(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 December 2005 (29.12.2005)

PCT

(10) International Publication Number
WO 2005/122956 A2

(51) International Patent Classification[7]: A61F 2/02

(21) International Application Number:
PCT/US2005/020476

(22) International Filing Date: 10 June 2005 (10.06.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/866,219 10 June 2004 (10.06.2004) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR FILLING A CAVITY

(57) Abstract: An implant for filling and/or distracting a body region, particularly a non-soft tissue cavity, has a plurality of segments wherein at least two of the segments are flexibly connected. The segments have a crush-strength sufficient to create and/or maintain the distraction of two or more non-soft tissue body surfaces, and to maintain the stability of the body region. The implant may be inserted into a cavity by an applicator having a cannula with a distal opening, and a rotary driver for applying force to move the implant within the cannula.

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METHOD AND APPARATUS FOR FILLING A CAVITY

FIELD

[0001] Described here are non-soft tissue cavity implants, implant applicators, delivery devices, and methods for using them. In particular, the description relates to implants having a plurality of flexibly connected segments having a strength sufficient to support, to fill, to create, to maintain, or to distract a non soft tissue cavity, such as might be found in a fractured vertebral body, intervertebral space, or other orthopedic applications, and methods and devices for inserting implants into non-soft tissue cavities such as bone cavities.

BACKGROUND

[0002] Proper treatment of orthopedic conditions such as trauma, fractures, non-unions, tumors, cysts, and certain fusion procedures may involve filling a cavity that has been created by the pathology itself or by the action of a surgeon. Often the cavities are compressed, and require that the surfaces of the cavity be distracted from one another and then supported to return the surrounding bone structure to its original anatomic position and form. Furthermore, because non-soft tissues such as bone have a structural and support role in the body, it is critical that such cavities be repaired to allow reliable strength and support. In addition, cavities should be filled so that they have a reliable strength and support, requiring implants that combine strength and support with flexible delivery control. It would also be advantageous for the implant to allow delivery of biologics and drugs, and possibly wound drainage to aid in the healing of the orthopedic condition.

[0003] Many orthopedic conditions can benefit from an implant capable of filling a cavity and providing strength and support, including intervertebral disc repair, vertebra restoration from compression fractures, repair necessitated by trauma, tumors, or fracture, and joint reconstruction, or other areas of tissue displacement. Intervertebral disc repair is one type of non-soft tissue treatment that may use devices and methods for separating, distracting, and stabilizing bone tissue. A significant challenge for intervertebral implants is the small size of the entry portal required to access the intervertebral space, as well as stabilization of the implant. The current practice of fusions (e.g., using pedicle screws and/or hook constructs in conjunction with an interverterbral body cage and/or bone graft or other intervertebral techniques) may be unsuccessful due to loosening, shifting, and other failures of the mechanical construct. In

addition, typical interbody implants currently in use are large, and thus require large entry ports. A large entry port can result in a high failure rate due to implant slippage and/or displacement.

[0004] Compression fractures are another type of hard (or non-soft) tissue injuries belonging to a class of conditions that may be treated using devices and methods for separating, distracting, and supporting a fractured bone. For example, vertebral compression fractures are crushing injuries to one or more vertebra. A vertebral compression injury may be the result of a trauma to the spine, an underlying medical condition, or a combination of a trauma and an underlying condition. Osteoporosis and metastatic cancers are common medical conditions that also contribute to vertebral compression fractures because they weaken spinal bone, predisposing it to compressive injury.

[0005] Osteoporosis is a degenerative disease that reduces bone density, and makes bone more prone to fractures such as compression fractures. An osteoporosis-weakened bone can collapse during even normal activity. According to the National Institute of Health, vertebral compression fractures are the most common type of osteoporotic fractures.

[0006] Vertebral fractures may be painful and may deform the shape of the spine, resulting in unhealthy pressure on other parts of the body, loss of height, and changes in the body's center of gravity. Untreated, such changes and the resulting discomfort can become permanent, since the bone heals without expanding the compression.

[0007] Existing methods of treating bone injuries such as compression fractures and bone voids may involve highly invasive or inadequate treatments. For example, one method of treatment is percutaneous vertebroplasty. Vertebroplasty involves injecting bone filler (such as bone cement) into the collapsed vertebra to stabilize and strengthen the crushed bone. In vertebroplasty, physicians typically insert a small diameter guide wire or needle along the pedicle path intended for the bone filler delivery needle. The guide wire is advanced into the vertebral body under fluoroscopic guidance to the delivery point within the vertebrae. The access channel into the vertebra may be enlarged to accommodate the delivery tube. In some cases, the delivery tube is placed directly into a vertebral body and forms its own opening. In other cases, an access cannula is placed over the guide wire and advanced into the vertebral body. In both cases, a hollow needle or similar tube is placed into the vertebral body and used to deliver the bone filler into the vertebra.

[0008] When filling a bone cavity with bone filler using traditional vertebroplasty, fillers with lower viscosities may leak. Further, even fillers having low viscosities may require the application of a high pressure to disperse the bone filler throughout the vertebral body. However, application of high pressure also increases the risk of bone filler extravasation from

the vertebral body. Conversely, injecting a bone filler having a higher viscosity may provide an even greater risk of "leaking" bone filler into sensitive adjacent body areas. Leaks or extrusion of the bone filler may be dangerous to a patient's health. For example, posterior extravasation from a vertebral body may cause spinal cord trauma, perhaps resulting in paralysis. Risk of leakage is even more acute when a bone filler is applied under pressure to expand a compression fracture, especially if the fracture has begun healing and requires substantial force to distract the cavity surfaces.

[0009] Furthermore, most bone cements and bone fillers are difficult to remove or to adjust. Removal and adjustment may be important when distracting a bone cavity. For example, removing a precise amount of bone filler may allow a surgeon to adjust the level of distraction of a vertebral compression fracture and correct the shape of the compressed bone. Many bone cements, once set, are difficult or impossible to remove without further, highly invasive, surgery. Even if the removal is attempted prior to the expiration of the setting time, the materials may have non-Newtonian flow characteristics requiring a substantial removal vacuum to achieve an initial and sudden movement.

[0010] In addition to traditional bone cements, a handful of other bone and other non-soft tissue, cavity filling materials have been suggested. In particular, biodegradable and/or bioabsorbable bone-filling devices have been suggested. For example, US patent 5,756,127 to Grisoni et al. describes a bioresorbable string of calcium sulfate hemihydrate (Plaster of Paris) beads and a means for producing these beads. However, the Grisoni device is not intended for distracting a non-soft tissue cavity, and has many disadvantages. Calcium sulfate hemihydrate (Plaster of Paris) and similar materials have low crush strength, making them unreliable as materials to distract and later support a bone cavity, particularly during the early stages of the healing process. Filling materials that are readily compressed or crushed, may shift within, or exit the bone cavity altogether, leading to detrimental changes in the shape of the corrected bone. Materials with low crush strength (particularly those materials having crush strengths less than that of normal bone) are poor choices in withstanding the stress of distracting the bone surfaces, and may be unable to maintain the distracted shape of the bone after filling a bone cavity. Similar materials are the subjects of US patent 6,579,533 to Tormala et al.

[0011] US patent 5,702,454 to Baumgartner describes an implant made of an elastic plastic for implanting into an intervertebral disk. Because the Baumgartner implant is elastic, it may be less effective for filling and distracting body cavities benefiting from implants having some stiffness, such as non-soft tissue cavities. This is particularly true where sustained distraction is desired.

[0012] US patent 6,595,998 to Johnson et al. describes a tissue distraction device in which wafers are inserted to distract a tissue cavity by forming a wafer stack within the cavity. However, Johnson's column of wafers is not amenable to providing uniform support to all surfaces of a bone cavity, when such support is needed. For example, a tissue cavity supported or distracted on all sides of the cavity may be more stable.

[0013] US Patent 5,958,465 to Klemm et al. describes a method and apparatus for making a drug containing implants in the form of a string of beads comprising chains of small drug-containing plastic bodies arranged in series on a surgical wire or thread. Similar drug implanted beads-on-a-string are described in US patent 6,183,768 to Harle and German Patents 2320373 to Klemm and 2651441 to Heusser. The Klemm, Harle, and Heusser implants are designed for drug delivery, and are embedded with one or more drugs which are released from the plastic (e.g. PMMA) beads (also called "corpuscles"). Thus, these implants may be limited in strength and durability because of the inclusion of a releasable drug, as well as the properties and shape of the implant beads.

[0014] In any event, none of the cited documents show the device and methods disclosed below.

[0015] The implant described below could be utilized in any area of non-soft tissue where the filling of a cavity with strength, stability and control is desired.

BRIEF SUMMARY

[0016] Broadly, described here are segmented implants for filling a non-soft tissue cavity, applicators for inserting implants, and methods of using the segmented implants and applicators to fill and/or distract tissue cavities. In particular, the implants described here may be used for filling and/or distracting non-soft tissue cavities such as a bone cavity. Generally, the segmented implants described here comprise a plurality of segments, where at least two of the segments are flexibly connected, and configured for insertion into a body region. The segments provide implant segment distractibility to the body region, and stability to the body region into which they are introduced. In some variations of the implant described herein, the segments have sufficient material strength to distract two or more non-soft tissue surfaces. In some versions, the material strength is crush strength, so that the segments of an implant have sufficient crush strength to allow and sustain the distraction of non-soft tissue surfaces. Thus, the implant is inserted into a cavity to distract, to expand, to reduce, or to support the cavity, typically filling the cavity and maintaining a desired shape.

[0017] At least a portion of the segments of the implant may be configured so that the implant may be introduced into a body region by engaging a rotating introducer member. For example, a rotatable driver may be used to introduce the segments of the implant into a body region using an applicator as described herein. In some versions, the segments are configured as pellets.

[0018] The implant may also include a fluent material (such as bone cement). Thus, for example, the fluent material may be added to a bone cavity that has been distracted by the flexibly connected segments of the implant. The segments may also include a channel or channels to facilitate the passage of a fluent material, for example a bone cement that may eventually harden. The fluent material could be inserted into a connective sheath or flexible tube that encloses the implant.

[0019] Two or more of the implant segments may be connected in any way allowing sufficient flexibility so that the implant may be introduced into body region such as a bone hollow. The implant segments may include a connection material for connecting segments of the implant. Connection material may comprise, for instance, a string, fiber or wire, variously of single or multiple strands. The connecting string, fiber or wire may be flexible to allow the segments to be inserted into the chosen treatment site. Suitable examples of fibers include those used as suture materials, biodegradable or not, e.g., polylactic acids, polyglycolic acids, mixtures and copolymers of polylactic and polyglycolic acids (PGLA such as "Vicryl" from Ethicon and "Dexon" from Davis & Geck), polydioxanone, various Nylons, polypropylene, silk, etc.). In this variation, the segments may comprise pellets with openings for stringing or be made adherent to a string, fiber or wire by means of manufacturing, glue, adhesive, or the like, or by simply placing the glue between the pellets. The wires may comprise one or more filaments comprising suitably biocompatible metals or alloys, e.g., stainless steels or superelastic alloys.

[0020] The segments may be connected by placement within a flexible tube, variously a solid or continuous walled tube, a solid or continuous walled tube having openings in the wall, or a netting woven from string or fiber. The flexible tube may comprise one or more membranes, optionally an expandable or a stretchable material. Suitable materials include polymers, (e.g., polyfluorocarbons such as the various Teflons (including PTFE and expanded PTFE -- ePTFE such as is sold as GORETEX), polypropylene, polyethylene, polyoxymethylene, polycarbonate, polyesters (including polyamides such as the Nylons), polyphenylene oxide, and polyurethane) or elastomeric polymers (e.g. various Silicones, natural rubber, butadiene-styrene rubber, carboxylic butadiene-styrene, butadiene-acrylonitrile rubber, carboxylic butadiene-acrylonitrile rubber, chlorobutadiene rubber, polybutadiene rubber, silicone rubbers, and acrylate rubbers,

perhaps vulcanized, and other elastomeric materials) or a composite material. The expandable membrane may optionally be filled, for example with a fluent material or a bone cement, before or after the implant has been inserted into the bone cavity. The flexible tube may comprise a woven or non-woven material of non-synthetic materials (e.g. cotton, silk, and the like), polymers such as those listed above, and blends or mixtures of the previously mentioned materials. The segments may also be connected by a string, fiber, or wire in addition to the flexible tube.

[0021] The segments may be connected by adhesives or glues, such as solvent- or catalyst-curable materials including silicone glues, rubbery epoxies, and adhesives suitable for the materials forming the segments.

[0022] The segments of the implant may be severable, singly or in groups, such as by severing the connection between the segments. The implant may be severed remotely by a user. The implant may be severed mechanically, chemically, thermally, or electrically. The implant may be severed while inserting it into a non-soft tissue cavity or after the implant has been inserted into a cavity. In one version, the connection material connecting flexibly connected segments may be removed from one or more segments without severing the material. For example, when a flexible joining material connecting the segments is a fiber, the fiber may be removed from the flexibly connected segments (e.g. pellets) after they have been inserted.

[0023] The implant may include segments that are movably connected along the axis of the implant. The segments may be slideably positioned within a flexible tube. The segments may be slidably connected on one or more stings, fibers, or wires. Some of the segments may be held in a fixed location while others are movable along the axis of the implant.

[0024] The implant may include segments of different sizes. The implant may include segments of different shapes, such as substantially spherical, substantially cubic, faceted or shaped to facilitate space packing within a cavity, or of random shapes. The segments may be cooperatively shaped to interlock or to interconnect to other nearby segments.

[0025] The implant may comprise coated segments. The segments may have a medicinal coating. The segments may include pellets with a coating that allows them to crosslink with each other. The segments may be porous or solid. The segments may be imbedded or infused with any compound, for example a therapeutic or medicinal compound so long as the segments provide distractability and stability to the body region into which they are inserted, e.g. a bone cavity.

