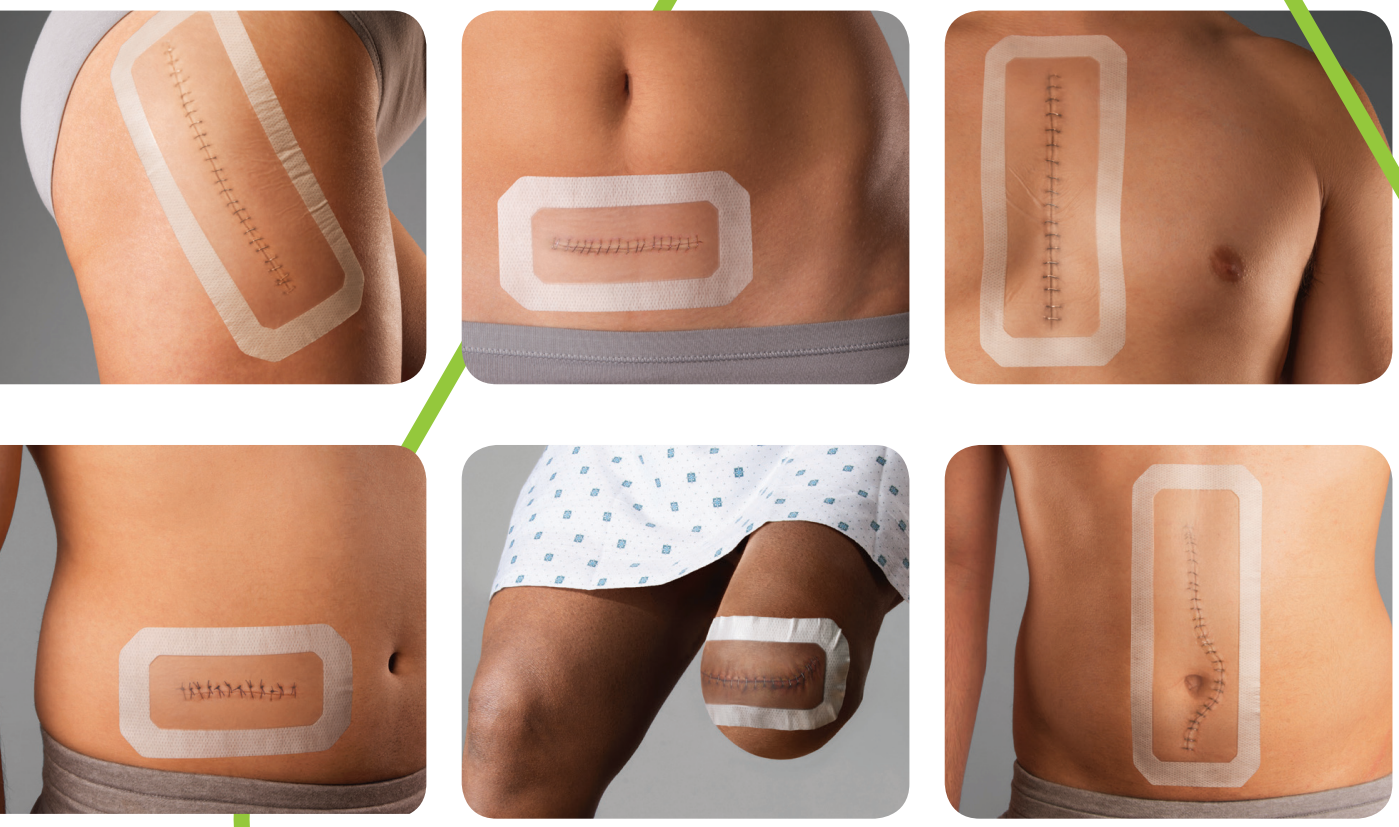


# BeneHold™ Post-Op Dressing with CHG

## Technical Bulletin

AVERY DENNISON | Medical

# Introduction

The main purpose of a surgical dressing is to provide an ideal environment for wound healing. Surgical dressings typically control postoperative bleeding, absorb exudate, provide protection for newly formed tissue, prevent surgical site infection and ease pain.[1]

