May 30, 1967 O. H. BANKER 3,322,121

SKIN-PUNCTURING UNIT WITH A COLLAPSIBLE PROTECTIVE COVER

Filed Nov. 26, 1965

Fig. 2.

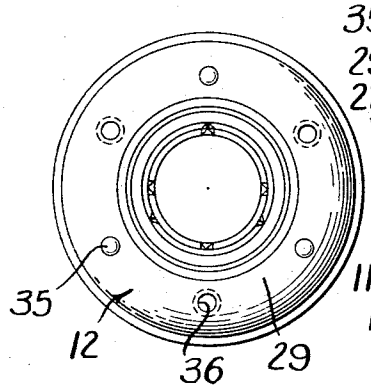


Fig. 1.

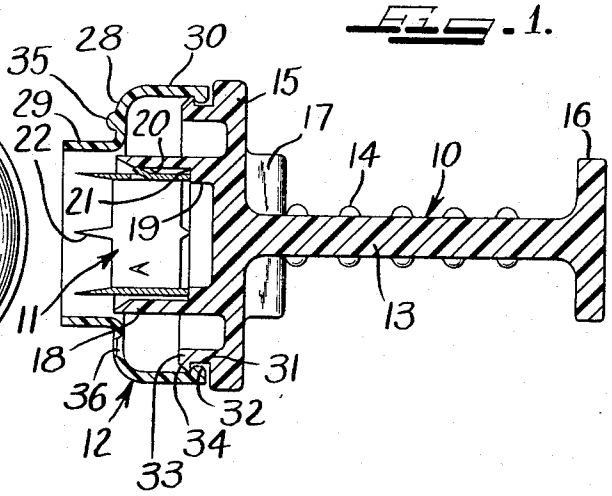


Fig. 3.

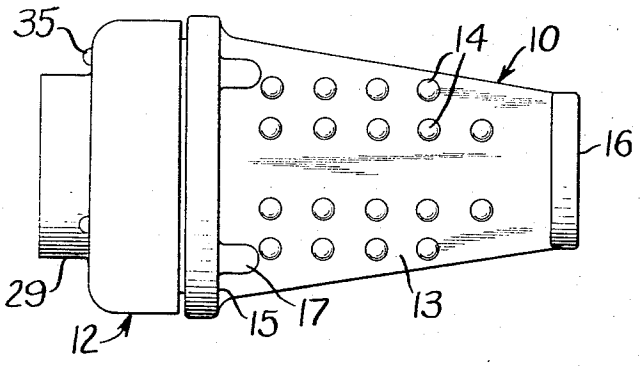


Fig. 4.

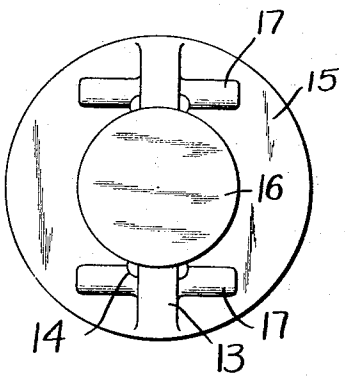


Fig. 6.

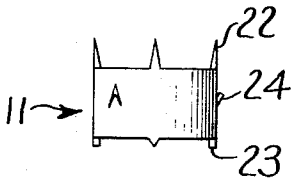


Fig. 5.

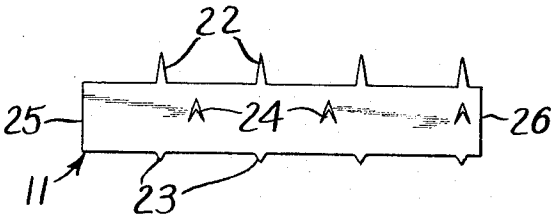
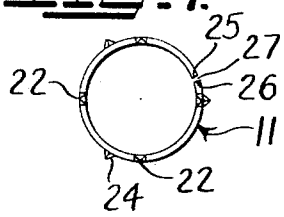


Fig. 7.



