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(71) Applicants: **SMITH & NEPHEW, INC.** [US/US]; 1450 Brooks Road, Memphis, Tennessee 38116 (US). **SMITH & NEPHEW ORTHOPAEDICS AG** [CH/CH]; Theilerstrasse 1A, 6300 Zug (CH). **SMITH & NEPHEW ASIA PACIFIC PTE. LIMITED** [SG/SG]; 29 Media Circle, #06-05, ALICE@Mediapolis, Singapore 138565 (SG).

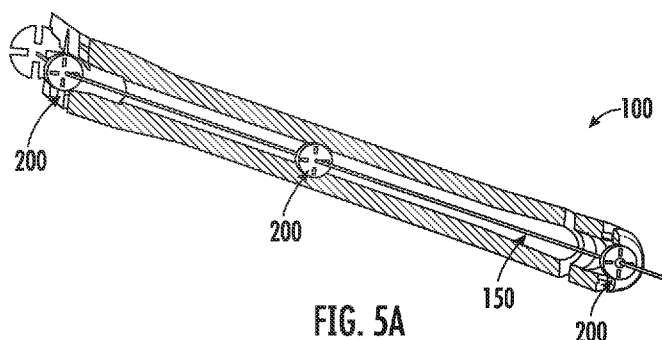
(72) Inventors: **ROSE, John**; Smith & Nephew, Inc., 1450 Brooks Road, Memphis, Tennessee 38116 (US). **WILSON, Darren J.**; T.J.Smith and Nephew Limited, 101 Hessle Road, Hull HU3 2BN (GB).

(74) Agent: **MOLARO, Giuseppe**; Kacvinsky Daisak Bluni PLLC, 2601 Weston Parkway, Suite 103, Cary, North Carolina 27513 (US).

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(54) Title: DUAL COATED ORTHOPAEDIC IMPLANT



(57) Abstract: Devices, systems, and methods for electroplating a gold/silver galvanic coating onto internal and external surfaces of orthopedic implants having complex shapes such as, for example, intramedullary nails having a cannulated bore. In accordance with features of the present disclosure, the internal surface of the cannulated bore can be coated in gold and silver by positioning an auxiliary anode through the cannulated bore. The auxiliary anode being held a distance from the internal surface of the cannulated bore via a plurality of spacers positioned along a longitudinal length of the cannulated bore of the IM nail. In one embodiment, the silver coating is arranged and configured to facilitate controlled release of silver ions from the internal and external surfaces of the implant reducing the risk of bacterial colonization.

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DUAL COATED ORTHOPAEDIC IMPLANT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This is a non-provisional of, and claims the benefit of the filing date of, pending U.S. provisional patent application number 63/120,445, filed December 2, 2020, entitled “Dual Coated Orthopaedic Implant,” the entirety of which application is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The present disclosure is directed to orthopedic implants and, more specifically, to orthopedic implants having a complex shape such as, for example, an intramedullary (“IM”) nail having a cannulated bore formed therein. More specifically, the present disclosure is directed to devices, systems, and methods for coating an IM nail having a cannulated bore. For example, devices, systems, and methods for applying a functional layer or coating to an internal surface of the cannulated bore of the IM nail and to an exterior surface of the IM nail.

BACKGROUND OF THE INVENTION

[0003] It is known in the art to apply coatings to orthopaedic implants. For example, it is known to electroplate orthopaedic implants with a silver coating. Electroplating offers advantages over other methods of depositing silver onto orthopaedic implants given that it can be applied to metal or polymeric substrates, produces high quality finishes after sterilization, and demonstrates statistical evidence of antimicrobial performance both in vivo and in clinical studies. In various embodiments, coating an implant with a silver coating may be accomplished by immersing the orthopaedic implant in tanks or baths in a series of liquid chemistries. Generally, these immersions include one or more cleaning steps, an activation step in which the surface of the orthopaedic implant is stripped of its passivation layer, and a plating step in which the orthopaedic implant is electrically charged to attract and attach metal atoms that are dissolved in the plating tanks or baths.

[0004] Generally speaking, a successful electroplate relies on three parameters: (a) activation, which is affected by concentration and type of acids used, (b) timing, the length of time the orthopaedic implant is exposed to air or water after activation affects the oxide layer of the sample, and (c) current density, applying a constant current density versus ramping the

applied current from 0 - 30A/cm² affects the grain morphology and adhesion of the coating particles.

[0005] One problem associated with electroplating orthopaedic implants is that, often times, orthopedic implants have a complex shape that is not conducive to application of a consistent coating. For example, intramedullary (IM) nails often have a complex shape including bends formed at the first or proximal end of the IM nail and at the second or distal end of the IM nail. In addition, IM nails may include a cannulated bore extending between the first and second ends thereof. For example, referring to **FIGS. 1A** and **1B**, an embodiment of a conventional IM nail 10 is illustrated. As shown, the IM nail 10 includes a complex shape with a Herzog bend at the first or proximal end 12, a distal bow at the second or distal end 14, a plurality of screw holes and/or slots 16 formed therein, and a cannulated bore 18 extending between the first and second ends 12, 14. During the coating process, the cannulated bore 18 can be particularly challenging since coating the internal surface of the cannulated bore 18 prevents use of line-of-sight processes for depositing a uniform layer of coating (e.g., silver) onto the internal surface of the cannulated bore 18.

[0006] Moreover, infection studies carried out with solid IM nails and cannulated IM nails emphasized the need for the application of antimicrobial coatings (e.g., silver) within the cannulated bore of the IM nail to prevent bacterial colonization. In one study, a solid IM nail was shown to have a greater than twofold higher resistance to infection (23%) compared to non-solid IM nails such as hollow IM nails (65%) and cannulated IM nails (61%), which was statistically significant ($p < 0.02$).

[0007] Another problem associated with electroplating is activating the surface of the orthopedic implant prior to plating. For example, orthopedic implants may be manufactured from titanium. Titanium is a very reactive metal. As a result, the oxides formed are rather tenacious and require more than the standard cleaning procedures. In addition, titanium can passivate very rapidly so there can be no delay between de-passivation and electroplating. As a result, referring to **FIG. 2**, physical vapor deposition (PVD) is often used to coat orthopedic implants. PVD sputtering is one known option to remove the oxide layer, however, it is a line-of-sight process requiring expensive vacuum equipment and sputtering targets. For example, in one known embodiment, an initial gold layer is applied to the exterior surface of the orthopedic implant using a vacuum process, followed by applying a silver layer onto the gold layer using electroplating. That is, in use, the process illustrated in **FIG. 2**, uses a vacuum process to remove oxygen from the titanium implant and then sputters a gold layer onto the exterior surface of the titanium implant. Thereafter, the implant is removed from the

PVD chamber and then placed within a bathing tank to electroplate silver onto the gold coating. Nickel plating is an alternative option, followed by a heat treatment to diffuse the nickel into the titanium. However, this option increases the risk of nickel allergies.

[0008] Thus, there remains a need for an improved, intramedullary nail including a silver coating applied onto an internal surface of a cannulated bore. In addition, there remains a need for an improved, purely electroplating process to apply an anti-microbial coating (e.g., a galvanic gold/silver coating) onto an orthopedic implant. In addition, there remains a need for an electroplating process that can apply an anti-microbial coating (e.g., a galvanic gold/silver coating) onto the internal and exterior surfaces of a cannulated orthopedic implant, such as a cannulated IM nail. Further, there is a need for an efficient way to activate the titanium prior to plating using chemical treatment. The present invention satisfies these needs and provides other benefits and advantages in a novel and unobvious manner.

SUMMARY OF THE INVENTION

[0009] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended as an aid in determining the scope of the claimed subject matter.

[0010] In one embodiment, provided herein is one or more improvements to conventional electroplating processes for enabling depositing a gold/silver galvanic coating onto the internal and external surfaces of orthopedic implants having complex shapes, such as intramedullary nails. Generally speaking, conventional methods of electroplating an irregularly shaped substrate such as, for example, an orthopedic implant, produces a coating having non-uniform deposit thicknesses because of varying distances between the cathode and anode of the electrolytic cell. Consequently, electroplating intramedullary nails, which range in length between 18 and 50 cm and have an inner diameter as small as 4.8 mm, are difficult to plate. Moreover, these nails are typically bent and bowed to conform to the internal contour of a human bone making it even more difficult to plate. To overcome these geometrical constraints, in accordance with one or more features of the present disclosure, an auxiliary anode wire may be positioned within the cannulated bore of an IM nail to facilitate coating the internal surface of the bore with gold and silver coatings. In various embodiments, the auxiliary anode wire may be pre-tensioned within the cannulated bore. In various embodiment, the auxiliary anode wire may be centered within the cannulated bore.

[0011] In various embodiments, a plurality of insulating spacers are positioned along and/or within the cannulated bore of the intramedullary nail to space the auxiliary anode wire a distance from the internal surface of the cannulated bore to prevent an electrical shorting.

[0012] In various embodiments, the auxiliary anode wire can be made from a range of materials including platinized titanium, platinized niobium, mixed metal oxides, stainless steel, silver, or platinum.

[0013] In various embodiments, the auxiliary anode wire has a diameter of 0.2 mm to 2 mm and preferably 0.3 mm to 0.7 mm. In some embodiments, the wire is 0.5 mm in diameter. Thus arranged, the auxiliary anode wire is rendered flexible and easier to tension.

[0014] In various embodiments, the application of the gold layer is used as a primer to improve the adhesion between the de-oxidized titanium surface of the implant and the electroplated silver. Exposing a small fraction of the gold under-layer enables the gold layer to behave as a counter-electrode increasing the rate of elution of silver ions from the surface.

[0015] In one embodiment, a method for applying a coating to an intramedullary nail including an exterior surface and a cannulated bore defining an internal surface is disclosed. The method comprising coupling a plurality of non-conductive spacers to the intramedullary nail; positioning an auxiliary anode wire into the cannulated bore of the intramedullary nail, the plurality of spacers holding the auxiliary wire a distance from the internal surface; electroplating a gold coating onto the internal surface of the intramedullary nail by placing the intramedullary nail including the plurality of spacers and the auxiliary anode wire into a first tank containing gold ions; removing the intramedullary nail including the plurality of spacers and the auxiliary anode wire from the first tank containing gold ions; and electroplating a silver coating onto the gold coating by placing the intramedullary nail including the plurality of spacers and the auxiliary anode wire into a second tank containing silver ions.

[0016] In one embodiment, the method further comprises applying an outer layer comprising of, or containing, antibiotic(s), antiseptic or antimicrobial coatings onto of the silver coating.

[0017] In one embodiment, the silver coating has a thickness of approximately 0.1 μm or less.

[0018] In one embodiment, at least one of the plurality of spacers is provided as an end cap arranged and configured to engage an end of the intramedullary nail.

[0019] In one embodiment, each of the plurality of spacers includes a plurality of openings formed therein to enable fluid flow during the coating process.

[0020] In one embodiment, the method further comprises reciprocating the intramedullary nail including the plurality of spacers and the auxiliary anode wire in the first and second tanks.

[0021] In one embodiment, the method further comprises pumping fluid through the cannulated bore of the intramedullary nail.

[0022] In one embodiment, the method further comprises removing the plurality of spacers and the auxiliary anode wire; electroplating a gold coating onto the external surface of the intramedullary nail by placing the intramedullary nail into the first tank containing gold ions; removing the intramedullary nail from the first tank containing gold ions; and electroplating a silver coating onto the external gold coating by placing the intramedullary nail into the second tank containing silver ions.

[0023] In one embodiment, the method further comprises pre-tensioning the auxiliary anode wire within the cannulated bore.

[0024] In one embodiment, a system for applying a coating to an intramedullary nail is disclosed. The system comprising an intramedullary nail including an exterior surface and a cannulated bore defining an internal surface; a plurality of non-conductive spacers coupled to the intramedullary nail, each of the plurality of non-conductive spacers including a hole and a plurality of openings; and an auxiliary anode wire positioned within the cannulated bore of the intramedullary nail, the auxiliary anode wire passing through the hole formed in the plurality of spacers so that the auxiliary wire is positioned a distance away from the internal surface; wherein the plurality of openings formed in the plurality of spacers facilitate fluid flow during application of a coating to the internal surface of the cannulated bore.

[0025] In one embodiment, the intramedullary nail, the plurality of spacers, and the auxiliary anode wire are arranged and configured to be placed with an electroplating tank containing gold ions for applying a gold coating onto the internal surface of the intramedullary nail.

[0026] In one embodiment, the intramedullary nail, the plurality of spacers, and the auxiliary anode wire are arranged and configured to be placed with a second electroplating tank containing silver ions for applying a silver coating onto the gold coating.

[0027] In one embodiment, the auxiliary anode wire is pre-tensioned within the cannulated bore.

[0028] In one embodiment, the plurality of spacers are arranged and configured to center the auxiliary anode wire within the cannulated bore.

[0029] In one embodiment, an intramedullary nail is disclosed. The intramedullary nail comprising an exterior surface; a cannulated bore defining an internal surface; a gold coating applied to the exterior surface; a gold coating applied to the internal surface of the cannulated bore; a silver coating applied to the gold coating applied to the exterior surface; and a silver coating applied to the gold coating applied to the internal surface.

