

Safe-T-Flush™ Pre-Filled Saline Syringe

1 Product Description

The Safe-T-Flush™ Pre-Filled Saline Syringe is a three-piece, sterile, single use syringe with a 6% conical taper luer connector, prefilled with 0.9% Sodium Chloride (0.9% NaCl) USP, and sealed with a nozzle cap.

2 Specification

PFSFS03 – 3cc / mL, PFSFS05 – 5cc / mL, PFSFS10 – 10cc / mL

3 Classification

Class IIb

4 Indications for Use

The Safe-T-Flush™ Pre-Filled Saline Syringe is intended to be used for the flushing of the central and peripheral vascular access devices.

5 Product Structure and Material

<i>Component</i>	<i>Material</i>	<i>Properties</i>
Barrel	PP 1350R	Transparent, high temperature resistant
Plunger	PP 1350R	Transparent, high temperature resistant
Gasket	Brominated Butyl Rubber	Black
Nozzle Cap	PP J-560M/White Master CM 10000	White
Scale Labeling	Plastic film (PVC)	Printed scale and UDI
Barrel Lubricant	HC-SS36	/
Sodium Chloride Injection	Sodium Chloride (NaCl) USP	0.9%

6 Biocompatibility

The device complies with the requirements of standard for biocompatibility of medical devices, ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

7 Sterilization

Steam or dry heat sterilization

8 Shelf Life

3 years

9 Storage

Device should be stored between the temperature of 59-86°F / 15-30°C

10 Package Information

<i>Specification</i>	<i>Material and Quantity</i>		
	<i>Single Package</i>	<i>Inner Box</i>	<i>Outer Case/Carton</i>
PFSFS03 – 3cc / mL	OPP Composite Film	Corrugated paper box /30pcs	A=B Double flute /600pcs
PFSFS05 – 5cc / mL	OPP Composite Film	Corrugated paper box /30pcs	A=B Double flute /600pcs
PFSFS10 – 10cc / mL	OPP Composite Film	Corrugated paper box /30pcs	A=B Double flute /300pcs