United States Patent

Rosenthal

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[45] **July 11, 1972**

[54] MULTIPLE PUNCTURE INJECTOR DEVICE

[72] Inventor: **Sol Roy Rosenthal,** 230 East Delaware Place, Chicago, Ill. 60611

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[21] Appl. No.: **8,625**

[52] **U.S. Cl.** **206/63.4,** 128/253

[51] **Int. Cl.** **A61b 19/02,** B65d 81/20

[58] **Field of Search** ..... 206/63.4, 63.2, 56 A, 56 AB; 128/253, 333, 314, 315, 329; 15/258

[56] **References Cited**

UNITED STATES PATENTS

3,289,670	12/1966	Krug et al.	128/253
3,131,410	5/1964	Anderson et al.	15/258
3,444,989	5/1969	Hertel et al.	128/253
3,221,739	12/1965	Rosenthal	128/253
2,817,336	12/1957	Kravitz et al.	128/253
3,070,102	12/1962	MacDonald	206/56 A

FOREIGN PATENTS OR APPLICATIONS

4,609	0/1915	Great Britain	15/258
1,309,352	10/1962	France	128/253

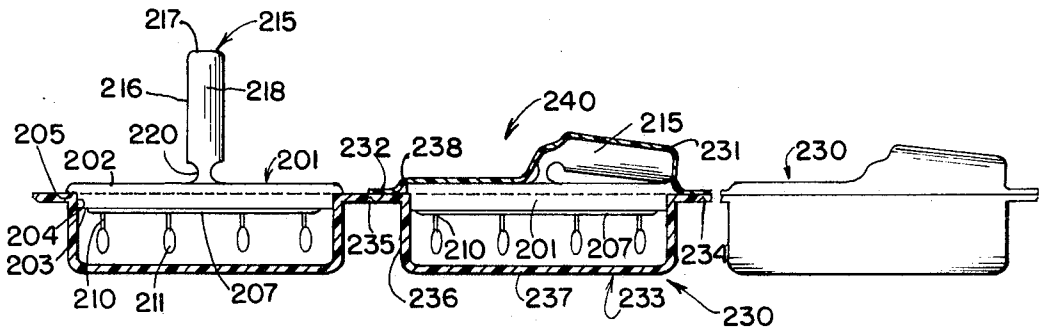
Primary Examiner—William T. Dixson, Jr.

Attorney—Prangley, Clayton, Mullin, Dithmar & Vogel

[57] **ABSTRACT**

A multiple puncture injector device for use in transcutaneous injection, the injector having a handle hingedly connected to the top surface of a base plate and movable between a use position in which the handle extends outwardly of the base plate and a storage position in which the handle is substantially parallel to the base plate to facilitate storage thereof; the base plates may be straight or arcuate; the handles may be locked in the use and storage positions. The injectors can be packaged in vacuum-packed hermetically sealed containers, which containers are connected one to another in end-to-end relationship to facilitate the detachment of a selected one of the packages.

