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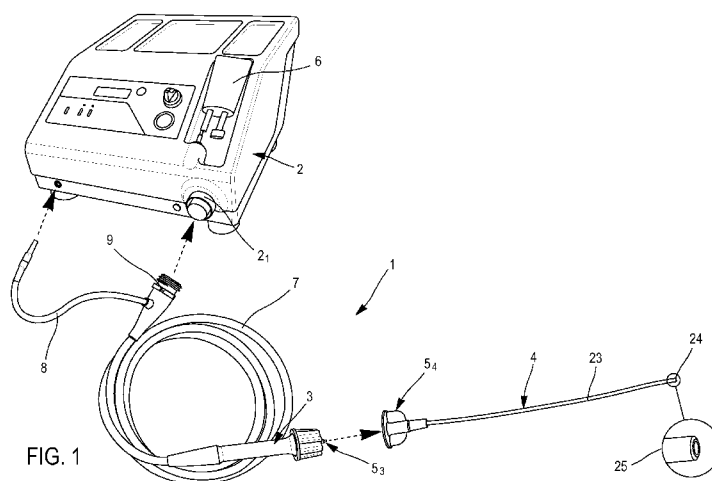
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(54) Title: DEVICE AND METHOD FOR INJECTING PULSED STEAM INTO A HUMAN OR ANIMAL VESSEL *E.G.* A VEIN



(57) Abstract: The purpose of the invention is to develop an improved device for injecting pulsed steam into a human or animal vessel (*e.g.* veins), especially tributaries and perforating veins to treat them through thermo fibrosis. The device of the invention includes a water pulse generator (2) that produces micro pulses of pressurized sterile water; a hand piece (3) that transforms pulses of water coming from the generator (2) into pulses of steam; an endoluminal catheter (4) with a tubular part (23) for delivering the steam into the vessel; connection means (5) between the hand piece (3) and the endoluminal catheter (4); and a programmable central processing unit (cpu) to control the water pulse generator (2) and the hand piece (3). The main features of the device according to the invention are: the tubular part (23) has a length comprised between 1 and 30 mm; and is made of a polymer; the distal end of the endoluminal catheter has a terminal and central opening and possibly transversal holes to treat dilated veins. For smaller veins and those close to the skin, the water pulse generator and the hand piece are designed and controlled by the cpu, so that pulses of steam are made from pulses of water which volumes are comprised between 5 and 70 μ l, and can be injected into the vessel at a controlled period comprised between one pulse/ 0.5 s and one pulse/ 2s and/or there are decompression means of the steam coming from the hand piece. The method for treating tributaries and perforating veins is another part of the invention.

**DEVICE AND METHOD FOR INJECTING PULSED STEAM INTO A HUMAN OR
ANIMAL VESSEL *E.G.* A VEIN**

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TECHNICAL FIELD OF INVENTION

The invention concerns a new device for treating pathological venous or arterio-venous diseases, in particular varicose veins, hemorrhoids, arterio-venous shunts or other vascular malformations, by injecting steam via the endoluminal route, and more particularly for treating tributaries and perforators veins through endovenous occlusion by thermofibrosis with the injecting steam. More precisely, the invention concerns a device for injecting pulsed steam into a human or animal vein.

BRIEF DISCUSSION OF RELATED ART

Patients with Chronic Superficial Venous Insufficiency (CSVI) usually present reflux in one or several saphenous trunks, and bulging varicose tributaries and perforators.

Saphenous trunks can be removed by surgery, chemical or thermal ablation.

Concerning thermal ablation of saphenous trunk, reference is made to US7753871-B which discloses a Steam Vein Sclerosis (SVS) device for delivering thermal energy to the venous wall, which results in vein wall fibrotic retraction and its subsequent definitive occlusion or obliteration. Thermal or steam ablation combines the advantages of thermal and chemical ablation. Steam ablation of saphenous trunks has been clinically used for several years with success. The device heats sterile water into steam and delivers the steam into the vein for coagulation of the vein in patients with superficial venous reflux. The steam heats the vein wall transferring thermal energy that raises the temperature of the vascular wall. The thermal energy destroys the intima and causes contraction and thickening of the collagen fibers within the adventitia and especially the media. The diameter of the vein is thus greatly reduced by contraction and thickening of collagen fibrils and also by the spasm induced by the increased temperature. These phenomena result in the occlusion of the venous lumen. Such a concept is faster and simpler and allows a homogenous diffusion of the heat. Moreover, pulsated steam is the best way to convey energy to tissues: it is an excellent heat conductor and avoids

carbonization encountered with other thermal approaches. The device is composed of equipment and disposables and consists in 3 main parts:

- a cold water pulse generator that produces micro pulses (80 μ l) of pressurized sterile water. The generator is composed of a pneumatic piston, a hydraulic pump and a sterile water flask. The pistons produce two phases: the filling up of the hydraulic pump with sterile water and the injection of this sterile water in the hand-piece /pipe.

- a hand piece / pipe that transforms pulses of water in pulses of steam. The heating element is incorporated into the hand piece, close to the distal end, allowing minimal energy loss.

- an endovenous metallic microtube for distributing the steam into the vein.

In practice, the injection unit is in addition combined with a water storage bag. The microtube for distributing the steam into the vein of internal diameter equal to 150 μ m and external diameter equal to 350 μ m. This microtube is connected to the distal end of the hand piece by any appropriate means. The microtube has transverse openings on a blunt end or a central opening on a non blunt end. The vein to be treated is punctured using a needle positioned in a small catheter about 5 cm long, the surface of which has been Teflon® treated, the needle being withdrawn after inserting the catheter at the surface of the skin. The microtube is introduced into the catheter until the distal end of the microtube reaches the end of the vein to be treated. The generator then sends pulses of cold water into the hand piece, which transforms these pulses into steam at a temperature of about 200°C and the steam then passes through the microtube to its distal end. Using the markings on the surface of the microtube, the operator progressively withdraws the microtube giving one or more pulses per centimeter depending on the diameter of the vessel.

The means of distributing the steam within the vessels (catheter) described in US7753871-B are adapted to saphenous veins but are not optimized to non-saphenous veins. The catheter used for saphenous trunks obliteration cannot be safely and efficiently used to treat non-saphenous veins like tributaries and perforators because of the length (45 to 60 cm) and low flexibility (has a metallic core) of the current catheter. It is not suitable for veins which are short, very tortuous and with a fragile wall (easy to be perforated) like tributaries and perforators veins. Moreover, the delivery of 70-80 μ l water pulses in the SVS device according to US7753871-B is not systematically adapted to all tributaries, specifically to the ones closed to the skin and for smaller veins (tributaries can have smaller diameters compared to saphenous). Finally, the reduction cost of the SVS device for treating non-saphenous veins, is required.

Treatments of non-saphenous varicose veins are currently carried out using 2 techniques:

- Ambulatory phlebectomy: removing the vein through small incisions using a "hook", usually under local or tumescent anesthesia.

1. This process is time consuming

2. It is often difficult to remove all the veins, especially if they are adhering to the skin, as in areas of lipodermatosclerosis.

3. Some pigmentation of the scars may occur.

4. Phlebectomy remains a relatively invasive method that is not easily accepted by patients as it is painful and surgically wounded. And it can be performed only in a surgical setting (operating room).

- Foam sclerosis consists in injecting in the vein a sclerosing agent mixed with air or another gas, usually CO₂.

1. On larger veins it is often followed by inflammatory reactions, pain and pigmentation of the skin. Thrombus removal can be necessary to treat these incidents.

2. Serious adverse events, such as transient ischemic attacks or ischemic strokes, have been reported with foam sclerotherapy

3. The quantity of foam injected per session is limited (Tegernsee's Consensus , 2006) so several sessions may be necessary, increasing the overall cost of this technique and requiring the patient to undergo several operations.

Thus, there is a need for a better way to treat tributary and perforator varicose veins with a procedure that is less time-consuming and that is minimally invasive and painfulness than phlebectomy, as well as less incidents-prone than foam sclerotherapy.

BRIEF DESCRIPTION OF THE INVENTION

The invention aims notably to reach at least one of the following purposes.

The purpose of the invention is to develop an improved device for injecting pulsed steam into a human or animal vessel (*e.g.*veins), especially tributaries and perforating veins to treat them through thermofibrosis.

Another purpose of the invention is to develop an improved device for injecting pulsed steam into a human or animal vessel (*e.g.*veins), especially tributaries and perforating veins to treat them through thermofibrosis, said device being reliable and performing.

