FDA

Class 2 Device Recall 3.2mm Proximal Reamer/Cannulated Drill

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See Related Information[22]

Date Initiated by Firm	September 13, 2018
Create Date	November 09, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0442-2019
Recall Event ID	81119[23]
Product Classification	Reamer[24] - **Product Code** HTO[25]
Product	3.2mm Proximal Reamer/Cannulated Drill provided as part of the Fibulock Fibular Nail System Pack. FibuLock Nail Procedure Pack: Contains instrumentation for the implantation of the FibuLock implant. Contents include: Actuation Driver, 6.2mm Reamer, 3.2mm Reamer, 2 mm Drill, Spade Tip Guide Wire, and 1.6mm x 12 K-Wire.
Code Information	Part #ST6100, Lot/Serial #'s: A251217-04, A011217-01, A011217-03, A091017-05, A101017-01, A111017-01, A121017-01, A121017-02, A131017-01, A140917-01, A161017-01, A171017-01, A181017-07, A221117-01, A271117-01, A281117-02, A291117-01, A291117-03, A301117-01, A281117-01.
Recalling Firm/ Manufacturer	Arthrex, Inc. 1370 Creekside Blvd Naples FL 34108-1945
Manufacturer Reason for Recall	There is potential to break during use.
FDA Determined Cause [2]	Software change control
Action	Arthrex sent letters to their consignees with the following instructions. 1. Immediately discontinue use, sale, and distribution of the affected product. 2. Please contact Arthrex Product Surveillance at 866-267-9138 or complaints@arthrex.com as soon as possible to arrange for return of the affected product. Our Product Surveillance Specialists can provide assistance regarding alternative solutions and are available to answer questions regarding credit for affected devices in your possession. 3. If you are an Arthrex agency, you do not need to notify any customers as Arthrex will be notifying customers directly. 4. If you are an Arthrex customer, you do not need to notify any patients of this product recall. 5. If you have any questions about this product recall, please contact Arthrex Product Surveillance at 866-267-9138 or complaints@arthrex.com.
Quantity in Commerce	832
Distribution	Distributed throughout the U.S. to the following states: NC, CA, NJ, CO, NV, UT, LA, KY, OH, AZ, MO, MN, TN, NY, WI, MA, PA, TX, IL, PA, AR, FL, IA, MI, AL, SD, OR, WA, MD, KS, and GA.
Total Product Life Cycle	TPLC Device Report[26]