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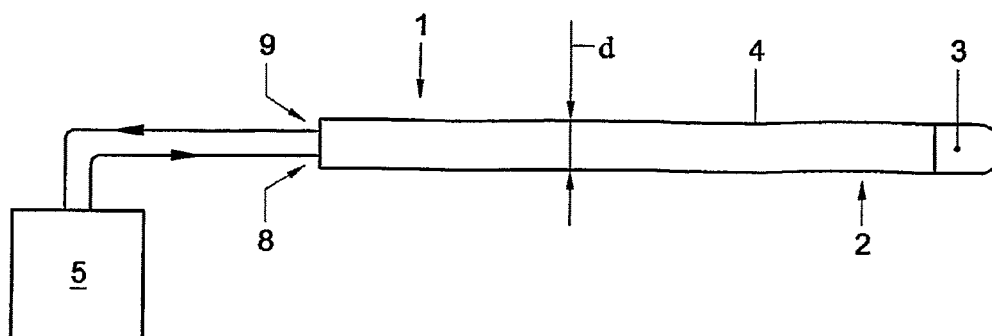


Fig. 1

(57) Abstract: Cryo probe, configured to be entered in a body for minimal invasive cryosurgery, having at least one internal channel for connection to a cryogenic fluid supply such that cryogenic fluid can be supplied to an end portion of the probe, wherein the end portion of the probe has an elongated cooling tip, comprising thermally conductive material for freezing tissue, which tip has a roughened surface for attachment of frozen tissue to the tip.

## CRYO PROBE, METHOD FOR SHAPING A CRYO PROBE

The invention relates to a cryo probe, configured to be entered in a body for minimal invasive cryosurgery, having at least one internal channel for connection to a cryogenic fluid supply such that cryogenic fluid can be supplied to an end portion of the probe, wherein the end portion of the probe has an elongated cooling tip, comprising thermally conductive material for freezing tissue.

The invention also relates to a method for shaping a cryo probe that is configured to be entered in a body, which probe has an elongated tip for freezing tissue to the tip, wherein the tip has a diameter of approximately 3 mm or smaller, preferably approximately 1.6 mm or smaller.

Furthermore, the invention relates to a method for performing cryosurgery.

Venous ulcers account for a large morbidity and high treatment costs, mainly because of the slow healing and high recurrence rate. Several methods are used to treat chronic venous insufficiencies in patients. At present, treatment of the superficial venous system in combination with dissection of Incompetent Perforating Veins (ICPV) is perceived to be a relatively successful method for treating for patients with chronic venous leg ulceration.

For treatment of venous ulcers in areas above the ankle, which can be caused by venous hypertension, it is preferred to apply dissection of ICPV in combination with dissection of the superficial venous system. The objective of ICPV is to decrease venous reflux and reduce ambulatory venous hypertension. Dissection of ICPV can for example be treated by Subfascial Endoscopic Perforating vein Surgery (SEPS), open perforantectomy (Linton procedure) and ultrasound-guided sclerotherapy.

For many surgeons SEPS is currently the surgical technique of choice in treating ICPV. This technique is mainly suitable for the treatment of

ICPV on the medial aspect of the lower leg. In this technique, a deflated balloon is inserted through a cut in the calf. Thereafter the balloon is inflated such that a space is created and the surgeon can access the perforating veins that are causing the problem. The perforating vein is then sealed or clipped so  
5 that blood cannot go through the vein at all, stopping the reflux. Due to compartmental tapering at the ankle, the narrow confines have proven challenging for SEPS.

Recently, a new way of dissecting ICPV, Cryo Perforator Surgery (CPS), has been developed. Some of the promising advantages of CPS are that  
10 it is less invasive than SEPS and provides access to substantially all of the ICPV regardless of their location, resulting in a more extensive therapeutic range. Also, CPS doesn't necessarily require intraluminal insertion of the cryoprobe in the ICPV, e.g. contrary to sclerotherapy. Moreover, the CPS procedure can be performed under local anaesthesia and is less invasive, as  
15 opposed to SEPS for example.

