January 16, 2014

URGENT FIELD SAFETY NOTICE: RA2013-105_Expanded lots

Dear Customer,

Affected product	XIA® TORQUE WRENCH	XIA® 3 TORQUE WRENCH	XIA® ELEGANCE SHORT TORQUE WRENCH	MANTIS REDUX TORQUE WRENCH
Reference Number	**03807028**	**48237028**	**482397028**	**48287028**
Previous Affected Lots	125710	11E042 11E044 11E047	11A957 11E035 11E036/R11E036	None
Additional Affected Lots	092793 097089 11E038 11E039 11E040 11E041 123746 127179 12D012	098525 118823 11E043 11E045 11E046 11E048 127647/R127647 12A646/R12A646	121098	098401 125708 125709 127051 12A641

Please find attached details of a Product Field Action that has been initiated by Stryker Spine concerning the above referenced devices. This is a lots expansion of the action originally initiated on September 12, 2013.

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 affected 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 has been taken to retrieve the affected devices from the market. You are required to read the attached Field Safety Notice, to quarantine the affected devices that are in your possession, to send them back to your distributor and then to sign and return the customer response form confirming that you have completed the actions requested by the manufacturer.

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 May 30, 2014 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.

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

Issue
Complaints have reported that the hex tip of the torque wrench fractured during final tightening. The hex tip of the wrench has broken off and separated from the main tube.

Potential Hazards
The tip of the instrument fractures during final tightening leading to additional surgery time needed to use another torque wrench or a universal tightener. This could possibly lead to effects of additional time under anesthesia due to extended surgery time.

The tip of the instrument fractures during final tightening leading to non-implantable grade material falling into the surgical site. This could possibly lead to infection, an injury to the surrounding musculature and/or an adverse reaction to non-implantable grade material.

The tip of the instrument fractures during final tightening and then the hex tip is implanted. This could possibly lead to an infection, a revision surgery to remove the tip, injury to soft tissue surrounding the fragment in the MR environment and/or an adverse reaction from non-implantable grade material.

The tip of the instrument fractures during final tightening leading to the surgeon over/under tightening the blocker with the Universal Tightener, if another torque wrench is not available. This could possibly lead to a mechanically compromised construct and a possible revision surgery.

Type of Action
This is a removal action. All affected devices shall be returned to your distributor.

Immediate Actions Required

1. Immediately check your internal inventory and quarantine all subject devices.
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. Please inform Stryker of any adverse events associated with the use of the subject devices.
    a. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.
6. Complete the attached customer response form and return it with the subject devices to the address indicated. *(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)*

We would like to reassure you that Stryker® 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 completing this action on time and apologize for any inconvenience this Field Safety Corrective Action may create.

Should you have any further enquiries or requirements concerning this action please contact the undersigned in the first instance.

Yours …..

RA2013-105_Expanded lots: PFA ACKNOWLEDGMENT FORM

Affected product	XIA® TORQUE WRENCH	XIA® 3 TORQUE WRENCH	XIA® ELEGANCE SHORT TORQUE WRENCH	MANTIS REDUX TORQUE WRENCH
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I acknowledge receipt of the Field Safety Notice for RA2013-105 and can confirm that:

We have not located any of these devices in our inventory. ***(please delete if not applicable)***	**YES/NO**
We have located all of the devices listed within our facility and can confirm that the actions requested by the manufacturer have been completed appropriately. All users are aware of the PFA.	**YES/NO**
The devices listed are no longer in service within our facility because they have been returned to Stryker.	**YES/NO**

We have further distributed subject devices to the following organizations:		
Facility Name		
Facility Address		
Form completed by:		

Contact Name _____ **Contact Facility** _____

Contact Address _____ **Contact Position** _____

_____ **Contact Tel No** _____

_____ **Contact Fax No** _____

_____ **Contact e-mail** _____

Please return the completed form to: