**Class 2 Device Recall Corail**

**New Search**

<table>
<thead>
<tr>
<th>Date Initiated by Firm</th>
<th>September 21, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create Date</td>
<td>April 11, 2019</td>
</tr>
<tr>
<td>Recall Status</td>
<td>Open, Classified</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-1127-2019</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>82353</td>
</tr>
<tr>
<td>Product Classification</td>
<td>Orthopedic manual surgical instrument</td>
</tr>
<tr>
<td>Product</td>
<td>CORAIL AMT STANDARD OFFSET NECK SEGMENT (STD). Pro. Code L20431</td>
</tr>
</tbody>
</table>

**Product Usage**

The affected CORAIL Neck Trials are surgical instruments used in CORAIL total and partial hip arthroplasty.

**Code Information**

| Code | 12129011 12128411 1226520 12307812 12307872 17005751 17813811 18127144 1817780 18602640 1865892 1874688 1874 |

**Recalling Firm/Manufacturer**

DePuy Orthopaedics, Inc.
700 Orthopaedic Dr
Warsaw IN 46582-3994

**For Additional Information Contact**

Complaints Team
866-611-9367

**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**

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-W9046 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.
3. Record the completed recombination form in your files along with this notice.

**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. Records: Retain a copy of the completed reconciliation form in your files along with this notice.

**Additional Questions**

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).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=171429

16/04/2019