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(54) **CAVITY FORMATION DEVICE**

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(60) Provisional application No. 60/194,685, filed on Apr. 5, 2000.

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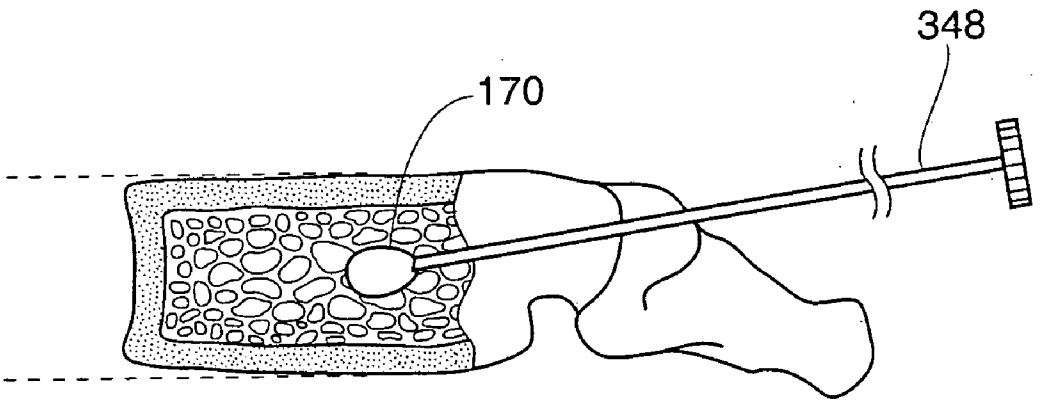
(52) **U.S. Cl.** **606/94**

(57) **ABSTRACT**

The present invention relates to devices and methods for treating fractured and/or diseased bone. More specifically, the present invention relates to devices and methods for repairing, reinforcing and/or treating fractured and/or diseased bone using various devices, including cavity-forming devices.



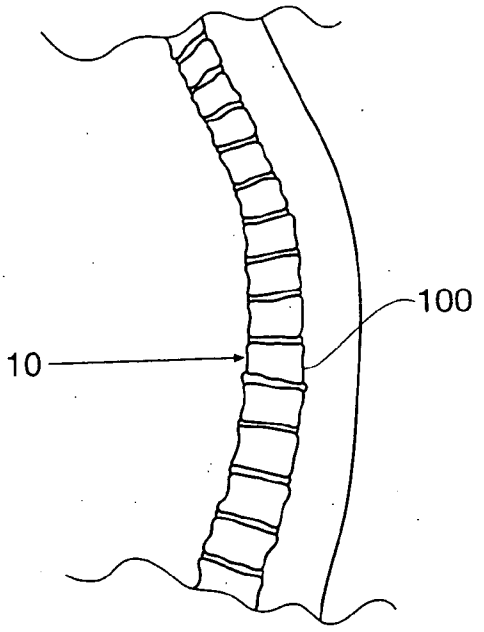


Fig. 1

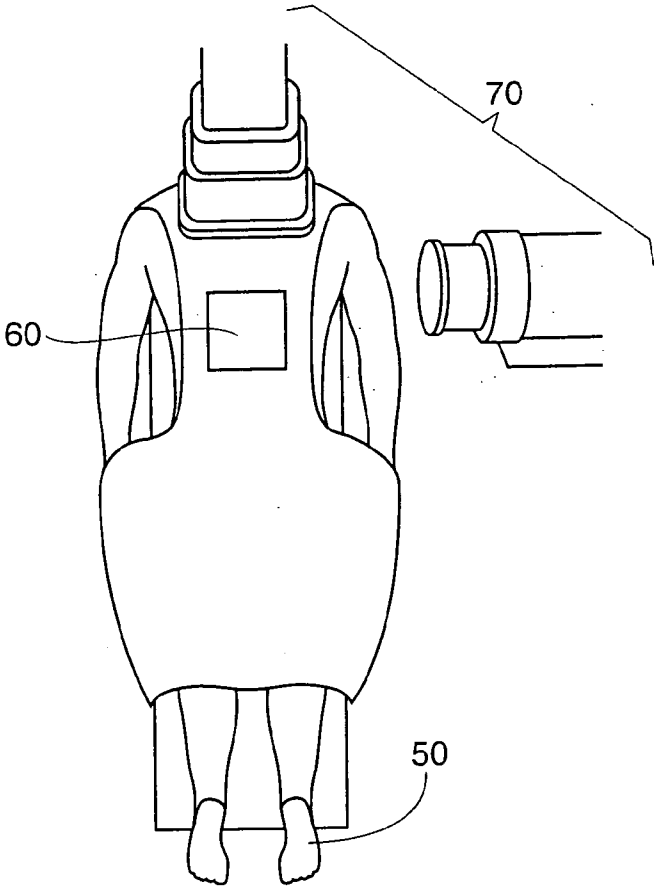


Fig. 2

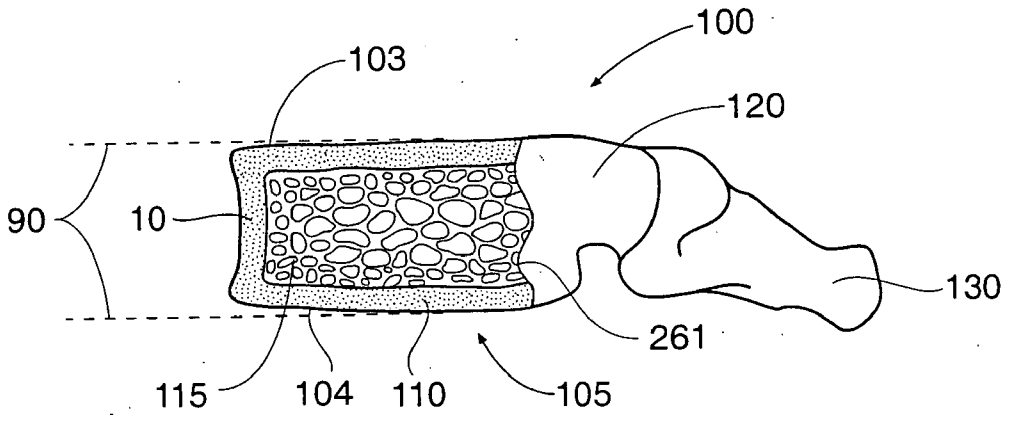

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Fig. 3

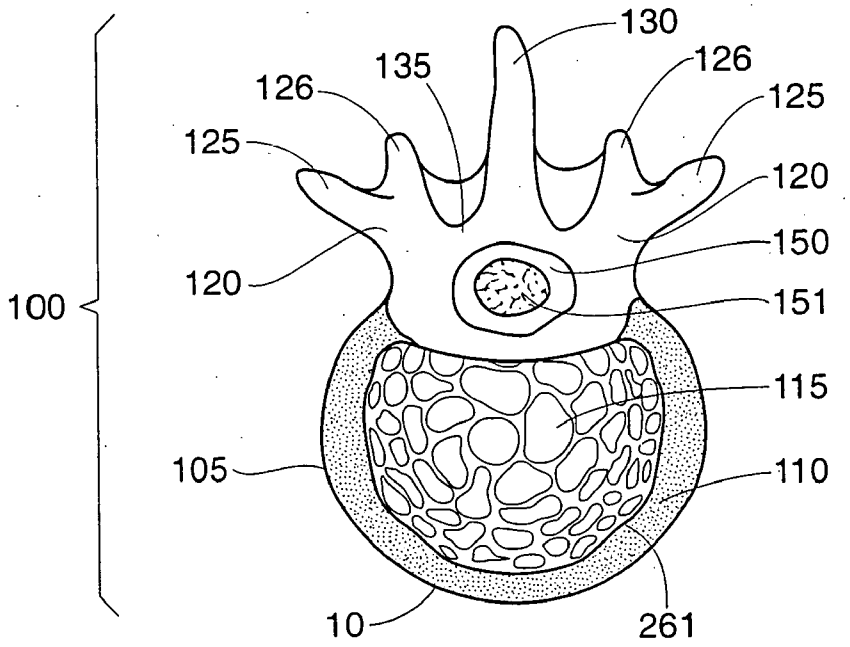
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Fig. 4

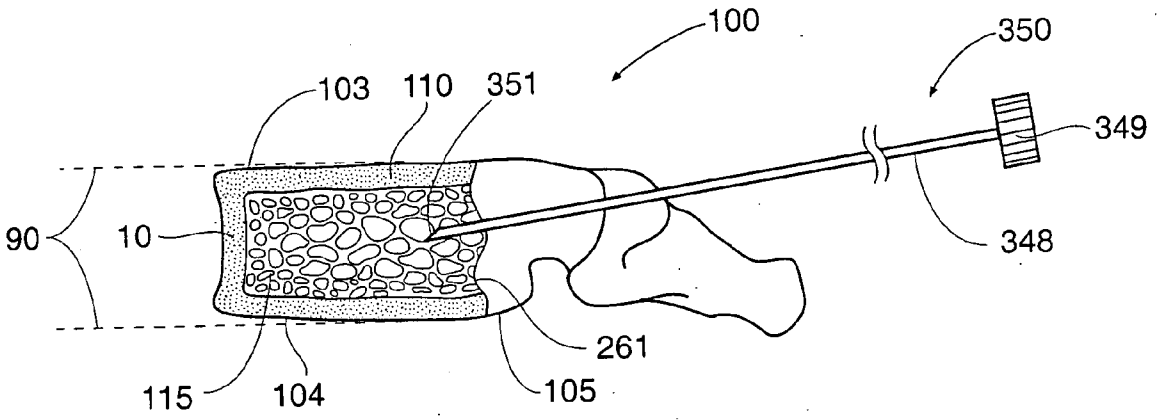
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Fig. 5a

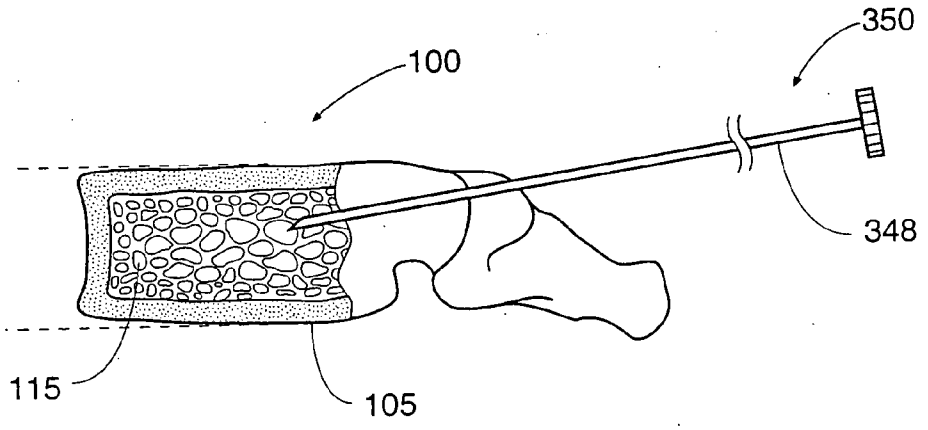
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Fig. 5b

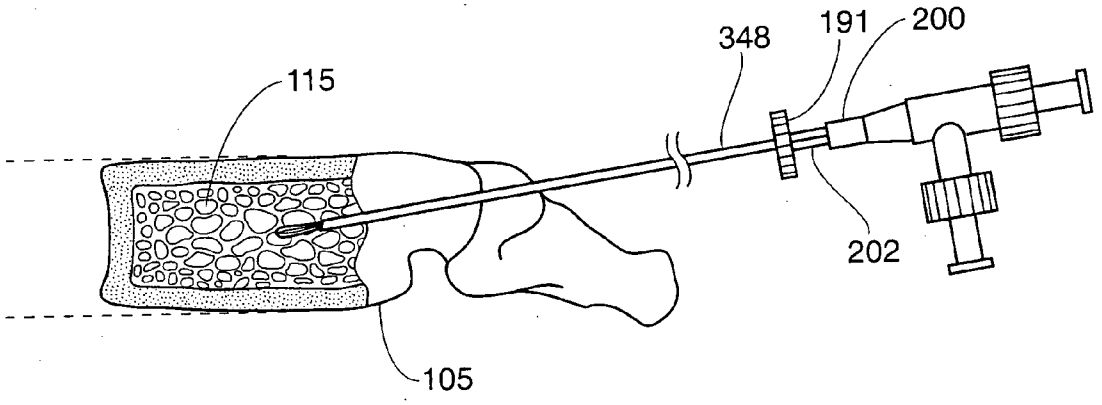
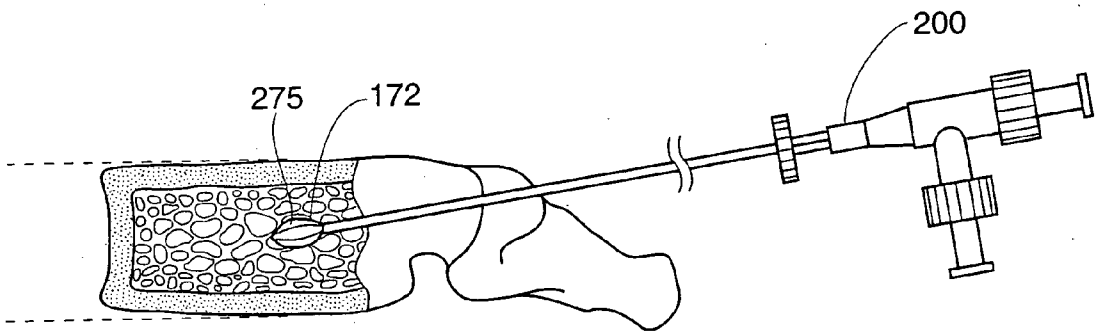


Fig. 5c



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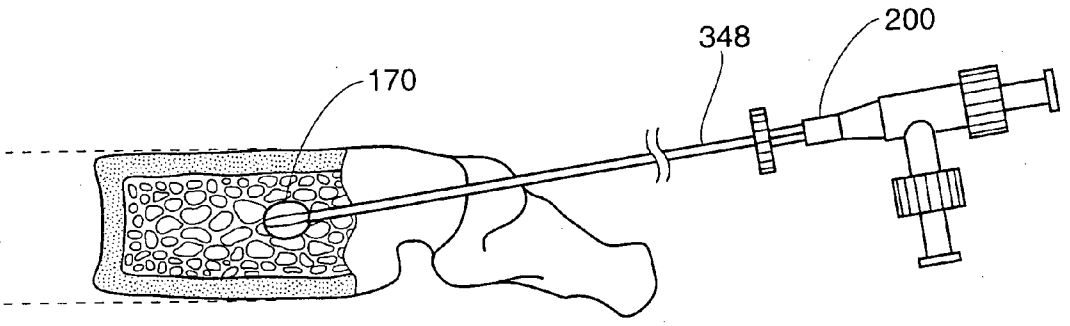

