Zimmer Biomet, Inc. Recalls Spinal Fusion and Long Bone Stimulators Due to Lack of Adequate Validation and Controls to Ensure Product Cleanliness

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

- Name: Osteogen Implantable Bone Growth Stimulator, SpF PLUS-Mini Implantable Fusion Stimulator, and the SpF-XL Implantable Spinal Fusion Stimulator
- Serial numbers: All serial numbers expiring prior to March 31, 2019 are affected.
- Manufacturing Dates: February 14, 2015 to April 11, 2017
- Distribution Dates: April 29, 2015, to March 31, 2018
- Devices recalled in the U.S: 1,360 units

Device Use

The Zimmer implantable bone growth and spinal fusion stimulators are used to help heal bone following spinal fusion surgery or to help heal broken long bones (those of legs or arms) in people who have a health condition or other factors that prevent their body from healing bone on its own. These stimulators are placed in a patient during surgery. Once in place they send a low level electrical signal to encourage the body's natural bone healing process.

Reason for Recall

Zimmer Biomet, Inc. is recalling the EBI Osteogen Implantable Bone Growth Stimulator, SpF® PLUS-Mini (60 µA/W) Implantable Spinal Fusion Stimulator, and the SpF®-XL IIb 2/DM Implantable Spinal Fusion Stimulator due to a lack of adequate validation and controls to ensure that final products were clean and free from bacteria and chemical residue. The lack of adequate validation and controls may or may not cause serious side effects for the patient including infection, tissue death, additional surgery for wound treatment and/or device removal, impaired wound and bone healing, the need for long-term antibiotic therapy, the potential for secondary gastroenteritis, swelling and infection around the spinal cord (**epidural abscess (https://medlineplus.gov/ency/article/001416.htm)**), paralysis, damage to other organs or death.

Who May be Affected

- Health care providers who use the EBI Osteogen Implantable Bone Growth Stimulator, SpF® PLUS-Mini (60 µA/W) Implantable Spinal Fusion Stimulator or SpF®-XL IIb 2/DM Implantable Spinal Fusion Stimulator.

- Patients who have been implanted with any of these stimulators after spinal fusion surgery or to help heal long bones.

What to Do

On February 19, 2018, Zimmer Biomet, Inc. issued an Urgent Medical Device Recall Notification Letter to all affected customers.

The letter instructed:

- Consignees: to return an acknowledgement of responsibilities and inform affected team members of the recall.
- Hospital risk managers: to set aside any product for sales representative or distributor pick-up.
- Surgeons: to continue monitoring patients who have one of the affected devices implanted.
- Distributors: to quarantine any devices in inventory and send them back to the firm. Distributors were also directed to identify all consignees with product so that sales representatives could work with consignees to reconcile all remaining product.

Contact Information

Customers with questions may contact Zimmer Biomet, Inc. at 574-371-3071, Monday through Friday, from 8:00 AM Eastern Standard Time to 5:00 PM Eastern Standard Time, or email at **CorporateQuality.PostMarket@zimmerbiomet.com (mailto:CorporateQuality.PostMarket@zimmerbiomet.com)**. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency.

Date Recall Initiated

February 19, 2018

How Do I Report a Problem?

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

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

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