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(54) **New footwear that improves the stability of pes valgus and healthy feet in infancy**

(57) This footwear was designed to correct foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, using a sole (3) of a non-abrasive material, principally in the area of the heel, to ensure that the geometric shape does not change with continuous use, with a central track of a lower density than the rest of the sole,

a high density footbed (6), comprising a cardboard footbed (7) and a cup (1), that consists of a hard part in the form of a channel, integrated in the shoe in the upper part of the sole (3) and aimed at guiding the footsteps, and a removable insole (4) made from a low density mouldable material, so that the whole shoe counteracts the typical rolling of the foot in pes valgus in the inside of the heel.

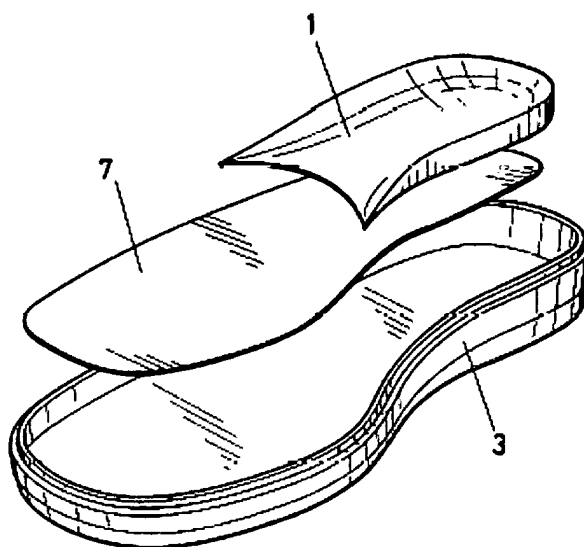


FIGURE 5

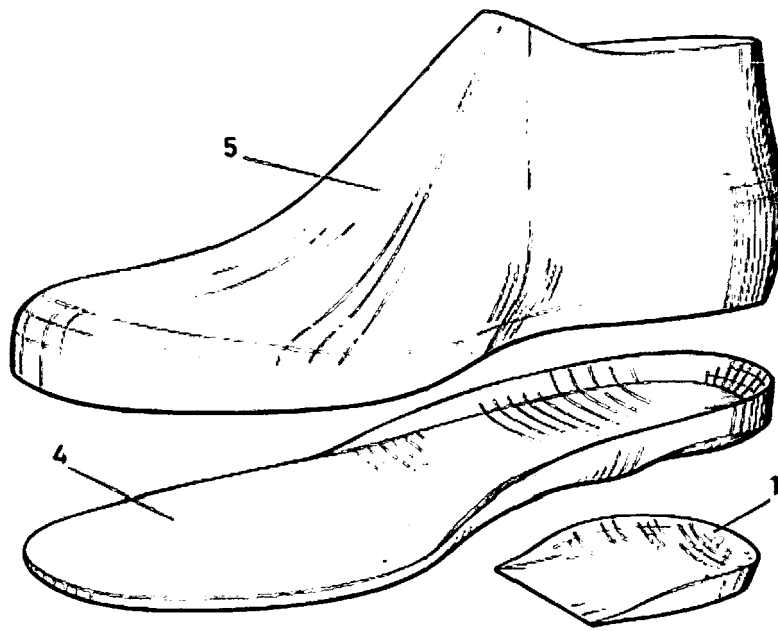


FIGURE 6

Description**Purpose of the invention**

[0001] This invention is aimed at providing new footwear for children that helps to prevent the appearance of certain pathologies. Specifically, it develops a system to correct foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology. However, it also aims to provide this new footwear with suitable characteristics, according to the functional needs and comfort of children when walking.

History of the invention

[0002] As it grows, the foot goes through a series of stages of development, that need to be recognised in order to identify what is normal and what is pathological at any given time. The footwear worn by children at each of these stages of development can have a critical effect on its development. In general, footwear should protect against aggression from the environment in which a child develops, safeguarding their physical and motor development. At the same time, it should provide thermal and mechanical comfort, while ensuring that it performs its function without causing lesions or damage, promoting normal growth and development. Footwear should also allow the child to feel the ground, so as to promote sensory stimulation, proper development of the nervous system and improved balance.

[0003] At birth and around the age of one year, the foot is mostly comprised of cartilage, and vulnerable to any external aggression. As a result, when the child starts to take his or her first steps, it is very important to prevent excessive weight, and to help the foot by using suitable footwear that controls the position of the heel, without restricting the toes too much.

