



Medtronic

URGENT FIELD SAFETY NOTICE

Medtronic Navigation Sterile Devices Recall

Medtronic Reference: FA615

May, 2014

Dear Healthcare Professional, Risk Manager:

At Medtronic, we are committed to continually evaluating and improving the quality and reliability of our processes, products and services. This letter is to notify you of a potential safety issue related to certain Medtronic single-use, disposable devices.

Details on affected devices:

The devices that are impacted by the Safety Notice are sterile, disposable medical devices that can be used in a variety of imaged guided, navigated surgical procedures. The specific device part numbers and lot numbers are attached to this notice as Attachment 1.

Description of the problem:

A review of the Medtronic internal returned goods procedures showed that there was not sufficient control to assure that returned, unused devices were appropriately examined for product and/or package damage. This review identified the sterile part numbers shown in Attachment 1 were processed through the returned goods procedures. A risk analysis was subsequently performed showing that, since there have been no complaints related to sterilization/package damage, there was no change in the likelihood of the scenario leading to harm. Although there have been no reports of issues related to product/package sterile barrier damage, we have elected to issue this safety notice to address this possibility.

Potential Patient Safety

A breach of the sterile packaging is generally detectable by users in the field and is likely to result in either return or scrap of the product. However, use of product with a compromised sterile barrier may result in infection in patients.

Recommendations on action to be taken by the user:

You will be contacted by a Medtronic representative who will make arrangements with you to visit your facility for the collection and return of any of these products, as appropriate. No charge replacement orders will be made at that time. Until such time as you are contacted by Medtronic, examine your inventory and if any of the affected products listed in Attachment 1 are found, please quarantine them for return to Medtronic.

Transmission of this Field Safety Notice:

Please refer this Safety Notice to all those within your facility that use the Medtronic parts numbers affected by this notice.

Medtronic has notified the Competent Authorities of your country of this recall.

Medtronic Navigation has an ongoing commitment and interest in promoting better healthcare and patient outcomes by keeping you apprised of information related to our devices and associated therapies.

Contact details:

If you have any questions regarding this action, please contact your Medtronic Navigation Representative.

Sincerely,

Medtronic Navigation Sterile Devices

Attachment 1 – Affected Devices

FA615

Description	Part Number	Lot Number
BAG 9732315 MOUSE STERILE 15 PK	9732315	5246110712 5316560113
BIOPSY NEEDLE KIT, 9733068, PASSIVE	9733068	66516213 66501413 66518413 66507713
BIT 9733516 2.9mm DRILL STERILE	9733516	130204G
DISP 9730950 STRL SPHERE, 1 PK INSERT	9730950	B135276281
DISP 9730951 STRL SPHERE, 5PK INSERT	9730951	B155300281
DRAPE 9732722 TUBE STERILE O-ARM 20PK	9732722	D120065 D121495 D121515 D120175 D122611 D101555
ENT PRGM 9734636 ADD FUSION NAV AxiEM	9734636	6917614
INST 9730541 HANDLE PADDLE, 1.19MM	9730541	402051764
INST 9731132 KIT CR REF FRAME DRIVER 5PK	9731132	r683
INSTRUMENT TRACKER 9733533XOM ENT 1PK	9733533XOM	130904C 131203A 131003 131024B 130815 130904C 130510 130708B 130716D 130204C 130418B 121128C 121218B 121218A 121128D 130409C 130409D 130123
KIT, 9731427, THORACIC TACTILE PROBES	9731427	6688089 6095124 6095129
MOUSE 9732721 STERILE O-ARM 10PK	9732721	5051140611 5336060213

		5162060112 4734921009
PACK 9731975 TUMOR RESECTION AXIEM CR	9731975	0006922410
PAK 9733497 NAV NIM-SPINE PEDICLE ACC KT	9733497	121130B
PATIENT TRACKER 9733534XOM ENT 1PK	9733534XOM	131212C 130827E 131113B 131203C 131113D 131018A 130212B 131105B 130429E 130815D 130815C 130409G 130510E 130422A 130410A 130510E
PIN, 9733235, 100MM, STERILE, PERC REF	9733235	2012110744 2013010347 2012081458
PIN, 9733236, 150MM, STERILE, PERC REF	9733236	2013041109
SHUNT KIT 9733605 NON-INVASIVE	9733605	120628B 130204E 130314H 121113H 130508B 130612A 120725C 130709 130325 130710 130729A 130826 130923B 131016C 131025F 131127A
SPHERES 8801071 1/TRAY 12PK	8801071	1203122
SPHERES 8801071 1/TRAY 12PK	8801071	1205291 1206251 1306081 1309101
SPHERES 8801075 5/TRAY 12PK	8801075	1207251

		1301091 1301081 1211141 1301151 1302051 1303141 1303121 1303191 1304031 1304081 1303071 1305271 1305221 1305311 1305281 1306181 1306211 1306231 1307041 1307051 1307111 1307131 1307121
TRAJ GUIDE KIT, 9733065, BIOPSY, EXT	9733065	0066225613 0066207713B 0066202413 0066212611 0066209012a
TRAJ GUIDE KIT, 9733066, BIOPSY, INT	9733066	066233912C 066201113B 066212611B 66209012
TUMOR RES. PACK 9733553 AxIEM S.M.	9733553	6402019 6402024
TUMOR RESECTION KIT 9733607 NON-INVASIVE	9733607	120416C 130103A 121030D 130605B 121010F 130612C 130625B 130709G 130923C 131009A 131105E 131212G

TUMOR RESECTION KIT 9733608 SKULL MOUNT	9733608	120725D 130404B
UPGRD PRGM 9734638 ADD AxiEM NAVIGATION	9734638	6148186