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Scribner et al.(10) **Pub. No.: US 2008/0065091 A1**(43) **Pub. Date: Mar. 13, 2008**(54) **METHODS AND APPARATUS FOR PLACING MATERIALS INTO BONE**(75) Inventors: **Robert M. Scribner**, Los Altos, CA (US); **Michael L. Reo**, Redwood City, CA (US); **Mark A. Reiley**, Piedmont, CA (US); **Ryan Boucher**, San Francisco, CA (US)

Correspondence Address:

Daniel D. Ryan
RYAN KROMHOLZ & MANION, S.C.
Post Office Box 26618
Milwaukee, WI 53226-0618 (US)(73) Assignee: **Kyphon Inc.**(21) Appl. No.: **11/978,274**(22) Filed: **Oct. 29, 2007****Related U.S. Application Data**

(62) Division of application No. 11/599,943, filed on Nov. 15, 2006, which is a division of application No.

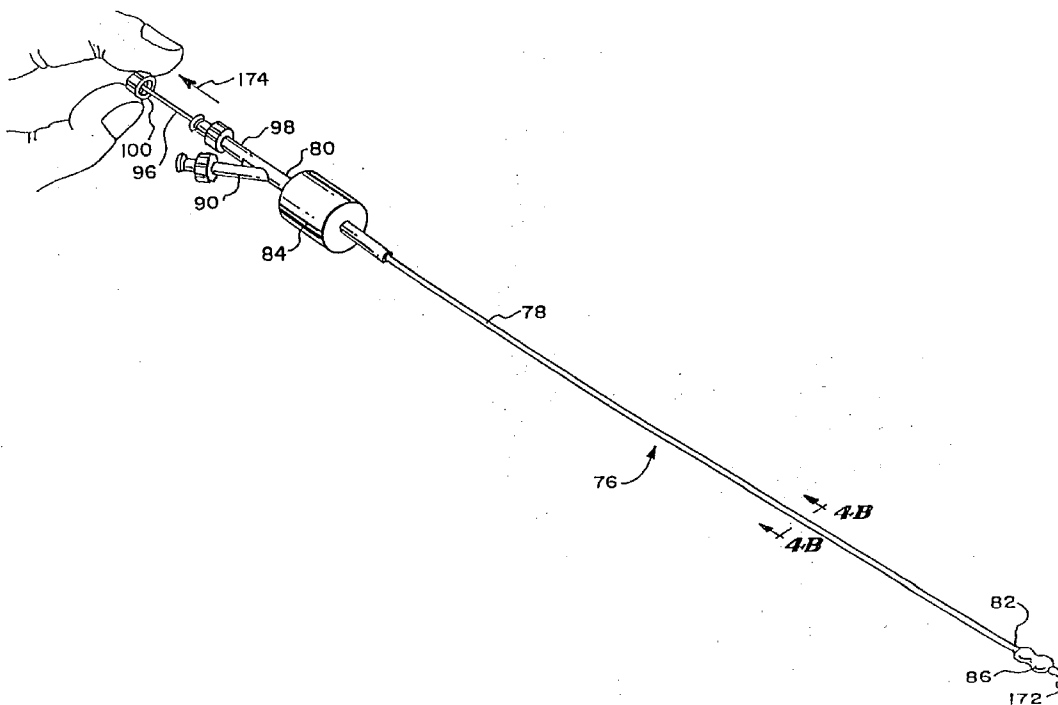
10/617,976, filed on Jul. 11, 2003, now Pat. No. 7,153,307, which is a division of application No. 09/804,107, filed on Mar. 12, 2001, now Pat. No. 6,613,054, which is a division of application No. 09/134,323, filed on Aug. 14, 1998, now Pat. No. 6,241,734.

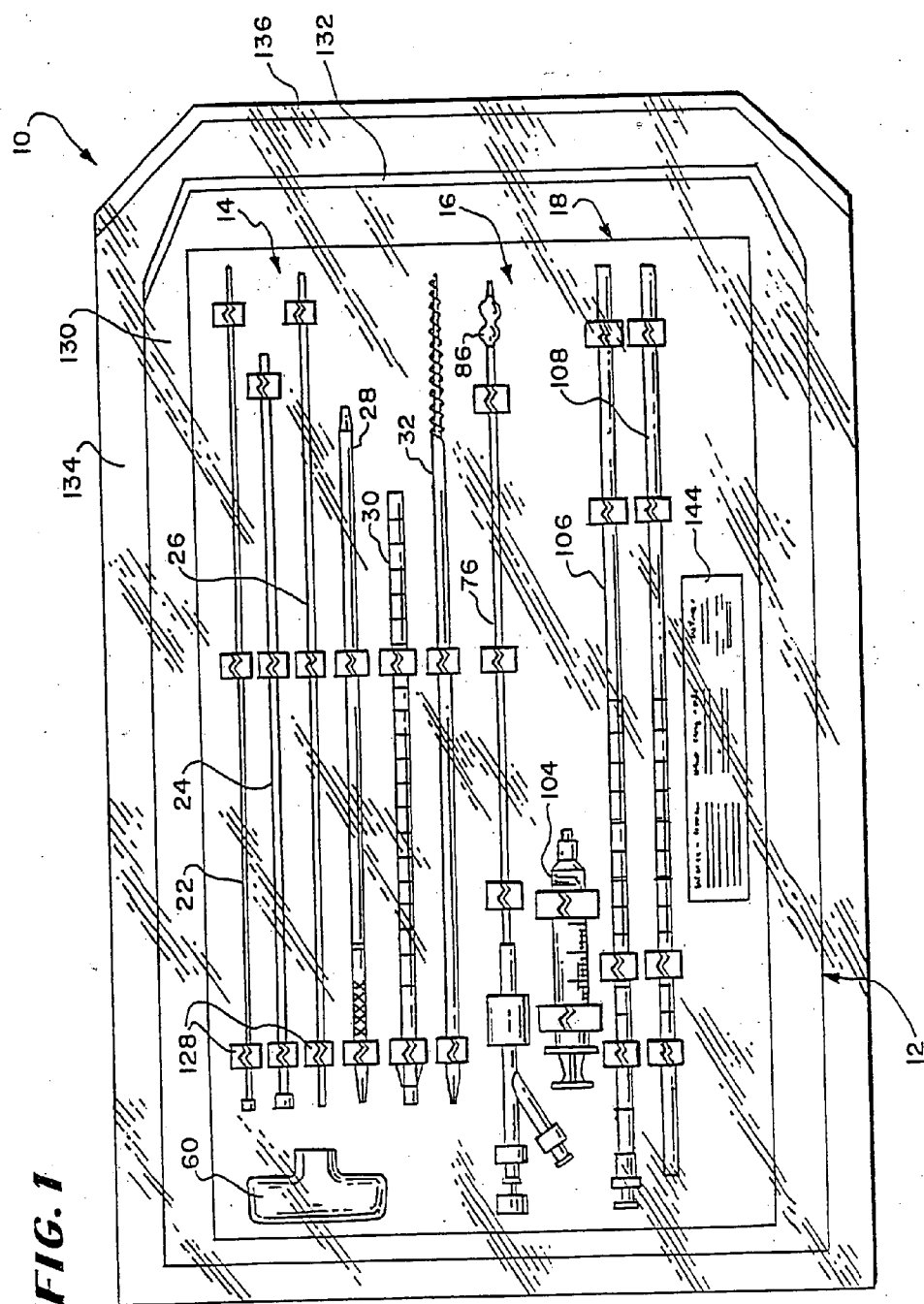
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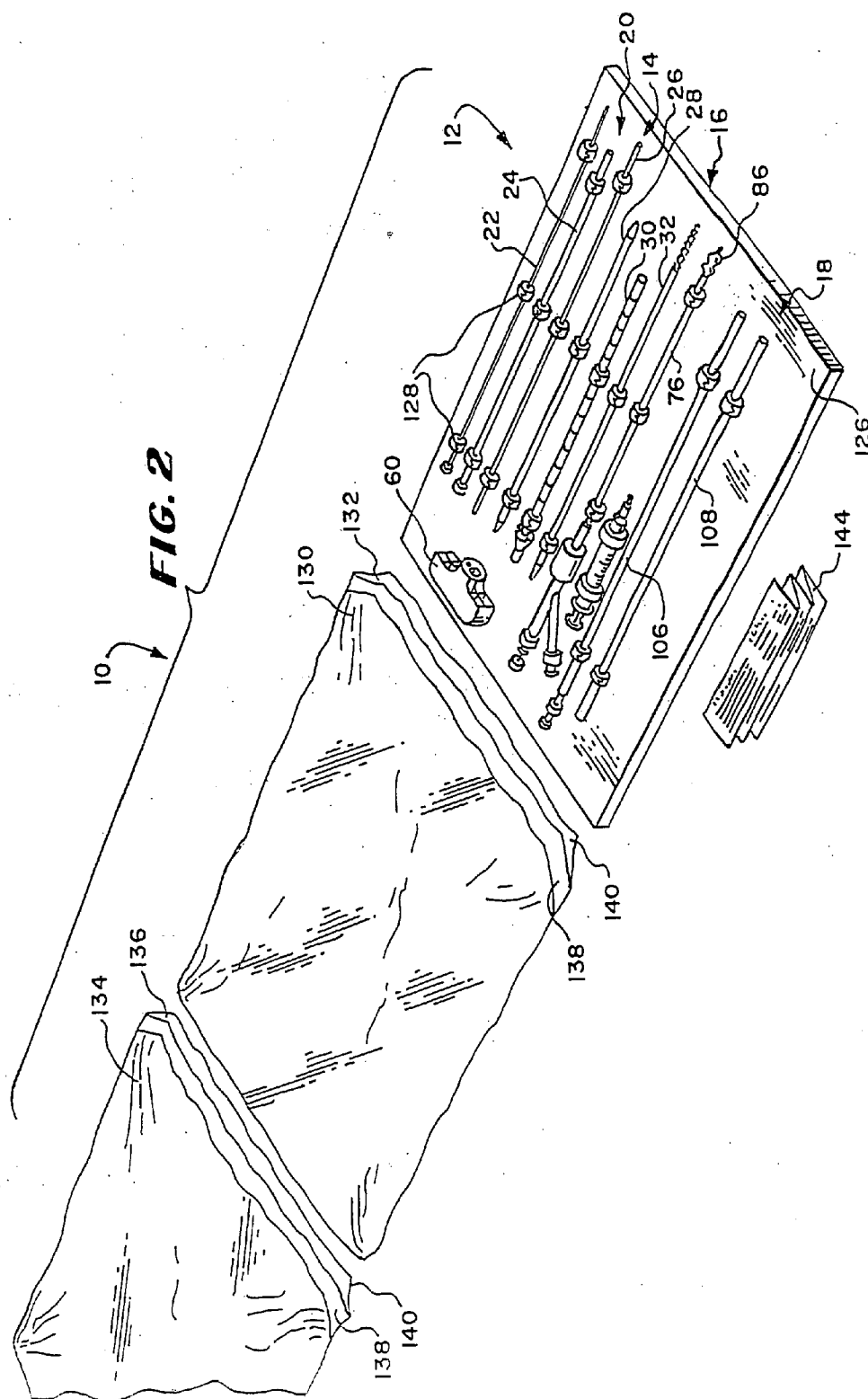
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ABSTRACT

A cannula establishes a subcutaneous path into bone. A tamping instrument can be manipulated independent of the cannula to enable insertion of the tamping instrument into the cannula, advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone, and withdrawal of the tamping terminus from the cannula. The tamping instrument includes at least one marking to visually gauge the advancement of a terminus of the tamping instrument relative to a distal end of the cannula.







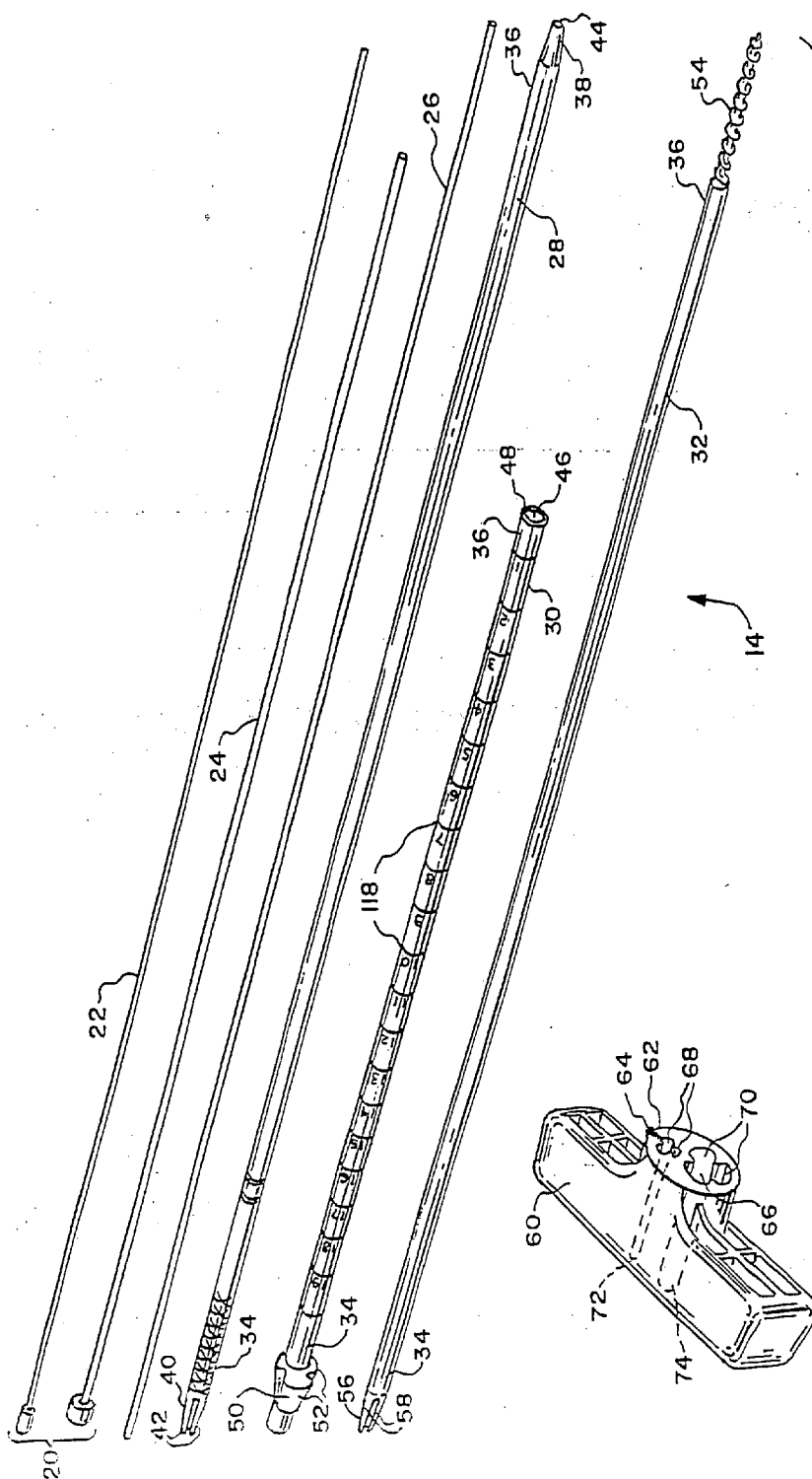
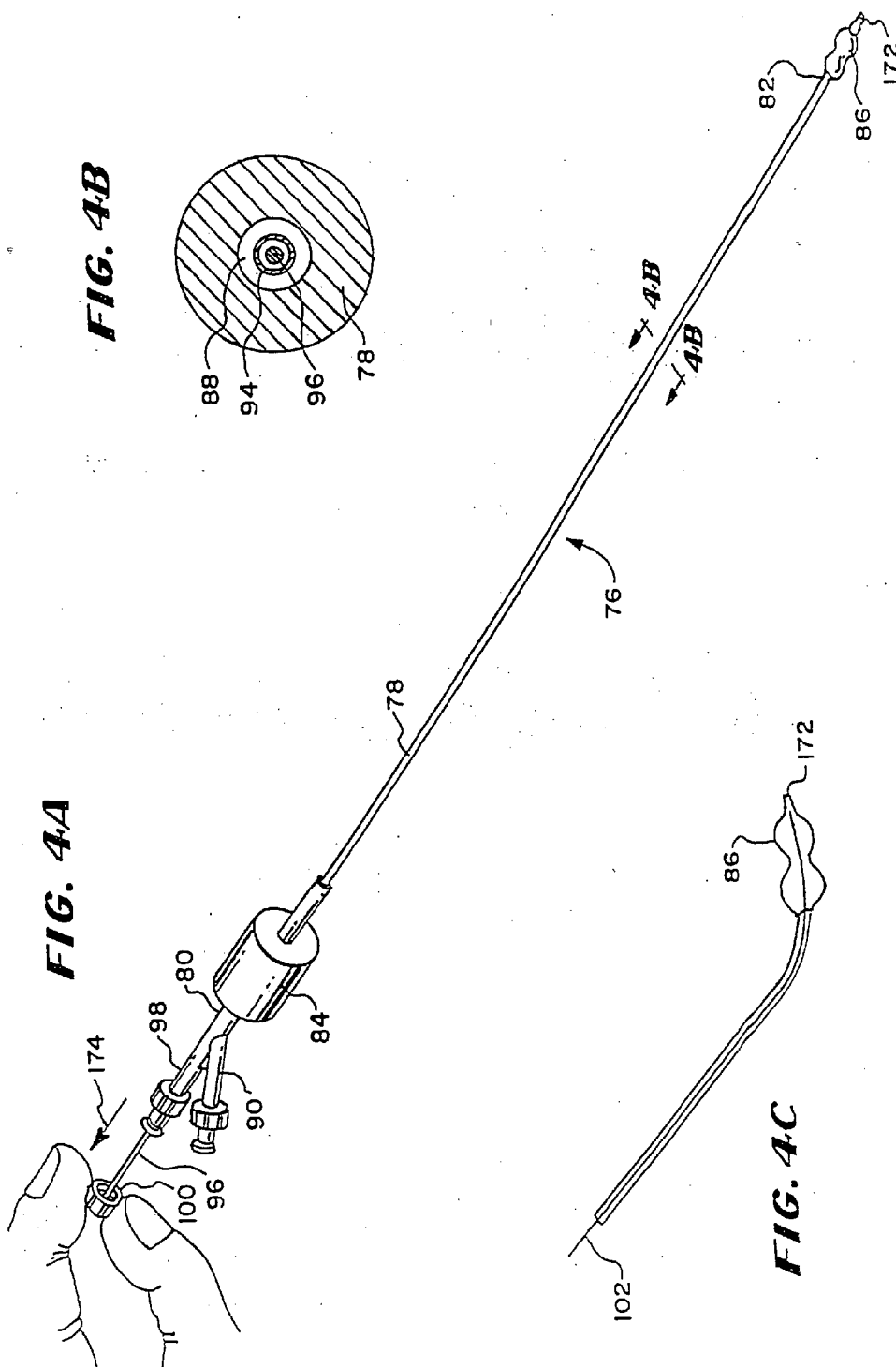


