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Stickl et al.

[11] **3,905,371**

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[54] **INOCULATING TOOLS FOR CUTANEOUS VACCINATION USING A DRY VACCINE**

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[30] **Foreign Application Priority Data**

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[52] **U.S. Cl.** **128/253**

[51] **Int. Cl.**[2] **A61B 17/20**

[58] **Field of Search** ..... 128/253, 329, 333, 2 R, 128/2 W

[56] **References Cited**

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Attorney, Agent, or Firm—Wolf, Greenfield & Sacks

[57] **ABSTRACT**

A rod inoculating tool for cutaneous smallpox vaccination using a dry vaccine has a head part terminating in a plurality of cutting edges so arranged in spatial relationship that, by virtue of surface tension, when the head is immersed in a liquid inoculent or vaccine, the liquid contracts into the space between the cutting edges to be held there firmly on freeze drying of the liquid inoculant or vaccine, the outer surface of the tool or cutting edges remaining substantially free from vaccine. At least the head part of the tool is preferably made from an anhydrous plastics material, e.g. polymethacrylate, which does not absorb water.

13 Claims, 10 Drawing Figures

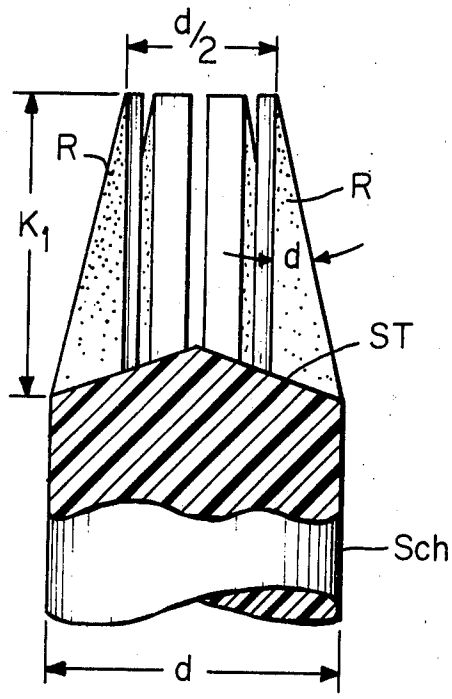


FIG. 1

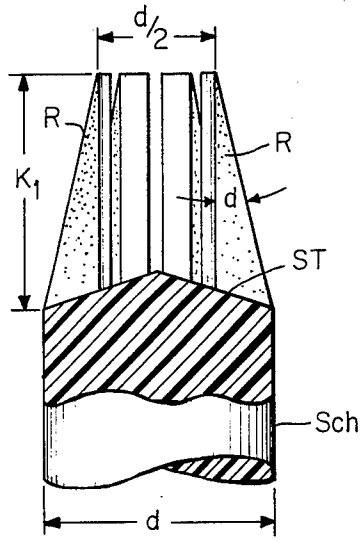


FIG. 2

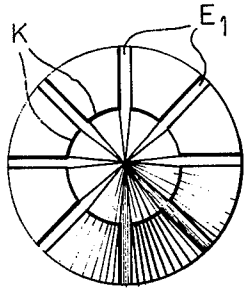


FIG. 3

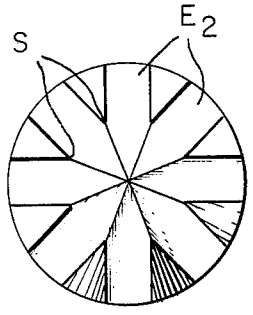


FIG. 4

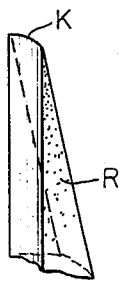
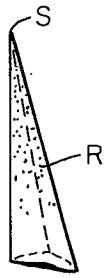