20 Claims, 18 Drawing Figures



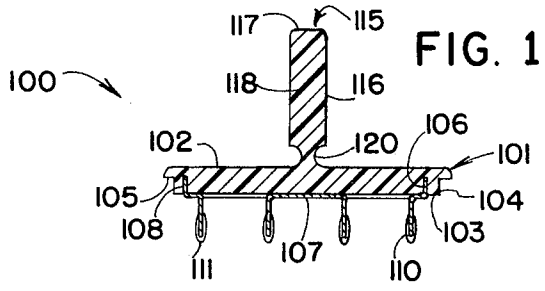


FIG. 1

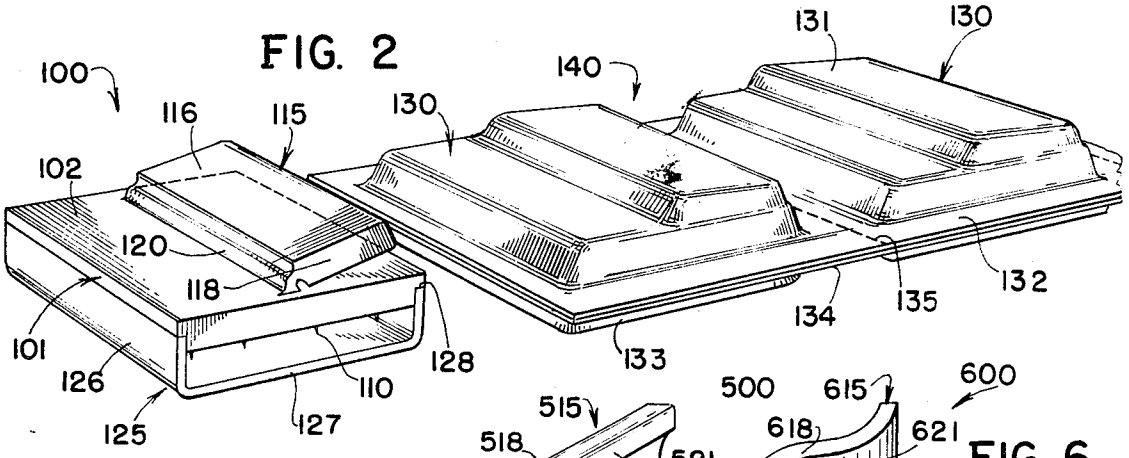


FIG. 2

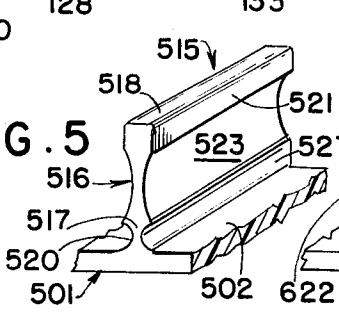


FIG. 5

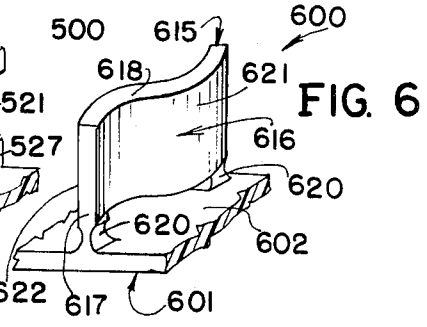


FIG. 6

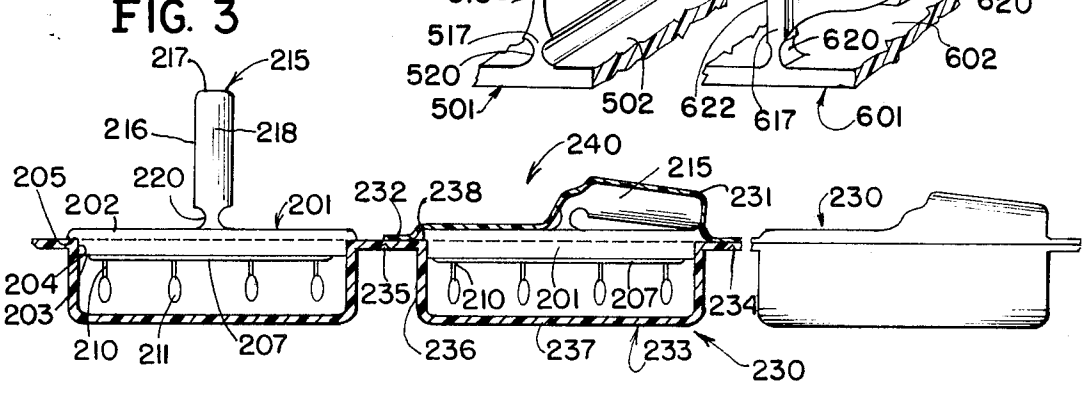


FIG. 3

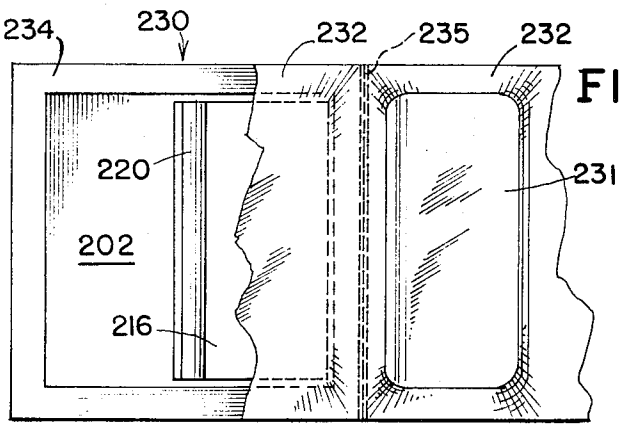


FIG. 4

Inventor
SOL ROY ROSENTHAL

BY

Prangley, Clayton, Mullin, Dithmar & Vogel. ATTYS.

