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(54) **FACIAL RECONSTRUCTION IMPLANT KIT**

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A61B 17/16	(2006.01)
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A61B 17/86	(2006.01)
A61B 17/88	(2006.01)
A61B 50/00	(2016.01)

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CPC ***A61B 50/30*** (2016.02); ***A61B 34/10*** (2016.02); ***B33Y 10/00*** (2014.12); *A61B 2017/00526* (2013.01); *A61B 17/1673* (2013.01); *A61B 17/176* (2013.01); *A61B 17/86* (2013.01); *A61B 17/8875* (2013.01); *A61B 2034/108* (2016.02); *A61B 2050/005* (2016.02); *A61B 2050/3006* (2016.02); *A61B 2050/3007* (2016.02)

(58) **Field of Classification Search**

CPC A61B 50/30–50/39

See application file for complete search history.

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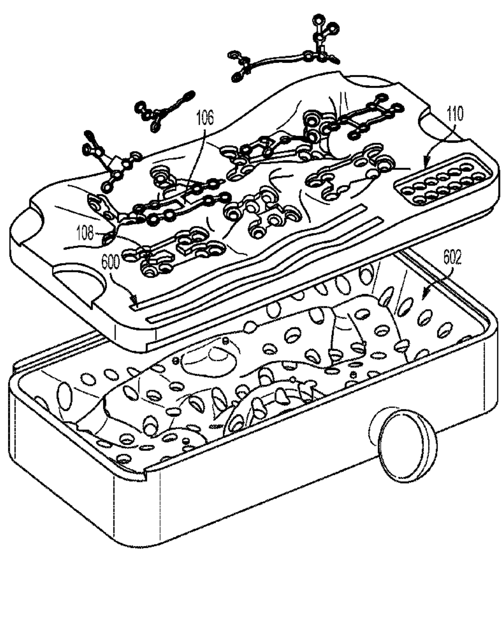
(57) **ABSTRACT**

In an aspect, a method of manufacturing a surgical kit includes providing one or more medical devices based on a three-dimensional (3D) image of an anatomical structure. The method additionally includes providing packaging based on the 3D image, and providing the surgical kit utilizing the packaging and the one or more medical devices. In another aspect, a surgical kit has one or more contoured packaging surface having a contour that matches a contour of an anatomical structure. The contoured packaging surface has one or more features for receiving one or more medical devices provided based on the contour in the 3D image. The surgical kit additionally has a lid connected under pressure with the one or more contoured packaging surface. The lid has apertures for sterilization of components of the one or more medical devices situated between the lid and the contoured packaging surface.

18 Claims, 6 Drawing Sheets



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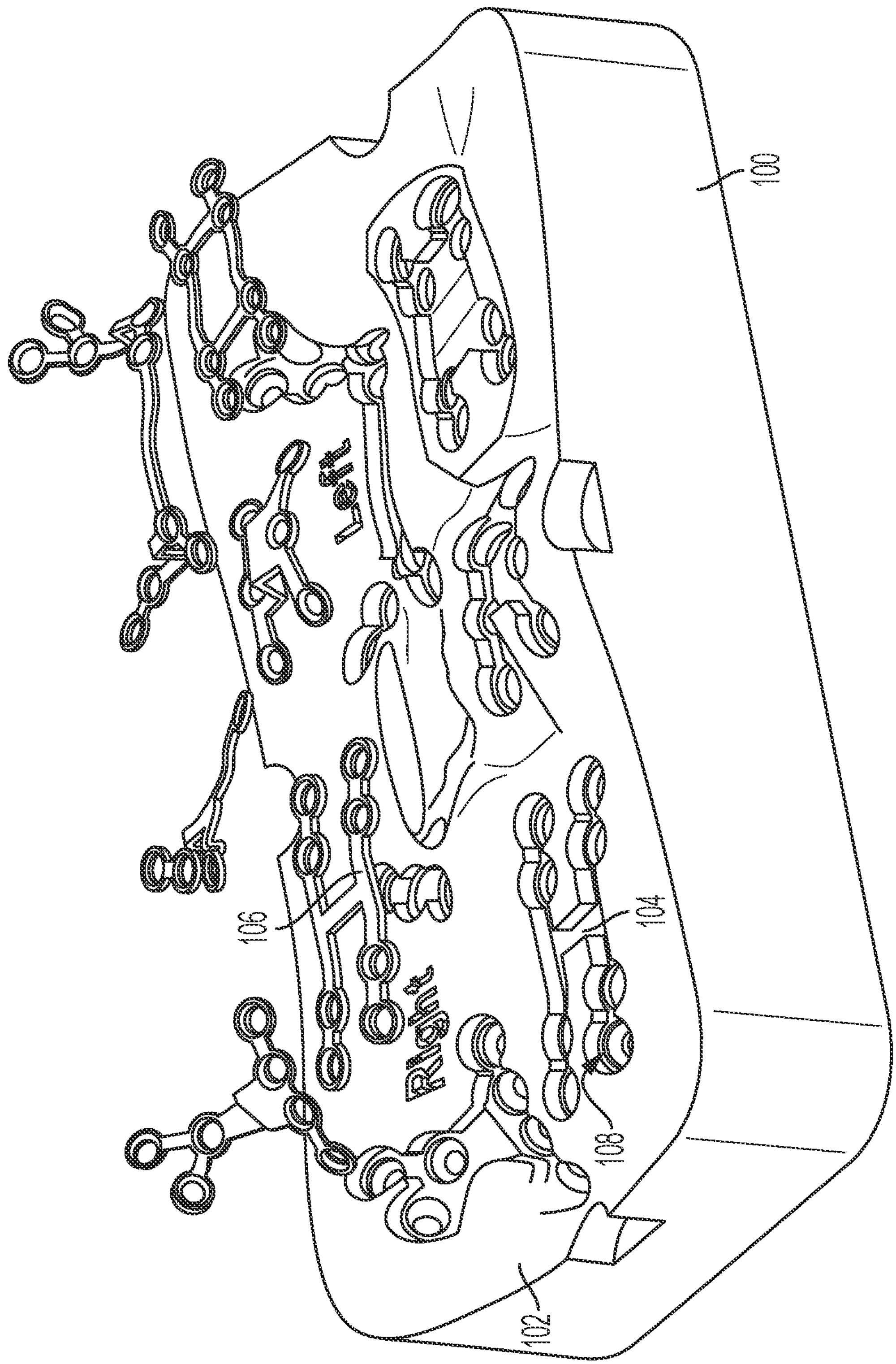

