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Urgent Medical Device Safety Notice

MEDICAL DEVICE SAFETY ALERT: Potential interference between Berchtold F-Generation LED Surgical Lights and the StealthStation® AxiEM™ or Fusion EM System

Date: October 27, 2014

Dear Healthcare Professional/Risk Manager:

At Medtronic, we are committed to continually evaluating and improving the quality and reliability of our processes, products and services. This letter is to notify you of a potential interference between Berchtold lights and the StealthStation® AxiEM™ or Fusion EM system.

Medtronic Neurosurgery is notifying you of the potential for electromagnetic interference (EMI) between Medtronic's StealthStation® AxiEM™ or Fusion EM technology and a version of Styker's Berchtold F-generation LED lights (models F528 and F628).

Affected serial numbers:

F528 Lights with a serial number smaller than 831800001526

F628 Lights with a serial number smaller than 831710002819

If you have purchased Berchtold F-generation lights and they are installed in OR rooms where the AxiEM™ or Fusion EM technology may be used, please check the serial numbers on the light heads. If they fall into one of the affected serial number ranges above, consider limiting use of the AxiEM™ or Fusion EM system to rooms that do not have these lights installed. If no alternative room is available, please ensure use of the lights according to the Berchtold Instruction for Use, maintaining a light head position at least 1-meter from the surgical site.

Description of the issue:

Through testing conducted with these two products by Berchtold and Medtronic, when the lights are positioned according to Berchtold's Instructions for Use – at a distance at least one meter from the patient – there is no interference. When the lights are positioned closer to the patient, the resulting EMI causes the StealthStation® AxiEM™ or Fusion EM system to cease tracking and display "red status", which prevents navigation until the EMI is removed. The testing confirmed that the StealthStation® AxiEM™/Fusion System meets specification, specifically since the "red status" functions as expected.

All Berchtold F-generation LED lights manufactured with serial numbers higher than those detailed above have been shown in testing to be compatible with the AxiEM™ or Fusion EM technology and do not cause the interference described in this letter.

If you have further questions regarding this communication, please contact your local Medtronic Neurosurgery or ENT Representative or call (877) 242-9504



Medtronic

Contact details:

If you have any questions regarding this action, please contact Medtronic Navigation Technical Services at 1-800-595-9709.

Sincerely,



**Michael Blasco
Regulatory Affairs Manager
Medtronic Navigation, Inc.**