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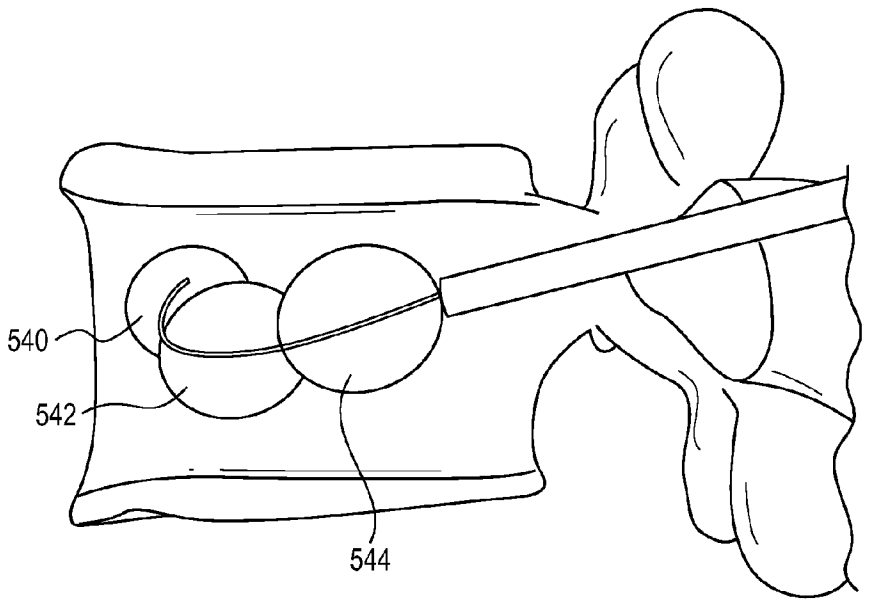

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An expandable member bone augmentation system and single-access-point methods for bone augmentation using same are provided. In certain embodiments, a pre-curved stylet with an overlying delivery tube may be used to target an approximately centered target site within a bone structure, facilitating direction thereto of an expandable member useful for creating a cavity that may receive curable material to restore bone height and/or to reinforce the bone structure. An expandable member such as, for example, a balloon can be used to create a plurality of voids by displacing bone material, where the voids can be filled with curable material to augment the bone.

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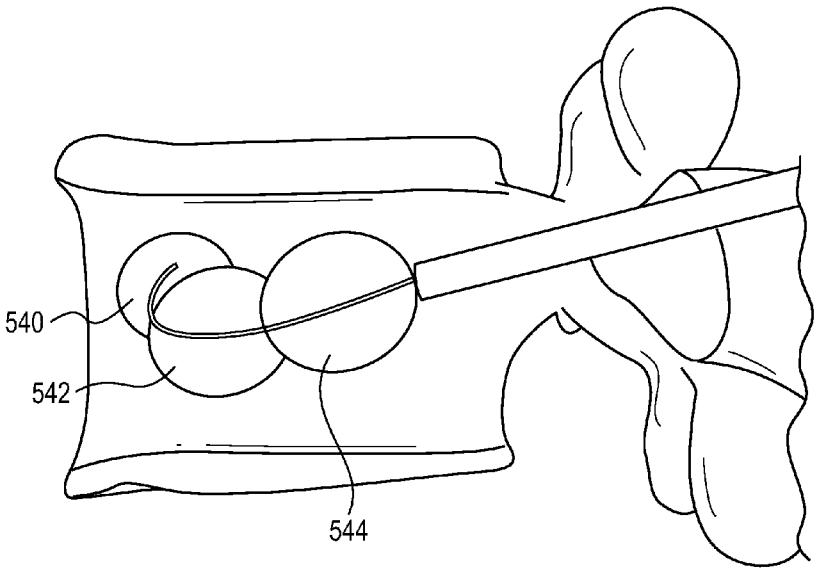

FIG. 8

(57) Abstract: An expandable member bone augmentation system and single-access-point methods for bone augmentation using same are provided. In certain embodiments, a pre-curved stylet with an overlying delivery tube may be used to target an approximately centered target site within a bone structure, facilitating direction thereto of an expandable member useful for creating a cavity that may receive curable material to restore bone height and/or to reinforce the bone structure. An expandable member such as, for example, a balloon can be used to create a plurality of voids by displacing bone material, where the voids can be filled with curable material to augment the bone.

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SYSTEMS FOR BALLOON-AIDED VERTEBRAL AUGMENTATION

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TECHNICAL FIELD

[0002] Embodiments disclosed herein generally relate to methods for stabilizing bone structures. More particularly, they relate to systems and methods for stabilizing and restoring the height of a bone structure such as, for example, a vertebral body.

BACKGROUND

[0003] Surgical intervention of damaged or compromised bone sites has proven highly beneficial for patients, including, for example, patients with back pain associated with vertebral damage. The vertebral damage may be due to injury and/or a degenerative condition such as, for example, aging and/or osteoporosis. The damage associated with these conditions may also affect long bones, the pelvis, and other bones.

[0004] Bones of the human skeletal system include mineralized tissue that may be generally categorized into two morphological groups: "cortical" bone and "cancellous" bone. Outer walls of all bones are composed of cortical bone, which is a dense, compact bone structure characterized by a microscopic porosity. Cancellous or "trabecular" bone forms the interior structure of bones. Cancellous bone is composed of a lattice of interconnected slender rods and plates known by the term "trabeculae".

[0005] During certain bone-related procedures, cancellous bone is supplemented by an injection of a palliative (or curative) material employed to

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stabilize the trabeculae. For example, superior and inferior vertebrae in the spine may be beneficially stabilized by the injection of an appropriate, curable material (e.g., PMMA or other bone cement or bone curable material). In other procedures, percutaneous injection of stabilization material into vertebral compression factors, by, for example, transpedicular or parapedicular approaches, has proven beneficial in relieving pain and stabilizing damaged bone sites. Such techniques are commonly referred to as vertebroplasty.

[0006] A conventional vertebroplasty technique for delivering the bone stabilizing material entails placing a cannula with an internal trocar into the targeted delivery site, generally conducted in a bipedicular manner (i.e., via two pedicles of a vertebra). The cannula and trocar 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. After the assembly is positioned in the cancellous bone, the trocar may be removed, leaving the cannula in the appropriate position for delivery of curable material that will reinforce and solidify the target site.

[0007] In some instances, an effectiveness of the procedure may be enhanced by forming a cavity or void within the cancellous bone, and then depositing the curable material in the cavity. For example, a balloon or other expandable device may be initially deployed and then expanded in a particular vertebroplasty procedure sometimes referred to as kyphoplasty. This action, in turn, compresses cancellous bone and other tissue to form a cavity, and may also cause a “height” of the bone to increase. As a point of reference, vertebroplasty is a common treatment for a fractured vertebral body, and the height of a fractured vertebral body is oftentimes significantly less than a native or natural height that existed before vertebral degeneration. It has been postulated that the height of a fractured vertebral body may be

restored or elevated to a near-normal state when subjected to internal expansion via a balloon or other expandable member (e.g., a mechanically, hydraulically, and/or pneumatically expandable member configured to displace bone material, which may be embodied as a balloon, a bag that is mesh, porous, or generally non-porous, a basket, or any other medically appropriate structure). The mechanics of height restoration in conjunction with vertebroplasty stabilization is currently unclear at best. For example, certain techniques may employ a bipedicular approach in which two balloons are inserted into the vertebral body and inflated, resulting in an increase in height (and the cavity or cavities described above).

[0008] There exists a need in the medical device field for improved systems and methods for restoring the height of, and stabilizing, a fractured vertebral body or other bone structure. In particular, it would be desirable to provide apparatus and methods to symmetrically provide bone augmentation that stabilizes a bone structure such as a vertebra, and that may also provide some height-restoration of said bone structure.

[0009] It may be desirable to provide a system and method that provides advantages with regard to reduced complexity and reduced procedure time while maintaining advantages of dual-balloon kyphoplasty and perhaps offering superior bone-centralization and symmetry of curable material placement, while offering a further advantage of a single surgical wound site rather than traditional bipedicular operations for vertebral procedures and other multi-puncture procedures for treatment of other bones.

BRIEF SUMMARY

[0010] In one aspect, embodiments disclosed herein may include a method of balloon-aided vertebroplasty, as well as methods for augmentation of other bones, using multiple inflations of a single balloon to facilitate the bone-augmentation. In certain embodiments, a pre-curved stylet may be used to

target an approximately centered target site within a bone structure, facilitating direction thereto of an expandable member useful for creating a cavity that may receive curable material to restore bone height and/or to reinforce the bone structure. The expandable member may be constrained by an outer tube during certain method steps, and exposed therefrom for other method steps, during which the expandable member may be inflated to create one or more cavities.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is an exploded view of a curable material delivery and height restoration system, using apparatus for bipedicular access;

[0012] FIGS. 2A and 2B illustrate use of the system of FIG. 1 in performing a height restoration and curable material delivery procedure relative to a vertebra, with the vertebra being shown from a superior perspective;

[0013] FIG. 2C is a lateral view of the vertebral body of FIGS. 2A and 2B;

[0014] FIGS. 3A-3B illustrate the system of FIG. 1 in further performing the height restoration and curable material delivery procedures with a bipedicular dual-balloon method;

[0015] FIGS. 4A-4H illustrate a system and method for transpedicular or parapedicular access providing stylet-guided, generally centralized location of a cavity/void and curable material placement therein;

[0016] FIGS. 5A-5D depict a method of bone augmentation including forming and filling a plurality of cavities through a single access point;

[0017] FIG. 6 shows a two-cavity implementation of the presently described methods where the cavities are substantially continuous so as to form a larger single cavity;

[0018] FIGS. 7 and 8 show, respectively top and side views of a three-cavity implementation of the described methods; and

[0019] FIG. 9 shows a side view of a two-cavity implementation of the present methods.

DETAILED DESCRIPTION

[0020] Embodiments are described with reference to the drawings in which like elements generally are referred to by like numerals. The relationship and functioning of the various elements of the embodiments may better be understood by reference to the following detailed description. However, embodiments are not limited to those illustrated in the drawings. It should be understood that the drawings are not necessarily to scale, and in certain instances details may have been omitted that are not necessary for an understanding of embodiments disclosed herein, such as – for example – conventional fabrication and assembly.

[0021] Various embodiments will be described more fully hereinafter. The invention is defined by the claims, may be embodied in many different forms, and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey enabling disclosure to those skilled in the art. As used in this specification and the claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise. The word "alternatively" and its variants are used inclusively rather than exclusively (i.e., "X, alternatively, Y" means "X and/or Y" rather than "only X *or* only Y") unless otherwise apparent.

[0022] Currently, balloon assisted vertebral augmentation procedures are performed using a bipedicular approach, which allows internal cavities to be created on both sides of a single vertebral body. Cement is then injected into both halves of the vertebral body through each of the pedicles or through one pedicle using a curved needle system, such as, for example, an AVAflex® system (CareFusion Corp., San Diego, Calif.). The proposed method uses a

device such as disclosed herein (with reference to FIGS. 4A-4F) to introduce a balloon, which can be inflated across the vertebral body midline (described below with reference to the method illustrated in FIGS. 5A-5D). It allows physicians to perform targeted balloon placement using the flexible, curved tip of the needle or stylet. It also reduces the need for doctors to perform bipedicular vertebral augmentation procedures on a single vertebral body. In a kyphoplasty procedure, it is often ideal to inflate a balloon through a single access point in a vertebral body to keep the procedure as minimally invasive as possible and minimize trauma to the pedicles. Knowing that vertebral bodies may be large compared to the balloon length, there may be advantages to using this device with the present method.

[0023] After inflating the balloon in a targeted area (which may be across/opposite the midline from the introducing/puncture site), the balloon may be retracted along the same pathway and re-inflated to create a larger cavity or two distinct cavities within a single vertebral body. This may be important because it mimics symmetric balloon inflation (cavity creation) in both halves of the vertebral body, as seen with the bipedicular approach shown in FIG. 3A, and it can also provide a larger cavity for cement containment. This concept is also valuable knowing that no two vertebral bodies are the same. Each will have a different geometry and fracture type. This concept provides the ability to position the balloon in distinct locations within the vertebral body through one access point. For example, a single path may allow the physician to stabilize both the upper and lower endplates. This method could stabilize a cleft fracture and then create a void in other location of the vertebral body. In addition to irregular bones, such as vertebral bodies, this method and tools may also be used to aid fracture repairs in other bones such as long bones and flat bones. Through a single access point, multiple voids may be created to fill fractures or facility screw or implant

placement. Therefore, there exists the need to create a product that will safely create a targeted large cavity or multiple generally distinct cavities within bone using a single access point approach.

[0024] One embodiment of a curable material delivery and height restoration system 10 is shown in FIG. 1. The system 10 includes a first delivery assembly 12a, a second delivery assembly 12b, and at least one source of curable material 16. The delivery assemblies 12a, 12b may be substantially identical, and each includes a cannula device 18a, 18b and a cavity-forming device 20a, 20b. Details on the various components are provided below. In general terms, however, the cannula devices 18a, 18b each include an access cannula 22a, 22b for insertion into a bone site of interest in a patient. In the embodiment depicted in FIG. 1, the bone site of interest is a vertebra 30. After the access cannulas 22a, 22b are desirably located relative to the vertebra 30, a portion of each of the cavity-forming devices 20a, 20b are delivered to the vertebra 30 via the corresponding access cannula 22a, 22b, and operated to form cavities. The second cavity-forming device 20b (alternatively the first cavity-forming device 20a) may be removed, and the source of curable material 16 connected to the second cannula 22b. In this regard, a delivery tube 14 may be employed, extending from the source 16 and through the second cannula 22b.

[0025] Thereafter, the curable material source 16 is operated to deliver curable material to the cavity via the second cannula 22b and/or the delivery tube 14. Subsequently, the first cavity-forming device 20a may be removed and the curable material source 16 is connected to the first cannula 22a (for example, via the delivery tube 14). The curable material source 16 is operated to deliver curable material into the corresponding cavity. With the approaches disclosed herein, the systems and methods disclosed herein will be able to provide for restore a height of the vertebra (or other bone site) 30 to a normal

or near-normal state, and the delivered curable material will provide desirable stabilization.

[0026] The system 10 may be used for a number of different procedures including, for example, vertebroplasty and other bone augmentation procedures in which curable material is delivered to a site within bone, as well as possibly to remove or aspirate material from a site within bone. The system 10 is highly useful for delivering a curable material in the form of a bone curable material. The phrase "curable material" within the context of the substance that may be delivered by the systems and methods described herein is intended to refer to materials (e.g., composites, polymers, and the like) that have a fluid or flowable state or phase and a hardened, solid or cured state or phase.

[0027] Curable materials may include, but are not limited to, injectable bone cements (such as polymethylmethacrylate (PMMA) bone curable material), which have a flowable state wherein they may be delivered (e.g., injected) by a cannula to a site and subsequently cure into hardened, cured material. Other materials such as calcium phosphates, bone in-growth materials, antibiotics, proteins, etc., may be used in place of, or to augment bone cement (but do not affect an overriding characteristic of the resultant formulation having a flowable state and a hardened, solid, or cured state). This would allow the body to reabsorb the curable material and/or improve the clinical outcome based on the type of filler implant material. Although FIG. 1 illustrates a single source of curable material 16, in other embodiments, two (or more) sources may be provided. The sources may contain identical curable material compositions; alternatively, the compositions may differ (e.g., a first source may contain bone cement, while a second source contains a mixture of bone cement and bone in-growth material).

