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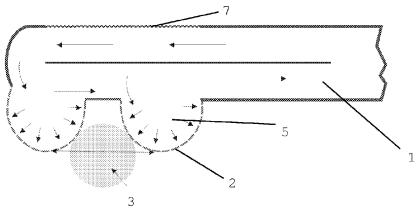


Fig. 2

(57) Abstract: The subject of the present invention is sharp/blunt trocar for freezing tissues containing sealed channels for conducting refrigerant in a continuous flow, connected with a pump and a container for the refrigerant, terminating in a freezing head, wherein the freezing head possesses at least one elastic surface (2), which changes shape and distends as a result of pumping refrigerant under pressure through the trocar forming a decompression chamber (5), in which refrigerant undergoes decompression causing the elastic surface (2) of the freezing head to cool, and the aforementioned elastic surface (2) is capable of fitting itself to the tissue being subjected to freezing (3). The subject of the present invention is also a the use of a sharp/blunt trocar in the downregulation of arterial blood pressure in the renal artery.





TROCAR WITH A FREEZING PROBE

The subject of the present invention is a sharp/blunt trocar with a freezing probe for freezing tissues and the use of the sharp/blunt trocar for freezing tissues in particular the sympathetic plexus leading to the kidneys and renal artery used in the regulation of arterial pressure.

Patent US 3298371 discloses a freezing probe used particularly in neurosurgery. The probe consists of ducts for conducting a freezing agent, i.e. liquid nitrogen, terminating in a heat-conducting head. The head contains a detector, which measures its temperature in real time in order to maintain appropriate conditions for the procedure. The aforementioned probe possesses a head with a diameter of about 0.09 inch, wherein it is not deformed elastically and thus is not useful in the effective freezing of tissues on a large surface such as the sympathetic plexus.

Patent US6306129 discloses in turn a system for cardiosurgery containing a compressor and a probe. The probe has a secondary cooling channel, which performs an initial cooling at a resting state. After the initial cooling, the main cooling stream is initiated, which facilitates temperatures near - 100°C. This probe does not possess an elastic head and therefore the active freezing surface is limited only to the tissue-head contact point. Large surface activity is thus difficult, particularly that of a cylindrical shape.

Patent US7063718 discloses a method and apparatus for performing a hypothermy of a selected organ without a significant effect on adjacent organs and tissues. The elastic catheter is inserted through the patient's vasculature in order to insert the end of the freezing probe through the

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artery that supplies the selected organ. The compressed pumped in through a catheter into refrigerant is decompressing element found near the end of the probe, wherein the refrigerant decompresses and evaporates which cools the elastic thermoconductive element in the probe's end. This leads to the cooling of blood flowing through a selected vessel, which then cools the selected organ. In one embodiment of said invention, the element responsible for heat exchange consists of a plurality of concentric tubes leading to the 10 return duct for the refrigerant. The nitinol tubes remain rectilinear at room temperature, whereas they change shape at low temperatures, leading to the formation of an elastic "basket", which allows for the easier insertion of into the patient's bloodstream catheter system substantially rectilinear but flexible tubes. After insertion 15 into the desired site, the refrigerant flow is initiated which causes a change in the geometry of the nitinol tubes and forms the basket thereby increasing the effective length of the refrigerant decompression path and by the same token decreasing the catheter length required to achieve the desired 20 temperature. Organ or tissue cooling occurs through the end of the probe, which is not elastic and facilitates cooling solely at the contact interface. It is thus not possible to simultaneously cool a larger surface, i.e. in cylindrical 25 form.

Patent application US2008071337 discloses a catheter capable of being placed for heating or cooling the surrounding fluid in a patients blood vessel. The catheter possesses a heat exchange element that contains a plurality of external surface irregularities in order to induce turbulence in the surrounding fluid. The catheter that supplies the refrigerant, the heat exchange cooling element, is equipped with balloons at its end, supplied by a separate duct. After inserting into an appropriate site, the working fluid supply catheter is

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withdrawn in order to provide a seal using the balloon. After sealing, the chamber is filled with the working fluid which cools the heat exchange element. The balloon solely has a sealing function, and thus does not provide any thermal activity. Moreover, the presented catheter provides solely fluid cooling and is thus not useful for the point cooling of organs or tissues. Moreover, the activity surface area is constant, not elastic, due to which there is no possibility to enclose a selected blood vessel in order to obtain better cooling.

