Code	UN-17-01	Rev No	04
App By	AB, LO	App Date	30/01/26

Field Safety Notice

Ref# FSN-2026-003 Dated 14/07/26

COMPANY: Unisurge International Limited.

SRN: GB-PR-000033353

ADDRESS: Farboud Innovation Park, Formula Drive, Newmarket, CB8 0BF, United Kingdom.

Phone Number / Email: moeed.hamid@unisurge.com

TO WHOM IT MAY CONERN

We have issued this Field Safety Notice in compliance with our Vigilance Procedure due to an issue that has been brought to the attention of Unisurge International Limited. Details of the issue and products affected are documented below.

We apologise for any inconvenience that this issue may cause. We are working with the MHRA to resolve the situation.

Please can you complete the attached documents and return by either of the following methods:

Email – moeed.hamid@unisurge.com

Please can you ensure this form is returned **as soon as possible** but by **midday on Monday 27 July 2026.**

Any queries or concerns regarding this notice should be addressed to the undersigned:

Yours sincerely,

Moeed Hamid
Head of Regulatory Affairs.
Email: moeed.hamid@unisurge.com
Mobile: 07935906108

Customer Service: 08455 213111
Website: *Click link below*
Contact Unisurge – Unisurge International Limited

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FIELD SAFETY NOTICE

Reference Number:	FSN-2026-003
Date:	14/07/2026
Type of Action:	☒ Product Recall ☐ Device Modification ☐ Labelling Update ☐ Software Update ☐ Advisory ☐ Other (specify)
1. Information on the Affected Device(s)	**DETAILS (IF ANY)**
Device Name:	List attached of procedure packs affected by recall (page 6)
Model / Catalogue Number:	List attached (page 6)
UDI-DI / UDI-PI:	N/A
Software Version (if relevant):	N/A
Lot/Serial Numbers:	List attached (page 6)
Quantity supplied	TBD
Manufacturing / Distribution Dates:	TBD
Country(ies) Affected	United Kingdom
2. Reason for the Field Safety Corrective Action	**DETAILS (IF ANY)**
Issue Identified:	All Unisurge Procedure packs that include the following BD product needs to be recalled. Field Safety Notice: Product Recall – Becton Dickinson (BD) Applicators Becton Dickinson UK Ltd has initiated a product recall for specific batches of one applicator due to concerns over sterile barrier integrity. This issue is related to potential open or incomplete seals on the applicator packaging which has been identified as a risk to sterile barrier integrity. of microbial contamination. Affected Products: • Chloraprep 1mL Applicator • REF: 270480 • Pack size: 60 applicators • Expiry Date: Up to 05/2029 • License Number: PL 05920/0002 **Actions Required:** • Immediately stop usage and distribution of the affected batches. • Quarantine all remaining stock. • Return batches through the approved return process to receive replacement products or credit. • Complete and submit the required response form to Becton Dickinson or your distributor by 27 July 2026, confirming the status of your stock and actions taken.

	Reporting of Adverse Reactions: Healthcare professionals are urged to report any adverse drug reactions (ADRs), particularly serious incidents like hospitalization or long-term disability, via the Yellow Card Scheme (accessible online, through the Yellow Card mobile app, or directly to the MHRA). **Support and Contact Information:** For further guidance or inquiries, customers can contact Becton Dickinson through the following channels: • Email: safetyinformation@bd.com • Phone: 08000437546 This recall has been coordinated with the Medicines and Healthcare Products Regulatory Agency (MHRA) under reference SUR-26-06099. It is vital to comply with all steps to ensure patient safety and successful recall completion
Root Cause (if known):	The reason for this recall is that BD has identified a potential risk to sterile barrier integrity due to potential open or incomplete seals on the applicator packaging.
Clinical Impact / Risk:	The clinical impact risk identified is the potential microbial contamination of the applicator's contents due to the compromised sterile barrier caused by wrinkling in the paper lidding material. If the sterility of the product is affected, it could result in serious infections for patients when the product is used. This risk underscores the importance of promptly discontinuing the use of the affected batches and following the recall process to mitigate patient safety concerns.
Reported Incidents:	None as of 13/07/2026
3. Actions to be Taken by the Customer/User	**DETAILS (IF ANY)**
Stop Use?:	☒ Yes ☐ No – [State if use should be stopped immediately]
Return of Device?:	☒ Yes ☐ No – [Describe how to return affected product]
Modification Required?:	☐ Yes ☒ No – [Instructions on applying any software updates, label corrections, etc.]
Replacement / Refund Offered?	TBD
User Notification to Others? Ask users to inform downstream distributors or relevant personnel	Please communicate this information to all the parties affective by this recall.