FIG. 7

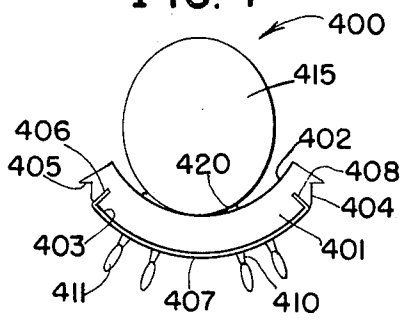


FIG. 9

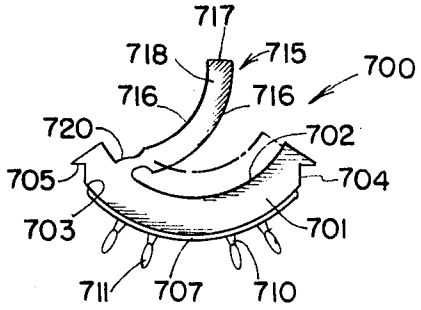


FIG. 8

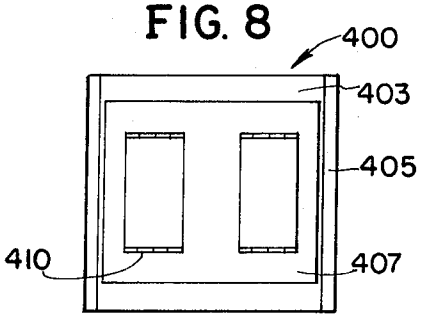


FIG. 10

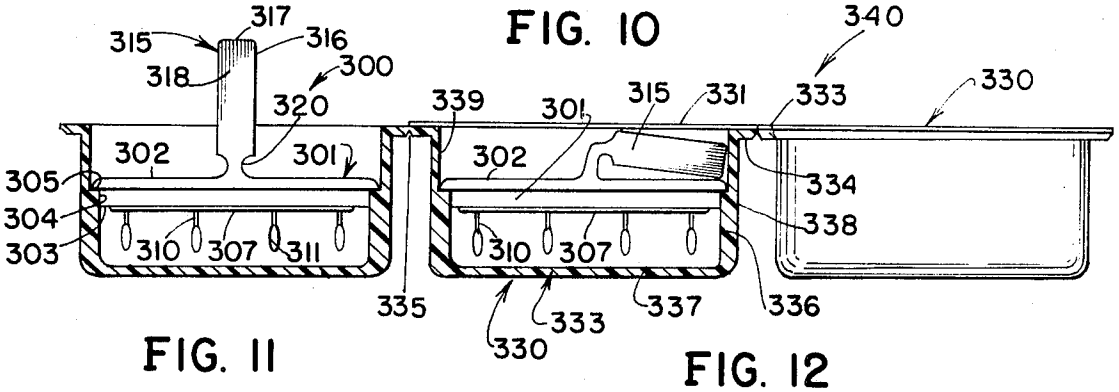


FIG. 11

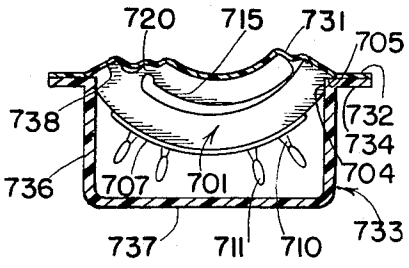


FIG. 12

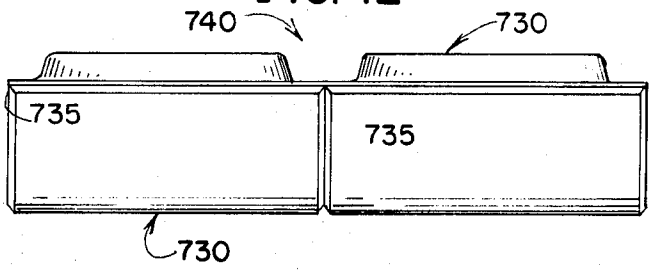


FIG. 13

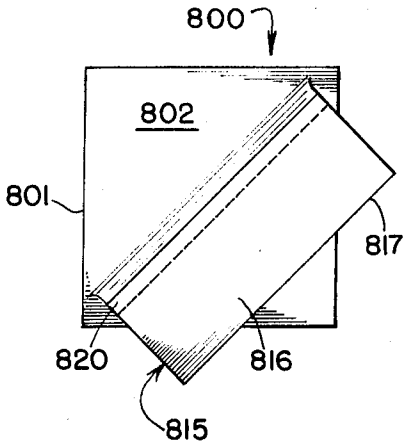


FIG. 14

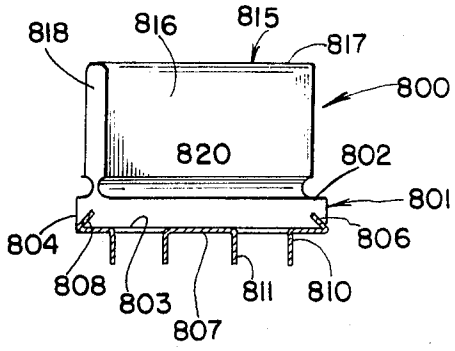


FIG. 15

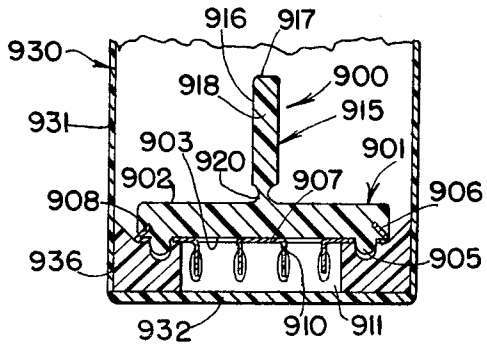


FIG. 16

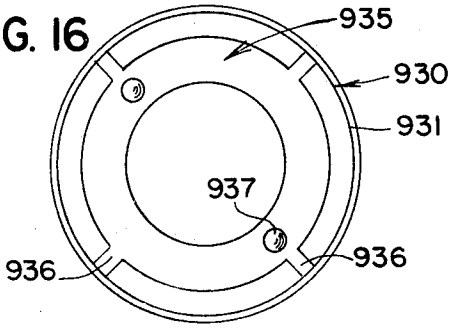


FIG. 17

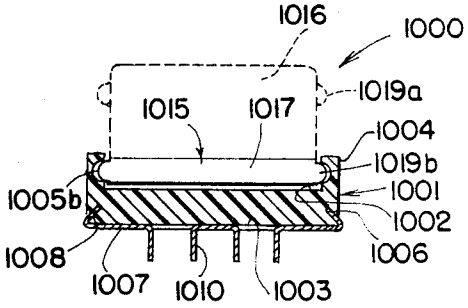
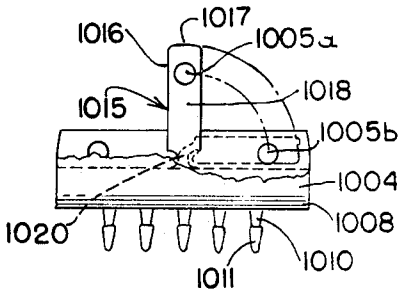


FIG. 18



MULTIPLE PUNCTURE INJECTOR DEVICE

This invention relates to a multiple puncture injector device for use in transcutaneous injection and more particularly to an injector with either a straight base or an arcuate base with a handle hingedly secured thereto to facilitate easy storage thereof.

An important object of the present invention is to provide a transcutaneous injector comprising a base plate having a top surface and a bottom surface, a plurality of tines carried by the bottom surface of the base plate extending outwardly therefrom and substantially normal thereto, and a handle hingedly connected to the top surface of the base plate, the handle being movable between a use position in which the handle is substantially normal to the base plate and extends outwardly therefrom and a storage position in which the handle is substantially parallel to the base plate to facilitate the storage of the injector.

Another object of the present invention is to provide a prepared package for an injector of the type set forth including a vacuum-packed hermetically sealed container disposed completely about the injector when the handle of the injector is in the storage position.

A further object of the present invention is to provide a series of prepared packages connected one to another in end-to-end relationship, the connections being adapted easily to be broken to detach a selected one of the series of prepared packages without detaching the others of the series of prepared packages, each of the packages being of the type set forth with the containers thereof having connecting flanges extending outwardly therefrom.

A further object of the present invention is to provide a transcutaneous injector comprising an arcuate base plate having a concave top surface and a convex bottom surface, a plurality of tines carried by the convex bottom surface of the base plate and extending outwardly therefrom, and a handle connected to the concave top surface of the base plate and extending outwardly therefrom, the injector being adapted to be rolled against the skin to puncture the skin at a plurality of points and introduce a biological substance carried by the tines into the body.

A still further object of the present invention is to provide a prepared package for an injector with an arcuate base plate of the type set forth, the package including a vacuum-packed hermetically sealed container disposed completely about the injector when the handle of the injector is in the storage position.

The invention, both as to its organization and method of operation, together with further objects and advantages thereof, will best be understood by reference to the following specification taken in connection with the accompanying drawings in which:

FIG. 1 is a view in vertical section of a transcutaneous injector incorporating therein features of the present invention;

FIG. 2 is a perspective view of a series of prepared packages for the injector of FIG. 1, one of the prepared packages having the cover off to show the inside arrangement thereof;

FIG. 3 is a side elevational view partly in vertical section of a series of prepared packages for the injector of FIG. 1;

FIG. 4 is a plan view of a portion of the series of prepared packages of FIG. 3;

FIG. 5 is a perspective view of an embodiment of a handle for the injector of FIG. 1;

FIG. 6 is a perspective view of an embodiment of a handle for the injector of FIG. 1;

FIG. 7 is a side elevational view of an injector having a fixed handle and an arcuate base;

FIG. 8 is a bottom view of the injector of FIG. 7;

FIG. 9 is a side elevational view of an injector having a hinged handle and an arcuate base;

FIG. 10 is a side elevational view partly in vertical section of a series of prepared packages for the injector of FIGS. 1;

FIG. 11 is a view in vertical section of the injector of FIG. 9 disposed within a vacuum-packed hermetically sealed container;

FIG. 12 is a side elevational view of a series of the packages of FIG. 11;

FIG. 13 is a plan view of an embodiment of the transcutaneous injector of FIG. 1;

FIG. 14 is a side elevational view of the injector of FIG. 13;

FIG. 15 is a view in vertical section of an injector mounted in a vacuum-packed hermetically sealed container;

FIG. 16 is a plan view of the container of FIG. 15 without the injector disposed therewithin;

FIG. 17 is a view in vertical section of a transcutaneous injector having means for locking the handle thereof in the use and storage positions thereof; and

FIG. 18 is a side elevational view partly broken away of the injector of FIG. 17.