The technical problem set forth before the present invention is to disclose such a sharp/blunt trocar so as to facilitate access to the renal artery and its connected sympathetic plexus, one which would facilitate the point freezing of the probed nerve, ganglion, tissue or blood vessel, wherein the achieved temperature would be lower than -50°C, and the probe active cooling surface area interface with the treated tissue is large, facilitating the simultaneous freezing of a selected blood vessel over a large portion of its circumference using a lower quantity of refrigerant, and the trocar has a simple construction and is inexpensive to produce, making it possible to deliver single-use, sterile devices of this type, while at the same time the freezing procedure will be faster, reducing the risk of postoperative complications. Unexpectedly, the aforementioned problems have been solved by the present invention.

The first subject of the present invention is a sharp/blunt trocar with a freezing probe for freezing tissues containing sealed channels for conducting a continuous flow of refrigerant, connected to a pump and a container for the refrigerant, terminating in a freezing head, characterised in that the freezing head possesses at least one elastic surface which changes shape and distends as a result of the flow of

therein that is pumped under pressure, forming decompression chamber, in which the refrigerant introduced via the channels 1 undergoes decompression and evaporation causing the surface of the elastic freezing head to cool, a the aforementioned elastic surface is capable of fitting itself to the tissue subjected to freezing. Preferably, the elastic surface occurs on the side wall of the freezing head. Equally preferably, the elastic surface occurs on the front wall of freezing head. In another preferable embodiment of the present 10 invention the elastic surface comprises a material selected from among for example PEBA, graphene, PET or other elastic polymers. In the next preferable embodiment of the present invention, the surface of the trocar, outside of the elastic is covered by a thermoinsulating material. surface, Preferably, the insulating material comprises an aerogel. In 15 another preferable embodiment of the present invention sharp/blunt trocar further comprises at least one outflow canal sealed via sealing portion to the channel, having at the end a nozzle which increases efficacy and targeting of the elastic surface. 20

The second subject of the present invention is the use of a sharp/blunt trocar as defined in the first subject of the present invention in the lowering of arterial blood pressure in the renal artery by freezing the nerve and/or plexus, which supplies the renal artery, through sympathetic innervation, halting the nerve's activity and halting the pressure regulatory mechanism.

A sharp/blunt trocar according to the present invention makes it possible to introduce it into a desired area and to freeze tissues locally. Due to its elastic surface, which adapts itself to the treated tissue, the freezing surface is enlarged and it is thus possible to freeze a large tissue surface in a single treatment step. The elastic surface makes it possible

to partially surround the treated tissue, i.e. artery, increasing treatment effectiveness and shortening treatment times. The use of materials that conduct thermal energy well decreases refrigerant requirements, due to lowered thermal loss. The use of a sharp/blunt trocar according to the present invention makes it possible to perform an arterial blood pressure reduction in the renal artery by freezing the nerve and halting the pressure regulatory mechanism without a surgical incision (not longer then 1.cm) in the skin, over a shorter time, decreasing the risk of postoperative complications.

Example embodiments of the present invention are shown in the illustration, in which Fig. 1 shows a longitudinal section of the freezing probe of the sharp/blunt trocar with the elastic 15 surface on the side of the freezing head, Fig. 2 shows a cross-section of the freezing probe of the trocar of Fig. 1 with two elastic surfaces during the treatment, Fig. 3. a, b, c shows consecutive configurations of the elastic surface, Fig. 4 shows the probe of a sharp/blunt trocar in top view, Fig. 5 shows a cross-section of the probe of a trocar of Fig. 20 4 along surface A-A, Fig. 6 shows a cross-section of the probe of a trocar of Fig. 4 along surface B-B, Fig. 5 shows a crosssection of the probe of a trocar of Fig. 7 along surface C-C, Fig. 8 shows a cross-section of the probe of a trocar of Fig. 4 along surface D-D, Fig. 9 shows a longitudinal section of a 25 probe of the sharp/blunt trocar with the elastic surface on the front wall of the freezing head, Fig. 10 shows a crosssection of the probe of a trocar of Fig. 9 along surface C-C, Fig. 11 shows a magnification of the freezing head of a trocar 30 of Fig. 9 during the unfolding of the elastic surface, Fig. 12 shows an unfolded, single-use probe of the freezing trocar of Fig. 9, Fig. 13 longitudinal section of the trocar of Fig. 9 in an embodiment with a spherical elastic surface, Fig. 14 shows the elastic surface of the freezing head of a trocar of

Fig. 9 during treatment, Fig. 15 shows another embodiment of the freezing head of the trocar of Fig. 2, Fig. 16 shows another embodiment of the freezing head of a trocar of Fig. 2, Fig. 17 shows another embodiment of the freezing head of a trocar of Fig. 2, covered by thermoinsulating material, Fig. 18 shows another embodiment of the freezing head of a trocar of Fig. 1, Fig. 19 shows the trocar with the probe of the present invention, Fig. 20 shows a needle with a sharp tip enabling passage through skin after insertion through trocar, Fig. 21 shows a pencil-point needle enabling safe passage through muscle and fat tissue after insertion through trocar, Fig. 22 shows the freezing probe of the present invention.

