stryker

Spine

January 2012

URGENT FIELD SAFETY NOTICE: RA2010-299

Dear Customer

Description: XIA 3 ANTI TORQUE KEY

Catalog #: 48237026

Lot #: 07F116 - 07F117 - 085525 - 086577 - 082578 - 087232 - 087233 - 088604

Please find attached a Product Field Notice that has been initiated by Stryker Spine concerning the above referenced devices.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site. In this case you are receiving the notice because you have potentially received non-conforming devices in the past and as a responsible manufacturer we feel that it is our duty to ensure that you are aware of the information contained within the manufacturer's Field Safety Notice.

This action requires only that you inspect your physical inventory, identify and remove from service any of the lots identified above then complete and return the attached customer response for to your local Stryker Distributor.

Please note that your signature on the following form only confirms that you received this notification and does not obligate you to take any additional action beyond what is called for in this notification letter.

Completing the Customer Response 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 (insert date) and your timely response will enable us to ensure that we meet this target and ensure that non conforming devices are removed from the market as quickly as possible.

Should you have any physical inventory, then on receipt of the returned customer Response Form a Stryker Representative will contact you to arrange for the return of subject devices and product replacement. If you have indicated that you do not have any physical inventory then we will update our files and no further communication will be sent. 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:
Tel:
Fax:

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 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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Stryker® Spine has initiated a Product Field Action concerning the above referenced devices.

Issue
Customer complaints have been received in which it has been reported that the interface between the blue handle & the tube had broken. These breakages have been reported to have occurred during surgery. The review of the returned devices showed that there are no detached fragments. The handle separates at the point where it is welded to the shaft,

Potential Hazards
The Anti Torque Key handle detaches from the tube during the final tightening torque. The surgeon has to use another Anti Torque Key if available or use another instrument. There is a potential risk of additional anaesthesia due to the use of an alternate instrument. The severity was identified as minimal with a low likelihood of occurrence.

We would like to reassure you that only the lot numbers identified above are affected by this action.

Patient Follow up
There is no requirement for additional patient follow up. The issue would be immediately obvious to the operating surgeon during the procedure.

Immediate Actions Required

1. Immediately check your internal inventory and quarantine all subject devices pending return to your local Stryker Distributor.
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. *(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 associated with the use of the subject devices.
    - Please comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.
7. Complete the attached customer response form and return to the address indicated.

Stryker® organisation maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We thank you sincerely for your help and support in ensuring that only conforming devices meeting Stryker's high internal standards remain on the market and apologize for any inconvenience this Field Safety Corrective Action may create.

If you have any further enquiries, please contact the undersigned in the first instance.

Yours faithfully,