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(54) **FOOTWEAR PROVIDED WITH A DEVICE FOR PRESSURE MASSAGE OF THE LOWER LIMBS**
SCHUH MIT EINER VORRICHTUNG ZUR DRUCKMASSAGE DER UNTEREN GLIEDMASSEN
ARTICLE CHAUSSANT POURVU D'UN DISPOSITIF DE MASSAGE PAR COMPRESSION DES
MEMBRES INFÉRIEURS

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EP 3 232 845 B1

Description

Technical Field

[0001] The present invention relates to a footwear provided with a device for pressure massage to the lower limbs.

Background Art

[0002] In the human body the blood, being pushed by the heart pump, moves through the circulatory system. From the heart the blood reaches the organs through the arterial system and, after contributing to the perfusion of organs and tissues, it returns to the heart through the venous system.

[0003] The veins which form the low pressure system are characterized by a thin wall; this latter is normally devoid of muscles except in the veins that have a diameter of at least about 1 mm. The thin wall associated with the large diameter of the venous vessels allows to store significant amounts of blood; in water balance conditions, 60-70% of all the blood, i.e. about 5 l in an adult, is located in the venous system of the large circle and a further 5% is present in the pulmonary veins of the small circle. This allows the venous system to function as the main control system for adjusting body water volume and blood pressure and volume.

[0004] Most of the veins contain special bicuspid or swallow's nest shaped valves, which are structurally similar to the semilunar valves of the heart and in fact work one way, i.e. they are oriented so as to carry the blood towards the heart, preventing its backward flow in the retrograde direction; these valves are often absent in perforating veins.

[0005] Thanks to their structure the veins are compressible through muscle contraction, which is exercised by the connective fascia and aponeurosis, inside the muscular lodges (deep veins), or by skin and subcutaneous tissue in the case of superficial veins (extra-fascial veins); the latter can be used as an external alternative path (shunt or by-pass) in case of phlebothrombosis.

[0006] During the return of venous blood from the lower limbs, several physiological mechanisms govern the venous and lymphatic outflow in deep and centripetal direction, taking advantage of the bone structure, the muscle bands, the peri-vascular connective bands and the venous valves. In these mechanisms of venous outflow both suction forces and driving forces intervene: the suction forces are based on the centripetal suction through breathing and muscular release; the driving forces are based on the arterial pressure remaining in the microcirculation, on the arterial pulse adjacent to the veins, on the foot push, on the muscular contraction that occurs mainly in the calf muscles as the gastrocnemius and the tibial muscle. The action of these forces varies significantly depending on the posture and the movement.

[0007] In a situation of immobility, in the standing po-

sition, the weight of the column of blood that goes from the right atrium of the heart to the internal tibial malleolus corresponds to the pressure in the distal veins of the lower limbs and is equal to about 90 mm Hg at the malleolus, while it is about 0 mm Hg at the right atrium. Under these conditions, given the lack of venous return, the venous valves are not activated, and the venous return of the deep veins of the lower limbs such as the tibial vein, the peroneal artery and the femoral artery is driven by the pulse wave of the arteries which run adjacent and parallel to the respective veins. As a consequence of all this, then, in an upright standing position, size and pressure of the superficial veins increase a lot favoring the onset of ectasias, i.e. dilated veins, and varicose veins, i.e. abnormal and curvy dilations, and telangiectasias, i.e. confluences of small dilated blood vessels that cause the appearance of red or bluish patches on the skin. In a degenerative vicious circle, the greater this phenomenon will be, the larger the diameter of the blood vessel.

[0008] Numerous types of stockings with differentiated elasticity have been proposed to prevent the onset of these diseases by means of a mainly static pressure on the lower limbs.

