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URGENT:
MEDICAL DEVICE RECALL

Everest® MI XT Tab Removal Tool

Attn: Materials Manager/Inventory Contacts
Recall Number: 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 product listed on the attached Business Reply Form and remove them from their point of use.
2. Use the Business Reply Form to reconcile any affected product. **Complete the Business Reply Form even if there is no affected product identified.**
3. Return the enclosed Business Reply Form by email to XXXXXXX@Stryker.com to confirm receipt of this notification/document product segregation.
4. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return and replacement of your product(s).
5. If you desire additional training associated with these instructions, please contact our Regulatory Compliance team by calling XXXXXX or by email at XXXXXXXX@Stryker.com, or contact your local Sales representative.
6. Maintain awareness of this communication internally until all required actions have been completed within your facility.
7. Inform Stryker if any of the subject devices have been distributed to other organizations. If so, provide contact details so Stryker can inform the recipients appropriately.

If you have any questions or concerns, please contact Regulatory Compliance at 201.749.8090.

On behalf of Stryker we thank you sincerely for your help and support in completing this action by the target date **November 30, 2020** 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,

XXXX

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Business Reply Form

Everest® MI XT Tab Removal Tool

Recall Number: 2525723
November XX, 2020

Please complete and sign this form. Email the completed form to XXXXXXXXX by **November 18, 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			