# URGENT: FIELD SAFETY NOTICE RA2012-169

**Dear Customer**

**Subject Devices** **XIA 3 TITANIUM ILIAC SCREWDRIVER**

**Serial Numbers** **10G637, 10G638, 10E852**

**Date range/scope** **Lot specifics**

Our manufacturer, Stryker Spine, has initiated a Product Field Action concerning the above referenced devices.

Our records indicate that you have been supplied with at least one of the subject devices. We therefore request that you read this notice carefully and complete the actions requested by the manufacturer.

**Issue**

Tip fracture. The threads of the Iliac Screwdriver unwind without separation from the main body of the screwdriver.

**Potential Hazards**

If the threads become overstressed and initiates tear and starts to unwind it could lead to an extended surgery time of less that 20 minutes.

This short delay should not lead to any complications for the patient(s).

**Scope of Action**

Lot specifics

**Patient/User Information**

Patient

Patient follow up is not necessary.

**Rationale for not requiring patient follow up**

No additional patient monitoring is required. Should a device thread have unwound during surgery it would have been immediately obvious to the operating surgeon who would have taken appropriate action.

**Mitigating Factors**

- When the thread on the sleeve un-winds the shaft can still be utilized to drive the bone screw into the Ilium. This allows minimal delay in surgery if a thread failure occurs. If the thread failure occurs on the first screw insertion, the shaft can still be used to drive the second screw without the sleeve.
- The Xia 3 one-piece (Self holding) Iliac Screwdriver (48231314) can be utilized. This screwdriver is an alternate driver in the standard set definition for the same application.

**Corrective Actions**

- Removal of the non conforming lots.

**Additional Information**

NA

**Immediate actions required by your facility**

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|---|---|
| 1 | 1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker<br>2. Circulate this Field Notice internally to all interested/affected parties.<br>3. Maintain awareness of this notice internally until all required actions have been completed within your facility.<br>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).<br>5. Complete the attached customer response form.<br>(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)<br>6. Please inform Stryker of any adverse events.<br>• Comply with any local regulations for reporting to your National Competent Authority.<br>7. Return the completed form and any affected devices to your local Stryker Representative. |
| 2 | Please respond to this notice before (insert date). The target date for closure of this action and upgrade of all subject devices is March 31, 2013. |

On receipt of the returned customer Response Form a Stryker Representative will contact you to arrange for credit of returned devices/ product replacement/ inspection upgrade of equipment/confirm updated records.

In line with the recommendations contained in the Meddev Vigilance Guidance document, Ref 2.12-1 this action has been notified 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 and appreciate your assistance in meeting this objective.

Should you have any queries concerning this matter please do not hesitate to contact the undersigned.

Yours …..