Comprehensive Reverse Shoulder by Zimmer Biomet: Class I Recall - High Fracture Rate

[Posted 02/16/2017]

AUDIENCE: Risk Manager, Orthopedics

ISSUE: Zimmer Biomet is recalling the Comprehensive Reverse Shoulder because these devices are fracturing at a higher rate than is stated in the labeling. Fractures may result in revision surgeries which could cause serious adverse health consequences such as permanent loss of shoulder function, infection, or rarely, death.

BACKGROUND: The Comprehensive Reverse Shoulder is a shoulder replacement device that is surgically implanted to help restore arm movement. This device is beneficial for patients with rotator cuff tears who have developed a severe type of shoulder arthritis known as arthropathy and previously failed shoulder joint replacement.

RECOMMENDATION: On December 20, 2016 Zimmer Biomet sent an Urgent Medical Device Recall Notice and a Certificate of Acknowledgement form to all affected customers. The notice asked customers to:

- Review the safety notice and ensure appropriate staff is aware of the notice.
- Identify and quarantine any affected devices in stock.
- The Zimmer Biomet sales representative will remove the affected device from the facility.
- Complete and return the Certificate of Acknowledgement form within 3 days via email to corporateequality.postmarket@zimmerbiomet.com.
- Retain a copy of the Certificate of Acknowledgement form for records in the event of a compliance audit.

The notice also stated that there are no specific patient monitoring instructions related to this recall that are recommended beyond existing surgical follow up protocol.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report (http://www.fda.gov/MedWatch/report)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[02/15/2017 - **Recall Notice (/MedicalDevices/Safety/ListofRecalls/ucm541862.htm)** - FDA]