[0026] In some variations of the implant, the segments have a crush strength sufficient to maintain the distraction of two or more surfaces of a bone cavity. In such variation, the

segments comprise a material selected to have a minimum adequate crush strength. In any case, the segments may comprise one or more polymers, one or more metals or alloys, and one or more inorganic materials such as ceramics and inorganic oxides and phosphates. The segments may comprise a variety of composite materials, e.g., layered, mixed, etc. The segment materials may comprise either or both of biodegradable and non-biodegradable materials. The implant may include segments of different compositions. In one version, at least one of the segments includes a radiopaque material to help in visualizing the implant assembly (e.g., during insertion).

[0027] Also described herein are implants for filling hard tissue cavities having a plurality of connected segments wherein at least two of the segments are flexibly connected. The segments are configured for insertion and packing into a hard tissue cavity and have a material strength allowing them to distract two or more of the hard tissue surfaces. In one version, the material strength is compressive strength. In one version, the segments have a compressive strength of greater than about 20 MPa. In one version, the segments of the implant assemblage have a compressive strength less than cortical bone. In one version, the segments of the implant assemblage have a compressive strength of between about 20 MPa and about 160 MPa. In one version, the segments of the implant have a compressive strength of between about 100 and 160 MPa.

[0028] In one version, an implant assemblage for filling a non-soft tissue cavity comprises an implant including a plurality of flexibly connected segments configured for insertion into a bone cavity. The implant segments have a crush strength sufficient to maintain the distraction of two or more bone surfaces and also to maintain a selected shape within the cavity. In one version, the implant segments have a sufficient crush strength to maintain the distraction and/or shape of a non-soft tissue cavity over time. Thus, the implant may be used to stabilize a body region after filling and/or distracting. In one version, the implant is intended for long-term use in a body region (e.g. hard tissue cavity).

[0029] Also described herein are applicators for introducing or inserting an implant into a tissue cavity comprising a cannula with a distal end that can be inserted into the cavity. A region at or near the distal end of the cannula is open to allow the passage of an implant into the cavity. The applicator can connect to a feed guide at the proximal end of the cannula so that an implant (for example, an implant comprising a plurality of flexibly connected segments) may be moved within the cannula from the feed guide using a rotating driver to apply force to at least one region of the implant (e.g. one region of an implant segment). The rotary driver may be located at least partly in the feed guide. The rotary driver may be located at least partly in the cannula.

[0030] Implants compatible with this applicator include particles, fluent material, pellets, and particularly linear arrays of material (e.g. a segmented implant). In one version, the implant applied by the applicator is the segmented implant assembly described herein. In one version, an implant compatible with the applicator is a loose pellet or segment. In one version, an implant compatible with the applicator is a quantum of any solid material desired to be packed into a tissue cavity.

[0031] The applicator may also include a force gauge configured to indicate the force applied by the driver to move the implant. In one version, the applicator includes a display. The display may indicate force applied, volume (cc) inserted, amount of implant inserted, and/or amount of implant material remaining in the applicator, for example.

[0032] The applicator may also include a trocar at the distal end of the cannula. The application may also include a gripper at the distal end of the cannula for gripping the bone, therefore resisting 'back out' once the implant material (e.g. implant segments) pack and exhibit resisting force to implant material advancement. The gripper may be engageable by a user.

[0033] The applicator may also include a switch-able gripper to resist implant material motion in either direction per user choice. The applicator may also include a cutter for cutting the implant, particularly when using the applicator with implants having severable segment connections, thereby severing the connection between the connected segments. The cutter may be a mechanical cutter, an electrical cutter, a chemical cutter or a thermal cutter. The cutter may be activated by an actuator controllable by a user.

[0034] The driver of the applicator may include any driver which actuates movement of the implant (or a part of the implant) by rotating a region of the driver that contacts at least a region of the implant. In one version, the rotating driver of the applicator includes an auger. For example, an applicator can insert or remove a segmented implant assembly by engaging at least one region of a segment of the implant. Rotating the auger one direction drives the implant forward (towards the distal end of the cannula), while rotating the auger in the opposite direction drives the implant backwards (towards the proximal end of the cannula). The auger may be at least partly located in the cannula of the applicator.

[0035] The applicator driver may comprise a cog configured to engage an implant. Rotating the cog one direction drives an implant forward (towards the distal end of the cannula), while rotating the cog in the opposite direction urges the implant back towards the proximal end of the cannula (removing them from the tissue cavity). In one version, the cog is a friction wheel.

[0036] The applicator may also include a controller for controlling the driver. The controller may be configured to activate the driver. The controller may be configured to determine the

direction of force applied by the driver (in the distal or proximal direction down the cannula). Applying force down the cannula in the distal direction moves an implant out of the distal end of the cannula (e.g. inserting an implant into a bone cavity); applying force down the cannula in the proximal direction moves an implant in the proximal direction (e.g., withdrawing an implant from a non-soft tissue cavity). The controller may also be configured to determine the amount of force applied by the driver. The controller may be configured to be manually operated by a user.

[0037] The feed guide of the implant may include a cartridge pre-loaded with an implant. The driver may engage the distal-most portion of an implant (e.g. a segment) of the preloaded implant and apply force to drive the implant distally down the cannula. The driver may also be configured to apply force in the proximal direction to withdraw the implant.

[0038] The applicator's distal cannula opening may be located on the distal end. The distal opening of the cannula may be located more proximally than the distal tip of the cannula to aid in inserting an implant in a cavity. In one version the distal opening of the cannula is located on an angle from the distal tip of the cannula. The distal opening of the cannula may be located on a side perpendicular to the long axis of the cannula.

[0039] Methods of distracting a non-soft tissue cavity (including a bone cavity) are described. A method of distracting a non-soft tissue cavity includes providing an implant for filling a bone cavity comprising a plurality of flexibly connected segments, where the segments have a crush strength sufficient to maintain the distraction of two or more tissue cavity surfaces. The method of distracting a non-soft tissue cavity further includes inserting the flexibly connected segments into the bone cavity.

[0040] Methods of filling a tissue cavity are described. A method of filling a tissue cavity includes providing an implant for filling a cavity, and providing an applicator for introducing the implant into the cavity. The applicator includes a cannula configured to pass at least a region of the implant, and a rotary driver at least partly within the cannula. The method further includes inserting the flexibly connected segments into the bone cavity. The methods of filling and/or distracting a bone cavity may also include using a rotating auger to drive the implant into the bone cavity.

[0041] The method of filling and/or distracting a non-soft tissue cavity may also include applying force to the implant to insert the implant within the bone cavity. The method of filling or distracting a bone cavity may also include measuring the force applied.

[0042] The method of filling and/or distracting a non-soft tissue cavity may also include removing the implant once a void is created within a non-soft tissue and/or a desired elevation or expansion of a cavity has been achieved.

[0043] The method of filling and/or distracting a non-soft tissue cavity may be performed where the bone cavity is a fractured vertebral body. This method may further include inserting the implant into the bone cavity until the normal height or shape of the vertebral body is substantially attained.

[0044] The method of filling and/or distracting a non-soft tissue cavity may include providing a fluent filler (e.g. a bone cement) within the cavity. In one version, the non-soft tissue cavity is a hard tissue cavity. In one version the non-soft tissue cavity is a bone cavity.

[0045] The method of filling and/or distracting a non-soft tissue cavity may also include providing a closure. Suitable closures include, but are not limited to, screw-type closures, particularly screw-closures. Suitable closures may also have a compaction enhancer, such as a spring element, to aid compaction and/or securing of the implant. The method of filling and/or distracting a non-soft tissue cavity may also include closing the soft-tissue cavity with a closure.

[0046] Also described herein are kits for filling a hard tissue cavity including an implant and an applicator. Implants appropriate for the kit include implant assemblages comprising a plurality of segments wherein at least two of the segments are flexibly connected and the implant segments are capable of distracting and providing stability to a non-soft tissue body region. Applicators appropriate for the kit comprise a cannula configured to pass at least a region of the implant and a rotary driver at last partly within the cannula configured to apply force to at least a region of the implant. The kits may also include fluent material (e.g. bone cement), one or more gauges (e.g. force gauge), and/or a display configured to show the status of the implant insertion. The display might show the force applied to an implant, the length of the implant inserted, the volume filled, etc. The kits may also include compaction tools, e.g., vibrational probes, tamps, etc. Kits may also include closures, e.g., screws, compaction screws, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

[0047] Embodiments or variations are now described by way of example with reference to the accompanying drawings.

[0048] Figs. 1A to 1E show variations of the described implant;

[0049] Figs. 2A to 2F show variations of the described implant;

[0050] Figs. 3A to 3E, 3G, 3I to 3T show variations of the described implant;

[0051] Figs. 3F, 3H, 3W and 3X illustrate variations of interlocking segments of the described implant;

[0052] Figs. 4A to 4D show variations of the described implant;

[0053] Fig. 5 illustrates a variation of an applicator for the implant;

[0054] Figs. 6A to 6C illustrate variations of the distal cannula tip of an applicator;

[0055] Figs. 7A and 7B show one variation of an applicator driver;

[0056] Fig. 7C shows another variation of an applicator driver;

[0057] Fig. 7D shows the relationship between an applicator and variations of the driver;

[0058] Figs. 8A to 8C show insertion of an implant into a vertebral body;

[0059] Figs. 9A and 9B show a screw closure compatible with the implants and applicators described herein. Fig. 9B is a schematic cross-section of the screw closure shown in Fig. 9A taken along the longitudinal plane A-A.

[0060] Fig. 10 shows a cutter for cutting segments of the implant as described herein.

DETAILED DESCRIPTION

[0061] In the drawings, reference numeral 10 generally denotes an exemplary embodiment of a segmented implant for distracting, filling, creating, or maintaining a cavity in a non-soft tissue. The implant, applicator, and methods of use may be used for distracting, supporting, filling, creating and maintaining the size of virtually any non-soft tissue cavity, particularly hard tissue cavities, including but not limited to: bone separations, fractures (including compression fractures), non-unions, removed tumors, removed cysts, in conjunction with joint replacement implants, and certain fusion procedures. Although example of implants, implant applicators, combinations of implants and applicators and methods of using the implants are described in the context of treating a vertebral compression fracture, the devices and methods of use described are not intended to be limited to vertebral compression fractures.

[0062] The implants, applicators and methods described herein are particularly relevant to insertion into body regions such as non-soft tissue cavities. Non-soft tissue cavities include hard tissues cavities such as cavities or voids such as bones, as well as cartilage, and bone connected to ligament and/or muscle, scar tissues, and other mineralized (e.g. calcified) tissues. Non-soft tissue cavities also include tissues cavities having at least one hard surface, including tissues having mixed compositions. For example, non-soft tissue cavities include cavities abutting bone, or cavities surrounded by bone, such as cavities within the spinal disk space, cavities within the bone marrow, and cavities adjacent to bone or bone and ligament.

[0063] Figs. 1A to 1E illustrate variations of implants for distracting or filling a tissue cavity. The implant **10** in each of figs. 1A to 1E includes a plurality of segments (illustrated as pellets) that are flexibly joined. Segments of the segmented implants may include one or more pellets.

A perspective view of an implant is shown in Fig. 1A. The segments **12** are shown as spherical pellets that are connected by a centrally located wire, string, or fiber **16**. The joined pellets form a connected construct seen as a flexible linear array that may be inserted into a cavity to distract the cavity walls, to fill the cavity, or to provide continuing support to the cavity. As used herein, unless the context makes clear otherwise, "distract" or "distracting" refers to the process of separating (or enlarging) the walls of a cavity, particularly a bone cavity.

Crush Strength

[0064] An implant may be used to distract, to fill, to create or to maintain the size or shape of a hard tissue body cavity such as a bone cavity. In one version, the described implant's segments **12** have crush strength adequate to withstand the forces required to distract and support the cavity without substantial compression or breaking of the segments. Crush strength is defined as average crush load per unit cross-sectional area at which the structure will break or crack, and may be expressed in pounds per square inch or megaPascals (MPa). Of course, the shape of a segment has both individual and group effects upon the crush strength of the implant after installation. The crush strength of an individual segment pellet, however, is a consideration for distracting a cavity. For roughly spherical pellets, force can be approximated as acting at discrete points on the surface of the sphere, so crush force may be approximated as the total force applied to crack the sphere. One factor effecting crush strength is compressible strength of the material.

Compressibility

[0065] It may be beneficial that the segments comprise any solid material having an appropriate compressible strength so that the implant assemblage is able to distract, fill and support a tissue cavity without substantially deforming. The segments preferably comprise biocompatible solids with high compressive strength. Compressibility and incompressibility generally describe the ability of molecules in a solid to be compacted or compressed (made more dense) under an applied force and/or their ability to return to their original density after removing the applied force. Compressibility of a solid may also be quantified by the bulk modulus of the substance (bulk modulus is the inverse of compressibility, and is the change in volume of a solid substance as the pressure on it is changed). A relatively incompressible material will have a higher bulk modulus than a more compressible material.

[0066] The compressive strength of cortical bone is approximately 166 MPa, and the compressive strength of cancellous (spongy) bone is approximately 4 MPa. In one version, the implant should have a compressive strength of greater than approximately 20 MPa. In one

version, the implant should have a compressive strength less than cortical bone. In one version, the implant has a compressive strength between about 20 and about 160 MPa. In one version, the implant has a compressive strength between about 91 and about 160 MPa. In one version, the implant has a compressive strength between about 100 and about 160 MPa. As a reference, the compressive strength of calcium sulfate is approximately 11 MPa.

Segment Materials

[0067] The crush strength of the implant depends to a large extent, on the segment crush strength, which is a function of the composition, and to a lesser degree, the shape of the segment.