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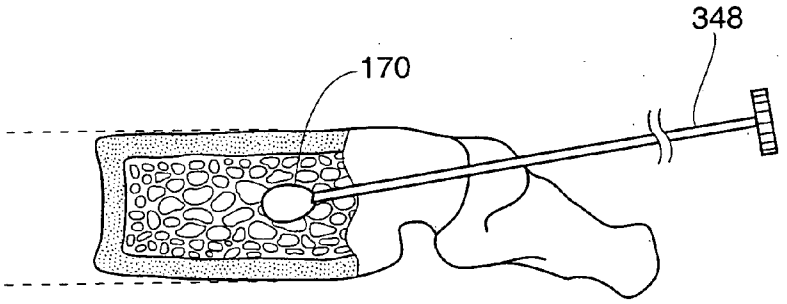

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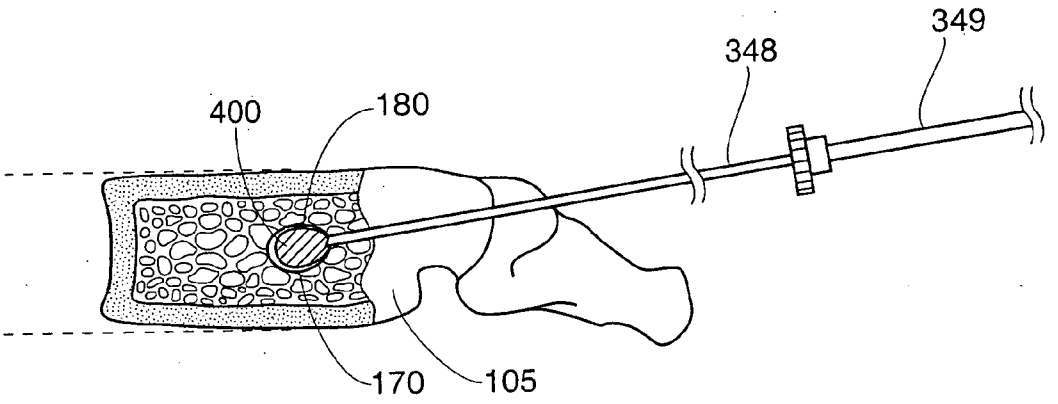

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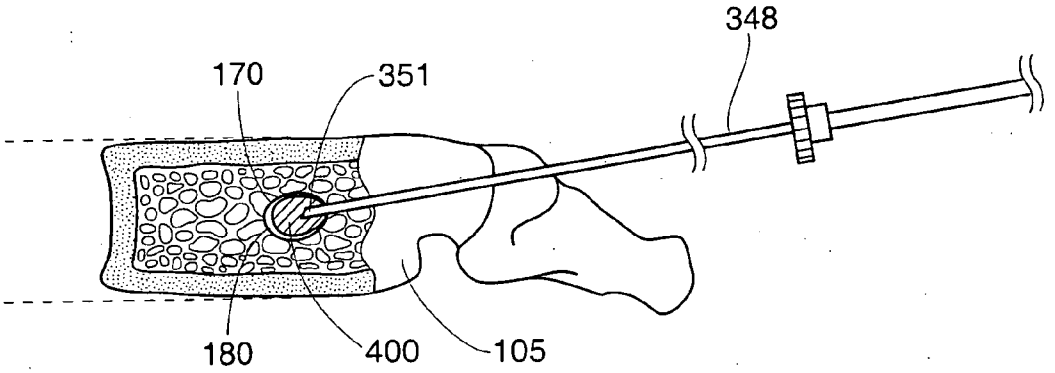

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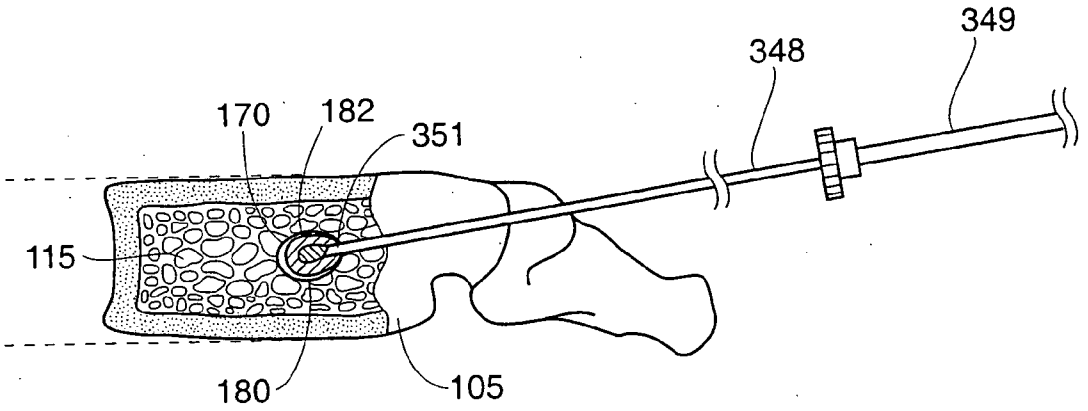


Fig. 5i

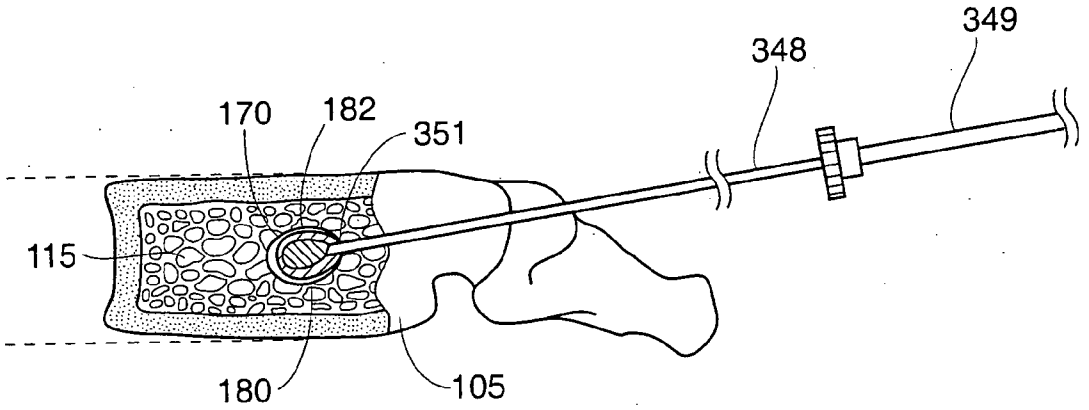
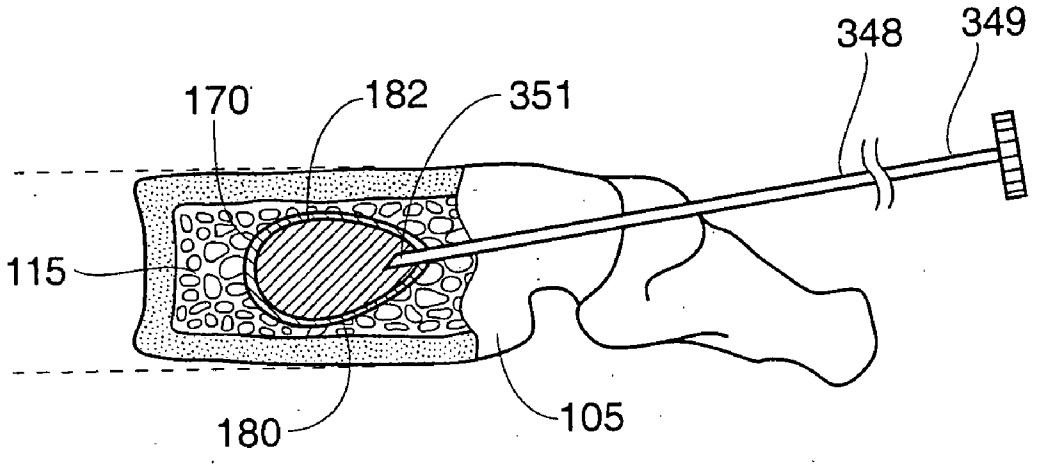


Fig. 5j



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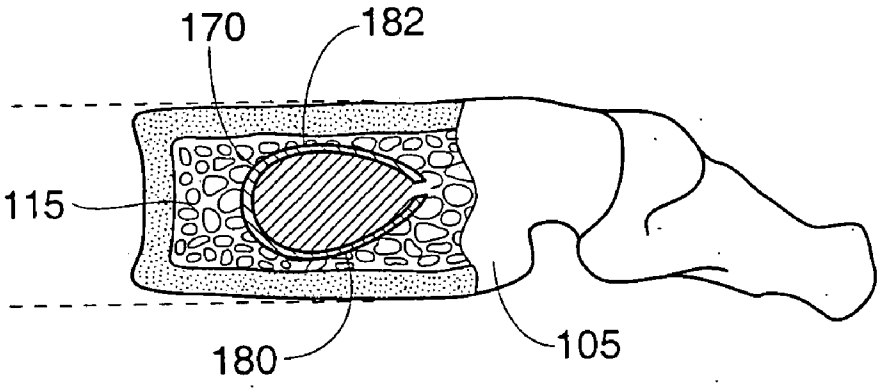

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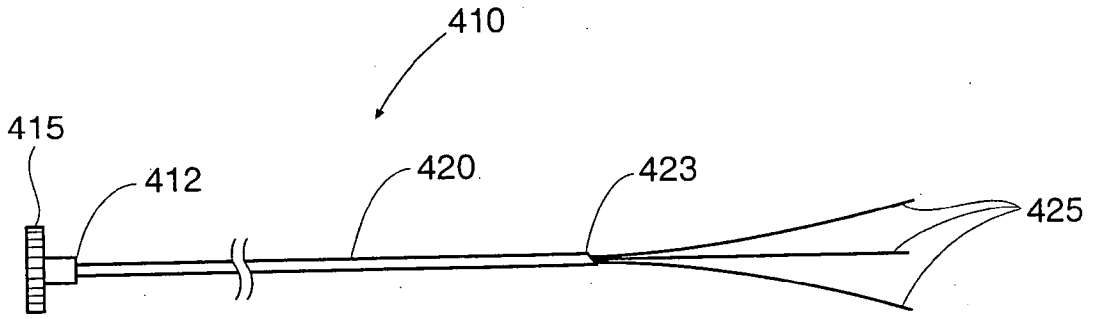

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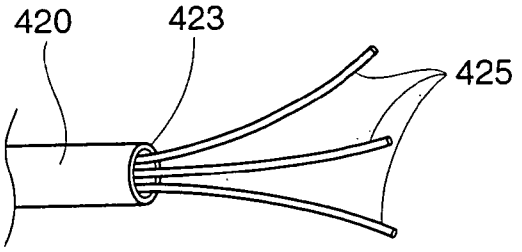
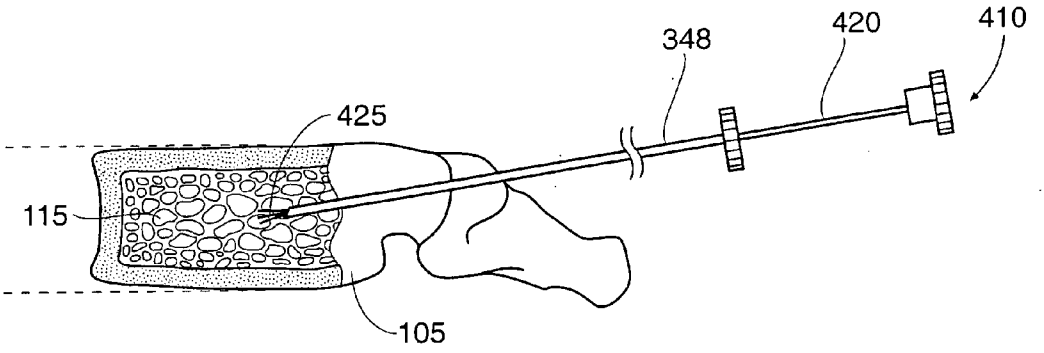


Fig. 6b



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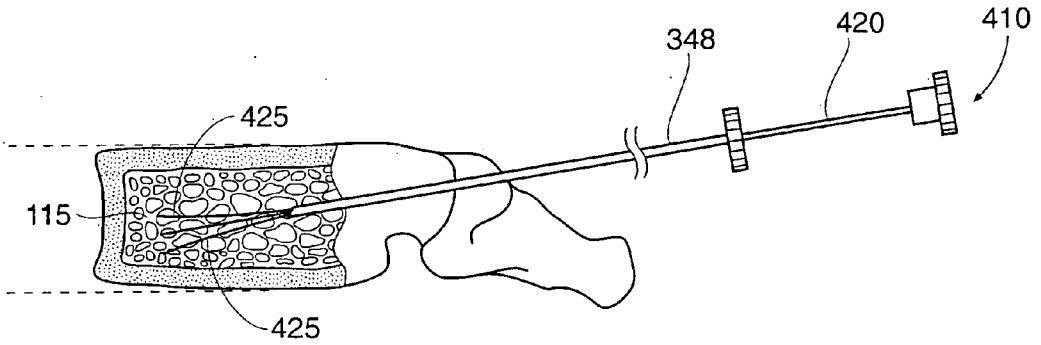

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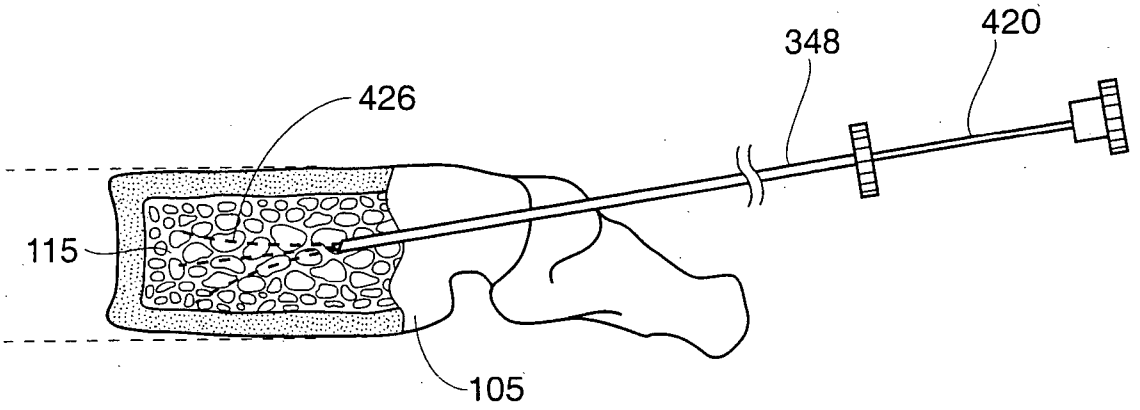