Example 1

10

Fig. 1 shows a sharp/blunt with an internally placed freezing probe. The freezing probe possesses an elastic surface 2 on the side of its head. The probe also contains sealed channels 1 that supply refrigerant to the elastic surface 2 of the freezing head. At the opposite side of the elastic surface 2 there is an identification area 7, which facilitates better visibility and localization during diagnosis using imageguided procedures with the help of medical imaging like computed tomography, magnetic resonance imaging ultrasonography. Fig. 3a shows an embodiment of the elastic surface 2 of the freezing probe of a shape reminiscent of pincers, ensuring a larger contact surface at the tissue circumference 3 with a cylindrical cross-section. Fig. 3b shows the next embodiment of the elastic surface 2 of a freezing probe with a flat surface for universal use. Fig. 3c shows an embodiment of the elastic surface 2 of a freezing probe with two separate areas, which makes it possible to freeze tissue 3 from two sides simultaneously. Fig. 2 shows a sharp/blunt trocar with a freezing probe o elastic surface 2 placed inside with a shape as in Fig. 3c. After placing the

PCT/PL2014/050066

trocar in an appropriate site of the body (the identification area 7 makes it possible to verify the location of the trocar), an expanding gas is introduced through the channels 1 that forms the elastic surface 2, in order to "inflate" the elastic surface 2 and to form the decompression chamber 5. The pumping is performed using a neutral gas, i.e. CO2. All other neutral gasses can be used to pump up the decompression chamber 5. After inflation, the refrigerant is introduced under pressure, i.e. liquid nitrogen, which in the formed decompression chamber 5 is decompressed and evaporates causing a drastic drop in the temperature inside the chambers 5. The elastic surface 2 is made of a durable elastic material with an excellent thermal conductivity, such as graphene, resulting in decreased thermal losses, and thinner elastic surfaces 2 may be used, thereby decreasing the amount of refrigerant necessary to perform the treatment. Fig. 4 shows a sharp/blunt trocar with a freezing probe with an elastic surface 2 shaped as in Fig. 3b in top view. Figs. 5, 6, 7, 8 show transverse sections through surfaces A-A, B-B, C-C, and D-D respectively as shown in Fig. 4. The above sections show that the elastic surface 2, that is used for freezing tissue 3, is located only on a particular, defined length, through which it is possible to manufacture a sharp/blunt trocar dedicated to particular medical uses. The trocar used makes it possible to freeze tissue 3 in a single operation, due to the elastic freezing surface 2, which has a desirable effect on the treatment time and risk of complications. Due to the use of an elastic surface 2 of a material with excellent thermal conductivity, it was possible to use a smaller quantity of refrigerant. The inflated elastic surface 2 formed a decompression chamber 5, which possessed a relatively large volume, achieving a low temperature, appropriate for the tissue freezing treatment, using a lower quantity of refrigerant, without the use of complicated heat exchangers.

Fig. 9 shows the next embodiment of a sharp/blunt trocar with a freezing probe for freezing tissues 3. In contrast to the trocar of Example 1, the elastic surface 2 is found at the front of the freezing head. Inside the probe, between the channels 1 supplying the refrigerant there is a pipe 6, which conducts the pumping gas to the elastic surface 2 and forms decompression chamber 5. This gas, as in Example 1, may be CO2. Fig. 10 shows a transverse cross-section along surface A-A of the sharp/blunt trocar with a freezing probe of Fig. 9. Fig. 11 shows the elastic surface 2 pumping process, forming a decompression chamber 5 with a neutral gas introduced using pipe 6. Fig. 12 shows an unfolded freezing probe placed inside the trocar, which discloses the simple construction of the freezing probe, enabling its production in the form of singleuse, sterile freezing probes for a dedicated use. Fig. 13 shows the trocar with a freezing probe of Fig. 9 during refrigerant flow, such as liquid nitrogen. The refrigerant undergoes decompression and evaporation in the formed decompression chamber 5 causing a rapid temperature drop. The trocar with a freezing probe shown possesses on its peripheral surface a channel 1 that gives access to a pipe 4 with excellent thermal insulation, which safeguards tissues against undesirable freezing. This pipe may be composed of an aerogel for example. Fig. 14 shows a trocar with a freezing probe as per Fig. 9 during the freezing treatment of tissues 3. In this case, the tissue 3 being frozen is the renal artery. As may be seen, the shape of the elastic surface adapts to the treated tissue, yielding a large interaction surface facilitating effective freezing.