In a study on the feasibility of CPS, prior to the treatment, the incompetent perforating veins were identified using duplex ultrasound (ATL 5000) and ink-marked on the skin. Using local anaesthesia, the perforating veins were approached percutaneously, placing a 14 GA Venflon canule at the  
20 fascia defect under ultrasound guidance. The Venflon canule could be placed intra or extraluminal near the ICPV. A cryoprobe of a type commercialised by Erbe®, 1.6 mm in diameter and with a smooth tip, was entered through the canule and frozen for 15 seconds at -89° Celsius. The perforating vein was freeze-attached to the cryoprobe and dissection was obtained by withdrawing  
25 the probe vigorously.

The treatment was considered successful when the incompetent perforator showed no signs of flow despite augmentation on the duplex scan. Follow-up duplex scans were performed two and four weeks after treatment, respectively. The total follow up for all patients was four weeks. The follow-up  
30 duplex scans showed successful treatment for 39% of the treated ICPV.

For the present invention, a goal is to improve the rate of successful treatments for CPS (Cryo Perforator Surgery), at least on ICPV (Incompetent Perforating Veins), while maintaining most of the current advantages of CPS.

This goal and/or other goals can be achieved by a minimal invasive cryosurgery instrument, comprising a cryo probe that is configured to be entered in a body, the probe having at least one internal channel for connection to a cryogenic fluid supply such that cryogenic fluid can be supplied to the probe, wherein an end portion of the probe has an elongated cooling tip, comprising thermally conductive material, for freezing tissue to the tip, which tip has a roughened surface for attachment of frozen tissue to the tip.

Tests have shown that by roughening the tip of a cryo probe the grip of the tip on the surrounding ice is substantially improved as compared to a conventional probe tip. With a cryo probe having a better grip the ICPV can be dissected in a more controlled and secure manner.

Although conventionally a cryo tip is constructed with a smooth tip, it appeared that also a roughened tip can be entered percutaneously into tissue without disadvantageous friction or damage to tissue. For example, in one application the roughened tip is entered through a perforating vein, of which at least a part is ICPV, until it reaches the intended ICPV part. After introduction, and when the probe tip is brought to a cryogenic temperature, the ICPV is frozen and attached to the tip and when the probe is pulled back the concerning ICPV is dissected. During entry the vein may be somewhat damaged by the roughened tip, however since the vein is dissected when pulling back the probe, damage that might have occurred will not affect the patient. In another exemplary application, the tip is entered through tissue that is less sensitive to the roughened surface of the tip. For example, the tip may be entered through subcutaneous fat, to which no harmful damage will be caused by the roughened tip.

In another application, the tip or at least a part of it, is initially covered by a cover and the tip is at least partially uncovered and brought into

contact with the ICPV before said tip is brought to said temperature. An example of a suitable cover is a tubular sheath or a cap. In use, the tip is entered with the cover until it reaches the desired location, after which the cover is removed, e.g. pulled back or destructed, or the tip is pushed through  
5 the cover, and the tissue concerned is frozen to tip. Thereafter the cryo probe is pulled back and the tissue dissected.

In again another application, a catheter is used to guide the cryo probe through the body. In use, the catheter is entered in the body of a patient and the cryo probe is guided through the catheter. When the catheter has  
10 reached a location close to the tissue that needs to be dissected, the tip is uncovered by moving the tip and catheter relative to each other, e.g. for a couple of mm's or cm's, such that the cryo tip is exposed and tissue can be frozen to the tip. Then the tissue is frozen and pulled back together with the cryo probe and/or the catheter.

15 As will be clear for the skilled person, the use of a cover or catheter, e.g. as an aid for the roughened cryo tip and/or protection for the tissue, may be advantageous or redundant, depending on the application.

With the roughened tip according to the invention, the contact surface between frozen ICPV tissue and the roughened tip is increased such  
20 that the frozen tissue remains better attached when the probe is pulled back. An improved grip of the tip on the surrounding frozen substance is obtained, such that the rate of successful treatment can be improved.

In a preferred embodiment, the roughened surface comprises diamond particles, i.e. a diamond dust, that are attached to the tip. While  
25 conventionally such a diamond particle coating is used in the art for its cutting or abrasive qualities on human tissue, here it principally leaves surrounding tissue unharmed, i.e. when being guided through the body, while exhibiting advantageous attachment qualities when it is under a cryogenic temperature. Moreover, the application of diamond particles attached to the tip is

advantageous because they may remain relatively unaffected when the probe is applied at cryogenic temperatures for multiple times.

