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 DEVICE FOR ABRADING AND APPLYING BIOLOGICALS
 TO THE SKIN OF A PATIENT
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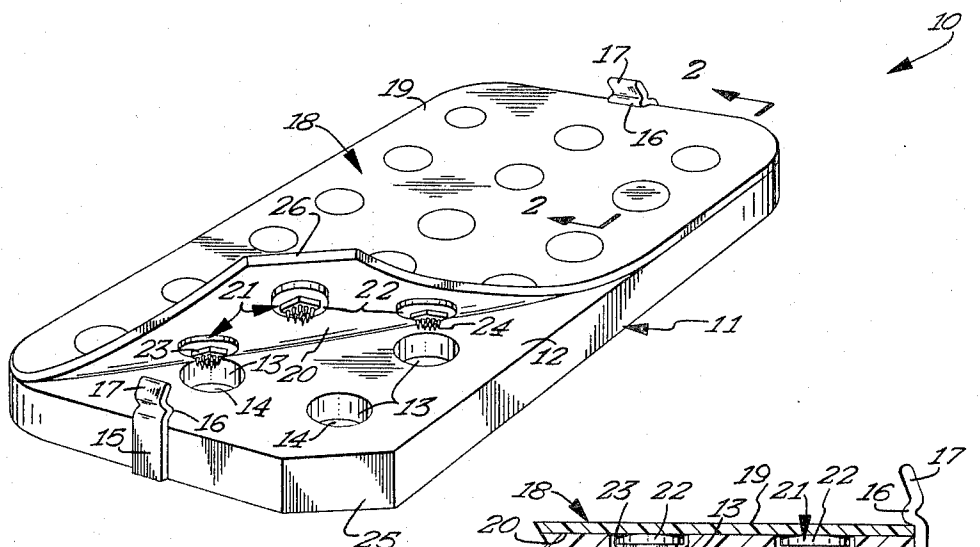


FIG 1

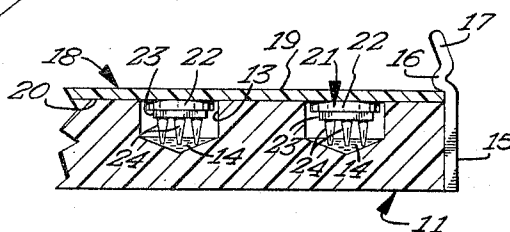


FIG 2

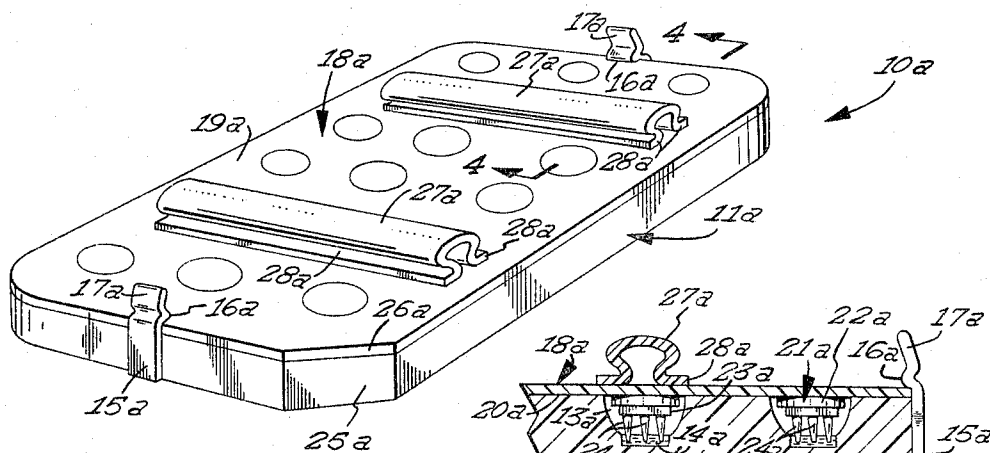


FIG 3

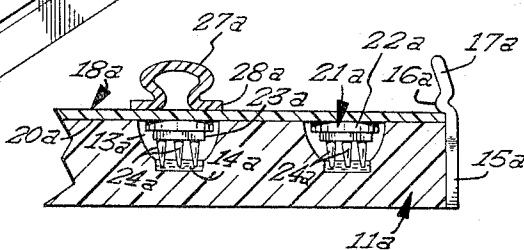


FIG 4

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DEVICE FOR ABRADING AND APPLYING BIOLOGICALS TO THE SKIN OF A PATIENT

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3 Claims. (Cl. 128—2)

This invention relates to a device for use in simultaneously producing a plurality of scratches at a specific body surface area such as the back of a patient and for simultaneously applying biologicals to such scratches.

