

3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad

Product Description

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad (CHG Gel Pad) is used to cover and protect vascular and non-vascular percutaneous medical devices. The CHG Gel Pad 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 CHG Gel Pad absorbs fluid.

In vitro testing (log reduction) demonstrates that the CHG Gel Pad has an antimicrobial effect against a variety of gram-positive and gram-negative bacteria, mold, and yeast.

Indications for Use

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad can be used to cover and protect catheter sites. Common applications include covering intravascular catheters and percutaneous devices.

Warnings

- 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad 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 GEL PAD HAS NOT BEEN ESTABLISHED IN CHILDREN UNDER 18 YEARS OF AGE.
- DO NOT USE TEGADERM™ CHG GEL PAD 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 (U.S.A.) restricts the device to sale by or on the order of a licensed health care professional.

Precautions

The CHG Gel Pad 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 gel pad. Do not stretch the CHG Gel Pad during application. Mechanical skin trauma may result if the CHG Gel Pad 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 CHG Gel Pad to prevent skin irritation and to ensure good adhesion.

Use care and cover the CHG Gel Pad to protect from water when showering.

The CHG Gel Pad has not been tested for use during radiation therapy.

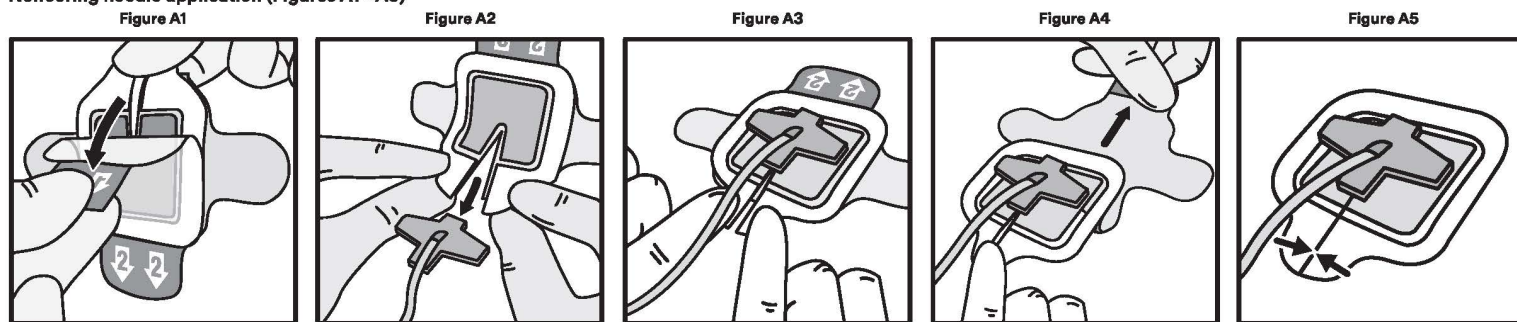
Instructions for Use: Refer to packaging figures and those included in package insert. Failure to follow the manufacturer's instructions for use may result in complications including skin irritation and/or maceration.

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

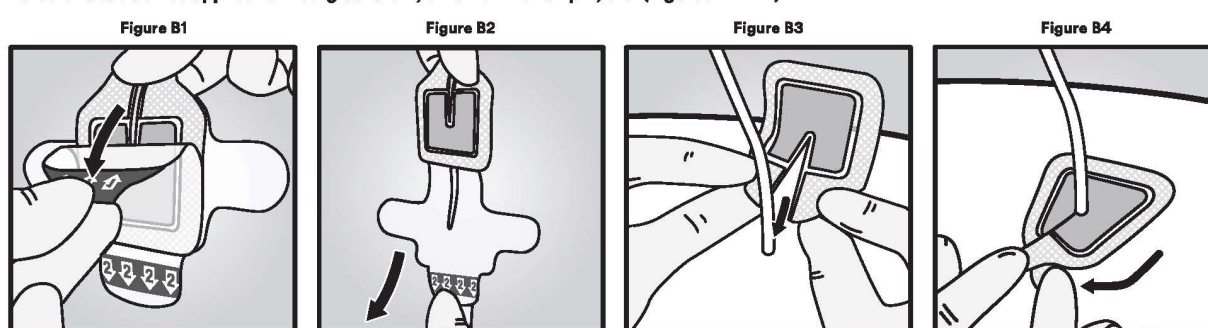
Any active bleeding at insertion site should be stabilized before applying gel pad.

