



URGENT MEDICAL DEVICE RECALL

cc: Chairman Medical Board and relevant Head of Departments

December 05, 2017

Product Field Action #: 1658081

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.

Actions Needed

1. Please inform users of this Urgent Product Recall and forward this notice to all individuals who need to be aware within your organization
2. Hospitals/Distributors: Complete and sign the enclosed Recall Notification Business Reply Form and email to ASEAN.PMS@stryker.com or hand to your Stryker representative.
3. Hospitals/Distributors: Return all affected products available at your location to the following address.

Stryker/PFA Product Returns
ATTN: Distribution Inventory Team
2555 Davie Road
Fort Lauderdale, FL 33317



Our records indicate that you have received the above referenced implant. It is our responsibility to ensure that customer who may have received this affected implant also receive this important communication.

Reporting of Adverse Events

Please report any adverse events or product quality problems associated with this device to Stryker. Healthcare Professionals may also report any suspected adverse events associated with these devices to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to Stryker will be investigated and subsequently reported to HSA.

Please assist us in meeting our obligations by returning the attached Recall Notification Business Reply Form within 5 business days.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact the undersigned.

Sincerely,

Sara Rodriguez Jato

Sara Rodriguez Jato
QA Lead
Stryker ASEAN
sara.jato@stryker.com
ASEAN.PMS@stryker.com
Tel. +84 (0)8 3827 5399 Ext.12



**URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM**

December 05, 2017

Product Field Action #: 1658081

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 have received the medical device correction notification from Stryker dated December 05, 2017 stating that it has initiated a voluntary, lot-specific recall for the MCK TIBIAL BASEPLATE-RM/LL-SZ 2 (Item: 180612; Lot Number: 26080317-01) and MCK TIBIAL BASEPLATE-RM/LL-SZ 7 (180617; Lot Number: 26150217-01) described above.

Hospital/Distributor Representative
(Signature)

Date _____

Hospital/Distributor Representative
(Print)

Name of Hospital/Distributor

Please complete this form within 5 business days and return it via email to ASEAN.PMS@stryker.com or hand it to your Stryker representative.