8

Another embodiment of blunt/sharp probe is illustrated in the Fig. 15. This probe is similar to that presented in Fig. 2. In contrast to the trocar of Fig. 2, Fig. 15 shows a blunt/sharp probe with two channels 1 enabling the inflow and outflow of a and/or refrigerant. The freezing probe possesses elastic or expandable surface 2 on one side of its head. The probe also contains outflow canal 8 sealed via sealing portion 10 to the inflow channel 1 that supply gas and/or refrigerant to the elastic surface 2 of the freezing head. A nozzle 9 is located at the end of an outflow canal 8 increasing efficacy and targeting of the elastic or expandable surfaces 2. Between portions of elastic surface 2 lies the possible location of a target 3 aimed at freezing, which can be the tissue. Presented embodiment of the above-mentioned blunt/sharp probe operates on the same principle as the probe of Example 1. Fig. 16 presents another embodiment of blunt/sharp probe similar to that illustrated in Fig. 15, with three channels 1 enabling the inflow and outflow of a freezing gas and/or refrigerant. The freezing probe possesses an elastic or expandable surface 2 on one side of its head. The probe also contains two outflow canals 8 sealed via sealing portion 10 to the inflow channels 1 that supply gas and/or refrigerant to the elastic surface 2 of the freezing head. Two nozzles 9 are located at the end of an outflow canals 8 increasing efficacy and targeting of the elastic or expandable surfaces 2. Between portions of elastic surface 2 lies the possible location of a target 3 aimed at freezing, which can be the tissue. Presented embodiment of the above-mentioned blunt/sharp probe operates on the principle as the probe of Example 1. Fig. 17 presents another embodiment of blunt/sharp probe similar to that illustrated in Fig. 15 and Fig. 16, with three channels 1 enabling the inflow and outflow of a freezing gas and/or refrigerant. The probe is enclosed/covered with an insulating material 4 enabling better

9

visualization under an image guided (computed tomography/ ultrasound) procedure and/or decreasing the risk of collateral damage. The freezing probe possesses an elastic or expandable surface 2 on one side of its head. The probe also contains outflow channels sealed to the inflow channels 5 that supply refrigerant to the elastic surface 3 of the freezing head. two outflow canals 8 sealed via sealing portion 10 to the inflow channels 1 that supply gas and/or refrigerant to the elastic surface 2 of the freezing head. Two nozzles 9 are located at the end of an outflow canals 8 increasing efficacy and targeting of the elastic or expandable surfaces 2. Between portions of elastic surface 2 lies the possible location of a target 3 aimed at freezing, which can be the tissue. Presented embodiment of the above-mentioned blunt/sharp probe operates on the same principle as the probe of Example 1. Fig. 18 presents another embodiment of blunt/sharp probe similar to that illustrated in Fig. 15, with two channels 1 in enabling the inflow and outflow of a freezing gas and/or refrigerant. The freezing probe possesses an elastic or expandable surface 2 on one side of its head. The probe also contains outflow canal 8 sealed via sealing portion 10 to the inflow channel 1 supply gas and/or refrigerant to the elastic or folded/expandable surface 2 of the freezing head. A nozzle 9 is located at the end of an outflow canal 8 increasing efficacy and targeting of the elastic or expandable surfaces 2. Different embodiments of blunt/sharp probe presented in the present Example 3 can possess different configurations of the elastic surface 2 including, but not limited to, presented in Figs. 3 a-c.

