URGENT MEDICAL DEVICE REMOVAL

July 26, 2018

Product Field Action: 1802553
Description: Vizadisc Knee Procedure Tracking Kit
Vizadisc Hip Procedure Tracking Kit
Catalog No.: 107120, 107130
Lot No.: 17097K, 17124K, 17129K, 17136K, 17143K, 17103H

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 Vizadisc Knee Procedure Tracking Kit and Vizadisc Hip Procedure Tracking Kit. 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 Vizadisc Knee Procedure Tracking Kit and Vizadisc Hip Procedure Tracking Kit have the potential to be damaged on the Vizadisc reflective material causing an inability to be detected by the camera. The Vizadisc is a small, circular disposable used to provide a reflective surface recognizable to the Mako system camera. The Vizadisc attaches to the arrays to provide constant location and orientation information to the Mako system while the probes can be used to register bone surfaces and instruments throughout a surgical case.

Potential Hazards

In the event of damage to the material on the Vizadisc Tracking Kit, the following potential hazard may occur:

- Inability of the Vizadisc to be detected by the Mako system

Potential Harms

The aforementioned hazards may result in the following potential harm:

- Complications associated with extended surgery time of 20 minutes while retrieving a secondary Vizadisc Tracking Kit

Risk Mitigation

1. Risk may be mitigated by performing a visual inspection of the discs during pre-surgery setup as the defect can be recognized due to apparent discoloration. If the defect was identified the disc could be replaced prior to surgery.

2. In the event that a Vizadisc is damaged, risk may be mitigated by testing the Vizadiscs by attaching to the probes and arrays during pre-surgery setup, as per Stryker's recommendations in "Surgical Technique Guide." This provides an opportunity for the user to show each instrument to the camera after assembly to confirm that all discs are detectable.

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 1802553

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 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]
Chia Nee Lim
Senior QA Specialist
Stryker ASEAN
[redacted]
ASEAN.PMS@stryker.com
Telephone: +65 6500 9518

URGENT MEDICAL DEVICE REMOVAL
NOTIFICATION BUSINESS REPLY FORM

July 26, 2018

Product Field Action: 1802553
Description: Vizadisc Knee Procedure Tracking Kit
Vizadisc Hip Procedure Tracking Kit
Catalog No.: 107120, 107130
Lot No.: 17097K, 17124K, 17129K, 17136K, 17143K, 17103H

I have received the medical device removal notification from Stryker dated July 26, 2018 stating that it has initiated a voluntary, lot-specific recall for the Mako Vizadisc Knee Procedure Tracking Kit and Mako Vizadisc Hip Procedure Tracking Kit (PN: 107120, 107130); Lot Number: 17097K, 17124K, 17129K, 17136K, 17143K, 17103H.

_____ _____

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.