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(54) **ADDITIVE MANUFACTURING TECHNIQUES FOR A SOCKET AND LINER COMBINATION DEVICE**

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(52) **U.S. Cl.**

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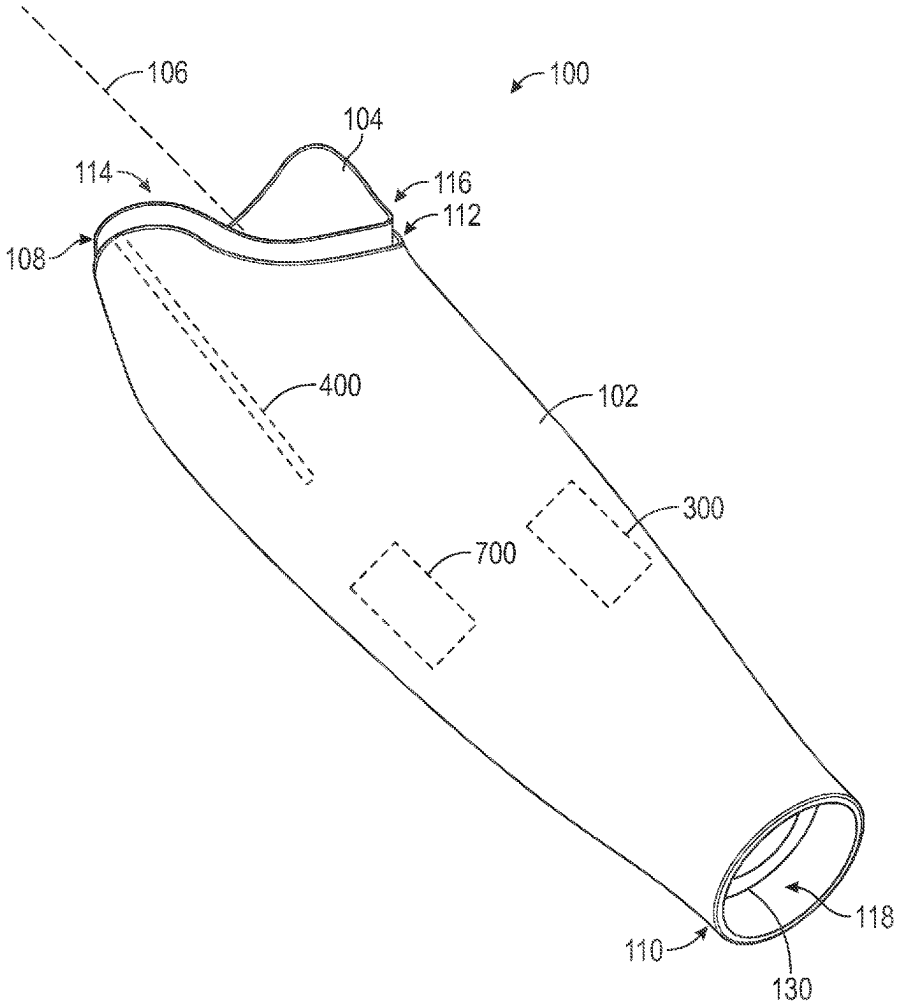
(57) **ABSTRACT**

A prosthetic assembly includes a socket and a liner. The socket includes a first interlocking feature and defines an inner volume. The liner includes a second interlocking feature. The first interlocking feature and the second interlocking feature are configured to engage each other when the liner is inserted into the inner volume of the socket. The liner is configured to receive a distal limb of a patient. At least one of the socket or the liner include inner voids extending within walls of the socket or the liner.



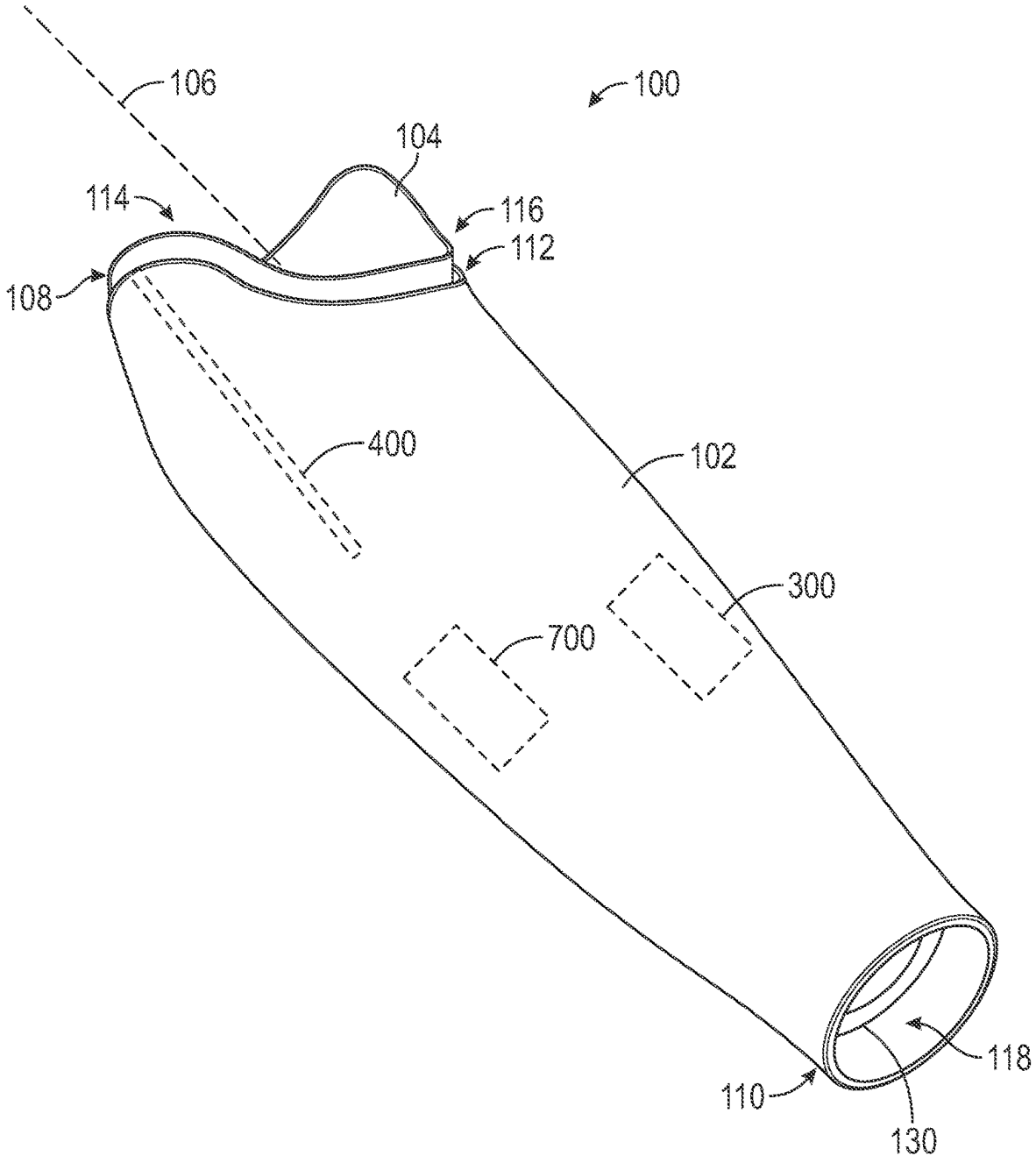


FIG. 1

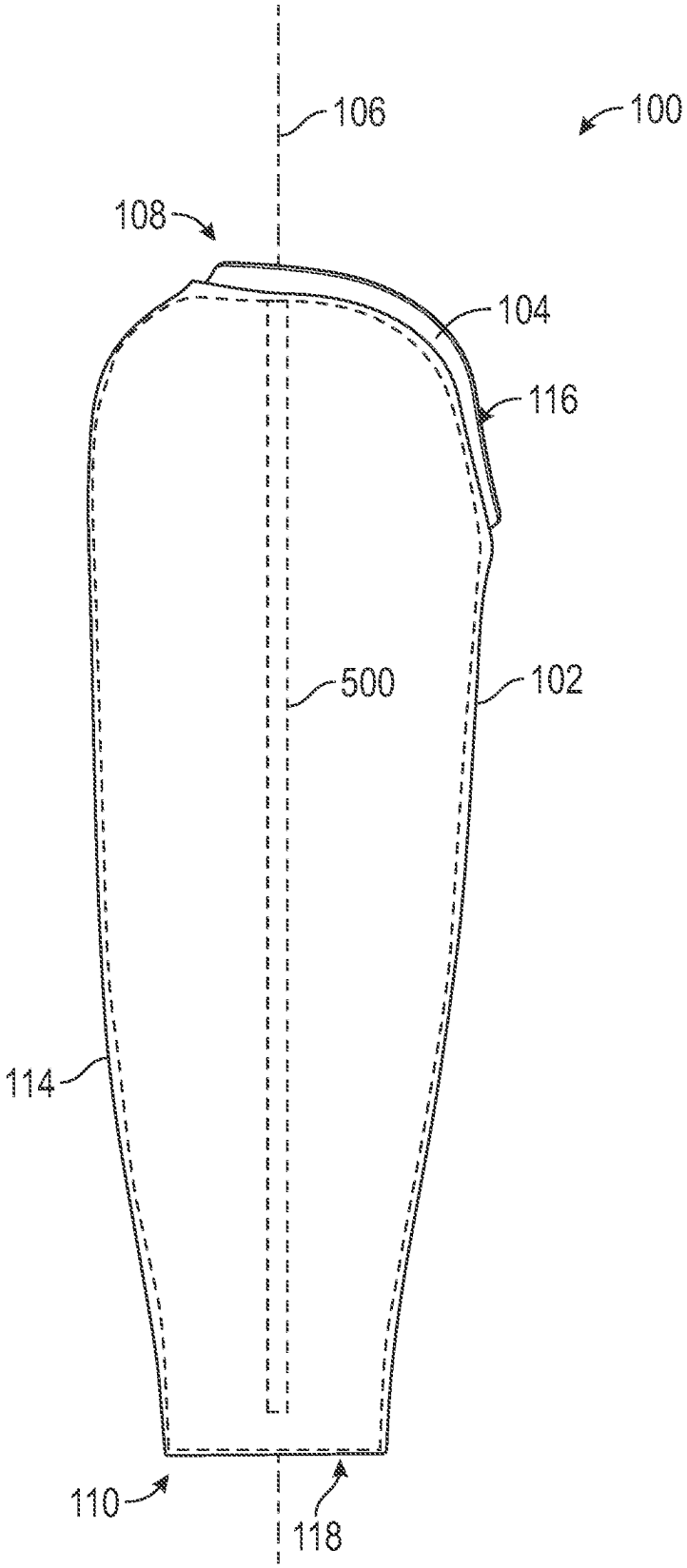


FIG. 2

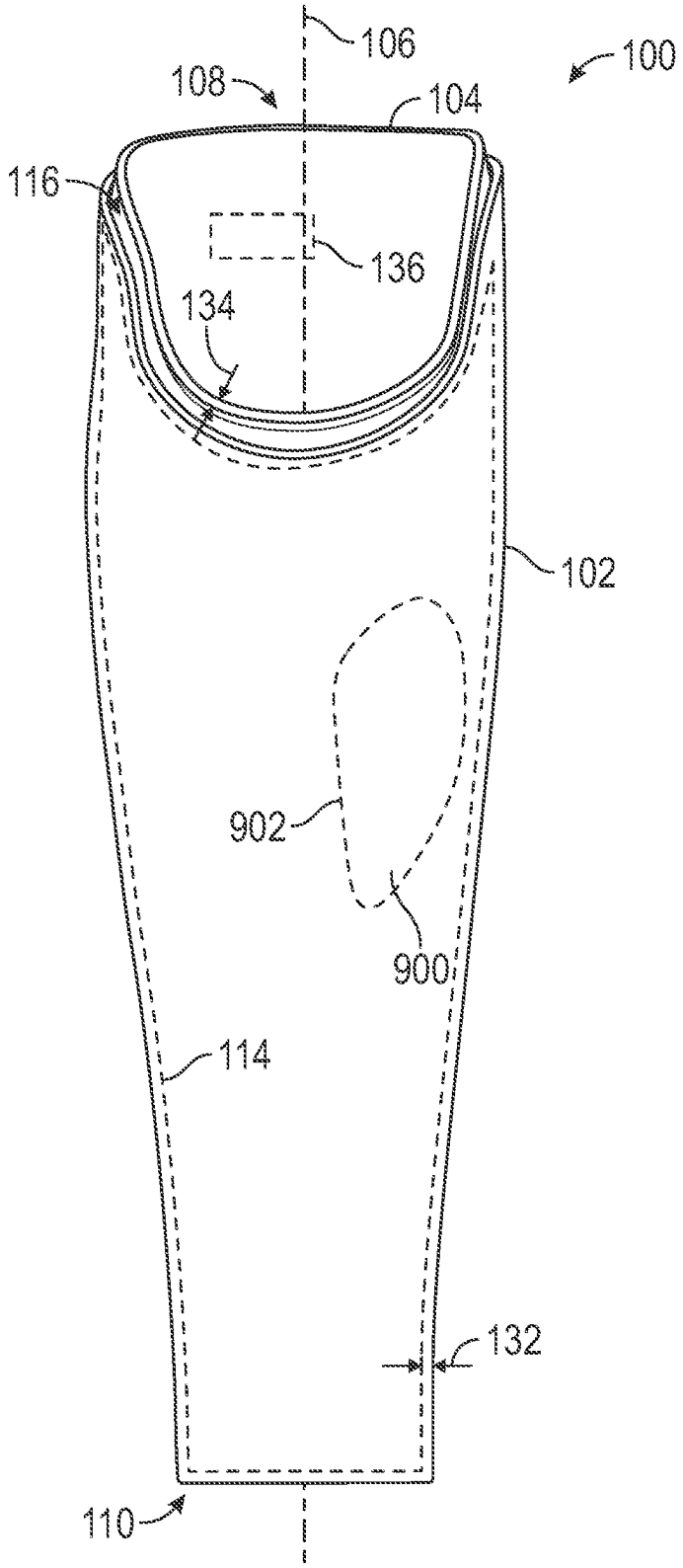


FIG. 3

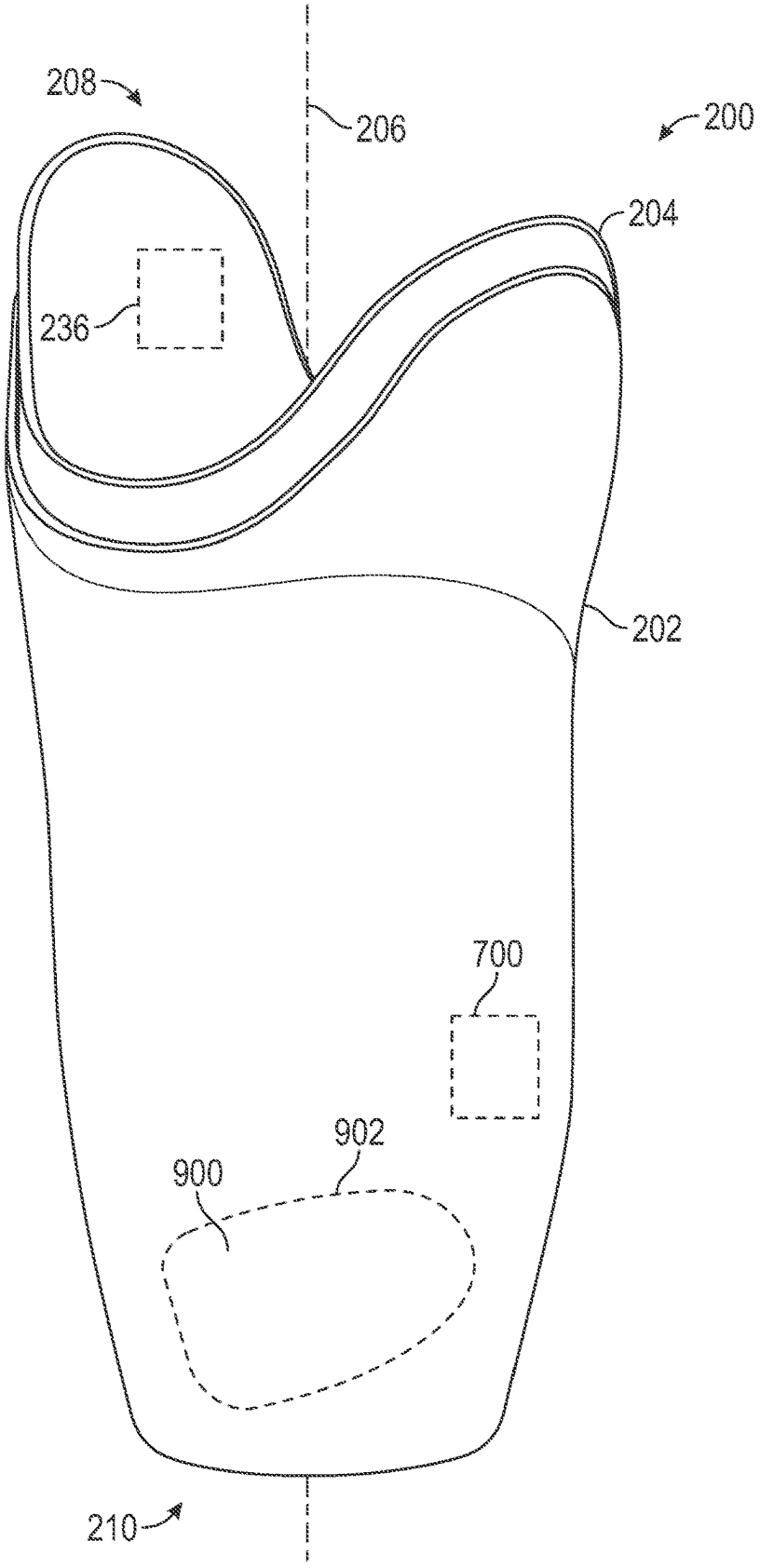


FIG. 4

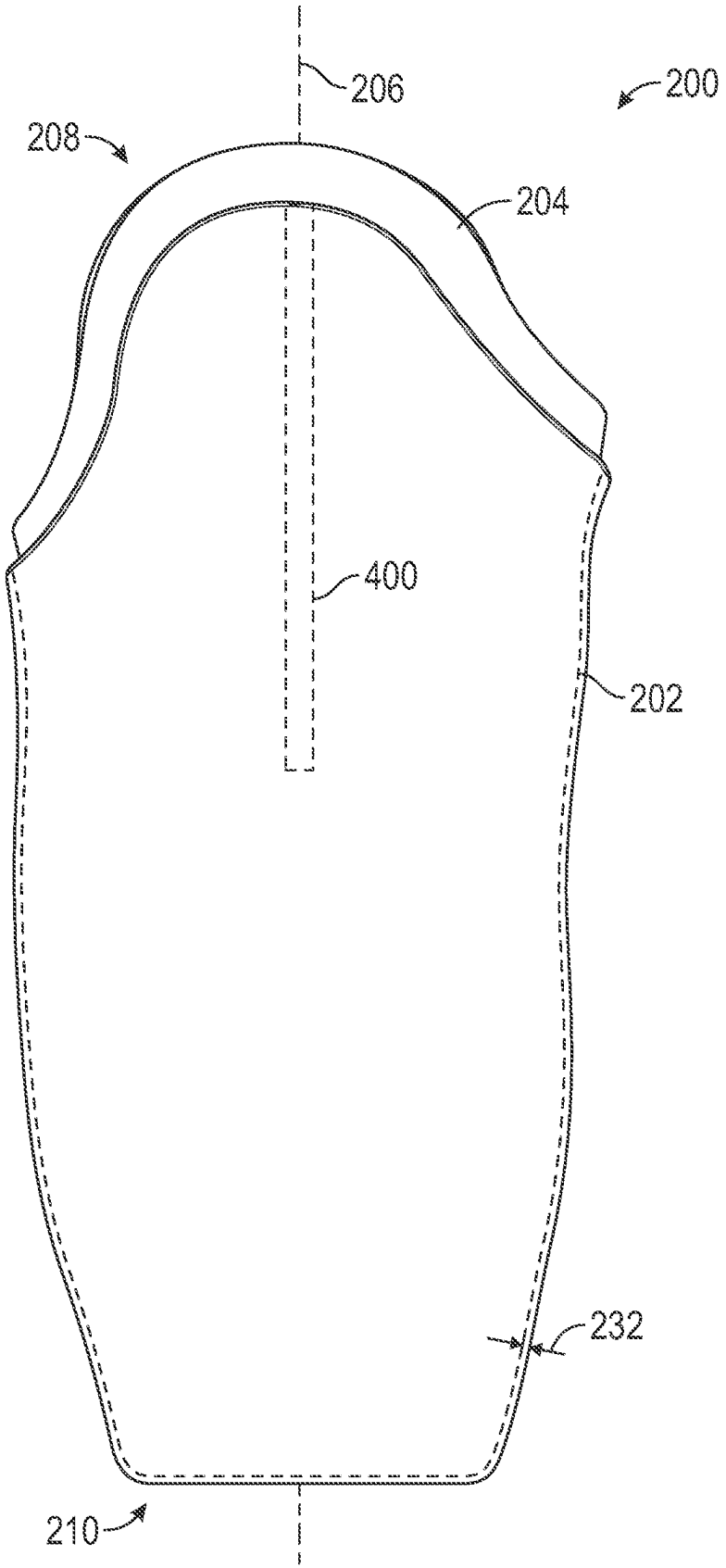


FIG. 5

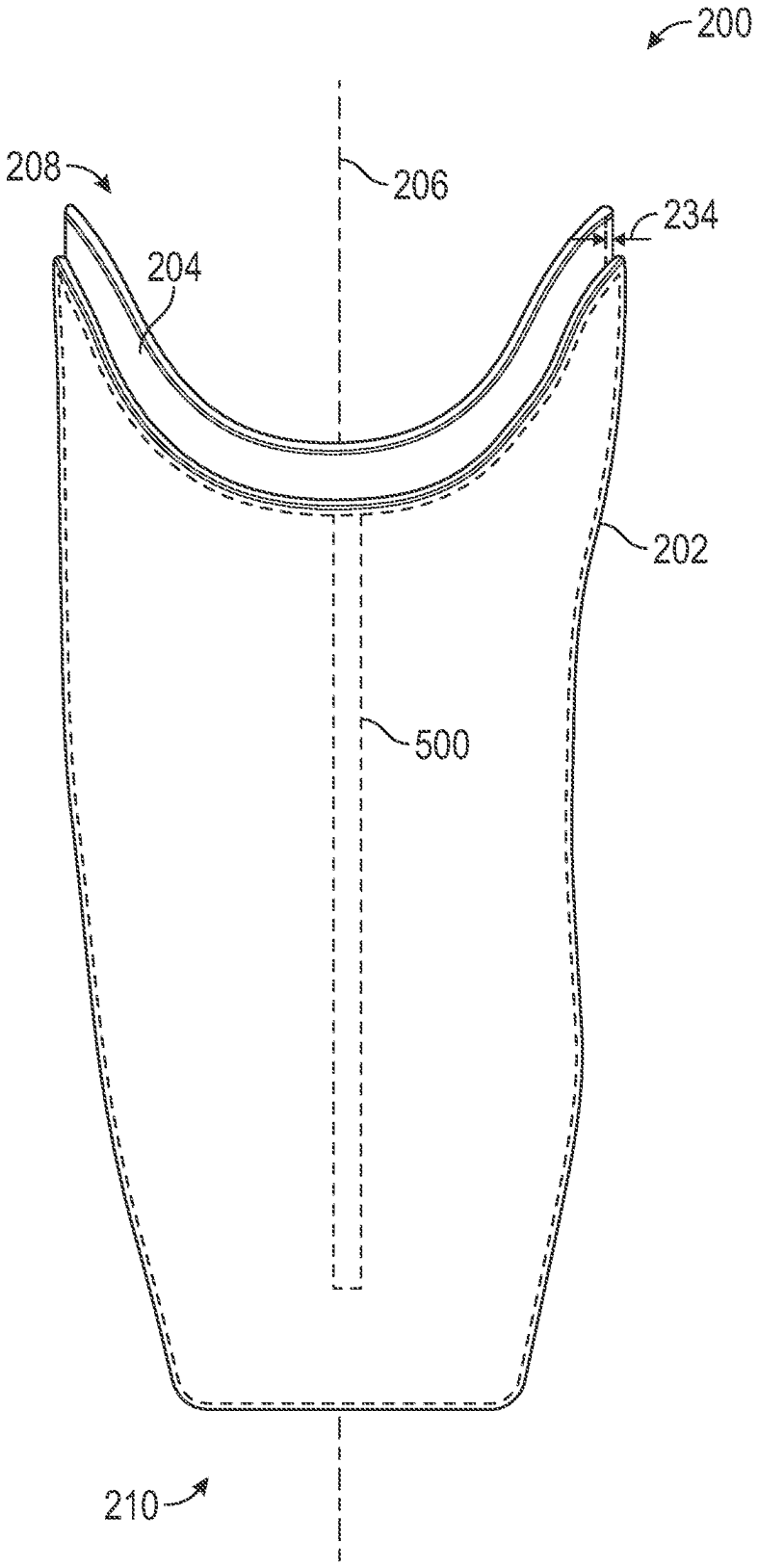


FIG. 6

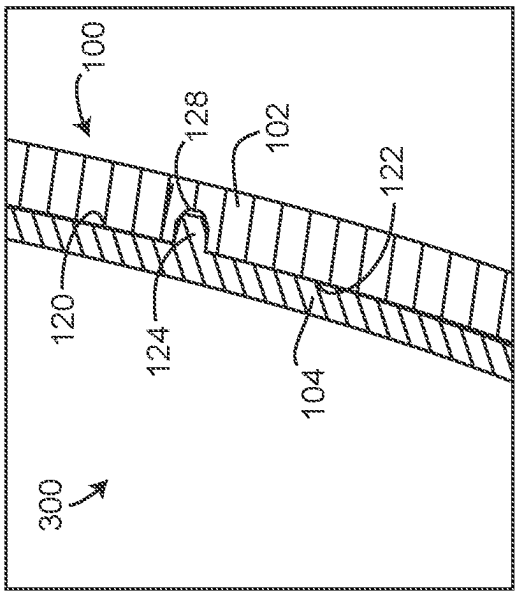


FIG. 8

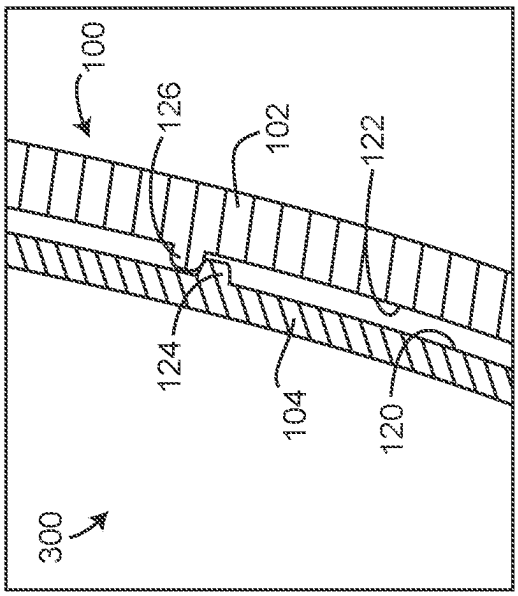


FIG. 7

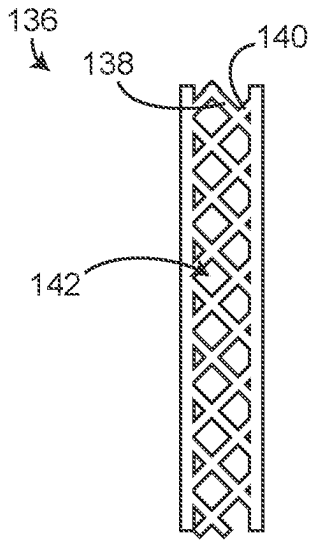


FIG. 9

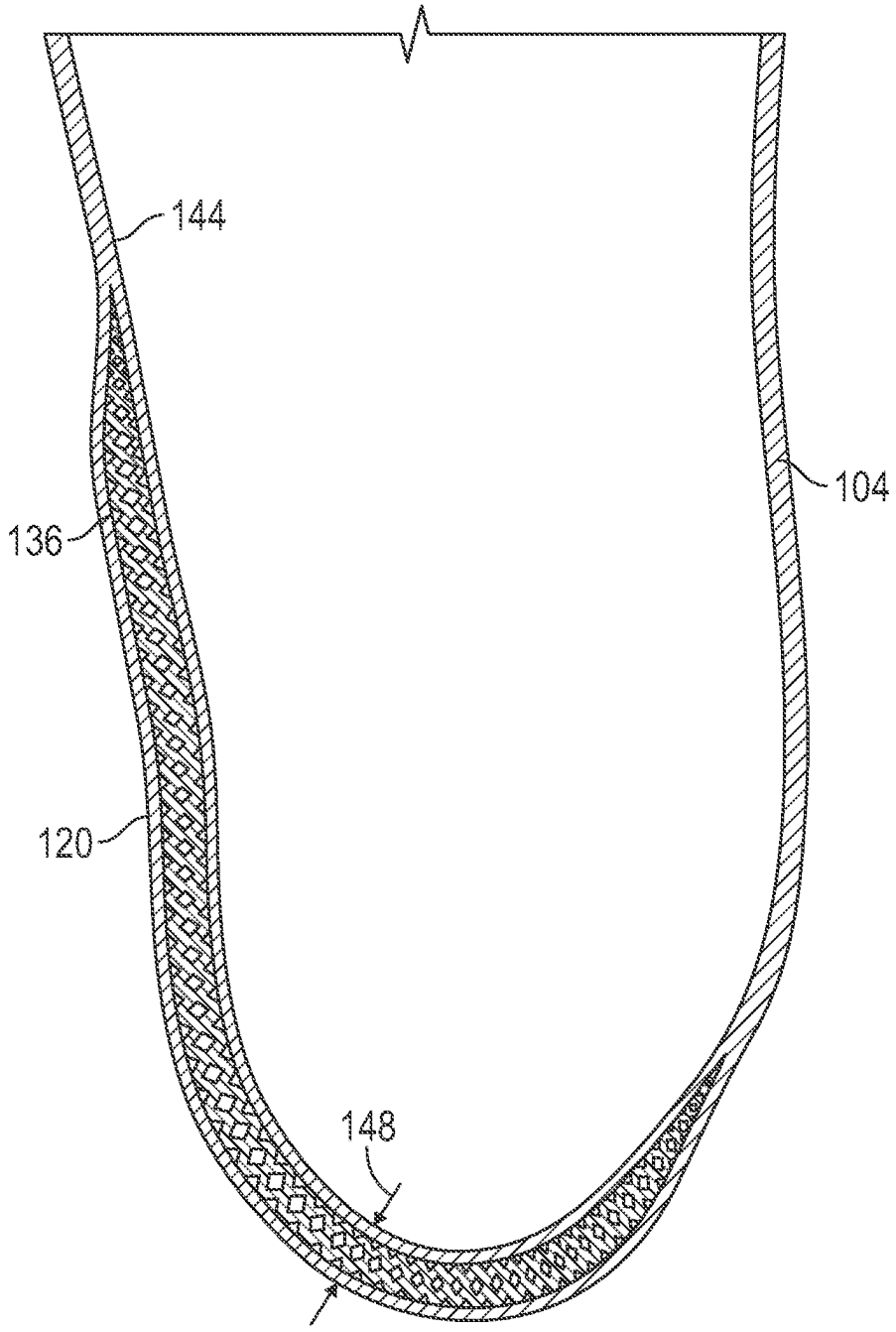


FIG. 10

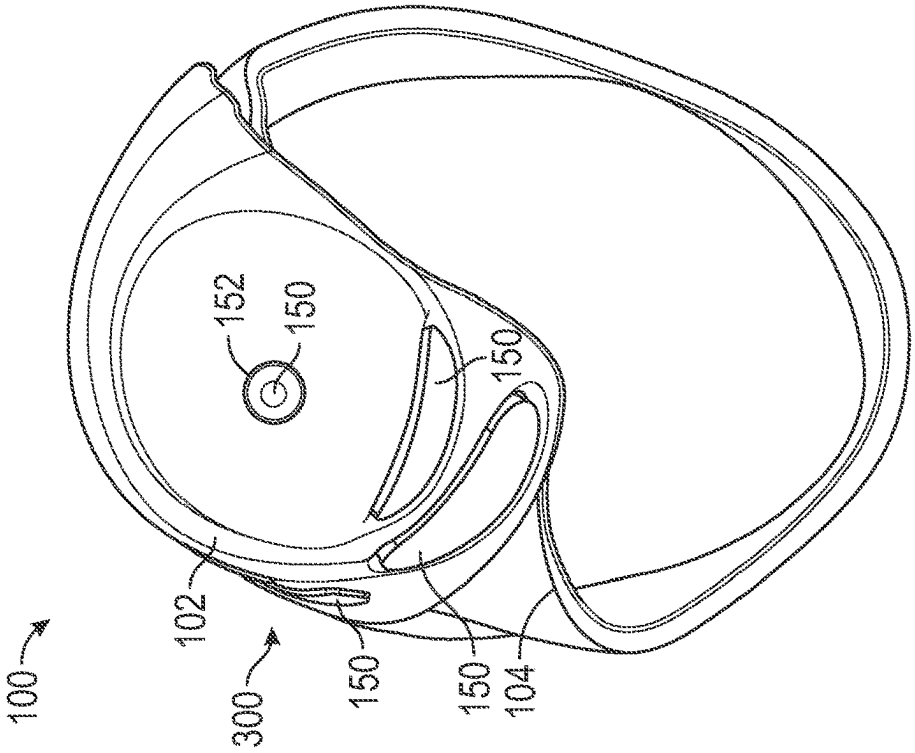

100
102
300