[0068] Materials with appropriate crush strength include, but are not limited to, metals, alloys, ceramics, certain inorganic oxides and phosphates, polymers, bone derived material, and combinations of these materials. The following descriptions of segment materials represent versions of the implant, and are not intended to limit the scope of the implant or segment materials. The implant segment may comprise, consist of, or consist essentially of the materials identified herein.

[0069] Bioabsorbable (or bioerodible) and non-bioabsorbable (or non-bioerodible) material may be used in the implant separately or in combination. Typically, the non-absorbable (or non-bioerodible) materials noted elsewhere provide segments and implants exhibiting a sustainable crush strength adequate to maintain the distraction of the cavity surfaces (e.g. bone cavity surfaces) over a long period of time. On the other hand, bioabsorbable (or bioerodible) segments exhibit a reduction in crush strength over time, as the material is acted upon by the body. However, bioabsorbable materials may also permit substantial tissue in-growth, allowing tissue to replace implant material while maintaining the distraction and supporting the filled cavity. In applications in which the likelihood of tissue re-growth is small, for example osteoporotic repair, a nonabsorbable implant may be desirable. Materials that are too rapidly bioabsorbed (for example, calcium sulfate hemihydrate) are generally inappropriate as segment materials, because they do not maintain the cavity structure and/or distraction.

[0070] Metals that may be used as segment materials include, but are not limited to, biocompatible metals and alloys, such as stainless steels, gold, silver, tantalum, cobalt chromium, titanium, platinum, rhodium, rhenium, ruthenium, and other alloys thereof, combinations thereof, or other equivalent materials.

[0071] Ceramic materials that may be used in the segments may include, but are not limited to, alumina, carbon or tricalcium phosphate or sintered masses or single crystals of hydroxyapatite. Ceramics capable of high crush strengths may be particularly relevant. Also useful are refractory metal and semi-metal oxides (tantalum oxides, aluminum oxides),

phosphates (calcium phosphates), phosphides, borides (niobium borides, tungsten borides), carbides (aluminum carbides, boron carbides, niobium carbides, silicon carbides, tantalum carbides, titanium carbides, tungsten carbides, vanadium carbides, zirconium carbides), nitrides (boron nitrides, chromium nitrides, silicon nitrides, tantalum nitrides, titanium nitrides, zirconium nitrides), silicides (tantalum silicides, tungsten silicides, zirconium silicides), their mixtures, variously sintered as porous particulates or as solid formations.

[0072] Inorganic materials that may be used as segment materials include, but are not limited to, hardened glasses including oxides of silicon, sodium, calcium and phosphorous and combinations thereof.

[0073] Polymers that may be used as segment materials include, but are not limited to, elastomers (natural and synthetic rubbers, silicone rubbers), polymethyl methacrylate (PMMA), polyetheretherketone (PEEK), polymethymethacrylate (PMMA), polyglycolic acid and/or polylactic acid compounds, polyvinylchloride (PVC), polyethylene (PE, HDPE, UHMWPE, etc.), polystyrene (PS), polyesters (PET, polycaprolacton, polyglycolied, poylactide, poly-*p*-dixanone, poly-hydroxy-butylate), polyamides (Nylons, aromatic polyamides), polypropylene (PP), fluorocarbon polymers (PTFE, PTFCE, PVF, FEP) and other biocompatible materials. Other suitable polymers include: collagen and/or collagen derivative preparations alone or in combination with other biomaterials, chitin and chitosan preparations.

[0074] Bone derived materials that may be used as segment materials include, but are not limited to, bone autografts, bone allografts, bone xenografts, bone-derived tissue, bone-derived collagen, and the like.

[0075] Any combinations of these materials may be used as a segment material. Segments may include pellets of any of these materials, or combinations thereof. Finally, suitable known materials acceptable for use as hard tissue implant materials include various osteogenic and osteoinductive compositions, and combinations thereof. Certain glassy carbon forms are also quite useful.

[0076] Segment materials may also comprise radiopaque materials to enhance visualization of the implant, or the segments may incorporate a radiopaque material as a part of a segment (e.g., coatings, dispersed, or core materials). Examples of radiopaque materials include but are not limited to, barium sulfate, tungsten, bismuth compounds, tantalum, zirconium, platinum, gold, silver, stainless steel, titanium, alloys thereof, combinations thereof, or other equivalent materials for use as radiographic agents.

Coatings

[0077] Segments may include coatings to modify the surface properties of the segments, to have a biological effect, and/or to facilitate the insertion or removal of the implant. The coatings may be of any thickness. In one version, the segment comprises layers of materials. In one version, the segment has a hollow core.

[0078] In one version of the implant described herein, a segment or segments may be coated with a therapeutic or medicinal material, such as an antibiotic. Additional medicinal materials may include, but are not limited to, anticoagulants and bone-growth promoting agents. In one version of the implant, the segments may be coated with a cross-linking or bonding compound that could facilitate adhesion either between the segments, with the body region, or both. In one version the segments are coated with a cross-linker that can be activated after insertion into the bone cavity, for example, by adding an activating compound, by time delay, or by temperature. In one version the segments are coated with a lubricant.

[0079] The segments may comprise one or more therapeutic or medicinal materials situated away from the surface, e.g., in pores within the segments.

Drug Delivery Using the Implant

[0080] The segments may also be embedded with one or more therapeutic or medicinal materials. For example, embedding the segments with an additional material may be particularly useful when the segment comprises a bioabsorbable (bioerodible) material. Thus, the segments may be used to deliver any drug or therapy. Drugs which are particularly useful may include, but are not limited to, growth factors and/or growth promoters (e.g. bone derived growth factors (BDGF), bone morphogenetic protein (BMP), etc.), antibacterials, antivirals, vascularizing agents, analgesics, anticoagulants, cell and/or gene therapies, etc.

[0081] In one version an implant including a drug is inserted at or near a wound site. After an appropriate time the implant is removed. Thus, the implant may serve as a removable wound packing material. In one version, the implant may be inserted with a removable drain. In one version, the implant functions as a removable drain.

[0082] Any portion of the implant may be coated with, implanted with, embedded with, or made from a therapeutic or medicinal material, including but not limited to those described herein.

Flexible Joining Material

[0083] The implant segments are connected in the implant as installed. The segments may be linked together in such a way that each segment in the implant is adjacent, perhaps directly

adjacent or in contact with at least one other segment. Generally, each segment in the implant is adjacent, perhaps directly adjacent or in contact with at most two other segments. In some variations, the assembled segments form a linear array. In the version of the implant shown in Figs. 1A to 1E, the segments are linked in a linear array by attachment to a wire, filament, or string **16**. The filament connecting the segments may comprise a separate, independent filament between each segment, or it may be a single continuous filament. The filament may comprise different materials, and may be different lengths. In one version of the implant, the filament comprises one or more monofilaments. In another version of the implant, the filament comprises one or more fibers. In a version of the implant, the filament comprises one or more wires. The filament may comprise a bioabsorbable material. The filament may be rapidly bioabsorbable because (unlike the segments) the filament is not typically load bearing in supporting the cavity.

[0084] In one version, the implant segments are connected in any way allowing sufficient flexibility to the resulting implant construct so that it may be introduced into a cavity such as a bone hollow. In one version, the implant segments are flexibly connected so that a segment may contact another segment upon being planted into a body region such as a bone hollow.

[0085] The connection material may comprise, for instance, a string, fiber or wire, variously of single or multiple strands. The connecting string or fiber may be flexible and allow the segments to be inserted into the treatment site. Suitable filament materials include virtually any biocompatible material, including but not limited to: natural materials (e.g. cottons, silks, collagen, etc), rubbers (e.g. natural and synthetic rubbers), composite yarns (e.g. carbon fiber yarns, ceramic fibers, metallic fibers), polymers (e.g. polyethylene, polyester, polyolefine, polyethylene terephthalate, polytetrafluoroethylene, polysulfone, nylons, polylactic acids, polyglycolic acids, mixtures and copolymers of polylactic and polyglycolic acids (PGLA such as "Vicryl" from Ethicon and "Dexon" from Davis & Geck), polydioxanone, various Nylons, polypropylene, etc., and the like). Suture material (natural and synthetic materials) are examples of particularly appropriate materials.

[0086] In one variation, the segments are adapted to connect to the filament, string or wire, for example, by having holes (through which the flexible joining material is threaded), by having attachment sites (to which the flexible joining material could be tied or otherwise attached), or by having a track or groove (which mate to the flexible joining material). In one variation the segments are adherent to the string or filament by a glue, adhesive, or the like.

[0087] In one variation, the segments are connected by adhesives or glues, such as solvent- or catalyst-curable materials including Silicone glues, rubbery epoxies, and adhesives suitable

for the materials forming the segments. In one variation the segments are connected only by adhesives or glues such as those mentioned above.

[0088] The joining material does not itself have to be flexible, so long as it allows flexibly joined segments of an implant to "flex." In one version of the implant, the segments are linked together by a solid linker. The implant is made flexible by incorporating a joint (e.g. socket type joins) between the solid linker and the segment. Solid linkers may be composed of the same material as the segments. Solid linkers may be wires made of one or more filaments comprising suitably biocompatible metals or alloys, e.g., stainless steels or superelastic alloys.

[0089] In the version of the implant shown in Fig 1E, the segments are linked together in linear array because they are held within a flexible tube **19**. A flexible tube may be made of virtually any material, so long as the final implant is adequately flexible to allow bending of the implant. The flexible tube comprises a solid or continuous walled tube, a solid or continuous walled tube having openings in the wall, or a netting woven from string or fiber. The flexible tube may comprise one or more membrane, optionally made of an expandable or a stretchable material.

[0090] In one version, the implant segments are linked by an expandable membrane. The expandable membrane material may be a fabric that has pores allowing passage of fluids and bone growth through it. For example, the membrane could be formed of a flexible polymeric fabric e.g., high molecular weight polyethylene. The flexible tube may be any material (e.g. woven, non-woven, extruded, etc) that is adequately flexible. In one version of the implant the segments within the flexible tube are also linked by a filament, wire or string.

[0091] The flexible joining material may comprise any suitable materials including but not limited to: polymers, (e.g., polyfluorocarbons such as the various Teflons (including PTFE and expanded PTFE -- ePTFE such as is sold as GORETEX), polypropylene, polyethylene, polyoxymethylene, polycarbonate, polyesters (including polyamides such as the Nylons), polyphenylene oxide, and polyurethane) or elastomeric polymers (e.g. various Silicones, natural rubber, butadiene-styrene rubber, carboxylic butadiene-styrene, butadiene-acrylonitrile rubber, carboxylic butadiene-acrylonitrile rubber, chlorobutadiene rubber, polybutadiene rubber, silicone rubbers, and acrylate rubbers, perhaps vulcanized, and other elastomeric materials) or a composite material.

[0092] The material used to join the segments may also have additional biological or mechanical properties. For example, the material may incorporate a therapeutic or medicinal agent for release (e.g., timed release). Examples of therapeutic agents include, but are not limited to, antibiotics, analgesics, anticoagulants, bone growth enhancing agents, cells or gene

therapies, etc. The material may also incorporate other agents and materials, for example, radiopaque materials to aid visualizing the implant.

[0093] The joining material may also be severable. It may be desirable to have implants of certain lengths (e.g. a certain number of segments). It may also be desirable to have implants that are continuous, and allow the user to select their length by removing or cutting the connection between any two segments. For example, the joining material may be severable by mechanical, thermal, chemical, or electrical means.

[0094] In one version, the joining material is removable from some or all of the segments during or after insertion into the cavity.

Segment Dimension

[0095] Figs. 1A to 4D show different variations of the segments **12** compatible with the implant **10**. In fig. 1 the segments are all shown as spherical pellets. Fig. 1B shows that the pellet size may vary. Fig. 1C shows that the spacing of the segments on the joining material (shown as a filament **16**) may vary. The lengths of the implant (e.g. number of pellets) may also vary. Larger **14** segments and smaller **18** segments are arranged in the linear array. Virtually any combination of segment sizes and shapes may be used in the implant. Varying the size as shown in figure 1B may change the manner that the implant "packs" within a bone cavity. For example, packing of different sized segments may allow different spacing between the segments, and therefore different opportunities for tissue in-growth into the implant, different structural properties, and different loading patterns of adjacent structures.

[0096] Segmented implants may be configured so that the implant is securely packed into the body region (e.g. non-soft tissue cavity). Size, shape, and spacing all contribute to the packability of the implant within the body region. For example, the same implant may have segments of different sizes, shapes and spacing in order to optimize packing. Additional factors such as the ability of one or more segments to move along the linear axis of the implant may also contribute to packing.

[0097] The size of the segments may be selected to optimize the insertion into the cavity and use of the implant applicator described below. Thus, the segments may describe a range of sizes suitable for use with an applicator and/or suitable for insertion into a bone cavity of given dimensions. In one version the segments are between 1 to 40 mm in diameter. In one version the segments are between 1 to 37 mm in diameter. In one version the segments are between 1 and 10 mm in diameter. In one version, the segments are between 1 and 6 mm in diameter. In one version the segments are approximately 3 mm in diameter. In one version the segment diameter

is an average segment diameter. In one version, the segment diameter is the maximum diameter of a segment.

[0098] The implant may have different inter-segment spacing. Fig. 1C shows implant segments **12** arranged in a linear array in which there are larger **20** gaps and smaller **22** gaps between adjacent segments. Different arrangements of segments along the linear array may also have desirable effects on the packing behavior of the implant and the severability of the implant. Fig. 1D shows a version of the implant in which the spacing between segments is extremely small **24**, potentially reducing the flexibility of the implant. However, implant flexibility may also be increased by using more elastic joining materials and potentially allow greater packing.

