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

Instructions for Use

Product Description

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing is used to cover and protect vascular access sites and to secure devices to the skin. The Chlorhexidine Gluconate I.V. Port Dressing is a two-part system consisting of a 1) bordered, transparent film cover dressing with an adhesive-free window and 2) a CHG gel pad device. The Chlorhexidine Gluconate I.V. Port Dressing is breathable and transparent, allowing continuous site observation.

The CHG gel pad contains 2% w/w Chlorhexidine Gluconate (CHG), an antiseptic agent with broad spectrum antimicrobial and antifungal activity. The gel pad absorbs fluid.

In vitro testing (log reduction and barrier) demonstrates that the Tegaderm CHG gel pad in the dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria, and yeast in the dressing. The cover dressing provides an effective barrier against external contamination, including fluids (waterproof).

Indications for Use

3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering intravascular catheters and percutaneous devices.

Warnings

- 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing should not be placed over infected wounds. It is not intended to be used as a treatment of percutaneous device-related infections.
- DO NOT PUNCTURE CHG GEL PAD WITH NONCORING NEEDLE.
- 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 CHLORHEXIDINE GLUCONATE I.V. PORT DRESSING HAS NOT BEEN ESTABLISHED IN CHILDREN UNDER 18 YEARS OF AGE.
- DO NOT USE TEGADERM™ CHG CHLORHEXIDINE GLUCONATE I.V. PORT DRESSING DIRECTLY OVER BURN INJURY.
- 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.
    - 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 used 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

This device is not intended to treat catheter-related bloodstream 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 clean, dry and free of detergent residue. Allow all preps and protectants to dry completely before applying the dressing system to prevent skin irritation and to ensure good adhesion.

Use care and cover the port dressing system to protect from water when showering.

The CHG gel pad device has not been tested for use during radiation therapy.

Instructions for Use: Refer to packaging figures and those included in package insert. Failure to follow the manufacturer's instructions for use may result in complications including skin irritation and/or maceration.

Site Preparation: Prepare port site according to institution protocol. Clipping of hair at site may improve dressing and CHG gel pad device adhesion. Shaving is not recommended. The skin should be clean, dry and free of detergent residue.

Any active bleeding at insertion site should be stabilized before applying dressing system.

Post Needle Insertion Application of CHG Gel Pad Device (Figures A1 to A5)

Figure A1

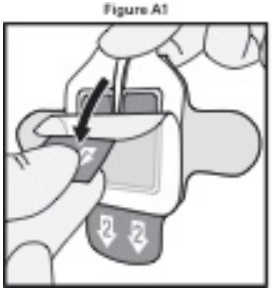

Figure A2

Figure A3

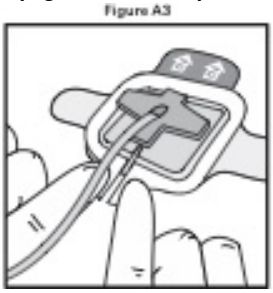

Figure A4

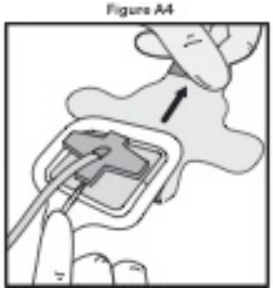

Figure A5

1. Open package and remove the sterile CHG gel pad device using aseptic technique.
2. Prepare port site and insert noncoring needle per facility protocol, allowing for a space under the noncoring needle for the CHG gel pad device of about ½ cm. Allow all preps and protectants to dry completely before applying dressing system to prevent skin irritation and to ensure good adhesion.

3. Under green tab labeled 1, grasp the soft cloth tabs. Peel and remove top liner and discard (Figure A1).
4. Do not unfold the liner. Pull the soft cloth tabs apart to widen the slit of the gel (Figure A2).
5. Using the soft cloth tabs center the device under the noncoring needle (Figure A3).
6. Press gently on the soft cloth tabs and remove liner labeled 2 in direction of arrow. (Figure A4).
7. If needed, using the soft cloth tabs, bring slit edges closer together. Do not stretch device during application. Mechanical skin trauma may result if the device is applied with tension (Figure A5).
8. Use firm pressure to smooth down device border and enhance adhesion.
9. Apply cover dressing as directed (Figures C1 to C5).

