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[54] **IMPLANT DEVICE**

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[51] **Int. Cl.**[2] **A61M 5/00**; A61M 31/00

[58] **Field of Search** ..... 128/221, 217, 264, 218 D, 128/214.4, 347, 2 B, 218 P, 215

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[57] **ABSTRACT**

A tubular member has a central longitudinal axial bore therethrough, a pointed elongated annular concavely bevelled implanting end and a charging end. The implanting and charging ends communicate with the bore. A first plunger having a solid pointed elongated annular concavely bevelled implanting end is adapted to be removably inserted in the bore for slidable movement therein. When the first plunger is completely inserted in the bore of the tubular member the implanting ends are aligned to form a complimentary substantially continuous, pointed, elongated, annular concavely bevelled penetration surface. The first plunger is slidably moveable in the bore of the tubular member from a first to a second position at which insertion of the first plunger in the bore is complete. Means are optionally provided for aligning the implanting ends at only the second position.

11 Claims, 4 Drawing Figures

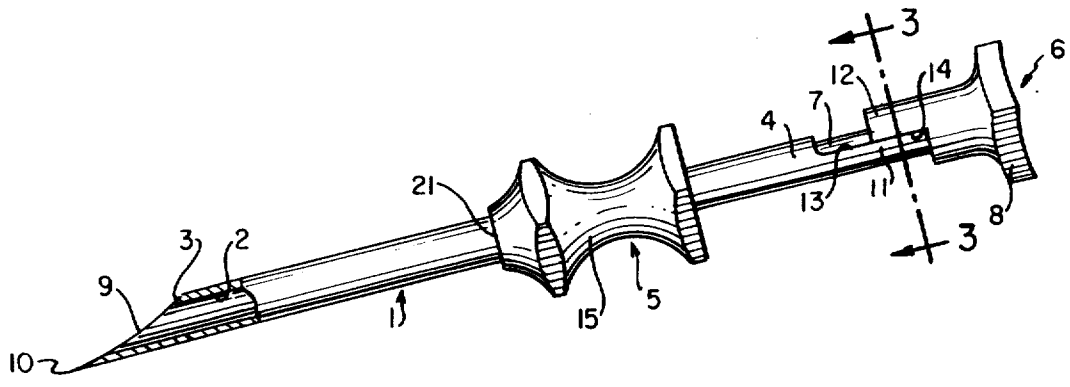


FIG. 1

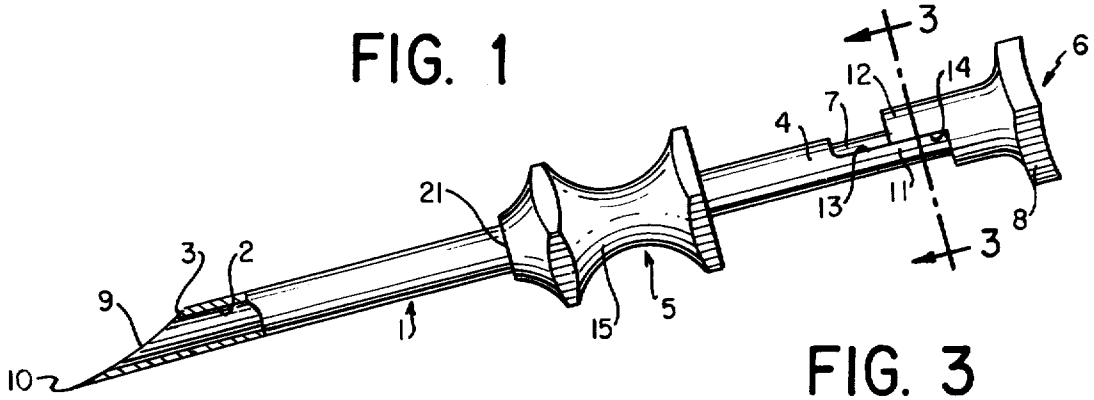


FIG. 2

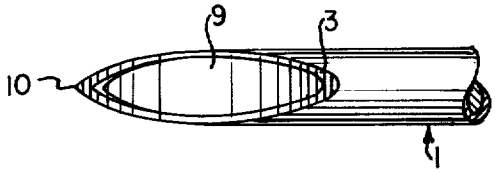


FIG. 3

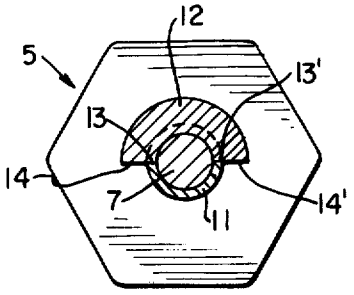
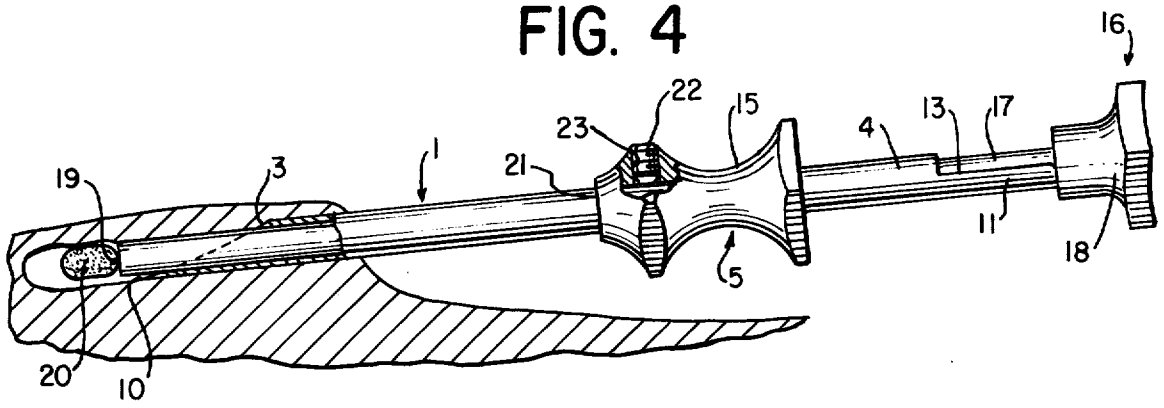


FIG. 4



IMPLANT DEVICE

The present invention relates to an improved device for administration of drugs. More particularly, the invention relates to an improved device for subcutaneous introduction of drug implants, preferably in pellet form.

Techniques and devices for introducing solid medicaments beneath the skin are known to the art. Medical use of drug implants was initiated as early as 1861, see Howard Jones, N., J. Hist. Med. 2, 201 (1947). Implants have advantageously been used for administration of hormones, such as testosterone, estradiol and other drugs, where slow, constant release and continuous absorption of a drug for prolonged time periods is desired. The long lasting effect of a drug implant frees the patient from the need to take multiple periodic parenteral or oral doses. Implant therapy is often in the long run more economical. Moreover, where a dosage regimen is critical use of implants eliminates the possibility of missed doses. Though clinical use of pellet implants has declined with the development of oral dosage forms, it nevertheless remains a valuable medical tool in for example, drug absorption studies. Surface area of an implant is readily determined and controlled. Moreover, the effective area of a pellet in contact with body tissues can be measured before and after implantation by simple direct inspection of the implant.

As stated heretofore, devices for subcutaneous introduction of implants are disclosed in the prior art. One such device comprises an injector needle, having a central longitudinal axial bore and a sharp bevelled end, a first plunger having a sharp bevelled end and a second plunger having a blunt end. The first plunger and the second plunger are each removably insertable within the bore of the injector needle. The technique employed with this prior art device is as follows:

The area wherein the pellet is to be inserted is anesthesized with a local anesthetic. A small incision is made in the skin to permit free passage of the injector needle. The first plunger is inserted into the bore of the injector needle, then the injector needle, with the first plunger in place, is inserted into the subcutaneous tissue. When insertion of the injector needle is complete the first plunger is withdrawn from the bore. A drug pellet is then introduced into the injector bore and gently forced down the bore and into the subcutaneous tissues with the blunt end of the second plunger. Once the pellet is fully inserted, the injector with the second plunger seated in the bore is simultaneously withdrawn. The incision is then closed with sutures, a clip, or an adhesive bridge, etc.

