

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 January 2009 (15.01.2009)

PCT

(10) International Publication Number
WO 2009/007997 A2

- (51) International Patent Classification:
A61M 5/315 (2006.01)
- (21) International Application Number:
PCT/IN2008/000269
- (22) International Filing Date: 28 April 2008 (28.04.2008)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
836/MUM/2007 27 April 2007 (27.04.2007) IN
- (71) Applicant (for all designated States except US): SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED [IN/IN]; Akota Road, Akota, Baroda 390 020 (IN).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): GOKHALE, Satish Madhukar [IN/IN]; Design Directions Pvt Ltd., 828, Shivaji Nagar, "rajeev", Prof.v.g.kale Road,, Off Bhandarkar Road, Lane #13, Pune 411 004 (IN). TAKALE, Abhijit [IN/IN]; Design Directions Pvt Ltd., 828, Shivaji Nagar, "rajeev", Prof.v.g.kale Road,, Off Bhandarkar Road, Lane #13, Pune 411 004 (IN). KANE, Prashant [IN/IN]; Sun Pharma Advanced Research Centre, Nima Compound, Near Pratham Enclave, Tandalja Road, Baroda 390 020 (IN).

- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

[Continued on next page]

(54) Title: APPLICATOR FOR ADMINISTERING ADJUSTABLE PRESET DOSE OF MEDICAMENT

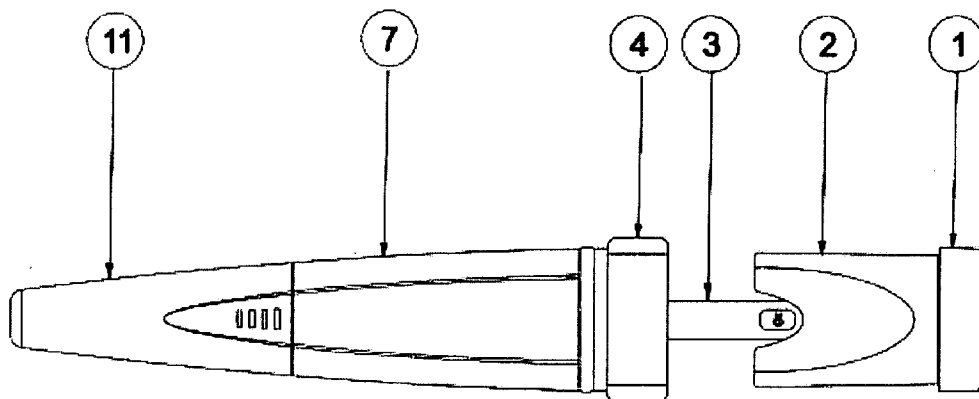


Figure 1

(57) Abstract: The present invention provides an applicator for administering adjustable preset dose of medicament comprising: a syringe enclosure; a syringe; a plunger rod with ratchets; a dose setting cap with snaps to snap on the ratchets on the plunger rod for adjusting and setting the medicament dose to be administered to the patient; and a dose locking cap for locking the medicament dose to be administered to the patient.

WO 2009/007997 A2



Published:

- *without international search report and to be republished upon receipt of that report*

**APPLICATOR FOR ADMINISTERING ADJUSTABLE PRESET DOSE OF
MEDICAMENT**

FIELD OF THE INVENTION

5 The present invention relates to an applicator for administering an adjustable preset dose of a medicament to a patient.

BACKGROUND OF THE INVENTION

10 Patients are often needed to be administered medicaments from an applicator by a health care provider at home. However, different amounts of the medicament are required to be administered to different patients, depending upon factors such as, the size and weight of the patient, the age of the patient, the sex of the patient, whether the patient is a child or an adult, etc. Currently, in order to administer the proper dose to the patient, applicators typically require that the device is manufactured such that the entire volume is metered to deliver the desired dose of the
15 medicament, or that the health care provider at home adjust the volume of the dose to be delivered. Both of these options, however, have certain inherent drawbacks. In the former case, the manufacturer is required to make several versions of a device, with each version having a different volume of the medicament. Further, because several different versions of the device are required, both the distributor of the medicament and the pharmacist are required to use more
20 "shelf space" by keeping an inventory of the various devices containing different amounts of the drug. In the latter case, it is more likely that the health care provider at home (as compared to a pharmacist) might make an error in setting the proper dosage. This could be especially important if the patient requires an immediate injection of the drug such as in a medical emergency.

25 United States Patent Application No. 2004/0162528 (assigned to Xcel Pharmaceuticals, Inc.) relates to a drug delivery system for administering an adjustable preset dose of a drug such as diazepam to a patient. The patent application relates to an apparatus for setting a dose of a drug in a syringe having a plunger, comprising an outer housing and an inner housing adapted for encircling the syringe, such that the inner housing is positioned within the outer housing to set the
30 dose of the drug. The apparatus may further comprise a dosage indicator disposed on the inner housing and an opening for viewing the dosage indicator on the outer housing. The apparatus may further consist of a locking assembly connected to the inner housing and the outer housing for fixing the relative positions of the inner housing and the outer housing such that the dosage indicator is viewable through the opening in the outer housing. In an embodiment, threading are

disposed on the exterior of the inner housing and the interior of the outer housing, such that the threading on the inner and outer housing are slidably disposed within each other and the relative axial positions of the inner and outer housings are adjustable by rotation of the outer housing relative to the inner housing. The threading on the inner and outer housings may be predetermined such that a desired predetermined dosage corresponds to a predetermined amount of rotation of the outer housing relative to the inner housing.

