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Groscurth et al.

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(45) **Date of Patent: Nov. 29, 2016**

(54) **EDENTULOUS SURGICAL GUIDE**

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(73) Assignee: **IBUR, LLC**, Troy, MI (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 225 days.

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(22) Filed: **Sep. 15, 2012**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61C 3/00 (2006.01)
A61C 1/08 (2006.01)

(52) **U.S. Cl.**
CPC ***A61C 1/084*** (2013.01)

(58) **Field of Classification Search**
CPC A61C 1/084; A61C 1/082; A61C 1/085
USPC 433/75–76, 72; 606/96–97, 99
See application file for complete search history.

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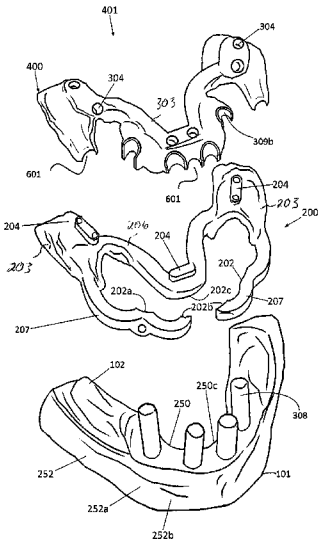
(74) *Attorney, Agent, or Firm* — Fishman Stewart PLLC

(57) **ABSTRACT**

A dental surgical drill guide assembly and method includes a surgical guide housing and a base frame that fits to both gum tissue and one or multiple small areas of jawbone. The apparatus may be configured to accurately place dental implants according to planned positions. Such apparatus may increase the stability of the surgical guide by clasping and/or contacting the jawbone, while improving the overall fit and minimizing the need of invasive surgery and flapping by also clasping and/or contacting selected areas of the gum tissue at the same time. Self-locking alignment members aid in easy removal, and re-installation, of the surgical guide housing to the base frame.

12 Claims, 12 Drawing Sheets



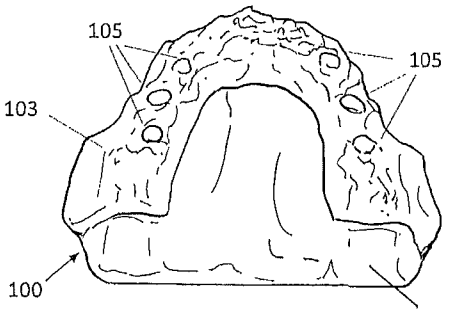


FIG. 1A

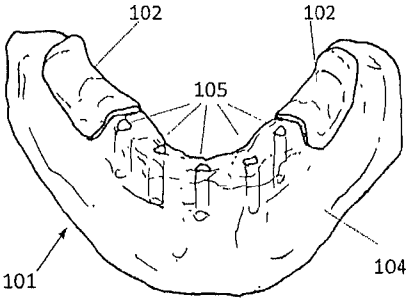


FIG. 1B

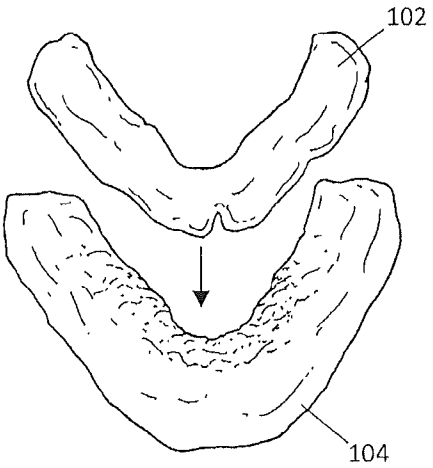


FIG. 1C

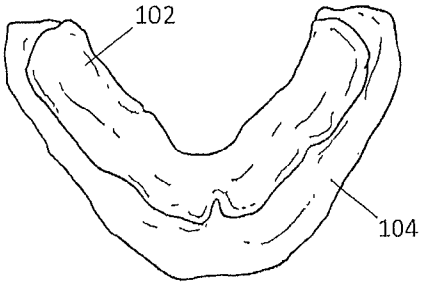


FIG. 1D

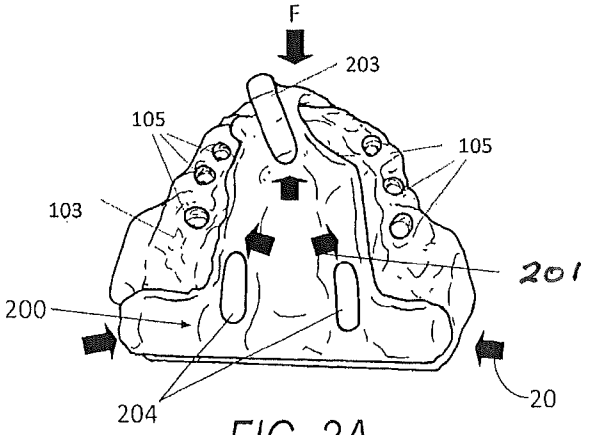


FIG. 2A

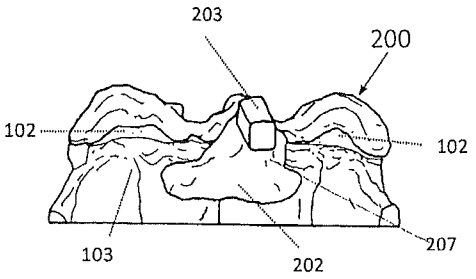
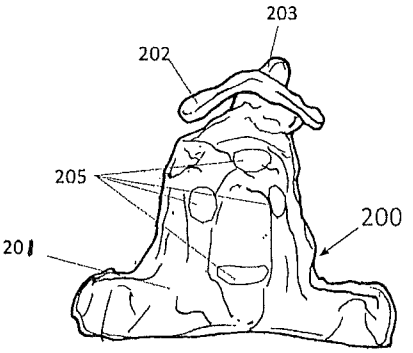


FIG. 2B



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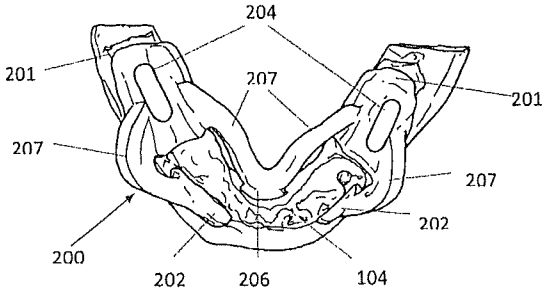


FIG. 2D

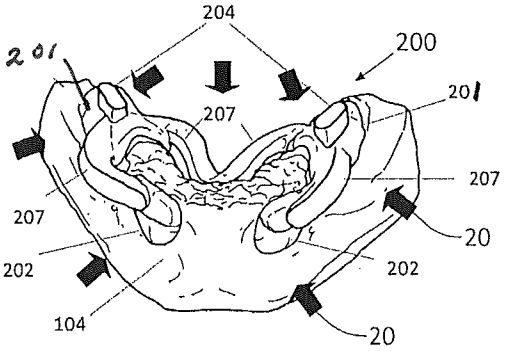


FIG. 2E

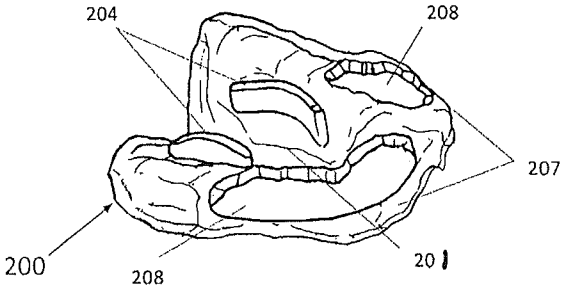


FIG. 2F

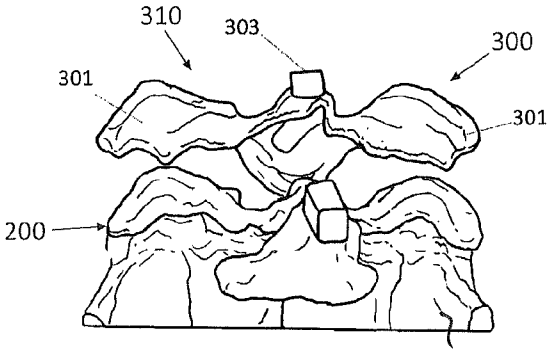


FIG. 3A

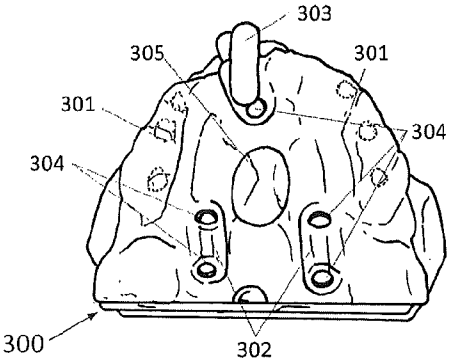
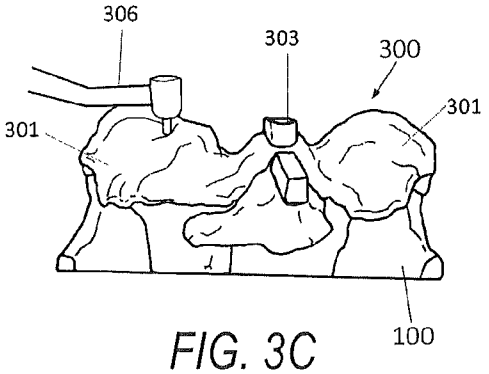


FIG. 3B



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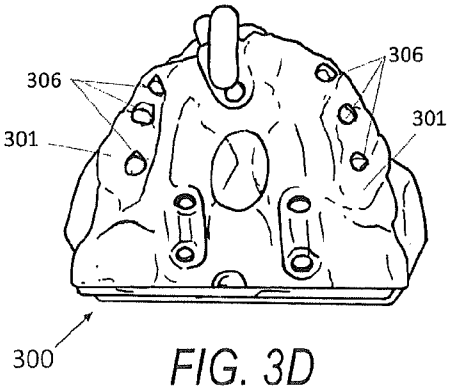
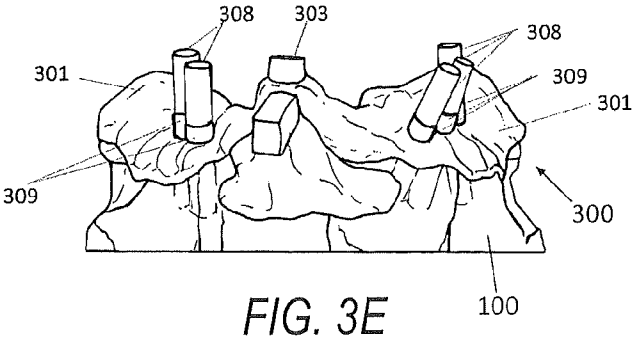


