URGENT FIELD SAFETY NOTIFICATION

Type of action:	Product Field Corrective Action
Ref :	FA2018-1641672
Description:	Ethernet to Fiber Optic Converters ref 200933 (Mako RIO System Spare Part)
RIO Systems affected:	See Annex I with the MAKO robotic that have affected Ethernet to Fiber Optic Converters installed.
Legal Manufacturer:	MAKO Surgical Corp. 2555 Davie Road. Fort Lauderdale. 33317

January 25, 2018

Dear Customer,

Stryker initiated a voluntary, lot specific, correction for the Mako System's Ethernet to Fiber Optic Converter Converter (200933). 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 Converter (200933) enables communication between the Mako Robotic Arm (RIO) (209917) 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 (207110). In the event a Mako System experiences a RIO Connection error, a network connection error message will appear on the system display. Please be aware that Ethernet to Fiber Optic converter (200933) is a spare part.
In order to check which Mako System is affected, please consult on attached annex 1.

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 (200933) resulting in a RIO Connection error .

Potential Harms

1. Complications associated with extended time of surgery (approximately 30 minutes) 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

error to continue with the Mako System until Stryker field service can replace the Ethernet to Fiber Optic Converter. Guidance Module. Mako Product Specialists are present at all cases and are trained on the by-pass

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. Circulate this Field Safety Notice internally to all interested/affected parties.
2. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a) Please provide contact details so that Stryker can inform the recipients appropriately.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.
3. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
4. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
   Therefore please complete even if you no longer have any of the subject devices in your physical inventory.
5. Return the completed form to your nominated Stryker Representative (indicated below) for this Action
6. Our Field Service Engineer will carry put the activities described in the section "Risk mitigation & Device Correction" during the MAKO system periodic maintenance according to the periods stablished.

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.

We request that you respond to this notice within XX calendar days from the date of receipt. The target date for completion of this action is 31 of December 2018 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:
Position:
Telephone:
Fax:
E-mail:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours Sincerely,

URGENT FIELD SAFETY NOTIFICATION
ACNOWLEDGEMENT FORM

January 24, 2018

Type of action: Product Field Corrective Action
Ref : FA2018-1641672
Description: Ethernet to Fiber Optic Converters ref 200933 (Mako RIO System Spare Part)
RIO Systems affected: See Annex I with the MAKO robotic that have affected Ethernet to Fiber Optic Converters installed.
Legal Manufacturer: MAKO Surgical Corp. 2555 Davie Road. Fort Lauderdale. 33317

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

We have not located any of these devices in our inventory:				
We have located the following devices:				
Product Description	Product Reference	Lot Number	Qty Implanted	Qty to return
			NA	NA
			NA	NA
			NA	NA
We have further distributed subject devices to the following organizations:				
Facility Name				
Facility Address				

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title		Stamp:	
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO OR EMAIL TO

ANNEX I

Please find enclosed the MAKO robots that have installed an affected spare part : Ethernet to Fiber Optic Converter

Mako Robotic Arm (RIO) affected				
ROB050	ROB250	ROB378	ROB450	ROB523
ROB058	ROB252	ROB382	ROB454	ROB526
ROB073	ROB253	ROB386	ROB461	ROB527
ROB082	ROB254	ROB387	ROB466	ROB534
ROB137	ROB255	ROB388	ROB469	ROB536
ROB144	ROB272	ROB390	ROB470	ROB537
ROB166	ROB273	ROB391	ROB474	ROB543
ROB168	ROB274	ROB396	ROB478	ROB546
ROB169	ROB275	ROB399	ROB479	ROB548
ROB181	ROB276	ROB403	ROB484	ROB549
ROB188	ROB289	ROB411	ROB494	ROB567
ROB194	ROB307	ROB412	ROB495	ROB580
ROB218	ROB309	ROB413	ROB496	ROB582
ROB219	ROB327	ROB414	ROB497	ROB588
ROB220	ROB341	ROB418	ROB509	ROB589
ROB222	ROB372	ROB423	ROB512	
ROB230	ROB373	ROB431	ROB519	
ROB233	ROB374	ROB435	ROB521	