An object of this invention is to provide a novel device wherein a plurality of spaced-apart cutaneous sites at a specific body surface area such as the back of a patient is simultaneously abraded to produce a plurality of scratches at such sites, and simultaneously applying biologicals, such as allergens, vaccines or the like, to such scratches whereby said device is especially adaptable in establishing the clinical diagnosis of atopic allergic diseases.

A more specific object of this invention is to provide a novel device which is specifically adaptable for use in the performance of a diagnostic technique for detecting the presence of atopic reagins in the skin of a patient, in which a plurality of skin abrading members of a multi-member abrading unit are simultaneously loaded with biologicals, such as allergens, and in which the multi-member abrading unit is applied and manipulated against a specific body surface area such as the back of a patient to thereby simultaneously produce a plurality of scratches at a plurality of cutaneous sites, and to simultaneously apply the biologicals carried by the abrading members to the cutaneous sites whereby such diagnostic procedures such as scratch tests in determining allergies in a patient may be very quickly and effectively carried out.

A further object of this invention is to provide a novel device of the class described for use in simultaneously abrading and applying biologicals to a plurality of cutaneous sites such as the back of a patient, wherein the biologicals to be applied are contained in a plurality of wells of a multi-well unit, thereby permitting a plurality of multi-member abrading units to be used successively with a single multi-well unit.

These and other objects and advantages of our invention will more fully appear from the following description made in connection with the accompanying drawings wherein like character references refer to the same or similar parts throughout the several views, and in which:

FIG. 1 is a perspective view of our novel device, and wherein one portion of the multi-member abrading unit is upwardly flexed to disclose the lower surface of the multi-member abrading unit and the upper surface of the multi-well unit;

FIG. 2 is a cross sectional view on an enlarged scale taken approximately along line 2—2 of FIG. 1 and looking in the direction of the arrows;

FIG. 3 is a perspective view of a modified form of our novel device; and

FIG. 4 is a cross sectional view on an enlarged scale taken approximately along line 4—4 of FIG. 3 and looking in the direction of the arrows.

Referring now to the drawing and more specifically to FIGS. 1 and 2 it will be seen that one embodiment of our novel device, designated generally by the reference numeral 10, is there shown. Our device is especially adaptable in performing the clinical diagnostic techniques, generally known as scratch tests, for detecting the presence of atopic reagins in a patient. In this

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particular technique, superficial scratches or abrasions about 1/8 inch long are made on the cleaned skin of an arm, forearm, or back of a patient and the allergenic materials are applied to the scratches. If atopic reagins are present, the reagin will combine with the related allergen which is applied to cause the release of histamine or a histamine-like substance by the affected tissues which results in a urticarial reaction. The specific cutaneous test sites are compared with the reaction at a controlled test cutaneous site to which diluents devoid of allergenic materials have been applied.

Referring again to FIGS. 1 and 2 it will be seen that the device 10 comprises a multi-well unit or structure 11 which, as seen, is of generally rectangular configuration presenting flat upper and lower surfaces and preferably constructed of a suitable generally impervious plastic material such as polyethylene, acrylic plastic or the like. The upper surface 12 of the multi-well unit 11 is substantially flat and this upper surface has a plurality of substantially identical, generally cylindrically shaped wells 13 formed therein and each terminating downwardly, as best seen in FIG. 2, in a generally conical sump portion 14.

The multi-well unit 11 also has a pair of retaining clip elements 15 secured to the respective end edges thereof and projecting upwardly therefrom in opposed relation with respect to each other. These retaining clip elements 15 are centrally located with respect to the end edges of the multi-well unit 11 and each is preferably constructed of a suitable plastic material having resilient flexible characteristics and each includes an overhanging generally arcuate latch portion 16 which terminates upwardly in a finger tab portion 17. Since the retaining clip elements 15 are preferably constructed of the same plastic material from which the multi-well unit 11 is formed, the lower terminal portion of each clip element may be secured to the associated end edge of the multi-well unit 11 by a suitable plasticizer, glue or any suitable securing means. With this arrangement, the upper portion of the clip elements may be flexed outwardly to a released position but will be normally urged to the locking position as illustrated in FIG. 2 because of the inherent resilient properties of the material from which the clip elements are made.

