### Class 2 Device Recall Medtronic

**Recall Date**: August 15, 2016  
**Recall Status**: Open  
**Recall Number**: Z-2541-2016  
**Recall Event ID**: 74672  
**510(K)Number**: K063091  
**Product Classification**: Mesh, surgical, polymeric - Product Code FTL  
**Product**: TRYX Neuro Absorbable Antibacterial Envelope  
**Product Usage**: Indicated for stabilization of implanted pacemakers (IPG) and/or implantable cardioverter defibrillators (ICD)  
**Code Information**:  
- NMRR6122  
- lot number  
- 16E03727  
- 16E05728  
- model number  
- NMRR6133  
- lot number  
- 16E02726  
- 16E09730  
**Recalling Firm/Manufacturer**: TRYX Inc.  
1 Deerpark Dr Ste G  
Monmouth Junction NJ 08852-1920  
**For Additional Information Contact**: Mr. Carlos Alfonzo  
732-246-8876  
**Manufacturer Reason for Recall**: TRYX products are being recalled since the processes of spaying, welding, drying oven and polymer were not adequately validated.  
**FDA Determined Cause**: Process control  
**Action**: Medtronic sent an Urgent Medical Device Recall letter dated June 2016 to affected customers. The letter identified the affected product problem and actions to be taken. Customers are asked to immediately remove and quarantine all unused product that remains in inventory, return unused product to Medtronic and contacted the local Medtronic representative or Customer Service at 800-848-9300 to assist with the return and credit of unused product. Medtronic will provide credit for all non-expired, unused product. The