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(54) **Title**: ANATOMICAL-POSITIONING APPARATUS AND METHOD WITH AN EXPANDABLE DEVICE

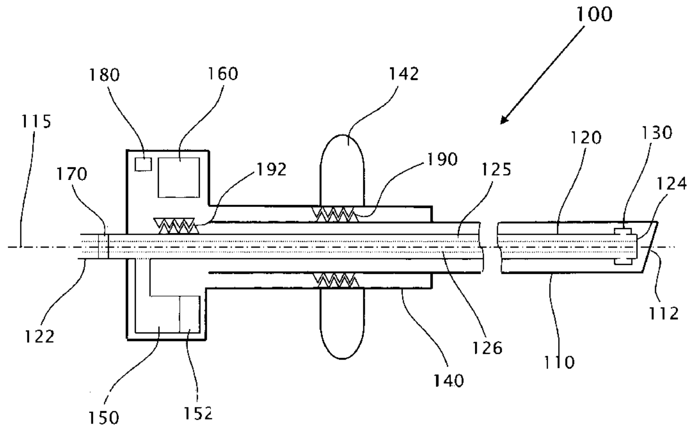

Fig 3

(57) **Abstract**: An anatomical-positioning apparatus for acquiring mechanical data from a tissue to facilitate determining type of the tissue and transition between different tissues and cavities. The anatomical-positioning apparatus includes a cannula, having a tip, an expandable device having a contracted form size and an expanded form size, wherein the expanded form size is substantially larger than the contracted form size. The anatomical-positioning apparatus further includes an introducer, having a longitudinal axis and a distal end, facilitating the introduction of the expandable device into the tissue, the expandable device being in a contracted state, an expanding-mechanism for expanding and contracting the expandable device, and a sensor for measuring physical parameters associated with the expandable device. An aspect of the present invention is to provide a method for acquiring mechanical data from a tissue by an expandable device, while the expandable device exerts pressure onto portions of the tissue.

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ANATOMICAL-POSITIONING APPARATUS AND METHOD WITH AN EXPANDABLE DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit under 35 USC 119(e) from US provisional application 61/354,225, filed on June 13th, 2010, the disclosure of which is incorporated by reference for all purposes as if fully set forth herein.

FIELD OF THE INVENTION

This invention relates to invasive medical devices and more particularly, the present invention relates to anatomical-positioning medical devices for controlled advancement thorough multiple tissues of various types and cavities disposed there between, until reaching a target position. For example, an Epidural anesthesia device to provide controlled access to the Epidural space, while preventing puncturing the Dura mater.

BACKGROUND OF THE INVENTION

In medical procedures, needle insertion and localization are issues of great importance. Misplacement of a needle tip or a trocar can harm essential tissues such as blood vessels, nerves or internal organs and lead to major complications. For example, during a procedure of Epidural anesthesia the needle tip should be placed inside the Epidural space (ES), to thereby facilitate administration of anesthetic agents. This has become a common and effective procedure for controlling pain during childbirth, major surgery, and chronic back pain.

Reference is made to Fig. 1, an illustration of the final stage of an Epidural anesthesia procedure. The tip of a needle **92** of a device **90**, for administering a medication into Epidural space **70**, is disposed inside Epidural space **70**, after being inserted through skin **30** and advanced between Spinous process **55** and through the subcutaneous fat layer **40**, the Supraspinous Ligament **50**, the Interspinous Ligament **52** and the Ligamentum Flavum (LF) **60**.

Overshooting of the tip of the needle beyond the ES may puncture the Dura mater **80** causing a leak of the cerebral-spinal fluid (CSF) from spinal cord **85** into the ES, leading to severe headaches (post dural puncture headaches syndrome).

The majority of current injection techniques are "blind" techniques, mainly tactile based. For example, the main technique of Epidural block is based on the "loss of resistance technique" (LORT). In LORT, a fluid or air filled syringe is attached to a needle. While the needle is advanced through different layers in the insertion site, the physician taps on the syringe. Inside dense Ligament layers, the physician fills a strong resistance, but when crossing the LF **60** and entering the ES **70**, there is a substantial loss of resistance so that the fluid or air from the syringe can be easily pushed into the low-pressured ES **70**, thus signaling the physician to stop advancing needle **92**.

In practice, the LORT holds some major disadvantages. Because of the elastic properties of the LF **60**, the elastic fibers are pushed by the needle and are stretched into the ES **70**. For this reason, the rupture of these fibers takes place deep inside the ES **70** increasing the risk of an overshooting of the needle tip into the Dura mater **80**. Moreover, the resolution of the non-controlled advancement-increments of the needle-tip is very limited and differs extensively from one physician to another. Another disadvantage of LORT is the relatively high risk of a false loss of resistance, taking place for instance inside the LF **60** due to a small space between adjacent fibers.

Figs. 2a-2d illustrate cross sectional views of the stages of a typical Epidural anesthesia procedure, including the penetration of Ligamentum Flavum **60** and including entering into Epidural space **70**. When needle **95** is advanced through Ligamentum Flavum **60**, the elastic fibers of Ligamentum Flavum **60** are stretched by pushing pressure exerted by needle **95** deep into Epidural space **70**, before entering Epidural space **70** (see Figs 2b and 2c). When the fibers reach a certain displacement, Ligamentum Flavum **60** ruptures and the needle penetrates into Epidural space **70**, as depicted in Fig. 2d, typically stopping a short distance (d_1) from Dura mater **80**. The displacement required for the fiber to rupture differs from one person to another due to physiologic variations in Ligamentum Flavum elasticity, thickness and other factors. However, using the prior art technique has an extensive risk of accidently puncturing the Dura mater due to overshooting of the needle.

US patent 5,188,594, given to Michael Zilberstein, provides a device and method for administering medicine into the Epidural space by first supplying air through a valve connected to a needle and provided with an inflatable element so that before the needle reaches the Epidural space the inflatable element is inflated. The needle is advanced and when the needle reaches the Epidural space **70** the inflatable element is deflated, which deflation is, typically, observed by the physician (or his/her stuff); medication is then administered through the valve and through the needle into the Epidural space.

There is a need for and it would be advantageous to have an injection device that can overcome the disadvantages mentioned hereabove, including the disadvantages of the LORT, and is relatively a low cost solution.

The terms “Epidural anesthesia procedure” and “Epidural block procedure” are used herein interchangeably.

SUMMARY OF THE INVENTION

By way of introduction, the principal intentions of the present invention include providing an anatomical-positioning apparatus, such as an injection device, that facilitates acquiring mechanical data from a mammalian tissue by an expandable device, while the expandable device exerts pressure onto portions of said mammalian tissue. Thereby facilitating to determine the type of a mammalian tissue, as well as determining transition between different mammalian tissues and cavities. An aspect of the present invention is to provide safe methods for advancing an introducer, typically a sharp introducer, from an elastic tissue to a soft tissue, such as from the Ligamentum Flavum to the Epidural space.

According to the teachings of the present invention there is provided an anatomical-positioning apparatus for acquiring mechanical data from a mammalian tissue to facilitate determining type of the tissue and transition between different tissues and cavities. The anatomical-positioning apparatus includes a cannula, having a tip at the distal section of the cannula, an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein the expanded form size is substantially larger than the contracted form size. The anatomical-positioning apparatus further includes an introducer, having a longitudinal axis and a distal end, facilitating the introduction of the expandable device into the mammalian tissue, the expandable device being in the contracted state, an expanding-mechanism for expanding and contracting the expandable device, and a sensor for measuring physical parameters associated with the expandable device, to thereby provide sensed data.

The sensed data is acquired while the expandable device exerts pressure onto portions of the mammalian tissue, to thereby facilitating determining the type of tissue that is in contact with the expandable device and to determine a transition between different tissues and cavities. The sensor includes one or more sensing devices selected from the group of devices consisting of a pressure sensor, strain gauge, force sensor, tactile sensor, displacement sensor, volume sensor, flow sensor and a piezoelectric transducer. Optionally, the sensing device includes an array of sensors disposed on the expandable device.

Typically, the sensed data is indicated by one or more indication devices selected from the group of devices consisting of a display, a gage, a light indicator, an audio indicator and a tactile indicator.

Optionally, the sensed data includes a measurement of the advancement of the cannula against the mammalian tissue, and wherein the displacement of the expandable device, along the longitudinal axis, is inferred from the sensed data.

Optionally, the sensed data includes a one-dimensional measurement of the displacement of the expandable device, during the expanding against the mammalian tissue or contracting away from the mammalian tissue.

Optionally, the sensed data includes one or more measurements selected from a group of measurements consisting of the pressure inside the expandable device, the volume of gas or fluid inside the expandable device, an external force applied on the expandable device by the mammalian tissue and the spatial pressure or spatial force applied on the expandable device by the mammalian tissue, while the expandable device exerts pressure onto portions of the mammalian tissue.

Optionally, the sensed data facilitates determining one or more measurements selected from a group of measurements consisting of the volume-pressure work performed by the expandable device, a volume-pressure profile of the expandable device, the work being done by the expandable device and the force-displacement profile of the expandable device, while the expandable device exerts pressure onto portions of the mammalian tissue.

The expandable device is securely attached to the tip of the cannula or on the external circumference of the cannula, proximal to the tip of the cannula and when the expandable device expands from the contracted state to the expanded form size, the expandable device is disposed outside the introducer, and a blunt contact surface is formed at the external surface of the expanded expandable device.

The expandable device protects the mammalian tissue or an anatomical structure ahead of the mammalian tissue, from being punctured by the introducer of the expandable device. The cannula protects the expandable device from being punctured by the introducer. Typically, the expandable device expands and contracts under fluid or gas pressure provided by the expanding-mechanism through the cannula.

In variations of the present invention, the introducer is an openable introducer, having an openable sharp tip, wherein the openable sharp tip of the openable introducer has a closed state and an open state, and wherein the expandable device is trapped inside the openable sharp tip, the openable sharp tip being in a closed state. Preferably, the expandable device facilitates the openable sharp tip to remain in the closed state, when the expandable device is loaded by a preconfigured expanding force and the sharp tip is situated in a high density tissue. The expandable device facilitates the opening of the openable sharp tip, when the expandable device is loaded be a preconfigured expanding force and the openable sharp tip enters a low density tissue or cavity. The closed state facilitates advancement of the openable introducer through the mammalian tissue, while the open state prevents advancement of the openable introducer through the mammalian tissue. It should be noted that the expandable device also protects soft tissues ahead of expandable device.

Optionally, the introducer is selected from the group consisting of a veress needle, an epidural needle, a biopsy needle, a trocar, a cannula, a catheter, a Tuohy type needle and a surgical instrument.

Optionally, the expandable device is selected from a group of devices consisting of a balloon, a membrane, a diaphragm, a spring and a flexible device. Optionally, the expandable device includes one or more mechanical devices selected from a group of devices consisting of a spring and a balloon enclosed in a conical element, wherein the conical element protects the balloon from being punctured.

Optionally, the cannula and the expandable device is introduced on-demand and can be withdrawn during a procedure in order to enable utilization of other tools inside the mammalian tissue.

Optionally, the cannula includes a double lumen, wherein a first lumen facilitates a pathway for the fluid or gas into the expandable device, and wherein a second lumen facilitates a pathway for one or more devices selected from a group of devices consisting of a thin needle, a catheter, an optical fiber, an electrode and a surgical instrument.

Optionally, the cannula includes a single lumen facilitating a pathway for the fluid or gas into the expandable device, and wherein the single lumen facilitating a pathway for an optical fiber or a miniature camera, to thereby facilitate visualization of the mammalian tissue through the expandable device, the expandable device being in contact with the mammalian tissue.

Preferably, the anatomical-positioning apparatus further includes an advancement mechanism for incrementally advancing, in a controlled manner, one or more devices selected from the group consisting of the introducer, the cannula and the expandable device. Optionally, the advancement mechanism is selected from the group of devices consisting of a motor based device, hydraulic device, gear based device and a screw based device. Optionally, the introducer can be advanced incrementally together with the cannula and the expandable device. Optionally, the introducer can be advanced incrementally with respect to the cannula and the expandable device.

Preferably, the anatomical-positioning apparatus further includes a processor facilitated to record and analyze the sensed data, to thereby determine the type of tissue that is in contact with the expandable device and to determine the transition between tissues and cavities, wherein the sensed data is acquired while the expandable device is expanding, contracting or in a steady expansion level.

It is an aspect of the present invention to provide a method for acquiring mechanical data from a mammalian tissue by an expandable device, while the expandable device exerts pressure onto portions of the mammalian tissue. The method includes the steps of:

a) providing an anatomical-positioning apparatus including a cannula, having a tip at the distal section of the cannula; an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein the expanded form size is substantially larger than the contracted form size, and wherein the expandable device is securely attached to the tip of the cannula or on the external circumference of the cannula, proximal to the tip of the cannula; an introducer, having a distal end, facilitating the introduction of the expandable device into the mammalian tissue, the expandable device being in the contracted state; an expanding-mechanism for expanding and contracting the expandable device; and a measuring-mechanism for measuring physical parameters associated with the expandable device, while the expandable device exerts pressure onto portions of the mammalian tissue

b) inserting the introducer inside the mammalian tissue, wherein the distal end of the introducer enters first;

c) advancing the expandable device through the introducer, using the cannula;

d) expanding the expandable device outside the distal end of the introducer;

e) measuring the physical parameters associated with the expandable device, while the expandable device exerts pressure onto portions of the mammalian tissue, thereby creating sensed data.

Preferably, the method further includes the step of analyzing the sensed data, using a processor, thereby determining the type of the mammalian tissue being in contact with the expandable device, and determining a transition between different mammalian tissues and cavities.

Optionally, in the method, the sensed data includes one or more measurements selected from a group of measurements consisting of the displacement of the expandable device and cannula, the pressure inside the expandable device, the volume of gas or fluid inside the expandable device, the external force applied on the expandable device by the mammalian tissue and the spatial pressure or spatial force applied on the expandable device by the mammalian tissue, while the expandable device exerts pressure onto portions of the mammalian tissue.

Optionally, in the method, the sensed data facilitates determining one or more measurements selected from a group of measurements consisting of the volume-pressure work performed by the expandable device, the volume-pressure profile of the expandable device, the work being done by the expandable device and the force-displacement profile of the expandable device, while the expandable device exerts pressure onto portions of the mammalian tissue.

Optionally, in the method, the measuring of the sensed data is performed during states selected from a group of states consisting of an expansion of the expandable device, a contraction of the expandable device and a displacement of the cannula and the expandable device, while the expandable device is expanded.

It is another aspect of the present invention to provide a spring-back method for a controlled insertion of an introducer into and through an elastic mammalian tissue. The spring-back method includes the steps of:

a) providing a device including a cannula, having a tip at the distal section of the cannula; an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein when in expanded state, the expandable device has a front end; wherein the expanded form size is substantially larger than the contracted form size; and wherein the expandable device is securely attached to the tip of the cannula or on the external circumference of the cannula, proximal to the tip of the cannula; an introducer, having a sharp tip at the distal end, facilitating the introduction of the expandable device into the mammalian tissue, the expandable device being in the contracted state; an expanding-mechanism for expanding and contracting the expandable device; and an advancement mechanism for incrementally advancing, in a controlled manner, devices selected from the group consisting of the introducer, the cannula and the expandable device;

b) expanding the expandable device by the expanding-mechanism, outside the tip of the introducer, whereby the expandable device exerts pressure onto portions of the mammalian tissue, wherein the mammalian tissue is initially in an undistorted position;

c) advancing the introducer incrementally to a preconfigured position situated beyond the undistorted position of the mammalian tissue, the mammalian tissue being pushed by the expandable device, wherein the tip of the introducer is posterior to the instantaneous position of the front end of the expandable device, with respect to the elastic tissue;

d) holding the introducer in secured position; and

e) contracting the expandable device at a preconfigured rate, thereby facilitating the mammalian tissue, being elastic, to spring back powerfully towards the undistorted position of the mammalian tissue, thereby penetrating the mammalian tissue by the tip of the introducer, being disposed beyond the undistorted position of the mammalian tissue.

Optionally, in the spring-back method, the incremental advancing of the introducer is performed while also incrementally advancing the expandable device, wherein the expandable device is expanded.

Optionally, in the spring-back method, the incremental advancing of the introducer is performed, while the expandable device is expanded and in steady position, wherein the introducer is incrementally displaced beyond the undistorted position of the mammalian tissue, and wherein the introducer tip is kept at a shorter distance from the mammalian tissue, with respect to steady position of the front end of the expandable device.

It is another aspect of the present invention to provide a method for a controlled insertion of a cannula, using an inner needle, into and through an elastic mammalian tissue, the method including the steps of:

a) providing a device including a cannula, having a double lumen and a tip at the distal section of the cannula; an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein when in expanded state, the expandable device has a front end; wherein the expanded form size is substantially larger than the contracted form size; and wherein the expandable device is securely attached on the external circumference of the cannula, proximal to the tip of the cannula; an introducer, facilitating the introduction of the expandable device into the mammalian tissue, the expandable device being in the contracted state; an expanding-mechanism for expanding and contracting the expandable device; an inner needle being introduced through the cannula; and an advancement mechanism for incrementally advancing, in a controlled manner, devices selected from the group consisting of the introducer, the cannula, the inner needle and the expandable device;

b) Advancing the cannula together with the inner needle outside distal tip of the introducer, wherein the tip of the inner needle is secured inside the cannula near the distal end of the cannula;

c) expanding the expandable device by the expanding-mechanism, whereby the expandable device exerts pressure onto portions of the mammalian tissue, wherein the mammalian tissue is initially in an undistorted position;

d) advancing the cannula together with the inner needle incrementally to a preconfigured position wherein the distal end of the cannula together with the tip of the inner needle are situated beyond the undistorted position of the mammalian tissue, the mammalian tissue being pushed by the expandable device;

e) locking the inner needle and the cannula in a secured position;

f) contracting the expandable device at a preconfigured rate, while unlocking the cannula, thereby facilitating the mammalian tissue, being elastic, to spring back powerfully towards the undistorted position of the mammalian tissue, while pushing backwards the cannula, thereby penetrating the mammalian tissue by the tip of the inner needle, being disposed beyond the undistorted position of the mammalian tissue;

g) incrementally advancing the cannula over the inner needle to a position wherein the distal end of the cannula shields the tip of the inner needle.

Optionally, the insertion method further includes the step of expanding the expandable device by the expanding-mechanism, thereby anchoring the cannula in position, upon transition of the expandable device from the elastic tissue into a different tissue or cavity.

It is yet another aspect of the present invention to provide a method for a controlled insertion of an openable introducer into and through a mammalian tissue, the method including the steps of:

a) providing a device including a cannula, having a double lumen; an openable introducer, including an openable sharp tip having a closed state and an opened state, wherein the closed state facilitates advancement of the openable introducer through the mammalian tissue; and wherein the open state prevents advancement of the openable introducer through the mammalian tissue; an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state.

When in expanded state, the expandable device has a front end. The expanded form size is substantially larger than the contracted form size. The expandable device is securely attached on the external circumference of the cannula, proximal to the tip of the cannula.

The openable introducer facilitates the introduction of the expandable device into the mammalian tissue, the expandable device being in the contracted state.

The expandable device facilitates opening of the tip of the openable introducer when the expandable device is in the expanded state wherein the tip enters a cavity or a low dense tissue;

The device further includes an expanding-mechanism for expanding and contracting the expandable device;

b) advancing the cannula together with the openable introducer into and inside the mammalian tissue, the openable sharp tip being in the closed state;

c) maintaining a constant preconfigured pressure inside the expandable device;

d) advancing the cannula together with the openable introducer until the tip of the openable introducer enters into a low density tissue or cavity; thereby facilitating rapid expanding of the expandable device by the expanding mechanism, the constant preconfigured pressure inside the expandable device being larger than the external pressure applied on the tip of the openable introducer by the low density tissue or cavity.

