

URGENT FIELD SAFETY NOTICE: RA2020-2362278

April XX, 2020

FCA identifier:	2362278
Type of action:	Field Corrective Action: Recall
Description:	Aleutian® AN (Anatomically Narrow) Lordotic Spreaders
Affected Catalog Number(s):	5203-901XX See Attachment for specific catalog numbers.
Affected Lot(s):	Lot Specific See Attachment

Dear Customer,

Product description

The Aleutian AN Lordotic Spreader consists of a titanium nitride coated tip and a shaft with a Hudson handle connection. It is intended to be used with a T-handle to insert the spreader and rotate 90 degrees to simulate the height of the cage and expand the disc space. The instrument is intended to be used in a sequential manner to determine the optimal implant size based on patient anatomy. The spreader is sized to match the profile of the different heights and lordosis of the implant.

Product issue

Stryker's Spine division received reports of intra-operative disassociation of the spreader tip from its shaft for the Aleutian AN Lordotic Spreaders. It was subsequently confirmed that specific lots of spreaders were not manufactured per the product drawings.

Potential hazard

The spreader's tip can separate from its shaft when the user attempts to remove the instrument from the disc space. Therefore, the potential hazard is incorrect function of the instrument, which may result in:

- Potential for nerve root injury during removal
- Prolongation of the operation to remove the spreader tip

Actions Needed:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

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

1. Immediately check your internal inventory and quarantine all subject devices pending to return to Stryker.
2. Circulate this Field Safety 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 organizations.
 - 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.

Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.
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 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 PFA.
 - a. On receipt of the form, a Stryker Representative will contact you to organize 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:

Telephone:

E-mail:

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 cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

REPLY FORM: RA2020-2362278

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I acknowledge receipt of the Field Safety Notice for RA2020-2362278 and can confirm that:

We have not located any of these devices in our inventory: (please delete if not applicable)			
We have located the following devices:			
Catalog number	Description	Lot number	Qty
We have further distributed subject devices to the following organizations:			
Facility Name			
Facility Address			
Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organization		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

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

RA2020-2362278 Attachment 1 – List of affected product codes/lot numbers

Catalog#	GTIN	Description	Lot # beginning with
5203-90107	10888857108202	24x4mm, 6	FKWV
5203-90109	10888857108226	24x6mm, 6	FKWW
5203-90111	10888857108240	24x8mm, 6	FKWX
5203-90113	10888857108264	24x10mm, 6	FKWY
5203-90115	10888857108288	24x12mm, 6	FKXA
5203-90121	10888857108349	24x4mm, 12	FKXB
5203-90123	10888857108363	24x6mm, 12	FKXC
5203-90125	10888857108387	24x8mm, 12	FKXD
5203-90127	10888857108400	24x10mm, 12	FKXE
5203-90135	10888857108486	24x4mm, 18	FKXF
5203-90137	10888857108509	24x6mm, 18	FKXG
5203-90139	10888857108523	24x8mm, 18	FKXH
5203-90149	10888857108622	28x4mm, 6	FKXJ
5203-90151	10888857108646	28x6mm, 6	FKXK
5203-90153	10888857108660	28x8mm, 6	FKXL
5203-90155	10888857108684	28x10mm, 6	FKXM
5203-90157	10888857108707	28x12mm, 6	FKXN
5203-90163	10888857108769	28x4mm, 12	FKXP
5203-90165	10888857108783	28x6mm, 12	FKXR
5203-90167	10888857108806	28x8mm, 12	FKXT
5203-90169	10888857108820	28x10mm, 12	FKXU
5203-90177	10888857108905	28x4mm, 18	FKXV
5203-90179	10888857108929	28x6mm, 18	FKXW
5203-90181	10888857108943	28x8mm, 18	FKXX