**BeneHold™ Post-Op Dressing with CHG** was designed to provide many of these key attributes. Those include the ability to absorb and contain exudate without leakage, cover and protect the post operative wound site, impermeability to water and bacteria, suitability of use with different types of wound closures and transparency for easy monitoring and assessment of the site.[1,2,3] In addition to these dressing characteristics, **BeneHold™ Post-Op Dressing with CHG** prevents external contamination of the post operative wound through the functions of the two different layers: the outer film layer and the adhesive layer. The outer film layer serves as a barrier that is impermeable to external contaminents, including fluids (waterproof), bacteria, viruses, and yeast.[2] The inner adhesive layer contains chlorhexidine gluconate, which is a well-known antiseptic.

## Product Summary

BeneHold™ Post-Op Dressing with CHG is a transparent film dressing featuring a unique, patented adhesive formulation that contains chlorhexidine gluconate (CHG).

The dressing was tested to evaluate its in vitro antimicrobial properties and also to evaluate its fluid handling capacity, barrier function, adhesiveness and safety profile.

By combining an antimicrobial agent (CHG) in the adhesive layer with a backing film that is impermeable to external contaminants, in vitro testing demonstrates that BeneHold™ Post-Op Dressing with CHG inhibits microbial growth within the dressing and prevents external contamination. Though it resembles a thin, transparent film dressing, its ability to both absorb and breathe allows for management of light to moderate levels of wound exudate, creating a moist wound environment conducive to wound healing.

## Indications For Use

The BeneHold™ Post-Op Dressing with CHG is intended to be used to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures and wires. The dressing may also be used to cover and secure primary dressings. The BeneHold™ Post-Op Dressing with CHG inhibits microbial growth within the dressing and prevents external contamination.



## Indications For Use (continued)

The dressing consists of a transparent film and a thin layer of acrylic adhesive containing CHG. CHG is a well-known antiseptic agent with broad-spectrum antimicrobial activity. The dressing is flexible, providing comfort during wear. The CHG contained within the adhesive provides sustained antimicrobial activity in the dressing, while the backing film acts as a selective filter allowing gases such as water vapor and oxygen to be easily exchanged while at the same time acting as a barrier to liquids, bacteria and viruses*.

## Mechanism Of Action

BeneHold™ Post-Op Dressing with CHG features a unique acrylic-based adhesive with two important functionalities: it has absorptive properties to manage fluid or exudate and also provides an antimicrobial effect to minimize microbial contamination and colonization of the dressing.

There are two components to the way BeneHold™ Post-Op Dressing with CHG manages moisture: absorption and breathability (FIG I). The hydrophilic nature of the wound contact layer adhesive allows it to absorb exudate, whereupon it turns into a soft gel that protects against dehydration. Meanwhile, the backing film is also breathable, allowing oxygen and moisture vapor exchange. These two components working together allow the dressing to manage light to moderate levels of exudate, creating a moist wound environment conducive to wound healing.

BeneHold™ Post-Op Dressing with CHG inhibits microbial growth within the dressing and prevents external contamination. Chlorhexidine gluconate (CHG) is formulated into the adhesive, and combined with a backing film that is impermeable to external contaminants, including fluids, bacteria, viruses and yeast.

FIGURE I

**ILLUSTRATION OF THE MECHANISM OF ACTION IN BENEHOLD™ CHG**

The post-op dressing technology absorbs moisture and fluids and acts as a water-resistant bacterial and viral barrier* within a thin, conformable design.

The transparent post-op dressing allows for visual monitoring of the site's condition.

BeneHold™ CHG adhesive technology has sustained antimicrobial activity against skin flora up to 7 days.[4]

*In vitro testing shows that the transparent film of the BeneHold™ Post-Op Dressing with CHG provides a barrier to viruses 27 nm in diameter or larger if the dressing remains intact. 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.