FIG. 3D



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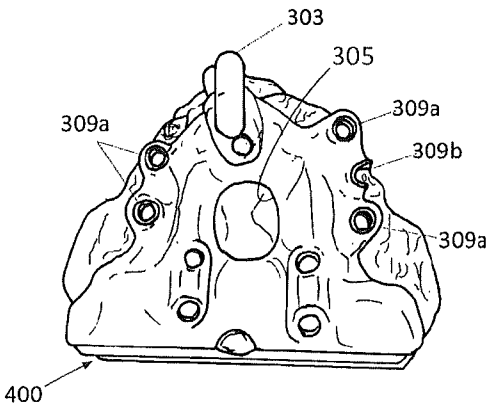
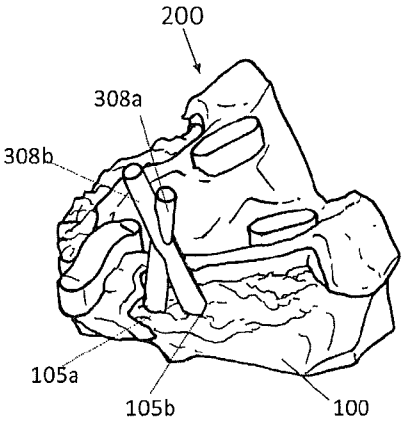


FIG. 4A



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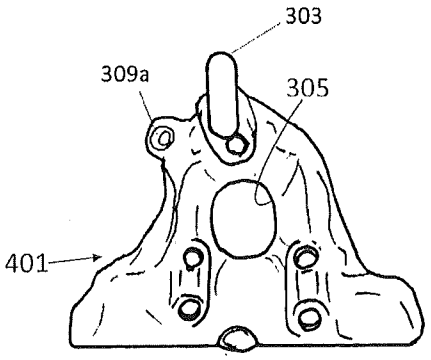

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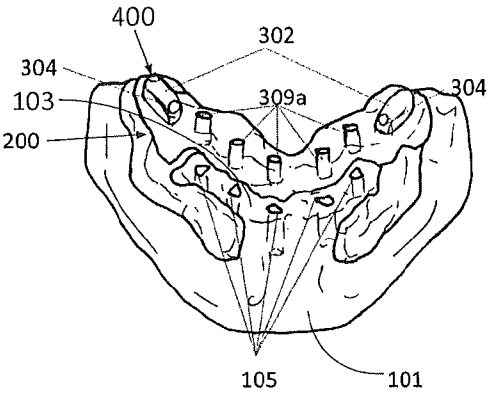

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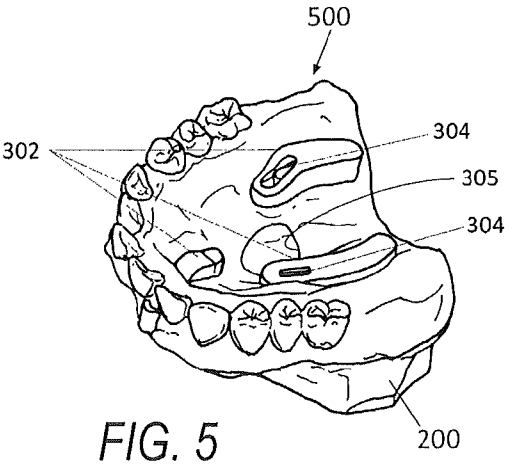

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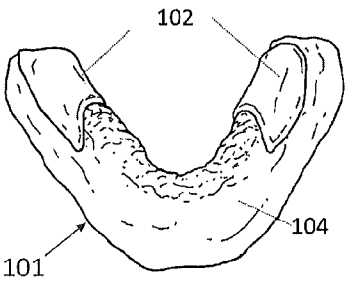

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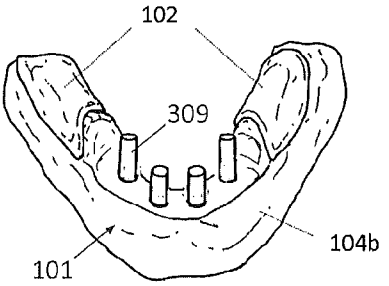

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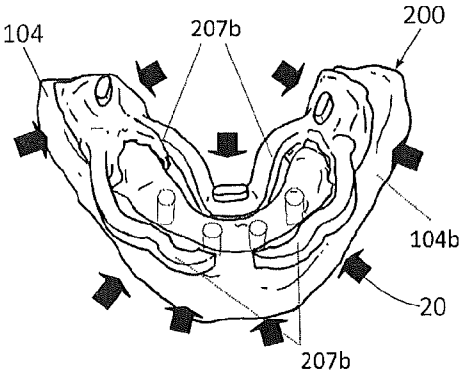

FIG. 6C

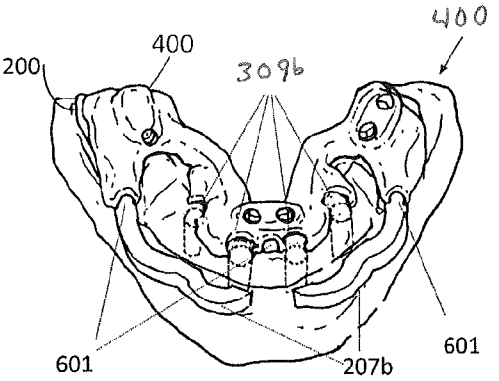

FIG. 6D

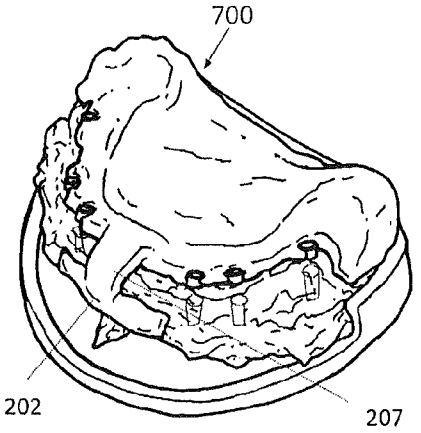

FIG. 7

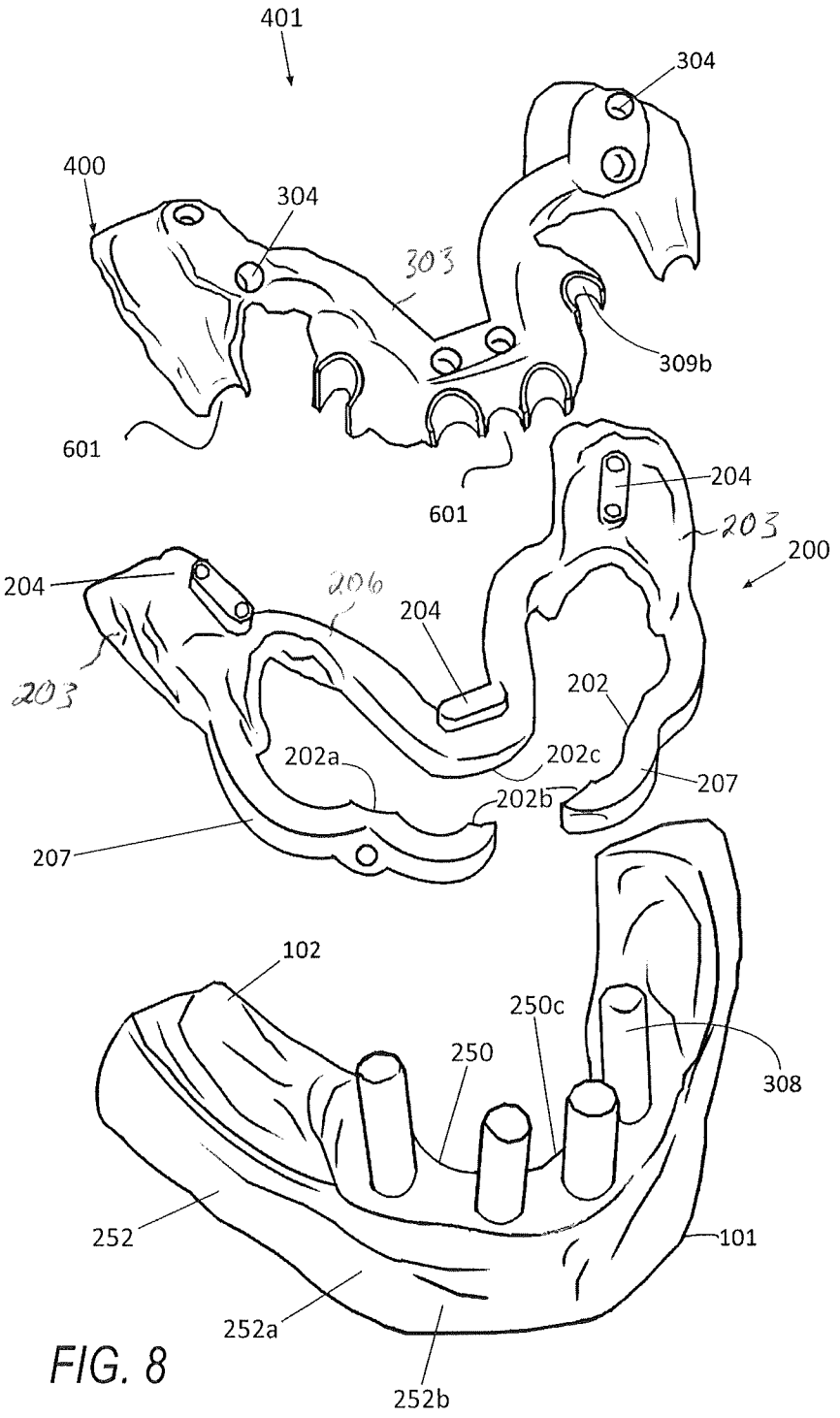
401
304
400
304
303
309b
601
601
204
203
200
204
206
204
203
202
202a
202c
207
202b
207
102
250c
250
308
252
101
252a
252b

