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August 26, 2024

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APPLICATION NUMBER: *62/818,082*
FILING DATE: *March 13, 2019*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US *62/818,082*

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

Rodney Glover
Certifying Officer

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Document Description: Provisional Cover Sheet (SB16)

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Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

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All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. — Add

Title of Invention	Improved Dental Prosthesis Scan-Flag Analog System and Methods
Attorney Docket Number (if applicable)	

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.
● No.
Yes, the invention was made by an agency of the United States Government. The U.S. Government agency name is:
Yes, the invention was under a contract with an agency of the United States Government. The name of the U.S. Government agency and Government contract number are:

PTO/SB/16 (02-18)
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Entity Status
Applicant asserts small entity status under 37 CFR 1.27 or applicant certifies micro entity status under 37 CFR 1.29

- (●) Applicant asserts small entity status under 37 CFR 1.27
- ( ) Applicant certifies micro entity status under 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
- ( ) No

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Signature	/Charles A. Rudisill/			Date (YYYY-MM-DD)	2019-03-13
First Name	Charles	Last Name	Rudisill	Registration Number (If appropriate)	

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Improved Dental Prosthesis Scan-Flag Analog System and Methods

Prosthetic dentistry has rapidly moved into the realm of digital design and manufacturing. This requires that a digital model is created from a physical model or impression to allow digital design and manufacturing techniques to produce a physical prosthetic that can be delivered to a patient for restoration of dental and oral structures. When restoring implants, an implant impression coping is used in the mouth to reference the position of the implant geometry relative to surrounding structures (e.g., gingiva, adjacent teeth, opposing teeth, etc.). Elastomeric impression materials are commonly used to "pick-up" the impression coping. Once removed from the mouth, an implant analog is attached to the impression coping that was "picked up" in the elastomeric impression by either a "closed tray" or "open tray" protocol. With the lab implant analog attached to the impression coping in the elastomeric impression, dental stone is flowed into the impression and allowed to harden before separation from the impression with a resultant dental cast. A scan flag is attached to the lab analog on the dental stone model and is scanned in by laser or optical scanning technology. The scan flag is used for design software to reference and replicate the accurate positioning of the virtual implant relative to the adjacent teeth, gingiva and opposing tooth, as well as the timing of the implant and other pertinent implant geometries. Once the virtual implant is accurately brought into the design software, a prosthetic can be designed by following the workflow in the design software. A completed design is post-, and a CAD file is used in CAM software to direct either the 3-D printing or milling of the designed prosthesis. The manufactured prosthesis is verified on the physical model prior to delivering to the dentist (if he outsourced to a laboratory) or the dental patient (if the prosthesis was manufactured in the dental clinic). It is currently the standard of care to verify the fit, form, and function on a physical model.

A common approach to full arch implant prosthetics is to use a multi-unit abutment that attaches to the implant. The multi-unit abutment interfaces with the mating surfaces of the final prosthetic. There are temporary cylinders and open/closed tray impression copings commercially available to be used in the impression procedure for creating a physical model that can then be digitized with commercially available scan flags for multi-unit abutments.

Recently, an impression scan flag was introduced to the market for a few major implant systems and the most common multi-unit geometry. This scan flag allows for an impression to be digitized and bypassing the creation of a stone model. A digital model is created directly from the elastomeric impression, a prosthesis is designed digitally and calculated with CAM software and both a 3-D printed model and 3-D printed or milled prosthesis is finished and tested on the 3-D printed model. The disadvantage of the 3-D printed model for full arch implant prosthetics is the positioning of the implant lab analog within the 3-D printed model introduces a degree of inaccuracy. Additionally, an impression only captures the implant or multi-unit abutment relative to the tissues and requires cumbersome steps to incorporate a provisional prosthesis or wax-up into the design software relative to the scan of the impression. A simpler approach would utilize a provisional prosthesis or duplicate prosthesis to capture the implant or multi-unit abutments relative to the tissues.

As described in Provisional Patent Application 62/774,402, filed 03 December 2018, and incorporated as reference in its entirety herein, a relatively easy procedure for incorporating a temporary coping into a prosthesis or duplicate prosthesis has been described utilizing a separable fastener and then creating a very precise screw-access channel through the mating surface of the temporary coping to the occlusal surface of the prosthesis with a pilot drill and a subsequent guided drill to follow the pilot hole expanding the screw-access hole to accommodate the head of the prosthetic screw. In particular, the prothesis used in this process may be a removable denture that was used immediately prior to implant surgery.

A summary description of the process described in the referenced patent application with an additional embodiment of this separable fastener for accurately digitizing implant positioning is described below. As shown in FIG. 1, the separable fastener may include a threaded metal fastener 101 with a post feature 101A on one end. The post feature is press-fit into the mating bore of the separable cap 102; the press-fit of the post and cap provide a designed amount of retention force, or axial pull-off force of the cap from the threaded post. Adhesives, insert-molding, snaps, etc, or other means may attach the post and cap, versus a press-fit. The short length of the post and threaded fastener allows separation at high degrees of angularity of the assembled parts in use. In an

embodiment the post is made from stainless-steel or titanium, and the cap of polymer such as PEEK or acetal.
Referrring to the figures, general process steps are described below for this embodiment:. A torx drive feature is shown in in the end of the cap 102.

FIG. 4 shows schematic representations of a human jaw portion 106 with implants (not shown) and abutments 107 installed. Prosthesis 103 is shown with occlusion side 104 and intaglio side 105. This prothesis may be, for example, a removable denture that was used prior to implant surgery or a duplicate of such an existing denture as described in the Provisional Patent Application 62/774,402 incorporated herein. Marking pickup caps 108 are installed onto abutments 107. The location of abutments 105 is marked onto the prosthesis using customary methods by mating the prosthesis with the abutments.
FIG. 5 shows the abutment positions 109 marked onto prosthesis 104.

FIG. 6 shows drilling of blind holes 110 slightly larger than copings112 in marked locations, with burr tool 111.

FIG. 7 shows installation of copings110 onto abutments 107 using separable fastener assembly 100, and torque-driver 113 (described in more detail later). The torque driver 113 prevents over-tighetening of cap 102 and possible separation of the cap from the post. The cap of the separable fastener may be mechanically captured or adhered to the insert, or may be designed to loosely fit in the bore of the coping as illustrated with axial force from tightening the separable fastener holding the coping to the abutment 107.

FIG. 8 shows application of acrylic or other adhesive into cavities 110 of prosthesis 103, which is subsequently fitted onto copings112.

FIG. 9 shows prosthesis 103 being mated with copings112. After the adhesive sets, the separable fasteners allow easy removal of the prosthesis from the abutments with the copings cemented into the prosthesis.. The caps 102 remain in in the prothesis with the copings112, while the posts 101 remain in the abutments.

FIG.10 shows the prosthesis with cemented copings112.

FIG. 11 shows removal of the threaded post 101 with removal tool 115.

FIG. 12 shows drilling of the small pilot hole 118 (e.g. approximately 1.4 mm diamenter), from the intaglio side of the prosthesis, out through the occlusion side; coping 112 serves as a guide for this hole. The PEEK cap 102 is drilled through in this operation.

FIG. 13 shows the small pilot holes 117 in the occlusion side of the prosthesis 103.

FIG. 14 shows enlarging of the pilot hole 117 to allow clearance for a prosthetic mounting screw 121. The clearance holes 119 are drilled down to the top of the coping using counterbore drill 118. This requires only a small diameter enlargment (for example approximately 2.4 mm).

FIG. 15 shows a step of a final reaming of the coping bore to clean out any debris or remaining material from the cap.

FIG 16 and FIG. 17 show final installatioin of prosthesis 103 onto abutments 107 using prosthetic screws 121. The screw holes may be subsequently filled to use the modified prothesis as a temporary or permanent prothesis.

Note in the above procedure that very little material is removed from the prosthesis during the installation process.

FIG. 25 and FIG 26 show an emodiment of a simple torque-driver 113. Shaft assembly 135 contains a spring friction cylinder portion 141 and drive portion 138 (such as standard Torx or hex drives). Spring 136 has an interference fit with cylinder 141, and thus when spring 136 is rotated in the “unwind” direction of the spring, a designed amount of slip torque is present between the spring and cylinder; in the “wind” direction, the spring binds on the cylinder. Slot 139 in drive cap 137 engages spring end 140, and snaps onto the end of the shaft assembly, thus when the cap is rotated in the clockwise direction, cylinder and drive slip at a known torque.

FIG. 27 shows an emodiemnt of a screw-extractor 115. The extractor utilizes a hollow metal tubular split-cylinder end portion 142 that spring-fits onto the end of the screw post, allowing removal of the separable fastener posts or other types of fasteners. FIG. 27 illustrates a hand-operated knurled end, but other torque tool systems known in the dental industry such as 3/32" friction and latch designs may be used.

The prothesis with screw-access channels may also be used as an accurate digital scan model of abutment positioning for creating a new prothesis. In this embodiment, dual purpose scan flag and lab analogs 122, FIG. 18 and FIG. 19 are fastened to the provisional or duplicate prosthesis 103. Features that may be present on the scan-flag/analog include a scan-flag reference portion 123 near the top of the analog, reference scan-flag features such as flats 124, axial and radial retention feature 128, screw attachment 125 for scanning fixture and/or reinforcement wire attachment. The abutment feature 126 are specific to various sytems commercially available; the figures show a tapered abutment 126 and female thread 127.

FIG. 20 and FIG. 21 show scan flag/analogs 122 attached to prosthesis 103 and copings 112 with screws 121.

FIG. 22 and FIG. 23 show prosthesis 103 with scan flags/analogs mounted to fixture 130 by attaching one or more scan flags 122 to the base with adjustable means to orient the prosthesis properly for scanning; for illustration an approximate mounting angle of 45 degrees is shown. In this example prosthesis is mounted to articulated arm 131 with screw 129 that fits into the threaded hole of scan-flag/analog 122. Base 132 is mounted onto the base of the scanning machine.

The provisional or duplicate prosthesis with attached scan flags/lab analogs is scanned into the design software. This process captures the accurate position of the implant multi-unit abutment relative to the soft tissues and it also captures the tested prosthetic contours to aid in the design of the definitive prosthesis. After the prosthesis has been scanned in, a physical model is created by creating a soft tissue moulage and pouring dental stone into the provisional or duplicate prosthetic utilizing the scan flags as the laboratory analogs.

FIG. 24 shows use of a solder or brazing preforms 133 to attach reinforcement wires 134 prior to pouring dental stone. Preforms 133 may be inserted into holes in the scan-flag/analogs and heated to attach wires/bars 134. Low temp solders, brazing compounds, and hot-melt adhesives may be utilized in a preform or dispensed method.

This method ensures a fast and efficient means of transferring all pertinent and relevant information required for designing a definitive prosthesis AND creating the most accurate and precise physical model that can be mounted in an articulator with the aid of a bite registration in preparation for post-processing of the machined prosthesis (e.g., verifying passivity of fit, verifying occlusion, etc.)

Variations of using the modified prothesis as a digital scan model will be recognized as possible to dental practitioners. For example, instead of using a dual purpose scan flag and lab analog, single purpose scan flags can be mounted into the provisional prothesis for scanning, and subsequently replaced with lab analogs prior to casting.

In addition to the screw attachment of the scan flags to the modified prothesis, scan flags may be attached to the prothesis with cemented copings of Fig. 10 prior to the drilling operations described in Figs. 12 and 13. In this case, a scan flag with a post feature equivalent to post feature 101A of separable screw would be inserted into copings 112 of the modified prothesis and retained by the embedded cap 102. If the separable fastener uses a snap-fit feature to retain the cap to the post, drilling may not be required through the prothesis to mount the scan flags or lab analogs to the prothesis or to attach the modified prothesis to the abutments after lab use. For example, Provisional Patent Application 62/774,402 describes the use of spring fingers and O-rings for separable fastening of the coping to the abutment for lift-off, and the use of films to prevent cement from entering interior portions of the separable fastener. Scan flags and lab analogs may also be engaged with transferred copings using similar mounting features as the post used in the transfer cementing process. The referenced patent application also includes separable systems in which the post attaches directly to the coping without a cap which may be applied for mounting scan flags or lab analogs as variations of the methods described above. Since the dimensions of the coping and its engagement with the abutment is precisely controlled, having snap-in scan flags engage

with a cavity between the top of the coping and the separable cap or an internal groove or other feature of the coping may be desirable.

In addition to the attachment of scan flags to a modified prothesis for digitization, the separable fastener may be used to transfer a coping and cap to a new impression after implant surgery. A scan flag or lab analog may be attached and held to the impression with transferred coping for digitization or casting by substituting the new impression for the modified prothesis in any of the processes above.