FIG. 1

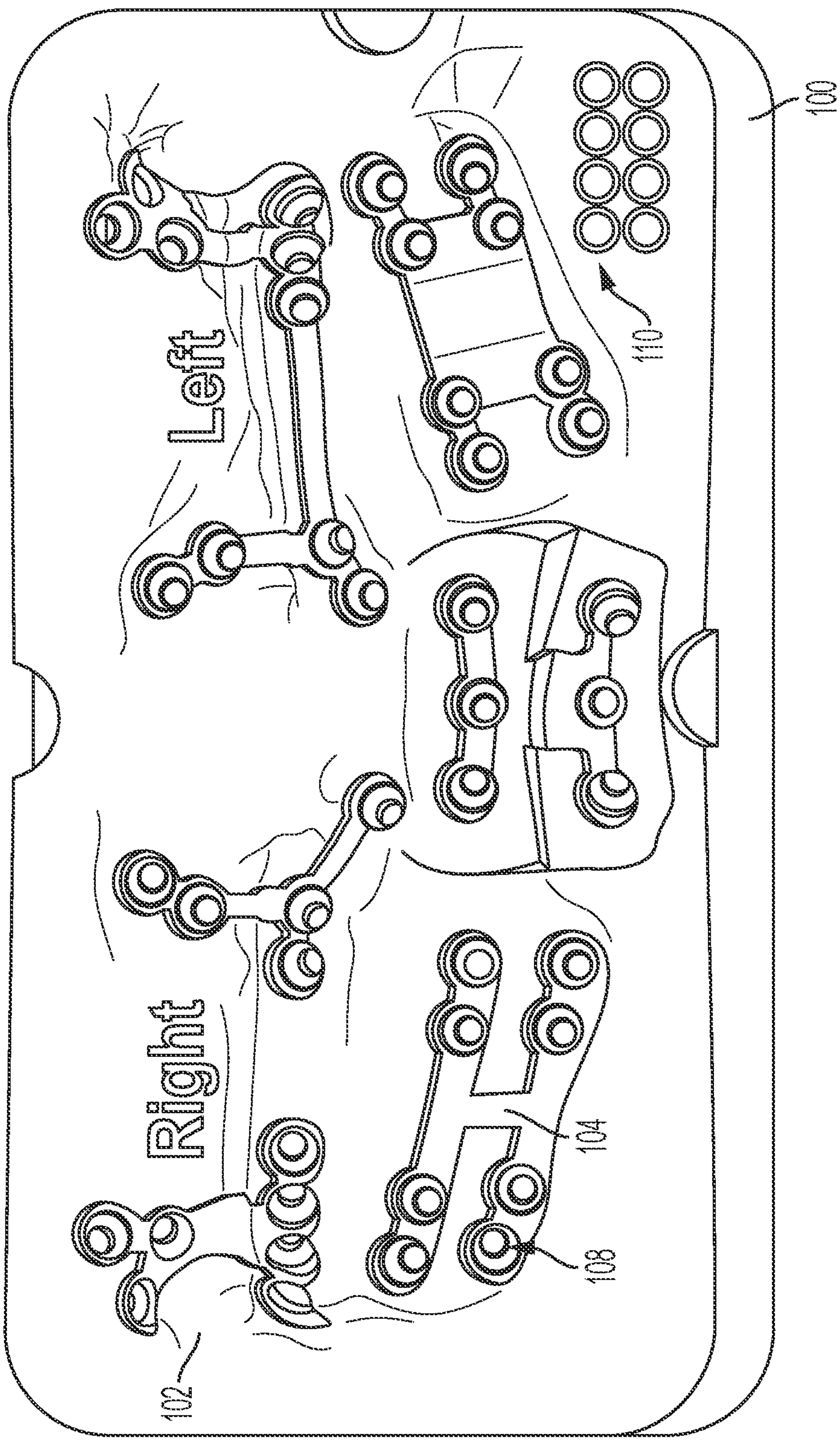

FIG. 2

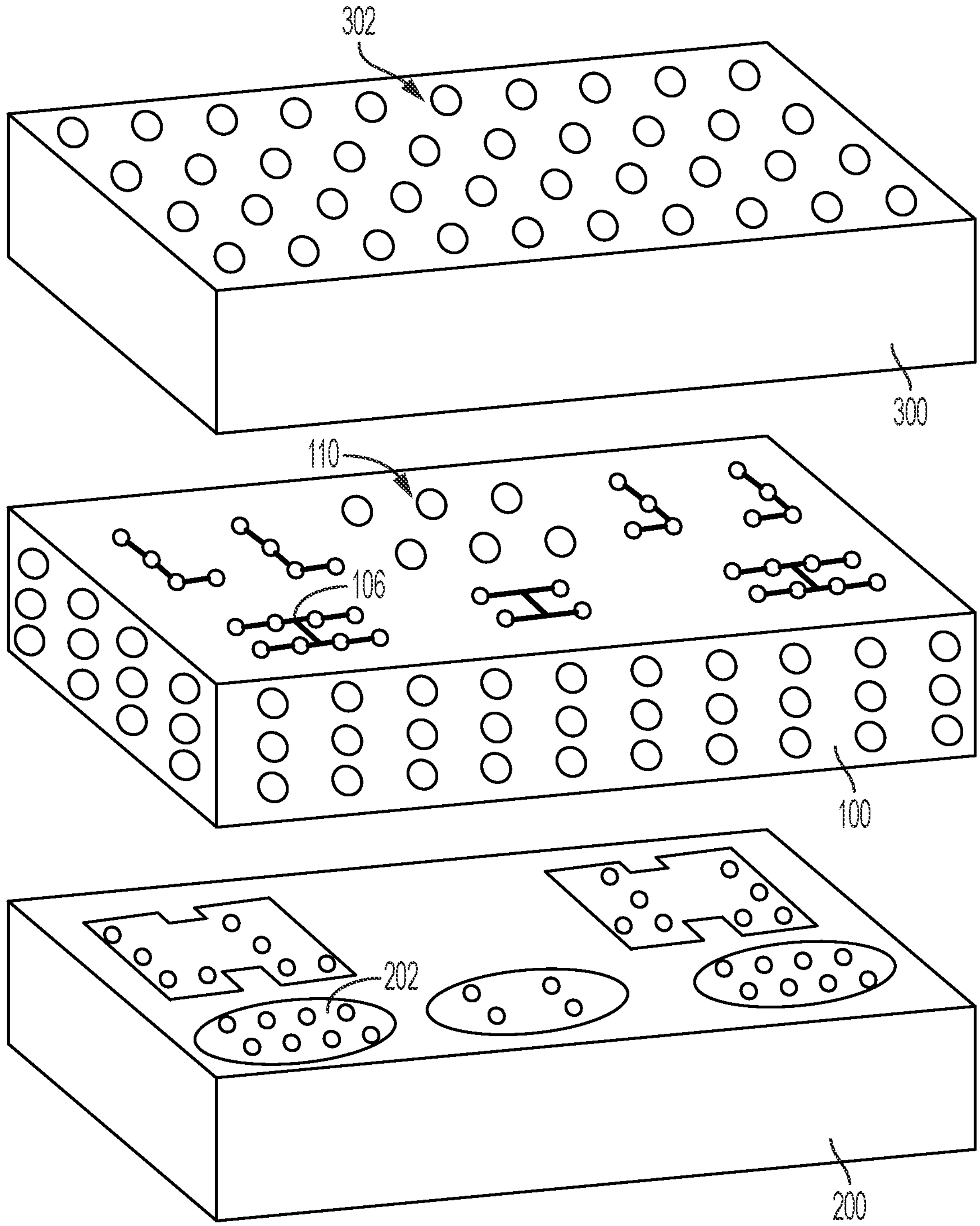

FIG. 3

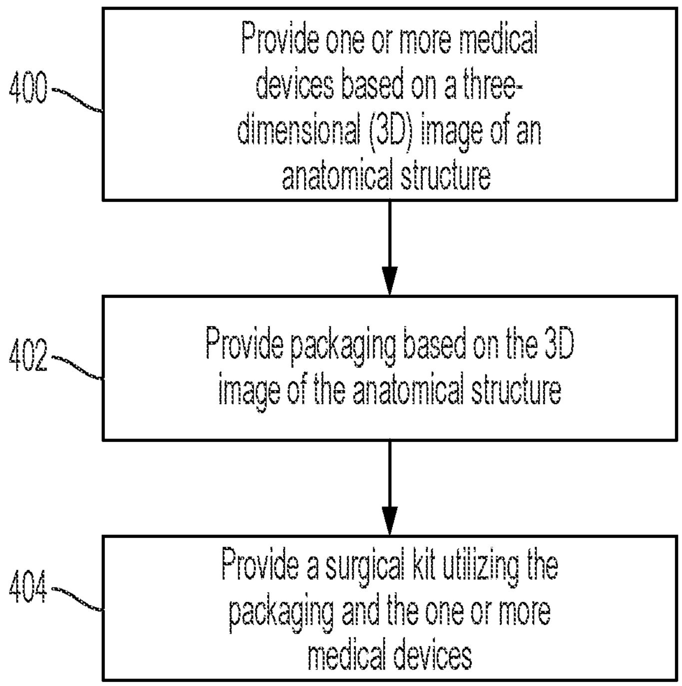
400
Provide one or more medical devices based on a three-dimensional (3D) image of an anatomical structure
402
Provide packaging based on the 3D image of the anatomical structure
404
Provide a surgical kit utilizing the packaging and the one or more medical devices