Furthermore, abovementioned goal and/or other goals can be achieved by a method for shaping a cryo probe that is configured to be entered  
5 in a body, which probe has an elongated tip for freezing tissue to the tip, wherein the tip has a diameter of approximately 3 mm or smaller, preferably approximately 1.6 mm or smaller, wherein the tip is roughened by creating recesses and/or projections in the tip.

Abovementioned goals can also be achieved by a method for  
10 performing cryosurgery, wherein a cryo probe is used, having an elongated cooling tip with a roughened surface for attachment of frozen tissue to the tip, wherein the probe is entered in a body and the tip is brought in proximity to a target tissue, wherein the tip is brought to a temperature under approximately -75°C such that said target tissue is frozen and attached to said tip and  
15 wherein the probe is withdrawn to dissect said target tissue.

In clarification of the invention, these and further embodiments of the invention, and advantages thereof will be further elucidated with reference to the drawing. In the drawing:

figure 1 shows a schematic illustration of a minimal invasive  
20 cryosurgery instrument;

figure 2 shows a cryo probe; and

figure 3 shows a cryo probe accompanied by an enlarged view of the tip of the probe.

In this description, identical or corresponding parts have identical or  
25 corresponding reference numerals. The exemplary embodiments shown should not be construed to be limitative in any manner and serve merely as illustration.

In this description, it should be understood that the words "cryo", "cryogenic", or the like refer to low temperatures, for example approximately -  
30 75° C or below, approximately -85°C or even approximately -180°C or lower

temperatures. "Cryo", "cryogenic", or the like should be understood as referring to temperatures that are used for freezing and attaching surrounding tissue, and should not be used in a limitative manner, as the skilled person will understand. While in other fields certain low temperatures may be referred to, 5 e.g. below  $-150^{\circ}\text{C}$ , these or any other convention known in that field concerning the use of the words "cryo", "cryogenic", or the like should not be construed as being limiting to the invention.

A schematic illustration of an example of a minimal invasive cryosurgery instrument 1 is shown in figure 1. The instrument 1 has a cryo 10 probe 2 comprising the end of the instrument 1 that is to be brought into the body of a patient. The cryo probe 2 has a tip 3 that is made of thermally conductive material to be able to locally freeze the environment. A shaft 4 is constructed to conduct cryogenic fluid, for example liquid nitrogen, from a cryogenic fluid vessel 5 to the tip 3, wherein the cryogenic fluid circulates from 15 the vessel 5 to the tip 3 and back, e.g. via channels 8, 9 of a cooling circuit. For example, the cooling circuit at least comprises a fluid inlet 8 and a fluid outlet 9, wherein the inlet 8 conducts a liquid nitrogen to the tip 3, where it evaporates and is conducted back to the vessel 5 through the outlet 9. Around the channels 8, 9 the shaft 4 comprises thermally insulating material up to the 20 tip 3.

Another cryo probe 2 is illustrated in figure 2. In this example, the shaft 4 and the tip 3 have a diameter  $d$  of approximately 1.6 mm. Other diameters of suitable cryo probes 2, suited for use in the field of minimal invasive surgery, are for example 2 mm, 2,4 mm, or 3 mm. For example, the 25 tip 3 may be made of a metal, for example titanium and/or surgical steel. In this example, the tip 3 has an elongate, cylindrical shape with a rounded end 10. The rounded end 10 may allow convenient passage through and/or along body tissue without unnecessarily damaging tissue. The shaft 4 is preferably flexible to be able to extend through a bended canal within a patient's body

and has a length such that the probe 2 may reach almost any desired location within the body.

Further illustrative examples of cryosurgery instruments 1 and techniques that may be used according to the invention are for example  
5 disclosed in GB 1 482 424 and WO 2006/034295.

In general, when performing cryosurgery, the probe 2 is entered in a body and the tip 3 is brought in proximity to a target tissue, wherein the tip is brought to a temperature under approximately -75°C, e.g. -89°C, such that said target tissue is frozen and attached to said tip and wherein the probe  
10 is withdrawn to dissect said target tissue.

