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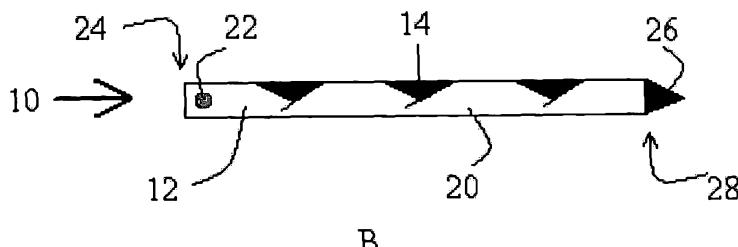
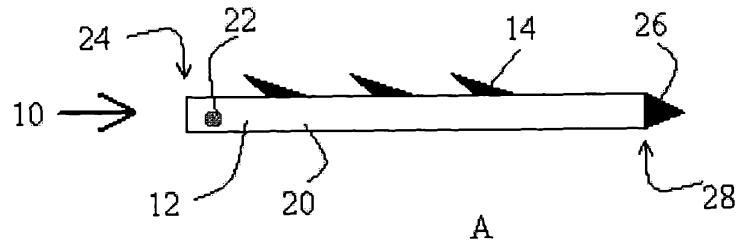
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(54) Title: DEVICE AND METHOD FOR TREATING VARICOSE VEINS



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(57) Abstract: A surgical instrument for treatment of superficial varicose veins in a body is provided. The surgical instrument includes at least one vein-engaging element disposed within or on a housing being adapted for insertion into a tissue. The at least one vein-engaging element is operable to a vein-engaging state whereby it protrudes from the housing at a length thereof.

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DEVICE AND METHOD FOR TREATING VARICOSE VEINS

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to devices for treating varicose veins in general,  
5 and in particular, to a surgical instrument for removing varicose veins.

Varicose veins are a condition of the superficial veins of the lower extremities in which one or more one-way valves within the veins have ceased to function efficiently, resulting in blood flow contrary to the normal direction of flow. This results in the build up of pressure inside portions of the vein, causing the veins to  
10 become abnormally twisted, distorted and prominent, yielding unsightly and often painful bulges on the lower extremities. Some 20% of women in the general population suffer from some degree of varicose veins. In some 5-7% of sufferers, an operation is required in order to remove the damaged veins, so as to permit blood flow through alternative routes. In others, cosmetic surgery and treatment are desired in  
15 order to remove the unsightly superficial varicose veins from the extremities.

The surgical instruments for removal of superficial varicose veins from lower extremities that can be found on the market today are relatively expensive, technically complex, complicated in use and require an incision through a skin layer over each superficial varicose vein or vein-knot (using the Winkling method) which is to be removed. The result can be ten to fifteen incisions during a single operation. These incisions result in the formation of many unattractive scars and, sometimes, in  
20 inflammation and infection.

One example of a conventional method and apparatus for removing varicose veins is described and claimed in US Patent 6,436,116 to Spitz et al. The method described in this patent includes making an incision through a skin layer of a patient, inserting a surgical instrument including a light source through the incision, visualizing the vein through the skin layer using the light source positioned subcutaneously and in proximity of the vein, and cutting the vein using the surgical instrument. The instrument further includes means for irrigating and tumescing a  
25 surgical region in proximity of the vein, and a vacuum source for aspirating cut venous tissue through the surgical instrument. This apparatus is very complicated, is complex to manufacture and maintain, and requires electricity to function.

A simpler apparatus is shown in US Patent 5,792,168. This apparatus is used to form an incision through the skin layer and engage a superficial vein for extraction of a segment of the vein through the incision. Once extracted, the exposed ends of the superficial vein may be ligated using known surgical techniques, and the ligated portions of the vein will return back through the incision. The apparatus of this patent includes a cylindrical shaft having a needle or scalpel at one end thereof for making an incision through the skin layer, and a cylindrical sleeve about the shaft arranged to slide relative to the needle. The facing surfaces of the needle and the cylindrical sleeve define a gripping region therebetween, and the gripping region can selectively engage the varicose vein to permit lifting of a selected portion of the vein out through the incision. This instrument also requires a separate incision above each vein to be treated.

Accordingly, there is a need for a surgical device for removing superficial varicose veins while requiring a relatively small number of incisions for effective treatment, and as a result improving cosmetic effects and reducing patient discomfort.

#### SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a surgical instrument for treatment of superficial varicose veins in a body comprising at least one vein-engaging element disposed within or on a housing being adapted for insertion into a tissue (e.g. subcutaneous tissue), the at least one vein-engaging element being operable to a vein-engaging state whereby the at least one vein-engaging element protrudes from the housing at a length thereof.

According to further features in preferred embodiments of the invention described below, the housing is a hollow tube.

According to still further features in the described preferred embodiments the surgical instrument further comprises a substantially tapered tip located at an end of the housing, the tip being designed for allowing introduction of the surgical instrument into an incision through a skin layer.

According to still further features in the described preferred embodiments the surgical instrument further comprises a substantially pointed tip located at an end of the housing, the tip being designed for allowing introduction of the surgical instrument into an incision through a skin layer.

According to still further features in the described preferred embodiments the at least one vein-engaging element is a toothed vein-engaging element.

According to still further features in the described preferred embodiments the housing comprises at least one longitudinal slit for enabling the at least one vein 5 engaging element disposed within the housing to protrude from the housing when in the vein engaging state.

According to still further features in the described preferred embodiments the at least one longitudinal slit is parallel to a longitudinal axis of the housing.

According to still further features in the described preferred embodiments the 10 surgical instrument further comprises a state selector mechanism designed to operate the at least one vein-engaging element to a vein-engaging state.

According to still further features in the described preferred embodiments the state selector mechanism includes a plunger being insertable into the housing.

According to still further features in the described preferred embodiments the 15 surgical instrument further comprising a locking element for locking the plunger when the vein-engaging element is in the vein-engaging state.

According to still further features in the described preferred embodiments the locking element includes a cylindrical collar about the plunger adapted and configured to frictionally engage a complementary depression in the hollow housing.

According to still further features in the described preferred embodiments the 20 state selector mechanism includes at least one spring being for urging the at least one vein-engaging element to a vein-engaging state.

According to still further features in the described preferred embodiments the state selector mechanism includes an electrically activated servo mechanism for 25 urging the at least one vein-engaging element to a vein-engaging state.

According to still further features in the described preferred embodiments the housing includes four longitudinal slits for enabling four toothed vein-engaging elements for selectively protruding through the slits, whereas the state selector mechanism is capable of simultaneously urging the four toothed vein-engaging 30 elements to a vein-engaging state.

According to still further features in the described preferred embodiments the surgical instrument has a length of about 12 to 16 cm and a width of about 2 to 8 mm.

According to another aspect of the present invention there is provided a method of treating superficial varicose veins in a body region, the method comprising: (a) forming an incision in a skin layer adjacent to the body region; (b) inserting, through the incision a surgical instrument having a housing configured with at least one vein-engaging element being operable to a vein-engaging state whereby it protrudes from a length of the housing; (c) activating the at least one vein engaging element to the vein-engaging state; and (d) removing the surgical instrument, thereby treating the superficial varicose veins in the body region.

According to still further features in the described preferred embodiments steps (a)-(d) are repeated, thus forming an at least one additional incision, wherein the distance between two adjacent incisions along the same vein is greater than about 10cm.

According to still further features in the described preferred embodiments step (b) is effected by inserting the surgical instrument into a varicose vein.

According to still further features in the described preferred embodiments step (c) is operable using a state selector forming a part of the surgical instrument.

According to still further features in the described preferred embodiments the housing is a hollow tube.

According to still further features in the described preferred embodiments the method further comprises a substantially pointed tip located at an end of the housing, the tip being designed for allowing introduction of the surgical instrument into an incision through a skin layer.

According to still further features in the described preferred embodiments the at least one vein-engaging element is a toothed vein-engaging element.

According to still further features in the described preferred embodiments the housing comprises at least one longitudinal slit for enabling the at least one vein engaging element disposed within the housing to protrude from the housing when in the vein engaging state.

The present invention successfully addresses the shortcomings of the presently known configurations by providing a surgical instrument which enables effective treatment of varicose veins through a small number of incisions and thus treatment therewith minimizes patient discomfort and scarring.

Definitions of the specific embodiments of the invention as claimed herein follow.

According to a first embodiment of the invention, there is provided a surgical instrument adapted to engage superficial varicose veins in a body from outside of the veins, said instrument comprising at least one vein-engaging element, characterized by:

5 said at least one vein-engaging element being disposed within a housing adapted for insertion into a tissue;

said at least one vein-engaging element comprising a plurality of teeth shaped to enable vein engagement disposed along said vein-engaging element; and

10 said at least one vein-engaging element being operable to a vein-engaging state in which said plurality of teeth protrude from said housing along a length of said housing, wherein said housing is fabricated from metal, rigid enough to support pivoting to any direction required in an incision, in order to engage a desired vein, and a portion of said rigid housing is configured to be manipulated by an operator.

According to a second embodiment of the invention, there is provided a method of 15 treating at least one superficial varicose vein in a body region, the method comprising:

(a) forming an incision in a skin layer adjacent to the body region;

(b) inserting, through said incision and adjacent to the outside of the at least one varicose vein, a surgical instrument having a housing configured with at least one vein-engaging element comprising a plurality of teeth configured to engage one or more veins from a location adjacent to an outside surface of the veins, whereby the teeth are disposed substantially along the entire length of said housing and protrude at a length of said housing;

20 (c) engaging, from the adjacent location, the outside of at least one of the at least one vein with said surgical instrument using the teeth which are disposed along the entire length of said housing;

(d) rotating said surgical instrument about its longitudinal axis; and

25 (e) removing said surgical instrument, thereby treating the at least one superficial varicose vein in the body region.

