URGENT Field Safety Notice: RA2013-095

FSCA Identifier: Product Field Action RA 2013-095

Type of Action: Field Safety Corrective Action

Description: Asnis III screws – two lots

Catalogue Nos: 604640 and 604642S

Lot Nos: 604640 – Lot R11482 and 604642S – Lot R09071

Dear Customer,

Stryker® Osteosynthesis has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue
Stryker received a report indicating that the length of the Cannulated Screw Asnis III, article# 604640, Lot R11482 is incorrect. Internal investigations reveal a partial packaging mix-up of the Cannulated Screw Asnis III, article# 604640, Lot R11482 and the Cannulated Screw Asnis III, article# 604642S, Lot R09071. The screw lengths partly differ from the label and could result in the surgeon implanting a screw that is 2mm longer than intended respectively 2mm shorter than intended.

Potential Hazards
The usage of these screws could potentially cause the insertion of a screw with incorrect screw length which in turn might lead to:

- Additional time under anesthesia due to prolongation of surgery;
- Soft / Hard tissue damage;
- Pain; and
- Motor loss.

Mitigating Factors

1. Fluoroscopy is used during the procedure to verify fracture reduction and position of the implants.
2. Due to the anatomic region and screw insertion procedure, it is likely that the surgeon will recognize an inappropriate screw length and halt the procedure.

Type of Action
Recall of subject devices

Immediate actions
Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions:

Our records indicate that you have received at least one of the subject devices listed above. We therefore request that you:

1. Please inform users of this Medical Device Field Removal and pass this notice to all those individuals who need to be aware within your organization.
2. Complete and sign the enclosed PFA Acknowledgment Form and return to Yrida Baldus by fax (+49 2065 837 120) or by email (yrida.baldus@stryker.com). A Stryker representative will then be in contact to arrange for product return.
3. Keep a copy of the completed and executed Business Reply Form for your records.
4. Report all adverse events or product quality problems to Stryker.

We sincerely regret any inconvenience that this action may cause you and on behalf of Stryker would like to thank you for your help and support in completing this action in a timely manner.

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

Yours faithfully

Yrida Baldus
Quality Assurance and Regulatory Affairs

Appendix:
PFA Acknowledgment Form

RA2013-095: PFA ACKNOWLEDGMENT FORM

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Catalogue Nos: 604640 and 604642S

Lot Nos: 604640 – Lot R11482 and 604642S – Lot R09071

I acknowledge receipt of the Field Safety Notice for RA2013-095 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*				
We have located the following devices:				
Product description	**Product Reference**	**Lot Number**	**Qty**	**Qty Quarantined**
We have further distributed subject devices to the following organisations:				
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 COMPLETE AND FAX THIS FORM TO +49 2065 837 120
OR EMAIL TO YRIDA.BALDUS@STRYKER.COM.