Simultaneous Application of the CHG Gel Pad Device and Noncoring Needle (Figure B1 to B5)

Figure B1 Figure B2 Figure B3 Figure B4 Figure B5

1. Open package and remove the sterile CHG gel pad device using aseptic technique.
2. Prepare port site and pre-fill noncoring needle system according to facility protocol. Allow all preps and protectants to dry completely before applying dressing system to prevent skin irritation and to ensure good adhesion.
3. Under green tab labeled 1, grasp the soft cloth tabs. Peel and remove top liner and discard (Figure B1).
4. Do not unfold device liner. Leave protective sheath in place over needle. Orient the CHG gel pad device facing upward and slide needle all the way into base of slit (Figure B2).
5. Wrap the CHG gel pad device around noncoring needle. Remove protective sheath and insert needle into port site per facility protocol (Figure B3).
6. Before removing liner, ensure needle is positioned all the way into base of slit. The CHG gel pad device may be adjusted under noncoring needle by grasping soft cloth tabs. Press gently on soft cloth tabs and remove liner labeled 2 in direction of arrow (Figure B4).
7. If needed, using soft cloth tabs, bring slit edges closer together. Do not stretch device during application. Mechanical skin trauma may result if device is applied with tension (Figure B5).
8. Use firm pressure to smooth down device border and enhance adhesion.
9. Apply cover dressing as directed (Figures C1 to C5).

Application of Cover Dressing (Figures C1 to C5)

Figure C1 Figure C2 Figure C3 Figure C4 Figure C5

1. Peel liner from dressing, exposing adhesive (Figure C1).
2. Select a border notch, center dressing over needle and position notch over tubing. Avoid overlapping dressing border onto CHG gel pad device (Figure C2).
3. Before removing frame, smooth down dressing edges. Do not stretch dressing during application. Mechanical skin trauma may result if dressing is applied with tension.
4. Slowly remove frame while smoothing down border edges, using firm pressure to enhance adhesion (Figure C3).
5. Orient notched tape strip toward dressing, under tubing, and apply onto the dressing border (Figure C4).
6. Loop tubing per facility protocol, apply documentation label over tubing (Figure C5).

Site Care

1. The site should be observed daily for signs of infection or other complications. If infection is suspected, remove the dressing and the CHG gel pad device, inspect the site directly, and determine appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, unusual odor or discharge.
2. Inspect the dressing system daily and change the components as necessary, in accordance with facility protocol. Dressing system 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 system is compromised.
3. Use care and cover the port dressing system to protect from water when showering.

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Port Dressing should be changed as necessary:

- If the cover 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 CHG gel pad device 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 gel pad device is not designed to absorb large quantities of blood or fluid.

Removal of Cover Dressing and the CHG Gel Pad Device

1) Cover Dressing: Stabilize tubing during dressing removal. Remove securement tape strips. Gently grasp an edge of the cover dressing and slowly peel from the skin in the direction of hair growth. Avoid skin trauma by peeling rather than pulling dressing up from skin.
2) CHG Gel Pad Device: Remove noncoring needle per facility protocol. Remove CHG gel pad device using soft cloth tabs. A medical adhesive solvent can be used to help remove the device border. If needed, use sterile alcohol swabs or wipes, or sterile solutions (i.e., sterile water or normal saline) to facilitate removal of the gel pad. Continue the low and slow removal method until the CHG gel pad device 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/tegadermchg

Catalog #	CHG Gel Pad Device Size	Average Amount of CHG per CHG Gel Pad Device (mg based on gel pad size)
1665	CHG Gel Pad Device Dimensions 6.2 cm x 4.9 cm (2 7/16 in x 1 15/16 in)	30

Explanation of Symbols

This product and package do not contain natural rubber latex.


Caution, see instructions for use


Do not use if package is damaged


Do not reuse


Use by date

Batch code


Manufacturer


Date of manufacture

Sterilized using ethylene oxide

Do not resterilize

Made in U.S.A. by

3M Health Care

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Issue Date: 2018-02
34-8723-4511-0