# Antimicrobial Efficacy[5]

**Introduction** A laboratory study was performed to determine the in vitro antimicrobial efficacy of BeneHold™ Post-Op Dressing with CHG against ten microorganisms commonly associated with surgical site infections. The test involves incubating the dressing while in contact with a known inoculum for seven days, then counting the number of surviving microorganisms in relation to the population remaining on a nonantimicrobial placebo dressing. The product's antimicrobial efficacy is expressed as the logarithmic reduction in survivors compared to the placebo.

**Test Methods** Testing was conducted according to a modified version of the methods described in the ISO 22196 standard for in vitro antimicrobial efficacy. BeneHold™ Post-Op Dressing with CHG was exposed to 10 representative microorganisms (TABLE I). For all samples, a minimum of $1x10^6$ (6-log) microbes were inoculated. After incubation the microorganisms were recovered from the test article in a neutralizing solution. The number of microorganisms recovered was determined and the reduction in the population was calculated using the placebo population as reference. In order to be considered antimicrobial, a minimum 4-log reduction in microbial count must be observed against bacteria and yeast.

TABLE I

**BENEHOLD™ POST-OP DRESSING WITH CHG SHOWS > 4 LOG REDUCTION AGAINST COMMON PATHOGENS ASSOCIATED WITH SURGICAL SITE INFECTIONS (SSI)**

| | *(%) OF SSI | ORGANISM TESTED | ISOLATE | 7-DAY >4 LOG REDUCTION |
|---|---|---|---|---|
| **GRAM-POSITIVE BACTERIA | | | | |
| STAPHYLOCOCCUS AUREUS (S. AUREUS) | 30.0% | S. aureus<br>Methicillin-resistant S. aureus (MRSA) | ATCC 33591<br>ATCC 6538 | YES<br>YES |
| COAGULASE-NEGATIVE STAPHYLOCOCCI | 13.7% | Staphylococcus epidermis (S. epidermis) | ATCC 12228 | YES |
| ENTEROCOCCUS SPECIES | 11.2% | Vancomycin-resistant enterococci (VRE) | ATCC 51575 | YES |
| **GRAM-NEGATIVE BACTERIA | | | | |
| ESCHERICHIA COLI (E. COLI) | 9.6% | E. coli | ATCC 8739 | YES |
| PSEUDOMONAS AERUGINOSA (P. AERUGINOSA) | 5.6% | P. aeruginosa | ATCC 9027 | YES |
| KLEBSIELLA PNEUMONIAE (K. PNUEMONIAE) | 3.0% | K. pneumoniae and<br>Carbapenem-resistant K. pneumoniae (CRE) | ATCC 4352<br>***ATCC BAA 1705<br>***ATCC BAA 1706 | YES<br>YES<br>YES |
| **YEAST | | | | |
| CANDIDA SPECIES | 2.0% | Candida albicans (C. albicans) | ATCC 10231 | YES |

*Hidron, A., et al. "Antimicrobial-Resistant Pathogens Associated With Healthcare-Associated Infections: Annual Summary of Data Reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006–2007". Infection Control and Hospital Epidemiology. 29(11): 996-1011 (2008). DOI: https://doi.org/10.1086/591861.

**Results based on the average of 3 batches; tests performed by an independent laboratory.

***Results based on one batch; tests performed in triplicate by an independent laboratory.



# Antimicrobial Efficacy[5] (continued)

**Results** No surviving microorganisms were recovered after seven days' contact with the BeneHold™ Post-Op Dressing with CHG. The seven-day log reduction relative to placebo was at least 5-log for each of the bacteria and at least 4-log for C. albicans (yeast).

**Conclusion** BeneHold™ Post Op Dressing with CHG was found to be effective against all ten microorganisms for seven days, including Carbapenem-Resistant Enterobacteriaceae (CRE), per the >4 log reduction criteria.*

*4-log reduction on yeast at initial time point

# Barrier Function: Waterproofness[5]

**Introduction** The objective of this test was to assess the waterproofness of the BeneHold™ Post-Op Dressing with CHG.

**Test Methods** The waterproofness of the outer layer of the dressing was determined using a method in accordance with the European Standard BS EN 13726:3:2003-Section 3.2.[6] A dressing specimen was used to completely cover the opening of a modified Paddington cup test cell which was filled completely with water. Dry filter paper was affixed to the upper surface and examined for wetness as a sign of water penetration after application of a 500 mm hydrostatic head.

