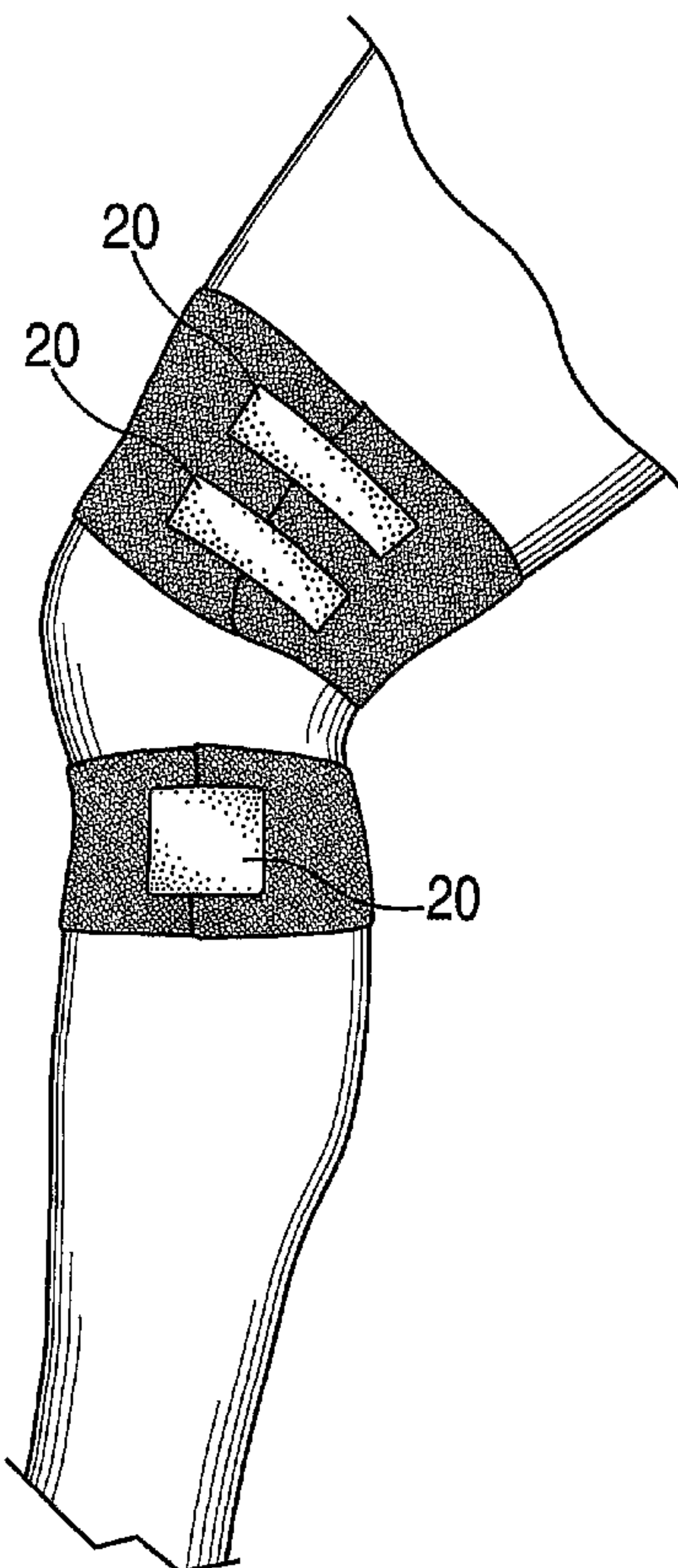




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 (54) Title: FLEXIBLE SUPPORT FOR GEL WRAPS



(57) Abrégé/Abstract:

A two-ply bandage for treatment of skin while providing orthopedic support having a first layer of gel for contacting the skin and a second layer of an elastic and supportive loop portion of a hook and loop fastener. The product is economically manufactured in the form of long rolls or as a sheet and is easily cut to any desired shape.

ABSTRACT

A two-ply bandage for treatment of skin while providing orthopedic support having a first layer of gel for contacting the skin and a second layer of an elastic and
5 supportive loop portion of a hook and loop fastener. The product is economically manufactured in the form of long rolls or as a sheet and is easily cut to any desired shape.

FLEXIBLE SUPPORT FOR GEL WRAPS

BACKGROUND OF THE INVENTION

The present invention relates to a medical or surgical
5 bandage suitable for use in providing musculo-skeletal
support and treatment of skin conditions.

SUMMARY OF THE INVENTION

The invention relates to positioning a gel against the
10 skin utilizing a stretchable bandage that is also intended
to provide the added benefit of orthopedic, or musculo-
skeletal, support for the joint or portion of the body on
which the bandage is wrapped.

More specifically, this invention relates to a
15 composite material consisting of two layers; a layer of gel
bonded to a stretchable carrier layer of a rigid and
elastic loop portion of a hook and loop fastener. The
stretch carrier layer is intended to be useful for
positioning the gel layer in place on the body while at the
20 same time providing substantial musculo-skeletal support to

the portion of the body around which the bandage is wrapped.

This invention relates to a composite structure which incorporates the pressure therapy features of a rigid yet stretchable carrier material with a silicone gel for treatment of skin conditions. Silicone gel materials are used in the medical field for the management of such conditions, for example, as dermal scarring, varicose veins and stasis ulcers. These silicone materials soften scar tissue and improve the cosmetic as well as functional aspects of scars for instance.

