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(56) Documents Cited:
WO 2014/080020 A1 **WO 2012/022810 A2**
WO 2003/039632 A2 **DE 102005006771 A1**
US 20070073232 A1

(58) Field of Search:
INT CL **A61J, A61M**
Other: **WPI, EPODOC.**

(54) Title of the Invention: **Closure member with septum**
Abstract Title: **Injection device**

(57) A medical injection device comprising a container having an inner storage for holding a fluid, a closure member having a septum barrier that provides a seal for the fluid in storage, a piston having a hollow needle that pierces the septum when pressure is applied to the rear of said container providing a flow path for said liquid. Preferably, the piston may have one or more seals that may be coated, constructed from one or more materials that includes elastomer blend, thermoplastic elastomer or a polymer. Preferably the inner storage will be pre-filled or have a method for re-filling. Preferably the combination of seals above the closure member septum will provide sterility during storage. Further embodiments will preferably include a modular dispenser for use with a smart phone, and a wearable device.

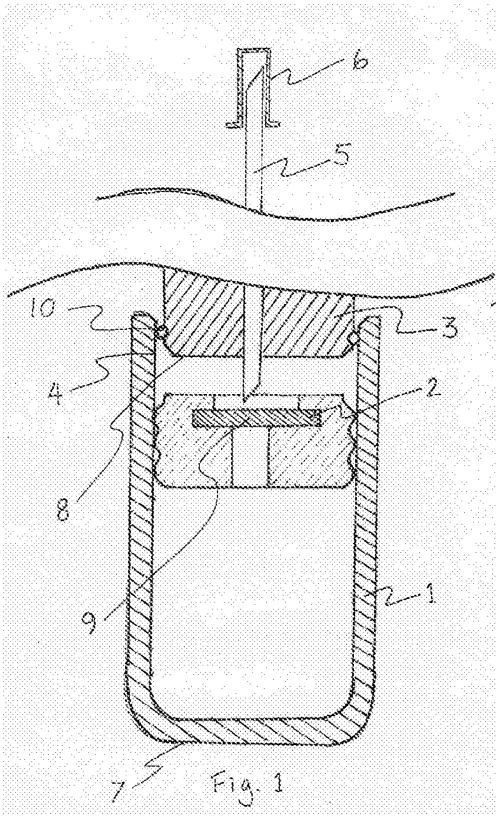

Fig. 1

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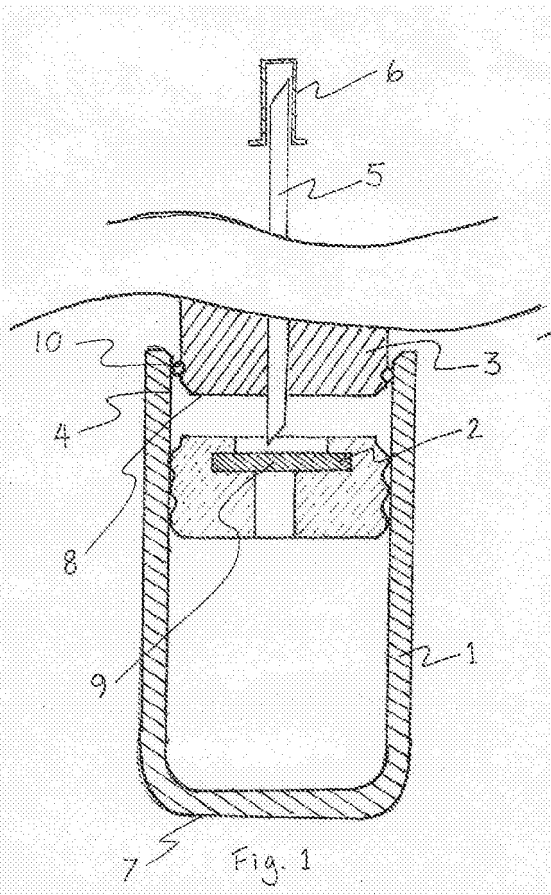

