TRANS RADIAL/ FEMORAL COMPRESSION DEVICE

1. PRODUCT DESCRIPTION:

The Seguro Trans Radial / Femoral Compression Device consist of the following components. These components may be packaged in a single pouch.

(1) Fastener with unilateral valve, tubing and inflatable balloon

(2) Colorless angio closure Band with transparent Balloon, having + shaped overall look. Four sides of pad have adhesive Pad.

(3) Air injection port vent tubing connected with balloon at one end and other end connected with unilateral valve.

(4) Pressure syringe

2. INTENDED USE:

Intended use of Trans Radial compression device

This product is an auxiliary device used for the compression of redial artery after Trans radial interventional procedure.

Intended use of Angie closure femoral compression device

It is pressure assisted devices are to assist for maintaining Hemostasis. The device is also indicated in the reduction of active compression time in femoral artery cannulation following diagnostic and interventional procedures

3. CONTRAINDICATIONS:

There are NO known contraindications for this device.

4. WARNING:

- This product is ETO sterilized and disposable for use. Do not re-sterilize or reuse.
- Do not use this device if the unit package or the product has been damaged or soiled.
- The device should be used immediately after opening the package and disposed of safely and properly after use.
- Do not inject air into any port other than the air injection port of this device. This could cause arterial or venous immobilization.
- Do not use the device for other purposes than to inflate the Trans Radial Compression and Angio Closure Femoral compression device. It is not designed for other purposes.
- The product can be inflated only by using the Trans Radial Compression and Angio Closure compression device. If other devices are used, adequate air compression cannot be achieved.
- Bleeding could occur if the adjustable fastener comes off during compression. Depending on the patient's wrist size and the way the device is applied, the adjustable fastener could come off. Fix the adjustable fastener in place with tape if necessary.
- Depending on the patient's condition and the degree of balloon pressure, and adverse event including artery occlusion, hypodermic hematoma, hemorrhage,

pail, or numbness may occur. Check the progress of the hemostasis and adjust the air pressure accordingly.

- Air injection volume and compression time may differ according to the patient's condition, the heparin volume, and the size of the puncture site. Check the puncture site and adjust accordingly.
- Do not inject more than 20mL of air. There is a possibility the device if this volume is exceeded
- Patient should not be left unattended while the device is in use.

Use in Special Patient Population: The Compress Trans Radial Compression or Angio Closure Femoral compression device is used for all ages of group.

5. PRECAUTIONS:

- The product is a disposable product.
- The product is a sterile product, do not use if package is damaged.
- The product has a shelf life of three years after sterilization and must be used within its shelf life.
- The product shall be stored in a cool, dry, clean and well-ventilated room free of corrosive gases.
- While using, be careful not to put excessive load on the balloon that could break it.
- Be careful that no foreign particles get into the air injection port when injection air. The air could leak.
- If there is itching or redness of the skin while compression, stop using and treat appropriately.
- At extremely low temperature, there is a possibility of damage due to decrease in resistance to shock.
- The device should be used immediately after opening the package and disposed of safely and properly after use.

6. SIDE EFFCET & CONTRAINDICATIONS:

Carefully read all instructions for use. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

7. PRODUCT INSTRUCTION:

Trans Radial Compression and Angio Closure Femoral compression are principally used for the compression hemostasis after percutaneous arterial interventional operations, and is mainly made of the medical high molecular materials that are commonly used globally such as polyurethane, polycarbonate, polyvinyl chloride etc. This product can apply mechanical pressure at the vessel puncture site in place of artificial hand compression hemostasis so as to make the patients more comfortable and reduce the workload of medical.

8. STRUCTURAL COMPOSITION OF THE PRODUCT:

This product is composed of inflatable balloon, unilateral valve and adjustable fastener and is used for radial artery. The structure is as follows:

9. OPERATION PROCEDURES:

- Withdraw the introducer sheath for 2-3 cm after procedure.
- Align the center Green mark of the compression device with the puncture site, and fix the fastener onto the Wrist for the tightness, it is the best to fix the compression device upon the wrist barely to move.
- Inject an appropriate volume of air into the balloon through the unilateral valve with the syringe in the package in order to make the balloon inflated (the nominal injection volume of air is 18mL and the maximal injection Volume of air is 20mL).
- Remove the sheath, and observe whether there is hemorrhage at the site of puncture. It there is hemorrhage, inject more air (the total volume should not exceed 20mL) until hemorrhage stops.
- Examine the hemostatic conditions, and adjust the air pressure with syringe.
- Note: If the fastener is released during use, hemorrhage may occur. The release of fastener is mainly related with the diameter of wrist and the manipulation of instrument.
- Before removing, confirm that bleeding has stopped.
- Note: This injection volume of air and compression time may vary with the conditions of patients, the dose heparin and the Z size of the site of puncture. Keep on observation on the site of puncture, make Corresponding adjustment, and avoid long time high pressure compression

10. MAIN PERFORMANCE INDICES:

Appearance: Transparent and smooth. Airproof: There should be no air leakage. Sterility: The product is sterilized by EO.

11. INDICATIONS:

This product is an auxiliary device used for the compression of radial artery after trans-radial interventional procedures.

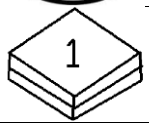
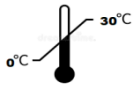
12. STORAGE:

- Storage temperature (10- 30 °C)
- Avoid Exposure to direct Sunlight or Heater.
- Keep the Product in a clean, organized cool and dry place

13. DISPOSAL:

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted hospital medical practice, and applicable local European and international disposal regulation.

Explanation of symbols as per MDD 93/42/EEC, ISO 15223-1:2021:

Sr. No.	Symbol	Meaning
1.		Symbol for "Reference number"
2.		Symbol for "Batch code"
3.		Symbol for "Date of manufacture"
4.		Symbol for "Use Before"
5.		Symbol for "Do not reuse"
6.		Symbol for" Manufacturer"
7.		Symbol for "Caution"
8.		Symbol for "Do Not use if package is damaged"
9.		Symbol for "Keep away from sunlight"
10.		Symbol for "Keep Dry"
11.		Symbol for Consult Instruction for Use
12.		Symbol for Do not Re-sterilize
13.		Symbol for Quantity
14.		Store at 0-30 ℃
15.		Non Pyrogenic

Warranty / Liability:

Although this product has been manufactured under carefully controlled quality conditions, Seguro Life Science has no control over the conditions under which this product is used. Seguro Life Science therefore disclaims all warranties both express and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Seguro Life Science shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Seguro Life Science to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular term held to be invalid.

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