

INTERNAL USE ONLY
— DO NOT PRINT THIS PAGE —

MMF-RM7249 Rev. 5 - Package Insert, IFU, HemCon Patch PRO
MS-RM4018

Folded Size: 4.25" x 5.5"

Color: Black, Black 70%

HemCon
Patch[®] PRO

Instructions for Use:

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

Intended Use / Indications: The HemCon Patch PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds intended for emergency use. The HemCon Patch PRO also controls bleeding in patients following hemodialysis and is indicated for the control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Description: The HemCon Patch PRO is a wound dressing manufactured from chitosan. When applied directly to the wound, the HemCon Patch PRO controls bleeding caused by extreme trauma. The HemCon Patch PRO 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.

Suggested Cardiac Catheterization Protocols Using the HemCon Patch PRO*†	
Compression Times Diagnostics (5F-8F)	5-10 minutes ^{1,2}
Compression Times Intervention (5F-8F)	10-15 minutes ^{1,2,4}
ACT Levels	Standard ACC Recommended Level <175 ⁵ <i>Performance evaluated across an ACT range of 159 – 343 ^{2,6}</i>
Ambulation Guidelines	2 hours ^{3,4}

* 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.

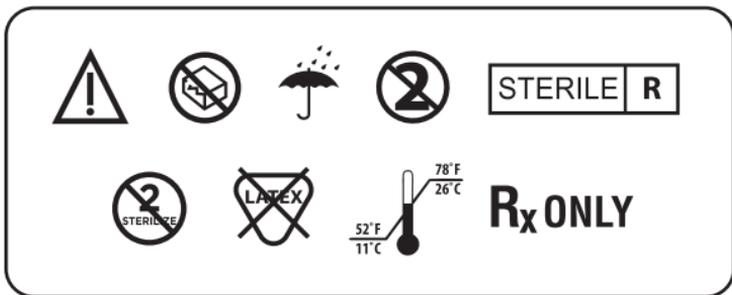
Note: with use of HemCon dressings there have been no reported occurrences or incidence is < 0.001%

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.

HemCon 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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 **HemCon**

by **Tricol** BIOMEDICAL INC