From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Small Battery Drive and Small Battery Drive II Adaptor and Light Adaptor by DePuy Synthes: Class I Recall - Possible Explosion Risk
Date: Thursday, September 29, 2016 10:18:15 AM

Small Battery Drive and Small Battery Drive II Adaptor and Light Adaptor by DePuy Synthes: Class I Recall - Possible Explosion Risk

AUDIENCE: Orthopedics, Risk Manager, Pharmacy

ISSUE: DePuy Synthes is recalling the Adaptor and Light Adaptor for their SBD and SBD II due to a potential for the adaptors to produce extreme internal pressure, which may cause the device to explode. The use of affected products may cause serious adverse health consequences, including death. Recalled products:

- Adaptor and Light Adaptor for Small Battery Drive and Small Battery Drive II
- Serial Numbers: 05.001.024 and 05.001.108
- Manufacturing Dates: October 6, 2005 to April 5, 2016
- Distribution Dates: January 2006 to June 2016
- Devices Recalled in the U.S.: 451 units distributed nationwide

BACKGROUND: The Adaptor and Light Adaptor are power sources for the DePuy Synthes Small Battery Drive (SBD) and the Small Battery Drive II (SBD II) surgical power tool systems. The SBD and SBD II power the Synthes Power Tool system, which includes attachments for drilling or cutting bone in orthopedic surgery. The adaptors and surgical tool systems are only used in hospitals and other health care facilities.

RECOMMENDATION: On January 15, 2016, DePuy Synthes sent an "Urgent Notice-Medical Device Recall" letter to all affected customers. The letter asked customers to:

- Identify and quarantine the device
- Contact DePuy Synthes Customer Support at 1-800-327-6887, to obtain a Return Materials Authorization Number
- Complete and return the Verification Section of the device recall letter to The Anspach Effort Inc. at 4500 Riverside Drive, Palm Beach Gardens, FL 33410
- Send a copy of the Verification Section to DePuy Synthes, Customer Quality Department through: Fax: 561-627-2682 or Scan/email: DPYUS-PowerToolsFieldActions.its.jnj.com
- Keep the recall notice visibly posted in your facility for awareness

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 Class I Recall notice, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm523001.htm

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