Class 2 Recall Medtronic Passive Biopsy Needle Kit

See Related Information[23]

Date Posted	August 03, 2015
Recall Status[1]	Open
Recall Number	Z-2324-2015
Recall Event ID	71756[24]
Product Classification	Neurological Stereotaxic Instrument[25] - **Product Code** HAW[26]
Product	Medtronic Passive Biopsy Needle Kit, Part Number 9733068 - Passive Biopsy Needle Kit. The image guided Passive Biopsy Needle is an accessory instrument with the StealthStation System. The Biopsy Needle is intended to be used for stereotaxy biopsy of brain tissue.
Code Information	LOT No: 066503515, 066504315, 066506515
Recalling Firm/ Manufacturer	Medtronic Navigation, Inc. 826 Coal Creek Cir Louisville, Colorado 80027-9710
For Additional Information Contact	Scott Hutton 720-890-3302
Manufacturer Reason for Recall	The adhesive between the sphere assembly and the biopsy needle shaft may be compromised, causing the sphere assembly to move on the needle shaft. This may result in inaccurate navigation and improper placement of the needles biopsy window in the brain.
Action	Medtronic sent an Urgent Medical Device Recall letter dated July 17, 2015, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to examine their inventory for any of the affected lots and quarantine them if found. They will be asked to complete a confirmation form indicating they have completed this action and are to email or fax the form to Medtronic. Customers will be asked to contact Medtronic to obtain a return material authorization number and arrange for no-charge replacements of impacted products. Customers with questions were instructed to contact Medtronic Technical Services at 800-595-9709. For questions regarding this recall call 720-890-3302.
Quantity in Commerce	1415 total
Distribution	Worldwide Distribution - US (nationwide) and Canada.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]