The aforementioned prior art device has, however, not proven successful since it suffers from several major defects. First, a preliminary surgical incision is required before the device can be employed. Second, if upon insertion into the subcutaneous tissues the injector needle with first plunger in place is not properly oriented, that is to say, the bevelled sharp end of the first plunger is not in alignment with the bevelled sharp end of the injector needle, insertion of the device will result in considerable tearing of the tissues.

The device of the present invention constitutes an improvement over the above described prior art device. Use of the present device obviates the need for preliminary surgical incision. The instant device makes a clean incision. No stitching or sutures are generally

thereafter required. Furthermore, in the device of the present invention, means are provided for preventing improper orientation of the sharp end of the injector needle and the sharp end of the first plunger whereby disadvantageous tearing of the skin and tissues is avoided.

The present invention will now be described in greater detail with reference to the accompanying drawings in which like elements are assigned the same numerical designation.

In the drawings:

FIG. 1 is a plan view, partially in section, of a preferred embodiment of the instant invention;

FIG. 2 is a top plan view showing the complimentary positioned ends respectively of the tubular member and first plunger of FIG. 1;

FIG. 3 is a cross-sectional view taken along the line 3—3 of FIG. 1, and

FIG. 4 is a plan view, partially in section, of the tubular member of FIG. 1 with the second plunger in place, and shown after delivery of a drug pellet.

Referring now to FIG. 1: Injector needle or tubular member 1 has a longitudinal axial bore 2 therethrough, a pointed elongated annular concavely bevelled implanting end 3 and a charging or inlet end portion 4. Bore 2 communicates with end 3 and with inlet end portion 4. A finger hold 5 which can also serve as an insertion limiting stop member is mounted on tubular member 1. A first plunger 6 comprised of solid rod portion 7, head portion 8 and a pointed elongated annular concavely bevelled end 9 is removably insertable in bore 2 of tubular member 1 for slidable movement therein along the longitudinal axis of said tubular member 1 from a first position to a second position. As shown in FIGS. 1 and 2, end 3 of tubular member 1 and end 9 of first plunger 6 are elongated and annular, more particularly they are substantially ellipsoidal. As is more clearly shown in FIGS. 2 and 4 ends 3 and 9 can be aligned to present a complimentary elongated annular concave surface. Means are provided on the first plunger 6 and on the tubular member 1 to ensure that this complimentary alignment of ends 9 and 3 occurs only at one position, viz. the second position referred to above.

As shown in FIG. 1 and 4, end portion 4 of tubular member 1 has a cutout forming a troughlike lip or projection 11 having shoulders 13 and 13' . Head portion 8 of first plunger 6 has a complimentary semicylindrical lip or projection 12 having shoulders 14 and 14' . As is clear from FIG. 3 lips or projections 11 and 12 will mesh in only one position, that is when shoulders 13 and 13' respectively are aligned opposed to and in contact with shoulders 14 and 14' . Moreover, rod portion 7 of first plunger 6 can only be inserted within bore 2 of tubular member 1 to the second position when projections 11 and 12 are positioned so that shoulders 13 and 13' are aligned with respect to shoulders 14 and 14' . When so aligned shoulders 14 and 14' can be slidably moved along opposing juxtaposed shoulders 13 and 13' from the first position to the second position at which point only ends 9 and 3 are in alignment as shown in FIGS. 1 and 2.

When at the second position, complimentary aligned ends 9 and 3 present a substantially continuous pointed elongated annular concavely bevelled tip. Providing the device of the present invention with such a tip accounts for certain significant advantages over prior art

straight bevelled tips. The device of the instant invention readily penetrates the skin and underlying subcutaneous tissue. No preliminary surgical incision is required. Less pain and tissue damage is occasioned and the need for surgical sutures to close the puncture is generally obviated.

Finger hold **5** is provided on tubular member **1.** Hold **5** optionally functions to limit the maximum depth of penetration of end **3** of tubular member **1** to the distance between point **10** of end **3** and shoulder portion **21** of body **15.** As shown in FIGS. **1** and **4** body **15** is preferably hour-glass shaped so as to provide a convenient gripping surface for the fingers. One end of hour-glass shaped body **15** is unitary with shoulder portion **21.** Hold **5** can be fixed in position on or unitary with tubular member **1.** Alternatively, it can be adjustable in position along tubular member **1.** This optional adjustability feature of hold **5** enables it to be positioned at any one of a plurality of points along the longitudinal axis of tubular member **1** thereby permitting regulation of the maximum depth of penetration of end **3** into the subcutaneous tissues.

Optional adjustability of the position of hold **5** on tubular member **1** can be attained by providing body **15** with releasable friction gripping means for frictionally lockiing body **15** in a selected fixed position on tubular member **1.** Alternatively, tubular member **1** can be provided with an external male threaded surface and body **15** with internal complimentary female threads or vice-versa whereby the position of hold **5** along the longitudinal axis of tubular member **1** can be suitably adjusted by threading body **15** toward or away from end **3.** Alternatively, as shown in FIG. **4** hold **5** has a longitudinal bore therethrough adapted to slidably receive tubular member **1.** A second internally threaded bore **23** is provided in body **15** and is adapted to receive therein complimentary threaded set screw **22.** Set screw **22** may be threaded into bore **23** to contact tubular member **1** and frictionally fix the position of hold **5** thereon. Set screw **22** can be provided with a slotted head adapted to receive a screwdriver to facilitate tightening of same. Other means for providing optional adjustability of the position of hold **5** on tubular member **1** will readily suggest themselves to the skilled artisan.

FIG. **4** illustrates a further embodiment of the device of the present invention, blunt plunger **16.** Plunger **16** is comprised of a solid rod **17** having an enlarged head portion **18** at one end and a blunt tip **19** at the other end. Like rod portion **7** of the first plunger **6,** rod **17** is adapted for removable insertion in bore **2** of tubular member **1** for slidable movement therein along the longitudinal axis of tubular member **1.** Head portion **18** is larger in diameter than the diameter of bore **2.** Thus it serves as a stop which limits the maximum extension of rod **17** within bore **2.** As shown in FIG. **4,** blunt plunger **16** is preferably of sufficient length so that when fully inserted within bore **2** of tubular member **1** blunt tip **19** of rod **17** extends beyond the tip **10** of end **3** of tubular member **1.** This facilitates complete removal of pellet **20** from bore **2.**

Understanding of how the components of the device of the present invention cooperate to achieve subcutaneous implant of a drug pellet is best acquired by a consideration of how the device is employed.

Rod portion **7** of the first plunger **6** is inserted within bore **2** of tubular member **1** so that shoulders **13** and **13'** of projection **11** of tubular member **1** are aligned opposed to and in juxtaposition with respect to shoulder **14** and **14'** of projection **12** of head portion **8** of the first plunger **6.** Rod portion **7** may then be slidably moved in the direction of stop **5** to the second position at which point only end **9** of the first plunger **6** and end **3** of tubular member **1** are complimentarily aligned and form with one another a substantially continuous, pointed, elongated, annular, concavely bevelled surface. Hour-glass shaped body **15** of hold **5** is then grasped between the pointer and index fingers with the thumb resting on head portion **8** of the first plunger **6.** Hand pressure is then applied to drive the complimentarily aligned ends of tubular member **1** and first plunger **6** into the subcutaneous tissues. Hold **5** optionally serves to limit the depth of penetration and may optionally be suitably adjusted prior to insertion of the device. When the desired degree of penetration is achieved the device is withdrawn slightly so as to leave in the subcutaneous tissues adjacent the withdrawn tip **10** a pocket adapted to receive a subsequently injected pellet. Thereafter first plunger **6** is completely withdrawn from bore **2** of tubular member **1.** A drug pellet **20** is placed on the troughlike lip or projection **11** then driven into and seated within the previously prepared pocket in the subcutaneous tissues by downward slidable movement of blunt plunger **16** in bore **2.** Since blunt tip **19** of plunger **16** extends beyond tip **10** of tubular member **1** complete release of pellet **20** from the device is assured. Once the pellet is seated the tubular member **1** and blunt plunger **16** are simultaneously withdrawn. No sutures are generally required to close the puncture.