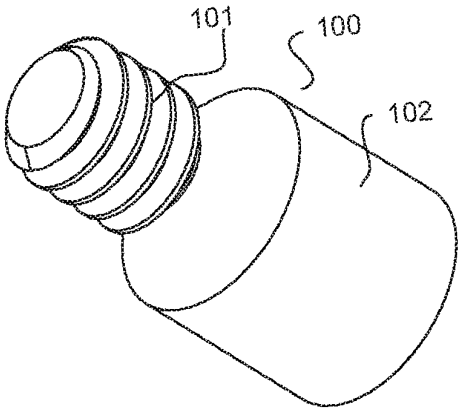


FIG. 1

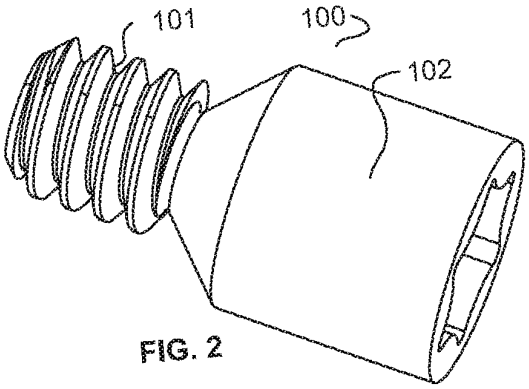


FIG. 2

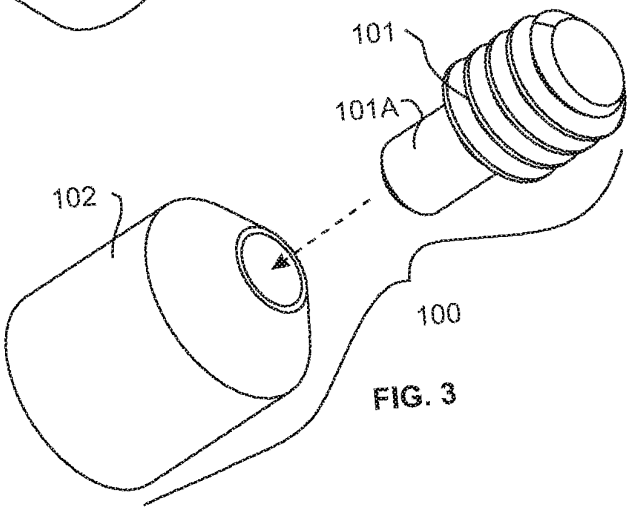


FIG. 3

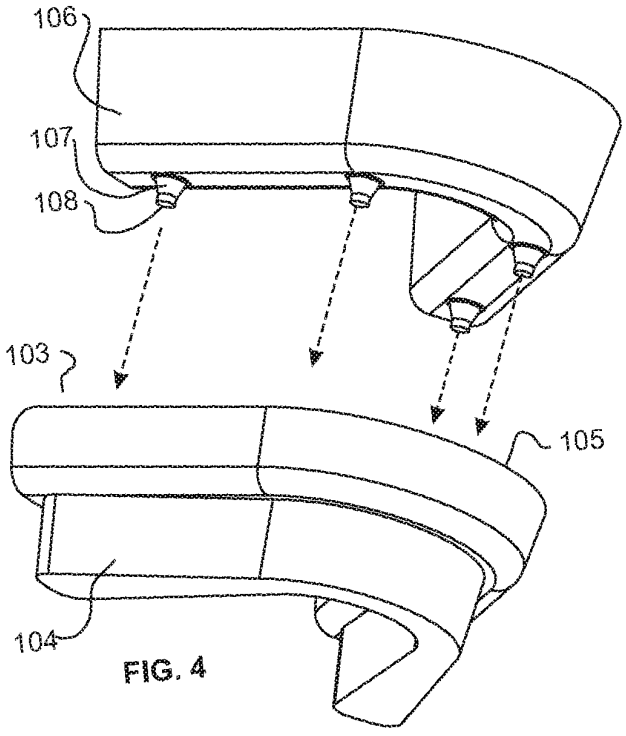


FIG. 4

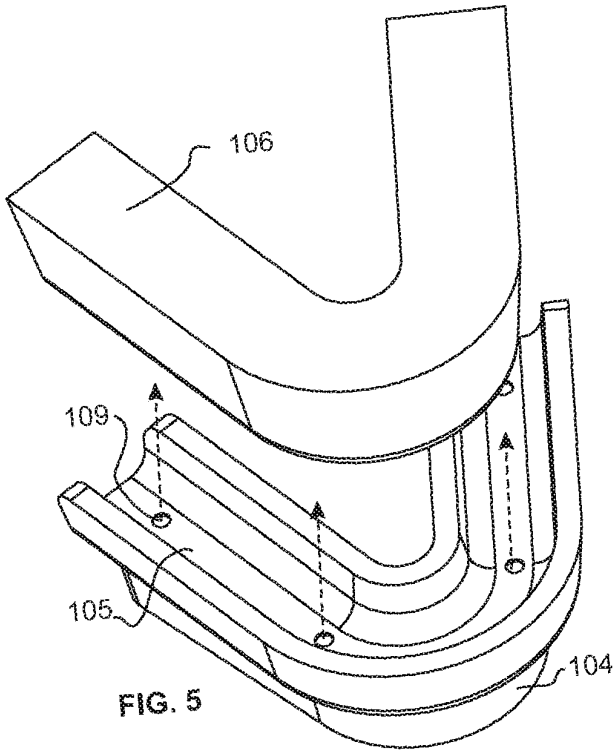