[Text continues on page 5.]

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable 5 methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10 The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and 15 readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

20 In the drawings:

FIGs. 1A-1M illustrate various embodiments of a surgical instrument for varicose vein treatment according to the teachings of the present invention.

25 FIGs. 2A-2B illustrate a side view of a surgical instrument constructed and operative in accordance with one embodiment of the present invention, in a non vein-engaging state (Figure 2A), and in a vein-engaging state (Figure 2B).

FIGs. 3A-3D illustrate a side sectional view (Figure 3A) and a cross sectional view (Figure 3B) of a surgical instrument constructed and operative in accordance with another embodiment of the present invention in an initial state prior to engaging a vein and at a vein-engaging state.

30 FIG. 4 illustrates a perspective view of a surgical instrument constructed and operative in accordance with another embodiment of the present invention.

FIG. 5 illustrates a side sectional view of a surgical instrument constructed and operative in accordance to an additional embodiment of the present invention in an initial state prior to being in a vein-engaging state.

5 FIG. 6 illustrates a side sectional view of a surgical instrument constructed and operative in accordance with yet another embodiment of the present invention in an initial state prior to being in a vein-engaging state.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 The present invention is of a surgical instrument/device and method for removing superficial varicose veins from a body, which instrument and method enable removal of several varicose veins through a single incision.

15 Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

20 Devices for removing varicose veins are well known in the art, see for example US Patent 6,436,116 to Spitz et al. and US Patent 5,792,168 to Surval. In order to be effective, such devices require an operator to perform numerous incisions in order to treat varicose vein present in a body region targeted for treatment.

The present invention describes an instrument of a design which specifically addresses this limitation of prior art devices.

25 Thus, according to one aspect of the present invention there is provided a surgical instrument for treatment of superficial varicose veins in a body.

As used herein the phrase varicose veins refers to abnormally swollen or dilated veins.

30 As used herein the term "treating" when relating to varicose veins, refers to attenuating, or eliminating varicose veins, preferably superficial varicose veins of the legs.

The surgical instrument of the present invention includes at least one vein-engaging element disposed within or on a housing which is adapted for insertion into a

tissue, such as subcutaneous tissue. As is further detailed hereinunder, the vein-engaging element is operable to a vein-engaging state whereby it protrudes from the housing at a length thereof.

Reference is now made to Figures 1A-1M, illustrating various embodiments of 5 the surgical instrument of the present invention, which is referred to hereinunder as surgical instrument 10.

Surgical instrument 10 includes a housing 12 and at least one vein-engaging element 14 (three are shown in Figures 1A-B) which is disposed within or on housing 12 (on one or more sides). Preferably, surgical instrument 10 also includes a state 10 selector mechanism 20 (also referred to hereinunder as mechanism 20) which is designed for urging vein engaging element 14 from a closed state to a deployed state (further described below).

Housing 12 can be designed as an elongated member, which can be hollow or partially hollow for containing vein-engaging element(s) 14 within it (as shown in 15 Figure 1B). Housing 12 can be a flattened hollow housing 12b, like a knife with an extendable blade as shown in Figure 1I, or a hollow tube 12b as shown in Figure 1J, or any other desired design having an interior volume for containing at least one vein 20 engaging-element 14 when in a non-deployed (closed) state. To enable deployment of vein engaging element 14, hollow housing 12 includes at least one opening that can be shaped as a circular hole or preferably a longitudinal slit 36 which is parallel to a longitudinal axis 38 of hollow housing 12 (as shown in Figure 1G). Alternatively, housing 12 may also be a non-hollow, in which case vein-engaging elements 14 are positioned adjacent to and preferably flush with housing 12 (as shown in Figure 1E). Preferably, housing 12 has a length (L) of about 12 – 16 cm (see Figures 1I-J), and a 25 diameter/width (D), which varies from about 2 to 8 mm (depending on the dimensions of the varicose veins or vein-knots).

Housing 12 is preferably formed with a tapered tip 25 (as shown in Figure 1I), or a pointed tip 26 (as shown in Figure 1J) at a distal end 28 thereof (distal - with respect to an operator). Such a tip configuration enables non-traumatic introduction 30 of surgical instrument 10 through an incision 30 made in skin layer 32 (as shown in Figures 1C-D). Tapered (25) or pointed (26) tips as well as housing 12 are preferably fabricated from any appropriate bio-compatible material, including, for example, polymers or metals or any combination thereof.

Vein engaging element 14 is constructed from any suitable material (e.g., a biocompatible metal or polymer or a combination thereof), and is configured for engaging a vein 34 when in a vein-engaging state (deployed state). Vein-engaging element 14 can be a toothed vein-engaging element 16 (as shown in Figures 1K-L), or 5 a hooked vein-engaging element 18 (as shown in Figure 1M). In any case, the shape and size of vein engaging element 14 is selected so as to enable vein engagement when surgical instrument 10 is in operation. Figure 1K illustrates a single toothed vein-engaging element 16 having a relatively wide base 13, narrowing to a sharp pointed tooth 15 at the outer edge. Furthermore, tooth 15 may have any desired shape 10 as long as it slopes towards proximal end 24 of surgical instrument 10 (towards an operator). Sharp pointed tooth 15 must slope towards proximal end 24, for puncturing, engaging and removing or tearing a wall of vein 34 while surgical instrument 10 is being removed (pulled out) from the tissue of the patient. Figure 1L illustrates a toothed vein-engaging element 16 having a plurality of sharp pointed 15 teeth 15. Using plurality of sharp pointed teeth 15 in a toothed vein-engaging element 14 enables treatment of vein 34 more efficiently, since it increases the likelihood of vein engagement. Figure 1M illustrates a hooked vein-engaging element 18 having the shape of a hook 19. According to this embodiment hook 19 catches onto vein 34 or its wall and when surgical instrument 10 is removed, hook 19 tears vein 34.

20 Vein engaging element 14 is operable from a closed state in which it is sequestered within housing 12 or flush against it (see Figures 1E-F) to a deployed state (vein engaging state - a state which enable element 14 to engage a vein), in which it protrudes from housing 12 (See Figure 1A). Figures 1E and 1F illustrate two 25 embodiments of vein-engaging element 14 placement. Figure 1E illustrates surgical instrument 10 constructed such that vein engaging element 14 is placed on housing 12. Figure 1F illustrates the surgical instrument 10 constructed such that the at least one vein engaging element 14 is placed within housing 12. In order to enable the latter embodiment, housing 12 is a hollow housing 12 (see Figures 1G-1J) having at least one longitudinal slit 36, which is parallel to a longitudinal axis 38 of the hollow 30 housing 12. Preferably, one to four slits 36 are included, depending on the width/diameter of housing 12. Additionally, slits 36 are preferably located symmetrically about hollow housing 12. If desired, slits 36 may be continuous for the entire length of hollow housing 12 as shown in Figure 1G, or constitute a plurality of

shorter slits 36 spaced from one another forming broken lines along the length of hollow housing 12 as shown in Figure 1H, to increase the housing's stiffness and strength.

State selecting mechanism 20 (also referred to herein as mechanism 20) is disposed within or on housing 12. Mechanism 20 is configured to be easily operated by an operator. Any one of several state selector mechanisms 20 can be utilized by surgical instrument 10. For example, springs, levers or cams which are disposed within or on housing 12, or a hydraulic mechanism (syringe-like) which is disposed within housing 12 can be utilized to activate deployment of vein engaging element 14. Such activation can be effected via twisting, pushing, pulling and the like. Alternatively, a simple electronic circuit which includes a power supply, switch and servo can be utilized for such purposes. One of ordinary skill in the art would be more than capable of designing and deploying various embodiments of state selector mechanism 20.

One embodiment of mechanism 20, illustrated in Figures 2A-B, is a plunger 40 which is suitable for use by a hollow housing 12 embodiment of surgical instrument 10. Plunger 40 is sized for insertion into hollow housing 12. Figure 2A illustrates surgical instrument 10 with the plunger 40 prior to activation of a vein-engaging state. Pushing plunger 40 between vein-engaging elements 14 causes sharp pointed teeth 15 of vein-engaging elements 14 to protrude through slits 36 (Figures 3C-3D), until wide base 13 is stopped by the edges of slits 36. Preferably, plunger 40 has a cone-shaped tip 42, which makes it easier to insert between the ends of the vein engaging elements 14, separate them, and urge them to slide towards their respective slits 36. Alternatively, vein engaging elements 14 can be coupled to one another or formed as a single expandable unit.

Preferably, a locking mechanism 44 is provided to lock plunger 40 in place in hollow housing 12 in the vein-engaging state of Figures 3C-3D. In the illustrated embodiment (Figures 3A-D), locking mechanism 44 includes a cylindrical collar 46 which is adapted and configured to seat in and frictionally engage a mating depression 48 within hollow housing 12. Alternatively, any other suitable locking mechanism can be employed to permit a surgeon to lock surgical instrument 10 in the vein-engaging state for ease of removal of surgical instrument 10 and the vein pieces from the tissue of a patient.

