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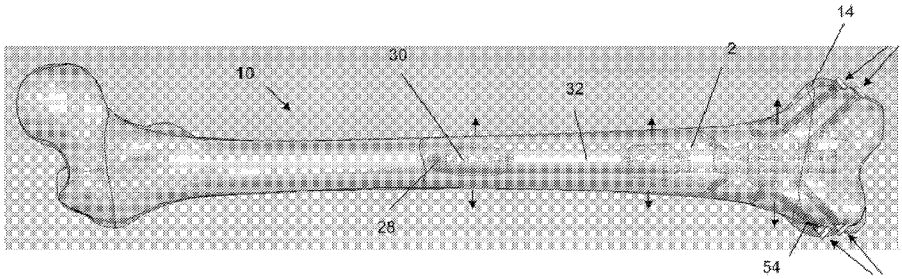

Fig. 19

(57) Abstract: A device for radial expansion in an endoluminal cavity in a bone is disclosed. The device can be used to treat bone fractures. The device can have a first radially expandable portion and a second radially expandable portion.

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TITLE OF THE INVENTION

EXPANDABLE ORTHOPEDIC DEVICE AND METHOD

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CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 61/022,613, filed 22 January 2008, which is incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates generally to a device and method for stabilizing bones and anchoring to bones and bone fragments.

2. Description of Related Art

[0003] Figure 1 illustrates a longitudinally split femur bone **8** with the proximal (coronal) end on the right. The femur **10** is a long bone. Bones, such as femurs, have hard, dense cortical outer bone **34**, and softer, less dense cancellous inner bone **4** that forms a lumen within the shell of cortical bone **34**. Figure 2 illustrates the endoluminal cavity **6** formed by the cancellous bone **4**.

[0004] Broken bones, such as long bone breaks, may be treated with fixation. Rigid stabilization rods are often attached to the pedicles of the vertebrae (not shown) with fixation screws. The fixation screws can be driven into the cortical outer shell of the bone.

SUMMARY OF THE INVENTION

[0005] An expandable orthopedic device is disclosed. The device can be a radially expandable attachment device. The device can be used for to therapeutically treat trauma injuries in bones, for example long bone fractures. The device can be fixed in the endoluminal cavity on two sides of a long bone break.

[0006] The device can have a structure that can radially expand inside a bone, for example in the endoluminal cavity of a long bone. For example, the device can have a stent-like expandable frame. The device can be implanted in the endoluminal cavity in a radially unexpanded configuration. The device can be radially expanded in the endoluminal cavity using a simple tool, both pump handles, rotational type tools (e.g., cams), or combinations thereof.

[0007] The devices can be made from metals, plastics, or combinations thereof, as disclosed infra. The device can be entirely metal, mixes of metal and plastic, entirely plastic, and the device can also have other polymers, agents, fillers and other materials disclosed infra. For example, the radially expandable portion of the device can be a first material (e.g., a first metal) and the remainder of the device can be primarily or entirely made from a second material (e.g., a second metal).

[0008] The expansion element can be configured to expand through cancellous bone, and stop when the expansion element contacts hard cortical bone and/or sufficient mechanical resistance. The expansion element can be configured to expand partially or completely into cortical bone, for example to anchor the expansion element into the cortical bone.

[0009] The device can be configured to apply a high level of radial force to the inner endoluminal wall of a bone or a low level of radial force.

[0010] The device can be designed to stop radially expanding based on displacement (e.g., an internal stop or extent of the length of the radial expansion). The device can be configured to fail mechanically once the device receives a specific mechanical load or resistance, for example for removal or replacement, and/or to prevent the device from over-stressing the bone (e.g., for the device to fail before the bone fails).

[0011] The device can contour to the inside of the cortical surface (i.e., outside of the endoluminal cavity) during radial expansion and can anchor to the cortical surface.

[0012] Part or all of the outside surface of the device can be textured (e.g., teeth, barbs, hooks, spikes, holes, ridges, knurls, combinations thereof), for example to increase anchoring or improve in-growth of the bone into or towards the device.

[0013] The textured surface can be configured to match the required loading. For example, the ridges can be oriented along the longitudinal axis of the device, for example, to resist torque loads on the device by pressing the ridges against the cortical bone accordingly (e.g., in the direction of the torque, producing additional resistance to the torque). The ridges can be oriented perpendicular to the longitudinal axis, for example to resist tensile or compressive loads on the device by pressing against the cortical bone accordingly.

[0014] The device can stabilize bone fragments, for example by acting as an endo-scaffold (i.e., a scaffold from within the bone) when in an expanded and/or contracted configuration.

[0015] One or more fixation screws can be screwed through bone and into the device – for example when the device is used as an endo-scaffold. The screws can, for example, brace or align the device against or with the bone. By fixing the bone to the device, the bracing element (e.g., fixation screw) can stabilize the bone by pushing the bone radially inward toward the central axis of the bone (e.g., not to one side or the other, for example like a typical external fixation plate or rod). The fracture or bone fragments can be pushed towards the device in the endoluminal cavity. The

screws used to screw bone fragments directly onto the device can be lag screws, for example with a distal machine thread.

[0016] The device can have any or all elements from any of the devices and/or be used with any method disclosed in U.S. Provisional Application No.: 60/906,791, filed 12 March 2007, and PCT App. No. US2008/003421 which are incorporated by reference herein in their entireties. The expandable sections can be made from any configuration (e.g., springs), not just radially expanding bending struts.

[0017] The device can be partially or completely hollow. For example, the device can be hollow along the length of the expandable section. The hollow section of the device can be filled with one or more cement, fillers, glues, and/or an agent delivery matrix and/or a therapeutic and/or diagnostic agent. Any of these cements and/or fillers and/or glues can be osteogenic and osteoinductive growth factors.

[0018] The device can be implanted anti-grade, retrograde, or constructed from segments from the center of a bone.

[0019] The device can be completely or partially bare or covered. The device can have a liner made from a thin film or fabric (e.g., plastic, metal). For example, the liner can control filler flow and/or improve screw anchoring (e.g., by attaching the fixation screw).

[0020] The device can be recovered and removed, or repositioned or otherwise adjusted within the endoluminal cavity.

[0021] The device can anchor against the cortical bone, for example reducing device motion. The device can be configured to be rigid or flexible.

[0022] The device can have one or more radially expandable sections. The expandable sections can be on one or both ends of the implants. The expandable sections can be located along the length of the device at regular or varying length intervals.

[0023] The expandable sections can be expanded in any direction (e.g., distal first, proximal last) or out of order along the length of the device. Some expandable sections can be left unexpanded. The expandable sections can be expanded in a sequence to best stabilize the fracture during deployment of the device.

[0024] The expandable sections can be used to move the fractured segments of the bone. For example, the expandable section can then be unexpanded and the device moved after the fractured segment of the bone is moved as desired.

[0025] The device, for example via the expandable sections, can be used to remove cancellous bone, for example by reaming the endoluminal bone cavity with the expandable section in a radially expanded and/or radially contracted configuration.

[0026] A main stem of a joint replacement or resurfacing device can be anchored by having one or more expandable sections in the main stem. The expandable section can be filled with a filler or other material disclosed herein.

[0027] The device can be sized and shaped to fit big and small bones (e.g., finger, femurs).

[0028] The device can have one or more external guides, for example ridges, rails, threaded holes, or combinations thereof, to guide the screws into the device.

[0029] The expandable sections can be expanded by inflating a balloon and/or screw jack (e.g., to bring the longitudinal ends of the expandable section nearer to each other), and/or expanding a wedge-jack inside of the expandable sections.

[0030] The fixation screws can have a polyaxial washer head, for example, to distribute stresses. The fixation screws can be linked to one another by a thread, suture, rod, plate, strap or combinations thereof.

[0031] The screws can pass through one or more (e.g., two) of the walls of the device. For example, the screw can enter one side and exit the opposite side of the device. A single screw can anchor through cortical bone on substantially opposite sides of the endoluminal cavity.

[0032] The fixation screws can have a distal thread. The distal thread can attach into a cell hole of the expandable sections.

[0033] The diameter of the screws can be sized to match the diameter of the cell hole.

[0034] The expandable section can have one or more layers of walls. The walls can have interconnected struts defining expandable cells. The struts can attach to each other at deformable, resilient and/or rigid joints. Any or all of the remainder of the device can have one or more walls.

[0035] The device can be configured so the (longitudinal axis of the) device can be straight and/or curved. The device can be configured to match the topography (i.e., shape) of the endoluminal cavity defined, for example, by the inner wall of the cortical bone. The device can be used to anchor a mesh, suture, or another implant. The device can be curved before radial expansion. The device can be curved and/or bent during radial expansion.

[0036] The expandable sections can expand to a round, square, triangular, contoured to the inner wall surface, or combinations thereof cross-sectional configuration. The expandable section can expand into a sphere, rectangle, cube, or contoured any shape to improve anchoring inside a bone.

[0037] The device can be used to fill a bone void (e.g., for vertobroplasty (also known as kyphoplasty), tumor therapy, trauma therapy).

[0038] Layers of metals,plastic,...

[0039] The device can be any length, for example sized to fit a schaphoid or femur.

[0040] The device can have expandable sections that can be configured to expand radially, planarly, curvedly, with corresponding wedges, as a polygon, or combinations thereof.

[0041] The expandable sections can self-expand (e.g., resilient expansion).

[0042] The device can be used with screws, wire, sutures, or combinations thereof. The expandable section can have many holes or few holes.

SUMMARY OF TH E FIGURES

[0043] Figures 1 and 2 are longitudinal sectional views of a femur.

[0044] Figure 3 illustrates a perspective view of a longitudinally sectioned femur.

[0045] Figure 4 is a sectional view of a femur with the cancellous bone removed.

[0046] Figures 5 and 6 illustrate a femur.

[0047] Figure 7 illustrates a variation of the device in a contracted configuration at a target site with the bone shown in partial see-through.

[0048] Figure 8 illustrates a variation of the device in an expanded configuration at a target site with the bone shown in partial see-through.

[0049] Figures 9a through 9c are radiographical images a variation of a method for deploying the device.

[0050] Figures 10a and 10b are radiographical images of side and end views, respectively, of a variation of the device at a target site in a long bone.

[0051] Figures 11a and 11b are radiographical images of a variation of the device at a target site in a radially expanded configuration.

[0052] Figures 12a and 12b are radiographical images of a variation of the device at a target site in a radially expanded configuration.

[0053] Figure 13 illustrates a femur.

[0054] Figure 14 illustrates a method of inserting a variation of the device into a femur.

[0055] Figure 15 is a variation of close-up A-A of Figure 14.

[0056] Figure 16 illustrates a variation of close-up A-A before the bone is closed (i.e., the fracture is reduced) and stabilized.

[0057] Figure 17 illustrates Figure 16 with the bone substantially closed and stabilized.

[0058] Figure 18 illustrates a femur.

[0059] Figures 19 and 20 illustrate a variation of the device at a target site with the bone shown in partial see-through.

[0060] Figure 21 illustrates that the variation of the device at a target site.

[0061] Figures 22a, 22b and 22c are progressively more magnified close-ups of the distal head of the femur in partial-see though with a device implanted in the femur.

[0062] Figure 23 illustrates an outside view of a variation of the device being inserted and expanded.

[0063] Figure 24 is a radiographical image of a variation of the device in an expanded configuration at a target site.

[0064] Figures 25a and 25b illustrate progressively more magnified close-ups of the device in a carpel bone with the bone shown in partial see-through.

[0065] Figures 26a and 26b illustrate progressively more magnified close-ups of the device in a wrist bone with the bone shown in partial see-through.

[0066] Figures 27a and 27b illustrate variations of transverse cross-sections of the device in unexpanded and expanded configurations, respectively.

[0067] Figures 28a through 28d are radiographical images of a varitiaon of a method for removing the device from a target site.

[0068] Figures 29a through 29d are side views of a variation of a method for removing the device and surrounding tissue.

[0069] Figures 30a through 30d illustrate variations of transverse cross-section C-C of Figure 10a.

[0070] Figures 31a and 31b are longitudinal sectional views of variations of the device in an expanded configuration with a locking rod.

DETAILED DESCRIPTION OF THE INVENTION

[0071] Figure 3 illustrates that all or part of the cancellous bone **4** can be removed from the endoluminal cavity **6** of a bone **8**, such as a long bone **8** such as the femur **10**. The cancellous bone **4** can be removed with a finger (as shown), if the cancellous bone **4** is sufficiently soft, or with a reamer or other tool. Figure 4 illustrates a femur **10** with the cancellous bone **4** removed from the endoluminal cavity **6**.

[0072] Figure 5 illustrates three exemplary indications for use of the device include trochanteric fractures **1**, mid-shaft fractures **2**, distal fractures **3**, and combinations thereof. Figure 6 illustrates the greater trochanter **16** and femoral head **12**. The trochanter fracture **14** can bisect the greater trochanter **16**.

[0073] Figure 7 illustrates that multiple expandable attachment devices **2** can be used in a procedure. For example, a first expandable attachment device **22** can be inserted through the collar **20** of a second expandable attachment device **24** to attach the two devices together.

[0074] The first expandable attachment device **22** can be inserted into the femoral head **12**. The second expandable attachment device **24** can be inserted along the endoluminal cavity **6** of the femoral shaft.

[0075] The first expandable attachment device **22** can have a traumatic screw or otherwise sharpened tip **26**. The screw tip **28** can be turned into the bone **8** to help drive and seat the expandable attachment device **2** against the bone **8**.

[0076] Either or both (shown as just the second) expandable attachment devices **22, 24** can have one or more radial expandable sections **30** and radial unexpandable sections **32**. Figure 8 illustrates that all (as shown) or some of the radial expandable sections **30** can be radially expanded after (or

before – not shown) the expandable attachment device **2** is inserted into the bone **8**. The expanded expandable sections **30** can secure one or both expandable attachment devices **22, 24** to the inside of the cortical bone **34**. At least one of the expandable sections **30** (e.g., the expandable section **30** of the first attachment device **22**) can be on a first side of the fracture **14**, and at least one of the expandable sections **30** (e.g., both expandable sections **36, 38** of the second attachment device **24**) can be on a second side of the fracture **14**.

[0077] Figure 9a illustrates that access to the endoluminal cavity **6** can be created by reaming through the cortical bone **34** and remaining out some or all of the cancellous bone **4**.

[0078] Figure 9b illustrates that the second expandable attachment device **24** and the first expandable attachment device **22** can be inserted into the bone **8**. The first expandable attachment device **22** can be inserted into the bone **8** after the second expandable attachment device **24**, for example to insert the first expandable attachment device **22** through the collar **20** (or other attachment element) of the second expandable attachment device **24**. Insertion of both expandable attachment devices **22** and **24** is shown by arrows.

[0079] Figure 9c illustrates that the first expandable attachment device **22** can be further inserted through the bone **8**, for example by rotating and pushing the first expandable attachment device **22** to utilize the screw tip **28** to drill through the bone **8**. The expandable section **30** on the first expandable attachment device **22** (and any other expandable sections **30** desired) can then be radially expanded, as shown by arrows.

[0080] Figure 10a illustrates a lateral view of the femur **10** with an expandable attachment device **2** inserted into the endoluminal cavity **6** and the expandable section **30** in a radially expanded configuration. The expandable section **30** can conform to the shape of the endoluminal cavity **6** and can secure the expandable section **30** to the cortical bone **34**. The expandable section **30** can have struts **40** that can define cells **42** (e.g., openings). The struts **40** can be joined to each other at joints. The struts **40** can be resiliently and/or deformably flexible and/or the joints can be resiliently and/or deformably flexible.

