BIOPATCH®
Protective Disk with CHG

CHG Sponge Dressing
Clinically Proven to Reduce Infections

vs.

GuardIVa®
Topical Hemostatic IV Dressing
Containing CHG as a Preservative
CDC Recommends a CHG Sponge Dressing. Why?

The CDC Guidelines’ stated intent is “to provide evidence-based recommendations for preventing intravascular catheter-related infections.”

For patients aged 18 years and older: Chlorhexidine-impregnated dressings with an FDA-cleared label that specifies a clinical indication for reducing catheter-related bloodstream infection (CRBSI) or catheter-associated bloodstream infection (CABSIs) are recommended to protect the insertion site of short-term, non-tunneled central venous catheters (1A). The updated recommendation has been designated Category 1A - the highest level of CDC recommendation for implementation.

Studies cited to support this CHG dressing recommendation were BIOPATCH Disk clinical studies. GuardIVa® Antimicrobial Hemostatic IV Dressing is currently being marketed as a CHG dressing following the CDC Guidelines’ publication. It does not have any randomized controlled studies supporting its efficacy in reducing infections.

BIOPATCH Disk is the only polyurethane foam protective disk with a cleared indication and proven to reduce the incidence of catheter-related bloodstream infections (CRBSIs), local infections and skin colonization in patients with central venous and arterial catheters.

Critical design & performance differences include:

- The proprietary BIOPATCH Disk foam is different in structure from GuardIVa®
  - BIOPATCH Disk contains more CHG (4X) than GuardIVa®
  - BIOPATCH Disk releases more CHG (5X) than GuardIVa®
  - GuardIVa® allows bacterial growth in vitro and BIOPATCH Disk does not

![Comparison of Total CHG Content](image)

Comparison of CHG Release

- *1. Bacteria starts repopulating the skin at about 18 hours. In vitro testing showed that by 18 hours BIOPATCH® had released 20 mg CHG, while GuardIVa® only released 2 mg
- *2. In vitro testing demonstrated that GuardIVa® releases the same amount of CHG in 7 days as released by BIOPATCH® in 3 hours

Cumulative CHG Release Comparison: Each test article was placed in 0.9% saline at room temperature for 24 hours. After 24 hours the discs were removed and the CHG concentration in the solution was measured by HPLC. The discs were then transferred to a fresh saline solution for the next 24 hour measurement for a total duration of 7 days.
Reducing CRBSIs Requires Evidence Based Medicine

**GuardIVa® is not a generic BIOPATCH Disk**

**BIOPATCH Disk Prevents Bacterial Growth**

- Inhibition of bacterial growth in the central opening (catheter insertion point)
- Inhibition of bacterial growth around perimeter of the BIOPATCH Disk

**GuardIVa® Allows Bacterial Growth**

- Bacteria (lack of inhibition) seen in central opening and around disk perimeter
- Visual bacterial growth seen beneath the GuardIVa® disk

**The highlighted studies were cited by the CDC for the 1A recommendation**

<table>
<thead>
<tr>
<th>BIOPATCH Disk</th>
<th>GuardIVa®</th>
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<tbody>
<tr>
<td>Lead Author</td>
<td>Statistically significant reduction of CRBSIs in central venous and arterial catheters</td>
</tr>
<tr>
<td>Timsit¹</td>
<td>✓</td>
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<tr>
<td>Garland⁷</td>
<td>n/a</td>
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<tr>
<td>Ho⁸</td>
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<tr>
<td>Levy⁹</td>
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<tr>
<td>Ruschulte¹⁰</td>
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<td>Maki¹¹</td>
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**HAS NEVER BEEN CLINICALLY SHOWN TO REDUCE INFECTION OR REDUCE CATHETER COLONIZATION**

**Evidence Based Decision Making**

Given the high costs and mortality¹² associated with CRBSIs, it is important to use a device with repeatedly proven efficacy in the reduction of CRBSI incidence, skin colonization, and local infections with catheter use.

The CDC guidelines provide evidence based recommendations for preventing CRBSIs. GuardIVa® currently does not have any clinical evidence showing a reduction in CRBSIs⁵. BIOPATCH Disk is the only CHG impregnated sponge dressing with a cleared indication for reducing CRBSIs, local infections and skin colonizations in patients with central venous and arterial catheters.
**Indication For Use**

BIOPATCH Disk containing Chlorhexidine Gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, peripherally inserted coronary catheters, mid-line catheters, drains, chest tubes, externally placed orthopedic pins, and epidural catheters. It is also intended to reduce local infections, catheter related bloodstream infections (CRBSIs), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.

**Clinical Trial Results**

A controlled, randomized, clinical trial consisting of 687 subjects with 1699 central venous or arterial catheter insertion sites was conducted at two centers.1

Results showed that the use of BIOPATCH Disk resulted in a statistically significant 44% reduction in the incidence of local infection (p<0.0001).

Results also showed that the use of BIOPATCH Disk resulted in a statistically significant 60% reduction in the incidence of catheter-related blood stream infections (p<0.026).

Results of this study also showed that use of BIOPATCH Disk resulted in statistically significant reduction in skin colonization of microorganisms commonly associated with CRBSI (p<0.05).

Patients randomized to the BIOPATCH Disk Treatment Group experienced no serious device-related adverse events.


**References:**


