

1 Sterile Disposable Needle

1.1 General Description

The proposed device, Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. The proposed device is provided sterile and single use.

The proposed device, Sterile Disposable Needle consist of three components 1) Needle 5) Needle Hub 6) Protective Cap. Detailed information of design drawing and design description are presented in *Section 5.6 Device Drawings* and *Section 5.7 Design Description*.

The proposed devices are available in various combination of needle gauge and length. The detailed device specification is presented in *Section 5.8 Specification*.

The proposed devices are sterilized by Ethylene Oxide to achieve a SAL of 10^{-6} and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 5 years. The detailed package description is presented in *Section 5.10 Packaging Description*. Detailed sterilization and shelf life information are provided in **Tab 12 Sterilization and Shelf Life**.

1.2 Mechanism of Action

The mechanism of action is the needle hub provide a standard female luer slip connector which may connect to a syringe with a male conical fitting. Then the needle tube is punctured into vein for injection operation, the fluid will flow into vein under the action the pull force of plunger.

1.3 Principle of Operation

The proposed device is operated manually.

1.4 Condition of Use

The proposed devices are intended for prescription use. The proposed device shall be used with syringe and operated by trained healthcare professions.