Fig. 1

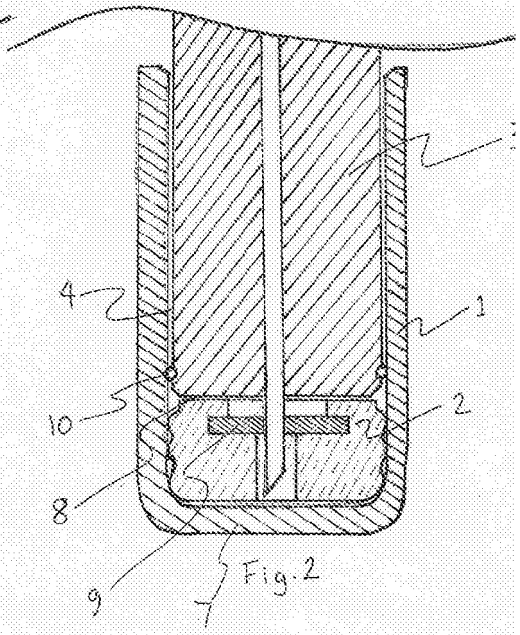

Fig. 2

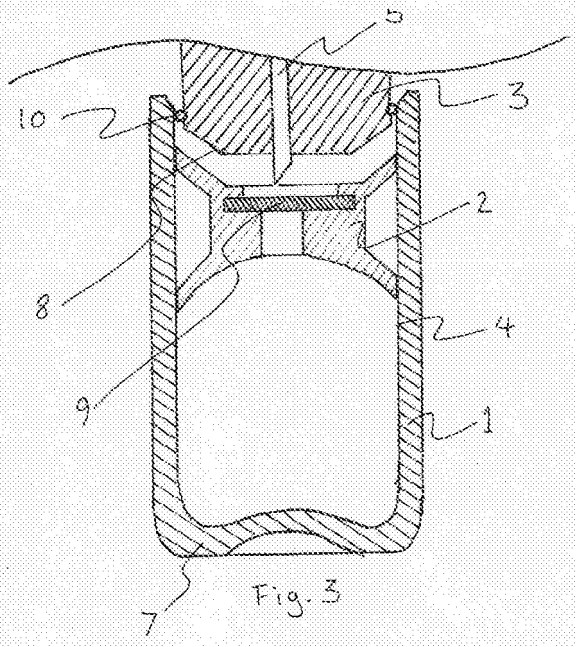

Fig. 3

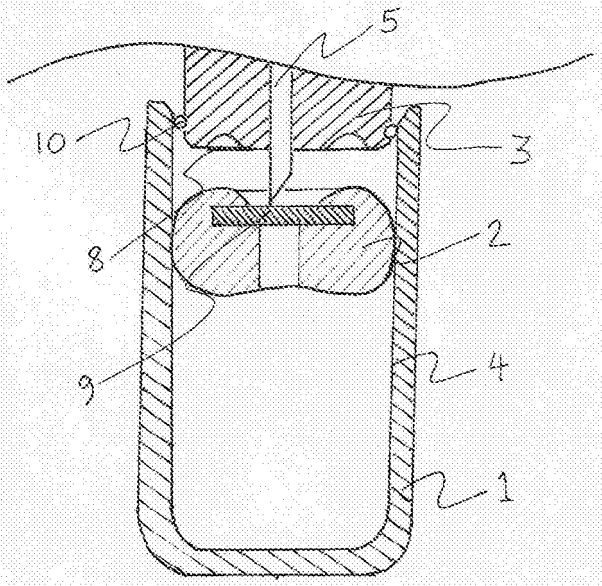

Fig. 4

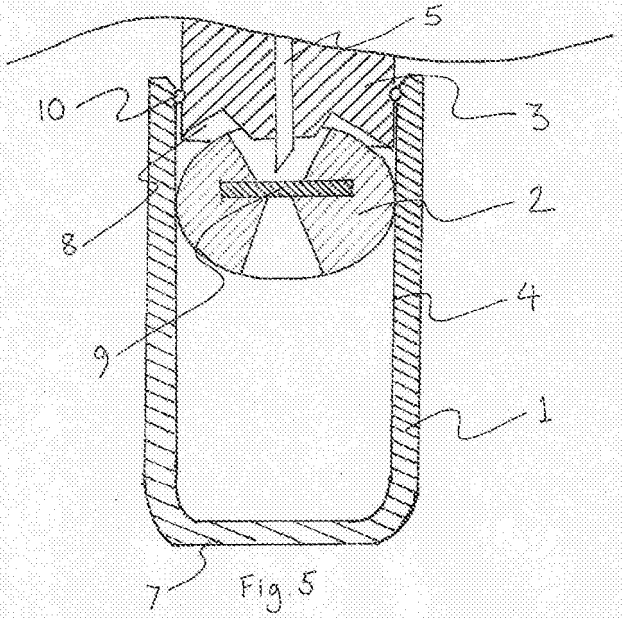

Fig. 5

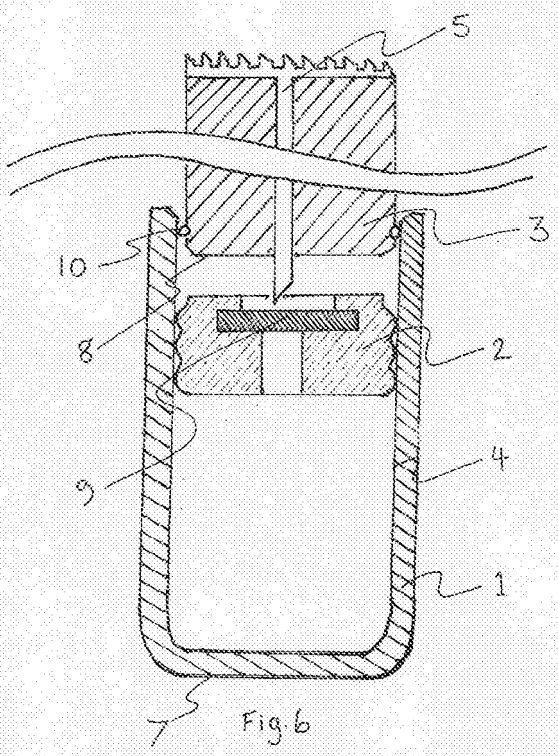

Fig.6

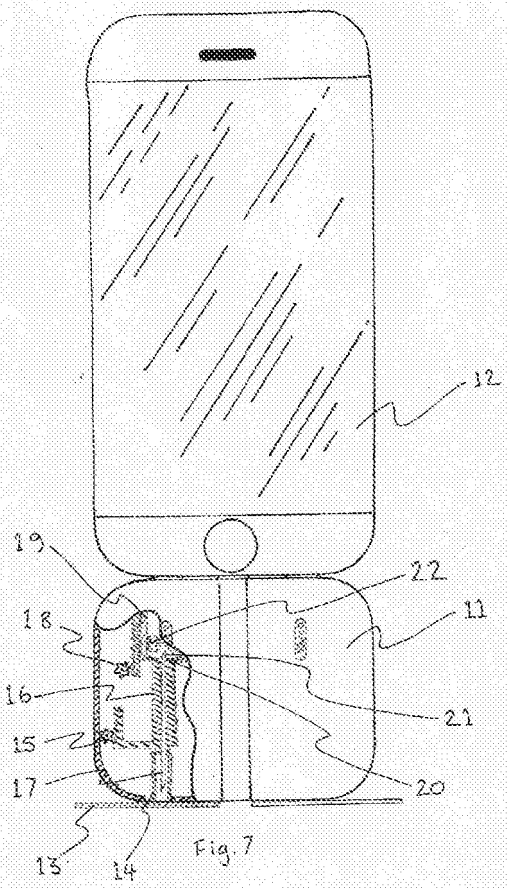

Fig. 7

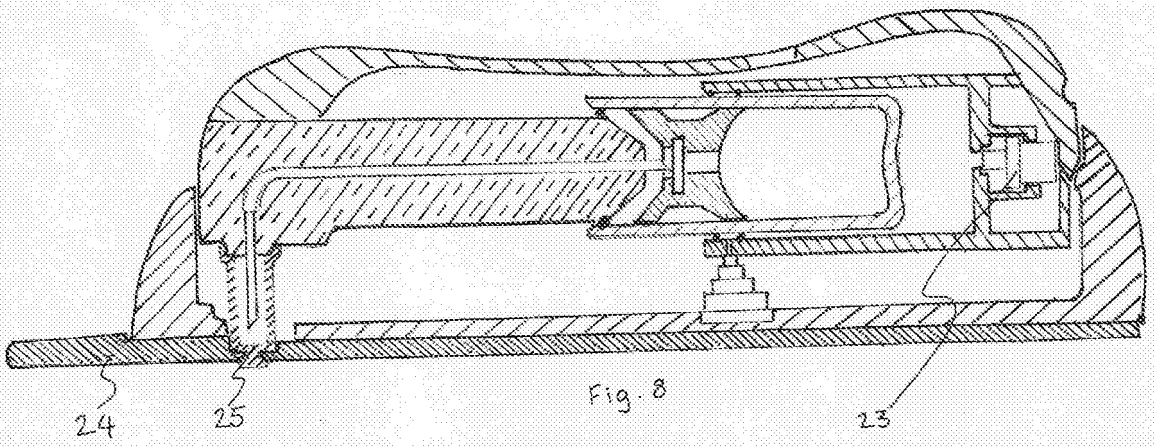

Fig. 8

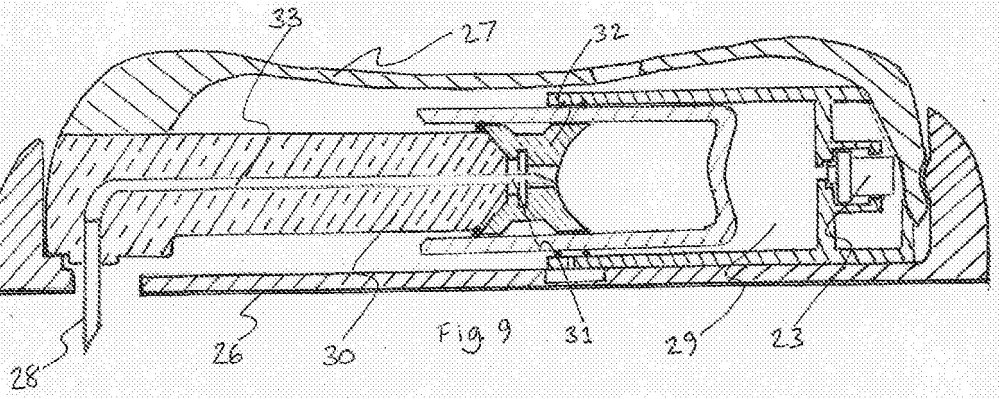

Fig 9

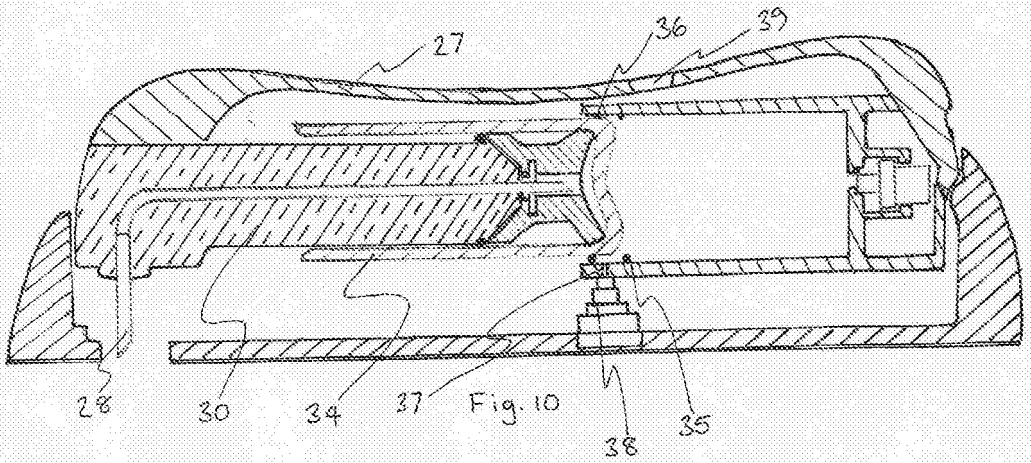

Fig. 10

The following terms are registered trade marks and should be read as such wherever they occur in this document:

Gore-tex
PEBAX

Title - Closure member with septum

Background - This invention relates to a primary container with a closure member which includes a piercing septum member. The piercing element is incorporated into a piston which also has an additional seal feature with container which creates an