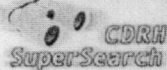




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Class 2 Device Recall Phoenix Femoral Nail System

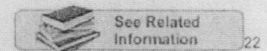


[510\(k\)](#)⁶ | [DeNovo](#)⁷ | [Registration & Listing](#)⁹ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹ | [PMA](#)¹² | [HDE](#)¹³ | [Classification](#)¹⁴ | [Standards](#)¹⁵ | [CFR Title 21](#)¹⁶ | [Radiation-Emitting Products](#)¹⁷ | [X-Ray Assembler](#)¹⁸ | [Medsun Reports](#)¹⁹ | [CLIA](#)²⁰ | [TPLC](#)²¹

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Class 2 Device Recall Phoenix Femoral Nail System

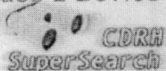


Date Initiated by Firm	August 09, 2016
Create Date	October 14, 2016
Recall Status ¹	Open ³ , Classified
Recall Number	Z-0084-2017
Recall Event ID	<u>75234</u> ²³
Product Classification	Orthopedic manual surgical instrument ²⁴ - Product Code LXH ²⁵
Product	Phoenix Recon Targeting Arm Guide, Surgical, 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, 386780
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 ²	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
Distribution	US Nationwide Distribution in the states of: MI, UT, SD, OH, WA, KS, MO, NJ, GA, and TX.



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Class 2 Device Recall Phoenix Femoral Nail System

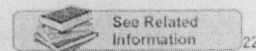


[510\(k\)](#)⁶ | [DeNovo](#)⁹ | [Registration & Listing](#)⁹ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹ | [PMA](#)¹² | [HDE](#)¹³ | [Classification](#)¹⁴ | [Standards](#)¹⁵ | [CFR Title 21](#)¹⁶ | [Radiation-Emitting Products](#)¹⁷ | [X-Ray Assembler](#)¹⁸ | [Medsun Reports](#)¹⁹ | [CLIA](#)²⁰ | [TPLC](#)²¹

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Class 2 Device Recall Phoenix Femoral Nail System



Date Initiated by Firm	August 09, 2016
Create Date	October 14, 2016
Recall Status¹	Open ³ , Classified
Recall Number	Z-0083-2017
Recall Event ID	75234 ²³
Product Classification	Guide, surgical, instrument ²⁴ - Product Code FZX ²⁵
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 (osteotomy) for correction of deformity, and for arthrodesis. These instruments are used in support of the surgery.
Code Information	Item number: 14-442008, Lot number: 2095181
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 Cause²	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
Distribution	US Nationwide Distribution in the states of: MI, UT, SD, OH, WA, KS, MO, NJ, GA, and TX.