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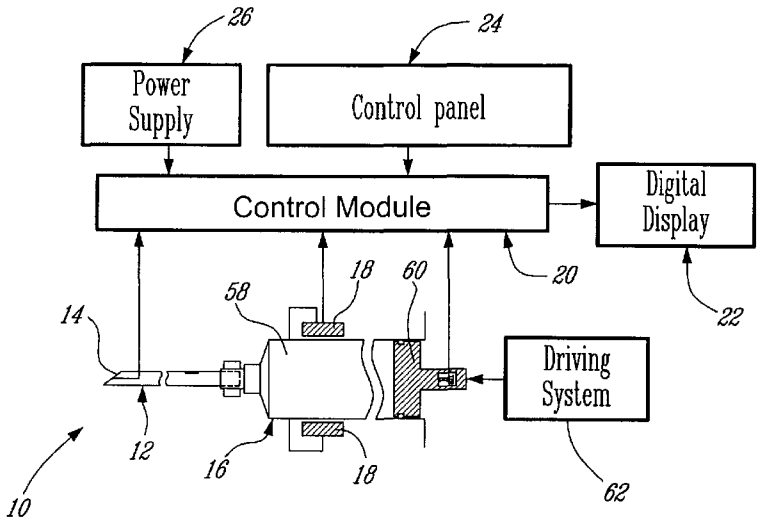
(54) **Title:** INTEGRATED CEMENT DELIVERY SYSTEM FOR BONE AUGMENTATION PROCEDURES AND METHODS



(57) **Abstract:** A bone cement delivery device (16,16a,16b,16c,16d,16e,16f) including a syringe body (58), a plunger (60), and a driving system (62) connected to the plunger (60) and sliding the plunger (60) within the syringe body (58) in a displacement-controlled and continuous manner to produce a steady flow of bone cement out of the syringe body (58). Also, a bone cement delivery device (16,16a,16b,16c,16d,16e,16f) including at least one sensor (18,18a,18b,18c,18d, 18e) for measuring a physical parameter of the bone cement within the body (58), the at least one parameter being indicative of a viscosity of the bone cement, and a display unit (22) receiving data from the sensor (18,18a,18b,18c,18d,18e) and displaying at least one of the physical parameter and the viscosity of the bone cement. Improved medical cannulae (12, 12a, 12b), an improved control system (102) for a bone cement delivery device (16,16a,16b,16c,16d,16e,16f), an improved cement delivery system (10) and related methods are also described.

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INTEGRATED CEMENT DELIVERY SYSTEM FOR BONE AUGMENTATION PROCEDURES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority on US Provisional Patent Application No. 60/789,891 filed April 7, 2006 which is incorporated by reference.

FIELD OF THE INVENTION

The present invention relates to an apparatus for performing bone augmentation procedures, and more particularly to a cement delivery system for such procedures and to a method for the use of such a system.

BACKGROUND ART

A number of different types of bone cement injection procedures are routinely practiced, among which is vertebroplasty, where bone cement, for example polymeric cement such as PMMA or mineral cement such as calcium-phosphate, is injected percutaneously under pressure through a long cannula into a fractured vertebrae. Unfortunately, several problems are generally encountered during bone cement injection procedures, as detailed below.

In bone cement injection procedures in general and in vertebroplasty in particular, the pressure required to inject cement can easily reach values beyond human physical limits (e.g. 150-200N). Consequently, the procedure may have to be aborted before its completion, or the physician's concentration may be unfortunately shifted to the application of a force sufficient to inject the cement instead of to the monitoring of the procedure itself.

A number of devices increasing the pressure applied to the cement are available, for example screw-driven injection devices. However, such devices usually require some attention from the physician, use elongated tubing and as such increase the injection pressure even more, cause the cement to be injected at high velocities under elevated pressure with little control on the injected cement volume or flow rate and/or offer limited monitoring capabilities, all of which may generally increase the risk of cement leakage. It is also known to lower the cement viscosity to ease the injection, however the lower viscosity of the cement may also generally increase the risk of cement leakage, and is some cases increase cement toxicity when liquid to powder ratios are increased.

In addition, existing cement delivery devices generally do not provide feedback of the intervertebral pressure during cement delivery. The intervertebral pressure, although small when compared to the cement injection pressure, is still relevant to the cement filling as high peaks in the intervertebral pressure have been reported to cause marrow displacement and lung embolism.

In vertebroplasty, extravasation, where cement leaks out of the anatomical boundaries of a vertebra through veins and cortical defects and into the surrounding tissue, generally occurs in a majority of the procedures performed with PMMA cement. While most leaks are inconsequential, every leak nevertheless exposes patients to serious risks, such as spinal cord and nerve root compression, pulmonary embolism, and possibly even death. Most of the current research in this area is directed towards improving the visualization techniques to detect leakage, such that when a serious leak is detected, the physician aborts the injection and performs emergency surgery if necessary. However, such visualization techniques do not allow the prevention of cement leakage or the prediction of the uniformity of the filling.

In addition, the cement infiltrating the bone cavities generally displaces the bone fluids (e.g. marrow, blood), which enter the cardiovascular system and can be lethal, for example causing pulmonary embolism leading to cardiac arrest. For this reason, physicians generally limit the number of bone cement injection procedures conducted on one patient in one setting.

Also, with calcium-phosphate (CaP) or mineral cements, formed by dispersing reactive CaP micro-particles in an aqueous medium, an effect often referred to as filter-pressing has been reported, where the cement separates under pressure such that only the aqueous medium passes through the cement delivery system while the particles remain behind where they may block the system.

Further, the viscosity of bone cement, which is a key factor in the uniformity of the cement filling, varies substantially, depending on various factors such as environmental conditions (e.g. temperature, humidity), the mixing technique used, as well as the batch and type of cement used. Physicians recognize both the importance of the viscosity and its variability, and often use visual inspection or contact to a latex glove to ensure the adequate viscosity of the cement. However, such methods are highly suggestive and as such do not offer results easily reproducible from one physician to another or even from one procedure to another for a same physician.

Accordingly, improvements are desirable.

SUMMARY OF INVENTION

It is therefore an aim of the present invention to provide an improved medical cannula.

It is also an aim of the present invention to provide an improved method of injecting bone cement within a bone.

It is also an aim of the present invention to provide an improved bone cement delivery device.

It is also an aim of the present invention to provide an improved viscosity sensing unit for a bone cement delivery device.

It is also an aim of the present invention to provide an improved control system for a bone cement delivery device.

It is also an aim of the present invention to provide an improved cement delivery system .

It is also an aim of the present invention to provide an improved method of extracting marrow from a bone.

It is also an aim of the present invention to provide an improved method of rinsing marrow within a bone.

It is also an aim of the present invention to provide an improved cannula and syringe body combination.

In accordance with the present invention, there is provided a bone cement delivery system comprising a rigid cannula having a tubular inner wall defining and surrounding a central conduit for bone cement delivery, the inner wall defining a distal outlet of the central conduit at a distal end of the cannula, a tubular outer wall extending around the inner wall and spaced apart therefrom to define a peripheral conduit around the central conduit, the outer wall defining a distal inlet of the peripheral conduit at the distal end of the cannula, and a proximal end of the cannula including a proximal inlet in communication with the central conduit and a proximal outlet in communication with the peripheral conduit.

Also in accordance with the present invention, there is provided a method of injecting bone cement within a bone, comprising injecting bone cement within the bone through a surgical site, and at least one of aspirating fluid from the bone through said surgical site simultaneously with the bone cement injection and measuring an internal pressure of the bone through said surgical site simultaneously with the bone cement injection.

Also in accordance with the present invention, there is provided a bone cement delivery device, comprising a syringe body for containing the bone

cement, a plunger snuggly and slidably received within the syringe body for pushing the bone cement out of the syringe body, and a driving system connected to the plunger and sliding the plunger within the syringe body in a displacement-controlled and continuous manner to produce a steady flow of bone cement out of the syringe body.

Also in accordance with the present invention, there is provided a bone cement delivery device comprising a body for containing the bone cement therein and for progressively injecting the bone cement therefrom for delivery into the bone, at least one sensor for measuring a physical parameter of the bone cement within the body, the at least one parameter being indicative of a viscosity of the bone cement, and a display unit receiving data from the sensor and displaying at least one of the physical parameter and the viscosity of the bone cement.

Also in accordance with the present invention, there is provided a viscosity sensing unit for a bone cement delivery device, the unit comprising at least one sensor for measuring a physical parameter of the bone cement directly within the bone cement delivery device, the at least one parameter being indicative of a viscosity of the bone cement, and a display unit receiving data from the sensor and displaying at least one of the physical parameter and the viscosity of the bone cement.

Also in accordance with the present invention, there is provided a method of injecting bone cement within a bone, comprising monitoring at least one parameter indicative of a viscosity of the bone cement directly within a bone cement delivery device, and injecting the bone cement in the bone with the delivery device based on the at least one parameter.

Also in accordance with the present invention, there is provided a control system for a bone cement delivery device, the control system comprising a delivery pressure sensor for measuring a cement delivery pressure and producing corresponding delivery pressure data, a control panel for receiving commands from a user and producing corresponding command data, a driving system for actuating the cement delivery device to deliver the bone cement, a control module for receiving the command data and the delivery pressure data, and for sending a control signal actuating the driving system based on the command data and the delivery pressure data such as to deliver the bone cement in a steady flow, and a display unit for receiving the pressure data from the control module and displaying delivery pressure information based on the delivery pressure data.

Also in accordance with the present invention, there is provided an integrated cement delivery system comprising a cement delivery device including

a syringe body for containing the bone cement, a plunger slidably received within the syringe body for pushing the bone cement out of the syringe body, and a driving system connected to the plunger and sliding the plunger within the syringe body, an injection pressure sensor measuring an injection pressure of the cement within the syringe body, a control system controlling the driving system in a displacement-controlled and continuous manner to produce a steady flow of bone cement out of the syringe body based on data from the injection pressure sensor and commands from a user, and a display unit displaying the data from the injection pressure sensor.

Also in accordance with the present invention, there is provided a method of extracting marrow from a bone, comprising injecting a thick liquid in the bone through a surgical site, displacing the marrow with the thick liquid, and extracting the marrow through said surgical site simultaneously with the thick liquid injection.

Also in accordance with the present invention, there is provided a method of rinsing marrow within a bone, comprising inserting a cannula in the bone, injecting a liquid in the bone through a first conduit of the cannula, and creating a pressure gradient between the first conduit and a second conduit of the cannula.

Also in accordance with the present invention, there is provided a medical cannula comprising at least one tubular wall defining and surrounding an injection conduit, the wall defining a distal outlet of the injection conduit at a distal end of the cannula, and a proximal end of the cannula including a proximal inlet in communication with the injection conduit, and an elastic and permeable membrane covering the distal outlet of the injection conduit for delivery of injected fluid therethrough.

Also in accordance with the present invention, there is provided, in combination, a cannula and a syringe body, the cannula defining an injection conduit having a constant diameter throughout a length thereof, and the syringe body includes a tapered distal end defining an outlet connected to the injection conduit of the cannula, the tapered distal end providing a progressive and constant diameter reduction between a remainder of the syringe body and the injection conduit.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference will now be made to the accompanying drawings, showing by way of illustration particular embodiments of the present invention and in which:

Fig. 1 is schematic representation of a cement delivery system according to a particular embodiment of the present invention;

Fig. 2 is a tridimensional cross-sectional view of a cannula according to a particular embodiment of the present invention;

Fig. 3 is a tridimensional cross-sectional view of a cannula according to an alternate embodiment of the present invention;

Fig. 4 is a side cross-sectional view of a screw delivery mechanism of the cannula of Fig. 3 according to a particular embodiment of the present invention;

Fig. 5A is a side cross-sectional view of a cannula according to an alternate embodiment of the present invention;

Fig. 5B is an enlarged, side cross-sectional view of a portion of the cannula of Fig. 5A;

Fig. 5C is an enlarged, side cross-sectional view of a portion of the cannula of Fig. 5A according to an alternate embodiment of the present invention;

Fig. 6 is tridimensional view of a proximal end of a cannula, which may be for example the cannula of any one of Figs. 2 to 5C, including a membrane according to a particular embodiment of the present invention;

Fig. 7 is a schematic tridimensional view of a proximal end of a cannula, which may be for example the cannula of any one of Figs. 2 to 5C, including an intravertebral pressure sensor according to a particular embodiment of the present invention;

Fig. 8 is a schematic side view of a cement delivery device according to a particular embodiment of the present invention;

Fig. 9 is a schematic side view of a cement delivery device according to an alternate embodiment of the present invention;

Fig. 10 is a schematic side view of a cement delivery device according to an alternate embodiment of the present invention;

Fig. 11 is a schematic side view of a syringe and cannula assembly according to a particular embodiment of the invention;

Fig. 12 is a schematic side view of a syringe including injection pressure sensors according to a particular embodiment of the present invention;

Figs. 13A-13C are schematic front views of syringes including different ultrasound viscosity sensors according to alternate embodiments of the present invention;

Fig. 14 is a tridimensional schematic view of a syringe including a dielectric viscosity sensor according to an alternate embodiment of the present invention;

Figs. 15A-15B are front and bottom schematic views of a syringe plunger including a dielectric or electro-resistive viscosity sensor according to an alternate embodiment of the present invention;

Fig. 16 is a graphical representation of an example of the Root Mean Square of an ultrasound pulse of the ultrasound sensors of Figs. 13A-13C;

Fig. 17 is a graphical representation of an example of the attenuation of the ultrasound pulse of the ultrasound sensors of Figs. 13A-13C;

Fig. 18 is a graphical representation of an example of a capacity, resistance, impedance and phase of the dielectric sensors of Fig. 14;

Fig. 19 is a block diagram of a control system according to a particular embodiment of the present invention;

Fig. 20 is a tridimensional view of a cement delivery device according to a particular embodiment of the present invention;

Fig. 21 is a tridimensional view of a cement delivery device according to an alternate embodiment of the present invention;

Fig. 22 is a tridimensional view of a cement delivery device according to an alternate embodiment of the present invention; and

Fig. 23 is a tridimensional view of a cement delivery system according to a particular embodiment of the present invention, shown here in combination with the cement delivery device depicted in Fig. 22.

DETAILED DESCRIPTION OF PARTICULAR EMBODIMENTS

Referring generally to Fig. 1, a cement delivery system according to a particular embodiment of the present invention is generally and schematically shown at 10. The system 10 generally comprises a cannula 12 which may include pressure sensors 14 to measure the intravertebral pressure, an assisted cement delivery device 16 delivering cement through the cannula 12 and including miniature viscosity sensors 18 to monitor a viscosity of the cement, a controller or control module 20, such as for example provided in an electronic circuit board including a microprocessor, for controlling or operating the cement delivery device 16, a digital display unit 22 for displaying sensor data during the procedure,

a control or regulation panel 24 for receiving instructions from a user, and a power supply 26 providing power to the system 10.

The different elements of the cement delivery system 10 are separately described in more detail in the following.

Cannulae 12

The cannula 12 in Fig. 1 can be a standard cannula or, alternately, one of the cannulae 12a,b,c shown in Figs. 2 to 7. The cannulae 12a,b,c described below allow for monitoring of the intravertebral pressures and/or aspiration of the vertebral body to drain the bone fluid (e.g. marrow, blood) that is displaced during the cement injection, such as to reduce cement leakage and reduce the risk of emboli. The cannulae 12a,b,c are preferably made of an appropriate type of metal or other rigid material, similarly to known single conduit cannula typically used in bone cement injection procedures.

In the case of vertebroplasty, the total pressure required for cement injection Δp_{mj} can be separated into the extravertebral cement delivery pressure Δp_{extra} required to force the cement through a cannula, the intravertebral cement infiltration pressure Δp_{inf} required to force the cement to penetrate the vertebral cavity, and the intravertebral bone marrow pressure Δp_{mar} within the vertebral body due to the hydraulic resistance of the vertebra, i.e. $\Delta p_{inj} = \Delta p_{extra} + \Delta p_{mf} + \Delta p_{mar}$. The extravertebral delivery pressure Δp_{extra} is generally the largest (e.g. up to 500 psi for mechanical injectors), while the infiltration pressure Δp_{mf} and the bone marrow pressure Δp_{mar} are generally much lower (e.g. 50 psi and 5 psi, respectively).

Monitoring of the internal bone pressure, or, in the case of vertebroplasty, of the intravertebral pressure (i.e. the infiltration pressure Δp_{mf} and the bone marrow pressure Δp_{mar}) ensures that there is no excess pressure in the bone (vertebral) cavity when delivering cement, as an elevated pressure may cause the cement to spread suddenly in uncontrolled fashion or cause lung emboli. The monitoring of the internal or intravertebral pressure can also be used as a predictor of leakage, since a sudden pressure drop may indicate the existence of a path of least resistance leading to cement leakage. The monitoring of the internal or intervertebral pressure thus allow for prevention of these complications.

Knowledge of the internal or intravertebral pressures also allows for the determination of the pressure within the cannula (e.g. extravertebral), which creates a diagnostic tool for the case in which the physician is not in a position to

deliver cement, for example indicating that the cannula is plugged or that the cement is not going into the bone (vertebral body).

Referring to Fig. 2, the cannula 12a includes an outer tubular wall 28a defining a proximal end 30 and a distal end 32. Concentric peripheral and central conduits 34a, 36a are separated by a thin tubular internal wall 38a extending in the cannula 12a spaced apart from the outer tubular wall 28a. The cannula 12a includes a side outlet 40a defined at the proximal end 30 and a series of fenestrations 42a defined at the distal end 32, both of which being in communication with the peripheral conduit 34a. The central conduit 36a is used to deliver the cement, while the peripheral conduit 34a is used to aspirate the vertebra to aspirate bone fluid (e.g. marrow, blood) during cement injection, or to measure the intravertebral cement infiltration or bone marrow pressures Δp_{mf} or $\Delta pmar$ through a pressure sensor 14 (see Fig. 1).

