(12) STANDARD PATENT (11) Application No. AU 2013205285 B2
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Force module for class II and class III correction and releasable distal connector for force module

(51) International Patent Classification(s)
A61C 7/36 (2006.01) ***A61C 7/10*** (2006.01)

(21) Application No: **2013205285** (22) Date of Filing: **2013.04.17**

(30) Priority Data

(31) Number	(32) Date	(33) Country
61/768,687	**2013.02.25**	**US**

(43) Publication Date: **2014.09.11**
(43) Publication Journal Date: **2014.09.11**
(44) Accepted Journal Date: **2015.10.22**

(71) Applicant(s)
ULTRADENT PRODUCTS, INC.

(72) Inventor(s)
RADMALL, Colby M.;WOOD, V. Timothy

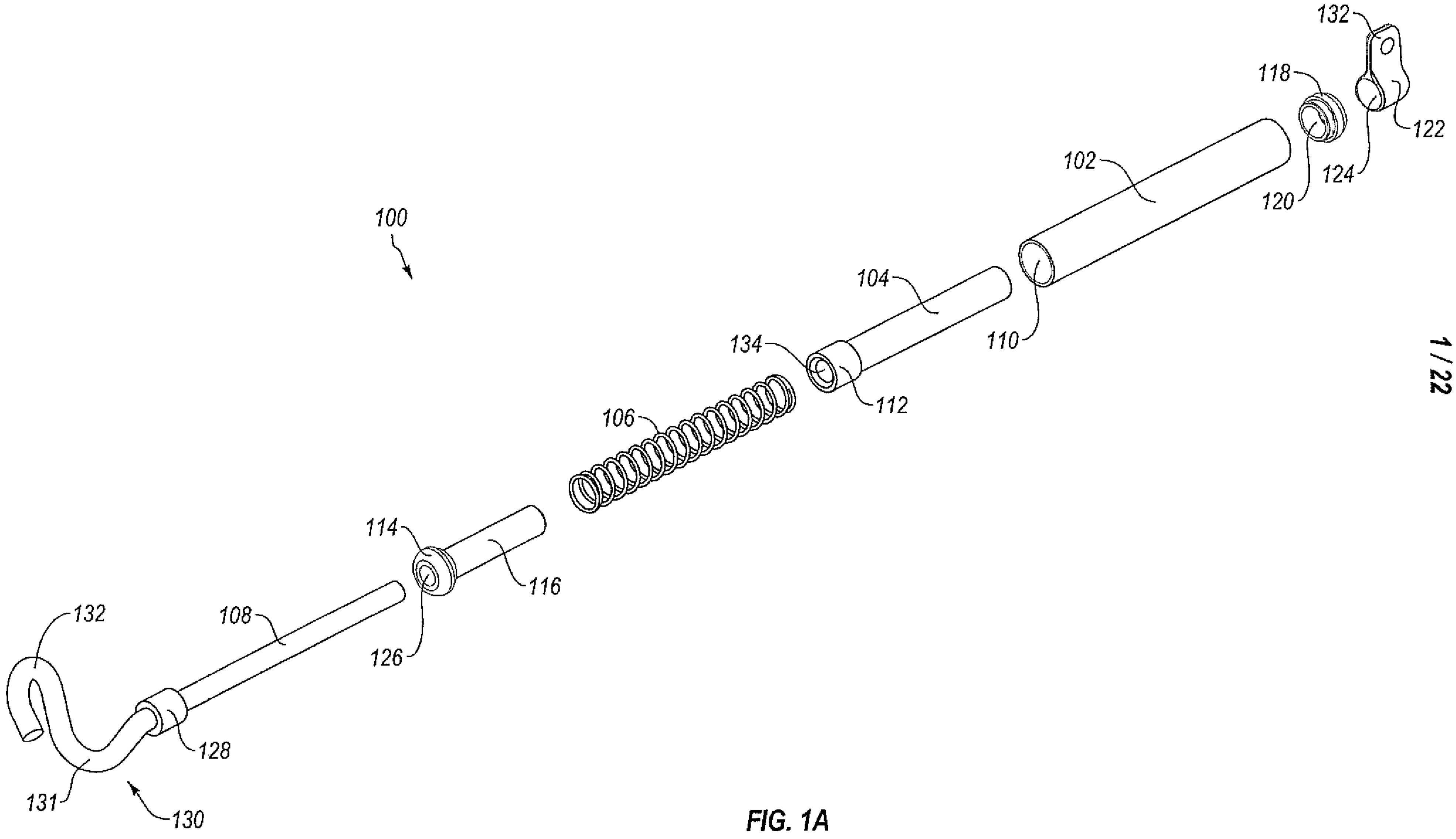
(74) Agent / Attorney
Griffith Hack, GPO Box 1285, Melbourne, VIC, 3001

(56) Related Art
US 5711667
US 4571178
US 7578672
US 6322357

2013205285 17 Apr 2013

ABSTRACT OF THE DISCLOSURE

Orthodontic force modules and assemblies for use in correcting class II and/or class III malocclusions include an elongate hollow outer body extending between proximal and distal ends, a plunger, spring, and push rod. The plunger and push rod are slidably received within different ends of the hollow outer body. The spring is positioned within the hollow outer body and provides an expansion force during use as the force modules or assemblies is compressed (*e.g.*, when closing the jaw). The expansion force provides a desired corrective force for corrective Class II and/or III malocclusions. The outer body, plunger, spring, and push rod can be configured in a telescoping relationship in order for the components to be telescopically compressed and expanded during use. The distal end can include a bendable pin or latch mechanism for attachment to a buccal tube. The push rod can include a hook, hole, or slot for attachment to an archwire.



100
102
104
106
108
110
112
114
116
118
120
122
124
126
128
130
131
132
132
134

FIG. 1A

2013205285 29 Sep 2015

FORCE MODULE FOR CLASS II AND CLASS III CORRECTION AND RELEASABLE DISTAL CONNECTOR FOR FORCE MODULE

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present invention is in the field of orthodontics, more particularly in the field of devices for correction of class II and/or class III malocclusions.

2. The Relevant Technology

Orthodontics is a specialized field of dentistry that involves the application of mechanical forces to urge poorly positioned or crooked teeth into correct alignment and orientation. Orthodontic procedures can be used for cosmetic enhancement of teeth, as well as medically necessary movement of teeth to correct overjets and/or overbites. For example, orthodontic treatment can improve the patient's occlusion, or enhanced spatial matching, of corresponding upper and lower teeth.

The most common form of orthodontic treatment involves the use of orthodontic brackets and wires, which together are commonly referred to as "braces." Orthodontic brackets are small slotted bodies configured for direct attachment to the patient's teeth or, alternatively, for attachment to bands which are, in turn, cemented or otherwise secured around the teeth. Once the brackets are affixed to the patient's teeth, such as by means of glue or cement, a curved arch wire is inserted into the bracket slots.

The brackets and the arch wire cooperate to guide corrective movement of the teeth into proper alignment. Typical corrective movements provided by orthodontic treatment can include lateral migration, torque, rotation, angulation, leveling, and other movements needed to correct the spacing and alignment of misaligned teeth.

The orthodontic treatment of some patients includes correction of the alignment of the upper dental arch relative to the lower dental arch. Certain patients have a condition referred to as a Class II malocclusion, which is a condition involving the posterior relationship of the mandible to the maxillae and in which the mesiobuccal cusp of the permanent maxillary first molar occludes mesial to the buccal groove of the permanent mandibular first molar (also known as retrognathia, or overjet). Other patients may have an opposite condition referred to as a Class III malocclusion wherein the lower dental arch is located forward of the upper dental arch when the jaws are closed (prognathia, or negative overjet).

Class II and Class III malocclusions may be corrected with the use of a force-applying system such as headgear, elastic, or an intraoral force module. Headgear is generally disfavored because it is bulky and often a source of embarrassment for the patient. Intraoral force modules have gained increasing acceptance as they can remain fixed in place over the course of treatment so as to typically not be removable by the patient, and are less aesthetically objectionable compared to traditional headgear.

Examples of intraoral force modules are disclosed in PCT Publication No. WO 2012/018648 and U.S. Patent Nos. 5,828,875; 5,738,514; 5,711,667; 5,562,445; 6,358,046; 6,162,051; 5,964,588; and 5,944,518, the disclosures of which are incorporated herein by reference. Although existing intraoral force modules represent an improvement over headgear, they still have deficiencies that provide opportunities for substantial improvement.

SUMMARY OF THE INVENTION

Disclosed herein are orthodontic force module assemblies and force modules for use in correcting class II and/or class III malocclusions. Also disclosed herein are selectively lockable and unlockable attachment devices for attaching an orthodontic force module to an orthodontic bracket, such as a buccal tube and an archwire or other orthodontic appliance. Associated methods of manufacture and use are also disclosed.

A first aspect of the invention provides an orthodontic force module assembly comprising a hollow outer body, a plunger (or plunger rod), a spring (such as a compressible coil spring, elastomeric device, or biasing member), and a push rod that, when assembled and placed in the mouth of a patient, cooperate together to provide forces for use in treating class II and/or class III malocclusions. The force module assembly can be provided disassembled, partially assembled, or fully assembled as desired. In addition, once assembled, it can be partially disassembled if desired to facilitate installation within the mouth of a patient.

The hollow outer body has a hollow interior that extends between a proximal end and a distal end. The outer body also includes a proximal opening at the proximal end and a distal opening at the distal end that provide access to the hollow interior. The plunger is slidably positionable through and within the distal opening and hollow interior of the outer body. When assembled during use, at least a proximal end of the plunger is positioned within the hollow interior of the outer body. According to one embodiment, the proximal end of the plunger is enlarged compared to a main shaft. A distal end cap having a distal passageway smaller than the proximal end of the plunger can be placed at the distal end of the outer body to confine the proximal end of the plunger within the hollow interior of the outer body when assembled. The main shaft of the plunger can be slidably disposed through the distal passageway of the distal end cap during use.

The spring is positionable within the hollow interior of the outer body and, when assembled during use, the spring bears against the plunger and can resist proximal movement of the plunger relative to the outer body. According to one embodiment, the spring bears against the proximal end of the plunger. As the plunger is moved proximally relative to the outer body, the spring can be compressed, which provides a countervailing force that urges the plunger distally during use. A proximal end cap having a proximal passageway smaller than the spring can be placed at the proximal end of the outer body in order to confine the spring within the hollow interior of the outer body when assembled.

The push rod is slidably positionable through the proximal passageway of the proximal end cap and into hollow interior of the outer body so that at least a distal end of the push rod is positioned within the hollow interior of the outer body during use. According to one embodiment, the push rod can move independently of and does not engage with the spring. This can permit free unbiased movement of the push rod in and out of the outer body during use. The push rod may include a detent, such as a stop, collar, protrusion, bend, or portion of varying diameter that cannot pass through the proximal passageway of the distal end cap. This can limit distal movement of the push rod relative to the outer body during use. In this way, further distal movement of the push rod can cause the outer body to move distally relative to the plunger and/or the plunger to move proximally relative to the outer body so as to compress the spring, which provides a countervailing force as noted above.

A second aspect of the invention provides an assembled orthodontic force module for use in correcting class II and/or class III malocclusions. The force module comprises a hollow outer body having a hollow interior extending between a proximal end and a distal end, a proximal opening at the proximal end, and a distal opening at the distal end. A plunger is at least partially slidably disposed through the distal opening and hollow interior of the outer body. A spring is positioned within the hollow interior of the outer body and bears against the plunger to resist proximal movement of the plunger relative to the outer body during use. A push rod is slidably positionable through the proximal opening and hollow interior of the outer body so that at least a distal end of the push rod being is positioned within the hollow interior of the outer body during use; and a detent disposed on the push rod that limits distal movement of the push rod relative to the outer body during use, wherein the outer body, plunger, spring, push rod, and detent cooperate so that, when the push rod has slidably advanced a predetermined distance through the hollow interior of the outer body during use, proximal movement of the plunger relative to the outer body causes compression of the spring, which provides a countervailing force that urges the plunger distally relative to the outer body. The outer body, plunger, spring, and push rod can have features and cooperate together as discussed above relative to the orthodontic force module assembly. A third aspect of the invention provides a method of assembling the orthodontic force module of the second aspect from the orthodontic force module assembly of the first aspect, the method comprising providing an orthodontic force module assembly of the first aspect; and assembling together the hollow outer body, the plunger, the spring, and the push rod to yield the orthodontic force module of the second aspect.

A forth of the invention provides a system comprising: an orthodontic force module or force module assembly of the first and second aspect; and a latch device for releasably attaching the orthodontic force module or force module assembly to an orthodontic buccal tube, arch wire or other orthodontic appliance, the latch device comprising: a rigid body comprising means for attaching the rigid body to an end of the orthodontic force module or force module assembly; a pin member pivotally attached to the rigid body and configured to be insertable into a passageway of an orthodontic buccal tube or other orthodontic appliance; and a latch member on the rigid body for selectively locking and unlocking the pin in a snap-fit relationship when selectively pivoted toward or away from the latch member.

A fifth aspect of the invention provides a method of releasably attaching an end of an orthodontic force module to a buccal tube or other orthodontic appliance, comprising; providing a buccal tube or other orthodontic appliance and a system of the forth aspect; inserting the pin member while in a released configuration relative to the latch member through a passageway of the buccal tube or other orthodontic appliance in order for a distal end of the pin member to extend beyond the passageway of the buccal tube or other orthodontic appliance; and inserting the distal end of the pin member into the latch member in order to lock the pin member relative to the rigid body.

According to other embodiments, orthodontic force modules and assemblies as disclosed herein can have other features, which can be provided separately or in combination. For example, the push rod can have a diameter so as to be slidably positionable through an axial passageway of the spring. The proximal end cap may further comprises a hollow distal extension that is positionable through the axial passageway of the spring in order to help support and prevent kinking during compression. The plunger can have an axial passageway configured to slidably receive a portion of the push rod as the spring is compressed beyond a certain point. In this way, the outer body, plunger, spring, and push rod can form a telescopic arrangement during use. The force module may be configured to provide a substantially smooth outer surface for patient comfort and that is substantially devoid of spaces or pockets where plaque or food debris can collect during use. The force module, including the outer body and plunger, can be low profile for reduced tissue damage.

One or more of the outer body, plunger, spring, and push rod may comprise at least one type of metal, such as stainless steel or other biologically compatible metal. According to another embodiment, at least some of the components of the orthodontic force modules may include a molded polymer material. To prevent fatigue and provide a spring that provides more reliable spring-back over time, the spring may comprise a Co-Cr-Ni alloy, such as Elgiloy®. According to one embodiment, the spring comprises a compressible coil spring.

The orthodontic force modules or assemblies as described herein may further include distal attachment means at or near a distal end of the plunger for attachment to a buccal tube or other orthodontic appliance and proximal attachment means disposed at or near a proximal end of the push rod for attachment to an arch wire and/or another appliance. The distal and proximal attachment means may comprise any attachment structures known and used in the art to attach orthodontic force modules to teeth. According to one embodiment, the distal attachment means may comprise a bendable wire or pin that can be inserted into an orthodontic headgear tube or buccal tube and bent around to fasten the plunger to the appliance.

The proximal attachment means at the proximal end of the push rod can include a hook (*e.g.*, a "shepherd's hook") or other appropriate device or shape for slidable or fixed attachment to an orthodontic archwire or bracket attached to upper or lower teeth during use. If included, the shepherd's hook preferably has a bend relative to the axis of the push rod shaft that is less than 120°, more preferably less than about 115°, and most preferably less than about 110° (*e.g.*, 105°). Alternatively, a rod with a hole or slot through a laterally extending flange can provide appropriate (*e.g.*, slidable) attachment to an orthodontic archwire.

The orthodontic force modules can be used to correct either Class II or Class III malocclusions depending on how they are attached to a person's teeth. To correct Class II malocclusions, the distal end of the plunger can be attached to a molar of the upper teeth (or maxilla), such as by a buccal tube or other orthodontic appliance, and the proximal end is attached at or near a canine of the lower teeth (or mandible), such as by an archwire. To correct Class III malocclusions, the attachment is reversed such that the distal end of the plunger can be attached to a molar of the lower teeth (or mandible), such as by a buccal tube or other orthodontic appliance, and the proximal end is attached at or near a canine of the upper teeth (or maxilla), such as by an archwire. Of course, the foregoing is merely suggestive and not a limiting description of how a practitioner may choose to use the orthodontic force modules.

