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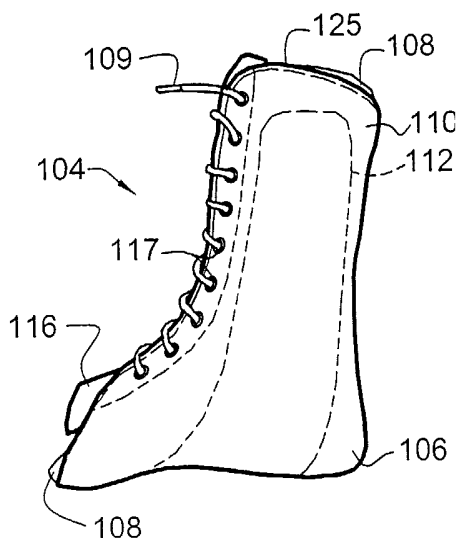
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(54) Title: SEMI-CUSTOM ANKLE BRACE SYSTEM



(57) Abstract: This invention relates to providing semi-custom ankle brace systems. Further, this invention relates to methods of fabricating semi-custom ankle brace systems. Further, this invention relates to methods of using semi-custom ankle brace systems. Even further, this invention relates to business systems for retail distribution of semi-custom ankle brace systems. The ankle brace system may comprise a unitary, heat-moldable ankle and arch support encased in soft inner and outer linings. The inner lining, outer lining, and unitary ankle support form a toeless boot with minimum bulk. The boot laces around the lower calf, ankle, heel, and arch, providing compression and assisting the unitary ankle support in providing medial and lateral foot support. The off-the-shelf ankle brace system is custom heat-molded to the end user.

WO 2004/016194 A2

## SEMI-CUSTOM ANKLE BRACE SYSTEM

### BACKGROUND

This invention relates to providing a semi-custom ankle brace system. More particularly, this invention concerns such a system for being of help to patients whose ankle conditions are of certain types that no longer permit them to walk properly without some sort of semi-custom orthotic. Further, this invention relates to methods of fabricating semi-custom ankle brace systems. Further, this invention relates to methods of using semi-custom ankle brace systems. Even further, this invention relates to business systems for retail distribution of semi-custom ankle brace systems.

Typically, individuals suffer from certain conditions of the feet that either greatly limit unaided mobility or require the use of aids such as walkers or canes in order for the individual to be mobile. Conditions which may cause this debilitating condition include tibialis tendinitis or rupture; degenerate joint disease; talocalcaneal varus or valgus; and severe pronation and/or trauma to ankle, subtalar area, or midtarsal. To treat these conditions necessarily requires a stabilizing-type apparatus in order to stabilize the ankle area, talocalcaneal, midtarsal, and subtalar joints, so that medial and lateral stability of the foot is achieved with the result that the patient enjoys the benefits of greater mobility.

The afflicted individual may try to correct the foot condition by the use of mechanical devices such as custom braces that attempt to stabilize the foot so that the heel is more aligned with the bones in the lower leg. Generally, the braces used for these types of ailments are large, thick, cumbersome, and expensive. The patient must purchase a shoe or shoes that are one or many shoe sizes larger than they would normally require, or the patient

must pay the expense of having a shoe made from a casting of their foot. Furthermore, less expensive, over-the-counter ankle braces do not provide adequate support, and chafe sensitive areas of the feet that do not conform to the off-the-shelf brace.

Thus there exists a need in treating the above-mentioned conditions of the feet for a semi-custom therapeutic ankle brace providing better support than over-the-counter ankle braces but with less expense and difficulty than with custom braces.

#### OBJECTS AND FEATURES OF THE INVENTION

A primary object and feature of the present invention is to fulfill the above-mentioned needs by the provision of a semi-custom ankle brace system overcoming the above-stated problems.

A further primary object and feature of the present invention is to provide such an ankle brace system that is efficient and permits the patient to wear essentially normal shoes. In addition, it is a primary object and feature of this invention to provide such a custom ankle brace system in connection with, and making use of, a novel semi-custom ankle brace.

Further, it is a primary object and feature of this invention to provide methods of fabricating novel semi-custom ankle brace systems. Further, is a primary object and feature of this invention to provide methods of using novel semi-custom ankle brace systems. Even further, it is a primary object and feature of this invention to provide novel business systems for use and retail distribution of semi-custom ankle brace systems.

Other objects and features of this invention will become apparent with reference to the following invention descriptions.

#### SUMMARY OF THE INVENTION

In accordance with a preferred embodiment hereof, this invention provides a semi-custom ankle brace system structured and arranged to stabilize an ankle of a leg, having a lower calf having an inside (medial) surface and an outside (lateral) surface, and having a foot having an arch and a heel and a toes portion, comprising, in combination: at least one unitary stiff support structured and arranged to stiffly support the ankle in relation to the foot, wherein such at least one unitary stiff support comprises stiff portions comprising , at least one medial stiff portion structured and arranged to support the inside (medial) surface of the lower calf, at least one lateral stiff portion structured and arranged to support the

outside (lateral) surface of the lower calf, and at least one arch stiff portion structured and arranged to support at least one substantial portion of the arch; wherein such at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to support the front surface of the lower calf, the rear surface of the lower calf, the top surface of the foot, nor the toes portion of the foot.

Moreover, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to support the heel. Additionally, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support consists essentially of at least one plastic material. Also, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support consists essentially of at least one thermoplastic material. In addition, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material. And, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material comprising substantial malleability at about 180 degrees Fahrenheit. Further, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support consists essentially of ORTHOPLAST® thermoplastic. Even further, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support is approximately one eighth of an inch thick, before pre-forming.

Moreover, it provides such a semi-custom ankle brace system, further comprising at least one inner lining structured and arranged to lie at least between essentially all of such unitary stiff support and the leg. Additionally, it provides such a semi-custom ankle brace system, wherein such at least one inner lining comprises at least one flexible material. Also, it provides such a semi-custom ankle brace system, wherein such at least one flexible material comprises at least one of the group consisting essentially of: fabric, padded nylon fabric, and leather. In addition, it provides such a semi-custom ankle brace system, further comprising at least one outer lining, structured and arranged to lie at least outside of and covering essentially all of such at least one unitary stiff support. And, it provides such a semi-custom ankle brace system, wherein such at least one outer lining comprises at least one flexible material. Further, it provides such a semi-custom ankle brace system, wherein

such at least one flexible material comprises at least one of the group consisting essentially of: fabric, padded nylon fabric, and leather.

Even further, it provides such a semi-custom ankle brace system, further comprising at least one attacher structured and arranged to attach such at least one inner lining with such at least one outer lining in such manner as to hold essentially all of such at least one unitary stiff support within such at least one inner lining and such at least one outer lining.

Moreover, it provides such a semi-custom ankle brace system, wherein such at least one attacher comprises at least one of the group consisting essentially of stitches and glue.

Additionally, it provides such a semi-custom ankle brace system further comprising at least one closure structured and arranged to adjustably tighten such semi-custom ankle brace system around the ankle. Also, it provides such a semi-custom ankle brace system wherein such at least one closure comprises at least one of the group consisting essentially of: grommet and lace, hook and loop fastener, elastic closure, and cinched strap.

In addition, it provides such a semi-custom ankle brace system, further comprising at least one tongue, structured and arranged to cover at least one gap under such at least one closure of such at least one semi-custom ankle brace system. And, it provides such a semi-custom ankle brace system, wherein such at least one tongue comprises at least one flexible material. Further, it provides such a semi-custom ankle brace system, wherein such at least one flexible material comprises at least one of at least one of the group consisting essentially of: fabric, padded nylon fabric, and leather.

Even further, it provides such a semi-custom ankle brace system: wherein such at least one medial stiff portion is structured and arranged to be placed essentially adjacent an inside (medial) surface of the lower calf; wherein such at least one lateral stiff portion is structured and arranged to be placed essentially adjacent an outside (lateral) surface of the lower calf; wherein such at least one arch stiff portion is structured and arranged to be placed essentially adjacent at least one substantial portion of the arch; and d) wherein such at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to be placed essentially adjacent a front surface of the lower calf, a rear surface of the lower calf, a top surface of the foot, nor the toes portion of the foot.

Further, it provides such semi-custom ankle brace system, for stabilizing an ankle of a leg, having a lower calf and a foot having an arch and a heel and a toes portion,

comprising, in combination: at least one adjustably tightenable portion structured and arranged to essentially surround the lower calf; and at least one other adjustably tightenable portion structured and arranged to essentially tighten around the ankle, the heel, and the arch; wherein such at least one semi-custom ankle brace system is structured and arranged to be worn inside of at least one standard shoe large enough to hold such at least one semi-custom ankle brace system; wherein such at least one semi-custom ankle brace system comprises at least one unitary stiff support structured and arranged to stabilize the ankle in relation to the foot in such at least one semi-custom ankle brace system; and wherein such at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material.

Even further, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material comprising substantial malleability at about 180 degrees Fahrenheit.

Moreover, it provides such a semi-custom ankle brace system, wherein such unitary stiff support comprises stiff portions comprising at least one medial stiff portion structured and arranged to be placed essentially adjacent an inside (medial) surface of the lower calf, at least one lateral stiff portion structured and arranged to be placed essentially adjacent an outside (lateral) surface of the lower calf, and at least one arch stiff portion structured and arranged to be placed essentially adjacent at least one substantial portion of the arch; wherein such at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to be placed essentially adjacent a front surface of the lower calf, a rear surface of the lower calf, a top surface of the foot, nor the toes portion of the foot. Additionally, it provides such a semi-custom ankle brace system, wherein such at least one unitary stiff support further comprises essentially no heel stiff portion structured and arranged to be placed essentially adjacent to the heel.

In accordance with another preferred embodiment hereof, this invention provides a method of fabricating a semi-custom ankle brace system, in a preset number of sizes, comprising the steps of: cutting at least one inner lining from at least one soft flexible material using at least one standard pattern of at least one preset size; attaching such at least one inner lining so that it contains at least one seam essentially parallel to the back of at least one heel from the bottom of the at least one heel to the top of such at least one semi-

custom ankle brace; cutting at least one outer lining from at least one soft flexible material using at least one standard pattern of at least one preset size; attaching such at least one outer lining so that it contains at least one seam essentially parallel to the back of at least one heel from the bottom of the at least one heel to the top of such at least one semi-custom ankle brace; cutting at least one unitary stiff support, using at least one standard pattern of at least one preset size, from at least one sheet of at least one thermally formable material; forming such at least one unitary stiff support to the shape of at least one standard sized last; holding such at least one unitary stiff support between such at least one inner lining and such at least one outer lining of such at least one semi-custom ankle brace; attaching at least one perimeter of such at least one inner lining and such at least one outer lining together, so as to encase such at least one unitary stiff support; attaching at least one edge of at least one tongue to at least one lining of such at least one ankle brace system; and attaching at least one adjustably tightenable closure in such at least one semi-custom ankle brace system.

Also, it provides such a method, wherein the step of attaching comprises the step of at least one of the group consisting essentially of stitching and gluing. In addition, it provides such a method, wherein the step of attaching at least one closure comprises the step of attaching at least one of the group consisting essentially of hook and loop fastener, elastic, and cinched strap. And, it provides such a method, wherein the step of attaching at least one closure comprises the step of inserting a plurality of eyelet grommets in such at least one semi-custom ankle brace system; and threading at least one lace through such plurality of eyelet grommets. Further, it provides such a method, further comprising the step of attaching such at least one inner lining and such at least one outer lining together around at least one portion of at least one perimeter of such at least one unitary stiff support. Even further, it provides such a method, wherein the step of attaching comprises the step of at least one of the group consisting essentially of stitching and gluing.

In accordance with another preferred embodiment hereof, this invention provides a method of using a semi-custom ankle brace system comprising the steps of: selecting at least one semi-custom ankle brace system of at least one appropriate size to fit at least one foot of at least one patient; placing at least one thermally protective sock on at least one foot of at least one patient; submerging such at least one ankle brace system in at least one fluid at at least one temperature and for at least one time sufficient to soften the at least one

thermoplastic material of such at least one semi-custom ankle brace system; placing such at least one semi-custom ankle brace system over such at least one thermally protective sock; tightening such at least one semi-custom ankle brace system to the at least one foot of the at least one patient; moving the at least one foot and its bone structure to at least one preferred position and holding the at least one foot until such at least one thermoplastic material of such at least one semi-custom ankle brace system cools; wherein such at least one semi-custom ankle brace system is given at least one semi-custom fit to the at least one patient's at least one foot.

And, it provides such a method, further comprising the step of placing at least one compression sock over such at least one semi-custom ankle brace system to apply compression evenly over the at least one foot. Further, it provides such a method, further comprising the step of placing at least one plastic bag over such at least one semi-custom ankle brace system, prior to placing such at least one compression sock over such at least one semi-custom ankle brace system.

