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UK

Field Safety Notice RA 2009-008: Reminder and Update

XX June 2011

Stryker Reference:	RA 2009-008
Type of Action:	Product Exchange
Affected Product:	Xcelerate Ceramic 4:1 Cutting Blocks
Product/Model Ref:	**SCORPIO**: 8000-0003, 8000-0004, 8000-0005, 8000-0006, 8000-0007, 8000- 0008, 8000-0009, 8000-0011, 8000-0013
Lot Numbers:	All lot numbers

Dear Customer,

In December 2009 Stryker Orthopaedics initiated a Field Safety Corrective Action which involved pre and post-operative inspection of the Scorpio 4 in 1 Ceramic Cutting Blocks. The objective of the inspection was to reduce intra-operative breakage of the devices.

The potential risks associated with this specific failure mode were identified as:

1. Ceramic rail cracks
   This hazard has no direct harms but may increase the chance of occurrence for other hazards.

2. Ceramic rail (or portion of rail) fully detaches from the block during surgery.
   The rail or portion of the rail is left within the patient's body causing possible:
   - discomfort
   - migration of debris to articulating surfaces leading potentially to undesired wear of the implant.

3. Ceramic rail (or portion of rail) detaches from block outside of the operating room.
   This hazard has no direct harms but may increase the chance of occurrence for other hazards listed.

4. Block is used for bone cuts without rail(s) present.
   The cuts may be inaccurate, leading to:
   - the need to make further cuts
   - the surgeon switching to use of cemented implants
   - increase in operating time

   Contact between the stainless steel saw blade and aluminium block creates aluminium debris causing possible:
   - patient discomfort
   - migration of debris to articulating surfaces leading potentially to undesired wear of the implant.

5. Saw blade to block contact deforms aluminum material.
   The surgeon fails to notice the exposed sharp area during handling and contact occurs leading to possible:
   - injury to surgeon/user
   - increased surgery time
   - patient infection from exposed/injured surgeon

As a temporary measure pending the availability of replacement devices, the manufacturer provided inspection protocols for the subject devices and requested that users verify functionality of the instrumentation in accordance with these protocols. We can now confirm that the manufacturer has completed the design, development and validation phases for the replacement devices and that production of replacement products is now underway.

In order to facilitate the exchange of subject devices we would request that you complete the attached customer response form detailing product within your location that needs to be replaced. On receipt of this response form a Stryker representative will contact you to arrange delivery of replacement product and collection of subject devices.

Should you have any queries at all regarding this Product Field Action please do not hesitate to contact the undersigned.

Please note that this communication has been copied to the National Competent Authority for your country.

Yours faithfully,

Daniel Rana
Quality Assurance & Regulatory Affairs

CUSTOMER RESPONSE FORM

Please complete this form even if you do not have any product to return. This will preclude the need for future notices

Stryker Reference: RA 2009-008

Product Description: Xcelerate Ceramic 4:1 Cutting Blocks

Product Code: **SCORPIO**: 8000-0003, 8000-0004, 8000-0005, 8000-0006, 8000-0007, 8000- 0008, 8000-0009, 8000-0011, 8000-0013

Lot Code: All

PLEASE TICK APPROPRIATE SECTION

❑ WE HAVE PHYSICALLY CHECKED ALL HOSPITAL LOCATIONS, AND WE DO NOT HAVE THE AFFECTED PRODUCT.

❑ PLEASE ARRANGE COLLECTION AND REPLACEMENT FOR THE FOLLOWING DEVICES THAT WE HAVE IDENTIFIED:

Product Code	Qty to be returned

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

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