There is a need in the medical and veterinary fields to combine supportive (pressure) therapy with a gel treatment, particularly on the extremities of the body. In the case of veterinary applications, fur is used herein interchangeably with skin. Supportive pressure therapy is useful, for example, to provide musculo-skeletal support for joints and muscles, and in the treatment of carpal tunnel syndrome, arthritis and tennis elbow. This is not easy or convenient under present methods. Typically in the medical and veterinary fields supportive pressure therapy

is provided using compression garments or wraps. When used with a gel, a person must typically apply a layer of gel to the area of the body to be treated followed by wrapping another material such as a compression garment or wrap to
5 keep the gel in position. The materials typically used don't provide the elastic support usually desired and therefore require many wraps of the material. Furthermore, typical materials lose much of their elasticity after only a couple of uses.

10 Hook and loop fasteners are now available with rigid yet stretchable loop portions that have a modulus of elasticity of about 50%, with no stretch memory. The strong elastic property provided by the stretchable loop portion makes it possible for a bandage using this material to be
15 wrapped only once around a part of the body while maintaining contact with the skin to be treated. By applying a surface layer of silicone gel to the flat side (non-loop surface) of a stretchable loop portion of a hook and loop fastener, it was discovered that bandages can be
20 produced which provide a surface layer of silicone for uniform skin contact with the intended added benefit of

musculo-skeletal support. The bandage of this invention having a stretchable loop portion as the carrier layer for the gel is intended to therefore follow the many shapes and anatomical contours of the body while at the same time
5 providing secure positioning of the gel on the skin of the user. The combination of stretch carrier and gel layer is intended to provide greater comfort to the user because the bandage allows for movement and flexing of the body without reduction in the bandages effectiveness, i.e. support and
10 resistance to slipping. Thus, the support provided by this invention is intended to offer the wearer of the bandage greater comfort and durability and is intended to make for the ideal bandage for repeated usage and/or usage over long periods of time.

15 This invention is intended to be an improvement over the prior art in that (a) the carrier material is rigid and elastic so that substantial orthopedic support (i.e., musculo-skeletal support) is intended to be provided by just a one layer wrapping, (b) the product is intended to
20 be far more durable than Lycra[®] and other known, thin elastic based products commonly available, (c) both

pressure and silicone therapies may be applied
concomitantly by this invention and therefore it is
intended to eliminate a separate and/or repeated process of
fitting more than one material individually, and (d)
5 patient compliance may be improved because continued, even
long term, comfortable use of the product is possible
without loss of support from the carrier material.
Furthermore, the carrier of the present invention is
intended to provide the added benefit of a bandage that
10 supplies even pressure to the body across the area of the
bandage being treated.

The manufacturing process of this invention is
intended to lend itself to large-scale production in either
flat sheets or long rolls. Final shapes of limitless
15 configurations are then intended to be easily cut from the
sheets or rolls. This is intended to provide for rapid and
cost effective production of custom-made shapes for any
given application or patient.

In a first broad aspect of the present invention,
20 there is provided a bandage comprising: a first layer of a
silicone gel, the first layer having a skin contacting

surface and an adhesion surface opposite the skin
contacting surface; and a second layer of an elastic and
supportive carrier, the second layer having an outer
surface and an adhesion surface bonded to the adhesion
5 surface of the first layer to form a continuous two-ply
composite; wherein the carrier is the stretchable loop
portion of a hook and loop fastener, the loop portion
having a loop surface and an opposite adhesion surface.

In a second broad aspect of the present invention,
10 there is provided a method of manufacturing a bandage
comprising: mixing a silicone gel; pouring the gel onto a
flat surface; settling the gel to a consistent thickness;
placing a clean, dry and elastic carrier layer of a loop
portion of a hook and loop fastener having a loop surface
15 and an adhesion surface onto the gel such that the adhesion
surface is in contact with the gel; curing the gel and the
carrier at a temperature of about 100 to 180 degrees
centigrade.

In a third broad aspect of the present invention,
20 there is provided a method of manufacturing a bandage
comprising: creating a bath of a silicone gel having a top

surface; unrolling onto the gel a clean, dry and elastic carrier layer of a loop portion of a hook and loop fastener having a loop surface and an adhesion surface such that the adhesion surface bonds with a layer of the gel; and, curing
5 the gel.

In a fourth broad aspect of the present invention, there is provided a method of manufacturing a bandage comprising: creating a bath of a silicone gel having a top surface; unrolling onto the gel a clean, dry and elastic
10 carrier layer of a loop portion of a hook and loop fastener having a loop surface and an adhesion surface such that the adhesion surface bonds with a layer of the gel; and, curing the gel at a temperature of about 100 to 180 degrees centigrade by passing the carrier and bonded gel through an
15 oven.

In a fifth broad aspect of the present invention, there is provided a method of manufacturing a bandage comprising: creating a river of a clean, dry and elastic carrier layer of a loop portion of a hook and loop fastener
20 having a loop surface and an adhesion surface; depositing onto the adhesion surface a silicone gel; passing the

carrier and gel into an oven, and curing at about 100 to 180 degrees centigrade.

In a sixth broad aspect of the present invention, there is provided a stretchable, supportive laminate wrap comprising: a silicone gel having a skin contacting
5 surface, the silicone gel being laminated to an elastic carrier wherein the carrier is the loop portion of a hook and loop fastener, the laminate wrap forming an integrated structure configured to have elasticity sufficient to
10 provide compression against a body surface without substantial fragmentation of the silicone gel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view illustrating the use of
15 one embodiment of this invention on the knee of a user.

FIG. 2 is an embodiment illustrating gel layer 5 bonded to carrier 10 having loop surface 15.

FIG. 3 illustrates carrier 10, having a loop surface 15, bonded to gel layer 5.

20 FIG. 4 illustrates closure strip 20.

FIG. 5 illustrates a method of manufacture using gel bath 30, carrier 10, and heating element 50.

FIG. 6 illustrates a river of carrier 10, uncured gel compound 40, and heating element 50.

5 FIG. 7 is a perspective view illustrating the use of particular embodiments of this invention adjacent to the knee joint of a user.