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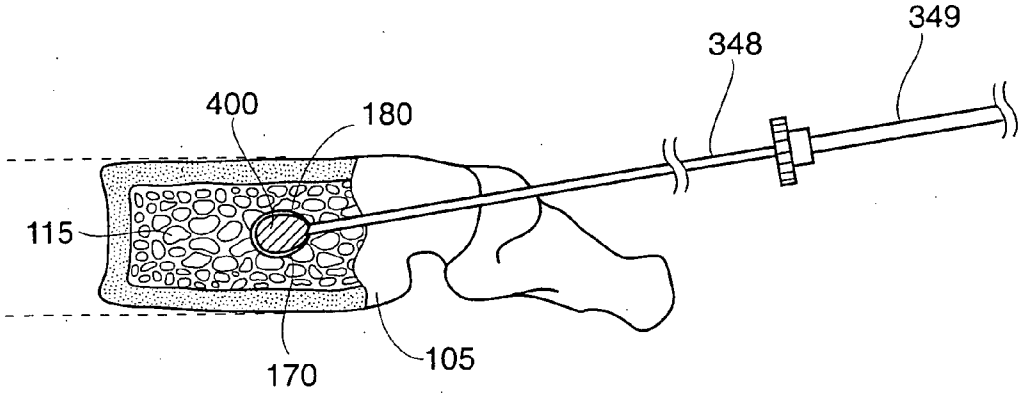
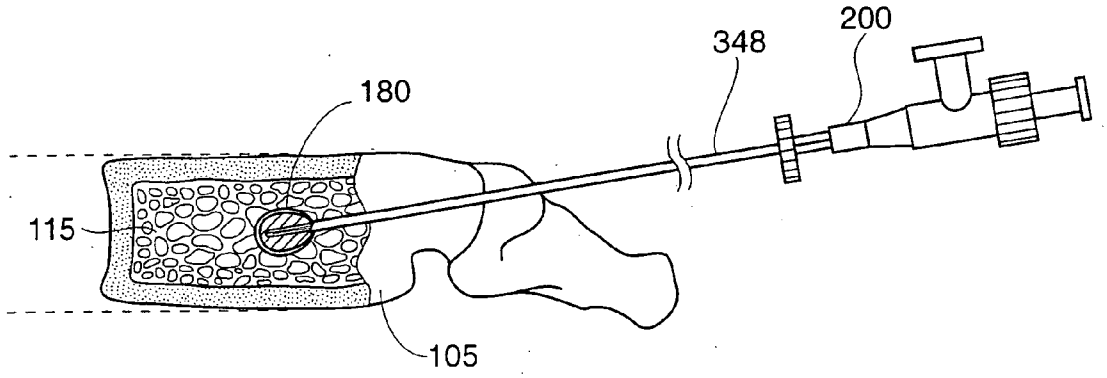


Fig. 8a



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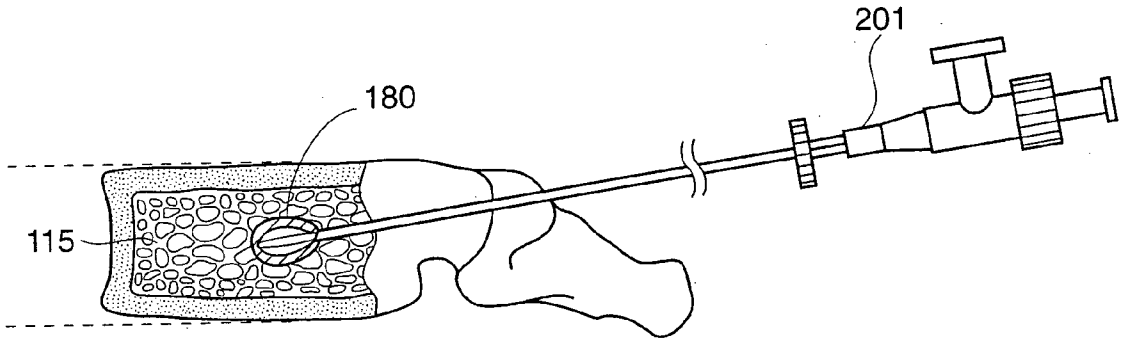

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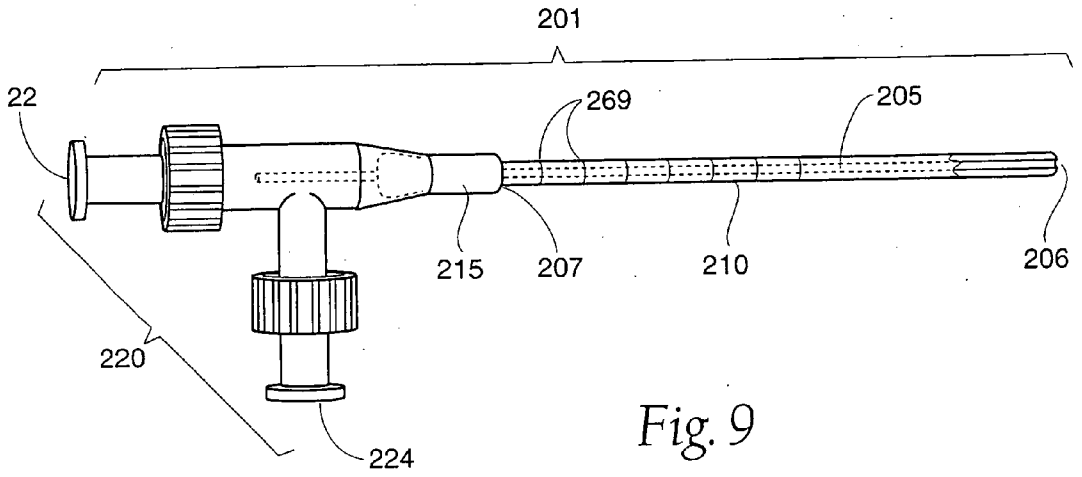

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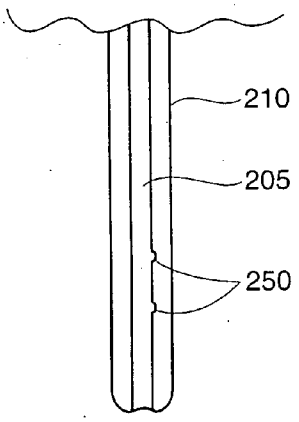