In the case where the peripheral conduit 34a is used to aspirate the vertebra, the fenestrations 42a represent a vent or a sink for the displaced bone fluid when the cement enters the vertebral cavities. In a particular embodiment, the aspiration is done manually using a standard syringe attached to the side outlet 40a to create a vacuum while the physician delivers the cement and to remove the bone fluid. In a more preferred embodiment, the aspiration is done in an automated manner and more specifically, in a volume controlled manner. The automated aspiration allows for cement to be injected at a given flow rate and for bone fluid to be aspirated at a slightly higher flow rate, such that the cement follows the displaced bone fluid and takes its place. One practical way of producing the vacuum for the automated aspiration is to use a vacuum pump connected to the side outlet 40a and applying for example a low-level vacuum in the range of 10 to 100 KPa. The vacuum pump is preferably regulated by a vacuum regulator (e.g. mechanical or electronic), which is regulated by the control module 20 as will be described in a following section.

In addition to removing bone fluid, the aspiration or vacuum creates a pressure gradient between the central conduit 36a and the peripheral conduit 34a, which creates a hydraulic force guiding the displacement of the bone fluid and the flow of the cement. This pressure gradient can be used to guide the cement flow to facilitate controlled and predictable filling with enhanced mechanical efficacy and reduced cement emboli.

In a particular embodiment where the peripheral conduit 34a is used to measure the intravertebral cement infiltration or bone marrow pressures Δp_{inf} or Δp_{mar}, the pressure sensor 14 (see Fig. 1) is provided at the proximal end of the

peripheral conduit 34a, and either air or liquid is used as a media to transfer the pressure wave generated in the vertebra when delivering cement from the distal end 32 of the cannula to the pressure sensor 14.

The cannula 12a may feature different fenestration patterns at its distal end 32 that that shown in order to meet different functions.

The cannula 12b shown in Fig. 3 is similar to the cannula 12a, and includes an outer tubular wall 28b, concentric peripheral and central conduits 34b, 36b separated by a thin tubular internal wall 38b spaced apart from the outer tubular wall 28b, as well as a side outlet 40b at the proximal end 30 and a series of fenestrations 42b at the distal end 32 which are both in communication with the peripheral conduit 34b. Like the cannula 12a, the central conduit 36b of the cannula 12b is used to deliver the cement while the peripheral conduit 34b is used to aspirate and drain the bone fluid as described above, or to measure the intravertebral cement infiltration or bone marrow pressures Δp_{inf} or Δp_{mar} through a pressure sensor 14 (see Fig. 1).

However, the cannula 12b also includes a side inlet 41 defined at the proximal end 30 in communication with the central conduit 36b, through which the cement enters the cannula 12b. The cannula 12b additionally includes a screw delivery mechanism 43 extending within the central conduit 36b along its length. In a particular embodiment, the screw delivery mechanism 43 is either a helical or spiral transport screw. The rotating screw delivery mechanism 43 facilitates the transport of the cement through the central conduit 36b in a precise manner.

The cannula 12b is thus especially useful for injecting cements that are difficult to inject because of phase separation, such as for example calcium phosphate (CaP), with the screw delivery mechanism 43 increasing the mixing of the cement to reduce the risk of phase separation. The screw delivery mechanism 43 also significant decreases the pressure required for cement delivery since the cement delivery by the screw delivery mechanism 43 requires little pressure when compared with simply pushing the cement though the elongated geometry of the cannula, and as such can also be used to transport thick PMMA cement. The use of thick cement reduces the risk of leakage, while the use of the screw delivery mechanism 43 facilitates the cement delivery without the need for excessive forces.

Although the rotation of the screw delivery mechanism 43 can be applied manually, in a particular embodiment the rotation is applied by a micro motor (not shown). As such, the pressure drop in the cannula 12b is overcome by the power of the micro-motor and the physician does not contribute to overcoming

this pressure. The rotation speed of the screw delivery mechanism 43 is regulated, for example by the control module 20 as will be further described below, to adjust for the desired delivery flow rate. As such, the physician can shift focus on the patient and on the surgery instead on being focused on delivering sufficient cement in the intervention. In a particular embodiment, where the central conduit 36b and screw 43 are designed for cement delivery at a speed 3 ml/minute, the micro-motor rotating the screw delivery mechanism 43 provides a power of approximately 52 mW.

In a particular embodiment, the screw delivery mechanism 43 is a typical delivery screw. However, in an alternate embodiment shown in Fig. 4, the screw delivery mechanism 43 is cannulated, i.e. an inner conduit 37 is defined within the screw delivery mechanism 43 along its length. This inner conduit 37 is preferably instrumented to measure the intravertebral cement infiltration pressure Δp_{inf}, with either air or liquid being used for the transfer of the infiltration pressure from the distal end of the screw to the proximal end of the screw, where a pressure sensor 14 (see Fig. 1) is mounted. The screw 43 may additionally feature radial fenestrations or vents that connect directly to its inner conduit 37. The peripheral conduit 34b is used to measure the intravertebral bone marrow pressure Δp_{mar} or to aspirate the bone fluid as the bone cement is delivered through the central conduit 36b.

The cannula 12c shown in Figs. 5A-5C includes concentric tubular inner, middle and outer walls 38c, 39, 28c, thus defining central, middle and peripheral concentric conduits 36c, 35, 34c. A side outlet 40c (see Fig. 5A) defined at the proximal end 30 and a series of fenestrations 42c (see Figs. 5B-5C) at the distal end 32 are both in communication with the peripheral conduit 34c. A second side outlet 45 defined at the proximal end is in communication with the middle conduit 35. The central conduit 36c is used to deliver bone cement.

Referring particularly to Fig. 5B, in one embodiment, fenestrations 47 are defined through the inner wall 38c, and the middle conduit 35 is used to measure the intravertebral cement infiltration pressure Δp_{inf} while the peripheral conduit 34c is used to aspirate the bone fluid or to measure the intravertebral bone marrow pressure Δp_{mar}. As described above, in a particular embodiment a pressure sensor 14 (see Fig. 1) is mounted to the proximal end of the middle conduit 35 and either air or liquid is used as a media to transfer the pressure wave generated in the vertebra when delivering cement from the distal end 32 of the cannula to the pressure sensor 14.

In another embodiment shown in Fig. 5C, the fenestrations 47' are alternately defined through the middle wall 39, and one of the middle and peripheral conduits 35, 34c is used to measure the intravertebral bone marrow pressure Δp_{mar} while the other is used to aspirate the bone fluid.

Alternately, the screw delivery mechanism 43 of the cannula 12b, with or without its inner conduit 37, can be integrated in a single conduit cannula or in a cannula having three conduits such as 12c.

The cannulae 12a,b,c thus allow for the bone fluid to be aspirated and the cement to be injected simultaneously and using a same operative site, without the need to use separate cannulae, which reduces the risks of complications.

The cannulae 12a,b,c can also advantageously be used to rinse the bone marrow and create a path favoring cement flow. Prior methods of rinsing the bone marrow usually necessitate the use of two separate surgical sites. With the cannulae 12a,b,c, pulsating or non pulsating fluid is injected through one of the conduits, creating a pressure gradient between the conduits and allowing for the rinsing process to be performed using a single cannula and thus a single surgical site. The rinsing process is done manually or automatically with the help of an automated system, applying a level of pressure similar to the one applied for bone fluid extraction. In an alternate embodiment, the rinsing process is performed through a smaller diameter tubing extending within the cannula (either 12a,b,c or single conduit cannula) extending deeper within the vertebra.

Fig. 6 shows a membrane 44 which is optionally attached at the distal end 32 of the central conduit 36a,b,c of any one of the cannulae 12a,b,c described above or, alternately, at the distal end of a single conduit cannula. The membrane 44 is preferably elastic and retractable, and has a permeability (illustrated by holes 46) that is roughly ten percent (10%) of the permeability of osteoporotic cancellous bone. The size and elasticity of the membrane 44 is preferably such as to define an expanded diameter of no more than 5 millimeters to ensure the least damage to the surrounding bone. The membrane 44 can be made of fabric tissue or preferably super elastic metals.

When the cement is delivered, it expands the membrane 44 and generates a state of uniform hydrostatic pressure inside the membrane 44. Specifically, the rate of cement flow exterior to the membrane 44 is controlled by the pressure gradient between the membrane 44 and the surrounding bone. The intravertebral pressure in the surrounding bone is insignificant, thereby imposing a constant uniform pressure gradient on the surface of the membrane 44. This uniform gradient leads to uniform and controlled flow of the cement through the

membrane 44 and in the environment. The membrane 44, due to the low permeability, is thus the guiding tool for the intravertebral flow. Thus, the membrane 44 ensures controlled slow and uniform expansion of the cement, and prevents preferential pressure gradients caused by local bone morphology and thereby, ensuring seepage flow and likely reducing leakage risk.

In the case where the internal bone pressure (e.g. intervertebral pressure) is not measured through a separate conduit of the cannula, the cannula preferably includes a pressure sensor 14 as shown in Fig. 7, such as a miniature MEM sensor, which is placed directly at its distal end 32 while ensuring that the flow is not obstructed. This provides direct readings of the internal or intravertebral pressure during the cement delivery process.

As mentioned above, any one of the cannulae 12a,b,c can take the place of the cannula 12 in the cement delivery system shown in Fig. 1. The cannulae 12a,b,c present the advantage of allowing for multiple operations (cement delivery and pressure measurements and/or bone marrow extraction and/or bone marrow rinsing) using a single site.

Although the cannulae 12a,b,c have been described mostly with relation to vertebroplasty, the cannulae 12a,b,c can alternately be used in other cement augmentation procedures where cement is injected into other anatomical locations (such as osteoporotic femur and distal radius) and where similar issues of high pressure exist. Additionally, the cannulae 12a,b,c can also be used in any appropriate type of percutaneous injection of viscous biomaterials into the human body (e.g., drug delivery using carriers, biometrices for tissue engineering).

In addition, the cannulae 12a,b,c can advantageously be used for bone marrow extraction for graft, blood disorders, stem cell transplantation or orthopedic procedures. Known methods of performing bone marrow extraction include directly using a syringe to remove the bone marrow, generally extracting mostly blood and a small quantity of marrow. With the cannulae 12a,b,c, a thick liquid is delivered through one of the conduits, invading the bone cavity saturated by bone marrow and as such displacing the bone marrow, which is then guided through suction into another conduit of the cannula, thus increasing the efficiency of the bone marrow extraction procedure.

Cement Delivery Device 16

It has been shown that when a fairly liquid cement is injected into a vertebra, the cement finds and flows through a path of least resistance, however when the cement is injected at a viscosity or degree of curing that is high enough,

it expands uniformly as if the path of leakage did not exist. Accordingly, by controlling the time of injection and thereby the cement viscosity, the incidence of leakage can be reduced considerably. The challenge is that cement generally ceases to be manually injectable with a standard syringe and cannula at about the minimal viscosity avoiding flowing through the path of least resistance.

Referring back to Fig. 1, the cement delivery device 16 generally includes a syringe body 58 and a syringe plunger 60 which is displaced within the body 58 by any adequate driving system 62, such as for example an electric motor, a pneumatic system or an hydraulic system. The driving system 62 is controlled or regulated by the control module 20, as will be described in a following section, such that the displacement of the plunger 60 is controlled, preferably advancing in a continuous manner (i.e. in a consecutive series of steps of equal duration and equally spaced apart, or with an uninterrupted motion at a constant speed) in the syringe body 58, such as to precisely deliver a given volume of cement, thus reducing undesired excess cement which increases leakage risks. In a particular embodiment, the driving system 62 allows for the delivery of a desired volume of cement with a precision of 50 micro liters. The driving system 62 generates an axial force on the plunger 60 which generates an injection pressure substantially greater than human physical limits and sufficient to deliver the cement, thus overcoming the limitation of excessive pressure and increasing the chances of being able to complete the procedure adequately. In a particular embodiment, the axial force generated by the driving system 62 is approximately 2KN. The increased injection pressure ensures the delivery of thicker cement, which substantially reduces the risks of cement leakage.

The driving system 62 delivers the cement continuously and slowly, for example at 3ml/minute, and in a particular embodiment, at most lOml/minute, resulting in a steady flow which enhances cement filling uniformity and reduces leakage risks by reducing undesired transient peaks in pressure.

The driving system 62 allows for a displacement controlled delivery which leads to stable flow conditions, thereby reducing the risk of sudden uncontrolled flow in the case of leakage.

Referring to Fig. 8, a particular embodiment 16a of the cement delivery device 16 is shown. The cement delivery device 16a includes a worm gear speed reduction mechanism 64 connected to the driving system 62, depicted here as an electric motor. The motor 62 powers the endless screw component 66 of the worm gear mechanism 64, which turns the wheel component 68 that rotates a threaded rod 70a. The threaded rod 70a is rotationally supported between two supports 72,

which also support a guidance rod 74 extending therebetween. A nut 76 is slidably retained by the guidance rod 74 and threadingly engaged to the threaded rod 70a. The rotation of the threaded rod 70a causes a lateral motion of the nut 76 and of a pushrod 78a connected thereto, the pushrod 78a activating the movement of the syringe plunger 60 within the body 58 of the syringe 114 to inject the cement. The guidance rod 74 ensures steady movement of the pushrod 78a for accurate cement delivery.

A number of alternate embodiments are possible. For example, in one alternate embodiment, the nut 76 is omitted, and the rotation of the threaded rod 70a directly applies a lateral force to the pushrod 78a which is threadingly engaged therewith and slidably received on the guidance rod 74. In another alternate embodiment, the pushrod 78a is omitted, and the nut 76 directly activates the movement of the plunger 60. In another alternate embodiment, the guidance rod 74 and pushrod 78a extend on opposed sides of the syringe body 58 for improved stability. In another alternate embodiment, the supports 72 can directly support and guide the threaded rod 70a, pushrod 78a and/or nut 76, and as such the guidance rod 74 can be omitted. In another alternate embodiment, the pushrod 78a or the nut 76 acts directly as the syringe plunger 60, thus reducing the number of necessary elements. Other modifications are also possible.

Referring to Fig. 9, another particular embodiment 16b of the cement delivery device 16 is shown. The cement delivery device 16b includes a spur gear and toothed rack speed reduction mechanism 82 connected to the driving system 62, shown here as an electric motor, through a pinion 80. The motor 62 rotates the pinion 80, which rotates the spur gear 84 of the mechanism 82, which in turn forces the movement of the toothed rack 86. The rack 86 is fixed to the pushrod 78b, so the movement of the rack 86 applies a lateral force to the pushrod 78b which activates the movement of the syringe plunger 60 inside the body 58 of the syringe 114 and forces the injection of the cement.

Referring to Fig. 10, another particular embodiment 16c of the cement delivery device 16 is shown. The cement delivery device 16c is simple and the driving system 62, whether electrical, pneumatic, hydraulic or other, is a linear motor, directly rotating and translating a threaded rod 70c. The threaded rod 70c is attached to an interchangeable head 88 that acts as the plunger 60 within the body 58 of the syringe 114. The lateral movement of the head 88 forces the injection of the cement.

Accordingly, any one of the devices 16a,b,c can take the place of the cement delivery device 16 in the cement delivery system 10 shown in Fig. 1.

Any one of the devices 16a,b,c can also be used in any appropriate orthopedic application where medical cement is injected.

Referring to Fig. 11, as suddenly contracting geometry from the cement delivery device 16 to the cannula 12 in conventional procedures can causes a substantial increase in injection pressure, in a particular embodiment the geometrical transition from the device 16 to the cannula 12, 12a,b,c is adapted, thereby minimizing unnecessary pressure loss. The diameter of the central conduit 36a,b,c of the cannula is constant, even in its proximal end 30, where the outer tubular wall 28a,b,c defines a connection element 87 such as for example a male Luer lock adapter. The syringe body 58 is tapered, for example defining a conical shape extending at an angle α (which in a particular embodiment is approximately 45°) from a remainder of the syringe body 58, up to a complementary connection element 89, such as for example a complementary female Luer lock adapter, surrounding the connection element 87 of the cannula 12, 12a,b,c. This provides a smooth transition between the diameter of the major part of the syringe body 58 and the constant diameter of the central conduit 36a,b,c, thus lowering the overall injection pressure, and as such facilitating the delivery of thicker cements. Such a connection can alternately be used in other types of syringes and delivery systems for cements or other thick medium, including manual delivery systems.

Referring to Fig. 12, in a particular embodiment the cement delivery device 16 (16a,b,c, or other) is instrumented to measure the injection pressure. The device 16 comprises injection pressure sensors 90 including a strain gauge bridge 92 embedded directly in the syringe plunger 60, such as to measure the overall injection pressure during the cement delivery process. In an alternate embodiment, the injection pressure sensors 90 include a force or loading cell embedded between the plunger and the displacing mechanism of the plunger. An example for such a load cell is a cylindrical load cell with two threads protruding from both sides.

The injection pressure can be calculated once the injection force and the cross-sectional area of the syringe are known. The injection pressure sensors 90, whether in the form of force sensors or in any other adequate form, can alternately be included in any other appropriate location of the cement delivery device 16, 16a,b,c, such as for example within the driving system 62.

With the knowledge of the injection pressure and of the internal bone pressure (e.g. intravertebral), the pressure drop in the cannula 12 can be determined, and as such, based on the known injection speed and cannula

dimensions, the viscosity of the cement can be determined through Hagen-Poiseuille's law.

Viscosity Sensor 18

As shown in Fig. 1, the cement delivery system 10 further includes viscosity sensors 18 providing continuous viscosity or curing readings of the polymerizing cement in the cement delivery device 16, without introducing any significant changes to the technique of vertebroplasty.

The role of cement viscosity or the degree of polymerization plays a significant part in the safety of vertebroplasty. More specifically, cement having a higher viscosity enhances the uniformity of the cement filling, thereby reducing the risk of cement leakage. Specifically, the viscosity sensors 18 monitor changing physical properties triggered by the cement polymerization. In particular embodiments, the sensors monitor acoustic properties of the cement, while in alternate embodiments the sensors monitor electrical properties of the cement. Alternately, other properties of the cement can be monitored, for example using piezo-electric sensors, a conductive grid, photonic sensors, reflective sensors, spectroscopic sensors, etc. The viscosity sensors 18 can be used in vertebroplasty but also in cement guns or delivery systems used in arthroplasty, or in any medical intervention where bone cements are used and where physicians require cement viscosity readings.