FIG. 3



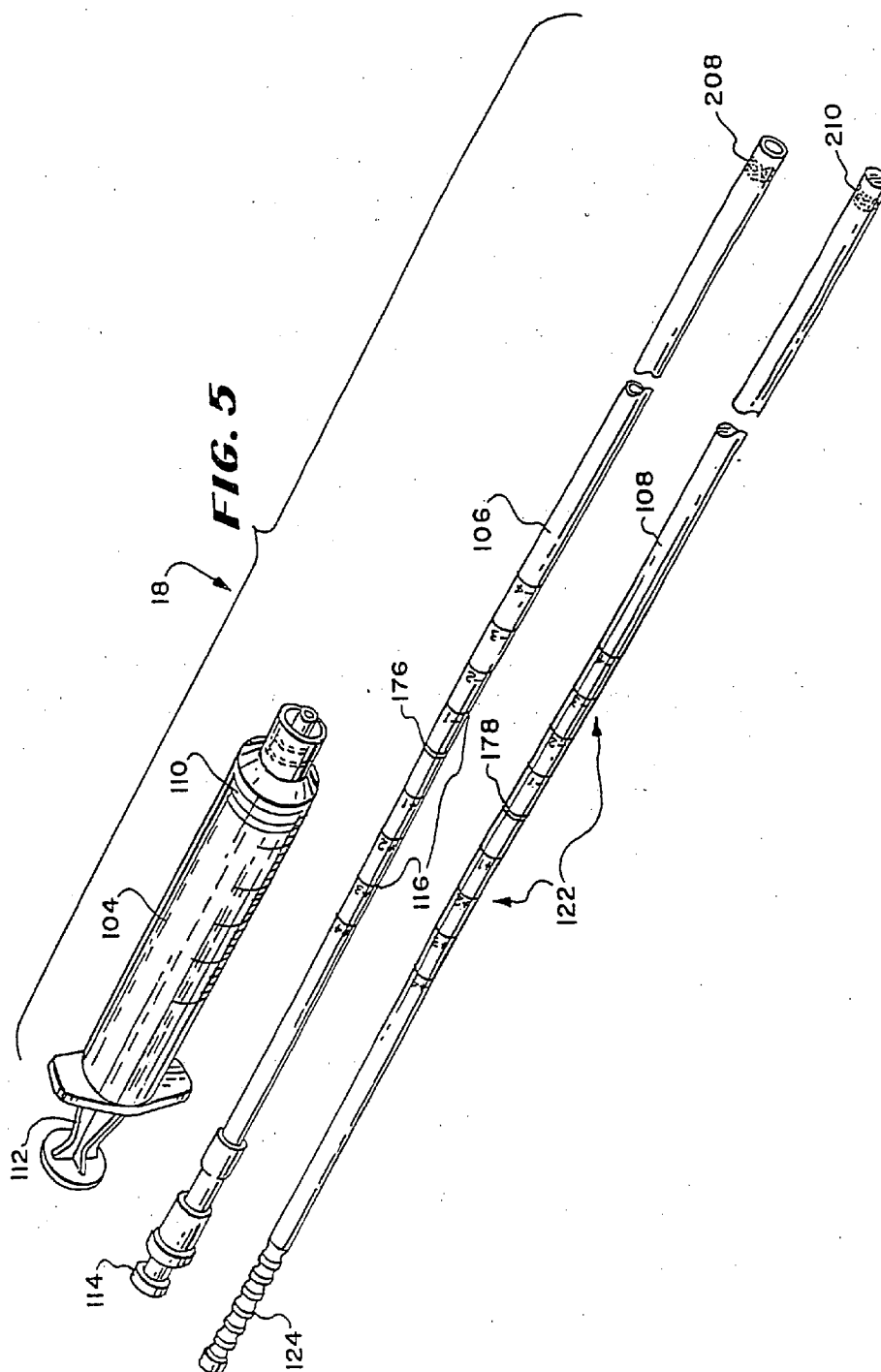


FIG. 6

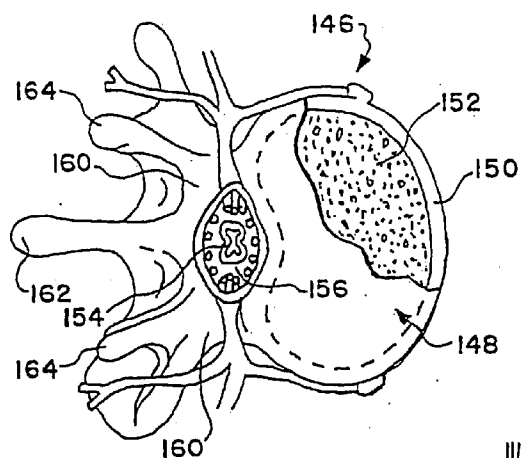


FIG. 7

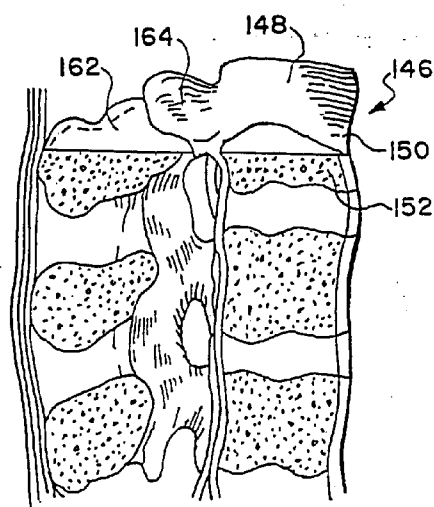


FIG. 8

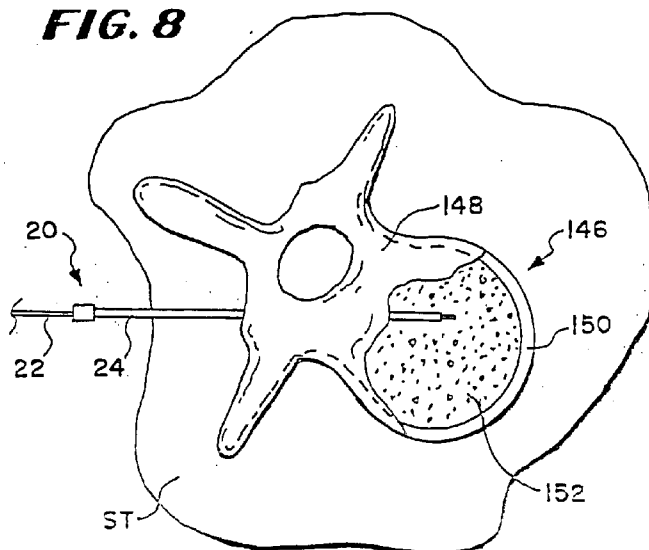


FIG. 9

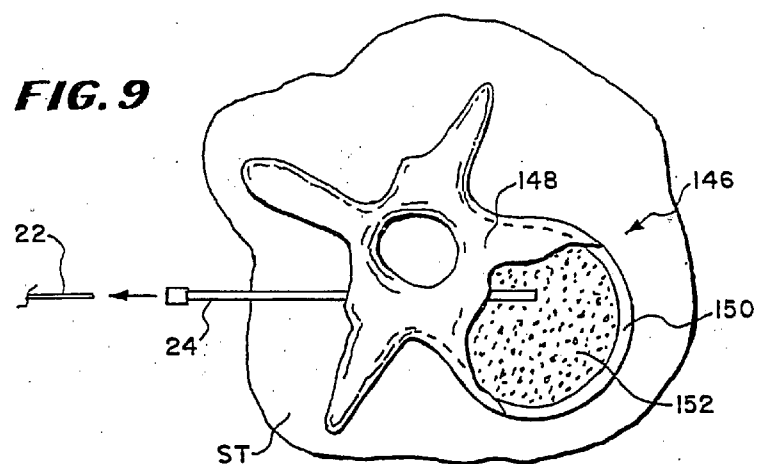


FIG. 10

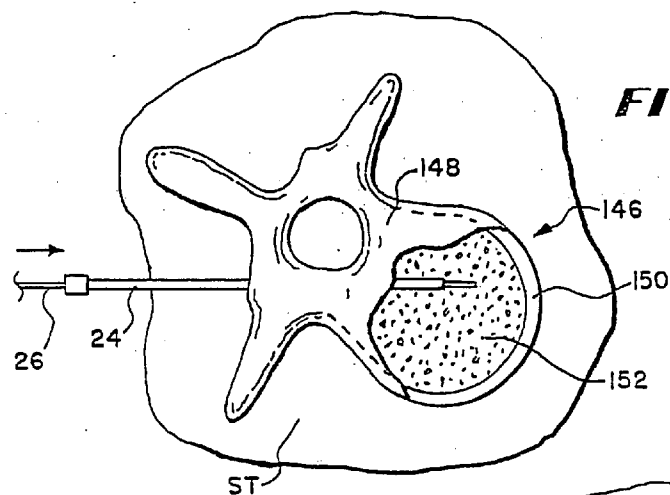
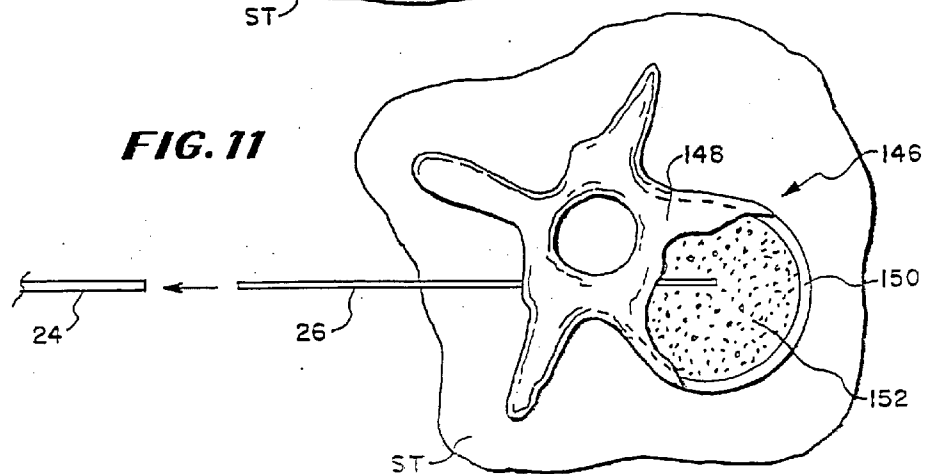
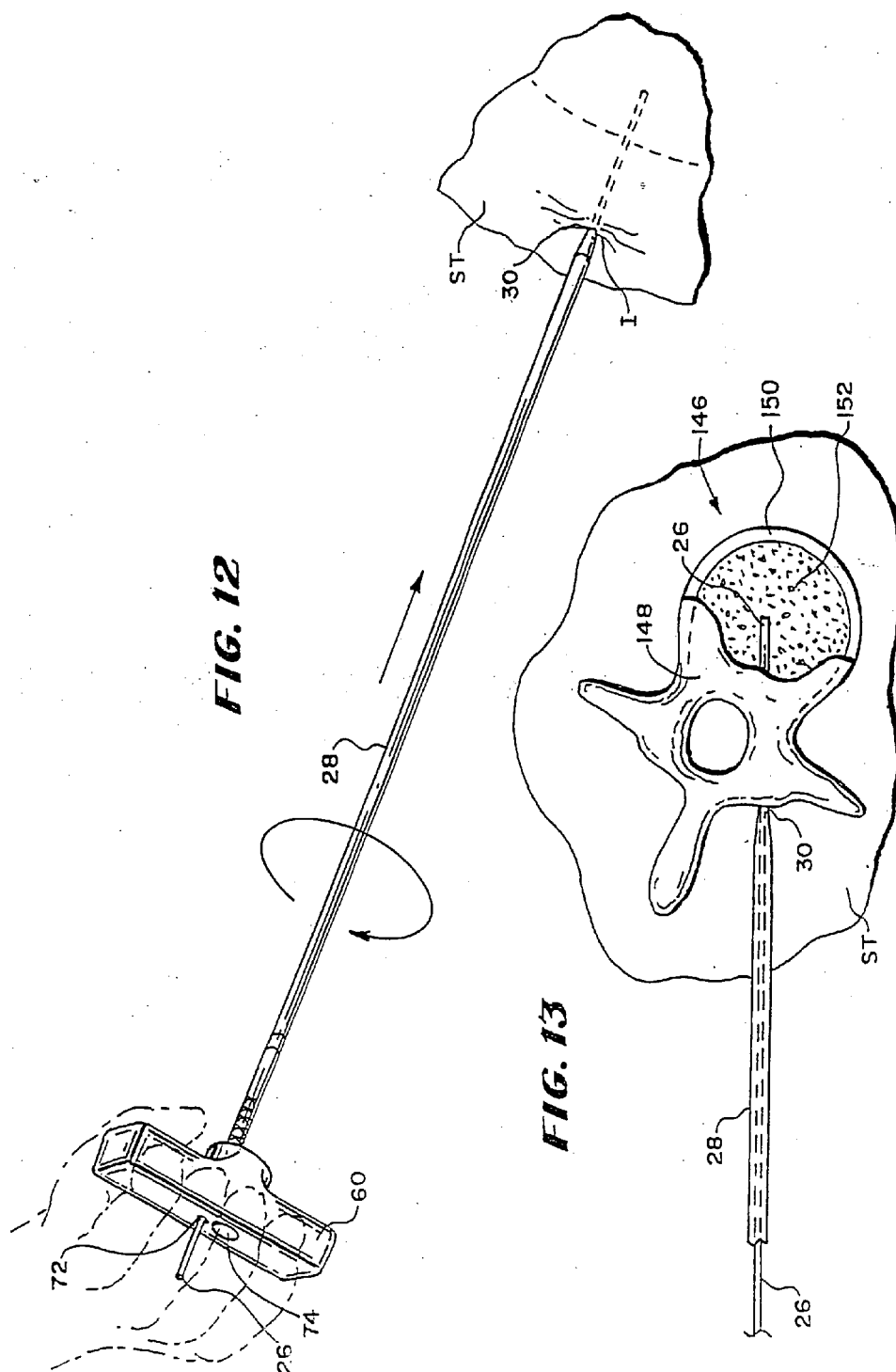
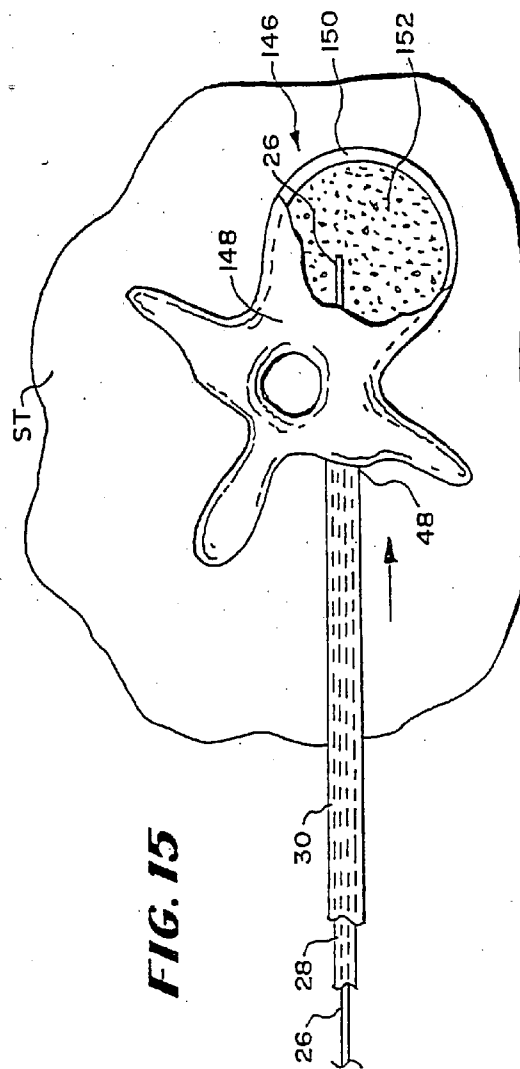
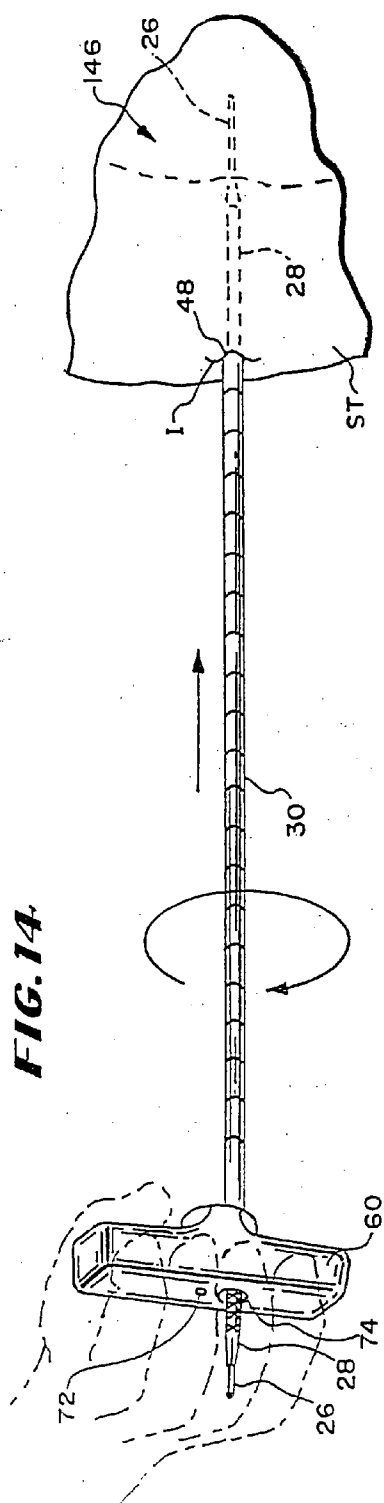