[0028] As mentioned above, the cannula devices 18a, 18b may be substantially identical, and each includes the outer/ access cannula 22a, 22b. The cannula 22a, 22b is provided to be positioned in (or immediately proximate) the target or injection site for delivery of the corresponding cavity-forming device 20a, 20b, as well as curable material. The cannula 22a, 22b preferably is made of a surgical grade of stainless steel, but may be made of known equivalent material(s) that are both biocompatible and substantially non-compliant at the expected operating pressures. The cannulas 22a, 22b each define a proximal region 40a, 40b, a distal end 42a, 42b, and a lumen 44a, 44b (referenced generally), respectively, to allow various equipment such as the cavity-forming device 20a, 20b, a delivery tube 14, one or more stylets (not shown here, but discussed and illustrated with reference to embodiments of FIGS. 4A-4H below), and/or other elements, to pass therethrough.

[0029] A handle 46a, 46b surrounds the proximal region 40a, 40b of the cannula 22a, 22b for manipulating the cannula 22a, 22b and for connecting the cannula 22a, 22b with one or more of the cavity-forming device 20a, 20b and/or the delivery tube 14. In some constructions, the cannula device 18a, 18b may further include a handle connector 48a, 48b serving as a proximal end of the corresponding cannula 22a, 22b. The handle connector 48a, 48b may simply be an extension of the cannula 22a, 22b. Alternatively, the handle connector 48a, 48b may incorporate features forming part of a locking mechanism component of the system 10. For example, the handle connector 48a, 48b may include a luer-lock type of connector, but other known connecting mechanism may be successfully interchanged (e.g., a conventional threaded hole, a threaded locking nut arrangement, etc.). Features of one suitable locking mechanism are described in U.S. Pat. No. 7,922,690.

[0030] The cavity-forming devices 20a, 20b may be substantially identical and may assume various forms appropriate for forming a void or cavity within bone. In this regard, each of the cavity-forming devices 20a, 20b includes an elongated body 60a, 60b distally connected to or forming a working end 62a, 62b. The elongated body 60a, 60b is sized to be slidably inserted within the lumen 44a, 44b of the corresponding cannula 22a, 22b, and may include one or more tubes, shafts, etc., necessary for operation of the corresponding working end 62a, 62b. Thereafter, a proximal region 64a, 64b of the elongated body 60a, 60b may be connected to or form a cannula connector 66a, 66b. The cannula connector 66a, 66b may assume various forms conducive for selective, rigid attachment to the corresponding handle connector 48a, 48b as described above (e.g., the cannula connector 66a, 66b and the corresponding handle connector 48a, 48b collectively form a locking mechanism), and thus may include or contain a luer-lock threaded fitting. Alternatively, the cannula connector 66a, 66b may be omitted, and depth markings (not shown) included along an exterior of the proximal region 64a, 64b that facilitate desired locating of the working end 62a, 62b relative to the corresponding cannula 22a, 22b as described below.

[0031] The working end 62a, 62b may include one or more components appropriate for forming a cavity or void within bone. For example, in some constructions, the working end 62a, 62b may include one or more expandable or inflatable members (e.g., a single balloon, multiple balloons, a single balloon with two or more discernable inflation zones, etc.) constructed to transition between a contracted (e.g., deflated) state in which the working end/balloon 62a, 62b may be passed through the corresponding lumen 44a, 44b, and an expanded (e.g., inflated) state in which the working end/balloon 62a, 62b expands and compacts contacted cancellous bone. In this regard, a size and shape of the working end/balloon 62a, 62b may be

predetermined and/or restrained with one or more additional components (not shown), such as internal and/or external restraints. In preferred embodiments the working end/balloon 62a, 62b will be structurally robust, able to withstand (e.g., not burst) at expected inflation pressures and when in contact with bone. Further, the first working end 62a and the second working end 62b may be identical or different.

[0032] The working ends/balloons 62a, 62b may be exteriorly coated with a material configured to resist bonding with the curable material being delivered to the vertebra 30. The anti-sticking coating may assume various forms as a function of the selected curable material, and in some embodiments is a silicone coating. Other materials exhibiting aversion to bonding with bone cement are also envisioned, for example, polypropylene. In related embodiments, a thin-walled expandable sleeve constructed of the selected anti-sticking material (e.g., a polypropylene sleeve) may be disposed over the working end/balloon 62a, 62b. Though not shown, one or both of the cavity-forming devices 20a, 20b may include a valve or similar component that operates to selectively seal the working end/balloon 62a, 62b.

[0033] The cavity-forming devices 20a, 20b each further include one or more additional components connected or operable through the proximal region 64a, 64b for actuating the corresponding working end 62a, 62b. By way of one non-limiting example, each of the cavity-forming devices 20a, 20b may include a source 68a, 68b of pressurized fluid (e.g., contrast medium) for inflating the balloon(s) carried or formed by the corresponding working end 62a, 62b. A hand-held, syringe-type pump may be used as the pressurized source. In other embodiments, a single one of the sources of pressurized fluid 68a or 68b may be provided and employed to inflate both of the working ends/balloons 62a, 62b individually. Appropriate balloon-inflation systems are well known and will readily be apparent to those of skill in the art.

[0034] Where provided, the delivery tube 14 is sized for insertion within the lumens 44a, 44b, and defines a distal tip 80 and a proximal section 82. As described below, the delivery tube 14 may be employed to deliver curable material to the target site. Thus, the delivery tube 14 has an outer diameter that is smaller than a diameter of the lumens 44a, 44b; however, the outer diameter of the delivery tube 14 preferably will not be so small as to allow curable material to readily travel around the outside of the delivery tube 14 and back into the corresponding cannula 22a, 22b.

[0035] A cannula connector 84 may be coupled to, or formed by, the proximal section 82 of the delivery tube 14. The cannula connector 84 is akin to the cannula connector 66a, 66b described above (e.g., combines with the selected handle connector 48a, 48b to form a locking mechanism), and thus may assume any of the forms previously described. Alternatively, the delivery tube 14, where provided, may form depth markings (not shown) along the proximal section 82 that facilitates desired locating of the distal tip 80 relative to the cannula 22a, 22b during use.

[0036] The delivery tube 14 is configured for fluid coupling to the curable material source 16. In some embodiments, a portion of the delivery tube 14 projects proximally beyond the cannula connector 84, and is fluidly coupled to the curable material source 16, for example via an injection connector 86. Alternatively, auxiliary tubing 88 may be provided with the curable material source 16, and fluidly connected to the delivery tube 14 via the cannula connector 84. In yet other embodiments, the delivery tube 14 is omitted, and the curable material source 16 connected directly to the handle connector/proximal end 48a, 48b (e.g., the auxiliary tube 88 is connected to the connector 48a, 48b; or the tubing 88 eliminated and the curable material source 16 (e.g., a syringe) directly coupled to the connector 48a, 48b).

[0037] The curable material source 16 may assume various forms appropriate for delivering the desired curable material, and may typically comprise a chamber filled with a volume of curable material and employing any suitable injection system or pumping mechanism to transmit curable material out of the chamber and through the delivery tube 14. Typically, a hand injection system is used where a user applies force by hand to an injector. The force is then translated into pressure on the curable material to flow out of the chamber. A motorized system may also be used to apply force.

[0038] Although the system 10 has been described as including the single source of curable material 16, in other constructions, a separate source of curable material 16 may be provided for each of the delivery assemblies 12a, 12b. Similarly, two (or more) of the delivery tubes 14 may be included. Along these same lines, the system 10 may be configured such that the curable material source 16 is directly connected to one or both of the cavity-forming devices 20a, 20b (e.g., the elongated body 60a of the first cavity-forming device 20a may form or terminate at a nozzle proximate (e.g., distal) the working end 62a and through with the curable material may be directly dispensed).

[0039] The system 10 and other systems and methods disclosed herein will be useful in performing a wide variety of height restoration and bone stabilization procedures as part of an overall curable material delivery procedure. As such, FIGS. 2A-3B illustrate use of the system 10 in restoring the height of, and delivering curable material into, a target site of a vertebra 100. In general terms, the vertebra 100 includes pedicles 102a, 102b and a vertebral body 104 defining a vertebral wall 106 surrounding bodily material 108 (e.g., cancellous bone, blood, marrow, and soft tissue). The pedicles 102a, 102b extend from the vertebral body 104 and surround a vertebral foramen 110. As a point of reference, systems of the present

disclosure may be suitable or readily adapted by those of skill in the art for accessing a variety of bone sites. Thus, although the vertebra 100 target site is illustrated, it is to be understood that other bone sites may be accessed and treated by the system 10 (e.g., femur, long bones, ribs, sacrum, etc.).

[0040] The first and second cannulas 22a, 22b may be employed to form first and second access paths to first and second target site locations 120a, 120b. For example, the cannulas 22a, 22b are inserted in a bipedicular fashion through respective ones of the pedicles 102a, 102b and into the bodily material 108. The cannulas 22a, 22b provide access to the corresponding target site 120a, 120b at the open distal ends 42a, 42b thereof. One or more stylets (not shown) may be employed to assist in forming/accessing the target sites 120a, 120b. For example, a series of differently-sized or configured (e.g., sharpened and blunt) stylets may be successively delivered through the respective cannula 22a, 22b to form a channel to the target site 120a, 120b. Alternatively, or in addition, an outer guide cannula (not shown) may be deployed to form an access path for subsequent insertion of the cannulas 22a, 22b.

[0041] After the cannulas 22a, 22b are positioned within the bodily material 108 at the desired target sites 120a, 120b, the cavity-forming devices 20a, 20b are assembled to the corresponding cannula 22a, 22b. For example, and as shown in greater detail in FIG. 2B, the elongated body 60a, 60b is slidably inserted within the corresponding cannula 22a, 22b, with the respective working end 62a, 62b being distally advanced therethrough. More particularly, with configurations in which the working end 62a, 62b is a balloon or other expandable member format, the working end/balloon 62a, 62b is transitioned to a contracted state (e.g., deflated) so as to be slidably received through the lumen 44a, 44b. The elongated body 60a, 60b is positioned relative to the corresponding cannula 22a, 22b

such that the respective working end/balloon 62a, 62b extends distal the corresponding cannula distal end 42a, 42b. For example, where the elongated body 60a, 60b may include depth markings as described above, the appropriate depth marking will be aligned with the corresponding handle connector 48a, 48b (FIG. 1), thereby ensuring that the working end/balloon 62a, 62b is fully deployed or extended beyond the corresponding cannula distal end 42a, 42b. In other constructions, upon connection of the cannula connector 66a, 66b and the corresponding handle connector 48a, 48b, the working end/balloon 62a, 62b is distal the corresponding distal end 42a, 42b and is positioned at the corresponding target site 120a, 120b. Placement of the cavity-forming devices 20a, 20b may be performed simultaneously or consecutively.

[0042] As a point of reference, FIG. 2C provides a lateral view of the vertebral body 104 in which the first working end/balloon 62a has been deployed (and in the contracted state). As shown, the vertebral body 104 is fractured (referenced generally at 122) and thus exhibits a fractured height H_F that is less than a natural or native height H_N (designated generally).

[0043] With reference to FIG. 3A, the cavity-forming devices 20a, 20b are operated to cause the corresponding working ends/balloons 62a, 62b to form first and second cavities or voids 124a, 124b, respectively, in the bodily material 108. For example, the working ends/balloons 62a, 62b may be expanded (e.g., inflated) substantially simultaneously. Alternatively, with embodiments in which a single inflation source 68a or 68b (FIG. 1) is provided, the first working end/balloon 62a is inflated and then sealed in the expanded or inflated state. The inflation source 68a or 68b is then fluidly connected to the second working end/balloon 62b and operated to cause expansion thereof. Following expansion of the working ends/balloon 62a, 62b, the expanded working ends 62a, 62b are both supporting the vertebral

body 108. In this regard, and as best illustrated in FIG. 3B, expansion of the working ends/balloons 62a, 62b not only forms the cavities 124a, 124b, but also restores or enhances a height of the fractured vertebral body 104. More particularly, a restored height H_R is established that beneficially approximates the natural height H_N. The restored height H_R may be the same as, slightly less than, or slightly greater than, the natural height H_N (FIG. 2C); in any event, the restored height H_R will be greater than the fractured height H_F (FIG. 2C).

[0044] Returning to FIG. 3A, the second cavity-forming device 20b is then operated to transition the second working end/balloon 62b from the expanded state to the contracted state (e.g., the second balloon 62b is deflated). In the contracted state of the second working end/balloon 62b, the second cavity-forming device 20b may be removed from the second cannula 22b.

[0045] Other embodiments of a system and method for bone augmentation are described with reference to FIGS. 4A-4H. A system 410 is illustrated in FIG. 4A that may be similar or identical in most respects to the system 10 described above, and corresponding reference numbers should be understood as analogous. Those of skill in the art will appreciate that system components described above with reference to FIGS. 1-3B may be used with the embodiments described below within the scope of the present disclosure. The system includes an access cannula 422 (preferably generally straightline in configuration), which is shown as engaged into a cancellous bone-including region 508 (that may also include marrow and other body material as noted above with reference to FIGS. 2A-3B) of a vertebra 500 via a vertebral pedicle 502 thereof. The distal end 442 of the access cannula 422 has been directed near a target region/site 520 that is generally central within the bone region 508. A portion

of the bone region 508 may be at least partially defined by a cortical rim 506 forming a boundary of the anterior vertebral body 504.

[0046] The target site 520 may be identified by a physician preparing for a vertebroplasty procedure. Identification of the target site may include generally determining a central location in the cancellous bone portion of the vertebra 500 that will substantially or at least generally support height-restoration and/or structural augmentation that preferably is at least generally symmetrical with respect to the vertebra and particularly with respect to damaged portion(s) thereof. Generally, the target site may be approximately centered within the bone structure. However, the target site is defined more generally as a pre-determined location within a bone structure that may be determined by treating personnel to provide for symmetrical application of force to treat a bone.

[0047] As shown in FIG. 4B, a stylet 470 may be directed through the access cannula 422. The stylet 470 snugly but slidably extends through an overlying delivery tube 414 that preferably is made a flexible polymer having some columnar strength (e.g., polypropylene, PEEK) that will maintain a patent longitudinal lumen upon withdrawal therefrom of the stylet 470. In some embodiments, the delivery tube may include a metal needle with a distal curved length and a distal terminus end opening through which the expandable member is deployed where the metal needle curve and the stylet curve are about the same when unconstrained and are constrained to a generally straightline orientation when constrained during passage through the access cannula. In some embodiments, the delivery tube may include a metal needle with a distal curved length and a distal-most straight length open at its distal terminus and configured to allow an expandable member to be deployed therefrom without significantly curving the expandable member during its deployment. The delivery tube 414 may include at least one radio-

opaque marker (e.g., near its distal end) and/or one or more visual indicia near its proximal end providing for user-observation regarding its distal end position relative to the access cannula of the system. The at least one radio-opaque marker includes that the delivery tube may itself be partially or wholly radiopaque. For example, in certain preferred embodiments, a PEEK (or other polymer) delivery tube 414 may be extruded with Barium in it (e.g., in the form of barium sulfate or another radiopaque material), such that some or all of the entire tube is radiopaque, obviating the need for other radio-opaque indicia.

[0048] The stylet 470 preferably is constructed including a memory metal material having a pre-set curve near its distal end. In this manner, the stylet 470 can be deflected to a generally straight orientation while it is being directed through the access cannula 422. The stylet and the delivery tube have sufficient length to extend through and be operable beyond the distal end 442 of the access cannula. Thus, as shown in FIG. 4B, in the time and space that the stylet 470 is advanced out of the distal end 442 of the access cannula 422, its pre-set curve is re-asserted such that the stylet 470 and overlying delivery tube 414 curve into the target region 520. The pre-set curve of the stylet 470 may be offset from its distal end sufficiently to provide a generally straightline portion of the stylet distal of its pre-set curve. A proximal-end structure of the stylet 470 may include indicia 471 showing the direction of curvature of the pre-set curve (FIG. 4C).

