**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:

1. **VCB**
2. **Strap**
3. **Window**
4. **Radial Balloon Valve**
5. **“Hook” Closure**
6. **“Loop” Closure**
7. **20 ml Syringe**

**NOTE:** ANY Luer SYRINGE MAY BE USED TO INFUSE OR DEFLATE THE ZEPHYR VCB.

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**Explanation of Symbols**

<table>
<thead>
<tr>
<th>Symbol Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilized with ethylene oxide gas</td>
<td>Caution</td>
</tr>
<tr>
<td>Do not resterilize</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>Do not re-use</td>
<td>n units per box</td>
</tr>
<tr>
<td>Do not use if package is damaged</td>
<td>Only</td>
</tr>
<tr>
<td>Keep dry</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Keep away from sunlight</td>
<td>Distributed by</td>
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</tbody>
</table>

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**Advanced Vascular Dynamics**

4292 SE International Way, #F
Milwaukee, 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. 5,427,239. Pats. Pending. ZEPHYR is a registered trademark of Advanced Vascular Dynamics, a Semler Technologies company.

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**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 uncontrollable 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.

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**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.
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**NOTE:**

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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.

   Smugly 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 Patent. 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: Patent 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 Patent. 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.

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.

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

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.