

PRODUCT NAME: Prefilled Syringe with sterile water and 10% Glycerine Solution

Follow manufacturer's instructions for use and institutional procedures for Foley catheterization:

DESCRIPTION:

The SPM's pre-filled syringe with sterile water & 10% Glycerin solution is a single-use, Non-toxic, sterile luer lock syringe, prefilled with sterile water & 10% Glycerin solution. The pre-filled syringe is intended for the safe and efficient inflation of indwelling urinary Foley catheter balloons. The Red coloured luer tip cap maintains a closed system which ensures the product sterility until used. The device is sterilized by Gamma Irradiation.

IMAGE OF THE DEVICE:



DEVICE VARIANTS:

S.No	Product Name	Volume	Packaging
1	Pre-filled Syringe with Sterile water & 10% Glycerin Solution	10 mL	Peel – Open (Blister)
2	Pre-filled Syringe with Sterile water & 10% Glycerin Solution	10 mL	Flow Laminate (Ribbon)

INTENDED PURPOSE:

The Pre-filled Syringe with sterile water & 10% Glycerin solution is intended for the safe and efficient inflation of indwelling urinary Foley catheter balloon.

INDICATIONS FOR USE:

The Pre-filled Syringe with sterile water & 10% Glycerin solution is intended for the safe and efficient inflation of indwelling urinary Foley catheter balloon during catheterization.

INTENDED PATIENT POPULATION:

The Pre-filled Syringe with sterile water & 10% Glycerin solution is intended to be used in patients irrespective of age and gender.

INTENDED USER:

The Pre-filled Syringe with sterile water & 10% Glycerin solution is intended to be used by the trained healthcare professionals like Doctors, paramedics, or nursing staff experienced in urinary catheterization.

INTENDED USE ENVIRONMENT:

The Pre-filled Syringe with sterile water & 10% Glycerin solution is intended to be used in hospital, or a clinical setting.

CLINICAL BENEFITS:

- The pre-filled syringe offers a ready-to-use system, which save preparation time and minimize errors.
- Avoid frequent filling of the Foley balloon, ensuring both economic and time savings

		
DATE: 26/05/2025	DATE: 26/05/2025	DATE: 26/05/2025
Prepared By Senior Executive- QA	Reviewed By QA- MR	Approved By Manager- RA/QA

- Minimize the risk of catheter dislocation by ensuring a constant optimum volume of balloon and resulting less discomfort.

PRINCIPLE OF OPERATION:

The In Pre-filled Syringe with sterile water & 10% Glycerin solution is a sterile luer lock syringe, prefilled with 10% sterile Glycerin solution intended for the safe and efficient inflation of the Foley catheter balloon. After the proper insertion of the Foley catheter, the luer tip cap is removed aseptically and the syringe is attached to the balloon inflation port of the Foley catheter. The prefilled solution is aspirated slowly by manually advancing the plunger. The healthcare professional will advise the sufficient volume of sterile solution injected. The unused portion of the product is discarded according to regional law for biomedical waste.

PERFORMANCE CHARACTERISTICS:

- The pre-filled luer lock syringe is compatible with the Foley catheter balloon inflation port.
- The sterile 10% Glycerin solution does not diffuse through the balloon as compare to the water.
- The glycerin solution is also a lubrication agent which is compatible and reduces irritation.

MATERIAL USED:

- Barrel - Polypropylene
- Plunger - Polypropylene
- Gasket - Bromobutyl Rubber (Medical grade)
- Lubricant - Silicone oil
- Luer Cap - Polypropylene
- Pre-filled solution - Sterile water & 10% Glycerin solution

CONTRAINDICATIONS:

The Pre-filled Syringe with sterile water & 10% Glycerin solution is contraindicated in following conditions:

S. No	Contraindications	Description
1	Allergy to Materials used in pre-filled syringe	Patients with known allergies or sensitivities to materials used in the Pre-filled Syringe with sterile water & 10% Glycerin solution (e.g. specific plastics or Needle) or the glycerin solution should avoid its use to prevent allergic reaction/take the safety measures.
2	Urinary Tract Infections (UTIs)	In patient with active UTI, the introduction of any foreign material, such as a Foley catheter inflated with glycerin solution, could potentially exacerbate the condition.
3	Urinary Bladder Injury	If the patient has a bladder injury, or trauma, the use of Foley catheter with glycerin solution may increase the risk of further complications or damage.
4	Device Misuse	If the pre-filled syringe is used incorrectly or damage, it could lead to injury or contamination. Ensure the pre-filled syringe is used according to manufacturer instructions.

