



**DATE:** March 12, 2014  
**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer  
**FROM:** *Kristen Harper*  
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program  
**SUBJECT:** Greatbatch, Inc. - RECALL [Medical Device]

**AFFECTED  
PRODUCT:** Standard Offset Cup Impactors

**SUMMARY:** Unclassified Recall; This voluntary field corrective action has been initiated because the sterilization recommendation in the Instructions for Use for the product did not meet requirements for sterility assurance, which has the potential to result in surgical infection.

For the Catalog Number, Part Number, and Part Name refer to the attached recall.

Greatbatch Inc. distributed Standard Offset Cup Impactors to customers in the United States.

**SUGGESTED  
ACTION:** For consumer inquiry only. Customers with questions may contact the company via telephone at 763-951-8235. Customers may also contact the company via e-mail at [FieldActionCenter@greatbatch.com](mailto:FieldActionCenter@greatbatch.com)

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

**Greatbatch, Inc. Issues Voluntary Field Corrective Action for  
Standard Offset Cup Impactor**

**Contact**

Consumer:  
763-951-8235

**Media:**

Christopher Knospe  
716-759-5727  
[cknospe@greatbatch.com](mailto:cknospe@greatbatch.com)

**FOR IMMEDIATE RELEASE** - January 29, 2014 - Frisco, TX - Greatbatch, Inc. initiated a voluntary field corrective action for all Standard Offset Cup Impactors after an internal review determined that the sterilization recommendation in the Instructions for Use for the product did not meet requirements for sterility assurance, which has the potential to result in surgical infection. No incidents have been reported during clinical use of the product, nor have there been any reported adverse events.

Greatbatch has developed new sterilization recommendations that meet acceptable sterility assurance levels (AAMI ST79 standard) and provided them to affected customers. Customers who have this product should immediately begin utilizing the new sterilization instructions.

The company has informed the FDA of this action, which impacts all Standard Offset Cup Impactors manufactured and distributed from 2004 to 2013 as follows:

**Name of Product: Standard Offset Cup Impactor**  
**Quantity: 4889**

<b>Catalog Number</b>	<b>Part Number</b>	<b>Part Name</b>
MIMP3100320	T12121	Impactor / M8 x 1
MIMP3100ADM01	T16604	Impactor notched connection
MIMP3100CH14	T11340	Impactor / M8 x 1
MIMP3100CHA04	T10281	Impactor / M10 x 1
MIMP3100CHA04	T10287	Impactor / M10
MIMP3100CHA04	T10491	Impactor / M8
MIMP3100CHA04	T10507	Impactor / M8 x 1
MIMP3100CHA04	T10600	Impactor / 3/8 - 32 UNEF
MIMP3100CHA04	T10604	Impactor / M6
MIMP3100CHA04	T10861	Impactor / M8
MIMP3100CHA04	T12230	Impactor / 7/16 - 20 UNF
MIMP3100CHA04	T12288	Impactor / M10 x 1
MIMP3100CHA04	T12305	Impactor JMM Q3
MIMP3100CHA04	T12391	Impactor / M10
MIMP3100CHA04	T12699	Impactor / M10
MIMP3100CHA04	T13344	Impactor / 7/16 - 20 UNF
MIMP3100CHA04	T13722	Impactor / 3/8 - 24 UNF
MIMP3100CHA04	T13999	Impactor / M10
MIMP3100CHA04	T14155	Impactor / M10
MIMP3100CHA04	T15752	Impactor / 3/8 - 24 UNF
MIMP3100CHA04	T15949	Impactor / 3/8 - 24 UNF
MIMP3100CHA04	T16117	Impactor / 3/8 - 24 UNF

