0.9% Sodium Chloride Injection Flush Syringe

Instruction for Use (IFU)

1. Device or Trade Name

Device name: 0.9% Sodium Chloride Injection Flush Syringe
Trade name: HP Flush™

2. Manufacturer and Address

Manufacturer**:** Zhejiang Hope Pharma Co., Ltd.
Address: Building 2 & Building 4 (Level 2 & 3 East), No. 1568 1st Binhai Avenue, Wenzhou Economic & Technological Development Zone, Wenzhou, Zhejiang, P.R.C., 325000
Tel: +86 13506510618

3. EU Authorized Representative and Address

EU Authorized Representative: MedPath GmbH
Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

4. Basic UDI

Basic UDI: 697611457C3C0034K

5. Device Description

The 0.9% Sodium Chloride Injection Flush Syringe is a sterile, single-use medical device composed of a polypropylene plastic syringe prefilled with 0.9% sodium chloride for injection, USP. Each syringe is sealed with a polypropylene tip cap. The syringe content is sterile, non-toxic, and non-pyrogenic. Each syringe is individually packaged in a polyethylene (PE) bag. The solution complies with the specifications outlined in the United States Pharmacopeia (USP) <40> monograph for sterile normal saline for injection.

Specifications Variant Description

Specifications	Contents
HBYC-3 mL	0.9% Sodium Chloride Injection Flush Syringe, 3 mL fill in 5 mL syringe
HBYC-5 mL	0.9% Sodium Chloride Injection Flush Syringe, 5 mL fill in 5 mL syringe
HBYC-10 mL	0.9% Sodium Chloride Injection Flush Syringe, 10 mL fill in 10 mL syringe

6. Intended Use

The 0.9% Sodium Chloride Injection Flush Syringe is intended for the flushing of in-situ vascular access devices.

This device is not intended for:

- Reconstitution of dry medicinal products.
- Dilution of medications.
- Use as intravenous therapy for sodium chloride administration.

7. Intended User

This device is for use only by healthcare professionals trained in vascular access procedures and experienced with this type of device.

8. Patient Population

The device is indicated for use in patients with indwelling peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), central venous catheters (CVCs), or implanted venous access ports, including both pediatric and adult populations.

9. Contraindications

No known contraindications.

10. Use Environment

The device is intended for use in clinical settings within non-sterile environments.

11. Side Effects, Interactions, and Complications

Section 5 of Chapter 38 'Flushing and Locking' in the *Infusion Therapy Standards of Practice (2024)* published by the *Infusion Nurses Society (INS)* describes potential product-related adverse effects:

—*5.If a patient reports disturbance in taste and odd / smell, inform them that prefilled flush syringes are occasionally associated with this and that it has been found to be more prominent when flushing central venous access devices (CVADs) than with peripheral intravenous catheters (PIVCs). The cause is thought to be substances leaching from the plastic syringe due to sterilization methods. These sensations may be significant enough to impact appetite and may increase nausea, especially if administered rapidly. This sensa-tion can be minimized with a slower injection rate. Reassure patient that sensation will subside when injection / flush has ceased.(III)*

The above information represents the current authoritative clinical standards regarding potential adverse effects associated with this product, as identified through our comprehensive literature review. These clinical observations are supported by moderate-level evidence (Grade B) derived from a randomized controlled trial involving 50 pediatric patients (age range: 6-18 years). *(Taste and Odour Disturbances in Pediatric Patients Undergoing IV Flush with Normal Saline Administered by Prefilled or Freshly Prepared Syringes: Randomized Single-Blind Study, David Mancini, Régis Vai lancourt, 2014),*Therefore, this provision shall be subject to periodic review and necessary updates in accordance with ongoing post-market clinical evaluation.

12. Sterilization

The device is sterilized by moist heat.

13. Storage

- Store at 20-25 ℃ (68-77 ℉).
- Do not freeze.
- Avoid exposure to high atmospheric pressure, direct sunlight, or moisture.
- Do not store in contact with corrosive substances or disinfectants.
- Store in a dry, well-ventilated area.

