URGENT MEDICAL DEVICE CORRECTION

CC: Chairman Medical Board and relevant Head of Departments

August 24, 2017

Product Field Action (s)#: 1470747, 1496626
Description: PKA and THA End Effector (EE) constants software
Catalog No.: See Appendix I for affected products registered in Singapore. There are other products affected globally, please contact your Mako Product Specialist with any questions.

Dear hospital representative,

Stryker Orthopaedics has initiated a voluntary correction 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 7, 2017 by Stryker.

Issue
During lab system testing it was observed that if more than 36 PKA EE or THA EE constants are loaded onto the Mako system (accessed via the Mako Registration Page), the dropdown menu would not display all EE constants at once. There has been one report of this issue in the field.

Actions
MAKO product specialist will be trained to maintain less than 25 EE constants on the Guidance Module. No further action is required from you.

Potential Hazards
The Mako system does not allow the MPS to select the appropriate EE constant

Potential Harm
Delay in surgery <1hr to sterilize a new EE

Please assist us in meeting our regulatory obligation by returning the attached Business Reply Form within **5 business days**. Complete and sign the enclosed Business Reply Form and email to regulatory@transmedicgroup.com**.**

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact the undersigned.

Sincerely,

[redacted]

Sara Rodriguez Jato
QA Lead
Stryker ASEAN
sara.jato@stryker.com
ASEAN.PMS@stryker.com
Tel. +84 (0)8 3827 5399 Ext.12

URGENT MEDICAL DEVICE CORRECTION
NOTIFICATION BUSINESS REPLY FORM

August 24, 2017

Product Field Action (s)#: 1470747, 1496626
Description: PKA and THA End Effector (EE) constants software
Catalog No.: See Appendix I for affected products registered in Singapore. There are other products affected globally, please contact your Mako Product Specialist with any questions.

I have received the medical device correction notification from Stryker Orthopaedics dated August 24, 2017 stating that it has initiated a field correction for the Mako PKA and THA applications described above.

_____ _____
Hospital Representative (Signature) Date

_____ _____
Hospital Representative (Print) Stamp

_____
Hospital Name and Address

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY EMAIL TO REGULATORY@TRANSMEDICGROUP.COM

Appendix I: Affect Product Part Numbers registered in Singapore

Part Number	Part Name
212210	PKA 2.5.6.4 Upgrade Disc
212211-99	PKA 2.5.6.4 Upgrade Kit (OUS)
212869	PKA 2.5.6.3+THA 3.1.1.1 DISC
212870	PKA 2.5.6.4+THA 3.1.1.1 DISC
212871-99	THA 3.1.1+PKA 2.5.6.3 Upgrade Kit OUS
212872-99	THA 3.1.1 + PKA 2.5.6.4 Upgrade Kit OUS
212874	TKA1.0 + PKA2.5.6.4 + THA3.1.1.1 Kit
212880	TKA 1.0+PKA 2.5.6.4+THA 3.1.1.1 DISC
204500	RESTORIS® PKA Application
204601	Hip + PKA Upgrade Disk
209233-99	PKA 2.5.6.1 Upgrade Disc (OUS)