United States Patent [19]

Hume

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[54] **DRESSING AND SUPPORT COMBINATION FOR THE TREATMENT OF INDOLENT ULCERS**

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[52] **U.S. Cl.** **128/165**, 128/156, 128/260

[51] **Int. Cl.** **A61f 13/02**, A61m 35/00

[58] **Field of Search** 128/268, 260, 165, 156, 128/155

[56] **References Cited**

UNITED STATES PATENTS

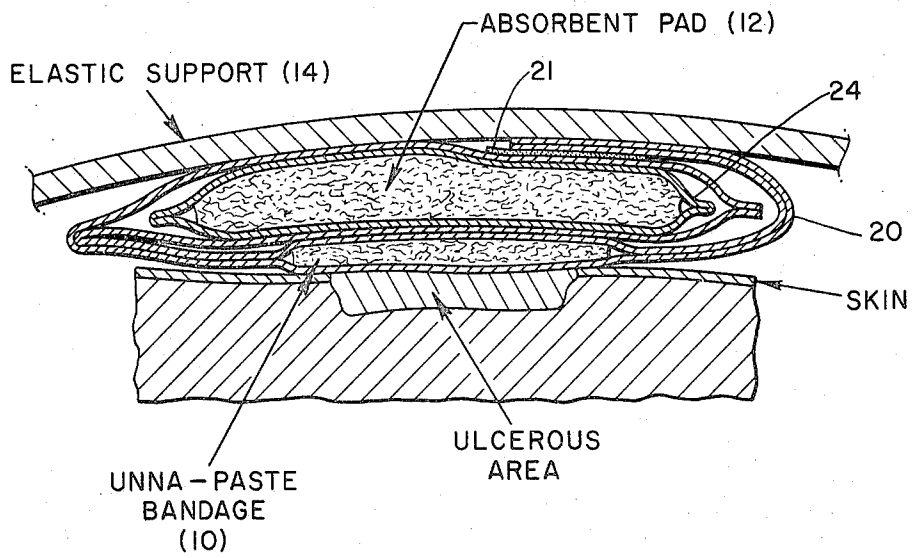
2,432,541	12/1947	Peck	128/268
2,560,712	7/1951	Bell	128/156
2,574,873	11/1951	Jobst	128/165
3,074,405	1/1963	Duensing	128/165 X
3,366,112	1/1968	Antonik	128/268

Primary Examiner—Aldrich F. Medbery

[57] **ABSTRACT**

A dressing and support combination for the treatment of indolent ulcers by the patient himself is provided employing a combination of a bandage impregnated with Unna Paste, an absorbent pad, and a gradient-pressure elastic support. Means are provided for anchoring the components against relative motion and for anchoring the dressing as a unit against motion relative to the support and the ulcerous area being treated. A prefabricated and packaged combination of the components is also provided.

