United States Patent

Reed

[15] **3,688,764**

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[54] **INTRACUTANEOUS INJECTION SYSTEM**

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[73] Assignee: **Bard-Hamilton Company, Inc.**, West Englewood, N.J.

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[52] **U.S. Cl.** .....**128/2 R**, 128/2 W, 128/213, 128/253, 128/333, 206/63.4

[51] **Int. Cl.** **A61b 10/00**

[58] **Field of Search**.....128/2 W, 2 G, 2 R, 213, 253, 128/333; 206/63.4

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[57] **ABSTRACT**

The present invention is directed to an intradermal injection system adapted for multiple mass use, particularly for mass diagnostic testing such as the Heaf Multiple Puncture Tuberculic Test.

The structure includes an elongated finger grip skin puncture applicator with a set of puncture points mounted in the base face of the applicator. Associated with the applicator is a solution holder having therein an antigen well of pre-determined capacity. An escape channel leading to an overflow well removes any excess antigen from the well. Upstanding from the center of the antigen well is a centering and stop element which cooperates with a correspondingly shaped depression inside the base of the applicator so that the applicator may be centered in the antigen well with all of the applicator puncture points wetted by the antigen solution therein to a pre-determined level.

4 Claims, 6 Drawing Figures

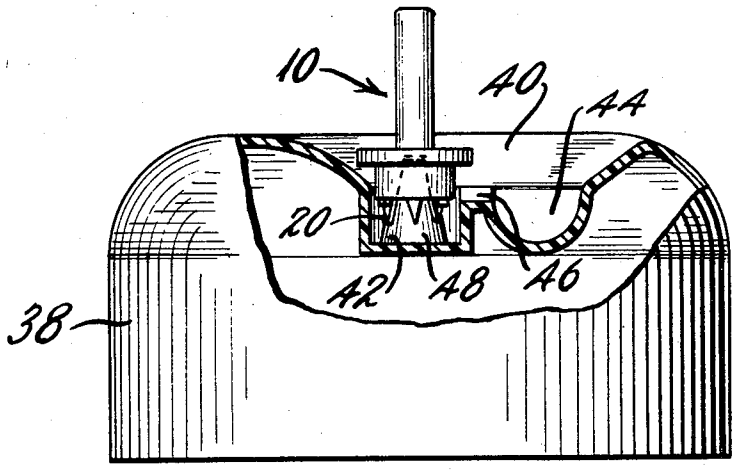


FIG. 1

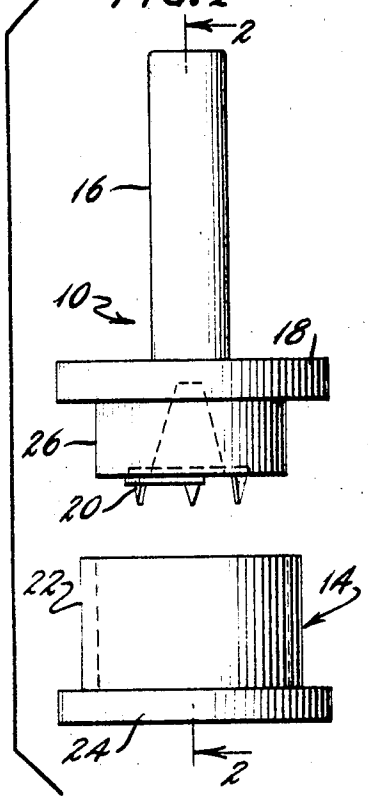


FIG. 2

