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(54) **Cushioning insole adjustment kit**

(57) Insole adjustment kit, the kit comprising an upper, elastic cushioning insole layer (101) and a lower, liquid filled insole layer (107) under the upper layer and at least one pocket (102,103) between the upper layer and the lower layer, the kit further comprising a number of inserts (104,105) dimensioned for insertion into the pocket, the inserts having mutually different degrees of hardness.

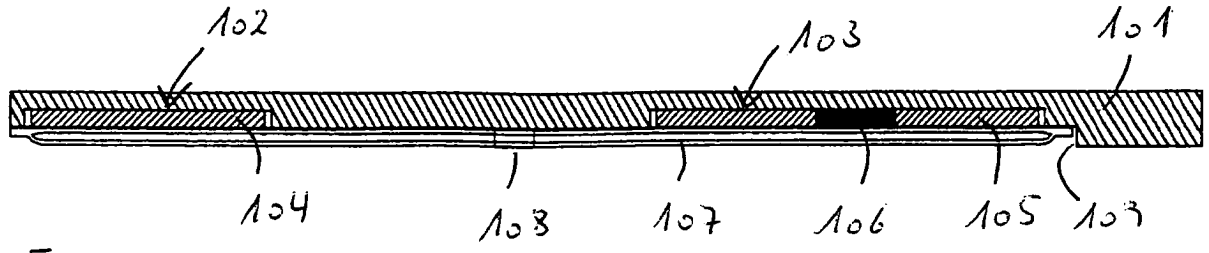

Fig. 1a

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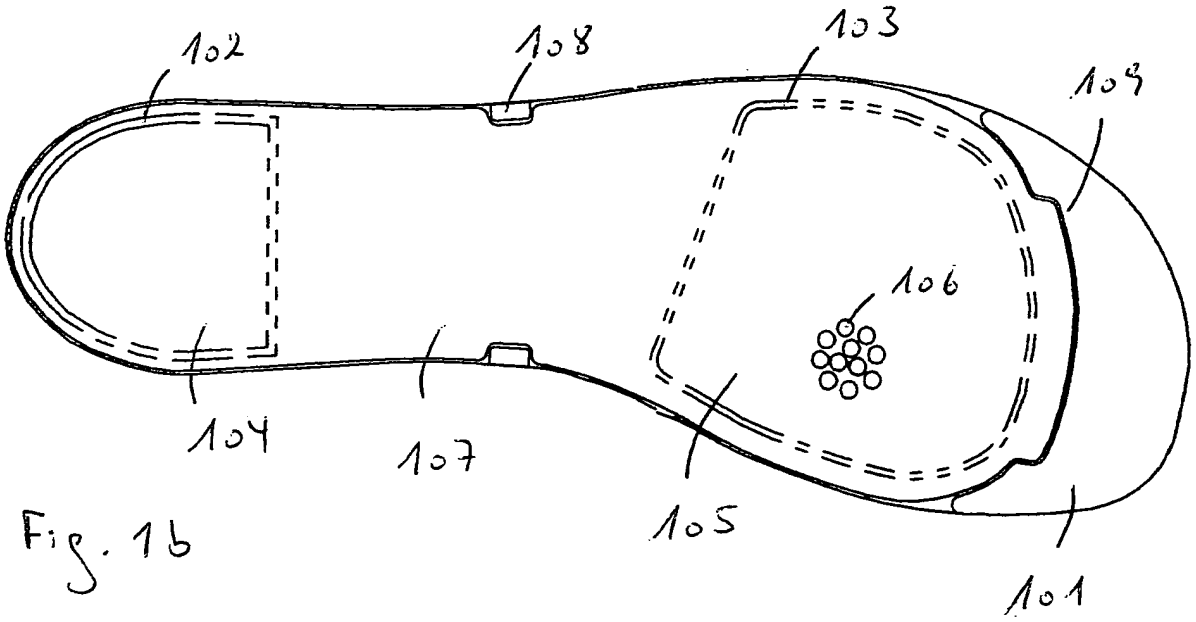

Fig. 1b

Description

FIELD OF THE INVENTION

[0001] The present invention relates to insoles with wound healing zones, predominantly for diabetes patients.

BACKGROUND OF THE INVENTION

[0002] Diabetes patients face a large risk to develop foot ulcers (decubitus) due to reduced blood circulation in the legs and the foot. Such wounds often lead to loss of job and social contact, and for the society it implies large costs. Investigations have shown that foot ulcers in the case of diabetics take on average 60 days to heal and with correspondingly large costs for wound healing medication and personnel during the healing period. Some wounds are not able to heal and develop in such a way that amputation of the foot or part of it is necessary. In Denmark, there are registered in the order of 10.000 open wounds among diabetics every year, and about 400 amputations are performed due to this cause.

[0003] US-patent No. 5,329,705 discloses a footgear with an inner sole having a grid of removable, resilient elements to provide relief to overloaded areas of the foot. The gear is all together a rather complicated boot-like structure only available at relatively high costs and impossible to integrate in a normal shoe. A like-wise system is disclosed in the US-patent application 2003/0212358 also having a boot-like appearance. These complicated structures illustrate the importance for diabetic patients and the society to reduce the risk for wound development and for healing the wounds most efficiently.

[0004] An improvement relatively to the rather bulky and uncomfortable above-mentioned boot-like structures is disclosed in the international patent application WO 02/34080 describing a custom foot bed device constructed using a curable substrate which is formed to the plantar surface of the foot except in the area occupied by spacers designated to off-load the wounds on the bottom of the boot. Though being an improvement on the general scale this kind of foot bed has disadvantages which will be more clearly from the following arguments.

[0005] The creation of wounds follows overload in the skin of the foot sole. This overload occurs when the pressure level multiplied by the time for this pressure level on a global area of the foot sole surpasses the carrying capacity of the skin itself. In order to prevent foot wounds, especially for diabetic patients, not only the reduction of the pressure is important, but also a reduction of the time for the load on the foot. When a local skin area under the foot experiences a continuing load, the blood circulation to this area is reduced, and the skin itself will die with time. For diabetic patients, the situation is critical, because diabetes, with time, reduces the blood circulation in the skin layer of the foot, such that even very small, local loadings can reduce the blood circulation in the skin itself at a rate that causes the cells to die. Often, this situation implies a delamination of the loaded skin layer, by which an inner cavity is created inside this skin layer. The skin cells below this cavity will be dead to a large extent, and the skin is loosing its flexibility. The result is, typically, a skin with small cracks, through which bacteria from the foot sole can get access into the hollow cavity in the skin. This leads to an inner inflammation in the skin with the result of a sudden open wound.

[0006] A further aggravation of the situation is the fact that diabetic patients often develop inflammation in the nerves (neoropathy) in the outermost ends of the nerves in the foot sole which reduces or entirely removes the feeling sensation. A normal feeling sensation in the foot sole automatically causes a person to change the position or the orientation of the body when a local area on the foot sole is subject to a critical load. This reduces the time of the loading and prevents overloading to lead to continuous damage of the foot. In contrast thereto, diabetic patients loose this automatic reaction pattern when the feeling sensation gets reduced or entirely removed due to nerve inflammation. The consequence for the diabetic patient is that the inflammation in the skin layers evolves without notice by the patient.

[0007] In order to relief certain areas where wounds are developing or have developed standardized, certain insoles have been developed. US-patent 5,768,803 discloses an insole having a bottom layer and a top layer where sections of the layers may be removed to create an empty space directly beneath a corresponding painful area of the foot. Even though this kind of insoles may prevent further pressure on a critical area under the foot, the remaining part of the foot is still exposed to the remaining load without any solution of a regulated time of this load, thus, further wounds easily develop on the other foot.

[0008] Prior art standardized insoles have not yet had success on the market, as they do not solve the problem with diabetic ulcers on the foot in a satisfactory way. Therefore, most of the pressures relieving insoles are, today, uniquely designed for each patient by orthopaedic or medical personnel. However, these individually constructed insoles have a number of disadvantages. For example, the time for manufacture of the insoles is long, the insoles are very expensive, insoles still do not reduce the loading time, the insoles typically reduce the blood circulation in the foot of the diabetic patient by fixating the foot, and the insoles are not manufactured in collaboration with the personnel that controls the skin of the patients foot, which makes the correct continuing adjustment of the insole difficult. On top of this, most of the individually adjusted insoles are constructed in a way to change the point of load, for example, by moving the load from the heel and the forefoot to the middle of the foot. The result is a fixation of the foot with unwanted reduced blood circulation, and, often, the hip and the bag are loaded in an unsuitable way.

DESCRIPTION / SUMMARY OF THE INVENTION

[0009] It is, therefore, the purpose of the invention to provide an insole for support of painful foot areas that is easy and fast to adjust in accordance with the needs of the patient and which can be provided at low cost. This purpose is achieved by an insole adjustment kit comprising an upper, elastic, cushioning insole layer and a lower, liquid filled insole layer under the upper layer and at least one pocket between the upper layer and the lower layer. The kit further comprising a number of inserts which are dimensioned for insertion into the pocket. The inserts have mutually different degrees of hardness.

[0010] An insole adjustment kit according to the invention has a number of advantages. First of all, the different number of inserts allows an individual adaptation to the needs of the user. Harder or softer inserts may be used in order to distribute the load on the foot over a larger or a smaller area. The liquid filled insole, typically filled with water, is constructed such that, during load, a hydraulic pressure is provided under the foot.