Optionally, in the method with the openable introducer, the device further includes an advancement mechanism for incrementally advancing, in a controlled manner, devices selected from the group consisting of the openable introducer, the cannula and the expandable device.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will become fully understood from the detailed description given herein below and the accompanying drawings, which are given by way of illustration and example only and thus not limitative of the present invention, and wherein:

Fig. 1 illustrates the Epidural space and surrounding anatomical structures with a needle properly inserted into the Epidural space;

Figs. 2a-2d (prior art) illustrate cross sectional views of the stages of a typical Epidural anesthesia procedure, including penetration of the Ligamentum Flavum and including entering into the Epidural space;

Fig. 3 is a schematic illustration of an anatomical-positioning apparatus, according to embodiments of the present invention.

Figs. 4a-4e illustrate cross sectional views of the distal portion of an anatomical-positioning apparatus as shown in Fig. 3, showing the stages of an Epidural anesthesia procedure, including expanding an expandable device inside the Ligamentum Flavum and inside Epidural space;

Fig. 5 illustrates another embodiment of an anatomical-positioning apparatus, according to embodiments of the present invention, having a spring and a conical element, shown in a closed state;

Fig. 6 illustrates the anatomical-positioning apparatus shown in Fig. 5, the conical element being in an opened state;

Fig. 7 is a graph that describes the resistance forces being measured when advancing a plastic tube with a surface area of ~4 mm^2 against Ligamentum and against Fat.

Fig. 8 is a graph that describes the resistance forces being measured when advancing a "Tuohy" 18G needle against Ligamentum and against Fat.

Fig. 9 is a schematic flow chart showing an exemplary method of determining a tissue type, as well as transition between different tissues and cavities, using an anatomical-positioning apparatus, according to embodiments of the present invention.

Figs. 10a-10e illustrate cross sectional views of the distal portion of an anatomical-positioning apparatus, as shown in Figs. 5 and 6, showing the stages of a spring-back method of safe penetration of the Ligamentum Flavum and entering into the Epidural space, during an Epidural anesthesia procedure.

Fig. 11 is a schematic flow chart showing an exemplary spring-back method as illustrated in Figs. 10a-10e.

Figs. 12a-12d illustrate side views of the distal portion of an anatomical-positioning apparatus, according to variations of the present invention, having a thin-needle being introduced through a cannula for facilitating a spring-back method.

Figs. 13a-13g illustrate cross sectional views of the distal portion of an anatomical-positioning apparatus, as shown in Figs. 12a-12d, showing the stages of a spring-back method of safe penetration of the Ligamentum Flavum and entering into the Epidural space, during an Epidural anesthesia procedure.

Fig. 14 is a schematic flow chart showing an exemplary spring-back method as illustrated in Figs. 13a-13g.

Fig. 15 illustrates the distal section of an anatomical-positioning apparatus, according to variations of the present invention, wherein the introducer includes an openable tip and wherein the openable tip is shown in a closed state.

Fig. 16a illustrates a cross sectional view of the distal portion of the anatomical-positioning apparatus shown in Fig. 15, wherein the introducer penetrates an mammalian tissue, such as the Ligamentum Flavum, and wherein the openable tip is shown in a closed state.

Fig. 16b illustrates a cross sectional view of the distal portion of the anatomical-positioning apparatus shown in Fig. 15, wherein the introducer penetrates a mammalian tissue, such as the Ligamentum Flavum, and wherein the openable tip is shown in an opened state.

Fig. 17 is a schematic flow chart showing an exemplary method safely penetrating the Ligamentum Flavum and entering Epidural space using the anatomical positioning apparatus illustrated in Figs. 15-16b.

Fig. 18a-18b illustrate side views of an anatomical-positioning apparatus, according to variations of the present invention, having a guide-wire attached to the expandable device for measuring the displacement of the expandable device.

DETAILED DESCRIPTION OF THE INVENTION

The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided ,so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

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. The methods and examples provided herein are illustrative only and not intended to be limiting.

Referring back to Fig. 1 illustrating Epidural space **70** and surrounding anatomical structures with a tip **92** of needle **90** properly inserted into Epidural space **70**.

Referring is also to Fig. 3, showing a schematic illustration of an exemplary anatomical-positioning apparatus **100**, according to preferred embodiments of the present invention. Anatomical-positioning apparatus **100** includes a housing **140** that secures both a sheath-shaped introducer **110**, having a longitudinal axis **115**, and an expandable device **130**, which expandable device **130** is securely attached to a cannula **120**. Anatomical-positioning apparatus **100** further includes a cannula **120**, having an opened proximal end **122**, a distal end **124**, and two lumens, wherein a first lumen **125** facilitates the insertion and evacuation of gas or fluid into expandable device **130**, and a second lumen **126** facilitates the insertion of various elongated devices such as a catheter. Expandable device **130** is securely attached to the external circumference of cannula **120**, proximal to tip **124** of cannula **120**.

In variations of the present invention, cannula **120** has an elongated hollow body (single lumen) facilitating the insertion and evacuation of gas or fluid into expandable device **130**, wherein expandable device **130** is securely attached to distal end **124** (tip) of cannula **120**. The elongated hollow body of cannula **120** can also provide a pathway for an optical fiber or a miniature camera, to thereby facilitate visualization of a mammalian tissue or cavity through expandable device **130**, when expandable device **130** is expanded.

In embodiments, introducer **110** can be a Veress needle, an Epidural needle, a biopsy needle, a trocar, a cannula, a catheter, a Tuohy type needle, a surgical instrument or any other sharp object facilitated to be inserted into at least one mammalian tissue.

It should be noted that the present invention will be described mostly in terms of an anatomical-positioning apparatus for performing a procedure of Epidural anesthesia, including determining the type of one or all tissues the introducer is advancing through, including Interspinous Ligament **52**, Ligamentum Flavum **60** and inside Epidural space **70**, as well as indicating transition between tissues and cavities. But the present invention is not limited to anatomical-positioning apparatus for performing a procedure of Epidural anesthesia, including determining the type of one or all tissues the introducer is advancing through and indicating transition between tissues and cavities. The present invention includes all anatomical-positioning apparatuses for determining the type of one or more tissues, the introducer is advancing through, as well as indicating transition between different tissues and cavities.

Distal end **112** of introducer **110** is typically, with no limitation, a sharp end. Cannula **120** can be made of any biocompatible material, preferably hard plastic or stainless still. Expandable device **130** can be expanded to a preconfigured volume or shape and have a preconfigured displacement along longitudinal axis **115** of introducer **110** using air or fluid passing through first lumen **125** of cannula **120** and into expandable device **130**.

Alternatively, the expandable device can be made of a shape memory alloy, such as NiTi alloy, so that under certain conditions (for instance, heat) it expands. Optionally, the expandable device can be expanded using a mechanical mechanism that is based on springs or any other mechanical element. In one preferred embodiment of the present invention, without limiting the scope of this invention, expandable device **130** is an inflatable balloon that can be made of any elastic material known in the art, such as polyurethane, flexible PVC, PET, nylon, nylon elastomers and thermoplastic elastomers.

Reference is now made to Figs. 4a-4e, illustrating cross sectional views of the distal portion of anatomical-positioning apparatus **100**, showing the stages of an Epidural anesthesia procedure, including the penetration of Ligamentum Flavum **60** and including entering into Epidural space **70**. Fig. 4a illustrates expandable device **130** as a balloon, being in a contracted state, while Fig. 4c illustrates expandable device **130** as a balloon, being in an expanded state. Proximal end **134** of expandable device **130** is securely attached to distal end **124** (tip) of cannula **120**.

In the contracted state, balloon **130** is completely deflated, and is protectively disposed inside introducer **110**. Balloon **130** is kept deflated by mechanical biasing force or by maintaining partial vacuum-pressure inside balloon **130**.

In the expanded state or in a partially expanded state, balloon **130** is popped out of introducer **110**, such that introducer **110** does not damage balloon **130**. Balloon **130** is kept inflated by providing controlled gas or fluid pressure into balloon **130**. When balloon **130** is inflated, distal end **132** of expandable device **130** forms a blunt surface.

Referring back to Fig. 3, Anatomical-positioning apparatus **100** further includes an expanding-mechanism **150** for expanding and contracting expandable device **130**. When expandable device **130** is a balloon, the expanding-mechanism, typically, includes a pump (not shown) for controllably pump gas (air) or fluid into and out of balloon **130**. Expanding-mechanism **150** may include a container **152** for holding gas or fluid.

Anatomical-positioning apparatus **100** further includes a sensor **170** for measuring physical parameters associated with expandable device **130**, while expandable device **130** exerts pressure onto portions of the mammalian tissue being operationally pressed by expandable device **130**. The measuring of the physical parameters, associated with expandable device **130**, facilitates determining the type of tissue that is in contact with a blunt external surface, typically distal surface **132** of balloon **130**, as well as determining transition between tissues and cavities.

The measuring of the physical parameters, associated with expandable device **130**, may take place when expandable device **130** expands, when expandable device **130** contracts, or when expandable device **130** is already expanded and in a steady state.

Reference is now made to Figs. 5-6, illustrating anatomical-positioning apparatus **200** including another embodiment of the expandable device, according to variations of the present invention.

As shown in Figs. 5 and 6, expandable device **230**, such as balloon **230**, includes having a proximal section **232** encapsulated inside a biasing element such as a helical spring **240** and a conical element **250** that are securely interconnected. When balloon **230** is inflated to a preconfigured volume, as depicted in Fig. 6, proximal section **232** of balloon **230**, having a diameter smaller than the internal diameter of introducer **110**, and distal section **234**, having a diameter that is typically, with no limitation, 1.1-4 times larger than the internal diameter of introducer **110**, and approximately 1.5-2 times larger, in the best mode.

Proximal end **238** of proximal section **232** of balloon **230** is securely attached to proximal end **248** of spring **240**, both of which are securely attached to distal end **124** (tip) of cannula **120**. The proximal end of distal end section **234** of balloon **230** is disposed at proximal end **252** of conical element **250**, wherein conical element **250** has a proximal end **252** and a distal end **254**, and wherein proximal end **252** of conical element **250** is securely attached to distal end **246** of spring **240**. Proximal end **252** of conical element **250** has a substantially constant diameter that fits inside the internal diameter of introducer **110**. In the collapsed state of expandable device **230**, distal end **254** of conical element **250** has a smaller or equal diameter to the diameter of proximal end **252** of conical element **250**. When expandable device **230** is expanded, distal end **254** of conical element **250** has a larger diameter than the internal diameter of introducer **110**.

As depicted in an exemplary embodiment in Fig. 6, conical element **250** includes on the distal section of conical element **250**, typically, the majority of the distal section of conical element **250**, a preconfigured number of elastic flaps **256** that are separated by a slot cut into the distal section of conical element **250**. Flaps **256** can operatively hingedly bend or deflect outwards as a result of pressure being built inside distal section **234** of balloon **230**, thus enabling distal section **234** of balloon **230** to expand to the preconfigured volume, distally outside of the typically sharp tip of introducer **110**.

Preferably, gas (preferably air) or fluid is injected through cannula **120** and into balloon **230**, thereby inflating balloon **230**. Hence, proximal section **232** of balloon **230** stretches spring **240** distally, towards distal end **112** of introducer **110**, and outside of distal end **112** of introducer **110**. As fluid pressure continues to build up, balloon further inflates to an extent that forces flaps **256** of conical element **250** to open, thus facilitating distal section **234** of balloon **230** to reach the preconfigured volume and surface area. Flaps **256** of conical element **250** protect distal section **234** of balloon **230** from being punctured by tip **112** of introducer **110**.

Upon deflation of balloon **230**, elastic flaps **256** apply the force, stored while being inflated, against distal section **234** of balloon **230**, thus collapsing distal section **234** of balloon **230** back into the smaller diameter of the contracted state. As the gas or fluid pressure inside balloon **230** continues to drop, balloon **230** further deflates and spring **240** returns to the unbiased position. Thereby, expandable device **230** is back inside introducer **110**, proximal to distal end **112**, as depicted in Fig. 5.

When the expandable device is expandable device **230**, the expanding-mechanism, typically, includes a pump (not shown) for controllably pump gas (air) or fluid into and out of balloon **230**, wherein the operation of the pump is synchronized with biasing element **240** and flaps **256**.

An aspect of the present invention is to facilitate determining the tissue type, as well as transition between tissues and cavities. The following describes a method describes the steps of an Epidural anesthesia procedure, by way of example, without limiting the scope of this invention. During Epidural anesthesia procedure, a physician performs procedural steps, in order to differentiate between Ligamentum Flavum **60** and Epidural space **70**, wherein a principle intention of the Epidural block procedure is to be able to stop the advancement of introducer **110** upon entering Epidural space **70**.

In an embodiment of the present invention, during the inflation of balloon **130**, a measurement that reflects the mechanical resistance of the tissue to the inflation of balloon **130**, is taken, using selected sensors **170** (see Fig. 3) disposed in pre configured location, within anatomical-positioning apparatus **100**. Such sensors can be force sensors, pressure sensors, displacement sensors, strain gauges, tactile sensors, volume sensors, flow sensors, piezoelectric sensors and any other sensors known in the art. The data collected by sensors **170** are sensed while expandable device **130** exerts pressure onto portions of the mammalian tissue. The sensed data is of physical parameters associated with expandable device **130**, and reflects mechanical properties of the tissue in which tissue expandable device **130** is disposed while obtaining the sensed data.

The measured physical parameters, associated with expandable device **130**, may include the pressure inside balloon **130**, the instantaneous volume of balloon **130**, the displacement of expandable device **130**, the external force applied on the expandable device by the mammalian tissue, spatial force or spatial pressure applied on expandable device **130** or any other measurement known in the art. Other data can be concluded by processing the sensed data using a processor **160**, such as the volume-pressure work performed by expandable device **130**, volume-pressure profile of expandable device **130**, work performed by expandable device **130** and force-displacement profile of expandable device **130**, while expandable device exerts pressure onto portions of a mammalian tissue, For example, a pressure sensor can measure the pressure that builds up inside balloon **130** for a given volume. According to the measurement, the type of tissue being pushed by balloon **130** is determined and a decision is made whether to advance introducer **110** by another increment or whether to stop introducer **110** from further advancing, due to entrance into Epidural space **70**.

The measurement may be continuous during the expansion, the contraction or the steady expanded state of expandable device **130**, thus providing a unique set of measurements for a specific tissue. For instance, a measurement of the external force applied by a mammalian tissue against an expanded expandable device **130** as a function of the displacement of expandable device **130**, may provide a curve that is typical for a certain type of tissue, for example an elastic tissue, and is substantially different from a non-elastic tissue.

The measurement can be of spatial force or spatial pressure applied on expandable device **130** by a mammalian tissue. In one embodiment, tactile sensors **175** disposed on expandable device **130** provide spatial data reflecting the mechanical resistance of the tissue being pressed by expandable device **130** in various locations along the circumference of expandable device **130.** Such measurements can facilitate determining the direction of the fibers of the mammalian tissue being pressed by the expandable device **130**. In addition, such measurements can facilitate determining the existence and direction of a hard tissue (such as a spinal process) that is in the vicinity of the mammalian tissue being pressed by the expandable device **130**.

Fig 18a-18b illustrate an embodiment of the present invention, wherein a distal tip **174** of a guide-wire **172** is attached to distal end **234** of balloon **230**, and proximal tip **176** of guide-wire **172** is located near a displacement sensor **170**. Upon expansion of balloon **230**, distal end **234** of balloon **230** advances forward along longitudinal axis **115**, thereby facilitating the advancement of guide-wire **172** along longitudinal axis **115**. Displacement sensor **170**, for example a photoelectric sensor, measures the displacement of proximal end **176** of guide-wire **172**, thereby facilitating determining the displacement of balloon **230** while exerting pressure on portions of a mammalian tissue.

The main advantage of the method for determining tissue type and transition between tissues and cavities by an expandable device is in actively acquiring data regarding a mammalian tissue, by deforming the tissue, in order to determine mechanical properties, such as elasticity, that can otherwise be hard to discover by a passive measurement. Moreover, the larger surface area of distal end **132** of balloon **130**, compared the to the tip surface area of tip **112** of introducer **110**, finds an expression in that the mechanical resistance of elastic tissues is being amplified by the larger surface area of distal end **132**, whereas the mechanical resistance of loose tissues does not change significantly. Thus, it is possible to differentiate between tissues types, although there are variations in population.

In addition, when measuring forces that develop against an introducer **110**, friction forces operating on the body of introducer **110** have major influence on the measurement. However, when measuring forces against an expandable device **130**, the friction forces operating on the body of introducer **110** have no effect on the measurement. Therefore, a measurement of mechanical resistance against an expandable device is less biased than a measurement against introducer **110**.

One more advantage is in the ability to perform multiple measurement by expandable device **130** whether in a specific anatomical location or in a series of locations along the path of tip **112** of introducer**110**.

Indicator **180** indicates the type of tissue being in contact with expandable device **130**, as well as possible transition between different tissues and cavities. Such an indication can be visual, for example using a display showing a curve of force versus displacement of expandable device, light indication, acoustic indication, for instance when expandable device reaches Epidural space, a gage and a tactile indication, for example a vibration that is indicative to the extent of tissue elasticity.

Referring back to Figs. 4a-4e, cross sectional views of the distal portion of anatomical-positioning apparatus **100** are illustrated, showing the stages of an Epidural anesthesia procedure, including the penetration of Ligamentum Flavum **60** and including entering into Epidural space **70**. In fig. 4a, Ligamentum Flavum **60** is shown in an undistorted position, as introducer **110** has not touched Ligamentum Flavum **60** as yet. In fig. 4b, introducer **110** has started to penetrate Ligamentum Flavum **60** and thereby, Ligamentum Flavum **60** is not in an undistorted position, the elasticity of the fibers of Ligamentum Flavum **60** cause Ligamentum Flavum **60** to bend into Epidural space **70** (see concavity **62** in Figs. 4b and 4c).

As the operator does not see and thereby does not know that introducer **110** has penetrated Ligamentum Flavum **60**, the operator activates expanding mechanism **150** to thereby expand balloon **130**. The elasticity of Ligamentum Flavum **60** responds to expanded balloon **130**, disposed inside Ligamentum Flavum **60**, to set a pressure level P_l inside balloon **130**. Knowing, for example the quantity of gas/fluid inserted by expanding mechanism **150**, processor **160** analyzes measured pressure P_l, to thereby provide the type of tissue balloon **130** is disposed in. In the described example, processor **160** activates indicator **180** to indicate to the operator that balloon **130** is disposed inside Ligamentum Flavum **60**.

Typically, the operator of anatomical-positioning apparatus **100** activates expanding mechanism **150** to bring back expand balloon **130** to contracted state. Alternatively, balloon **130** automatically contracts back to a contracted state. Then, the operator activates an incremental mechanism for controllably advancing both introducer **110** and cannula **120** further towards Epidural space **70**. The operator may activate an introducer-incremental-advancing-mechanism **190** (see Fig. 3) and/or a cannula-incremental-advancing-mechanism **192**. As the incremental advancing is repeatably performed by the operator, introducer **110** ruptures Ligamentum Flavum **60** penetrates into Epidural space **70**, as depicted in Fig. 4d. Introducer-incremental-advancing-mechanism and cannula-incremental-advancing-mechanism **192** are shown in Fig. 3 schematically. The incremental advancing mechanism may be embodied in ways know in the art, such as a screw based mechanism having threads with a preconfigured pitch of 0.5-2 mm, a step motor etc.