FIG. 8

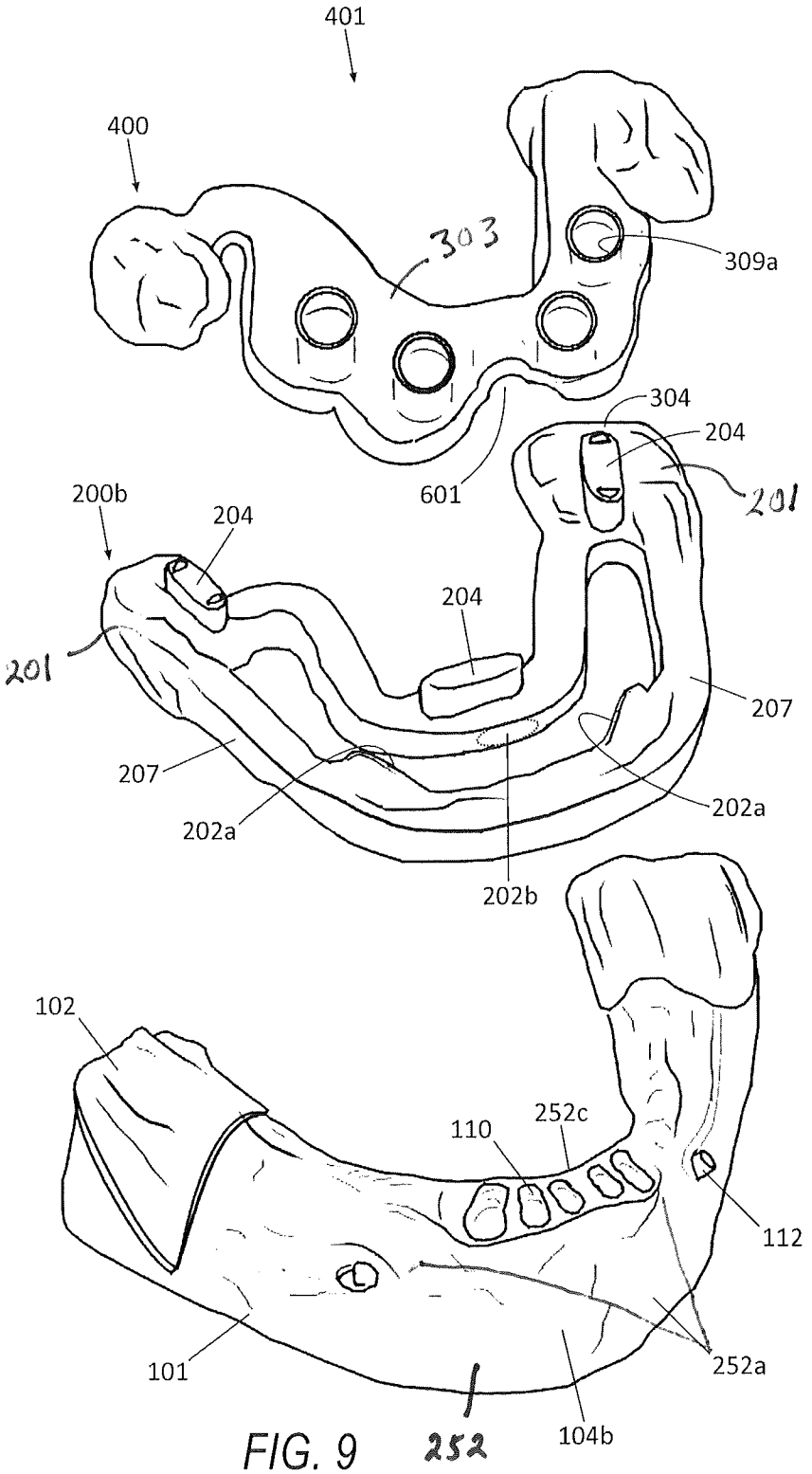
401
400
303
309a
304
204
601
201
200b
204
204
201
207
207
202a
202a
202b
102
110
252c
112
101
252a
252
104b

FIG. 9

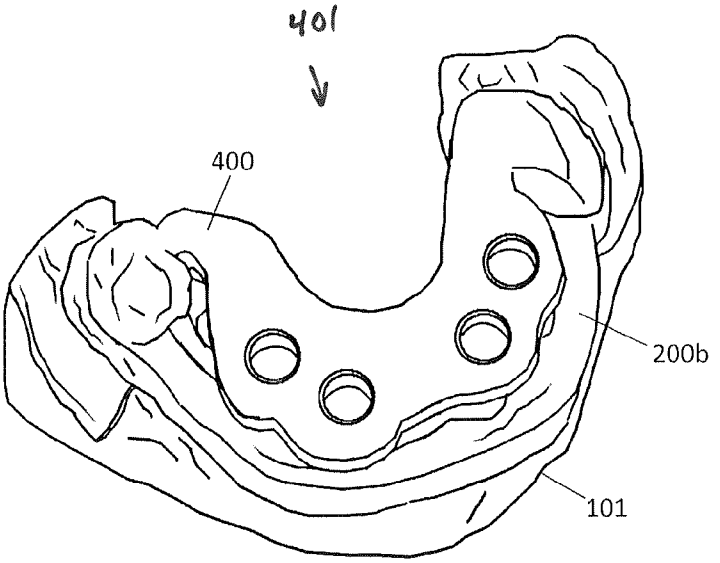
401
400
200b
101

FIG. 10

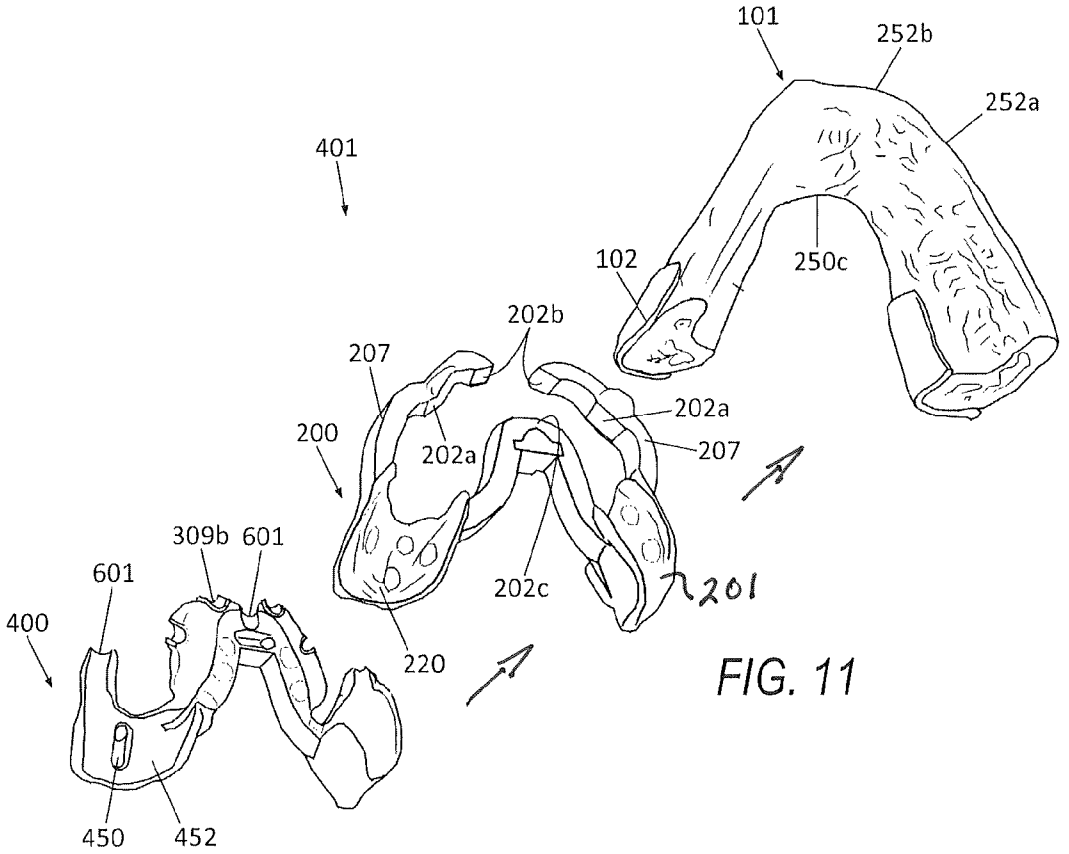
101
252b
252a
401
102
250c
202b
207
202a
200
202a
207
309b
601
601
202c
201
400
220
450
452