[0004] The most critical stage in a child's musculoskeletal and neurological development is when he/she starts to walk, at between 10 and 18 months. This is the period when they attempt to achieve verticality, when almost anything is possible when it comes to supporting the body, and what may be nothing more than a transition towards "normality" should not necessarily be viewed as pathological. Some children fall frequently, others stand with their foot pointing inwards, others point their feet outwards, etc. Furthermore, at this stage the physiological transition from Genu Varum ("bowleggedness") to Genu Valgum ("x-shaped legs") takes place, and vice versa, until the muscles of the feet strengthen. This also has repercussions on the means of supporting the feet. There is also an increase in the plantar fat pad of the arch or inner arch, which can give the appearance of a false flat foot. In light of all of the above, it is very difficult to talk about flat footedness or Genu Valgum, which tend to be false problems, often exacerbated by maternal worry and mothers being kept more or less uninformed by one or more doctors. From one to 4 years the child gradually improves his/her balance and acquires experience on how to stay standing and walk. From this moment, the muscles begin to exercise themselves, gradually hardening the ligaments and the bones until the arch is practically formed, and the foot adopts the characteristic form of an adult foot. Until the age of 7, the child's gait matures until it has acquired the adult pattern, and finally, from 7 to 14 years, the child increases his/her physical activity considerably.

[0005] However, many children still present with weak ligaments at 4 years. As a result, these children do not have a fully formed arch and occasionally the talotibial joint is not in line with the vertical axis. In this case, we say that the child is presenting with pes valgus because of weak ligaments that do not allow the foot's structure to be tightened in order to line it up, making its basic function of support to be fulfilled.

[0006] Depending on the gravity of the situation, various solutions are applied, from exercises aimed at strengthening the muscles, to walking on tiptoe, to the use of suitable orthopaedic insoles, to surgical treatment (only in approximately 5% of cases). For example, we know of document WO 90/05504, which describes a method of manufacturing a plaster of Paris insole to correct pes valgus by controlling the front, middle and back of the foot. Document WO 00/15163 also describes a device designed to correct pes valgus, consisting of a sort of brace that corrects the position of the big toe.

[0007] This invention, however, is not designed for use with the user's footwear. Instead, it uses specially adapted footwear for the correction of pes valgus. The internal system cannot move about within the footwear, thereby preventing unwanted internal postures and deformities that could have a negative effect on the foot. It remains perfectly in place and adapted to the shape of the foot, without squashing it. It also adapts to the movements of the foot, providing a stable gait with no need to exert unnecessary pressure. Another of the fundamental characteristics of the invention consists of adapting the last of the shoe, ensuring that it fits the shape of the foot perfectly, preventing looseness in the heel area that could lead to instability, while nevertheless allowing the toes to move freely.

Description of the invention

[0008] The footwear we suggest to improve the stability of pes valgus and healthy feet in children consists of a system to correct the movement of the feet in children with a slight tendency to walk with their heel facing outwards, also known as pes valgus, ensuring the characteristics and functional needs to provide comfort for children when walking. It is important to stress that the footwear is designed to have an effect on subjects with only a slight tendency towards pes

valgus, but who clearly present with the pathology. It can be used in healthy subjects, without having any negative effect on them. However, if used in subjects with marked pes valgus, while it will improve their gait, there is no proof that it will cure the pathology.

[0009] The development of the footwear was based on a series of tests and analyses that are presented below.

[0010] Firstly, in order to develop the project, it was necessary to characterise the gait pattern, i.e. we needed to determine the scientific basis required to establish the needs of the infant population in terms of footwear to correct the gait pattern in children with a tendency to develop pes valgus in healthy feet. To this end, the gait pattern of 35 children aged between 2.5 and 11 years was analysed. The criterion used to choose the subjects was to cover the age range of the different stages of maturity of gait (1-4, 4-7 and 7-11 years), and to use both healthy subjects and subjects with pes valgus.

[0011] Different types of testing were carried out in order to characterise the gait pattern, based on analyses of foot pressure when bare or wearing shoes. Firstly, in order to obtain the distribution of plantar pressure while walking with shoes on, instrumented insoles were used. A shoe that would interfere as little as possible with the natural gait pattern of a child was chosen. Every child walked three times straight through a special area, and the plantar pressure between the foot and footwear was measured to find the characteristic plantar register for each child. Secondly, in order to complete the information characterising the distribution pattern of plantar pressure, records were obtained from the same sample of children walking barefoot, using a pressure platform. Two types of assessment were carried out: firstly, as with the test using shoes, the children were asked to walk straight through an area designed for the purpose, and the plantar pressure between foot and floor was measured, with three repetitions per child. The children were then asked to stand with their feet still on a platform, to register the pressure in the standing position.