Fig. 10

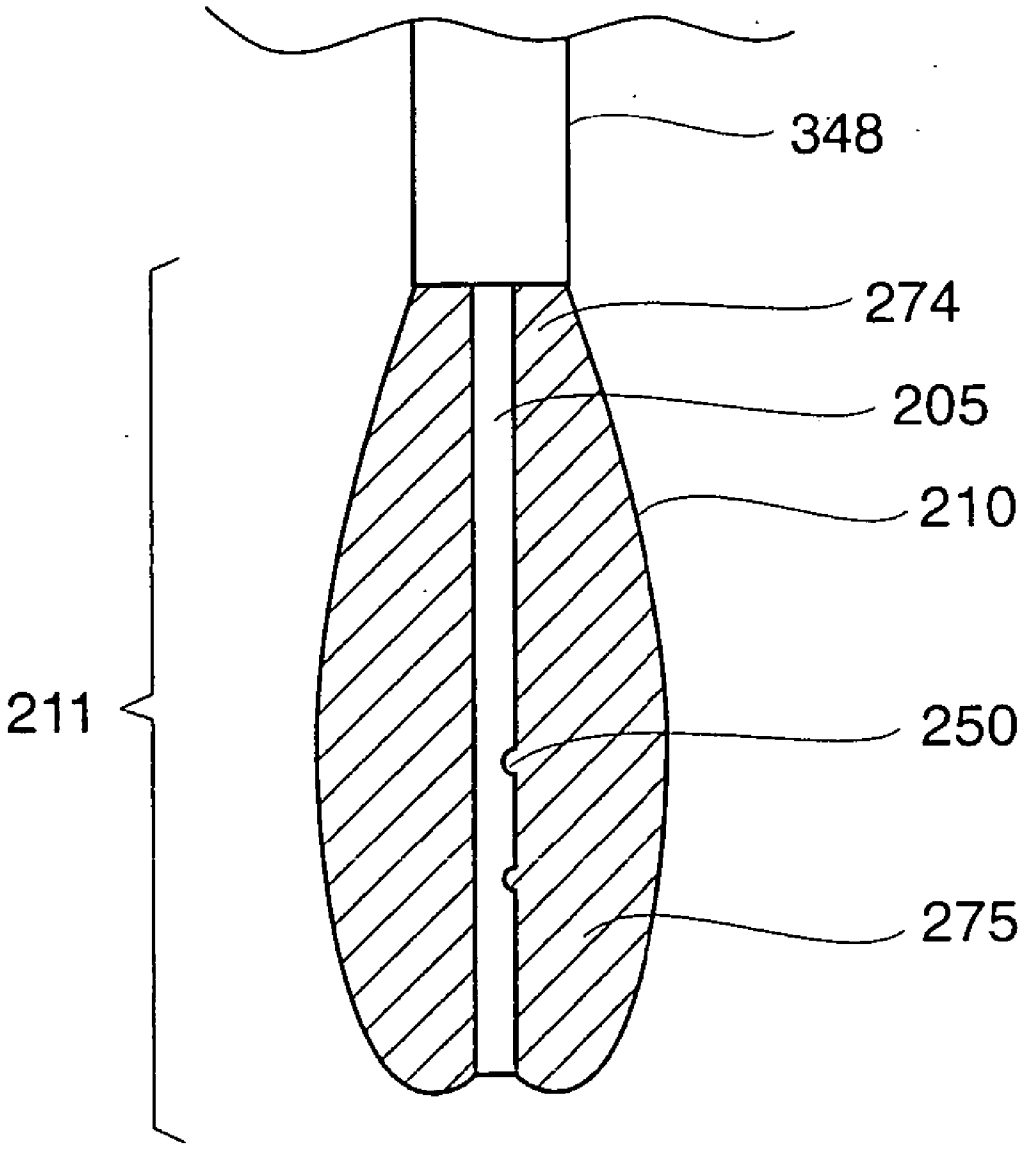


Fig. 11

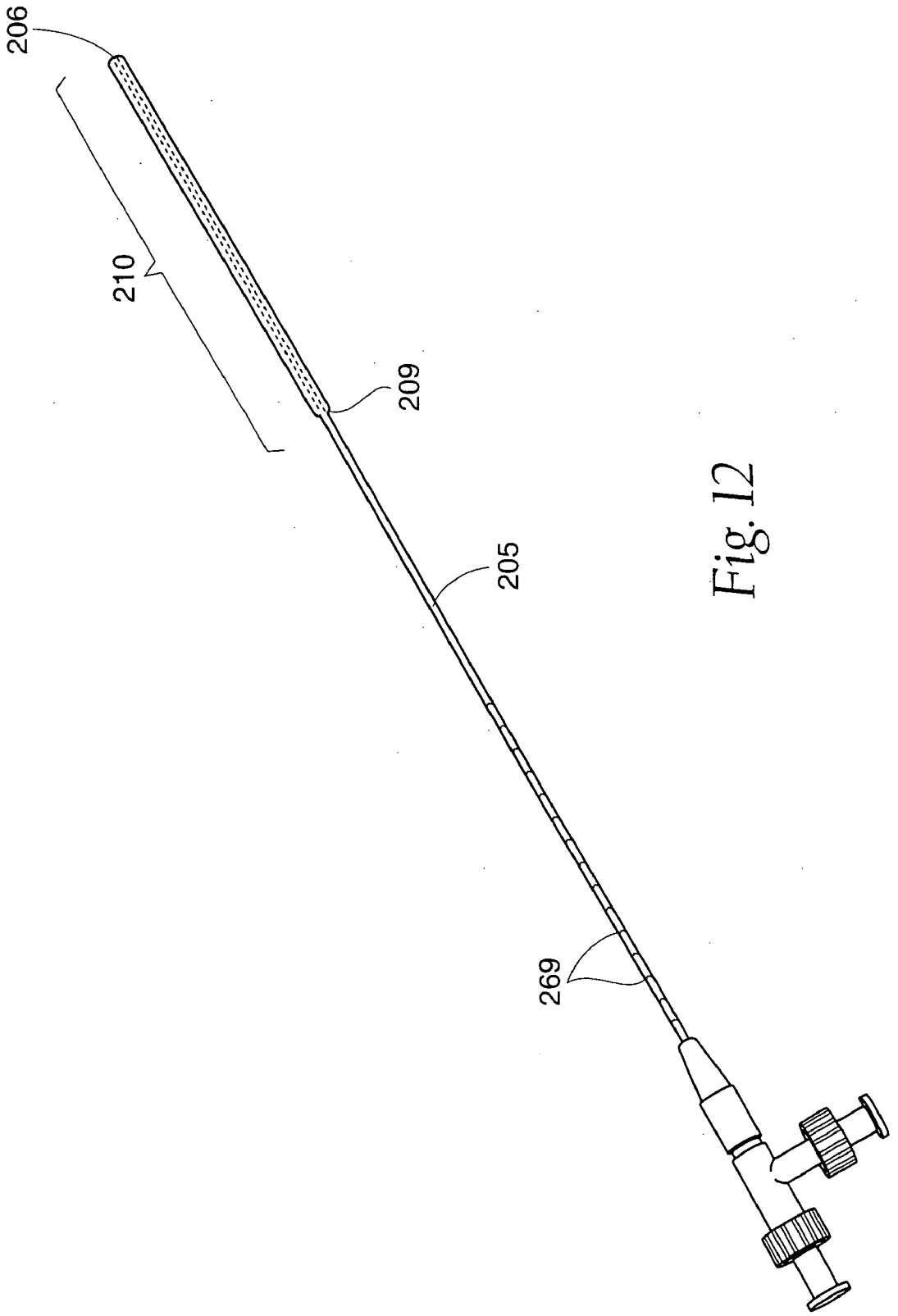


Fig. 12

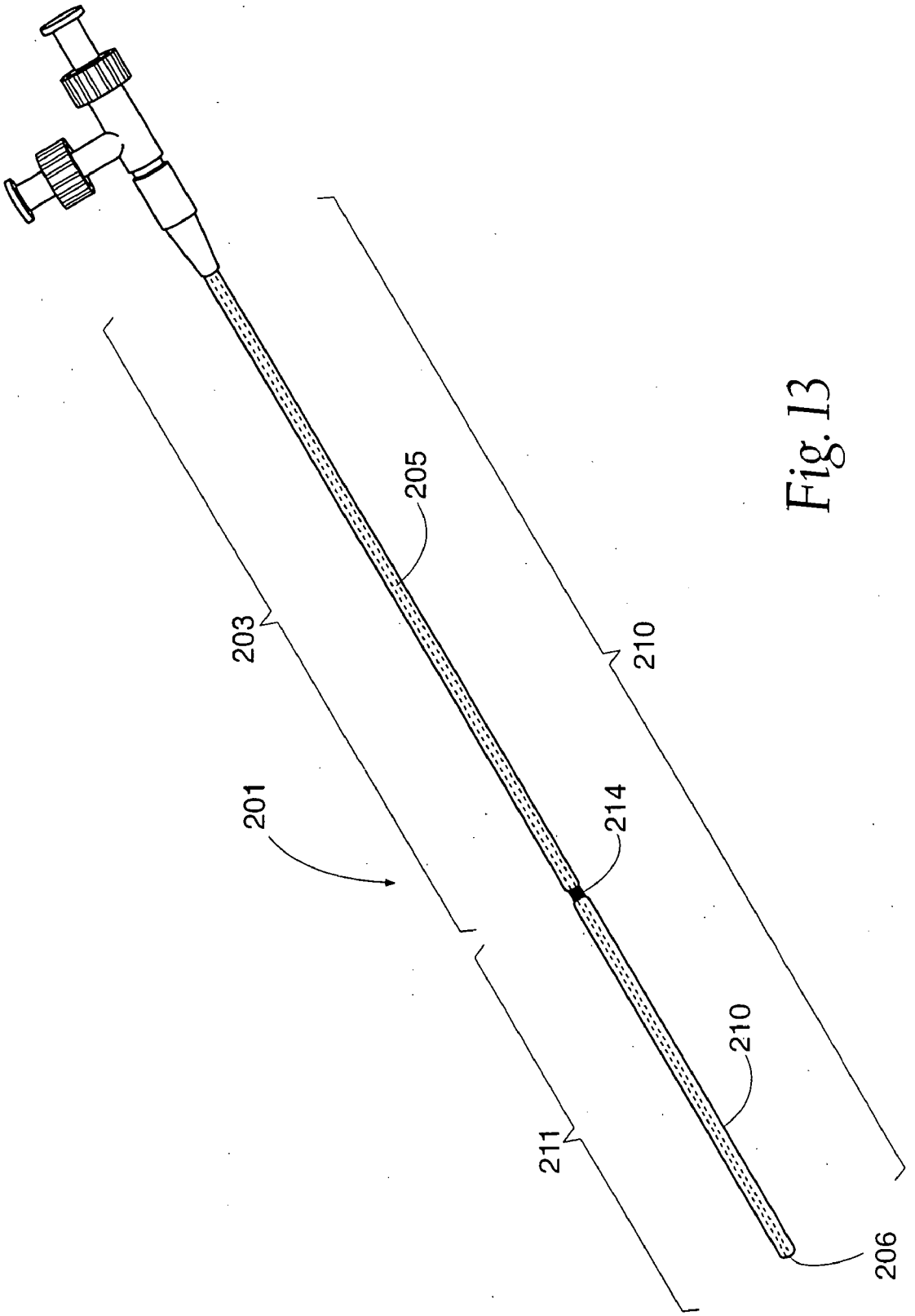


Fig. 13

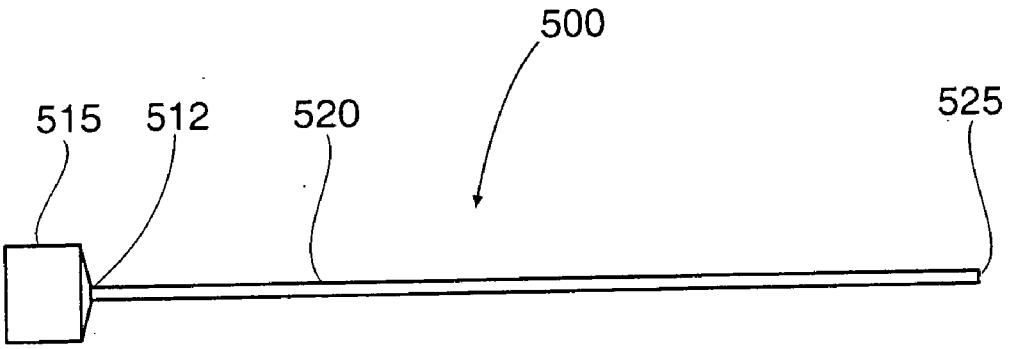


Fig. 14

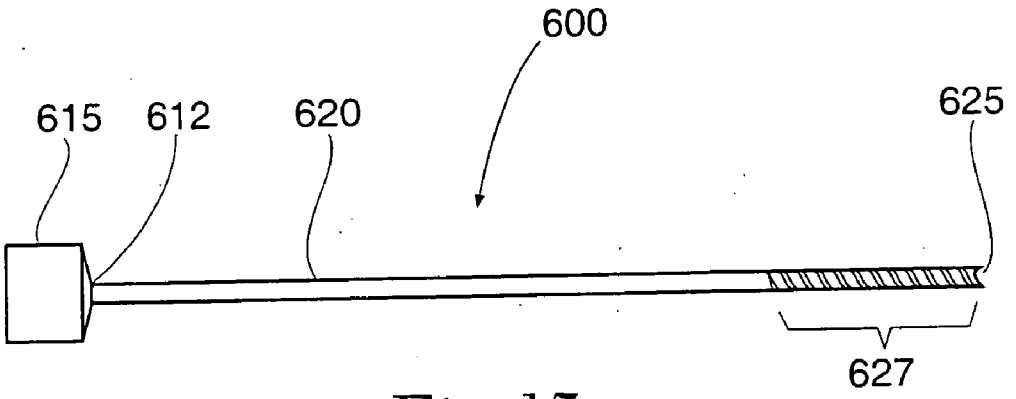


Fig. 15

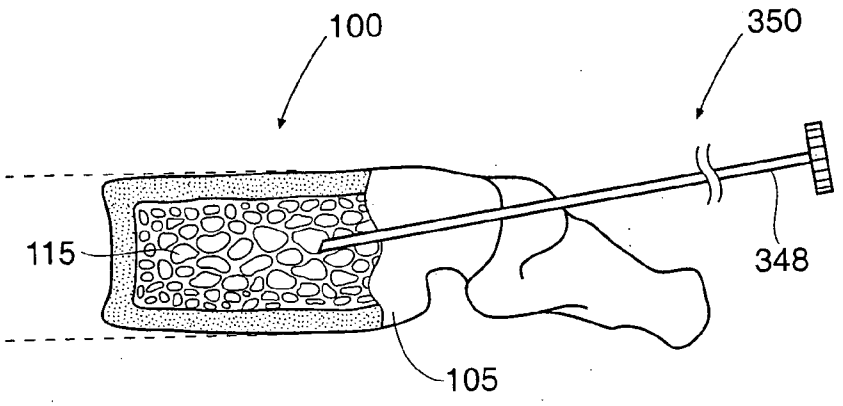


Fig. 16a

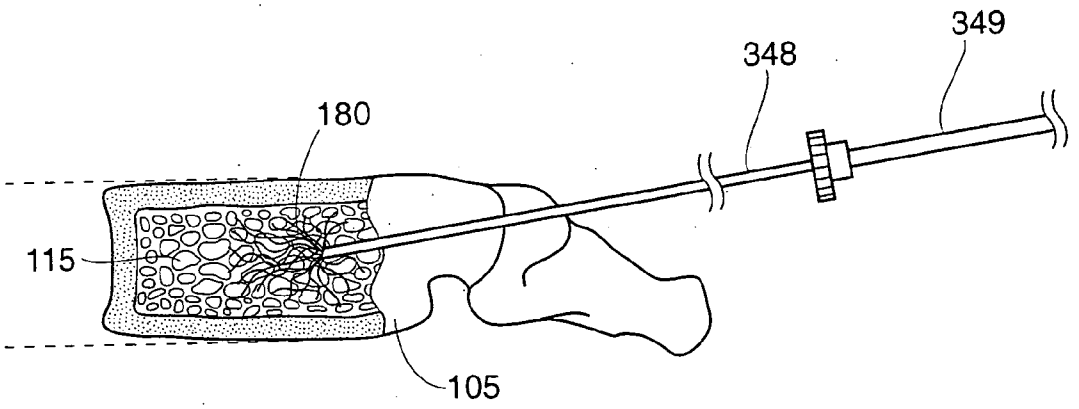
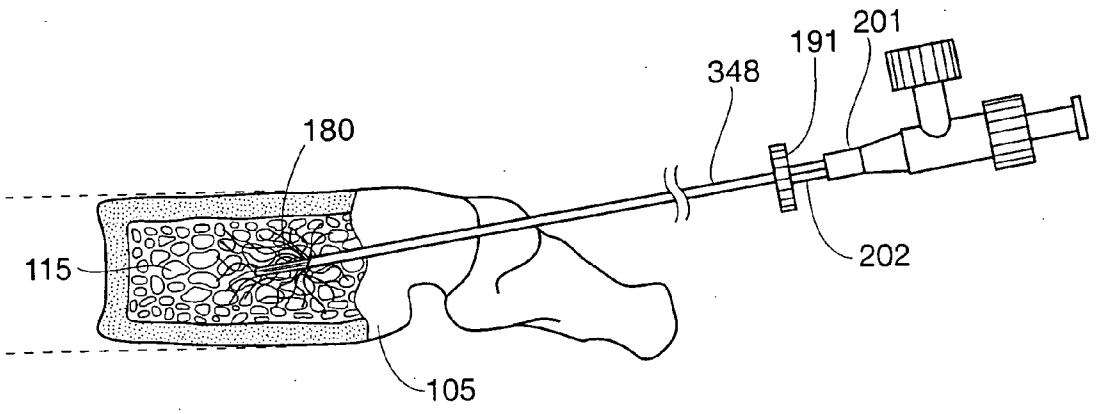


Fig. 16b



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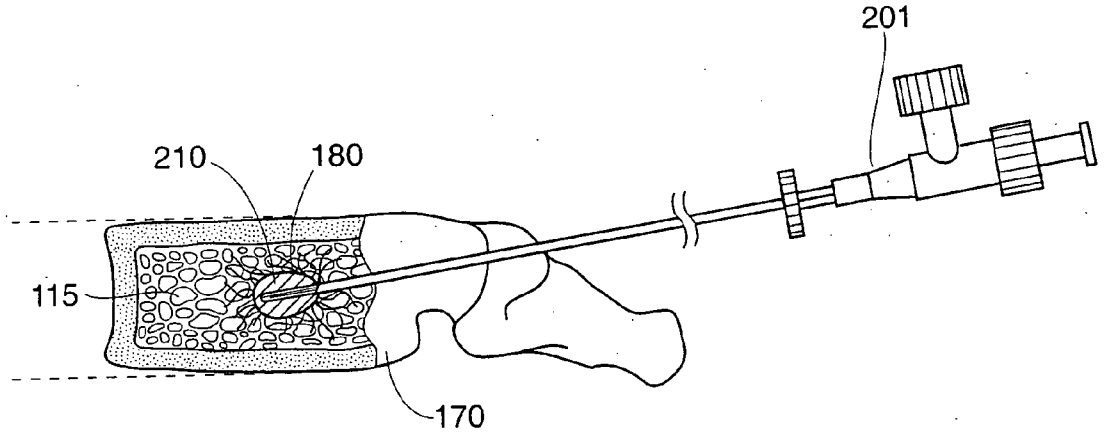

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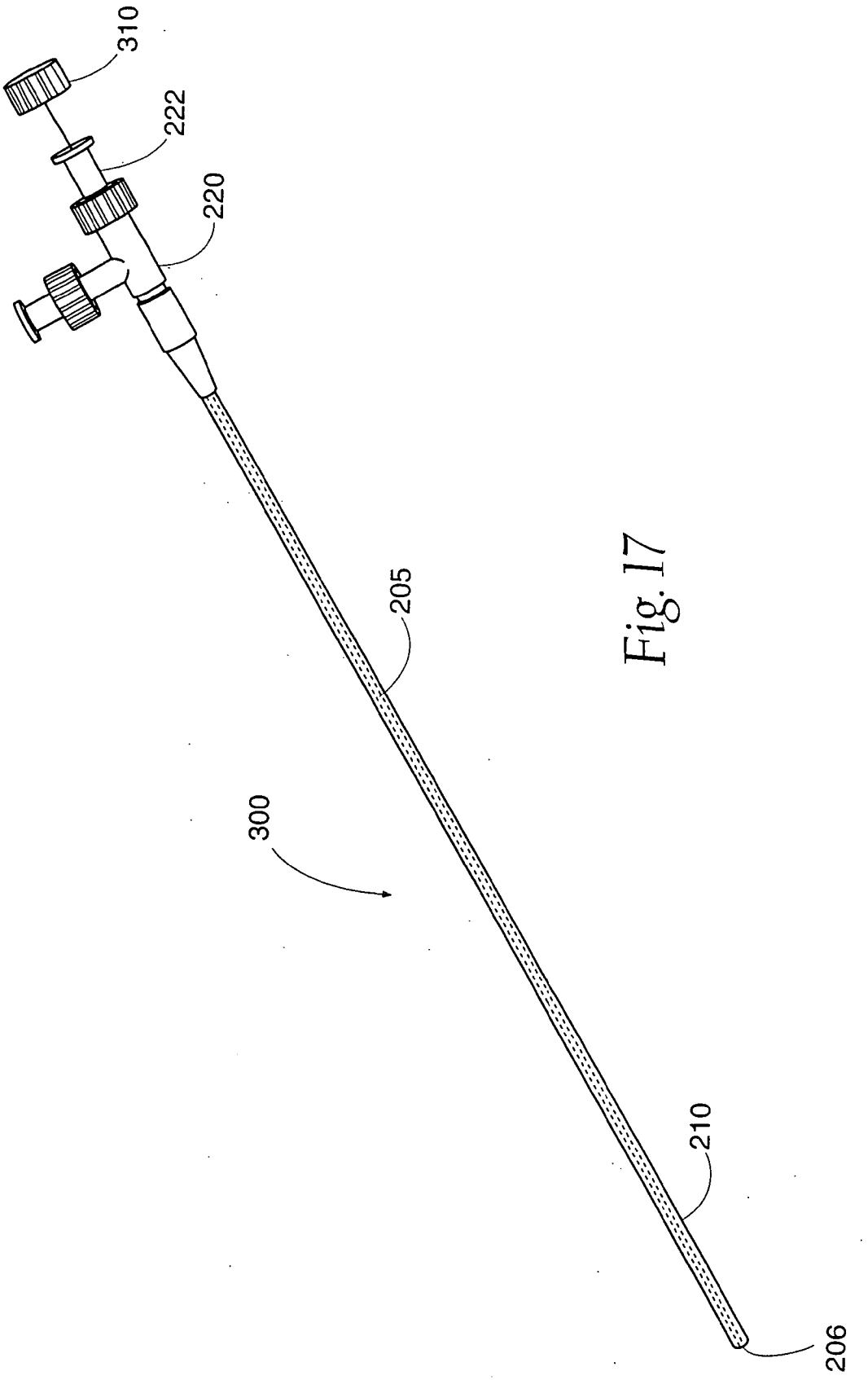

