

Reprocessed by



Instructions for Use Reprocessed Compression Sleeves

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Compression Sleeves are sold as Non-sterile.

Explanation of Icons



Date of Reprocessing

REF

Ascent Product Code



Do Not Reuse



See Instructions For Use

Reprocessed Compression Sleeves

Compression Sleeve Description

Compression sleeves are part of an external compression system, in which intermittent or sequential compression is provided using a pump/controller and limb garment. The system consists of the following three main components: a control unit, inflatable limb sleeves and conduit tubing with detachable connections.

Indications for Use

When coupled with an appropriate inflation system, compression devices are intended for use in preventing deep vein thrombosis (DVT), diminishing post-operative pain and swelling, enhancing blood circulation, and reducing wound healing time.

Contraindications for Use

Reprocessed compression sleeves are contraindicated in the presence of the following conditions:

- Extreme limb deformity
- Congestive heart failure
- Active infection
- Severe arteriosclerosis or other ischemic vascular disease
- Massive edema of the legs or arms due to congestive heart failure
- Risk factors for pre-existing DVT or PE, including prolonged bed rest
- Acute stages of inflammatory phlebitis
- In situations where increased lymph and blood flow is undesirable
- Any local condition in which the garments would interfere, such as: gangrene, dermatitis, untreated or infected wounds, recent skin grafts, known or suspected deep venous thrombosis or thrombophlebitis, immediate post-operative vein ligation
- Any pain or numbness
- Pulmonary embolism or edema
- Arterial occlusion

Warnings

- Prior to use, read and follow the Operator's Manual for the compression pump.
- Do not repair or replace the tubing connectors as this may result in unwanted inflation of the sleeves.
- Do not operate in the presence of flammable gases (e.g. flammable anesthetics).
- Do not expose to excessive heat or freezing.
- Patients with diabetes, poor circulation, insensitive extremities, fragile skin, those on anticoagulation therapy and those predisposed to tissue viability problems should receive special attention. Use the lowest effective pressure and timing and additional padding.
- Check the patient every 8 to 12 hours for skin reddening and any early signs of tissue viability problems. Discontinue treatment according to clinical judgment.
- Compression therapy may contribute to circulatory failure if excess inflation pressure is applied or if patient has peripheral vascular ischemic disease.
- Compression therapy may increase the risk for compartment syndrome or peripheral neuropathy.

Precautions

- Ensure proper sleeve positioning to lower the risk of pressure points on the limb.
- Use of anti-embolism stockings under compression devices may provide greater comfort to the patient.
- Ensure proper connections to the external pump controller.
- Ensure that tubing is not kinked or twisted as this could restrict airflow.
- Maximum inflation pressure should not exceed patient's diastolic pressure. Check for dorsalis pedis and posterior tibial pulses during maximal inflation.
- Do not elevate patient's feet above the level of the heart.
- Immediately remove sleeves if patient experiences numbness, tingling or leg pain.
- To minimize local air movement, turn sleeve cooling off when using sleeves in the operating room.
- If compression is interrupted for more than 30 minutes in patients at risk for deep venous complication, resume continuation of the compression therapy only after noninvasive reevaluation of the new situation.

Additional Precautions

Compression Sleeves Designed for Foot Application

- Place the inflatable bladder under the arch of foot.
- Inflate only after proper placement.
- Refrain from walking and weight bearing while wearing foot sleeves.
- Periodically check for impulse under arch of foot, fit and overall skin condition as well as skin condition under stockings or stockinettes.

Reprocessed Compression Sleeves

Adverse Reactions – None.