Instructions for Use:

Noncoring needle application (Figures A1 - A5)



Percutaneous device application: Surgical drain, external fixation pin, etc. (Figures B1 - B4)



1. Open package and remove sterile CHG Gel Pad using aseptic technique.
2. Prepare skin surrounding the percutaneous device per facility protocol allowing all preps to dry completely before application to prevent skin irritation and ensure good adhesion.
3. Remove liners according to figures then apply CHG Gel Pad to the device site using firm pressure to enhance adhesion.
4. To prepare for an easy removal when used with an additional dressing, place CHG Gel Pad around the device ensuring that the device rests upon the slit of the gel pad.
5. Per facility protocol, the CHG Gel Pad may be used in combination with a transparent semipermeable film dressing.

Site Care (Clinician should follow standard precautions and wear the appropriate personal protective equipment when exposure to blood or body fluids is anticipated):

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, 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 CHG Gel Pad daily and change as necessary, in accordance with facility protocol. The CHG Gel Pad 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 or CHG Gel Pad is compromised.

3. Use care and cover the CHG Gel Pad to protect from water when showering.

The 3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad should be changed as necessary:

- If the CHG Gel Pad or 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 appears to be saturated or overly swollen*

*Note: To test if the CHG Gel Pad is fully saturated, lightly press down on a corner of the CHG Gel Pad with gloved finger. If the CHG Gel Pad remains displaced once gloved finger is removed, the dressing system should be changed.

Note: Tegaderm™ CHG Gel Pad is not intended to absorb large quantities of blood or fluid.

Removal:

1. Remove transparent semipermeable dressing in a low and slow manner, stabilizing the catheter or percutaneous device.
2. CHG Gel Pad may remain attached to the transparent semipermeable film dressing during removal. Stretch release may be required to help release the film dressing from the CHG Gel Pad.
3. If needed, use sterile alcohol swabs or wipes, or sterile solutions (i.e., sterile water or normal saline) to facilitate removal of the CHG Gel Pad.

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 system is guaranteed unless individual package is damaged or open.

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

Catalog #	CHG Gel Pad Size	Average Amount of CHG per CHG Gel Pad (mg based on gel pad size)
1664	CHG Gel Pad Dimensions : 6.2 cm x 4.9 cm (2 7/16 in x 1 15/16 in)	30 mg

Explanation of Symbols:

Symbol Title	Symbol	Description and Reference
Manufacturer		Indicates the medical device manufacturer as defined in Medical Device Regulation (EU) 2017/745 formerly EU Directive 93/42/EEC. Source: ISO 15223, 5.1.1
Date of manufacture		Indicates the date when the medical device was manufactured. Source: ISO 15223, 5.1.3
Use-by date		Indicates the date after which the medical device is not to be used. Source: ISO 15223, 5.1.4
Batch code		Indicates the manufacturer's batch code so that the batch or lot can be identified. Source : ISO 15223, 5.1.5
Sterilized using ethylene oxide		Indicates a medical device that has been sterilized using ethylene oxide. Source: ISO 15223, 5.2.3
Do not resterilize		Indicates a medical device that is not to be resterilized. Source: ISO 15223, 5.2.6
Do not use if package is damaged or open		Indicates a medical device that should not be used if the package has been damaged or opened. Source: ISO 15223, 5.2.8
Upper limit of temperature		Indicates the upper limit of temperature to which the medical device can be safely exposed. Source: ISO 15223, 5.3.6
Do not reuse		Indicates a medical device that is intended for one use or for use on a single patient during a single procedure. Source: ISO 15223, 5.4.2
Caution		Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. Source: ISO 15223, 5.4.4
Natural rubber latex is not present		Indicates natural rubber or dry natural rubber latex is not present as a material of construction within the medical device or the packaging of a medical device. Source: ISO 15223, 5.4.5 and Annex B
RX only		Indicates that U.S. Federal Law restricts this device to sale by or on the order of [specific licensed provider]. 21 Code of Federal Regulations (CFR) sec. 801.109(b)(1)

For more information, see HCBGregulatory.3M.com

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3M Company

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