11 Claims, 8 Drawing Figures



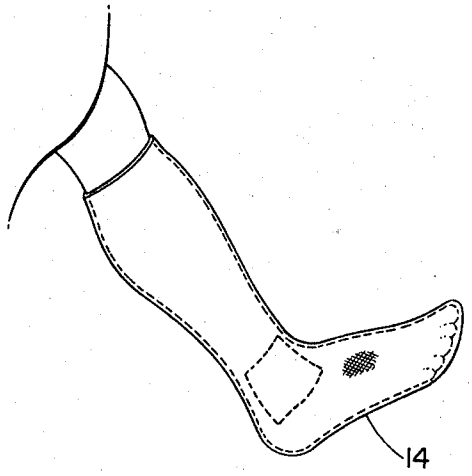


FIG. 1

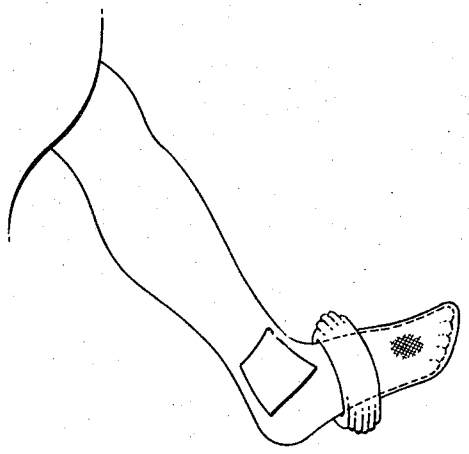


FIG. 2

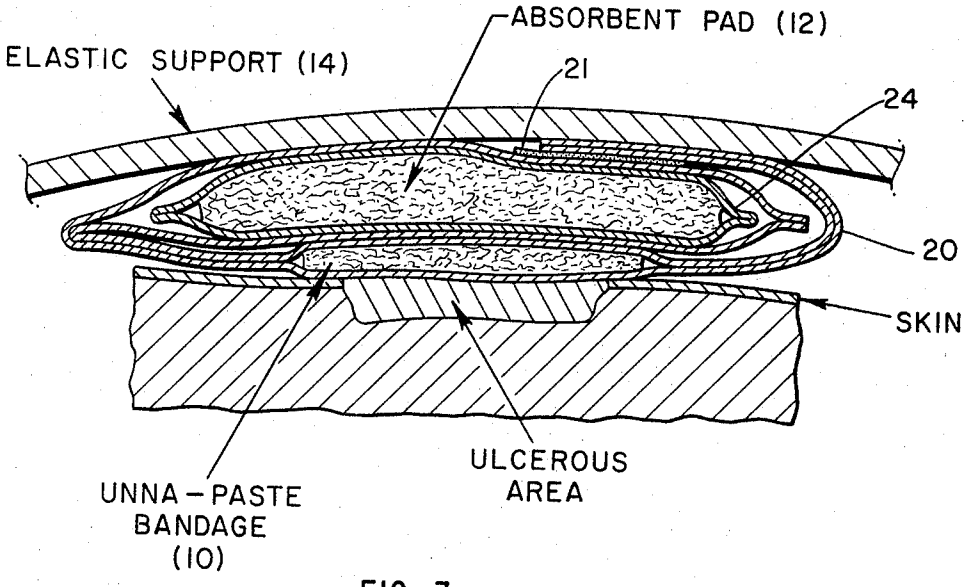


FIG. 3

FIG. 4

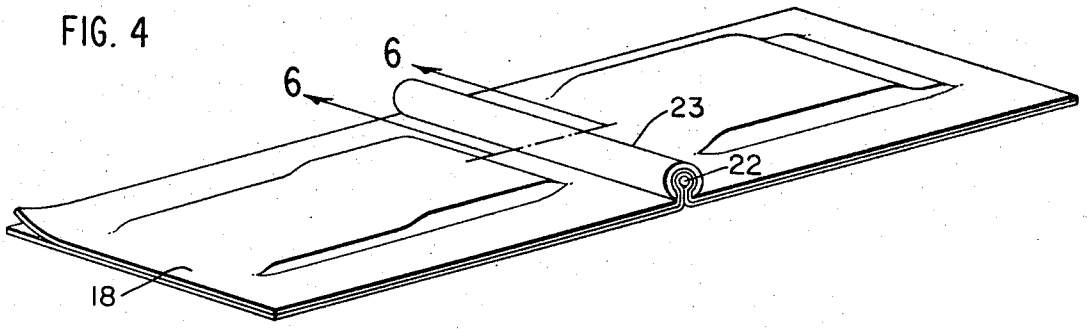


FIG. 5

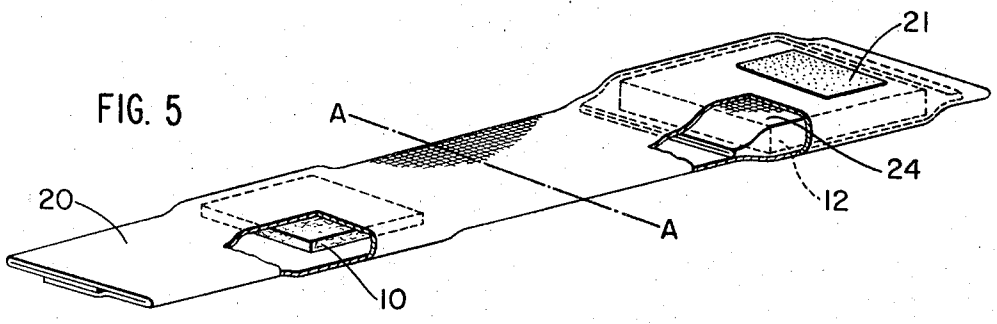
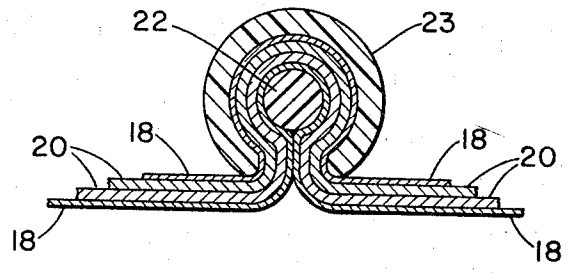