Directions for Use

1. Remove the device from the package.
2. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Return the device and packaging to Ascent Healthcare Solutions if it is not in acceptable condition for the procedure.
3. Prepare sleeve for correct positioning following the directions and symbols/icons on the inside of the sleeve or otherwise provided by the original equipment manufacturer.
4. Center patient's limb on the inside of the sleeve.
5. Before starting to wrap the garment around the leg, make sure the pump controller is in the OFF position.
6. Start by wrapping the side without a hook tape or fastener. Follow by wrapping the side with fasteners.
7. Wrap the sleeve snugly around the patient's limb with the inflatable bladder on the rear side of patient's extremities. Attach the hook/fastener securely to the sleeve, starting with the ankle of the patient's limb. Achieve a snug and secure, but not too tight, fit around all sections of the patient's limb.
8. If more than one limb is to receive treatment, repeat the above steps on the other side.
9. In the case of single leg application, refer to the *Quick Reference Chart Of Compression Therapy Settings* contained within this booklet.
10. Do not position the sleeve such that the tubing can form pressure points on the patient's limb. If a patient will be placed in certain surgical positions like kneeling or similar positions, rotation of the sleeve with the tubing facing away from the patient will prevent pressure points.
11. Before attaching the sleeve to the air tubing, make sure the tubing is not kinked or twisted.
12. Attach the air tubing to the pump. Push the connectors together firmly to properly engage. To uncouple the connectors, firmly pull them apart.
13. Adjust the pump pressure to the recommended pressure setting for the sleeve in use, unless otherwise directed by the physician.
14. Turn the control unit ON after the tubing is correctly attached to the sleeve and the control unit.
15. Depress the sleeve-cooling button, if cooling is desired.
16. Device is intended for use during a single patient procedure.

Additional Directions for Use

Compression Sleeves Designed for Foot Application

1. Apply stocking or stockinette over foot and ankle and smooth any wrinkles.
2. Place the inflatable bladder under the arch of the foot.
3. Close the fastener over the top of the foot. Next bring the rear strap around the heel and close the fastener.
4. Position the foot below heart level during pump operation for best results.

Quick Reference Chart of Compression Therapy Settings

| | Compatible Pump Models | Pressure in mmHg | Timing in Seconds | Single Leg Application |
|--------------------------------------|---|--|------------------------------------|---|
| Healthcare Service and Supply | Alternative Leg Pressure® ALP 501 | 40-120 Target: 40 mmHg suggested | Inflation: 12 Deflation: 48 | Leave unused air outlet free. |
| Huntleigh Healthcare | Huntleigh® Flowtron® AC500 and AC550 | 26-60 Target: 40 mmHg suggested | Inflation: 12 Deflation 48 | Leave unused air outlet free. |
| Kendall® Impad™ Series | Kendall® AV5000 | 60-200 | Inflation: 1 or 3 Deflation: 20 | Independent controls for each limb. |
| Kendall® SCD™ Series | Kendall® 5315, 5320, 5325, 6325, 7325 | 35-55 | Inflation: 11 Deflation: 60 | Attach unused sleeve to air outlet connector. |
| Venodyne® | Venodyne® 510 | 38-52 | Inflation: 12 Deflation: 48 | Attach unused sleeve to air outlet connector. |
| Aircast® VenaFlow® | Venaflow® 30A, 30AXL, 30AXXL | 45-140 Target: 45-52 | Inflation: 6 Deflation: 54 | Attach unused sleeve or cuff to air outlet connector. |

Reprocessed Compression Sleeves

Quick Reference Chart of Compression Therapy Settings (Continued)

| | Compatible Pump Models | Pressure in mmHg | Timing in Seconds | Single Leg Application |
|--|--|--|---|------------------------|
| AlbaHealth | PAS [®] II Pulsatile Anti-Embolism System 022000 and 023000 | 35-95 Target: 65 | Inflation: 20 Deflation: 60 | NA |
| KCI | KCI 2110 (for sleeve models 112491, 112492, 112497) KCI 2600 (for sleeve models 112453, 112452) KCI PlexiPulse [®] (for sleeve models 235342, 235343, U40010) | 2110 = 45 2600 = 30-50 PlexiPulse [®] = 140-180 | 2110 = Inflation : 15 Deflation: 45 2600 = Inflation: 30 Deflation: 30 PlexiPulse = Inflation: 20 Deflation: 60 | NA |
| Hill-Rom ActiveCare | ActiveCare DVT System | Calf Cuffs: 50 Thigh Cuffs: 50 Foot Cuffs: 130 | <u>Thigh</u> Inflation: 30-43 Deflation: 60 <u>Calf</u> Inflation: 30-38 Deflation: 60 <u>Foot</u> Inflation: 15-23 Deflation: 30 <u>Calf-Foot</u> Inflation: Calf: 0-8, Foot: 20-28 & 40-48 Deflation: Calf: 60 Foot: 20, 40,60 | NA |
| Kendall SCD Express[™] | SCD EXPRESS Compression System | Leg Sleeves: 45 Foot Cuffs: 130 | Leg Sleeves: 11 Seconds Compression Foot Cuffs: 5 Seconds Compression Decompression time based upon Vascular Refill Detection measurement | NA |

Reprocessed Compression Sleeves

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