Another example of force module attachment means includes a latch mechanism. The latch mechanism can include a rigid body with means for attaching the rigid body to an end of an orthodontic force module, a pin member pivotally attached to the body and configured to be insertable into an orthodontic buccal tube or other orthodontic appliance, and a latch member on the body for selectively locking and unlocking the pin in a snap-fit relationship when selectively pivoted toward or away from the latch member. According to one embodiment, the latch member comprises a pair of spaced apart prongs that temporarily spread apart when the pin member is inserted or removed from the latch member. This device may provide for an easier install and can provide an audible noise, which indicates that the clip as been attached or detached. The pin member advantageously can have a length that is greater than a length of a passageway through an orthodontic buccal tube or other orthodontic appliance so that a distal portion of the pin member can extend beyond the passageway when inserted through the passageway in order to permit the distal portion of the pin member to be received by the latch member. One or more of the rigid body, pin member, and latch member may comprise one or more types of metal.

Orthodontic force module assemblies as disclosed herein may optionally further include one or more orthodontic buccal tubes or other orthodontic appliance, which are configured for attachment to a tooth and include a passageway for receiving a corresponding pin or wire attached to a distal end of the plunger. Orthodontic force module assemblies as disclosed herein may also optionally further include one or more orthodontic arch wires configured for attachment to orthodontic brackets on a person's teeth or bands attached to a person's molars. The force modules can provide a smooth outer surface for increased comfort and hygiene.

These and other benefits, advantages and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the manner in which the above recited and other benefits, advantages and features of the invention are obtained, a more particular description of the invention briefly described above, by way of example only, will be rendered by reference to specific embodiments thereof which are illustrated in the appended non-

2013205285 29 Sep 2015

limiting drawings. The drawings depict only typical embodiments of the invention and are not therefore to be considered limiting of its scope.

Figure 1A is an exploded perspective view illustrating an exemplary embodiment of an exemplary orthodontic force module or force module assembly as disclosed herein;

Figure 1B is a perspective view illustrating the exemplary orthodontic force module or force module assembly of Figure 1A assembled together;

Figure 1C is a cutaway view of the hollow outer body of the assembled orthodontic force module or force module assembly of Figure 1B in order to illustrate a coil spring positioned within the hollow interior of the hollow outer body in extended condition;

Figures 2A-2C illustrate an alternative embodiment of a push rod for use in the disclosed force modules and force module assemblies having alternative structure or means for attachment to an archwire or other orthodontic appliance;

Figures 3A and 3B illustrate another embodiment of a push rod for use in the disclosed force modules and force module assemblies having alternative structure or means for attachment to an archwire or other orthodontic appliance;

Figure 4A is a perspective view illustrating the exemplary orthodontic force module or force module assembly of Figures 1A-1C with the push rod advanced distally relative to the outer body;

Figure 4B is a cutaway view of the hollow outer body of the orthodontic force module or force module assembly of Figure 4A in order to illustrate the coil spring positioned within the hollow interior of the hollow outer body in extended condition;

Figure 4C is a perspective view illustrating the exemplary orthodontic force module or force module assembly of Figures 1A-1C with the push rod advanced distally relative to the outer body and the plunger partially advanced proximally relative to the outer body;

Figure 4D is a cutaway view of the hollow outer body of the orthodontic force module or force module assembly of Figure 4C in order to illustrate the coil spring positioned within the hollow interior of the hollow outer body in a partially compressed condition;

Figure 4E is a perspective view illustrating the exemplary orthodontic force module or force module assembly of Figures 1A-1C with the push rod advanced distally relative to the outer body and the plunger fully advanced proximally relative to the outer body;

Figure 4F is a cutaway view of the hollow outer body of the orthodontic force module or force module assembly of Figure 4E in order to illustrate the coil spring positioned within the hollow interior of the hollow outer body in a substantially fully compressed condition;

Figures 5A-5E are perspective views illustrating an orthodontic force module or force module assembly in which a pin is used to attach an end of the force module or assembly to an orthodontic buccal tube;

Figures 6A-6D are perspective views illustrating an orthodontic force module or force module assembly with a latch mechanism used to attach an end of the force module or assembly to an orthodontic buccal tube; and

Figures 7A and 7B are perspective views of a patient's upper and lower jaws in which a force module or force module assembly as disclosed herein has been installed between the upper and lower jaws to correct a class II malocclusion.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Introduction

The present invention is directed to orthodontic force modules and force module assemblies for use in correcting class II and/or class III malocclusions. In one embodiment, the force module includes a hollow elongate body extending between a distal end and a proximal end; a plunger slidably positionable within the hollow elongate body; a spring (such as a compressible coil spring, elastomeric spring or spring like body, or other biasing member) that bears against the plunger to resist movement; and a push rod slidably positionable within the hollow elongate body.

When the orthodontic force module or assembly is attached between teeth of the upper and lower jaw (*e.g.*, for class II correction), a distal end of the plunger may be attached to a posterior tooth (*e.g.*, a molar) on the upper jaw (maxilla) while the proximal end of the push rod may be attached to a canine of the lower jaw, such as by means of archwire connection on mesial attachment (or mandible attachment). The spring provides an expansion force relative to the plunger and push rod in order for the orthodontic force module or assembly to apply corrective forces for correction of a class II correction.

The orthodontic force module of the assembly can be used to correct Class III malocclusions by configuring the force module so that the proximal end is attached to a canine of the upper jaw by an archwire connection on mesial attachment (or maxillary attachment) and the distal end is attached a posterior tooth (*e.g.*, a molar) of the lower jaw (or mandible).

II. Exemplary Orthodontic Force Modules and Assemblies

Reference is now made to the drawings. Figures 1A-1C illustrate an exemplary embodiment of an exemplary orthodontic force module or force module assembly as disclosed herein for use in correcting Class II and/or Class III malocclusions. Figure 1A is an exploded perspective view of an orthodonic force module or force module assembly 100. Force module or assembly 100 includes an elongate hollow outer body 102, a plunger 104 (which can be embodied or exemplified as a rod or plunger rod), a compressible coil spring 106, and a push rod 108 that are configured to fit together in a telescopic configuration when assembled during use, as shown in Figures 1B and 1C.

Returning to Figure 1A, elongate hollow outer body 102 extends between proximal and distal ends and includes a hollow interior 110 that opens at proximal and distal ends of outer body 102. Outer body 102 is shown having a substantially circular cross section so as to substantially cylindrical but could have other cross sectional shapes as desired (*e.g.*, oval, square, triangular, etc.). Hollow interior 110 of outer body 102 has a diameter sufficiently large so that at least a portion of plunger 104, coil spring 106, and push rod 108 can be positioned within hollow interior 110 of outer body 102 when assembled together.

According to one embodiment, plunger 104 further includes an enlarged proximal end portion 112 that is enlarged compared to the shaft of plunger 104 extending distally from proximal end portion 112. A distal end cap 118 having a distal passageway 120 attaches to, or is integrally formed together as a single piece with, the distal end of outer body 102 and cooperates with plunger 104 when assembled to permit slidable movement of plunger 104 relative to outer body 102 while confining proximal end portion 112 within the hollow interior 110 of outer body 102 when assembled. In particular, distal passageway 120 is advantageously smaller than enlarged proximal end portion 112 so as to block passage of proximal end portion 112 through distal passageway 120 but large enough to receive and permit slidable movement of the shaft of plunger 104 when assembled and during use.

A proximal end cap 114, which may have a hollow distal extension 116, and a proximal passageway 126 attaches to the proximal end of outer body 102 in order to confine coil spring 106 within hollow interior 110 of outer body 102 when assembled. Hollow distal extension 116 is inserted through a proximal section of coil spring 106 when assembled, which may support and prevent kinking of coil spring 106 when compressed during used.

Proximal end cap 114 also cooperates with push rod 108 when assembled to permit slidable movement of push rod 108 relative to outer body 102 during use. The distal end and shaft of push rod 108 are smaller than proximal passageway 126 of proximal end cap 114 so as to permit slidable movement of push rod 108 relative to outer body 102. Push rod 108 further includes a collar 128 or other detent member (*e.g.*, a protrusion or bend) that limits distal movement of push rod 108 relative to outer body 102. In this embodiment, push rod 108 does not engage with and therefore moves without being directly biased by coil spring 106. In this way, push rod 108 can freely slide proximally and distally relative to outer body 102 until collar 128 or another detent member makes abutment with proximal end cap 114 and/or the proximal end of outer body 102. The distal end of push rod 108 can also be freely inserted through and withdrawn from proximal passageway 126 of proximal end cap 114. Nevertheless, push rod 108 may optionally include an enlarged distal end (not shown) to limit proximal movement and withdrawal of push rod 108 from hollow interior of outer body 102. Distal movement of push rod 108 causes the distal end of push rod 108 to extend beyond distal extension 116 of proximal end cap 114, through an axial passageway through coil spring 106, and approach proximal end 112 of plunger 104. The push rod 108 and plunger 104 are brought closer together as the coil spring 106 is compressed. According to the embodiment shown in Figure 1A, plunger 104 further includes a hollow passageway 134 therethrough that permits push rod 108 to be telescopically received within plunger 104 during use to permit further compression of force module or assembly 100 depending on the force applied by the patient's jaw relative to the counter force exerted by the coil spring 106.

Force module or assembly 100 further includes a hook 130 or other attachment device extending from a proximal end of push rod 108 for use in attaching push rod 108 to an orthodontic bracket or archwire during use in correcting a Class II and/or Class III malocclusion. An end piece 122 configured to fit onto the distal end of plunger 104 carries a flange 132 or other means for use in attaching the plunger 104 to an orthodontic bracket during use. In this embodiment, end piece 122 has a recess 124 therethrough that is sized and configured to fit over the distal end of plunger 104. End piece 122 also includes a passage that permits push rod 108 to pass therethrough.

As illustrated in Figure 1A, hook 130 is a "shepherd's hook" having a main curved section 131 extending beyond collar 128 and having a bend angle, or angle of curvature, relative to the longitudinal axis of push rod 108. The angle of the main curved section 131 of hook 130 can have an angle that is less than 120°, less than about 117.5°, less than about 115°, less than about 110°, less than about 105°, or less than about 100°. Hook 130 can further include an auxiliary bend 132, which can wrap around to as to lock the hook in a slidable configuration relative to an archwire attached to a person's teeth during use. In this configuration, the orthodontic force module can be used to correct both Class II and III malocclusions depending on how the device is attached to the person's teeth.

Figures 1B and 1C are perspective views that show exemplary orthodontic force module or force module assembly 100 of Figure 1A assembled together. Figure 1C further shows a cutaway view of outer body 102 in order to reveal coil spring 106 in extended condition within hollow interior 110 of outer body 102. As shown in Figures 1B and 1C, outer body 102, plunger 104, compressible coil spring 106, and push rod 108 fit together in a telescopic configuration when assembled. In the configuration shown in Figures 1B and 1A, a portion of push rod 108 is inserted partially through proximal passageway 126 of proximal end cap 114.

Push rod 108 is able to slide within proximal passageway 126 and hollow interior 110 without interference or force being applied by coil spring 106 until collar 128 abuts proximal end cap 114. In this way, slidable movement of push rod 108 relative to outer body 102 does not cause force module or assembly 100 to exert significant orthodontic forces until collar 128 abuts proximal end cap 114 and coil spring 106 is caused to become compressed by cooperative interaction between collar 128, proximal end cap 114, coil spring 106, and proximal end 112 of plunger 104. In addition, push rod 108 can be withdrawn entirely from proximal passageway 126 of end cap 114 and hollow interior 110 of outer body 102. This can facilitate installation to and/or removal of orthodontic force module or force module assembly 100 from a jaw of a patient.

Figures 2A-2C illustrate an alternative embodiment of a push rod 208 for use in the disclosed force modules and force module assemblies having alternative structure or means for attachment to an archwire or other orthodontic appliance. A collar or detent 228 can be included to limit distal movement of push rod 208. As shown, rather than including a hook, such as a shepherd's hook 130 as in push rod 108, push rod 208 includes a laterally extending flange 234 having a hole 236 therethrough large enough to permit passage of an archwire. Hole 236 can have any desired or appropriate angle, such as a hole defined by walls that are essentially parallel to the longitudinal axis of push rod 208, as illustrated in Figure 2B, or a hole defined by walls that are angled relative to the longitudinal axis of push rod 208, as illustrated in Figure 2C. According to one embodiment, the angle α of hole 236 can be selected depending on the angle of the push rod 208 relative to an archwire on a patient's teeth when the force module is in use. For example, if a hole that is parallel to the axis of push rod 208 is understood to be 0°, an angled hole 236 will typically be greater than 0° and less than 90° and can be in a range of about 5° to about 90°, or about 7.5° to about 80°, or about 10° to about 70°, or about 15° to about 65°, or about 20° to about 60°.

Figures 3A and 3B illustrate another alternative embodiment of a push rod 308 for use in the disclosed force modules and force module assemblies having alternative structure or means for attachment to an archwire or other orthodontic appliance. A collar or detent 328 can be included to limit distal movement of push rod 308. As shown, rather than including a hook, such as shepherd's hook 130 as in push rod 108 or a flange with a hole as in push rod 208, push rod 308 includes a laterally extending flange or extension 344 having a slot 346 therethrough large enough to permit passage of an archwire therethrough. Slot 346 can have any desired or appropriate angle relative to the longitudinal axis of push rod 308, as illustrated in Figure 3B. According to one embodiment, the angle α of slot 146 can be selected depending on the angle of the push rod 308 relative to an archwire on a patient's teeth when the force module is in use. For example, if a slot that is parallel to the axis of push rod 308 is understood to be 0°, an angled slot 346 will typically be greater than 0° and less than 90° and can be in a range of about 5° to about 90°, or about 7.5° to about 80°, or about 10° to about 70°, or about 15° to about 65°, or about 20° to about 60°.

Figures 4A-F illustrate an exemplary orthodontic force module or force module assembly 400 similar to force module or force module assembly 100 illustrated in Figures 1A-1C in various positions and stages of compression as push rod 408 advances distally relative to outer body 402 and plunger 404 advances proximally relative to outer body 402.

Figures 4A and 4B show a configuration of orthodontic force module or force module assembly 400 in which push rod 408 has been fully inserted distally relative to outer body 402 so that collar 428 makes abutment with proximal end cap 414. As best seen in Figure 4B, coil spring 406 remains in an extended configuration within outer body 402 because distal movement of push rod 408 relative to outer body 402 does not by itself cause coil spring 406 to be compressed (or become more compressed if coil spring 406 is already partially compressed when in the fully extended configuration within outer body 402) until collar 428 makes abutment with proximal end cap 414. Push rod 408 is shown passed through distal extension 416 of proximal end cap 414 so that the distal end of push rod 408 extends through an axial passageway through coil spring 406. As will be shown below, further compression of force module or force module assembly 400 and coil spring 406 causes the distal end of push rod 408 to be telescopically received within passageway 434 of plunger 404.

Figures 4C and 4D show a configuration of orthodontic force module or force module assembly 400 in which push rod 408 has been fully inserted distally relative to

2013205285 29 Sep 2015

outer body 402 so that collar 428 makes abutment with proximal end cap 414 and so that, in addition, plunger 404 has been partially moved proximally relative to outer body 402. As best seen in Figure 4D, coil spring 406 is partially compressed within outer body 402 between proximal end cap 414 and proximal end portion 412 of plunger 404. This partial compression (or further compression) of coil spring 406 results in the exertion of a countervailing force against proximal end cap 414 and proximal end portion 412 of plunger 404 that resists proximal movement of plunger relative to outer body 402 and urges plunger 404 distally relative to outer body 402. The force exerted by coil spring 406 against proximal end portion 412 of plunger 404 and proximal end cap 414 can vary depending on the strength of the spring 406 and the amount to which it has been compressed. The force applied by the coil spring 406 is directly related (or essentially equal) to the forces applied by orthodontic force module or force module assembly 400, through the plunger 404 and push rod 408, to the teeth to which they are attached.

Figures 4E and 4F show a configuration of orthodontic force module or force module assembly 400 in which push rod 408 has been fully inserted distally relative to outer body 402 so that collar 428 makes abutment with proximal end cap 414 and so that, in addition, plunger 404 has been fully moved proximally relative to outer body 402 so that end piece 422 makes abutment with distal end cap 418 and/or the distal end of outer body 402. Alternatively, end piece 422 can stop short of end cap 418 (*e.g.*, so as to avoid overstressing the joint between end piece 422 and plunger 404) by abutment of distal extension 416 of end cap 414 to proximal end 412 of plunger 404 (*e.g.*, so that distal extension 416 has a length and diameter so as to abut rather than pass through or terminate shy of proximal end 412).