In particular embodiments shown in Figs. 13A-13C, the miniature viscosity sensors 18a,b,c include an ultrasound emitter 94a,b,c and an ultrasound receiver 96a,b,c positioned around the syringe body 58. The emitter 94a,b,c sends out an ultrasound signal that goes through the cement and reaches the receiver 96a,b,c. The sensors 18a,b,c measure the pulse attenuation, time delay, traveling speed, and the intensity of the ultrasound signal. These quantities change as the cement polymerizes in the syringe body 58. When these readings are known, the cement properties are determined accurately. The sensors 18a,b,c are non-invasive and non-intrusive, forming an integral and reusable part of the cement delivery system 10. The ultrasound signal can be longitudinal or transversal.

In the embodiment shown in Fig. 13A, both the emitter 94a and receiver 96a of the sensor 18a are integrated into one unit. In the embodiment shown in Fig. 13B, the emitter 94b and receiver 96b of the sensor 18b are two isolated entities or components that are located at the opposite sides of the syringe body 58. In the embodiment shown in Fig. 13C, the receiver 96c and emitter 94c are positioned at two different locations one a same side of the syringe body 58.

The initial pulse and the attenuated pulse are triggered, controlled or regulated and analyzed by the control module 20 (see Fig. 1), as will be described in a following section.

The display unit 22 (see Fig. 1) displays various information obtained from the sensors 18a,b,c, which include for example : the attenuation or dampening of the original signal compared to the received signal, the velocity at which the signal travels through the cement, the delay time which is the time taken by the pulse to travel through the cement, and the Root mean square (RMS) which measures the intensity of the received signal. The delay time and the velocity are interrelated because of the fixed diameter of the syringe.

In alternate embodiments shown in Figs. 14-15 the miniature viscosity sensors 18d,e include dielectric or electro-resistive sensors. The dielectric sensors measure the capacitive and conductive properties of the polymerizing cement, and the electro-resistive sensors measure the resistive properties of the cement. An advantage of the dielectric and electro-resistive sensors is that they can be integrated in the electronic circuit board including the control module 20.

In the embodiment shown in Fig. 14, the dielectric sensor 18d is reusable and is an integral component of the cement delivery system 10. This sensor 18d comprises two thin metallic plates 98 with a convex geometry, or any other appropriate geometry, adapted to partially surround the syringe body 58 and defining a capacitor or condenser. The two plates 98 are spring loaded through springs 100. Once the standard syringe body 58 is placed between the two plates 98, the springs 100 clamp the syringe body 58 and ensure direct physical contact between the two plates 98 and the syringe body 58 filled with the cement. An alternating current is sent through the two plates 98 and the reading of the capacitive and conductive changes on the digital display provide information on the cement polymerization process.

In a particular embodiment, the syringe body 58 has an elliptical or rectangular cross-section, which increases the uniformity of the electric field and as such the stability of the measurements. The rectangular cross-section, or alternately, a square cross-section (the corners of which can be rounded to facilitate sealing with the plunger) advantageously increases the capacity and also provide the advantage of ensuring that the distance between the plates 98 is constant and known, which further increases the stability of the measurements. Alternately, the syringe body 58 can have a more standard round cross-section.

In an alternate embodiment, the plates are integrated into the standard syringe body 58, thereby leading to an instrumented disposable syringe.

Electroless metallic coating can be used to coat the syringe body 58 to form the plates. The functional thickness of the plates is preferably no more than a few microns, mainly because of the capacitive and conductive changes that take place on the atomic level. In a non-invasive version of the sensor, the thin plates are placed on the outer surface of the syringe body 58, in a geometry similar to that of the plates 98 shown in Fig. 14 to define a capacitor or condenser. In an invasive version of the sensor, which can be either a dielectric or an electro-resistive sensor, the plates are positioned on the inner surface of the syringe body 58 (not shown) or on the tip of the plunger 60 to form the sensor 18e shown in Fig. 15. In both cases, the plates act as electrodes of the electro-resistive sensor or as a capacitor of the dielectric sensor. Such instrumented syringes can be produced on a large scale at reasonable cost.

For both reusable and disposable sensors, the electrical signals indicating the change in the capacitive and conductive properties or resistive properties of the cement is processed and analyzed by the control module 20, and displayed on the display unit 22 of the system 10 (see Fig. 1), as will be further detailed in a following section.

Any one of the viscosity sensors 18a,b,c,d,e can take the place of the viscosity sensor 18 of the cement delivery system 10 shown in Fig. 1.

The viscosity sensors 18a,b,c,d,e can define, together with the display unit 22, a viscosity sensing unit which can be used in any medical intervention where bone cements are used and where physicians require cement viscosity readings, and in combination with any other appropriate cement delivery device 16.

Ultrasound miniature viscosity sensor experiment

The ultrasound viscosity sensors 18a,b,c were tested according to the following. An ultrasound pulse was sent to a 10 cc syringe, and the Root Mean Square (RMS), attenuation, and the velocity were measured. We also examined the use of longitudinal versus transverse ultrasound waves in addition to two frequencies of 1 and 5 MHz, although it should be understood that other frequencies can be used. The emitter and receiver were positioned around the syringe using a custom made holder. A pulse generator was used to trigger the initial pulse. The attenuated pulse received was amplified and displayed on the oscilloscope. The data was processed and analyzed using a pc.

The results of the experiment are shown in Figs. 16-17. The times indicated in these figures represent the time after cement mixing. Time 0 is the point in time where the two components were mixed. Likewise, time 600 is ten

minutes after cement mixing. Fig. 16 shows the evolutions of Root Mean Square (RMS) over the period of polymerization of the cement. The curve shows an initial plateau, followed by a significant drop and a slight increase. The curve also shows interesting features around 600 seconds and 800 seconds after the mixing. Fig. 17 shows the attenuation of the signal over time. Both figures show constant change up to roughly 7 minutes. Within two minutes thereafter, there is a significant increase because of the polymerization. Finally, the signal levels off. These two curves are similar to the viscosity curve or the heat production curve when testing cement in a rheometer or a calorimeter.

Dielectric miniature sensor experiment

The dielectric viscosity sensors 18d,e were tested according to the following. In the reusable embodiment, a sensor was custom made to host the syringe filled with cement. In the disposable embodiment, a metallic coating was used to produce the plates on the outer surface of the syringe. Also, some measurements have been taken with an invasive disposable dielectric sensor. For the data acquisition, a RCL meter was used to replace the control module 20 of the system 10 and to measure the capacitive and conductive changes of the cement.

The results are shown in Fig. 18, where the times depicted in the figures indicate the point in time after the cement has been mixed. Fig. 18 shows both the capacitive as well as the conductive changes measured when using the non-contact sensor. It is used as a representation of the results that can be obtained from a dielectric sensor. The figure depicts that significant changes in both capacitive and resistive changes take place as time proceeds and these changes are reproducible and can be used to monitor the advancement of cement polymerization.

Control System 102

Referring to Fig. 19, in a particular embodiment an integrated cement delivery system such as shown in Fig. 1 includes a control system 102. In a particular embodiment, the control system 102 allows the cement delivery system 10 to enhance the uniformity of the cement filling through the controlled injection of a cement of adequate viscosity in a precise and continuous manner, the regulation of the internal and injection pressures, the immediate depressurization of the vertebra, and the monitoring and feedback provided to the physician.

The control system 102 comprises the control module 20, the intravertebral pressure sensors 14, viscosity/curing sensors 18, injection pressure

sensors 90, control panel 24 and a home position switch 104 all sending signals to the control module 20, and the display unit 22 and driving system 62 receiving signals from the control module 20. The home position switch 104 ensures the accurate positioning of the driving system 62. The switch 104 can be, for example, an optical sensor or a mechanical switch, or an external sensor attached to the cannula 12.

The digital display unit 22 is a tool to monitor the cement injection process. The display unit 22 displays data received from the control module 20 such as cement viscosity, total injection pressure, cannula delivery pressure, intravertebral pressure, cement delivery rate or speed, total injected volume, etc. All of these readings are displayed graphically and/or numerically. The display unit 22 can be integrated in the cement delivery device 16 as will be further detailed below. In addition or in the alternative, the display unit 22 can include an external large screen connected to the cement delivery device 16 for better display and readability.

In a particular embodiment, the control module 20 is provided by an electronic circuit board (not shown) including a microprocessor, the electronic circuit board having four objectives: (a) management of the power supply of the sensors 14, 18, 90 and the driving system 62; (b) gathering and processing signals and instructions from the sensors 14, 18, 90 and the physician; (c) advancing the syringe plunger 60 of the cement delivery device 16; and (d) outputting signals for the display unit 22. The electronic circuit board uses the external power supply 26 (see Fig. 1) for objective (a), which in the embodiments shown is a DC power supply of 24V/1 .5-3A. The control module 20 performs the other objectives.

In particular embodiments, the control module 20 has the additional objective of controlling the vacuum applied to the cannula 12a,b,c for bone fluid extraction through a vacuum regulator such as to synchronize the bone fluid extraction with the cement injection, and/or controlling the micro-motor rotating the screw delivery mechanism 43 of the cannula 12b.

In the case where a pneumatic or hydraulic cement delivery device 16 is used, the control module 20 regulates the cement delivery process through adequate proportional, differential or integral mechanisms for regulation.

In the embodiment shown, the inputs of the control module 20 include viscosity or polymerization data from the viscosity sensors 18, injection pressure data (such as injection force) from the injection pressure sensors 90 and intravertebral pressure data from the intravertebral pressure sensors 14. The

signals from the sensors 14, 18, 90 can be amplified and digitized if required, for example if the sensors 14, 18, 90 generate relatively weak analog output signals.

The inputs received by the control module 20 further include a home position signal from the home position switch 104, as well as various control signals coming from the control panel 24, generated when the physician uses the command buttons, switches, knobs, etc. of the control panel 24. In a particular embodiment, the control signals are digital signals. The physician thus controls the injection process directly using the control panel 24. In a particular embodiment, the control signals from the control panel 24 include, for example, the desired cement delivery speed and volume, and commands to turn the system on, open the system to insert a syringe body, ready the plunger and syringe body for cement injection, inject the cement, reset for a different syringe body, reverse flow direction during the cement delivery, aspirate the bone marrow at a given speed, etc.

The outputs of the control module 20 include one or more actuation signals to control the driving system 62. In a particular embodiment, the actuation signals include a first signal starting/stopping the driving system 62, a second signal directing the driving system 62 to turn or translate in one of two opposed directions (e.g. clockwise or counterclockwise rotation) so that the physician can use the system to both fill and empty the syringe body 58, and a third signal providing the speed of the movement of the plunger (e.g. signal in the form of a pulse instructing the driving system 62 to move one step, the control module 20 controlling the speed and number of steps, and as such the displacement of the plunger 60, through the number and rate of the pulses). In a particular embodiment, a driver (not shown) is interposed between the control module 20 and the driving system 62 in order to implement the actuation signal(s). The driver can be in the form of hardware or alternately be programmed in the microprocessor of the circuit board providing for the control module 20.

The other outputs of the control module 20 include the data to be displayed on the display unit 22 as mentioned above (e.g. viscosity, pressures, cement delivery rate or speed, total injected volume), as well as actuation signals to the micro-motor of the screw delivery mechanism 43 and/or to the vacuum system of the cannula 12a,b,c, if required.

In use and in a particular embodiment, the physician gives a command to open the device so that a syringe body can be inserted therein, for example by pressing a corresponding button on the control panel 24 to produce a corresponding control signal, preferably at the point of time of cement mixing.

This causes the control module 20 to command the driving system 62 with the corresponding actuation signal(s) to move the syringe plunger 60 backwards until the home position switch 104 is activated, emitting the home position signal. Upon reception of the home position signal, the control module 20 stops the driving system 62 with the appropriate actuation signal(s), and the physician inserts the new syringe body 58. In this example the syringe body 58 is inserted in the delivery device already filled with cement, however as mentioned above the syringe body can alternately be inserted when empty and the system can be used to fill the syringe body with cement prior to injection.

When the syringe body 58 is inserted in the cement delivery device 16, the physician gives a second command to move the plunger 60 to an initial position for injection, for example by pressing a corresponding button on the control panel 24 to produce a corresponding control signal. This would typically occur soon (e.g. approximately one minute or less) after mixing of the cement. Upon reception of the control signal corresponding to the second command, the control module 20 instructs the driving system 62 to move the plunger 60 forward, for example step by step, with the corresponding actuation signal(s), until the injection pressure sensor 90 provides injection force data indicating that the plunger 60 is beginning to inject the cement from the syringe body 58. The control module 20 reads the data coming from the injection pressure sensor 90 and the other sensors 14, 18. Upon reception of the adequate injection force data, the driving system 62 is stopped by the control module 20 with the adequate actuation signal(s), and the control module 20 starts to continually send information to display on the display unit 22 and/or a computer.

After the plunger 60 is in position, the physician gives a third command to inject the cement, for example by pressing a corresponding button on the control panel 24 to produce a corresponding control signal. The physician typically gives this third command when the display unit 22 shows that the cement viscosity is appropriate. The control module 20 reads the data from the sensors 14, 18, 90, and calculates the needed injection force and the corresponding parameters (e.g. torque, speed) of the driving system 62. The control module 20 then activates the driving system 62, and as such the cement injection, through use of the corresponding actuation signal(s), in order to move the plunger 60 in a displacement-controlled, continuous manner. As well, at the same time, the control module 20 sends all the necessary information, including the data from the sensors 14, 18, 90, to the display unit 22 and/or computer. In a particular embodiment, the control module 20 only moves the driving system 62 as long as

the physician gives the corresponding injection command, for example by holding a button depressed in the control panel 24, and if the command is broken (e.g. button released), the control module 20 stops the driving system 62 with the appropriate actuation signal(s) so that the injection is halted.

In a particular embodiment, the control module 20 provides pressure pulsations on the cement during delivery through actuating the driving system 62 in a pulsed manner. Pulsation enhances cement flow, and reduces the delivery pressure. An adequate mode of pulsation changes as the cement polymerizes. The pulsation mode will likely depend on the cement, and can be determined using a rheometer.

The cement delivery device 16 can also deliver haptic feedback of the intravertebral pressure to the physician. The control module 20 in this case gathers intravertebral signals, magnifies them, and sends a feedback signal to generate a contact force on the physician's hand during cement delivery, for example through a portion of the control panel 24. This feedback can be integrated in all designs.

Global design

The cement delivery device 16 can be presented in a plurality of various exterior designs to achieve the present invention, any one of which can include and enclose any one of the mechanisms shown in Figs. 8-10, a combination thereof, or any other appropriate mechanism transmitting power from the driving 62 to the syringe plunger 60.

Fig. 20 illustrates a particular embodiment 16d of the cement delivery device 16, which is in the shape of a cement gun and is simple and portable. The device 16d comprises three principle parts: a body HOd, a handle 112, and a syringe 114. The body 11Od includes on a top face thereof the display unit 22, for example in the form of a LCD display screen, and command buttons 118 forming part of the control panel 24 to ensure easy access and utilization, the command buttons 118 allowing the physician to generate the control signals described above and shown in Fig. 19. The device 16d is operated by the handle 112, which is solidly attached to the body HOd. The handle 112 includes a command button 120 on the front thereof to control the cement injection, forming a second part of the control panel 24. In a particular embodiment, the command button 120 allows the physician to give the third or injection command described above.

Once the syringe 114 is filled with cement, it is positioned in a cylindrical cavity defined in a block 122 which is part of the body 11Od. The

device 16d also includes a translucent syringe support 124 that is screwed into the block 122. This stabilized the syringe 114 and eases the injection.

Fig. 21 illustrates another particular embodiment 16e of the cement delivery device 16, which is a portable apparatus comprising two principle parts: a body HOc and a syringe 114. The body HOe provides an easy to use and consistent interface, including the display unit 22, for example in the form of a large LCD display, and command buttons 126 defining part of the control panel 24 and located directly underneath the display unit 22 for easy access. In a particular embodiment, the command buttons 126 allow the physician to generate some of the control signals described above and shown in Fig. 19. The body 11Oe also includes two flexible levers 128 placed on opposite sides of the display unit 22 and forming another part of the control panel 24, to allow the physician to provide others of the control signals described above, such as for example the desired injection volume and speed of the cement. The body 11Oe is curved on both sides to allow for comfortable hand control of the levers 128.

Fig. 22 illustrates another particular embodiment 16f of the cement delivery device 16, which is also simple and easy to use. The device 16f is vertically attached to a fixing bar 130, for example by surrounding fastener tightened by a screw, allowing the position of the device 16f to be easily adjusted on the bar 130.

The device 16f comprises three principle parts: a body 11Of, the fixing bar 130, and a syringe 114. The body 11Of includes on a side thereof a syringe support 140 that secures the syringe 114 once it is filled with cement. A pushrod such as shown for example at 78a,b in Figs. 8-9 protrudes from the body 11Of and engages the plunger 60 of the syringe 114, such that the movement to the pushrod 78a,b activates the plunger 60 which moves inside the syringe body 58 to force the injection of the cement.

The device 16f includes the display unit 22 on a front face of the body 11Of, for example in the form of a large LCD display, thus improving visibility and access to the results. The control panel 24 is in the form of command buttons 136 placed underneath the display unit 22 where they are easily accessible. In a particular embodiment, the command buttons 136 allow the physician to generate the control signals described above and shown in Fig. 19. The body 11Of further includes, on a side thereof, a button 138 to control a light.

Fig. 23 shows a design for the cement delivery system 10 according to a particular embodiment which allows reduced x-rays exposure for the physician. The device 16f of Fig. 22 is shown supported by a flexible arm 142 which is

attached to an upright post 144 extending from a base 146. Also supported on the post in an auxiliary control panel 148 allowing remote control of the position of the arm 142 and/or the same controls/commands provided by the control panel 24. Further supported on the post are auxiliary display units 150 providing a larger, easier to read display for the information displayed on the display unit 22 and/or any additional pertinent information, such as fluoroscopic visualization data. It is understood that the configuration of Fig. 23 can alternately be used with any other appropriate design for the cement delivery device 16.