Compliance Confirmation Form?	Attached ☒ Yes ☐ No Please fill out the form and return to your Unisurge customer service representative.
4. Actions Planned by the Manufacturer	**DETAILS (IF ANY)**
- Description of corrective action (e.g., redesign, training, risk update)	**Actions Required:** • **Immediately stop usage and distribution** of the affected batches • **Quarantine** all remaining stock. • Return batches through the approved return process to receive replacement products or credit. • Complete and submit the required response form to Becton Dickinson or your distributor by 27 July 2026, confirming the status of your stock and actions taken. **Reporting of Adverse Reactions:** Healthcare professionals are urged to report any adverse drug reactions (ADRs), particularly serious incidents like hospitalization or long-term disability, via the **Yellow Card Scheme** (accessible online, through the Yellow Card mobile app, or directly to the MHRA). This recall has been coordinated with the Medicines and Healthcare Products Regulatory Agency (MHRA) under reference SUR-26-06099. It is vital to comply with all steps to ensure patient safety and successful recall completion
- Estimated timeline for completion	
- Confirmation of Competent Authorities notified	MHRA MORE system has been updated.
5. Transmission of this FSN	
Please ensure this notice is forwarded to all those who need to be aware within your organization and to any organisation where the potentially affected devices have been transferred.	
6. Contact Point	**DETAILS (IF ANY)**
Contact Person:	Moeed Hamid
Title:	Head Of Reg Affairs.
Phone: [+XX-XXXXXXX]	+44 08455 213111 Ext 318 or Ext 376 or 323
Email: [contact@example.com]	moeed.hamid@unisurge.com

7. Acknowledgment Form (To Be Filled and Returned by the customer)	
We acknowledge receipt of this FSN and confirm the required actions have been taken.	
Organisation Name:	
Contact Person:	
Date:	
Signature:	
☐ We confirm that we have read and understood the FSN.	
☐ We confirm that we have taken the required actions as instructed.	

Tick the appropriate box below:

☐ We do not have any of the affected packs at any location within our facility.

OR

☐ We have packs affected by this recall in our possession, and I confirm that the packs have been quarantined and will be returned to Unisurge.

Please complete the following table:

Reference (F code)	**Lot Number (W number)**	**Number of units returned** *(please specify if these are packs or boxes)*

Attached Product List:

F code	Product Name	Lot Number
F810425.E	Pack Cannulation	W554870
F810425.E	Pack Cannulation	W559082
F810425.E	Pack Cannulation	W561680
F810496.B	IV CANNULATION PACK	W554250
F810496.B	IV CANNULATION PACK	W553606
F810523.C	Pack Cannulation	W553446
F810523.C	Pack Cannulation	W555072
F810523.C	Pack Cannulation	W558836
F810523.C	Pack Cannulation	W559993
F810523.C	Pack Cannulation	W563046
F810591	Pack Cannulation With Tegaderm Dressing	W552417
F810591	Pack Cannulation With Tegaderm Dressing	W556514
F810591	Pack Cannulation With Tegaderm Dressing	W559321
F810591	Pack Cannulation With Tegaderm Dressing	W562547
F810620	Pack Cannulation 2	W553462
F810639.C	Pack Cannulation Neonatal	W553360
F810639.C	Pack Cannulation Neonatal	W557658
F810639.C	Pack Cannulation Neonatal	W558840
F810639.C	Pack Cannulation Neonatal	W559323
F810639.C	Pack Cannulation Neonatal	W562261
F810673	Pack IV Cannulation (Chloraprep)	W553182
F810731	Pack Chest Drain (Sterile Extras)	W561999
F810766	Pack IV Cannulation Small Baby	W555080
F810766	Pack IV Cannulation Small Baby	W556304
F810766	Pack IV Cannulation Small Baby	W561226
F810980	Pack Neonatal IV Cannulation	W557013
F811040.B	Pack Cannulation	W552930
F811040.B	Pack Cannulation	W557018
F811040.B	Pack Cannulation	W561486