FIG. 5

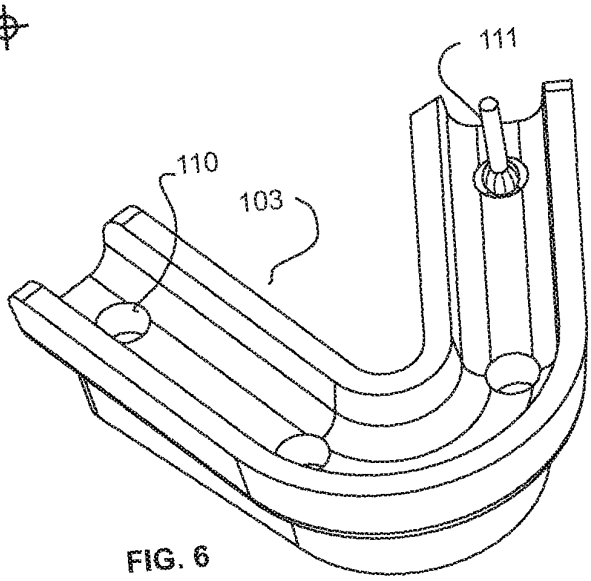


FIG. 6

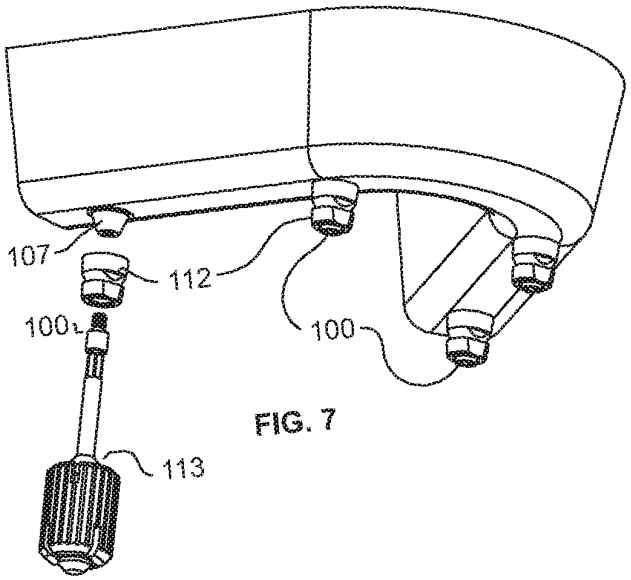


FIG. 7

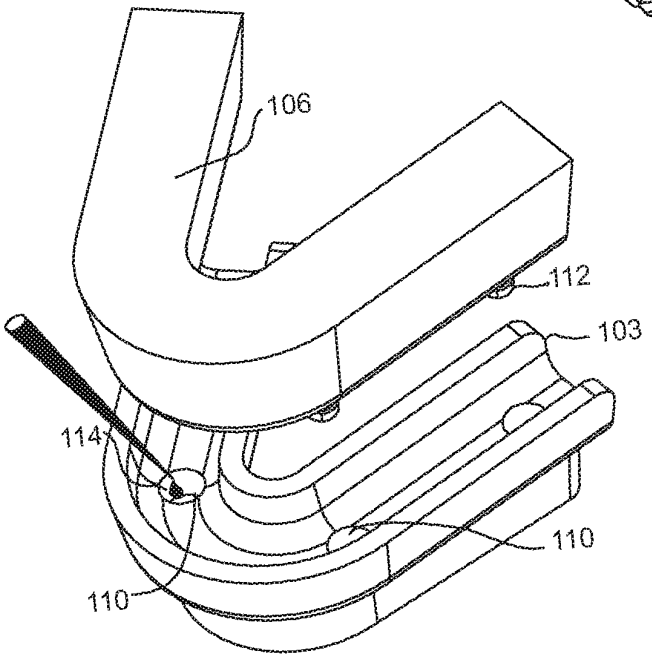


FIG. 8

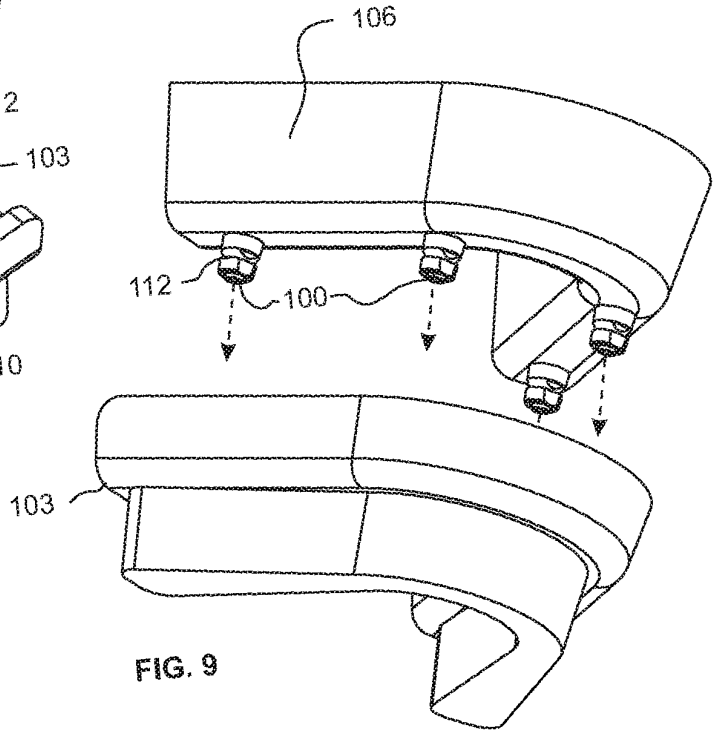


FIG. 9