There is particularly a need for applicators for the treatment of patients who experience epileptic seizures. Typically, patients who suffer increased and intermittent seizure activity due to epilepsy are treated via a rectal drug applicator that administers a pre-set dose of a drug such as diazepam in a gel form. However, there is a need for a system that employs a conventional syringe for delivering an adjustable pre-set dosage of a medicament. Though the drug delivery system disclosed in United States Patent Application No. 2004/0162528 can administer an adjustable preset dose of a medicament to a patient, there is a need for applicators capable of delivering an adjustable pre-set dosage of a medicament and which use less complex mechanisms and are easier to make than the delivery system disclosed in the '528 application.

OBJECT OF THE INVENTION

It is the object of the present invention to provide an applicator for administering an adjustable preset dose of a medicament to a patient.

SUMMARY OF THE INVENTION

The present invention provides an applicator for administering adjustable preset dose of medicament comprising:

- a syringe enclosure;
- a syringe;
- a plunger rod with ratchets;
- a dose setting cap with snaps to snap on the ratchets on the plunger rod for adjusting and setting the medicament dose to be administered to the patient;
- and a dose locking cap for locking the medicament dose to be administered to the patient.

5 **DETAILED DESCRIPTION OF THE PRESENT INVENTION**

The device of the present invention is illustrated by embodiments described here in below.

BRIEF DESCRIPTION OF THE DRAWINGS

Many aspects of the invention can be better understood with reference to the following drawings.

10 The components in the drawings are not necessarily to scale, emphasis instead being placed upon clearly illustrating the principles of the present invention. Moreover, in the drawings, like reference numerals designate corresponding parts throughout the several views.

Figure 01: Applicator assembly-top view

15 Figure 02: Applicator assembly- Isometric view

Figure 03: Applicator assembly- longitudinal section view

Figure 04: Syringe enclosure- isometric front view

Figure 05: Dose setting cap- section view

Figure 06: Dose setting cap- isometric view

20 Figure 07: Dose locking cap- Front view

Figure 08: Plunger Rod- top, front, isometric and right side views

Figure 09: Dose setting and locking assembly- top, front, isometric and right side views

Figure 10: Dose setting and locking assembly- exploded view

Figure 11: Dose locking assembly- exploded view

25 Figure 12: Plunger details- exploded view

The figures only represent embodiments of the present invention. The embodiments are meant only for the purpose of illustration of the present invention. Different parts of the device of these embodiments are labeled in Figures 1 to 12 and the labeling is described in the schedule of the
30 reference numerals herein below.

Schedule of reference numerals:

01: Dose locking cap

02: Dose setting cap

- 03: Plunger rod
- 04: Plunger lock
- 05: Rubber bush fitting inside the syringe
- 06: Glass syringe
- 5 07: Syringe enclosure
- 08: Silicon bush
- 09: Syringe adaptor
- 10: Sealing pin
- 11: tip cover
- 10 12: Dose indicator window
- 13: Leak detection holes
- 14: Ratchet on the plunger
- 15: Ratchet (circular) on dose locking cap
- 16: Ratchet (circular) on dose setting cap
- 15 17: Circular female snap on dose setting cap
- 18: Snap on dose setting cap
- 19: Projection on dose locking cap
- 20: Groove on plunger
- 21: Circular male snap on dose locking cap

20

The present invention provides a rectal applicator which uses a conventional syringe for delivering an adjustable pre-set dosage of a medicament, such as for example, diazepam into the rectal region of the patient. The applicator of the invention has the advantages that different sizes of syringes can be housed in the same applicator and a range of doses can be delivered from the same applicator. The dose of the medicament to be administered by the applicator can be easily

25 set by the pharmacist and locked, so that this set dose cannot be changed. The health care provider at home can then administer this set dose of medicament to the patient, thus minimizing the probability of any errors in the administration of the required dose of the medicament to the patient.

30

An embodiment of the present invention comprises an applicator for administering adjustable preset dose of medicament comprising a syringe enclosure; a syringe; a plunger rod with ratchets; a dose setting cap with snaps to snap on the ratchets on the plunger rod for adjusting and setting the medicament dose to be administered to the patient; and a dose locking cap for locking

the medicament dose to be administered to the patient. The entire assembly of the applicator of this embodiment is shown in Figures 1, 2 and 3.

5 The syringe enclosure (7) of the applicator of the present invention houses the syringe to be used (Figures 1, 2, 3 and 4). The syringe enclosure (7) is designed in such a way that at least one syringe can be housed in the enclosure. Two different syringes, for example, 3ml or 5ml syringe can be housed in the syringe enclosure by changing the syringe adapter (9) for each of the syringe. The syringe enclosure can also be made to house only a single type of syringe. Since there are extremely close tolerances between the syringe (6) and the syringe enclosure (7), there are chances that the syringe enclosure may crack. In order to avoid this possibility, a silicon bush (8) is provided as a cushion between the syringe and the syringe enclosure (Figure 3). The syringe enclosure at its dispensing end also has an integrated tip, which is to be inserted in the rectal region of the patient for administering the dose of the medicament from the applicator. Leak detection holes (13) are provided in the front side of the syringe enclosure to detect leakage of medicament (Figure 4). The sealing pin (10) is housed in the tip cover (11) (Figure 1 and 3). This sealing pin ensures that there is no leakage of the medicament inside the syringe enclosure. The syringe in the syringe enclosure further contains a plunger (4) that is designed such that it goes into a rubber bush (5) fitted inside the syringe at one end (Figure 3) and has the cap mechanism (1 and 2) fitted on it at the other end (Figure 1, 2 and 3).