aseptic barrier between the piercing event and the closure member septum. A closed end container (1) holding a drug substance for dispensing is sealed with the closure member and septum (2). A piston including a piercing element (3) mounted above the closure member septum, is sealed (10) within side the container walls (4). The other end of the piercing element has one or more needles to be inserted into the patient allowing the fluid to be expelled, before the device can be used the insertion element (5) needs to have an aseptic cover (6) removed. For a flow path to be generated force is applied to the rear of the container (7), this intern drives the closure member septum towards the piercing feature and the piston shoulder forms (8), as the container moves forward the septum (9) is pierced and creates a fluid path to the patient.
This primary container is particularly adapted for pre-filled administration, for parenteral drug delivery for a number of different disorders or for emergency use.
The use of pre-filled devices is expected to accelerate over the coming decades. For the pharmaceutical and biotech companies, the advantages of pre-filled devices are minimising drug waste; increasing product life span, delivering reliable performance and enhancing the level of market share are some of the driving market demands. For healthcare workers, pre-filled devices are recognised as an efficient, safe and convenient method for drug administration. Furthermore, the ease at which a patient can self-administer many types of injectable drugs make pre-filled devices of healthcare treatment out of hospital and into the home setting, another important factor is these devices enhance compliance and adherence by the operators.

Statement of invention - The objective of the invention is to overcome any coring of a closure member which can block the piercing element and prevent drug from being delivered to the patient, this present invention proposes one or more septum elements to eliminate this occurrence.
The container only has one opening therefore providing a greater barrier for the fluid retained reduces any evaporation loss over the shelf life of the drug. The invention provides a single dose of formulation for dispensing from 0.1 mL to 30 mL.
An advantage of the invention is the septum can be used to fill the container reducing gas bubble or headspace above the drug, reducing the gas bubble improves the stability of oxygen sensitive compounds and limits any closure member movement.
Another benefit with the septum it reduces the risk of particulates entering the container solution.