[0011] This hydraulic pressure reduces the pressure load on the foot sole by distributing the pressure over a bigger area. In addition, the liquid filled insole under the foot of the patient causes relatively large movements of the foot, even during very small changes of the point of gravity of the diabetic patient. As a consequence, the critical kind of load on exposed local areas on the foot is reduced, which is especially important if the diabetic patient has neoropathy.

[0012] The cushioning upper layer and the inserts with adoptable cushioning inserts provide a three dimensional surface against the foot sole, when the foot is standing on the insole, which results in a larger supporting surface and a pressure equilibrium. Furthermore, this three dimensional supporting surface acts on the liquid filled layer, such that the pressure from the foot is distributed over an even larger area, resulting in a relief of the load against the foot sole, which is much larger by this combination than the sum of the pressure relief by the cushioning upper layer, the inserts or the liquid layer alone.

[0013] Preferably, the upper or the lower layers are both dimensioned to extend over the entire sole of the foot. This is, however, not strictly necessary, especially, if only part of the foot is desired to provide a pressure relief. Typically, the pocket is positioned under the forefoot, where a large part of the pressure is experienced, or under the heel of the foot, or under both depending on which area is desired to be relieved. If there are wounds both on the forefoot and on the heel, an insole according to the invention may still be of great help, even though the pressure from the heel is transferred to the forefoot and the pressure from the forefoot to the heel. The reason for this is that the steady movement of the liquid from the forefoot to the heel and back changes the pressure in the wounded areas continuously, such that blood circulation is rather promoted than prohibited.

[0014] The pocket may also be placed in the middle of the foot with openings towards the sides of the sole. This may be used for establishing protection especially at the inner and outer side of the middle part of the foot, a location causing problems especially for heavy weight people.

[0015] As a conclusion, an insole according to the invention has a number of advantages. First of all, the pronounced pressure equalisation over a larger area has the effect of pressing relief in the skin, which eases the blood circulation. Secondly, the liquid filled layer increases the movement of the foot and the time of load is reduced in this way. In addition, the increased movement of the foot increases the blood circulation in the foot on a general basis, such that the entire insole according to the invention has a substantially prophylactic effect.

[0016] When pre-states of wounds occur under the foot of diabetic patients, it is of utmost importance that a pressure relief is performed immediately and that the relief can be adjusted individually by competent personnel, in dependence of the skin of the foot sole. Therefore, the system according to the invention is designed in a way that the inserts are part of the kit and have different hardness with corresponding cushioning properties.

[0017] In a practical embodiment the pocket is provided as a recess extending into the underside of the upper layer. The depth of the recess is less than the height of the upper layer, such that the recess only extends partly into the upper layer and there is still a part of the upper layer covering the recess.

[0018] The inserts are dimensioned to fit into the pockets, but may have a thickness that is less than the pocket in order to combine different inserts into the same pocket. For example, the inserts may be dimensioned for insertion of a first insert with a lower hardness than a second insert that is placed underneath the first insert. In this case, the insole adjustment kit according to the invention provides the possibility of a great variation of adjustment in accordance with a need of a foot of a diabetic patient or other kind of patient with pre-states of wounds under the foot.

[0019] In order to achieve a pronounced relief of pressure on a certain area under the foot, the inserts may be provided with a region under the specific risk area for sore, where the compression resistance is lower than in the rest of the insert. Such a reduced compression resistance can be provided by a perforation through the insert. A perforation in the insert is easily provided by the medical or orthopaedic personnel during the adaptation of the insole to the specific skin conditions of the foot of the patient.

[0020] In order to optimize the pressure relieving properties of the liquid filled insole, the pocket may be filled with a first, upper insert and a harder, lower insert, where the second, lower insert has a lateral extension less than the first insert. The hard, second insert may be provided with a lateral extension that is adapted to exert a pressure on the underlying liquid filled insole to a correct degree as estimated or calculated by the orthopaedic or medical

personnel during adaptation of the insole. Such an estimation or calculation may require some kind of experience by the personnel, but once this experience has been gained, the kit according to the invention contains the equipment necessary for providing an insole within a very short time, for example within an hour or less, which is almost immediately after consultation of an expert by the patient searching pressure relief. This minimises damage to the skin of the foot and prevents possible sore creation and a later risk for a final amputation.

[0021] Instead of a perforation, the area of the sole may be entirely relieved by providing a hole in the insert. Thus, the region of the foot with the risk for a sore would only experience a very light pressure of the upper layer, which is pressed into the hole of the insert and where the insert presses upon the liquid layer creating a pressure equalisation over a larger area without exerting pressure on the sore.

[0022] The upper layer may suitable be provided by a polymer foam, for example expanded ethylene-vinyl-acetate.

