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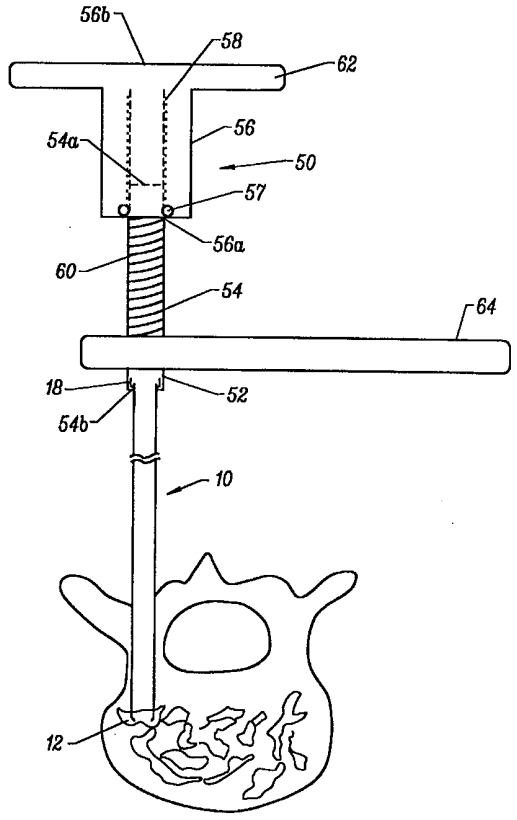
(54) Title: PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

(57) Abstract

A pressure applicator for applying pressure to a slurry of bone implant material, e.g., PMMA. A pressure applicator or driver includes a column which is provided with threads on the exterior thereof for mating with internal threads of a handle. A stabilizer handle is provided for the operator to grasp and steady the device as he turns the handle to apply pressure to the PMMA within the column. A luer–lock or other connecting device is provided for attaching the driver to the cannula that will deliver the bone implant material to the desired site. Pressures of about 1000–2000 psi are expected to be generated by this device.



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PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

TECHNICAL FIELD

The present invention relates to instruments for more accurately controlling the placement thereof, during surgical procedures for the repair of hard tissue by injection of hard tissue implant materials. Procedures for such repair include hip augmentation, mandible augmentation, and particularly vertebroplasty, among others.

BACKGROUND ART

Polymethylmethacrylate (PMMA) has been used in anterior and posterior stabilization of the spine for metastatic disease, as described by Sundaresan et al., "Treatment of neoplastic epidural cord compression by vertebral body resection and stabilization." *J Neurosurg* 1985;63:676-684; Harrington, "Anterior decompression and stabilization of the spine as a treatment for vertebral collapse and spinal cord compression from metastatic malignancy." *Clinical Orthodpaedics and Related Research* 1988;233:177-197; and Cybulski, "Methods of surgical stabilization for metastatic disease of the spine." *Neurosurgery* 1989;25:240-252.

Deramond et al., "Percutaneous vertebroplasty with methyl-methacrylate: technique, method, results [abstract]." *Radiology* 1990;117 (suppl):352; among others, have described the percutaneous injection of PMMA into vertebral compression fractures by the transpedicular or paravertebral approach under CT and/or fluoroscopic guidance. Percutaneous vertebroplasty is desirable from the standpoint that it is minimally invasive, compared to the alternative of surgically exposing the hard tissue site to be supplemented with PMMA or other filler.

The general procedure for performing percutaneous vertebroplasty involves the use of a standard 11 gauge Jamshidi needle. The needle includes an 11 gauge cannula with an internal stylet. The cannula and stylet are used in conjunction to pierce the cutaneous layers of a patient above the hard tissue to be supplemented, then to penetrate the hard

cortical bone of the vertebra, and finally to traverse into the softer cancellous bone underlying the cortical bone.

A large force must be applied by the user, axially through the Jamshidi needle to drive the stylet through the cortical bone. Once penetration of the cortical bone is achieved, additional downward axial force, but at a reduced magnitude compared to that required to penetrate the cortical bone, is required to position the stylet/ tip of the cannula into the required position within the cancellous bone. When positioned in the cancellous bone, the stylet is then removed leaving the cannula in the appropriate position for delivery of a hard tissue implant material to reinforce and solidify the damaged hard tissue.

A syringe is next loaded with polymethyl methacrylate (PMMA) and connected to the end of the cannula that is external of the patient's body. Pressure is applied to the plunger of the syringe to deliver the PMMA to the site of damaged bone at the distal end of the cannula. Because in general, 10cc syringes are only capable of generating pressures of about 100-150 psi, this places a limitation on the viscosity of the PMMA that can be effectively "pushed through" the syringe and cannula and fully delivered to the implant site. Of course, the use of a small barrel syringe, e.g., a 1 cc syringe enables the user to generate higher driving pressures. For example pressures of 1000 psi and possibly as high as 1200-1500 psi (depending upon the strength of the user and the technique) may be generated using a 1 cc syringe. A serious limitation with the use of a 1 cc syringe, however, is that it will not hold a large enough volume to complete the procedure in one step or "load" and must be reloaded several times to complete the procedure, since, on average, about 3.5 cc of implant material per side of the vertebral body are required for an implantion procedure. This makes the procedure more complicated with more steps, and more risky in that the polymerization of the implant material causes it to become increasingly more viscous during the additional time required for reloading. Another problem with a 1 cc syringe is lack of control, as high pressures are generated in a "spike - like" response time and are not continuously controllable.

A viscous or paste-like consistency of PMMA is generally believed to be most advantageous for performing percutaneous vertebroplasty. Such a consistency insures that the implant material stays in place much better than a less viscous, more liquid material. Additionally, when PMMA is implanted percutaneously, the need to inject it through a relatively narrow needle or cannula also greatly increases the need for a high pressure

driver. Still further, implantation of PMMA into a relatively closed implantation site (e.g., trabecular bone) further increases the resistance to flow of the PMMA, at the same time increasing the pressure requirements of the driver. Thus, there is a need for a high pressure applicator that has enough storage capacity to perform a complete implantation procedure without having to reload the device in the midst of the procedure, and which is consistently controllable, for an even, constant application of pressure during delivery of the entirety of the implant material.

Leakage or seepage of PMMA from the vertebral implant site can cause a host of complications some of which can be very serious and even result in death. For example, Weil et al. reported cases of sciatica and difficulty in swallowing which were related to focal cement leakage, *Radiology* 1996;Vol 199, No. 1, 241-247. A leak toward the distal veins poses an even more serious risk, since this can cause a pulmonary embolism which is often fatal.

