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(54) **DIABETIC FOOTWEAR**

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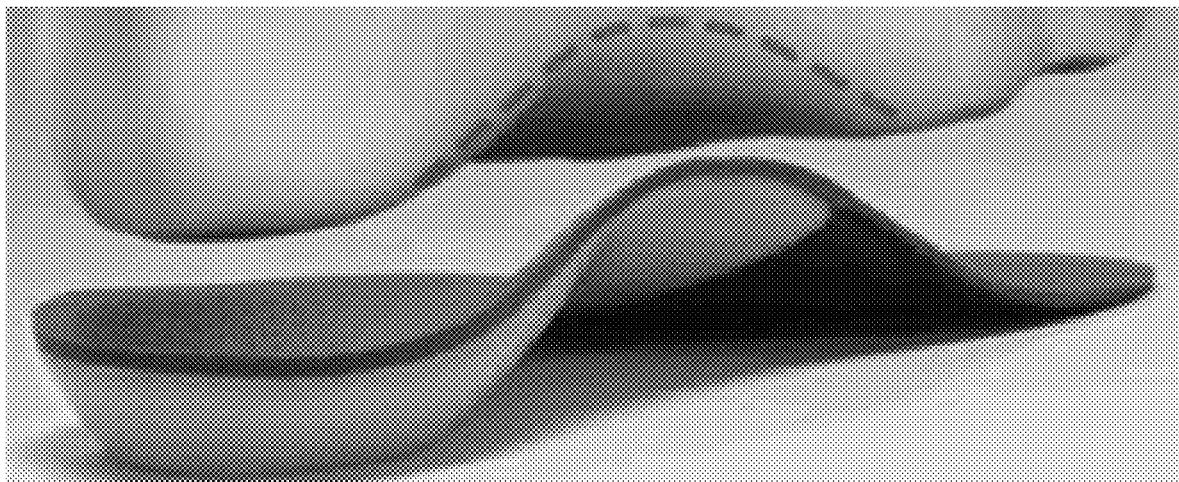
(57) **ABSTRACT**

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A custom fitted shoe for diabetic patients including a custom insole and a custom upper, both manufactured from a whole-foot impression, the custom upper featuring a widened toe box, extra cushioning in the big toe, pinky toe, and heel regions, and elastic in the ankle region, and dual fastening system including elastic laces and removable Velcro fastening system; the custom insole feature toe wells and toe separation ridges to prevent toes from contacting and rubbing against one-another.

Related U.S. Application Data

(60) Provisional application No. 62/752,556, filed on Oct. 30, 2018.



