

DePuy Synthes Recalls Power Tool System Battery Adaptors Due to Possible Explosion Risk

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- 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

Device Use

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.

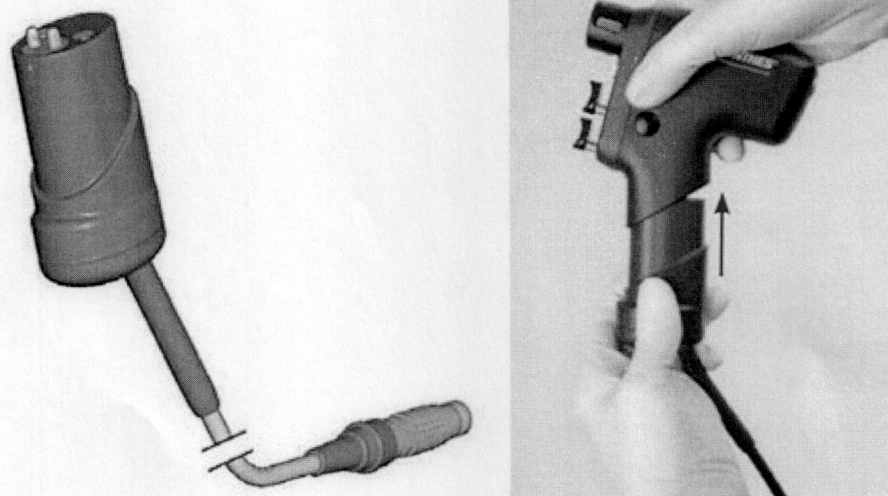


Figure: Adaptor (Left) and Adaptor plugged into SBDII (Right)

Reason for Recall

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.

Who May be Affected

- Surgeons and other health care providers using the Adaptor and Light Adaptor SBD and SBD II with their DePuy Synthes Power Tool systems.
- Patients undergoing surgeries involving these tool systems and adaptors.
- Bystanders or other staff who are in an operating room where these tool systems and adaptors are used.

What to Do

On June 24, 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

Contact Information

Health care professionals and consumers with questions are instructed to contact the Customer Quality at-1-800-327-6687 #3, with any questions related to this recall.

Date Recall Initiated:

June 24, 2016

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)

[2015 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm429489.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

[2014 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm384921.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)