The device 10 includes a multi-member abrading unit or structure 18 comprised of a generally rectangular body member 19 having substantially flat upper and lower surfaces and conforming generally in configuration and size to the multi-well unit 11. This body member 19 is preferably constructed of a suitable plastic material and preferably has a thickness dimension of a magnitude whereby the body member has flexible generally resilient characteristics. It is preferred that the body member 19 be formed from either one sixteenth inch polyethylene sheet although it may also be made from one sixteenth inch acrylic sheet. The substantially flat lower surface 20 of the body member 19 has a plurality of spaced-apart substantially identical skin abrading members 21 secured thereto. It will be noted that the skin abrading members 21 are symmetrically arranged with respect to each other and the particular number and spacing of these skin abrading members corresponds to the arrangement, spacing and number of wells 13 of the multi-well unit 11.

Each skin abrading member 21 includes a substantially flat circular disc-shaped positioning element 22 which is only slightly smaller than the cross sectional area of the wells 13. Each positioning element 22 has a centrally located, generally rectangular shaped embossed or platform element 23 integrally formed therewith from which depends a plurality or cluster of substantially identical pointed abrading elements 24 which are disposed in substantially parallel relation with respect to each other.

The positioning element, embossed element and abrading elements of each skin abrading member are preferably of integral construction and are preferably formed from the polyethylene or acrylic plastics in a suitable molding operation. These skin abrading members may be also integrally formed with the body member or may be formed separately therefrom and thereafter secured to the lower surface 20 of the body member 19.

It will be seen that when the body member 19 is positioned in superimposed engaging relation with the multi-well unit 11, the skin abrading members 21 will each position the cluster of abrading elements thereof in one of the wells 13 so that the abrading elements 24 depend into the conical sump portions 14 of the wells. The biological material to be applied to the patient will be in liquid form and this liquid substance will accumulate in the sump portion of each well 13. Since the abrading elements 24 project downwardly into such biological substance, the liquid substance will accumulate between the cluster of abrading elements for each abrading member as a result of capillary action to thereby load each abrading member with the biological substance for application to the patient.

It will be seen that when the multi-member abrading unit 18 is applied to the multi-well unit 11, the upper surface 12 of the multi-well unit 11 will be engaged in substantially sealing relation by the lower surface 20 of the body member 19. The overhanging latch portion 16 of the retaining clip elements 15 will engage the upper surface of the body member 19 and hold the multi-member abrading unit 18 against the multi-well unit 11. The points of the abrading elements 24 will be immersed in the liquid allergenic substance and the device will be in condition for use.

In the embodiments of the device disclosed, a plurality of cutaneous sites are simultaneously abraded with the abrading members and the allergenic substances are simultaneously applied to such abraded cutaneous sites. It will be seen that the embodiments of the device disclosed is capable of simultaneously abrading eighteen cutaneous sites and for applying allergenic or controlled material to such sites. The particular number of cutaneous sites to be abraded will be dependent upon the number of materials to be tested and this number may be varied. It will also be noted that the wells 13 and the skin abrading members 21 are arranged in symmetrical lengthwise and transverse rows and the spacing between the skin abrading members is sufficient to avoid crowding of the cutaneous sites thereby permitting interpretation of any positive reactions that might result.

During use of our novel device, it is contemplated that several multi-member abrading units 18 may be used with a single multi-well unit since patients are frequently tested for substantially the same group of allergenic diseases. It will be appreciated, that patients having hypersensitivity to certain allergens which affect the upper and lower respiratory tracts often results in conditions called hayfever and asthma. Therefore patients quite often develop a hypersensitivity to common inhalant allergens such as pollens, molds and the like. The multi-well unit may have a number of these inhalant allergens therein and different multi-member abrading units may be used successively with a single multi-well unit for testing this kind. In order to facilitate interpretation of any urticarial reactions to such tests when multi-member abrading units are successively used with a single multi-well unit, each multi-member abrading unit is provided with an indicia element which is to be disposed in registering relation with a corresponding indicia element on the multi-well unit during the immersion or loading step of the multi-member abrading unit.

