

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Femoral Compression Device**  
**Manufactured by SterilMed, Inc.**  
**11400 73<sup>rd</sup> Avenue North**  
**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

This device is a reprocessed femoral compression device from an original equipment manufacturer (OEM) that is intended for use in the compression of the femoral artery or vein after catheterization.

The OEM packaged 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 DESCRIPTION

The device consists of an arch with a sterile pneumatic pressure dome and a connection tubing and belt. The device is applied on the patient with the dome over the femoral artery or vein and the belt around the patient. The user controls the inflation of the dome by increasing or decreasing the pressure with a connected, manual pump (a Luer Adapter is included to utilize many non-Femostop pump/hand aneroids). The dome applies a mechanical pressure over the spot where there is bleeding, while the arch and belt absorb and evenly distribute the opposite force from the dome.

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.

Reprocessed femoral compressor devices have been cleaned, evaluated for continued integrity, and resterilized 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 and ensure the number of times reprocessed.

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**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. Patients with severe peripheral vascular disease may develop deep vein thrombus with use of this device.
2. Damage may be caused to femoral artery grafts or vein grafts when using this device.

## **WARNINGS AND PRECAUTIONS**

1. The user of the device should have adequate training and a thorough understanding of the use and applications of this product.
2. SterilMed's femoral compression device contains a compression arch with pneumatic pressure bubble, pressure tubing and belt. The FemoStop™ Pump/hand aneroid may be retained at the facility for use with the SterilMed device. Other available pumps/hand aneroids may be suitable for this application.
3. Inspect the device carefully prior to use to verify that all parts are present and undamaged. If the device appears damaged or the package/product appears compromised, do not use.
4. Do not leave the artery completely blocked for more than 2-3 minutes.
5. The device should only be used by or under the supervision of physicians trained in femoral artery or vein compression procedures.
6. Use of the device is not intended to replace careful monitoring of the patient. The patient should be monitored frequently while the device is in use.
7. For successful compression, the device must be snugly secured around the patient's hips before pressure is applied. This device should not be used on very large patients where the belt appears too short to allow for proper compression.
8. Carefully tighten the belt and ensure that the hard plastic rim around the pressure dome is not causing undue pressure on the patient's tissue.
9. Do not leave the device on the patient for inappropriately long compressions as tissue damage may be produced. If longer compressions are necessary, briefly interrupt compression at least every three hours.
10. The initial inflation pressure should be 10-20 mm Hg above the systolic pressure or slightly higher as necessary to control bleeding.
11. Keep pressure low while removing the sheath so that damage to the sheath is avoided and milking of the sheath does not occur.
12. After sheaths are removed, pressures higher than the initial pressure may be required to control the bleeding. Exceeding pressures above 200 mm Hg may indicate the need to secure the belt more snugly.
13. As pressure is reduced, be sure skin folds do not pull up into the dome folds. Gentle pressure on the skin around the dome will stretch the skin folds and aid in removing it from the dome folds.

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## DIRECTIONS FOR USE

1. Prior to applying the device, place the belt around the patient's hips so it is equally extending on both sides and in line with the puncture site.
2. Examine the puncture site for any preexisting hematomas.
3. Note patient's current blood pressure and initially inflate dome to a pressure of 10-20 mm Hg above the systolic pressure.
4. Being careful not to contaminate the surface of the pressure bubble, place the pressure arch on the patient with the pressure bubble directly over the puncture site. NOTE: the exact position of the dome in relation to the puncture site will vary depending on angle of insertion of sheath into vessel and thickness of patient's tissue.
5. Place belt ends through the belt locks on each side of the pressure arch. Be sure to center the pressure bubble over the puncture site while tightening the belt and have the arch lying level and straight across the groin area.
6. Attach the connecting tubing to the pump making sure the control knob is closed.
7. Prior to inflating the dome, pull back slightly on the sheaths so that the hubs are not under the dome.
8. Begin to inflate the dome to 20 or 30 mm Hg while simultaneously removing the *venous* sheath. Add additional pressure as needed to control bleeding.
9. Continue to inflate the device while withdrawing the *arterial* sheath. The initial inflation pressure should be 10-20 mm Hg above the systolic pressure, or slightly higher as necessary to control bleeding. NOTE: The sheath should be completely removed in the 60-80 mm Hg range. Exceeding pressures above 200 mm Hg may indicate the need to secure the belt more snugly.
10. When the sheath is fully removed, increase dome pressure to a point that achieves hemostasis, maintaining initial hemostasis pressure for 1-2 minutes.
11. Once hemostasis is achieved lower the dome pressure until a pedal pulse is palpable, extremity color is good and hemostasis is maintained.
12. When removing the device, gradually lower the pressure by one-half, as long as hemostasis is maintained, and observe for 2-3 minutes. Continue deflating in this manner till the dome is completely deflated.
13. Carefully loosen the belt, but leave in place. Gently lift the dome and observe the puncture area.
14. If bleeding occurs, quickly reposition and recompress the site. If complete hemostasis has been established remove the device according to facility procedure.

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## **POTENTIAL ADVERSE EVENTS**

The following potential risks may be associated with femoral compressor placement. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Bleed-back with loss of pressure
2. Femoral nerve palsy
3. Nerve and/or tissue damage
4. Blood clots
5. Skin redness
6. Blistering
7. Bruising
8. Clot embolization during removal of catheter or sheath
9. Ecchymosis
10. Infection
11. Necrosis
12. Numbness
13. Obstruction of vascular grafts
14. Pressure injury to nerves

## **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 or sterility compromise.

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

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 as well as achievement of sterility. Validated methods are used for cleaning, packaging, and routine sterilization. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

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*\* Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:*

*\* Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.*

*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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