A preferred use for cryo probes 2 according to the invention is cryo perforator surgery (CPS) which may concern dissection of incompetent perforating veins (ICPV). A scenario for use of a cryo probe 2 according to the invention may be the same as known from CPS, or CPS studies. When an  
15 ICPV is located, the tip 3 is guided to the ICPV, such that the tip 3 of the probe 2 touches, or nearly touches, the ICPV. When the tip 3 touches, or is at least close enough to the ICPV concerned, the tip 3 is brought to the desired temperature, e.g. -89°C, such that the incompetent perforating vein freezes. The probe 2 is then pulled back such that the vein is torn off and the vein will  
20 no longer cause undesirable venous reflux.

Although CPS has promising advantages as opposed to other methods for ICPV surgery, the rate of success of conventional CPS is still not optimal because the perforating vein is not always dissected.

It has been found that when pulling back a cryo probe of a known  
25 type, the ice that has been formed around the tip 3 is sometimes left behind. The probe is pulled out of the ice, because the pulling force that the probe of the known type exerts is not enough to pull the ice out of its surroundings. This may be explained in the fact that the probe 2 and the tip 3 thereof are relatively smooth, to slide through the human body 2 relatively conveniently,

which is necessary to prevent damaging tissue along the way into or out of the body.

In an embodiment of the invention, the surface of the tip 3 is roughened, which provides for better attachment of the tissue to the tip 3.

5 Advantageously, in use, the tip 3 will not unnecessarily damage tissue while being entered into the body. For roughening the surface, diamond particles 6, i.e. diamond dust, may be attached to the tip 3, providing for a diamond coating 7 on the tip 3. Figure 3 shows an enlargement of a tip 3 with a diamond coating 7 comprising diamond particles 6. In an embodiment, the  
10 diamond particles 6 have an average diameter of about 20 micron, but of course this may vary substantially and higher or lower average diameters may also be advantageously applied. For example different diameters varying from 5 micron to 50 micron, or even 100 micron, could be applied. The diamond particles 6 may be secured to and/or embedded in the tip 3 by any suitable  
15 method. A diamond coating 7 may be particularly suitable for use of the invention because it will not degrade when used multiple times at cryogenic temperatures. Also, it is relatively biocompatible and durable material. With these advantages, the small particle size allows the tip 3 to be entered into tissue without damaging it, while maintaining a relatively strong adhesion  
20 properties to ice, i.e. under cryogenic temperatures.

As an aid in guiding the roughened tip 3, a catheter may be used. In use, before guiding the probe 2 through the body, the catheter is entered in the body, e.g. up to a location near to the tissue that is intended to be dissected. Then, the tip 3 is guided to the tissue and the catheter is pulled back such that  
25 the tip 3 is exposed, after which said tissue can be frozen and pulled back by the probe 2.

As another aid in guiding the roughened tip 3, a cover can be used that covers the tip 3, or at least a part of it. The cover can be retracted or destructed when the tip 3 has reached the tissue that is aimed for dissection.  
30 Then, the tissue can be frozen to the tip 3 and the whole is pulled back.

Preferably, after use, tissue that might be attached is removed and the roughened tip 3 is sterilised such that it can be re-used. Diamond dust, i.e. diamond particles 6, has been proven to be suitable for re-sterilisation.

Instead of or next to diamond particles 6, other particles and/or  
5 coatings can be applied to the tip 3. For example, suitable particles may include carbon and/or silicium, as these materials may also allow micron sized recesses and projections to be created on the tip 3. Other materials that are suitable may be recognised by the skilled person. Furthermore, recesses and/or  
10 projections can be shaped in the tip 3, by shaping and/or treating the surface, e.g. without adding particles. In this case, also a roughened surface with good attachment properties can be obtained. For example, scratches, cuts, or the like, may be applied to the surface of the tip 3. The projections and/or recesses that are formed may have heights and/or depths, respectively, approximately equal to one of said diameters of said diamond particles 6 mentioned above.  
15 Likewise, the relatively small size of the recesses and/or projections of the roughened surface of the tip 3 may provide for a strong grip on the ice while showing advantageously minimal friction or damage to surrounding tissue.

