stryker

RA2020-2525723
URGENT FIELD SAFETY NOTICE

Everest® MI XT Tab Removal Tool

Attn: Materials Manager/Inventory Contacts
Recall Number: RA2020-2525723
November XX, 2020

Product affected

Catalog number	GTIN	Product description	Lot numbers	Distribution Dates
5101-90195	10888857290679	Everest® MI XT Tab Removal Tool (i.e. All-In-One Tab Removal Tool)	JUFT, JUGX, KEFE, KUBJ, KVNT, KYRR, MAJR	September 23, 2019 – August 12, 2020

Product description

The Tab Removal Tool is used to break the tab off the Everest XT screw by rocking the instrument back and forth until the entire tab is fully detached from the screw head.

Product issue

Stryker identified a trend for reports of Everest MI XT Tab Removal Tool handles cracking and/or separating at the internal threaded interface between the tool's metal shaft and Radel® plastic handle, the result of the Radel® plastic handle reacting with non-medical grade Loctite® threadlocker applied to the tool's internal threading. Stryker has not received any reports of harm to users or patients associated with this nonconformance.

Potential risks

1. Instrument handle fracture prior to or during surgery, resulting in tissue injury to patient or surgeon/OR staff (i.e. if sharp edges result from fracture).

   Note: None of the complaint devices received by Stryker exhibited sharp edges.

2. Non-sterile portion of the handle (or Loctite threadlocker) becomes exposed and contaminates set, resulting in contaminated surgical site and potential for infection and/or further intervention to manage infection.

   Note: This potential risk is higher for immunocompromised patients, since their overall risk of infection is higher.

3. Intra-operative exposure of Loctite to surgical wound. In the event that the Loctite is observed and a patient's tissue is exposed, typical surgical practice when noticing a foreign substance on an instrument is to irrigate the wound. This serves the purpose of washing out the substance and decreasing any risk of local tissue reaction related to contact.

Actions needed

1. Immediately check your internal inventory to locate the affected products and put them in quarantine.
2. Circulate this Field 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. Even if you have distributed all product to another location, please complete the attached business reply form and indicate each location that received product.
    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 devices.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
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 any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this FSCA.
    a. On receipt of the form, a Stryker Representative will contact you to organise 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 do not hesitate to contact them directly.

Name:
Position:
E-mail:
Phone:

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

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

Sincerely,

stryker

Business Reply Form

Everest® MI XT Tab Removal Tool

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Please complete and sign this form. Email the completed form to XXXXXXXXX by **November xx, 2020**.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product	Lot numbers	Quantity on hand*
5101-90195	Everest® MI XT Tab Removal Tool (i.e. All-In-One Tab Removal Tool)	JUFT	
		JUGX	
		KEFE	
		KUBJ	
		KVNT	
		KYRR	
		MAJR	

*If no affected devices are available for return please enter 0 (zero).

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			