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H. KRAVITZ

3,136,314

VACCINATING DEVICES

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Fig. 1

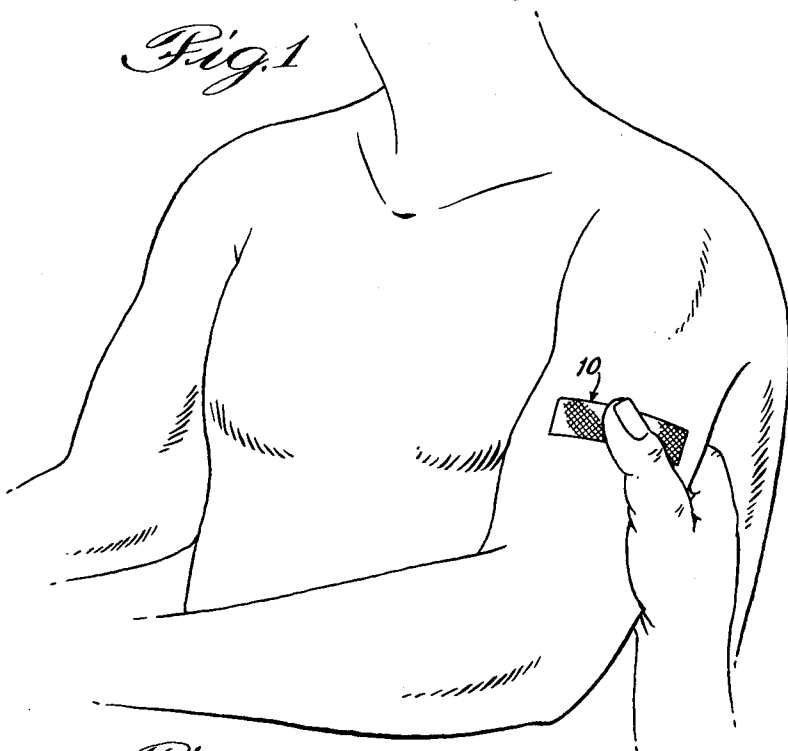


Fig. 2

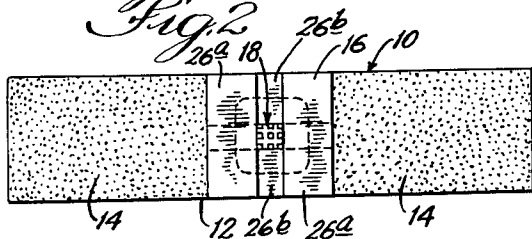


Fig. 4

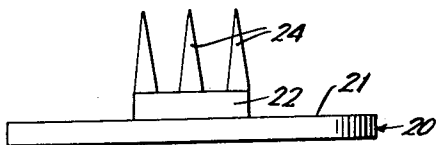


Fig. 3

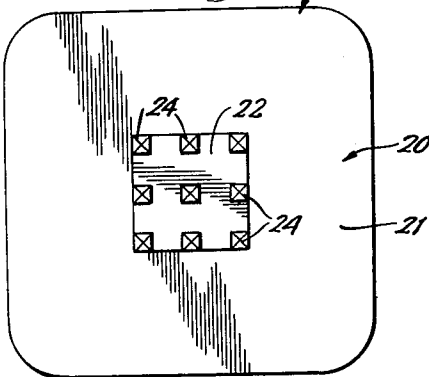
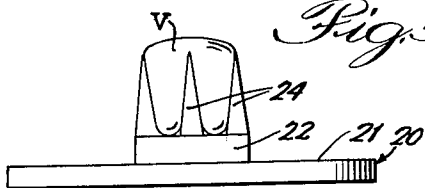


Fig. 5



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3,136,314

VACCINATING DEVICES

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4 Claims. (Cl. 128—253)

This invention relates to an improved means and method for vaccinating and more particularly this invention is an improvement over Patent No. 2,817,336 of which I am co-inventor.

In the said Patent No. 2,817,336 there is pointed out the desirability of obtaining as uniform and small a scar as possible resulting from a vaccination, such as for smallpox and the like. Furthermore, the device of the said patent desirably will produce multiple simultaneous punctures in a vaccinating operation thereby insuring the possibility of the vaccination "taking," while limiting the area of the resulting scar to a pre-selected area and simultaneously avoiding the possibility of accidentally elongated scars.

One object of the instant invention is to provide a reliable and inexpensive vaccinating instrument which will consistently provide a high percentage of "takes" and will produce a scar of limited area and will provide simultaneous multiple punctures during a vaccination operation.