Since the anatomical-positioning apparatus **100** is held by the operator's hands and is inserted into a living body, movements of both the operator and the patient may interfere with positioning of tip **112** of introducer **110** inside a mammalian tissue.

Therefore, when using the incremental advancing mechanism, the anatomical-positioning apparatus **100** may be stabilized by securing housing **140** of apparatus **100** against the entrance site of introducer **110**, for instance, the back of a patient.

When the operator activates expanding mechanism **150** to thereby expand balloon **130**, the fat tissue inside Epidural space **70** responds to expanded balloon **130** to set a pressure level P_2 (see Fig. 4e) inside balloon **130**. Knowing, for example the quantity of gas/fluid inserted by expanding mechanism **150**, processor **160** analyzes measured pressure P_2, to thereby provide the type of tissue balloon **130** is disposed in. In the described example, processor **160** activates indicator **180** to indicate to the operator that balloon **130** is disposed inside Epidural space **70**.

An exemplary experiment:

In Fig. 7, the graph describes the resistance forces being measured when advancing a plastic tube with a surface area of ~4 mm^2 against a Ligamentum and against fat (wherein the fat simulates the Epidural fat tissue in Epidural space **70**). The plastic tube simulates the blunt surface of balloon **130,** having a larger surface area than a needle tip. In Fig. 8, the graph describes the resistance forces being measured when advancing a "Tuohy" 18G needle against a Ligamentum and against fat. The graphs demonstrate a substantial bigger resistance forces measured in the Ligamentum, when advancing a plastic tube, compared to advancing the needle. However, no significant difference in the resistance forces was measured when advancing the plastic tube or the needle against fat tissue. Therefore, the method of measuring forces against an expandable device holds some major advantages and facilitates setting a threshold for differentiating between tissues with different mechanical properties.

Therefore, it is clear that displacing an elastic tissue increases its mechanical resistance, thereby increasing the pressure measured inside a balloon **130**, while the resistance of a non elastic and low density tissue remains substantially unchanged under similar displacement. Hence, active measurement of the resistance of a tissue, while expanding or contracting balloon **130** provides data that facilitate determining the type of tissue balloon **130** is situated in.

In variation of the present invention, a ratio between the previous measurement and current measurement is calculated. If the ratio is smaller than a preconfigured threshold value, it is determined that balloon **130** is still inside the Ligamentum Flavum **60**, and introducer **110** is incrementally advanced. If the ratio is bigger than the preconfigured value, it means that introducer **110** is inside Epidural space **70**. Balloon **130** is deflated and cannula **120** is removed from anatomical-positioning apparatus **100** to enable threading of a catheter through introducer **110** to administrate anesthetics.

Reference is now made to Fig. 9, a schematic flow chart, showing an exemplary method **300** of determining the tissue type and transition between tissues and cavities, according to embodiments of the present invention. Method **300** begins by administrating introducer **110** of anatomical-positioning apparatus **100** into a mammalian tissue. Method **300** proceeds with the following steps:

Step 310: controllably advancing introducer **110** into a mammalian tissue.

The operator of anatomical-positioning apparatus **100** controllably advances introducer **110** inside a mammalian tissue.

Step 320: advancing expandable device **130** through introducer **110**, using cannula **120**, to a predetermined displacement.

The operator advances expandable device **130** through introducer **110**, using cannula **120**, to a predetermined displacement. Preferably, the operator uses a cannula-incremental-advancing-mechanism **192**, to controllably advance expandable device **130**.

Step 330: expanding expandable device **130**.

Expandable device **130** is popped out of introducer **110** and expanded, typically by pressurized flow of gas (typically, air) or fluid, performed by expanding mechanism **150**.

Step 340: measuring physical parameters associated with expandable device **130**.

Typically, the pressure inside expandable device **130** is measured as a function of the volume of gas/fluid flown into expandable device **130**, and/or the external force applied on expandable device as a function of the displacement of expandable device, and/or any other physical feature being measured during expansion, contraction or expanded steady state of expandable device **130**.

Step 350: check if it is the first measuring for the current tissue type.

If it is the first measuring for the current tissue type, go to step **370**.

Else, preferably, compare current measurement with a previous measurement, typically, the last measurement.

Step 360: check, preferably by processor **160**, if the current measurement differs from a previous measure.

If the current measurement is substantially the same (within a preconfigured threshold value) as the previous measurement, go to step **380**.

Else, it is likely that the current measurement was measured in a different tissue type, compared to the tissue type in which the previous measurement was taken.

Step 365: indicating a tissue transition.

Indicator **180** indicates a tissue transition event, using an acoustic, visual or any other indicatory signal.

Step 370: determining the tissue type.

Determine, preferably by processor **160**, the tissue type, for example, by comparing the measured physical parameters to a database.

Step 380: indicating the tissue type.

Indicator **180** indicates a tissue type to the operator.

Step 390: contracting expandable device **130**.

Expandable device **130** is contracted by expanding mechanism **150**, typically by evacuating the gas or fluid from within expandable device **130**, and thereby, the contracted expandable device **130** also returns back into introducer **110**.

Step 395: check if procedure is complete.

If the operator requests the termination of the process, terminate process.

Else, go to step **310**.

An aspect of the present invention is to provide a method of advancing introducer **110** accurately to a preconfigured in-vivo location, for example, into Epidural space **70**, in an Epidural anesthesia (block) procedure. Since, Overshooting of tip **112** of introducer **110** beyond Epidural space **70** may puncture Dura mater **80**, it would be advantageous to have a procedure that substantially reduce the risk of tip **112** of introducer **110** puncturing Dura mater **80**. It is the intention of the present invention to provide a spring-back method of erupting Ligamentum Flavum **60**, such that introducer **110** is inside Epidural space **70** at a distance d_2 (see Fig. 10e) from Dura mater **80**, wherein distance d_2 is substantially larger than distance d_1 (see Fig. 2d): $d_2 >> d_1$. The spring-back method is designed for penetrating elastic tissues, and takes advantage of the elasticity of that tissue.

The principle idea behind the various spring-back methods is to bring tip **112** of introducer **110** to a special position beyond virtual line **65**, denoting the undistorted position of the wall of Ligamentum Flavum **60** that is the internal wall of Epidural space **70**; keep introducer **110** spatially stationary; use expandable device **130** of anatomical-positioning apparatus **100** to further push elastic Ligamentum Flavum **60** by a preconfigured distance; contract expandable device **130** at once and return expandable device **130** back inside introducer **110**. Thereby, the elasticity of Ligamentum Flavum **60** moves Ligamentum Flavum **60** towards the undistorted position **65**, rapidly. Thereby, spearingly meeting tip **112** of introducer **110**, on the way back, which cause Ligamentum Flavum **60** to rupture after one or more spring-back iterations.

In Figs. 10a-10e, a spring-back method, according to embodiments of the present invention, for puncturing, for example, Ligamentum Flavum **60** using, for example, expandable device **230** of anatomical-positioning apparatus **200** (Figs. 5 and 6), is illustrated. The spring-back method is described through the Epidural block procedure, without limiting the scope of this invention.

Reference is now made to Fig. 11, a schematic flow chart, showing an exemplary method **400** of safely advancing an introducer **110** into Epidural space **70** then further administrating medication or anesthetics through a catheter into Epidural space **70**, during an Epidural block procedure, according to embodiments of the present invention. Method **400** begins by administrating introducer **110** of anatomical-positioning apparatus **200** into a mammalian tissue, as shown in Fig. 10a. Method **400** proceeds with the following steps:

Step 410: securing introducer **110**, containing cannula **120**, in Ligamentum Flavum **60**.

The operator of anatomical-positioning apparatus **200** secures introducer **110**, containing cannula **120**, in Ligamentum Flavum **60**, Ligamentum Flavum **60** being an elastic tissue (See Fig. 10b). The elastic tissue stretches slightly beyond the original, undistorted position **65**. Introducer **110** is advanced into Ligamentum Flavum **60** after departing from Interspinous Ligament **52**.

Step 420: inflating balloon **230** to facilitate engagement with the fibers of Ligamentum Flavum **60**.

The operator activates expandable mechanism **150** and thereby, expandable device **230** is disposed out of introducer **110** and distal section **234** of balloon **230** expanded, typically by pressurized flow of gas (typically, air) or fluid, performed by expanding mechanism **150**. Distal section **234** of balloon **230** expands against flaps **256** of conical element **250**, causing flaps **256** to open outwardly, thereby protecting balloon **230** from being punctured by tip **112** of introducer **110** (Fig, 10c).

Step 430: controllably advancing introducer **110** and cannula **120** to a predetermine displacement to stretch the elastic tissue (Ligamentum Flavum **60**).

The operator advances introducer **110** together with cannula **120** and expandable device **230** using introducer-incremental-advancing-mechanism **190** and cannula-incremental-advancing-mechanism **192** respectively, to a predetermined displacement (See Fig. 10d), while expandable device **230** is steadily expanded. Thereby, elastic tissue stretches extensively beyond the original, undistorted position **65** of the elastic tissue wall.

Step 440: locking introducer **110**.

Locking introducer **110** in position, using introducer-incremental-advancing-mechanism **190**.

Step 450: deflating balloon **230**, which returns into introducer **110**.

The operator rapidly deflates expandable device **230** to facilitate a rapid return of balloon **230** into introducer **110**. In a preferred embodiment, conical element **250** and spring **240** facilitate the rapid return on balloon **230** into introducer **110**.

Ligamentum Flavum **60** rapidly returns to the undistorted position, towards and possibly over introducer **110**. If tip **112** of introducer **110** is disposed beyond the original, undistorted position **65** of Ligamentum Flavum **60**, introducer **110** penetrates Ligamentum Flavum **60** at a predetermined location.

Step 460: inflating balloon **230** to anchor introducer **110** and to thereby prevent damage to soft tissue.

Balloon **230** is inflated to anchor introducer **110** and to thereby prevent introducer **110** from advancing forward towards soft tissues, thus protecting them. For example, if introducer is inside Epidural space, there is a need for protecting Dura mater **80** or other anatomical structures inside Epidural space such as blood vessels, from being punctured by introducer **110**.

Step 465: check if Epidural space **70** identified.

Follow the procedure, such as method **300**, to identify the type of tissue. If the fat tissue of Epidural space **70** is not identified, but rather that Ligamentum Flavum **60** is still identified, go to step **430**.

Else, optionally, proceed with the Epidural block procedure.

Step 470: indicating a tissue transition, using acoustic or visual signal.

Indicator **180** indicates a tissue transition event (from Ligamentum Flavum **60** to Epidural space **70**), using an acoustic, visual or any other indicatory signal.

Step 480: administrating saline into Epidural space **70** through introducer **110**.

Administrate saline into Epidural space **70** through introducer **110** to thereby locally enlarge Epidural space **70** to facilitate insertion of a catheter.

Step 485: deflating balloon **230** and withdrawing cannula **120**.

Deflate balloon **230** and withdraw cannula **120** to facilitate insertion of a catheter.

Step 490: threading a catheter through introducer **110**.

A catheter is inserted to Epidural space **70** through introducer **110**.

Step 495: administrating medication or anesthetics through the catheter.

Administrate medication or anesthetics through the catheter.

In Figs. 12a-12d, another anatomical-positioning apparatus **500** facilitating a spring-back method, according to other embodiments of the present invention, for puncturing, for example, Ligamentum Flavum **60** using, for example, expandable device **530** of anatomical-positioning apparatus **500**, is illustrated. The spring-back method is described through the Epidural block procedure, without limiting the scope of this invention. Anatomical-positioning apparatus **500** includes a cannula **520**, typically a double lumen cannula, and a thin-needle **510** facilitated to incrementally advance with respect to cannula **520**. The expandable device includes a balloon **530** disposed on the external circumference of cannula **520**, proximal to distal end **524** of cannula **520**.

Figs. 13a-13g illustrate cross sectional views of the distal portion of anatomical-positioning apparatus **500**, showing the stages of a spring-back method of safe penetration of an elastic tissue, for example, Ligamentum Flavum **60** using, for example, expandable device **530** of anatomical-positioning apparatus **500**, is illustrated.

In this spring-back method, when the elasticity of Ligamentum Flavum **60** rapidly moves Ligamentum Flavum **60** back towards the undistorted position **65**, Ligamentum Flavum **60** is spearingly meeting the tip of thin-needle **510**, rather than tip **112** of introducer **110**. Eventually, thin-needle **510** causes Ligamentum Flavum **60** to rupture after one or more spring-back iterations.

Reference is now made to Fig. 14, a schematic flow chart, showing an exemplary method **600** of safely advancing an inner needle **510** and a cannula **520** into Epidural space **70** then further administrating medication or anesthetics through the catheter into Epidural space **70**, during an Epidural block procedure, according to embodiments of the present invention. Method **600** begins by administrating introducer **110** of anatomical-positioning apparatus **500** into a mammalian tissue (See Fig. 13a). Method **600** proceeds with the following steps:

Step 610: securing introducer **110**, containing cannula **520** and inner needle **510**, in Ligamentum Flavum **60**.

The operator of anatomical-positioning apparatus **500** secures introducer **110**, containing cannula **520** and inner needle **510**, in Ligamentum Flavum **60**, Ligamentum Flavum **60** being an elastic tissue (See Fig. 13b). The elastic tissue stretches slightly beyond the original, undistorted position **65**. Introducer **110** is advanced into Ligamentum Flavum **60** after departing from Interspinous Ligament **52**.

Step 615: Controllably drawing introducer **110** backwards, with respect to cannula **520**.

The operator draws introducer **110** backwards, with respect to cannula **520** (see Fig. 13c), to facilitate engagement of cannula **520** and balloon **530**, attached thereto, with the fibers of Ligamentum Flavum **60**.

Step 620: inflating balloon **530**.

The operator activates expandable mechanism **150** and thereby, balloon **530** is expanded (see Fig. 13d), typically by pressurized flow of gas (typically, air) or fluid, performed by expanding mechanism **150**. Balloon **530** expands against the fibers of Ligamentum Flavum **60**.

Step 630: controllably advancing cannula **520** and inner needle **510** by a predetermine displacement to stretch the elastic tissue (Ligamentum Flavum **60**).

The operator advances cannula **520** (together with the expanded balloon **530)** and inner needle **510** by a predetermined displacement (see Fig. 13e). Thereby, elastic tissue stretches extensively beyond the original, undistorted position **65**.

Step 640: spatially locking cannula **520** and inner needle **510** in current location.

Locking cannula **520** and inner needle **510** in position, using inner needle-incremental-advancing-mechanism and cannula-incremental-advancing-mechanism **192**.

Step 650: simultaneously, deflating balloon **530** and unlocking cannula **520**.

Simultaneously, deflating balloon **530** and unlocking cannula **520**.

Ligamentum Flavum **60** rapidly returns to the undistorted position, towards and possibly over inner needle **510**. If the tip of inner needle **510** is disposed beyond the original, undistorted position **65** of Ligamentum Flavum **60**, inner needle **510** penetrates Ligamentum Flavum **60** at a predetermined location (see Fig. 13f).

Step 655: controllably advancing cannula **520** over and beyond the tip of inner needle **510**.

The operator advances cannula **520** over and beyond the tip of inner needle **510**, wherein cannula **520** serves both as a sheath for inner needle **510** to protect the immediate surroundings of inner needle **510** (see Fig. 13g) and as a pathway for the insertion of a catheter.

Step 660: inflating balloon **530** to anchor cannula **520** and to thereby prevent damage to soft tissue.

Balloon **530** is inflated to anchor cannula **520** and to thereby prevent damage to soft tissue (see Fig. 13g). Should distal end **524** of cannula **520** have reached Epidural space **70**, prevent unwarranted motion of cannula **520** inside Epidural space **70**.

Step 665: check if Epidural space **70** identified.

Follow the procedure, such as method **300**, to identify the type of tissue. If the fat tissue of Epidural space **70** is not identified, but rather that Ligamentum Flavum **60** is still identified, go to step **630**.

Else, optionally, proceed with the Epidural block procedure.

Step 670: indicating a tissue transition, using acoustic or visual signal.

Indicator **180** indicates a tissue transition event (from Ligamentum Flavum **60** to Epidural space **70**), using an acoustic, visual or any other indicatory signal.

Step 680: Withdrawing inner needle **510** and administrating saline into Epidural space **70** through cannula **520**.

Withdraw inner needle **510** to facilitate a pathway for administrating saline into Epidural space **70** through cannula **520** to thereby locally enlarge Epidural space **70** to facilitate insertion of a catheter.

Step 685: Threading a catheter through cannula **520**.

A catheter is inserted to Epidural space **70** through cannula **520**.

Step 690: deflating balloon **530** and withdrawing cannula **520** and introducer **110**.

Deflating balloon **530** and withdrawing cannula **520** and introducer **110**, so that only a catheter is placed inside Epidural space **70.**

Step 695: administrating medication or anesthetics through the catheter.

Administrate medication or anesthetics through the catheter.

An aspect of the present invention is to provide an anatomical-positioning apparatus and method of use thereof, having an introducer with an openable tip.

The principle idea behind an introducer with an openable tip is to have a balloon trapped inside the openable tip. The openable tip of the introducer has a closed state and an opened state, wherein in the closed state the openable tip forms a sharp tip facilitating penetration in and through a tissue, and wherein in the opened state the openable tip expands to forms a blunt surface, anchoring the introducer in position.

A preconfigured pressure is maintained inside the balloon trapped inside the openable tip. As long as introducer with a openable tip is situated inside a tissue, such as Ligamentum Flavum **60**, wherein the pressure applied on the openable tip by the tissue exceeds the preconfigured pressure inside the balloon, the openable tip stays in a closed state. Once the openable tip of the introducer moves into a softer tissue, such as in Epidural space **70**, wherein the surrounding pressure, due to tissue properties, is significantly lower than the internal pressure inside the balloon, the balloon expands rapidly. Thereby, the expanding balloon causes the openable tip of the introducer to open and anchor the openable tip of the introducer inside Epidural space **70**, wherein the balloon protects tissues and anatomical structures ahead of it.

Figs. 15, 16a and 16b, illustrate the distal section of an anatomical-positioning apparatus **700**, according to variations of the present invention, includes an introducer **710** having an openable tip **750**, for puncturing a tissue, for example, Ligamentum Flavum **60**. Anatomical-positioning apparatus **700** is described through the Epidural block procedure, without limiting the scope of this invention. Fig. 15 illustrates openable tip **750** in a closed state. Fig. 16a illustrates openable tip **750** in a closed state penetrates through a tissue, such as Ligamentum Flavum **60**. Fig. 16b illustrates openable tip **750** in an opened state after penetrating into a softer tissue, such as Epidural space **70**.

Anatomical-positioning apparatus **700** further includes a cannula **720** having an expandable device **730**, typically a balloon, wherein proximal end **732** of balloon **730** is securely attached to the external circumference of cannula **720**, proximal to distal end **724** of cannula **720**. Openable tip **750** includes a preconfigured number of elastic flaps **756** that are separated by a slot cut into the distal section of flexible tip **750**. Typically, flaps **756** have a pointing tip and can operatively hingedly bend or deflect outwards as a result of a preconfigured pressure being built inside balloon **732**, when the pressure external to flaps **756** is lower than the pressure inside balloon **732**. Otherwise, balloon **730** stays trapped inside openable tip **750** of introducer **710** and thereby, openable tip **750** can be advanced through tissue.