Fig. 17

Fig. 19

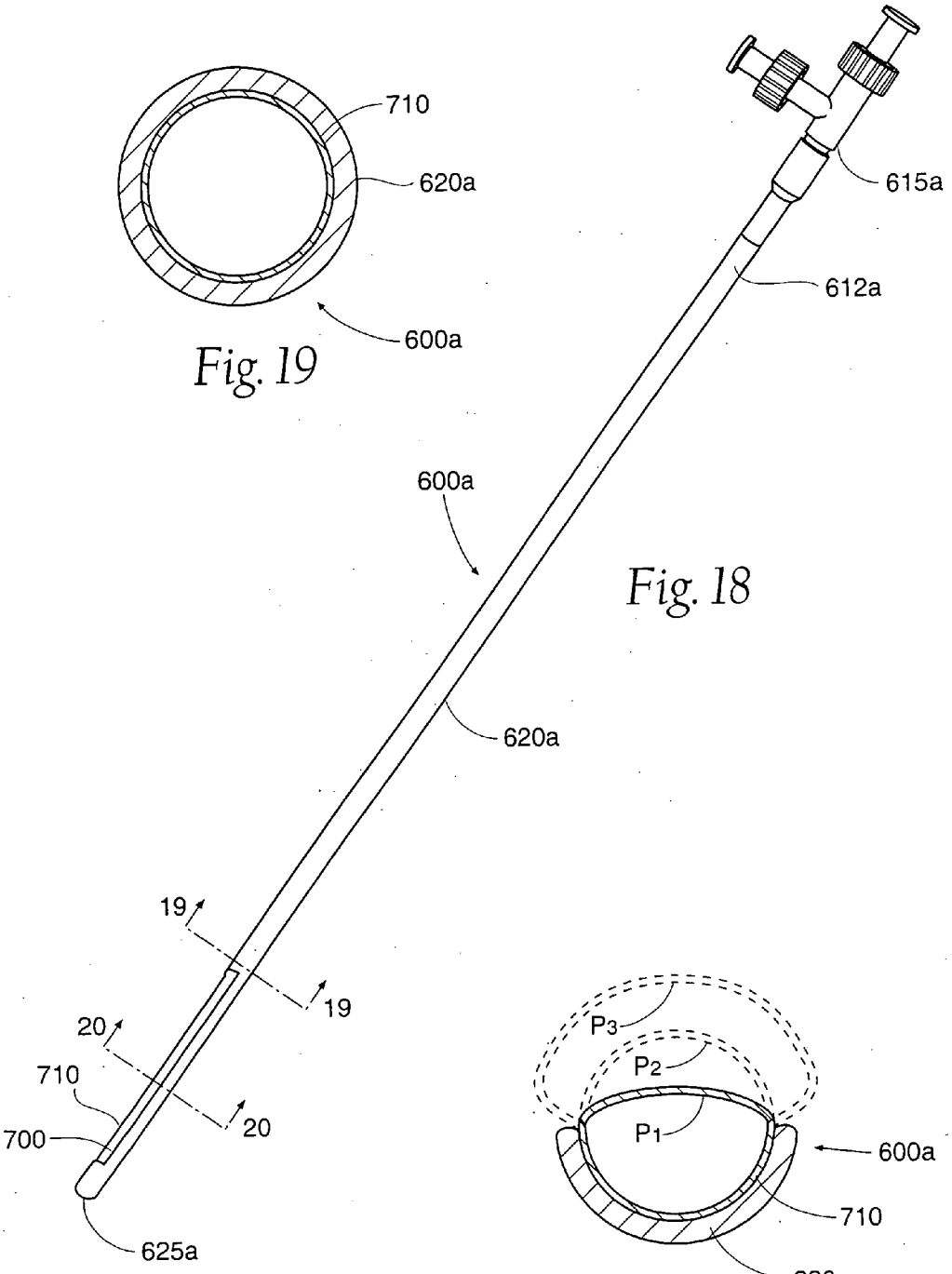

Fig. 18

Fig. 20

CAVITY FORMATION DEVICE

RELATED APPLICATIONS

[0001] This is a divisional application of co-pending U.S. application Ser. No. 09/827,260 filed 5 Apr. 2001, which claims the benefit of provisional Application Ser. No. 60/194,685 filed 5 Apr. 2000, and which is also a continuation-in-part of application Ser. No. 09/134,323 filed 14 Aug. 1998, now U.S. Pat. No. 6,241,734.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to devices and methods for treating fractured and/or diseased bone. More specifically, the present invention relates to devices and methods for repairing, reinforcing and/or treating fractured and/or diseased bone using various devices, including cavity-forming devices.

[0004] 2. Description of the Background

[0005] Normal healthy bone is composed of a framework made of proteins, collagen and calcium salts. Healthy bone is typically strong enough to withstand the various stresses experienced by an individual during his or her normal daily activities, and can normally withstand much greater stresses for varying lengths of time before failing. However, osteoporosis or a host of other diseases, including such diseases as breast cancer, hemangiomas, osteolytic metastases or spinal myeloma lesions, as well as the long term excessive use of alcohol, tobacco and/or various drugs, can affect and significantly weaken healthy bone over time. If unchecked, such factors can degrade bone strength to a point where the bone is especially prone to fracture, collapse and/or is unable to withstand even normal daily stresses.

[0006] Unfortunately, losses in bone strength are often difficult to discover until bone integrity has already been seriously compromised. For instance, the effects of osteoporosis are often not discovered until after a bone fracture has already occurred, at which time much of the patient's overall bone strength has typically weakened to dangerous levels. Moreover, as most bone development occurs primarily during childhood and early adulthood, long-term losses in bone strength are typically irreversible. In addition, many bone diseases, including osteoporosis, cancer, and other bone-related disorders, are not routinely curable at our current stage of medical development.

[0007] For many individuals in our aging world population, undiagnosed and/or untreatable bone strength losses have already weakened these individuals' bones to a point that even normal daily activities pose a significant threat of fracture. For example, when the bones of the spine are sufficiently weakened, the compressive forces in the spine can often cause fracture and/or deformation of the vertebral bodies. For sufficiently weakened bone, even normal daily activities like walking down steps or carrying groceries can cause a collapse of one or more spinal bones, much like a piece of chalk collapses under the compressive weight of a human foot. A fracture of the vertebral body in this manner is typically referred to as a vertebral compression fracture. Researchers estimate that at least 25 percent of all women, and a somewhat smaller percentage of men, over the age of 50 will suffer one or more vertebral compression fractures due to osteoporosis alone. In the United States, it is estimated that over 700,000 vertebral compression fractures occur each year, over 200,000 of which require some form of hospitalization. Other commonly occurring fractures resulting from weakened bones can include hip, wrist, knee and ankle fractures, to name a few.

[0008] Fractures such as vertebral compression fractures often result in episodes of pain that are chronic and intense. Aside from the pain caused by the fracture itself, the involvement of the spinal column can result in pinched and/or damaged nerves, causing paralysis, loss of function, and intense pain which radiates throughout the patient's body. Even where nerves are not affected, however, the intense pain associated with all types of fractures is debilitating, resulting in a great deal of stress, impaired mobility and other long-term consequences. For example, progressive spinal fractures can, over time, cause serious deformation of the spine ("kyphosis"), giving an individual a hunched-back appearance, and can also result in significantly reduced lung capacity and increased mortality.

[0009] Until recently, treatment options for vertebral compression fractures, as well as other serious fractures and/or losses in bone strength, were extremely limited—mainly pain management with strong oral or intravenous medications, reduced activity, bracing and/or radiation therapy, all with mediocre results. Because patients with these problems are typically older, and often suffer from various other significant health complications, many of these individuals are unable to tolerate invasive surgery. In addition, to curb further loss of bone strength, many patients are given hormones and/or vitamin/mineral supplements—again with mediocre results and often with significant side effects.

[0010] Over the past decade, a technique called vertebroplasty has been introduced into the United States. Vertebroplasty involves the injection of a flowable reinforcing material, usually polymethylmethacrylate (PMMA—commonly known as bone cement), into a fractured, weakened, or diseased vertebral body. Shortly after injection, the liquid filling material hardens or polymerizes, desirably supporting the vertebral body internally, alleviating pain and preventing further collapse of the injected vertebral body.

[0011] While vertebroplasty has been shown to reduce some pain associated with vertebral compression fractures, this procedure has certain inherent drawbacks. The most significant danger associated with vertebroplasty is the inability of the practitioner to control the flow of liquid bone cement during injection into a vertebral body. Although the location and flow patterns of the cement can be monitored by CT scanning or x-ray fluoroscopy, once the liquid cement exits the injection needle, it naturally follows the path of least resistance within the bone, which is often through the cracks and/or gaps in the cancellous and/or cortical bone. Moreover, because the cancellous bone resists the injection of the bone cement and small diameter needles are typically used in vertebroplasty procedures, extremely high pressures are required to force the bone cement through the needle and into the vertebral body. Bone cement, which is viscous, is difficult to inject through small diameter needles, and thus many practitioners choose to "thin out" the cement mixture to improve cement injection, which ultimately exacerbates the leakage problems. In a recent study where 37 patients with bone metastases or multiple myeloma were treated with

vertebroplasty, 72.5% of the procedures resulted in leakage of the cement outside the vertebral body. Cortet B. et al., Percutaneous Vertebroplasty in Patients With Osteolytic Metastases or Multiple Myeloma (1998). Moreover, where the practitioner attempts to "thin out" the cement by adding additional liquid monomer to the cement mix, the amount of unpolymerized or "free" monomer increases, which can ultimately be toxic to the patient.

[0012] Another drawback of vertebroplasty is due to the inability to visualize (using CT scanning or x-ray fluoroscopy) the various venous and other soft tissue structures existent within the vertebra. While the position of the needle within the vertebral body is typically visualized, the location of the venous structures within the vertebral body are not. Accordingly, a small diameter vertebroplasty needle can easily be accidentally positioned within a vein in the vertebral body, and liquid cement pumped directly into the venous system, where the cement easily passes out the anterior and/or posterior walls of the vertebrae through the anterior external venous plexus or the basivertebral vein.

[0013] Another significant drawback inherent in vertebroplasty is the inability of this procedure to restore the vertebral body to a pre-fractured condition prior to the injection of the reinforcing material. Because the bone is fractured and/or deformed, and not repositioned prior to the injection of cement, vertebroplasty essentially "freezes" the bone in its fractured condition. Moreover, it is highly unlikely that a traditional vertebroplasty procedure could be capable of restoring significant pre-fracture anatomy—because bone cement flows towards the path of least resistance, any en-masse movement of the cortical bone would likely create gaps in the interior and/or walls of the vertebral body through which the bone cement would then immediately flow.

[0014] A more recently developed procedure for treating fractures such as vertebral compression fractures and other bone-related disorders is known as Kyphoplasty™. See, for example, U.S. Pat. Nos. 4,969,888 and 5,108,404. In Kyphoplasty, an expandable body is inserted through a small opening in the fractured or weakened bone, and then expanded within the bone. This procedure compresses the cancellous bone, and desirably moves the fractured bone to its pre-fractured orientation, creating a cavity within the bone that can be filled with a settable material such as cement or any number of synthetic bone substitutes. In effect, the procedure "sets" the bone at or near its pre-fracture position and creates an internal "cast," protecting the bone from further fracture and/or collapse. This procedure is of course suitable for use in various other bones as well.

[0015] While Kyphoplasty can restore bones to a pre-fractured condition, and injected bone filler is less likely to leak out of the vertebral body during a Kyphoplasty procedure, Kyphoplasty requires a greater number of surgical tools than a vertebroplasty procedure, at an increased cost. Moreover, Kyphoplasty tools are typically larger in diameter than vertebroplasty tools, and thus require larger incisions and are generally more invasive.

SUMMARY OF THE INVENTION

[0016] The present invention overcomes many of the problems and disadvantages associated with current strategies and designs in medical procedures to repair, reinforce and/or treat weakened, diseased and/or fractured bone. In one preferred embodiment, the present invention relates to improved vertebroplasty procedures and surgical instruments which facilitate such procedures.

[0017] In a general embodiment of the method of the present invention, an insertion device, preferably an eleven gauge spinal needle assembly, is inserted into a targeted vertebral body using fluoroscopic x-ray to monitor the positioning of the needle. A cavity-forming device is inserted through the needle into the vertebral body. The cavity-forming device desirably compresses cancellous bone in the vicinity of the distal tip of the needle—forming a small cavity within the bone. The cavity-forming device is removed and cement is introduced through the spinal needle. Bone filler such as bone cement mixed with a fluoroscopic agent is injected into the cavity using x-ray fluoroscopy to monitor the flow of the bone filler within the vertebral body. Bone filler introduction is halted when a desired fill amount is reached, the fractured portions of the vertebral body approach and/or return to their pre-fractured position, or bone filler leakage is imminent. Because a cavity is created within the vertebral body prior to bone filler introduction, very low injection pressures can be used, significantly reducing the possibility of cement leakage. In addition, the creation of desired flowpaths permits a greater control in the placement of the bone filler material within the vertebral body.

[0018] In another general embodiment of a method of the present invention, an insertion device, such as a commercially available spinal needle assembly, is inserted through a cortical bone region and into a cancellous bone region of a targeted bone using fluoroscopic x-ray to monitor the positioning of the needle. A first material, such as a bone filler, is introduced into the cancellous bone region through the insertion device. An expandable structure is then inserted through the insertion device and expanded in the bone, compressing the first material and/or cancellous bone, thereby creating a cavity and/or a barrier region of compressed cancellous bone substantially surrounding the cavity. A second material, which may be of the same material as the first material, is then introduced through the insertion device into the bone. If desired, the first material can comprise a material having sufficient strength to support the cavity during the surgical procedure, thereby preventing collapse of the cavity upon contraction and removal of the expandable structure. Such first material could include, but is not limited to, bone cement, bone graft material or metallic and nonmetallic stents.

[0019] In a further embodiment, the methods of the present invention are performed on a compressed and/or fractured vertebra to strengthen the vertebra, returning it, at least partially, to its pre-fractured position, protect the vertebra from further fracture or collapse, and/or alleviate the pain associated with spinal fractures and compressions.

