3M™ Tegaderm™ CHG

Chlorhexidine Gluconate I.V. Securement Dressing

General Description

Catalog Numbers - 1657R 1658R 1659R 1660R

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 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. The gel pad absorbs fluid.

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

Tegaderm CHG is CE marked as a Class III sterile medical device and fulfils the essential requirements of the Medical Device Directive 93/42/EEC. **Note:** This Document is valid for the European Union only. The registration status in other geographies must be confirmed.

**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. The barrier to viruses is due to the physical properties of the dressing, rather than the ancillary properties of CHG.

Intended Use

3M™ Tegaderm™ CHG Chlorhexidine Gluconate IV 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 blood stream infections. Tegaderm CHG is intended to reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.

Intended User:

The intended users of this device are clinicians who have training and experience with IV site care and who are familiar with applying, monitoring, and removing IV securement dressings. These clinicians can range from certified nursing assistants to physicians. In out-patient or home care situations, patients, or their caregiver, may be responsible for observing the status of their catheter and their dressing.

Contraindications

None

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.

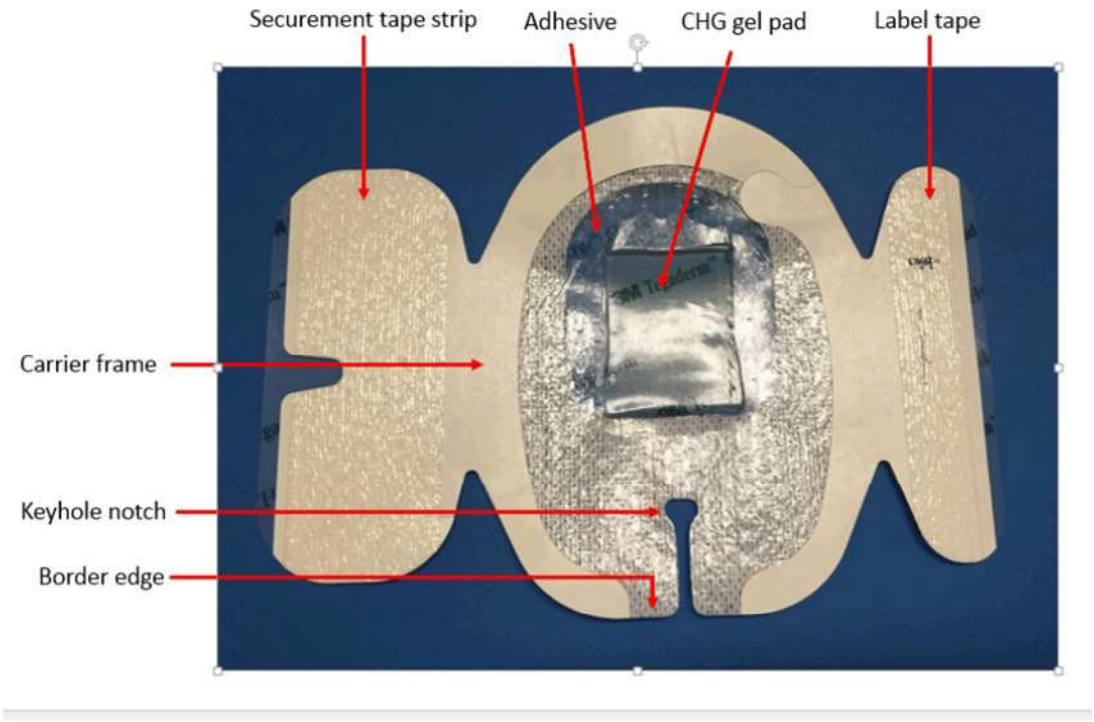
Precautions

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 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.

Please refer to Instructions for Use for detailed product and handling information.

Product Composition



The dressing notch and securement tape strip of 1657R have perforations that can be opened to conform around large catheters or other devices. The use of the perforations is optional.

Components	Raw Material
Tape Strips	Polyurethane with acrylate adhesive / Polyester nonwoven with acrylate adhesive
Gel Pad	Gel pad containing CHG
Product Liner	Printed silicone-coated film
Label tape	Polyurethane with acrylate adhesive / Polyester nonwoven with acrylate adhesive
Film Laminate:	Polyurethane with acrylate adhesive
Border	Polyester nonwoven/acrylate adhesive
Carrier frame	Silicone-coated paper

Packaging Composition

Each dressing is packaged into a pouch. Several pouches are packaged into a primary carton. Then several cartons are placed in a master carton.