[0012] Secondly, after characterising the gait pattern, the morphology of the childrens' feet was analysed, to determine the development of the foot at ages between 2.5 and 11 years of age. These data were subsequently used to define the last and insoles of the children. The basis for this was an analysis of records from the morphological database of Instituto de Biomecánica de Valencia (Valencia Institute of Biomechanics), which we completed by adding 3D digitisation of the foot of the children, using a digital scanner. The tests in this phase were carried out at the same time as the gait pattern tests, using the same children.

[0013] Thirdly, with the data collected from the characterisation of the gait pattern and the morphological analysis, the process of developing pes valgus was characterised, as was the influence that footwear has on this. This phase included two stages:

a) Clinical diagnosis. A clinical diagnosis was carried out to determine whether or not the children involved in the study presented with pes valgus, supported by the visual analysis carried out during the testing and the analysis of the plantar pressure records for bare feet. As a result of this analysis, the children were classified into three types in relation to pes valgus: healthy, valgus and undefined. The subjects were then divided into three stages:

■ Stage 1: 2 to 5 years. Practically all of the children presented with one pes valgus, due to weak ligaments caused by the immaturity of the structures. At this stage it is impossible to tell whether a child is going to develop the pathology or not, except for some very extreme cases, which places them outside the scope of the project, in any case.

■ Stage 2: 6 to 7 years. This age range corresponds to the end of the stage of maturity of gait, in which its pattern starts to be defined. There was a balance between healthy children and those with pes valgus. This is where the pathology might start to develop or the structures start to harden and the muscles to strengthen. This age range is therefore of particular interest when correcting the gait pattern associated with this pathology.

■ Stage 3: 7 to 12 years. The majority of the children presented with the pathology or were healthy, with the latter being the largest group. At this stage, it is already clear whether or not a child has developed the pathology. This stage is when a child starts to increase their activity. It would therefore be interesting to use footwear to correct the gait pattern of children with pathological tendencies.

The results obtained from the clinical diagnosis were as follows:

Child	Age	Weight	Foot size	Pathology
31	2,5	18	25	valgus-healthy
2	2,5		24	valgus-healthy
22	2,5	12	23	valgus
19	2,5	18	26	valgus
8	3,0	19	27	valgus-healthy

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(continued)

	Child	Age	Weight	Foot size	Pathology
5	20	4,0	25,4	28	valgus
	16	4,0	16	26	healthy
	4	4,0	21		valgus-healthy
	6	4,5	17	27	valgus-healthy
10	28	5,0	24	31	valgus
	33	5,0	25	31	valgus
	10	5,0	19	30	valgus
15	29	5,0	19	29	valgus-healthy
	17	5,0	16	28	valgus
	34	5,0	19	28	valgus
	24	6,0	22	31-32	healthy
20	30	6,0	33,5	34	valgus
	13	6,0	31	33	healthy
	5	6,0	21	30	valgus-healthy
25	25	6,0	18	29	valgus
	32	6,5	25	32	healthy
	18	6,5	2	31	valgus
	14	7,0	42	35	valgus
30	7	7,0	39	34	healthy
	15	8,0	35	34	healthy
	1	8,0	30	33	valgus
35	26	8,0	30	33	valgus
	21	8,0		32	valgus-healthy
	12	9,0	34	34	healthy
	23	9,0	24	32	healthy
40	11	10	38	38	healthy
	9	10	30	34	healthy
	35	11	40	39	healthy
45	3	11	43	39	valgus
	27	11	40	36	healthy

We concluded the following from the analysis:

- From 2.5 to 5 years of age, the majority of children presented with pes valgus.
- From 6 to 7 years of age, approximately half of the children presented with pes valgus.
- From 8 years of age, only some of the children developed the pathology.