FIG. 5



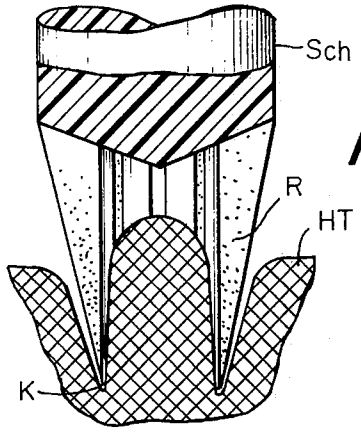


FIG. 6

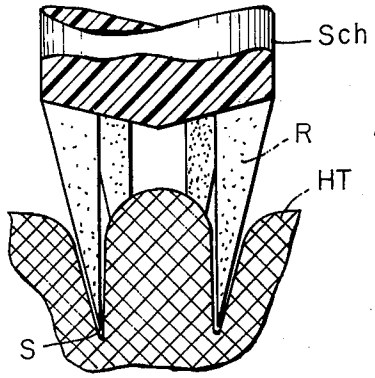


FIG. 7

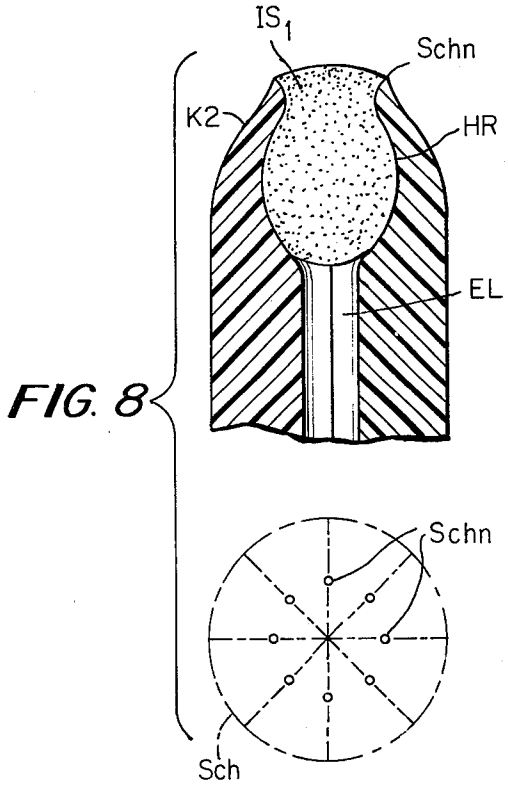


FIG. 8

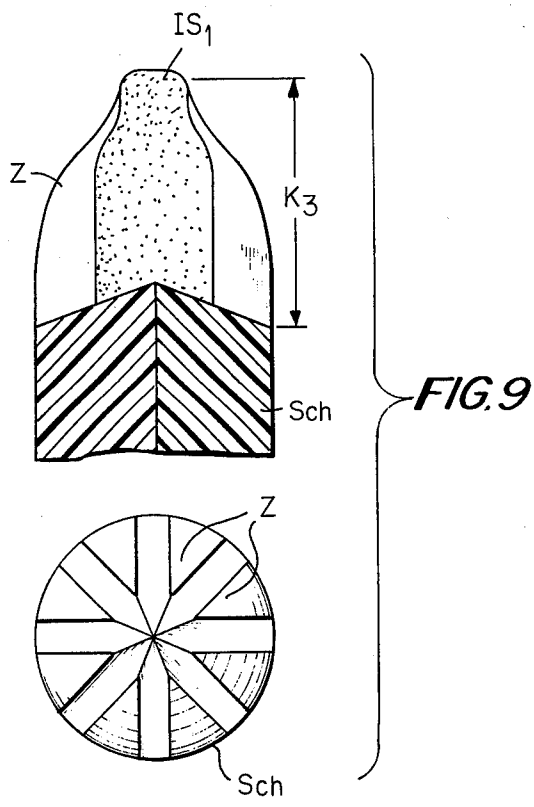


FIG. 9

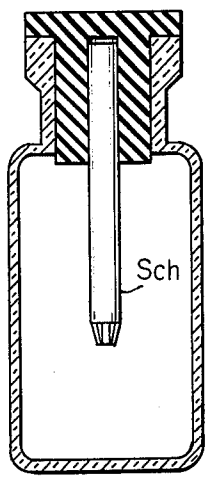


FIG. 10

INOCULATING TOOLS FOR CUTANEOUS VACCINATION USING A DRY VACCINE

BACKGROUND OF THE INVENTION

This invention relates to rod inoculating tools having a head part terminating in a plurality of cutting edges, for cutaneous smallpox vaccination using a dry vaccine.