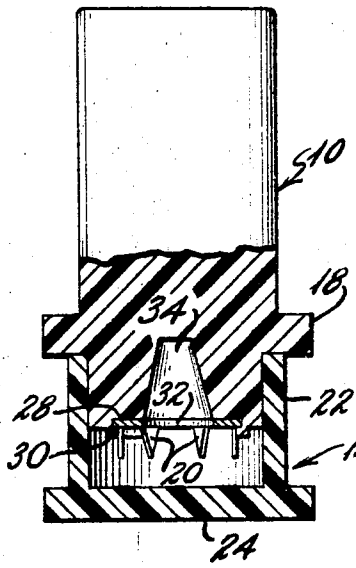


FIG. 3

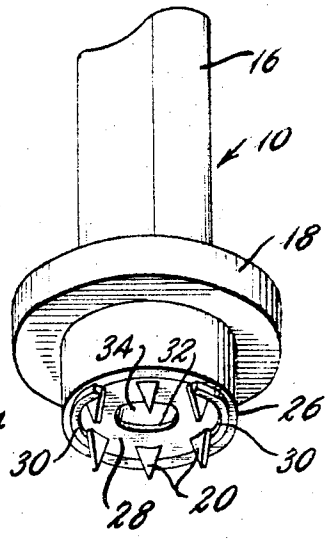


FIG. 4

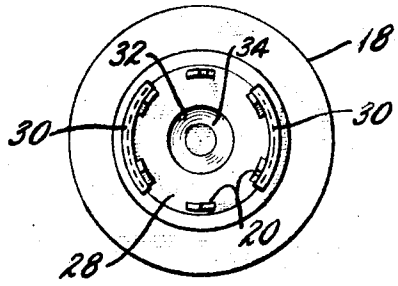


FIG. 5

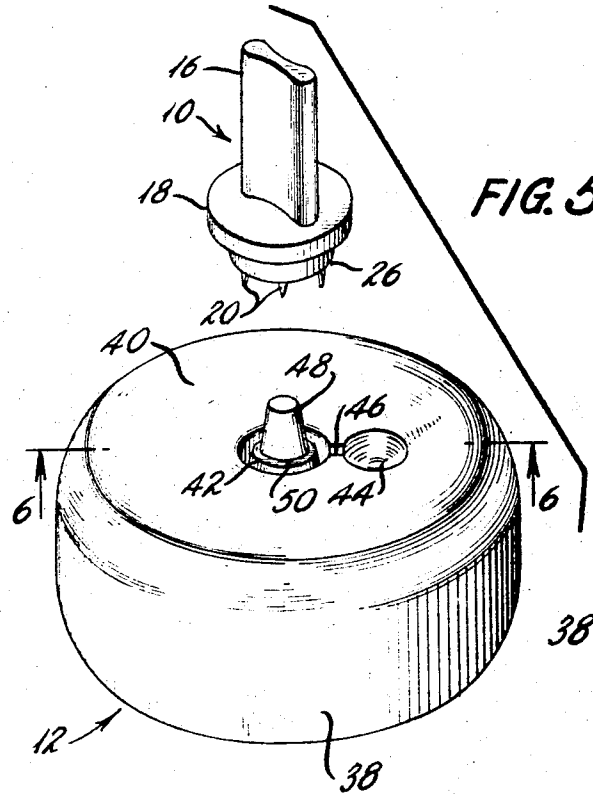
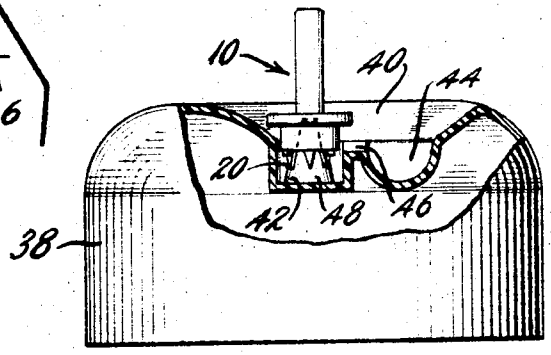


FIG. 6



INTRACUTANEOUS INJECTION SYSTEM

The present invention relates to an intracutaneous injection system comprising a skin puncture applicator and a solution holder and is explicitly intended for mass testing or treatment of an intracutaneous nature. In particular, the present system is adapted to mass conduct of the multiple puncture tuberculin test known as the Heaf Test, and will be described for exemplary purposes in terms of this particular usage.

A principal problem in mass testing, e.g. for tuberculosis, resides in the need for sterile equipment of an inexpensive nature. Desirably, the equipment must be utilizable (safely) by technicians or semi-skilled personnel. An important criterion, one which applies to individual tests as well as mass tests, is that the proper amount of medicament must be applied. In mass screening this requirement is translated into the usual statement that uniform dosages must be employed.

An obvious way to insure uniform dosages is to package the medicament in dosage units. However, for mass testing, such an expedient sharply raises the medicament cost of the test program. The present invention allows for bulk packaging of the medicament and relies on the structure of the skin puncture applicator and an associated antigen solution holder to insure that each test is conducted with the same medicament dosage.