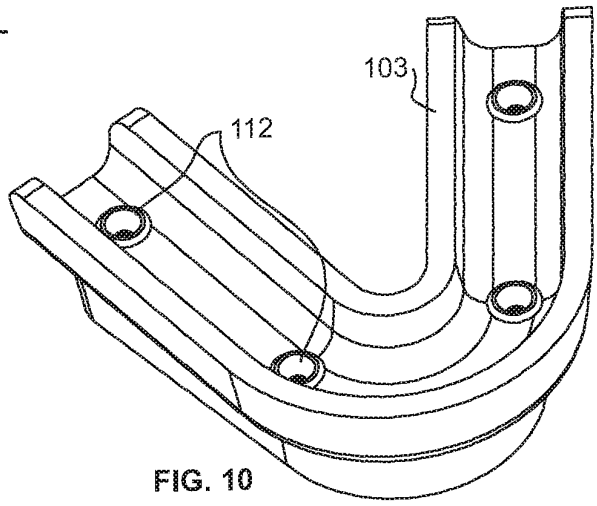


FIG. 10

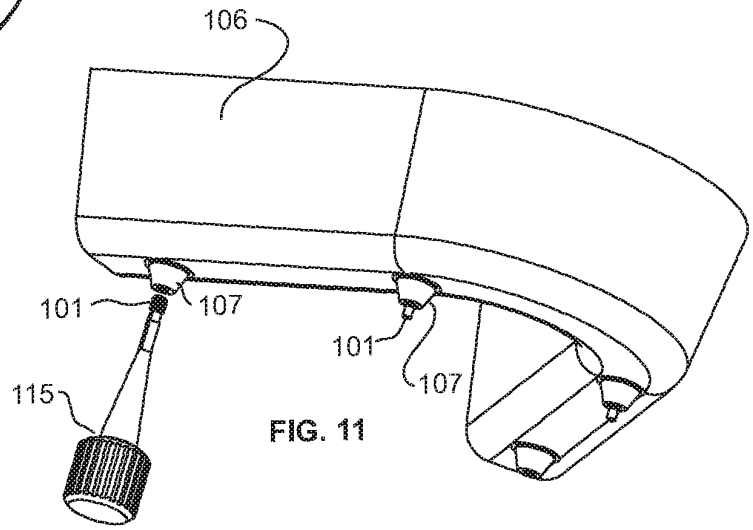


FIG. 11

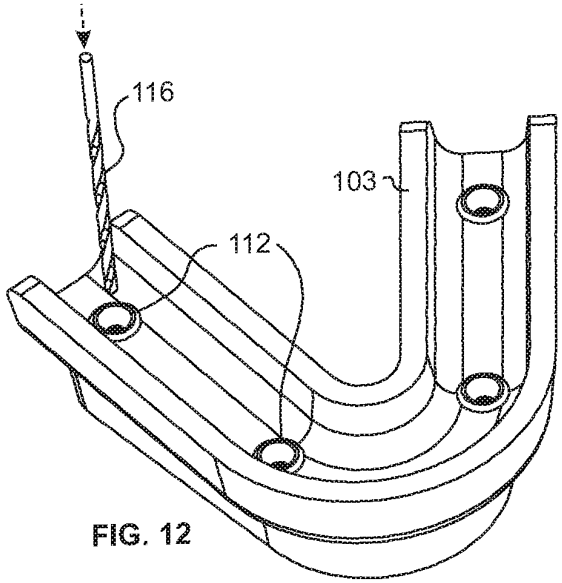


FIG. 12

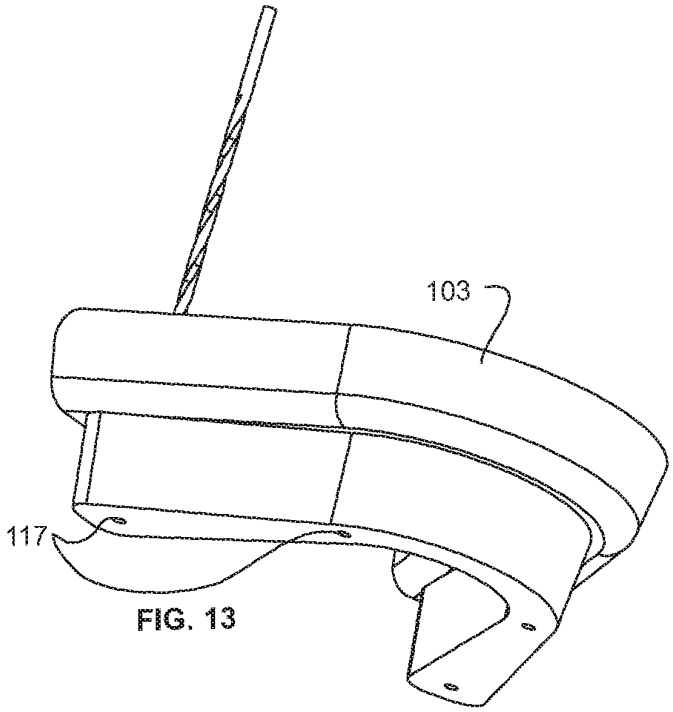


FIG. 13

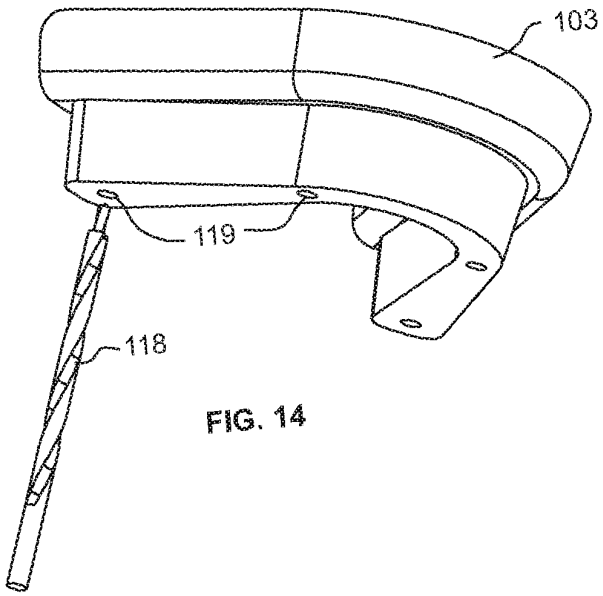


