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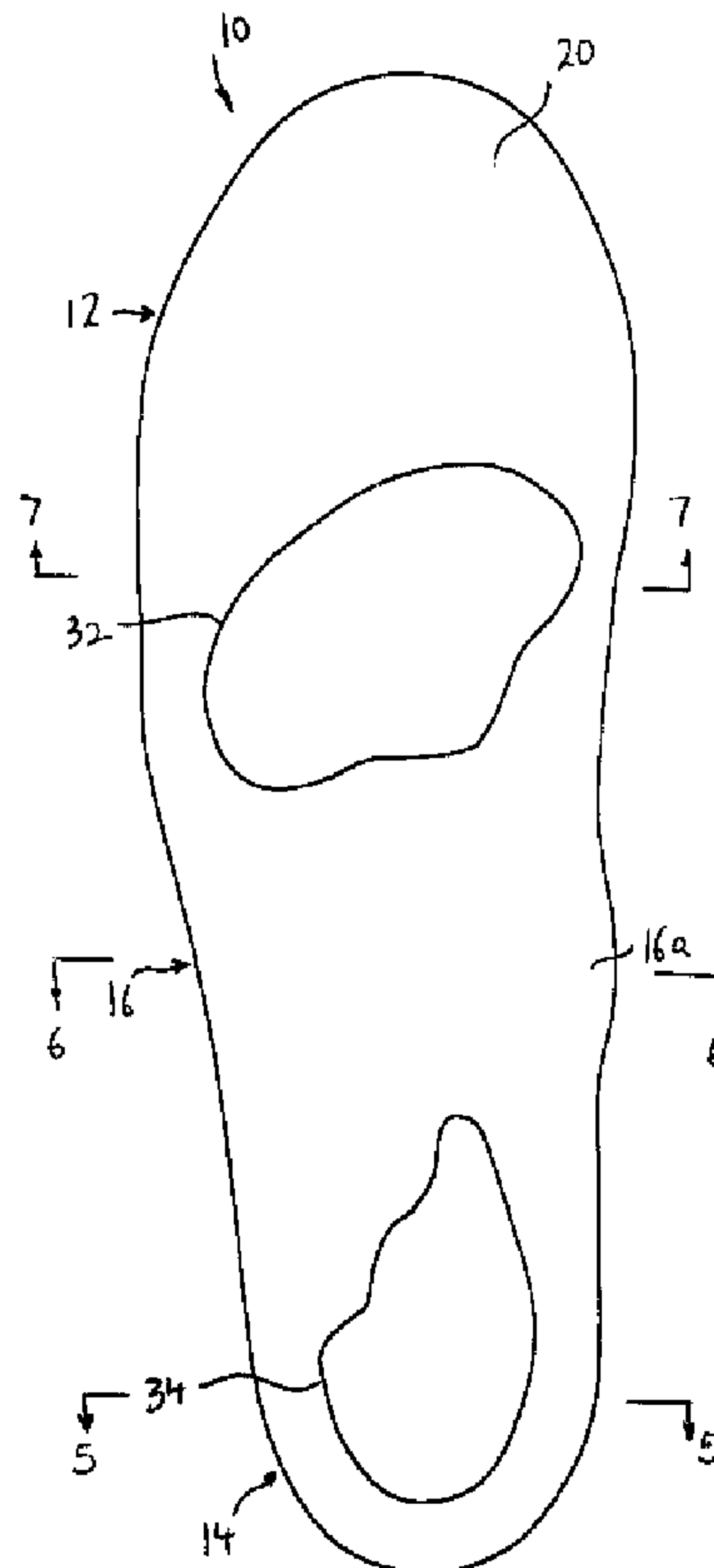
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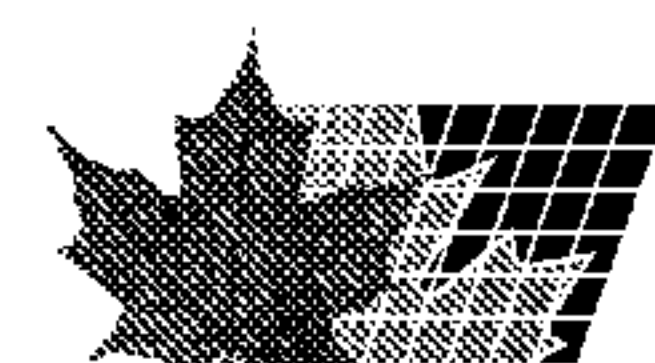
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(57) Abrégé/Abstract:

A full length insole for use with footwear, is formed by a first layer including a forefoot portion extending at least to metatarsals of a foot, a heel portion, a mid portion connecting together the forefoot portion and the heel portion, the mid portion including a medial arch portion, an upper surface extending along the forefoot, mid and heel portions on which a person stands; and a lower



(57) Abrégé(suite)/Abstract(continued):

surface extending along the forefoot, mid and heel portions, the lower surface including a shallow recess, the first layer being made of a material of a first hardness; a force line insert secured in the recess and having a shape that follows a greatest area of force of the foot on the upper surface during a normal stride, the force line insert being made of a material of a second hardness which is less than the first hardness; a forefoot pillow formed as a raised area at the upper surface at the forefoot portion to provide additional cushioning thereat and shaped to conform to a pressure area of the foot so as to include a front edge that extends forwardly to a greater extent at a medial side of the insole; and a heel pillow formed as a raised area at the upper surface at the heel portion to provide additional cushioning thereat and shaped to enhance progression of a gait to guide the foot toward the medial arch portion.

ABSTRACT OF THE DISCLOSURE

A full length insole for use with footwear, is formed by a first layer including a forefoot portion extending at least to metatarsals of a foot, a heel portion, a mid portion connecting together the forefoot portion and the heel portion, the mid portion including a medial arch portion, an upper surface extending along the forefoot, mid and heel portions on which a person stands, and a lower surface extending along the forefoot, mid and heel portions, the lower surface including a shallow recess, the first layer being made of a material of a first hardness; a force line insert secured in the recess and having a shape that follows a greatest area of force of the foot on the upper surface during a normal stride, the force line insert being made of a material of a second hardness which is less than the first hardness; a forefoot pillow formed as a raised area at the upper surface at the forefoot portion to provide additional cushioning thereat and shaped to conform to a pressure area of the foot so as to include a front edge that extends forwardly to a greater extent at a medial side of the insole; and a heel pillow formed as a raised area at the upper surface at the heel portion to provide additional cushioning thereat and shaped to enhance progression of a gait to guide the foot toward the medial arch portion.

WORK INSOLES**BACKGROUND OF THE INVENTION**

The present invention relates generally to insoles for footwear, and more particularly, to improved
5 insoles particularly adapted for working people that spend much time on their feet.

There are many working people, such as construction workers, cashiers, etc., that spend most of their working time in a standing position. Further,
10 much of this standing occurs on hard floors, such as concrete floors or the like. This has the tendency to cause lower back pain and lower extremity pain.