[0081] Figure 10b illustrates an axial view of the femur **10** with the expandable attachment device **2** inserted. Figure 10b illustrates a variation of transverse cross-section C-C of Figure 10a.

[0082] Figures 11a and 11b illustrate the expandable attachment device **2** deployed in an osteopenic hip (i.e., in the femur **10**). Figures 12a and 12b illustrate the expandable attachment device **2** deployed in a healthy hip (i.e., in the femur **10**).

[0083] Figure 13 illustrates that a fracture **14** can be in the femur shaft **44**. Figures 14 and 15 illustrate that the expandable attachment device **2** can be removably attached to a deployment tool **46**. The distal end **48** of the deployment tool **46** can removably attach to the proximal end of the expandable attachment device **2**. The deployment tool **46** can position the expandable attachment

device **2** (as shown by arrow in Figure 14). The deployment tool **46** can control radial expansion **68** of each expandable section **30, 32** in unison or independently of one another.

[0084] The deployment tool **46**, the expandable attachment device **2** or another tool can be used to create a port **50** into the endoluminal cavity **6** and to ream part or all of the endoluminal cavity **6**.

[0085] The expandable section **30** can have teeth and/or helical threads **52**. The teeth or threads **52** can be configured to anchor to the cortical bone **34** when the expandable section **30** is in a radially expanded configuration. The expandable attachment device **2** can have an atraumatic tip **26**.

[0086] Figure 16 illustrates that the first expandable section **36**, shown at the distal end **48** of the expandable attachment device **2** (which is closer to the proximal end of the femur **10**) can be radially expanded first, as shown by arrows. The first expandable section **36** can take on the cross-section of a circle, square, triangle, oval, or otherwise contour to the shape of the endoluminal cavity **6** (as shown – see also Figures 27a and 27b), or combinations thereof. The teeth **52** can engage the cortical bone **34** and anchor the expandable section **30** to the cortical bone **34**.

[0087] Figure 17 illustrates that the deployment tool **46** can pull, as shown by arrow, the proximal end of the femur **10** toward the distal end **48** of the femur **10** to close the fracture **14**. The force to pull the proximal end of the femur **10** toward the distal end **48** of the femur **10** can be transmitted through the unexpandable section **32** and the first expandable section **36** which can be anchored against the cortical bone **34** of the proximal femur **10**. The second expandable section **38** can then be radially expanded and the deployment tool **46** can be disconnected and removed from the treatment site (not shown).

[0088] Figure 18 illustrates a fracture **14** at the distal end **48** of the femur **10**. Figures 19 and 20 illustrate that the one or more fixation screws **54** can be inserted in one or more directions through the bone **8**, and/or across the expandable attachment device **2** and/or the fracture **14**. The screws **54** can be inserted through the cells **42** of the expandable section **30**. The screws **54** can be sized to be the same size or smaller than the cells **42** when the expandable section **30** is in a radially contracted or radially expanded configuration. The cells **42** can be internally threaded to engage the screws 54. The cells **42**, or other holes on the expandable support device can be smaller than, the same size or larger than the screws diameter. For the cells **42** or holes larger than the screws 54, the screws 54 can slide through the hole during and after deployment.

[0089] Figure 21 illustrates that the expandable attachment device **2** can be used for distal radius **72** fracture **14** repair. Additional pins **56** can be placed to secure or control the bone **8** fragments before, and/or during, and/or after deployment of the expandable attachment device **2**. The expandable attachment device **2** can be straight or have a substantially non-zero radius of curvature **74**. The unexpandable sections **32** and/or the expandable sections **30** can be straight or have a substantially non-zero radius of curvature **74**.

[0090] Figures 22a through 22c illustrate that the expandable attachment device **2** can be used for proximal humerus fracture **14** repair.

[0091] Figures 23 and 24 illustrate that the device **2** can be inserted and expanded in an endoluminal cavity **6**. Figure 23 illustrates an external view of the insertion and expansion of the device **2** through the endoluminal channel **6**. Figure 24 illustrates that the bone fixation screws **54** can be inserted through (i.e., nested in) the cells **42** of the expandable section **30**. The bone fixation screws **54** can be nested (e.g., pressed against, wedged against) through the cells **42** and/or with the other bone fixation screws **54**.

[0092] Figures 25 and 26 illustrate that the expandable attachment device **2** can be deployed in a phalange **58**. For example, the device **2** can be used to treat a broken phalange **58**. The expandable attachment device **2** can be modular. The first expandable section **36** can be removed from the second expandable section **38**. The unexpandable section **32** can have an interlocking configuration. The physician can construct the expandable attachment device **2** in vivo or in the operating room before or during deployment, for example, to select the best total length of the device to insert, and/or to use combinations of expandable sections **30** with different (or the same) sizes of radial expansion **68**.

[0093] A traumatic tip **26** (e.g., the screw tip **28**) can be covered by an atraumatic tip **26** (e.g., end cap **60**) before or after insertion **62** of the device in the treatment site.

[0094] Figures 26a and 26b illustrate that the expandable attachment device **2** can be deployed in the scaphoid **64**. The expandable attachment device **2** can have a proximal anchor **66**. The end cap **60** can have a traumatic sharp point, for example, to drive through the bone **8**. The proximal anchor **66** can be hit or struck with a hammer or mallet, for example to drive the expandable attachment device **2** into the scaphoid **64** and/or to radially expand the expandable section **30** (e.g., when the resistance against the end cap **60** is greater than the force of the hammer, the expandable section **30** can radially expand).

[0095] Figures 27a and 27b illustrate that the expandable section **30** of the expandable attachment device **2** can radially expand to fit the shape of the endoluminal cavity **6**. Figure 27a illustrates a transverse cross-section of the bone **8** with the device **2** inserted into the endoluminal cavity **6**. Figure 27b illustrates that the expandable section **30** can radially expand, as shown by arrows, and deform to substantially the same shape as the inner wall of the endoluminal cavity **6**. The expandable section **30** can match the interior bone surface contour. For example, this fitting of the expandable section **30** can increase the anchoring force, torque resistance and healing of the bone into the expandable section (i.e., through cells of the stent-like expandable section

[0096] Figures 28a through 28d illustrate a sequential method for recovering (i.e., removing) the expandable attachment device **2** from a treatment site. Figure 28a illustrates that the device **2** can be deployed in a femur, for example extending into the greater trochanter. Figure 28b illustrates

that the expandable section **30** can be radially contracted, as shown by arrows. Figure 28c illustrates that the device **2** can be unscrewed,, or otherwise rotated and/or translated, as shown by arrows, out of the deployment site. Figure 28d illustrates that the endoluminal cavity **6** can remain in the absence of the device **2**. The endoluminal cavity **6** can be completely or partially filled with a material listed herein, such as a bone morphogenic protein or morselized bone.

[0097] Figures 29a through 29d illustrate variations of the distal end **60** of the expandable attachment device **2** during or after removal from or repositioning in a treatment site. The device **2** can be removed from a bone in which the device **2** has been deployed and through which bone has grown.

[0098] The expandable section **30**, and/or any other hollow section of the device **2** with fluid communication with the outside of the device **2**, can be more than about 75% filled, for example about 100% filled with in-grown bone, for example femoral head cancellous bone. The expandable section **30** and hollows of the device **2** can be packed with bone during or after implantation. Merely for example, the deployment site can be in or near a trochanter.

[0099] Figure 29a illustrates that the expandable section **30** of the device **2** can be packed with in-grown bone when implanted in the target site. Figure 29b illustrates that the expandable section **30** can be partially radially compressed, as shown by arrows. The packed in-grown bone can exit the expandable section **30** via the cells in the stent configuration. Figure 29c illustrates that the expandable section can be further radially compressed, for example returning the radius of the expandable section **30** to the pre-expansion diameter, and/or an even smaller or a larger diameter than that of the pre-deployment configuration. Figure 29d illustrates that the expandable support device **2** can be rinsed and/or otherwise cleaned to remove some or all of the bone extending from the cells of the expandable section **30**.

[0100] The device **2** can be withdrawn from and/or repositioned at the target site at any point during the compression of the expandable section **30** shown in Figures 29a through 29d, but more force may be needed to withdraw the device **2** when the expandable section **30** is in an expanded configuration.

[0101] Figure 30a illustrates that a hollow channel **100** can be defined within the expandable section **30**. The hollow channel can be packed, as described herein.

[0102] Figure 30b illustrates that the expandable section **30** can have a bladder or bag **102** attached to the radially inner surfaces of any or all of the struts **40**. The bag **102** can be an open, closed (e.g., contained), or closeable structure. The bag **102** (shown filled) can be filled with any material disclosed herein, or combinations thereof, for example morselized bone or bone morphogenic protein. The bag **102** can be porous or non-porous. The bag **102** can be a textile. The bag can cover all or a portion of the expandable section **30**. The bag **102** can be partially or completely

filled (e.g., by feeding, pumping) before, during or after deployment and expansion of the device **2** in the target site.

[0103] Figure 30c illustrates that the bag **102** can be unattached to the struts **40**. For example, the bag can be loose in the hollow channel **100** or the bag can be attached to the device at one or more of the longitudinal ends of the hollow channel **100**.

[0104] Figure 30d illustrates that one or more locking rods **104** can be inserted into the expandable section **30** when the expandable section **30** is in an expanded configuration. The locking rods **104** can be oriented transversely, as shown, and/or longitudinally. The locking rod **104** can be resiliently attached to one or more struts and deploy automatically when the expandable section **30** is expanded.

[0105] Figure 31a illustrates that the locking rod **104** can be oriented longitudinally. The locking rod **104** can have distal attachment elements **106**, such as one or more threads, ribs, snaps, brads, nuts, clips or combinations thereof, at the distal end of the locking rod. The distal attachment elements **106** can be configured to engagably and releasably attach to one or more distal receiving elements **108** at the distal end of the device **2**, such as one or more threads, ribs, snaps, brads, nuts, clips, or combinations thereof.

[0106] The locking rod can have proximal attachment elements **110**, such as one or more threads, ribs, snaps, brads, nuts, clips or combinations thereof, at the proximal end of the locking rod **104**. The proximal attachment elements **110** can be configured to engagably and releasably attach to one or more proximal receiving elements **112** at the proximal end of the device **2**, such as one or more threads, ribs, snaps, brads, nuts, clips or combinations thereof.

[0107] The locking rod **104** can fix the length between the distal end and the proximal end of the expandable portion **30**. The distal attachment elements **104** can engage the distal receiving elements **106** and the proximal attachment elements **108** can engage the proximal receiving elements **110**, for example minimizing and/or substantially eliminating the radial compression and longitudinal expansion of the expandable section **30**.

[0108] Figure 31b illustrates that the locking rod can have one or more intermediate attachment elements **114** such as one or more threads, ribs, snaps, brads, nuts, clips or combinations thereof. The intermediate attachment elements **114** can be located at a position along the locking rod **104** between the distal attachment elements **106** and the proximal attachment elements **110**, for example, such that the intermediate attachment elements **114** can be between the first expandable section **36** and the second expandable section **38** during use. The intermediate attachment elements **114** can be configured to engagably and releasably attach to one or more intermediate receiving elements **116** along the device **2** between the first expandable section **36** and the second expandable section **38**. The intermediate receiving elements **116** can be one or more threads, ribs, snaps, brads, nuts, clips or combinations thereof. The intermediate attachment elements **114** can engage the

intermediate receiving elements **116**, for example, minimizing and/or substantially eliminating the shift of radial expansion to or from the first expandable section **36** from or to, respectively, the second expandable section **38**.

[0109] Any or all elements of the device and/or other devices or apparatuses described herein can be made from, for example, a single or multiple stainless steel alloys, nickel titanium alloys (e.g., Nitinol), cobalt-chrome alloys (e.g., ELGILOY® from Elgin Specialty Metals, Elgin, IL; CONICHROME® from Carpenter Metals Corp., Wyomissing, PA), nickel-cobalt alloys (e.g., MP35N® from Magellan Industrial Trading Company, Inc., Westport, CT), molybdenum alloys (e.g., molybdenum TZM alloy, for example as disclosed in International Pub. No. WO 03/082363 A2, published 9 October 2003, which is herein incorporated by reference in its entirety), tungsten-rhenium alloys, for example, as disclosed in International Pub. No. WO 03/082363, polymers such as polyethylene teraphathalate (PET), polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), poly ester amide (PEA), polypropylene, aromatic polyesters, such as liquid crystal polymers (e.g., Vectran, from Kuraray Co., Ltd., Tokyo, Japan), ultra high molecular weight polyethylene (i.e., extended chain, high-modulus or high-performance polyethylene) fiber and/or yarn (e.g., SPECTRA® Fiber and SPECTRA® Guard, from Honeywell International, Inc., Morris Township, NJ, or DYNEEMA® from Royal DSM N.V., Heerlen, the Netherlands), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ketone (PEK), polyether ether ketone (PEEK), poly ether ketone ketone (PEKK) (also poly aryl ether ketone ketone), nylon, polyether-block co-polyamide polymers (e.g., PEBAX® from ATOFINA, Paris, France), aliphatic polyether polyurethanes (e.g., TECOFLEX® from Thermedics Polymer Products, Wilmington, MA), polyvinyl chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), absorbable or resorbable polymers such as polyglycolic acid (PGA), poly-L-glycolic acid (PLGA), polylactic acid (PLA), poly-L-lactic acid (PLLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic, radioactive, radiopaque materials, a biomaterial (e.g., cadaver tissue, collagen, allograft, autograft, xenograft, bone cement, morselized bone, osteogenic powder, beads of bone) any of the other materials listed herein or combinations thereof. Examples of radiopaque materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys, tantalum and gold.

[0110] Any or all elements of the device and/or other devices or apparatuses described herein, can be, have, and/or be completely or partially coated with agents and/or a matrix a matrix for cell ingrowth or used with a fabric, for example a covering (not shown) that acts as a matrix for cell ingrowth. The matrix and/or fabric can be, for example, polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), poly ester amide (PEA), polypropylene, PTFE, ePTFE, nylon, extruded collagen, silicone, any other material disclosed herein, or combinations thereof.

[0111] The device and/or elements of the device and/or other devices or apparatuses described herein and/or the fabric can be filled, coated, layered and/or otherwise made with and/or from cements, fillers, glues, and/or an agent delivery matrix known to one having ordinary skill in the art and/or a therapeutic and/or diagnostic agent. Any of these cements and/or fillers and/or glues can be osteogenic and osteoinductive growth factors.

[0112] Examples of such cements and/or fillers includes bone chips, demineralized bone matrix (DBM), calcium sulfate, coralline hydroxyapatite, biocoral, tricalcium phosphate, calcium phosphate, polymethyl methacrylate (PMMA), biodegradable ceramics, bioactive glasses, hyaluronic acid, lactoferrin, bone morphogenic proteins (BMPs) such as recombinant human bone morphogenetic proteins (rhBMPs), other materials described herein, or combinations thereof.