[0009] Ambulation facilitates both the venous and the lymphatic outflow by producing at each step a real "muscle squeezing" of the veins, with subsequent venous valves activation that reduces the venous pressure at the ankle joint to 20-30 mm Hg. In fact, the venous system of the lower limbs is constituted by the superficial plantar veins, which form the so-called sole of Lejars, the deep plantar veins and the superficial dorsal veins of the foot, from which both the large and the small saphenous veins begin. The latter are in communication with the deep veins (tibial, peroneal, femoral veins, etc ...) through the perforating veins. During walking the weight is loaded on the forefoot and on the venous sole of Lejars, and the blood therein is pushed in deep and centripetal direction towards the heart. The subsequent contraction of the calf muscles as well as the muscles of the anterior compartment of the leg, during the movement of plantar flexion and extension, gives speed to the blood mass and carries it into the popliteal system. At the next step, then, the knee flexion promotes emptying into the popliteal vein which is the major route of drainage into the deep venous system of the thigh where the most proximal pump mechanisms that facilitate the venous outflow to the heart begin to operate. Therefore, the foot, the ankle and the calf muscles form the so-called peripheral heart, which contributes to the venous outflow from the limbs to the heart through a mechanism of dynamic massage. This massage applies a variable pressure to venous vessels starting from the foot area and gradually reaching the calf and the thigh. The physiological mechanism which assists in the venous outflow activated by walking can be ineffective due to factors related to an inadequate muscle tone, for example in the elderly or in patients put on bed rest for a long time, for example following a fracture, with resulting immobility or to the presence of ectasias and var-

icose veins. Such a presence can make the healthy effect of ambulation less effective, and further make walking very painful and difficult. The ambulation works if done for an appropriate time, while patients with venous insufficiency of the lower limbs often have difficulty or pain on walking, and this triggers a vicious circle: they walk little and this makes them feel bad; because they feel bad they walk even less. Finally elderly and/or obese patients have an accumulation of body mass not homogeneous in the whole body, for which the increase of abdominal mass and of the region above the knee joint often does not match a corresponding increase in muscle mass below the knee.

[0010] This means that in these subjects the volume of venous blood whose outflow can be facilitated thanks to the mechanism of squeezing of both the plantar muscles and the tibialis gastrocnemius, is not sufficient to improve the whole venous outflow, the venous blood and lymphatic system being positioned in regions situated in the knee or up the entire leg.

[0011] GB2263405A describes a pneumatic device that provides a sequential compression on an edematous leg during the ambulation, designed to treat patients with lymphedema and venous insufficiency. Such pneumatic device is embedded in a shoe and has two cavities respectively housed in the sole in the metatarsal region and in the heel, respectively. The metatarsal cavity, called metatarsal donor cell, is in communication with a respective higher sleeve, called receiving higher cell, which is provided in the shoe at the calf. The cavity of the heel, called donor cell of the heel, is in communication with a respective lower sleeve, which is provided in the shoe at the ankle. An arrangement such as that described above has the problem that the transmission of pneumatic pressure between the donor cells and the receiving cells is unsatisfactory because the alternate crushing action of the two cavities produces only a displacement of air between the respective cells, and not a significant increase of pressure, such as to determine an effective pumping action; furthermore, as shown in the only figure of the above mentioned English document, even this minimum pumping effect of the metatarsal cell is antagonistic to that of the heel, since the metatarsal cell is connected to the superior part of the upper sleeve, and the heel cell is attached to the inferior part of the lower sleeve.

[0012] A similar effect, but applied to the hips of the user, is described in EP 0 039 629. US 6,554,785 describes an orthopedic device which includes an air bladder and a flanked gel bladder in order to be in contact with a patient's leg. The air bladders are fixed on the side of the shoe upper in the desired position. Provided in the device according to the above mentioned document is a check valve projecting outwardly from the air bladder that adjusts the air pressure of the device inflating and deflating it. This adjustment serves to maintain more or less adherent the gel bladder to the body part of the patient in which the device is worn. The gel bladder can be removed from the device to enable both the heating and

the cooling depending on the therapeutic needs. A similar combination of air and gel bladders is also provided in US 5,088,478. The adjustment of the air bladders pressure from the outside by means of a pump is also in GB 817,521.