In an embodiment, recesses are created in the tip 3, for example by removing material from the tip 3. In this case, care should be taken that the  
20 tip 3 maintains protected against leakage of nitrogen fluid. In an advantageous embodiment, a coating is applied on the tip 3 and/or projections are shaped in or on the tip 3, such that a certain solidness and/or thickness of the material of the tip 3 is upheld, e.g. to prevent that cryogenic fluid leaks from the probe 2.

25 Diamond particles 6, or other suitable particles and/or coatings, can for example be attached to the tip 3 with the aid of chemical vapour deposition (CVD) and/or a plasma assisted surface treatment method, e.g. plasma CVD, although the particles 6 may for example also be mechanically embedded or adhesively secured. CVD and/or plasma assisted surface treatment methods  
30 are able to apply a micron sized thin coating in a relatively controlled way,

while the surface of, in this case, the tip 3 remains relatively unaffected. Furthermore, by use of such methods the diamond coating 7 is suited to remain secured to the tip 3 surface under cryogenic temperatures and for multiple uses. Other advantages of such methods are known in the art.

5 A study was made for testing the grip a cryo probe 2 according to the invention. The tested embodiment had a roughened tip 3, in this case by means of a diamond coating 7 with diamond particles 6 having an average diameter of approximately 20 micron. It appeared that conventional cryo probes, without diamond coating 7, had insufficient grip on the ice. After the  
10 test, the results of the test with a conventional probe were compared with the results of the test of the probe 2 according to the invention.

Both probes were hung in a small chamber of distilled water. The water was frozen around the probe and after 5 seconds, a pulling force was exerted on the cryo probes, via a tension spring, by means of a linear electro  
15 motor, until the probes were pulled out of the ice. The pulling force was digitally measured in kilograms (kg), by means of a linear potentiometer, and noted in a spreadsheet in Excel®, at the moment of pulling the probe out of the ice. The whole test was repeated 50 times for each probe and the results were processed by statistical computer software (SPSS 11.0®). Table 1 summarises  
20 some of these results.

Table 1

	Conventional probe	Diamond coated probe	P-value
Average	2.95 kg	10.67 kg	>.0001
Confidence Interval (95%)	2.65 – 3.25 kg	9.87 – 11.48 kg	
Median	2.90 kg	10.95 kg	>.0001

The conventional cryo probe showed an average pulling force of 2.95  
25 kg, a median of 2.90 kg, and had a 95% confidence interval between 2.65 and 3.25 kg. The diamond coated cryo probe 2 showed an average pulling force of

10.67 kg, a median of 10.95 kg, and had a 95% confidence interval between 9.87 and 11.48 kg.

5 The test showed that for the cryo probe 2 having a roughened surface the pulling force was much higher before the probe 2 would loose grip on the ice. In particular the pulling force needed to pull the cryo probe 2 with a roughened surface out of the ice was 3.6 times higher than the pulling force that was needed for a conventional cryo probe. Therefore, it is assumed that the cryo probe 2 according to the invention has a stronger grip on ice, i.e. frozen tissue, than the conventional probe.

10 It shall be obvious that the invention is not limited in any way to the embodiments that are represented in the description and the drawings. Many variations and combinations are possible within the framework of the invention as outlined by the claims. Combinations of one or more aspects of the embodiments or combinations of different embodiments are possible within the  
15 framework of the invention. All comparable variations are understood to fall within the framework of the invention as outlined by the claims.

