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Behzadi et al.

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(54) **MATERIALS IN ORTHOPEDICS AND FRACTURE FIXATION**

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(Continued)

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(58) **Field of Classification Search**

None

See application file for complete search history.

(73) Assignee: **Kambiz Behzadi**, Pleasanton, CA (US)

(56) **References Cited**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 828 days.

U.S. PATENT DOCUMENTS

4,608,053 A 8/1986 Keller
5,330,477 A * 7/1994 Crook A61B 17/70
606/280

(Continued)

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FOREIGN PATENT DOCUMENTS

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WO 2007096476 A2 8/2007

OTHER PUBLICATIONS

Related U.S. Application Data

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Amorphous Metals Information, https://www.globalspec.com/learnmore/materials_chemicals_adhesives/metals_alloys/amorphous_metals#:~:text=Amorphous%20metals%2C%20also%20known%20as,random%20arrangement%20in%20the%20solid, accessed Apr. 11, 2023.*

(Continued)

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A61F 2/34 (2006.01)

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(74) *Attorney, Agent, or Firm* — PATENT LAW

OFFICES OF MICHAEL E. WOODS; Michael Woods

(52) **U.S. Cl.**

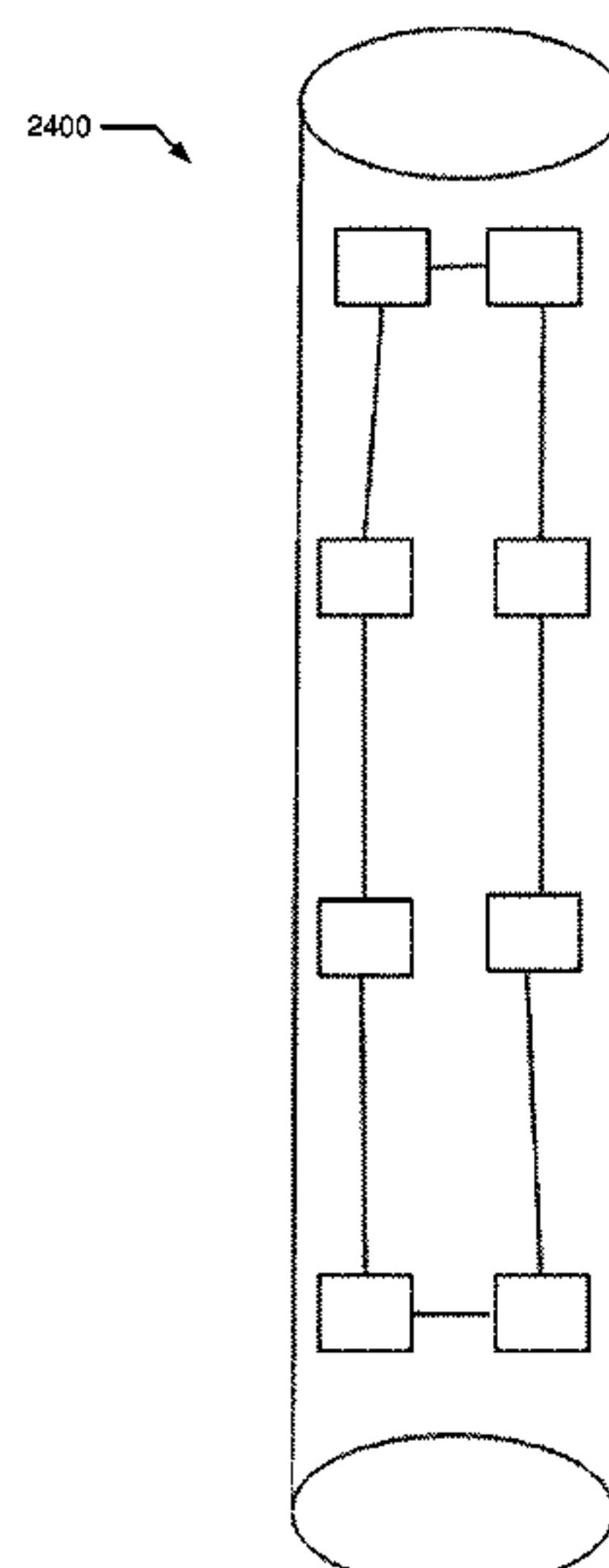
CPC **A61F 2/34** (2013.01); **A61B 17/60** (2013.01); **A61B 17/7283** (2013.01); **A61F 2/28** (2013.01); **A61F 2/30771** (2013.01); **A61B 17/66** (2013.01); **A61B 34/10** (2016.02); **A61B 2017/00526** (2013.01); **A61B 2017/00862** (2013.01); **A61B 2017/00964** (2013.01); **A61B 2017/564** (2013.01); **A61B 2034/105** (2016.02); **A61F 2/3094** (2013.01); **A61F 2/4609** (2013.01); **A61F 2002/2825** (2013.01); **A61F 2002/30224** (2013.01); **A61F**

(57)

ABSTRACT

A system and method for improving upon an ability of a surgeon to repair traumatic bone injury using new materials, components, and structures. A structure may be used as an implant or a component of an external fixator for a fractured long bone with that structure having anisotropic and viscoelastic properties, such as through additive manufacturing techniques.

2 Claims, 18 Drawing Sheets



Related U.S. Application Data

of application No. 16/532,448, filed on Aug. 5, 2019, now abandoned, which is a division of application No. 15/592,233, filed on May 11, 2017, now abandoned, which is a continuation-in-part of application No. 15/406,752, filed on Jan. 15, 2017, now abandoned, which is a continuation-in-part of application No. 15/234,927, filed on Aug. 11, 2016, now Pat. No. 10,864,083.

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(56) **References Cited**

U.S. PATENT DOCUMENTS

5,358,532	A	10/1994	Evans et al.
5,702,473	A	12/1997	Albrektsson et al.
5,713,901	A	2/1998	Tock
6,048,365	A	4/2000	Burrows et al.
6,197,062	B1	3/2001	Fenlin
6,231,612	B1	5/2001	Balay et al.
7,875,083	B2	1/2011	Sudmann
10,299,930	B2	5/2019	Behzadi
2005/0004680	A1	1/2005	Saladino et al.
2005/0015154	A1	1/2005	Lindsey et al.
2007/0219641	A1	9/2007	Dorr et al.
2007/0233065	A1 *	10/2007	Donofrio A61B 8/4472 606/309
2008/0051779	A1 *	2/2008	Mackenzie A61B 17/62 606/57
2008/0091271	A1	4/2008	Bonitati et al.
2008/0234833	A1	9/2008	Bandoh et al.
2008/0255560	A1	10/2008	Myers et al.

2010/0010640	A1 *	1/2010	Gerold A61B 5/4839 623/24
2012/0296234	A1 *	11/2012	Wilhelm A61B 17/7216 600/587
2013/0211535	A1	8/2013	Cueille
2014/0012391	A1	1/2014	Gugler et al.
2014/0058526	A1	2/2014	Meridew et al.
2014/0128986	A1	5/2014	Podolsky
2014/0303743	A1	10/2014	Choudhury et al.
2014/0363481	A1	12/2014	Pasini et al.
2014/0370462	A1	12/2014	Porter et al.
2014/0371897	A1	12/2014	Lin et al.
2015/0216668	A1	8/2015	Smith
2015/0250505	A1 *	9/2015	Ross A61B 17/7044 606/258
2017/0290666	A1	10/2017	Behzadi
2017/0290667	A1	10/2017	Behzadi
2017/0340448	A1	11/2017	Behzadi
2017/0354505	A1	12/2017	Behzadi
2021/0307786	A1 *	10/2021	Ross A61B 5/6878

OTHER PUBLICATIONS

PCT International Search Report for International application No. PCT/US17/26417, dated Jul. 3, 2017.

PCT Written Opinion of The International Searching Authority for International application No. PCT/US17/26417 dated Jul. 3, 2017. International Search Report regarding International application No. PCT/US2017/037042 dated Oct. 6, 2017.

Written Opinion of the International Searching Authority regarding International application No. PCT/US2017/037042 dated Oct. 6, 2017.

U.S. Appl. No. 16/588,416, filed Sep. 30, 2019, Kambiz Behzadi.

U.S. Appl. No. 16/693,214, filed Nov. 22, 2019, Kambiz Behzadi et al.

U.S. Appl. No. 16/842,470, filed Apr. 7, 2020, Kambiz Behzadi et al.

U.S. Appl. No. 62/319,377, filed Apr. 7, 2016, Kambiz Behzadi.

U.S. Appl. No. 62/348,987, filed Jun. 12, 2016, Kambiz Behzadi.

U.S. Appl. No. 15/234,927, filed Aug. 11, 2016, Kambiz Behzadi.

U.S. Appl. No. 15/406,752, filed Jan. 15, 2017, Kambiz Behzadi.

U.S. Appl. No. 15/458,586, filed Mar. 14, 2017, Kambiz Behzadi.

U.S. Appl. No. 15/592,233, filed May 11, 2017, Kambiz Behzadi.

U.S. Appl. No. 16/032,867, filed Jul. 11, 2018, Kambiz Behzadi.

U.S. Appl. No. 16/258,635, filed Jan. 27, 2019, Kambiz Behzadi.

U.S. Appl. No. 16/267,345, filed Feb. 4, 2019, Kambiz Behzadi.

U.S. Appl. No. 16/267,813, filed Feb. 5, 2019, Kambiz Behzadi.

U.S. Appl. No. 16/271,860, filed Feb. 10, 2019, Kambiz Behzadi.

U.S. Appl. No. 16/532,448, filed Aug. 5, 2019, Kambiz Behzadi.

