

Reprocessed by









Instructions for Use Reprocessed Femoral Compression Device

Reprocessed Device for Single Use

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

- **STERILE**
- **LATEX FREE**

Explanation of Icons

	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
	Ascent Product Code
	Do Not Reuse
	See Instructions For Use

Reprocessed Femoral Compression Device

Device Description

A femoral compression device is used for femoral artery punctures following vessel cannulation and allows sustained flow to distal extremity.

Ascent supplies the plastic arch with pneumatic pressure dome and tubing (sterile) and the belt (non-sterile). The reusable RADl Pump/Manometer is not supplied or reprocessed by Ascent. While reprocessed devices may contain labeling that may be trademarked by RADl or Bard USCl, Ascent assumes sole responsibility for safety and effectiveness of the product.

Indications for Use

This compression device is indicated for the compression of the femoral artery or vein following catheterization.

Contraindications for Use

Femoral compression presents a significant risk for deep vein thrombosis in patients with severe peripheral vascular disease. Femoral artery or vein grafts are also at significant risk for damage with use of this device.

Warnings

- Prior to use, read and follow instructions of the FemoStop System User Manual.
- The device should fit snugly around the hips before pressure is applied. The belt may be too short for patients with wide hips.
- Tighten the belt cautiously so that the hard plastic rim around the pressure dome does not make a forceful contact with patient tissue.
- To control bleeding, initial inflation of the device must be at least 10-20 mmHg above systolic pressure. Higher pressure may be necessary once the sheaths are removed. Pressure > 200 mmHg may indicate that the belt requires tightening.
- Avoid extended occlusion of the vessel. The artery should not be completely blocked for more than 2-3 minutes.
- Prolonged compressions can result in tissue damage. Compression therapy should be interrupted and surrounding tissues inspected at least every 3 hours.

Femoral compression may result in clot embolization during removal of the catheter, blistering and/or infection of the skin, tissue necrosis, obstruction of vascular grafts, and neural compression injury with subsequent sensory and motor deficits.

Precautions

- Femoral compression should only be performed by physicians trained in the procedure.
- Femoral compression devices are never intended to replace careful and rigorous monitoring of the patient. Frequent and deliberate monitoring of the patient is necessary during normal use.
- Prior to use, check that the sterile packaging is intact.
- Low pressure should be maintained while removing the sheath to avoid a 'milking' effect or damage to the sheath. Slight bleeding at the site during sheath removal may be acceptable.
- When releasing pressure, gently press down on the skin around the dome and stretch the skin folds slightly to ensure they do not pull up into the dome fold.
- Periodic calibration of the FemoStop Pump to an accuracy of +/- 6 mmHg is recommended.

Potential Adverse Events

- Tissue necrosis
- Blistering of the skin/skin abrasion
- Compression injuries to nerves with subsequent sensory and motor deficits
- Femoral artery and/or vein thrombosis
- Embolization
- Bleeding or hematoma
- Arterio-venous fistula or pseudoaneurysm may result from the use of this device
- Acute distension or rupture of a pseudoaneurysm during compression repair

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Carefully examine the puncture site area for any pre-existing hematoma. Fitting the dome on larger patients may displace fatty tissue which falsely appears to be a developing hematoma. Note patient's blood pressure.
3. Before removing the sheath, place the belt under and around patient hips. Pull the belt an equal length up each thigh so that the ends are directly opposite each other and in line with the sites of puncture.
4. Remove the plastic arch from the pouch and position its dome over the puncture site, taking care to preserve sterility of the dome area. Withdraw introducer hubs so as to just clear the rim of the dome (about 1 inch).

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5. CENTER THE DOME DIRECTLY OVER THE ARTERIAL PUNCTURE, which will vary depending on angle of insertion of the introducer sheath and distance from skin to artery (typically about 1 cm above and 1 cm medial to the surface skin incisions). Sterile dressing materials such as sterile gauze, wound bandage, or abdominal pads may be used and placed between the femoral compression device dome and the patient's puncture site during use.
6. Pass the strap through either end of the sidearm locks by fully compressing the lever. The strap should be adjusted to a snug but comfortable fit, with the arch lying level and squarely across the groin area.
7. Tighten THE BELT cautiously, so that hard plastic rim does not make forceful contact with patient tissues. Successful femoral compression depends upon a snug fit around the hips prior to pressurizing the dome.
8. Attach the radi manometer securely to the dome pressure line.
Close the manometer by rotating its control knob fully clockwise.
9. REMOVE THE VENOUS SHEATH while simultaneously inflating the dome to 20 to 30 mmHg. Augment the pressure as necessary to control bleeding.
10. REMOVE THE ARTERIAL SHEATH, while continuing to inflate the dome. Pressure should be maintained at 10-20 mmHg above systolic pressure, or higher as necessary to maintain hemostasis. The sheath should be removed completely (typically at 60-80 mmHg) by the time initial pressure is reached. Pressure > 200 mmHg may indicate the belt needs to be tightened.
11. Monitor Hemostasis and dome pressure carefully during femoral compression. In particular, compliance of the dome may change during the initial minutes of using the device and cause a slight pressure drop. Augment pressure as needed in order to control bleeding and maintain hemostasis.
12. Avoid extended occlusion of the vessel. Maintain the initial hemostatic pressure for 1-2 minutes and then open the manometer slightly (counterclockwise) to lower the pressure. Control bleeding while also looking for a good pedal pulse and foot color.
13. WHENEVER REDUCING PRESSURE, stretch the skin folds around the dome site to ensure that the skin folds do not pull up into the dome folds.
14. Tissue damage can occur with prolonged compression. Discontinue therapy and inspect tissues at least once every three hours.
15. DISCONTINUE COMPRESSION by gradually lowering pressure by half and observe the puncture site for several minutes while continuing to monitor hemostasis. Repeat this step until dome is fully deflated.
16. Inspect the puncture site by loosening the belt (on the puncture side) without detaching it from the arm. Lift dome gently off to visualize the puncture and recompress as necessary.
17. Remove the arch and belt once hemostasis is established and dress the wound as per standard hospital procedure. The belt may be discarded.

Returning the Compression Device to Ascent for Reprocessing

- Hospital policies regarding protective clothing and bloodborne pathogens exposure should be followed for handling of all contaminated devices.
- DO NOT WIPE THE INFLATION DOME WITH ALCOHOL, SALINE, WATER OR DISINFECTANTS, as this can damage the device.
- Gently coil the tubing to avoid crimping. Wrap the belt around the sharp edges of the arch to prevent them from coming in contact with the inflation dome.
- Place the device in the Ascent collection container.
- To prevent damage to the product during shipping, Do not overpack.
- When the container is at most $\frac{3}{4}$ full, place it in the pre-addressed carton provided by Ascent. Seal the carton and deliver it to the shipping department.

FemoStop is a registered trademark of RADI Medical Systems AB.
Bard and USCI are registered trademarks of C.R. Bard, Inc.

Reprocessed Femoral Compression Device

Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. 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.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then 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.