

URGENT: MEDICALDEVICE RECALL

Chesapeake® Anterior Lumbar Removal Tool

Attn: Quality or Materials Manager / Inventory Contacts

Recall Number: RA2021-2792467

September, 2021



Product affected

Catalog number	GTIN	Product description	Lot numbers	Distribution Dates
2008-90068	10888857025844	Chesapeake AL Removal Tool	CCUNA, HYMJ, KNCU	February 26, 2018 - June 4, 2021

Product description

Chesapeake AL implants are hollow tube structures with openings that can be packed with bone graft and allow for passage of screws for fixation to the vertebral body. The Chesapeake AL Removal Tool is a multicomponent instrument (arms fixed by pins) that is used to remove the implant from the vertebral body, if necessary.

Product issue

Stryker received reports of a small number of units from one lot of Chesapeake AL Removal Tool, catalog number 2008-90068, arriving to customers with missing pins and/or in a state of disassembly. Disassembly was observed upon receipt, during inspection, prior to use in any surgical procedure.

The subject lot and two additional lots of this instrument were subsequently determined to be affected by a manufacturing nonconformance affecting the pins.

No adverse events have been reported for this issue.

Potential risks

The pin(s) dislodges from the instrument during a procedure and enters the surgical cavity, requiring intraoperative removal. If the pin is not noticed intraoperatively, revision surgery may be required. It should be noted, however, the event would be readily recognizable to the user as the instrument will disassemble if any of the pins dislodge.

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 <u>Spine-RegulatoryActions@Stryker.com</u> to confirm receipt of this notification/document product segregation. Your account's Stryker Spine Sales Representative will arrange for retrieval and removal of any instruments associated with this recall.
- 4. 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 our Regulatory Compliance team by calling 201.749.8090 or by email at Spine-RegulatoryActions@Stryker.com, or contact your local Sales representative.
- 5. Maintain awareness of this communication 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. If so, provide contact details so Stryker can inform the recipients appropriately.

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
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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 by the target date **September 30, 2021** 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,



Once again, please email Spine-RegulatoryActions@Stryker.com the enclosed acknowledgement of this notification.

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Business Reply Form

Chesapeake® Anterior Lumbar Removal Tool

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Please complete and sign this form. Email the completed form to <u>Spine-RegulatoryActions@Stryker.com.</u>by **September xxx, 2021**.

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*
2008-90068	Chesapeake AL Removal Tool	CCUNA, HYMJ, KNCU	

^{*}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		