20

The dual mechanism of the dose locking cap (1) and the dose setting cap (2) ensures that a range of doses of the medicament to be administered can be set in the same device. Both the caps are of an elliptical cross section and fit onto the plunger rod (3) where the steps of setting the dose of the medicament and locking of the same can be performed (Figure 1, 2 and 3). The dose locking cap (1) has various numbers on it indicating the set dosage. The dosage numbers can be viewed through the dose indicator window (12) on the plunger rod (3) (Figure 8 and 9). Only one dose that is set can be viewed at a time through the dose counter indicator window (12) clearly indicating the dosage that is being set. The dose setting cap and the dose locking cap are pre-assembled on the plunger rod. In order to set the dose of the medicament to be administered, the dose setting cap (2) is moved linearly along the plunger rod over the ratchet on the plunger (14) and is snapped onto the required dose position by the snap (18) on the dose setting cap (Figure 5 and 9). The dose set can be seen through the dose indicator window (12), provided on the plunger rod. Once the dose is set satisfactorily, then the dose locking cap (1) is turned clockwise by 90 degrees in order to lock the dose. This turning of the dose locking cap leads to a ratchet on dose setting

30

cap (16) interlocking with the ratchet (15) on dose locking cap (Figure 10). Also the rod of the locking cap gets fitted into the plunger because of its elliptical nature, when the dose locking cap is turned by 90 degrees (Figure 10). Additionally a projection (19) on the dose locking cap gets locked in the groove (20) on the plunger (Figure 11 and 12). Due to the locking of the elliptical cap onto the plunger rod, the dose of the medicament set is locked and it cannot be unset unless the entire device is broken. The combination of the ratchet mechanism on the plunger rod (14), the snap (18) on dose setting cap makes the dose setting easy. The ratchet (15) on dose locking cap and the ratchet (16) on the dose setting cap; the elliptical cross section of the rod of the dose locking cap which fits in the plunger; and the projection (19) on the dose locking cap and the groove (20) on the plunger locks the set dose.

A plunger lock (4) is designed so that while setting the dose, the plunger does not move and dispense the medicament (Figure 1 and 2). The plunger lock is designed in red color thereby indicating that the device is not ready to use, when the lock is in place. In order to use the device, the plunger lock is removed, exposing a green area below the plunger lock, which indicates the device is ready to use.

The applicator of this embodiment is used to dispense medicaments to the patients in the following way:

Firstly the dose setting cap and the dose locking cap are assembled in the assembly unit. The dose locking cap is pressed on the dose setting cap till circular male snap (21) on the dose locking cap fits/snaps on to the circular female snap (17) on the dose setting cap. Then the assembly of the dose setting cap and the dose locking cap is placed on the plunger till the snap (18) on the dose setting cap snaps to the first ratchet (14) on the plunger.

In order to set the prescribed dose, the pharmacist moves the dose setting cap (2) along the plunger rod linearly over the ratchet (14) on the plunger and snaps (18) at predefined positions. This dose set can be seen through the dose indicator window (12), provided on the plunger rod. Once the dose is set satisfactorily, then the dose locking cap (1) is turned clockwise by 90 degrees by the pharmacist. This turning of the dose locking cap leads to a ratchet on dose setting cap (16) interlocking with the ratchet (15) on dose locking cap. Also the rod of the locking cap gets fitted into the plunger because of its elliptical nature, when the dose locking cap is turned by 90 degrees. Additionally a projection (19) on the dose locking cap gets locked in the groove (20) on the plunger. Due to the locking of the elliptical cap onto the plunger rod, the dose of the

medicament set is locked and it cannot be unset unless the entire device is broken. After setting a prescribed dosage by turning a locking cap by 90 degrees, the pharmacist removes the plunger lock and hands over the device to user for application.

- 5 The health care provider at home removes the tip cap, removes the sealing pin from the tip of the cover and inserts the tip of the applicator into the rectal region of the patient and presses the dose locking cap (1) by applying push force on the locking cap till dose setting cap front end touches the syringe enclosure and stops the further motion. This displaces the plunger (3) through the adjusted distance to dispense the set dose of the medicament through the tip of the applicator.
- 10 health care provider then pulls out the applicator, pulls back the dose locking cap (1), and holds the applicator in a vertical position (with the tip facing towards the ground) in a wash basin or an appropriate disposal place and removes the unused medicament (if any) from the applicator and appropriately disposes the applicator.
- 15 Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. It should be emphasized that the above-described embodiments of the present invention, particularly any "preferred" embodiments, are merely possible examples of the
- 20 invention of implementations, merely set forth for a clear understanding of the principles of the invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

25

30

We claim:

1. An applicator for administering adjustable preset dose of medicament comprising:
a syringe enclosure;
5 a syringe;
a plunger rod with ratchets;
a dose setting cap with snaps to snap on the ratchets on the plunger rod for adjusting and setting
the medicament dose to be administered to the patient;
and a dose locking cap for locking the medicament dose to be administered to the patient.
- 10 2. An applicator as in claim 1, wherein the dose locking cap comprises dosage numbers on it.
3. An applicator as in claim 2, wherein the dosage numbers on the dose locking cap are viewed
through a dose counter indicator window on the plunger rod.
4. An applicator as in claim 1, wherein the dose setting cap and the dose locking cap are pre-
assembled on the plunger rod.
- 15 5. An applicator as in claim 1, wherein the dose locking cap (1) is turned clockwise by 90 degrees
in order to lock the dose.
6. An applicator as in claim 7, wherein a ratchet on dose setting cap interlocks with the ratchet on
the dose locking cap.
7. An applicator as in claim 7, wherein a projection on the dose locking cap gets locked in the
20 groove on the plunger rod.
8. An applicator as in claim 1, further comprising a plunger lock to immobilize the plunger rod
while setting the dose of the medicament.

25

30

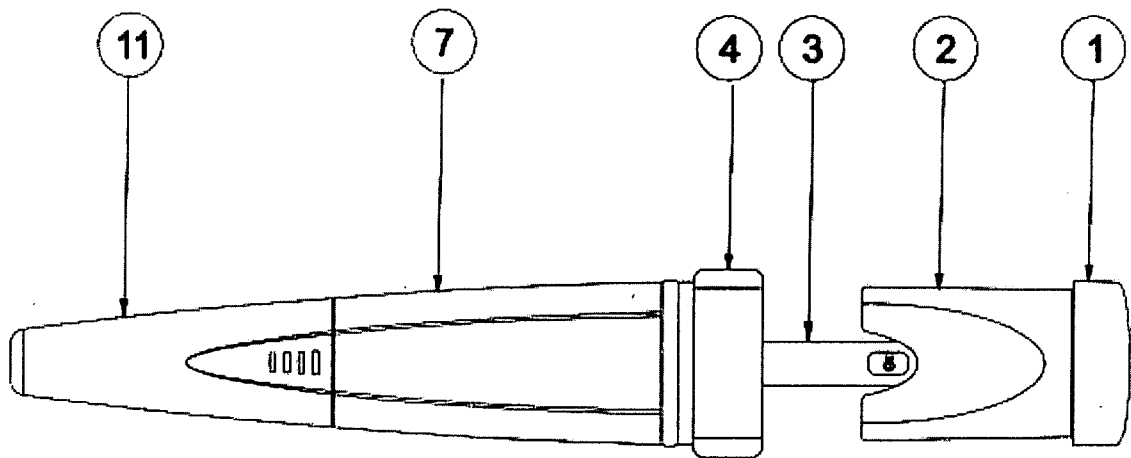


Figure 1

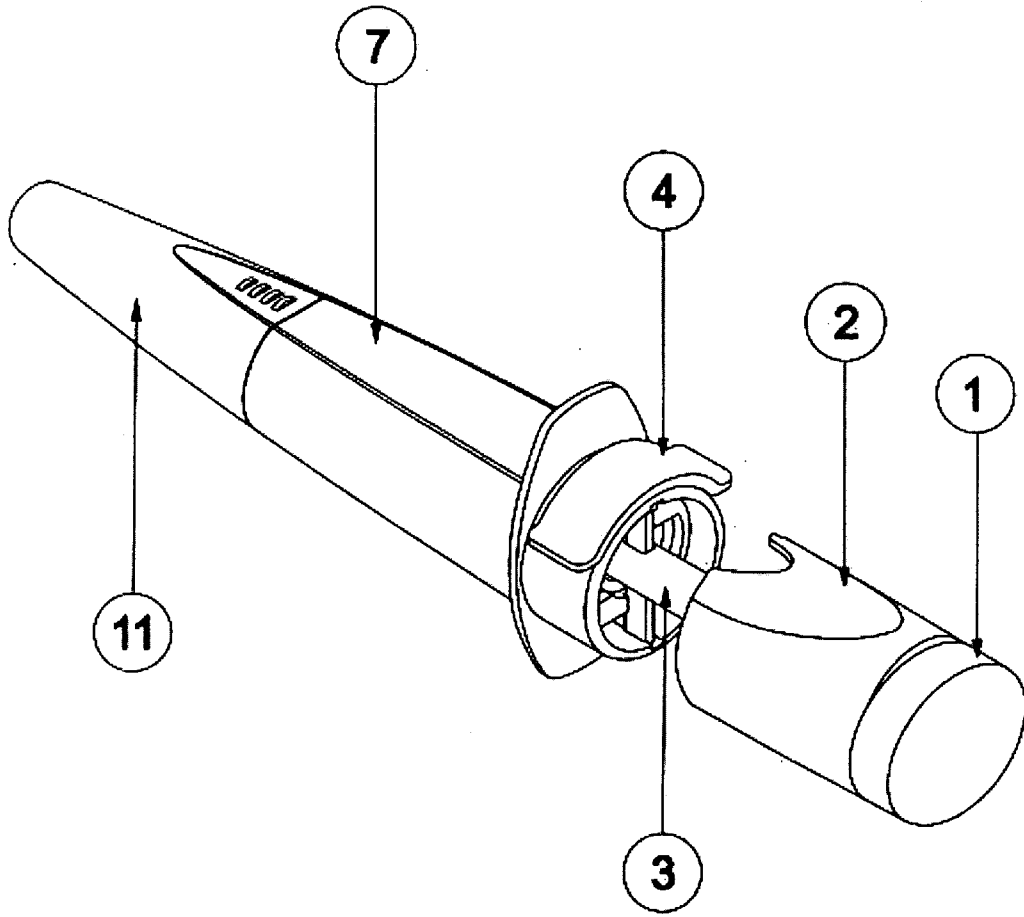


Figure 2