FIG. 4

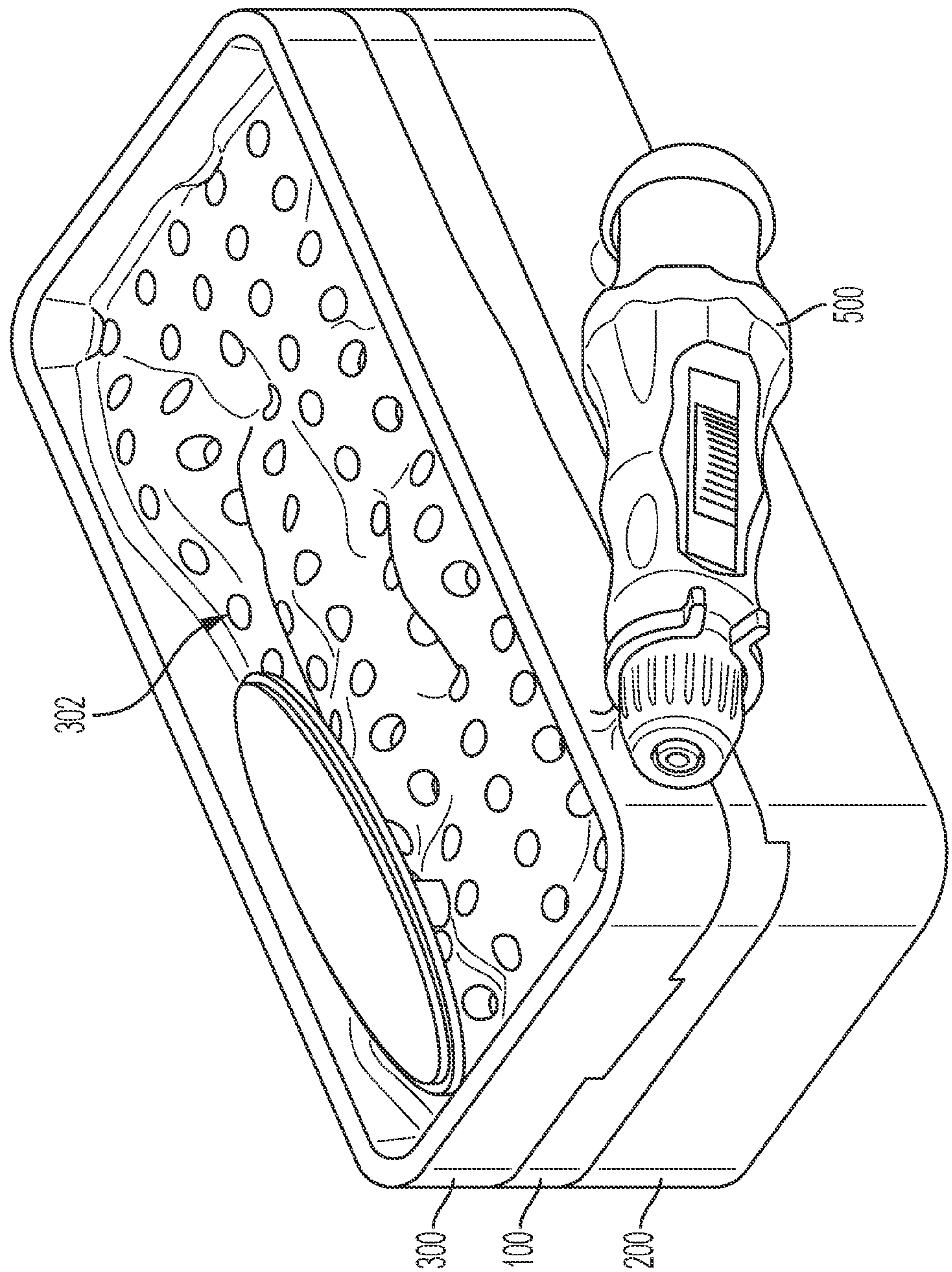

FIG. 5

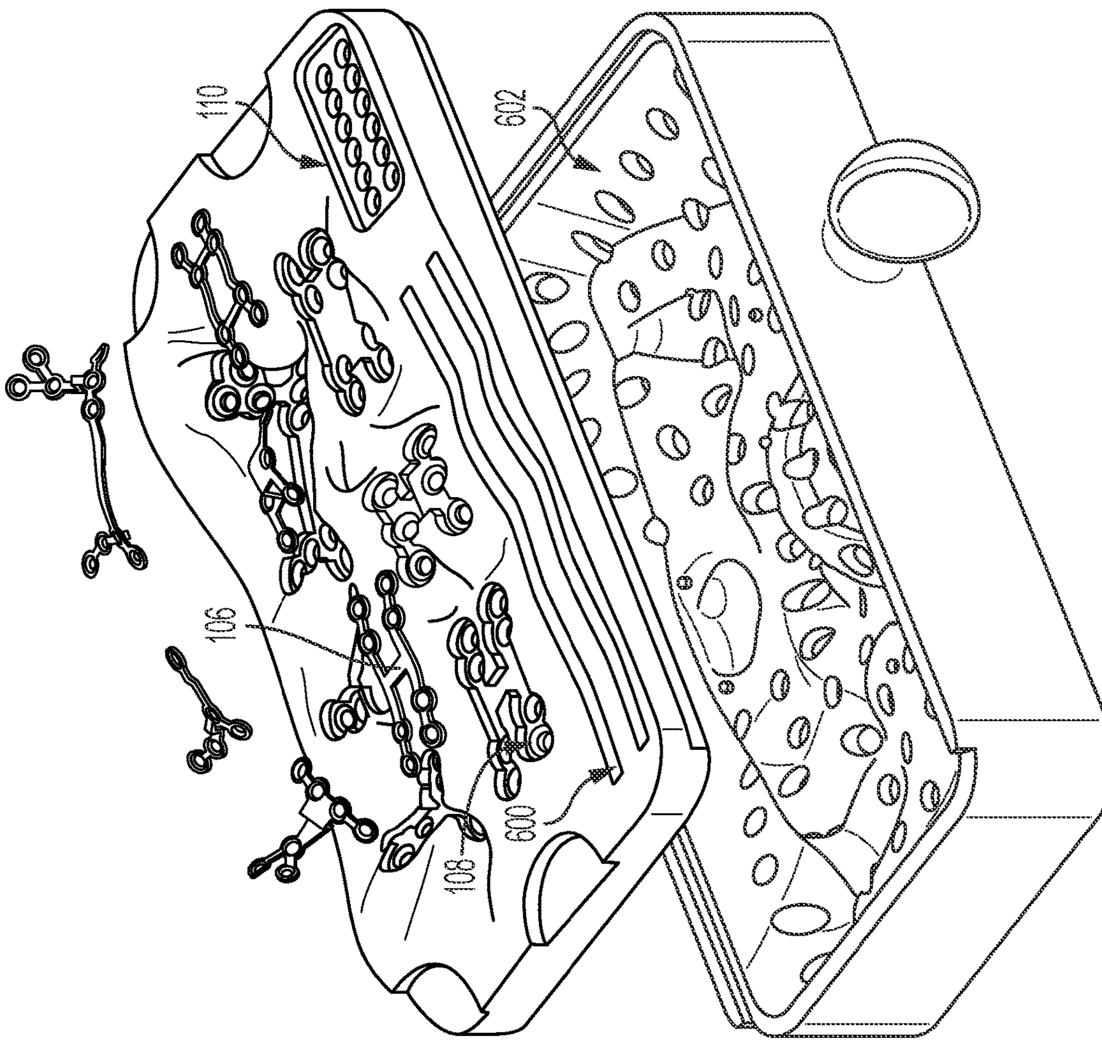

FIG. 6

FACIAL RECONSTRUCTION IMPLANT KIT

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a divisional of U.S. patent application Ser. No. 16/891,570 filed on Jun. 3, 2020, which claims priority to U.S. Provisional Application No. 62/856,498 filed Jun. 3, 2019 and entitled "FACIAL RECONSTRUCTION IMPLANT KIT," the disclosure of each of which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

The present disclosure generally relates to surgical kits that may be used during osteotomy procedures, such as facial reconstruction procedures. The present disclosure also provides a method for manufacturing such surgical kits.

BACKGROUND

An osteotomy procedure is generally performed to correct bone-related defects and/or abnormalities. The procedure may include a surgical operation where a surgeon (e.g., an orthopedic surgeon) cuts a bone to shorten, lengthen, and change its alignment. For example, an illustrative osteotomy procedure, such as orthognathic surgery (also referred to as corrective jaw surgery) may include surgically cutting or dividing the bones of mandible and/or maxilla and then repositioning the cut pieces in the desired alignment to correct a deformity in the jaw. Some osteotomy procedures may involve reconstructing a cosmetic defect—which may be a birth defect, or may be caused by other factors, for instance, deformities formed due to other corrective surgical procedures—by embedding one or more implants (e.g., a titanium mesh/plate) at/around the defective region to correct the defect. To illustrate, excising a tumor from a tumorous bone generally produce cosmetic defects that can have negative effects on a patient's appearance. Therefore, to improve the patient's lifestyle, surgeons often reconstruct the defect by inserting one or more implants at/around the defective region of the bone to reconstruct the bone to its original form.

