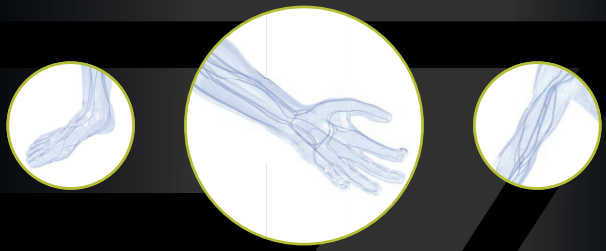


SIMPLIFY PATENT HEMOSTASIS

ZEPHYR™

VASCULAR COMPRESSION BAND

Procedure Guide

Cordis

ZEPHYR™

VASCULAR COMPRESSION BAND

ZEPHYR™ VCB DEPLOYMENT AND PATENT HEMOSTASIS

1. PREPARATION

- Use sterile or aseptic technique to remove the ZEPHYR™ Band from the pouch.
- Withdraw the sheath approximately 2-3cm out of the puncture site. Ensure the puncture site area is dry.

Note: Refer to institutional protocols for patient preparation pre-compression band application.

2. PLACEMENT

- Place the Strap (with balloon uninflated) around the wrist with the tube facing towards the patient (right wrist). For left wrist deployment, the tube faces away from the patient.
- Valve tubing can face either direction.

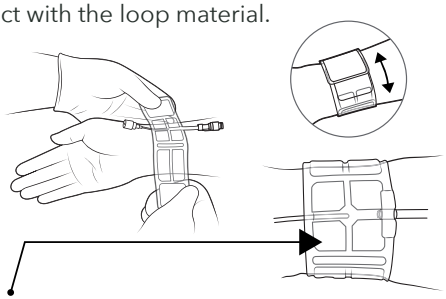
Recommend valve tubing is on the opposite side of sheath.

- Place balloon 'window' over sheath and puncture site.

The sheath and skin puncture site should be clearly visible under the balloon 'window'.

The transparent cross-hairs of the compression balloon must be facing up. The ZEPHYR™ VCB logo must be legible (not mirror-image).

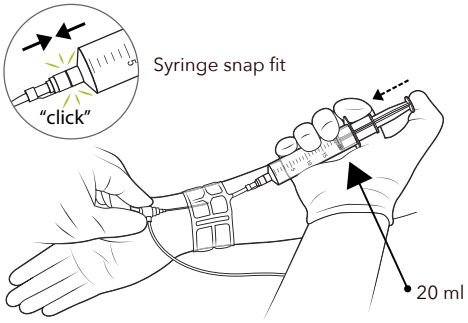
- Snugly fasten the device around the extremity by placing the hook material over the loop material and pressing. At least half of the hook material must be in contact with the loop material.



Puncture site should be generally centered under the balloon window

3. INITIAL BALLOON INFLATION

- Draw 20ml of air.
- Snap syringe nozzle into valve of balloon so that it 'clicks' into place
- Inject the air into the balloon and pull the sheath.
- Ensure no bleeding or oozing from puncture site.



4. ENSURE PATENCY

- Remove air until a flash of blood is observed.
- Immediately re-inflate with 2ml of air (or until bleeding stops).
- Assess distal radial perfusion to ensure Patent Hemostasis while occluding the ulnar artery proximal to the wrist.

  If patency is not observed, slowly remove air from balloon until patency is observed without puncture site oozing.

  Hold the syringe plunger continuously to prevent air from escaping suddenly.

5. COMPRESSION TIME

- Refer to institutional protocols for post-procedure radial artery hemostasis compression time.

ZEPHYR™ VCB ADJUSTMENT AND REMOVAL

1. ENSURE PATENCY

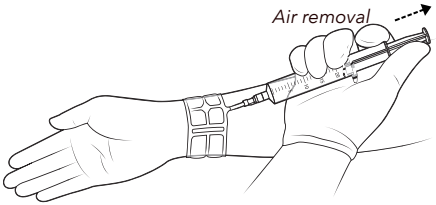
- Check to ensure vessel patency every 15 minutes starting with patient's arrival in recovery area.

Note: Refer to institutional protocols for post-procedure hemostasis.

2. COMPRESSION ADJUSTMENT

- In accordance with institutional protocol, compression may be reduced during the hemostasis period if no oozing at the puncture site.
- Control the syringe plunger when removing air from the balloon.

Note: if oozing or re-bleed occurs, re-inflate the balloon until bleeding stops. Check vessel patency.



3. REDUCING COMPRESSION

- At the end of the recommended compression time, slowly remove air from the balloon until all compression is removed according to institutional protocol.
- If bleeding is present, re-inflate balloon to restore Patent Hemostasis and re-check vessel patency. Wait 30 minutes and then repeat this step. (Step 3).

4. DEVICE REMOVAL

- Once all compression is released and hemostasis confirmed, gently separate the hook and loop fastener and palpate under the balloon to separate the strap from the skin.
- Carefully remove the ZEPHYR™ VCB from the puncture site, taking care not to disrupt the clot.
- Apply dressing and discard the device per institutional protocol.

5. COMPRESSION TIME

- Refer to institutional protocols for post-procedure radial artery hemostasis compression time[1].

1. The following suggested guidelines[2] for compression times apply to patients having sheaths sized 6F or smaller:
• For patients with prophylactic heparin onboard up to 5,000 units, device removal can commence 60 minutes following deployment.
• For patients with anticoagulation of more than 5,000 units of heparin, device removal can commence 90 minutes following deployment.
• Patients with IV platelet inhibitor drugs onboard, INR of >2, or who have uncontrolled hypertension may require longer hold times.

2. This is a guide only. Hospital protocols and physician instructions must be followed. The ZEPHYR Vascular Compression Band removal protocols should be consistent with needs of the provider(s) and patient. Air injection volume and compression time may differ according to the patient's condition, anticoagulation, and the size of the arteriotomy. Check the puncture site frequently and adjust accordingly.

For Healthcare Professionals Only.
Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, suggested procedure, warnings and precautions.
As part of its continuous product development policy, Cordis reserves the right to change product specifications without prior notification.
Please contact your Cordis representative for additional product availability information. ZEPHYR Band is manufactured by Advanced Vascular Dynamics and distributed by Cordis.

CE 2460

Cordis. GO BEYOND