

SEAL-ONE® USER MANUAL

All-In-One Radial Compression Device

Cardiovascular



PEROUSE
MEDICAL



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▶ DESCRIPTION

SEAL-ONE

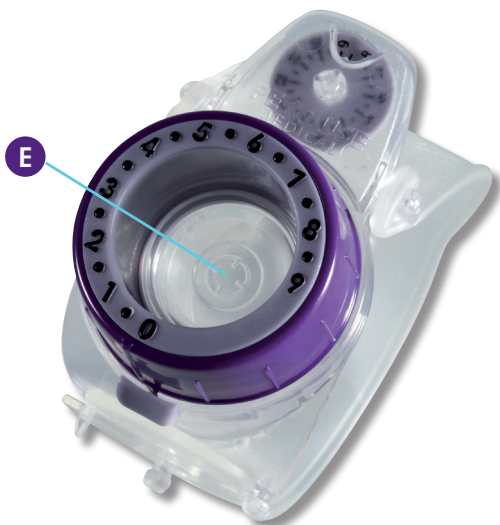
- The **Seal-One**® radial compression device is used to compress the puncture site following all minimally invasive radial approach procedures.

SEAL



- A** Compression – decompression scale
- B** Compression – decompression wheel
- C** Decompression safety button
- D** Time indicator
- E** Central landmark for the compression pad

- ONE

**REMARK**

The decompression wheel is for indicative purposes only and facilitates decompression management by the nursing staff.

The Seal-One® may be used on the right or left wrist.



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► COMPRESSION

SEAL-ONE

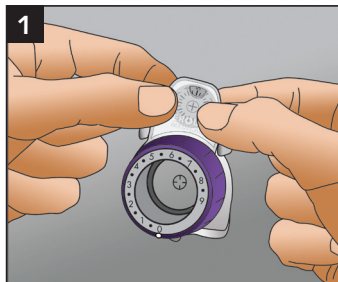
COMPRESSION

- Before positioning the **Seal-One**[®] on the patient wrist, check that the compression wheel is correctly set to 0 (on the compression scale).

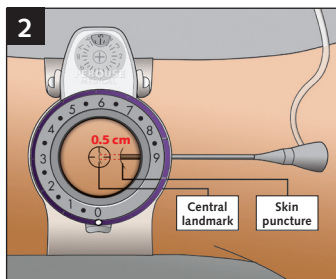
The patient should be instructed not to move the **Seal-One**[®] system nor modify the settings due to the risk of bleeding and bruising.

The patient should call the medical staff immediately if he/she experiences pain or bleeding.

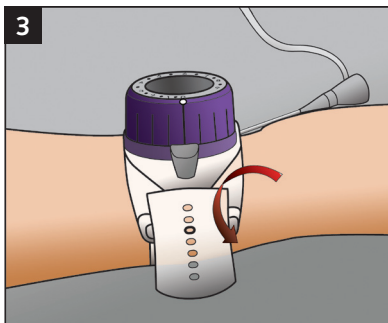
- Set the device placement time by turning the time indicator. Push the indicator backwards towards the transparent base to lock it **1**.



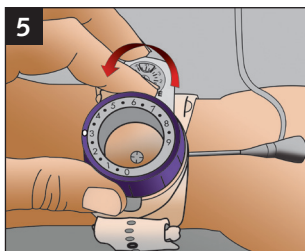
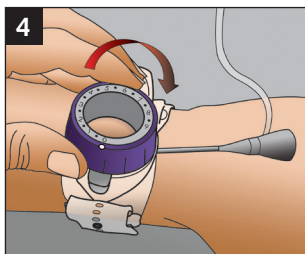
- Withdraw the introducer sheath approximately 2-3 cm.
- Position the **Seal-One®** ensuring that the central landmark is 0.5 cm proximal to the puncture site **2**.



- Adjust and fix the wrist strap. The wrist strap snug and safety clip must be on the practionner side. Clip the safety strap. The wrist strap may be folded back on itself if it is too long **3**.