[0049] In certain embodiments, a system may include a plurality of stylets, each having a different pre-set curve. In this manner, a physician may determine a desirable stylet curvature to reach the target region and select an appropriate stylet. Each stylet may be individually packaged and clearly marked with size and/or curvature, as well as providing other visual indicia of properties of interest to a physician. In use, the physician may determine a

desired curvature path between the distal end 442 of the access cannula and the approximate center of the target site (e.g., in the middle of the pre-determined location, which may or may not be generally centered within a bone portion), select a guide stylet including a distal preset curve corresponding to said curvature path from a plurality of guide stylets having different preset curvatures, and insert the selected stylet through the delivery tube before directing the assembled stylet and overlying tube to the target site.

[0050] As shown in FIG. 4C, the stylet 470 may be withdrawn from the delivery tube 414 (which is shown as slightly retracted from its furthest extension point) after having created a generally tubular path or void 521 in the material 508 in the target region 520. Thereafter, as shown in FIG. 4D, a cavity-forming device, which may include a working end embodied as – for example –a distal balloon 462, may be directed into the path 521 formed by the stylet 470. A wire or other support structure (not shown) may be provided in the cavity-forming device end 462 to enhance its trackability and pushability through/into the path 521. As a point of reference, FIG. 4E provides a lateral view of the vertebral body 504 wherein the working end/balloon 462 has been deployed (and is still in a contracted state). As shown, the vertebral body 504 being treated is anteriorly fractured (referenced generally at 522) and thus exhibits a fractured height H_F that is less than a natural or native height H_N (designated generally).

[0051] In one preferred embodiment of a method, the delivery tube 414 may be extended all the way to the end of a cavity/void 521 formed with the stylet 470. Thereafter, the cavity-forming device may be extended through the delivery tube 414 until its working end/balloon 462 contacts the bone at the distal end thereof. This may protect, e.g., a balloon or other distal expandable member of the cavity forming device from external damage during

introductory movement and provide for its placement in a desired location and orientation. Thereafter, the delivery tube 414 may be withdrawn sufficiently to allow cavity-forming expansion of the working end/balloon 462 as described below. Those of skill in the art will appreciate that one or more of the cavity-forming device, working end/balloon 462 thereof, and the delivery tube may include visual indicia (e.g., markings on the user-held end, radio-opaque indicia at or near the distal end) that enable a user to determine the relative positions of those components to perform a method as described. In this or other embodiments, the inner diameter of the delivery tube 414 and/or the external surface(s) of the cavity forming device(s) may be lubriciously coated (e.g., with silicone, PTFE, and/or another lubricious material).

[0052] With reference to FIG. 4F, the cavity-forming device may be operated to cause its corresponding working end/balloon 462 to form a (preferably approximately, generally, or substantially centered) cavity/ void in the body material 508. For example, the working end/balloon 462 may be expanded (e.g., inflated). As best illustrated in FIG. 4G, expansion of the working end/balloon 462 not only forms the cavity, but may also restore or enhance a height of the fractured vertebral body 504. More particularly, a restored height H_R is established that may beneficially approximate the natural height H_N. Such a restored height H_R may be the same as, slightly less than, or slightly greater than, the natural height H_N (FIG. 4E); in any event, any restored height H_R will be greater than the fractured height H_F (FIG. 4E). If desired for fluoroscopic visualization, radio-opaque contrast material may be provided into the cavity, internal to or external of the expandable member. Transpedicular access for kyphoplasty at a target site approximately centered in the cancellous bone may not be easily achievable without the curved stylet approach of the present disclosure. The limits of patient anatomy, the desirability of minimizing procedure time (for the sake of,

e.g., cost and patient health), and the desirability of minimizing patient recovery time all provide for advantages of the present methods and systems.

[0053] Thereafter, the expandable member's working end/balloon 462 may be withdrawn. Then, as shown in FIG. 4H, curable material 530 may be delivered into the cavity via the delivery tube 414. In this or other embodiments, the curable material may delivered in a more targeted manner via a curved delivery cannula directed though the access cannula into the cavity. In such an embodiment, the delivery tube 414 may be removed as an intermediate step before introducing the curved delivery cannula, or the curved delivery cannula can be directed through the delivery tube 414.

[0054] Methods and devices for use in introducing curable material via a curved access cannula in a manner useful within the presently disclosed systems and methods are disclosed in U.S. Pat. Nos. 7,713,273; 7,799,035; 8,128,633; and 8,226,657, as well as U.S. Pat. App. Publ. No. 2010/0087820. It should be understood and appreciated that the "delivery cannula" described therein may include a pre-set curve with structure and function described herein in reference to a "stylet." As such the term "stylet" as used herein is defined to include a delivery cannula that has an internal delivery lumen dimensioned and oriented for delivering curable material. This definition may therefore, in some embodiments, provide a stylet that is embodied as a delivery cannula, while – in other embodiments – provide a stylet separate from a delivery cannula. Specifically, in the methods described above, and those described below, a delivery cannula or stylet, which may be embodied as an AVAflex® Curved Vertebral Augmentation Needle (CareFusion Corp., San Diego, Calif.), can be used. In this manner the curable material will be directed through the lumen of the cannula/ stylet (e.g., stylet 470) into the space created by an expandable device.

[0055] Stated differently, a delivery cannula may be provided with temperature-dependent multi-curve structure and function. This cannula may further include an overlying delivery tube 414 and be operated in the manner described above for a stylet, except that the curable material may be introduced through the delivery cannula (e.g., after it is withdrawn; the expandable member is introduced, activated, and withdrawn; then the delivery cannula – potentially pre-loaded with curable material – is reintroduced).

[0056] In some embodiments, a delivery cannula may include a closed distal end terminus and a side-facing opening near the terminus, where the opening is oriented along an outside surface of the curved portion of the delivery cannula near its closed distal end terminus. It may also include proximal-end indicia that show the direction of distal cannula curvature. The curvature of the delivery cannula may be configured to correspond to the pre-set curve of a separate stylet 470, or the stylet 470 may – instead of being constructed as a solid-cross-section stylet – be constructed as a/the precurved delivery cannula as described above. In some embodiments, the delivery cannula/ stylet may be pre-loaded with curable material before the delivery cannula is directed through the guide cannula, in order to decrease procedure time and reduce the likelihood of a bolus during introduction of the curable material.

[0057] A method for single-access-point provision of one or a plurality of generally distinct or continuous cavity(ies) is described with reference to FIGS. 4A-4H and FIGS. 5A-9. The method may be used different bones of a patient body, and the method here is illustrated with access through a single pedicle of a patient vertebra. A single unipedicular access path may allow the physician to stabilize both the upper and lower vertebral endplates. This method could stabilize a cleft fracture and then create a void in other location of the vertebral body.

[0058] In one embodiment of a method, an expandable member, which may be embodied as a balloon 462, may be directed to a target region 520 in the manner described above with reference to FIGS. 4A-4E, where the balloon 462 is within a delivery tube 414. The target site 520 may be well across a left-right lateral midline, and the balloon 462 inflated as shown in FIG. 5A. Next, the balloon 462 may be deflated to leave a first cavity 540.

[0059] Thereafter, the delivery tube 414 can be retracted with the balloon 462 to position the balloon 462 in a desired location. In the event that the balloon was withdrawn into the lumen of the delivery tube 414, the delivery tube may be further retracted to expose and allow the balloon 462 to be reinflated as shown in FIG. 5B, forming a second cavity 542. In the method step illustrated in FIG. 5C, the delivery tube 414 is advanced into the first cavity 540, where curable material 530 may be delivered via the delivery tube 414.

[0060] In a preferred variant of the method, the delivery tube 414 may be completely withdrawn along with the balloon 462, and the curable material may be delivered via a delivery cannula. The delivery cannula may be embodied, for example, as the stylet discussed above (e.g., as a shape-memory stylet, such as – for example – used in the AVAflex® system) advanced into and through the cavities in the absence of the delivery tube 414, then retracted during progressive delivery of curable material. In another variant method, a delivery cannula/stylet may be disposed through the delivery tube 414 after the balloon 462 has been completely withdrawn following formation of the desired cavities.

[0061] Then, the delivery tube 414 (or other delivery device, such as a delivery cannula/stylet/needle) may further be withdrawn while still delivering curable material 530 sufficient to fill the first cavity 540 and the second cavity 542, generally separate from the first cavity, as shown in FIG. 5D. In

some embodiments, less than the entire cavity may be filled. That is, as noted above, in certain embodiments where injection of curable material is effected through a stylet, the stylet may be disposed through the delivery tube 414, or the delivery tube may be completely withdrawn along with the balloon, after which a delivery cannula/ stylet (shown parenthetically in the alternative as reference 470, although a preferred delivery stylet will actually deliver curable material from a side aperture) is advanced into the position of the delivery tube 414 shown in FIG. 5C and curable material is delivered therethrough as illustrated, with the delivery cannula/ stylet (not shown) being retracted during material delivery. Stated differently, in FIGS. 5C and 5D, the curable material delivery structure labeled with reference number 414 may instead be embodied as a delivery cannula/stylet (such as, for example, an AVAflex® needle/ cannula/ stylet of the type described above).

[0062] Those of skill in the art will appreciate that, in other embodiments of the method, two, three or more cavities may be formed in this manner. The cavities may be generally separate and distinct, as shown in FIG. 5D and, somewhat less separate, in FIG. 7, or they may overlap: that is, the serial inflation/deflation of the balloon 462 may be done to form an overlapping series of generally continuous cavities, as shown in FIG. 6, such that the result is generally a single larger overall cavity. Each of FIGS. 5A-7 shows a top-down view of a vertebra. However, it should be appreciated that the offset of a plurality of cavities in a bone mass may also be manifested in an anterior-posterior aspect (whether vertebral, as illustrated, or in a different bone type such as a long bone (e.g., femur), other irregular bone (e.g., sacrum), flat bone (e.g., a pelvic bone), or other bone type).

[0063] The anterior-posterior offset aspect of cavity formation using the present method is illustrated in FIGS. 8-9, which show, respectively, a two-cavity and a three-cavity aspect from a side view perspective. A treating

physician can determine the number, orientation (posterior versus inferior, left versus right, and anterior versus posterior), size, and relative overlap - if any – of a plurality of cavities, based upon the bone being targeted and the desire for restoration and/or repair.

[0064] Specifically, FIG. 9 shows a side view embodying the described method as having formed two cavities, a first cavity 540 of which is mostly anterior of the second cavity 542. The second cavity overlaps with and is substantially continuous with the first cavity. FIG. 8 shows a side view perspective of first, second, and third cavities 540, 542, 544 shown top-down in FIG. 7. The contour of a solid-body stylet 472 is shown extended through the cavities, with the delivery tube not extended over its length, in order to provide some positional perspective regarding the path of a delivery tube 414 (and/or delivery cannula 470) and balloon during the inflation/deflation/retraction that formed the cavities. As such, it should be appreciated that such a stylet 472 may be used to position the delivery tube 414 for delivering curable material in the manner described above with reference to FIGS. 5C-5D. Alternatively, as discussed above, the stylet may be embodied as a stylet with a lumen (e.g., configured as a pre-curved delivery cannula stylet 470) which can be used for initial cannulation/ cavity-formation, withdrawn from the delivery tube 414 to allow operation of a balloon or other expandable member, then reintroduced for use in delivering curable material.

[0065] The cavities are offset from each other along each of the anterior-posterior, left-right, and top-bottom axes of the vertebra. This illustration provides one example of how a single access point (e.g., unipedicular approach in a vertebra) may provide for treatment throughout a bone. Specific location of cavities for treatment will, of course, vary based upon

assessment of patient need, the type of bone being treated, and other medically relevant indicia.

[0066] Those of skill in the art will appreciate that embodiments not expressly illustrated herein may be practiced within the scope of the claims, including that features described herein for different embodiments, and in different claims, may be combined with each other and/or with currently-known or future-developed technologies while remaining within the scope of the claims. This includes providing the apparatus, a kit, and/or instructions (spoken, written, or otherwise) for conducting the inventive methods herein described. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation. It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting. And, it should be understood that the following claims, including all equivalents, are intended to define the spirit and scope of this invention. Furthermore, the advantages described above are not necessarily the only advantages of the invention, and it is not necessarily expected that all of the described advantages will be achieved with every embodiment.

CLAIMS:

1. Use of a system for stabilizing a bone structure, the system comprising:

an access cannula with a longitudinal axis,

the access cannula being configured to be directed into a bone structure;

a polymer delivery tube,

the polymer delivery tube being configured to be directed through an access site into the bone structure, to extend through and beyond a distal end of the access cannula to a first target region to form a tubular cavity along a delivery tube length within the bone structure, and to retract longitudinally from a distal portion of the tubular cavity;

an expandable member,

the expandable member being configured to expand in the distal portion of the tubular cavity to form a first cavity having a larger diameter than the tubular cavity, to deflate and then retract longitudinally with the delivery tube to a desired location in the tubular cavity that is nearer to the access site than the location of the first cavity, and to expand again in the desired location of the tubular cavity to form a second cavity with a larger diameter than the tubular cavity and disposed between the first cavity and the access site; and

a curable material,

the curable material being configured to fill at least a portion of the first cavity and the second cavity.

2. The use of claim 1, where the system further comprises a stylet configured to be disposed longitudinally through the delivery tube and configured to be removable therefrom, said stylet having either a solid cross-section or an internal delivery lumen dimensioned and oriented for delivering the curable material.

3. The use of claims 1 or 2, where the bone structure is selected from a group consisting of a vertebra, a long bone, an irregular bone, and a flat bone.

4. The use of claim 3, where the bone structure is a vertebra, and the access cannula is configured to be directed through a single pedicle of the vertebra.

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5. The use of any one of claims 1 to 4, where the expandable member is configured to form the second cavity generally separate and distinct from the first cavity, except for a connecting portion of the tubular cavity.

6. The use of any one of claims 1 to 4, where the expandable member is configured to form the second cavity substantially continuous with the first cavity.

7. The use of any one of claims 1 to 6, where the expandable member includes a fluid-inflatable balloon configured to create a cavity by displacing material adjacent the tubular cavity.

8. The use of any one of claims 1 to 7, where the expandable member is further configured to expand yet again in a still less-distal portion of the tubular cavity to form at least a third cavity, and where the curable material is configured to fill at least a portion of the at least third cavity.

9. The use of any one of claims 1 to 8, where the expandable member is configured to form the first cavity and the second cavity offset relative to each other with respect to a longitudinal axis of the access cannula.

10. The use of any one of claims 1 to 9, where the system further comprises a delivery cannula, the delivery cannula being configured to be directed to the first and/or the second cavity, and where a distal portion of the delivery cannula includes an internal delivery lumen dimensioned and oriented to deliver the curable material.

11. A system for stabilizing a bone structure, the system comprising:
an access cannula with a longitudinal axis,
the access cannula being configured to be directed into a bone structure;
a polymer delivery tube,
the polymer delivery tube being configured to be directed through an access site into the bone structure, to extend through and beyond a distal end of the access cannula to a first target region to form a tubular cavity along a delivery tube length within the bone structure, and to retract longitudinally from a distal portion of the tubular cavity;

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an expandable member,

the expandable member being configured to expand in the distal portion of the tubular cavity to form a first cavity having a larger diameter than the tubular cavity, to deflate and then retract longitudinally with the delivery tube to a desired location in the tubular cavity that is nearer to the access site than the location of the first cavity, and to expand again in the desired location of the tubular cavity to form a second cavity with a larger diameter than the tubular cavity and disposed between the first cavity and the access site; and

a curable material,

the curable material being configured to fill at least a portion of the first cavity and the second cavity.

12. Use of the system of claim 11 for stabilizing the bone structure of a vertebra, a long bone, an irregular bone, and a flat bone.