FIG. 11







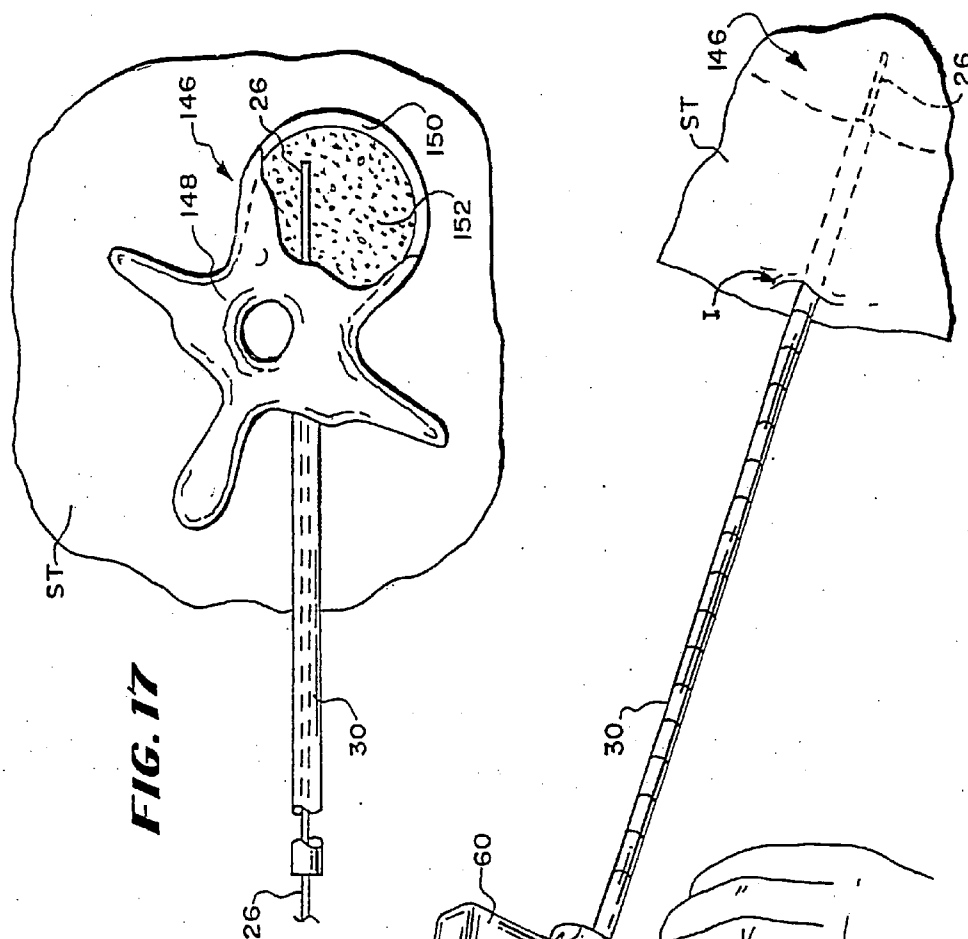


FIG. 17

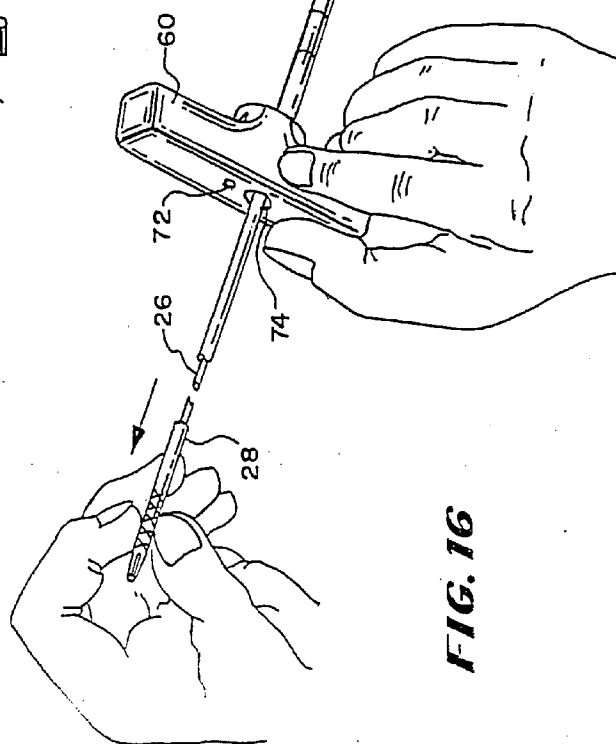
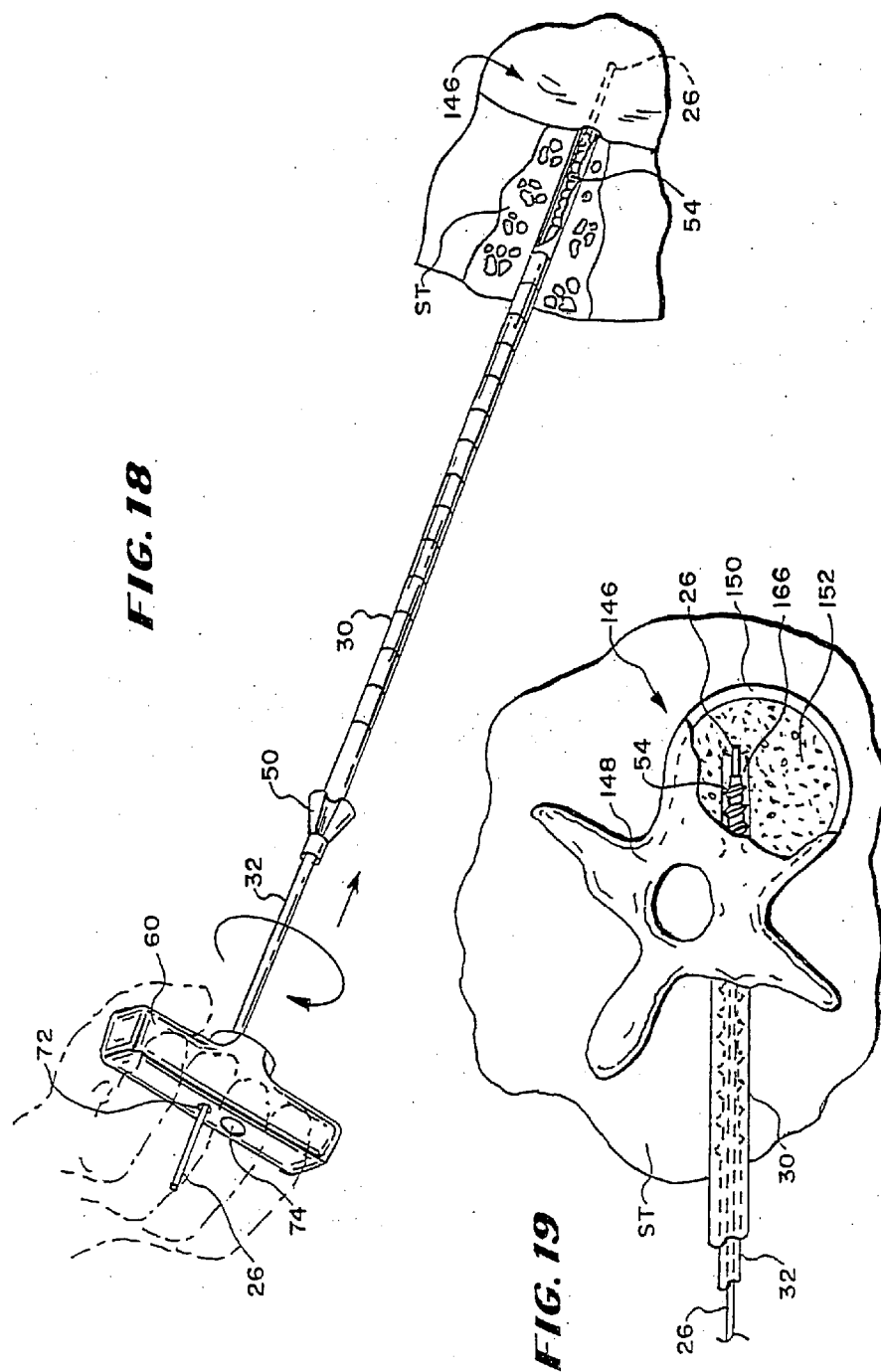


