dermaflush™

Pre-Filled Flush Syringe

Instructions for Use

Manufactured for:
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IMPORTANT: Carefully read and understand all instructions, indications, warnings and precautions and directions for use prior to using the dermaflush™ Pre-Filled Flush Syringe. Failure to do so could result in compromised patient safety, patient complications and/or insufficient treatment.

DermaFlush™
Pre-Filled Flush Syringe

Intended Use Flush syringes are medical devices used to deliver a solution to clear or flush a catheter or access port.

A flush is the method of clearing intravenous lines (IVs), central lines or arterial lines of any medicine or other perishable liquids to keep the lines (tubes) and entry area clean and sterile. When used correctly, saline flushes are generally safe and well tolerated by patients

Indication for Use 0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations for the appropriate device

Mode of Action

The mode of action of a flush syringe involves clearing intravenous (IV) lines, central lines, or arterial lines to maintain their patency and prevent blockages. Here's how it works:

Flushing the Line: A sterile solution (typically 0.9% sodium chloride) is injected into the IV line using a syringe to remove residual medication, blood, or other debris.

Preventing Occlusions: The flush helps prevent clot formation and ensures the catheter remains open for medication delivery.

Reducing Infection Risk: Proper flushing minimizes the risk of catheter-related bloodstream infections (CRBSI) by keeping the line clean.

Ensuring Medication Delivery: Flushing before and after medication administration prevents drug interactions and ensures the full dose reaches the patient.

Maintaining Pressure: A 10mL syringe is often recommended to maintain correct pressure and avoid catheter damage

Device Overview

Intended Users

The product is intended to be used by qualified and trained healthcare professionals, such as doctors, nurses, and paramedical staff, who are trained in IV access management and flushing procedures. It is not intended for use by untrained persons or patients themselves.

Intended Patient Population

The device is suitable for use in patients of all age groups, including pediatric, adult, and geriatric patients, as clinically appropriate.

Contraindications

Allergic Reactions / Hypersensitivity – Do not use in patients with known allergies or hypersensitivity to saline, sodium chloride, heparin (if applicable), or other flushing solutions.

Fluid Overload Risk / Sodium Restriction – Use is contraindicated in patients with conditions requiring restricted fluid or sodium intake, such as congestive heart failure, severe renal insufficiency, or sodium retention disorders.

Air Embolism Risk – Improper use, including failure to expel air from the syringe, may result in air embolism and serious complications.

Infectious Complications – Use of non-sterile syringes or improper technique may increase the risk of catheter-related bloodstream infections (CRBSI).

Extravasation – Incorrect administration may result in leakage of solution into surrounding tissues, leading to irritation or tissue damage.

Detailed Description

The main parts of the DermaFlush are mentioned below

The major components of the Flush Syringe: Raw Material	**Component**
Polypropylene	Barrel & Plunger
Synthetic rubber	Gasket
Polypropylene	Luer Lock Cap
Sodium Chloride	0.9% NaCl Saline Solution
Silicone 12500	Lubricant

Operational Instructions for Use

Preparation

· Ensure hands are clean and dry before handling the device.
· Use appropriate aseptic technique in accordance with institutional protocols.

Remove from Packaging

· Carefully remove the Dermaflush prefilled flush syringe from the sterile packaging.
· Do not use the syringe if the packaging is damaged, open, or compromised.

Visual Inspection

· Inspect the syringe barrel, plunger, and tip cap for cracks, defects, or leakage.
· Verify the solution is clear and free from visible particulate matter.
· Do not use if discoloration, cloudiness, or leakage is observed.

Break the Seal

· With the tip cap still securely in place, gently push the plunger forward to break the internal seal.
· Do not remove the tip cap during this step.

Remove Tip Cap

· Remove the tip cap by twisting or pulling it off using aseptic technique.
· Avoid touching the luer tip to maintain sterility.

Expel Air

· Hold the syringe upright with the tip pointing upward.
Gently tap the barrel if necessary to allow air bubbles to rise.
· Slowly advance the plunger until all air is expelled and a drop of solution appears at the tip.

Connection to Access Device

· Attach the syringe securely to the compatible IV access device, catheter, or injection port as required.
· Ensure a proper connection to prevent leakage or disconnection during flushing.

Flushing

· Slowly inject the solution using steady pressure.
· Do not apply excessive force, as this may damage the catheter or vascular access device.

Completion

· Once flushing is complete, disconnect the syringe from the access device using aseptic technique.

Disposal

· Discard the used syringe immediately after use.
· Do not reuse or re-sterilize.
· Dispose of the device in accordance with local biomedical waste disposal regulations.

⚠ Warnings and Precautions

- Single use only. Do not reuse or re-sterilize.
- Expel air prior to use to prevent air embolism.
- Do not use if packaging is damaged or expired.
- Use aseptic technique at all times.

Storage and Transportation

Dermaflush Prefilled Flush Syringe should be stored and transported in a clean, dry environment, away from direct sunlight and excessive moisture. Store in a protected area to maintain sterility and product integrity under the following conditions:

· Storage Temperature: +5°C to +40°C
· Relative Humidity: 20% to 75%
· Transportation Temperature: –10°C to +50°C

Do not freeze. Protect from excessive heat, humidity, and sunlight during storage and transport.

Disposal

After use, dispose of the Dermaflush Prefilled Flush Syringe and its packaging in accordance with hospital procedures, administrative guidelines, and local biomedical waste regulations.

Sterility and Single Use

Dermaflush Prefilled Flush Syringe is supplied as a STERILE, single-use device.
Do not reprocess, reuse, or re-sterilize. Reuse may compromise device performance, sterility, and patient safety.

Gamma Label Color Stability

The color stability of gamma indicator labels may be affected by the following conditions, which may cause fading or discoloration:

· Relative humidity above 80% and temperature above 30°C
· Exposure to solvent vapors
· Contact with adhesives
· Exposure to acidic or alkaline vapors
· Direct sunlight exposure
· Prolonged exposure to high humidity and elevated temperature during transportation

Disclaimer

Alera Medtech LLC is not responsible for any damage or harm resulting from misuse, improper handling, or reuse of the device.
Any serious incident or adverse event related to this device should be reported to Alera Medtech LLC and to the U.S. Food and Drug Administration (FDA).

This section contains important safety information. Please read and understand all warnings, cautions, and instructions for use prior to using the DermaFlush™ Pre-Filled Flush Syringe.

The following symbols may appear in this IFU, on the Dermaflush device and on the dermaflush packaging. Some of the symbols represent standards and compliances associated with the DermaFlush™ Pre-Filled Flush Syringe and its use.


Warning


Keep dry


Quantity


Caution


Do not re-use


Consult instructions for use


Date of Manufacture


Do not use if package is damaged


Manufacturer

Catalog Number

Lot Number

Device is sterile

Do not re-sterilize


Single sterile barrier system


Expiry date

This device is to be sold by or on the order of a physician only

Quantity


Keep away from direct sunlight

Medical Device

Sterilized using irradiation


Storage Temperature Range +10℃ to +55℃