* cited by examiner

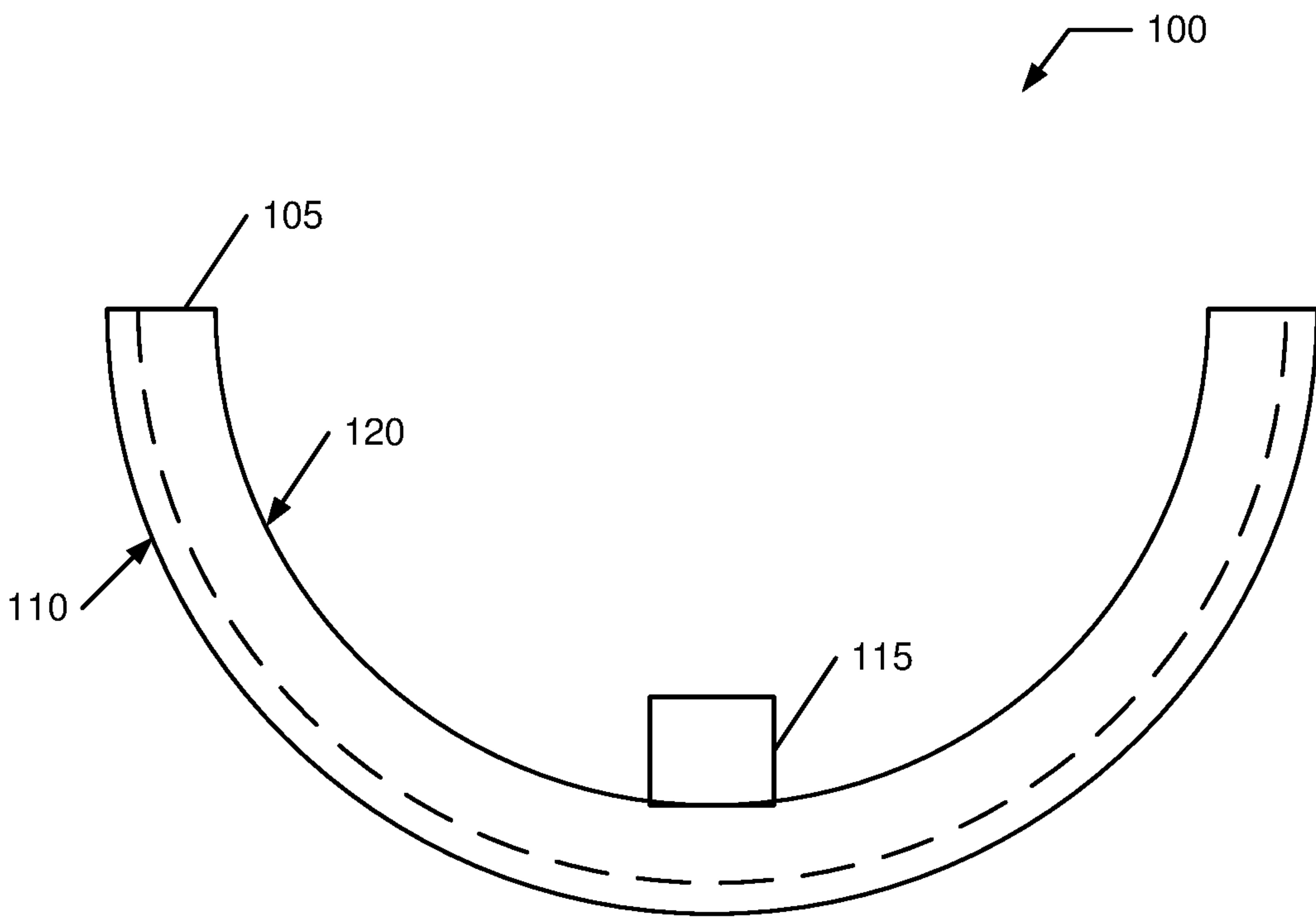


FIG. 1

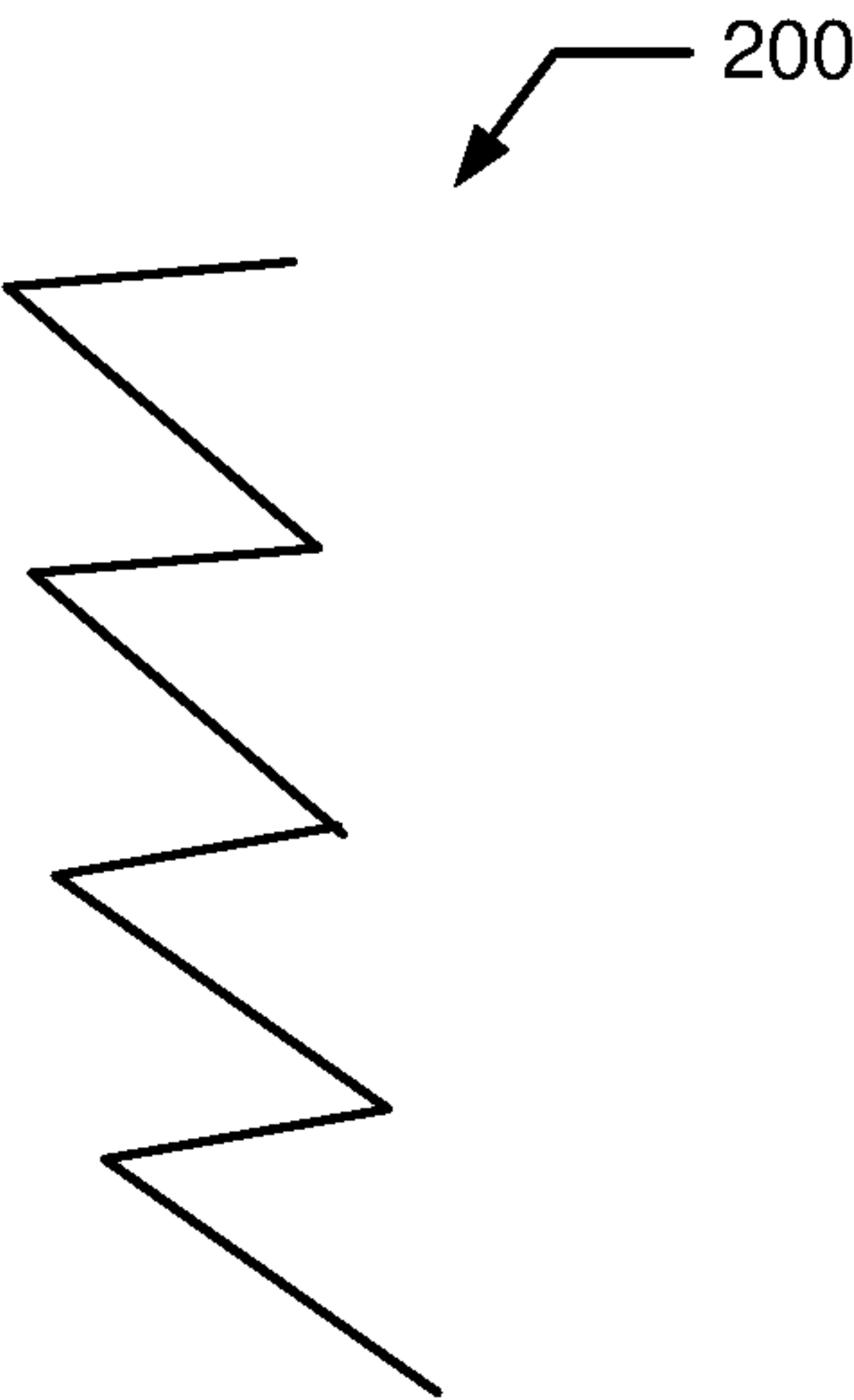


FIG. 2

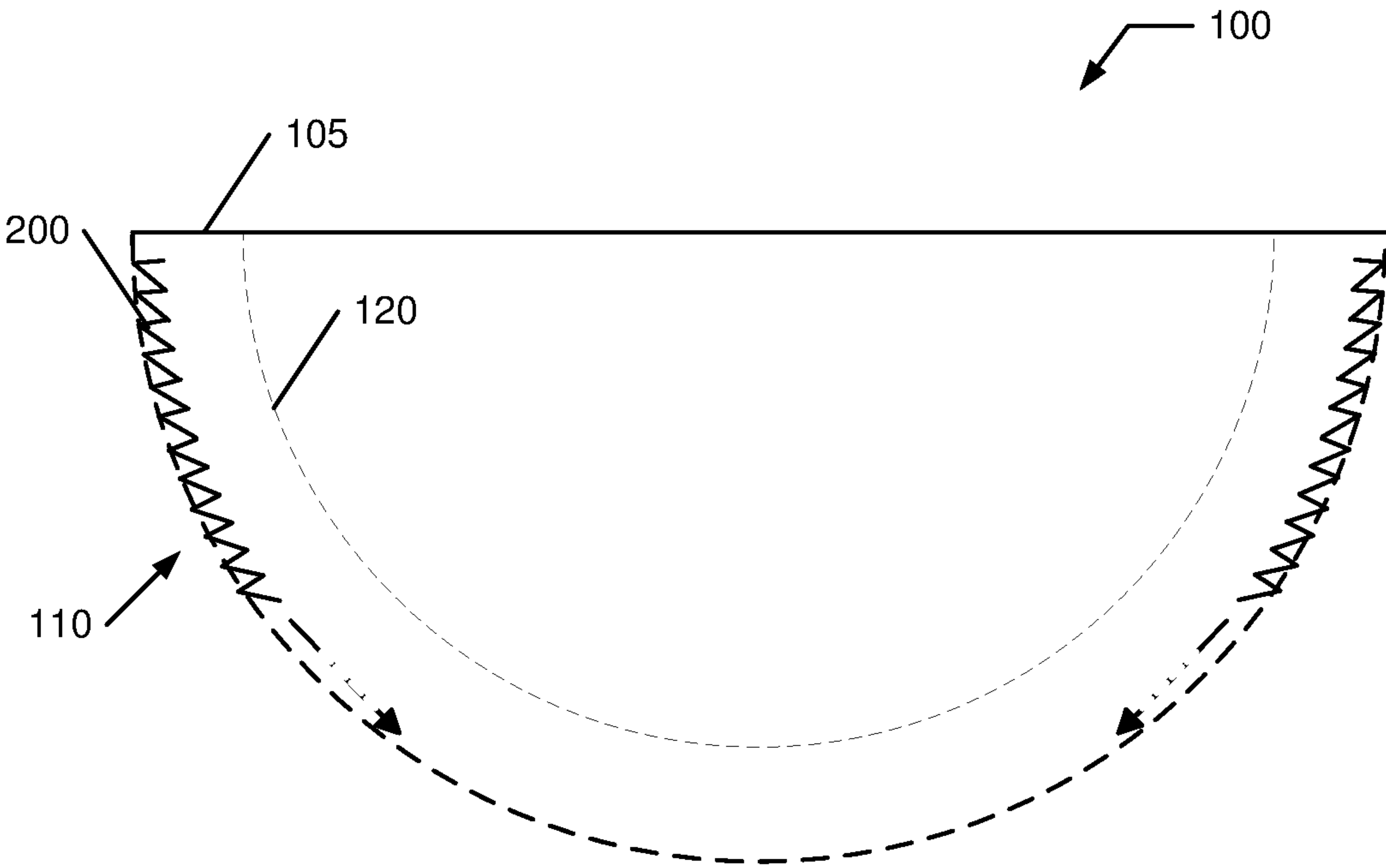


FIG. 3

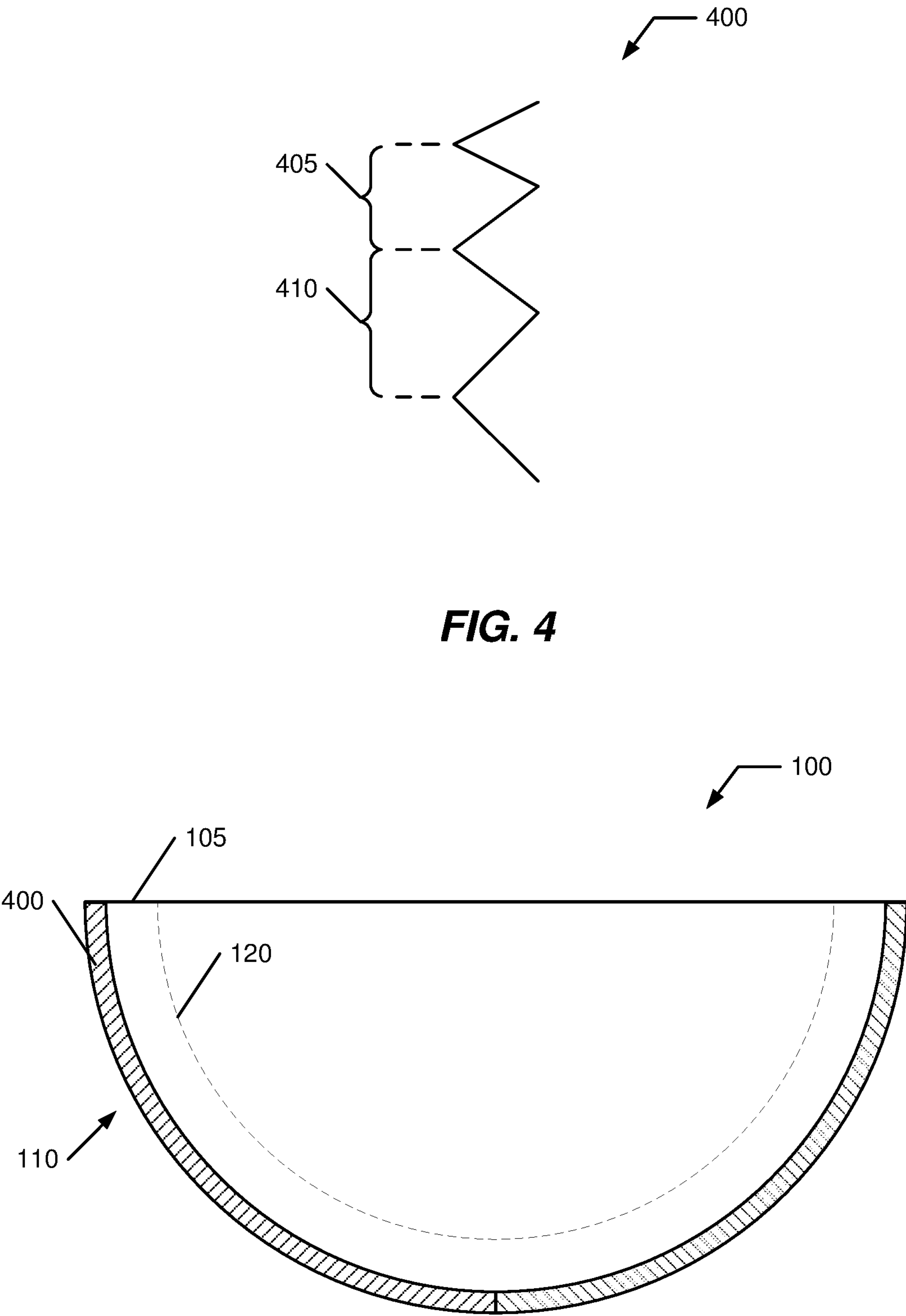


FIG. 4

FIG. 5

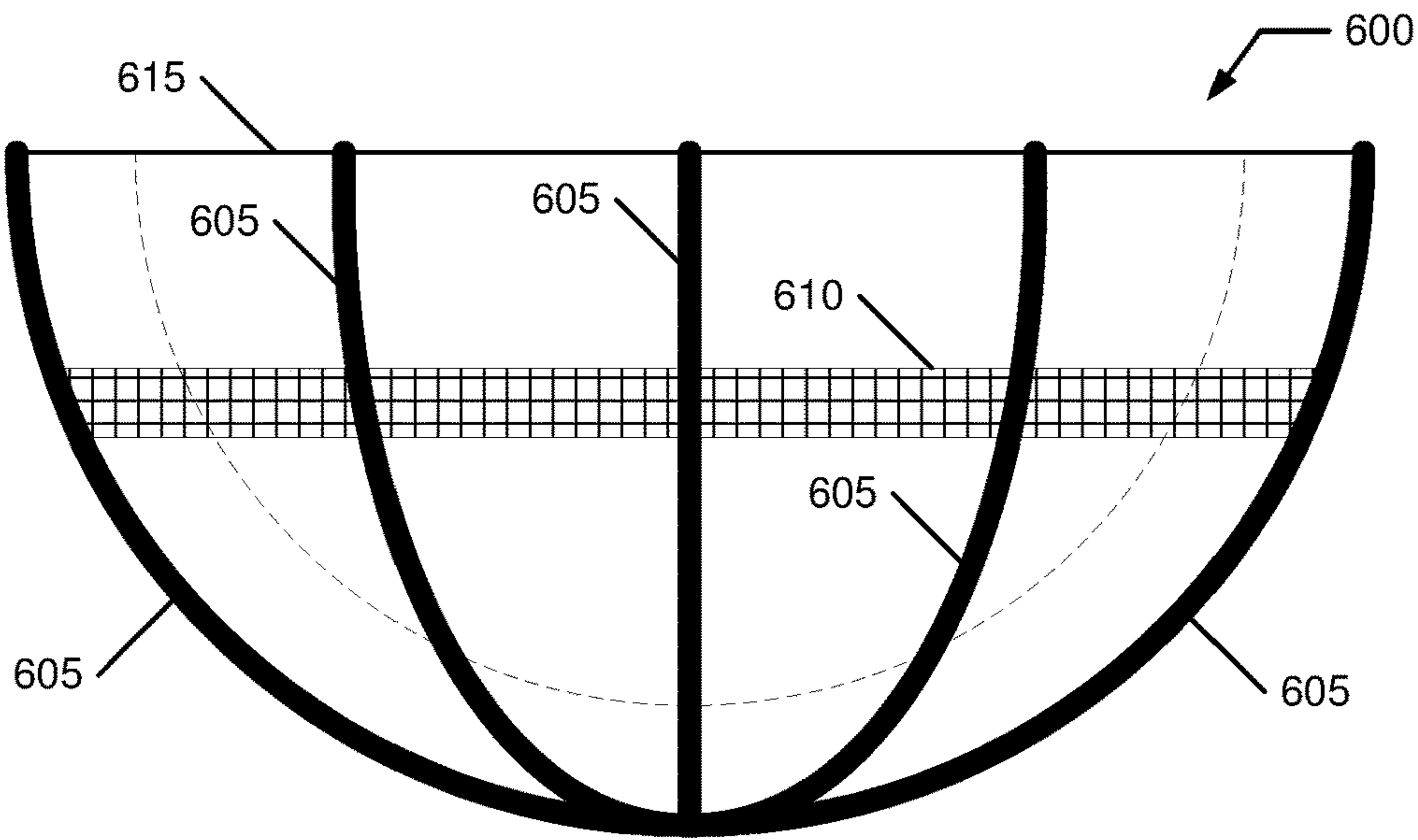


FIG. 6

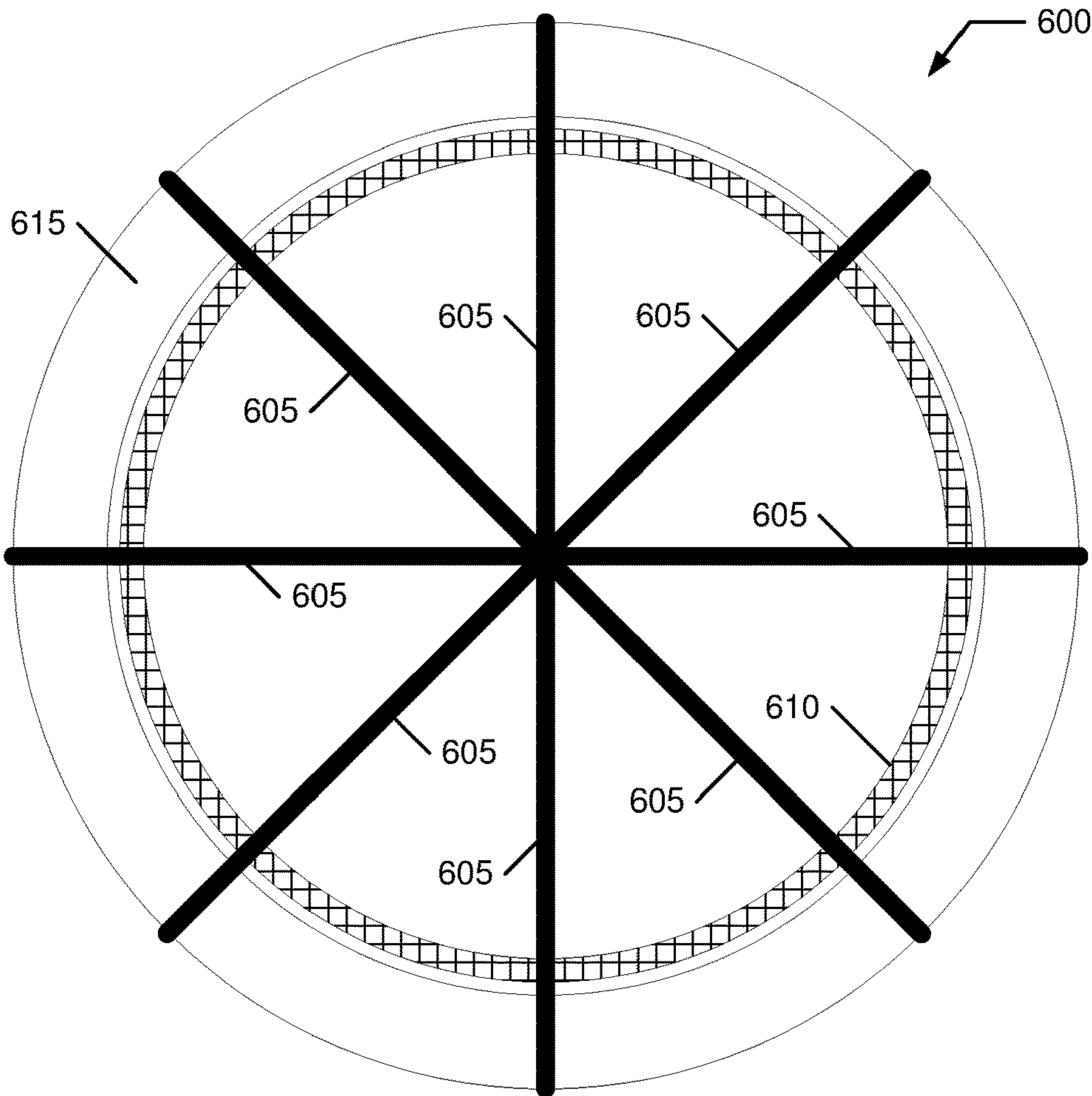


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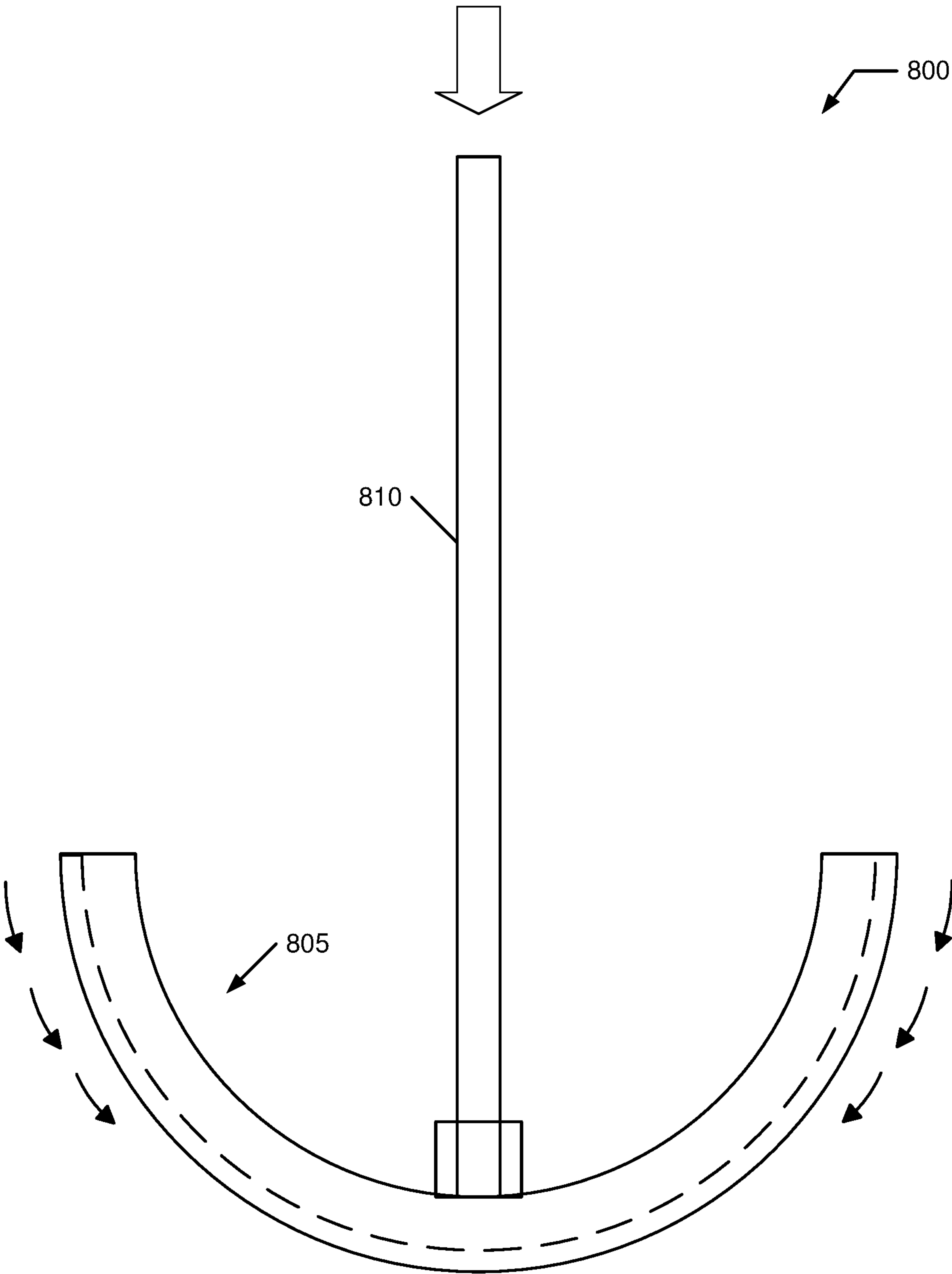


