Instructions for Use Instructions for Use
Reprocessed Sequential Compression Devices – Rev 7-6-2020
(Aka: SCDs, Compression Sleeves, and DVTs)

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 processed using high-level disinfection techniques. This device is non-sterile.
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:
Sequential Compression Devices (SCDs) are devices that are designed to help prevent Deep Vein Thrombosis, DVT, by providing intermittent pneumatic compression, with thus use of a compatible compression pump, to the leg and/or foot to increase venous blood flow. SCDs can be applied to one or both lower extremities, depending on the patient's specific needs. SCDs are shaped like "sleeves" that wrap around the legs and inflate strategically designed chambers with air one at a time. This imitates walking and helps prevent blood clots.

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 high-level disinfection.

Indications for Use:
Patients who are on bed rest or immobile because of an illness, injury, or surgery are at risk for developing Deep Vein Thrombosis (DVT). Early ambulation is the best preventive strategy; however, when this is not an option, sequential compression devices, which are used with their associated compression pump, can be helpful.

Contraindications for Use:
SCDs are contraindicated in the following situations:
a) For patients who have severe arteriosclerosis or other ischemic vascular disease.
b) For patients who have massive edema on the legs or pulmonary edema from congestive heart failure.
c) For patients who have an extreme deformity of the area where the SCD is applied.
d) For patients who have active infections in the area where an SCD would be positioned on the body.
e) For patients who are either suspected or known to have a preexisting DVT, thrombophlebitis or pulmonary embolism.
f) For patients who have congestive heart failure or any condition where increased fluid to the heart may be detrimental.
g) For patients who have existing pulmonary edema.
h) For patients who have skin or tissue conditions such as dermatitis, immediate post-operative vein ligation, gangrene or recent skin graft or other skin or tissue conditions which may be impacted using an SCD.

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.
d) Inappropriate use of this device may result in injury to the patient. Make sure that this SCD is properly connected to the compression 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.
e) 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.
f) 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.
g) Do not use this device for any other purpose other than those indicated in these instructions.
h) 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.
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) SCDs should be removed immediately if the patient experiences numbness or pain or if the patient experiences any unexplained sensations.
k) If this SCD is used prophylactically to prevent DVT, the continuous use of this device is recommended. Any interruption of 30 minutes or longer of the use of this device in these situations should be done in consultation with the patient's physician.
l) Evaluate the patient every 8 to 12 hours for any signs of skin or tissue problems. Discontinue the use of this device if skin irritation or tissue problems are noted.
m) Do not remove a patient's SCD while the device is inflated as this may cause injury to the patient and may damage the device.
n) For the most effective results and greater patient comfort, use anti-embolism stockings under the SCD.
o) Do not elevate the patient's feet above the level of the heart.
p) The maximum inflation pressure used for the SCD should not exceed the patient's diastolic pressure.
q) Do not walk while wearing a foot compression sleeve.

Directions for Use:

General

a) Store SCDs 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.
c) Measure the patient's leg to select the correct size of the device that will be appropriate for the patient.
d) Patients should be instructed in the proper use of the system and should be directed to report any problems to their healthcare professionals.
e) This system should be used continuously until the patient is fully ambulatory.
f) If the SCD cannot be applied to the patient during surgery, the SCD can be applied to the patient following the surgical procedure.
g) For use in non-surgical situations, the SCD should be used as recommended by a physician and as soon as the risk of DVT has been identified.
h) This device is used in combination with a power air pump. 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 maintenance of complementary components.

Packaging

a) Do not use this device is the packaging has been prematurely open or if there is damage to the package.
b) The packaging of this device contains removable labels which can be affixed to the patient's medical records file.

Device Inspection

a) Inspect the device to ensure its physical integrity. If the device is damaged in a way that would make it unacceptable for patient use, do not use the device. Return the damaged device along with this packaging to Green OR for evaluation.
b) Prior to the utilizing the device, verify the overall compatibility of the device with its complimentary accessories.

Device Usage

a) Cleanse the patient's legs and feet as necessary.
b) Place the patient in the supine position.
c) Open the Velcro fasteners on the sleeve.
d) Unfold the garments, and smooth out any wrinkles. Position the inflatable bladder on the back side of the patient's limb with the cut out behind the knee. The outlet tube on the garment should not be in direct contact with the patient's skin.
e) Wrap the garment around the patient's leg and secure the hook tabs. Leave 1-2 fingerbreadths of space between the leg and the sleeve.
f) Attach the garments to the tube which leads to the compression air pump.
g) Rotate the outlet tube of the garment to eliminate kinks in the tubing.
h) Position the device in such a way so that the tubing will not form pressure points on the patient's limb. To minimize pressure points, position the device with the tubing facing away from the patient.
i) During ambulation or transport, secure the air pump and secure excess tubing to prevent any potential trip hazard.
j) Garments should be removed regularly to inspect the skin. Before removing the garment from the patient, turn off the compression pump and disconnect the tubing connectors. Unfasten the Velcro and remove the garment from the patient.
a) This device is for single use only. Do not reuse. Return the used SCDs to Green OR in the collection containers provided to your facility.

Additional Usage Instructions for SCDs designed for Foot Applications:

a) Place the garment over the foot and ankle and smoot out any wrinkles.
b) Place the inflatable bladder under the arch of the foot.
c) Close the Velcro fastener over the top of the foot.
d) Fasten the rear strap around the heel and close the Velcro fastener.
e) Position the foot below the heart level during use of this device.

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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