Class 2 Device Recall Phoenix Femoral Nail System

Date Initiated by Firm: August 09, 2016
Create Date: October 14, 2016
Recall Status: Open, Classified
Recall Number: Z-0084-2017
Recall Event ID: 7523423
Product Classification: Orthopedic manual surgical instrument - Product Code LX2
Product: Phoenix Recon Targeting Arm Guide. Surgical Instrument for the sleeve and Orthopedic Manual Surgical Instruments for the Arm

Product Usage:
The Phoenix Femoral Nail System is to be implanted into the femur for alignment, stabilization and fixation of fractures caused by trauma or disease, and the fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity, and for arthrodesis. These instruments are used in support of the surgery.

Code Information: Item number: 14-442018, Lot number: , 290610, 290620, 388780
Recalling Firm/Manufacturer: Zimmer Biomet, Inc.
56 E Bell Dr
Warsaw IN 46582-6989
For Additional Information Contact: Customer Service
800-348-2759

Manufacturer Reason for Recall: Old revisions and new revisions of the soft tissue sleeve and recon targeting arm are not interchangeable, as the new revision tissue sleeve will not fit into the old revision targeting arm. The old revision tissue sleeve has too much clearance with new revision targeting arm. Risks of encountering the affected product include: the correct instrument may not be readily available for the procedure causing the surgeon to complete the procedure by hand, or a delay in surgery greater than 30 minutes may occur while another Recon Targeting Arm or Recon Soft tissue Sleeve is located or while the surgeon completes the procedure by hand.

FDA Determined Cause: Finished device change control
Action: On 8/9/2016, URGENT MEDICAL DEVICE RECALL REMOVAL notifications were sent to the affected consignees via courier. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification. For questions or concerns call the customer call center at 1-800-348-9500 ext 1251 between 8:00 am and 5:00pm EST, Monday through Friday. Alternatively, your questions may be sent by email to CPWARFieldAction@zimmerbiomet.com.

Quantity in Commerce: 31
Class 2 Device Recall Phoenix Femoral Nail System

Date Initiated by Firm: August 09, 2016
Create Date: October 14, 2016
Recall Status: Open, Classified
Recall Number: Z-0083-2017
Recall Event ID: 7523423
Product Classification: Guide, surgical instrument - Product Code FZX

Product:
Phoenix Recon Soft Tissue Sleeve
Guide, Surgical, Instrument for the sleeve and Orthopedic Manual Surgical Instruments for the Arm

Product Usage:
The Phoenix Femoral Nail System is to be implanted into the femur for alignment, stabilization, and fixation of fractures caused by trauma or disease, and the fixation of femurs that have been surgically prepared (ostectomy) for correction of deformity, and for arthrodesis. These instruments are used in support of the surgery.

Code Information:
Item number: 14-442008, Lot number: 2065181

Recalling Firm/Manufacturer:
Zimmer Biomet, Inc.
56 E Bell Dr
Warwick IN 46582-6989

For Additional Information Contact:
Customer Service
800-348-2759

Manufacturer Reason for Recall:
Old revisions and new revisions of the soft tissue sleeve and recon targeting arm are not interchangeable, as the new revision tissue sleeve will not fit into the old revision targeting arm. The old revision tissue sleeve has too much clearance with new revision targeting arm. Risks of encountering the affected product include: the correct instrument may not be readily available for the procedure causing the surgeon to complete the procedure by hand; or a delay in surgery greater than 30 minutes may occur while another Recon Targeting Arm or Recon Soft tissue Sleeve is located or while the surgeon completes the procedure by hand.

FDA Determined Cause:
Finished device change control

Action:
On 8/9/2016, URGENT MEDICAL DEVICE RECALL REMOVAL notifications were sent to the affected consignees via courier. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification. For questions or concerns call the customer call center at 1-800-348-9500 ext 1251 between 8:00 am and 5:00pm EST. Monday through Friday. Alternatively, your questions may be sent by email to CPWARFieldAction@zimmerbiomet.com.

Quantity in Commerce: 31

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