FIG. 8

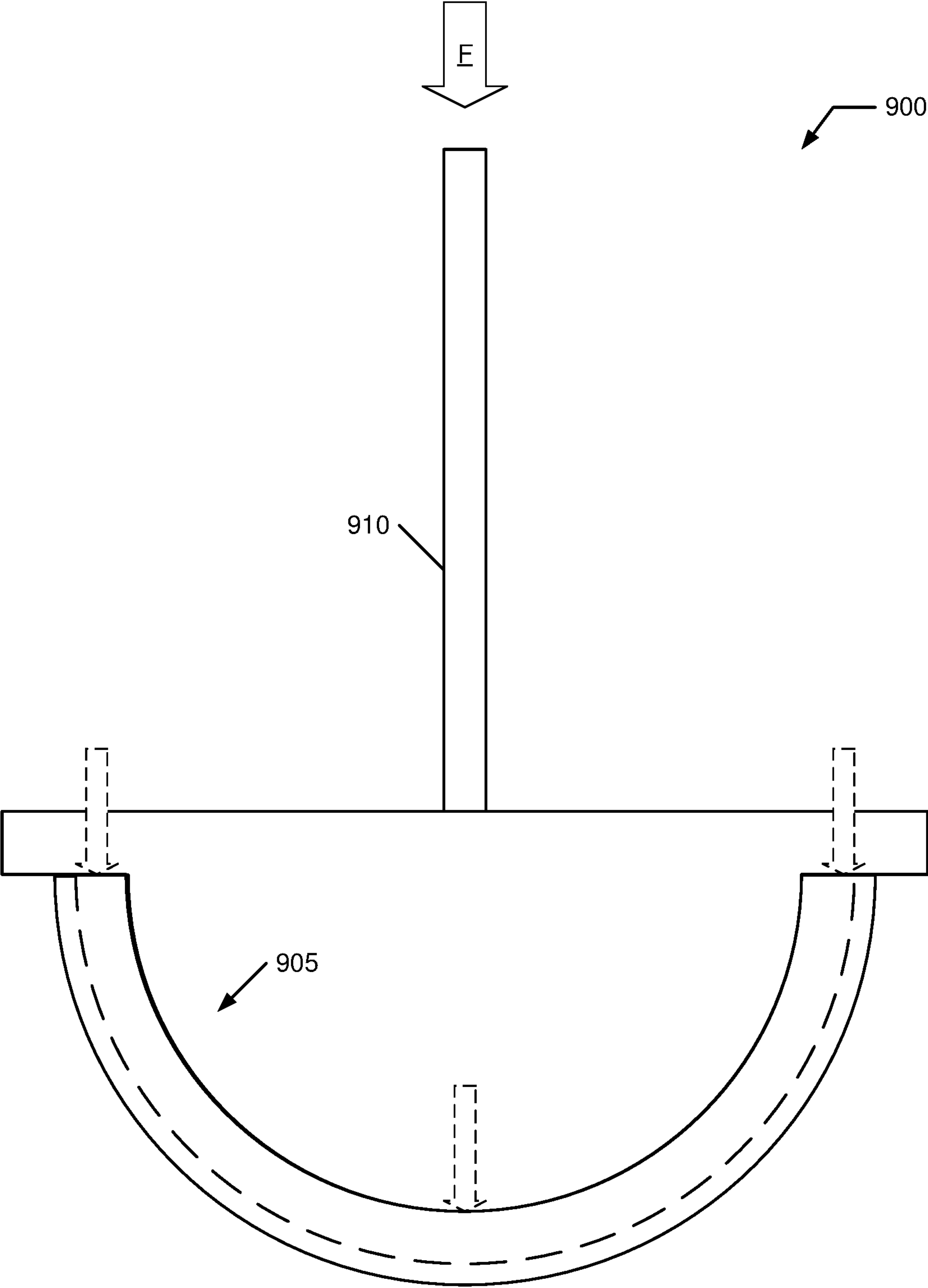


FIG. 9

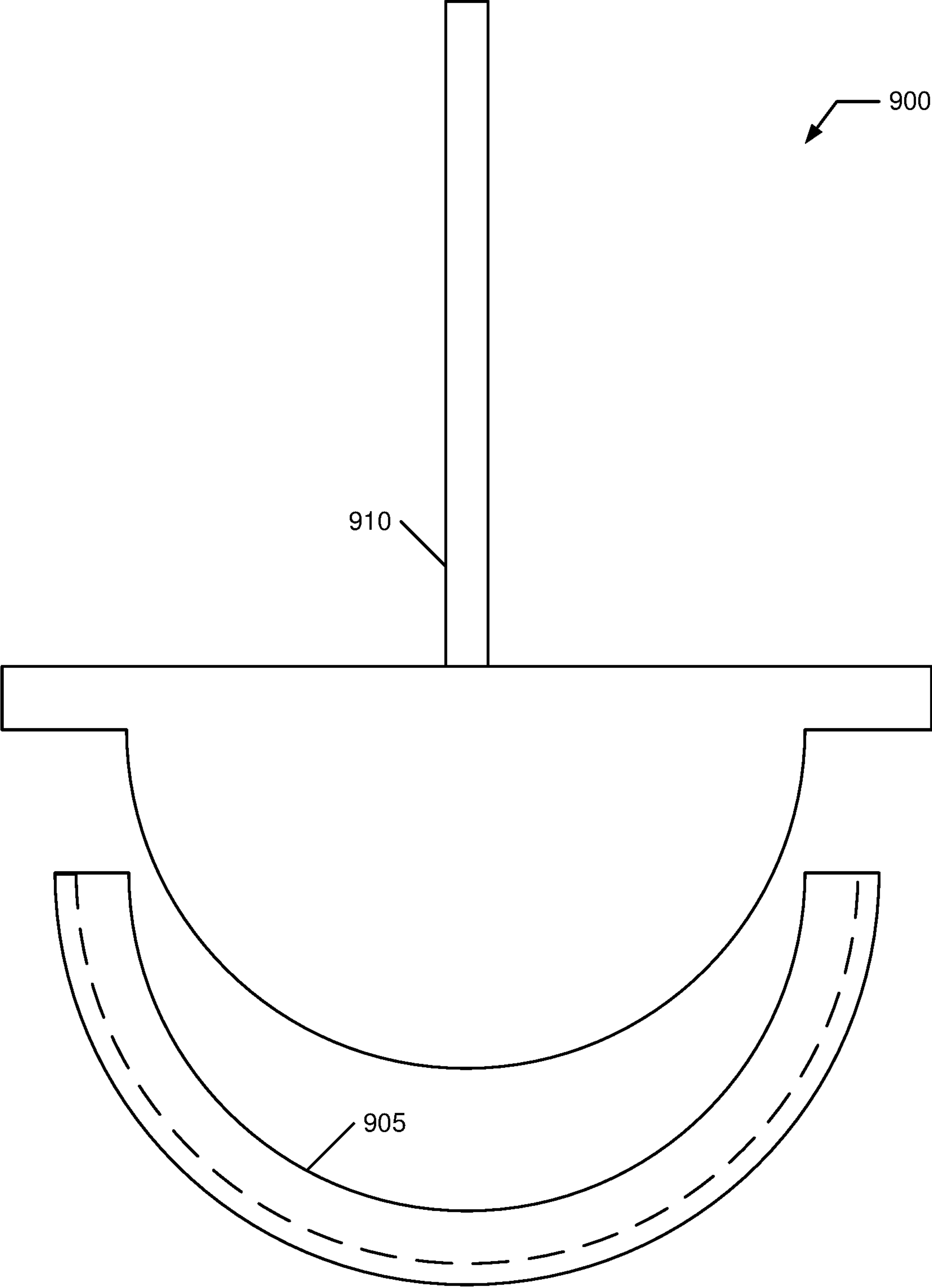


FIG. 10

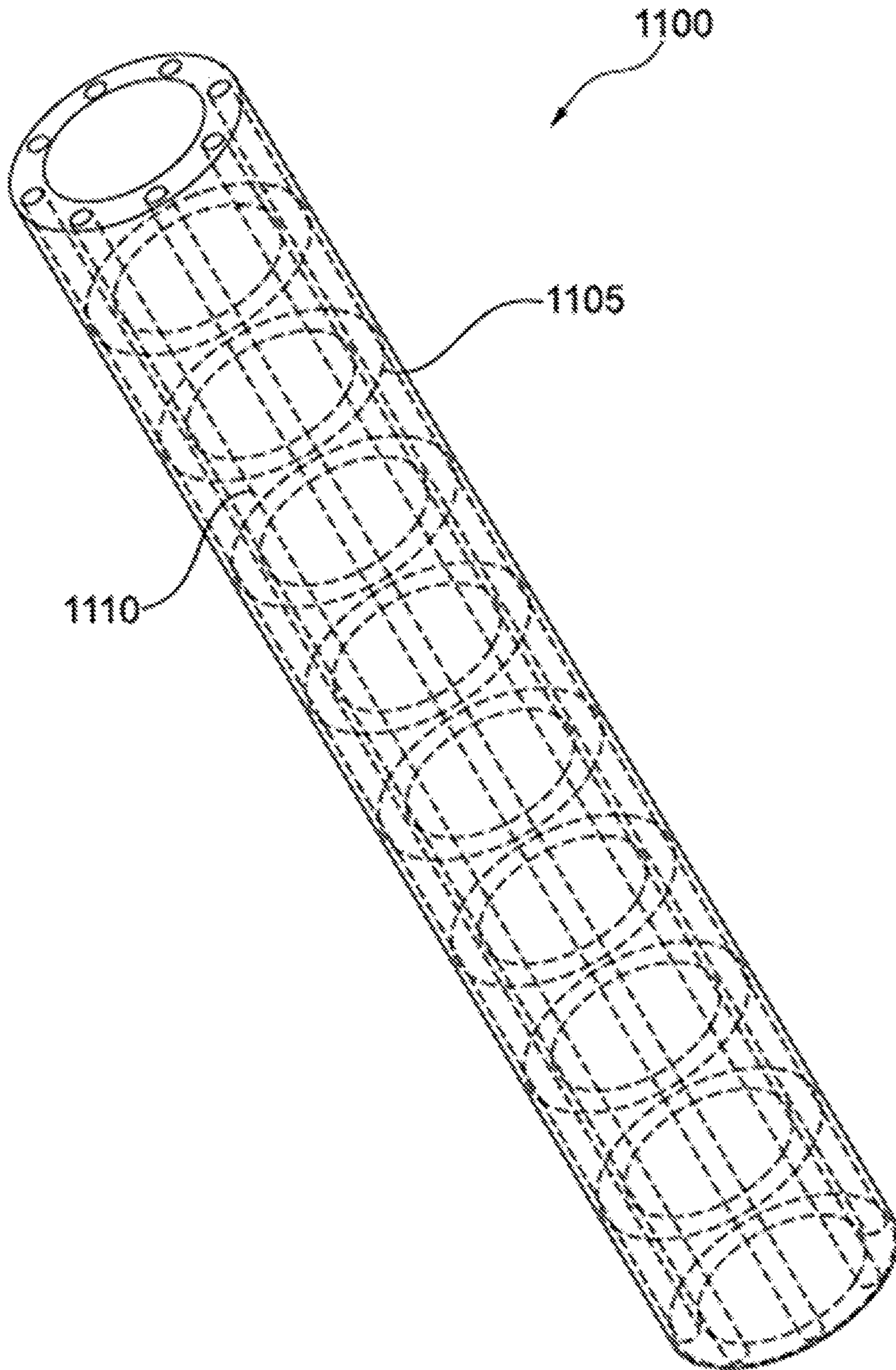


FIG. 11

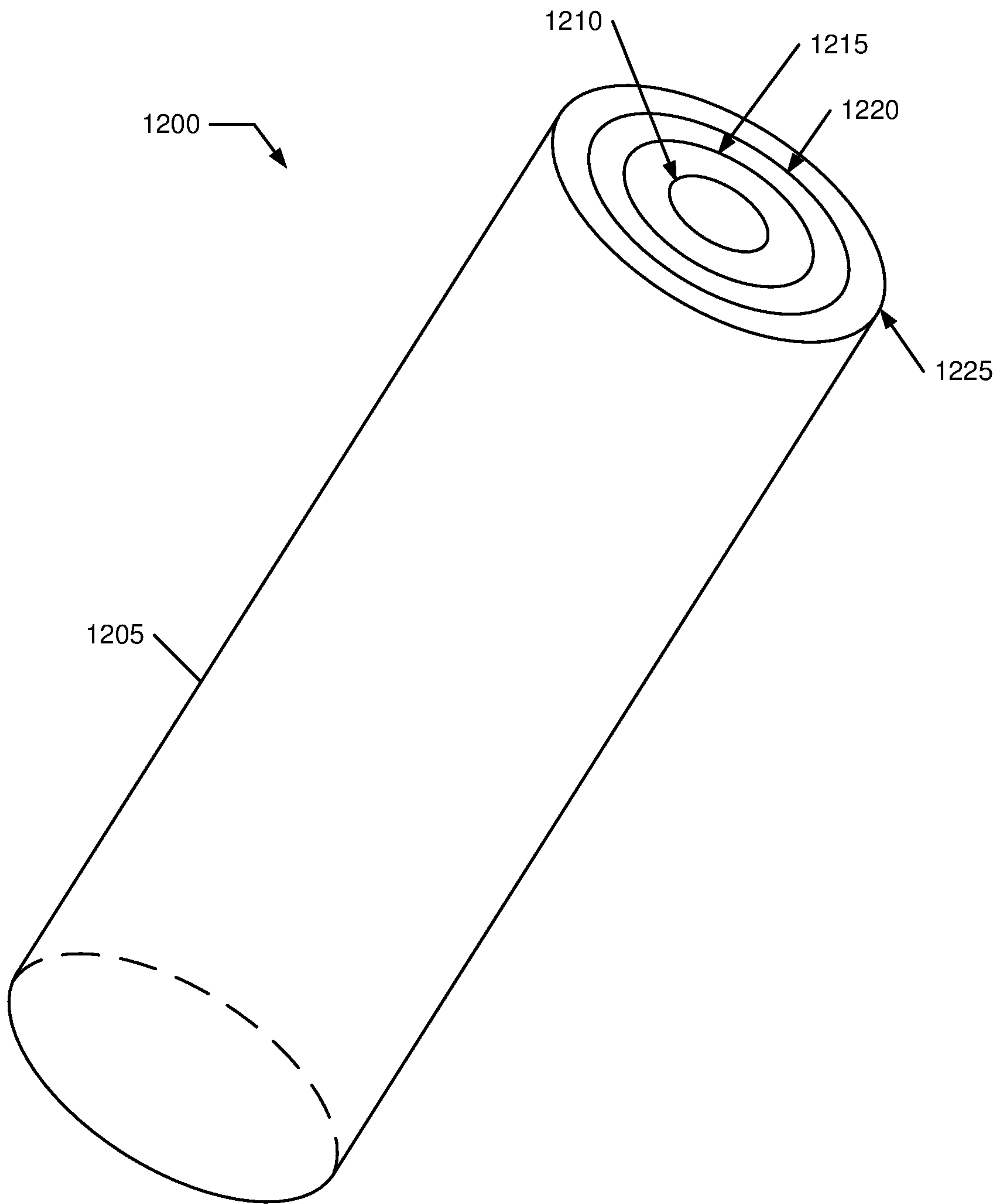


FIG. 12

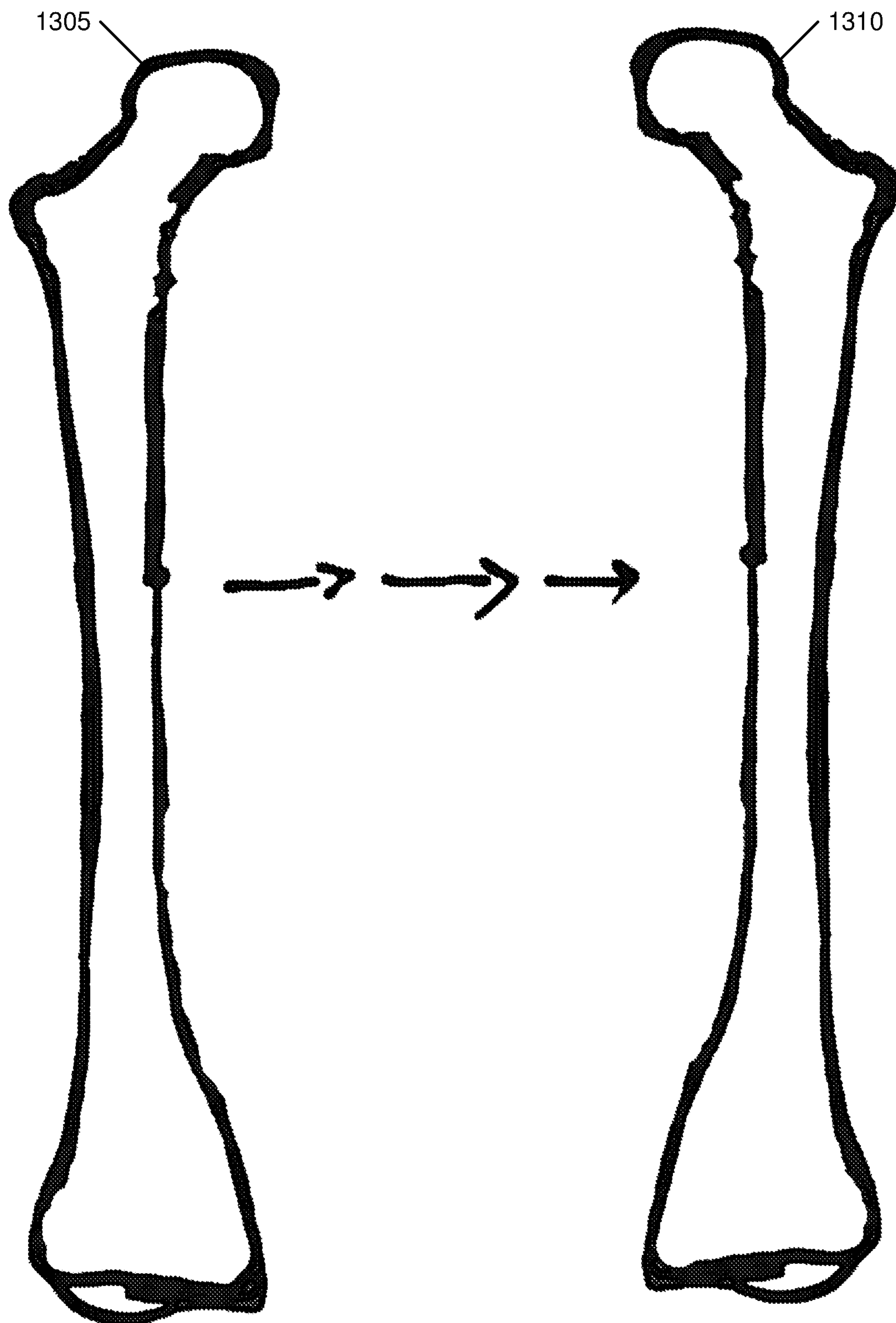


FIG. 13

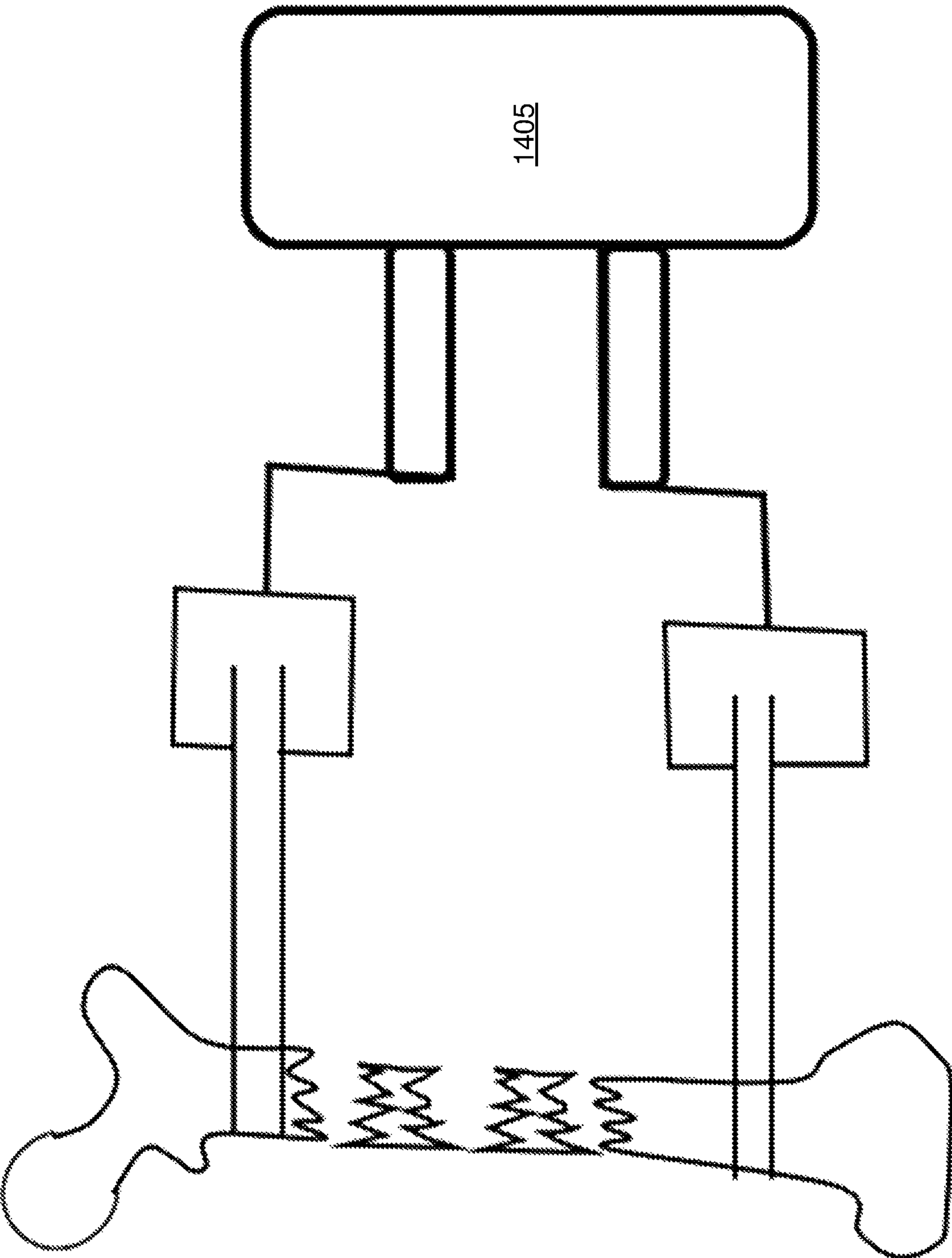


FIG. 14

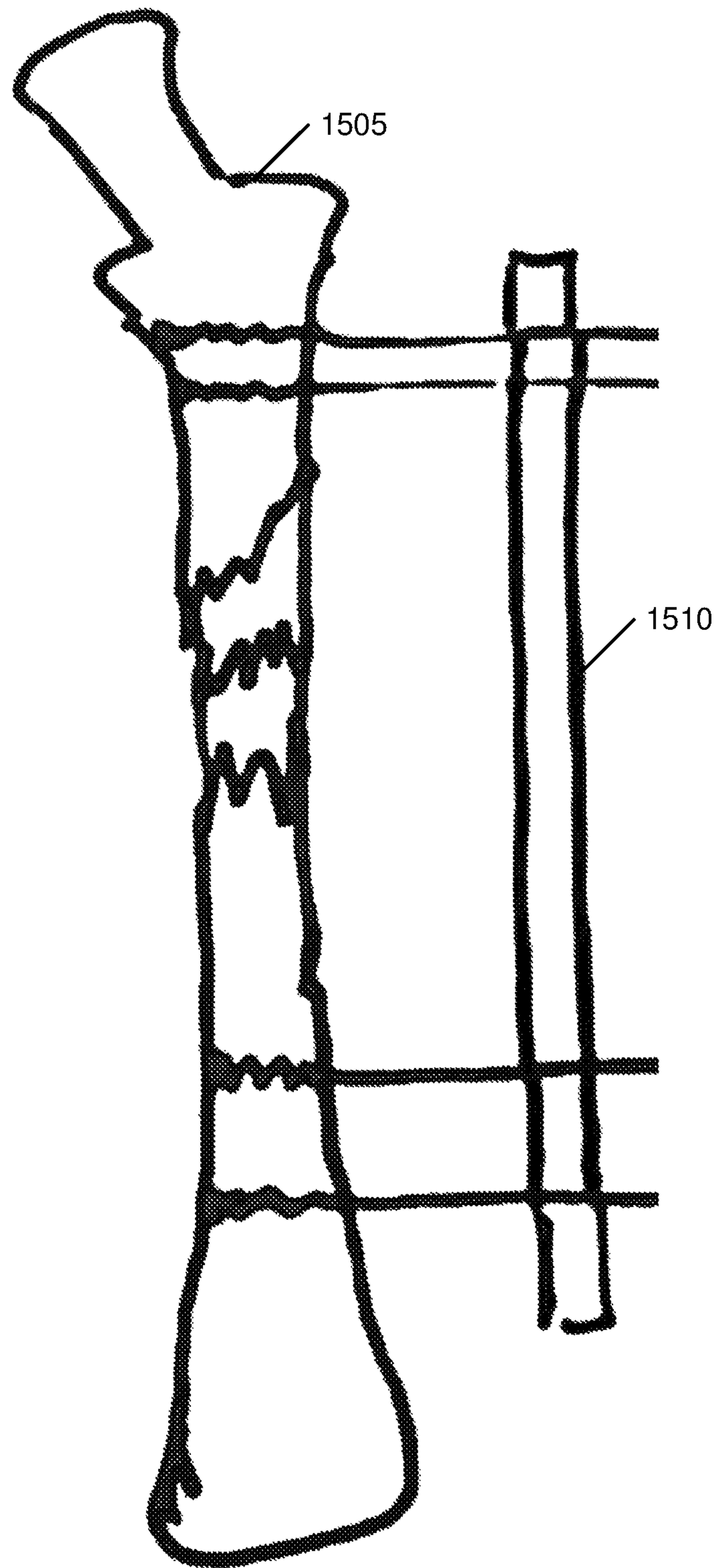


FIG. 15

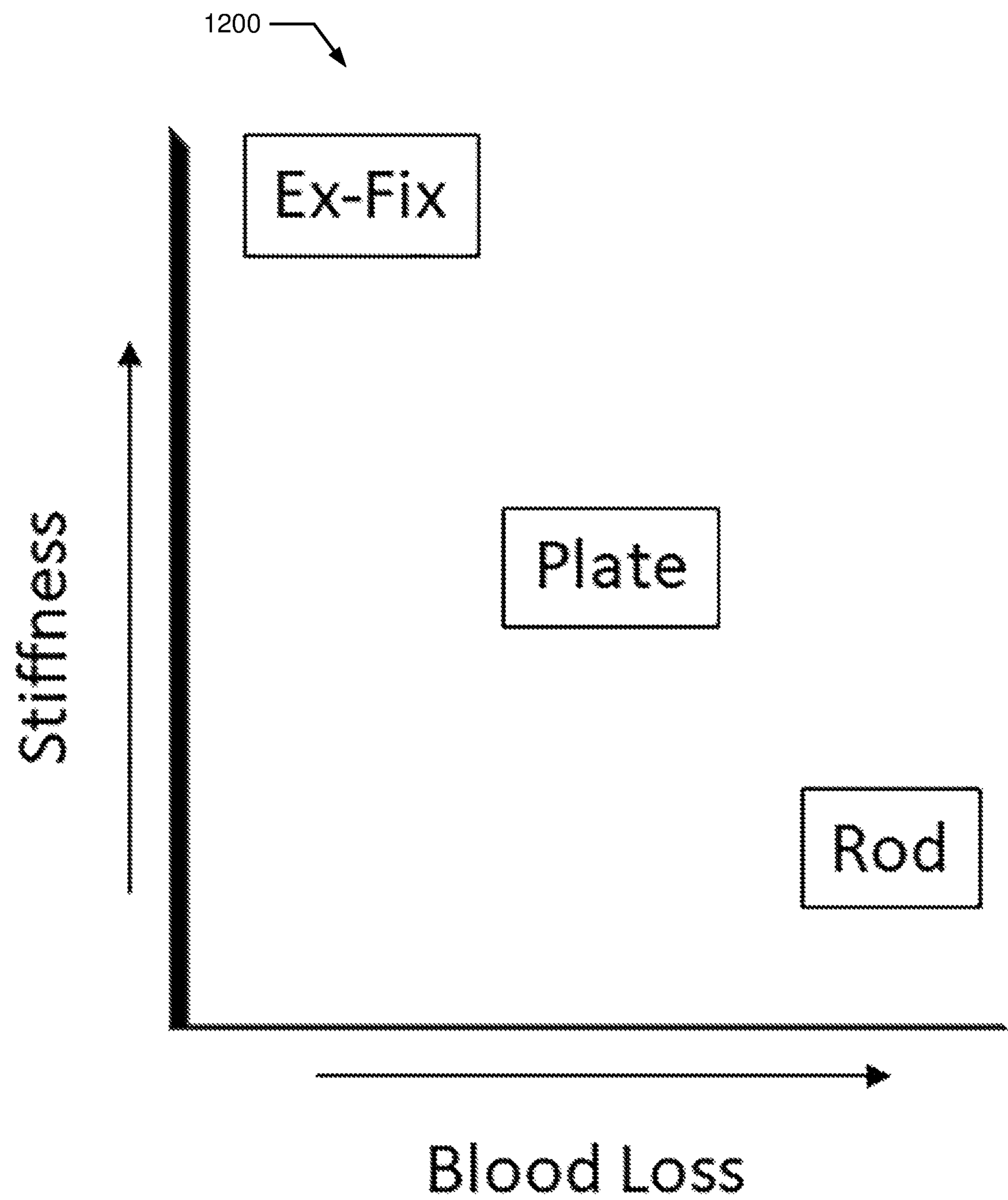


FIG. 16

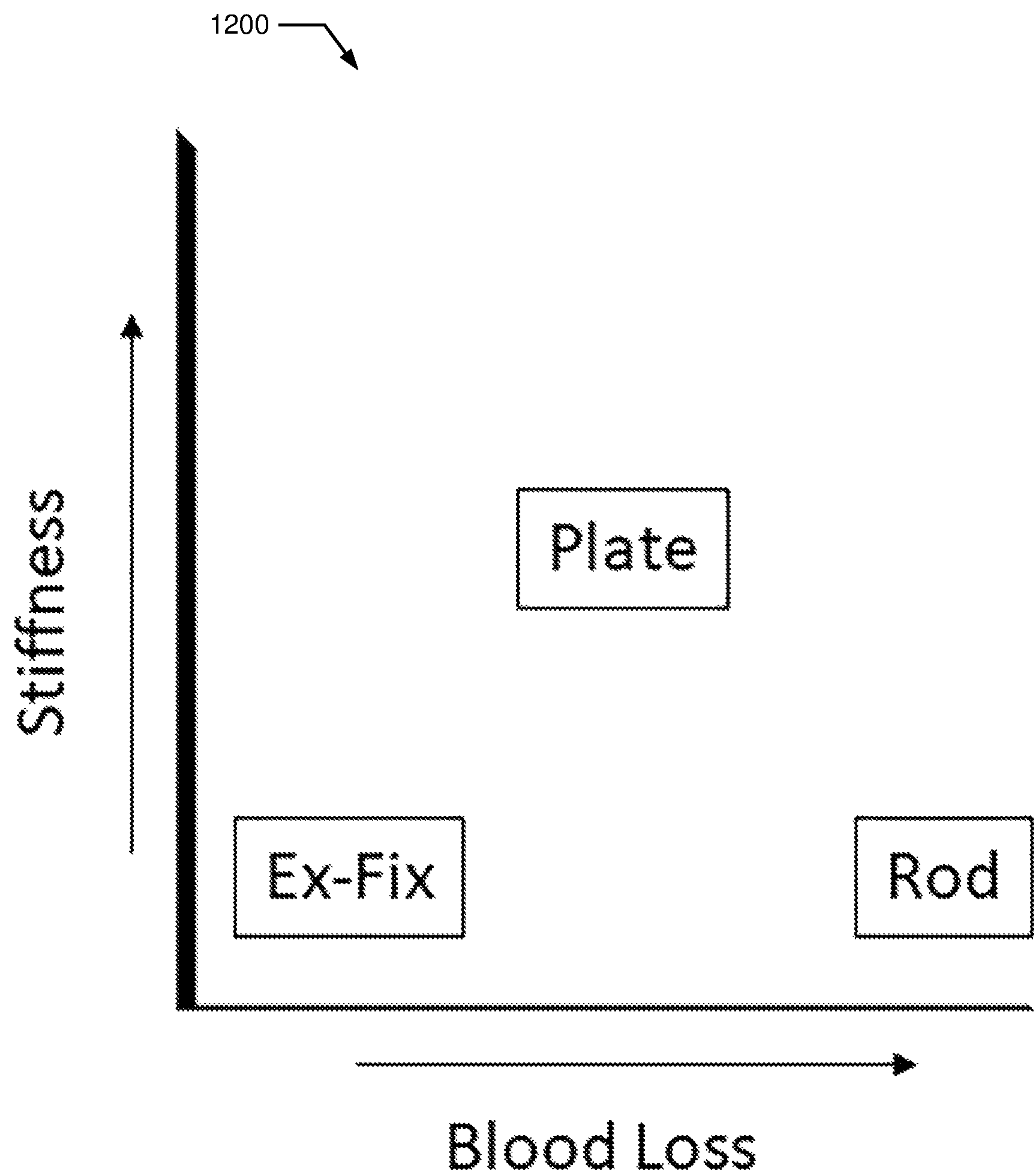


FIG. 17

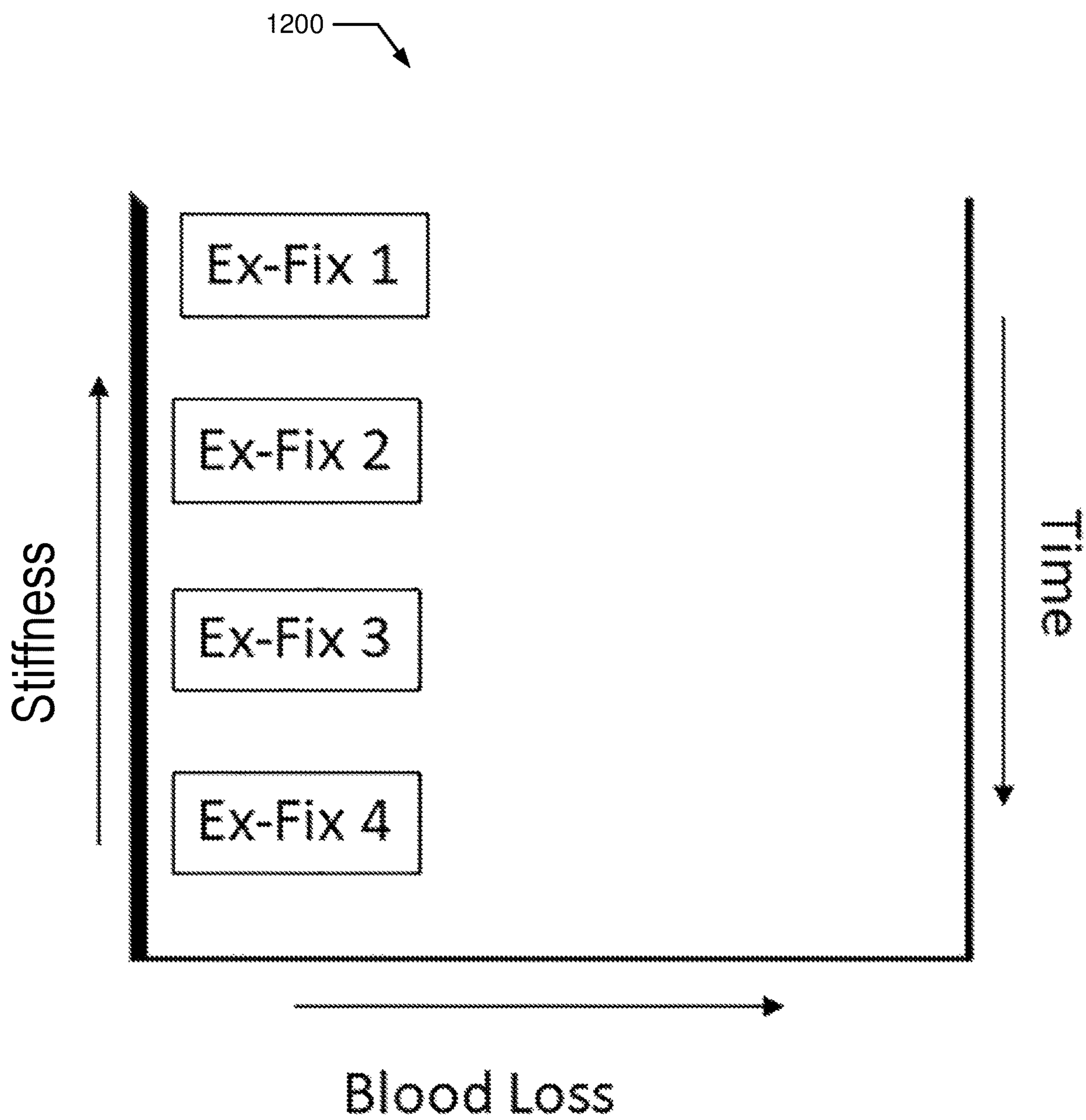


FIG. 18

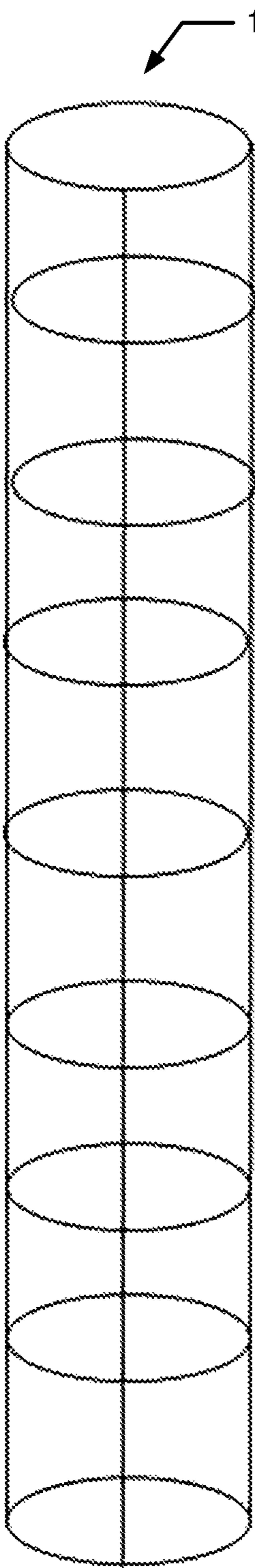


FIG. 19

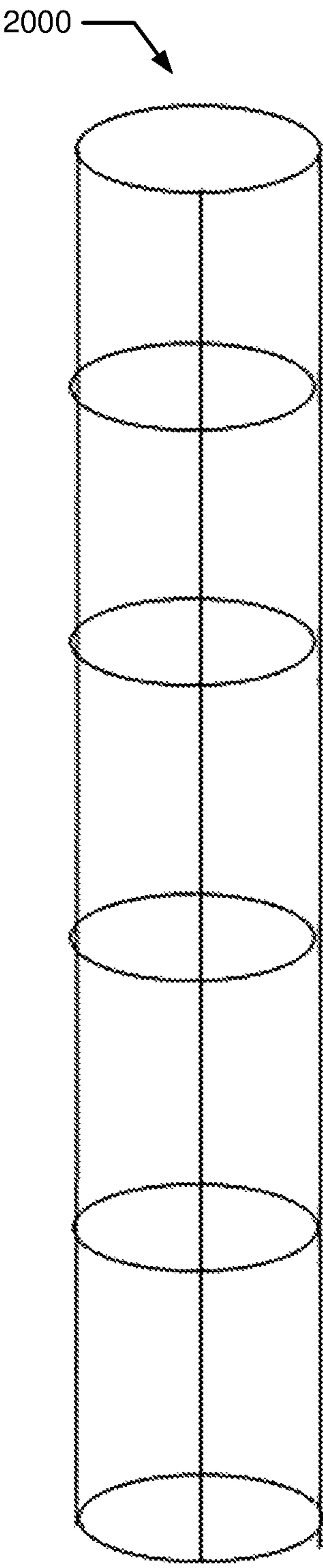


FIG. 20

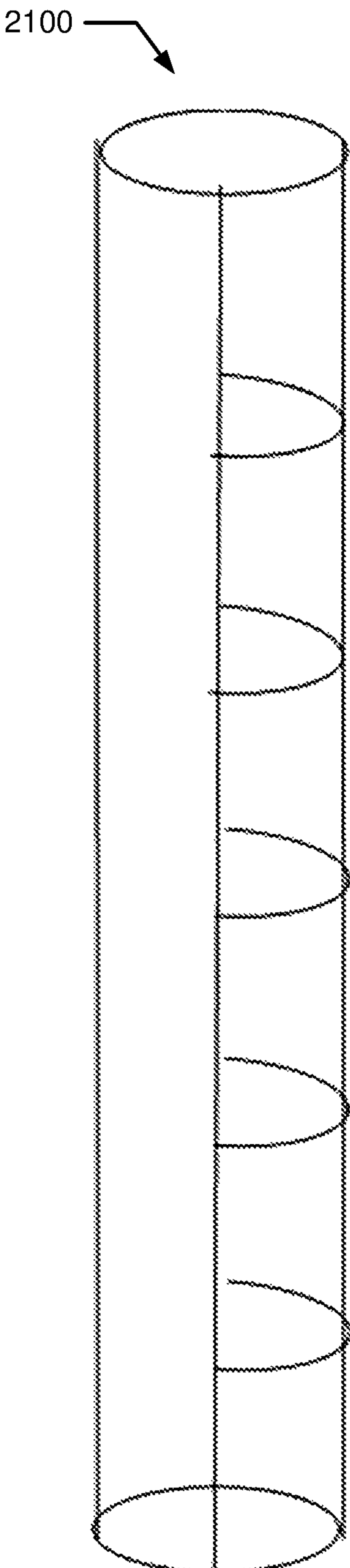


FIG. 21

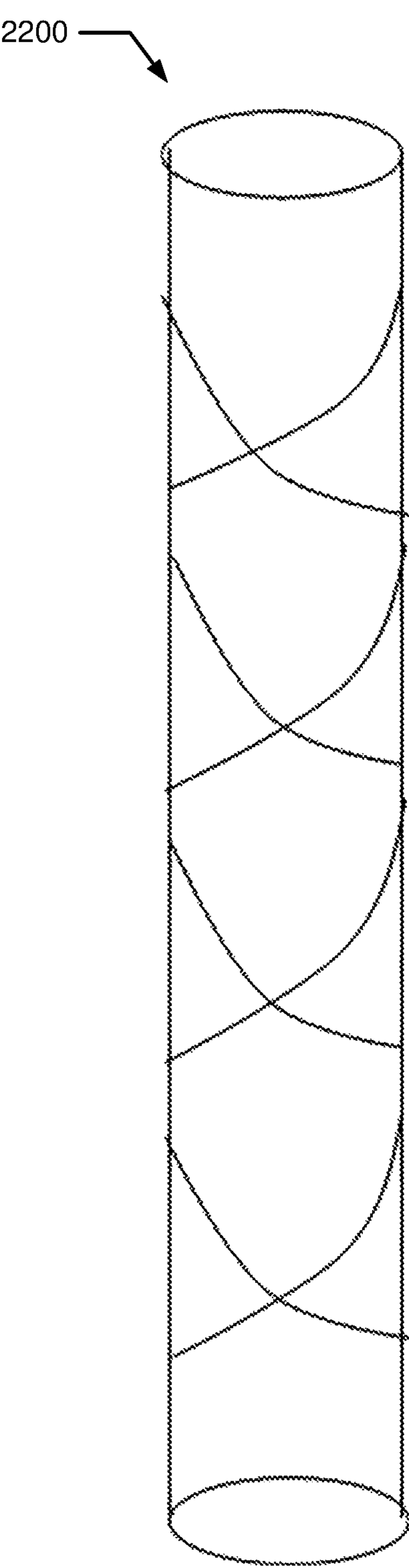


FIG. 22

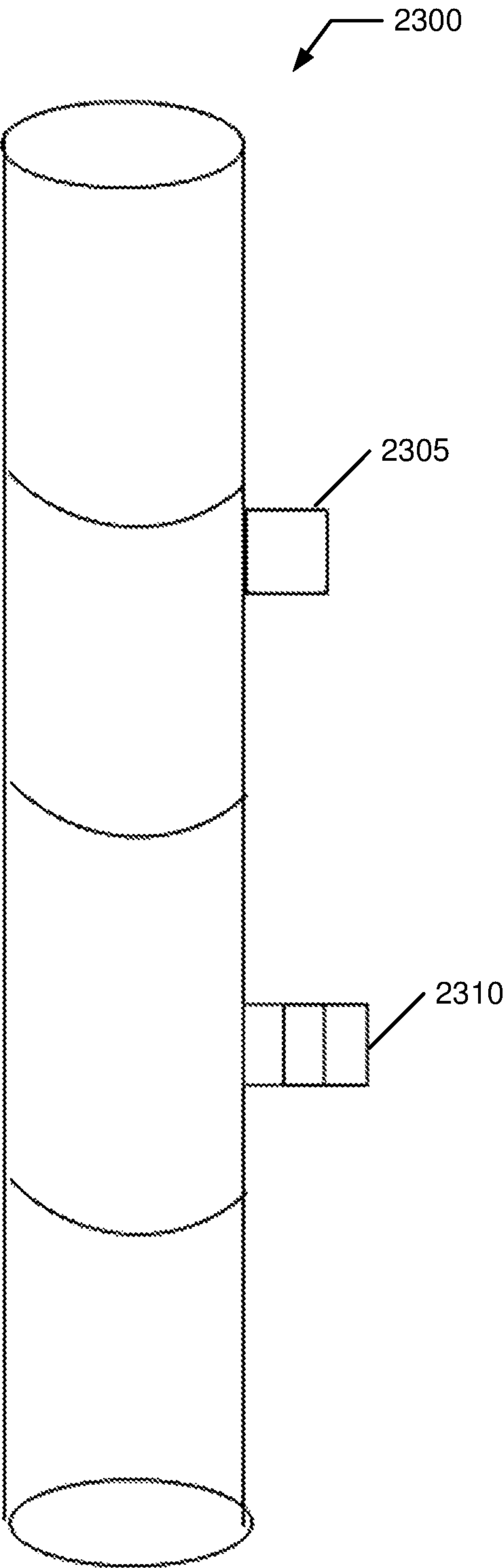


FIG. 23

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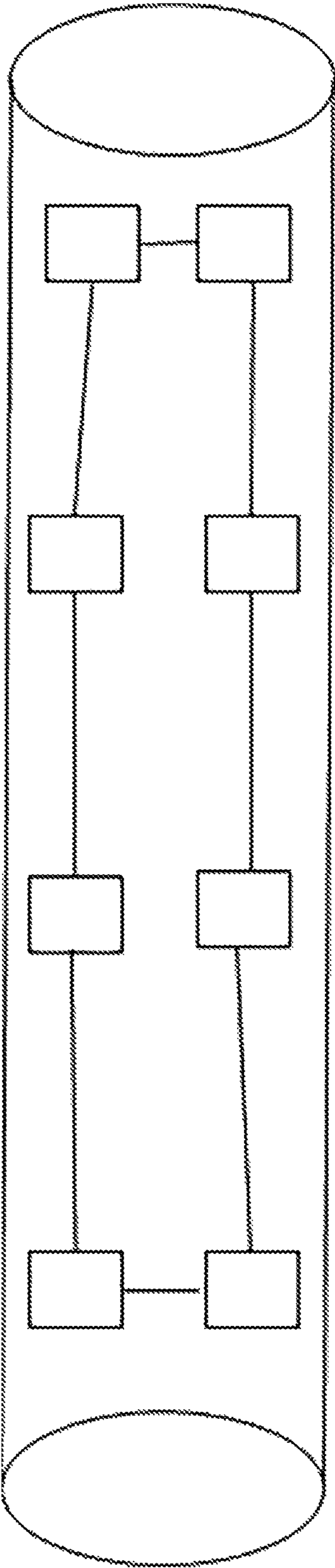


