Greatbatch

URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION NOTIFICATION

PLEASE READ THOROUGHLY

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

Greatbatch Medical – Standard Offset Cup Impactor with POM-C Handle

STANDARD OFFSET CUP IMPACTORS ARE SHIPPED WITH IFU MAN-000002 HAS BEEN UPDATED. MAN-000002 REV E CONTAINS THE ACCURATE INSTRUCTIONS

Previous Instructions Rev D

WARNINGS

- Do not exceed 137°C.
- Do not use highly alkaline (pH>9) solutions.
- Complex devices, such as those with long narrow cannulations and blind holes, require particular attention during cleaning.

PACKAGING

- ~~Instruments may be loaded into delicated instrument trays or sterilization trays.~~
- Wrap in accordance with local procedures using standard wrapping techniques

STERILIZATION

- All Greatbatch Medical surgical instruments must be sterilized prior to use.
- Use a validated, properly maintained and calibrated steam sterilizer.
- The following cycles have 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.

Updated Instructions Rev E

WARNINGS

- Do not exceed 137°C.
- Do not use highly alkaline (pH>9) solutions.
- Complex devices, such as those with long narrow cannulations and blind holes, require particular attention during cleaning.
- ***Do not sterilize offset cup impactors with hard plastic handle grips in instrument trays as this may result in a non-sterile device. These devices must be sterilized in the individually wrapped configuration.***

PACKAGING

- Wrap in accordance with local procedures using standard wrapping techniques.

STERILIZATION

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

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

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.

URGENT MEDICAL DEVICE
CORRECTIVE ACTION NOTIFICATION
Standard Offset Cup Impactor with POM-C (Blue) Handle
Specialty Restoration ADM Curved Cup Holder

October 07, 2016

Product Field Action: RA 2016-136

Description:	OFFSET CUP IMPACTOR
Catalog No:	T6318
Lot Code:	All

Description:	SPECIALTY RESTORATION ADM CURVED CUP HOLDER
Catalog No:	I-H1702HF00
Lot Code:	All

Dear Stryker Distributor,

Greatbatch Medical, ("Greatbatch"), Manufacturer of the Standard Offset Cup Impactor with POM-C (Blue) Handle, distributed by Stryker Orthopaedics as the Offset Cup Impactor and Specialty Restoration ADM Curved Cup Holder, has initiated a correction associated with these instruments. This letter communicates the hazards identified by Greatbatch and provides for risk mitigation identified by Stryker following Stryker's review of the updated sterilization parameters communicated by Greatbatch.

Issue:

The Standard Offset Cup Impactor with POM-C (Blue) Handle (T6318) and Specialty Restoration ADM Curved Cup Holder (I-H1702HF00) are distributed as an individual device (not part of a kit) and validated for sterilization as an individually wrapped device and for inclusion in a dedicated case.

Greatbatch has communicated that Instructions for Use provided with the device (IFU, MAN-000002, Rev. D) contains inaccurate information, stating that:

- Devices may be loaded into dedicated instrument trays or sterilization trays
- Fully loaded case/trays may require longer dry time

Greatbatch reports that recent sterilization testing performed in a dedicated instrument case revealed that the device did not meet an acceptable sterility assurance level using the sterilization parameters identified in IFU MAN-000002 Rev D. The location of the failure was under the POM-C (Blue) handle.

The Standard Offset Cup Impactor with POM-C (Blue) handle is provided non-sterile and must be sterilized prior to use in surgery.

Our records indicate that you have received the above referenced instrument. It is our responsibility to ensure that customers who may have received this affected instrument also receive this important communication.

Potential Hazard:

Greatbatch has determined that when a Standard Offset Cup Impactor with POM-C (Blue) Handle (T6318) and Specialty Restoration ADM Curved Cup Holder (I-H1702HF00) handle is sterilized when placed in a dedicated instrument case per the current Instructions for Use (IFU), the device might not be sterile and, if used during a surgical procedure, there is potential for infection.

Currently, Greatbatch reports 1 complaint pertaining to insufficient dry time. No complaints of patient infection and no adverse events related to this issue have been reported.

Risk Mitigation

Please follow the instructions outlined in the attached cleaning instructions from Greatbatch (IFU MAN-000002 Rev. E)

Actions required by you:

1. If your branch or hospital still has a T6318 impactor in use, you may continue to use this instrument. **However, you must follow the updated cleaning instructions provided by Greatbatch.** Greatbatch reports that recent sterilization testing performed in a dedicated instrument case revealed that the device did not meet an acceptable sterility assurance level using the sterilization parameters identified in IFU MAN-000002 Rev D.
2. If you cannot comply with the attached Greatbatch cleaning instructions, you should discontinue use of this instrument and order a 510912 replacement impactor, as detailed below.
3. Contact a customer service representative to initiate the order process of a new 510912 impactor. Please notify the representative if you are unable to comply with the updated cleaning instructions so the impactor can be immediately replaced.
4. All future impactor orders must be placed with part number 510912. The T6318 part number is no longer available.

Please assist us in meeting our regulatory obligation by emailing the attached Acknowledgement Form within 5 business days to:
SO_M_Product_Field_Action_Response@stryker.com

URGENT MEDICAL DEVICE
CORRECTION NOTIFICATION
Standard Offset Cup Impactor with POM-C (Blue) Handle
Specialty Restoration ADM Curved Cup Holder

October 07, 2016

Product Field Action: RA2016-136

Description:	OFFSET CUP IMPACTOR
Catalog No:	T6318
Lot Code:	All

Description:	ATTESTATION/ACKNOWLEDGEMENT FORM FOR SPECIALTY RESTORATION ADM CURVED CUP HOLDER
Catalog No:	I-H1702HF00
Lot Code:	All

I have received the notification from Stryker Orthopaedics dated October 07, 2016 stating that Greatbatch Medical, the Manufacturer of the Standard Offset Cup Impactor, which is distributed by Stryker Orthopaedic as the Offset Cup Impactor (T6318) and Specialty Restoration ADM Curved Cup Holder (I-H1702HF00), initiated a Product Correction for these instruments.

_____ _____

Stryker Orthopaedics Representative (Signature) Date

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Stryker Orthopaedics Representative (Print)

PLEASE COMPLETE THIS FORM AND RETURN IT BY USING THE EMAIL LISTED BELOW:

Email to: SO_M_Product_Field_Action_Response@stryker.com

Enclosed: Greatbatch Urgent Medical Device Field Corrective Action Notification