Figures 3A-3D illustrate a side sectional view and a cross sectional view of surgical instrument 10 constructed and operative in accordance with one embodiment of the present invention in an initial state prior to being in a vein-engaging state. In the embodiment described herein, the state selecting mechanism 20 is the plunger 5 illustrated in Figures 2A-2B herein above. Surgical instrument 10 includes a tube shaped hollow housing 12, and further includes four longitudinal slits 36 which are parallel to longitudinal axis 38 of hollow housing 12. Furthermore, in this embodiment, slits 36 are located symmetrically about hollow tube housing 12. Additionally, four toothed vein-engaging elements 16 are disposed within hollow 10 housing 12. Furthermore, toothed vein-engaging elements 16 are adapted and configured to selectively partially protrude through longitudinal slits 36. Moreover, a configuration of vein-engaging elements 16 disposed around (e.g., following a radial pattern) the tube shaped hollow housing 12 is preferred, in order to permit the tearing and/or removal of more than one vein 34 at a time.

15 It will be appreciated that the thickness of the vein-engaging elements and the length of the teeth thereon depend on the diameter of hollow housing 12. When the instrument is assembled and ready for use, before insertion of the plunger, the teeth of vein-engaging elements 16 are hidden inside housing 12. Since the teeth slope away from the tip of the instrument, even if they protrude slightly prior to deployment, they 20 will be pushed back inside the tube as long as the instrument is being inserted into the body. Once the instrument is in place, and the plunger has been inserted to the end of the tube, the teeth preferably protrude about 0.5 to 1 mm from the slits. It will further be appreciated that the length and width of longitudinal slits 36 must be sized to ensure a tight fit of wide base 13 of vein-engaging elements 14, so that vein-engaging 25 elements 14 cannot fall out of housing 12 through slits 36 during use.

In the above described embodiment, vein-engaging elements 14 are not coupled to one another, but rather support one another inside the tube shaped hollow housing 12. Additionally, plunger 40 is arranged to slide between wide bases 13 of vein-engaging elements 14 and urge them apart from one another and outwards 30 towards slits 36 of housing 12.

Reference is now made to Figure 4 illustrating a perspective view of a surgical instrument 10 constructed and operative in accordance with another embodiment of the present invention. In the embodiment described herein, the state selecting

mechanism 20 is the plunger 40 as described in Figures 3A-3D herein above. In this embodiment, the housing 12 is a flattened housing 12a, similar to a knife having an extendable blade. One or two vein-engaging elements 14 are disposed within housing 12a, as is a plunger 40 for urging the at least one vein-engaging element 14 outwards 5 to the vein-engaging state.

Reference is now made to Figure 5 illustrating a side sectional view of a surgical instrument 10 constructed and operative in accordance with an additional embodiment of the present invention in an initial state prior to being in a vein-engaging state. In the embodiment described herein, the state selecting mechanism 20 includes a switch and a pushing element 60 having a conical tip 42 as in the case of the plunger 40 described in Figures 2A-B. Pushing element 60 is for urging the at least one vein-engaging element 14 to protrude through the at least one longitudinal slit 36 to a vein-engaging state (as was described for the plunger 40 in the previous embodiments herein above). Pushing element 60 is advanced forward by releasing at 10 least one spring 64 disposed within housing 12 by activating the switch of state selector 22. Additionally, state selector 22 can have an option of fixing pushing element 60 in the vein-engaging state after the release of spring 64.

Reference is now made to Figure 6 illustrating a side sectional view of a surgical instrument 10 constructed and operative in accordance with yet another embodiment of the present invention in an initial state prior to being in a vein-engaging state. In the embodiment described herein, state selecting mechanism 20 comprises a pushing element 60 having a conical tip 42 as in the case of the spring described in Figure 5. Pushing element 60 is for urging vein-engaging element 14 to protrude through longitudinal slit 36 to a vein-engaging state (as was described in the previous embodiments herein above). According to this embodiment, pushing element 60 is advanced forward by activating an electrical circuit 68 disposed within housing 12. A power source 70 (e.g., a battery) is disposed within housing 12 for enabling the activation of the electrical circuit 68. Furthermore, state selector 22 is used for activating the electrical circuit, thus advancing pushing element 60 to a vein-engaging state. Additionally state selector 22 can have an option of fixing pushing element 60 in the vein-engaging state after activating electrical circuit 68.

As is mentioned hereinabove, surgical instrument 10 is utilized to treat varicose veins.

Figures 1C and 1D illustrate use of one embodiment of surgical instrument 10. In Figure 1C surgical instrument 10 is inserted into and through vein 34 to be treated prior to being in a vein-engaging state. Surgical instrument 10 is then activated to a vein-engaging state and pulled back, thus tearing vein 34. It will be appreciated that 5 although such intra-vein insertion may be unintentional, surgical instrument 10 can still be utilized to tear vein 34 whereas prior art devices, such as that described in US Patent 5,792,168, would be incapable of such functionality.

In Figure 1D surgical instrument 10 is inserted into the body and along vein 34 to be treated prior to being in a vein-engaging state. Surgical instrument 10 is then 10 activated to a vein-engaging state and pulled back, thus tearing vein 34.

Figure 2B illustrates use of surgical instrument 10 which includes plunger 40 as mechanism 20. Pressing plunger 40 causes vein-engaging elements 16 to protrude through longitudinal slit 36, for example, about 0.5 mm, and hook into or tear the wall of the adjacent varicose vein 34 or vein knot 34. Preferably, plunger 40 is locked in this 15 state, for ease of continued operation. Surgical instrument 10 can be removed now from the incision 30. As surgical instrument 10 is removed, toothed vein-engaging elements 16 may be pulled against, and hook onto or pass through, additional varicose veins 34 or vein knots 34. Surgical instrument 10 may be rotated about its longitudinal axis 38 while adjacent to treated vein 34, before or while the surgical instrument 10 is removed 20 through the incision 30. The damaged vein portions which are hooked on vein-engaging elements 14, will be torn, and possibly pulled free from the body of the patient. If surgical instrument 10 is disposable, it may now be disposed of together with any removed vein portions. It will be appreciated that, in many cases, it is sufficient to tear 25 the wall of the varicose vein 34, in order for it to cease functioning in a pathogenic manner (i.e. varicose state). The bleeding usually stops without assistance or by applying momentary pressure on incisions 30, and big subcutaneous hematomas are highly unusual. In the few cases where it is required, pressure can be applied or the vein ends can be tied, as is well known in the art.

This procedure is now repeated on subsequent veins 34 and vein-knots 34 30 preferably using new surgical instrument 10 that is introduced into the same incision 30. It will be appreciated that surgical instrument 10 can be pivoted to any direction required in an incision 30, in order to engage the desired vein. Thus, by using one incision 30 and sequentially introducing one or more instruments from different directions (any direction

around the incision), the surgeon can remove all problematic veins within a radius approximately equal to the working length, L, of the surgical instrument 10, for example, 12-16 cm. It will further be appreciated that the use of a single incision to remove multiple varicose veins substantially reduces hematoma in the area following surgery.

5 If necessary, one or two additional incisions may be made in other areas having a vein or several veins to be removed, and the above procedure is repeated. In this fashion, by using the surgical instrument of the present invention, maximal clinical treatment and cosmetic effect can be achieved using only 2-3 small incisions. It will be appreciated that this is significantly fewer incisions than are typically 10 required in a conventional operation. The Examples section below provides results obtained using the surgical instrument of the present invention. As is shown therein, the surgical instrument of the present invention is highly efficient in treating varicose veins.

It is a particular feature of the present invention that a plurality of veins can be 15 removed or torn through a single incision, unlike using conventional techniques. This has several advantages. First, the possibility of infection is greatly reduced. Second, fewer incisions cause less trauma to the area. Third, the number of scars is significantly reduced as compared to prior art devices and techniques, thereby providing the desired 20 cosmetic effect and effective treatment with fewer complications, while leaving the extremities much more attractive looking.

It will be appreciated that the surgical instrument of the present invention can also be used in cases where treatment is not immediately prescribed and yet cosmetic benefits can be gained.

25 As used herein, the term "about" denoted +/- 10%.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made. It will further be appreciated that the invention is not limited to what has been described hereinabove merely by way of 30 example. Rather, the invention is limited solely by the claims which follow.

Additional objects, advantages, and novel features of the present invention will become apparent to one ordinarily skilled in the art upon examination of the following

examples, which are not intended to be limiting. Additionally, each of the various embodiments and aspects of the present invention as delineated hereinabove and as claimed in the claims section below finds experimental support in the following examples.

5

## EXAMPLES

Reference is now made to the following examples, which together with the above descriptions; illustrate the invention in a non limiting fashion. Two clinical trials using the surgical instrument for varicose vein treatment are described herein below; 10 the first trial relates to usage of the surgical instrument in cadavers and the second for the usage in patients.

### EXAMPLE 1

Using the surgical instrument of the present invention, the present inventors 15 performed a trial procedure on 30 lower body limbs of 15 cadavers (Table 1 below).

*Table 1*

Limb No.	Age of deceased	Gender	Limb (Right/Left)	Number of Incisions	Incision Length
1	70	F	R & L	3	5 mm
2	43	M	R & L	3	5 mm
3	48	M	R & L	3	5 mm
4	84	M	R & L	3	5 mm
5	84	F	R & L	4	5 mm
6	58	M	R & L	4	5 mm
7	56	M	R & L	4	5 mm
8	74	F	R & L	2	5 mm
9	54	M	R & L	4	5 mm
10	48	M	R & L	4	5 mm
11	34	M	R & L	4	5 mm
12	54	M	R & L	4	5 mm
13	50	M	R & L	4	5 mm
14	Age not known	F	R & L	4	5 mm
15	52	F	R & L	4	5 mm

As is outlined in Table 1 above, the age of the deceased ranged between 34-84 20 years old, and the trial group included 10 males and 5 females. The surgical instrument used in this trial had a diameter of 4mm, and thus the incisions made in the

skin layer where 5mm long. Furthermore, the incisions were made in skin regions suspected of being adjacent to veins. Extended varicose veins where observed in 5 of the cadavers.

5 In all cases where varicose veins were identified they veins were successfully engaged and torn, and removal of the surgical instrument indicated that no tissue other than vein and subcutaneous adipose tissue were substantially damaged by the instrument (no remains of muscle or nerve tissue were observed on the instrument).

10 The results of this trial illustrated that the surgical instrument of the present invention can be successfully used in human tissue and that the vein engaging elements of the surgical instrument as well as their placement on the housing of the instrument enable highly effective grasping and tearing of varicose veins even in cases where such veins are extended and entangled.

In addition, the above described trial also illustrated that:

- (i) the surgical instrument of the present invention can be used for treating 15 varicose veins having a small diameter of about 1 mm;
- (ii) use of the surgical instrument of the present invention enables complete removal of all varicose veins through 2-4 incisions only; and
- (iii) in configurations having one or two vein-engaging elements and a pointed tip, there is no need for performing incisions, since the pointed tip of the 20 surgical instrument can be used for penetrating the skin; in such cases there will be no need for stitches following removal of the surgical instrument.

#### **EXAMPLE 2**

25 The trial procedure described above was repeated on a group of patients. The purpose of this trial was to examine the use of the surgical instrument when applied for removal of varicose veins in a living human tissue. The operations where carried out on 5 lower body limbs of 4 patients (see Table 2 below). The age of the patients operated on ranged between 29-60 years old, and the sampling group included one male and 3 females. All females where post partum, one of which was operated on 30 both legs. Four operations took place under general anesthesia while only was performed using epidural. All patients required standard superficial varicose vein removal, which includes performing incisions in the groin area and the leg. In two of the cases, two incisions were required while for the other three cases three incisions

where required. The procedure took between 5 and 10 minutes to complete and in all cases there were no internal bleeding observed and no hematomas were formed. External bleeding was stopped using applied pressure for 1-3 minutes. In five surgical procedures a total of 13 incisions where made, of which only 9 required stitching.

5 Following surgery, all patients were immediately bandaged with standard elastic bandages and re-bandaged the following day. During the first twelve weeks following surgery, pain-relief medication was prescribed (non-narcotic analgesic) and none of the patients complained of strong pain which could be indicative of under-skin hematomas or nerve damage. This was probably due to the small number of incisions

10 and therefore reduced damage to the tissue. During a 7-10 day recovery period no complications were observed and all of the patients returned to normal life including work.

Table 2

No.	Age	Gender	Limb (Right/Left)	Number of Incisions	Anesthesia	Complications
1	60	M	R	2	general	None
2*	29	F	R	3	general	None
			L	2	general	None
3	48	F	L	3	general	None
4	54	F	R	3	epidural	None

\*operated on both legs

15

The clinical trial described above conclusively shows that the surgical instrument is highly effective for varicose vein treatment procedures in that it has shown to have positive affects both from the cosmetic point of view and from the clinical point of view.

20

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be 25 provided separately or in any suitable subcombination.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations

will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent application mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

The term "comprise" and variants of the term such as "comprises" or "comprising" are used herein to denote the inclusion of a stated integer or stated integers but not to exclude any other integer or any other integers, unless in the context or usage an exclusive interpretation of the term is required.

Any reference to publications cited in this specification is not an admission that the disclosures constitute common general knowledge in Australia.

The claims defining the invention are as follows:

1. A surgical instrument adapted to engage superficial varicose veins in a body from outside of the veins, said instrument comprising at least one vein-engaging element characterized by:
  1. said at least one vein-engaging element being disposed within a housing adapted for insertion into a tissue;
  2. said at least one vein-engaging element comprising a plurality of teeth shaped to enable vein engagement disposed along said vein-engaging element; and
  3. said at least one vein-engaging element being operable to a vein-engaging state in which said plurality of teeth protrude from said housing along a length of said housing, wherein said housing is fabricated from metal, rigid enough to support pivoting to any direction required in an incision, in order to engage a desired vein, and a portion of said rigid housing is configured to be manipulated by an operator.
2. The surgical instrument according to claim 1, wherein said housing includes at least one longitudinal slit disposed substantially along an entire length of the housing configured to allow said at least one vein-engaging element to assume said vein-engaging state.
3. The surgical instrument according to claim 1 or claim 2, further comprising a state selector mechanism configured to press against said at least one vein-engaging element, thereby causing said at least one vein-engaging element to assume said vein-engaging state, and further comprising a locking mechanism for locking said surgical instrument in the vein-engaging state.
4. The surgical instrument according to claim 3, wherein said state selector mechanism includes an electrically powered mechanism for urging said at least one vein-engaging element to said vein-engaging state.
5. The surgical instrument according to any one of claims 1 to 4, wherein at least a portion of said housing comprises a hollow tube and said at least one vein-engaging element is configured to be located within said hollow tube prior to assuming said vein-engaging state.
6. The surgical instrument according to any one of claims 1 to 5, wherein said at least one vein-engaging element is configured to provide at least one of:
  1. puncturing a vein;

- (b) engaging a vein;
- (c) tearing at least a portion of a vein;
- (d) ensnaring at least a portion of a vein;
- (e) wrapping at least a portion of a vein around said housing while rotating said housing along a longitudinal axis of said housing; and
- (f) severing a first portion of a vein from a second portion of a vein.

7. A method of treating at least one superficial varicose vein in a body region, the method comprising:

- (a) forming an incision in a skin layer adjacent to the body region;
- (b) inserting, through said incision and adjacent to the outside of the at least one varicose vein, a surgical instrument having a housing configured with at least one vein-engaging element comprising a plurality of teeth configured to engage one or more veins from a location adjacent to an outside surface of the veins, whereby the teeth are disposed substantially along the entire length of said housing and protrude at a length of said housing;
- (c) engaging, from the adjacent location, the outside of at least one of the at least one vein with said surgical instrument using the teeth which are disposed along the entire length of said housing;
- (d) rotating said surgical instrument about its longitudinal axis; and
- (e) removing said surgical instrument, thereby treating the at least one superficial varicose vein in the body region.

8. The method according to claim 7, wherein said surgical instrument is operable to a vein engaging state, said method further comprising, after said inserting, activating said at least one vein-engaging element to said vein engaging state.

9. The method according to claim 7 or claim 8, wherein said engaging includes manipulating said surgical instrument to provide at least one of:

- puncturing;
- engaging with said at least one vein-engaging element; and
- tearing.

10. The method according to claim 9, wherein said manipulating further comprises at least one of:

- (i) pivoting said housing on a plane parallel to a surface of said skin layer;
- (ii) ensnaring at least a portion of at least one of the at least one vein;
- (iii) rotating said housing along a longitudinal axis of said housing;
- (iv) wrapping at least a portion of said at least one vein around said housing;
- (v) pulling at least a portion of said at least one vein; and
- (vi) severing a first portion of said at least one vein from a second portion of said vein and leaving said vein in said body region.

11. The method according to claim 10, wherein said surgical instrument is operable to a vein-engaging state, said method further comprising, after said inserting, activating said at least one vein-engaging element to said vein engaging state;

wherein said incision comprises at least one first incision and following said removing:

- (f) forming a second incision in a skin layer adjacent to the body region, said second incision located a distance of about twice a length of said surgical instrument from said at least one first incision;
- (g) inserting said surgical instrument through said second incision;
- (h) activating said at least one vein-engaging element to said vein-engaging state;
- (i) manipulating said surgical instrument; and
- (j) removing said surgical instrument, thereby treating at least one of the at least one superficial varicose vein in the body region.

12. The method according to any one of claims 7 to 11, wherein said housing includes at least one longitudinal slit configured to allow said at least one vein-engaging element to assume said vein-engaging state.

13. The method according to any one of claims 7 to 12, wherein said at least one vein-engaging element includes a plurality of vein-engaging elements longitudinally spaced along said housing.

14. The method according to any one of claims 7 to 13, wherein said forming, said inserting, said activating, said engaging, and said removing are repeated, thus forming at least one additional incision, wherein the distance between two adjacent incisions along the same vein is greater than about twice a length of said surgical instrument.

15. The method according to any one of claims 7 to 12, wherein said at least one vein-engaging element includes a plurality of vein-engaging elements; and

wherein said engaging includes simultaneously engaging the outside of a plurality of veins with said plurality of vein-engaging elements.

16. The method according to any one of claims 7 to 15, wherein said rotating includes hooking the at least one vein on said surgical instrument.

17. The method according to any one of claims 7 to 16, wherein said removing said surgical instrument includes at least one of:

puncturing a wall of the at least one vein;

removing a wall of the at least one vein;

tearing a wall of the at least one vein;

removing at least a portion of the at least one vein through said incision; and

hooking onto or passing through at least one additional vein or vein knot.