In accordance with another preferred embodiment hereof, this invention provides a method for retail distribution of semi-custom ankle brace systems, to be worn inside shoes, comprising the steps of: providing to orthotics retailers at least one inventory listing of such at least one semi-custom ankle brace systems in at least one range of sizes no greater than available shoe sizes; providing to such retailers at least one price at which such retailers may order and purchase such initial selection of such semi-custom ankle brace systems; taking at least one first order from such retailers and providing to such retailers such at least one initial selection of such at least one semi-custom ankle brace systems; and providing at least one training to such retailers in proper application and fitting, using conformation of low-temperature thermoplastic unitary stiff supports of such at least one semi-custom ankle brace systems. Even further, it provides such a method, further comprising providing to such retailers at least one price at which such retailers may re-order and purchase at least one additional stock of such at least one semi-custom ankle brace systems; the method, further comprising taking at least one additional order from such retailers and providing to such retailers such at least one additional stock of such at least one semi-custom ankle brace systems as required to replenish such retailers stocks. Even further, it provides such a method, wherein the step of providing at least one training to such retailers comprises the

step of providing at least one in-person training. Even further, it provides such a method, wherein the step of providing at least one training to such retailers comprises the step of providing at least one training material. Even further, it provides such a method, wherein the step of providing at least one training material further comprises the step of providing at least one video training material in the form of at least one of the group consisting essentially of DVD, CD-Rom, and videotape.

In accordance with another preferred embodiment hereof, this invention provides a semi-custom ankle brace system for stabilizing an ankle of a leg, having a lower calf having an inside (medial) surface and an outside (lateral) surface, and having a foot having an arch and a heel and a toes portion, comprising, in combination: unitary stiff support means for stiffly supporting the ankle in relation to the foot; wherein such unitary stiff support means comprises stiff portions comprising at least one medial portion to support the inside (medial) surface of the lower calf, at least one lateral portion to support the outside (lateral) surface of the lower calf, and at least one arch portion to support at least one substantial portion of the arch; wherein such unitary stiff support means further comprises essentially no stiff portions to support front surfaces of the lower calf, rear surfaces of the lower calf, top surfaces of the foot, nor toes portions of the foot. Even further, it provides such a semi-custom ankle brace system, wherein such unitary stiff support means further comprises essentially no stiff portions structured and arranged to support the heel.

Even further, it provides such a semi-custom ankle brace system, further comprising inner lining means for lying between essentially all of such unitary stiff support means and such leg. Even further, it provides such a semi-custom ankle brace system, further comprising outer lining means for lying outside and covering essentially all of such unitary stiff support means. Even further, it provides such a semi-custom ankle brace system, further comprising attachment means for attaching such inner lining means with such outer lining means in such manner as to hold essentially all of such unitary stiff support means within such lining means. Even further, it provides such a semi-custom ankle brace system, further comprising adjustably tightenable closure means for adjustably closing such semi-custom ankle brace system around the ankle. Even further, it provides such a semi-custom ankle brace system, further comprising tongue means for covering at least one gap under the closure means of such semi-custom ankle brace system.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front perspective view of a foot of a patient wearing a semi-custom ankle brace according to the present invention and used by the patient while wearing an essentially normal shoe.

FIG. 1a is a perspective view illustrating the ankle brace system.

FIG. 2 is a side view of a preferred embodiment of the semi-custom ankle brace of this invention illustrating the location of the thermoplastic unitary stiff supports within the cloth ankle brace.

FIG. 3 is a three-quarters rear view illustrating a single vertical seam of the boot along the back of the ankle brace.

FIG. 4 is a perspective view illustrating the inside of the boot and how the tongue of the boot attaches to the main portion of the boot.

FIG. 4a is a perspective view of an alternate embodiment of the semi-custom ankle brace of the current invention.

FIG. 5 is a top view of how the thermoplastic material is cut prior to pre-forming around a last.

FIG. 6 illustrates cutting the inner lining during the assembly of the semi-custom ankle brace.

FIG. 6a illustrates cutting the unitary stiff support during the assembly of the semi-custom ankle brace.

FIG. 6b illustrates placing the preformed unitary stiff support around the inner lining during the assembly of the semi-custom ankle brace.

FIG. 6c illustrates cutting the outer lining during the assembly of the semi-custom ankle brace.

FIG. 6d illustrates a fully assembled semi-custom ankle brace.

FIG. 7 illustrates a cut-out thermoplastic unitary stiff support.

FIG. 7a illustrates a side perspective view of the thermoplastic unitary stiff support being pre-formed on a last.

FIG. 7b illustrates a back perspective view of the thermoplastic unitary stiff support being pre-formed on a last.

FIG. 7c illustrates a cooled, pre-formed thermoplastic unitary stiff support.

FIG. 8a illustrates the process of submersing the semi-custom ankle brace in hot water to soften the enclosed unitary stiff support.

FIG. 8b illustrates the step of placing the heated semi-custom ankle brace over the thermally protective sock and wearer's foot.

FIG. 8c illustrates the process of placing the compression sock over the semi-custom ankle brace on the patient's foot.

FIG. 8d illustrates the process of the skilled fitter holding the patient's foot in the corrected position while the unitary stiff support cools.

FIG. 9 illustrates a retail distribution system for semi-custom ankle bracing systems according to a preferred business method of the present invention.

FIG. 10 illustrates a diagram of the steps of fabricating a semi-custom ankle brace according to a preferred embodiment of the present invention.

FIG. 11 illustrates a diagram of the steps of using a semi-custom ankle brace according to a preferred embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE BEST MODE AND PREFERRED EMBODIMENTS OF THE INVENTION

FIG. 1 illustrates the semi-custom ankle brace **104** of this invention according to a preferred embodiment thereof. Shown is a shoe **102** preferably worn over the semi-custom ankle brace **104**, both holding the patient's foot **100**. Typically, the semi-custom ankle brace **104** allows for the patient to wear a standard shoe size only  $\frac{1}{2}$  size larger than normal. The semi-custom ankle brace **104** provides marked improvement in foot/ankle support for patients with a range of common foot/ankle ailments. Each semi-custom ankle brace **104** is uniquely molded, as hereinafter set out, to meet the specific needs and physical properties of the individual patient's foot **100**.

Ailments suggesting the use of the semi-custom ankle brace **104** are ailments such as arthritis, trauma, tendonitis, pronation, inversion, eversion, and bony prominences that would make it difficult for the patient to wear a shoe **102**, as illustrated in FIG. 1, and difficult to walk without the use of a brace. Often these patients have had one or more surgeries and may have sensitive scarred areas as well. It is noted for vocabulary purposes that a patient typically has a leg; a lower calf with an inside (medial) surface and an outside (lateral) surface; and a foot having an arch, a heel, and toes.

FIG. 1a illustrates the semi-custom ankle brace **104** according to the embodiment of FIG. 1. Preferably, the semi-custom ankle brace **104** comprises a toeless boot **106**. Preferably, the toeless boot **106** consists of an inner lining **108** and an outer lining **110**, preferably made of soft, flexible materials, and encasing a unitary stiff support **112**, as illustrated in FIG. 2. Semi-custom ankle brace **104** further comprises attachment means for attaching the parts of semi-custom ankle brace **104** together, preferably stitches and glue. Semi-custom ankle brace **104** further comprises closure means for adjustably tightening semi-custom ankle brace **104** around the lower calf, ankle, heel, and arch, such as, for example, eyelets and laces, hooks and loops, elastic closures, and cinched straps.

Preferably, semi-custom ankle brace **104** consists of three individual layers: the inner lining **108**, the unitary stiff support **112**, and the outer lining **110**. The various layers comprising the semi-custom ankle brace **104** are made so as to be conformable to the contours of each patient's foot.

Preferably, inner lining **108** and outer lining **110** are both arranged to cover the ankle, lower calf, upper foot, and mid-foot, with an opening being left down the entire front, as shown in FIG. 1a. Preferably, inner lining **108** lies between essentially all of unitary stiff support **112** and the patient's leg, as shown in FIG. 4 (embodying herein inner lining means for lying between essentially all of said unitary stiff support means and said leg.)

Preferably, outer lining **110** lies outside of, and covers essentially all of, unitary stiff support **112**, as shown in FIG. 1a (embodying herein outer lining means for lying outside and covering essentially all of said unitary stiff support means).

Preferably, the portion of semi-custom ankle brace **104** that lies above the top of the foot is structured to be adjustably tightenable around the lower calf. Preferably, the portion of semi-custom ankle brace **104** that lies below the top of the foot is structured to be adjustably tightenable around the heel, ankle, and arch.

The tongue **116** is preferably made from the same flexible material as the rest of the toeless boot **106** of the semi-custom brace **104**, as shown. Preferably, tongue **116** covers the gap in the front of semi-custom ankle brace **104**, under the closure means, protecting the patient from chafing against the closure means (embodying herein tongue means for covering the gap under the closure means of said semi-custom ankle brace system).

Upon reading this specification those with ordinary skill in the art will understand

that, under appropriate circumstances, such as, for example, available materials, user preference, advances in technology, etc., other soft, flexible materials substantially impervious to water damage, such as, for example, fabric, cotton, polyester, felt, woven fabric, knitted fabric, nonwoven fabric, leather, 2.5 oz chromium tanned cowhide leather, etc., may suffice for the inner lining, outer lining, and tongue.

Preferably, unitary stiff support **112** is used to provide substantially rigid support for the patient's foot **100**, and to maintain the patient's sole in a relatively horizontal plane when the lower leg is vertical, thus assisting the patient to walk as normally as possible.

Preferably, unitary stiff support **112** consists of essentially three portions: a support portion **710** placed essentially adjacent to and supporting the medial (inside) surface of the lower calf; a support portion **700** placed essentially adjacent to and supporting the lateral (outside) surface of the lower calf; and a support portion **715** placed essentially adjacent to and supporting a substantial portion of the arch of the foot. These portions permit unitary stiff support **112**, in combination with toeless boot **106**, to provide medial and lateral support to the ankle. Preferably, no stiff support portions are provided to be placed adjacent to or support: the front or back surfaces of the lower calf; the top surface of the foot; or the toes portion of the foot. Under appropriate circumstances, not preferred presently, an additional stiff support portion of unitary stiff support **112** may be provided to be placed adjacent to and support the heel (embodying herein a semi-custom ankle brace system for stabilizing an ankle of a leg, having a lower calf having an inside (medial) surface and an outside (lateral) surface, and having a foot having an arch and a heel and a toes portion, comprising, in combination: unitary stiff support means for stiffly supporting the ankle in relation to the foot; wherein said unitary stiff support means comprises stiff portions comprising at least one medial portion to support the inside (medial) surface of the lower calf, at least one lateral portion to support the outside (lateral) surface of the lower calf, and at least one arch portion to support at least one substantial portion of the arch; wherein said unitary stiff support means further comprises essentially no stiff portions to support front surfaces of the lower calf, rear surfaces of the lower calf, top surfaces of the foot, nor toes portions of the foot. Also, embodying herein wherein said unitary stiff support means further comprises essentially no stiff portions structured and arranged to support the heel).

Preferably, the adjustably tightenable closure is structured to adjustably tighten the

semi-custom ankle brace **104** around the ankle. The adjustably tightenable closure is preferably structured to close the front of semi-custom ankle brace **104** between point **260** and point **261**, as shown in FIG. 2. In a preferred embodiment, the closure comprises eyelet grommets **117** and laces **109** as illustrated in FIG. 2 (embodying herein adjustably tightenable closure means for adjustably close said semi-custom ankle brace system around the ankle). FIG. 4a illustrates an alternate preferred embodiment wherein the closure may be hook and loop fasteners **400**.

Upon reading this specification, those with ordinary skill in the art will understand that, under appropriate circumstances, such as user preference, available materials, advances in technology, other methods of adjustably closing semi-custom ankle brace **104**, such as hook and loop fasteners, elastic closures, cinched straps, etc., may suffice.

The attachment means, comprising attachers, are preferably structured to attach the various parts of semi-custom ankle brace **104** to each other. For example, attachers preferably join the linings **108** and **110** to each other and join the tongue **116** to the linings **108** and **110** and join the closure means to the toeless boot **106** and join the back seams **113** and **114** of the linings **108** and **110**. Attachers may comprise stitches, glue, melt welding, or other appropriate means for joining flexible materials together (embodying herein attachment means for attaching said inner lining means with said outer lining means in such manner as to hold essentially all of said unitary stiff support means within said lining means).

Upon reading this specification those with ordinary skill in the art will understand that under appropriate circumstances, such as materials requirements, user preference, advances in technology, etc., other attachment means, such as glue, melt welding, edge binding, etc., may suffice.

FIG. 2 is a side view illustrating the preferred location of the unitary stiff support **112** within the semi-custom ankle brace **104**. Unitary stiff support **112** preferably is held between inner lining **108** and outer lining **110**. Preferably, unitary stiff support **112** is fabricated from plastic, thermoplastic, low-temperature thermoplastic, or low-temperature thermoplastic comprising substantial malleability at about 180 degrees Fahrenheit. Most preferably, the unitary stiff support **112** is fabricated from ORTHOPLAST® thermoplastic,

manufactured by Johnson and Johnson. Preferably, unitary stiff support **112** is fabricated from a sheet of one-eighth-inch-thick thermoplastic.