Example 4

Figures 19-22 show the whole trocar including freezing probe of Example 1. Figure 19 presents the trocar, which could be used in an intervention to guide the probe through tissue

decreasing the risk of infection. It possesses marks for judgment of depth of tissue penetration as well as an isolating layer 4 and a standard luer lock root. The tip is cut in a safe manner to adjust to the inserted probe or needle decreasing risk of damage to tissue while passing through it. Figure 20 presents a needle with a sharp tip enabling passage through skin after insertion through trocar. Figure 21 presents a pencil-point needle enabling safe passage through muscle and fat tissue decreasing risk of tissue laceration of e.g. vessels. Figure 22 presents a simple freezing probe, for example from Example 1. With a freezing tip and an inflow and outflow channels 1 for the freezing gas. In figures a typical dimensions of trocar and probe are also presented.

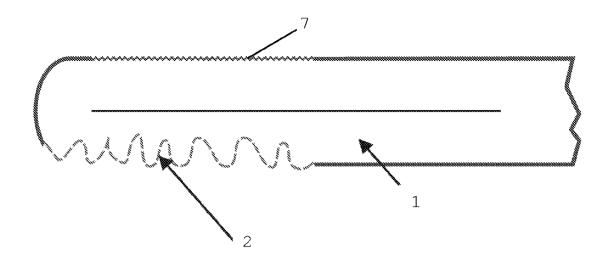
Example 5

We used the trocar of Example 1 for the regulation of arterial hypertension. The trocar facilitated simple access to the renal artery 3 and to the sympathetic plexus leading to the kidneys and artery, which regulates arterial pressure. Access to the renal artery 3 did not require any surgical incision in the skin (no incision longer than 1 cm). The access was through the patients back where the probe was inserted transdermally, inserting paravertebrally at L1/L2 through the soft tissues and accessing the area of the renal artery 3. The procedure was performed using a sharp/blunt trocar equipped with a freezing probe. The inhibition of the sympathetic plexus was realised through freezing the nerve or plexus, which supplies the renal artery, through sympathetic innervation, to a temperature below -50°C, wherein freezing caused the nerve to deactivate and thus to shut down pressure upregulating system (Renin-Angiotensin-Aldosterone axis).

Claims

- Sharp/blunt trocar with a freezing probe for freezing tissues containing sealed channels for conducting refrigerant in a continuous or algorithmic interrupted flow, connected with a pump and a container for the refrigerant, terminating in a freezing head, characterised in that the freezing head possesses at least one elastic surface (2), which changes shape and distends as a result of the flow of gas pumped under pressure through the trocar forming a decompression chamber
 (5), into which the refrigerant is supplied through channels (1) and then undergoes decompression and evaporation causing the elastic surface (2) of the freezing head to cool, and the aforementioned elastic surface (2) is capable of fitting itself to the tissue subjected to freezing (3).
- 15 2. Sharp/blunt trocar according to Claim 1, characterised in that elastic surface (2) occurs on the side wall of freezing head.
- 3. Sharp/blunt trocar according to Claim 1, characterised in that elastic surface (2) occurs on the front wall of freezing 20 head.
 - 4. Sharp/blunt trocar according to any of Claims from 1 to 3, characterised in that elastic surface (2) comprises a material selected from among: PEBA, graphene, PET or other suitable polymers.
- 5. Sharp/blunt trocar according to any of Claims from 1 to 4, characterised in that the surface of the trocar, except the elastic surface (2), is covered by a thermoinsulating material (4).

- 6. Sharp/blunt trocar according to Claim 5, characterised in that the insulating material can comprise an aerogel.
- 7. Sharp/blunt trocar according to any of Claims from 1 to 6, characterised in that, it further comprises at least one outflow canal (8) sealed via sealing portion (10) to the channel (1), having at the end a nozzle (9) which increases efficacy and targeting of the elastic surface (2).
- 8. The use of a sharp/blunt trocar as defined in Claims from 1 to 7 in the downregulation of arterial blood pressure in the 10 renal artery by freezing the nerve and/or plexus, which supplies the renal artery through sympathetic innervation, halting the nerve's activity and halting the pressure regulatory mechanism.