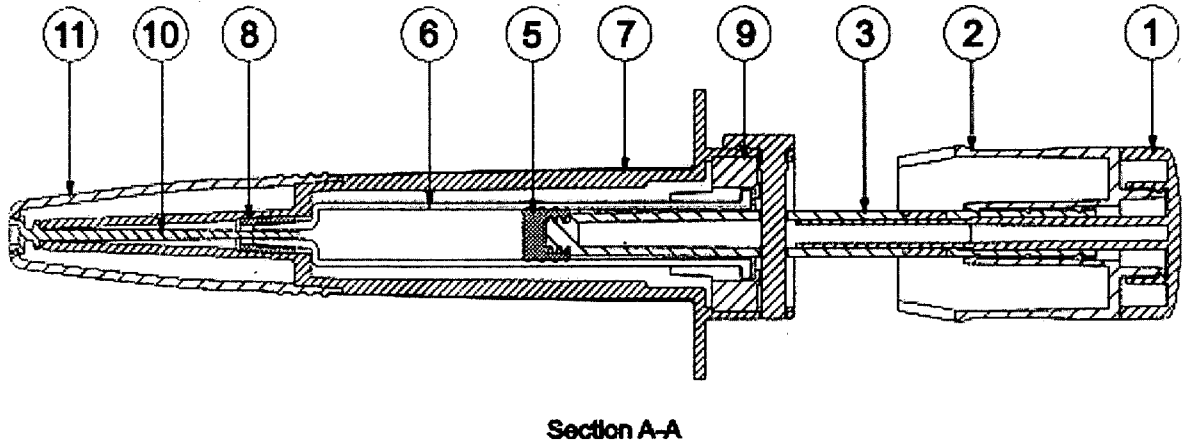


Figure 3

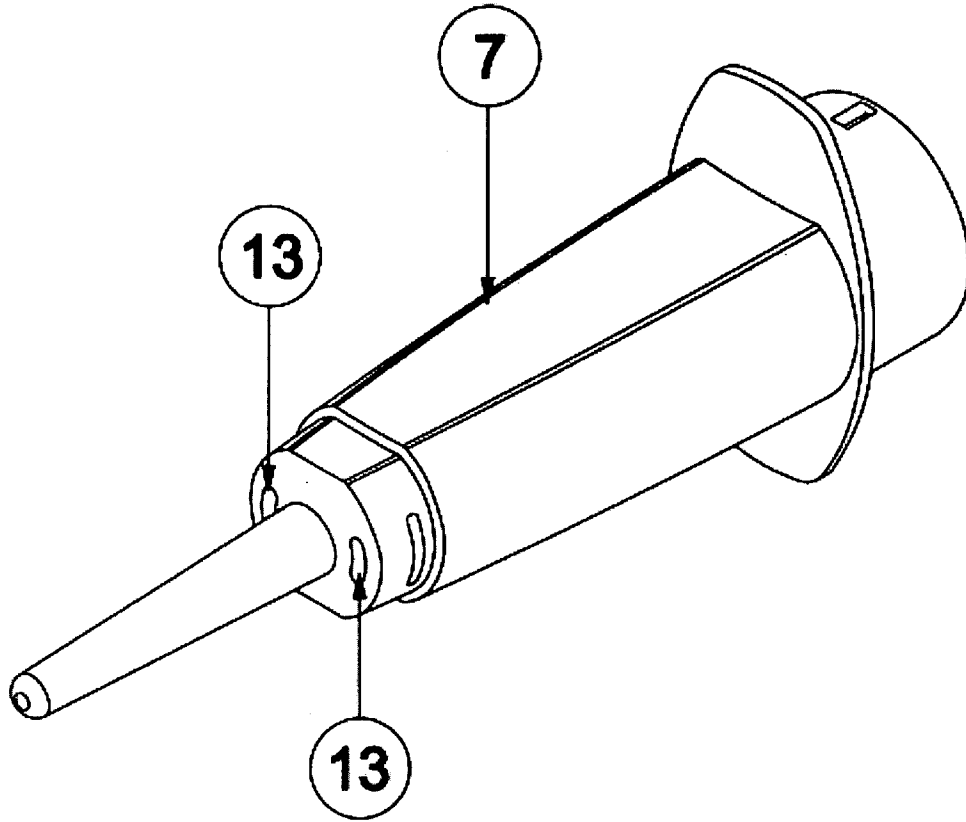
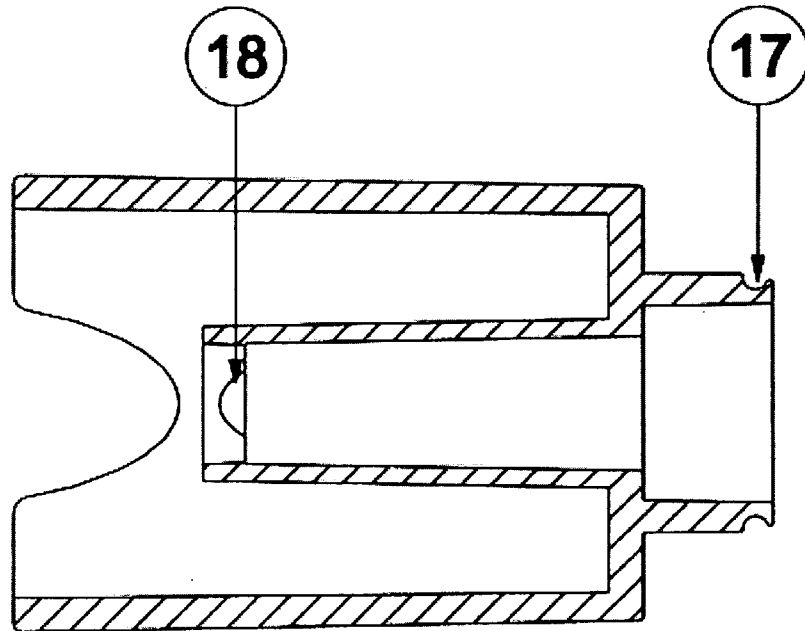


