

INSTRUCTIONS FOR USE

SPM/TF- CE/ Flush Syringe- Blister/IFU- 08, Rev. No.: 09 Date: 11/05/2026



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INSTRUCTION FOR USE

Flush Syringe (Prefilled 0.9 % saline solution)

 DATE: 11-05-2026	 DATE: 11-05-2026	 DATE: 11-05-2026
Prepared By Executive- QARA	Reviewed By Head-RA	Approved By Managing Director/Auth. Signatory

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For Sterile Variant Only

Follow manufacturer's instructions for use and institutional procedures for flush administration.

DESCRIPTION

Flush Syringe (Prefilled 0.9 % saline solution) is a ready-to-use flush syringe intended to clear intravenous lines. Flush Syringe (Prefilled 0.9 % saline solution) is a polypropylene pre-filled syringe that contains sterile, non-pyrogenic 0.9% w/v sodium chloride (saline) solution. Flush Syringe (Prefilled 0.9 % saline solution) is a sterile, single-use, non-toxic and non-pyrogenic medical device. It is sterilized by gamma irradiation.

A Flush Syringe (Prefilled 0.9 % saline solution) is used to help prevent vascular access systems from becoming blocked and to help remove any medication that may be left at the catheter site. The syringe is designed for manual use.

IMAGE OF THE DEVICE



Figure 1: Flush Syringe (Prefilled 0.9 % saline solution)

MODELS

Sr. No.	Device / Model / Size / Variant	Catalogue No. / UDI-DI / Remarks
1.	3ml	1BO7R3S
2.	5ml	1BO7R5S
3.	10ml	1BO7RXS
4.	3ml in 10ml	1BO7R3XS
5.	5ml in 10ml	1BO7R5XS
6.	3ml in 5ml	1BO7R35S
7.	20ml	1BO7RYS
8.	50ml	1BO7RZS
9.	100ml	1BO7RGS
10.	3ml	1BV7B3D
11.	5ml	1BV7B5D
12.	10ml	1BV7BXD
13.	3ml in 10ml	1BV7B3XD
14.	5ml in 10ml	1BV7B5XD
15.	3ml in 5ml	1BV7B35D

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16.	20ml	1BV7PYD
17.	50ml	1BV7PZD
18.	100ml	1BV7PGD

INTENDED PURPOSE

Flush Syringe (Prefilled 0.9 % saline solution) is intended for flushing compatible intravenous administration sets and indwelling intravenous access devices.

INDICATIONS FOR USE

- Flush Syringe (Prefilled 0.9 % saline solution) is designed to be used with ISO compliant luer components for intravenous applications.
- Flush Syringe (Prefilled 0.9 % saline solution) is intended to be used FOR FLUSHING ONLY.
- Flush Syringe (Prefilled 0.9 % saline solution) is not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated.

INTENDED PATIENT POPULATION

Flush Syringe is intended to be used in patients irrespective of age and gender.

INTENDED USER

Flush Syringe is intended to be used by trained healthcare professionals including doctors, registered practitioners, paramedics or nursing staff experienced in the use of vascular access devices.

INTENDED USE ENVIRONMENT

Flush Syringe is intended to be used in hospitals and clinics.

CLINICAL BENEFITS

- Reduces number of steps for the user as compared to a conventional IV injection used for flushing to manually prepare a flush syringe.
- Saves time because of its ready-to-use application
- Reduces the risk of contamination due to less exposure to environment before use

PRINCIPLE OF OPERATION

Flush Syringe is used to flush out compatible intravenous administration sets and indwelling intravenous access devices. It helps to prevent blockage and remove any medicine left in the catheter. The mechanical pressure is generated in syringe through manual push to eject 0.9% w/v sodium chloride (saline) solution.

Sodium chloride is an electrolyte that is used to maintain the balance of fluid in and around the body cells and tissues once administered.

PERFORMANCE CHARACTERISTICS

- Interoperability with Vascular Access Devices (VAD).
- Successful Flushing

MATERIALS USED

- **Barrel, Plunger & Tip Cap** - Polypropylene
- **Gasket** - Bromo butyl rubber (Latex-free)
- **Gasket Mixing** - Silicon 1000 CST
- **Barrel spray** - Silicon 1000 CST
- **Sodium Chloride** - 0.9% w/v sodium chloride (saline) solution

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CONTRAINDICATIONS

- Do not use if the patient has a known allergy to any of its components, materials, or 0.9% w/v sodium chloride solution. It may lead to an allergic response resulting in anaphylaxis.
- Do not use if the intravenous administration sets and/or indwelling intravenous access devices are contaminated by microorganisms or the human body (skin) around the access device is inflamed
- Do not use in patients suffering from hypernatremia and fluid retention when the administration of sodium or chloride could be clinically detrimental.