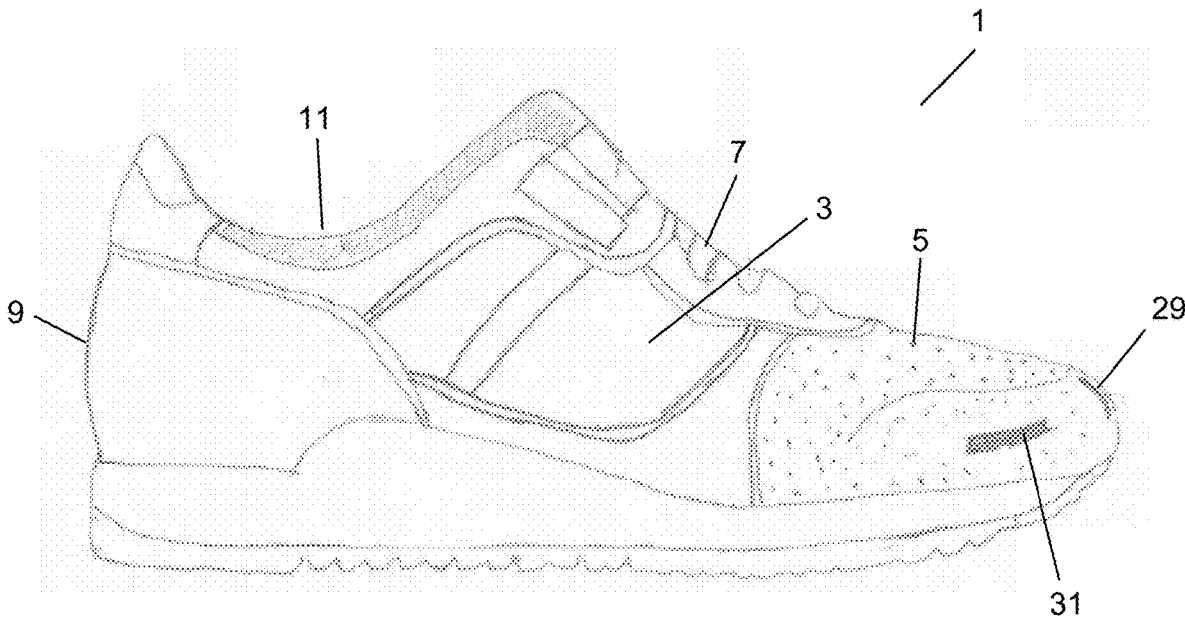


FIGURE 1

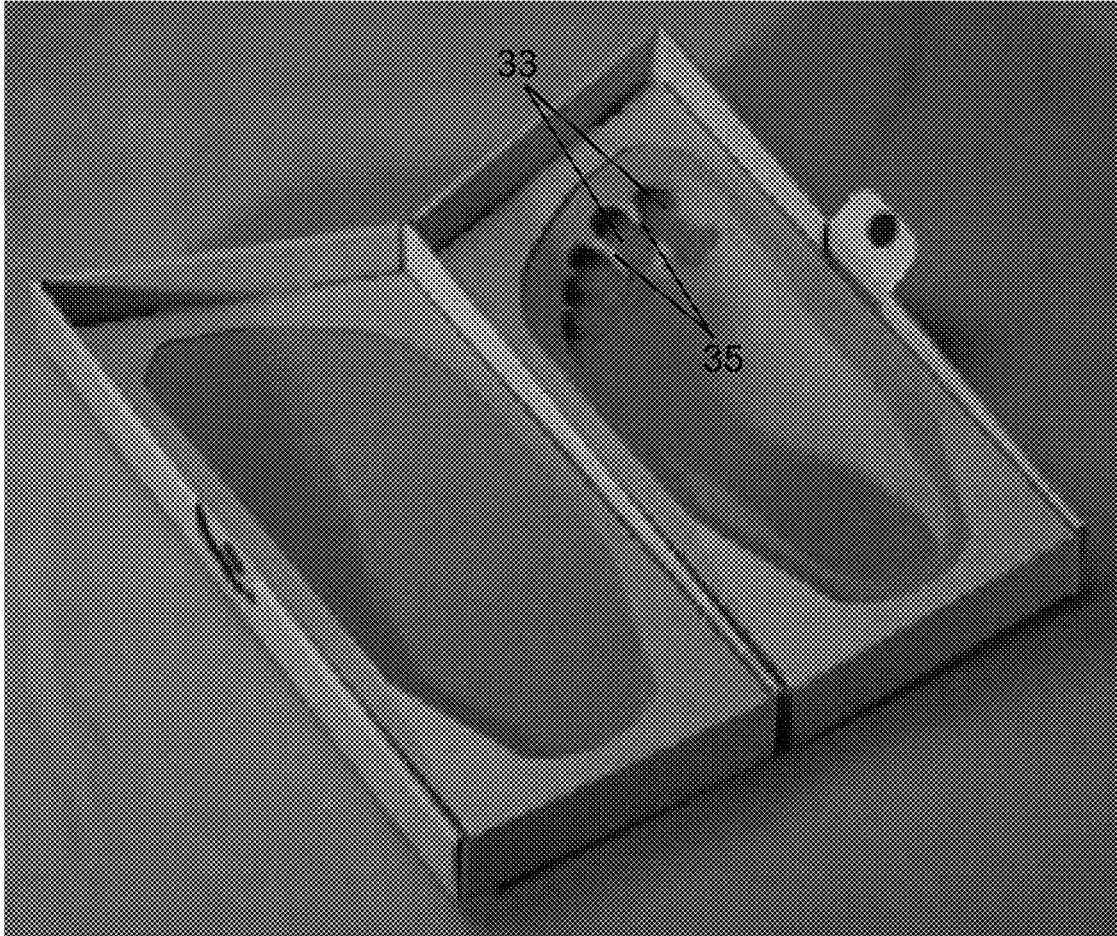


FIGURE 2

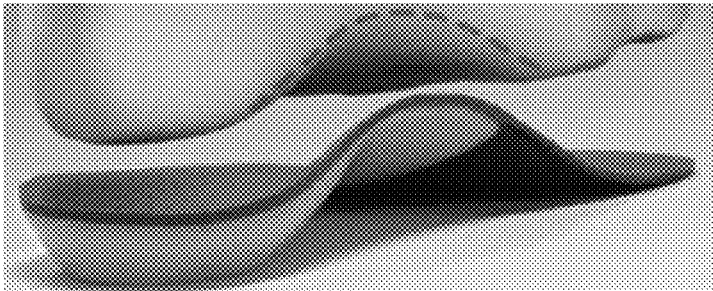


FIGURE 3

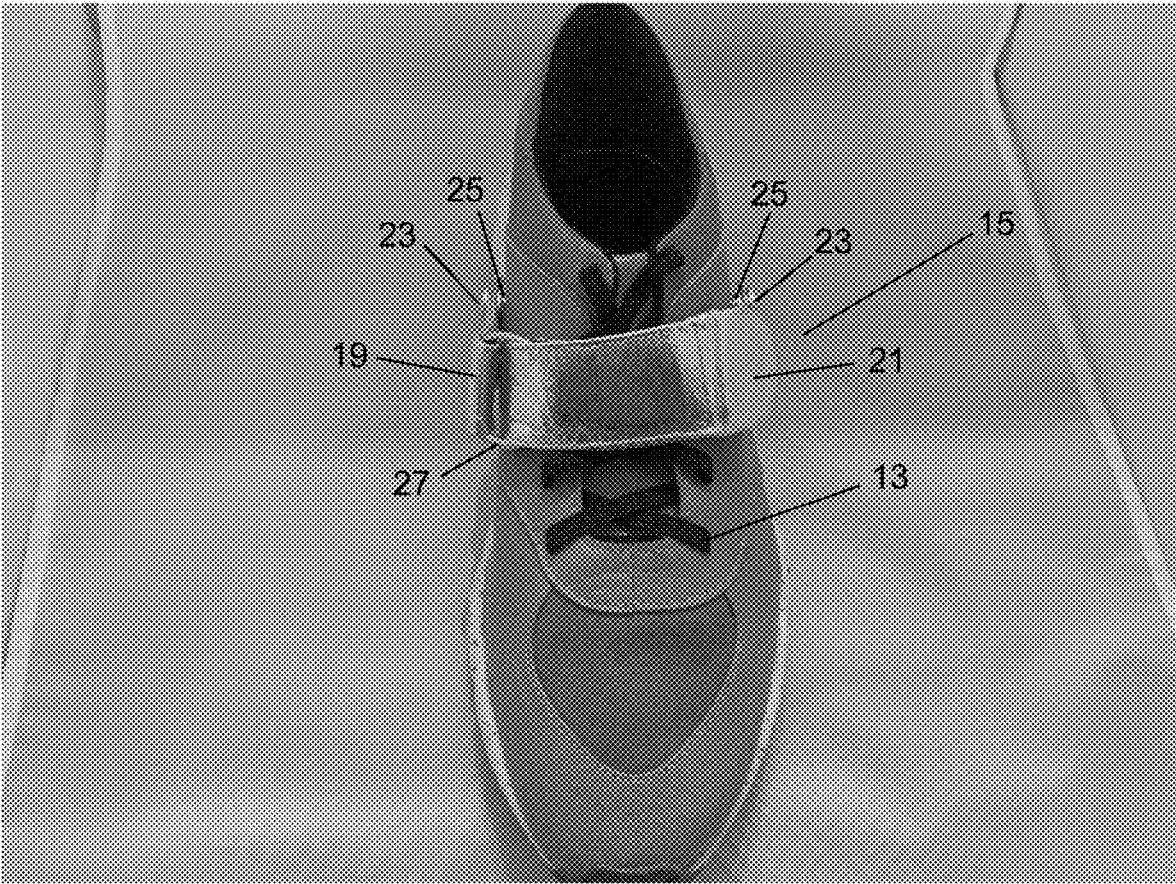


FIGURE 4



FIGURE 5

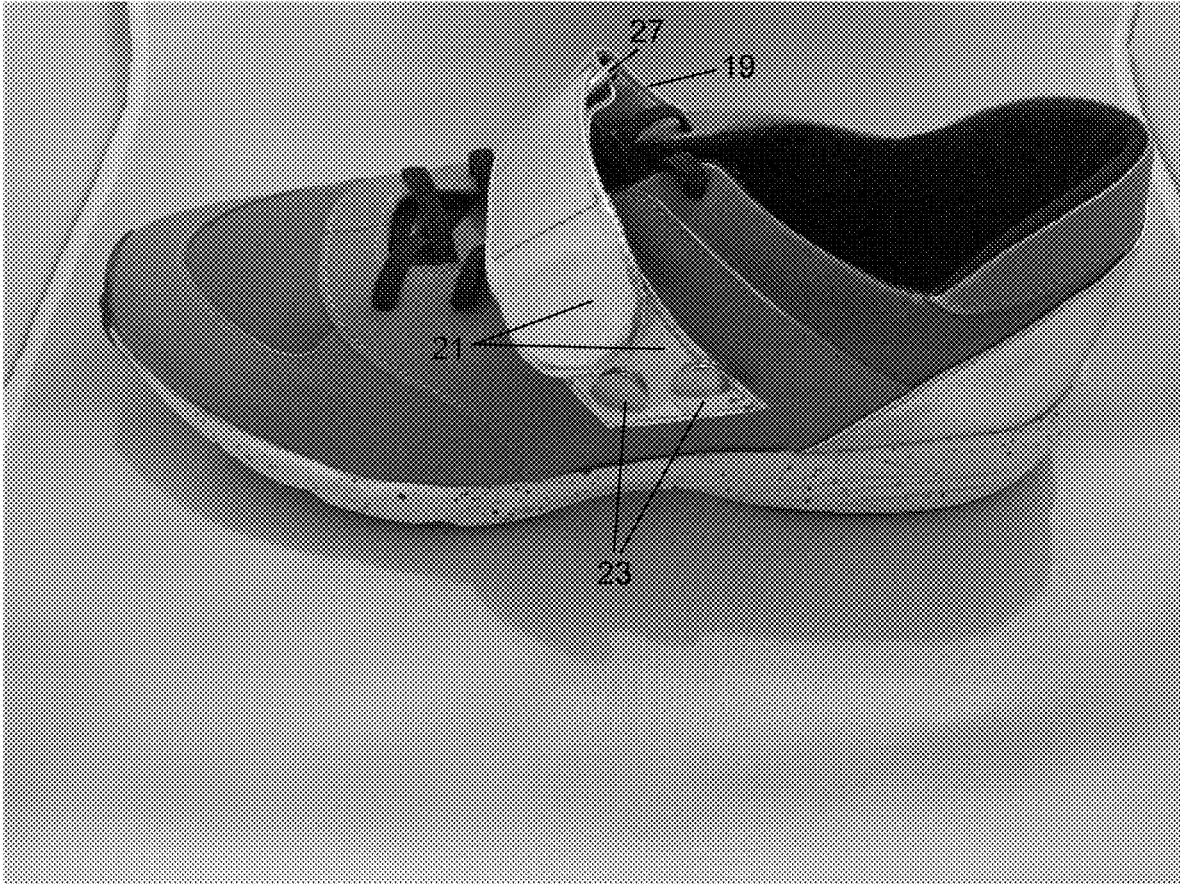


FIGURE 6

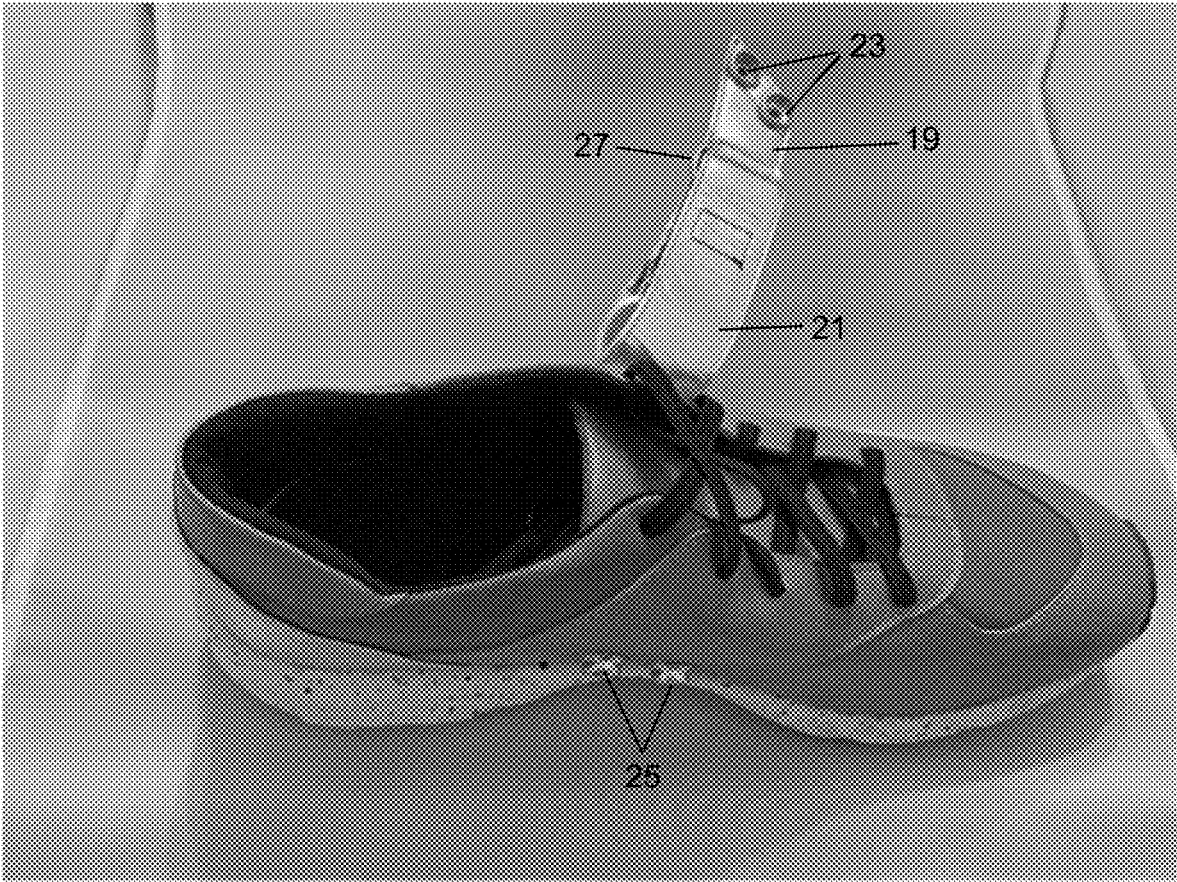


FIGURE 7

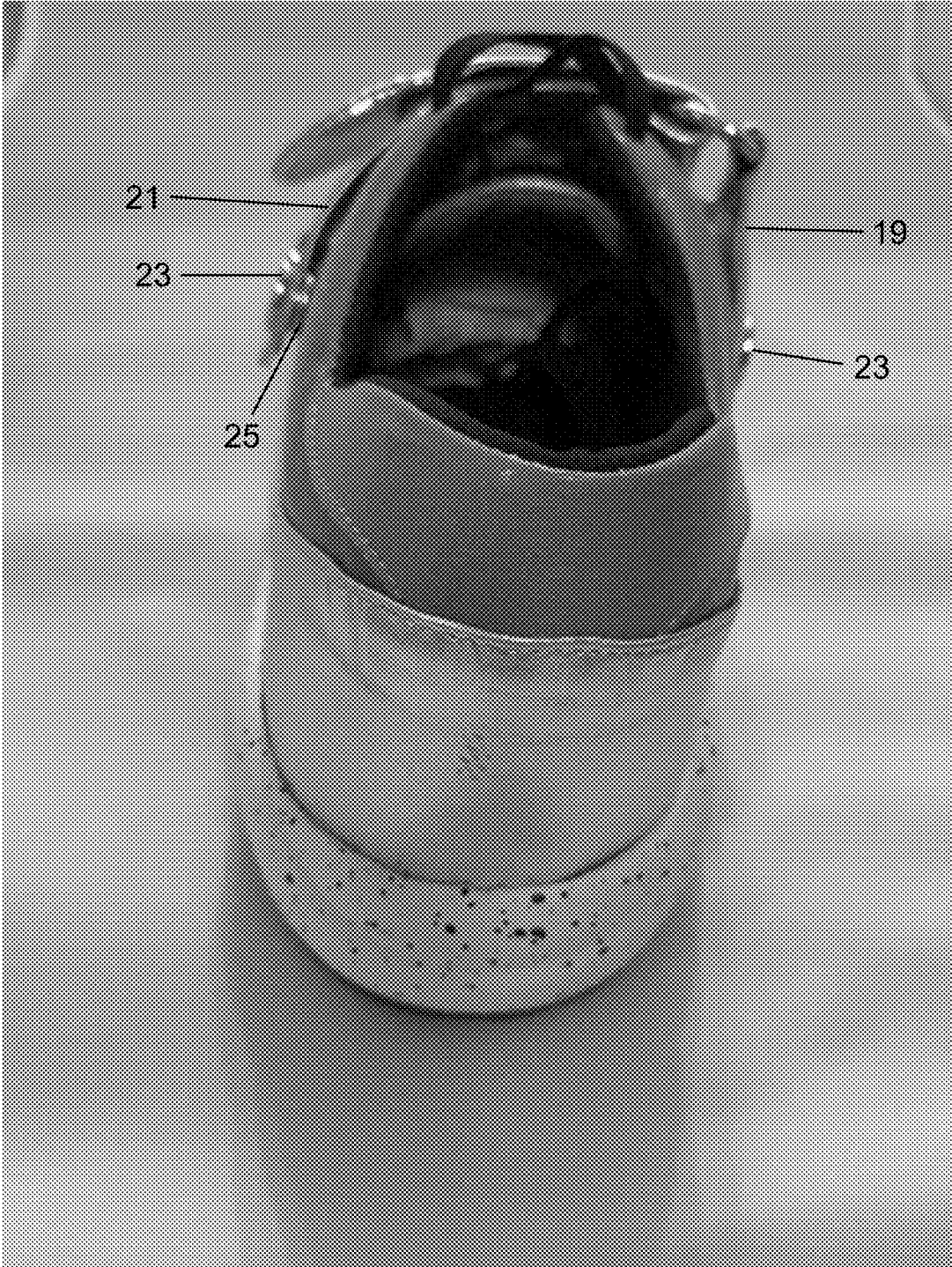


FIGURE 8

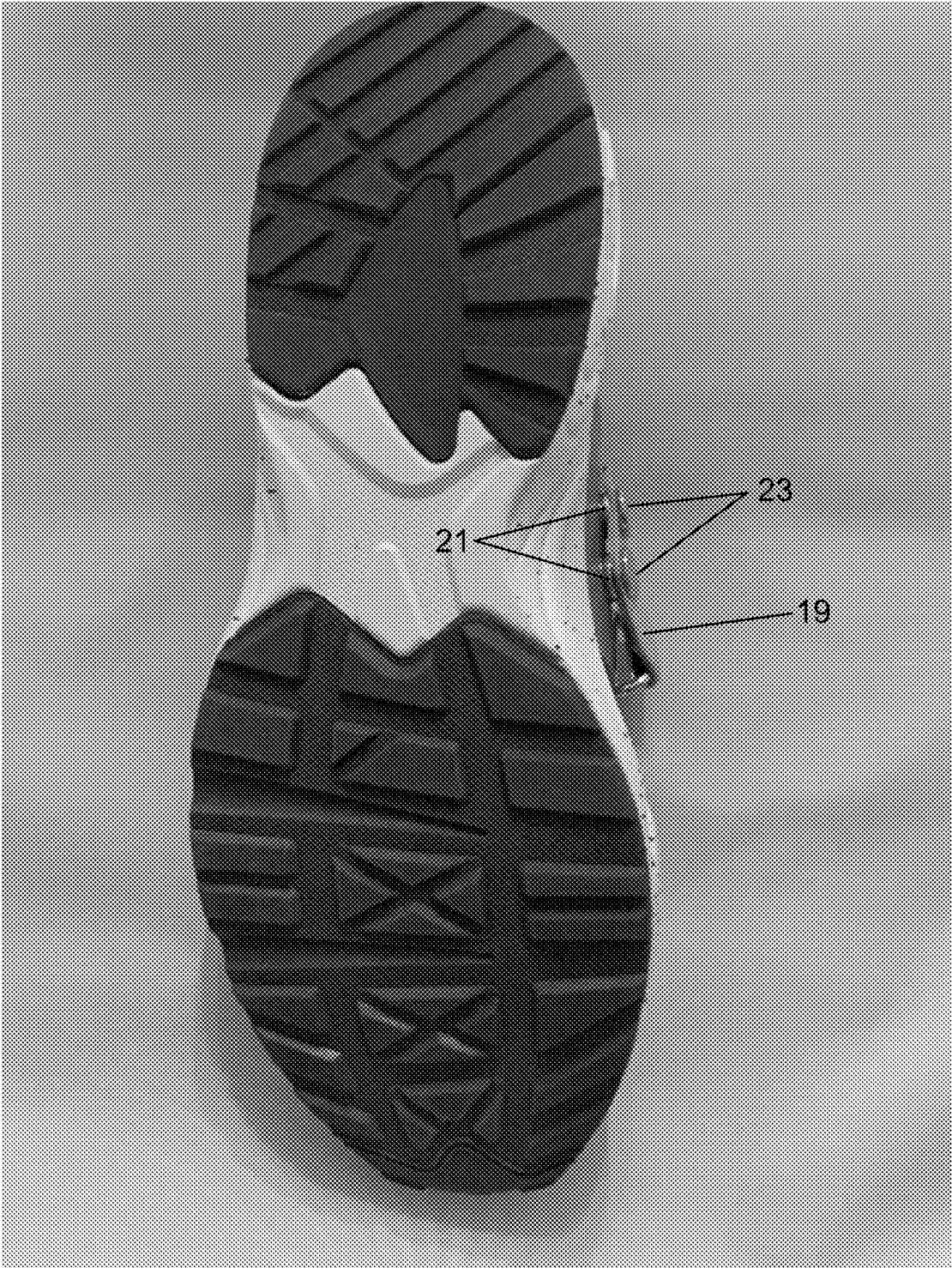


FIGURE 9

DIABETIC FOOTWEAR

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to footwear for patients with diabetes.