FIG. 24

MATERIALS IN ORTHOPEDICS AND FRACTURE FIXATION

CROSS REFERENCE TO RELATED APPLICATIONS

This Application is a Continuation-in-part of application Ser. No. 16/588,416 filed on Sep. 30, 2019; application Ser. No. 16/588,416 is a Continuation-in-part of application Ser. No. 16/532,448 filed on Aug. 5, 2019; application Ser. No. 16/532,448 is a Division of application Ser. No. 15/592,233 filed on May 11, 2017; application Ser. No. 15/592,233 is a Continuation-in-part of application Ser. No. 15/406,752 filed on Jan. 15, 2017; application Ser. No. 15/406,752 is a Continuation-in-part of application Ser. No. 15/234,927 filed on Aug. 11, 2016; application Ser. No. 15/234,927 claims the benefit of U.S. Provisional Application 62/319,377 filed on Apr. 7, 2016; also is related generally to U.S. Patent Application No. 61/921,528 filed 29 Dec. 2013, to U.S. Patent Application No. 61/980,188 filed 16 Apr. 2013, U.S. patent application Ser. No. 14/584,656 filed 29 Dec. 2014 (now U.S. Pat. No. 9,168,154), to U.S. patent application Ser. No. 14/585,056 filed 29 Dec. 2014 (now U.S. Pat. No. 9,220,612), to U.S. patent application Ser. No. 14/923,203 filed 26 Oct. 2015, to U.S. patent application Ser. No. 14/969,721 filed 15 Dec. 2015, to U.S. Patent Application No. 62/277,294 filed 11 Jan. 2016, to U.S. patent application Ser. No. 14/965,851 filed 10 Dec. 2015, to U.S. patent application Ser. No. 15/055,942 filed 29 Feb. 2016, and to U.S. patent application Ser. No. 15/092,384 filed 6 Apr. 2016, all the contents of which are all hereby expressly incorporated in their entirety by reference thereto for all purposes.

FIELD OF THE INVENTION

The present invention relates generally to mechanical assembly and assemblies for bone fracture repair, and more specifically, but not exclusively, to a reducing and fixating a bone fracture using adjustable/variable anisotropic components having a set of tuned/tunable stiffness elements.

BACKGROUND OF THE INVENTION

The subject matter discussed in the background section should not be assumed to be prior art merely as a result of its mention in the background section. Similarly, a problem mentioned in the background section or associated with the subject matter of the background section should not be assumed to have been previously recognized in the prior art. The subject matter in the background section merely represents different approaches, which in and of themselves may also be inventions.

The incorporated patents and applications often address a problem of applied forces in the assembly and installation of mechanical systems, such as a prosthesis used in orthopedic surgery.

There are many considerations regarding the use of applied impact forces in orthopedic surgery and in particular the use of a hammer or a mallet to apply an impact force. Much work has been done to help understand, control, modulate, and replace the impaction forces created by the surgeon's mallet. Some of the incorporated references have described various components of these applied forces, often using orthopedics as an example though the invention is not required to be so limited. The use of a mallet in orthopedics creates a momentum or an impulse and effects of the impulse

in creating an impaction force can be broken down into its components, including magnitude, frequency and dwell time. Some of the incorporated references include systems and methods of substituting an installation force for the impaction force in orthopedic surgery. Embodiments of the incorporated references may allow the surgeon to perform some of these surgeries in a safer and more controlled fashion by rethinking conventional procedures related to a prosthesis. Further, some of the incorporated references relate to assembly of a prosthesis for use in an orthopedic procedure.

The collection of incorporated references includes multiple embodiments of multiple inventions, with some of these embodiments including a use of vibratory force/energy that disclosed as important for addressing problems with application of impaction forces.

In some of the embodiments of the incorporated patents and applications, there is a discussion that there may be significant advantage to use of controlled installation forces communicated to a prosthesis or prosthesis component at higher (including ultrasonic) frequencies. Some or a significant portion of these advantages may relate to differences between kinetic and static coefficients of friction, and/or vibratory modes of the installation site (bone) or mating component for a prosthetic assembly, among other possible explanations. These features may allow a prosthesis (or portion thereof) vibrating at an appropriate mode to diminish, sometimes significantly, forces resisting installation or assembly, respectively. With these diminished forces, the surgeon may be able to employ decreased installation forces which allow easier and safer insertions. In some embodiments, the embodiment may allow for a concurrent ability to align the prosthesis during/after installation as part of the same procedure with the same tools. This is in contrast to conventional systems which employ one set of tools for insertion and then another set of tools after insertion to correction malpositioning. Some embodiments of the present invention may allow for concurrent insertion and desired positioning.

Current surface treatment of a prosthesis is designed for porous metal ingrowth bonding of a prosthesis to bone (in contrast to a use of cement to bond a prosthesis to bone). In general the porous implants are typically created as "composite structures" consisting of a substrate typically made of either cobalt chrome or titanium alloy (which carries the patient's weight), and a porous surface which is designed to enhance osseointegration of the implant (referred to as "porous coating"). The porous coating includes microstructural features such as peaks, valleys and deep caves. This mimics the structure of trabecular/cancellous bone with its three-dimensional and interconnecting network of pores and capillary properties. The porous coating aids in initial scratch fixation as well as long term fixation through osseointegration of bone with the surface of the bone. Recently, there have been many advances in the creation of the porous coating that more accurately resemble the trabecular bone. These techniques all involve multiple steps in the creation of the porous coating surface and subsequent bonding of this surface to the alloy substrate. Today, the majority of porous coatings are made of titanium or tantalum. These porous coatings are textured with desirable mechanical properties closer to bone and with desirable porosity. They are created separately and applied to the actual implant (as a composite structure) via variety of bonding methods including plasma spray, chemical etching thin films and plates, chemical and/or physical vapor disposition, sintering, brazing, diffusion bonding, gluing or cementing, and the like). Thus, the

porous coating that is seen on the surface of a typical conventional prosthesis is: i) a composite structure that must be added to the substrate, and ii) a randomized pattern with no preferential orientation and or design.

Fixation of hip and knee replacement implants to bone is critical to the success of the procedure. A variety of roughened surfaces and three-dimensional (3-D) porous surfaces have been used to enhance biological fixation on orthopedic implants for over 30 years. More recently, highly porous metals have emerged as versatile biomaterials that may enhance fixation to bone and are suitable to a number of applications in hip and knee replacement surgery. The advantages provided by these newly developed porous metals may improve cementless fixation and long-term patient outcomes in hip and knee replacement.

Thermal spray technologies involving the melting and subsequent spraying of metal feedstock have been leveraged by various implant manufacturers to apply highly roughened commercially pure titanium (CPTi) and titanium (Ti) alloy coatings onto implants used in hip and knee arthroplasty. These include wire arc deposition, plasma spray, sintering porous beads, diffusion bonding of titanium coatings, advanced highly porous coating technologies using tantalum and titanium, among other procedures.

Current installation procedures for some prosthesis, such as for an acetabular cup, include attachment of a rod axially aligned with a longitudinal axis of the prosthesis that is used to apply the impacting forces and impact the prosthesis into the bone to the desired depth.

Repair to traumatic bone injury is complex and each repair modality may offer various advantages and disadvantages.

It may be advantageous for a system and method to improve upon an ability of a surgeon to repair traumatic bone injury using new materials, components, and structures.

BRIEF SUMMARY OF THE INVENTION

Disclosed is a system and method for improving upon an ability of a surgeon to repair traumatic bone injury using new materials, components, and structures.

The following summary of the invention is provided to facilitate an understanding of some of the technical features related to surface treatment for mating/contacting surfaces of a prosthesis or a prosthesis component and is not intended to be a full description of the present invention. A full appreciation of the various aspects of the invention can be gained by taking the entire specification, claims, drawings, and abstract as a whole. The present invention is applicable to other prosthesis devices in addition to acetabular cups, to other mechanical systems for reduced force insertion of one structure into another, and to other configurations and arrangements of exterior surface structures than those presented or described herein. Embodiments of the invention may include materials used in a structure that may be used as an implant or a component of an external fixator for a fractured long bone with that structure having anisotropic and viscoelastic properties, such as through additive manufacturing techniques.

In an embodiment of the present invention, an implant may include a surface treatment for aiding operations with the implant. For example, some surface treatments provide an asymmetry in installation versus removal to bias the associated implant deeper into an installation site.

An embodiment of the present invention includes a surface treatment, whether produced as an innate outer surface

feature of the device during manufacture or added to a surface (e.g., an outer surface) of a device, such as, for example, a retrofit solution. The surface treatment provides an asymmetric relative force for the device in cooperation with material of an installation side (e.g., easier to push the prosthesis into a bone than to extract the prosthesis from the bone). For example, the treatment includes provision of various exterior structures that interact with material of the installation site more strongly in one relative direction (e.g., removal or disassembly from the installation site) than in another direction (e.g., insertion or assembly into the installation site). For example, the surface treatment of the prosthesis collectively offers less resistance to installation than removal.

An embodiment of the present invention may implement two-dimensional asymmetric biasing such as described with insertion of a prosthesis into an undersized cavity for Intra-medullary nails (IM) nails or rods used for fixation of long bones in traumatic situations, including femur, tibia and humerus as well as radius and ulna.

An embodiment of the present invention may provide for both asymmetric relative forces while also including enough randomization for porous ingrowth of bone for post-installation bonding enhancement. The surface treatment and/or the ingrowth structures may be microscopic and/or macroscopic.

An embodiment of the present invention may include exterior surface structures and configurations that provide an acute angle relative to an insertion path. For example, when installing an acetabular cup into a prepared installation site of an acetabulum, the cup follows a path as it is inserted into the desired location and depth. Exterior surface portions of the cup are in contact with, and move past, the bone of the walls of the installation site. For one type of surface treatment, exterior surface structures of the surface treatment could be angled relative to the walls. The angles could be angled acutely forward (e.g., towards a bottom of the installation site) which may increase installation forces and decrease removal forces, angled perpendicularly which may be neutral as to directionally, and/or angled backward (e.g., away from the bottom of the installation site) which may increase removal forces and decrease installation forces. The magnitude, and differences, of these asymmetric forces may be influenced by many different factors including materials of the exterior surface elements and complementary material of the contacting surfaces of the installation site, characteristic size and arrangement of the exterior surface elements, design goals, and/or intended use.

An embodiment of the present invention may include exterior surface structures and configurations that provide pitched structures, relative to an insertion path, that vary over the surface that provide for asymmetric relative installation forces.

An embodiment of the present invention may include a specially configured exterior surface to present a two-dimensional or a three-dimensional variable stiffness that is more conducive for transmission of force and energy longitudinally (e.g., parallel to the insertion path) and less conducive to circumferential transmission (e.g., perpendicular to the insertion path). That is, there is an asymmetry of the structural response of the surface treatment to make it easier to move along the path while retaining the circumferential integrity for being held in place once installed.

An embodiment of the present invention may include use of additive manufacturing techniques to produce a final prosthesis having an integrated surface treatment that may

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not require a multi-step process of applying a porous surface treatment to an underlying prosthetic foundation.

An embodiment of the present invention may include use of subtractive manufacturing techniques to produce a final prosthesis having an integrated surface treatment that may not require a multi-step process of applying a porous surface treatment to an underlying prosthetic foundation.

An embodiment of the present invention may include a different installation adaptor for applying forces used to locate a prosthesis within a bone. The conventional method of using an apex-attached rod to apply the forces may be thought of as “pulling” the prosthesis through the installation site. In contrast, an embodiment may include an attachment modality or adaptor that operates on the perimeter and/or inside surfaces to push the prosthesis through the bone. These embodiments may implicate other embodiments regarding 2D/3D wall configuration for interacting the prosthesis with the installation site.

An embodiment of the present invention may be adapted for impact installation and is not limited to other non-impactful installation procedures which may reduce a magnitude of the impact force needed and which may reduce risks of shattering bone at the installation site.

An embodiment of the present invention may include a cream, paste, gel, or other substance that may be applied to contacting surfaces of a prosthesis to be forced into an installation site. This surface treatment may function similar to a lubricant or “shaving cream” to allow to contacting surfaces to more easily move past each other and reduce a magnitude of forces used for an installation. This surface treatment may be combined with other disclosed embodiments and may be dynamically applied as the prosthesis is about to be installed at the installation site.

An embodiment of the present invention may include use of the disclosed embodiments and implementations for assembling a prosthesis (inserting one component of a modular prosthesis into a mating receptacle of another component of the modular prosthesis).

An embodiment of the present invention may include a method for producing a prosthesis for installation into a medullary cavity of a bone, the cavity providing a resistive force for installation, including a) manufacturing additively an elongate structure for the prosthesis, the elongate structure including a foundation and a surface; and b) during the manufacturing step a) establishing one or more portions of the structure with a bias for installation; wherein a first portion of the one or more portions includes a first region of the foundation, wherein a second portion of the one or more portions includes a second region of the foundation, and wherein the first portion and the second portion are cooperatively configured to produce a two-dimensional asymmetric stiffness implementing the bias for insertion into the medullary cavity.

An embodiment of the present invention may include an implant for insertion into a medullary cavity of a bone, the cavity providing a resistive force for installation, including an elongate structure including a proximal end, a distal end spaced apart from the proximal end, a longitudinal axis extending between the ends, and a portion having a foundational bias for installation into the cavity; and a first set of regions of the elongate structure and a second set of regions of the elongate structure; wherein the regions are cooperatively configured to produce a two-dimensional asymmetric stiffness implementing the foundational bias for insertion into the medullary cavity.

An embodiment of the present invention may include a method for repairing a fracture of a long bone, including a)

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producing a template of the long bone; b) reducing the fracture using said template to produce a reduced fractured long bone; and c) fixing said reduced fractured long bone using an exterior structure spanning a length of the fracture wherein said exterior structure includes an anisotropic and viscoelastic component.

An embodiment of the present invention may include an external fixator for a set of fractures in a long bone, including a spanning structure having a length spanning the set of fractures, said spanning structure including a rigid component including an anisotropic and viscoelastic material; and a set of couplers fixing said spanning structure to the long bone.

An embodiment of the present invention may include a bone implant, including an elongate core; and a set of concentric layers disposed around said core; wherein said elongate core and each layer of said set of concentric layers have varying moduli of elasticity.

An embodiment of the present invention may include a method for repairing a fracture of a long bone using a template of the long bone, including a) reducing the fracture using the template to produce a reduced fractured long bone; and b) fixing the reduced fractured long bone using an exterior structure spanning a length of the fracture wherein the exterior structure includes a first anisotropic component having a first stiffness profile; and c) replacing the first anisotropic component, after a period of healing of the long bone with the first anisotropic component, with a second anisotropic component having a second stiffness profile, the second stiffness profile different from the first stiffness profile.

An embodiment of the present invention may include an external fixator for a set of fractures in a long bone, including a spanning structure having a length spanning the set of fractures, the spanning structure compatible with a set of two or more rigid components, each the rigid component including an anisotropic component having a distinct stiffness profile, distinct within the set of two or more rigid components; and a set of couplers fixing the spanning structure to the long bone; wherein the spanning structure includes a rigid component engagement system configured to allow substitution of a first one rigid component of the set of rigid components with a second one rigid component of the set of rigid components while the spanning structure is coupled to the long bone.

An embodiment of the present invention may include a method of varying, over time and the course of fracture healing, the material properties of metallic and composite rods used as spanning devices for fixation of long bone fractures.

An embodiment of the present invention may include a method of varying, over time and course of fracture healing, the stiffness properties of metallic and composite rods used as spanning devices for fixation of long bone fractures.

An embodiment of the present invention may include a method for utilizing programmable smart composites to allow sensing of stress, strain, impact, acceleration, vibration and subsequent computation and communication through an actuation response within the composite to allow progressively more load sharing responsibilities by the long bone fracture over time.

An embodiment of the present invention may include a method to allow autonomous preprogrammed load sharing, over a defined period of time, between a spanning composite smart “robotic material rod” used for fracture fixation, and a healing long bone fracture.

An embodiment of the present invention may include a method of allowing the healing fractured long bone to be exposed to a variety and different combinations of types of stress including compression, shear, torsion, bending and tension, over various periods of time within the healing timeline.

An embodiment of the present invention may include a method of producing anisotropic rods for use in external fixation of long bones.

An embodiment of the present invention may include a method of producing "robotic material rods" for use in external fixation of long bones.

An embodiment of the present invention may include a method of rod exchange in clinic to allow increasing exposure to stress of a healing long bone.

An embodiment of the present invention may include a method of rapid fracture stabilization that minimizes blood loss, surgical dissection and maximizes healing potential of bone.

An embodiment of the present invention may include a method of fracture stabilization that allows manipulation of stresses (forces) experienced by the healing bone to promote either enchondral bone formation over intramembranous (primary) bone formation and vice versa.

An embodiment of the present invention may include a method of fracture stabilization with an external fixator that allows direct addition of subsonic or ultrasonic vibration to the external fixator apparatus to allow enhanced bone healing.

A method for repairing a fracture of a bone using a template of the bone, including a) reducing the fracture using the template to produce a reduced fractured bone; and b) fixing the reduced fractured bone using a structure spanning a length of the fracture wherein the structure includes an anisotropic component having a variable stiffness profile, the anisotropic component including a set of non-biodegradable/non-bioabsorbable stiffness elements, and the anisotropic component including a set of biodegradable/bioabsorbable stiffness elements with the variable stiffness profile changing in a predetermined manner responsive to a degradation/absorption of the set of degradable/absorbable stiffness elements; and c) degrading/absorbing selectively, in situ, the set of degradable/absorbable stiffness elements during healing of the fracture without a stiffness-affecting degradation/absorption of the set of non-biodegradable/non-bioabsorbable stiffness elements, while the structure spans the length of the fracture.

A method for repairing a fracture of a bone using a template of the bone, including a) reducing the fracture using the template to produce a reduced fractured bone; and b) fixing the reduced fractured bone using a structure spanning a length of the fracture wherein the structure includes an anisotropic component having a variable stiffness profile, the anisotropic component including a set of robotic materials with the variable stiffness profile changing in a predetermined manner responsive to a stiffness reconfiguration by the set of robotic materials; and c) adjusting, in situ, the stiffness profile using the set of robotic materials during healing of the fracture, while the structure spans the length of the fracture.

A fixator for a set of fractures in a bone, including a spanning structure having a length spanning the set of fractures, the spanning structure including an anisotropic component having a variable stiffness profile responsive to a selective degradation of a set of degradable/absorbable stiffness structures while not degrading/absorbing non-degradable/nonabsorbable stiffness structures; and an applica-

tor, coupled to the spanning structure, configured to position and apply the spanning structure to the bone after a reduction of the set of fractures.

Any embodiment of the present invention may be superior through manipulation of the friction between contacting surfaces of the prosthesis relative to the material of the installation site. The BMD3 vibratory mechanism may contribute to shifting some or all of the frictional forces from a static coefficient of friction regime to a kinetic coefficient of friction regime. Other factors may also be contributing to a reduction in installation forces required. Similarly, some of the effects of the surface treatment and/or surface application may implicate, at least partially, a transformation of some or all of the resistive forces into the kinetic coefficient of friction regime.

