



INSTRUCTION FOR USE

Prefilled Heparin Flush Syringe (10 IU/mL, 100 IU/mL)

PRODUCT NAME: Prefilled Heparin Flush Syringe

DESCRIPTION:

The 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. The syringe is prefilled with sterile Heparin Sodium solution at a concentration of 10 IU/mL or 100 IU/mL. The device is **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 USE/ PURPOSE:

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

INTENDED PATIENT POPULATION:

Adult population

INTENDED USER:

The device is intended for use by trained and qualified healthcare professionals.

INTENDED USE ENVIRONMENT:

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

CLINICAL BENEFITS

- Maintains catheter patency
- Ready-to-use sterile solution

PERFORMANCE CHARACTERISTICS:

- Ready-to-use prefilled syringe.
- Compatible with applicable Luer access systems.
- Delivers the specified heparin flush solution.
- Intended to maintain patency of compatible vascular access devices.

CONTRAINDICATIONS:

- Do not use in patients with known hypersensitivity to heparin or components of the product.

- Do not use in patients with a known history of heparin-induced thrombocytopenia (HIT). Do not use where administration of heparin is contraindicated due to active or uncontrolled bleeding.

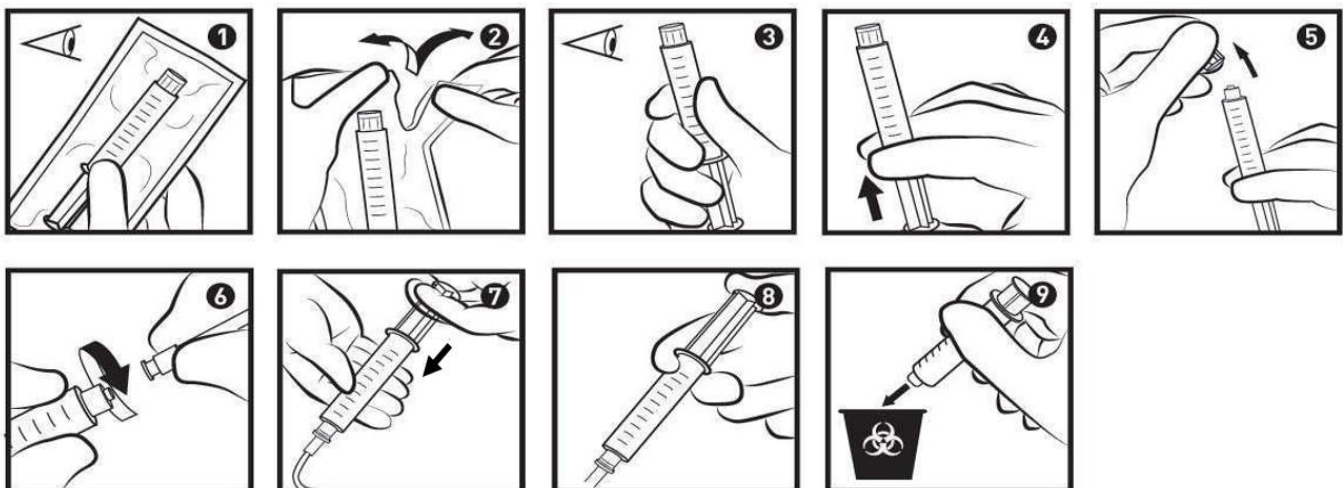
POTENTIAL COMPLICATIONS:

Possible adverse reactions may include haemorrhage, thrombocytopenia, heparin-induced thrombocytopenia, hypersensitivity reactions and local injection-site reactions.

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)**



WARNINGS & PRECAUTIONS :

- For use by trained healthcare professionals only.

- For single use only. Do not reuse, reprocess or resterilize.
- Do not use if the package is damaged, opened or past the expiry date.
- Do not use if the solution is cloudy, discoloured or contains visible particles.
- Confirm the heparin concentration before use.
- Not intended for therapeutic anticoagulation.
- Not intended for intramuscular administration.
- Use aseptic technique during connection and administration.
- Do not pull the plunger backwards before use.
- Do not apply excessive force if resistance is encountered during flushing.
- Use only with compatible Luer access devices.
- Use according to the vascular access device manufacturer's instructions and applicable clinical/institutional protocol.
- Discontinue use and seek appropriate medical management if an adverse reaction is suspected.

SHELF LIFE:

24 months from the date of manufacture, when stored under the specified storage conditions.

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 the used syringe and any unused solution in accordance with applicable hospital procedures and biomedical waste requirements.
- Do not reuse the device.
- Dispose of expired or damaged products in accordance with applicable local requirements.

REPORTING OF ADVERSE EVENTS:

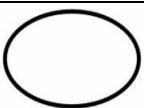
Any suspected adverse event or product complaint associated with the device should be reported to the manufacturer. Medical device adverse events may also be reported through the Materiovigilance Programme of India (MvPI), as applicable.

INSTRUCTION FOR USE

SPMM/RA//IND/76/PHFS /IFU, Rev. 00, **Date:** 07-10-2026

<u>MANUFACTURER AND MANUFACTURING SITE</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. Email: info@spmmedicare.com Web Site: www.spmmedicare.com

EXPLANATION OF SYMBOLS:

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch/LOT code
	Country and date of manufacturer		Use-by date
	Do not re-sterilize		Medical Device
	Consult instructions for use		Do not use if package is damaged
	Keep away from sunlight		Unique Device Identifier
	Do not re-use		Sterilized using Gamma Irradiation
	Keep dry		Contains biological material of animal origin
	Single Sterile Barrier System		

Revision History:

Rev. No	Reason for Change	Revision Date
00	Initial Release	07-10-2025