5 Another purpose of the invention is to develop an improved device for injecting pulsed steam into a human or animal vessel (*e.g.*veins), especially tributaries and perforating veins to treat them through thermofibrosis, said device satisfying the requirement of administering safely and therapeutically efficiently steam into the tributaries and perforating veins.

10 Another purpose of the invention is to develop an improved device for injecting pulsed steam into a human or animal vessel (*e.g.*veins), especially tributaries and perforating veins to treat them through thermofibrosis, said device being cheap and simple to manufacture.

Another purpose of the invention is to develop an improved device for injecting pulsed steam into a human or animal vessel (*e.g.*veins), especially tributaries and perforating veins to treat them through thermofibrosis, said device enabling treatment methods with at least one of the following advantages:

- 15 1: 5 min with steam instead of 30 min with surgery
- 2: no need of removal of the vein, since thermofibrosed
- 3: no pigmentation (due to the surgical removal) since any removal of the vein
- 4: minimally invasive in this case: percutaneous insertion of the catheter
- 5: no inflammatory reaction since any chemical agent is delivered
- 20 6: all the veins can be treated in only one session. (Generally, when using a sclerosing agent, small volumes of the said chemical agent can be injected because of possible inflammatory reactions.)

In this respect, the invention concerns a device for injecting pulsed steam into a human or animal vessel (*e.g.*veins) including:

- 25 • a water pulse generator that produces micro pulses of pressurized sterile water;
- a hand piece or heating element that transforms pulses of water coming from the generator into pulses of steam;
- an endoluminal catheter for delivering the steam into the vessel;

- connection means between the hand piece and the endoluminal catheter;
- and a programmable central processing unit (cpu) to control the water pulse generator and the handpiece;

wherein

- 5 a. the endoluminal catheter (4) comprises a tubular part (23) which length L (in cm) is comprised between the following ranges (limits included) given in an increasing order of preference: [1 ; 30], [2 ; 28], [3 ; 27], [4 ; 26], [5; 25], [6 ; 24], [8 ; 22], [10 ; 20];
- b. the tubular part of the endoluminal catheter is made of a flexible, biocompatible, thermically insulating and thermically resistant material, preferably of a non-metallic
10 material, more preferably a polymer;
- c. the distal end of the endoluminal catheter has a terminal and central opening.

In a particularly preferred embodiment, the connection means comprise a distal coupling part designed to cooperate with a proximal coupling part of the endoluminal catheter, and the proximal coupling part of the endoluminal catheter comprises:

- 15 ○ a terminal flange ring which is the proximal end of the tubular part of the endoluminal catheter,
- as well as a socket through which goes the tubular part of the endoluminal catheter, said tubular part being able to slide in the socket as far as the flange ring be stopped against a sealing joint inside the socket, this latter being made of a non-flexible,
20 biocompatible, thermically insulating and thermically resistant material, preferably of a non-metallic material, more preferably a polymer.

The tightness of the connection between the hand piece and the endoluminal catheter is actually improved through the use of such a sealing joint included in the connection means.

Advantageously, at least one of the following characteristics (d) (e) and/or (f) is implemented:

- 25 d. the endoluminal catheter has at least one transversal hole in addition to the terminal and central opening;
- e. the water pulse generator and the hand piece are designed and controlled by the cpu, so that pulses of steam are made from pulses of water which volumes are comprised between

5 and 70 μ l, preferably 10 and 50 μ l, and can be injected into the vessel at a controlled period comprised between one pulse/ 0.5 s and one pulse/ 2s;

f. there are decompression means of the steam coming from the hand piece.

The implementation of characteristics (d), (e) and (f) depends on the type/shape, diameter and
5 localization of the vein to be treated.

The transversal hole(s) for the endoluminal [characteristic (d)] is preferable for dilated veins, for example veins presenting pseudo aneurysmal dilatation and/or having a diameter of more than 3 mm. In this embodiment with the transversal hole(s) [characteristic (d)], the endoluminal catheter allow the vapor to exit by the sides of the endoluminal catheter. The transversal hole(s) is (are)
10 designed to allow the treatment of dilated and tortuous veins by a multidirectional dispersion of steam and/or to decrease of at least 10% of the pressure of the water steam, coming from the heating element. The number of holes is preferably comprised between one and eight, preferably between two and four. The diameter of the holes is comprised between 0.05 mm and the internal diameter of the endoluminal catheter. The holes could be on the whole length of the endoluminal
15 catheter, preferably close to the distal end.

Whereas for veins closed to the skin and/or having a diameter equal to or less than 3 mm, at least one of the following characteristics (e) and/or (f) is implemented.

The device according to the invention concerns more particularly human or animal vessels as
20 blood vessels, preferably veins, and more preferably tributaries or perforators veins.

According to a remarkable feature (e) of the invention, the device comprises decompression means of the steam coming from the hand piece, in order to relieve the walls of the veins.

In a preferred embodiment, these decompression means comprise a chamber which is, for
25 example, integral with the connection means. This chamber defines a space which allows the pressure of the water steam, coming from the heating element, to decrease before going through the endoluminal catheter.

Preferably, the decompression chamber is designed so as to induce a decrease comprised between
30 10% and 50% of the pressure of the water steam, coming from the heating element.

According to an interesting embodiment of the decompression means, the decompression chamber is a tubular coupling part which is assembled in the extension of the hand piece outlet.

The decompression chamber (50) includes a tubular part, wherein the steam pulses coming from the hand piece are discharged. The internal diameter (d_t) of the tubular part of the decompression chamber is larger than the internal diameter (d_o) of the hand piece outlet. For instance, in an increased order of preference, $d_t \geq 1.2 d_o$; $d_t \geq 1.5 d_o$; $d_t \geq 1.8 d_o$; $d_t \geq 2 d_o$; $3 d_o \geq d_t \geq 2 d_o$; $d_t = 2.5 d_o$. Concretely, d_t is e.g. between about 1 to 5 mm, preferably about 2.5 mm.

And the length of said tubular part is comprised, in an increased order of preference about 5 to about 60 mm; about 10 to about 50 mm; about 20 to about 35 mm.

Preferably, the endoluminal catheter has a circular cross-section and an internal diameter (in an increased order of preference) between about 0.05 mm to 2.5 mm, 0.1 mm to 2.0 mm; 0.30 mm to 0.8 mm; 0.40 mm to 0.7 mm, 0.50 mm to 0.60 mm e.g. 0.56 mm

Preferably, the outer diameter of the endoluminal catheter is comprised diameter (in an increased order of preference) between about 0.1 mm to 3,0 mm, 0.50 mm to 2.0 mm; 0.60 mm to 1.60 mm; 0.70 mm to 1.40 mm; 0.90 mm to 1.2 mm; 1.0 mm to 1.1 mm, e.g. 1,07 mm.

In a preferred embodiment, the distal end of the endoluminal catheter has a blunt, especially rounded off, shape, which is safer with respect to the risk of tearing/perforating the vessel wall. Advantageously, the radius of curvature of said distal end is comprised between 0.10 mm and 0.85 mm, preferably between 0.20 and 0.30 mm.

In a first embodiment, the device according to the invention is designed so as to be used in a method for treating tributaries consisting in using the device according to the invention, wherein

- i. the tubular part of the endoluminal catheter is introduced into a patient's vein to be treated and positioned within the section of the vein to be treated through multiple punctures; each of them corresponding to a given segment of vein to be treated;
- ii. several pulses of pressurized overheated steam are delivered consecutively towards the vein, and the surrounding venous tissue that becomes heated and begins to shrink;
- iii. the tubular part of the endoluminal catheter remains active until there has been sufficient shrinkage of the vein;
- iv. the extent of shrinkage of the vein is possibly detected by appropriate detection means, preferably Doppler echography.

In a second embodiment, the device according to the invention is designed so as to be used in a method for treating by direct obliteration, a tortuous perforating vein longer than 2cm and extending between a superficial vein and a deep vein, wherein:

- i. the tubular part of the endoluminal catheter is introduced under echo guidance in the perforator, at least 2cm from the deep vein,
- ii. at least 3 pulses of pressurized overheated steam are delivered,
- iii. then the tubular part of the endoluminal catheter is removed of a distance of about 1 cm and 3 other pulses are emitted.