As a result of this pain, working people tend to alter their posture and gait, in an attempt to
15 alleviate this pain.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide an insole that overcomes the
20 problems with the aforementioned prior art.

It is another object of the present invention to provide an insole that relieves lower back pain and lower extremity pain.

It is still another object of the present
25 invention to provide an insole which works faster and better than conventional insoles in relieving lower back pain and lower extremity pain.

It is yet another object of the present invention to provide an insole that provides cushioning and shock
30 absorption at every point along the foot stride.

It is a further object of the present invention to provide an insole that provides additional shock absorption where needed at high force areas along the foot stride.

35 It is a still further object of the present invention to provide an insole that provides a biomechanical effect in rolling through the gait, to enhance the stance and correct gait of the foot.

In accordance with an aspect of the present invention, a full length insole for use with footwear, comprises a first layer including a forefoot portion extending at least to metatarsals of a foot, a heel portion, a mid portion connecting together the forefoot portion and the heel portion, an upper surface extending along the forefoot, mid and heel portions and on which a person stands, and a lower surface extending along the forefoot, mid and heel portions, the lower surface including a shallow recess, the first layer being made of a material of a first hardness; and a force line insert secured in the recess and having a shape that follows a greatest area of force of the foot on the upper surface during a normal stride, the force line insert being made of a material of a second hardness which is less than the first hardness.

The recess and the force line insert preferably each have a height of approximately 2 mm. Also, the force line insert and the recess have substantially the same shape and dimensions. Preferably, the first layer is made from a urethane foam having a Shore "00" durometer hardness in the range of approximately 45-75, with a more preferred range of approximately 55-65, and with a preferred value of approximately 60, and the force line insert is made from a urethane foam having a Shore "00" durometer hardness in the range of approximately 35-65, with a preferred range of approximately 45-55, and with a preferred value of approximately 50.

The force line insert includes a heel insert portion having a first width for accommodating a heel of the foot during a heel strike and to provide cushioning thereof; a mid insert portion connected at one end with the heel insert portion and which has a second width less than the first width; and a forefoot insert portion connected with an opposite end of the mid insert portion and which has a shape that extends forwardly to a greater extent at a medial side of the

insole in correspondence with a positioning of the metatarsals of the foot. Preferably, a forward edge of the forefoot insert portion has an angled arcuate shape.

5 In addition, the heel portion of the insole is cupped to maintain the heel in the heel portion.

 The mid portion includes a medial arch portion positioned adjacent to the mid insole portion. The medial arch portion has a height greater than a
10 remainder of the mid portion, and includes spaced apart, transverse oriented grooves defining transverse flex members therebetween which effectively function as springs.

 In accordance with another aspect of the present
15 invention, a full length insole for use with footwear, comprises a forefoot portion extending at least to metatarsals of a foot; a heel portion; a mid portion connecting together the forefoot portion and the heel portion, the mid portion including a medial arch
20 portion; an upper surface extending along the forefoot, mid and heel portions on which a person stands; a lower surface extending along the forefoot, mid and heel portions; a forefoot pillow formed as a raised area at the upper surface at the forefoot portion to provide
25 additional cushioning thereat and shaped to conform to a pressure area of the foot so as to include a front edge that extends forwardly to a greater extent at a medial side of the insole; and a heel pillow formed as a raised area at the upper surface at the heel portion
30 to provide additional cushioning thereat and shaped to enhance progression of a gait to guide the foot toward the medial arch portion.

 The forefoot and heel pillows provide an extra thickness of the same material as a remainder of the
35 insole at the forefoot and heel portions, and are formed integrally as a single molded piece therewith. The extra thickness is less than approximately 3 mm.

The heel pillow has a shape of a wing that is oriented rearwardly. The wing has a greater width at a rear portion thereof and tapers in width in a forward direction, while also pointing toward the medial arch portion.

In accordance with still another aspect of the present invention, a full length insole for use with footwear, comprises a first layer including a forefoot portion extending at least to metatarsals of a foot, a heel portion, a mid portion connecting together the forefoot portion and the heel portion, the mid portion including a medial arch portion, an upper surface extending along the forefoot, mid and heel portions on which a person stands, and a lower surface extending along the forefoot, mid and heel portions, the lower surface including a shallow recess, the first layer being made of a material of a first hardness; a force line insert secured in the recess and having a shape that follows a greatest area of force of the foot on the upper surface during a normal stride, the force line insert being made of a material of a second hardness which is less than the first hardness; a forefoot pillow formed as a raised area at the upper surface at the forefoot portion to provide additional cushioning thereat and shaped to conform to a pressure area of the foot so as to include a front edge that extends forwardly to a greater extent at a medial side of the insole; and a heel pillow formed as a raised area at the upper surface at the heel portion to provide additional cushioning thereat and shaped to enhance progression of a gait to guide the foot toward the medial arch portion.

The above and other features of the invention will become readily apparent from the following detailed description thereof which is to be read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top plan view of a left insole according to the present invention;

Fig. 2 is a top plan view of a right insole according to the present invention;

Fig. 3 is a bottom plan view of the right insole of Fig. 2;

Fig. 4 is a bottom plan view of the left insole of Fig. 1;

Fig. 5 is a cross-sectional view of the left insole, taken along line 5-5 of Fig. 1;

Fig. 6 is a cross-sectional view of the left insole, taken along line 6-6 of Fig. 1; and

Fig. 7 is a cross-sectional view of the left insole, taken along line 7-7 of Fig. 1.

DETAILED DESCRIPTION

As discussed above, there are many working people, such as construction workers, cashiers, etc., that spend most of their working time in a standing position. Further, much of this standing occurs on hard floors, such as concrete floors or the like. This has the tendency to cause lower back pain and lower extremity pain. Further, these people also tend to alter their posture and gait, in an attempt to alleviate this pain.

The present invention is designed to alleviate such lower back pain and lower extremity pain, while enhancing the stance and correct gait of the foot.

Referring to the drawings in detail, a left insole 10 and a right insole 11 according to the present invention are adapted to be placed in articles of footwear, as is well known. Insoles 10 and 11 are particularly adapted to alleviate lower back pain and lower extremity pain. Only the left insole 10 will now be described, with the understanding that right insole 11 will be the mirror image of insole 10.

Specifically, insole 10 has the shape of a human left foot and therefore includes a curved toe or forefoot portion 12, a heel portion 14, and a mid portion 16 which connects forefoot portion 12 and heel portion 14 together. Heel portion 14 has a greater thickness than toe portion 12. For example, heel portion 14 can have a thickness of about 5-8 mm, while toe portion can have a thickness of about 1-6 mm.

Insole 10 is formed by a lower layer 18 and a top cover 20 secured to the upper surface of lower layer 18, along forefoot portion 12, cupped heel portion 14 and mid portion 16, by any suitable means, such as adhesive, RF welding, etc.

