



URGENT MEDICAL DEVICE CORRECTION NOTIFICATION RIO internal cPCI Card Cage

June 12, 2017

Product Field Action #: 1379533
Description: Mako RIO internal cPCI Card Cage
Catalog No.: 201337
Lot Code: 05212015

Dear Risk Manager,

Stryker/Mako has initiated a voluntary correction for a specific lot of cPCI card cages described above. The intent of this letter is to list all known hazards potentially associated with the below noted issue and list the risk mitigation factors associated with the use of the above-referenced cPCI card cages.

Issue

During a complaint investigation, Stryker identified an issue in a cPCI card cage in which the 3.3 VDC lug was cross threaded. This condition resulted in an intermittent power connection in the cPCI card cage and led to an intermittent or total loss of system power. Stryker believes this was an isolated event and there were no reported injuries.

Potential Hazards

Powering down of the system due to intermittent or total loss of power.

Potential Hazard: Unavailable Mako system.

Potential Harms:

1. Extended surgery time of ≤ 15 min.
2. Extended surgery time of > 30 min.

Risk Mitigation

All RIO systems with this lot of cPCI card cage installed will be inspected by a Mako Field Service Engineer. If an affected cPCI card cage is identified, replacement of the card cage will be performed to prevent intermittent or total loss of power to the Mako system.

Actions Needed

Our records indicate that you have received a Mako system with a cPCI card cage from the above referenced lot. Stryker\Mako Service personnel will contact you and schedule time to inspect and, if necessary, replace the card cage. In the meantime, you may continue to use your MAKO system.

1. Please inform users of this Urgent Medical Device Recall and forward this notice to all those individuals who need to be aware within your organization.
2. 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 fax or email a copy to 855-544-4807 or strykerortho7391@stericycle.com

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at (954) 628-0502.

Sincerely,



Clayton Odor
Sr. Director QA

**URGENT MEDICAL DEVICE
CORRECTION NOTIFICATION
HOSPITAL RISK MANAGEMENT BUSINESS REPLY FORM**

June 12, 2017

Product Field Action #: 379533
Description: Mako RIO internal cPCI Card Cage
Catalog No.: 201337
Lot Code: 05212015

I have received the medical device recall notification from Stryker/Mako dated June 12, 2017 stating that they initiated a field correction for the instrument described above.

Risk Manager
(Signature)

Date

Risk Manager
(Print)

FACILITY NAME
(Print)

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

Email: strykerortho7391@stericycle.com
Fax: 855-544-4807