POTENTIAL COMPLICATIONS:

Possible complications with Pre-filled syringe with sterile water & 10% Glycerin solution may encounter some challenges like:

		
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- Leakage of the pre-filled solution due to defect or damage luer tip cap and can lead to product contamination. Do not use leaked or damage product.
- The improper insertion of the catheter may cause the bladder injury or trauma to the patient.
- The partial or incomplete catheter insertion and forced balloon inflation may cause serious urethral injuries to the patient.
- The excessive solution aspirated to inflate the balloon (more than its balloon capacity) may result in bursting of balloon which causes serious urinary tract injuries.

INSTRUCTIONS FOR USE:

To ensure a sterile application of the product, the health-care worker must comply with the procedures provided for by the health-care institution, applying an aseptic technique to the entire procedure.

- **Step 1.** Carefully inspect the unit packaging. Do not use if the unit packaging is damaged, not intact, or the product is expired.
- **Step 2.** Aseptically peel-open (paper pouch) or tear along the perforation (ribbon pouch) and take out the syringe. Visually inspect the prefilled syringe and its content for clarity, discoloration or leakage prior to use. Do not use if any of the above is observed within the syringe.
- **Step 3.** Carefully remove the protective cap and hold the tip of syringe upward and gently depress the plunger to expel air (if any).
- **Step 4.** Aseptically attach the luer connector of the syringe tip to the balloon inflation port of the Foley catheter. (Avoid any contamination)
- **Step 5.** Slowly inject the suggested volume of the solution for accurate and effective anchoring of the balloon in the Foley catheter (Note: Always use the volume advised in the Foley catheter instructions for use for inflating the balloon)
- **Step 6.** After use, dispose the empty syringe or any unused in accordance with local or regional laws for medical waste.

HOW SUPPLIED:

The Pre-filled Syringe with sterile water & 10% Glycerin solution is supplied in individually packed in paper pouch / ribbon pouch complete with clear instructions for use and 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.
- **Single Use Only:** The pre-filled solution is designed for single use. Do not reuse or re-sterilize.
- **Proper Handling:** Handle with care to avoid damage to the device, which could compromise its sterility and functionality.
- **Inspect Before Use:** Ensure all components are present and undamaged before use.
- Do not use for drugs reconstitution/dilution, Injection or Rehydration.
- **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:

- Check the integrity and functionality of the pre-filled syringe before use. Do not use if the package is open or damaged.

		
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- Handle the device with care & in aseptic condition. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps, etc.
- Inspect the product prior to use. Do not use, if the solution is not colourless or contains particles.
- Always use the volume recommended in the Foley catheter instructions for use for inflating the balloon.
- Always ensure the urine is drained from the bladder before the Foley catheter insertion and balloon inflation.
- Prior to balloon inflation using the pre-filled syringe, always ensure that the Foley catheter is fully inserted into the bladder.
- Do not Re-sterilize. Do not Re-use.
- Keep out of reach and sight of children.
- Do use after the Expiry Date.

CAUTIONS: 

- Store in a cool and dry place
- Discard after single uses
- Do not use if the package is open or damage
- Do not store at extreme temperature and humidity
- Dispose the blood/medicine contaminated product as per local applicable laws.

STORAGE:

Store at controlled temperature (10 to 40°C) and do not freeze.

EXPIRATION PERIOD:

Pre-filled Syringe with sterile water & 10% Glycerin solution 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 done as biomedical waste.
- Leftover products should be disposed as biomedical waste.

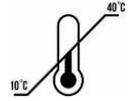
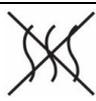
REPORTING:

In case of any adverse events and/or potential threat/ 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.

		
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<p><u>LEGAL MANUFACTURER AND MANUFACTURING FACILITY</u></p> <p>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</p>	<p><u>AUTHORIZED REPRESENTATIVE</u></p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">EC REP</div> <p>MEDDEVICES LIFESCIENCES B. V. Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31 202254558 Email: info@meddevices.net</p>
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EXPLANATION OF SYMBOLS:

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Date & Country of manufacturing		Use-by date
	Do not re-sterilize		Temperature Limit
	Consult instructions for use		Do not use if package is damaged and consult <i>instructions for use</i>
	Keep away from sunlight		Non-Pyrogenic
	Do not re-use		Sterilized using Gamma Irradiation
	Keep dry		Handle with care

<p><u>N. R. Dukare.</u></p> <p>DATE: 26/05/2025</p> <p>Prepared By Senior Executive- QA</p>	<p><u>Atawati</u></p> <p>DATE: 26/05/2025</p> <p>Reviewed By QA- MR</p>	<p><u>V. Srinivas</u></p> <p>DATE: 26/05/2025</p> <p>Approved By Manager- RA/QA</p>
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	This side up		Maximum stacking limit
	Do not use hook		Recycling
	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System
	Single Sterile Barrier System with protective packaging outside		Biological risks

<u>N. R. Dukare.</u>		
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