Title: WATER RESISTANT, NON-ENCAPSULATED UNDERCAST PADDING

Abstract: An undercast padding for being placed on an injured limb before application of a cast includes a foam substrate having an array of spaced-apart, relatively large openings therethrough, and first and second film layers applied to opposite sides of the substrate. The layers each have an array of spaced-apart, relatively small openings therethrough, wherein some of the film layer openings reside in overlying registration with a respective substrate opening and some others of the film layer openings reside in overlying registration with the substrate.

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WATER RESISTANT, NON-ENCAPSULATED UNDERCAST PADDING

Technical Field and Background of the Invention

[0001] This invention relates to an undercast padding of the type used to protect and cushion the skin of a patient from the relatively rigid material of a cast, such as constructed of plaster of Paris or synthetic cast tape.

[0002] Traditional cast padding is constructed from a simple stockinette and padding material made from cotton or synthetic fibers and offers poor or no water resistant capability. A cast is typically worn for a period of 6-8 weeks. During this period of time, traditional casts having a water-absorbent stockinette can promote skin maceration, discomfort and breed bacteria-causing odor as perspiration and water from washing and bathing migrates to and through the stockinette. The stockinette remains wet or damp for an extended period of time, causing the problems mentioned above.

[0003] The present invention provides a more conformable, water-resistant padding at a reduced cost as compared to water resistant products already available in the market. The present invention is directed to a construction that overcomes the drawbacks of water-resistant undercast paddings such as that found in U.S. patents 5102711 and 5277954. For example, the film/foam substrate has higher elongation in the width direction and provides a higher stretch during application that results in a better conforming padding, which can be easily molded around a limb. Due to the improved padding/cushioning as compared to similar products known in the prior art, the undercast padding of the present invention requires less layers during application. The present invention also has an adhesive layer incorporated on either or both film surfaces. The tacky surface, when applied away from the skin, adheres to itself to form a smoother underlayer for a cast. Additionally, it provides a non-slip effect under the cast tape and keeps the padding in position to facilitate easier application of the cast tape.
[0004] A water-resistant undercast padding such as disclosed and claimed in this application can help alleviate skin maceration problems which generally require additional treatment or therapy and eliminates the need for frequent cast changes. The present invention accommodates bathing, showering and contact with water without significant penetration of water into the padding, therefore keeping the skin relatively dry. In addition, the padding of the present invention provides improved conformability, cushioning, breathability, ease of application and a low profile as compared to water-resistant products currently in the market.

**Summary of the Invention**

[0005] Therefore, it is an object of the invention to provide a water resistant undercast padding material.

[0006] It is another object of the invention to provide a undercast padding that is comfortable when worn under a plaster or synthetic cast tape cast.

[0007] It is another object of the invention to provide a undercast padding that is relatively thin and thus provides a low profile undercast padding layer even when properly overlapped during application.

[0008] It is another object of the invention to provide a undercast padding that is breathable.

[0009] These and other objects of the present invention are achieved in the preferred embodiments disclosed below by providing an undercast padding product, comprising a foam substrate having first and second major sides; first and second opposed side edges, and an array of spaced-apart, relatively large openings. A first film layer is applied to a first major side, or first and second film layers are applied to the first and second major sides of the substrate, each having an array of spaced-apart, relatively small openings therethrough. A first plurality of the film layer openings reside in overlying registration with a respective substrate opening and a second plurality of the film layer openings reside in overlying registration with the substrate.
[0010] According to one preferred embodiment of the invention, the array of ventilation openings in the film layers comprise ranks and files of regularly spaced-apart perforations.

[0011] According to another preferred embodiment of the invention, the substrate layer comprises a closed cell foam selected from the group consisting of acrylis, nitriles, polyurethane, styrene-butadiene rubber, ethylene vinyl alcohol (EVA), polyvinyl acetate (PVAC), neoprene, polyvinylidene chloride (PVDC), polyvinyl chloride (PVC), polyolefins such as polyethylene (PE) or combinations and blends thereof.

[0012] According to yet another preferred embodiment of the invention, the film layers comprise a film selected from the group consisting of polyethylene (PE), polyethylene terephthalate (PET), polyurethane (PU), polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (e-PTFE), and polyvinylidene chloride (PVDC).

[0013] According to yet another preferred embodiment of the invention, the film layers are adhered to the substrate by a pressure-sensitive adhesive.

[0014] According to yet another preferred embodiment of the invention, an embossed pattern is applied to at least a first major surface thereof, the pattern being defined by spaced-apart channels.