Referring to FIG. 1, there is disclosed an injector **100** having a substantially flat base plate **101**, the base plate **101** including a top surface **102** and a bottom surface **103** spaced apart and parallel thereto. Extending upwardly from opposed side edges of the bottom surface **102** are two spaced-apart and generally parallel abutment surfaces **104**, each of the abutment surfaces **104** leading to a shoulder **105** generally parallel to the top surface **102**. Two parallel spaced-apart grooves **106** are cut into the bottom surface **103** and extend for a predetermined distance from the bottom surface **103** toward the top surface **102**, the grooves **106** being spaced apart a preselected distance to receive therein a metal plate **107** having upturned flanges **108**, the flanges **108** being spaced apart a predetermined distance and being of a predetermined length securely to fit within the grooves **106**. The metal plate **107** may be mounted in the base plate **101** in a variety of ways, the above-described method being selected merely for purposes of illustration. Outwardly depending from and substantially normal to the metal plate **107** are a plurality of tines **110**, the tines **110** carrying on the ends thereof distal from the metal plate **107** a biological substance **111**.

The injector **100** is provided with a handle **115**, the handle **115** being connected to the top surface **102** of the base plate **101** and positioned generally parallel to the side edges of the base plate **101**, the handle **115** further including two spaced-apart and parallel side walls **116** interconnected by a top wall **117** and two parallel spaced-apart end walls **118**. The handle **115** is hingedly connected to the top surface **102** of the base plate **101** by a hinge **120**, the hinge **120** being integral with the handle **115** and the base plate **101** and being of reduced cross section as compared to the handle **115**. The handle **115** is movable between a use position, as shown in FIG. 1, in which the handle **115** is substantially normal to the base plate **101** and extends outwardly therefrom and a storage position in which the handle **115** is substantially parallel to the base plate **101** to facilitate the storage of the injector **100**, all as hereinafter explained.

Referring now to FIG. 2, there is shown in the left-hand portion thereof the injector **100** in position to be packaged, the injector **100** being provided with a U-shaped cover **125**, the U-shaped cover **125** including two parallel spaced-apart side walls **126** interconnected by a bottom wall **127**, the top edge of each of the side walls **126** forming an abutment surface **128**. The side walls **126** of the U-shaped cover **125** are spaced apart a predetermined distance so as to receive thereon the shoulders **105** of the injector **100** and firmly to engage the abutment surfaces **104** of the injector **100** with the adjacent side wall **126** of the U-shaped cover **125**. The vertical lengths of the side walls **126** are selected so as to position the bottom wall **127** of the U-shaped cover **125** away from the tines **110** and the biological substances **111** carried thereon when the injector **100** is positioned in use on the U-shaped cover **125**, thereby to maintain the tines **110** out of contact with the container material as hereinafter explained.

There is further shown in the right-hand portion of FIG. 2 a container **130** for the combination of the injector **100** and the U-shaped cover **125**, the container **130** including a top layer **131** of synthetic plastic resin film of the type which, when applied to a solid surface and heated, molds itself into a shape

conforming to the outer adjacent surface of the solid. The top layer **131** has extending outwardly completely around the periphery thereof a top flange **132**. The container **130** further includes a bottom layer **133** of synthetic plastic resin film of the type which, when applied to a solid surface and heated, molds itself into a shape conforming to the outer adjacent surface of the solid. The bottom layer **133** is disposed about the U-shaped cover **125** to substantially encircle the same and includes a bottom flange **134** extending completely around the periphery of the U-shaped cover **125**, which flange **134** is substantially coextensive with the top flange **132**. The top flange **132** and the bottom flange **134** are of the type of synthetic plastic resin which seals when heated, thereby to form a container **130** suitable for the storage of the injector **100** when the tines **110** thereof carry a non-living biological substance thereon, the container **130** being sealed after the injector **100** has been sterilized with ethylene oxide gas or by other means well known in the art. When the tines **110** of the injector **100** carry thereon a living biological substance, the injector **100** must be stored under vacuum and the container **130** must be hermetically sealed to prevent the biological substance from being contacted by air or moisture. To this end, the container **130** may be made from glass or a metal foil, as previously disclosed in my co-pending patent application entitled VACUUM-PACKED HERMETICALLY SEALED MULTIPLE PUNCTURE DEVICE, filed on June 16, 1969, Ser. No. 833,299.

Intermediate adjacent containers **130**, either the top flange **132** of the bottom flange **134** or both are scored as at **135** to provide connections between a series of prepared packages **140** connected one to another in end-to-end relationship, the connections therebetween being adapted easily to be broken to detach a selected one of the series of prepared packages **140** without detaching the others of the series of prepared packages.

There is further disclosed, as shown in FIG. **3**, an injector **200** having a substantially flat base plate **201**, the base plate **201** including a top surface **202** and a bottom surface **203** spaced apart and parallel thereto. Extending upwardly from opposed side edges of the bottom surface **202** are two spaced-apart and generally parallel abutment surfaces **204** leading to a shoulder **205** generally parallel to the top surface **202**. Two parallel spaced-apart grooves (not shown) are cut into the bottom surface **203** and extend for a predetermined distance from the bottom surface **203** toward the top surface **202**, the grooves being spaced apart a preselected distance to receive therein a metal plate **207** having upturned flanges (not shown), the flanges being spaced apart a predetermined distance and of a predetermined length securely to fit within the grooves. Outwardly depending from and substantially normal to the metal plate **207** are a plurality of tines **210**, the tines **210** carrying on the ends thereof distal from the metal plate **207** a biological substance **211**.

The injector **200** is provided with a handle **215**, the handle **215** being connected to the top surface **202** of the base plate **201** and positioned generally parallel to the side edges of the base plate **201**, the handle **215** further including two spaced-apart and parallel side walls **216** interconnected by a top wall **217** and two spaced-apart end walls **218**. The handle **215** is hingedly connected to the top surface **202** of the base plate **201** by a hinge **220** being integral with the handle **215** and being of reduced cross section as compared to the handle **215**. The handle **215** is movable between a use position, as shown in the left-hand portion of FIG. **3**, in which the handle **215** is substantially normal to the base plate **201** and extends outwardly therefrom and a storage position, as shown in the middle portion of FIG. **3**, in which the handle **215** is substantially parallel to the base plate **201** to facilitate the storage of the injector **200**, all as hereinafter explained.

Referring now to the middle portion of FIG. **3**, there is shown the injector **200** in position to be packaged in a container **230**, the container **230** including a top layer **231** of synthetic plastic resin film of the type which, when applied to a solid surface and heated, molds itself into a shape conforming to the outer adjacent surface of the solid. The top layer **231** has extending outwardly completely around the periphery thereof, a top flange **232**, see particularly FIG. **4**. The container **230** further includes a bottom layer **233** of synthetic plastic resin which is rigid and retains its shape and rigidity when subjected to moderately elevated temperatures, the bottom layer **233** including two parallel spaced-apart side walls **236** interconnected by a bottom wall **237**, the top edges of the side walls **236** being formed into shoulders **238**. A bottom flange **234** extends outwardly completely around the periphery of the bottom layer **233**, the bottom flanges **234** of adjacent containers **230** being connected and scored as at **235** to provide connections between a series of prepared packages **240** connected one to the other in end-to-end relationship, the connection therebetween being adapted easily to be broken to detach a selected one of the series of prepared packages **230** without detaching the others of the series of prepared packages.