FIG. 16



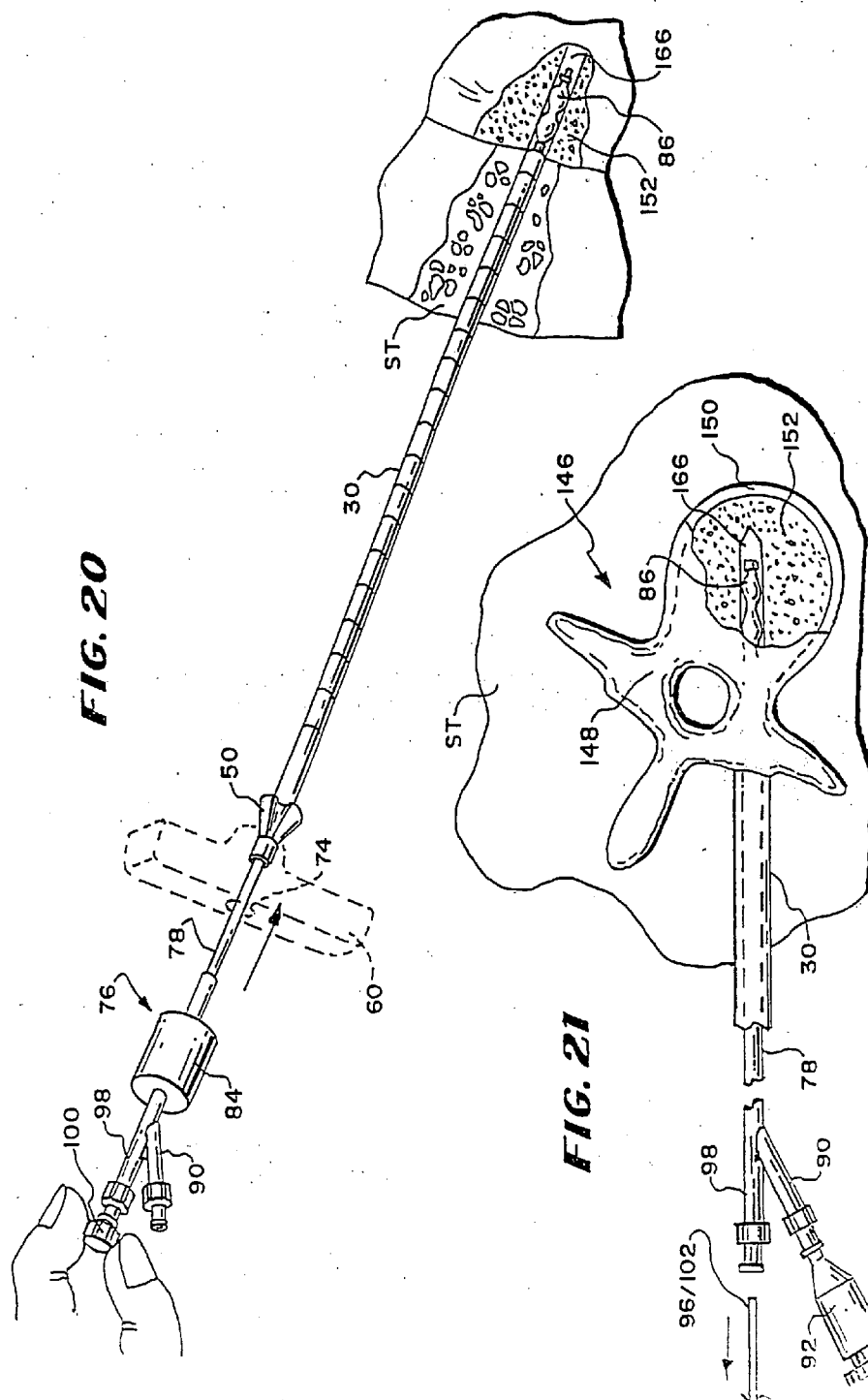


FIG. 22

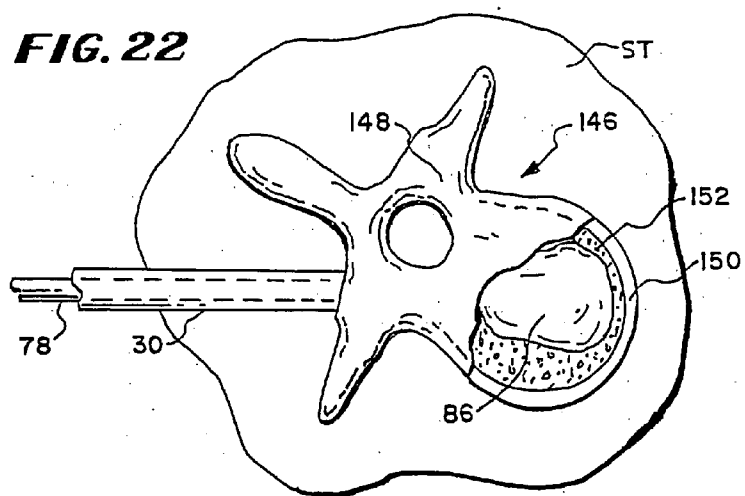


FIG. 23

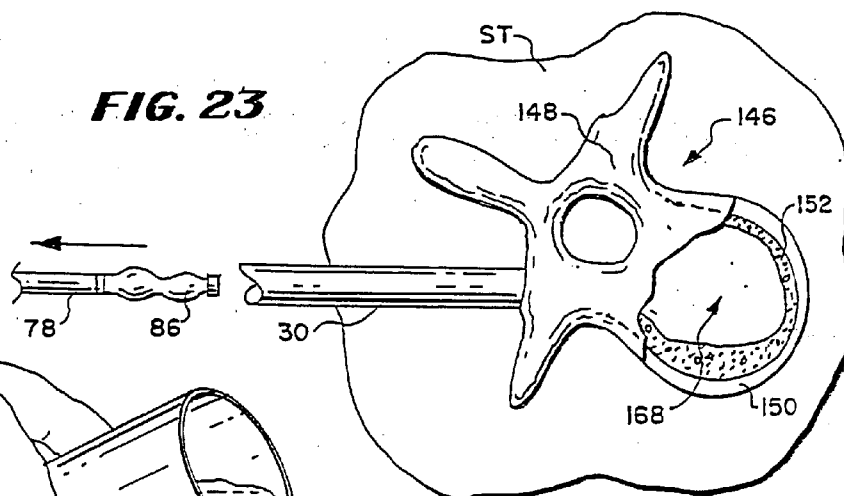
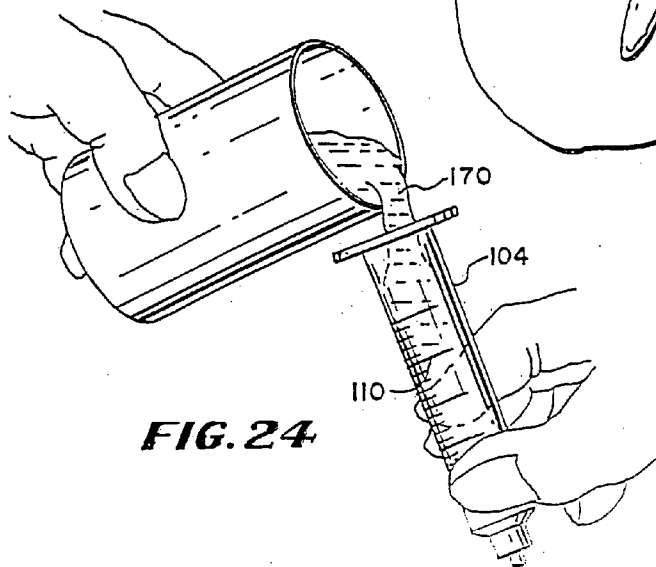
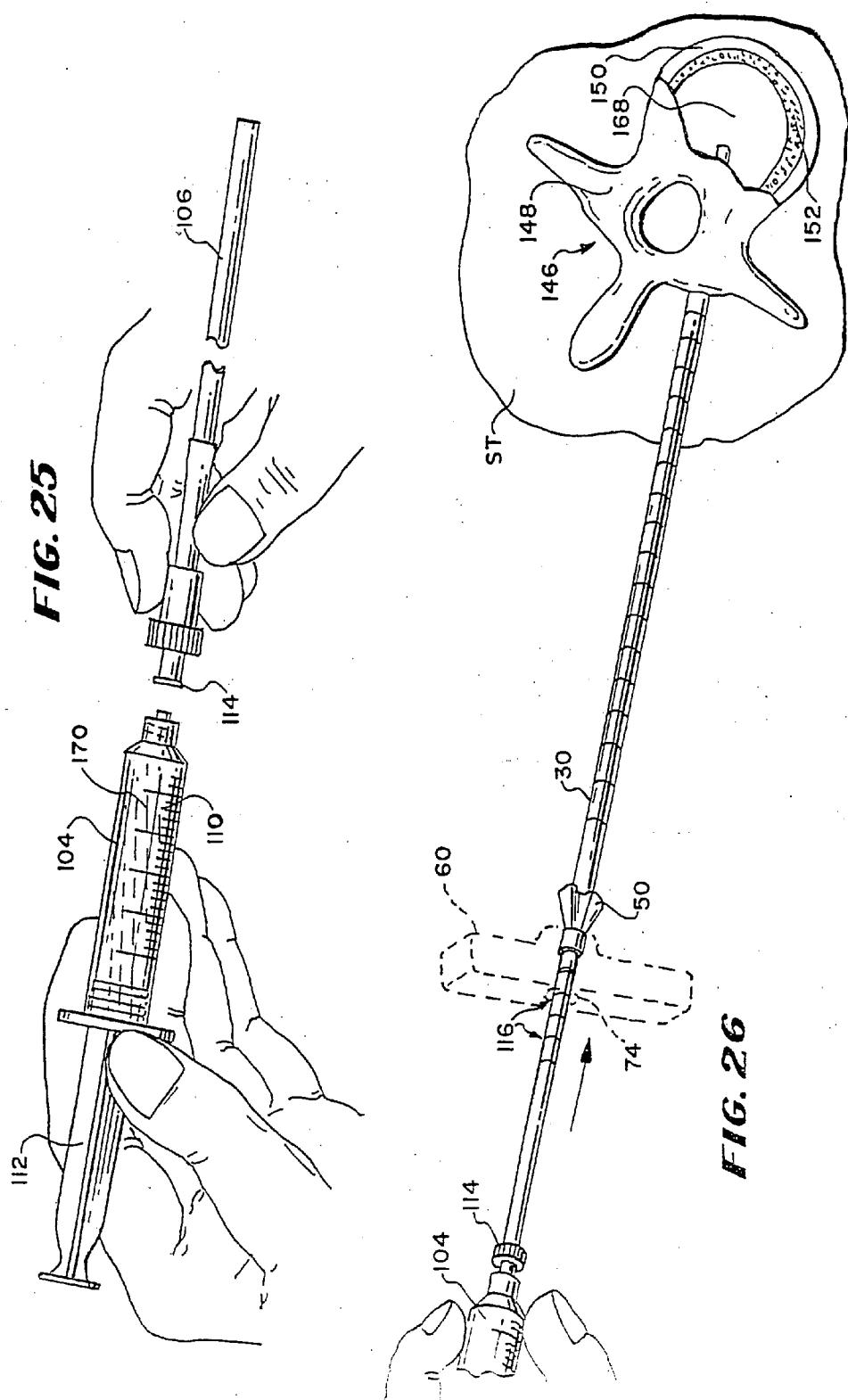


FIG. 24





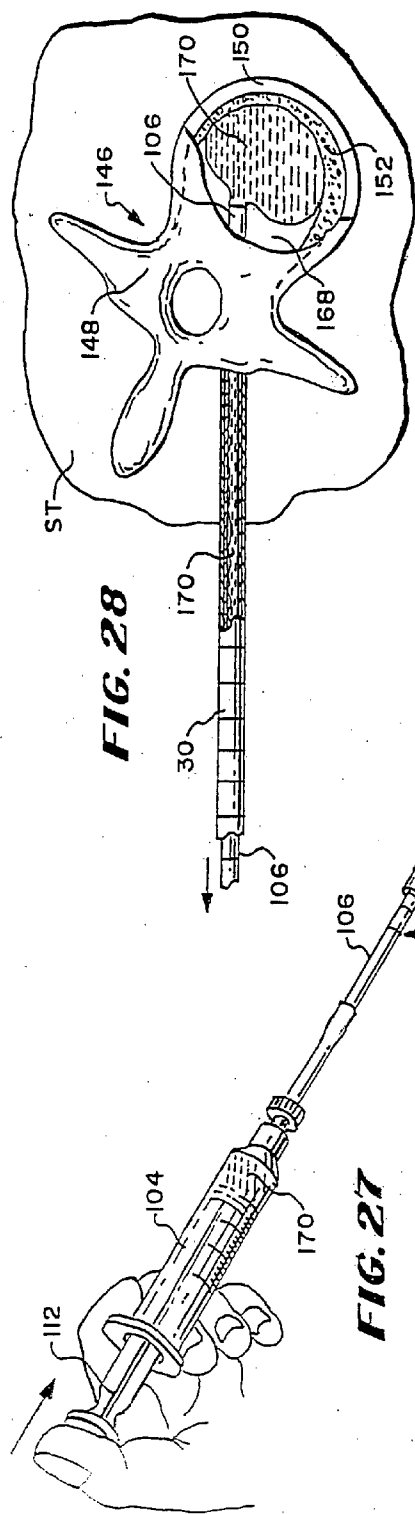


FIG. 28

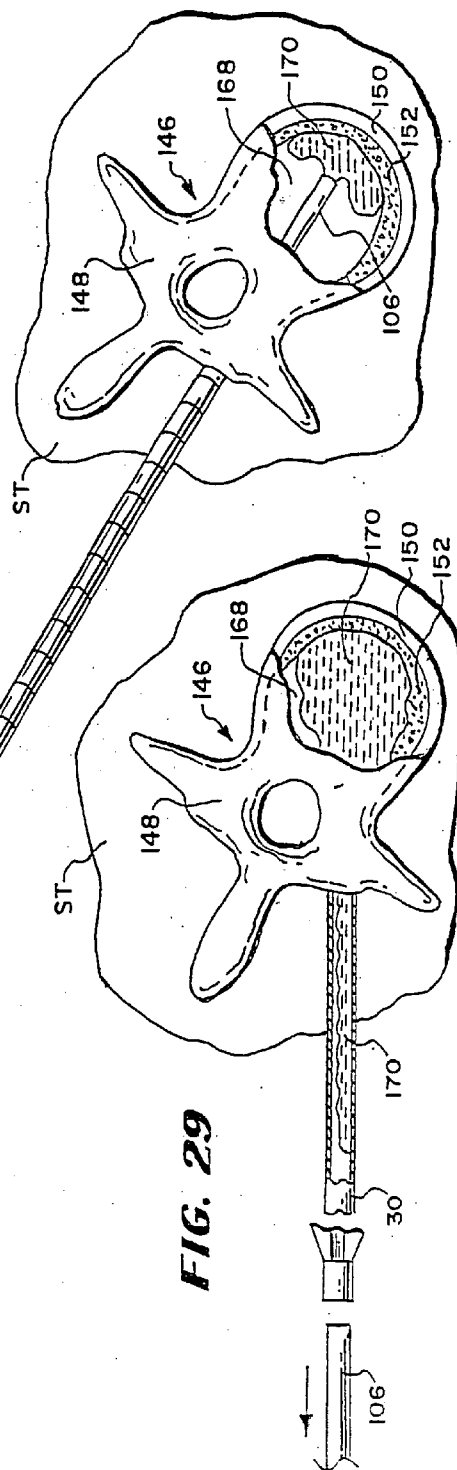
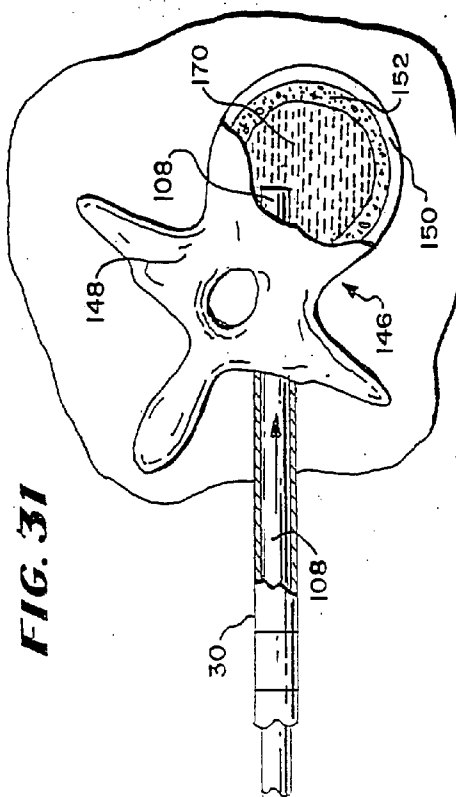
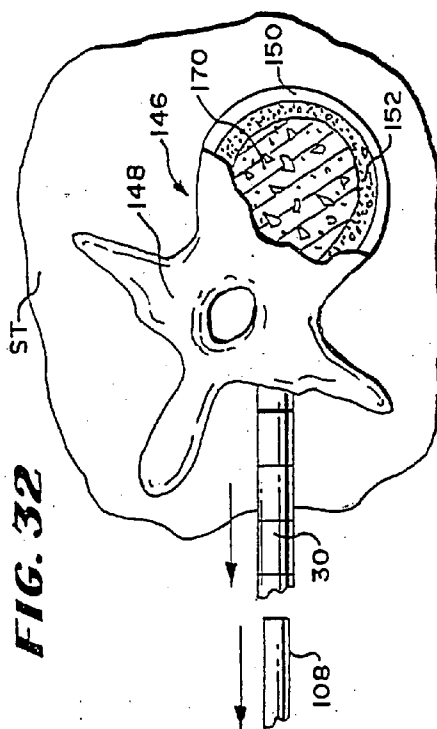
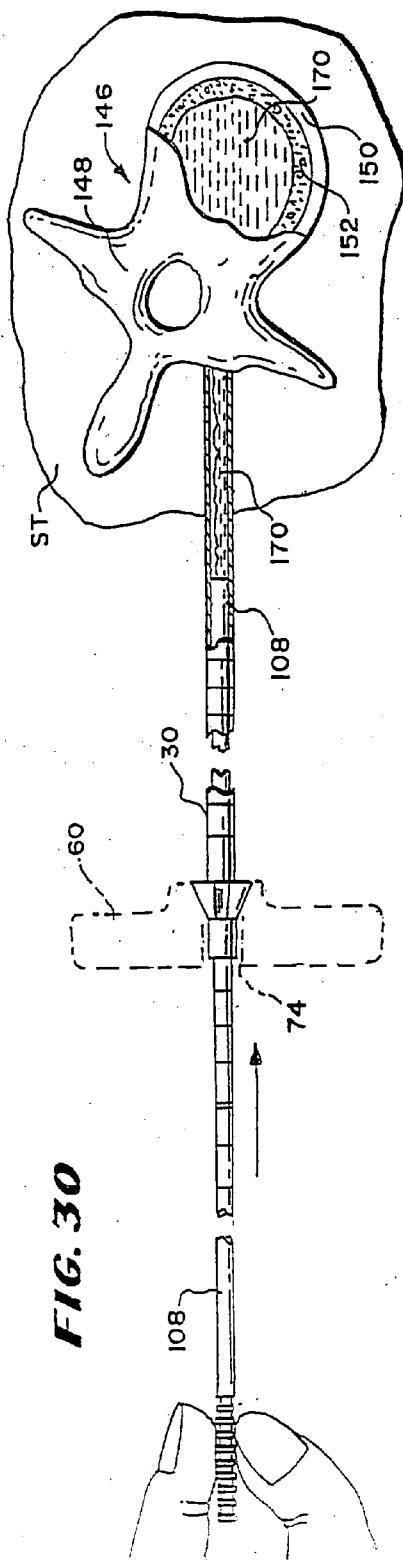