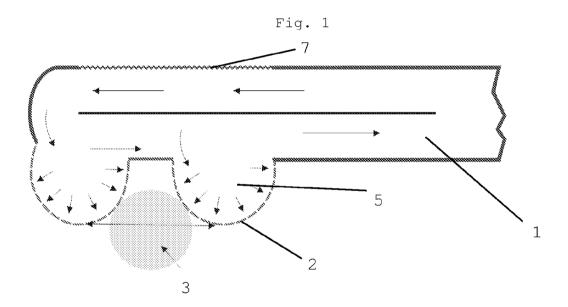


Fig. 2



Fig. 3a

Fig. 3b

Fig. 3c

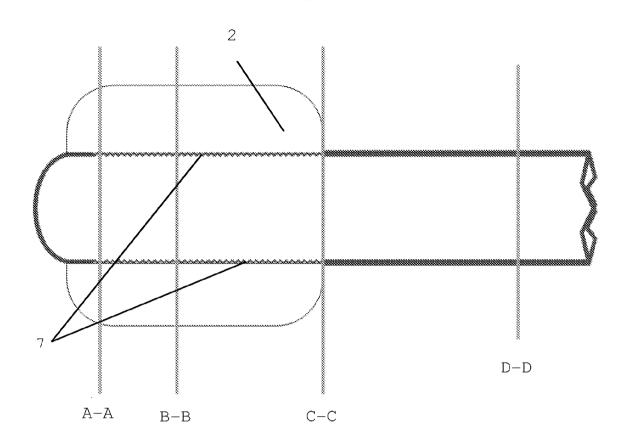


Fig. 4

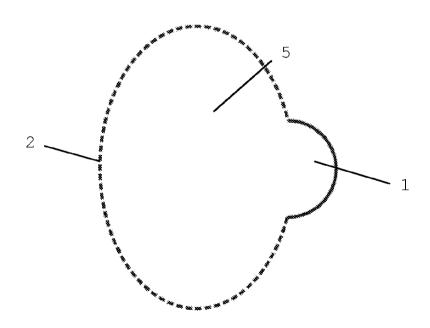


Fig. 5

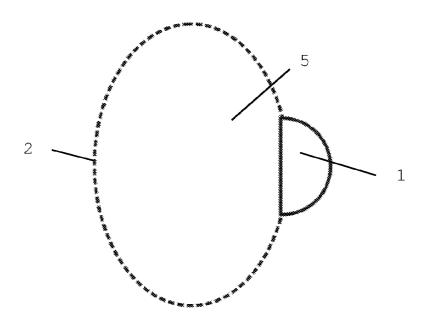


Fig. 6

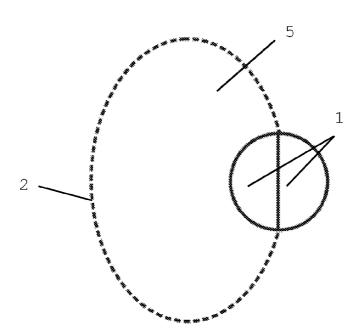


Fig. 7

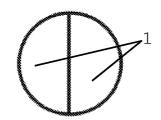


Fig. 8

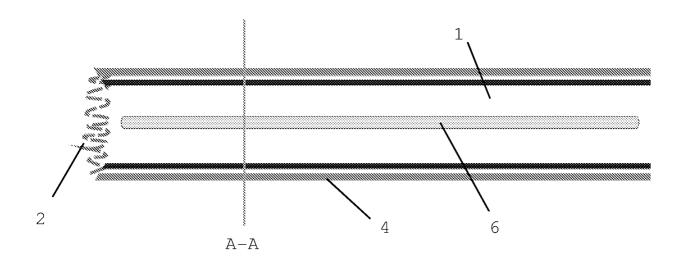


Fig. 9

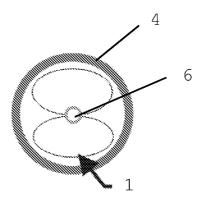


Fig. 10

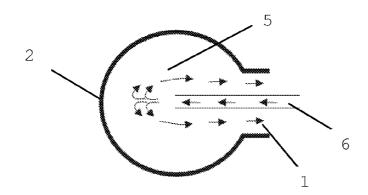


Fig. 11

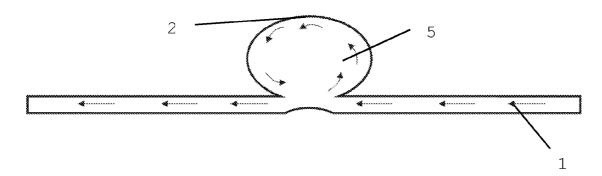


Fig. 12

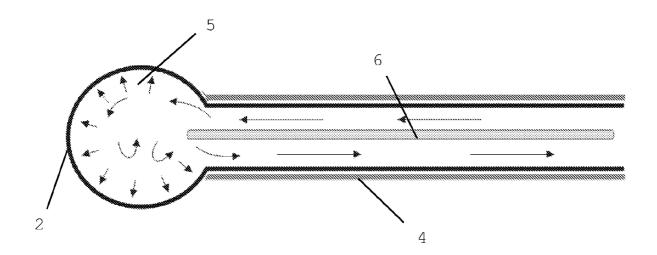


Fig. 13

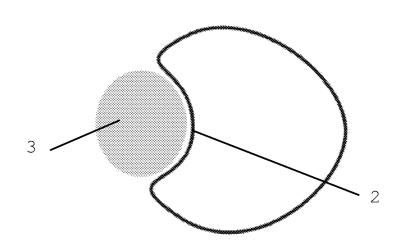
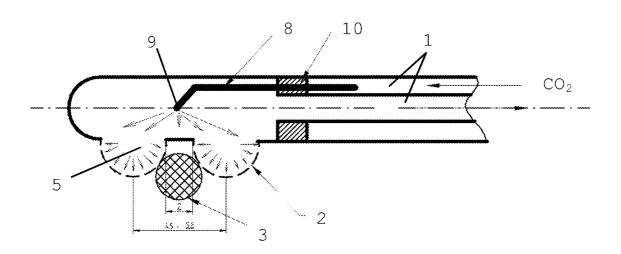