**Results** No water was observed to penetrate any of the test specimens. The specimens passed the waterproofness test.

**Conclusion** BeneHold™ Post-Op Dressing with CHG is waterproof.

## Barrier Function: Bacterial Barrier[5]

**Introduction** The objective of this test was to assess the bacterial barrier properties of the BeneHold™ Post-Op Dressing with CHG over seven days.

**Test Methods** Placebos of BeneHold™ Post-Op Dressing with CHG were placed adhesive-side down on top of purple agar 0.5% supplemented dextrose plates. A challenge organism suspension containing $10^6$cfu/mL was then placed on top of the film. After seven days of contact the agar was inspected for signs of bacterial growth, evidenced by a color change in the agar from purple to yellow. The test was performed with P. aeruginosa (ATCC 9027), MRSA (ATCC 33591), S. epidermidis (ATCC 12228), K. pneumoniae (ATCC 4352) and VRE (ATCC 51575).

**Results** All purple agar 0.5% supplemented dextrose plates remained purple, indicating that none of the microorganisms tested passed through the film.

**Conclusion** BeneHold™ Post-Op Dressing with CHG is a barrier to bacteria.

## Barrier Function: Viral Barrier[5]

**Introduction** The objective of this test was to assess the ability of the BeneHold™ Post-Op Dressing with CHG to act as a barrier to viruses.

**Test Methods** Viral barrier testing was conducted according to ASTM standard F1671. A sterile placebo was exposed to a solution of Bacteriophage Phi-X174 (one of the smallest known viruses – diameter 27 nm)[7] on the film side of the dressing. A pressure cycle of 5 minutes at 0 psig, 1 minute at 2 psig and 54 minutes at 0 psig was applied. At the end of the test the adhesive side of the dressing was tested for presence of bacteriophage.

**Results** There were no detectable quantities of bacteriophage virus collected on the adhesive side of the placebo samples.

**Conclusion** BeneHold™ Post-Op Dressing with CHG is a barrier to viruses larger than 27 nm.



## Fluid Management & Adhesion: Unique Moisture Management[5]

**Introduction** Proper moisture balance is key to good wound care: a wound environment that is too wet or too dry can have an adverse effect on healing.[8] Wound dressings can play an important role in maintaining the optimal conditions for moist wound healing. There are two main components to the mechanism by which BeneHold™ Post-Op Dressing with CHG manages moisture:

- FLUID RETENTION The dressing soaks up moisture and exudate into the absorbent adhesive layer, which transforms into a soft gel that retains it. The static absorption quantifies how much fluid can be retained.
- BREATHABILITY Moisture can pass through the dressing and escape through the waterproof barrier film in the form of water vapor. The moisture vapor transmission rate (MVTR) quantifies the speed of escape.

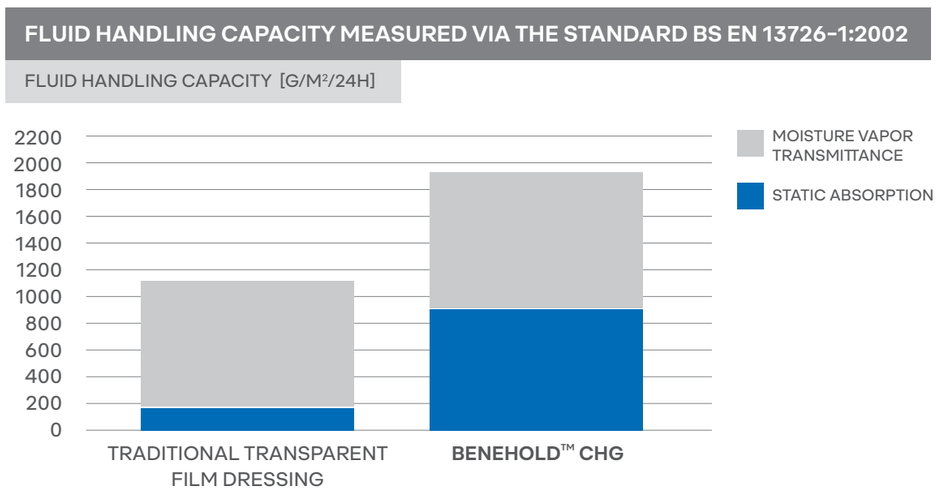
The sum of the MVTR and static absorption is the total fluid handling capacity, which represents the total moisture management capability of a dressing.