[0020] In one embodiment of the present invention, a cavity-forming device comprises a balloon catheter. The balloon catheter desirably incorporates a hollow tube which extends through a balloon material. At the proximal end of the catheter, the tube and expandable structure are connected to a fitting. At the distal end, the expandable structure is secured directly to and/or around the hollow tube. The distal

end of the expandable structure and the distal end of the hollow tube are sealed. Near the distal end of the hollow tube are one or more openings through which an inflation medium passes in and out of the hollow tube to expand and contract the expandable structure.

[0021] The balloon catheter of the present invention may be inserted through an insertion device, such as an eleven gauge needle assembly, into a bone, such as a vertebral body, with the distal end of the catheter extending beyond the needle to a length determined by the physician. When the catheter is filled with an inflation medium, the portion of the catheter extending beyond the needle expands outward, compressing cancellous bone and forming a desired cavity within the vertebral body.

[0022] In another embodiment of the present invention, the cavity-forming device comprises a shaft incorporating one or more wires or "bristles" at the distal end. The cavity-forming device is desirably inserted through an insertion device, such as a spinal needle, into a cancellous region of a bone, such as a vertebral body. As the bristles enter the vertebral body, they displace cancellous bone in a controlled manner, creating one or more small pathways or cavities in the cancellous bone. The cavity-forming device is removed from the vertebral body and needle, and bone filler is introduced into the vertebral body. The bone filler, which normally flows towards the path of least resistance, will initially flow through the small cavities. If desired, the physician can interrupt introduction of bone filler and create additional cavities by reinserting the cavity-forming device. By creating desired pathways through cancellous bone, the present invention reduces opportunities for cement leakage outside of the vertebral body and/or improves distribution of bone filler through a significant portion of the vertebral body.

[0023] Other objects, advantages, and embodiments of the invention are set forth in part in the description which follows, and in part, will be obvious from this description, or may be learned from the practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] **FIG. 1** is a diagram of a spine with a compression fracture in one vertebrae;

[0025] **FIG. 2** is a diagram of a patient about to undergo surgery;

[0026] **FIG. 3** is a lateral view, partially broken away and in section, of a lumbar vertebra depicting a compression fracture;

[0027] **FIG. 4** is a coronal view of a lumbar vertebra;

[0028] **FIG. 5A** is a lateral view of a lumbar vertebra depicting a spinal needle inserted into the vertebral body;

[0029] **FIG. 5B** is a lateral view of the lumbar vertebra of **FIG. 5A**, with the stylet removed from the spinal needle;

[0030] **FIG. 5C** is a lateral view of the lumbar vertebra of **FIG. 5B**, with a cavity-forming device constructed in accordance with one embodiment of the present invention inserted into the vertebral body;

[0031] **FIG. 5D** is a lateral view of the lumbar vertebra of **FIG. 5C**, with the cavity-forming device inflated;

[0032] **FIG. 5E** is a lateral view of the lumbar vertebra of **FIG. 5D**, with the cavity-forming device deflated;

[0033] **FIG. 5F** is a lateral view of the lumbar vertebra of **FIG. 5E**, with the cavity-forming device removed from the vertebral body;

[0034] **FIG. 5G** is a lateral view of the lumbar vertebra of **FIG. 5F**, with a bone filler injected into the vertebral body;

[0035] **FIG. 5H** is a lateral view of the lumbar vertebra of **FIG. 5G**, with the spinal needle advanced into the cavity;

[0036] **FIG. 5I** is a lateral view of the lumbar vertebra of **FIG. 5H**, with a second bone filler injected into the vertebral body;

[0037] **FIG. 5J** is a lateral view of the lumbar vertebra of **FIG. 5I**, with additional bone filler injected into the vertebral body;

[0038] **FIG. 5K** is a lateral view of the lumbar vertebra of **FIG. 5J**, with additional bone filler injected into the vertebral body;

[0039] **FIG. 5L** is a lateral view of the lumbar vertebra of **FIG. 5K**, with the spinal needle removed from vertebral body;

[0040] **FIG. 6A** is a side view of a cavity-forming device constructed in accordance with an alternate embodiment of the present invention;

[0041] **FIG. 6B** is a close-up view of the distal end of the cavity-forming device of **FIG. 6A**;

[0042] **FIG. 7A** is a lateral view of a lumbar vertebra, depicting the cavity-forming device of **FIG. 6A** being inserted into the vertebra;

[0043] **FIG. 7B** is a lateral view of the lumbar vertebra of **FIG. 7A**, with the cavity-forming device deployed within the vertebra;

[0044] **FIG. 7C** is a lateral view of the lumbar vertebra of **FIG. 7B**, with the cavity-forming device withdrawn from the vertebra;

[0045] **FIG. 8A** is a lateral view of a lumbar vertebra, depicting an alternate procedure for treating a vertebral body in accordance with the teachings of the present invention;

[0046] **FIG. 8B** is a lateral view of the lumbar vertebra of **FIG. 8A**, with a cavity-forming device inserted into the bone filler;

[0047] **FIG. 8C** is a lateral view of the lumbar vertebra of **FIG. 8B**, with the cavity-forming device expanded in the cavity;

[0048] **FIG. 9** is a side view of a cavity-forming device constructed in accordance with one embodiment of the present invention;

[0049] **FIG. 10** is a close-up view of the distal end of a cavity-forming device of **FIG. 9**;

[0050] **FIG. 11** is a close-up view of the distal end of a balloon catheter protruding from the distal end of a needle, depicting the inflation of the balloon material with an inflation medium;

[0051] **FIG. 12** is a side view of a cavity-forming device constructed in accordance with an alternate embodiment of the present invention;

[0052] **FIG. 13** is a side view of a cavity-forming device constructed in accordance with another alternate embodiment of the present invention;

[0053] **FIG. 14** is a side view of a cavity-forming device constructed in accordance with another alternate embodiment of the present invention;

[0054] **FIG. 15** is a side view of a cavity-forming device constructed in accordance with another alternate embodiment of the present invention;

[0055] **FIG. 16A** is a lateral view of a lumbar vertebra, depicting an alternate procedure for treating a vertebral body in accordance with the teachings of the present invention;

[0056] **FIG. 16B** is a lateral view of the lumbar vertebra of **FIG. 16A**, with bone filler injected into the vertebra;

[0057] **FIG. 16C** is a lateral view of the lumbar vertebra of **FIG. 16B**, with a cavity-forming device inserted into the vertebra;

[0058] **FIG. 16D** is a lateral view of the lumbar vertebra of **FIG. 16C**, with the cavity-forming device expanded in the cavity;

[0059] **FIG. 17** is a side view of a cavity-forming device constructed in accordance with another alternate embodiment of the present invention;

[0060] **FIG. 18** is a side view of a cavity-forming device constructed in accordance with another alternate embodiment of the present invention;

[0061] **FIG. 19** is a cross-sectional view of the cavity-forming device of **FIG. 18**, taken along line **19-19**; and

[0062] **FIG. 20** is a cross-sectional view of the cavity-forming device of **FIG. 18**, taken along line-**20-20**.

DESCRIPTION OF THE INVENTION

[0063] As embodied and broadly described herein, the present invention is directed to surgical methods for repairing, reinforcing and/or treating weakened, diseased and/or fractured bone. The present invention is further directed to various devices for facilitating such surgical methods.

[0064] **FIG. 1** depicts a typical human spine **1**, in which a compression fracture **10** has occurred in a lumbar vertebra **100**. As best shown in **FIG. 3**, vertebra **100** has fractured, with the top and bottom plates **103** and **104** depressing generally towards the anterior wall **10** of the vertebra **100** and away from their pre-fracture, normally parallel orientation (indicated generally as parallel lines **90**).

[0065] **FIG. 4** depicts a coronal (top) view of the vertebra of **FIG. 3**. Vertebra **100** includes a vertebral body **105**, which extends on the anterior (i.e. front or chest) side of the vertebra **100**. Vertebral body **105** is approximately the shape of an oval disk, with an anterior wall **10** and a posterior wall **261**. The geometry of the vertebral body **105** is generally symmetric. Vertebral body **105** includes an exterior formed from compact cortical bone **110**. The cortical bone **110** encloses an interior volume of reticulated cancellous, or spongy, bone **115** (also called medullar bone or trabecular bone).

[0066] The spinal canal **150** is located on the posterior (i.e. back) side of each vertebra **100**. The spinal cord **151** passes through the spinal canal **150**. A vertebral arch **135** surrounds the spinal canal **150**. Left and right pedicles **120** of the vertebral arch **135** adjoin the vertebral body **105**. The spinous process **130** extends from the posterior of the vertebral arch **135**, as do the left and right transverse processes **125** and the mamillary processes **126**.

[0067] **FIG. 2** depicts a patient **50** prepared for disclosed methods of the present invention. These procedures can be performed on an outpatient or inpatient basis by a medical professional properly trained and qualified to perform the disclosed procedures. Desirably, the patient will be placed under general or local anesthetic for the duration of the surgical procedures.

[0068] In one embodiment of the present invention, a surgical method comprises inserting an insertion device **350** (see **FIG. 5A**) percutaneously into the bone, such as a fractured vertebral body **105** through, preferably, a targeted area of the back, depicted as **60** in **FIG. 2**. The insertion device **350** may be any type and size of hollow instrument, preferably having a sharp end. In one preferred embodiment, the insertion device **350** comprises a hollow needle of approximately eleven gauge diameter. An eleven gauge needle is preferred for the procedure because it incorporates a hollow lumen of sufficient size to permit the passage of various instruments and materials, yet the overall size of the needle is small enough to minimize bone and tissue damage in the patient. It should be understood, however, that various other size needle assemblies, including needles of six to 14 gage, could be used with the devices and methods of the present invention, with varying results. In addition, various other access instruments, such as those described in U.S. Pat. Nos. 4,969,888, 5,108,404, 5,827,289, 5,972,015, 6,048,346 and 6,066,154, each of which are incorporated herein by reference, could be used in accordance with the teachings of the present invention, with varying results.

[0069] The insertion device **350** is preferably comprised of a strong, non-reactive, and medical grade material such as surgical steel. If desired, the insertion device **350** is attached to a manipulating assembly which is comprised of a non-reactive and medical grade material including, but not limited to, acrylonitrile-butadiene-styrene (ABS), polyethylene, polypropylene, polyurethane, Teflon, or surgical steel. **FIG. 5A** depicts a commercially available needle assembly typically used with various embodiments of the present invention, which are further described below.

[0070] As shown in **FIG. 5A**, an insertion device **350**, such as an eleven gauge biopsy needle (commercially available from Becton Dickinson & Co of Franklin Lakes, N.J.) can be inserted through soft tissues of the back and into the vertebral body **105**. Generally, the approach for such a procedure will be transpedicular, although various other approaches, including lateral, extrapedicular and/or anterior approaches, could be used, depending upon the level treated and/or intervening anatomical features well known to those of ordinary skill in the art. In one embodiment, the device **350** comprises a needle body **348** and a stylet **349**, as is well known in the art. During insertion of the device **350**, the

location of the device **350** is desirably monitored using visualization equipment such as real-time X-Ray, CT scanning equipment **70** (see **FIG. 2**), MRI, or any other monitoring equipment commonly used by those of skill in the art, including computer aided guidance and mapping equipment such as the systems commercially available from BrainLab Corporation or General Electric Corporation.

[**0071**] In one preferred embodiment, the distal end **351** of the insertion device **350** is positioned in the vertebral body **105**, preferably at a location towards the posterior side of the vertebral body **105**. If desired, the distal end **351** could be positioned in various locations throughout the vertebral body **105**, including towards the anterior side. Once in position, the stylet **349** of the insertion device **350** may be removed, see **FIG. 5B**, and a cavity-forming device **200** may be inserted through the shaft **348** and into the vertebral body **105**. See **FIG. 5C**. The cavity-forming device **200**, which is desirably comprised of a biologically compatible and medically acceptable material, can be a small mechanical tamp, reamer, hole punch, balloon catheter (as described below) or any appropriate device which is capable of displacing cancellous bone. Once the cavity-forming device is positioned within the vertebral body **105**, it is used to displace cancellous bone **115**, thereby creating a cavity **170**. See **FIG. 5F**.

[**0072**] In one embodiment, shown in **FIGS. 9 and 10**, the cavity-forming device comprises a balloon catheter **200**. The balloon catheter **200** desirably extends across at least 20% of the vertebral body, but could extend greater or lesser amounts, depending upon the desired size of the cavity to be produced. In this embodiment, as the balloon catheter **201** is expanded, cancellous bone is displaced generally outward from the cavity **170** in a controlled manner, desirably forming a compressed-bone region **172** around a substantial portion of the outer periphery of the cavity **170**.

[**0073**] The balloon catheter **200**, which will be described in more detail below, is sized or folded to fit through the hollow interior of the shaft **348** and into a vertebral body **105**. Once in a desired position within the vertebral body **105**, the balloon catheter **190** is filled with a pressurized filling medium **275** appropriate for use in medical applications including, but not limited to, air, nitrogen, saline or water. See **FIGS. 5D and 11**. In a preferred embodiment, the filling medium **275** is a radiopaque fluid (such as Conray® fluid available commercially from Mallinkrodt, Inc., of St. Louis, Mo.), which allows the physician to visualize the catheter **190** during inflation. If desired, alternate ways of expanding the catheter, including mechanical expanders, jacks, expanding springs and/or expanding/foaming agents, could be used, with varying results.

[**0074**] In one embodiment, the catheter **201** is expanded to any appropriate volume which creates a cavity **170** within the vertebral body **105**. In a preferred embodiment, the catheter **201** is expanded to at least 0.20 cc in volume, but could be expanded to significantly greater sizes, such as 1, 2, 4, 6 or 8 cc, depending upon bone quality and density. After cavity creation, the catheter **201** is deflated (see **FIG. 5E**) and removed from the vertebral body **105** and shaft **348** (see **FIG. 5F**). Bone filler **180** is introduced through the shaft **348** and into the vertebral body **105** using any type of plunger, extruder and/or feed line assembly **349** compatible with the needle body **348**. Once injection of bone filler is complete, the shaft **348** can be withdrawn.

[**0075**] If desired, a portion of the balloon catheter **201** could be temporarily or permanently left within a vertebral body **105**. For example, after cavity formation and removal of the inflation medium, the deflated expanded section of the balloon catheter **201** could be refilled with bone filler **180** and left within the vertebral body **105**. Alternatively, the inflation medium **275** could comprise bone filler **180**. After the balloon catheter **201** is filled with such an inflation medium, at least a portion of the catheter **201** could be left permanently within the cavity **170**. In an alternate embodiment, the catheter **201** which is intended to remain with the cavity **170** could comprise a bio-absorbable material and/or fabric/mesh material as the expandable structure.