Fig. 14



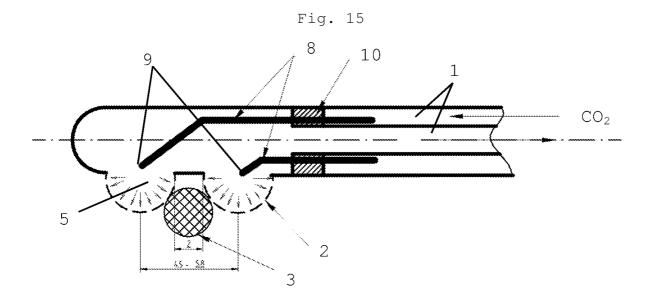


Fig.16

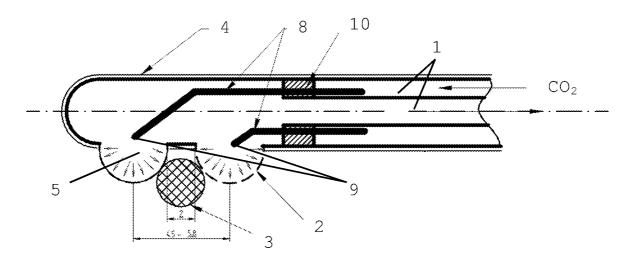


Fig. 17

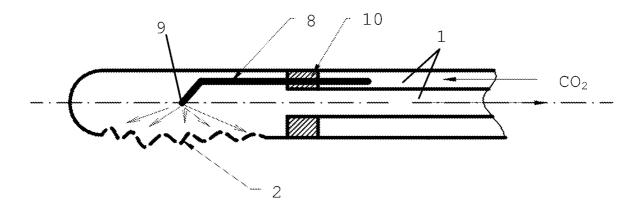
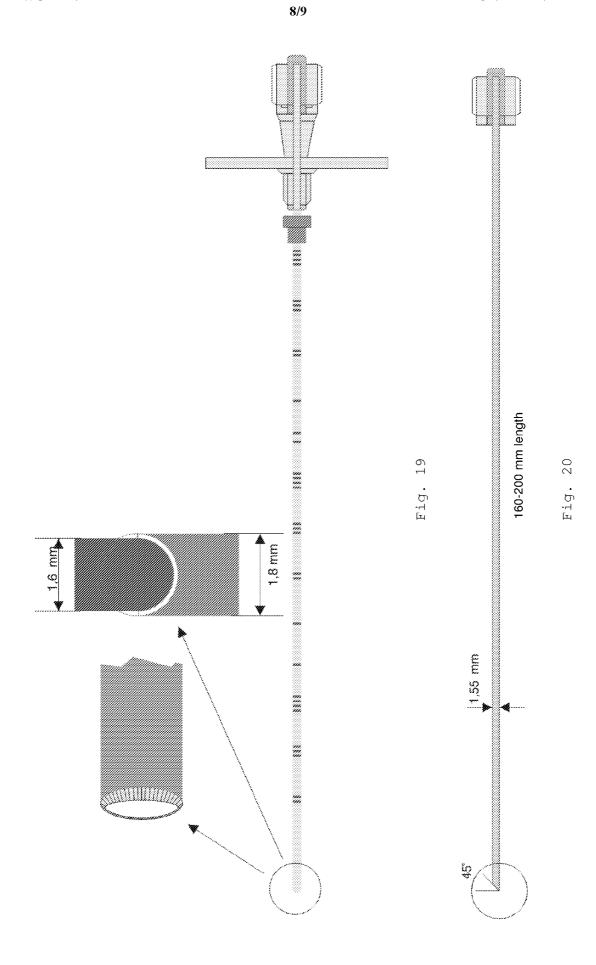
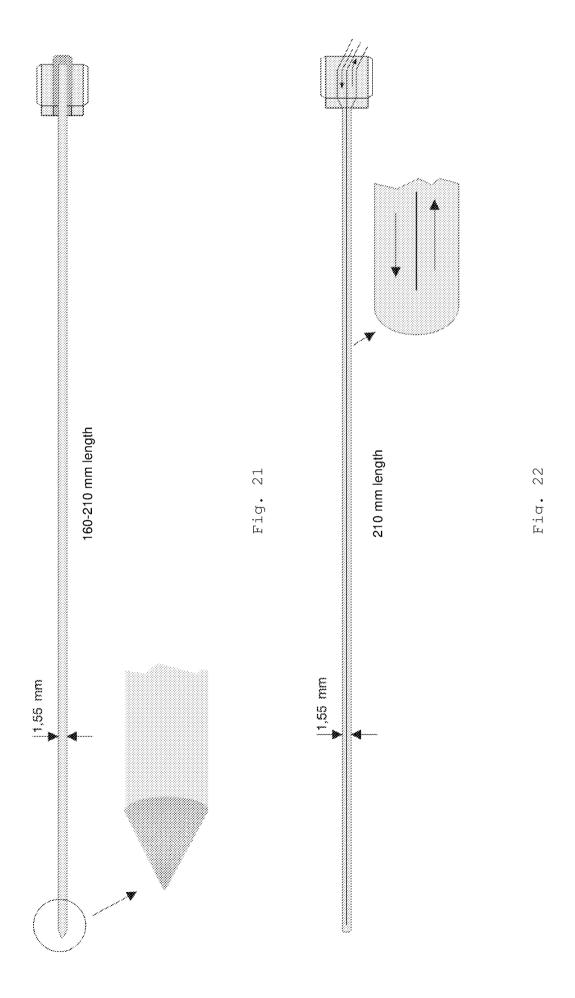


Fig. 18





INTERNATIONAL SEARCH REPORT

International application No PCT/PL2014/050066

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B18/02 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							
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched							
Electronic d	ata base consulted during the international search (name of data ba	se and, where practicable, search terms use	;d)				
EPO-Internal, WPI Data							
C. DOCUMENTS CONSIDERED TO BE RELEVANT							
Category*	Citation of document, with indication, where appropriate, of the rel	evant passages	Relevant to claim No.				
X	US 2012/089047 A1 (RYBA ERIC [US] ET AL) 12 April 2012 (2012-04-12) paragraphs [0110], [0122], [0168], [0184] - [0186], [0220], [0224], [0225]; figures 16A-B,18A-B,26,27		1-7				
Х	US 2005/043724 A1 (RYBA ERIC [US 24 February 2005 (2005-02-24) paragraphs [0013], [0019], [00 [0028]; figure 3	1-4,7					
X	US 2001/037081 A1 (HEINER WILFRE [NL]) 1 November 2001 (2001-11-0 columns 13,29,34; figure 2	1,2,4,7					
	ner documents are listed in the continuation of Box C.	X See patent family annex.					
"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		"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					
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Name and n	nailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fay: (+31-70) 340-3016	Authorized officer Link, Tatiana					

International application No. PCT/PL2014/050066

INTERNATIONAL SEARCH REPORT

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. X Claims Nos.: 8 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					
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:					
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.:					
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

Information on patent family members

International application No
PCT/PL2014/050066

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 2012089047 A1	12-04-2012	CN 1035 EP 26 US 20120	307277 A1 547229 A 500784 A1 089047 A1 019156 A1	09-02-2012 29-01-2014 12-06-2013 12-04-2012 09-02-2012
US 2005043724 A1	24-02-2005	CA 24 EP 15 JP 20050 KR 200500	201680 A1 470891 A1 508309 A1 066319 A 020588 A	10-03-2005 22-02-2005 23-02-2005 17-03-2005 04-03-2005 24-02-2005
US 2001037081 A1	01-11-2001	DE 601 EP 11	114486 D1 114486 T2 129669 A1 037081 A1	08-12-2005 27-07-2006 05-09-2001 01-11-2001