Attempts have been made to increase the ability to apply pressure to drive PMMA to the vertebral implant site by providing a smaller barrel syringe, but this holds less volume and must be refilled once or several times to deliver enough volume of PMMA to the site. Since there is a limited amount of time to work with PMMA before it begins to polymerize or set up, this type of procedure is more difficult to successfully complete within the allotted time, and thus poses an additional risk to the success of the operation.

Accordingly, there exists a need for an improved apparatus and procedure for controllably applying higher pressures to a source of hard tissue implant material to successfully implant the material at the desired location in a single batch, for the performance of vertebroplasty and particularly, percutaneous vertebroplasty.

DISCLOSURE OF THE INVENTION

Disclosed is a high pressure applicator for driving the delivery of a hard tissue implant material. In a preferred embodiment, the applicator includes an exteriorly threaded column for receiving and containing a hard tissue implant material. The exteriorly threaded column is open at one end and is provided with a transfer fitting at the other end. An interiorly threaded column is provided which is mateable with the exterior threads on the exteriorly threaded column. The interiorly threaded column is open at one end and closed at the other end.

A stabilizer is fixedly attached to the exteriorly threaded column and radially extends therefrom to provide a user a mechanical advantage upon grasping, which prevents the exteriorly threaded column from rotating during rotation of the interiorly threaded column. A handle is fixed to and extends radially from the internally threaded column to provide the user a mechanical advantage upon grasping, thereby increasing a maximum torque that can be applied to the interiorly threaded column.

The high pressure applicator is capable of controllably generating pressures of up to about 3000 psi for driving hard tissue implant materials. The transfer fitting preferably comprises a luer lock.

The high pressure applicator according to the present invention includes a chamber for receiving a volume of the hard tissue implant material that is sufficient to complete an implantation procedure without the need to refill the chamber during the implantation procedure. Means for manually applying pressure to the chamber are provided and are capable of applying controllable pressures of up to about 3000 psi to the chamber. A stabilizer is fixedly attached to at least a portion of the chamber and radially extends therefrom to provide a user a mechanical advantage upon grasping.

A method of implantation of a hard tissue implant material is disclosed to include inserting a delivery tube into a hard tissue site where implantation of a hard tissue implant material is desired; connecting a high pressure applicator containing a predetermined volume of hard tissue implant material to the delivery tube; and applying a high pressure to the hard tissue implant material with the high pressure applicator, to drive the hard tissue implant material through the delivery tube and into the site.

The application of high pressure to the hard tissue implant material is preferably performed at a pressure of at least about 1000 psi. The high pressure application can be applied within a pressure range of about 1000 to 2000 psi, and up to about 3000 psi.

The insertion of the delivery tube into the hard tissue site further includes inserting a stylet into the site where implantation of a hard tissue implant material is desired; and guiding the delivery tube over the stylet into the site where implantation of a hard tissue implant material is desired. Further, the stylet is removed from within the delivery tube prior to connecting the high pressure applicator to the delivery tube.

The insertion of the delivery tube into the hard tissue site is preferably monitored using an imaging device, which preferably includes a fluoroscopic device. Additionally,

the viewing the delivery of hard tissue implant material into the site is preferably monitored using an imaging device, preferably a fluoroscopic device, wherein the application of a high pressure is controlled according to feedback observed from the viewing.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a diagram of an initial phase of insertion of a stylet into an implant site;

Figure 2 shows the stylet having penetrated the cortical bone and approaching cancellous bone;

Figure 3 shows the stylet having reached the desired site of implantation;

Figure 4 illustrates the positioning of a cannula by guiding it along the stylet;

Figure 5 is a view of the cannula in position at the desired site of implantation, with the stylet still in position;

Figure 6 is a view after the stylet has been removed and the high pressure applicator has been mounted to the cannula;

Figure 7 is a view of high pressure applicator after being loaded with a hard tissue implant material and assembled;

Figure 8 is an alternative embodiment of what is shown in Figure 6; and

Figure 9 is a view of the high pressure applicator used in the embodiment of Figure 8.

BEST MODE FOR CARRYING OUT THE INVENTION

The present invention substantially improves the delivery of hard tissue implant sites to the targeted zone of implantation, and is especially well suited for percutaneous deliveries. The present invention substantially reduces several of the risk factors associated with the performance of percutaneous vertebroplasty. Additionally, the present invention enables an increase in an upper acceptable viscosity value of the implant to be delivered because of the increase in the amount of pressure available for controllably driving the delivery.

An example of a procedure for performing percutaneous vertebroplasty is illustrated in Figures 1-6 . A stylet 1 is provided which has a length that is more than sufficient to span the distance from the epidermis of a patient to the cancellous bone tissue in the vertebra, in the preferred configuration. Typically the length of the stylet would be about

three inches or greater, but lesser lengths may also be employed as well, depending on the size of the patient. Of course, if other hard tissues are to be accessed, the length of the stylet can be readily modified without departing from the inventive features of the present invention.

The stylet 1 is preferably made of a surgical grade of stainless steel, but other known equivalent biocompatible metals and materials may be used for the same purpose. Ideally, the stylet, or at least a distal end thereof, will be radiopaque so that it can be monitored using fluoroscopy, CT or other imaging techniques during the procedure to help determine the depth and location of the penetration.

A first or distal end of the stylet 1 ends in a point 2 which is sharp and adapted to penetrate hard tissue when axially loaded. Extending from the tip 2 in the example shown in Figure 1 are self-tapping threads 4. However, other procedures may employ a stylet which does not have self tapping threads, but rather, is simply forced into the implantation site so that the point 2 pierces a pathway to the site of implantation. The self-tapping threads 4 provide an advantage in that once the tip 2 has penetrated the cortical bone (e.g., see Figure 2), the operator of the stylet can than proceed to advance the stylet by torquing the stylet, which engages the self-tapping threads 4 in the cortical bone 103 and begins to screw the stylet 1 into the cortical bone 103, as illustrated in Figure 2.

Turning to Figure 1, a preferred example of depth guided instruments will now be described. A stylet 1 is provided which has a length that is more than sufficient to span the distance from the epidermis of a patient to the cancellous bone tissue in the vertebra, in the preferred configuration. Typically the length of the stylet would be about three inches or greater, but lesser lengths may also be employed as well, depending on the size of the patient. Of course, if other hard tissues are to be accessed, the length of the stylet can be readily modified without departing from the inventive features of the present invention.

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4. The self-tapping threads 4 provide an advantage in that once the tip 2 has penetrated the cortical bone (e.g., see Figure 2), the operator of the stylet can than proceed to advance the stylet by torquing the stylet, which engages the self-tapping threads 4 in the cortical bone 103 and begins to screw the stylet 1 into the cortical bone 103. Rotation of the stylet 1 is continued, to advance the stylet into the bone, while monitoring the advancement with some type of imaging technique, e.g., fluoroscopy or equivalent. Advancement is continued until the tip 2 reaches the site at which it is desired to deliver the implant material. Usually this site is in the cancellous bone as shown in Figure 3, but could be anywhere within the bone where there is osteoporosis, fracture or other defect.