In the Patent No. 2,817,336 there is broadly disclosed the concept of a multiple point vaccinator from whence vaccine may be dispensed. In the practical development of a reliable vaccinator I have discovered a particular embodiment of a multiple point vaccinator which has many desirable and advantageous features and I also discovered a novel, simplified and improved means of vaccinating which insures a very high percentage of "takes" and greatly alleviates many problems heretofore involved in the vaccinating of children.

Very simply, I have discovered that in a reliable vaccinator there should be a selected number of discrete points located at a selected spacing to insure adequate number of punctures while limiting the size of scar to as small an area as practicable.

I have further discovered that with a multiple number of points clustered in a selected area the length of the points is critical since if the points are too short, vaccinating requires excessive pressures and does not produce the reliability obtainable with points of the optimum length, while if the points are too long the control of manipulating the vaccinator may be adversely affected.

I have further discovered that with the use of a cluster of multiple vaccinating points there exists an entirely new method of vaccinating which includes the steps of depositing and locating vaccine upon the points and maintaining the vaccine on the points adjacent the tips thereof, so that a single pressing of the cluster of points against the skin of the person being vaccinated simultaneously effects the desired multiple puncturing of the skin and application of vaccine to the desired area, thereby effecting a less complicated and more rapid vaccinating of a person.

Thus, an object of this invention is to provide a vaccinator which embodies therein a requisite number of scarifying points in a limited area to effect reliable vaccinating.

And another object of this invention is to provide an improved method of vaccinating.

In the production of a reliable, multiple point, vaccinator it is economically desirable to provide a relatively inexpensive vaccinator that may preferably be discarded after a single use. Heretofore, vaccinators have been made of metal, but multiple point vaccinators of metal are relatively expensive and it has not, heretofore, been thought possible to construct vaccinators from other materials.

It is, therefore, still another object of this invention to

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provide an effective and reliable multiple point vaccinator made of a plastic material thereby permitting vaccinators embodying the improved features disclosed herein to be economically produced by mass production methods and thereby affording the marketing of a disposable, improved multiple point vaccinator.

As will become apparent from the disclosure herein-after, the device of this invention may also be useful in effecting tuberculin testing and its use will be an improvement over the existing tests by the Vollmer patch method or by the Mantoux technique, and represents a refinement of the multiple-puncture tuberculin test of Heaf.

Thus, still a further object of this invention is to provide an improved method of tuberculin testing and to provide an instrument by means of which tuberculin testing may be effected.

Further objects and advantages of this invention will become apparent as the following description proceeds and the features of novelty which characterize this invention will be pointed out with particularity in the claims annexed to and forming part of this specification.

A preferred embodiment of the invention is shown in the accompanying drawings, in which:

FIGURE 1 is an illustrative view wherein is shown one form of the invention herein being used in vaccinating a person;

FIGURE 2 is a plan view, substantially to scale, of the form of vaccinator shown in FIGURE 1;

FIGURE 3 is a greatly enlarged plan view of the scarifying portion of the vaccinator of FIGURE 2, and includes the vaccinator's rigid pressure base and cluster of puncture points extending therefrom;

FIGURE 4 is a side elevation view of the pressure base and puncture points seen in FIGURE 3; and

FIGURE 5 is similar to FIGURE 4 and shows the puncture points of the scarifier with an amount of vaccine carried by said puncture points, as they would when the vaccinator is being used in one of the manners described herein.

Referring now to the drawings, there is illustrated in FIGURE 1 the upper portion of the torso of a person being vaccinated, and there is shown disposed on the upper left arm of said person one form of vaccinating device of this invention, generally indicated at 10. It will be seen that the central part of the vaccinating device 10 is being forced against the skin of the upper left arm by thumb pressure of the person doing the vaccinating.

In the technique of vaccination with the device 10, the skin of the lateral aspect of the upper arm is first cleansed with acetone in the established manner and, in a first method of operation of the device herein disclosed, a drop or more of the vaccine, consisting of vaccine lymph in a solution of glycerine, is deposited onto the cleansed skin, again in the customary manner. A sterile vaccinator 10 which includes an adhesive strip is then adhesively applied to the skin of the vaccinee so that the puncture points thereof, which will be hereinafter described, are positioned directly above the deposited vaccine, and the pressure of the thumb of the person performing the vaccination forces the puncture points against the skin, as seen in FIGURE 1, through the liquid vaccine thereon. The vaccinator 10 is then removed and discarded. This first method of use has heretofore been generally disclosed in the said Patent 2,817,336.

