	POLY MEDICURE LIMITED Plot No.104-105, Sector-59, HSIIDC Industrial Area, Ballabgarh, Faridabad-121004, Haryana, INDIA, Phone: +91-129-3355070, 4287000 Website: WWW.POLYMEDICURE.COM	Page No. 1 of 5
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FIELD SAFETY NOTICE - LET/QA/2026/053		

FIELD SAFETY NOTICE - LET/QA/2026/053

Type of Action: Product withdrawal of affected batches

Subject: Potential quality issue in Fannin IV Fluid Infusion Set (1029DFXVAFE)

Dear Valued Customer:

Poly Medicure Limited would like to inform you of a Field Safety Notice (FSN) concerning the Fannin IV Fluid Infusion Set with Back check valve, supplied exclusively for the UK market. This Field Safety Notice is issued to inform you of a potential quality issue identified through customer feedback and as a precautionary measure to prioritize patient safety, we have decided to withdraw all affected stock.

Description of the Problem:


Poly Medicure Limited has received customer feedback reporting leakage of the Fannin IV Fluid Infusion Set during use. Leakage observed at the junction between the Back Check Valve (BCV) and stopcock of the Extension line in the Fannin IV Fluid Infusion Set. An increased trend of complaints related to leakage from the BCV joint has been observed since mid-December 2025. The investigation into the root cause is ongoing, however Poly Medicure Limited has decided to withdraw all affected batches, manufactured between July and December 2025.

Affected Devices:

Product Code	Device Description	NHSSC Reference
1029DFXVAFE	Autofusion IV Fluid Infusion Set	FSB2116



Details of these affected batches are provided in Annex-II.

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Device Description and Intended Use:

The Fannin IV Fluid Infusion Set (1029DFXVAFE) is a sterile, single-use medical device intended for the administration of intravenous fluids and medications into a patient’s vascular system via a compatible vascular access device. The Back Check Valve is designed to prevent backflow and reduce the risk of contamination or unintended fluid movement.

Potential Risks:

Leakage at the Back Check Valve (BCV) joint may lead to interruption or under-delivery of infusion, potential air ingress into the infusion line, and fluid leakage during administration.

While the overall occurrence of this issue is low, it is notably elevated within the identified affected batches. The clinical impact is considered potentially low to moderate, depending on the type of fluid or medication being administered and the clinical context of use.

- **To date, no serious patient harm has been reported.**
- **No Fannin IV Fluid Infusion Set (1029DFXVAFE) are distributed outside UK market.**

Reason for this Field Safety Notice (FSN):


This Field Safety Notice is issued following customer feedback indicating leakage from a particular joint of the Fannin IV Fluid Infusion Set (1029DFXVAFE). As the issue may affect device integrity, Poly Medicure Limited has initiated withdrawal of affected batches, manufactured between July to December 2025, supplied to Fannin UK Ltd.

Required Customer Actions:

- Identify and quarantine all remaining stock as per Annex-II. Stop using and distributing the affected batches immediately.
- If already in use, closely inspect the device during priming and administration and replace the device if any leakage is observed.
- Follow local hospital protocol for product withdrawal and return.
- Complete and return Annex-I Acknowledgment Form and await further instruction from your supplier regarding the return of affected batches and stock replacement.
- Ensure this notice and product documentation are circulated to all relevant staff, including clinical, procurement, and risk management teams.

Required Fannin (Distributor) actions:

- Disseminate this FSN to all relevant customers
- Identify and quarantine all remaining stock as per Annex-II
- Quarantine and return all unused units of the affected batches to Poly Medicure Limited

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- Continue to monitor any unusual deviations and report them promptly to Poly Medicure Limited, through your usual vigilance channel.

Transmission of this Field Safety Notice:

This FSN should be forwarded to all who need to be aware within your organization, including those who manage, use, or maintain these devices. If you have supplied this product to another organization, please ensure this notice is passed on accordingly.

Actions Taken by Poly Medicure Limited (Manufacturer):

- Withdrawal of all affected batches manufactured for the UK market between July and December 2025. Please refer to Annex-II.
- Notification to competent authorities in accordance with vigilance requirements.
- Strengthened in-process controls by enhancing inspections and verification throughout the manufacturing process.
- Implementation of appropriate Corrective and Preventive Actions (CAPA).

Contact Information:

Manufacturer:

Poly Medicure Limited
Plot No.104-105, Sector-59, HSIIDC Industrial Area,
Ballabgarh, Faridabad-121004, Haryana, INDIA,
Tel: +91-129-3355070, 4287000
E-mail: info@polymedicure.com

Distributor:

Fannin UK Ltd,
Westminster Industrial Estate,
Repton Road, Measham, Swadlincote, Derbyshire,
DE12 7DT, United Kingdom
Tel.: +44(0)1453874130
Email: serviceuk@fannin.eu

Acknowledgement of Receipt:

Please confirm receipt of this Field Safety Notice (FSN) and indicate that you have implemented the above instructions, by returning the attached Annex-I, acknowledgment form.

We sincerely regret the inconvenience caused and appreciate your cooperation in ensuring patient safety and clinical practice compliance.

Yours Sincerely,

For Poly Medicure Limited



RD Sharma
Person Responsible for Regulatory Compliance

**POLY MEDICURE LIMITED**

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Date: 1st May, 2026**FIELD SAFETY NOTICE - LET/QA/2026/053****Annex-II - List of Batches affected by this FSN:**

Product Code	Batch Number	Mfg. Date	Exp. Date
1029DFXVAFE	6227125G	2025-07	2030-08
1029DFXVAFE	6227225G	2025-07	2030-08
1029DFXVAFE	6227325G	2025-07	2030-08
1029DFXVAFE	7072925G	2025-07	2030-08
1029DFXVAFE	7073025G	2025-07	2030-08
1029DFXVAFE	7073225G	2025-07	2030-08
1029DFXVAFE	6329325L	2025-10	2030-09
1029DFXVAFE	6333825L	2025-10	2030-09
1029DFXVAFE	6333925L	2025-10	2030-09
1029DFXVAFE	6352425L	2025-10	2030-09
1029DFXVAFE	6352525L	2025-10	2030-09
1029DFXVAFE	6352625L	2025-10	2030-09
1029DFXVAFE	6409525N	2025-12	2030-11
1029DFXVAFE	6409625N	2025-12	2030-11
1029DFXVAFE	6397625N	2025-12	2030-11
1029DFXVAFE	6399125N	2025-12	2030-11