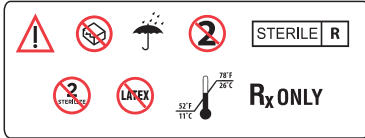


**INTERNAL USE ONLY**  
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 Manufactured for:  
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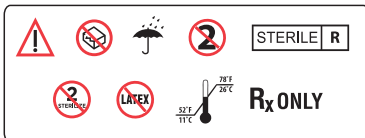
**HEMCON**<sup>®</sup>

The blood stops here.<sup>™</sup>

**OneStop<sup>™</sup> Vascular**

RM7316 Rev 1

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**OneStop<sup>™</sup> Vascular**

RM7316 Rev 1

**Instructions for Use:**

1. Allow nickel size (~ 2 cm) drop of blood to form at puncture site. Blood is required for dressing to adhere. (Do not cleanse puncture site or moisten with saline solution).
2. With printed side facing up, place dressing directly on puncture site. Dressing can be cut to size. Do not remove the backing.
3. Hold digital pressure until bleeding is controlled.
4. After bleeding has stopped, secure OneStop™ Vascular with appropriate dressing (not included).
5. Recheck the wound for potential bleeding as necessary. If hemostasis is not achieved or for recurrent bleeding, remove dressing with saline or water and re-apply a new dressing until hemostasis is achieved.
6. Remove dressing within 48 hours by irrigating with saline or water, while gently pulling up on the corner of the dressing.

**Intended Use / Indications:** The dressing is intended for the local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: skin surface puncture sites, vascular procedure sites, and sites involving percutaneous catheters, tubes and pins.

**Description:** The OneStop™ Vascular is a wound dressing manufactured from chitosan. When applied directly to the wound, the dressing controls bleeding. The dressing offers an antibacterial barrier against a wide range of gram positive and gram negative organisms, including antibiotic resistant *Staphylococcus aureus* (MRSA), *Enterococcus faecalis* (VRE) and *Acinetobacter baumannii*. Only single strains of most species mentioned have been studied.

**Cautions / Warnings:** Do not use if seal is broken and/or contents are wet. Do not apply over eyes. Use promptly after opening. Contains chitosan from shellfish. For external use only, do not implant. Not for consumption, do not eat. Single use only. Discard any unused portion of the product. Do not resterilize. Not made with natural rubber latex.

**Seek Medical Attention:** If bleeding does not stop or redness or swelling occurs. If you suspect an allergic reaction. For severe wounds that have breached the dermis to avoid potential complications due to internal bleeding.

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**Suggested Cardiac Catheterization Protocols Using the OneStop™ Vascular \*†**

Compression Times Diagnostics (5F-8F)	5-10 minutes <sup>1,2</sup>
Compression Times Intervention (5F-8F)	10-15 minutes <sup>1,2,4</sup>
ACT Levels	Standard ACC Recommended Level <175 <sup>5</sup> Performance evaluated across an ACT range of 159 - 343 <sup>2,6</sup>
Ambulation Guidelines	2 Hours <sup>3,4</sup>

\*Tricol Biomedical recognizes that unique circumstances may exist for each patient and facility. Individual circumstances may be outside the scope of these suggested protocols. Tricol recommends the best clinical judgment for these patients.

†HemCon has not been evaluated in controlled, randomized trials of radial catheterization procedures using anticoagulation mixes, aggressive sheath pull times, and high ACT levels.

**Potential Complications:** Potential procedural inherent complications include, but are not limited to, hematoma formation, recurrent bleeding, pseudo-aneurisms, thrombosis of vessel, introduction into vascular space, infection, and wound dehiscence. Treat these issues with standard institution protocol.

**Note:** with use of HemCon dressings there have been no reported occurrences or incidence is < 0.001%

**Storage Conditions:** Best stored at room temperature.

**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Tricol Biomedical Study & Industry References:

- 1 Usage of Chitosan for Femoral (USF) hemostasis after percutaneous procedures: comparative open label study (Meir Medical Center)
- 2 Use of the HemCon Patch to Control Bleeding in a Sheep Femoral Arterial Sheath Puncture Model (Oregon Health & Sciences University)
- 3 Post-Procedural Ambulation Guidelines Following Catheterization (HemCon)
- 4 Cath Lab Case Study of HemCon Bandages (St. Elizabeth Medical Center)
- 5 Bashore, Thomas M. et al. "American College of Cardiology/ Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards." Journal of the American College of Cardiology, Vol. 37, No. 8, 2001.
- 6 Initial Experience with the HemCon Bandage for Vascular Access Management in a Diverse Pediatric and Adult Congenital Heart Disease Patient Population (Rush University Medical Center)

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