POTENTIAL COMPLICATIONS

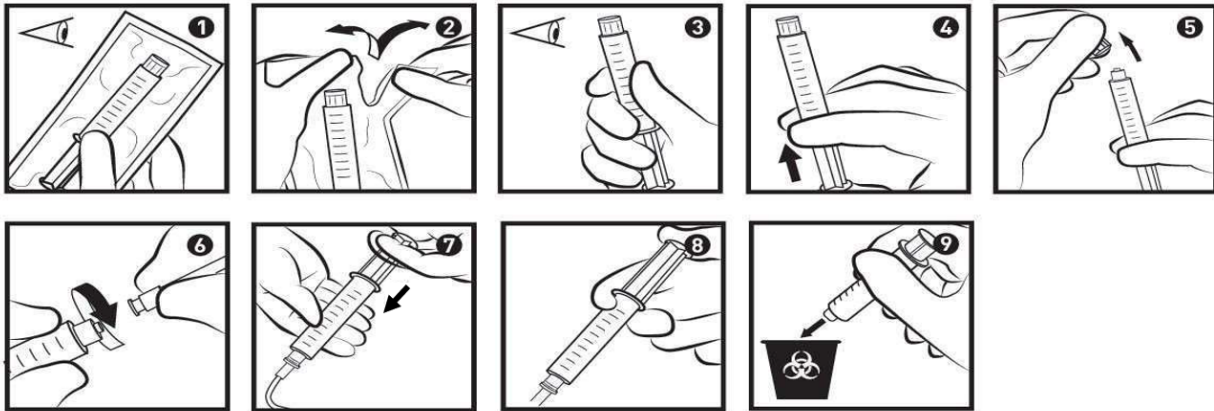
- Possible complications and/or adverse reactions associated with flushing may include sepsis or septicaemia, infections (localized/systemic) exposure to bloodborne pathogens, air embolism, particulate embolism, blood clots, thrombophlebitis, leakage that may lead to hazardous drug/fluid exposure, irritation, a transitory taste or odour during flushing. The use of contaminated normal saline products may lead to infection and possibly death.
- Not using an aseptic technique and failure to adhere to flushing guidelines may lead to catheter failure, catheter related complications such as occlusion, infiltration, extravasation, erythema, swelling, pain, injury, infection, sepsis, or death.

DIRECTIONS FOR USE:

- **Step 1.** Inspect the product packaging. Do not use if the unit packaging is damaged or not intact. (Figure-1).
- **Step 2.** Peel open the package as shown (Figure-2).
- **Step 3.** Inspect the solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged. (Figure-3)
- **Step 4.** Ensure the cap is in place, then depress the plunger to release the stopper seal and activate the syringe. Improper activation may make the syringe difficult to use and/or cause plunger rod separation. Never draw back the plunger rod, as the product may become contaminated (Figure 4).
- **Step 5.** Remove the tip cap by twisting it off using aseptic technique. Hold the syringe unit upright and prime it to expel any air bubbles if present. (Figure 5)
- **Step 6.** The syringe is now ready to use. Per institutional protocol, attach the flush syringe to the access device and flush (Figure 6).
- **Step 7.** Flush the required amount of saline by pressing the syringe plunger slowly to avoid excessive pressure. If you experience plunger resistance, it is recommended, do not apply excessive force. Do not pull or bend the plunger sideways. (Figure 7)
- **Step 8.** Use in accordance with intravenous tubing or indwelling device manufacturer's recommendation. After flushing, gently remove the syringe from the access device. (Figure 8)
- **Step 9.** Discard the empty unit after use. Discard any unused portion. Do not reuse disposable syringes. (Figure 9)

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HOW SUPPLIED

Flush Syringe is supplied sterile and packed in a paper pouch. Thirty (40) such pouches are enclosed within a printed duplex box. The overall packing contains eight (8) duplex boxes and external identification stickers.

