

[Recipients Address]

August 28, 2017

Device Field Safety Corrective Action / Recall

Reference: R-2017-20

Concerned Devices: Trigen Meta-Tan Nail (71649634)

Product No.	Description	Batch No. / UDI No.
71649634	META-TAN 10MM X 34CM LEFT	16CM03554

Shipment Date: 12/8/2016 thru 1/7/2017

Dear Customer

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove a single lot of TRIGEN META-TAN NAIL 10mm x 34 CM Left due to a labeling error. The incorrect Chartstik label was for a D-RAD Smart Pack opposed to the TRIGEN META-TAN Nail 10mm x 34 CM left..

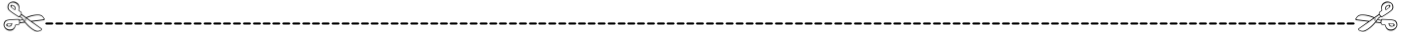
Required Actions:

- Please ensure that all affected patient files are updated accordingly
- Please follow the instructions on the attached Response Form.

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

Risks to Health	In the event the affected product is presented for use the device will perform as intended. However, in the event a revision surgery is warranted, the chartstik error could lead to confusion during preparation.
Actions to be taken by the user	<ol style="list-style-type: none"> 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 Corrective Action 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 hereby confirm that we are aware of this Field Safety Notice. The Field Safety Notice was communicated within our organisation.

Please mark accordingly:

- In our facility we do not have any of the affected product in stock
or
- We will return the following products:

Product	Description	Lot Number	Qty. to be Returned
71649634	META-TAN 10MM X 34CM LEFT	16CM03554	

Institution: _____ Reference: R-2017-20

Name: _____ Date / Signature: _____