stryker

URGENT
Medical Device Recall

Universal Joint Screwdriver

Attn: Risk Manager, OR Director, Materials Manager

Recall Number: RA2023-3390720

September X, 2023

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling 5 specific lots of the Universal Joint Screwdriver.

Catalog number	Description	GTIN	Affected Lots	Distribution dates
6003-100-110	Universal Joint Screwdriver	04546540502087	1000491614 1000495789 1000499428 1000501513 1000502651	20JUN2022 – 16FEB2023

Product description

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

Product issue

The shaft and tip component of the Universal Joint Screwdriver was manufactured with the incorrect raw stainless steel material.

Potential risks

There is a potential for breakage to occur during use, which could result in potential metal fragments. If the failure occurred near an open incision, removal of metal fragments could be required.

Actions to be taken

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.
We therefore request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory to locate the product(s) listed on the attached Business Reply Form, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.

2. Sign and return the enclosed Business Reply Form by email to <xxx@stryker.com> to confirm receipt of this notification/documenting product disposition.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** 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 eliminate the need for us to send further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.

3. Upon receipt of the completed Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details so that we can inform the recipients appropriately.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.

6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

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:

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.121 and EU 2017/745, 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 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

Account number:
Account name:
Account Address:

Universal Joint Screwdriver

September X, 2023

Recall Number: RA2023-3390720

Catalog number	Description	Affected Lots	Qty on hand*
6003-100-110	Universal Joint Screwdriver	1000491614	
6003-100-110	Universal Joint Screwdriver	1000495789	
6003-100-110	Universal Joint Screwdriver	1000499428	
6003-100-110	Universal Joint Screwdriver	1000501513	
6003-100-110	Universal Joint Screwdriver	1000502651	

*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**	

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			

☐ **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 :

Stryker Instruments 1941 Stryker Way Portage, MI 49002 USA