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stryker®
UK

URGENT Field Safety Notice: RA 2015-047

25 February 2016

Product Code	Lot Numbers	Description
See attached list	See attached list	RESTORIS MCK Baseplate

Dear Customer,

Stryker® Orthopaedics has initiated a voluntary product recall for the product described above. The intent of this letter is to list all known hazards potentially associated with the below noted issue and list the risk mitigation factors associated with the use of the product.

Issue:
We have become aware that there is the potential for the sterile barrier for the RESTORIS MCK Baseplate to be breached. To date, four Product Experience Reports were received from the field for this issue.

The potential risks associated with this event are listed below.

Potential Hazards:
There is a potential that the device is not utilized during surgery, as planned. The foreseeable sequence of events is that the damaged sterile barrier is recognized by the OR nurse and the device is not used. This may result in the following potential hazardous situations and patient harms:
Delay in surgery <5 minutes while new device is obtained.
There is a potential for the device to be utilized during surgery. Although the package damage was observed in the reported cases, if the damaged sterile barrier is not recognized by the OR nurse the device may be used. This may result in the following potential hazardous situations and patient harms:
Non-sterile implant leading to infection.

Risk Mitigation
Risk to the patient is mitigated by the OR inspection of device packaging as the damage to the sterile barrier may be noticed prior to the procedure as it was in the reported cases. According to the device Instructions for Use provided with each package, the end user is instructed not to use the device if the seal or package is breached.

Our records indicate that you have received the above referenced product. It is our responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.

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RS11877

Actions Required

1. Immediately check your internal inventory and quarantine any subject devices that are located.

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 Nina Goddard by fax (01635 262 464) or by e-mail (nina.goddard@stryker.com).

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

6. Upon receipt of a completed response form, a Stryker Representative will contact your facility to arrange collection of any affected devices that have been located on site and to arrange any replacements that are required.

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

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

On behalf of Stryker we thank you sincerely for your help and support in completing this action 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.

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

Yours faithfully,

Nina Goddard
Quality Assurance and Regulatory Affairs

Affected Lot Numbers

Product Code	Lot Numbers
180601	26110111, 26300512-01, 26110112-01, 26090311-01
180602	LET1484311012, 26020812-01, 26220512-01, 26180711-01, 26120211-01, 26301011-01, 26161111-01, 26220512-02
180603	LET1388860512, 26010511-01, 26310811-01, 26050112-01
180604	26090512-01, 26280412-01
180605	26310512-01, 26270512-01, 26250511-01
180606	LET1464570912, 26300412-01, 26140412-01, 26050212-01
180607	26211011-01, 26040212-01, 26330512-01, 26090611-02 26070811-01, LET1406460512, 26230411-01
180608	26141111-01
180611	26131111-01, 26050211-01
180612	26190911-01, 36010112-1, 26070212-01, 26410611-01, 26020411-01, 26060211-01
180613	26271011-01, 26240711-01
180614	36031211-1, 26180512-01, 26440611-01, 26190612-01
180615	26100512-01
180616	26160212-01, 26340712-01, 26300811-01, 26171111-01, 26350512-01, 26310612-01
180617	26310412-01, 26160711-01, 26210511-02, 26061011-01, 26240411-01, LOT1388810512
180618	26360512-01, 26060311-01, 26061211-01

RA 2015-047: PFA Acknowledgement Form

Product Code	Lot Numbers	Description
See attached list	See attached list	RESTORIS MCK Baseplate

I acknowledge receipt of the Field Safety Notice for RA 2015-047 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.