DISCLAIMER:

- The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for institutional protocols or the physician's experience and judgment in treating any specific patient. All available data, including the patient's signs and symptoms and other diagnostic test results, should be considered before determining a specific treatment.
- The **ZEPHYR** VCB's compression force is designed to automatically decrease by up to 40% in 3 hours as observed in laboratory testing.

CAUTION:

- The **ZEPHYR** VCB 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 the **ZEPHYR** VCB is in use.
- The **ZEPHYR** VCB should be used only for hemostasis of a puncture site on a patient's limb. Sterile or aseptic technique should be used.

PRECAUTIONS

- Sterility of package contents is not guaranteed if the individual packages are previously damaged or opened. Only new, sterile **ZEPHYR** VCBs taken from factory-sealed pouches, should be used.
- The **ZEPHYR** VCB is a single-use, sterile device. Attempts to re-use or re-sterilize may result in device breakage or malfunction resulting in patient injury or infection. Do not use if the package has been opened or damaged.
- Do not use alcohol, disinfectants, or any other liquids with the **ZEPHYR** VCB or on the patient while the **ZEPHYR** VCB is being applied. The **ZEPHYR** VCB must be deployed onto a dry site.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- The **ZEPHYR** VCB deployment should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device.
- Use caution when applying compression with the **ZEPHYR** VCB, taking care not to overtighten it.
- Do not over-inflate the balloon. Over-inflation can result in balloon damage that compromises the performance of the **ZEPHYR** VCB.
- Only insert the nozzle of the syringe into the valve on the **ZEPHYR** VCB. **Do not insert the nozzle of the syringe into a Luer connector or valve on a sheath or any other device.**
- Do not inject any liquids into the **ZEPHYR** VCB balloon.
- Use caution if deploying the **ZEPHYR** VCB onto a patient with uncontrolled hypertension or systolic pressure of more than 180mmHg.
- When operating the syringe, control the plunger by pressing on the end at all times.
- Ensure correct placement, alignment and securement of the **ZEPHYR** VCB.
- Patients should not be left unattended while the **ZEPHYR** VCB is in use.
- Do not leave the **ZEPHYR** VCB on for inappropriately long periods of time as tissue damage may occur.
- Do not apply if the circumference of the wrist at the puncture site is too large or small, exceeding the size range of the **ZEPHYR** VCB.
- Instruct the patient not to touch or bump the **ZEPHYR** VCB or move their hand or wrist during compression.
- Monitor the patient during the compression period for bleeding, hematoma or thrombosis, and to ensure proper deployment and patent distal blood flow through the ulnar and radial arteries.

CONTRAINDICATIONS

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

Explanation of Symbols			
STERILE EO	Sterilized with ethylene oxide gas		Caution
	Do not resterilize		Consult instructions for use
	Do not re-use	n	n units per box
	Do not use if package is damaged	Rx Only	Caution: Federal (USA) law restricts this device to sale by or on order of a physician
	Keep dry		Manufacturer
	Keep away from sunlight		Distributed by

Advanced Vascular Dynamics
4252 SE International Way, #F
Milwaukie, Oregon 97222 USA

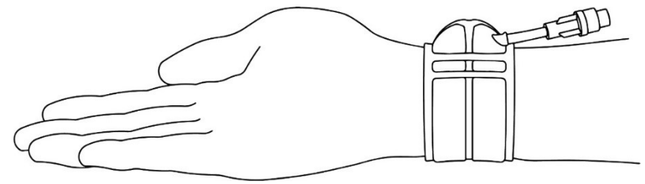
Cordis Corporation
14201 North West 60th Ave
Miami Lakes, Florida 33014 USA

This product is not made with natural rubber latex, DEHP or other phthalates. The **ZEPHYR** VCB contains no user-repairable parts.
U.S. Pat. No. 9,427,239. Pats. Pending. **ZEPHYR®** is a registered trademark of Advanced Vascular Dynamics, a Semler Technologies company.

