

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® Band 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.

The ZEPHYR® Vascular Compression Band is indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or leg, including: radial, brachial, dorsalis pedis, or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis, and in anticoagulation therapy.

CAUTION: The ZEPHYR® Vascular Compression Band must be applied by a physician, nurse or technician experienced with vascular procedures. The patient must be checked regularly for arterial patency, bleeding, hematoma or thrombosis while ZEPHYR® Band is in use. The ZEPHYR® Band should be used only for hemostasis of a puncture site on a patient's limb. Sterile or aseptic technique should be used.

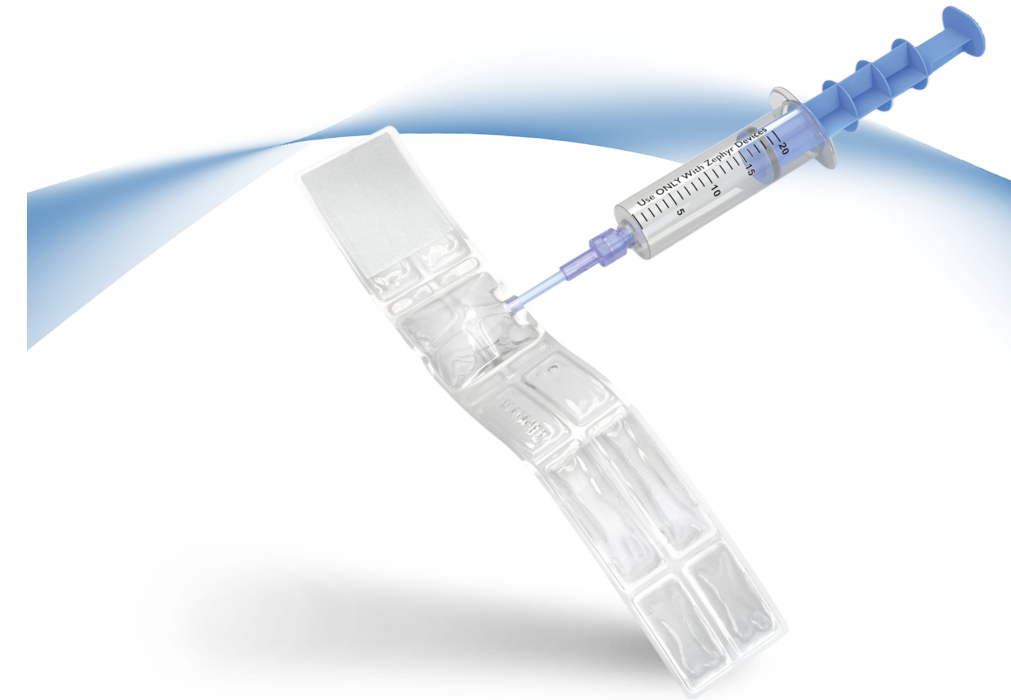
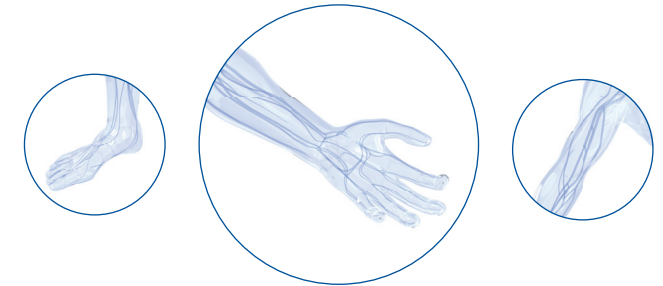
CONTRADICTIONS: Patients with infection or other serious skin diseases at the site of puncture and patients with an abnormal Allen test or radial pulse, or insufficient blood supply in the ulnar or radial arteries.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

IMPORTANT INFORMATION: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions. ZEPHYR® Vascular Compression Band is manufactured by Advanced Vascular Dynamics and distributed by Cordis. CORDIS and Cordis LOGO are trademarks of Cordis and may be registered in the US and/or in other countries. All other marks are the property of their respective owners.

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RADIAL PROCEDURE GUIDE



Simplify Patent Hemostasis

ZEPHYR® BAND 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.
- Valve tubing can face either direction.

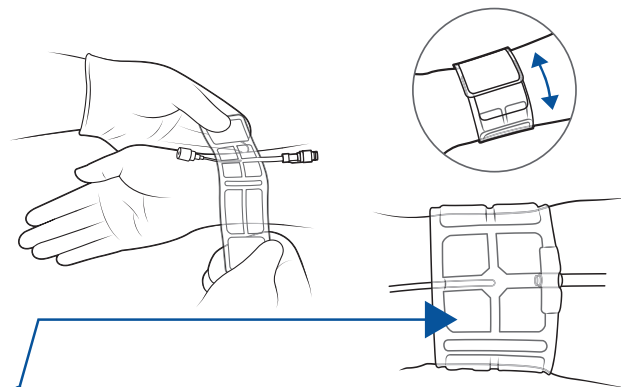
Recommend valve tubing is on the opposite side of sheath.

- 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® Band logo must be legible (not mirror-image).

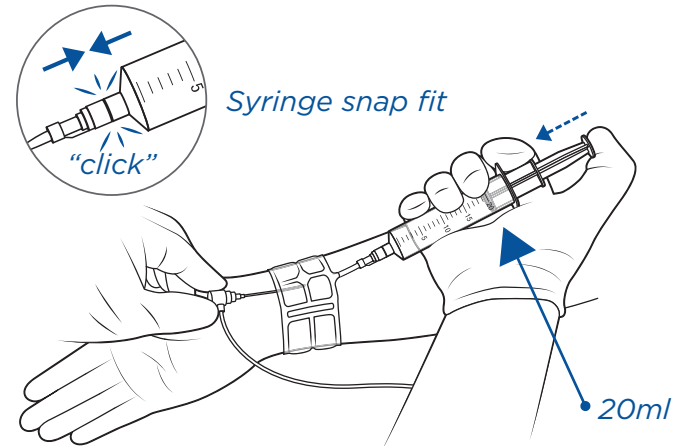
- Snugly fasten the device around the extremity by placing the hook material over the loop material and pressing. At least half of the hook material must be in contact with the loop material.



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. If using a standard luer syringe, rotate vs. snap.
- Inflate the balloon, pull the sheath, and titrate compression according to institutional protocol and the IFU.
- 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.

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ZEPHYR® BAND ADJUSTMENT AND REMOVAL

1. ENSURE PATENCY

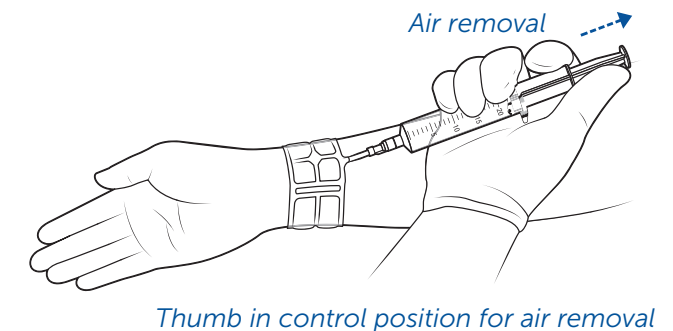
- Check to ensure vessel patency every 15 minutes starting with patient's arrival in recovery area.

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.

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).