URGENT FIELD SAFETY NOTICE: RA2016-060
2.3MM Tapered Router

ATTN: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

XXXXX, 2016

Catalogue Numbers: 5407-FA2-023
Product description: 2.3MM Tapered Router
Lot Numbers: see below

Dear Customer,

Please find attached details of a Product Action that has been initiated by Stryker Instruments concerning the above referenced subject devices. This action has been taken to ensure that users are aware of important Information concerning the devices listed above.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

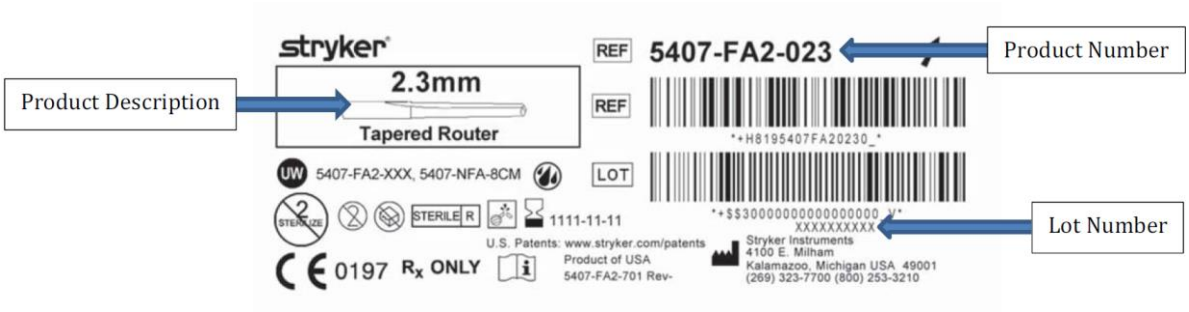
The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling the 2.3MM Tapered Router, Product Number 5407-FA2-023.

Stryker Product Number	Product Description	Lot Numbers
5407-FA2-023	2.3MM Tapered Router	15077027, 15077067, 15077097, 15078087, 15105017, 15108017, 15108047, 15108077, 15108087, 15108097, 15146017, 15146027, 15146037, 15146047

Reason for Voluntary Recall:
A variation in flute depth on the listed routers was observed. The variation in flute depth may cause the routers to be more susceptible to breakages.

Risk to Health:
Injury to critical soft tissue requiring surgical intervention may occur.

Product Description:
A router is a cutting accessory used in the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otology /Neurotology/ Otorhinolaryngology; Craniofacial (bones of the skull and supraorbital region); and Sternotomy. They are intended to be used with the Stryker CORE™ system.



Actions to be taken by the Customer/User:

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
    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.
5. 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.
6. 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. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within **XXX** 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.

Yours Sincerely,

XXXXXX

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ACKNOWLEDGMENT FORM

Quantity Shipped	Product Number	Lot Number of Recalled Product	Quantity On Hand (Each)

If you don't have any recalled routers on hand, please indicate "0" in the "Quantity On Hand" box (above).
Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.

Acct: Account #:

Print Customer Name | Customer Title

Contact Phone Number | Customer Signature | Date

Email Address | Fax Number

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

Name Address City State Zip

Contact Person Part Number(s) and Quantities