Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed Compression Sleeves Exposed to Vaporized Hydrogen Peroxide (VHP)

Reprocessed Device for Single Use

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

- NON-STERILE
- NOT MADE WITH NATURAL RUBBER LATEX

Explanation of Symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
	ISO 15223-1 Clause 5.1.3	2497	Manufacturing Date (Reprocessing Date)	Indicates the date which the medical device is manufactured
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Clause 5.2.7	2609	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.

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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
- Any pain or numbness
- Pulmonary embolism or edema
- Arterial occlusion
- 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.

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.

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 Stryker Sustainability 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 Original Equipment Manufacturer Operation Manual for Compression Therapy Settings.
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
- Apply stocking or stockinette over foot and ankle and smooth any wrinkles.
- Place the inflatable bladder under the arch of the foot.
- Close the fastener over the top of the foot. Next bring the rear strap around the heel and close the fastener.
- 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**
Currie Medical Specialties, Inc.	Alternative Leg Pressure® ALP 501	40-120 Target: 40 mmHg suggested	Inflation: 12 Deflation: 48	Leave unused air outlet free.
ArjoHuntleigh AB	Huntleigh® Flowtron®	26-60 Target: 40 mmHg suggested	Inflation: 12 Deflation 48	Leave unused air outlet free.
Kendall® Impad™ Series	Kendall® AV5000 and AV6060	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.
Medline	Vaso-Force™ annd Hemo-Force™	40-80 Target: 40	Inflation: 12 Deflation: 48	NA
KCI	KCI 2600 and KCI PlexiPulse®	2600 = 30-50 PlexiPulse® = 140-180	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	Thigh Inflation: 30-43 Deflation: 60 Calf Inflation: 30-38 Deflation: 60 Foot Inflation: 15-23 Deflation: 30 Calf-Foot 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

*Refer to OEM literature for guidance

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

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This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.