

URGENT:
MEDICAL DEVICE RECALL

VariAx®2 LOCKING SCREW

Attn: Health Care Professionals, Operators of Medical Devices, Distributors

Reference Number: RA2026-4311120

22-April-2026

Product Affected

Catalog number	UDI	Product description	Batch Lot #	Distribution Dates
657328	07613327087031	VariAx2 LOCKING SCREW, Full Thread, 3.5 X L28MM	AM5253	16-Jan-2025 to 10-Dec-2025

The purpose of this notification is to advise that Stryker is conducting a recall on one specific lot of VariAx® 2 Locking Screws. Please refer to the table above for the catalog and lot number in scope of this recall that was identified as disseminated to distributors and end users.

Product description VariAx® 2 Screws are used with the compatible plating system or as standalone implants. They include Locking Screws, Locking Pegs, Bone Screws, Emergency Screws, and related Washers. VariAx Locking Screws are composed of Ti6Al4V ELI, anodization grade III as per ASTM F136, ISO 5832-3, AMS 2488D standard. The affected part is a Locking Screw VariAx2 T10 Full Thread, 3.5mm/ L28mm. This product is provided non-sterile.

Product issue Subsequent to product complaints, Stryker has confirmed that one lot of VariAx® 2 Locking Screws was manufactured without the hexalobular feature required for mating with the associated screwdriver, see Figure 1 below.

Potential risks The hazard associated with this issue is the loss of function of the implant and impaired mating with the associated screwdriver.



Figure 1: VariAx 2 Locking Screw without missing hex feature

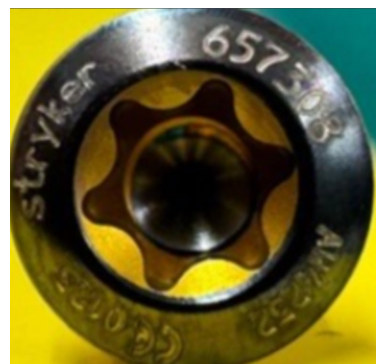


Figure 2: VariAx 2 Locking Screw with hex feature

Business Reply Form

Account name:
Account Address:

VARIAX® 2 LOCKING SCREW

Reference Number: RA2026-4311120

22-APRIL-2026

Please complete and sign this form. Email the completed form to memphis.fieldaction@stryker.com by **6-May-2026**.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product description	Lot #	Quantity for Return* (Missing hex feature)	Total Quantity Inspected*
657328	VariAx2 LOCKING SCREW, Full Thread, 3.5 X L28MM	AM5253		

*If all devices have been used and 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, if possible:

Product(s) Distributed		Quantity Distributed	
Facility Name		Contact Person	
Full Address			

- I have read and understand 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 _____