As best seen in Figure 4F, coil spring 406 is highly (or maximally) compressed within outer body 402 between proximal end cap 414 and proximal end portion 412 of plunger 404. Depending on the relative lengths of outer body 402, plunger 404, and push rod 408, end piece 422 may include a distal recess therethrough for permitting passage of the distal end of push rod 408 therethrough. In actual use, the coil spring 406 may or may not become fully compressed such that the amount of compression shown in Figures 4E and 4F may be illustrative only. The high compression of coil spring 406 results in maximum countervailing force being exerted against proximal end cap 414 and proximal end portion 412 of plunger 404 that urges plunger 404 distally relative to outer body 402. As before, the force exerted by coil spring 406 against proximal end portion 412 of plunger 404 and proximal end cap 414 can vary depending on the strength of the spring 406 and the amount to which it has been compressed. In addition, the expansion force applied by the coil spring 406 is directly related (or essentially equal) to the forces applied by orthodontic force module or force module assembly 400, through the plunger 404 and push rod 408, to the teeth to which they are attached.

Figures 5A-5E are perspective views illustrating an orthodontic force module or force module assembly as disclosed herein in which a pin attachment member is used to attach an end of the force module or assembly to an orthodontic buccal tube. As shown in Figure 5A, an orthodontic force module or force module assembly 500 includes an outer body 502, a plunger 504, a coil spring (not shown) within the hollow interior of outer body 502, and a push rod 508. These may cooperate in the same or different manner as in the embodiment shown in Figures 1-4.

Force module or assembly 500 further includes an end piece 522 positioned at the distal end of plunger 504 with a flange 532 or other means for use in attaching plunger 504 to an orthodontic bracket during use. In this embodiment, a pin 534 is used to attach plunger 504 to buccal tube 550. Pin 534 includes a distal end 536 for insertion through a longitudinal passageway 552 through a tube 554 of buccal tube 550. Pin 534 also includes a proximal end 538 that is pivotally attached to flange. In the illustrated embodiment, proximal end 538 is shown positioned through a corresponding hole in flange 532. Proximal end 538 of pin 534 may include an enlarged head on a proximal side of flange 532 to prevent withdrawal of pin 534 from the hole in flange 532. Proximal end 538 of pin 534 as shown also includes a bend on a distal side of flange 532 to prevent further insertion of pin 534 into the hole in flange 532. In this way, the bend and the enlarged head in proximal end 538 of pin cooperate with flange 532 to retain pin 534 in a desired, non-removable, yet pivoting attachment to flange 532. The pivoting aspect of pin 534 permits rotational movement of force module or assembly 500 relative to buccal tube 550 during use.

As shown in Figure 5B, pin 534 is inserted through longitudinal passageway 552 of tube 554 until distal end 536 emerges through and beyond tube 534. Thereafter, and as shown in Figure 5C, distal end 536 of pin 534 is bent around tube 534 in order to securely attach pin 534 to buccal tube 550. To remove force module or assembly 500 from buccal tube 550, distal end 536 is bent back into a substantially straight configuration and/or other position sufficient to permit withdrawal of distal end 536 of pin 534 from tube 534.

Figures 5D and 5E show force module or assembly 500 being attached to buccal tube 550 when attached to a patient's tooth 560. As shown in Figure 5D, distal end 536 of pin 534 is inserted through the tube of buccal tube 550. The pivoting attachment of proximal end 538 of pin 534 permits rotation of force module or assembly 500 during placement so as to facilitate the procedure. As shown in Figure 5E, plunger 504 of force module or assembly 500 is secured to buccal tube 550 by bending distal end 536 of pin 534 around the tube of buccal tube 550.

III. <u>Exemplary Latch Mechanism For Selective Attachment And Release Of An Orthodontic Force Module Or Assembly To A Buccal Tube</u>

Figures 6A-6D are illustrate an exemplary latch mechanism used to selectively attach and detach an end of an orthodontic force module or force module assembly 600 to a buccal tube 650. As shown in Figure 6A, force module or assembly 600 includes an outer body 602, a plunger 604, a coil spring (not shown) within the hollow interior of outer body 602, and a push rod 608. A hook 630 extending from a proximal end of push rod 608 and a flange 634 extending from a distal end of plunger 604 are used in attaching force module or assembly 600 to a patient's jaw during a procedure to correct a Class II or Class III malocclusion.

As further illustrated, the latch mechanism includes a main latch body 670 attached to flange 634 as shown by a first pivot connection or structure 672. A pivot pin 674 is pivotally connected to latch body 670 by a second pivot connection or structure 676. A latch member 678 includes a pair of spaced apart prongs with a space therebetween. Alternatively, the latch member can be a single prong or clip. Latch member 678 permits pivot pin 674 to be received and selectively locked between the prongs of latch member 678 (or adjacent to single prong clip) in a snap-fit relationship when rotated toward latch member 678, as illustrated in Figure 6A. Pivot Pin 674 can be selectively unlocked from latch member 678 when sufficient force is applied to overcome the snap-fit relationship and pivot pin 674 is rotated away from latch member 678.

Figures 6B-6D illustrate the latch mechanism being used to selectively lock force module or assembly 600 to buccal tube 650 attached to a tooth 660. As illustrated in Figure 6B, a distal end of pivot pin 674 is positioned near a proximal opening or passageway 652 through a tube 654 of buccal tube 650. First pivot connection or structure 672 and/or second pivot connection or structure 676 permit force module or assembly 600 to be placed in a desired configuration relative to the latch mechanism during the installation process. As illustrated in Figure 6C, the distal end of pivot pin 674 is inserted through and emerges beyond tube 654. Thereafter, second pivot connection or structure 676 permits body 670 of the latch mechanism to be rotated toward pivot pin 674 in order for latch member 678 to be brought closer to the distal end of pivot pin 674. As illustrated in Figure 6D, further rotation of body 670 toward pivot pin 674 brings latch member 678 into locked engagement with the distal end of pivot pin 674. Once force module or assembly 600 has been attached to buccal tube 650, it may be attached to a tooth on an opposing jaw side by means of hook 630 at the proximal end of push rod 608.

As illustrated in Figure 6B, buccal tube 650 can include an auxiliary hook 656 and latch mechanism can also include an auxiliary hook 680 for attachment of elastic members as desired to effect a desired orthodontic treatment.

Figures 7A and 7B illustrate an orthodontic force module or force module assembly 700 as disclosed herein attached between a patient's upper and lower jaws to correct a class II malocclusion. A distal end of force module or assembly 700 is attached to a buccal tube 750 on a posterior tooth (*e.g.*, molar) of a patient's upper jaw. A proximal end of force module or assembly 700 is attached to a bracket or archwire on an anterior tooth (*e.g.*, canine) of a patient's lower jaw.

Figure 7A illustrates the configuration of force module or assembly 700 when the patient's jaws are fully closed, wherein force module or assembly 700 is at maximum compression. In this configuration, collar 728 bears against outer body 702 and plunger 704 is advanced proximally within outer body. This causes a compressible spring (not shown) within outer body 702 of force module or assembly 700 to exert a force that urges the teeth of the upper jaw and/or lower jaw of the patient to move relative to each other in order to correct a Class II malocclusion. In this example, force module or assembly 700 exerts a force that corrects an overjet of the upper jaw relative to the lower jaw.

Figure 7B illustrates the configuration of force module or assembly 700 when the patient's jaws are in an open position. In this configuration of force module or assembly 700, push rod 708 is in an extended position such that collar 728 of push rod 708 does not bear against the proximal end of outer body 702. In this configuration, the compressible spring within outer body 702 of force module or assembly 700 does not exert a force to the dental arches of the upper jaw and/or lower jaw of the patient. Corrective forces progressively exerted on the upper and lower jaw as the patient brings the upper and lower jaws together.

IV. Exemplary Materials Used To Manufacture An Orthodontic Force Module Or Assembly And Latch Mechanism

The orthodontic force modules and assemblies of the present invention may be formed from any suitable material(s), such as one or more metals or allows and/or polymers. According to one embodiment, at least the outer body, plunger and push rod can be made from stainless steel (*e.g.*, 316L) or other biocompatible metal or alloy. According to another embodiment, at least some of the components of the orthodontic force modules and assemblies may include a molded polymer material.

To prevent fatigue and provide a spring that provides more reliable spring-back action and consistent corrective forces over time, the spring may comprise a Co-Cr-Ni alloy, such as Elgiloy®. According to one embodiment, the spring comprises a compressible coil spring.

The components of the orthodontic force modules and assemblies may be manufactured using any appropriate molding and/or machining process known in the art and that is suitable for the particular material being acted upon. For example, at least some of the components may be made by machining, casting, injection molding, metal injection molding (MIM), additive manufacturing processes, drawing and the like.

Machining at least the elongate body may be advantageous as better accuracy of the component dimensions may be possible as compared to alternative techniques (*e.g.*, drawing). Such improved accuracy provides for better fit as well as improved wall thickness. Miniaturization of the components, increased strength, and accurate fit are possible by machining. For example, a machined elongate body may include a wall thickness substantially greater than that of existing devices formed by drawing.

Furthermore, the overall dimensions of machined devices, particularly width, are significantly less than existing devices. This provides a device having significantly lower profile compared to existing force modules, which increases comfort and reduces contact with soft oral tissue during use. Moreover, machining can provide enhanced durability compared to devices made by metal injection molding.

It will also be appreciated that the present claimed invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word “comprise” or variations such as “comprises” or “comprising” is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

It is to be understood that, if any prior art publication is referred to herein, such reference does not constitute an admission that the publication forms a part of the common general knowledge in the art, in Australia or any other country.

2013205285 29 Sep 2015

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An orthodontic force module assembly for use in correcting class II and/or class III malocclusions, comprising:

a hollow outer body having a hollow interior extending between a proximal end and a distal end, a proximal opening at the proximal end, and a distal opening at the distal end;

a plunger slidably positionable through the distal opening and hollow interior of the outer body, at least a proximal end of the plunger being positioned within the hollow interior of the outer body during use;

a spring positionable within the hollow interior of the outer body, the spring configured to bear against the plunger and resist proximal movement of the plunger relative to the outer body during use;

a push rod slidably positionable through the proximal opening and hollow interior of the outer body, at least a distal end of the push rod being positioned within the hollow interior of the outer body during use; and

a detent disposed on the push rod that limits distal movement of the push rod relative to the outer body during use,

wherein the outer body, plunger, spring, push rod, and detent cooperate so that, when the push rod has slidably advanced a predetermined distance through the hollow interior of the outer body during use, proximal movement of the plunger relative to the outer body causes compression of the spring, which provides a countervailing force that urges the plunger distally relative to the outer body.

2. An orthodontic force module for use in correcting class II and/or class III malocclusions, comprising:

a hollow outer body having a hollow interior extending between a proximal end and a distal end, a proximal opening at the proximal end, and a distal opening at the distal end;

a plunger at least partially slidably disposed through the distal opening and hollow interior of the outer body;

a spring positioned within the hollow interior of the outer body, the spring bearing against the plunger and resisting distal movement of the plunger relative to the outer body during use;

a push rod slidably positionable through the proximal opening and hollow interior of the outer body, at least a distal end of the push rod being positioned within the hollow interior of the outer body during use; and

a detent disposed on the push rod that limits distal movement of the push rod relative to the outer body during use,

wherein the outer body, plunger, spring, push rod, and detent cooperate so that, when the push rod has slidably advanced a predetermined distance through the hollow interior of the outer body during use, proximal movement of the plunger relative to the outer body causes compression of the spring, which provides a countervailing force that urges the plunger distally relative to the outer body.

3. An orthodontic force module or force module assembly as in claim 1 or 2, wherein the push rod has a diameter so as to be slidably positionable through an axial passageway of the spring.

4. An orthodontic force module or force module assembly as in claim 3, wherein the plunger has an axial passageway configured to slidably receive a portion of the push rod as the spring is compressed.

5. An orthodontic force module or force module assembly as in claim 4, wherein the outer body, plunger, spring, and push rod form a telescopic arrangement during use.

6. An orthodontic force module or force module assembly as in any one of claims 1 to 5, further comprising a distal end cap at the distal end of the outer body and a proximal end cap at the proximal end of the outer body, the distal and proximal end caps confining the spring within the hollow interior of the outer body during use.

7. An orthodontic force module or force module assembly as in claim 6, wherein the plunger further comprises an enlarged proximal end, the distal end cap providing a distal passageway that is smaller than the enlarged proximal end of the plunger so as to confine the enlarged proximal end of the plunger within the hollow interior of the outer

body during use while permitting a remaining portion of the plunger to slidable move through the distal passageway of the distal end cap.

8. An orthodontic force module or force module assembly as in claim 6, the proximal end cap providing a proximal passageway that is smaller than the detent on the push rod so as to prevent passage of the detent though the proximal passageway while permitting a remaining portion of the push rod to slidable move through the proximal passageway of the proximal end cap.

9. An orthodontic force module or force module assembly as in claim 8, the proximal end cap further comprising a hollow distal extension that is positionable through an axial passageway of the spring.

10. An orthodontic force module or force module assembly as in any one of claims 1 to 9, further comprising distal attachment means at or near a distal end of the plunger for attachment to a bracket and/or arch wire and proximal attachment means disposed at or near a proximal end of the push rod for attachment to an arch wire and/or a bracket.

11. An orthodontic force module or force module assembly as in claim 10, wherein the proximal attachment means comprises a hook.

12. An orthodontic force module or force module assembly as in claim 10, wherein the hook comprises a shepherd's hook having a main bend with an angle relative to a longitudinal axis of the push rod of less than 120°.

13. An orthodontic force module or force module assembly as in any one of claims 10 to 12, wherein the proximal attachment means comprises a flange extending laterally from an end of the push rod and a hole or slot through the flange that permits passage of an archwire therethrough.

14. An orthodontic force module or force module assembly as in claim 13, wherein the hole or slot has an angle relative to a longitudinal axis of the push rod in a range of about 5° to about 90°.

15. An orthodontic force module or force module assembly as in claim 14, wherein the hole or slot has an angle relative to a longitudinal axis of the push rod in a range of about 10° to about 70°.

16. An orthodontic force module or force module assembly as in claim 15, wherein the hole or slot has an angle relative to a longitudinal axis of the push rod in a range of about 20° to about 60°.

17. An orthodontic force module or force module assembly as in any one of claims 10 to 16, wherein the distal attachment means comprises a flange at or near a distal end of the plunger and a bendable wire extending from the flange and insertable into a buccal tube.

18. An orthodontic force module or force module assembly as in any one of claims 10 to 16 wherein the distal attachment means comprises:

a pin member pivotally attached to an attachment body and that is insertable into a passageway of a buccal tube or other orthodontic appliance; and

a latch member on the attachment body for selectively locking and unlocking the pin in a snap-fit relationship.

19. An orthodontic force module or assembly as in any one of claims 1 to 18, wherein the outer body has a cross section that is substantially circular.

20. An orthodontic force module or force module assembly as in any one of claims 1 to 19, wherein the outer body, plunger, spring, and push rod comprise at least one type of metal.

21. An orthodontic force module or force module assembly as in claim 20, wherein the compressible spring comprises Co-Cr-Ni alloy.

22. An orthodontic force module or force module assembly as in any one of claims 1 to 21, wherein the spring is a compressible coil spring.

2013205285 29 Sep 2015

23. An orthodontic force module assembly as in claim 1, wherein the force module provides a substantially smooth outer surface substantially devoid of spaces or pockets where plaque or food debris can collect during use.

24. An orthodontic force module as in claim 2, further comprising an orthodontic buccal tube or other orthodontic appliance configured for attachment to a tooth and a passageway for receiving a corresponding pin or wire attached to a distal end of the plunger.

25. An orthodontic force module as in claim 2, further comprising an orthodontic arch wire configured for attachment to orthodontic brackets on a person's teeth or a band on a person's molar for attachment to a proximal end of the push rod.

26. A method of assembling the orthodontic force module of claim 2 from the orthodontic force module assembly of claim 1, the method comprising providing an orthodontic force module assembly as in claim 1; and assembling together the hollow outer body, the plunger, the spring, and the push rod to yield the orthodontic force module as in claim 2.

27. A system comprising:

an orthodontic force module or force module assembly as in claim 1 or 2; and

a latch device for releasably attaching the orthodontic force module or force module assembly to an orthodontic buccal tube, arch wire or other orthodontic appliance, the latch device comprising:

a rigid body comprising means for attaching the rigid body to an end of the orthodontic force module or force module assembly;

a pin member pivotally attached to the rigid body and configured to be insertable into a passageway of an orthodontic buccal tube or other orthodontic appliance; and

a latch member on the rigid body for selectively locking and unlocking the pin in a snap-fit relationship when selectively pivoted toward or away from the latch member.