Summary of the Invention

[0013] Therefore, an object of the present invention is to obtain an increase of the effect of pressure on the limb in a footwear adapted to improve the blood flow, the comfort and the lower limb muscle performance by exploiting the leg muscle contraction exerted during the ambulation.

[0014] In this area of interest, another object of the present invention is to provide a footwear adapted to exert a winding-down action and to improve the venous outflow from the lower limbs by means of a dynamic massage produced by the application of a variable pressure to the tissues and to the venous vessels from plantar area and gradually up to the veins of the leg and, in some cases, the thigh.

[0015] A further object of the invention to exert the effect of the massage from the outside towards the inside of the leg by a centripetal action, and with progression from bottom to top.

[0016] The mentioned technical task and the specified aims are substantially achieved by a footwear provided with a device for pressure massage of the lower limbs, comprising the technical characteristics exposed in one or more of the appended claims.

[0017] The footwear provides an antigravity effect proportional to the mass of the wearer, thanks to the pressure exerted by the body weight on the sole.

[0018] Further, the massage provided by the device according to the present invention is gradual, and its frequency is in sync with the gait of the shoe wearer.

[0019] It should not be underestimated that these effects are obtained without the use of any electronic control device or mechanical pumps, and this guarantees restrained cost and weight of the device, and, therefore, better portability.

Brief Description of Drawings

[0020] Further characteristics and advantages of the present invention will become more apparent from the indicative, and therefore non-limiting description of a preferred but not exclusive embodiment of a footwear provided with a device for pressure massage to the lower limbs, as illustrated in the accompanying drawings in which:

- Figure 1 is a partial cross sectioned view of a footwear according to the present invention, when worn.

Description of an embodiment of the invention

[0021] Referring to the figure, a footwear provided with

a device for pressure massage to the lower limbs according to the present invention is shown therein. The footwear has a sole 1 and an upper 2. The upper 2 is preferably elastic so as to be adherent to the limb of the person wearing the footwear. The sole 1 is provided internally with a forefoot chamber 3 and a heel chamber 4.

[0022] The forefoot chamber 3 is in communication via a flexible duct 5 with at least one fluid inflatable bladder 6 that is removably positioned on the inside of the upper 2, for example at the calf. The forefoot chamber 3, the flexible duct 5 and the inflatable bladder 6 constitute a first part of the device for pressure massage. The removable positioning of the inflatable bladder 6 can be obtained with Velcro® strips (not shown), that allow to choose the desired position, as in the prior art. As already known from the prior art, flanked internally to the inflatable bladder 6 is an isolated bladder 8 full of gel that is in contact with the body part, for example, the calf, of the shoe wearer according to the present invention.

[0023] The heel chamber 4 is in communication via a flexible duct 9 with at least one fluid inflatable bladder 10 removably positioned on the inside of the upper 2, for example, at the instep. The heel chamber 4, the flexible duct 9 and the inflatable bladder 10 constitute a second part of the device for pressure massage. The removable positioning of the inflatable bladder 10 can be obtained with Velcro® strips 7, that allow to choose the desired position, as in the prior art. As for the inflatable bladder 6, also internally put beside the inflatable bladder 10 is an isolated bladder 11 full of gel that is in contact with the body part, for example the instep, of the shoe wearer according to the present invention.

[0024] Similarly to the known technique, air is present in the two above described parts of the device for the pressure massage, so the device is of a pneumatic type. The internal pressure can be adjusted by means of a pump and a pressure gauge, not shown, according to the known technique. Alternatively, the fluid in the device is a liquid.

[0025] According to the present invention, provided between the forefoot chamber 3 and the heel chamber 4 is a central cavity 13 which accommodates a rigid insert 14. The central cavity 13 of the sole 1 is located in correspondence of the "vault triangle", and the rigid insert 14 functions at least as both a lever fulcrum for the sole 1 and a foot sole massage. The rigid insert 14 is made of a material more rigid than the rubber used for the sole 1.