Reference is now made to Fig. 17, a schematic flow chart, showing an exemplary method **800** of administrate medication or anesthetics through the catheter into Epidural space **70**, during an Epidural block procedure, according to embodiments of the present invention. Method **800** begins by administrating introducer **710** of anatomical-positioning apparatus **700** into a mammalian tissue wherein openable tip **750** of introducer **710** is in closed state. Method **800** proceeds with the following steps:

Step 810: controllably advancing introducer **710**, containing cannula **720**, into and inside an elastic tissue.

The operator advances introducer **710**, containing cannula **720**, into and inside a soft tissue with high surrounding pressure, such as Ligamentum Flavum **60**. Openable tip **750** is in a closed state.

Step 820: inflating balloon **730** to maintaining a constant pressure inside balloon **730**.

The operator activates an expandable mechanism **150** to inflate balloon **730** and to thereby, maintaining a constant preconfigured pressure inside balloon **730**. Situated inside a soft tissue, having fibers that exert pressure on the external sides of flaps **756** the pressure being greater than the pressure inside balloon **730**, openable tip **750** remain in a closed state.

Step 830: controllably advancing introducer **710** and cannula **720** into Epidural space **70**, the openable tip being in closed state.

The operator further advances introducer **710** and cannula **720**, openable tip **750** remaining in closed state. Once openable tip **750** of introducer **710** enters Epidural space **70**, the external pressure exerted on the external sides of flaps **756** drops substantially, bellow the preconfigured pressure inside balloon **730**. As a result, openable tip **750** opens up into an opened state as balloon **730** expands inside Epidural space **70**, thus protecting soft tissues and structures ahead of balloon **730**.

Step 870: indicating a tissue transition, using acoustic or visual signal.

The indicator of anatomical-positioning apparatus **700** indicates a tissue transition event (from Ligamentum Flavum **60** to Epidural space **70**), using an acoustic, visual or any other indicatory signal.

Step 880: administrating saline into Epidural space **70** through cannula **720**.

Administrate saline into Epidural space **70** through cannula **720** to thereby locally enlarge Epidural space **70** to facilitate insertion of a catheter.

Step 885: threading a catheter through cannula **720**.

A catheter is inserted to Epidural space **70** through cannula **720**.

Step 890: deflating balloon **730** and withdrawing introducer **710** and cannula **720**.

Deflate balloon **730** and withdrawing introducer **710** and cannula **720**.

Step 895: administrating medication or anesthetics through the catheter.

Administrate medication or anesthetics through the catheter.

The invention being thus described in terms of several embodiments and examples, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art.

WHAT IS CLAIMED IS:

1. An anatomical-positioning apparatus for acquiring mechanical data from a mammalian tissue to facilitate determining type of said tissue and transition between different tissues and cavities, comprising:

a) a cannula having a tip at the distal section of said cannula;

b) an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein said expanded form size is substantially larger than said contracted form size;

c) an introducer, having a longitudinal axis and a distal end, facilitating the introduction of said expandable device into said mammalian tissue, said expandable device being in said contracted state;

d) an expanding-mechanism for expanding and contracting said expandable device; and

e) a sensor for measuring physical parameters associated with said expandable device, to thereby provide sensed data, while said expandable device exerts pressure onto portions of said mammalian tissue, to thereby facilitating determining the type of tissue that is in contact with said expandable device and to determine a transition between different tissues and cavities,

wherein said expandable device is securely attached to said tip of said cannula or on the external circumference of said cannula, proximal to said tip of said cannula; and

wherein when said expandable device expands from said contracted state to said expanded form size, said expandable device is disposed outside said introducer, and a blunt contact surface is formed at the external surface of said expanded expandable device.

2. The anatomical-positioning apparatus as in claim 1, wherein said expandable device protects said mammalian tissue or an anatomical structure ahead of said mammalian tissue, from being punctured by said introducer of said expandable device.

3. The anatomical-positioning apparatus as in claim 1, wherein said cannula protects said expandable device from being punctured by said introducer.

4. The anatomical-positioning apparatus as in claim 1, wherein said expandable device expands and contracts under fluid or gas pressure provided by said expanding-mechanism through said cannula.

5. The anatomical-positioning apparatus as in claim 1, wherein said sensor includes one or more sensing devices selected from the group of devices consisting of a pressure sensor, strain gauge, force sensor, tactile sensor, displacement sensor, volume sensor, flow sensor and a piezoelectric transducer.

6. The anatomical-positioning apparatus as in claim 5, wherein said sensing device includes an array of sensors disposed on said expandable device.

7. The anatomical-positioning apparatus as in claim 1, wherein said sensed data is indicated by one or more indication devices selected from the group of devices consisting of a display, a gage, a light indicator, an audio indicator and a tactile indicator.

8. The anatomical-positioning apparatus as in claim 1, wherein said introducer is an openable ~~introducer, having an openable sharp tip; wherein said openable sharp tip~~ of said openable introducer has a closed state and an open state; and wherein said expandable device is trapped inside said openable sharp tip, said openable sharp tip being in a closed state.

9. The anatomical-positioning apparatus as in claim 8, wherein said expandable device facilitates said openable sharp tip to remain in said closed state, when said expandable device is loaded by a preconfigured expanding force and said sharp tip is situated in a high density tissue; wherein said expandable device facilitates the opening of said openable sharp tip, when said expandable device is loaded be a preconfigured expanding force and said openable sharp tip enters a low density tissue or cavity; wherein said closed state facilitates advancement of said openable introducer through said mammalian tissue; and wherein said open state prevents advancement of said openable introducer through said mammalian tissue.

10. The anatomical-positioning apparatus as in claim 1, wherein said introducer is selected from the group consisting of a veress needle, an epidural needle, a biopsy needle, a trocar, a cannula, a catheter, a Tuohy type needle and a surgical instrument.

11. The anatomical-positioning apparatus as in claim 1, wherein said expandable device is selected from a group of devices consisting of a balloon, a membrane, a diaphragm, a spring and a flexible device.

12. The anatomical-positioning apparatus as in claim 11, wherein said expandable device comprises one or more mechanical devices selected from a group of devices consisting of a

spring and a balloon enclosed in a conical element, wherein said conical element protects said balloon from being punctured.

13. The anatomical-positioning apparatus as in claim 1, wherein said cannula and said expandable device is introduced on-demand and can be withdrawn during a procedure in order to enable utilization of other tools inside said mammalian tissue.

14. The anatomical-positioning apparatus as in claim 4, wherein said cannula includes a double lumen, wherein a first lumen facilitates a pathway for said fluid or gas into said expandable device, and wherein a second lumen facilitates a pathway for one or more devices selected from a group of devices consisting of a thin needle, a catheter, an optical fiber, an electrode and a surgical instrument.

15. The anatomical-positioning apparatus as in claim 4, wherein said cannula includes a single lumen facilitating a pathway for said fluid or gas into said expandable device, and wherein said single lumen facilitating a pathway for an optical fiber or a miniature camera, to thereby facilitate visualization of said mammalian tissue through said expandable device, said expandable device being in contact with said mammalian tissue.

16. The anatomical-positioning apparatus as in claim 1 further comprises an advancement mechanism for incrementally advancing, in a controlled manner, one or more devices selected from the group consisting of said introducer, said cannula and said expandable device.

17. The anatomical-positioning apparatus as in claim 16, wherein said advancement mechanism is selected from the group of devices consisting of a motor based device, hydraulic device, gear based device and a screw based device.

18. The anatomical-positioning apparatus as in claim 16, wherein said introducer can be advanced incrementally together with said cannula and said expandable device.

19. The anatomical-positioning apparatus as in claim 16, wherein said introducer can be advanced incrementally with respect to said cannula and said expandable device.

20. The anatomical-positioning apparatus as in claim 1 further comprises a processor facilitated to record and analyze said sensed data, to thereby determine said type of tissue that is in contact with said expandable device and to determine said transition between tissues and cavities, wherein said sensed data is acquired while said expandable device is expanding, contracting or in a steady expansion level.

21. The anatomical-positioning apparatus as in claim 1, wherein said sensed data includes a measurement of the advancement of said cannula against said mammalian tissue, and wherein the displacement of said expandable device, along said longitudinal axis, is inferred from said sensed data.

22. The anatomical-positioning apparatus as in claim 1, wherein said sensed data includes a one-dimensional measurement of the displacement of said expandable device, during said expanding against said mammalian tissue or contracting away from said mammalian tissue.

23. The anatomical-positioning apparatus as in claim 1, wherein said sensed data includes one or more measurements selected from a group of measurements consisting of the pressure inside said expandable device, the volume of gas or fluid inside said expandable device, an external force applied on said expandable device by said mammalian tissue and the spatial pressure or spatial force applied on said expandable device by said mammalian tissue, while said expandable device exerts pressure onto portions of said mammalian tissue.

24. The anatomical-positioning apparatus as in claim 20, wherein said sensed data facilitates determining one or more measurements selected from a group of measurements consisting of the volume-pressure work performed by said expandable device, a volume-pressure profile of said expandable device, the work being done by said expandable device and the force-displacement profile of said expandable device, while said expandable device exerts pressure onto portions of said mammalian tissue.

25. A method for acquiring mechanical data from a mammalian tissue by an expandable device, while said expandable device exerts pressure onto portions of said mammalian tissue, the method comprising the steps of:

a) providing an anatomical-positioning apparatus including:

    i. a cannula having a tip at the distal section of said cannula;

    ii. an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein said expanded form size is substantially larger than said contracted form size, and wherein said expandable device is securely attached to said tip of said cannula or on the external circumference of said cannula, proximal to said tip of said cannula;

iii. an introducer, having a distal end, facilitating the introduction of said expandable device into said mammalian tissue, said expandable device being in said contracted state;

iv. an expanding-mechanism for expanding and contracting said expandable device; and

v. a measuring-mechanism for measuring physical parameters associated with said expandable device, while said expandable device exerts pressure onto portions of said mammalian tissue;

b) inserting said introducer inside said mammalian tissue, wherein said distal end of said introducer enters first;

c) advancing said expandable device through said introducer, using said cannula;

d) expanding said expandable device outside said distal end of said introducer; and

e) measuring said physical parameters associated with said expandable device, while said expandable device exerts pressure onto portions of said mammalian tissue, thereby creating sensed data.

26. The method as in claim 25 further including the step of analyzing said sensed data, using a processor, thereby determining the type of said mammalian tissue being in contact with said expandable device, and determining a transition between different mammalian tissues and cavities.

27. The method as in claim 25, wherein said sensed data includes one or more measurements selected from a group of measurements consisting of the displacement of said expandable device and cannula, the pressure inside said expandable device, the volume of gas or fluid inside said expandable device, the external force applied on said expandable device by said mammalian tissue and the spatial pressure or spatial force applied on said expandable device by said mammalian tissue, while said expandable device exerts pressure onto portions of said mammalian tissue.

28. The method as in claim 26, wherein said sensed data facilitates determining one or more measurements selected from a group of measurements consisting of the volume-pressure work performed by said expandable device, the volume-pressure profile of said expandable device, the work being done by said expandable device and the force-displacement profile of said expandable device, while said expandable device exerts pressure onto portions of said mammalian tissue.

29. The method as in claim 25, wherein said measuring of said sensed data is performed during states selected from a group of states consisting of an expansion of said expandable device, a contraction of said expandable device and a displacement of said cannula and said expandable device, while said expandable device is expanded.

30. A method for a controlled insertion of an introducer into and through an elastic mammalian tissue, the method comprising the steps of:

a) providing a device including:
    i. a cannula having a tip at the distal section of said cannula;
    ii. an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein when in expanded state, said expandable device has a front end; wherein said expanded form size is substantially larger than said contracted form size; and wherein said expandable device is securely attached to said tip of said cannula or on the external circumference of said cannula, proximal to said tip of said cannula;
    iii. an introducer, having a sharp tip at the distal end, facilitating the introduction of said expandable device into said mammalian tissue, said expandable device being in said contracted state;
    iv. an expanding-mechanism for expanding and contracting said expandable device; and
    v. an advancement mechanism for incrementally advancing, in a controlled manner, devices selected from the group consisting of said introducer, said cannula and said expandable device;
b) expanding said expandable device by said expanding-mechanism, outside said tip of said introducer, whereby said expandable device exerts pressure onto portions of said mammalian tissue, wherein said mammalian tissue is initially in an undistorted position;
c) advancing said introducer incrementally to a preconfigured position situated beyond said undistorted position of said mammalian tissue, said mammalian tissue being pushed by said expandable device, wherein said tip of said introducer is posterior to the instantaneous position of said front end of said expandable device, with respect to said elastic tissue;
d) holding said introducer in secured position; and

e) contracting said expandable device at a preconfigured rate, thereby facilitating said mammalian tissue, being elastic, to spring back powerfully towards said undistorted position of said mammalian tissue, thereby penetrating said mammalian tissue by said tip of said introducer, being disposed beyond said undistorted position of said mammalian tissue.

31. The method as in claim 30, wherein said incremental advancing of said introducer is performed while also incrementally advancing said expandable device, wherein said expandable device is expanded.

32. The method as in claim 30, wherein said incremental advancing of said introducer is performed, while said expandable device is expanded and in steady position, wherein said introducer is incrementally displaced beyond said undistorted position of said mammalian tissue, and wherein said introducer tip is kept at a shorter distance from said mammalian tissue, with respect to steady position of said front end of said expandable device.

33. A method for a controlled insertion of a cannula, using an inner needle, into and through an elastic mammalian tissue, the method comprising the steps of:

a) providing a device including:
   i. a cannula having a double lumen and a tip at the distal section of said cannula;
   ii. an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state, wherein when in expanded state, said expandable device has a front end; wherein said expanded form size is substantially larger than said contracted form size; and wherein said expandable device is securely attached on the external circumference of said cannula, proximal to said tip of said cannula;
   iii. an introducer, facilitating the introduction of said expandable device into said mammalian tissue, said expandable device being in said contracted state;
   iv. an expanding-mechanism for expanding and contracting said expandable device;
   v. an inner needle being introduced through said cannula; and
   vi. an advancement mechanism for incrementally advancing, in a controlled manner, devices selected from the group consisting of said introducer, said cannula, said inner needle and said expandable device;

b) Advancing said cannula together with said inner needle outside distal tip of said introducer, wherein said tip of said inner needle is secured inside said cannula near the distal end of said cannula;

c) expanding said expandable device by said expanding-mechanism, whereby said expandable device exerts pressure onto portions of said mammalian tissue, wherein said mammalian tissue is initially in an undistorted position;

d) advancing said cannula together with said inner needle incrementally to a preconfigured position wherein said distal end of said cannula together with said tip of said inner needle are situated beyond said undistorted position of said mammalian tissue, said mammalian tissue being pushed by said expandable device;

e) locking said inner needle and said cannula in a secured position;

f) contracting said expandable device at a preconfigured rate, while unlocking said cannula, thereby facilitating said mammalian tissue, being elastic, to spring back powerfully towards the undistorted position of said mammalian tissue, while pushing backwards said cannula, thereby penetrating said mammalian tissue by said tip of said inner needle, being disposed beyond said undistorted position of said mammalian tissue; and

g) incrementally advancing said cannula over said inner needle to a position wherein said distal end of said cannula shields said tip of said inner needle.

34. The method as in claim 33 further comprises the step of expanding said expandable device by said expanding-mechanism, thereby anchoring said cannula in position, upon transition of said expandable device from said elastic tissue into a different tissue or cavity.

35. A method for a controlled insertion of an openable introducer into and through a mammalian tissue, the method comprising the steps of:

a) providing a device including:

    i. a cannula having a double lumen;

    ii. an openable introducer, including an openable sharp tip having a closed state and an opened state, wherein said closed state facilitates advancement of said openable introducer through said mammalian tissue; and wherein said open state prevents advancement of said openable introducer through said mammalian tissue;

iii. an expandable device having a contracted form size, when in a contracted state, and an expanded form size, when in an expanded state,

wherein when in expanded state, said expandable device has a front end;

wherein said expanded form size is substantially larger than said contracted form size;

wherein said expandable device is securely attached on the external circumference of said cannula, proximal to said tip of said cannula;

wherein said openable introducer facilitates the introduction of said expandable device into said mammalian tissue, said expandable device being in said contracted state; and

wherein said expandable device facilitates opening of said tip of said openable introducer when said expandable device is in said expanded state wherein said tip enters a cavity or a low dense tissue;

iv. an expanding-mechanism for expanding and contracting said expandable device;

b) advancing said cannula together with said openable introducer into and inside said mammalian tissue, said openable sharp tip being in said closed state;

c) maintaining a constant preconfigured pressure inside said expandable device; and

d) advancing said cannula together with said openable introducer until said tip of said openable introducer enters into a low density tissue or cavity; thereby facilitating rapid expanding of said expandable device by said expanding mechanism, said constant preconfigured pressure inside said expandable device being larger than the external pressure applied on said tip of said openable introducer by said low density tissue or cavity.

36. The method as in claim 35, wherein said device further includes an advancement mechanism for incrementally advancing, in a controlled manner, devices selected from the group consisting of said openable introducer, said cannula and said expandable device.