Claims

1. Cryo probe, configured to be entered in a body for minimal invasive cryosurgery, having at least one internal channel for connection to a cryogenic fluid supply such that cryogenic fluid can be supplied to an end portion of the probe,  
5 wherein the end portion of the probe has an elongated cooling tip, comprising thermally conductive material for freezing tissue, which tip has a roughened surface for attachment of frozen tissue to the tip.
2. Cryo probe according to claim 1, wherein the tip comprises recesses and/or projections that have a depth and/or height, respectively, from the main  
10 surface of the tip, of approximately 100 micron or less, preferably approximately 25 micron or less.
3. Cryo probe according to claim 1 or 2, wherein the roughened surface comprises particles that are attached to the tip.
4. Cryo probe according to claim 3, wherein the particles comprise  
15 diamond particles, in particular diamond dust.
5. Cryo probe according to claim 3 or 4, wherein the particles have a particle size that is smaller than approximately 100 micron, wherein the particle size is preferably smaller than approximately 25 micron.
6. Cryo probe according to any of claims 3 - 5, wherein the particles are  
20 attached to the tip by means of chemical vapour deposition (CVD) and/or a plasma assisted surface treatment method.
7. Cryo probe according to any of the preceding claims, wherein the tip has a diameter of approximately 3 mm or smaller, preferably approximately 1.6 mm or smaller.
- 25 8. Assembly of a cryo probe according to any of the preceding claims and a catheter for guiding the tip of the probe through the body.

9. Assembly of a cryo probe according to any of the claims 1 – 7 and a cover, wherein, at least in use, the cover extends over at least a part of the tip.
10. Elongated cooling tip, preferably for use in a probe according to any of the claims 1 - 7, comprising thermally conductive material for freezing  
5 tissue, which tip has a roughened surface for attachment of frozen tissue to the tip.
11. Method for shaping a cryo probe that is configured to be entered in a body, which probe has an elongated tip for freezing tissue to the tip, wherein the tip has a diameter of approximately 3 mm or smaller, preferably  
10 approximately 1.6 mm or smaller, wherein the tip is roughened by creating recesses and/or projections on the tip.
12. Method according to claim 11, wherein the recesses and/or projections are created by depositing particles on the tip, preferably diamond particles, to roughen the surface of the tip.
- 15 13. Method according to claim 11 or 10, wherein the diamond dust particles are deposited by means of a plasma surface treatment method.
14. Method for performing cryosurgery, wherein a cryo probe is used, preferably a cryo probe according to any of the claims 1 – 7, having an elongated cooling tip with a roughened surface for attachment of frozen tissue  
20 to the tip,
- wherein the probe is entered in a body and the tip is brought in proximity to a target tissue, wherein the tip is brought to a temperature under approximately -75°C such that said target tissue is frozen and attached to said tip and wherein the probe is withdrawn to dissect said target tissue.
- 25 15. Method for performing cryosurgery according to claim 14, wherein the tip is initially covered by a cover and wherein the tip is at least partially uncovered and brought into contact with said tissue before said tip is brought to said temperature.
16. Method according to claim 14 or 15, wherein said probe is guided  
30 through the body using a catheter.

17. Method according to claim 16, wherein said catheter forms said initial cover for said tip, and wherein the tip is uncovered by moving the tip and catheter relative to each other.