FIG. 11

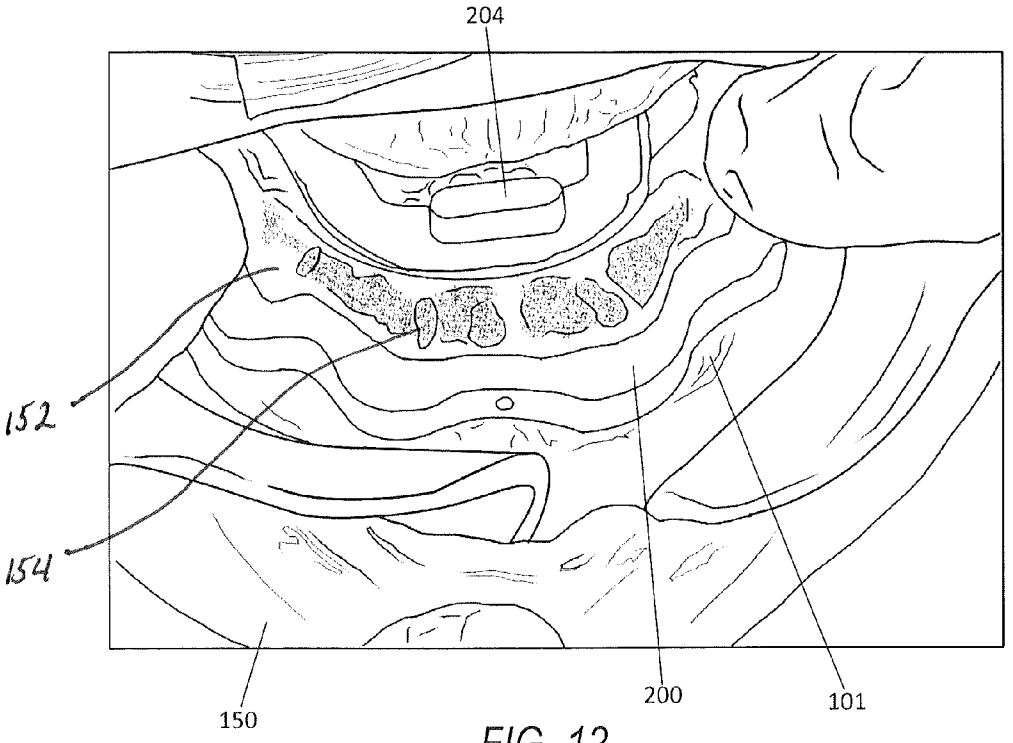

FIG. 12

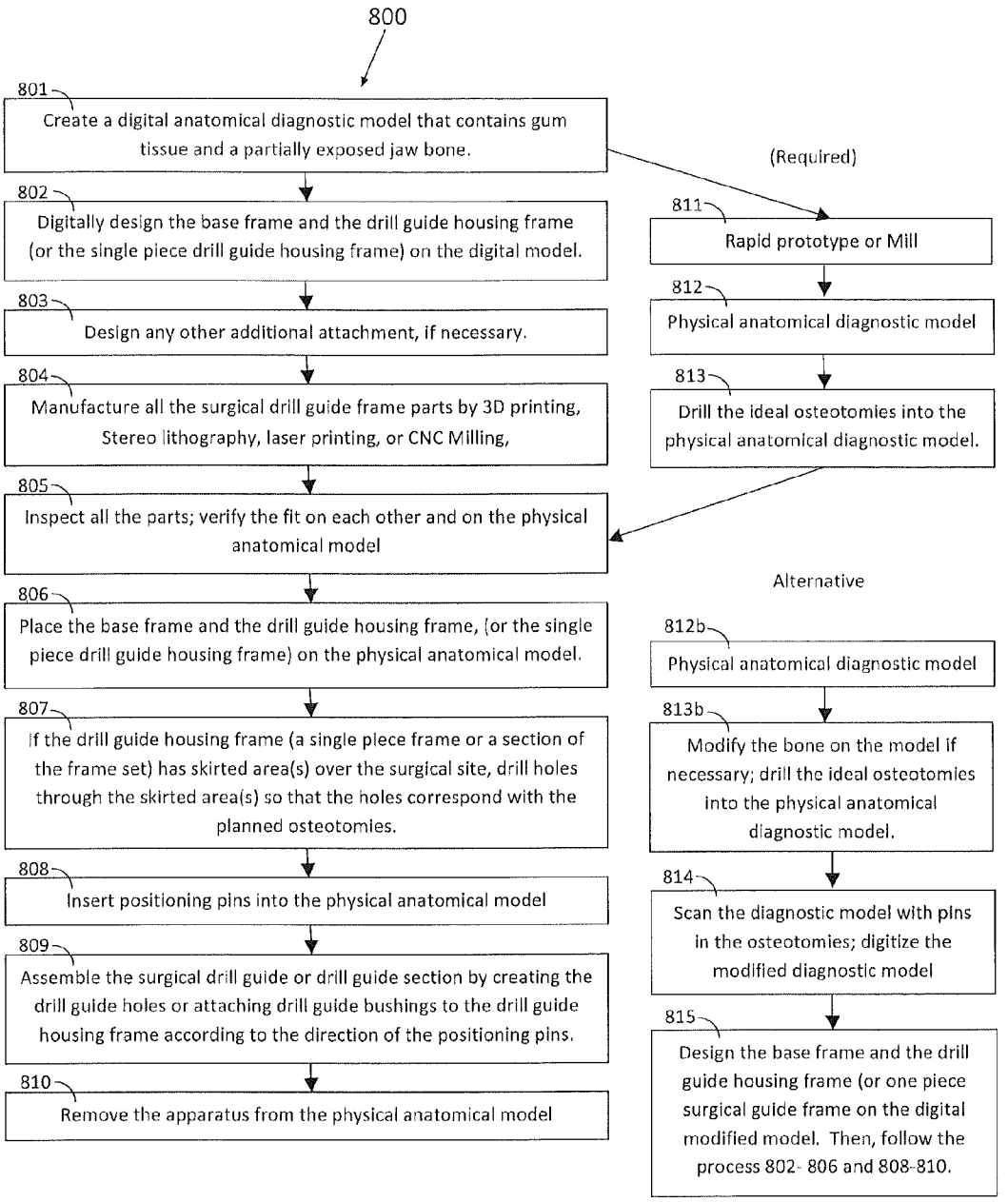
800
801
Create a digital anatomical diagnostic model that contains gum tissue and a partially exposed jaw bone.
802
Digitally design the base frame and the drill guide housing frame (or the single piece drill guide housing frame) on the digital model.
803
Design any other additional attachment, if necessary.
804
Manufacture all the surgical drill guide frame parts by 3D printing, Stereo lithography, laser printing, or CNC Milling,
805
Inspect all the parts; verify the fit on each other and on the physical anatomical model
806
Place the base frame and the drill guide housing frame, (or the single piece drill guide housing frame) on the physical anatomical model.
807
If the drill guide housing frame (a single piece frame or a section of the frame set) has skirted area(s) over the surgical site, drill holes through the skirted area(s) so that the holes correspond with the planned osteotomies.
808
Insert positioning pins into the physical anatomical model
809
Assemble the surgical drill guide or drill guide section by creating the drill guide holes or attaching drill guide bushings to the drill guide housing frame according to the direction of the positioning pins.
810
Remove the apparatus from the physical anatomical model
(Required)
811
Rapid prototype or Mill
812
Physical anatomical diagnostic model
813
Drill the ideal osteotomies into the physical anatomical diagnostic model.
Alternative
812b
Physical anatomical diagnostic model
813b
Modify the bone on the model if necessary; drill the ideal osteotomies into the physical anatomical diagnostic model.
814
Scan the diagnostic model with pins in the osteotomies; digitize the modified diagnostic model
815
Design the base frame and the drill guide housing frame (or one piece surgical guide frame on the digital modified model. Then, follow the process 802- 806 and 808-810.

FIG. 13

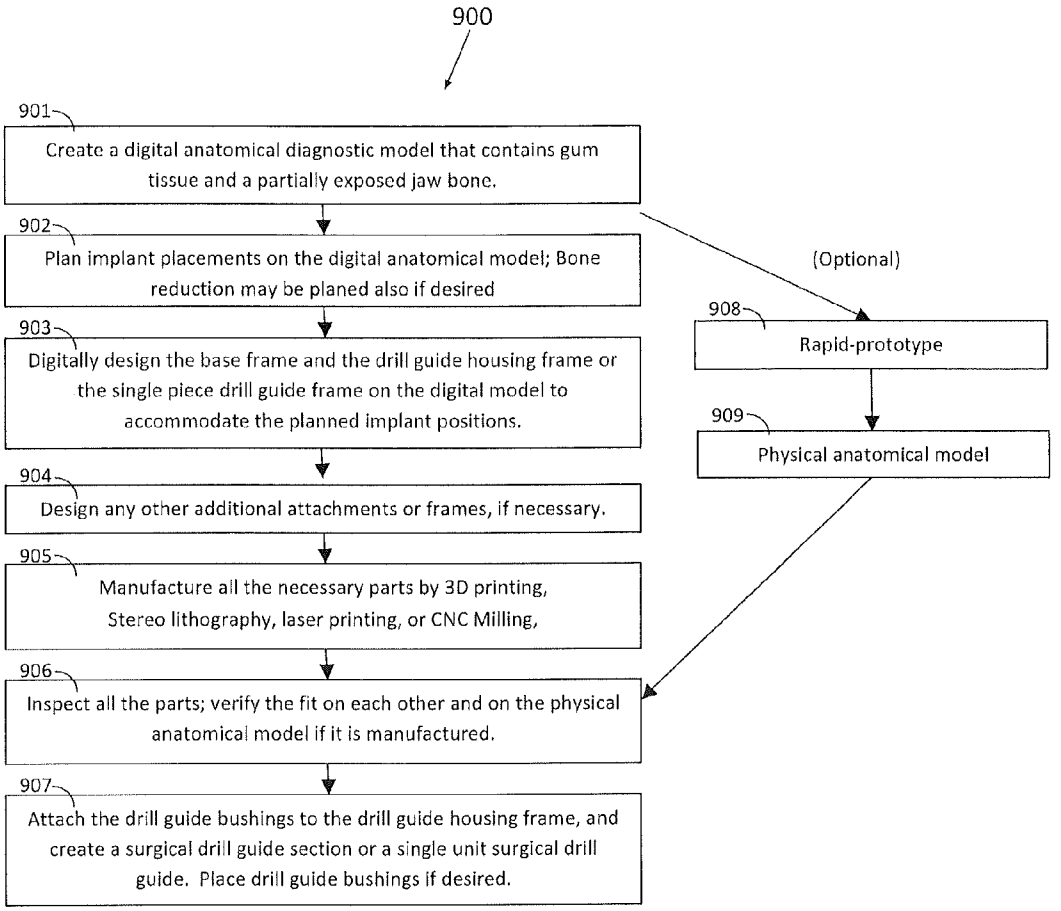
900
901
Create a digital anatomical diagnostic model that contains gum tissue and a partially exposed jaw bone.
902
Plan implant placements on the digital anatomical model; Bone reduction may be planed also if desired
903
Digitally design the base frame and the drill guide housing frame or the single piece drill guide frame on the digital model to accommodate the planned implant positions.
904
Design any other additional attachments or frames, if necessary.
905
Manufacture all the necessary parts by 3D printing, Stereo lithography, laser printing, or CNC Milling,
906
Inspect all the parts; verify the fit on each other and on the physical anatomical model if it is manufactured.
907
Attach the drill guide bushings to the drill guide housing frame, and create a surgical drill guide section or a single unit surgical drill guide. Place drill guide bushings if desired.
(Optional)
908
Rapid-prototype
909
Physical anatomical model

FIG. 14

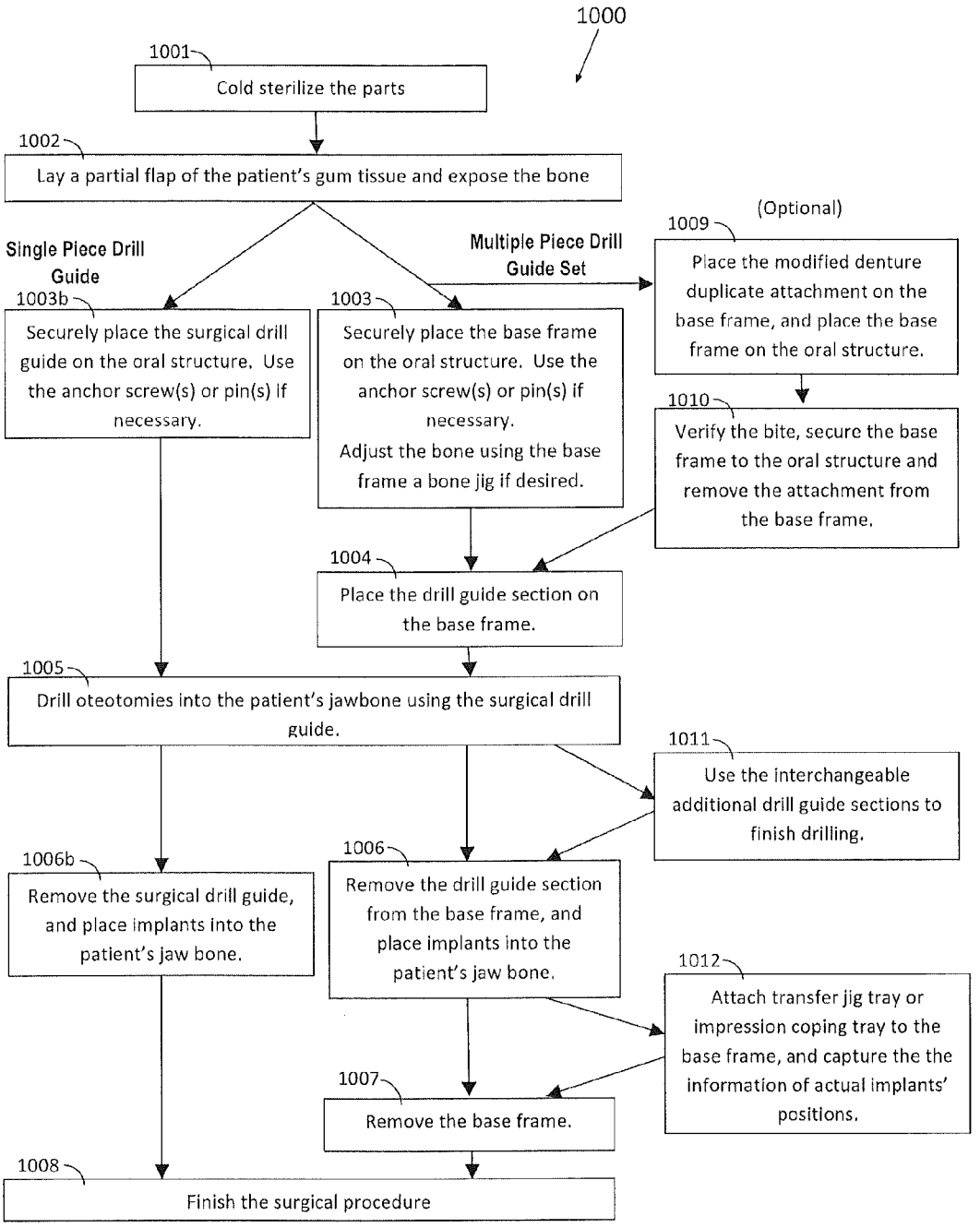
1000
1001
Cold sterilize the parts
1002
Lay a partial flap of the patient's gum tissue and expose the bone
Single Piece Drill Guide
Multiple Piece Drill Guide Set
(Optional)
1009
Place the modified denture duplicate attachment on the base frame, and place the base frame on the oral structure.
1003b
Securely place the surgical drill guide on the oral structure. Use the anchor screw(s) or pin(s) if necessary.
1003
Securely place the base frame on the oral structure. Use the anchor screw(s) or pin(s) if necessary.
Adjust the bone using the base frame a bone jig if desired.
1010
Verify the bite, secure the base frame to the oral structure and remove the attachment from the base frame.
1004
Place the drill guide section on the base frame.
1005
Drill oteotomies into the patient's jawbone using the surgical drill guide.
1011
Use the interchangeable additional drill guide sections to finish drilling.
1006b
Remove the surgical drill guide, and place implants into the patient's jaw bone.
1006
Remove the drill guide section from the base frame, and place implants into the patient's jaw bone.
1012
Attach transfer jig tray or impression coping tray to the base frame, and capture the the information of actual implants' positions.
1007
Remove the base frame.
1008
Finish the surgical procedure

FIG. 15

EDENTULOUS SURGICAL GUIDE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application Ser. No. 61/535,698, filed Sep. 16, 2011, which is hereby expressly incorporated by reference in its entirety.

FIELD OF THE INVENTION

An improved dental implant method and apparatus is disclosed, and, more particularly, a surgical guide that can be fit to a patient's jawbone.

BACKGROUND AND SUMMARY OF THE INVENTION

Dental implants are commonly used in today's dental practices to support various prostheses. Challenges to the successful placement of dental implants include poor bone quality and various hidden anatomical features such as nerves, roots, and sinus cavities. Surgical preplanning methods and drill guide apparatuses may be used to better address these challenges. With edentulous cases, surgical drill guide apparatuses can be divided into two categories: bone borne surgical drill guides and gum tissue borne surgical guides.

Bone borne surgical drill guides are made to fit on a patient's jawbone, and can be made from either a digital jawbone model or rapid-prototyped physical jawbone model of the patient. The primary problem with bone borne surgical guides is the invasiveness of the amount of flapping of the gum tissue that the surgeon has to create in order for the guide to fit correctly on the patient jawbone. The amount of flapping required increases the likelihood of surgical risks and complications, including blood loss, infection, healing problems, and overall pain experienced by the patient. Flapping and suturing also requires a great deal of surgical time. In addition to the problems associated with the surgical procedure, difficulties may also arise when the jawbone has low density, which happens often with Maxilla bones in posterior region. Low bone density makes it difficult to define the contour of the bone in CT images, which may cause the bone borne surgical drill guide to fit poorly. Thus, the use of bone borne surgical drill guides has drawbacks and it would be preferred to overcome their associated problems.

Gum tissue borne surgical drill guides are made to fit on top of a patient's gum tissue without the need for any surgical incisions to stabilize the guide. In order to create this type of surgical guide, the surface scan data of the gum tissue and the tomography data of the jawbone need to be accurately aligned and mapped. For this purpose, usually an imaging template is worn by the patient during tomography scanning, and the fiducial markers on the device are used for alignment of the different data sets. While this method is less surgically invasive than the bone borne method, gum tissue borne surgical guides lack stability. Gum tissue is in a constant state of movement and drift, and is also pliable with pressure. Moreover, certain health conditions and even the intake of certain foods make gum tissue more prone to swelling. These conditions may prevent the accurate positioning of the device in the mouth. Here, even if the surgeon uses anchor screws, they may be securing the device in the wrong position. This type of surgical drill guide sacrifices accuracy for convenience. Thus, it would be preferred to overcome these problems.

Accordingly, it would be desirable to provide a stable and accurate surgical drill guide apparatus that requires only minimum flapping and fits to both gum tissue and one or multiple small areas of jawbone. Such apparatus may increase the stability of the surgical guide by clasping and/or contacting the jawbone, while improving the overall fit and minimizing the need of flapping by also clasping and/or contacting selected areas of the gum tissue at the same time. The apparatus may be configured to accurately place dental implants according to the planned positions.

It would also be preferable to provide an apparatus that may be custom designed to suit the unique anatomical features of each individual. The device may be designed on a digital anatomical jawbone model with accurately mapped and aligned gum tissue information, and may be rapid prototyped or milled as a drill guide frame or frame set. Also, the apparatus may be made by hand on the rapid prototyped or CNC milled physical anatomical model that partially exposes the jawbone structure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a top view of an upper jaw anatomical diagnostic model with gum tissue and a partially exposed bone structure;

FIG. **1**B is a perspective front view of a lower jaw anatomical diagnostic model with gum tissue and a partially exposed bone structure;

FIG. **1**C is a perspective front view of a lower jawbone digital image and a gum tissue image which are about to be aligned;

FIG. **1**D is a perspective front view of a lower jaw bone digital image aligned with the gum tissue digital image;

FIG. **2**A is a top view of an exemplary base frame for an upper jaw on a diagnostic model with gum tissue and a partially exposed bone structure;

FIG. **2**B is a side view of the exemplary base frame for the upper jaw on FIG. **2**A diagnostic model;

FIG. **2**C is a bottom view of the exemplary base frame for the upper jaw shown in FIG. **2**A;

FIG. **2**D is a top view of an exemplary base frame for a lower jaw on a diagnostic anatomical model with gum tissue and a partially exposed bone structure;

FIG. **2**E is a perspective front view of the exemplary base frame for the lower jaw on the same anatomical diagnostic model shown in FIG. **2**D;

FIG. **2**F is a perspective view of an exemplary base frame for the upper jaw;

FIG. **3**A is a side view of the exemplary drill guide housing frame for the upper jaw about to be attached to the exemplary base frame on the anatomical model;

FIG. **3**B is a top view of the FIG. **3**A drill guide housing frame, with skirted area on the base frame and the physical anatomical diagnostic model;

FIG. **3**C is a side view of the FIG. **3**A drill guide housing frame, with a hand piece drilling holes into the skirted areas;

FIG. **3**D is a top view of the FIG. **3**A exemplary drill guide housing frame, with holes that correspond with planned osteotomies on the physical anatomical diagnostic model;

FIG. **3**E is a side view of the FIG. **3**D physical anatomical diagnostic model, with positioning pins and drill guide bushings placed into the planned osteotomies through the holes on the skirt portion of the drill guide housing frame;

FIG. **4**A is a top view of an exemplary drill guide section for the upper jaw placed on the base frame and the physical anatomical diagnostic model;

FIG. **4**B is a perspective view of the FIG. **4**A anatomical diagnostic model with base frame and positioning pins, showing intersecting osteotomy angulations;

FIG. **4**C is a top view of an exemplary interchangeable additional drill guide section with a tube surgical drill guide bushing;

FIG. **4**D is a top view of an exemplary surgical drill guide section for the lower jaw placed on the base frame and the physical diagnostic anatomical model;

FIG. **5** is a perspective view of an exemplary modified denture duplicate attachment for an upper jaw attached to a base frame;

FIG. **6**A is a perspective front view of an exemplary anatomical diagnostic model with a partially exposed lower jaw bone before adjustment;

FIG. **6**B is a perspective front view of the exemplary anatomical diagnostic model with a partially exposed modified lower jaw bone with planned osteotomies;

FIG. **6**C is a perspective front view of an exemplary base frame on the diagnostic anatomical model;

FIG. **6**D is a perspective front view of an exemplary drill guide section placed on the base frame and the anatomical diagnostic model;

FIG. **7** is a perspective view of an exemplary one piece drill guide on a physical anatomical diagnostic model;

FIG. **8** is an exploded perspective view of the FIG. **6**D drill guide assembly;

FIG. **9** is an exploded perspective view of another exemplary drill guide assembly;

FIG. **10** is the FIG. **9** drill guide assembly in assembled form;

FIG. **11** is a bottom perspective exploded view of the FIG. **8** assembly;

FIG. **12** is the base frame of the FIG. **9** drill guide assembly shown positioned within the mouth of a patient.

FIG. **13** is a diagram of the edentulous surgical drill guide manufacturing process for a model based implant placement planning;

FIG. **14** is a diagram of the edentulous surgical drill guide manufacturing process for a digital implant placement planning; and

FIG. **15** is a diagram of how to utilize the edentulous surgical drill guide during the surgery.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the discussion that follows and also to the drawings, illustrative approaches are shown in detail. Although the drawings represent some possible approaches, the drawings are not necessarily to scale and certain features may be exaggerated, removed, or partially sectioned to better illustrate and explain the present disclosure. Further, the descriptions set forth herein are not intended to be exhaustive or otherwise limit or restrict the claims to the precise forms and configurations shown in the drawings and disclosed in the following detailed description.

FIGS. **1**A and **1**B illustrate patient specific digital or physical dental anatomical diagnostic models **100** and **101** that expose the partial upper jawbone bone structures **103** and a lower jawbone **104** at the surgical sites and the areas of interest. In areas where the bone structures are not exposed, the model has gum tissue surface structures **102**. As in FIGS. **1**A and **1**B, these gum tissue surface structures **102** usually appear towards the distal end of the posterior regions and the palatal area of the upper jaws.

FIGS. **1**C and **1**D depict a digital image of a lower jawbone **104** and a digital image of the gum tissue surface structures **102** positioned relative to one another, from which diagnostic anatomical models like **1**A and **1**B are created.

The bone structure data can be obtained by tomography imaging devices such as CT and CB CT, and may be exported as a file format, such as STL, suitable for reverse engineering and 3D imaging. Then the data file can be accurately aligned with the surface scan data of the gum tissue **102** obtained by devices such as laser and optical scanners by means of matching fiducial markers on the imaging apparatus that the patient wears during the tomography scan to the markers' positional information on the surface scan data. If the bottom of the apparatus represents the patient's gum tissue surface, the image of the patient's gum surface can also be obtained by scanning the imaging apparatus alone using a tomography device. In this case, these two CT data files can be aligned by the fiducial marker location(s) after each structure is thresholded and is exported as a proper file format for modeling. If a radio opaque duplicated denture is used as an imaging apparatus, the bone structure data and the gum surface data can be obtained with a single CT scan of the patient with the imaging apparatus in place. After the necessary structures are properly aligned in a file format suitable for 3D modeling, the data files can be combined and used to design a digital anatomical diagnostic model with a partially exposed bone structure in the area of the surgical site.

The osteotomies of simulated dental implant placements **105** may be created either digitally on the digital anatomical diagnostic model or manually on the rapid-prototyped physical anatomical diagnostic model. Then a drill guide apparatus may be designed on this type of digital anatomical diagnostic model so that it will accommodate drill guide bushings or holes which guide the surgical drill according to the planned osteotomies either on the digital anatomical diagnostic model or the physical anatomical diagnostic model. Alternatively, the whole apparatus can be designed manually on this type of physical anatomical diagnostic model with dental materials such as, but not limited to, light cured composite, cold cured resin or acrylic, or thermoplastic.

FIGS. **2**A-E are exemplary designs of a base frame **200** for an upper jaw (FIGS. **2**A-**2**C) and a lower jaw (FIGS. **2**D & **2**E). The base frame **200** may be made of a transparent or semi-transparent resin or other composite material that gives the surgeon maximum visibility of the surgical site, but it may also be made of a colored resin and other composite material or metal that provides the base frame **200** with enough rigidity for stability and the right amount of flexibility in clasping areas. In order to obtain rigidity and flexibility in different areas, the frame **200** may be designed to have thick areas and thin areas accordingly within the frame. Overall however, the base frame can be more flexible than one piece surgical guide since the surgical drill guide section placed on top of it can solidify the whole drill guide assembly and the flexibility allows the device to clasp on to the undercut easily. The base frame **200** is shown positioned on top of the upper jawbone structure **103**. A plurality of osteotomies of simulated dental implant placements **105** are shown about the periphery of the upper jawbone structure **103**. A handle **203** is secured towards a forward portion of the base frame **200** which is used to aid in the maneuverability of the base frame **200**. Interlocking connectors **204** are firmly mounted to, or formed part thereof, the base frame **200**, and provide guides for the surgical drill guide housing

frame **300** to connect thereto. The arrows **20** depict potential pressure impinging points for the drill guide housing frame **300** to impinge upon.

FIG. **2**D shows a base frame **200** on the type of anatomical models explained above, and gum tissue contact portions (such as base members) **201** are placed on the gum tissue areas of the model. Although this portion may have broad area contacts with the gum tissue **102**, it may also have strategically placed smaller spot contact areas **205** as shown in FIG. **2**C. In some designs, certain areas of gum tissue contact portions (such as base members) can be used to place temporary anchors through the gum tissue into the patient jawbone by small screws, pins or other fastening devices.

The surgical device (also referred to as a base frame) **200** may also have one or more clasping lateral contacts **202** (See FIGS. **2**B-**2**E) that may simply contact the lateral wall of the exposed jawbone **103** and **104** or engage its undercut. As shown in one exemplary design of the base frame **200** for a lower jaw **104** (FIGS. **2**D & **2**E), clasping lateral contacts **202** may be connected to the base member **201** by stabilizing/clasping arms **207** that may or may not have contact with the oral structure. The stabilizing/clasping arms **207** extend out from a base frame **200** and/or drill guide housing frame **300** which may be turn into a drill guide housing section **400** with drill guide bushings. When the frame is placed on the oral structure or anatomical diagnostic model, the stabilizing/clasping arms **207** slightly flex out and then clasp securely onto the oral structure **104**. Although the stabilizing/clasping arms **207** are illustrated as peninsulas that extend out of the tissue contact area, the stabilizing/clasping arms **207** may be continuously connected to the tissue area like in the exemplary base frame **200** shown in FIG. **2**F. Clasping lateral contact area **202** may also be used for placing a temporary anchor directly into the jawbone **104** if the patient's oral structure does not allow the device to have enough retention.

Similar to the clasping lateral contacts **202**, one or more occlusal/lateral stabilizing rests **206** (FIG. **2**D) may be strategically placed to contact the jawbone **104** to work along with the base member **201** and the clasping lateral contact **202** in order for the device **202** to be securely positioned inside of the patient's oral structure (See FIG. **12**). This section may also be connected to the gum tissue contact portion **201** by at least one stabilizing/clasping arm **207**.

The arrows on FIGS. **2**A, **2**E and **6**C indicate the direction of force **20** applied from each contact point to the oral structure, and show how stabilizing/clasping arms **207** help fixate the device **200** in place.

Although it is not illustrated, due to a particular shape of the jawbone **103**, **104**, the base frame **200** may be designed to have only tissue contacts without any jawbone contact and to have a separate detachably attachable part that snaps onto it and engage the jawbone. Alternatively, this bone clasping part can be a latch connected to the base frame **200** by a hinge.

The base frame **200** may also include a handle **203** on FIGS. **2**A-**2**C that may be used when removing the device from the oral structure, and an interlocking connector **204** (FIGS. **2**A, **2**B, **2**D, **2**E) that securely connects the base frame **200** to a surgical drill guide housing frame **300** (FIGS. **3**A-**3**E, and FIGS. **4**A, & **4**C). The handle **203** may also be a handle/connector, a part of which works as a male interlocking connector. FIG. **2**F illustrates the base frame **200** having connectors **204** that are secured to the upper service thereof. Stabilizing arms **207** are positioned around its outer periphery with openings **208** being positioned adjacent thereto.

FIG. **3**A illustrates an exemplary drill guide housing frame **300** configured to be disposed on the base frame **200**, which collectively form an assembly **310**. Material requirements for the drill guide housing frame **300** are same as the specifications for the base frame **200**. The drill guide housing frame **300** may securely snap onto the base frame **200** by the interlocking connectors **204** (FIGS. **2**A, **2**C, **2**D, **2**E) and the connector receptors **304** (FIG. **3**B), also by the handle **203** and handle/connector receptors **303** (FIGS. **3**A-**3**D), along with various stabilizing rests and/or clasping contact areas between the two devices **200**, **300**. As illustrated, the interlocking connectors **204** on the base frame **200** may be male connectors with strategically placed slight undercuts, and the connector receptors **302** and **303** on the drill guide housing frame **300** may be female connectors. However, various types of different connector mechanisms can be used for this purpose. Similar to the handle/connector **203** on the base frame **200**, the handle/connector receptor **303** may be used when removing the device from the base frame **200**, and it may also be used as a receptor for the handle/connector **203**. Similar to the contact points/areas of the base frame to the oral structure, the drill guide housing frame **300** may have clasping or resting contact points/areas to the base frame **200** besides the connectors. These contact points/areas may be strategically placed to work together along with the connectors not only to ensure a secure fit of the part to the base frame **200** but also to lock in the entire device (the base frame and the drill guide housing section) onto the oral structure by adding an extra layer of thickness and applying more clasping force. The base frame **200** and the surgical drill guide housing **300** may be designed to work together to make the assembly **310** set snugly fit onto the oral structure **100** and yet have great rigidity so that it is very stable in the patient's mouth as well as on the physical anatomical diagnostic model. Although not illustrated, the frames may be fastened together using any other suitable fasteners including, but not limited to, screws, pins and latches.

The holes **304** on the connector receptors **302** and handle/connector receptor **303** shown on FIGS. **3**B and **3**D are liquid escape holes **304** that allow excess moisture and debris to escape so that they will not be trapped in-between the devices **200** and **300**. It should be noted that the liquid escape holes **304** can be created in different areas of the drill guide housing frame **300**. The larger opening holes **305** in the middle of the devices **300** and **401** in FIGS. **4**A and **4**C are clearance openings for fastening anchor devises such as screws and pins that are used to fasten the base frame **200** onto the jawbones **103** and **104** without engaging with the drill guide housing frame **300**. However, the larger opening holes **305** may also be used as liquid escape holes **304**.

Unlike the handles **203** and **303**, other exemplary handles may not have a connecting function. The handles may be on either one or both of the base frame **200** and the drill guide housing frame **300**, and there may be more than one handle **203** and **303** on both frames. Moreover, the handles on the base frame **200** and the drill guide housing frame **300** can work together as a combination handle unit. Ideally, the combination handle unit is designed to leave a small space at least in a certain area between the devices' handles so that a hand instrument or other types of tools can be inserted into the space to pry the frames apart. Also, similar spaces **601**

for the instrument may be created between the frames in other areas to make the separation of the frame easier. See FIGS. **6**D, **8** and **11**.

Optionally, the device may also feature skirted areas **301** (FIG. **3**B) over the intended surgical site(s). This feature may be useful when the surgeon plans the osteotomies **105** on a physical anatomical model and the device is rapid prototyped or CNC milled from the design created on the digital anatomical model. The skirted areas may be a thin shell that extends from the device **300** and covers the intended surgical site(s). The purpose of this feature is to provide base structure for the surgical drill guide site(s). When the osteotomies are planned on a rapid-prototyped or milled physical anatomical model, the implant positions and angulations are unknown at the time of manufacturing of the surgical drill guide frame or frame set. By having a thin skirted area **301** over the intended implant site as a base structure, it may be easier to prepare the surgical drill guide site(s) on the device **300**. Also, the skirted area **301** can be made so that the top surface or the bottom surface of the section represents the patient's gum tissue **102**. It can also be made so that the bottom surface of the section sits on top of the bone, a certain distance away from the bone below or above the gum tissue. By going through the procedure that is shown on FIG. **3**C, the holes **306** that correspond with the planned osteotomies **308** will be created on the skirt as shown on FIG. **3**D. Drill **306** is used to create the holes **306**. When the surgical drill guide sites are prepared on the physical anatomical model **100**, positioning pins **308** may be used to set the angulations of the osteotomies and to position the surgical drill guide parts **309** as shown in FIG. **3**E.

FIG. **4**A illustrates an exemplary surgical drill guide section **400** that was trimmed after surgical drill guide sites are prepared so that the device **400** may provide improved surgical site visibility and good facility for irrigation. Optionally, metal or ceramic tube type **309***a* or open-face type **309***b* surgical drill guide bushings can be attached to the device **400**, but the device may not have any added parts to the drill guide site. If the implant placement is digitally planned on the digital anatomical model prior to the model manufacturing, the drill guide housing frame **300** can be digitally designed like this illustration, without any skirted area **301**, so that the drill guide bushings **309***a* and **309***b* can be attached to the device **400** right after manufacturing. Another exemplary surgical drill guide section **400** shown in FIG. **4**D for a lower jawbone **101** snapped on to the base frame **200** illustrates the space **105** between jawbone surface **103** and the bottom of the drill guide housing frame **400** over the surgical site, which may be preferred by surgeons for the better irrigation. However, as previously described, the bottom surface of the drill guide housing frame may be set at a different height.

FIG. **5** illustrates the modified duplicated denture appliance **500** attached to the base frame **200**. One way of creating this appliance is to scan the patient's denture or duplicated denture surfaces, align the data to the anatomical model, and modify it to fit on the base frame **200**. This appliance **500** may have features such as connector receptors **302**, irrigation holes **304**, and openings for fastening anchor devices **304** just like a surgical drill guide housing frame **300**. This appliance **500** may be used to verify the position of the base frame or the single piece surgical guide with patient's bite. Other examples of attachments include, but are not limited to, an implant pick up impression tray, an implant transfer jig tray, and a bone adjustment jig.

Advantages of the drill guide assembly **310** having the base frame **200** and the drill guide housing frame **300** may include: 1) Interchangeable multiple guide frames **300** can be used during the surgery while the base frame **200** can be securely positioned in the patient oral structure; 2) If, for any reason, the doctor changes the positioning of one or more of the implants from the original plan, and cannot use the surgical drill guide for those particular site(s), or needs to work on the bone, he/she can temporarily remove the drill guide housing frame **300** from the base frame **200** without disturbing the position of the base frame **200**; 3) Various types of additional attachments can be placed on the base frame **200** without the drill guide parts covering the surgical sites. The drill guide assembly **310** is especially beneficial when the base frame needs to be temporarily anchored to the patient's jawbone.

More than one surgical drill guide section **400** may be needed in order to accommodate a surgery's specific needs. As illustrated with the positioning pins **308***a* and **308***b* in FIG. **4**B, two of the intended osteotomies **105***a* and **105***b* are very close to each other and have intersecting positioning angulations. In this case, a second surgical drill guide section, **401** in FIG. **4**C may be created for one of the planned osteotomies **105***a*. This type of additional surgical guide section **401** is detachably attachable to the base frame **200** and is interchangeable with the first surgical drill guide section **400**. Alternatively, smaller parts that house the surgical drill guide bushings **309** or drill guide holes for specific implant placement sites may be attached to the first surgical drill guide section **400**. Although it is not illustrated, another benefit for having additional surgical drill guide section **401** is to accommodate larger size surgical drill guide bushings, **309***a* and **309***b* that are subsequently used for finish drilling osteotomies **105**.

FIGS. **6**A-**6**D represent a situation in which the doctor decides to reduce the jawbone prior to implant placement. FIG. **6**A is an anatomical diagnostic model of a lower jaw **101** which shows a gum tissue portion **102** and a partially exposed bone structure **104**. The doctor may wish to modify the bone **104***b* prior to the implant placement as in FIG. **6**B. In this case, the base frame **200** (FIG. **6**C) may be designed according to the doctor's specification either on the digital model or the physical anatomical diagnostic model so that it can be used as a bone reduction jig. FIG. **6**C illustrates a base frame (**200**) on an anatomical diagnostic model with a modified lower jawbone **104**. A drill guide section **400** FIG. **6**D may be designed on top of the base frame **200** to be used for implant placement.

Various types of additional detachably attachable appliances can be added to the surgical drill guide **400**. One example of an additional appliance is a modified duplicated denture attachment **500**.

It will be appreciated that the surgical drill guide can be manufactured as single piece **700** (FIG. **7**) that contacts both gum tissue and exposed bone. Single piece apparatus **700** has combined functions of both base frame **200** and the surgical drill guide section **300**. The device may have all or some of the features described above, or it may include different types of attachments. Lateral contacts **202** on the forward edge are connected to an arm **207**, which may be a part of the single piece guide **700**.

FIG. **8** is an exploded view of a two part surgical drill guide assembly **401** that is shown in FIG. **6**D. The assembly consists of the surgical drill guide section **400** and the interlocking base frame **200**. Collectively, the drill guide section **400** and base **200** can be snapped together and strategically placed relative to the lower jaw **101** which, in this instance, is a physical diagnostic anatomical model of a lower jaw for a human being. The base **200** has a base

member **201** at a rearward portion, a first outwardly extending clasping or stabilizing arm **207**, and a second arm **207** that extends from the base member **201**. The arms may have flattened portions and are resilient for placing a force on a jaw. The base **200** is operable to be received on the lower jaw **101** and located relative to the interior (or lingual/palatal) **250** and exterior (or facial) **252** surfaces of the lower jaw **101**. In particular, the base frame **200** further has lateral contacts **202** at internal locations, which are strategically located to impinge upon exterior surface **252** of the lower jaw **101**. For example, lateral clasping contact **202***a* is operable to impinge upon exterior contact **252***a*. Likewise, lateral clasping contact **202***b* is designed to strategically impinge upon contact surface **252***b* in two locations relative to the exterior surface **252** of the lower jaw **101**. Likewise, lateral (or stabilizing) contact **202***c* is located on an outwardly extending portion of the base frame **200**, and is operable to engage interior surface **250***c* of the lower jaw **101**. These contact points, and others, are designed to impinge forces **20** (See FIGS. **2**A, **2**E and **6**C) for aiding and positioning, the base frame **200** relative to the lower jaw **101**.

Once the base frame **200** has been positioned relative to the lower jaw **101**, the surgical drill guide section of **400** has receptacles that are snapped to interlocking connectors **204** that, in the exemplary model, are positioned at three locations about the base frame **200**. It will be appreciated that more, or fewer, interlocking connectors **204** can be provided. The locking fit between the interlocking connectors **204** and the corresponding female receptacles that are on the underneath side of the surgical drill guide section **400**, create a snap-fit type connection. This snap-fit configuration provides for ease of separability of the drill guide section **400** and the base frame **200**, as well as provides a self-centering locating arrangement for making sure the assembly **401** is properly fit together. The drill guide section **400** may include a flattened center portion **303** that has a plurality of bushings **309***a* or **309***b* extending through the flattened center portion. The drill guide section **400** further may have water escape holes **304**, along with the open face drill guide bushings **309***b*, as well as a separation feature or openings **601** at three locations, which aid in separating the drill guide section **400** and the base frame **200**. The openings **601** are sufficient to allow a device, for example a dental instrument, to be inserted between the drill guide section **400** and the base frame **200**, so as to allow ease of separation of the two components.

The open face drill guide bushings **309***b* provide a guide mechanism for receiving positioning pins **308**. The bushings are preferably made of metal and they are anchored in the guide section **400**. The positioning pins **308** may be made of metal or hard plastic and are placed into the planned osteotomies within the lower jaw anatomical diagnostic model **101** and are configured to receive the bushings **309***b*, which helps align the drill guide bushings **309***b* relative to the jaw **101**. At the surgery drill guide bushings guide the drills to create osteotomies for implant placement.

FIG. **9** illustrates another exemplary drill guide assembly **401** including a drill guide section **400** and a base frame **204***b*, which also works as a bone reduction jig. The assembly **401** can be positioned relative to exposed bone area **104***b* of a lower jaw **101**, which, in this visual, is a diagnostic anatomical lower jaw model. This particular lower jaw model **101** includes extracted teeth sockets **110**, which can be either recently extracted teeth or digitally simulated planned teeth extraction, a gum tissue area **102**, and nerve endings **112**. The base frame **200***b* has interlocking connectors **204** formed on the upper surface of the base frame **200***b* that can be integrally molded to the base frame **200***b*. Lateral clasping contacts **202***a* and lateral stabilizing rest **206** are positioned about an interior surface of the clasping/stabilizing arm **207** and form pressure points for impinging upon exterior surface **252** of the lower jaw **101** at points **252***a*, and **252***c*, respectively.

The surgical drill guide section **400** is shown ready to be positioned and connected to the base frame **200***b*. Drill guide bushings **309***a* are provided within holes for receiving positioning pins **308**. An opening **601** is provided to help in separating the drill guide section **400** from the base frame **200***b*.

FIG. **10** illustrates the FIG. **9** surgical drill guide assembly **401** in an assembled condition. The drill guide **400** is shown in place relative to the base frame **200***b* which in turn, is positioned relative to the lower jaw **101**.

FIG. **11** illustrates a bottom perspective view of the FIG. **6** surgical drill guide assembly **401**. From this perspective, the underside of the base frame **200** and the drill guide section **400** can be more readily observed. The lower jaw **101** is shown with gum tissue **102**. The base frame **200** has scalloped or saddle shaped base member **201** that are received by the gum tissue areas **102** of the lower jaw **101**. The clasping arm **207** has impinging areas **202***a* and **202***b* that impinge upon surfaces **252***a* and **252***b*, respectively, of the jaw **101**. Likewise, impinging surface **206** impinges upon corresponding internal surface **250***c* of the jaw **101** so as to provide an inwardly impinging force **20** as previously depicted in FIG. **6**C.

The surgical drill guide section **400** has receptacles on the underside surface **452** that are operable to lockingly engage with interlocking connectors **204** (FIG. **9**) of the base frame **200**. Openings **601** provide a gap between the surgical drill guide **400** and the base frame **200** so as to allow for ease of separation between these two components. The recess **450** is slightly larger in physical configuration than the interlocking connector **204**. The interlocking connector **204** is sufficiently resilient, as is the receptacle **450**, so as to provide a positive snap-fit locking configuration between the components **400** and **200**. Once together, an interlocked assembly **401** is created, which can be easily aligned relative to the jaw **101**.

FIG. **12** illustrates a perspective view of the base frame **200**, which is functioning here as a bone reduction jig, being positioned relative to the lower jaw **101** in the context of a mouth **150**. It depicts the lower jawbone having a shaved section **152** according to the clasping arm portion of the base frame **200**. Extracted teeth sockets **110** are present and depict the location of the extracted teeth. An interlocking connector **204** is shown and is operable and ready to receive the surgical drill guide section **400** (not shown).

FIG. **13** and FIG. **14** show different manufacturing methods of using an edentulous surgical drill guide or assembly **401**. FIG. **13** illustrates a model based implant placement planning method **800** and FIG. **9** illustrates a digital implant placement planning method **900**. Both methods start with a digital anatomical diagnostic model, with partially exposed jawbone **101** in the area of interest, in a file format such as STL that allows reverse engineering and 3D modeling **801** and **901**. The digital anatomical diagnostic model **801** can be obtained by accurately aligning the surface scan data of the patient's mouth or dental cast and the tomography scan data that is volume rendered and converted to a compatible file format. Since all the devices are patient specific, the design and features of the apparatus is planned according to the patient's oral structure, bone condition, and the surgical needs. Although the apparatus can be created as one single

surgical guide as described in the diagram in FIG. **7**, the same or similar procedure may be applied when using a multiple piece guide.

In both methods, a technician digitally designs the base frame **200**, and the drill guide housing frame **300**, along with additional frames and attachments, if any, using reverse engineering software program such as Geomagic, Radidform, and 3 Matics, optionally combined with 3D modeling software such as Rhinoceros 3D and Solidworks (See steps **802**, **902**, **803** and **903**). The base frame **200** (FIG. **2**) can be designed first on the digital model with partially exposed bone just in the area of the surgical site **802** and **903** and then the drill guide housing frame section **300** (FIG. **3**) can be designed on both the digital anatomical diagnostic model and the base frame (**802** and **902**). By doing so, the surgical guide can be designed to obtain better fit and stability, because 1) it avoids bone contact in the areas where the density of the bone is too close to that of the soft tissue for its contour to be accurately defined in the CT images when the bone is porous, and 2) it also clasps onto rigid bone areas instead of contacting the malleable tissue surface alone. Subsequently, if additional frames or attachments are needed, they can be designed to fit on the base frame **200** and/or the surgical drill guide housing frame **300** according to the part's function **803** and **903**. Some of the features and functions of the apparatus are the same or similar for the model based implant placement planning or the digital implant placement planning. However, several differences may be found in features and methods between for these two situations.