A cannula 10 is provided which includes an elongated tubular structure 11 to be positioned in the cancellous bone or other implantation site for delivery of PMMA or other bone implant material therein. The tubular structure 11 of the cannula 10 is preferably made of a surgical grade of stainless steel, but may be made of known equivalent materials, similarly to the stylet 1 discussed above. Preferably, at least a distal end of the tubular structure is radiopaque. The tubular structure 11 has an inside diameter which is only slightly larger than the outside diameter of the stylet 1, so that the cannula may effortlessly pass axially over the stylet, while at the same time being supported and guided by the stylet. A first or distal end 12 of the cannula is preferably (but not necessarily) beveled to ease the penetration of the cannula through the cutaneous and soft tissues, and especially through the hard tissues.

Surrounding the second end of the tubular structure 11 is a connector 18 (Figure 6) for linking the cannula 10 with a pressure applicator according to the present invention, for supplying the PMMA or other implantable material that is to be injected via tubular structure 11. Preferably, connector 18 is a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded hole, a threads and locking nut arrangement, etc.

As shown in Figures 4-5, the cannula 10 is advanced over the stylet, until visualization of the process indicates that the end of the cannula 12 is substantially even with the tip of the stylet 2, whereby it is confirmed that the cannula is properly positioned for delivery of the implant material. Next the stylet 1 is removed from the site, either by reverse rotation or by simply withdrawing it. At the same time the cannula 10 is maintained in position to be readied for delivery of the implant material.

A pressure applicator 50 according to the present invention is next mounted to the connector 18 at the end of cannula 10, as shown in Figure 6. The pressure applicator 50 is provided with a fitting 52 which is designed to form a pressure tight connection with the connector 18. As mentioned above, the preferred type of connection is a Luer-lock type connection, but alternative, equivalent types of connectors may be employed. The pressure applicator further includes a first column 54 for receiving and containing the hard tissue implant material. The first column 54 is open at one end 54a for receiving the implant material. At the other end 54b of the first column is a much smaller opening which ends with the connector or transfer fitting 52.

A second column 56 is provided for overfilling first column 54 and providing a pressure seal therewith. Preferably, the second column is interiorly threaded 58 and the interior threads 58 mate with exterior threads 60 provided on the first column 54. However, other equivalent types of driving arrangements, e.g., a ratchet and pawl arrangement or other equivalent arrangements could be used in place of the mating threads, so long as adequate pressure is able to be generated and maintained between the two columns for providing the driving force for the implant material.

Column 56 is open at end 56a for receiving the first column 54 therein. At the opposite end 56b, column 56 is closed to enable a generation of pressure within the two columns as they are moved toward one another and column 56 passes over column 54. Preferably, at least one sealing element 57 (e.g., an O-ring) is provided in the interface between columns 54 and 56 to maintain a high pressure fitting therebetween.

A handle 62 is mounted on the column 56 to provide additional leverage for driving the column 56 with respect to column 54. In the example shown in Figure 6, the handle 62 is provided at the closed end 56b to provide a greater mechanical advantage for torquing column 56 about its longitudinal axis. Of course, the handle could be provided anywhere along the column 56 so long as it extends the effective radius for torquing about the longitudinal axis. For other types of driving mechanisms other types of handles might be employed. For example, a lever might extend from the column in an embodiment using a ratchet and pawl type of driving mechanism.

A stabilizer 64 is fixedly attached or mounted to the first column 54. The stabilizer 64 may be grasped by the operator and provides leverage against rotation of the first column 54 during driving of the second column 56. Preferably, the stabilizer 64 is in

the form of a lever as shown in Figure 6, but alternative embodiments of the stabilizer may include a circular handle, etc. so long as an equal mechanical advantage is provided to the user.

The above described components of the pressure applicator 50 are all preferably formed of polycarbonate. However, any other materials which are durable, sterilizable and biofriendly, such as stainless steel, could be readily substituted.

Prior to mounting the pressure applicator 50 on the cannula 10, a hard tissue implant material 66 is loaded into the first column 54 and the second column 56 is connected with the first column 54 in preparation for implantation, see Figure 7. The first column is then rotated slightly with respect to the second column until a minimal amount of tissue implant material is expressed from the fitting 52 end, to ensure that no air has been entrapped in the applicator. The cannula 10 is backfilled with saline, tissue implant material 66, or other biocompatible fluid in order to displace the air therefrom. The pressure applicator 50 is then mounted onto the cannula 10 as described above and shown in Figure 6. The operator next grasps the handle 62 in one hand and the stabilizer 64 in the other and begins to torque the handle 62 while maintaining the stabilizer 64 in its position. When operated as described, the pressure applicator is capable of generating pressures of about 1000 to 2000 psi within the columns, which is a high driving force that is applied to the implantable material 66.

Torquing of the handle 62 with respect to the stabilizer 64 is continued until a sufficient amount of implant material 66 has been delivered to the implant site as verified by an appropriate imaging technique. Advantageously, the pressure applicator 50 allows a first column 54 which is large enough in volume to contain sufficient implant material for an entire implantation process so that there is no need to refill the column 54 in the midst of a procedure.

A modification of the apparatus described above is shown in Figure 8. In this embodiment, cannula 10' includes a modified tubular structure design. The first or distal portion 11a of the tubular structure is of the same dimensions as the embodiment of Figures 1-6. The second or proximal portion 11b of the cannula 10', however, has a substantially larger diameter than that of the first portion 11a. Preferably, the diameter of second portion 11b is about twice the diameter of the first portion 11a, although any increase in the

diameter of the second portion 11b over that of the first portion 11a will decrease the pressure requirement for effective delivery of the material to be implanted.

The first and second portions 11a,11b have approximately equal lengths, but this is governed by the anatomy of the site to be accessed. In the "average" percutaneous vertebroplasty situation, the first portion 11a is required to be about 1.5" long, as this is the length that is needed for traversing the cortical bone of the pedicle. Thus, the first portion should not be significantly enlarged due to the size constraints of the pedicle, the safety risks to the spinal column and aorta which are increased when the cannula size is increased intravertebrally, and by the desire to remove as little bone as possible when entering with the stylet and cannula, among other factors.

However, the portion of the cannula which will occupy the soft tissues can be significantly expanded without substantially adversely effecting the patient. Given the benefits of reducing the required injection pressure and ensuring a better delivery of the bone implant material, such a modification becomes a viable option.

