



URGENT FIELD SAFETY NOTICE

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 60885

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **MR Surgical Suite II Table Transfer Release**

GE Healthcare has recently become aware of a potential safety issue with the table transfer release of the MR Surgical Suite II MR system. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The issue may cause an unexpected function loss of the patient transfer mechanism that allows the patient to be moved between the MR and surgical tables. This could delay care and handling of a patient during surgical or interventional procedures. GE has received one complaint of a transfer board not releasing from the MR table preventing the transfer board from moving to the surgical table. There have been no injuries reported as a result of this issue.

Safety Instructions

You may continue to use the table. Monitor for any issues in releasing the table. If you see this issue, contact a GE Field Engineer.

Affected Product Details

MR Surgical Suite Option, model numbers M8074SS, M8053SS, and M0074SS.

Product Correction

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

Toll Free number: 8001243002 SaudiArabiaServiceCenter@ge.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer – Medical Solutions
GE Healthcare