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

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Description

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

Tegaderm™ CHG I.V. Securement 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 I.V. site.

In vitro testing (log reduction and barrier testing) demonstrates that the Tegaderm™ CHG gel pad in the Tegaderm™ CHG I.V. Securement Dressing has an antimicrobial effect against, and is a barrier to, a variety of gram-positive and gram-negative bacteria, and yeast in the dressing. The gel pad absorbs fluid.

*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.

Tegaderm™ CHG I.V. Securement Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

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 securing and covering IV catheters, other intravascular catheters and percutaneous devices.

Tegaderm™ CHG I.V. Securement Dressing is intended to reduce vascular catheter colonization and catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.

Warnings

- DO NOT USE TEGADERM™ CHG I.V. SECUREMENT DRESSING 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 MUCOUS MEMBRANES.
- THE SAFETY AND EFFECTIVENESS OF TEGADERM™ CHG I.V. SECUREMENT DRESSING HAS NOT BEEN ESTABLISHED IN CHILDREN UNDER 18 YEARS OF AGE.
- DO NOT USE TEGADERM™ CHG I.V. SECUREMENT DRESSING DIRECTLY OVER BURN INJURY.
- 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 I.V. Securement Dressing should not be placed over infected wounds. This device is not intended to treat catheter-related bloodstream infections (CRBSI) or other percutaneous device-related infection.

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 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.

Clinical Trial Results

3M Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing is supported by a randomized, multi-arm, controlled clinical trial consisting of 1,879 subjects with 4,163 central venous and arterial catheters conducted at 11 hospitals in France (12 ICUs). This trial found that the addition of 3M Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing in institutions already following routine infection control techniques led to a reduction in catheter colonization and catheter-related infections. The full study details are available in 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 Crit Care Med. 2012;186(12): 1272-1278.

The Timsit study defined a catheter-related bloodstream infection (CRBSI) as:

"CRBSI was a combination of (a) one or more positive peripheral blood cultures sampled immediately before or within 48 hours after catheter removal; (b) a positive quantitative catheter-tip culture positive (using the 1,000 CFU/ml threshold when vortexing technique was used or 100 CFU/ml threshold when sonication technique was used) for the same microorganisms (same species and same susceptibility pattern) or a blood-culture differential time-to-positivity of 2 hours or more; and (c) no other infectious focus explaining the positive blood cultures. In patients with blood cultures positive for coagulase-negative staphylococci, the same pulse-field gel electrophoresis patterns in the catheter tip and blood cultures was required for a diagnosis of CRBSI."

Utilizing the definition of CRBSI described in the Timsit et al. (2012) publication, the study authors found that a dressing containing CHG (i.e. Tegaderm CHG Securement Dressing), reduced the risk of CRBSI by 57% compared to dressings without CHG (control). The following results were obtained:

Control Group (non CHG dressing)		Test Group (Tegaderm™ CHG I.V. Securement Dressing)		Comparison		P-value
Patients with Infection	Infections per 1000 Catheter Days	Patients with Infection	Infections per 1000 Catheter Days	Percent Reduction in Patients with Infections	Percent Reduction per 1000 Catheter Days	
2.2% (21/941)	1.29	0.96% (9/938)	0.52	57%	60%	0.020

It should be noted that the Timsit definition differs from the CRBSI definition published by the Infectious Diseases Society of America (IDSA). See below for the IDSA definition. As a sensitivity analysis for the Timsit study results, the data was re-analyzed applying the Infectious Diseases Society of America (IDSA) 2009 guidelines, *Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Diseases Society of America.* In a re-analysis of all 31 CRBSI cases, each subject was reviewed to determine whether they fully satisfied criteria for CRBSI per the IDSA Guidelines.

The IDSA 2009 guidelines use the following definition for CRBSI:

"Catheter related Bacteremia or fungemia in a patient who has an intravascular device and >1 positive blood culture result obtained from the peripheral vein, clinical manifestations of infection (e.g., fever, chills, and/ or hypotension), and no apparent source for bloodstream infection (with the exception of the catheter). One of the following should be present: a positive result of semiquantitative (>15 cfu per catheter segment) or quantitative (>102 cfu per catheter segment) catheter culture, whereby the same organism (species) is isolated from a catheter segment and a peripheral blood culture; simultaneous quantitative cultures of blood with a ratio of >3:1 cfu/mL of blood (catheter vs. peripheral blood); differential time to positivity (growth in a culture of blood obtained through a catheter hub is detected by an automated blood culture system at least 2 h earlier than a culture of simultaneously drawn peripheral blood of equal volume)."

The following results were obtained from the re-analysis with the IDSA guidelines:

Control Group (non CHG dressing)		Test Group (Tegaderm™ CHG I.V. Securement Dressing)		Comparison		P-value
Patients with Infection	Infections per 1000 Catheter Days	Patients with Infection	Infections per 1000 Catheter Days	Percent Reduction in Patients with Infections	Percent Reduction per 1000 Catheter Days	
1.7% (16/941)	0.94	0.85% (8/938)	0.46	50%	51%	0.095

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. The dressing notch of 1657 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 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 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 IV 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 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 I.V Securement 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 gel pad is not designed to absorb large quantities of blood or fluid.

Removal
Stabilize catheter during removal of the 3M™ Tegaderm™ CHG I.V. Securement 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. If needed, sterile alcohol swabs or wipes, or sterile solutions (i.e., sterile water or normal saline) may be applied 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 additional information visit www.3M.com/tegadermchg

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

If you have any questions or comments, in the USA please contact the 3M Health Care Customer Help line at 1-800-228-3957.

In Canada, contact 3M Canada Company, P.O. Box 5757, London, Ontario, N6A 4T1, 1-800-364-3577.

For further information outside the United States, contact your local 3M representative or contact us at www.3M.com and select your country.

Symbol Glossary

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
Do not re-use		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

For more information see, HCBGregulatory.3M.com

Made in USA with Globally Sourced Materials

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