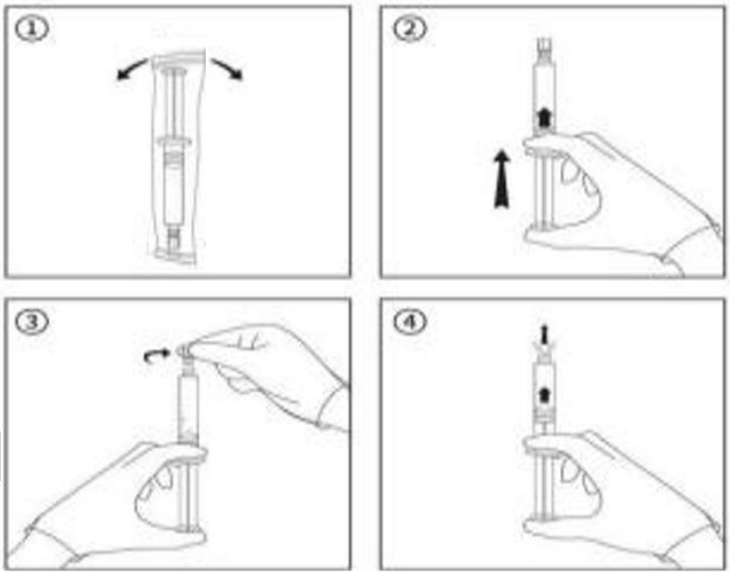
14. Warnings

A. Do not place the syringe on a sterile field.
B. Do not use after the expiration date.
C. Do not use if packaging is damaged or not intact.
D. Do not use if there is evidence of leakage.
E. Do not use if the syringe tip cap is detached.
F. Do not use if the solution appears discolored, cloudy, hazy, contains precipitate, or shows any visible foreign matter.
G. Do not re-sterilize the device.

15. Caution

A. For intravenous flush use only.
B. Only the fluid path is sterile.
C. Use only under the supervision of a physician or licensed healthcare practitioner.
D. Not intended for the injection of medications.
E. For single-use only; reuse may result in infection or injury.
F. Follow institutional policies and applicable regulations.
G. Re-use may lead to infection or other diseases/injuries.
H. In 2024, the Infusion Therapy Standards of Practice (Infusion Nurses Society) recommended using a flush volume at least twice the internal volume of the catheter system (including catheter and add-on devices). Larger volumes (e.g., 5 mL for PIVCs, 10 mL for CVADs) may improve removal of fibrin deposits, precipitated drugs, and other debris. Flush volume should be selected based on catheter type and size, patient age and weight, and type of infusion therapy. Final clinical use should be determined by the treating healthcare professional.

16. Setup



A. Peel open the package using aseptic technique. (Figure 1)
B. With the tip cap still in place, gently depress the plunger to reduce resistance. (Figure 2)
C. Twist off the syringe tip cap. (Figure 3)
D. Hold the syringe upright and expel any air bubbles. (Figure 4)
E. Attach the syringe to the IV access device, such as a valve, port, or needleless connector, and flush according to institutional protocols and policies.
F. Discard the used syringe and any remaining solution after use. Do not reuse.

17. Shelf Life

Two years from the date of production.

18. Clinical Benefits

HP Flush ™ 0.9% Sodium Chloride Injection Flush Syringe is a prefilled, single-use 0.9% sodium chloride syringe designed to:

- Reduce manual preparation steps and time required for saline syringes.
- Improve clinical workflow efficiency.
- Minimize potential contamination risks associated with manual preparation of saline flush syringes.

19. Reporting of Serious Incidents

In accordance with Medical Device Regulation (EU) 2017/745, any serious incident involving this device must be reported to the manufacturer and the competent authority of the Member State in which the user or patient is located.

20. Disposal of Medical Waste

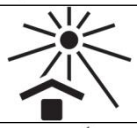
Dispose of the used device and any residual solution in accordance with applicable local regulations on medical waste within the relevant EU Member State.

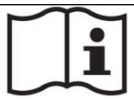
21. Date of Issue of the IFU

The date of issue of this IFU is 2025/06/14. Information regarding the latest revision is available in the device's technical documentation.

22. Symbols and Their Meanings

The following symbols are used on the device labeling and packaging. Definitions are provided in accordance with ISO 15223-1 and applicable regulatory guidance:

Graphic	Title
	Manufacturer
	Batch code
	Authorized representative in the European Union
	Catalogue number
	Non-pyrogenic
	Keep away from sunlight
	Keep dry
	Fragile, handle with care
	This way up
	Sterilized using steam or dry heat
	Sterile fluid path
	Contains no natural rubber latex
	DEHP-free
	Medical device
	Do not use if package is damaged and consult instructions for use

	Do not re-use
	CE marking with notified body code
	Date of manufacture
	Use-by date
	Caution
	Consult instructions for use
	Do not resterilize
	Unique device identifier
	Temperature limit (20 ℃ to 25 ℃)
	Sterile fluid path sterilized using steam or dry heat; single sterile barrier system with protective packaging outside
	Sterile fluid path sterilized using steam or dry heat; single sterile barrier system