[0030] In accordance with one or more features of the present disclosure, as provided for herein, the coating is arranged and configured to provide controlled release of silver ions from the internal and external surfaces of the IM nail thereby reducing the risk of bacterial colonization by creating a potential difference between the gold and silver layers. In addition, the galvanic coating significantly reduces progressive corrosion of the underlying titanium, which has been observed with other silver electroplated orthopedic devices. The electroplating process can be adapted to create counter-electrodes to increase the amount of silver ions eluted off the surface by exposing underlying areas of the gold, which are at higher risk of bacterial colonization such as a screw hole, bore or key-way that can readily trap bacteria and promote fluid stasis (stagnation).

[0031] Further features and advantages of at least some of the embodiments of the present invention, as well as the structure and operation of various embodiments of the present invention, are described in detail below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate the embodiments of the invention and together with the written description serve to explain the principles, characteristics, and features of the invention. In the drawings:

[0033] **FIGS. 1A and 1B** illustrate various views of an embodiment of a conventional intramedullary nail, the intramedullary nail including a complex shape having a cannulated bore;

[0034] **FIG. 2** is a block diagram illustrating a conventional process for coating an intramedullary nail;

[0035] **FIG. 3** illustrates a cross-sectional view of an intramedullary nail in accordance with one or more features of the present disclosure, the intramedullary nail including dual coated internal and external surfaces;

[0036] **FIG. 4** is a graph illustrating burst release of an optional overlayer of antiseptic and a controlled release of silver in accordance with one or more features of the present disclosure;

[0037] **FIGS. 5A-5C** illustrate various longitudinal, cross-sectional views of an embodiment of a cannulated intramedullary nail using spacers and an auxiliary anode wire to facilitate application of the gold/silver galvanic coating onto the internal surface of the cannulated bore in accordance with one or more features of the present disclosure;

[0038] **FIGS. 6A and 6B** illustrate various views of alternate embodiments of spacers that may be used to facilitate application of the gold/silver galvanic coating onto the internal surface of the cannulated bore in accordance with one or more features of the present disclosure;

[0039] **FIG. 7** illustrates various views of alternate embodiments of spacers and caps that may be used to facilitate application of the gold/silver galvanic coating onto the internal surface of the cannulated bore in accordance with one or more features of the present disclosure;

[0040] **FIG. 8A** illustrates various views of one of the spacers shown in **FIG. 7**;

[0041] **FIG. 8B** illustrates various views of an alternate embodiment of one of the spacers shown in **FIG. 7**;

[0042] **FIGS. 9A-9D** illustrate various views of an intramedullary nail including the spacers and caps shown in **FIGS. 7-8B**;

[0043] **FIG. 10A** illustrates an embodiment of a process map for a method of electroplating the internal surface of an intramedullary nail in accordance with one or more features of the present disclosure;

[0044] **FIG. 10B** illustrates an embodiment of a process map for a method of electroplating the external surface of an intramedullary nail in accordance with one or more features of the present disclosure;

[0045] **FIGS. 11A-11C** illustrate various views of an intramedullary nail prior to electroplating in accordance with the process outlined in **FIGS. 10A and 10B**;

[0046] **FIG. 12** illustrates a schematic illustration of an embodiment of a system used to electroplate a first layer onto the intramedullary nail in accordance with one or more features of the present disclosure;

- [0047] **FIG. 13** illustrates a perspective, cross-sectional longitudinal view of an intramedullary nail in accordance with one or more features of the present disclosure;
- [0048] **FIG. 14** illustrates a schematic illustration of an embodiment of a system used to electroplate a second layer onto the intramedullary nail in accordance with one or more features of the present disclosure;
- [0049] **FIG. 15** illustrates a perspective, cross-sectional longitudinal view of an intramedullary nail in accordance with one or more features of the present disclosure;
- [0050] **FIG. 16A** illustrates a perspective view of an intramedullary nail including a plastic member arranged and configured to facilitate holding of the intramedullary nail during the electroplating steps in accordance with one or more features of the present disclosure;
- [0051] **FIG. 16B** illustrates a perspective view of the plastic member shown in **FIG. 16A**;
- [0052] **FIG. 17** illustrates a schematic illustration of an embodiment of a system used to electroplate a first layer onto the intramedullary nail in accordance with one or more features of the present disclosure;
- [0053] **FIG. 18** illustrates a schematic illustration of an embodiment of a system used to electroplate a second layer onto the intramedullary nail in accordance with one or more features of the present disclosure; and
- [0054] **FIG. 19** is a graph illustrating release profiles of single and dual coating chlorhexidine gluconate in accordance with one or **more** features of the present disclosure.
- [0055] It should be understood that the drawings are not necessarily to scale and that the disclosed embodiments are sometimes illustrated diagrammatically and in partial views. In certain instances, details which are not necessary for an understanding of the disclosed methods and devices or which render other details difficult to perceive may have been omitted. It should be further understood that this disclosure is not limited to the particular embodiments illustrated herein. In the drawings, like numbers refer to like elements throughout unless otherwise noted.

DETAILED DESCRIPTION OF THE INVENTION

[0056] Various features of devices, systems, and methods for coating an orthopedic implant such as, for example, a cannulated intramedullary (IM) nail will now be described more fully hereinafter with reference to the accompanying drawings, in which one or more features of the devices, systems, and methods will be shown and described. It should be

appreciated that the various features may be used independently of, or in combination, with each other. It will be appreciated that the devices, systems, and methods as disclosed herein may be embodied in many different forms and should not be construed as being limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will convey certain features of the devices, systems, and methods to those skilled in the art.

[0057] The following description of the depicted embodiment(s) is merely exemplary in nature and is in no way intended to limit the invention, its application, or uses.

[0058] While the present disclosure will be described and illustrated in connection with an IM nail, and more specifically, a cannulated IM nail, it should be appreciated that one or more features of the present disclosure may have applicability to other orthopedic implants. As such, the present disclosure should not be limited to a cannulated IM nail unless specifically claimed. In addition, as will be described herein, in accordance with one or more features of the present disclosure, the depicted embodiment illustrates electroplating the internal surface of a titanium, cannulated IM nail separately from the exterior surface of the titanium, cannulated IM nail. However, it should be appreciated, in some embodiments, that the internal and exterior surfaces may be electroplated simultaneously. In addition, and/or alternatively, it is envisioned that the devices, systems, and methods may have applicability to implants made from other suitable materials. As such, the present disclosure should not be limited other than as provided for in the claims.

[0059] Referring to **FIG. 3**, an example embodiment of an IM nail 100 including a cannulated bore 118 in accordance with one or more features of the present disclosure is shown. Thus arranged, the IM nail 100 includes an exterior surface 110 and an internal surface 112. As illustrated, in one embodiment, the exterior and internal surfaces 110, 112 each include a dual coating consisting of an inner layer of a gold coating, which acts as the bonding layer and a carrier, and an outer layer of a silver coating. During an electroplating process, the silver electrode (coating) serves as an anode and the implant component (titanium) to be coated serves as a cathode. After application of a voltage, electrons (e-) and silver ions (Ag+) migrate from the silver nitrate electrolyte solution to the implant component to form the desired silver layer. The components are subsequently treated and cleaned. As will be described in greater detail herein, the external and internal surfaces 110, 112 are each coated with a gold layer 120 to adhere to the external and internal surfaces of the IM nail, followed by a silver layer 122 applied onto the gold layer 120 so that the silver layer 122 is properly adhered to the titanium surfaces of the IM nail 100. In one embodiment, the gold layer 120 is applied using an electroplating technique. Thereafter, the silver layer 122 is also

applied using an electroplating technique. As will be described in greater detail below, a wire 150 (e.g., an auxiliary anodized wire or electrode) is positioned into the cannulated bore 118 of the IM nail 100 to facilitate application of the gold and silver layers 120, 122 onto the internal surface 112 of the cannulated bore 118. Thereafter, as illustrated, in one embodiment, the gold/silver galvanic coating is followed by an optional outer layer of an antiseptic or antibiotic agent 124, such as chlorhexidine gluconate or gentamycin to provide a concomitant bolus release treatment for more challenging cases. Collectively, this combination provides both short and long-term antimicrobial protection for both short-term, surgeon related (iatrogenic) infections, delayed infections, and late (hematogenous) infections.

[0060] In use, the amount of silver deposited onto the orthopedic implant, and more specifically, the gold-plated layer of the IM nail, can be controlled by the current density and duration in the electroplating tank. The rate of silver release can be controlled galvanically by altering the ratio of gold (cathode) to silver (anode) in the electro-chemical cell or creating a counter-electrode by exposing a proportion of the underlying gold surface to the electrolyte. In accordance with one or more features of the present disclosure, a special plating deposit, referred to herein as a strike or flash coating, may be used to form a very thin (typically less than 0.1 μm thick) layer with high quality and good adherence to the underlying substrate. This can be used as a foundation for subsequent plating processes or it can be used on its own to provide an ultra-thin layer of galvanic silver. A strike or flash coating uses a high current density and a bath with a low ion concentration. The graph in **FIG. 4** illustrates exemplary release rates for each layer (e.g., antiseptic release and silver release). As illustrated, in accordance with one or more features of the present disclosure, the coatings facilitate both a fast or burst release of antiseptic along with a slower, controlled release of silver over a period of months. However, as illustrated, the slower, controlled release of silver only lasts months (e.g., a couple of months) rather than years as conventional silver coatings take. That is, by providing a thin, flash layer of silver, the duration of silver release is minimized compared to conventional silver coated implants, which is preferable for trauma patients receiving an IM nail to prevent the release of silver ions for years to come, which may have a detrimental effect on the patient's health. Thus arranged, the burst release of antiseptic prevents, or at least minimizes, the onset of immediate infections following surgery while the slower, controlled release of silver prevents, or at least minimizes, the onset of later infections while avoiding release of silver for years to come. That is, conventional silver coated implants such as, for example, MUTARS[®] knee revision implant manufactured by

Implantcast GmbH, have a silver coating applied to the outer surfaces of the implant to a thickness of 15 μ m ($\pm$ 5 μ m) thick. In contrast, in accordance with one or more features of the present disclosure, the silver strike or flash coating, is applied to a very thin (typically less than 0.1 μ m thick) layer, which reduces the amount of silver release to a period of no more than a couple of months, which is preferred for trauma patients receiving an IM nail (longer durations of silver release may increase the risk of adverse events associated with the silver coating such as argyria, liver and kidney damage, irritation of the eyes, skin, respiratory, and intestinal tract, and changes in blood cells).

[0061] In accordance with one or more features of the present disclosure, in an example method of coating the cannulated IM nail 100, a first optional step may include grit blasting the IM nail 100. For example, after the machining steps for forming the IM nail, the IM nail is grit blasted with an alumina oxide media to create a roughened surface to help adhere the initial gold layer.

[0062] Next, in accordance with one or more features of the present disclosure, a wire 150 (e.g., an auxiliary anodized wire or electrode) is positioned (e.g., strung) through the cannulated bore 118 of the IM nail 100. In use, the wire 150 needs to be spaced a distance from the internal surface 112 of the cannulated bore 118 without contacting the internal surface 112 of the cannulated bore 118 to prevent a short circuit in the system. Ensuring that the wire 150 does not contact the internal surface 112 of the cannulated bore 118 can be challenging especially when considering the complex shape of the IM nail 100 including: the length of the IM nail, the small diameter (approx. 5 mm) of the cannulated bore, and the bends (approx. 10-degree Herzog bend and a 2-degree bow) formed at the first and second ends of the IM nail.

[0063] Referring to **FIGS. 5A-5C**, in accordance with one or more features of the present disclosure, to properly space the wire 150 a distance from the internal surface 112 of the cannulated bore 118, the wire 150 is held in place with a plurality of non-conductive fixtures or spacers 200 (terms used interchangeably herein without the intent to limit or distinguish) positioned along a longitudinal length of the cannulated bore 118. In use, the plurality of spacers 200 are arranged and configured to position the wire 150 away from the internal surface 112 of the cannulated bore 118 thereby ensuring that the wire 150 does not contact the internal surface 112. In one embodiment, the plurality of spacers 200 are arranged and configured to centrally position the wire 150 within the cannulated bore 118.

[0064] In one embodiment, the plurality of spacers 200 may be manufactured from a polymeric material, although other non-conductive materials may be used. For example, the

plurality of spacers 200 may be manufactured from polypropylene, polytetrafluoroethylene, or nylon. In one particular embodiment, the wire 150 may be in the form of a fully annealed, round silver round wire having a diameter of 0.2 mm to 2 mm, and preferably 0.3 mm to 0.7 mm. In one embodiment, the wire has a diameter of approximately 0.5 mm, although this is but one configuration and other configurations and sizes of wires are envisioned. The utilization of an auxiliary anode wire 150 prevents a local depletion of the silver ions in the solution in the cannulated bore 118.

[0065] In one embodiment, the plurality of spacers 200 may be provided in the form of end caps, intermediate spacers, or a combination thereof. As illustrated in **FIGS. 5A-5C**, the plurality of spacers 200 may be positioned at the first and second ends of the IM nail 100. In addition, one or more additional spacers 200 may be positioned within the cannulated bore 118 along a longitudinal length of the cannulated bore 118. In one embodiment, a spacer 200 may be positioned within the cannulated bore 118 at set intervals or lengths. Alternatively, a spacer 200 may be positioned within the cannulated bore 118 as needed, such as, for example, whenever a bend occurs within the IM nail. The spacers 200 may be coupled to the IM nail 100 via any suitable mechanism now known or hereafter developed including, for example, snap-fit, friction-fit, adhesives, or the like.