The currently used manufacturing techniques for implants allows for reconstruction of the cosmetic defects. However, the conventional production techniques are costly and can require complex intraoperative processes. Further, surgeons, in some scenarios, may be required to change the shape of an implant in the operating room during surgery. For example, in the operating room during the surgery, a surgeon may need to trim the edges of an implant (e.g., titanium mesh) to affix the implant at a desired position. Furthermore, a surgeon normally selects surgical guides and surgical screws with associated drills and drivers from among a large array of such implements, and determines the correct guides, screws, drills, and drivers by trial and error during the surgical procedure. Not only the surgical facility is also required to maintain a large inventory of surgical guides and surgical screws with associated drills and drivers, these actions (i.e., changing the shape of the implant and selecting surgical guides and screws from an array of options) are difficult and time consuming, especially when performed during the surgery, and therefore can cause complications for a patient.

SUMMARY

The present disclosure describes various embodiments of a surgical kit and method of manufacturing the surgical kit. The disclosed surgical kit may be designed to provide visual aid to the surgeon during the surgery. To illustrate, the surgical kit may be designed to have one or more contoured surfaces that are custom designed for every patient in that each one of the one or more contoured surfaces matches contour of one or more anatomical structures recreated using a 3D image (e.g., MRI, CT scan, etc.) of the one or more defective anatomical structures. In aspects, the disclosed surgical kit may be designed to include one or more surgical devices (e.g., pre-formed implants) for use during a surgery. To further illustrate, the surgical kit may also include one or more surgical devices, such as pre-formed implants (e.g., titanium mesh), which may be positioned/disposed on the contoured surface corresponding to the structural feature that the surgeon plans to reconstruct. As such, the surgical kits manufactured with the foregoing design visually aids the surgeon during surgery in that the contoured design helps the surgeon in selecting the right implant from the one or more pre-formed implants based on the portion of the anatomical structure being reconstructed and facilitates precise reconstruction of the cosmetic defects as the implants are specifically designed based on the contour of the patient.

In some embodiments, the surgical kit may be not be fully custom designed for each patient. For example, some surgical kits may be designed based on age, ethnicity, gender, or generic physical makeup of the anatomical structure upon which the surgeon is to operate. Nonetheless, the semi-custom design of the surgical kit also visual aids the surgeon during the surgery and also helps the surgeon in selecting the right implant from the one or more pre-formed implants based on the portion of the anatomical structure being reconstructed.

In some embodiments, the surgical kit unit may also have one or more features that provides additional visual aid to the surgeon. For example, in the case of a custom designed surgical kit, the contoured surface of the kit may include one or more features, such as apertures, which may be holes for receiving surgical screws that are selected based on thickness/depth of bone exhibiting the contour in the 3D image of the desired bone of the patient. In the case of a semi-custom surgical kit, the contoured surface of the kit may have one or more features, which may be holes for receiving surgical screws that are selected based on generic thickness/depth of the bone in question. In either case, the surgical kit may additionally include surgical fixation devices (e.g., screws) that are selected ahead of time for performing the surgery, thus avoiding the need for surgeons to determine the correct lengths and/or widths of surgical screws during surgery, and also avoiding the need for the surgical facility to stock a large inventory of surgical screws.

In some embodiments, the surgical kit disclosed herein may be a part of a larger surgical kit that includes other medical devices (e.g., surgical guides, surgical drills, etc.) that may be used during the surgery. In some embodiments, instead of being a part of a larger surgical kit, the surgical kit disclosed herein includes features that allow the other medical devices (e.g., surgical guides, surgical drills, etc.) to append to the surgical kit. In some embodiments, the surgical kit disclosed herein include features that allow medical devices such as surgical guides to be disposed within the surgical kit.

In an aspect, a method of manufacturing a surgical kit includes providing one or more medical devices based on a three-dimensional (3D) image of an anatomical structure. The method additionally includes providing packaging based on the 3D image of the anatomical structure. The method further includes providing the surgical kit utilizing

the packaging and the one or more medical devices. In aspects, the medical devices may include pre-formed implants that have been stamped into a shaped contour using contoured plates 3D printed (or fabricated using other additive manufacturing techniques) from a 3D image containing an image of a surface of a bone exhibiting the contour. At least part of the packaging may also be 3D printed based on this same contour. The surgical kit may have a lid connected under pressure with the one or more contoured packaging surface. The lid has apertures formed therein for sterilization of at least part of at least one of the one or more medical devices situated beneath the lid and atop the one or more contoured packaging surface.

The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the disclosed methods and apparatuses, reference should be made to the implementations illustrated in greater detail in the accompanying drawings, wherein:

FIG. **1** is a perspective view of a contoured packaging surface in accordance with embodiments of the present disclosure;

FIG. **2** is a top view of the contoured packaging surface of FIG. **1**;

FIG. **3** is a perspective view of a surgical kit having layered packaging surfaces and a lid in accordance with embodiments of the present disclosure;

FIG. **4** is a flow diagram illustrating a method of manufacturing a surgical kit in accordance with embodiments of the present disclosure;

FIG. **5** is a perspective view of a surgical kit including the contoured packaging surface of FIG. **1**, the layered packaging surface lid of FIG. **3**; and

FIG. **6** is a exploded view of the contoured packaging surface of FIG. **1** and the layered packaging surface of FIG. **5**.

It should be understood that the drawings are not necessarily to scale and that the disclosed embodiments are sometimes illustrated diagrammatically and in partial views. In certain instances, details which are not necessary for an understanding of the disclosed methods and apparatuses or which render other details difficult to perceive may have been omitted. It should be understood, of course, that this disclosure is not limited to the particular embodiments illustrated herein.

DETAILED DESCRIPTION

For the sake of illustration and clarity, this disclosure primarily presents examples and embodiments with respect to orthognamic/facial surgical applications. However, it should be appreciated that the disclosure is not intended to be limited to the examples and embodiments with respect to orthognamic surgical applications, but is to be accorded the widest scope consistent with the principles and novel features of the surgical kits disclosed ahead. Thus, the description ahead is provided to enable any person skilled in the art to make or use the disclosure. Various modifications to the disclosure will be readily apparent to those skilled in the art, and the generic principles of the use and manufacturing of surgical kits defined herein may be applied to other variations as well (e.g., using the invention while performing different (e.g., metacarpals-related) reconstruction surgeries.

The detailed description set forth below, in connection with the appended drawings, is intended as a description of various possible configurations and is not intended to limit the scope of the disclosure. Rather, the detailed description includes specific details for the purpose of providing a thorough understanding of the inventive subject matter. It will be apparent to those skilled in the art that these specific details are not required in every case and that, in some instances, well-known structures and components are shown in block diagram form for clarity of presentation.

FIG. **1** illustrates a contoured packaging surface **100** in accordance with embodiments of the present disclosure. The contoured packaging surface **100** may be a part of a surgical kit, an example of which is further described ahead in FIG. **3**. The contoured packaging surface **100** may have a top surface **112**, sides **114**, a bottom surface **116**. In aspects, the sides **114** may be parallel to each other and may include one or more features, such as features **118**, for carrying the contoured packaging surface **100**. In aspects, the bottom surface **116** is designed such that it can stack (or nest within) on other packaging surfaces. To illustrate, bottom surface **116** may include features (e.g., lining at the bottom boundary of the bottom surface **116**) that facilitates stacking the packaging surface **100** together with another packing surface so as to prevent them from coming apart. In aspects, the features at the bottom surface **116** may be such that the packaging surface **100** and the other packing surface it could be attached to can be drawn away from each other with the application of some finite force. In aspects, the other packaging surface upon which the packaging surface **100** may be stacked on may include features, such as recesses, for receiving medical devices that are selected and/or manufactured based on the contour and/or selected surgical screws.

In aspects, the top surface **112** may have a contour **102** that matches contour of an anatomical structure (e.g., nasal bone) recreated using a 3D image (e.g., MRI, CT scan, etc.) of the defective anatomical structure upon which a surgeon may operate. In other words, the contour **102** may resemble the recreated contours of the defective anatomical structure, which the surgeon may reconstruct. In aspects, the contour **102** may include multiple contours (e.g., contours of different sides of the anatomical structure) of the defective anatomical structure. To illustrate, assume that a surgeon plans to reconstruct a nasal bone defect in a patient; the contour **102**, in such a scenario, may include multiple contours, where each contour of the multiple contours may match the contour of the portion of the nasal bone which is to be reconstructed by the surgeon. For example, the part of the top surface **112** labeled "Left" may include a contour that match the left side of the nasal defect which is to be reconstructed and the one labeled "Right" may include a contour that match the right side of the nasal defect which is to be reconstructed.

In aspects, the contour **102** may match contours multiple different anatomical structures (e.g., nasal bone, jaw bone, etc.) recreated using 3D images (e.g., MRI, CT scan, etc.) of the defective anatomical structures In other words, the contour **102** may resemble the recreated contours of multiple defective anatomical structures. In aspects, the contour **102** may include multiple contours for each one of the defective anatomical structures. To illustrate, assume that a surgeon plans to reconstruct both a nasal bone and a jaw bone defect in a patient; the contour **102**, in such a scenario, may include one or more contours for each one of the defect. In such embodiments, the part of the top surface **112** depicted to be labeled "Left" may be labeled "Nasal bone" indicating that the contours in that portion of the top surface are recreated contours of the nasal bone, and the part of the top surface **112** depicted to be labeled "Right" may be labeled "Jaw bone" indicating that the contours in that portion of the top surface are recreated contours of the jaw bone.

In aspects, the contour **102** may further be designed to include one or more surgical devices (e.g., pre-formed implants, surgical guides, etc.) for use during surgery. To illustrate, the contoured packaging surface **100** may have one or more features, such as recesses **104**, for receiving implants, such as contoured bone plates **106**, which may be pre-formed using different material such as trimmed titanium mesh as described in U.S. patent application Ser. No. 16/378,446, which is incorporated in this application in its entirety). In aspects, the one or more surgical devices may be positioned on the contour **102** at a shape that substantially matches a shape of the anatomical structure where the one or more surgical device may be used. Continuing the above-noted example of nasal bone defect, the contoured bone plates **106** positioned on the "Left" side may be used by the surgeon to reconstruct the left side of the patient's nasal bone, and the contoured bone plates **106** positioned on the "Right" side may be used to reconstruct the right side of the patient's nasal anatomical structure. Similarly, continuing the above-noted example of both nasal and jaw bone defect, the contoured bone plates **106** positioned on the "Nasal bone" side may be used by the surgeon to reconstruct the nasal bone, and the contoured bone plates **106** positioned on the "Jaw bone" side may be used to reconstruct the jaw bone.

In aspects, the contour **102** may be custom designed for every patient in that contour **102** match contour of one or more three-dimensional (3D) images of one or more anatomical structures, such as one or more facial bones of a patient in a magnetic resonance image (MRI), computerized tomography (CT) scan, or the like. To illustrate, a custom designed contour **102** may include contours of different portions of one or more anatomical structures for every patient that will be operated upon by the surgeon. In such contours, the one or more pre-formed implants (e.g., titanium mesh) positioned/disposed on the contoured surface may be precisely designed and manufactured for every patient, thereby reducing the possibility of the surgeon having to change the shape of the implant during surgery, as is the case with conventional implants. In some embodiments, however, the surgical kit may be not be fully custom designed for each patient. For example, some surgical kits may be designed based on age, ethnicity, gender, or generic physical makeup of the anatomical structure upon which the surgeon is to operate.

In some embodiments, the contoured packaging surface **100** may also include one or more features that provide additional aid to the surgeon. For example, in the case of a custom designed surgical kit, the contour **102** may include one or more features, such as apertures **108**, which may be holes for receiving surgical screws that are selected based on thickness/depth of bone exhibiting the contour in the 3D image of the desired bone of the patient. On the other hand, in the case of a semi-custom surgical kit, the contoured surface of the kit may have one or more features, which may be holes for receiving surgical screws that are selected based on generic thickness/depth of the bone in question. In either case, the surgical kit may additionally include surgical fixation devices (e.g., screws) that are selected ahead of time for performing the surgery, thus avoiding the need for surgeons to determine the correct lengths and/or widths of surgical screws during surgery, and also avoiding the need for the surgical facility to stock a large inventory of surgical screws.