FIG. 6



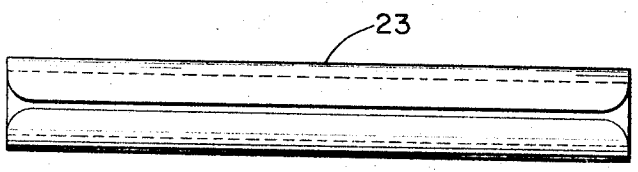


FIG. 7

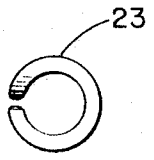


FIG. 8

DRESSING AND SUPPORT COMBINATION FOR THE TREATMENT OF INDOLENT ULCERS

BACKGROUND OF THE INVENTION

This invention relates to a medical dressing for use in the healing of ulcers due to chronic insufficiency of the valves of the veins. It is useful for healing certain other indolent ulcers of the lower limb. It is well known that venous ulcers heal poorly without expert medical care when they afflict patients who must be up and about and for whom treatment in bed or in a hospital constitutes a burden or inconvenience. Ambulatory care of such ulcers is successful to the extent that the physician skillfully applies a compound dressing (bandages). However, it is known that this treatment often fails because of wrongly selected materials, too little or too much pressure incorporated in applying the dressing, or unfamiliarity with the best practice in this type of management. In addition, the presently employed techniques are time consuming, require the physician to reapply the dressing at weekly intervals, preclude bathing while the treatment is in process, and represent such complexities that some practitioners avoid undertaking the management of venous ulcers. As a result, much disability is suffered by patients for lack of a more effective solution to the problem.

Conversely, when the dressings have been properly applied, it has been done at relatively great expense of clinical and professional time to say nothing of materials. It is estimated that a single properly applied dressing of this sort represents a total cost of about $30.00.

The general problem, therefore, to which this invention is directed is the provision of an inexpensive dressing combination which is suitable and effective for the treatment of indolent or the like ulcers which dressing can be applied and used by the patient with minimal professional supervision.

More specific problems, however, in the solution of this general problem should be considered. First, with respect to the fundamental defect involved, namely valvular insufficiency of certain perforating veins of the lower leg, it is the counterpressure supplied by an external support which supports the veins against venous hypertension and thereby induces healing in spite of full ambulatory activity. Thus, in the conventional dressing used for this condition, although several of the dressing layers are essential to protect the skin and absorb drainage from the unhealed ulcer, it is the pressure component that is most important in healing the ulcer. Too much or too little pressure will serve the purpose less well. In practice, the pressure is achieved by the use of a resilient adhesive plaster, and the physician must apply this component with consumate skill, starting at the top of the calf where it is wrapped relatively loosely, and continuing in overlapping relation down the leg, exercising slightly greater pressure with each turn until the ulcer is reached and passed, but with slightly less pressure around the foot and instep where the additional pressure of the shoe will add to the net sum of the compression, and ending finally at the base of the toes. No alternative exactly substitutes for the physicians' skill in applying the pressure component of the dressing, yet it must be acknowledged that many practitioners are unaware of the principles involved, or have not become familiar with the technique and some, when they attempt it, find the results far from satisfactory. The skill of the experienced specialist can be closely approximated in regard to the pressure applied by a type of pressure gradient elastic stocking, being a custom-fit support available under a physician's prescription. In current practice these are ordinarily worn by patients only after the ulcer has been healed because exudate draining from the ulcer tends to destroy the resiliency of the fabric of the stocking.

Thus it is important to recognize that the total pressure contact with the limb must be a gradient, greatest at the point furthest from the heart and progressively less proceeding up to the knee. The pressure gradient is considered in relation to the standing position and is particularly important when the patient walks, for then the incompetent perforating veins referred to above transmit the high exercise venous pressure to the damaged skin aggravating the condition most seriously. In fact, with the patient recumbent, as during the hours of sleep, no pressure is needed at all, particularly if the bed is elevated by blocks under the foot end as is customarily prescribed in treating this condition. The pressure component therefore could be dispensed with at night and is required only when the patient is up and about. However, there is no practical way this diurnal requirement can be met by the patient, for only the physician can apply the complex components of the compound dressing with the special type of pressure needed, and then only at intervals of once a week as a matter of practical convenience. Ideally the entire dressing might be removed at night and discarded along with the contained exudate permitting bathing and leaving the limb free during sleep for relief of the maceration which results from the fact the entire leg needs to be enclosed by the dressing. It is out of the question for the patient to enjoy access to daily dressing changes by a physician and unfortunately only a skilled professional could perform this service daily for himself.

