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: Open, Classified
Recall Number: Z-2755-2017
Recall Event ID: 77623
510(K) Number: K053087
Product Classification: Powered laser surgical instrument - Product Code GEX
Lot Numbers: 211158059, 211560097, 211959870, 12473141, 212707035, 211158151, 211594328, 211975586, 212503634, 212745660, 211158152, 211599898, 211987673, 212504463, 212706255, 21181212, 211628257, 212127654, 212549456, 212912501, 211181547, 211908665, 212141557, 212553428, 211184941, 211916062, 212143636, 212632884, 211555011, 211926889, 212434500, 212647830, 211555017, 211950736, 212434805, 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: 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.