

April 19, 1966

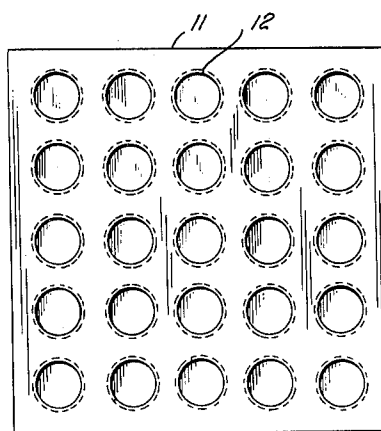
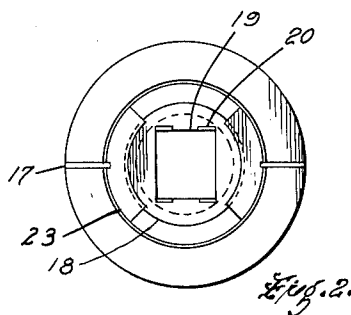
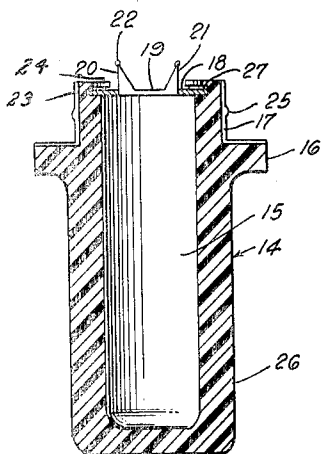
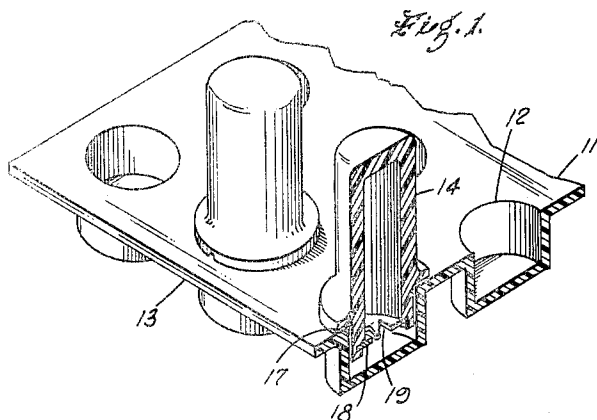
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3,246,647

DISPOSABLE INTRACUTANEOUS INJECTOR

Filed July 23, 1962

2 Sheets-Sheet 1



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DISPOSABLE INTRACUTANEOUS INJECTOR

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2 Sheets-Sheet 2

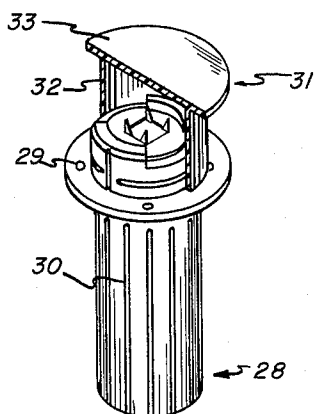


FIG-5

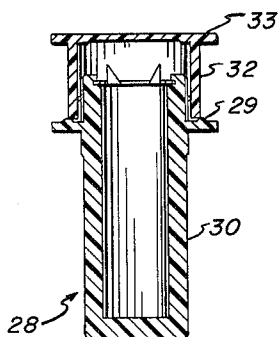


FIG-6

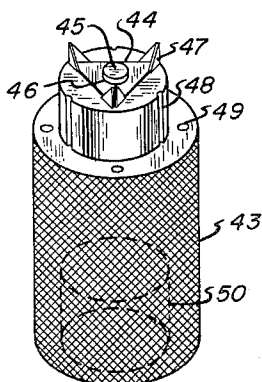


FIG-7

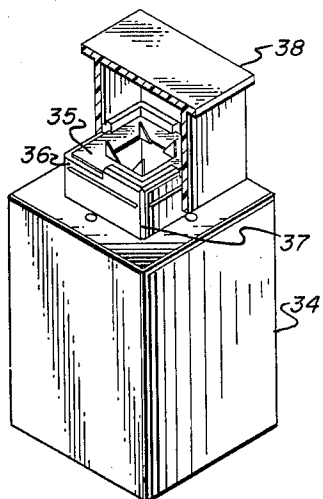


FIG-8

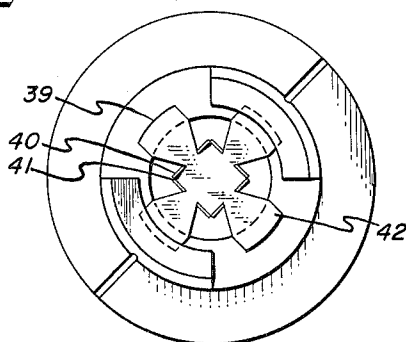


FIG-9

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3,246,647

DISPOSABLE INTRACUTANEOUS INJECTOR
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Filed July 23, 1962, Ser. No. 211,799
5 Claims. (Cl. 128—253)

This application is a continuation-in-part of our ap-
plication Serial Number 36,038, filed June 14, 1960, en-
titled "Multiple Disposable Intracutaneous Injector Pack-
age," now Patent Number 3,123,212, dated March 3, 1964.

This invention relates to a single-use injector for ad-
ministering intracutaneous injections of a biologically-
active substance in which a pronged metal plate is as-
sembled to a plastic holder.

Intracutaneous injectors are employed in medical prac-
tices for a wide variety of purposes, including diagnostic,
prophylactic and therapeutic uses. In the past, fluids,
greases, ointments, powders, crystals, and the like, con-
taining or composed of allergens, which are materials
capable of eliciting an allergic reaction, as well as vaccinia-
virus type products which are materials capable of eliciting
a vesiculopustular lesion, as well as toxins, antitoxins,
toxoids, sera, and the like, have been placed in or on
abraded or scratched skin areas, or have been pressed
through the skin surface by puncturing instruments.

Vaccines such as for smallpox or antigens for histo-
plasmosis may be used. A tetanus toxoid booster can
be administered also fungal antigens such as blastomycin
and coccidioidin can be placed on the prongs. A diluent
may be used to moisten the biologic just prior to ad-
ministration.

It is desirable that such materials, here classed as
biologics, be administered as rapidly and inexpensively as
possible. It is also desirable that such biologics be in
such form that they may be administered in large numbers
by unskilled labor under the supervision of a single
physician. For the treatment of epidemics, it may be
necessary to vaccinate or treat thousands of persons with
biologics in a minimum of time, and under unfavorable
conditions, with a minimum of medical supervision.

The present disposable intracutaneous injector is de-
signed so that the administration may be accomplished
in a minimum of time by persons having a minimum of
skill to persons who may not be accustomed to medical
treatment. Such groups include military forces, native
populations, victims in a disaster area or an epidemic
area, or a potential epidemic area, or the like.

It is desirable that the injectors be single-use devices.
If the injector is discarded after a single use, resteriliza-
tion is not required, and the likelihood of the transmis-
sion of blood-borne diseases such as homologous serum
hepatitis is minimized. In allergy tests, if the injector
is used but once, there is no possibility of a carry-over
from one test to the next which might interfere with the
reliability of results.

Our invention provides as the injector a single-use,
handled holder which may be conveniently of plastic and
which has an injection plate at one end on which the
biologic substance is placed. The holder may be stored
in a sheet containing a series of cups or with individual
caps, or stacked, so that one holder is the cap for the next
holder, and which may, with some biologics, be sterilized
in place, thus permitting the economical use of such
holders. Other advantages and details will appear from
the following description in conjunction with the accom-
panying drawings in which:

FIGURE 1 shows the assembled device with some of
the injectors removed.

FIGURE 2 is a bottom view of a single injector.

FIGURE 3 is a sectional view through a single injector,
shown bottom end up.

