U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Zimmer M/L Taper with Kinectiv Technology Prosthesis Femoral Stems and Necks Higher than Expected Levels of Manufacturing Residues

Recall Class: Class I

Date Recall Initiated: June 8, 2015

Device: **Affected lot numbers and item descriptions are listed below**.

Manufacturing and distribution dates: March 31, 2015 through April 20, 2015

Use: The Zimmer M/L Taper with *Kinectiv* Technology Femoral Stems and Necks are Tivanium® alloy implants used for hip replacements that allow the surgeon to fit the implant specifically to the patient. During hip replacement surgery, the damaged portions of the hip joint are removed and replaced with an integrated system of products, which includes the femoral stem and neck.

Recalling Firm:
Zimmer, Inc.
1800 West Center Street
Warsaw, IN 46580

Reason for Recall: The company found a process monitoring failure that led to higher than expected amounts of manufacturing residues left on the devices. These residues can cause serious adverse health issues including allergic reactions, pain, infections, or death. Use of these products may require the need for a revision surgery to replace the affected implant.

The company has not received any complaints related to this issue for any of the lots in distribution.

Public Contact: Questions or concerns should contact the customer call center at 1-877-946-2761 between 8:00 am and 5:00pm EST.

FDA District: Detroit District Office

More Information about this Recall:
On May 18, 2015, Zimmer issued recall notification letters and instructions for distributors and hospital staff.

Instructions for distributors:

1. Review the notification and ensure affected personnel are aware of the contents.

2. Locate all affected product identified in the recall letter and quarantine them immediately.
3. Carry out a physical count of all affected product in your territory and complete the Inventory Return Certification Form sent by the company. Email a completed copy of the form to **corporatequality.postmarket@zimmer.com (mailto:corporatequality.postmarket@zimmer.com)**.
4. Return the recalled product along with the completed Inventory Return Certification Form.
5. Please notify Zimmer of any hospitals that you have further distributed the affected product to. In addition, identify the surgeons that have implanted this product. Supply the information for any hospitals that you have identified, as well as the affected surgeons using the provided spreadsheet template. The template will be emailed to you for completion and return to corporatequality.postmarket@zimmer.com.

Instructions for hospital staff, including risk managers and surgeons:

1. Review the notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer sales representative with the quarantine of any affected product.
3. Your Zimmer sales representative will remove the recalled product from your facility.

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.

Products Being Recalled:

Part Number	Lot Number	Item Description
00771301300	62885058	MOD ML TAPER FEM ST 13.5
00771301100	62885040	MOD ML TAPER FEM ST 11
65771301100	62939041	MOD ML TAPER FEM ST 11 HATCP
00771301000	62938997	MOD ML TAPER FEM ST 10
00771300500	63006851	MOD ML TAPER FEM ST 5
00771300900	62927082	MOD ML TAPER FEM ST 9.0
00771300500	63006852	MOD ML TAPER FEM ST 5
00771301100	62905574	MOD ML TAPER FEM ST 11
00771300600	63024189	MOD ML TAPER FEM ST 6
00771301100	62998426	MOD ML TAPER FEM ST 11
00771301100	63024240	MOD ML TAPER FEM ST 11

Part Number	Lot Number	Item Description
00771300900	63024220	MOD ML TAPER FEM ST 9.0
00771300700	63024204	MOD ML TAPER FEM ST 7.5
00771301000	63024229	MOD ML TAPER FEM ST 10
00771301000	63024230	MOD ML TAPER FEM ST 10
00771301100	63024239	MOD ML TAPER FEM ST 11
00771300700	63024205	MOD ML TAPER FEM ST 7.5
00771300700	63024206	MOD ML TAPER FEM ST 7.5
00771301100	63024241	MOD ML TAPER FEM ST 11
00771300900	63024219	MOD ML TAPER FEM ST 9.0
00771301200	63024262	MOD ML TAPER FEM ST 12.5
00771301100	63024238	MOD ML TAPER FEM ST 11
00771301300	63024245	MOD ML TAPER FEM ST 13.5
00771301100	63024237	MOD ML TAPER FEM ST 11
00771300700	63024201	MOD ML TAPER FEM ST 7.5
00771301000	63024228	MOD ML TAPER FEM ST 10
00771300900	63024218	MOD ML TAPER FEM ST 9.0
00771300600	63024187	MOD ML TAPER FEM ST 6
00771300900	63024217	MOD ML TAPER FEM ST 9.0
00771301200	63024263	MOD ML TAPER FEM ST 12.5
00771300900	63024221	MOD ML TAPER FEM ST 9.0
00771301200	63024261	MOD ML TAPER FEM ST 12.5
00771300700	63024203	MOD ML TAPER FEM ST 7.5
00771301200	62927123	MOD ML TAPER FEM ST 12.5
00771300900	62927083	MOD ML TAPER FEM ST 9.0
00771300900	63024216	MOD ML TAPER FEM ST 9.0
00771300600	63024188	MOD ML TAPER FEM ST 6
00771300700	63024202	MOD ML TAPER FEM ST 7.5
00771300600	63024184	MOD ML TAPER FEM ST 6
00771301100	63024234	MOD ML TAPER FEM ST 11
00771300900	63024210	MOD ML TAPER FEM ST 9.0
00771300700	63024195	MOD ML TAPER FEM ST 7.5
00771300700	63024196	MOD ML TAPER FEM ST 7.5

Part Number	Lot Number	Item Description
00784801400	62924878	KINECTIV MODULAR NECK X
00771300900	63024211	MOD ML TAPER FEM ST 9.0
00771301000	63024226	MOD ML TAPER FEM ST 10
00771300700	63024197	MOD ML TAPER FEM ST 7.5
00771300600	63024186	MOD ML TAPER FEM ST 6
00771300700	63024198	MOD ML TAPER FEM ST 7.5
00771300700	63024199	MOD ML TAPER FEM ST 7.5
00771301200	63024258	MOD ML TAPER FEM ST 12.5
00771300900	63024214	MOD ML TAPER FEM ST 9.0
00771301200	63024256	MOD ML TAPER FEM ST 12.5
00771301000	63024227	MOD ML TAPER FEM ST 10
00771300900	63024213	MOD ML TAPER FEM ST 9.0
00771301200	63024259	MOD ML TAPER FEM ST 12.5
00771301100	63024236	MOD ML TAPER FEM ST 11
00771300900	63024215	MOD ML TAPER FEM ST 9.0
00771301100	63024235	MOD ML TAPER FEM ST 11
00771301200	63024257	MOD ML TAPER FEM ST 12.5
00771300500	63024180	MOD ML TAPER FEM ST 5
00771300600	63024183	MOD ML TAPER FEM ST 6
00771301300	62939008	MOD ML TAPER FEM ST 13.5
00771300700	63024193	MOD ML TAPER FEM ST 7.5

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)

2013 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384618.htm)