Class 2 Recall Persona Stemmed 5 Degree Cemented Tibia

See Related Information[22]

Date Posted	November 08, 2014
Recall Status[1]	Open
Recall Number	Z-0198-2015
Recall Event ID	69397[23]
Product Classification	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer[24] - **Product Code** JWH[25]
Product	Persona Stemmed 5 Degree Cemented Tibia Product Usage: This device is indicated for patients with severe knee pain and disability due to: Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis. Collagen disorders, and/or avascular necrosis of the femoral condyle. Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy. Moderate valgus, varus, or flexion deformities. The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. This device is intended for cemented use only.
Code Information	Part Number 42-5320-079-02 Lot Number 62613813 Part Number 42-5320-071-02 Lot Number 62625781 Part Number 42-5320-075-01 Lot Number 62619031 Part Number 42-5320-075-01 Lot Number 62619040 Part Number 42-5320-079-01 Lot Number 62626696 Part Number 42-5320-071-01 Lot Number 62625790
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	Cleaning process validation failure.
Action	Zimmer sent an Urgent Medical Device Recall letter dated October 9, 2014 to affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to: 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. 4. If after reviewing this notification you have further questions or concerns please call the customer call center at 1-800-348-2759. Hours of operation are Monday through Friday, 8 a.m. through 8 p.m. EST.
Quantity in Commerce	138 units
Distribution	US Nationwide Distribution and countries of Austria ,Belgium, Switzerland, Germany, France, United Kingdom, Italy and South Africa.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]

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