URGENT MEDICAL DEVICE RECALL

cc: Chairman Medical Board and relevant Head of Departments

March 15, 2018

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,

MAKO Surgical Corp (a division of Stryker and hereinafter referred to as MAKO) 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 in December 01, 2017. An initial communication was dated December 5th, 2017. As stated in the initial communication, MAKO has completed technical and medical assessments and is providing this follow-up communication to list all known hazards potentially associated with the use of the above referenced products and list the risk mitigation factors.

Issue

MAKO 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

In the event of a product mix between the MCK Tibial Baseplate-RM/LL Size 2 or 7, the following potential hazard has been identified:

1. During a Partial Knee Surgery, using a RESTORIS MCK Implant System, packaging is opened to reveal a different size tibial baseplate than indicated on the label.

Potential Harms

1. Complications associated with extended surgery time of less than 15 minutes

Risk Mitigation

The difference in Size 2 RM/LL implant and Size 7 RM/LL implant is easily identified by the end user (Size 2 is length x width 41mm x 23mm and size 7 is 56mm x 30.5mm). In light of the obvious nature of the size discrepancy, it is unlikely this discrepancy would go unnoticed and implanted during surgery.

Actions Needed

2. Please inform users of this Urgent Product Recall and forward this notice to all individuals who need to be aware within your organization

3. Hospitals/Distributors: Complete and sign the enclosed Recall Notification Business Reply Form and email to ASEAN.PMS@stryker.com or hand to your MAKO representative.

4. Hospitals/Distributors: Return all affected products available at your location to the following address.

   ATTN: Transmedic Pte Ltd
   5 Jalan Kilang Barat
   9th Floor Petro Centre
   Singapore 159349

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 MAKO. 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 MAKO 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,

[redacted]

QA Lead
Stryker ASEAN
[redacted]
ASEAN.PMS@stryker.com
Tel. +84 (0)8 3827 5399 Ext.12

URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM

March 15, 2018

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 MAKO dated March 15, 2018 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 MAKO representative.