URGENT MEDICAL DEVICE CORRECTION

January 21, 2018

Product Field Action #: 1641672
Description: Mako RIO System - Ethernet to Fiber Optic Converter
Catalog No.: See attached list
RIO Systems: See attached list

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, correction for the Mako System's Ethernet to Fiber Optic Converter. 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
Through complaint investigation and in-process testing, Stryker has discovered that certain Ethernet to Fiber Optic Converters did not pass testing due to a RIO Connection error. The Ethernet to Fiber Optic Converter enables communication between the Mako Robotic Arm (RIO) and the Guidance Module during Total Hip Arthroplasty (THA), Total Knee Arthroplasty (TKA) and Partial Knee Arthroplasty (PKA) procedures. A RIO Connection error will occur when communication is lost between the RIO and the Guidance Module. In the event a Mako System experiences a RIO Connection error, a network connection error message will appear on the system display.

Potential Hazards
In the event of a RIO Connection error, the following potential hazards may occur:

1. Unrecoverable hardware malfunction of the Ethernet to Fiber Optic converter resulting in a RIO Connection error

Potential Harms

1. Complications associated with extended time of surgery due to (a) Mako Product Specialist (MPS) by-passing the connection error through an Ethernet cable (detailed further below); or (b) continuing surgical procedure with manual instrumentation
    a. Conversion from Mako PKA to manual PKA
    b. Conversion from Mako PKA to manual TKA
    c. Conversion from Mako THA to manual THA
    d. Conversion from Mako TKA to manual TKA

Risk Mitigation & Device Correction
In the event of a RIO Connection error, the on-site MPS is trained to perform troubleshooting steps on the system to restore the connection. The on-site MPS is trained to by-pass the RIO Connection error by utilizing a backup Ethernet cable as part of the troubleshooting process. The backup Ethernet cable is stored within the cover of the Guidance Module. Mako Product Specialists are present at all cases and are trained on the by-pass method. These cables for the by-pass method are available to each MPS, which should allow cases involving a RIO Connection

error to continue with the Mako System until Stryker field service can replace the Ethernet to Fiber Optic Converter.

Finally, as part of ongoing Mako System maintenance, all Ethernet to Fiber Optic Converters subject to this action will be replaced with updated converters during scheduled maintenance intervals.

Actions Needed

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

2. Complete and sign the enclosed Business Reply Form and hand to your Transmedic Pte. Ltd representative or email to regulatory@transmedicgroup.com.

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 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 Business Reply Form within 5 business days.

Sincerely,

[redacted]

On behalf of Stryker
Sara Rodriguez Jato
QA Lead
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Tel. +84 (0)8 3827 5399 Ext.12

[redacted]

On behalf of Transmedic Pte. Ltd
Ignatius Chew
Regulatory Affairs Associate
Transmedic Pte Ltd
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List of affected products registered in Singapore*

Part number	Product description
201251	RIO® Guidance Module
203999	RIO® Surgical Arm
204000	2.1 RIO® Robotic Arm Int. Orth. System
204410	RIO® Guidance & Camera Assy (crated)
204417	RIO® Surgical Arm (crated)
207110	RIO® Guidance Module
209999	3.0 RIO® RoboticArm - MICS

*Please note that this list includes products registered in Singapore only and other products not registered in Singapore may be affected

List of affected RIO robots in Singapore

ROB168
ROB255
ROB543
ROB588

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NOTIFICATION BUSINESS REPLY FORM

January 21, 2018

Product Field Action #: 1641672
Description: Mako RIO System - Ethernet to Fiber Optic Converter
Catalog No.: See attached list
RIO Systems: See attached list

I have received the medical device correction notification from Stryker dated January 21, 2018 stating that it has initiated a field correction for the Mako RIO System's Ethernet to Fiber Optic Converter described above.

_____ _____
Facility Representative Date
(Signature)

_____
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: