URGENT MEDICAL DEVICE REMOVAL

May 16, 2018

Product Field Action : 1749458
Description: Mako RIO System Irrigation Clip (Partial Knee Application only)
Catalog No.: 111690
Lot No.: 176364, 178346, 181337, 185213, 186561, 189709, 190559, 193643, 195763A1

Dear Customer,
cc: Chairman Medical Board and relevant Head of Departments

MAKO Surgical Corp (a division of Stryker and hereinafter referred to as Stryker) has initiated a voluntary, lot-specific recall for the Mako RIO System Irrigation Clip (Partial Knee Application only). The intent of this letter is to list known hazards and harms potentially associated with the aforementioned product and list any risk mitigation factors.

Issue

Stryker has discovered that specific lots of the Mako RIO System Irrigation Clip have the potential to fracture. The RIO System Irrigation Clip is a sterile disposable, used to direct saline flow for the burring tool during a Mako Partial Knee surgery.

Potential Hazards

In the event of a break in the Mako RIO System Irrigation Clip, the following potential hazards may occur:

- Fractured device
- Foreign object (i.e. inert particulate left in wound)

Potential Harms

The aforementioned hazards may result in one or more of the following potential harms:

- Complications associated with extended surgery time of > 15 min
  - While retrieving a secondary RIO System Irrigation Clip; or
  - While attempting to irrigate inert particulate from wound site
- Poor implant performance
- Inflammatory response
- Pain and/or poor soft tissue function

Risk Mitigation

1. Inert Particulates: The Mako RIO System Irrigation Clip is made from a surgical grade liquid crystal polymer. Particulates of this polymer would be inert if left in the surgical wound.

2. Lavage Steps: As part of either an intentional attempt to remove any possible Mako RIO System Irrigation Clip particulates or during routine surgical lavage steps, there exists the potential that these efforts could remove a fragment of the Mako RIO System Irrigation Clip from the surgical wound. This would mitigate the hazards of foreign inert particulates in the surgical wound.

Actions Needed

1. Please inform users of this Urgent Medical Device Removal and forward this notice to all individuals who need to be aware within your organization.

2. Complete and sign the enclosed Recall Notification Business Reply Form and email a copy to ASEAN.PMS@stryker.com or hand to your MAKO product representative.

3. Return all affected products available at your location to the following address.

   Transmedic Pte Ltd
   5 Jalan Kilang Barat
   9th Floor Petro Centre
   Singapore 159349
   Ref. PFA 1749458

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 Stryker will be investigated and subsequently reported to HSA.

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

Please assist us in meeting our regulatory obligation by returning the attached Urgent Medical Device Removal 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]

Sara Rodriguez Jato
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URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM

May 16, 2018

Product Field Action : 1749458
Description: Mako RIO System Irrigation Clip (Partial Knee Application only)
Catalog No.: 111690
Lot No.: 176364, 178346, 181337, 185213, 186561, 189709, 190559, 193643, 195763A1

I have received the medical device correction notification from Stryker dated May 16, 2018 stating that it has initiated a voluntary, lot-specific recall for the Mako RIO System Irrigation Clip (Partial Knee Application only) (Item: 111690; Lot Number: 176364, 178346, 181337, 185213, 186561, 189709, 190559, 193643, 195763A1).

_____ _____

Hospital/Distributor Representative (Signature) | Date

_____

Hospital/Distributor Representative (Print)

_____ _____

Name of Hospital/Distributor | Stamp

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