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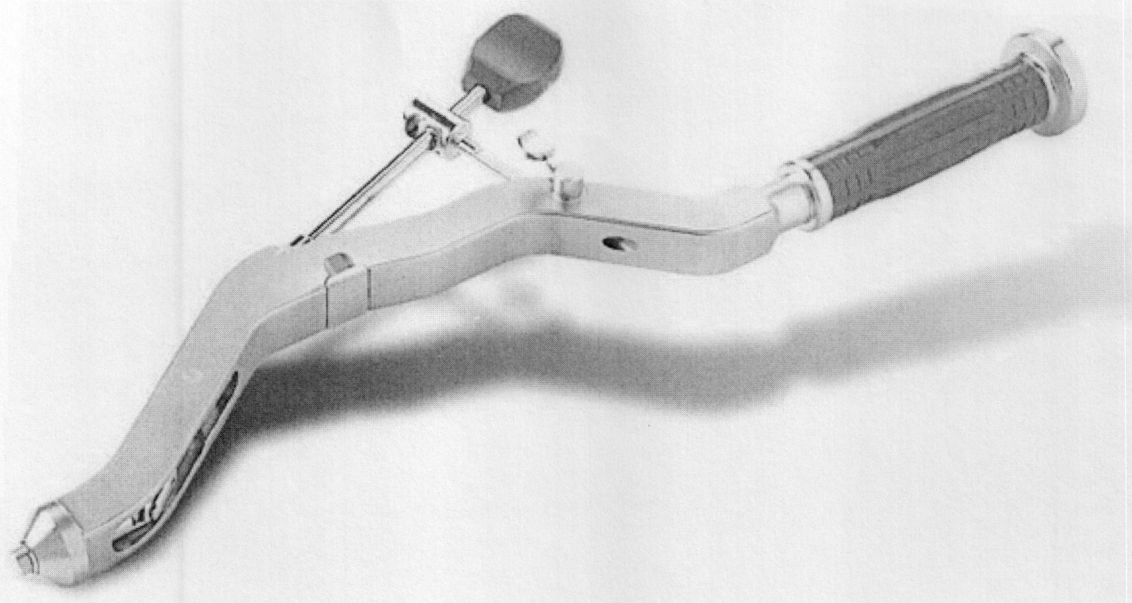
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Greatbatch Medical Recalls Standard Offset Cup Impactor Used for Hip Joint Replacement due to Inadequate Sterilization

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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:

- Standard Offset Cup Impactor with POM-C Handle
- Model Numbers: T6318; T7821; T8042; T8043; T8044; T8088; T8143; T8177; T8184; T8333; T8468; T8487; T9196; T9316; T9348; T9360; T9747; T9894; T9954; T9955; T10243; T10281; T10287; T10600; T10491; T10753; T10861; T11209; T11340; T11506; T12230; T12699; T12861; T13344; T13480; T13642; T13722; T14384; T15311; T15752; T15949; T16427; T16611; T16661; T16934; T17203; T17238; T17321; T17650; T17703
- Distribution Dates: July 30, 2004 to December 22, 2015
- Manufacturing Dates: January 2004 to December 2013
- Devices Recalled in the U.S.: 2906

Device Use

The Standard Offset Cup Impactors are reusable handheld devices used during hip joint replacement surgeries to implant cups in the hip socket (acetabulum). The device is provided as non-sterile and must be sterilized prior to use in surgery.

During hip replacement surgery, the ball (femoral head) is removed and replaced with a prosthetic ball, and the acetabulum is removed and replaced with a prosthetic cup.

Reason for Recall

Greatbatch Medical is recalling the Standard Offset Cup Impactor with a POM-C handle that failed sterility testing when sterilized in a dedicated instrument case. Non-sterile surgical devices can lead to infections, and other serious adverse health consequences, including death.

Who May be Affected

- Health care providers using this device during hip replacement surgeries

- All patient groups undergoing hip replacement procedures involving the Standard Offset Cup Impactor

What to Do

Greatbatch has developed new sterilization recommendations that meet acceptable sterility assurance levels. The device must be individually wrapped during sterilization processing.

On July 29, 2016, Greatbatch Medical informed its customers via letter to follow the updated sterilization instructions.


Contact Information

Customers with questions may contact Greatbatch via telephone at 1-619-498-9487 between the hours of 8:00 am (CT) and 5:00 pm (CT). Customers may also contact the company via email at FieldActionCenter@greatbatch.com (<mailto:FieldActionCenter@greatbatch.com>).

Date Recall Initiated:

July 29, 2016

Additional Resources

Greatbatch press release - Greatbatch, Inc. Issues Voluntary Field Corrective Action for Standard Offset Cup Impactor (<http://investor.greatbatch.com/phoenix.zhtml?c=122233&p=irol-newsArticle&ID=2222863>) 
(<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)

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>) either online, by regular mail or by FAX to 1-800-FDA-0178.

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