

20 May 2016

URGENT: MEDICAL DEVICE RECALL

Dear OR Supervisor/Risk Manager:

Medtronic Powered Surgical Solutions is conducting a voluntary field action to remove all Midas Rex Sagittal Saws. The Midas Rex Sagittal Saw is used with the Medtronic Integrated Power Console (IPC®) System. The IPC® System is indicated for the incision / cutting, removal, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures. The Sagittal Saws are individually packaged re-usable devices that require sterilization prior to each use. The following Sagittal Saw models are affected by this action:

Item Number	Item Description	Serial Numbers
ES300	Saw Sagittal	All
ES300-R	Saw Sagittal Refurbished	All
ES310	Saw Sagittal, Finger	All
ES310-R	Saw Sagittal, Finger Refurbished	All

REFERENCE IMAGES



ES300 Sagittal Saw



ES310 Finger Control Sagittal Saw

THE ISSUE

This action is being taken to reduce the risk of injury associated with the potential for leakage of fluid into the motor through the Rocker Housing Seal. The Rocker Housing Seal is intended to prevent ingress of fluid into the Sagittal Microsaws during use and decontamination. Although there have been no reports of fluid leakage occurring in the field, engineering testing of the seal identified the potential for leakage to occur. In assessing the risk of this potential failure, testing was conducted that indicated the gravity displacement sterilization cycle which is included in the IPC® User Manual may not be adequate to ensure sterility of internal motor components if fluid ingress occurs beyond the Rocker Housing Seal. In the event that fluid leaks into the motor through the Rocker Housing Seal, and gravity displacement sterilization method is used, if fluid leaks from the motor during use and this fluid contacts the patient surgical site, there is a potential for infection to occur.

ACTION REQUIRED

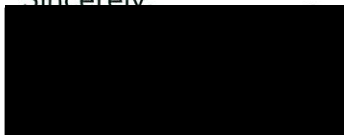
This letter includes a list of the affected Sagittal Saws that our records indicate have been provided to you. Please immediately compare your inventory of Sagittal Saws against the list provided and return all listed Sagittal Saws with a completed "Customer Accountability Form" included with this letter to your local Medtronic Sales representative.

REPLACEMENT

Medtronic Powered Surgical Solutions has limited ability to provide replacement product. We are committed to provide replacements based on the limited availability at our disposal. Your local Medtronic Sales representative and our customer service department are available to assist you with this field action.

We apologize for the inconvenience associated with this issue. We, at Medtronic Powered Surgical Solutions, remain committed to providing you with the highest quality products to meet your patient's needs. If you have any questions or comments, please contact your local Medtronic Sales representative.

Sincerely,



Jennifer Cho
Business Director, RTG SEA
Medtronic International Ltd