[0066] As illustrated, in one embodiment, each of the plurality of spacers 200 include a hole and a plurality of openings. In use, the hole is arranged and configured to enable the auxiliary anodized wire 150 to pass therethrough. The plurality of openings are arranged and configured to enable electroplating fluids to flow through the spacers 200. While the spacers 200 have been shown as having a specific shape, it should be appreciated that the spacers may have any shape and/or configuration arranged and configured to position the wire 150 away from the internal surface 112 and to enable fluid to flow therethrough. For example, as illustrated in **FIG. 6A**, the spacers may include a plurality of perforations 202 to ensure fluid (e.g., fresh electrolyte) can flow through the cannulated bore 118 during the coating process. Alternatively, referring to **FIG. 6B**, the spacer 200 can take the shape of a brush having a plurality of bristles (e.g., a web-like structure) to prevent the wire 150 from contacting the internal surface 112 of the cannulated bore 118 while ensuring that fluid can flow therethrough during the coating process.

[0067] Alternative designs for spacers for positioning the wire 150 in the cannulated bore 118 are depicted in **FIGS. 7-9D**. As illustrated, the spacer 200 may include a pair of distal and proximal spacers 200 arranged and configured to engage the ends of the IM nail 100. For example, the spacers 200 may include bores or recesses for receiving the ends of the IM nail

100. In addition, as illustrated, one or more caps 210 such as, for example, threaded screws may be provided, although other configurations of caps are envisioned. In use, the one or more caps 210 are arranged and configured to cover, block, or seal the screw holes or slots formed in the IM nail during the coating process.

[0068] As previously mentioned, in use, the spacers 200 are arranged and configured to maintain the wire 150 a distance away from the internal surface 112 of the cannulated bore 118. The spacers 200 are also arranged and configured to allow fluid (e.g., electrolyte) to flow through the cannulated bore 118 during the coating process while the IM nail 100 is being reciprocated either sideways or vertically in the tank, as will be described in greater detail below. In one embodiment, the spacers 200 are arranged and configured to centralize and pre-tension the wire 150 through the cannulated bore 118. **FIGS. 8A** and **8B** illustrate alternate embodiments of spacers (e.g., end caps) that may be used to tension and centralize the wire 150 in the center of the cannulated bore 118 of the IM nail 100 and which allow fluid (e.g., electrolyte) to flow through the cannulated bore 118 while the IM nail 100 is reciprocated in the electroplating tank. **FIGS. 9A-9D** illustrate the spacers (e.g., end caps) shown in **FIGS. 8A** and **8B** coupled to the first and second ends of the IM nail 100. In the embodiment depicted in **FIGS. 9A-9D**, the spacers are designed specifically for a 10 mm diameter IM nail.

[0069] In accordance with one or more features of the present disclosure and with reference to **FIGS. 10A** and **10B**, an embodiment of a process map or method for electroplating the internal and external surfaces of an IM nail will be shown and described. In use, the method for electroplating the internal and external surfaces of an IM nail may be used in combination with the spacers 200 disclosed above in connection with **FIGS. 3-9D**. Alternatively, it is envisioned that the method for electroplating the internal and external surfaces of an IM nail may be used separately from the spacers 200 disclosed above.

[0070] In one embodiment, as will be described in connection with **FIGS. 10A** and **10B**, the process map or method for electroplating the internal and external surfaces of an IM nail include multiple independent steps or stages. For example, with reference to **FIG. 10A**, the method may include an initial stage for electroplating the internal surfaces of an IM nail such as, for example, internal surface 112 of the cannulated bore 118. Thereafter, with reference to **FIG. 10B**, the method may include a second or subsequent stage for electroplating the exterior surfaces of an IM nail such as, for example, exterior surface 110.

[0071] While **FIGS. 10A** and **10B** will show and describe the process map or method as utilizing separate and independent steps for coating the internal and exterior surfaces of the

IM nail, it is envisioned that the internal and exterior surfaces may be coated simultaneously. For example, as will be described herein in connection with **FIGS. 10A** and **10B**, the internal surface may be initially coated with a gold layer, followed by a silver layer, followed by coating the exterior surface with a gold layer, and then a silver layer. However, it is envisioned that the internal and exterior surfaces may simultaneously receive the gold layer followed by the silver layer. Moreover, it is envisioned, the internal surface may be initially coated with a gold layer, followed by coating the exterior surface with the gold layer, or vice-versa, and then coating the internal and exterior surfaces with the silver layer. As such, the method for electroplating the internal and exterior surfaces of the IM nail should not be limited to separate and independent steps unless explicitly claimed.

[0072] Generally speaking, as will be described in greater detail herein, the method for electroplating the surfaces of the IM nail includes preparing, cleaning, masking, activating, and plating (e.g., coating). In accordance with one or more features of the present disclosure, the electroplating method facilitates electroplating a titanium implant by removing oxide from the implant while enabling a gold coating layer to be applied in a single step without requiring a vacuum process.

[0073] In one embodiment, with reference to **FIG. 10A**, the method includes cleaning and masking the internal surface 112 of the IM nail 100 as needed. In use, the surface of the IM nail may be cleaned via any suitable method now known or hereafter developed such as, for example, using methylene chloride, ultrasonic cleaning in alkali detergent, sulphuric acid, rinsing, and any combination thereof as illustrated. In order to ensure proper adhesion of the coating layers to the internal surface of the cannulated bore, the internal surface of the IM nail should be completely devoid of oils, die releasing films, oxides, alloying inclusions, heat treat scale, etc. Consequently, in one embodiment, the internal surface of the IM nail may be initially cleaned by a solvent, such as, for example, methylene chloride for two minutes at room temperature (RT) to remove any grease and organic material. Thereafter, the IM nail may be masked as needed and further cleaned using, for example, ultrasonic cleaning in alkali detergent, sulphuric acid, and rinsing.

[0074] Once the surface of the IM nail is suitably cleaned, the internal surface of the cannulated bore may be activated via any suitable method now known or hereafter developed such as, for example, using an activator (e.g., procirc or the like), econoclense ECN, sulphuric acid, rinsing, or any combination thereof. Finally, once the internal surface of the cannulated bore has been cleaned and activated, the internal surface may be coated using electroplating by applying a gold layer onto the internal surface followed by a silver layer.

As previously described, application of the gold and silver layers or coatings may be facilitated by using a plurality of spacers coupled to the IM nail to position an auxiliary anodized wire into the cannulated bore. As previously discussed, an optional antiseptic coating layer may be applied over the silver coating.

[0075] Once the internal surface of the cannulated bore has been coating, the method may include a subsequent or second stage for electroplating the external surfaces of the IM nail such as, for example, external surface 110 of IM nail 100. In one embodiment, with reference to **FIG. 10B**, the method includes removing any masking tape applied during the first stage. In addition, the auxiliary anode wire is removed from the cannulated bore. Thereafter, similar to the first stage, the method includes cleaning the exterior surface of the IM nail as needed. In use, the surface of the IM nail may be cleaned via any suitable method now known or hereafter developed such as, for example, using ultrasonic cleaning in alkali detergent, sulphuric acid, rinsing, and any combination thereof as illustrated. In one embodiment, the exterior surfaces of the IM nail are masked as needed using, for example, an insulating tape or a liquid electrical tape, which can be later removed using, for example, methylene chloride. Thereafter, once the surface is suitably cleaned, the exterior surface of the IM nail may be activated via any suitable method now known or hereafter developed such as, for example, using an activator (e.g., procirc or the like), econoclense, sulphuric acid, rinsing, or any combination thereof. Finally, once the exterior surface of the IM nail has been cleaned and activated, the exterior surface may be coated using electroplating by applying a gold layer onto the exterior surface followed by a silver layer. As previously discussed, an optional antiseptic coating layer may be applied over the silver coating.

[0076] More specifically, with reference to **FIGS. 11A-11C**, the IM nail 100 is prepared prior to electroplating. As illustrated, the IM nail 100 may be coupled to a fixture, a part holder, etc. 300 arranged and configured to hold the IM nail 100. The IM nail 100 includes a plurality of spacers 200 as previously described herein. Subsequently, an auxiliary anode wire 150 is positioned through the cannulated bore 118 of the IM nail 110, the spacers 200 positioning the wire 150 such that the wire 150 does not contact the internal surface 112 of the cannulated bore 118 of the IM nail 100 (e.g., the proximal and distal ends of the IM nail 100 are fitted with spacers 200 and one or more caps 210 are positioned within selected transverse screw holes formed in the IM nail to cover, block, or seal the screw holes formed in the IM nail during the coating process). In one embodiment, the auxiliary anode wire 150 is centralized within the cannulated bore 118 of the IM nail 100, tensioned, and connected to the part holder 300. In one embodiment, as illustrated, the IM nail 100 may be attached to

the part holder 300 at an angle of approximately 30 degrees relative to horizontal to allow fluid drainage through the cannulated bore 118, although this is but one configuration and other angles are envisioned. As illustrated, the IM nail 100 is also electrically connected to the part holder 300 via supports 302 to form the cathode and complete the circuit.

[0077] Once the IM nail 100 has been properly prepared, an optional electrical continuity test may be carried out to make sure that the tensioned auxiliary anode wire 150 located in the cannulated bore 118 of the IM nail 100 is not touching the internal surface 112 of the IM nail 100 (cathode), which would cause an electrical short circuit.

[0078] Once the IM nail 100 has been properly prepared, referring once again to **FIG. 10A**, the IM nail 100 may be ultrasonically cleansed (step 3). In one particular embodiment, the IM nail 100 is subjected to an ultrasonic cleaning with an alkaline detergent for two minutes at 40 degrees Celsius and then the cleaning fluid is allowed to drain off. For example, a tank may be used to ultrasonically clean the IM nail 100 in alkaline detergent. As an example, the detergent may be a low alkali non-etch cleaner, such as PMD cleaner. As illustrated in steps 4–6, the IM nail 100 may be treated with de-ionized (DI) water and a sulphuric acid rinse. For example, the IM nail 100 may be thoroughly rinsed in DI water at RT followed by a rinse in 5 percent w/w sulphuric acid followed by an additional rinse in DI water at RT. For example, a rinse tank may be used to rinse the IM nail 100 after ultrasonic cleaning.

[0079] In step 7, the passivation layer may be removed using, for example, chemical activation, to ensure the new surface adheres to the base metal and creates a good bond. In order to provide a complete and continuous electroplated surface and improve the bonding between the gold strike and the metal (e.g., titanium) surface of the IM nail 100, the passivation layer should be removed by, for example, slightly etching the surface, stripping oxides and metal from the surface to expose pure metal atoms. For example, the IM nail 100 may be subjected to five percent w/w PMD Chemicals PROCIRC 1320 Cleaner/Activator at 20 degrees Celsius for 4-6 minutes. Utilization of PROCIRC facilitates activation of the titanium surface to receive the gold coating. Alternatively, other suitable forms of activation may be utilized. For example, as an alternative to PROCIRC, and as titanium oxide is also sensitive to HF at different concentrations, e.g., etching the surface with Hf-containing media (e.g., 12ml Hf + 70ml H₂O₂, or 3ml HF + 6ml HNO₃ + 50ml H₂O, both room temperature <20 seconds) is an options as well. leaving the titanium surface terminated with H or F atoms. Other de-passivating agents include 25% DI water, 25% Sulfuric acid, 50% Nitric acid, and 120 g/L Ammonium bifluoride. Carrying out the activation process in an inert gas

atmosphere may also be preferable as well from a quality control perspective. In step 8, the IM nail 100 may be rinsed in DI water.

[0080] In step 9, the IM nail 100 may be electrochemically cleaned. For example, the activated IM nail 100 may be subjected to an electrochemical cathodic clean in cyanide cleaner for 30 seconds at RT. For example, PMD Chemicals Econoclense may be used. Econoclense ECN is a low foaming, non-silicate, electrolytic, cyanide-based cleaner for ferrous and non-ferrous metals. Utilization of Econoclense ECN facilitates cleaning and de-activation of the titanium surface (e.g., removal of oxides).

[0081] In step 10, the electrochemical cleaned IM nail 100 may be subjected to a rinse in DI water at RT. In step 11, the IM nail 100 may be rinsed in sulphuric acid. In step 12, the IM nail 100 may be rinsed in DI water.

[0082] In step 13, the internal surfaces 112 of the cannulated bore 118 of the IM nail 100 may be electroplated with a noble metal. For example, a gold plating deposit, which is called a "strike" or "flash", may be used to form a very thin plating or coating (e.g., typically 0.1 μm thick) with high quality and good adherence to the de-oxidized titanium substrate. This serves as a foundation for the subsequent silver-plating processes. In one embodiment, the gold is pure to avoid any variations in the deposition rate. Other suitable base layers may be used such as, for example, rhodium (e.g., a white gold used in dental castings), platinum, iridium, or palladium. The activated titanium IM nail 100 may be immersed in the gold plating bath while still wet to protect the surfaces from oxidation. For example, a gold electroplating tank may be used to coat the internal surface 112 of the cannulated bore 118 of the IM nail 100 (cathode) using a current of about 0.5 amperes. The amount of current applies varies by implant size, and current density should be 30-50 A per square foot, and preferably 40A per square foot.

