Smith & Nephew, Inc.
Global Field Actions
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Smith+Nephew

<Recipients Address>

URGENT FIELD SAFETY NOTICE:
Product Recall

Date Issued: 20-Nov-2023

Reference: R-2023-13

Legal Manufacturer: Smith & Nephew, Inc.

Concerned Devices: R3 0 HOLE ACET SHELL 54MM

Product No.	Description	Batch No.
71331854	R3 0 HOLE ACET SHELL 54MM	23HM03659

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc., has initiated a field action to voluntarily remove one batch of R3 0 HOLE ACET SHELL 54MM due to a manufacturing error that resulted in a package containing an R3 3 HOLE ACET SHELL 54MM instead of a R3 0 HOLE ACET SHELL 54MM as described on the product label.

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 discrepancy is identified during operation. A back-up shell is utilized to complete the surgery without a significant delay. There is no hazardous situation and no harm. In the worst case scenario the discrepancy is identified during operation. A back-up shell is not readily available to be used, and the surgeon decides to complete the surgery with the 3 HOLE shell without a significant delay. The 3 HOLE shell performs the same intended function as the 0 HOLE shell. Hole covers can be used if desired. There is no hazardous situation and no harm.
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 R3 0 HOLE ACET SHELL 54MM. 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 complete the Customer Response form and email or fax it to your national Smith+Nephew agency/distributor.

	4. Return quarantined product 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.

Smith+Nephew

Customer Response Form

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

Reference: R-2023-13
Concerned Devices: R3 0 HOLE ACET SHELL 54MM, batch 23HM03659

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>		

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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 - returned as indicated in **Section 4** below. Complete **Section 4** with material, batch/serial, and quantity information related to devices to be returned.

4. Devices to be Returned		
Material Number	Batch or Serial Number	Quantity Quarantined and to be returned

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.