Upon reading this specification, those with ordinary skill in the art will understand that, under appropriate circumstances, such as available materials, user preference, advances in technology, etc., other low temperature thermally formable materials, such as MULTIFORM PLASTIC™, X-LITE PLUS™, EZEFORM SPLINTING MATERIAL™, MULTIFORM CLEAR™, etc., may suffice.

FIG. 3 is a three-quarters rear view illustrating a single vertical seam **114** of the toeless boot **106** according to the preferred embodiment of FIG. 1. Preferably, the seam **114** follows the back of the heel in a vertical fashion, up the back of the toeless boot **106**, as shown. Upon reading this specification those of skill in the art will understand that under appropriate circumstances, such as wide feet, user preference, etc., other seam placements and quantities, such as two seams going up opposite sides of the heel, two seams going from the heel toward the top of the foot, three seams, etc., may suffice.

FIG. 4 is a perspective view illustrating the inner lining **108**, and also illustrating how the tongue **116** of the toeless boot **106** preferably attaches to the front edge **109** of the toeless boot **106**.

FIG. 4 also illustrates a single vertical seam **113** of the toeless boot **106** according to the preferred embodiment of FIG. 1. Preferably, the seam **113** follows the back of the heel in a vertical fashion, up the inside back of the toeless boot **106**, as shown. Upon reading this specification those of skill in the art will understand that, under appropriate circumstances, such as wide feet, user preference, etc., other seam placements and quantities, such as two seams going up opposite sides of the heel, two seams going from the heel toward the top of the foot, three seams, etc., may suffice.

FIG. 4a illustrates an alternate preferred embodiment wherein the closure may be hook and loop fasteners **400**. One or more hook and loop fasteners **400** may be used. Preferably, hook and loop fasteners **400** comprise at least one loop portion **405** and at least one hook portion **410**.

Upon reading this specification, those skilled in the art will understand that, under appropriate circumstances, such as available materials, user preference, etc., other hook and loop fastener arrangements, such as reversing the positions of the hook portion and the loop

portion, wider straps, one wide strap, etc., may suffice.

FIG. 5 is a top view showing how the thermoplastic material of unitary stiff support **112** is preferably cut prior to performing and assembling within the toeless boot **106**. Preferably, the unitary stiff support **112** is cut from a flat sheet of the thermoplastic material. Most preferably, the unitary stiff support **112** is preformed using low heat and a last **118** prior to holding unitary stiff support **112** in the layers of the toeless boot **106**. Most preferably the unitary stiff support **112** is molded to its final shape when heated and conformed to the patient's foot **100**, as is further described below.

FIGS. 6, 6a, 6b, 6c, and 6d illustrate a preferred method of making the semi-custom ankle brace **104**. Preferably, the first step in making a semi-custom ankle brace **104** is cutting an inner lining **108** and a tongue **116** (as shown in FIG. 6) and an outer lining **110** (as shown in FIG. 6c) from a soft flexible material, preferably using a standard pattern. Such standard patterns may conform to various preset sizes, the selection of which is based on customer demands, for example, XS, S, M, L, and XL. In the preferred embodiment, the inner lining **108**, outer lining **110**, and tongue **116** preferably consist of a soft flexible material substantially impervious to water damage, most preferably a soft padded-nylon fabric.

Specifically shown in FIG. 6d is a perspective view of the preferred semi-custom ankle brace **104**, having an outer lining **110** substantially covering a pre-determined length of the patient's calf, a substantial portion of the patient's sole, and, under appropriate circumstances, the patient's heel.

FIG. 6d illustrates the preferred cut-out shape of a unitary stiff support **112**, which in the preferred embodiment is made of a thermoplastic such as ORTHOPLAST®. Preferably, unitary stiff support is then pre-formed on a last **118**.

Preferably, in the next step, the inner lining **108** is attached, preferably stitched, along the posterior of the semi-custom ankle brace **104** extending from the patient's heel upward to the top of the semi-custom ankle brace **104**, forming seam **113** (as in the example shown in FIG. 4).

The outer lining **110** is also attached, preferably stitched, along the posterior of the semi-custom ankle brace **104** extending from the patient's heel upward to the top of the semi-custom ankle brace **104**, forming seam **114** (as in the example shown in FIG. 3).

FIG. 6b illustrates pre-formed unitary stiff support **112** being placed in its preferred proper position relative to inner lining **108**.

FIG. 7 –7c illustrate more details about preferred pre-forming of the unitary stiff support **112** for use within the material layers in making the semi-custom ankle brace **112**.

FIG. 7 shows the approximate shape of unitary stiff support **112**, which is preferably cut with dimensions of approximately 16” by 24” from a sheet of heat formable material. In the preferred embodiment, an ORTHOPLAST® thermoplastic material is used.

FIG. 7a illustrates the next step of fabrication, wherein the unitary stiff support **112** is thermally formed to the shape of a standard sized last **118**, the selection of which is based on customer demands.

FIG. 7b illustrates a back view of the pre-formed unitary stiff support **112** on the last **118**.

FIG. 7c illustrates that cooled, pre-formed unitary stiff support **112** maintains its shape after being removed from last **118**.

After the pre-forming step, the pre-formed unitary stiff support **112** is preferably placed and held between the inner and outer linings of the semi-custom ankle brace **104**, as is shown in FIGS. 6b and 6d.

Preferably, the outer lining **110** is then attached to the inner lining **108** along the perimeter **125** of the inner lining **108** and the outer lining **110**, thereby forming the toeless boot **106**, which holds and contains unitary stiff support **112**. Also, preferably, the inner lining **108** and outer lining **110** may be attached together along at least part of the perimeter of unitary stiff support **112**, illustrated by the dashed lines, which also indicate unitary stiff support **112** in FIG. 6d, in order to prevent unitary stiff support **112** from sliding within semi-custom ankle brace **104**.

Preferably, next, the tongue **116** may be attached to the edge **109** of semi-custom ankle brace **104**, as shown in FIG. 4. Tongue **116** may be attached to either edge of semi-custom ankle brace **104**, as desired.

Preferably, the last step in the making of the semi-custom ankle brace **104** is the attachment of the adjustably tightenable closure. One preferred embodiment of a closure is laces and grommets.

FIG. 1a shows the laces **109** and grommets **117** along the front centerline of the foot;

however, the placement of the closure may be altered to provide a more comfortable fit to the patient when required without detracting from the present invention. The final fitting and adjustments, if needed, will be as determined by the skill and experience of the brace maker or fitter.

Upon reading this specification, those skilled in the art will understand that under appropriate circumstances, an opening may be made in toeless boot **106**, in order to permit unitary stiff support **112** to be temporarily removed by the patient, in order to permit easy laundering of toeless boot **106**. For example, an opening may be made along the perimeter **125** of toeless boot **106** at either the front sole portion, at the top of the back of the calf, or in the back seam **114** of outer lining **110**. Under appropriate circumstances, an opening also permits an alternate method of construction, wherein toeless boot **106** is partially or completely constructed prior to insertion of preformed unitary stiff support **112**. An opening may also comprise a closure, such as, for example, hook and loop fasteners, a zipper, or a button.

FIG. 8a illustrates the preferred method of fitting the semi-custom ankle brace **104**. Prior to the initial semi-custom ankle brace **104** fitting process, a person skilled in the art of foot ailments and brace making (the fitter **129**) performs an examination of the patient's foot **100**. A determination of the closest size semi-custom ankle brace system **104** needed by the patient is made. The appropriate size of semi-custom ankle brace system **104** is then selected, ordered, and received by the retailer.

Preferably, next, the fitter **129** places a thermally protective sock **128** over the foot and lower leg of the patient.

Preferably, as illustrated in FIG. 8a, the semi-custom ankle brace **104** is then heated in hot water **124** to a temperature, and for a time, sufficient to make unitary stiff support **112** within semi-custom ankle brace **104** substantially malleable. Preferably, when unitary stiff support **112** is made of approximately one-eighth-inch thick ORTHOPLAST®, semi-custom ankle brace **104** is heated in hot water **124** of approximately 180 degrees Fahrenheit for approximately 2-3 minutes, unitary stiff support **112** is substantially malleable so that one of ordinary skill in the art can conveniently deform and shape unitary stiff support **112** with their hands (heat protective gloves may be needed.)

Upon reading this specification, those with ordinary skill in the art will understand that, under appropriate circumstances, such as materials requirements, user preference, advances in technology, conditions of end use, etc., other approximate temperatures, such as 120 degrees Fahrenheit, 160 degrees Fahrenheit, 212 degrees Fahrenheit, etc., may suffice.

FIG. 8b shows the preferred next step of use, wherein semi-custom ankle brace **104** is placed over the thermally protective sock **128** while unitary stiff support **112** is still substantially malleable. Preferably, semi-custom ankle brace **104** is then tightened and adjusted, by use of the closure, to provide an optimal fit to the patient.

FIG. 8c illustrates an optional use step wherein a fitter **129** may apply a compression sock **126** over semi-custom ankle brace **104** in order to further conform semi-custom ankle brace **104** to the patient. In another optional step, when a compression sock **126** is used, a plastic bag (not shown) may be placed over semi-custom ankle brace **104** prior to placing compression sock **126** over semi-custom ankle brace **104**. The plastic bag, which is slippery, makes it easier to apply compression sock **126**.

FIG. 8d illustrates the next preferred step of fabrication, wherein fitter **129** adjusts the position of the patient's foot **100** to the clinically proper position. Preferably, the compression sock **126** (or fitter **129**, by hand) then uniformly conforms the shape of the unitary stiff support **112** to the patient's foot **100** while it cools, as shown.

Once the unitary stiff support has cooled and hardened, a semi-custom fit of the semi-custom ankle brace **112** has been achieved.

Alternatively, under appropriate circumstances, such as where toeless boot **106** has an opening, the foregoing steps may be used to shape unitary stiff support **112** to the patient's foot **100** prior to inserting unitary stiff support **112** into toeless boot **106**.

FIG. 9 illustrates a retail distribution system for semi-custom ankle brace systems **198** according to a preferred business method of the present invention. Preferably, the semi-custom ankle bracing systems **198** are sold through a network of orthotics retail distributors **202**. A central distribution center **200** preferably provides a ready-to-ship inventory **204**, a customer order system **206**, and a packaging/shipping component **208**, as shown.

Preferably, the distribution center **200** provides the retail distributors **202** an inventory listing of the available semi-custom ankle bracing systems **198**. The inventory listing may be published via the Internet or by printed catalog.

Preferably, a distribution representative assists new retailers in making an initial selection of the semi-custom ankle bracing systems **198** necessary for start-up retail sales. Preferably, pricing to the retail distributors **202** is established through the distribution representative or through published lists. Retail distributors **202** order **203** and are preferably sold an initial stock of semi-custom ankle bracing systems.

Preferably, training **210** is provided to instruct retailers in the proper application and fitting of the semi-custom ankle bracing systems **198** using thermoplastic molding methods. Preferably, training is self directed, provided on media such as compact disks, DVDs, or videotape. Under appropriate circumstances, other training methods, such as on-site or remote location instruction, may be used. Preferably, subsequent to initial start-up sales, retail distributors **202** re-order and purchase additional stock of the semi-custom ankle bracing systems **198** at a price to replenish depleted stocks.

Thus, preferably, the steps for retail distribution of semi-custom ankle brace systems comprise the following steps.

A first step is to provide an inventory listing of semi-custom ankle brace systems, in a range of sizes, to an orthotics retailer (embodying herein the step of providing to orthotics retailers at least one inventory listing of such at least one semi-custom ankle brace systems in at least one range of sizes no greater than available shoe sizes).

A second step is to provide a price for the inventory to an orthotics retailer (embodying herein the step of providing to such retailers at least one price at which such retailers may order and purchase such initial selection of such semi-custom ankle brace systems).

A third step is to take a first order for semi-custom ankle brace systems from the orthotics retailer and supply semi-custom ankle brace systems to the retailers (embodying herein the step of taking at least one first order from such retailers and providing to such retailers such at least one initial selection of such at least one semi-custom ankle brace systems).

A fourth step is to provide training in fitting the semi-custom ankle brace systems to the orthotics retailer (embodying herein the step of providing at least one training to such retailers in proper application and fitting, using conformation of low-temperature thermoplastic unitary stiff supports of such at least one semi-custom ankle brace systems).

The provided training may be in-person training (embodying herein the step of providing at least one in-person training) or training materials (embodying herein the step of providing at least one training material). The training materials may be videos provided on DVDs, CD-Roms, or videotape (embodying herein the step of providing at least one video training material in the form of at least one of the group consisting essentially of DVD, CD-Rom, and videotape).

An optional fifth step is to provide orthotics retailers with a price for re-ordering semi-custom ankle braces (embodying herein the step of providing to such retailers at least one price at which such retailers may re-order and purchase at least one additional stock of such at least one semi-custom ankle brace systems).