The elements of the cement delivery device 10 thus help improve bone cement injection procedures, such as vertebroplasty. The displacement controlled cement delivery device 16a,b,c advantageously provides for a continuous, slow and precise cement delivery, with an injection pressure exceeding pressures that can be manually applied, thus allowing for thicker cement to be delivered. The viscosity sensors 18 provide for real time, in-situ monitoring of the cement curing, within the syringe body 58, thus allowing for the cement to be injected at its optimum viscosity. The cannulae 12a,b,c allow for bone marrow aspiration simultaneously with bone cement injection, which guides the bone cement within the bone as well as reduces the risks of emboli. The cannulae 12a,b,c with an intervertebral or other inner bone pressure sensor 14, either connected to a cannula conduit or embedded in the cannula itself, allow for monitoring of the intravertebral pressure, to ensure that there is no excess pressure within the bone, as well as for providing an indication that cement leakage is about to occur or is starting when a sudden drop of pressure is detected. The syringe equipped with a pressure sensor 90 allows for the determination of the injection pressure, which provides information on the pressure drop within the cannula and as such on the viscosity of the bone cement. Any one of these elements can be integrated in a typical cement delivery system, or alternately be combined with any one, any group of, or all of the others.

In a particular embodiment, the cement delivery system 10 is an integrated cement delivery system and includes the displacement-controlled cement delivery device 16a,b,c, the pressure sensors 14 and/or 90, the viscosity sensors 18, and the control system 102 including the control module 20, the display unit 22 and the control panel 24. This integrated system advantageously improves the safety and predictability of cement delivery, by providing warnings when the pressure is out of normal ranges, controlling the delivery of bone cement, and insuring that the cement has an appropriate viscosity on delivery to minimize the risk of leakage.

The cement delivery system 10 of the present invention allows the physician to control cement delivery by deciding on the injection rate and mode, total injection volume, and period of cement delivery. If required, the physician can adjust and overwrite the settings of the system 10.

The cement delivery system 10 described herein provides the advantage of concomitantly overcoming the limitation of excessive pressure and providing assistance to enhancing filling uniformity such as to reduce the risk of cement leakage. Additionally, the cost effective system 10 can be simply incorporated into the vertebroplasty procedure without substantially affecting or changing how the procedure is performed. Another advantage is that it provides physicians with real time monitoring of the cement delivery process, which is vital to guiding the intravertebral flow and preventing leakage, instead of reacting to visual fluoroscopic clues once leakage has occurred. Thus, the cement delivery system 10 allows the physician to prevent, or at least reduce the risk of, leakage rather than detecting it.

The system 10 also allows the guiding of the intravertebral cement filling during cement delivery, for example with the cannulae 12a,b,c, thereby enhancing filling uniformity and reducing leakage risk. Flow guidance is also improved by delivering cement of adequate viscosity. The miniature viscosity sensors 18 provide constant readings of polymerizing cement viscosity such as to inject cement having an optimal viscosity.

The system 10 ensures slow and continuous cement delivery, thereby leading to low intravertebral pressure and enhancing smoothness and precision of delivery. Accurate cement delivery and low pressure reduces leakage risk. More explicitly, precise delivery ensures exact filling volume, thereby reducing undesired excess cement which increases leakage risk. Continuous delivery results in steady flow, thereby reducing undesired transient peaks in pressure which augment leakage risk. Displacement-controlled delivery leads to stable cement flow conditions, thereby reducing the risk of sudden uncontrolled flow, which is difficult to monitor under fluoroscopy. Delivery forces of at least 2 KN reduce the risk of insufficient filling when delivering thick cement. With live monitoring of pressures and viscosity during procedures, physicians are alerted by acoustic or visual signals when polymerizing cement attains adequate viscosity of safe delivery. With this strengthening tool, physicians are alerted when delivery results in high unsafe pressures. Finally, with slow cement delivery, the physician has sufficient time to monitor intravertebral filling and if necessary to intervene,

thereby preventing further leakage. The extended time of monitoring and reaction combined with fluoroscopic visualization enhance procedural safety.

The system 10, through the designs shown for the devices 16d,e,f, is ergonomically designed. The cement delivery device 16 is light and in a particular embodiment weighs approximately 0.5 kg. Physicians interact with it in a simple manner. The system 10 is also economical in design, with the main components being reusable. Disposable items are specialized syringes and cannulae, which can be bundled in a set.

The system 10 resulted from a thorough biomechanical understanding of the cement delivery process and forces governing the intravertebral flow in vertebroplasty. The system 10 and currently used fluoroscopic visualization can advantageously complete each other by attacking the problem from two different, yet, complimentary angles, the system 10 allowing a substantial reduction in the risk of leakage while the fluoroscopic visualization allowing the detection of leakage if leakage does occur. Thus, when combined together the two methods can provide a safer and more reliable vertebroplasty procedure, assisting the physician in foreseeing and preventing cement leakage.

CLAIMS

1. A bone cement delivery system comprising a rigid cannula having:

a tubular inner wall defining and surrounding a central conduit for bone cement delivery, the inner wall defining a distal outlet of the central conduit at a distal end of the cannula;

a tubular outer wall extending around the inner wall and spaced apart therefrom to define a peripheral conduit around the central conduit, the outer wall defining a distal inlet of the peripheral conduit at the distal end of the cannula; and

a proximal end of the cannula including a proximal inlet in communication with the central conduit and a proximal outlet in communication with the peripheral conduit.

2. The bone cement delivery system according to claim 1, further comprising a tubular middle wall extending between the inner and peripheral walls and spaced apart therefrom to define a middle conduit around the central conduit, the peripheral conduit being defined around the middle conduit.

3. The bone cement delivery system according to claim 2, further including a pressure sensor connected to the proximal end of the cannula such as to sense an internal pressure at the distal end of the cannula through the middle conduit.

4. The bone cement delivery system according to claim 1, further including a pressure sensor connected to the proximal outlet such as to sense an internal pressure at the distal inlet through the peripheral conduit.

5. The bone cement delivery system according to claim 1, further including a rotatable screw delivery mechanism extending within the central conduit along a length thereof.

6. The bone cement delivery system according to claim 5, wherein the rotatable screw delivery mechanism includes an inner conduit defined therewithin and along a length thereof, the inner conduit being concentric with the central conduit.

7. The bone cement delivery system according to claim 6, further including a pressure sensor connected to a proximal outlet of the inner conduit such as to sense an internal pressure at the distal end of the cannula through the inner conduit.

8. The bone cement delivery system according to claim 1, wherein the tubular inner wall defines a rotatable screw delivery mechanism extending within the peripheral conduit along a length thereof, such that the central conduit is defined inside the screw delivery mechanism.

9. The bone cement delivery system according to claim 1, further including an elastic and permeable membrane covering the distal outlet of the central conduit for delivery of injected fluid therethrough.

10. The bone cement delivery system according to claim 9, wherein the cannula is used to deliver bone cement, and the membrane has a permeability of approximately 10% that of osteoporotic cancellous bone.

11. The bone cement delivery system according to claim 9, wherein the size and elasticity of the membrane is such as to define an expanded diameter of at most 5 mm.

12. The bone cement delivery system according to claim 1, wherein the peripheral wall includes fenestrations defined therein in communication with the peripheral conduit.

13. A method of injecting bone cement within a bone, comprising:

injecting bone cement within the bone through a surgical site; and

at least one of aspirating fluid from the bone through said surgical site simultaneously with the bone cement injection and measuring an internal pressure of the bone through said surgical site simultaneously with the bone cement injection.

14. The method according to claim 13, wherein the method comprises aspirating the fluid from the bone through said surgical site simultaneously with the bone cement injection and measuring the internal pressure of the bone through said surgical site simultaneously with the bone cement injection.

15. The method according to claim 13, wherein the method comprises aspirating the fluid from the bone through said surgical site simultaneously with the bone cement injection, and wherein injecting the bone cement is performed at a first flow rate and aspirating fluid from the bone is performed at a second flow rate, the second flow rate being equal to or slightly higher than the first flow rate such that the injected cement takes a place of the aspirated fluid.

16. The method according to claim 13, further including inserting a cannula in the bone through said surgical site, and wherein injecting the bone cement includes injecting the bone cement through a first conduit of the cannula, and the at least one of aspirating the fluid and measuring the internal pressure is performed through at least a second conduit of the cannula.

17. The method according to claim 13, wherein the bone is a vertebra, and measuring the internal pressure of the bone includes at least one of measuring a cement infiltration pressure required to force the cement to penetrate a cavity of the vertebra and measuring an intravertebral bone marrow pressure.

18. A bone cement delivery device, comprising:

a syringe body for containing the bone cement;

a plunger snuggly and slidably received within the syringe body for pushing the bone cement out of the syringe body; and

a driving system connected to the plunger and sliding the plunger within the syringe body in a displacement-controlled and continuous manner to produce a steady flow of bone cement out of the syringe body.

19. The bone cement delivery device according to claim 18, wherein the driving system slides the plunger in a stepped manner.

20. The bone cement delivery device according to claim 18, wherein the driving system applies a force approximately 2 KN on the plunger against the bone cement.

21. The bone cement delivery device according to claim 18, wherein the driving system slides the plunger to obtain a flow rate of bone cement out of the syringe body of at most 1Oml/min.

22. The bone cement delivery device according to claim 18, wherein the driving system includes one of an electric motor, a hydraulic system and a pneumatic system.

23. The bone cement delivery device according to claim 18, wherein the driving system slides the plunger to inject a given quantity of bone cement out of the syringe body, the given quantity having at least a precision of 50 micro liters.

24. The bone cement delivery device according to claim 18, further including a display unit displaying information on a quantity of bone cement injected from the syringe body.

25. The bone cement delivery device according to claim 18, wherein the cement delivery device further include at least one pressure sensor for measuring a pressure applied by the plunger on the bone cement.

26. The bone cement delivery device according to claim 25, wherein the at least one pressure sensor include a strain gauge or a loading cell connected to the plunger.

27. The bone cement delivery device according to claim 18, further including a cannula having a proximal end connected to an outlet of the syringe body and a distal end, the cannula including a pressure sensor for measuring a pressure at the distal end.

28. The bone cement delivery device according to claim 18, wherein the device further includes a cannula defining a bone cement conduit having a constant diameter throughout a length thereof, and the syringe includes a tapered distal end defining an outlet connected to the bone cement conduit of the cannula, the tapered end providing a progressive and constant diameter reduction between a remainder of a body of the syringe and the bone cement conduit.

29. The bone cement delivery device according to claim 28, wherein the tapered end forms- an angle of approximately 45° with the remainder of the syringe body.

30. The bone cement delivery device according to claim 18, further comprising at least one sensor for measuring a physical parameter of the bone cement within the syringe body, the at least one parameter being indicative of a viscosity of the bone cement.

31. A bone cement delivery device comprising:

a body for containing the bone cement therein and for progressively injecting the bone cement therefrom for delivery into the bone;

at least one sensor for measuring a physical parameter of the bone cement within the body, the at least one parameter being indicative of a viscosity of the bone cement; and

a display unit receiving data from the sensor and displaying at least one of the physical parameter and the viscosity of the bone cement.

32. The bone cement delivery device according to claim 31, wherein the sensor includes at least one of a dielectric, an electro-resistive, an electric and an ultrasound sensor.

33. The bone cement delivery device according to claim 31, wherein the sensor is integral with the body.

34. The bone cement delivery device according to claim 33, wherein the sensor includes a metallic coating on a surface of the body, the metallic coating defining a capacitor.

35. The bone cement delivery device according to claim 31, wherein the sensor includes at least one electrode in contact with the bone cement.

36. The bone cement delivery device according to claim 31, wherein the sensor includes metallic plates removably clamping the body therebetween, the metallic plates defining a capacitor.

37. The bone cement delivery device according to claim 31, wherein the sensor includes an ultrasound receiver and an ultrasound emitter positioned around the body in functional relationship with one another.

38. A viscosity sensing unit for a bone cement delivery device, the unit comprising:

at least one sensor for measuring a physical parameter of the bone cement directly within the bone cement delivery device, the at least one parameter being indicative of a viscosity of the bone cement; and

a display unit receiving data from the sensor and displaying at least one of the physical parameter and the viscosity of the bone cement.

39. The viscosity sensing unit according to claim 38, wherein the sensor includes at least one of a dielectric, an electro-resistive, an electric and an ultrasound sensor.

40. The viscosity sensing unit according to claim 38, wherein the sensor includes metallic plates for removably clamping a body of the delivery device therebetween, the body containing the bone cement and the metallic plates defining a capacitor.

41. The viscosity sensing unit according to claim 38, wherein the sensor include an ultrasound receiver and an ultrasound emitter positioned around a body of the delivery device, the body containing the bone cement.

42. The viscosity sensing unit according to claim 38, wherein the sensor includes at least one electrode in contact with the bone cement.

43. A method of injecting bone cement within a bone, comprising monitoring at least one parameter indicative of a viscosity of the bone cement directly within a bone cement delivery device, and injecting the bone cement in the bone with the delivery device based on the at least one parameter.

44. The method according to claim 43, wherein the monitoring of the at least one parameter is performed in real time.

45. The method according to claim 43, further comprising recording viscosity data provided by the monitoring of the at least one parameter throughout the injection of the bone cement.

46. The method according to claim 43, wherein monitoring the at least one parameter includes monitoring at least one of electrical and acoustic properties of the bone cement.

47. A control system for a bone cement delivery device, the control system comprising:

a delivery pressure sensor for measuring a cement delivery pressure and producing corresponding delivery pressure data;

a control panel for receiving commands from a user and producing corresponding command data;

a driving system for actuating the cement delivery device to deliver the bone cement;

a control module for receiving the command data and the delivery pressure data, and for sending a control signal actuating the driving system based on the command data and the delivery pressure data such as to deliver the bone cement in a steady flow; and

a display unit for receiving the pressure data from the control module and displaying delivery pressure information based on the delivery pressure data.

48. The control system according to claim 47, wherein the control module is part of an electronic circuit board.

49. The control system according to claim 47, further comprising a viscosity sensor for measuring at least one parameter of the bone cement within the cement delivery device and producing corresponding viscosity data, the at least one parameter being indicative of a viscosity of the bone cement, and wherein the control module receives the viscosity data and sends the viscosity data to the display unit, the display unit displaying viscosity information based on the viscosity data.

50. The control system according to claim 47, further comprising an internal pressure sensor for measuring an internal pressure within the bone and producing corresponding internal pressure data, and wherein the control module receives the internal pressure data and sends the internal pressure data to the display unit, the display unit displaying internal pressure information based on the internal pressure data.

51. The control system according to claim 47, wherein the control module sends the control signal such as to actuate the driving system at a constant speed.

52. The control system according to claim 47, wherein the control module sends the control signal such as to actuate the driving system in a stepped manner.

53. The control system according to claim 47, further comprising a vacuum regulator for regulating an application of vacuum to aspirate bone fluid from the bone, the control module further sending an additional control signal actuating the vacuum regulator in coordination with the actuation of the driving system.

54. The control system according to claim 47, wherein the control panel is adapted to generate a feedback force on the user, the control module further sending a feedback signal to the control panel for generating the feedback force based on the delivery pressure data.

55. An integrated cement delivery system comprising:

a cement delivery device including a syringe body for containing the bone cement, a plunger slidably received within the syringe body for pushing the bone cement out of the syringe body, and a driving system connected to the plunger and sliding the plunger within the syringe body;

an injection pressure sensor measuring an injection pressure of the cement within the syringe body;

a control system controlling the driving system in a displacement-controlled and continuous manner to produce a steady flow of bone cement out of the syringe body based on data from the injection pressure sensor and commands from a user; and

a display unit displaying the data from the injection pressure sensor.

56. The cement delivery system according to claim 55, further comprising a cannula connected to an outlet of the syringe body, and an internal

pressure sensor measuring a pressure at a distal end of the cannula, the display unit displaying data from the internal pressure sensor.

57. The cement delivery system according to claim 55, further comprising viscosity sensors measuring at least one parameter of the bone cement within the syringe body, the at least one parameter being indicative of a viscosity of the bone cement, the display unit displaying data from the viscosity sensor.

58. A method of extracting marrow from a bone, comprising injecting a thick liquid in the bone through a surgical site, displacing the marrow with the thick liquid, and extracting the marrow through said surgical site simultaneously with the thick liquid injection.

59. The method according to claim 58, further including inserting a cannula in the bone through said surgical site, and wherein injecting the thick liquid includes injecting the liquid through a first conduit of the cannula, and extracting the marrow includes extracting the marrow through a second conduit of the cannula.

60. A method of rinsing marrow within a bone, comprising inserting a cannula in the bone, injecting a liquid in the bone through a first conduit of the cannula, and creating a pressure gradient between the first conduit and a second conduit of the cannula.

61. The method according to claim 60, wherein the liquid is injected in a pulsating manner.

62. A medical cannula comprising:

at least one tubular wall defining and surrounding an injection conduit, the wall defining a distal outlet of the injection conduit at a distal end of the cannula, and a proximal end of the cannula including a proximal inlet in communication with the injection conduit; and

an elastic and permeable membrane covering the distal outlet of the injection conduit for delivery of injected fluid therethrough.

63. In combination, a cannula and a syringe body, the cannula defining an injection conduit having a constant diameter throughout a length thereof, and

the syringe body includes a tapered distal end defining an outlet connected to the injection conduit of the cannula, the tapered distal end providing a progressive and constant diameter reduction between a remainder of the syringe body and the injection conduit.

64. The combination according to claim 62, wherein the tapered distal end forms an angle of approximately 45° with the remainder of the syringe body.