[0023] Liquid filled layers may be provided by production methods as described in International patent applications WO97/03583, WO01/08523, WO02/28216, WO01/08523 by Vindriis.

SHORT DESCRIPTION OF THE DRAWINGS

[0024] The invention will be explained in more detail with reference to the drawing, where

- FIG. 1 illustrates an insole according to the invention, a) is a cross section and b) is a view from the underside,
- FIG. 2 a) - d) shows different inserts,
- FIG. 3 illustrates an insole with a laterally small insert above a large insert, a) is a cross section and b) is a view from the underside
- FIG. 4 illustrates an insole with pockets of different heights, a) is a cross sectional view of a first embodiment, b) is a view from the underside, and c) is a cross section of a further embodiment,
- FIG. 5 illustrates an insole with an insert under the middle of the foot.

DETAILED DESCRIPTION / PREFERRED EMBODIMENT

[0025] FIG. 1a is a cross sectional view of an insole from a kit according to the invention. The upper layer 101, for example suitably made of polymer foam, has a first pocket 102 and a second pocket 103 between the upper layer 101 and a lower, liquid filled layer 107. The liquid filled layer may be made of two plastic sheets welded at the borders to provide a closed cavity filled with liquid, typically water.

[0026] The pockets 102 and 103 are provided as recesses in the upper layer 101. Inside the pocket 102 under the heel area, an insert 104 has been provided. In the pocket 103 under the forefoot, an insert 105 has been provided which has a perforation 106 in order to provide less pressure against the foot sole than the area surrounding the perforation 106.

[0027] As it appears in greater detail in FIG. 1b, the lower, liquid filled layer 107 is situated between fixation elements 108 and 109 in order to prevent that the lower layer 107 slides relatively to the upper layer 101. After insertion of the inserts 104, 105, the lower layer may be glued on the inserts 104, 105 and the upper layer 101 in order to achieve a proper final fixation ready for use.

[0028] FIG. 2 illustrates a number of different inserts 105. The first insert in FIG. 2a has a perforation 106 for pressure reduction against the foot sole in the area of the perforation 106. In order to reduce the pressure against the foot sole even further, a hole 201 through the insert may be provided. In a further development, a combination of holes and perforation pattern may be provided, for example as illustrated in FIG. 2c with a perforation 203 surrounding a larger hole 202. In FIG. 2d, a likewise arrangement of an insert 105 with a hole 205 and a perforation 206 surrounding the hole is illustrated. However, in this case, the perforation 206 and the hole 205 are provided in an area, where the insert 105 has a region 204 with a softer material than the remaining part of the insert. These drawings illustrate the multiple possibilities in adjustment of an insole for a diabetic patient by a simple kit according to the invention.

[0029] FIG. 3 illustrates an insole, where the heel insert 104 and the forefoot insert 105 are each provided with a hole 303 and 301, respectively. Under the first insert 105, a second insert 302 is provided, where the lateral dimension of the second insert is smaller than the lateral dimension of the first insert, the first insert 105 having a lateral extension corresponding to the lateral extension of the pocket 103. The smaller, second insert 302 is a thin, flexible and relatively hard plate for distributing pressure from the upper, softer insert 105 over a larger area on the liquid filled, lower layer 107.

[0030] FIG. 4 illustrates an insole with an upper layer 401, in which the recess 403 in the forefoot region is deeper than the recess 402 in the heel region. Among the inserts 404 and 405, only the insert 405 in the forefoot, as illustrated in FIG. 4a and 4b is provided with a hole 406. In addition, a small, pressure distributing plate 407 is provided in the pocket 401, the pressure distributing plate 407 having a lateral dimension larger than the lateral extension of the hole 406.

[0031] In FIG. 4c, the recess 403 in the forefoot region is filled with two inserts 408 and 410, each insert having a hole 409, 411, where the hole in the upper insert is smaller than the hole in the loser insert, resulting in a gradual pressure on the foot sole around the hole. In addition, the hardness of the two inserts 408 and 410 may be different.

[0032] As it appears from the foregoing, a kit for an

insole according to the invention provides an advantageous system with many degrees of freedom, yet easily and quickly adjusted. The benefit for the patient is an almost immediate relief, whereas the benefit for the society is reduced costs for treatment at a later stage, where medication and surgery is necessary if the potential damages are not prevented by immediate action at an early stage.

[0033] For heavy weight people, there is a substantial risk that the feet sink down and thereby gets flat-footed. The reason is not well established, but it is believed that reduced blood circulation has influence on this phenomenon. In this case, it may be relevant to use an insert 501 under the middle part of the foot, which is illustrated in FIG. 5, showing an insole 500 formed after the flat foot of an overweight person. In the figure, three inserts 501, 502 and 503 are illustrated, each insert adapted to the needs and cushioning effect desired for the specific person. The inserts 501, 502, 503 may be provided with different perforations or holes in accordance with the needs of the patient and as explained in the foregoing in connection with inserts.

