XX December 2017

URGENT Field Safety Notice: RA 1658081

FSCA Identifier: Product Field Action RA 1658081

Product description: MCK TIBIAL BASEPLATE-RM/LL-SZ 2
MCK TIBIAL BASEPLATE-RM/LL-SZ 7

Item No.: 180612; Lot Number: 26080317-01
180617; Lot Number: 26150217-01

Dear Customer,

Stryker has initiated an urgent, voluntary, lot-specific recall for the MCK TIBIAL BASEPLATE-RM/LL-SZ 2 and MCK TIBIAL BASEPLATE-RM/LL-SZ 7 referenced above. The intent of this letter is to inform you of the product recall that was initiated on December 01, 2017 by Stryker, and to list known hazards potentially associated with the use of the above referenced products and list the risk mitigation factors.

Issue

Stryker has discovered that the packaging of certain sizes and lots of the above-referenced product may contain the incorrect product and/or label. Two reports were received with the product/label discrepancy. In one report, the labeling of the implant box outer label stated Size 2 RM/LL, and the labeling of the implant sticker (Patient label) located inside the outer box stated Size 7 RM/LL. The correct implant Size 2RM/LL was inside the box. The patient label was incorrect in this report. The second report described that a size 2 implant was in a box labeled as a size 7 implant.

Potential Hazards

Technical and medical assessments are currently underway to determine any potential hazards associated with the use of the product. Additional communication will be forwarded upon completion of the internal investigation on this issue.

Risk Mitigation

The difference in Size 2 RM/LL implant and Size 7 RM/LL implant is easily identified by the end user and would not likely be implanted as the discrepancy would be obvious.

Immediate Actions

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.

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.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a)Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within XX calendar days from the date of receipt. The target date for completion of this action is XX XXX 2017 and your timely response will enable us to ensure that we meet this target.

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:	XXXXXXX
Position:	XXXXXXX
Telephone:	XXXXXXX
Fax:	XXXXXXX
E-mail:	XXXXXXX

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.

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

Yours faithfully,

RA 1658081: PFA Acknowledgement Form

FSCA Identifier: Product Field Action RA 1658081

Product description: MCK TIBIAL BASEPLATE-RM/LL-SZ 2
MCK TIBIAL BASEPLATE-RM/LL-SZ 7

Item No.: 180612; Lot Number: 26080317-01
180617; Lot Number: 26150217-01

I acknowledge receipt of the Field Safety Notice for RA1658081 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 Implanted	Qty to return
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 XXXXXX
OR EMAIL TO XXXXXX