Fig. 8 is a perspective view illustrating the use of an embodiment of the present invention about the thigh of a
10 user, and showing loop surface 15 of the bandage and closure strips 20.

DETAILED DESCRIPTION OF THE INVENTION

The description provided below references FIGS. 1
15 through 8 as part of the disclosure and the associated reference numerals.

The device of the present invention, shown in Figs. 1 through 3, 7 and 8, is generally described as a rigid yet stretchable bandage with a silicone gel coating 5 on one
20 side. The carrier 10 is a thick, stretchable loop portion of a hook-and-loop fastener such as Velcro®. In a

particular embodiment, carrier 10 is about 1/8 inch thick. The silicone gel used in gel 5 is commercially available as either a 1:1, 3:1, or 10:1 mixture of a polydiorganosiloxane resin and a catalyst. Generally speaking, the silicone gel is an addition cured polydimethyl-siloxane gel. This type of gel is well described in the literature, including some of the existing patent literature (e.g. U.S. Pat. No. 4,991,574 ("Pocknell")). There is no particular reason to limit our device to silicone gel, if there are other gels that provide clinical benefit. Further, additives may be introduced into the gel, including, for example, oils, Ben-GayTM, and other topical medications and emollients that seep into the skin area on which the gel is applied. Although other gels may be used, silicone gel is intended to have the special benefit of reducing the appearance of hypertrophic and keloid scarring. The intended advantages of silicone gel are widely known and are also well described in the existing patent literature (e.g. U.S. Pat. Nos. 5,759,560 ("Dilon"), 5,656,279 ("Dillon"), and 5,895,656 ("Hirschowitz et al.")). Silicone gel is also

known to be hydrophobic, so it won't break down or change characteristics in the presence of water or sweat. Cured silicone gel is cohesive (retains its shape) but is not very strong. It can be easily torn, and to be handled by
5 the average person, it must be reinforced with some alternate carrier material.

In the present invention, carrier 10 is illustratively a commercially available loop portion of a stretchable hook-and-loop fastener such as, for example Velstretch®.
10 This "stretch" carrier is essentially the traditional loop portion of a hook-and-loop fastener woven with an elastic material. Depending on the degree of "stretch" needed, different elastic interweaves may be used, and from which a stretch of approximately 50% in one direction may be
15 obtained. This carrier, or substrate, provides the backbone, or compressive force, necessary to apply the silicone gel to any contour on the body, especially joints, both large and small, while also providing the intended benefit of support to the underlying tissue. The thickness
20 of the carrier also provides support to the joint, so that the pain and discomfort of joint inflammation due to a

variety of medical conditions is intended to be minimized. An added intended benefit of the carrier is to provide protection, for example, from abrasion, to the surface of the skin upon which the invention is applied. The support
5 and protective aspects of the present invention, as described above, easily lend themselves to uses on animals as well.

In a particularly illustrative embodiment, the "fuzzy" side or "loop" side 15 of the carrier 10 is used as the
10 carrier for the gel. The bandage may be secured about the afflicted joint or area of the body with a complimentary strip of the hook portion 20 (Fig. 4) of a hook and loop fastener material which may be used to keep the bandage closed around the joint or area of the body. Multiple
15 strips or one large strip of width equal to approximately the width of the bandage may also be used to provide proper securing of the bandage as shown in Fig. 7.

In one particularly illustrative embodiment, the combined product of this invention has the "loop" side, or
20 loop portion 15 (the soft side), of the stretch carrier 10 on one side and a layer of silicone gel on the other. The

gel goes against the skin, and the product is fixed in place by wrapping the body portion with the bandage and applying a complimentary "hook" or closure strip 20 of fastener material at any point along the bandage seam.

5 An embodiment of this invention could be provided in a roll form, about 3" wide by about 1 foot long for applications such as those currently employing use of an Ace® type bandage. In this configuration, the present invention can replace the application of Ace-type bandages
10 for musculo-skeletal support and other orthopedic bandages which are specially configured to fit knees, ankles, wrists, elbows, and other problematic joints. Other dimensions applicable to specific applications are also contemplated, such as for use around a thigh or forearm.

15 It is an embodiment of the present invention for the stretchable carrier 10 to provide a platform for the gel to be continuously applied against any existing scar, which will in turn provide the widely understood benefit of reduced scar appearance. Because the gel is deposited on
20 the carrier 10 while the carrier 10 is in the un-stretched position, it should be understood that, as the carrier 10

is expanded, the gel also expands in the same direction. This will allow air to circulate into the treated area, reducing discomfort due to sweating, yet still provide the benefit of the gel applied against the scar. Further, as
5 the carrier 10 is expanded and then closed using the hook section, the carrier 10 provides compression and support to the affected area.

The silicone gel is intended to provide an additional comfort factor of "coolness" against the skin, which is not
10 diminished to any large degree by keeping the present invention in place for the required period. Because the present invention is intended to be comfortable, supportive, adaptable, stretchable, trimmable, usable on any joint or area of the body around which it can be
15 wrapped, it is expected to result in higher patient compliance with the treatment.

A method of manufacturing the present invention is shown in Fig. 5, and described as follows.

The desired gel is mixed as designated by the material
20 manufacturer, i.e. 1:1, 3:1, or 10:1 parts resin and

catalyst, although the mixture can be varied to obtain different degrees of tack from the final cured gel. The mixture is poured onto a flat surface, such as large sheet of polycarbonate, and allowed to settle until it is a

5 consistent thickness. The gel, after having been allowed to settle, has a consistent thickness and is surrounded by an appropriate sized wall to contain the gel on the polycarbonate surface. In one embodiment, the gel thickness is approximately 2mm, although the thickness may vary from

10 as little as .5mm up to 4mm. Meanwhile, the carrier 10 may be washed in a mild soapy solution such as Ivory® soap to remove the oils and agents used in processing the fabric, and allowed to air dry. After the gel is settled to a consistent thickness (about 20-60 minutes) the dry carrier

15 10 is placed on top with the loop surface of the carrier 10 away from the gel. The assembled materials are then allowed to cure. In an illustrative embodiment, the combined gel and carrier 10 are placed in an oven 50 for 1-3 hours and at a temperature of about 100 to 180 degrees centigrade

20 until the gel is cured. The cured, assembled materials are

then removed from the oven 50 and can then be cut into any shape desired.

