SoloStar - principles of operation

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1.1 OVERVIEW

1.1.1 Description of SoloStar®

SoloStar® injection system is a device that provides a method of accurately injecting a selected dose of insulin through a single lumen hypodermic needle. SoloStar® is intended to be used for self-injection by patients. Patients who are not able to handle the device properly (according to Health Care Professional's assessment) require assistance from a third person. SoloStar® system is a disposable insulin injection system that by design, cannot be reused.

In appearance and general handling characteristics, SoloStar® injection system is similar to other pen injectors used for the administration of insulin.

The dose to be injected is pre-selected by rotating a dosage selector at the rear end of the device. The number of selected insulin units is displayed in the thread insert (dose window) on the side of the pen. Before the injection, a pen injector needle is mounted onto the front end of the device and inserted under the skin. The dose is delivered by pressing the button until it is in its original end position.

SoloStar® pen is a fully disposable injection system, offering a simple handling, by eliminating the need for cartridge change.
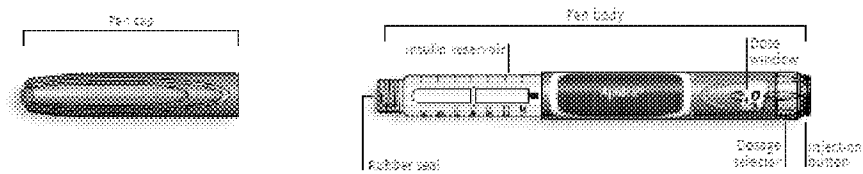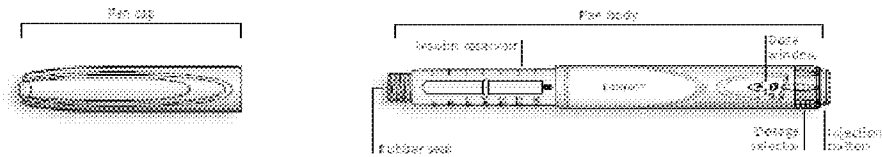

Figure 1 - Apidra® SoloStar®

Figure 2 - Lantus® SoloStar®

The injection system provides a method of accurately injecting a selected dose. Dose setting is a mechanical process.

The dialing mechanism allows dosage in one insulin unit increments. It provides a maximum of 80 insulin units in one dosing. The total content of the cartridge is 300 insulin units.

For the safety and convenience of the user, as well as for the protection of the cartridge, a pen cap has been incorporated as part of the pen system.

1.1.2 Cap and Cartridge Holder subassembly

As detailed below, a printed cartridge holder (12) is pre-assembled into the pen cap (13) and delivered to the final assembly. The cartridge holder printing helps the patient to determine, as an indication, how much insulin is left in the cartridge (14).

A threaded end on the cartridge holder allows the patient to attach a pen-injector needle. A needle is not delivered with SoloStar® pen-injector.
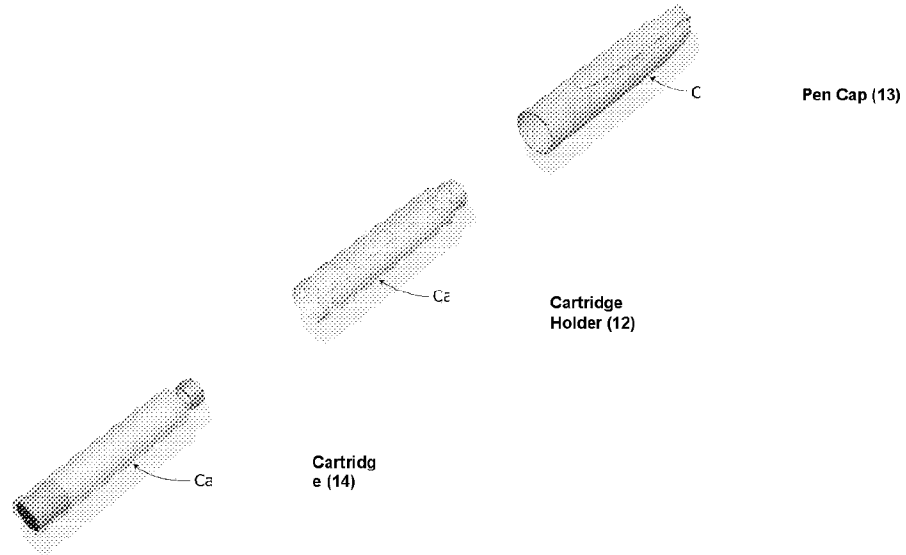

Figure 3 - Cap and Cartridge Holder subassembly

There are snap features between cartridge holder and pen cap that allow the pen cap to be fixed onto the cartridge holder in defined positions. The removal method for the cap is pull-off. The pen cap is designed to protect the cartridge from damage and dirt. The clip on the pen cap allows attachment to a shirt or jacket pocket.

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