**Test Methods** The fluid handling capacity test was performed following the standard BS EN 13726-1:2002. Test articles are placed onto Paddington cups filled with 20 mL of a 0.9 percent saline solution and then left in an oven at 37˚C for 24 hours. The MVTR and static absorption were gravimetrically calculated.

**Results** The BeneHold™ Post-Op Dressing with CHG has an MVTR of 1060 g/m2-day, which is comparable to a traditional transparent film dressing. Uniquely, in comparison to traditional transparent film dressings, it also has the added capability to statically absorb 900 g/m2-day (FIG II).

FIGURE II

**FLUID HANDLING CAPACITY MEASURED VIA THE STANDARD BS EN 13726-1:2002**




**Conclusion** BeneHold™ Post-Op Dressing with CHG manages moisture through a combination of both fluid retention and breathability. These two components working together allow the dressing to manage light to moderate levels of exudate, enabling a moist wound environment conducive to wound healing.

# Secure Adhesion[5]

**Introduction** The main purpose of a surgical dressing is to provide an ideal environment for wound healing. Surgical dressings typically control postoperative bleeding, absorb exudate, provide protection for newly formed tissue, prevent surgical site infection, and ease pain.[1] It is important that the post op dressing has the proper balance of secure adhesion, yet gentle enough to be removed without incident to the wound site.

**Test Methods** A healthy human dressing wear time study was conducted to assess the adhesive performance of BeneHold™ Post-Op Dressing with CHG. Forty panelists were recruited and divided into groups assigned to wear either a small (8.0 cm x 15.0 cm) or a large (10.0 cm x 25.0 cm) dressing on either the lower abdomen or back. The dressings were applied according to a randomization schedule that ensured equitable distribution of the two dressing sizes and where they were applied. The dressings were evaluated daily by a study monitor who assessed the percentage area of adhesive lift and recorded the date, time, and reasons why any detached dressing was lost. The study concluded after seven days of wear time and any dressing remaining at that time were removed.

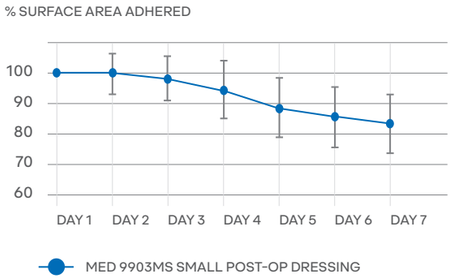
**Results** All 40 participants enrolled in the study completed it and wore the dressings for the entire 7 days. In the panel who wore the small dressings, one BeneHold™ Post-Op Dressing with CHG fell off on Day 6, while the remaining dressings (95%) remained adhered until the end of the study. In the panel who wore the large post-op dressings, two BeneHold™ Post-Op Dressing with CHG fell off unintentionally before day 7. The remaining dressings (90%) remained adhered to the test sites until the end of the study. In both panels, an average of 90% of the dressings' surface areas remained adhered throughout the first four days of wear, and by the end of the 7 day test period this declined slightly to 80%.

**Conclusion** In a 7-day healthy-human volunteer study where the dressings were applied over the lower abdomen or back, more than 92% of the BeneHold™ Post-Op Dressing with CHG stayed in place, well-secured to the skin throughout the entire week of wear time, and no dressings were lost within the first 5 days of wear. BeneHold™ Post-Op Dressing with CHG can be worn securely on the skin for up to seven days.