[**0076**] In creating the cavity **170**, the inflation of the catheter **201** causes the expandable material **210** to press against the cancellous bone **115** which may form a compressed bone region or "shell"**172** along much of the periphery of the cavity **170**. This shell **172** will desirably inhibit or prevent bone filler **180** from exiting the cavity **170**, thereby inhibiting extravazation of the bone filler and/or facilitating pressurization of the bone filler **180**, if desired, within the cavity. As the pressure in the cavity **170** increases, the walls of the cavity **170** will desirably be forced further outward by the bone filler **180**, compressing additional cancellous bone within the vertebral body **105** and/or increasing the size of the cavity **170**. If sufficient pressure is available, and integrity of the shell **172** can be maintained without significant leakage of bone filler **180**, pressures capable of moving fractured cortical bone can be developed.

[**0077**] In one embodiment of the present invention, after cavity formation, an amount of a material, such as a bone filler **180**, is introduced through the shaft **348** into the vertebral body **105** under low pressure. The amount of bone filler will desirably be more than the volume of the cavity **170**, however, less bone filler may be introduced with varying results. Once the cavity **170** is substantially filled, the continued introduction of bone filler **180** will desirably pressurize the bone filler **180** in the cavity **170** such that the increased pressure will cause at least a portion of the walls of the cavity to move outward, thereby enlarging the cavity **170** and further compressing cancellous bone and/or moving cortical bone. Desirably, introduction of the bone filler **180** will continue until bone filler leak from the vertebral body appears imminent, the cortical bone has regain its pre-fractured position and/or the practitioner determines that sufficient bone filler **180** has been injected into the bone. If desired, the physician can utilize the cavity-forming device to create additional cavities for bone filler, or the shaft **348** can be removed from the vertebral body to completed the procedure.

[**0078**] The bone filler **180** could be any appropriate filling material used in orthopedic surgery, including, but not limited to, allograft or autograft tissue, hydroxyapatite, epoxy, PMMA bone cement, or synthetic bone substitutes such Osteoset® from Wright Medical Technology, medical grade plaster of paris, Skeletal Repair System (SRS®) cement from Norian Corporation, or collagraft from Zimmer. As bone filler **180** is introduced into the vertebral body **105**, the introduction is desirably monitored by x-ray fluoroscopy, or any other appropriate monitoring device or method, to ensure that bone filler **180** does not flow outside of the vertebral body **105**. To facilitate visualization, the bone filler **180** may be mixed with a fluoroscopic agent, such

as radio opaque barium sulfate. In another embodiment, the bone filler **180** could comprise a mixture of bone cement and a thixotropic material which desirably limits and/or prevents extravazation of the bone cement.

[**0079**] In an alternate embodiment of the disclosed method, shown in **FIGS. 5G through 5L**, a first bone filler **180** is introduced into the cavity **170**, the amount of first bone filler **180** being desirably less than or approximately equal to the volume of the cavity **170**. For example, if the balloon catheter **200** utilized to create the cavity **170** was inflated with 1.0 cc of inflation fluid, then less than or approximately 1.0 cc of bone filler **180** will initially be injected into the cavity **170**. Of course, if desired, an amount of first bone filler **180** greater than the cavity volume could be injected into the cavity. The shaft **348** is then re-positioned within the vertebral body **105**, see **FIG. 5H**, with the distal end **351** of the device **350** desirably located within the bolus **400** of first bone filler **180** contained in the cavity **170**. As best shown in **FIG. 5I**, a second amount of bone filler **182** is then injected into the vertebral body **105**, which desirably forces the first amount of bone filler **180** outward against the walls of the cavity **170**. Desirably, the first amount of bone filler **180** will resist extravazating out of the cavity **170** and will push outward against the walls of the cavity **170**, further compressing the cancellous bone **115** and/or increasing the size of the cavity **170**. Introduction of the second amount of bone filler **182** will desirably continue until bone filler leak from the vertebral body appears imminent, the cortical bone has regained its pre-fractured position, and/or the practitioner determines that sufficient bone filler **180** has been injected into the bone. If desired, the physician could reinsert a catheter **200** to create an additional cavity, or the shaft **348** can be removed to complete the procedure.

[**0080**] **FIGS. 8A through 8C** depict an alternate embodiment of the disclosed method, in which the practitioner introduces a first material, such as a bone filler **180**, into the cavity **170**, and subsequently inserts a cavity-forming device **200** into the bone. The cavity-forming device **200** is then expanded, and desirably compresses the bone filler **180** against the walls of the cavity, sealing any significant cracks and/or venous passages through which the cement will flow. In one further embodiment, a practitioner may wait to allow the first bone filler to harden partially or fully prior to removing the cavity-forming device and/or prior to introducing a second material, such as a bone filler. The second material (not shown) can subsequently be injected into the vertebral body with little fear of leakage. If desired, this method could be utilized whenever cement leakage appears imminent, and can be repeated multiple times until the practitioner determines that sufficient bone filler **180** has been injected into the bone. In addition, the practitioner could repeat this procedure until the cortical bone has regained its pre-fractured position. In an alternate embodiment, the practitioner could utilize a cavity-forming device prior to the introduction of the first bone filler, and then introduce the first bone filler into the cavity, subsequently follow one or more of the described methods.

[**0081**] The first bone filler will desirably comprise a material that can be introduced into the cavity, but which will resist extravazation out of the cavity and/or vertebral body when the second bone filler is injected into the cavity. In one embodiment of the invention, the first and second bone fillers comprise bone cement, with the first bone cement being more resistant to extravazation than the second bone cement. For example, the ingredients of the first bone cement could be specifically tailored such that the first bone cement cures faster than the second bone cement. Alternatively, the first bone cement could be prepared and/or introduced into the vertebral body before the second bone cement, allowing the first bone cement to partially or fully cure before the second bone cement. Alternatively, the curing and/or hardening of the first bone cement could be accelerated (by applying heat, for example) or curing and/or hardening of the second bone cement could be retarded (by cooling, for example). In another embodiment, the first and second bone fillers comprise bone cement, with the first bone cement desirably being more viscous than the second bone cement. In another alternate embodiment, the first bone filler comprises an expandable structure, such as a stent.

[**0082**] In another embodiment, the first bone filler comprises a material more viscous than the second bone filler, the first and second bone fillers comprising different materials. In another embodiment, the first bone filler comprises a material which is more resistant to extravazation into the cancellous bone than the second bone filler. In another embodiment, the first bone filler comprises a material having particles generally larger than particles in the second bone filler. In a further embodiment, the particles of the first bone filler are generally larger than the average pore size within the cancellous bone. In another embodiment, the first bone filler comprises a settable material, such as a two-part polyurethane material or other curable bio-material.

[**0083**] **FIGS. 16A through 16D** depict an alternate embodiment of the disclosed method, in which a first material, such as a bone filler **180**, is initially introduced into the cancellous bone **115** of a human bone, such as a vertebral body **105**. An expandable structure **210**, such as that found at the distal end of a balloon catheter **200**, is subsequently inserted into the vertebral body **105**. The expandable structure **210** is then expanded, which displaces the bone filler **180** and/or cancellous bone **115**, creating a cavity **170** within the vertebral body **105**. In one embodiment, the expansion of the expandable structure **210** forces the bone filler **180** further into the cancellous bone **115**, and/or further compresses cancellous bone. To minimize bone filler **180** leakage, the bone filler may be allowed to partially or completely harden prior to expansion of the expandable structure **210**. Alternatively, the expandable structure **210** may be expanded, and the bone filler **180** allowed to partially or completely harden around the expandable structure **210**. In either case, a second material, optionally additional bone filler, may be introduced into the cavity **170**. In one embodiment, the second material is a material which supports the bone in a resting position. This method may be utilized whenever cement leakage appears imminent, and may be repeated multiple times until the practitioner determines that sufficient amounts and varieties of material have been introduced into the bone. Alternatively, the practitioner could halt introduction of filler material when the cortical bone regains or approximates its pre-fractured position.

[**0084**] By creating cavities and/or preferred flowpaths within the cancellous bone, the present invention obviates the need for extremely high pressure injection of bone filler into the cancellous bone. If desired, the bone filler could be

injected into the bone at or near atmospheric and/or ambient pressures, or at pressures less than approximately 400 pounds per square inch, using bone filler delivery systems such as those described in co-pending U.S. patent application Ser. No. 09/134,323, which is incorporated herein by reference. Thus, more viscous bone fillers (such as, for example, thicker bone cement) can be injected into the bone under low pressures (such as, for example, exiting the delivery device at a delivery pressure at or near ambient or atmospheric pressure), reducing opportunities for cement leakage and/or extravazation outside of the bone.

Cavity-Forming Devices

[0085] The present invention also includes cavity-forming devices constructed in accordance with the teachings of the disclosed invention. In one embodiment, the cavity-forming device comprises a balloon catheter **201**, as shown in **FIGS. 9, 10**, and **11**. The catheter comprises a hollow tube **205**, which is desirably comprised of a medical grade material such as plastic or stainless steel. The distal end **206** of the hollow tube **205** is surrounded by an expandable material **210** comprised of a flexible material such as commonly used for balloon catheters including, but not limited to, metal, plastics, composite materials, polyethylene, mylar, rubber or polyurethane. One or more openings **250** are disposed in the tube **205** near the distal end **206**, desirably permitting fluid communication between the hollow interior of the tube **205** and the lumen formed between the tube **205** and the expandable structure **210**. A fitting **220**, having one or more inflation ports **222**, **224**, is secured to the proximal end **207** of the tube **205**. In this embodiment, once the catheter **201** is in its desired position within the vertebral body **105**, an inflation medium **275** is introduced into the fitting **220** through the inflation port **222**, where it travels through the fitting **220**, through the hollow tube **205**, through the opening(s) **250** and into the lumen **274** between the expandable structure **210** and the hollow tube **205**. As injection of the inflation medium **275** continues, the pressure of the inflation medium **275** forces the expandable structure **210** away from the hollow tube **205**, inflating it outward and thereby compressing cancellous bone **115** and forming a cavity **170**. Once a desired cavity size is reached, the inflation medium **275** is withdrawn from the catheter **200**, the expandable structure collapses within the cavity **170**, and the catheter **200** may be withdrawn.

[0086] For example, a balloon catheter **201** constructed in accordance with one preferred embodiment of the present invention, suitable for use with an 11-gauge needle, would comprise a hollow stainless steel hypodermic tube **205**, having an outer diameter of 0.035 inches and a length of 10.75 inches. One or more openings **250** are formed approximately 0.25 inches from the distal end of the tube **205**. In a preferred embodiment, the distal end **206** of the hollow tube **205** is sealed closed using any means well known in the art, including adhesive (for example, UV 198-M adhesive commercially available from Dymax Corporation—cured for approximately 15 minutes under UV light).

[0087] In one embodiment, the hollow tube **205** is substantially surrounded by an expandable structure **210** comprising an extruded tube of polyurethane (for example, TEXIN®**5290** polyurethane, available commercially from Bayer Corporation). In one embodiment, the polyurethane tube has an inner diameter of 0.046 inches, an outer diameter of 0.082 inches, and a length of 9½ inches. The distal end of the polyurethane tube is bonded to the distal end **206** of the hollow tube **205** by means known in the art, such as by a suitable adhesive (for example, UV 198-M adhesive). Alternatively, the polyurethane tube may be heat sealed about the distal end **206** of the hollow tube **205** by means well known in the art. A ¾ inch long piece of heat shrink tubing **215** (commercially available from Raychem Corporation), having a 3/16 inch outer diameter, may be secured around the proximal end of the polyurethane tubing. In one embodiment, the proximal end of the hollow tubing **205** is inserted into the fitting **220** and the heat shrink tubing **215** is desirably bonded into the fitting **220** using a suitable adhesive known in the art, such as UV 198-M. The fitting **220**, which may be a Luer T-fitting, commercially available from numerous parts suppliers, may be made of any appropriate material known to those of skill in the art. The fitting **220** comprises one or more ports **222**, **224** for attachment to additional instruments, such as pumps and syringes (not shown). If desired, the hollow tube **205** can similarly be bonded into the fitting **220** using a suitable adhesive. Alternatively, as shown in **FIG. 12**, the expandable structure **210** could be significantly shorter than the hollow tube **205** and be bonded at its distal end **206** and its proximal end **209** to the hollow tube **205**.

[0088] The hollow tube **205** and one or more openings **250** facilitate the withdrawal of inflation medium from the catheter during the disclosed procedures. When a catheter is deflated, the expandable structure **210** will normally collapse against the tube **205**, which can often seal closed the lumen (in the absence of at least one secondary withdrawal path) and inhibit further withdrawal of inflation medium from the expanded structure **210** of a catheter. However, in an embodiment of the disclosed invention, the one or more openings **250** near the distal end of the tube **205** allow inflation medium **275** to be drawn through the hollow hypodermic tube **205**, further deflating the expandable structure **210**. The strong walls of the hollow hypodermic tube **205** resist collapsing under the vacuum which evacuates the inflation medium, maintaining a flowpath for the inflation medium and allowing the inflation medium to be quickly drawn out of the catheter, which desirably permits deflation of the catheter in only a few seconds.

[0089] In the disclosed embodiment, as the catheter **201** is inflated, the inflation medium **275** will typically seek to fill the entire lumen between the expandable structure **210** and the hollow tube **205**, thus expanding the catheter **201** along the entire length of the expandable structure **210**. However, because much of the catheter **201** is located within the lumen of the shaft **348**, with the distal end **206** of the catheter **201** extending into the vertebral body **105**, the shaft **348** will desirably constrain expansion of the expandable structure **210**, causing the expandable structure **210** to expand primarily at the distal end **206** of the catheter **200**. Desirably, further insertion or withdrawal of the catheter **201** will alter the amount of the expandable structure **210** extending from the distal end of the shaft **348**, thereby increasing or decreasing the length of the expandable structure **210** that is free to expand within the vertebral body **105**. By choosing the amount of catheter **201** to insert into the vertebral body **105**, the practitioner can alter the length of the expandable structure, and ultimately the size of the cavity **170** created by the catheter **201**, during the surgical procedure. Therefore,

the disclosed embodiments can obviate and/or reduce the need for multiple catheters of varying lengths. If desired, markings **269** (see **FIG. 9**) can be placed along the proximal section of the catheter which correspond to the length of the catheter **201** extending from the shaft **348**, allowing the practitioner to gauge the size of the expandable structure **210** of the catheter **200** within the vertebral body **105**. Similarly, in an alternate embodiment as disclosed below, the cavity-forming device **201** could incorporate markings corresponding to the length of the bristles **425** extending beyond the tip of the shaft **348**.