28. A system as in claim 27, wherein the means for attaching the rigid body to an end of the orthodontic force module or force module assembly comprises at least one of a protrusion or a recess.

2013205285 29 Sep 2015

29. A system as in claim 27 or 28, wherein the rigid body, pin member, and latch member comprises one or more types of metal.

30. A system as in any one of claims 27 to 29, wherein the latch member comprises a pair of spaced apart prongs that temporarily spread apart when the pin member is inserted or removed from the latch member.

31. A system as in any one of claims 27 to 30, wherein the pin member has a length that is greater than a length of a passageway through an orthodontic buccal tube or other orthodontic appliance so that a distal portion of the pin member can extend beyond the passageway when inserted through the passageway in order to permit the distal portion of the pin member to be received by the latch member.

32. A method of releasably attaching an end of an orthodontic force module to a buccal tube or other orthodontic appliance, comprising;

providing a buccal tube or other orthodontic appliance and a system as in any one of claims 27 to 31;

inserting the pin member while in a released configuration relative to the latch member through a passageway of the buccal tube or other orthodontic appliance in order for a distal end of the pin member to extend beyond the passageway of the buccal tube or other orthodontic appliance; and

inserting the distal end of the pin member into the latch member in order to lock the pin member relative to the rigid body.

33. A method as in claim 32, further comprising unlocking the distal end of the pin member from the latch member and removing the pin member from the passageway of the buccal tube or other orthodontic appliance.

