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**Technical IFU**

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**Prefilled Sodium Citrate Flush Syringe 4%, (w/v) Solution**

 DATE: 07/10/2025	 DATE: 07/10/2025	 DATE: 07/10/2025
<b>Prepared By</b> Assistant Manager- QA	<b>Reviewed By</b> RA Manager	<b>Approved By</b> Manging Director

## INSTRUCTION FOR USE

Doc. No.: SPM/IFU/ PFS with Sodium citrate /56. A - Rev. 02, Date: 03/10/2025

Follow manufacturer's instructions for use and institutional procedures for Sodium Citrate Solution administration:

**PRODUCT NAME:** Prefilled Sodium Citrate Flush Syringe 4%, (w/v) Solution

**DESCRIPTION:**

The SPM'S Prefilled Sodium Citrate Flush Syringe is a standard polypropylene luer lock syringe pre-filled with sterile 4% w/v Sodium Citrate solution. The syringe facilitates safe and quick flushing of venous access device using Sodium Citrate solution. The Prefilled Sodium Citrate Flush Syringe is non-pyrogenic, single use, non-toxic device and free from natural rubber latex and DEHP. The pre-filled syringe is sterilized by Gamma irradiation sterilization. The duration of the use is Short term.

A Sodium citrate solution is used to prevent vascular access systems from becoming blocked and to help remove any medication that may be left at the catheter site designed for manual use.

**IMAGE OF THE DEVICE:**



**DEVICE VARIANTS:**

S. No	Product Description	Volume	Tip Cap Color
1	Prefilled Syringe with Sodium Citrate 4% (w/v) solution,	3ml	Yellow
2	Prefilled Syringe with Sodium Citrate 4% (w/v) solution,	5ml	Yellow
4	Prefilled Syringe with Sodium Citrate 4% (w/v) solution,	10ml	Yellow

**INTENDED PURPOSE:**

Prefilled Syringe with Sodium Citrate solution is intended for flushing compatible intravenous administration sets and indwelling intravenous access devices.

**INDICATIONS FOR USE:**

- Prefilled syringe with Sodium Citrate solution is intended to maintain patency of an indwelling intravenous access device.
- Prefilled syringe with Sodium Citrate solution is preventing clotting in IV access medical devices (e.g., catheters) before and during operation/procedure.

**INTENDED PATIENT POPULATION:**

Prefilled Syringe with Sodium Citrate solution is intended to be used in patients who required venous access such as haemodialysis, CVC, etc.

**INTENDED USER:**

The intended users for the Prefilled Syringe with Sodium Citrate solution are healthcare professionals like medical practitioner, nurses, and other paramedic staff.

**INTENDED USE ENVIRONMENT:**

Prefilled Syringe with Sodium Citrate solution is intended to be used in healthcare environment like hospitals and clinics.

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## CLINICAL BENEFITS

- The device 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
- Provides a secure, leak-proof connection that minimizes the risk of contamination, maintaining the integrity of both the medication and the sterile environment.

## PRINCIPLE OF OPERATION:

The Prefilled Syringe with Sodium Citrate solution is a ready-to-use, sterile luer lock syringe 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 users remove the cap and apply mechanical pressure through manual push to eject sterile Sodium Citrate solution, and disposes of the syringe safely after use.

## PERFORMANCE CHARACTERISTICS:

- The Sodium Citrate pre-filled syringe simplifies the flushing process of the vascular access device with a ready-to-use design, ideal for both healthcare professionals and the patients.
- Interoperability with vascular access devices.
- The pre-filled syringe reduces the potential dosing errors.
- Maintains a sterile environment for the medication until use, minimizing infection risk.
- Successful flushing.

## MATERIAL USED:

- Barrel, Plunger Rod – Polypropylene
- Tip Cap – Polypropylene + Colorant
- Gasket – Bromobutyl Rubber (Latex-free)
- Lubricant - Silicone 1000 CST (with hexane)
- Pre-filled solution – Sterile Sodium Citrate 4% (w/v) solution,

## CONTRAINDICATIONS:

The use of Prefilled Syringe with Sodium Citrate solution is contraindicated in following cases:

S.NO	CONTRAINDICATIONS	DESCRIPTION
1	Prior Medical History	The patients with History of Sodium Citrate-induced thrombocytopenia and Sodium Citrate-induced thrombocytopenia and thrombosis. Avoid the use of the device.
2	Know Allergies or hypersensitivities	Do not use in patient with allergy or hypersensitivity to Sodium Citrate and other materials used in Syringe (e.g., Anaphylactic reactions, etc.)
3	Severe Haemorrhage or Bleeding Disorders	In patients with active infections or conditions that increase infection risk, using a contaminated or improperly sterile solution or syringe could exacerbate their condition.
4	Device Misuse	If the Sodium Citrate prefilled syringe is damaged or used incorrectly, it could lead to improper dosing or injury.

