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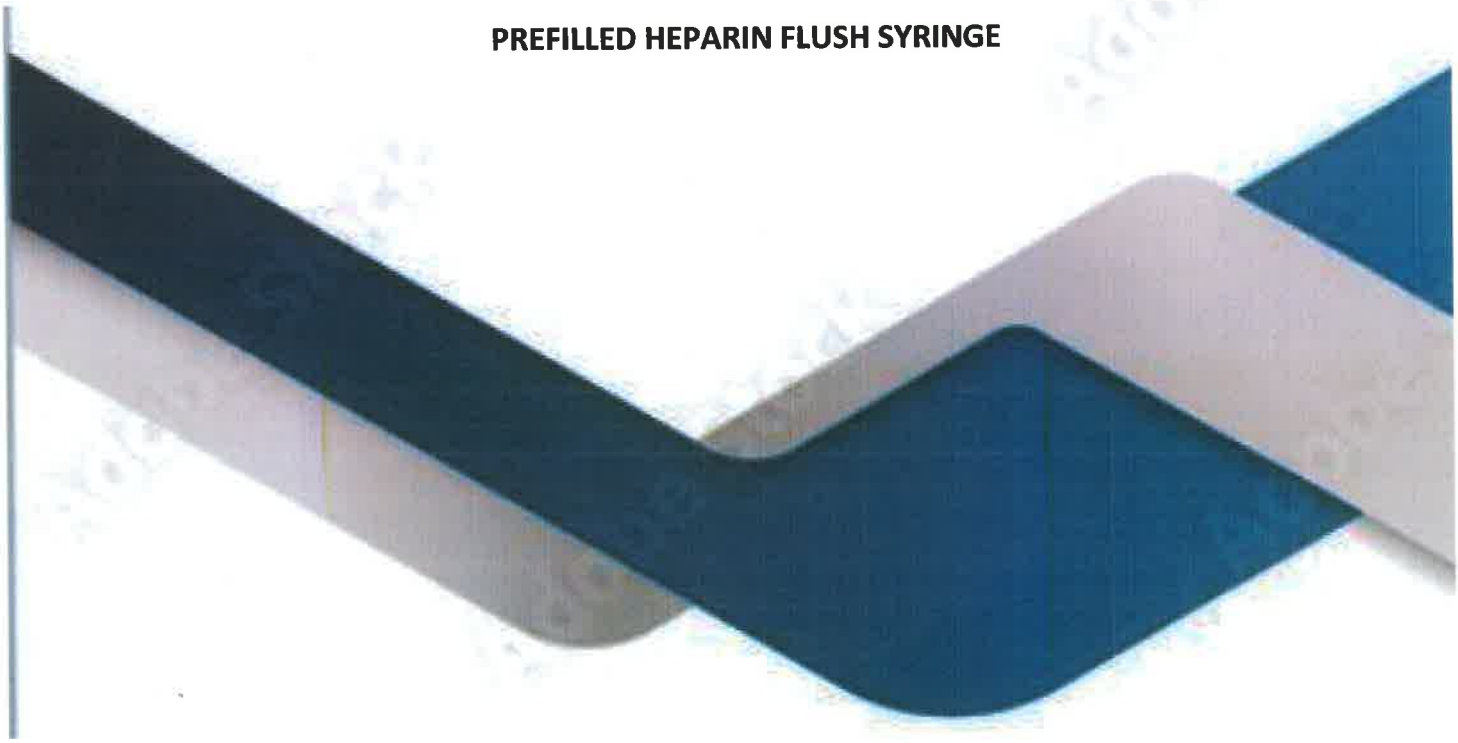
Technical IFU

PREFILLED HEPARIN FLUSH SYRINGE



PREPARED BY	REVIEWED BY	APPROVED BY
DATE: 19/01/2026	N.R.Oulkar DATE: 19/01/2026	DATE: 19/01/2026
EXECUTIVE-QARA	HEAD RA	MANAGING DIRECTOR/ AUTHO. SIGNATORY

PRODUCT NAME: Prefilled Heparin Flush Syringe

Follow manufacturer's instructions for use and institutional procedures for Heparin Flush administration:

DESCRIPTION:

The SPM Prefilled Heparin Flush Syringe is a sterile, single-use, polypropylene luer-lock syringe prefilled with sterile Heparin Sodium solution (10 IU/mL or 100 IU/mL). The device is intended to facilitate flushing of compatible intravenous administration sets and indwelling intravenous access devices.

Heparin Sodium is an **ancillary medicinal substance** that acts in a **supportive role** to the medical device. The medicinal substance complies with applicable **Pharmacopoeial and medicinal product regulatory requirements**.

The device is **latex-free**, **DEHP-free**, **non-pyrogenic**, **non-toxic**, and sterilized using **gamma irradiation**.