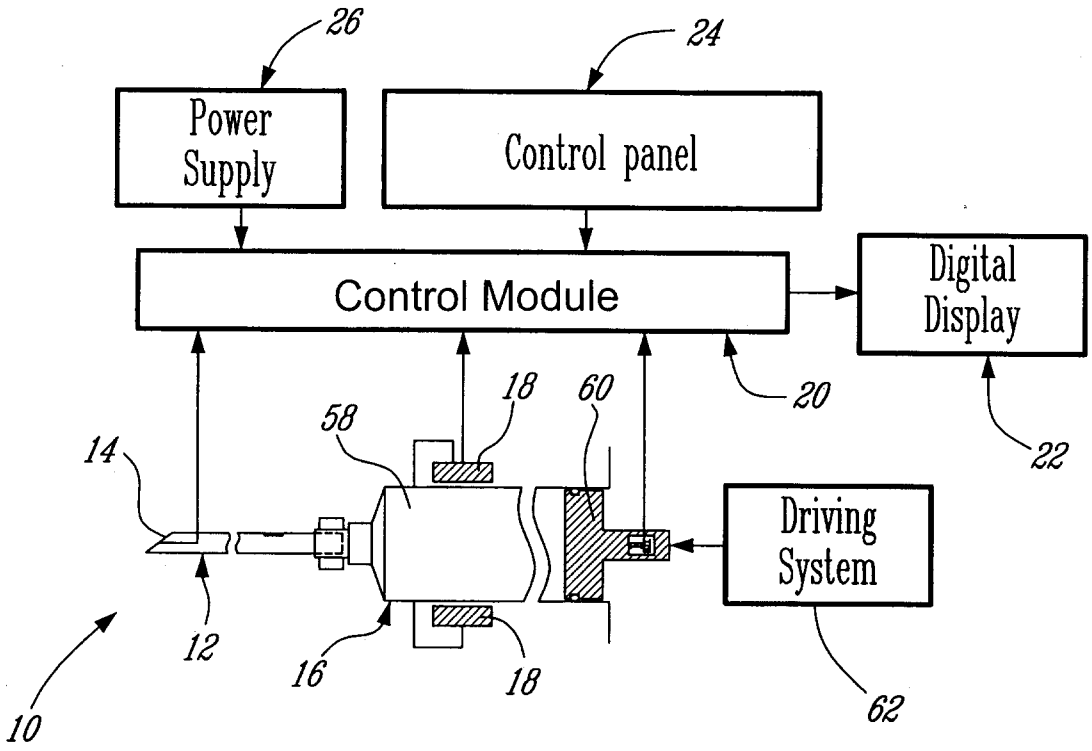
26
24
Power Supply
Control panel
Control Module
Digital Display
18
60
58
20
22
14
Driving System
12
16
18
10
62