[0099] The segments may also be slideable (or partially slideable) in one (e.g. the long or linear) axis of the implant. In one version of the implant some of the segments are slideable and some of the segments are fixed to the joining material. In at least one version of the implant, the slideable segments allow the implant to be "tensioned" by tightening the joining material, tending to stiffen the implant, perhaps to aid in anchoring the implant or distracting a bone separation, or in anchoring another implant or device.

[00100] The segments of the implant may also have different shapes, allowing different packing and implantation properties. Fig. 2 shows examples of segments with different shapes. Fig. 2A and 2B show a schematic and perspective view of cubic segment **202** shapes with rounded edges. The parallel faces of these segments **204** allow closer packing between adjacent segments. Fig. 2C is also an implant with cubic segments **206**. Fig. 2D shows an implant with rectangular-shaped segments **208**. Fig. 2E shows an implant with cylindrical segments **210**. Fig. 2F shows an implant with a slightly more complex segment shape having more than six faces. Virtually any shape that will allow the implant to fill a cavity to distract a cavity, create a cavity, and/or tighten or secure another implant, may be used. As used herein, unless the context makes it clear otherwise, "fill" means that the bone cavity is supported in three dimensions.

[0100] The implant assemblage described herein describes space-filling implants (for filling, distracting, void creation, etc.). Thus, implant segments may be adapted specifically to fill three dimensional spaces.

[0101] The implant may have segments of different shapes, including shapes that are configured to communicate with each other, for example, to interlock. Several examples of interlocking shapes are shown in Fig. 3A to 3X. In Fig. 3A to 3G, the bullet-shaped **302** segments have a front end **306** and a back end **304**, and at least some of them may slide along the axis of the linear array of the implant **10**. The back end of one segment can engage with the front end of an adjacent segment as shown **310**.

[0102] The segments may also be shaped to engage non-adjacent segments, for example, by having side faces that engage with other segments. The segments may also be shaped to engage with the walls of the cavity.

[0103] In Fig. 3E to 3G, the segments have a bullet shape with a conical nose **320**, a cylindrical body **322**, a conical recessed rear **324**, with linear and rotational inner-locking features, **326**. Fig. 3F shows a frontal view of two segments interlocked; figs. 3E and 3G show linked segments. The external surface has an advancing helical ramp **330** for assistance in advancement of a segment relative to adjacent segments when an axial load and rotational load are simultaneously applied to the implant. These features aid in compacting and elevating the hard tissue around the cavity being filled. The flexible rear extension **334** with external round **332** increase the likelihood of interstitial placement.

[0104] In Figs. 3H to 3K, the implant comprises common segment shapes that have six over-lapping male spherical ball geometries creating a complex external multiply spherical surface **340**. Fig. 3H shows three segments interacting. Figs. 3I to 3K show linked segments. These segments may interlock because of the spheres nesting within the adjacent segments' depression created by the curved (e.g., semi-spherical) segment surfaces creating multiple coincident mating tangency points **342**. The segments can be arranged along the connective member in a common entry and exit orientation **344** as in figs. 3I and 3K or an alternating pattern **346** as in fig. 3J.

[0105] In figs. 3L and 3M, the implant **10** consists of two different segment shapes alternating and repeating along the connective member. The first segment **350** is similar to the segment described in figs. 3H to 3K consisting of six over-lapping male spherical ball geometries **340**. The second segment **352** is a segment that has six female spherical recesses **354** that will enable tight interlocking and packing of the implant within the cavity.

[0106] In figs. 3N and 3P the implant **10** consists of two different segment shapes alternating and repeating along the connective member. The first segment **352** is similar to the segment in figs. 3L and 3M. The second segment **356** is spherical. The configuration of this implant affords a tight packing with numerous mating receptacles open to accept the spherical segments and thus may be less dependent on packing order than other versions.

[0107] In fig. 3Q, the implant **10** consists of two different segment shapes alternating and repeating along the connective member. The first segment **360** is arrowhead-shaped with front **361** and rear faces **362** pointed and made up of two angled faces. The second segment **365** is an elongated arrowhead with otherwise similar front and rear faces. The segments can be arranged in a manner that will allow a control of the desired mating and direction that the segments will

follow once the segments leave the delivery cannula and meet resistance within the cavity. The direction change will be dictated by slight angular differences between the mating arrowheads.

[0108] In fig. 3R the implant comprises common segments shaped like coins **370** with conical spikes **372** protruding from the faces of the coins. The coin faces **374** have holes through them **376** that facilitates stacking of the coins, and the spikes are conically shaped to facilitate the self-centering stacking of the segments. The stacked coins create common tangency points 180 degrees opposed from each other that create two parallel planes of support.

[0109] In fig. 3W the segments have a cross-sectional area that is rectangular with various previously described front and rear geometries.

[0110] In fig. 3X the segment cross-section is triangular with various previously described front and rear geometries. In some versions, the segments can have polygonal cross-sections, for example, hexagonal, octagonal, etc.

[0111] The aspect ratio of the segments' length relative to the segments' height and width can be varied in order to allow variations of stacking, packing, steering or elevating, depending on the desired result.

[0112] Many of the implant segments shown (e.g. figs. 1, 2 and 3A-3K and 3Q – 3T) are illustrated as substantially 'solid.' Implant segments may also be hollow or have passages for either the joining material or additional material such as a fluent material (e.g. cement). Implant segments may also be porous, for example, to facilitate tissue in-growth, or reduce overall segment weight. Fig. 4A and 4B show an implant that has passages **402**. Fig. 4C and 4D show an implant with pores, or hollow spaces, **404** that do not span the length of the segment. In one version the pores **404** are dimples.

[0113] Implant segments may also be used with a fluent material. Examples of fluent materials include cements (e.g. bone cements, synthetic bone graft cements, etc.), therapeutics (e.g. bone morphogenic proteins, cells or gene therapies, bone growth factors), or combinations or substitutions thereof. In one version the fluent material is applied into the cavity after the implant has been inserted. In one version the fluent material is added before the implant. In one version, the fluent material is added concurrent with insertion of the implant. In one version the fluent material is inserted into the flexible joining material (e.g. a flexible tube around the implant segments). The flexible tube may be impermeable to the fluent material, keeping it substantially contained within the bone cavity.

Applicator

[0114] An applicator may be provided to insert a material such as the implant into a cavity to fill or distract the cavity, and/or to create or expand a cavity. The applicators described herein

may be used to insert or remove an implant described herein. The applicators described herein may be used with any compatible material, including but not limited to individual pellets, fluent materials, and linear arrays of any materials desirable for insertion or removal from the body.

[0115] Fig. 5 shows an applicator **50** useful for inserting an implant into a cavity (e.g. a bone cavity). The applicator has a cannula **502** having a distal and a proximal end and a lumen **506** with a handle **505** to aid in controlling the distal end orientation of the cannula. An implant **10** can be inserted into a bone cavity from the distal end of the cannula through an opening at the distal end **508**. A feed guide **504** connects to the proximal end of the cannula. The feed guide can insert or withdraw the implant in and out of the lumen of the cannula through an opening in the proximal end of the cannula. An applicator may also have a handle **510** or a feed chamber to store implant material.

Cannula

[0116] The cannula may be an elongated tubular member having a lumen or passage to facilitate the movement of an implant through the cannula. The inner lumen of the cannula may be configured to hold and allow the passage of an implant. The inner surface of the lumen may be size-matched to the diameter of the implant. Alternatively, the size of the implant (e.g. segment size) may be limited by the inner diameter of the applicator cannula. The inner surface of the cannula may include a material that facilitates the movement of an implant (for example, a friction-reducing coating or a lubricant). The cannula may also allow the passage of a secondary filling material (e.g. a fluent material) before, after and/or during the insertion of an implant. An applicator cannula may be flexible or rigid.

[0117] The cannula may also have a fastener towards the distal end to hold the cannula in place on the outer surface of the bone being treated. A fastener or gripper near the distal end of the cannula may be used to aid the user in holding an applicator steady while inserting the implant to distract a bone cavity. In one version the distal end of the cannula is threaded to facilitate insertion into, for example, the pedicle of a vertebra. The threads may further serve as a fastener or gripper.

[0118] The distal end of an applicator cannula may be adapted to aid in penetrating and/or distracting a bone cavity. In one version, the distal end of the cannula includes a trocar. In one version, the distal end of the cannula includes a spreader to separate bone surfaces and aid insertion of an implant.

[0119] The distal opening of an applicator cannula may be located at the distal-most part of the cannula, or it may be located all or partly on the perpendicular axis of the cannula (e.g. on the side of the cannula, or at an angle), allowing more directional filling of a bone cavity by an

applicator. Fig. 6A shows the distal end of an applicator cannula in which the distal opening is the extreme distal end of the cannula. The implant **10** exits the applicator **502** through the cannula's distal opening **508**, and begins to fill the bone cavity **602**, as shown.

[0120] Fig. 6B shows the distal end of an applicator cannula in which the distal opening **508** is at a 45° angle from the long axis of the cannula. Thus the implant **10** is inserted into the bone cavity **602** at a 45° angle relative to the cannula. Fig. 6C shows the distal end of an applicator cannula in which the distal opening **508** is at a 90° angle from the long axis of the cannula. Thus the implant **10** is inserted into the bone cavity **602** perpendicular to the cannula.

[0121] The outer surface of the cannula may have graduated indicia that provide depth of penetration information during insertion by the user.

[0122] An applicator may be operated with a guide cannula. In one version, an applicator cannula fits into the lumen of a guide cannula; the guide cannula is used to locate and prepare the bone cavity for insertion of the implant by an applicator. In one version, an applicator cannula locks into a guide cannula and the guide cannula is secured to the bone that is being operated upon.

[0123] An applicator may also include a cutter configured to sever the implant by removing the connection between two of the segments in the linear array of an implant. An example of a cutter **1001** is shown in fig. 10. The cutter may be located at least partly at the distal end of the cannula. The cutter may be located at least partly within a region of the inner lumen of the cannula. In one version the cutter is located at an outer surface **509** of the distal end of an applicator cannula, adjacent to the distal opening **508**. Rotating an external sheath drives a cutting edge across the cannula's distal opening thereby severing the connection between implant segments. In this version the cutter is actuated by rotating the external sheath 510. As illustrated in fig. 10, the cutter may be a mechanical cutter capable of applying force to sever the implant. Additional examples of mechanical cutters include but are not limited to, a blade, a scissor-like cutter, and the like. The cutter may be an electrical cutter capable of applying electrical energy to sever the implant. The cutter may be a chemical cutter capable of chemically severing the implant, for example, by applying a compound that reacts with the joining material of the implant. The cutter may be a thermal cutter which acts, for example, by heating the material connecting the segments causing it to release. The cutter may be any combination of mechanical, electrical, chemical and thermal cutter. The cutter may be controlled by a cutting controller. The cutting controller may be controlled directly by the user, or as part of a system.

Driver

[0124] An applicator may further comprise a driver for applying force to the implant in order to move the implant within the cannula to insert the implant into or withdraw the implant from a bone cavity. An applicator may be a mechanical drive (e.g. linear driver, a rotary driver, etc.), a pneumatic driver, hydraulic driver, a magnetic driver, an electric driver, or any combination thereof. Examples of drivers include, but are not limited to, rotating auger drivers, and rotating cog drivers. The driver is preferably a rotatable driver. Force generated by the driver is transferred to the implant (or a part of the implant), moving the implant within the cannula, in either the proximal or distal direction. In one version, the driver is located at least partly within the cannula. In one version the driver is located at least partly within the feed guide. An introducer member may comprise a driver as described here.

[0125] Applicator drivers engage at least a region of an implant. Figs. 7A and 7B illustrate a cog driver **702** engaging at least part of an implant **10**. As the cog is rotated about its central axis **708**, in the direction indicated by the arrows (**704** and **706**), the implant is moved in the complimentary direction because segments of the implant **12** have engaged with the cog teeth **712** and are pulled or pushed in the direction of the rotation as shown. Because the segments of the implant are connected, movement of at least one of the segments results in moving the implant. An applicator driver may comprise more than one cog, or a cog and other driver components. Figs. 7A and 7B also show the driver (a cog) at least partly in the lumen **506** of the applicator cannula **502**.

[0126] In one version, the cog is a friction wheel. In one version, an outer surface of the friction wheel driver engages one or more regions of an implant (e.g. a segment). When the cog is a friction wheel, it may not have "teeth" which engage the implant.

[0127] Figure 7C shows a rotating auger driver. In one version, the auger is a continuously threaded rod **720**; the implant's segments **12** fit within the threading gaps **722**. In one version, the rotating auger is located at least partly within the cannula. At least some of the implant segments are seated in the auger and are prevented from rotating around the long axis of the auger, for example by the geometry of the cannula or chamber surrounding the auger. Rotating the auger forces the segments (and thus the implant) to move down the long axis of the rod. Reversing the direction of rotation of the auger changes the direction that the implant moves. An applicator driver may comprise more than one auger, or an auger and other driver components.

[0128] A driver may also be at least partially within the cannula. In one embodiment the cannula lumen contains a rotatable auger. In one version the driver is entirely located within the cannula.

[0129] A driver may be located at the proximal end of the applicator cannula, as indicated in Fig. 7D. Force applied by the driver moves an implant within the cannula, into or out of the bone cavity **602**. The driver may be capable of moving an implant into or out of a bone cavity by changing the direction that force is applied to the implant. An applicator driver may be attached to, integral to, or coupled to a feed guide.

Feed Guide

[0130] An applicator may include a feed guide **504** for loading the applicator cannula with an implant. A feed guide may be coupled to the proximal end of the cannula as shown in fig. 5. A feed guide may comprise a chamber, a cartridge, a track, or other such structure in which an implant can be held. The feed guide may orient the implant for inserting or withdrawing from the cannula. The feed guide may also assist in engaging an implant with a driver.