DEVICE VARIANTS:

Sr. No	Product Description	Volume
1	Prefilled Heparin Flush Syringe (10 IU/ML, 100 IU/mL,)	3ml
2	Prefilled Heparin Flush Syringe (10 IU/ML, 100 IU/mL)	5ml
3	Prefilled Heparin Flush Syringe (10 IU/ML, 100 IU/mL,)	10ml

INTENDED PURPOSE:

Prefilled Heparin Flush Syringe is a single-use, short term-use device intended for maintenance of patency of vascular access device only.

INDICATIONS FOR USE:

The Heparin Flush Syringe is indicated for maintaining patency and preventing clot formation in indwelling intravenous access devices such as catheters, ports, and IV cannulas. It is not indicated for systemic anticoagulation or for use during surgical procedures.

INTENDED PATIENT POPULATION:

Adults and paediatric patients, including neonates

PATIENT CONTACT & BIOLOGICAL SAFETY:

The device is an externally communicating medical device with indirect blood path contact via an indwelling catheter. Contact is transient (<60 minutes) per use.

Biological evaluation has been performed in accordance with ISO 10993:2020, and results demonstrate the device is biocompatible and acceptable for the intended clinical use.

INTENDED USER:

The intended users for the Heparin Flush Syringe are trained healthcare professionals such as registered nurses, medical practitioners, or paramedics who are qualified and authorized by institutional or national guidelines to administer intravenous flushes using Heparin.

INTENDED USE ENVIRONMENT:

Heparin Flush Syringe is intended to be used in healthcare environment like hospitals and clinics.

CLINICAL BENEFITS

- Maintains catheter patency
- Reduces preparation steps and handling errors
- Ready-to-use sterile solution

Benefit–Risk Statement:

The clinical benefits of maintaining vascular access patency **outweigh the known and residual risks** associated with heparin when the device is used as intended.

PRINCIPLE OF OPERATION:

The Heparin flush syringe 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 heparin sodium solution, and disposes of the syringe safely after use.

PERFORMANCE CHARACTERISTICS:

- The Heparin flush 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 – Polypropylene
- Plunger Rod – Polypropylene
- Tip Cap – Polypropylene + Colorant
- Gasket – Bromo butyl Rubber
- Lubricant - Silicone 1000 CST (with hexane)
- Prefilled solution (Sterile Heparin sodium solution (10 IU/ML, 100 IU/mL):

Composition: Each mL Contains:	**Quantity per mL**
Heparin Sodium USP (Derived *from porcine)*	10 IU/ml; 100 IU/ ml
Sodium Chloride USP	8 mg

Monobasic Sodium Phosphate (Monohydrate) USP	2.3 mg
Dibasic Sodium Phosphate (Anhydrous) USP	0.5 mg
Water for Injection USP	q.s. to 1 mL

PATIENT CONTACT INFORMATION AND CONTACT DURATION:

The pre-filled Heparin Flush Syringe is an externally communicating medical device with indirect blood path contact, achieved through connection to an indwelling intravenous catheter. Patient contact occurs exclusively via the heparin sodium solution during the flushing procedure and is limited to a transient duration of less than 60 minutes per use.

Each device is intended for **single use only** on **one individual patient during a single procedure** and must not be reused or reprocessed. The patient contact is **transient and non-repeating**, and this contact classification has been used to determine the applicable biological evaluation endpoints in accordance with **ISO 10993:2020**. Based on this defined contact type and duration, the device has undergone biological evaluation and testing, and the results demonstrate that the materials are biocompatible and acceptable for the intended clinical use.

CONTRAINDICATIONS:

The use of pre-filled heparin flush syringe is contraindicated in following cases:

S.NO	CONTRAINDICATIONS	DESCRIPTION
1	Prior Medical History	The patients with History of heparin-induced thrombocytopenia and heparin-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 heparin or porcine derived products (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 Heparin prefilled syringe is damaged or used incorrectly, it could lead to improper dosing or injury.

POTENTIAL COMPLICATIONS:

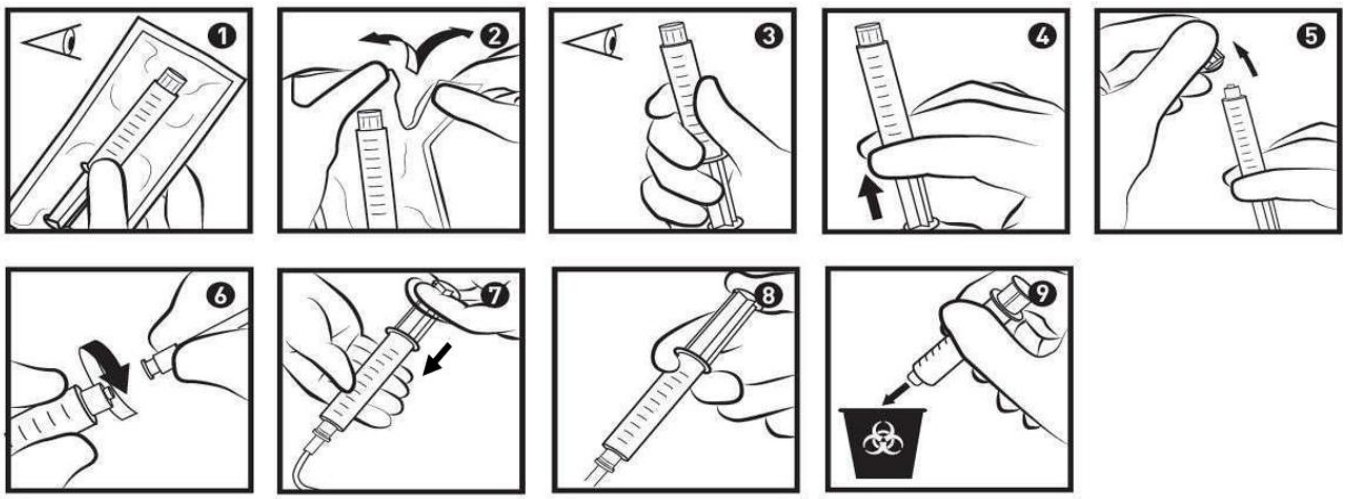
Possible complications or adverse reactions associated with prefilled Heparin flush syringe may include haemorrhage, thrombocytopenia, Heparin-induced Thrombocytopenia, injection site irritation, general hypersensitivity reactions, etc.

INSTRUCTIONS FOR USE:

The pre-filled Heparin flush syringe 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 Peel open the pouch. (**Figure.2**)

- **Step 3.** Visually inspect the pre-filled solution. Do not use, if the solution appears cloudy, hazy or contains a precipitate. (**Figure.3**)
- **Step 4.** 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. (**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.** Inject the required amount of pre-filled solution by pressing the 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**)



HOW SUPPLIED:

The pre-filled Heparin flush syringe is supplied in both sterile fluid path and externally sterile, single-use, packed individually in Blister 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 Heparin flush syringe is not intended for intramuscular administration.
- Single Use Only: The Heparin flush syringe is intended for single use only. Reprocessing may compromise sterility, biocompatibility, and functional integrity.
- Proper Handling: Handle the device with care to avoid damage that could compromise sterility or functionality.
- Inspect Before Use: Check that all components are intact and the prefilled solution is clear and free of particulate matter. Do not use if the solution appears cloudy, discoloured, or contains precipitate.
- Allergic Reactions: Verify the patient's medical history for any known allergies to materials used in the Heparin flush syringe.
- Clinical Monitoring: Discontinue use if coagulation tests show excessive prolongation, or if signs of haemorrhage or thrombocytopenia occur.
- Heparin Concentration Warnings: Use the appropriate Heparin concentration based on the patient population. 100 USP Units/mL is not suitable for neonates, paediatric patients, or the elderly. Incorrect concentration may cause serious adverse events, including bleeding or heparin-induced thrombocytopenia. Always confirm concentration and patient suitability prior to use.
- Follow Instructions: Use the device strictly as per the Instructions for Use to minimize the risk of complications.
- Dispose Properly: Dispose of the used device according to applicable local regulations for medical waste.

PRECAUTIONS:

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

- 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.
- Not indicated for anticoagulation treatment.

EXPIRATION PERIOD:

Pre-filled Heparin flush syringe	**Shelf Life from date of manufacturing**
10 IU/ML, 100 IU/mL	24 Months

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.

CLEANING, STORAGE AND DISPOSAL INFORMATION

Cleaning:

- This device is for single-use only. Cleaning or reprocessing is not permitted. Reuse may compromise sterility and safety.

Storage:

- Store in a cool, dry place at a controlled temperature at 10 to 32 Degree Celsius.
- Do not freeze.
- Protect from direct sunlight, excess moisture, and physical damage.

Disposal:

- Dispose of used devices immediately after use in appropriate sharps or biomedical waste containers, in accordance with hospital protocols and local regulatory requirements.
- Do not dispose of the syringe with general waste.
- Dispose of unused product past its expiration date in accordance with institutional and national regulations.
- 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 discarded as biomedical waste.
- Leftover products should be disposed of 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. Additionally, notify the competent authority of the member state where the user and/or patient is established, as per local regulatory requirements.

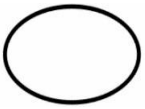
LEGAL MANUFACTURER AND MANUFACTURING FACILITY

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

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
	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		Medical Device

	Model number		Single Sterile Barrier System
	Unique Device Identifier		The device is free from Natural Rubber Latex
	Biological risks		Contains biological material of animal origin

Revision History:

Rev. No	Reason for Change	Revision Date	Approved By
00	Initial Release	02-07-2025	Mr. Umang Mathur
01	Added caution point	06-09-2025	Mr. Umang Mathur
02	Change in intended use	19-01-2026	Mr. Umang Mathur