Such inoculating tools are known (see for example U.S. Pat. No. **3,034,507**); they have a head part with a plurality of cutting edges extending parallel with one another, which are dipped into liquid vaccine which is then freeze dried on the cutting edges. it has been found that with these inoculating tools, due to vibration, the vaccine clings poorly to the tips or, if it initially clings, then it tends to break off during transport or during storage of the inoculating tools, but in any case prior to their use. Apart from this fact, the disposition and construction of the cutting edges do not permit agreeable and pain-free inoculation.

SUMMARY OF THE INVENTION

The invention aims at providing an inoculating tool for cutaneous smallpox vaccination using a dry vaccine, with which there is a high degree of security that the vaccine actually takes effect when the inoculating tool is used, and which permits of substantially pain-free inoculation.

To this end, the present invention consists in an inoculating tool provided with a head part terminating in a plurality of cutting edges, for cutaneous smallpox vaccination using dry vaccine, characterized in that by virtue of its spatial construction, the head part of the inoculating tool is constructed as an arrangement for holding the dry vaccine and which, after the vaccine applied to the head part in liquid form has been freeze dried, positively retains the said vaccine.

According to a further development of the invention, the head part of the inoculating tool may consist of a pointed circular cone, wherein slot-like incisions form circularly disposed serrations, on which and between which the freeze-dried vaccine is positively held. According to the relevant width of the slot-like incisions, so the resultant serrations terminate in elongated or in pointed cutting edges.

The head part of the inoculating tool may, however, also consist either of a substantially closed hollow body which has not only a ventilating aperture provided in its bottom but only one approximately circular aperture leading to the head end and the outer rim of which has short cutting edges at regular intervals, or alternatively it may consist of a plurality of more or less claw-like inwardly inclined pointed cutting edges distributed evenly around the circular periphery of the inoculating tool.

The essential feature of all forms of embodiment of the inoculating tool according to the invention resides therefore in the fact that the head part of the inoculating tool is so constructed that the freeze dried vaccine is retained on the head part in a positive manner, care being of course taken that, during inoculation, the dry vaccine can come in contact with the tissue fluid of the person to be inoculated.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be more readily understood, reference is made to the accompanying drawings which illustrate diagrammatically and by way of example, several embodiments thereof, and in which:

FIG. **1** is a section through one embodiment of vaccinating tool;

FIGS. **2** and **3** are plan views of an inoculating tool according to FIG. **1** but with narrow and broad slots respectively;

FIGS. **4** and **5** are perspective views of a serration of the inoculating tool of FIGS. **2** and **3** respectively;

FIGS. **6** and **7** each show a cross-section through the inoculating tools according to FIGS. **2** and **3** respectively when applied to the skin;

FIGS. **8** and **9** show further embodiments of inoculating tool according to the invention; and

FIG. **10** shows an inoculating tool in a storage vessel.

DETAILED DESCRIPTION OF THE DRAWINGS

The inoculating tool according to FIG. **1** consists of a cylindrical plastics shank Sch (for example, of a diameter *d* of approximately **3** mm and a length of approximately **30** mm), terminating at its head part K_1 in a truncated circular cone (with an opening angle 2α of approximately **30°**). It is important to use for the inoculating tool a synthetic plastics material which is water-resistant and which absorbs no water, e.g. polymethacrylate. The circular cone has a plurality of, e.g. eight, incisions enclosing the longitudinal axis of the circular cone (see FIGS. **2** and **3** which form slots E_1, E_2, of different widths), so that serrations (of approximately **2.8** mm height above the base area of the cone) disposed in a small circle (of approximately *d*/**2** diameter) are formed, of which the lateral faces formed by the slotting are intentionally roughened as shown at R. The inside face of these serrations extend parallel with the axis of the circular cone, while the outside faces of the serrations are of course parts of the surface of the circular cone.

