

ICU/Stepdown

ABG lab draws

Access port rebleeds

Central lines

Tracheostomy sites

Ventilator/chest tubes

ER/Urgent Care

Lacerations and abrasions

Open fractures

OR/Surgery Centers

Biopsies for dermatology

Surgical site oozing and protection

Plastic surgery incisions

Sternal wounds

Wound Debridement

Positive Outcomes. STAT.

FLEXIBLE HEMOSTATIC GAUZE DRESSING FOR OOZING TO SEVERE BLEEDING CONTROL

HemCon GuardaCare PRO provides immediate bleeding control and best possible patient care in trauma and 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 minutes¹⁻³; minimizes blood loss. Reduced blood loss can reduce the need for transfusions.
- **Dependable:** Non-shedding; 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; available in a range of sizes to address a variety of wound types.
- **Safe:** No pro-clotting agents; works independently of the clotting cascade; offers antibacterial effectiveness within the dressing against 26 organisms including MRSA, VRE, *A. baumannii* and *C. difficile**; no known contra-indications.



HemCon
GuardaCare
PRO dressing
applied with
pressure to
help control
bleeding during
breast reduction
procedure.

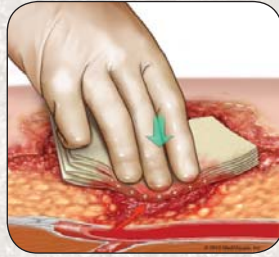


INDICATION FOR USE

The HemCon GuardaCare PRO is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

HOW HEMCON DRESSING WORK

GuardaCare PRO is a z-folded, chitosan impregnated gauze. Chitosan is a naturally occurring, biocompatible polysaccharide and the hemostatic properties of chitosan enhance the ability of the medical gauze to control bleeding. The robust uniformly applied chitosan coating on the gauze, allows for optimal chitosan blood interaction to effectively control bleeding. The chitosan further reduces blood loss by helping the dressing conform to the wound site while providing a physical barrier to prevent bleeding. This mechanism of action supports localized clotting within and on the gauze to stop bleeding quickly and independently of the clotting cascade. The dressing readily conforms to wound surfaces with complex geometries to allow efficient staunching of all bleeding.



APPLICATION GUIDE

1. Place or pack dressing completely over the source of bleeding. Make sure to contact all bleeding surfaces. More than one dressing may be required.
2. Apply pressure until bleeding is controlled.
3. After bleeding has stopped, secure GuardaCare PRO with appropriate dressing (not included).

REMOVAL INSTRUCTIONS

- The HemCon GuardaCare PRO can remain in place up to 48 hours.
- Dressing should easily peel away from the wound.
- If dressing has adhered* to the wound, irrigate with saline or water to facilitate removal.

* Depending on the condition of the wound, the dressing may stick if left on wound beyond 48 hours.

REDUCTION OF MICROORGANISMS

HemCon GuardaCare PRO was tested for reduction of microorganisms against the following species. The log reduction data demonstrates the level of antibacterial effectiveness within the dressing. Not applicable for part number 1090.

Organism	Gram Stain	Log Reduction
Staphylococcus aureus (MRSA) ATCC 33591	+	>5.0
Staphylococcus aureus (MRSA) ATCC BAA-1556	+	>5.1
<i>Staphylococcus epidermidis</i> ATCC 12228	+	>4.4
<i>Pseudomonas aeruginosa</i> ATCC 9027	-	>5.1
Enterococcus faecalis (VRE) ATCC 51299	+	>5.4
<i>Acinetobacter baumannii</i> ATCC 15308	-	>5.2
<i>Citrobacter freundii</i> ATCC 8090	-	>5.2
<i>Enterobacter cloacae</i> ATCC 13047	-	>4.9
<i>Streptococcus mutans</i> ATCC 25175	+	>4.7
<i>Streptococcus pneumoniae</i> ATCC 10015	+	>5.4
<i>Escherichia coli</i> ATCC 8739	-	>4.9
<i>Klebsiella pneumoniae</i> ATCC 4352	-	>5.2
<i>Streptococcus pyogenes</i> ATCC 19615	+	5.0
<i>Salmonella choleraesuis</i> ATCC 10708	-	>4.6
<i>Stenotrophomonas maltophilia</i> ATCC 12714	-	>5.1
<i>Citrobacter koseri</i> ATCC 25408	-	>4.7
<i>Proteus mirabilis</i> ATCC 4630	-	>5.0
<i>Proteus vulgaris</i> ATCC 12454	-	>4.6
<i>Moraxella catarrhalis</i> ATCC 8193	-	>4.9
Clostridium difficile ATCC 9689	+	>5.0
<i>Shigella species</i> ATCC 11126	-	>4.3
<i>Micrococcus luteus</i> ATCC 49732	+	>5.0
<i>Vibrio cholerae</i> ATCC 11558	-	>4.0
<i>Enterobacter aerogenes</i> ATCC 13048	-	>5.0
Enterococcus faecalis (VRE) ATCC 700802	+	>5.3
<i>Serratia marcescens</i> ATCC 13880	-	>4.5

*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 GuardaCare PRO, 2in x 2in, 8 ply	1012	10/bx, 100/cs
HemCon GuardaCare PRO, 4in x 4in, 8 ply	1013	10/bx, 100/cs

FDA 510K: 092357

Tax ID: 81-2091181

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EC REP CEpartner4U, Esdoornlaan 13, 3951DB Maarn, The Netherlands - www.cepartner4u.eu



CONTACT US DIRECTLY

U.S. & Canada Toll Free: 877.247.0196

Phone: +1.503.245.0459

www.tricolbiomedical.com • info@tricolbiomedical.com

Tricol
BIOMEDICAL INC

720 SW Washington Street, Suite 200 • Portland, OR 97205-3504

1. Rall JM, et al. "Comparison of novel hemostatic dressings with QuikClot combat gauze in a standardized swine model of uncontrolled hemorrhage." *Journal of Trauma Acute Care Surg.* 2013 Aug; 75(2 Suppl 2):S150-6.

2. Schwartz MD, et al. "Comparison to Two Package Hemostatic Gauze Dressings in a Porcine Hemorrhage Model." *Prehospital Emergency Care.* Vol. 15, No. 4. October/December 2011.

3. Xie, Hua, et al. "Comparison of Hemostatic Efficacy of ChitoGauze and Combat Gauze in a Lethal Femoral Arterial Injury in Swine Model." *ATACCC* 2009.