March XX, 2014

Dear Valued Customer,

The purpose of this letter is to advise you that Greatbatch Medical has an update to the global Field Corrective Action for the Standard Offset Cup Impactor that was initiated January, 2014. Our records indicate you have received at least one of these devices since the product was first released in 2004.

REASON FOR UPDATE:

When Greatbatch sent the first notification in January, Greatbatch had one acceptable sterilization parameter. Greatbatch has continued to work on additional parameters and Greatbatch has now validated an additional sterilization parameter (validated to a Sterility Assurance Level (SAL) of at least 10^{-6}). The table below reflects both recommended sterilization parameters:

Cycle Type	Temperature °Celsius (Minimum)	Exposure Time (Minimum)	Dry Time (Minimum)*
Pre-vacuum	135°C	3 minutes	60 minutes
Pre-vacuum	134°C	18 minutes	30 minutes

In addition, during the course of the investigation for this issue, Greatbatch has identified additional Standard Offset Cup Impactors that your company has purchased. The enclosed Field Corrective Action Response Form identifies all impacted devices that your company has purchased from Greatbatch.

This update to the Field Corrective Action has also been communicated to the appropriate regulatory authorities.

INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS FIELD CORRECTIVE ACTION

1. Review the enclosed **Field Corrective Action Response Form**. This Form contains important information about your specific account. It must be returned to us even if you do not have any Standard Offset Cup Impactors your possession. For your convenience, we have pre-populated the Form with information we have in our records concerning the Standard Offset Cup Impactors shipped to you since the product was released in 2004.

2. Examine your inventory and identify all Standard Offset Cup Impactors that are in your possession. **Immediately inform those responsible for sterilization of the devices to utilize the updated instructions and ask them to add this Field Corrective Action Notice**

to the filed copy of the Instructions for Use. These instructions are provided below and also included in a separate document that may be posted for personnel who perform sterilization activities.

Sterilization Instructions

- All Greatbatch Medical surgical instruments must be sterilized prior to use.
- Use a validated, properly maintained and calibrated steam sterilizer.
- The following cycle has been validated to provide a sterility assurance level of 10^{-6}:

Cycle Type	Temperature °Celsius (Minimum)	Exposure Time (Minimum)	Dry Time (Minimum)*
Pre-vacuum	135°C	3 minutes	60 minutes
Pre-vacuum	134°C	18 minutes	30 minutes

*Fully loaded cases/trays may require longer dry time. The instructions provided above have been validated by the manufacturer of the medical device as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing, as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieve the desired result. This normally requires validation and routine monitoring of the process.

3. It is not necessary that you return devices to Greatbatch. Devices sterilized via a validated method, such as the sterilization instruction provided in item 2 above are suitable for use.

4. If you have purchased or received Standard Offset Cup Impactors either directly or indirectly, from Greatbatch that you have distributed to customers, please immediately notify your customers of this Field Corrective Action and inform them of the updated sterilization instructions. If you prefer, please call us at 1-763-951-8235 or email us at FieldActionCenter@Greatbatch.com to provide us with your customer information. We will be happy to contact your customers directly regarding this matter.

5. Complete the **Field Corrective Action Response Form** and return to Greatbatch per the following instructions:

   - Enclose the completed **Field Corrective Action Response Form** in a FedEx envelope
   - Use the pre-paid packaging label provided by Greatbatch
   - Submit the package to FedEx for shipping and delivery to:

     Greatbatch
     Attn: [redacted] / Standard Cup Impactor Field Corrective Action
     2300 Berkshire Lane North
     Plymouth, Minnesota 55441, USA

OR

- Complete and scan the Field Corrective Action Response Form
- Email the completed form to: **FieldActionCenter@Greatbatch.com**

6. You have concluded the actions to be taken in response to this Field Corrective Action. We sincerely thank you for your assistance.

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure patient and customer satisfaction. If you have any questions or need help is completing these actions, please contact your local Greatbatch Medical representative, contact us at 1-763-951-8235, or e-mail us at FieldActionCenter@Greatbatch.com and we will be happy to assist you.

Sincerely,

[redacted]
Global Quality and Compliance Program Manager
Greatbatch, Inc.
2300 Berkshire Lane North
Plymouth, Minnesota 55441, USA

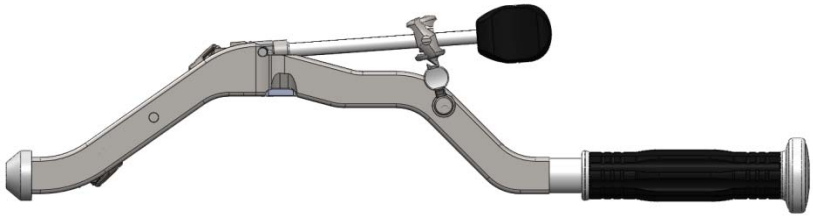
Enclosures:

1) Updated Sterilization Instructions for Standard Offset Cup Impactor
2) Field Corrective Action Response Form
3) Original Field Corrective Action Notification
4) Pre-paid return shipping label

URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION

Please Immediately Post this notice where sterilization of Standard Offset Cup Impactors occurs

Updated Sterilization Instructions For: Greatbatch Medical – Standard Offset Cup Impactor



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*For more complete information on this notification reference Greatbatch Field Corrective Action Notification