[0015] According to yet another preferred embodiment of the invention, an embossed pattern is applied to first and second major surfaces thereof. The pattern is defined by spaced-apart channels extending inwardly into the substrate from opposing sides and form areas of reduced thickness in the substrate separating the channels of the first major surface from the channels of the second major surface.

[0016] According to yet another preferred embodiment of the invention, the embossed pattern comprises ranks and files of quadrilaterals.

[0017] According to yet another preferred embodiment of the invention, the openings in the film layers comprise perforations formed by inward ruptures of the film.
According to yet another preferred embodiment of the invention, the openings in the substrate comprise holes formed by removing spaced-apart areas of foam from the substrate.

According to yet another preferred embodiment of the invention, the perforations are spaced-apart to provide approximately 10-40 perforations per cm², and an approximate area of the perforations in relation to the area of the film layers of 4 mm² per cm².

According to yet another preferred embodiment of the invention, the holes in the substrate are approximately 1-8 mm in diameter and are spaced-apart approximately 1-10 mm to provide approximately 2-12 holes per cm².

According to yet another preferred embodiment of the invention, the approximate area of the holes in relation to the area of the substrate is 20 mm² per cm².

According to yet another preferred embodiment of the invention, the relationship of the area of the perforations in each film layer to the holes in the substrate per unit of area of the undercast padding is approximately 1 to 5.

A method of forming an undercast padding in accordance with a preferred embodiment of the invention includes the steps of forming relatively small, spaced-apart openings in first and second film layers, forming relatively large, spaced-apart openings in a foam substrate layer, and adhering the first film layer to a first major surface of the substrate and the second film layer to a second major surface of the substrate to form a lamination, wherein a first plurality of the film layer openings reside in overlying registration with a respective substrate opening and further wherein a second plurality of the film layer openings reside in overlying registration with the substrate.

According to yet another preferred embodiment of the invention, the method includes the step of embossing the adhered substrate and film layers to form pads separated by channels of reduced thickness.
[0025] According to yet another preferred embodiment of the invention, the channels extend along the length and across the width of the undercast padding in mutually perpendicular relation.

[0026] According to yet another preferred embodiment of the invention, the openings in the film layers are formed by rupturing the film, and the openings in the substrate are formed by removing foam material from the substrate.

[0027] According to yet another preferred embodiment of the invention, the step of embossing comprises the step of forming uniform ranks and files of quadrilaterals separated by mutually-perpendicular and intersecting channels.

[0028] According to yet another preferred embodiment of the invention, the step of embossing comprises the step of forming mutually-perpendicular and intersecting channels defining pads therebetween, wherein the channels extend into the substrate in spaced-apart relation to the opposing film layer.

Brief Description of the Drawings

[0029] Some of the objects of the invention have been set forth above. Other objects and advantages of the invention will appear as the invention proceeds when taken in conjunction with the following drawings, in which:

[0030] Figure 1 is a perspective view of a roll of an undercast padding according to one embodiment of the invention;

[0031] Figure 2 is a major surface plan view of the undercast padding;

[0032] Figure 3 is a perspective view of a length of the undercast padding;

[0033] Figure 4 is a cross-sectional view of the undercast padding taken along line 4--4 of Figure 3;

[0034] Figure 5 is an enlarged view of the cross-section shown in Figure 4;

[0035] Figure 6 is a perspective view of the undercast padding with the layers separated for clarity;
[0036] Figure 7 is a view illustrating application of the undercast padding to the wrist and forearm;
[0037] Figures 8 and 9 illustrate preparation of a cast tape for application over the undercast padding;
[0038] Figures 10 and 11 illustrate application of the cast tape to the undercast padding; and
[0039] Figure 12 illustrates the completed cast.