An optional seventh step is to take another order for semi-custom ankle brace systems from the orthotics retailer and supply additional semi-custom ankle brace systems to the retailers (embodying herein the step of taking at least one additional order from such retailers and providing to such retailers such at least one additional stock of such at least one semi-custom ankle brace systems as required to replenish such retailers stocks).

FIG. 10 illustrates a diagram of an example of the steps of a preferred method of fabricating **500** a semi-custom ankle brace **104** according to the present invention.

Preferably, a first step is to cut **505** an inner lining **108** from a soft flexible material using a pattern of a preset size (embodying herein cutting at least one inner lining from at least one soft flexible material using at least one standard pattern of at least one preset size).

Preferably, a second step is to attach **510** the heel seam **113** of the inner lining **108** from the bottom of the heel to the top of the semi-custom ankle brace **104** (embodying herein attaching such at least one inner lining so that it contains at least one seam essentially parallel to the back of at least one heel from the bottom of the at least one heel to the top of such at least one semi-custom ankle brace).

Preferably, a third step is to cut **515** an outer lining **110** from a soft flexible material using a pattern of a preset size (embodying herein cutting at least one outer lining from at least one soft flexible material using at least one standard pattern of at least one preset size).

Preferably, a fourth step is to attach **520** the heel seam **114** of the outer lining **110** from the bottom of the heel to the top of the semi-custom ankle brace **104** (embodying herein attaching such at least one outer lining so that it contains at least one seam essentially

parallel to the back of at least one heel from the bottom of the at least one heel to the top of such at least one semi-custom ankle brace).

Preferably, a fifth step is to cut **525** a unitary stiff support **112** from a thermally formable material using a pattern of a preset size (embodying herein cutting at least one unitary stiff support, using at least one standard pattern of at least one preset size, from at least one sheet of at least one thermally formable material).

Preferably, a sixth step is to form **530** the unitary stiff support **112** to the shape of a standard sized last (embodying herein forming such at least one unitary stiff support to the shape of at least one standard sized last).

Preferably, a seventh step is to hold **535** the unitary stiff support **112** within the inner **108** and outer **110** linings (embodying herein holding such at least one unitary stiff support between such at least one inner lining and such at least one outer lining of such at least one semi-custom ankle brace).

Preferably, an eighth step is to attach a perimeter **125** of the inner **108** and outer **110** linings together, forming toeless boot **106** (embodying herein attaching at least one perimeter of such at least one inner lining and such at least one outer lining together, so as to encase such at least one unitary stiff support).

Preferably, a ninth step is to cut **545** a tongue **116** from a soft flexible material using a pattern of a preset size (embodying herein cutting at least one outer lining from at least one soft flexible material using at least one standard pattern of at least one preset size).

Preferably, a tenth step is to attach **550** a tongue **116** to the side **109** of the toeless boot **106** (embodying herein attaching at least one edge of at least one tongue to at least one lining of such at least one ankle brace system).

Preferably, an eleventh step is to attach **555** an adjustably tightenable closure to toeless boot **106**, thereby forming semi-custom ankle brace **104** (embodying herein attaching at least one adjustably tightenable closure in such at least one semi-custom ankle brace system).

An optional eleventh step is to attach **560** the inner and outer linings of semi-custom ankle brace **104** together around the perimeter of the unitary stiff support **112**, forming a pocket to prevent unitary stiff support **112** from sliding inside semi-custom ankle brace **104** (embodying herein the step of attaching such at least one inner lining and such at least one

outer lining together around at least one portion of at least one perimeter of such at least one unitary stiff support).

FIG. 11 illustrates a diagram of an example of the preferred steps of a method of using **600** a semi-custom ankle brace **104** according to the present invention.

A first preferred step is select **605** a semi-custom ankle brace system **104** of an appropriate size for the patient (embodying herein the step of selecting at least one semi-custom ankle brace system of at least one appropriate size to fit at least one foot of at least one patient).

A second preferred step is to place **610** a thermally protective sock **128** on the patient's foot (embodying herein the step of placing at least one thermally protective sock on at least one foot of at least one patient).

A third preferred step is to submerge **615** the semi-custom ankle brace **104** in hot water **124** until unitary stiff support **112** is substantially malleable (embodying herein the step of submerging such at least one ankle brace system in at least one fluid at at least one temperature and for at least one time sufficient to soften the at least one thermoplastic material of such at least one semi-custom ankle brace system).

A fourth preferred step is to place **620** the semi-custom ankle brace **112** over the thermally protective sock **128** on the patient (embodying herein the step of placing such at least one semi-custom ankle brace system over such at least one thermally protective sock).

A fifth preferred step is to tighten **625** the semi-custom ankle brace system **104** until a clinically desired tension is achieved (embodying herein the step of tightening such at least one semi-custom ankle brace system to the at least one foot of the at least one patient).

An optional sixth step is to place **620** a plastic bag (not shown) over the semi-custom ankle brace **104** (embodying herein the step of placing at least one plastic bag over such at least one semi-custom ankle brace system, prior to placing such at least one compression sock over such at least one semi-custom ankle brace system).

A seventh preferred step is to place **635** a compression sock **128** over the semi-custom ankle brace **104** (embodying herein the step of placing at least one compression sock over such at least one semi-custom ankle brace system to apply compression evenly over the at least one foot).

An eighth preferred step is to position **640** the foot **100** in a clinically desirable position while the thermoplastic cools (embodying herein the step of moving the at least one foot and its bone structure to at least one preferred position and holding the at least one foot until such at least one thermoplastic material of such at least one semi-custom ankle brace system cools).

A ninth preferred step is to hold the foot **100** in a clinically desirable position until unitary stiff support **112** has cooled sufficiently to no longer be substantially malleable (embodying herein the step of wherein such at least one semi-custom ankle brace system is given at least one semi-custom fit to the at least one patient's at least one foot).

Although applicant has described applicant's preferred embodiments of this invention, it will be understood that the broadest scope of this invention includes such modifications as diverse shapes, colors, sizes, and materials. Such scope is limited only by the below claims as read in connection with the above specification.

Further, many other advantages of applicant's invention will be apparent to those skilled in the art from the above descriptions and the below claims.

What is claimed is:

- 1) A semi-custom ankle brace system structured and arranged to stabilize an ankle of a leg, having a lower calf having an inside (medial) surface and an outside (lateral) surface, and having a foot having an arch and a heel and a toes portion, comprising, in combination:
  - a) at least one unitary stiff support structured and arranged to stiffly support the ankle in relation to the foot, wherein said at least one unitary stiff support comprises stiff portions comprising
    - i) at least one medial stiff portion structured and arranged to support the inside (medial) surface of the lower calf,
    - ii) at least one lateral stiff portion structured and arranged to support the outside (lateral) surface of the lower calf, and
    - iii) at least one arch stiff portion structured and arranged to support at least one substantial portion of the arch;
  - b) wherein said at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to support the front surface of the lower calf, the rear surface of the lower calf, the top surface of the foot, nor the toes portion of the foot.
- 2) The semi-custom ankle brace system according to Claim 1, wherein said at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to support the heel.
- 3) The semi-custom ankle brace system according to Claim 1, wherein said at least one unitary stiff support consists essentially of at least one plastic material.
- 4) The semi-custom ankle brace system according to Claim 3, wherein said at least one unitary stiff support consists essentially of at least one thermoplastic material.
- 5) The semi-custom ankle brace system according to Claim 4, wherein said at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material.
- 6) The semi-custom ankle brace system according to Claim 5, wherein said at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material comprising substantial malleability at about 180 degrees

Fahrenheit.

- 7) The semi-custom ankle brace system according to Claim 3, wherein said at least one unitary stiff support consists essentially of ORTHOPLAST® thermoplastic.
- 8) The semi-custom ankle brace system according to Claim 3, wherein said at least one unitary stiff support is approximately one eighth of an inch thick, before pre-forming.
- 9) The semi-custom ankle brace system according to Claim 1, further comprising at least one inner lining structured and arranged to lie at least between essentially all of said unitary stiff support and the leg.
- 10) The semi-custom ankle brace system according to Claim 9, wherein said at least one inner lining comprises at least one flexible material.
- 11) The semi-custom ankle brace system according to Claim 10, wherein said at least one flexible material comprises at least one of the group consisting essentially of:
  - a) fabric
  - b) padded nylon fabric
  - c) leather.
- 12) The semi-custom ankle brace system according to Claim 1, further comprising at least one outer lining, structured and arranged to lie at least outside of and covering essentially all of said at least one unitary stiff support.
- 13) The semi-custom ankle brace system according to Claim 12, wherein said at least one outer lining comprises at least one flexible material.
- 14) The semi-custom ankle brace system according to Claim 13, wherein said at least one flexible material comprises at least one of the group consisting essentially of:
  - a) fabric
  - b) padded nylon fabric
  - c) leather.
- 15) The semi-custom ankle brace system according to Claim 1, further comprising at least one attacher structured and arranged to attach said at least one inner lining with said at least one outer lining in such manner as to hold essentially all of said at least one unitary stiff support within said at least one inner lining and said at least one outer lining.

- 16) The semi-custom ankle brace system according to Claim 15, wherein said at least one attacher comprises at least one of the group consisting essentially of
  - a) stitches
  - b) glue.
- 17) The semi-custom ankle brace system of Claim 1, further comprising at least one closure structured and arranged to adjustably tighten said semi-custom ankle brace system around the ankle.
- 18) The semi-custom ankle brace system of Claim 17, wherein said at least one closure comprises at least one of the group consisting essentially of:
  - a) grommet and lace
  - b) hook and loop fastener
  - c) elastic closure
  - d) cinched strap.
- 19) The semi-custom ankle brace system according to Claim 1, further comprising at least one tongue, structured and arranged to cover at least one gap under said at least one closure of said at least one semi-custom ankle brace system.
- 20) The semi-custom ankle brace system according to Claim 19, wherein said at least one tongue comprises at least one flexible material.
- 21) The semi-custom ankle brace system according to Claim 20, wherein said at least one flexible material comprises at least one of at least one of the group consisting essentially of:
  - a) fabric
  - b) padded nylon fabric
  - c) leather.

- 22) The semi-custom ankle brace system according to Claim 1:
- a) wherein said at least one medial stiff portion is structured and arranged to be placed essentially adjacent an inside (medial) surface of the lower calf;
  - b) wherein said at least one lateral stiff portion is structured and arranged to be placed essentially adjacent an outside (lateral) surface of the lower calf;
  - c) wherein said at least one arch stiff portion is structured and arranged to be placed essentially adjacent at least one substantial portion of the arch; and
  - d) wherein said at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to be placed essentially adjacent a front surface of the lower calf, a rear surface of the lower calf, a top surface of the foot, nor the toes portion of the foot.
- 23) A semi-custom ankle brace system, for stabilizing an ankle of a leg, having a lower calf and a foot having an arch and a heel and a toes portion, comprising, in combination:
- a) at least one adjustably tightenable portion structured and arranged to essentially surround the lower calf; and
  - b) at least one other adjustably tightenable portion structured and arranged to essentially tighten around the ankle, the heel, and the arch;
  - c) wherein said at least one semi-custom ankle brace system is structured and arranged to be worn inside of at least one standard shoe large enough to hold said at least one semi-custom ankle brace system;
  - d) wherein said at least one semi-custom ankle brace system comprises at least one unitary stiff support structured and arranged to stabilize the ankle in relation to the foot in said at least one semi-custom ankle brace system; and
  - e) wherein said at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material.

- 24) The semi-custom ankle brace system according to Claim 23, wherein said at least one unitary stiff support consists essentially of at least one low-temperature-thermoplastic material comprising substantial malleability at about 180 degrees Fahrenheit.
- 25) The semi-custom ankle brace system according to Claim 23, wherein said unitary stiff support comprises stiff portions comprising
- a) at least one medial stiff portion structured and arranged to be placed essentially adjacent an inside (medial) surface of the lower calf,
  - b) at least one lateral stiff portion structured and arranged to be placed essentially adjacent an outside (lateral) surface of the lower calf, and
  - c) at least one arch stiff portion structured and arranged to be placed essentially adjacent at least one substantial portion of the arch;
  - d) wherein said at least one unitary stiff support further comprises essentially no stiff portions structured and arranged to be placed essentially adjacent a front surface of the lower calf, a rear surface of the lower calf, a top surface of the foot, nor the toes portion of the foot.
- 26) The semi-custom ankle brace system according to Claim 25, wherein said at least one unitary stiff support further comprises essentially no heel stiff portion structured and arranged to be placed essentially adjacent to the heel.

- 27) A method of fabricating a semi-custom ankle brace system, in a preset number of sizes, comprising the steps of:
- a) cutting at least one inner lining from at least one soft flexible material using at least one standard pattern of at least one preset size;
  - b) attaching such at least one inner lining so that it contains at least one seam essentially parallel to the back of at least one heel from the bottom of the at least one heel to the top of such at least one semi-custom ankle brace;
  - c) cutting at least one outer lining from at least one soft flexible material using at least one standard pattern of at least one preset size;
  - d) attaching such at least one outer lining so that it contains at least one seam essentially parallel to the back of at least one heel from the bottom of the at least one heel to the top of such at least one semi-custom ankle brace;
  - e) cutting at least one unitary stiff support, using at least one standard pattern of at least one preset size, from at least one sheet of at least one thermally formable material;
  - f) forming such at least one unitary stiff support to the shape of at least one standard sized last;
  - g) holding such at least one unitary stiff support between such at least one inner lining and such at least one outer lining of such at least one semi-custom ankle brace;
  - h) attaching at least one perimeter of such at least one inner lining and such at least one outer lining together, so as to encase such at least one unitary stiff support;
  - i) attaching at least one edge of at least one tongue to at least one lining of such at least one ankle brace system; and
  - j) attaching at least one adjustably tightenable closure in such at least one semi-custom ankle brace system.
- 28) The method according to Claim 27, wherein the step of attaching comprises the step of at least one of the group consisting essentially of
- a) stitching
  - b) gluing.

- 29) The method according to Claim 27, wherein the step of attaching at least one closure comprises the step of attaching at least one of the group consisting essentially of
- a) hook and loop fastener
  - b) elastic
  - c) cinched strap.
- 30) The method according to Claim 27, wherein the step of attaching at least one closure comprises the step of inserting a plurality of eyelet grommets in such at least one semi-custom ankle brace system; and threading at least one lace through such plurality of eyelet grommets.
- 31) The method according to Claim 27, further comprising the step of attaching such at least one inner lining and such at least one outer lining together around at least one portion of at least one perimeter of such at least one unitary stiff support.
- 32) The method according to Claim 31, wherein the step of attaching comprises the step of at least one of the group consisting essentially of
- a) stitching
  - b) gluing.

- 33) A method of using a semi-custom ankle brace system comprising the steps of:
- a) selecting at least one semi-custom ankle brace system of at least one appropriate size to fit at least one foot of at least one patient;
  - b) placing at least one thermally protective sock on at least one foot of at least one patient;
  - c) submerging such at least one ankle brace system in at least one fluid at at least one temperature and for at least one time sufficient to soften the at least one thermoplastic material of such at least one semi-custom ankle brace system;
  - d) placing such at least one semi-custom ankle brace system over such at least one thermally protective sock;
  - e) tightening such at least one semi-custom ankle brace system to the at least one foot of the at least one patient;
  - f) moving the at least one foot and its bone structure to at least one preferred position and holding the at least one foot until such at least one thermoplastic material of such at least one semi-custom ankle brace system cools;
  - g) wherein such at least one semi-custom ankle brace system is given at least one semi-custom fit to the at least one patient's at least one foot.
- 34) The method according to Claim 33, further comprising the step of placing at least one compression sock over such at least one semi-custom ankle brace system to apply compression evenly over the at least one foot.
- 35) The method according to Claim 33, further comprising the step of placing at least one plastic bag over such at least one semi-custom ankle brace system, prior to placing such at least one compression sock over such at least one semi-custom ankle brace system.

- 36) A method for retail distribution of semi-custom ankle brace systems, to be worn inside shoes, comprising the steps of:
- a) providing to orthotics retailers at least one inventory listing of such at least one semi-custom ankle brace systems in at least one range of sizes no greater than available shoe sizes;
  - b) providing to such retailers at least one price at which such retailers may order and purchase such initial selection of such semi-custom ankle brace systems;
  - c) taking at least one first order from such retailers and providing to such retailers such at least one initial selection of such at least one semi-custom ankle brace systems; and
  - d) providing at least one training to such retailers in proper application and fitting, using conformation of low-temperature thermoplastic unitary stiff supports of such at least one semi-custom ankle brace systems.
- 37) The method according to Claim 36, further comprising providing to such retailers at least one price at which such retailers may re-order and purchase at least one additional stock of such at least one semi-custom ankle brace systems;
- 38) The method according to Claim 36, further comprising taking at least one additional order from such retailers and providing to such retailers such at least one additional stock of such at least one semi-custom ankle brace systems as required to replenish such retailers stocks.
- 39) The method according to Claim 36, wherein the step of providing at least one training to such retailers comprises the step of providing at least one in-person training.
- 40) The method according to Claim 36, wherein the step of providing at least one training to such retailers comprises the step of providing at least one training material.

- 41) The method according to Claim 40, wherein the step of providing at least one training material further comprises the step of providing at least one video training material in the form of at least one of the group consisting essentially of
- a) DVD
  - b) CD-Rom
  - c) videotape.
- 42) A semi-custom ankle brace system for stabilizing an ankle of a leg, having a lower calf having an inside (medial) surface and an outside (lateral) surface, and having a foot having an arch and a heel and a toes portion, comprising, in combination:
- a) unitary stiff support means for stiffly supporting the ankle in relation to the foot; wherein said unitary stiff support means comprises stiff portions comprising
    - i) at least one medial portion to support the inside (medial) surface of the lower calf,
    - ii) at least one lateral portion to support the outside (lateral) surface of the lower calf, and
    - iii) at least one arch portion to support at least one substantial portion of the arch;
  - b) wherein said unitary stiff support means further comprises essentially no stiff portions to support front surfaces of the lower calf, rear surfaces of the lower calf, top surfaces of the foot, nor toes portions of the foot.
- 43) The semi-custom ankle brace system according to Claim 42, wherein said unitary stiff support means further comprises essentially no stiff portions structured and arranged to support the heel.
- 44) The semi-custom ankle brace system according to Claim 42, further comprising inner lining means for lying between essentially all of said unitary stiff support means and said leg.
- 45) The semi-custom ankle brace system according to Claim 42, further comprising outer lining means for lying outside and covering essentially all of said unitary stiff support means.

- 46) The semi-custom ankle brace system according to Claim 42, further comprising attachment means for attaching said inner lining means with said outer lining means in such manner as to hold essentially all of said unitary stiff support means within said lining means.
- 47) The semi-custom ankle brace system according to Claim 42, further comprising adjustably tightenable closure means for adjustably closing said semi-custom ankle brace system around the ankle.
- 48) The semi-custom ankle brace system according to Claim 42, further comprising tongue means for covering at least one gap under the closure means of said semi-custom ankle brace system.

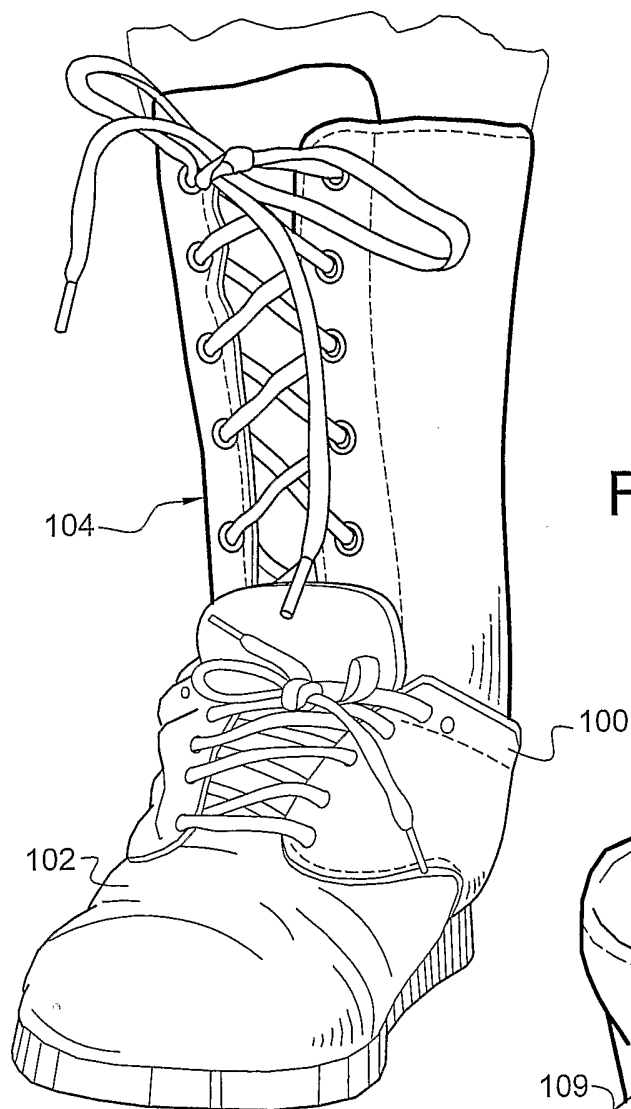


FIG. 1

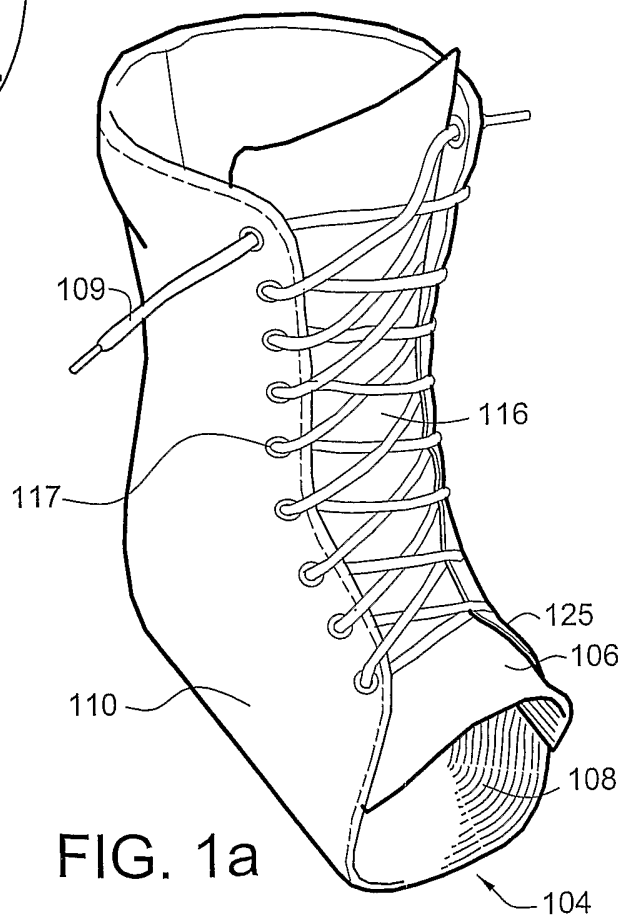


FIG. 1a

2/10

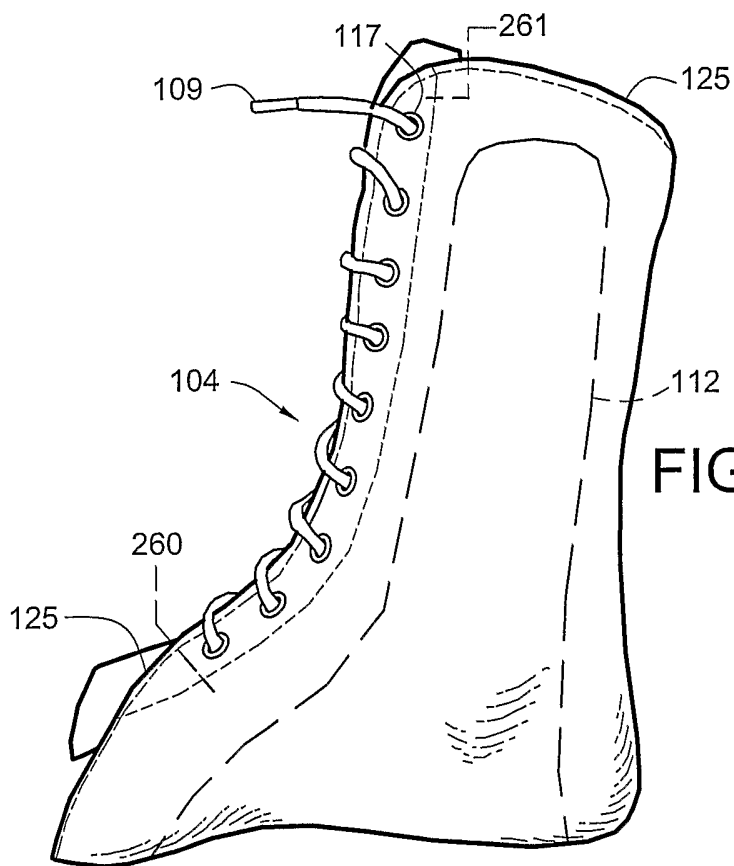


FIG. 2

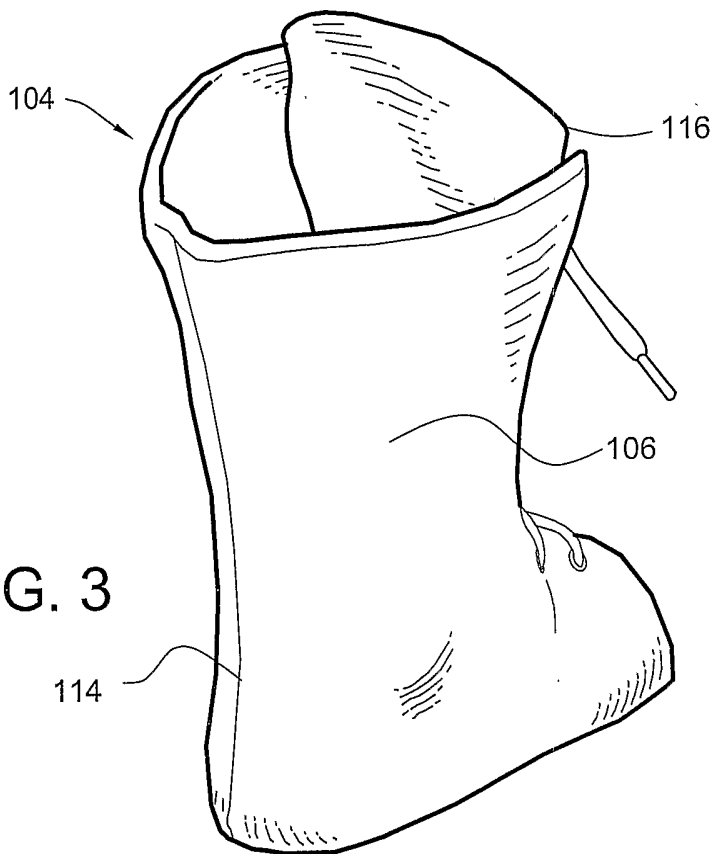


FIG. 3

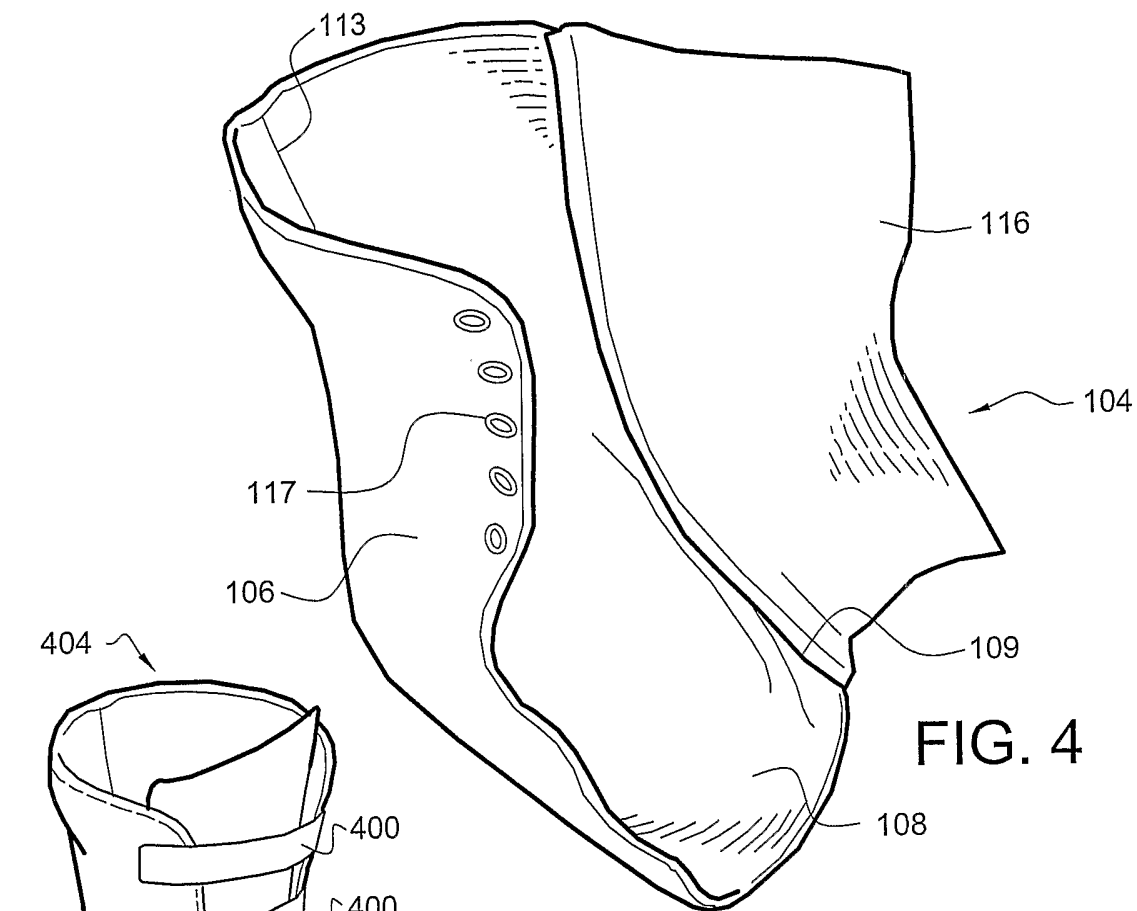


FIG. 4

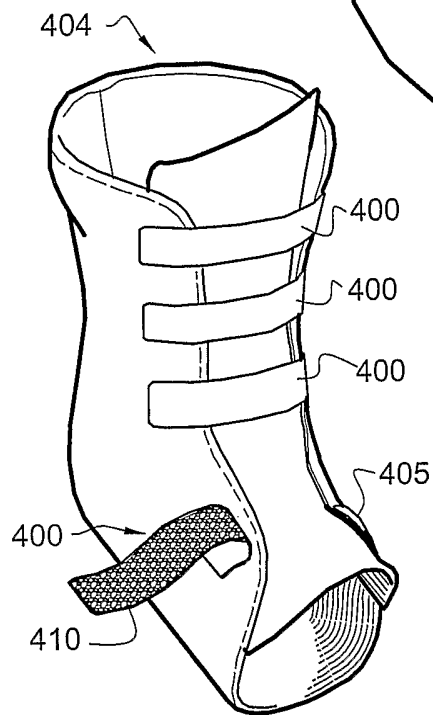


FIG. 4a

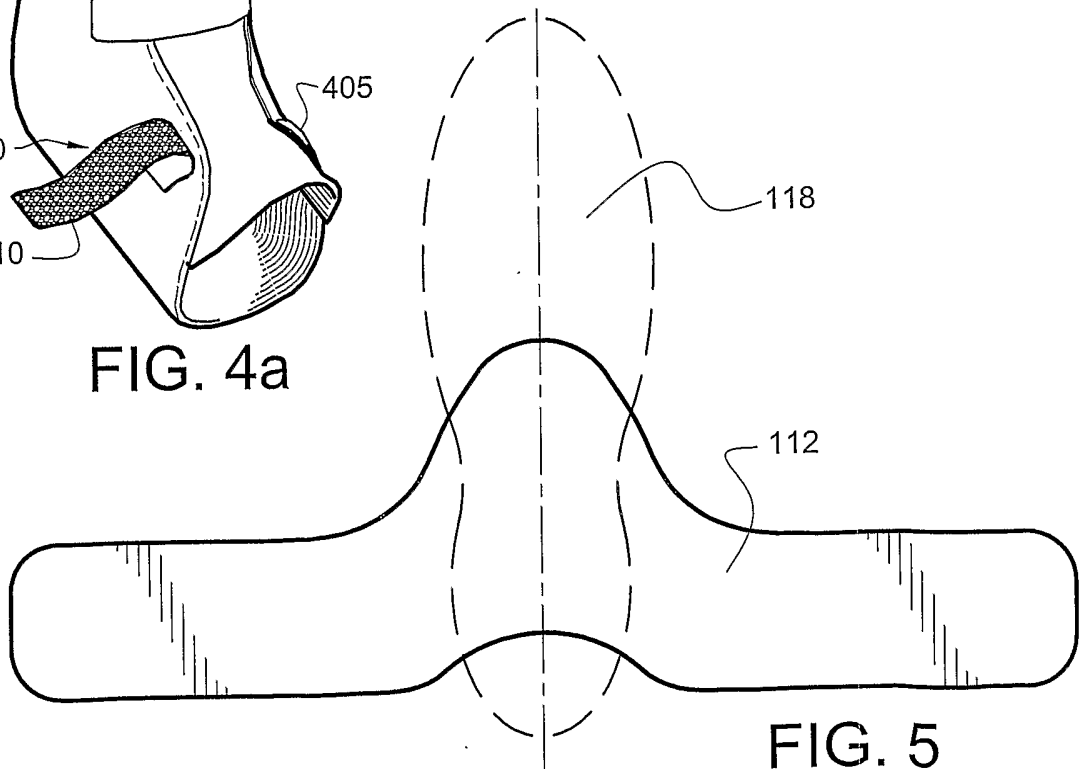
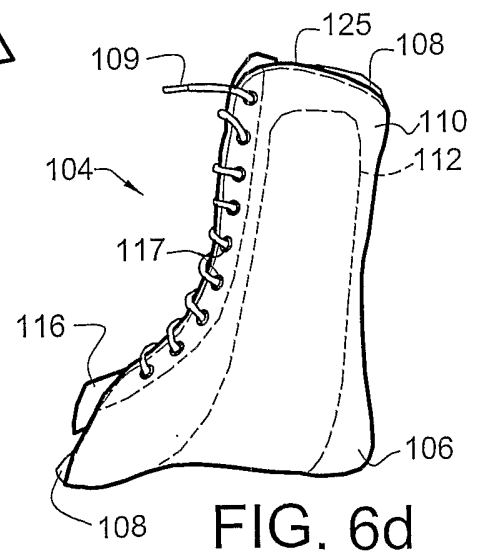
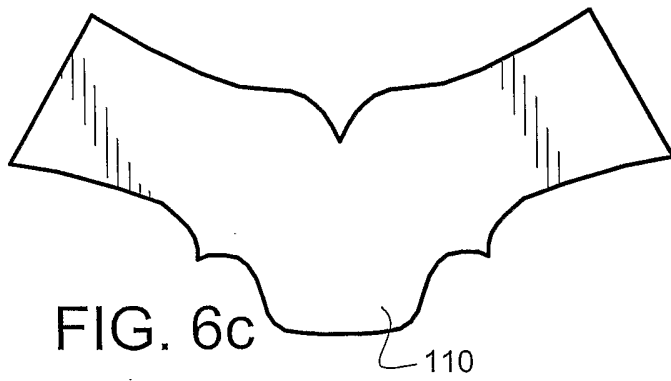
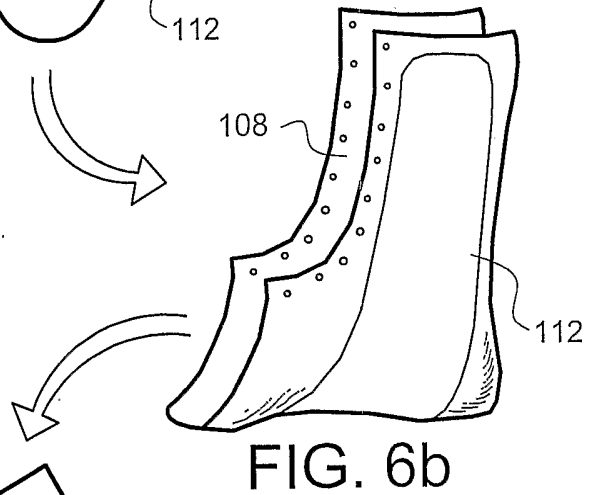
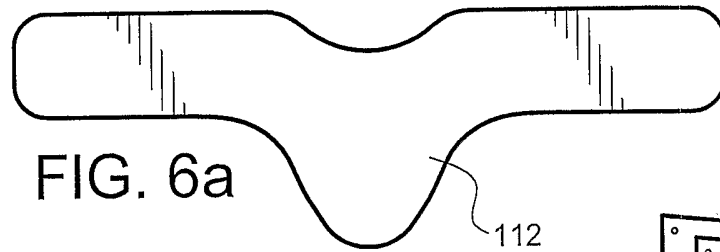
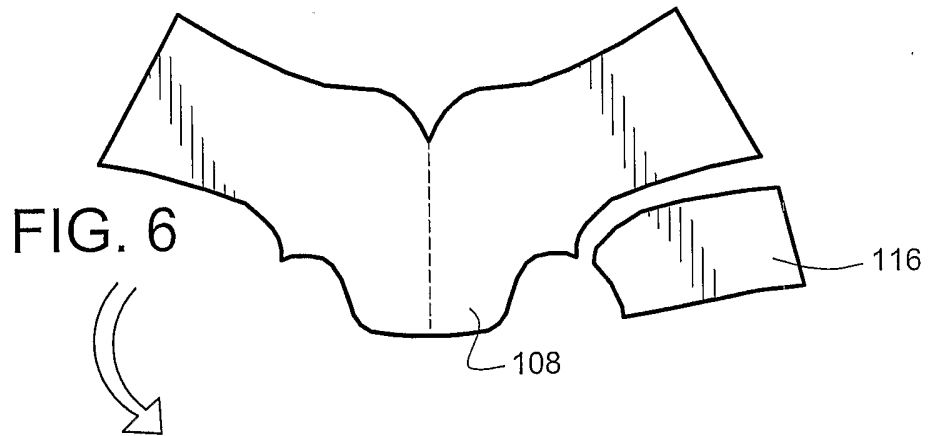
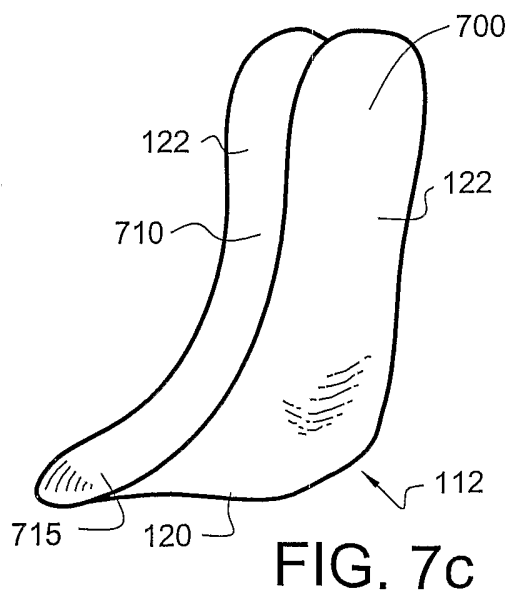
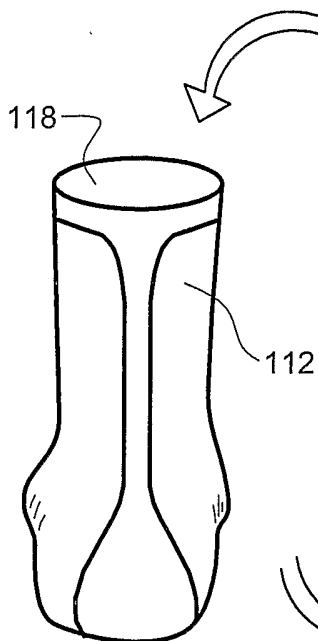
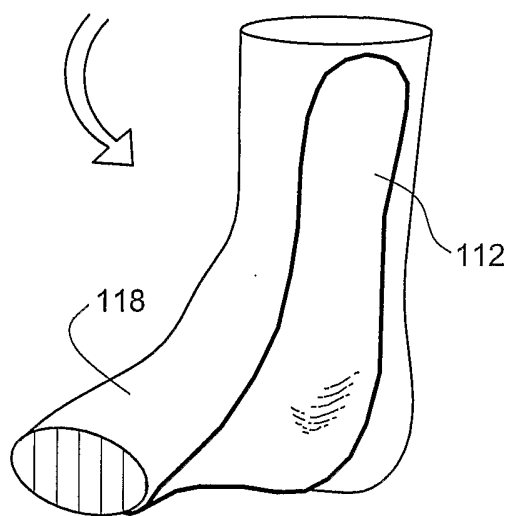
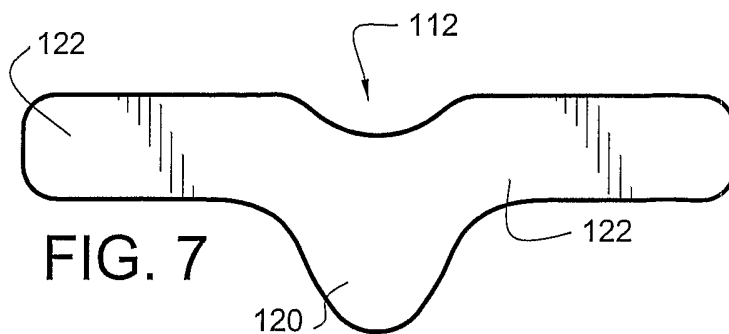


