Stryker Europe, Middle East & Africa
Regus, Les Espaces de Sophia
80, Route des Lucioles, BP 037
Sophia Antipolis Cedex
06901
France

Our manufacturer has notified us of a Product Field Action concerning the Medical Devices referenced below. Our records indicate that you have been supplied with some of the subject devices. We would request therefore that you read this notice carefully and follow the instructions provided by the manufacturer

We would like to reassure you that only the devices listed are affected by this action.

On behalf of Stryker we would like to thank you in advance for your cooperation and support in this matter

Please note that in accordance with the Medical Device Directive and the Meddev Vigilance Guidance Document this Field Safety Corrective Action has been notified to the National Competent Authority of all countries where subject devices have been distributed
This Field Safety Notice has been issued in accordance with the European Competent Authority detailed below

Date of report	2009-12-11
Stryker Internal Reference Number	**RA2009-008**
Name of Manufacturer	Stryker Orthopaedics Mahwah
Website address	www strykerorthopaedics com
National Competent Authority	if appropriate - please delete if not
Regulatory Agency Reference No	if appropriate - please delete if not

Local Contact Information

Contact Person	
Contact tel number	
Contact e-mail	

Product Information

Product Description	Xcelerate Ceramic 4 1 Cutting Blocks
Product Code/Catalogue No from	SCORPIO 8000-0003, 8000-0004, 8000-0005, 8000-0006, 8000-0007, 8000-0008, 8000-0009, 8000-0011, 8000-0013
Product Code/Catalogue No to	DURACON 8000-7010, 8000-7020, 8000-7040, 8000-7050, 8000-7060
Lot Numbers	All Lots
Software version (if applicable)	Not applicable
Quantities distributed to your facility	
Expiration date of product	Not applicable
Expected shelf life/product life	Not applicable

Issue

Description of problem

Stryker Orthopaedics has become aware that the ceramic guide rails, within the XCelerate 4 1 Ceramic Cutting Blocks, may fracture and displace from the block The size of the pieces that can be displaced range from small fragments to complete rails

Population concerned

Patient's undergoing TKR with surgeon using cutting block in question

Potential Hazards associated with use of device

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 or portion of the rail if 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

Mitigating circumstances/precautionary measures

It is possible to continue using devices providing that the devices are inspected prior to and after each use Comprehensive instructions have been provided to ensure that this process is very clearly defined

Specific advice for surgeons regarding patients with implanted devices

Whilst Stryker recognises that the treating physician is best placed to determine individual patient care and treatment we can confirm that our expert Health Care Professional has determined that there is no potential clinical situation that either requires or would be benefited by additional non routine follow up visits for patients In the unlikely event that the patient becomes symptomatic as a result of this situation they will present to the physician for follow up There is no way to predict if and when this event will occur by additional follow up

Communications/Attachments

Customer response form	Indicate number of pages
Inspection Process	Indicate number of pages

Immediate Actions

1 Immediately locate and inspect subject devices
Quarantine any devices failing inspection pending return to Stryker

2 Ensure that an ongoing inspection process is put in place to ensure that all subject devices are inspected prior to and after each use, in accordance with the inspection instructions provided by the manufacturer

3 Immediately quarantine any units failing inspection and return to Stryker Distribution site or Stryker Authorised Dealer

4 Complete the Customer Acknowledgement Form and return to local Stryker Distribution site or Stryker Authorised Dealer

5 Ensure that copies of this FSN are circulated internally to all affected users

6 Display the notice prominently until all required actions have been completed within the facility

7 Immediately inform Stryker of any adverse events concerning use/attempted use of subject devices

8 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.

9 Comply with any national regulations concerning notification of adverse events to National Regulatory Bodies

10 Should you wish to make an immediate return of shubject devices then please contact your Stryker Representative, details below to discuss

11 Should you have any queries concerning this action please contact the undersigned

Product Return Information

1 **Complete the attached customer response form**
(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 notices

2 **Return the completed form** to:

3

Name

Position

Signature