FIG. **2** provides a top view of the contoured packaging surface **100** of FIG. **1**. As shown in FIG. **2**, in addition to contour **102**, recesses **104** for bone plates **106**, and apertures **108**, the contoured packaging surface **100** may have additional apertures **110**. The additional apertures may be through holes that receive surgical screws, which may be extra screws or may permit some or all of the apertures **108** to be open for sterilization purposes (as is further described below). In aspects, the contoured packaging surface **100** may include extra implants as duplicates.

FIG. **3** illustrates a surgical kit having contoured packaging surface **100** and layered packaging surface **200**, and a lid **300**. Here, contoured packaging surface **100** corresponds to the contoured packaging surface of FIGS. **1** and **2**; it is depicted to be opened on a bottom so that it can be stacked or nested atop contoured packaging surface **200**. In the illustrated example, the layered packaging surface **200** may have features, such as recesses, for receiving medical devices (e.g., surgical guides **202** and/or drills and drivers) that are selected and/or manufactured based on the contour and/or selected surgical screws. In aspects, layered packaging surface **200** may be contoured or flat; if contoured, the layered packaging surface **200** may exhibit a same contour as surface **100**. Layered packaging surface **200** may be connected under pressure beneath contoured packaging surface **100**. In this case, additional apertures **110** on a top and/or sides of layered packaging surface **100** may allow sterilization of medical device components (e.g., screw threads, surgical guides **202**, and/or drills and screw drivers) situated between the surfaces **100** and **200**. In this way, a layered package of custom manufactured and selected medical devices (e.g., bone plates, surgical screws, surgical guides, drills, and/or screw drivers) for a specific surgery on a specific patient may be provided in such a way that it can be inserted in an autoclave and successfully sterilize all of the medical devices prior to surgery. Alternatively or additionally, the medical devices and the interior kit surfaces may all be sterilized and sealed prior to shipping and delivery of the completed kit to a surgical facility at which the surgery is performed.

As mentioned above, packaging surface **100** has a contour that matches a contour of an anatomical structure (e.g., nasal bone), and the contoured packaging surface **100** has one or more features (e.g., recesses) formed therein for receiving one or more medical devices (e.g., bone plates and surgical screws) provided based at least in part on the contour of the anatomical structure in a 3D image (e.g., MRI, CT scan, etc.). The lid **300** may be connected under pressure with the contoured packaging surface **100**, and the lid **300** may have apertures **302** formed therein for sterilization of at least part of at least one of the one or more medical devices (e.g., bone plates and screw heads) situated beneath the lid **300** and atop the contoured packaging surface **100**. In aspects, the lid **300** may have a reverse contour that mates with the contour of the contoured packaging surface **100** in such a way that the medical devices (e.g., bone plates and surgical screws) are secured in place when the lid **300** is connected to the contoured packaging surface **100**.

FIG. **4** illustrates a method of manufacturing a surgical kit in accordance with embodiments of the present disclosure. Beginning at block **400**, the method includes providing one or more medical devices based on a three-dimensional (3D) image of one or more anatomical structure. For example, block **400** may include using a 3D printer to manufacture contoured implants that match a contour of the anatomical structure of the 3D image. In aspects, the 3D printer may be used to print contoured plates that exhibit the contour of the portion of the anatomical structure being reconstructed. In aspects, the contoured plates be stamped into a shape matching the contour. The shaped contoured plates may then be trimmed to provide the contoured implants. Alternatively or additionally, block **400** may include at least one of selecting or manufacturing one or more surgical guides based on the contour of the 3D image. Alternatively or additionally, the block **400** may include selecting one or more surgical screws based on a thickness of bone exhibiting the contour of the 3D image. Alternatively or additionally, block **400** may include selecting at least one of one or more drills or one or more screwdrivers based on the selection of the one or more surgical screws. The method may proceed from block **400** to block **402**.

At block **402**, the method includes providing packaging based on the 3D image of the anatomical structure. For example, block **402** may include using a 3D printer to manufacture at least one contoured packaging surface exhibiting a contour of the anatomical structure of the 3D image. Alternatively or additionally, block **402** may include using the 3D printer to manufacture at least two packaging surfaces that are configured to be at least one of nested or stacked one atop another, at least one of the at least two packaging surface being the contoured packaging surface. Alternatively or additionally, block **402** may include providing recesses for receiving contoured implants, the recesses having through holes for receiving screws selected based on a thickness of bone exhibiting the contour of the 3D image. The method may proceed from block **402** to block **404**.

At block **404**, the method includes providing the surgical kit utilizing the packaging and the one or more medical devices. For example, block **404** may include situating the one or more medical devices in the packaging, and connecting the packing under pressure with a lid having apertures formed therein for sterilization of the one or more medical devices. It is also envisioned that block **404** may include sterilizing (e.g., in an autoclave) the interior of the surgical kit and sealing the surgical kit (e.g., in a medical grade plastic wrap or shrink wrap). The sealed kit may further be irradiated before shipping, with instructions to the surgical facility to sterilize the kit again prior to surgery.

FIG. **5** illustrates a surgical kit manufactured according to the method of FIG. **4** and including the contoured packaging surface **100**, the layered packaging surface **200**, and the lid **300** of FIG. **3**. Here, the layered packaging surface **200** is configured as a bottom of the kit. Apertures **302** in lid **300** permit sterilization of medical device components located between contoured packaging surface **100** and lid **300**. Features provided on sides of the lid **300** and layered packaging surface **200** are configured to receive and hold a screwdriver handle **500**.

FIG. **6** illustrates additional features of the contoured packaging surface **100** and the layered packaging surface **200** of the kit of FIG. **5**. For example, the layered packaging surface **200**, being configured as a bottom of the kit, has apertures formed therein that permit sterilization of medical device components located between layered packaging surface **200** and contoured packaging surface **100**. For example, the layered packaging surface **200** provides a contoured space **602** with features for receiving surgical guides for the bone plates **106**. Also, contoured packaging surface **100** has features **600**, such as recesses, that are configured to receive surgical drills and driver shafts that are suitable for use with the screws stored in apertures **108** and/or **110**. With apertures formed in a bottom of the surgical kit, as shown, need is reduced or eliminated for apertures in a side of the kit or additional apertures in the contoured packaging surface **100**. Stated differently, all of the apertures in the contoured packaging surface **100** may located in an interior region of the kit, and all of the apertures may be used to hold the selected surgical screws.