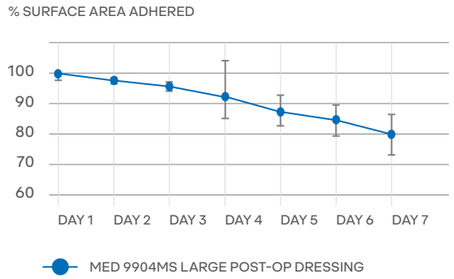
FIGURES III & IV

**AVERAGE PERCENTAGES OF THE SURFACE AREA ADHERED TO FOR:**

MED 9903MS
**SMALL POST-OP DRESSING**




MED 9904MS
**LARGE POST-OP DRESSING**




Note: Data points for FIGURE III: MED 9903MS (•) as well as data points for FIGURE IV: MED 9904MS (•) represent the mean percentage of adhered surface area with error bars representing the standard error of the mean (SEM).



# Safety Profile: Cytotoxicity[5]

**Introduction** Most dressings containing an antimicrobial have the beneficial effect of reducing skin microflora. The ideal dressing design incorporates the minimum amount of antimicrobial agent to be effective. As the content increases, so does the risk of adverse side effects they may cause. The primary objective of the study was to evaluate the biocompatibility of BeneHold™ Post-Op Dressing with CHG.

**Test Methods** The BeneHold™ Post-Op Dressing with CHG was tested following the BS EN ISO 10993-5:2009 standard for in vitro cytotoxicity testing (agarose overlay method). In addition, the BeneHold™ Post-Op Dressing with CHG was subjected to skin irritation and sensitization testing according to the standard BS EN ISO 10993-10:2013. The CHG concentration in the BeneHold™ Post-Op Dressing with CHG is 4%.

**Results** BeneHold™ Post-Op Dressing with CHG was found to be non-cytotoxic, non-irritating and non-sensitizing as noted in the following Table II.

TABLE II

| SUMMARY OF THE BIOCOMPATIBILITY TESTING | |
|---|---|
| **TEST** | **RESULT** |
| **CYTOTOXICITY** AGAROSE OVERLAY[2] | GRADE 0 |
| **ISO SKIN IRRITATION**[2] | PRIMARY IRRITATION SCORE 0.2 |
| **SENSITIZATION** ISO MAXIMIZATION IN GUINEA PIG[2] | NON-SENSITIZING |

**Conclusion** BeneHold™ Post-Op Dressing with CHG, while demonstrating solid in vitro antimicrobial efficacy, was found to be non-cytotoxic, non-irritating, and non-sensitizing in contact with skin.

## Irritation Study On Healthy Human Skin[5]

**Objective** The objective of this study was to assess the propensity of BeneHold™ Post-Op Dressing with CHG to irritate the skin.

**Synopsis** The BeneHold™ Post-Op Dressing with CHG were applied to healthy human volunteers' lower abdomen or back for 7 days or until the dressing fell off. After removal of the dressing, the skin underneath the dressing was graded using the Berger-Bowman scale[9] for skin irritation.

**Results** All 40 participants wore the BeneHold™ Post-Op Dressing with CHG for the entire 7 days or until they fell off. None of the participants had an irritation score of ≥2.

TABLE III

| PERCENTAGE OF RESPONSES FOR EACH DRESSING ON IRRITATION SCORE | | | | |
|---|---|---|---|---|
| **POST-OP DRESSING** | NO EVIDENCE OF IRRITATION | MINIMAL ERYTHEMA, BARELY PERCEPTIBLE | DEFINITE ERYTHEMA, READILY VISIBLE; MINIMAL EDEMA OR MINIMAL POPULAR | ERYTHEMA AND PAPULES |
| | SCORE =0 | SCORE =1 | SCORE =2 | SCORE ≥3 |
| **MED 9903MS SMALL** (N=20) | 80 | 20 | 0 | 0 |
| **MED 9904MS LARGE** (N=20) | 65 | 35 | 0 | 0 |

**Conclusion** BeneHold™ Post-Op Dressing with CHG was found to be non-irritating to healthy human skin. The adhesive did not potentiate any skin irritation. The dressings did not cause any damage to the skin.