[0131] In one version, a feed guide is preloaded with an implant. For example, it may be advantageous to have the feed guide be a pre-loaded cartridge holding an implant. Such a feed guide may be separately sterilized and interchangeable between applicators.

[0132] In one version, the feed guide includes a track configured to guide an implant. A track may keep the implant from jamming or tangling within the applicator. A track may further allow a long implant to be stored compactly. The feed guide may also help regulate the amount of force needed to move the implant.

[0133] In one version the feed guide may be configured to engage an implant into a driver. In one version a driver is at least partly contained within the feed guide. In one version the feed guide attaches to a driver. In one version the feed guide is configured as an opening in the cannula into which an implant may be manually inserted.

Controller

[0134] An applicator for inserting an implant may also include a controller for controlling the applicator driver. A controller may be manually or automatically operated. A controller may control the force applied by the driver. The controller may control the rate of insertion/withdrawal of an implant. A controller may control the direction that force is applied (e.g. forward/reverse). A controller may be operated by a user.

[0135] An applicator may also include detectors or indicators for registering implant and applicator parameters. In one version an applicator includes a detector for determining and/or

indicating the force applied by the applicator to insert or withdraw an implant. When a cavity is being filled, and particularly when a bone cavity is being distracted, an implant may be applied using a force adequate to insure that the implant is properly positioned within the cavity. Thus it may be important to monitor force and pressure applied to the implant or volume of implants, and/or the tissue. Feedback mechanisms may also be used to regulate the actions of the applicator, including the force applied by the applicator.

[0136] An applicator may also include detectors or indicators for indicating the status of the implant. For example, a sensor may indicate the amount of implant inserted, the amount of implant left in the applicator, and/or the position of the implant within the applicator or the bone cavity. In one version, the applicator includes a force gauge for detecting the force applied by the applicator on the implant being inserted. The applicator may also include a display capable of indicating a status. Examples of the kinds of status that the display could indicate include, but are not limited to, force applied, total volume, linear feed rate, volume feed rate, amount of implant material inserted, and/or amount of implant material remaining in the applicator.

Implants Compatible with the Applicator

[0137] The application described herein may be used with any compatible implant, including but not limited to discrete (loose) pellets or segments of any material (including segments or pellets as described herein), fluent materials (e.g. cements, bone fillers, etc.), and any implant, particularly those comprising a linear array of elements. Such applicators may also be useful for filling and distracting bone cavities. In one version the applicator comprises a cannula and a driver where the driver further comprises an auger or a cog. The auger or cog propels the discrete pellet, fluent material, or combination of implants, discrete pellets and/or fluent material, down the cannula in order to fill or distract the cavity into which the cannula has been inserted. It may be particularly advantageous to use the applicator with flexibly connected implants, including those described herein, because the applicator may be used to controllably insert and remove flexibly connected implants.

[0138] Additional exemplary applications of the applicator and/or implants as described herein are given below. These examples are intended only to illustrate various embodiments of the implant, applicator, and methods of use, and are not intended to be in any way limiting.

Examples

[0139] In general, the implants and/or applicators described herein may be used to distract an existing body region. In one version, the body region is a non-soft tissue cavity. In one version,

the body region is a hard tissue cavity, such as a bone cavity arising from a tumor, injury or surgery.

[0140] Fig. 8A to 8C shows an example of inserting an implant into a bone cavity **602**. In this example, the bone cavity is part of a vertebral compression fracture. Other examples of bone disorders and fractures which may be distracted include, but are not limited to, tibial plateau fractures, femoral head necrosis, osteonecrosis of the hip, knee injury, etc. Figure 8A shows an applicator **502** inserted into a vertebral compression fracture **804** through the vertebral pedicle **808**; the applicator is inserting an implant **10** into the collapsed region. The implant is shown as a linear array of pellets **12**. These segments of the implant may be continuously added to the bone cavity to first fill and pack within the cavity. Once the cavity is filled, adding further segments elevates the collapsed bone. Fig. 8B shows the bone cavity after it has been distracted by application of the implant. While some of the individual segments of the implant remain joined and connected to the applicator, the user may adjust the amount of distraction by removing and/or adding segments of the implant until the shape of the collapsed vertebra has been set to an optimal shape. In one version, the optimal shape is the natural (uncompressed) position.

Compaction of the implant within a cavity

Once an implant is inserted, it may be compacted within the body cavity by packing the individual segments. Any appropriate device or method may be used to compact the implant segments. These include utilizing vibration (e.g. ultrasonics, through the delivery of a second cannula or probe, for example, through the second pedicle) or physical compaction (e.g. using a curved probe or tamp through a pedicle path or with an internal or external sheath. Compaction may be particularly useful when filling hard tissue cavities such as bone cavities.

Closing the filled cavity

[0141] A cavity opening through which an implant was inserted may be closed and/or sealed to maintain the compaction, and to prevent the loss of implant material from the cavity. After filling and/or distracting a cavity, a user may cut the implant and remove the applicator cannula. Fig. 8C shows that the user may also block **802** or otherwise close the opening into the bone cavity, for example, by the local application of a cement material through the cannula (or another cannula). Other methods for closing the void may include tapered pins, screws with blunt head and tip, or even screws with compressible tip members such as a spring to absorb, minimize, or prevent settling of the implant.

[0142] Fig. 9 shows an example of a screw closure **900** for use with an implant that comprises a spring **903** for applying pressure to an implant within a cavity. The screw includes threads **905**. After distracting and/or filling a hard tissue cavity as described, the screw closure is screwed into the opening through which the implant was inserted. The spring-loaded tip **910** of the screw is blunt, and applies pressure onto the inserted implant. Thus, the screw can minimize any settling or further compaction that may occur after the insertion of the implant by applying pressure to help keep the implant compacted.

[0143] In general, implants and applicators as described herein may be used for filling cavities that do not require distraction.

[0144] A secondary filling material may also be used. For example, when filling a bone cavity, fluent bone filler may also be used to fill the cavity in addition to the solid implant. The combination of hard segment and fluid filler may provide added stability. The fluent material (e.g. cement) may also harden into a solid. In addition, the implant segments may reduce leakage of additional bone filler (such as bone cement) by blocking openings in the cavity that fluent filler would otherwise leak through. Less fluent filler may be needed if it is used after the solid implant, further reducing the risk of harmful leakage. In one version, secondary filling material may be applied in conjunction with an expandable membrane around the implant segments, preventing any substantial leakage from the bone cavity.

[0145] In general, the implants and/or applicators described herein may be used to distract a cavity without being left in the cavity after distraction. For example, an implant may be used to create or enlarge a cavity. In one example, an implant may be inserted into a body region void to expand the void. The surfaces of the body region void will be compressed by the implant, causing it to expand. After removing the implant, the cavity may remain expanded, facilitating further procedures (e.g. insertion of additional devices or materials, etc). Similarly, a hard tissue cavity such as a bone cavity may be enlarged or reshaped by inserting an implant which can then be removed or left within the non-soft tissue cavity.

[0146] It may be desirable to leave the implant in the tissue for an extended period of time, up to and including the lifetime of the patient. In one version, the implant is a permanent implant for filling and/or distracting body regions to provide long-term support and shape to the body region. In one version, the implant is intended to be used for a period of at least six months. In one version, the implant is intended to be used for a period of at least a year. In one version, the implant is intended to be used for a period of many years. Implants intended for long-term use may be made of materials which do not lose a significant amount of their strength or shape over time after implantation.

[0147] In general, the implants and/or applicators described herein may be used to secure another implant. For example, a bone screw may be inserted into an implant filling a bone cavity. This may be particularly useful when it is desirable to use a bone screw in weakened (e.g. osteoporotic or necrotic) bone tissue. In another version, the implant described herein may be inserted to secure an existing implant.

[0148] In summary, the described implants, applicators and methods of using them may be used to fill and/or distract a non-soft tissue including a bone cavity, in particular a vertebral compression fracture. The implant may achieve many advantages not realized with other devices intended to fill and/or distract a bone cavity. In particular, the implant described herein substantially reduces the chance of harmful leakage of bone filler material and provides three-dimensional support to the bone cavity.

[0149] Although the above examples have described primarily the filling of bone cavities, and particularly vertebral compression fractures, the implant, applicator and methods described herein may be used on any tissue cavity, including but not limited to those arising from trauma, fractures, non-unions, tumors, cysts, created by a pathology or by the action of a surgeon. It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the described device as specifically shown here without departing from the spirit or scope of that broader disclosure. The various examples are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS

What is claimed is:

1. A segmented implant for introduction into a body region that is at least partially surrounded by non-soft body tissue, comprising a plurality of implant segments,

wherein at least two of the plurality of implant segments are flexibly connected and at least a portion of the segments comprise shapes configured to cooperate in enhancing segment packing and provide implant segment distractibility to the body region and form stability to a body region into which the segments have been introduced.

2. The segmented implant of claim 1, wherein at least a portion of the implant segments are configured to be introduced into the body region by engaging a rotating introducer member.

3. The segmented implant of claim 1, wherein at least a portion of the flexibly connected implant segments are configured to be introducible into the body region by engaging a rotating introducer member.

4. The segmented implant of claim 1, wherein at least a portion of the segments are comprised of one or more materials having sufficient material strength to provide implant segment distractibility to the body region.

5. The segmented implant of claim 4, wherein the material strength is crush strength.

6. The segmented implant of claim 1, wherein at least some of the segments are differently shaped from other of the segments

7. The segmented implant of claim 1, wherein at least a portion of the segments are comprised of one or more materials having material strength and the one or more shapes cooperate with the material strength of the materials to provide form stability and implant segment distractibility to the body region into which the segments have been introduced.

8. The segmented implant of claim 7, wherein the material strength is crush strength.

9. The segmented implant of claim 1, wherein more than two of the plurality of implant segments are flexibly connected.

10. The segmented implant of claim 1, wherein the majority of implant segments are flexibly connected.

11. The segmented implant of claim 1, wherein the implant segments are configured to provide distractibility and form stability to a body region comprising a bone cavity.

12. The segmented implant of claim 1, wherein the implant segments are configured to provide distractibility and form stability to a body region comprising a void between tissue surfaces.

13. The segmented implant of claim 1, wherein the at least two of the plurality of implant segments that are flexibly connected, are connected by a filament.

14. The segmented implant of claim 1, wherein the at least two of the plurality of implant segments that are flexibly connected are connected by a fiber.

15. The segmented implant of claim 1, wherein the at least two of the plurality of implant segments that are flexibly connected are within a flexible tube.

16. The segmented implant of claim 1, wherein the at least two of the plurality of implant segments that are flexibly connected are within a flexible tube comprised of a woven material.

17. The segmented implant of claim 1, further comprising a settable fluent material.

18. The segmented implant of claim 17, wherein the fluent material is a bone cement.

19. The segmented implant of claim 1, wherein at least a portion of the implant segments are different sizes than at least one other implant segment of the plurality of implant segments.

20. The segmented implant of claim 1, wherein at least some of the segments are movably connected along an axis of the implant.

21. The segmented implant of claim 1, wherein the implant segments are selectively severable.

22. The segmented implant of claim 21, wherein the implant segments are remotely severable by a user.

23. The segmented implant of claim 21, wherein the implant segments are mechanically severable.

24. The segmented implant of claim 21, wherein the implant segments are chemically severable.

25. The segmented implant of claim 21, wherein the implant segments are thermally severable.

26. The segmented implant of claim 21, wherein the implant segments are electrically severable.

27. The segmented implant of claim 1, wherein said at least one of the segments comprises a radiopaque material.

28. The segmented implant of claim 1, wherein at least some of the segments comprise a biodegradable material.

29. The segmented implant of claim 1, wherein at least some of the segments comprise a material that is not substantially biodegradable.

30. The segmented implant of claim 1, wherein at least some of the segments comprise a polymer.

31. The segmented implant of claim 1, wherein at least some of the segments comprise a metal.

32. The segmented implant of claim 1, wherein at least some of the segments comprise a composite material.

33. The segmented implant of claim 1, wherein at least one of the segments comprise a medicinal.

34. The segmented implant of claim 1, wherein at least some of the segments comprise a coating.

35. The segmented implant of claim 34, wherein the coating is a medicinal coating.

36. The segmented implant of claim 34, wherein the coating is a cross-linker.

37. An implant assemblage for filling a bone cavity comprising:

an implant comprising a plurality of flexibly connected segments configured for insertion into a bone cavity;

wherein said segments have a crush strength sufficient to maintain the distraction of two or more bone surfaces and further

wherein said implant assemblage is configured to maintain a shape within the cavity.

38. The assemblage of claim 37, wherein at least one segment is a substantially cubic shape with rounded edges.

39. The assemblage of claim 37, wherein at least one segment has two or more faces.

40. The assemblage of claim 37, wherein a plurality of the segments can interlock with other segments.

41. The assemblage of claim 37, wherein at least one segment is configured to engage non-adjacent segments.

42. The assemblage of claim 37, wherein at least one segment is a substantially solid shape.

43. The assemblage of claim 37, wherein at least one segment is a substantially hollow shape.

44. The s assemblage of claim 37, wherein at least one segment is configured to have passages therethrough.

45. The assemblage of claim 37, wherein at least one segment is a substantially different shape than at least one other segment.

46. The assemblage of claim 45, wherein the different segment shapes are located adjacent to each other in a repeating pattern.

47. The assemblage of claim 37, wherein at least one segment is a different size than at least one other segment.

48. The assemblage of claim 37, wherein segments of different sizes are arranged adjacent to each other in a repeating pattern.

49. The assemblage of claim 37, wherein at least one segment has a polygonal cross-section.

50. The assemblage of claim 37, wherein at least one segment has a triangular cross-section.

51. The assemblage of claim 37, wherein at least one segment has a rectangular cross-section.

52. The assemblage of claim 37, wherein the distance between at least two adjacent segments is different than the distance between other adjacent segments.

