DESCRIPTION
This combination of Femoral Femoral Compression System consists of an arch with a sterile pneumatic pressure dome, an integrated pump with a manometer and a belt and is called Femostop Gold Femoral Compression System. The pressure dome is placed over the vessel puncture site in the groin. The belt is placed around the patient. The dome applies mechanical pressure over the vessel puncture site to induce hemostasis. The pressure of the dome is controlled by the integrated pump and the manometer. The arch and the belt provide counter pressure for the dome.

INDICATION FOR USE
Femoral Femoral Compression System is indicated for use in the compression of the femoral artery or vein after vessel cannulation and in ultrasound-guided compression repair of a pseudoaneurysm at the femoral artery or vein.

CONTRAINDICATIONS
- Severe peripheral vascular disease due to the risk of arterial thrombosis.
- Critical limb ischemia.
- Oozing skin necroses and/or infection.
- Bowing of the femoral artery or vein.
- The inability to adequately compress due to e.g. existing very large hematomas, excessive pain or overlying skin changes.
- Patients not suitable for compression of their femoral artery due to leg or femoral arterial narrowing/ligation.
- Femoral arterial graft or vein graft due to the risk of damage.
- Ultrasound-guided compression repair of infected femoral pseudoaneurysms.

ADVERSE EVENTS
Possible adverse effects that may result from the use of this device include but are not limited to:
- Tissue necrosis.
- Blistering.
- Bleeding.
- Ultrasound-guided compression repair of a pseudoaneurysm during compression repair.

WARNINGs
- For one time use only. Do not reuse or reprocess. Do not use if the original sterile package is not intact. Inspect the package carefully prior to use to verify that all parts are present and undamaged.
- Avoid exposing the pump to any liquid.
- Ensure that the pinch clamp is open when increasing or decreasing the pressure.
- Ensure that the control knob on the pump is closed when increasing the pressure and open when decreasing the pressure.
- Cases should be performed by physicians and/or nurses trained in femoral compression.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may be produced.
- A brief interruption at least every three hours of pressure is recommended during long compression periods (replace compression using Femostop Femoral Compression System with manual compression during this break to limit new flow into the pseudoaneurysm).
- Inappropriately long compression and/or reinsertion may increase the risk for thrombosis or embolization which could lead to patient injury or death.

PRECAUTIONS
- Femoral Femoral Compression System should only be used for ultrasound-guided compression repair of a pseudoaneurysm in the femoral artery, by physicians trained in the treatment of pseudoaneurysms.
- Remove the venous sheath from the skin overlying the pseudoaneurysm. As the skin will heal and fibrosis may cause the pseudoaneurysm to recede.
- If an error code appears on the display (E01, E02, E03, etc.) an error has occurred. Replace Femostop Femoral Compression System with a new one. See table 1 for more information.
- Caution: The pump software will automatically shut down 72 hours after activation and will show an error code if any attempts to nacivate. If an error code shows or the display goes blank before or during use, replace the device with a new unit.
- Do not apply pressure to a femoral artery stent due to risk of damage.

ADDITIONAL WARNINGS AND PRECAUTIONS FOR ULTRASOUND-GUIDED COMPRESSION REPAIR OF A PSEUDOANEURYSM IN THE FEMORAL ARTERY
- Avoid releasing pressure suddenly to reduce any risk of flushing thrombotic material into the artery.
- Release of thrombotic material may result in embolization which could lead to patient injury.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may be produced.
- A brief interruption at least every three hours of pressure is recommended during long compression periods (replace compression using Femostop Femoral Compression System with manual compression during this break to limit new flow into the pseudoaneurysm).
- Inappropriately long compression and/or reinsertion may increase the risk for thrombosis or embolization which could lead to patient injury or death.

DIRECTION FOR USE FOR COMPRESSION OF THE FEMORAL ARTERY OR VEIN AFTER VESSEL CANNULATION
Start by activating the pump. Prior to activating the pump, loosen the control knob to enable pulling the red battery release. Pull the red battery release contact in - the direction of the arrow (see figure). When “O” is shown on the display, the activation sequence is complete and the pump ready to use.