Any of the embodiments described herein may be used alone or together with one another in any combination. Inventions encompassed within this specification may also include embodiments that are only partially mentioned or alluded to or are not mentioned or alluded to at all in this brief summary or in the abstract. Although various embodiments of the invention may have been motivated by various deficiencies with the prior art, which may be discussed or alluded to in one or more places in the specification, the embodiments of the invention do not necessarily address any of these deficiencies. In other words, different embodiments of the invention may address different deficiencies that may be discussed in the specification. Some embodiments may only partially address some deficiencies or just one deficiency that may be discussed in the specification, and some embodiments may not address any of these deficiencies.

Other features, benefits, and advantages of the present invention will be apparent upon a review of the present disclosure, including the specification, drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying figures, in which like reference numerals refer to identical or functionally-similar elements throughout the separate views and which are incorporated in and form a part of the specification, further illustrate the present invention and, together with the detailed description of the invention, serve to explain the principles of the present invention.

FIG. 1 illustrates a sectional side view of an embodiment of the present invention;

FIG. 2 illustrates a sectional side view of an embodiment of a surface treatment;

FIG. 3 illustrates a sectional side view of an embodiment of the surface treatment of FIG. 2 applied to a prosthesis of FIG. 1;

FIG. 4 illustrates a sectional side view of an alternative embodiment of a surface treatment;

FIG. 5 illustrates a representative sectional side view of an embodiment of the alternative surface treatment of FIG. 4 applied to a prosthesis of FIG. 1;

FIG. 6 illustrates a side view of a prosthesis including a two-dimensional asymmetrical stiffness;

FIG. 7 illustrates a top view of the prosthesis of FIG. 6;

FIG. 8 illustrates a side view of a pulling of a prosthesis along an installation path responsive to an apex-attached force applicator;

FIG. 9 illustrates a side view of a pushing of a prosthesis along an installation path responsive to a whole-surface interior adaptor force applicator;

FIG. 10 illustrates a side view of the whole-surface interior adaptor force application disengaged from the prosthesis to better illustrate its configuration;

FIG. 11 illustrates an alternative embodiment of a two-dimensional asymmetric implant illustrated in FIG. 6-FIG. 7;

FIG. 12 illustrates an implant in a rod format including a varying cross-sectional stiffness; and

FIG. 13-FIG. 15 illustrate a sequence of process steps for repairing a fracture;

FIG. 13 illustrates an acquisition of an image for robotic reduction;

FIG. 14 illustrates a robotic reduction of a fracture of a long bone;

FIG. 15 illustrates use of an external fixator for securing a reconstructed long bone;

FIG. 16-FIG. 18 illustrate a relationship between a rigidity of a fixator construct and blood loss typically associated with three types of surgery;

FIG. 16 illustrates that external fixators to be the stiffest construct and associated with the least amount of blood loss or surgical dissection;

FIG. 17 illustrates an external fixator that is made less stiff than plates and rods due to a change in material properties of a rod used in external fixation;

FIG. 18 illustrates an external fixator that includes a capacity to change/adjust its stiffness properties over time;

FIG. 19-FIG. 23 illustrate various anisotropic rods that may be use for external fixation of long bone fractures;

FIG. 19 illustrates an anisotropic rod for external fixation including a set of orthogonal stiffness structures;

FIG. 20 illustrates an anisotropic rod for external fixation similar to FIG. 19, including a different number of longitudinally extending stiffness structures;

FIG. 21 illustrates an anisotropic rod for external fixation similar to FIG. 19 and FIG. 20, including a different arrangement of longitudinally extending stiffness structures;

FIG. 22 illustrates an anisotropic rod for external fixation similar to FIG. 19-FIG. 21, including a different arrangement of orthogonal stiffness structures;

FIG. 23 illustrates an active anisotropic rod which may include a configuration similar to rods of FIG. 19-FIG. 22, or other arrangements of stiffness structures; and

FIG. 24 illustrates an anisotropic rod that may be used in an external fracture fixation solution, rod may include a robotic material or construction with sensing, actuation, computation and communication.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the present invention provide a system and method for improving upon an ability of a surgeon to repair traumatic bone injury using new materials, components, and structures. The following description is presented to enable one of ordinary skill in the art to make and use the invention and is provided in the context of a patent application and its requirements.

Various modifications to the preferred embodiment and the generic principles and features described herein will be readily apparent to those skilled in the art. Thus, the present invention is not intended to be limited to the embodiment shown but is to be accorded the widest scope consistent with the principles and features described herein.

Definitions

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as

commonly understood by one of ordinary skill in the art to which this general inventive concept belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and the present disclosure, and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

The following definitions apply to some of the aspects described with respect to some embodiments of the invention. These definitions may likewise be expanded upon herein.

As used herein, the term “or” includes “and/or” and the term “and/or” includes any and all combinations of one or more of the associated listed items. Expressions such as “at least one of,” when preceding a list of elements, modify the entire list of elements and do not modify the individual elements of the list.

As used herein, the singular terms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to an object can include multiple objects unless the context clearly dictates otherwise.

Also, as used in the description herein and throughout the claims that follow, the meaning of “in” includes “in” and “on” unless the context clearly dictates otherwise. It will be understood that when an element is referred to as being “on” another element, it can be directly on the other element or intervening elements may be present therebetween. In contrast, when an element is referred to as being “directly on” another element, there are no intervening elements present.

As used herein, the term “set” refers to a collection of one or more objects. Thus, for example, a set of objects can include a single object or multiple objects. Objects of a set also can be referred to as members of the set. Objects of a set can be the same or different. In some instances, objects of a set can share one or more common properties.

As used herein, the term “adjacent” refers to being near or adjoining. Adjacent objects can be spaced apart from one another or can be in actual or direct contact with one another. In some instances, adjacent objects can be coupled to one another or can be formed integrally with one another.

As used herein, the terms “connect,” “connected,” and “connecting” refer to a direct attachment or link. Connected objects have no or no substantial intermediary object or set of objects, as the context indicates.

As used herein, the terms “couple,” “coupled,” and “coupling” refer to an operational connection or linking. Coupled objects can be directly connected to one another or can be indirectly connected to one another, such as via an intermediary set of objects.

The use of the term “about” applies to all numeric values, whether or not explicitly indicated. This term generally refers to a range of numbers that one of ordinary skill in the art would consider as a reasonable amount of deviation to the recited numeric values (i.e., having the equivalent function or result). For example, this term can be construed as including a deviation of ± 10 percent of the given numeric value provided such a deviation does not alter the end function or result of the value. Therefore, a value of about 1% can be construed to be a range from 0.9% to 1.1%.

As used herein, the terms “substantially” and “substantial” refer to a considerable degree or extent. When used in conjunction with an event or circumstance, the terms can refer to instances in which the event or circumstance occurs precisely as well as instances in which the event or circum-

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stance occurs to a close approximation, such as accounting for typical tolerance levels or variability of the embodiments described herein.

As used herein, the terms “optional” and “optionally” mean that the subsequently described event or circumstance may or may not occur and that the description includes instances where the event or circumstance occurs and instances in which it does not.

As used herein, the term “size” refers to a characteristic dimension of an object. Thus, for example, a size of an object that is spherical can refer to a diameter of the object. In the case of an object that is non-spherical, a size of the non-spherical object can refer to a diameter of a corresponding spherical object, where the corresponding spherical object exhibits or has a particular set of derivable or measurable properties that are substantially the same as those of the non-spherical object. Thus, for example, a size of a non-spherical object can refer to a diameter of a corresponding spherical object that exhibits light scattering or other properties that are substantially the same as those of the non-spherical object. Alternatively, or in conjunction, a size of a non-spherical object can refer to an average of various orthogonal dimensions of the object. Thus, for example, a size of an object that is a spheroidal can refer to an average of a major axis and a minor axis of the object. When referring to a set of objects as having a particular size, it is contemplated that the objects can have a distribution of sizes around the particular size. Thus, as used herein, a size of a set of objects can refer to a typical size of a distribution of sizes, such as an average size, a median size, or a peak size.

FIG. 1 illustrates a sectional side view of an embodiment of the present invention represented using a prosthesis 100 including a foundation portion 105 and an exterior contacting portion 110. In some cases, prosthesis 100 may include an optional mounting structure 115 attached to, or integrated with, an interior wall 120.

Prosthesis 100 in FIG. 1 is an acetabular cup used in total hip replacement medical procedures. Prosthesis 100 is installed into a prepared installation site of an acetabulum that defines a reamed socket in a portion of bone of an acetabulum that is about equal to a diameter of the acetabular cup. When installed, exterior contacting portion 110 contacts the bone portion of the installation site. Installation of an acetabular cup requires that it be forced into the installation site while exterior contacting portion 110 is engaged, in varying degrees, with the living bone. Some of the disclosed embodiments provide materials, configuration, arrangement, and orientation of surface elements defined by exterior contacting portion 110 that provide, collectively, an overall asymmetric force with respect to one or more of the contacted portions of the bone portion. In this context, asymmetric force means that engagement forces between the bone portion and prosthesis 100 have a magnitude in one direction of motion (e.g. deeper into the installation) as compared to another direction (e.g., removal from the installation site) that are different. For example, contacting portion 110 may result in installation forces with respect to the installation site that are less than removal forces from the installation site once installed. Other directions and other asymmetries are possible that for some embodiment it may be desirable to have installation forces be greater than removal forces. A magnitude of the asymmetry may be determined by different factors appropriate for a particular embodiment.

Prosthesis 100 depicted as including at least two portions: foundation portion 105 and exterior contacting portion 110

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which is not meant to imply any particular manufacturing process, configuration, or arrangement beyond the presence of two functional portions.

Foundation portion 105 may be thought of as providing structural integrity and strength for weight-bearing and loading, and support for exterior contacting portion 110. Exterior contacting portion 110 defines the surface elements that produce aggregate asymmetric forces during contacted motion with bone of the installation site.

Foundation portion 105 and exterior contacting portion 110 may be formed in many different ways. As illustrated in FIG. 1, exterior contacting portion 110 is integrally produced with foundation portion 105 during manufacturing of prosthesis 100. For example, additive manufacturing techniques may be used to define the different portions at different points during the manufacturing. Three-dimensional (3D) printing is a representative class of additive manufacturing equipment that may be used to seamlessly produce prosthesis 100 with exterior contacting portion 110 seamlessly integrated with foundation portion 105.

In other embodiments, prosthesis 100 may be produced using a two-step process in which foundation portion 105 is manufactured first and then in a separate manufacturing process exterior contacting portion 110 is added onto desired surfaces of foundation portion 105 to produce prosthesis 100. In some cases, exterior contacting portion 110 may be produced first as a template and then foundation portion added later.

For purposes of this invention, the term “surface treatment” is used to include all these implementations of exterior contacting portion 110. This term is not limited to any particular arrangement or configuration of exterior contacting portion 110.

As noted herein, one desirable feature of current prosthetic implants includes a surface arrangement for a randomized exterior that includes pores/cavities/voids of a particular characteristic that are used to promote bone in-growth for bonding prosthesis 100 at the installation site. Some configurations of exterior contacting portion 110 may be configured with such in-growth bonding features implemented consistent with the manufacturing technique for prosthesis 100. The surface treatment itself may include a microscopic and/or a macroscopic characteristic dimension for the implementing structural elements.

For example, with the use of additive manufacturing, the set of instructions for forming prosthesis 100 result from a set of instructions executed by the additive manufacturing equipment. That set of instructions may be defined by various 3D design tools and various mathematical instructions. Those instructions may include a superposition of asymmetric structural elements and randomized void-definition processes such that exterior contacting portion 110 includes both of these characteristics. In other embodiments, void-definition processes may be applied to prosthesis 100 after exterior contacting portion 110 is produced with asymmetric force producing structures. Similarly, asymmetric biasing structures may be later added to a device having existing ingrowth structures.

In some cases, prosthesis 100 may be provided with mounting structure 115 which may be implemented in many different ways and used as a mechanism to secure an external tool to prosthesis 100. In one case, structure 115 may include a solid structure attached at an apex of interior surface 120. That solid structure may further define an externally accessible cavity including threaded sidewalls.

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The external tool may include an extension having an exterior threaded surface complementary to the threaded sidewalls of structure **115**.

In use, an operator may attach the external tool (an example is illustrated later in FIG. **8**) to mounting structure **115** and begin to apply an inserting force prosthesis **100** into an installation site. That inserting force may be a non-impacting force applied by a BMD-type device as described in the incorporated patents and applications or it may be an impacting force applied by a mallet, hammer, or the like. Exterior contacting portion **110** may be configured so a net insertion-resisting force relative to the side walls of the installation is less than a net withdrawal-resisting force relative to the side walls. This arrangement may allow for decreased installation forces as opposed to a prosthesis having an outer surface with symmetric or randomized resisting forces. In some implementations, each incremental depth increase may be performed with less inserting force and each position may be thought of being anchored in place with a bias to increasing the installation depth responsive to forces applied to and by the external tool.

In some embodiments, when the asymmetric forces have enough differential, and when the installation site is prepared in an appropriate fashion, some embodiments may allow for insertion to result from generalized low-level vibration or periodic forces that bias prosthesis ever deeper into the installation site.

FIG. **2** illustrates a sectional side view of an embodiment of a surface treatment **200**. Surface treatment **200** includes a series of asymmetric “steps” that may be included as all, or a portion of, exterior contacting portion **110**, extending 360 degrees around foundation portion **105** when viewed from above. FIG. **3** illustrates a sectional side view of a surface treatment **200** included as part of prosthesis **100** as exterior contacting portion **110**. In some embodiments, surface treatment **200** may not extend over an entire height of prosthesis **100**. In some embodiments, surface treatment **200** may not include a regular step profile. The step profile of surface treatment **200** is representative of asymmetrically angled surface elements of the type that may be used for asymmetric resisting forces.

FIG. **4** illustrates a sectional side view of an alternative embodiment of a surface treatment **400**. Surface treatment **400** illustrates a concept of variable pitch in which a first distance **405** between a first set of adjacent peaks of surface treatment **400** is different than a second distance **410** between a second set of adjacent peaks of surface treatment **400**. There are many different possible implementations for surface treatment **400**. While surface treatment **400** is illustrated as having continuously variable distances between a pair of peaks, surface treatment **400** may also be implemented as having a first portion of substantially matching (or varying using a first variable peak profile) pitch distances and then having one or more additional portions, each portion including substantially matching (or varying using the same or additional variable peak profiles) pitch distances within its portion. That is to say, a top portion, perhaps a top quarter or a top third of prosthesis **100**, for example, may include a first configuration for pitches as part of surface treatment **400** while a bottom portion, perhaps a bottom quarter or a bottom third of prosthesis **100**, for example, may include a second configuration for pitches as part of surface treatment **400**. FIG. **5** illustrates a representative sectional side view of surface treatment **400** included with prosthesis **100** as exterior contacting portion **110**. The variable pitches may provide for asymmetric resisting forces. As illustrated, surface treatment **400** includes a generally symmetric peak

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pattern. In some embodiments, surface treatment **400** may include a modification of surface treatment **200** to include one or more regions of variably spaced “asymmetrically-angled peaks” when included as part of exterior contacting portion **110**.

The distribution of these portions may be other than this example (top and bottom portions) and different regions and portions may have different expanses (e.g., a top third and a bottom quarter) for example. In other embodiments, exterior contacting portion **110** may include one or more regions of surface treatment **200** and one or more regions of surface treatment **400**.

FIG. **6** illustrates a side view of a prosthesis **600** including a two-dimensional asymmetrical stiffness configuration, and FIG. **7** illustrates a top view of prosthesis **600**. Prosthesis **600** includes a set of ribs **605** and one or more planks **610** disposed as part of a prosthetic body **615**, represented as an alternative acetabular cup. Body **615** may be implemented in conventional fashion or may include an arrangement consistent with prosthesis **100**. Ribs **605** and plank(s) **610** are configured to provide an asymmetric two-dimensional (2D) stiffness to body **615** that may be more conducive to transmission of force and energy through the longitudinal axis of the cup as opposed to circumferentially. Ribs **605** are longitudinally extending inserts within body **615** (and/or applied to one or more exterior surfaces of body **615**). Plank(s) **610** is/are laterally extending circumferential band(s) within body **615** (and/or applied to one or more exterior surfaces of body **615**). For example, planks **610** may be “stiffer” than ribs **605** (or vice-versa) to produce a desired asymmetric functional assembly that may provide for an undulatory body motion as it is installed into position.

The illustration of FIG. **6** is not to be understood as implying that the present invention requires that ribs and planks be maintained at relative right angles as illustrated. In some implementations, to achieve a desired affect or motion, other angular relationships between the ribs and planks are possible (e.g., 30, 45, 60 degree relationships, or more generally an angular (which may be constant or varying at different locations) range of 5-90 degrees).

An alternate implementation could include other arrangements of intersecting multidimensional (e.g., 2D or 3D structures) such as a pair of counter-cyclical helical structures implemented in a body of a prosthesis. That is, for a prosthesis having a particular axis, one structure is installed clockwise about that axis and another structure is installed counterclockwise about that axis. The frequency of wrap, material type, tension, nature of integration, and other factors influence the asymmetric stiffness imparted by these structures that in turn may influence a resulting undulatory motion in response to forces moving the prosthesis along an installation path. In some cases, it may be desired to provide a particular undulation motion for removal rather than for installation as the present invention is not constrained to just improving installation of a prosthesis into a bone.

In some embodiments, a use of a tool, for example a BMD prototype, allows an operator to insert a prosthesis with more control and less force. Use of such a tool coupled with prosthesis **600** that has an asymmetrical “structural” and hence asymmetrical “functional” propensity for longitudinal seating, the operation may be able to be completed with less force, and thus more safely, efficiently, and/or accurately.

The acetabular cup and all implants in orthopedic surgery may benefit from various types of differentiation (where the structure of the implant in and by itself) enhances the functionality of the implant. Prosthesis **600** may alternatively, or in addition, include a “cross helical arrangement”

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of fibers, strands, cables, ropes, or other structures to be simulated on the surface of, or in the body of, prosthetic implants (e.g., acetabular cups) and hence the creation of “two dimensional stiffness”. The creation of “fiber angels” on the surface of the implant creates better and easier seating of the implant, with more efficient transmission of force from an insertional tool to the cup (implant) to the pelvic bone.

Prosthesis 600 may be referred to generally as an “intelligent prosthesis” and acetabular cup where the manipulation of the structure and surface of the implant significantly affects the functionality of the implant particularly during the actual surgery, this implant will have been fine-tuned functionally to insert. This cup through its inherent structural specifications discussed above will complement the use of BMD vibratory insertional tool (bidirectional or unidirectional versions). This concept may apply to many different orthopedic implants used for reconstruction and trauma, and other structures to be inserted or assembled together.

FIG. 8 illustrates a side view of a system 800 pulling a prosthesis 805 along an installation path responsive to an apex-attached force applicator 810. In some cases, for a prosthesis having 2D functional asymmetry, it may be desirable or undesirable to pull prosthesis 805 in such as fashion depending upon the differing moduli of stiffness and arrangement of components. In some arrangements, it may be undesirable to pull prosthesis into position in the manner illustrated in FIG. 8.

FIG. 9 illustrates a side view of a system 900 pushing of prosthesis 905 (e.g., prosthesis 600) along an installation path responsive to a whole-surface interior adaptor force applicator 910, and FIG. 10 illustrates a side view of system 900 with whole-surface interior adaptor force applicator 910 disengaged from prosthesis 905 to better illustrate its configuration. Applicator 910 sits into prosthesis 905 and “pushes” it down into position. In some embodiments may provide that “pushing” prosthesis 905 into position with applicator 910 (such as a BMD or a BMD-type device) possibly engages an undulatory motion of prosthesis 905 more effectively, such as in some cases when prosthesis 905 includes an embodiment of prosthesis 600 configured for undulation in response to an appropriate series longitudinal insertion forces F.s

Another embodiment of the present invention may include a material applied alone or as part of another surface treatment to contacting surfaces of a prosthesis. This embodiment includes a completely novel idea for insertion of a prosthesis such as an acetabular cup. Depending upon context, there are materials that may significantly decrease relative friction between two contacting objects moving past each other. A use of a BMD vibrational tool may help to facilitate the use of similar concept. An embodiment may include a bio-absorbable or bio-degradable material (e.g., a paste, cream, gel, or other substance) configured for use during the insertion process, e.g., of an acetabular cup into the acetabulum, to decrease the relative forces between contacting surfaces at the cup and bone interface. For example, this material could be an antibiotic paste that absorbs immediately after insertion, or a rapidly dissolving paste such as calcium hydroxylapatite (HA) $[Ca_{10}(OH)_2(PO_4)_6]$, Beta tricalcium phosphate, an HA/B TCP combination; all of which can be made into paste and slurries that dissolve over controlled amounts of time. An embodiment of the present invention may include use of a surface-applied material (such as a cream, gel, paste or the like) to minimize relative forces during the insertion/assembly of an implant with a tool, such as the BMD prototype or other installation

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tool. Of course, this idea applies to other implants, for example those that require the use of force and that would benefit from the BMD vibrational insertion tool, as well as other procedures and tools.