[0026] The location of the bladders can be changed according to the needs or preferences of the person wearing the shoe according to the present invention. The set of expandable structures is arranged so that the massaging wave action created during the ambulation is always directed from below, i.e. from the back of the foot, upward to the ankle, then to the lower part of the calf, and finally to the upper part of the calf.

[0027] The following describes the operation of the footwear according to the present invention.

[0028] At each step the normal walking movement first

involves the support of the weight on the back of the foot carrying the weight, with the front part of the foot being lifted, and progressively the passage of the weight toward the front of the same foot. Finally the foot is completely unloaded and rises when it advances. This is a progressive action that can be schematically divided into four steps listed below. At the same time the weight is loaded on the other foot, where a sequence or distribution of loads similar to that described previously is repeated.

[0029] The invention takes advantage of this dynamic to perform, at each step, a dynamic pressure massage on the lower limbs according to a lifting or moving forward phase, a bearing initial phase, a bearing intermediate phase, and a bearing final phase.

[0030] In the lifting or moving forward phase, the foot is raised to advance, and the weight is loaded on the other foot. So the device is in idle state with both chambers of forefoot and heel in the extended original form. At this phase there is no squeezing action of the veins that also recover volumes and forms of rest. In the original form the inflatable bladders can be completely deflated or pre-inflated according to the desired setting. The pre-inflation is by means of valves placed in the cavities of the sole, for example with a 50 or 100 ml plastic syringe.

[0031] In the bearing initial phase, that is when the heel rests on the ground, the body weight is temporally loaded on the rear of the foot. Due to the weight the heel chamber is compressed and its volume decreases. The air contained therein flows to the inflatable bladder that thus increases in volume and provides a pressure massage to the veins located on the dorsum of the foot, on the ankle and in the sole of Lejars. The elasticity of the shoe upper fabric cooperates in adjusting the pressure on the venous system. The presence of isolated blisters containing gels that are compressed by the increase in volume allows a great match of the shoe upper to the ankle.

[0032] In the bearing intermediate phase, when the load is on the central insert, the weight passes from the heel part to the forefoot. Now, the insert, which has a great stiffness in the central part of the sole, exerts a pressure as a reaction to the load of the weight localized under the "vault triangle" helping to squeeze the foot deep veins (plantar veins). In this phase the heel chamber and its inflatable bladder begin to return to their original shape by reducing the pressure on the dorsum of the foot and on the ankle. The forefoot chamber starts to shrink.

[0033] In the bearing final phase, when the load is on the forefoot, the weight goes completely on the forefoot. Due to the weight the forefoot chamber is compressed and its volume decreases. The air contained therein flows towards the respective inflatable bladder, which thus increases in volume and applies an adjuvant effect (pressure massage) to the muscular squeezing of the veins placed in the leg and in the back of the knee. The elasticity of the shoe upper fabric cooperates in adjusting the pressure on the venous system. The possible presence of blisters containing gel that are compressed by the increase in volume allows a great match of the shoe upper

to the leg.

[0034] The mechanism described in the previous points is repeated alternately on the two lower limbs, carrying out a cyclic pressure massage on their venous systems.

[0035] The dimensions of the tanks in the sole, of the elastic bladders and of the elastic upper enable the implementation of squeezing pressures (pressure massage) between 18 mm Hg (corresponding to class 1 of elastic stockings) and 46 mm Hg (corresponding to class 3 of elastic stockings).