Fig. 1

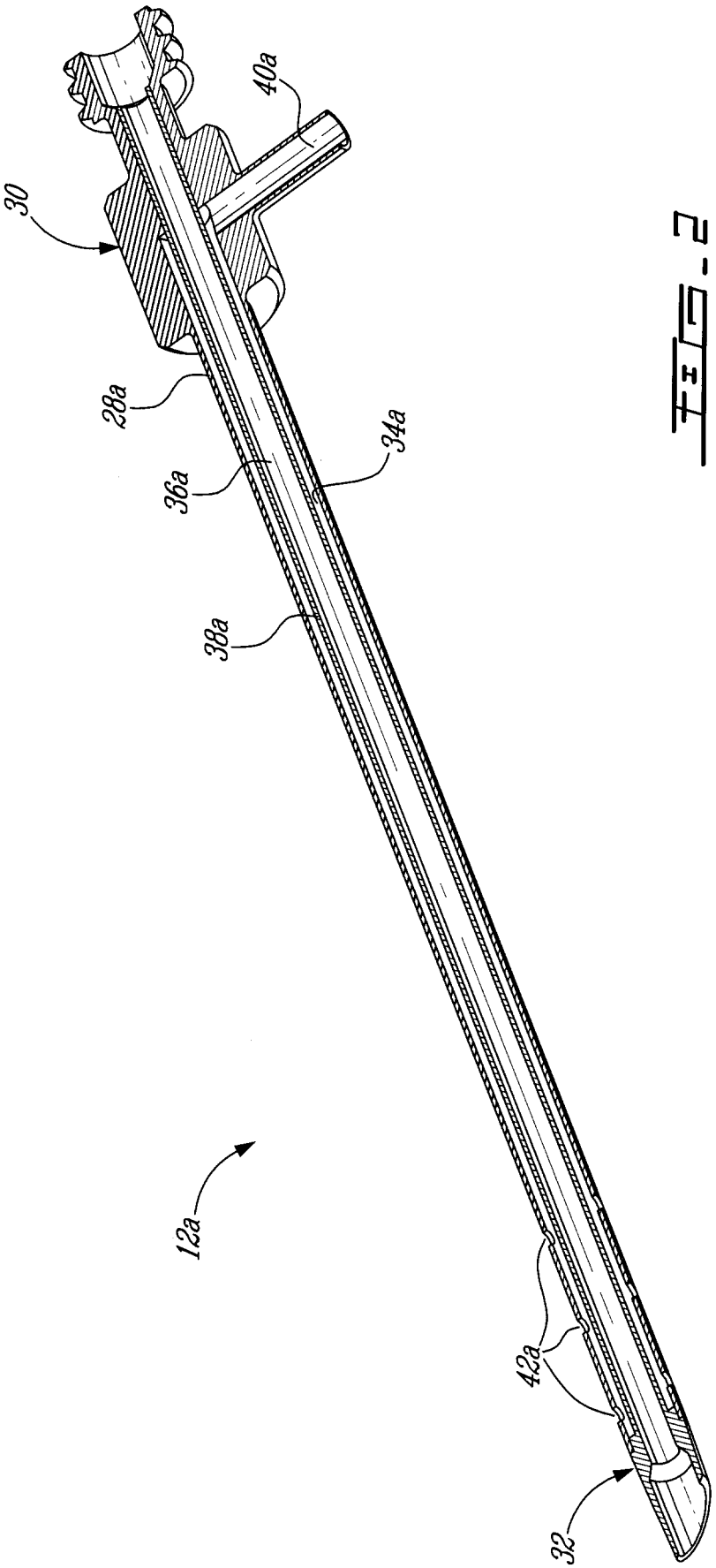

Fig. 2

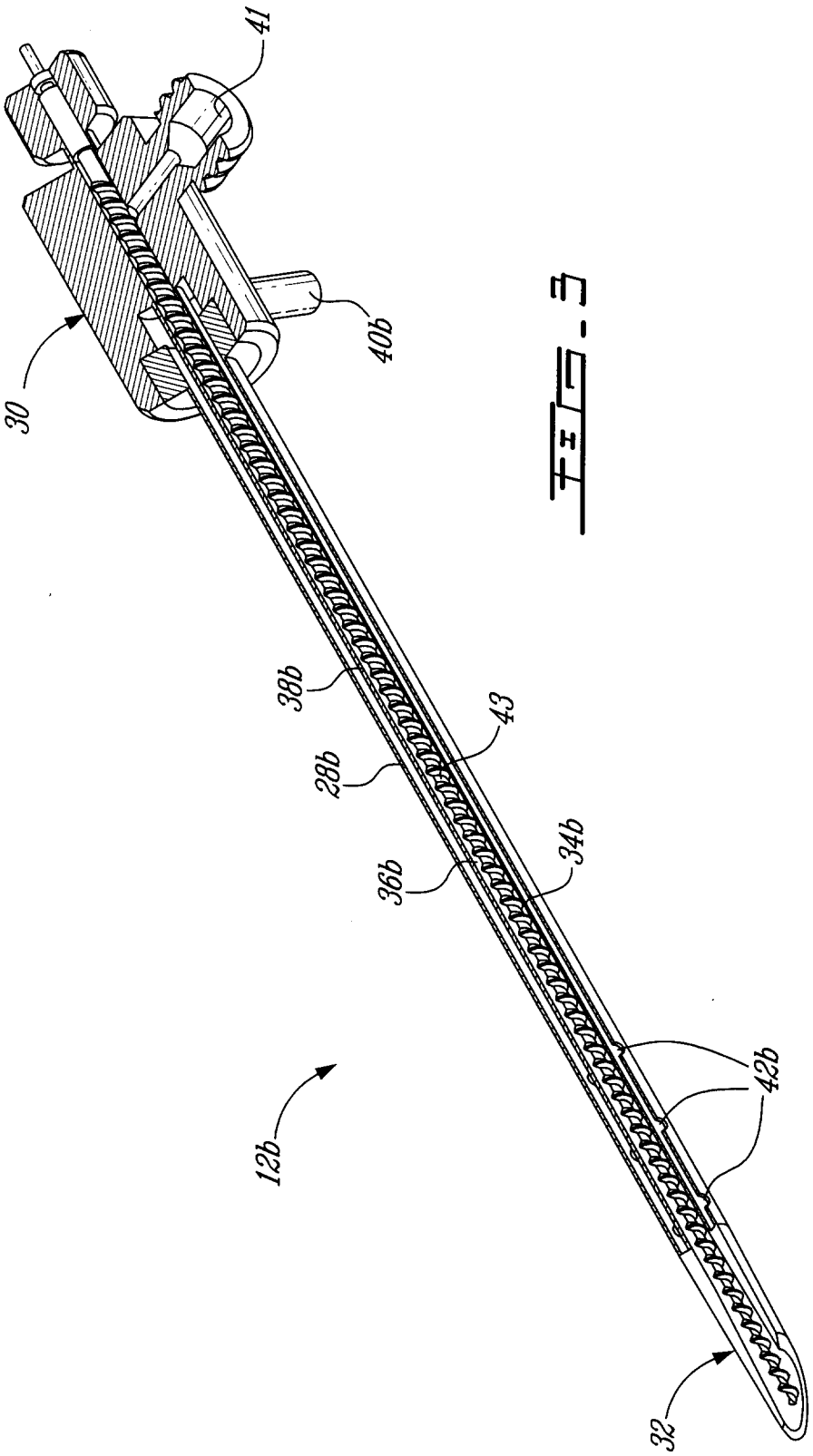

Fig. 3

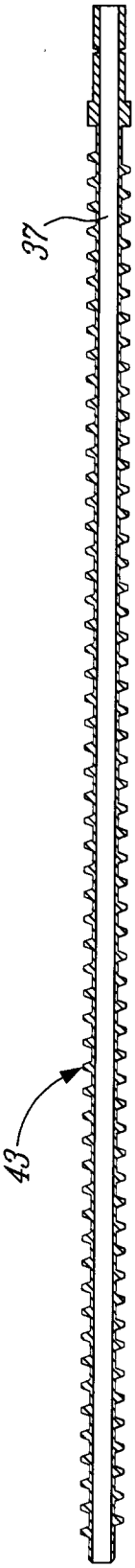

FIG. 4

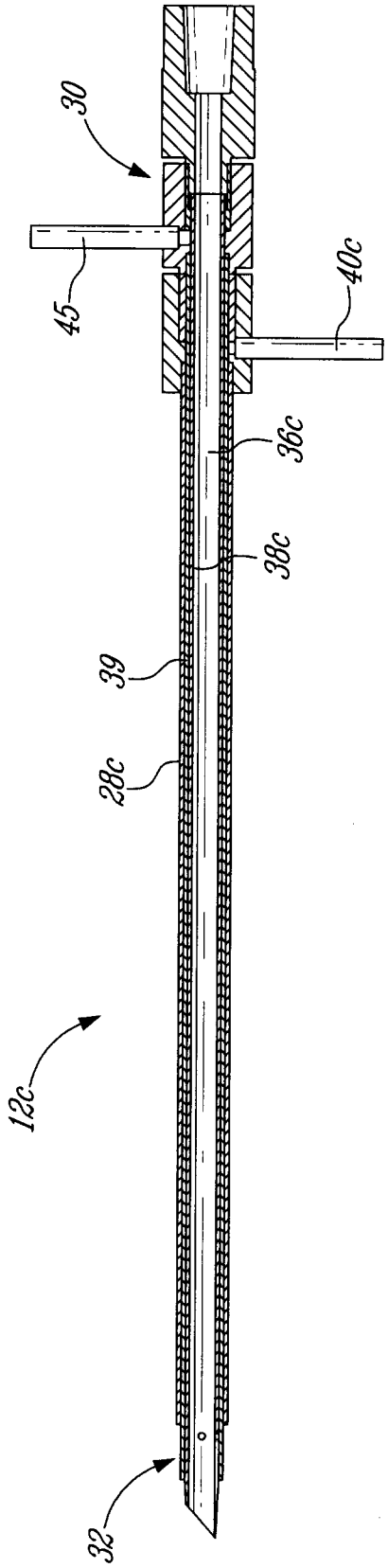

FIG. 5A

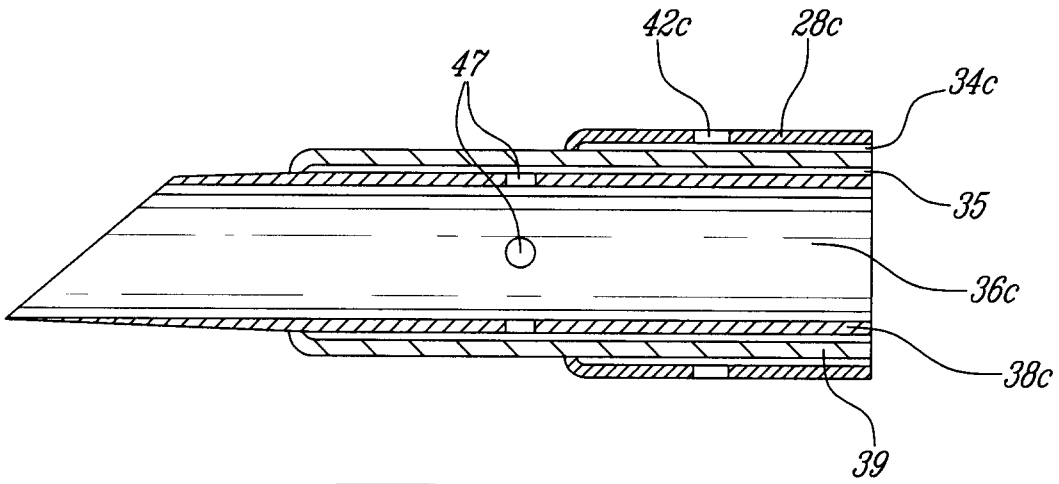

Fig. 5B

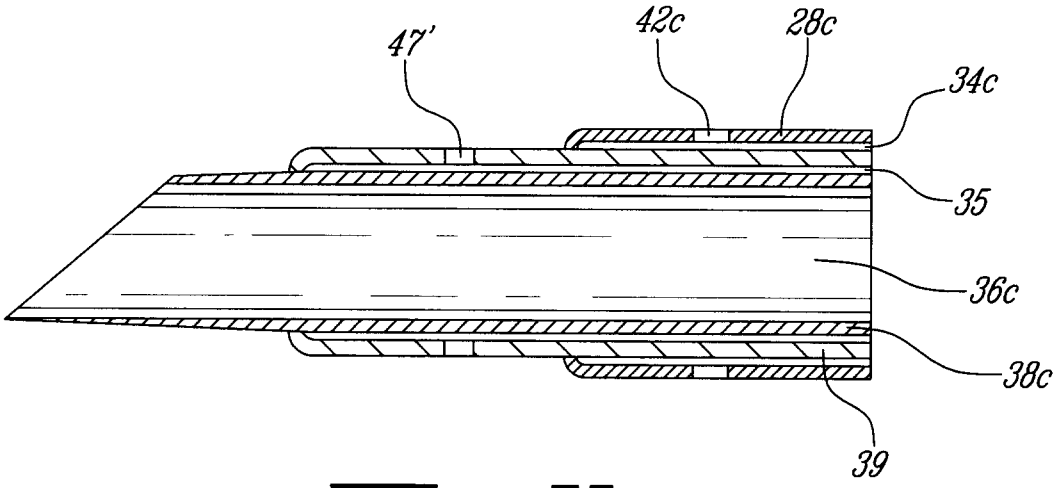

Fig. 5C

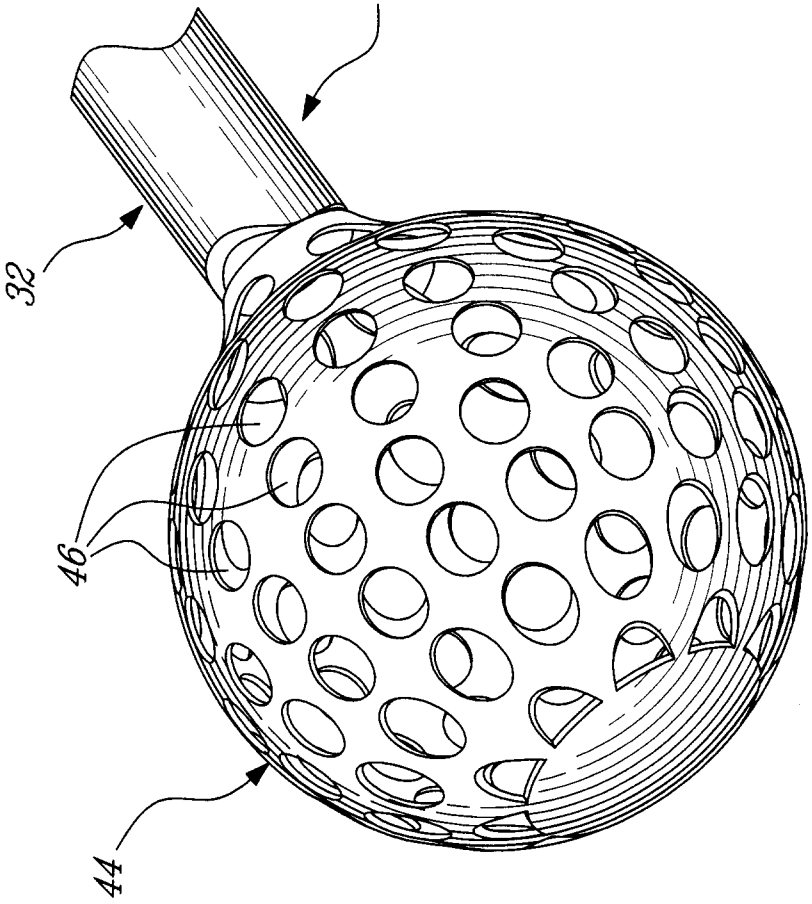

FIG. 6

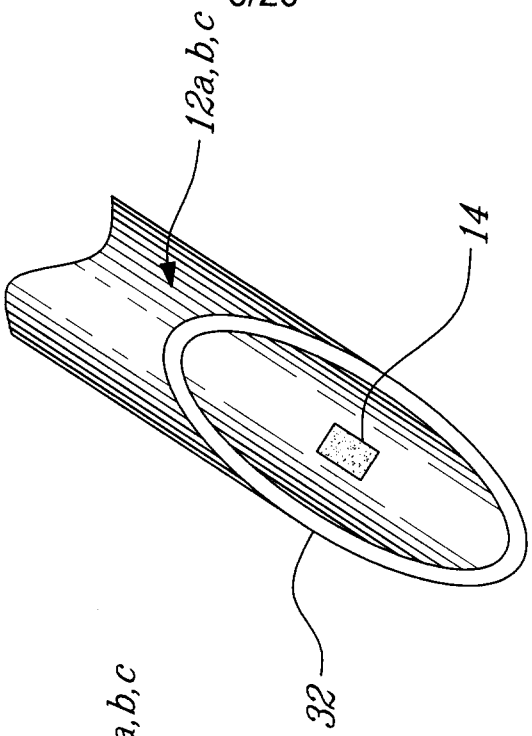

FIG. 7

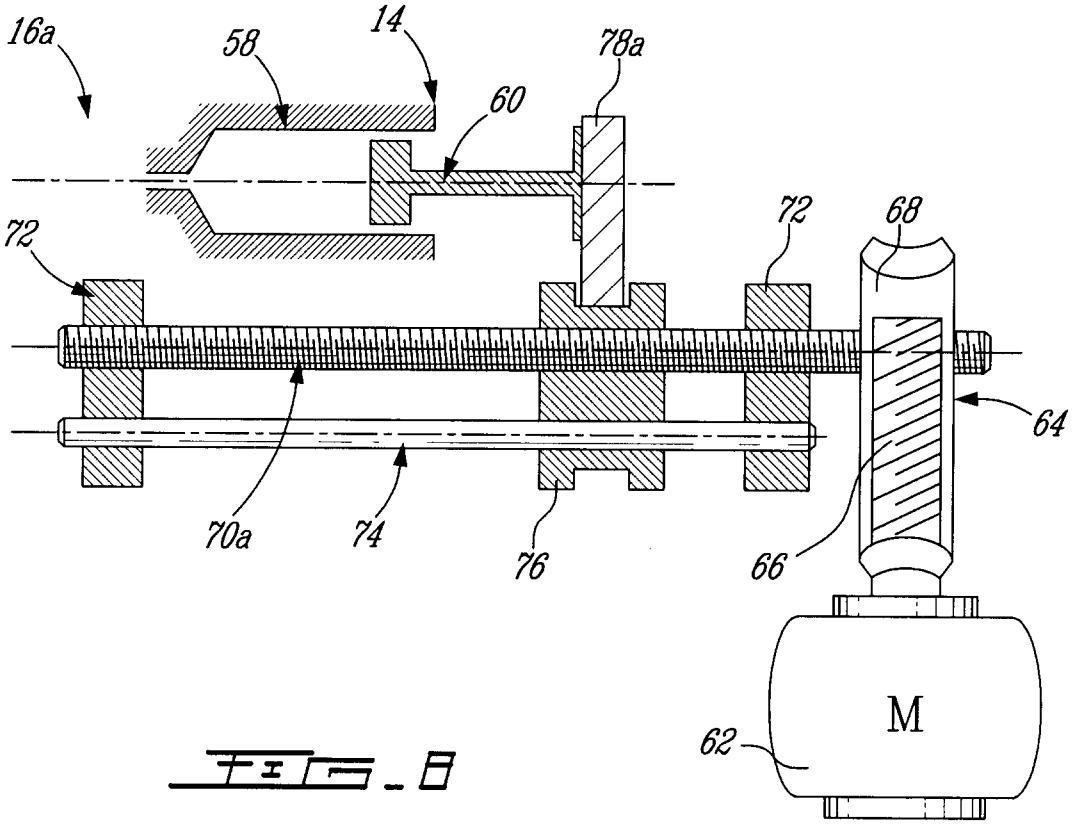
16a
58
14
78a
60
72
68
72
64
70a
74
76
66
M
62