The pressure applicator 50' is essentially the same as that in the previous embodiment, with modifications as follows. The pressure applicator 50' is provided with a fitting 52' which is designed to form a pressure tight connection with the connector 18' and is therefore of a significantly larger diameter than the connector 52. Additionally, the first column 54' is essentially open at both ends 54a' and 54b' as it does not taper or tapers much less than the previous embodiment at opening 54b'. As mentioned above, the preferred type of connection is a Luer-lock type connection, but alternative, equivalent types of connectors may be employed.

Like pressure applicator 50, the components of the pressure applicator 50' are all preferably formed of polycarbonate. However, any other materials which are durable, sterilizable and biofriendly, such as stainless steel, could be readily substituted.

Prior to mounting the pressure applicator 50' on the cannula 10', a hard tissue implant material 66 is loaded into the first column 54 and the second column 56 is connected with the first column 54 in preparation for implantation. The pressure applicator 50' is then mounted onto the cannula 10' as shown in Figure 8. The operator next grasps the handle 62 in one hand and the stabilizer 64 in the other and begins to torque the handle 62 . When operated as described, the pressure applicator is capable of generating

controllable and sustainable pressures of up to about 3000 psi within the columns, which is a high driving force that is applied to the implantable material 66.

Alternative to the direct connection of the pressure applicator 50 to the connector 18 via fitting 52, as shown in Figure 6, a high pressure tubing 70 may be and preferably is interconnected between the pressure applicator 50 and the cannula 10, as shown in Figure 10. Preferably, the tubing 70 is a braided, reinforced polyurethane tubing rated up to at least 1200 psi, although alternative, equivalently performing high pressure tubing may be substituted. The tubing 70 has male 72 and female 74 connectors for forming pressure tight seals with fitting 52 and connector 18, respectively.

The tubing 70 enables both the applicator 50, and thus the user's hand to be distanced from the radiographic field or other viewing field, which is advantageous both for safety purposes as well as improving the procedure. This embodiment is particularly advantageous for the most frequent set-ups where bi-planar viewing is performed and two imaging devices are oriented at 90° to one another about the implantation site. One of the advantages which is gained that improves the procedure, is that the viewing instrumentation can be moved closer to the actual implantation site, thereby providing a more magnified view.

It is preferred that the tubing 70 is mounted to the pressure applicator prior to mounting on the cannula fitting 18. After filling the pressure applicator with implant material as described above, the tubing 70 is mounted to fitting 52. A small amount of pressure is next applied to the implant material to express the implant material until a minimal amount exits the open end of the tubing (i.e., the end where connector 74 is located). The tubing 70 is then connected to the connector 18 of the cannula 10 for implantion of the implant material into the desired location. Although the foregoing is the desired order of connection so that the air space in the tubing can be prefilled with implant material, it is not the only possible progression for the procedure. Alternatively, the tubing 70 can be connected to the fitting 18 of the cannula 10 and the tubing 70 and cannula 10 are then backfilled with saline, implant material, or other biocompatible fluid to displace any air residing in the structures. After filling of the pressure applicator 50 with implant material, the tubing can be connected to the fitting 52 and implantion of the implant material can be rapidly commenced thereafter.

Although there have been described devices for percutaneous delivery of a hard tissue implant material, with a limited selected number of alternative embodiments in accordance with the invention for the purpose of illustrating the manner in which the invention may be used to advantage, it will be appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art should be considered to be within the scope of the invention as set forth in the claims which follow.

CLAIMS

1. A high pressure applicator for driving the delivery of a hard tissue implant material, comprising:

an exteriorly threaded column for receiving and containing a hard tissue implant material, said exteriorly threaded column being open at one end and being provided with a transfer fitting at the other end;

an interiorly threaded column mateable with exterior threads on said exteriorly threaded column, said interiorly threaded column being open at one end and closed at the other end;

a stabilizer fixedly attached to said exteriorly threaded column and radially extending therefrom to provide a user a mechanical advantage upon grasping said stabilizer, thereby preventing said exteriorly threaded column from rotating during rotation of said interiorly threaded column.

2. The high pressure applicator of claim 1, further comprising:

a handle fixed to and extending radially from said internally threaded column to provide the user a mechanical advantage upon grasping said handle, thereby increasing a maximum torque that can be applied to said interiorly threaded column.

3. The high pressure applicator of claim 1, wherein said applicator is capable of generating pressures of up to about 3000 psi for driving hard tissue implant materials.

4. The high pressure applicator of claim 1, wherein said transfer fitting comprises a luer lock.

5. A high pressure applicator for driving the delivery of a hard tissue implant material, comprising:

a chamber for receiving a volume of the hard tissue implant material that is sufficient to complete an implantation procedure without the need to refill said chamber; and

means for manually applying pressure to said chamber, wherein said means for manually applying pressure are capable of applying pressures of at least 1000 psi to said chamber.

6. The high pressure applicator of claim 5, wherein said means for manually applying pressure are capable of applying pressures of up to about 2000 psi to said chamber.

7. The high pressure applicator of claim 5, wherein said means for manually applying pressure are capable of applying pressures of up to about 3000 psi to said chamber.

8. The high pressure chamber of claim 5, further comprising:

a stabilizer fixedly attached to at least a portion of said chamber and radially extending therefrom to provide a user a mechanical advantage upon grasping said stabilizer.

9. A method of implantation of a hard tissue implant material, comprising:

inserting a delivery tube into a hard tissue site where implantation of a hard tissue implant material is desired;

connecting a high pressure applicator containing a predetermined volume of hard tissue implant material to said delivery tube;

applying a high pressure to the hard tissue implant material with said high pressure applicator, to drive the hard tissue implant material through said delivery tube and into the site.

10. The method of claim 9, wherein said applying a high pressure comprises applying a pressure of at least about 1000 psi.

11. The method of claim 10, wherein said applying a high pressure comprises applying a pressure of about 1000 to 2000 psi.

12. The method of claim 10, wherein said applying a high pressure comprises applying a pressure of up to about 3000 psi.

13. The method of claim 9, wherein said inserting a delivery tube into a hard tissue site comprises:

inserting a stylet into the site where implantation of a hard tissue implant material is desired; and

guiding said delivery tube over said stylet into the site where implantation of a hard tissue implant material is desired.

14. The method of claim 13, further comprising:

removing said stylet from within said delivery tube prior to said connecting a high pressure applicator containing a predetermined volume of hard tissue implant material to said delivery tube.

15. The method of claim 9, further comprising:

viewing the insertion of said delivery tube into the hard tissue site using an imaging device.

16. The method of claim 15, wherein said imaging device comprises a fluoroscopic device.

17. The method of claim 9, further comprising:

viewing the delivery of hard tissue implant material into the site using an imaging device, wherein said application of a high pressure is controlled according to feedback observed from said viewing.