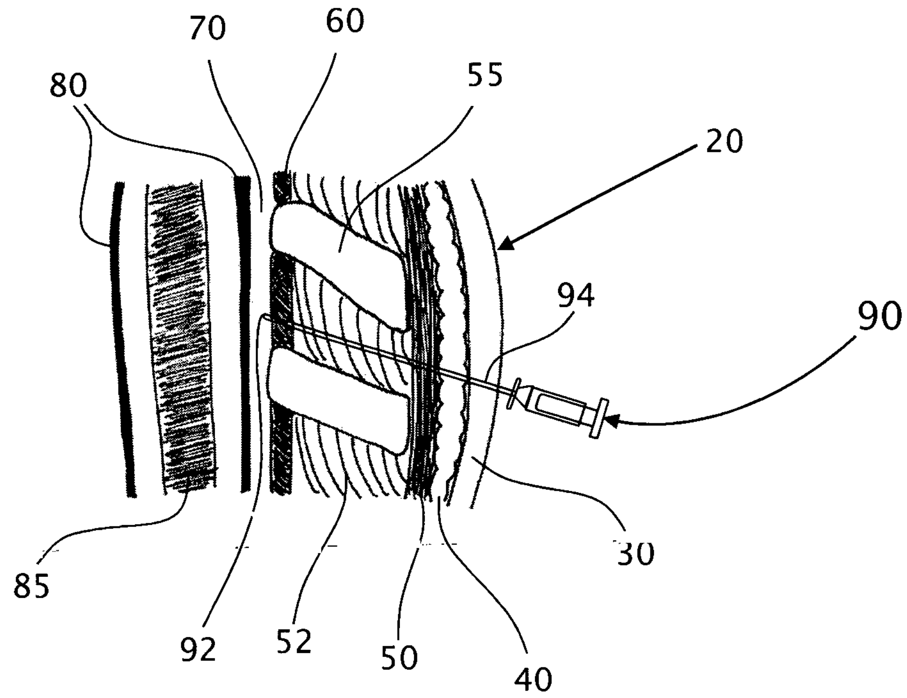
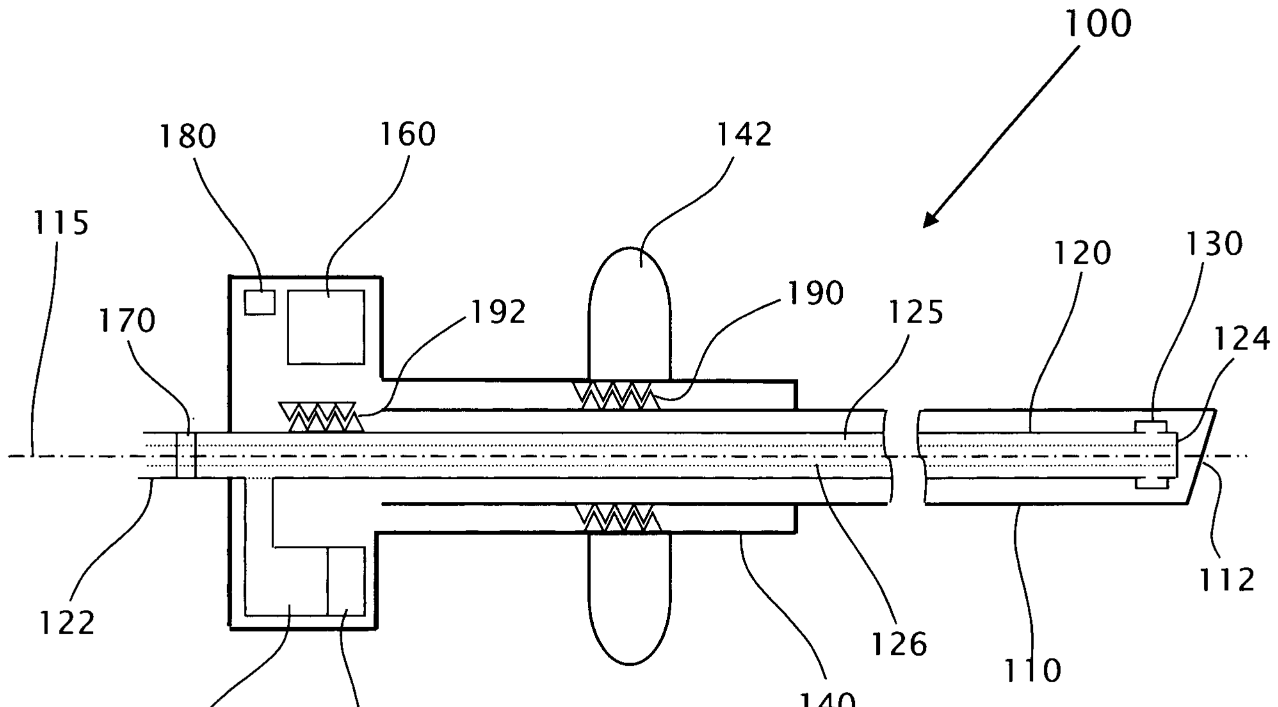

70
60
80
55
20
94
90
85
30
92
52
50
40

Fig 1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170
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150
152

Fig 3

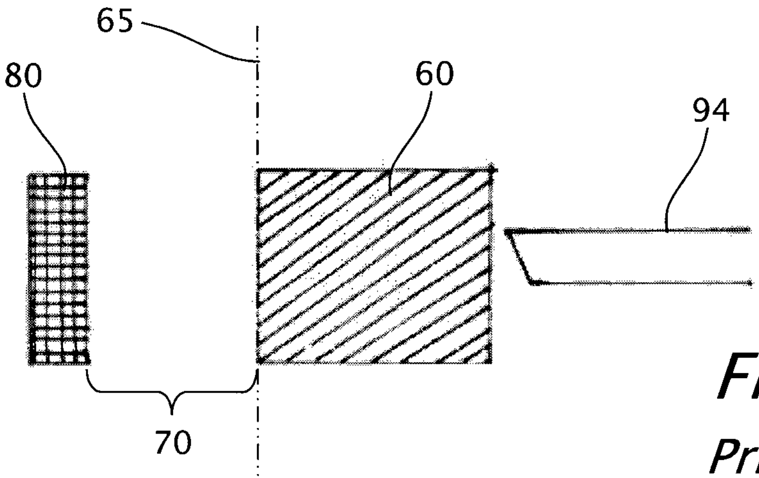


Fig 2a
Prior art

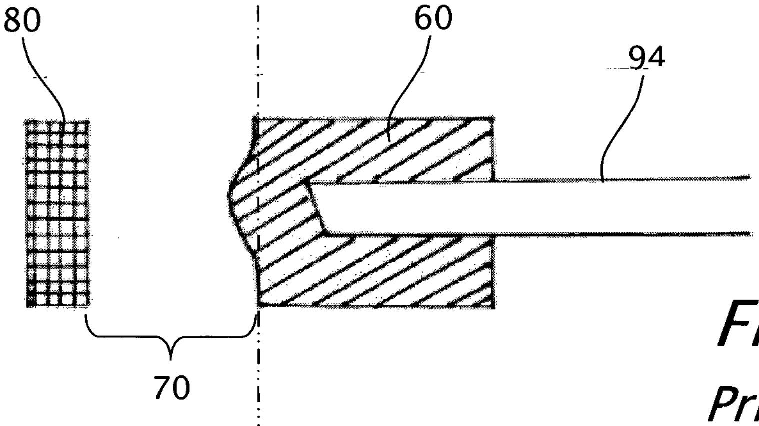


Fig 2b
Prior art

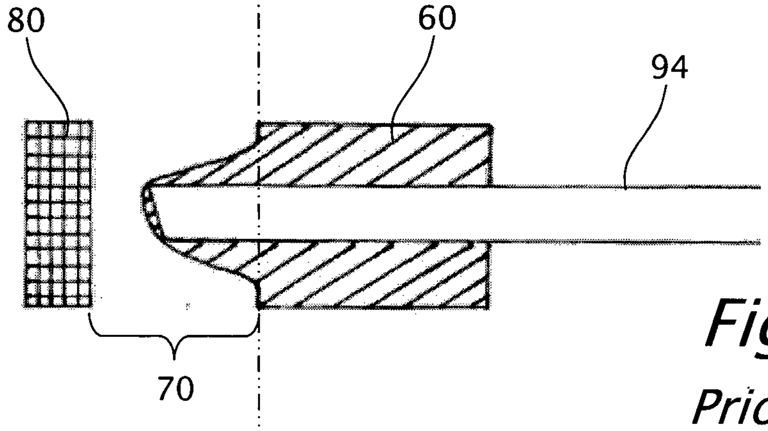


Fig 2c
Prior art

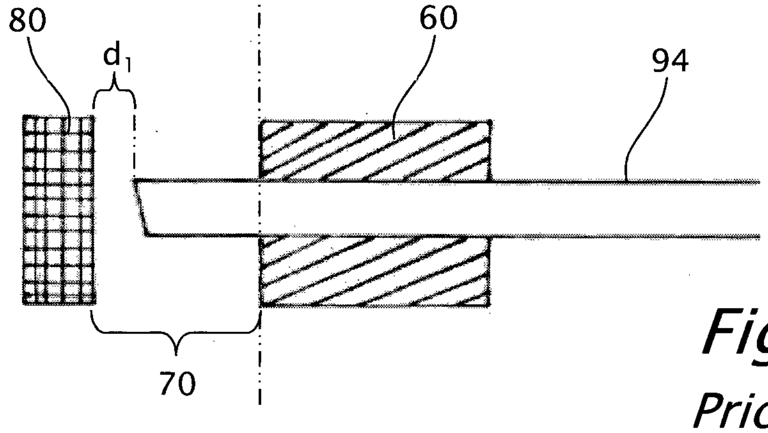


Fig 2d
Prior art

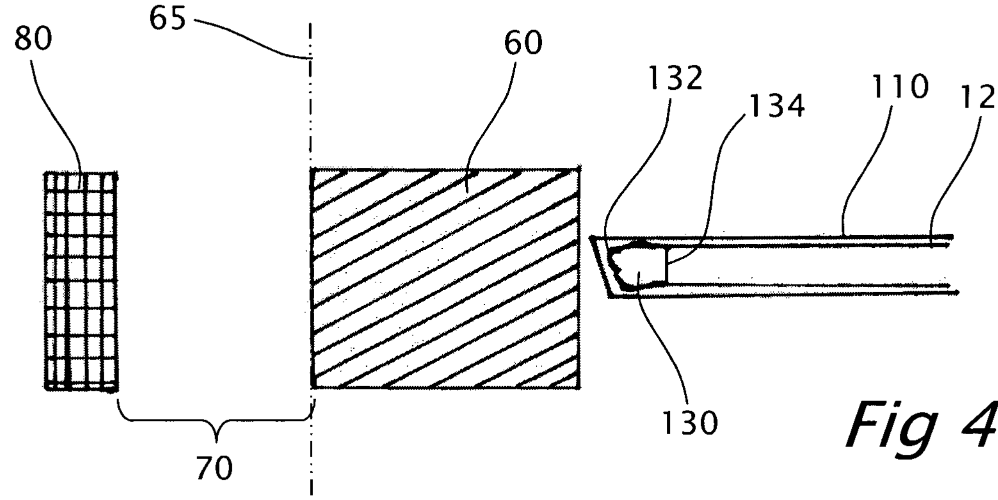


Fig 4a

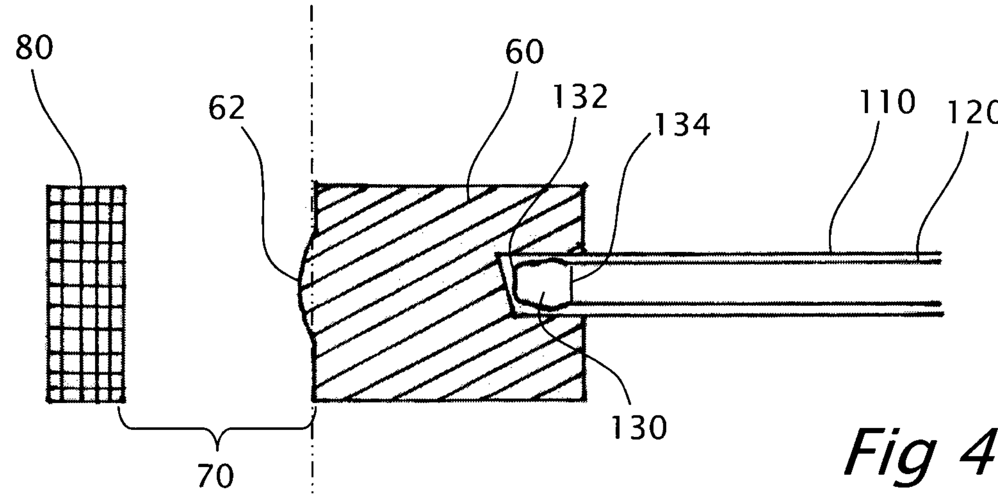


Fig 4b

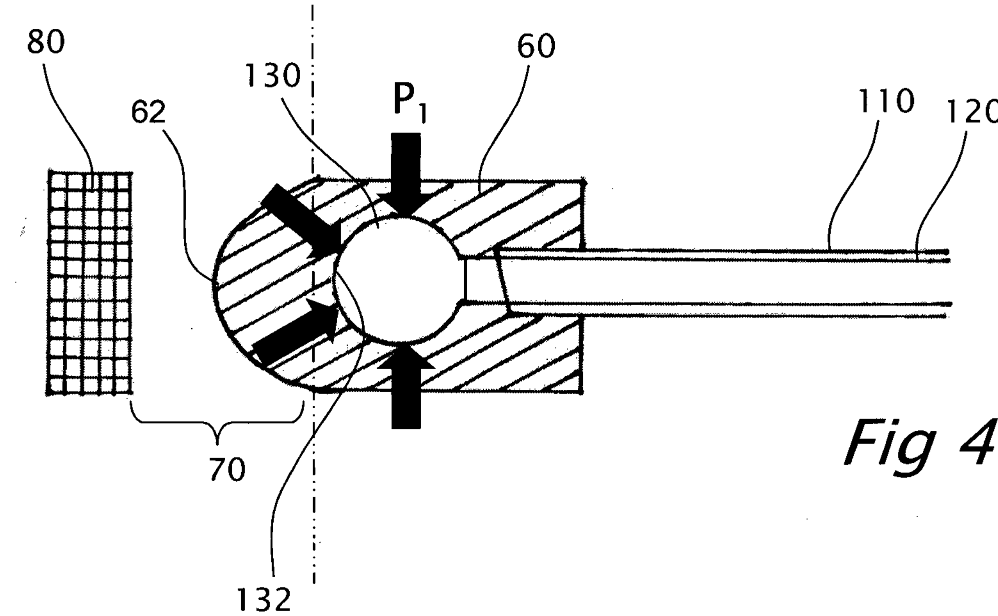


Fig 4c

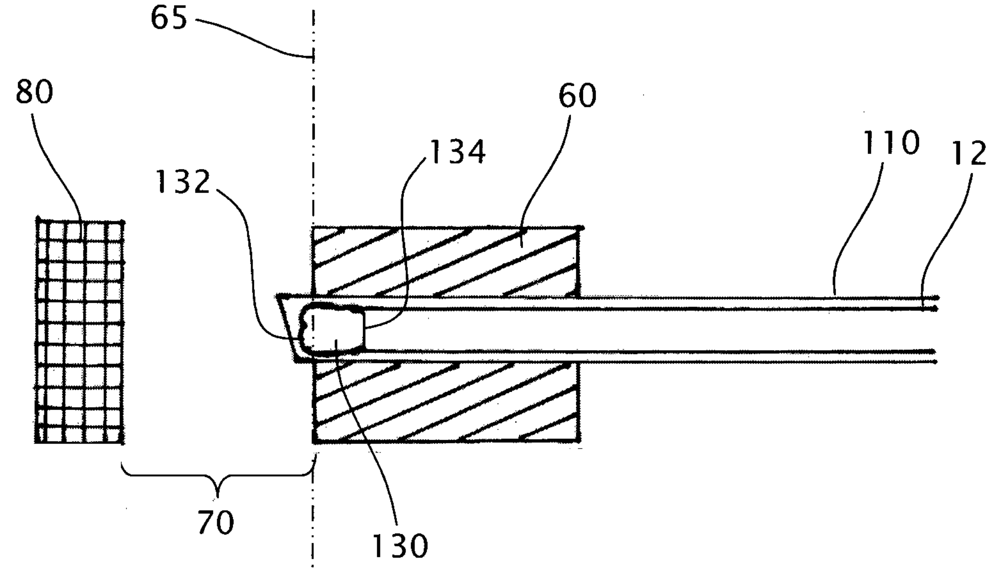


Fig 4d

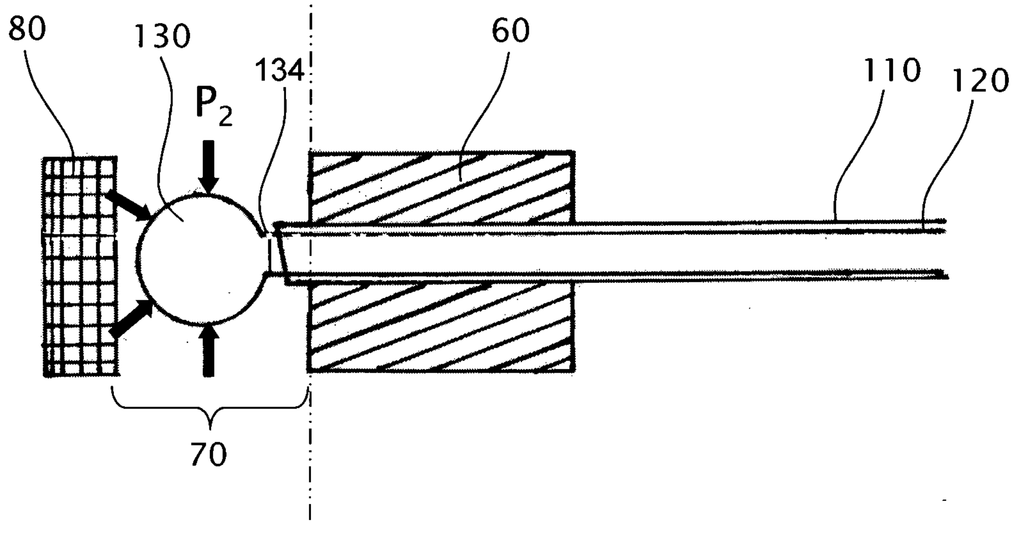


Fig 4e

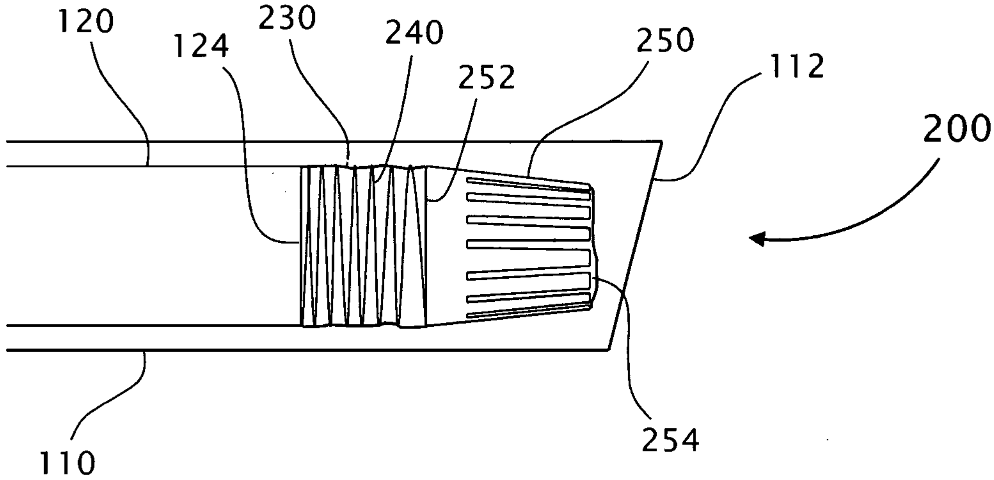
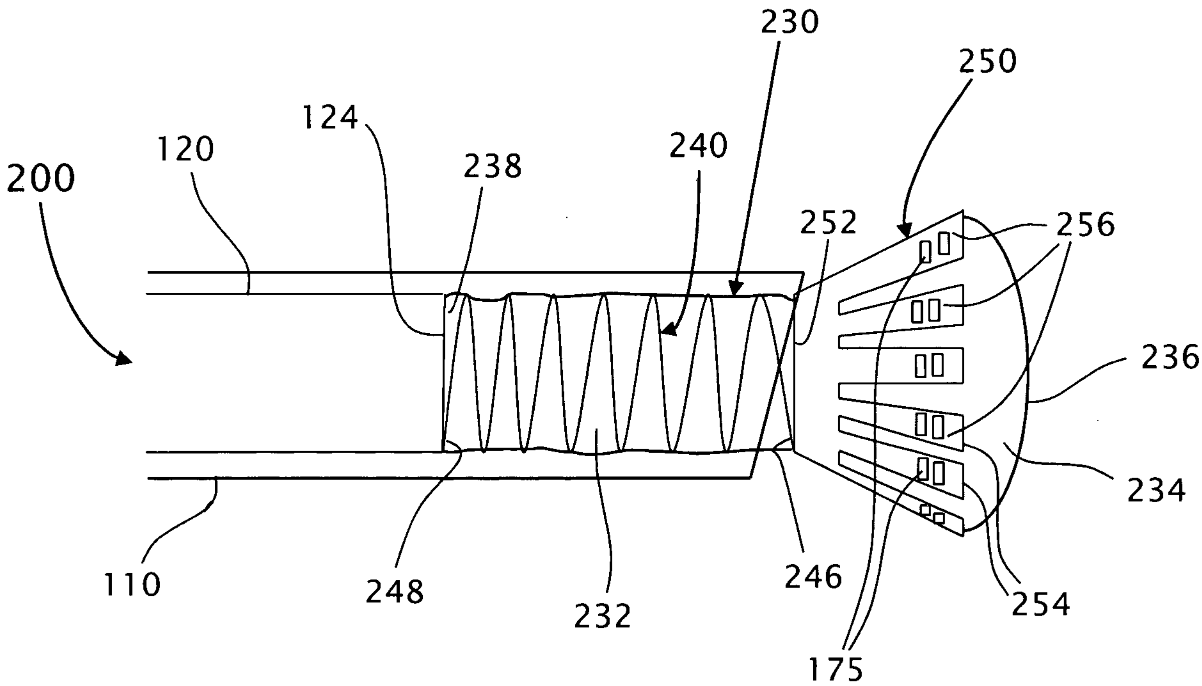

