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

Field Safety Notice

Ref# FSN-2026-002 dated 04-06-2026

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 15th of June 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

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

FIELD SAFETY NOTICE

Reference Number:	**FSN-2026-002**
Date:	04-06-2026
Type of Action:	☒ Product Recall ☐ Device Modification ☐ Labeling Update ☐ Software Update ☐ Advisory ☐ Other (specify)
1. Information on the Affected Device(s)	**DETAILS (IF ANY)**
Device Name:	List Attached: Unisurge Product Affected by BD Product **ChloraPrep 1mL Applicator** **ChloraPrep Frepp™ 1.5 ml Applicators** **REF: 270480 and 270299**
Model / Catalogue Number:	Lits attached
UDI-DI / UDI-PI:	NA
Software Version (if relevant):	NA
Lot/Serial Numbers:	List Attached
Quantity supplied	TBD
Manufacturing / Distribution Dates:	TBD
Country(ies) Affected	United Kingdoms
2. Reason for the Field Safety Corrective Action	**DETAILS (IF ANY)**
Issue Identified:	All Unisurge Procedure packs that include the following BD product need 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 two applicators due to concerns over sterile barrier integrity. This issue is related to wrinkling of the paper lidding, which may compromise the seal and pose a risk of microbial contamination. **Affected Products:** 1. **ChloraPrep 1mL Applicator** ○ **REF**: 270480 ○ **Pack size**: 60 applicators ○ **Expiry Date**: Up to 02/2028 ○ **License Number**: PL 05920/0002 2. **ChloraPrep Frepp™ 1.5mL Applicator** ○ **REF**: 270299 ○ **Pack size**: 20 applicators ○ **Expiry Date**: Up to 01/2028 ○ **License Number**: PL 05920/0001

	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 **June 15, 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**: [Contact Email] • **Phone**: [Contact Number] This recall has been coordinated with the Medicines and Healthcare Products Regulatory Agency (MHRA) under reference **SUR-26-06093-FA**. It is vital to comply with all steps to ensure patient safety and successful recall completion
Root Cause (if known):	The root cause identified for the recall is a **potential risk to sterile barrier integrity** due to **wrinkling of the paper lidding material**, which may extend to the seal area. This compromise in the sterile barrier could lead to a risk of microbial contamination during use.
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 04-06-2026
3. Actions to be Taken by the Customer/User	**DETAILS (IF ANY)**
Stop Use?:	☒ Yes ☐ No – Use should be stopped immediately
Return of Device?:	☒ Yes ☐ No – Please confirm the quantity of the affected stock available with you and we will arrange the recall.

Modification Required?:	☐ Yes ☒ No
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 sign the section of this form allocated for customer.
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 **June 15, 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-26-06093-FA**. It is vital to comply with all steps to ensure patient safety and successful recall completion.
- Estimated timeline for completion	15-06-2026
- Confirmation of Competent Authorities notified	MHRA MORE system is update

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 organization where the potentially affected devices have been transferred. TBD

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.	
Organization 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 tables:

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

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

ATTACHED PRODUCT LIST :

A. Unisurge Procedure packs identified to be affected by this RECALL by BD.

Product List: For 1.5 ml Chlora prep.

F code	Lot number
F810641-NS.C	W557009
F810601.C	W558227
F100165.C	W558068
F810632.C	W558510
F811037	W557962
F810641-NS.C	W557009
F810641-NS.C	W556515
F810641-NS.C	W555375
F100165.C	W556429
F810641-NS.C	W556301
F302952	W550366
F810531.C	W553607
CPC-06901.B	W553620
F810387	W553954
F810641-NS.C	W549960
F810632.C	W553962
F100165.C	W554352
F810489	W554782
F810531.C	W554784
F810641-NS.C	W550166
F810531.C	W550678
F810489	W551812
F811036	W551822
F810641-NS.C	W548178
F811037	W548514
F810641-NS.C	W548507
F811036	W548513
F810531.C	W549229
F100165.C	W549748
F811037	W550451
F810531.C	W548169
F810601.C	W548263
F810641-NS.C	W547732
F100165.C	W548335
F810641-NS.C	W545788
F811037	W545517

F810641-NS.C	W545226
F810632.C	W546400
F810641-NS.C	W545788
F810641-NS.C	W546401
F810641-NS.C	W547218
F811036	W544668
F810387	W544982
F810489	W544987
F810641-NS.C	W542059
F810531.C	W545508
F810641-NS.C	W544991
F811037	W545517
F100165.C	W542695
F811037	W542869
F810641-NS.C	W542762
F810531.C	W543577
F810489-	W544117
F810601.C	W544660
F811036	W544668
F810641-NS.C	W542059
F810489	W542507
F811036	W542069
F810641-NS.C	W541111
F810641-NS.C	W539065
F100165.C	W538869
F810641-NS.C	W539626
F811036	W542069
F811037	W539636
F810632.C	W539929
F810531.C	W540793
F810641-NS.C	W539065
F100165.C	W538869
F810601.C	W537132
F810641-NS.C	W536366
F810641-NS.C	W536540
F810641-NS.C	W537133
F810489	W538495
F810531.C	W538496
F810666	W533368
F810641-NS.C	W535158
F810531.C	W536535
F810632.C	W536539
F100165.C	W536294
F810387	W536709

F810531.C	W536535
F810638	W534053
F810489	W534595
F810531.C	W534737
F810531.C	W533183
F810489	W531909
F81038	W532173

B. Unisurge Procedure packs identified to be affected by this RECALL by BD.

Product List: For 1.0 ml Chlora prep.

F code	Lot number
F810731	W551001
F810496.B	W551813
F810767	W553970
F810425.E	W550992
F810980	W551279
F810766	W551819
F810591	W552417
F810496.B	W549955
F811040.B	W549457
F810523.C	W549957
F810639.C	W550441
F810591	W547216
F810731	W548181
F810767	W548510
F810523.C	W548168
F810496.B	W546806
F810767	W546813
F810731	W546999
F811040.B	W547000
F810591	W547216
F810523.C	W545784
F810425.E	W545219
F812141	W543843
F810766	W546012
F810591	W543579
F810496.B	W543732
F810767	W543738
F812143	W543845
F600919.B	W548127
F812142	W543844

F810523.B	W544119
F811040.B	W544363
F810639.C	W543132
F810496.B	W545223
F810425.E	W543300
F812141	W542962
F812142	W542963
F812143	W542964
F810425.E	W542051
F810425.E	W543300
F810496.B	W541414
F810523.B	W540792
F810425.E	W540792
F810496.B	W539620
F810766	W539631
F810767	W539632
F811040.B	W540269
F810425.E	W539339
F810425.E	W538259
F810523.B	W538261
F810731	W536243
F810425.E	W536530
F810731	W536685
F810523.B	W536534
F810591	W537131
F810591	W535995
F810731	W536243
F811040.B	W534060
F810980	W534324
F810523.B	W533909
F810496.B	W535472
F811040.B	W535478
F810496.B	W531910
F810425.E	W530297
F810496.B	W531222
F810591	W531225
F810523.B	W531624
F811040.B	W531649
F810425.E	W528788
F810523.B	W529273
F811040.B	W529738
F8110425.E	W530297
F810639.C	W530304
F810591	W527991

F810731	W528476

End of report.