Lower layer 18 can be made from any suitable material including, but not limited to, any flexible material which can cushion and absorb the shock from heel strike on the insole. Suitable shock absorbing materials can include any suitable foam, such as but not limited to, cross-linked polyethylene, poly(ethylene-vinyl acetate), polyvinyl chloride, synthetic and natural latex rubbers, neoprene, block polymer elastomer of the acrylonitrile-butadiene-styrene or styrene-butadienestyrene type, thermoplastic elastomers, ethylenepropylene rubbers, silicone elastomers, polystyrene, polyurea or polyurethane; most preferably a polyurethane foam made from flexible polyol chain and an isocyanate such as a monomeric or prepolymerized diisocyanate based on 4,4'-diphenylmethane diisocyanate (MDI) or toluene diisocyanate (TDI). Such foams can be blown with freon, water, methylene chloride or other gas producing agents, as well as by mechanically frothing to prepare the shock absorbing resilient layer. Such foams advantageously can be molded into the desired shape or geometry. Non-foam elastomers such as the class of materials known as viscoelastic polymers, or silicone gels, which show high levels of damping when tested by

dynamic mechanical analysis performed in the range of -50 degrees C to 100 degrees C may also be advantageously employed. A resilient polyurethane can be prepared from diisocyanate prepolymer, polyol, catalyst and stabilizers which provide a waterblown polyurethane foam of the desired physical attributes. Suitable diisocyanate prepolymer and polyol components include polymeric MDI M-10 (CAS 9016-87-9) and Polymeric MDI MM-103 (CAS 25686-28-6), both available from BASF, Parsippany, N.J.; Pluracol 945 (CAS 9082-00-2) and Pluracol 1003, both available from BASF, Parsippany, N.J.; Multinol 9200, available from Mobay, Pittsburgh, Pa.; MDI diisocyanate prepolymer XAS 10971.02 and polyol blend XUS 18021.00 available from the Dow Chemical Company, Midland, Mich.; and Niax 34-28, available from Union Carbide, Danbury, Conn. These urethane systems generally contain a surfactant, a blowing agent, and an ultra-violet stabilizer and/or catalyst package. Suitable catalysts include Dabco 33-LV (CAS 280-57-9, 2526-71-8), Dabco X543 (CAS Trade Secret), Dabco T-12 (CAS 77-58-7), and Dabco TAC (CAS 107-21-1) all obtainable from Air Products Inc., Allentown, Pa.; Fomrez UL-38, a stannous octoate, from the Witco Chemical Co., New York, N.Y. or A-1 (CAS 3033-62-3) available from OSI Corp., Norcross, Ga. Suitable stabilizers include Tinuvin 765 (CAS 41556-26-7), Tinuvin 328 (CAS 25973-55-1), Tinuvin 213 (CAS 104810-48-2), Irganox 1010 (CAS 6683-19-8), Irganox 245 (CAS 36443-68-2), all available from the Ciba Geigy Corporation, Greensboro, N.C., or Givisorb UV-1 (CAS 057834-33-0) and Givisorb UV-2 (CAS 065816-20-8) from Givaudan Corporation, Clifton, N.J. Suitable surfactants include DC-5169 (a mixture), DC190 (CAS 68037-64-9), DC197 (CAS 69430-39-3), DC-5125 (CAS 68037-62-7) all available from Air Products Corp., Allentown Pa. and L-5302 (CAS trade secret) from Union Carbide, Danbury Conn. Alternatively, lower layer 18 can be a laminate construction, that is, a multilayered

composite of any of the above materials. Multilayered composites are made from one or more of the above materials such as a combination of polyethylene vinyl acetate and polyethylene (two layers), a combination of
5 polyurethane and polyvinyl chloride (two layers) or a combination of ethylene propylene rubber, polyurethane foam and ethylene vinyl acetate (3 layers).

Preferably, lower layer 18 is made from a urethane molded material.

10 Top cover 20 can be made from any suitable material including, but not limited to, fabrics, leather, leatherboard, expanded vinyl foam, flocked vinyl film, coagulated polyurethane, latex foam on scrim, supported polyurethane foam, laminated
15 polyurethane film or in-mold coatings such as polyurethanes, styrene-butadiene-rubber, acrylonitrile-butadiene, acrylonitrile terpolymers and copolymers, vinyls, or other acrylics, as integral top covers. Desirable characteristics of top cover 20
20 include good durability, stability and visual appearance. It is also desirable that top cover 20 have good flexibility, as indicated by a low modulus, in order to be easily moldable. The bonding surface of top cover 20 should provide an appropriate texture in
25 order to achieve a suitable mechanical bond to the upper surface of lower layer 18. Preferably, the material of top cover 20 is a fabric, such as a brushed knit laminate top cloth (brushed knit fabric/urethane film/non-woven scrim cloth laminate) or a urethane knit
30 laminate top cloth. Preferably, top cover 20 is made from a polyester fabric material.

Lower layer 18 can be prepared by conventional methods such as heat sealing, ultrasonic sealing, radio-frequency sealing, lamination, thermoforming,
35 reaction injection molding, and compression molding and, if necessary, followed by secondary die-cutting or in-mold die cutting. Representative methods are taught, for example, in U.S. Pat. Nos. 3,489,594;

3,530,489 4,257,176; 4,185,402; 4,586,273, in the Handbook of Plastics, Herber R. Simonds and Carleton Ellis, 1943, New York, N.Y., Reaction Injection Molding Machinery and Processes, F. Melvin Sweeney, 1987, New York, N.Y., and Flexible Polyurethane Foams, George Woods, 1982, New Jersey. Preferably, the innersole is prepared by a foam reaction molding process such as taught in U.S. Pat. No. 4,694,589.

During use, insole 10 is placed in a shoe so that the medial side of mid portion 16 rests against the inside of the shoe. Forefoot portion 12 may end just in front of the metatarsals. However, insole 10 is preferably a full length insole, that is, extends along the entire foot.

Typically, insole 10 would be sized corresponding to shoe sizes and would be provided in sized pairs. Alternatively, insole 10 may be trimmed to the requirements of the user. In this regard, arcuate pattern trim lines 22a-22d may be formed on the lower surface of forefoot portion 12 of insole 10, and which are representative of various sizes of the human foot. For example, insole 10 may be provided for a woman's shoe size of 10-11, with first continuous pattern trim line 22a being representative of a smaller size insole for a woman's shoe size 9, second continuous pattern trim line 22b extending around the periphery of toe portion 12 indicative of another size of insole for a woman's shoe size 8, third continuous pattern trim line 22c extending around the periphery of toe portion 12 indicative of another size of insole for a woman's shoe size 7, and fourth continuous pattern trim line 22d extending around the periphery of toe portion 12 indicative of another size of insole for a woman's shoe size 6. If the user requires a size other than the original large size, the wearer merely trims the insole with a scissors or cutting instrument, using pattern trim lines 22a-22d, to achieve the proper size. The

pattern trim lines may be imprinted by conventional printing techniques, silkscreening and the like. As an alternative, pattern trim lines 22a-22d may be formed as shallow grooves, or be perforated, so that a smaller
5 size insole may be separated by tearing along the appropriate trim lines, which tearing operation is facilitated by the inclusion of perforations. Thus, forefoot portion 12 can be trimmed so that forefoot portion 12 fits within the toe portion of a shoe.