120
230
240
124
252
250
112
200
110
254

Fig 5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240
120
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200
252
256
236
234
110
248
232
246
254
175

Fig 6

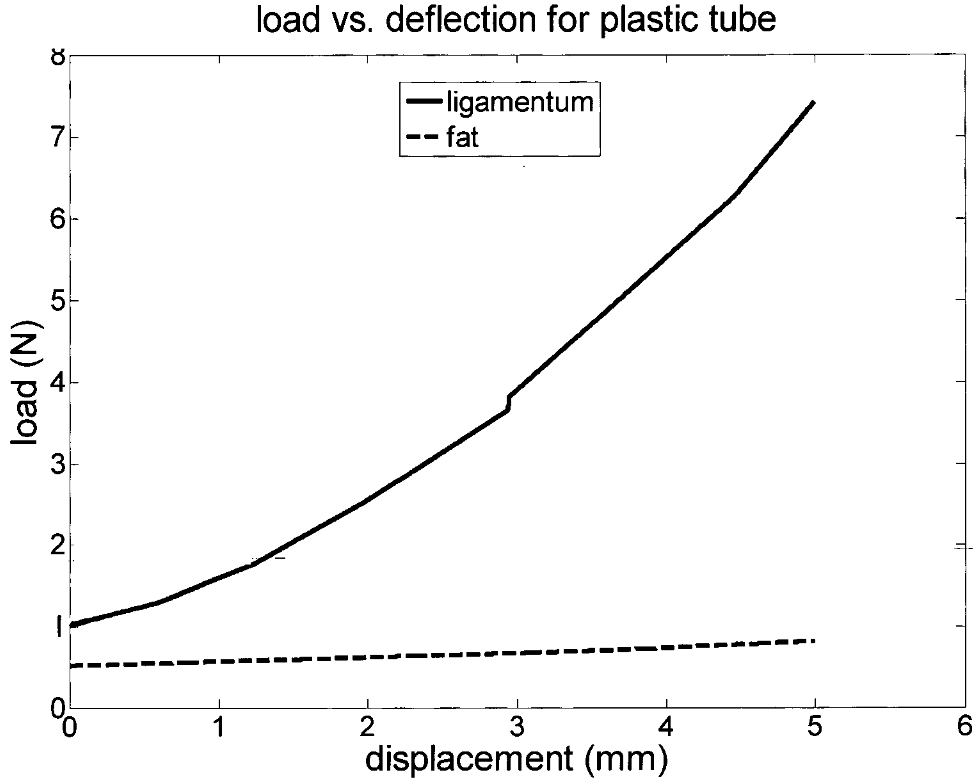
load vs. deflection for plastic tube
ligamentum
fat
load (N)
displacement (mm)
0
1
2
3
4
5
6
7
8

Fig 7

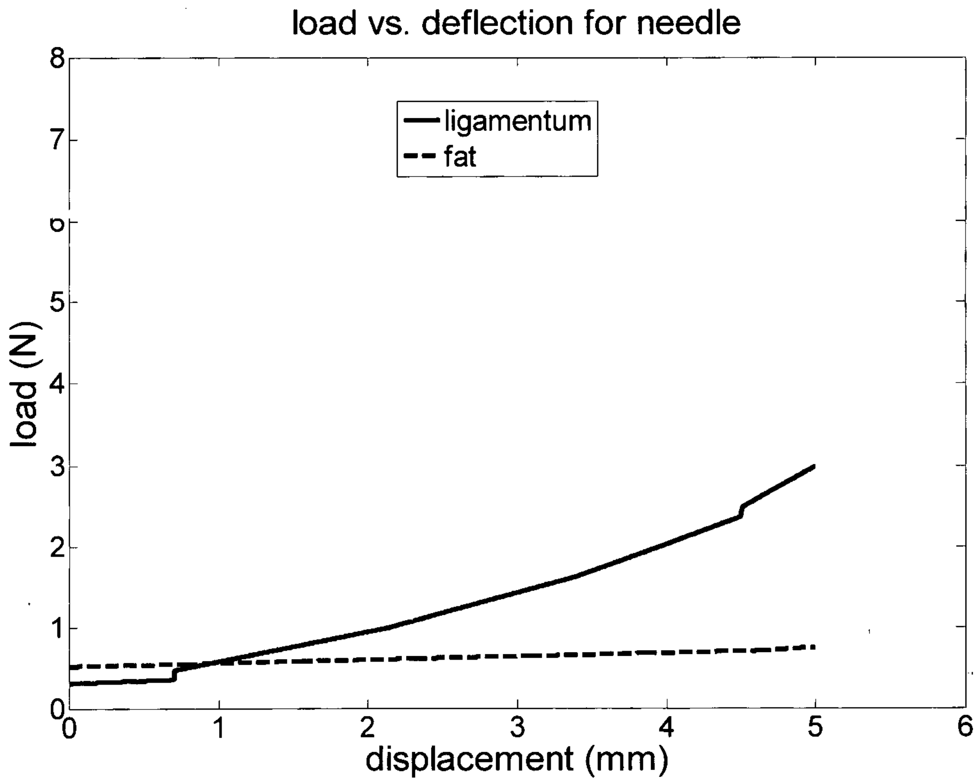
load vs. deflection for needle
ligamentum
fat
load (N)
displacement (mm)
0
1
2
3
4
5
6
7
8

Fig 8

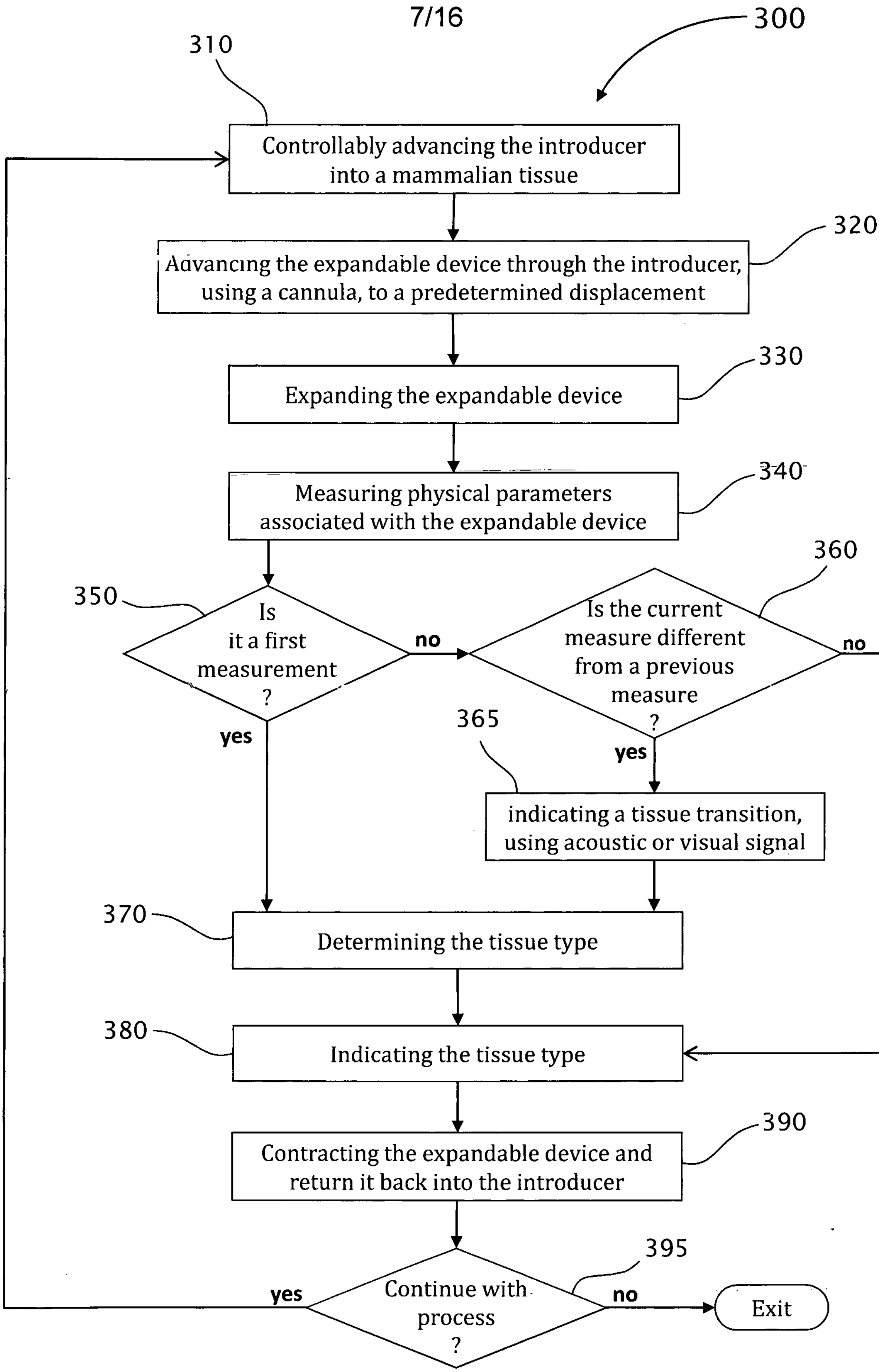
300
310
Controllably advancing the introducer into a mammalian tissue
320
Advancing the expandable device through the introducer, using a cannula, to a predetermined displacement
330
Expanding the expandable device
340
Measuring physical parameters associated with the expandable device
350
Is it a first measurement ?
no
yes
360
Is the current measure different from a previous measure ?
no
yes
365
indicating a tissue transition, using acoustic or visual signal
370
Determining the tissue type
380
Indicating the tissue type
390
Contracting the expandable device and return it back into the introducer
395
Continue with process ?
yes
no
Exit

Fig 9

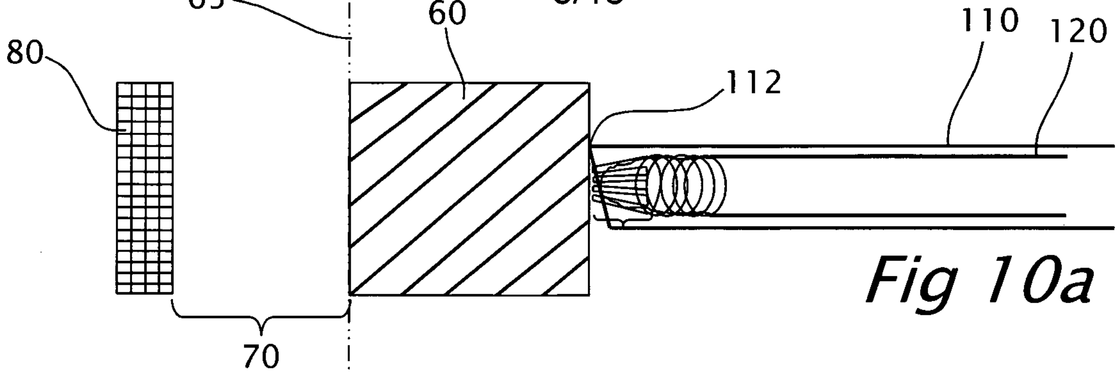

Fig 10a

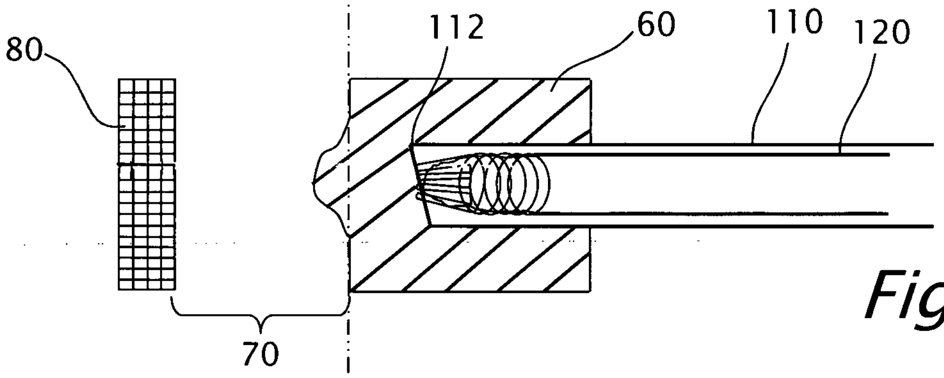

Fig 10b

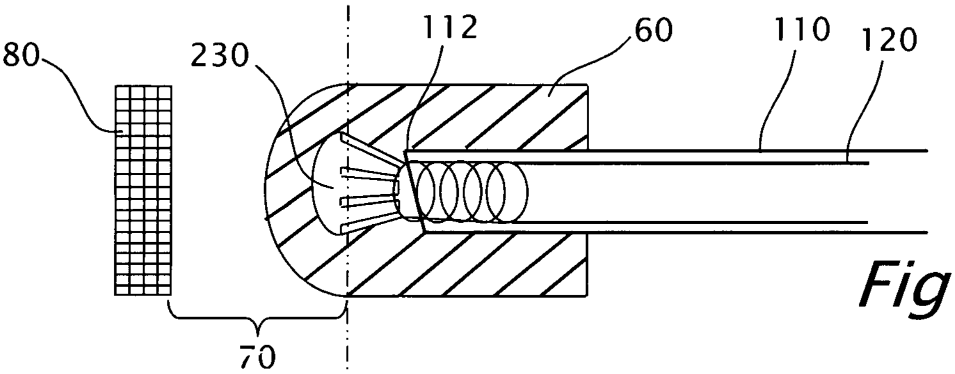

Fig 10c

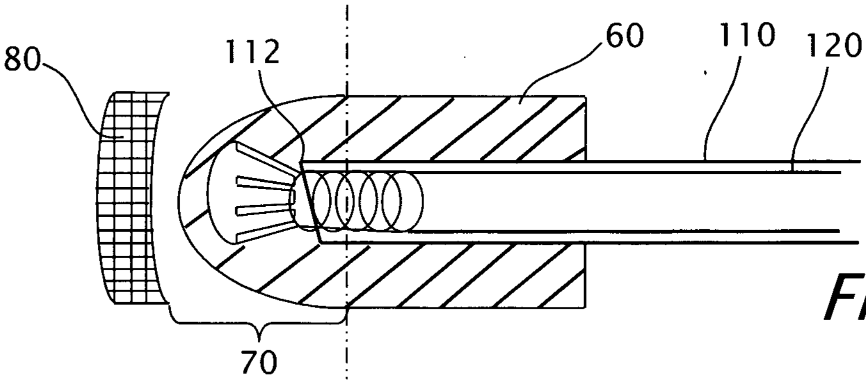

Fig 10d

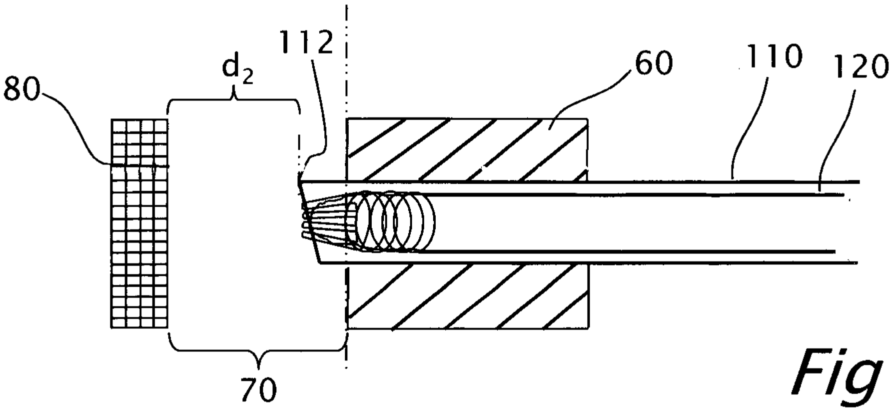

Fig 10e

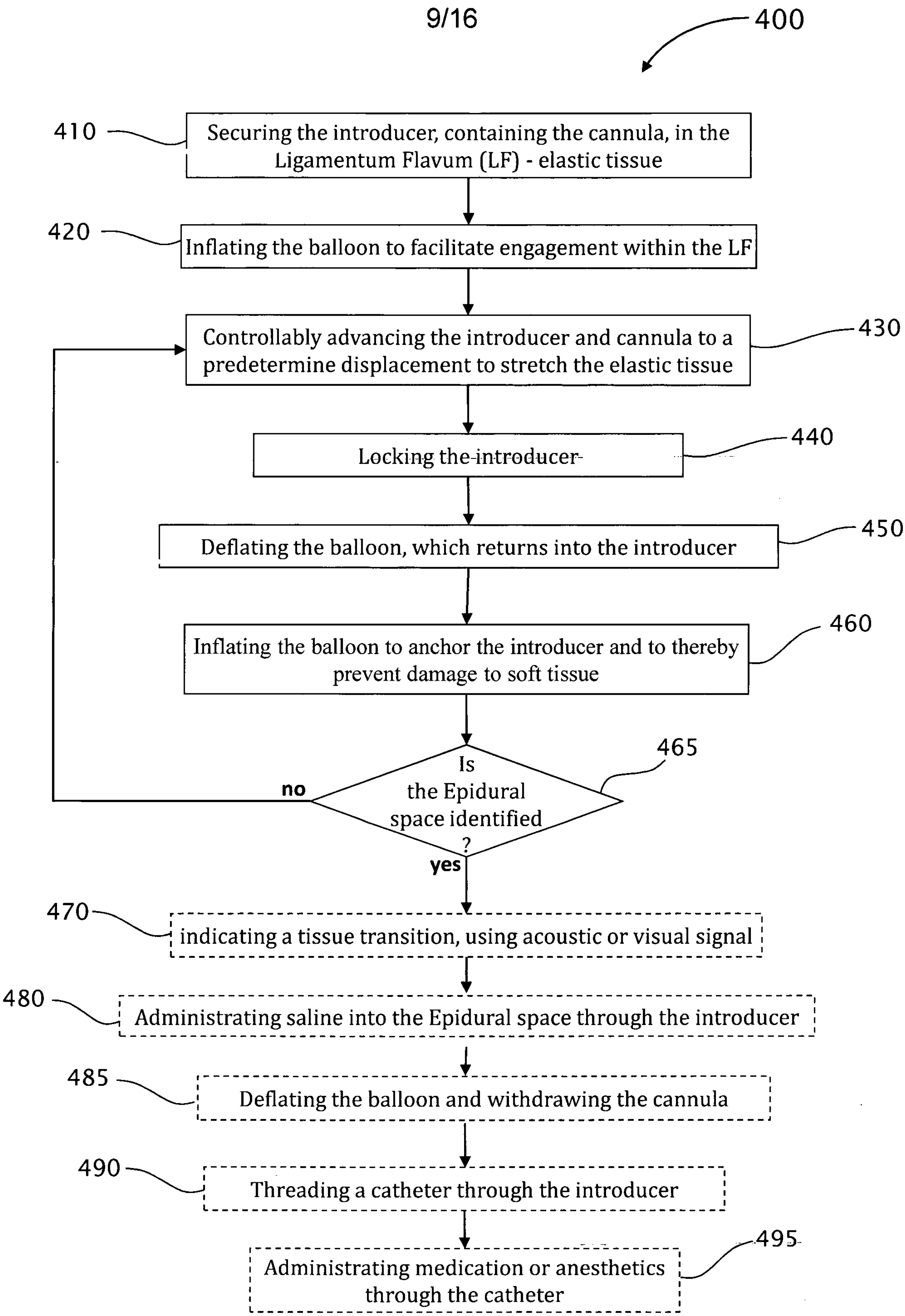
400
410
Securing the introducer, containing the cannula, in the Ligamentum Flavum (LF) - elastic tissue
420
Inflating the balloon to facilitate engagement within the LF
430
Controllably advancing the introducer and cannula to a predetermine displacement to stretch the elastic tissue
440
Locking the introducer
450
Deflating the balloon, which returns into the introducer
460
Inflating the balloon to anchor the introducer and to thereby prevent damage to soft tissue
465
Is the Epidural space identified ?
no
yes
470
indicating a tissue transition, using acoustic or visual signal
480
Administrating saline into the Epidural space through the introducer
485
Deflating the balloon and withdrawing the cannula
490
Threading a catheter through the introducer
495
Administrating medication or anesthetics through the catheter