Packaging Level	Material
Pouch:	Heat-sealed, ethylene oxide permeable pouch (paper/plastic film)
Primary Carton:	Clay coated, newsback (Material made from recycled paperboard and aqueous coating to protect the printing)
Master Carton:	Corrugated box

Product Range

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

Catalog number	Dressing Dimensions	Average amount of CHG per dressing (mg based on gel pad size)	Contents
1657R	8.5 cm x 11.5 cm	45	25 dressings/box 4 box/case
1658R	10 cm x 12 cm	45	25 dressings/box 4 box/case
1659R	10 cm x 15.5 cm	78	25 dressings/box 4 box/case
1660R	7 cm x 8.5 cm	15	25 dressings/box 4 box/case

GENERAL CHARACTERISTICS

Parameter	Product Performance	Test Method	Results
Sterility	Sterile unless package is damaged or opened	Sterilization validation	Pass
Shelf life	2 year minimum shelf life	Bench Study	Pass
Wear time	Can be worn for 7 days / Can stay on for 7 days	Customer Evaluation & Randomized Controlled Trial	Pass

Performance	Permeable to moisture vapor and gases	**Bench Study**	-Upright MVTR of dressing with gel pad and adhesive free window Minimum of 400g/m2/24hrs (Pattern Coated Border Minimum of 500g/m2/24hrs) -Inverted MVTR of dressing with gel pad and adhesive free window Minimum of 4000 g/m2/24hrs (Pattern Coated Border Minimum of 500g/m2/24hrs)
CRBSI (Catheter-related bloodstream infections)	Intended to Reduce Catheter-related bloodstream infections	Randomized Controlled Trial (consisting of 1879 subjects with 4163 central venous and arterial catheter insertion sites)	- 60% reduction in the incidence of CRBSI (statistically significant). - Demonstrate statistically significant reduction in skin colonization and catheter colonization in the chlorhexidine vs. non-chlorhexidine group
Antimicrobial activity	Gel pad reduces skin flora and preventing its re-growth	Study on healthy volunteers	Suppression of re-growth of normal skin flora for up to 10 days

Antimicrobial activity	Gel pad has broad spectrum antimicrobial activity	In vitro testing	Antimicrobial effect against a variety of gram-positive and gram-negative bacteria and yeast, incl. organism most commonly associated with CRBSI
Visibility	Transparent gel pad allows continuous visualization of the insertion site [1) & 2)]	Customer Evaluation	Confirmed
Visibility	Insertion site remains visible under transparent gel pad after absorption of moderate fluid & blood	Customer Evaluation	Confirmed
Visibility/ Conformability	Transparent gel pad molds / conform around catheter and hub	Customer & Nurse Evaluation	Confirmed
Microbial barrier	Dressing is a microbial barrier and protects insertion site against a variety of gram-positive & -negative bacteria and yeast, incl. organism most commonly associated with CRBSI	Barrier assay and viral penetration study	Confirmed
Viral barrier	Dressing provides a viral barrier from viruses 27nm in diameter (e.g. HCV) or larger (e.g. HBV and HIV) while dressing remains intact w/o leakage	Viral penetration study	Confirmed
Effects	CHG is not inactivated by alcohol, PVPI and CHG or by blood or by Cavilon™ No Sting Barrier Film (CNSBF)[3]	In-House Study Fluid Absorption Study, Literature Bench study	Confirmed

Compatibility	Tegaderm™ CHG is compatible with CT and MRI. MR safe. Radiologically transparent	ASTM F2503 – 13, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Article: Shellock FG, Woods TO, Crues JV, 3rd. MR Labeling information for implants and devices ASTM F 640-07, Procedure (Method A)	Confirmed
Compatibility	Tegaderm™ CHG is compatible with catheter materials	Catheter compatibility testing (Physical tests)	Confirmed

1) "Supports compliance with the 2011 INS Standards of Practice by facilitating visualization of the insertion site." (Replace with National Guidelines when applicable)

2) 'Supports compliance with the 2011 CDC Guidelines for Prevention of Intravascular Catheter-Related Infections through the use of a transparent dressing.

3) CNSBF should be carefully applied to the skin, avoiding the area immediately surrounding the insertion site and where the CHG gel pad is placed.

SAFETY AND SKIN TOLERABILITY (1)
All tests conducted according to GLP (good laboratory practice)
as described by the FDA (21CFR Part 58) and according respective EU standards

3M™ Tegaderm™ CHG Dressing is categorized as a surface device having permanent (> 30 days) contact with breached or compromised surfaces. As such, the guidance suggests that cytotoxicity, irritation, sensitization, genotoxicity and sub chronic toxicity be conducted on patient contacting materials.

The studies completed to assess the biocompatibility of 3M™ Tegaderm™ CHG Dressing were conducted on the gel pad containing CHG and the transparent adhesive dressing. The results of the studies listed below confirm the biocompatibility of the 3M™ Tegaderm™ CHG Dressing.