In the specific construction of the improved vaccinator 10, that is shown in FIGURES 2-4, there is provided an elongated fabric, or plastic, strip 12 preferably having pressure sensitive adhesive-coated, exposable, portions 14 disposed on opposite sides of a central portion 16 of strip 12. Positioned centrally of the said center strip portion 16 is a scarifier generally indicated at 18, the details of

construction of which are more clearly seen in FIGURES 3 and 4.

The scarifier 18 includes a flat, generally square, pressure base 20 that is thin but relatively rigid. A raised platform 22 is located centrally of the square base 20. Projecting upwardly from the platform 22 are nine puncture points 24, each of which is in the form of a tapered pyramid, the opposite sides of which have therebetween an included angle of about 12 degrees. The nine puncture points 24 are equally spaced, as shown, and are arranged in a predetermined pattern of three straight rows each containing three points. Certain edges of the bases of the points 24 coincide with the peripheral edge of platform 22, thereby locating the points 24 inwardly of the periphery of platform 22. The platform has a square area with an edge dimension in the order of 0.3 centimeter. The extended tips of the puncture points 24 are spaced approximately 0.3 centimeter from the upper side of the pressure base 20, and the height, or thickness, of the platform 22 is approximately one-quarter of the said spacing. The platform serves to prevent smearing of the vaccine during the vaccination.

The arrangement of the platform 22 centrally of pressure base 20 provides a border portion 21 on the base that is of substantially uniform width and completely surrounds the platform 22. Because of the close spacing of the points 24, they are referred to as being clustered centrally of the base 20.

The provision of the border portion 21 insures that the area of the back side of pressure base 20 is many times the area in which the cluster of points 24 is located. The width of the border portion 21 is substantially the same dimension as the edge width of the platform 22, so that the area of base 20 is about nine times the area of the platform 22. The border portion 21 also provides means for securing the scarifier 18 to the strip 12 and, for example, it will be seen in FIGURE 2 that with the scarifier 18 positioned centrally on the adhesive strip 12, a retaining means in the form of a plurality of adhesive retaining strips 26a and 26b are provided which overlie portions of the border area 21 and which thereby secure the scarifier 18 to the strip 14 with the platform 22 and the puncture points 24 thereon extending above such retaining means.

The use of the adhesive strip 12 provides a means for securing the vaccinator 10 to the skin of the person to be vaccinated, so that there is eliminated any substantial lateral movement between the puncture points 24 and the area of the skin onto which is deposited the vaccine. It will be understood that, when packaged, the adhesive portions 14 of the strip will be protected as will be the entire vaccinator 10, so as to provide a sterile device ready for use.

The scarifier 18 disclosed herein provides a novel means of utilization thereof in the effecting of vaccinations. The vaccine material is, as earlier stated, a vaccine lymph in a glycerine carrier, thereby providing a liquid having viscosity greater than water. The cluster of nine elongated puncture points 24, within a limited square area of 0.3 cm. along a side, provides a considerable amount of surface area on both the upper side of the platform 22 and along the sides of the pyramids 24 relative to only the surface area of platform 22. I have discovered that when a drop of vaccine material is deposited, or loaded, onto the said cluster of points, rather than onto the skin of the person to be vaccinated, the surface tension between the vaccine and the contacted surfaces of the puncture points 24 and platform 22 is such that the vaccinator 10, or the scarifier 18, may be manipulated to any position whatsoever without the vaccine leaving the puncture points. In other words, with vaccine loaded on the scarifier 18, as illustrated in FIGURE 5, the scarifier 18 may even be turned completely upside down and the vaccine will not run off the points.

The latter feature provides a very important advantage in the effecting of vaccinations because it is now possible to eliminate the necessity of registering the puncture points with the drop of vaccine that is on the skin, as is utilized in the first method earlier described.

Thus, the second method of operation disclosed herein comprises first cleansing the upper arm of the person to be vaccinated in the usual manner, then taking the vaccinator, or scarifier, and depositing, or loading, an amount of vaccine V onto the puncture points 24 so that the vaccine will assume the position on the points as illustrated in FIGURE 5. Then the scarifier 18, or the vaccinator 10, with the vaccine on the puncture points thereof, is placed point first against a selected skin area of the person, while simultaneously applying manual pressure through the thumb, or fingers, against the back side of the pressure plate 20. Since the vaccine is immediately adjacent the tips of the pressure points 24 which effect scarification of the skin, and upon the vaccine liquid contacting the skin, the surface tension is broken sufficiently to have the vaccine flow onto the sacrificed, or punctured, skin area. Thus, application of the vaccine and scarification, or multiple puncturing, are accomplished simultaneously and the intermediate step of applying vaccine to the person's skin is eliminated. It has been discovered that the latter method of vaccinating is much more rapidly and easily performed than the previous method.