FIG. 5

4/10





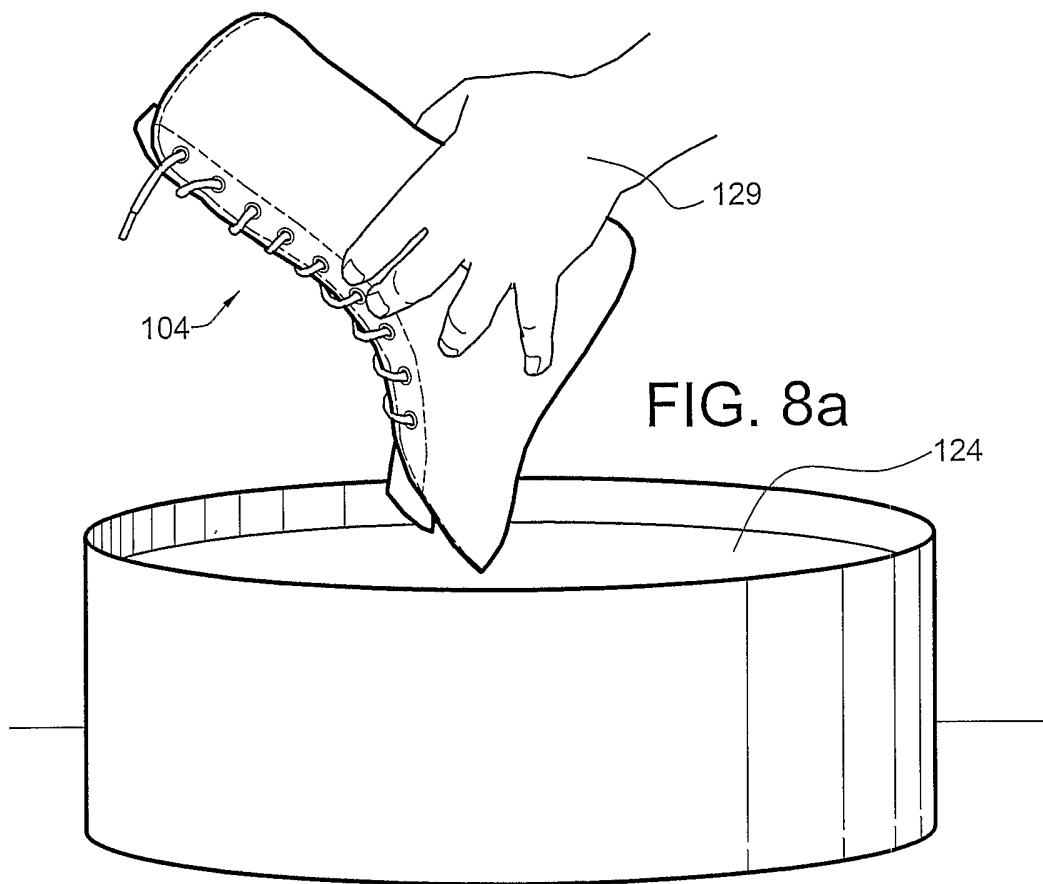


FIG. 8a

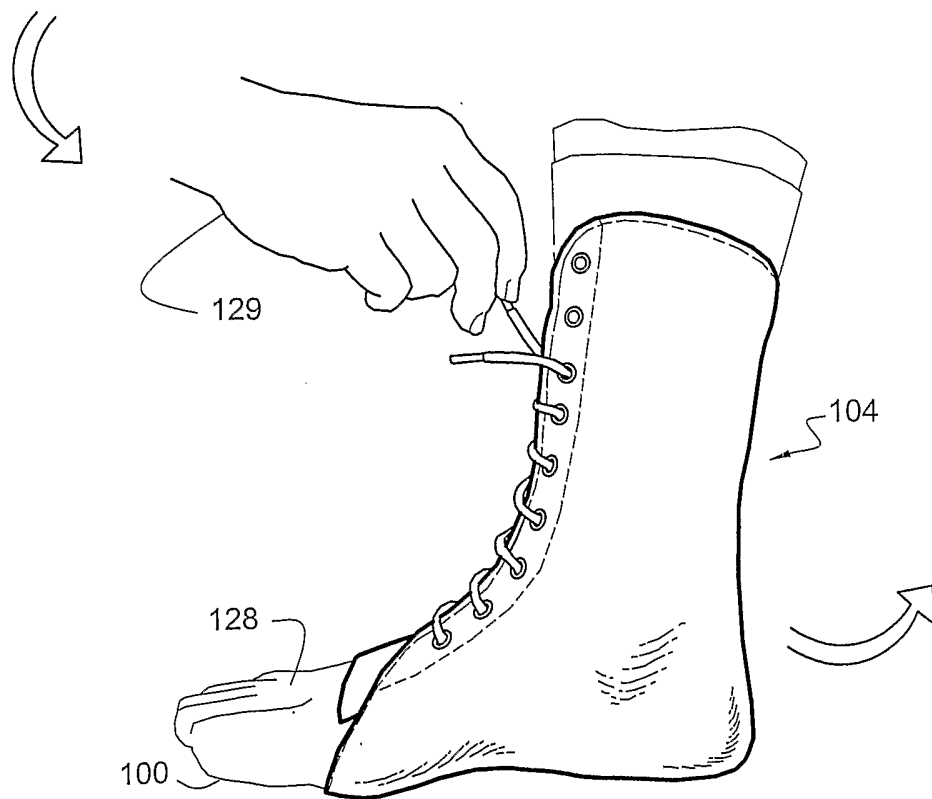
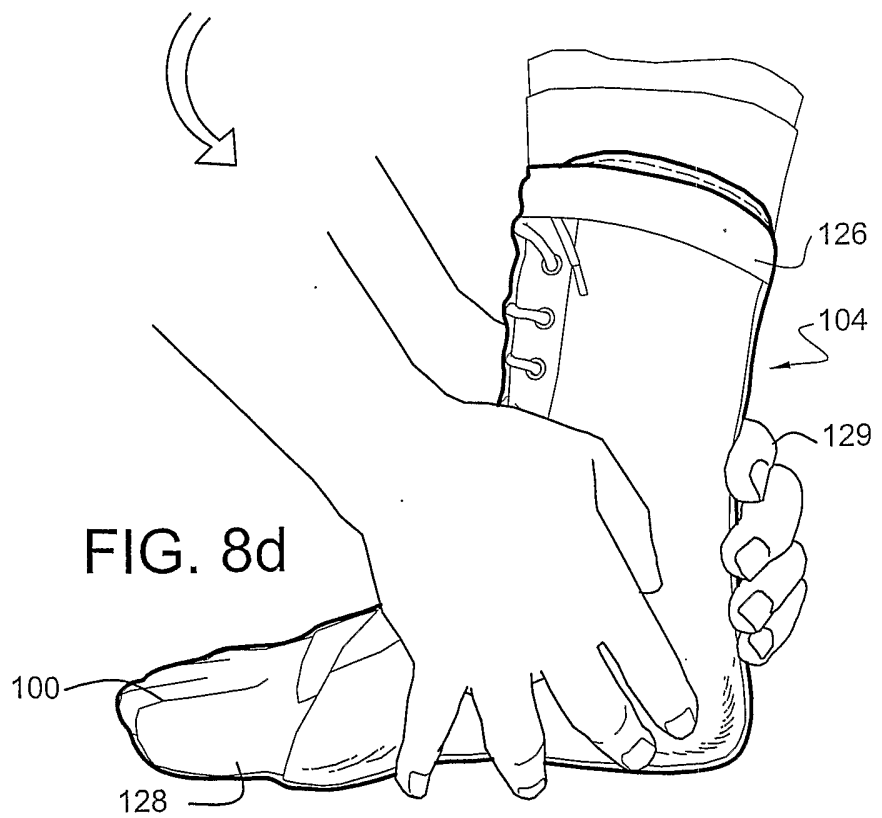
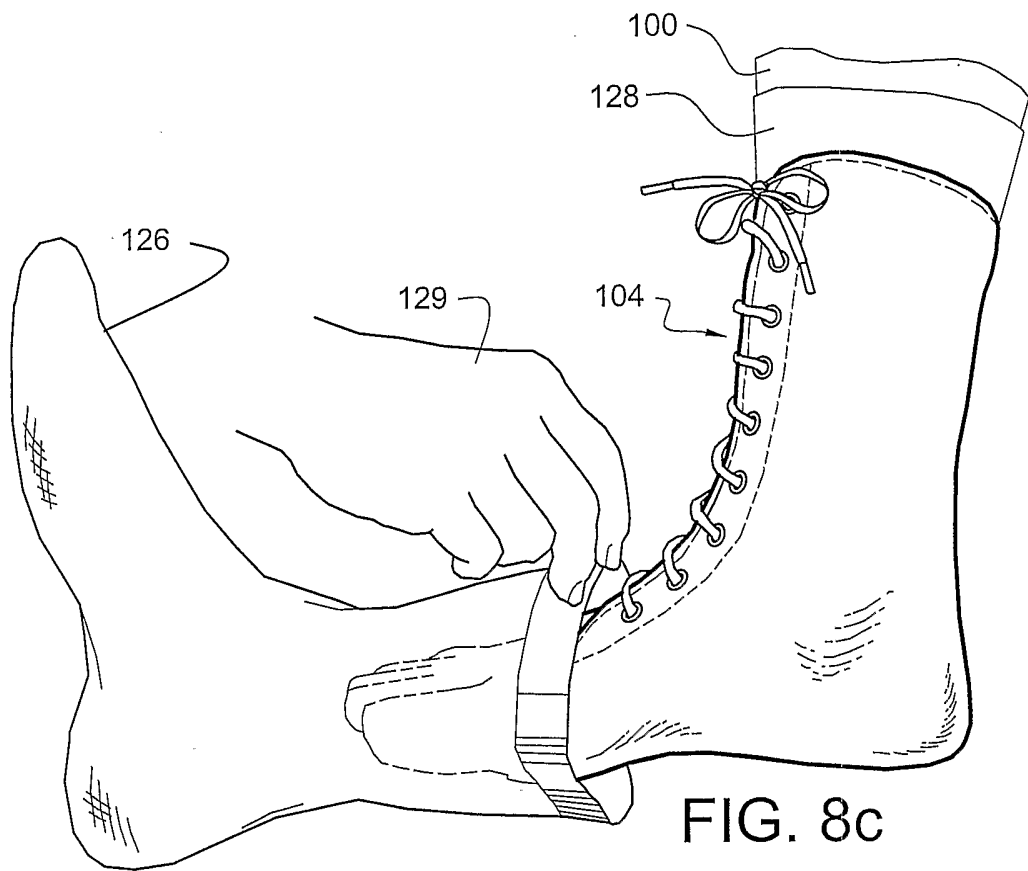