[0113] The agents within these matrices can include any agent disclosed herein or combinations thereof, including radioactive materials; radiopaque materials; cytogenic agents; cytotoxic agents; cytostatic agents; thrombogenic agents, for example polyurethane, cellulose acetate polymer mixed with bismuth trioxide, and ethylene vinyl alcohol; lubricious, hydrophilic materials; phosphor cholene; anti-inflammatory agents, for example non-steroidal anti-inflammatories (NSAIDs) such as cyclooxygenase-1 (COX-1) inhibitors (e.g., acetylsalicylic acid, for example ASPIRIN® from Bayer AG, Leverkusen, Germany; ibuprofen, for example ADVIL® from Wyeth, Collegeville, PA; indomethacin; mefenamic acid), COX-2 inhibitors (e.g., VIOXX® from Merck & Co., Inc., Whitehouse Station, NJ; CELEBREX® from Pharmacia Corp., Peapack, NJ; COX-1 inhibitors); immunosuppressive agents, for example Sirolimus (RAPAMUNE®, from Wyeth, Collegeville, PA), or matrix metalloproteinase (MMP) inhibitors (e.g., tetracycline and tetracycline derivatives) that act early within the pathways of an inflammatory response. Examples of other agents are provided in Walton et al, Inhibition of Prostoglandin E_2 Synthesis in Abdominal Aortic Aneurysms, *Circulation*, July 6, 1999, 48-54; Tambiah et al, Provocation of Experimental Aortic Inflammation Mediators and Chlamydia Pneumoniae, *Brit. J. Surgery* 88 (7), 935-940; Franklin et al, Uptake of Tetracycline by Aortic Aneurysm Wall and Its Effect on Inflammation and Proteolysis, *Brit. J. Surgery* 86 (6), 771-775; Xu et al, Sp1 Increases Expression of Cyclooxygenase-2 in Hypoxic Vascular Endothelium, *J. Biological Chemistry* 275 (32) 24583-24589; and Pyo et al, Targeted Gene Disruption of Matrix Metalloproteinase-9 (Gelatinase B) Suppresses Development of Experimental Abdominal Aortic Aneurysms, *J. Clinical Investigation* 105 (11), 1641-1649 which are all incorporated by reference in their entireties.

[0114] Other examples of fractures types that can be treated with the disclosed device and method include Greenstick fractures, transverse fractures, fractures across growth plates, simple fractures, wedge fractures, complex fractures, compound fractures, complete fractures, incomplete fractures, linear fractures, spiral fractures, transverse fractures, oblique fractures, comminuted fractures, impacted fractures, and soft tissue tears, separations (e.g., avulsion fracture), sprains, and

combinations thereof. Plastic deformations of bones can also be treated with the disclosed device and method.

[0115] Other examples of bones that can be treated with the disclosed device and method include the fingers (e.g., phalanges), hands (e.g., metacarpals, carpus), toes (e.g., tarsals), feet (metatarsals, tarsus), legs(e.g., femur, tibia, fibula), arms (e.g., humerus, radius, ulna), scapula, coccyx, pelvis, clavicle, scapula, patella, sternum, ribs, or combinations thereof. For example, the device can be used in the femoral neck, femoral shaft, proximal or distal tibia or the shaft of the tibia, the humerus, the forearm, the ankle, small bones, the clavicle, and for revision surgery, such as hoip revision surgery.

[0116] Any elements described herein as singular can be pluralized (i.e., anything described as "one" can be more than one). Any species element of a genus element can have the characteristics or elements of any other species element of that genus. The above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination.

CLAIMS

We Claim:

1. A method for repairing a bone fracture comprising:

inserting into an endoluminal channel a device having a first radially expandable portion and a second radially expandable portion, wherein the device has an unexpandable length between the first radially expandable portion and the second radially expandable portion..

2. The method of Claim 1, further comprising positioning the first radially expandable portion on a first side of the fracture.

3. The method of Claim 2, further comprising positioning the second radially expandable portion on a second side of the fracture.

4. The method of Claim 3, further comprising radially expanding the first radially expandable portion.

5. The method of Claim 4, further comprising radially expanding the second radially expandable portion.

6. The method of Claim 1, further comprising radially expanding the first radially expandable portion.

7. The method of Claim 6, further comprising radially expanding the second radially expandable portion.

8. The method of Claim 1, further comprising inserting a fixation device through the bone and the first radially expandable portion.

9. The method of Claim 5, further comprising inserting a fixation device through the bone and the first radially expandable portion.

10. The method of Claim 6, wherein radially expanding the first radially expandable portion comprises deforming the first radially expandable portion to substantially fit an inner contour of the endoluminal channel.

11. The method of Claim 6, further comprising radially contracting the first radially expandable portion, and further comprising repositioning the device in the endoluminal channel or removing the device from the endoluminal channel.

12. The method of Claim 6, wherein the first radially expandable portion is substantially hollow, and further comprising filling the first radially expandable portion with a filler.

13. The method of Claim 12, wherein the filler comprises bone.

14. The method of Claim 12, wherein the filler comprises a protein.

15. The method of Claim 12, wherein filling comprises filling into a contained bladder.

16. The method of Claim 6, further comprising locking the first radially expandable portion in an expanded configuration.

17. A method for repairing a bone fracture comprising:

inserting into an endoluminal channel a device having a first radially expandable portion and a second radially expandable portion.

18. The method of Claim 17, further comprising radially expanding the first radially expandable portion and the second radially expandable portion.

19. The method of Claim 18, wherein inserting comprises screwing the device into the bone.

20. A method for repairing a bone fracture comprising:

inserting into an endoluminal channel a support element having a first radially expandable portion at a first length along the support element and wherein the expandable portion defines a hollow channel,

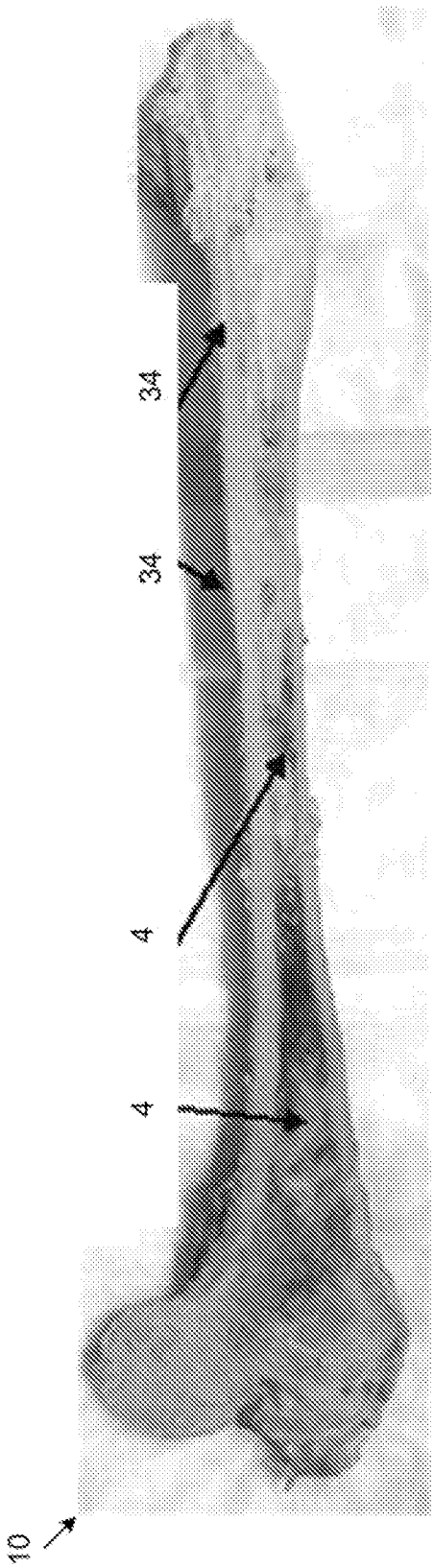
radially expanding the first radially expandable portion,

inserting a locking rod into the hollow channel, and

attaching the locking rod to the support element distal and proximal to the first radially expandable portion.

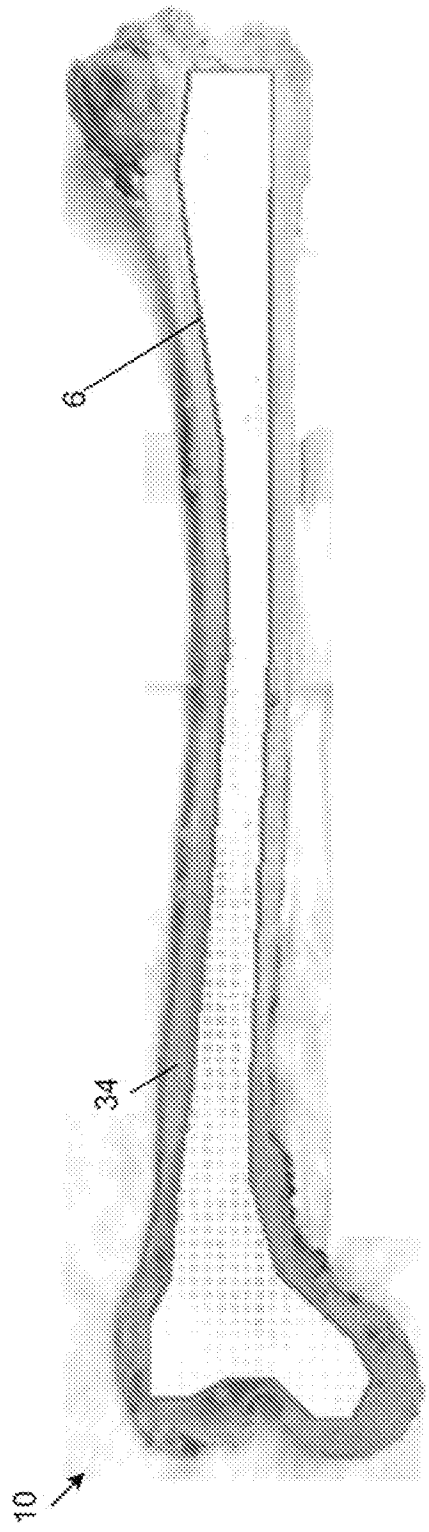
21. The method of Claim 20, further comprising filling the hollow channel with a filler.

22. the method of Claim 20, wherein the support element has a second radially expandable portion at a second length along the support element, the method further comprising radially expanding the second radially expandable portion, and attaching the locking rod to the support element distal and proximal to the second radially expandable portion.



