URGENT MEDICAL DEVICE REMOVAL

January 21, 2018

Product Field Action #: 1657945
Description: Mako Onlay Insert Extractor
Item No.: 160430
Lot No.: 19020414, 19090616, 19090915, 19100616, 19100915, 19110317, 19110616, 19110616, 19110915, 19110915, 19130315, 19140315, 19451016, 19471016, 19490515, 19500515, 19510515, 19520515, 19530515, 26051212, 26070512, 26080913, 26130512, 26170513, 26201111, 26290412, 26440912

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 Onlay Insert Extractor. The intent of this letter is to list known hazards and harms potentially associated with the aforementioned product and list any risk mitigation factors.

The Mako Onlay Insert Extractor is an optional reusable instrument that is part of the Restoris® MCK (MultiCompartmental Knee) Unicondylar (Uni) system. The Onlay Insert Extractor may be used during Restoris® MCK Uni surgery to remove the Onlay Insert Trial after trialing has been performed.

Issue

Stryker has received a report that a hinge pin disassociated from the Mako Onlay Insert Extractor. In the reported case, the disassociated hinge pin was discovered on the back table prior to being used during surgery and a backup device was available and used to complete the procedure.

Potential Hazards

In the event of a disassociated hinge pin, the following potential hazards may occur:

- Disassociated Hinge Pin
- Foreign Object (i.e. Hinge Pin left in wound)
- Excessive Metal Wear Debris

Potential Harms

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

- Complications associated with extended surgery time of > 30 min.
- Poor implant performance
- Adverse local tissue reaction and/or Inflammatory Response
- Pain and/or poor soft tissue function (i.e., muscle, tendon), potentially necessitating revision surgery

Risk Mitigation

1. Optional Instrument: Because the Mako Onlay Insert Extractor is an optional instrument, risk can be mitigated by not using the extractor. A similar instrument may be utilized to lift up the removal holes at the front of the trial insert for extraction.

2. Functional Inspection: In the event the Mako Onlay Insert Extractor is utilized, risk may be mitigated by performing an inspection of the instrument prior to use, as per Stryker's recommendations in "Instructions for: Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices."

3. Lavage Steps: As part of the routine surgical lavage steps, there exists the potential that these steps could remove an unnoticed Hinge Pin left in the surgical wound. This would mitigate the hazards of foreign object and excessive metal wear debris 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 hand to your Transmedic Pte. Ltd representative or email to regulatory@transmedicgroup.com.

3. Return all affected products available at your location to your Transmedic Pte. Ltd representative.

Please report any adverse events or product quality problems associated with this device to Stryker (ASEAN.PMS@stryker.com) or to your local Transmedic Pte. Ltd representative. Alternatively, healthcare professionals may report any suspected adverse events associated with these devices to the Medical Device Branch, Health Products Regulation Group, HSA at Tel: 6866 1048, Fax: 6478 9028, 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 may have received the above referenced instrument. 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]

On behalf of Stryker
Sara Rodriguez Jato
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[redacted]

On behalf of Transmedic Pte. Ltd
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URGENT MEDICAL DEVICE REMOVAL
NOTIFICATION BUSINESS REPLY FORM

January 21, 2018

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I have received the medical device removal notification from Stryker dated January 21, 2018 stating that it has initiated a voluntary recall for the Mako Onlay Insert Extractor (PN 160430) described above.

_____ _____
Facility Representative (Signature) Date

_____
Facility Representative (Print Name)

_____
Facility Name

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND HAND IT TO YOUR LOCAL TRANSMEDIC Pte. Ltd REPRESENTATIVE OR RETURN IT VIA EMAIL TO regulatory@transmedicgroup.com: