URGENT FIELD SAFETY NOTIFICATION
For Customers

Type of action:	Field Safety Corrective Action (FA2017-047)
PN affected:	See Appendix I
Product Description:	MAKO PKA & THA software of RIO system (MAKO Robot)
Legal Manufacturer:	MAKO Surgical Corp. 2555 Davie Road. Fort Lauderdale. 33317

13rd of September, 2017

Dear Customer

Stryker Orthopaedics has initiated a voluntary field safety corrective action for the Mako PKA and THA End Effector (EE) constants dropdown software discrepancy as described below. The purpose of this letter is to inform you of the product correction that was initiated on August by Stryker.

Issue

During lab system testing it was observed that if more than 36 PKA EE or THA EE constants / EE serial numbers are loaded onto the Mako system (accessed via the Mako Registration Page), the dropdown menu would not display all End Effector constants / EE serial numbers at once so, due the EE constant in use could not be selected, the MAKO System cannot be used. There have been no reports of this issue in the field.

Potential Hazards

- If more than 36 PKA EE or THA EE constants are loaded onto the Mako system, it does not allow the Mako Product Specialist (MPS) to select the appropriate End Effector constant in use.

  The likelihood of MAKO systems will exhibit >36 EE constants is remote for European markets.

Potential Harm

- Delay in surgery < 30 minutes but <1hr to sterilize another End Effector which constant is downloaded (for PKA interventions PNs 111758 / 111770 or 206967 / 205020 for THA interventions).

  If there is no EE used before (meaning it constant is already downloaded in the system) available and there are >36 EE constants, then MAKO robot cannot be used. The likelihood of MAKO systems will exhibit >36 EE constants is remote for European markets.

Required Actions

Our records indicate that you have received the above referenced product. Please assist us in meeting our regulatory obligation by:

1. Reviewing this Notification and locate any MAKO device within your facility.
2. Completing the *attached acknowledgement form* (page 5) indicating that you have received this Important Medical Device Correction letter and return it signed to us with the information about the MAKO devices you have at your facilities. *(Please complete this form even if you do not have any product. This will preclude the need to Stryker to send any reminder notice)*

3. Please contact with your Mako Product Specialist to agree an appointment. Mako Product Specialist will inspect your device prior to the next procedure and, if necessary, will contact a Field Service Engineer to initiate the corrective field action in your Mako device.
4. Please inform Stryker of any adverse events associated with the use of the subject devices.
5. There is no further action required from your side.

We request that you respond to this notice within 7 calendar days from the date of receipt.

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:
Email:

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,

stryker

URGENT FIELD SAFETY NOTIFICATION
ACNOWLEDGEMENT FORM

Type of action: Field Safety Corrective Action (FA2017-047)
PN affected: See Appendix I
Product Description: MAKO PKA & THA software of RIO system (MAKO Robot)

I have received the field safety notification from Stryker dated on _____ stating that it has initiated a field safety corrective action for the Mako PKA and THA applications described above.

Fulfilled by:

Name	
Position	
Phone number	
Email	
Hospital name	
Hospital address	
Hospital Stamp	
Date	

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL OR FAX LISTED BELOW:

Affect Product Part Numbers

Part Number	Part Name
207323-99	Upg Kit, MAKOPlasty PKA v2.5 software OUS
207480	MAKOplasty® PKA 2.5 & THA 2.0 Post-Upgrade
208259	Upgrade Kit, PKA 2.5.4 SW
208259-01	Upgrade Kit, PKA 2.5.5 SW, IT
208259-99	Upgrade Kit PKA 2.5.4 OUS
208260	Upgrade Kit, PKA 2.5.4 + THA 2.0.4 SW
208260-01	Upg Kit, PKA 2.5.5 + THA 2.0.5 IT
208260-99	Upgrade Kit PKA 2.5.4 & THA 2.0.4 OUS
208584-01	Cover Ltr, PKA 2.5.5 THA 2.0.5 IT
208795	Upg Kit, PKA 2.5.6
208795-01	UPG KIT, PKA 2.5.6.1 IT
208795-03	Upg Kit, PKA 2.5.6.1DE.1
209444	Upg Kit PKA 2.5.6.1 OUS
209445	Upg Kit THA 2.1.1 PKA 2.5.6.1 OUS
209981	PKA Upgrade Kit
211584	RIO® Partial Knee Software Application
211586	PKA 2.5.6.2 Upgrade Kit
211587	THA 3.1 + PKA 2.5.6.2 Upgrade Kit
212041	PKA 2.5.6.3 Upgrade Kit
212042	THA 3.1 + PKA 2.5.6.3 Upgrade Kit
212043	RIO® Partial Knee Software Application
212043-01	RIO® Partial Knee S/W App Italian
212043-03	RIO® Partial Knee S/W App German
212043-04	RIO® Partial Knee S/W App French
212099	Upgrade Disk PKA 2.5.6.3
212099-01	Upgrade Disk PKA 2.5.6.3.IT.1 Italian
212099-03	Upgrade Disk PKA 2.5.6.3.DE.1 German
212099-04	Upgrade Disk PKA 2.5.6.3.FR.1 French
212102	PKA 2.5.6.3 Upgrade Kit
212102-01	PKA 2.5.6.3 Upgrade Kit Italian
212102-03	PKA 2.5.6.3 Upgrade Kit German
212102-04	PKA 2.5.6.3.FR.1Upgrade Kit(French)
212102-99	PKA 2.5.6.3 Upgrade Kit (OUS)
212103	THA 3.1.1+PKA 2.5.6.3 Upgrade Kit
212103-01	THA 3.1.1+PKA 2.5.6.3 Upgrade Kit Italian
212103-03	THA 3.1.1+PKA 2.5.6.3 Upgrade Kit German
212103-99	THA 3.1.1+PKA 2.5.6.3 Upgrade Kit OUS
212210	PKA 2.5.6.4 Upgrade Disc
212210-01	PKA 2.5.6.4 Upgrade Disc Italian
212210-03	PKA 2.5.6.4 Upgrade Disc German