The bottom layer **233** of the container **230** performs the same function as the U-shaped cover **125** previously described in that the side walls **236** and shoulders **238** thereon are spaced apart a predetermined distance so as to receive thereon the shoulders **205** of the injector **200** and firmly to engage the abutment surface **204** of the injector **200** with the adjacent side wall **236** of the bottom layer **233**. The vertical lengths of the side walls **236** are selected so as to position the bottom wall **237** of the bottom layer **233** away from the tines **210** and the biological substance **211** carried thereby when the injector **200** is positioned within the container **230**, thereby to maintain the tines **210** out of contact with the container **230**. In lieu of the shoulders **238**, an internal ridge (not shown) positioned on the bottom wall **237** of the bottom layer **233** of the container **230** may be used to support the injector **200** when the injector **200** is disposed within the container **230**, thereby to maintain the tines **210** out of contact with the container **230**. The container **230** herein may also be made impervious to air and moisture, i.e., hermetically sealed, for the storage of an injector **200** carrying on the tines **210** thereof a living biological substance, all as hereinbefore explained.

There is further disclosed, as shown in FIG. **10**, an injector **300** having a substantially flat base plate **301**, the base plate **301** including a top surface **302** and a bottom surface **303** spaced apart and parallel thereto. Extending upwardly from opposed side edges of the bottom surface **302** are two spaced-apart and generally parallel abutment surfaces **304** leading to a shoulder **305** generally parallel to the top surface **302**. Two parallel spaced-apart grooves (not shown) are cut into the bottom surface **303** and extend for a predetermined distance from the bottom surface **303** toward the top surface **302**, the grooves being spaced apart a preselected distance to receive therein a metal plate **307** having upturned flanges (not shown), the flanges being spaced apart a predetermined distance and of a predetermined length securely to fit within the grooves. Outwardly depending from and substantially normal to the metal plate **307** are a plurality of tines **310**, the tines **310** carrying on the ends thereof distal from the metal plate **307** a biological substance **311**.

The injector **300** is provided with a handle **315**, the handle **315** being connected to the top surface **302** of the base plate **301** and positioned generally parallel to the side edges of the base plate **301**, the handle **315** further including two spaced-apart and parallel side walls **316** interconnected by a top wall **317** and two spaced-apart end walls **318**. The handle **315** is hingedly connected to the top surface **302** of the base plate **301** by a hinge **320** being integral with the handle **315** and being of reduced cross section as compared to the handle **315**. The handle **315** is movable between a use position, as shown in the left-hand portion of FIG. **3**, in which the handle **315** is substantially normal to the base plate **301** and extends outwardly therefrom and a storage position, as shown in the middle portion of FIG. **10**, in which the handle **315** is substantially parallel to the base plate **301** to facilitate the storage of the injector **300**, as is hereinafter explained.

Referring now to the middle portion of FIG. 10, there is shown the injector 300 in position to be packaged in a container 330, the container 330 including a top layer 331 of a rigid synthetic plastic resin having extending outwardly therefrom and completely around the periphery thereof a top flange 332. The container 330 further includes a bottom layer 333 of a rigid synthetic plastic resin, the bottom layer 333 including two parallel side walls 336 interconnected by a bottom wall 337. Spaced a preselected distance from the bottom wall 337 along each of the side walls 336 is a shoulder 338, the shoulders 338 being cut into the respective side walls 336 to provide a portion 339 of the side walls 336 extending above the shoulders 338 having a reduced thickness. The portions 339 of the side walls 336 extend upwardly and are formed into a bottom flange 334 extending completely around the periphery of the bottom layer 333, the bottom flanges 334 being substantially coextensive with the upper flanges 332 and being secured and scored as at 335 to provide connections between a series of prepared packages 340 connected one to the other in end-to-end relationship, the connections therebetween being adapted easily to be broken to detach a selected one of the series of prepared packages 340 without detaching the others of the series of prepared packages.

The side walls 336 and particularly the portions 339 having a reduced thickness are spaced apart a predetermined distance so as to receive therein and on the shoulders 338 formed thereby the shoulders 305 of the injector 300 and firmly to engage the abutment surfaces 304 of the injector 300 with the adjacent side walls 336 of the bottom layer 333 of the container 330. The lengths of the side walls 336 are selected so as to position the injector 300 completely within the vertical extent thereof when the handle 315 of the injector 300 is in the storage position thereof and to position the bottom wall 337 of the container 330 away from the tines 310 and the biological substances 311 carried thereon when the injector 300 is positioned for storage within the container 330, thereby to maintain the tines 310 out of contact with the container 330. The container 330 herein may also be made impervious to air and moisture, i.e., hermetically sealed, for the storage of an injector 300 carrying on the tines 310 thereof a living biological substance, all as hereinbefore explained.

With reference to FIGS. 7 and 8, there is disclosed an injector 400 having an arcuate base plate 401, the arcuate base plate 401 including a concave top surface 402 and a convex bottom surface 403, the convex bottom surface 403 being spaced apart and generally parallel to the top surface 402. Extending diagonally upwardly from opposed side edges of the convex bottom surface 403 are two spaced-apart abutment surfaces 404, each of the abutment surfaces 404 leading to a shoulder 405, the shoulders 405 extending diagonally outwardly and away from the adjacent abutment surface 404 to form an inverted "V" therebetween. Two spaced-apart grooves 406 are cut into the convex bottom surface 403 extending toward the concave top surface 402, the grooves 406 being spaced apart a preselected distance to receive therein a metal plate 407 having upturned flanges 408, the flanges 408 being spaced apart a predetermined distance and being of a predetermined length securely to fit within the grooves 406. Outwardly depending from the metal plate 407 are a plurality of tines 410, the tines 410 carrying on the ends thereof distal from the metal plate 407 a biological substance 411.

The injector 400 is provided with a handle 415, the handle 415 being fixedly connected to the concave top surface 402 of the arcuate base plate 401 as at 420. The handle 415 forms a plane parallel to the direction in which the injector 400 is rolled to introduce the biological substance 411 on the distal ends of the tines 410 into a body, all as hereinafter explained.

With reference to FIG. 5, there is shown therein a portion of an injector 500, the injector 500 having a base plate 501 with a top surface 502. Disposed upon the top surface 502 of the injector 500 is a handle 515, the handle 515 being an alternate embodiment for the handle 415 for the injector 400 or being an alternate embodiment for the handle 115 of the injector 100. The handle 515 is hingedly connected as at 520 to the base plate 501, as hereinbefore described with reference to injectors 100, 200 and 300. The handle 515 includes two spaced-apart generally parallel side walls 516 interconnected by a pair of upstanding end walls 517 and a top wall 518. Each of the side walls 516 has a vertical portion 521 extending downwardly from the top wall 518, a lower arcuate portion 522 extending upwardly from the top surface 502 of the base plate 501 and an arcuate gripping section 523 intermediate the vertical portion 521 and the arcuate portion 522 and interconnecting the same to form a handle 515 easily gripped by the fingers to manipulate the injector 500.

With reference to FIG. 6, there is shown therein a portion of an injector 600, the injector 600 having a base plate 601 with a top surface 602. Disposed upon the top surface 602 of the injector 600 is a handle 615, the handle 615 being an alternate embodiment for the handle 115 of the injector 100. The handle 615 is hingedly connected as at 620 to the base plate 601, the hinged connections 620 being spaced apart to allow the handle 615 to assume a storage position wherein the handle 615 is substantially parallel to the base plate 601. The handle 615 is S-shaped and includes two spaced-apart generally parallel side walls 616 interconnected by two spaced-apart end walls 617 and a top wall 618. The side walls 616 are complementary in shape and are formed of a right-hand curve as at 621 which leads to a left-hand curve as at 622, all as viewed in FIG. 6, to form a handle 615 easily gripped by the fingers to manipulate the injector 600.

With reference to FIGS. 9, 11 and 12, there is disclosed an injector 700 having an arcuate base plate 701, the arcuate base plate 701 including a concave top surface 702 and a convex bottom surface 703 being spaced apart and generally parallel to the top surface 702. Extending diagonally upwardly from opposed side edges of the convex bottom surface 703 are two spaced-apart abutment surfaces 704, each of the abutment surfaces 704 leading to a shoulder 705, the shoulders 705 extending diagonally outwardly and away from the adjacent abutment surface 704 to form an inverted "V" therebetween. Two spaced-apart grooves (not shown) are cut into the convex bottom surface 703 extending toward the concave top surface 702, the grooves being spaced apart a preselected distance to receive therein a metal plate 707 having upturned flanges (not shown), the flanges being spaced apart a predetermined distance and being of a predetermined length securely to fit within the grooves. Outwardly depending from the metal plate 707 are a plurality of tines 710, the tines 710 carrying on the ends thereof distal from the metal plate 707 a biological substance 711.

The injector 700 is provided with a handle 715, the handle 715 being connected to the concave top surface 702 of the arcuate base plate 701 and including two spaced-apart arcuate and parallel side walls 716 interconnected by a top wall 717 and end walls 718. The handle 715 is hingedly connected to the concave top surface 702 of the arcuate base plate 701 adjacent one of the side edges thereof by a hinge 720, the hinge 720 being integral with the handle 715 and the arcuate base plate 701 and being of reduced cross section as compared to the handle 715. The handle 715 is movable between a use position (the solid line position in FIG. 9) in which the handle 715 is spaced from the arcuate base plate 701 and a storage position (the dotted line position in FIG. 9) in which the handle 715 is substantially parallel to the arcuate base plate 701 to facilitate the storage of the injector 700, all as hereinafter explained. The degree of curve of the side walls 716 of the handle 715 is selected so that the handle 715 securely fits adjacent to the concave top surface 702 of the arcuate base plate 701 when the handle 715 is in the storage position thereof.

Referring now to FIG. 11, there is shown the injector 700 in a container 730, the container 730 including a top layer 731 of synthetic plastic resin film of the type which, when applied to a solid surface and heated, molds itself into a shape conforming to the outer adjacent surface of the solid. The top layer 731 has extending outwardly completely around the periphery thereof a top flange 732. The container 730 further includes a

bottom layer **733** of synthetic plastic resin which is rigid and retains its shape and rigid character when subjected to moderately elevated temperatures, the bottom layer **733** includes two parallel spaced-apart side walls **736** interconnected by a bottom wall **737**, the top edge of the side walls **736** being formed into shoulders **738**. A bottom flange **734** extends outwardly completely around the periphery of the bottom layer **733**, the bottom flanges **734** of adjacent containers **730** being connected and scored as at **735** to provide connections between a series of prepared packages **740** connected one to the other in end-to-end relationship, the connections therebetween being adapted easily to be broken to detach a selected one of the series of prepared packages **740** without detaching the others of the series of prepared packages.

The bottom layer **733** of the hermetically sealed container **730** performs the same function as the U-shaped cover **125** previously described in that the side walls **736** and shoulders **738** thereon are spaced apart a predetermined distance so as to receive thereon the shoulders **705** of the injector **700** and firmly to engage the abutment surfaces **704** of the injector **700** with the adjacent side wall **736** of the bottom layer **733**. The vertical lengths of the side walls **736** are selected so as to position the bottom wall **737** of the bottom layer **733** away from the tines **710** and the biological substance **711** carried thereby when the injector **700** is positioned in use within the container **730**, thereby to maintain the tines **710** out of contact with the container **730**. The container **730** herein may also be made impervious to air and moisture, i.e., hermetically sealed, for the storage of an injector **700** carrying on the tines **710** thereof a living biological substance, all as hereinbefore explained.

Referring to FIGS. **13** and **14**, there is disclosed an injector **800** having a substantially flat base plate **801**, the base plate **801** including a top surface **802** and a bottom surface **803** spaced apart and parallel thereto. Extending upwardly from opposed side edges of the bottom surface **802** are two spaced-apart and generally parallel abutment surfaces **804**. Two spaced-apart grooves **806** are cut into the bottom surface **803** and extend diagonally upwardly toward the top surface **802** for a predetermined distance from the bottom surface **803**, the grooves **806** being spaced-apart a preselected distance to receive therein a metal plate **807** having diagonally upturned flanges **808**, the flanges **808** being spaced-apart a predetermined distance and of a predetermined angle and being of a predetermined length securely to fit within the grooves **806**. Outwardly depending from and substantially normal to the base plate **807** are a plurality of tines **810**, the tines **810** carrying on the ends thereof distal from the metal plate **807** a biological substance **811**.

The injector **800** is provided with a handle **815**, the handle **815** being connected to the top surface **802** of the base plate **801** and positioned generally diagonally to the side edges of the base plate **801**, i.e., from corner to corner thereof, the handle **815** further including two spaced-apart and parallel side walls **816** interconnected by a top wall **817** and two spaced-apart end walls **818**. The handle **815** is hingedly connected to the top surface **802** of the base plate **801** by a hinge **820**, the hinge **820** being integral with the handle **815** and the base plate **801** and being of reduced cross section as compared to the handle **815**. The handle **815** is movable between a use position in which the handle **815** is substantially normal to the base plate **801** and extends outwardly therefrom and a storage position in which the handle **815** is substantially parallel to the base plate **801** to facilitate the storage of the injector **100**. The diagonal positioning of the handle **815** is advantageous in that it provides for a better gripping surface when using the injector **800** for inoculation purposes.

Referring to FIGS. **15** and **16**, there is disclosed an injector **900** similar in construction to the injector **100** with the metal plate **907** being mounted to the base plate **901** in a fashion similar to that disclosed in injector **800**. It is seen, therefore, that the metal plate **900** carrying the tines **910** depending therefrom may be mounted to the base plate **901** by various methods, the particular method chosen herein being a matter of choice.

The injector **900** may optionally include two buttons or knobs **905** depending from the bottom surface **903** of the base plate **901** and spaced apart 180°, the number of knobs **905** in excess of two and the angular placement thereof being a matter of choice. The injector **900** is provided with a handle **915**, which handle **915** is of the same type as hereinbefore disclosed and may be positioned as shown, generally parallel to the side edges of the base plate **901** or positioned diagonally with respect thereto.

There is further disclosed a container **930**, which container may be made of glass if the biological substance **911** carried by the tines **910** is a living substance to hermetically seal the same, the container **930** including a side wall **931** and a bottom wall **932**, a top (not shown) is provided for the container **930**, which top may be hermetically sealed to the side wall **931**. Disposed within the container **930** is a spacer ring **935**, the spacer ring **935** being generally annular in shape and having spaced at 90° intervals around the periphery thereof beveled side spacers **936**. The beveled side spacers **936** serve to position the spacer ring **935** within the container **930** and to position the injector **900** in registry over the spacer **935** when the injector **900** is introduced into the container **930**, as hereinafter explained. The spacer ring **930** is further provided with knob or button receptacles **937** spaced in angular relationship corresponding to the angular relationship between the knobs or buttons **905** depending from the base plate **901** of the injector **900** and the number of buttons **905** which may be used. Upon introduction of the injector **900** into the container **930**, the beveled side spacers **936** of the spacer ring **935** guide the injector **900** to a registry position above the spacer ring **935**. Thereafter, the injector **900** is rotated until the knobs or buttons **905** are positioned above and fit within the receptacles **937**, thereby to position the injector **900** in the storage condition thereof within the receptacle **937**, it being noted that the vertical length of the spacer ring **935** is of sufficient distance to maintain the tines **910** out of contact with the container **930**. Subsequent hermetic sealing of the container **930** under vacuum will provide for a substantial shelf life of the living biological substance **911** carried by the tines **910**.

Referring now to FIGS. **17** and **18**, there is disclosed therein an injector **1000** similar in construction to the injector **900** except that there is provided spaced apart and upwardly extending and generally parallel side walls **1004**, each of the side walls **1004** carrying on the inside surface thereof two spaced-apart button receptacles **1005** each positioned near a respective end of the side wall **1004** adjacent to the top wall **1002** of the base plate **1001**. The handle **1015** is provided on each end wall **1018** thereof with a button **1019** adapted to fit within one of the receptacles **1005**.

As shown in the drawings, when the handle **1015** is in the storage position thereof, the full-line position in FIG. **17** and the phantom-line position in FIG. **18**, the buttons **1019** are positioned within their respective button receptacles **1005**, thereby to lock the handle **1015** in the storage position thereof. When the handle **1015** is in the use position thereof, the phantom-line position in FIG. **17** and the full-line position in FIG. **18**, the handle **1015** is maintained in position by the positioning of the handle of the user. It will be appreciated that the side walls **1004** of the injector **1000** are made of resilient material, thereby to permit dislodgement of the buttons **1019** from the respective receptacles **1005** therefor in order to move the handle **1015** from the use position thereof to the storage position thereof, the side walls **1004** having a vertical extent about the distance above the base plate **1002** as the handle **1015** is in the storage position thereof. It is further pointed out that the upwardly extending side walls **1004** are but one means for locking the handle **1015** in the desired position thereof, it being understood that other friction members may be used to accomplish the same purpose and it is intended that the above-illustrated means is but one illustration of locking means for the hinged handle of the present invention.

Further constructional details and the operation of the device will now be described. The metal plates hereinbefore described are relatively thin, about 0.025 millimeters thick

and have depending therefrom relatively short tines about 2 millimeters in length, the tines being spaced apart from about 2 to 10 millimeters, depending on the type of innoculation to be performed, the tines being spaced from the edge of the base plate about 1.5 to about 3.5 millimeters. Generally, the biological substance is applied to the distal 1 millimeter of the tines and thereafter dried or freeze-dried. The biological substance is introduced into the body through the skin when the injector and the tines are pressed by a person holding the injector against the skin. The inoculation with a multiple puncture disc having a substantially flat base plate of the type illustrated in FIGS. **1** to **4** and **10** herein, is well known in the art and these devices, in general, are the subject of U.S. Pat. Nos. 2,619,962; 3,072,122; 3,221,739 and 3,221,740, all issued to me.

The biological substance placed on the tines may be chosen from a living virus such as small pox, measles, yellow fever, rabies, influenza, mumps or german measles; a living bacteria such as bacillus Calmette and Guerin (BCG), H37Ra (human attenuated tubercle bacilli); a non-living substance for skin testing for tuberculins, histoplamims, coccidioidins, sensitins in general or allergens; or a non-living substance for vaccinating for typhoid, paratyphoid, cholera or pertussis. Particularly where the biological substance is a living or visible bacteria or virus, prolonged contact with air or moisture is detrimental and the shelf life of any of the injectors described herein carrying a viable biological substance can be substantially increased by maintaining the injector under vacuum after the drying or freeze-drying of the biological substance on the tines.

The biological substance may be freeze-dried on the tines by a process described in the aforementioned U.S. patents granted to me, and during the time that the injectors are in the vacuum chamber subsequent to the freeze-drying of the biological substance, the container materials may be applied thereto to insure the retention of a vacuum within the containers if the vacuum is desired to be retained. Alternately, and particularly where the injectors carry a living biological substance, the injectors with the freeze-dried biological substance may be transported from the chamber for freeze-drying to a second vacuum chamber wherein the vacuum-packed hermetically sealed containers are applied thereto, which container may be made of plastic glass or metal foil.

