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]

August 17, 2020

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

Reference: R-2020-18
Concerned Devices: SPEEDSTITCH NEEDLE

Catalog Number	Description	Lot Numbers
OM-8850	SPEEDSTITCH NEEDLE	2018434, 2018934, 2019558, 2019559, 2019929, 2019930, 2020931, 2022111, 2022641, 2030008, 2032212, 2032526, 2033815, 2036941, 2037604, 2038701, 2039699, 2040500, 2042295, 2044957, 2047483, 2048575 & 2051239

Dear Customer:

This letter is to inform you that ArthroCare Corporation has initiated a field action to voluntarily remove multiple lots of SPEEDSTITCH Needles due to a supplier error where a portion of the raw material was inadvertently mixed. As a result, some needles may be made of commercially pure titanium as opposed to 304 stainless steel which does not meet the specification and could potentially break during use.

Risks to Health	In the most likely event, a titanium needle is inadvertently used and results in a surgical delay less than 30 minutes should the device break during use and is retrieved. In the worst case, the needle breaks during use and results in a surgical delay or an irretrievable broken device piece.
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-2020-18

Name: _____ Date / Signature: _____