10 In accordance with the present invention, insole 10 is formed with a structure to alleviate lower back pain and lower extremity pain. Specifically, insole 10 is provided with a shallow recess 24 about 2 mm deep at the lower surface of lower section 18. Shallow recess
15 24 follows the greatest line of force of the foot during a normal stride, that is, in a single limb stance phase. When walking, the foot first impacts at the heel with a large force, for example, up to three times a normal standing force, and then moves toward
20 the forefoot. The heel lifts off of the insole slightly at the position of contact of the mid-foot with the insole and then transfers to the forefoot. At the forefoot, the foot transfers from the position of the fifth metatarsal to the first metatarsal, where
25 push-off occurs at the big toe of the foot.

Shallow recess 24 has a shape to follow this line of force, and to cover the high force areas during this stride.

In accordance with the present invention, a force
30 line insert 26 having a thickness of about 2 mm and having the same shape as shallow recess 24, is secured within shallow recess. Force line insert 26 is made from a softer or more cushioning material than the remainder of lower section 18 of insole 10. For
35 example, lower section 18 of insole 10 can be made from a urethane foam having a Shore "00" durometer hardness in the range of approximately 45-75, more preferably in the range of approximately 55-65, and with a preferred

hardness of approximately 60, while force line insert 26 can be made from a softer urethane foam having a Shore "00" durometer hardness in the range of approximately 35-65, more preferably in the range of approximately 45-55, and with a preferred hardness of approximately 50. A preferred material for force line insert 26 is the material sold by Rogers Corporation of Rogers, Connecticut under the trademark "PORON". Preferably, force line insert 26 is formed first, and then placed in a mold, where the remainder of lower section 18 of insole 10 is molded thereon, and thereby bonded to the PORON material of force line insert 26 during the molding operation.

Thus, the force line shape of insert 26 provides a softer material along the center of pressure of the gait line. As a result, force line insert 26 provides cushioning and shock absorption at every point along the stride.

As shown, force line insert 26 includes a heel insert portion 26a of a width intended to accommodate the heel during the heel strike and provide cushioning thereof. From heel insert portion 26a, insert 26 tapers in width to a mid insert portion 26b at mid portion 16. The reason for the taper is that the cushioning material of insert 26 is not needed as much at this position, since there is more surface area of the foot in contact with the upper surface of insole 10 to spread out the forces more evenly, and because, as will be explained hereinafter, the foot is guided toward medial arch portion 16a of mid portion 16 which absorbs much of the forces.

From mid insert portion 26b, insert 26 increases in width to a forefoot insert portion 26c. Forefoot insert portion 26c has a shape that extends forwardly to a greater extent at the medial side of insole 10 in correspondence with the configuration of the metatarsals. As a result, the forward edge of forefoot insert portion 26c has an angled arcuate shape.

Thus, with the initial heel strike, heel insert portion 26a functions to provide greater cushioning and shock absorbing at the heel. As the foot moves forwardly, there is still a line of contact at the mid-foot, but medial arch portion 16a also absorbs much of the force, so as to provide an evening out of the force at the mid-foot. As a result, the width of mid insert portion 26b can be reduced. Thereafter, the foot transfers to the forefoot, and particularly, from the fifth metatarsal to the first metatarsal, where push-off occurs at the big toe of the foot. Such force can be up to three times the normal standing force. Forefoot insert portion 26c is shaped to follow this line of force, and provide extra cushioning and shock absorbing during this action.

It will be appreciated that heel portion 14 is preferably a cupped heel portion. Specifically, as shown, heel portion 14 includes a relatively flat central portion 14a, and a sloped side wall 14b that extends around the sides and rear of central portion 14a. Generally, when a heel strikes a surface, the fat pad portion of the heel spreads out. The cupped heel portion thereby stabilizes the heel of the person and maintains the heel in heel portion 14, to prevent such spreading out of the fat pad portion of the heel, and to also prevent any side to side movement of the heel in heel portion 14. This ensures that heel insole portion 26a operates properly on the foot.

With respect to medial arch portion 16a, the arch can be built into insole 10 in one of two ways. First, arch portion 16a can be filled or built up with a bulky cushioning material. This, however, provides the disadvantage that it might not be capable of use in a shoe already having a built in arch support, since it may be too bulky. Therefore, the preferred manner of forming medial arch portion 16a according to the present invention is to build up the height of medial arch portion 16a, but to provide spaced apart,

transverse oriented grooves or recesses 28 therein, which define transverse flex members 30 therebetween which effectively function as springs. The advantage of using flex members 30 is that the bulk of arch portion 16a is not needed and thereby greatly reduced. It therefore becomes easier and better to use flex members 30 with shoes, since they can be used in shoes with or without a built in arch support.

Flex members 30 function in concert with force line insert 26 to provide even cushioning support and shock absorption over the entire mid-foot area during mid-stance phase. Because of flex members 30, the width of mid insole portion 26b can be reduced. The use of flex members 30, by themselves, however, has been known in insoles sold more than one year ago, but the combination with force line insert 26 is new.

In addition to force line insert 26, another important feature of the present invention is the addition of forefoot pillow 32 and heel pillow 34.

Pillows 32 and 34 provide an extra thickness of the same material as lower layer 18 and are formed integrally as a single piece therewith during the molding operation of insole 10. Pillows 32 and 34 are provided at the two areas with the greatest force. Since the cushioning energy is directly proportional to thickness, the cushioning effect is normally achieved with increasing bulk of the entire insole. The present invention accomplishes this by increasing the bulk slightly by up to approximately 3 mm in thickness above the upper surface of the insole, only at the areas where the greatest forces result during walking.

When walking, the heel of the foot normally hits on the outside of the heel and rolls toward the medial arch. Thus, pillow 34, in addition, to providing cushioning at the heel, is shaped to enhance the rolling or progression of the gait, and thereby guides the foot toward medial arch portion 16a. Thus, heel pillow 34 functions as a guide as well as providing

extra cushioning. In this regard, pillow 34 has the shape of a wing that is oriented rearwardly. Thus, pillow 34 has a greater width at the rear portion and tapers in width, while also pointing toward medial arch portion 16a.

At the forefoot, pillow 32 provides the same two functions. Normally, when walking, the foot moves from the fifth metatarsal to the first metatarsal and then the person pushes off from the big toe. Pillow 32 thereby has a shape similar to forefoot insole portion 26c, that is, with an arcuate front edge that extends forwardly to a greater extent at the medial side of insole 10.

Pillows 32 and 34 thereby enhance the stance and correct walking gait, while also providing cushioning.

Thus, while force line insert 26 provides cushioning and shock absorption at every point, pillows 32 and 34 provide a different function of shock absorption where needed, as well as a biomechanical effect in aiding the foot in rolling through the gait.

Tests were performed with insoles 10 and 11. Specifically, 103 people were evaluated over a four week period with insoles 10 and 11.

The following Table I shows a four week period of people wearing insoles 10 and 11 on a visual analog scale (VAS), which is a widely accepted method for evaluating pain.