FIGURE 4 shows the cupped retaining sheet.

FIGURE 5 is a pictorial view of a holder with a sep-
arate individual round cap.

FIGURE 6 is a sectional view of the holder of the in-
jector of FIGURE 5.

FIGURE 7 is a pictorial view in partial section of a
square holder with a square plate and square cap.

FIGURE 8 is the end view of a holder in which the
injector plate is of a shape resembling in part a Maltese
cross with the prongs in pairs.

FIGURE 9 shows a stackable holder with a triangular
injector plate.

A cupped sheet 11 is formed from a single sheet of
disposable material such as plastic by a deep drawing or
molding operation. For example, a sheet of thermo-
plastic resin may be warmed sufficiently to be readily
deformable and a plurality of retaining cups 12 can be
drawn therein to form a molded sheet 13. A thick sheet
having cut-out cups may be used, but the molded sheet
uses less material. Preferably, the retaining cups are
comparatively shallow and cylindrical having a right cir-
cular cross-section. Other sections can be used for the
cup if the holder has a cooperating, mating shape. Con-
veniently, the cupped sheet, as shown in FIGURE 4, is
formed into segments of a convenient size. For instance,
five cups by five cups giving a total of twenty-five.

In each such cup, as shown in FIGURE 1, is a holder
14. The holder may be of solid or hollowed material,
preferably plastic. The hollow 15 in the holder reduces
the weight and saves material costs, but is not otherwise
essential to the invention. The end of the holder fitting
into the cup has a shoulder 16 spaced from the end so as
to support the holder in a cup with the injector plate 18,
later described, out of contact with the bottom of the
cup.

Formed into the side of the holder and the sheet con-
tacting face of the shoulder is a gas vent 17. This gas
vent is a small groove to permit the access of gases to and
from the portion of the cup 12 which is otherwise sealed
off by the holder and its shoulder. Such gas vent 17 can
be comparatively small, of the order of a couple of thou-
sandths of an inch or larger. It is designed to permit
the interior of each cup to be evacuated and to permit
a sterilizing gas, such as ethylene oxide, to penetrate into
and come in contact with the contents of the cup after the
holders are assembled to a protective cover, such as the
molded sheet 13, or the individual caps described below.

At one end of the holder 14 is an injector plate 18
which is conveniently of a stainless metal, such as stain-
less steel or a nickel alloy or plated metal, which has a
cut-out hole 19. At least part of the metal cut out from
the hole 19 is bent into prongs 20. Conveniently, the
prongs are bent in a multiple die-forming operation in
which first an octagonal hole is formed, and in which
next the triangular segments, to change the octagon to a
square, are cut along two sides from the metal plate and
bent at approximately a right angle thereto to form prongs
20. Preferably, the points 21 of the prongs are in sub-
stantially the same plane. The prongs are of such length
as to insure the adequate penetration of a biologic ma-
terial through a thick-skinned patient and yet are short
enough not to damage the tender skin of younger patients.
A total length of from two to five millimeters for humans,
and from two to ten millimeters for animals, is normally
preferred, the length of the prongs being measured from
the end of the holder. Adjacent the points on the prongs
is a groove 22.

The injector plate 18 is held adjacent the end of the
holder by plate supporting arms 23 which extend from
the main body of the holder and have therein a groove

27. Conveniently, two plate supporting arms are used, which are formed to hold a round injector plate adjacent the end of the holder. Plate retaining protuberances 24 formed adjacent the groove serve to retain the injector plate in position. The plate retaining protuberances are preferably small enough and flexible enough for the injector plates to be readily snapped into position by hand during assembly.

The end of the holder may have a holder retaining ridge 25 formed on the external surface to reduce the area in contact with the retaining cups or caps. The holder retaining ridge is sufficiently flexible to retain the holder and the cup or cap even if there is a commercial variation in size relationships. Because the area in contact is small, the friction between the holder and the cup or cap is comparatively slight. If molding tolerances are small, a separate holder retaining ridge may not be necessary.

Certain variations of the holder are shown in FIGURES 5 to 9.

In FIGURE 5 is shown a modified holder 28 which is generally cylindrical and which has protuberances 29 to space the individual cap 31 from the shoulder of the modified holder instead of a separate gas vent. The individual cap consists of a round cylindrical shield 32 which slides on the outside of a cylindrical portion of the holder and a flat top 33. For convenience in handling, the modified holder 28 has flutes 30 therein to reduce chances of slippage. Otherwise the construction is similar to the prior modification. The single holder with an individual cap is particularly convenient where only one person at a time is to be treated with a diagnostic or therapeutic biologic.

Conveniently, the holders 28 may be given different colors to identify the different biologics and aid in preventing a possible confusion where a plurality of various biologics may be administered.

In FIGURE 7 is a modification showing a square holder 34 having a square injector plate 35 on the square injector plate support 36. In this configuration the corners of the support are beveled. The beveled corners 37 act as gas passages so that separate gas vents are not required, and protuberances hold the cap slightly off the shoulder. A square individual cap 38 covers and protects the biologic until time for use. A square or multiple-sided holder has an added advantage because it will not roll if placed on a flat surface. If separate holders are to be used the square shape can be quite advantageous to the user; although it may be slightly more costly to produce as round molding dies are usually the most economical.

In FIGURE 8 is shown a configuration in which a cross plate 39 is used as the injector plate. The cross plate may conveniently be a symmetrical square cross having rounded ends. A pointed prong is cut from each side of each of the four arms of the cross and bent inwardly to form double prongs 40. By having separate prongs from each side of each arm bent together as pairs, the pairs of prongs have a capillary gap between them which is particularly efficient in holding liquid biologics, which may then be dried in situ for preservation and storage. The liquid is drawn into the gap between the prongs so that larger doses of uniform size may be conveniently administered. The capillary gap 41 between the prongs may vary from almost indiscernable to in the neighborhood of half a millimeter depending upon the size of dosage desired.

The cross arms 42 are held in the plate supporting arms as previously described.

In FIGURE 9 is shown a modification which can have the advantages of both the single and the multiple package in a single form. In this form a knurled holder 43 is used, on the end of which a triangular plate 44 is fastened. The triangular plate 44 is held on by a retaining knob 45 which conveniently is part of the plastic

holder which is deformed by heat or pressure or both to hold the triangular plate 44 in position. The retaining knob 45 extends through a plate hole 46 which is just big enough to fit over the knob, and be held as the knob is expanded. Adjacent each of the triangular corners is a double prong 47 cut from the same sheet and bent up to form double prongs with a capillary gap therebetween. Grooves 48 and protuberances 49 are formed on the end of the knurled holder so that sterilizing gas can penetrate. At the other end of the knurled holder is a stacking recess 50. The stacking recess is of such size that one such holder may be inserted into the stacking recess of a cooperating holder so that any number can be formed into a single stack. Either a cap such as shown in the preceding figures, or a knurled holder without an injector plate is used at the front end. In use the stack serves as a convenient handle and after each use the end holder is drawn off and discarded, leaving the subsequent holder ready for the next patient.

Whereas the stacking holder of FIGURE 9 is shown with three pairs of prongs, obviously the same type of holder could be used with a plate having a different number of corners or with internal corners. The various modifications shown in the separate figures are combinable in different orders. Such modifications immediately suggest themselves to those skilled in the art.

