April 2017

URGENT Field Safety Notice: RA 2017-039

FSCA Identifier: Product Field Action RA 2017-039

Type of Action: Field Safety Corrective Action

Legal Manufacturer: Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland

Catalog #	Manufacturer Part Name	Lot #
33625110	Standard Lag Screw Omega 110mm Length	V06279
33625105	Standard Lag Screw Omega 105mm Length	V06269

Dear Customer,

Stryker GmbH, Division Trauma and Extremities is recalling the devices identified above. The purpose of this letter is to inform about the actions and the hazards associated with the use of the products.

Reason for Recall

Stryker received a complaint from the field regarding a Standard Lag Screw Omega 110mm LENGTH (Cat# 33625110 & Lot# V06279). The end customer reported via sales rep, that the lag screw was not completely cannulated and the guide wire could not go through the cannula of the screw. No harm reported.

The investigation revealed that the obstruction is related to a metal burr in the cannula of the screw which was not removed during manufacturing. The nonconformance is limited to 2 batches.

Potential Hazards

In most cases the surgeon would detect significant resistance when passing the lag screw over the guide wire and would not continue using the screw. A different screw would be available and used, resulting in a minor delay in surgery of <15 minutes.
Only in the case that the surgeon does not notice or ignores the resistance the following theoretical scenarios can happen:

- The guide wire may got stuck in the cannulated screw which could cause metal debris to fall into the patient as well as prolongation of surgery time, as both screw and guide wire need to be replaced.
- The guide wire may got jammed in the lag screw cannula. Only when the surgeon ignores the instructions and warnings given in the related IFU ([1] V15011 Rev N) to continuously screen the position of the guide pin with an image intensifier the guide wire can theoretically pushed out of the femoral head and may hit blood vessels.

Stryker UK
Stryker House, Hambridge Road, Newbury, Berks. RG14 5AW | P +44 1635 262400 | F +44 1635 580300| stryker.com

Mitigating Factors

The obstruction in the cannula of the screw is easily recognizable for the user.

The surgeon would detect significant resistance when passing the lag screw over the guide wire and would not continue using the screw.

Warnings in the related IFU ([1] V15011 Rev N):

"Warnings

•It is particularly important to continuously screen with an image intensifier during guide wire insertion and whenever cannulated instruments are advanced over a guide wire. Frequent screening should also be carried out during screw insertion. In all cases, the benefit of fluoroscopy should be weighed against the risk from radiation exposure on an individual patient basis, in the line with requirements of SI2000 N°1059 (The lonising Radiation Regulations – Medical Exposure)." [Original Statements]

Type of Action

Recall of subject devices.

Immediate Action

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:

1. Immediately check your internal inventory and quarantine all subject devices pending to return to Stryker.

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.

    a) *Please provide contact details so that Stryker can inform the recipients appropriately*
    b) *If you are a Distributor, note that you are responsible for notifying your affected customers.*

5. Please inform Stryker of any adverse events concerning the use of the subject devices. Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.

6. Complete the attached customer response form. 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.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.
   On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is 2nd June 2017 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: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
Fax: 01635 262 464
E-mail: nina.goddard@stryker.com

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 faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

Figure 1: Affected screw with guide wire.

RA 2017-039: PFA Acknowledgement Form

FSCA Identifier: Product Field Action RA 2017-039

Type of Action: Field Safety Corrective Action

Legal Manufacturer: Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland

Catalog #	Manufacturer Part Name	Lot #
33625110	Standard Lag Screw Omega 110mm Length	V06279
33625105	Standard Lag Screw Omega 105mm Length	V06269

I acknowledge receipt of the Field Safety Notice for RA 2017-039 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 Implanted**	**Qty to return**
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO nina.goddard@stryker.com