[0036] The inner surface of the device has "mesh pockets" facing towards the interior, positioned in correspondence with the expandable bladders. These pockets are in a large mesh synthetic fabric, in very thin wire, and are used to position, if required, "medicated non-adhesive strips" so as to prevent shifting during the ambulation. This device used with medicated non-adhesive strips would allow the percutaneous administration of drugs, which not only would be made for simple contact as in the normal pharmacological sticking plasters, but would be improved by the combined action of the massage pressure and the drug contact. When isolated bladders filled with heatable or coolable gel are used, a thermal effect is added. The medicated non-adhesive strips allow the use of drug formulations adaptable to the single patient or subject, and are devoid of sticky substances, which are often irritating or nagging for the patient, which is often also bearer of injuries or skin ulcers. The medicated non-adhesive strips are held in place thanks to the mesh pocket and the presence of small Velcro® strips that, when the medicated strips are not used, are covered by a band of canvas that is in contact with the leg.

[0037] Provided in the upper part of the device, in the superior frame of the shoe upper, is a small housing of about 3-4 cm x 3-4 cm. In this housing a small digital instrument powered by a small solar cell or a small lithium battery ("button" type) can be inserted. This instrument is a device counting steps (pedometer) and other parameters such as heart rate, the "pulse" and the total pressure exerted during the ambulation. Measurement data are visible on a small LCD display on the instrument. Since there are two instruments, the one for the right limb device and the other for the left limb device, the measurement data in the display will pertain to the single limb wearing that device. Therefore the comparison of measurement data pertaining to the right limb with those pertaining to the left limb will tell the doctor or the physiotherapist "how much" massage each of the two limbs has received, and other information useful to quantize the hemodynamics of the limb during ambulation and also will enable any dystonias or asynchronies of the gait to be highlighted. These instruments are supplied separately and can be positioned by the physician only if necessary, therefore they do not affect the price of the device in the basic version. In fact, for the daily use of the device it is not necessary to perform this functional measurement, which can be rather useful information to the doctor only

sporadically as a verification of the possible improvement of the patient.

5 Claims

1. A footwear provided with a device for pressure massage to the lower limbs, comprising a sole (1) and an upper (2), the sole (1) being provided with a forefoot chamber (3) and a heel chamber (4), each of said chambers communicating with respective fluid inflatable bladders (6, 10) through its flexible ducts (5, 9) in a manner adjustable from outside, inflatable bladders (6, 10) that are removably positioned within of the upper (2) and are flanked internally to respective isolated bladders (8, 11) being filled with gel and adapted to be in contact with parts of the body of the wearer of said footwear, **characterized in that** provided between the forefoot chamber (3) and the heel chamber (4) is a central cavity (13) housing a rigid insert (14) adapted to act as a lever fulcrum for the sole (1).
2. The footwear according to claim 1, wherein said forefoot and heel chambers (3, 4), the flexible ducts (5, 9) and the inflatable bladders (6, 10) contain a gaseous fluid.
3. The footwear according to claim 1, wherein said forefoot and heel chambers (3, 4), the flexible ducts (5, 9) and the inflatable bladders (6, 10) contain a liquid fluid.
4. The footwear according to claim 1, wherein said isolated bladders (8, 11) are connected removably to said inflatable bladders (6, 10).
5. The footwear according to claim 1, wherein said forefoot and heel chambers (3, 4) are adapted to alternately empty and fill during walking in order to produce a wave of massage through the action of pressure exerted by the weight of the body with a massaging effect directed from the bottom upwards with intensity and frequency proportionate to ambulation.
6. The footwear according to claim 1, wherein said isolated bladders (8, 11) filled with gel are subjected to heating or cooling depending on therapeutic requests.

Patentansprüche

1. Schuh mit einer Vorrichtung zur Druckmassage der unteren Gliedmaßen, umfassend eine Sohle (1) und ein Obermaterial (2), wobei die Sohle (1) mit einer Vorderfußkammer (3) und einer Fersenkammer (4) ausgestattet ist, wobei eine jede Kammer mit jewei-

ligen mit Fluid aufblasbaren Membranen (6, 10) durch deren Schlauchleitungen (5, 9) auf eine verstellbare Weise von außen kommuniziert, aufblasbare Membranen (6, 10), die entferntbar innerhalb des Obermaterials (2) positioniert und innenseitig neben jeweiligen isolierten Membranen (8, 11) angeordnet sind, die mit Gel gefüllt und ausgelegt sind, um mit Teilen des Körpers des Nutzers des Schuhs in Kontakt zu sein, **dadurch gekennzeichnet, dass** zwischen der Vorderfußkammer (3) und der Fersenkammer (4) ein mittlerer Hohlraum (13) bereitgestellt ist, in dem ein steifer Einsatz (14) untergebracht ist, der ausgelegt ist, um als Hebelpunkt für die Sohle (1) zu wirken.

