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stryker®

Orthopaedics

January 19, 2015

IMPORTANT MEDICAL DEVICE CORRECTION

SUBJECT: RIO® Robotic Arm Interactive Orthopedic System; all serial numbers.

Dear Distributor,

This letter is to inform you of an action MAKO Surgical Corp. is taking to implement an improved control mechanism for the burr motor used with the PKA application. MAKO Surgical Corp. is implementing the improved control mechanism to address seven reports where the burr motor used with the PKA application continued to spin outside of the stereotactic boundary while the control switches were not activated (foot pedal and trigger not pressed). In all cases the physician detected that the burr motor was still enabled and communicated with the Makoplasty Sales Specialist (MSS) to disable the motor. No injuries were reported.

MAKO Surgical Corp.'s engineering team has addressed the issue through an improved control mechanism. In accordance with regulatory requirements, we are communicating the implementation of this improved control mechanism to all affected customers. The new control mechanism will be shipped to you (at no charge) for a mandatory field upgrade. MAKO's international sales representative will coordinate with you on the timing for receipt of your upgrade.

Actions:

- The RIO system can continue to be used. The likelihood of occurrence is rare (0.035% of cases) and, the event is readily detectable and resolved. To resolve the event during a case, click on **"Reset Cutter"** from the Options Menu which will stop the burr from spinning and turn off the irrigation pump.
- Enclosed with this letter is a confirmation reply form. After reviewing this correction letter, please sign and return the form in the self-addressed envelope provided. Alternately, you may fax a copy of the signed form to +1.954.423.1547, ATTN: Quality Assurance. A signed, scanned copy may also be emailed to: SYKMakoFLQualitySystems@stryker.com
- If you have further distributed the device into commercial operations, please take steps per your distributor agreement to communicate this action to your customers. As mentioned above, the new control mechanism will be forwarded to you to support your field upgrade.

MAKO Surgical Corp. is conducting this correction to the distributor level, and has informed the appropriate regulatory bodies of this correction. We apologize for any inconvenience this action may present for you, and invite you, should you have any questions regarding this correction letter, to contact us at +1.954.628.1721 (English inquiries only).

Thank you,

[redacted]

Clayton Odoi
Sr. Director QA/RA

Enc. (1) Acknowledgement Form