Fig 11

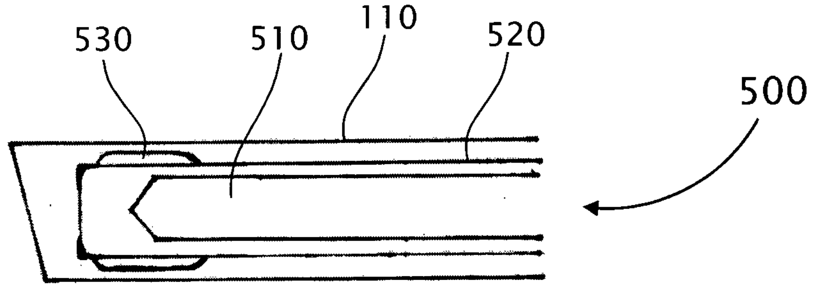

Fig 12a

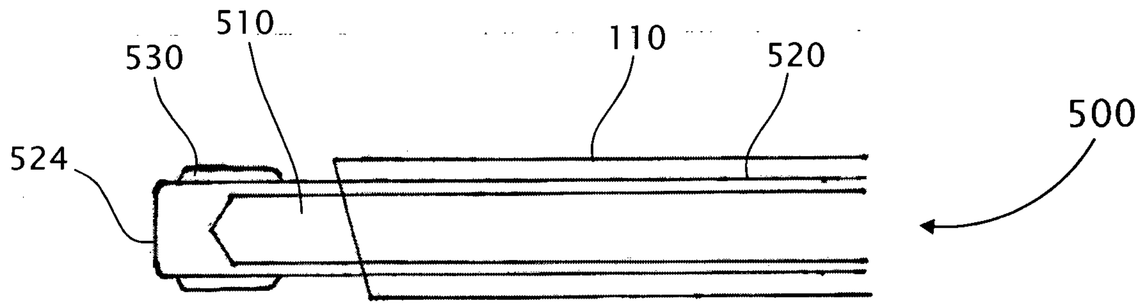

Fig 12b

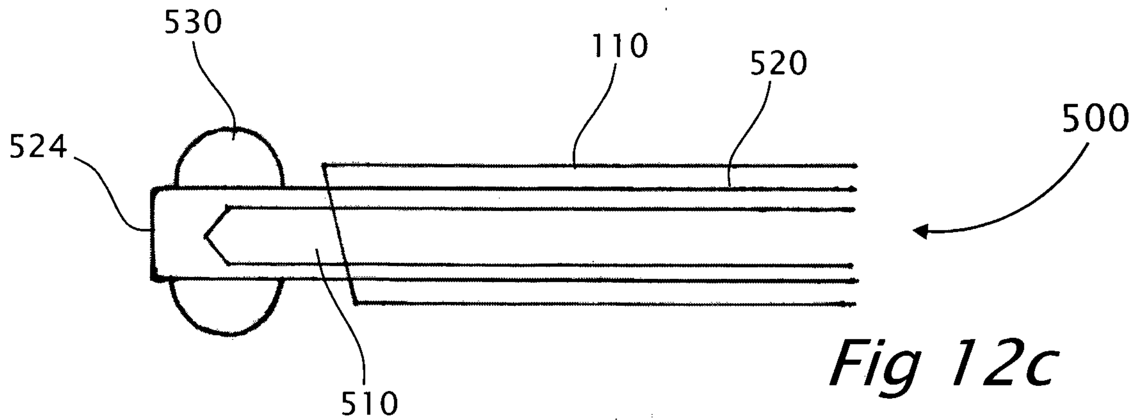

Fig 12c

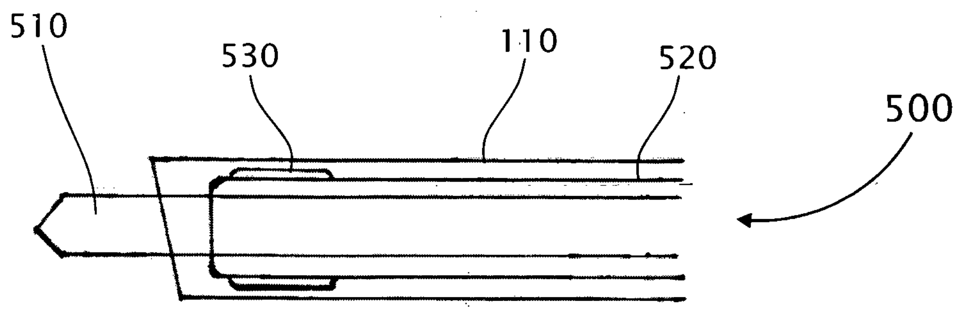

Fig 12d

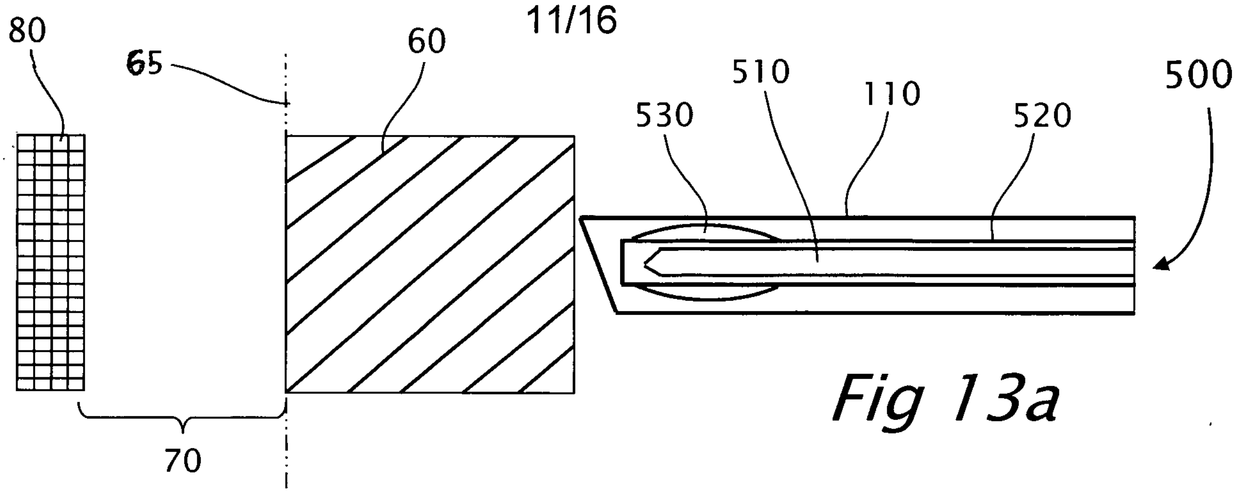

Fig 13a

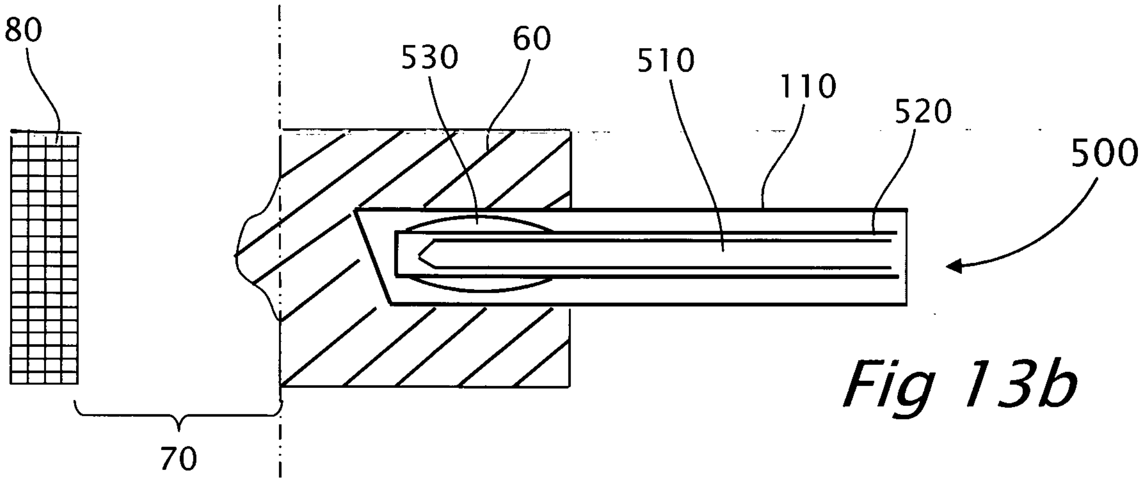

Fig 13b

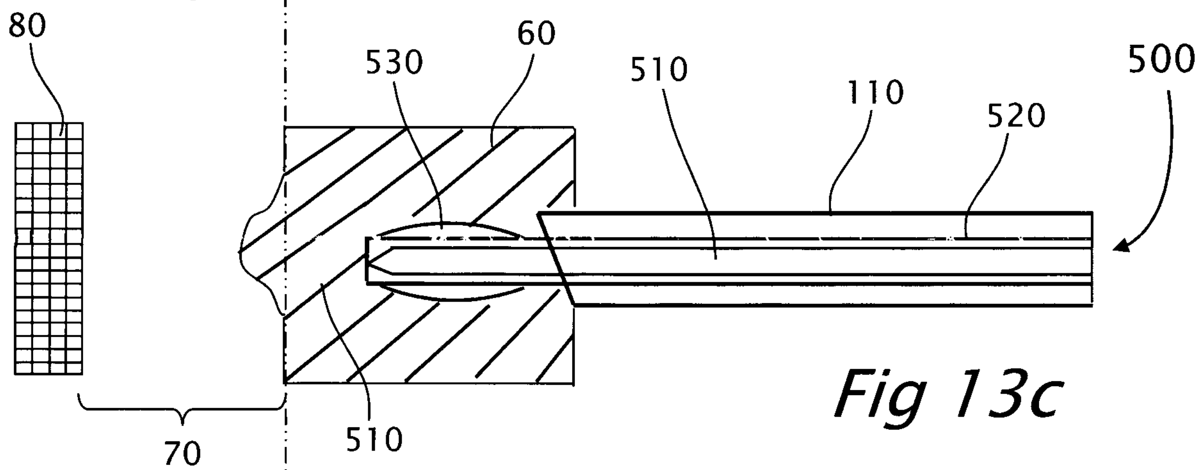

Fig 13c

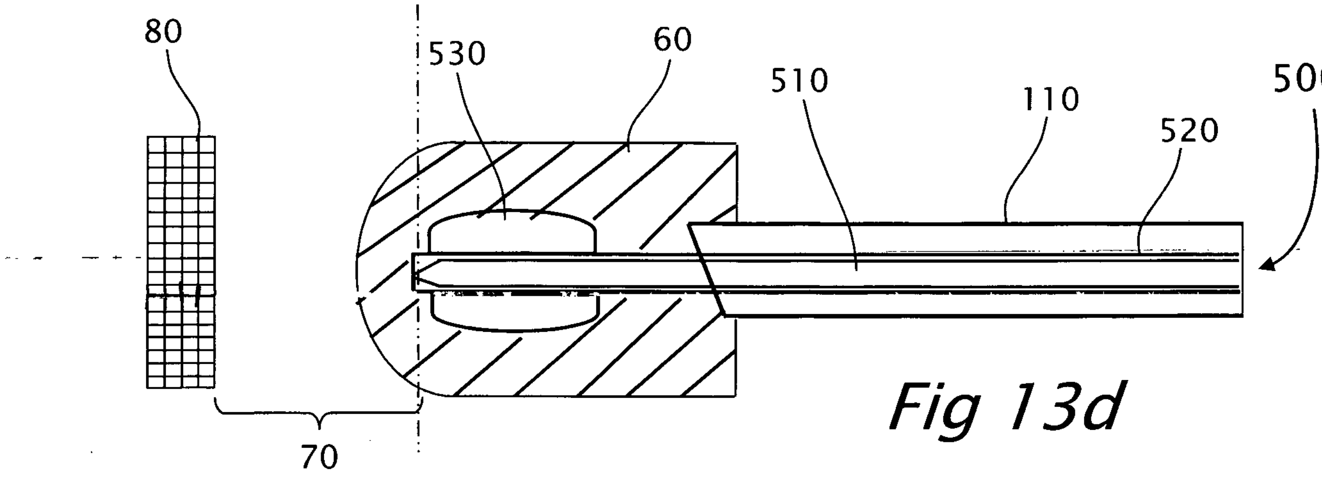

Fig 13d

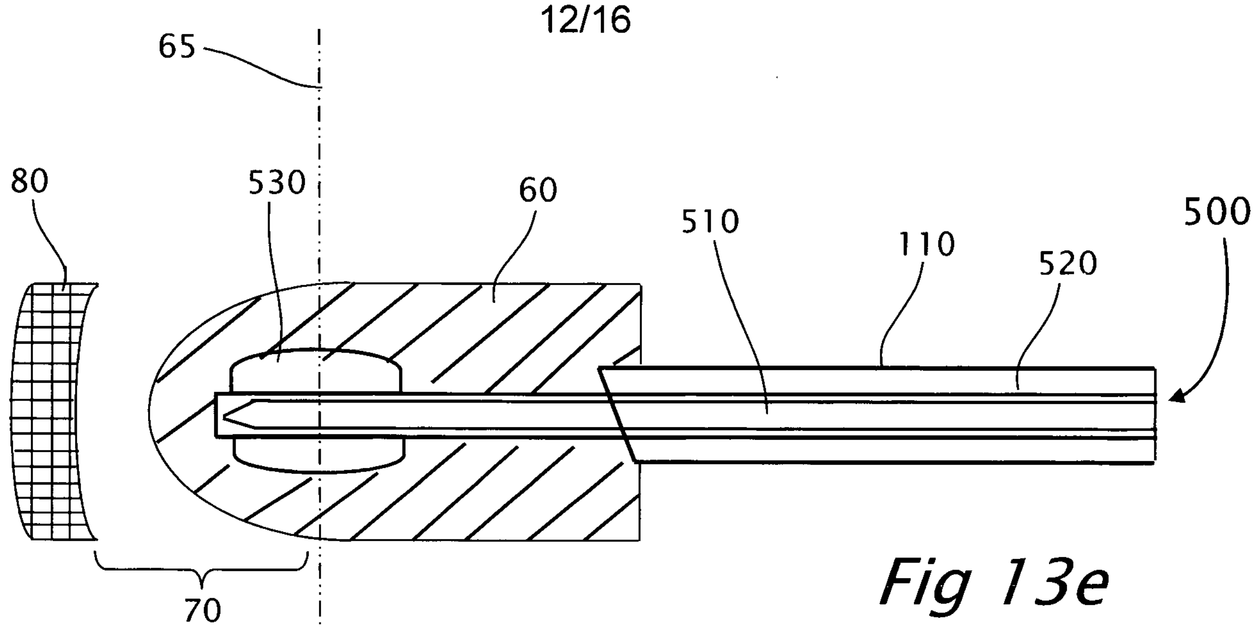

Fig 13e

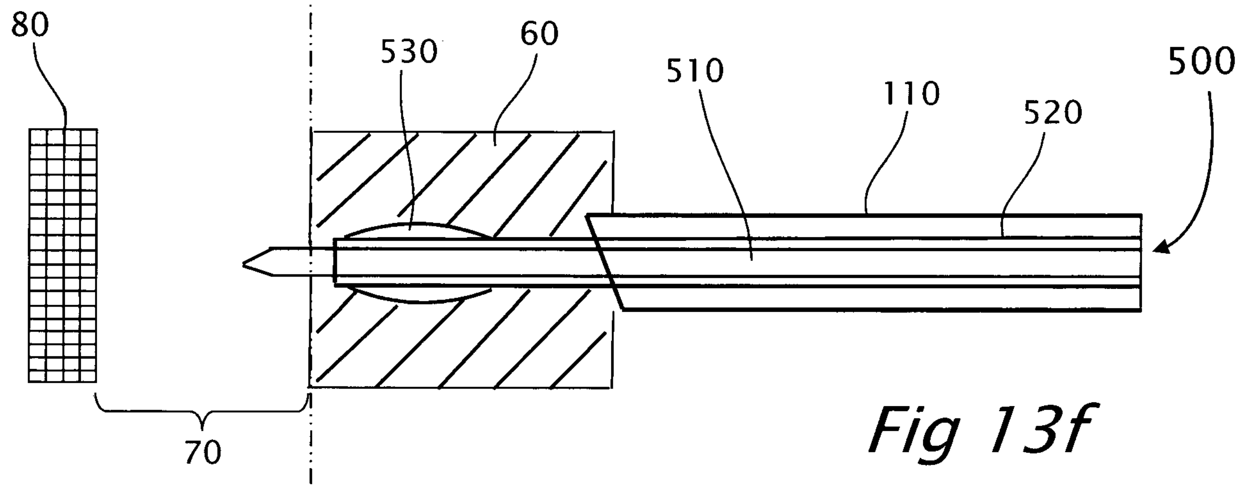

Fig 13f

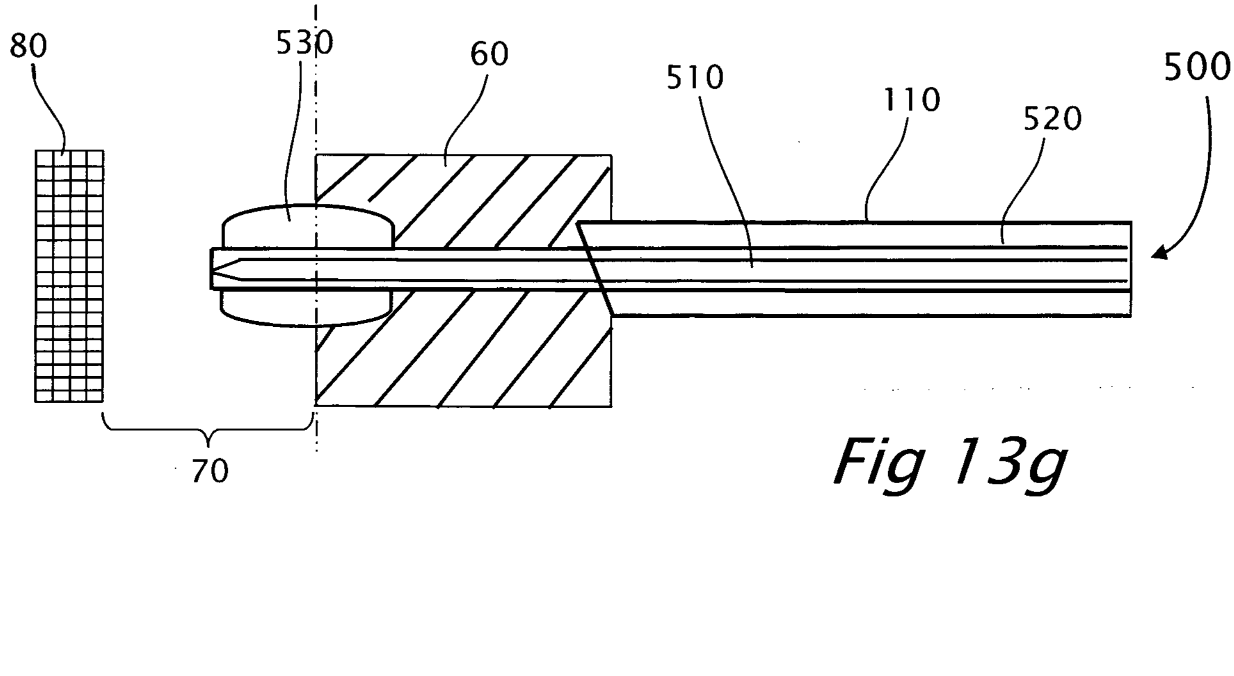

Fig 13g

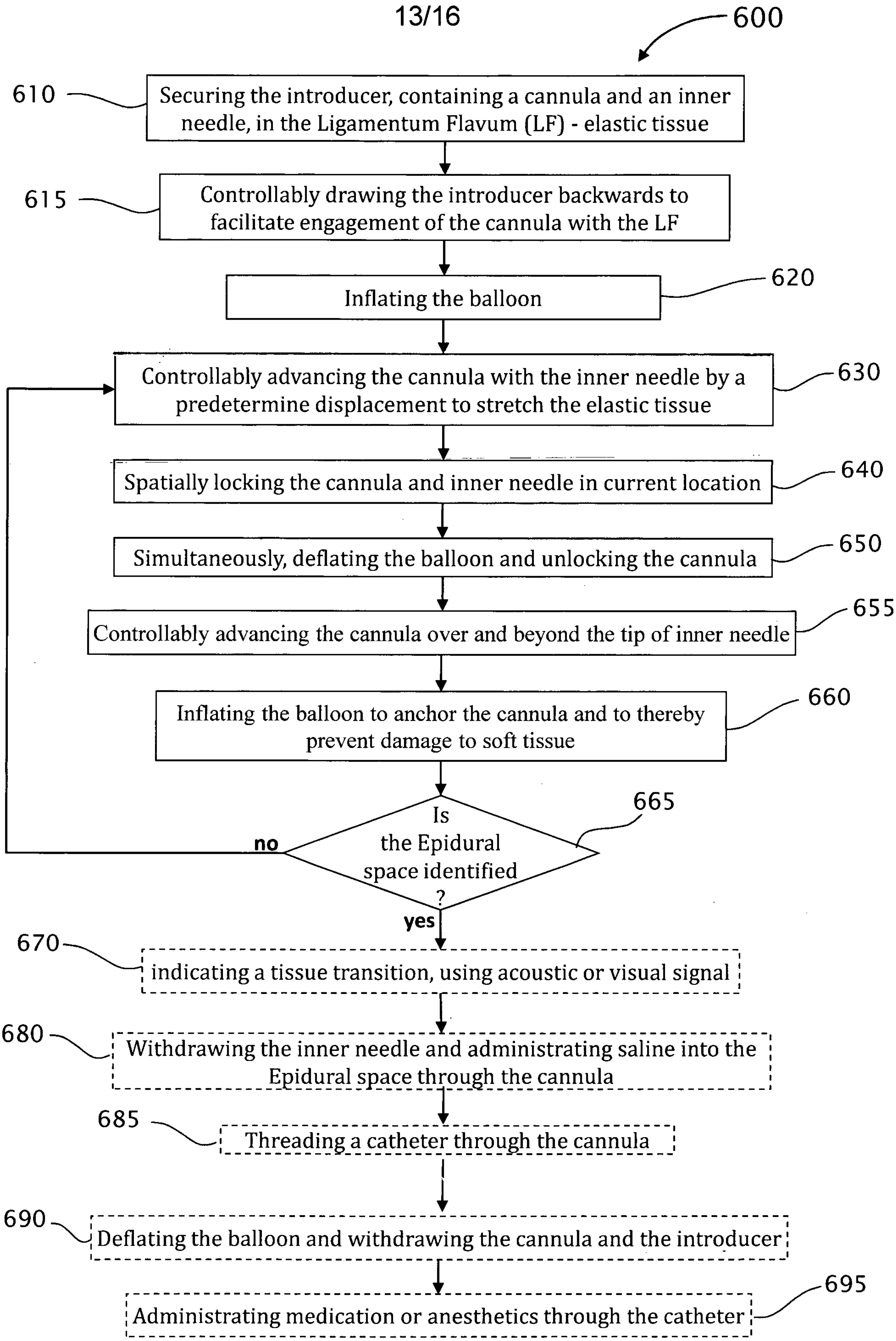
600
610
Securing the introducer, containing a cannula and an inner needle, in the Ligamentum Flavum (LF) - elastic tissue
615
Controllably drawing the introducer backwards to facilitate engagement of the cannula with the LF
620
Inflating the balloon
630
Controllably advancing the cannula with the inner needle by a predetermine displacement to stretch the elastic tissue
640
Spatially locking the cannula and inner needle in current location
650
Simultaneously, deflating the balloon and unlocking the cannula
655
Controllably advancing the cannula over and beyond the tip of inner needle
660
Inflating the balloon to anchor the cannula and to thereby prevent damage to soft tissue
665
Is the Epidural space identified ?
no