Surface treatment and/or application of a surface material may reduce installation forces. One possible theory is that the surface treatment and/or surface material manipulates of the applicable friction coefficients through shifting a contribution from static to kinetic coefficients as well as reducing the applicable static and/or kinetic coefficient. For a surface treatment such as a paste, slurry, ice, or the like, such manipulation may be temporary during the time that the prosthesis is installed. Thereafter the values for the coefficients may revert to the previous, unaltered values. This may be used to advantage in helping to improve the retentive forces holding the prosthesis in place after installation.

Described herein is use of a paste or slurry that absorbs over time after installation (in some cases quickly such as ice) after the insertion (HA) $[Ca_{10}(OH)_2(PO_4)_6]$, Beta tricalcium phosphate, and HA/B TCP combination, all of which may be made into a paste and/or a slurry that can be applied to the surface of the cup and dissolve over a controlled period of time, preferably immediately after the insertion of the cup is complete. In addition, there is another concept that uses a more simple and ubiquitous phenomena to reduce installation forces (e.g., possibly to reduce the applicable coefficients of friction), in order to allow easier insertion of the acetabular prosthesis into the acetabulum. That is to create a simple method of freezing sterile water on the cup and within the porous coating surface of the cup to provide a full or partial ice film at the juncture of the cup and the bone of the installation site. The porous coating comprises of microstructural features such as peaks, valleys and deep caves. In one sense, this structure may mimic the structure of trabecular/cancellous bone with its three-dimensional and interconnecting network of pores and capillary properties. The porous coating aids in initial scratch fixation as well as long term fixation through osseointegration of bone with its surface. Recently, there have been many advances in the creation of the porous coating that more accurately resemble the trabecular bone. Filling these gaps with sterile ice water that is then frozen is expected to dramatically decrease the applicable installation forces (possibly by reducing the applicable coefficients of friction) and hence FR (resistive force for insertion of a cup into a cavity). This method of using ice water is ideal in that as soon as the cup is exposed to the body fluids the ice will melt returning the coefficient of static friction (for the cup/cavity interface) to its original value before the application of ice. In this manner whether a biological paste, antibiotic paste, or ice is utilized, the coefficient of static friction may be temporarily (disarmed) so that easy insertion can occur. All of these methods whether they rely on the paste, slurry or ice perform the same function to temporarily diminish the FR or applicable resistive force(s) for the cup/cavity interaction, and resolve shortly after insertion, and thereby return the relative forces to unaltered values—except that after installation these resistive now resist removal in contrast to resisting installation. This is akin to “tricking” the body to open up a short window of time to allow easy insertion of a prosthesis. This is a new and novel method that can be utilized to make acetabular cup insertion easier with any insertion tool or method, including with the disclosed and incorporated devices, systems, and methods.

FIG. 11 illustrates an alternative embodiment of a two-dimensional asymmetric implant 1100 similar to prosthesis 600 illustrated in FIG. 6-FIG. 7 and described herein.

Implant **1100** is illustrated as an intramedullary rod, also sometimes referred to as an intramedullary nail (IM nail) or inter-locking nail or Küntscher nail, which may or may not include proximal or distal fixation. Implant **600** may include an elongate structure forced into a medullary cavity of a bone, such as used to treat trauma (e.g., fractures of long bones of the body). Implant **1100** conforms generally to prosthesis **600**, and its options, except for the shape and use. Implant **1100** includes a set of circumferential ribs **1105** and a set of longitudinally-extending planks **1110** that have a rigidity/flexibility different from ribs **1105**. For example, it may be desirable to provide ribs **1105** more rigid than planks **1110**. FIG. **11** illustrates an implementation having ribs **1105** being circumferential (and more rigid) and planks **1110** being longitudinal (and less rigid relative to ribs **1105**). In some embodiments and implementations, ribs **1105** and planks **1110** may have a different orthogonal relationship with planks not parallel to a longitudinal axis in contrast to that illustrated in FIG. **11**. Further, some embodiments and implementations may include counter-directional helical regions defining differential bias. Counter-directional helical regions may have differing relative twist rates along the longitudinal axis. Further, some embodiments may include a surface treatment as described herein. For example, a surface treatment may be included in addition to, or in lieu of, the foundational asymmetric biasing arrangement. The surface treatment may be asymmetrically biased to aid in implantation or aid in removal, depending upon an intended direction of installation into a bone cavity.

Described herein and in the incorporated patent applications are embodiments that may include several concepts involving manufacturing of orthopedic implants (including additive manufacturing “AD”) to enhance one or more functions of those implants.

These functions may include two, three, or more dimensional stiffness (undulatory motion) which may create a bias for insertion for example for (an acetabular cup or IM rod), external surface preparation (e.g., at a micron level) with bias for insertion, and “variable stiffness prosthesis” (e.g., adjusting a porosity and a crystalline structure at the microscopic level) simulating natural local mechanical properties of bone (to prevent stress shielding and bone resorption). Variable stiffness prosthesis may also be invoked to build prosthesis that can better withstand high local stresses at prosthesis to prosthesis interfaces (as in the trunnion/head junctions) to prevent tribocorrosion and fretting and to address a problem of trunnionosis. Embodiments have described a two-dimensional stiffness of implants (e.g., with ribs and planks) for use with vibratory insertion forces for easier insertion.

Disclosed herein is an expansion on the embodiments of functional implants which can be created with or without AD for use in trauma and tumor and reconstructive surgeries.

The science of fracture healing continues to be elucidated. There are several concepts worth quick review. Traumatic fractures of long bones are generally stabilized in one of three methods: a) intramedullary rod fixation, b) plate-fixation, and c) external fixation. There are advantages and disadvantages to each of these techniques. Certain negative traits are generally attributed to each of these fixation techniques that can lead to poor healing of the fractured bone (Non-unions).

1. Plate Fixation: This method of fixation has generally been associated with extensive periosteal (the external covering of bone) stripping of bone, which can lead to devascularization of bone and therefore slow, or non-healing of

fractured bone. More recent techniques emphasize less dissection of the surface covering of bone (less periosteal stripping) to maintain vascularity and allow better healing; bridging with a plate. The second negative issue associated with plate fixation is that metal plates are rigid and with multiple points of fixation with screws a very rigid construct is created that can affect proper bone healing, again leading to delayed union or non-union.

2. A quick review of the biology of fracture healing follows. Bone formation is either “Enchondral” as in long and short bones or “Intramembranous” as in flat bones of the skull. The inner two thirds of cortical long bones are vascularized by nutrient arteries that pass through the diaphyseal cortex and enter the IM canal; these arteries get damaged when reaming is done to prepare the canal for a rod. The outer one third of the cortical bone derives blood from the periosteal membrane vessels, which are at risk from periosteal stripping that occurs during exposure for plate fixation.

Fractures commonly heal with a combination of enchondral (cartilaginous base) and intramembranous (primary) bone formation. Motion at the fracture site results in healing primarily through enchondral ossification, whereas stability at the fracture site enables direct ‘primary bone formation’ through intramembranous ossification. Fracture healing occurs in a sequence of biologic stages including inflammation, hematoma maturation, hypertrophic cartilage formation, new bone formation and remodeling to mature bone [Callus Formation].

Bone is a live structure with 70% of its extracellular matrix composed of mineral components, and 30% composed of organic components (90% type 1 collagen and 5% noncollagenous proteins). The structure of cortical bone shows cortical lamellar bone: interstitial system, osteonal lamellae, and outer circumferential system. There is an intricate vascular system to provide nutrition to the living cells in bone (osteocytes). The complex arrangement of the microstructure and meso-structure of bone including the lamellar rings and interstitial lamellar and external circumferential lamellar system is noted. A combination of the microstructure, mesostructure and macrostructure of bone may allow bone to be anisotropic and viscoelastic in nature. Viscoelastic material has properties that are rate dependent or have time-dependent responses to applied force. An anisotropic material has properties that differ depending on the direction of load. Bone, muscle, ligament, and tendons all are anisotropic and viscoelastic. An isotropic material has the same mechanical properties in all directions. In general metals and ceramics are isotropic.

Too rigid a fixation may interfere with the above process of callus and subsequent bone formation.

3. External fixation has an advantage of not damaging either the endosteal or periosteal blood supplies however it has a bad reputation of being an extremely stiff construct that limits physiological motion required for formation of callus/bone. Its use is therefore limited to open fractures. It is rarely used as a definitive form of routine fracture fixation.

4. IM rod fixation traditionally has been the most accepted form of long bone fixation due to higher and more rapid healing than the other two techniques. It is postulated that this form of fixation allows more physiological transmission of loads across the fracture site allowing natural callus formation and bone healing. However, this process typically requires reaming of the diaphyseal canal, which damages the endosteal blood supply to bone, and as well there is a general physiological cardiopulmonary risk to the patient with the

process of reaming and intramedullary rod application: fat emboli to the lungs, which is a disadvantage to a trauma patient.

A problem is that bone is anisotropic, and the metals used to stabilize bone for fracture fixation are isotropic. Conventional metal and materials used in implants, rods, and prosthetics is rigid in all directions and does not allow varying physiological loads to the bone. This disparity could block the necessary and appropriate allowance of physiological motion required for proper fracture healing. Some embodiments of the present invention are intended to produce a better metal that simulates bone's material and mechanical properties (e.g., to use in fracture fixation) in order to allow natural healing of bone in fracture care. Currently there are five different ways a bone can be stressed: a) tension, b) compression, c) torsion, d) bending, and e) shear.

It is not known or well understood what type or combination of physiological stresses leads to or (are necessary) for optimal physiological callus formation. This is a subject of future investigations.

Some embodiments of the present invention may include specification and use of anisotropic and viscoelastic metals and materials. Since the crystalline and lattice structure of metal and other materials can be manipulated and microscopic and mesoscale levels. The Young's modulus of elasticity for cortical bone is approximately 20 GPa (Gigapascals). The modulus of elasticity for stainless steel is about 200 GPa, and that of titanium is about 100 GPa.

An embodiment may include manufacturing of crystalline metal and material in such a way to simulate the internal architecture of compact and cortical bone. With osteonal lamelle, interstitial lamelle, and circumferential lamelle of concentric cortical bone. It may be that this microscale and mesoscale architecture is what provides anisotropic and/or viscoelastic nature to bone.

Alternatively implants and rods may be created with variable decreasing or increasing stiffness concentric rings, as in the structure of trees, again simulating natural engineering concepts that likely confer anisotropic and viscoelastic properties. FIG. 12 illustrates an implant 1200 in a rod format including a varying cross-sectional stiffness. A shaft 1205 of implant 1200 may include a core 1210, and three layers (a layer 1215, a layer 1220, and a layer 1225). Each layer may include a different modulus of elasticity as follows: core 1210=80 GPa, layer 1215=60 GPa, layer 1220=40 GPa, and layer 1225=20 GPa. Other implementations may have other arrangements and modulus distributions.

At a microscopic level an embodiment may include simulation of a triple helix structure of collagen fibrils arranged in specific quarter-stagger array seen in electron microscopy, potentially conferring the viscoelastic nature to bone. Also, an embodiment may include an oblique arrangement of metallic "fibrils" to simulate an oblique arrangement of collagen fibers in bone.

Ultimately when a proper anisotropic and viscoelastic metal is created, it may completely change the way fracture fixation is approached. Formation of anisotropic metals in addition to the discovery of the optimal physiologic loading for callus formation can make future fracture fixation less invasive and more effective.

Anisotropic/Viscoelastic metals and materials may be used for plate-fixation, intramedullary rod fixation, and external fixation.

There may be a particular advantage for use of anisotropic metals and other materials with external fixators, particularly in a case of a trauma patient and an injured soldier or warrior.

When external fixators are attached to anisotropic metals that allow transmission of certain physiological stress at the fracture site, it is predicted that callus formation may not be impeded, but rather enhanced. Should an external fixator be effective in allowing healing to take place (without risk of non-union; to which it generally has a high association), the need for additional dissection through (by periosteal stripping for plate fixation) or (reaming for intramedullary rod fixation) would be obsolete and unnecessary. The surgeon would apply the Shantz pins to the cortical bone above and below the fracture and apply the spanning anisotropic metal bars. Fracture healing could occur rapidly, and the fixator would be removed. This would confer a huge advantage to the injured soldier who is typically a multi trauma patient under huge cardiopulmonary and physiological loads. In fact, IM rod fixation has been generally the fixation of choice but has definite negative physiological consequences. Similarly, plate fixation can be applied too rigidly leading to non-union and requires extra dissection with additional surgery and bleeding.

Should fractures for trauma patients be effectively treated with external fixators, minimum physiological and cardiopulmonary load may be imparted to the patient. Also, there is less bleeding and less operative time.

Some embodiments may include a concept of fracture fixation with robotic surgery and computer navigation. Currently robotic surgery computer navigation is common in the orthopedic operating room, however, typically relegated to arthroplasty surgery. Computer navigation and robotics have an ability to landmark a position of the patient's bones in the operating room (OR) space. Computerized tomography (CT) based techniques may match a previously imaged bone to the patient's body in the OR space.

An embodiment of the present invention may include the following process for fracture fixation and stabilization for the trauma patient:

1. CT of the opposite extremity (or for the soldier, a set of extremities are imaged before deployment) is obtained. The opposite extremity is a close approximation of the injured extremity in more than 99% of cases. A mirror image of the studied body part (for example of a femur) is produced in the robot, or computer navigation

2. External fixator pins are applied above and below the fracture site, and these Shantz pins are attached to the robot or computer navigation system. The arms of the computer will use the template of the uninjured bone (mirror image with right-left reversal) to propose a close estimation of the fractured bone. The computer/robot will reduce the fracture through internal software program that tells it to re-approximate the fractured fragments to the model derived from the CT of the uninjured side.

3. Once the reduction is complete, the surgeon applies the anisotropic and viscoelastic metal bars to span the fracture. There will be no need for additional surgery or conversion to plates and or rods.

4. Rods and implants of varying stiffness can be produced (all anisotropic/viscoelastic in nature) that can easily be exchanged in clinic when the construct requires adjustment (e.g., to be more or less stiff).

This process is believed to include a novel method of fracture fixation and treatment that can revolutionize fracture care especially in trauma patient and injured soldier.

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FIG. 13-FIG. 15 illustrate a sequence of process steps for repairing a fracture, FIG. 13 illustrates an acquisition of an image for robotic reduction; FIG. 14 illustrates a robotic reduction of a fracture of a long bone; and FIG. 15 illustrates use of an external fixator for securing a reconstructed long bone. In this process a long bone has been severely fractured. In some cases, it may be anticipated that serious injury to a bone may occur (e.g., a soldier deployed to a hostile area) and a CT scan may be prepared in advance and retained for use in an event that injury occurs. In FIG. 13, an advance CT image was not obtained so a CT image of a corresponding uninjured bone 1305 is obtained and a right-left reversal of the image produces a template 1310 for the fractured bone.

FIG. 14 includes a robot 1405 that uses template 1310 to reduce the fractured elements of long bone 1410. FIG. 15 includes the robotically reduced (per template 1310) long bone 1505 to which an exterior fixator 1510 is applied. Fixator 1510 includes an anisotropic and viscoelastic bar as described herein.

Current surgical fixation of fractures in orthopedic surgery has taken three forms, all of which have distinct advantages and disadvantages. As a matter of quick review, fracture fixation may include: (i) open reduction internal fixation; (ii) open or closed reduction and intramedullary rod fixation; and/or (iii) closed reduction external fixation.

A variety of these three fixation methods are generally used for fixation of long bones which includes femur, tibia, humerus, radius and ulna.

External fixation is primarily relegated to temporary initial fixation of open fractures which involve open wound contamination of bone from the outside world. These injuries generally preclude the use of metal inside or on bone, due to the fact that introduction of metal in open fractures would contribute to the development of deep infection and osteomyelitis. Therefore, external fixation of long bone fractures is almost never used as the definitive technique for long bone fracture fixation. Most often a high velocity fracture that is initially fixed with External fixation is “converted” to either internal fixation with intra-medullary rods or a plate and screws.

The main theoretical advantage of external fixation considered by orthopedic surgeons is its ability to stabilize the fracture without introduction of metal in the wound. Another very significant advantage of the external fixator is that it by no means disrupts the already compromised blood supply of the fractured bone. These theoretical advantages however have not been able to be exploited over the last 30 years because of a specific disadvantage of the external fixator, which specifically have to do with the material properties of the rods used in external fixation systems. These rods are extremely stiff constructs that categorically doom long bone fractures to non-union (non-healing). As discussed in this application, fractures commonly heal with a combination of enchondral (cartilaginous base) and intramembranous (primary) bone formation. Motion at the fracture site results in healing primarily through enchondral ossification, whereas stability at the fracture site enables direct ‘primary bone formation’ through intramembranous ossification.

The exact biology of fracture healing has yet to be elucidated, however, in general it is believed that too rigid or too flexible fixation, regardless of implant, leads to non-union or non-healing with the fracture site with new bone.

An embodiment of the present invention includes a system of fracture fixation that allows just the right amount of motion or “micromotion” which allows for rapid and pro-

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gressive healing of the fractured bone with new healthy bone rather than with fibrous tissue.

Nature’s fracture healing occurs in a sequence of biologic stages including inflammation, hematoma maturation, hypertrophic cartilage formation, new bone formation and remodeling to mature bone [Callus Formation]. Too little or too much ambient stress or stresses can disrupt this natural healing process.

Therefore, a theoretical advantage of external fixation of long bones, which is smaller and quicker surgery with minimal blood loss and minimal destruction of blood supply, has been overshadowed by its distinct empirical disadvantage of stiffness of the construct which leads to non-union. This may lead to underutilization of this external fracture fixation system.

Without use of external fracture fixation, orthopedic surgeons rely on other fixation systems/methods that clearly destroy the blood supply to bone primarily because these fixation methods are less stiff and do not doom the fracture to non-union.

Intramedullary fixation of long bones is one such technique which involves (a) reaming of the intramedullary canal and (b) placement of a metallic rod within the canal. Both of these actions destroy the endosteal blood supply of bone. Additionally, intramedullary fixation of long bone fractures places significant unwanted cardiopulmonary stress on an already injured patient due to production of fat emboli in the reaming and rod placement process.

Plate fixation of long bone fractures involves periosteal stripping, which destroys the external blood supply to bone. Plate fixation includes a plate construct that is generally more stiff than intramedullary rod fixation. Original techniques of rigid plate fixation used multiple screws that involved increased rates of non-union. These issues led to development of newer techniques of “bridging” plates, in which the plates are slid over the periosteum with minimal stripping and fewer points of fixation to bone with screws. This modification of plate fixation technique allows a more flexible construct that is less susceptible to non-union and has gained widespread acceptance.

FIG. 16-FIG. 18 illustrate a relationship between a rigidity of a construct and blood loss typically associated with three types of surgery: (a) external fixator, plate fixation, and intramedullary rod. FIG. 16 illustrates that external fixators to be the stiffest construct and associated with the least amount of blood loss or surgical dissection. FIG. 17 illustrates an external fixator that is made less stiff than plates and rods due to a change in material properties of a rod used in external fixation. FIG. 18 illustrates an external fixator that includes a capacity to change/adjust its stiffness properties over time. For example, the fixator may be very rigid initially and progressively become less stiff, allowing progressive exposure to varying levels and/or combination of stresses including tension, compression, torsion, bending and shear.

An embodiment of the present invention may include a system and method allowing modulation and control of stiffness properties, a time-varying stiffness profile (including an elastic modulus and Poisson’s ratio) of a fixation system that may be manipulated over time to produce varying levels and types of stress to healing bone. Such a system may reverse an early disadvantage of external fixation systems (stiffness), and on top of that produce an advantage that may not be immediately available to plate and intramedullary rod fixation since these methods do not allow easy and frequent exchange of a construct spanning the fracture site.

Reduction of the fracture: one difficulty in fracture fixation of long bones, especially lower extremity long bones that are covered with strong muscles, includes obtaining a “reduction”. To obtain a proper reduction, fragments of a fracture are placed in close to anatomic alignment or at least in acceptable mechanical alignment, before any kind of spanning permanent fixation is applied with plates, rods or fixators.

The process of obtaining a reduction is itself a difficult process employing significant force and traction apparatuses with a variety of reduction maneuvers by the surgeon. This method of fracture reduction, which involves placing the patient on a fracture table and applying ever increasing levels of traction to the leg through a post placed in the groin and pushing and pulling on the leg with a crutch, is itself arcane and does not take advantage of available robotic technologies which can be much more precise in producing the proper amount of force for fracture reduction.

In an incorporated priority application, a method is described for obtaining reduction using robotic machines. Current robotic techniques are either image based, or non-image based. Image based robotics use radiography or computed tomography to obtain a virtual plan of the patient’s bone. In the operating room the patient’s bone is registered and matched with the virtual plan already in the software. In this manner the robotic and navigation systems have the ability to know the exact position of patients bone the operating room space.