FIG. 29



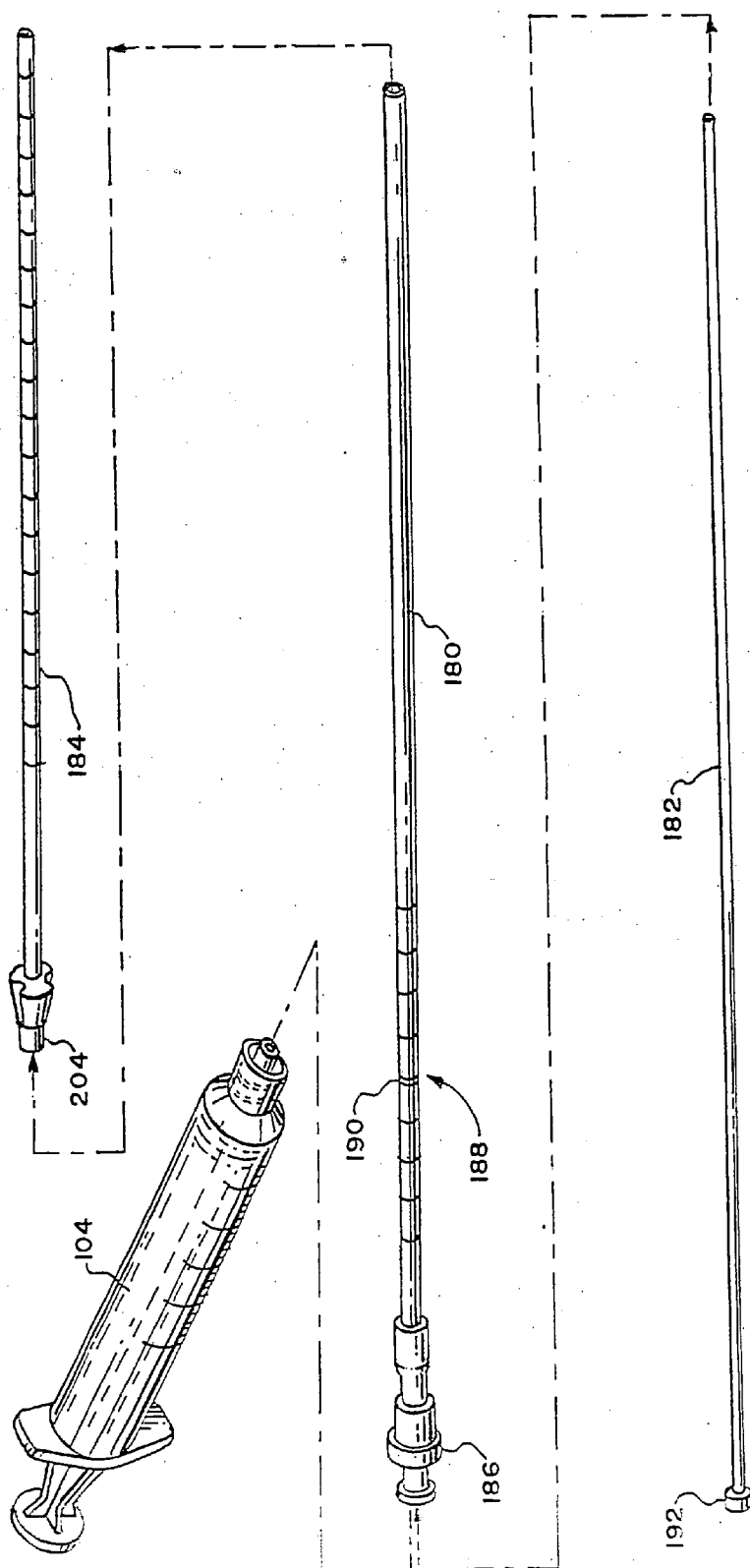


FIG. 33

FIG 34

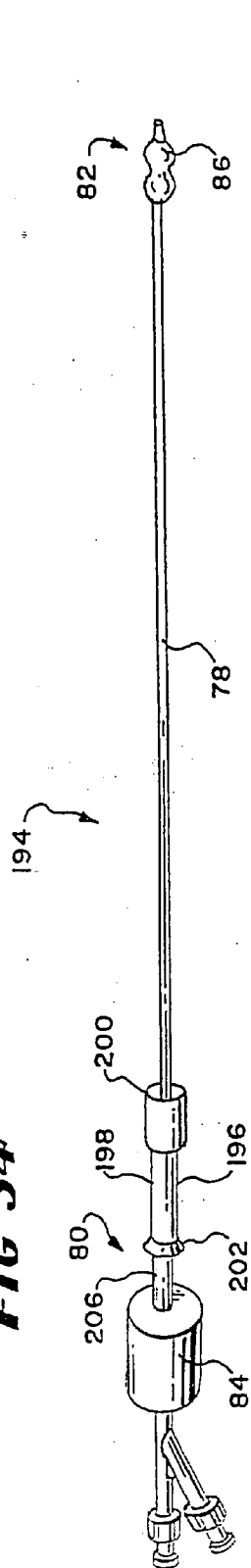


FIG. 35

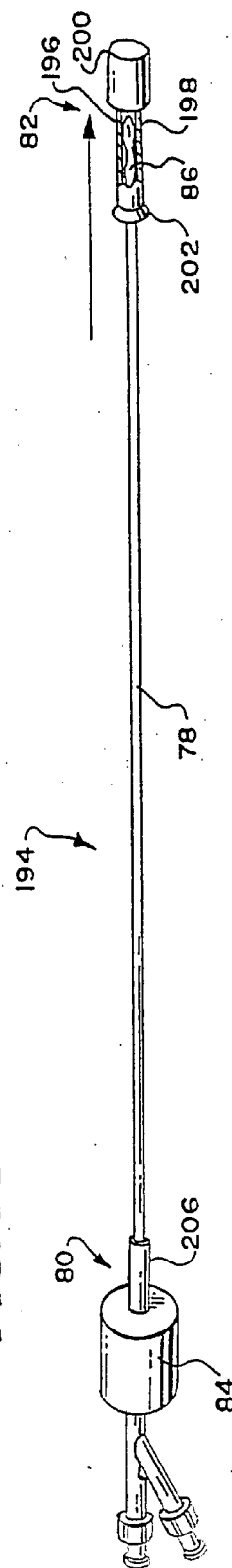


FIG. 36

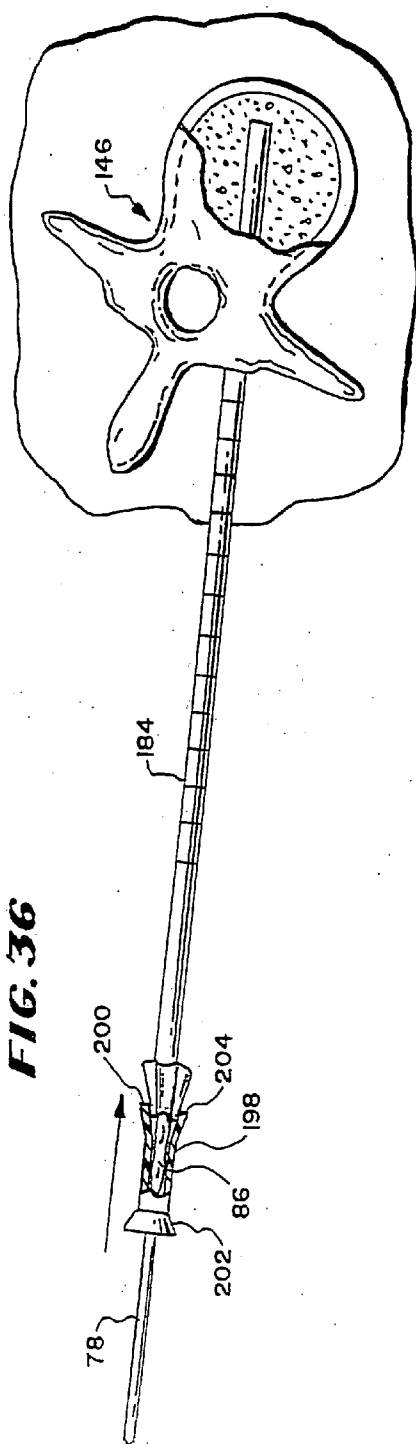
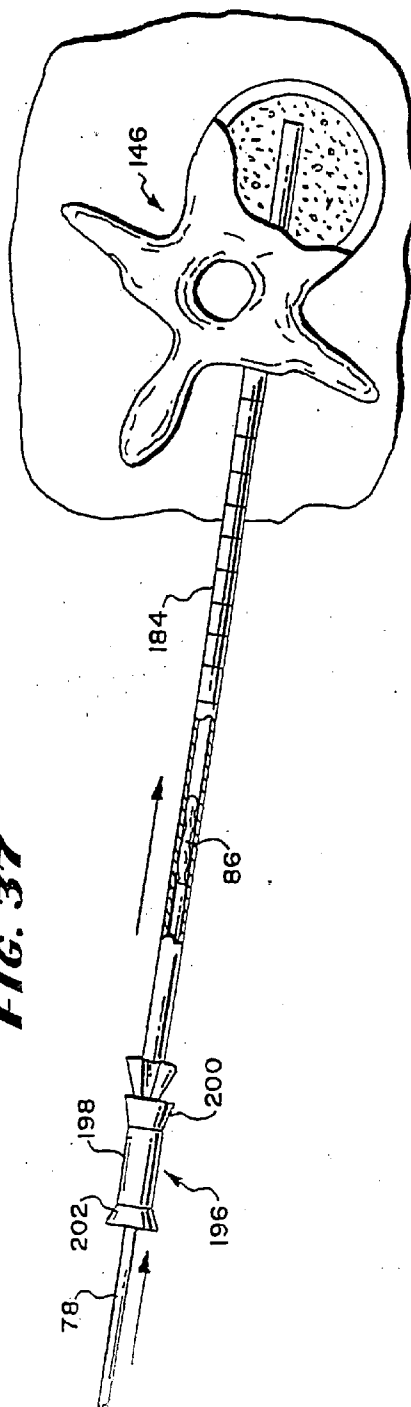


FIG. 37



METHODS AND APPARATUS FOR PLACING MATERIALS INTO BONE

RELATED APPLICATIONS

[0001] This application is a divisional of co-pending U.S. patent application Ser. No. 11/599,943, filed Nov. 15, 2006, and entitled "Systems and Methods for Placing Materials into Bone," which is a divisional of U.S. patent application Ser. No. 10/617,976, filed Jul. 11, 2003 (now U.S. Pat. No. 7,153,307), which is a divisional of U.S. patent application Ser. No. 09/804,107, filed Mar. 12, 2001 (now U.S. Pat. No. 6,613,054), which is a divisional of U.S. patent application Ser. No. 09/134,323, filed Aug. 14, 1998 (now U.S. Pat. No. 6,241,734).

FIELD OF THE INVENTION

[0002] The invention generally relates to the treatment of bone conditions in humans and other animals.

BACKGROUND OF THE INVENTION

[0003] Injection devices similar to a household caulking gun are used to inject bone cement into bone. A typical bone cement injection device has a pistol shaped body, which supports a cartridge containing bone cement. A trigger actuates a spring-loaded ram, which forces a volume of bone cement in a viscous condition through a suitable nozzle and into the interior of a bone targeted for treatment. According to the teachings of U.S. Pat. Nos. 4,969,888 and 5,108,404, a cavity can be first formed by compacting cancellous bone inside the bone, into which the bone cement is injected. Conventional cement injection devices provide no opportunity to override the spring action and quickly terminate the flow of cement, should the cavity fill before the spring-actuated load cycle is completed. Furthermore, once the spring-actuated mechanism is triggered, conventional cement injection devices do not permit the injection volume or inject rate to be adjusted or controlled in real time, in reaction to cancellous bone volume and density conditions encountered inside bone.

[0004] In a clinical procedure called vertebroplasty, bone cement is injected at high pressure (typically, about 700 psi) into the interior of a vertebral body, without the prior formation of a cavity. Because high pressure is used, there is little opportunity to quickly and accurately adjust cement flow in reaction to bone volume and density conditions encountered. Momentum generated by high pressure-induced cement flow continues to propel cement into the targeted bone site even after termination of the high pressure.

[0005] As a result of the relatively high pressure that conventional procedures rely upon, coupled with the effective lack of a short response time, the targeted bone interior can suddenly overflow. Excess filling material can be forced outside the bone interior, and into adjoining tissue regions, where the presence of filling material is not required or desired.

[0006] For these and other reasons, there is a need for new systems and methods for placing material into bones, with greater rate and volume control, a faster response time, and without requiring the use of high pressure.

SUMMARY OF THE INVENTION

[0007] The invention provides instruments, systems, and methods, which, in use, enable greater control over the placement of materials into bone.

[0008] One aspect of the invention provides apparatus including a cannula for establishing a subcutaneous path into bone. The apparatus includes a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula. The tamping instrument is sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula, advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone, and withdrawal of the tamping terminus from the cannula.

[0009] Another aspect of the invention provides a method. The method comprises deploying an expandable device through a percutaneous path into a vertebral body having cancellous bone volume to create a cavity in the cancellous bone volume. The method includes advancing a tamping instrument through a percutaneous cannula to deliver material into the cavity. The method includes visually gauging the advancement by observing at least one predetermined visually observable marking on the tamping instrument to determine a position of a terminus of the tamping instrument relative to a distal end of the cannula.

[0010] The material can comprise, e.g., at least one of bone cement, autograft material, allograft material, calcium carbonate, demineralized bone matrix material, calcium phosphate.

[0011] Features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a plane view of a kit housing a system of functional instruments, which, in use, gain subcutaneous access to the inside of a bone to compact cancellous bone and form a cavity for therapeutic purposes;

[0013] FIG. 2 is an exploded perspective view of the kit shown in FIG. 1;

[0014] FIG. 3 is a perspective view of the subcutaneous access instrument group that forms a part of the system shown in FIG. 1;

[0015] FIG. 4A is a perspective view of the cavity forming instrument that forms a part of the system shown in FIG. 1;

[0016] FIG. 4B is a section view of the catheter tube of the cavity forming instrument, taken generally along line 4B-4B in FIG. 1;

[0017] FIG. 4C is an end view of an alternative embodiment of the cavity forming instrument shown in FIG. 4A, having a prebent stylet;

[0018] FIG. 5 is a perspective view of the material introducing instrument group that forms a part of the system shown in FIG. 1;

[0019] FIGS. 6 and 7 are, respectively, top and side views of a human vertebral body;

[0020] FIG. 8 is a top view of a vertebral body during insertion of a spinal needle instrument to begin a bone access procedure;

[0021] FIGS. 9 to 11 are top views showing subsequent steps, after insertion of the spinal needle instrument shown in FIG. 8, of inserting a guide pin instrument into the vertebral body;

[0022] FIG. 12 is a perspective view showing a subsequent step, after insertion of the guide pin instrument shown in FIGS. 9 to 11, which deploys an obturator instrument deployed over the guide pin instrument with aid of a handle;

[0023] FIG. 13 is a top view of the vertebral body, with the obturator instrument shown in FIG. 12 deployed;

[0024] FIG. 14 is a perspective view showing a subsequent step, after insertion of the obturator instrument shown in FIG. 12, which uses the handle shown in FIG. 12 to aid in the deployment of a cannula instrument over the obturator instrument;

[0025] FIG. 15 is a top view of the vertebral body, with the cannula instrument shown in FIG. 14 deployed;

[0026] FIG. 16 is a perspective view showing a subsequent step, after insertion of the cannula instrument shown in FIG. 14, which removes the obturator instrument from the cannula instrument, to leave the cannula instrument and guide pin instrument in place;

[0027] FIG. 17 is a top view of the vertebral body, after the obturator removal step shown in FIG. 16, leaving the cannula instrument and guide pin instrument in place;

[0028] FIG. 18 is a perspective view showing a subsequent step, after removal of the obturator instrument shown in FIG. 16, which uses the handle shown in FIG. 14 to aid in the deployment of a drill bit instrument through the cannula instrument along the guide pin instrument;

[0029] FIG. 19 is a top view of the vertebral body, as the drill bit instrument shown in FIG. 18 is deployed with aid of the handle to open a passage into the interior volume of the vertebral body;

[0030] FIG. 20 is a perspective view showing a subsequent step, after removal of the drill bit instrument and guide pin instrument shown in FIG. 18, of deploying the cavity forming instrument into the vertebral body;

[0031] FIG. 21 is a top view of the vertebral body, as the expandable structure carried by the cavity forming instrument shown in FIG. 2b is deployed into the interior volume of the vertebral body;

[0032] FIG. 22 is a top view of the vertebral body, as the expandable structure shown in a collapsed condition in FIG. 21 is expanded to compact cancellous bone and form a cavity;

