URGENT FIELD SAFETY NOTICE
X-Core 2, Ti Core, Static

Date: 09 November 2022

Commercial Name: X-CORE 2, Ti Core, Static

Device Type:
The NuVasive X-Core Expandable VBR System is a vertebral body replacement (VBR) device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues.

Unique Device Identifier:
887517424204, 887517424211, 887517426277, 887517426284, 887517434210, 887517434227

Part Numbers:
7160012, 7160014, 7180016, 7180018, 7220016, 7220018

Type of Action:
Advisory Notice

Description of the Issue:
NuVasive, Inc. voluntarily issues this Field Safety Notice to inform healthcare providers of an update to the instructions for use of the X-Core 2, Ti Static Core, implant.
NuVasive received post-market feedback indicating difficulty in disengaging the Inserter from the X-Core, Static Core implant. The current Instructions for Use (IFU) and Surgical Technique Guide (STG) prescribe the ability to use all Static cores with multiple Inserters. The investigation showed that regular (non-dismantlable) inserters may not allow the instrument to fully disengage from the implant.

NuVasive is updating the IFU and STG to clarify the best fit inserter with each core which can help prevent the user experiencing interference when removing the inserter from the Static Core. The interference condition improves when dismantlable inserters are used.
The table below shows the changes from the prior to the current NuVasive® X-Core® Expandable VBR System NuVasive® X-Core® Mini Cervical Expandable VBR System IFU and STG:

IFU Section	Prior IFU and STG Language	Updated IFU and STG Language
WARNINGS, CAUTIONS AND PRECAUTIONS	In order to ensure proper inserter/implant engagement, the inserter's-colored distal tip must face up toward the like-colored spinning sleeve of the implant.	When assembling the construct with static cores, only utilize dismantlable inserters. When utilizing Ø16mm static cores, refer to the Surgical Technique for instructions on removing the internal gear drive from the appropriate dismantlable inserter. To help achieve proper inserter/implant engagement, the inserter's colored distal tip must

IFU Section	Prior IFU and STG Language	Updated IFU and STG Language
	To ensure proper anatomical alignment, the rounded corners of the X-Core shape endcaps must face anterior during implant construction and placement. Care should be taken to ensure that all components are ideally fixated prior to closure.	face up toward the like-colored spinning sleeve of the implant. To help achieve proper anatomical alignment, the rounded corners of the X-Core shape endcaps must face anterior during implant construction and placement. Care should be taken to confirm that all components are ideally fixated prior to closure.
	Other changes to clarify instructions.	

Recommended User Action:

This FSN details updates to the IFU document that physicians should consult prior to and during patient care of those being treated with Static X-Core devices. This interference presents when attempting to engage or disengage the Static Core implant from the inserter.

- The IFU and STG should be consulted on an ongoing basis before and throughout patient treatment.
- A NuVasive representative will be contacting your office or you to help with any questions or concerns.
- Acknowledgement of these changes is critical. Please review, complete, sign and return the attached Consignee Confirmation Form in accordance with the directions on the form (accompanying this notification).

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware of it within your organization.

Please report all device-related incidents to the manufacturer via email at complaints@nuvasive.com, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

This notice will be reported to all applicable regulatory authorities.

Patrick Yrigoyen
Sr. Director, Global Quality

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Type of Action: Advisory Notice

Action being taken by the manufacturer: IFU Change

Consignee Confirmation Form

It is important that your organization takes the actions detailed in this FSN and confirms that you have received this FSN. Please complete and return this form to NuVasive via Docusign (as received) or by emailing complaints@nuvasive.com.

Your organization's reply is the evidence we need to monitor the dissemination of this notice.

Customer Name:
_____

Address:
_____

_____

Phone:
_____

(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the *10 November 2022 X-Core 2, Ti Core, Static* Field Safety Notice

_____	_____	_____
Name/Title	**Signature**	**Date**