150
150
104
150
152
150

FIG. 12

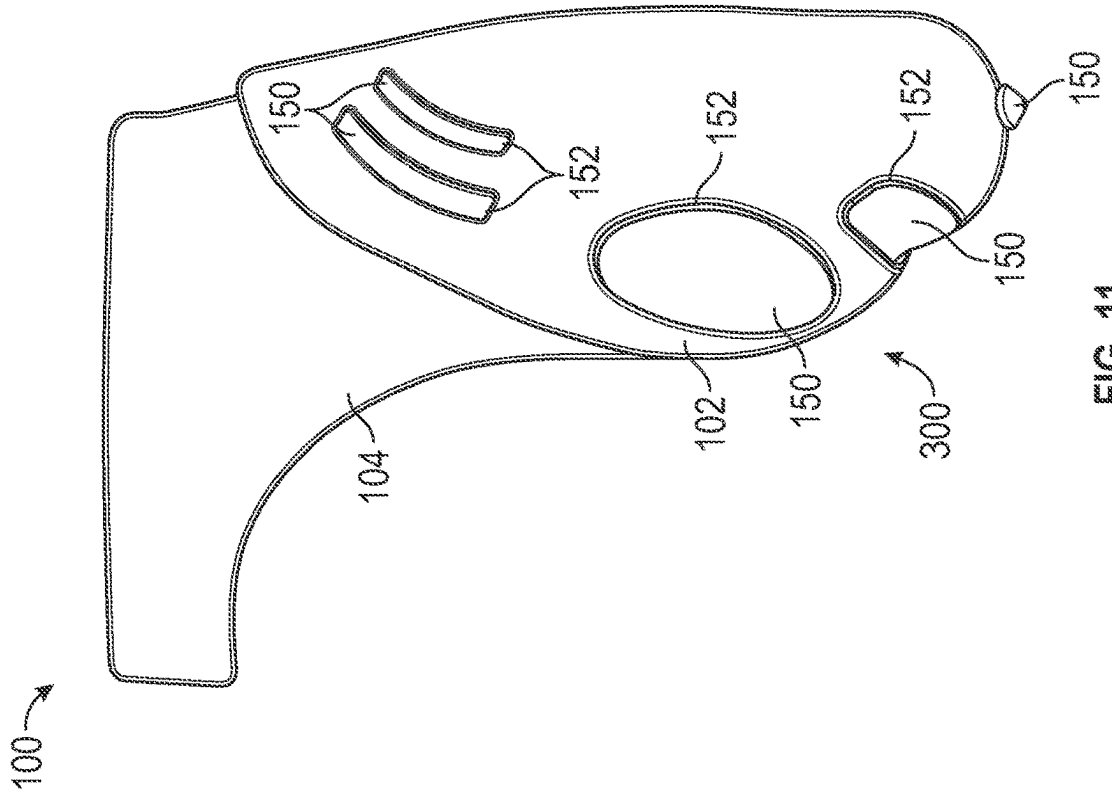

100
104
102
150
300
150
152
152
150
150
152
150

FIG. 11

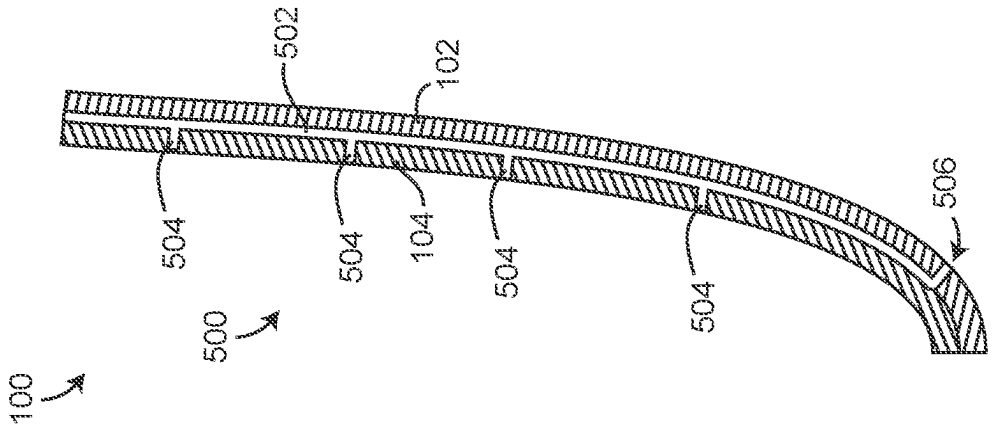

502
102
504
504
104
504
504
506
500
100

FIG. 14

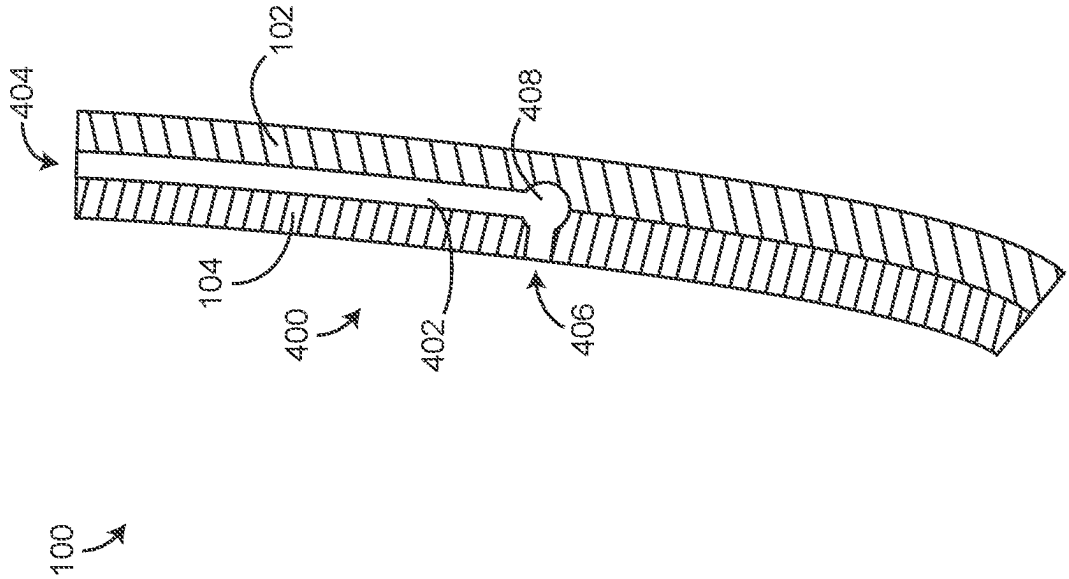

404
102
408
104
400
402
406
100

FIG. 13

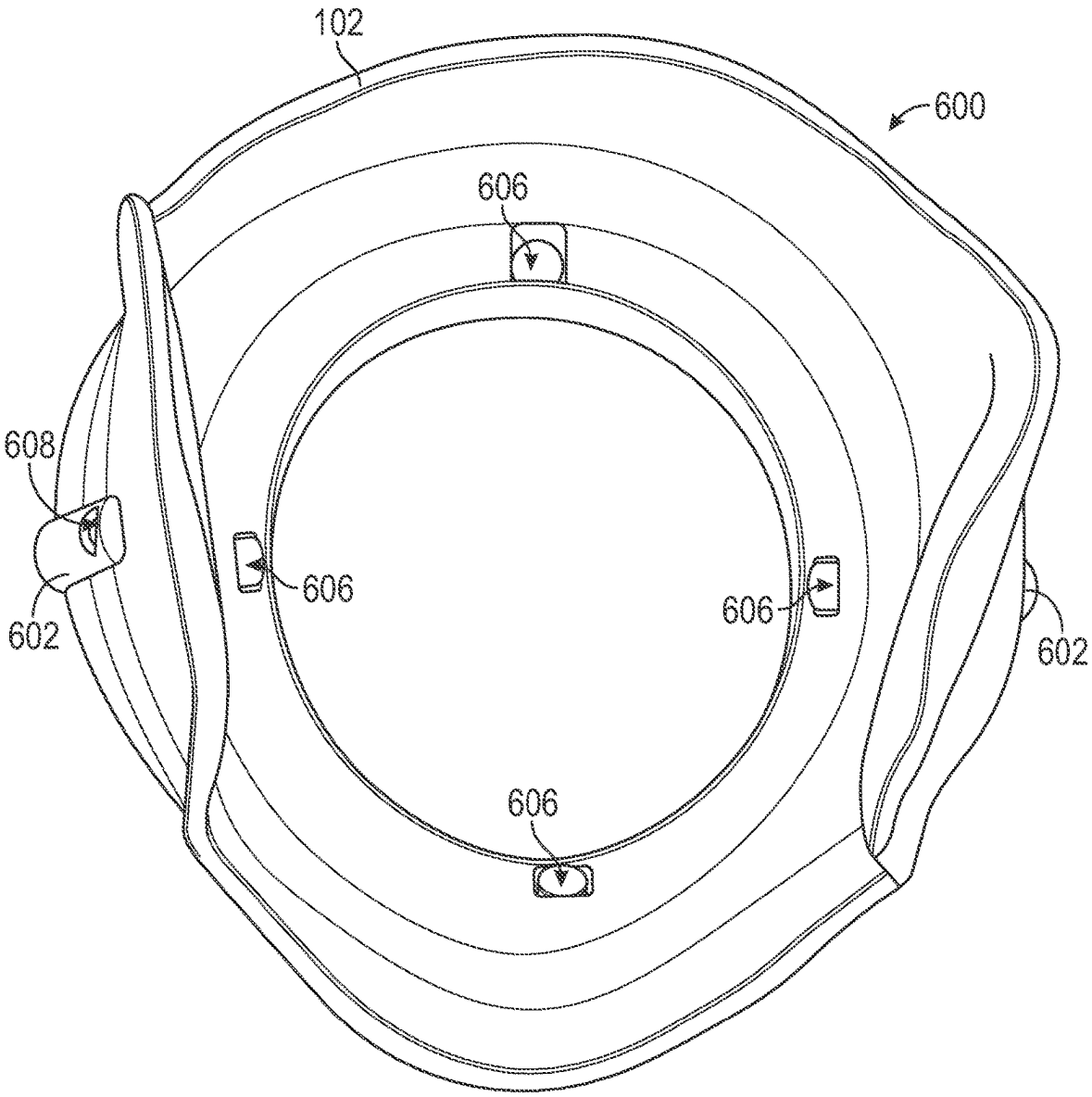


FIG. 15

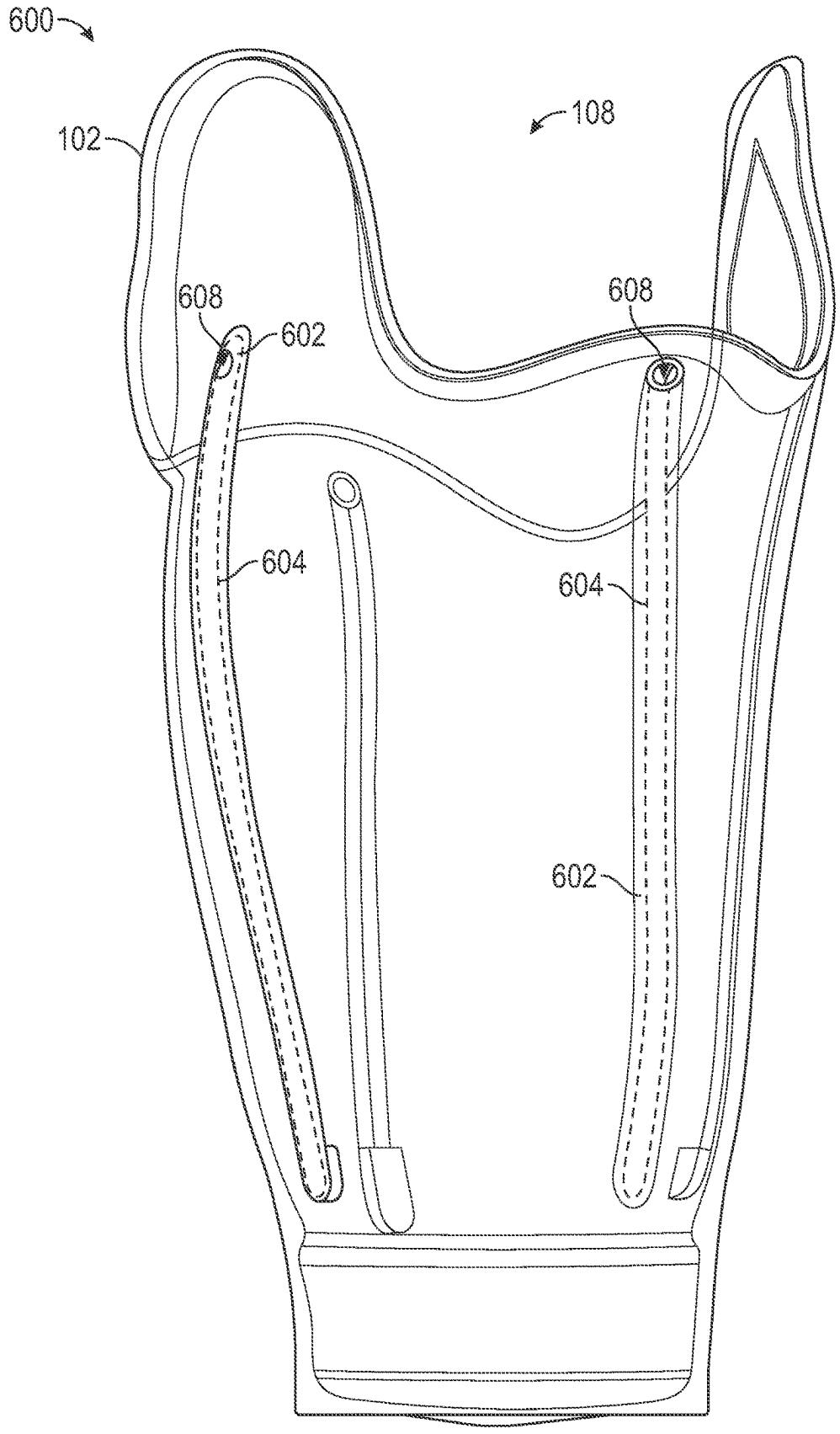


FIG. 16

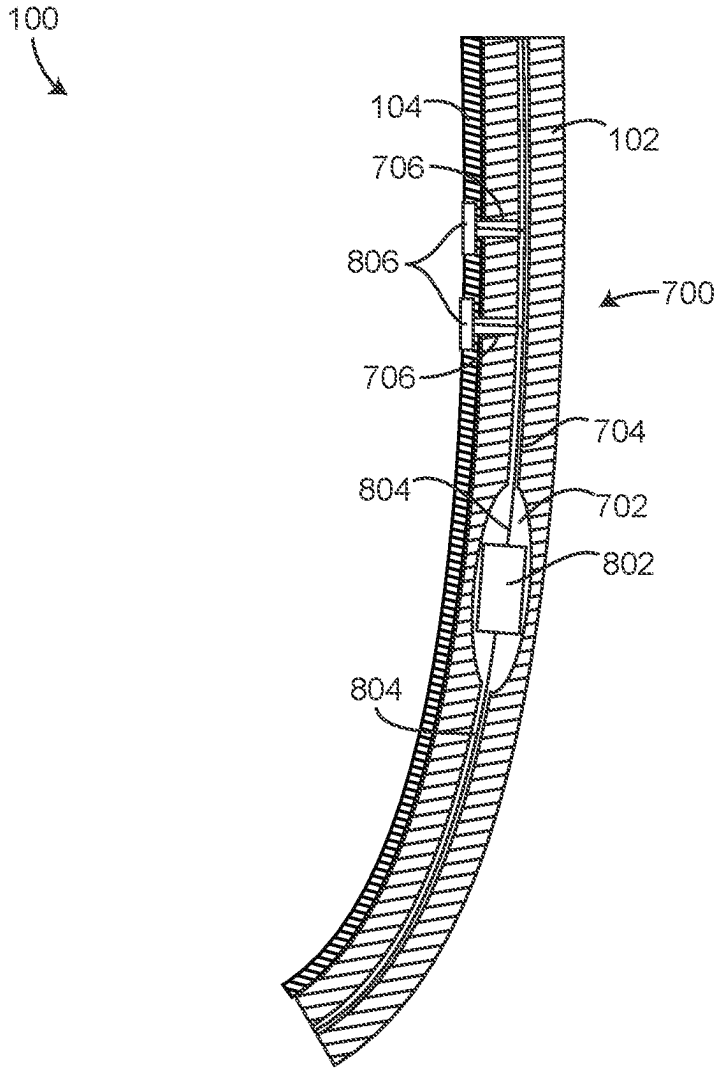


FIG. 17

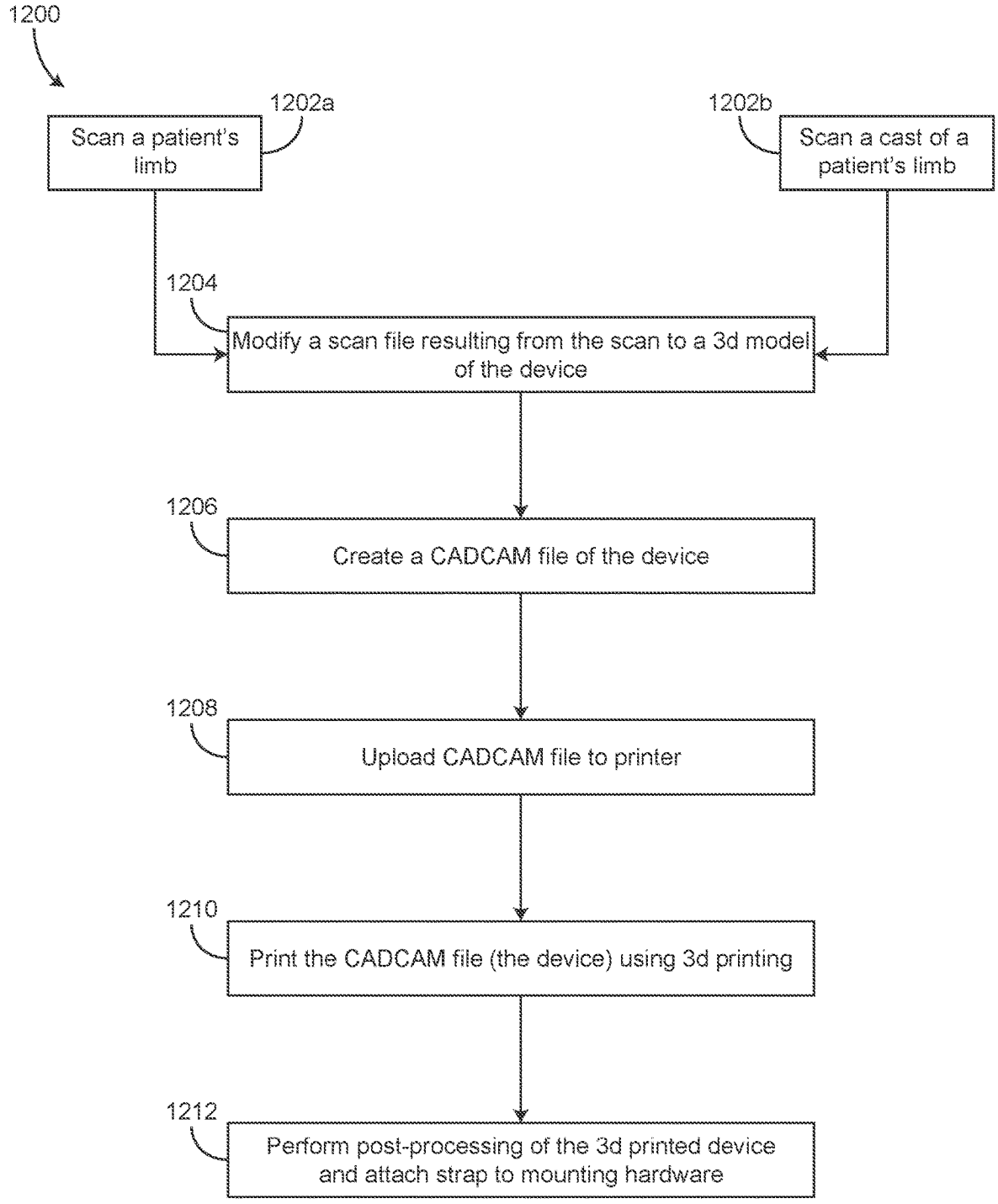

1200
1202a
Scan a patient's limb
1202b
Scan a cast of a patient's limb