[0034] Inserts may be inserted into the upper, cushioning insole from the underside of the upper cushioning insole. However, if a more flexible solution is desired, there may be provided access to the pockets from the side of the upper part. For example, there may be provided access to the front pocket under the forefoot from the front of the insole. Likewise, there may be provided access to a heel pocket from the back of the insole or from the side of the insole. For the middle insert, there may be provided access from the side of the insole.

[0035] During assembly of an insole from an insole kit according to the invention, the inserts may be placed directly in the pockets with access from the underside of the upper part. Then, the lower, liquid filled part is glued, welded, or otherwise fastened to the upper part of the insole. By using accesses to the pockets from the sides, inserts may be exchanged on demand even after assembly of the insole. For example, the combination of a plurality of inserts in one pocket may be amended during change of conditions for the foot, for example during healing, which makes the kit according to the invention even more flexible.

Claims

1. Insole adjustment kit, the kit comprising an upper, elastic, cushioning insole layer and a lower, liquid filled insole layer under the upper layer and at least one pocket between the upper layer and the lower layer, the kit further comprising a number of inserts dimensioned for insertion into the pocket, the inserts having mutually different degrees of hardness.

2. Insole adjustment kit according to claim 1, wherein the upper or the lower layer or both are dimensioned to extend over the entire sole of the foot.

3. Insole adjustment kit according to claim 1 or 2, wherein a pocket is positioned under the heel of the foot.

4. Insole adjustment kit, wherein a pocket is located under the middle of the foot.

5. Insole adjustment kit according to any preceding claim, wherein the pocket is a recess extending into the underside of the upper layer, the depth of the recess being less than the height of the upper layer.

6. Insole adjustment kit according to claim 5, wherein a pocket is accessible from the side of the upper layer.

7. Insole adjustment kit according to any preceding claim, wherein at least one of the number of inserts has a region where the compression resistance is lower than in the rest of the insert.

8. Insole adjustment kit according to claim 7, wherein the region comprising a perforation through the insert

9. Insole adjustment kit according to any preceding claim, wherein at least some of the number of inserts are dimensioned for insertion of at least two insert into the pocket.

10. Insole adjustment kit according to claim 9, wherein the two inserts are dimensioned for insertion of a first insert above a second insert, wherein the first has a lower hardness than the second insert.

11. Insole adjustment kit according to claim 9 or 10, wherein the second insert has a lateral extension less than the first insert.

12. Insole adjustment kit according to claim 9, 10, or 11, wherein the first insert has a first region where the compression resistance is lower than in the rest of the first insert, wherein the second insert has a second region where the compression resistance is lower than in the rest of the second insert, the first and the second regions have different dimensions and an at least partly overlap.

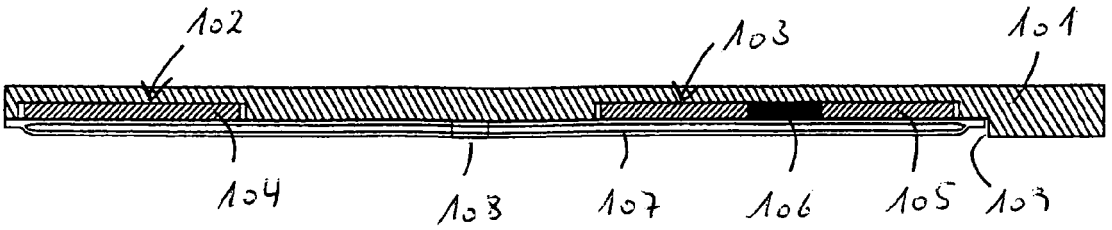
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Fig. 1a