[0033] FIG. 23 is a top view of the vertebral body, after removal of the expandable structure, showing the cavity formed by compacting cancellous bone;

[0034] FIG. 24 is a perspective view of the syringe of the material introducing instrument group, shown in FIG. 5, being filled with a material selected for introduction into the cavity shown in FIG. 23;

[0035] FIG. 25 is a perspective view of the syringe shown in FIG. 24 being joined to a nozzle, which also forms a part of the material introducing instrument group 20; shown in FIG. 5;

[0036] FIG. 26 is a perspective view showing the syringe and attached nozzle shown in FIG. 25 being deployed through the cannula instrument in preparation of introducing material into the cavity;

[0037] FIGS. 27 and 28 are perspective and top views, respectively, showing the syringe and attached nozzle shown in FIG. 26 in use to inject material into the cannula instrument for passage into the cavity;

[0038] FIG. 29 is a top view of the vertebral body after a measured volume of material has been injected and the syringe and attached nozzle withdrawn from the cannula instrument;

[0039] FIG. 30 is a top view showing the deployment of a tamping instrument, which forms a part of the material introducing instrument group shown in FIG. 5, being deployed in the cannula instrument;

[0040] FIG. 31 is a top view showing advancement of the tamping instrument in the cannula instrument to displace and distribute material from the cannula instrument into the cavity;

[0041] FIG. 32 is a top view of the vertebral body after removal of the tamping instrument and cannula instrument, showing the cavity, now filled with the material;

[0042] FIG. 33 is a perspective view of a reduced diameter cannula instrument and associated reduced diameter material introducing instruments, which embody features of the invention;

[0043] FIG. 34 is a perspective view of a cavity forming instrument having an expandable cavity forming structure, which, in use, is deployed using the reduced diameter cannula instrument shown in FIG. 33, the cavity forming instrument having a sliding introducer sleeve shown in its rearward position;

[0044] FIG. 35 is a perspective view of the cavity forming instrument shown in FIG. 34, with the introducer sleeve moved forward to overlie and compress the expandable cavity forming structure;

[0045] FIG. 36 is a perspective view of the cavity forming structure shown in FIG. 35, with the introducer sleeve (shown partially in section) coupled to the proximal end of the cannula instrument, to guide the expandable structure compressed within the sleeve into the reduced diameter cannula instrument without damage; and;

[0046] FIG. 37 is a perspective view of the cavity forming structure shown in FIG. 36, after the expandable structure has been guided by the introducer sleeve into the cannula instrument and is being advanced through the cannula instrument for deployment in bone.

[0047] The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0048] FIGS. 1 and 2 show a system 10 of functional instruments. In use, certain instruments of the system 10 are deployed in a purposeful manner to penetrate tissue and gain subcutaneous access to the inside of a bone. Inside bone,

other instruments of the system **10** are deployed to form a cavity in cancellous bone, into which a material is placed for therapeutic purposes.

[0049] In the illustrated embodiment, the system **10** is arranged as a prepackage kit **12** in three functional instrument groups **14**, **16**, and **18**. The first group **14** (which FIG. 3 shows outside the kit **12**) comprises instruments whose purpose is to gain subcutaneous access to a bone interior. The second group **16** (which FIG. 4 shows outside the kit **12**) comprises an instrument whose function is to create a cavity in cancellous bone. The third group **18** (which FIG. 5 shows outside the kit **12**) comprises instruments whose function is to introduce a material into the cavity.

[0050] The kit **12** can take various forms. In the illustrated embodiment, the kit **12** comprises a sterile, wrapped assembly.

[0051] Further details of each functional instrument group **14**, **16**, and **18** and the kit **12** follow.

I. The Subcutaneous Access Instrument Group

[0052] The number and type of instruments in the group **14** can vary. FIG. 3 shows five representative instruments, each having a different size and function.

[0053] A. The Spinal Needle and Guide Pin

[0054] As FIG. 3 shows, one instrument comprises a conventional spinal needle assembly **20** and a guide pin instrument **26**.

[0055] In use, the spinal needle assembly **20** establishes the initial subcutaneous path leading to the targeted treatment site. The guide pin instrument **26** is deployed through this path, followed by progressively larger instruments, as will be described later.

[0056] The spinal needle assembly **20** comprises a stylet **22**, which is slidably deployed within a stylus **24**. The stylus **24** typically has, for example, about an eleven gauge diameter. Other gauge diameters can be used, according to the gauge of the guide pin instrument **26** used.

[0057] In use, the guide pin instrument **26** is deployed through the subcutaneous path established by the spinal needle assembly **20**, by exchange with the needle stylet **22**. The guide pin instrument **26** serves to guide the establishment of the main operative pathway to the targeted treatment site.

[0058] The remaining instruments **28**, **30**, and **32** in the group **14** share some common features, although they are intended, in use, to perform different functions. These instruments **28**, **30**, and **32** are each made of a rigid, surgical grade plastic or metal material. These instruments **28**, **30**, and **32** each comprises an elongated, cylindrical body having a proximal end **34** and a distal end **36**.

[0059] B. The Obturator Instrument

[0060] The instrument **28** functions as an obturator. Its distal end **36** is tapered to present a penetrating surface **38**. In use, the surface **38** is intended to penetrate soft tissue in response to pushing or twisting forces applied by the physician at the proximal end **34**.

[0061] The proximal end **34** of the obturator instrument **28** presents a flanged surface **40**, which tapers from a larger

outer diameter to a smaller outer diameter in the direction of the proximal end **34**. The flanged surface **40** includes an array of circumferentially spaced teeth **42**.

[0062] An interior lumen **44** extends through the obturator instrument **28** from the distal end **36** to the proximal end **34**. The interior lumen **44** is sized to accommodate the guide pin instrument **26**, as will be described in greater detail later.

[0063] C. The Cannula Instrument

[0064] The instrument **30** functions as a cannula or guide sheath. The cannula instrument **30** is somewhat larger in diameter than and not as long as the obturator instrument **28**. The cannula instrument **30** includes an interior lumen **46** that extends from its distal end **36** to its proximal end **34**. The interior lumen **46** is sized to accept the obturator instrument **28**. The size of the interior lumen **46** permits a physician to slide and rotate the cannula instrument **30** relative to the obturator instrument **28**, and vice versa, as will be described in greater detail later.

[0065] The distal end **36** of the cannula instrument **30** presents an end surface **48**. In use, the end surface **48** of the cannula instrument **30** is intended to penetrate soft tissue surrounding the obturator instrument **28** in response to pushing or twisting forces applied at the proximal end **34**.

[0066] The proximal end **34** carries an enlarged fitting **50**. The fitting **50** tapers from a larger diameter to a smaller diameter in the direction of the proximal end **34**. Like the tapered flange **40** on the obturator instrument **28**, the tapered fitting **50** has an array of circumferentially spaced teeth **52**. The tapered fitting **50** of the cannula instrument **30** possesses a larger maximum outer diameter than the maximum outer diameter of the tapered flange **40** of the obturator instrument **28**.

[0067] The cannula instrument **30** includes measured markings **118** along its length (see FIG. 3). The measured markings **118** gauge the depth of insertion. The markings **118** can be placed, for example, at one centimeter intervals. As FIG. 3 shows, the markings **118** can be consecutively numbered, beginning at the distal end **36**, so that the physician can ascertain the insertion depth at a glance.

[0068] D. The Drill Bit Instrument

[0069] The instrument **32** functions as a drill bit. The drill bit instrument **32** has generally the same physical dimensions as the obturator instrument **28**. Like the obturator instrument **28**, the drill bit instrument **32** is intended, in use, to fit for sliding and rotational movement within the interior lumen **46** of the cannula instrument **30**.

[0070] The distal end **36** of the drill bit instrument **32** includes machined cutting edges **54**. In use, the cutting edges **54** are intended to penetrate hard tissue in response to rotation and longitudinal load forces applied at the proximal end **34** of the drill bit instrument **32**.

[0071] The proximal end **34** presents a tapered flange **56**, which is substantially identical to the flange **40** on the obturator instrument **28**. Like the obturator instrument **28**, the tapered flange **56** changes from a larger diameter to a smaller diameter in the direction of the proximal end **34**. The tapered flange **56** of the drill bit instrument **32** also includes an array of circumferentially spaced teeth **58**. The form and

orientation of the teeth **58** on the drill bit instrument **32** correspond to the form and orientation of the teeth **42** on the obturator instrument **28**.

[0072] E. The Handle

[0073] The group includes a handle **60**. The handle **60** engages the functional instruments **28**, **30**, and **32** in a removable, slip fit fashion to aid a physician in manipulating the instruments during use.

[0074] The handle **60** is made from a molded or cast rigid plastic or metal material. The handle **60** is shaped to be comfortably and securely grasped by a normal human hand. The shape and size to accommodate this function can, of course, vary. In the illustrated embodiment, the handle **60** is elongated along a main axis to fit comfortably across the palm of the hand.

[0075] The handle **60** includes a center post **62**, which is integrally molded to the handle **60** about its geometric center. The center post **62** extends downward to give the handle **60** a general T-shape.

[0076] The handle **60** includes two interior cavities or sockets **64** and **66** in the center post **62**. The sockets guide the attachment between the handle **60** and the instruments **28**, **30**, and **32**. The first and second sockets **64** and **66** are sized to present unique attachment sites for different functional instruments.

[0077] The first socket **64** includes an array of circumferentially spaced grooves **68**, which, in form and orientation, match the teeth **42** and **58** at the proximal ends **34** of the obturator instrument **28** and the drill bit instrument **32**. The first socket **64** accepts the tapered flange **40** or **56** of either the obturator instrument **28** or the drill bit instrument **32**. The teeth **42** and **58** of either tapered flange **40** or **56** mesh in a slip-fit with the grooves **68** of the first socket **64**. The running slip-fit allows longitudinal force to be applied to either instrument **28** or **32** through the handle **60**. The running slip-fit also prevents relative rotation between either instrument **28** or **32** and the first socket **64**, thereby permitting torsional or twisting forces to be applied to either instrument **28** or **32** by the handle **60**, with an increased mechanical advantage.

[0078] The second socket **66** is larger than the first socket **64** and is sized to accept the larger tapered fitting **50** of the cannula instrument **30**. The second socket **66** includes an array of circumferentially spaced grooves **70**, which, in form and orientation, match the teeth **52** on the tapered fitting **50**. The teeth **52** of the tapered fitting **50** mesh in a slip-fit with the grooves **70** of the second socket **66**. The running slip-fit allows both longitudinal and torsional forces to be applied to the cannula instrument **30** through the handle **60**, with increased mechanical advantage.

[0079] As shown in phantom lines in FIG. 3, a first passage **72** extends through the top of the handle **60**, through the center post **62**, and into the first socket **64**. The passage **72** is generally aligned with the center of the first socket **64** and is sized to pass the guide pin instrument **26** (see FIG. 12).

[0080] Likewise, as also shown in phantom lines in FIG. 3, a second passage **74** extends through the top of the handle **60**, through the center post **62**, and into the second socket **66**. The passage **74** is generally aligned with the center of the

second socket **66** and is sized to pass the either obturator instrument **28** or the drill bit instrument **32** (see FIG. 14).

[0081] Further details of the handle **60** can be found in co-pending U.S. patent application Ser. No. 09/014,229, filed Jan. 27, 1998, and entitled AA Slip-Fit Handle for Hand-Held Instruments that Access Interior Body Regions.

[0082] Further details regarding the use of the handle **60** and the associated instruments **26**, **28**, and **30** will be provided later.

II. The Cavity Forming Instrument

[0083] As FIG. 4A shows, the group **16** includes an instrument **76**, which is deployed through the cannula instrument **30** to a location inside bone (see FIG. 20). When so deployed, the instrument **76** serves to form a cavity in cancellous bone.

[0084] The instrument **76** can be constructed in various ways. In the illustrated embodiment, the instrument **76** includes a flexible catheter tube **78** having a proximal end **80** and a distal end **82**. The proximal end **80** carries a handle grip **84** to facilitate gripping and maneuvering the catheter tube **78**. The materials for the catheter tube **78** are selected to facilitate its advancement through the cannula instrument **30**. The catheter tube **78** can be constructed, for example, using standard flexible, medical grade plastic materials, like vinyl, nylon, polyethylenes, ionomer, polyurethane, and polyethylene terephthalate (PET). The catheter tube **78** can also include more rigid materials to impart greater stiffness and thereby aid in its manipulation. More rigid materials that can be used for this purpose include stainless steel, nickel-titanium alloys (Nitinol material), and other metal alloys.

[0085] The distal end **82** of the instrument **76** carries an expandable structure **86**. In the illustrated embodiment, the expandable structure **86** is made from a polyurethane or an elastomer (e.g., silicone or nylon) material. The structure **86** has been preformed to possess a desired shape by exposure to heat and pressure, e.g., through the use of conventional thermoforming techniques.

[0086] As FIG. 4B shows, the catheter body **78** includes an interior lumen **88**, which communicates with the interior of the structure **86**. A fitting **90** on the proximal end **80** of the catheter tube **78** (see FIG. 4B) communicates with the lumen **88**. The fitting **90** couples the lumen **88** to a source **92** of fluid, e.g., sterile saline (see FIG. 21), or a radiopaque contrast medium.

[0087] The fluid is introduced from the source **92** into the structure **86** under positive pressure, causing the structure **86** to expand. During expansion inside bone, the material selected for the structure **86** preferably resists deformation, so that the expanded shape inside bone essentially corresponds to its expanded shape outside bone, i.e., when in an open air environment. This allows the physician to select in an open air environment a structure **86** having an expanded shape desired to meet the targeted therapeutic result, with the confidence that the expanded shape inside bone will be similar in important respects. In addition to being able to expand its volume while resisting deformation inside bone, the material of the structure **86** preferable withstands abrasion, tearing, and puncture when in contact with cancellous bone.

[0088] The shape of the structure **86**, when expanded inside bone, is selected by the physician, taking into account the morphology and geometry of the site to be treated. The shape of the cancellous bone to be compressed, and the local structures that could be harmed if bone were moved inappropriately, are generally understood by medical professionals using textbooks of human skeletal anatomy along with their knowledge of the site and its disease or injury. The physician is also able to select the expanded shape inside bone based upon prior analysis of the morphology of the targeted bone using, for example, plain film x-ray, fluoroscopic x-ray, or MRI or CT scanning. The expanded shape inside bone is selected to optimize the formation of a cavity that, e.g., when filled with a suitable material, provides support across the region of the bone being treated.

[0089] As one general guideline, in cases where the bone disease causing fracture (or the risk of fracture) is the loss of cancellous bone mass (as in osteoporosis), the selection of the expanded shape of the structure **86** inside bone should take into account that from 30% to 90% of the cancellous bone volume should be compacted. Another general guideline is the amount that the targeted fractured bone region has been displaced or depressed. The expansion of the structure **86** within the cancellous bone region inside a bone can elevate or push the fractured cortical wall back to or near its anatomic position occupied before fracture occurred.

[0090] In the illustrated embodiment (see FIG. 4A), the structure **86** possesses a preformed hour-glass or peanut shape. This shape is selected in contemplation of deploying the structure **86** in a vertebral body, as will be described in greater detail later.

[0091] To facilitate deployment of the structure **86** through the cannula instrument **30**, the catheter tube **78** includes a second interior lumen **94**. The lumen **94** extends from a second fitting **98** on the proximal end **80** of the catheter tube **78**, through the body of the cannula tube **78**, and through the interior of the structure **86** to the tip end **172** of the structure **86**. The lumen **94** receives a generally stiff stylet **96**, which can be made from a molded plastic or stainless steel material. The stylet **96** is inserted through the fitting **98** into the lumen **94**, and includes a threaded coupling **100** to secure the stylet **96** against movement. The presence of the stylet **96** serves to keep the structure **86** in the desired distally straightened condition during passage through the cannula instrument **30** into the targeted tissue region. Once the structure **86** is free of the cannula instrument **30** and inside bone, the stylet **96** can be withdrawn (shown by arrow **174** in FIG. 4A). This returns normal flexibility to the catheter tube **78** and facilitates manipulation of the structure **86** inside bone. With the stylet **96** withdrawn, the lumen **94** can also serve as a pathway for introducing rinsing liquid or to aspirate debris from the bone.