Description of the Background

[0002] More than 30 million Americans, or 9% of the population, have diabetes, a fourfold increase since 1980, and 1.5 million Americans are diagnosed with diabetes every year. Diabetics are prone to circulatory issues and nerve damage in the foot. Without proper foot care and shoe support, nerves in the feet can become damaged (called sensory diabetic neuropathy, or SDN). SDN causes the foot to lack feeling throughout the muscles and can lead to higher risk of infections due to the toes not being able to function properly. About 60 percent of all non-traumatic lower-limb amputations among people aged 20 years or older occur in people diagnosed with diabetes.

SUMMARY OF THE INVENTION

[0003] The present invention addresses the specialized footwear needs of diabetic patients that are not met by the prior art by featuring a shoe and custom 3D-printed insole with toe separation ridges. The invention focuses on specific areas of the feet that are most likely to suffer from SDN. Among the parts of the feet that are deemed more critical to maintaining circulation and comfort include: the big toe, the small toe (“pinky”), certain points in the front of the arch area (pad of the foot), certain points in the heel, and the back of the foot. There is also friction on the tops and bottoms of the toes, where additional diabetic ulcers appear. The invention is characterized by a shoe portion and a custom-fitted insole. The shoe features a breathable textile material and design features will help diabetic individuals improve their physical activity and foot mobility. Innovative features of the shoe include breathable fabric, unique ankle shoe design, targeted cushioning including, a soft thin layer of cushion lining for the big toe and pinky toe, alternative fastening options including Velcro and elastic laces. The 3D printed insole is custom fit for each individual user, and features custom fit toe impressions to separate the toes and prevent them from rubbing against each other (i.e., prevent or reduce toe-to-toe rubbing), and improved flexibility and breathability in the arch, toe, and heel areas.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] FIG. 1 is a side view of a shoe for diabetic patients according to an embodiment of the invention.

[0005] FIG. 2 is an example of a foot imprint kit according to an embodiment of the invention, showing toe wells and toe separation ridges that will be reflected in the custom insole of the invention.

[0006] FIG. 3 is perspective view of a prior art insole

[0007] FIG. 4 is an overhead front view of a shoe for diabetic patients according to an embodiment of the invention.

[0008] FIG. 5 is an overhead right side view of a shoe for diabetic patients according to an embodiment of the invention.

[0009] FIG. 6 is an overhead left side view of a shoe for diabetic patients according to an embodiment of the invention.

[0010] FIG. 7 is an overhead right side view of a shoe for diabetic patients according to an embodiment of the invention, with a Velcro strap unfastened.

[0011] FIG. 8 is an overhead rear view of a shoe for diabetic patients according to an embodiment of the invention.

[0012] FIG. 9 is a bottom view of a shoe for diabetic patients according to an embodiment of the invention.

[0013] Features in the attached drawings are numbered with the following reference numerals:

1	shoe
2	insole
3	upper
5	vent holes
7	tongue
9	heel area
11	ankle area
13	elastic laces
15	velcro closure system
17	eyelets
19	velcro inboard section
21	velcro outboard section
23	strap snaps
25	shoe snaps
27	velcro closure system ring
29	big toe area
31	pinky toe area
33	toe wells
35	toe separation ridges

DETAILED DESCRIPTION

[0014] Referring to the figures, the shoe 1 for diabetic patients according to the invention preferably features a custom insole 2 and an upper 3. The upper 3 is preferably made entirely of open pore flexible material or have significant regions made of open pore flexible material to allow air circulation into and out of the interior foot area. According to a preferred embodiment, the open pore flexible material is provided at least in the top and side areas adjacent the wearer’s toes. In addition to being manufactured entirely or partially of open pore flexible material, the upper may feature vent holes 5 in the material of the shoe upper 3 to increase air circulation. The material of the upper 3 is also preferably made from hydrophobic materials to minimize accumulation of moisture. The tongue 7 of the shoe is preferably made of the same or similar open pore material, additionally including a reticulated foam layer for padding. The shoe according to the invention also features additional heel area 9 and ankle area 11 support in the form of reticulated foam padding lining the top edges of the shoe where it contacts the wearer’s angle and Achilles tendon. The padding of the area at the back of the foot may extend to the bottom of the heel to reduce rubbing and improve comfort. The area of the shoe adjacent the ankle may be made of elastic material, to facilitate putting on and removal of the shoe.

