

URGENT-FIELD SAFETY NOTICE - LET/QA/2023/066

URGENT: FIELD SAFETY NOTICE - LET/QA/2023/066

Polyflush Syringe, 0.9% Sodium chloride (0.9% NaCl), (Saline Solution Pre-Filled Syringes Single Sterile), Batch Number: 8281422M, Quantity: 41,520 Pcs.

Type of Action: **Advisory**

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel, Nursing, Pharmacy, Anesthetists

This letter contains important information which requires your immediate attention.

Dear valued Customer,

Poly Medicure Ltd is issuing the Field Safety Notice for the "Polyflush Syringe", 0.9% Sodium chloride (0.9% NaCl), Saline Solution Pre-Filled Syringe-10ml Single Sterile, to inform customers of a potential risk of use of empty syringe (i.e. without saline).

Description of the Problem:

Received a complaint regarding 10ml Polyflush syringe (0.9% sodium chloride), catalogue number 90318. Two syringes from the same Lot, 8281422M, were found empty i.e. without saline solution.

Image of device received from distributor:



Product Codes affected: 90318, Prefilled Syringe with 0.9% Sodium Chloride -10ml Single Sterile

- Batch Number: 8281422M
- Exp. Date: 2025-10
- Qty. supplied: 41,520 pcs.

Polymed is investigating this issue. Please note that our assembly line is automatic provided with in-process controls to mitigate these adversity. Each lot is tested by quality control and released only if complying with the specification including extractable volume of saline in the syringe.

Risk of use of empty syringe is mitigated by providing following safety information in Instructions for use (IFU)-

- Open the pack and remove the syringe.
- Visually inspect product for particulate matter and discoloration prior to use according to warning and precautions.
- Check that syringe tip cap is in place. Inspect the clarity of solution visually.
- Depress plunger with tip cap to release the stopper seal.
- Push syringe plunger to expel the air.

Do not use devices if no solution is observed when expelling the air.

Presence of saline solution can be seen visually when user check the clarity of solution and push the syringe plunger to expel the air. During this activity, such devices are immediately identified and not used.

	POLY MEDICURE LIMITED Plot No. 34, Sector-68, IMT, Faridabad-121004 Haryana, INDIA, Phone: +91-129-3355070, 4287000 Website: WWW.POLYMEDICURE.COM	Page No. 2 of 3
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Also, Warnings and Precautions in IFU says:

- **Visually inspect the contents of each prefilled syringe for clarity, particulate matter, precipitate, discoloration and leakage prior to use. Do not use if any of the aforementioned is observed.**

The Field Safety Notice is intended to provide mitigation steps to be taken in order to provide greater awareness when using the pre-filled syringes with Saline Solution 0.9% at healthcare facilities.

Actions Required by You:

1. Please follow Instructions for use and check the device for presence of saline solution before use.
2. Return the Customer Response Form annex here to info@polymedicure.com as soon as possible.

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your local representative or notice by info@polymedicure.com.

We confirm that the appropriate regulatory agencies have been informed of these actions.

Poly Medicure is committed to improve every day the safety of medical devices. We apologies for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.


Yours sincerely,



RD Sharma

General Manager- CQRA and PRRC

Date: 19th May, 2023

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ANNEX- 1 (Customer Response Form)

Please read in conjunction with Field Safety Notice and return completed and signed form as soon as possible to info@polymedicure.com

I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Name of Facility:

Email Address:

Telephone Number:

Name:

Signature:

Date:

Please return your completed and signed Acknowledgement Form to:

info@polymedicure.com