The present invention also lends itself well to mass production by coextrusion as shown in Fig. 5. In this
5 embodiment, stretchable carrier 10 is continuously unrolled from a large roll of material onto a bath 30 of gel. As the carrier 10 is removed from the bath 30 a layer of gel 40 adheres to the carrier 10 and settles to a uniform thickness. The stream of combined carrier/gel is then
10 passed through a heating oven 50 and cured. At the other end of the oven 50 are take-up rolls and/or cutting fixtures to facilitate rolling or cutting the cured product into any desired configuration.

In another embodiment shown in Fig 6, an amount of gel
15 40 is deposited onto a river of carrier 10 as the carrier 10 passes beneath the gel. A layer of gel is formed on the side of the carrier 10 opposite the loops and the gel is allowed to settle to a uniform thickness. The river of combined carrier/gel material is then passed through a
20 heating oven 50 and cured. At the other end of the oven 50 are take-up rolls and/or cutting fixtures to facilitate

rolling or cutting the cured product into any desired configuration.

Using either of the previous embodiments, there are specific production techniques which will result in a
5 consistent layer of gel being applied to the flat side of the stretch carrier 10, opposite the loop side.

What is claimed is:

1. A bandage comprising:

5 a first layer of a silicone gel, said first layer having a skin contacting surface and an adhesion surface opposite said skin contacting surface; and

10 a second layer of an elastic and supportive carrier, said second layer having an outer surface and an adhesion surface bonded to said adhesion surface of said first layer to form a continuous two-ply composite; wherein said carrier is the stretchable loop portion of a hook and loop fastener, said loop portion having a loop surface and an opposite adhesion surface.

15 2. The bandage of claim 1 wherein said carrier has an elastic modulus of about 50%.

20 3. The bandage of claim 1 further comprising a closure strip for removably securing the bandage around a part of the body, said closure strip having the hook portion of a hook and loop fastener.

4. A method of manufacturing a bandage comprising:
mixing a silicone gel;
pouring said gel onto a flat surface;
settling said gel to a consistent thickness;
- 5 placing a clean, dry and elastic carrier layer of a
loop portion of a hook and loop fastener having a loop
surface and an adhesion surface onto said gel such that the
adhesion surface is in contact with the gel;
curing said gel and said carrier at a temperature of
10 about 100 to 180 degrees centigrade.
5. The method according to claim 4, wherein said carrier
layer is rigid.
- 15 6. The method according to claim 4, wherein said carrier
layer has a modulus of elasticity of about 50%.
7. A method of manufacturing a bandage comprising:
creating a bath of a silicone gel having a top
20 surface;

unrolling onto said gel a clean, dry and elastic
carrier layer of a loop portion of a hook and loop fastener
having a loop surface and an adhesion surface such that
said adhesion surface bonds with a layer of said gel; and,
5 curing said gel.

8. A method of manufacturing a bandage comprising:
creating a bath of a silicone gel having a top
surface;

10 unrolling onto said gel a clean, dry and elastic
carrier layer of a loop portion of a hook and loop fastener
having a loop surface and an adhesion surface such that
said adhesion surface bonds with a layer of said gel; and,
curing said gel at a temperature of about 100 to 180
15 degrees centigrade by passing said carrier and bonded gel
through an oven.

9. The method according to claim 8, further comprising
the step of rolling up said gel and carrier.

20

10. The method according to claim 8, further comprising the step of cutting the gel and carrier into desired shapes.
- 5 11. A method of manufacturing a bandage comprising:
creating a river of a clean, dry and elastic carrier layer of a loop portion of a hook and loop fastener having a loop surface and an adhesion surface;
depositing onto said adhesion surface a silicone gel;
10 passing said carrier and gel into an oven, and
curing at about 100 to 180 degrees centigrade.
12. The method according to claim 11, further comprising the step of rolling up said gel and carrier.
- 15 13. The method according to claim 11, further comprising the step of cutting the gel and carrier into desired shapes.
- 20 14. A stretchable, supportive laminate wrap comprising:

a silicone gel having a skin contacting surface, said
silicone gel being laminated to an elastic carrier wherein
said carrier is the loop portion of a hook and loop
fastener, said laminate wrap forming an integrated
5 structure configured to have elasticity sufficient to
provide compression against a body surface without
substantial fragmentation of said silicone gel.

15. The laminate wrap of claim 14, wherein the carrier has
10 an elastic modulus of about 50%.

16. The laminate wrap of claim 14, further comprising a
closure strip for removably securing the laminate wrap
around a part of a body, said closure strip having the hook
15 portion of a hook and loop fastener.

17. The laminate wrap of claim 14, wherein the silicone
gel contains an additive.

20 18. The laminate wrap of claim 14, which is in the form of
a sheet or a roll.

19. The laminate wrap of claim 14, wherein the silicone gel is a cured polydiorganosiloxane resin.

5 20. The laminate wrap of claim 14, wherein the silicone gel contains an additive which is a topical medication or an emollient.

21. The laminate wrap of claim 16, wherein the laminate
10 wrap is secured around the body part with the closure strip, whereby the secured laminate wrap provides musculo-skeletal support to the body part.