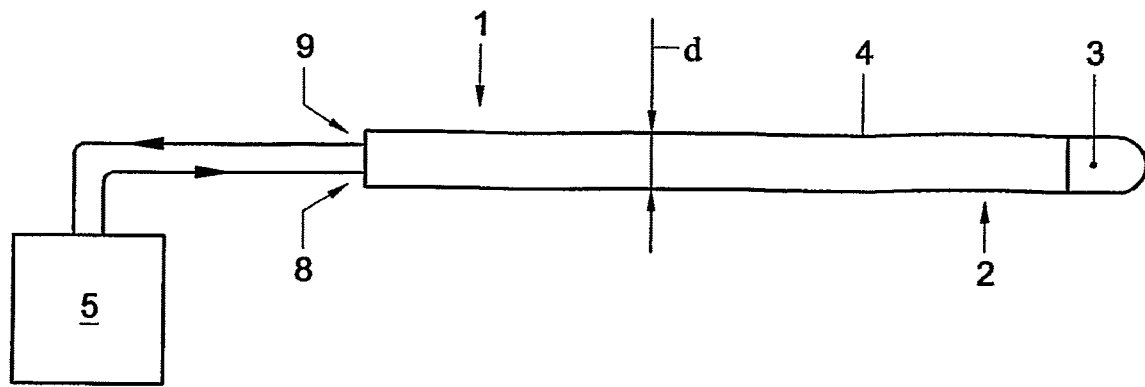


Fig. 1

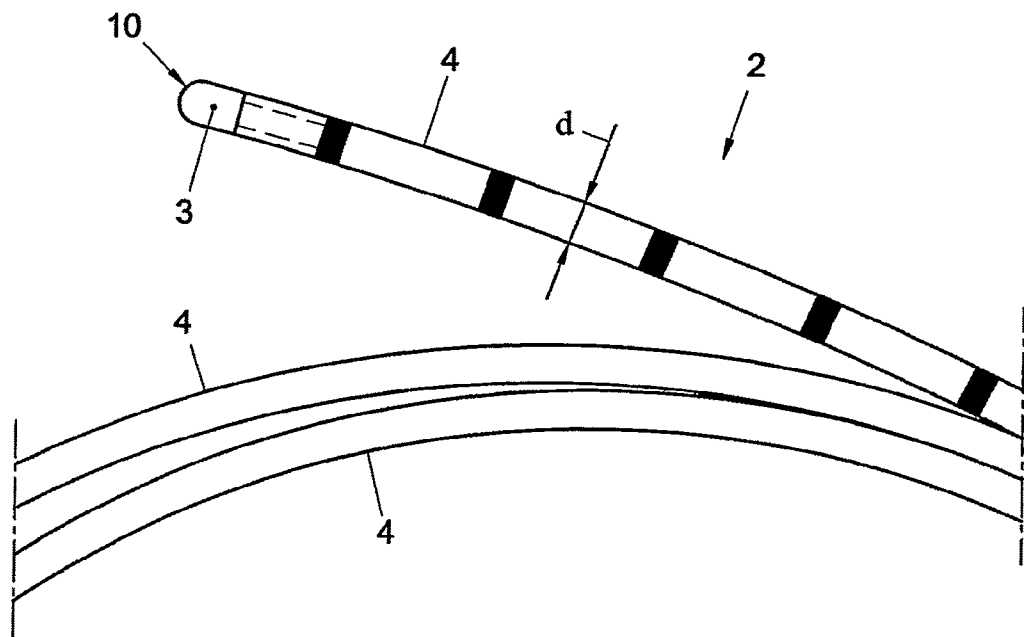


Fig. 2

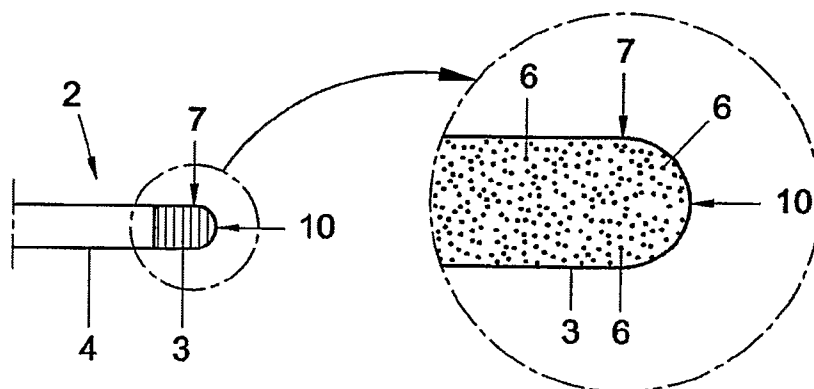


Fig. 3

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/NL2007/050293

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61B18/02 A61F9/00

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 practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/41784 A (LEHRER AHARON [IL]; BEN NUN YEHOASHUA [IL]) 13 November 1997 (1997-11-13) page 18, line 4; claim 1; figure 1 -----	1-5,10
X	US 6 551 309 B1 (LEPIVERT PATRICK J M [US]) 22 April 2003 (2003-04-22) paragraphs [0063], [0066]; claim 1 -----	1,7,8, 10,11
A	US 2004/078033 A1 (LEVIN ALEXANDER [IL]) 22 April 2004 (2004-04-22) paragraph [0018]; claim 1 -----	1-13

☐ 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 document 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

9 October 2007

Date of mailing of the international search report

23/11/2007

Name and mailing address of the ISA/  
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Authorized officer

Chopinard, Marjorie

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/NL2007/050293

### Box 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.: 14-17  
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 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 fee, this Authority did not invite payment of any additional fee.
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.

☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No

PCT/NL2007/050293

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