18. A surgical instrument substantially as hereinbefore described with reference to Figures 2A, 2B, and 4.

19. A method as defined in claim 7 and substantially as hereinbefore described with reference to pages 12 and 13 of 'Description of the Preferred Embodiments'.

Date: 25 July 2011

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Figure 1A

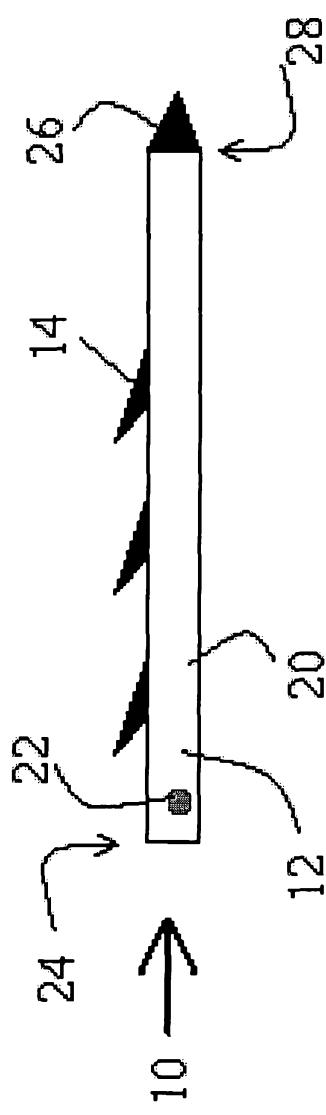
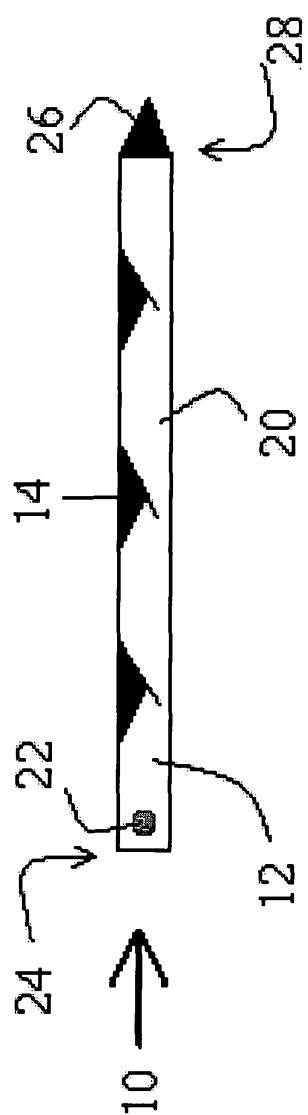


Figure 1B



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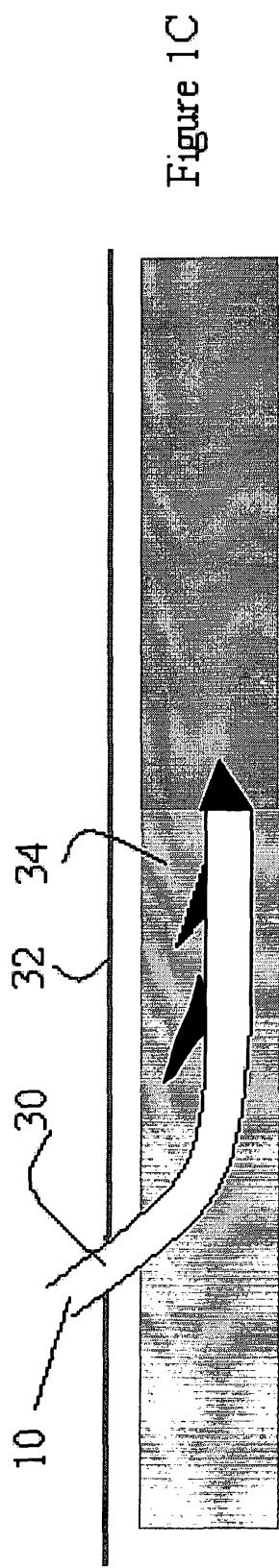
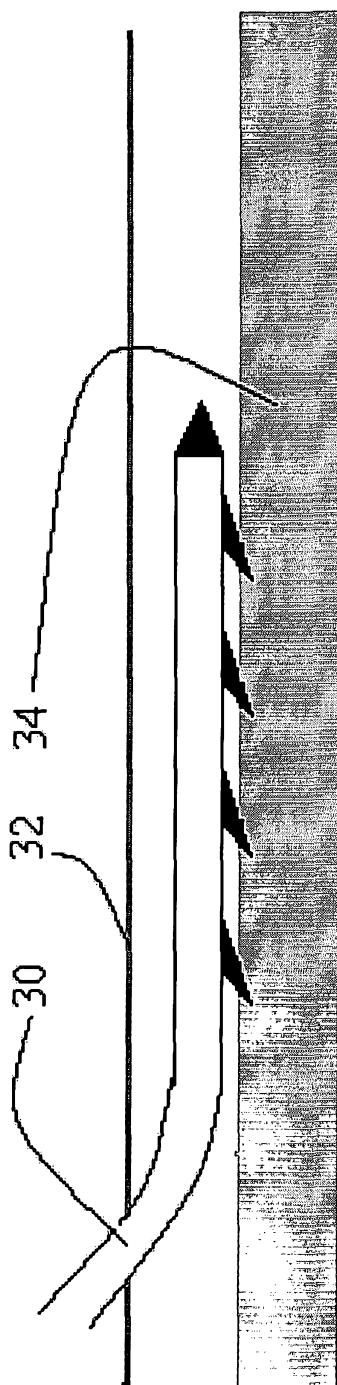


