3M™ Tegaderm™ Antimicrobial Transparent Dressing
3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing

Product Description

3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing consist of a polyurethane film coated with a transparent chlorhexidine gluconate (CHG) acrylic adhesive. CHG, a broad spectrum antimicrobial/antifungal agent known to inhibit microbial growth has been formulated into the acrylic adhesive.

The transparent film is breathable, allowing oxygen and moisture vapor exchange, yet is impermeable to external contaminants, including fluids (waterproof), bacteria, viruses*, yeast, and mold. The dressing must remain intact to protect the IV site from external contaminants.

3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing is bordered, notched and reinforced with soft cloth tape and is designed to provide securement around catheters and other devices.

In vitro testing (time kill) demonstrates that 3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing have an antimicrobial effect against a variety of gram-positive bacteria, gram-negative bacteria, yeast and mold in the dressing.

****In vitro*** testing shows that the film of the dressing provides a barrier to viruses 27 nm in diameter or larger while the dressing remains intact without leakage. These results have not been studied with regard to prevention of viral infection. No clinical study has been conducted regarding the ability of the dressing to prevent viral infections.

Indications for Use

3M™ Tegaderm™ Antimicrobial Transparent Dressing and 3M™ Tegaderm™ Antimicrobial I.V. Advanced Securement Dressing are intended to be used to cover and protect catheter sites and to secure devices to the skin. Common applications include covering and securing IV catheters, other intravascular catheters and percutaneous devices.

Warnings

- DO NOT USE 3M™ TEGADERM™ ANTIMICROBIAL TRANSPARENT DRESSING AND 3M™ TEGADERM™ ANTIMICROBIAL I.V. ADVANCED 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 CONTACT OF THIS DEVICE WITH EARS, EYES, MOUTH OR MUCOUS MEMBRANES.
- DO NOT USE THIS DEVICE ON PATIENTS WITH A KNOWN HYPERSENSITIVITY TO CHLORHEXIDINE GLUCONATE. ADVERSE REACTIONS SUCH AS IRRITATIONS, SENSITIZATION AND GENERALIZED ALLERGIC REACTIONS HAVE BEEN REPORTED WITH THE USE OF CHLORHEXIDINE GLUCONATE.
- IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY AND, IF SEVERE, CONTACT A PHYSICIAN.
- INTENDED FOR SINGLE PATIENT USE ONLY.
- DO NOT REUSE. AS WITH ALL ADHESIVE-BASED PRODUCTS, ADHESIVE EFFECTIVENESS AND FUNCTIONALITY CAN DECLINE AFTER THE FIRST USE AND THE PRODUCT WILL NOT PERFORM AS SPECIFIED. REUSE MAY LEAD TO INFECTION OR OTHER ILLNESS/INJURY.

Precautions

The dressing should not be placed over infected wounds. This device is not intended to treat, prevent, or reduce catheter-related bloodstream infections (CRBSIs) or other percutaneous device-related infections. This device has not been studied in a randomized clinical study to determine its effectiveness in preventing such infections.

Active bleeding at insertion sites should be stabilized before applying the dressing.

Do not stretch the dressing before applying it to the skin. Dressings applied under tension can cause trauma to the skin.

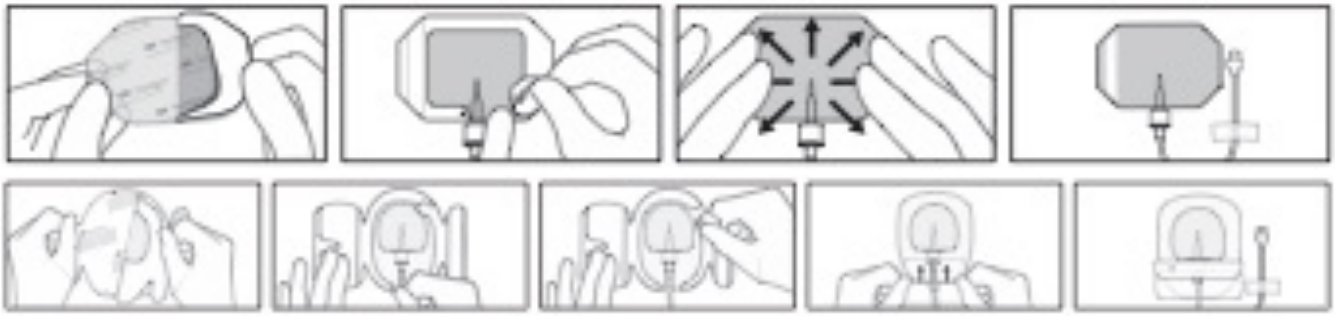
To ensure good adhesion and to help prevent skin irritation, remove detergent residues and allow all skin preparations and protectants to dry completely before applying the dressing to the skin.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

For proper use, clinicians should be trained in the use of this device.

Instructions for Use:

Failure to follow the manufacturer's instructions may result in complications including skin irritation and/or maceration.



Site Preparation:

1. Prepare the site in accordance to facility protocol.
2. Stabilize any active bleeding before applying the dressing.
3. Ensure the skin is clean, dry and free from detergent, lotion and soap residues.
4. Ensure all skin preps and protectants dry completely before applying the dressing. This will promote optimal adhesion to the skin and help minimize any skin irritation.
5. Clipping of hair at site may improve dressing adhesion. Shaving is not recommended.

Dressing Selection

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

Dressing Application:

1. Prep the catheter site according to your facility's protocol. Let all prep solutions dry completely. Remove the liner from the dressing, exposing the adhesive surface of the dressing.
2. Center the transparent portion of the dressing over the insertion site. Do not stretch the dressing during application. Press the transparent portion of the dressing into place.
3. While slowly peeling off the paper frame, smooth down the dressing edges with your fingertips. Apply firm pressure to the entire dressing to enhance dressing adhesion.
4. After the dressing has been applied, apply additional tape to further secure I.V. tubing or to stabilize the catheter.
5. Document dressing change information on label according to facility protocol. Remove label from frame and place on dressing.

Removal:

1. Remove any tape strips applied to the top of the 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. If needed, a medical adhesive solvent can be used to help remove the dressing. Continue the low and slow removal method until the dressing is completely removed.

Site Care:

1. The site should be observed at least daily for signs of infection or other complications. If infection is suspected, remove the dressing, inspect the site directly, and determine the appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, or unusual discharge or odor.
2. Change the dressing as necessary, in accordance with facility protocols. At a minimum, dressings should be changed at least every 7 days. Change the dressing more frequently if the site has high levels of exudate or if the dressing integrity has become compromised.
3. The dressing should be changed sooner than 7 days if:
   - the dressing becomes loose, soiled or compromised in any way
   - the site is obscured or no longer visible
   - there is visible drainage underneath the dressing

Storage/ Shelf Life/Disposal

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. If any damage to the packaging is observed, the sterility of the dressing may be compromised. Do not use if packaging is damaged.

How supplied

3M™ Tegaderm™ Antimicrobial Transparent Dressing

Catalog number	Dressing Size	Target Amount of CHG per dressing (mg)
9124	6 cm x 7 cm	4.04 mg

3M™ Tegaderm™ Antimicrobial IV Advanced Securement Dressing (with borders)

Catalog number	Dressing Size	Target Amount of CHG per dressing (mg)
9132	7 cm x 8.5 cm	5.65 mg

For questions or comments, contact the 3M Health Care Customer Help Line at 1-800-228-3957.

Explanation of Symbols

Not Made With Natural Rubber Latex


Caution, see instructions for use


Do not use if package is damaged


Do not reuse


Use by date

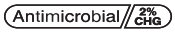
Batch code


Manufacturer


Date of manufacture

Sterilized using ethylene oxide

Do not resterilize



Dressing containing 2% Chlorhexidine Gluconate

Made in U.S.A. with globally
sourced materials by

3M Health Care

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