Instructions for Use
Reprocessed Tourniquet Cuffs – Rev 7-6-2020

a) This device has been reprocessed for 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 pneumatic tourniquet cuff is part of a system that includes a pressure regulated control unit, a tourniquet cuff, with either a single or dual bladder, and a hose assembly that connects the control unit to the tourniquet cuff. The tourniquet cuff is wrapped around a patient's limb and is then inflated with air. Inflation of the tourniquet cuff causes compression on the patient's blood vessels which restricts blood flow to the operative field. Tourniquet cuffs are available in various sizes to accommodate a wide range of limb circumferences.

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:
Tourniquet cuffs are indicated for use on patients who require surgery on their extremities where temporary occlusion of blood flow is desired.

Contraindications for Use:
Tourniquets are contraindicated in the following situations:
a) For neonates.
b) For patients with peripheral vascular disease.
c) For patients with thrombosis, or embolism.
d) For patients who have an open fracture of the extremity.
e) For patients who have severe crushing injuries.
f) For patients who have skin grafts in the area where a tourniquet would be applied.
g) For patients with diabetes mellitus.
h) For patients undergoing elbow surgery.
i) For patients with severe hypertension.
j) For patients with a compromised vascular circulation.
k) For patients requiring lengthy hand reconstructive surgery.
l) For patients with sickle cell or clotting disease.

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 SCDs 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 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 and training on the use of tourniquet cuffs. If further information is required, consult medical literature regarding use, techniques, principle complications and hazards prior to the use of this device.
d) Inappropriate use of this device may result in injury to the patient.
e) Make sure that this tourniquet cuff is properly connected to the air pump otherwise the performance of this device may be compromised. If further information is required, consult medical literature regarding use, techniques, principle complications and hazards prior to the use of this device.
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) Do not repair or replace the tubing connectors on this device. If the tubing is damaged in any way, return the device along with its packaging to Green OR for evaluation.
h) Do not use this device for any other purpose other than those indicated in these instructions.
i) Since this device is used along with other devices, prior to use, ensure compatibility with all devices to be used during this surgical procedure.
j) Ensure that the tourniquet cuff is properly positioned on the patient with adequate pressure for the appropriate amount of time. Monitor the pressure being applied to ensure that adequate pressure is maintained.
k) Placing the tourniquet cuff over the peroneal or ulnar nerve can cause nerve damage or paralysis.
l) Do not rotate the tourniquet on the patient once it has been inflated otherwise such rotation could cause damage to the underlying tissue.
m) Use extreme caution when using sharp objects such as needles, towel clips, leg holders and other equipment to avoid damage to the tourniquet cuff.
n) Do not remove the tourniquet cuff while the device is inflated as this may cause injury to the patient and may damage the device.

Adverse Reactions
a) Pain or stiffness of the patient's limb.
b) Weakness of the patient's limb.
c) Discoloration of the patient's skin.
d) Motor paralysis.
e) Reactive hyperemia.
f) Loss of sense of stimuli response to touch and pressure.

Directions for Use:

General

a) Store tourniquet cuffs away from moisture, freezing and/or 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. Do not attempt to re-sterilize.

c) Preoperative skin preparations should not be applied to the area under the tourniquet cuff.

d) Prior to surgery, select the proper size of the tourniquet cuff that will be appropriate for the size of the patient's limb.

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) Wrap the tourniquet cuff around the patient's limb until it is snug and secure. Smooth out any wrinkles which may exist.

b) Properly position the tourniquet cuff tubing so that it will not kink. Note that kinking of the tubing may impede air flow to the tourniquet cuff.

c) Connect the tourniquet cuff to the pressure regulated control unit.

d) Apply the minimum pressure to achieve the desired compression.

e) Follow all established guidelines to determine inflation, duration of procedure, pressure setting, timing of inflation and timing of release.

f) When compression is no longer required, delate the tourniquet rapidly to prevent enlarged or swollen areas.

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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