

RESPENDIAL

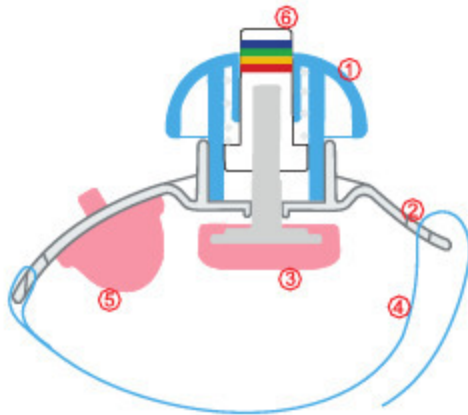
RESPENDIAL Radial Artery Compression Device Instruction for use



RESPENDIAL Radial Artery Compression Device

Instruction for use

EN



- ① Turn Cap
- ② Wrist Plate
- ③ Cushion
- ④ Band
- ⑤ Assistant locking cap
- ⑥ White marker
(reference pressure 90-150 mmHg)
- Blue marker
(reference pressure 125-185 mmHg)
- Green marker
(reference pressure 155-205 mmHg)
- Yellow marker
(reference pressure 175-215 mmHg)
- Red marker
(reference pressure 195-295 mmHg)

Indication: This is a compression device to assist hemostasis of the radial artery after a transradial procedure.

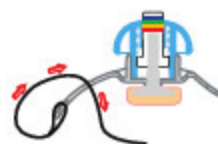
Precautions & Warnings

- This device is recommended for the Patients whose wrist circumferences are between 100mm to 240mm.
- During the operation, it is recommended that the medical assistants keep the patient's wrist straight. At the same time, the patient should avoid strenuous activity of the arm which is receiving treatment. After the procedure, the patient should refrain from bending his/her wrist for 2 hours and from moving the wrist for 4-6 hours, and the patient should keep the wrist at a suspended position.
- If the cushion pressure is too high, an adverse event may occur. The patient may experience artery occlusion, hypodermic hematoma, hemorrhage, pain, or numbness. The severity depends on the patient's condition. If above symptom occurs, please check the progress of the homeostasis and turn the turn cap to adjust the cushion pressure accordingly.
- Sterilization validity: 3 years
Exp. Date: see packaging.
- This device is designed to be used by an experienced physician or a trained medical staff.
- This device should be used immediately after opening the package. Do not turn the Turn Cap excessively in order to avoid stick fast or screw loose.
- Do not use this device if unit package or the device has been damaged or soiled.
Disposed of safely and properly as medical rubbish after use.
- Do not soak or wipe the device with agents containing organic solvents. Such agents may cause damage to the device.
- This device is sterilized with Ethylene Oxide. It is for single use only, please do not re-sterilize or re-use. otherwise, it may bring infection.
- If the package has been opened or the device has been damaged or soiled, please do not use this device.
- Avoid exposure to water, direct sunlight, extreme temperature, or high humidity during storage.

Introductions

Pre-Procedure

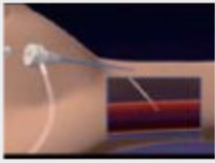
1. Clean and sterilize the puncture point and then wipe it dry with a piece of sterile gauze.
2. Open the package and take out the compression device.
3. Adjust the position of the band according to the circumference of the wrist:
 - For thin wrist (circumference from 100mm to 140 mm), adjust as right illustrations.
 - For normal or plump wrist (circumference from 140mm to 240 mm), no need for adjustment. Use it directly.



- ① Take down the assistant locking cap.



- ② Thread through the hole on the wrist plate according to the illustration, and then fasten it,



- A** Post operation:
Pull out of the sheath for 2-3cm, make sure there is no apparent vasospasm (otherwise you should make proper treatment first).



- B** Press the cushion **③** on the puncture site.
The orientation of the device is not same for being used on left or right wrist: the fixed end of the band should be at the same side as the little finger is. Put a sterile gauze under the cushion in summer to prevent skin adhesive or slip caused by sweatiness.



- C** Pull the band **④** through the wrist plate ensure that the top of the white marker **⑤** aligns at the same level with the turn cap **①**, fix the band.
The pressure is around 90 mmHg now.



- D** Turn the turn cap clockwise to the top of the 2nd green marker **⑥**, the Pressure is around 155 mmHg now. The relationship between the pressure and the marker is as following:

Green marker = 155 mmHg-205 mmHg

Red marker = 195 mmHg-295 mmHg



- E** Press both ends of the wrist plate to make it upwarped in the middle, pull out the sheath and then release the pate immediately so that the plate would contact the skin tightly. Adjust the turn cap to proper pressure to ensure hemostasis and a stable pulse rate.

- If there is an obvious bleeding, turn the turn cap clockwise until the bleeding stopped.
- If the patient feels numb or painful, turn the turn cap count-clockwise. But make sure there is no obvious bleeding.
- After above operation, check the radial artery and ulnar artery to ensure they have apparent pulse.

- F** The duration of hemostasis is uncertain for different patients, it depends on patients, physical condition, the volume of the injected heparin and the diameter of the sheath.

- G** According to the clinical state, after a proper period, the pressure should be released. Turn the turn cap half to one circle count-clockwise every 45-60 min after the first release. If there is a bleeding, re-adjust the cap to ensure the hemostasis.

- H** After a successful hemostasis, remove the device and protect the puncture point with sterile gauze for around 24 hours.



Consult instructions for use



Date of manufacture



Catalogue number



Single Use Only, Do not re-use



Lot Number



Expiration Date



Sterile, Ethylene Oxide



European Representative



Manufacturer