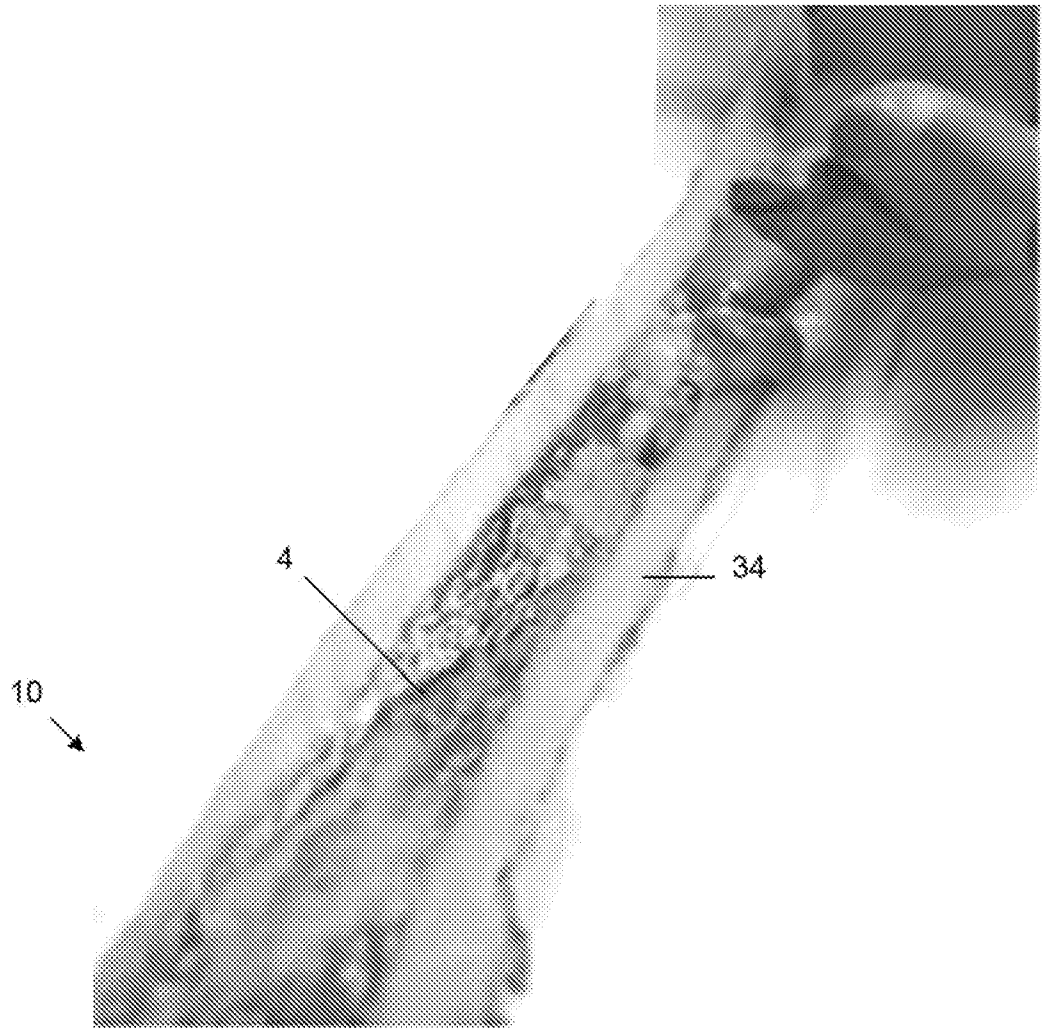
NOT INVENTION

Fig. 1

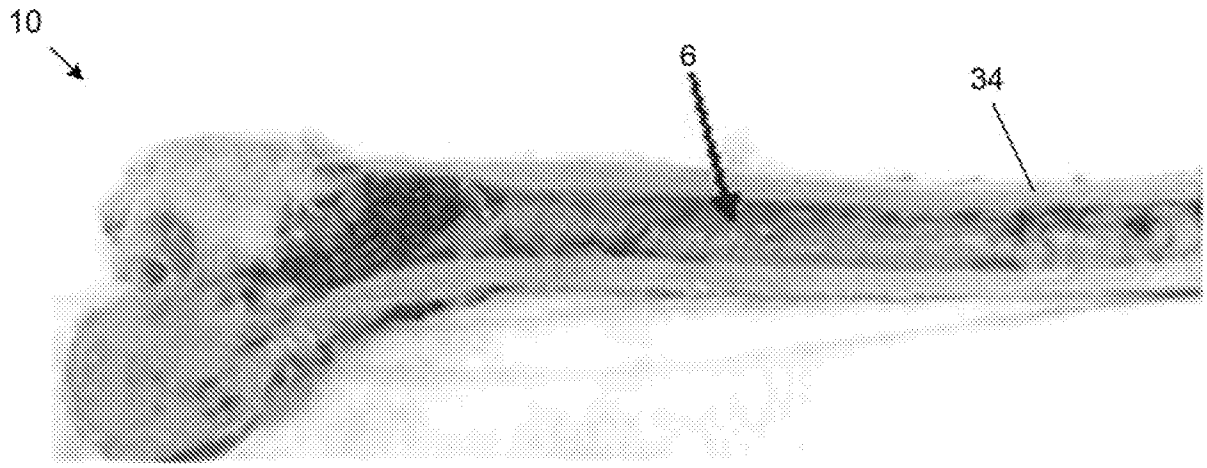


NOT INVENTION

Fig. 2



NOT INVENTION
Fig. 3



NOT INVENTION
Fig. 4

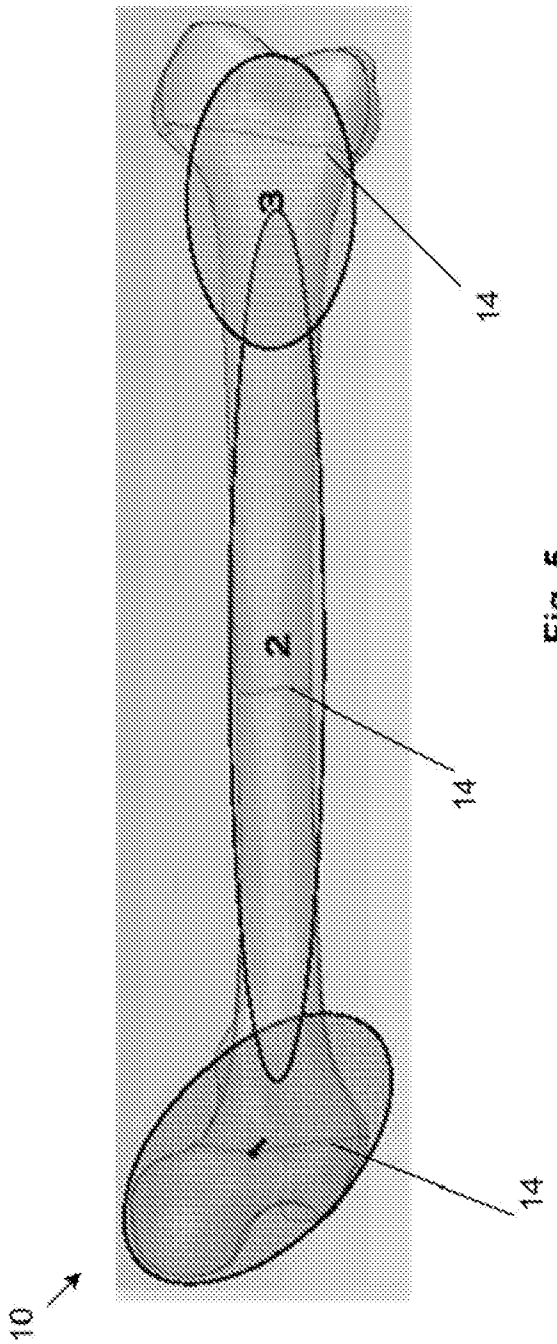


Fig. 5

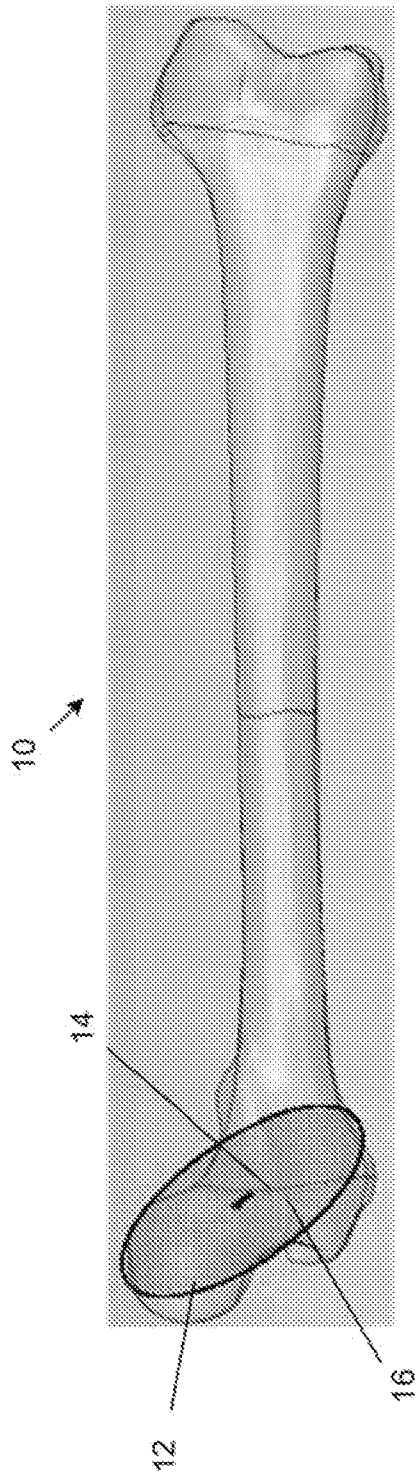


Fig. 6

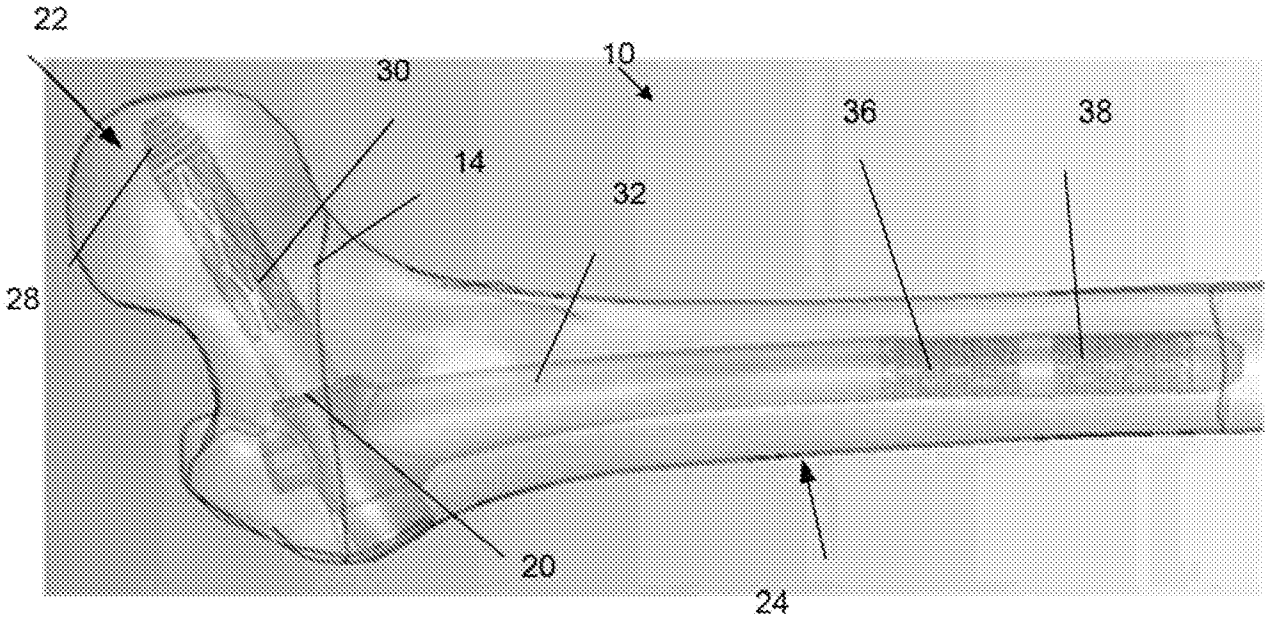


Fig. 7

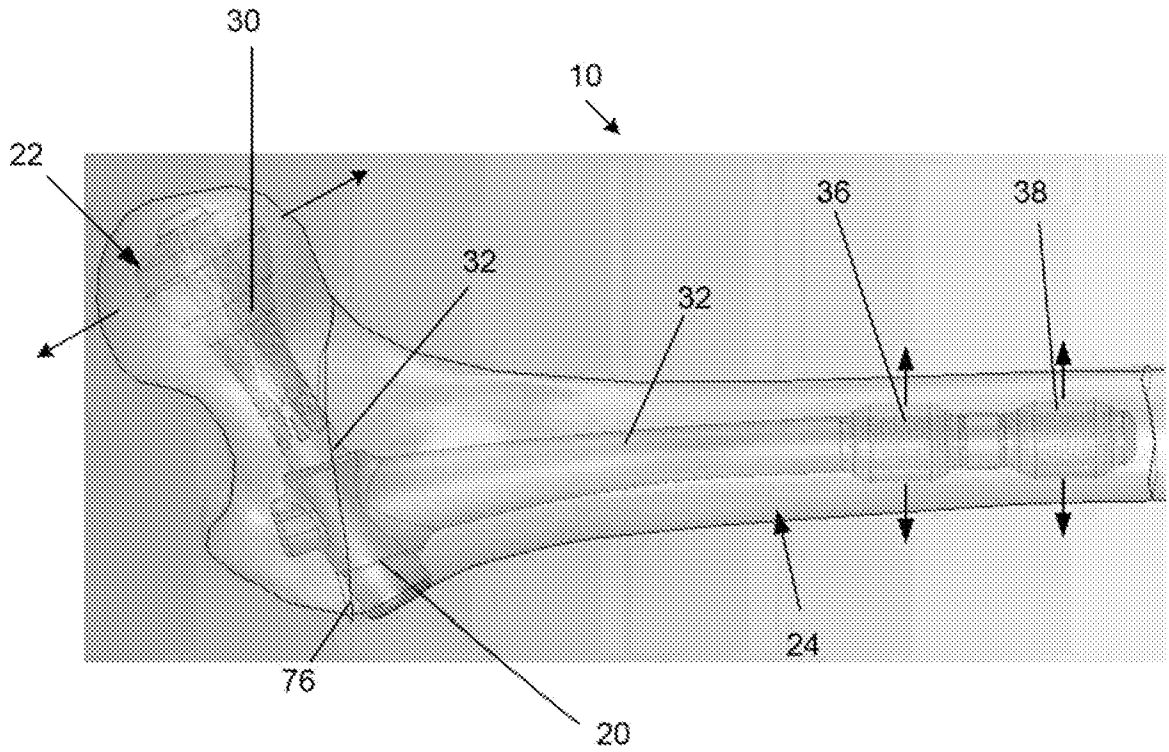


Fig. 8

Fig. 9a

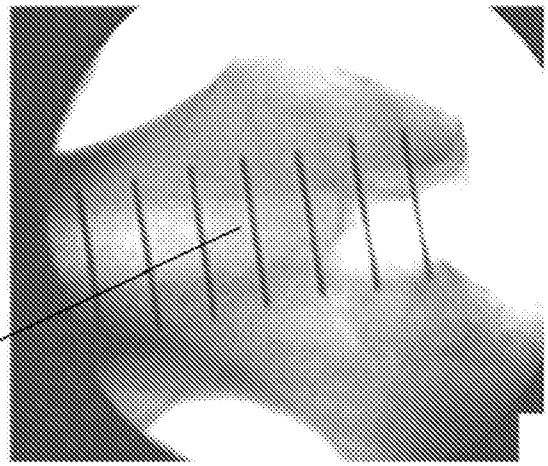


Fig. 9b

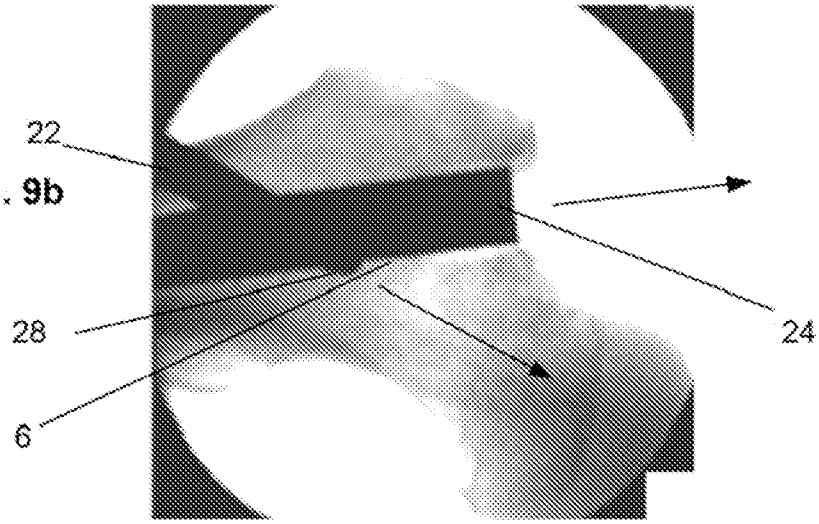
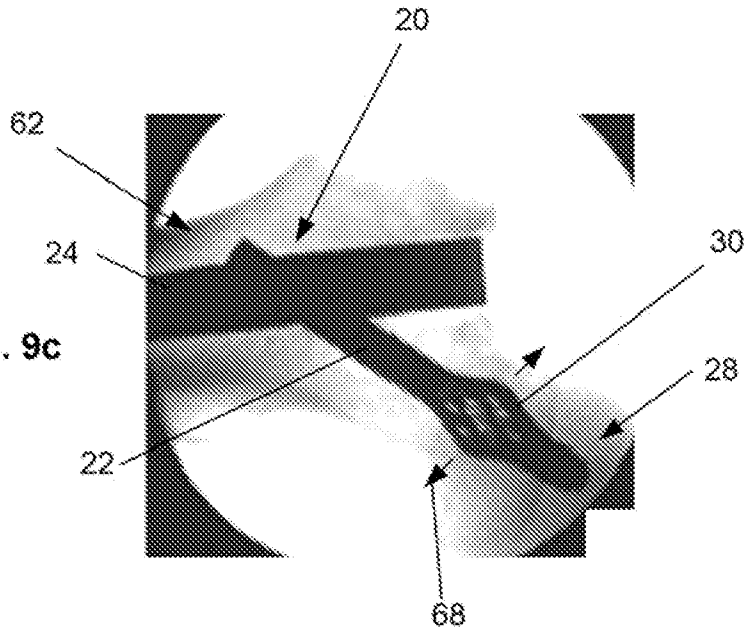


