

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Compression Sleeves**  
**Manufactured by SterilMed, Inc.**  
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**Maple Grove, MN 55369**  
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**www.SterilMed.com**

**Caution: Federal law restricts this device to sale by or on the order of a physician.**

## INDICATIONS FOR USE

These devices are reprocessed compression sleeves from various original equipment manufacturers (OEM). Compression sleeves are designed to provide external intermittent or sequential limb compression to artificially imitate the pumping action of the lower limbs to prevent deep vein thrombosis; enhance venous and arterial circulation; and reduce lower limb pain and swelling.

Each OEM provided an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

## DEVICE DESCRIPTIONS

Reprocessed Compression Sleeves are inflatable devices that are fitted to a patient's foot and/or leg. They are connected to a separate pneumatic compressor providing intermittent or sequential pressure. When the sleeve compresses, the veins collapse, forcing blood to flow. When pressure is reduced, the sleeve deflates, allowing the veins to fill with blood. The cycle is then repeated.

These compression sleeves are garments that contain either single or multiple inflatable bladders and fit onto a patient's leg and/or foot. These garments come in foot, knee, and thigh length. They are comprised of plastic or cloth covered plastic, and are connected to a separate pneumatic compressor, which provides either intermittent or sequential pressure.

Devices are reprocessed under contract with the health institution that previously used the device. The devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

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These compression sleeves have been cleaned, evaluated for continued integrity, and packaged prior to use. These devices were shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times reprocessed .

**This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.**

## **CONTRAINDICATIONS**

1. Any local limb condition in which compression sleeves would interfere, such as:
  - a. Dermatitis,
  - b. Vein ligation (immediate post-operative),
  - c. Gangrene,
  - d. Recent skin graft.
2. Severe arteriosclerosis or other ischemic vascular disease,
3. Massive edema of limbs,
4. Extreme deformity of limbs,
5. Suspected pre-existing deep venous thrombosis,
6. Conditions where an increase of fluid to the heart may be detrimental,
7. Congestive Heart Failure,
8. Thrombosis,
9. Phlebitis,
10. Pulmonary embolism,
11. Pulmonary edema,
12. Infected or insensitive extremity.

## **WARNINGS AND PRECAUTIONS**

SterilMed compression sleeves are reprocessed for a single use only and must be returned for reprocessing prior to another use.

1. The user of the device should have adequate training and a thorough understanding of the use and applications of compression sleeves.
2. The device and packaging should be inspected prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Verify appropriate compatibility of all equipment and accessories prior to use.
4. Proper application and connection to the pump is essential.
5. Kinked or twisted tubing may restrict airflow.
6. The compression device should be removed if the patient experiences tingling, numbness or pain.
7. Interruption of external pneumatic compression for a substantial length of time is discouraged.

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8. The compression sleeve can be an explosion hazard. Do not use in the presence of flammable anesthetics.
9. Check regularly for patient discomfort and tenderness.
10. Check for skin irritation and use additional padding according to clinical judgment.
11. Special attention, including additional padding and checking every shift change, should be given to patients with poor circulation, fragile skin, insensitive extremities, diabetics and those who may be predisposed to tissue viability problems, including those receiving anticoagulation therapy.
12. Minimize pressure effects by reducing the impulse pressure and setting the impulse duration to short. Check for skin reddening, and any other early signs of pressure effects, which may lead to tissue viability problems and use additional padding or discontinue treatment according to clinical judgment.
13. Do not attempt to repair or replace broken tubing connectors as hazardous inflation of the sleeves may occur.
14. Verify all appropriate accessories/equipment and settings to be used with compression sleeves.

If Using a Cast Pad:

15. The cast inflation pad must be placed directly under the arch of the foot.
16. Do not inflate cast pad until the cast is fully hardened.
17. Check that the impulse is felt directly under the arch of the foot. If not, adjust the inflation accordingly.

**DIRECTIONS FOR USE**

1. Remove the garment(s) from the bag. The garment may be used on either extremity.
2. Unfold the garment and position the garment so that it is behind or under the calf or thigh, and the tubing connector is located near the ankle. For foot garment, place inflatable portion under the arch for the foot.
3. Snugly wrap the garment around the patient's limb making sure that the inflatable portion is directly behind the calf or thigh, or under arch of foot, and fasten. The sleeve should fit securely but not tightly around the limb. The foot garment fastens over the top of the foot.
4. Repeat the procedure for the other limb.
5. If only one garment is to be used, leave the other pump connector free.
6. Attach the garments firmly to the pump tubing by the clicking together the mating snap connectors. Make certain that the connectors are fastened securely.
7. Plug the pump into a nearby electrical outlet.
8. Adjust the pump pressure to the recommended pressure setting (generally 35-55 mmHg) unless otherwise specified by a physician.
9. Use the on/off switch on the pump to turn the pump on.

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## **POTENTIAL ADVERSE EVENTS**

The following potential risks may be associated with the use of compression sleeves. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Pressure sores, ulcers
2. Pain
3. Allergic reaction
4. Blisters
5. Burning
6. Swelling
7. Profuse perspiration
8. Rash
9. Redness
10. Skin discoloration
11. Itching

## **GENERAL INSTRUCTIONS AND INFORMATION**

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage. The manufacturer packaged an Instruction for Use document with the original device, and the health institution that wishes the device to be reprocessed should retain this original document.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to those physicians and/or staff trained in use of this device and associated equipment.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

## **METHODS TO TEST REPROCESSED DEVICES**

Devices have been tested to demonstrate biocompatibility following reprocessing. Validated methods are used for cleaning and packaging. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

*Instructions for Use can be found at [www.SterilMed.com](http://www.SterilMed.com). Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.*

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