URGENT FIELD SAFETY NOTICE: RA2016-150
MIS (MINIMALLY INVASIVE SURGERY) TOOLSTEEL BURS (USED WITH STRYKER CORE™ SYSTEM)

ATTN: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

Dec XX, 2016

Product Number	Product Description	Lot Number(s)
8450-009-030	3.0MM Precision Round, 13cm	16032017
8450-009-040	4.0MM Precision Round, 13cm	16029017
8450-010-040	4.0MM Round, 13cm	16060017
8450-107-525	2.5MM Prcsn Mtch Hd, 13cm	16056017
8450-107-530	3.0MM Prcsn Mtch Hd, 13cm	16054017
8470-009-030	3.0MM Precision Round, 16cm	16049017 16053017
8470-009-040	4.0MM Precision Round, 16cm	16038017

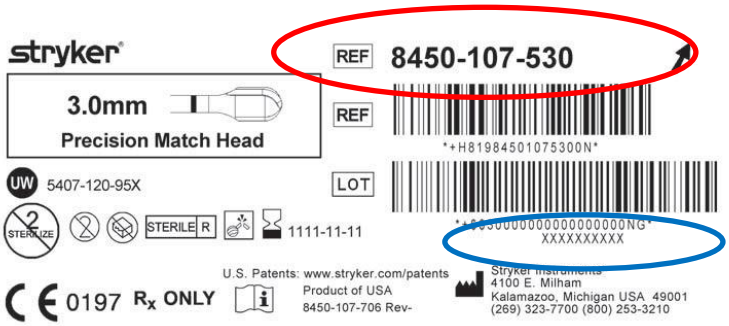
Please find attached details of a Product Action that has been initiated by Stryker Instruments concerning the above referenced subject devices. This action has been taken to ensure that users are aware of important Information concerning the devices listed above.
The purpose of this letter to advise you that Stryker Instruments is voluntarily recalling specific lots of MIS Toolsteel Burs. These burs are used in conjunction with the Stryker CORE™ System.

Reason for Voluntary Recall:
Corrosion may be present on the recalled Burs.

Risk to Health:
Use of a bur with corrosion may lead to a foreign body reaction (inflammation) necessitating medical intervention.

Product Description:
The MIS attachments and cutting accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE™) Console and electric and pneumatic motors. When used with these motors, the MIS attachments and cutting accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications.

Location of Product Number (red circle), Lot Number (blue circle):



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

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 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 Giudance document Ref 2.12-1, we can confirm that thisFSCA 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,

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