yes
670
indicating a tissue transition, using acoustic or visual signal
680
Withdrawing the inner needle and administrating saline into the Epidural space through the cannula
685
Threading a catheter through the cannula
690
Deflating the balloon and withdrawing the cannula and the introducer
695
Administrating medication or anesthetics through the catheter

Fig 14

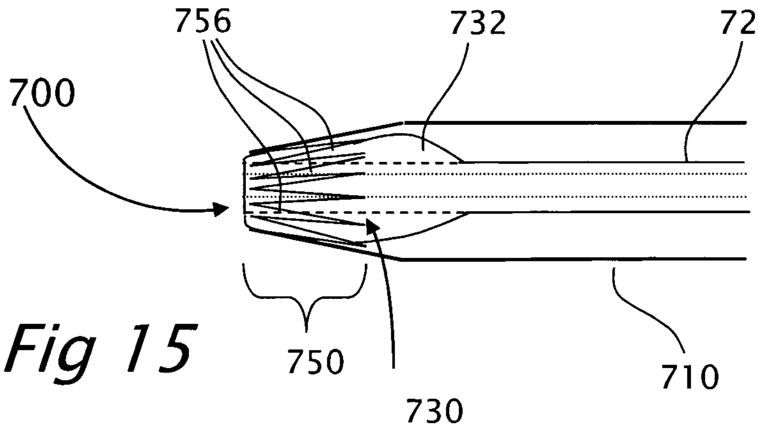

Fig 15

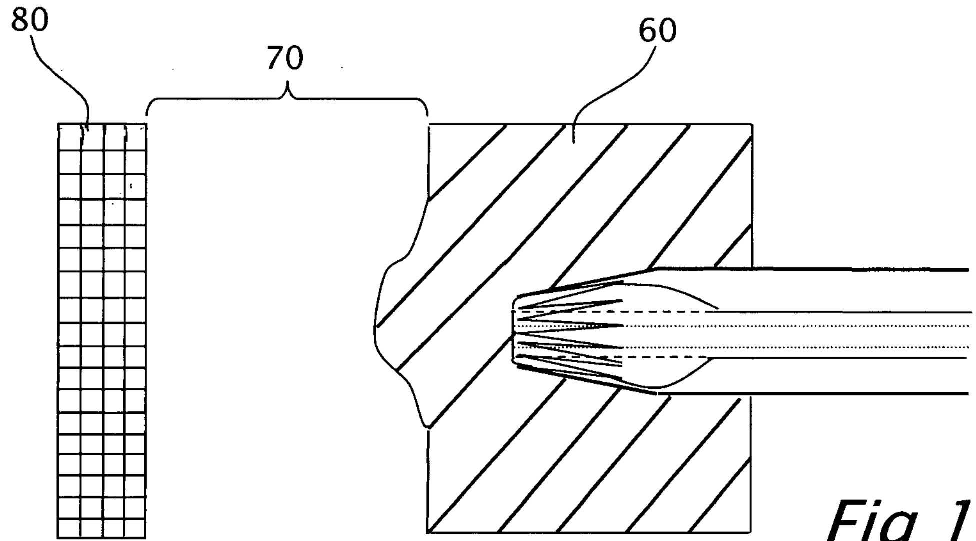

Fig 16a

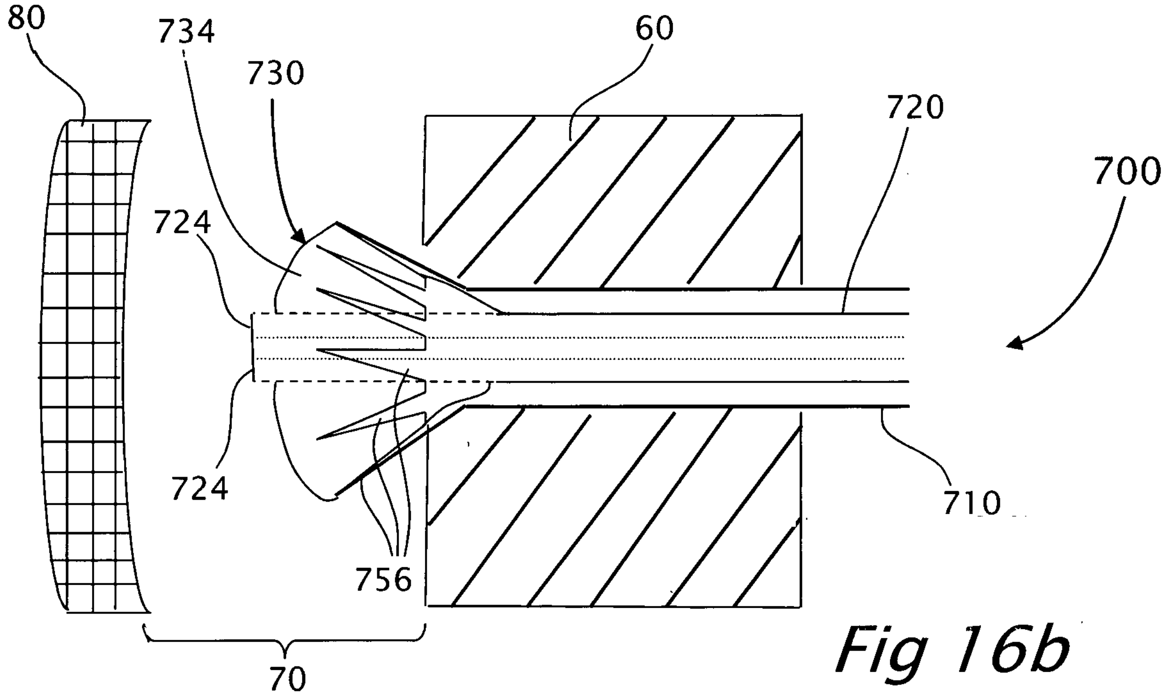

Fig 16b

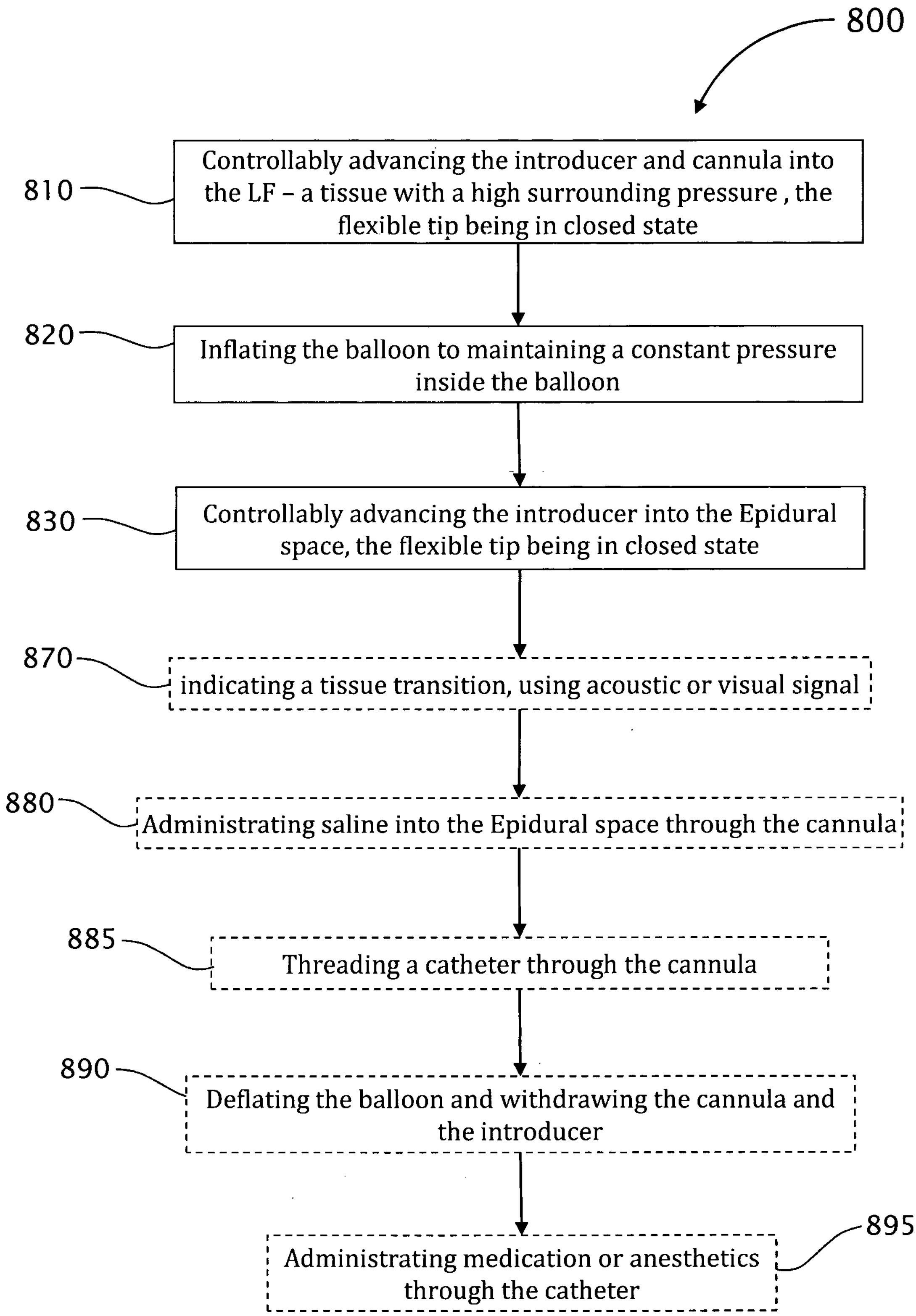
800
810
Controllably advancing the introducer and cannula into the LF – a tissue with a high surrounding pressure , the flexible tip being in closed state
820
Inflating the balloon to maintaining a constant pressure inside the balloon
830
Controllably advancing the introducer into the Epidural space, the flexible tip being in closed state
870
indicating a tissue transition, using acoustic or visual signal
880
Administrating saline into the Epidural space through the cannula
885
Threading a catheter through the cannula
890
Deflating the balloon and withdrawing the cannula and the introducer
895
Administrating medication or anesthetics through the catheter

Fig 17

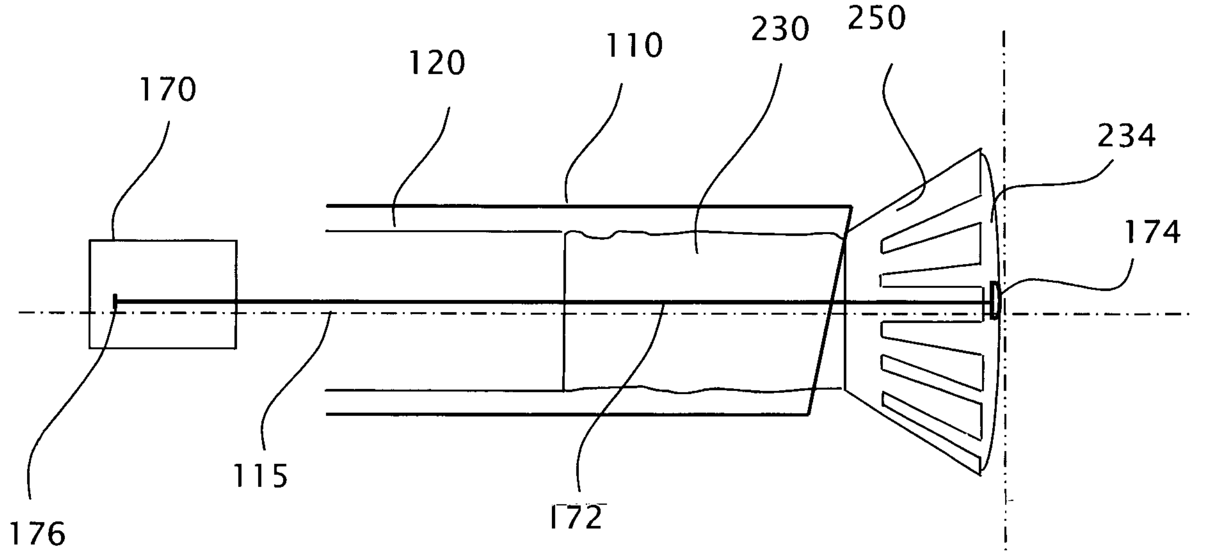

Fig 18a

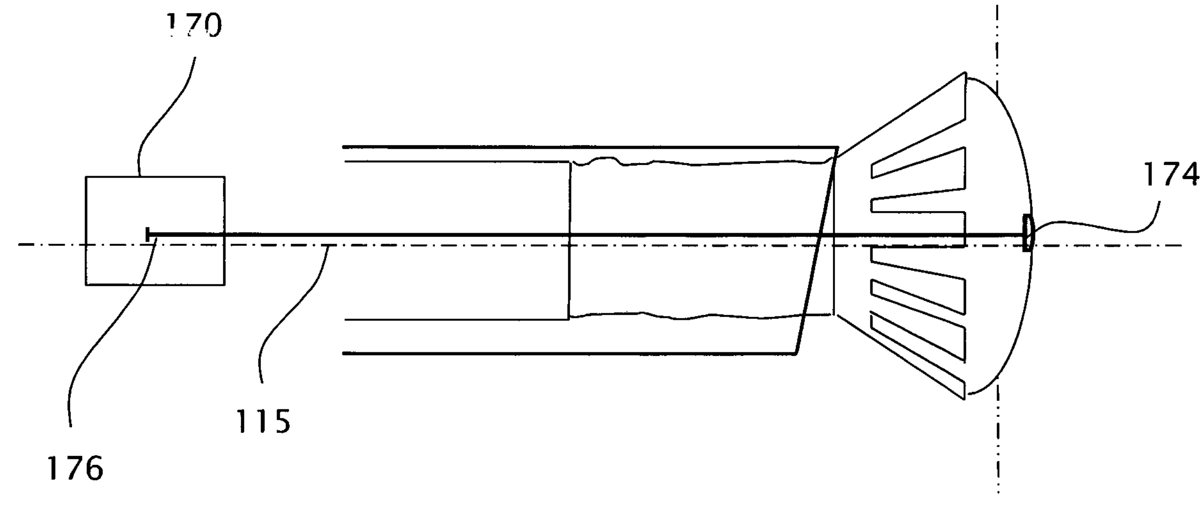

Fig 18b