Instructions for Use
Reprocessed Coblators – Rev 7-6-2020
(Aka: ENT Ablation Electrodes, Coblation Wands, and Plasma Wands)

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:

Coblators, ENT Ablation Wands, Coblation Wands, and/or Plasma Wands, hereinafter referred to as Coblators, are radiofrequency surgical devices which are powered by a generator or controller, hereinafter referred to as a generator, and which are designed for the hemostasis of blood vessels and the removal and dissection of tissue during otorhinolaryngology (ENT) surgical procedures. 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:

Coblators are intended for the ablation, resection and coagulation of soft tissues and for hemostasis of blood vessels during surgical procedures in the throat. Coblators are used in connection with an electrosurgical power generator and utilize a conductive irrigant.

Contraindications for Use:

Reprocessed Coblators are contraindicated in the following situations:

a) For use in non-ENT surgical procedures.
b) For surgical procedures where a conductive irrigant, such as saline or Ringer's lactate, is not used.
c) For patients with cardiac pacemakers or other electronic device implants.
d) For any other condition where a surgical procedure on the tonsils and adenoids are contraindicated for any reason.
e) For any surgical procedure where the reduction of soft tissue in the throat is 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 Coblators only and are not to be used as instructions for use for any other ENT surgical device or techniques.
c) This device is intended for use by a licensed physician who has a thorough understanding of the techniques and principles of electrosurgical procedures and who have received adequate training with ENT surgical procedures. Inappropriate use may result in burn hazards to the patient and/or the physician, may cause electrical shock to either the patient 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.
d) Since this device is designed for use with a compatible electrosurgical generator to power this device, follow all safety instructions as outlined within the manufacturer's Operator's Manual for the electrosurgical generator.
e) Never touch the electrode tip while power is being supplied to the device as such action may shock the user. Touching the electrode tip while power is being supplied to the device may also present a burn hazard to the user, and/or may damage the 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) Never insert or withdraw the Coblator while the device is activated.
h) Do not use this device without a conductive irrigant such as saline or Ringer's lactate and ensure that the tip of the device is surrounded by this conductive irrigant solution prior to activation of the device.
i) Do not allow grounded metal parts to come in contact with the patient during use of this device.
j) Do not allow the cables of this device or other lead wires to come in contact with the patient during the use of this device.
k) Do not place multiple cables parallel with each other during the use of this device.
l) Do not allow the Coblator 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.
m) The suction pinch clamp should be in the fully closed position when being used without a suction source to avoid possible burns from the liquid back flow.
n) Do not bend Coblators that are not designed to be bent. Consult the OEM for more information regarding whether the original device is bendable.
o) Do not use the Coblator as a tool to mechanically displace tissue and do not use the Coblator as a prying or scrubbing tool, as this may result in damage to the electrode tip.
p) Do not use this device in the presence of flammable solutions or gases, or within an oxygen enriched environment as such may result in a fire hazard.
q) To avoid inadvertent tissue damage, 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.
r) Do not insert the Coblator in to an obstructed passageway as patient injury or product damage may result.
s) To avoid capacitive coupling and inadvertent burning of surrounding tissue, only activate this device when it is in contact with the target tissue.
t) Set the voltage/power on the generator to the lowest possible setting that provides the desire surgical effect. Consult the Operator's Manual of the manufacturer's generator for more information regarding power settings.

u) This electrosurgical device may adversely affect the operation of other electronic equipment being used during the procedure. As such, monitor the use of all equipment being used during this procedure and keep monitoring electrodes as far as possible from this device during use.
v) Continuous activation of the Coblator for more than 30 seconds is not recommended as such use could cause excessive thermal spread and unintended damage to the surrounding tissues.
w) Monitor hemostasis throughout the procedure and take corrective action to ensure hemostasis is achieved.
x) This device provides suction for the removal of small particles from the surgical field. It is not intended for large volume suction.
y) Do not allow the connector of the wand to the generator to come in contact with any fluids.

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 Coblators 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 Coblator 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

a) Prepare the patient pre-operatively according to standard procedures.
b) Only use conductive irrigant solution, such as saline or Ringer's lactate, and ensure proper irrigation of the electrode tip during activation.
c) Place the control value unit on an IV pole at least three feet above the patient.
d) Verify that the power generator or controller is switched to the OFF position or is in standby mode.
e) Connect the IV tubing to the device.
f) Connect the suction tubing of the device to a standard surgical suction unit.
g) Using direct visual or endoscopic guidance, carefully insert the tip of the Coblator in to the cavity of the throat and against the tissue to be ablated or coagulated.
h) Turn on the power generator and set the power output according to the recommended settings of the OEM. Use the lowest power setting needed to achieve the desired effect.
i) Using the foot control or hand switch, adjust the voltage set points to the ablation or coagulation function based upon the desired effect.
j) To maximize performance, keep the Coblator in motion while the device is activated.
k) If an alarm is sounded while the device is activated, deactivate the device immediately.
l) After use, disconnect the wand from the power generator and the suction pump and then withdraw the device from the patient.
m) 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:

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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