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stryker®
UK

URGENT Field Safety Notice: RA 2016-074

05 July 2016

Product Code	Lot Numbers	Description
0930-9-003	All lots manufactured between January 1995 and October 2005	Exeter Rasp Handle

Dear Distributor/ Risk Management/Surgeon:

On 22 June, 2016 Stryker® Orthopaedics ("Stryker") initiated a voluntary, lot-specific recall for the Exeter Rasp Handle instrument referenced above. The intent of this letter is to list all known hazards potentially associated with the use of the instrument covered by this Safety Notice and list the risk mitigation factors.

Issue:

Stryker has received customer inquiries stating that a rivet or rivets came off an Exeter Rasp Handle. These inquiries are associated with Exeter Rasp Handles manufactured between January 1995 and October 2005.

Please be advised that the Exeter Rasp Handles in the scope of this action have a green plastic cover on the handle. Exeter Rasp Handles with a metallic silver cover on the handle are not within scope and are not affected by this Field Safety Notice.

The potential risks associated with these events are listed below.

Actual Hazards:

In the event that a rivet comes off the Exeter Rasp Handle (refer to below image) there is a potential for:

1. Surgical delay of ≤15 minutes to locate the fragmented rivet(s).
2. Surgical delay of ≤15 minutes to procure the sterile replacement rasp handle from within the hospital.
3. Surgical delay of 16 to 30 minutes to procure and sterilize a replacement rasp handle from within the hospital.
4. Fragmented rivet(s) cannot be located by surgical staff and an intra-operative x-ray is required to locate and remove any fragmented rivet(s) which has fallen into the patient wound, leading to a delay in surgery of 31-60 minutes.

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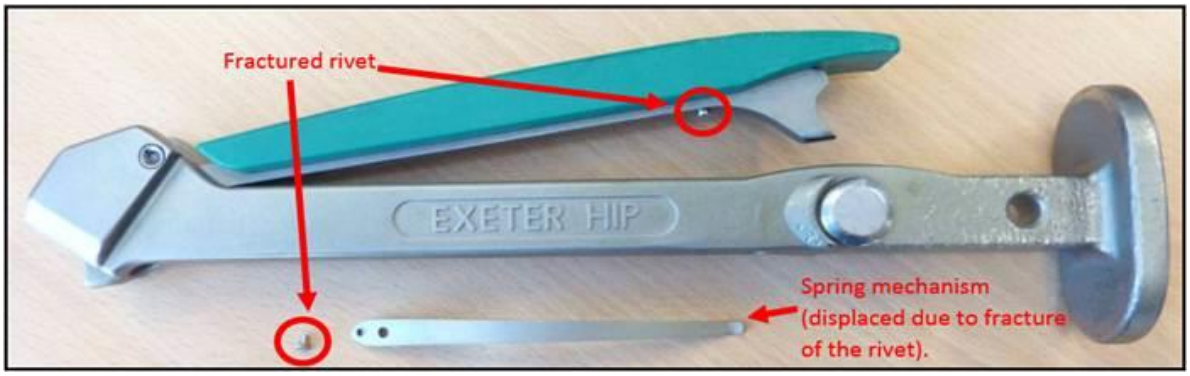
RS11877

5. Fragmented rivet(s) cannot be located by surgical staff and an intra-operative x-ray is required to locate and remove any fragmented rivet(s) which has fallen into the patient wound. A delay is also encountered to procure and sterilize a replacement rasp handle from within the hospital. Surgery is delayed by 31-60 minutes.



Example of fractured rivet.

The aforementioned actual hazards may result in one or more of the following patient harms:

1. Complications associated with extended hip surgery time of ≤15 minutes.
2. Complications associated with extended hip surgery time of 16 to 30 minutes.
3. Complications associated with extended hip surgery time of 31 to 60 minutes.

Potential Hazards:

In the event that a rivet comes off the handle and fragments, then the following potential hazards may occur:

1. Unidentified fragmented rivet remains in the patient wound, the rivet is identified in a post-operative x-ray/MRI, and a revision surgery is performed to remove the fragmented rivet.
2. Unidentified fragmented rivet remains in patient.

The aforementioned potential hazards may result in one or more of the following patient harms:

1. Revision surgery.
2. Inflammatory response.

Risk Mitigation

The Exeter Rasp Handle is a reusable instrument. Pursuant to the Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices (Lit. # LSTPI-B Rev. 2, Page 8), inspection of reusable instruments prior to use may identify loose or damaged rivets leading to the device being discarded and thus mitigating the actual and potential hazards.

Our records indicate that you have received the above referenced instrument. Please assist us in meeting our regulatory obligation by:

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. Complete the attached customer response form and return the form and any affected devices to your local Stryker Representative.
(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)

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

7. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.

We request that you respond to this notice within 7 calendar days from the date of receipt. Your timely response will enable us to ensure that we meet our target closure date.

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
Email: nina.goddard@stryker.com
Telephone: 01635 262476

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.

Stryker maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize 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.

Nina Goddard
Quality Assurance and Regulatory Affairs

RA 2016-074: PFA Acknowledgement Form

Product Code	Lot Numbers	Description
0930-9-003	All lots manufactured between January 1995 and October 2005	Exeter Rasp Handle

I acknowledge receipt of the Field Safety Notice for RA 2016-074 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**
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.