Smith & Nephew, Inc.
Global Field Actions
1450 Brooks Road
Memphis, TN 38116
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Smith+Nephew

<Recipients Address>

URGENT FIELD SAFETY NOTICE: Correction

Date Issued: 06-July-2023

Reference: C-2023-05

Legal Manufacturer: Smith & Nephew Medical Limited

Concerned Devices: No-Sting SKIN-Prep Wipes and No-Sting SKIN-Prep Swabs

Product No.	Description	Batch No.
59420600, 59420700, 66800712, 66800787, 66800788, 66800789, 66800790	No-Sting SKIN-Prep Wipes and No-Sting SKIN-Prep Swabs	See Appendix 1

Dear Customer:

This letter is to inform you that Smith & Nephew Medical Limited has initiated a field action to voluntarily remove certain batches of No-Sting SKIN-Prep Wipes and No-Sting SKIN-Prep Swabs due to a manufacturing error resulting in the presence of acetic acid causing a vinegar-like odor and potential minor skin irritation.

This field action has been reported to the relevant competent authorities.

Patient Impact
Smith+ Nephew recommends that physicians maintain their routine patient follow-up protocol.

Risks to Health	In the most likely scenario, the user opens the product, detects the odor, and does not continue to use the product. There is no harm. In the worst case scenario, the user opens the product and uses the NSSP wipes/swabs. The patient's skin is exposed to an increased level of acetic acid, potentially resulting in minor skin irritation.
Actions to be taken by the user	1. Ensure that the contents of this Field Safety Notice are read and understood by those within your organisation who may use No-Sting SKIN-Prep Wipes and No-Sting SKIN-Prep Swabs 2. Locate and quarantine affected devices immediately. If you have further distributed the product to other organisations, please inform them at once of this Field Action and provide to them a copy of this letter. 3. Please discard affected product at your facility.

	4. Please complete the Customer Response form and email or fax it to your national Smith+Nephew agency/distributor. 5. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

If you or any of the healthcare providers you serve have any questions regarding this information, please contact your national Smith+Nephew agency/distributor.

Smith+Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.

Thank you for your attention and cooperation.

Appendix 1: Product part and batch numbers

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Customer Response Form

Please read in conjunction with the Field Safety Notice and return the completed and signed Customer Response Form by <date>.

Reference: C-2023-05
Concerned Devices: No-Sting SKIN-Prep Wipes and No-Sting SKIN-Prep Swabs

1. Return Acknowledgement details	
Email	<Local market to add>
Customer Helpline	<Local market to add>
Fax	<Local market to add>

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

2. Customer Details			
Healthcare Organisation / Facility Name*	<Fillable form field>		
Name of **all** Facilities/Hospitals covered by this response*	<Fillable form field>		
Facility / Hospital Address*	<Fillable form field>		
Telephone Number	<Fillable form field>	Email address	<Fillable form field>
Name of your supplier / wholesaler (if not Smith+Nephew)	<Fillable form field>		
Healthcare Organisation / Facility Stamp (if available)	<Fillable form field>		

3. Customer action undertaken on behalf of Healthcare Organisation / Facility Please complete/tick as appropriate.		
☐ Yes	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	
☐ Yes ☐ No	Has your Healthcare Organisation / Facility distributed the product to other organisations? If you have answered yes, tick all that apply: *	
	☐ I have identified customers that received or may have received this device.	
	☐ I have informed the identified customers of this FSN.	
	☐ I have received confirmation of reply from all identified customers.	
☐ Yes	I performed all actions requested by the FSN. *	
Tick Appropriate Response:*	☐ Yes	Neither I nor any of my customers has any affected devices in inventory.
	☐ Yes	In our Organisation / Facility we have concerned devices that: - have been placed in quarantine and - discarded as indicated in **Section 4** below. Complete **Section 4** with material, batch/serial, and quantity information related to devices discarded.

4. Devices Discarded		
Material Number	Batch or Serial Number	Quantity Discarded

Print Name*	<Fillable form field>		
Signature*	<Fillable form field>	Date*	<Fillable form field>

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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Appendix 1: Part and Batch Numbers

Part Number	Batch
59420600	71430
59420600	71660
59420600	71860
59420600	72090
59420600	72210
59420600	72330
59420600	72780
59420600	73020
59420600	73030
59420600	73320
59420600	73420
59420600	73600
59420600	73850
59420600	74020
59420600	74240
59420600	74640
59420600	74890
59420600	75220
59420600	75340
59420700	65630
59420700	65850
59420700	65980
59420700	66210
59420700	66520
59420700	66670
59420700	72790
66800712	65350
66800787	67340
66800788	67660
66800788	67750
66800788	67770
66800788	67860
66800788	73460
66800789	73820
66800790	66790