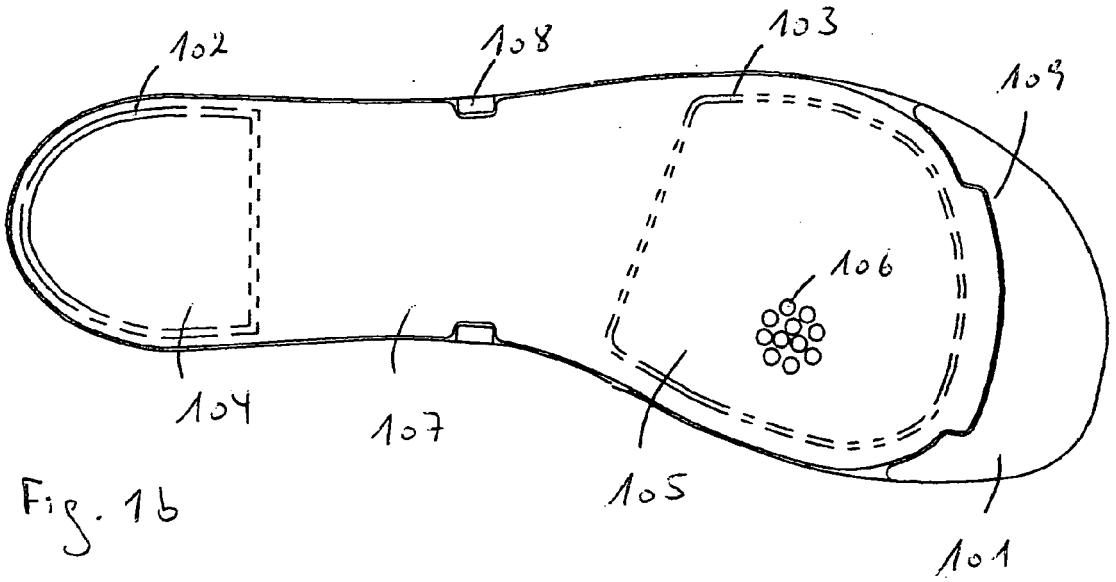
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Fig. 1b

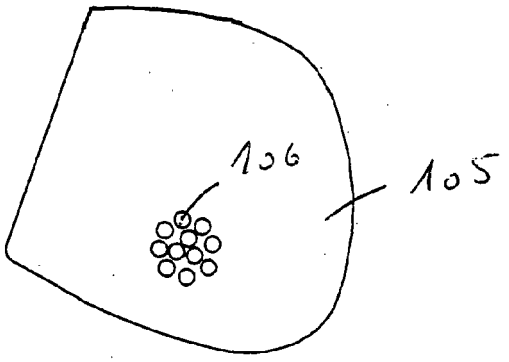

Fig. 2a

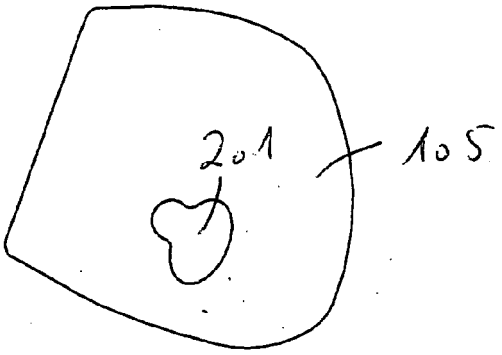

Fig. 2b

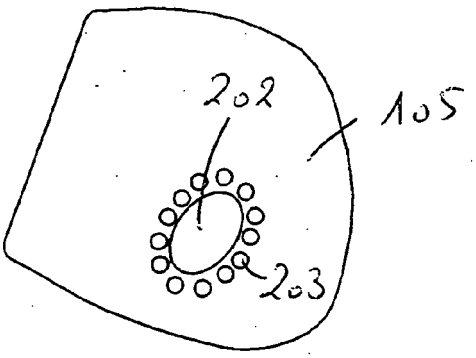

Fig. 2c

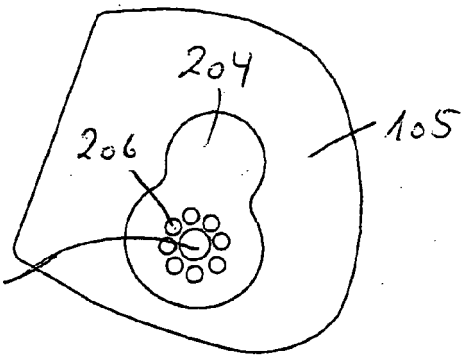

Fig. 2d

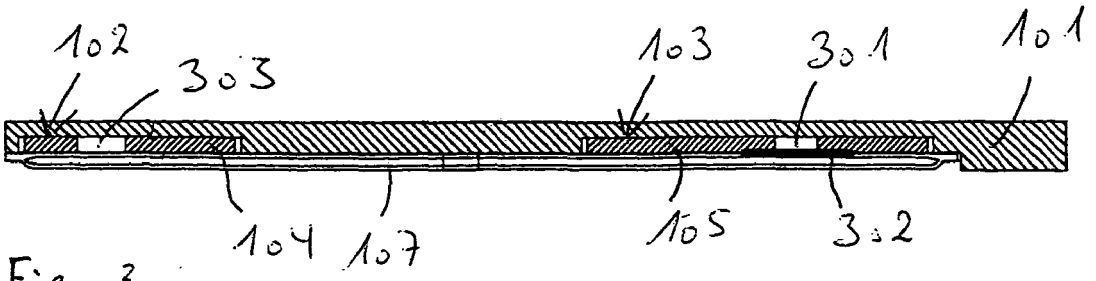
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Fig. 3a