22. The laminate wrap of claim 21, wherein the body part
15 is a joint or a muscle.

23. The laminate wrap of claim 22, wherein the joint is a knee, an ankle, a wrist, or an elbow.

20 24. The laminate wrap of claim 21, for use in a veterinary application.

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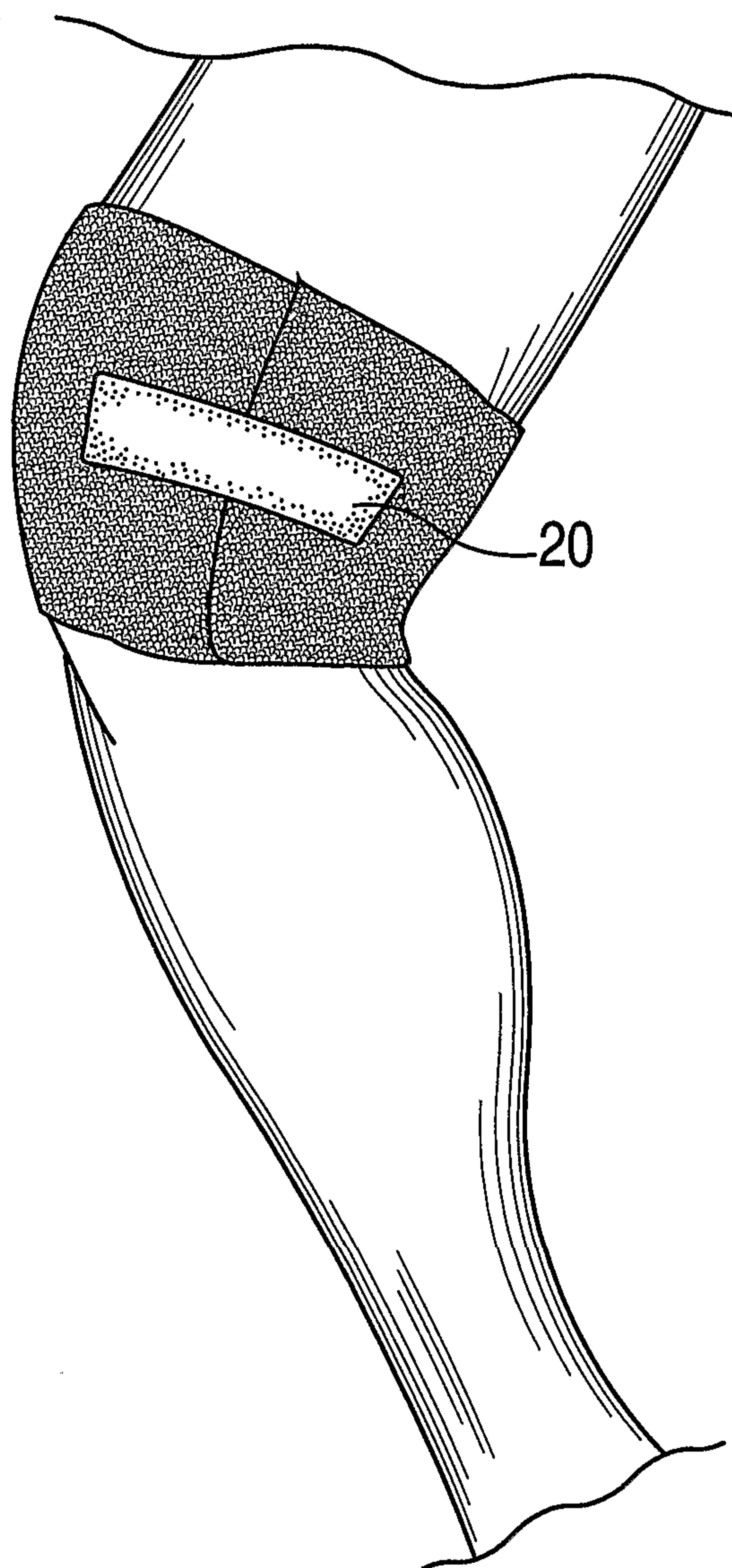