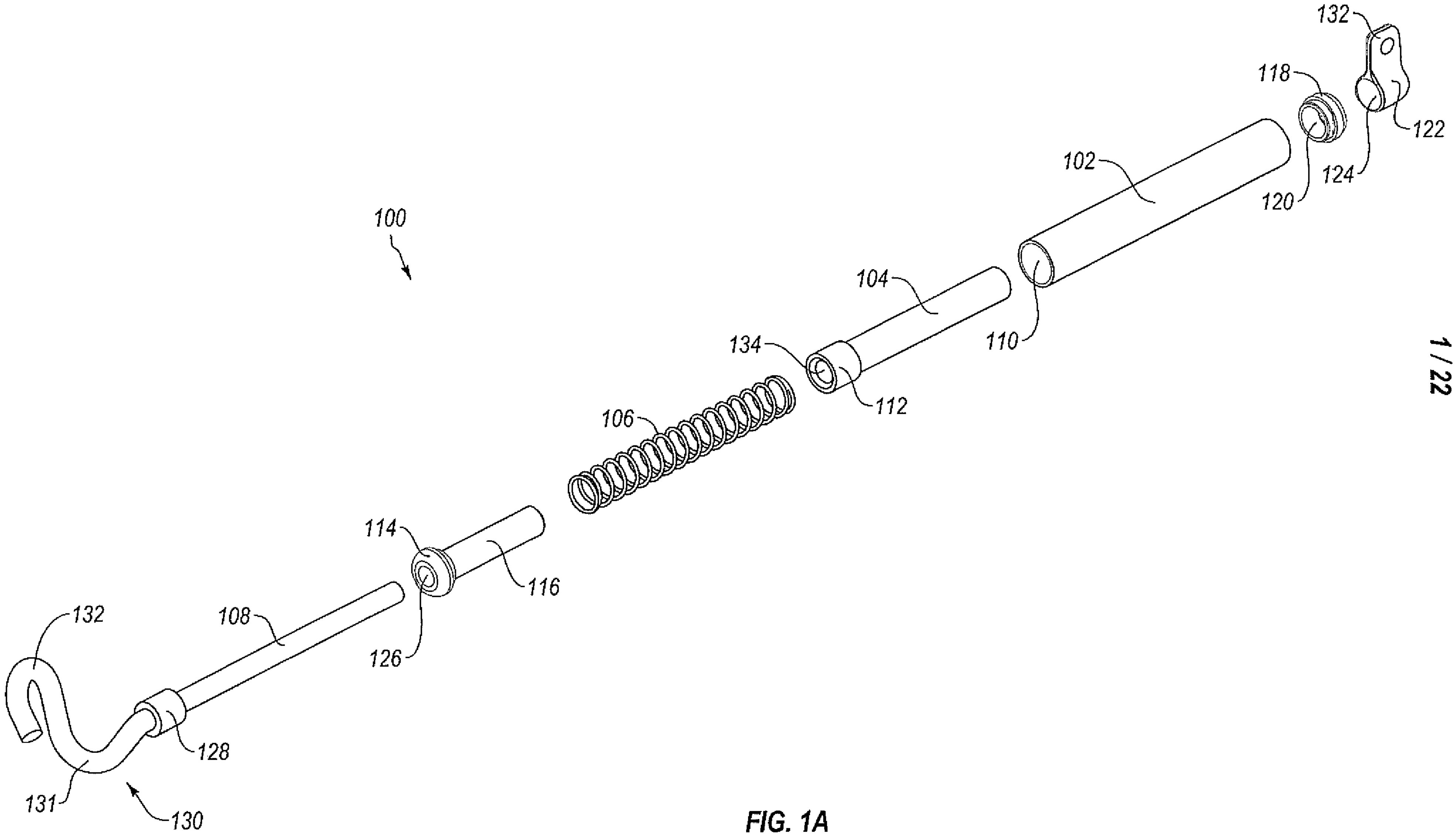

100
102
104
106
108
110
112
114
116
118
120
122
124
126
128
130
131
132
134

FIG. 1A

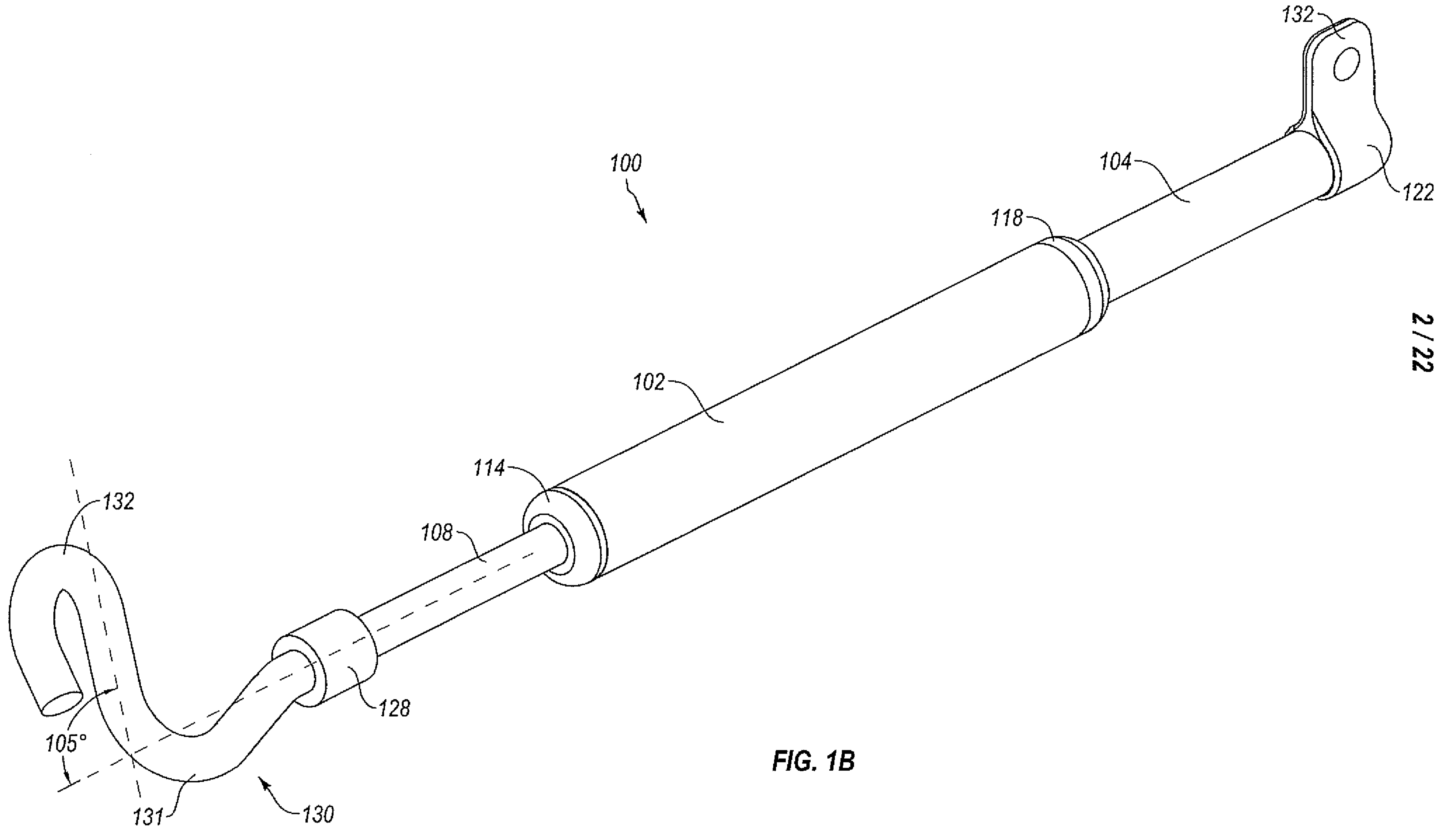


FIG. 1B

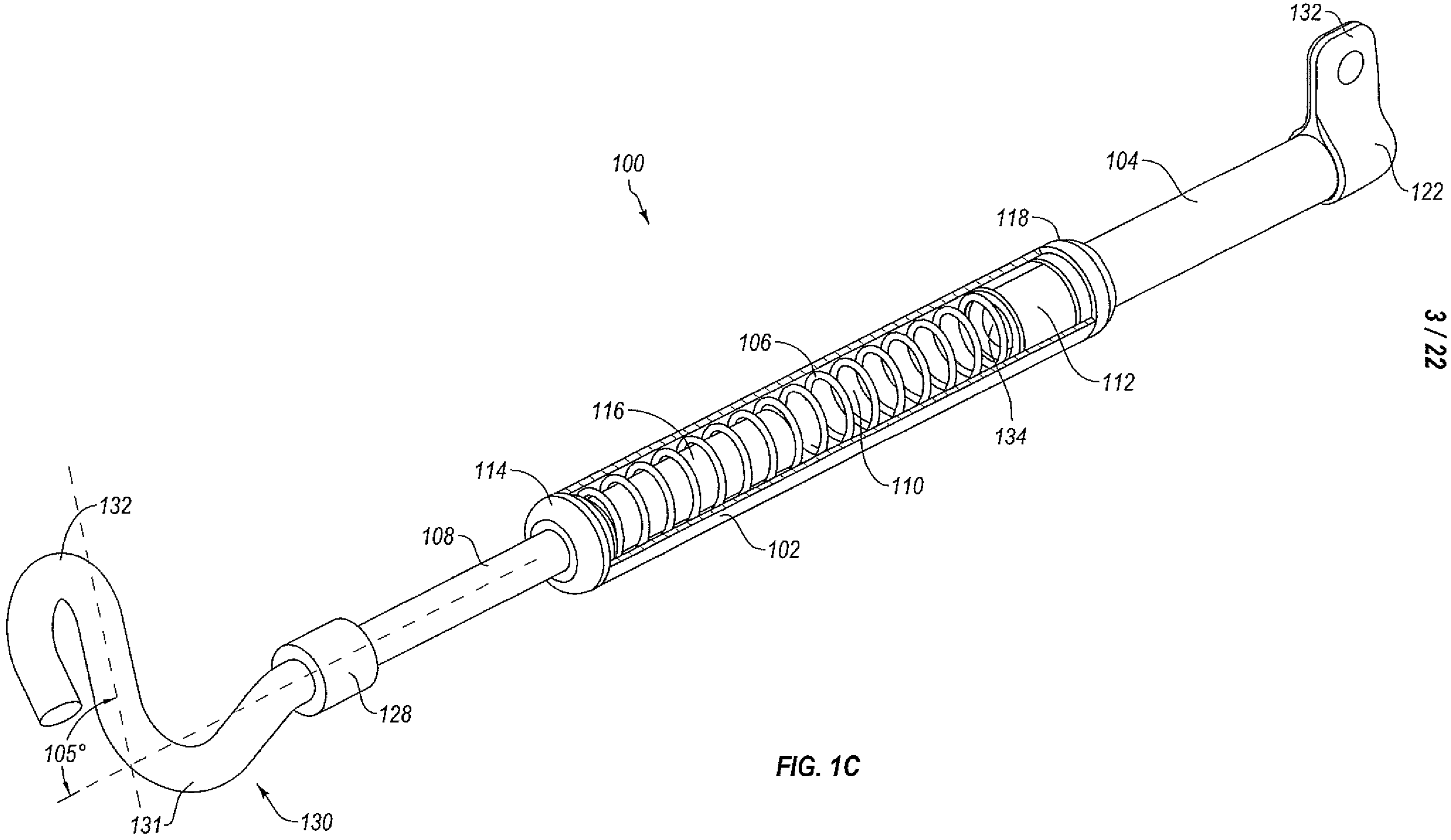

100
132
104
122
118
106
112
116
134
114
110
132
108
102
128
105°
131
130

FIG. 1C

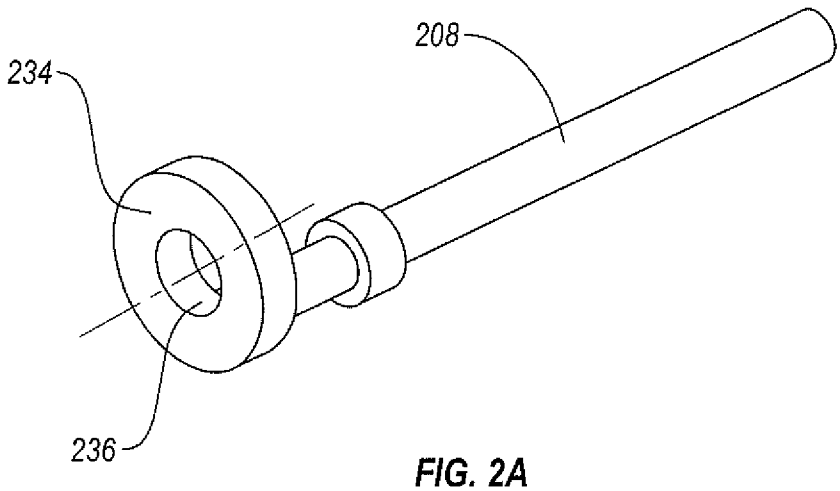


FIG. 2A

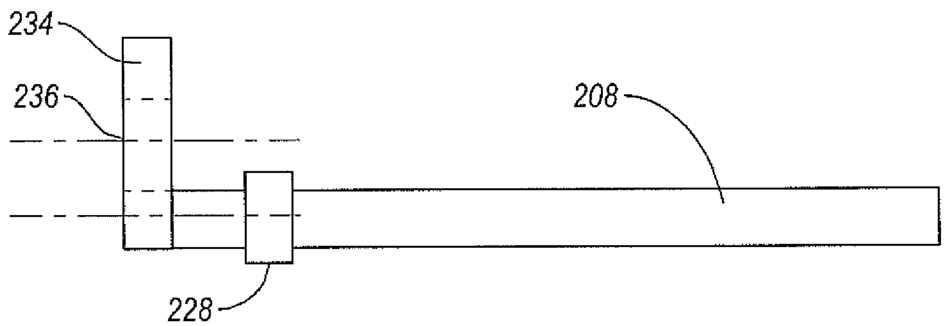


FIG. 2B