[0083] As previously mentioned in connection with **FIGS. 11A-11C**, the IM nail 100 may be supported on a fixture or part holder 300 in the tank to allow electrolyte to flow through the cannulated bore 118. With reference to **FIG. 12**, the IM nail 100 may be reciprocated (e.g., moved within the tank during the plating process) to allow the electrolyte to flow through the cannulated bore 118 of the IM nail 100. Pumps may also be used to ensure that there is a constant flow of electrolyte in the tank. A stagnant solution may not contain enough electrolyte causing variations in the thickness of the gold and silver electroplated layers. Consequently, solution movement is desirable for complex shapes with cannulations in order to prevent the supply of ions from being exhausted in the tank. Measuring the concentration of the electrolyte at the entry and exit of the IM nail 100 may be

desirable. Alternatively, one could measure the flow rate to keep the concentration within a target range. That is, it has been found that improvements to the coating finish may be achieved by increasing the agitation of the solution by devising a method for passing solution through the cannulated bore throughout the plating process. For example, a reciprocating workpiece or cathode bar albeit restricted by the end caps holding the auxiliary anode wire 150. Additionally, one of ordinary skill in the art would understand the current passed may be varied (in small increments/decrements) and looking at any resultant changes in appearance to determine an optimum setting. More specifically, in accordance with one or more features of the present disclosure, the solutions within the bathing tanks are preferably agitated during the coating process. In use, any suitable form of agitating the solution within the bathing tanks may be used including, for example, air via an air pump, or mechanical agitation, e.g., a small electric motor with an impeller to produce the flow of water. It has been found that agitation helps with the removal of materials from the metal surface, increasing the electrode potential making plating more efficient and also preventing the build-up of impurities in the surface layer.

[0084] In one embodiment, the electrolyte solution may be potassium gold cyanide. KAu(CN)_2 , which can be deactivated into a potassium gold cyanate (KAuOCN) salt after use enabling the residual gold to be recycled. In one embodiment, the electrolyte solution may be maintained at $\text{pH} = 4.5$, and a temperature of 35 ± 3 degrees C for approximately 90 seconds with a DC current of 0.5A. Accurate and controlled direct current (DC) supply also is desirable (milliamp scale) in order to control the deposition rate of the gold layer. The amount of current applies varies by implant size, and current density is optimally 30-50 A per square foot, and preferably 40A per square foot. With reference to **FIG. 13**, a longitudinal section of the IM nail 100 is shown, the auxiliary anode wire 150 used to deposit electroplated gold being positioned within the cannulated bore 118 of the IM nail 100 can be seen to be “pre-tensioned” thus preventing the wire 150 from contacting the internal surface 112 of the cannulated bore 118 of the IM nail 100 using insulating spacers 200.

[0085] In step 14, the IM nail 100 electroplated with gold on the internal surface may be cleaned to achieve good quality plating and to ensure that the electrolyte is kept in prime condition. For example, in step 14, the IM nail 100 electroplated with gold on the internal surface may be rinsed in DI water followed by a rinse in 5 percent w/w sulphuric acid followed by an additional rinse in DI water at RT (steps 15 and 16). Thus arranged, this type of rinse cycle prevents embrittlement, which could make the coatings prone to failure when

under stress. Using a thin flash coating instead of a thicker electroplate would also reduce the risk of embrittlement.

[0086] In step 17, the internal surface 112 of the cannulated bore 118 of the IM nail 100 may now be electroplated with silver. For example, with reference to **FIG. 14**, in one embodiment, a gold electroplated IM nail 100 may be immersed in a second tank containing a silver potassium cyanide electrolyte solution maintained at a pH of 11.97 and temperature of 23 ± 3 degrees C. The electrolyte may contain a brightener, such as ammonium thiosulfate, selenous acid, antimony potassium tartrate, or potassium tartrate, to control the appearance of the final implant. In one embodiment, the anode may be made from either solid silver or silver nitrate salt granules. The IM nail 100 may be left in the tank for 90s with a DC current of 0.5A. Pumps may be used to ensure that there is a constant flow of electrolyte through the cannulated bore 118. In one embodiment, the current density may be approximately 10A per square foot. The resultant silver coating may be verified by X-ray florescence and may be between 0.1 and 1 μm . The silver electroplating may be used to coat the nail (cathode) on the internal surfaces. **FIG. 15** illustrates a longitudinal section of the IM nail 100, the auxiliary anode wire 150 used to deposit electroplated silver onto the gold layer being positioned within the cannulated bore 118 of the IM nail 100 can be seen to be pre-tensioned thus preventing the wire 150 from contacting the internal surface 112 of the cannulated bore 118 of the IM nail 100 using, for example, a plurality of spacers 200 positioned along the length of the IM nail 100.

[0087] Finally, in steps 18-20, the IM nail 100 may be rinsed in DI water, then sulphuric acid, and then again in DI water.

[0088] Referring once again to **FIG. 10B**, stage 2 illustrates the electroplating process of the external surfaces 110 of the IM nail 100. As illustrated, in one embodiment, in step 1, the masking tape and auxiliary anode wire 150 are removed. The masking tape may be removed mechanically or chemically so that the external surfaces 110 of the IM nail 100 can be exposed to gold and silver plating in subsequent steps. The spacers 200 are also removed. In some embodiments, with reference to **FIGS. 16A** and **16B**, one of the ends (e.g., the proximal end) of the IM nail 100 may be fitted with a plastic member 320 such as, for example, a bolt which may be used to hold the IM nail 100 electrically during the electroplating steps. As illustrated, the plastic member 320 may be a plastic M4 bolt, which may be attached to the IM nail 100, although this is but one configuration. The silver electroplated surfaces created on the inside surfaces are resistant to any additional treatments in the process.

[0089] As illustrated, in one embodiment, steps 2-11 are substantially similar to those described above in connection with stage 1. In step 12, the external surfaces 110 of the IM nail 100 are electroplated in gold, which does not require the use of an auxiliary anode. The gold coating conditions are substantially similar to those described above in connection with coating the internal surface 112. **FIG. 17** depicts schematically the gold electroplating step used to coat the IM nail 100 (cathode) on the external surface 110.

[0090] In steps 13-15, the IM nail 100 electroplated with gold on the external surface may be cleaned to achieve good quality plating and to ensure that the electrolyte is kept in prime condition. For example, the IM nail 100 with gold on the external surfaces may be rinsed in DI water followed by a rinse in 5 percent w/w sulphuric acid followed by an additional rinse in DI water at RT. Thereafter, the IM nail 100 may be transferred to the silver electroplating tank. In step 16, the external surfaces of the IM nail 100 may be electroplated in silver. The silver coating conditions are substantially similar to those described above in connection with coating the internal surface 112 of the cannulated bore 118 of the IM nail 100. **FIG. 18** depicts schematically the silver electroplating step used to coat the nail (cathode) on the external surfaces.

[0091] In steps 17-19, the IM nail 100 electroplated with gold and silver on the external surfaces may be rinsed in DI water, followed by sulphuric acid and then again in DI water. The IM nail 100 may then be air dried with compressed air.

[0092]

[0093] While the present process maps or method have been described in connection with an IM nail 100, it will be appreciated that the method may be used to coat other implants such as, for example, screws. As such, the process maps or methods of the present disclosure should not be limited to IM nails unless explicitly claimed.

[0094]

[0095] With additional reference to **FIG. 19**, in accordance with one or more features of the present disclosure, thinner silver-plated coatings or “flashes” (e.g., a coating layer of approximately 1 μm or less) have the advantage of a lower inventory of silver and reduced risk of fracture under stress. Exposure of the underlying gold coating at one section of the IM nail, such as the proximal section, has the advantage of reducing the overall quantity of silver, and introducing a counter-electrode to accelerate the release of silver in vivo. It also provides product differentiation.

[0096] Referring to Table 1 below, example embodiments of ranges and temperatures for each step is provided. More specifically, Table 1 provides optimum electrolyte temperatures

for gold and silver plating for Ti implants. In one embodiment, thermostatic tank heaters could be used in a production environment to ensure controlled temperature during plating. In some embodiments, it is possible to electroplate internal and external surfaces simultaneously. However, the clamps should be moved to an alternative position in order to avoid any unwanted witness marks exposing the underlying metal. In one embodiment, the IM nail may be held through a slot or screw hole such as, for example, at the proximal end and subjected to cleaning, activation, and plating steps. The coated end of the IM nail may then be masked, and the fixtured proximal end in stage 1 subjected to the cleaning, activation, and plating steps.

Table 1

Step No.	Description	Chemicals	Time (mins)	Temperature (°C)
1	Clean	Methylene chloride	2	RT
2	Clean	Alkaline detergent, with ultrasonics	2	40°C
3	Rinse	DI water	Rinse	RT
4	Rinse	5% w/v Sulphuric acid (H ₂ SO ₄)	Rinse	RT
5	Rinse	DI water	Rinse	RT
6	Remove passivation layer/Activate titanium	5% w/v cleaner	5	RT
7	Rinse	DI water	Rinse	RT
8	Electrochemical clean	cyanide cleaner 25% ECN: 75% DI water	0.5	RT
9	Rinse	DI water	Rinse	RT
10	Rinse	5% w/v Sulphuric acid (H ₂ SO ₄)	Rinse	RT
11	Rinse	DI water	Rinse	RT
12	Gold Plate	- Electrolyte - KAu(CN)₂, Potassium gold cyanide - Anode – platinized titanium - pH = 4.5 - Ideal current density = 40A/square foot	1.5	35 ± 3°C
13	Rinse	DI water	Rinse	RT
14	Rinse	DI water	Rinse	RT

15	Rinse	5% w/v Sulphuric acid (H ₂ SO ₄)	Rinse	RT
16	Silver plate	- Electrolyte – Silver potassium cyanide (KAg(CN)₂) + brightener (5/10% w/v potassium hydroxide) - Anode – Silver nitrate granules - pH = 11.97 - Ideal current density = 10A/square foot	1.5	23°C ± 3°C
17	Rinse	DI water	Rinse	RT
18	Rinse	5% w/v Sulphuric acid (H ₂ SO ₄)	Rinse	RT
19	Rinse	DI water	Rinse	RT
20	Dry	Compressed air	-	-

[0097] Additionally, alternative methods may be used for removal of passivation layer. Several conventional methods are known for deoxidizing titanium and its alloys. The most common methods are ion sputtering in an inert gas such as pure argon, abrasive blasting, a molten salt bath, and pickling in an aqueous solution of nitric acid and hydrofluoric acid. The problem with titanium is that once the oxide layer is removed, water from the electrolyte will react with it immediately. Abrasive blasting roughens the surface, producing uneven metal removal and its use is limited to regular shapes. Moreover, articles having complex surfaces with hidden areas cannot be completely deoxidized using this method. Molten salt baths require extremely high temperatures and normally produce a stained surface. The stain is usually removed with a post-treatment to complete the process. It is also impractical to descale large articles with this process. Pickling in an aqueous solution of nitric acid, hydrochloric acid, hydrofluoric acid and water results in a dark rough etched surface and are susceptible to hydrogen embrittlement and intergranular corrosion.

[0098] In some embodiments, the gold can be applied with either electroplating, immersion or electroless plating given that the gold layer does not need to be greater than 0.5 µm thick and could be as low as 0.05 µm thick. Alternative noble metals for priming the titanium are rhodium, platinum, palladium and iridium.

[0099] There also is a potential opportunity to deliberately limit the coverage of electroplated silver onto the gold layer to create a counter-electrode, which could enhance the galvanic release of silver in specific “hot spots” on the implant.

[00100] In some embodiments, there is an alternative coating processes: (a) gold immersion followed by electroless silver plating. In various embodiments, this alternative method may include step 1: cleaning and activating the implant using hot alkaline detergent cleaning agent. Step 2: de-oxidizing the titanium implant chemically. Step 3: rinsing in DI water. Step 4: gold immersion (non-line of sight) coating internal and external surfaces. Step 5: rinsing in DI water. Step 6: electroless silver plating or pulse plating to achieve a denser coating of silver. In the case of electroless silver plating, a composition including an aqueous solution of a water-soluble silver salt such as silver nitrate, ammonium hydroxide as a complexing agent, ammonium carbonate and/or bicarbonate as a stabilizer and hydrazine hydrate as a reducing agent. The composition of this aqueous solution is substantially free of non-volatile components that cause impure plating, allowing for improved appearance and properties of the plated silver. Further, the process generates essentially no hazardous substances and the absence of non-volatile components avoids the accumulation of by-products that degrade the plating bath, allowing for virtually unlimited replenishment of the bath. Free from flux-density and power supply issues, it provides an even deposit regardless of workpiece geometry. Step 7: rinsing in DI water.