13. Use of a system for stabilizing a bone structure, the system comprising:

an access cannula with a longitudinal axis,

the access cannula being configured to be directed into a bone structure through only a single access point;

an expandable member configured to be deployed through the access cannula into the bone structure and configured to be expanded, contracted, moved, then re-expanded along a track, which is curved with respect to the longitudinal axis of the access cannula and is within the bone structure, more than one time to form a plurality of cavities within the bone structure;

a pre-curved stylet including an internal delivery lumen dimensioned and oriented for delivering curable material; and

a curable material,

the curable material being configured to fill the plurality of cavities at least partially via the pre-curved stylet and the internal delivery lumen.

14. The use of claim 13, where the bone structure is selected from a group consisting of a vertebra, a long bone, an irregular bone, and a flat bone.

15. The use of claim 14, where the single access point through which the access cannula is configured to be directed is comprised by a pedicle of the vertebra.

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16. The use of any one of claims 13 to 15, where the expandable member is configured to form the plurality of cavities generally continuous together to form a larger cavity along the curved track.

17. The use of any one of claims 13 to 16, where the plurality of cavities includes three or more cavities.

18. The use of any one of claims 13 to 17, wherein the system further comprises

a delivery tube coaxially disposed through the access cannula with a stylet disposed longitudinally through the delivery tube to form the curved track;

the stylet being configured to be removable from the delivery tube; and

the expandable member being further configured to be directed through the delivery tube.

19. The use of any one of claims 13 to 18, where the expandable member includes a fluid-inflatable balloon configured to create a cavity by displacing material adjacent the tubular cavity.

20. The use of any one of claims 13 to 19, where each cavity of the plurality of cavities is offset relative to other cavities with respect to the longitudinal axis of the access cannula.

21. A system for stabilizing a bone structure, the system comprising:

an access cannula with a longitudinal axis,

the access cannula being configured to be directed into a bone structure through only a single access point;

an expandable member configured to be deployed through the access cannula into the bone structure and configured to be expanded, contracted, moved, then re-expanded along a track, which is curved with respect to the longitudinal axis of the access cannula and is within the bone structure, more than one time to form a plurality of cavities within the bone structure;

a pre-curved stylet including an internal delivery lumen dimensioned and oriented for delivering curable material; and

a curable material,

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the curable material being configured to fill the plurality of cavities at least partially via the pre-curved stylet and the internal delivery lumen.

22. Use of the system of claim 21 for stabilizing the bone structure of a vertebra, a long bone, an irregular bone, and a flat bone.

23. Use of a system for stabilizing a bone structure of a patient, said system comprising:

a generally straight access cannula having a longitudinal axis,

the access cannula being configured for directing a distal end of the access cannula into the bone structure near a target site;

a delivery tube,

the delivery tube being configured to be positioned through the access cannula such that a distal curved portion of the delivery tube, no longer constrained by the access cannula, assumes a curve within the bone structure with respect to the longitudinal axis of the access cannula;

a cavity-forming device comprising an elongate body and an expandable member coupled to the elongate body;

the expandable member being configured to be positioned within a curved path of the bone structure distal to the delivery tube at the target site, and to expand to form a cavity; and

a curable material,

the curable material being configured to be deliverable through the delivery tube and into the cavity.

24. The use of claim 23, wherein said cavity-forming device further comprises a flexible support structure within the expandable member, said the expandable member being further configured to be positioned distal to the delivery tube such that the flexible support structure assumes a curved configuration within the curved path of the bone structure.

25. The use of claims 23 or 24, wherein the cavity formed within the bone structure is offset relative to the longitudinal axis of the access cannula.

26. The use of claim 25, wherein the expandable member is configured to form the cavity within the bone structure offset relative to the distal curved portion of the delivery tube.

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27. The use of any one of claims 23 to 26, wherein the bone structure comprises a vertebral body, the delivery tube being configured to be positioned within the vertebral body such that at least a portion of the curved path extends beyond a centerline of the vertebral body opposite the access cannula.

28. The use of any one of claims 23 to 27, wherein when the expandable member is configured to be positioned within the curved path, the delivery tube is further configured to be withdrawn within the bone structure while the expandable member is initially disposed within the delivery tube, and the expandable member is further configured to be exposed at the target site when the delivery tube is withdrawn.

29. The use of any one of claims 23 to 28, where the expandable member is further configured to be directed in a contracted state coaxially within the delivery tube until the expandable member contacts the bone structure at the distal end of the delivery tube.

30. The use of any one of claims 23 to 29, where the system further comprises a stylet configured to be positioned coaxially within the delivery tube, and where the stylet and the delivery tube are further configured to be directed through the access cannula to form the curved path with the delivery tube.

31. The use of any one of claims 23 to 30, where the system further comprises a plurality of stylets each having a different distal pre-set curved portion, the plurality of stylets each being configured for use following determination of a curvature of the curved path between the distal end of the access cannula and the target site and selection of one of the plurality of stylets having the pre-set distal pre-set curved portion corresponding to the determined curvature of the curved path.

32. The use of claim 31, wherein the delivery tube is a metal needle having the curved distal portion and is configured to direct the expandable member in a contracted state through the curved path and to deliver the curable material through the metal needle and into the cavity.

33. The use of claim 32, where the expandable member is further configured to be directed in the contracted state coaxially within the delivery tube beyond the distal end of the delivery

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tube to the target site with the flexible support structure being further configured to provide trackability and pushability to the expandable member of the cavity-forming device as the expandable member is directed into the curved path.

34. A system for stabilizing a bone structure of a patient, said system comprising:

a generally straight access cannula having a longitudinal axis,

the access cannula being configured for directing a distal end of the access cannula into the bone structure near a target site;

a delivery tube,

the delivery tube being configured to be positioned through the access cannula such that a distal curved portion of the delivery tube, no longer constrained by the access cannula, assumes a curve within the bone structure with respect to the longitudinal axis of the access cannula;

a cavity-forming device comprising an elongate body and an expandable member coupled to the elongate body;

the expandable member being configured to be positioned within a curved path of the bone structure distal to the delivery tube at the target site, and to expand to form a cavity; and

a curable material,

the curable material being configured to be deliverable through the delivery tube and into the cavity.

35. Use of the system of claim 34 for stabilizing the bone structure of a vertebra, a long bone, an irregular bone, and a flat bone.

36. Use of a system for stabilizing a bone structure of a patient, said system comprising:

a generally straight access cannula having a longitudinal axis,

the access cannula being configured for directing a distal end of the access cannula into the bone structure near a target site;

a delivery tube,

the delivery tube being configured to be positioned through the access cannula such that a distal curved portion of the delivery tube, no longer constrained by the access cannula, lines a curved path to the target site within the bone structure with respect to the longitudinal axis of the access cannula;

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a cavity-forming device comprising an elongate body and an expandable member coupled to the elongate body;

the delivery tube being further configured to be withdrawn within the bone structure while the expandable member is initially disposed within the delivery tube, and

the expandable member being further configured to be exposed within the curved path of the bone structure distal to the delivery tube at the target site when the delivery tube is withdrawn and to expand to form a cavity; and

a curable material,

the curable material being configured to be deliverable through the delivery tube and into the cavity.

37. The use of claim 36, wherein said cavity-forming device further comprises a flexible support structure within the expandable member, the expandable member being further configured to be positioned distal to the delivery tube such that the flexible support structure assumes a curved configuration within the curved path of the bone structure.

38. A system for stabilizing a bone structure of a patient, said system comprising:

a generally straight access cannula having a longitudinal axis,

the access cannula being configured for directing a distal end of the access cannula into the bone structure near a target site;

a delivery tube,

the delivery tube being configured to be positioned through the access cannula such that a distal curved portion of the delivery tube, no longer constrained by the access cannula, lines a curved path to the target site within the bone structure with respect to the longitudinal axis of the access cannula;

a cavity-forming device comprising an elongate body and an expandable member coupled to the elongate body;

the delivery tube being further configured to be withdrawn within the bone structure while the expandable member is initially disposed within the delivery tube, and

the expandable member being further configured to be exposed within the curved path of the bone structure distal to the delivery tube at the target site when the delivery tube is withdrawn and to expand to form a cavity; and

a curable material,

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the curable material being configured to be deliverable through the delivery tube and into the cavity.

39. Use of the system of claim 38 for stabilizing the bone structure of a vertebra, a long bone, an irregular bone, and a flat bone.

40. A kit comprising an access cannula, a polymer delivery tube, an expandable member, a curable material, and instructions for using the kit for stabilizing a bone structure;

the access cannula having a longitudinal axis and being configured to be directed into a bone structure;

the polymer delivery tube being configured to be directed through an access site into the bone structure, to extend through and beyond a distal end of the access cannula to a first target region to form a tubular cavity along a delivery tube length within the bone structure, and to retract longitudinally from a distal portion of the tubular cavity;

the expandable member being configured to expand in the distal portion of the tubular cavity to form a first cavity having a larger diameter than the tubular cavity, to deflate and then retract longitudinally with the delivery tube to a desired location in the tubular cavity that is nearer to the access site than the location of the first cavity, and to expand again in the desired location of the tubular cavity to form a second cavity with a larger diameter than the tubular cavity and disposed between the first cavity and the access site; and

the curable material being configured to fill at least a portion of the first cavity and the second cavity.

41. A kit comprising an access cannula, an expandable member, a pre-curved stylet, a curable material, and instructions for using the kit for stabilizing a bone structure;

the access cannula having a longitudinal axis and being configured to be directed into a bone structure through only a single access point;

the expandable member being configured to be deployed through the access cannula into the bone structure and configured to be expanded, contracted, moved, then re-expanded along a track, which is curved with respect to the longitudinal axis of the access cannula and is within the bone structure, more than one time to form a plurality of cavities within the bone structure;

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the pre-curved stylet including an internal delivery lumen dimensioned and oriented for delivering curable material; and

the curable material being configured to fill the plurality of cavities at least partially via the pre-curved stylet and the internal delivery lumen.

42. A kit comprising an access cannula, a delivery tube, a cavity-forming device, a curable material, and instructions for using the kit for stabilizing a bone structure of a patient:

the access cannula being generally straight and having a longitudinal axis and being configured for directing a distal end of the access cannula into the bone structure near a target site;

the delivery tube being configured to be positioned through the access cannula such that a distal curved portion of the delivery tube, no longer constrained by the access cannula, assumes a curve within the bone structure with respect to the longitudinal axis of the access cannula;

the cavity-forming device comprising an elongate body and an expandable member coupled to the elongate body;

the expandable member being configured to be positioned within a curved path of the bone structure distal to the delivery tube at the target site, and to expand to form a cavity; and

the curable material being configured to be deliverable through the delivery tube and into the cavity.

43. A kit comprising an access cannula, a delivery tube, a cavity-forming device, a curable material, and instructions for using the kit for stabilizing a bone structure of a patient:

the access cannula being generally straight and having a longitudinal axis and being configured for directing a distal end of the access cannula into the bone structure near a target site;

the delivery tube being configured to be positioned through the access cannula such that a distal curved portion of the delivery tube, no longer constrained by the access cannula, lines a curved path to the target site within the bone structure with respect to the longitudinal axis of the access cannula;

the cavity-forming device comprising an elongate body and an expandable member coupled to the elongate body;

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the delivery tube being further configured to be withdrawn within the bone structure while the expandable member is initially disposed within the delivery tube,

the expandable member being further configured to be exposed within the curved path of the bone structure distal to the delivery tube at the target site when the delivery tube is withdrawn and to expand to form a cavity; and

the curable material being configured to be deliverable through the delivery tube and into the cavity.

44. The kit of any one of claims 40 to 43, wherein the instructions for use comprise instructions to form at least two cavities within the bone structure.

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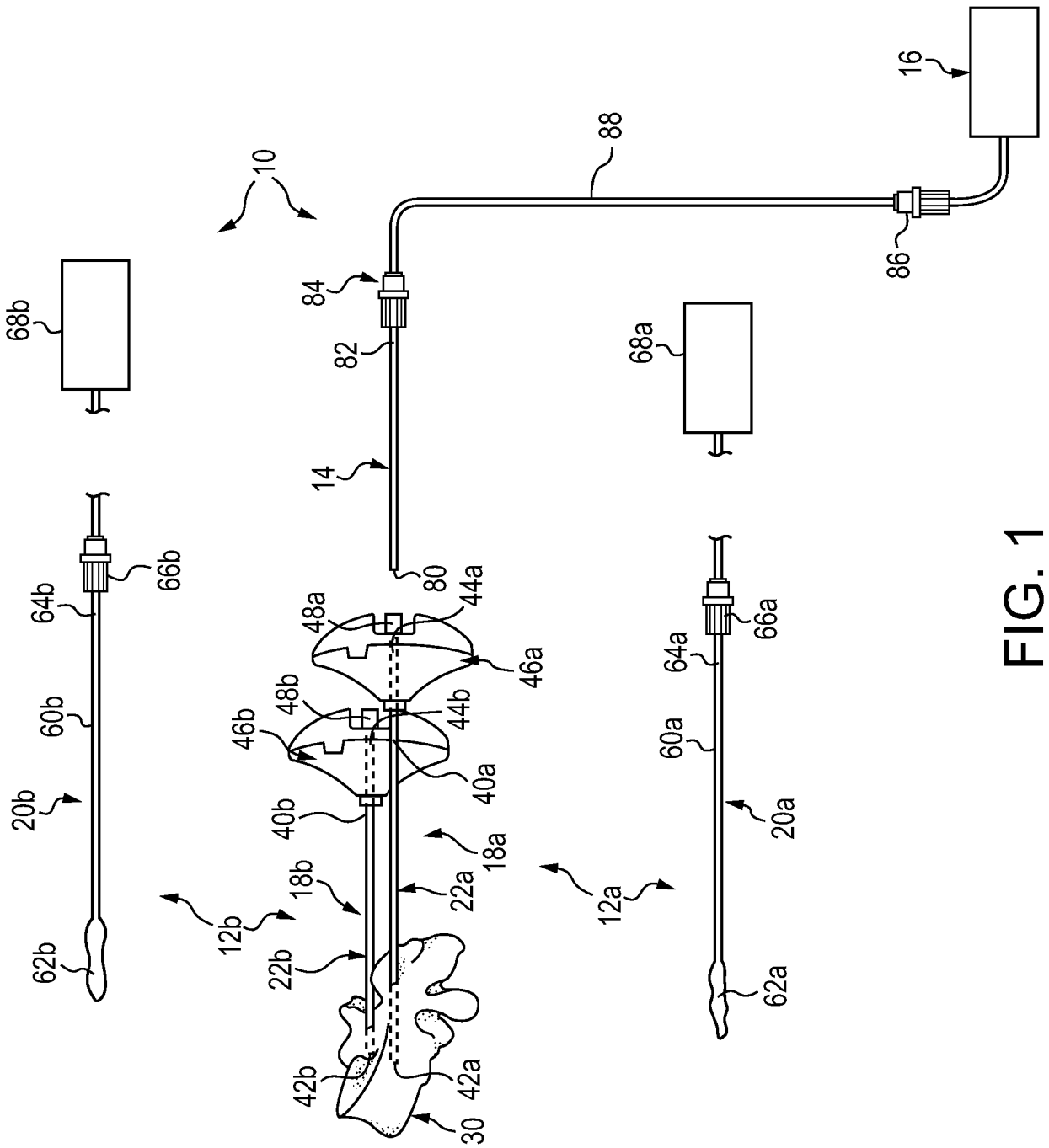
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FIG. 1