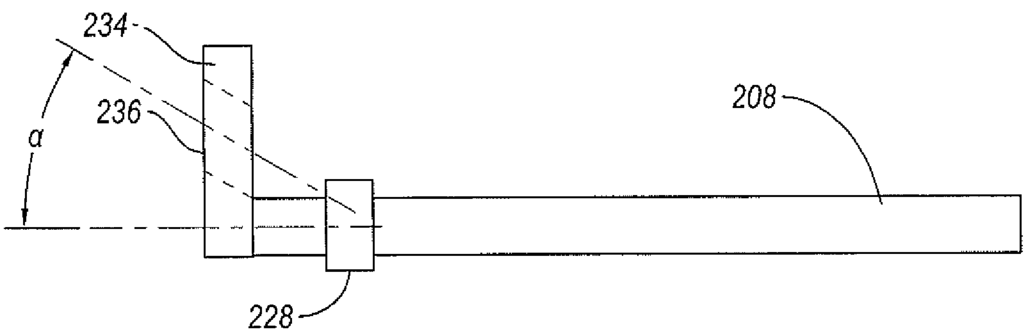


FIG. 2C

20132052855 17 Apr 2013

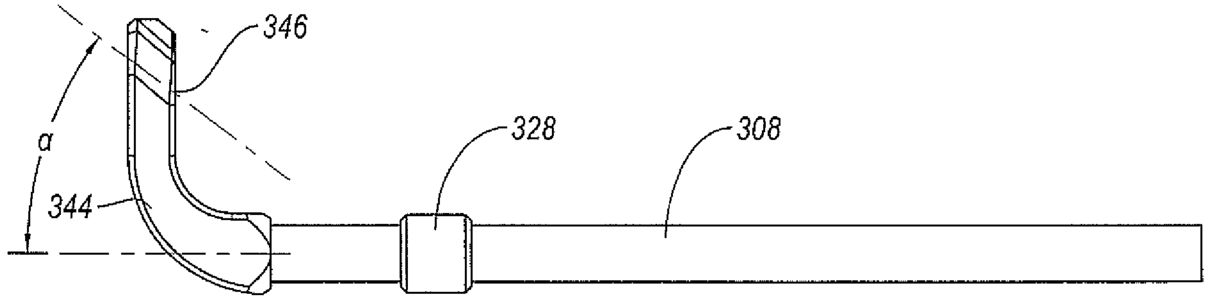


FIG. 3A

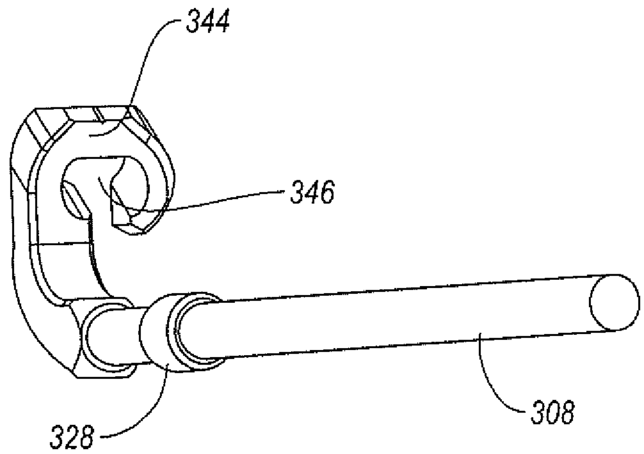


FIG. 3B

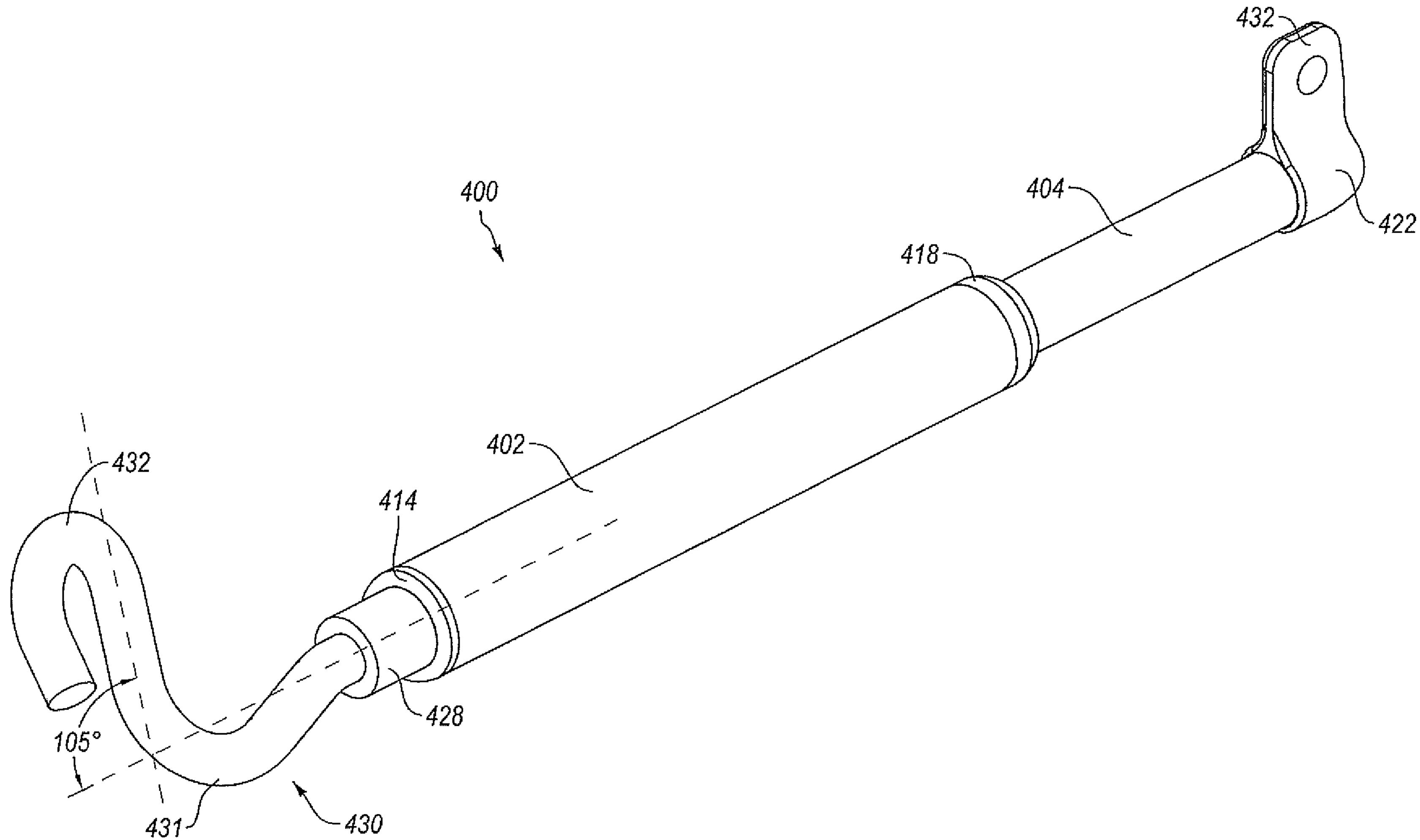


FIG. 4A

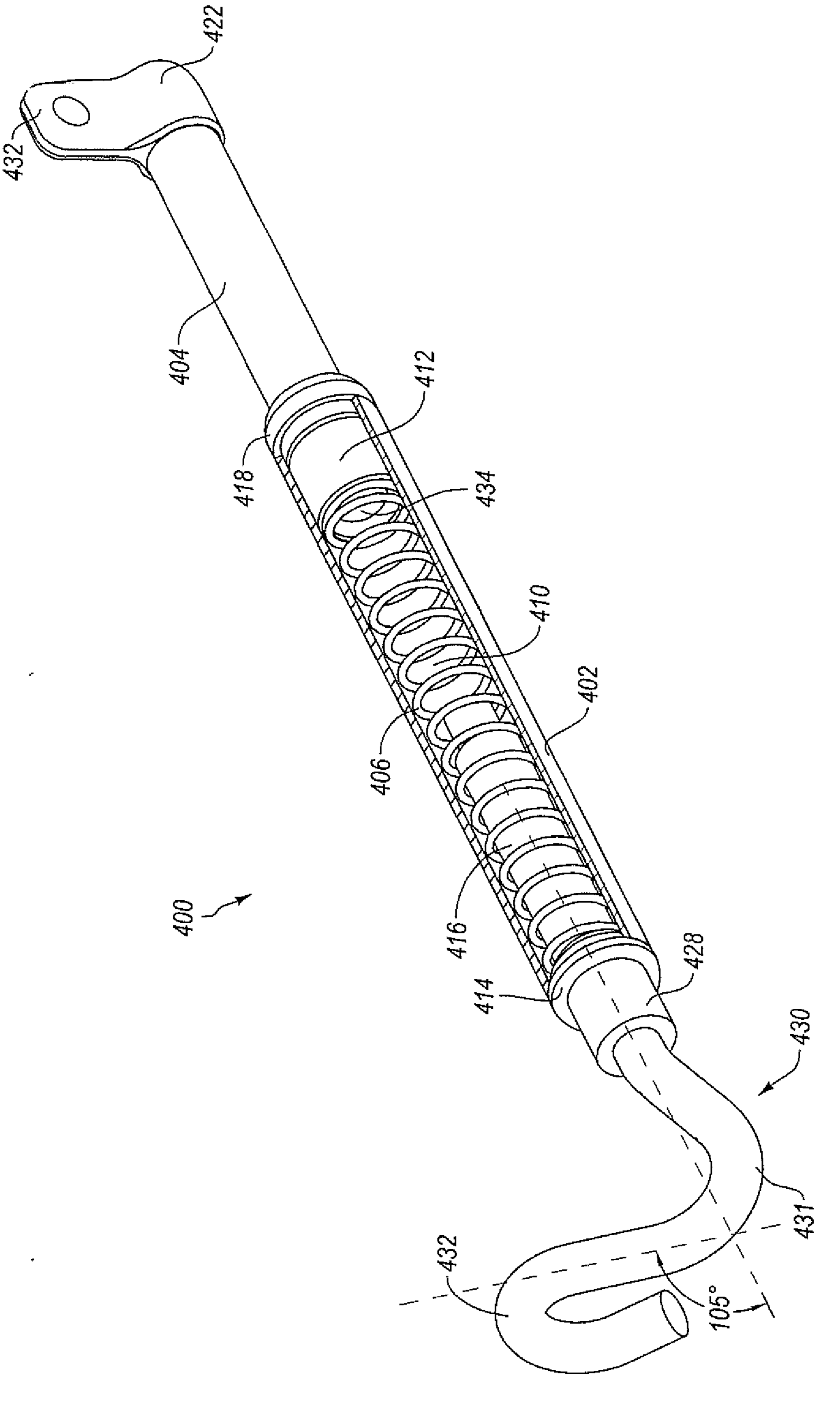

422
432
404
412
418
434
410
402
406
400
416
428
414
430
431
432
105°

FIG. 4B

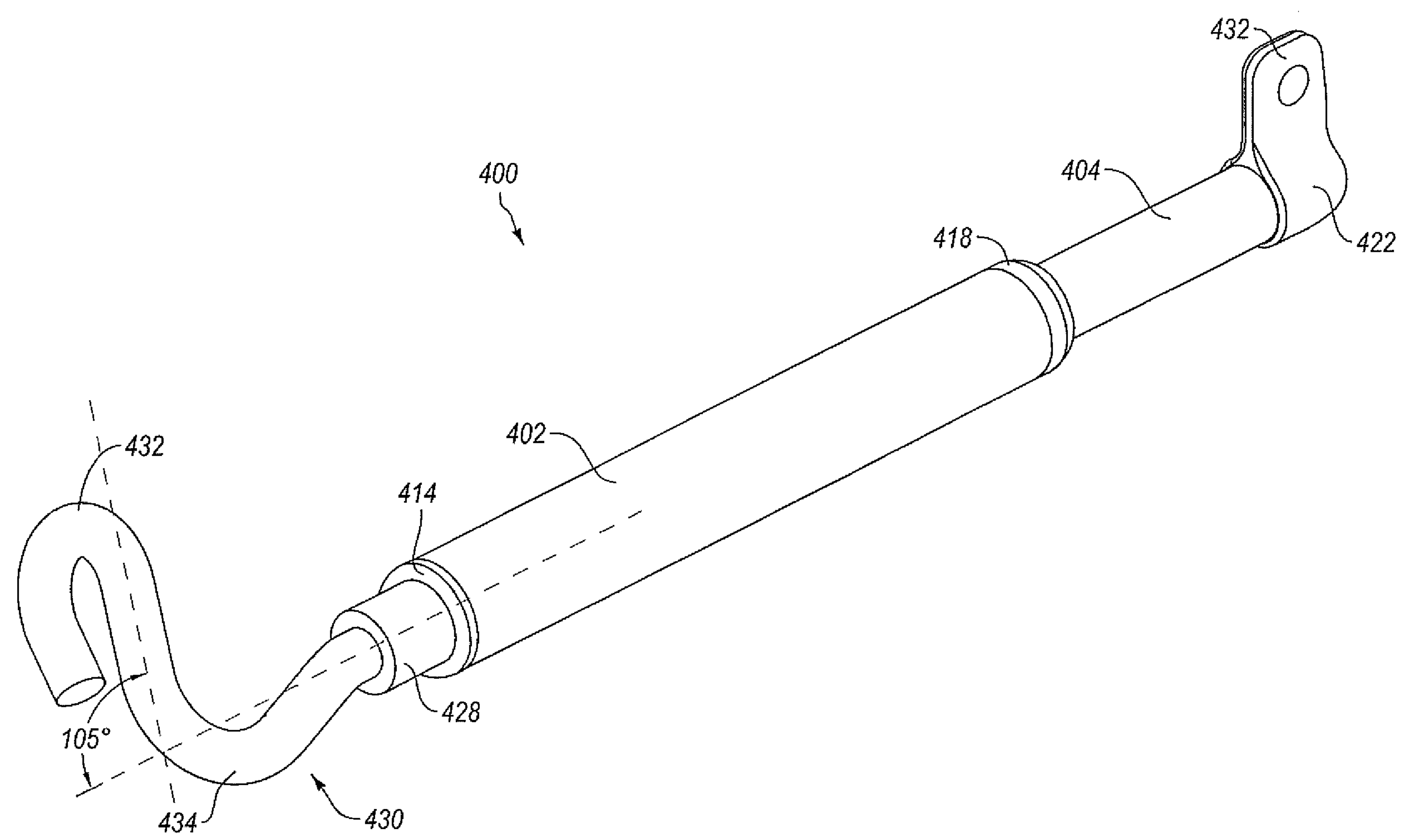


FIG. 4C

20132052285 17 Apr 2013