Fig. 9c



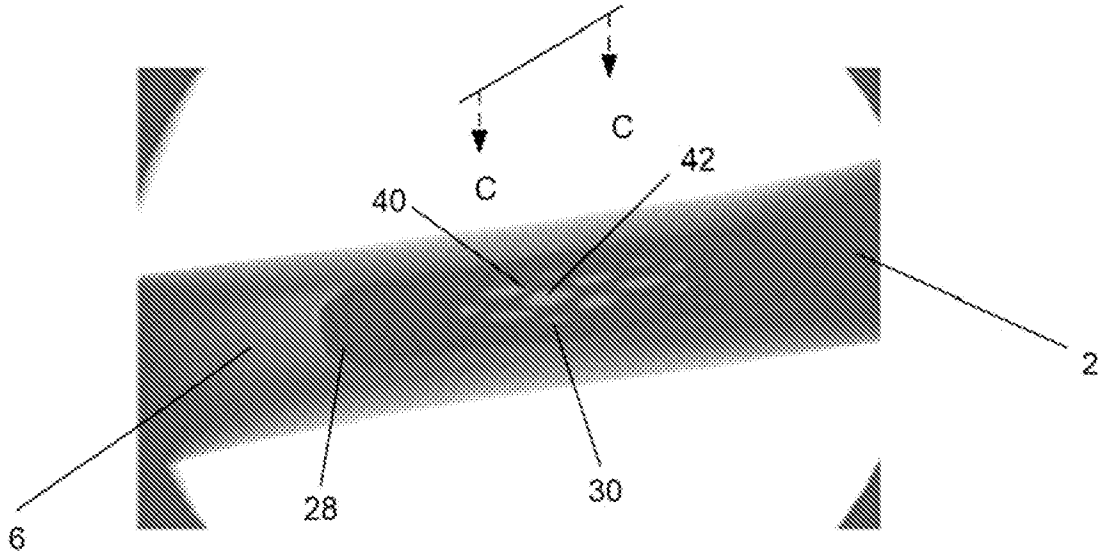


Fig. 10a

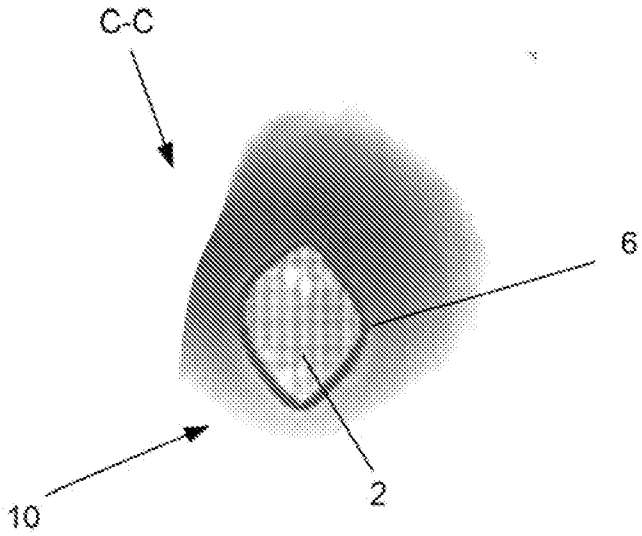


Fig. 10b

Fig. 11a

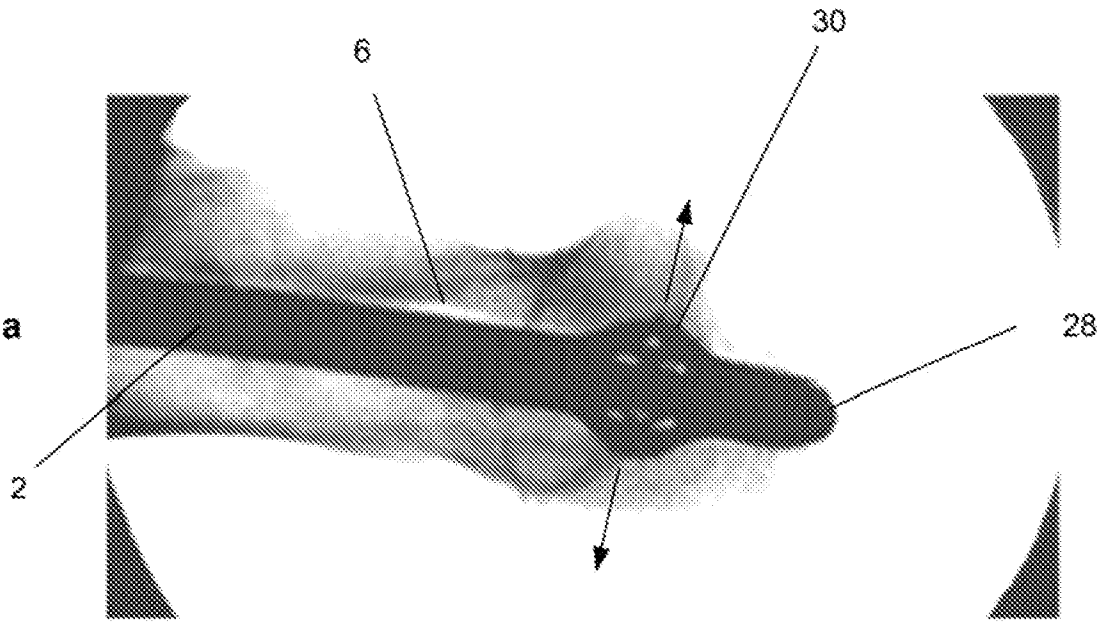
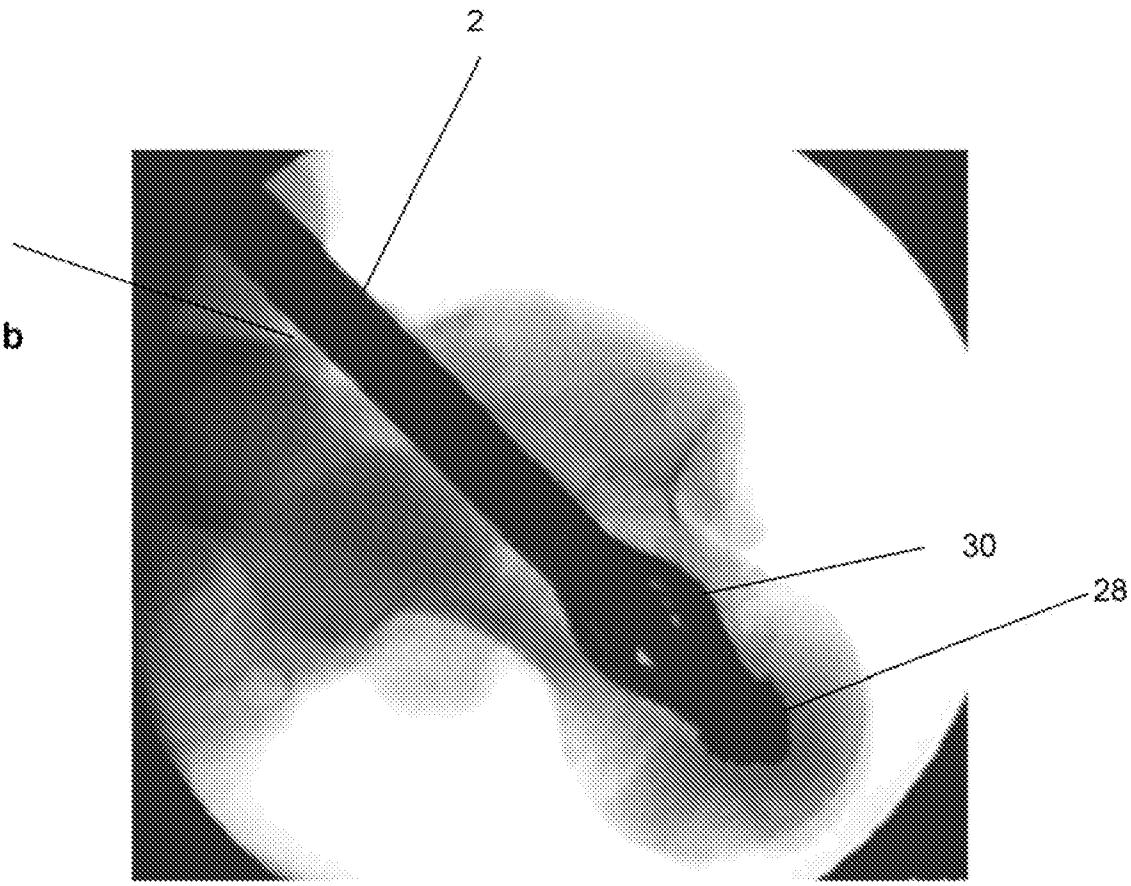