The results of vaccinating with the vaccinator here disclosed are excellent regardless of which method is used, although the second method is superior in that it takes less time and is wonderfully effective with infants and small children because preparation time, which is usually a period when the child is tensed, frequently tearful, and on occasions almost hysterical, is almost completely eliminated. The percentage of "takes" with the second method has been greater than with any other method tried. An important additional result that has been noted was that with the multiple punctures performed by the scarifier 18, there were no instances where infants or young children ran high temperatures as a result of the vaccinations. On the other hand, with the standard techniques utilizing a needle for effecting successive multiple punctures through a drop of vaccine spread on the skin, there is usually a substantial percentage of instances, in the practice of most pediatricians, where the infants run high temperatures of 103°-104° F., rectally.

The scarifier 18 is made from materials that are non-reactive to the vaccine. Such materials include stainless steel and hard plastic materials, such as acrylic resin plastic known by the trade name "Lucite." A stainless steel scarifier made in accordance with the constructions shown in FIGURES 3 and 4 is a relatively expensive device, since the points must be formed by a relatively expensive machining procedure. However, such a scarifier may be autoclaved after each use and may be used many times. It has now been determined that a scarifier of machined "Lucite" plastic, of substantially the same shape as shown in FIGURES 3 and 4, will give equally satisfactory scarifying and vaccinating results. It is therefore anticipated that vaccinators similar in shape and form to FIGURES 3 and 4 may be satisfactorily molded from plastic in multiple cavity molds, in mass production at relatively low costs.

It is contemplated that a multiple puncture instrument and process as herein disclosed, may also be utilized in tuberculin testing. The accepted methods of tuberculin testing heretofore employed are the Vollmer patch test, and the Mantoux technique. The patch test has undesirable features, since the patch frequently falls off and, furthermore, the patch's rubbing against the surface of the skin may cause secondary irritations that make proper reading of the test results difficult. The Mantoux technique requires an intracutaneous introduction of tuberculin, and is a very delicate technique requiring skill and

considerable time of a trained technician. Furthermore, the use of the Mantoux on infants is fraught with considerable bedlam which is disconcerting both to the doctor, the mother, and to the patients who are awaiting treatment and may hear the screaming.

In 1951, Professor Frederick Heaf suggested using a multiple puncture tuberculin test which has been practiced in recent years by means of a spring-activated lancet device, which must be sterilized by flaming after each use. Even then, serious study has been given to the likelihood of serum hepatitis by reason of multiple use of the instrument. Thus, the instruments presently utilizing the Heaf technique are expensive and require cleaning and flame sterilization for re-use, and may even be unsafe.

Clearly, the multiple punctures of the instrument herein disclosed may be utilized to effect multiple-puncture tuberculin testing by the techniques herein described, and since said device, when molded from plastic, will be inexpensive and may be discarded after a single use, the expense of cleaning and possibility of serum hepatitis may be ruled out, thereby providing a superior instrument and technique.

In the use of the device herein for tuberculin testing, either of the two techniques disclosed may be utilized but, again, it is preferred that the method used be the one where the tuberculin solution is applied to the puncture points 24, and the scarifier 18 with the tuberculin thereon is then pressed against the skin of the person to be tested, after which the scarifier 18 may be discarded and a new device utilized for the next individual.

The length of the puncture points is important because if the points are too short there may be insufficient penetration into the deeper layer of the epidermis, and if the points are too long they will draw blood and hurt and may result in secondary infections. The preferable length of points 24 is one that effects only piercing of the outer layer of skin under ordinary manual pressure against base 20 without drawing blood.

The spacing of tips of points 24 within 0.3 cm. is related to the size of a normal drop of vaccine which, when deposited on the skin, lies in an area of about 1/8-inch diameter. By grouping, or clustering, the points 24 so close together, the cosmetic appearance of scars resulting from use of scarifier 18 is an improvement over scars obtained by previous techniques, because the new scars are very small and are of substantially uniform dimension and appearance.

Because of the tendency of the peripherally located points 24 to depress the skin, it will be desirable to make the center point 24 just slightly longer than the other points of the cluster to insure puncturing of the skin by the center point.