Figure 4



Section B-B

Figure 5

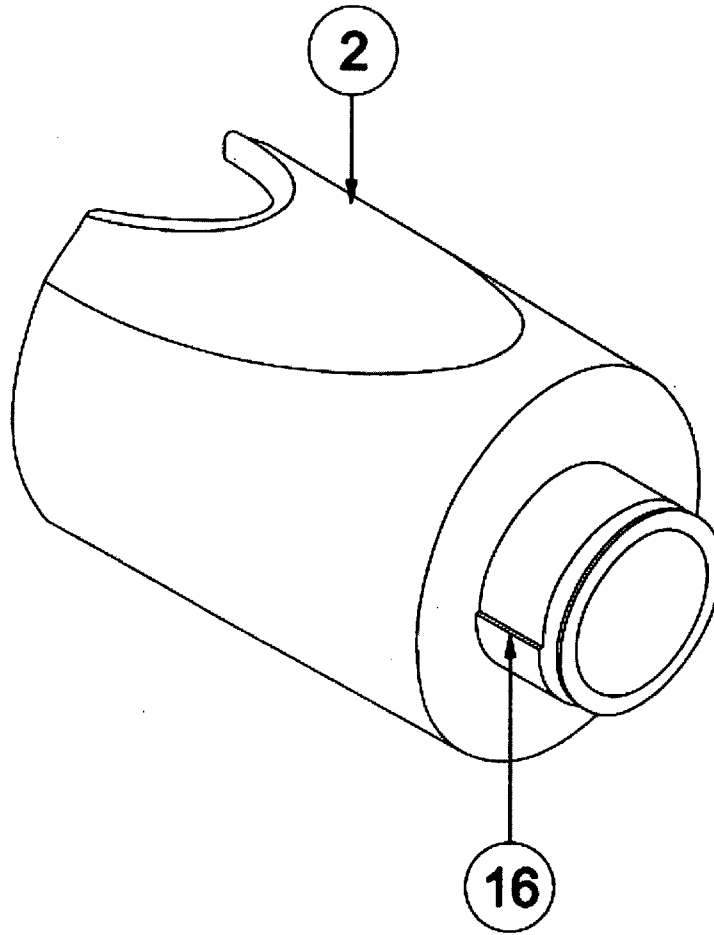


Figure 6

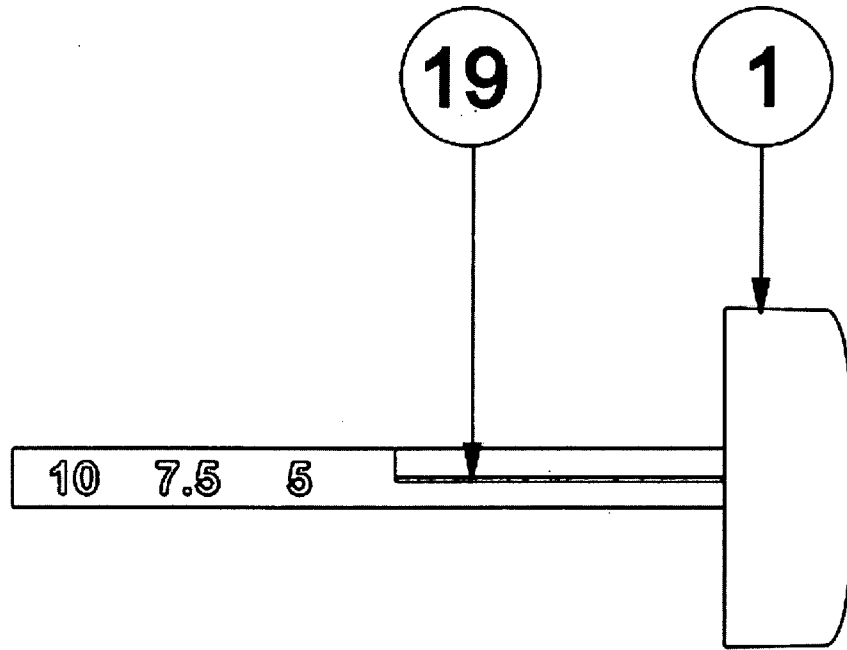