FIG. 1

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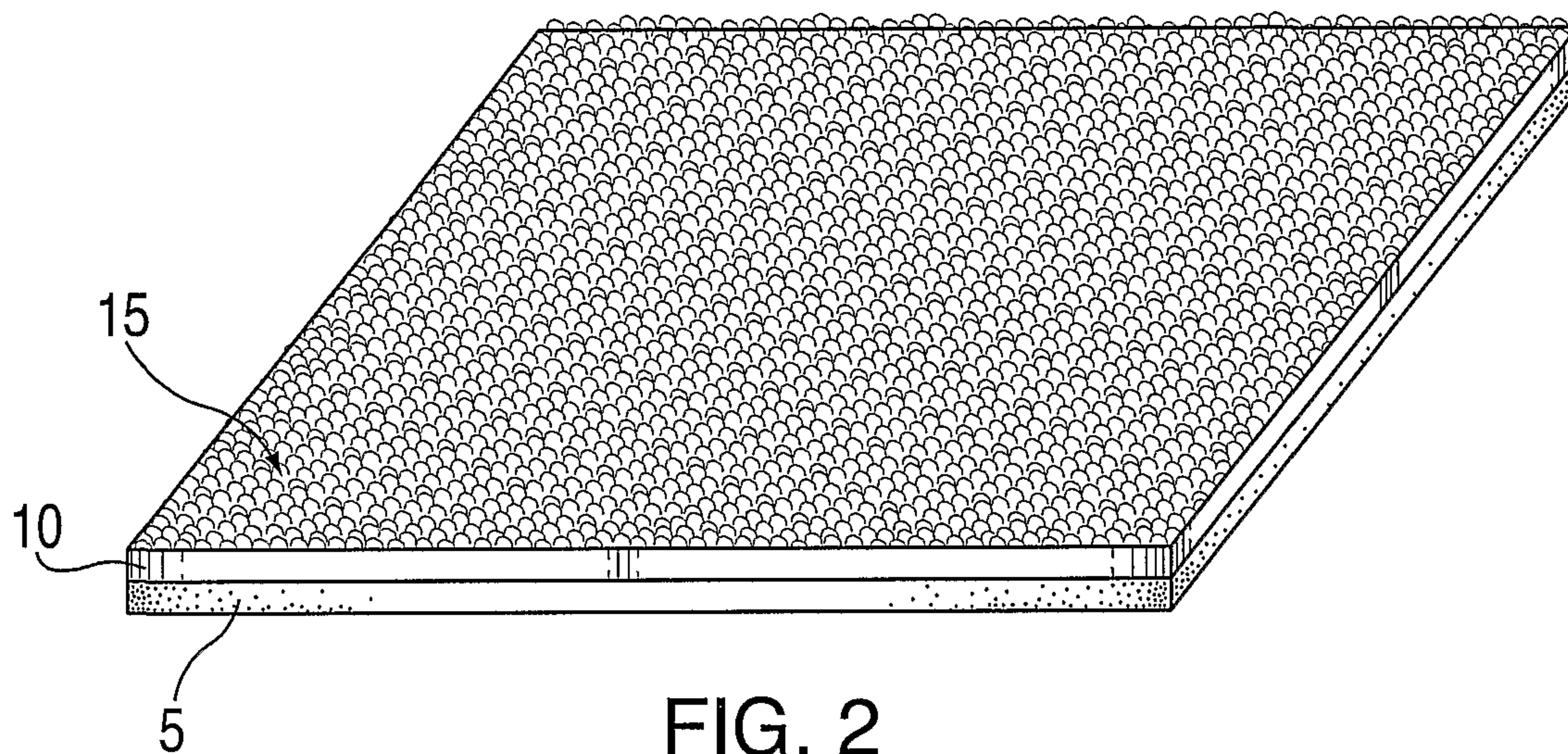


