	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/2026/007		

FIELD SAFETY NOTICE - LET/QA/2026/007

Type of Action: Voluntary product withdrawal of affected batches

Subject: Potential quality issue in Fannin Double Chambered Blood Set (7017DF4X and 7017DF4XMY)

Dear Valued Customer

Poly Medicure Limited would like to inform you of a Field Safety Notice (FSN) concerning the Fannin Double Chambered Blood Set, supplied exclusively for the UK and Irish 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 prioritise patient safety, we have decided to withdraw all affected batches.

Background:

Poly Medicure Limited has received customer feedback reporting leakage of the Fannin Double Chambered Blood Set during use. Our initial assessment indicates potential leakage may occur at a particular joint, compromising the integrity of the device during administration of blood or blood components. The investigation into the root cause is ongoing, however Poly Medicure Limited has decided to withdraw all affected batches, manufactured between April and September 2025.

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

Potential Risks:

Leakage from the Fannin Double Chambered Blood Set (7017DF4X and 7017DF4XMY) during use may result in:


- Interruption of blood or blood component delivery
- Exposure risk to clinical staff
- Air entrainment
- Delay in patient treatment

To date, no serious patient harm has been reported.

No Fannin Double chambered Blood Sets are distributed outside UK and Ireland.

Reason for this Field Safety Notice (FSN):

This Field Safety Notice is issued following customer feedback indicating leakage from a particular joint of the Double Chambered Blood Set (7017DF4X and 7017DF4XMY). As the issue may affect device integrity, Poly Medicure Limited has initiated a voluntary withdrawal of affected batches, manufactured between April to September 2025, supplied to Fannin UK.

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Required Customer Actions:

- Identify and quarantine all remaining stock as per Annex-II. Stop using and distributing the affected batches immediately
- 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
- Return all unused units of the affected batches to Poly Medicure Limited
- 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 organisation, including those who manage, use, or maintain these devices. If you have supplied this product to another organisation, please ensure this notice is passed on accordingly.

Actions Taken by Poly Medicure Limited (Manufacturer):

- Voluntary withdrawal of all affected batches manufactured for the UK and Irish market between April and September 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).

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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, Unit 200, Repton Road,
Westminster Industrial Estate,
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

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Annex-I - Acknowledgment Form

We acknowledge receipt of the Field Safety Notice (FSN) from Poly Medicure Limited, regarding withdrawal of the affected Fannin Double Chambered Blood Sets (7017DF4X and 7017DF4XMY).

Customer / Distributor Name: _____

Customer Address: _____

Contact Person: _____


Contact Email Address: _____

Signature: _____

Date: _____

The duly completed form must be returned to the following address: info@polymedicure.com before February 15, 2026.

Product Code	Batch Number	Quantity Returned

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Annex-II - List of Batches affected by this FSN:

Product Code	Batch Number	Mfg. Date	Exp. Date
7017DF4X	2512355D	2025-04	2030-03
7017DF4X	2512356D	2025-04	2030-03
7017DF4X	2512357D	2025-04	2030-03
7017DF4XMY	2512358D	2025-04	2030-03
7017DF4XMY	2512358D	2025-04	2030-03
7017DF4X	2512878E	2025-05	2030-04
7017DF4X	2512879E	2025-05	2030-04
7017DF4X	2512880E	2025-05	2030-04
7017DF4X	2512881E	2025-05	2030-04
7017DF4X	2512882E	2025-05	2030-04
7017DF4X	2512963E	2025-05	2030-04
7017DF4XMY	2512884E	2025-05	2030-04
7017DF4X	2512964E	2025-05	2030-04
7017DF4X	2513650F	2025-06	2030-05
7017DF4X	2513651F	2025-06	2030-05
7017DF4X	2513652F	2025-06	2030-05
7017DF4X	2513653F	2025-06	2030-05
7017DF4X	2513654F	2025-06	2030-05
7017DF4X	2513655F	2025-06	2030-05
7017DF4X	2514112G	2025-07	2030-06
7017DF4X	2514113G	2025-07	2030-06
7017DF4X	2514114G	2025-07	2030-06
7017DF4XMY	2514115G	2025-07	2030-06
7017DF4XMY	2514630H	2025-08	2030-07
7017DF4X	2515005K	2025-09	2030-08
7017DF4X	2515006K	2025-09	2030-08
7017DF4X	2515007K	2025-09	2030-08
7017DF4XMY	2515008K	2025-09	2030-08
7017DF4X	2515470K	2025-09	2030-08
7017DF4X	2515471K	2025-09	2030-08
7017DF4X	2515472K	2025-09	2030-08
7017DF4X	2515473K	2025-09	2030-08
7017DF4X	2515527K	2025-09	2030-08
7017DF4X	2515528K	2025-09	2030-08