Figure 7

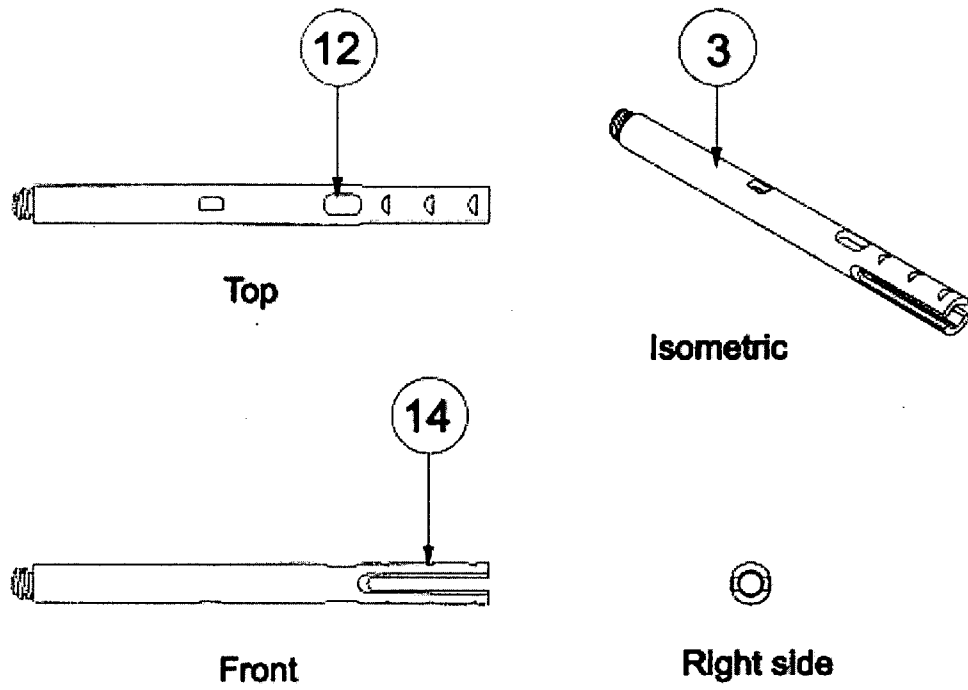


Figure 8

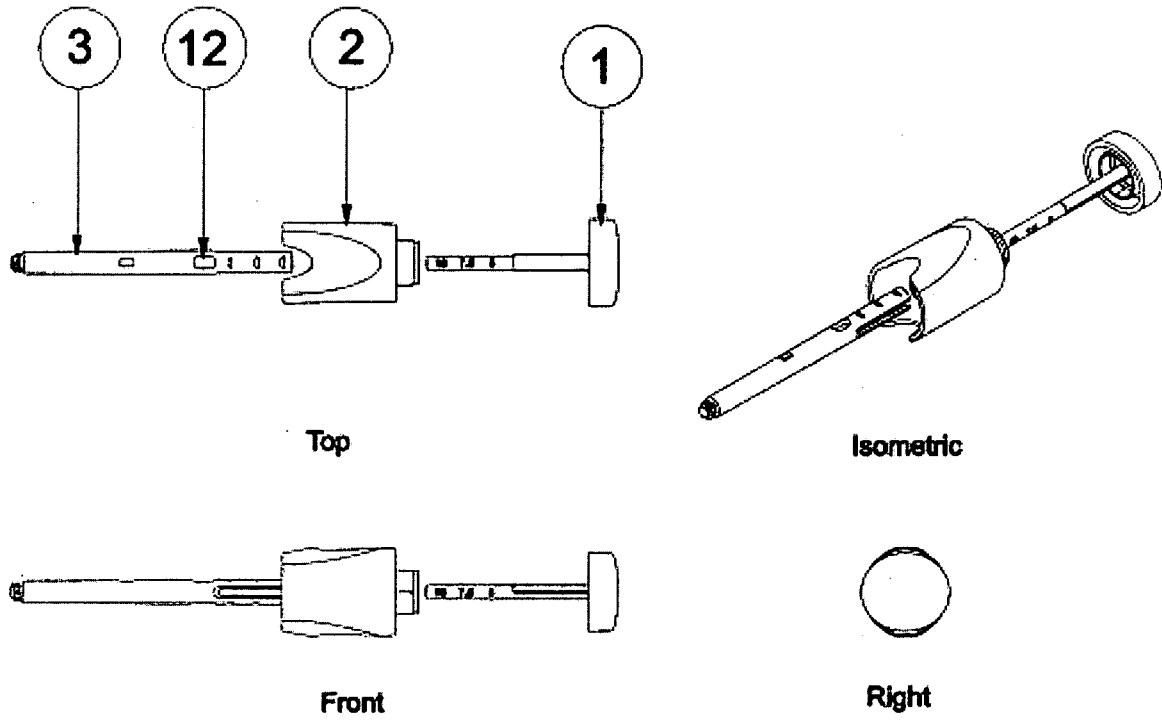


Figure 9

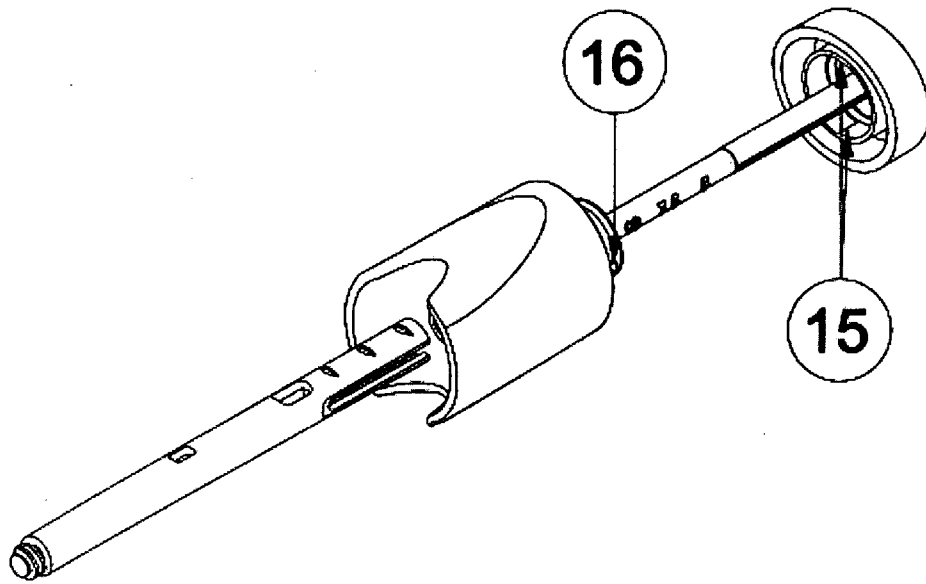