<b>Catalog Number</b>	<b>Part Number</b>	<b>Part Name</b>
MIMP3100CHA04	T16427	Impacteur
MIMP3100CHA04	T16611	Impactor / 5/16 - 24 UNF
MIMP3100CHA04	T16661	Impactor / M10 x 1
MIMP3100CHA04	T16829	Impactor / M8
MIMP3100CHA04	T17062	Impactor / 3/8 - 16 UNC
MIMP3100CHA04	T17203	Impactor / 3/8 - 24 UNF
MIMP3100CHA04	T17238	Impactor / 7/16 - 20 UNF
MIMP3100CHA04	T17321	Impactor / M10
MIMP3100CHA04	T6318	Impactor / 3/8 - 24 UNF
MIMP3100CHA04	T7821	Impactor / M6
MIMP3100CHA04	T8042	Impactor / 3/8 - 16 UNC
MIMP3100CHA04	T8043	Impactor / 5/16 - 24 UNF
MIMP3100CHA04	T8044	Impactor Biomet ES
MIMP3100CHA04	T8087	Impactor / M7 x 1
MIMP3100CHA04	T8088	Impactor / 3/8 - 32 UNEF
MIMP3100CHA04	T8093	Impactor / M8
MIMP3100CHA04	T8095	Impactor / M6
MIMP3100CHA04	T8143	Impactor / 1/4 - 28 UNF
MIMP3100CHA04	T8177	Impactor / 1/4 - 28 UNF
MIMP3100CHA04	T8184	Impactor / 3/8 - 16 UNC
MIMP3100CHA04	T8277	Impactor / M6
MIMP3100CHA04	T8310	Impactor / 3/8 - 24 UNF
MIMP3100CHA04	T8333	Impactor / M8 x 1
MIMP3100CHA04	T8468	Par la génération des textes
MIMP3100CHA04	T9109	Impactor / M10
MIMP3100CHA04	T9196	Par la génération des textes
MIMP3100CHA04	T9205	Impactor / M10 x 1
MIMP3100CHA04	T9316	Impactor / M6
MIMP3100CHA04	T9348	Impactor / M10 x 1
MIMP3100CHA04	T9360	Impactor / M8
MIMP3100CHA04	T9556	Impactor / M8
MIMP3100CHA04	T9557	Impactor / 3/8 - 24 UNF
MIMP3100CHA04	T9747	Impactor / M14 x 1.5
MIMP3100CHA04	T9894	Impactor / M10
MIMP3100CHA04	T9954	Impactor / M8
MIMP3100CHA04	T9955	Impactor / 1/4 - 28 UNF
MIMP3100CHA04	T9999	Impactor / M10 x 0.75
MIMP3100CHA041	T12861	Impactor / 5/16 - 24 UNF
MIMP3100CHA042	T13480	Impactor / M10 x 1
MIMP3100CHA05	T8487	Impactor / M8
MIMP3100CHA08	T10243	Impactor / M14 x 1.5
MIMP3100CHA09	T10484	Impactor / 3/8 - 24 UNF
MIMP3100CHA10	T10753	Impactor / M14 x 1.5
MIMP3100CHA10	T13642	Impactor / M14 x 1.5
MIMP3100CHA12	T11209	Impactor / M8



Catalog Number	Part Number	Part Name
MIMP3100CHA14	T14384	Impacteur
MIMP3100CHA17	T15311	Impacteur
MIMP3100CHA60	T15822	Impactor notched connection
MIMP3100CHA62	T16934	Impactor / 3/8 - 24 UNF
MIMP3100CHAN043	T12767	Impactor JMM Q3

Greatbatch Inc. distributed Standard Offset Cup Impactors to customers in the following countries: Australia, Austria, Belgium, China, France, Germany, Greece, Ireland, Italy, Japan, Luxembourg, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, Taiwan, the United Kingdom, and the United States.

Customers with questions may contact the company via telephone at 763-951-8235. Customers may also contact the company via e-mail at [FieldActionCenter@greatbatch.com](mailto:FieldActionCenter@greatbatch.com) Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: <http://www.fda.gov/MedWatch/report.htm>
- Regular Mail or Fax: Download form <http://www.fda.gov/MedWatch/getforms.htm> 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

**About Greatbatch, Inc.**

Greatbatch, Inc. (NYSE: GB) provides top-quality technologies to industries that depend on reliable, long-lasting performance. The company develops and manufactures critical medical device technologies for the cardiac, neuromodulation, vascular and orthopaedic markets; and batteries for high-end niche applications in the portable medical, energy, military, and other markets. Additional information is available at [www.greatbatch.com](http://www.greatbatch.com).

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