The effect of this spatial development of the serrations is that by virtue of its surface tension, the vaccine applied to the head part of the inoculating tool by immersion into the inoculating fluid or vaccine, contracts into the entire space between the serrations, in other words also in the incisions, so that the conical outer surfaces of the serrations remain substantially free from vaccine.

When the inoculating tool is dipped into the inoculating fluid, in order to avoid an air bubble settling between the closely disposed serrations and which could prevent the inoculating fluid penetrating the space between the serrations, the incisions into the circular cone are guided obliquely upwardly (approximately at **40°** to the base area of the circular cone) with respect to the point of the circular cone, so that, at the base between the serrations, a cone ST is formed which has an opening angle of approximately **100°**. An air bubble present between the serrations can then flow off outwardly on the oblique cone faces of the slot-like incisions.

Upon freeze drying of the vaccine, the vaccine between the serrations and the vaccine which has penetrated into the incisions form a firmly cohesive composition which is locked in the slots, i.e. positively held, which resists all vibrations in transport. Only when the inoculating tool (see FIGS. **6** and **7**) is applied on the skin HT of a person to be inoculated does the tissue fluid emerging from the skin dissolve the vaccine cling-

ing to the serrations of the inoculating tool so that the inoculant will now penetrate the skin tissue. The serrations constructed as elongated edges K or as pointed cutting edges S, according to the width of the slot-like incisions E_1, E_2, in either case stretch taut the skin located between the serrations; the edges K however (see FIG. 6) stretch the outer layers of the skin only in such a way that tissue fluid emerges from the living tissue cells, without piercing the skin, whereas the pointed edges S (see FIG. 7) actually penetrate the outer layers of the skin.

Since upon vaccination not the entire quantity of vaccine held on an inoculating tool is immediately released and consumed, one and the same vaccinating tool may be used to effect further inoculations on the body of the same subject; only when the tool is applied to the skin for the third time does the chance of a successful inoculation drop to 50%. After the inoculation, the inoculating tool utilized is used up; therefore, it is a disposable item for the inoculating practitioner who is himself substantially safeguarded against inadvertent self-infection while the subject to be inoculated is at the same time also safeguarded against the transmission of hepatitis.

The vaccine used in the case of the inoculating tool according to the invention contains for example, per cu.cm. in the dissolved state, an average of 5×10^8 infectious virus particles of Elstree strain vaccinia virus, which is capable of multiplication. Thus, this vaccine complies with the requirements of the World Health Organization; it does however meet the still farther-reaching claims of the Federal Health Office.

When it is used, the inoculating tool is applied firmly against the skin of the subject, which has been previously cleansed with alcohol or the like and dried, the part of the skin in the circle formed by the serrations of the inoculating tool projecting convexly (see FIGS. 6, 7). When this happens, by virtue of the fact that the serrations (elongated edges K or cutting edges S) are in a small circle one beside another, the subject has hardly any feeling of pain (so-called fakir effect). When the inoculating tool has been lifted off the skin, only a star-shaped pattern is generally visible for a short time.

After the vaccine has been applied to the head part and then freeze dried, and until such time as it is used, the inoculating tool according to the invention is stored in an air-tight fashion in a glass vessel (see FIG. 10) which is filled with inert gas and which is sealed by a rubber stopper which is particularly suitable for the purpose.

For the construction of the head part of the inoculating tool, while respecting the idea underlying the invention and outlined here, there are still further possibilities, two of which, by way of example, will be briefly explained hereinafter.