Advantages - Examples of the invention and embodiments will now be described by referring to the accompanying drawings:

Figure 1 shows a sectional view of the primary container including the closure member and septum prior to actuation of the contents; and
Figure 2 shows the closure position post use, with the fluid contents dispensed;
Figure 3 is a sectional view of a quad closure member embodiment with a formed piston profile to match the top of the closure member to aid engagement and enhance sealing, the base of the closure member is also formed in the same profile of the container base to reduce ullage;
Figure 4 and 5 are sectional views of alternative embodiments prior to use;
Figure 6 is a sectional view with a cap removed from the patient end with multiple small needles exposed;
Figure 7 shows a modular (11) embodiment that can be attached to a smart phone (12) or similar device, the cut away section shows a peal-able base (13) which is connected to the needle cover (14), once removed, the first gears (15) is used to drive the piston (16) and assemble forward inserting the needle (17) into the patient, the second gear (18) is used to move the the primary container (19) forward onto the piston (20) where the rear piston piercing element (21) is driven through the closure member septum (22) allowing the contents to be discharged into the patient. This embodiment allows for more control over settings such as injection depth, dose, speed of

injection, indicators, it can reduce errors by providing reminders and prompts through the user sequence steps on the smart device. Incorporating this module (11) onto a smart device (12) also allows real-time and historic data to be captured, prescribers and payers can also be notified to aid user interaction and marketing;
Figures 8 to 10 are sectional views of a wearable device embodiment that is configured with a gas propulsion valve (23) to drive the primary container, Figure 8 is in its un actuated position with the peal-able base (24) and the needle cap (25) still attached. Figure 9 shows the base (24) and needle cap (25) removed, the wearable device is then pressed on to the patients skin, an adhesive layer (26) provides attachment to the skin, by pressing the top body (27) down the needle (28) is inserted into the patient, the propulsion valve (23) is then moved forward opening a flow path for the gas to be expelled into a chamber (29) which in turn drives the primary container forward towards the piston (30) the needle (31) on the piston then pierces the septum (32) creating a flow of fluid through the piston channel (33) and the needle (31) inserted in the patient. Figure 10 shows the primary container (34) has emitted all the fluid and the container has travelled beyond a seal (35), but not beyond the main chamber seal (36), this open pathway (37) allows the gas to enter a collapsed piston (38), as the gas expends the piston drives the top body (27), piston (30) and primary container (34) up, this then retracts the needle (28) from the patients skin and renders the the device needle safe and provides a visual (39) and tactile indication that the device has completed dispensing the fluid. The device can then be removed from the skin.

Detailed description - The closure member described is preferably made of an elastomer material, but may also be made from other suitable materials known to those skilled in the art, such as a low density polyethylene (LDP) or high density polyethylene (HDP) which could provide compatibility and seal integrity with the container. The closure member has a shoulder which the septum sits above, this feature provides additional resistance when being pierced, aiding elimination of coring. The septum can be made from a number of materials such as butyl rubber, synthetic polyisoprene rubber, PTFE, silicone, Gore-Tex or any other gas permeable and hydrophobic materials. The septum can also be made from multi-layer material or have additional profiling to aid piercing characteristics. Other suitable elastomer materials include halo-butyl, hydrogenated nitrile, polychloroprene, EPDM, FPDM/PP, polyamide, Hytrel, PEBAX or an elastomeric material that is FDA compliant and has low extractable and leachable profiles. The closure member septum may also be made from any other suitable material known to those skilled in the art of primary container design. Both the closure member and septum can also be coated to aid formulation compatibility and also for aiding break loose and glide force profiles. The septum and the closure member are ideally formed integrally to enhance the sealing properties.

The present invention provides a closure member and septum suitable for sealing on outlet of a container, which moves inside the container. The piercing of the septum with the hollow needle through the closure member advantageously allows fluid to be dispensed from the container with minimal force. The hollow needle can be run all the way through the piston or has a channel that can incorporate a needle at the primary container end and have one or more needles at the patient end connected to the piston. The container comprises a casing defining an outlet and an interior. A metered dose of fluid medicament is pre-filled into the interior of the container. The container is constructed from glass, or an impermeable polymer, or both or be multi-layered and be coated to reduce friction or enhance stability characteristics. The piston at the container end has at least one o-ring or similar seal to provide sterility at the piercing end into the closure member septum, this can be integrated onto the piston to reduce components. To make sure the piston is sealed within the container the cap at the patient end needs to be removed to aid positioning the piston into the top of the container opening, once positioned the patient needle end needs to be covered by a cap.
The primary container can be used with various energy sources to drive the container towards the piston such as spring, gas or propellant, motor such as a stepper motor, direct current motor or a linear actuator, it can also be forced manually or be used with other driving energy technologies.