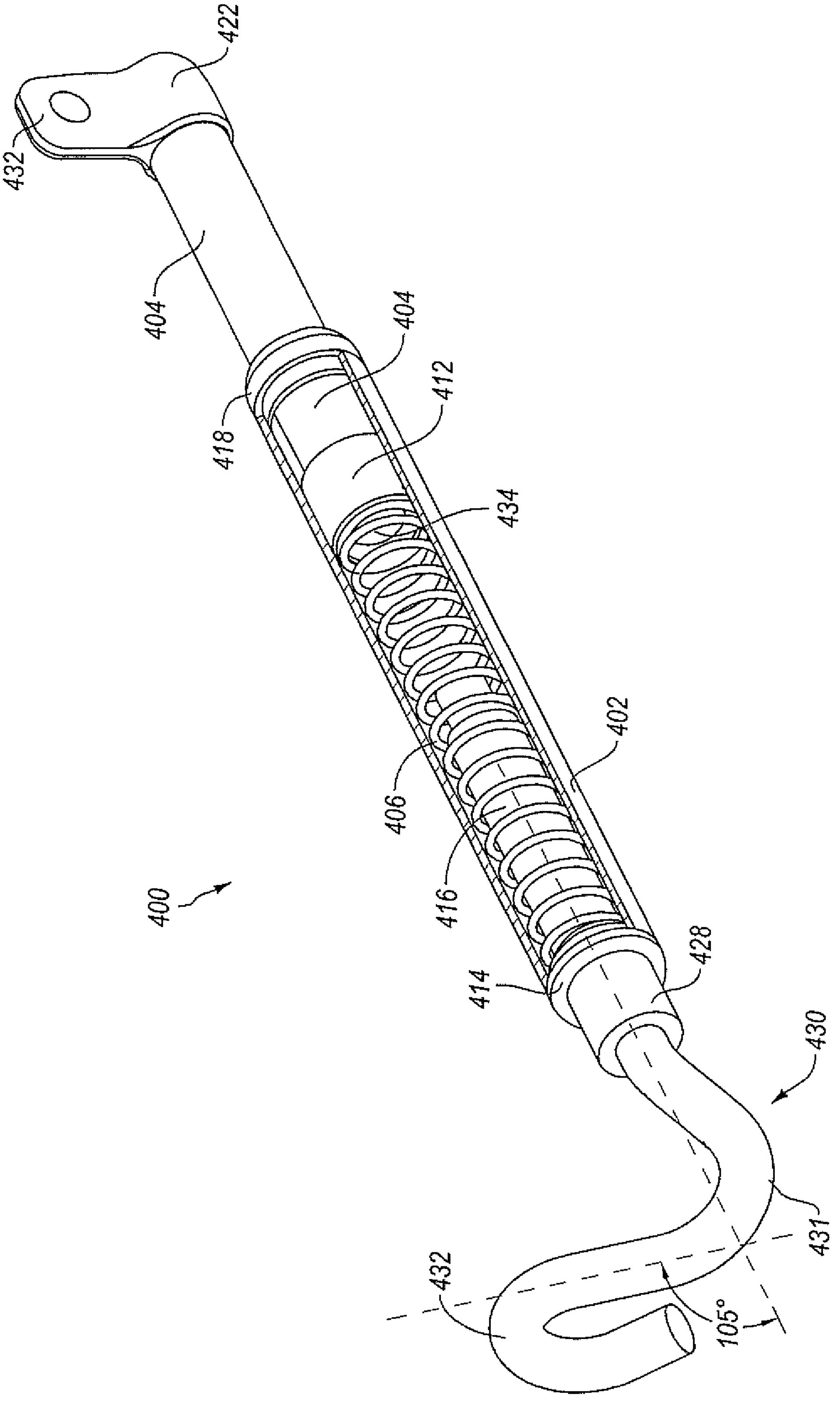


FIG. 4D

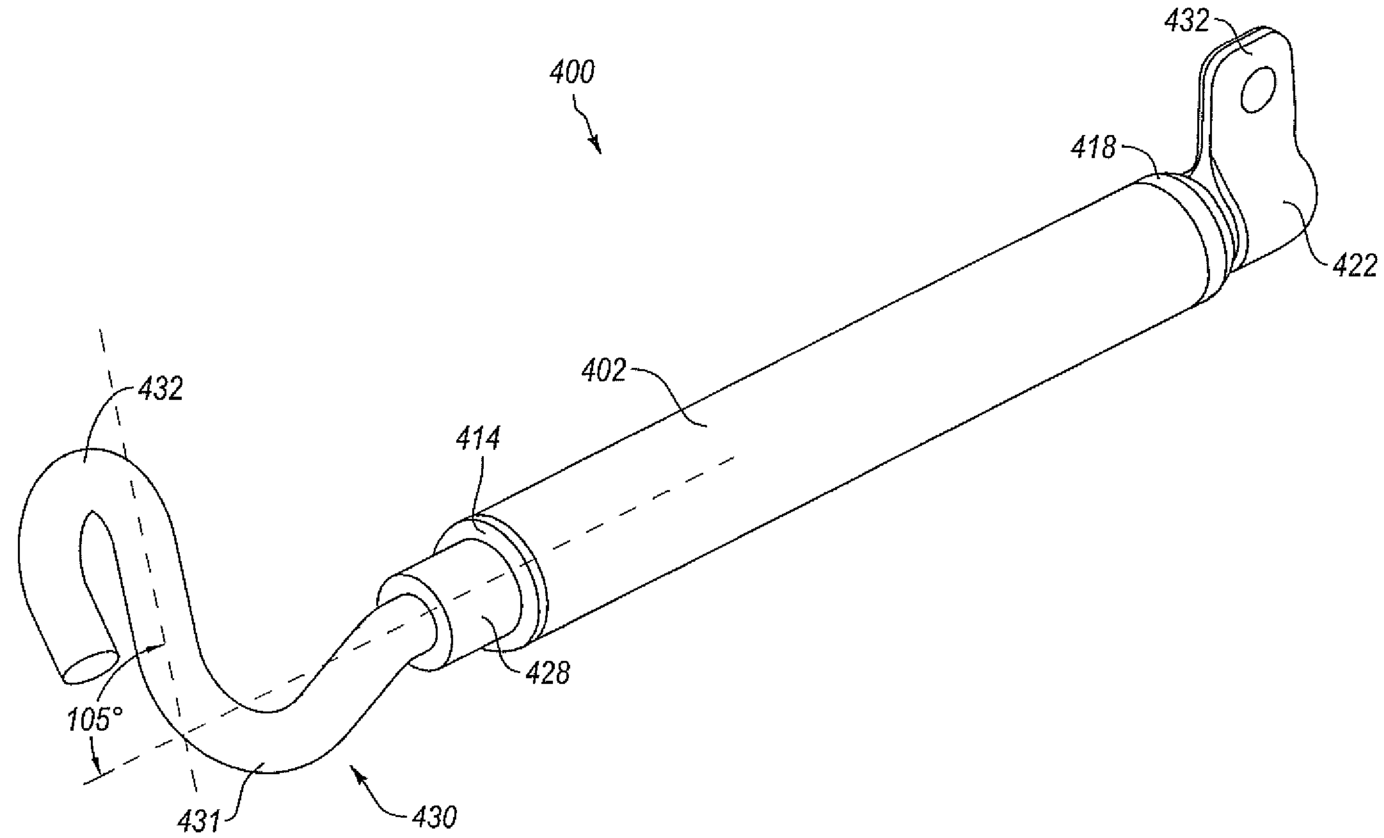


FIG. 4E

2013205285 17 Apr 2013

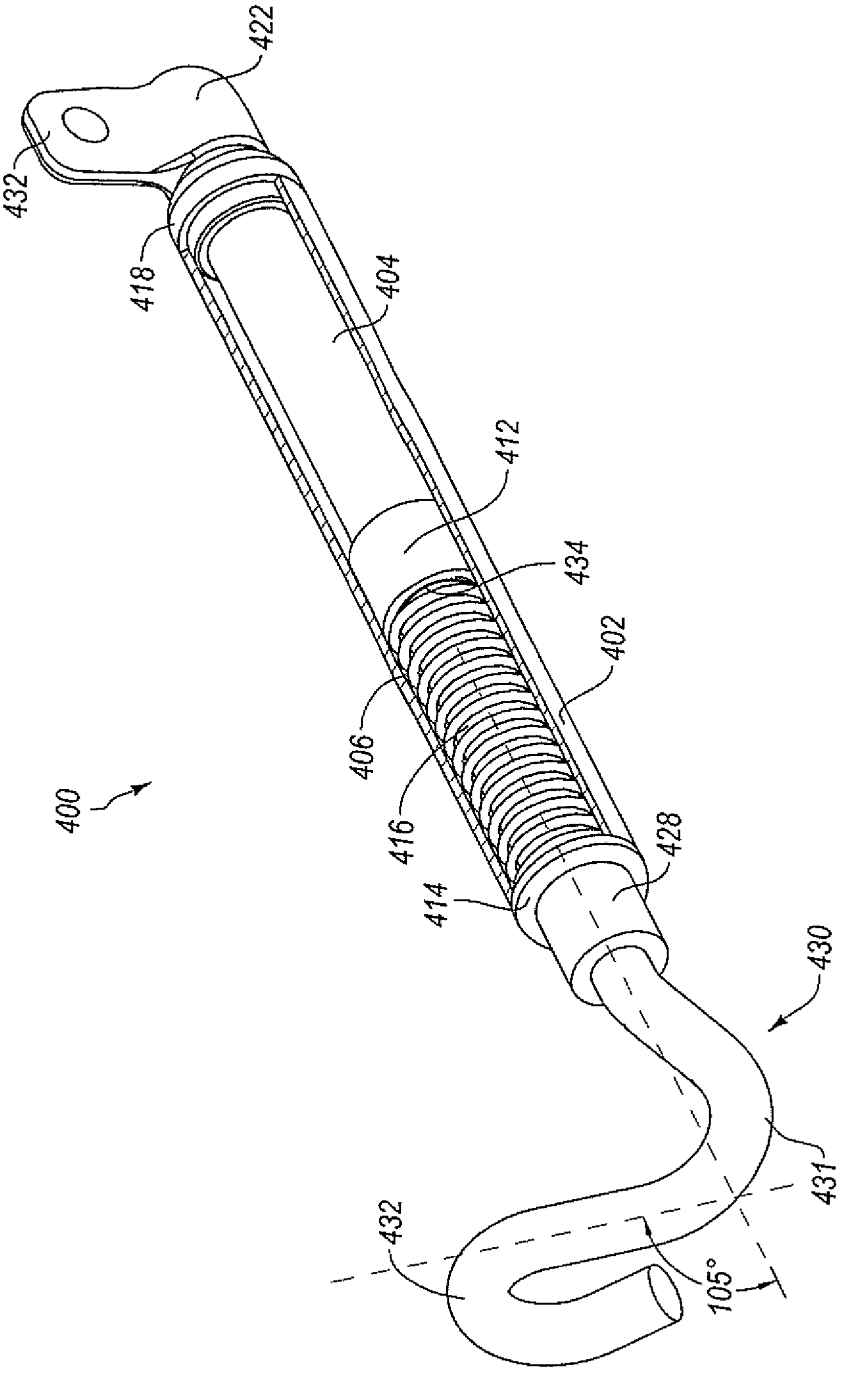


FIG. 4F

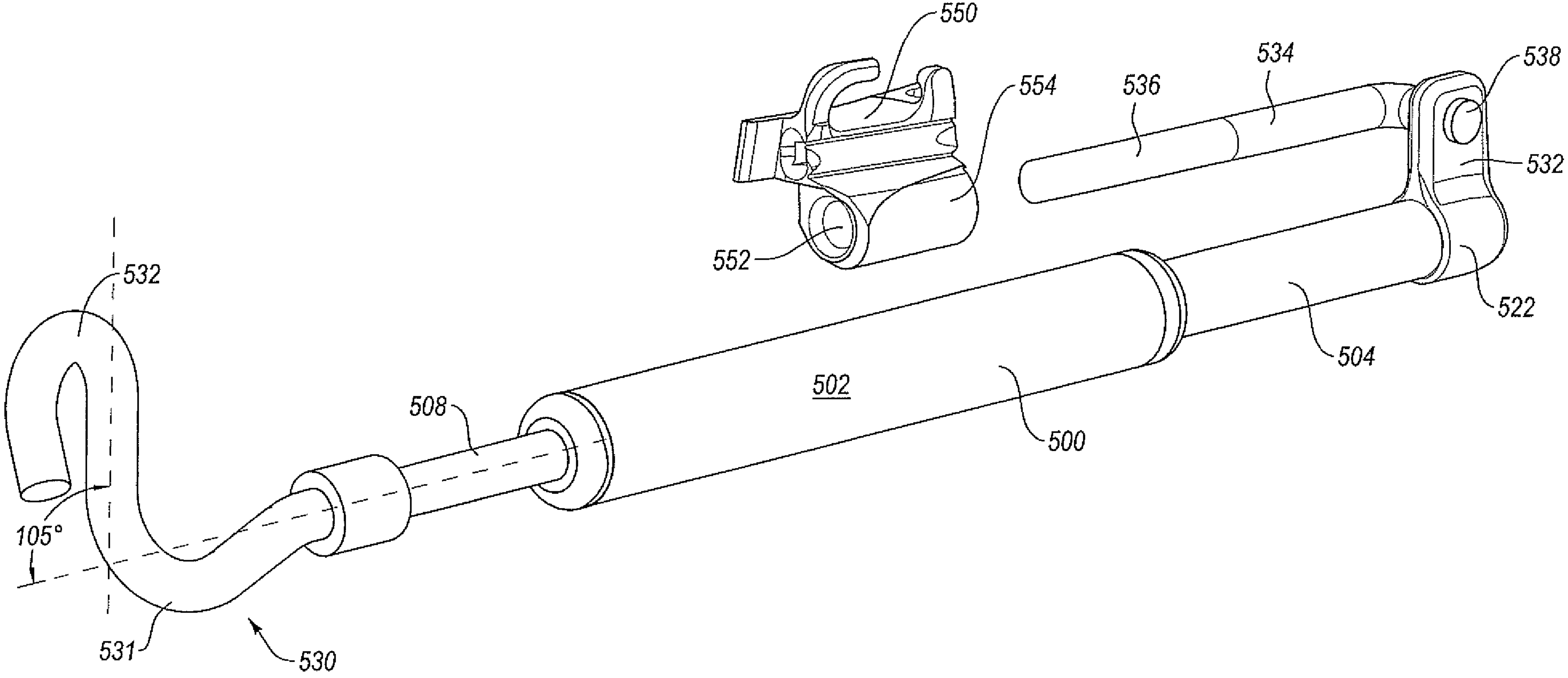


FIG. 5A

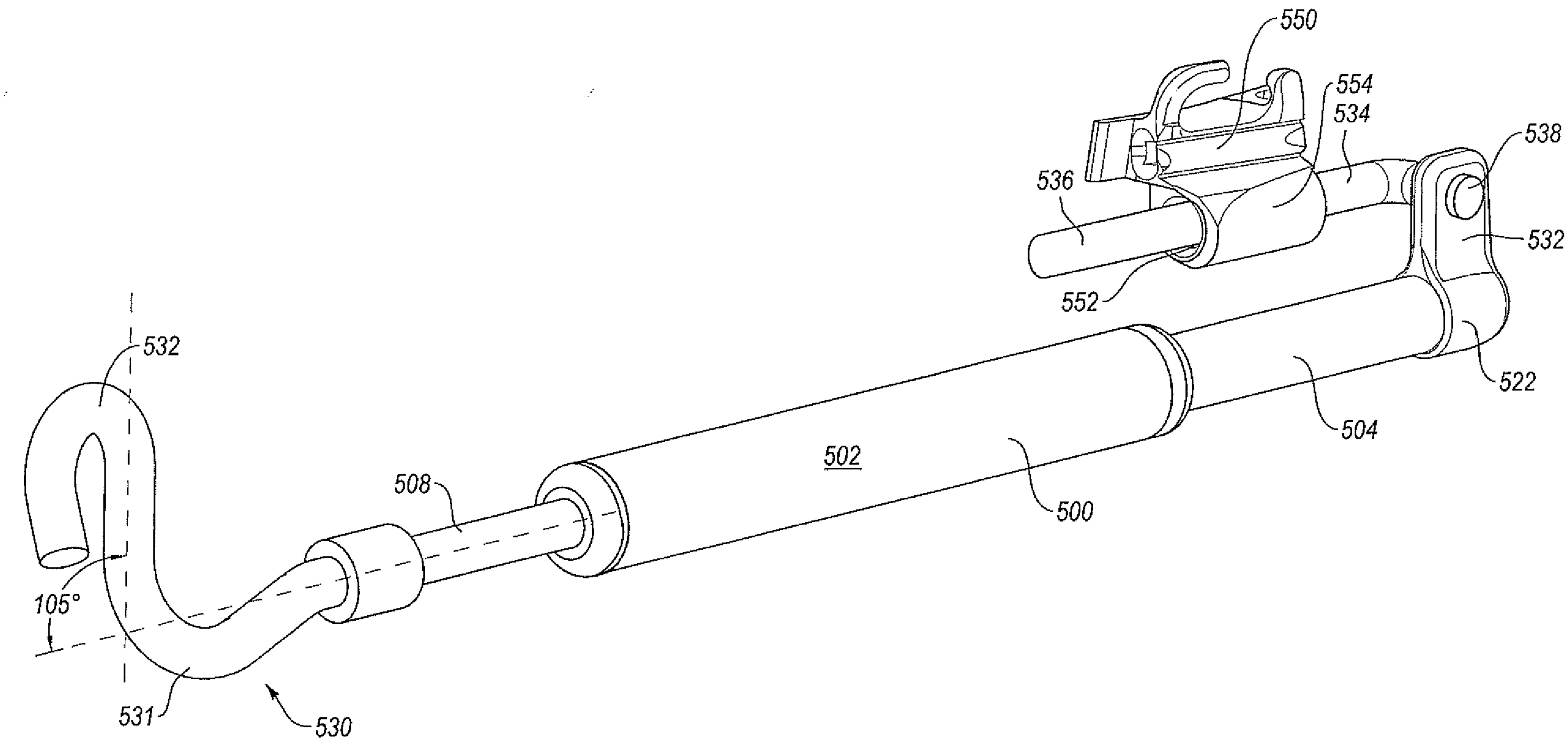


FIG. 5B

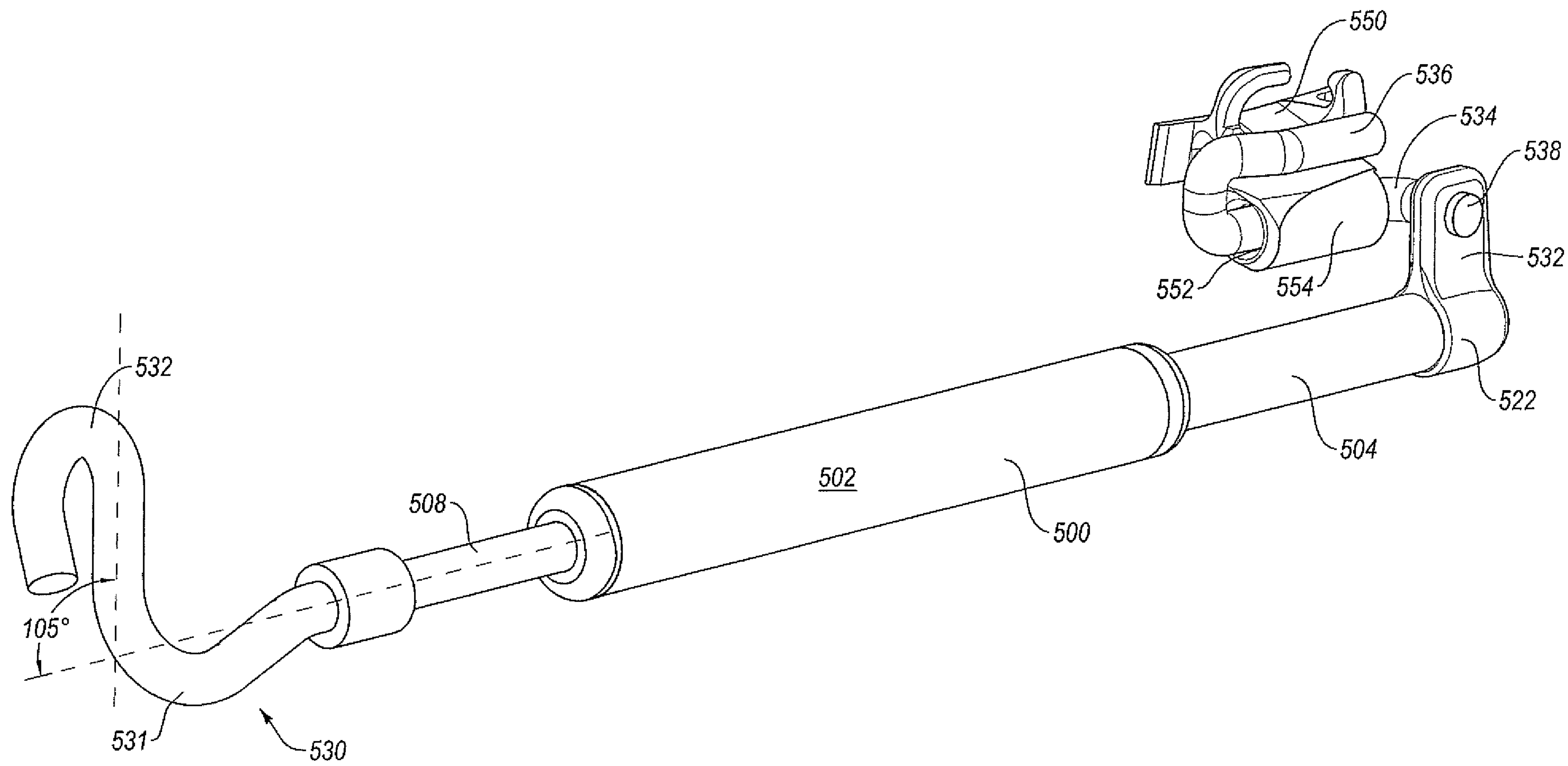


FIG. 5C

20132052851 17 Apr 2013

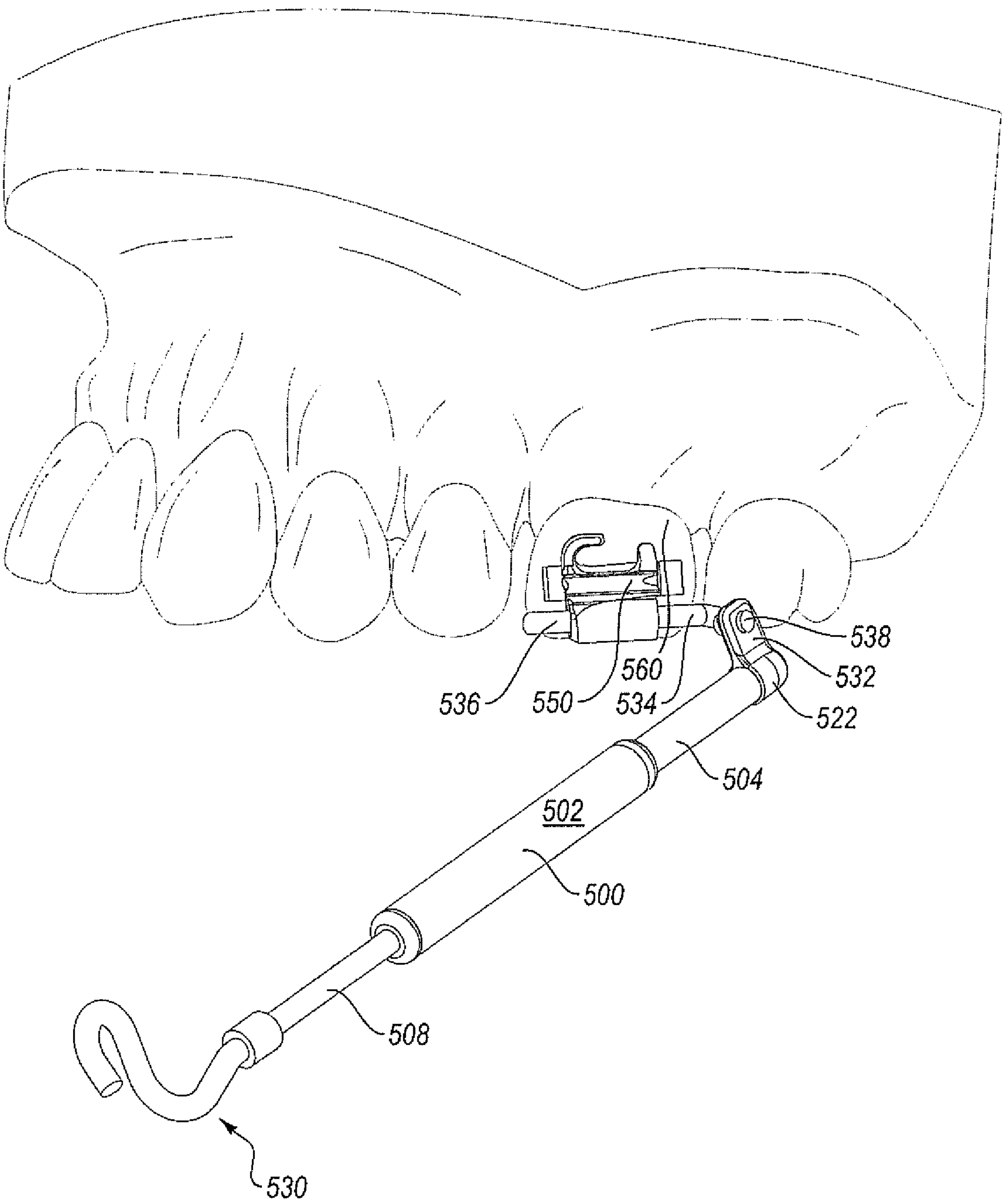