Description of the Preferred Embodiment and Best Mode
[0040] Referring now specifically to the drawings, a undercast padding according to the present invention is illustrated in Figure 1 and shown generally at reference numeral 10. While the undercast padding 10 can be formed in any desired width or length, the undercast padding 10 shown in Figures 1, 2 and 3 is 7.5 cm (3 in.) wide and is formed into a roll during manufacture for shipping and storage until use. The undercast padding 10 is easily applied from the roll, as shown in Figure 7.
[0041] The undercast padding 10 is formed from a lamination of a foam substrate 11 overlaid with two film layers 12 and 13. The film layers 12 and 13 can be attached to the two major sides of the foam substrate 11 by thermal or ultrasonic adherence, by a pressure-sensitive adhesive, by application of heat and pressure, or a combination of these methods. The preferred method of attachment is by means of heat and pressure sufficient to maintain the film layers 12 and 13 in place in overlying registration with the substrate 11. The substrate 11 is preferably a polyethylene closed cell foam, and the film layers 12 and 13 are preferably polyethylene film. Alternatively, only a single film layer may be adhered to one of the sides of the substrate 11.
[0042] The undercast padding 10 is embossed with a grid pattern comprised of intersecting elongate channels 15 of reduced thickness defining ranks and files of pads 17. The pads 17 maintain the original thickness of the substrate 11 and the two film layers 12 and 13. As is best shown in Figures 4 and 5, the embossing does not extend
completely through the thickness of the undercast padding 10, but only so far into the thickness of the undercast padding 10 as necessary to form distinct channels 15 and thus the pads 17. Likewise, the end edges and side edges of the undercast padding 10 are not sealed or otherwise enclosed, but exposed. For this reason, the undercast padding 10 is referred to as being non-encapsulated and is thus distinguished from prior art products having encapsulated ranks and files of pillow-shaped pads.

[0043] Embossing is preferably accomplished by application of heat and pressure onto one side of the undercast padding 10, thus forming the channels 15 on the film layer 12.

[0044] By continued reference to Figures 4 and 5, and also to Figure 6, it will be observed that the top and bottom film layers 12 and 13 are each provided with a multitude of very small, closely spaced-apart perforations 20, preferably formed by punching the film layers 12 and 13 in such manner that the perforations 20 are formed by displacing small areas from the major surface plane of the film layers 12 and 13, rather than by punching and detaching material to form distinct holes where material has been removed. Formation of the perforations 20 may take place before the films 12 and 13 are applied to the substrate 11, or after application to the substrate has occurred. Preferably the perforations 20 are formed before the film layers 12 and 13 have been applied to the substrate 11. If perforation takes place after application of the films 12 and 13 to the substrate, the perforations 20 are formed by projections being penetrated into the undercast padding 10 from one side, with both films 12 and 13 being perforated at the same time. It is not essential that the same number, size, shape or spacing of the perforations 20 be present in both of the films 12 and 13. In particular, when perforation occurs from one side, fewer and/or smaller perforations 20 may be formed in the film layer on the reverse side of the substrate 11.

[0045] The substrate 11 is punched to form an array of relatively large, spaced-apart holes 22, as best shown in Figure 6. As shown in Figures 4, 5 and 6, some of the perforations 20 in the film layers 12 and 13 overlie the holes 22 in the substrate 11,
while others reside over the solid areas of the substrate 11. Collectively, this arrangement provides both resistance to penetration by water while at the same time providing a high degree of air and vapor transfer. In addition, the perforations 20 and holes 22 collectively decrease the weight and density of the undercast padding 10, provide a substantially increased amount of stretch in both the length-wise and width-wise directions, and enable the undercast padding 10 to be easily torn by hand as needed to sever a length of the undercast padding 10 from a roll, or to shape an area of the undercast padding 10 during application.

[0046] If the perforations 20 are formed after application of the film layers 12 and 13 to the substrate 11, punctures formed in the foam of the substrate 11 incident to formation of the perforations 20 close together.

[0047] Application of the film layers 12 and 13 may achieved by moving a strip of the substrate 11 along a process line where strips of the film layers 12 and 13 are dispensed from rolls and applied to opposite sides of the substrate 11. If integration of the layers is accomplished by use of an adhesive, it may be applied just before lamination to the film layers 12 and 13 to the substrate, or pre-applied to the film during manufacture. The film layers 12 and 13 are adhered by passing the assembly through a pair of nip rolls. If the adhesive is a heat-activatable adhesive, heat is applied at or near the point of lamination. The undercast padding 10 is then passed through another set of rolls that emboss the grid pattern onto the laminated structure by formation of the channels 15. Embossing may take place on both sides of the undercast padding 10, or only on a single side. Even when embossing occurs only from one side, the heat and pressure may be sufficient to transfer the shape to the reverse side, leaving the similar, though less distinct pattern on the reverse side. Figures 4, 5 and 6 illustrate a undercast padding 10 embossed from both sides, i.e., pressure is applied to both the film layer 12 and the film layer 13.

