

Urgent Field Safety Notice

AxiEM™ ENT Suction Unable to Navigate

Recall

June 2017

Medtronic reference: FA775

Dear Customer/Distributor,

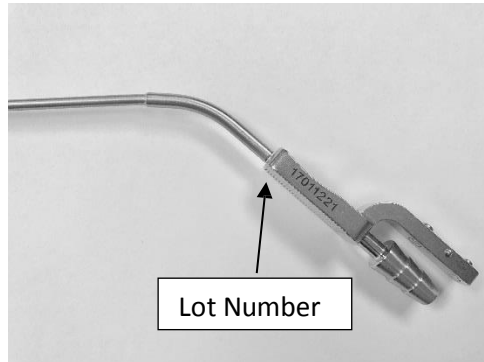
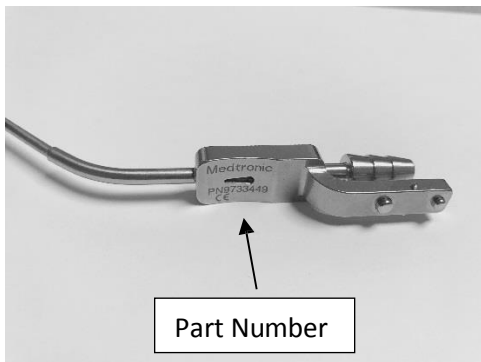
This letter is to notify you of an issue with specific lots of navigated AxiEM™ ENT Suction instruments (see Appendix A for affected model and lot numbers). Please read this letter carefully and follow the outlined instructions.

Description of the Issue: Medtronic has become aware that specific lots of AxiEM™ ENT Suction instruments 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 to be taken:

1. Immediately identify and quarantine all affected product in your inventory. 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. Return all affected product in your inventory to Medtronic. Your Medtronic Representative will assist you in the return and replacement of this product as necessary.



The Competent Authority of your country has been notified of this action.

We are committed to patient safety and appreciate your prompt attention to this matter. Please do not hesitate to contact your Medtronic representative at <XXXX> if you have any questions regarding the content of this letter.

Sincerely,

Country/BU manager

Appendix A: list of affected part and lot numbers

Product Information											
Model Number(s)/ Catalog Number(s):	<p>Part Numbers: 9733449 Straight Suction EM, ENT 9733450 Curved Suction 70, EM 9733451 Short Curved Suction 90, EM 9734308 Suction Small AxiEM™ ENT</p> <p>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™</p>										
Affected Lots:	<p>Affected instruments can be identified by the instrument lot numbers listed below:</p> <table border="1"> <thead> <tr> <th>Part Number</th> <th>Lot Number</th> </tr> </thead> <tbody> <tr> <td>9733449</td> <td>17022809, 17030108, 17022207, 17022106, 17020805, 17020904, 17021798, 17020987, 17011896, 17011221, 17011220, 16122237, 16122236, 16121661, 16121260, 16121259, 16112958</td> </tr> <tr> <td>9733450</td> <td>17030722, 17022421, 17022020, 17020619, 17011918, 17012417, 17010602, 16122724, 16122239, 16122038, 16120563, 16112362</td> </tr> <tr> <td>9733451</td> <td>17030728, 17022027, 17021426, 17013125, 17012724, 17011303, 16122767, 16122066, 16112965, 16112164</td> </tr> <tr> <td>9734308</td> <td>17022451, 17011750, 16120349, 16082989, 16081888, 16071987, 16062713, 16060712</td> </tr> </tbody> </table>	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
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Product Description & Usage:	<p>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.</p> <p>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.</p>										