For further understanding of the invention, reference is now made to the attached drawing wherein:

FIG. 1 is a side view of the medicament applicator and a protective cap therefor;

FIG. 2 is a section taken along line 2—2 of FIG. 1 showing the applicator and cap assembled;

FIG. 3 is a perspective view of the applicator;

FIG. 4 is an elevational view of the skin puncture end of the applicator;

FIG. 5 is a perspective view of the applicator and the solution holder; and

FIG. 6 is a partially broken away section taken along line 6—6 of FIG. 5.

The intracutaneous or intradermal injection system of the present invention comprises a skin puncture applicator **10** and a solution holder **12**. For sterile storage and shipment of the applicator, a protective cap **14** is provided.

The applicator itself comprises a finger grip handle **16**, preferably of the bi-concave shape shown in FIGS. **3** and **5**. The bi-concave shape permits a good finger grip. Near the base end of applicator **10** is an annular circular flange **18** which seats over the top edge of cylindrical body **22** of the protective cap **14** so that for sterile shipment and storage the puncture points **20** on the base face of applicator **10** are suspended above the bottom wall **24** of the cap **14**, as is illustrated in FIG. **2**. Flange **18** also serves as a shield preventing contact between the holder's fingers and the medicament.

Beneath flange **18** and forming part of the applicator **10** is a cylindrical body portion **26** and the skin puncture points **20** are mounted on the base face at the bottom thereof. The puncture points **20**, six annularly positioned points being illustrated (the usual number for the Heaf test), form part of a metallic insert piece **28** set into the base face of body portion **26**. Suitably, insert piece **28** is formed from sheet stock, e.g. stainless steel, by stamping out the desired peripheral point configuration, then upending the puncture points perpendicular to the remainder of the insert piece **28**. The central aperture **32** in insert piece **28** may be stamped out when the points are formed. Insert piece **28** is retained at the base end of applicator **10** by a friction grip or by an overhand engagement with lip-like projections **30** formed on the base face of applicator **10**.

An important structural feature of application **10** is the central cone or frustro-conic depression **34** centrally of the base face. As is shown in FIG. **4**, central opening **32** in insert piece **28** underlies depression **34** and the individual puncture points **20** are symmetrically disposed therearound, so that a projection corresponding in shape to central depression **34** can be employed as a centering expedient.

The skin puncture applicator **10** can be employed, as is, for single tests according to the usual techniques for such tests. For example, the antigen may be placed directly on a small (about 1 inch square) clean skin region and the puncture point applicator pushed in at that region so that the six puncture points penetrate the upper layers of the skin and force antigen from the surface intracutaneously. The applicator, which is relatively inexpensive, may be considered as a disposable unit and discarded. The same applicator structure, however, is equally adapted for mass testing wherein it is employed in combination with medicament or antigen holder **12**.

As is shown in FIGS. **5** and **6**, solution holder **12** has the general shape of an inverted cup wherein a cylindrical skirt **38** supports an upper depressed surface area **40** which contains thereon an antigen well **42**, an overflow well **44**, and a connecting escape channel **46**. Should excess antigen be placed in well **42**, the excess will overflow through escape channel **46** into overflow well **44**, from which, at some convenient time, it may be recovered (by a sterile eyedropper), and recovered or returned to antigen well **42**. Upstanding from the center of antigen well **42** is a frustro-conic projection **48** corresponding in shape and dimensions to central depression **34** in the base face of applicator **10**. Projection **48** and aperture **34** cooperate so that when the applicator **10** is inserted into antigen well **42** the applicator is centered and all the puncture points **20** are wet with the antigen therein, without coming into contact with the well walls.

The projection **48** on solution holder **12** and central depression **34** on the applicator **10** constitutes also a stop structure which prevents the user from inserting applicator **10** too deeply into well **42**. Desirably, a ridge **50** formed peripherally around projection **48** at an appropriate level thereon acts as a visual filling indicator and can also form a portion of the stop structure. Thus, when the applicator **10** is fully inserted into solution well **42**, as is illustrated in FIG. **6**, the inside rim of the metallic insert **28** (surrounding its central aperture **32**) comes into abutting contact with ridge **50**; the entire area of each puncture point **20** is then wetted by the solution in well **42**. Any excess solution, in well **42**, is forced into escape channel **46** and overflows into overflow well **44**. At this time the puncture points **20** are spaced apart from the well side and bottom walls as is shown in the drawing and are neither bent nor blunted by contact with the well walls. This maintains the desired degree of test uniformity in a mass testing pro-

gram. Alternatively, the flat top of projection **48** can serve as the stop element by abutting the flat end of depression **34**, ridge **50** then serving a visual indicator purpose only.