With this arrangement, each successive multi-member abrading unit will be related to the multi-well unit in precisely the same position as the preceding unit. This arrangement also presents each multi-member abrading unit

to be applied to the surface of each succeeding patient in precisely the same position so that the technician or doctor may very readily and easily interpret any reactive results.

This indicia element for the multi-well unit 11 comprises an oblique edge 25 formed in one corner of the multi-well unit and a similar indicia element 26 formed by an oblique edge at one corner of the body member 19. Thus when the indicia elements 25 and 26 are disposed in registering relation with respect to each other, each succeeding multi-member abrading unit 18 will be disposed in the same relation as the other multi-member abrading units used with the same multi-well unit 11. Similarly when a plurality of such multi-member abrading units are used with a single multi-well unit and applied to different patients, by relating the indicia 26 in a particular predetermined orientation for each patient, each multi-member abrading unit may be applied, for example, to the back of each patient in substantially the same manner.

Referring now to FIGS. 3 and 4, a modified form of our device is there shown and is designated generally by the reference numeral 10a. The device 10a also includes a multi-well unit 11a having a plurality of similar wells 13a formed in the upper surface thereof and symmetrically arranged in transverse and longitudinal rows. These wells 13a, however, terminate downwardly in a reduced substantially cylindrically shaped sump portion 14a, as best seen in FIG. 4. The multi-well unit 11a is otherwise identical to that disclosed in FIGS. 1 and 2. Thus the multi-well unit 11a is provided with retaining clips 15a of identical construction to the retaining clips of the embodiments of FIGS. 1 and 2.

The device 10a also includes a multi-member abrading unit or structure 18a comprised of a body member 19a having a plurality of end abrading members 20a affixed to the lower surface thereof and arranged in symmetrical transverse and longitudinal rows. The skin abrading members 21a are of identical construction to those disclosed in the embodiment of FIGS. 1 and 2.

The body member 19a of the multi-member abrading unit 18a is provided with a pair of substantially identical elongate channel-shaped handle members 27a each having outturned lower flanges 28a which are secured to the upper surface of the multi-member abrading unit 18a. The multi-member abrading unit 18a is also constructed of the same plastic flexible resilient material as the embodiment of FIGS. 1 and 2 and except for the handle member 27a, the multi-member abrading unit 18a is identical in construction to the previously discussed embodiment. The sump portions 14a of the embodiment of FIGS. 3 and 4 are shaped to receive the lower terminal portions of the abrading elements 24a to thereby load these abrading elements with a liquid biological substance such as an allergen or the like. It is pointed out that the embodiment illustrated in FIGS. 3 and 4 will be used in substantially the same manner as that illustrated in FIGS. 1 and 2.

When our device is used in performing a diagnostic technique generally known as the scratch test, the multi-well unit as well as the multi-member abrading unit will be rendered sterile by following certain sterilizing procedures. The device 10 including the multi-well unit and the multi-member abrading member 18 may be placed in an autoclave and sterilized by steam under pressure.

Thereafter, the biologicals to be used are placed in the wells 13, each well containing a different material. If the biological substance comprises allergens, dry allergenic powders may be used which are dissolved in alkaline solution or extracts prepared with glycerin or other solvents and preservatives may be used. It is preferred that the biological substance fill the sump portion of each well whereby when the multi-member abrading unit is applied to the multi-well unit, the lower terminal portions of the abrading elements will be immersed in the bio-

logical substances. The indicia elements 25 and 26 will be disposed in registering relation with each other and the positioning element 22 of each skin abrading member will facilitate positioning of the skin abrading members into the respective wells. The device with the allergenic materials within the wells may be prepared prior to the testing and placed in a suitable storage receptacle or the like.

When the tests are performed, the multi-member abrading unit 18 is removed from the multi-well unit 11 and applied to a particular body surface area preferably the back of a patient, only slight pressure being exerted. Simultaneously during the pressing of the multi-member abrading unit, the unit is manipulated or moved bodily laterally to produce a plurality of scratches at a plurality of cutaneous sites and the allergenic material will be simultaneously applied to the scratched cutaneous sites. It is pointed out that the scratches or abrasions produced should not be deep enough to cause bleeding and the multi-member abrading unit should be moved only enough so that a relatively short scratch is produced by each abrading element. Such a scratch should be not over 1/8 inch long.

