prevahex™ CHX

ANTIMICROBIAL TRANSPARENT
THIN FILM DRESSING
CHX: The Chlorhexidine Advantage™

INSTRUCTIONS FOR USE

PRODUCT AVAILABILITY:

Catalog Number	Size	Case Contents
1483CH prevahex™	1.75” X 1.75”	4 Boxes @ 100 Dressings/Box
1484CH prevahex™	2.375” x 2.75”	4 Boxes @ 100 Dressings/Box
1485CH prevahex™	4” x 4.75”	4 Boxes @ 50 Dressings/Box
1488CH prevahex™	2.8” Diameter	4 Boxes @ 100 Dressings/Box

NOT MADE WITH NATURAL RUBBER LATEX | Rx ONLY

INSTRUCTIONS FOR USE

Product Description

prevahex™ Antimicrobial Transparent Thin Film Dressing with Chlorhexidine is used to cover and protect wound sites, percutaneous medical devices including catheters, and wound closure devices in the same manner as traditional transparent film dressings. The prevahex™ dressing also secures primary dressings to skin. The dressing consists of a clear, non-latex, polyurethane film coated with an antimicrobial acrylic-based adhesive containing 10% wt./wt. chlorhexidine. The prevahex™ dressing is a clear film dressing which allows the site or the wound to be constantly monitored and assessed. The dressing is self-adhesive and breathable, allowing for good oxygen and moisture vapor exchange.

prevahex™ dressings provide an effective barrier against external contamination including fluids (waterproof), bacteria, viruses* and yeasts. *In vitro* testing** (1, 3 and 7 day time kill) demonstrates that the chlorhexidine incorporated in prevahex™ dressings has an antimicrobial effect against a broad spectrum of gram-positive bacteria, gram-negative bacteria, and yeasts, including methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-resistant *Staphylococcus epidermidis* (MRSE), vancomycin-resistant *Enterococcus faecalis* (VRE), *Enterococcus faecium*, multiple drug-resistant *Enterococcus faecium* (MDR), *Pseudomonas aeruginosa, Escherichia coli, Serratia marcescens, Candida albicans, Candida parapsilosis,* and *Candida tropicalis.*

* *In vitro* testing has proven that the prevahex™ dressing provides a viral barrier from viruses 27 nm in diameter, (e.g., HCV) or larger (e.g., HBV and HIV) while the dressing remains intact without leakage. *In vitro* effectiveness does not predict clinical performance.

** *In vitro* effectiveness does not predict clinical performance.

Indications for Use

prevahex™ Antimicrobial Transparent Thin Film Dressings are intended to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures and wires.

The prevahex™ dressing may also be used to cover and secure primary dressings. The prevahex™ dressing inhibits microbial growth within the dressing and prevents external contamination.

Warnings

prevahex™ DRESSINGS SHOULD NOT BE USED AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.

prevahex™ DRESSINGS SHOULD NOT BE USED ON BURNS.

prevahex™ DRESSINGS SHOULD NOT BE USED ON PREMATURE INFANTS OR INFANTS YOUNGER THAN 2 MONTHS OF AGE. USE OF prevahex™ ON PREMATURE INFANTS MAY RESULT IN HYPERSENSITIVITY REACTIONS OR NECROSIS OF THE SKIN.

prevahex™ DRESSINGS SHOULD NOT BE USED AS THE PRIMARY MEANS TO FIX ARTERIAL CATHETERS OR ARTERIAL CANNULAE.

prevahex™ DRESSINGS ARE FOR EXTERNAL USE ONLY AND SHOULD NOT BE ALLOWED TO CONTACT EARS, EYES, MOUTH OR MUCOUS MEMBRANES.

prevahex™ DRESSINGS SHOULD NOT BE USED ON PATIENTS WITH KNOWN HYPERSENSITIVITY OR ALLERGY TO CHLORHEXIDINE. THE USE OF CHLORHEXIDINE CONTAINING PRODUCTS HAS BEEN REPORTED TO CAUSE IRRITATIONS, SENSITIZATION AND GENERALIZED ALLERGIC REACTIONS. Hypersensitivity reactions associated with topical use of chlorhexidine have been reported in several countries. The most serious reactions (including anaphylaxis) have occurred in patients treated with lubricants containing chlorhexidine, which were used during urinary tract procedures. Preparations of this type are not approved for sale in the USA under any circumstances. Caution should be used when using chlorhexidine containing preparations, and the patient should be observed for possibility of hypersensitivity reactions.

IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY, AND IF SEVERE, CONTACT A PHYSICIAN.

Precautions

prevahex™ dressings are not intended to treat surgical site infections (SSI), catheter-related blood stream infections (CRBSI) or other percutaneous device-related infections and has not been studied in a randomized clinical study as to its effectiveness in preventing such infections.

Hemostasis of any insertion site should be achieved before applying the dressing.

The dressing should not be stretched during application as tension may cause skin trauma.

The skin should be dry and free of soap residue to prevent skin irritation and to ensure good adhesion of the dressing. Allow skin preparation solutions and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion to the skin.

Active Ingredients

Chlorhexidine reduces the incidence of bacterial colonization within the entire dressing.

Directions for use

Prepare the site as protocol dictates. Open the sterile pouch and remove the prevahex™ dressing.

Application

1. Hold the flap of the top white paper frame and the printed bottom paper release liner and peel apart to expose the adhesive surface underneath top paper frame. Place the exposed adhesive on the skin and smooth the dressing over the skin to ensure good adhesion. Discard the printed paper release liner.

2. Locate the tear notch (if applicable) on the center perimeter on one side of the white paper frame, and tear frame starting by separating both sides of the tear notch. Peel away the paper frame from the adhered dressing starting at one side of the separated tear notch (if applicable) and continue around the perimeter of the dressing.

3. Smooth the dressing over the skin towards the edges to ensure good adhesion.

4. Once removed from the applied dressing, the paper frame includes an adhesive note layer tape that may be used to write notes related to the dressing application. If used, the writing of any information on this adhesive note layer must be completed prior to separation from the frame and reapplication on the top of the dressing already on the patient's skin.

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 and may be needed more frequently with highly exudative sites if the integrity of the dressing becomes compromised.

3. The dressing should be changed as necessary:
   a. If the dressing becomes loose, soiled or compromised in any way
   b. If the site is obscured or no longer visible
   c. If there is visible drainage

Note: The prevahex™ dressing is not designed to absorb blood or fluid.

Dressing Removal

Change dressing as good nursing practices dictate. To remove the dressing, gently lift one edge of the dressing and slowly peel away.

Storage Information and Shelf Life

- The dressing should be stored in a cool, dry place (≤ 75°F).
- Provided that the integrity of the pouch is not compromised in any way, the pouch will serve as an effective sterile barrier until the use-by date printed on the pouch.
- The use-by date of the prevahex™ dressing is provided on the pouch.

Sterility

Sterile unless package is damaged or open.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician.

Explanation of Symbols

STERILE R	Sterilized using irradiation		Use-by date
	Do not use if package is damaged	LOT	Lot number
Rx ONLY	Caution: US federal law restricts this device to sale by or on the order of a physician.		Do not reuse
REF	Catalog number		Caution, see instructions for use

Medical Device Reporting:

Any potential incidents involving entrotech life sciences products should be reported immediately by calling: +1 (415) 513-4494

entrotech life sciences inc.
Made in the USA for entrotech life sciences inc.
475 Sansome Street, San Francisco, CA 94111 USA
prevahexchx.com info@prevahexchx.com