As may be seen, there has been provided an inoculation device which is smaller, lighter, easier to manufacture and easier to use than the inoculation devices heretofore provided. For instance, the handles of the inoculation devices described in my previously-mentioned co-pending application are on the order of about 30 millimeters high and about 15 millimeters in diameter, whereas the inoculation devices of the present invention have flat handles about 15 millimeters by 15 millimeters square and only about 1 to 2 millimeters thick. The inoculation devices of the present invention may carry either living biological substances or non-living biological substances; however, if a living biological substance is used, then the injector must be vacuum-packed and hermetically sealed. Even in the case where a synthetic plastic material is used to package an injector carrying a life biological substance, the injector so packaged may be introduced into a suitable container and thereafter hermetically sealed under vacuum to provide a predetermined shelf life for the injector. In such a case as this, several injectors packaged in plastic may be introduced into the same container for subsequent hermetic sealing thereof.

In view of the foregoing, it is apparent that there has been provided an injector device for use in transcutaneous injections and package therefor, while there has been described what is at present considered to be the preferred embodiment of the invention, it will be understood that various modifications may be made therein and it is intended to cover in the appended claims all such modifications as fall within the true spirit and scope of the invention.

What is claimed is:

1. A transcutaneous injector comprising a base plate having a top surface and a bottom surface, a plurality of tines carried by said bottom surface of said base plate extending outwardly therefrom and substantially normal thereto, and a one-piece handle integral with said top surface of said base plate and hingedly connected thereto, said one-piece handle having a reduced cross section adjacent to said top surface of said base plate, said one-piece handle being movable between a use position in which said one-piece handle is substantially normal to said base plate and extends outwardly therefrom and a storage position in which said one-piece handle is substantially parallel to said base plate to facilitate the storage of said injector.

2. The transcutaneous injector set forth in claim **1**, wherein said base plate and said handle are formed of a synthetic plastic resin.

3. The transcutaneous injector set forth in claim **1**, wherein said tines are formed from a metal plate carried by said base plate.

4. The transcutaneous injector set forth in claim **1**, wherein said handle is integral with said base plate.

5. The transcutaneous injector set forth in claim **1**, wherein said handle is rectangular in shape, and hinged to said base plate along the entire length of said handle.

6. The transcutaneous injector set forth in claim **1**, wherein said handle is S-shaped, thereby to provide opposed gripping surfaces on the side walls thereof.

7. The transcutaneous injector set forth in claim **1**, wherein said handle is positioned diagonally along said top surface of said base plate.

8. The transcutaneous injector set forth in claim **1**, wherein said handle is positioned parallel to opposed side edges of said base plate.

9. A prepared package for a transcutaneous injector comprising a container, a transcutaneous injector entirely disposed within said container, said injector including a base plate having a top surface and a bottom surface, a plurality of tines carried by said bottom surface of said base plate extending outwardly therefrom and substantially normal thereto, said tines carrying a biological substance on the distal ends thereof, and a one-piece handle integral with said top surface of said base plate and hingedly connected thereto, said handle having a reduced cross section adjacent to said top surface of said base plate, said one-piece handle being movable between a use position in which said one-piece handle is substantially normal to said base plate and extends outwardly therefrom and a storage position in which said one-piece handle is substantially parallel to said base plate, said one-piece handle being in said storage position when said injector is disposed within said container, and means for maintaining said tines out of contact with said container when said injector is disposed within said container.

10. The prepared package set forth in claim **9**, wherein said container includes a substantially rigid bottom portion adapted to house said injector therein to maintain said tines out of contact with said substantially rigid bottom portion.

11. The prepared package set forth in claim **9**, wherein said base plate includes a pair of abutment surfaces positioned along opposed side edges of said base plate, and said container includes a substantially rigid bottom portion having a pair of shoulders carried by opposed side walls thereof, each of said shoulders being adapted to receive a respective one of said abutment surfaces, said shoulders being spaced from the bottom wall of said rigid bottom portion a distance greater than the distance between the distal end of said tines and said abutment surfaces, whereby to maintain said tines out of contact with said container when said injector is disposed within said container.

12. The prepared package set forth in claim **9**, wherein said means for maintaining said tines out of contact with said container include a substantially rigid U-shaped cover adapted to support said base plate, the bottom wall of said U-shaped cover being spaced apart in use from said base plate a distance greater than the length of said tines so as to maintain said tines out of contact with said container.

13. The prepared package set forth in claim 9, wherein said means for maintaining said tines out of contact with said container include an annular member disposed within said container and adapted to receive said injector with the tines thereof disposed within said annular member.

14. The prepared package set forth in claim 9, wherein said container is vacuum-packed and hermetically sealed.

15. The prepared package set forth in claim 9, wherein said container is a vacuum-packed hermetically sealed metal foil.

16. The prepared package set forth in claim 9, wherein said package is connected to another of said prepared package in end-to-end relationship, said connection being adapted easily to be broken to detach a selected one of said prepared packages.

17. The prepared package set forth in claim 9, wherein said package is vacuum-packed and hermetically sealed and connected to another of said vacuum-packed hermetically sealed prepared package in end-to-end relationship, said connection being adapted easily to be broken to detach a selected one of said prepared packages.

18. A transcutaneous injector comprising an arcuate base plate having a concave top surface and a convex bottom surface, a plurality of tines carried by said convex bottom surface of said base plate and extending outwardly therefrom, and a one-piece handle integral with and hingedly connected to said concave top surface of said base plate and extending outwardly therefrom, said one-piece handle having a reduced cross section adjacent to said base plate, said one-piece handle being movable between a use position and a storage position, said injector being adapted to be rolled against the skin to puncture the skin at a plurality of points and introduce a biological substance carried by said tines into the body.

19. The transcutaneous injector set forth in claim 18, wherein said handle is fixedly connected to said concave top surface of said base plate and forms a plane substantially parallel to the direction said injector is rolled when introducing the biological substance into the body.

20. A prepared package for a transcutaneous injector comprising a container, a transcutaneous injector entirely disposed within said container, said injector including a base plate having a top surface and a bottom surface, a plurality of tines carried by said bottom surface of said base plate extending outwardly therefrom and substantially normal thereto, said tines carrying a biological substance on the distal ends thereof, and a handle hingedly connected to said top surface of said base plate, said handle being movable between a use position in which said handle is substantially normal to said base plate and extends outwardly therefrom and a storage position in which said handle is substantially parallel to said base plate, said handle being in said storage position when said injector is disposed within said container, a substantially rigid U-shaped cover adapted to support said base plate, the bottom wall of said U-shaped cover being spaced apart in use from said base plate a distance greater than the length of said tines so as to maintain said tines out of contact with said container when said injector is disposed therewithin.

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