In a third embodiment, the device according to the invention is designed so as to be used in a method for treating by indirect obliteration, a perforating vein of 2 cm long or less and extending between a superficial vein and a deep vein, wherein:

- i. the tubular part of the endoluminal catheter is introduced distally in the superficial vein, guided upward proximal to the perforator;
- ii. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the upward side of the superficial vein;
- iii. the tubular part of the endoluminal catheter is removed downward proximal to the perforator;
- iv. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the downward side of the superficial vein.

In another aspect, the invention relates to a method for treating tributaries consisting in using the device according to the invention, wherein

- i. the tubular part of the endoluminal catheter is introduced into a patient's vein to be treated and positioned within the section of the vein to be treated through multiple punctures; each of them corresponding to a given segment of vein to be treated;
- ii. several pulses of pressurized overheated steam are delivered consecutively towards the vein, and the surrounding venous tissue that becomes heated and begins to shrink;
- iii. the tubular part of the endoluminal catheter remains active until there has been sufficient shrinkage of the vein;

- iv. the extent of shrinkage of the vein is possibly detected by appropriate detection, preferably Doppler echography.

Preferably, the segments' length is 4 to 12 cm, preferably 6 to 10 cm.

According to a remarkable feature of the invention, a maximum of 6 pulses are delivered at the same catheter location to avoid overheating at this level.

Preferably, local anesthesia is carried out with 5 to 10 cc of anesthetic, infiltrated between the vein and the skin.

In a variant, skin cooling is used, with skin temperatures down to 4/6°C.

In another aspect, the invention relates to a method of applying steam with a catheter for treating perforating veins, by direct or indirect obliteration.

In the embodiment of direct obliteration for a perforator long and tortuous i.e longer than 2cm: and extending between a superficial vein and a deep vein, said method consists in using the device herein defined, wherein:

- i. the tubular part of the endoluminal catheter is introduced under echo guidance in the perforator, at least 2cm from the deep vein,
- ii. at least 3 pulses of pressurized overheated steam are delivered,
- iii. then the tubular part of the endoluminal catheter is removed of a distance of about 1 cm and 3 other pulses are emitted.

In the embodiment of indirect obliteration for short perforators, i.e a 2 cm long or less perforating vein extending between a superficial vein and a deep vein, said method consisting in using the device according to claim 1, wherein:

- i. the tubular part of the endoluminal catheter is introduced distally in the superficial vein, guided upward proximal to the perforator;
- ii. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the upward side of the superficial vein;

- iii. the tubular part of the endoluminal catheter is removed downward proximal to the perforator;
- iv. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the downward side of the superficial vein.
- 5 v. the tubular part of the endoluminal catheter is introduced distally in the superficial vein, guided upward proximal to the perforator;
- vi. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the superficial varicose.

10 DEFINITIONS

Any singular in this text shall correspond to a plural and reciprocally.

According to the present invention:

- 15 ○ "*usable length L*" is the length of the endoluminal catheter, and more precisely of its (external) tubular part which can be introduced into the vessels. L is shown on Figures 3A, 3B & 4.
- "*thermofibrosis*" means for instance occlusion or obliteration of the veins by means of endoluminal injection of steam pulses.
- "*flexible*" means for instance a characterization by a standard mechanical test giving a flexural modulus lower than 2900 psi (corresponding to about 20 GPa).
- 20 ○ "*biocompatible*" means for instance a characterization by standard biological tests such as cytotoxicity, sensitization, irritation/intracutaneous, acute systemic toxicity, hemocompatibility.
- "*thermically insulating*" means for instance a characterization by a standard physical test giving a thermal conductivity lower than 30 BTU-in/ft²-hr-°F.
- 25 ○ "*thermically resistant*" means for instance a characterization by a standard physical test giving a melting point higher than 212°F (100°C).

- " *water* " means for instance any pharmaceutically acceptable liquid injectable into human or animal body (vessels), notably aqueous liquid such as water, aqueous solution, physiological serum mix of water with another liquid (e.g. alcohol), possibly containing active principle and/or ingredient.
- 5 ○ " *about* " means for instance an approximation of more or less 5 %, preferably 1 %. It should be considered that all the figures herein are given with this approximation.

DETAILED DESCRIPTION OF THE INVENTION

10 The invention and the advantages resulting from it are illustrated hereinafter by an example of embodiment in reference to the attached figures.

Figure 1 is a diagram of the device according to the invention.

Figure 2 is a cross-section in the longitudinal median plan of the hand piece pertaining to the device according to the invention.

15 Figure 3A is a detailed and exploded representation of the section in the longitudinal median plane of the distal terminal part of the hand piece represented on the figure 2 and of the endoluminal catheter.

Figure 3B is a representation analogous to figure 3A in which all the elements shown on figure 3A are assembled.

20 Figure 4 is a cross-section in the longitudinal median plan of the catheter presenting a terminal and central opening plus lateral/transversal holes.

Figure 4A is a detailed and enlarged view of the proximal coupling part of the endoluminal catheter of figure 4.

Figure 4B is a detailed and enlarged view of the distal part of the endoluminal catheter tubular part of figure 4.

25 Figure 5 is a schematic view of the leg of a patient with varicosities to be treated by means of the device according to the invention, several introducers being punctured in several injection points of the ill vein.

Figure 6 shows the introduction of the endoluminal catheter of the device according to the invention into one of the introducers shown on figure 5.

The device shown on figure 1 is designed for injecting pulsed steam directly within a human or animal vessel, especially a vein. Such a device designated by reference 1 is composed of:

- 5 - a water pulse generator 2 that produces micro pulses of pressurised sterile water;
- a hand piece 3 that transforms pulses of water coming from the generator 2 into pulses of steam;
- an endoluminal catheter 4 for delivering the steam into the vessel, especially the vein;
- connection means 5 between the hand piece 3 and the endoluminal catheter 4;
- 10 - a central processing unit (cpu), for instance a programmable electronic card not shown onto the attached drawings;
- a sterile water storage bag 6 intended to feed the water pulse generator 2 with sterile water;
- a pipe 7 which links the output of the water pulse generator 2 to the inlet of the hand
- 15 piece 3;
- and decompression means 50 in the extension of the outlet 30 of the hand piece 3.

The water pulse generator 2 can be as the one described in the US 7,753,871-B2 as well as the one described in WO2006/108974-A1. For example, the water pulse generator 2 includes an

20 injection unit comprising a pneumatic piston, a hydraulic pump both controlled by the cpu also included in the water pulse generator 2. The pneumatic piston (*e.g.* a large-sized pneumatic cylinder) which can also be piezoelectric or mechanical is integral with the small-sized hydraulic cylinder travelling in the chamber of the hydraulic pump where the water is pressurized. This piston and this hydraulic pump work in two phases: the filling up of the hydraulic pump with

25 sterile water coming from the storage bag 6 and the injection of this sterile water in the pipe 7 which feeds with pulses of sterile water the hand piece 3, itself terminated in a tube fed by the water storage bag 6. The stroke, force and speed of travel of the pneumatic cylinder are programmed in the cpu to the desired frequency, volume and pressure of injection of the water pulses into the pipe 7 and the hand piece 3. This water pulse generator 2 is naturally connected to

30 an electrical source which feeds the injection unit and the cpu as well as the hand piece 3 which should produce heat by joule effect to transform pulses of water coming from the generator 2 into pulses of steam delivered at the outlet 5₃ of the hand piece 3. The power supply of the hand piece 3 is got by means of a cable 8 which is plugged in the front of the water pulse generator 2.

