

Urgent Field Safety Notice

PSS Midas Rex® Sagittal Saws Models ES300, ES300-R, ES310, ES310-R Recall

May 2016

Medtronic reference: FA718

Dear HCP, 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 during subsequent use fluid leaks from the motor and this fluid contacts the patient surgical site, there is a potential for infection to occur. This risk is lower if the vacuum sterilization method is used.

ACTION REQUIRED

Medtronic requests that you:

- Immediately quarantine all Sagittal Saws from your inventory.
- Return all Sagittal Saws in your inventory to Medtronic.

REPLACEMENT

We are committed to provide replacements based on the limited availability at our disposal. Your Medtronic Representative will assist you with ordering replacement devices and returning affected devices as needed.

Medtronic has notified the Competent Authority of your country of this action.

We apologise for the inconvenience associated with this issue. We 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 Medtronic representative.

Sincerely,