[00101] In accordance with one or more features of the present disclosure, devices, systems and methods for activating and electroplating a complex orthopedic implant such as, for example, an IM nail, manufactured from titanium in a non-line of site fashion using an auxiliary anode wire positioned within the cannulated bore of the IM nail is provided. This process adaptations outlined herein ensure that the internal cannulated bore is fully protected in a continuous layer of antimicrobial silver. The ability to control the ratio of anode (silver coating) to cathode (gold coating) by controlling current density during electroplating in order to limit the amount and duration of silver release from the surfaces of the implant (from 50:1 to 10:1). The ability to create a gold counter-electrode to increase the rate of silver release off the surface of the implant by limiting the coverage of the silver layer over the gold strike. This also has the advantage of providing color differentiation and limiting the amount of silver on the final product.

[00102] The foregoing description has broad application. Accordingly, the discussion of any embodiment is meant only to be explanatory and is not intended to suggest that the scope of the disclosure, including the claims, is limited to these example embodiments. In other words, while illustrative embodiments of the disclosure have been described in detail herein, it is to be understood that the inventive concepts may be otherwise variously embodied and

employed, and that the appended claims are intended to be construed to include such variations, except as limited by the prior art.

[00103] The term "a" or "an" entity, as used herein, refers to one or more of that entity. As such, the terms "a" (or "an"), "one or more" and "at least one" can be used interchangeably herein. The use of "including," "comprising," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Accordingly, the terms "including," "comprising," or "having" and variations thereof are open-ended expressions and can be used interchangeably herein. The phrases "at least one", "one or more", and "and/or", as used herein, are open-ended expressions that are both conjunctive and disjunctive in operation.

[00104] All directional references (e.g., proximal, distal, upper, underside, lower, upward, downward, left, right, lateral, longitudinal, front, back, top, bottom, above, below, vertical, horizontal, radial, axial, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present disclosure, and do not create limitations, particularly as to the position, orientation, or use of this disclosure. Connection references (e.g., attached, coupled, connected, and joined) are to be construed broadly and may include intermediate members between a collection of elements and relative movement between elements unless otherwise indicated. As such, connection references do not necessarily infer that two elements are directly connected and in fixed relation to each other. Identification references (e.g., primary, secondary, first, second, third, fourth, etc.) are not intended to connote importance or priority but are used to distinguish one feature from another. The drawings are for purposes of illustration only and the dimensions, positions, order and relative sizes reflected in the drawings attached hereto may vary.

CLAIMS

What is claimed is:

1. A method for applying a coating to an intramedullary nail including an exterior surface and a cannulated bore defining an internal surface, the method comprising:

coupling a plurality of non-conductive spacers to the intramedullary nail;

positioning an auxiliary anode wire into the cannulated bore of the intramedullary nail, the plurality of spacers holding the auxiliary wire a distance from the internal surface;

electroplating a gold coating onto the internal surface of the intramedullary nail by placing the intramedullary nail including the plurality of spacers and the auxiliary anode wire into a first tank containing gold ions;

removing the intramedullary nail including the plurality of spacers and the auxiliary anode wire from the first tank containing gold ions; and

electroplating a silver coating onto the gold coating by placing the intramedullary nail including the plurality of spacers and the auxiliary anode wire into a second tank containing silver ions.

2. The method of claim 1, further comprising applying an outer layer comprising of, or containing, antibiotic(s), antiseptic or antimicrobial coatings onto of the silver coating.

3. The method according to any of the preceding claims, wherein the silver coating has a thickness of approximately 0.1 μm or less.

4. The method according to any of the preceding claims, wherein at least one of the plurality of spacers is provided as an end cap arranged and configured to engage an end of the intramedullary nail.

5. The method according to any of the preceding claims, wherein each of the plurality of spacers includes a plurality of openings formed therein to enable fluid flow during the coating process.

6. The method according to any of the preceding claims, further comprising reciprocating the intramedullary nail including the plurality of spacers and the auxiliary anode wire in the first and second tanks.

7. The method of claim 6, further comprising pumping fluid through the cannulated bore of the intramedullary nail.

8. The method according to any of the preceding claims, further comprising:
removing the plurality of spacers and the auxiliary anode wire;
electroplating a gold coating onto the external surface of the intramedullary nail by placing the intramedullary nail into the first tank containing gold ions;
removing the intramedullary nail from the first tank containing gold ions; and
electroplating a silver coating onto the external gold coating by placing the intramedullary nail into the second tank containing silver ions.

9. The method according to any of the preceding claims, further comprising pre-tensioning the auxiliary anode wire within the cannulated bore.

10. A system for applying a coating to an intramedullary nail, the system comprising:
an intramedullary nail including an exterior surface and a cannulated bore defining an internal surface;

a plurality of non-conductive spacers coupled to the intramedullary nail, each of the plurality of non-conductive spacers including a hole and a plurality of openings; and

an auxiliary anode wire positioned within the cannulated bore of the intramedullary nail, the auxiliary anode wire passing through the hole formed in the plurality of spacers so that the auxiliary wire is positioned a distance away from the internal surface;

wherein the plurality of openings formed in the plurality of spacers facilitate fluid flow during application of a coating to the internal surface of the cannulated bore.

11. The system of claim 10, wherein the intramedullary nail, the plurality of spacers, and the auxiliary anode wire are arranged and configured to be placed with an electroplating tank containing gold ions for applying a gold coating onto the internal surface of the intramedullary nail.

12. The system of claim 11, wherein the intramedullary nail, the plurality of spacers, and the auxiliary anode wire are arranged and configured to be placed with a second electroplating tank containing silver ions for applying a silver coating onto the gold coating.

13. The system of claim 10, wherein the auxiliary anode wire is pre-tensioned within the cannulated bore.

14. The system of claim 10, wherein the plurality of spacers are arranged and configured to center the auxiliary anode wire within the cannulated bore.

15. An intramedullary nail comprising:

an exterior surface;

a cannulated bore defining an internal surface;

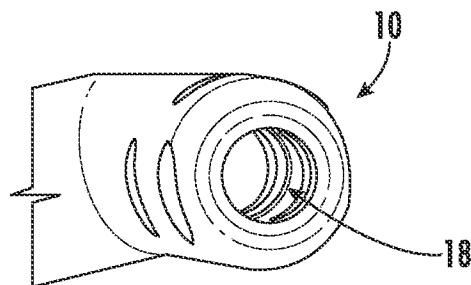
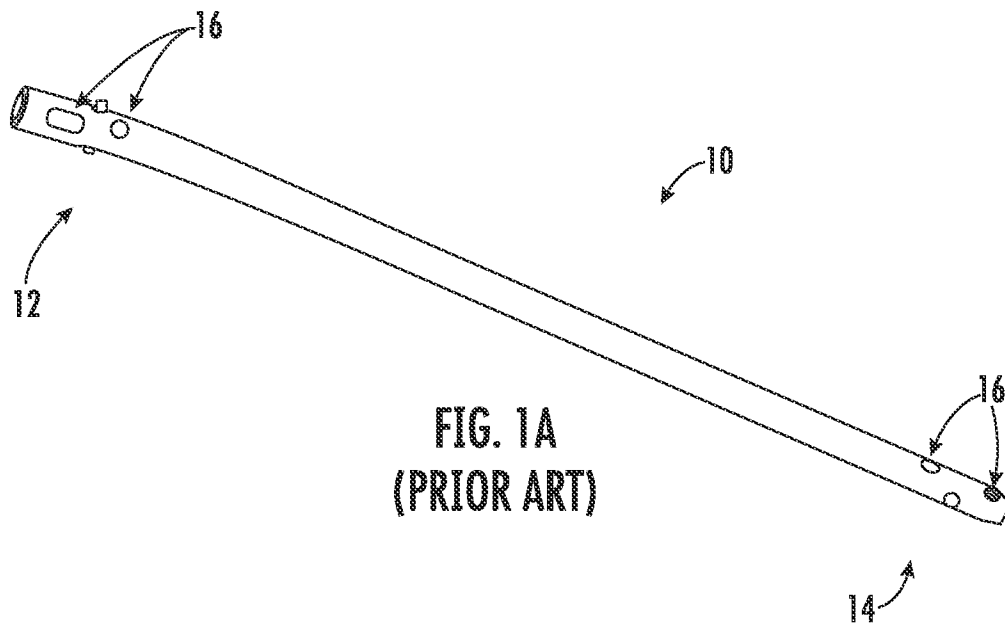
a gold coating applied to the exterior surface;

a gold coating applied to the internal surface of the cannulated bore;

a silver coating applied to the gold coating applied to the exterior surface; and

a silver coating applied to the gold coating applied to the internal surface.

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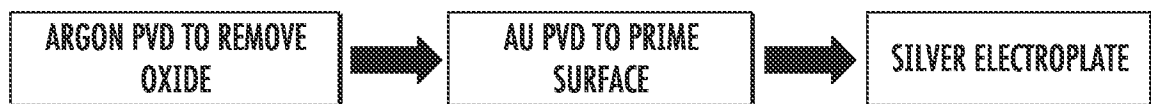


FIG. 2
(PRIOR ART)

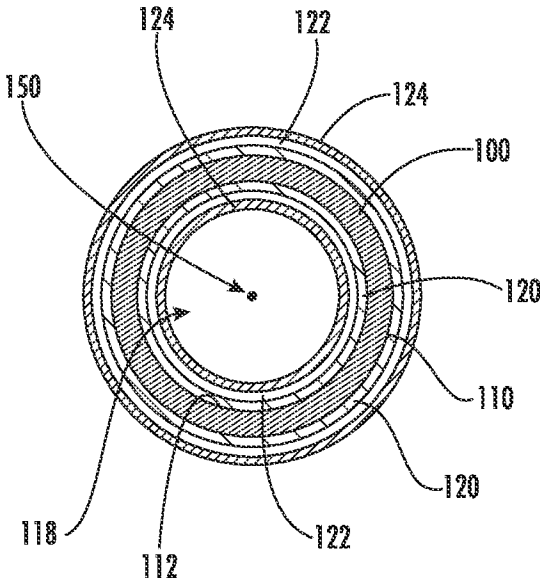


FIG. 3

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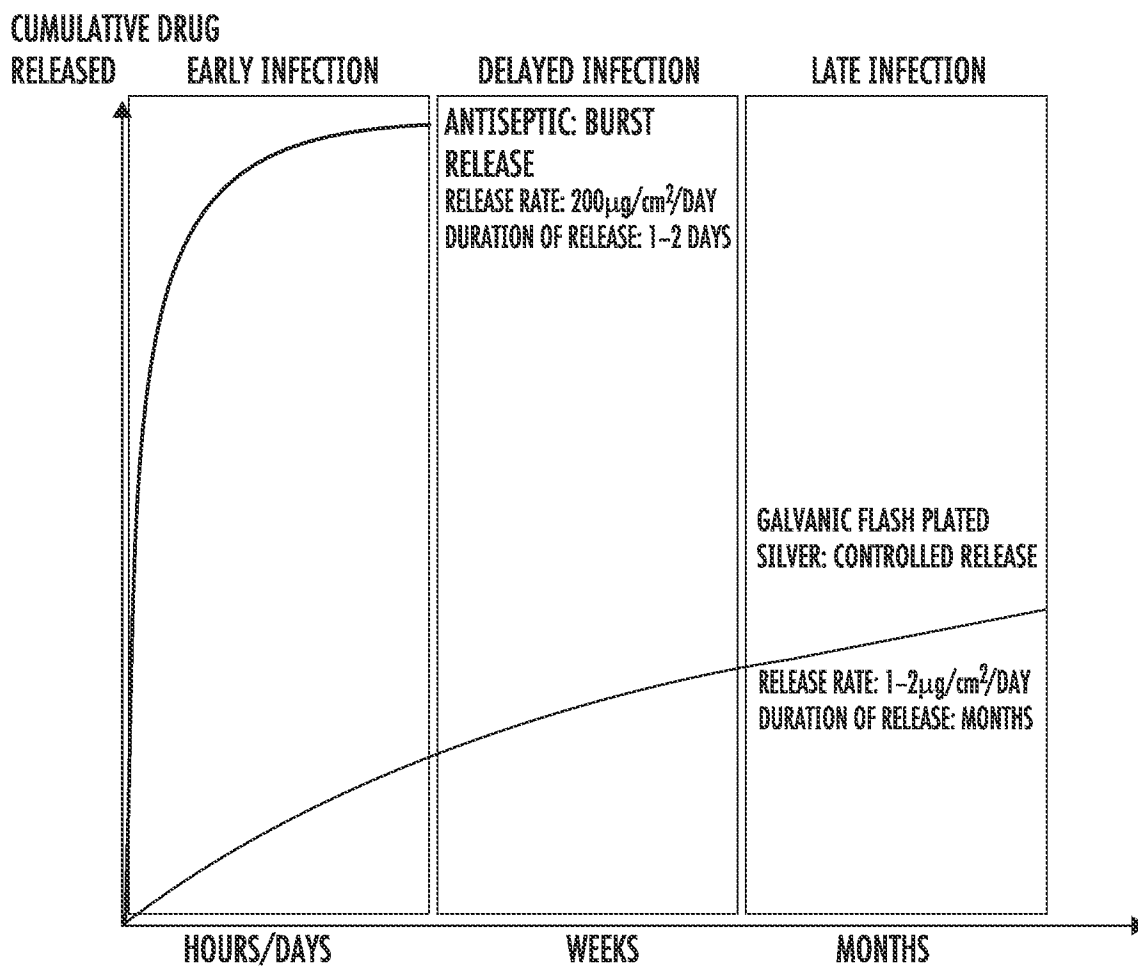
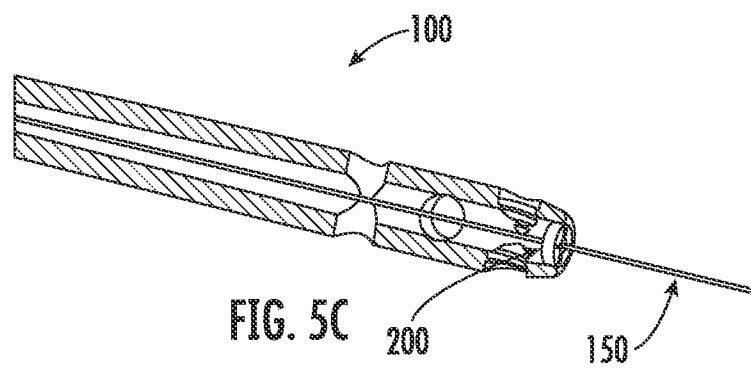
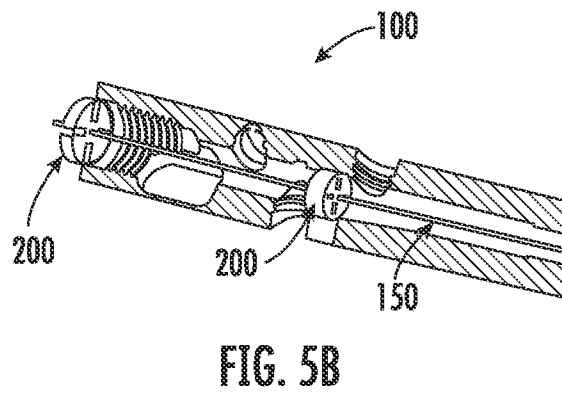
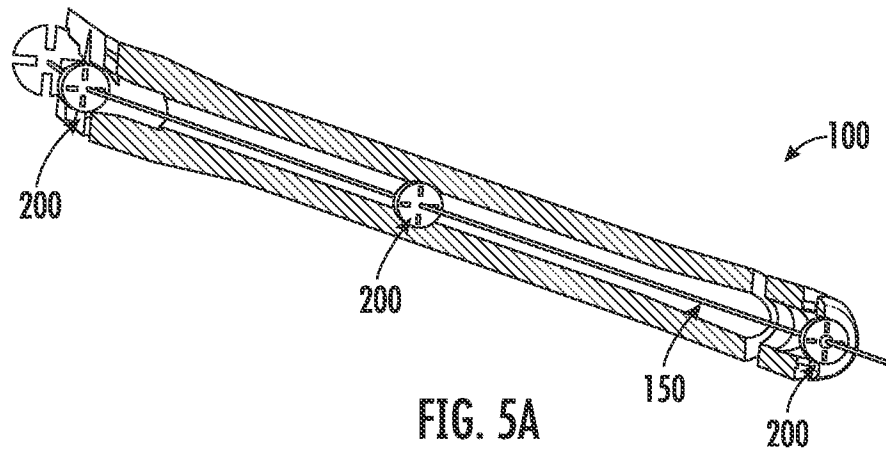