18. The method of claim 17, wherein said imaging device comprises a fluoroscopic device.

19. The method of claim 9, wherein said connecting said high pressure applicator to said delivery tube comprises connecting said high pressure applicator directly to said delivery tube.

20. The method of claim 9, wherein said connecting said high pressure applicator to said delivery tube comprises connecting said high pressure applicator to a high pressure tube and in turn connecting said high pressure tube directly to said delivery tube.

21. The method of claim 9, wherein said connecting said high pressure applicator to said delivery tube comprises connecting said high pressure applicator to a high pressure tube which has been connected to said delivery tube.

22. A system for implantation of hard tissue material comprising:

a high pressure applicator for driving a delivery of the hard tissue implant material;

a delivery tube for insertion into a hard tissue site of implantation; and

means for interconnecting said high pressure applicator and said delivery tube.

23. The system of claim 22, wherein said means for interconnecting comprises interfitting Luer lock connectors on said high pressure applicator and said delivery tube, respectively.

24. The system of claim 22, wherein said means for interconnecting comprises:

a first pressure fitting on said delivery tube;

a second pressure fitting on said high pressure applicator; and

a portion of high pressure tubing interconnectable between said first and second pressure fittings.

25. The system of claim 22, further comprising a stylet which is insertable into said hard tissue implantation site to guide said insertion of said delivery tube.

26. The system of claim 22, wherein said high pressure applicator comprises a reservoir for containing the hard tissue implant material prior to implantation.

27. The system of claim 26, wherein said reservoir is capable of containing at least 7 cc of the hard tissue implant material.

28. The system of claim 26, wherein said reservoir is at least partially defined by a pair of interfitting cylindrical portions of said high pressure applicator.

29. The system of claim 22, wherein said high pressure applicator further comprises a stabilizer fixedly attached thereto and extending therefrom to provide a user a mechanical advantage upon grasping said stabilizer.

30. The system of claim 22, wherein said applicator is capable of generating pressures of up to about 3000 psi for driving the hard tissue implant material.