[0092] In the illustrated embodiment, the stylet **96** is biased toward a generally straight condition. In an alternative embodiment (see FIG. 4C), a stylet **102** can have a preformed memory, to normally bend its distal region. The memory is overcome to straighten the stylet **102** when confined within the cannula instrument **30**. However, as the structure **86** and distal region of the preformed stylet **102** advance free of the cannula instrument **30**, to pass into the targeted region, the preformed memory bends the distal region of the stylet **102** and thereby shifts the main axis of

the expandable structure **86**. The prebent stylet **102**, positioned within the interior of the structure **86**, aids in altering the orientation of the structure **86**, bringing it into better anatomic alignment with the targeted region.

[0093] Other types of instruments that can form cavities in cancellous bone and other interior body regions are described in copending U.S. patent application Ser. No. 09/055,805, entitled A Structures and Methods for Creating Cavities in Interior Body Regions, @ filed Apr. 6, 1998.

III. The Material Introducing Instrument Group

[0094] The group **18** includes instruments **104**, **106**, and **108** which serve to convey and compact a selected material inside the cavity formed by the structure **86**. The material in the cavity provides a desired therapeutic result, e.g., replacement of tissue mass, or renewed interior support for the bone, or the delivery of medication, or combinations thereof. Accordingly, the material to perform this function can be selected from among, e.g., a material that sets to a hardened condition, including bone cement, autograft tissue, allograft tissue, synthetic bone substitute, as well as a medication, or combinations thereof.

[0095] In the illustrated embodiment, the group **18** comprises material injection instruments **104** and **106** and a material tamping instrument **108**, which deliver material at a low delivery pressure, i.e., a pressure no greater than about 360 psi.

[0096] A. Low Pressure Material Injection Instruments

[0097] In the illustrated embodiment, the material is injected by use of a conventional syringe **104**, to which a specially designed injection nozzle **106** is coupled. A manual actuated syringe with a push plunger can be used. Alternatively, a LeVeen Inflation Syringe with threaded plunger can be used, which can be actuated manually or by use of a mechanical actuator.

[0098] In the illustrated embodiment, the syringe **104** is made from a clear plastic material. The syringe **104** includes a chamber **110**, which receives the material to be injected. The material is expressed from the chamber **100** by a manually advanced syringe piston **112** (see also FIG. 25).

[0099] The injection nozzle **106** connects by a threaded connector **114** to the end of the syringe **1049** (see also FIG. 25). In the illustrated embodiment, the nozzle **106** is made from a generally flexible, inert plastic material, such as such as polyethylene or another suitable polymer. Alternatively, the nozzle **106** can be made from a generally rigid plastic or metal material.

[0100] The injection nozzle **106** is sized to be advanced through the cannula instrument **30** (see FIG. 26). The nozzle **106** includes measured markings **116** along its length. The markings **116** can be placed, for example, at one centimeter intervals, to correspond with the markings **118** on the cannula instrument **30**, so that the relative position of the nozzle **106** within the cannula instrument **30** can be gauged. The markings **118** can, e.g., include a set point **176**. Alignment of the set point **176** at the proximal end **34** of the cannula instrument **30**, indicates that the distal end of the nozzle **106** is located in an aligned relationship with the distal end **36** of the cannula instrument **30**. In this arrangement, the markings **118** are consecutively numbered with

positive numbers proximally of the set point 176 and with negative numbers distally of the set point 176. The physician is thereby able to tell at a glance the location of the distal end of the nozzle 106, in terms of how far beyond or short of the distal end 36 of the cannula instrument 30 it is.

[0101] In use, the distal end of the nozzle 106 is located beyond the distal end 36 of the cannula instrument 30 within the cavity formed in the targeted tissue region. As FIG. 5 shows, the distal end of the nozzle 106, when made from a plastic material, can carry at least one radiopaque marker 208, to enable remote visualization of the nozzle position within the body. The syringe 104 ejects a predetermined volume of material into the nozzle 106 in a low pressure stream into the cavity. As the material fills the cavity, the nozzle (still ejecting material) is retracted from the cavity and into the cannula instrument 30 itself. Further details of this function and result will be provided later.

[0102] B. The Material Tamping Instrument

[0103] The group 18 also includes a material tamping instrument 108. The tamping instrument 108 is made from generally rigid, inert plastic or metal material. The tamping instrument 108 is also sized to be advanced into the cannula instrument 30 (see FIG. 30). The free end 124 of the tamping instrument 108 is ribbed or contoured to facilitate gripping the instrument 108 during use.

[0104] The tamping instrument 108 includes measured markings 122 along its length. The markings 116 can be placed, for example, at one centimeter intervals, to correspond with the markings 118 on the cannula instrument 30, so that the relative position of the tamping instrument 108 within the cannula instrument 30 can be gauged. Like the nozzle 106, the markings 122 on the tamping instrument 108 includes a set point 178, which indicates when the distal end of the tamping instrument 108 aligns with the distal end 36 of the cannula instrument 30. Also like the nozzle 106, the markings 122 on the tamping instrument 108 are consecutively numbered with positive numbers proximally of the set point 178 and with negative numbers distally of the set point 178. The physician is thereby able to tell at a glance the location of the end of the tamping instrument 108, in terms of how far beyond or short of the distal end 36 of the cannula instrument 30 it is. As FIG. 5 also shows, the end of the tamping instrument 108, when made from a plastic material, can carry at least one radiopaque marker 210, so that its position can be visualized from outside the body.

[0105] After withdrawal of the nozzle 106 from the cannula instrument 30, residual material is left in the cannula instrument 30. The purpose of the tamping instrument 108 is to displace the residual material out the distal end 36 of the cannula instrument 30 and into the cavity, to thereby fill the cavity without exerting undue pressure within the bone. The tamping instrument 108 thereby serves to clear residual material from the cannula instrument 30, to assure that the desired volume of material is delivered into the cavity. The removal of residual material from the cannula instrument 30 by the tamping instrument 108 also prevents seepage of material into surrounding tissue regions upon removal of the cannula instrument 30. The tamping instrument 108 also compacts the material uniformly within the cavity, again without undue pressure. Further details of these functions and results will be discussed later.

IV. The Kit

[0106] As FIGS. 1 and 2 show, in the illustrated embodiment, the kit 12 includes an interior tray 126 made, e.g., from die cut cardboard, plastic sheet, or thermo-formed plastic material. The tray 126 includes spaced apart tabs 128, which hold the various instruments in a secure position during sterilization and storage prior to use.

[0107] When packaged as a sterile assembly, the kit 12 includes an inner wrap 130, which is peripherally sealed by heat or the like, to enclose the tray 126 from contact with the outside environment. One end of the inner wrap includes a conventional peel-away seal 132, to provide quick access to the tray 126 at the instant of use, which preferably occurs in a sterile environment, such as within an operating room.

[0108] When packaged as a sterile assembly, the kit 12 also includes an outer wrap 134, which is also peripherally sealed by heat or the like, to enclose the inner wrap 130. One end of the outer wrap includes a conventional peel-away seal 136, to provide access to the inner wrap 130 and its contents. The outer wrap 134 can be removed from the inner wrap in anticipation of imminent use, without compromising sterility of the contents of the kit 12.

[0109] As FIG. 2 shows, each inner and outer wrap 130 and 134 includes a peripherally sealed top sheet 138 and bottom sheet 140. In the illustrated embodiment, the top sheet 138 is made of transparent plastic film, like polyethylene or MYLAR7 material, to allow visual identification of the contents of the kit 12. The bottom sheet 140 is made from a material that is permeable to ETO sterilization gas, e.g., TYVEK7 plastic material (available from DuPont).

[0110] In the illustrated embodiment, the tray 126 presents the instruments groups 14, 16, and 18 in an ordered, organized layout, which is arranged to aid the physician in carrying out the intended procedure. For example, the layout of the tray 126 can present the instruments groups 14, 16, and 18 in top-to-bottom order, according to sequence of intended use. For example, in a typical bone access procedure (as will be demonstrated in greater detail later), the stylet 22 and stylus 24 of the spinal needle assembly 20 are deployed first, followed by the guide pin instrument 26, followed by the obturator instrument 28, then the cannula instrument 30, then the drill bit instrument 32, then the cavity forming instrument 76, then the syringe 104 and nozzle 106 instruments, and lastly the tamping instrument 108. Accordingly, the tray 126 packages these instruments and components in a top-to-bottom order, with the spinal needle assembly 20 topmost, the guide pin instrument 26 next, the obturator instrument 28 next, and so on, with the tamping instrument 108 lowermost on the tray 126.

[0111] In this layout, the handle 60 is packaged to the side of the access instrument group 14. The tray 126 can include written labels (not shown) identifying the components contained in the kit 12.

[0112] The kit 12 also preferably includes in the tray 126 directions 144 for using the contents of the kit 12 to carry out a desired procedure. An exemplary procedure which the directions 144 can describe will be explained later.

[0113] When packaged as a sterile assembly, the directions 144 can also include the statement "For Single Patient Use Only" (or comparable language) to affirmatively caution

against reuse of the contents of the kit 12 whose performance characteristics and efficacy degrade after a single use. The spinal needle assembly 20, the cavity forming instrument 76, and the material introducing instruments 104, 106, and 108 should, for these reasons, be used but a single time and then discarded. The directions 144 also preferably affirmatively instruct against resterilization of at least these contents of kit 12, and also instructs the physician to dispose of at least these contents of the kit 12 upon use in accordance with applicable biological waste procedures.

[0114] The presence of the instrument groups 14, 16, and 18 packaged in the sterile kit 12 verifies to the physician that the contents are sterile and have not been subjected to prior use. The physician is thereby assured that the instrument groups meet established performance and sterility specifications.

[0115] It should be appreciated that the various instruments contained in the kit 12 can be packaged into several, smaller functional kits. For example, a first kit can package the access instrument group 14, a second kit can package the cavity forming instrument group 16, and a third kit can package the material introduction instrument group 18. FIGS. 1 and 2 illustrate one of many different possible embodiments.

V. Illustrative Use of the System

[0116] The following describes use of the instrument groups 14, 16, and 18 packaged in the kit 12 in the context of treating bones. This is because the instruments of the groups 14, 16, and 18 can be advantageously used for this purpose. Still, it should be appreciated that one or more of the instrument groups, used alone or in association with other instruments, can perform other diagnostic or therapeutic functions in other interior regions of the body.

[0117] In particular, the instrument groups 14, 16, and 18 will be described with regard to the treatment of human vertebra. It should be appreciated, however, their use is not limited to human vertebrae. The instrument groups 14, 16, and 18 can be used in association with hand-held instruments in the treatment of diverse human or animal bone types.

[0118] A. The Vertebral Body

[0119] As FIGS. 6 and 7 show, a typical vertebra 146 includes a vertebral body 148, which extends on the anterior (i.e., front or chest) side of the vertebra 146. The vertebral body 148 has the shape of an oval disk. The vertebral body 148 includes an exterior formed from compact cortical bone 150. The cortical bone 150 encloses an interior volume of reticulated cancellous, or spongy, bone 152 (also called medullary bone or trabecular bone).

[0120] The spinal cord 154 passes through the spinal canal 156 of the vertebra 146. The vertebral arch 158 surrounds the spinal canal 156. The pedicles 160 of the vertebral arch 158 adjoin the vertebral body 148. The spinous process 162 extends from the posterior of the vertebral arch 158, as do the left and right transverse processes 164.

[0121] B. Treatment of a Vertebral Body

[0122] During a typical procedure, a patient lies on an operating table. The patient can lie face down on the table, or on either side, or at an oblique angle, depending upon the physician's preference.

[0123] The physician or surgical assistant removes the outer and inner wraps 130 and 134 of the kit 12, exposing the tray 126 for use. The physician acquires the spinal needle assembly 20 from the tray 126. As FIG. 8 shows, the physician introduces the spinal needle assembly 20 into soft tissue ST in the patient's back. Under radiologic or CT monitoring, the physician advances the spinal needle assembly 20 through soft tissue down to and into the targeted vertebra 146. The physician will typically administer a local anesthetic, for example, lidocaine, through assembly 20. In some cases, the physician may prefer other forms of anesthesia.

[0124] The physician directs the spinal needle assembly 20 to penetrate the cortical bone 150 and the cancellous bone 152 of the targeted vertebral body 148. Preferably the depth of penetration is about 60% to 95% of the vertebral body 148.

[0125] FIG. 8 shows gaining access to cancellous bone through the side of the vertebral body 148, which is called postero-lateral access. However, access may be indicated through a pedicle 160, which is called transpedicular access. The type of access is based upon the objectives of the treatment or for other reasons, based upon the preference of the physician.

[0126] As FIG. 9 shows, after positioning the spinal needle assembly 20 in cancellous bone 152, the physician holds the stylus 24 and withdraws the stylet 22. The physician acquires the guide pin instrument 26 from the tray 126. As FIG. 10 shows, while still holding the stylus 24, the physician slides the guide pin instrument 26 through the stylus 24 and into the cancellous bone 152. The physician now removes the stylus 24 (see FIG. 11), leaving the guide pin instrument 26 deployed within the cancellous bone 152.

[0127] The physician next acquires the obturator instrument 28 and the handle 60 from the tray 126. The physician slides the obturator instrument 28 over the guide pin instrument 26, distal end first. The physician slides the guide pin instrument 26 through the first passage 72 and the first socket 64 of the handle 60. As FIG. 12 shows, the physician slides the handle 60 along the guide pin instrument 26 toward the tapered flange 40 of the obturator instrument 28, until achieving a running slip-fit between the first socket 64 and the tapered flange 40, in the manner previously described. The obturator instrument 28 is now ready for use.

[0128] As FIG. 12 shows, the physician makes a small incision I in the patient's back. The physician twists the handle 60 while applying longitudinal force to the handle 60. In response, the surface 38 of the obturator instrument 28 rotates and penetrates soft tissue ST through the incision I. The physician may also gently tap the handle 60, or otherwise apply appropriate additional longitudinal force to the handle 60, to advance the obturator instrument 28 through the soft tissue along the guide pin instrument 26 down to the entry site (see FIG. 13). The physician can also tap the handle 60 with an appropriate striking tool to advance the surface 30 of the obturator instrument 28 into the side of the vertebral body 148 to secure its position (as FIG. 13 shows).

[0129] The physician next slides the handle 60 along the guide pin instrument 26 away from the obturator instrument 28 to disengage the tapered flange 40 from the first socket 64. The physician then proceeds to slide the handle 60 completely off the guide pin instrument 26.

[0130] The physician acquires the cannula instrument 30 from the tray 126. As FIG. 14 shows, the physician slides the cannula instrument 30 over the guide pin instrument 26, distal end first, and, further, over the obturator instrument 28, until contact between the end surface 48 and soft tissue ST. The physician now slides the guide pin instrument 26 and obturator instrument 26 through the second passage 74 and second socket 66 of the handle 60. The physician slides the handle 60 toward the tapered fitting 50 of the cannula instrument 30 until a running slip-fit occurs between the second socket 66 and the tapered fitting 50, as previously described. The cannula instrument 30 is now ready for use.

[0131] As FIG. 14 shows, the physician applies appropriate twisting and longitudinal forces to the handle 60, to rotate and advance the cannula instrument 30 through soft tissue ST along the obturator instrument 28. As FIG. 15 shows, when the end surface 48 of the cannula instrument 30 contacts cortical bone, the physician can appropriately tap the handle 60 with a striking tool to advance the end surface into the side of the vertebral body 148 to secure its position.

[0132] As FIG. 16 shows, the physician now withdraws the obturator instrument 28, sliding it off the guide pin instrument 26. This leaves the guide pin instrument 26 and the cannula instrument 30 in place, as FIG. 17 shows. The physician next slides the handle 60 along the guide pin instrument 26 away from the cannula instrument 30 to disengage the tapered fitting 50 from the second socket 66. The physician then slides the handle 60 completely off the guide pin instrument 26.

[0133] The physician now acquires the drill bit instrument 32 from the tray 126. As FIG. 18 shows, the physician slides the drill bit instrument 32 over the guide pin instrument 26, distal end first, through the cannula instrument 30 until contact between the machined surface 54 and bone tissue occurs. As FIG. 18 also shows, the physician next leads the guide pin instrument 26 through the first passage 72 and first socket 64 of the handle 60. The physician slides the handle 60 along the guide pin instrument 26 toward the tapered flange 56 of the drill bit instrument 32, until a running slip-fit occurs between the first socket 64 and the tapered flange 56, as previously described. The drill bit instrument 32 is now ready for use.