INVENTOR
OSCAR H. BANKER

BY Charles F. Vaytech
Atty.

United States Patent Office 3,322,121 Patented May 30, 1967

3,322,121

SKIN-PUNCTURING UNIT WITH A COLLAPSIBLE PROTECTIVE COVER

Oscar H. Banker, 261 Breezewood Drive, Bay Village, Ohio 44140

Filed Nov. 26, 1965, Ser. No. 509,755
3 Claims. (Cl. 128—253)

This application is a continuation-in-part of my copending application, Ser. No. 380,869, filed July 7, 1964, for Skin Puncturing Unit.

This invention relates to disposable skin-puncturing devices, such as are used by physicians to inject an antigen or a vaccine into the skin of a patient to determine the presence or absence of a specific disease, or to inoculate a patient against a disease.

It has been proposed to the medical arts to simplify the introduction of antigens, vaccines, or the like, under the skin of a patient by providing the substance to be introduced in a disposable package, the package comprising a rigid holder to be grasped by the physician, a tined member held by the rigid backing member and containing at the tips of the tines the substance to be introduced, and a protective cover for the tines to prevent accidental injury or treatment by the physician or nurse administering the substance, as well as to protect the tines from contact with dirt or other unsanitary conditions. Such devices, however, have proved to be expensive, and it is accordingly an object of this invention to provide a disposable, tined, skin-puncturing unit which is very inexpensive to make and which will maintain the skin-puncturing tines of the device in sterile condition until the device is used.

Another object of this invention is the provision of a skin-puncturing device which provides at all times complete protection for the physician against infection from any of the substances which might be injected into the patient's skin by the physician with the aid of said device.

As a more specific object, this invention has within its purview the provision of a holder for the tines of a skin-puncturing device wherein said holder is made of a molded plastic, and the device as a whole is so constructed as to avoid the use of threaded and machined parts.

These and other objects of this invention will become apparent from the following detailed description when taken together with the accompanying drawings in which;

FIG. 1 is a side elevational view in section of an assembled skin-puncturing device made in accordance with this invention;

FIG. 2 is an end elevational view of the device of FIG. 1;

FIG. 3 is a plan view of the device of FIG. 1;

FIG. 4 is an end elevational view of the device of FIG. 1 taken from the end opposite to that of FIG. 2;

FIG. 5 is a plan view of the tined element of the device in an intermediate stage of its manufacture;

FIG. 6 is a side elevational view of the tined element of the device in its completed form;

FIG. 7 is a plain view of the tined element of FIG. 6.

By way of general description, the skin-puncturing device of this invention is comprised of a molded plastic holder adapted to be grasped between the thumb and forefinger of the physicial or nurse, said holder having a centrally located depression in one end into which is pressed a strip of stainless steel, or the like, which has been stamped to form sharply pointed tines and which has been bent to fit into the cavity with a snug or press fit. A protective cover is placed over the end of the holder to which the tined sheet metal strip has been attached, the cover being longer than the tines so that contact is established first with the protective cover rather than with the tines.

The cover is of such configuration as to yield when pressed endwise so that the tines may be exposed to enter the skin of the patient when endwise pressure is continued upon the device. Prior to use, the prepared devices are frictionally held on racks containing recesses into which the covered tined ends of the devices are inserted, thereby protecting the contents of the tined ends from inadvertent endwise pressure as well as from dust and dirt and also providing a safe storage place for the prepared devices to minimize the possibility of injury to the physician or nurse.

Referring now to the drawings for a detailed description of the illustrative embodiment of the invention shown therein, and particularly to FIG. 1, said device is comprised of a rigid, single-piece molded holder **10**, a stamped metal tined element **11**, and a flexible protective cover **12** for the tined element.