FIG. 5D

2013205285 17 Apr 2013

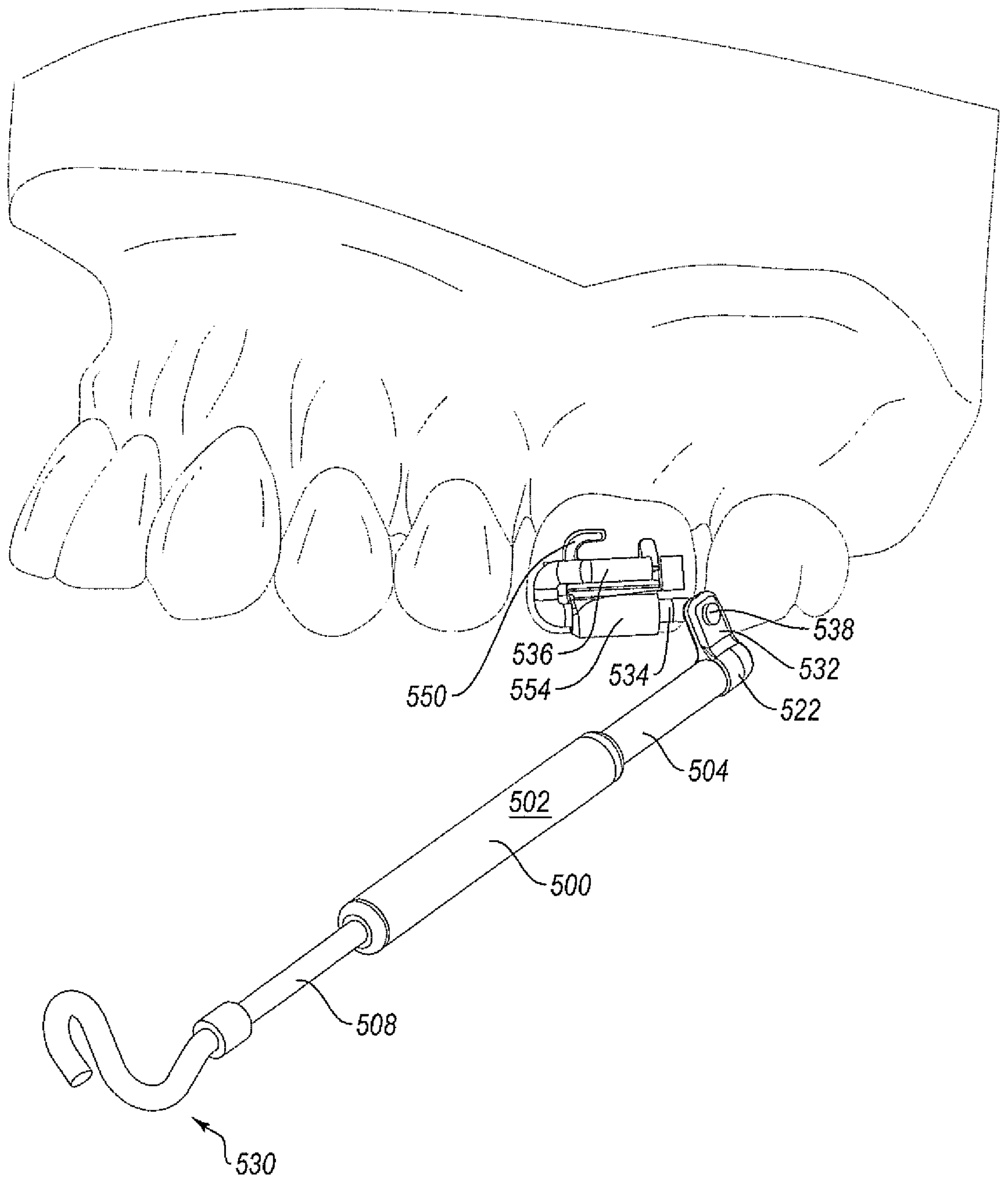


FIG. 5E

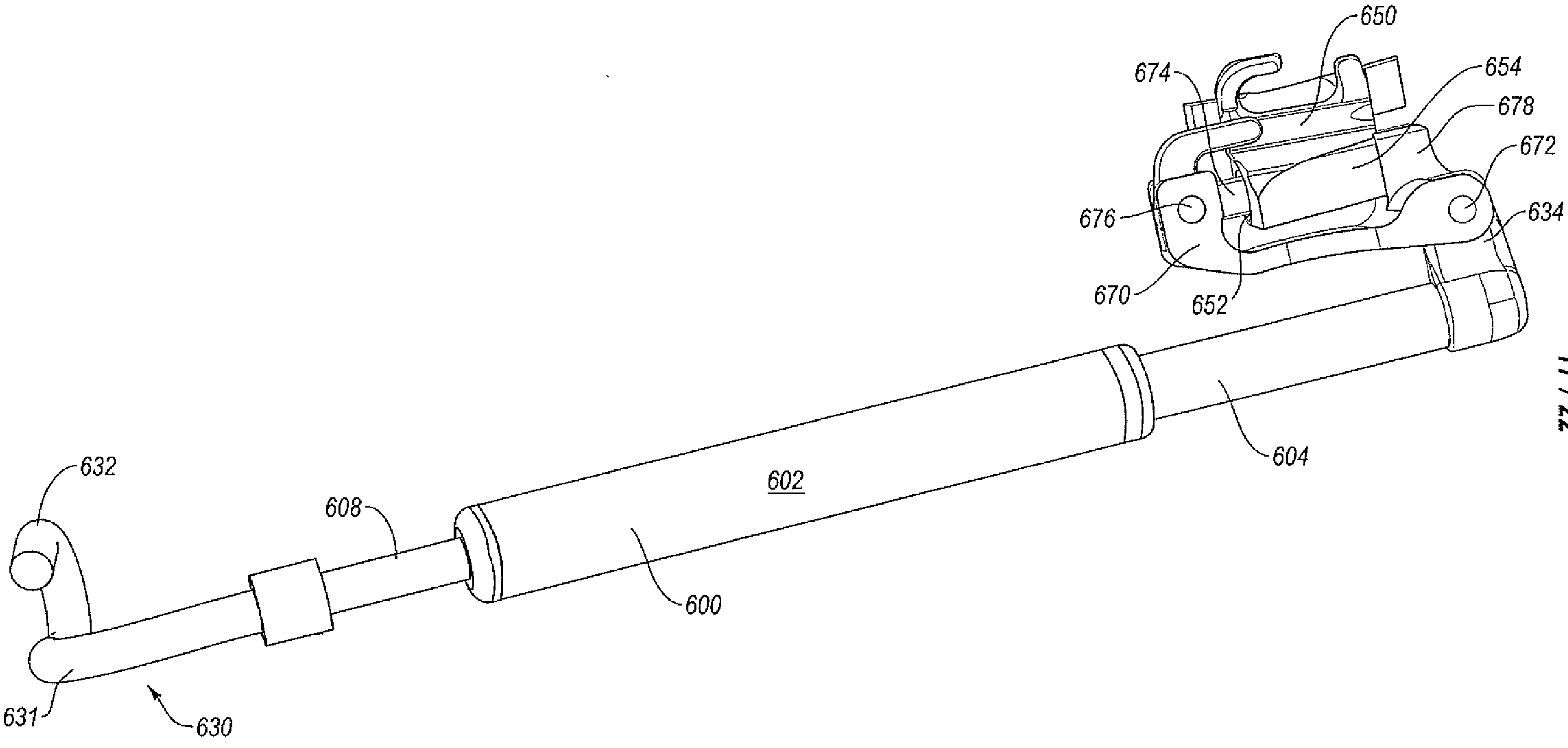


FIG. 6A

20132052285 17 Apr 2013

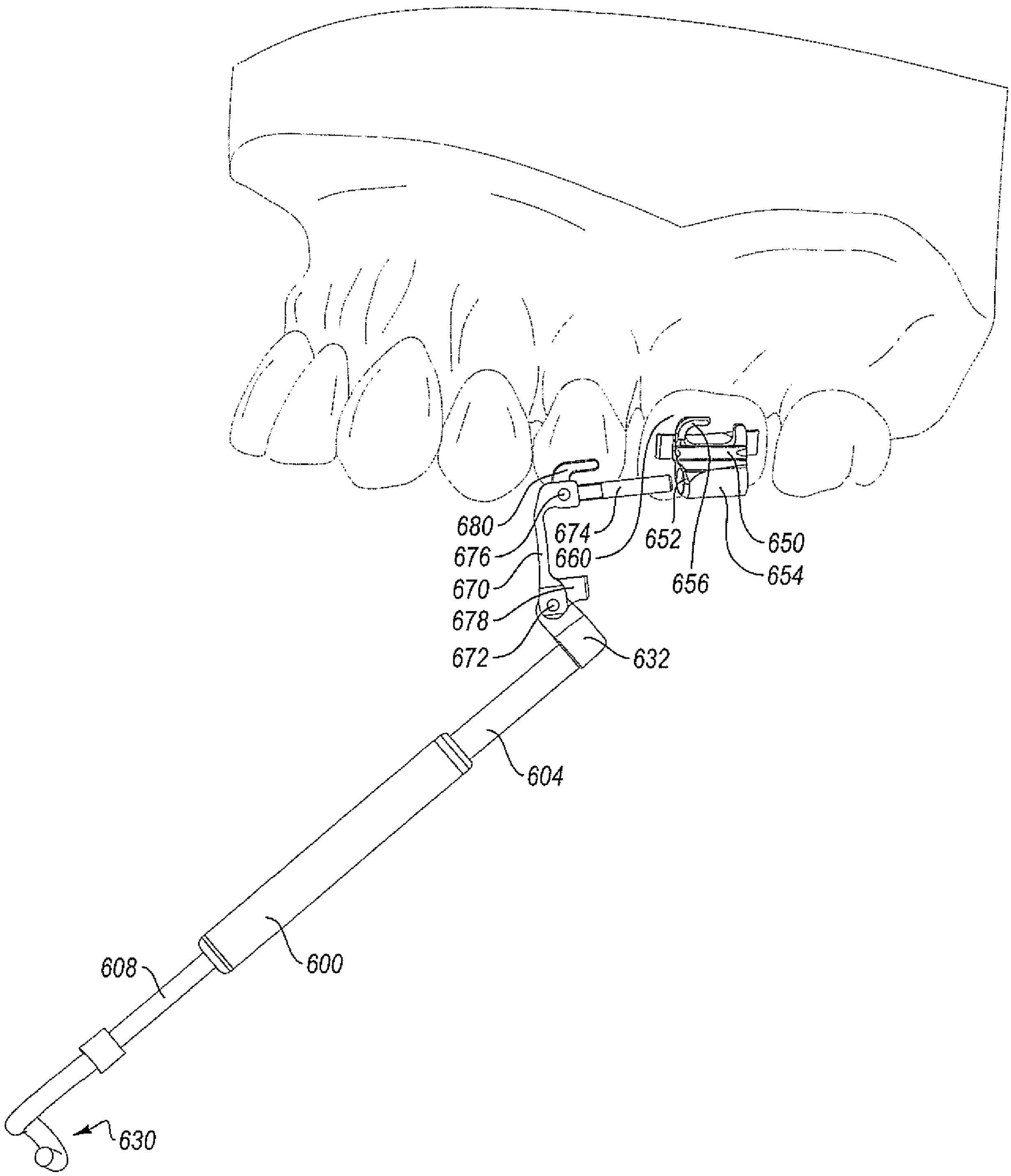


FIG. 6B

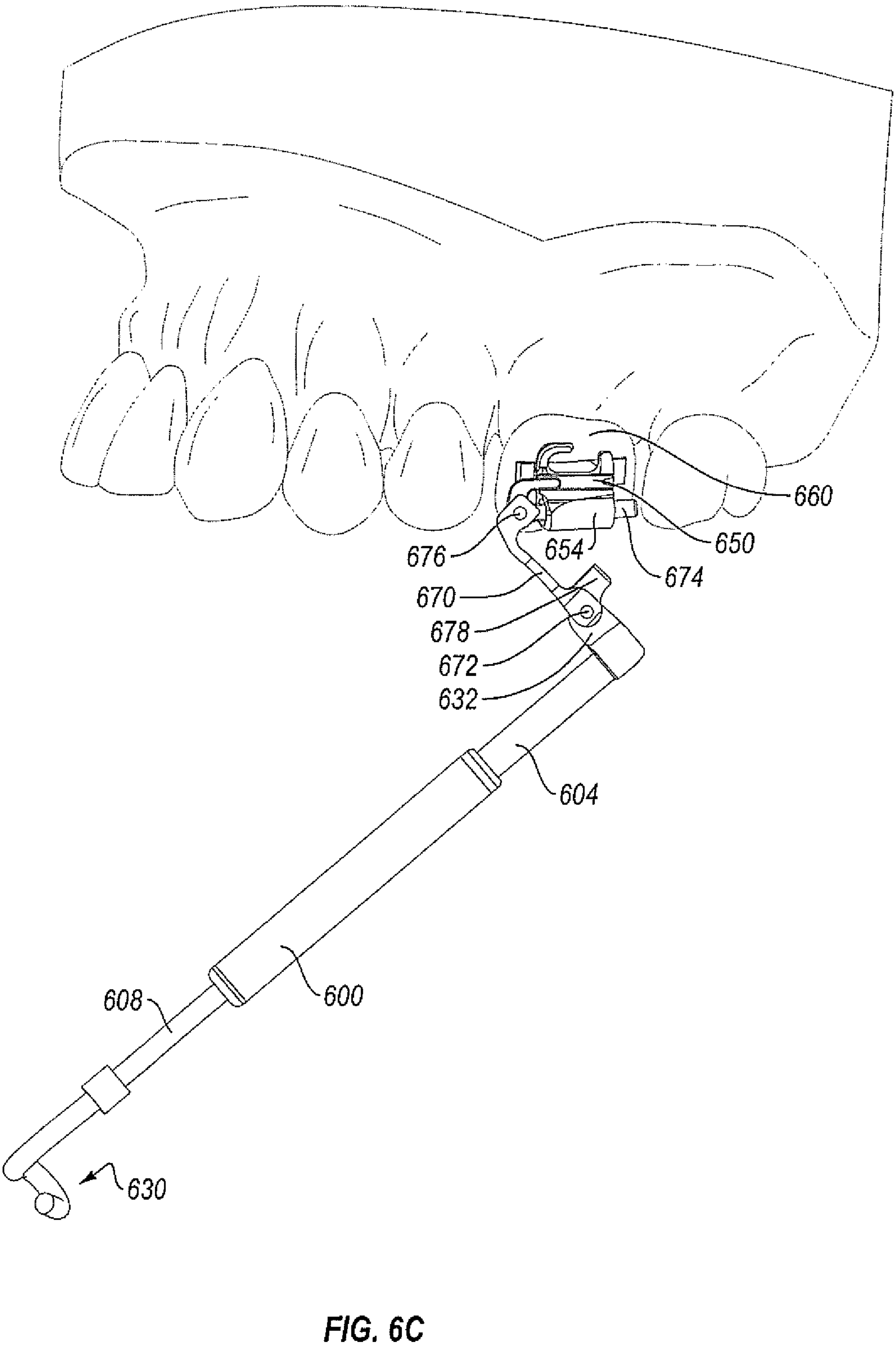


FIG. 6C

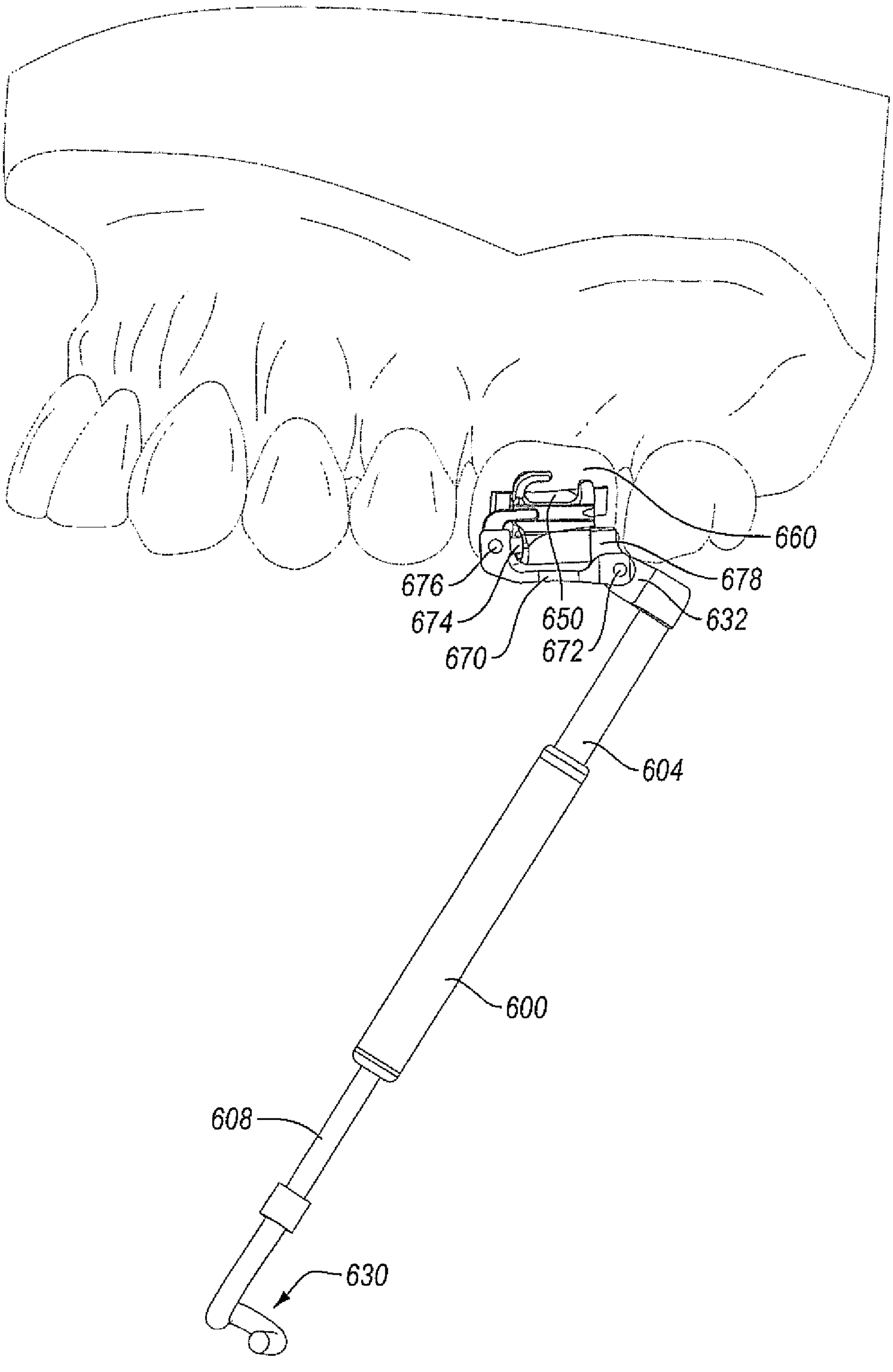


FIG. 6D

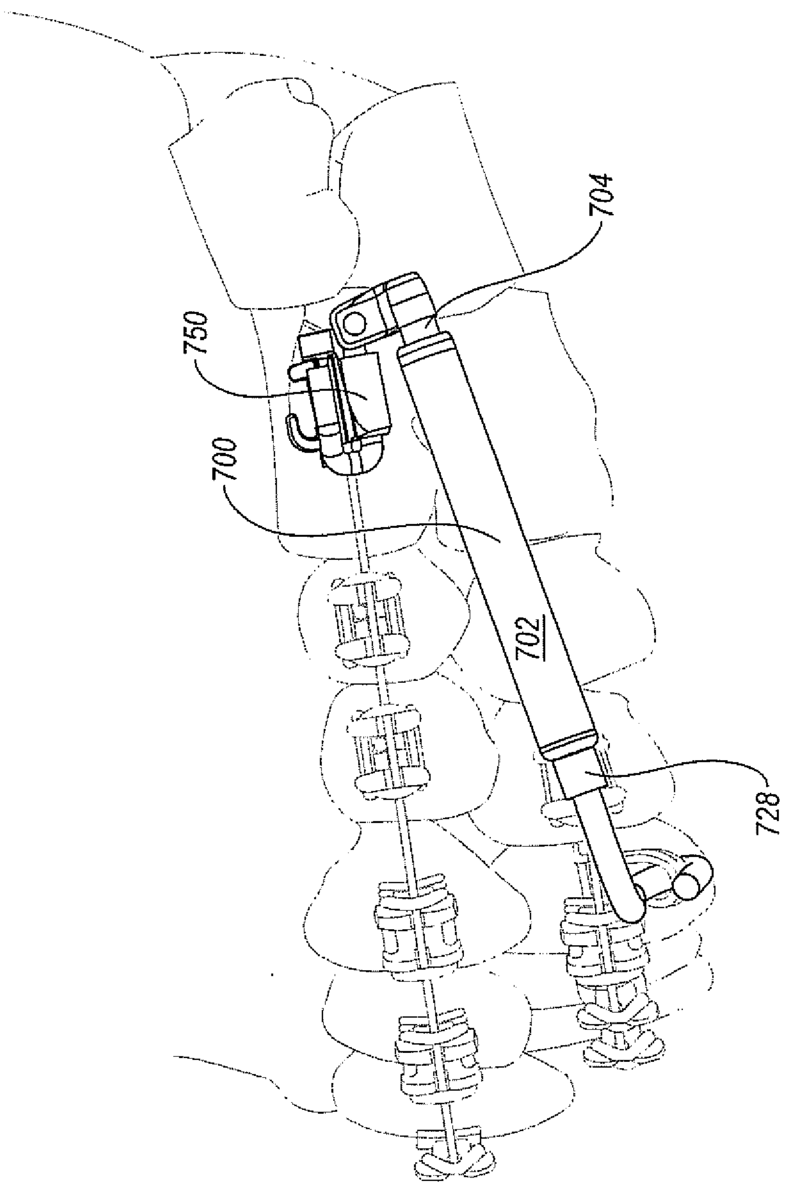


FIG. 7A

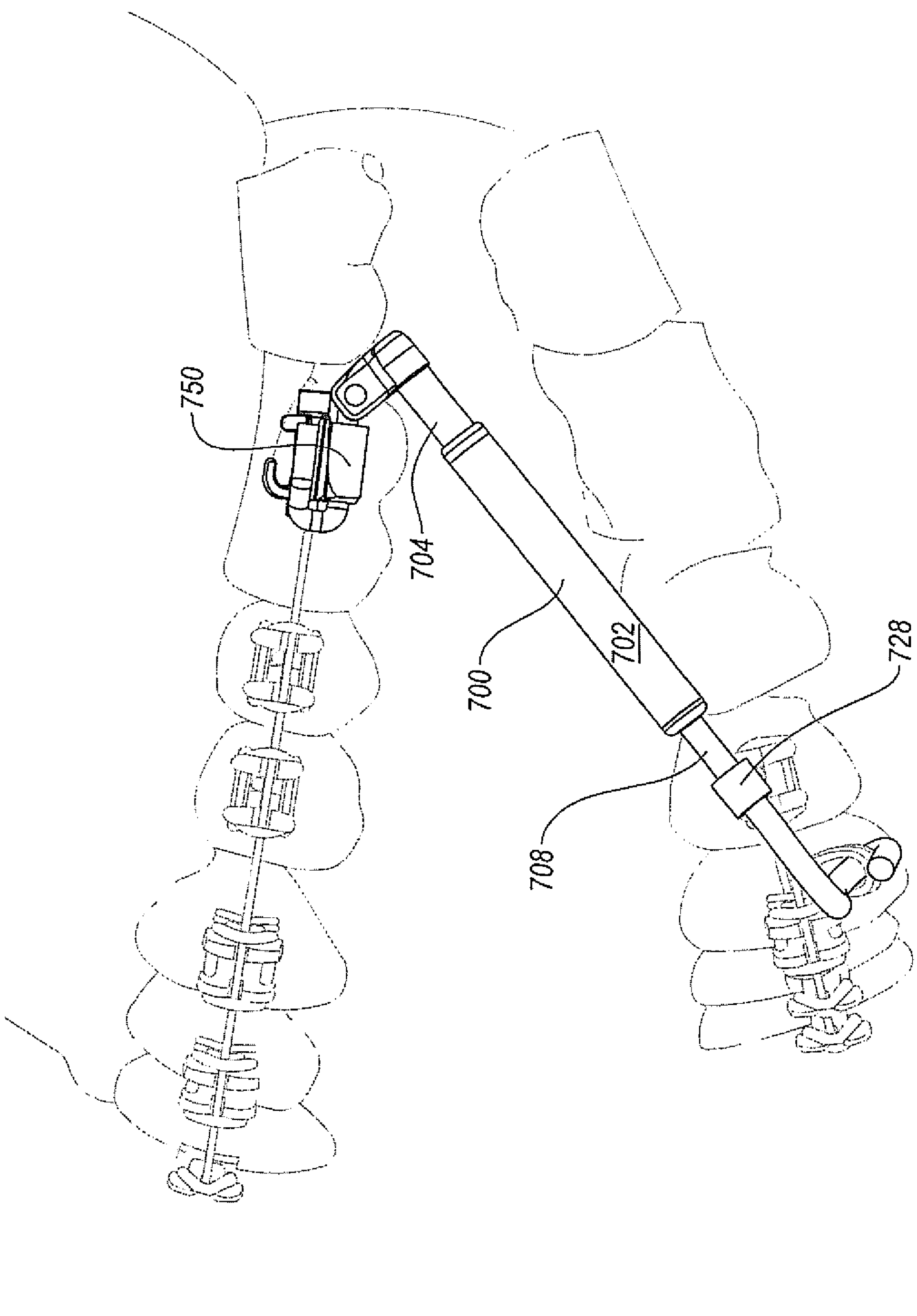


FIG. 7B