## Precautions

BeneHold™ Post-Op Dressing with CHG should not be placed over infected wounds. This device is not intended to treat Surgical Site Infections (SSI's) 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 wound 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.

## Warnings

BeneHold™ Post-Op Dressing should not be used as a replacement for sutures and other primary wound closure methods.

BeneHold™ Post-Op Dressing should not be used on third degree burns.

Do not use BeneHold™ Post-Op 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.

BeneHold™ Post-Op Dressing should not be used as a primary means to fix arterial catheters or arterial cannulae.

For external use only. Do not allow contact of the BeneHold™ Post-Op Dressing with ears, eyes, mouth or mucous membranes.

Do not use the BeneHold™ Post-Op Dressing 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 of the BeneHold™ Post-Op Dressing immediately and, if severe, contact a physician.

Stop using the BeneHold™ Post-Op Dressing if the patient experiences symptoms such as: wheezing or difficulty breathing, swelling face, hives that can quickly progress to more serious symptoms, severe rash or shock (which is a life threatening condition that occurs when the body is not getting enough blood flow). These symptoms are associated with an allergic reaction to CHG.

Patients must be questioned about any prior allergic reactions to a medical device containing chlorhexidine gluconate. Alternatives must be considered under such circumstances.

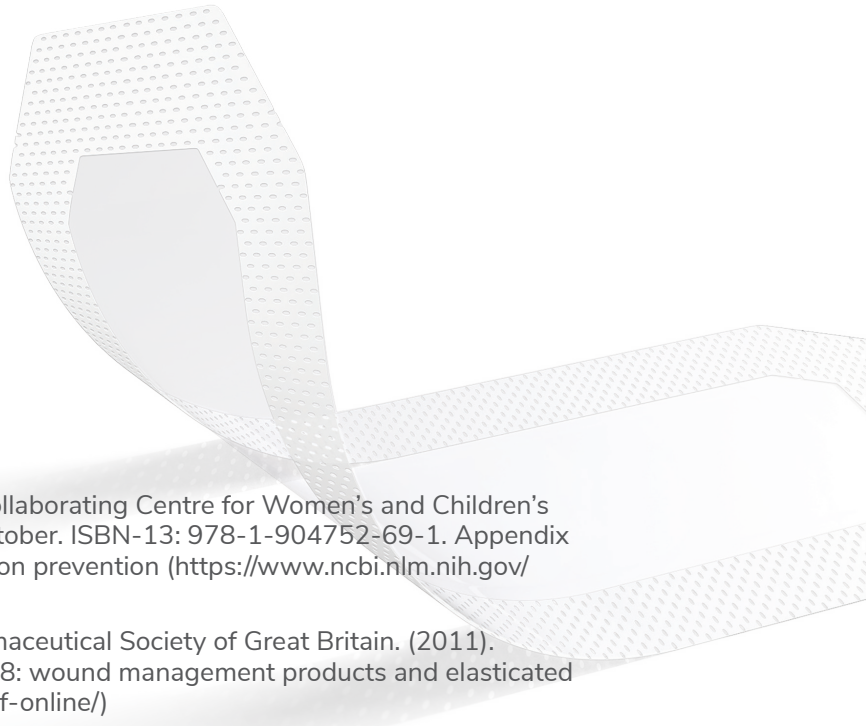
Literature searches found hypersensitivity reactions associated with the topical use of chlorhexidine gluconate have been reported in several countries. Caution should be used when using chlorhexidine containing preparations, and the patient should be observed for the possibility of hypersensitivity reactions.

Do not use on immune compromised patients or patients with underlying skin pathology which compromises the epidermal barrier. Use of this product may result in erosive contact dermatitis.

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 or injury.

Store dressing in a cool, dry place. Keep away from direct sunlight. Do not store above 25°C/77°F. Do not use if packaging is damaged.



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