The practical consideration of having the physican skillfully apply the compound pressure dressing at a convenient interval, such as once a week, requires that an absorbent component be included that will contain all exudate between dressing changes. Here again the volume of the absorbent component (usually a cotton filled pad) is critical, for too little absorbing capacity allows overflow, which is aesthetically troublesome and provokes maceration of the skin or dermatitis. Conversely too much absorbent material compromises the pressure component by diffusing the pressure from the ulcer and reducing the effective pressure which constitutes the healing principal. The current method is thus a compromise which would be far less delicately balanced if the dressing were changed daily, in as much as less absorbency would be required, and in fact the absorbency would be suited more precisely to the amount of drainage, as experience with the situation at hand reveals, and the proper gradient pressure could be applied with minimal dissipation due to the interposed absorbent component.

The paste component applied to the skin, known as Unna's paste, includes zinc oxide, gelatin and glycerin and is well-suited to protecting the skin from maceration by perspiration and neutralizing the irritating effect of the exudate. However, to maintain this component in the same way that all the other layers are kept in place, the paste layer too in the conventional dressing must be applied from the knees to the toes using an impregnated bandage. This wastefully covers much uninvolved skin, though this is necessary for the lack of

any other practical means to hold it where it is needed over and around the ulcer and to protect the skin from maceration due to perspiration under the dressing which necessarily covers the entire leg.

So it is seen that the best practice now involves wasteful use of excessive materials in order to hold all layers in place and represents a compromise between direct counter pressure over the ulcer and the need of absorbency which it itself directly related to the interval between dressing changes.

Accordingly, the provision of a disposable dressing suitable for daily self application by the patient under a custom-fit pressure gradient stocking represents a radical departure from current practice, which is, nevertheless, soundly based on the pathophysiologic defect that must be overcome, and embodying convenience features, while obviating the need for frequent dressing changes by (at the best) a highly trained specialist or (rather worse) a uniformed practitioner using less than ideal technique. The proposed dressing described below will predictably upgrade the standard of medical care of this condition, relieve suffering for this humble but widespread affliction and lead to earlier and more effective treatment of such ulcers before they become serious by virtue of the practical and convenient specifications embodied.

SUMMARY OF THE INVENTION

The present invention accomplishes these objectives in the following manner. It makes use of a conventional heavy duty gradient-pressure elastic support, typically an elastic stocking, which is sold under prescription, to accommodate the pressure requirements of the individual patient. In general terms, the dressing comprises an Unna-Paste gauze bandage dimensioned to cover the ulcerous area plus a small marginal area, and an absorbent, cotton-wool filled pad in a porous gauze jacket covering the Unna-Paste bandage. The elastic support is pulled (rolled) over the pad and holds it in place.

More specifically, the dressing is packaged as a unit with the Unna-Paste bandage and the absorbent pad joined. The dressing is sealed within an impervious envelope in such a way that the unit can be stored without migration of the Unna Paste into the absorbent pad. The impervious envelope is, of course, removed when the dressing is being prepared for use.

In order to prevent the absorbent pad from moving relative to the elastic support, a quasi adhesive coating or surface layer may be applied to the back of the absorbent pad. In one embodiment, an elongated flattened gauze tube is employed with the Unna-Paste bandage positioned within it at one end and the absorbent pad positioned within it at the other end. With this latter arrangement, the impervious envelope is sealed around the dressing and in the area of the gauze tube between the bandage and the pad. Thereafter, when the envelope is removed, the gauze tube is bent over upon itself in such a way that the pad completely covers one side of the bandage. on the outside of the pad, the gauze tube contacts the resilient support. A contact adhesive or teasel member on this part of the surface of the gauze tube then serves to hold the dressing against motion relative to the support and ulcerous area, and to anchor the far end of the gauze tube when the unpackaged item is folded back on itself, thereby maintaining the working alignment of the two components.

The dressing is furthermore adapted for a relatively short period of use, for example 48 hours. This requires only a double thickness of standard gauze and ½ oz. of Unna-Paste per square foot of area for the bandage. Also, it permits the use of a pad of cotton-wool of only 1 oz. per square foot.

These weights and dimensions are important in the context because they can be employed under a standard heavy duty elastic support without creating any undue local pressure points, whereas a standard 7 day-dressing would be too thick and could not be used.

