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

T: + 1 901 396 2121
T: 1 800 821 5700 (USA toll free)
www.smith-nephew.com

Smith+Nephew

<Recipients Address>

URGENT FIELD SAFETY NOTICE:
Product Recall

Date Issued: 29 October 2024

Reference: R-2024-11

Legal Manufacturer: Smith & Nephew, Inc.

Concerned Devices: BIORAPTOR PK Suture Anchors

Product No.	Description	Batch No.	Unique Device Identifier(s)
72201541	BIRPTR 2.3 PK SUTURE ANCHOR W/ ULTRAB	2146369 2151242	03596010595072
72201542	BIRPTR 2.3 PK SUT ANCHR W/ ULTRAB BLK	2151690 2151691 2153489	03596010595089
72203280	BIORAPTOR CRV 2.3 PK SA UB COBRD BLACK	2151422	03596010656452
72203281	BIORAPTOR CRV 2.3 PK SA UB COBRD BLUE	2151692	03596010656469

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a Field Action to voluntarily remove seven (7) lots of BIORAPTOR Suture Anchors due to a potential for sterile barrier breach. Under certain shipping conditions, the distal end of the inserter can potentially pierce the packaging tray, compromising the sterile barrier.

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.

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Risks to Health	In the most-likely scenario, the packaging does not fully constrain the device, allowing the device to move within the tray. The device does not breach the packaging, and the device is used as intended. There is no hazardous situation or harm. In the worst-case scenario, the packaging does not fully constrain the device, allowing the device to move within the tray. The distal end of the inserter penetrates the tray, and the sterile barrier is breached. The breach is not identified prior to use, and the contaminated device is used in surgery and implanted without knowledge of the contamination. The patient is exposed to the contamination, which may result in joint space infection.
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 BIORAPTOR PK Suture Anchors. 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.

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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: R-2024-11
Concerned Devices: BIORAPTOR PK Suture Anchors

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.