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URGENT:
MEDICAL DEVICE RECALL

Everest® MI XT Inner and Outer Dilators

Attn: Quality or Materials Manager / Inventory Contacts
Recall Number: RA2021-2895946
January , 2022

Product affected

Catalog number	UDI	Product description	Lot numbers	Distribution Dates
5101-90167	10888857261204	Everest MI XT Inner Dilator	See list on page 3	July 13, 2018 – October 21, 2021
5101-90168	10888857261211	Everest MI XT Outer Dilator	See list on page 3	

Product description

The Inner and Outer Dilators are plastic instruments in the Everest MI (Minimally Invasive) XT Spinal System used to dilate tissue during pedicle screw placement.

Product issue

Stryker received two (2) complaints for units from specific lots of Inner and Outer Dilators, catalog numbers 5101-90167 and 5101-90168, not fitting together properly during a surgical procedure. Some dilators from these lots and from other lots were subsequently determined to be affected by a manufacturing nonconformance.

No adverse events have been reported for this issue.

Potential risks

Inability to dilate the tissue properly with the dilators may potentially result in surgical delay so an alternate set of dilators can be obtained from a second Everest MI XT set. If another set is not available, the surgeon may either have to convert to an open procedure or reschedule the procedure.

Actions needed

Our records indicate that you previously purchased products associated with the affected recalled lots.

We request that you read this notice carefully and complete the following actions:

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. Quarantine all subject devices and return them to Stryker

3. In the interim, until units can be removed from your facility by Stryker, there are no additional actions that users can and should take once the product has been segregated and removed from point of use.

   - If you desire additional training associated with these instructions, please contact your local Sales representative.

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

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

6. Inform Stryker if any of the subject devices have been distributed to other organizations.
   - Please provide contact details so that Stryker can inform the recipients appropriately.
   - If you are a Distributor, note that you are responsible for notifying your affected customers.

7. Please inform Stryker of any adverse events concerning the use of the subject devices.
   - Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

8. 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.**

9. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
   - On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request your support in finalizing the required steps within 14 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: email:

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 support in completing this action within the target date 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, remain on the market.

Sincerely,

XXXXXXX XXXXXXX
RAQA Specialist

Business Reply Form - Response required

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Everest® XT MI Inner and Outer Dilators

Recall Number: RA2021-2895946

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If affected inventory, please provide information below. (Attach additional sheet if needed.)

Catalog number	Product	Impacted Lot numbers (starting with)	Quantity on hand*
5101-90167	Everest XT MI Inner Dilator	JUJF	
		KFMV	
		KUPG	
		KYYU	
		MDRB	
		NDMK	
		NDMX	
		NXJK	
5101-90168	Everest XT MI Outer Dilator	HCBN	
		HCBP	
		JUJJ	
		KFMX	
		KUPH	
		KYYV	
		MDPF	
		NAKJ	
		NDGT	
		PCCN	

- **Customers must complete the form even if you do not have inventory.**

Customer information

Customer name _____

Name of person completing this form_____Title_____

Direct phone #_____Email_____

Address_____City_____State____ Postal code _____

Country _____

If you have further distributed subject devices, please provide information below.

Product code	Serial/Lot number	QTY	Facility Name	Facility Address	Contact person

I have read and understood the instructions provided and acknowledge receipt of the subjected FSN. ☐

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter. ☐

Name (print)_____Signature_____Date _____

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL, XX, OR FAX, XXX