Fig. 11b



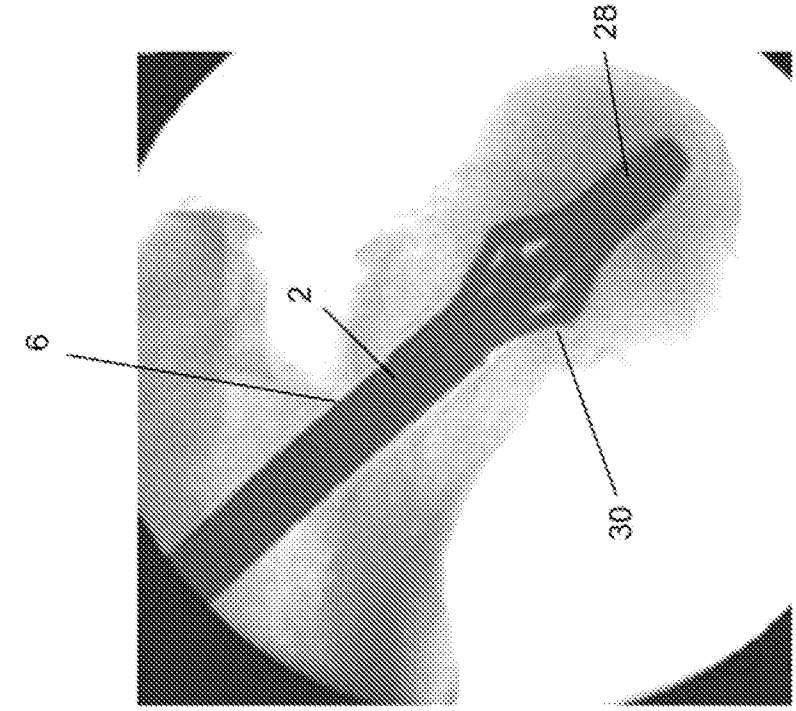


Fig. 12b

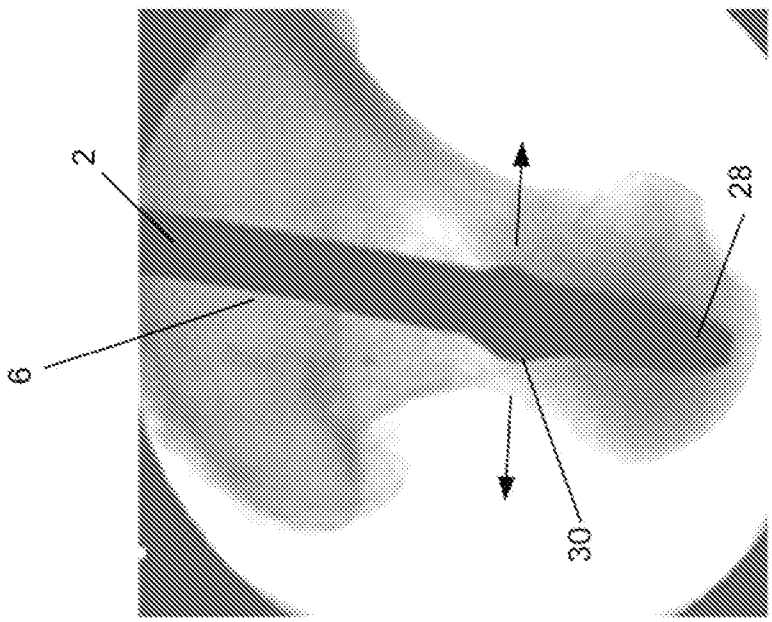


Fig. 12a

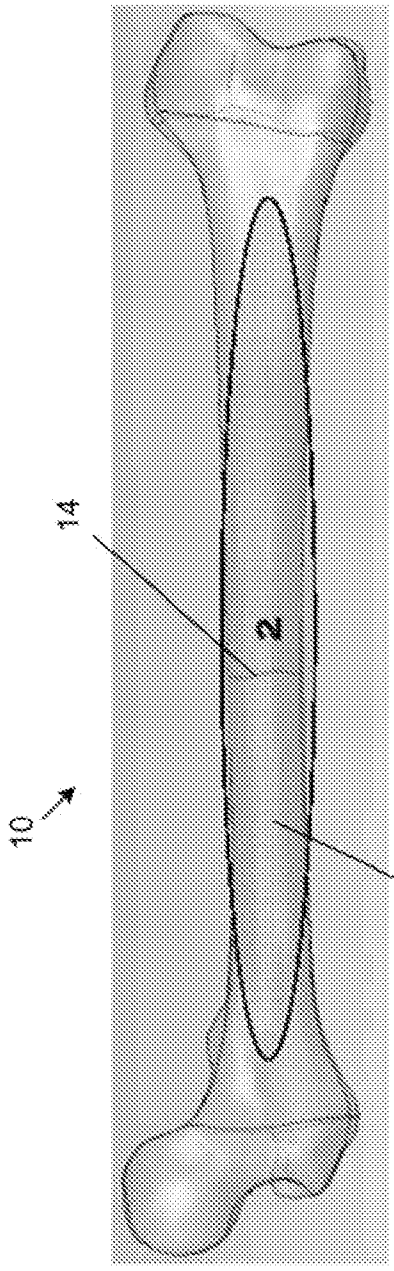


Fig. 13

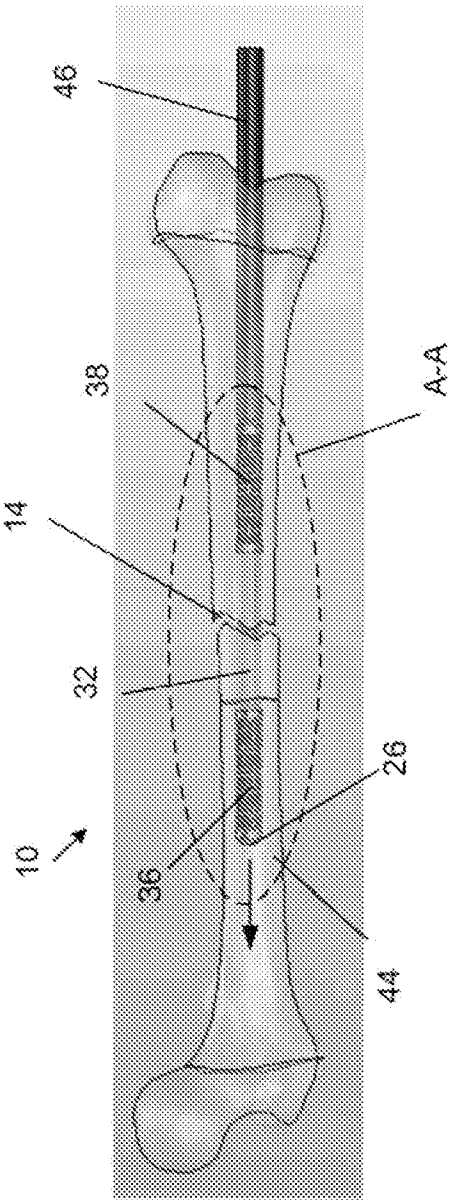


Fig. 14

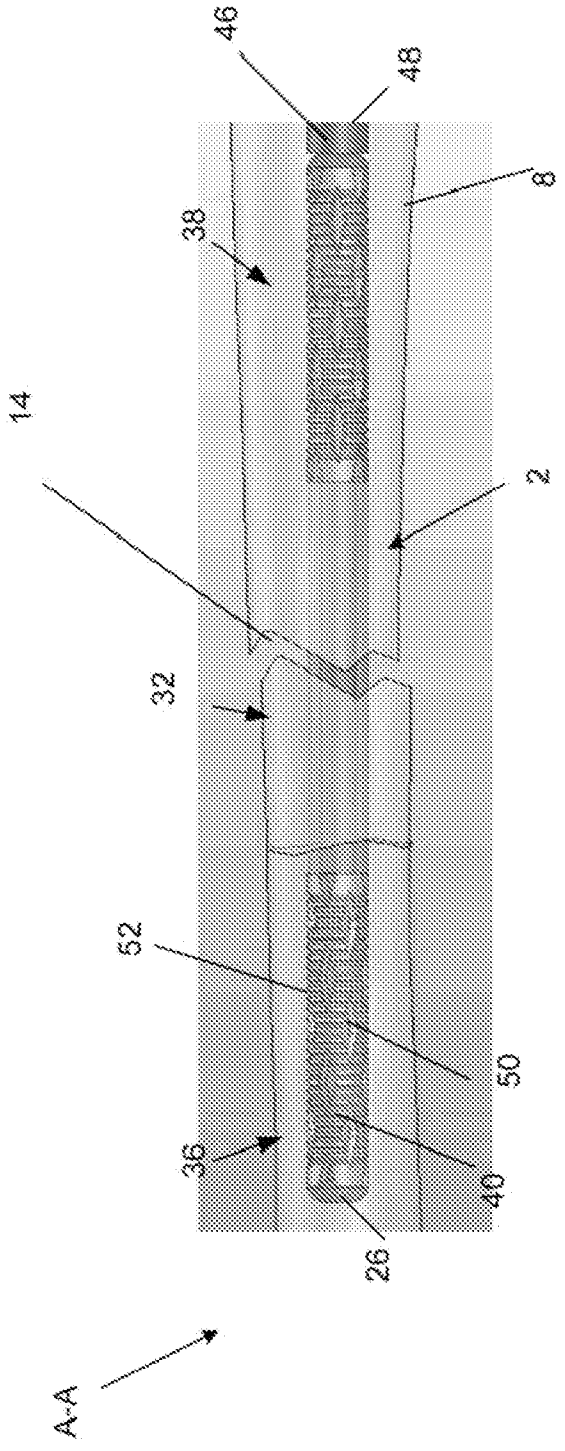


Fig. 15

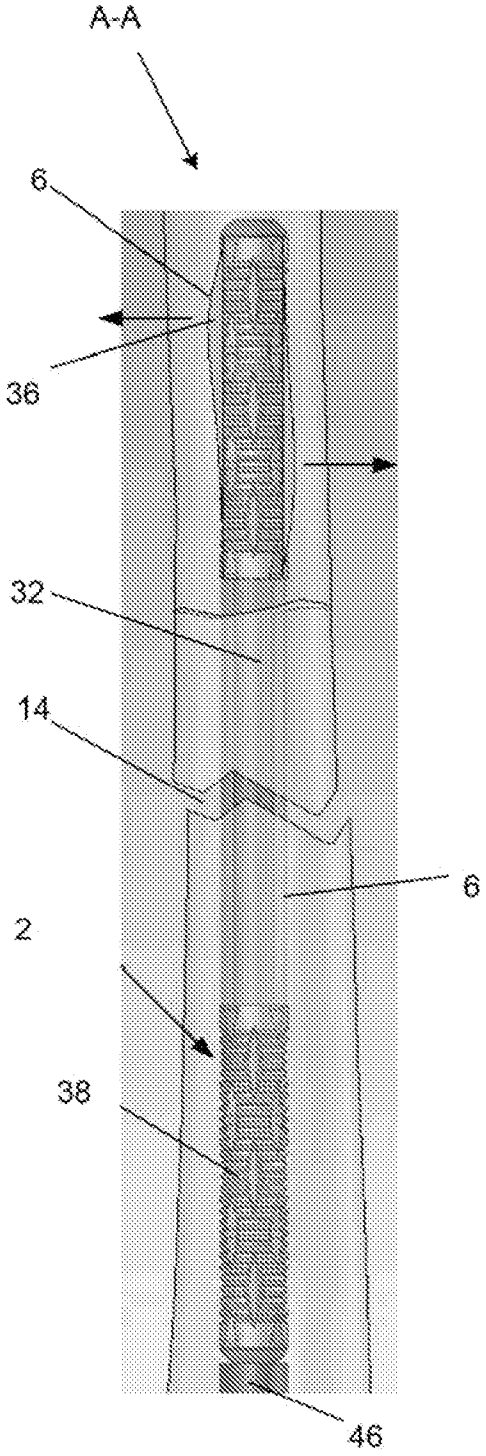


Fig. 16

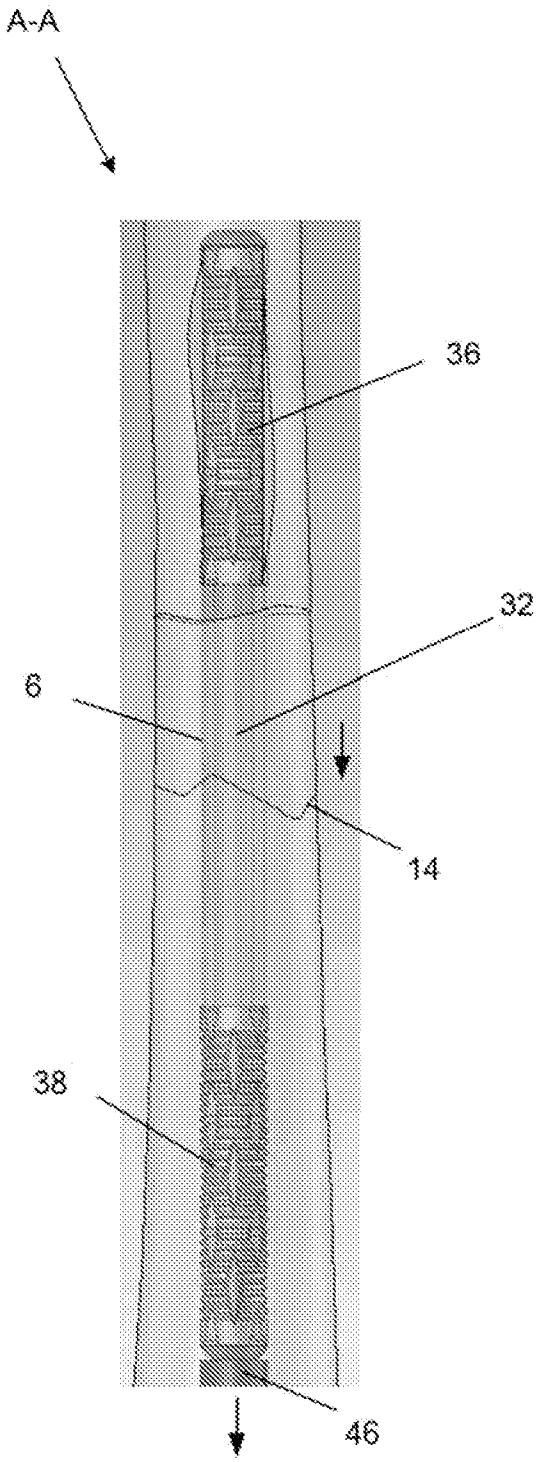


Fig. 17

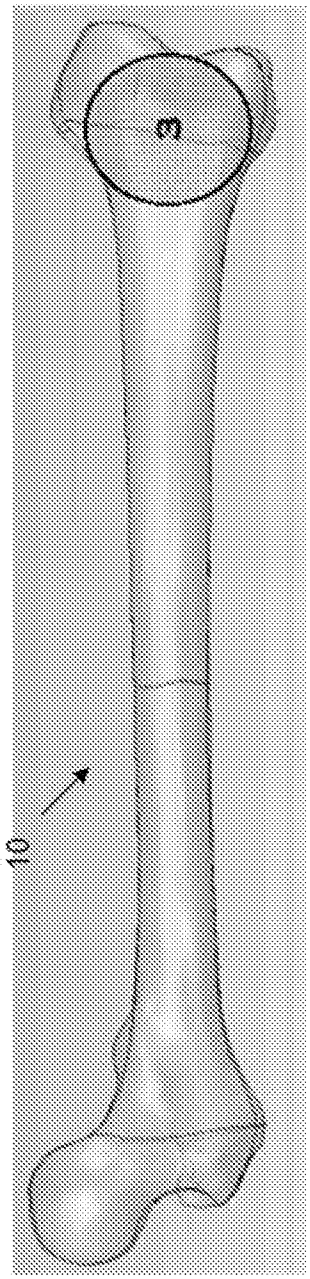


Fig. 18

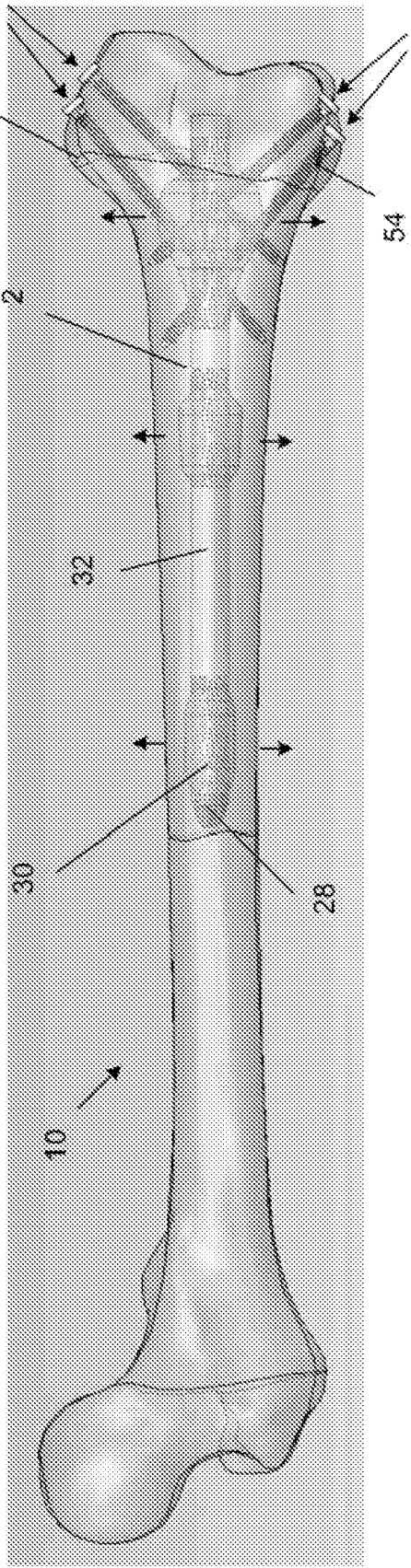


Fig. 19

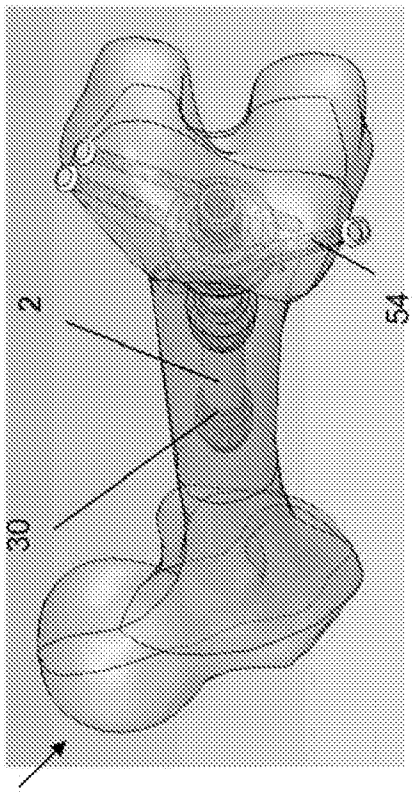


Fig. 20

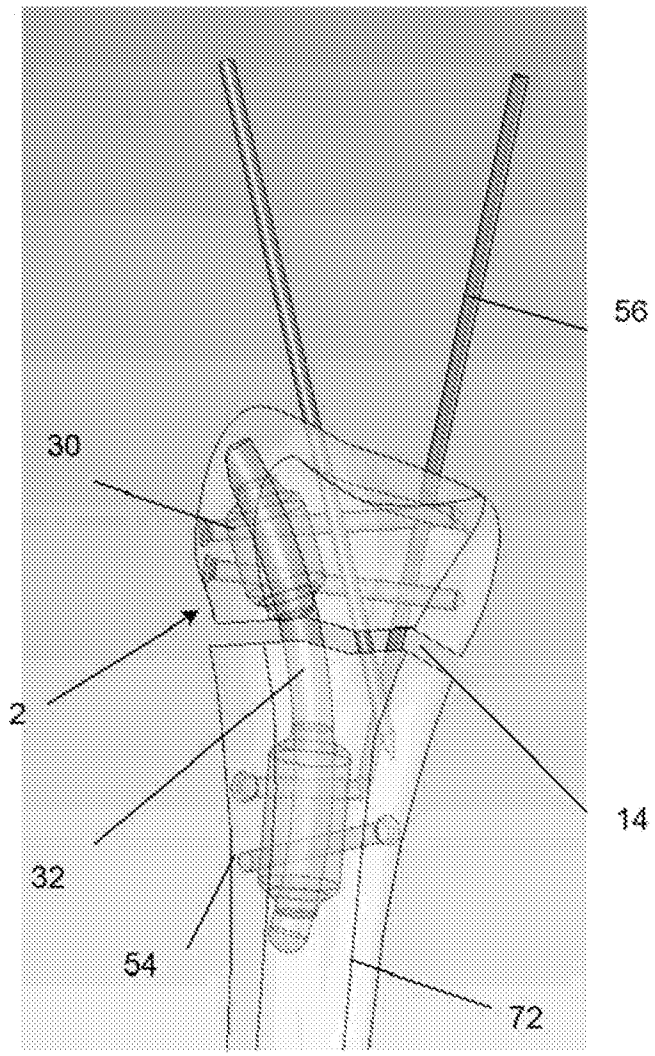


Fig. 21

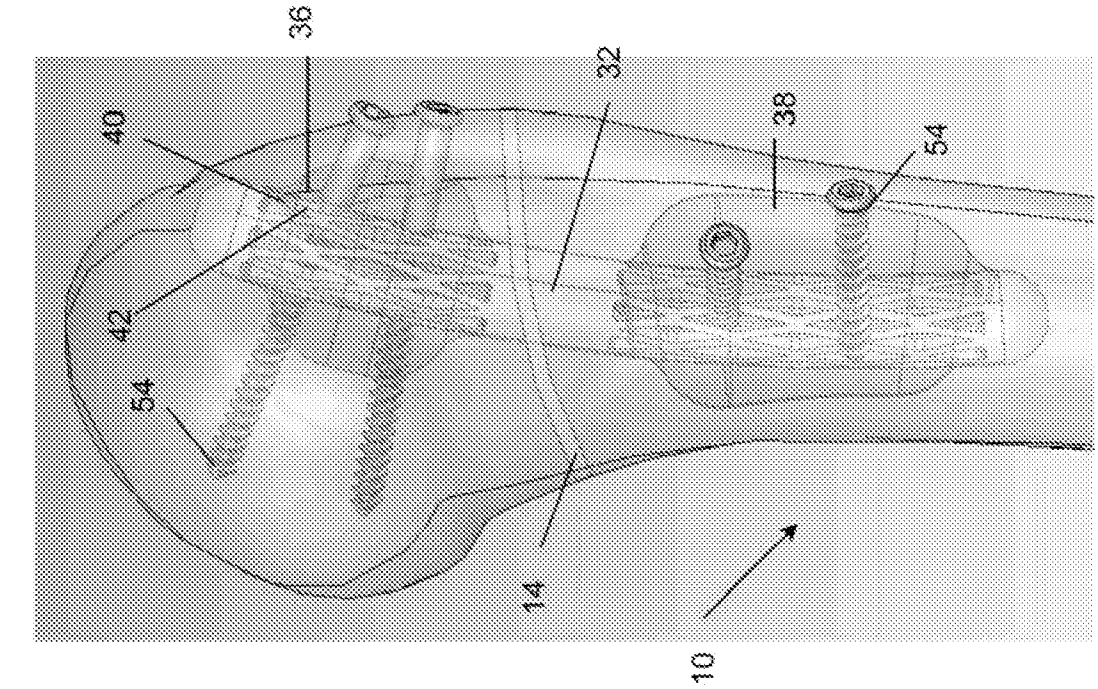


Fig. 22c

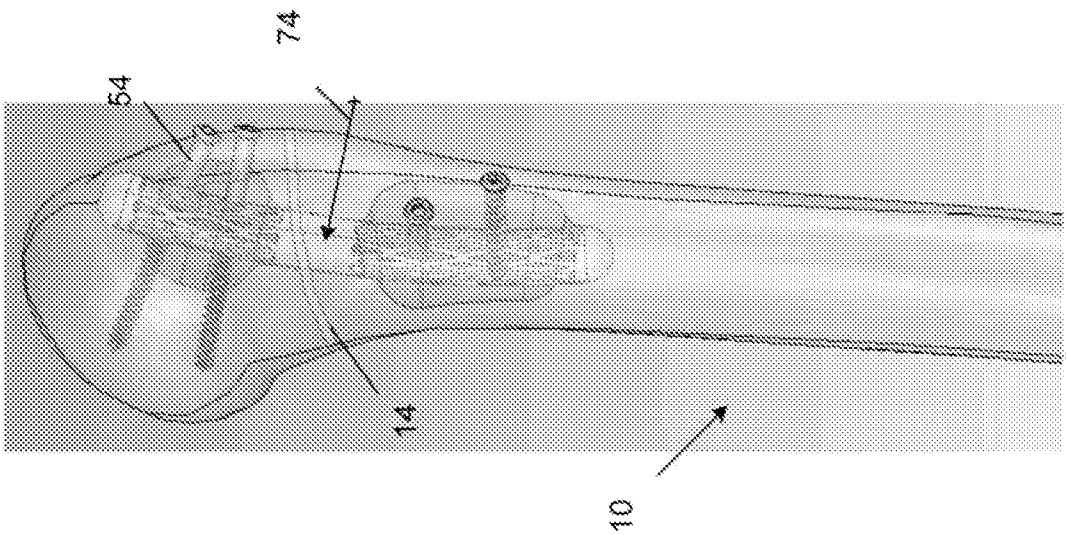


Fig. 22b

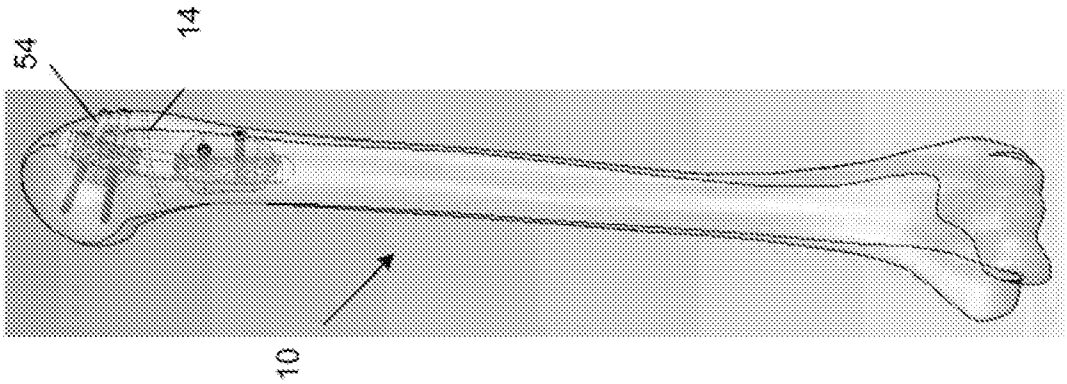


Fig. 22a

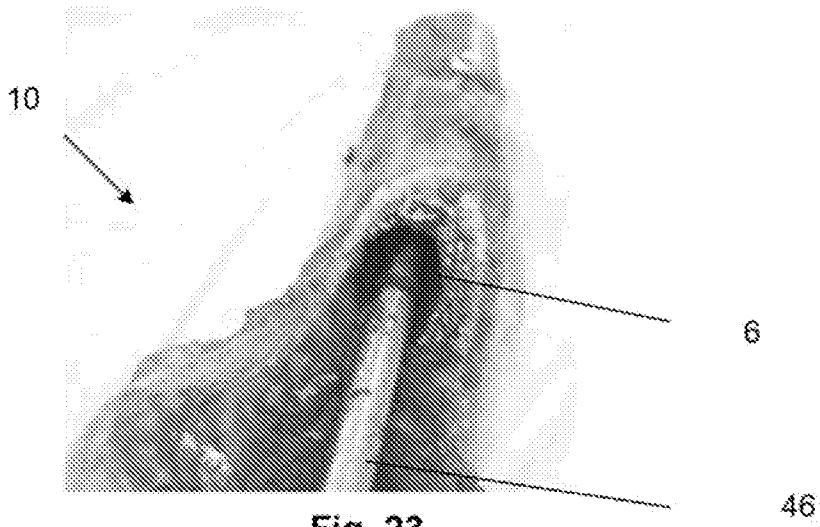


Fig. 23

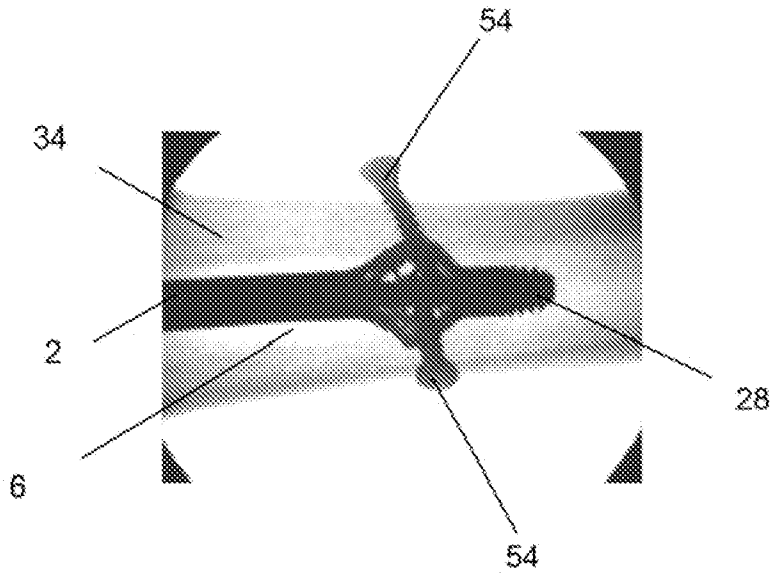


Fig. 24

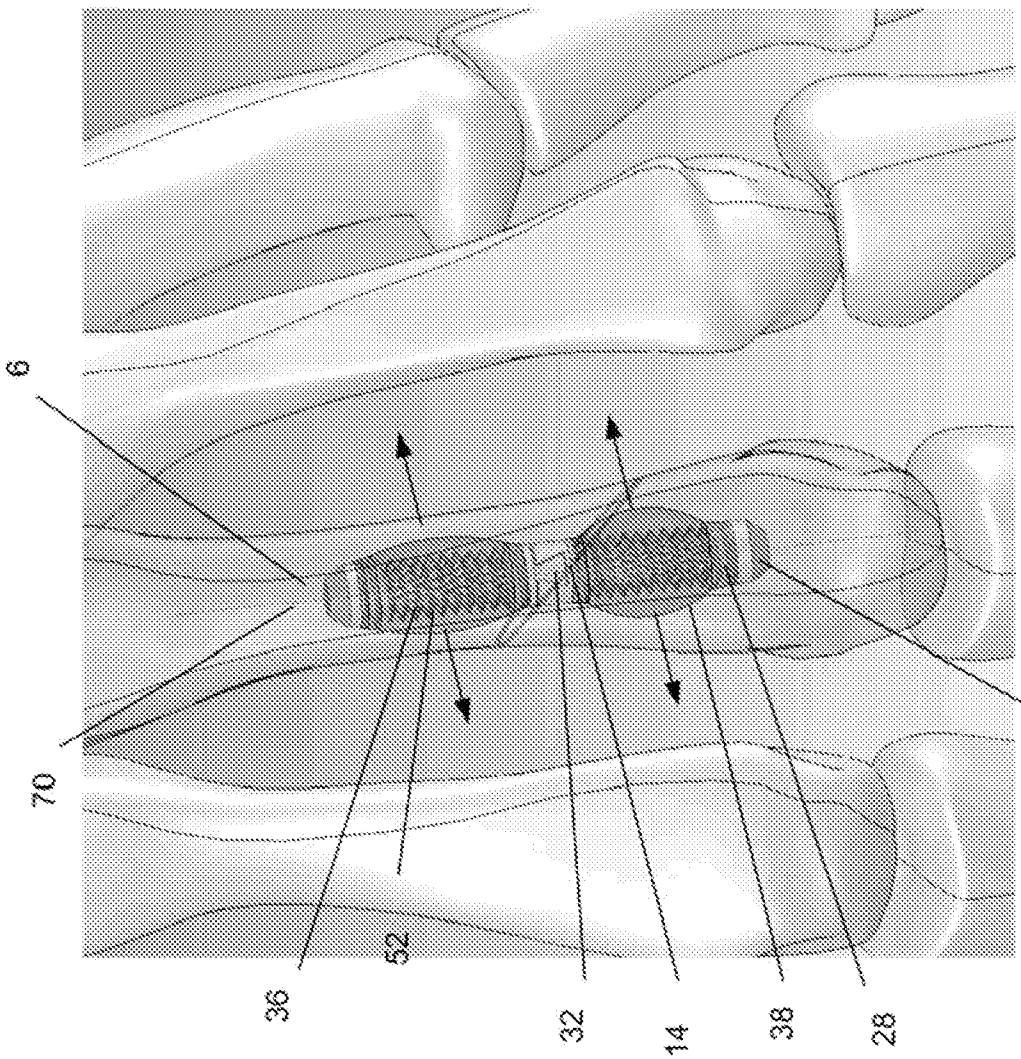


Fig. 25b

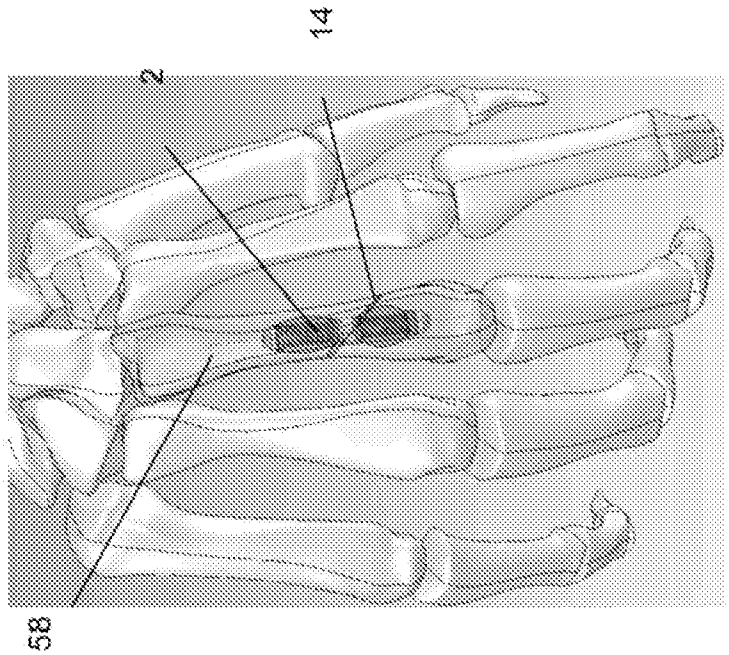


Fig. 25a

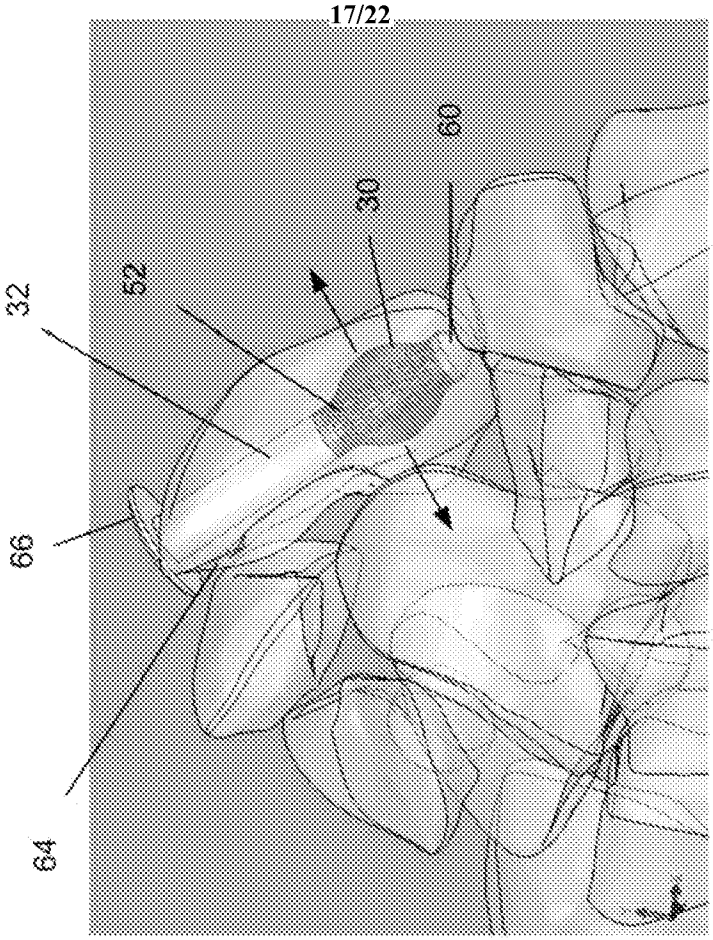


Fig. 26b

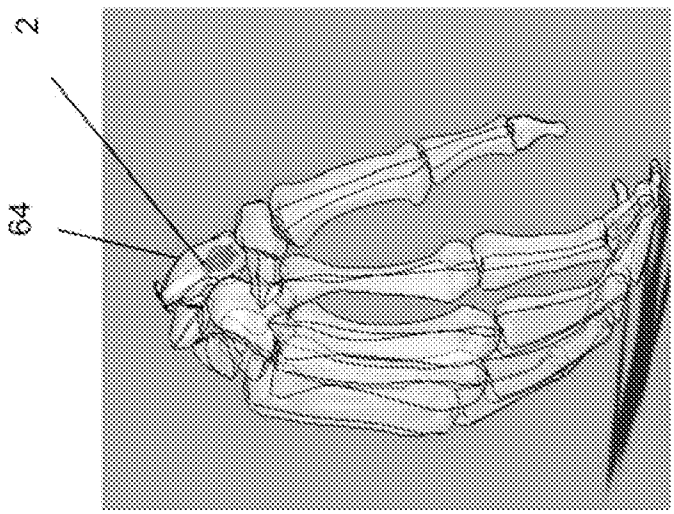