Fig. 8

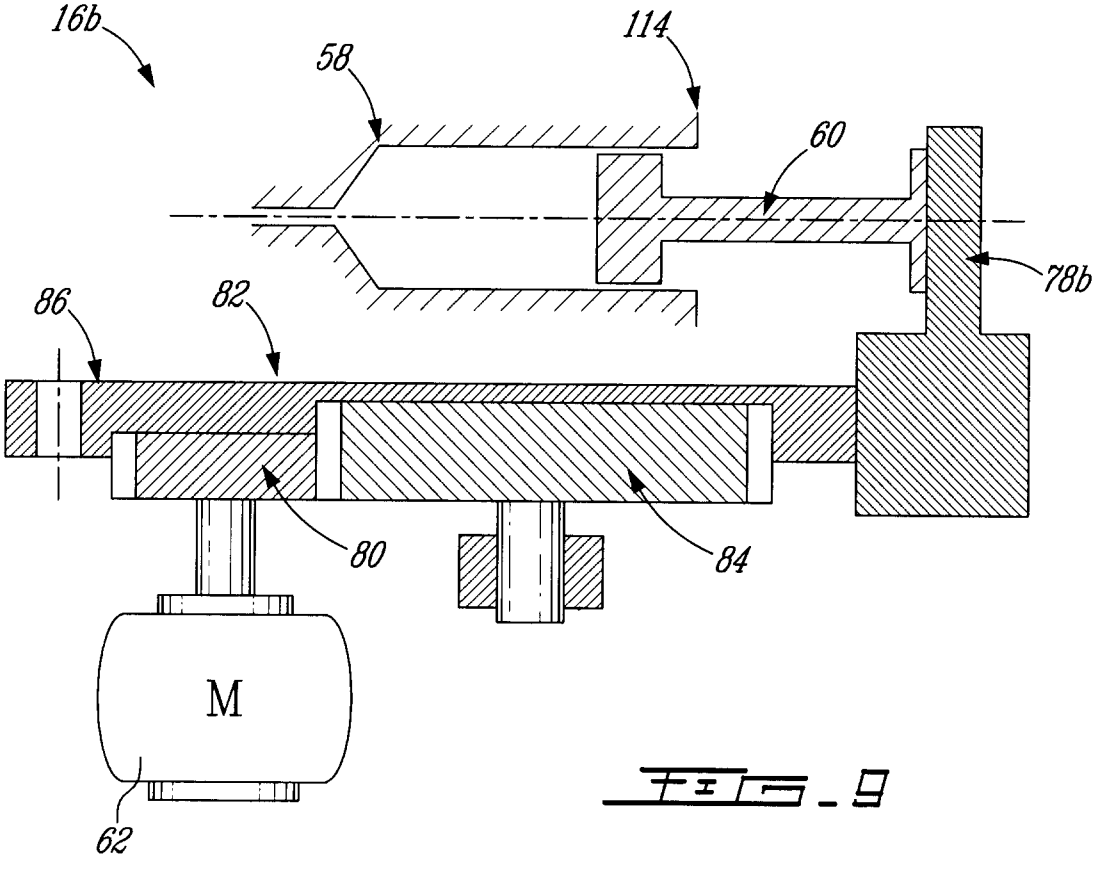
16b
58
114
60
78b
86
82
80
84
M
62

Fig. 9

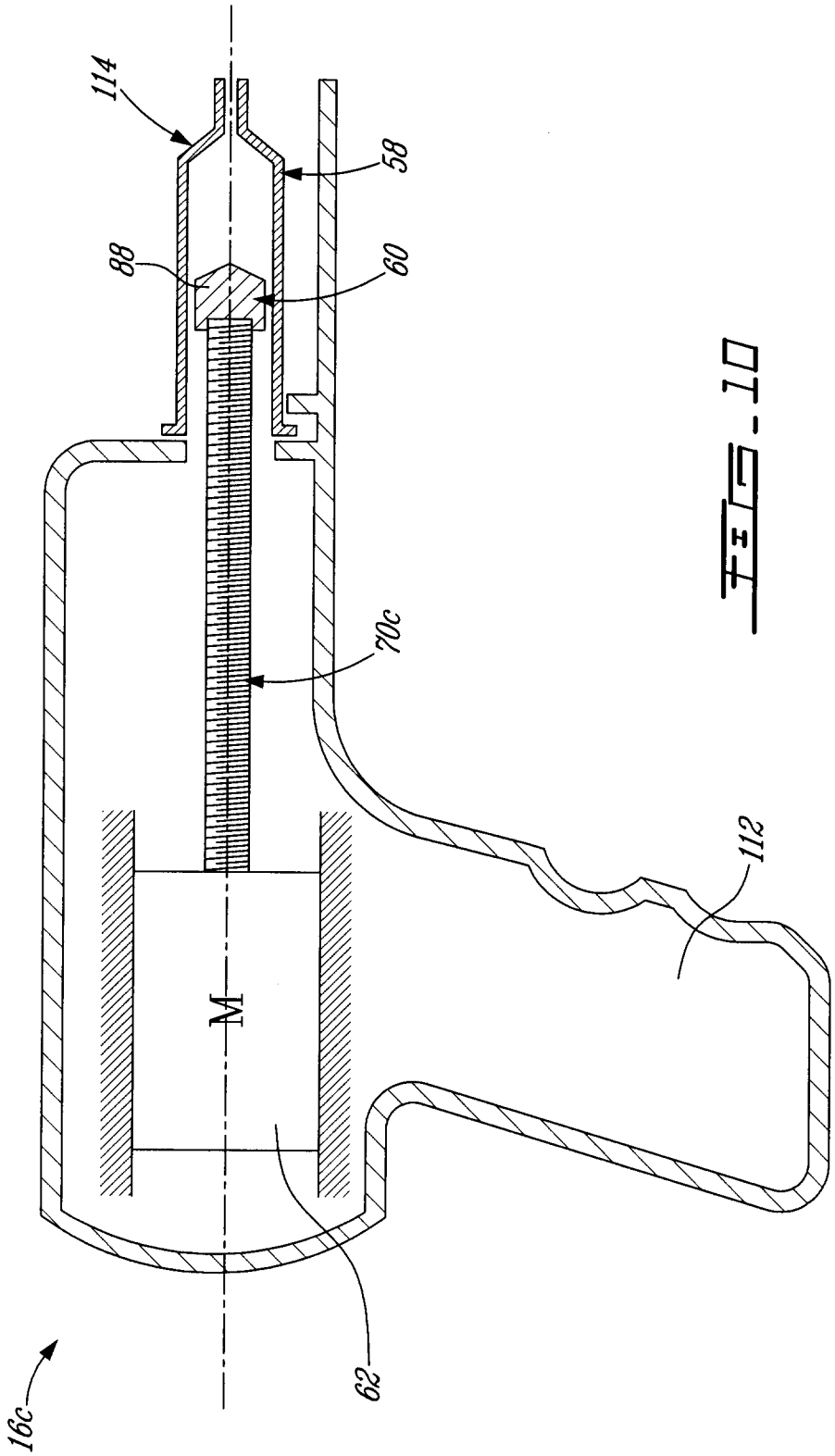

Fig. 10

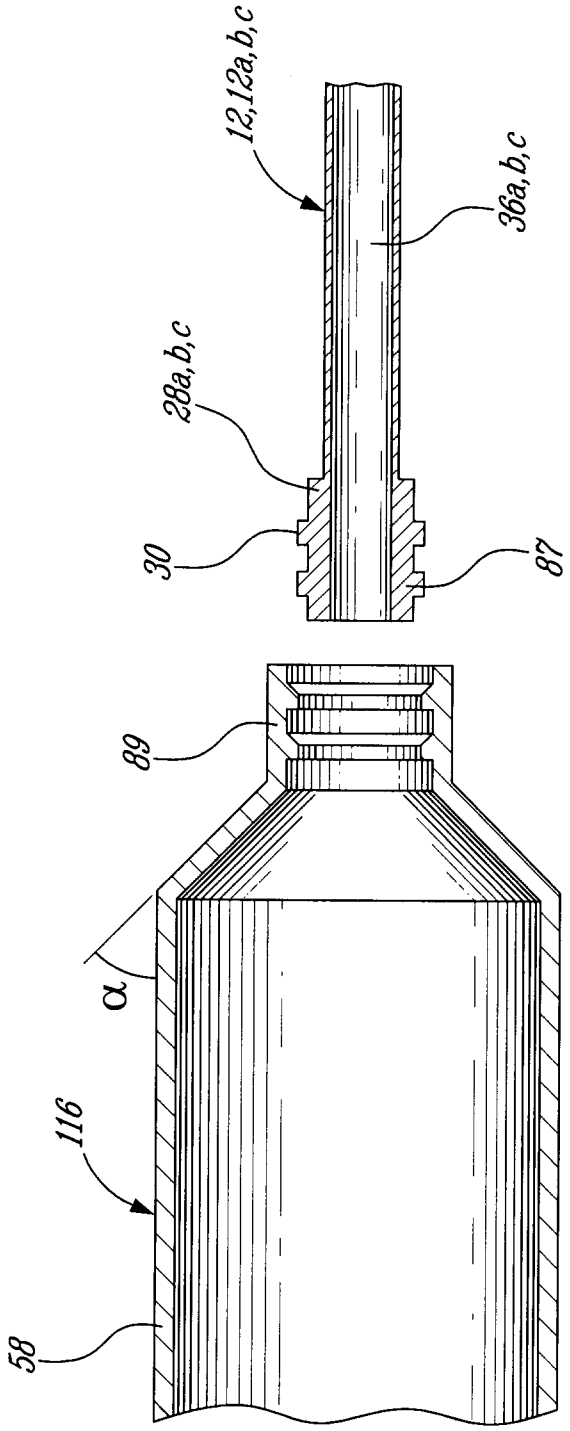

Fig-11

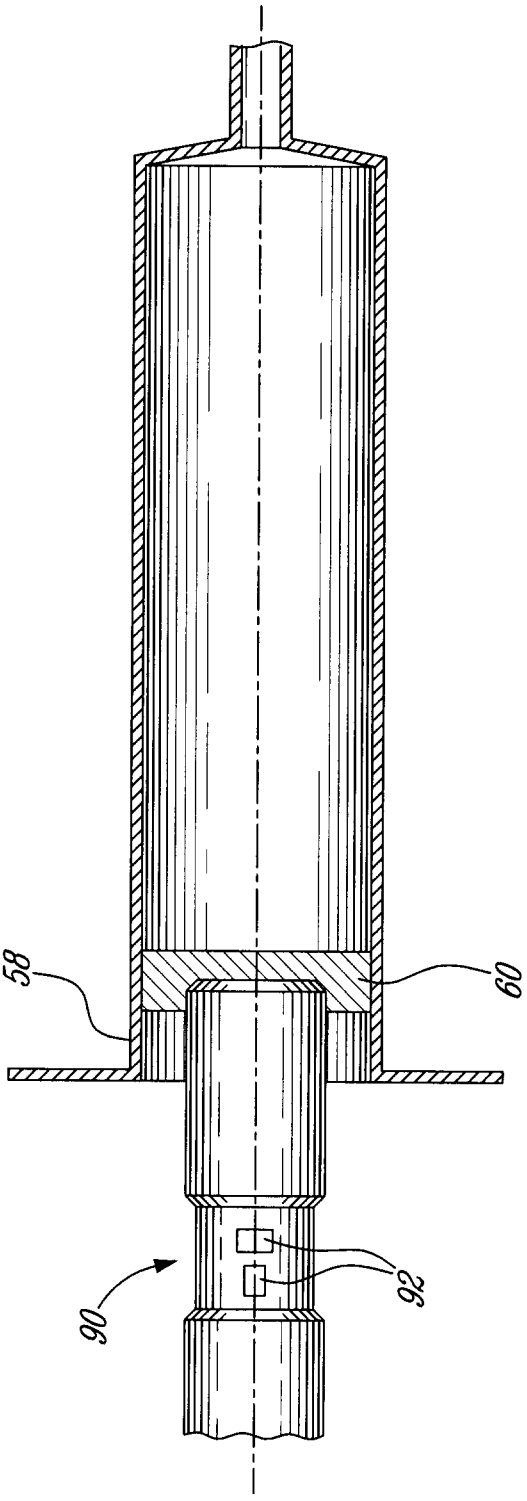

FIG. 12

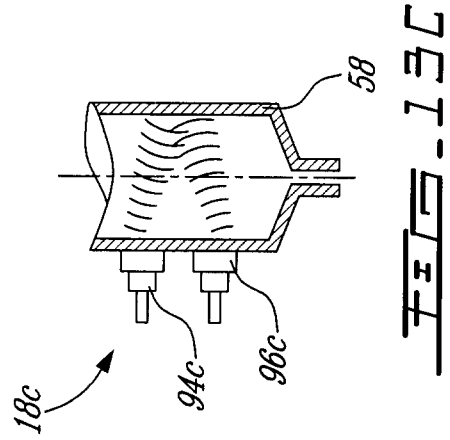

FIG-13C

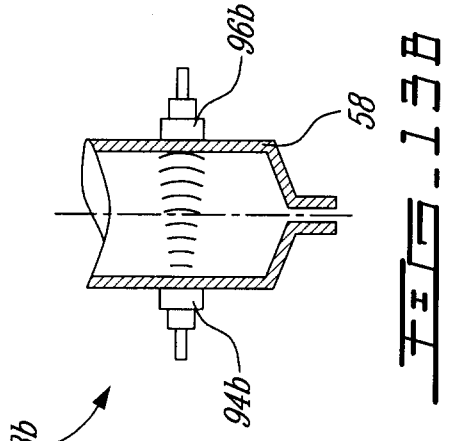

FIG-13B

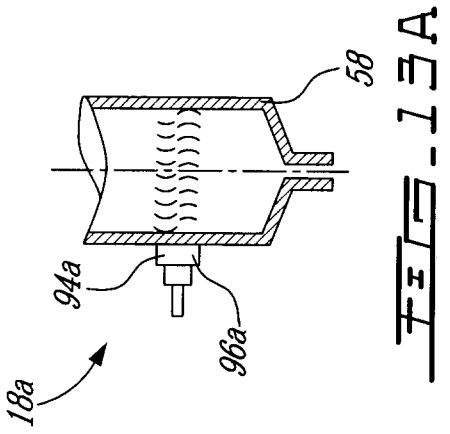

FIG-13A

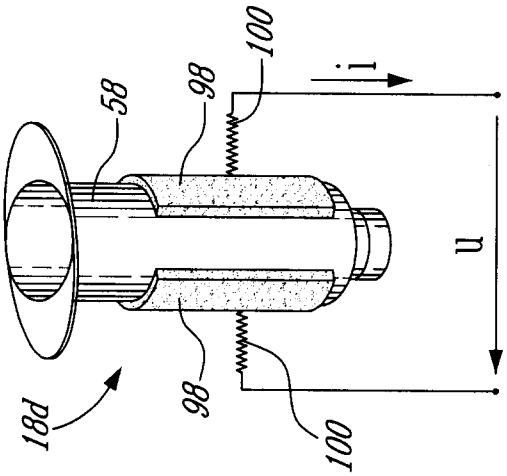

FIG-14

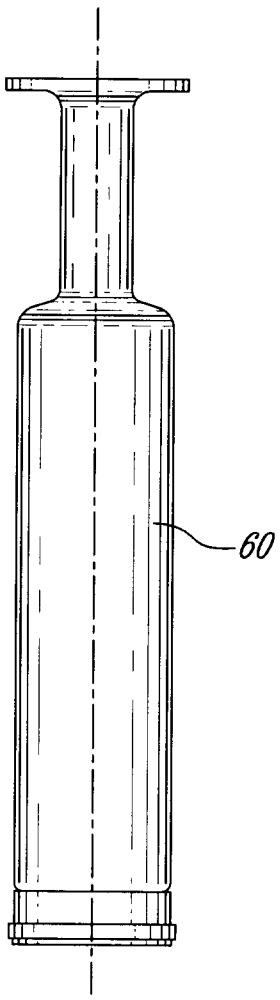

FIG_15A

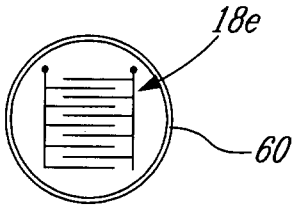

FIG_15B

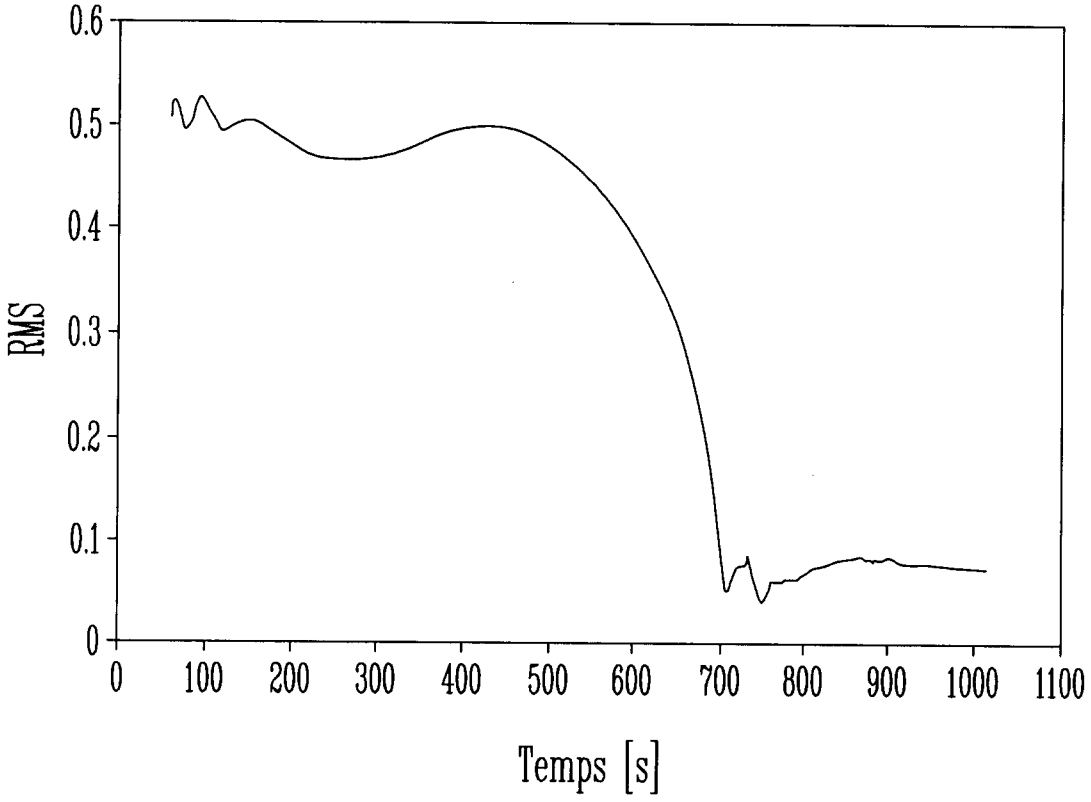
0.6
0.5
0.4
0.3
0.2
0.1
0
RMS
0
100
200
300
400
500
600
700
800
900
1000
1100
Temps [s]

Fig. 16

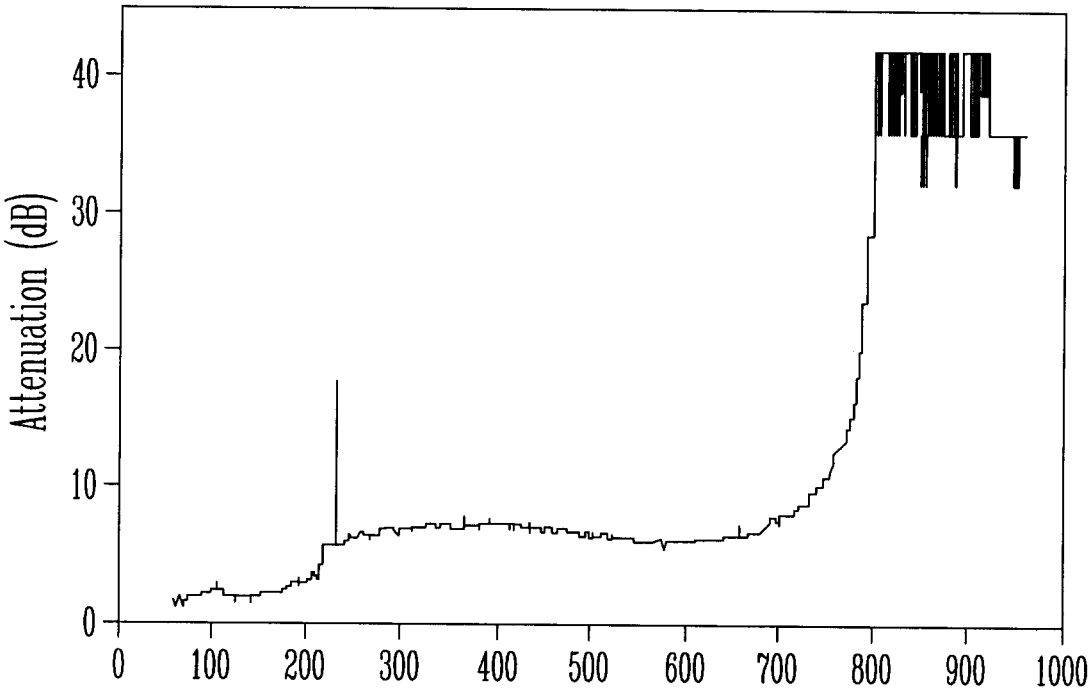
Attenuation (dB)
0
10
20
30
40
0
100
200
300
400
500
600
700
800
900
1000

Fig. 17

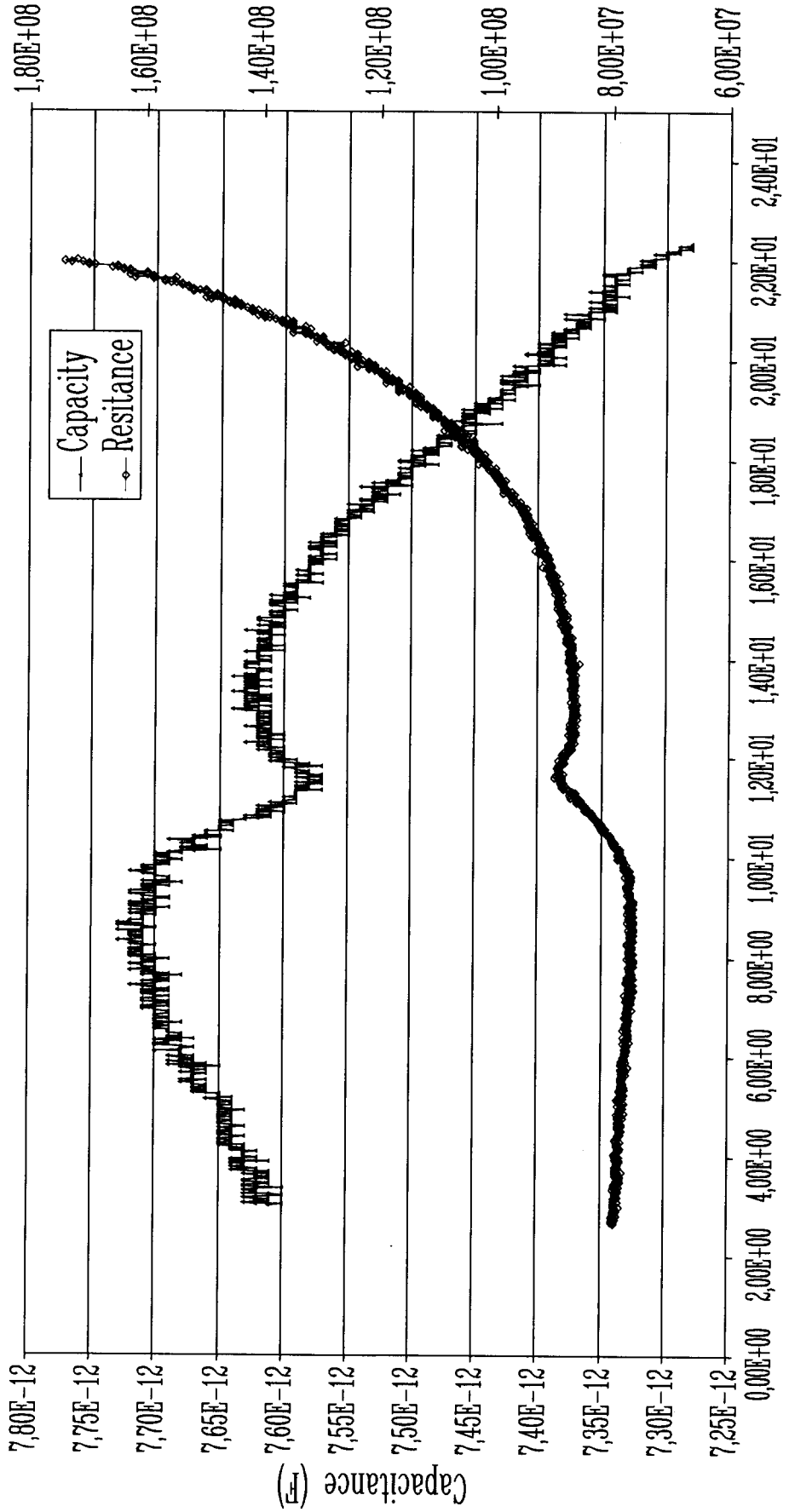
Capacitance and resistive changes of polymerising cement
Capacity
Resitance
Capacitance (F)
7,80E-12
7,75E-12
7,70E-12
7,65E-12
7,60E-12
7,55E-12
7,50E-12
7,45E-12
7,40E-12
7,35E-12
7,30E-12
7,25E-12
1,80E+08
1,60E+08
1,40E+08
1,20E+08
1,00E+08
8,00E+07
6,00E+07
0,00E+00
2,00E+00
4,00E+00
6,00E+00
8,00E+00
1,00E+01
1,20E+01
1,40E+01
1,60E+01
1,80E+01
2,00E+01
2,20E+01
2,40E+01
Time (min)

Fig. 18

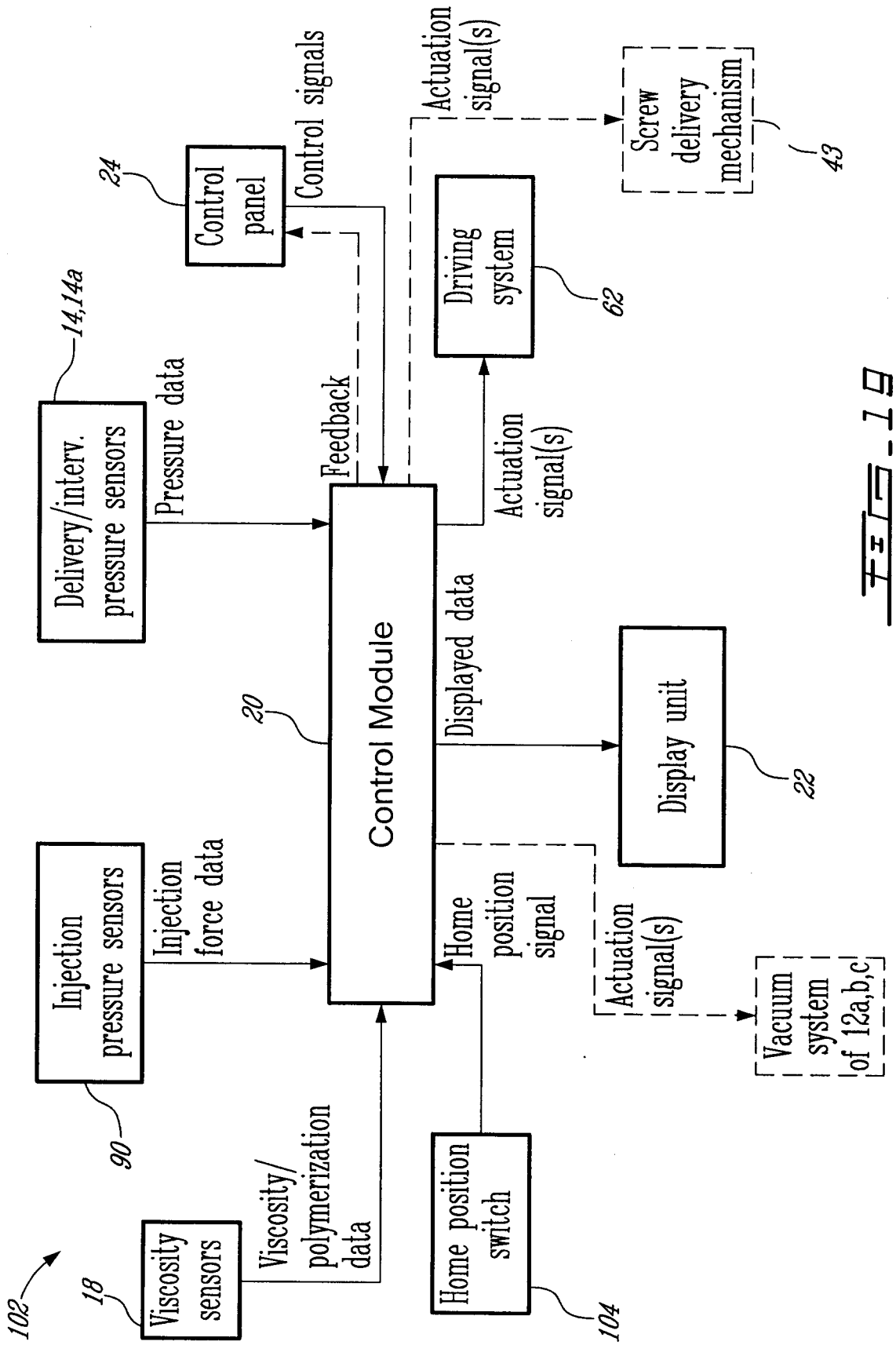
102
18
Viscosity sensors
Viscosity/ polymerization data
90
Injection pressure sensors
Injection force data
Home position switch
104
Home position signal
Actuation signal(s)
Vacuum system of 12a,b,c
20
Control Module
Displayed data
Display unit
22
Feedback
Actuation signal(s)
Driving system
62
Actuation signal(s)
Screw delivery mechanism
43
Control signals
24
Control panel
14,14a
Delivery/interv. pressure sensors
Pressure data