212210-04	PKA 2.5.6.4 Upgrade Disc French
212211-01	PKA 2.5.6.4.IT.1 Upgrade Kit Italian
212211-03	PKA 2.5.6.4.DE.1 Upgrade Kit German
212211-04	PKA 2.5.6.4.FR.1 Upgrade Kit (French)
212211-99	PKA 2.5.6.4 Upgrade Kit (OUS)
212211-99~	PKA 2.5.6.4 Upgrade Kit (OUS)
212212-99	THA 3.1.1 + PKA 2.5.6.4 Upgrade Kit OUS
212220	THA 3.1.1 + PKA 2.5.6.4 Upgrade Disc
212220-01	THA 3.1.1 + PKA 2.5.6.4 Upgrade Disc IT
212220-03	THA 3.1.1 + PKA 2.5.6.4 Upgrade Disc DE
212220-04	THA 3.1.1 + PKA 2.5.6.4 Upgrade Disc FR
212869	PKA 2.5.6.3+THA 3.1.1.1 DISC
212869-01	PKA 2.5.6.3.IT.1+THA 3.1.1.1.IT.1 DISC
212869-03	PKA 2.5.6.3.DE.1+THA 3.1.1.1.DE.1 DISC
212869-04	PKA 2.5.6.3.FR.1+THA 3.1.1.1.FR.1 DISC
212870	PKA 2.5.6.4+THA 3.1.1.1 DISC
212870-01	PKA 2.5.6.4.IT.1+THA 3.1.1.1.IT.1 DISC
212870-03	PKA 2.5.6.4.DE.1+THA 3.1.1.1.DE.1 DISC
212870-04	PKA 2.5.6.4.FR.1+THA 3.1.1.1.FR.1 DISC
212871	PKA2.5.6.3 + THA3.1.1.1 Kit
212871-15	THA 3.1.1 + PKA 2.5.6.3 Upgrade Kit(AUS)
212871-99	THA 3.1.1+PKA 2.5.6.3 Upgrade Kit OUS
212872	PKA2.5.6.4 + THA3.1.1.1 Kit
212872-15	THA 3.1.1 + PKA 2.5.6.4 Upgrade Kit(AUS)
212872-99	THA 3.1.1 + PKA 2.5.6.4 Upgrade Kit OUS
212873	TKA1.0 + PKA2.5.6.3 + THA3.1.1.1 Kit
212874	TKA1.0 + PKA2.5.6.4 + THA3.1.1.1 Kit
212879	TKA 1.0+PKA 2.5.6.3+THA 3.1.1.1 DISC
212880	TKA 1.0+PKA 2.5.6.4+THA 3.1.1.1 DISC
213166	PKA 2.5.6.4 + THA 3.1.2 DISC
213167	PKA 2.5.6.3 + THA 3.1.2 DISC
213168	PKA 2.5.6.3 + THA 3.1.2 KIT
213168-15	PKA 2.5.6.3 + THA 3.1.2 KIT (AUS)
213169	PKA 2.5.6.4 + THA 3.1.2 KIT
213170	TKA 1.0 + PKA 2.5.6.3 + THA 3.1.2 KIT
213171	TKA 1.0 + PKA 2.5.6.4 + THA 3.1.2 KIT
213172	TKA 1.0 + PKA 2.5.6.4 + THA 3.1.2 DISC
213173	TKA 1.0 + PKA 2.5.6.3 + THA 3.1.2 DISC
213492	TKA 1.0 + PKA 2.5.6.3 + THA 3.1.2 KIT