Fig. 26a

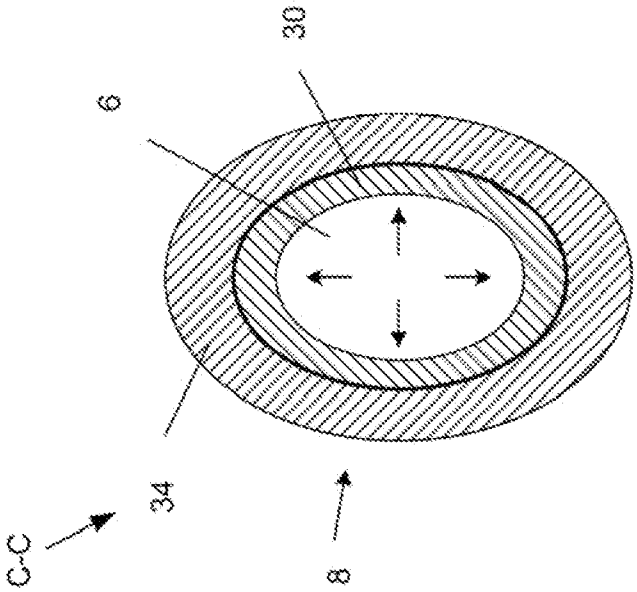


Fig. 27b

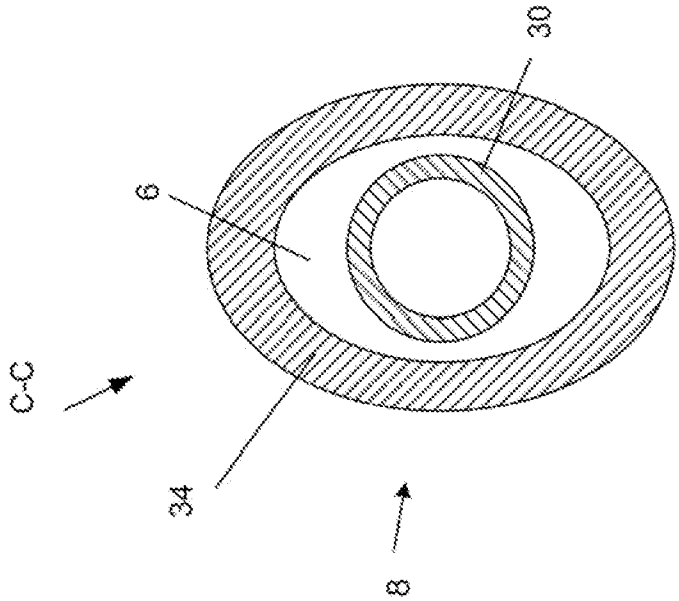


Fig. 27a

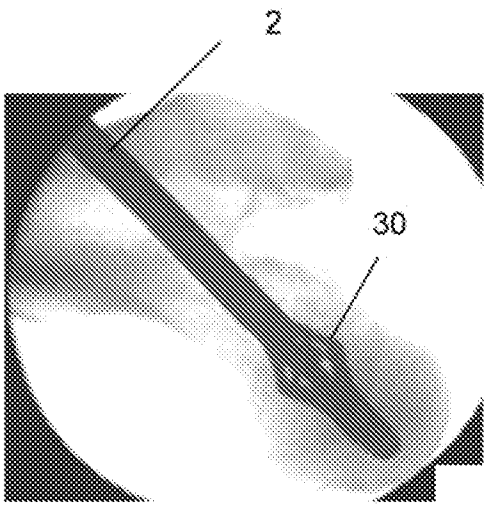


Fig. 28a

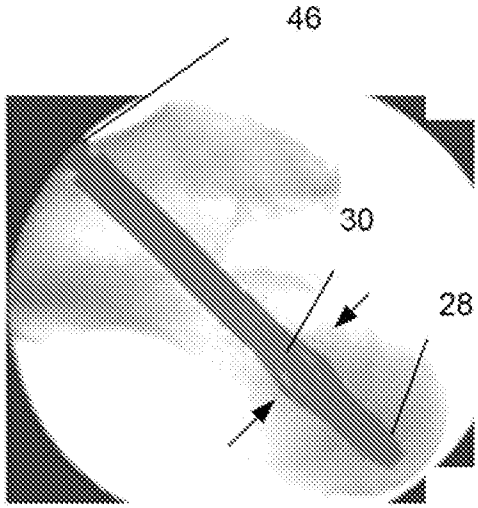


Fig. 28b

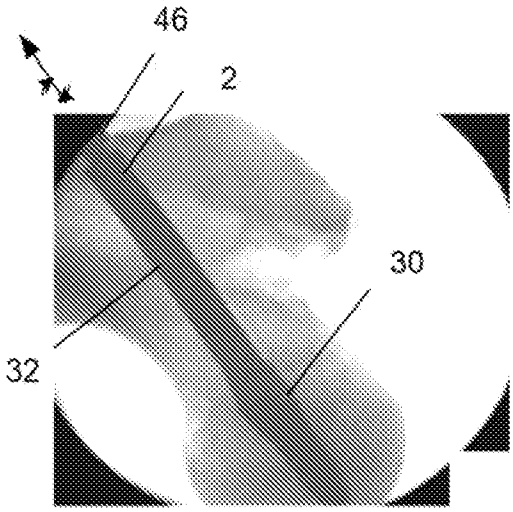


Fig. 28c

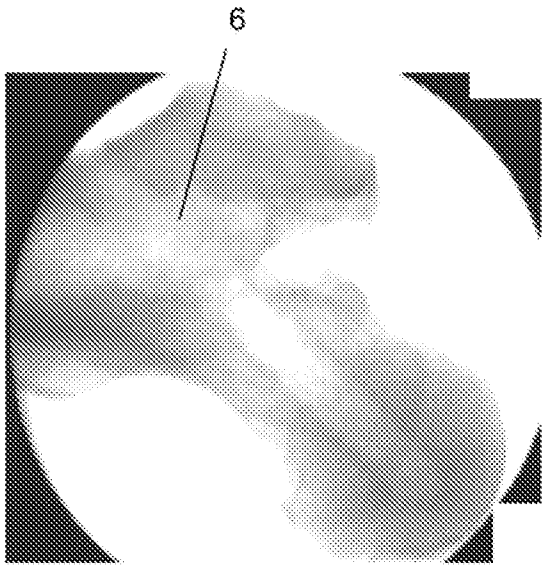


Fig. 28d

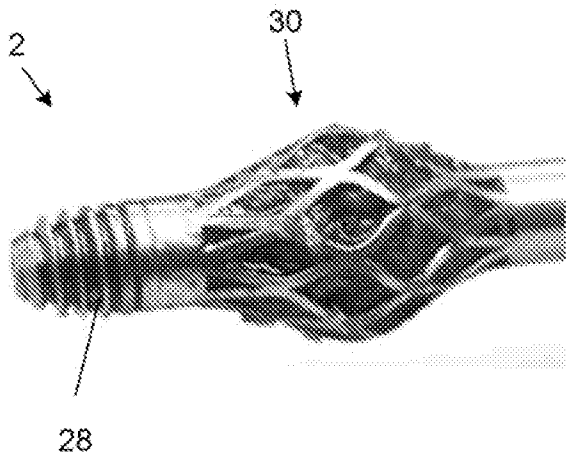


Fig. 29a

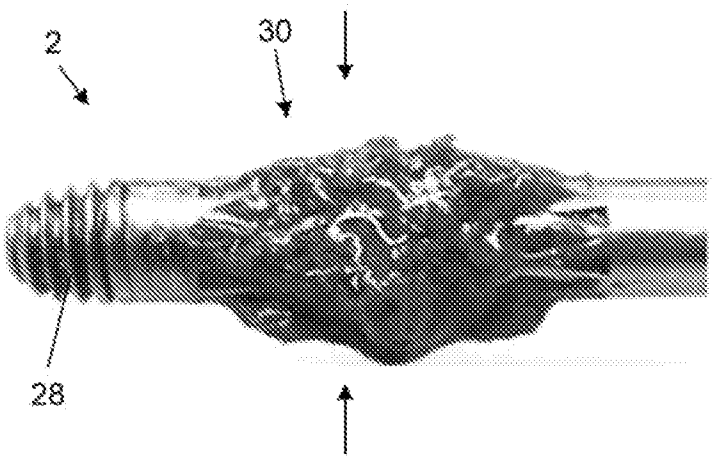


Fig. 29b

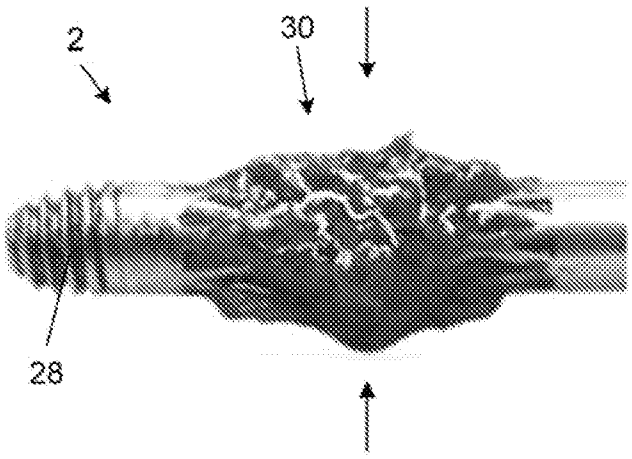


Fig. 29c

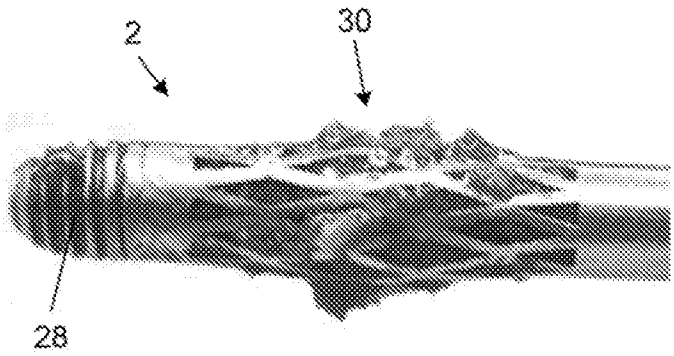


Fig. 29d

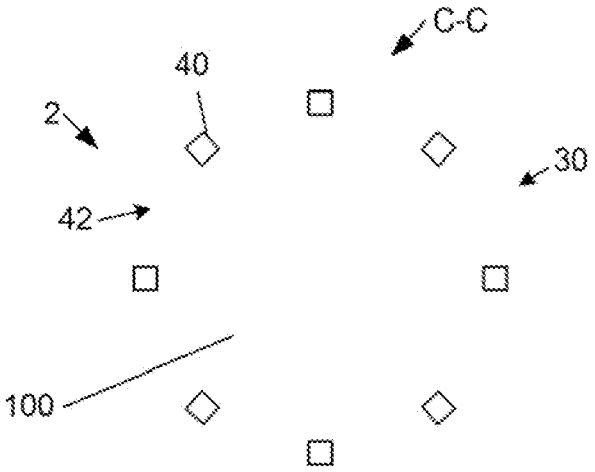


Fig. 30a

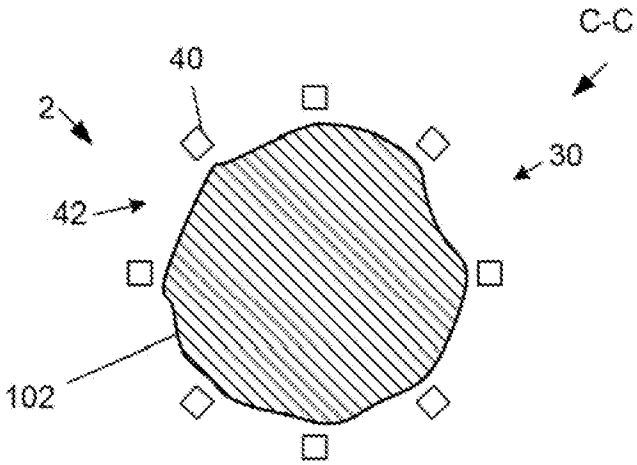


Fig. 30c

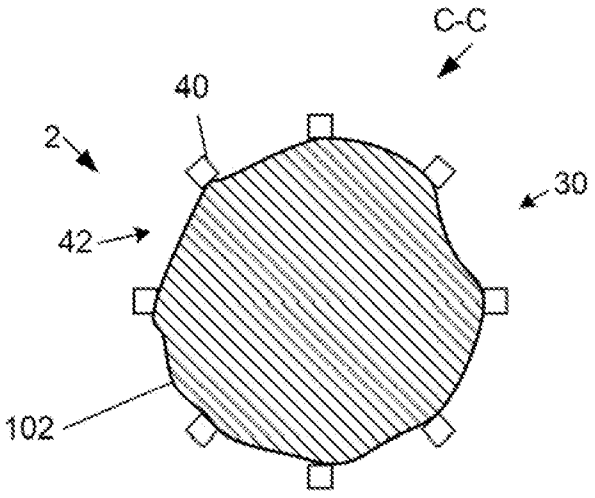


Fig. 30b

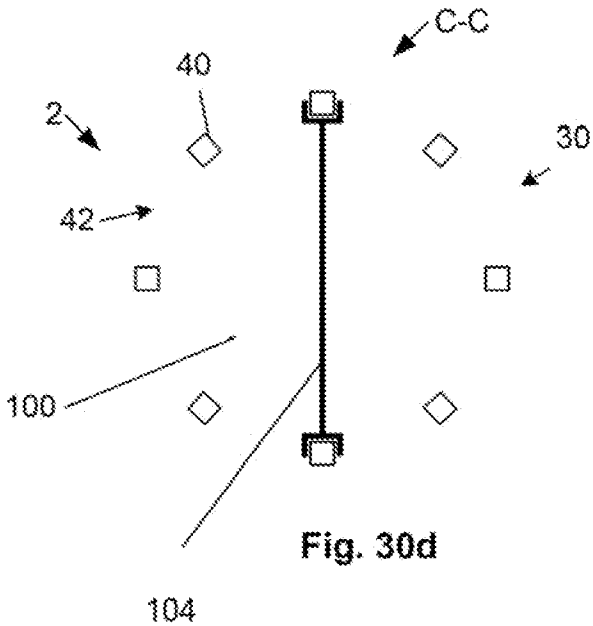


Fig. 30d

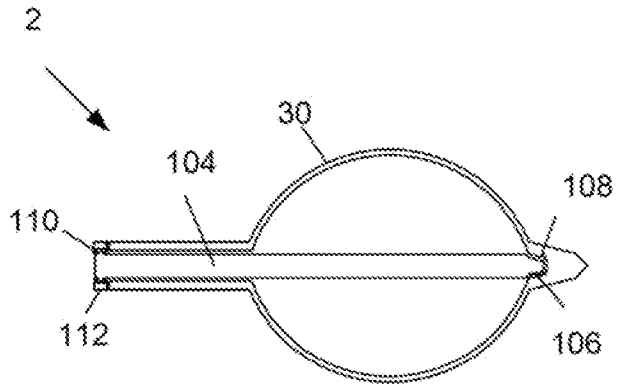


Fig. 31a

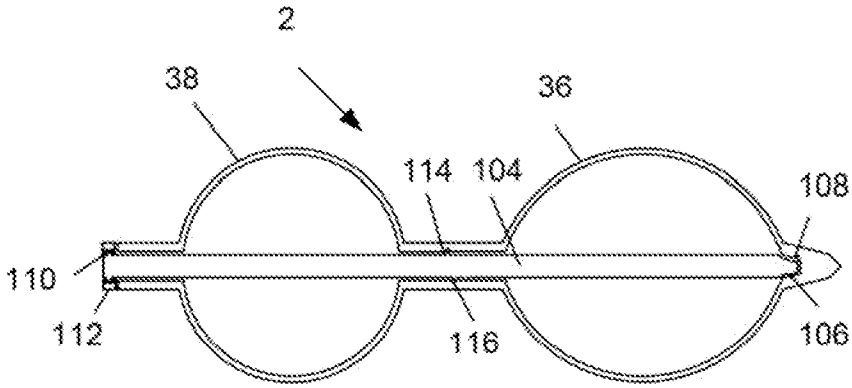


Fig. 31b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/31727

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/58, A61B 17/60, A61F 2/00 (2009.01)
USPC - 606/105
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC (8) - A61B 17/58, A61B 17/60, A61F 2/00 (2009.01)
USPC - 606/105

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 606/53, 60, 62, 63, 64, 86R; 623/11.11, 16.11, 23.47 - see keywords below

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (USPT, PGPB, EPAB, JPAB); Google Scholar - Bone, fracture, endoluminal channel, radially, expandable, Greenhalgh, Romano, repair, medullary, cavity

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0032444 A1 (MISCHE) 14 March 2002 (14.03.2002), abstract, Fig. 1B, 2A, 10 and 12A, para [0004], [0018], [0023], [0029], [0034]-[0036].	1-22
Y	US 2007/0244485 A1 (GREENHALGH et al.) 18 October 2007 (18.10.2007), Fig. 1 an 72, para [0025], [0074], [0075], [0126], [0135], [0136], [0114].	1-22
Y	US 6,554,833 B2 (LEVY et al.) 29 April 2003 (29.04.2003), Fig. 6B	1-16

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search
27 February 2009 (27.02.2009)

Date of mailing of the international search report
10 MAR 2009

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