



Instructions for Use

Reprocessed Medtronic Midas Rex Bone Mill Bowl Assembly – Rev 10-06-2020

- a) This device has been reprocessed by Green OR.
- b) This device is a reprocessed device designed for an additional Single Use.
- c) This device has been sterilized using Ethylene Oxide Gas. Do not use this device if the packaging has been prematurely opened or damaged.
- d) Federal law restricts this device to sale by or on the order of a licensed physician.
- e) To ensure the safe and effective use of this device, read the Instructions for Use in its entirety prior to using this device.
- f) For further information regarding this device, contact Green OR at 1-866-783-6006.

Device Description:

The Medtronic Midas Rex[®] Bone Mill Bowl Assembly is part of the Midas Rex[®] Electric Bone Mill which is intended to mill bone, producing bone particles 1 to 5 mm in size. It consists of a bowl and a cap.

Following the use of this device within a clinical setting, Green OR received this device and subsequently performed a complete reprocessing of the device including identification, decontamination, cleaning, refurbishing, testing, inspection, packaging, labeling and sterilization with ethylene oxide.

Indications for Use:

The Medtronic Midas Rex[®] Bone Mill Bowl Assembly is indicated for use in spinal and orthopedic procedures to provide a container to grind bone.

Contraindications for Use:

Reprocessed Midas Rex[®] Bone Mill Bowl Assembly is contraindicated in the following situation:
This device is contraindicated any time a spinal or orthopedic procedure is also contraindicated.

Warnings and Precautions:

- a) Original Equipment Manufacturers (OEMs) provide Instructions for Use (IFUs) with the original device. When a health facility reprocesses that original device through a third-party FDA registered reprocessing company, the health facility needs to keep the original OEM IFU as this original OEM IFU, and any materials associated with it, supersede all other instructions.
- b) These instructions apply to Green OR's Midas Rex[®] Bone Mill Bowl Assembly only and are not to be used as instructions for use for any other devices or techniques, nor are they intended to be used as instructions for use of the complementary components that may be used in this system. Read and follow the instructions for this device as well as those for the other instruments to be used in combination with this device prior to use.
- c) This device is intended for use by a licensed physician who has a thorough understanding of the techniques and principles of spinal and orthopedic procedures and who has received adequate training with spinal and orthopedic surgeries and, in particular, has received training on the use of Midas Rex[®] Bone Mill Bowl Assembly as part of the Midas Rex[®] Electric Bone Mill.

- d) Do not use this device for any other purpose other than those indicated in these instructions.
- e) Careful handling of this device is necessary to avoid damage or breakage. Always inspect the device prior to use to ensure device integrity. Do not use the device if any damage is identified.
- f) Since this device is used along with other devices, prior to use, ensure compatibility with all devices.
- g) DO NOT operate the Midas Rex[®] Bone Mill without wearing eye protection.
- h) DO NOT modify accessories. Performance could be diminished with modified accessories.
- i) DO NOT operate Midas Rex[®] Bone Mill without securing cap.
- j) DO NOT come in contact with the interior of the bowl or cap during the milling of bone.
- k) The addition of any liquid to the milling process should be administered in small volume to prevent leakage.
- l) DO NOT process more than six bone pieces approximately 1.5 cm³ in size at one time.
- m) DO NOT process more than a total of 40 cc of bone during any one surgical procedure.
- n) DO NOT over process bone.

Directions for Use:

General

- a) Store Midas Rex[®] Bone Mill Bowl Assembly away from moisture and direct heat.
- b) Do not use expired devices. If the expiration date has passed, either return the device to Green OR for consideration to be reprocessed or discard the device.

Packaging

- a) Inspect the packaging before opening. Since the contents of this package are intended to be sterile, if the packaging has been damaged or compromised in any way, do not use this device as sterility may be affected. Return the device with this packaging to Green OR. Green OR will evaluate whether or not the device can be successfully reprocessed for another single use.
- b) If the packaging has been opened or compromised, but the device has not been used, do not attempt to re-sterilize the device and do not use this device on a subsequent procedure. Return the device with this packaging to Green OR. Green OR will evaluate whether or not the device can be successfully reprocessed for another single use.
- c) The packaging of this device contains removable labels which can be affixed to the patient's medical records file.



Device Inspection

- d) With the use of sterile technique, remove the device from the packaging.
- e) Inspect the device to ensure its physical integrity. If the device is damaged in a way that would make it unacceptable for processing, do not use the device. Return the damaged device along with this packaging to Green OR for evaluation.
- f) Prior to utilizing the device, verify the overall compatibility of the device with its complimentary accessories.

Device Usage

- g) Press bowl firmly onto the Midas Rex[®] Bone Mill until an audible click (lock) is heard.
- h) Observe that both of the release buttons are fully out.
- i) Secure cap onto bowl by rotating counterclockwise.
- j) Limit the amount of bone pieces to a maximum of six at one time (approximately 1.5 cm³ in size).
- k) Milling time is dependent on the density of the patient's bone, the ratio of cancellous and cortical bone, the size of the individual particles and the batch amount of the bone to be processed.
- l) The addition of any liquid to the milling process should be administered in small volume to prevent leakage.
- m) Always check bone after 10-15 seconds to gauge quality of milling.
- n) Take care to process bone to the desired particle size. Avoid over processing bone.
- o) If the blade becomes inoperable (jams or runs very slowly) stop operation of the Midas Rex[®] Bone Mill and remove bowl cap and use a spatula to free the bone and the blade. Remove some of the bone if needed to obtain proper operating speed.
- p) After removing the bone particles from the bowl, the milling process may be repeated with additional specimens, as needed. (Up to a total of 40cc of bone may be processed during any one surgical procedure.)
- q) Do not reuse or re-sterilize this device. Return the used device to Green OR in the collection containers provided to your facility.

Note: The names of other companies and products which may have been mentioned herein may be trademarks of their respective companies.

Note: Green OR is not liable for any damages caused by any defect in material, design or workmanship by the OEM or by any act of omission by the OEM.

Packaging Symbols:

	Production batch number
	Green OR, LLC's part number
	Quantity of devices in package
	Manufacturer
	Date of manufacture
	Date of expiry
	Sterilized using ethylene oxide
	Caution, consult accompanying documents
	Do not reuse
	Do not re-sterilize

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