Figure 10

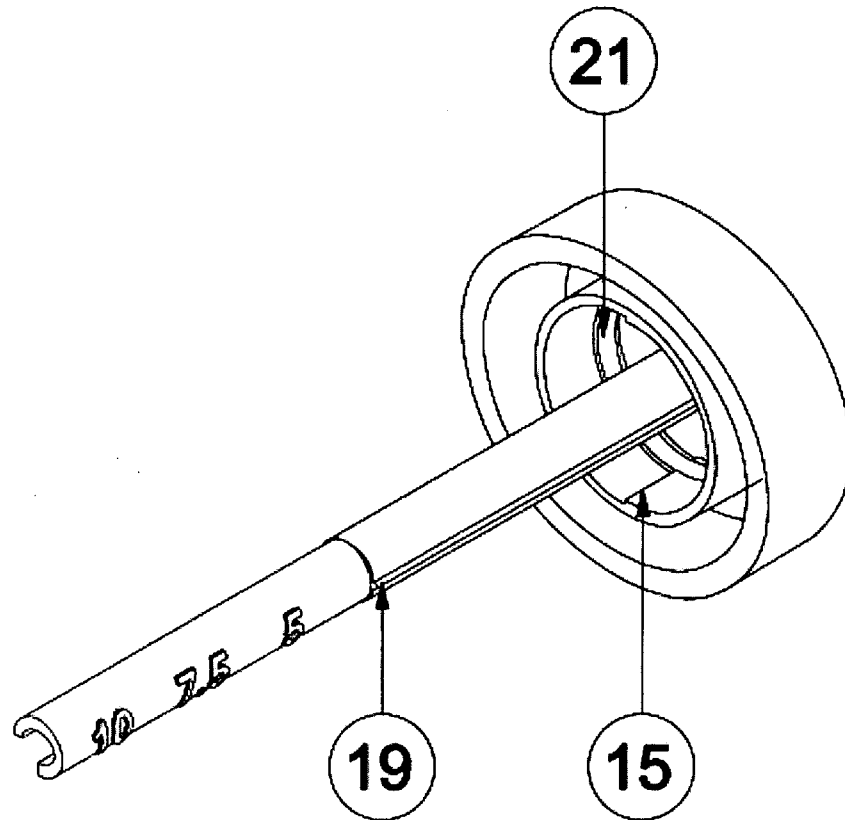


Figure 11

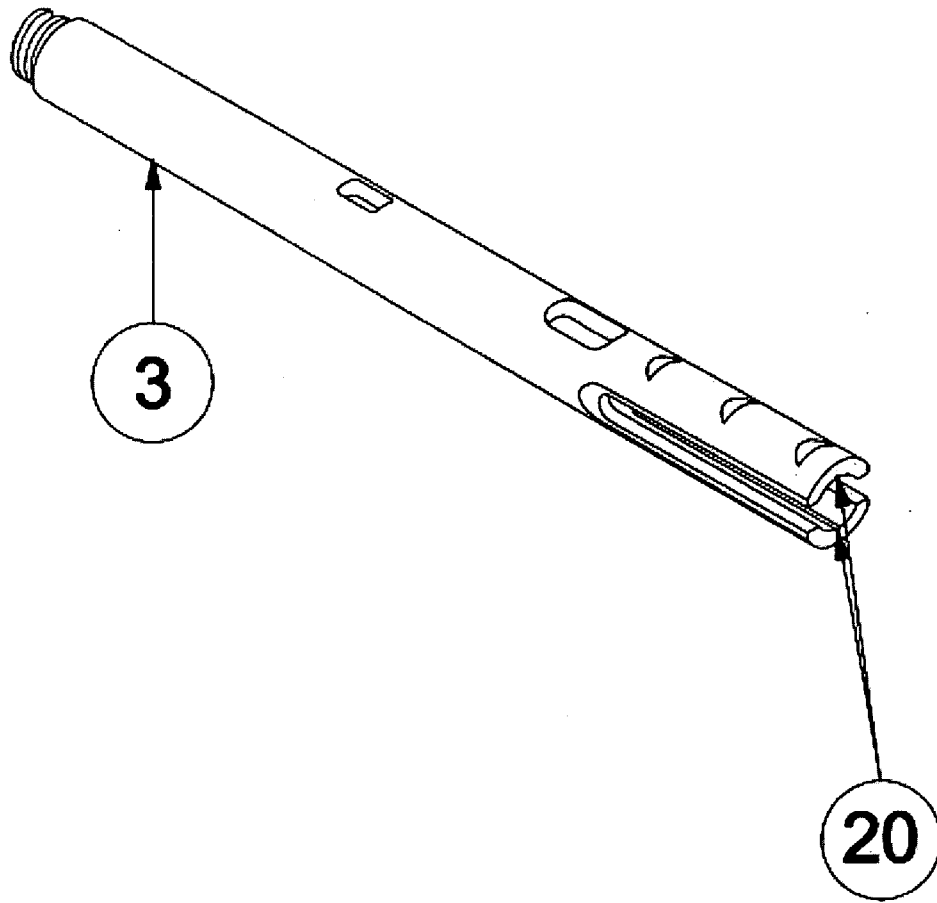


Figure 12