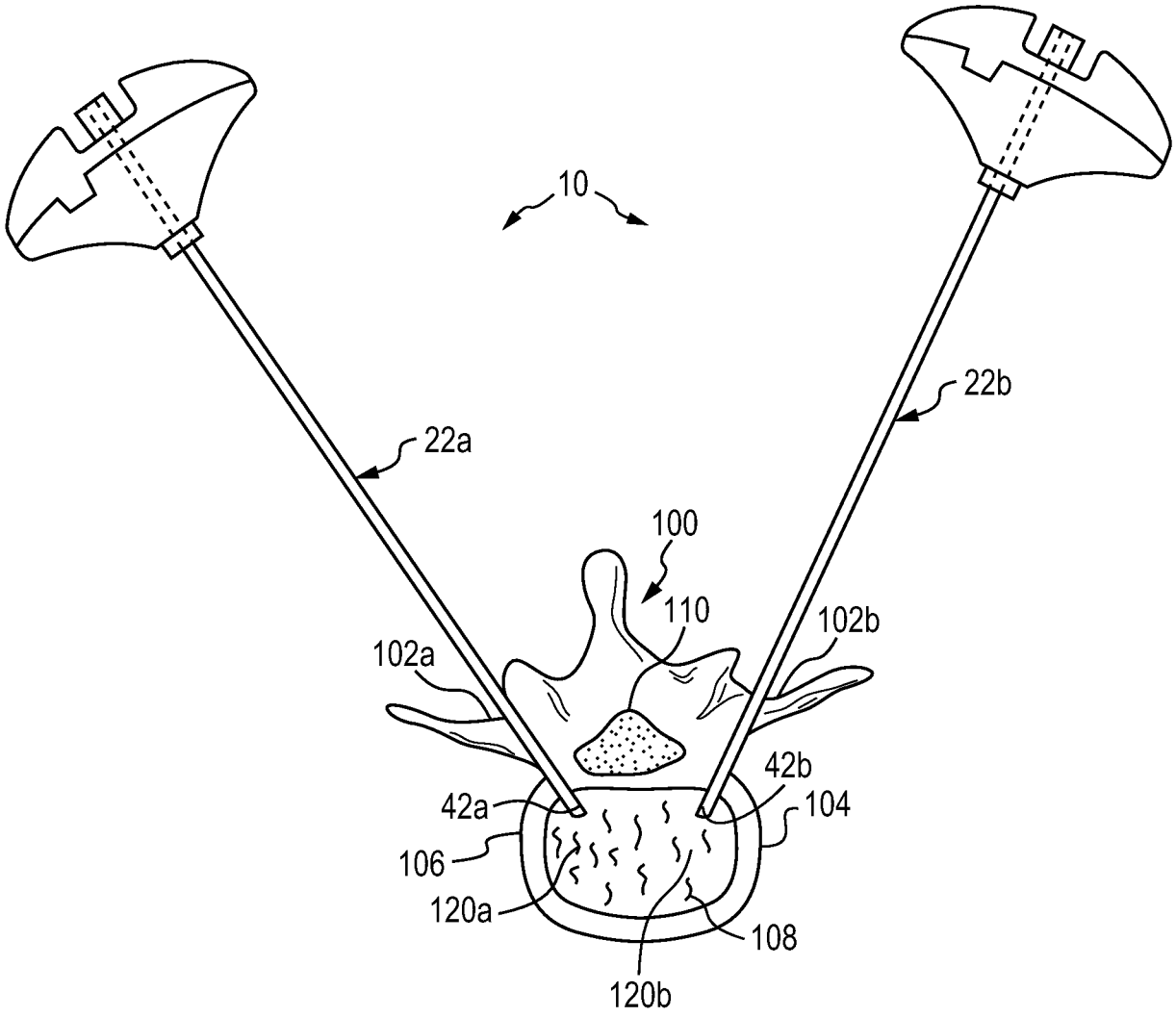

FIG. 2A

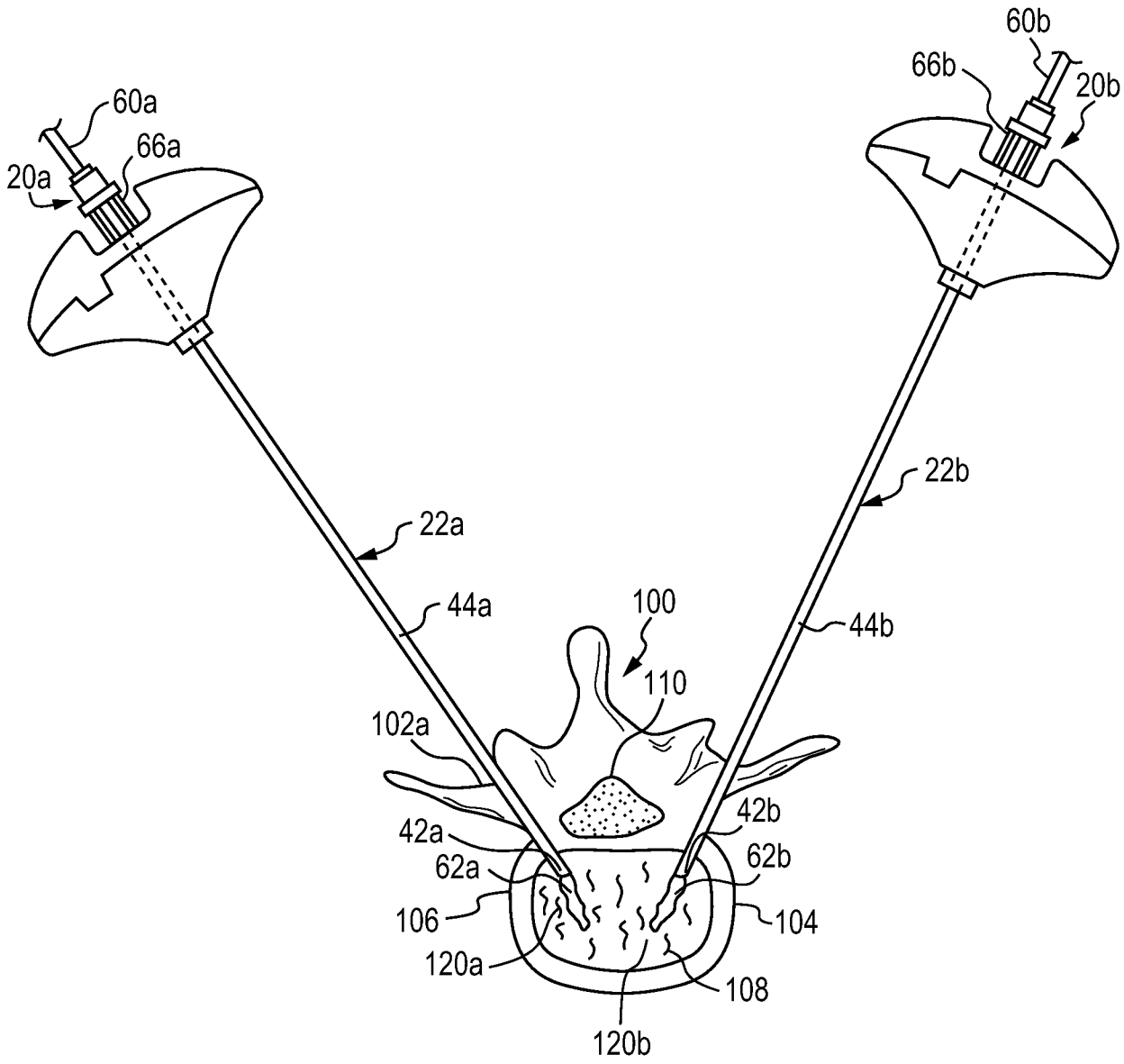
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FIG. 2B