TABLE I

Variable (Back Pain)	Number of Subjects	Mean VAS Score	Standard Deviation
Baseline (week 0)	104	57.57	14.89
Week 1	103	37.17	20.12
Week 2	103	30.81	19.93
Week 4	103	22.48	20.50

It will be appreciated that the back pain significantly decreased from the baseline to week 1, and continued to decrease thereafter to week 4. Similar tests with conventional insoles show that, although many insoles normally relieve some pain, the present invention works faster and better than conventional insoles that provide shock absorption. Thus, the results of the tests with insoles 10 and 11 showed significant relief of lower back pain and lower extremity pain.

The change in back pain VAS score from the baseline is shown by the following Table II:

TABLE II

Variable (Change in Back pain VAS)	Mean change in VAS score	Standard Deviation	Prob> T
Week 1 from Baseline	20.19	22.15	0.0001
Week 2 from Baseline	26.81	22.93	0.0001
Week 4 from Baseline	35.14	23.90	0.0001

In Table II, the designation Prob>|T| refers to the probability that the data is significantly accurate and relevant. The small percentage confirms the accuracy and relevancy of the data.

The same analysis was performed with the lower extremity pain, and is presented in Tables III and IV below:

TABLE III

5	Variable (Lower Extremity Pain)	Number of Subjects	Mean VAS Score	Standard Deviation
	Baseline (week 0)	104	35.56	23.00
	Week 1	103	27.13	20.43
	Week 2	103	25.32	22.10
10	Week 4	103	19.94	21.50

TABLE IV

15	Variable (Change in Lower Extremity Pain VAS)	Mean change in VAS score	Standard Deviation	Prob> T
20	Week 1 from Baseline	8.01	21.19	0.0002
	Week 2 from Baseline	10.07	23.03	0.0001
25	Week 4 from Baseline	15.46	24.15	0.0001

Subjective tests were also performed. At baseline week 0, 98% of the subjects considered insoles 10 and 11 moderately, very or extremely comfortable. At week 4, 92.3% considered the insoles moderately, very or extremely effective in relieving pain. Also, at week 4, over 80% of the subjects considered that insoles 10 and 11 were moderately, very or extremely effective in relieving tired, achy feet (83.5%) as well as tired, achy legs (81.3%).

Thus, insoles 10 and 11 provided significant relief of lower back pain and lower extremity pain after only one week, with further decreases in pain in weeks 2 and 4.

Although the present invention uses the term insole, it will be appreciated that the use of other

equivalent or similar terms such as innersole or insert are considered to be synonymous and interchangeable, and thereby covered by the present claimed invention.

Further, although the present invention has been
5 described in connection with insoles, the present invention can be incorporated directly into the sole of a shoe, and the present invention is intended to cover the same. In this regard, reference is made in the claims to a full length insole for use with footwear,
10 which can include a removable insole or an insole built into a shoe.

Having described specific preferred embodiments of the invention with reference to the accompanying drawings, it will be appreciated that the present
15 invention is not limited to those precise embodiments and that various changes and modifications can be effected therein by one of ordinary skill in the art without departing from the scope or spirit of the invention as defined by the appended claims.

CLAIMS:

1. A full length insole for use with footwear,
comprising:
 - a first layer including:
 - a forefoot portion extending at least to
5 metatarsals of a foot;
 - a heel portion;
 - a mid portion connecting together said
forefoot portion and said heel portion;
 - an upper surface extending along said
10 forefoot, mid and heel portions and on which a person
stands; and
 - a lower surface extending along said
forefoot, mid and heel portions, said lower surface
including a shallow recess;
 - 15 said first layer being made of a material of
a first hardness; and
 - a force line insert secured in said recess and
having a shape that follows a greatest area of force of
the foot on said upper surface during a normal stride,
20 said force line insert being made of a material of a
second hardness which is less than said first hardness.
2. An insole according to claim 1, wherein said
recess and said force line insert each have a height of
approximately 2 mm.
3. An insole according to claim 1, wherein said force
line insert and said recess have substantially the same
shape and dimensions.
4. An insole according to claim 1, wherein said first
layer is made from a urethane foam having a Shore "00"
durometer hardness in the range of approximately 45-75,
and said force line insert is made from a urethane foam
5 having a Shore "00" durometer hardness in the range of
approximately 35-65.

5. An insole according to claim 4, wherein said first layer has a Shore "00" durometer hardness in the range of approximately 55-65, and said force line insert has
10 a Shore "00" durometer hardness in the range of approximately 45-55.

6. An insole according to claim 5, wherein said Shore "00" durometer hardness of said first layer is approximately 60, and said Shore "00" durometer hardness of said force line insert is approximately 50.

7. An insole according to claim 1, wherein said force line insert includes:

a heel insert portion having a first width for accommodating a heel of the foot during a heel strike
5 and to provide cushioning thereof;

a mid insert portion connected at one end with said heel insert portion and which has a second width less than said first width; and

a forefoot insert portion connected with an
10 opposite end of said mid insert portion and which has a shape that extends forwardly to a greater extent at a medial side of the insole in correspondence with a positioning of the metatarsals of the foot.

8. An insole according to claim 1, wherein a forward edge of said forefoot insert portion has an angled arcuate shape.

9. An insole according to claim 1, wherein said heel portion of said insole is cupped to maintain said heel in said heel portion.

10. An insole according to claim 1, wherein said mid portion includes a medial arch portion positioned adjacent to said mid insole portion.

11. An insole according to claim 10, wherein said medial arch portion has a height greater than a remainder of said mid portion, and includes spaced apart, transverse oriented grooves defining transverse flex members therebetween which effectively function as springs.

12. A full length insole for use with footwear, comprising:

a forefoot portion extending at least to metatarsals of a foot;

5 a heel portion;

a mid portion connecting together said forefoot portion and said heel portion, said mid portion including a medial arch portion;

10 an upper surface extending along said forefoot, mid and heel portions on which a person stands;

a lower surface extending along said forefoot, mid and heel portions;

15 a forefoot pillow formed as a raised area at the upper surface at said forefoot portion to provide additional cushioning thereat and shaped to conform to a pressure area of the foot so as to include a front edge that extends forwardly to a greater extent at a medial side of said insole; and

20 a heel pillow formed as a raised area at the upper surface at said heel portion to provide additional cushioning thereat and shaped to enhance progression of a gait to guide the foot toward said medial arch portion.

13. An insole according to claim 12, wherein said forefoot and heel pillows provide an extra thickness of the same material as a remainder of said insole at said forefoot and heel portions, and are formed integrally as a single molded piece therewith.

14. An insole according to claim 13, wherein said extra thickness is less than approximately 3 mm.

15. An insole according to claim 12, wherein said heel pillow has a shape of a wing that is oriented rearwardly.

16. An insole according to claim 15, wherein said wing has a greater width at a rear portion thereof and tapers in width in a forward direction, while also pointing toward said medial arch portion.

