

Acute trauma wounds

Blast injuries

Lacerations

Motor Vehicle Accidents

Puncture Wounds

Trauma

Wound Debridement

Diabetic Foot Ulcers

Pressure Ulcers (partial and full thickness)

Venous Ulcers

Surgical Site Incisions

Pacemaker pockets

## Positive Outcomes. STAT.

### DOUBLE-SIDED HEMOSTATIC DRESSING FOR OOZING TO SEVERE BLEEDING CONTROL

*HemCon ChitoFlex PRO Hemostatic Dressing is a versatile hemostatic dressing, ideal for a variety of wound types and applications from trauma to wound care.*

- **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 minutes<sup>1-5</sup>; 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:** No pro-clotting agents; 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 ChitoFlex PRO dressing applied to a facial laceration wound to stop bleeding.



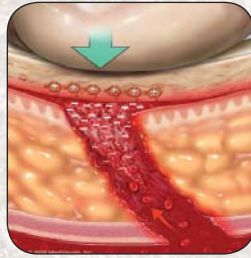


## INDICATION FOR USE

The HemCon ChitoFlex PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds, intended for emergency use. The HemCon ChitoFlex 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. Dressing is active (adherent) on both sides. Care needs to be taken so that the dressing does not stick to gloves. If necessary, the dressing can be cut or folded to the size of the wound.
2. Push dressing completely into wound track. Use enough ChitoFlex PRO to fill the wound and contact all bleeding surfaces.
3. Back dressing with gauze and hold pressure until bleeding is controlled.
4. Apply outer dressing wrap (not included) to secure dressing on wound site, if required.

## REMOVAL INSTRUCTIONS

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

## REDUCTION OF MICROORGANISMS

HemCon ChitoFlex 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
<b><i>Staphylococcus aureus</i> (MRSA) ATCC 33591</b>	<b>+</b>	<b>&gt;4.0</b>
<i>Staphylococcus epidermidis</i> ATCC 12228	+	>5.2
<i>Salmonella choleraesuis</i> ATCC 10708	-	>5.1
<i>Pseudomonas aeruginosa</i> ATCC 9027	-	>4.3
<b><i>Enterococcus faecalis</i> (VRE) ATCC 51299</b>	<b>+</b>	<b>&gt;5.4</b>
<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
<b><i>Clostridium difficile</i> ATCC 9689</b>	<b>+</b>	<b>&gt;5.6</b>
<i>Streptococcus pneumoniae</i> ATCC 10015	+	5.8
<i>Shigella species</i> 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
<b><i>Acinetobacter baumannii</i> ATCC 15308</b>	<b>-</b>	<b>&gt;4.2</b>
<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

Product	Part Number	Configuration
HemCon ChitoFlex PRO, 1 in x 3 in	1008	5/bx, 100/cs

FDA 510K: K080818  
Tax ID: 81-2091181

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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.

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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.