FIG. 8b



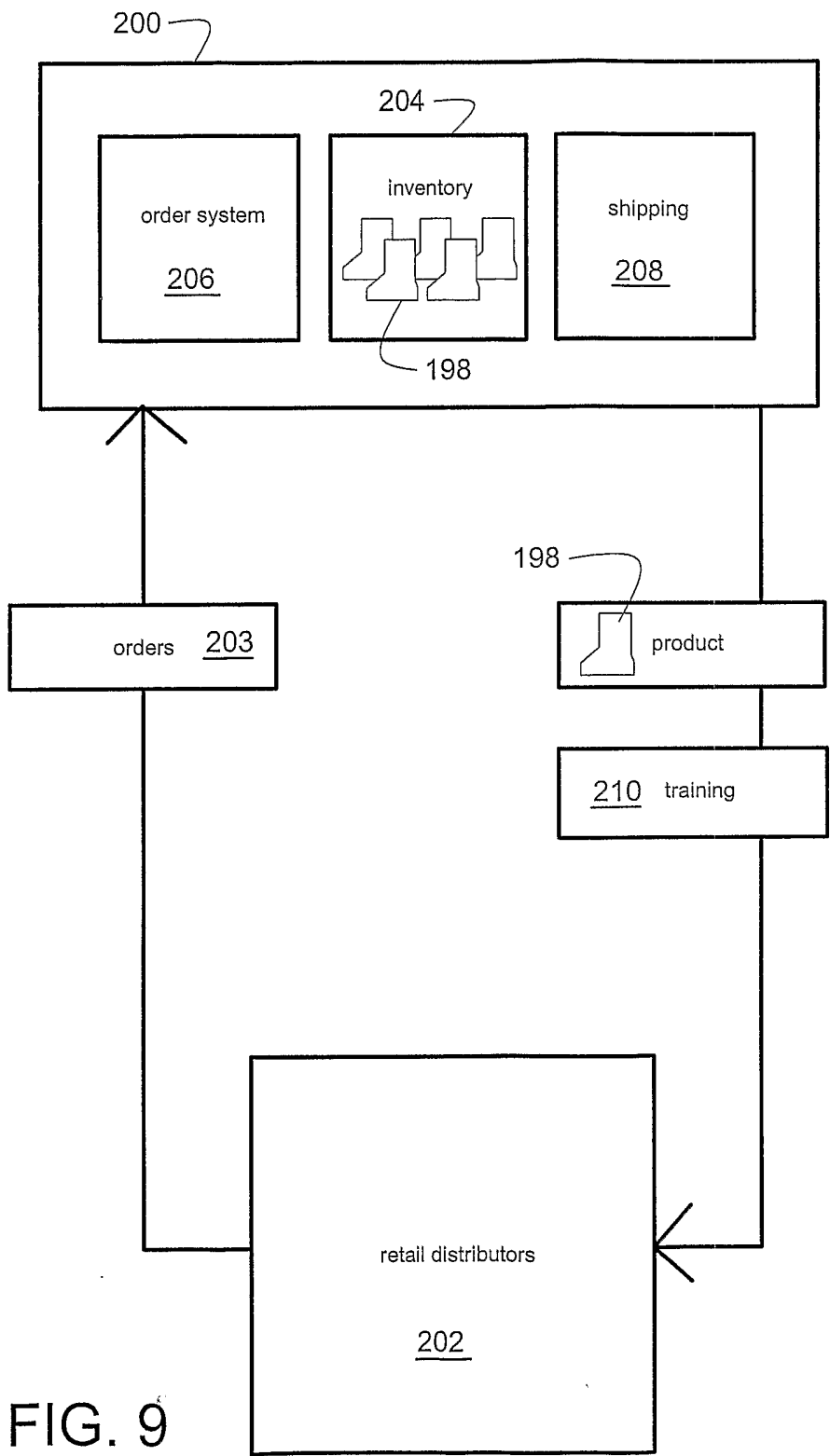


FIG. 9

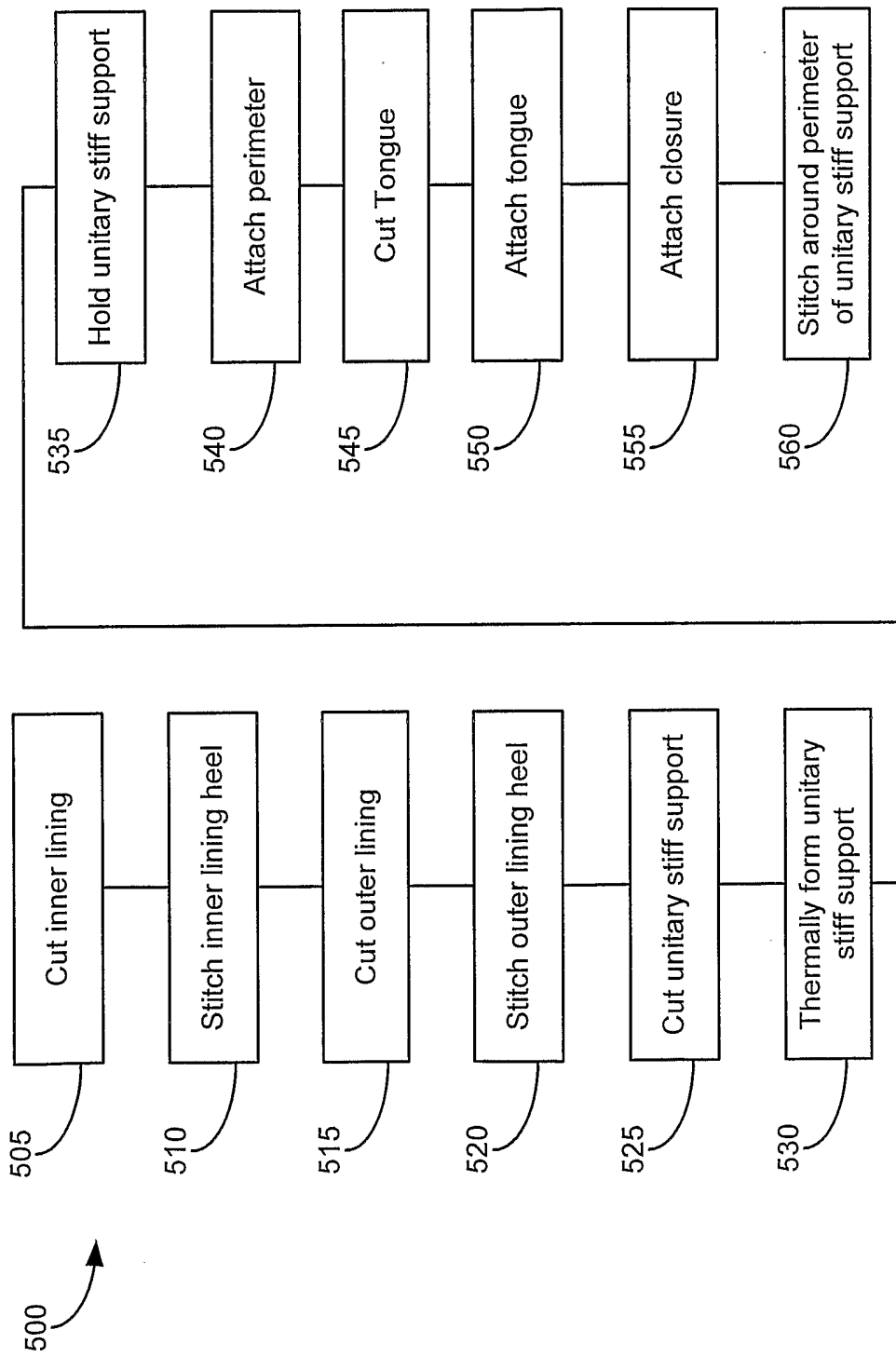


FIG. 10

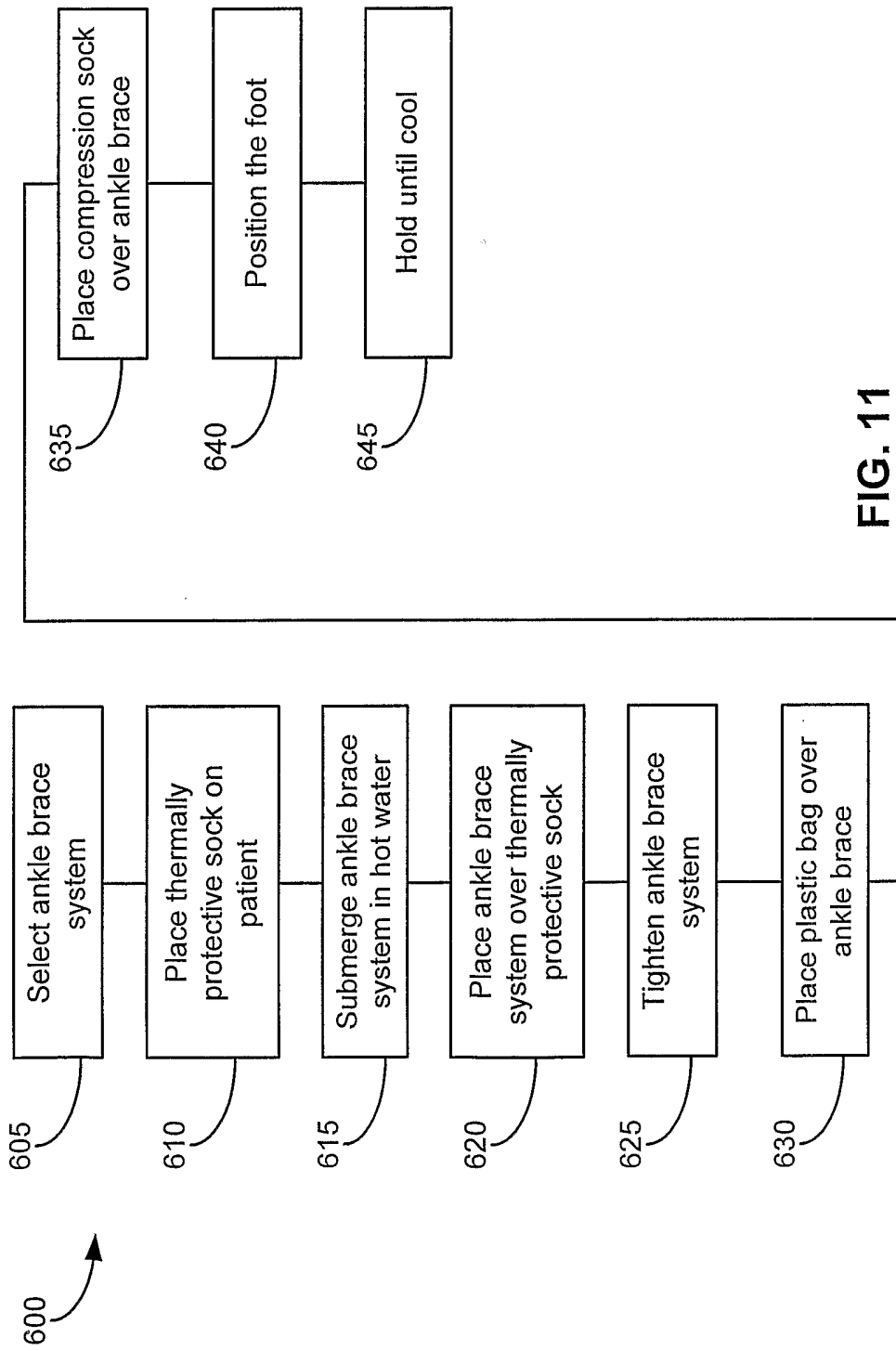


FIG. 11