1204
Modify a scan file resulting from the scan to a 3d model of the device
1206
Create a CADCAM file of the device
1208
Upload CADCAM file to printer
1210
Print the CADCAM file (the device) using 3d printing
1212
Perform post-processing of the 3d printed device and attach strap to mounting hardware

FIG. 18

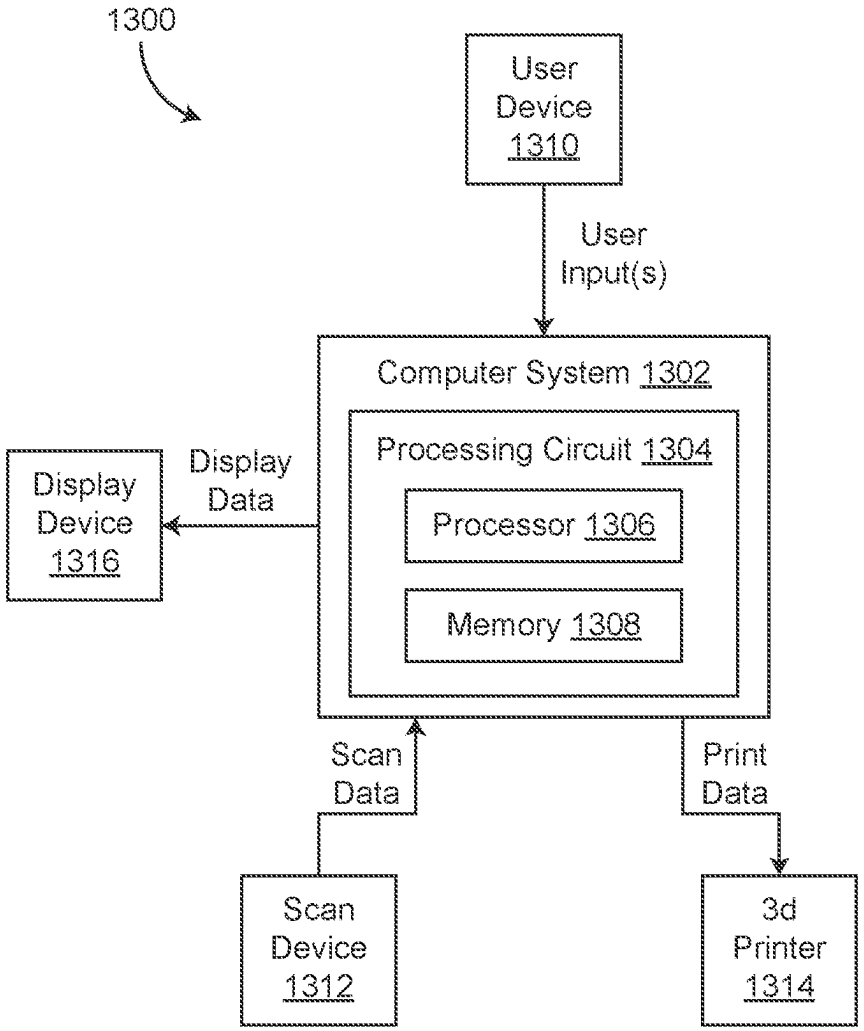

1300
User Device 1310
User Input(s)
Computer System 1302
Processing Circuit 1304
Processor 1306
Memory 1308
Display Device 1316
Display Data
Scan Data
Print Data
Scan Device 1312
3d Printer 1314