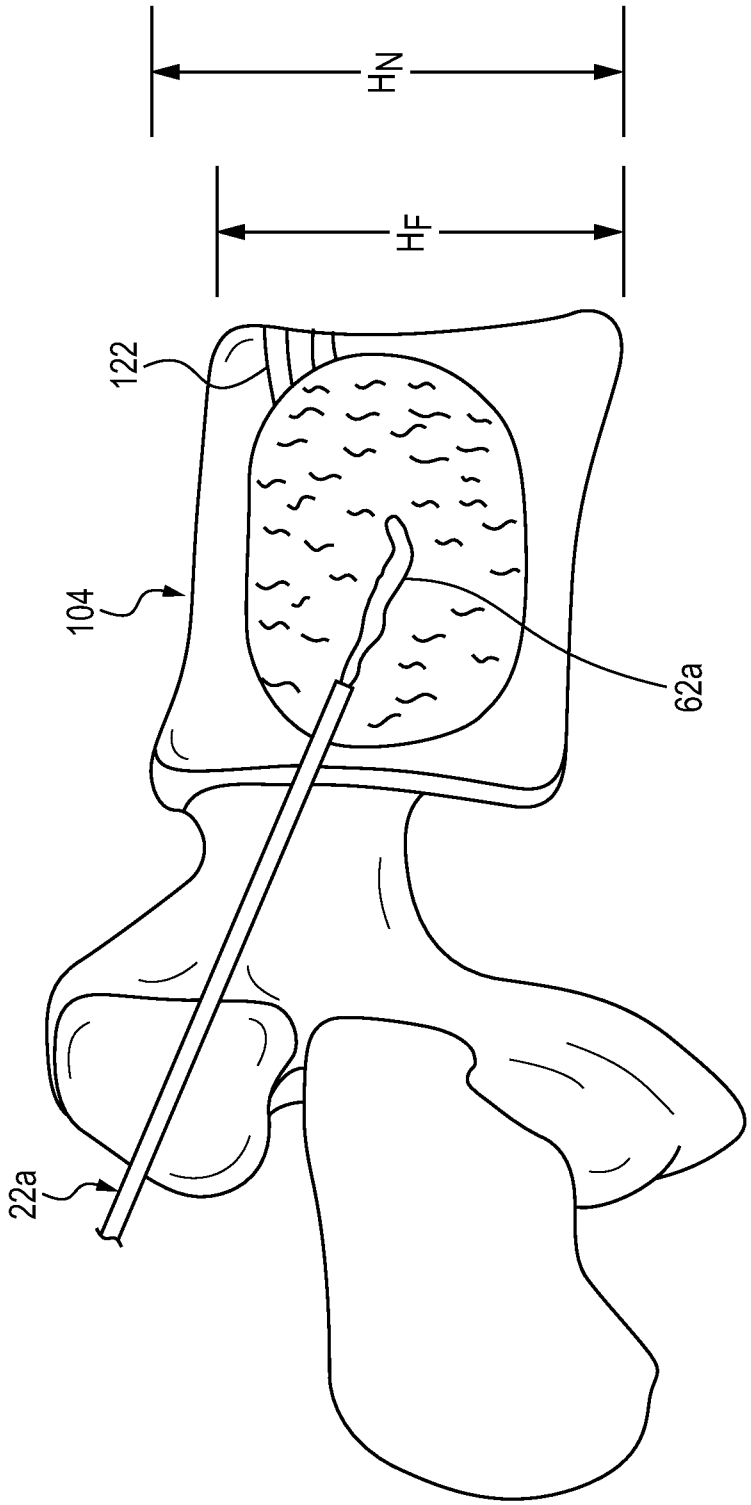


FIG. 2C

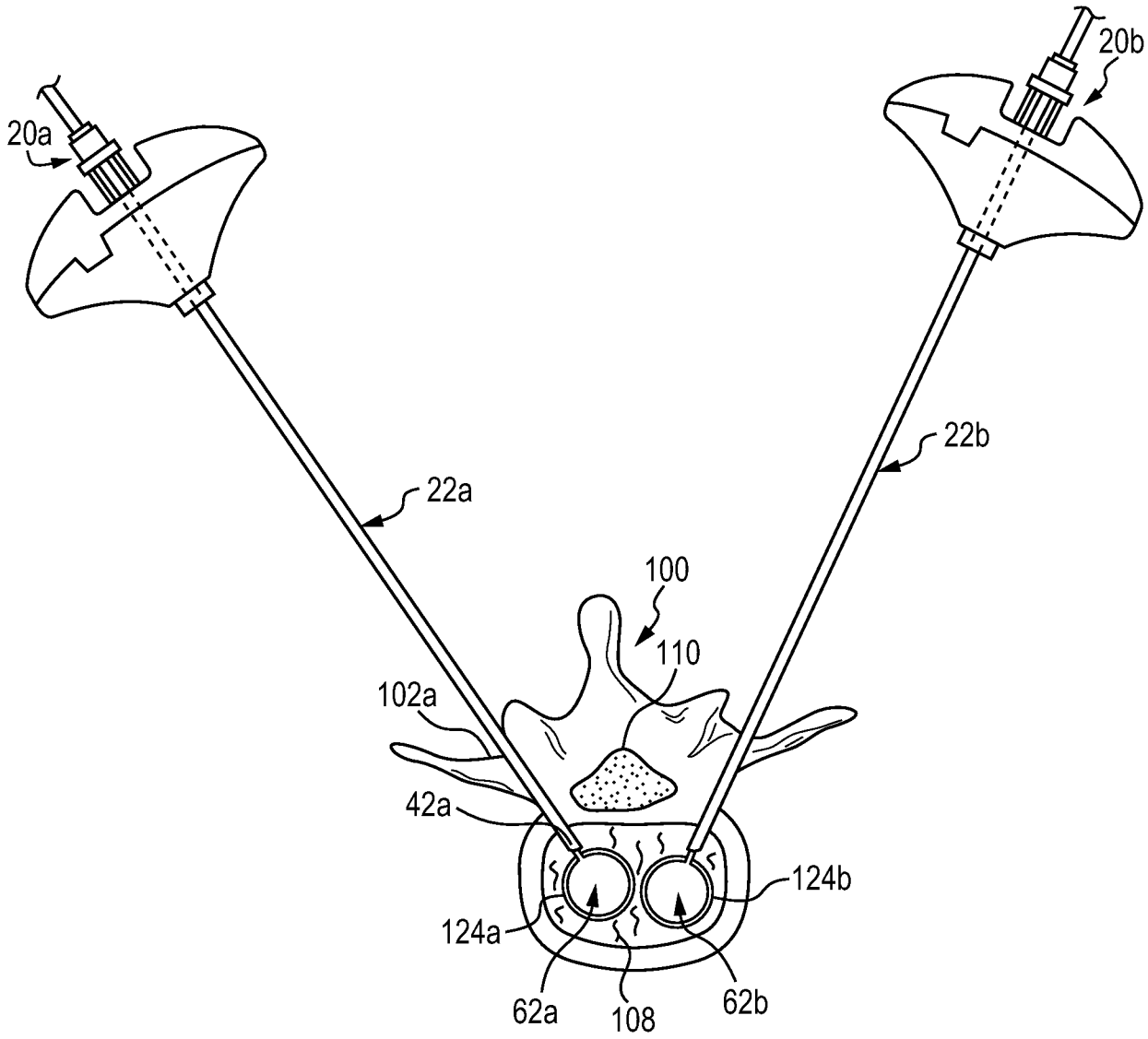


FIG. 3A

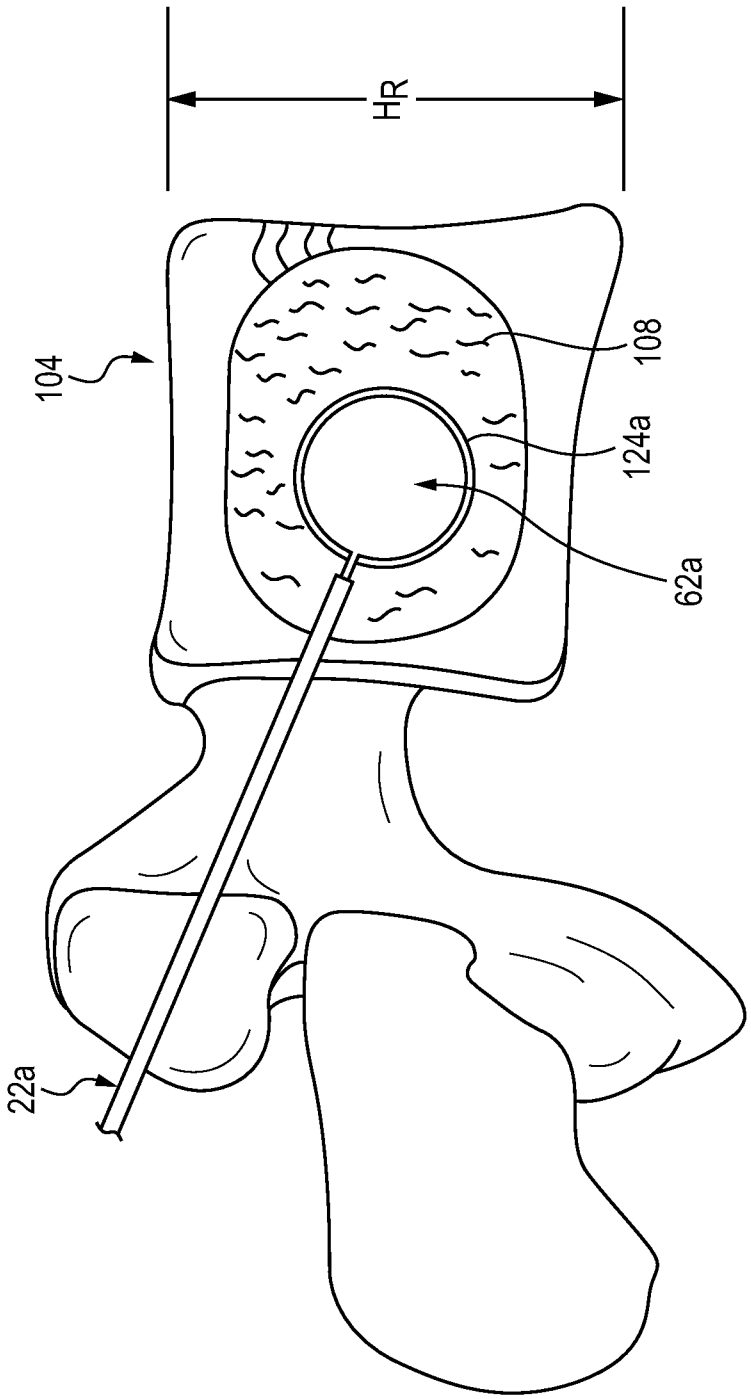


FIG. 3B

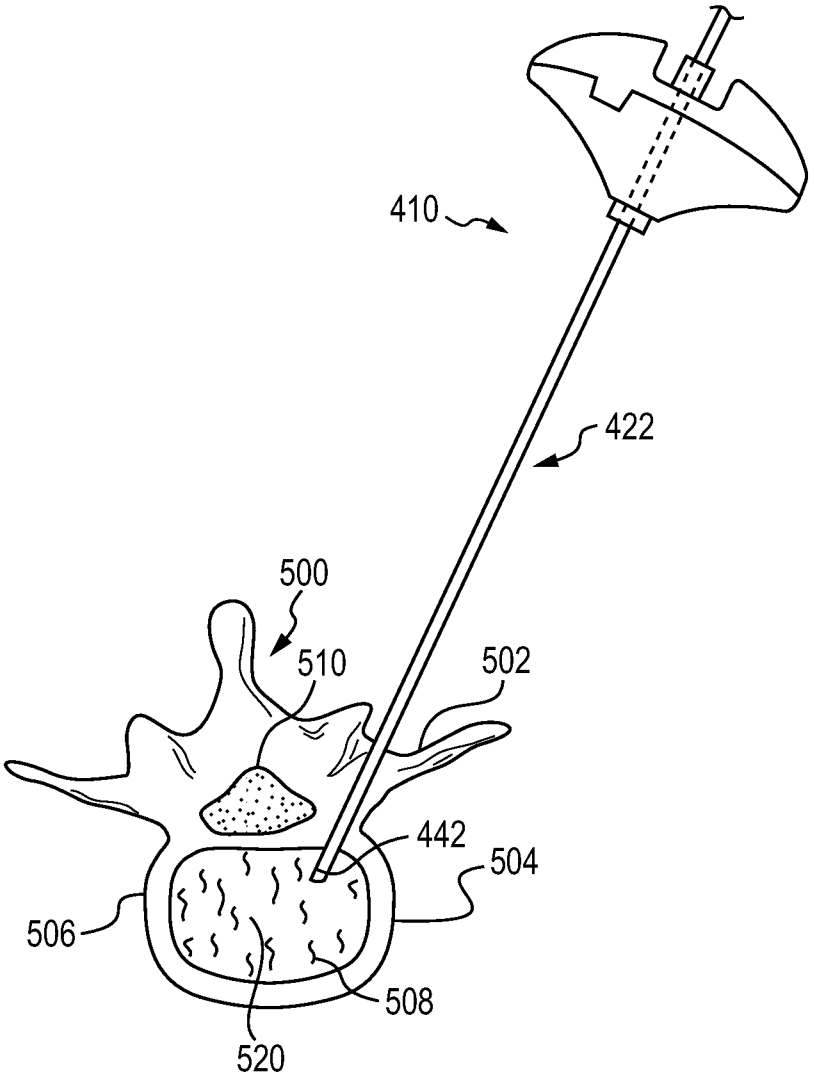


FIG. 4A

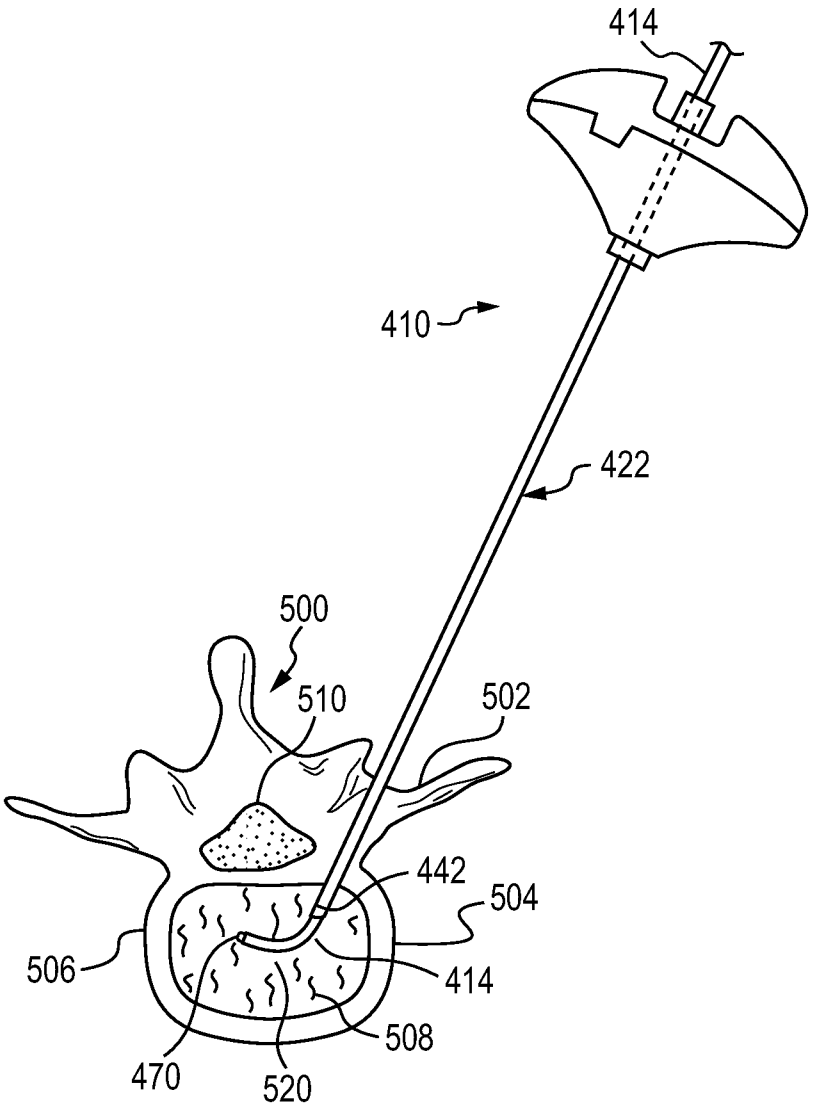


FIG. 4B

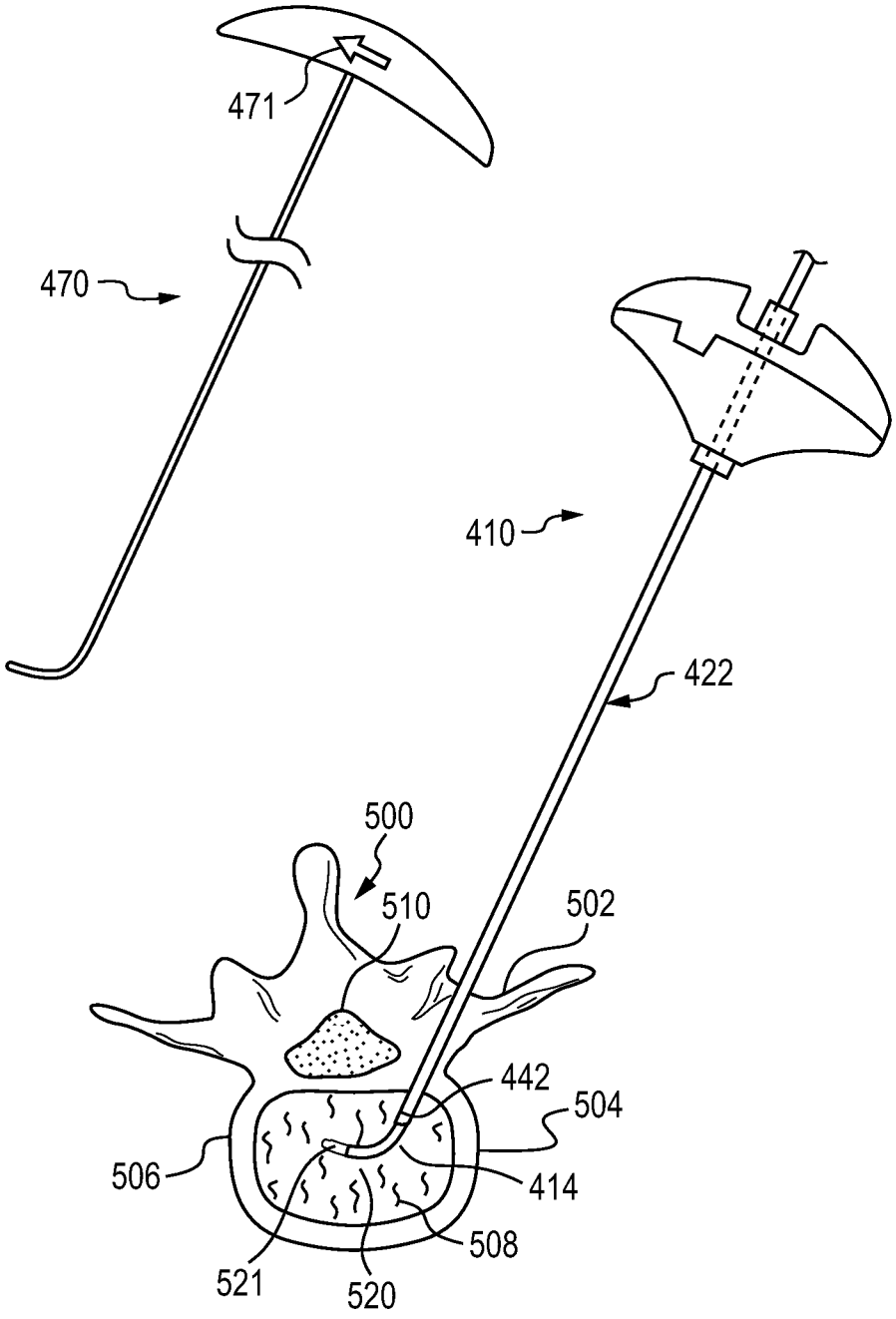


FIG. 4C

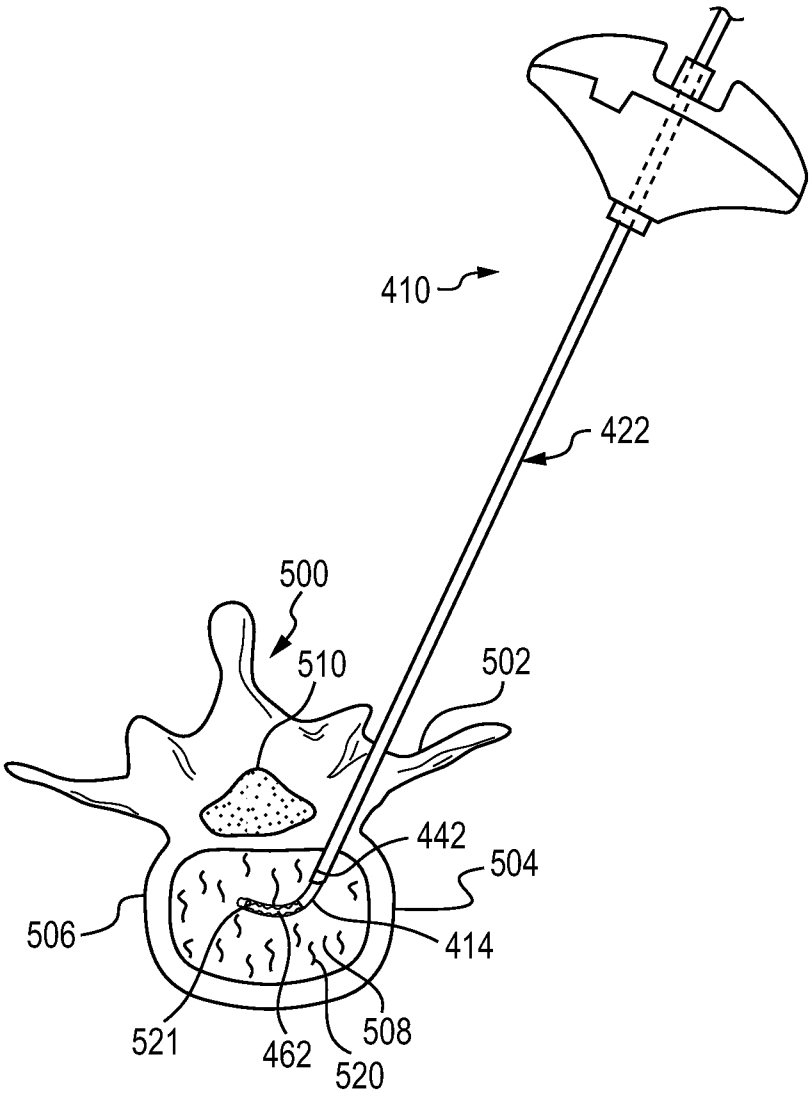