[**0090**] In an alternate embodiment, shown in **FIG. 13**, the length of an expandable section **211** of the catheter can be further constrained by securing and/or adhering the expandable structure **210** at a secondary location **214** along the hollow tube **205**, thereby limiting expansion beyond the secondary location **214**. For example, if a desired maximum length of the expandable section **211** were 3 inches, then the expandable structure **210** could be secured to the hollow tube **205** at a secondary location **214** approximately three inches from the distal end **206** of the hollow tube **205**. This arrangement would desirably allow a practitioner to choose an expanded length of the expandable section **211** of up to three inches, while limiting and/or preventing expansion of the remaining section **203** of the catheter **201**. This arrangement can also prevent unwanted expansion of the portion **202** of the catheter extending out of the proximal end **191** of the shaft body **348** (see **FIG. 5C**).

[**0091**] As previously noted, in the disclosed embodiment, the expandable structure is desirably secured to the distal end of the hollow tube, which will facilitate recovery of fragments of the expandable structure **210** if the expandable structure **210** is torn or damaged, such as by a complete radial tear. Because the hollow tube **205** will desirably remain attached to the fragments (not shown) of the expandable structure **210**, these fragments can be withdrawn from the vertebral body **105** with the hollow tube **205**. In addition, the distal attachment will desirably prevent and/or reduce significant expansion of the expandable structure **210** along the longitudinal axis of the hollow tube **205**.

[**0092**] **FIG. 17** depicts a cavity-forming device **300** constructed in accordance with an alternate embodiment of the present invention. Because many of the features of this embodiment are similar to embodiments previously described, like reference numerals will be used to denote like components. In this embodiment, the hollow tube **205** extends through the fitting **220**, such as a t-shaped fitting, and is secured to a cap **310**. In a preferred embodiment, the hollow tube **205** is capable of rotation relative to the fitting **220**. If desired, a seal (not shown), such as a silicone or teflon o-ring, can be incorporated into the proximal fitting **222** to limit and/or prevent leakage of inflation medium past the hollow tube **205**.

[**0093**] In use, a cavity-forming device **300** compresses cancellous bone and/or forms a cavity in a manner similar to the embodiments previously described. However, once the cavity is formed and withdrawal of the device **300** is desired, the cap **310** can be rotated, twisting the expandable material **210** relative to the fitting **220** and drawing the expandable structure **210** against the hollow tube **205**, desirably minimizing the overall outside diameter of the expandable portion of the device **300**. The device **300** can then easily be withdrawn through the shaft **348**. Even where the expandable structure **210** has plastically deformed, or has failed in some manner, the present embodiment allows the expandable structure **210** to be wrapped around the hollow tube **205** for ease of withdrawal and/or insertion. Alternatively, the hollow tube **205** may be capable of movement relative to the longitudinal axis of the fitting **220**, which would further stretch and/or contract the expandable structure **210** against the hollow tube **205**.

[**0094**] **FIGS. 6A and 6B** depict a cavity-forming device **410** constructed in accordance with an alternate embodiment of the present invention. Cavity-forming device **410** comprises a shaft **420** which is desirably sized to pass through the shaft **348** of an insertion device **350**. A handle assembly **415**, which facilitates manipulation of the cavity-forming device **410**, is secured to the proximal end **412** of the shaft **420**. One or more wires or "bristles"**425** are secured to the distal end **423** of the shaft **420**. The bristles **425** can be secured to the shaft **420** by welding, soldering, adhesives or other securing means well known in the art. Alternatively, the bristle(s) **425** can be formed integrally with the shaft **420**, or can be etched from a shaft using a laser or other means well known in the art. The bristles and shaft may be formed of a strong, non-reactive, and medical grade material such as surgical steel. In one embodiment, the bristles **425** extend along the longitudinal axis of the shaft **425**, but radiate slightly outward from the shaft axis. In this manner, the bristles **425** can be collected or "bunched" to pass through the shaft **348**, but can expand or "fan" upon exiting of the shaft **348**. If desired, the bristles can be straight or curved, to facilitate passage through the cancellous bone **115**. In addition, if desired, one or more of the bristles **425** may be hollow, allowing a practitioner to take a biopsy sample of the cancellous bone during insertion of the device **410**.

[**0095**] As shown in **FIG. 7**, the cavity-forming device **410** can desirably be inserted through a shaft **348** positioned in a targeted bone, such as a vertebral body **105**. As the bristles **425** enter the cancellous bone **115**, the bristles **425** will desirably displace the bone **115** and create one or more cavities **426** or preferred flowpaths in the vertebral body. If desired, a practitioner can withdraw the bristles **425** back into the shaft **348**, reposition the cavity-forming device **410** (such as by rotating the device **410**), and reinsert the bristles **425**, thereby creating additional cavities in the cancellous bone **115**. After removal of the cavity-forming device **410**, a material, such as a bone filler (not shown), may be introduced through the shaft **348**. The bone filler will desirably initially travel through the cavities **426** created by the bristles **425**. If desired, a practitioner may interrupt introduction of the bone filler and create additional cavities by reinserting the cavity-forming device **410**. In addition, in the event bone filler leakage occurs or is imminent, a practitioner can interrupt bone filler injection, create additional cavity(ies) as described above, wait for the introduced/leaking bone filler to harden sufficiently to resist further extravazation, and then continue introduction of bone filler. As previously described, the bone filler could comprise many different materials, or combinations of materials, with varying results.

[**0096**] **FIG. 14** depicts a cavity-forming device **500** constructed in accordance with an alternate embodiment of the present invention. The cavity-forming device **500** comprises

a shaft **520** which is sized to pass through the shaft **348** of an insertion device **350**. A handle assembly **515**, which facilitates manipulation of the cavity-forming device **500**, is secured to the proximal end **512** of the shaft **520**. The shaft **520** of the cavity-forming device **500** is desirably longer than the shaft **348** of the insertion device **350**. The distal end **525** of the shaft **520** can be beveled (not shown) to facilitate passage through cancellous bone **115**, or can be rounded or flattened to minimize opportunities for penetrating the anterior wall **10** of the vertebral body **105**. In addition, if desired, the distal **525** end of the shaft **520** could be hollow (not shown), allowing the practitioner to take a biopsy sample of the cancellous bone **115** during insertion of the device **500**.

[**0097**] **FIG. 15** depicts a cavity-forming device **600** constructed in accordance with an alternate embodiment of the present invention. Cavity-forming device **600** comprises a shaft **620** which is sized to pass through the shaft **348** of an insertion device **350**. A handle assembly **615**, which facilitates manipulation of the cavity-forming device **600**, is secured to the proximal end **612** of the shaft **620**. The shaft **620** is desirably longer than the shaft **348** of insertion device **350**. The distal end **625** of the shaft **620** can be beveled (not shown) to facilitate passage through cancellous bone **115**, or can be rounded or flattened to minimize opportunities for penetrating the anterior wall **10** of the vertebral body **105**. In this embodiment, the distal end **625** of the device **600** incorporates drill threads **627** which can facilitate advancement of the device **600** through cancellous bone **115**. In addition, if desired, the distal **625** end of the shaft **620** could be hollow, allowing the practitioner to take a biopsy sample of the cancellous bone **115** during insertion of the device **600**.

[**0098**] After removal of the device(s), bone filler (not shown) may be introduced through the shaft **348**. Desirably, the bone filler will initially travel through the cavity(ies) created by the device(s). If desired, a practitioner can interrupt introduction of bone filler and create additional cavity(ies) by reinserting the device(s). In addition, in the event bone filler leakage occurs or is imminent, the practitioner can interrupt bone filler introduction, create additional cavity(ies) as described above, wait for the introduced/leaking bone filler to harden sufficiently, and then continue introducing bone filler. As previously described, the bone filler could comprise many different materials, or combinations of materials, with varying results.

[**0099**] **FIGS. 18-20** depicts a cavity-forming device **600***a* constructed in accordance with another alternate embodiment of the present invention. Because many of the components of this device are similar to those previously described, similar reference numerals will be used to denote similar components. Cavity-forming device **600***a* comprises a shaft **620***a* which is sized to pass through the shaft **348** of an insertion device **350**. A handle assembly **615***a*, which facilitates manipulation of the cavity-forming device **600***a*, is secured to the proximal end **612***a* of the shaft **620***a*. The shaft **620***a* is desirably longer than the shaft **348** of insertion device **350**. The distal end **625***a* of the shaft **620***a* can be rounded or beveled to facilitate passage through cancellous bone **115**, or can be or flattened to minimize opportunities for penetrating the anterior wall **10** of the vertebral body **105**.

[**0100**] An opening or window **700** is desirably formed in the shaft **620***a*. As shown in **FIGS. 19 and 20**, an expandable structure **710** is located at least partially within the shaft **620***a*, desirably at a position adjacent the window **700**. Upon introduction of inflation fluid through a lumen extending through the shaft **620***a*, the expandable structure **710** expands and at least a portion of the expandable structure **710** will extend out of the shaft **620***a* through the window **700**. Desirably, as the structure continues to expand, the expandable structure **710** will "grow" (P**1** to P**2** to P**3** in **FIG. 20**) through the window **700**, thereby compacting cancellous bone, creating a cavity and/or displacing cortical bone. Upon contraction of the expandable structure **710**, most of the expandable structure **710** will desirably be drawn back into the shaft **620***a* for removal of the tool from the vertebral body. In one embodiment, at least a portion of the material comprising the expandable structure **710** will plastically deform as it expands.

[**0101**] The expandable structure **710** may be comprised of a flexible material common in medical device applications, including, but not limited to, plastics, polyethylene, mylar, rubber, nylon, polyurethane, metals or composite materials. Desirably, the shaft **620***a* will comprise a material that is more resistant to expansion than the material of the expandable structure **710**, including, but not limited to, stainless steel, ceramics, composite material and/or rigid plastics. In an alternate embodiment, similar materials for the expandable structure **710** and shaft **620***a* may be used, but in different thickness and/or amounts, thereby inducing the expandable structure to be more prone to expansion than the shaft **620***a* material. The expandable structure **710** may be bonded directly to the shaft **620***a* by various means well known in the art, including, but not limited to, means such as welding, melting, gluing or the like. In alternative embodiments, the expandable structure may be secured inside or outside of the shaft **620***a*, or a combination thereof.

[**0102**] As previously noted, any of the cavity-forming devices **500**, **600** and **600***a* may be inserted through a shaft **348** positioned in a targeted bone, such as a vertebral body **105**. As the device(s) enter the cancellous bone **115**, they will desirably displace the bone **115** and create one or more cavities in the vertebral body. If desired, the physician can withdraw the device(s) back into the shaft **348** and reinsert as necessary to create the desired cavity(ies) in the cancellous bone **115**.

[**0103**] In the embodiment of a cavity-forming device of **FIGS. 18-20**, the cavity-forming device **600***a* may be utilized without an associated insertion device. In such a case, the cavity-forming device desirably will incorporate a sharpened distal tip capable of penetrating the soft tissues and cortical/cancellous bone of the vertebral body. If desired, the distal tip can be hollow or a solid construct. Similarly, the window may extend around more or less of the periphery of the shaft **620***a*, depending upon the size and configuration of the expandable structure and the desired strength of the cavity-forming device.

[**0104**] By creating one or more cavities within the cancellous bone **115**, the cavity-forming devices of the present invention desirably create preferred flowpaths for the bone filler **180**. In addition, the cavity-forming devices can also desirably close and/or block other natural flowpaths out of the cavity, such as veins and/or cracks in the cancellous bone. Moreover, methods and devices disclosed herein can be used to manipulate bone filler already introduced into the

bone. Thus, the present invention reduces opportunities for cement leakage outside of the vertebral body and/or improves the distribution of bone filler throughout significant portions of the vertebral body. In addition, the creation of cavities and desired flowpaths described in the present invention permits the placement of biomaterial more safely, under greater control and under lower pressures.

[0105] In addition to the specific uses described above, the cavity-forming devices and methods described herein would also be well-suited for use in treating and/or reinforcing weakened, diseased and/or fractured bones and other organs in various locations throughout the body. For example, the disclosed devices and methods could be used to deliver reinforcing materials and/or medications, such as cancer drugs, replacement bone cells, collagen, bone matrix, demineralized calcium, and other materials/medications, directly to a fractured, weakened and/or diseased bone, thereby increasing the efficacy of the materials, reinforcing the weakened bone and/or speed healing. Moreover, injection of such materials into one bone within a body could permit the medication/material to migrate and/or be transported to other bones and/or organs in the body, thereby improving the quality of bones and/or other organs not directly injected with the materials and/or medications.

[0106] Other embodiments and uses of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. All documents referenced herein are specifically and entirely incorporated by reference. The specification and examples should be considered exemplary only with the true scope and spirit of the invention indicated by the following claims. As will be easily understood by those of ordinary skill in the art, variations and modifications of each of the disclosed embodiments can be easily made within the scope

1-5. (canceled)

6. An apparatus, comprising:

a shaft having a distal end, a lumen and a longitudinal axis, the shaft configured to be percutaneously inserted into a vertebral body, the shaft having an elongate opening proximate to the distal end, the elongate opening having a longitudinal axis substantially parallel to the longitudinal axis of the shaft, the shaft formed of a metal having a thickness; and

an expandable structure having a range of motion between a collapsed configuration and an expanded configuration, at least a portion of the expandable structure being disposed within the lumen and adjacent the elongate opening of the shaft when in the collapsed configuration, at least a portion the expandable structure extending through the elongate opening when in the expanded configuration, the expandable structure formed of a metal having a thickness,

the expandable structure having a radial distance from the longitudinal axis of the shaft that increases for at least a portion of its range of motion from the collapsed configuration to the expanded configuration, the expandable structure compacting cancellous bone within the vertebral body during at least the portion of its range of motion from the collapsed configuration to the expanded configuration when disposed within the vertebral body,

the thickness of the metal of the expandable structure being less than the thickness of the metal of the shaft such that the expandable structure is less resistant to expansion than the shaft.

7. The apparatus of claim 6, further comprising:

a handle coupled to the shaft and the expandable structure, the handle configured to move the expandable structure between the collapsed configuration and the expandable configuration.

8. A method, comprising:

inserting percutaneously a shaft into a vertebral body, the shaft having a distal end, a lumen and a longitudinal axis, the shaft having an elongate opening proximate to the distal end, the elongate opening having a longitudinal axis substantially parallel to the longitudinal axis of the shaft;

moving an expandable structure from a collapsed configuration to an expanded configuration such that cancellous bone within the vertebral body is compacted, at least a portion of the expandable structure being disposed within the lumen and adjacent the elongate opening of the shaft when in the collapsed configuration, at least a portion the expandable structure extending through the elongate opening when in the expanded configuration, the expandable structure having a radial distance from the longitudinal axis of the shaft that increases for at least a portion of its motion from the collapsed configuration to the expanded configuration;

moving the expandable structure from the expanded configuration to the collapsed configuration to define a cavity including at least a portion of the compacted cancellous bone;

removing the expandable structure from the shaft while leaving the shaft percutaneously inserted into the vertebral body; and

filling at least a portion of the cavity with a bone filler.

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