53. The assemblage of claim 37, wherein at least one segment is substantially slideable with respect to adjacent segments.

54. An applicator for inserting an implant into a tissue cavity comprising:

a cannula having a distal end and proximal end and a distal opening and a proximal opening;

a feed guide connected to the proximal end of said cannula so that the proximal opening of said cannula is in fluid connection with said feed guide; and

a driver at least partially within said feed guide for applying force to at least one portion of an implant wherein said force is applied by rotating at least a region of said driver in contact with the implant.

55. The applicator of claim 54, wherein said tissue cavity is a non-soft tissue cavity.

56. The applicator of claim 54, further comprising a force gauge configured to detect the force applied by said driver.

57. The applicator of claim 56, further comprising a display configured to show the force detected by said force gauge.

58. The applicator of claim 54, further comprising a trocar located at the distal end of said cannula.

59. The applicator of claim 54, further comprising a fluent material source configured to connect to said cannula for delivering a fluent material.

60. The applicator of claim 54, wherein said implant comprises one or more loose pellets.

61. The applicator of claim 54, further comprising a gripper located distally on the cannula.

62. The applicator of claim 54, wherein said implant is a segmented implant comprising a plurality of flexibly connected segments.

63. The applicator of claim 62, further comprising a cutter configured to sever a connection between at least two of said flexibly connected segments.

64. The applicator of claim 63 wherein said cutter is a mechanical cutter.

65. The applicator of claim 64, further comprising an actuator for activating said cutter by a user.

66. The applicator of claim 54, wherein said driver comprises a rotatable auger.

67. The applicator of claim 66, wherein said auger is located at least partially in said cannula.

68. The applicator of claim 54, wherein said driver comprises at least one cog.

69. The applicator of claim 54, further comprising a controller for controlling said driver.

70. The applicator of claim 69, wherein said controller is configured to control the force applied by said driver.

71. The applicator of claim 69, wherein said controller is configured to control the direction of rotation of said driver so as to allow both insertion and removal of said implant.

72. The applicator of claim 69, wherein said controller is manually controlled.

73. The applicator of claim 54, wherein said feed guide comprises a cartridge pre-loaded with said implant.

74. The applicator of claim 54, wherein said distal opening of said cannula is at least partly on a side perpendicular to the long axis of said cannula.

75. The applicator of claim 54, wherein said distal opening of said cannula opens at an angle perpendicular to the long axis of said cannula.

76. An applicator for inserting and removing an implant into a tissue cavity comprising:

a cannula having a distal end and proximal end and a distal opening and a proximal opening;

a driver at least partially within said cannula for applying force to at least one portion of an implant wherein said force is applied by rotating at least a region of said driver in contact with the implant.

77. An applicator for inserting and removing a bone filler into a bone cavity comprising:

a cannula having a distal end and proximal end and a distal opening and a proximal opening; and

a rotatable auger configured to fit at least partly into said cannula to propel a bone filling material out of said distal end of said cannula.

78. An applicator for inserting and removing a bone filler into a bone cavity comprising:

a cannula having a distal end and proximal end and a distal opening and a proximal opening; and

a rotatable cog configured to fit at least partly into said cannula to propel a bone filling material out of said distal end of said cannula.

79. A method of filling a tissue cavity comprising:

providing an implant for filling a cavity;

providing an applicator for introducing the implant into the cavity, wherein the applicator comprises a cannula configured to pass at least a region of the implant, and a rotary driver at least partially within said cannula; and

introducing the implant into the cavity by rotating the driver.

80. A method of filling a non-soft tissue cavity comprising:

providing an implant for filling a tissue cavity comprising a plurality of flexibly connected segments;

providing an applicator for introducing the implant into the cavity, wherein the applicator comprises a cannula configured to pass at least a region of the implant, and a rotary driver at least partially within said cannula; and

inserting the implant into the cavity by rotating the driver;

providing a closure configured to close the cavity; and

closing the cavity with the closure.

81. A kit for filling a non-soft tissue cavity comprising:

a segmented implant comprising a plurality of segments wherein at least two of the segments are flexibly connected; and

an applicator configured for inserting a segmented implant into cavity wherein the applicator comprises a cannula configured to pass at least a region of the implant, and a rotary driver at least partially within said cannula configured to apply force to at least a region of the implant.

82. The kit of claim 81, further comprising a fluent material.

83. The kit of claim 81, further comprising a feed guide.

84. The kit of claim 81, further comprising a gauge.

85. The kit of claim 84, wherein the gauge is a force gauge.

86. The kit of claim 81, further comprising a display.

87. The kit of claim 81, further comprising a closure.

88. The kit of claim 81, further comprising a compaction device.

89. A segmented implant for introduction into a body region that is at least partially surrounded by non-soft body tissue, comprising a plurality of flexibly connected implant segments,

wherein the plurality of implant segments are within a flexible tube and at least a portion of the segments provide implant segment distractibility and form stability to the body region into which the segments have been introduced.

90. A segmented implant for introduction into a body region that is at least partially surrounded by non-soft body tissue, comprising a plurality of implant segments, wherein at least one segment comprises a different form than an adjacent implant segment, and at least two of the plurality of implant segments are flexibly connected, and wherein at least a portion of the implant segments provide implant segment distractibility to the body region and form stability to a body region into which the segments have been introduced.

91. A method of distracting a non-soft tissue cavity with an implant having a plurality of flexibly connected implant segments, wherein the plurality of implant segments are within a flexible tube and at least a portion of the segments provide implant segment distractibility and form stability to the body region into which the segments have been introduced, the method comprising:

inserting the flexibly connected segments into the cavity.

92. The method of claim 91, wherein the implant segments are inserted into the cavity by applying force to at least one segment of the implant.

93. The method of claim 92, further comprising measuring the applied force.

94. The method of claim 91, wherein said non-soft tissue cavity is a bone cavity.

95. The method of claim 94, wherein the bone cavity is a fractured vertebral body.

96. The method of claim 95, further comprising inserting the segmented implant into the fractured vertebral body until the normal height of the vertebra is substantially attained.

97. The method of claim 96, further comprising severing the implant behind the last segment inserted.

98. The method of claim 94, further comprising the step of providing fluent bone filler within the bone cavity.

99. The method of claim 91, further comprising the step of applying fluent bone filler within the flexible tube.

100. The method of claim 91, wherein the step of inserting the flexibly connected segments into the cavity comprises inserting the flexibly connected segments into the cavity through a cannula.

101. The method of claim 91, wherein the step of inserting the flexibly connected segments into the cavity comprises inserting the flexibly connected segments into the cavity using an auger.

102. The method of claim 91, further comprising closing the cavity using a closure.

103. The method of claim 102, wherein the step of closing the cavity using a closure comprises closing the cavity using a screw closure.

104. The method of claim 91, further comprises compacting the flexibly connected segments.

FIG. 1A

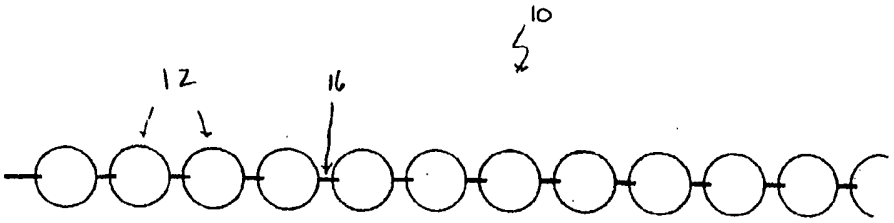


FIG. 1B

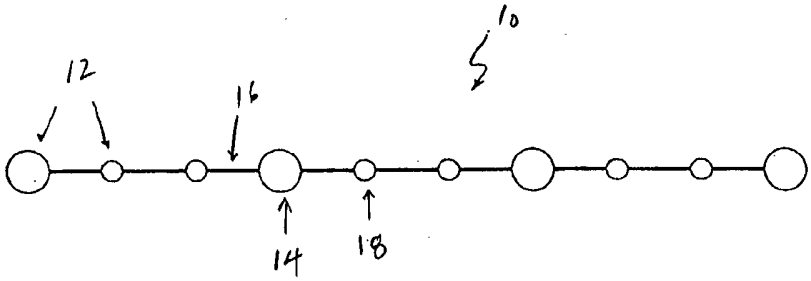


FIG. 1C

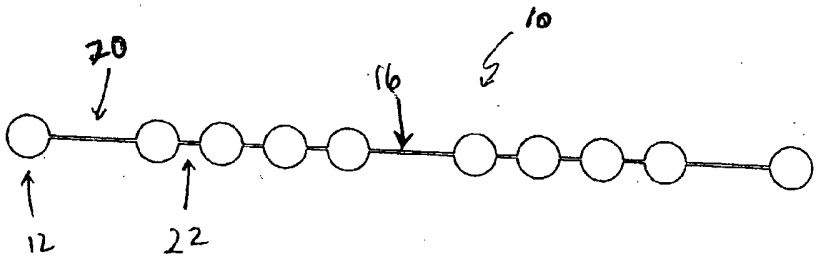


FIG. 1D

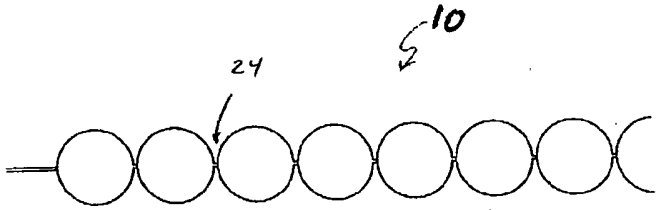
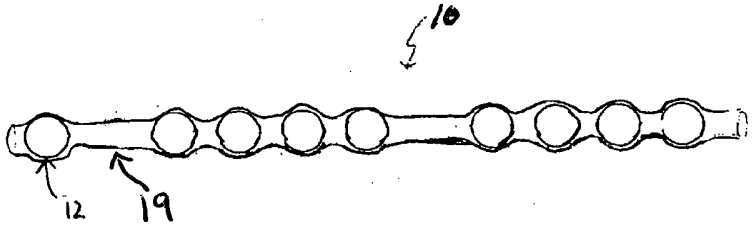