The cluster of abrading elements for each skin abrading member will contain approximately 0.01 cc. of allergenic material, this material adhering or clinging to each cluster as a result of capillary action when immersed in the multi-well unit 11. It is pointed out that the allergenic material in one of the wells will contain a controlled substance which has been made with diluents devoid of allergenic principle. As pointed out above, the union of the reagin in the skin with the related allergenic substance causes the release of histamine or a histamine-like substance by the tissues and results in a urticarial reaction. Ordinarily this usually consists of a wheel of variable size and shape surrounded by erythema and frequently accompanied by pruritus. The flexible and resilient characteristics of the multi-member abrading unit 18 permits a technician or worker to apply the multi-member abrading unit to a specific body surface area such as the back of a patient even though this back surface does not present a planar surface.

In determining the number of tests to be performed, several factors will be considered such as the history of the patient, the severity of the symptoms, his age, and the nature and concentration of the allergens employed. Although a predetermined number of skin abrading members (eighteen) have been illustrated for each multi-member abrading unit, it is pointed out that this number may be varied and it is also pointed out that controlled or non-allergenic material may be placed in other wells if the number of skin abrading members exceed the number of tests to be performed. It is also pointed out that one patient may be treated by materials located in two separate devices since quite often the number of allergenic materials to be tested may be quite large.

After a period of approximately fifteen or twenty minutes has expired, the allergenic materials are removed from the skin, and the reactions at the test sites are read and interpreted on the basis of a comparison with the controlled test site which as pointed out above constitutes diluents applied to the skin which diluents are devoid of allergenic factors.

From the foregoing it will be seen that we have provided a novel apparatus for use in simultaneously abrading and applying biological substances including antigens pertinent to a plurality of cutaneous sites located at a specific body surface area such as the back of a patient.

It will be noted from the preceding paragraphs that our novel apparatus is especially adaptable for use in performing simultaneously a plurality of scratch tests to determine the presence of atopic reagins in the skin of a patient

to establish the clinical diagnosis of atopic allergy diseases.

Thus it will be seen that our novel device is especially adaptable for facilitating diagnostic procedures in determining the hypersensitivities of a patient to certain allergens and the like.

It will, of course, be understood that various changes may be made in the form, details, arrangement and proportions of the various parts without departing from the scope of our invention.

What is claimed is:

1. A device for use in simultaneously abrading and applying biologicals to a plurality of cutaneous sites at a specific body surface area such as the back of a patient, said device comprising:

a multi-well structure having a substantially planar upper surface and having a plurality of recesses formed in said upper surface to thereby define a plurality of wells, said wells adapted to contain different liquid biological substances therein,

a multi-member abrading structure comprising a flexible body member having a substantially flat lower surface positioned upon and sealingly engaging the upper surface of said multi-well structure, said body member being removable from said multi-well structure, and being capable of flexing movement to accommodate the contours of a body area of a patient,

a plurality of spaced-apart similar skin abrading members affixed to the lower surface of said body member and projecting therefrom, each of said skin abrading members including a positioning element corresponding in shape to the configuration of said wells and being slightly smaller in size than the cross sectional size of said wells, each positioning element extending downwardly into one of said wells and spaced inwardly of the sides of the associated well, each skin abrading member including a plurality of elongate abrading points affixed to and depending from the associated positioning element and adapted to extend into one of the wells for immersion in the specific liquid biological substance therein when said wells contain such liquid biological substances, whereby when said multi-member abrading structure is removed from said multi-well structure, and pressed and manipulated against the specific body surface area such as the back of a patient, a plurality of scratches will be simultaneously produced and the liquid biological substances carried by the abrading members will be simultaneously applied to the cutaneous sites.

2. The device as defined in claim 1 and releasable locking means on one of said multi-well and multi-member abrading structures releasably engaging the other of said structures to releasably hold said structures in interengaging relationship.

3. The device as defined in claim 1 and a plurality of spaced apart handle members affixed to said multi-member abrading structure to facilitate application thereof to the surface area of the patient.

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