Instructions for Use
Reprocessed Orthopedic Manual Devices – 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:
This orthopedic manual device has been designed for orthopedic surgical procedures on the knee, elbow, shoulder, ankle and/or wrist.

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:
Orthopedic manual devices are indicated for use in orthopedic surgical procedures on the knee, elbow, shoulder, ankle and/or wrist

Contraindications for Use:
Reprocessed orthopedic manual devices are contraindicated in the following situations:
a) For use in non-arthroscopic procedures.
b) For procedures where there is not adequate joint space or distention for a complete arthroscopic inspection.
c) When the size or model of the shave, abrader or burr is inappropriate for the surgical procedure.
d) 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 orthopedic manual devices 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 with these devices.
c) This device is intended for use by a licensed physician who has a thorough understanding of the techniques and principles of arthroscopic surgical procedures and in particular has received training on the use of orthopedic manual devices.
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) Verify compatibility of all device components with each other.
f) 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.
g) 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.
h) Do not allow the orthopedic manual device 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.
i) Do not bend or alter the shape of this orthopedic manual device.
a) Orthopedic manual devices which come in contact with blood and/or other bodily fluids should be treated as “potentially infectious materials” after use. Wear appropriate personal protective equipment when handling any potentially infection material. Return the used orthopedic manual devices to Green OR in the collection containers provided to your facility.
j) All employees who are exposed to “potentially infectious materials” must be offered immunization against hepatitis B by their healthcare facility.

Directions for Use:
General
a) Store orthopedic manual devices 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) For a complete set of direction on the use of complimentary components used with this device, consult the manufacturer’s Operator’s Manual.

Packaging
a) Inspect the packaging before opening. Since the contents of this package are intended to be sterile, if the package has been damaged or compromised in any way, do not use this device as sterility may be compromised. 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

a) With the use of sterile technique, remove the device from the packaging and place it in a sterile work area.
b) Inspect the device to ensure its physical integrity. If the device is damaged in a way that would make it unacceptable for surgery, do not use the device. Return the damaged device along with this packaging to Green OR for evaluation.
c) Prior to the utilizing the device, verify the overall compatibility of the device with its complimentary accessories.

Device Usage

a) Prepare the patient pre-operatively according to standard procedures.
b) Follow suitable surgical protocol throughout this procedure.
c) 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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