FIG. 4

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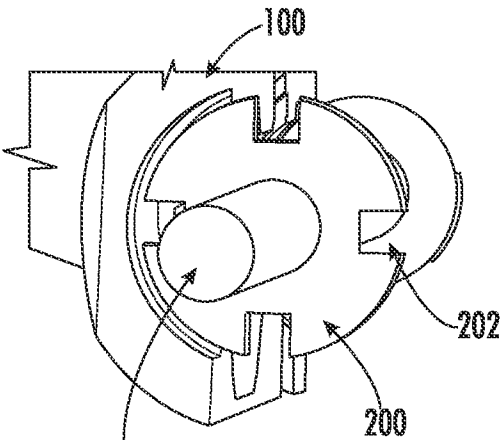


FIG. 6A

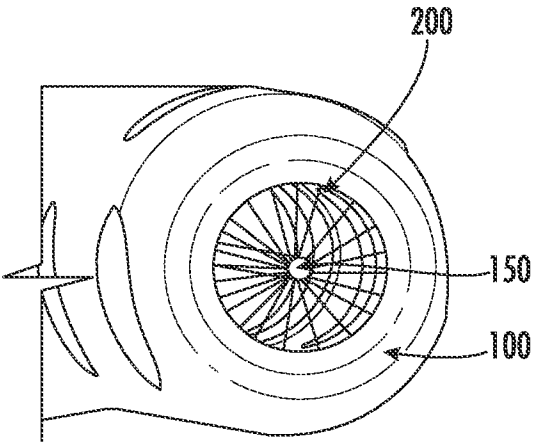
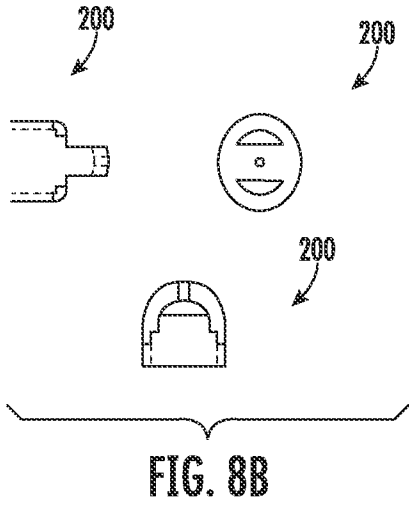
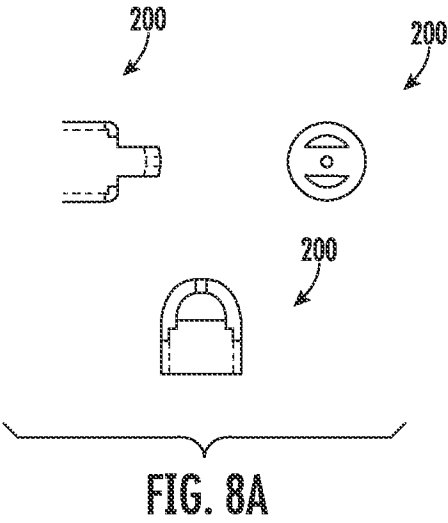
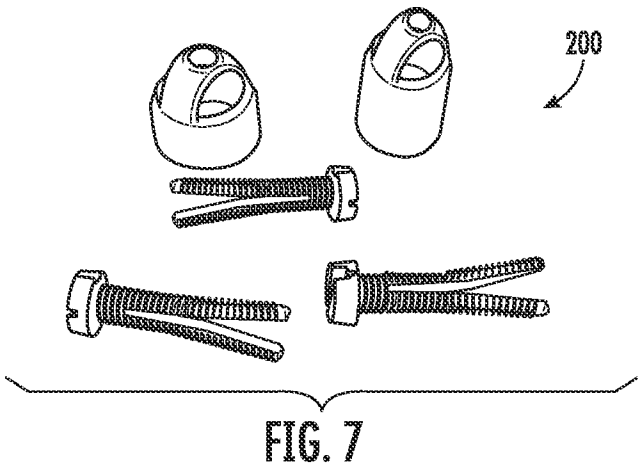


FIG. 6B



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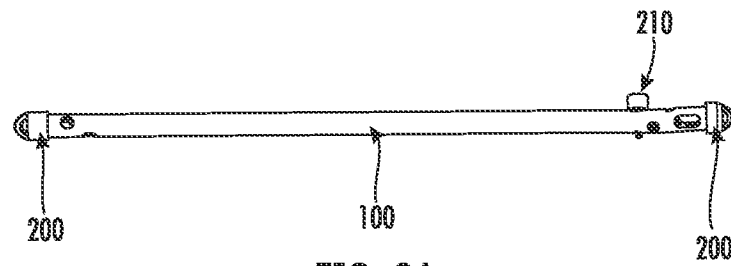