Note: If an error code appears on the display (E01, E02, E03, etc.) an error has occurred. Replace Femostop Femoral Compression System with a new one. See table 1 for more information.

Remember: The compression sequence is complete and the pump is ready to use.

Note: Ensure that the control knob on the pump is closed when increasing the pressure and open when decreasing the pressure.

To remove the arterial sheath, begin to increase pressure to 60 – 80mmHg. Withdraw the arterial sheath at about 30mmHg. Do not over-tighten the belt.

To remove the venous sheath, increase the pressure to 20 or 30mmHg (see figure). Remove the venous sheath at between 20-30mmHg. Add extra pressure if needed to control any bleeding.

When using the ultrasound transducer, confirm that it is possible to eliminate blood flow into the pseudoaneurysm. Do not apply pressure to the pseudoaneurysm. See table 1 for more information.

1. Check pedal pulse to determine what is a normal pedal pulse for the patient.
2. Administer appropriate anesthetics/analgesics.
3. Place the belt under and around the patient’s hips, so that it is pulled up equally on both sides and the belt is snug but comfortable fit around the patient (see figure 5). The arch should lie level and squarely across the groin area.
4. mattress the pseudoaneurysm, its neck and the femoral artery. Carefully examine these areas for the presence of flow.
5. Avoid releasing pressure suddenly to reduce any risk of flushing thrombotic material into the artery.
6. Release of thrombotic material may result in embolization which could lead to patient injury.

Note: If an error code shows or the display goes blank before or during use, replace the device with a new unit.

7. Palpate the entrance site of the sheath(s) at the femoral artery/vein and place the center of the dome over the puncture site (see figure 4). While removing the introducer hub, perform a quick check to ensure that the dome is level and squarely across the groin area.

Note: The specific position of the arterial puncture site relative to the skin incision will vary depending on the angle of insertion of the introducer sheath and the distance from the skin to the artery.

8. Thread the belt through the locks at either end of the arch by fully compressing the levers. Do not leave arterial compression belt completely for more than 3 minutes to prevent ischemia. Check pedal pulse periodically to confirm whether or not flow remains in the vessel.

9. Palpate the pseudoaneurysm, its neck and the femoral artery. With color Doppler try to locate the pseudoaneurysm, its neck and the femoral artery. Note: If an error code shows or the display goes blank before or during use, replace the device with a new unit.

10. Thread the belt through the locks at either end of the arch by fully compressing the levers. Do not leave arterial compression belt completely for more than 3 minutes to prevent ischemia. Check pedal pulse periodically to confirm whether or not flow remains in the vessel.

11. Thread the belt through the locks at either end of the arch by fully compressing the levers. Do not leave arterial compression belt completely for more than 3 minutes to prevent ischemia. Check pedal pulse periodically to confirm whether or not flow remains in the vessel.

12. Place belt under and around the patient’s hips, so that it is pulled up equally on both sides and the belt is snug but comfortable fit around the patient. The arch should lie level and squarely across the groin area.

Caution: Ensure that the clamp is open when increasing or decreasing the pressure.

To remove the venous sheath, increase the pressure to 20 or 30mmHg (see figure). Remove the venous sheath at between 20-30mmHg. Add extra pressure if needed to control any bleeding.

Caution: Ensure that the clamp is open when increasing or decreasing the pressure.

To remove the arterial sheath, begin to increase pressure to 60 – 80mmHg. Withdraw the arterial sheath at about 30mmHg. Do not over-tighten the belt.

Note: If an error code appears on the display (E01, E02, E03, etc.) an error has occurred. Replace Femostop Femoral Compression System with a new one. See table 1 for more information.

Note: If the puncture site oozes blood as pressure is reduced, raise the pressure slightly. If significant bleeding and/or infection.

13. Continue the maintenance pressure according to facility guidelines specified for the type of pseudoaneurysm.
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15. Remove the venous sheath at between 20-30mmHg. Add extra pressure if needed to control any bleeding.
16. Carefully loosen the belt on the puncture side of the patient (without totally removing it from the arch) and gently roll the dome off the puncture site. If completely blocking the patient, anticoagulant level, the interventional procedure performed, and the sheath French size...