From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, May 30, 2017 2:42 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Product Recall - Zimmer Biomet

SpF PLUS-Mini and SpF XL IIB Implantable Spinal Fusion Stimulators by Zimmer Biomet: Class I Recall - Potential for Harmful Chemicals

AUDIENCE: Risk Manager, Orthopedics, Patient, Surgery

ISSUE: Zimmer Biomet is recalling the SpF PLUS-Mini and SpF XL IIb Implantable Spinal Fusion Stimulators due to higher than allowed levels of potential harmful chemicals, which may be toxic to tissues and organs (cytotoxicity) and that were found during the company's routine monitoring procedure. A cytotoxicity test is a part of the biological evaluation of medical devices to ensure compatibility with the device and the human body. A positive cytotoxicity test (failed result) can indicate that a device contains potential harmful chemicals at amounts or levels that could be dangerous to the patient.

The use of affected product may cause serious adverse health consequences, including but not limited to chronic infections, long-term hospitalization due to additional surgical procedures, paralysis, and death.

- See the Recall Notice for a list of affected serial numbers.
- Distribution Dates: March 28, 2017 to April 6, 2017
- Manufacturing Dates: October 11, 2016 to January 18, 2017

BACKGROUND: The Zimmer Biomet SpF PLUS-Mini and SpF XL IIb Implantable Spinal Fusion Stimulators are used during spinal fusion surgery to increase the possibility of permanently connecting two or more bones of the spine (backbone) together. The device is implanted into the patient's back and provides constant electrical stimulation to the surgical site.

RECOMMENDATION: On April 20, 2017 Zimmer Biomet sent an Urgent Medical Device Removal notification to all affected customers. The notice instructed customers to:

- Review notification and distribute the information to all appropriate personnel.
- Quarantine all affected products.
- The Zimmer Biomet sales representative will remove the affected product from the facility.
    - If the product was purchased directly from the company, follow the instructions on the Certificate of Acknowledgment form provided by Zimmer Biomet to complete the return.
- Return the form to corporatequality.postmarket@zimmerbiomet.com or via fax to 574-372-4265.
- Retain a copy of the Acknowledgement Form with the field action records.
- Surgeons are reminded that normal clinical monitoring is recommended for 3-6 months post operatively for any patient with the affected devices implanted.

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
- Download form 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

Read the MedWatch safety alert, including a link to the FDA recall notice, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm561044.htm

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.