Chlorhexidine Gluconate IV Securement Dressing

Description:
Tegaderm™ CHG dressing consists of a transparent adhesive dressing and an integrated gel pad containing 2% w/w Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity.

The transparent film provides an effective barrier against external contamination including fluids (waterproof), bacteria, viruses* and yeast, and protects the IV site.

*In vitro testing (time kill and zone of inhibition) demonstrates that the Tegaderm™ CHG gel pad in the dressing has an antimicrobial effect against a variety of gram-positive and gram-negative bacteria, and yeast. The gel pad absorbs fluid.

Tegaderm™ CHG dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

Indications: 3M™ Tegaderm™ CHG Chlorhexidine Gluconate IV Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

Warning:
• DO NOT USE TEGADERM™ CHG DRESSINGS ON PREMATURE INFANTS OR INFANTS YOUNGER THAN 2 MONTHS OF AGE. USE OF THIS PRODUCT ON PREMATURE INFANTS MAY RESULT IN HYPERSENSITIVITY REACTIONS OR NECROSIS OF THE SKIN.
• FOR EXTERNAL USE ONLY. DO NOT ALLOW THIS PRODUCT TO CONTACT EARS, EYES, MOUTH OR MUCCOUS MEMBRANES.
• DO NOT USE THIS PRODUCT ON PATIENTS WITH KNOWN HYPERSENSITIVITY TO CHLORHEXIDINE GLUCONATE. THE USE OF CHLORHEXIDINE GLUCONATE CONTAINING PRODUCTS HAS BEEN REPORTED TO CAUSE IRRITATIONS, SENSITIZATION, AND GENERALIZED ALLERGIC REACTIONS. Hypersensitivity reactions associated with topical use of Chlorhexidine Gluconate have been reported in several countries. The most serious reactions (including anaphylaxis) have occurred in patients treated with lubricants containing Chlorhexidine Gluconate, which were used during urinary tract procedures. Preparations of this type are not approved for sale in the U.S. under any circumstances. Caution should be taken when using Chlorhexidine Gluconate containing preparations, and the patient should be observed for the possibility of hypersensitivity reactions.
• IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY, AND IF SEVERE, CONTACT A PHYSICIAN.

Caution: Federal Law restricts the device to sale by or on the order of a licensed health care professional.

Precautions: 3M™ Tegaderm™ CHG Dressing should not be placed over infected wounds. This device is not intended to treat catheter-related blood stream infections (CRBSI) or other percutaneous device-related infection and has not been studied in a randomized clinical study as to its effectiveness in preventing such infections.

Any active bleeding at the insertion site should be stabilized before applying the dressing. Do not stretch the dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.

The skin should be dry and free of detergent residue to prevent skin irritation and to ensure good adhesion. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion.

Instructions for Use:
Failure to follow the manufacturer’s instructions for use may result in complications including skin irritation and/or maceration.

Dressing Selection: Choose a dressing large enough to provide at least one-inch margin of adherence on dry, healthy skin around the catheter site.

Site Preparation: Prepare the site according to institution protocol. Clipping of hair at the site may improve dressing adhesion. Shaving is not recommended. The skin should be clean, dry and free of detergent residue. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion. Any active bleeding at the insertion site should be stabilized before applying the dressing.

Application:
1. Open package and remove sterile dressing.
2. Peel the liner from the dressing, exposing the adhesive surface.
3. Center the gel pad over the catheter site and smooth down dressing edges. Do not stretch dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.
4. Slowly remove the frame while smoothing down the transparent film dressing edges.
5. Smooth the transparent film dressing from the center towards the edges, using firm pressure to enhance adhesion.
6. The sterile tape strips can be used: under the catheter wings or hub - to protect the skin; over the catheter wings or hub - to enhance catheter stability; to secure IV tubing or to stabilize catheter lumens.
7. Document dressing change information on the label according to facility's protocol. Remove label from frame and place on the dressing.

Site Care:
1. The site should be observed daily for signs of infection or other complications. If infection is suspected, remove the dressing, inspect the site directly, and determine appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, or unusual odor or discharge.
2. Inspect the dressing daily and change the dressing as necessary, in accordance with facility protocol. Dressing changes should occur at least every 7 days, per current CDC recommendations and may be needed more frequently with highly exudative sites or if integrity of the dressing is compromised.

The Tegaderm™ CHG dressing should be changed as necessary:
- If the dressing becomes loose, soiled or compromised in any way
- If the site is obscured or no longer visible.
- If there is visible drainage outside the gel pad
- If the dressing appears to be saturated or overly swollen*

*Note: To test if the dressing is fully saturated, lightly press down on a corner of the gel pad with your finger. If the gel pad remains displaced once your finger is removed, the dressing should be changed.

Note: Tegaderm™ CHG dressing is not designed to absorb large quantities of blood or fluid.

Removal: Gently grasp an edge of the transparent dressing and slowly peel the dressing from the skin in the direction of hair growth. Avoid skin trauma by peeling the dressing back, rather than pulling it up from the skin. Use sterile alcohol swabs or wipes, or sterile solutions (i.e., sterile water or normal saline) to facilitate removal of the gel pad. If needed, a medical adhesive solvent can be used to help remove the dressing border.

Continue the low and slow removal method until the dressing is completely removed.

Shelf Life and Storage Information: For best results, store in a cool, dry place. For shelf life, refer to the expiration date on the package. Sterility of the dressing is guaranteed unless individual package is damaged or open.

For additional information visit www.3M.com/tegadermchglg.

<table>
<thead>
<tr>
<th>Catalog #</th>
<th>Dressing Size</th>
<th>Average amount of CHG per dressing (mg based on gel pad size)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1657</td>
<td>8.5 cm x 11.5 cm (3-1/2 x 4-1/2 in)</td>
<td>45</td>
</tr>
<tr>
<td>1658</td>
<td>10 cm x 12 cm (4 x 4-3/4 in)</td>
<td>45</td>
</tr>
<tr>
<td>1659</td>
<td>10 cm x 15.5 cm (4 x 6-1/8 in)</td>
<td>78</td>
</tr>
<tr>
<td>1660</td>
<td>7 cm x 8.5 cm (2-3/4 x 3-3/8 in)</td>
<td>15</td>
</tr>
</tbody>
</table>

Explanation of Symbols

2. Do not reuse

Sterile unless package opened or damaged

This product and package do not contain natural rubber latex

STERILE EO. Sterilized using ethylene oxide

Do not re-sterilize