

**URGENT:  
MEDICAL DEVICE 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

- Immediately** check your internal inventory to locate the product listed on the attached Business Reply Form and remove them from their point of use.



## Business Reply Form

### Chesapeake<sup>®</sup> Anterior Lumbar Removal Tool

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Please complete and sign this form. Email the completed form to [Spine-RegulatoryActions@Stryker.com](mailto:Spine-RegulatoryActions@Stryker.com) 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:

<b>Printed Name</b>		<b>Title</b>	
<b>Signature</b>		<b>Phone</b>	
<b>Date</b>		<b>Email</b>	

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

<b>Product(s) Distributed</b>		<b>Quantity Distributed</b>	
<b>Facility Name</b>		<b>Contact Person</b>	
<b>Full Address</b>			