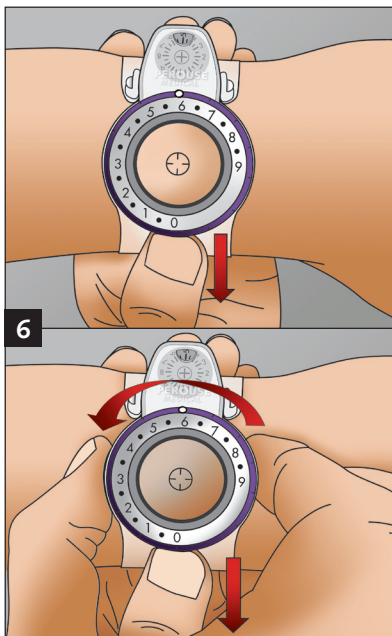


- Turn the compression wheel clockwise to initiate compression to level 3 **4**.
Check that the compression wheel is back-locked in position by turning it anti-clockwise until it locks **5**.
Remove the introducer sheath completely.
Increase the compression level until bleeding stops.

**REMARK**

If the back-locked position is inoperative, do not use the device.

- Decompress by pressing the safety button and turning the compression wheel simultaneously anti-clockwise **6**. Discontinue decompression once a drop of blood is visible. Compress again until bleeding stops. If a drop of blood is not visible, position the compression level at 3.



SEAL

- After positioning the **Seal-One**[®], check that the radial artery is not occluded by excessive compression from the device, using a Doppler or pulse oximeter. If so, reduce the compression level.

Under usual conditions of use the **Seal-One**[®] is designed only to compress the radial artery (the ulnar artery is not usually compressed and venous return is not blocked).

The compression levels and times may vary between patients depending on the dose of anticoagulants received and the diameter of the puncture site. Adjust the level and duration of pressure according to these different parameters.

- ONE

COMPRESSION





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▶ DECOMPRESSION

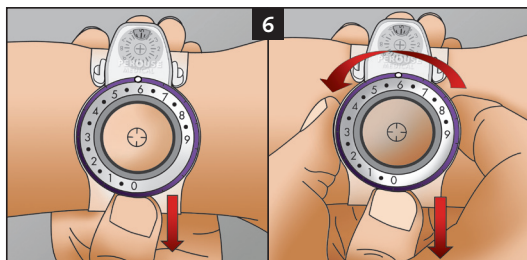
SEAL-ONE

- The artery is decompressed in steps.

After 30 minutes minimum, decompress by pressing the safety button and turning the compression wheel simultaneously anti-clockwise **6** to reduce compression (eg from level 6 to level 4)*.

After 15 minutes minimum without bleeding, reduce compression (eg from level 4 to level 2)*. Upon reaching the zero decompression level, wait for 15 minutes minimum and remove.

** If bleeding occurs, turn the compression wheel again on the clock-wise position until bleeding stops.*



Decompression time is patient dependent and varies according to co-morbidities, procedure duration, anticoagulation treatment and the size of the arterial puncture site.

WARNING

*The **Seal-One**® device should not be left in place for more than 5 hours without physician approval. Excessive compression may lead to arterial occlusion.*

- It is possible to write on the wrist strap with ballpoint pen or indelible felt pen, to indicate the times at which the device was checked and steps during decompression. The dedicated positions for this are shown by the following symbols at the ends of the wrist strap:



- Bleeding may occur when reducing the pressure. Readjust the compression level and wait before decompressing further.
- Before removing the device, ensure that no bleeding is present.

▶ WARNING

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

Re-use of the **Seal-One**[®] is strictly prohibited. If the product is reused its functionality would be entirely altered. In addition, the iatrogenic risk from inter-patient cross-transmission would be high.

The **Seal-One**[®] must be used by trained medical staff.

Do not leave the patient unsupervised when using the **Seal-One**[®].

Do not use the device if damaged or if it hasn't been properly adjusted to the wrist.

Do not contaminate the **Seal-One**[®] compression pad with blood before positioning the device.

Do not apply pressure to the upper part of the compression pad.

After use, dispose of product and packaging in accordance with hospital administrative and/or local government policy.



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▶ SIDE EFFECTS

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- Depending on the patient state and level of compression applied with the device, side-effects such as occlusion of the radial artery, hypodermal haematoma, haemorrhage, pain, or numbness may occur. Control bleeding and optimally adjust the level of compression as a result.

If the skin becomes itchy or red during compression, stop using the **Seal-One®** and treat appropriately.

The patient should be instructed not to move the **Seal-One®** system nor modify the settings due to the risk of bleeding and bruising. The patient should call the medical staff immediately if he/she experiences pain or bleeding.

▶ FEATURES

- Accessory free
- Compression targeting the radial artery
- Enhanced visibility of the puncture site
- Secured decompression
- Display of positioning time

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