## POTENTIAL COMPLICATIONS:

Possible complications or adverse reactions associated with Prefilled Syringe with Sodium Citrate solution, may include haemorrhage, thrombocytopenia, injection site irritation, general hypersensitivity reactions, etc. The chelation of calcium ions may resulting in hypocalcaemia and hypernatremia, as well as possible emergence of paraesthesia and/or dysgeusia.

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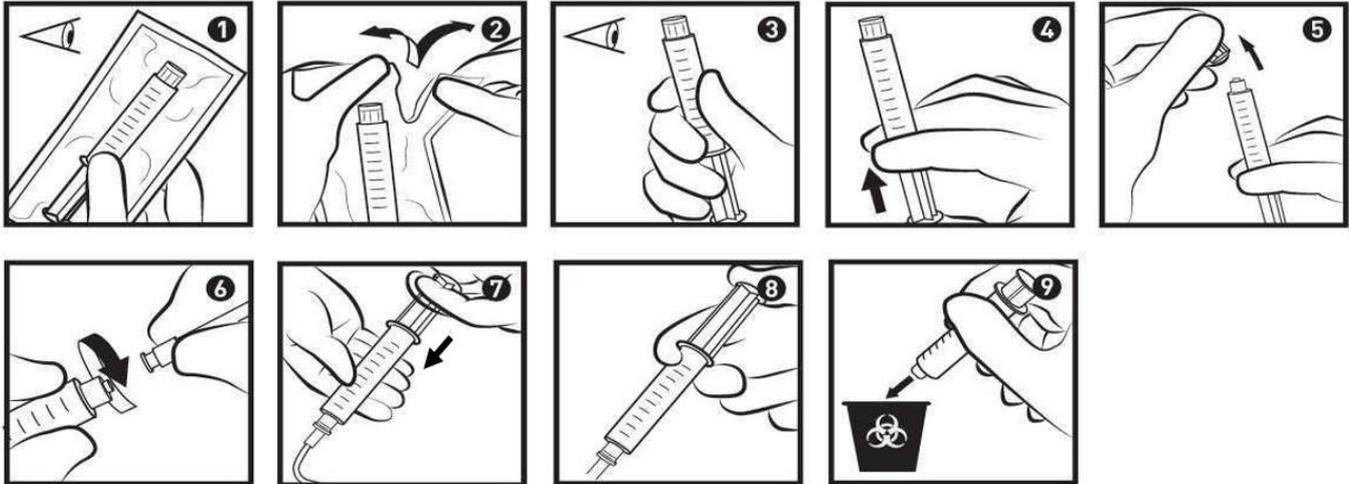
### INSTRUCTIONS FOR USE:

The Prefilled Syringe with Sodium Citrate solution, is a sterile, pyrogen-free device. If the tip cap is in place, the syringe is intact & there is no evidence of leakage. Handle aseptically.

- **Step 1.** Carefully inspect the package. Do not use, if the package is open or syringe is damaged. (*Figure.1*)
- **Step 2.** Remove plastic packaging by tearing along the perforation (Ribbon) or Peel open the pouch (Blister). (*Figure.2*)
- **Step 3.** Carefully inspect if a solution is discoloured, cloudy, hazy, or contains a precipitate, or if the syringe is damaged. (*Figure.3*)
- **Step 4.** Clear the catheter of any remaining closure solutions by aspirating into an empty sterile syringe (*Figure.4*)
- **Step 5.** Flush each catheter lumens using sterile isotonic solution (0.9% Sodium Chloride) to remove any remaining blood components from previous procedures.
- **Step 6.** With the tip cap is still on, Push plunger rod slightly to activate the syringe. Never draw back the plunger rod as the product may contaminate.
- **Step 7.** 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 8.** The syringe is now ready to use. As per institutional protocol, attach the flush syringe to the access device without any contamination. (*Figure.6*)
- **Step 9.** Slowly inject the required amount of pre-filled solution by slowly pressing the plunger to avoid excessive pressure. If you experience plunger resistance, it is recommended, do not apply excessive force. Do not pull or bend the plunger. (*Figure.7*)
- **Step 10.** 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 11.** Discard the empty unit after use. Discard any unused portion. Do not reuse disposable syringes. (*Figure.9*)

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### HOW SUPPLIED:

The Prefilled Syringe with Sodium Citrate solution is supplied in both sterile fluid path and externally sterile, single-use, packed individually in Ribbon or Paper pouch, complete with instructions for use and necessary accessories (if any).