We can therefore deduce that the critical stage for preventing pes valgus is between 5 and 7 years of age, when the muscles and structures are still strengthening. It is during this stage that efforts to correct the standard gait of children with pathological tendencies should focus.

b) Biomechanical analysis. Secondly, the data obtained from the tests using footwear were analysed from a biomechanical

viewpoint. After dividing the data into the three stages and assessing the results, we came to the following conclusions: In Stage 1, at 2.5 to 5 years, it was almost impossible, from a biomechanical viewpoint, to distinguish between healthy children and those with pes valgus, based on the data obtained from tests using footwear. However, at Stage 2, between the ages of 6 and 11 years, clear differences were seen between healthy children and those with pes valgus. These differences are apparent from a comparison between the average maximum pressure produced when walking and the standard distribution of plantar pressure. There are different maximum values in the group of valgus children for the forefoot and the hindfoot. In the hindfoot, there were significant differences in distribution and, above all, in the magnitude of the pressure registered, with valgus children showing lower pressure, also centred in the middle of the footstep. In the forefoot, there were differences in the distribution of pressure, which was more concentrated and displaced to the lateral area of the footstep in children characterised as valgus.

There were also significant differences when comparing the gait pattern in healthy and valgus children from 6 to 11 years. At the moment of contact with the floor, valgus children were seen to make contact with greater intensity. As full support is produced, the transfer of pressures to the forefoot takes place without developing the mechanism that raises the plantar; therefore the forefoot is supported practically without passing through the area between the forefoot and hindfoot. Finally, during the impulsion phase, children with pes valgus tend to compensate the rolling of the foot towards the medial area, by pushing harder on the lateral side of the forefoot. In general, this behaviour is justified by a weakness of the structures in children with pes valgus, which makes the foot much less efficient in completing its functions of support and propulsion, with the resulting variation in gait pattern.

[0014] All of the information gathered from the tests described above were used to develop the design criteria, taking into account not only the general criteria of comfort and health, but also the fact that children with slight tendencies to develop pes valgus require footwear that is capable of correcting the gait pattern, in order to prevent the development of pes valgus. Footwear needs to support the correct development of the gait pattern without interfering in a negative manner.

[0015] The geometric shape of the surface of footwear that comes into contact with the sole of the child's foot is therefore defined, in order to correct the gait pattern. A geometric shape was formed for the sole, footwear and insole, in the form of a channel aimed at guiding the child's footstep, facilitating the correct distribution of dynamic pressures, but not impacting negatively on its development. This geometric shape counteracts the typical rolling of the foot with pes valgus onto the inside of the heel, guiding it so as to achieve uniform support for the heel area, as seen in healthy children. The shape is also designed so as not to interfere with the development of the gait pattern in healthy children, since they develop a different footfall that is already in line with the geometrically established pathway, therefore not affecting them.

Description of the drawings

[0016] To complete the description provided herein, with a view to ensuring better comprehension of the characteristics of the invention. According to a preferential example of the practical completion of the design, the following set of drawings accompanies this description and forms an integral part hereof. They give an illustrative but not exhaustive representation of the invention. Figure 1 shows a ground view of the footwear, representing the three section axes A-A', B-B', C-C', serving as a basis for figures 2, 3 and 4.

Figure 2 shows a transversal section of the footwear from section axis C-C'.

Figure 3 shows a transversal section of the footwear from section axis B-B'.

Figure 4 shows a transversal section of the footwear from section axis A-A'.

Figure 5 shows the placement of the cup in relation to the insole, on which the last is placed during the manufacturing process.

Figure 6 shows the placement of the cup in relation to the insole cardboard insole and the sole.

Preferential completion of the invention

[0017] The proposed invention is based on achieving the shape of the footwear from the design for the sole (3) and the footbed (6), with a geometric design in the upper part that houses an insole (4) with the shape of the base. The sole (3) and the footbed (6) are high density, while the insole (4) is low density, in order to permit the geometric effect.

[0018] This is a new footwear design, based on a combination of geometric shape and materials. A cup (1) is created in the heel area, designed to redirect the foot when pressure is applied, inducing correct posture. This cup (1) consists

of a hard part in the form of a channel, integrated in the footwear between the footbed (6) and the insole (4) on the back part of the sole (3). An insole (4) is placed over the cup (1). The insole is removable, and made of material that is sufficiently mouldable to allow the placement of the cup (1) to have the desired effect. The insole (4) has an upper geometric shape that houses the foot anatomically and a lower shape that fits into the cup (1). Thus, if we remove the

[0019] The last (5) needs to adjust properly to the shape of the foot. It was specially designed to take into account the anthropometric shape of an average foot. Any looseness in the heel area could cause increased instability. The cleavage line between the instep and the heel is designed to close the footwear and adjust the last (5), similar to the cleavage line that follows the tip of the metatarsals. Therefore the design must be adhered to in these areas, to ensure proper adjustment. There must however be room in the toe area, to allow them to move. This permits slight alterations to the last (5) proposed, according, for example, to aesthetic considerations, provided that such alterations do not affect the system.