17. A full length insole for use with footwear, comprising:

a first layer including:

5 a forefoot portion extending at least to metatarsals of a foot;

a heel portion;

a mid portion connecting together said forefoot portion and said heel portion, said mid portion including a medial arch portion;

10 an upper surface extending along said forefoot, mid and heel portions on which a person stands; and

a lower surface extending along said forefoot, mid and heel portions, said lower surface including a shallow recess;

15 said first layer being made of a material of a first hardness;

a force line insert secured in said recess and having a shape that follows a greatest area of force of the foot on said upper surface during a normal stride, said force line insert being made of a material of a second hardness which is less than said first hardness;

20 a forefoot pillow formed as a raised area at the upper surface at said forefoot portion to provide additional cushioning thereat and shaped to conform to a pressure area of the foot so as to include a front

edge that extends forwardly to a greater extent at a medial side of said insole; and

30 a heel pillow formed as a raised area at the upper surface at said heel portion to provide additional cushioning thereat and shaped to enhance progression of a gait to guide the foot toward said medial arch portion.

18. An insole according to claim 17, wherein said force line insert and said recess have substantially the same shape and dimensions.

19. An insole according to claim 17, wherein said first layer is made from a urethane foam having a Shore "00" durometer hardness in the range of approximately 45-75, and said force line insert is made from a
5 urethane foam having a Shore "00" durometer hardness in the range of approximately 35-65.

20. An insole according to claim 19, wherein said first layer has a Shore "00" durometer hardness in the range of approximately 55-65, and said force line
10 insert has a Shore "00" durometer hardness in the range of approximately 45-55.

21. An insole according to claim 20, wherein said Shore "00" durometer hardness of said first layer is approximately 60, and said Shore "00" durometer hardness of said force line insert is approximately 50.

22. An insole according to claim 17, wherein said force line insert includes:

a heel insert portion having a first width for accommodating a heel of the foot during a heel strike
5 and to provide cushioning thereof;

a mid insert portion connected at one end with said heel insert portion, positioned adjacent said

medial arch portion, and having a second width less than said first width; and a forefoot insert portion connected with an opposite end of said mid insert portion and which has a shape that extends forwardly to a greater extent at a medial side of the insole in correspondence with a positioning of the metatarsals of the foot.

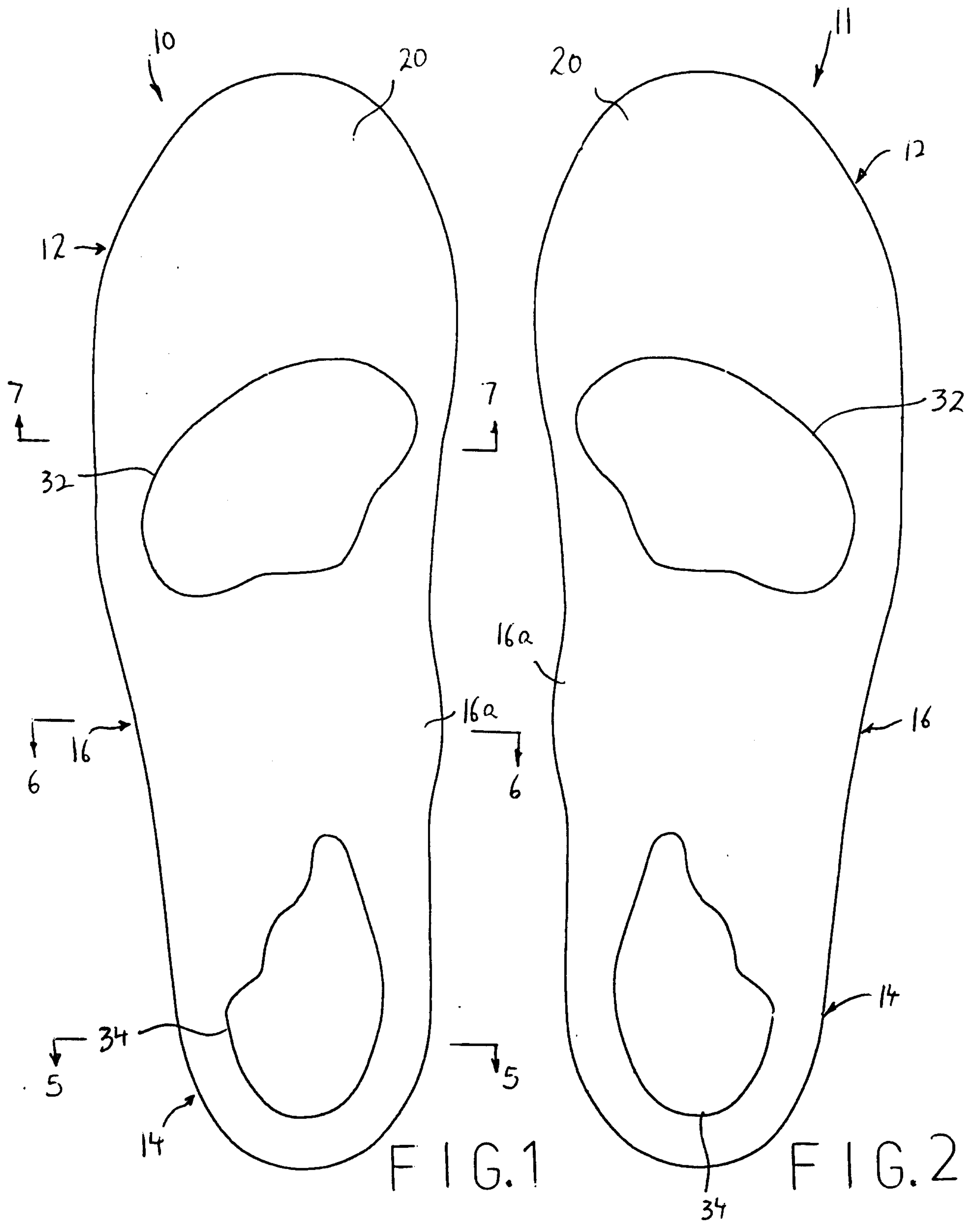
23. An insole according to claim 17, wherein a forward edge of said forefoot insert portion has an angled arcuate shape.

24. An insole according to claim 17, wherein said medial arch portion has a height greater than a remainder of said mid portion, and includes spaced apart, transverse oriented grooves that define transverse flex members therebetween which effectively function as springs.

25. An insole according to claim 17, wherein said forefoot and heel pillows provide an extra thickness of the same material as a remainder of said insole at said forefoot and heel portions, and are formed integrally as a single molded piece therewith.

26. An insole according to claim 17, wherein said heel pillow has a shape of a wing that is oriented rearwardly.

27. An insole according to claim 26, wherein said wing has a greater width at a rear portion thereof and tapers in width in a forward direction, while also pointing toward said medial arch portion.