According to an important feature of the invention, the water pulse generator 2 and the hand piece 3 are designed and controlled by the cpu so that pulses of steam are made from pulses of water which volume is comprised between 5 and 70 μl , preferably 10 and 50 μl , and can be injected into the pipe 7 at a controlled period of one pulse every 0,5 to 2 seconds. The hand piece 3 which is shown in detail in figures 2 & 3, is analogous to the hand piece described in columns 4 and 5, figures 2 and 3 of the US 7,753,871-B2. The attached figures 2, 3A, 3B show the hand piece 3 linked (e.g by screwing), through the pipe 7's proximal end 9, to the outlet 2₁ of the water pulse generator 2, said outlet 2₁ supplying the water pulses produced by the injection unit. Moreover, the pipe 7's proximal end 9 is also connected to the water pulse generator 2 through the power supply cable 8. The outlet 2₁ of the water pulse generator 2 is plugged, into the proximal end 9 of the pipe 7, to a tube 10 running through the pipe 7 and the hand piece 3. Water pulses produced by the generator 2 are transported by this tube 10 to the hand piece 3. The tube 10 is made of stainless steel and has a given resistivity, for example 72 $\mu\Omega/\text{cm}$. The distal end of the tube 10 is coiled around a portion of a stainless steel tube 11 of low resistance forming a spiral 12. The portion of the stainless steel tube 11 in contact with the spiral 12 is covered by an electrical and a thermal insulating sheath 13. The proximal end 14 of the portion of the tube 11 is in contact with an electrical conductor 15 which forms the power supply 8. The distal end 16 of the portion of the tube 11 has an opening 17 allowing the distal end 18 of the spiral 12 to pass so as to be in contact with the electrical conductor formed by the portion of low resistance of the stainless steel tube 11. As figures 3A and 3B show, the distal end of the portion of tube 11 has no insulating sheath, thus allowing current to pass from the stainless steel tube 11 into the spiral 12 to allow heating to occur into the spiral part of the tube 10 and not in the straight part between its proximal end 19 of the injection unit outlet and the proximal end 20 of the spiral 12. The straight part of the tube 10 has a low resistivity braided copper sheath. The screw thread of the proximal end of the pipe 7 provides the hydraulic connection which at the same time serves as electrical ground. The spiral 12 has an electrical and thermo-insulated sheath 21. Moreover the distal end of the hand piece 3 is fitted with a silicon part 22 which avoids the hand piece 3 heating up too much. The current circulates in the electrical conductor 15, in the stainless steel tube 11 of lower resistance, then in the spiral 12 to return via the tube 10 to the electrical ground at the proximal end 9 of the pipe 7.

This hand piece 3 is a heating element capable to transform pulses of water coming from the water pulse generator 2 in pulses of steam. The heating spiral 12 which is above described is close to the distal end of the hand piece 3, allowing minimal energy loss. Pulses of steam

produced at the distal end 18 of the spiral 12 are propelled outside the hand piece 3 through the outlet 30 of the hand piece 3.

As shown on figures 3A, 3B, 4, 4A & 4B, the hand piece 3 is assembled through its outlet 30 to the endoluminal catheter 4, by the connection means 5 which comprises a distal coupling part 5₃ (male part) which is integral with a tubular decompression chamber 50 which forms the decompression means of the steam pulses coming the outlet 30 of the hand piece 3. Said distal coupling part 5₃ (male part) is designed to cooperate with a proximal coupling part 5₄ (female part) of the endoluminal catheter 4. Concretely, the male part 5₃ is intended to be introduced and fixed (e.g. by screwing) into the female part 5₄.

In this non limitative embodiment, the tubular decompression chamber 50 is so a coupling part which is assembled in the extension of the hand piece outlet 30, this latter being tightly fixed (e.g. by screwing) into a housing 30' at the proximal end of the chamber 50. The decompression chamber 50 includes a tubular part 51, wherein the steam pulses coming from the hand piece 3 are discharged. The internal diameter d_i of the tubular part 51 of the decompression chamber 50 is larger than the internal diameter d_o of the hand piece outlet 30. For instance, $d_i = 2.5(d_o)$ and d_i is about 2.5 mm. And the length of said tubular part 51 is comprised, about 20 to about 35 mm and, for instance, is about 28 mm.

In this non limitative embodiment, the proximal coupling part 5₄ of the endoluminal catheter 4 comprises a terminal flange ring 26, as well as a socket 27 through which goes the tubular part 23 (length L) of the endoluminal catheter 4. This tubular part 23 can slide in the socket 27 as far as the flange ring 26 be stopped against an annular sealing joint 28 inside the socket 27.

As it appears on figures 4 & 4A, the flange ring 26 is composed of (e.g. metallic) funnel-shaped piece 26₁ which is fixed into the proximal end part 26₂ of the tubular part 23 of the catheter 4. Said proximal end part 26₂ is inside the socket 27, in the nozzle 27₁ of the socket 27. Said proximal end part 26₂ is not included in the length L of the tubular part 23 of the catheter 4. Length L corresponds to the tubular part 23 which protrudes from the nozzle 27₁. The annular sealing joint 28 is lodged against a shoulder 27₂ of the distal nozzle 27₁ and the outer face of the flange ring 26, more precisely of the proximal end part 26₂, is blocked against the joint 28.

As shown in figure 3B, the screwed connection between 5₃, the distal coupling part 5₃ of the tubular decompression chamber 50 and the proximal coupling part 5₄ of the socket 27, ensures a significant and longstanding compression of the sealing joint 28. The introduction by screwing of the distal coupling part 5₃ into the proximal coupling part 5₄ is done as far as the bottom flange

29 of the socket 27 comes into contact against the wall of the distal end of the compression chamber 50, whereas the flange ring 26 of the proximal end of the catheter 4 is in tight contact with the outlet of the decompression chamber 50. The compressed sealing joint 28 ensures the water/steam-tightness:

- 5 ○ of the connection between the flange ring 26 and the outlet of the decompression chamber 50;
- and of the connection between the flange ring 26 and the outside of the socket nozzle 27₁ and of the proximal end part 26₂ of the tubular part 23 of the catheter 4

10 Moreover, the proximal housing 30' of the chamber 50 is also tightly secured to the outlet 30 of the hand piece 3.

15 The tubular part 23 of the endoluminal catheter 4 is advantageously made of a non metallic plastic polymer tube, for example in PolyTetraFluoroEthylene (Teflon®), said tube 23 being flexible, biocompatible, thermically insulating and thermically resistant. The distal end 24 of this non metallic polymer tube 23 has a terminal and central opening 25 shown on figure 1. This central and terminal opening 25 has a blunt, especially rounded off shape, which radius of curvature is comprised between 0.20 and 0.30 mm, e.g. 0.25 mm. At its proximal end, the tube 23 comprises the flange ring 26. Said tube 23 goes through and slides in the socket 27 which includes the female part 5₄ of the connection means 5. This sliding is possible as far as the flange ring 26 be stopped against the sealing joint 28 located at the back and inside the female part 5₄ of the socket 27.

20 The funnel-shaped piece 26₁ of the flange ring 26 is composed of stainless steel or polymer, preferably Stainless steel AISI 304L.

25 The socket 27 is composed of an electrical insulating and/or thermoresistant material (polymer, ceramic...), preferably Polyether ether ketone (PEEK). The sealing joint 28 is composed of polymer, preferably silicon.

 According to one of the essential features of the invention, the endoluminal catheter's length L (mm) from the distal end of the socket 27 to the distal end 24 of this non metallic polymer tube 23. L is comprised between [10; 20], e.g. 15 cm.

30 The catheter 4 is capable to withstand high temperatures e.g. between 212°F (100°C) and 482°F (250°C), and to repeated heat pressures.

The L length protruding tubular part 23 of the catheter 4 has an outer diameter e.g. comprised between 0.1 mm and 3.0 mm, advantageously 1.07 mm and an inner diameter e.g. comprised between 0.1 mm to 1.8 mm, advantageously 0.56 mm.

5 In order to streamline repeated pulses over heated water vapour into the veins, the lumen of the catheter 4 has a substantially and uniformly circular cross-section from the proximal end to the distal end 25. The diameter of the lumen is e.g. comprised between 0.1 mm to 1.8 mm, preferably 0.56 mm. The outer diameter is between 1.0 and 3.0 mm, for example is 1.07 mm.

10 The terminal and central opening (or hole) 25 is designed to deliver the steam forward and to avoid delivering steam directly to the wall of the vein and consequently to the skin. The diameter of the central opening 25 is substantially equal to the inner diameter of the catheter 4 and so is in direct continuity to the distal end and the proximal end of the catheter 4. It allows the delivery of steam all within and along the lumen of the vein. The rounded off or blunt shape of this central makes it possible to introduce safely the catheter 4 into tortuous tributary veins, hindering perforations or any traumatism of the wall of the vein.

15 In case of dilated veins, for example veins presenting pseudo aneurysmal dilatation and/or veins having a diameter greater than e.g. 3mm, the catheter 4 is designed with transversal holes 25₁, 25₂ in addition to the terminal and central opening 25', as shown on figure 4, in which the same references as in figures 3A & 3B designate the same elements. This allows to deliver steam in a multidirectional way. As this feature allows also to decrease the pressure of the water steam
20 coming from the heating element, there is no risk of vein wall perforation and/or skin burn.

Preferably, the endoluminal catheter 4 is a single use sterile unit.