[0020] The footbed (6) is composed of two parts, the cardboard footbed (7), used during the construction of the footwear serves as a base for the insole (4), with a flat and flexible shape to adapt to the last (5) and the cup (1). There is also a cup (1), situated at the rear of the heel of the insole (4), shaped into a rigid material to channel the footstep.

[0021] The sole (3) needs to fit the basic needs of the user and the specific requirements of the system's innovative design. Thus, the material of the floor should be slightly abrasive, principally in the heel area, with a view to ensuring that its shape does not change with continuous use. The sole (3) should also facilitate the path of the child's centre of mass along the track of the sole defined from studies of healthy children, so that it stabilises the child's footstep. To achieve this, we either create a double density sole in which the central track has a lower density than the rest of the sole, or the thickness of that area is reduced to facilitate distortion, thus stabilising the footstep.

[0022] The shape of the cut should generally adhere to the shape of the last (5). The height of the cut should be at least 46 mm from the base of the insole (4) to the leg at the lowest part of the cut.

Claims

1. This footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, using a last (5) that can be adjusted to the shape of the foot, so that the cleavage line between the instep and the heel and the cleavage line that follows the line of the tips of the metatarsals are adjusted by the last (5), closing the shoe, and leaving room in the toe area for them to move, **designed to** include a sole (3) made from unobtrusive material, principally in the area of the heel, aimed at preserving the geometric shape with continuous use. The shoe also has a high density footbed (6) comprising a cardboard footbed (7) and a cup (1), aimed at guiding the footsteps, and a removable insole (4) made of a mouldable low density material, ensuring that the shoe counteracts the typical rolling of pes valgus in the inside of the heel.
2. The footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, according to claim 1, **designed because** the cup (1) consists of a hard part in the form of a channel, integrated in the back of the shoe's sole (3).
3. The footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, according to claim 1, **designed because** the removable insole (4) has a flat upper shape that is anatomically designed to house the foot, and a lower shape that fits into the cup (1).
4. The footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, according to claim 1, **designed because** the insole (3) has a central track (2) of a lower density than the rest of the sole, facilitating the path of the child's centre of mass.
5. The footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, according to claim 4, **designed because** the central track (2) is formed by creating a double density sole (3).
6. The footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, according to claim 4, **designed because** the central track (2) is formed by reducing the thickness in relation to the sole (3).
7. The footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, according to claim 1, **designed because** the geometrically flat cardboard

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footbed (7) is flexible, allowing it to adapt to the last (5) and the cup (1), and is used when building the shoe, to serve as a base for the insole (4).

- 5 8. The footwear corrects foot movement in children with a slight tendency to develop pes valgus, without changing the gait of children without this pathology, according to previous claims, **designed because** the geometry of the shoe's cut is moulded to the shape of the last (5) so that the height of the cut needs to be at least 46 mm from the base of the insole (4) to the leg at the lowest part of the cut.

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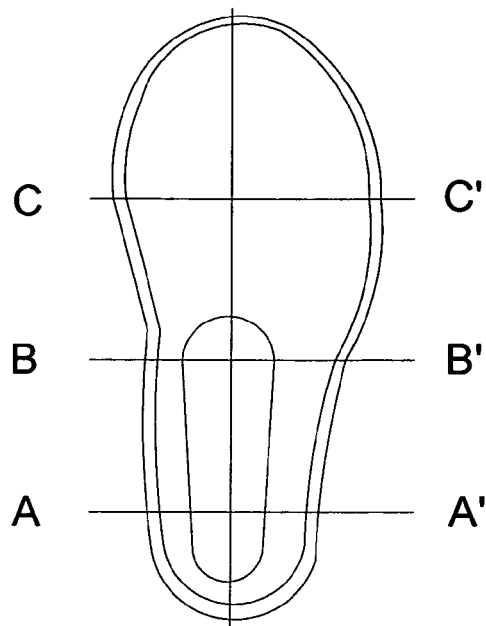
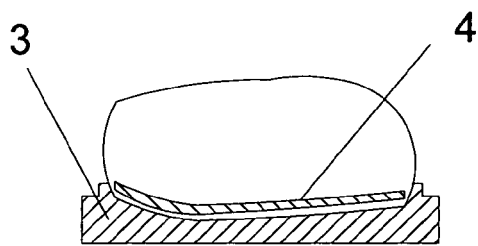
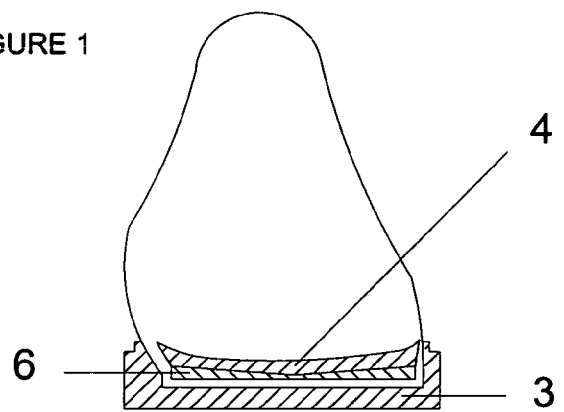


