

Hemodialysis

Home dialysis

AVF: Arteriovenous Fistula

AVG: Arteriovenous Graft

Peritoneal dialysis

CAPD: Continuous Ambulatory Peritoneal Dialysis

APD: Automated Peritoneal Dialysis

Catheter bleeding

De-clot procedures



Positive Outcomes. STAT.

DOUBLE-SIDED HEMOSTATIC DOT FOR BLEEDING CONTROL FOLLOWING DIALYSIS

HemCon Dot is an ideal dialysis clinic management tool, allowing for quick patient turns and improved patient experience.

- **Cost effective:** Rapid bleeding control helps reduce chair time to maximize patient turns and can result in less comebacks due to less rebleeding.
- **Fast Hemostasis:** Stops bleeding at percutaneous needle access sites in minutes¹⁻⁴, even anti-coagulated patients; minimizes blood loss.
- **Dependable:** Helps preserve fistulas and grafts. Maintains structural integrity that won't crack, crumble or shed in wounds; works on anti-coagulated patients; 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. No delay in dialysis prepare and clean up time.
- **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
ChitoDot used to
control bleeding
in two minutes in
dialysis patient.



INDICATION FOR USE

The HemCon ChitoDot is intended for 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: lacerations, abrasions, nose-bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

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. Allow a small amount of blood to surface on the skin. Blood is required for the bandage to seal the wound.
2. Apply HemCon ChitoDot directly on the puncture site, both sides are active.
3. Apply direct pressure to wound until bleeding is controlled.
4. After bleeding has stopped, secure HemCon ChitoDot with appropriate dressing.
5. Keep bandage dry.

REMOVAL INSTRUCTIONS

- Remove bandage within 48 hours by soaking thoroughly with water or saline to loosen from wound and skin and gently pull off the bandage.

REDUCTION OF MICROORGANISMS

HemCon ChitoDot 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 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
<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

Product	Part Number	Configuration
HemCon ChitoDot, 3/4in (1.9cm) Ø	1093	50/bx, 500/cs

FDA 510K: K150916

Tax ID: 81-2091181

MMF-238 Rev. 3 4/18

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1. Bachtell, Nathan, et al. "Treatment of Dialysis Access Puncture Wound Bleeding with Chitosan Dressings." *Dialysis & Transplantation* Nov. 2006: 1 – 6.

2. Kazuhiko Shibata, et al. Japan. "Randomized Trial comparing New Chitosan-Based Bandage with Kaltostat Hemostatic Dressing to Control Bleeding from Hemodialysis Puncture Site". Presented at 49th ERA-EDTA (European Renal Association – European Dialysis and Transplant Association Congress), Paris, France. May 24-27, 2012.

3. Shibata, Kazuhiko, et al. "New Chitosan-Based Bandage Stops Severe Bleeding from Hemodialysis Puncture Site in 2 Minutes." Presented at The 56th Congress of the Japanese Society for Dialysis Therapy. June, 2011.

4. Misgav, Mudi, et al. "Chitosan-Based Dressing Decreases Bleeding Time From Hemodialysis Access Puncture Wound Bleeding". Presented at Advanced Technology Applications for Combat Casualty Care (ATACCC 2007). August 2007.