Claims -

1. A container for holding medicament, the container comprising inner storage for holding fluid and a closure member with a septum which provides a seal for the fluid in storage, upon increased pressure of the container the piston and hollow needle are forced into the container, piercing the closure member septum providing an outflow of fluid through the needle and piston.
2. A container according to claim 1, where the piston has one or more seals above the closure member septum and the piercing needle, to provide sterility during storage.
3. A container according to claim 1 or claim 2, wherein the closure member has a shoulder that runs circumferentially inside the closure member where the septum sits on providing a smaller channel for the needle to penetrate that reduces ullage.
4. A container according to claim 3, wherein the closure member has a shoulder that runs circumferentially inside the closure member where the septum sits that aids piercing of the septum.
5. A container according to claim 3 or claim 4, wherein the outer circumferential edge of the closure member and septum seals the interior of the casing.
6. A container according to any one of the proceeding claims, further comprising at least one sealing portion of the closure member engaged with the casing.
7. A container where the closure member septum can be used for filling through and then seal whilst being within the container casing.
8. A container according to any of the proceeding claims wherein the closure member is displaceable relatively to the container casing wherein, in use, displacement of the closure member septum increases the pressure in the interior of the container prior to being pierced.
9. A container according to any one of the proceeding claims, wherein the closure member is made of an elastomer blend, thermoplastic elastomer or a polymer.
10. A container according to claim 9, wherein the septum is made from one or more materials.
11. A container according to claim 10, wherein the septum has a top layer profile to aid piercing.
12. A container according to any of the proceeding claims, wherein the closure member and septum are coated.
13. A closure member according to claim 9 to 12 wherein, said closure member and septum are integrally formed.
14. A container according to any one of the proceeding claims, wherein said container is a pre-filled vial of medicament.
15. A container comprising a piston and hollow needle for piercing the septum and displacing the closure member within the container.
16. A piston according to claim 15, wherein the face of the piston has a similar profile to the closure member top face to to aid engagement and sealing properties.
17. A piston according to claim 16, wherein the piston has a conical flange.
18. A container substantially as herein described and with reference to the accompanying figures.
19. A closure member and septum substantially as herein described and with reference to the accompanying figures.
20. A modular dispenser for a smart phone as herein described and with reference to the accompanying figures.
21. A wearable device substantially as herein described and with reference to the accompanying figures.

Intellectual Property Office

Application No:	GB1603436.5	**Examiner:**	Mr Gary Clements
Claims searched:	1-21	**Date of search:**	12 July 2016

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-17	WO03/039632 A2 (MERIDIAN MEDICAL TECHNOLOGIES INC)-See description and figures 1-13.
X	1 at least	DE102005006771 A1 (ZIHLMANN)-See WPI abstract and figures 1-10.
X	1-17	US2007/0073232 A1 (PICKHARD)-See description and figures 1-7h.
X	1-17	WO2014/080020 A1 (DUNNE)-See description and figures 1-12d.
X	1-17	WO2012/022810 A2 (PEDERSEN, et al.)-See EPODOC abstract and figures 1-13b.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61J; A61M

The following online and other databases have been used in the preparation of this search report

WPI, EPODOC.

Intellectual Property Office

International Classification:

Subclass	Subgroup	Valid From
A61J	0001/06	01/01/2006
A61J	0001/05	01/01/2006
A61J	0001/14	01/01/2006
A61J	0001/20	01/01/2006
A61M	0005/145	01/01/2006
A61M	0005/24	01/01/2006