Parameter	Product Performance	Test Method	Results
Biocompatibility	Safe for intended use	ISO 10993-Part 1 (biological evaluation of medical devices- evaluation and testing) ISO 14971 (application of risk management to medical devices)	In compliance In compliance- All documentation completed
Cytotoxicity: - CHG gel pad - Adhesive - Transparent Film - Soft Cloth border - Tape Strip	Potential to damage cell	ISO 10993-5	Moderate Cytotoxic* In compliance
Skin irritation - CHG gel pad - Adhesive - Transparent Film - Soft Cloth border - Tape Strip	Gentle to skin/ Minimal irritation	ISO 10993-10 (Primary skin irritation)	In compliance
Skin tolerability - CHG gel pad - Adhesive - Transparent Film	Weak sensitizing potential	ISO 10993-10 Delayed contact dermal sensitization (Buehler method) or Guinea Pig Maximisation Test (Magnussen Klingman)	In compliance
Genotoxicity - CHG gel pad - Adhesive - Transparent Film	Potential for genetictoxicity	Bacterial Reverse Mutation & Chromosomal Aberration	Pass

Parameter	Product Performance	Test Method	Results
Sub chronic Toxicity - CHG gel pad - Adhesive - Transparent Film	Potential for adverse effects on internal organs	90-day Sub chronic toxicity	Pass
Sensitization [3) +4)] for EU	No sensitization induced [3) +4)] for EU	Human Repeat Insult Patch Test (HRIPT): tested on 97-persons	Confirmed
Sensitivity [3) +4)] for EU	Low dermatitis potential [3) +4)] for EU	Human Repeat Insult Patch Test (HRIPT): tested on 97-persons Randomized Clinical Trial (RCT)	Confirmed

* Moderate Cytotoxic:
Antimicrobial agents, including CHG, are known to have some cytotoxic effects; however it is not expected that this will have a relevant clinical impact to intact or breached skin.

Sensitization: 3) +4) for EU

3) This claim needs the qualification "Not for use on premature infants or persons with known sensitivity to CHG"

4) In Europe this claim also needs the qualification:
"THE SAFETY AND EFFECTIVENESS OF TEGADERM™ CHG DRESSINGS HAS NOT BEEN EVALUATED IN CHILDREN UNDER 18 YEARS OF AGE"

SAFETY AND SKIN TOLERABILITY (2)

Parameter	Product Performance	Test Method	Results
Basic safety/ absence of toxic compounds	Free of: - PVC - Natural rubber Latex - Colophony	Raw Material Information, Formulation, Composition, LCM	Confirmed
	No antimicrobial compounds intentionally added; except CHG as intended	Raw Material Information, Formulation, Composition, LCM	Confirmed

Parameter	Product Performance	Test Method	Results
Basic safety/ absence of Substances of Very High Concern	The substances of the REACH SVHC candidate list as of 16th July 2019 are not present at or above 0,1% in the product or subcomponents of the product.	Raw Material Information, Formulation, Composition	Confirmed

FLUID HANDLING CAPACITY

Parameter	Product Performance	Test Method	Results
Absorbency	CHG gel Absorbs up to moderate fluids (Perspiration, exudate and blood)	Randomized Clinical Trial (RCT) Fluid Absorption study	Confirmed (8x its weight of saline and 3x its weight in blood)

EASE OF USE

Parameter	Product Performance	Test Method	Results
Dressing Application	Permits clinician to apply dressing w/o sticking to gloves	Design - Adhesive free carrier frame	Confirmed
Dressing Application	Intuitive to use and allows hassle-free application	Customer Evaluation	Confirmed
Package opening	Can be opened sterilely and easily	Customer Evaluation	Confirmed

PACKAGING RELATED INFORMATION

Packaging standards

Parameter	Product Performance	Norm	Status
Labeling information supplied by manufacturer	Legally correct labeling	EN1041	In compliance
Symbols used for labeling of medical devices	Legally correct symbols used	ISO 15223	In compliance
Sterile Barrier System (SBS)	Sterile unless package is damaged or opened	EN ISO 11607- Part 1&2	In compliance
Undesirable components of packaging	Free of substances of very high concern (SVHCs) in >0,1% in weight concentration	EC Regulation 1907/2006 (REACH) for any packaging article as described in directive 94/62/EC from the EU	Stated in supplier contracts
Undesirable components of packaging	Free of PVC (polyvinylchloride) Free of silica gel Totally Chlorine Free bleaching	3M internal standards	Stated in supplier contracts
Undesirable components of packaging	Sum concentration level of Lead, Cadmium, Mercury and Hexavalent Chromium not to exceed 100ppm (by weight)	Article 9 of EC directive 94/62/EC	Stated in supplier contracts

CERTIFICATIONS

Type of Certification	3M Company Certifications	Certifying Body	Results
ISO 13485:2016	3M Company 2510 Conway Ave. St. Paul, MN 55144 U.S.A.	Certified by BSI (CE0086)	In compliance

Type of Certification	3M Company Certifications	Certifying Body	Results
93/42/EEC Annex II.3 and II.4	3M Company 2510 Conway Ave. St. Paul, MN 55144 U.S.A.	Certified by BSI (CE0086)	In compliance

Additional information:

The information provided in this technical data sheet related to material content represents 3M's knowledge and belief as of the date it is provided, which may be based in whole or in part on information provided by suppliers to 3M.

This Technical Data Sheet is approved by 3M Regulatory Affairs:
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