FIG. 14

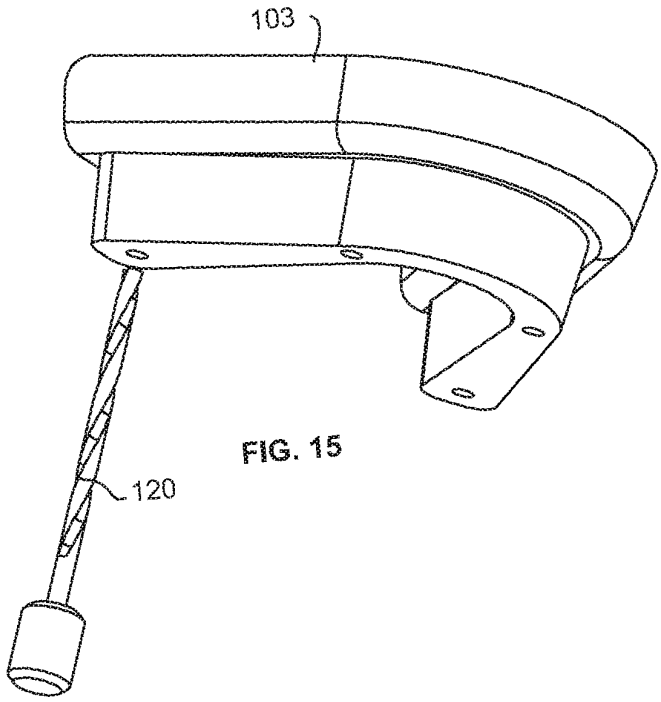


FIG. 15

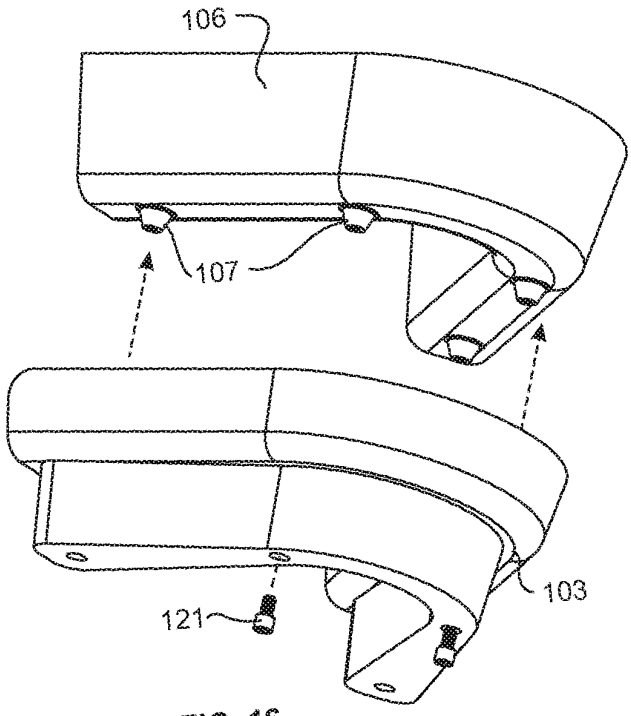


FIG. 16

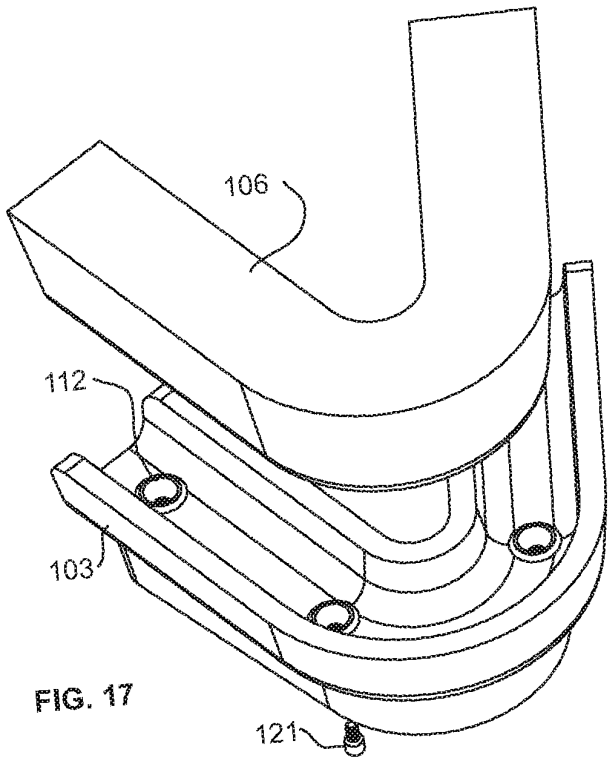


FIG. 17

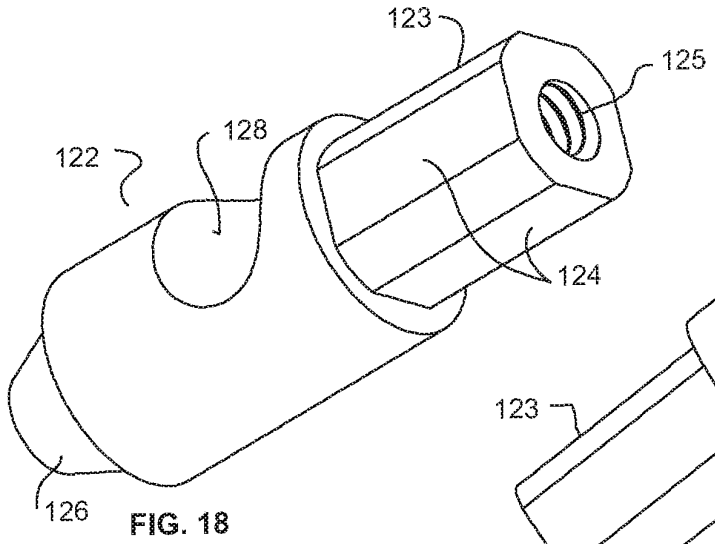


FIG. 18