FIG. 4D

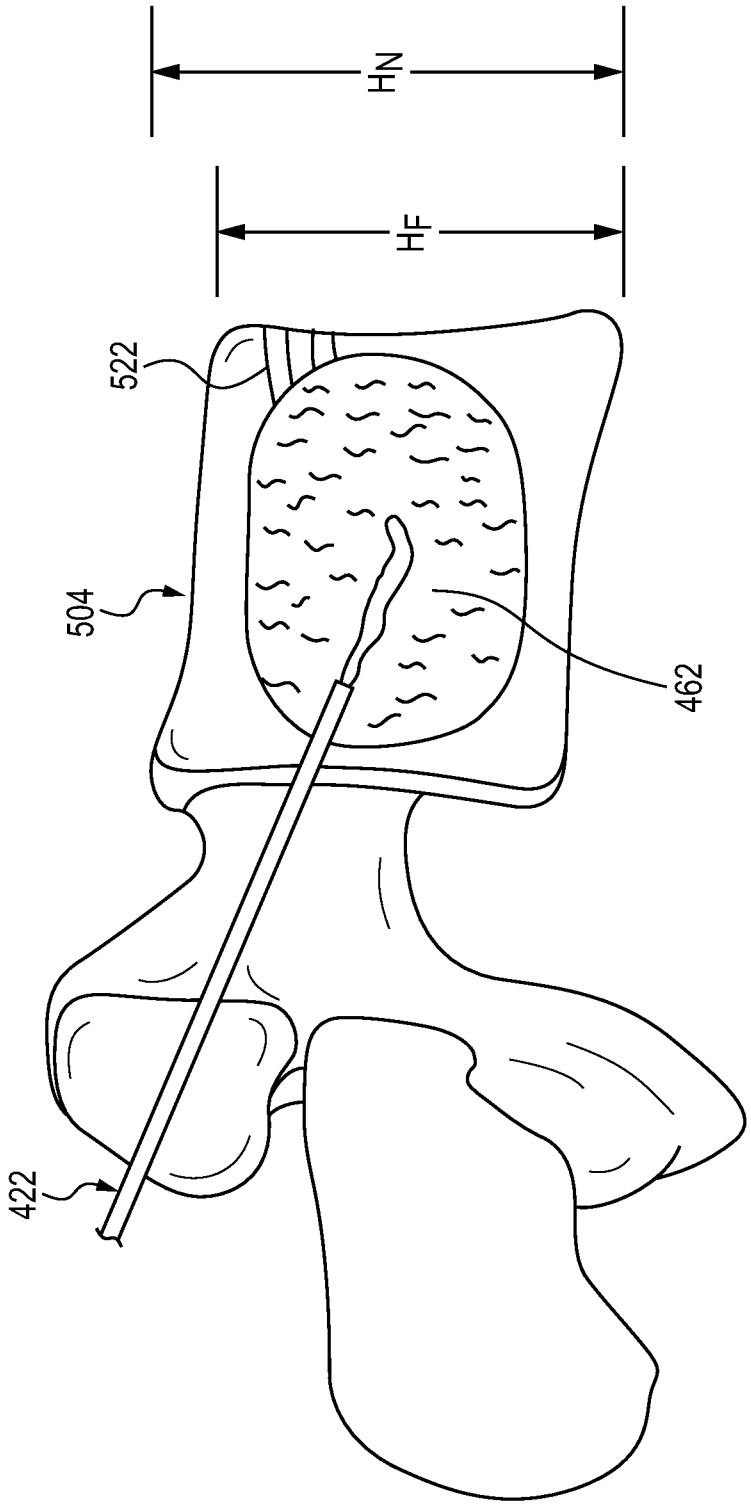


FIG. 4E

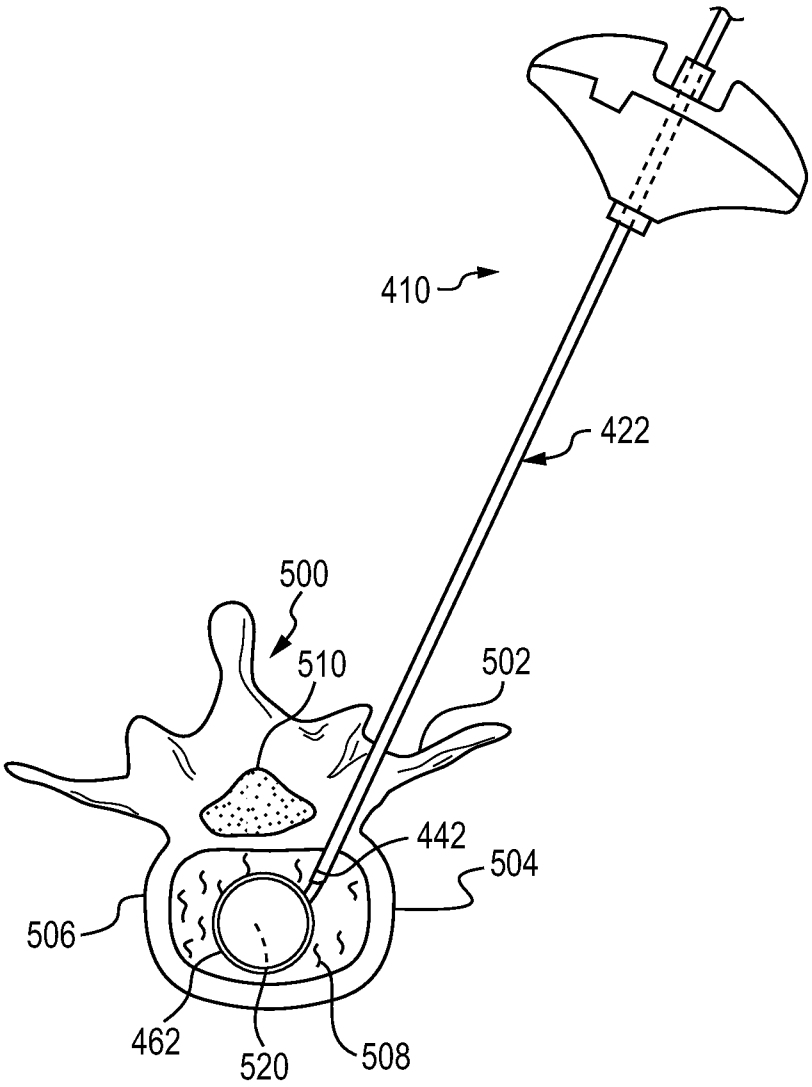


FIG. 4F

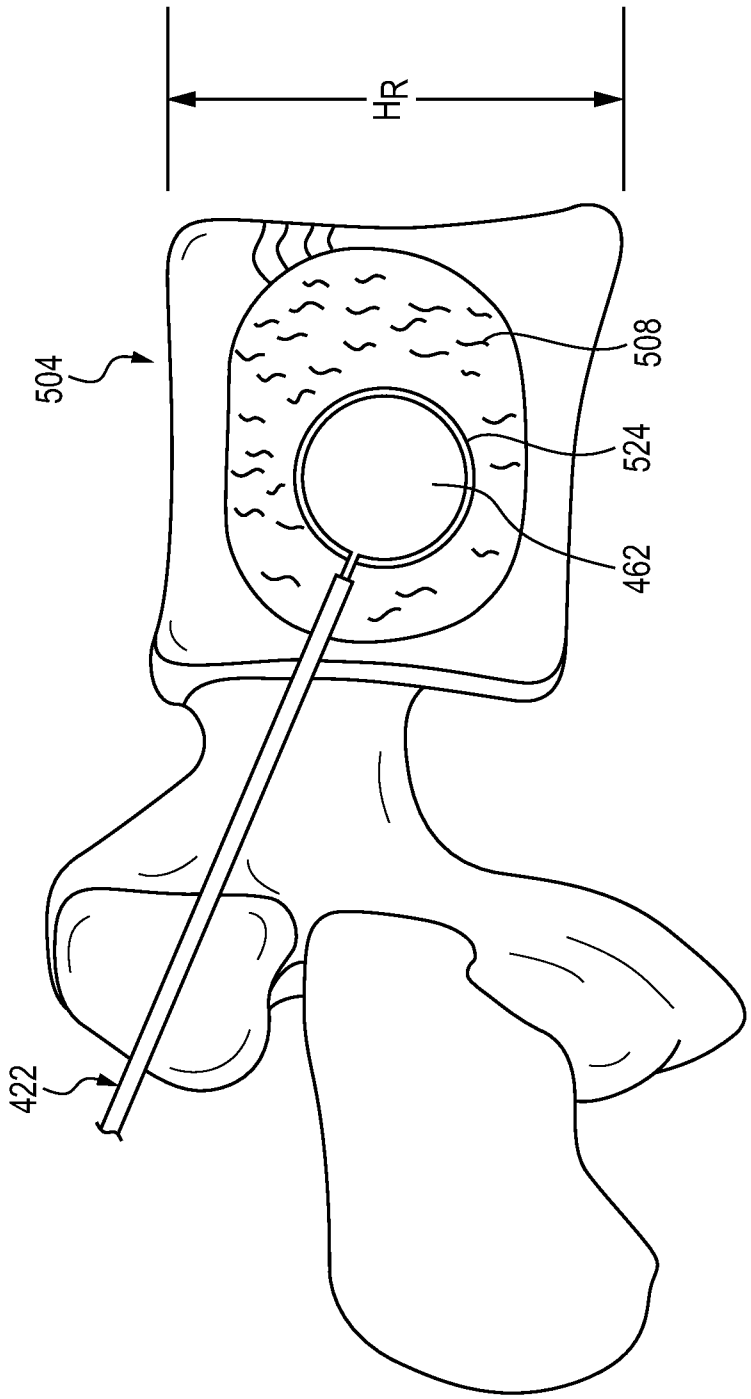


FIG. 4G

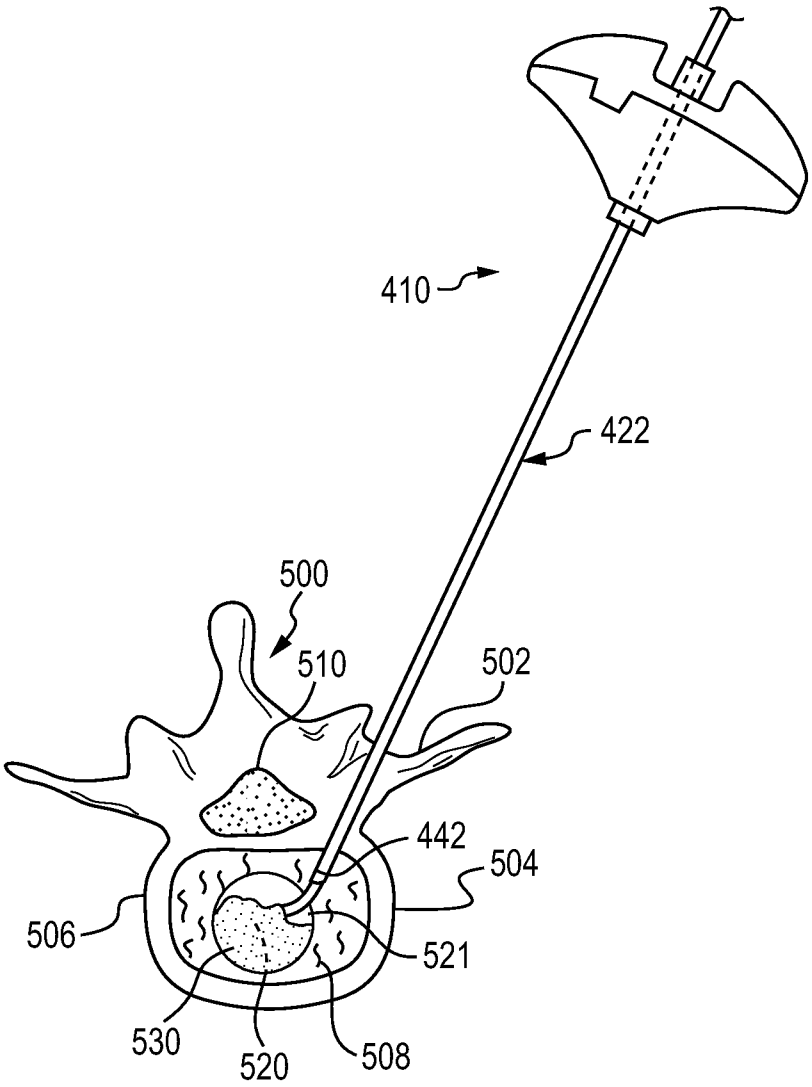


FIG. 4H

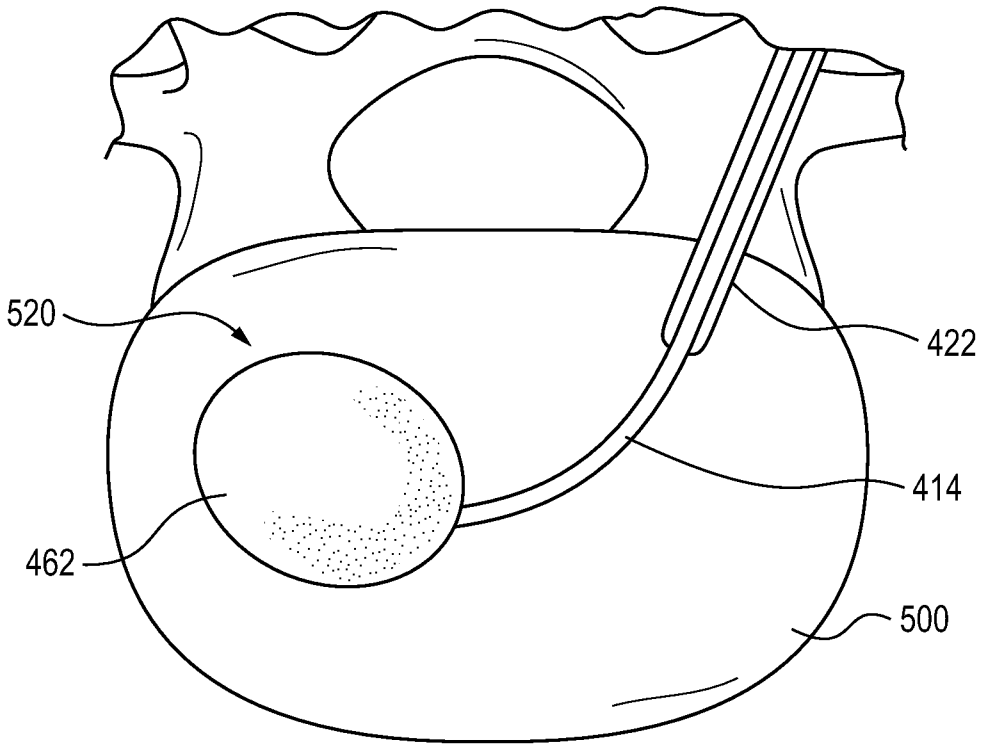


FIG. 5A

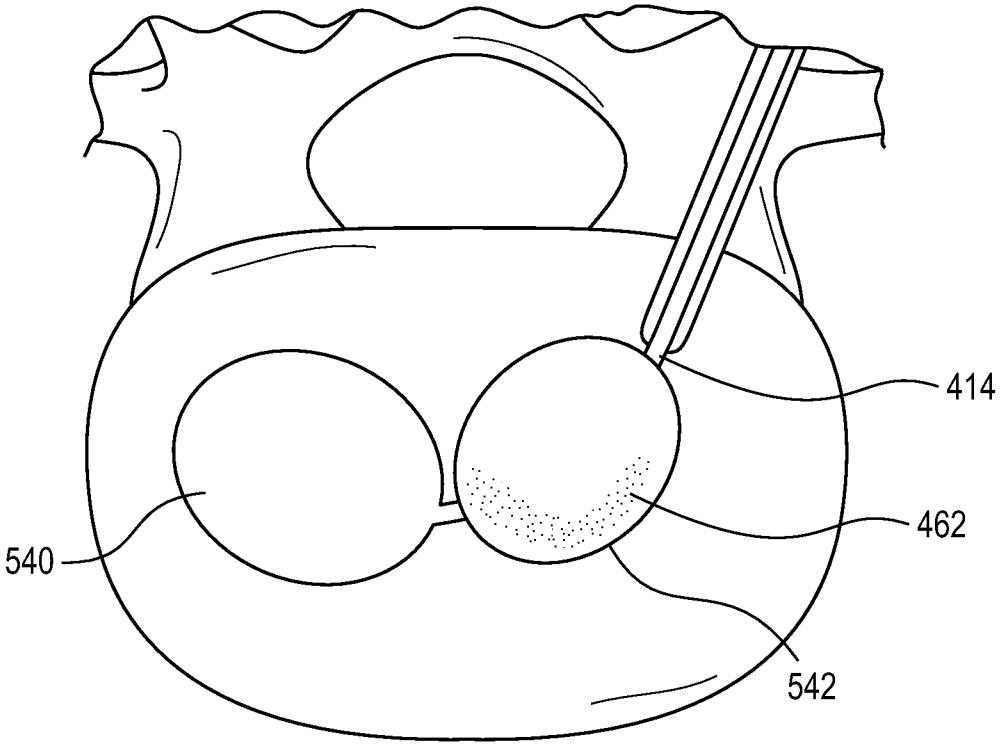


FIG. 5B

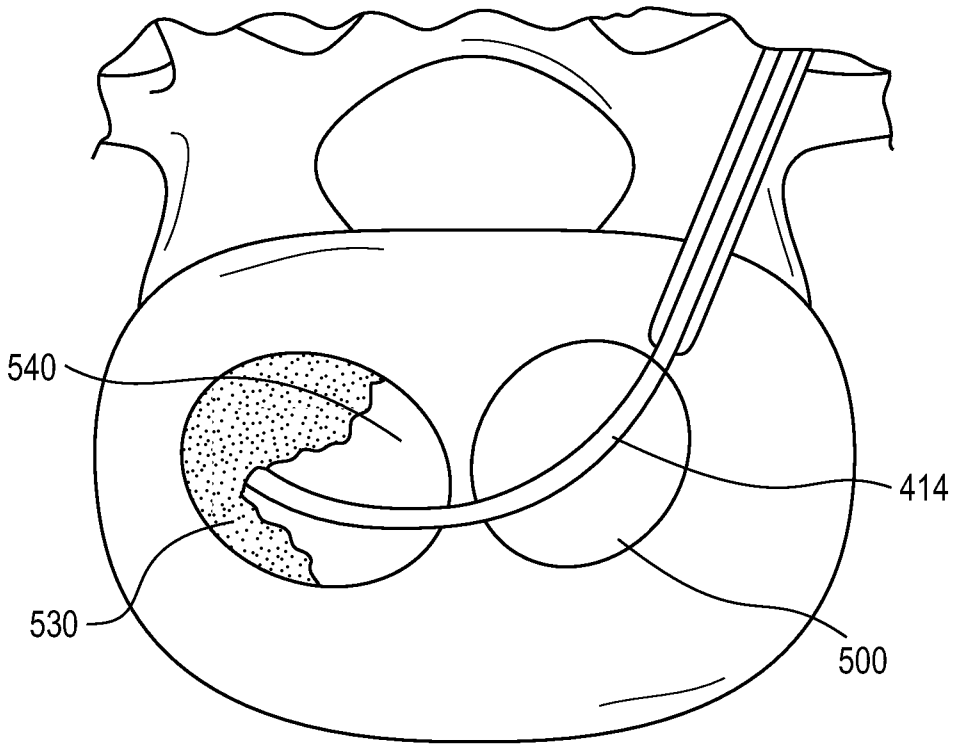