The molded holder **10** is comprised of a generally flat, relatively thin section **13** which may have any desired configuration, but which in the illustrative embodiment, as shown in FIG. 3, has a simple trapezoidal outline and has spaced integral buttons **14** molded on both surfaces thereof. It is contemplated that the physician or nurse will hold the device by its section **13**, and the buttons will thus function to prevent slipping of the device in the fingers. At its left-hand end, as viewed in FIG. 1, holder **10** has a circular disc or flange **15** in which the tined element **11** is held, and at its opposite end is a smaller disc or flange **16** which is contacted by the fingers of the physician or nurse when the device is to be withdrawn either from its holder or from the skin of the patient. The precise contour of the end **16** is not material to this invention and it may be circular as shown, or it may be square, or any desired configuration which does not unduly complicate the molding of the holder. Reinforcing gussets **17** are molded integrally between flange **15** and section **13** to strengthen said section at its juncture with flange **15** against side forces which may be brought to bear upon flange **15** during the application of the device to the skin of the patient.

Flange **15** has a cylindrical extension **18** formed preferably concentrically with said flange and extending outwardly axially beyond said flange. Said cylindrical extension **18** is hollow and has a first recess **19** molded therein and an enlargement of the recess **20** extending to the outer end of the cylindrical extension. The bottom **21** of the enlargement **20** forms a radial abutment or shoulder for locating the tined element **11** in the holder.

The material of which holder **10** is made may be any of the thermo-plastic resins, such as polystyrene, which is water resistant, light weight, and has good dimensional stability.

Tined element **11** (as shown in FIGS. 5, 6, and 7) is comprised of a thin sheet of stainless steel which has been stamped to form a plurality of sharp tines **22** extending in the plane of the metal sheet from one side thereof and a plurality of short nibs **23**, which may or may not be pointed, extending in the plane of the sheet but from the side thereof opposite that on which tines **22** are formed. Three preferably pointed tabs **24** are struck outwardly from the plane of the metal sheet between the sides thereof and located closer to tines **22** than to nibs **23**. The tips of tabs **24** are pointed in the same direction as tines **22**.

Tined element **11** may be formed in a punch press as a flat sheet which is then curled or rolled, as the case may be, into a cylinder such as shown in FIG. 6. The ends **25** and **26** of the sheet are brought in close proximity to one another and the element is left with a resilient tendency to expand beyond the diameter afforded by the enlargement **20** of the recess **19**. Thus, as shown in FIG. 7, a slight gap **27** is left between the ends of the rolled sheet.

Tined element **11** is inserted into the enlargement **20** of recess **19** in a manner to cause the nibs **23** to contact the bottom **21** of the enlargement and with tabs **24** bearing against the cylindrical wall of said enlargement. The tined element **11** is thus held in spaced relation to the walls of enlargement **20** and to the bottom **21** thereof to permit sterilization of the assembled tined element **11** and holder **10** by an appropriate fluid either liquid or gas. The gap **27** allows for adjustment for manufacturing errors in the holder **10** and the tined element **11**. The resilient tendency to expand presses the tabs **24** against the walls of enlargement **20**, and the pointed ends of the tabs, being directed toward the open end of extension **18** tend to "bite" into the said walls to hold tined element **11** in its recess against withdrawal therefrom.

The flexible protective cover **12** is comprised of a molded elastomer such as polyethylene and is of generally cylindrical form, one end of which is stepped or reduced in diameter so that the connecting portion between the two ends forms a diaphragm **28**. The reduced end **29** has an inner diameter which is greater than the external diameter of the extension **18** on flange **15** to allow the extension to be telescoped into end **29**. The opposite end **30** has an internal bead **31** which is adapted to be snapped into a groove **32** formed in a shoulder **33** on flange **15**. The edge **34** of shoulder **33** is chamfered to promote the expansion of bead **32** thereover and the subsequent contraction into groove **32**. A plurality of buttons **35** are formed on the exterior of shoulder **28**, and one or more small openings **36** may be formed in said shoulder **28**, the purpose of both of which being to promote circulation of sterilizing fluid around and through the interior of the cover **12**, when the device is mounted on a tray. The outer diameter of cover **12** at the bead **31** is less than the diameter of flange **15** for reasons to be hereinafter described.