FIG. 19

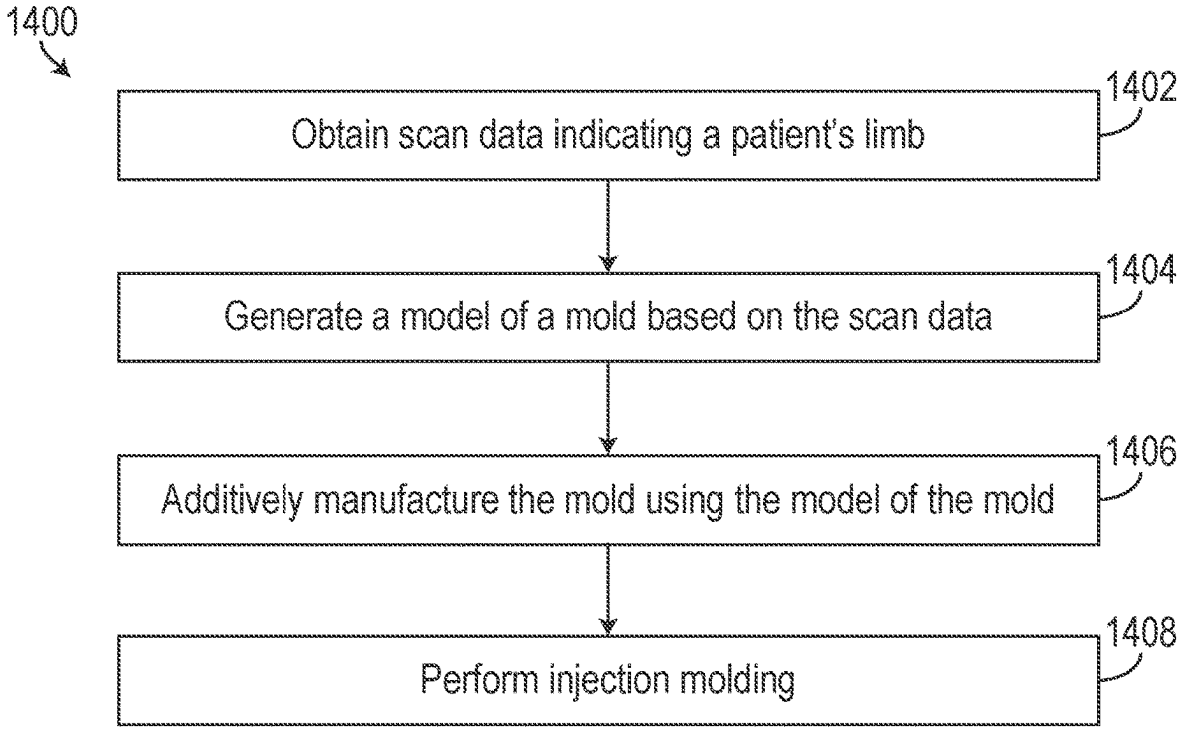

1400
Obtain scan data indicating a patient's limb
1402
Generate a model of a mold based on the scan data
1404
Additively manufacture the mold using the model of the mold
1406
Perform injection molding
1408

FIG. 20

ADDITIVE MANUFACTURING TECHNIQUES FOR A SOCKET AND LINER COMBINATION DEVICE

CROSS-REFERENCE TO RELATED PATENT APPLICATION

[0001] This PCT application claims the benefit of and priority to U.S. Provisional Application No. 63/423,311, filed Nov. 7, 2022, the entire disclosure of which is incorporated by reference herein.

BACKGROUND

[0002] The present disclosure relates generally to prosthetics and orthotics. More particularly, the present disclosure relates to additive manufacturing of protective devices, prosthetics and/or orthotics.

SUMMARY

[0003] One implementation of the present disclosure is a prosthetic assembly, according to some embodiments. In some embodiments, the prosthetic assembly includes a socket and a liner. In some embodiments, the socket includes a first interlocking feature and defines an inner volume. In some embodiments, the liner includes a second interlocking feature. In some embodiments, the first interlocking feature and the second interlocking feature are configured to engage each other when the liner is inserted into the inner volume of the socket. In some embodiments, the liner is configured to receive a distal limb of a patient. In some embodiments, at least one of the socket or the liner include inner voids extending within walls of the socket or the liner.

[0004] In some embodiments, the inner voids include a first set of internal channels for heat dissipation from the patient's distal limb to facilitate cooling of the patient's distal limb. In some embodiments, the inner voids include a second set of internal channels for moisture evaporation from the patient's distal limb to facilitate evaporation of sweat or bodily fluids from the patient's distal limb. In some embodiments, the inner voids include a third set of internal channels for electrical components. In some embodiments, the third set of internal channels are configured to receive at least one sensor or transducer and at least one myoelectric wire. In some embodiments, the electrical components include components of a Peltier cooling system. In some embodiments, the inner voids include a fourth set of internal channels configured to provide therapy or medication to the patient's distal limb.

[0005] In some embodiments, at least one of the socket or the liner includes a variable thickness along a longitudinal length or radial direction of the socket or the liner. In some embodiments, the liner includes a lattice structure. In some embodiments, the lattice structure is positioned at a distal end of the liner and positioned between a double wall of the liner. In some embodiments, the lattice structure is configured to facilitate desired transfer of forces between the prosthetic assembly and the patient's distal limb, to absorb impact forces, and to reduce shear stress.

[0006] In some embodiments, the prosthetic assembly is an above-the-knee or below-the-knee lower limb prosthetic assembly. In some embodiments, the prosthetic assembly is an above-the-elbow, below-the-elbow, at the wrist, or a finger upper limb prosthetic assembly.

[0007] In some embodiments, the socket is manufactured from a thermoplastic or a thermoplastic reinforced with high strength material. In some embodiments, the liner is manufactured from a flexible silicone material or a higher durometer rubber. In some embodiments, an exterior surface of the liner and an internal surface of the socket are configured to engage each other to define sealed vacuum sections between the liner and the socket. In some embodiments, other sections of the liner and the socket do not define sealed vacuum sections.

[0008] In some embodiments, the prosthetic assembly is entirely manufactured through at least one of additive manufacturing or injection molding. In some embodiments, at least one of the liner or the socket include connection points configured to couple additional componentry to the prosthetic assembly. In some embodiments, the connection points include an extrusion or a recess disposed on the liner or the socket.

[0009] In some embodiments, the first interlocking feature is a protrusion and the second interlocking feature is a void. In some embodiments, the protrusion is configured to be received within the void to removably couple the socket with the liner.

[0010] In some embodiments, the first interlocking feature is a void and the second interlocking feature is a protrusion. In some embodiments, the protrusion is configured to be received within the void to removably couple the socket with the liner. In some embodiments, the socket and the liner conform to an anatomical shape of the patient's distal limb.

[0011] Another implementation of the present disclosure is a method for manufacturing a prosthetic assembly that includes a socket and a liner, according to some embodiments. In some embodiments, the method includes using a digital scanner to capture an anatomical structure of a patient's distal limb, an anatomical structure of a cast of the patient's distal limb, or an anatomical structure of a mold of the patient's distal limb to generate a scan file. In some embodiments, the method includes converting the scan file to a design file. In some embodiments, the method includes modifying the design file to generate a model of the liner and a model of the socket. In some embodiments, the model of the liner and the model of the socket include interlocking features. In some embodiments, the liner is configured to be received within the socket. In some embodiments, the method includes manufacturing the design file to produce the liner and the socket of the prosthetic assembly using at least one of an additive manufacturing process using an additive manufacturing device or an injection molding process.

[0012] In some embodiments, modifying the design file includes using build-ups, reductions, or other adjustment to generate the model of the liner and the model of the socket. In some embodiments, modifying the design file further includes designing at least one of the model of the liner or the model of the socket to include inner voids extending within walls of the model of the socket or the model of the liner.

[0013] In some embodiments, the inner voids include a first set of internal channels for heat dissipation from the patient's distal limb to facilitate cooling of the patient's distal limb. In some embodiments, the inner voids include a second set of internal channels for moisture evaporation from the patient's distal limb to facilitate evaporation of sweat or bodily fluids from the patient's distal limb. In some

embodiments, the inner voids include a third set of internal channels for electrical components. In some embodiments, the third set of internal channels are configured to receive at least one sensor or transducer and at least one myoelectric wire. In some embodiments, the electrical components include components of a Peltier cooling system. In some embodiments, the inner voids include a fourth set of internal channels configured to provide therapy or medication to the patient's distal limb.

[0014] In some embodiments, modifying the design file includes adjusting a thickness of the model of the socket or the model of the liner. In some embodiments, the thickness of at least one of the socket or the liner is variable along a longitudinal length or radial direction of the socket or the liner.

[0015] In some embodiments, modifying the design file further includes building a lattice structure on the model of the liner. In some embodiments, the lattice structure is positioned at a distal end of the liner and positioned between a double wall of the liner. In some embodiments, the lattice structure is configured to facilitate desired transfer of forces between the prosthetic assembly and the patient's distal limb, to absorb impact forces, and to reduce shear stress.

[0016] In some embodiments, the prosthetic assembly is an above-the-knee or below-the-knee lower limb prosthetic assembly. In some embodiments, the prosthetic assembly is an above-the-elbow, below-the-elbow, at the wrist, or a finger upper limb prosthetic assembly.

[0017] In some embodiments, manufacturing the socket includes using a thermoplastic or a thermoplastic reinforced with high strength material to fabricate the socket. In some embodiments, manufacturing the liner includes using a flexible silicone material or a higher durometer rubber to fabricate the liner.

[0018] In some embodiments, an exterior surface of the liner and an internal surface of the socket are configured to engage each other to define sealed vacuum sections between the liner and the socket. In some embodiments, other sections of the liner and the socket do not define sealed vacuum sections.

[0019] In some embodiments, the prosthetic assembly is entirely manufactured through at least one of additive manufacturing or injection molding. In some embodiments, at least one of the liner or the socket include connection points configured to couple additional componentry to the prosthetic assembly.

[0020] In some embodiments, the connection points include an extrusion or a recess disposed on the liner or the socket. In some embodiments, the interlocking features include a protrusion and a void. In some embodiments, the protrusion is configured to be received within the void to removably couple the socket with the liner. In some embodiments, the socket and the liner conform to an anatomical shape of the patient's distal limb.

[0021] In some embodiments, converting the scan file to the design file includes converting the scan file to a computer assisted design (CAD) or computer assisted manufacturing (CAM) model. In some embodiments, the method further includes uploading design file to a 3D printer. In some embodiments, the socket and the liner of the prosthetic assembly are custom made based on anatomy, requests, and needs for the patient.

[0022] In some embodiments, the method further includes assembling the liner and the socket of the prosthetic assembly. In some embodiments, the liner and the socket of the prosthetic assembly are configured to undergo minor shape adjustments without sustaining structural damage.

[0023] This summary is illustrative only and is not intended to be in any way limiting. Other aspects, inventive features, and advantages of the devices or processes described herein will become apparent in the detailed description set forth herein, taken in conjunction with the accompanying figures, wherein like reference numerals refer to like elements.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The disclosure will become more fully understood from the following detailed description, taken in conjunction with the accompanying figures, wherein like reference numerals refer to like elements, in which:

[0025] FIG. **1** is a perspective view of an upper limb prosthetic socket and an interfacing liner, according to some embodiments.

[0026] FIG. **2** is a side view of the prosthetic socket and interfacing liner of FIG. **1**, according to some embodiments.

[0027] FIG. **3** is a front view of the prosthetic socket and interfacing liner of FIG. **1**, according to some embodiments.

[0028] FIG. **4** is a perspective view of a lower limb prosthetic socket and an interfacing liner, according to some embodiments.

[0029] FIG. **5** is a side view of the lower limb prosthetic socket and the interfacing liner of FIG. **4**, according to some embodiments.

[0030] FIG. **6** is a front view of the lower limb prosthetic socket and interfacing liner of FIG. **4**, according to some embodiments.

[0031] FIG. **7** is a sectional view of interlocking protrusions of the prosthetic socket and interfacing liner of FIGS. **1-3** or FIGS. **4-6**, according to some embodiments.

[0032] FIG. **8** is a sectional view of interlocking protrusions and recesses of the prosthetic socket and interfacing liner of FIGS. **1-3** or FIGS. **4-6**, according to some embodiments.

[0033] FIG. **9** is a diagram of a lattice structure, according to some embodiments.

[0034] FIG. **10** is a side sectional view of the liner of FIGS. **1-3** or FIGS. **4-6** including the lattice structure of FIG. **9** disposed between walls along a bottom portion of the liner, according to some embodiments.

[0035] FIG. **11** is a side view of the prosthetic socket and interfacing liner of FIGS. **1-3** or FIGS. **4-6** including interlocking openings and protrusions, according to some embodiments.

[0036] FIG. **12** is a bottom view of the prosthetic socket and interfacing liner of FIG. **10**, according to some embodiments.

[0037] FIG. **13** is a sectional view of the prosthetic socket and interfacing liner of FIGS. **1-3** or FIGS. **4-6** including therapy passageways, according to some embodiments.

[0038] FIG. **14** a sectional view of the prosthetic socket and interfacing liner of FIGS. **1-3** or FIGS. **4-6** including a vent passageway, according to some embodiments.

[0039] FIG. **15** is a top view of the socket of FIGS. **1-3** illustrating venting channels and openings, according to some embodiments.

[0040] FIG. **16** is a side view of the socket of FIG. **15** illustrating the venting channels, according to some embodiments.

[0041] FIG. **17** is a side sectional view of the socket of FIGS. **1-3** or the socket of FIGS. **4-6** including electrical channels and/or voids configured to receive one or more electrical components, according to some embodiments.

[0042] FIG. **18** is a flow diagram of a process for additively manufacturing any of the prosthetic devices of FIGS. **1-17**, according to some embodiments.

[0043] FIG. **19** is a block diagram of an additive manufacturing system architecture configured to implement the process of FIG. **18**, according to some embodiments.

[0044] FIG. **20** is a flow diagram of a process for manufacturing any of the prosthetic devices of FIGS. **1-17** using injection molding, according to some embodiments.

DETAILED DESCRIPTION

[0045] Before turning to the FIGURES, which illustrate the exemplary embodiments in detail, it should be understood that the present application is not limited to the details or methodology set forth in the description or illustrated in the FIGURES. It should also be understood that the terminology is for the purpose of description only and should not be regarded as limiting.

Overview

[0046] Referring generally to the FIGURES, an upper or lower limb prosthetic socket may be additively manufactured in combination with a corresponding interfacing liner device. In some embodiments, the socket and the liner cooperatively define a combination device and are configured to interlock with each other (e.g., selectably or upon insertion of a patient's distal limb with the liner placed over the patient's distal upper or lower limb). In some embodiments, an entirety of the combination device is additively manufactured (e.g., by a 3D printer) using a layer-by-layer process. In some embodiments, one or more components of the combination device are manufactured by an injection molding process. In some embodiments, a system of strategically placed cutouts and/or extrusions between the socket and the liner overlap so that the socket and the liner interlock or couple with each other.