The device of the present invention can be readily fabricated out of for example stainless steel, carbon steel, hyperchrome steel, chromium, nickeloid, platinum, platinum iridium, gold or silver. Other materials will readily suggest themselves to those skilled in the art.

A further optional modification of the preferred embodiment of the instant invention is the provision of a protective guard for point **10** of end **3** of the tubular member **1.** The protective guard may be rigid or plastic material. The guard is preferably a tubular sleeve closed at one end and open at its other end and is adapted to receive through the open end and encase and protect point **10** of end **3.**

What is claimed is:

1. An implant device comprising:

a. a tubular member having a central longitudinal axial bore therethrough, a pointed elongated annular concavely bevelled implanting end, and a charging end, each of said ends communicating with said bore;

b. a plunger having a solid, pointed, elongated annular concavely bevelled end, said plunger being removeably inserted in said bore and slideably movable therein along the longitudinal axis of said tubular member from a first position to a second position at which maximum insertion of the plunger into the bore is obtained and the implanting end of the tubular member and the pointed end of the plunger are aligned to form a complimentary substantially continuous pointed elongated annular concavely bevelled penetration surface; and

c. means for aligning said implanting end and said pointed end, said means for aligning being only one semicircular projection on the charging end of the

tubular member, said first projection extending for a distance in the axial direction whereby a pill receiving trough is formed for facilitating introduction of an implant dosage form into the bore of the tubular member, and a second semi-circular projection on the plunger, the first and second projections being complimentary and alignable at only the second position, alignment of the first and second projections serving to simultaneously align said implanting end and said pointed end, said first projection being an extension of the charging end and having a first shoulder and a second shoulder, said plunger having a head portion the diameter of which is larger than the diameter of bore of the tubular member, said second projection being an extension of the head portion of the plunger and having a third shoulder and a fourth shoulder, said plunger being movable within said bore from the first position to the second position only when the first and second shoulders are aligned opposed to and in sliding contact respectively with the third and fourth shoulders.

2. The device as claimed in claim **1** further including an insertion limiting stop member on said tubular member for limiting the maximum depth of penetration of the implanting end of the tubular member.

3. The device as claimed in claim **2** wherein the stop member is fixed in position on the tubular member.

4. The device as claimed in claim **2** wherein the stop member is adjustable in position on the tubular member.

5. The device as claimed in claim **4** wherein said stop member has a longitudinal axial bore adapted to receive said tubular member for slidable movement therein further including gripping means for releasably frictionally fixing the stop member in a selected position on said tubular member.

6. The device as claimed in claim **4** wherein the stop member has a first longitudinal axial bore, the tubular member is disposed within, and slidably movable along the axis of, said first longitudinal axial bore, said stop member having an internally threaded second bore communicating with the first longitudinal axial bore, and a complimentary threaded set screw in said second bore threadable into frictional engagement with the tubular member to fix the position of the stop member on the tubular member.

7. The device as claimed in claim **2** wherein said stop member is substantially hour-glass shaped.

8. The device as claimed in claim **2** wherein said stop member **7** also serves as a finger hold.

9. The device as claimed in claim **1** further including means on the tubular member for facilitating gripping of the device.

10. The device as claimed in claim **1**, wherein said implanting end and said pointed end are substantially ellipsoidal.

11. The device as claimed in claim **1** wherein the first projection is a cutout of the charging end of the tubular member and the second projection is a cutout of the head portion of the plunger.

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