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Class 2 Device Recall Visualase(TM) Cooled Laser Applicator System (VCLAS) 15MM TIP

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Class 2 Device Recall Visualase (TM) Cooled Laser Applicator System (VCLAS) 15MM TIP

Date Initiated by Firm	June 07, 2017
Date Posted	July 03, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2755-2017
Recall Event ID	77623[23]
510(K)Number	K053087[24]
Product Classification	Powered laser surgical instrument[25] - **Product Code** GEX[26]
Product	Medtronic Visualase(R) Cooled Laser Applicator System (VCLAS) 15MM TIP, REF 9735561, (1) Laser Diffusing Fiber - 600um Core, 15mm Tip, (1) Cooling Catheter with 3M(TM) SteriStrip(TM), (1) Pump Tubing Set, (1) Drainage Bag. Medtronic Navigation, Inc. Louisville, CO 80027
Code Information	Lot Numbers: 211158059, 211560973, 211959879, 12473141, 212707035, 211158151, 211594328, 211977586, 212503634, 212745660, 211158152, 211599898, 211987873, 212504463, 212796559, 211181212, 211628257, 212127654, 212549456, 212912501, 211181547,211908695, 212141557,, 212553428, 211184941, 211916062, 212148368, 212632884,211555011, 211926889, 212434500, 212647830, 211555017, 211950736, 212438405, 212701679.
Recalling Firm/ Manufacturer	Medtronic Navigation, Inc. 826 Coal Creek Cir Louisville CO 80027-9710
For Additional Information Contact	Thomas Reimann 720-890-3241
Manufacturer Reason for Recall	Medtronic has become aware that the VCLAS 15MM TIP cap, also referred to as Tuohy Borst Adapter (TBA), may not be capable of creating a seal around the optical fiber to ensure adequate saline flow through the cooling system. When the TBA is unable to seal around the optical fiber, low retention force to the optical fiber may occur, causing saline to leak out of the TBA.
FDA Determined Cause [2]	Component design/selection
Action	Medtronic sent an Urgent Medical Device Safety Alert dated June 1, 2017, to all affected customers. Actions to be taken: 1. Please examine your inventory and if any of the affected products listed above are found, immediately quarantine them for return to Medtronic. 2. Complete and follow instruction 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 to Medtronic Technical Services at 651-367-7075. 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. For further questions please call (720) 890-3241.