[0047] The combination device may be used for either lower extremity or upper extremity patients and may include one or more attachment points or external receiving members configured to couple external componentry with the socket and/or the liner. In some embodiments, one or more channels, voids, depressions, openings, apertures, grooves, etc., are formed in the liner or the socket to facilitate venting and/or heat dispersion thereby resulting in improved comfortability for the patient. For example, the combination device can include channels that are configured to extend along a path such that gravity may facilitate drawing moisture away from the patient's limb and allowing evaporation of the moisture (e.g., sweat or other bodily fluids) into an external environment. Advantageously, these channels may reduce sweat buildup in the bottom of the socket which improves comfortability of the combination device relative to other prosthetic sockets that do not include venting for moisture. The liner may include a lattice structure positioned according to needs of the patient to absorb impact forces and properly distribute forces on the patient's residual or distal limb.

[0048] The techniques described herein for additive manufacturing can additionally be used to manufacture the prosthetic, orthotic, connection insert, or related medical devices as described in U.S. Patent Application Pub. No.: 2018/0353308 A1, filed Jul. 31, 2018, the entire disclosure of which is incorporated by reference herein. Further, any of the additive manufacturing techniques as described in U.S. Patent Application Pub. No.: 2018/0353308 A1 may be used to manufacture any of the devices described herein.

[0049] In some embodiments, the prosthetic, orthotic, connection insert, protective device, etc., as described herein are manufactured using any of the techniques as described in U.S. Pat. No. 10,766,246 B2, filed Dec. 15, 2014, the entire disclosure of which is incorporated by reference herein.

Upper Extremity Prosthetic Socket

[0050] Referring to FIGS. **1-3**, a prosthetic assembly, a prosthetic device assembly, an upper extremity prosthetic socket assembly, a combination device, etc., shown as upper extremity combination device **100** includes a socket **102** (e.g., an external device, an exterior device, a shell, etc.) and a liner **104** (e.g., an internal device, an interior device, a sleeve, a limb contacting device, etc.). The socket **102** includes or defines a first end **108** and a second end **110**. The socket **102** also defines an inner volume **114** (e.g., an interior, a compartment, a void, etc.) that is configured to receive the liner **104**. The socket **102** may include a first opening **116** at the first end **108** into which the liner **104** may be inserted and a second opening **118** at the second end **110**. In some embodiments, the first opening **116** is configured to provide an open end of the socket **102** so that the user can insert their distal upper limb (with the liner **104** installed onto the user's distal upper limb). In some embodiments, the second opening **118** is smaller in size than the first opening **116**. In some embodiments, the socket **102** includes connection structure **130** (e.g., threads, interlocking members, openings, recesses, annular grooves, an adapter, a mount, etc.) that are positioned at the second end **110** and configured to couple (e.g., threadingly, interlockingly, slip fit, press fit, via fasteners, etc.) with an attachable or external componentry. In some embodiments, the connection structure **130** is disposed on the liner **104** so that the attachable or external componentry can be coupled with the liner **104**. In some embodiments, the liner **104** is configured to directly couple, abut, contact, seal with, engage, etc., the patient's distal upper limb (e.g., along inner surfaces of the liner **104**). In some embodiments, an exterior surface of the liner **104** is configured to directly couple, abut, contact, interlock with, seal with, engage, etc., an interior surface of the socket **102**. In some embodiments, the liner **104** is configured to releasably couple with the socket **102** through interlocking features **300**.

[0051] The combination device **100** may be an above the elbow or a below the elbow prosthetic assembly. The socket **102** and the liner **104** may have contours or geometry that substantially matches the contours and geometry of the patient's residual limb. The liner **104** and the socket **102** may be configured to surround, enclose, or fully receive the patient's residual limb. In some embodiments, structural contours of the liner **104** and the socket **102** on either exterior or interior surfaces of the liner **104** and the socket **102** match or correspond with anatomical contours of the patient's residual limb (e.g., the patient's residual upper limb, or the patients residual lower limb in the case of the combination device **200** described below). In some embodiments, the socket **102** is configured to provide proper

distribution of forces across the patient's residual or distal limb. In some embodiments, an entirety of the components of the combination device **100** are manufactured through additive manufacturing.

[0052] In some embodiments, the combination device **100** is an above-the-elbow prosthetic assembly. In some embodiments, the combination device **100** is a below-the-elbow prosthetic assembly. In some embodiments, the combination device **100** is an at the wrist prosthetic assembly. In some embodiments, the combination device **100** is an at the finger prosthetic assembly.

Lower Extremity Prosthetic Socket

[0053] Referring to FIGS. **4-6**, a prosthetic assembly, a prosthetic device assembly, a lower prosthetic socket assembly, a combination device, etc., shown as lower extremity combination device **200** includes a socket **202** and a liner **204**. The socket **202** and the liner **204** may be similar to the socket **102** and the liner **104** as described in greater detail above with reference to the combination device but are configured for a lower limb application (e.g., an above the knee application, a below the knee application, etc.). The combination device **200** similarly defines a longitudinal axis **206**, a first end **208**, and a second end **210**. In some embodiments, the socket **202** includes interfacing features to couple the combination device **200** with a pylon. It should be understood that the combination device **200** may have any similar features as the combination device **100** but is configured for lower extremity applications. In particular, the combination device **200** may have different geometry or contours specific for the lower limb application. In some embodiments, various internal channels of the combination device **200**, as described in greater detail below, are configured to facilitate gravitational force so that moisture travels in a downwards direction. The combination device **200** may also interlock or couple with external componentry similarly to the combination device **100**. In some embodiments, the socket **202** and/or the liner **204** include attachment points for the external componentry. In some embodiments, an entirety of the components of the combination device **100** are manufactured through additive manufacturing. In some embodiments, the socket **102** is configured to provide proper distribution of forces across the patient's residual or distal limb.

Interlocking Features

[0054] Referring to FIGS. **7-8**, the interlocking features **300** are shown according to some embodiments. The interlocking features **300** facilitate removably interlocking or fixing the liner **104** with the socket **102**. It should be understood that while the interlocking features **300** are described herein as being disposed on or formed on the socket **102** and the liner **104**, the interlocking features **300** shown herein can also be used (e.g., disposed on, formed on, etc.) the socket **202** and the liner **204** of the lower limb combination device **200**.

[0055] Referring particularly to FIG. **7**, an inner surface **122** of the socket **102** includes a protrusion **126** (e.g., an extrusion, an extension, an inwards extending member, etc.). An outer surface **120** of the liner **104** includes a protrusion **124** (e.g., an extrusion, an extension, an outwards extending member, etc.). When the liner **104** is inserted into the socket **102**, the protrusion **124** may be translated past the protrusion **126**. The protrusions **124** and **126** may abut each other and thereby interlock the liner **104** with the socket **102** (e.g., removably). In some embodiments, one or both of the protrusions **124** and **126** are configured to deform as the liner **104** is inserted into the socket **102** so that sufficient clearance is provided and the protrusions **124** and **126** can be transitioned into the relative arrangement shown in FIG. **7** (or out of the arrangement shown in FIG. **7**).

[0056] Referring particularly to FIG. **8**, the socket **102** includes a recess **128** (e.g., a depression, a groove, a recess, a void, etc.) that is configured to receive the protrusion **124** to removably couple the liner **104** with the socket **102**. In some embodiments, the protrusion **124** is configured to deform as the liner **104** is inserted into the socket **102** and expand into the recess **128** to removably couple the liner **104** with the socket **102**. In some embodiments, the recess **128** is formed within the outer surface of the liner **104** and the protrusion **124** is formed along the inner surface of the socket **102** so that the protrusion **124** extends from the socket **102** and is received within the recess **128** of the liner **104**. It should be understood that the socket **102** and the liner **104**, or the socket **202** and the liner **204**, may include any number of protrusions, recesses, geometry, etc., or combination thereof, in order to couple the liner **104** with the socket **102** (or to couple the liner **204** with the socket **202**) when the liner **104** is inserted into the socket **102** (or when the liner **204** is inserted into the socket **202**).

[0057] Referring to FIGS. **11-12**, the interlocking features **300** are shown according to some embodiments. The socket **102** includes multiple openings **152** having shapes corresponding to protrusions **150** of the liner **104**. In some embodiments, the protrusions **150** of the liner **104** have irregular shapes, slot shapes, curved shapes, circular shapes, etc., and the socket **102** has openings **152** (e.g., holes, windows, apertures, etc.) having corresponding shapes and positions so that the openings **152** of the socket **102** are configured to receive the protrusions **150** when the liner **104** is inserted into the socket **102** to thereby removably couple (e.g., secure) the liner **104** with the socket **102**. In some embodiments, the protrusions **150** of the liner **104** may be used as a gripping surface in addition to an interlocking member to couple the liner **104** with the socket **102**. For example, the protrusions **150** can be used to assist the patient in picking up objects using the device **100**. The protrusions **150** may provide an interfacing portion having variable geometry (e.g., a "roughened" surface) to improve gripping of the device **100** by a clinician or patient.

Variable Thickness

[0058] Referring to FIGS. **2** and **5**, the socket **102** or the socket **202** are shown having a thickness **132** or **232**, respectively. It should be understood that while the description herein is with reference to the thickness **132** of the socket **102**, anything said herein with reference to the thickness **132** of the socket **102** may also be true of the thickness **232** of the socket **202**.

[0059] In some embodiments, the thickness **132** is uniform along a longitudinal length (e.g., along the longitudinal axis **106**). In some embodiments, the thickness **132** is variable or changing along the longitudinal length of the socket **102**, and/or along a radial direction as measured about the longitudinal axis **106**. In this way, the thickness **132** of the socket **102** can vary (e.g., increase or decrease) along at least one dimension of the socket **102**. In some embodiments, the

variable thickness **132** defines different zones which have different relative thickness (e.g., thin zones and thicker zones). The thickness **132** may vary in one or two dimensions about the socket **102** in order to accommodate anatomy, requests, and/or needs of the patient.

[0060] Referring to FIGS. **3** and **6**, the liner **104** and the liner **204** are shown having thickness **134** and thickness **234**, respectively. It should be understood that while the description herein is with reference to the thickness **134** of the liner **104**, anything said herein with reference to the thickness **134** of the liner **104** may also be true of the thickness **234** of the socket **202**.

[0061] In some embodiments, the thickness **134** is uniform along the longitudinal length (e.g., along the longitudinal axis **106**). In some embodiments, the thickness **134** is variable or changing along the longitudinal length of the liner **104**, and/or along a radial direction as measured about the longitudinal axis **106**. In this way, the thickness **134** of the socket **102** can vary (e.g., increase or decrease) along at least one dimension of the liner **104**. In some embodiments, the varying thickness **134** defines different zones which have different relative thickness (e.g., thin zones and thicker zones). The thickness **134** may vary in one or two dimensions about the liner **104** in order to accommodate anatomy, requests, and/or needs of the patient. The thickness of the liner **104**, the liner **204**, the socket **102**, or the socket **202**, may have variable thickness in order to accommodate anatomy, requests, and needs of the patient.

Administered Therapy

[0062] Referring to FIGS. **1** and **13**, the combination device **100** may include internal passageways, internal voids, passages, openings, channels, pockets, voids, grooves, etc., shown as therapy passages **400**. In some embodiments, the therapy passages **400** are formed within the socket **102**, within the liner **104**, or both the socket **102** and the liner **104** (e.g., between the socket **102** and the liner **104**). Referring particularly to FIG. **13**, the therapy passages **400** can include a passageway **402**, an inlet **404**, an outlet **406**, and a void **408**. In some embodiments, the therapy passages **400** are formed within the socket **102**. In some embodiments, the inlet **404** is formed at the first end **108** of the combination device **100** so that therapy or medication can be introduced into the therapy passages **400**. In some embodiments, the outlet **406** is configured to deliver the therapy or medication to an interior of the liner **104** so that the medication (e.g., a topical medication) is applied to the patient's distal limb. In some embodiments, the combination device **200** also includes therapy passages **400** as described herein. In some embodiments, the therapy passages **400** are similarly configured as the venting passages **500** or the venting passages **600** described in greater detail below. In some embodiments, the therapy passages **400** can be used to provide anti-inflammatory, anti-bacterial, or pain relief medication to the patient's distal limb. In some embodiments, the therapy passages **400** include multiple perforations or small holes so that the medication is released to the patient's distal limb over time. In some embodiments, the therapy passages **400** are formed entirely within the socket **102** or the socket **202**, entirely within the liner **104** or the liner **204**, or within both the socket **102** (or the socket **202**) and the liner **104** (or the liner **204**).

Lattice Structure

[0063] Referring to FIGS. **3** and **9-10**, the liner **104** may include a lattice structure **136** that is configured (e.g., targeted, positioned, etc.) to reduce shear stress and impact forces. In some embodiments, the liner **204** also includes a lattice structure **236** that is the same as or similar to the lattice structure **136** described herein with reference to FIGS. **3** and **9-10**. In some embodiments, lattice structures **136** are positioned at a bottom of the liner **104** in order to absorb impact. In some embodiments, the lattice structure **136** are positioned in order to reduce translational forces due to scarring of the patient's limb.

[0064] Referring particularly to FIG. **9**, the lattice structure **136** is shown to include multiple first members **138** arranged in a first array and extending in a first direction. In some embodiments, the first members **138** extend parallel with each other or are non-parallel with each other. In some embodiments, the first members **138** extend along a substantially straight path. In some embodiments, the first members **138** extend along a curved path. In some embodiments, the first members **138** are spaced uniformly. In some embodiments, the first members **138** are spaced non-uniformly.

[0065] Referring still to FIG. **9**, the lattice structure **136** further includes multiple second members **140** that are arranged in a second array and extend in a second direction that is different than the first direction. The second members **140** can similarly extend in parallel with each other, or may extend non-parallel with each other. The second members **140** can similarly extend along a substantially straight path, a curved path, may be spaced uniformly and/or may be spaced non-uniformly. The second members **140** and the first members **138** may be integrally formed with each other and can define cells **142** (e.g., open spaces).

