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.