The tips of the prongs forming the points are dipped in a biologic liquid. The biologic may be stored on the points in liquid form or the liquid on the prongs may be frozen and the moisture evaporated therefrom, or the moisture may be allowed to evaporate without prefreezing. The holders are assembled by pressing them into the cups with the handle section 26 extending above the cupped sheet 11. If the biologic is one which is not inactivated by a sterilizing gas, the holders may be assembled in the cups in the sheets. Each sheet of cups may then be wrapped in a film (e.g., polyethylene) permeable to a sterilizing gas, and a number of these wrapped sheets containing the cupped holders may be placed in a final carton. These packed, but unsealed, cartons are placed in a chamber and then subjected to the effects of a sterilizing gas such as ethylene oxide or propylene oxide or a mixture of such sterilizing gases, with a suitable inert, fire-preventing diluent such as carbon dioxide or a haloalkane. For example, a mixture containing 20 percent ethylene oxide and 80 percent carbon dioxide may be introduced into the chamber under a positive pressure of 15 pounds per square inch. This gas contains 600 milligrams of ethylene oxide per liter and obtains contact with the biologic to be sterilized by penetrating the sheet wrapping and flowing through the gas vents 17. After a 3½ to 4½ hour sterilization at 32° ± 2° C. and 40 ± 10 percent relative humidity, the assembled cartons are flushed out with sterile and pyrogen-free air, and are covered; thus readying them for storage or shipment. Other sterilizing cycles may be used.

These sterilizing techniques are suitable for materials used to determine sensitivity prior to the administration of prophylactic or therapeutic doses (such as gas gangrene antitoxin) and for diagnostics (e.g., Old Tuberculin, lymphogranuloma venereum skin test antigen), and for allergen tests.

For biologics which would be damaged by a sterilizing gas, either radiation sterilization may be used for the molded sheets and the holders, including the plates, may be sterilized separately and the biologic applied to the prongs adjacent the points by sterile techniques.

In general, test or diagnostic biologics containing non-viable organisms may be sterilized with ethylene oxide or other sterilizing gas. Live virus products, such as vaccinia (smallpox vaccine), should be handled by sterile techniques, as the sterilizing gases inactivate such live viral products.

Modifications of the invention within the scope of the

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appended claims are obvious to those skilled in the art.

We claim:

1. An intracutaneous injector comprising: a holder of rounded configuration having an essentially cylindrical handle section at one end, at least two plates supporting arms at the other end, a shoulder between said ends adapted to support the holder, a metal injector plate between and held by the plate supporting arms, and integral prongs on said plate extending away from the handle section of the holder, the apexes of said prongs forming injector points, said plate being substantially flat except for said prongs.

2. The injector of claim 1 in combination with a cup-shaped cover which is slidably fitted over said supporting arms and said metal injector plate, thereby protecting said plate and the prongs thereon from contamination from time of manufacture to time of use.

3. An intracutaneous injector comprising: a holder having an essentially cylindrical handle section, a shoulder between the ends of said handle section adapted to support said holder, supporting means at one end of said handle section, a one-piece metal plate fixed on said supporting means, said plate having adjacent to each of its corners a set of two prongs bent at right angles to the plate and closely adjacent to each other whereby a liquid by capillarity, when placed on said prongs, is drawn into the gap between said prongs, said plate being substantially flat except for said prongs, and protuberances on said shoulder to hold a protective cover spaced slightly from said shoulder and in position to protect the prongs.

4. An intracutaneous injector comprising, in combination: a removable cover means, a rounded one-piece plastic holder having an essentially cylindrical handle section, a shoulder between the ends of said handle section adapted to support said holder, supporting means on one end of said handle section, a one-piece metal plate having integral multiple sets of two prongs bent at right angles to the plate and closely adjacent to each other whereby

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a liquid by capillarity, when placed on said prongs is drawn into the gap between said prongs, said plate being substantially flat except for said prongs and held in place by said supporting means, said removable cover means being positioned on said shoulder and over said prongs, thus protecting the prongs from time of manufacture to time of use, and a gas vent on said shoulder to permit the passage of gas into said cover means.

5. An intracutaneous injector comprising: a rounded one-piece plastic holder having an essentially cylindrical handle section, a shoulder on said section, a flat plate support at one end of said handle section, at least two plate supporting arms adjacent to and integral with said plate support to hold a plate thereon, and a one-piece metal plate having integral prongs attached to and extending away from the holder, with the apexes of the prongs forming injection points, said plate being substantially flat except for said prongs, the other end of said handle section having therein a stacking recess to fit over a plate support and plate on a like injector.

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