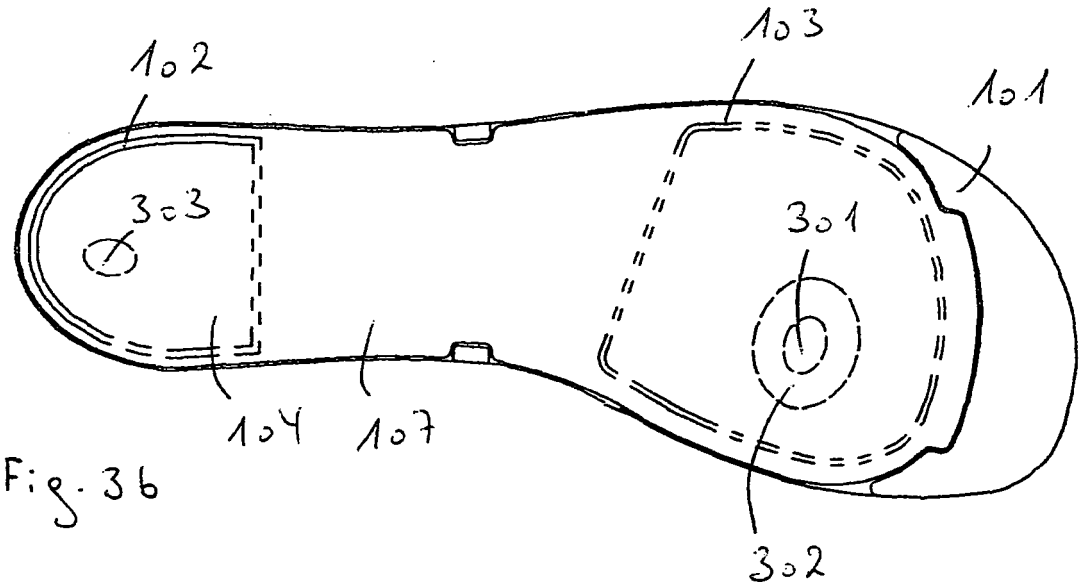
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Fig. 3b

