URGENT FIELD SAFETY NOTICE

Stryker 2.3mm Tapered Router

Recall Number: RA2022-3036404

Attn: Risk Manager, Materials Manager, OR Director

June X, 2022

The purpose of this notification is to advise you Stryker Instruments is voluntarily recalling 5 specific Lots of the 2.3mm Tapered Router.

Product Image	Catalog number	Description	GTIN	Affected Lots
	5820071023	2.3mm Tapered Router	07613327294910	22011017 21330017 20216017 20140017 20139027

Product description

The 2.3mm Tapered router is an attachment within the Elite accessories group intended to cut bone and bone cement in the following manner: drilling, reaming, decorticating, shaping, and smoothing.

Product issue

There is a potential for the core diameter to be undersized, which may lead to the router breaking. To date, Stryker has not been made aware of any adverse events related to this issue.

Risk to health

A break can lead to unintended metal fragments in the surgical site resulting in the potential for surgical intervention or damage to critical neurological or vascular structures.

Product identification

Location of Product Number (Grey) and Lot Number (Gold) on Stryker labels:

Actions to be taken

Our records indicate a 2.3mm Tapered Router from catalog no. 5820071023 was/were previously distributed directly to your facility.

1. **Immediately check your internal inventory and quarantine all subject devices pending return to Stryker**.
    a. Circulate this Field Safety Notice internally to all interested/affected parties.

2. 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.

3. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

4. **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.
    a. Therefore, **please complete even if you no longer have any of the subject devices in your physical inventory.**

5. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

6. Upon receipt of the recalled product, Stryker will contact you to arrange for replacement product.

We request your support in finalizing the required steps within 14 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: email:

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

Sincerely,

XXXXXXX XXXXXXX
RAQA Specialist

Business Reply Form

Account number:
Account name:
Account Address:

RA2022-3036404- Stryker 2.3mm Tapered Router

June xx, 2022 .

Catalog number	Product	Lot number	Quantity on hand*
5820571023	2.3mm Tapered Router		

☐ If you no longer have affected product on hand, please check here.
- Please state disposition of product no longer on hand: _____

Customer information

Customer name _____

Name of person completing this form_____Title_____

Direct phone #_____Email_____

Address_____City_____State____ Postal code _____

Country _____

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

Product(s) distributed		**Quantity distributed**	
Facility name		**Contact person**	
Full address			

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

Name (print)_____Signature_____Date

Return completed Business Reply Form to xxxxx@stryker.com.