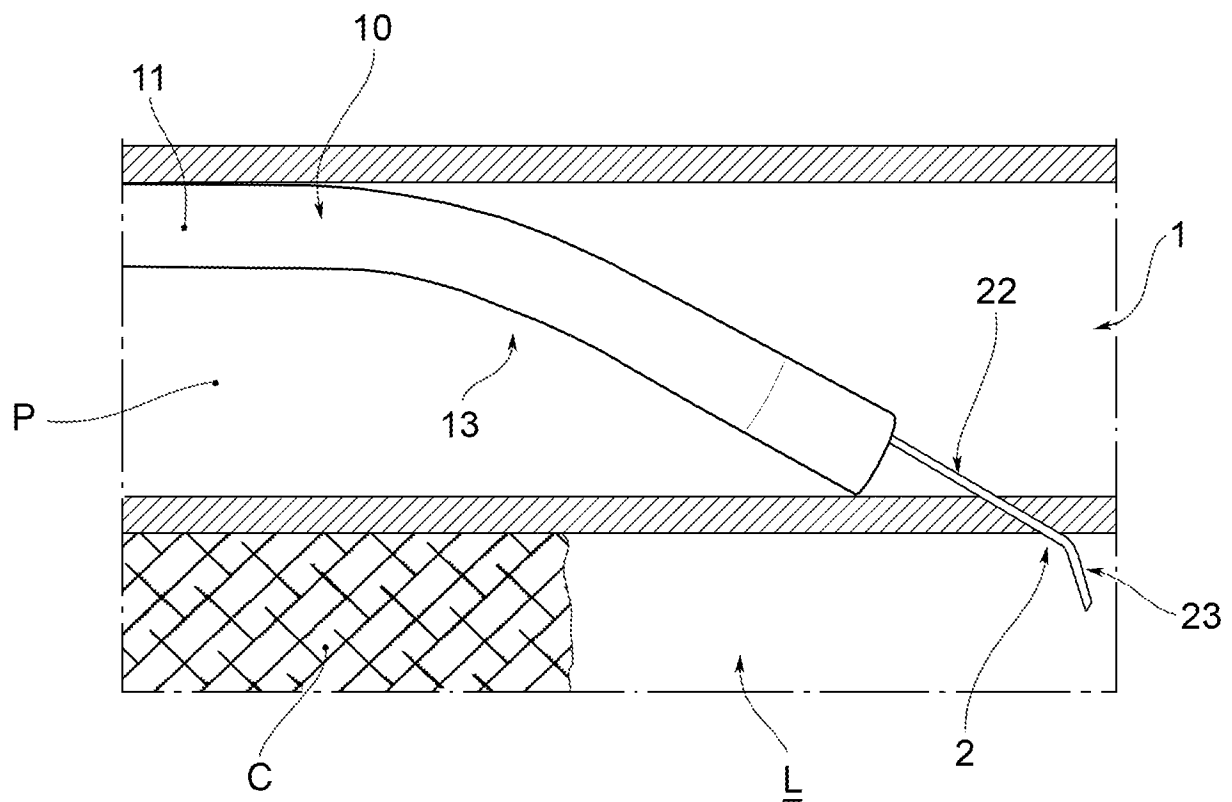


FIG.5b

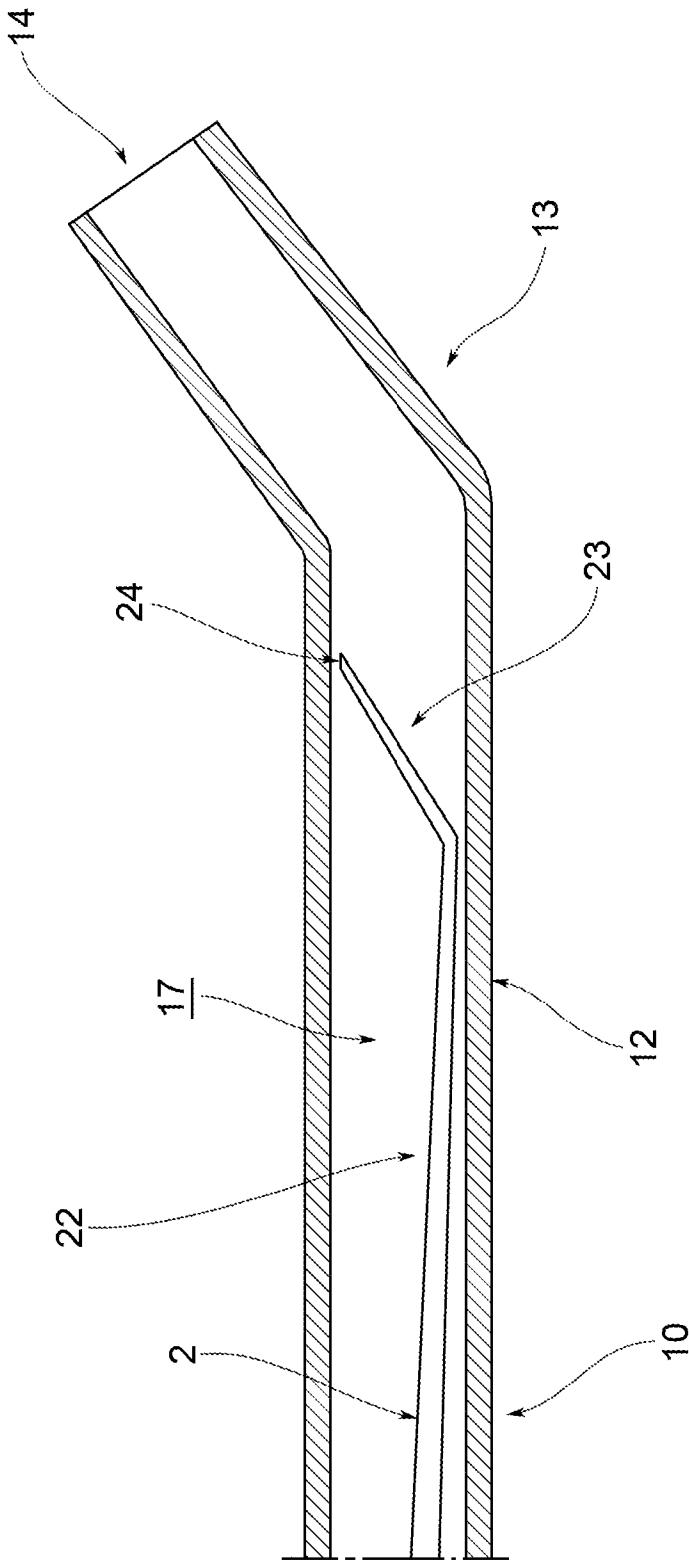


FIG.6

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2018/055858

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/01 A61B17/22
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)

A61M A61B

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)

EP0-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 2015/320975 A1 (SIMPSON JOHN B [US] ET AL) 12 November 2015 (2015-11-12) paragraphs [0008], [0009], [0010], [0013], [0015], [0044] - [0047], [0049], [0054]; figures 1A, 1B, 2A-2B11A-12D	1-10
A	----- WO 2009/144561 A2 (KARDIA S R L [IT]; FERRARESI ROBERTO [IT]) 3 December 2009 (2009-12-03) page 4, lines 8-9 page 5, line 4 - page 6, line 18 page 11, line 15 - page 12, line 18 figures 4-8, 18-23 ----- -/--	1-10

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

5 October 2018

Date of mailing of the international search report

17/10/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Chabus, Hervé

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2018/055858

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.: 11-14
because they relate to subject matter not required to be searched by this Authority, namely:
Method claims 11-14 relate to a method of treatment of the human body by surgery (Rule 39.1(iv) PCT).
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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2018/055858

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2015/032141 A1 (SILVESTRO CLAUDIO [IT]) 29 January 2015 (2015-01-29) paragraphs [0001], [0036], [0038], [0049], [0063] - [0071]; figures 2, 3, 4A-4D, 13-23 -----	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2018/055858

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2015320975 A1	12-11-2015	US 2015320975 A1	12-11-2015
		WO 2014039096 A1	13-03-2014

WO 2009144561 A2	03-12-2009	NONE	

US 2015032141 A1	29-01-2015	EP 3027257 A1	08-06-2016
		US 2015032141 A1	29-01-2015
		WO 2015017052 A1	05-02-2015
