Instructions for Use
Reprocessed Carpal Tunnel Blades – 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:
Endoscopic Carpal Tunnel Release is a minimally invasive surgical procedure designed to cut the carpal tunnel ligament in a patient's wrist. A tiny incision is made at the base of the wrist though which an endoscope can be placed, which allows visualization and identification of the transverse carpal ligament. A carpal tunnel blade is part of a system that also includes an endoscope, a light source and a video camera. The endoscope allows the surgeon to position the carpal tunnel blade directly beneath the transverse carpal ligament. Once in place, a trigger-system releases and elevates a small retractable blade which is used to cut the carpal ligament.

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:
Carpal Tunnel Blades are designed to cut the transverse carpal ligament.

Contraindications for Use:
Reprocessed carpal tunnel blades are contraindicated in the following situations:
a) Abnormalities of the wrist.
b) Do not use when other surgeries of the wrist are 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 carpal tunnel blades only and are not to be used as instructions for use for any other 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 a thorough understanding of the techniques and principles of carpal tunnel release surgery and who have received adequate training on the use of carpal tunnel blades.
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 endoscope, 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 carpal tunnel blade as such action may injure the user and may damage the device.
i) 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.
j) The blade assembly must be locked with the blade lock screw after insertion in to the hand piece. Failure to do so my result in patient injury.
k) Do not over tighten the blade lock screw as such could prevent the blade from retracting properly. Over tightening may result in injury to the patient.

Directions for Use:
General
a) Store carpal tunnel blades 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) This device is used in combination with a hand piece and an endoscope. Consult the manufacturer's Operator's Manual for these complimentary units for direction on making the proper connections, and for other parameters of use such as disinfection and sterilization of complementary components.

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 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 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 insert it in to the hand piece.
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.
d) A tiny incision is made at the base of the wrist though which the endoscope can be placed, which allows visualization and identification of the transverse carpal ligament.
e) The endoscope allows the surgeon to position the carpal tunnel blade directly beneath the transverse carpal ligament. Once in place, a trigger-system releases and elevates a small retractable blade which is used to cut the carpal ligament.

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:

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

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