WARNINGS

- Do not reuse. Re-use may lead to infection or other illness.
- Do not re-sterilize the device by any method. Do not reprocess. It is not intended to be reprocessed and used again, even on the same patient.
- Reprocessing may compromise sterility, biocompatibility, and functional integrity of the device.
- SPM Medicare assumes no liability for the devices that have been re-use or re-sterilized.
- Do not use it if the product has been left at freezing temperature.
- Do not use the device after expiry date or the unit package or content is damaged.
- Store at specified temperature and humidity.
- Small parts are a potential choking hazard. After use, discard small parts according to the hospital protocol.
- Do not use it if the solution is cloudy or colored, contains a precipitate, or has any type of suspended particulate matter.

PRECAUTIONS

- Flush Syringe is designed to be used with ISO luer compliant components for intravenous applications
- Check the product for visual defects/cracks.
- Gradation is provided on the syringe to flush the required amount of saline.
- Avoid crushing and crimping damage to the product due to the application of surgical instruments such as forceps.
- Store at a controlled temperature (10-40°C) and humidity (55% - 75%). Do not leave at freezing temperature.
- Check with drug manufacturer instructions for use to ensure compatibility with 0.9% w/v sodium chloride solution before use. If 0.9% w/v sodium chloride solution is not compatible, follow the drug manufacturer's instructions for flushing practices, or first flush the vascular access device (VAD) with a compatible solution to remove traces of the medication in accordance with manufacturer and institution policies.
- Clinicians should consider the patient's specific medical conditions, treatment needs, age, and weight that may require restricted sodium or fluid intake when deciding to flush with 0.9% w/v sodium chloride.
- Saline flushes should be taken into account when prescribing fluids to not exceed fluid intake guidelines. Follow instructions for use, and institution procedures for flush administration.

CAUTIONS: 

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- Carefully read all instructions prior to use.
- Do not use if the package is open or damaged.
- For single use only. Discard any partially used product.
- The solution and fluid path are sterile and non-pyrogenic if the tip cap is in place, the syringe is intact, and there is no evidence of leakage. Use proper aseptic technique.

STORAGE

Store at a controlled temperature (10-40°C). Do not store at freezing temperature.

EXPIRATION PERIOD

The device has a shelf life of 3 years from the date of manufacturing. The product should not be used after the indicated sterility expiration date.

RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase information, your reference, and reason for return. Please contact your local distributor office regarding product return/exchange.

DISPOSAL OF THE USED DEVICE

- Disposal of the used product should be done according to hospital procedures, State Regulations, national legislation or regional legislation.
- Device should be disposed after use on individual patient during a single procedure.
- Disposal of the packaging material should be done as biomedical waste.
- Any open packaging should be disposed as biomedical waste.
- Leftover products should be disposed as biomedical waste

REPORTING

In case of any adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product-related and that were not previously expected in nature, severity or occurrence, contact the manufacturer or authorized representative and competent authority of the member state where the user and/or patient is established.

REGISTERED ADDRESS AND MANUFACTURING FACILITY

<u>LEGAL MANUFACTURER AND MANUFACTURING FACILITY</u>	<u>AUTHORIZED REPRESENTATIVE</u>
 Manufacturer: SPM Medicare Pvt, Ltd B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. Manufacturing Site 1- B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. Manufacturing Site 2- Industrial Building Plot no 26, Sector 158, Noida, Gautam buddha, Nagar, Uttar Pradesh, 201305. Customer care: No.: +91-840-7070-718 Email: info@spmmedicare.com Web Site: www.spmmedicare.com	EC REP CMC MEDICAL DEVICES & DRUGS S.L. C/ Horacio Lengo, 18 29006, Málaga, Spain Customer Care No.: +34 951 214 054 Email: info@cmcmmedicaldevices.com

EXPLANATION OF SYMBOLS

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Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Country & Date of manufacturing		Use-by date
	Do not re-sterilize		Temperature Limit
	Consult instructions for use		Non-Pyrogenic
	Keep away from sunlight		Sterilized using irradiation
	Do not re-use		Model number
	Fragile, handle with care		Maximum stacking
	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System
	Authorized representative in the European Community		Sterile
	Do not use if package is damaged		Keep dry

Revision History:

Rev. No	Document Section	Reason for Change	Date	Approval
09	REGISTERED ADDRESS AND MANUFACTURING FACILITY	Change of Authorized Representative.	11/05/2026	Managing Director