FIG. 3

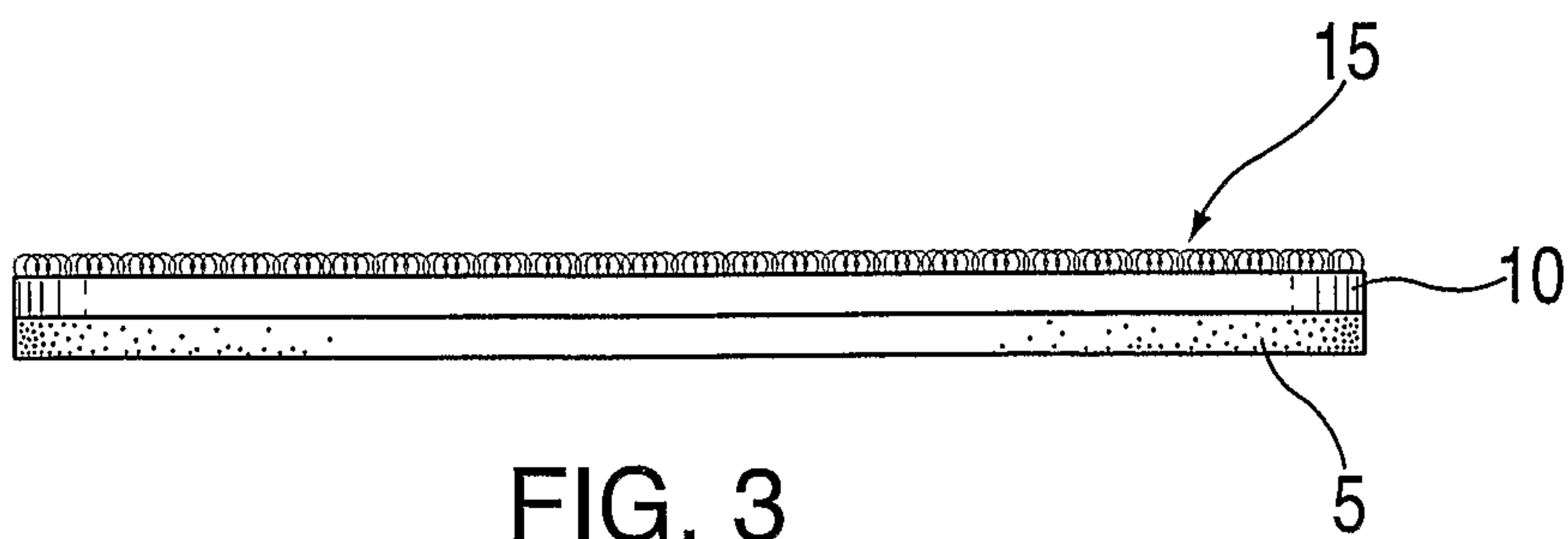




FIG. 4

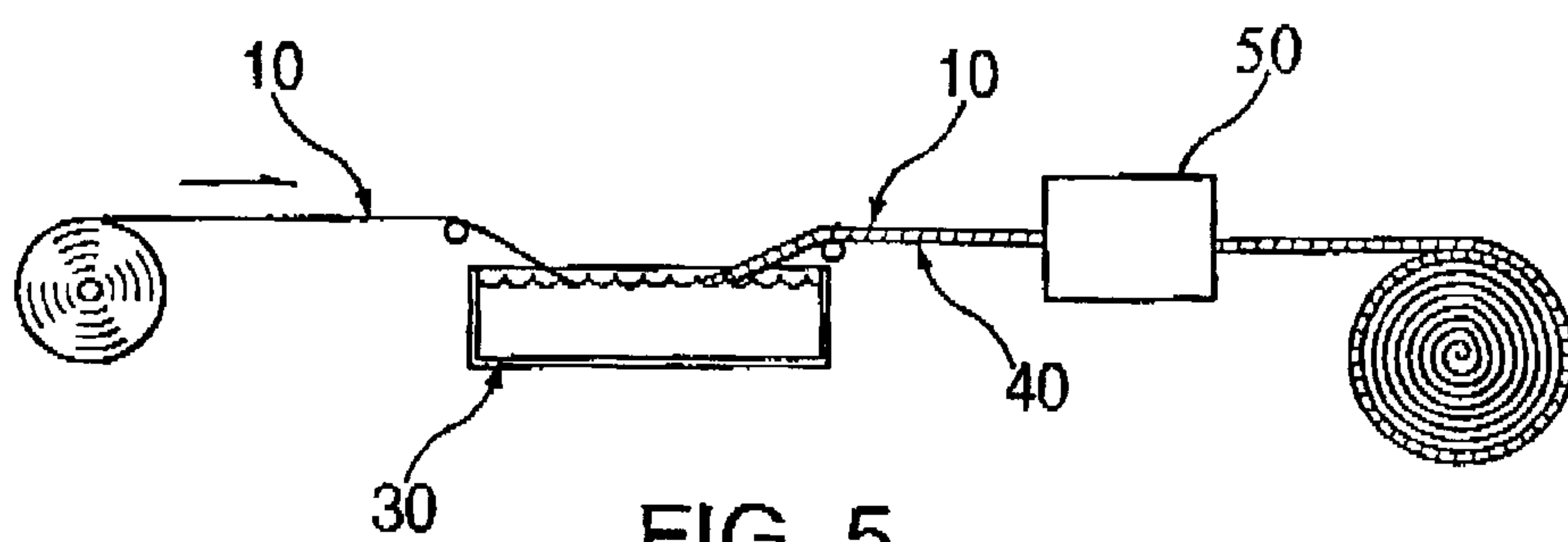


FIG. 5