As shown in FIG. 1, the reduced end **29** extends normally axially beyond the tips of the tines **22** so that contact between the tips of the tines and any flat object at the open end of cover **12** is inhibited. It is contemplated that tines **22** will be coated with the antigen to be introduced under the skin of the patient and that the coating operation will be effected after assembly of the tined element **11** with holder **10** but before cover **12** is placed thereover. Thus the antigen may be applied in an automatic manner by mounting the holders on a suitable conveyor (not shown) on which they may be supported by end **16** and dipping the holder and assembled tined element into a container holding the antigen to be applied. After the antigen has been applied to tines **22**, cover **12** is placed against flange **15** and the bead **31** is snapped into its groove **32**, thereby making cover **12** thereafter a part of the device. When the antigen is to be applied to a patient's skin the device is simply pressed against the skin until end **29** of cover **12** is moved back axially toward flange **15**, thereby exposing the tine **22** and allowing them to be pressed into the patient's skin. After the antigen has been applied, the entire device may be discarded and destroyed. Until the device is destroyed, the cover **12** protects the personnel responsible for its destruction from contact with the tines and possible infection and injury thereby.

The foregoing description is merely illustrative of a preferred embodiment of the skin-puncturing device of this invention and the scope of the invention therefore is not to be limited thereto, but is to be determined by the appended claims.

I claim:

1. A device for use in introducing a substance under the skin of a patient, said device comprising a rigid holder having a substantially flat portion adapted to be held between the fingers and a head portion disposed transversely to the general plane of the substantially flat portion, a tined element secured to said head portion with the tines thereof extending generally in a direction parallel with the flat portion, and a generally cylindrical guard for the tines, said guard comprising a flexible sleeve having a reduced end encircling and extending axially beyond the tines, its opposite end expanded over the head portion and supported resiliently thereon, and an axially expansible and contractible intermediate section, and means on the head for guiding said reduced end of the guard, said guide means comprising an extension surrounding and extending generally parallel to said tines with a maximum outside transverse dimension slightly smaller than the internal transverse dimension of said reduced end, said guide terminating short of the outer ends of the tines adjacent said reduced end, said tines being adapted to carry the substance to be introduced under the skin of a patient, and said sleeve contracting with axial pressure upon the reduced end thereof, whereby the reduced end is telescopically guided by said guide means to prevent contact with the tines and to expose the tines and the substance carried thereby.

2. A device as described in claim **1**, said head having a circular recess and said tined element comprising a longitudinally split cylindrically formed metal sheet having tines extending from one end thereof nibs extending from the opposite end thereof and tabs extending outwardly from the side thereof, said nibs contacting the bottom of said recess and said tabs contacting the sides of the recess to space said tined element from the bottom and sides of the recess.

3. A device as described in claim **1**, said head portion having a round outer periphery and said reduced end guiding means comprising a cylindrical axial extension of reduced diameter relative to said head portion, said cylindrical axial extension having a circular recess therein, said tined element comprising a longitudinally split cylindrically formed metal sheet disposed in said circular recess and provided with tines extending axially out of said recess, said reduced end of said sleeve encircling the tines adapted to receive therein the said cylindrical axial extension, and said intermediate section comprising a radially disposed diaphragm connected to both ends.

References Cited

UNITED STATES PATENTS

2,845,065	7/1958	Gabriel	128—215
3,021,942	2/1962	Hamilton	128—221 X
3,123,212	3/1964	Taylor et al.	128—253 X
3,134,380	5/1964	Armao	128—215
3,221,739	12/1965	Rosenthal	128—253

RICHARD A. GAUDET, *Primary Examiner.*

R. L. FRINKS, *Assistant Examiner.*