FIGURE 1



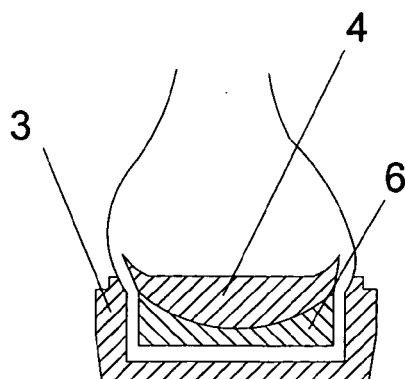
C-C'

FIGURE 2



B-B'

FIGURE 3



A-A'

FIGURE 4

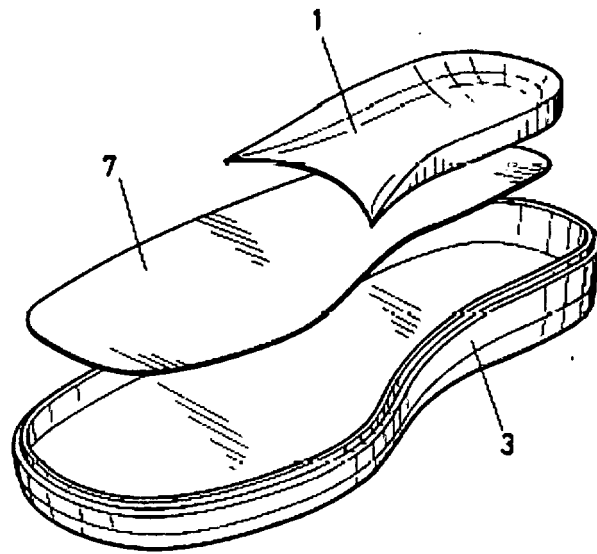


FIGURE 5

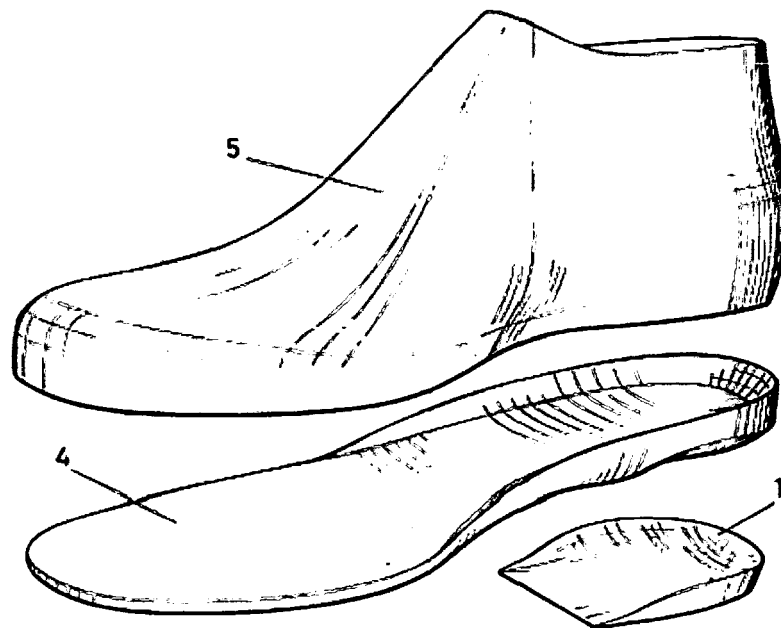


FIGURE 6



European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 07 02 4262

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CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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EPO FORM 1503 03.82 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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