



**Instructions for Use**  
**Reprocessed Arthroscopic Shavers, Abraders & Burrs – Rev 7-6-2020**

- 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:**

Arthroscopic shavers, abrasers and burrs, which have been reprocessed by Green OR, include an abrader, a burr or blade at the end of a long rod that rotates within a hollow stainless-steel housing. The housing has a window cut out on one side of the distal end, allowing the burr to cut one part of the intended anatomy, while the adjacent one is still protected by the housing on the opposite side of the, abrader, burr or blade. This system is connected to a motorized hand piece which drives the internal abrader, burr or blade inside the outer housing and provides suction to remove tissue and/or bone which has been cut during the surgical procedure.

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:**

Arthroscopic shavers, abrasers and burrs are indicated for use in orthopedic surgical procedures on the knee, elbow, shoulder, ankle and/or wrist.

**Contraindications for Use:**

Reprocessed shavers, abrasers and burrs are contraindicated in the following situations:

- a) For use in non-arthroscopic procedures.
- b) For surgical procedures where an appropriate solution is not used as an irrigant.
- c) For procedures where there is not adequate joint space or distention for a complete arthroscopic inspection.
- d) On obese patients.
- e) On patients who exhibit ankyloses or instability.
- f) On patients with a Varus or valgus deformity that is severe enough to cause instability, severely restricts the range of motion, or cause extreme malalignment (15° Varus, 30° valgus).
- g) Synovectomy in patients who have progressed beyond the phase of synovial proliferation or in patients when the articular cartilage is eroded because of advanced rheumatoid arthritis.
- h) When the size or model of the shaver, abrader or burr is inappropriate for the surgical procedure.
- i) For any other condition where an arthroscopic procedure is contraindicated for any reason.

**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 arthroscopic shavers, abrasers and burrs only and are not to be used as instructions for use for any other arthroscopic device or techniques, nor are they intended to be used as instructions for use of the complementary components used in this system.
- c) This device is intended for use by a licensed physician who has received adequate training with arthroscopic surgical procedures and has received training on the use of arthroscopic shavers, abrasers and burrs.
- d) Inappropriate use may result in injury to the patient and/or the physician or may cause damage to the medical equipment being used for this procedure. If further information is required, consult medical literature regarding use, techniques, principle complications and hazards prior to the use of this device.
- e) Since this device is designed for use with a compatible hand piece and generator to power this device, follow all safety instructions as outlined within the manufacturer's Operator's Manual for the hand piece and generator.
- f) Verify compatibility of all device components with each other.
- g) Careful handling of this device is necessary to avoid damage or breakage. Always inspect the device prior to use to ensure device integrity and do not use the device if any damage is identified.
- h) Never touch the shaver, abrader or burr tip while power is being supplied to the device as such action may injure the user and may damage the device.
- i) Never insert or withdraw the shaver, abrader or burr while the device is activated.
- j) To avoid inadvertent injury to the patient and/or damage to the device, make sure that the distal tip of the device, (the working end of the device) is visible during the use of this device. If you do not have a clear visual of the working tip of this device during the procedure, do not activate this device.
- k) Shavers, abrasers and burrs are most effective at RPMs below 3,000. Use of this device above 6,000 RPM is not recommended and could cause excessive particulates.
- l) Blood vessels extend in to the cortical layer of subchondral bone. As such, do not abrade bones deeper than 1 to 2 mm in to the cortex and cancellous bone.
- m) Do not allow the arthroscopic shaver or burr to come in contact with other metal objects, such as the operating room table, IV poles, other devices, staples or clips while the device is activated as such action may cause damage to the device and may cause injury to the patient.
- n) The tip of the shaver or burr must be irrigated periodically (general recommendation is once per minute) to cool the blade and prevent excised tissue from accumulating.
- o) Do not run this device without adequate irrigation as such may cause damage to the device.



- p) Do not run this device without adequate suction for the duration of the surgical procedure
- q) Do not bend or alter the shape of the shaver, abrader or burr.
- r) Do not bend the outer stainless-steel housing.
- s) Do not lubricate the shaver, abrader or burr.
- t) Do not allow the rotating shaver, abrader or burr to come in contact with any other surgical instrument as such action may injure the patient and may damage the device. If such contact occurs, inspect both devices to ensure that there is no damage. If such action has caused damage to the device, do not continue the use of the device. Return damaged devices to Green OR for inspection.
- u) Do not apply excessive pressure or "side-load" the arthroscopic shaver, abrader or burr during use. Such action may dull the shaver blade, abrader or burr and may produce metal particulate.

**Adverse Reactions:**

None known.

**Directions for Use:**










**General**

- a) Store arthroscopic shavers, abraders and burrs away from moisture, freezing, 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.
- c) Select the arthroscopic device to be used based upon its size, tip configuration and function that will be the most appropriate for the patient and the procedure.
- d) This device is used in combination with a hand piece and a power generator or controller and various accessories. Consult the manufacturer's Operator's Manual for these complimentary units for direction on making the proper electrical connections, power settings, operation, setting alarm modes, and for other parameters of use such as disinfection and sterilization of complementary components.

**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
<b>STERILE EO</b>	Sterilized using ethylene oxide
	Caution, consult accompanying documents
	Do not reuse
	Do not re-sterilize

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