Figure 1D

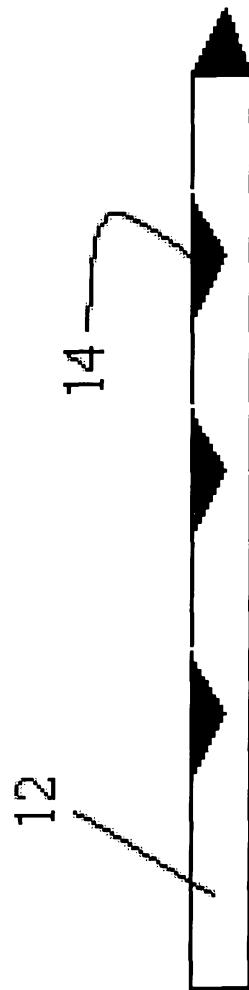


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Figure 1E



Figure 1F



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Figure 1G

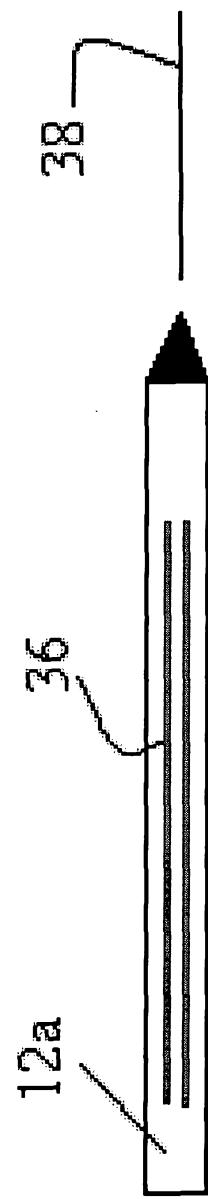


Figure 1H

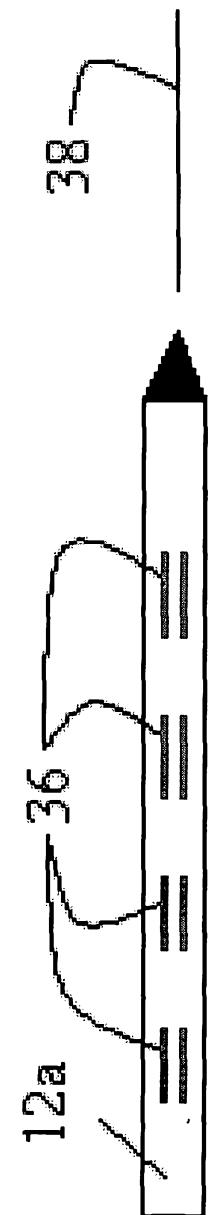


Figure II

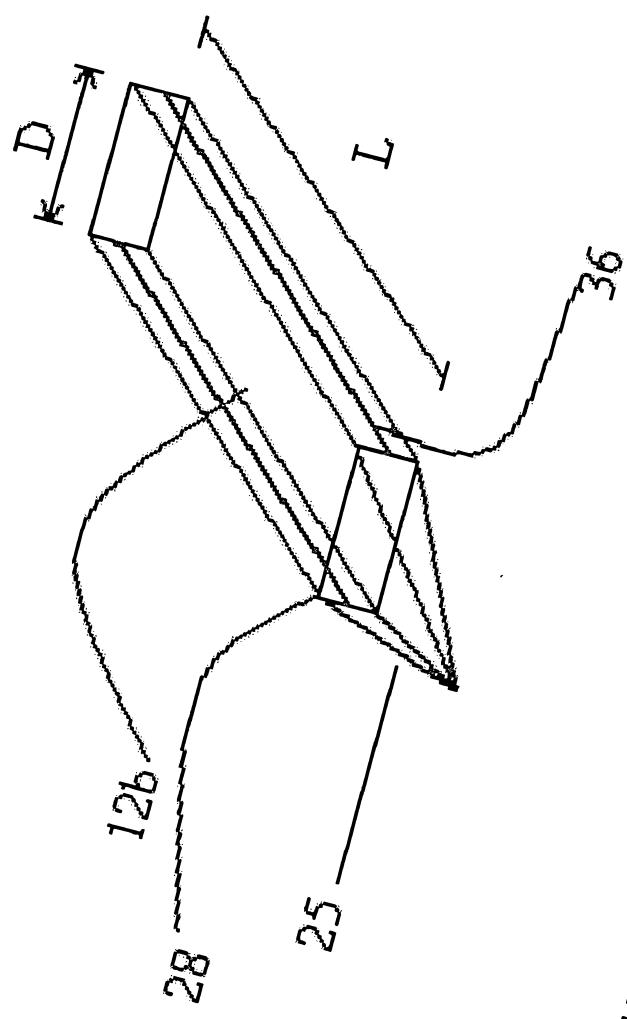


Figure IJ

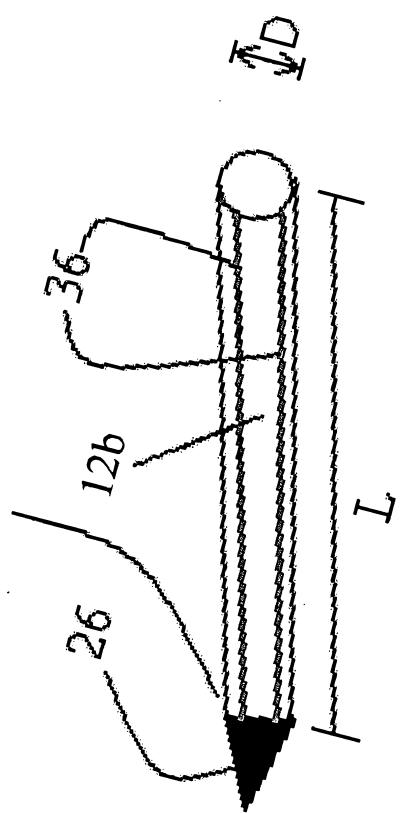


Figure 1K

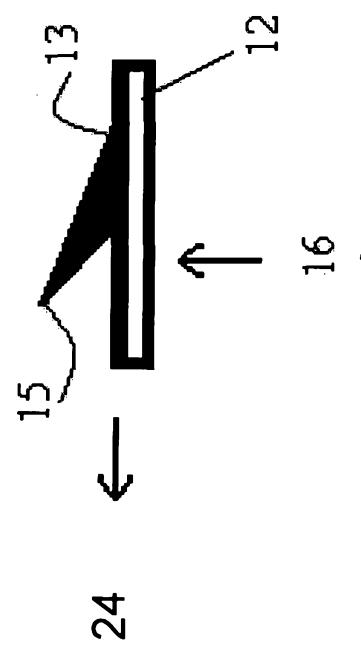
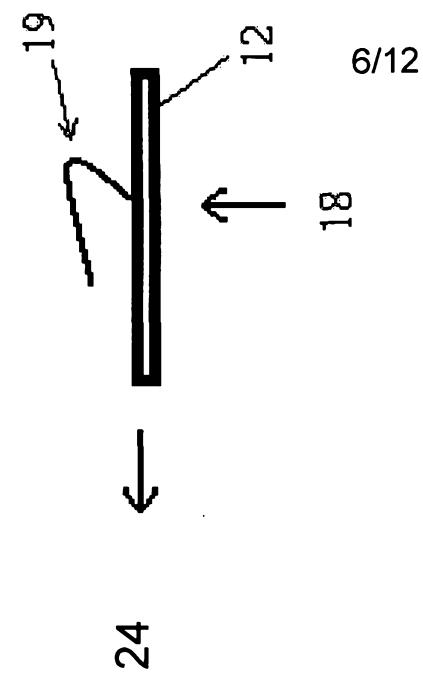
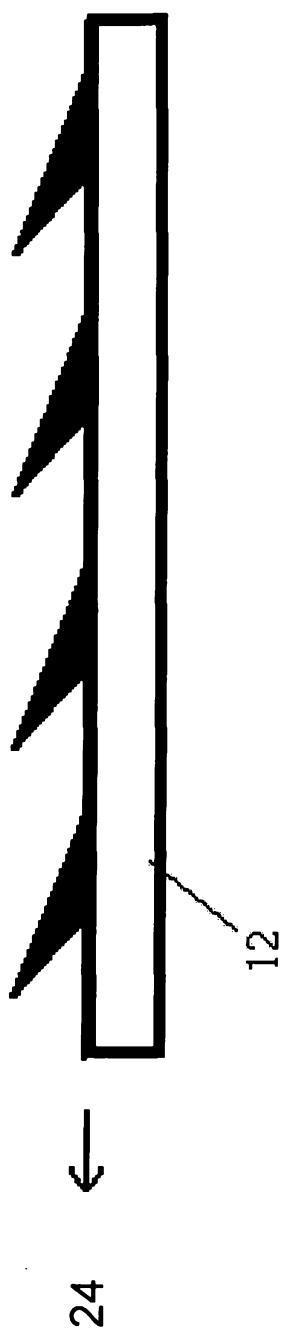


Figure 1L



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Figure 2A

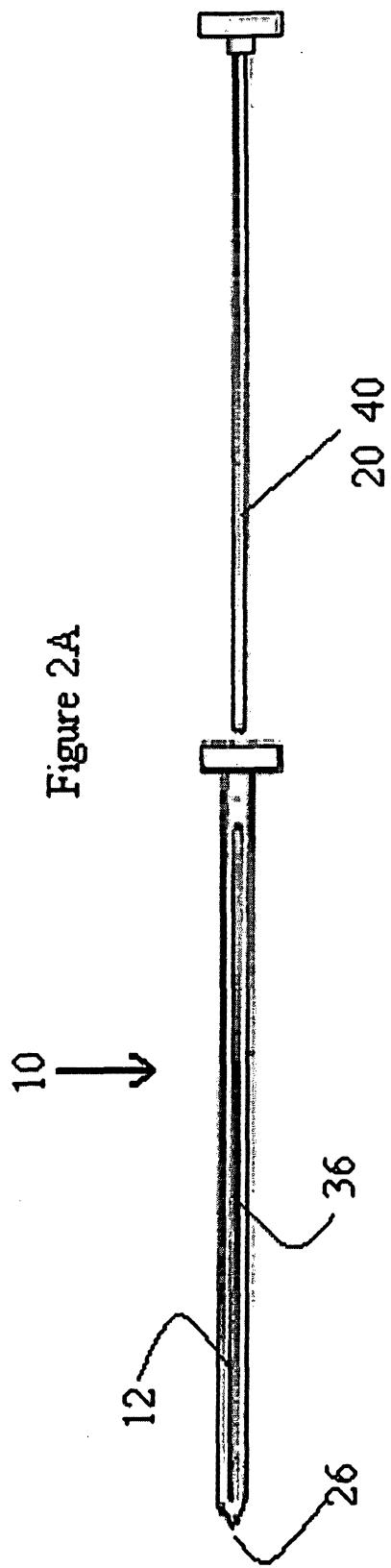
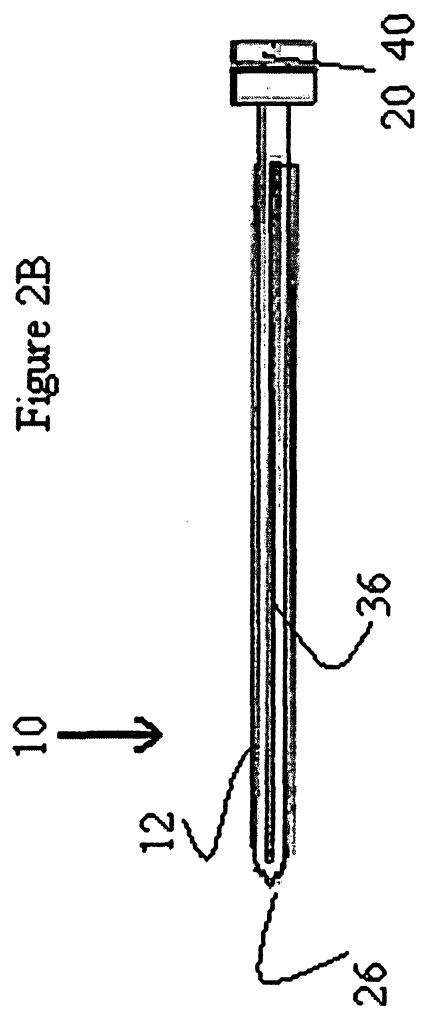
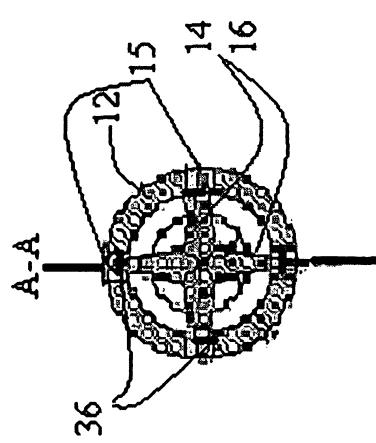
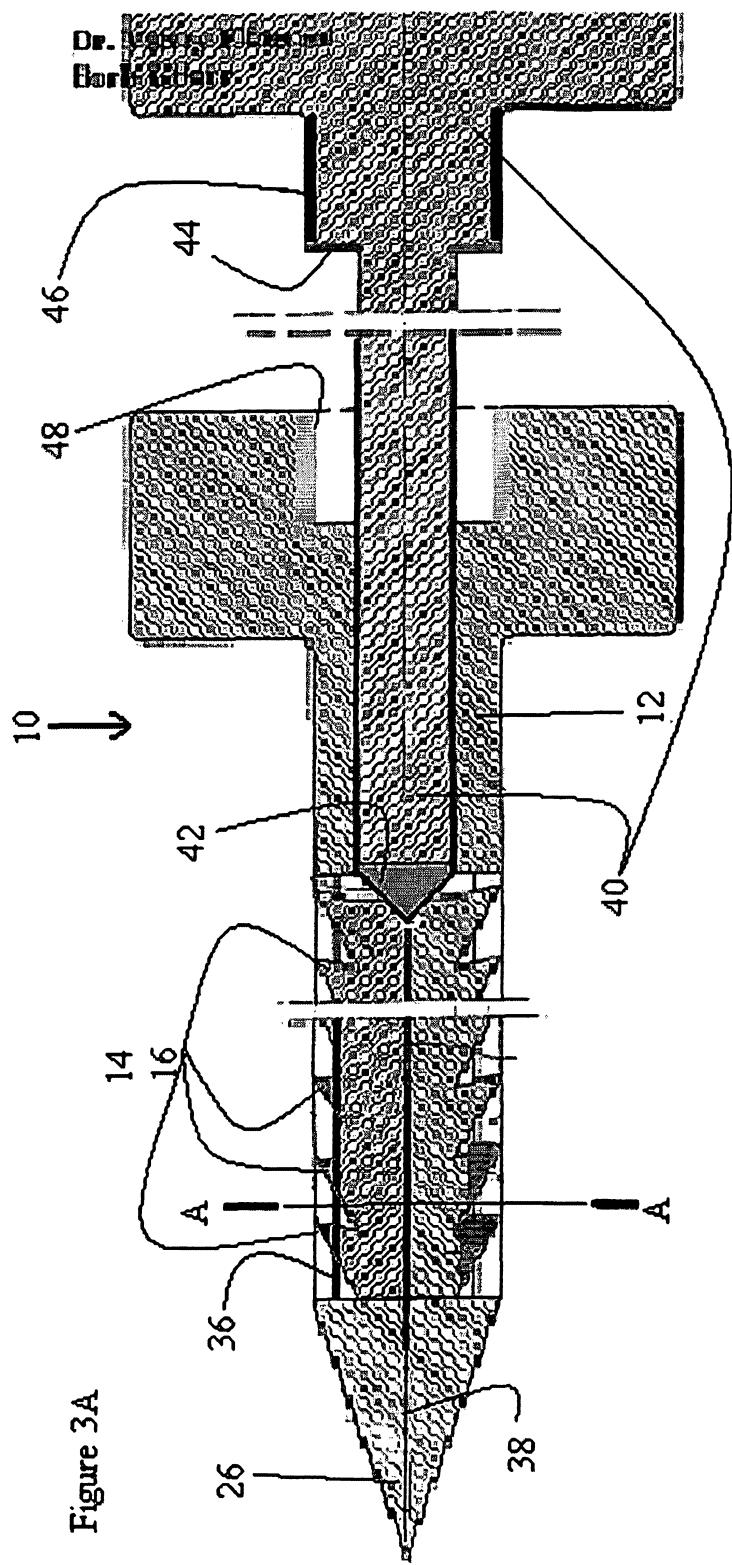