Cordis®
A Cardinal Health company

User Guide

ZEPHYR® Vascular Compression Band for Radial Artery Hemostasis



INDICATION FOR USE

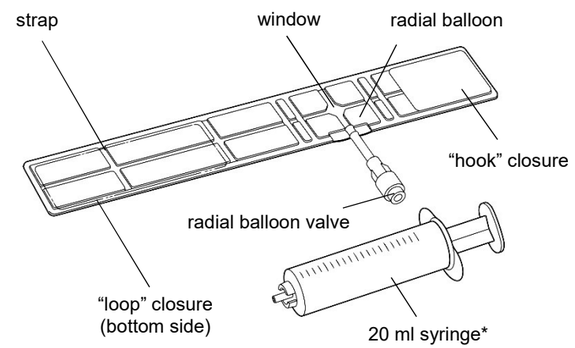
The **ZEPHYR®** Vascular Compression Band (VCB) is indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or leg, including: radial, brachial, dorsalis pedis, or tibial blood vessels, arterial or venous line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

NOTE: This User Guide is provided for the radial artery hemostasis specifically.

DESCRIPTION

The **ZEPHYR** VCB applies compression over a blood vessel in a patient's arm to help achieve patent hemostasis. Each VCB includes the following:

Figure 1: Device Schematic



Model 190101 REGULAR Size 9.75" / 25 cm long
Model 190102 LARGE Size 11.75" / 30 cm long (with an extender not shown in Figure 1)

* **NOTE:** ANY LUER SYRINGE MAY BE USED TO INFLATE OR DEFLATE THE **ZEPHYR** VCB.

INSTRUCTIONS FOR USE

Clinicians should always follow institutional protocols for post-procedure hemostasis when deploying the **ZEPHYR** VCB. Inspect the **ZEPHYR** VCB for damage prior to use. Properly size the **ZEPHYR** VCB to each patient's wrist.

DEPLOYMENT AND PATENT HEMOSTASIS

1. **Preparation**. At the end of the catheterization procedure, inform the patient they should not use any muscles in the hand or wrist and perform other post-procedure activities as per institutional protocol. Use sterile or aseptic technique to remove the **ZEPHYR** VCB from the pouch. Withdraw the sheath approximately 2-3 centimeters out of the puncture site. Ensure that the puncture site area is dry.

2. **Placement**. Place the Strap (with balloon uninflated) around the wrist with the tubes facing either direction (operator preference), with the sheath and skin puncture site showing in the 'window'. The puncture site should be generally centered under the balloon.

Figure 2. Placing the ZEPHYR VCB on the wrist

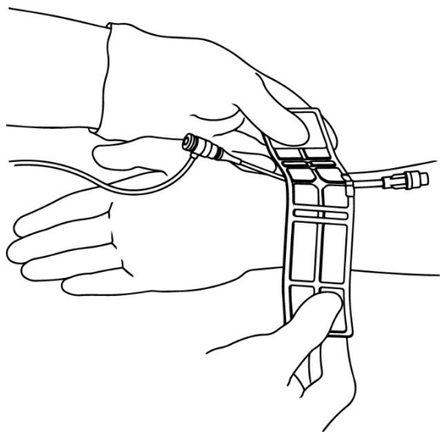


Figure 3. Close-up of sheath under the window

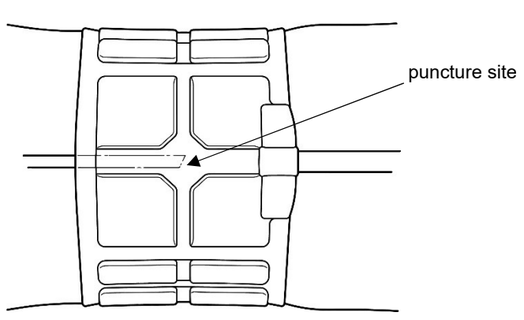
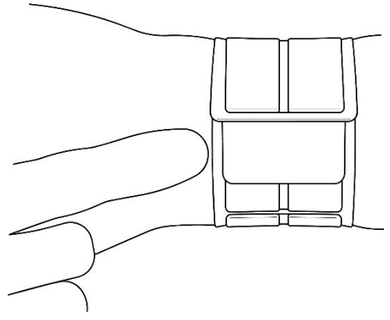


Figure 4. Hook-loop contact

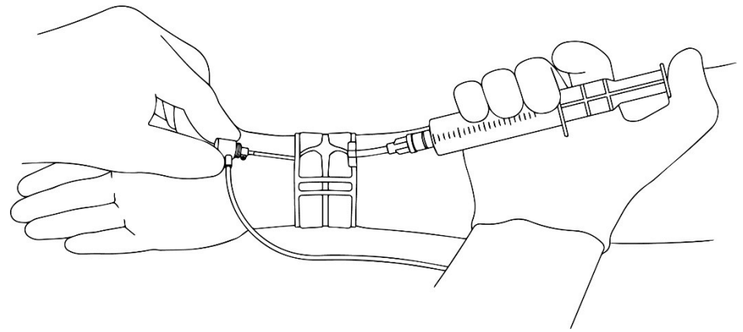


Optionally, at the discretion of the operator, a piece of sterile gauze or hemostatic material may be placed under the radial balloon during deployment.

Snugly fasten the device around the patient's wrist by placing the hook material over the loop material and pressing. The strap should not be able to twist around the wrist. At least half of the hook material must be in contact with the loop material.

3. **Initial Balloon Inflation**. Draw 20 ml of air into the inflation syringe and firmly press the syringe nozzle onto the valve of the balloon so that it 'clicks' into place. Inject the air into the balloon and pull the sheath. Ensure there is no bleeding or oozing from the puncture site and wipe away any blood. Refer to institutional protocols for post-procedure radial hemostasis.

Figure 5. Inflating the balloon and pulling the sheath



NOTE: DO NOT insert the **ZEPHYR** VCB syringe into any fitting, valve or connector except for the **ZEPHYR** VCB balloon valve with the light blue insert.

4. **Ensure Patency**. Remove air until a flash of blood is observed, then immediately re-inflate with 2 ml of air or until bleeding stops. Immediately assess distal perfusion to ensure Patent Hemostasis while occluding the ulnar artery proximal to the wrist. If patency is not observed, slowly remove air from the balloon until vessel patency is observed without puncture site oozing. Be sure to continuously hold the plunger to keep all the air from escaping suddenly. Periodically observe the patient's vital signs and assess hand perfusion and puncture site status in accordance with institutional protocol. There should be no bleeding or oozing from the puncture site.

   NOTE: Patency should be observed in the radial artery distal to the point of compression, with no bleeding at the puncture site.

5. **Compression Time**. The **ZEPHYR** VCB should be left on the patient's wrist, unless directed otherwise by physician's orders or patient conditions. Refer to institutional protocols for post-procedure radial artery hemostasis compression time.

   NOTE: If oozing or re-bleed occurs, draw 10 ml of air into the syringe and slowly re-inflate the balloon only until the oozing or bleeding stops. Check vessel patency.

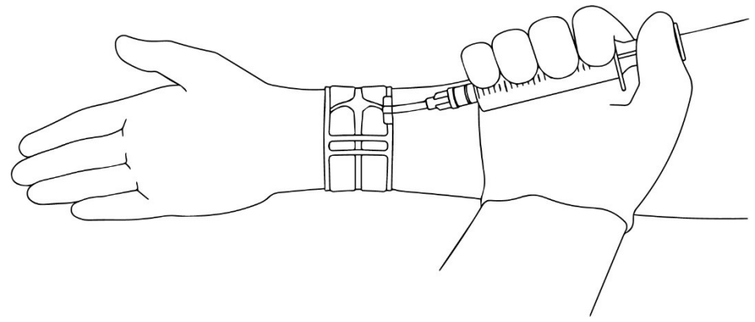
ADJUSTMENT AND REMOVAL

NOTE: If the **ZEPHYR** VCB syringe is misplaced, any Luer Slip or Luer Lock syringe may be used for inflating or deflating the balloon.

1. **Ensure Patency**. Check to ensure vessel patency every 15 minutes starting with the patient's arrival in the recovery area. Radial artery patency should be maintained throughout the hemostasis period.

2. **Compression Adjustment**. In accordance with hospital protocol or at the discretion of the operator, compression may be reduced during the hemostasis period as long as there is no oozing at the puncture site – be sure to control the plunger on the syringe when removing air from the balloon. Radial artery patency should be maintained at all times. If oozing or bleeding occurs at any time, re-inflate the balloon until oozing or bleeding stops and re-check vessel patency.

Figure 6. Syringe attached to the ZEPHYR VCB, pulling air out



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

4. **Device Removal.** After all compression is released and hemostasis confirmed, gently separate the hook and loop material and palpate under the radial balloon to separate the strap from the skin. Carefully remove the **ZEPHYR** VCB from the puncture site, being careful not to disrupt the clot. Apply a dressing and discard the device per institutional protocol.