[0015] According to a preferred embodiment of the invention, the shoe is provided with both elastic laces 13 and Velcro-style hook and loop type closure systems 15 for user flexibility and comfort. The removable elastic laces 13 may be threaded through a plurality of eyelets 17 on each side of

the upper across the tongue section. In addition, a removable Velcro-strap is provided with snaps that may be snapped and unsnapped from corresponding snaps on each side of the shoe. According to this embodiment, the Velcro-strap may comprise an inboard section **19** and an outboard section **21**. The inboard section is preferably provided at one end with has one or more strap snaps **23** that snap onto and off of corresponding shoe snaps **25** affixed to the inboard side (e.g., right side of a left shoe) of the shoe. The other side of the inboard section has a ring **27** for engaging the outboard section of the Velcro strap. The outboard Velcro strap **21** is provided at one end with strap snaps **23** that snap onto and off of corresponding shoe snaps **25** affixed to the outboard side (e.g., left side of a left shoe) of the shoe. The opposite end of the outboard Velcro strap section is configured to be long enough to be threaded through the ring **27** at the proximate end of the inboard Velcro section, and turned back on itself where corresponding sections of hook and loop cause the outboard Velcro strap to be secured to itself. According to an alternate embodiment, the outboard section may be configured the same as the inboard section, with snaps at one end and a ring at the other end, and the inboard and outboard sections may be joined by a third piece comprising a Velcro strap which may be looped through the rings at the ends of both inboard and outboard sections and fastened to itself. Any one or more of the inboard section, the outboard section, and the central Velcro section may be provided with an elastic portion to provide additional comfort and flexibility.

[0016] The Velcro strap system **15** may be used alone, or in conjunction with the elastic laces **13**. In the case that the elastic laces are used alone, the inboard and outboard sections of the Velcro strap may be unsnapped from the shoe and stored for later use. Likewise, in the case that the Velcro strap is used alone, the elastic laces may be removed and stored for later use.

[0017] Referring now to the interior of the shoe, the shoe is provided with an interior padding layer preferably made from open pore reticulated foam to reduce moisture retention, provide cushioning and to reduce rubbing and wear on the foot. According to a preferred embodiment, the interior surface of the shoe is devoid of stitching in the areas that contact the foot to avoid irritation. Additional padding is provided in the big toe area **29** and pinky toe area **31**.

[0018] According to a preferred embodiment, the shoe is provided with an enlarged toe box to provide additional comfort and to prevent the rubbing of the toes against the inside surface of the shoe and against each other.

[0019] The shoe insole **2** is custom fitted to the wearer. According to a preferred embodiment, an impression is taken of the wearer's entire foot including to and just above the ankle, and a custom insole is 3D printed, including toe wells **33** and toe separation ridges **35** to separate the toes

while inside the shoe and prevent them from rubbing against one-another. The toe separate ridges **35** preferably extend a distance above the top surface of the insole sufficient to prevent the wearer's toes from touching and rubbing against one-another. According to various embodiments, the height of the toe separation ridges **35** extend 10%, 20%, 30%, 40%, 50% or more of the height of the toes. However, in order to ensure circulation through and among the toes, the height of the toe separation ridges **35** is preferably not more than $\frac{2}{3}$ the height of the wearer's toes.

[0020] The insole **2** preferably features three layers, a top padded layer with extra padding in areas prone to wear and blistering; a rigid middle layer to provide arch support, and overall shape, and a bottom layer comprising a slip-resistant material. The shoe is also custom constructed according to the whole-foot impression, with the interior dimensions of the shoe are constructed to allow for entry of the insole overall custom fit of insole and upper.

[0021] The sole of the shoe includes heel and toe box areas made of a flexible and cushioned material, where the middle section of the sole, between the heel and toe box areas are made of a more rigid material to provide for arch support.

[0022] According to a preferred embodiment of the invention, a kit is provided for making an impression of the user's feet to the ankle. The impressions may be made at the user's home and sent to the manufacturer for manufacture of the custom shoes, or they may be made at a retail location or at a physician's office. Once the manufacturer receives the custom foot impressions, a custom insole is 3D printed, and a corresponding shoe is custom manufactured, tailored to the custom insole and the user's foot.

1. A shoe insole comprising toe wells and toe separation ridges configured to prevent a wearer's toes from touching one-another.

2. A shoe comprising a shoe insole, said shoe insole comprising toe wells and toe separation ridges configured to prevent a wearer's toes from touching one-another.

3. A method for constructing a shoe comprising taking an impression of the intended wearer's entire foot up to the ankle, manufacturing a custom insole according to the impression, said custom insole comprising two wells and toe separate ridges configured to prevent the intended wearer's toes from touching one-another, and manufacturing a custom shoe according to the impression, and inserting the custom insole into the custom shoe.

4. The shoe insole according to claim **1**, wherein said toe separate ridges extend upward from a top surface of said insole no more than $\frac{2}{3}$ the height of the wearer's toes.

5. The shoe according to claim **2**, further comprising elastic laces and a removable hook and loop strap.

6. The shoe according to claim **2**, wherein said removable hook and loop strap comprises an elastic section.

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