Fig. 19

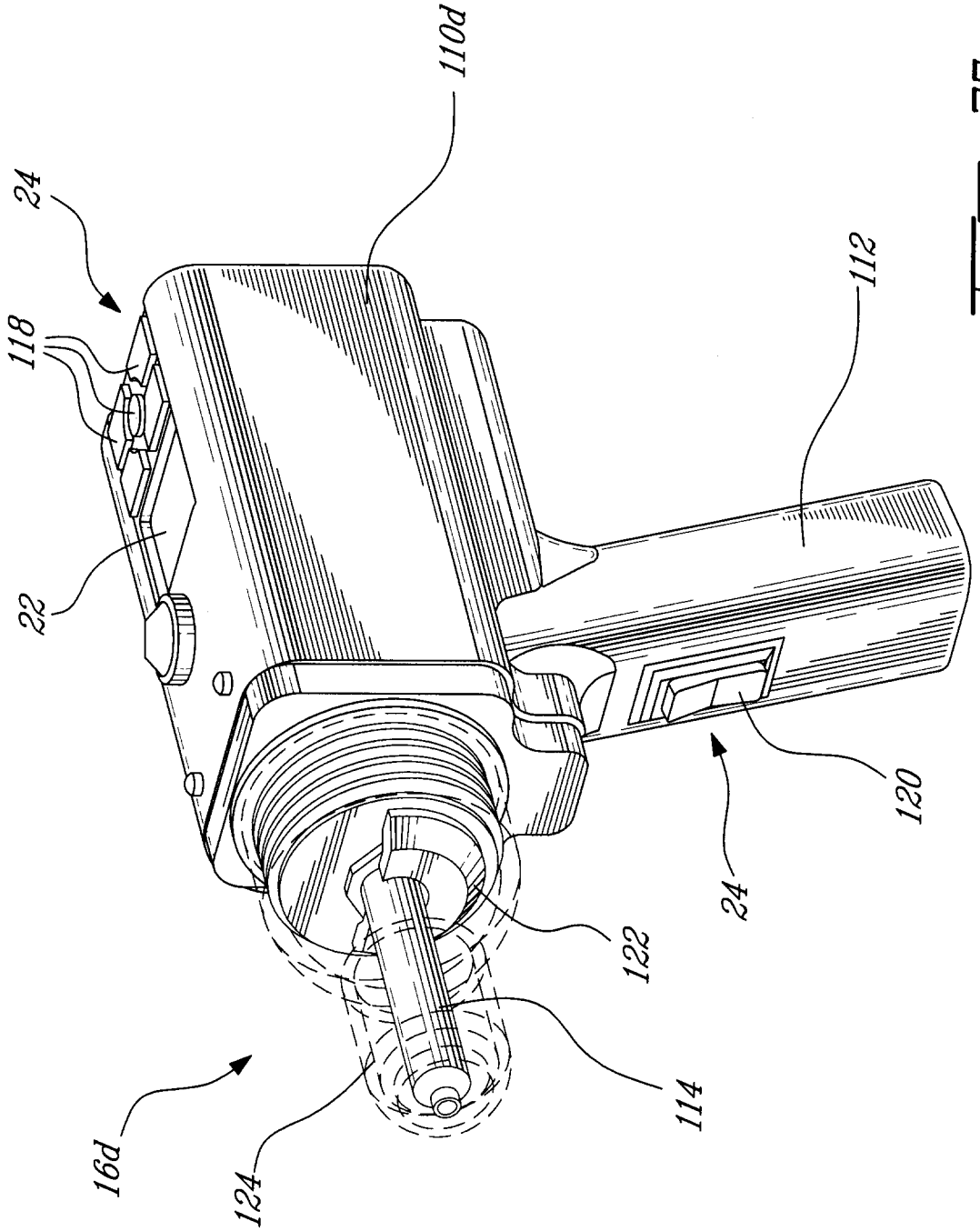

FIG. 20

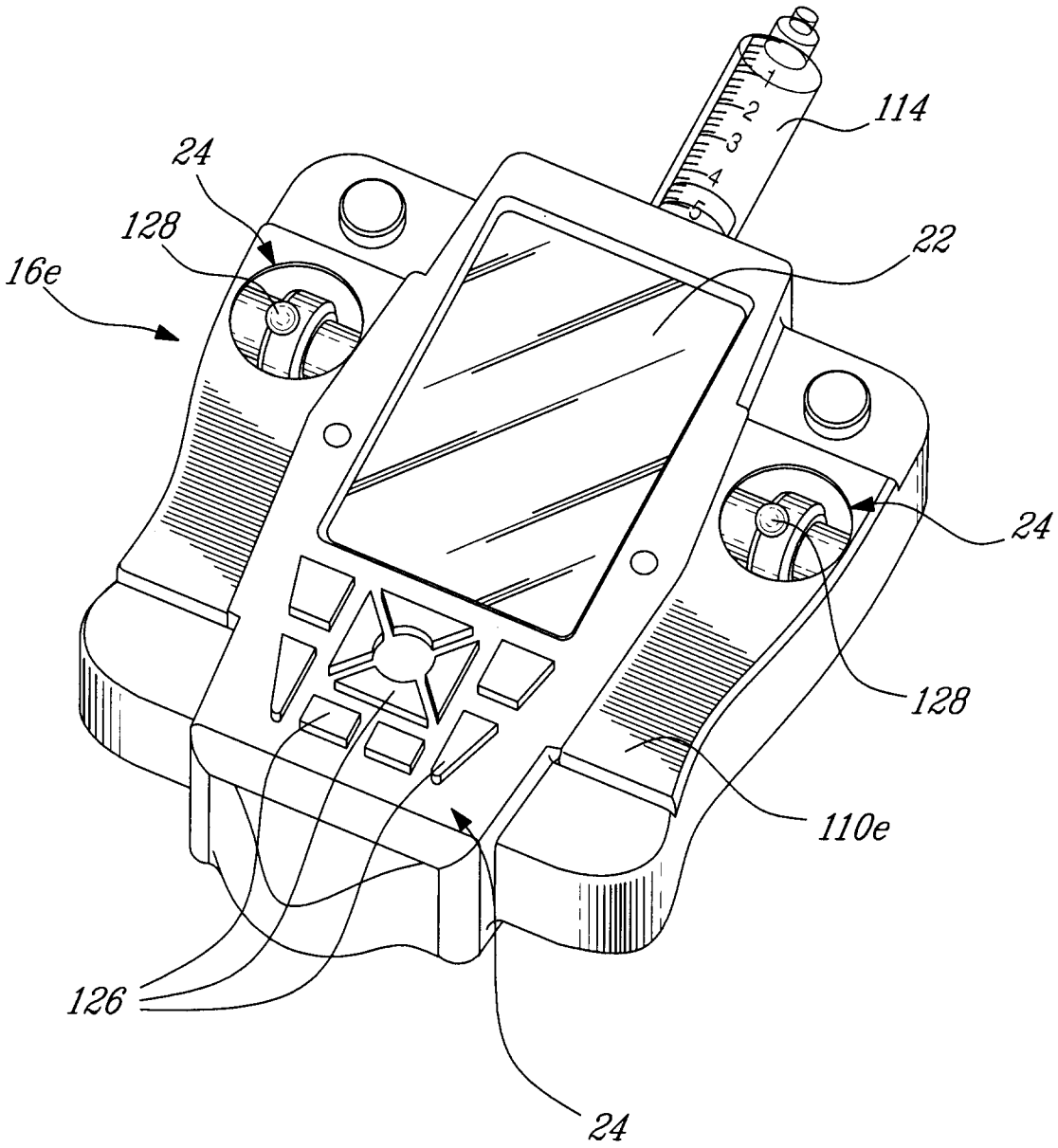

Fig. 21

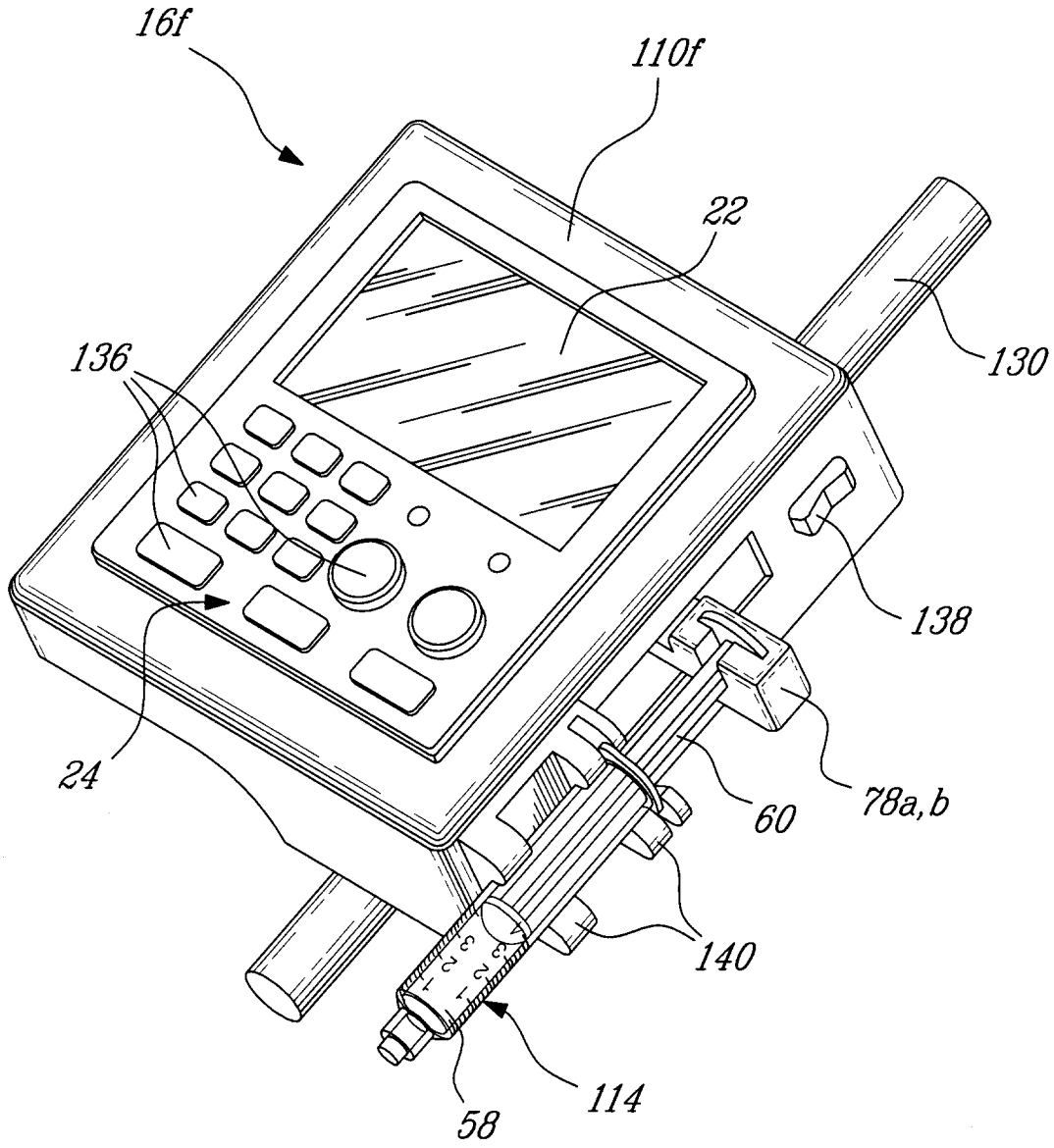

FIG. 22

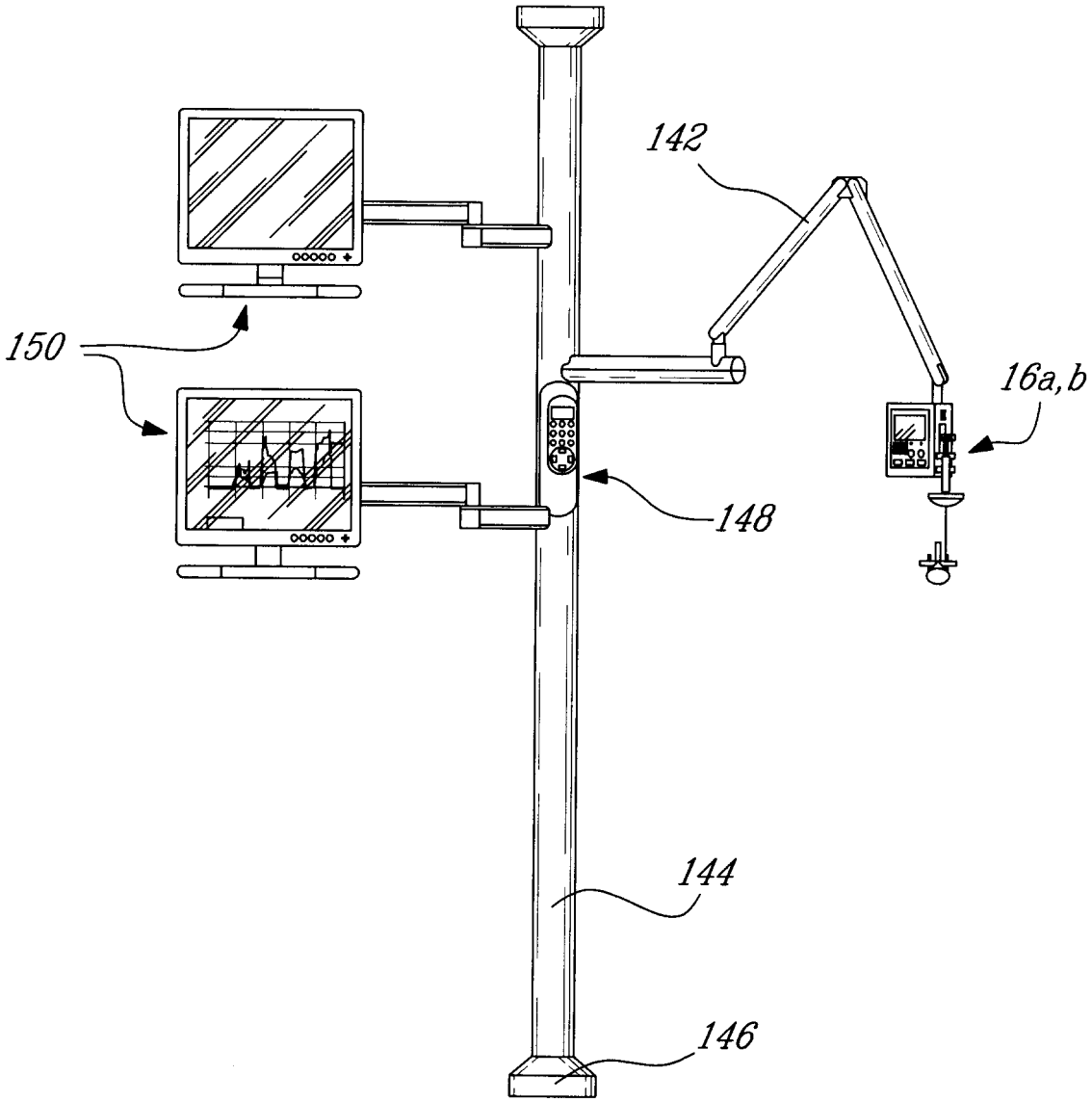

FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2007/000579

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61M 31/00*** (2006.01) , ***A61B 17/56*** *(2006.01)* , ***A61M 1/00*** (2006.01) , ***A61M 5/158*** (2006.01) , ***A61M 5/178*** (2006.01) , ***A61M 5/20*** **(2006.01); A61M 5/32** (2006.01), **GOIL 19/08** (2006.01); **GOIN 11/00** (2006.01), *A61B* 5/05 (2006.01)

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: ***A61M 31/00*** (2006.01) , ***A61B 17/56*** **(2006.01),** ***A61M 1/00*** **(2006.01),** ***A61M 5/158*** (2006.01), ***A61M 5/178*** (2006.01), ***A61M 5/20*** (2006.01) , ***A61M 5/32*** (2006.01), ***GOIL 19/08*** (2006.01) **,** ***GOIN 11/00*** (2006.01) **,** ***A61B 5/03*** (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Delphion, Canadian Patents Database, QPAT, Esp@cenet

Search terms: bone cement, cannula, vertebroplasty, bone, PMMA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 5108404 A (Scholten A., et al.) 28 April 1992 (28-04-1992) * Entire Document *	1-12
A	CA 2545436 Al (Jonsson, S., et al.) 19 May 2005 (19-05-2005) * Entire Document *	1-12
X	US 2004/0260303 Al (Carrison, H F.) 23 December 2004 (23-12-2004) * para. 22-36 *	18, 19, 22, 28-29
X	US 2006/0074433 Al (McGill S., et al.) 6 April 2006 (06-04-2006) * pages 2-3, figure 1*	18, 19. 22, 28-29, 63, 64
Y		18-30, 55-57
X	WO 02/000143 Al (Sand, P.M., et al.) 3 January 2002 (03-01-2002) * Entire Document *	18, 19, 22, 28-29

[ ] Further documents are listed in the continuation of Box C. [x] See patent family annex.

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not m conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled m the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 June 2007 (14-06-2007)	25 July 2007 (25-07-2007)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, Cl 14 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec KlA 0C9
Facsimile No.: 001-819-953-2476

Authorized officer

Brandie Moschuk 819- 934-8535
Yasin Bismilla 819-934-6240

INTERNATIONAL SEARCH REPORT

International application No
PCT/CA2007/000579

Box No. **II** **Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons

1 [X] Claim Nos 13-17, 43-46 and 58-61

because they relate to subject matter not required to be searched by this Authority, namely

methods of medical treatment of the human or animal body, namely, a method of injecting bone cement within a bone, a method of extracting marrow from a bone and a method of rinsing marrow within a bone

2 [ ] Claim Nos

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically

3 [ ] Claim Nos

because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6 4(a)

Box No. Ill **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows

See extra sheet (page 5)

1 [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2 [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees

3 [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos

4 [ ] No required additional search fees were timely paid by the applicant Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claim Nos

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation

[ ] No protest accompanied the payment of additional search fees

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	CA 2575699 A1 (Beyar, M , et al) 2 February 2006 (02-02-2006) * figure IB, pages 16, 17, 22 and 24 *	31-33, 35, 36-40, 47-52, 54
Y		24-27, 30, 55-57
X	CA 2524140 A1 (Richter, J , et al) 4 December 2003 (04-12-2003) * page 3, figure 1*	62
X, E	WO 2006/062939 A2 (Trackai, C , et al) 15 June 2006 (15-06-2006) * Entire Document *	18, 31, 38, 47

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/CA2007/000579

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INTERNATIONAL SEARCH REPORT

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International application No
PCT/CA2007/000579

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/CA2007/000579

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Continuation of Box. No. Ill

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

Group A
Claims 1 to 12 are directed to a bone cement delivery system comprising a rigid cannula with coaxial conduits

Group B
Claims 18 to 30 and 55 to 57 are directed to a bone cement delivery device comprismg a syringe body, a plunger and a driving system

Group C
Claims 31 to 42 are directed to a bone cement delivery device and a viscosity sensing unit comprising at least one sensor and a display unit

Group D
Claims 47 to 54 are directed to a control system comprising a delivery pressure sensor, a control panel, a driving system, a control module and a display unit.

Group E
Claims 62 to 64 are directed to a medical cannula

The claims must be limited to one inventive concept as set out in Rule 13 of the PCT.

Claims 13-17, 43-46 and 58-61 have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention group.