Accordingly, the invention comprises a dressing and support combination for venous ulcers including a gradient-pressure elastic support covering the ulcerous area plus a major area both toward and away from the heart relative to the location of the ulcer, an Unna-Paste bandage covering the ulcer, an absorbent pad covering the bandage, and means anchoring the pad both to the bandage and to the elastic support. It also comprises a bandage package comprising an ointment impregnated bandage portion, a sealed impervious envelope surrounding said bandage portion, an absorbent pad portion, and means joining said bandage and pad portions. Still further it comprises an elongated flattened gauze tube with said bandage portion positioned within it at one end and said pad portion positioned within it at the other end. Even more specifically, the invention comprises such a dressing for venous ulcers additionally comprising no more than two layers of gauze and about ½ oz. per square foot of ointment, an absorbent pad on said bandage of cotton wool having a weight of about 1 oz. per square foot, and said elastic support covering and holding said pad in place.

THE DRAWINGS

Preferred embodiments are shown in the accompanying drawings in which:

FIG. **1** is a side view of a lower leg to which the dressing of the invention has been applied;

FIG. **2** is a side view of the dressing of FIG. **1** during the application stage;

FIG. **3** is a cross-sectional view of the dressing applied to an ulcerous area;

FIG. **4** is a perspective view of a packaged dressing;

FIG. **5** is a perspective view of the dressing of FIG. **4** with the package cover removed, and with two portions of the gauze tube cut away to expose the bandage and the pad;

FIG. **6** is a side view, along the line **6—6** of FIG. **4**, of the seal between the pad and the bandage;

FIG. **7** is a side view of the sealing cylinder of FIG. **6**;

and

FIG. **8** is an end view of the sealing cylinder of FIG. **6**.

DESCRIPTION OF THE INVENTION

The major components of the dressing comprise a bandage **10** which is impregnated with Unna Paste, (an ointment consisting of zinc oxide in a vehicle of glycerin and gelatin), an absorbent pad **12**, and a heavy duty gradient pressure elastic stocking **14**.

The bandage and pad combination is prefabricated in several sizes and shaped to accommodate variously sized and located ulcers. A standard size for the bandage **10** is 3 inches square, to go with a 4 inch square absorbent pad **12**. The elastic stocking **14** is also made

in numerous sizes and shapes and must be fitted to the individual patient with care.

In assembling the dressing, the ulcer is first cleaned annd dermatitis, if present, is treated as may be appropriate. The bandage and absorbent pad combination is then placed over the ulcer with the bandage in contact with the ulcer. The elastic stocking is then rolled up and over the ulcer. When in place, the stocking holds the pad and bandage from slipping, see FIGS. 2 and 3.

In the preferred embodiment the combination is designed for 48 hours maximum usage. In this context, the bandage **10** comprises a double ply of matted gauze impregnated with about ½ oz. of Unna Paste per square foot, and the pad **12** comprises cotton-wool having a weight of about 1 oz. per square foot. In normal use with such components the migration of exudate into the pad is such that the bandage will remain therapeutically effective throughout a 48-hour period.

In one form of the invention, the bandage and pad are made up as a unit and packaged in an envelope **18**, see FIG. **4**. The envelope **18** is made of a suitable foil or impervious plastic. The bandage and pad combination in this embodiment is formed within a gauze tube **20**, with the bandage **10** within the tube **20** at one end, and the pad **12** within the tube **20** at the other end. In use, the pad and bandage combination is folded along the line AA of FIG. **5** so that one side of the bandage is exposed and the other is completely covered by the pad as in FIG. **3**. When so arranged, the Unna Paste and exudate from the ulcer migrate through the porous walls of the gauze tube **20** into the pad **12**, and the porous nature of the gauze allows the necessary ventilation. A contact adhesive surface or teasel member **21** may be provided on the gauze tube **20** in the area of contact with the support **14** directly above the pad **12**. The functions of such a member are twofold, namely (1) to anchor the far end of the gauze tube and thus ensure the configurational integrity of the dressing unit as in FIG. **3**, and (2) to provide a bond to the support **14** to minimize relative motion between the elastic support and the dressing.