FIG. 5C

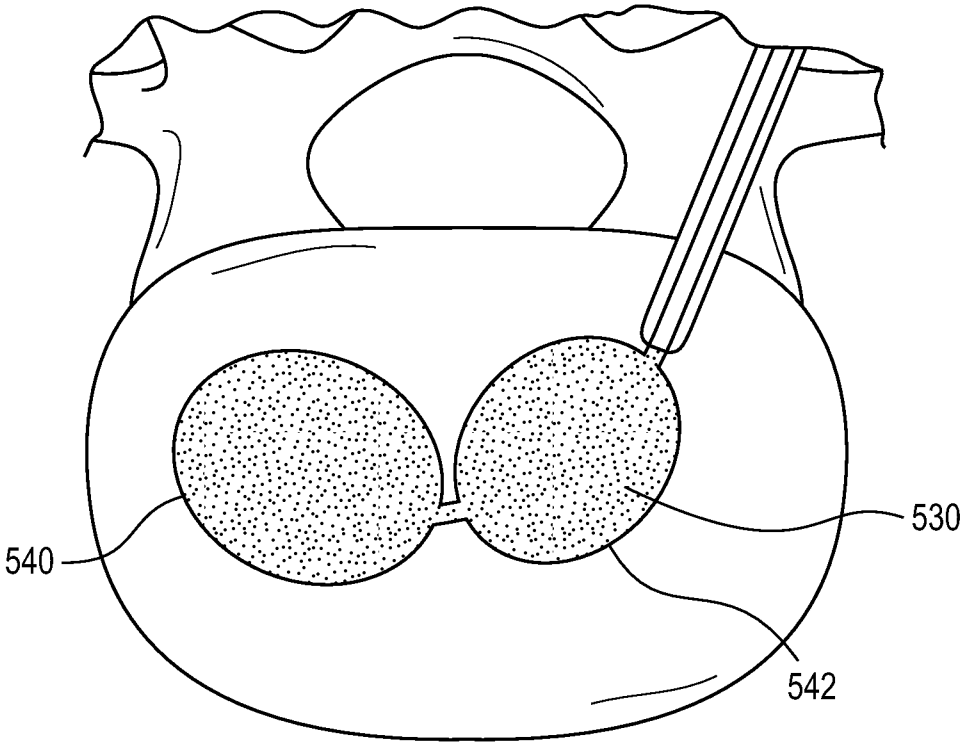


FIG. 5D

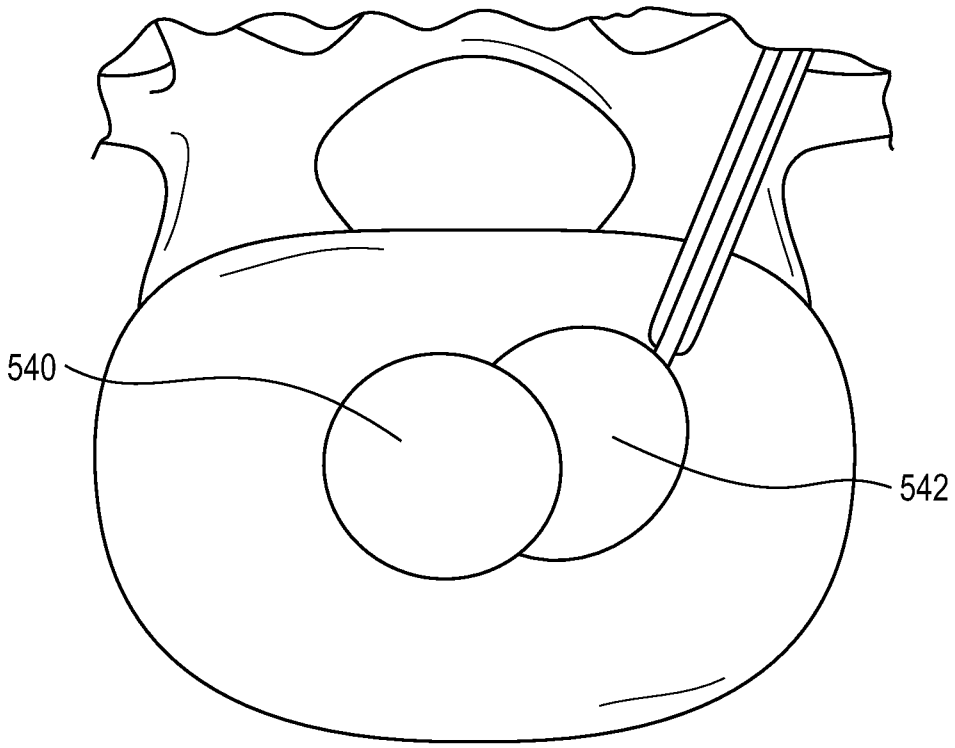


FIG. 6

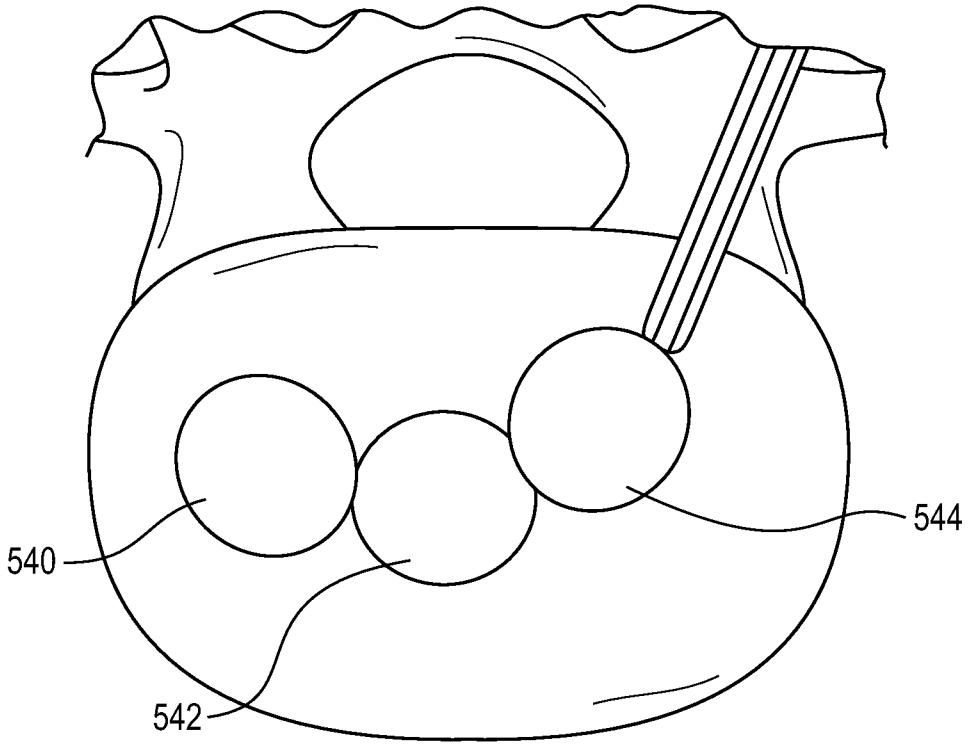


FIG. 7

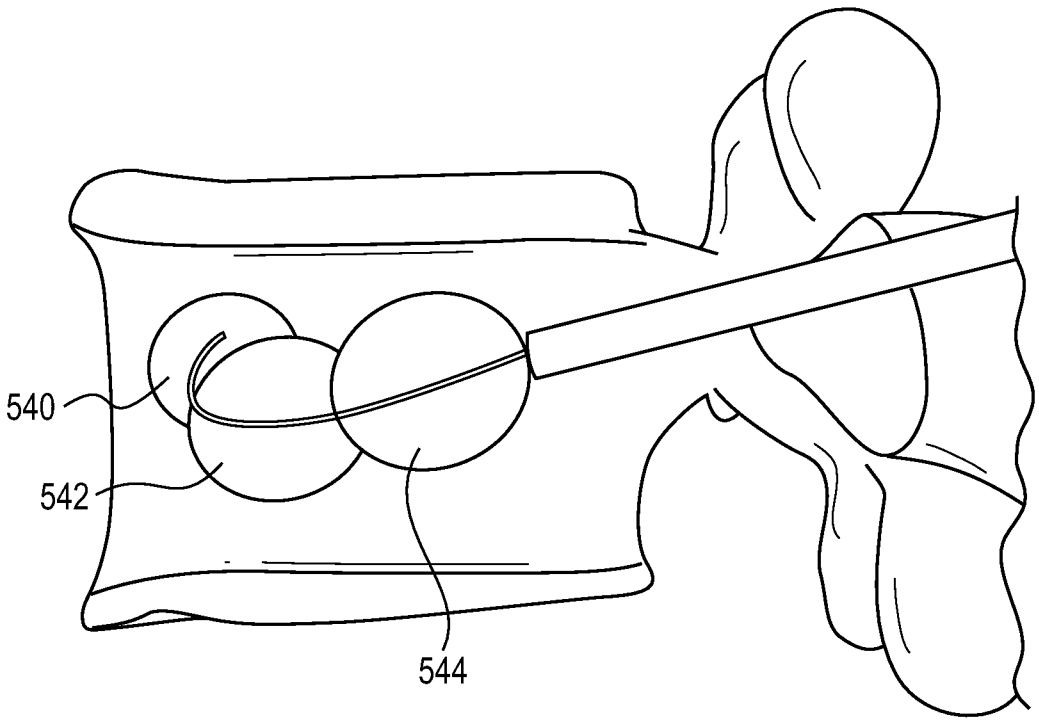


FIG. 8

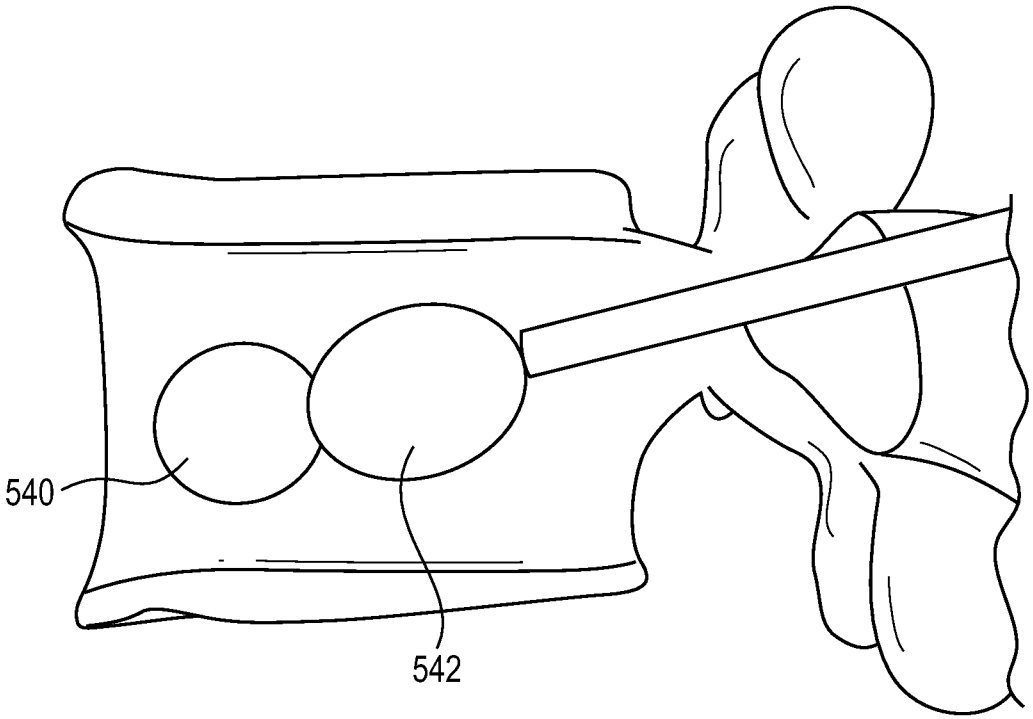
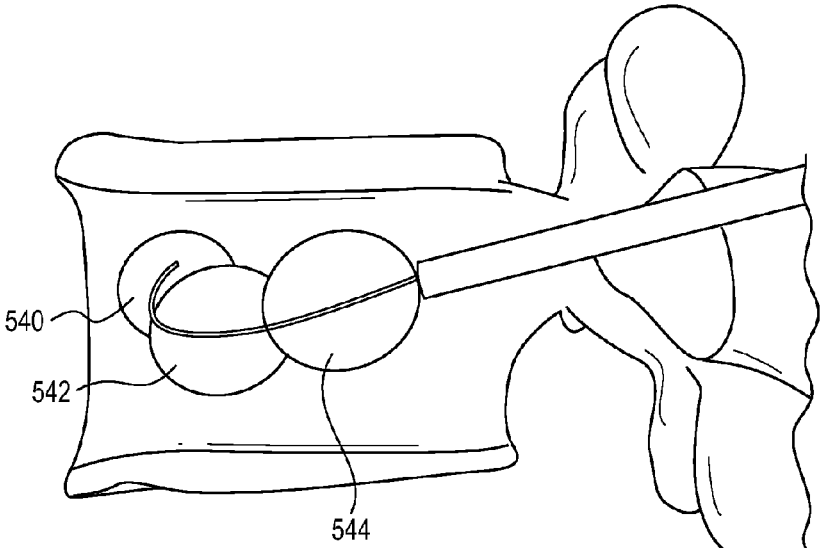


FIG. 9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