FIG. 1E



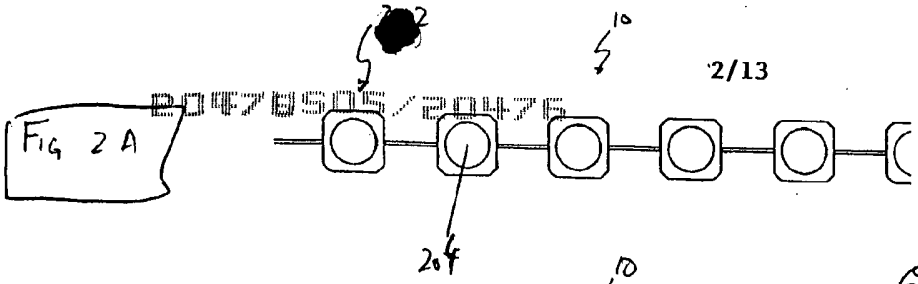


Fig 2A

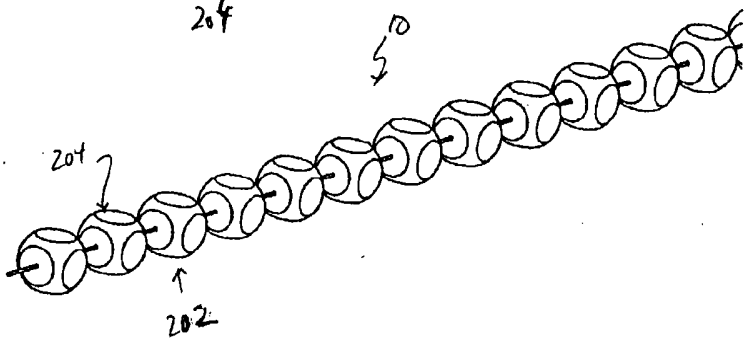


Fig. 2B

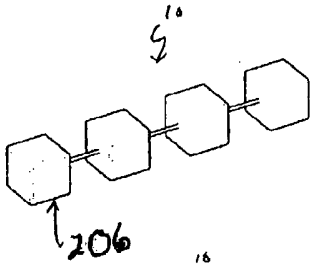


Fig 2C

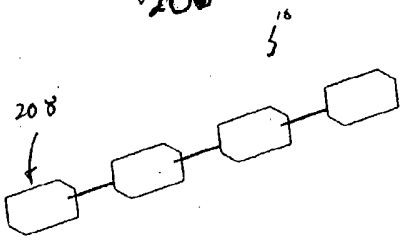


Fig 2D

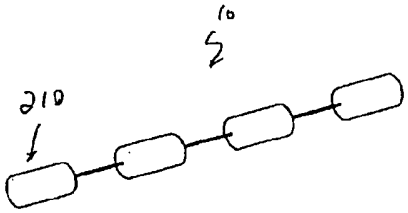


Fig. 2E

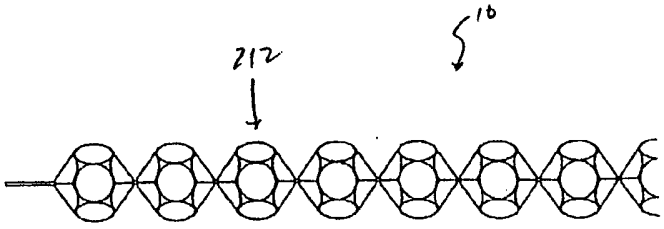


Fig 2F

FIG 3 A

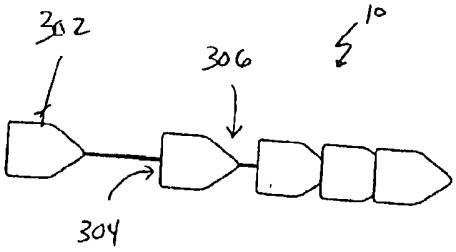


FIG. 3B

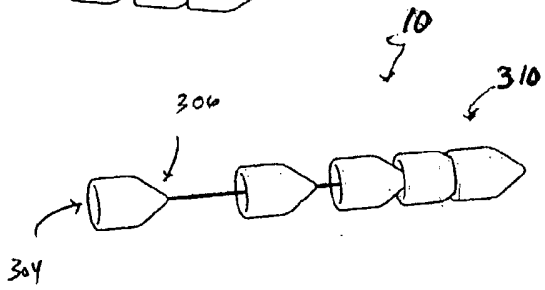


FIG 3 C

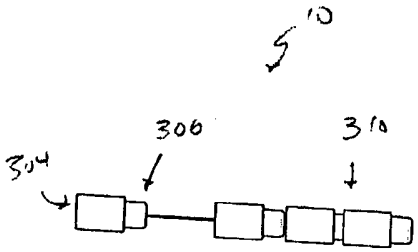


FIG. 3 D

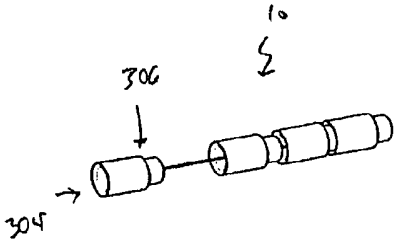


Fig 3E

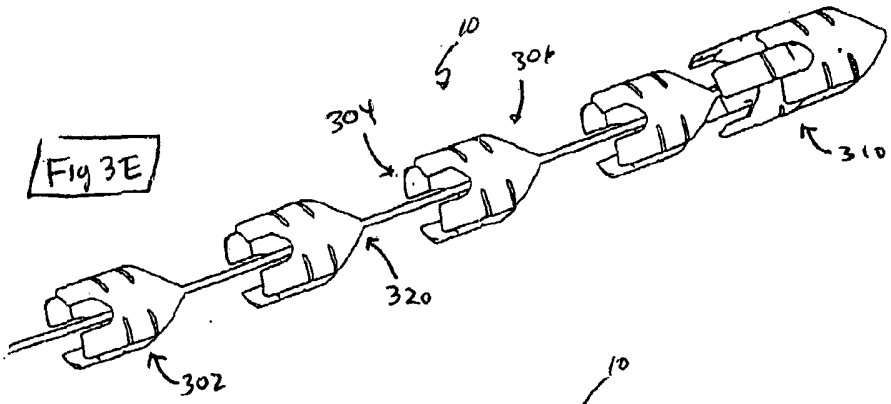


Fig 3F

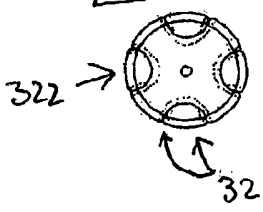


Fig 3G

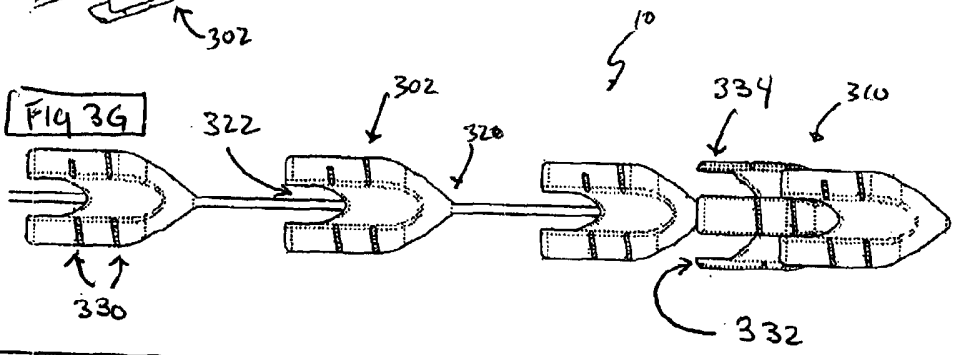


Fig 3H

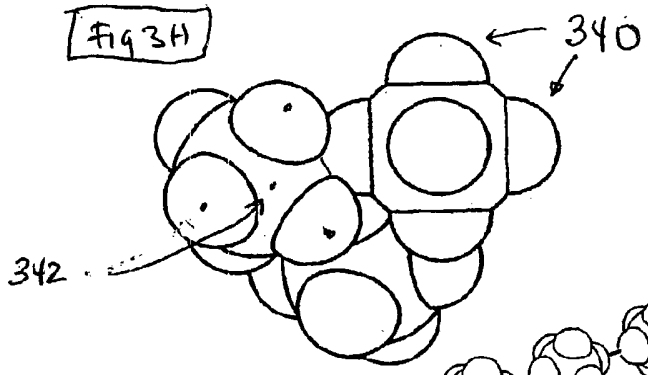


Fig 3I

Fig 3J

Fig 3K

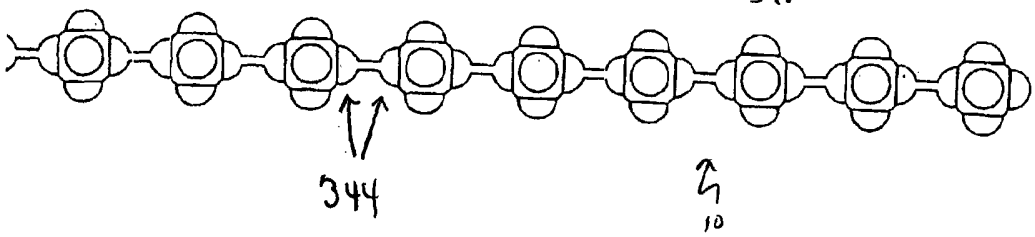


Fig 3L

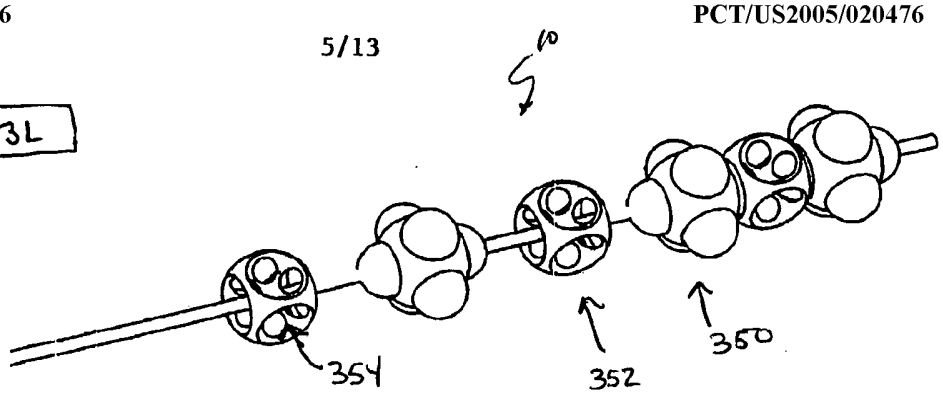


Fig 3M

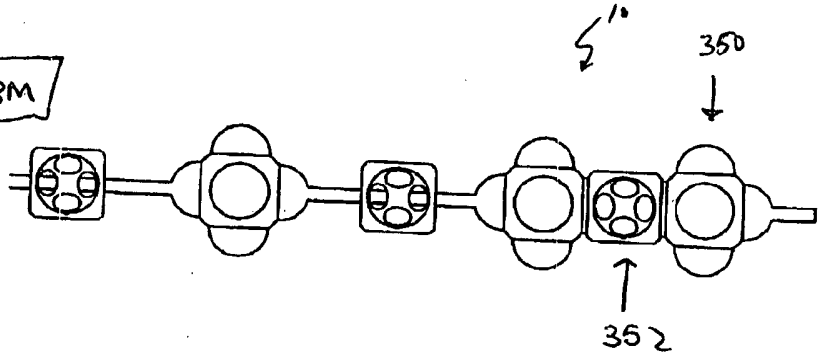


Fig 3N

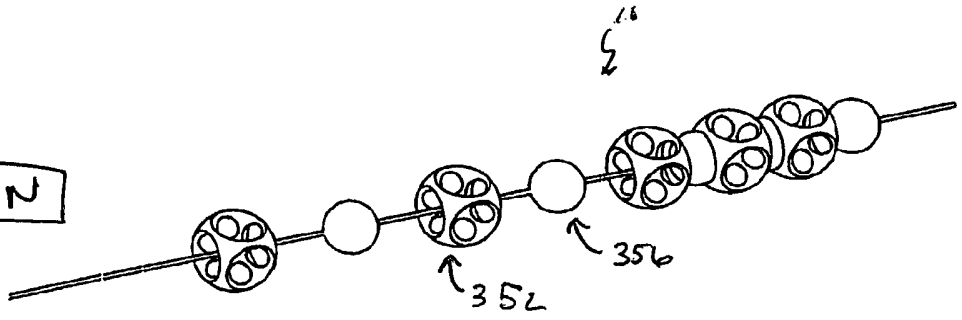


Fig 3P

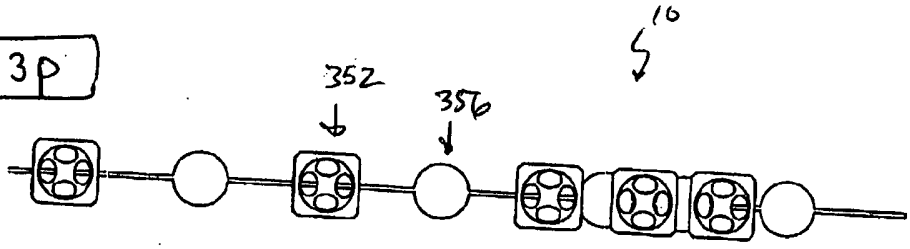
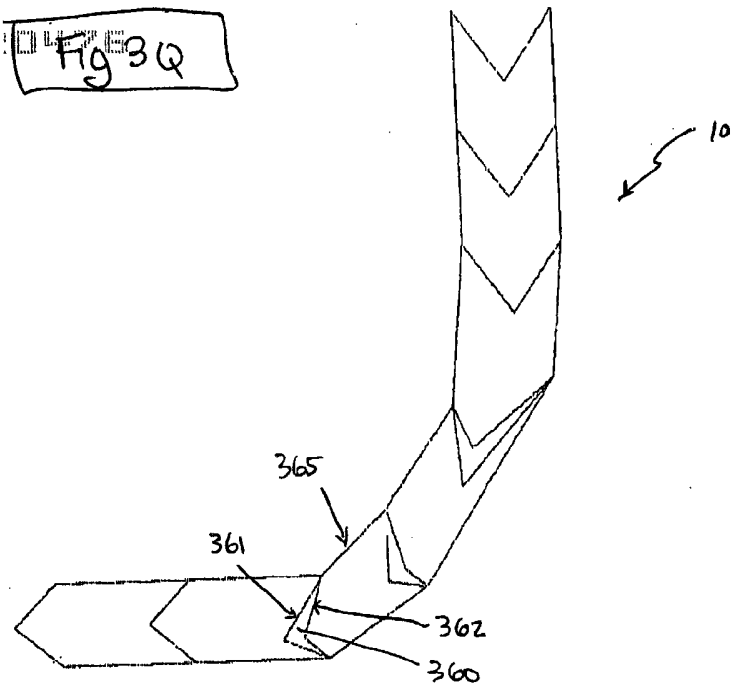


Fig 3Q



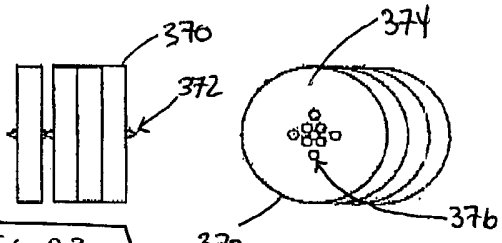


Fig 3R

Fig 3S

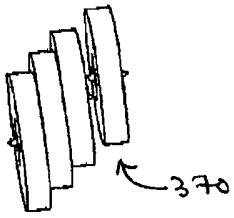


Fig. 3T

Fig. 3W

Fig. 3X

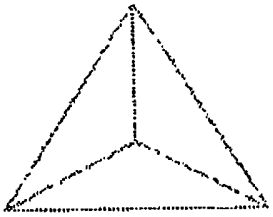


Fig. 4 A

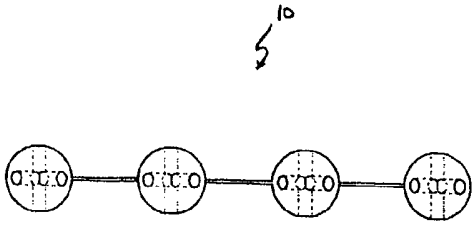


Fig. 4B

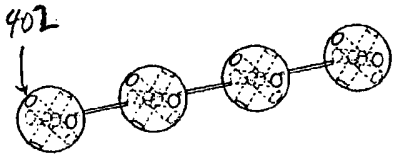


Fig 4C

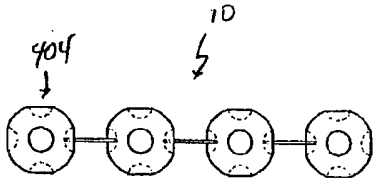


Fig 4D

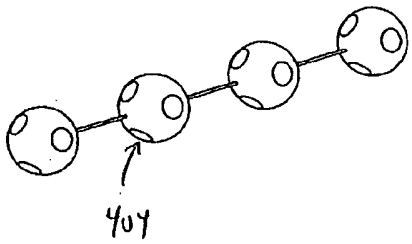
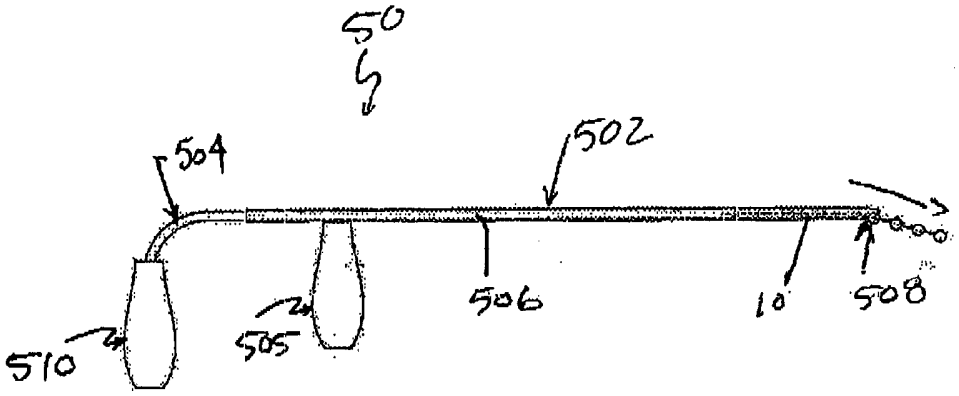