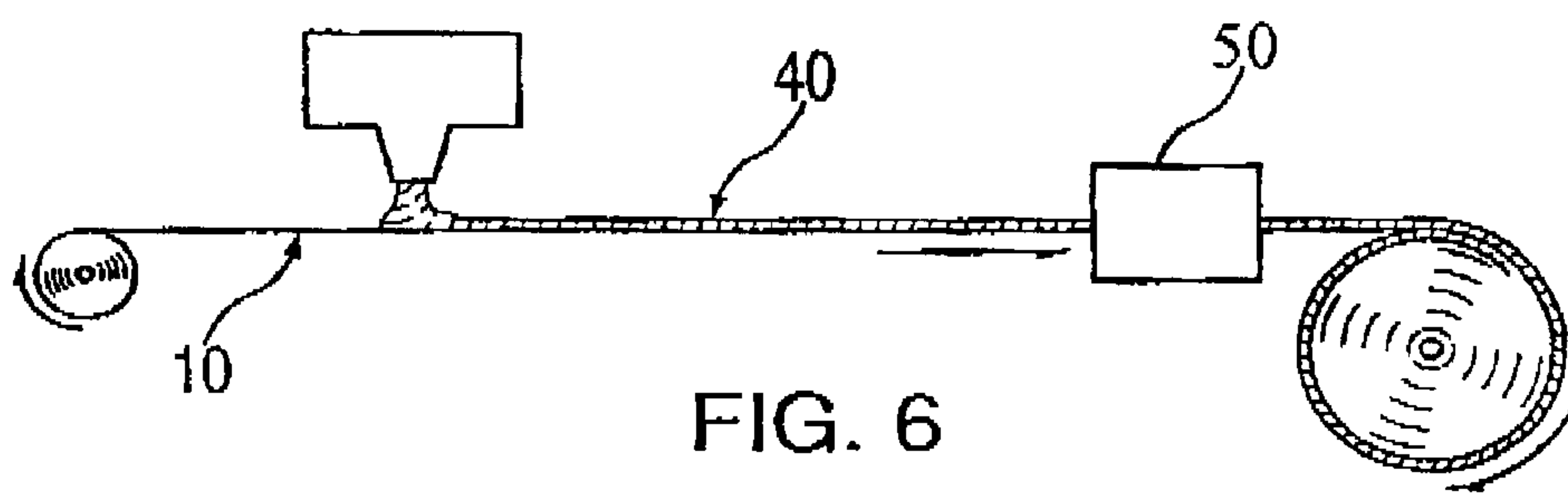


FIG. 6

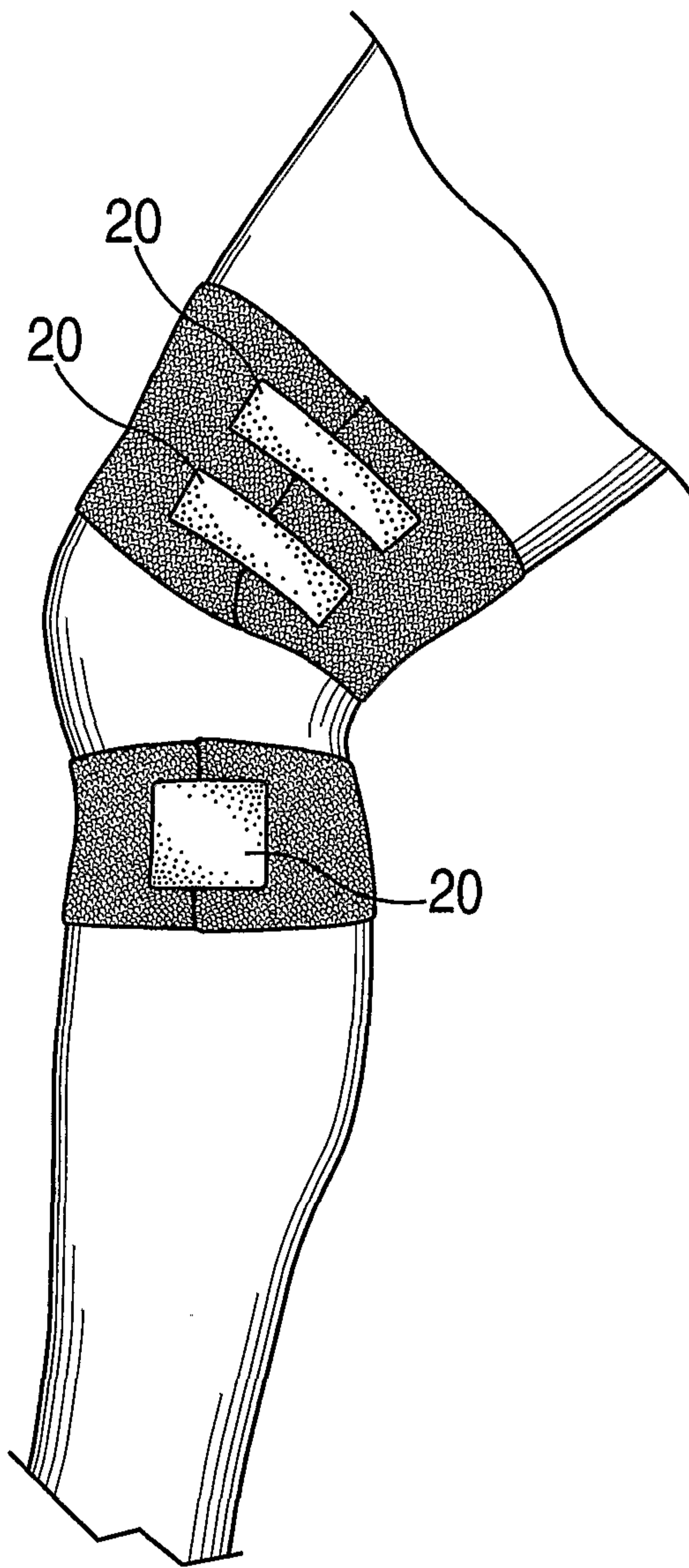


FIG. 7

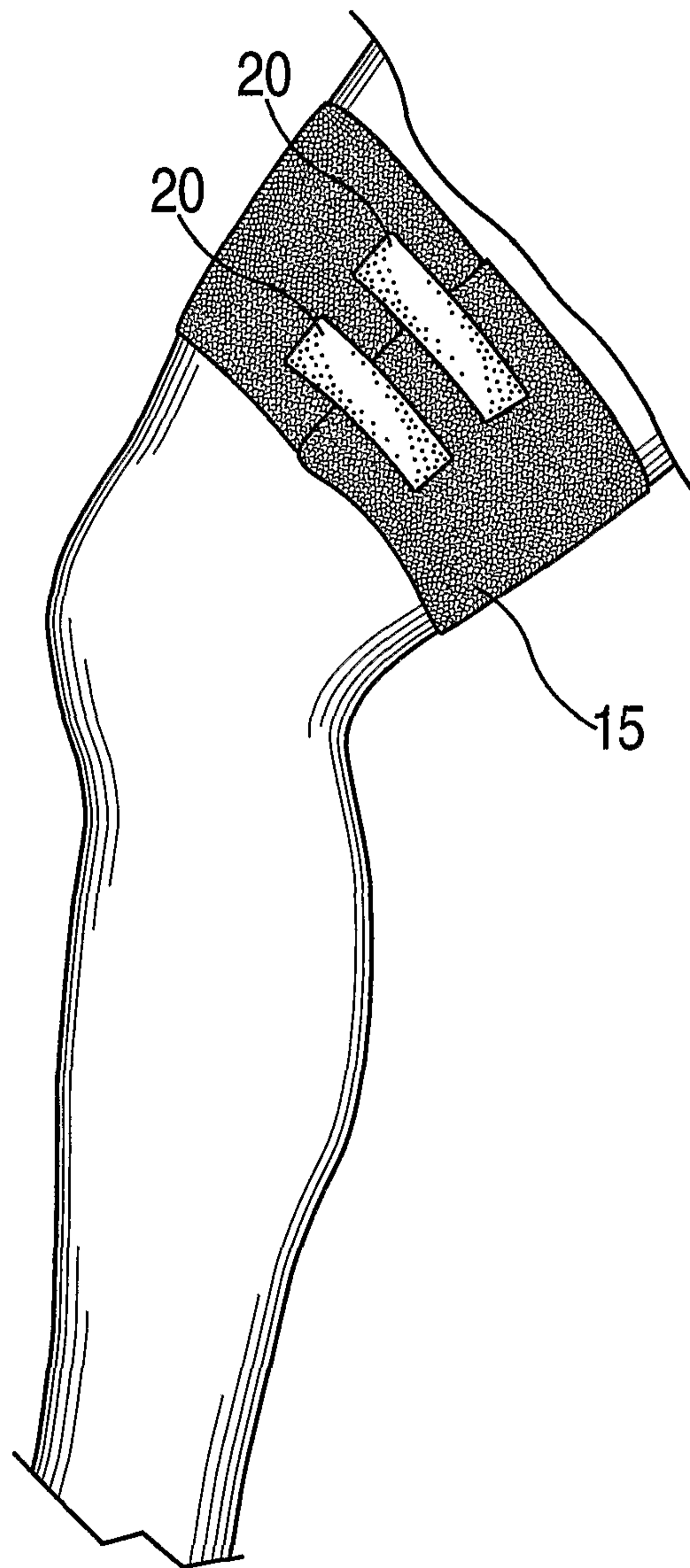


FIG. 8