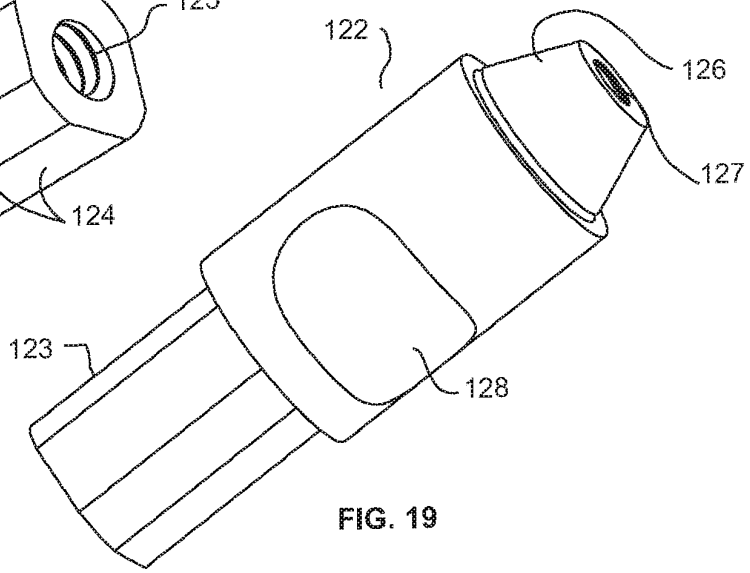


FIG. 19

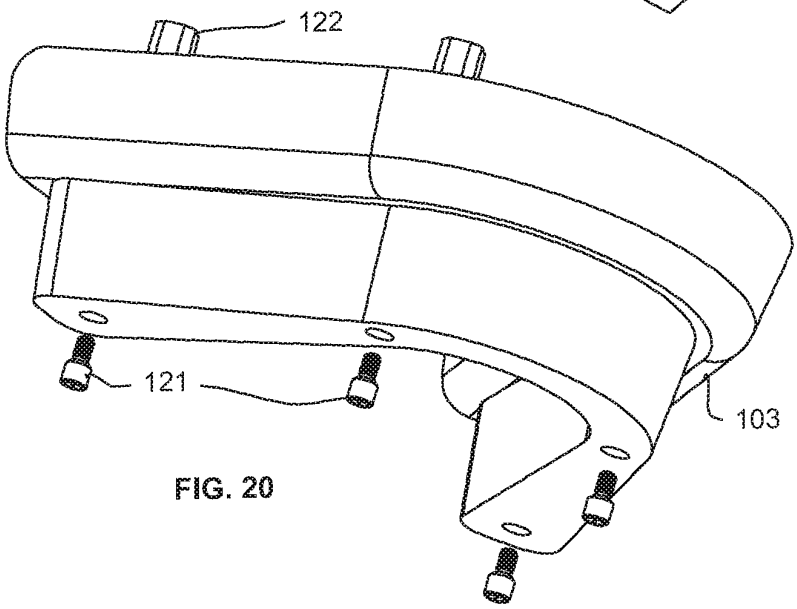


FIG. 20

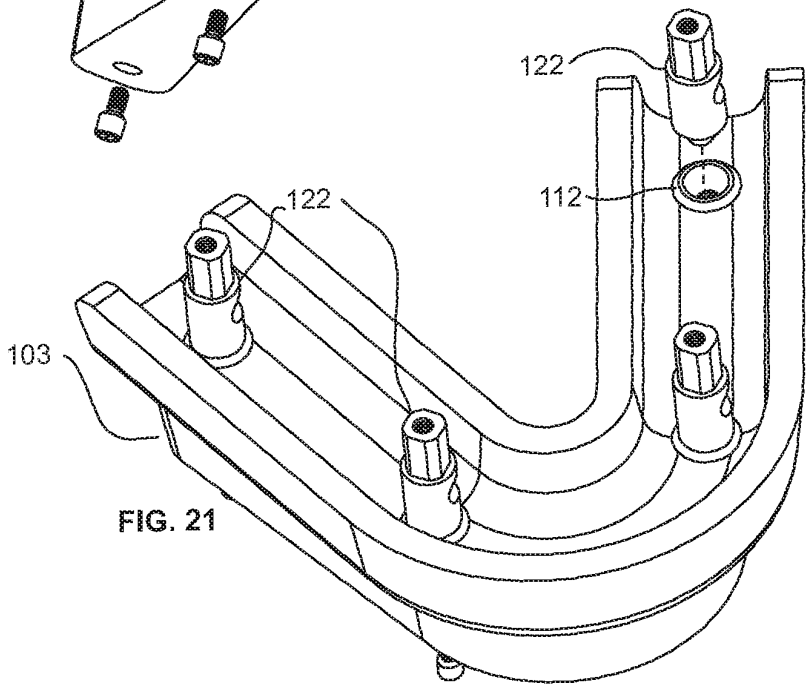


FIG. 21

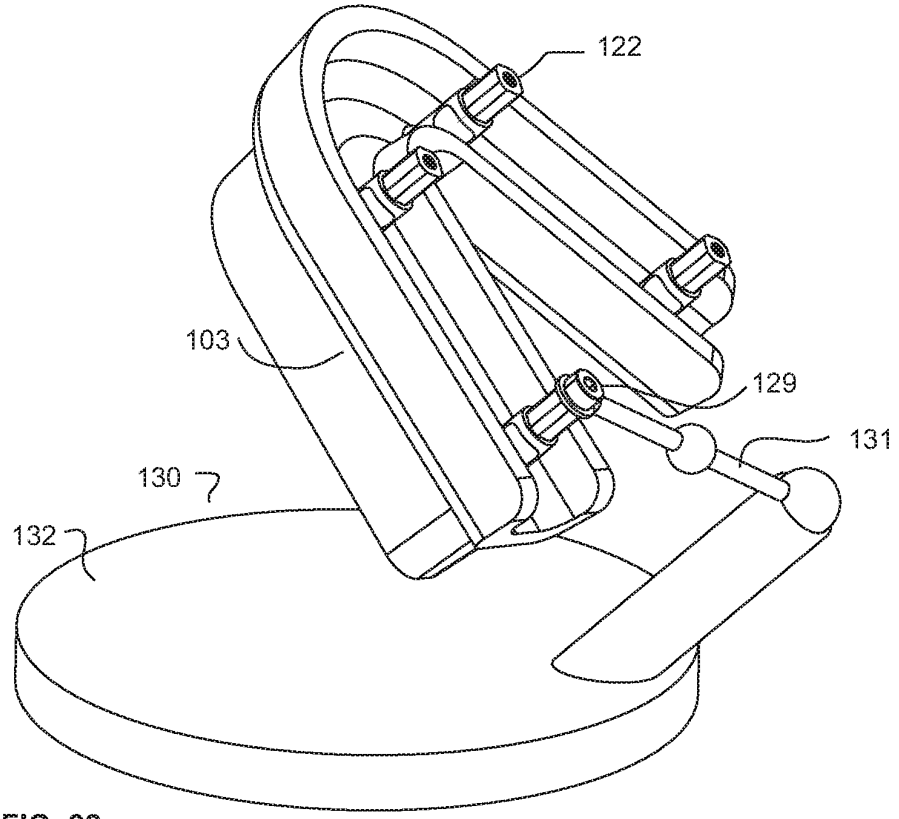
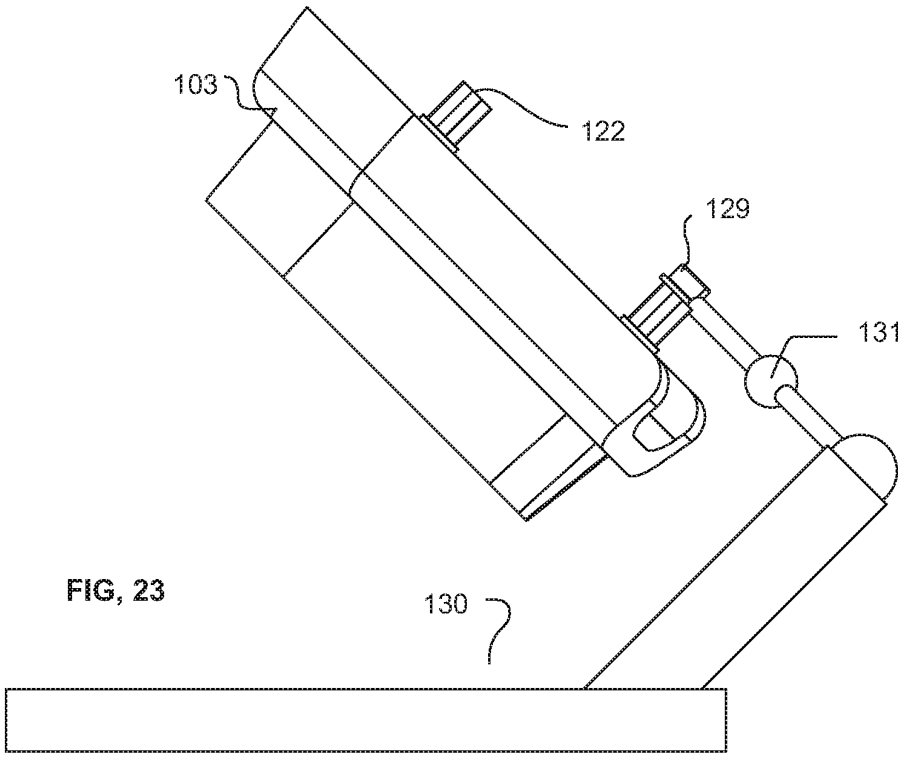


