Instructions for Use
Reprocessed Aquamantys Bipolar Sealers – Rev 7-1-2020

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) Use of this device should be limited only to physicians who have been adequately trained in performing electrosurgical procedures.
f) To ensure the safe and effective use of this device, read the Instructions for Use in its entirety prior to using this device.
g) For further information regarding this device, contact Green OR at 1-866-783-6006.

Device Description:

Aquamantys Bipolar Sealers use technology that combines radiofrequency (RF) energy and saline to provide hemostatic sealing and coagulation of soft tissue and bone. The combination of RF energy and saline allows the device to operate at approximately 100˚C, far less than other electrosurgical devices. By controlling bleeding, Aquamantys bipolar sealers has been shown to significantly reduce the incidence of hematoma and reduce surgical time in a variety of procedures and may reduce the need for hemostatic agents. 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:

Aquamantys Bipolar Sealers are intended for endoscopic and open abdominal, orthopedic, spine and thoracic procedures. These devices are used in connection with an electrosurgical generator with a rotary peristaltic pump.

Contraindications for Use:

a. Reprocessed Aquamantys Bipolar Sealers are contraindicated in the following situations:
    i. Dura
    ii. Nerve Roots
    iii. Skin and Skin Edges
    iv. Intact Nerves
    v. Intact Tendons & Ligaments
    vi. Epidural Veins
    vii. Bone Surfaces That Are Intended to be Fused
    viii. Vertebral End Plates After Discectomy
    ix. Subcutaneous Tissue
b. These devices are not intended for contraceptive tubal coagulation.

Warnings and Precautions:

a. The cable on the device should be positioned in a way to avoid contact with the patient or other cables.
b. Use the lowest setting possible to achieve the desired tissue effect to avoid overtreatment which could result in swelling, fluid, seroma, or unintended tissue necrosis. High power settings may result in deeper tissue effect than lower power settings.
c. The depth of effect is deeper and increases with time if the electrodes are held stationary with less depth of effect if the electrodes are moved over tissue.
d. Use caution to avoid inadvertent treatment of tissue, nerves, and adjacent anatomy.
e. Activating these devices with the tips pointing upward may result in inadequate saline flow to the intended treatment area.
f. Ensure that saline is flowing at all times during activation.
g. For proper performance, make sure that both electrodes are in contact with the tissue being treated.
h. If the flow of saline should stop during the procedure, stop using the device and attempt to resume saline flow. Ensure that the pump tubing segment has been loaded properly into the pump head located on the generator and that the saline bag is not empty. If unable to resume saline flow, discontinue the use of the device and obtain a new device to continue the surgical procedure. Return the device that malfunctioned to Green OR Device Reprocessing Solutions for evaluation.
i. This device is not intended to be bent, or used as a pry, or any other use not cleared by the FDA. Bending or using the device as a pry could cause part breakage.
j. The combination of Radio Frequency and saline may result in a deeper tissue effect than conventional Radio Frequency devices and has the potential to cause hot saline to run-off onto delicate structures. To minimize the potential of damage to delicate anatomy, use suction to remove saline run-off and/or use other protective measures and necessary.
k. Use suction to avoid activating the device in a pool of saline or blood. Activating in pooled saline or blood may reduce the hemostatic effectiveness of the device, and/or may cause the electrode to become clogged.
l. To ensure proper function of the device, the tip of the suction wand should not come any closer to the electrodes than 1 – 2 mm and should not come in contact with the electrodes.
m. Overuse or excessive application of this device may result in contraction, inflammation, or necrosis of tissue.
n. Use of this device on skin may result in incisional complications such as necrosis or desiccation of the skin.
o. Use the device with caution in the presence of pacemakers, as electrosurgical devices may cause interference with pacemakers or other active implants.
p. Place any monitoring electrodes being used as far away as possible from the device to avoid electrical interference with monitoring equipment. Avoid needle-monitoring electrodes.
q. Use monitoring systems incorporating high frequency current limiting devices.
r. DO NOT use electrosurgery in the presence of flammable anesthetics or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents, as fire could result.
s. Close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the Aquamantys in the pump head while the pump head motor is turning.

t. Do not peel saline delivery segment apart from the electrical cable before placing the pump segment in the pump head. Peeling the tubing first increases the potential for loading the pump segment in the reversed position.

Adverse Reactions:
Due to the electrosurgical nature of this device, it is possible that use of this device may cause damage to surrounding tissue.

Directions for Use:
General
a) Store Aquamantys devices 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.
c) Select the specific Aquamantys 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 power generator or controller and various accessories. Consult the manufacturer's Operator's Manual for these accessories 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.

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 or if you observe kinks or cracks to the device's insulation, do not use the device. Return the damaged device along with this packaging to Green OR for evaluation.
c) Prior to the procedure, verify the overall compatibility of the device with its complimentary accessories.

Device Usage
Step 1:
a) Prepare the patient pre-operatively according to standard procedures.
b) Open the devices package using aseptic technique and deliver the device to the sterile field.
c) Using aseptic technique, pass the capped drip chamber or spike of the saline line off the sterile field, making sure to maintain an adequate length of saline line and electrical cable on the sterile filed.
d) Connect the Aquamantys to the pump generator.

Step 2:
a) Open the saline pump.
b) Place the saline tube in the center of the guide slots in the pump segment. The black tubing connector must be positioned toward the front panel of the generator with the white tubing connector positioned closest to the back of the generator then close the saline pump.

Step 3:
a) Only use sterile conductive irrigant solution, such as saline or Ringer's lactate, which is in close proximity to the Pump Generator
b) Remove the protective cover over the spike at the end of the Aquamantys saline delivery tubing.
c) Using aseptic technique, spike the bag of sterile saline solution.
d) If the drip chamber is present, squeeze the drip chamber once or twice to fill the drip chamber to a level of at least one third full.
e) Open the vent cap if the source of sterile saline solution s a non-vented glass bottle.

Step 4:
a) Press the START PRIME button on the front panel of the Pump Generator. This action must be taken after saline has been properly hooked up and saline bag has been spiked, but before activating the device on tissue.
b) Allow for priming cycle to complete prior to activating the device or pressing the START PRIME button again.

Step 5:
a) Set the RF power using the POWER SETTIGN buttons located on the front panel of the selected Pump Generator.
b) Press the up button to increase the RF power and press the down button to decrease RF power.

Steps 6:
Select the desired saline flow rate setting by pressing the appropriate "Saline Flow Rate" button located on the front panel of the selected Pump Generator.

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

Green OR, LLC, 17685 Juniper Path, Suite 314, Lakeville, MN 55044 www.thegreenor.com 1-866-783-6006