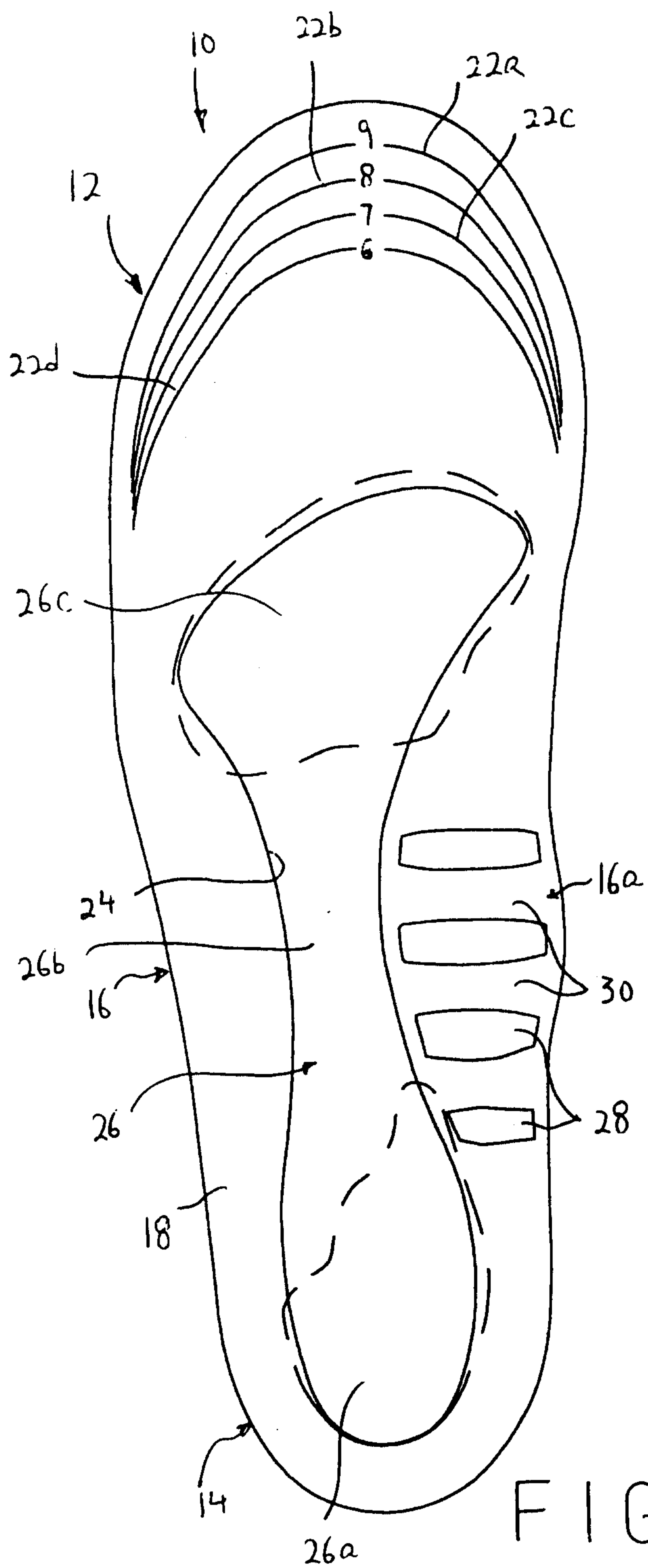


FIG. 3

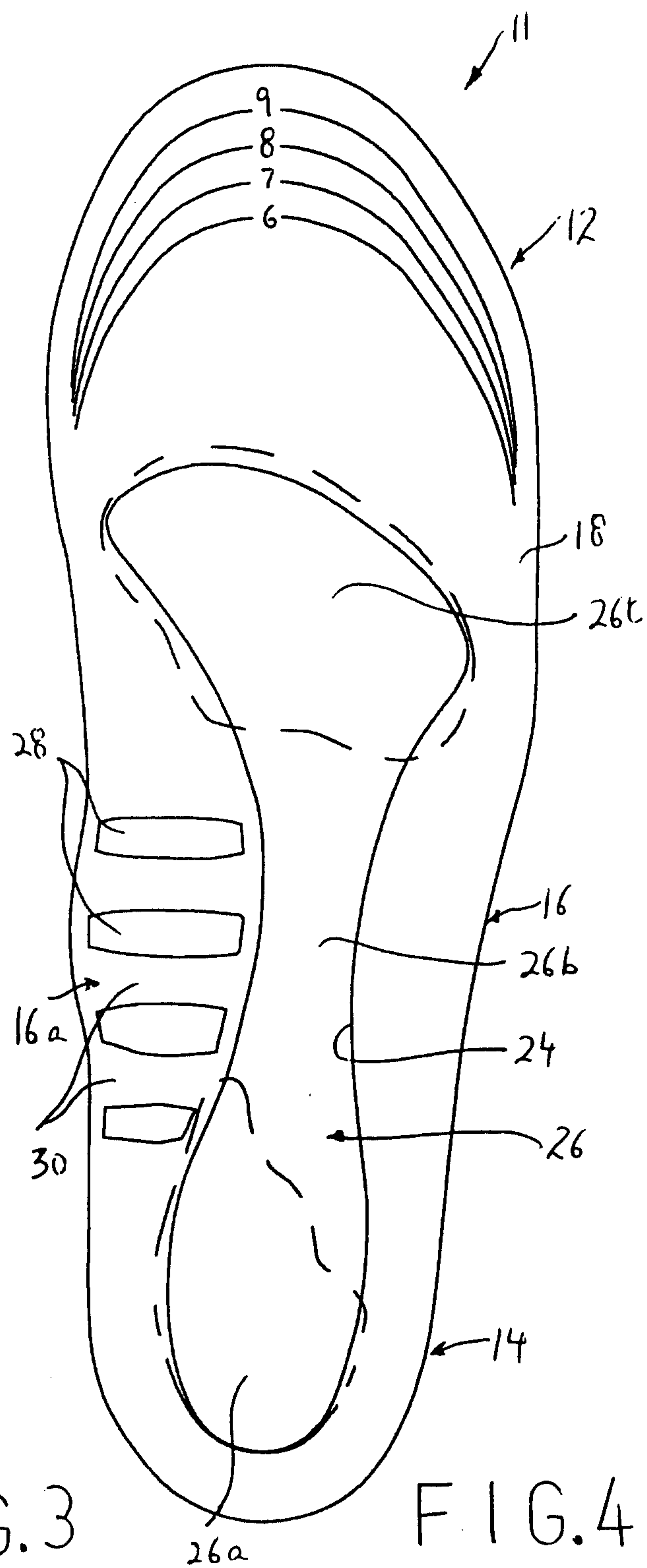


FIG. 4

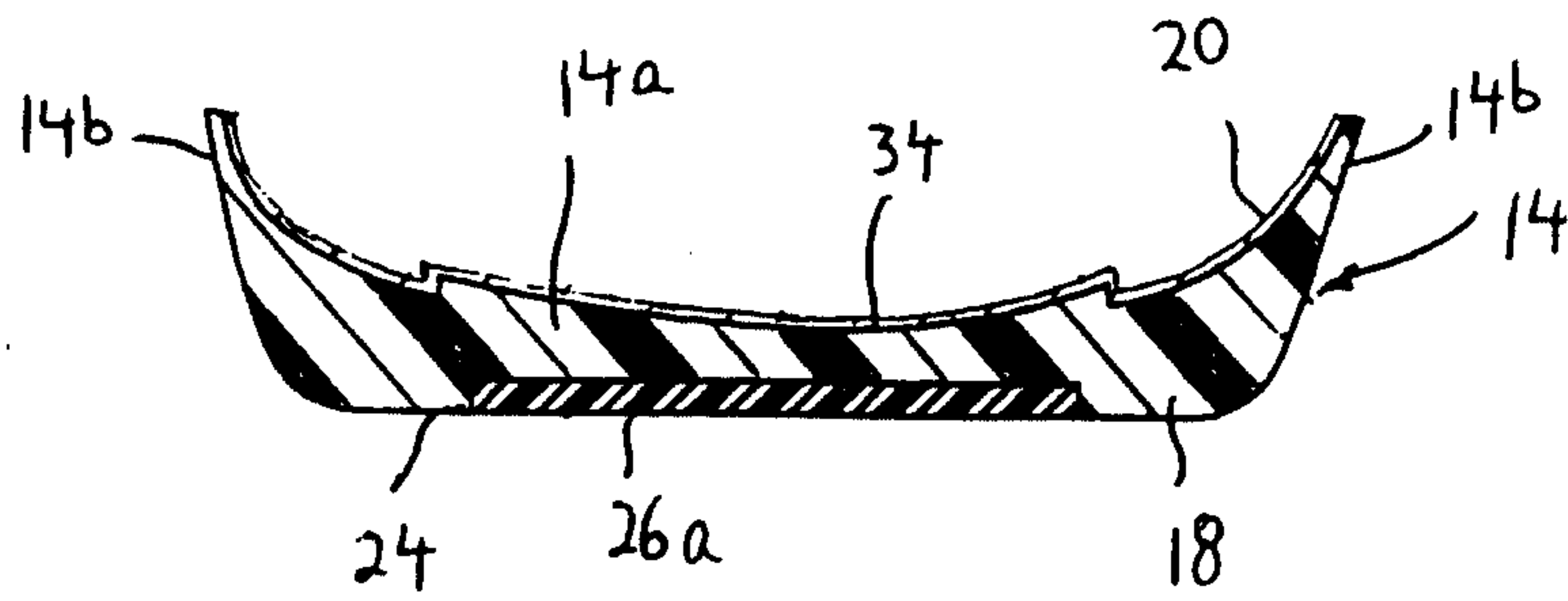