[0066] Referring particularly to FIG. **10**, the lattice structure **136** is disposed along the liner **104** between an interior surface **144** of the liner **104** and the outer surface **120** of the liner **104**. In some embodiments, the liner **104** includes double-walled sections (e.g., along a bottom or distal end of the liner **104**) within which the lattice structure **136** is positioned. In some embodiments, the lattice structure **136** has a width **146** that can be variable along different portions in order to provide different amount of impact absorption or distribute forces as desired. In some embodiments, the lattice structure **136** is a pattern of depressions or recesses formed in the interior surface **144** of the liner **104** or the outer surface **120** of the liner **104**. In some embodiments, the lattice structure **136** is additionally or alternatively disposed on the interior surface **122** of the socket **102**. In some embodiments, the lattice structure **136** function as a spring or a damper responsive to forces or compression, and characteristics of the lattice structure **136** (e.g., thickness or width **146** of the double walls, a thickness of the members **138** or **140**, etc.) in order to tune a desired dynamic response of the lattice structure **136**.

Venting Structures

[0067] Referring to FIGS. **1**, **6**, and **14**, the combination device **100** or the combination device **200** may include venting structure **500** that are configured to facilitate improved heat transfer (e.g., heating dispersion) and/or evaporation of bodily fluids of the patient's residual limb. The venting structure **500** can include passageways, pas-

sages, etc., configured to fluidly couple different portions of the combination device **100** or the combination device **200** with an external environment to facilitate proper cooling of the patient's residual limb and evaporation of moisture or bodily fluids (e.g., sweat).

[0068] Referring particularly to FIG. **14**, the venting structure **500** can be formed between the liner **104** and the socket **102** (or between the liner **204** and the socket **202**). In some embodiments, the venting structure **500** includes a passageway **502** that extends along a portion of the socket **102**. The passageway **502** can be formed within the socket **102**, within the liner **104**, or cooperatively between the socket **102** and the liner **104** (e.g., with formed recesses between the socket **102** and the liner **104** that cooperatively form the passageway **502** when the liner **104** is installed into the socket **102**). In some embodiments, the venting structure **500** includes one or more openings, holes, bores, apertures, perforations, slots, etc., shown as passages **504** that extend through the liner **104** so that an interior of the liner **104** (e.g., within which the patient's residual limb is positioned) can fluidly couple with the passageway **502**. In some embodiments, the venting structure **500** also includes an outlet **506** (e.g., an opening, a hole, a bore, a passage, etc.) formed in the socket **102** that vents the passageway **502** to an external environment of the socket **102**. In some embodiments, the outlet **506** is formed and extends through the socket **102** (e.g., a sidewall of the socket **102**). In some embodiments, the combination device **100** includes multiple venting structures **500** disposed about the combination device **100** (or the combination device **200**) that facilitate improved heat transfer (e.g., cooling) and evaporation (e.g., of sweat) to facilitate improved comfort for the patient when wearing the combination device **100** or the combination device **200**.

[0069] Referring to FIGS. **15-16**, the venting structure **500**, shown as venting structures **600**, may be formed within the socket **102**. The socket **102** is shown to include multiple vents (e.g., channels) formed within walls of the socket **102**. The socket **102** may include ribs, ridges, etc., shown as protrusions **602** that extend lengthwise along the socket **102**. The venting structure **600** includes channels **604** (e.g., passages, inner volumes, voids, etc.) that extend through the protrusions **602** in the lengthwise direction. The venting structures **600** also include openings **608** positioned at a first end of the channels **604** (e.g., at an upper end of the channels **604**, proximate the first end **108**) disposed on an outer surface of the socket **102**, and openings **606** positioned at a second end of the channels **604** (e.g., at a lower end of the channels **604**, proximate the second end **110**) disposed on the inner surface **122** of the socket **102**. The venting structure **600** can be used alternatively or in addition to the venting structure **500**. In some embodiments, the openings **606** are configured to correspond or match with correspondingly positioned openings, channels, inner volumes, recesses, etc., of the liner **104** when the liner **104** is installed in the socket **102**. The venting structures **600** are configured to facilitate improved cooling, airflow, and evaporation. The venting structure **600** can also be used to provide therapy to the patient's distal limb or to receive electrical components. It should be understood that any number of venting structures **600** may be used in the combination device **100** or the combination device **200**.

[0070] In some embodiments, one or more of the channels, vents, internal volumes, etc., described herein with reference to FIGS. **13-16** can be used to dissipate heat, with separate channels to dissipate moisture. Channels that are used to dissipate moisture may direct the moisture downwards (e.g., in a direction of gravitational force) so that the moisture is drawn out of the combination device **100** or the combination device **200**. Channels that are used to dissipate heat may generally extend outwards. In some embodiments, the combination device **100** or the combination device **200** include openings that extend through their liners and sockets and are aligned when assembled so that heat may be dissipated outwards.

Electrical Components

[0071] Referring to FIGS. **1**, **4**, and **17**, the combination device **100** and/or the combination device **200** include one or more electrical voids **700** configured to receive one or more electrical components such as sensors, wires, controllers, batteries, circuits, feedback devices, etc. In some embodiments, the electrical voids **700** are formed in the socket **102** and are configured to enclose or substantially surround the electrical components. In some embodiments, the electrical voids **700** are configured to receive a Peltier cooling system and components of the Peltier cooling system. In some embodiments, the electrical voids **700** are configured to receive myoelectric parts, a stimulus unit (e.g., a TENS unit), etc.

[0072] As shown in FIG. **17**, the socket **102** (or alternatively the socket **202**) may include a channel **704** (e.g., a passageway, a passage, an elongated void, etc.) that extends along a length of the socket **102**. In some embodiments, the electrical voids **700** (e.g., channels, inner volumes, bores, apertures, internal structure, etc.) includes a chamber **702** within the socket **102** that is configured to receive an electrical device **802** (e.g., a controller, a microcontroller, a microprocessor, a programmable logic controller, a battery, a battery cell, an energy storage device, etc.). In some embodiments, the channel **704** is configured to receive one or more electrical cords, shown as cords **804**. The cords **804** can extend through the inner volumes of the socket **102** and provide electrical power to various of the electrical devices of the combination device **100** and/or to provide electrical communications to or from the various electrical devices. In some embodiments, the electrical voids **700** include one or more passageways **706** that extend through the socket **102** towards the liner **104**. The liner **104** can also include one or more portions of the passageways **706** through which the cords **804** extend. In some embodiments, one or more sensors or feedback devices, shown as electrical input/output devices **806** are electrically coupled with the cords **804**. In some embodiments, the cords **804** are myoelectric wires. In some embodiments, the electrical device **802** and the electrical input/output devices **806** are configured to communicate wirelessly (or wirelessly with an external computing device such as a smart phone) using a wireless communications protocol such as Bluetooth, LoRa, Zigbee, Near Field Communications, etc.

[0073] The electrical input/output devices **806** may be received within a recess or a groove on an inner surface of the liner **104**. In some embodiments, the electrical input/output device **806** include any of, or any combination of, a temperature sensor, a cooling device, a humidity sensor, a tactile feedback device, a haptics feedback device, an electrical stimulation feedback device, a force transducer, a biomechanical interface, a microprocessor knee, electrodes, etc. The electrical input/output devices **806** may generally be

transducers that are configured to use electrical energy and/or communications to provide feedback to the patient's residual limb, or that are configured to monitor a condition and generate communications responsive to and related to the condition (e.g., temperature, humidity, etc.).

Selective Vacuum Regions

[0074] Referring to FIGS. **3** and **4**, the combination device **100** or the combination device **200** can include vacuum sections or regions, shown as vacuum regions **900**. The regions **900** may be fluidly sealed and decoupled from other regions between the socket **102** and the liner **104** (or between the socket **202** and the liner **204**). In some embodiments, the vacuum regions **900** include a seal **902** that extends along a path defining boundaries of the vacuum regions **900**. The seal **902** may be formed on the outer surface **120** of the liner **104** or the liner **204**, and the inner surface **122** of the socket **102** or the socket **202**. In some embodiments, the seal **902** has the form of a protrusion on outer surface **120** of the liner **104** or the liner **204** that extends to define the boundary of the vacuum region **900**. The protrusion (e.g., the seal **902**) may seal with the corresponding inner surface **122** of the socket **102** or the socket **202**. The seal **902** may also have the form of a protrusion on the inner surface **122** of the socket **102**, or a channel on the inner surface **122** of the socket **102** that receives the protrusion on the outer surface **120** of the liner **104** to thereby fluidly seal the liner **104** with the socket **102**. In some embodiments, an inner volume is defined between the outer surface **120** of the liner **104** and the inner surface **122** of the socket **102**, with a perimeter or boundary defined by the seal **902**. Advantageously, the vacuum regions **900** can be designed or disposed around the combination device **100** or the combination device **200** in order to provide desired therapy for the patient. In some embodiments, the socket **102** and the liner **104** (or the socket **202** and the liner **204**) can be design such that indexing between the socket **102** and the liner **104** facilitate certain sections of the combination device **100** (or the combination device **200**) to function under vacuum while other sections do not function under a vacuum for proper device suspension.

Additive Manufacturing Process

[0075] Referring particularly to FIG. **18**, a flow diagram of a process **1200** for producing or manufacturing the combination device **100** or the combination device **200** is shown, according to some embodiments. Process **1200** includes steps **1202**-**1212** and can be performed using an additive manufacturing system (e.g., system **1300** as described in greater detail below with reference to FIG. **19**).

[0076] Process **1200** includes scanning a patient's distal or residual limb (step **1202***a*) or scanning a cast of a patient's distal limb (step **1202***b*). In some embodiments, step **1202***a* or step **1202***b* is performed using a scanning device (e.g., scan device **1312** as described in greater detail below with reference to FIG. **19**). The patient's limb can be scanned directly (step **1202***a*), or a cast of the patient's limb may be scanned (step **1202***b*). In some embodiments, performing step **1202***a* or step **1202***b* results in the generation of a scan file.

[0077] Process **1200** includes modifying a scan file resulting from the scan (e.g., resulting from performing step **1202***a* or step **1202***b*) to a 3d model of a device (e.g., the liner **104**, the socket **102**, the liner **204**, and/or the socket **202**) (step **1204**), according to some embodiments. In some embodiments, step **1204** is performed on a computer system based on one or more user inputs or inputs from a health care provider. For example, step **1204** can include adjusting a thickness of the device of the scan file at different locations. In some embodiments, step **1204** includes digitally using buildups or reductions to the thickness of the 3d model of the device to achieve a desired thickness that yields a desired corresponding deformation or flexion when the device is loaded. Step **1204** may include performing smoothing on the 3d model. For example, step **1204** can be performed by computer system **1302** based on one or more user inputs or inputs from a health care provider obtained from user device **1310** (described in greater detail below with reference to FIG. **19**). In some embodiments, step **1204** includes defining channels, voids, passages, inner volumes, etc., in order to provide venting passages, therapy passages, heat dissipation passages, electrical device voids, etc. In some embodiments, step **1204** includes adding geometry to the 3d model of the devices (e.g., the liner **104** and the socket **102**) so that the liner **104** and the socket **102** are configured to interlock when assembled. In some embodiments, step **1204** includes positioning or adding lattice structures along various portions of the liner of the 3d models of the device (e.g., the liner **104**, the liner **204**, etc.). The step **1204** can include defining (e.g., on the 3d models) any of the geometry of the venting passages **600**, the venting passages **500**, the electrical voids **700**, the therapy passages **400**, the protrusions **150**, the openings **152**, the lattice structures **136**, the protrusions **124**, the protrusions **126**, or the recesses **128**.

[0078] Process **1200** includes creating a computer assisted design (CAD) and/or a computer assisted manufacturing (CAM) file of the device (e.g., the liner **104** and the socket **102**, the liner **204** and the socket **202**, etc.) (step **1206**), according to some embodiments. Process **1200** also includes uploading the CAD/CAM file to a printer (e.g., 3d printer **1314**) (step **1208**), according to some embodiments. Steps **1206** and **1208** can be performed by computer system **1302** (e.g., in response to a user input such as from a health care provider) as described in greater detail below with reference to FIG. **19**.

[0079] Process **1200** includes printing the CAD/CAM file using 3d printing (e.g., to generate the device, the combination device **100**, the combination device **200**, etc.) (step **1210**), according to some embodiments. In some embodiments, step **1210** includes performing additive manufacturing (e.g., dispensing or outputting layers consecutively on top of each other) to produce the device. In some embodiments, the additive manufacturing is performed using a single uniform material such as a thermoplastic (e.g., nylon, a flexible silicone or similar material, etc.) or a thermoplastic reinforced with high strength material (e.g., a thermoplastic infused with carbon). The resulting device or 3d printed component can have variable thickness as defined by the CAD/CAM file. In some embodiments, both of the liner **104** and the socket **102** (or the liner **204** and the socket **202**) are manufactured from a single uniform material such as silicone. In some embodiments, the liner **104** is an integrally formed piece, and the socket **102** is similarly a single, integrally formed piece. The liner **204** may also be a single integrally formed piece, and the socket **202** may also be a single, integrally formed (e.g., continuous) piece. In some embodiments, using flexible silicone, and/or the presence of

voids, internal passages, etc., facilitates reduced weight of the combination device **100** or the combination device **200**. Advantageously, reducing the weight of the combination device **100** or the combination device **200** may facilitate improved patient comfort.

[0080] Process **1200** includes performing post-processing on the 3d printed device (step **1212**), according to some embodiments. For example, step **1212** can include removing excess material that is dispensed during step **1210** (e.g., during fabrication of the device). Step **1212** can be performed by a technician. Additional post-processing can be performed based on anatomy or needs of the patient. In some embodiments, the socket **102** and the liner **104**, or the socket **202** and the liner **204** can be modified or adjusted (e.g., by applying heat and being deformed) to provide proper distribution of forces across the patient's distal limb after the fabrication process. In some embodiments, the socket **102**, the liner **104**, the socket **202**, and/or the liner **204** are configured to be adjusted a minor amount after being manufactured without sustaining structural damage.

[0081] In some embodiments, the device that is produced by performing process **1200** is a lower extremity prosthetic socket, with a varying thickness (e.g., cross-sectional thickness) throughout. The device can provide proper stability and distribution of forces when worn, and is produced using additive manufacturing techniques. The thickness of the device can be modified in any area to accommodate the anatomy of the patient as well as any additional requirements the patient may have. The device is created using 3D printing, wherein the material composition is of a single uniform substance and can provide extra comfort to the patient when worn due to its lightweight properties, according to some embodiments.

Additive Manufacturing System Architecture

[0082] Referring now to FIG. **19**, a system **1300** for additive manufacturing of prosthetic, orthotic, or protective devices is shown, according to some embodiments. System **1300** includes a user device **1310**, a display device **1316**, a computer system **1302**, a scan device **1312**, and a 3d printer or additive manufacturing machine **1314**.