[0134] As shown by FIG. 18, guided by X-ray (or another external visualizing system), the physician applies appropriate twisting and longitudinal forces to the handle 60, to rotate and advance the cutting edge 54 of the drill bit instrument 32 to open a passage 166 (see FIG. 19) through the bone tissue and completely into the cancellous bone 152. The drilled passage 166 preferably extends no more than 95% across the vertebral body 148.

[0135] The physician now slides the handle 60 along the guide pin instrument 26 away from the drill bit instrument 32 to disengage the tapered flange 56 from the first socket 64. The physician, further, slides the handle 60 completely off the guide pin instrument 26. The physician can now remove the drill bit instrument 32 and the guide pin instrument 26, leaving only the cannula instrument 30 in place. The passage 166 made by the drill bit instrument 32 remains. Subcutaneous access to the cancellous bone 152 has been accomplished.

[0136] The physician can now acquire the cavity forming instrument from the tray 126. As FIG. 20 shows, the

physician can advance the expandable structure 86 through the cannula instrument 30 and passage 166 into the interior volume of the vertebral body 148, as FIG. 21 also shows. The structure 86 is in its normally collapsed and not expanded condition during deployment. The stylet 96 or 102 is inserted in the lumen 94 of the catheter tube 78 to provide added stiffness to the structure 86 while being passed through the cannula instrument 30.

[0137] As shown in phantom lines in FIG. 20, the physician can, if desired, reconnect the handle 60 to the cannula instrument 30, to help stabilize the cannula instrument 30 while deploying the structure 86. The second passage 74 of the handle accommodates the catheter tube 78 and the structure 86, when collapsed.

[0138] As FIG. 21 shows, the structure 86 is oriented in the desired way in the passage 166. As before explained, the bent stylet 102 can aid in this task. Before, during, or after the orientation process, the stylet 96 or 102 can be withdrawn (as FIG. 21 shows), to open the lumen 94 for use to pass a rinsing liquid or negative aspiration pressure.

[0139] Sterile liquid is conveyed under pressure from the source 92 through the lumen 88 into the structure 86. As FIG. 22 shows, the structure 86 expands inside bone. Expansion of the structure 86 compresses cancellous bone 152 in the vertebral body 148.

[0140] The compression forms an interior cavity 168 in the cancellous bone 152. As FIG. 23 shows, subsequent collapse and removal of the structure 86 leaves the cavity 168 in a condition to receive a filling material.

[0141] The compaction of cancellous bone 152 can also exert interior force upon cortical bone, making it possible to elevate or push broken and compressed bone back to or near its original prefracture, or other desired condition.

[0142] Upon formation of the cavity 168, the physician acquires the syringe 104 and injection nozzle 106 from the kit 12. As FIG. 24 shows, the physician fills the syringe chamber 110 with the desired volume of filling material 170. As FIG. 25 shows, the physician attaches the nozzle 106 to the filled syringe 104. As FIG. 26 shows, the physician inserts the nozzle 106 a selected distance beyond the distal end 36 of the cannula instrument 30 and into the cavity, guided by the markings 116.

[0143] As shown in phantom lines in FIG. 26, the handle 60 can remain attached to the cannula instrument 30 to provide stability, as the second passage 74 of the handle accommodates the nozzle 106.

[0144] As FIG. 27 shows, the physician manually advances the piston 112 to cause the material 170 to flow through and out of the nozzle 106 and into the cavity. As material 170 fills the cavity, the physician withdraws the nozzle from the cavity and into the cannula instrument 30. The cannula instrument 30 channels the material 170 flow toward the cavity 168. As FIG. 28 shows, the cement material 170 flows in a stream into the cavity 168.

[0145] If the selected material 170 is bone cement, the cement material 170 is placed into the syringe chamber 110 shortly after it is mixed from two materials (e.g., in an external mixing device), while it is in a low viscosity, relatively free flowing liquid state, like a thin pancake batter.

In time (e.g., about two minutes after mixing), the consistency of the cement material **170** will change to a substantially putty-like character.

[0146] The physician operates the syringe **104** to expel the cement material **170** from the chamber, through the nozzle **106**, first into the cavity and then into the cannula instrument **30**. Typically, at the end of the syringe injection process, material **170** should extend from the cavity and occupy about 40% to 50% of the cannula instrument **30**.

[0147] When a desired volume of cement is expelled from the syringe **104**, the physician withdraws the nozzle **106** from the cannula instrument **30**, as FIG. 29 shows. The physician may first rotate the syringe **104** and nozzle **106**, to break loose the material **170** in the nozzle **106** from the ejected bolus of material **170** occupying the cannula instrument **30**.

[0148] The physician acquires the tamping instrument **108** from the kit **12**. As FIG. 30 shows, the physician advances the tamping instrument **108** through the cannula instrument **30**. As phantom lines in FIG. 30 show, the handle **60** can remain attached to the cannula instrument **30** to provide stability, as the second passage **74** of the handle accommodates the tamping instrument **108**.

[0149] The distal end of the tamping instrument **108** contacts the residual volume of cement material **170** in the cannula instrument **30**. As FIGS. 30 and 31 show, advancement of the tamping instrument **108** displaces progressively more of the residual material **170** from the cannula instrument **30**, forcing it into the cavity **168**. The flow of material **170** into the cavity **168**, propelled by the advancement of the tamping instrument **108** in the cannula instrument **30**, serves to uniformly distribute and compact the material **170** inside the cavity **168**, without the application of undue pressure.

[0150] The use of the syringe **104**, nozzle **106**, and the tamping instrument **108** allows the physician to exert precise control when filling the cavity with material **170**. The physician can immediately adjust the volume and rate of delivery according to the particular local physiological conditions encountered. The application of low pressure (i.e., no greater than 360 psi), which is uniformly applied by the syringe **104** and the tamping instrument **108**, allows the physician to respond to fill volume and flow resistance conditions in a virtually instantaneous fashion. The chance of overfilling and leakage of material **170** outside the cavity is significantly reduced.

[0151] When the physician is satisfied that the material **170** has been amply distributed inside the cavity **168**, the physician withdraws the tamping instrument **108** from the cannula instrument **30**. The physician preferably first twists the tamping instrument **108** to cleanly break contact with the material **170**. The handle **60** can now be removed and the cannula instrument **30** withdrawn, as FIG. 32 shows. The incision site is sutured closed. The bone treatment procedure is concluded.

[0152] Eventually the material **170**, if cement, will harden a rigid state within the cavity **168**. The capability of the vertebral body **148** to withstand loads is thereby improved.

[0153] The selected material **170** can be an autograft or allograft bone graft tissue collected in conventional ways. For example, the graft material can be in paste form, as

described by Dick, A Use of the Acetabular Reamer to Harvest Autogenic Bone Graft Material: A Simple Method for Producing Bone Paste, @ Archives of Orthopaedic and Traumatic Surgery (1986), 105: 235-238, or in pellet form, as described by Bhan et al, A Percutaneous Bone Grafting for Nonunion and Delayed Union of Fractures of the Tibial Shaft, @ International Orthopaedics (SICOT) (1993) 17: 310-312, both of which are incorporated herein by reference. Alternatively, the bone graft tissue can be obtained using a Bone Graft Harvester, which is commercially available from SpineTech. Using a funnel, the paste or pellet graft tissue material is loaded into the cannula instrument **30**. The tamping instrument **108** is then advanced into the cannula instrument **30** in the manner previously described, to displace the paste or pellet graft tissue material out of the cannula instrument **30** and into the cavity.

[0154] The selected material **170** can also comprise a granular bone material harvested from coral, e.g., ProOsteonJ calcium carbonate granules, available from Interpore. The granules are loaded into the cannula instrument **30** using a funnel and advanced into the cavity using the tamping instrument **108**.

[0155] The selected material **170** can also comprise demineralized bone matrix suspended in glycerol (e.g., GraftonJ allograft material available from Osteotech), or SRSJ calcium phosphate cement available from Novian. These viscous materials, like the bone cement previously described, can be loaded into the syringe **104** and injected into the cavity using the nozzle **106**, which is inserted through the cannula instrument **30** into the cavity. The tamping instrument **108** is used to displace residual material from the cannula instrument **30** into the cavity, as before described.

[0156] The selected material **170** can also be in sheet form, e.g. CollagraftJ material made from calcium carbonate powder and collagen from bovine bone. The sheet can be rolled into a tube and loaded by hand into the cannula instrument **30**. The tamping instrument **108** is then advanced through the cannula instrument, to push and compact the material in the cavity.

VI. Alternative Embodiments

[0157] The use of low pressure delivery of material **170** frees the system **10** from the need to accommodate relatively large diameter, high pressure delivery devices. The interior diameter of the cannula instrument **30** can be downsized accordingly, thereby minimizing the dimensions of the subcutaneous pathway to gain access to the targeted bone region.

[0158] Typically, when low pressure material injection instruments are used, the largest tool that the reduced-diameter cannula instrument must accommodate is the expandable cavity-forming structure **82**. The structure **82** presents a minimal profile during deployment, as it can be collapsed and, if desired, a lubricous coating may also be applied to the exterior of the structure **82** to facilitate its passage through the reduced-diameter cannula instrument.

[0159] A. Low Pressure Material Injection Instruments

[0160] FIG. 33 exemplifies low pressure material injection instruments **180** and **182** that function in association with a cannula instrument **184** having a reduced interior diameter, e.g. only about 3.4 mm or less.

[0161] One instrument **180** comprises a reduced-diameter nozzle. As FIG. 33 shows, the nozzle **180** is sized to pass through the reduced-diameter cannula instrument **184**, to thereby pass into bone in the manner previously shown in FIG. 26. The reduced-diameter nozzle **180** connects by a threaded connector **186** to the syringe **104**. For material strength, despite its reduced dimension, the nozzle **180** is preferably formed from a rigid metal material, e.g., stainless steel.

[0162] As FIG. 33 shows, the reduced-diameter nozzle **180** also includes measured markings **188** along its length, as previously described. The markings **188** include a set point **190**, as previously described, which aligns with the proximal end of the cannula instrument **184** when the distal ends of the cannula instrument **184** and the nozzle **180** align.

[0163] The other reduced diameter instrument **182** comprises a stylet, which is sized to pass through the interior bore of the nozzle **180**. The stylet **182** includes a handle **192**, which rests on the proximal connector **186** of the nozzle **180** when the stylet **182** is fully inserted into the nozzle **180**. When the handle **192** is rested, the distal ends of the stylet **182** and nozzle **180** align. The presence of the stylet **182** inside the nozzle **180** closes the interior nozzle bore.

[0164] In use, the nozzle **180** is coupled to the syringe **104** and inserted through the cannula instrument **184** into the material-receiving cavity **168** formed in cancellous bone, in the same manner shown in FIG. 26. Material in the syringe **104** is injected at low pressure through the nozzle **180** into the cavity **168**. As before explained, as the cavity **168** progressively fills with material, the nozzle **180** is withdrawn back into the cannula instrument **184**. Typically, when the injection of material is completed, material extends from the cavity **168** and occupies about 40% to 50% of the cannula instrument **184**.

[0165] At this point, the nozzle **180** can be fully withdrawn from the cannula instrument **184** and unthreaded from the syringe **104**. The stylet **182** can be advanced into the nozzle **180**, to bring the handle **192** at rest against the connector **186**, thereby clearing residual material from the nozzle **180**. The nozzle **180** and stylet can then be inserted as a nested unit into the cannula instrument **184**. Nested together, the nozzle **180** and stylet **182** form a tamping instrument. Upon advancement through the cannula instrument **184**, the nested nozzle **180** and stylet **182** displace residual material from the cannula instrument **184** into the cavity **168**, in generally the same manner as previously shown in FIGS. 30 and 31, thereby uniformly compacting material within the cavity **168** in a controlled fashion and without undue pressure.

[0166] Alternatively, a single-piece tamping instrument, separate from the nozzle **180**, can be provided, downsized to fit through the reduced-diameter cannula instrument **184**. In this embodiment, the stylet **182** is not necessary, unless it is desired to reclaim material from the nozzle.

[0167] B. Cavity Forming Instrument

[0168] FIG. 34 shows a cavity forming instrument **194** intended to be deployed through the reduced-diameter cannula instrument **184**, shown in FIG. 33. In many respects, the instrument **194** is like the instrument **76**, previously described and shown in FIG. 4A, and common reference numerals will be assigned to common structural elements.

The instrument **184** includes a flexible catheter tube **78** having a proximal end **80** and a distal end **82**. The proximal end **80** carries a handle grip **84**, and the distal end **82** carries an expandable structure **86**, which, when deployed in bone, compacts cancellous bone and forms the cavity **168**.

[0169] Unlike the previously-described instrument **76**, the instrument **194** carries an introducer sleeve **196**. The introducer sleeve **196** slides along the catheter tube **78** between the handle grip **84** and the expandable structure **86**. The introducer sleeve **196** includes a tubular main body **198** with a forward collar **200** and a rear collar **202**.

[0170] The introducer sleeve **196** normally occupies an advanced position on the instrument **194**, as shown in FIG. 35. In this position, the main body **198** overlies and surrounds the expandable structure **86**. The main body **198** is sized to compress the structure **86** to an outside diameter that is slightly less than the interior diameter of the reduced-diameter cannula instrument **184**.

[0171] As FIG. 35 shows, when the introducer sleeve **196** occupies the advanced position, the forward collar **200** extends beyond the distal end of the compressed expandable structure **86**. As FIG. 36 shows, in this position, the forward collar **200** presents itself for engagement with the proximal end **204** of the cannula instrument **184**. The forward collar **200** is sized to have an interior diameter that makes friction-fit engagement about the proximal end **204** of the cannula instrument **184**.

[0172] As FIG. 36 shows, when it is time to deploy the expandable structure **86** through the cannula instrument **184**, the physician engages the forward collar **200** of the introducer sleeve **196** in a friction fit about the proximal end **204** of the cannula instrument **184**. As FIG. 37 shows, advancing the catheter tube **78** moves the compressed structure **86** through the main body **198** of the sleeve **196** and into the bore of the cannula instrument **184**. The engagement of the forward collar **200** about the proximal cannula end **204** aligns the axis of the structure **86** with the axis of the cannula instrument **184**, while compressing the structure **86** to a diameter smaller than the interior of the cannula instrument **184**. Upon advancement of the catheter tube **78**, the introducer sleeve **196** guides the structure **86** into the cannula instrument **194** without tearing or other damage.

[0173] Once the expandable structure **86** is advanced through the cannula instrument **184** and into bone, the physician can slide the introducer sleeve **196** rearward away from the proximal cannula end **204**, to break the friction fit between the end **204** and the forward sleeve. As FIG. 34 shows, the rear collar **202** of the sleeve **196** is sized to make a snap fit engagement about a stem **206**, which surrounds the catheter tube **78** near the handle **84**. The snap fit engagement stabilizes the position of the sleeve **196** during subsequent use and manipulation of the cavity-forming instrument **194**.

[0174] The features of the invention are set forth in the following claims.

We claim:

1. Apparatus for delivering material into bone comprising a cannula for establishing a subcutaneous path into bone, and a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula, the tamping instrument being sized and configured

for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula, advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone, and withdrawal of the tamping terminus from the cannula.

2. Apparatus according to claim 1 wherein the tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula.

3. Apparatus according to claim 1 wherein the tamping instrument includes at least one additional marking to visually gauge advancement of the terminus relative to the distal end of the cannula.

4. Apparatus according to claim 1 wherein the material comprises at least one of bone cement, autograft material, allograft material, calcium carbonate, demineralized bone matrix material, calcium phosphate.

5. A method comprising

providing apparatus as defined in claim 1, and

manipulating the apparatus to deliver material into bone relying at least in part upon the at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula.

6. A method according to claim 1 wherein the material comprises at least one of bone cement, autograft material, allograft material, calcium carbonate, demineralized bone matrix material, calcium phosphate.

7. A method comprising

deploying an expandable device through a percutaneous path into a vertebral body having cancellous bone volume to create a cavity in the cancellous bone volume,

advancing a tamping instrument through a percutaneous cannula to deliver material into the cavity, and

visually gauging the advancement by observing at least one predetermined marking on the tamping instrument to determine a position of a terminus of the tamping instrument relative to a distal end of the cannula.

8. A method according to claim 1 wherein the material comprises at least one of bone cement, autograft material, allograft material, calcium carbonate, demineralized bone matrix material, calcium phosphate.

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