3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing

(GB)

Description:

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing is used to cover and protect catheter sites and to secure devices to skin. It is available in a variety of shapes and sizes.

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 gel pad absorbs fluid. The transparent film provides an effective barrier against external contamination including fluids (waterproof), bacteria, viruses* and yeast, and protects the I.V. 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.

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

*In vitro testing shows that the transparent film of the Tegaderm™ CHG dressing provides a viral barrier from viruses 27 nm in diameter or larger while the dressing remains intact without leakage. This barrier to viruses is due to the physical properties of the dressing, rather than the ancillary properties of CHG.

Indications:

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include central venous and arterial catheters, other intravascular catheters and percutaneous devices. Tegaderm™ CHG Dressing is intended to reduce skin colonization and catheter colonization and to suppress regrowth of microorganisms commonly related to bloodstream infections. Tegaderm™ CHG is intended to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.

Warnings:

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.

THE SAFETY AND EFFECTIVENESS OF TEGADERM™ CHG DRESSINGS HAS NOT BEEN EVALUATED IN CHILDREN UNDER 18 YEARS OF AGE. FOR EXTERNAL USE ONLY. DO NOT ALLOW THIS PRODUCT TO CONTACT EARS, EYES, MOUTH OR MUCOUS 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. IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY, AND IF SEVERE, CONTACT A PHYSICIAN.

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. Caution should be used when using chlorhexidine gluconate containing preparations, and the patient should be observed for the possibility of hypersensitivity reactions.

Precautions:

3M™ Tegaderm™ CHG dressing should not be placed over infected wounds. It is not intended to be used as a treatment of percutaneous device-related infections.

In the case of clinical wound infection, systemic antibacterials should be used if indicated.

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 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.

Do not reuse. Reuse may result in compromising product integrity and lead to device failure.

Clinical Trial Results: A randomized, controlled clinical trial consisting of 1879 subjects with 4163 central venous and arterial catheter insertion sites was conducted at 11 hospitals (1). Results showed that the use of Tegaderm™ CHG resulted in a statistically significant 67% reduction in the incidence of catheter-related bloodstream infections ($P=0.02$). Study results also demonstrate a statistically significant reduction in skin colonization ($P<0.001$) and catheter colonization ($P<0.0001$) in the chlorhexidine vs. non-chlorhexidine group.

Variable	Non-chlorhexidine vs. chlorhexidine dressings (941 patients/2055 catheters vs. 938 patients/2108 catheters)
Catheter-related bloodstream infection	
Incidence densities (n per 1000 catheter-days)	1.3 vs. 0.5
Hazard ratio	0.402 [0.186 to 0.868], $P=0.02$
Catheter colonization	
Incidence densities (n per 1000 catheter-days)	10.9 vs. 4.3
Hazard ratio	0.412 [0.306 to 0.559], $P<0.0001$

(1) Timsit JF et al Randomized Controlled Trial of Chlorhexidine Dressing and Highly Adhesive Dressing for Preventing Catheter-Related Infections in Critically Ill Adults *Am. J. Respir. Crit. Care Med. 2012; 186:1272-1278*

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 (2.5 cm) margin of adherence on dry, healthy skin around the catheter site. The dressing notch of 1657R has perforations that can be opened to conform around large catheters or other devices.

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 liner from dressing, exposing adhesive surface.
3. Avoid stretching the dressing during application to reduce the risk of mechanical skin trauma.
4. Center the gel pad over the catheter insertion site. Apply firm pressure to entire dressing starting in the center to the outer frame edges to enhance adhesion.
5. Slowly remove frame while smoothing down transparent film dressing edges.
6. Smooth the transparent film dressing from the center towards the dressing edges, using firm pressure to enhance adhesion.
7. After dressing has been applied, apply the sterile tape strip(s) to further secure I.V. tubing or to stabilize catheter. Refer to figures on packaging.
8. Document dressing change information on label according to facility protocol. Remove label from frame and place on 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 a minimum of every 7 days, per current Centers for Disease Control and Prevention (CDC) recommendations. Dressing changes may be needed more frequently with highly exudative sites.

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
- 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:

Stabilize catheter during removal of the 3M™ Tegaderm™ CHG Dressing

1. Remove documentation label and securement tape strip(s) from top of dressing.
2. Using a low and slow removal technique, start removing the dressing from where the catheter or tubing exits the dressing toward the catheter insertion site. Avoid skin trauma by peeling the dressing back, rather than pulling it up from the skin.
3. When the CHG gel pad is exposed, grasp a corner of the gel pad and the transparent film dressing between thumb and finger.
4. Apply sterile alcohol swabs or wipes, or sterile solutions (i.e., sterile water or normal saline) between gel pad and skin to facilitate removal of the gel pad dressing. If needed, a medical adhesive solvent can be used to help remove the dressing border.
5. 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 further information outside the United States, contact your local 3M representative or contact us at www.3M.com and select your country.

Catalog #	Dressing Size	Average Amount of CHG per Dressing (mg based on gel pad size)
1657R	8.5 cm x 11.5 cm (3-1/2 X 4-1/2 in)	45
1658R	10 cm X 12 cm (4 X 4-3/4 in)	45
1659R	10 cm x 15.5 cm (4 X 6-1/8 in)	78
1660R	7 cm x 8.5 cm (2-3/4 x 3-3/8 in)	15
1877R	8.5 cm x 11.5 cm (3-1/2 x 4-1/2 in)	45
1879R	10 cm x 15.5 cm (4 x 6-1/8 in)	78

Explanation of Symbols

- Not Made With Natural Rubber Latex
- Caution, see instructions for use
- Do not use if package is damaged or open
- Do not reuse
- Use by date
- LOT Batch code
- Manufacturer
- STERILE EO Sterilized using ethylene oxide
- Do not resterilize

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Tegaderm™ CHG

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