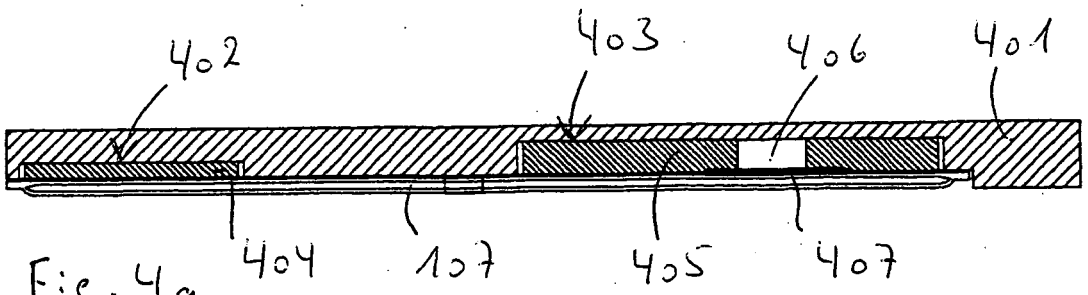

Fig. 4a

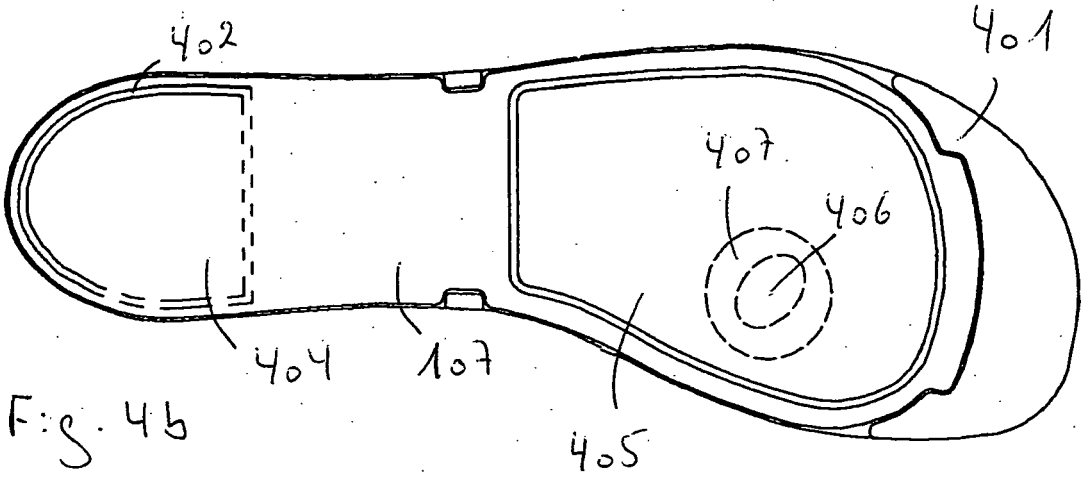

Fig. 4b

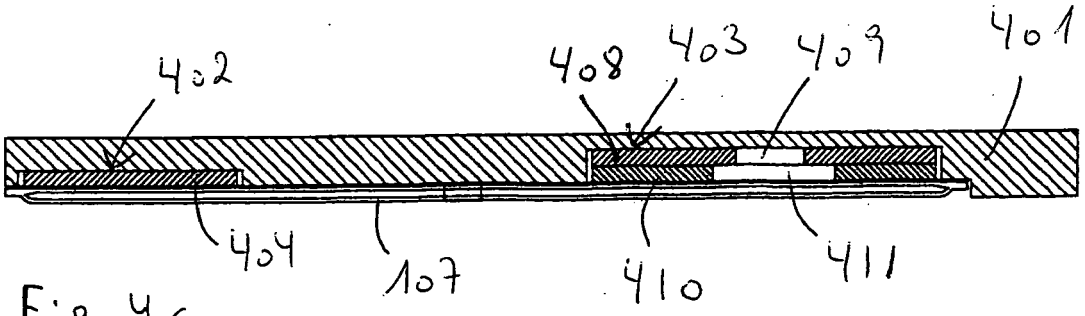

Fig. 4c

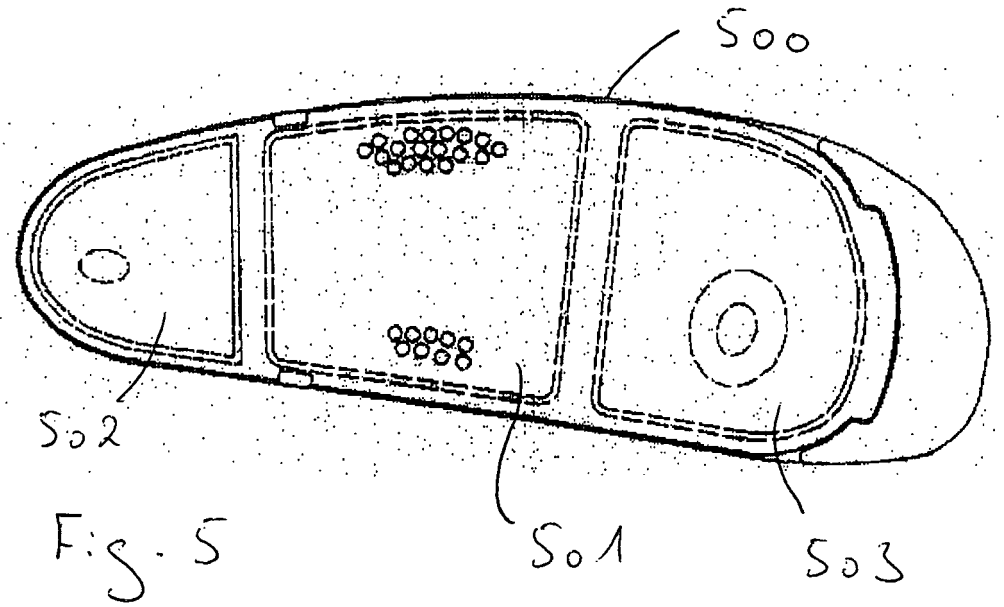

Fig. 5

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 06 01 7513

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X Y	US 6 000 147 A (KELLERMAN DAVID [US]) 14 December 1999 (1999-12-14) * column 5, line 28 - line 55 * * column 9, line 8 - column 11, line 58; figures *	4 1-3,5-12	INV. A43B17/02 A61F5/14
Y	US 2004/168354 A1 (NGUYEN HIENVU CHUC [US]) 2 September 2004 (2004-09-02) * abstract * * paragraph [0001] - paragraph [0003] * * paragraph [0010] - paragraph [0039]; figures *	1-3,5-12	
X A	WO 2006/035469 A2 (DIOMEDI RICCARDO [IT]; MARTORELLI EROS [IT]) 6 April 2006 (2006-04-06) * page 4, line 2 - page 8, line 9; figures *	4 1-3,5-12	
X Y	WO 02/05672 A (KELLERMAN COMPANY LLC [US]) 24 January 2002 (2002-01-24) * page 19, line 18 - page 20, line 14; figures 15a-15c *	4 1-3,5-12	TECHNICAL FIELDS SEARCHED (IPC) A43B A61F
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	25 January 2007	Schölvinck, Thérèse

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 06 01 7513

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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