

Universal Joint Screwdriver

Attn: Materials Manager, OR Director, Risk Manager
Recall Number: RA2025- 3886477
March, 2025



The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling 8 specific lots of the Universal Joint Screwdriver.

Catalog number	Description	GTIN	Affected Lots	Distribution dates
6003-100-110 / 6003100110	Universal Joint Screwdriver	04546540502087	1000530579 1000530603 1000532954 1000534168 1000549586 1000553021 1000555951 1000558234	05JUL2023-09AUG2024

Product Description

The Universal Joint Screwdriver is intended for adjustment and tightening/loosening operations of Stryker Navigation surgical instruments.

Product Issue

The tip component of the Universal Joint Screwdriver may break off during use. The devices utilize a clamping tool that delivered too much force during manufacturing, resulting in product deformation.

Potential Risks

There is a potential for breakage to occur during use, which could result in fragments within the surgical field. Fractured metal that enters a patient may require medical intervention.

Actions To Be Taken

1. Immediately review your inventory to locate and quarantine any affected products at your facility.
2. Return the enclosed Business Reply Form (BRF), even if the affected product is no longer in inventory, to the email xxx@stryker.com.
3. Upon receipt of the completed BRF, Stryker will provide a shipping label to return recalled product on-hand.
5. A replacement will be provided upon receipt of the recalled product.
6. Maintain awareness of this communication internally and 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 accordingly.

We appreciate your cooperation, and we recognize the inconvenience this may cause your accounts. Thank you for your support on this important matter. 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: _____

On behalf of Stryker, we thank you sincerely for your help 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,

Business Reply Form

Universal Joint Screwdriver

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Please choose the most appropriate option below and complete this form. Email the completed form to xxx@stryker.com.

RESPONSE IS REQUIRED.

- No remaining affected products on-hand.
- I, the customer, choose to return the following product(s) for replacements:

Catalog number	Description	Affected Lots	Qty on hand*
6003-100-110 6003100110	Universal Joint Screwdriver	1000530579	
		1000530603	
		1000532954	
		1000534168	
		1000549586	
		1000553021	
		1000555951	
		1000558234	

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Form completed by:

Facility Name			
Facility Address			
Printed Name		Title	
Email		Phone	
Signature		Date	

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

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

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

Please return the completed form to xxx@stryker.com.