### WARNINGS:

- **For Professional Use Only:** This device must be used by trained healthcare professionals only.
- **Sterile Packaging:** Do not use if the packaging is damaged or opened prior to use.
- **Not Intended for Intramuscular use:** The Prefilled Syringe with Sodium Citrate solution, is not intended for Intramuscular use.
- **Discontinue its use:** Discontinue use of the syringe, if coagulation test is excessively prolonged, or if haemorrhage or thrombocytopenia occurs.
- **Single Use Only:** The Sodium Citrate pre-filled flush syringe is designed for single use. The Re-processing of the device may compromise the sterility, biocompatibility, and functional integrity of the device.
- **Proper Handling:** Handle with care to avoid damage to the device, which could compromise its sterility and functionality.
- **Allergic Reactions:** Check patient history for allergies to materials used in the Sodium Citrate prefilled syringe.
- **Inspect Before Use:** Ensure all components are present and undamaged before use. Do not use if the prefilled solution appears cloudy, coloured, or contains any precipitate of sended particulate matter.
- **Follow Instructions:** Carefully follow the included instructions for use to avoid complications.
- **Dispose Properly:** Dispose of the device in accordance with local regulations for medical waste.

### PRECAUTIONS:

- The Prefilled Syringe with Sodium Citrate solution, is designed to be used for direct flushing or with ISO luer compliant components for Intravenous application.
- Perform patient's Blood coagulation tests before the Sodium Citrate flushing.
- Graduation is provided on the syringe, to inject the required dose.
- Check the product for defects/cracks or change in appearance of pre-filled solution.
- Avoid crushing and crimping damage to the product due to the application of surgical instruments like forceps, etc.



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- Store at specified temperature and humidity.
- Check with the manufacturer instructions for use to ensure the sterility, compatibility, and functionality of the device before use.

## **CAUTIONS:**

- The Federal Law restricts this device to sale by for or order by physician.
- Carefully read all instructions prior to use.
- Hold the syringe in upward direction and expel the bubbles from the syringe.
- For single use only. Discard after single use.
- Don't use if the package is open or damage.
- Do not store at extreme temperature and humidity.
- Dispose the contaminated/ used product as per local applicable laws.

## **STORAGE:**

Store in cool and dry place at controlled temperature (5 to 30°C or 41 to 86°F). Do not freeze. Store away from direct sunlight.

## **EXPIRATION PERIOD:**

The Prefilled Syringe with Sodium Citrate 4% (w/v) solution has a shelf-life of 36 months (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, regional legislation or National 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 done 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.

<b><u>LEGAL MANUFACTURER AND MANUFACTURING FACILITY</u></b>	<b><u>AUTHORIZED REPRESENTATIVE</u></b>		
 <b>Manufacturer:</b> <b>SPM Medicare Pvt, Ltd</b> B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. <b>Manufacturing Site 1-</b> B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. <b>Manufacturing Site 2-</b> Industrial Building Plot no	<table border="1"><tr><td>EC</td><td>REP</td></tr></table> <b>MEDDEVICES LIFESCIENCES B. V.</b> Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31 202254558 Email: <a href="mailto:info@meddevices.net">info@meddevices.net</a>	EC	REP
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26, Sector 158, Noida, Gautam buddha, Nagar, Uttar Pradesh, 201305. Customer care: No.: +91-840-7070-718 Email: <a href="mailto:info@spmmedicare.com">info@spmmedicare.com</a> Web Site: <a href="http://www.spmmedicare.com">www.spmmedicare.com</a>	
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### EXPLANATION OF SYMBOLS:

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Country and date of manufacturer		Use-by date
	Do not re-sterilize		Temperature Limit (°C & °F)
	Consult instructions for use		Do not use if package is damaged and consult instructions for use
	Keep away from sunlight		Non-Pyrogenic
	Do not re-use		Sterilized using Gamma Irradiation
	Keep dry		Handle with care
	This side up		Maximum stacking
	Do not use hook		The device is free from Natural Rubber Latex

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	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System with protective packaging outside
	Recycling		Biological risks
	Fragile, handle with care		