2. Schuh nach Anspruch 1, wobei die Vorfuß- und die Fersenkammer (3, 4), die Schlauchleitungen (5, 9) und die aufblasbaren Membranen (6, 10) ein gasförmiges Fluid enthalten.

3. Schuh nach Anspruch 1, wobei die Vorfuß- und die Fersenkammer (3, 4), die Schlauchleitungen (5, 9) und die aufblasbaren Membranen (6, 10) ein flüssiges Fluid enthalten.

4. Schuh nach Anspruch 1, wobei die isolierten Membranen (8, 11) entferntbar mit den aufblasbaren Membranen (6, 10) verbunden sind.

5. Schuh nach Anspruch 1, wobei die Vorderfuß- und die Fersenkammer (3, 4) ausgelegt sind, um abwechselnd beim Laufen entleert und gefüllt zu werden, sodass eine Massagewelle durch die Druckwirkung erzeugt wird, die durch das Gewicht des Körpers ausgeübt wird, mit einem Massageeffekt, der von unten nach oben gerichtet ist, mit einer Intensität und Frequenz proportional zum Gang.

6. Schuh nach Anspruch 1, wobei die mit Gel gefüllten isolierten Membranen (8, 11) je nach den therapeutischen Anforderungen geheizt oder gekühlt werden.

chaussant, **caractérisé en ce qu'**une cavité centrale (13), logeant un insert rigide (14) adapté pour agir comme un point d'appui de levier pour la semelle (1), est prévue entre la chambre d'avant-pied (3) et la chambre de talon (4),

2. Article chaussant selon la revendication 1, dans lequel lesdites chambres d'avant-pied et de talon (3, 4), les conduits flexibles (5, 9) et les vessies gonflables (6, 10) contiennent un fluide gazeux.

3. Article chaussant selon la revendication 1, dans lequel lesdites chambres d'avant-pied et de talon (3, 4), les conduits flexibles (5, 9) et les vessies gonflables (6, 10) contiennent un fluide liquide.

4. Article chaussant selon la revendication 1, dans lequel lesdites vessies isolées (8, 11) sont reliées de façon amovible à ladite vessie gonflable (6, 10).

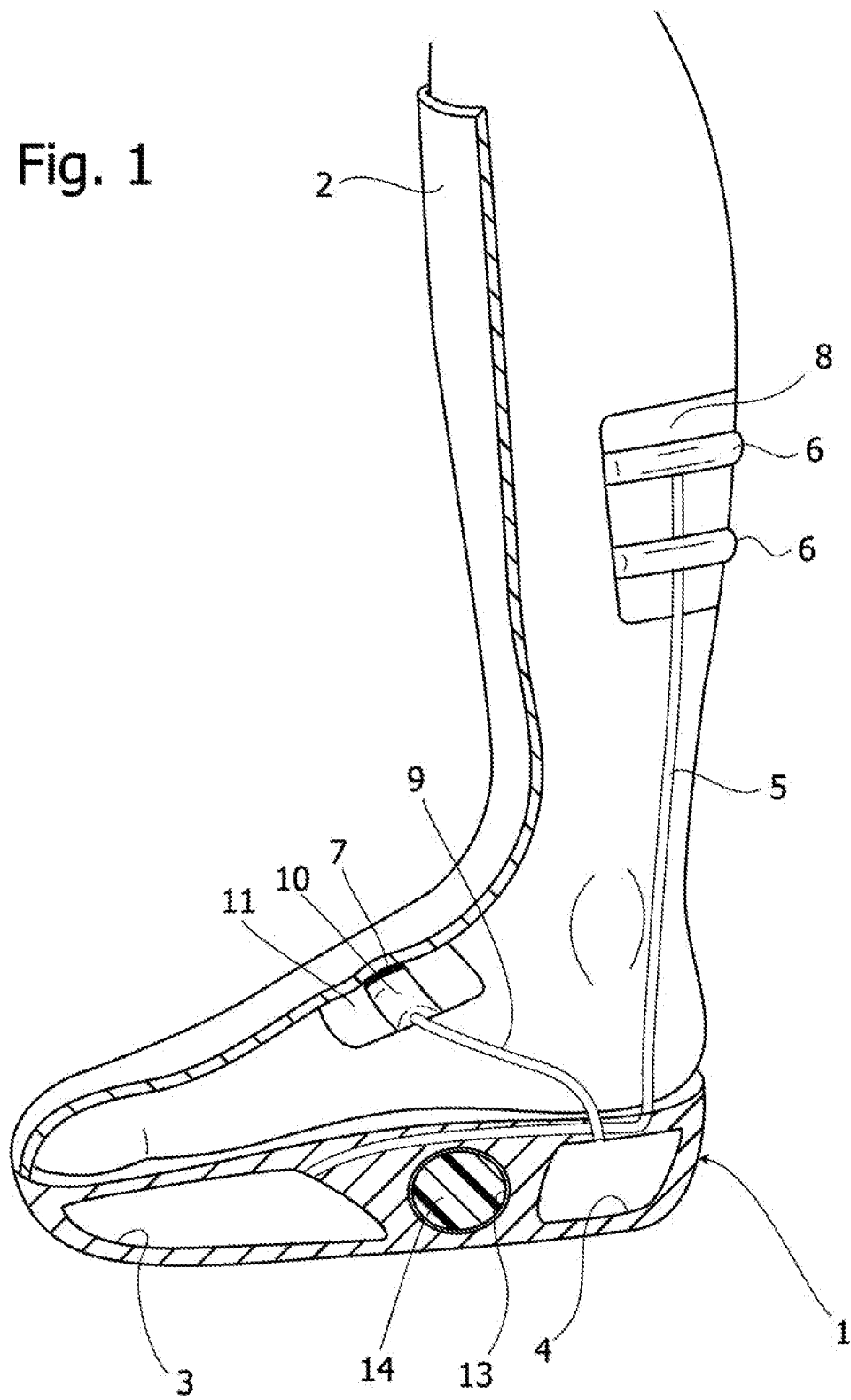
5. Article chaussant selon la revendication 1, dans lequel lesdites chambres de l'avant-pied et de talon (3, 4) sont adaptées pour se vider et se remplir alternativement pendant la marche afin de produire une onde de massage grâce à l'action de compression exercée par le poids du corps avec un effet massant orienté du bas vers le haut avec une intensité et une fréquence proportionnelles à la marche.

6. Article chaussant selon la revendication 1, dans lequel lesdites vessies isolées (8, 11) remplies de gel sont chauffées ou refroidies selon les exigences thérapeutiques.

Revendications

1. Article chaussant pourvu d'un dispositif de massage par compression sur les membres inférieurs, comprenant une semelle (1) et une tige (2), la semelle (1) étant pourvue d'une chambre d'avant-pied (3) et d'une chambre de talon (4), chacune desdites chambres communiquant avec des vessies gonflables de fluide (6, 10) respectives grâce à ses conduits flexibles (5, 9) de façon réglable de l'extérieur, des vessies gonflables (6, 10) étant positionnées de façon amovible à l'intérieur de la tige (2) et sont flanquées en leur sein de vessies isolées (8, 11) respectives étant remplies d'un gel et adaptées pour être en contact avec des parties du corps du porteur dudit article

Fig. 1



REFERENCES CITED IN THE DESCRIPTION

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