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(54) Title: PREFILLED CONTAINER SYSTEMS

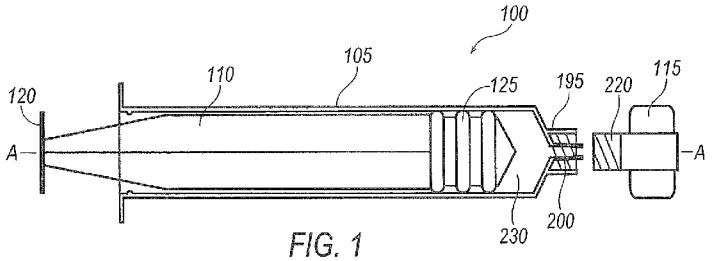

FIG. 1

(57) Abstract: A syringe assembly (100) may include a plunger (110) having a stopper (125). A barrel (105) may be configured to receive the plunger at an open first end (180). A tip cap (115) may be removably attached to the second end (185) and may form a chamber (230) within the barrel between the plunger and tip cap. The chamber may be configured to contain a sterilization sensitive material. The barrel may be formed of a plastic material having a high barrier property configured to create a barrier between the sterilization sensitive material and gases produced for sterilization purposes such that the sterilization sensitive material remains unchanged during a sterilization procedure.

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AMENDED CLAIMS
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1. A syringe assembly 100, comprising:

a plunger 110 including a stopper 125;

a barrel 105 having an open first end 180 and an opposite second end 185, wherein the open first end 180 is configured to receive the plunger 110;

a tip cap 115 removably attached to the second end 185 and configured to form a chamber 230 within the barrel 105 between the stopper 125 and the tip cap 115, wherein the chamber 230 is configured to contain a sterilization sensitive material, and

wherein the barrel 105 is formed of a plastic material configured to create a barrier between the sterilization sensitive material and gases produced for sterilization purposes such that the sterilization sensitive material remains unchanged during a sterilization procedure.

2. The syringe assembly 100 of claim 1, wherein the plastic material includes at least one of a cyclic olefin polymer (COP) and a cyclic olefin copolymer (COC).

3. The syringe assembly 100 of claims 1 or 2, wherein the stopper 125 is formed of a thermoplastic elastomer configured to create a barrier between the sterilization sensitive material and the gases produced from sterilization.

4. The syringe assembly 100 of claim 3, wherein the elastomer is a butyl rubber.

5. The syringe assembly 100 of any of the proceeding claims, wherein the stopper 125 includes at least one wiper 150 extending radially outwardly and configured to engage an inside surface of the barrel 105 creating a leak free mechanical engagement.

6. The syringe assembly 100 of claim 5, wherein the barrel 105 includes a barrel flange 210 extending radially inwardly of an inner surface of the barrel 105, whereby the barrel flange is configured to engage a plunger flange 170 or at least one wiper 105 to prevent expulsion of the plunger 110 from the barrel 105.

7. The syringe assembly 100 of any of the preceding claims, wherein the sterilization

procedure includes at least one of EtO sterilization and autoclaving.

8. A packaged kit , comprising:

a plastic container system 100 having a plunger 110 and a barrel 105 configured to receive the plunger 110, wherein the plunger 110 includes a stopper 125 and the barrel 105 is configured to receive the plunger 110 at an open first end 180;

the container system 100 further including a tip cap 115 removably attached to a second end 185 of the barrel 105 and configured to form a sealed chamber 230 within the barrel 105 between the stopper 125 and the tip cap 115, wherein the chamber 230 is configured to contain a sterilization sensitive material,

further wherein the barrel 105 is formed of a plastic material having configured to create a barrier between the sterilization sensitive material and gases produced for sterilization purposes such that the sterilization sensitive material remains unchanged during a sterilization procedure, and

a packaging into which the container system is received.

9. The packaged kit of claim 8, wherein the plastic material having includes at least one of a cyclic olefin polymer (COP) and a cyclic olefin copolymer (COC).

10. The packaged kit of claims 8 or 9, wherein the stopper 125 is formed of a thermoplastic elastomer configured to create a sealed barrier between the sterilization sensitive material and the gases produced for sterilization purposes.

11. The packaged kit of claim 10, wherein the elastomer is a butyl rubber.

12. The packaged kit of any of claims 8-11, wherein the stopper 125 includes at least one wiper 150 extending radially outwardly from a cylindrical portion 140 of the plunger 110 and configured to create a mating surface with the inside of the barrel 105 creating a leak free mechanical engagement.

13. The packaged kit of any of claims 8-12, wherein the barrel 105 includes a barrel flange 210 extending radially inwardly of an inner surface of the barrel 105, whereby the

barrel flange is configured to engage a plunger flange 170 or at least one wiper 105 to prevent expulsion of the plunger 110 from the barrel 105.

14. The packaged kit of any of claims 8-13, wherein the sterilization procedure includes at least one of EtO sterilization and autoclaving.

15. The packaged kit of any of claims 8-14, further comprising a vial 240 configured to contain a vial sterilization sensitive material and constructed of a material configured to create a barrier between the vial sterilization sensitive material and the gases produced for sterilization purposes such that the vial sterilization sensitive material remains unchanged during a sterilization procedure.

16. A method of sterilizing, comprising:

assembling a syringe assembly 100 including:

inserting a tip cap 115 at an end of a barrel 105;

filling the barrel 105 with sterilization sensitive material at an opposite end of the barrel 105; and

inserting a plunger 110 into the barrel 105 at the opposite end to seal the material within the barrel 105;

inserting the syringe assembly 100 into a package so as to create a packaged kit; and

performing terminal sterilization of the packaged kit, wherein upon exposure to sterilization, the sterilization-sensitive material remains substantially unchanged.

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18. Canceled.

19. Canceled.

20. Canceled.