In an incorporated priority application, it was suggested that in high velocity trauma, whether in motor vehicle accidents or in injured warriors, athletes, or other high-risk individuals, a CT or X-ray of the uninjured bone (for example the contralateral femur) be obtained. Subsequently through a software program, a three-dimensional computer model of the imaged bone be created and then reversed to be used as a template for reduction of the injured bone. Through this process the fractured extremity could be reconstructed by application of Schanz screws to proximal and distal fragments of the fractured bone, and subsequently attaching the Schanz screws to the proximal and distal arms of a robotic tool. The robotic system would then produce just the proper amount of traction and force to reduce (approximate) the broken bone pieces to the closest approximation of the virtual template obtained through the mirror image process. Some individuals, particularly high-risk individuals such as deployed soldiers, first responders, athletes, and others, may predefine (such as pre-imaging) certain body structures with information to enable rapid and accurate reduction. For example, periodic or pre-deployment data may be prepared and stored in an event that reduction, particularly for extreme bone fracturing, is desired.

The same process of producing a reverse template can also be accomplished through image free navigation systems. For example, the non-injured femur of a patient can be registered in the OR space using optical or infrared tracking technology. Reference trackers and frames are used to locate and register the un-injured limb in the OR space, after which a with the use of existing human anatomy data sets, a three-dimensional computer model of the patient’s femur is created and reversed.

Ultimately image based and image free robotic systems can produce a three-dimensional computer model of the patient’s un-injured extremity and reversing the image to produce a template for the injures extremity. A robotic tool could then produce a reduction maneuver without excessive force, where the initial external fixation rods are applied. The surgery can be completed within a fraction of what is

currently required to fix a traumatic long bone fracture (for example, 30 minutes instead of 3-4 hours).

Subsequently rods of differing material properties are exchanged for the external fixation system in clinic to expose the fracture to varying and progressive levels of stress (as well as combination of stresses, e.g., more compression and bending and less torsion and shear) conducive to fracture healing.

Option 1. anisotropic rods—an earlier patent application, U.S. application Ser. No. 15/458,586, now U.S. Pat. No. 10,299,930, hereby expressly incorporated by reference, proposes variable material properties prosthesis such that a graded non-homogeneous prosthesis has a tendency not to stress shield and or bone resorb in order to allow optimal osteointegration of a prosthesis. Another earlier application, U.S. application Ser. No. 15/234,927, hereby expressly incorporated by reference, proposes a multi-dimensional stiff prosthesis with ribs and planks with a built-in propensity for insertion into bone when exposed to a driven vibratory motion. Subsequent papers discussed a combination of variable material properties prosthesis with multi-dimensional stiffness (ribs and planks), which produces a prosthesis that has a bias for insertion, does not bone resorb or stress shield, and resists fracture at cellular junctions of a graded non-homogenous prosthesis.

In an embodiment of the present invention including a robotic fracture fixation with external fixators, once a difficult process of reduction is achieved, such as with a robotic tool, the embodiment may include system and method of rod exchange of varying material properties, over different time periods, to allow progressive exposure of bone to stress and specifically different combination stresses to stimulate bone healing.

For example, current knowledge about an optimal level of stress and micromotion for fracture healing is lacking and non-existent. An embodiment may include a development of a set of anisotropic rods for external fixation of long bones. These rods can be metallic or composite. They allow differing levels and types of stress to be transferred to a stabilized fracture. A stabilized fracture may then be nursed progressively with increasing levels of stress to a rapid healing process. For example, it is likely appropriate to have rigid fixation of a fracture for the first three weeks for pain management and to allow soft tissues to stabilize, however, after the first three weeks, rigid fixation maybe detrimental to callus formation. Slow and progressive compression at the fracture site that occurs over three months may be ideal to fracture healing. In that scenario the external fixation rods can be simply exchanged, in clinic, with rods that remain stiff in bending, shear, torsion and tension but allow progressively more compression, such that the rods elastic modulus in compression becomes progressively lower and lower over the time of fracture healing. The time periods are representative, with different values for the initial rod stiffness and duration, and installation periods of subsequent external rods, may include differing appropriate values.

Any combination of the anisotropic material properties can be accomplished. For example, it may be discovered that at 6 to 8 weeks addition of increasing bending and torsional moments and are beneficial to fracture healing. This particular anisotropic rod (metallic or composite) can be made and used at the proper time through a simple exchange process in clinic.

The biology of fracture fixation and the optimal stresses required for fracture healing continues to improve but is not yet completely elucidated. However, once an accurate model or formula is known, model-compliant external fixators can

become the fracture fixation of choice for long bone fractures using the model to determine the material properties and installation/application durations for specific rods in this set of rods. At that point external fixation of long bone fractures with reduction (direct or indirect visualization or robotic reduction) will not only perform the surgery with less mechanical and surgical trauma but also the anisotropic rods allow just the right combination of stresses to be transferred to the fracture site over time for optimal and rapid healing.

Some examples of anisotropic rods that may be used in the set of rods may include variations of a structure such as the intramedullary nail described in the U.S. patent application Ser. No. 15/406,752, expressly incorporated herein by reference thereto (e.g., an intramedullary (IM) nail with ribs and planks). That particular IM nail includes ribs that are more flexible and planks that are more rigid, such as inspired for the purpose of undulatory motion where an applied energy to the longitudinal axis of the nail tends to propagate longitudinally as opposed to being dissipated radially. For the process of fracture fixation with external fixation, such rods can be created with a smaller number of planks (rings) which would make the rod less stiff in compression, or alternatively the planks can be created as half or $\frac{3}{4}$ planks in various arrangements within the foundation of the rod, which may make the rod more flexible in bending. The ribs can be placed in a helical pattern, which may produce a rod that is more flexible in torsion. Any combination of ribs and planks within the foundation of the intramedullary nail will change its mechanical and material properties. These anisotropic rods can then be conveniently exchanged in the clinician's office at various times during fracture healing process. Finally, for fractures that are at risk of non-union addition of vibration in subsonic and ultrasonic forms to the rod, which is then transferable to the fracture site, can be utilized as a stimulus to induce rapid bone formation.

FIG. 19-FIG. 23 illustrate various anisotropic rods that may be used for external fixation of long bone fractures. FIG. 19 illustrates an anisotropic rod for external fixation including a set of orthogonal stiffness structures, including a number of longitudinally extending stiffness structures (e.g., ribs) and a series of circumferential parallel stiffness structures (e.g., planks) perpendicular to the longitudinal stiffness structures, these structures disposed within a foundation of the rod or on a surface of the foundation. The same foundation with a different arrangement of stiffness structures exhibits different material properties of the rod as described herein (e.g., bending, torsion, and the like). The stiffness structures in cooperation with the foundation producing a desired stiffness profile for the rod.

FIG. 20 illustrates an anisotropic rod for external fixation similar to FIG. 19, including a different number of longitudinally extending stiffness structures (e.g., ribs) and a series of circumferential parallel stiffness structures (e.g., planks) perpendicular to the longitudinal stiffness structures, these structures disposed within a foundation of the rod or on a surface of the foundation. The stiffness profile of the rod in FIG. 20 may be different from the stiffness profile in FIG. 19, responsive to the different arrangement of stiffness structures.

FIG. 21 illustrates an anisotropic rod for external fixation similar to FIG. 19 and FIG. 20, including a different arrangement of longitudinally extending stiffness structures (e.g., ribs) and a series of circumferential parallel stiffness structures (e.g., planks) perpendicular to the longitudinal stiffness structures, these structures disposed within a foundation of the rod or on a surface of the foundation. The stiffness profile

of the rod in FIG. 21 may be different from the stiffness profile in FIG. 19 and FIG. 20, responsive to the different arrangement, shape, and, disposition of stiffness structures (e.g., the "planks" extend partially through a thickness of the rod).

FIG. 22 illustrates an anisotropic rod for external fixation similar to FIG. 19-FIG. 21, including a different arrangement of orthogonal stiffness structures (e.g., a set of counter-rotational helical stiffness structures), these structures disposed within a foundation of the rod or on a surface of the foundation. The stiffness profile of the rod in FIG. 21 may be different from the stiffness profile in FIG. 19 and FIG. 20, responsive to the different arrangement, shape, and, disposition of stiffness structures (e.g., the set of counter-rotational helical structures).

FIG. 23 illustrates an active anisotropic rod 2300 which may include a configuration similar to rods of FIG. 19-FIG. 22, or other arrangements of stiffness structures. Rod 2300, in contrast to the passive anisotropic rods of FIG. 19-FIG. 22, may include one or more motion drivers, such as a subsonic driver 2305 and/or an ultrasonic driver 2310. Motion from the motion drivers may assist with the healing of a bone fracture when used in an external fixation solution.

Robotic Materials

Recent advances in manufacturing combined with miniaturization of electronics has enabled a new class of materials termed "robotic materials" that far transcend classic composite material in functionality. Current state of the art allows composites to be integrated with sensors and actuators at high densities, and in combination with small microprocessors the robotic materials can function autonomously. With further advances in material science, computer science, distributed algorithms and manufacturing processes composites can integrate sensing, data collection and actuation with higher levels of self-governing functionality. Robotic materials can enable smart composites to autonomously change their shape, stiffness and physical appearance in a fully programmable way. For example, current technology exists that enables airplane wings to adapt their aerodynamic profile due to varying stresses in the environment. Integrating sensors and actuators into composites is becoming increasingly common, and with further advances embedded computation and communication will become more common place. Materials that self-diagnose, and self-repair are ubiquitous in biological systems, some of which can adapt to changing loads such as human bone or trees that can grow additional roots to accommodate changing load requirements.

This concept is particularly attractive for rods used in external fixation of fractured long bones of humans. As discussed earlier the main disadvantage of the external fixation systems has been the fact that they are extremely rigid. Titanium, cobalt chrome, and stainless steel both of which are commonly used for external fixation rods are five and ten times more stiff than human cortical bone respectively. Given the fact that there is a significant value proposition of minimal dissection and blood loss with more rapid and reliable healing of long bones, it may be a favorable trade-off to produce smart composite rods with increased functionality with sensing, actuation and computation functionality for external fixation systems in order to eliminate nonunion of long bones and barbaric open surgeries with extensive blood loss and negative cardiopulmonary impact on already physiologically compromised patients.

Smart materials were made possible by development of microelectromechanical systems MEMS, which then allowed for manufacturing of microscale structures with the

same processes that are used in conventional analog and digital semiconductor circuits, permitting their tight integration within composites.

Robotic material integrates dedicated sensors that in combination with appropriate signal processing, let the composite identify and respond to the environmental patterns.

Actuation refers to changing the material properties of the underlying base material. Some possible actuations are expanding, contracting, changing stiffness, changing surface texture, or changing color. One common approach for a variety of variable stiffness actuators is sandwiching a thermoplastic between two metals plates and then exploiting the thermoplastic's change in stiffness with increasing temperature. When the thermoplastic is at low temperature, the metal plates are tightly coupled together, acting as a single stiff composite. At higher temperatures, the thermoplastic has much less resistance to shear and the plates act as if they were uncoupled from each other, creating a composite with much lower stiffness. Similar functionalities can be accomplished with shape memory polymers and particle jamming techniques.

Local computation is accomplished through local algorithms, where from a computational perspective, robotic materials may be viewed as amorphous or spatial computers, which attempt to formalize a distributed computation model for systems that are limited to local communication and limited computational resources at each node. In the future a key challenge in amorphous computing is how to design local integrations so that a desired global behavior can emerge.

Local communication requires embedded communication not only to transport sensing and control information but also for more complex spatial dynamics to occur. Local computation in robotic material s offers not only local preprocessing of sensing information but also the routing of information through a computer network, such as a shared communication channel that is arbitrated by all participants of the network, a problem that has been widely studied in sensor networks.

Sensing, actuation, computation, and communication and power infrastructure can be integrated into composites at high densities in a scalable fashion. Instead of silicon-based computation, robotic materials could also perform computation using polymer electronics.

Robotic material require control at two different levels: (i) local control of each actuator using feedback from appropriate sensors, and (ii) global control that implements a desired spatiotemporal pattern across the material either in a distributed or centralized manner.

In summary robotic materials are a new class of multifunctional materials that are enabled by recent advances in material science, electronics, distributed computation, and manufacturing. Although composites now include the ability to sense damage and self-repair, none of the state-of-the-art composites fully integrate sensing, actuation, computation and communication.

From the standpoint of long bone fracture fixation in humans, robotic materials hold great potential. External fixation of long bone fractures is the least invasive procedure. Reduction of the fracture may be automated with image based and image free robotic navigation systems. Fracture healing can be dramatically augmented with use of programmable robotic material used as smart composite rods that can enhance fracture healing in a much more substantial way that is imaginable with current techniques.

For example, robotic material used for external fixation rods can be preprogrammed to progressively vary their

stiffness over a period of 3 months or to progressively allow more bending and or torsional stresses to the healing bone. That progression may not be monotonic or uniform but may vary based upon various biologic (healing status) or environmental factors (e.g., time of day, activity level). Robotic material can be embedded with mechanical sensors that measure applied force, strain and deflection, as well as accelerometers and Inertial measuring units IMUs that detect impacts and orientation with respect to gravity, all of which can be used to access the process of fracture healing. For example, certain robotic material rods can be embedded with "variable stiffness actuators" that progressively decrease compressive stiffness of the rod, while other robotic material rods can be incorporated to assess sense strain and stress being experienced at the fracture site. In this manner a programmable "load sharing" construct can be created to properly allow increasing levels of stress and stimulation necessary for a healthy robust healing process.

FIG. 24 illustrates an anisotropic rod 2400 that may be used in an external fracture fixation solution. Rod 2400 may include a robotic material or construction with sensing, actuation, computation and communication, generally illustrated as the interconnected network of functional elements collectively implementing the external fracture fixation solution. Rod 240 may include discrete circuit boards, wiring and structural material embedded into a composite form producing the dynamically variable stiffness profile for rod 2400.

An embodiment of the present invention discusses use of replaceable anisotropic rods for external fracture fixation because other fixation methods may not be as conducive to easy replacement and substitution, over time during the healing process, of a fixator component having varying stiffness profiles. Internal rods, or fixation plates, based on current techniques and solutions, do not allow easy or risk-free substitution as surgery is required for replacement/substitution of such solutions.

Robotic materials may be embedded into an intermedullary channel as an intramedullary rod that does not need to be removed. As well, plates usually utilized for open reduction internal fixation can be constructed from robotic material which would then allow custom adjustments of the anisotropic behavior of the plate (or IM rod) based on the needs of the healing fractured bone at various points in time. because the stiffness profile may be adjusted without removal from the channel, including pre-programmed variations or remotely directed (e.g., wireless) variations in stiffness profiles.

Another solution for embedded anisotropic fixator components may include use of dissolvable/reabsorbable stiffness structures used in cooperation with non-dissolvable/absorbable structures. Such anisotropic fixators may include a subset of stiffness structures disposed within the foundation of the device, and another subset of stiffness structures disposed on a surface of the foundation. Some or all of the surface stiffness structures may be dissolvable/absorbable when installed into location. Over time, the degradation of the dissolvable stiffness structures changes the stiffness profile similar to the changes resulting from periodic replacement of rods in external fixation solutions. In this way, benefits of varying stiffness profiles for internal fixator constructs may be available as different options for the surgeon.

Dissolvable or reabsorbable materials are used in biodegradable materials for bone repair purposes. The choice between using degradable and non-degradable devices for orthopedic and maxillofacial applications must be carefully

weighed. Traditional biodegradable devices for osteosynthesis have been successful in low or mild load bearing applications. However, continuing research and recent developments in the field of material science has resulted in development of biomaterials with improved strength and mechanical properties. Such materials are designed to be completely biodegraded and absorbed into the body.

Embodiments of the present invention include implementations in which the structure includes absorbable/degradable and non-absorbable stiffness structures. The degradation over time is predesigned to change the stiffness profiles of the fixator in a predetermined manner so that the varying stiffness profile improves bone healing, especially as compared to an unchanging stiffness profile or a randomly changing stiffness profile that results from unplanned or undirected degradation.

As discussed above regarding replacement/substitution of anisotropic rods having varying stiffness profiles, the incremental changes in the stiffness profiles over time during the healing time frame improves bone healing as compared to fixators with non-varying stiffness profiles. Various models and bone-healing biology may define one or more local optimizations that may be implemented by, influenced by, controlled by, or otherwise defined by varying a stiffness profile of a fixator construct in a particular way during the healing process. The substitution/replacement of anisotropic structures over time corresponding to such a model improves the healing of the bone. The anisotropic structures may be periodically changed to approximate the model. The degradable fixator changes constantly and more gradually without a requirement of clinic visits and may more closely track the model.

Degradable materials for engineering use in dentistry and orthopedics continue to develop. A reference describing some aspects of such materials is provided in Z. Sheikh et al., "BIODEGRADABLE MATERIALS FOR BONE REPAIR AND TISSUE ENGINEERING APPLICATIONS" Materials (Basel) 2015 Sep. 8(9)—published online 2015 Aug. 31, 5744-5794, this reference hereby expressly incorporated by reference thereto in its entirety.

The system and methods above have been described in general terms as an aid to understanding details of preferred embodiments of the present invention. In the description herein, numerous specific details are provided, such as examples of components and/or methods, to provide a thorough understanding of embodiments of the present invention. Some features and benefits of the present invention are realized in such modes and are not required in every case. One skilled in the relevant art will recognize, however, that an embodiment of the invention can be practiced without one or more of the specific details, or with other apparatus, systems, assemblies, methods, components, materials, parts, and/or the like. In other instances, well-known structures, materials, or operations are not specifically shown or described in detail to avoid obscuring aspects of embodiments of the present invention.

Reference throughout this specification to "one embodiment", "an embodiment", or "a specific embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention and not necessarily in all embodiments. Thus, respective appearances of the phrases "in one embodiment", "in an embodiment", or "in a specific embodiment" in various places throughout this specification are not necessarily referring to the same embodiment. Furthermore, the particular features, structures, or characteristics of any specific embodiment of the

present invention may be combined in any suitable manner with one or more other embodiments. It is to be understood that other variations and modifications of the embodiments of the present invention described and illustrated herein are possible in light of the teachings herein and are to be considered as part of the spirit and scope of the present invention.

It will also be appreciated that one or more of the elements depicted in the drawings/figures can also be implemented in a more separated or integrated manner, or even removed or rendered as inoperable in certain cases, as is useful in accordance with a particular application.

Additionally, any signal arrows in the drawings/Figures should be considered only as exemplary, and not limiting, unless otherwise specifically noted. Combinations of components or steps will also be considered as being noted, where terminology is foreseen as rendering the ability to separate or combine is unclear.

The foregoing description of illustrated embodiments of the present invention, including what is described in the Abstract, is not intended to be exhaustive or to limit the invention to the precise forms disclosed herein. While specific embodiments of, and examples for, the invention are described herein for illustrative purposes only, various equivalent modifications are possible within the spirit and scope of the present invention, as those skilled in the relevant art will recognize and appreciate. As indicated, these modifications may be made to the present invention in light of the foregoing description of illustrated embodiments of the present invention and are to be included within the spirit and scope of the present invention.

Thus, while the present invention has been described herein with reference to particular embodiments thereof, a latitude of modification, various changes and substitutions are intended in the foregoing disclosures, and it will be appreciated that in some instances some features of embodiments of the invention will be employed without a corresponding use of other features without departing from the scope and spirit of the invention as set forth. Therefore, many modifications may be made to adapt a particular situation or material to the essential scope and spirit of the present invention. It is intended that the invention not be limited to the particular terms used in following claims and/or to the particular embodiment disclosed as the best mode contemplated for carrying out this invention, but that the invention will include any and all embodiments and equivalents falling within the scope of the appended claims. Thus, the scope of the invention is to be determined solely by the appended claims.

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. A method for repairing a fracture of a bone using a template of the bone, comprising the steps of:

- a) reducing the fracture to produce a reduced fractured bone; and
- b) fixing said reduced fractured bone using a structure spanning a length of the fracture wherein said structure includes an amorphous composite material component having a variable material properties profile, said amorphous composite material component having a set of internal structures including a sensing element, a computational element, and an actuation element, said set of internal structures configured for implementing said variable material properties; and
- c) adjusting, in situ, said variable material properties while said structure spans said length of the fracture.

2. The method of claim 1 wherein said step of fixing and said step of adjusting are configured to provide a load-sharing of the fracture between said reduced fractured bone and said amorphous composite material component, further comprising the steps of:

d) sensing an internal loading force component of said load-sharing in said amorphous composite material component responsive to said sensing element; and thereafter

e) modifying said variable material properties using said actuation element producing a modified material property of said amorphous composite material component; and thereafter

f) adjusting a loading force component of said load-sharing in said fractured bone responsive to said modified material property.

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