FIG. 9A

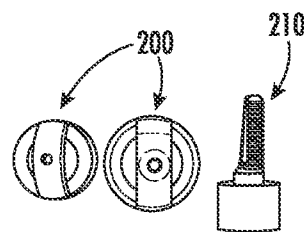


FIG. 9B

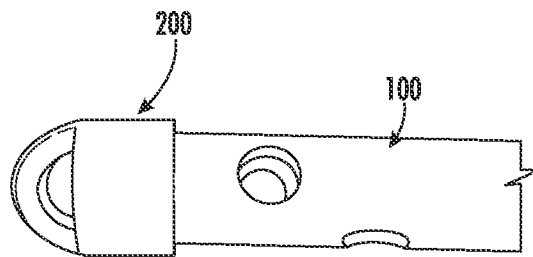


FIG. 9C

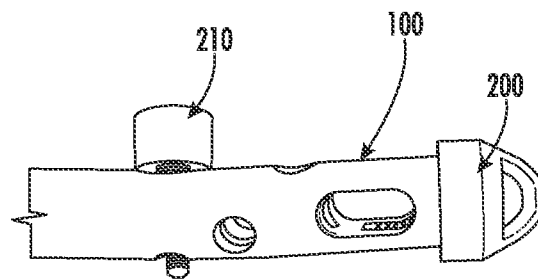


FIG. 9D

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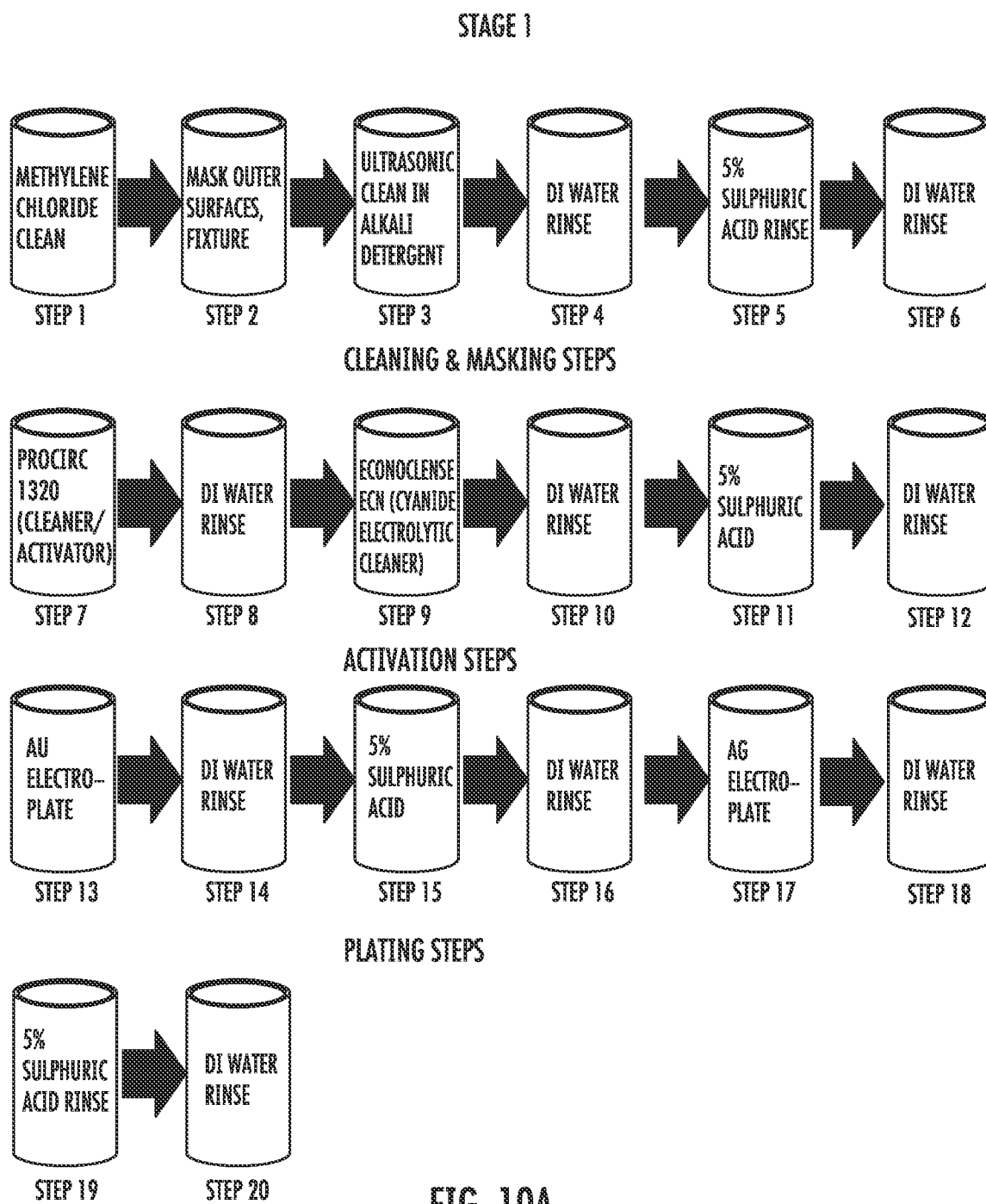
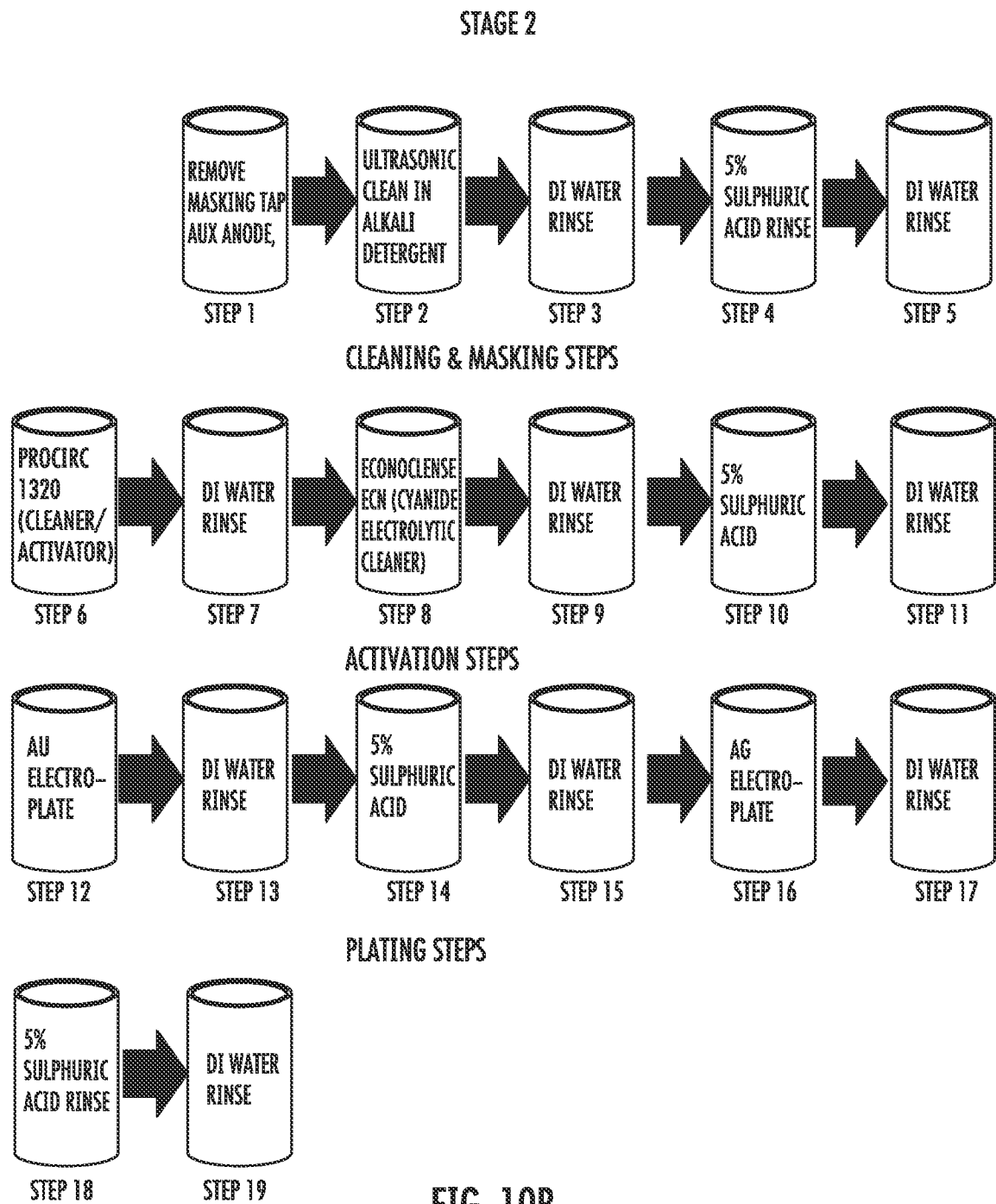
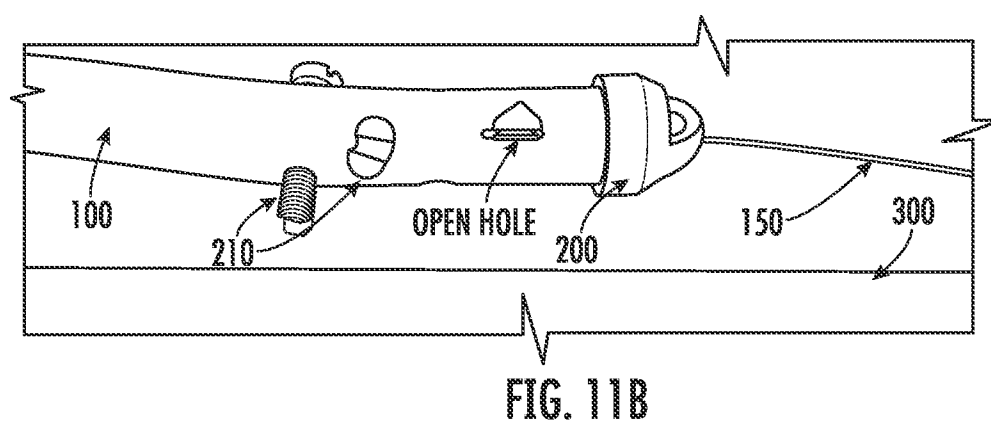
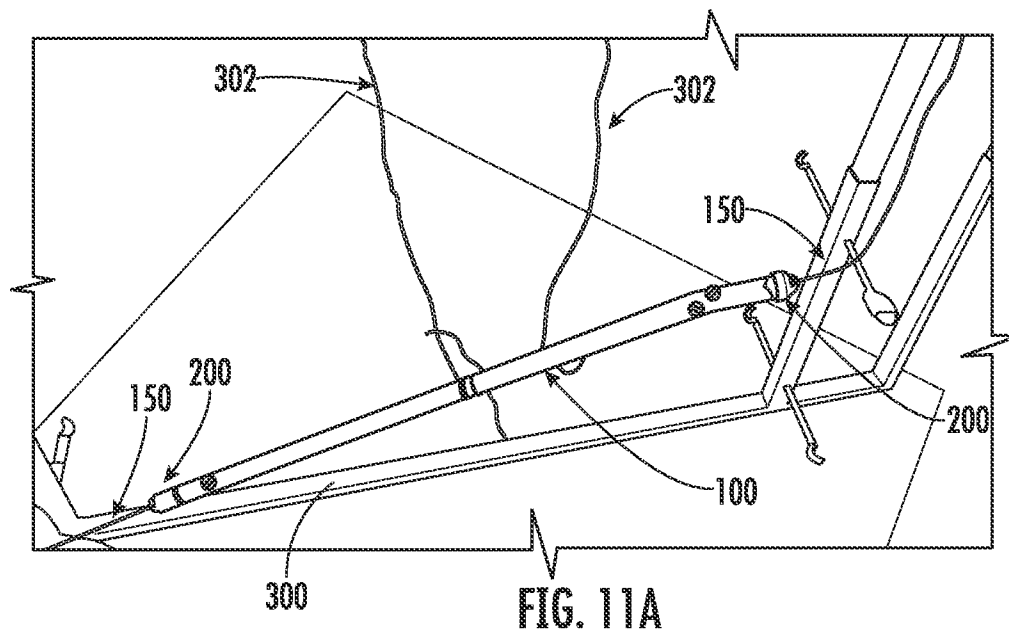


FIG. 10A

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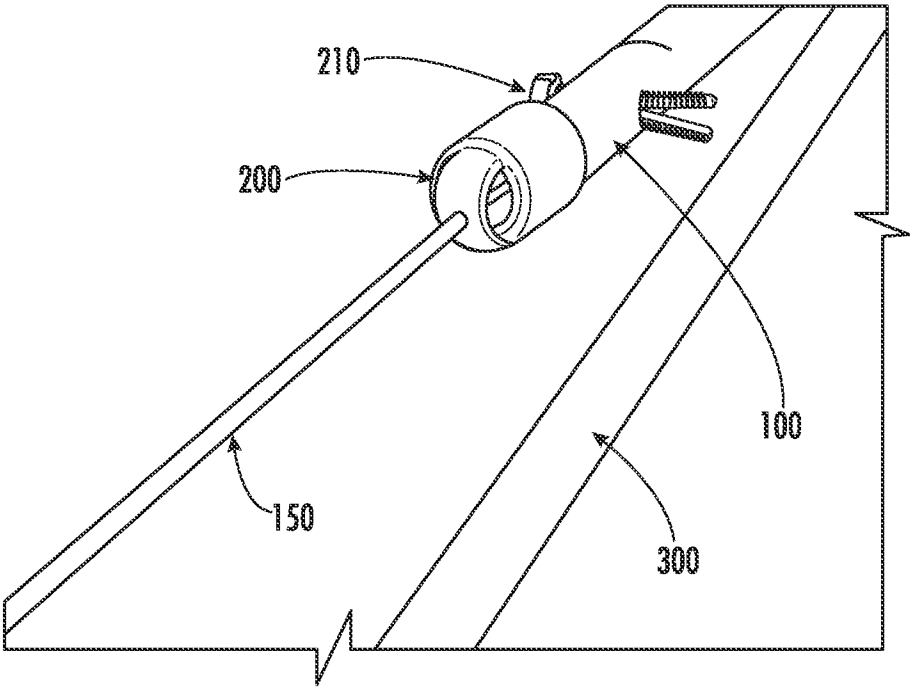


FIG. 11C

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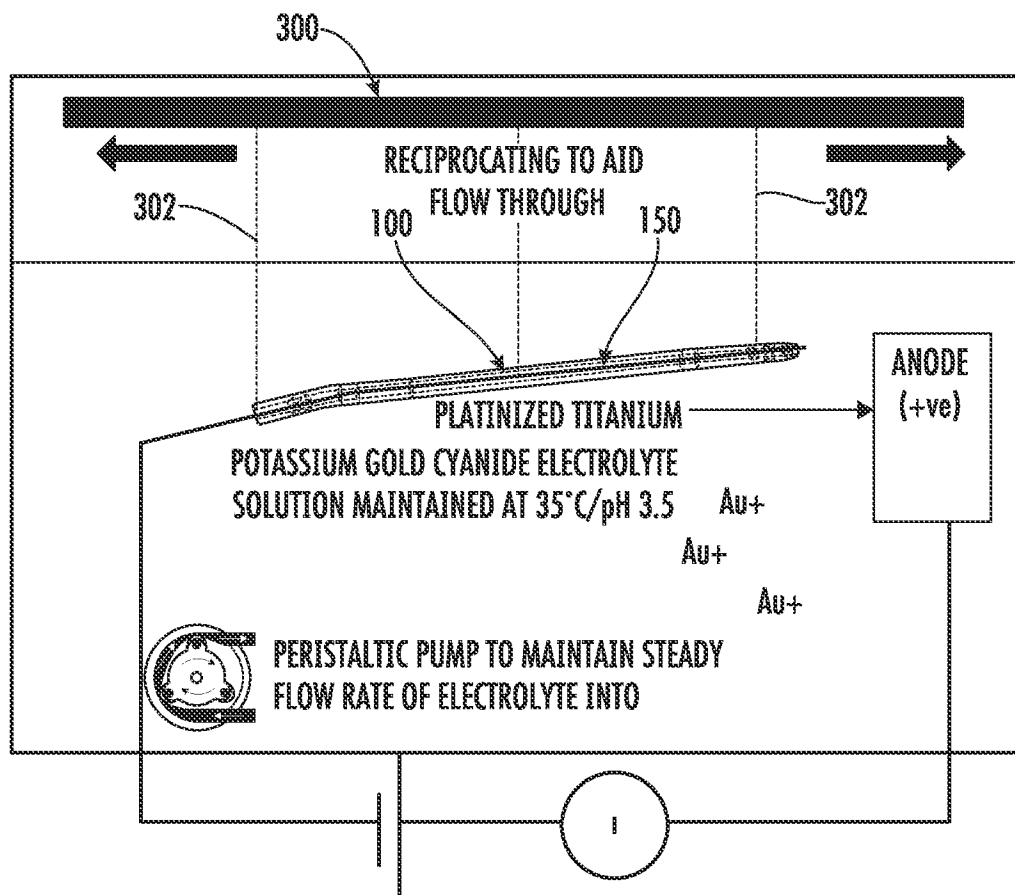