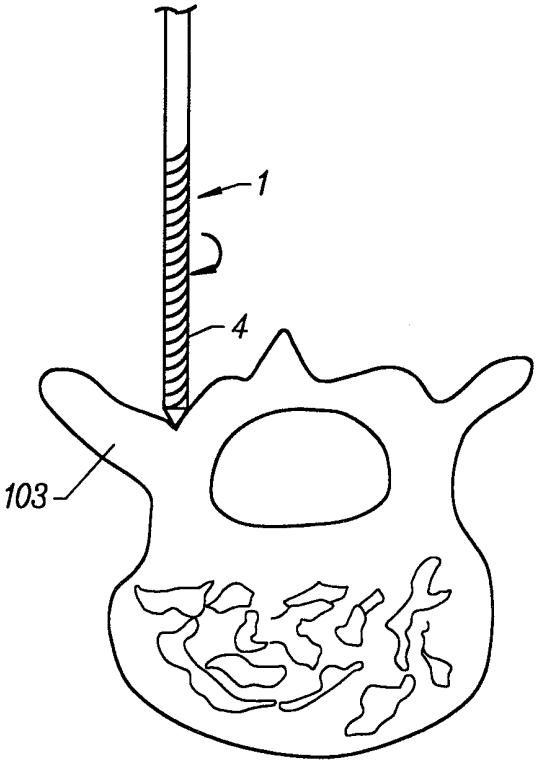

FIG. 1

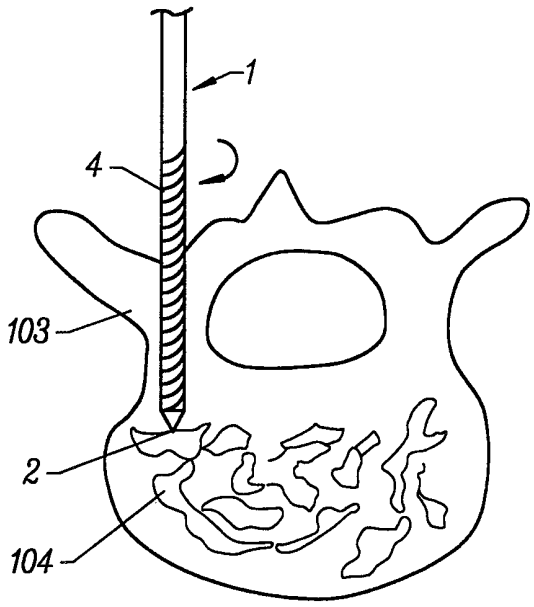

FIG. 2

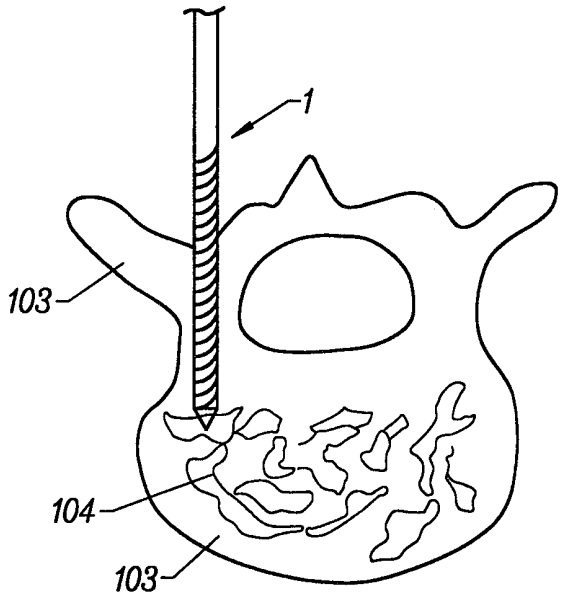

FIG. 3

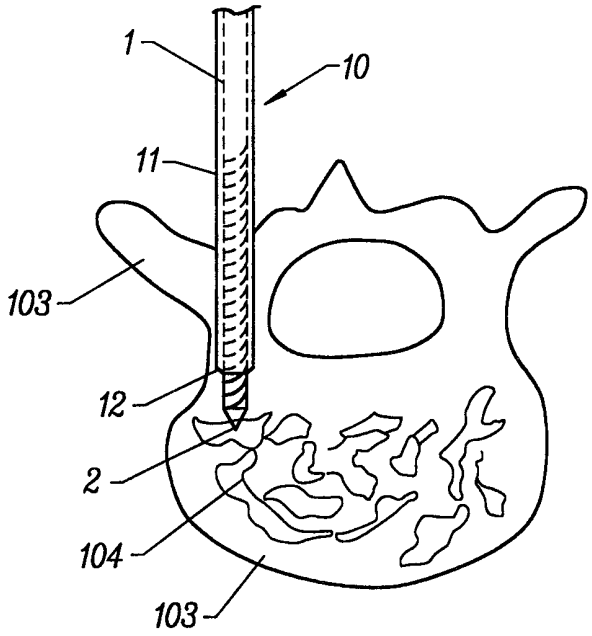

FIG. 4

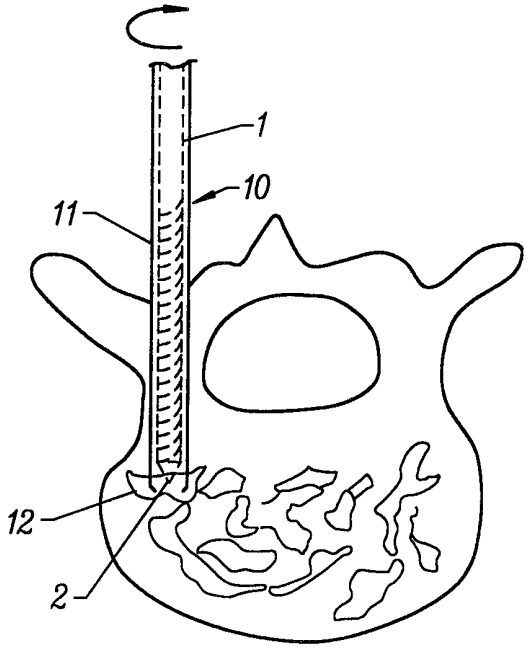

FIG. 5

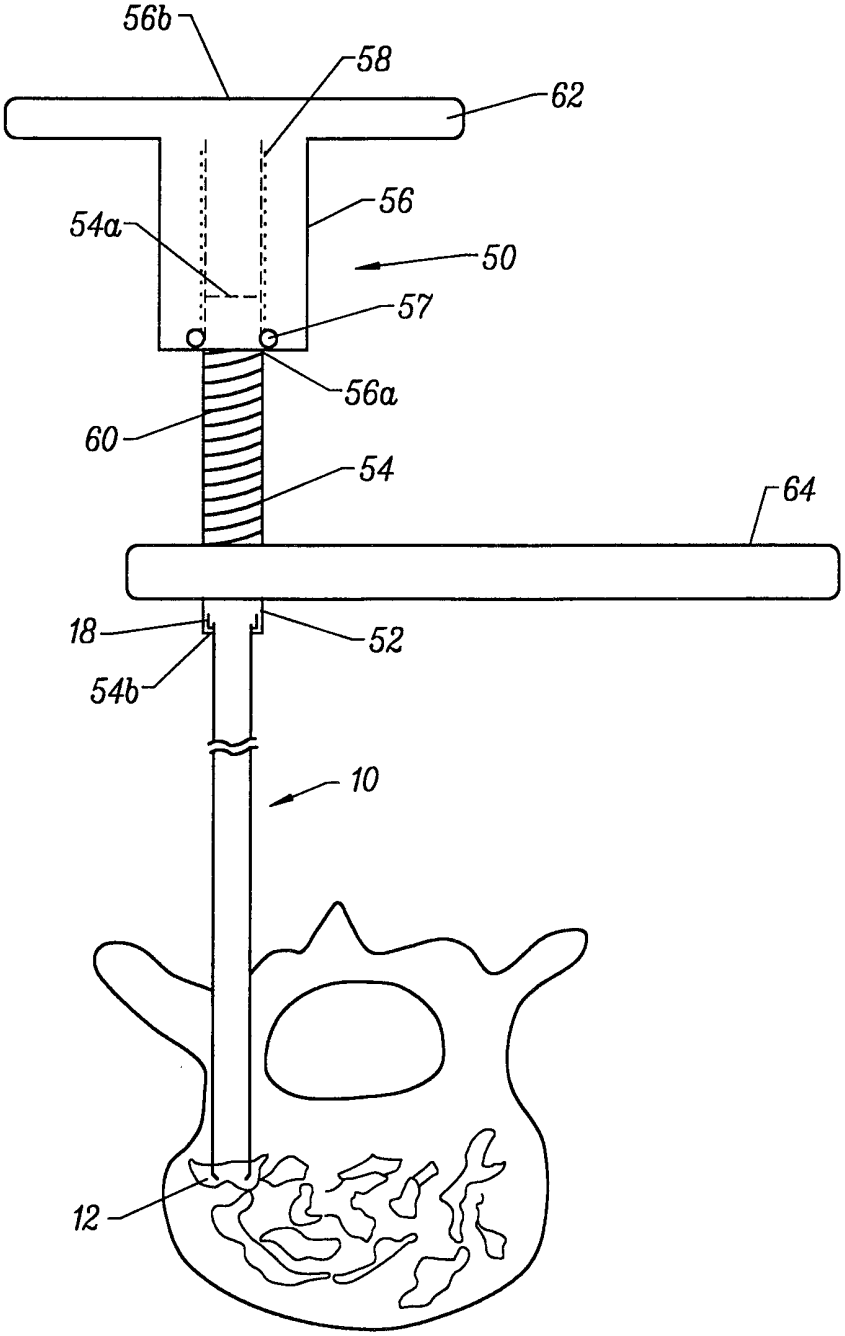

FIG. 6

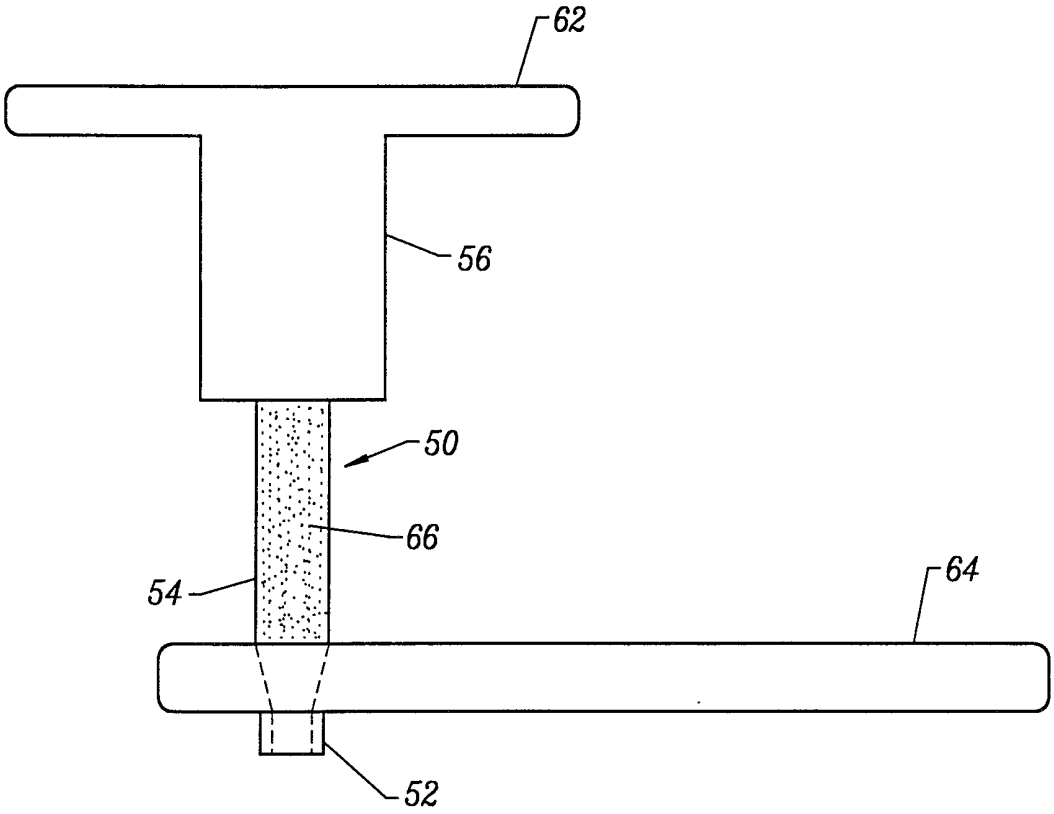

FIG. 7

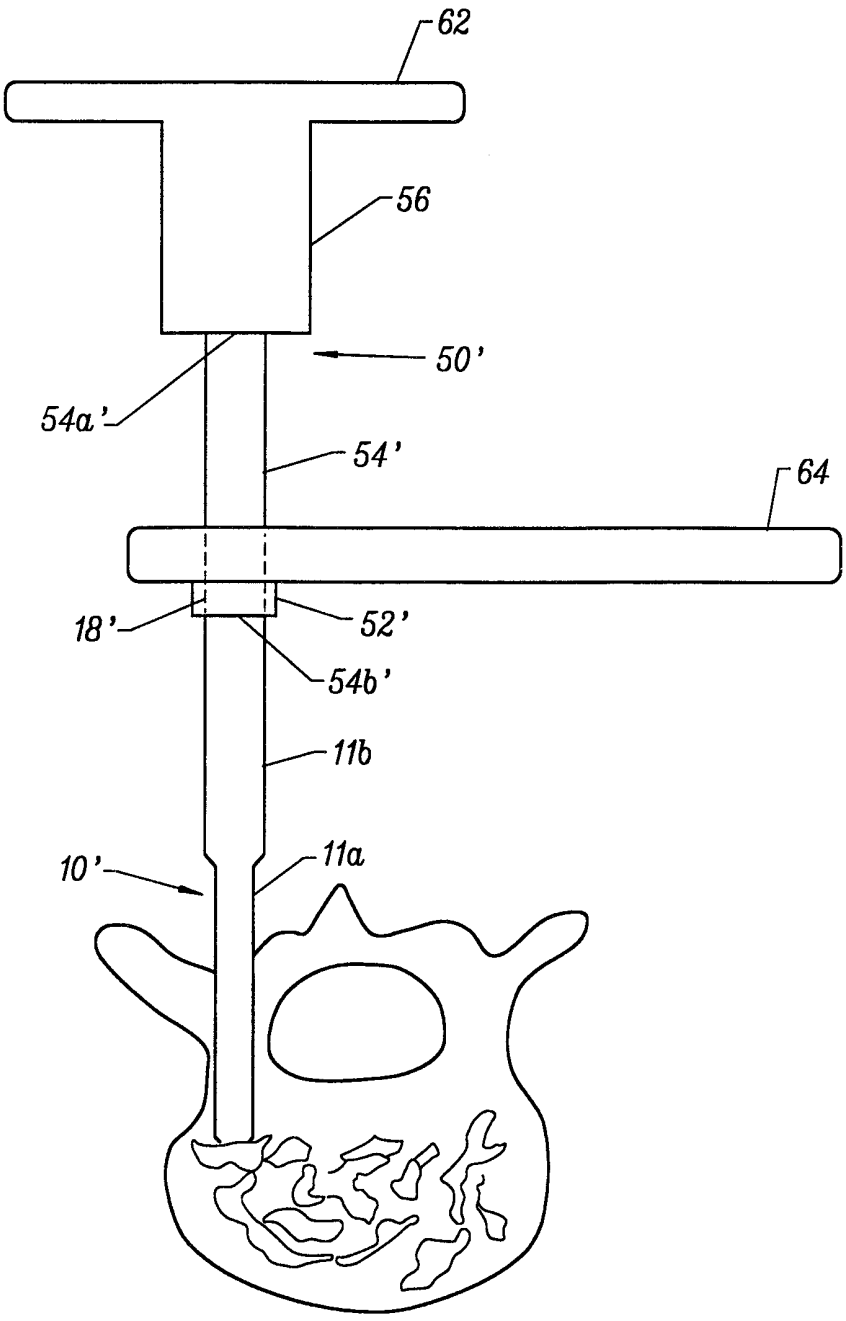

FIG. 8

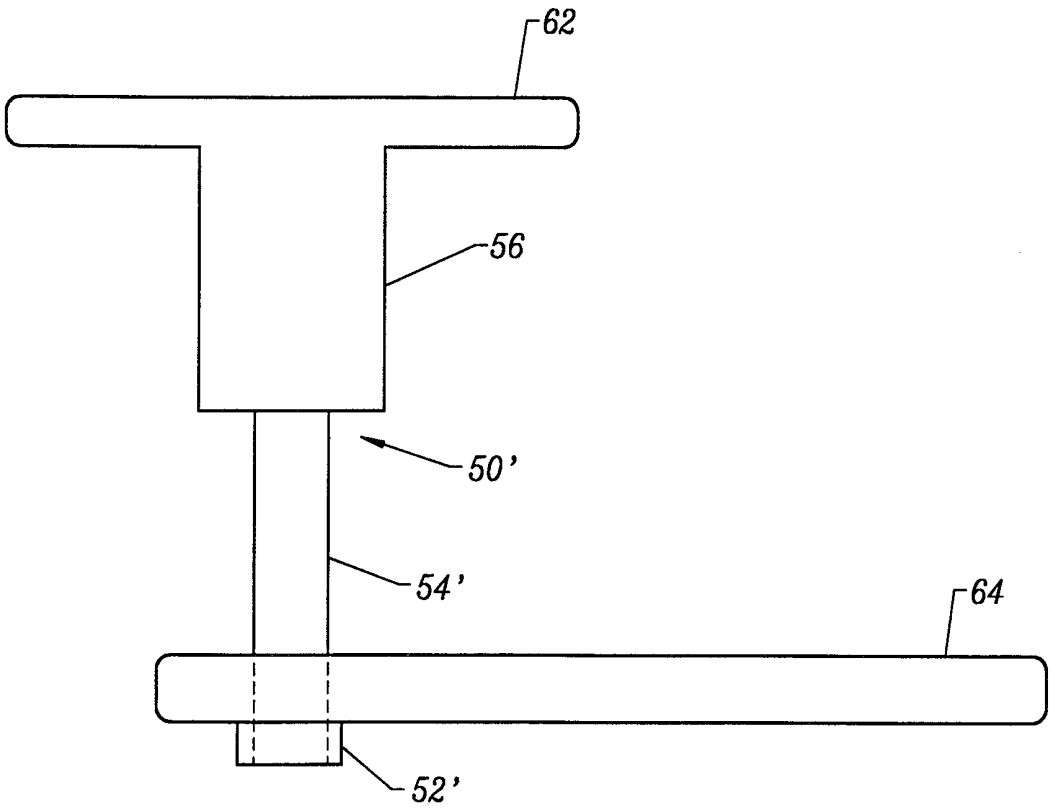

FIG. 9

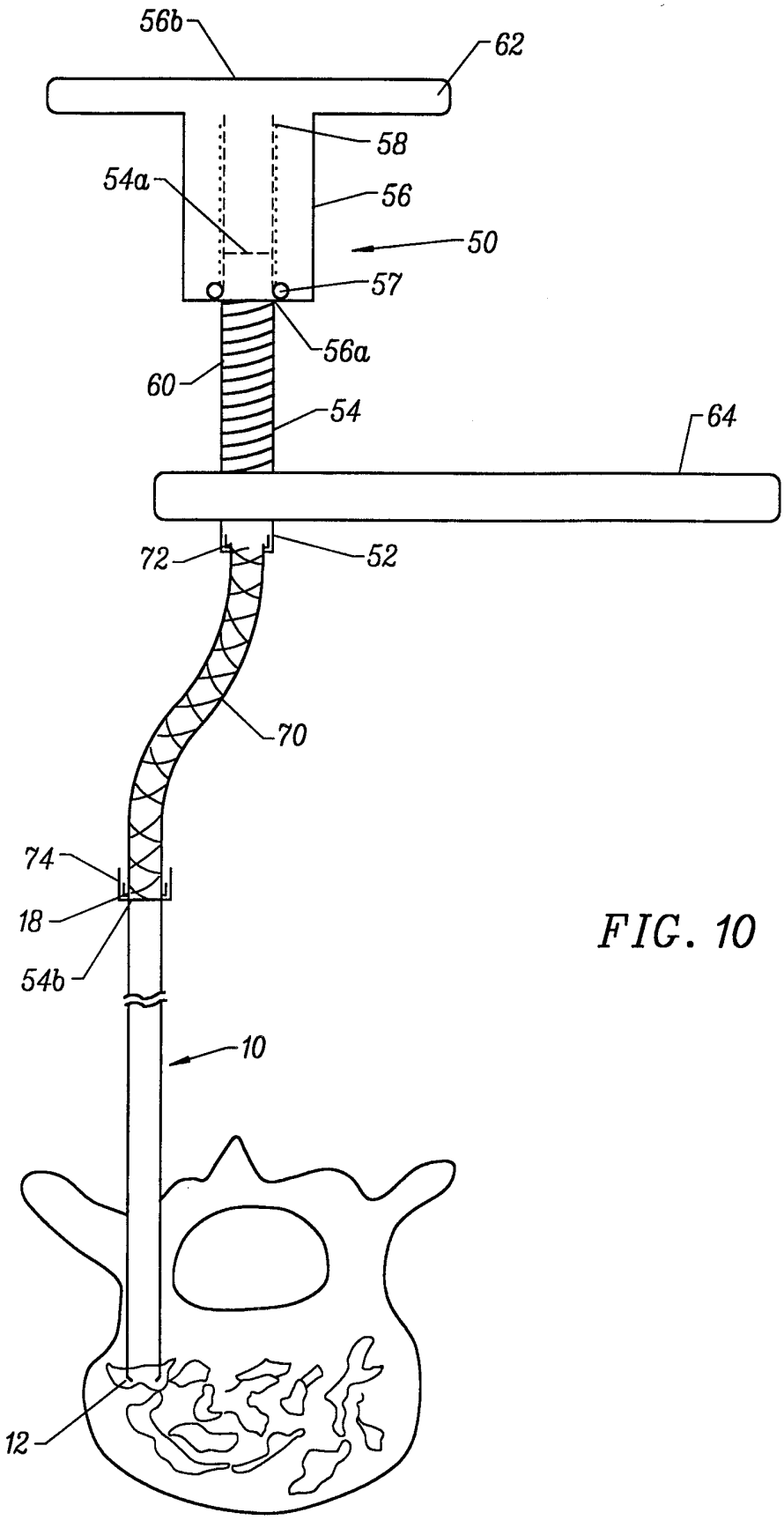

FIG. 10

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 99/06470

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/46 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	DE 34 43 167 A (ORTHOPLANT ENDOPROTHETIK) 5 June 1986 see the whole document	5-8,22, 26,29,30 1-4