[0048] The assembled undercast padding 10 is then rolled into a suitable-length roll and packaged for shipment and storage until ready for use.
The foam utilized for the substrate 11 can be formed from acrylics, nitriles, polyurethane, styrene-butadiene rubber, ethylene vinyl alcohol (EVA), polyvinyl acetate (PVAC), neoprene, polyvinylidene chloride (PVDC), polyvinyl chloride (PVC), polyolefins such as polyethylene (PE) or combinations and blends thereof, but is preferably polyurethane. The foam substrate 11 can be manufactured either as an open cell, closed cell or reticulated cell with a rigid, semi-rigid or flexible hardness. The substrate 11 in the preferred embodiment is a flexible polyurethane closed cell foam.

The film layers 12 and 13 can be constructed from the same material or can be of two different types. The film layers 12 and 13 can be constructed using polyethylene (PE), polyethylene terephthalate (PET), polyurethane (PU), expanded polytetrafluoroethylene (e-PTFE), polyvinylidene chloride (PVDC) or any suitable polymer offering the desired properties. The film layers 12 and 13 prevent or significantly reduce water or perspiration from coming in direct contact with the foam substrate 11, thus providing a significant degree of water-resistance. Film thickness can vary from .01mm to .5mm. The preferred film layers 12 and 13 are a 2 mil polyethylene-based material that is flexible, moisture impervious and fungal-resistant.

The adhesive used can be any pressure-sensitive adhesive approved for use in medical products that come into contact with the skin. The adhesive layer can be 0.02-2.5 mil thick.

According to one preferred embodiment of the undercast padding 10, the perforations 20 are approximately 0.5 mm in length and width. However, the perforation process preferably results in an irregular hole caused by the rupture of the film layers 11 and 12 at the point of perforation. The irregularity of the perforations 20 is believed to reduce liquid moisture transfer by decreasing capillary ingress. The punching of the perforations 20 results in hole ruptures that are generally tapered inwardly towards the substrate 11, thus further reducing the tendency of liquid moisture to penetrate past the film layers 12 and 13, while permitting unimpeded air and vapor transfer.
[0053] In one preferred embodiment of the undercast padding 10, the perforations 20 are spaced-apart to provide approximately 16 perforations cm², or an approximate area of the perforations 20 in relation to the area of the film layers 12 and 13 of 4 mm² per cm².

[0054] The holes 22 in the substrate 11 are approximately 5 mm in diameter and are spaced-apart approximately 5 mm to provide approximately .8 holes 22 per cm², or an approximate area of the holes 22 in relation to the area of the substrate 11 of 20 mm² per cm². Therefore, in one preferred embodiment, the relationship of the area of the perforations 20 to the holes 22 per unit of area of the overall undercast padding 10 is approximately 1 to 5, or 20 percent.

[0055] Referring now to Figure 7, the undercast padding 10 is applied to the injured limb in a conventional manner. As noted above, the stretch provided by the undercast padding 10 permits a fast, accurate, closely-conforming application without wrinkles or creases. The compressibility of the undercast padding 10 reduces thickness and ridges at the overlap points.

[0056] As is shown in Figures 8-12, after application of the undercast padding 10, a conventional cast tape 30 is wetted, Figure 8, excess water removed by wringing, Figure 9, and applied to the injured limb, Figures 10-12, taking care in the usual manner to avoid overlapping the undercast padding 10 on opposite ends, leaving a short width of exposed undercast padding 10.

[0057] An undercast padding is described above. Various details of the invention may be changed without departing from its scope. Furthermore, the foregoing description of the preferred embodiment of the invention and the best mode for practicing the invention are provided for the purpose of illustration only and not for the purpose of limitation—the invention being defined by the claims.
We claim:

1. An undercast padding product, comprising:
   (a) a foam substrate having first and second major sides and first and second opposed side edges, and an array of spaced-apart substrate openings therethrough; and
   (b) a first film layer applied to one of the first and second major sides of the substrate to provide a water resistant yet breathable undercast padding.

2. An undercast padding product according to claim 1, wherein the at least first film layer includes an array of ventilation openings comprising ranks and files of spaced-apart perforations.

3. An undercast padding product according to claim 1, wherein the substrate layer comprises a foam selected from the group consisting of acrylics, nitriles, polyurethane, styrene-butadiene rubber, ethylene vinyl alcohol (EVA), polyvinyl acetate (PVAC), neoprene, polyvinylidene chloride (PVDC), polyvinyl chloride (PVC), polyolefins such as polyethylene (PE) or combinations and blends thereof.

4. An undercast padding product according to claim 1, wherein the at least first film layer comprises a film selected from the group consisting of polyethylene (PE),
polyethylene terephthalate (PET), polyurethane (PU), polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (e-PTFE), and polyvinylidene chloride (PVDC).