For mass testing with the system of the present invention the tuberculin antigen may be procured in bulk solution and the test program commenced by placing whatever number of drops, three, four, five that are required to fill well **42** to the level indicated by the ridge **50**. Any accidental overfilling will drain through escape channel **46** into overflow well **44** (from which the antigen may be retrieved). After every five or six tests, an additional drop of tuberculin antigen solution is added to well **42** to maintain the desired level of solution in the well. Accordingly, each successive test is carried out with the proper quantity of solution on the puncture points **20** of applicator **10**. Any solution which wets the surface of insert piece **28** has no effect on the test and, constitutes a small wastage. When the test series is completed, the solution holder **12** may be discarded (along with the test antigen remaining in well **42**), the solution holder **12** is a relatively inexpensive, one-time use, disposable article. However, it may be noted that the same solution holder **12** is employed for a series of tests, e.g. 1 day's use. However, disposition of applicator **10** after each individual test might be unreasonably wasteful. Accordingly, for use of the present system for mass testing purposes, applicator **10** may, if desired, be meticulously cleaned and sterilized and reused, the applicator being, however, ultimately discarded as a disposable item.

Regardless of whether the intent is to employ applicator **10** on a strictly one-time basis or for a reasonable number of tests, many standard materials are available from which applicator and holder may be formed, notably, the thermoplastic resins such as polyvinylchloride, polystyrene, polyethylene, polypropylene, etc., all of which can be readily molded into the desired shaped with conventional techniques and equipment. The thermoplastic resins exhibit sufficient structural stability so that the well **42** and escape channel **46** may be formed with volumetric accuracy and projection **48** and its ridge **50** can be accurate enough to mate with central depression **34** and central aperture **32** of applicator **10**. In addition, the standard thermoplastic resin moldings can include a lip **30** for the friction or overlap fit which retains the metallic insert piece **28** on the base face of applicator **10**.

Although the structure of the present invention has been described in terms of the Heaf Multiple Puncture Tuberculin Test, it should be appreciated that the same or essentially the same structure is equally applicable to other intracutaneous injections of a mass nature, including both diagnostics and immunizations such as vaccinations. The only expressly contemplated change in the system for other uses is substitution of the six pointed insert piece **28** by a like insert piece having whatever skin puncture or scarifying points are preferred for the particular usage.

What is claimed is:

1. An intracutaneous applicator system comprising an intradermal applicator member removably received in a solution supply holder, said member and holder cooperating to apply solution to said applicator for intradermal injections, said applicator having a base injection surface, a plurality of puncture or scarifying means located on said surface and projecting therefrom, a centrally located depression in said surface, a first well in said holder, an upstanding projection in said first well of a predetermined shape and extending into said depression to center the applicator member in relation to said first well and limiting the depth of penetration of said base surface and puncture means into said first well, an overflow well located in said holder, an escape channel means in the top of said holder and communicating with both said wells whereby excess solution placed in said first well will pass to said overflow well to limit the amount of solution in said first well to a predetermined level, said level being related to the limited depth of penetration of said applicator by said upstanding projection so that only said puncture means are coated with said solution and not said base surface thus facilitating that an accurately determined amount of solution will be on said applicator when used on a patient.

2. A system as in claim **1** wherein said upstanding projection has a peripheral ridge thereon, the shape of said projection and depression being such that said ridge is sized to contact the area of said base surface to limit the depth of penetration of said applicator into said first well, said ridge also acting as a visual indicator for determining when said first well has a predetermined amount of solution therein.

3. A system as in claim **1** wherein the top of said holder is generally depressed, said first well and upstanding projection being located in the center of said depressed top and said overflow well being located adjacent said first well.

4. A system as in claim **1** wherein said upstanding projection and said depression are both frustro-conical in shape and said puncture or scarifying means are integral with an insert piece located on said base surface, said insert piece having a central aperture overlying the opening of said depression, said puncture or scarifying means being equally spaced from said depression.

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