FIG. 12

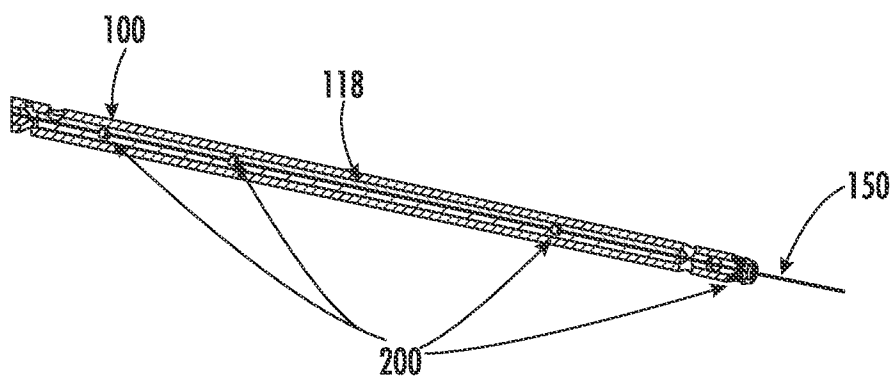


FIG. 13

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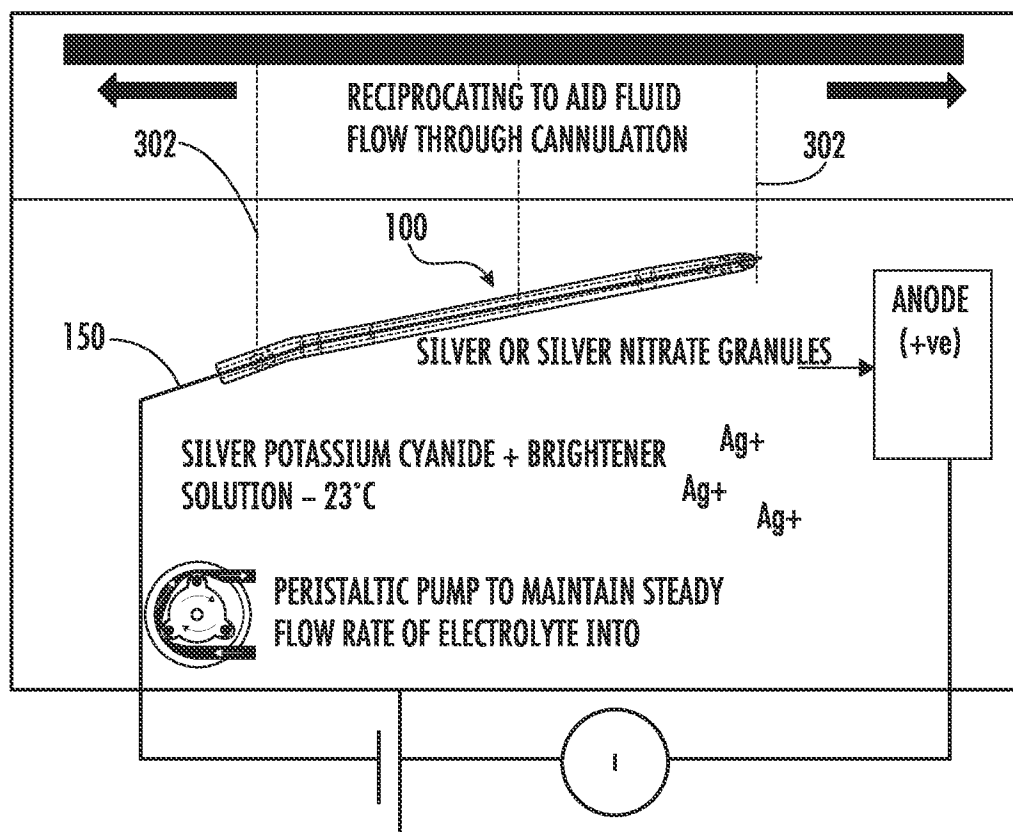


FIG. 14

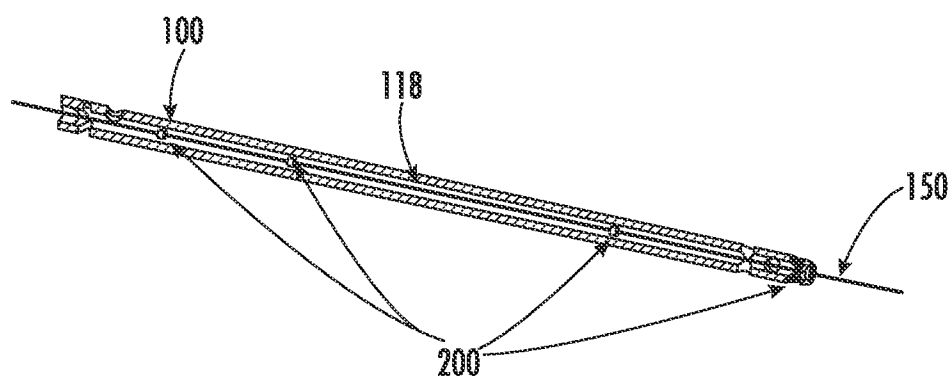


FIG. 15

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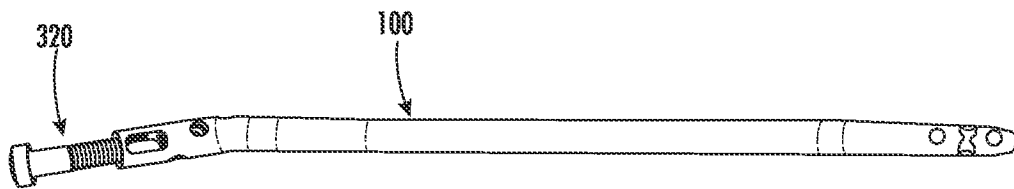


FIG. 16A

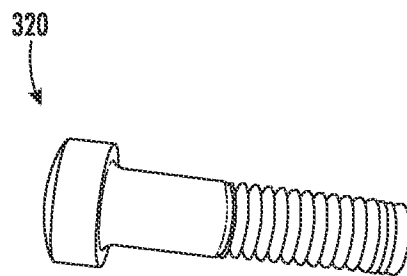


FIG. 16B

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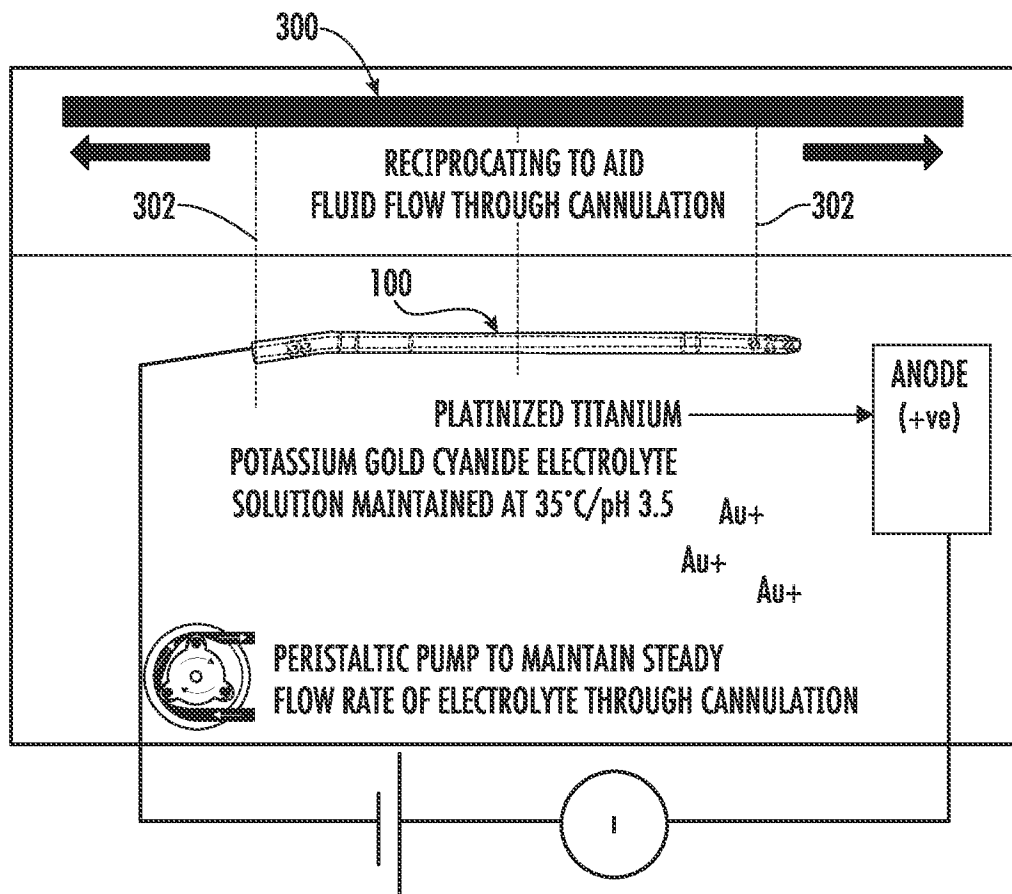


FIG. 17

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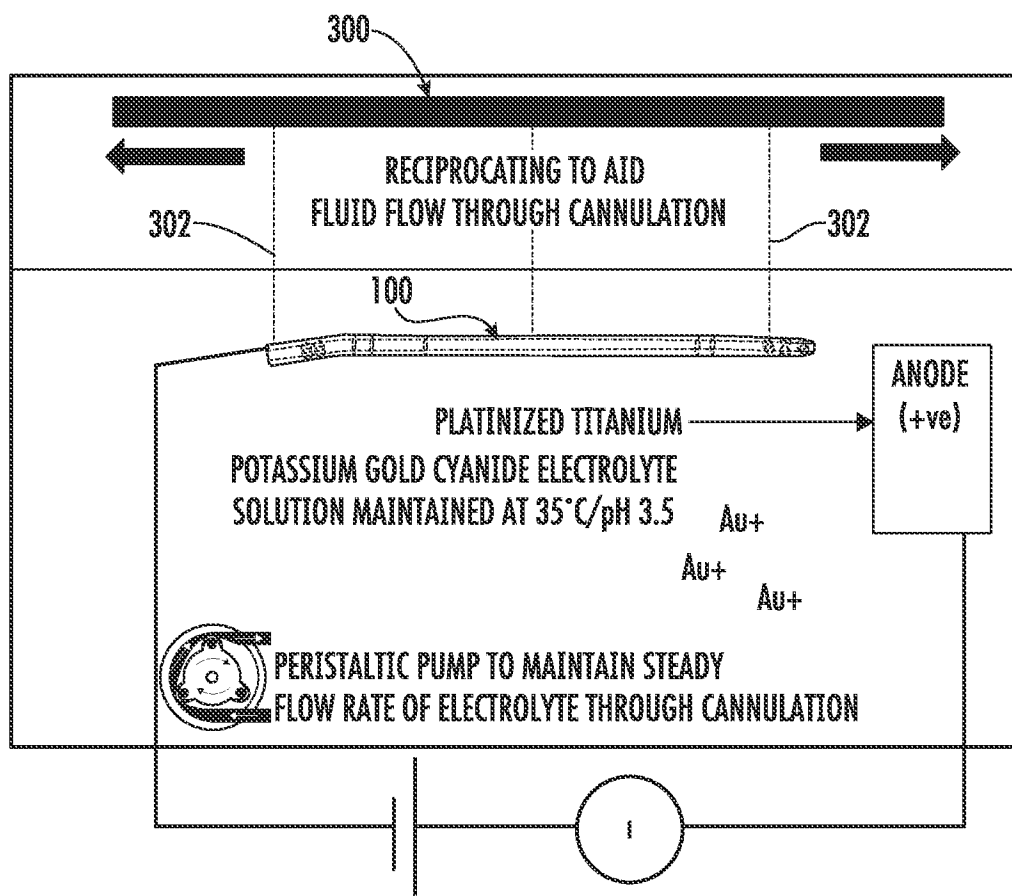


FIG. 18

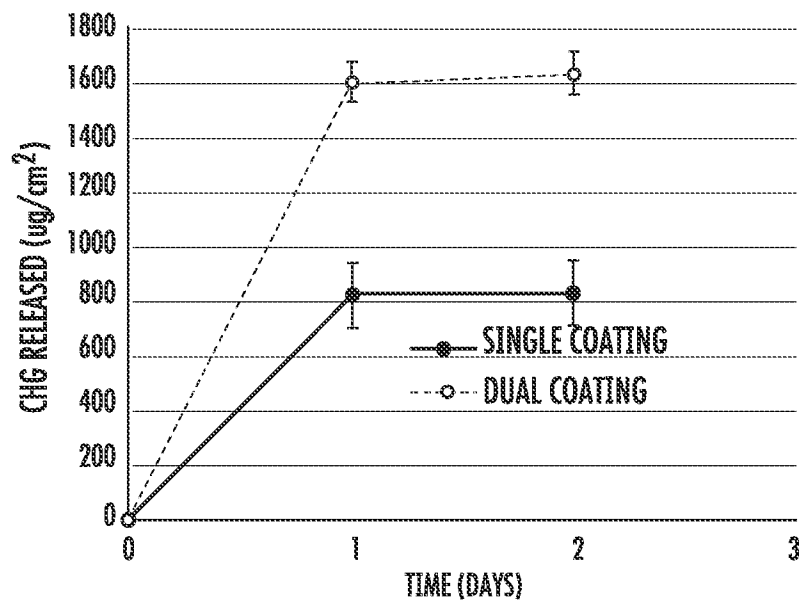


FIG. 19

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2021/061350

A. CLASSIFICATION OF SUBJECT MATTERINV. **A61L31/08** **A61L31/16**

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WILDING CHRIS P ET AL: "Can a Silver-Coated Arthrodesis Implant Provide a Viable Alternative to Above Knee Amputation in the Unsalvageable, Infected Total Knee Arthroplasty?", THE JOURNAL OF ARTHROPLASTY, ELSEVIER, AMSTERDAM, NL, vol. 31, no. 11, 22 April 2016 (2016-04-22), pages 2542-2547, XP029781352, ISSN: 0883-5403, DOI: 10.1016/J.ARTH.2016.04.009	15
A	page 2543 -----	1-14



Further documents are listed in the continuation of Box C.



See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

15 March 2022

Date of mailing of the international search report

23/03/2022

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2

NL - 2280 HV Rijswijk

Tel. (+31-70) 340-2040,

Fax: (+31-70) 340-3016

Authorized officer

Fort, Marianne