Those of skill would further appreciate that the various illustrative logical blocks, modules, circuits, and algorithm steps described in connection with the disclosure herein may be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, circuits, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. Skilled artisans may implement the described functionality in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the present disclosure. Skilled artisans will also readily recognize that the order or combination of components, methods, or interactions that are described herein are merely examples and that the components, methods, or interactions of the various aspects of the present disclosure may be combined or performed in ways other than those illustrated and described herein.

As used herein, including in the claims, the term "and/or," when used in a list of two or more items, means that any one of the listed items can be employed by itself, or any combination of two or more of the listed items can be employed. For example, if a composition is described as containing components A, B, and/or C, the composition can contain A alone; B alone; C alone; A and B in combination; A and C in combination; B and C in combination; or A, B, and C in combination. Also, as used herein, including in the claims, "or" as used in a list of items prefaced by "at least one of" indicates a disjunctive list such that, for example, a list of "at least one of A, B, or C" means A or B or C or AB or AC or BC or ABC (i.e., A and B and C) or any of these in any combination thereof.

The previous description of the disclosure is provided to enable any person skilled in the art to make or use the disclosure. Various modifications to the disclosure will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other variations without departing from the spirit or scope of the disclosure. Thus, the disclosure is not intended to be limited to the examples and designs described herein but is to be accorded the widest scope consistent with the principles and novel features disclosed herein.

Although embodiments of the present application and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification.

The invention claimed is:

1. A method of manufacturing a surgical kit, the method comprising:

providing one or more medical devices based on a three-dimensional (3D) image of an anatomical structure; and

providing packaging based on the 3D image of the anatomical structure, said packaging configured to accept the one or more medical devices,

wherein the providing packaging based on the 3D image of the anatomical structure includes using a 3D printer to manufacture at least one contoured packaging surface exhibiting a contour of the anatomical structure of the 3D image, and

wherein the using the 3D printer to manufacture the at least one contoured packaging surface includes using the 3D printer to manufacture at least two packaging surfaces that are configured to be at least one of nested or stacked one atop another, at least one of the at least two packaging surfaces being the contoured packaging surface.

2. The method of claim **1**, wherein the providing one or more medical devices based on the 3D image includes at least one of:

manufacturing contoured implants that match a contour of the anatomical structure of the 3D image;

at least one of selecting or manufacturing one or more surgical guides based on the contour of the 3D image;

selecting one or more surgical screws based on a thickness of bone exhibiting the contour of the 3D image; or

selecting at least one of one or more drills or one or more screwdrivers based on the selection of the one or more surgical screws.

3. The method of claim **1**, wherein the using the 3D printer to manufacture the at least one contoured packaging surface includes providing recesses for receiving contoured implants, the recesses having through holes for receiving screws selected based on a thickness of bone exhibiting the contour of the 3D image.

4. The method of claim **1**, further comprising:

situating the one or more medical devices in the packaging; and

connecting the packaging under pressure with a lid having apertures formed therein for sterilization of the one or more medical devices.

5. The method of claim **4**, further comprising sterilizing the interior of the surgical kit.

6. The method of claim **5**, further comprising sealing the surgical kit after sterilizing the interior of the surgical kit.

7. The method of claim **1**, further comprising manufacturing contoured implants that match a contour of the anatomical structure of the 3D image, wherein manufacturing the contoured implants comprises manufacturing contoured plates.

8. The method of claim **7**, wherein manufacturing the contoured plates comprises stamping the contoured plates into a shape matching the contour of the anatomical structure of the 3D image.

9. The method of claim **8**, manufacturing the contoured plates further comprises trimming the contoured plates after the contoured plates are stamped into the shape.

10. The method of claim **1**, further comprising labeling the at least one contoured packaging surface with a name of the anatomical structure.

11. The method of claim **1**, wherein the providing packaging based on the 3D image of the anatomical structure includes:

providing a contoured packaging surface having one or more recesses configured to receive the one or more medical devices and exhibiting a contour of the anatomical structure of the 3D image; and

providing a lid having apertures.

12. The method of claim **11**, further comprising:

situating the one or more medical devices in the one or more recesses of the contoured packaging surface; and

putting the lid on the contoured packaging surface with pressure so that a top surface of the contoured packaging surface is covered by the lid and the one or more medical devices are disposed between the lid and the contoured packaging surface.

13. The method of claim **12**, further comprising sterilizing the one or more medical devices after putting the lid on the contoured packaging surface with pressure, wherein the apertures of the lid allow the sterilization of the one or more medical devices disposed between the lid and the contoured packaging surface after putting the lid on the contoured packaging surface with pressure.

14. The method of claim **13**, wherein the sterilizing the one or more medical devices comprises inserting the contoured packaging surface and the lid into an autoclave.

15. The method of claim **11**, further comprising providing a layered packaging surface having apertures and recesses configured to receive one or more second medical devices.

16. A method of manufacturing a surgical kit, the method comprising:

providing one or more medical devices based on a three-dimensional (3D) image of an anatomical structure,

providing packaging based on the 3D image of the anatomical structure, said packaging configured to accept the one or more medical devices, wherein the providing packaging based on the 3D image of the anatomical structure includes:

providing a contoured packaging surface having one or more recesses configured to receive the one or more medical devices and exhibiting a contour of the anatomical structure of the 3D image; and providing a lid having apertures; and

providing a layered packaging surface having apertures and recesses configured to receive one or more second medical devices;

situating the one or more second medical devices in the one or more recesses of the layered packaging surface; and

putting the layered packaging surface under the contoured packaging surface with pressure so that a top surface of the layered packaging surface is covered by the contoured packaging surface and the one or more second medical devices are disposed between the contoured packaging surface and the layered packaging surface.

17. The method of claim **16**, further comprising sterilizing the one or more second medical devices after putting the layered packaging surface under the contoured packaging surface with pressure, wherein the apertures of the layered packaging surface allow the sterilization of the one or more second medical devices disposed between the contoured packaging surface and the layered packaging surface.

18. The method of claim **17**, wherein the sterilizing the one or more second medical devices comprises inserting the contoured packaging surface and the layered packing surface into an autoclave.

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