Figure 2B



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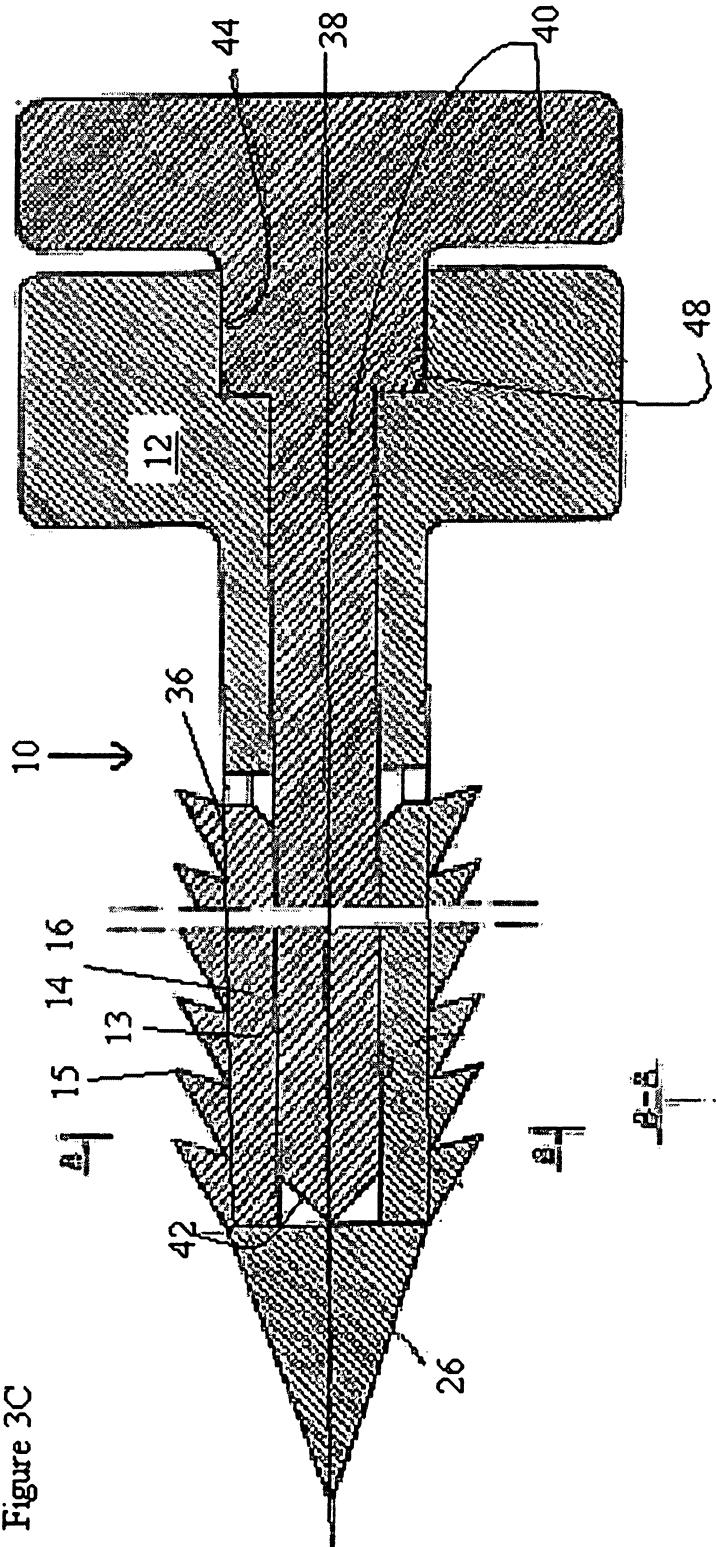


Figure 3C

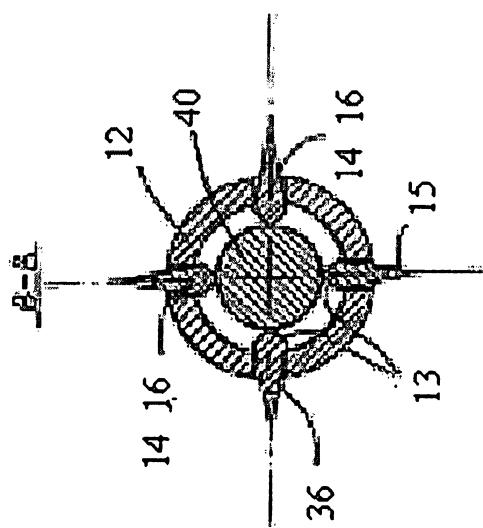
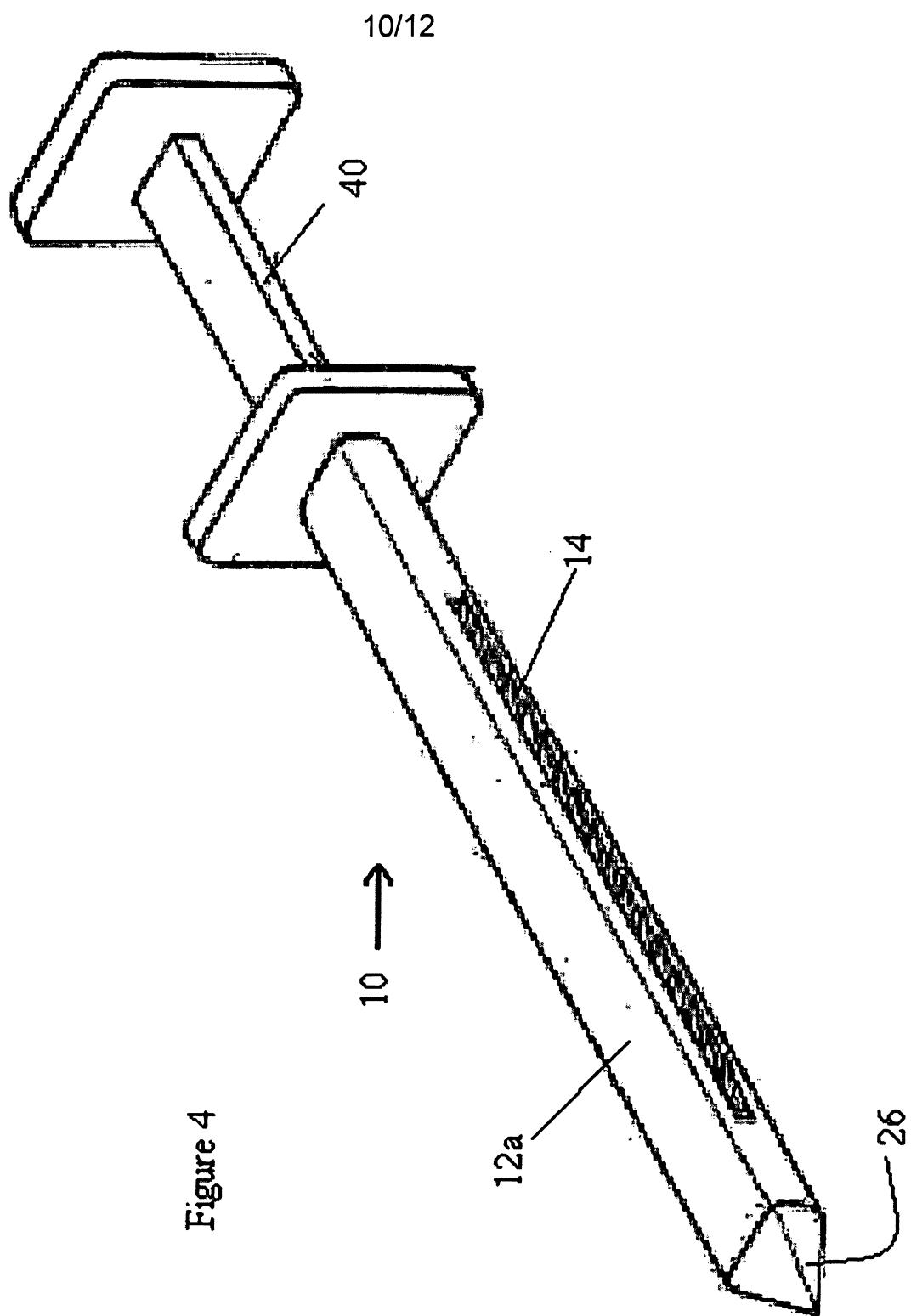


