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Smith+Nephew

[Recipients Address]

[Notification date]

URGENT FIELD SAFETY NOTICE:
Medical Device Field Safety Notice for Recall

Reference: R-2020-03
Concerned Devices: Footprint Ultra PK Suture Anchor

Catalog Number	Description
72202901	FOOTPRINT Ultra PK Suture Anchor, 4.5mm
72202902	FOOTPRINT Ultra PK Suture Anchor, 5.5mm

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc., has initiated a voluntary recall to remove specific lots of the Footprint Ultra PK Suture Anchor due to a packaging design related issue. The space between the device and the packaging permits excessive movement which could potentially lead to the displacement of the anchor's tip protector allowing the tip of the anchor to create a sterile breach.

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

Risks to Health	In the most likely scenario the user would identify the pouch breach prior to use. The device would not be used, the exchange could result in minor surgical delay. In the worst-case the breach is not noticed and a non-sterile device is used. The use of the device could result in the potential for a biologic response, such as infection to the patient. There have been no reports of the worst-case.
Actions to be taken by the user	1. Locate and quarantine affected unused devices immediately. 2. Return quarantined product to your national Smith+Nephew agency/distributor. 3. Complete the return slip and fax it to your national Smith+Nephew agency/distributor. 4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 5. Please maintain awareness on this notice and resulting action until the Field Safety Notice for Recall is terminated to ensure effectiveness of the action.

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.

If you have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

☐ We confirm the receipt of this Field Safety Notice for Recall.

In our facility we have _____ *[Qty]* concerned devices which we will return.

_____ *[Qty]* concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2020-03

Name: _____ Date / Signature: _____