Medtronic

Medtronic
49 Changi South Avenue 2
Singapore 486056
Singapore

URGENT: MEDICAL DEVICE RECALL
AxiEM™ ENT Suction Unable to Navigate

June 25, 2017

Dear Healthcare Professional:

This letter is to notify you of an issue with specific lots of navigated AxiEM™ ENT Suction instruments. Please review your inventory, follow the instructions in this letter, and complete the Consignee Response Form attached with this letter.

Product Information

Model Number(s)/ Catalog Number(s):

Part Numbers:
9733449 Straight Suction EM, ENT
9733450 Curved Suction 70, EM
9733451 Short Curved Suction 90, EM
9734308 Suction Small AxiEM™ ENT

The following kits may contain an affected instrument:
9733452 and 9733452-G02 ENT Instrument Set
9733908 Fusion ENT Instrument Kit
9734378 ENT AxiEM™ Instrument Set
9734636 ENT Prgm Add Fusion Nav AxiEM™

Affected Lots:

Affected instruments can be identified by the instrument lot numbers listed below:

Part Number	Lot Number
9733449	17022809, 17030108, 17022207, 17022106, 17020805, 17020904, 17021798, 17020987, 17011896, 17011221, 17011220, 16122237, 16122236, 16121661, 16121260, 16121259, 16112958
9733450	17030722, 17022421, 17022020, 17020619, 17011918, 17012417, 17010602, 16122724, 16122239, 16122038, 16120563, 16112362
9733451	17030728, 17022027, 17021426, 17013125, 17012724, 17011303, 16122767, 16122066, 16112965, 16112164
9734308	17022451, 17011750, 16120349, 16082989, 16081888, 16071987, 16062713, 16060712

Product Description & Usage:

The suction devices are part of a family of reusable ENT instruments that are used with the StealthStation™ AxiEM™ surgical navigation system. The AxiEM™ system is an electromagnetic (EM) tracking solution for surgical tools. The system measures an induced voltage created by local magnetic fields from a set of coils in the transmit coil array (TCA). Each surgical tool has a set of receiving coils to sense the magnetic field strength. Using a mathematical algorithm, the position and orientation of the instrument can be computed and overlaid/registered to imagery on a computer monitor, resulting in the ability to track the instrument tip in relation to the patient's anatomy.
AxiEM™ ENT Suction devices are used as suction and pointing devices. The suction devices are intended to have an ENT Instrument Tracker mounted on it.

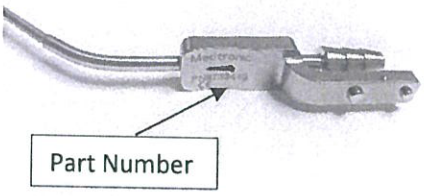
Issue Description:

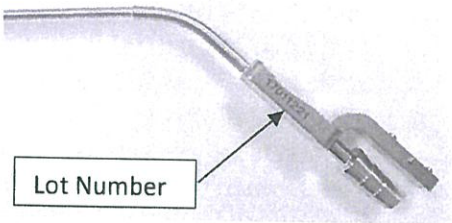
Medtronic has become aware that the specific lots of AxiEM™ ENT Suction instruments noted above are not able to pass instrument verification. Instrument verification is a step in the software which is performed prior to the use of each instrument. This verification step confirms device tracking functionality and prevents use of the device if a passing verification is not achieved. The impacted devices were made with a particular stainless steel stock material that exhibits magnetic characteristics (magnetic permeability), causing interference with electromagnetic (EM) tracking capability of the StealthStation™.

If this issue presents during surgery, it may result in surgery being extended to troubleshoot the issue, discontinuation of navigation, or aborting surgery if alternative instruments are not available to proceed. There have been no reports of patient injury.

Actions:

1. Please examine your inventory and if any of the affected products listed above are found, immediately quarantine them for return to Medtronic. If the product has been removed from its original packaging, the part number and lot number can be found printed directly on the device as shown in the pictures below.





2. If you have affected products, contact Medtronic Technical Services at 1-800-595-9709 to receive a return material authorization (RMA) and arrange for their return and no charge replacements. Once an RMA number is obtained, ship the affected product to Medtronic, Inc. Product Services, 1480 Arthur Ave., Louisville, CO 80027 referencing the RMA number.
3. Complete and follow instructions on the attached **Consignee Response Form**. Sign and date the bottom of the form and then return the form to Medtronic at RS.NavFCA@medtronic.com or fax it to Medtronic Technical Services at 651-367-7075.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact Medtronic Technical Services at 1-800-595-9709.

Sincerely,

[redacted]

Tom Reimann
Senior Director of Quality
Medtronic Neurosurgery

CC: Chairman of Medical Board and relevant HoDs

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Medical Device Recall
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Consignee Response Form

We acknowledge the receipt of the Medical Device Safety Alert information and will alert the appropriate personnel using these devices.

Facility Name: _____ RMA#: _____

Facility Address: _____

City, State, and Zip Code: _____

Contact Name and Title (please print): _____

Phone Number: _____

Answer one of the following: (check as applicable)

☐ I have examined our inventory of Medtronic AxiEM™ ENT Suction(s) covered by this notification and do not have any of the affected devices.

☐ I have examined our inventory of Medtronic AxiEM™ ENT Suction(s) and have the following affected devices to be returned:

Part Number	Lot Number	Quantity

Contact Signature_____ Date: _____

Return Instructions

Complete and return this form to rs.navfca@medtronic.com or fax to (+65 6776 6355).

If you have questions or need replacement product, contact Technical Services at 1-800-595-9709.