Said catheter 4 (tube 23) can be introduced percutaneously into the veins to deliver locally the right amount of energy provided by the steam to obliterate the veins.

25 These 10 cm/20 cm long catheters 4 with a unique and central hole 25 at its distal end is adapted to the small diameter and to the tortuosity of the veins, tributaries and perforators.

The introduction of the catheter 4 (tube 23) into the vein is done by means of introducers 100 which are punctured into the vessel and more particularly into the tributaries or perforators vein to be treated.

The treatment of tributaries is described hereinafter in reference to figures 5 & 6.

The catheter 4 (tube 23) is introduced into a patient and positioned within the section of the vein to be treated through multiple punctures. This puncturing of these introducers 100 is done by means of a needle positioned in a small catheter of 5 cm long constituting the introducers 100. Once these introducers 100 are punctured into the veins to be treated, forming several injection points, the endoluminal catheter 4 (tube 23) can be introduced into the vein through the introducers 100, as shown in figure 6. The catheter has a length and a diameter sufficient to deliver pressurized overheated steam towards the vein, and the surrounding venous tissue that becomes heated and begins to shrink. The catheter remains active until there has been sufficient shrinkage of the vein. The extent of shrinkage of the vein can be detected by Doppler echography.

So for treating these veins, the catheter 4 is entered under echo guidance, and stays in place while several pulses of steam are delivered consecutively. One can feel the steam travelling along the vein through the skin by applying one hand over the anatomical territory of the vein.

Thus, 6 to 10 cm segments can be treated, by delivering e.g. a maximum of 6 pulses at the same catheter location to avoid overheating at this level. Local anesthesia is used: e.g. 5 to 10 cc are infiltrated between the vein and the skin. Skin cooling can be substituted or conjugated to such an injection of anesthetic, with skin temperatures down to e.g. 39.2/42.8°F (4/6°C).

The vein could still be visible under the skin, but should not be painful. Disappearance will take several months, up to 6 if the vein was large.

Post-operatively, it is useful to control the patient at 1 or 2 weeks: if a lot of thrombus is seen at the Duplex examination, a puncture can be made with a 21G needle for evacuation.

Usually, no pain and no inflammatory reaction are experienced, a significant advantage when compared to foam sclerosis.

The treatment of perforators is described hereinafter

There are two methods according to the invention: direct and indirect obliteration

Direct obliteration is feasible if the perforator is long and tortuous (more than 2cm): under echo guidance the catheter is introduced into the perforator, at least 2cm from the deep vein. For instance, 3 pulses are emitted, then the catheter is retracted 1 cm and 3 other pulses are emitted.

Indirect obliteration is safer for short perforators (less than 2cm): the catheter is introduced distally in the superficial vein, guided upstream or downstream proximal to the perforator. The vein is obliterated by means of pulses of steam. The catheter is then moved downstream or upstream respectfully proximal to the perforator. The vein is then obliterated by means of pulses

of steam. Thanks to these downstream and upstream obliteration, the perforator cannot drain into the superficial varicose.

In both methods the catheter 4 (tube 23) is introduced into the veins through an introducer 100 (as shown in figure 6).

CLAIMS

1. Device (1) for injecting pulsed steam into human or animal vessel including:

- a water pulse generator (2) that produces micro pulses of pressurized sterile water;
- a hand piece (3) that transforms pulses of water coming from the generator (2) into pulses of steam;
- an endoluminal catheter (4) for delivering the steam into the vessel;
- connection means (5) between the hand piece (3) and the endoluminal catheter (4);
- and a programmable central processing unit (cpu) to control the water pulse generator (2) and the handpiece (3);

10 wherein

- a. the endoluminal catheter (4) comprises a tubular part (23) which length L (in cm) is comprised between the following ranges (limits included) given in an increasing order of preference: [1 ; 30], [2 ; 28], [3 ; 27], [4 ; 26], [5; 25], [6 ; 24], [8 ; 22], [10 ; 20];
- b. the tubular part (23) of the endoluminal catheter (4) is made of a flexible, biocompatible, thermically insulating and thermically resistant material, preferably of a non-metallic material, more preferably a polymer;
- c. the distal end (24) of the endoluminal catheter (4,23) has a terminal and central opening (25).

2. Device (1) according to claim 1 wherein the connection means (5) comprise a distal coupling part (5₃) designed to cooperate with a proximal coupling part (5₄) of the endoluminal catheter (4), and wherein the proximal coupling part (5₄) of the endoluminal catheter (4) comprises:

- a terminal flange ring (26) which is the proximal end of the tubular part (23) of the endoluminal catheter (4),
- as well as a socket (27) through which goes the tubular part (23) of the endoluminal catheter (4), said tubular part (23) being able to slide in the socket (27) as far as the flange ring (26) be stopped against a sealing joint (28) inside the socket (27), this latter being made of a non-flexible, biocompatible, thermically insulating and

thermically resistant material, preferably of a non-metallic material, more preferably a polymer.

3. Device (1) according to claim 1 wherein at least one of the following characteristics (d) (e) and/or (f) is implemented:

- 5 d. the tubular part (23) of the endoluminal catheter (4) has at least one transversal hole (25₀₁, 25₀₂) in addition to the terminal and central opening (25);
- e. the water pulse generator (2) and the hand piece (3) are designed and controlled by the cpu, so that pulses of steam are made from pulses of water which volumes are comprised between 5 and 70 μ l, preferably 10 and 50 μ l, and can be injected into the vessel at a
10 controlled period comprised between one pulse/ 0.5 s and one pulse/ 2s;
- f. there are decompression means (50) of the steam coming from the hand piece (3).
4. Device (1) according to claim 1, wherein the decompression means comprise a chamber (50) which is preferably integral with the connection means (5), defining a space (51) which allows the pressure of the water steam, coming from the hand piece (3), to decrease before
15 going through the endoluminal catheter (4).
5. Device (1) according to claim 4 wherein the decompression chamber (50) is a tubular coupling part (51) which is assembled in the extension of the hand piece (3) outlet (30), said decompression chamber (50) including a tubular part (51), wherein the steam pulses coming from the hand piece (3) are discharged, and wherein the internal diameter d_t of the tubular
20 part (51) of the decompression chamber (50) is larger than the internal diameter d_o of the hand piece (3) outlet (30), and preferably, in an increased order of preference, $d_t \geq 1.2 d_o$; $d_t \geq 1.5 d_o$; $d_t \geq 1.8 d_o$; $d_t \geq 2 d_o$; $3 d_o \geq d_t \geq 2 d_o$; $d_t = 2.5 d_o$.
6. Device (1) according to claim 1 wherein the distal end (24) of the endoluminal catheter (4) (23) has a blunt, especially a rounded off, shape.
- 25 7. Device (1) according to claim 1 which is designed so as to be used in a method for treating tributaries consisting in using the device (1), wherein
- i. the tubular part (23) endoluminal catheter (4) is introduced into a patient's vein to be treated and positioned within the section of the vein to be treated through multiple punctures; each of them corresponding to a given segment of vein to be treated;

- ii. several pulses of pressurized overheated steam are delivered consecutively towards the vein, and the surrounding venous tissue that becomes heated and begins to shrink;
 - iii. the tubular part (23) endoluminal catheter (4) remains active until there has been sufficient shrinkage of the vein;
 - 5 iv. the extent of shrinkage of the vein is possibly detected by appropriate detection means, preferably Doppler echography.
8. Device (1) according to claim 1 which is designed so as to be used in a method for treating by direct obliteration, a tortuous perforating vein longer than 2 cm and extending between a superficial vein and a deep vein, wherein:
- 10 i. the tubular part (23) endoluminal catheter (4) is introduced under echo guidance in the perforator, at least 2 cm from the deep vein,
- ii. at least 3 pulses of pressurized overheated steam are delivered,
- iii. then the tubular part (23) endoluminal catheter (4) is removed of a distance of about 1 cm and 3 other pulses are emitted.
- 15 9. Device (1) according to claim 1 which is designed so as to be used in a method for treating by indirect obliteration, a perforating vein of 2 cm long or less and extending between a superficial vein and a deep vein, wherein:
- i. the tubular part (23) endoluminal catheter (4) is introduced distally in the superficial vein, guided upward proximal to the perforator;
- 20 ii. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the upward side of the superficial vein;
- iii. the tubular part (23) endoluminal catheter (4) is removed downward proximal to the perforator;
- 25 iv. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the downward side of the superficial vein.
10. Method for treating tributaries consisting in using the device (1) according to claim 1, wherein

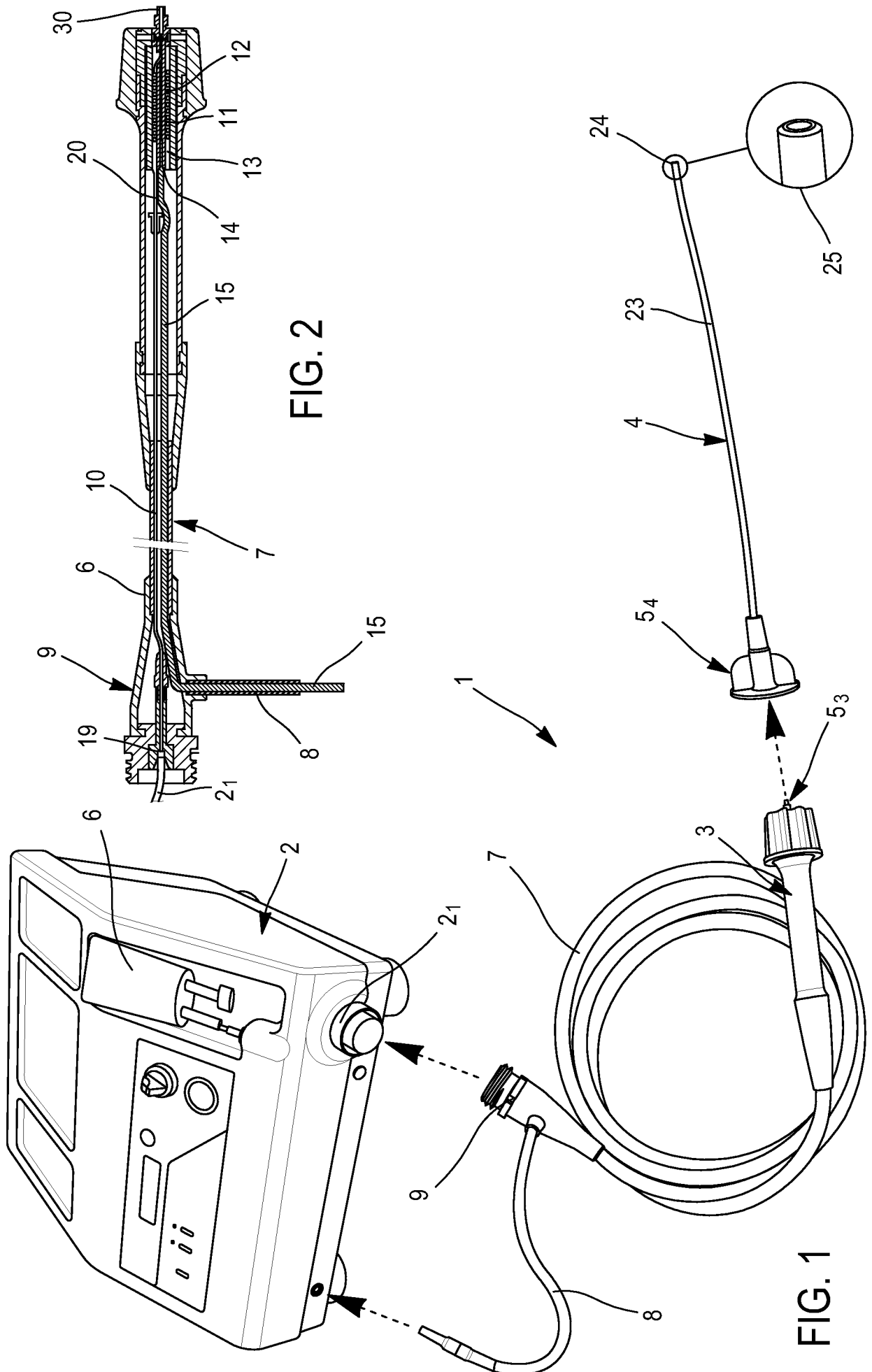
- i. the tubular part (23) endoluminal catheter (4) is introduced into a patient and positioned within the section of the vein to be treated through multiple punctures; each of them corresponding to a given segment of vein to be treated;
 - ii. several pulses of pressurized overheated steam are delivered consecutively towards the vein, and the surrounding venous tissue that becomes heated and begins to shrink;
 - iii. the tubular part (23) endoluminal catheter (4) remains active until there has been sufficient shrinkage of the vein;
 - iv. the extent of shrinkage of the vein is possibly detected by appropriate detection, preferably Doppler echography.
11. Method according to claim 10, wherein the segments' length is 4 to 12 cm, preferably 6 to 10 cm.
12. Method according to claim 10, wherein a maximum of 6 pulses are delivered at the same catheter location to avoid overheating at this level.
13. Method according to claim 10, wherein local anesthesia is carried out with 5 to 10 cc of anesthetic, infiltrated between the vein and the skin.
14. Method according to claim 10, wherein local anesthesia is carried out by skin cooling, with skin temperatures down to 39.2/42.8°F (4/6°C).
15. Method for treating by direct obliteration, a tortuous perforating vein longer than 2 cm and extending between a superficial vein and a deep vein, said method consisting in using the device (1) according to claim 1 wherein:
- i. the tubular part (23) endoluminal catheter (4) is introduced under echo guidance in the perforator, at least 2cm from the deep vein,
 - ii. at least 3 pulses of pressurized overheated steam are delivered,
 - iii. then the tubular part (23) endoluminal catheter (4) is removed of a distance of about 1 cm and 3 other pulses are emitted.
16. Method for treating by indirect obliteration, a 2 cm long or less perforating vein extending between a superficial vein and a deep vein, said method consisting in using the device (1)

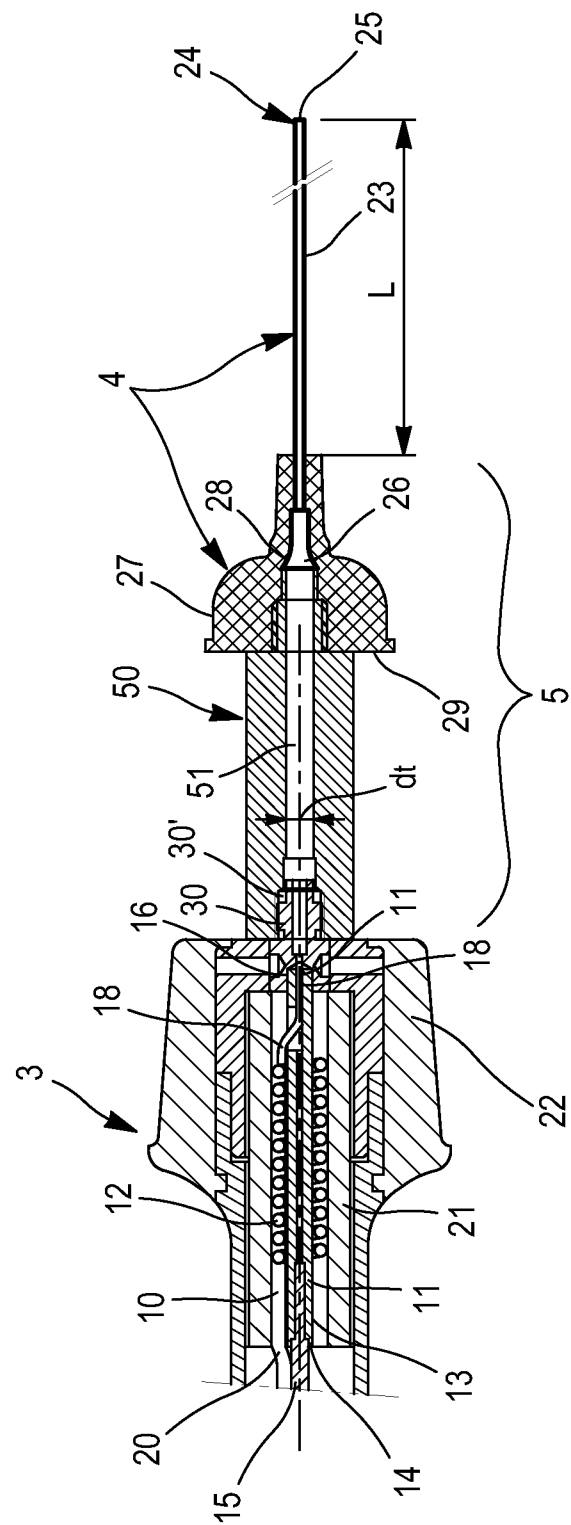
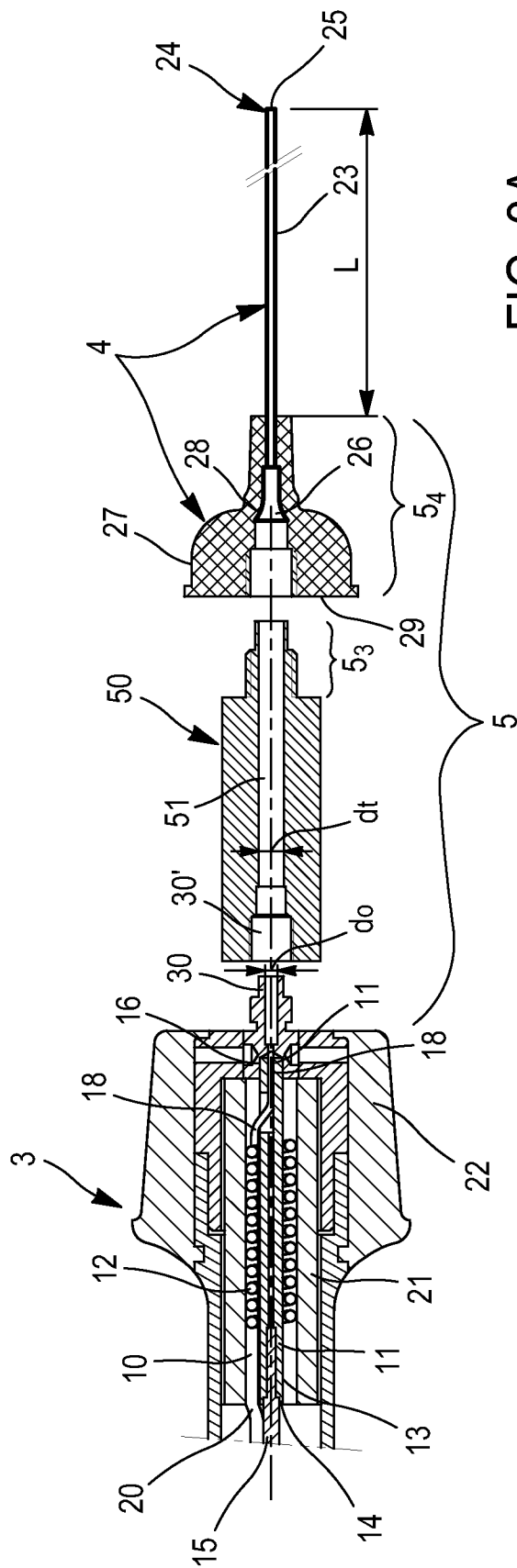
according to claim 1, wherein:

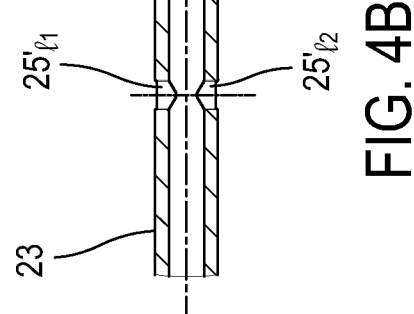
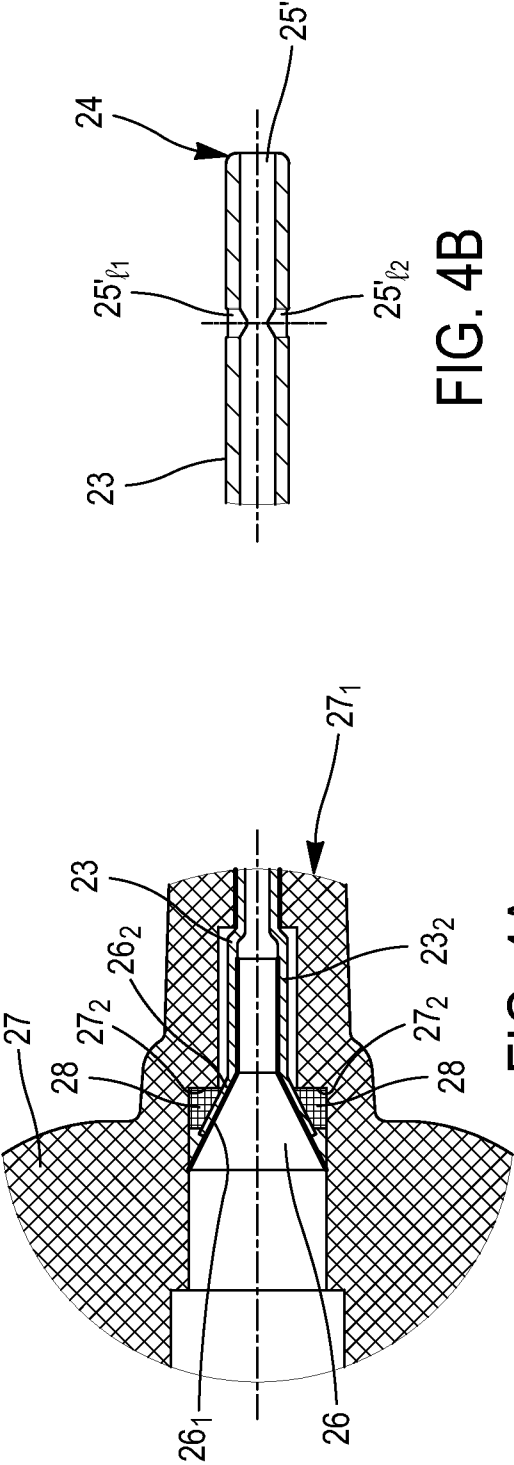
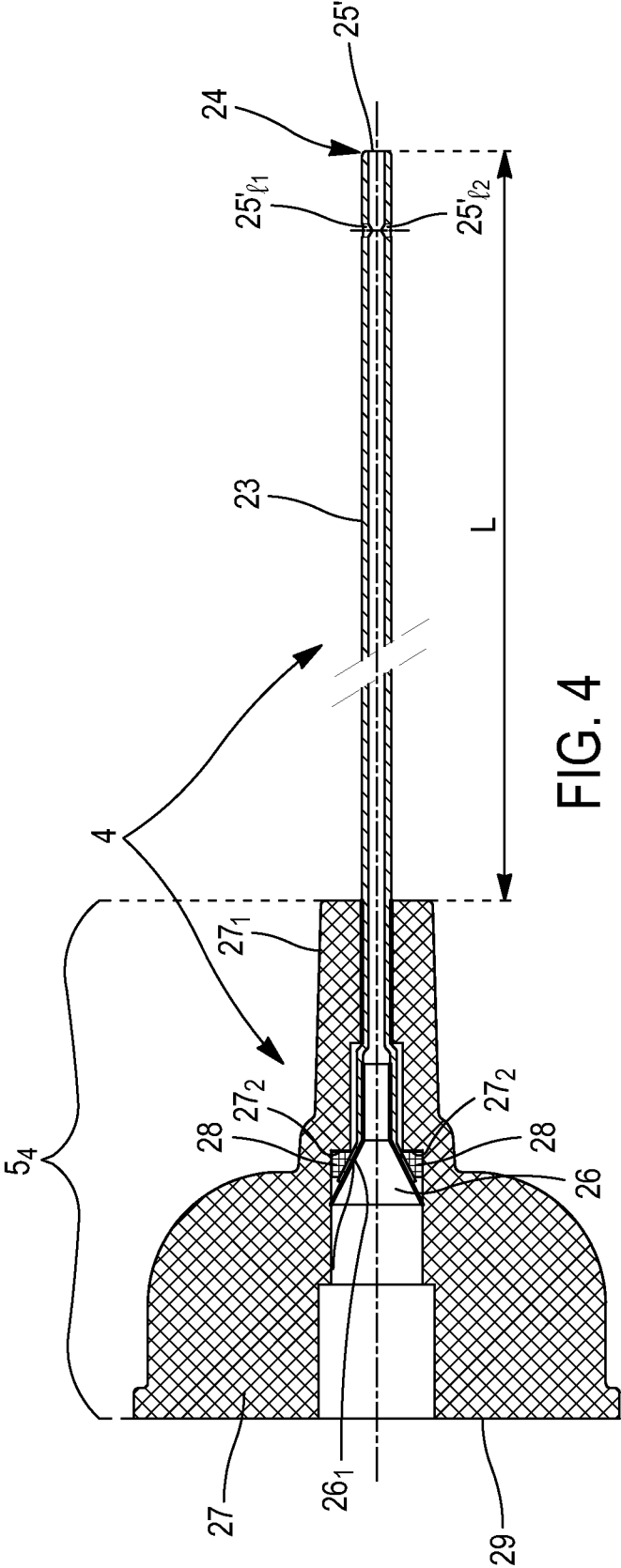
- i. the tubular part (23) endoluminal catheter (4) is introduced distally in the superficial vein, guided upward proximal to the perforator;
- ii. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the upward side of the superficial vein;
- iii. the tubular part (23) endoluminal catheter (4) is removed downward proximal to the perforator;
- iv. the vein is obliterated by delivering at least 3 pulses of pressurized overheated steam, so that the perforator cannot drain in the downward side of the superficial vein.

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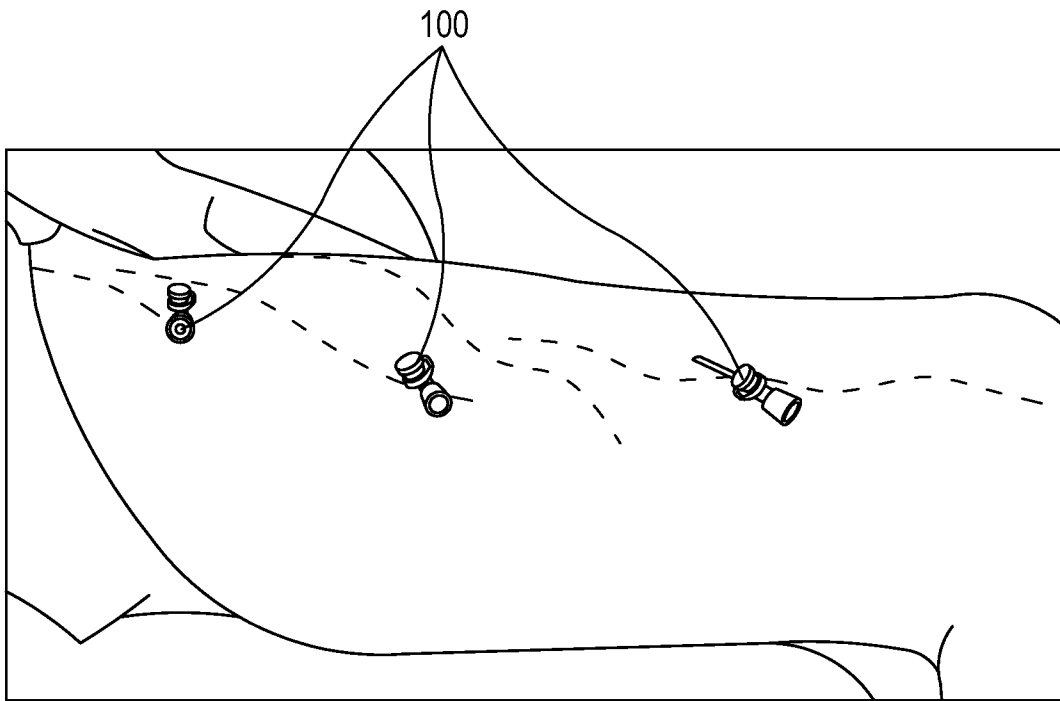


FIG. 5

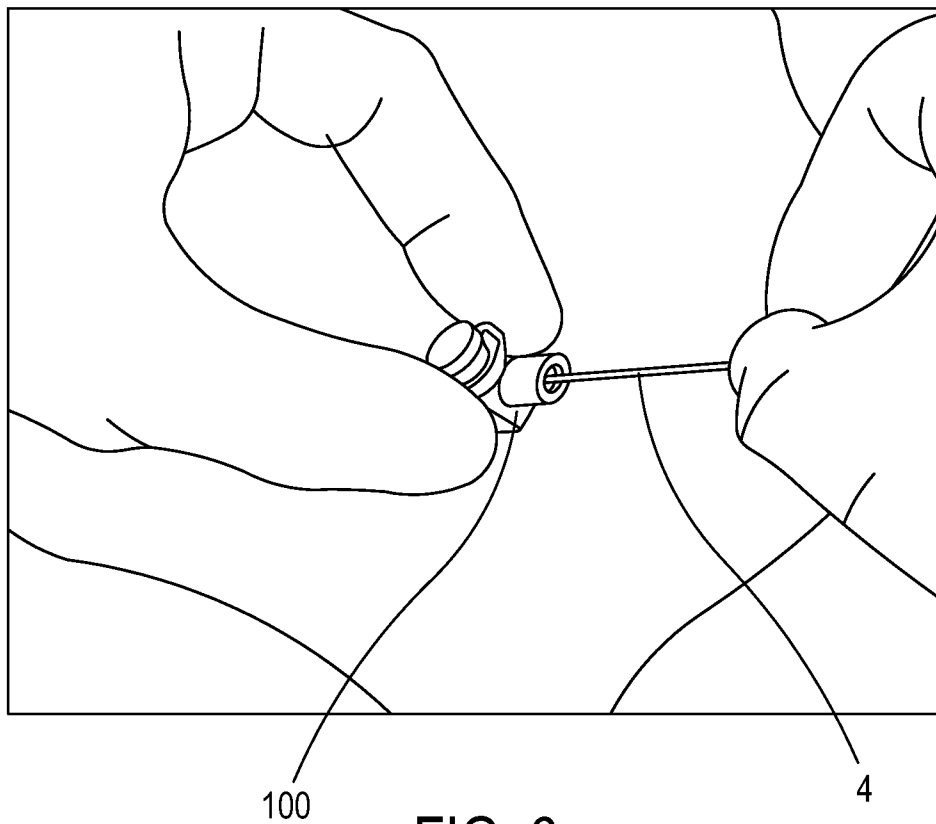


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/051765

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/04
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 data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/069821 A1 (THERMEMED CORP [US]) 12 September 2002 (2002-09-12) abstract claim 46 page 29, lines 8-13 figures 1,2,19a,19b,20	1-9
A	----- WO 2009/009398 A1 (TSUNAMI MEDTECH LLC [US]; HOEY MICHAEL [US]; SHADDUCK JOHN H [US]) 15 January 2009 (2009-01-15) abstract claims figures	1-9
A	----- WO 97/18765 A1 (ARTHROCARE CORP [US]) 29 May 1997 (1997-05-29) claims figures	1-9
	----- -/-	



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

16 November 2011

Date of mailing of the international search report

24/11/2011

Name and mailing address of the ISA/

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

Türkavci, Levent

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/051765

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/11927 A2 (MAMAEV GENNADY VIKTOROVICH [RU]) 9 March 2000 (2000-03-09) abstract figures -----	1-9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2011/051765

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 02069821	A1	12-09-2002	NONE
WO 2009009398	A1	15-01-2009	EP 2170198 A1 07-04-2010 WO 2009009398 A1 15-01-2009
WO 9718765	A1	29-05-1997	AT 208589 T 15-11-2001 AU 702687 B2 04-03-1999 CA 2237947 A1 29-05-1997 DE 69617047 D1 20-12-2001 DE 69617047 T2 11-07-2002 EP 0886493 A1 30-12-1998 EP 1080680 A1 07-03-2001 JP 3215434 B2 09-10-2001 JP H11501555 A 09-02-1999 JP 2000060868 A 29-02-2000 US 5697882 A 16-12-1997 US 5871469 A 16-02-1999 US 6224592 B1 01-05-2001 US 6416507 B1 09-07-2002 US 6416508 B1 09-07-2002 US 6632220 B1 14-10-2003 US 7201750 B1 10-04-2007 US 2004087937 A1 06-05-2004 US 2007179497 A1 02-08-2007 US 2009069807 A1 12-03-2009 WO 9718765 A1 29-05-1997
WO 0011927	A2	09-03-2000	RU 2193871 C2 10-12-2002 WO 0011927 A2 09-03-2000

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/051765

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.: **10-16**
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 10-16

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery The methods according to independent claims 10,15,16 define surgery methods practised on the human body because they claim introducing a catheter in to a human being. So the International Searching Authority is not required to perform a search regarding claims 10,15,16 and the related dependent claims 11-14 (Rule 35 and 39.1 (iv) PCT).