In the case of the inoculating tool according to FIG. 8, the head part K_2 has a substantially closed hollow space HR which in addition to a naturally required vent aperture EL, for example at the base of the hollow space, has only one aperture leading to the head end, the outer edge thereof being provided with short cutting edges Schn disposed at regular intervals. As shown in FIG. 8, the hollow space HR may have a spherical shape; it could however for example also be more elongated or transversely extended. The vaccine IS_1 which is introduced into such a space in liquid form and then freeze dried is reliably safeguarded against crumbling away due to vibration. For the manufacture of an inoculating tool which is thus shaped, it is advantageous to form it from two pieces divided in the direction of its longitudinal axis and which are then held together for example by welding.

The inoculating tool shown in FIG. 9 has a head part K_3 which consists of a plurality of more or less claw-like, inwardly inclined serrations Z distributed evenly over the circular periphery of the inoculating tool and between which the freeze dried vaccine IS_2 is likewise retained with considerable security. This construction which can be advantageously constructed likewise in two parts, like the embodiment shown in FIG. 8, otherwise corresponds substantially to the inoculating tool shown in FIG. 1.

We claim:

1. An inoculating tool for cutaneous smallpox vaccination using dry vaccine and having a shank terminating in a head of smaller cross-section than that of the shank, said head having a coaxial bore and a plurality of radially extending slot-like incisions extending outwardly from the bore and enclosing the longitudinal axis of the head to thereby define a plurality of serrations, each serration having an inwardly facing wall or edge extending substantially parallel to the longitudinal axis of the head, the walls of the serrations defined by the incisions having a roughened surface so as to permit positive locking of the dried vaccine in the area between the serrations and also extending substantially parallel to the longitudinal axis of the head, facing walls of adjacent serrations being parallel and extending radially of the head.

2. The inoculating tool of claim 1 wherein the head is in the form of a truncated circular cone and the serrations are staggered by identical angles with respect to one another.

3. The inoculating tool of claim 2 wherein the slot-like incisions are relatively narrow so that each of the serrations terminates in an elongated cutting edge.

4. The inoculating tool of claim 2 wherein the slot-like incisions are relatively broad so that each of the serrations terminates in a pointed cutting edge.

5. The inoculating tool of claim 2 wherein the plurality of serrations total at least four each terminating in a cutting edge and all formed in a circular locus.

6. The inoculating tool of claim 5 wherein the diameter of the circular locus is about one half the diameter of the shank.

7. The inoculating tool of claim 1 wherein the head has a substantially closed hollow space which in addition to a vent aperture provided at the base, has only one approximately circular aperture leading to the head end, the outer edge of the aperture being provided with a plurality of short cutting edges at regular intervals.

8. The inoculating tool of claim 1 wherein the head carries, distributed evenly over the circular periphery of the inoculating tool, a plurality of approximately claw-like inwardly inclined serrations.

9. The inoculating tool of claim 7 wherein the inoculating tool consists of two pieces, divided in the direction of its longitudinal axis, which are rigidly secured together.

10. The inoculating tool of claim 8 wherein the inoculating tool consists of two pieces, divided in the direc-

tion of its longitudinal axis, which are rigidly secured together.

11. The inoculating tool of claim **1** wherein at least the head of the inoculating tool consists of an anhydrous plastic material which does not absorb water.

12. The inoculating tool of claim **11** wherein the anhydrous plastic material comprises polymethacrylate.

13. An inoculating tool for cutaneous smallpox vaccination using dry vaccine and having a shank terminating in the head of smaller cross-section than that of the shank, said head having a coaxial bore and a plurality of slot-like incisions enclosing the longitudinal axis of the head to thereby define a plurality of serrations, each serration having an inwardly facing wall or edge extending substantially parallel to the longitudinal axis of the head, the walls of the serrations defined by the incisions having a roughened surface so as to permit positive locking of the dried vaccine in the area between the serrations, wherein the head is in the form of a truncated circular cone and the serrations are staggered by identical angles with respect to one another, wherein the slot-like incisions extend obliquely upwardly towards the point of the circular cone through the circular cone so that an obtuse angle is formed at the base between the serrations.

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