While the device herein has been described for use in effecting vaccination against smallpox or in effecting tuberculin testing, it will be readily apparent to those skilled in the art that the device and its method of use may be successfully used in other related fields, such as, for example, in effecting virus inoculations.

Although the arrangement of points 24 as herein disclosed locates the points in a rectangular pattern, it will be understood that the points may be arranged in a predetermined circular pattern, or triangular pattern, or any other pattern, as long as the points are clustered closely so as to yield a cosmetically small scar and so that with a drop of vaccine deposited thereon, said drop of vaccine will be retained on the points regardless of the attitude of the points.

While there has been shown and described a particular embodiment of this invention, it will be obvious to those skilled in the art that various changes and modifications may be made therein without departing from the invention and, therefore, it is intended in the appended claims to cover all such changes and modifications as fall within the true spirit and scope of the invention.

What I claim as new, and desire to secure by Letters Patent of the United States, is:

1. A device for applying a biological substance to the skin of a person by providing simultaneous multiple skin punctures comprising, in combination: a plurality of spaced, elongated, points clustered in a pre-determined pattern into a pre-selected regular area whose width dimension is in the order of 0.3 centimeter; a rigid, pressure-transmitting base supporting the cluster of points centrally thereof on one side of the base, the other side of the base providing a manually engageable area that is many times greater than the area in which the points are clustered and against which manual pressure may be exerted during an operation, of application of the biological substance, by pressing the cluster of points against a selected skin area of a person; and a raised platform located centrally on said base and projecting abruptly from said base and being of substantially the same area as the pre-selected area in which the points are clustered and having a width dimension in the order of 0.3 centimeter, and said cluster of points extending outwardly from said platform and being of a length to effect penetration into the deeper layer of the epidermis, but being short enough so that blood will not be drawn or will result in secondary infection.

2. A device for applying a biological substance to the skin of a person by providing simultaneous multiple skin punctures comprising, in combination: a plurality of spaced, elongated, points clustered in a pre-determined pattern into a pre-selected regular area whose width dimension is in the order of 0.3 centimeter; and a rigid, pressure-transmitting base supporting the cluster of points centrally thereof on one side of the base, the tips of said points being spaced from the base a distance in the order of 0.3 centimeter, and a border portion on said base of substantially uniform width completely surrounding said pre-selected area, and the width of said border portion being of the same order as the width of the pre-selected area, thereby providing that the manually engageable area of the other side of the base is many times greater than the area in which the points are clustered.

3. A device for applying a biological substance to the skin of a person by providing simultaneous multiple skin punctures comprising, in combination: a plurality of spaced, elongated, points clustered in a pre-determined pattern into a pre-selected regular area whose width dimension is in the order of 0.3 centimeter; a rigid, pressure-transmitting base supporting the cluster of points centrally thereof on one side of the base, the other side of the base providing a manually engageable area that is many times greater than the area in which the points are clustered and against which manual pressure may be exerted during an operation, of application of the biological substance, by pressing the cluster of points against a selected skin area of a person; and said cluster of points being of selected number and spacing within the pre-selected area having a width dimension of 0.3 centimeter, whereby when a selected specimen of vaccine lymph in glycerine is deposited on the cluster of points, the surface tension between said specimen and said cluster of points will effect retention of said specimen on the cluster of points even when the device is held at an attitude with the points pointing downwardly.

4. A device for applying a biological substance to the skin of a person by providing simultaneous multiple skin punctures comprising, in combination: a plurality of spaced, elongated, points clustered in a pre-determined pattern into a pre-selected regular area whose width dimension is in the order of 0.3 centimeter; a rigid, pressure-transmitting base supporting the cluster of points centrally thereof on one side of the base, the other side of the base providing a manually engageable area that is many times greater than the area in which the points are clustered and against which manual pressure may be

exerted during an operation, of application of the biological substance, by pressing the cluster of points against a selected skin area of a person; a raised platform located centrally on said base and projecting abruptly from said base and being of substantially the same area as the pre-selected area in which the points are clustered and having a width dimension in the order of 0.3 centimeter, with said cluster of points extending outwardly from said platform; and said cluster of points being of selected number and spacing within the pre-selected area having a width dimension of 0.3 centimeter, whereby when a selected specimen of vaccine lymph in glycerine is deposited on the cluster of points, the surface tension between said specimen and said cluster of points will effect retention of said specimen on the cluster of

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points even when the device is held at an attitude with the points pointing downwardly.

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