URGENT FIELD SAFETY NOTICE: RA2013-156

Description: Navigation Compatible Accolade Broach Handle

Catalogue Number: 2124-1400

Lot Number: All Lots

Date

Dear Customer

Please find attached details of a Product Action that has been initiated by Stryker Orthopaedics 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. You are required to read the attached Field Safety Notice and then sign and return the Customer Response Form confirming that you have completed the actions requested by the manufacturer. 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.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is April 30th of 2014 and your timely response will enable us to ensure that we meet this target.

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: E-mail:

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....

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Date,

Dear Customer

Stryker® Orthopaedics ("Stryker®") has initiated a Product Action for the Navigation Compatible Accolade Broach Handle referenced above. Stryker® received reports from the field of the impaction plate disassociating/fracturing from the main body of the broach handle.

Potential Hazards

The impaction plate disassociates from the broach handle body.

The foreseeable sequence of events is as follows:

1. Total hip surgery has progressed to a point where the surgeon needs to use broaches/rasps to prepare the femoral canal.
2. The surgeon chooses to use the Navigation Compatible Accolade Broach Handle for the broaching procedure.
3. While either impacting or extracting a femoral broach/rasp, the impaction plate separates from the body of the broach handle.
4. As the Navigation Compatible Accolade Broach Handle is no longer capable of impacting/extracting the broach/rasp, an alternative broach handle is retrieved (from an instrument tray that is present within the operating room).

The above scenario may result in a delay in surgery of less than 5 minutes and a potential harm of complications associated with that delay.

Risk Mitigation Factors

Inspection of mating devices as described in the Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices (ref. LSPTI-B, 08/12; Page 8) indicates, "For devices that may be impacted, check that the device is not damaged to the extent that it malfunctions" and "Instruments with moving parts should be operated to check correct operation". Performing this check may prevent parts with weld cracks, which could signal a weakened weld that could lead to fracture and detachment of the impaction plate, from getting into the operating room.

Regarding any Navigation Compatible Accolade Broach Handle (2124-1400) in your possession, please follow the below advice:

1. Immediately check your internal inventory and quarantine all subject devices.
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 organizations. *(Please provide contact details so that Stryker can inform the recipients appropriately).*
5. Complete the attached customer response form.
   (Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice)6. Please inform Stryker of any adverse events concerning the use of the subject devices.
   a) Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority
7. Complete the attached customer response form.
8. Return the completed form to your nominated Stryker Representative.
   a) On receipt of the form a Stryker representative will contact you to arrange for the collection of any remaining inventory.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please contact your local Sales Representative.

URGENT FIELD SAFETY NOTICE: RA2013-156
Customer Response Form

Description: Navigation Compatible Accolade Broach Handle
Catalogue Number: 2124-1400
Lot Code: All Lots

I have received Field Safety Notice RA2013-156 and confirm the following :

❑ WE HAVE PHYSICALLY CHECKED OUR INVENTORY AND WE DO NOT HAVE THE AFFECTED PRODUCT(S).

❑ WE HAVE SOME/ALL OF THE ITEMS REFERENCED IN THE ENCLOSED LETTER. WE WILL BE RETURNING _____ AFFECTED PRODUCT(S).

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND FAX TO (local RAQA contact).

_____ _____
Customer Name (Signature) Date

_____
Hospital Name Stamp

Please fax this signed and dated form to **(local RAQA contact).**