5. An undercast padding product according to claim 1, wherein the at least first film layer is adhered to the substrate.

6. An undercast padding product according to claim 1, and including an embossed pattern applied to at least a first major surface thereof, the pattern being defined by spaced-apart channels.

7. An undercast padding product according to claim 1, and including an embossed pattern applied to first and second major surfaces thereof, the pattern being defined by spaced-apart channels extending inwardly into the substrate from opposing sides and forming areas of reduced thickness in the substrate separating the channels of the first major surface from the channels of the second major surface.

8. An undercast padding product according to claim 7, wherein the embossed pattern comprises ranks and files of quadrilaterals.
9. An undercast padding according to claim 1, wherein the at least first film layer includes perforations formed by inwardly-directed ruptures of the film.

10. An undercast padding according to claim 1 or 9, wherein the openings in the substrate comprise holes formed by removing spaced-apart areas of foam from the substrate.

11. An undercast padding according to claim 9, wherein the film perforations are spaced-apart to provide approximately 16 perforations cm$^2$, and an approximate area of the perforations in relation to the area of the film layers of 4 mm$^2$ per cm$^2$.

12. An undercast padding according to claim 10, wherein the holes in the substrate are between approximately 1-8 mm in diameter and are spaced-apart between approximately 2-15 mm to provide approximately .8 holes 22 per cm$^2$.

13. An undercast padding according to claim 10, wherein the approximate area of the holes in relation to the area of the substrate is 20 mm$^2$ per cm$^2$. 
14. An undercast padding according to claim 10, wherein the relationship of the area of the perforations in each film layer to the holes in the substrate per unit of area of the undercast padding is approximately 1 to 5.

15. An undercast padding product, comprising:
   (a) a foam substrate having first and second major sides and first and second opposed side edges, and an array of spaced-apart, relatively large openings therethrough; and
   (b) first and second film layers applied, respectively, to the first and second major sides of the substrate, the first and second layers each having an array of spaced-apart, relatively small openings therethrough, wherein a first plurality of the film layer openings reside in overlying registration with a respective substrate opening and further wherein a second plurality of the film layer openings reside in overlying registration with the substrate.

16. An undercast padding according to claim 15, wherein the holes in the substrate are approximately 5 mm in diameter and are spaced-apart between approximately 5 mm to provide approximately .8 holes 22 per cm².

17. A method of forming an undercast padding, comprising the steps of:
   (a) forming relatively small, spaced-apart openings in a first film layer;
(b) forming relatively large, spaced-apart openings in a foam substrate layer;
and
(c) applying the first film layer to a first major surface of the substrate to form a lamination.

18. A method according to claim 17, and including the step of embossing the substrate and first film layer to form pads separated by channels of reduced thickness.

19. A method according to claim 18, wherein the channels extend along the length and across the width of the undercast padding in mutually perpendicular relation.

20. A method according to claim 17, wherein the openings in the film layer are formed by rupturing the film, and the openings in the substrate are formed by removing foam material from the substrate.

21. A method according to claim 18, wherein the step of embossing comprises the step of forming uniform ranks and files of quadrilaterals separated by mutually-perpendicular and intersecting channels.
22. A method according to claim 18, wherein the step of embossing comprises the step of forming mutually-perpendicular and intersecting channels defining pads therebetween, wherein the channels extend into the substrate in spaced-apart relation to the opposing film layer.

23. A method according to claim 17, wherein the step of forming the openings in the film layers is performed after the step of adhering the film layers to the substrate.

24. A method according to claim 22, wherein the first plurality of the film layer openings reside in overlying registration with a respective substrate opening and further wherein a second plurality of the film layer openings reside in overlying registration with the substrate.

25. A method of forming an undercast padding, comprising the steps of:
   (a) forming relatively small, spaced-apart openings in first and second film layers;
   (b) forming relatively large, spaced-apart openings in a foam substrate layer;
   (c) adhering the first film layer to a first major surface of the substrate and the second film layer to a second major surface of the substrate to form a lamination, wherein a first plurality of the film layer openings reside in overlying registration with a respective substrate opening and further wherein a second plurality of the film layer openings reside in overlying registration with the substrate.
Fig. 12
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : B32B 3/00
US CL : 428/140
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 428/140, 131, 138; 602/3; 604/369

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
<tr>
<td>Y</td>
<td>US 5,916,184 A (MCKEEL) 29 June 1999 (29.06.1999), see whole document.</td>
<td>1-25</td>
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<tr>
<td>Y</td>
<td>US 4,516,572 A (SCHLEIN) 14 May 1985 (14.05.1985), see whole document.</td>
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