FIG. 22



FIG, 23

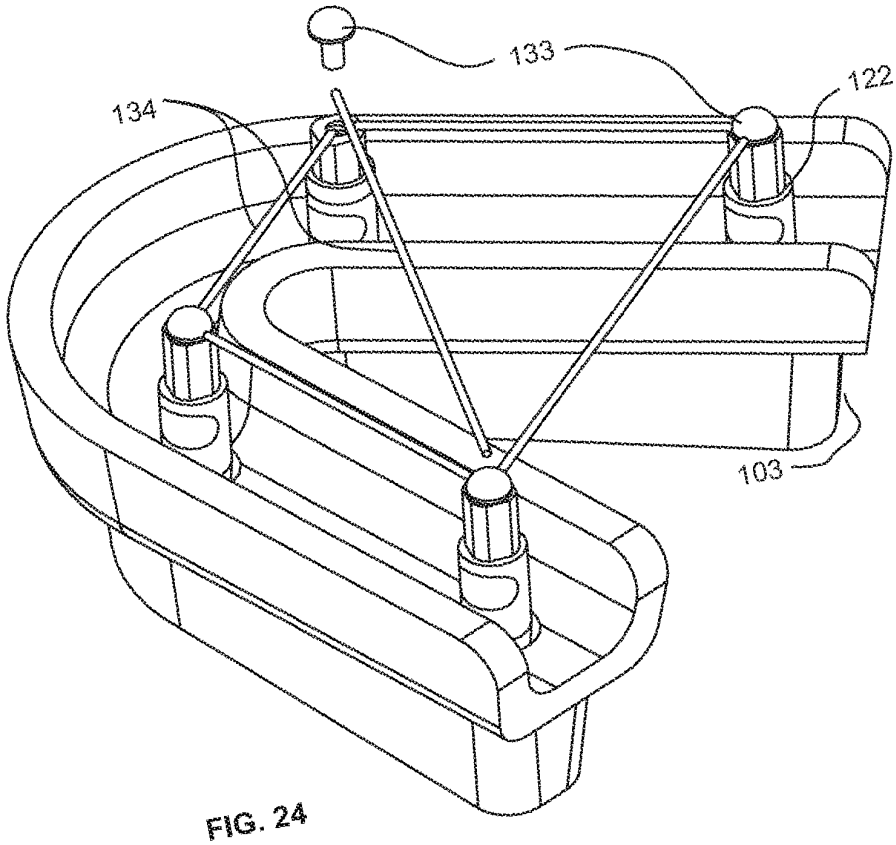


FIG. 24

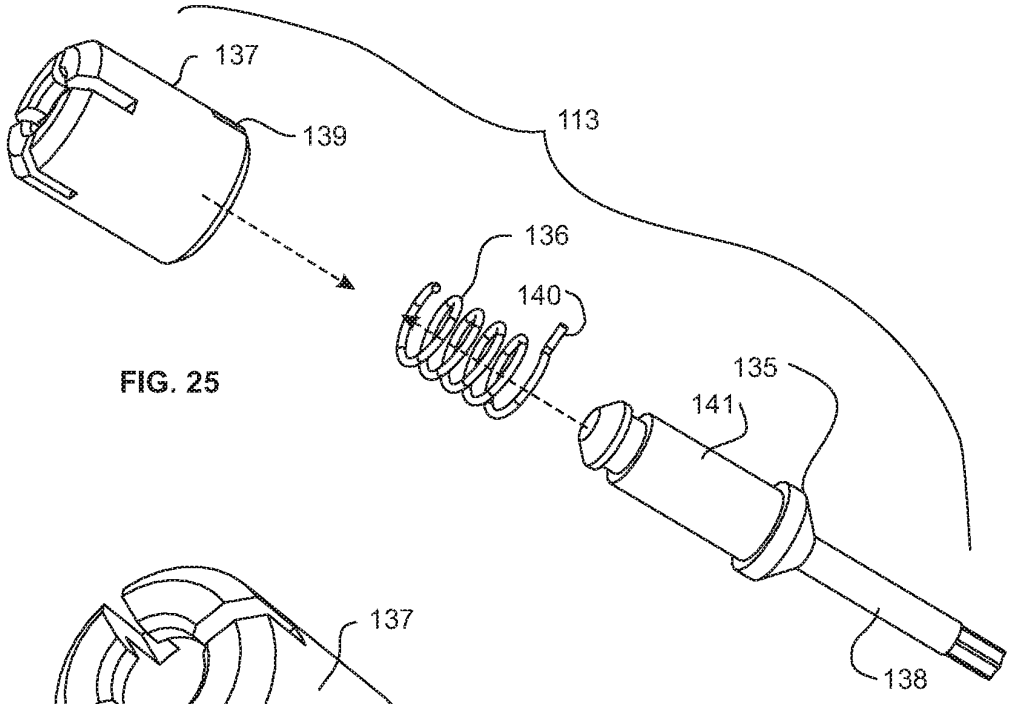


FIG. 25

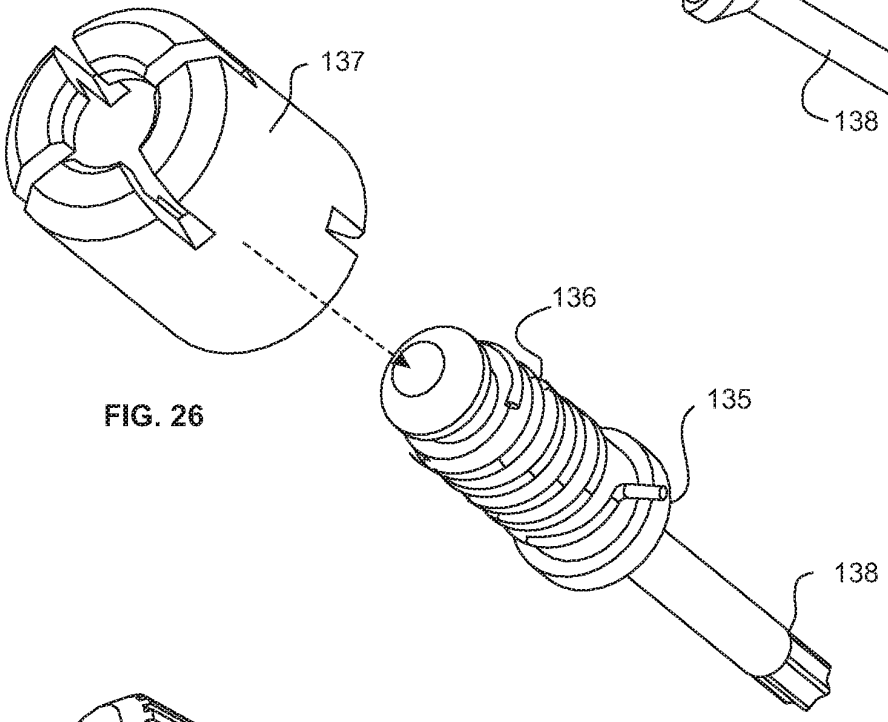


FIG. 26

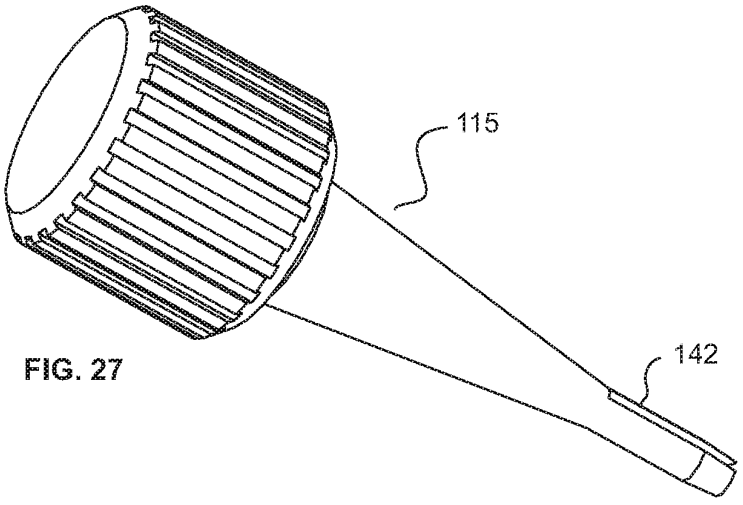


FIG. 27

Electronic Acknowledgement Receipt	
EFS ID:	35417678
Application Number:	62818082
International Application Number:	
Confirmation Number:	3729
Title of Invention:	Improved Dental Prosthesis Scan-Flag Analog System and Methods
First Named Inventor/Applicant Name:	Brandon Dale Kofford
Correspondence Address:	Charles Rudisill - 3908 Bamburgh Lane - Apex NC 27539 US 919-362-6098 charlesr@apextecinc.com
Filer:	Charles Rudisill
Filer Authorized By:	
Attorney Docket Number:	
Receipt Date:	13-MAR-2019
Filing Date:	
Time Stamp:	22:58:48
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$140

RAM confirmation Number	031419INTEFSW23042700
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Provisional Cover Sheet (SB16)	pp-Improved-Dental-Prosthesis-Scan-Flag-Analog-System-SB16cover.pdf	2032389 37570aa03ec5552a1d4478f9010a12a57dbaa305	no	4
Warnings:					
Information:					
2	Specification	PP-Improved-dental-scan-flag-analog-13mar2019-final-text.pdf	116809 a658bc2f3e9e5bdc0d938fc56f563f7e480fe9a4	no	7
Warnings:					
Information:					
3	Drawings-only black and white line drawings	pp-improved-dental-scan-flag-analog-13mar2019-final-figs.pdf	284833 b5a63cc90f6977175f761e191cca341c83c496bf	no	8
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	29553 a3135df0f93a3781e26fc03f2513b82cf97a1fdf	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2463584		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.