

**INTERNAL USE ONLY**  
**— DO NOT PRINT THIS PAGE —**

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**RM7114 Rev. 4 – Package Insert, IFU, GuardaCareXR**

**MS–RM4039**

**Size: 2 up on an 8.5" x 11" folded to 4.25" x 5.5"**

**Color: Black, 10% Black**

# HemCon GuardaCare®XR Surgical

## Hemostatic Temporary Surgical Dressing

### INDICATIONS:

HemCon GuardaCareXR Surgical is intended for use as a hemostatic dressing for temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.

### DEVICE DESCRIPTION:

HemCon GuardaCareXR Surgical is a hemostatic temporary surgical dressing comprised of a chitosan coated polyester/rayon blend, non-woven, medical-grade gauze, and a single radio-opaque element. The dressing is z-folded and packaged in a sterile double pouch.

### AVAILABLE CONFIGURATIONS:

Product Code	Description and Size	Per Box
1031	HemCon GuardaCareXR Surgical, 2in x 2in, 8ply	10 dressings
1032	HemCon GuardaCareXR Surgical, 4in x 4in, 8ply	10 dressings
1033	HemCon GuardaCareXR Surgical, 4in x 2yds	5 dressings

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Developed by and manufactured for:



**Tricol Biomedical, Inc.**

720 SW Washington Street, Suite 200

Portland, OR 97205-3504 U.S.A.

Toll Free (U.S. & Canada) 877.247.0196

www.tricolbiomedical.com – info@tricolbiomedical.com

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RM7114 Rev. 4

**INSTRUCTIONS FOR USE:**

1. Place or pack dressing completely over the source of bleeding. Make sure to contact all bleeding surfaces.
2. Apply pressure until bleeding is controlled. More than one dressing may be required to control bleeding.
3. Remove dressing within 24 hours by gently pulling on the edge of the dressing. If dressing is difficult to remove, wet with normal saline solution and reattempt removal.

**ADDITIONAL NOTES:**

- Show product removal directions on package to medical personnel if patient is transported and dressing remains in place.
- If dressing must be cut, make sure it contains the radiopaque element.

**PRECAUTIONS:**

- GuardaCareXR Surgical dressing is supplied as a sterile, single-use dressing. Do not re-use. Do not re-sterilize.
- If cutting the dressing to a smaller desired size, be sure to include the radiopaque element in the parts you are planning to use. Discard any unused portion of the product.
- If you suspect an allergic reaction, seek medical attention.
- Remove the GuardaCareXR Surgical within 24 hours.
- If bleeding resumes after careful removal of the dressing, the use of standard surgical techniques may be required to adequately repair the source of bleeding.

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**WARNINGS:**

- GuardaCareXR Surgical is not intended as a substitute for meticulous surgical technique, the use of sterile procedures, and the proper application of ligatures or other conventional procedures to control bleeding.
- GuardaCareXR Surgical is not intended to be left within the body cavity.
- GuardaCareXR Surgical must not remain on the wound for more than 24 hours.
- The safety and effectiveness of the HemCon GuardaCareXR Surgical dressing for use in neurological, ophthalmic, spinal, GI, orthopedic (bone repair), all anastomoses (including vascular) have not been established.
- Contains chitosan from shellfish.
-   Do not use if seal is broken and/or contents are wet.
-  Single Use Only. Re-use could result in cross infection and/or loss of efficacy.
-  Not made with natural rubber latex.
-  Sterile
-  Do not re-sterilize.
- **R<sub>x</sub> ONLY** U.S. Federal law restricts this device to sale by or on the order of a physician.

**STORAGE:**

Controlled Room Temperature

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