

Rad-Band™ Topical Hemostat



**Vascular
SOLUTIONS**



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Rad-Band™ Topical Hemostat Model 3505

Instructions For Use

USA CAUTION

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

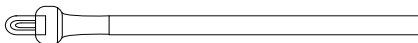
CAUTION

The Rad-Band procedure should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device.

DEVICE DESCRIPTION

Each Rad-Band topical hemostat consists of the following components:

- Application device consisting of an adjustable retention strap and non-woven gauze pad.



Hemostasis is achieved by the adjunct compression delivered by the application device.

The Rad-Band has been sterilized with irradiation.

INDICATIONS

The Rad-Band is applied topically and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

CONTRAINDICATIONS

There are no contraindications for the Rad-Band.

WARNINGS

Do not apply occlusive pressure using the Rad-Band. Arterial damage and thrombosis may result. Check pulses frequently to maintain arterial flow, and loosen the retention strap as necessary.

The Rad-Band is supplied sterile for single use only. Do not re-sterilize.

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PRECAUTIONS

Do not use the Rad-Band if the packaging has been damaged.

The Rad-Band should not be used in the presence of infection.

It should be used with caution in contaminated areas of the body.

ADVERSE EVENTS

Other potential adverse events include allergic reaction or radial artery occlusion, local venous thrombosis, hematoma formation, recurrent bleeding, peripheral nerve damage and complex regional pain syndrome.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the Rad-Band. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended to be a substitute for the physician's experience and judgment in treating any specific patient.

Carefully inspect the Rad-Band packaging and components for damage prior to use.

APPLICATION PROCEDURE

1. Using sterile technique, open the foil pouch and transfer the Rad-Band into the sterile field.
2. Place the Rad-Band around the patient's forearm with the Rad-Band pad over the access site and the clasp on the thumb side of the forearm.
3. Secure the Rad-Band loosely around the forearm by threading the retention strap through the opening in the clasp and gently pulling the strap.

4. As the introducer sheath or needle is removed, apply non-occlusive manual compression by placing the Rad Band gauze pad directly over the source of the bleeding.
5. Tighten the Rad-Band by pulling on the retention strap until the device is secure on the patient's wrist and cessation of bleeding is observed, but arterial pulses are still present.
Warning: Do not apply occlusive pressure using the Rad-Band. Arterial damage and thrombosis may result. Check pulses frequently to maintain arterial flow, and loosen the retention strap as necessary.
6. Monitor the site per institutional protocol.
7. Observe for hemostasis by loosening the retention strap gradually. To loosen or remove the retention strap, compress the protruding tab on the clasp and slowly loosen the strap to the desired tension.
8. Once hemostasis is achieved either:
 - Carefully remove the Rad-Band, being careful not to disrupt the clot, and dispose of it properly. Apply dressing of choice.
 - OR
 - Secure the Rad-Band pad by applying slight compression directly on the retainer while sliding the retention strap out of the side groove on the retainer. Apply downward pressure on the release tab of the Rad-Band pad with one hand. With the other hand slowly pull the retainer back leaving the Rad-Band pad in place and being careful not to disrupt the clot. Apply dressing of choice.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the Rad-Band topical hemostat is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the Rad-Band topical hemostat. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

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PATENTS AND TRADEMARKS

International and U.S. patents pending.