Figure 3D



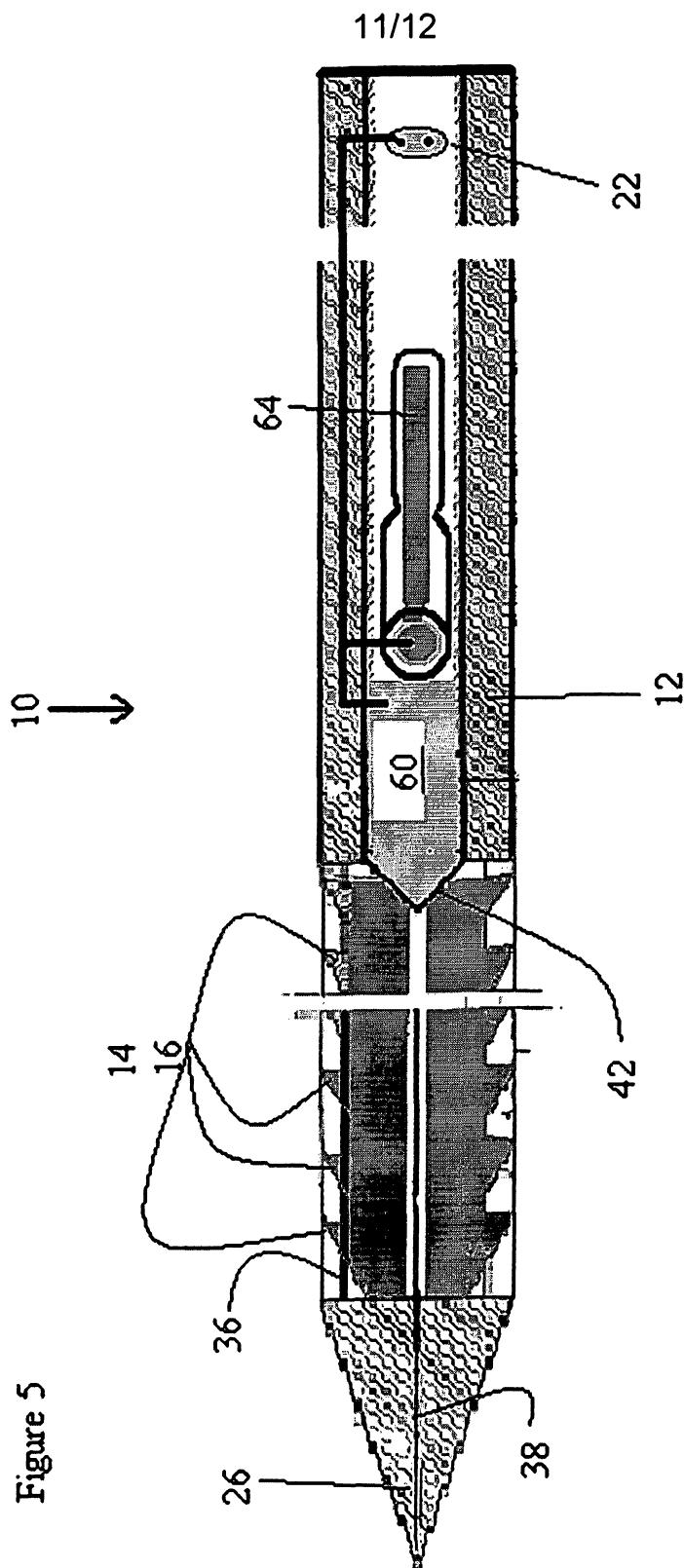


Figure 5

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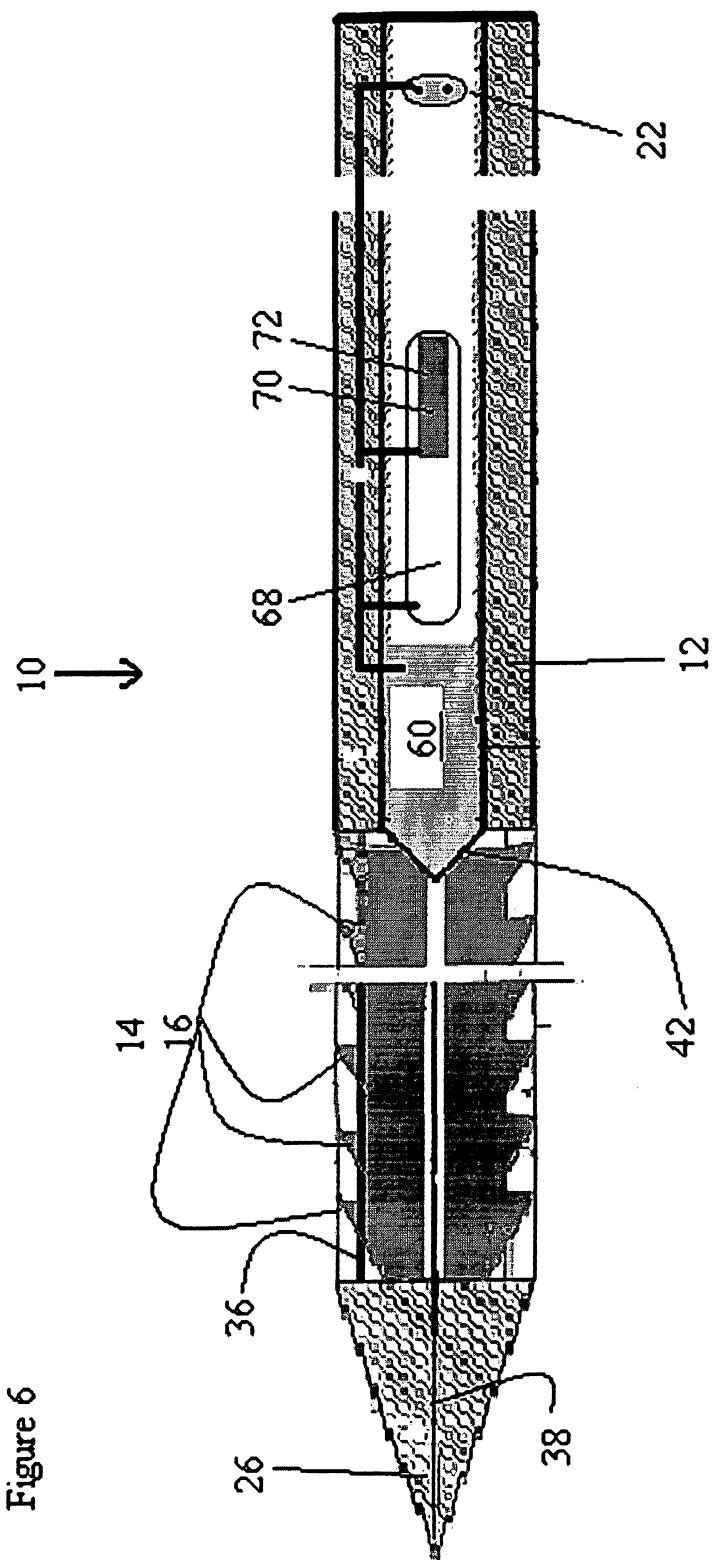


Figure 6