FDA

Class 2 Device Recall Corail

See Related Information[22]

Date Initiated by Firm	September 21, 2018
Create Date	April 11, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1127-2019
Recall Event ID	82353[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	CORAIL AMT STANDARD OFFSET NECK SEGMENT (STD), Pro. Code L20431 Product Usage: The affected CORAIL Neck Trials are surgical instruments used in CORAIL total and partial hip arthroplasty.
Code Information	lots 1212901 1218481 1226220 1230761 1230762 1700575 1781381 1812714 1817780 1860264 1865892 1874689 1874692 1874695 1885306 1899212 1899213 1910187 1979239 2002010 2024019 2043428 2043428 2078239 2078239 2102693 2102693 2129111 2129111 2153317 2153317 2153318 2153318 2153319 2153319 2153320 2153320 2163174 2163174 2249115 2249116 2252364 2274452 2275487 2284306 2284307 2309644 2309645 2309646 2336389 2336390 2362086 2362087 2380243 2384473 2384474 2386339 2401664 2401665 2416615 2416617 2416618 2465273 2465274 2465275 2465287 2490513 2490514 2513465 2513466 2526363 2526364 2539884 2539885 2565583 2572825 2572826 2602513 2602514 2605764 2605765 2643408 2643409 2648066 2648067 2673433 2673434 2691497 2691501 2739089 2739090 2749282 2749283 2774407 2774408 2774409 2774410 2795717 2795718 2795719 2811227 2811228 2811233 2811234 2836707 2836708 2836709 5001519 5001520 5001521 5001522 5005846 5005847 5008238 5008239 5009208 5016192 5016193 5016194 5016195 5016196 5019838 5019841 1812714A 1812714A
Recalling Firm/ Manufacturer	DePuy Orthopaedics, Inc. 700 Orthopaedic Dr Warsaw IN 46582-3994
For Additional Information Contact	Complaints Team 866-811-9367
Manufacturer Reason for Recall	There is the potential for debris/material to be found behind the O-rings in the neck trials.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	On September 21, 2018, the firm notified customers via email that rework was required for the affected product. Customers were advised that the three affected product codes were produced with an O-Ring until a 2010 design change removed the O-Ring as a rolling change. Customers were provided with work instructions for how to rework the product by removing the O-Ring. Please Take the Following Urgent Actions: 1. Please continue to follow the instructions for use in IFU-W90946 Rev B regarding cleaning of these devices. 2. Immediately review your inventory and rework the affected units. Your DePuy Synthes Sales Consultant can assist with the rework. o Reconciliation Form: Complete the reconciliation form and return to your sales consultant or fax to 574-371-4939 or email to klong16@its.jnj.com within five (5) days of this notice. o Records: Retain a copy of the completed reconciliation form in your files along with this notice. 3. Additional Notifications: o Notify surgeons at your facility by providing them with a copy of this notice. Forward this notice to others in your facility that need to be informed. For product-related questions, please contact your local DePuy Orthopaedics, Inc. Sales Consultant. For clinical questions from surgeons, please contact DePuy Orthopaedics, Inc.s Scientific and Medical Affairs mailbox RA-DPYUS-DePSynSc@ITS.JNJ.com. For questions about the information provided, please contact Kim Earle, Senior Recall Coordinator, at 574-371-4917 (M-F; 8 a.m. 5 p.m. EDT).