FIG 5



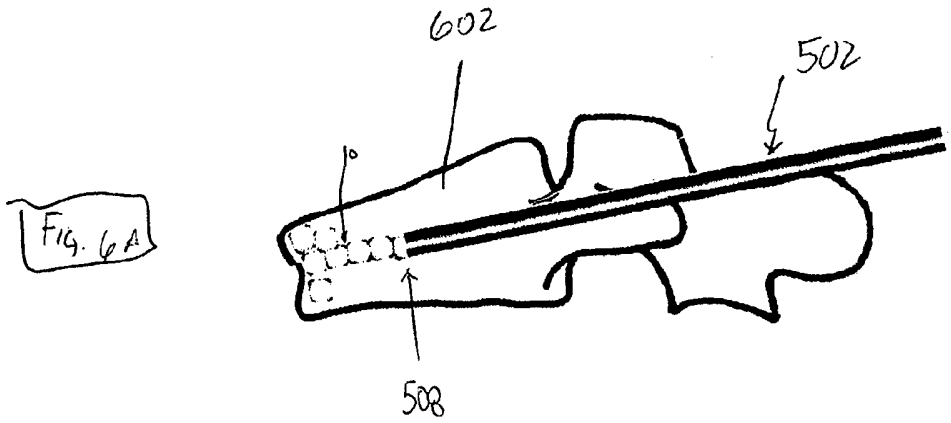


Fig. 6A

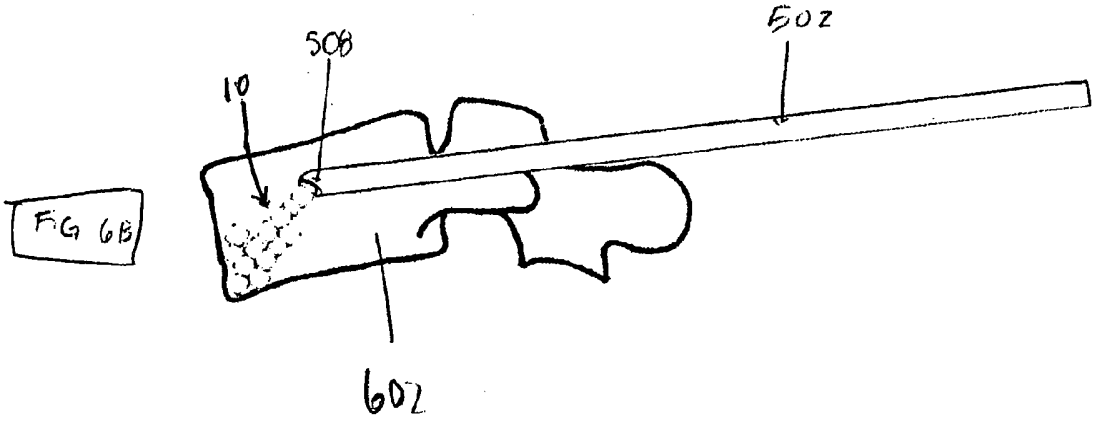


Fig 6B

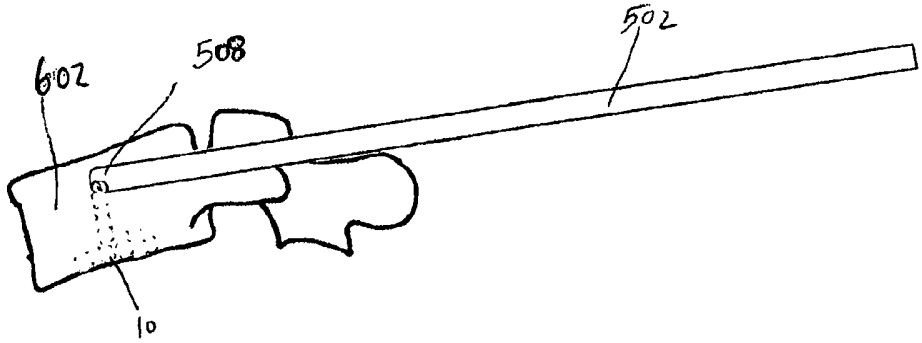


Fig. 6C

Fig 7A

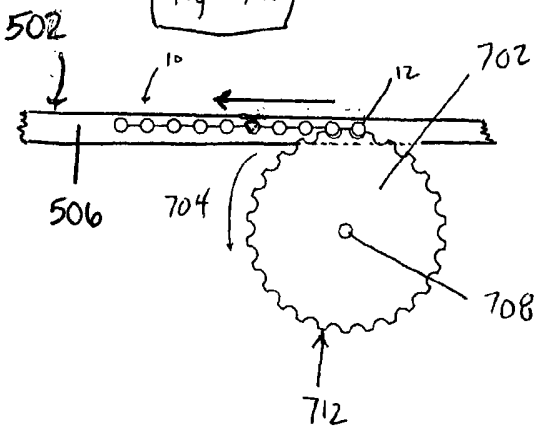
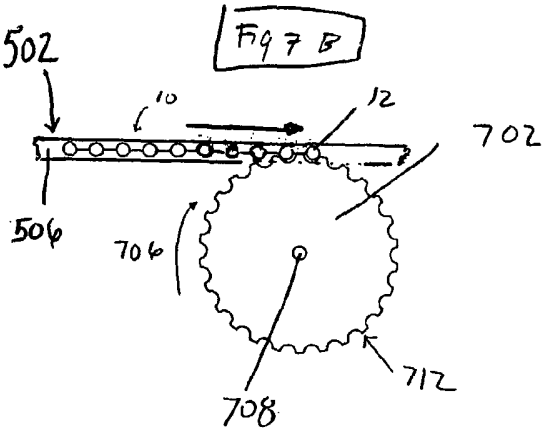


Fig 7B



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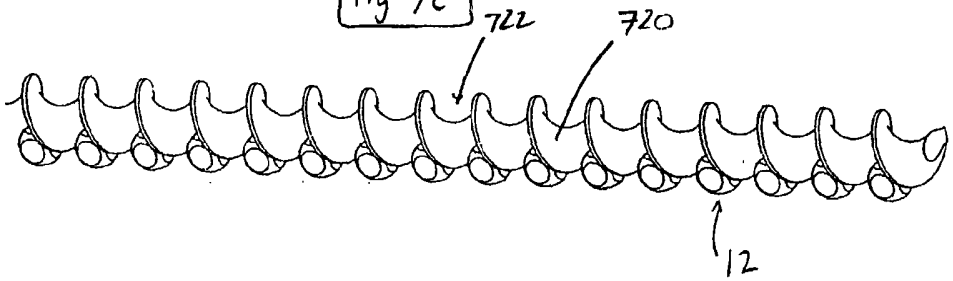

Fig. 7D

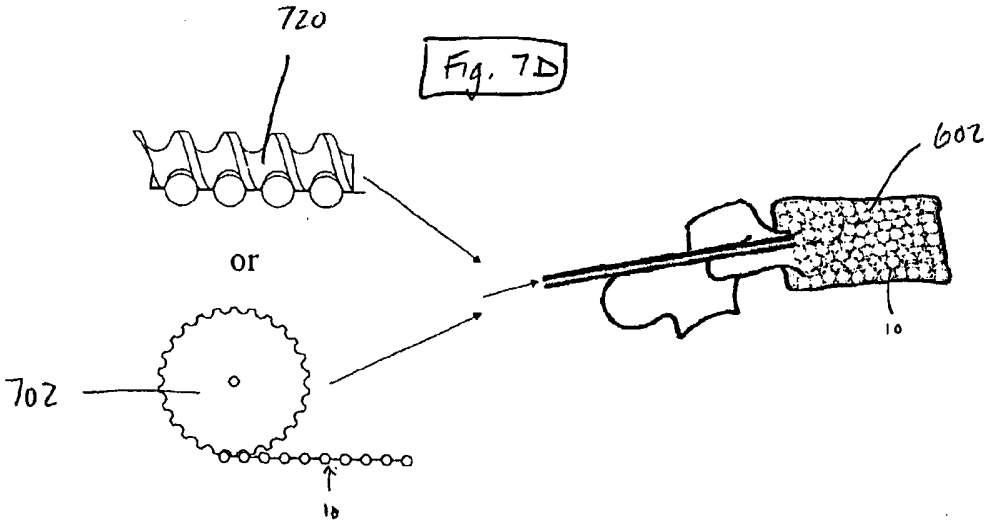

Fig 8A

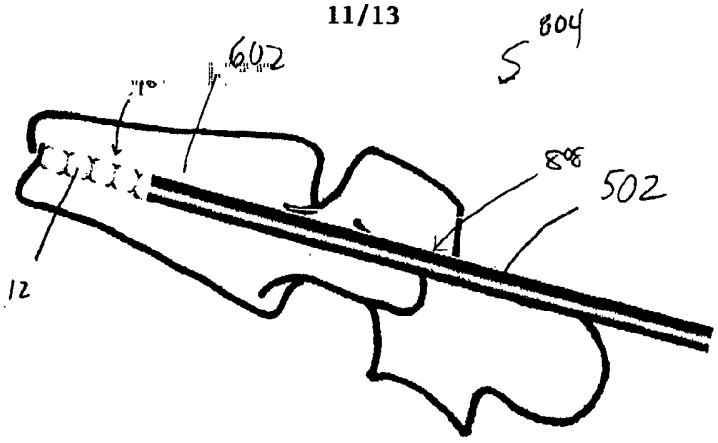

Fig. 8B

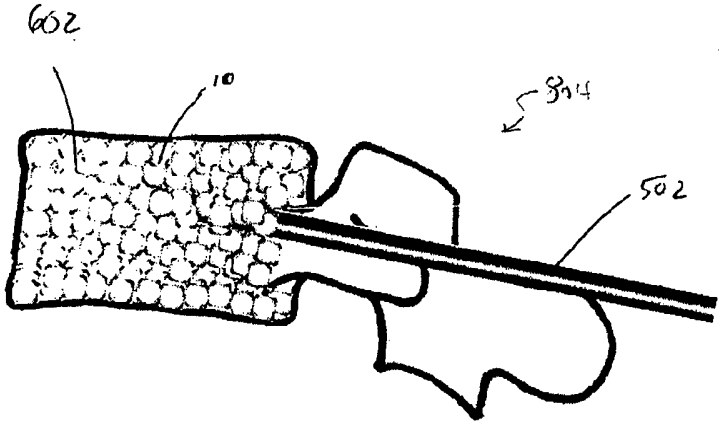

Fig. 8C

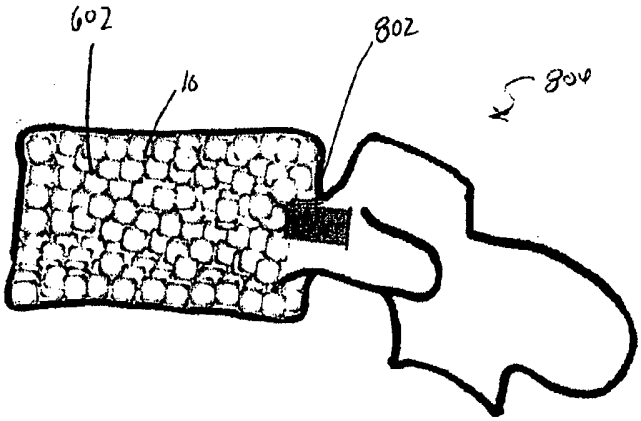

Fig. 9A

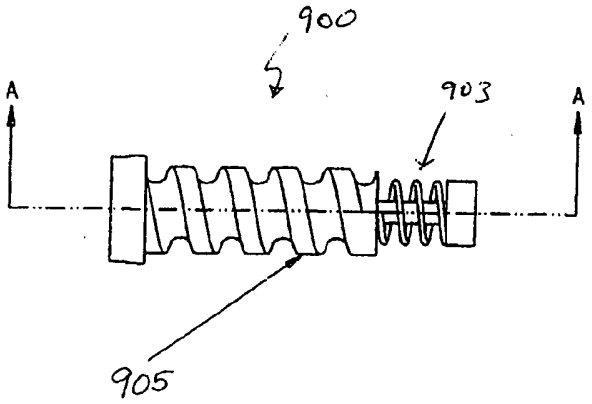

Fig 9B

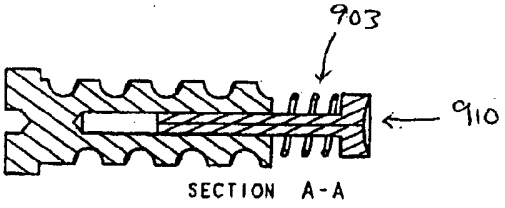

Fig. 10