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UK

URGENT Field Safety Notice: RA 2014-173 – Product Recall

28th January 2015

FSCA Identifier: RA 2014-173

Type of Action: Field Safety Corrective Action – product recall

Description: Ivory Reamer 10mm and 11mm – several lots

Legal Manufacturer: Stryker Trauma AG, Bohnackerweg 1, 2545 Selzach, Switzerland

Product Code	Description	Laser-Marking Lot Number	Packaging Lot Number
2322010	Ivory Reamer ø10mm / 6 Teeth	WO1201823	WO1301003, WO1302353, WO1303403
2322020*	Ivory Reamer ø11mm / 6 Teeth	WO1201569	WO1204040, WO1205698, WO1300890, WO1300938, WO1301004, WO1301516, WO1302009, WO1302354
		WO1301517	WO1303404
		WO1201569*	Ancillary Set Ivory with Part # XSEIV000205 and Packaging Lot # WO1205936, WO1206989

**Ivory Reamers 2322020, laser-marked with Lot WO1201569, have been partly distributed within the Ancillary Sets Ivory. The Ancillary sets and their content are not recalled.*

Please note: *some products have been distributed and labelled by former manufacturer Memometal Technologies, Rue Blaise Pascal, 35170 Bruz, France*

Dear Customer,

Stryker Trauma and Extremities 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.

Intended Use of Subject Devices

The subject devices are intended for the following:

1. Arthroplasty of the trapezo-metacarpal joint for treatment of arthritis of the thumb (rhizarthritis – Dell Stages II, III or IV).
2. Revision Surgery.

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Issue

During an internal workshop it was found that the reamers have a smaller tip diameter than intended. Further investigations confirmed that for the referenced lots the smaller tip could result in the surgeon reaming a smaller cavity and consequently in a non-fit compared to the trial and the implant cup.

Potential Hazards

A smaller cavity could cause additional reaming by using a raspatory or a similar instrument, or, if not recognised, higher insertion forces, which in turn might lead to:

- Additional time under anesthesia due to prolongation of surgery
- Additional Hard tissue damage
- Arthrodesis of the CMC joint
- Suboptimal implant fit

Mitigating Factors

1. The non-fit of the trial indicates a wrong product. Orthopedic surgeons customarily fit the size of the cavity to the prosthesis.
2. Fluoroscopy is used during the procedure to verify position of the trials and implants.
3. The patient is typically under local anesthesia.
4. As per the IFU, 'any excessive activity requesting the operated articulation is highly disadvised.'
5. Follow up procedures ensure free movement authorisation and define activity limits after implantation.

Type of Action

Recall of subject devices.

Immediate actions

1. Immediately check your internal inventory and quarantine any unused 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.

    a) Please provide contact details so that Stryker can inform the recipients appropriately.

5. Complete the attached customer response form and return to Daniel Rana by fax (01635 262 464) or by e-mail (daniel.rana@stryker.com).

    a) Please complete this form even if you do not have any products to return. This will preclude the need for Stryker to send any reminder notice.

    b) Upon receipt of a completed customer response form, a Stryker representative will contact you to arrange collection and replacement of subject devices.

6. Please inform Stryker of any adverse events concerning the use of the subject devices.

    a) Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

Stryker maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologise for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours faithfully,

Daniel Rana
Quality Assurance and Regulatory Affairs

RA 2014-173: PFA Acknowledgement Form

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I acknowledge receipt of the Field Safety Notice for RA 2014-173 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 which require replacement:			
Product Description	**Product Reference**	**Lot Number**	**Qty**
We have further distributed subject devices to the following organisations:			
Facility Name and Address			

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

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO DANIEL.RANA@STRYKER.COM.