June 21, 2016

URGENT FIELD SAFETY NOTICE: RA2016-094

FSCA Identifier: Product Field Action RA 2016-094

Type of Action: Field Safety Corrective Action

Description: Mislabeling T2 Nail

Legal Manufacturer Stryker Trauma GmbH, Prof.-Kuentscher-Strasse 1-5, 24232 Schoenkirchen/Kiel, Germany

Catalogue number	Product name	Lot #
18251128S	Femoral Nail A/R Ø 11x280	K288335RA (1 unit)
18260930S	T2 SCN Ø9x300	K836729RA (1 unit)

The affected products have not been imported nor distributed in Singapore

Dear Customer,

Please find attached details of a voluntary Field Safety Corrective Action that has been initiated by Stryker Trauma GmbH, Division Trauma and Extremities for a single unit of **Femoral Nail A/R Ø 11x280** and a single unit of SCN Ø9x300. It was found through review of packaging that 1 unit of **Femoral Nail, A/R T2 Ø10x320 (**article # 18251032S) was labelled as **Femoral Nail A/R Ø 11x280** (article # 18251128S) and that that 1 unit of **T2 Tibial Nail, Standard Ø9x300** (article # 18220930S) was labelled as **T2 SCN Ø9x300** (article # 18260930S) and were shipped to market. Stryker Trauma GmbH, Division Trauma and Extremities is recalling these two specific device.

Potential Harm

The mislabelled T2 Femoral Nail will be identified in all probability at latest during insertion by intraoperative fluoroscopy and detected as too long because the tip of the nail will stop in the marrow cavity prior to reaching the intended position at the driving end of the nail. Only exceptionally it will protrude into the knee joint (antegrade insertion) or perforate the bone in the area of the piriformis fossa (retrograde insertion) when the nail is inserted with brute force by a careless surgeon without intraoperative check of the nail position by fluoroscopy. Both malpositions would be detected intraoperatively at latest prior to insertion of the distal (antegrade nailing) or proximal (retrograde nailing) locking screws. Both potential perforations would result in bone damage.

The mislabeled T2 Tibia Nail does not bear any relevant risk as the mislabeling will be most probably detected prior to implantation. However the mislabeled product will be removed from the market.

Mitigating Factors

The mislabelled T2 Femoral Nail will be identified in all probability at latest during insertion by intraoperative fluoroscopy and detected as too long because the tip of the nail will stop in the marrow cavity prior to reaching the intended position at the driving end of the nail.

T2 Tibia nail and SCN articles have different receptions for the nail adapter of the Target Device. Thus the mislabeling will be most probably detected prior to implantation.

Affected customers are requested to read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending to return to Stryker.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility

4. Inform Stryker if any of the subject devices have been distributed to other organisations.

    a) *Please provide contact details so that Stryker can inform the recipients appropriately*
    b) *If you are a Distributor, note that you are responsible for notifying your affected customers.*

5. Please inform Stryker of any adverse events concerning the use of the subject device.
   Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.

6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have the subject device in your physical inventory.

7. Return the completed form to the undersigned or your Stryker Representative. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt. Your designated contact person for this action is given below. Should you have any queries concerning this matter, please contact the signatory.

On behalf of Stryker we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

[redacted]

Sara Jato
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FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

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I acknowledge receipt of the Field Safety Notice for RA2016-094 and can confirm that:

We have not located any of these devices in our inventory: ***(please delete if not applicable)***				
We have located the following devices:				
Product description	**Product Reference**	**Lot Number**	**Qty**	**Qty Quarantined**
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				
Form completed by:				

Contact Name _____ **Contact Facility** _____

Contact address _____ **Contact Position** _____

_____ **Contact Tel No** _____

_____ **Contact Fax No** _____

_____ **Contact e-mail** _____

PLEASE COMPLETE AND FAX THIS FORM TO YOUR STRYKER REPRESENTATIVE