FIG. 5

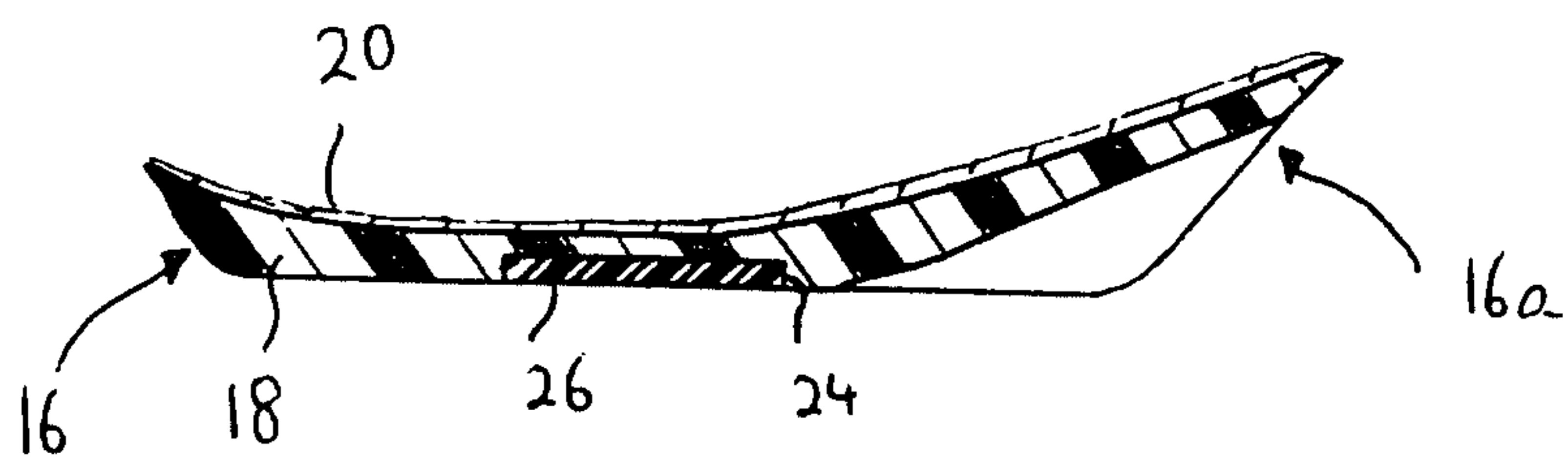


FIG. 6

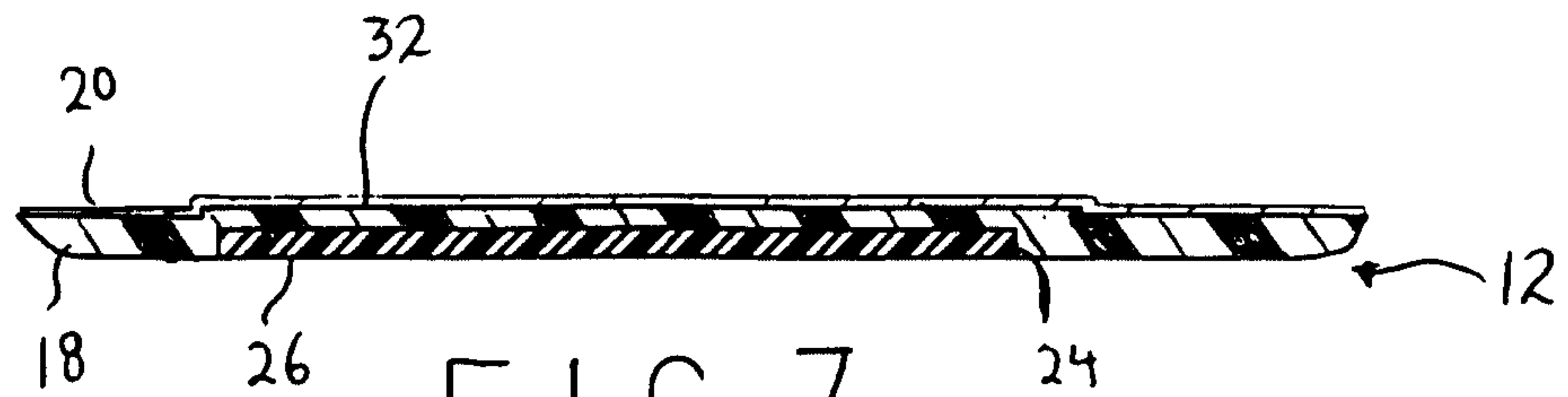


FIG. 7