Y A	US 5 653 730 A (HAMMERSLAG JULIUS G) 5 August 1997 see column 13, line 66 - column 14, line 46; figure 6	1-4 1,5
X A	US 4 312 343 A (LEVEEN HARRY H ET AL) 26 January 1982 see column 2, line 29 - line 44; figure 1	22,26,28 1,5
X A	US 5 372 583 A (ROBERTS CRAIG P ET AL) 13 December 1994 see abstract; figure 2	22 1,5

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 June 1999	02/07/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

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INTERNATIONAL SEARCH REPORT

Inte: ›nal Application No
PCT/US 99/06470

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 793 363 A (AUSHERMAN RONALD W ET AL) 27 December 1988 see abstract; figure 3	1,5, 22-24
A	US 4 189 065 A (HEROLD WOLF-DIETRICH) 19 February 1980 see abstract; figure 1	1,5,22
A	US 3 750 667 A (PSHENICHNY N ET AL) 7 August 1973 see abstract; figures 1-4	1,5,22
A	US 5 660 186 A (BACHIR JOSEPH S) 26 August 1997 see column 8, line 53 - column 9, line 65; figure 10	1,5,22

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INTERNATIONAL SEARCH REPORT

I. national application No.
PCT/US 99/06470

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: claims 9-21
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - ethod for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

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

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 99/06470

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