In order to prevent migration of the Unna Paste during storage, the envelope **18** is sealed around the gauze tube **20** and across the area of the tube **20** between the bandage **10** and the pad **12**. This seal is effected by conventional adhesives or heat sealing around the edges, and by an additional double fold and crimp in the area between the bandage **10** and the pad **12**. In this latter area the seal is maintained tight by forming the double fold and crimp around a rod **22** and pinching the crimp by sliding a sealing cylinder **23** over it in such a way that a portion of the double fold adjacent to the metal rod **22** is squeezed together by the cylinder **23**. As FIG. **6** indicates, the rod **22** creates a ridge so that the cylinder will not pull directly off.

When the patient desires to apply the dressing, he slides off the sealing cylinder, cuts the margins of the envelope, and peels the envelope off of the central area. Then he folds the two components together locking the gauze end of the bandage to a portion of the teasel member **21**. Next he applies the composite bandage to the ulcer and rolls up the elastic stocking. This is a quick and economical operation. It can be performed without the need of professional assistance by any patient who is capable of putting on the elastic support without assistance.

The components can be adapted for shorter or longer periods of use, but in the present context, there is a special relationship between the components as set forth. They can be employed with a gradient-pressure elastic support which fits the particular patient and which is preferably adapted with a pressure applying component specifically designed to provide pressure against the particular ulcerous area being treated. A bulkier dressing may change the pressure gradient too much to function properly.

Various modifications also come within the spirit of the invention. For example, the pad **12** may be given a shallow conical or shallow pyramidal shape so as to reduce the tendency that a flat pad has to diffuse the pressure. In such an embodiment, the added material centrally of the pad serves to maintain the required healing pressure on the ulcer. Such an embodiment is particularly useful when the ulcer is in a recessed area such as directly below or to the rear of the malleolar projections of the ankle. Another modification has to do with the form and structure of the elastic support. It is contemplated that an elastic boot-like member incorporating very light vertical stiffeners may be used. Such a boot-like member is provided with means for opening it so as to be removable as an ordinary boot. This opening is secured across the front by laces or a zipper, or even by mating teasel surfaces. The attending physician will then designate and mark a line to which the boot should be laced or closed to provide the correct pressure in the right place. Some highly indolent patients are not sufficiently competent to use such a boot without assistance, but many are, and even when incompetent, such assistance as would be needed in any case would usually not require a doctor. The advantages of simple removal, and vertical stiffness of this embodiment have an important cooperative relationship with the bandage and pad components described above.

In addition, a pair of interlocking, teasel-type surfaces can be provided for the end of the gauze tube and the area **21** to anchor the dressing in place and to the stocking. Also a mildly interlocking surgical felt can be used. The absorbent pad **12** may be provided with a gauze jacket **24** which would serve to hold the shape of the pad during use, and to further protect the stocking from migration of Unna Paste or other exudate from the ulcer.

I claim:

1. A dressing for indolent ulcers comprising a bandage impregnated with an ointment for application to and treatment of a venous ulcer of the skin, an absorbent pad over said bandage, a gradient-pressure stocking over said pad, and means at a predetermined location between said stocking and pad for interlocking and preventing relative motion therebetween.

2. The dressing of claim **1** further characterized by a non-impervious jacket covering said pad.

3. The dressing of claim **1** further characterized by a contact adhesive surface on said pad in position to contact said support.

4. The dressing of claim **1** further characterized by the weight of said ointment in said bandage being about ½ oz. per square foot, and said absorbent pad being cotton-wool having a weight of about 1 oz. per square foot.

5. The dressing of claim **1** further characterized by said ointment being Unna Paste.

6. The dressing of claim 1 further characterized by said pad having a greater central thickness whereby pressure applied to it is concentrated centrally rather than diffused.

7. The dressing of claim 1 further characterized by both said means for interlocking comprising a teasel member.

8. The combination of claim 1 further characterized by said stocking comprising a boot-like construction including an opening along the front for quick removal, and means in said opening for securing the sides thereof so as to apply pressure to said ulcer and hold said stocking in place, and vertical stiffeners in said stocking.

9. A dressing comprising, a bandage impregnated with an ointment, an absorbent pad dimensioned and adapted for use with said bandage, a permeable tube covering said bandage and pad with said bandage and pad separated longitudinally from each other in said tube, a removable impervious envelope encompassing said tube, and sealing means between said bandage and said pad for preventing seepage of said ointment into said pad during storage.

10. The dressing of claim 9 further characterized by the sealing means including a rod around which the tube covered by the envelope in the area between the bandage and the pad is wrapped, and clamping means for holding the wrapped materials in place.

11. The dressing of claim 9 further characterized by means for interlocking said pad and bandage against relative motion when in use, and for interlocking said pad against motion relative to a support which may be placed over said pad during use.

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