

Acute trauma wounds

Amputations

Blast injuries

Lacerations

Gunshot and Stab Wounds

Motor Vehicle Accidents

Trauma

Wound Debridement

Diabetic Foot Ulcers

Pressure Ulcers (partial and full thickness)

Venous Ulcers

Surgical Site Incisions

Positive Outcomes. STAT.

HEMOSTATIC BANDAGE FOR OOZING TO SEVERE BLEEDING CONTROL IN TRAUMA AND WOUND CARE

HemCon Bandage PRO is ideally suited for quick bleeding control in a variety of external wound types and is easily administered with current protocol of dressing and direct pressure.

- **Cost effective:** Lower cost than other alternatives; standardizes the number of SKUs ordered. Rapid bleeding control can result in less need for cauterization.
- **Fast Hemostasis:** Stops bleeding from oozing to severe arterial in minutes¹⁻⁵; minimizes blood loss. Reduced blood loss can reduce the need for transfusions.
- **Dependable:** Maintains structural integrity that won't crack, crumble or shed in wounds; creates a strong clot; provides localized support of clotting.
- **Easy to Use:** Reduces direct pressure protocol to free up staff; intuitive application requires limited training; addresses a variety of wound types.
- **Safe:** works independently of the clotting cascade; provides an antibacterial barrier against 24 microorganisms including MRSA, VRE, *A. baumannii* and *C. difficile*; no known contra-indications.



HemCon Bandages or gauze pad (left upper shoulder) being applied with pressure to multiple stab wound patient



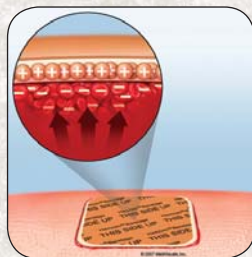
HemCon® Bandage PRO

INDICATION FOR USE

The HemCon Bandage PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds, intended for emergency use. The HemCon Bandage 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.

HOW HEMCON BANDAGES WORK

HemCon products are made from chitosan, a naturally occurring polysaccharide. Chitosan is positively charged, attracting negatively-charged red blood cells and platelets. This ionic interaction creates a supportive, primary seal at the wound site independent to the clotting cascade to control all degrees of bleeding.



APPLICATION GUIDE

1. Apply HemCon Bandage PRO directly over actively bleeding wound with tan backing away from wound. If necessary, the bandage can be cut or folded to the size of the wound.
2. Hold pressure until bleeding is controlled.
3. Apply outer bandage wrap (not included) to secure dressing on wound site, if required.
4. 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.

REMOVAL INSTRUCTIONS

- The HemCon Bandage PRO can remain in place for up to 48 hours and should be removed with water or saline.

REDUCTION OF MICROORGANISMS

HemCon Bandage PRO was tested for reduction of microorganisms against the following species. The log reduction data demonstrates the antibacterial barrier effect.

Organism	Gram Stain	Log Reduction
<i>Escherichia coli</i> ATCC 8739	-	>5.2
<i>Klebsiella pneumoniae</i> ATCC 4352	-	>5.3
<i>Streptococcus pyogenes</i> ATCC 19615	+	>5.5
<i>Staphylococcus aureus</i> (MRSA) ATCC 33591	+	>4.0
<i>Staphylococcus epidermidis</i> ATCC 12228	+	>5.2
<i>Salmonella choleraesuis</i> ATCC 10708	-	>5.1
<i>Pseudomonas aeruginosa</i> ATCC 9027	-	>4.3
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	+	>5.4
<i>Enterococcus faecalis</i> ATCC 700802	+	>5.4
<i>Serratia marcescens</i> ATCC 13880	-	5.0
<i>Stenotrophomonas maltophilia</i> ATCC 12714	-	>5.1
<i>Streptococcus mutans</i> ATCC 25175	+	>5.2
<i>Clostridium difficile</i> ATCC 9689	+	>5.6
<i>Streptococcus pneumoniae</i> ATCC 10015	+	5.8
<i>Shigella</i> species ATCC 11126	-	>5.4
<i>Enterobacter aerogenes</i> ATCC 13048	-	>5.0
<i>Proteus mirabilis</i> ATCC 4630	-	>5.2
<i>Proteus vulgaris</i> ATCC 12454	-	>4.8
<i>Citrobacter freundii</i> ATCC 8090	-	>4.3
<i>Enterobacter cloacae</i> ATCC 13047	-	>4.2
<i>Acinetobacter baumannii</i> ATCC 15308	-	>4.2
<i>Moraxella catarrhalis</i> ATCC 8193	-	>4.1
<i>Micrococcus luteus</i> ATCC 49732	+	4.9
<i>Vibrio cholerae</i> ATCC 11558	-	>4.9

Data on file at Tricol. In vitro study. Log reduction at 24 hours in colony forming units (CFUs) using Antibacterial AATCC Test Method 100-2004. Only single strains of most species have been studied. The clinical utility of these results is unknown. Testing was performed by an independent, certified, contract laboratory.

ORDER INFORMATION

Part Number	Part Number	Configuration
HemCon Bandage PRO, 4in x 4in	1003	5/bx, 100/cs

FDA 510K: K080818

Tax ID: 81-2091181

MMF-225 Rev. 4 (US) 04/18

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1. Bulger EM, et al. "An evidence-based prehospital guideline for external hemorrhage control: American College of Surgeons Committee on Trauma." *Prehospital Emergency Care*. 2014 Apr-Jun; 18(2): 163-73.

2. Brown, Mark, et al. "Experience with Chitosan Dressings in a Civilian EMS System" *The Journal of Emergency Medicine* (Nov 2007).

3. Gustafson, Scott B., et al. "Chitosan Dressing Provides Hemostasis in Swine Femoral Arterial Injury Model." *Prehospital Emergency Care* 11 (2007) 172 – 178.

4. Wedmore, Ian, et al. "A Special Report on the Chitosan-based Hemostatic Dressing: Experience in Current Combat Operations." *Journal of Trauma: Injury, Infection and Critical Care* 60.3 (2006): 655 – 658.

5. Pusateri, Anthony E., et al. "Effect of a Chitosan-Based Hemostatic Dressing on Blood Loss and Survival in a Model of Severe Venous Hemorrhage and Hepatic Injury in Swine." *Journal of Trauma: Injury, Infection and Critical Care* 54 (2003): 177 – 182.