



URGENT FIELD SAFETY NOTICE

Type of action: Product Recall

Company: Farla Medical Ltd, Unit 2, Staples Corner Business Park, 1000 North Circular Rd, London, NW2 7JP, United Kingdom

Date: 3rd April 2025

Reference Number: CCR170

Farla Medical are issuing this recall notice to inform you of a product recall involving all detailed lots of the below mentioned product list (Appendix 1).

Our records indicate that you may have purchased this product, and this letter requires your immediate attention.

DESCRIPTION OF THE DEFECT

This notification is issued in response to the release of medical devices into the UK market by Farla Medical, which were manufactured by an external subcontractor. Unfortunately, the sterility and performance of these products cannot be assured. It has come to our attention that the subcontractor may not have adhered to the required regulatory oversight, resulting in potential non-compliance with the essential safety and performance standards outlined under UK Medical Device Regulations.

While no immediate adverse events or customer complaints have been reported, the deviation from regulatory requirements means that the quality and performance of these products cannot be fully guaranteed. In order to mitigate any potential risks, Farla Medical Ltd is taking immediate corrective action to remove the affected devices from the market and prevent any further distribution.

ACTIONS TO BE TAKEN BY FARLA MEDICAL

Farla Medical Ltd has initiated an investigation into the cause of the issue with the subcontractor and will put corrective actions in place to ensure future products are not affected.

ACTIONS TO BE TAKEN BY THE CUSTOMER

We request that you check your inventory for the items within the scope of this recall notice, and if you have the items identified please cease use and distribution of the stock and quarantine immediately.

Please ensure that other relevant staff in your organisation are aware of this issue. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



If the affected product has already been safely used, then no further product-related action is required.

Please promptly return the attached Recall Acknowledgement Letter & Form (QPD-29 -Iss. 7.0) to acknowledge receipt of this Notice.

Please note, if the Recall Acknowledgement Letter & Form (QPD-29-Iss. 7.0) along with the affected product is not returned within 21 days from the date of this notification, Farla Medical Ltd., must proceed with the closure of the corrective action involved. The deadline for return of the affected stock is the 24th of May 2025. After this date it will not be possible to replace the affected stock

Return address for affected stock: Loading Bay 1, Old Bay House, River Road, CT13 9FN, Kent

Affected stock will be replaced 3 months after the deadline return date above.

Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action.

We appreciate your cooperation, and we recognise the inconvenience this may cause your facility. Thank you for your support on this important matter.

Yours sincerely,

Samuel Zalcborg

Managing Director

DocuSigned by:

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**Appendix 1:**

Product Code	Product Name	Lot Number	Expiry Date
F54181	MediDrape Utility Drape 45 x 75cm Sterile Pack of 40	22033101	30/03/2025
F54181	MediDrape Utility Drape 45 x 75cm Sterile Pack of 40	22041001	30/04/2025
S42-8185	Instramed Thread Retriever 25cm Sterile	22052012	30/05/2025
S42-8185	Instramed Thread Retriever 25cm Sterile	UIR0103-2022	28/02/2027
2023	Instramed National Renal Pack	211029	30/09/2026
5022	Instramed Medium Dressing Pack	21060113	30/05/2026
6042	Instramed Teales Vulsellum Forceps Straight Plastic Handle 23cm	22052026	30/05/2025
6056	Instramed Iris Forceps Non-Toothed 10.5cm Plastics Handle	22052002	31/05/2025
7040	Instramed Hand Towel Sterile	22052502	30/05/2025
7040	Instramed Hand Towel Sterile	22052502	30/05/2025
7860	Instramed 1st Trimester Tray Pack with Curved Forceps	22052510	30/05/2025
7860	Instramed 1st Trimester Tray Pack with Curved Forceps	22052511	30/05/2025
400500	Instramed Sponge Forceps 23.5cm Single	22052009	30/05/2025
400500	Instramed Sponge Forceps 23.5cm Single	43829	30/10/2025
400900	Instramed Coil Remover Forceps 25cm	22052001	30/05/2025
500500	Instramed Polypropylene Gallipot 60ml Sterile Single	21100101	30/09/2026
500500	Instramed Polypropylene Gallipot 60ml Sterile Single	22032501	31/03/2025
500512	Instramed Polypropylene Gallipot 120ml Sterile Single	22033104	30/03/2025