[0083] Computer system **1302** is configured to receive scan data from scan device **1312**, according to some embodiments. Computer system **1302** can be a desktop computer, a laptop, a remote computing system, a smart phone, a tablet, a personal computing device, etc. Computer system **1302** includes a processing circuit **1304** having memory **1308** and a processor **1306**. Processor **1306** can be implemented as a general-purpose processor, an application specific integrated circuit (ASIC), one or more field programmable gate arrays (FPGAs), a group of processing components, or other suitable electronic processing components.

[0084] Memory **1308** (e.g., memory, memory unit, storage device, etc.) may include one or more devices (e.g., RAM, ROM, Flash memory, hard disk storage, etc.) for storing data and/or computer code for completing or facilitating the various processes, layers and modules described in the present application. Memory **1308** may be or include volatile memory or non-volatile memory. Memory **1308** may include database components, object code components, script components, or any other type of information structure for supporting the various activities and information structures described in the present application. According to an exemplary embodiment, memory **1308** is communicably connected to processor **1306** via processing circuit **1304** and includes computer code for executing (e.g., by processing circuit **1304** and/or processor **1306**) one or more processes described herein.

[0085] Computer system **1302** can be configured to run CAD computer software to facilitate the design and production of any of combination device **100** and/or combination device **200**, or the components of combination device **100** or combination device **200** thereof. Computer system **1302** is configured to receive scan data from scan device **1312**, according to some embodiments. In some embodiments, the scan data is a scan file obtained from scan device **1312**. In some embodiments, a technician may scan device **1312** to scan a patient's residual limb or a cast of the patient's residual limb, thereby generating the scan data.

[0086] When the scan data is provided to computer system **1302**, computer system **1302** can generate a CAD or CAM file. A user (e.g., a health care provider) can then provide inputs (e.g., via user device **1310**) to adjust geometry, thickness, etc., of the CAD or CAM file. More generally, computer system **1302** may use the scan data to generate a digital representation of a device to be manufactured for the patient's residual limb. Computer system **1302** can provide display data to display device **1316** (e.g., a computer screen, a display screen, etc.) so that the digital representation is visually displayed in real-time. The user or health care provider can then view real-time changes or updates as the user changes or adjusts the CAD or CAM file.

[0087] For example, the user may adjust the CAD or the CAM file so that the design gradually tapers or thickens in different areas. In some embodiments, the user or the health care provider may use data from different experiments to identify areas where a patient may experience high stress. The user may decrease thickness of the CAD or CAM file at areas where high stress is experienced so that the 3d printed device may flex or deform. This can allow the 3d printed device to be more comfortable for the patient. In some embodiments, thickness of the 3d printed devices is maintained above a minimum thickness value. The user can also use knowledge regarding different weight lines of the patient to determine which areas of the CAD or CAM file/model should have decreased or increased thickness. The user may also use historical data to determine which areas or portions of the 3d printed device or the CAD/CAM file/model should have increased or decreased thickness (e.g., wall thickness). The user may also use the CAD/CAM file or model in order to produce a model of a mold.

[0088] Once the user (e.g., the health care provider) has adjusted or manipulated the CAD/CAM file/model, the user can prompt computer system **1302** to export the file/model to 3d printer **1314** as print data. Computer system **1302** can convert the adjusted, manipulated, or updated CAD/CAM file/model to a file type that is compatible with 3d printer **1314** (e.g., a Standard Tessellation Language (STL) file). Computer system **1302** then provides the print data to 3d printer **1314**.

[0089] The 3d printer **1314** can be any additive manufacturing machine or device that is configured to successively provide or discharge layers of material onto each other to form or construct a part. 3d printer **1314** may be configured to dispense material (e.g., one or more powder materials that can form nylon when combined with fusing/detailing agents and exposed to fusing light, or any other dispensable materials) in layers to fabricate the CAD/CAM file. The 3d

printer **1314** may manufacture parts directly or may manufacture molds of parts for use in an injection molding process.

[0090] Advantageously, the systems and methods described herein can be used to produce 3d printed prosthetics, orthotics, or protective devices that interlock with each other, and include various internal passages for medication, therapy, electrical component placement, heat transfer, or evaporation (e.g., venting). Traditional molding methods do not offer the same flexibility of variable wall thickness, the ability to provide integrally formed interlocking members, and various internal passages, voids, or buildups.

Injection Molding Process

[0091] Referring particularly to FIG. **20**, a flow diagram of a process **1400** for producing or manufacturing the combination device **100** or the combination device **200** is shown, according to some embodiments. Process **1400** includes steps **1402**-**1408** and can be performed using an additive manufacturing system (e.g., system **1300**). Process **1400** may be performed to advantageously facilitate injection molding of one or more custom fit components for a patient. For example, the process **1400** can advantageously combine scanning techniques with additive manufacturing techniques and injection molding techniques to provide a robust custom-fit prosthetic or orthotic. The process **1400** can be performed using a flexible silicone material, a higher durometer rubber, or any other material capable of being injection molded. The process **1400** can be performed to additively manufacture a mold and to perform injection molding using a silicone material having a shore between 20a and 70a.

[0092] Process **1400** includes obtaining scan data indicating a patient's limb (step **1402**), according to some embodiments. The patient's limb can be a patient's residual limb or a patient's distal limb. Step **1402** can include performing step **1202***a* or step **1202***b* of process **1200**, as described in greater detail above. For example, step **1402** may include obtaining scan data of a patient's residual limb, a cast of the patient's limb, etc., using a scanning device. The scan data may indicate geometry of the patient's residual limb and can be used as a basis for designing a prosthetic or orthotic for the patient.

[0093] Process **1400** includes generating a model of a mold based on the scan data (step **1404**). The model of the mold may be a model of any of the liner **104**, the socket **102**, the liner **204**, or the socket **202**. The model may be a CAD model, a CAM model, or any other computer design model indicating geometric shape and size of the liner **104**, the socket **102**, or the socket **202**. In some embodiments, step **1404** can include performing step **1204** of process **1200**, as described in greater detail above. Step **1404** may include performing one or more modeling techniques (e.g., buildups, extrusions, reductions, adjustments, etc.) in order to produce the model based on the scan data. The model of the mold can have the form of a cavity configured to receive an injection of a material in order to produce any of the liner **104**, the socket **102**, or the socket **202**. It should be understood that step **1404** can include the development and generation of a single model of a mold, or multiple models of molds that are configured to interlock and couple with each other (e.g., the socket **102** and the liner **104**). Step **1404** can also include defining various channels or inner volumes that may be contained within a single device or defined between a first and a second device when assembled. For example, step **1404** can include defining channels, voids, passages, inner volumes, etc., in the model of the mold in order to provide venting passages, therapy passages, heat dissipation passages, electrical device voids, etc.

[0094] Process **1400** includes additively manufacturing the mold using the model of the mold generated in step **1404** (step **1406**), according to some embodiments. In some embodiments, step **1406** can include performing any of steps **1206**, **1208**, or **1210** of process **1200**, as described in greater detail above with reference to FIG. **18**. For example, step **1406** can include creating a CAD/CAM file of the mold (step **1206**), uploading the CAD/CAM file of the mold to a printer (e.g., 3d printer **1314**) (step **1208**), and printing the CAD/CAM file using 3d printing (step **1210**) to additively manufacture the mold. In some embodiments, step **1406** includes converting the model of the mold into a format that is usable by an additive manufacturing system. Step **1406** may include generating instructions for a layer by layer additive manufacturing process (e.g., printhead paths and deposit controls) in order to additively manufacture the mold.

[0095] Process **1400** includes performing injection molding on the mold (step **1408**), according to some embodiments. Step **1408** may be performed by injecting a material into the mold additively manufactured in step **1306** to construct the device (e.g., device **100**, device **200**, etc.). In some embodiments, the material that is injection molded into the mold to manufacture the device can be a single uniform material such as a thermoplastic (e.g., nylon, a flexible silicon or similar material, etc.). The material may additionally or alternatively be a higher durometer rubber such as thermoplastic polyurethane. In some embodiments, process **1400** can include post-processing of the device, as described in greater detail above with reference to step **1212** of FIG. **18**. Advantageously, process **1400** combines scanning processes, modeling processes, additive manufacturing, and injection molding in order to provide a robust custom-fit prosthetic or orthotic. It should be understood that process **1400** as described herein with reference to FIG. **20** may be implemented to manufacture a prosthetic or orthotic device for a patient's lower limb (e.g., a patient's leg), a patient's upper limb (e.g., a patient's arm), a patient's foot, a patient's hand, a head wearable orthotic, or any other prosthetic or orthotic configured to be worn by a patient.

Configuration of Exemplary Embodiments

[0096] As utilized herein, the terms "approximately", "about", "substantially", and similar terms are intended to have a broad meaning in harmony with the common and accepted usage by those of ordinary skill in the art to which the subject matter of this disclosure pertains. It should be understood by those of skill in the art who review this disclosure that these terms are intended to allow a description of certain features described and claimed without restricting the scope of these features to the precise numerical ranges provided. Accordingly, these terms should be interpreted as indicating that insubstantial or inconsequential modifications or alterations of the subject matter described and claimed are considered to be within the scope of the invention as recited in the appended claim.

[0097] It should be noted that the terms "exemplary" and "example" as used herein to describe various embodiments is intended to indicate that such embodiments are possible examples, representations, and/or illustrations of possible

embodiments (and such term is not intended to connote that such embodiments are necessarily extraordinary or superlative examples).

[0098] The terms "coupled," "connected," and the like, as used herein, mean the joining of two members directly or indirectly to one another. Such joining may be stationary (e.g., permanent, etc.) or moveable (e.g., removable, releasable, etc.). Such joining may be achieved with the two members or the two members and any additional intermediate members being integrally formed as a single unitary body with one another or with the two members or the two members and any additional intermediate members being attached to one another.

[0099] References herein to the positions of elements (e.g., "top," "bottom," "above," "below," "between," etc.) are merely used to describe the orientation of various elements in the figures. It should be noted that the orientation of various elements may differ according to other exemplary embodiments, and that such variations are intended to be encompassed by the present disclosure.

[0100] Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Conjunctive language such as the phrase "at least one of X, Y, and Z," unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, Z, X and Y, X and Z, Y and Z, or X, Y, and Z (i.e., any combination of X, Y, and Z). Thus, such conjunctive language is not generally intended to imply that certain embodiments require at least one of X, at least one of Y, and at least one of Z to each be present, unless otherwise indicated.

[0101] It is important to note that the construction and arrangement of the systems as shown in the exemplary embodiments is illustrative only. Although only a few embodiments of the present disclosure have been described in detail, those skilled in the art who review this disclosure will readily appreciate that many modifications are possible (e.g., variations in sizes, dimensions, structures, shapes and proportions of the various elements, values of parameters, mounting arrangements, use of materials, colors, orientations, etc.) without materially departing from the novel teachings and advantages of the subject matter recited. For example, elements shown as integrally formed may be constructed of multiple parts or elements. It should be noted that the elements and/or assemblies of the components described herein may be constructed from any of a wide variety of materials that provide sufficient strength or durability, in any of a wide variety of colors, textures, and combinations. Accordingly, all such modifications are intended to be included within the scope of the present inventions. Other substitutions, modifications, changes, and omissions may be made in the design, operating conditions, and arrangement of the preferred and other exemplary embodiments without departing from scope of the present disclosure or from the spirit of the appended claim.

1. A prosthetic assembly comprising:

a socket comprising a first interlocking feature, the socket defining an inner volume;

a liner comprising a second interlocking feature, wherein the first interlocking feature and the second interlocking feature are configured to engage each other when the liner is inserted into the inner volume of the socket, the liner configured to receive a distal limb of a patient;

wherein at least one of the socket or the liner comprise a plurality of inner voids extending within walls of the socket or the liner, wherein the plurality of inner voids comprise a first set of internal channels for heat dissipation from the patient's distal limb to facilitate cooling of the patient's distal limb, a second set of internal channels for moisture evaporation from the patient's distal limb to facilitate evaporation of sweat or bodily fluids from the patient's distal limb, and a third set of internal channels for electrical components, the third set of internal channels configured to receive at least one sensor or transducer and at least one myoelectric wire.

2-4. (canceled)

5. The prosthetic assembly of claim **1**, wherein the electrical components comprise components of a Peltier cooling system.

6. The prosthetic assembly of claim **1**, wherein the plurality of inner voids comprise a fourth set of internal channels configured to provide therapy or medication to the patient's distal limb.

7. The prosthetic assembly of claim **1**, wherein at least one of the socket or the liner comprises a variable thickness along a longitudinal length or radial direction of the socket or the liner.

8. The prosthetic assembly of claim **1**, wherein the liner comprises a lattice structure, the lattice structure positioned at a distal end of the liner and positioned between a double wall of the liner, the lattice structure configured to facilitate desired transfer of forces between the prosthetic assembly and the patient's distal limb, to absorb impact forces, and to reduce shear stress.

9. The prosthetic assembly of claim **1**, wherein the prosthetic assembly is an above-the-knee or below-the-knee lower limb prosthetic assembly.

10. The prosthetic assembly of claim **1**, wherein the prosthetic assembly is an above-the-elbow, below-the-elbow, at the wrist, or a finger upper limb prosthetic assembly.

11. The prosthetic assembly of claim **1**, wherein the socket is manufactured from a thermoplastic or a thermoplastic reinforced with high strength material.

12. The prosthetic assembly of claim **1**, wherein the liner is manufactured from a flexible silicone material or a higher durometer rubber.

13. The prosthetic assembly of claim **1**, wherein an exterior surface of the liner and an internal surface of the socket are configured to engage each other to define sealed vacuum sections between the liner and the socket, wherein other sections of the liner and the socket do not define sealed vacuum sections.

14. The prosthetic assembly of claim **1**, wherein the prosthetic assembly is entirely manufactured through at least one of:

additive manufacturing; or

injection molding.

15. The prosthetic assembly of claim **1**, wherein at least one of the liner or the socket comprise connection points configured to couple additional componentry to the prosthetic assembly.

16. The prosthetic assembly of claim **15**, wherein the connection points comprise an extrusion or a recess disposed on the liner or the socket.

17. The prosthetic assembly of claim **1**, wherein the first interlocking feature comprises a protrusion and the second interlocking feature comprises a void, wherein the protrusion is configured to be received within the void to removably couple the socket with the liner.

18. The prosthetic assembly of claim **1**, wherein the first interlocking feature comprises a void and the second interlocking feature comprises a protrusion, wherein the protrusion is configured to be received within the void to removably couple the socket with the liner.

19. The prosthetic assembly of claim **1**, wherein the socket and the liner conform to an anatomical shape of the patient's distal limb.

20-44. (canceled)

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