

[Recipients Address]

June 24, 2020

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

Reference: R-2020-11

Concerned Devices: SUTUREFIX ULTRA 1.7MM Drill, Small

| Product No. | Description                        | Batch No. |
|-------------|------------------------------------|-----------|
| 72203855    | SUTUREFIX ULTRA 1.7MM Drill, Small | 2038366   |
|             |                                    | 2039311   |
|             |                                    | 2046505   |

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a field safety corrective action to voluntarily remove a group of SUTUREFIX ULTRA, 1.7MM DRILL (S) due to a packaging error. The packaging indicated the drill should be a 1.7mm twist drill (S), however, the package contained a 1.7 mm (XL) drill. The overall length of the XL is longer than the (S) drill.

|  |   |
|--|---|
| <b>Risks to Health</b>                 | In the event an affected device is presented, the use of the instrument could potentially result in the device drilling to an improper depth. In the worst case, the incorrect depth could potentially lead to patient harm due to over drilling into significant structures such as a nerve and/or artery. We have received no complaints for the worst case.  |
| <b>Actions to be taken by the user</b> | <ol style="list-style-type: none"> <li>1. Locate and quarantine affected unused devices immediately.</li> <li>2. Return quarantined product to your national Smith+Nephew agency/distributor.</li> <li>3. Complete the return slip and e-mail it to your national Smith+Nephew agency/distributor.</li> <li>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.</li> <li>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.</li> </ol> |

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 hereby 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-2020-11

Name: \_\_\_\_\_ Date / Signature: \_\_\_\_\_