FIG. **13** illustrates a workflow **800** of a model based surgical planning. When the implant placement is planned on an aligned physical anatomical diagnostic model **812** created by rapid prototyping **811** the digital model **801**, the technician needs to design the drill guide housing frame or housing frame section **300** on the digital anatomical diagnostic model without knowing the exact plan of implants' positioning. Naturally, the device is designed as a base structure of the surgical guide that will be assembled manually on the physical anatomical model. Thus, the device often has the skirted area **301** (FIG. **3**B) that extends over the intended site so that it is easier for the clinician or technician to assemble the surgical drill guide later on a physical anatomical diagnostic model (See steps **806-809**). Similarly, other special parts that work on the physical model may also be designed to aid the surgical guide assembly. Meanwhile, a physical anatomical diagnostic model is manufactured by rapid prototyping or CNC milling (See steps **811-812**), and ideal osteotomies are simulated on the physical anatomical diagnostic model by a qualified clinician (Step **813**). Alternatively, the modified anatomical diagnostic model with positioning pins placed into the osteotomies can be digitized by surface scanning (Step **814**), and the drill guide **200**, **400** or **700** may be designed on the modified digital anatomical diagnostic model. If bone reduction is planned on a physical anatomical diagnostic model then the doctor can drill the ideal osteotomies into the physical model, (See step **813***b*).

After all the parts are designed on the digital diagnostic model, they are manufactured by rapid prototyping such as 3D printing and stereolithography or CNC milling **804**, cleaned, inspected, and verified on the physical anatomical model **805**. Place the base frame and the drill guide housing frame **200** on the physical anatomical model **100**, as shown in step **806**.

If the drill guide housing frame has skirted areas **301** (FIG. **3**B) over the surgical site, drill holes may be placed through the skirted areas **301** with a hand piece **306** (FIG. **3**C) so that the holes correspond with the planned osteotomies. Since the drill guide housing frame is usually made with a transparent or semi-transparent material, the simulated osteotomies on the model is visible thorough the thin skirted areas **301**, and corresponding holes can be made. Positioning pins **308** may be inserted into the osteotomies on the anatomical model through the holes of the skirted areas **808**. Drill guide bushings **309** may be placed with respect to the positioning pins **308** and the bushings' distance may be set from the oral structure according to the preference. As briefly described above, the top or the bottom of the skirted areas **301** may be set at, below or above the gum tissue surface **102**.

Alternatively, the bottom of the skirted areas **301** may be made to contact the exposed bone. If the diameter of holes on the skirt is close to the inner diameter of the drill guide bushing, the bushing can rest on the skirted areas. The holes of the skirted areas **301** may also be made larger so that extra parts to control the height can be inserted onto the positioning pins **305**. It should also be noted that the drill guide housing frame **300** may be configured to accommodate various types of interchangeable drill guide bushings as well as most of depth control surgical guide system parts sold by various implant companies. After the positions are set, the bushings maybe attached to the drill guide housing frame with light cured composite or other adhesive materials **809**. Additional light cured composite may be added to the frame to increase the rigidity of the device. Light cured composite may be added around the positioning pins on the skirted areas **301** instead of bushings to conform drill guide holes or slots. When finished, the positioning pins may be removed from the physical anatomical model **810**. The skirted area can be then trimmed by a hand piece as previously described. Additional drill guide frames, if any, can be made by repeating the process. With a model based implant placement system, it may also be possible to manually create a surgical drill guide that clasps the gum tissue and the jawbone with similar features without any digitally designed frame structures. It should be noted that the skirted area may not be necessary if the anatomical diagnostic model is surface scanned after the doctor drills the osteotomies, and the apparatus is designed on the modified digital model.

FIG. **14** illustrates a flowchart of digital surgical planning. When the implant placement is planned digitally on an aligned digital anatomical diagnostic model **902** as illustrated in FIG. **14**, the creation of physical anatomical diagnostic model may be optional. In this case, the technician can design the drill guide housing frame according to the simulated osteotomies on the digital anatomical model. Thus, there may be no need to create any skirted area. The support structure and receptor sites for the drill guide bushings can be digitally designed **903** so that the device is ready to receive the parts after prototyping. If any drill guide bushing parts with depth control function are going to be used, the device can be designed to receive those parts at the exact locations to accommodate the function. If the jaw bone **101** is reduced on the digital anatomical diagnostic model, the base frame **200** may be designed to function as a bone reduction jig.

Similar to the method for a model based implant placement system, the drill guide housing frame **300** is manufactured, along with the base frame and other additional frames and accessories, by rapid prototyping or CNC milling **905**. After cleaning and inspection **906**, the preferred drill guide bushings **309** can be placed into the drill guide frame **300** and secured by light cured composite or other adhesive material. For some type of drill guide bushings (**309**) adhe-

sives may not be needed. The drill guide may also be created with built-in drill guide holes or slots without any separate parts if the device is made of an appropriate harder material such as metal.

FIG. **15** illustrates a flowchart of how the apparatus **401** can be utilized **1000** during an implant placement surgery. It will be appreciated that the steps can be modified, yet remain within the spirit of the exemplary embodiments herein. It should be noted that there are many variations to the workflow, and this chart is not intended to teach the surgical procedure itself. As is the case with the explanation of diagrams in FIG. **13** and FIG. **14**, the following explanation is directed to a multiple piece drill guide system **401**.

Prior to the surgery, all the parts of the drill guide set **401** are properly sanitized according to the material's requirement. For example, if the parts are rapid prototyped with resin, cold sterilization methods may be appropriate. However, heat sterilization may be used for different materials with high temperature tolerance **1001**. Lay a partial flap of the patient's gum tissue to expose the jawbone in the area of interest **1002**. In rare occasions, the surgeon may choose to flap only the areas that the bone clasping contact portions of the devise will contact with, leaving the gum tissue over the implant sites. The base frame **200** or the single piece surgical drill guide **300** may be securely placed on the oral structure **100** and in contact with both gum tissue and the exposed bone (See steps **1003** and **1003***b*). Additional attachments may be added to the device for bone clasping. Depending on the patient's oral structure, anchor screws or pins may be used for securing the position of the device. Bone adjustment or bone grafting may be done before or after the placement of the base frame **200**. If the bone adjustment is needed, the base frame may be used as a jig or an additional bone adjustment jig can be attached to the base frame **200** for this process.

Optionally, a modified denture duplicate attachment **500** (FIG. **5**) can be used on the base frame **200**. In that case, verify the device's poisoning with bite to secure the base frame **200** to the oral structure, and then remove the attachment portion, leaving the base frame **300** on the oral structure **1009** and **1010**.

After the base frame is securely placed, attach the drill guide section **300** to the base frame **200** (step **1004**) in order to drill osteotomies into the jawbone (step **1005**). The interchangeable additional drill guide sections may be used to complete the osteotomies **1011**. When finished, the drill guide section **400** may be removed from the base frame (**200**), and the implants may be placed into the jawbone (see step **1006**). Should a certain type of surgical guide tube system be adopted into the drill guide frame **300**, the surgeon may place the implants through the drill guide tube bushings **1009** prior to the removal of the drill guide section **400**.

The surgeon may choose to take a fixture level index for the record of implant positions at this point. In that case, he/she may be able to do so by altering the surgical guide section **400** into a transfer jig tray or by using a separate transfer jig tray that attaches to the base frame **200** (See step **1012**). One advantage of utilizing the drill guide section **400** is that the actual positioning information can be easily transferred back to the physical anatomical model. The model can be adjusted, if necessary, and the prosthesis can be created on it without making a separate brand new model.

After the base frame is removed **1007** the surgeon can complete the surgery by placing cover screws or healing caps, and suturing the gum tissue over the cover screw or around the healing caps. Alternatively, the immediate loading procedure may be followed, and the prosthesis that had been designed on the digital or the physical anatomical model can be placed **1008**.

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

1. A dental tray set comprising:

a base frame that is designed on a dental model containing surface information of gum tissue area and an exposed bone structure of a particular patient, the base frame being operable to engage at least one area of a patient's jawbone and further being operable to engage at least one area of a patient's gum tissue the base frame further having an exterior surface; and

at least one surgical guide section having an exterior surface that extends over at least a portion of the exterior surface of the base frame, and that is attachable to the base frame;

wherein the combination of the base frame and the at least one surgical guide section engage both the at least one area of a patient's jawbone and also engage the at least one area of a patient's gum tissue;

wherein the base frame includes two spaced-apart base portions, an arm distinct from the stabilizing arm disposed therebetween, and a stabilizing arm extending from each of the base portions, each of the stabilizing arms being pliable and operable to exert an inwardly facing force on a jawbone at a plurality of contact points, the contact points laterally spaced along each stabilizing arm, at least one of the laterally spaced contact points of at least one stabilizing arm positioned and configured to contact a partially exposed jawbone.

2. The dental tray set as claimed in claim **1**, the tray being configured to receive a patient's jaw with partial exposed bone structure, the jaw being represented by a jaw physical anatomical diagnostic model.

3. The dental tray set as claimed in claim **1**, wherein the exterior surface of the surgical guide section includes an attachment member, wherein the exterior surface of the base frame includes an interlocking connector with an exterior profile that is operable to receive the attachment member of the surgical guide section.

4. The dental tray set as claimed in claim **1**, further comprising a handle that may be connected to the surgical guide section.

5. The dental tray set as claimed in claim **1**, wherein the surgical guide section has an irrigation hole.

6. The dental tray set as claimed in claim **1**, wherein the base frame engages at least one limited area of a patient's jawbone, and the surgical guide section includes guides for directing a surgical drill to drill an osteotomy into a patient's jawbone.

7. The dental tray set as claimed in claim **1**, wherein the surgical guide section has at least one drill guide to drill at least one osteotomy into a patient's jawbone.

8. The dental tray set as claimed in claim **1**, further comprising an appliance that is attachable either to the base frame or the surgical guide section, the appliance being configured to be used as at least one of an implant transfer attachment, an implant pickup coping tray, a bone adjustment jig, and a modified duplicated denture tray.

9. The dental tray set as claimed in claim **1**, wherein the base frame works as a bone reduction jig.

10. The dental tray set as claimed in claim **1**, wherein the dental tray set is operable to be first mounted to an anatomical diagnostic model, and the tray set then can be detached from the anatomical model and then be mounted to a patient's mouth.

11. The dental tray as claimed in claim **1**, wherein the guide section includes two spaced-apart guide portions, an arm disposed therebetween, the spaced-apart guide portions and the arm of the guide section overlap with and engage the spaced-apart base portions and arm of the base frame by way of a plurality of interlocking connectors.

12. The dental frame as claimed in claim **1**, wherein points of non-contact are defined between adjacent ones of the plurality of contact points.

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