Instructions for Use
Reprocessed GlideScope® Video Laryngoscope Stats – Rev 7-27-2020

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:
GlideScope® Video Laryngoscope Stats are designed to house the Video Baton as part of a GlideScope® AVL Single-Use Video Laryngoscope System. GlideScope® Video Laryngoscope Stats provide a consistently clear view of a patient's airway, enabling quick tracheal intubation during an endoscopy of the larynx.

GlideScope® Video Laryngoscope Stats are available in a selection of sizes depending on the patient's weight.

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:
GlideScope® Video Laryngoscope Stats are indicted for use in endoscopic procedures to enclose and protect the Video Baton.

Contraindications for Use:
Reprocessed GlideScope® Video Laryngoscope Stats are contraindicated in the following situation:
This device is contraindicated any time an endoscopic minimally invasive procedure is also 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 GlideScope® Video Laryngoscope Stats only and are not to be used as instructions for use for any other devices 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 of the techniques and principles of endoscopic procedures and who have received adequate training with laryngoscopic surgeries and, in particular, has received training on the use of GlideScope® Video Laryngoscope Stats as part of the GlideScope® AVL Single-Use Video Laryngoscope System.
d) As standard operating procedure, follow all precautions typically utilized during minimally invasive laryngoscopic procedures.
e) Do not use this device for any other purpose other than those indicated in these instructions.
f) Careful handling of this device is necessary to avoid damage or breakage. Always inspect the device prior to use to ensure device integrity. Do not use the device if any damage is identified.
g) Since this device is used along with other devices, prior to use, ensure compatibility with all devices to be used during the surgical procedure especially the Video Baton. Use the following table to select the Video Baton/Stat combination:

Stat Size	Video Baton
0, 1, 2, 2.5	1-2
3, 4	3-4

h) To avoid damage to the Stat and/or Video Baton, ensure that the logo on the side of the Video Baton and the logo on the side of the Stat are aligned.
i) In combination with a clinical assessment of the patient and the experience and judgment of the clinician, select the Stat size that is appropriate for the patient using the table below:

Stat Size	Patient's Weight
0	< 1.5 kg (3.3 lbs)
1	1.5 – 3.6 kg (3.3 – 8.4 lbs)
2	1.8 – 10 kg (4 – 22 lbs)
2.5	10 – 28 kg (22 – 61 lbs)
3	> 10kg (> 22 lbs)
4	> 40kg ((> 88 lbs)

j) Inappropriate use of this device may result in minor damage to the soft tissues within the throat, the lips and the tongue, major injuries to the larynx and pharynx as well as tooth damage.
k) For best results, position the patient's head in such a way as to avoid harm and use extreme caution when inserting this device into the patient's mouth. If further information is required, consult medical literature regarding use, techniques, principle complications and hazards prior to the use of this device.
l) To minimize the risk of damage or injury use sufficient but not excessive force when inserting the Stat (lifting force: approximately 0.5 –1.5 kg (1 – 3.5 lbs))
m) Use appropriate care when removing the device.

Adverse Reactions:

a) Bleeding
b) Vocal cord spasm
c) Mouth or throat ulcers or abscesses
d) Injury to tongue, lips or teeth
e) Swelling or blockage of the airway
f) Hoarseness
g) Infection

Directions for Use:

General

a) Store GlideScope® Video Laryngoscope Stats 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 device size to be used based upon the patient's weight and the procedure to be performed and select the corresponding Video Baton.

Packaging

a) Inspect the packaging before opening. Since the contents of this package are intended to be sterile, if the packaging has been damaged or compromised in any way, do not use this device as sterility may be affected. 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.
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 for evaluation.
c) Prior to 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) Using sterile technique, slide the Video Baton into the Stat until it clicks into place. Do not remove the Stat from the pouch until you are ready to begin the intubation.
c) Follow suitable surgical protocol throughout the procedure.
d) When introducing the Stat in to the patient, use continuous and controlled pressure. Do not use excessive force.
e) After use withdraw the device very carefully from the patient.
f) 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

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