Instructions For Use

(Please Read Carefully Before Using)

Product Description

BIOPATCH® Protective Disk with CHG is a hydrophilic polyurethane absorptive foam with Chlorhexidine Gluconate (CHG). The foam material absorbs up to eight times its own weight in fluid, while the CHG incorporated into the dressing inhibits bacterial growth under the dressing.

Chlorhexidine Gluconate is a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity.

Indication For Use

BIOPATCH® containing Chlorhexidine Gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, peripherally inserted coronary catheters, mid-line catheters, drains, chest tubes, externally placed orthopedic pins, and epidural catheters. It is also intended to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.

Precautions

BIOPATCH® should not be placed over infected wounds. It is not intended to be used as a treatment of percutaneous device-related infections.

Warnings

WARNING: DO NOT USE BIOPATCH® ON PREMATURE INFANTS. USE OF THIS PRODUCT ON PREMATURE INFANTS HAS RESULTED IN HYPERSENSITIVITY REACTIONS AND NECROSIS OF THE SKIN.

FOR EXTERNAL USE ONLY. DO NOT ALLOW THIS PRODUCT TO CONTACT THE EYES, EARS, MOUTH, OR MUCOUS MEMBRANES.

THE SAFETY AND EFFECTIVENESS OF BIOPATCH® HAS NOT BEEN ESTABLISHED IN CHILDREN UNDER 16 YEARS OF AGE.

DO NOT USE BIOPATCH® DIRECTLY OVER BURN INJURY OR ON PATIENTS WITH A KNOWN SENSITIVITY TO CHLORHEXIDINE GLUCONATE. ADVERSE REACTIONS TO CHLORHEXIDINE GLUCONATE SUCH AS DERMATITIS, HYPERSENSITIVITY, AND GENERALIZED ALLERGIC REACTIONS ARE VERY RARE, BUT IF ANY SUCH REACTIONS OCCUR, DISCONTINUE USE OF THE DRESSING IMMEDIATELY.

HYPERSENSITIVITY REACTIONS ASSOCIATED WITH THE 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.

Labeling Symbols

②	Do not reuse	STERILIZE	Do not resterilize
⚠	Caution! See instructions for use		Do not use if package is damaged
LOT	Batch code	⌛	Use by
REF	Catalogue number		Manufacturer
59°F 15°C – 86°F 30°C	Temperature limitation		
STERILE EO	Sterilized using ethylene oxide		
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of the physician or practitioner.		

BIOPATCH®

Protective Disk with CHG

STERILE EO

Manufactured for
ETHICON, INC.
Somerville, NJ 08876 USA

U.S. customers: to order product call 1-800-255-2500; for product quality and technical questions call 1-877-384-4266.

ETHICON™

CAUTION SHOULD BE USED WHEN USING CHLORHEXIDINE CONTAINING PRODUCTS IN INFANTS. THE PATIENT SHOULD BE OBSERVED FOR THE POSSIBILITY OF HYPERSENSITIVITY REACTIONS. THE GOVERNMENT OF JAPAN HAS REPORTED ANAPHYLACTOID-TYPE ADVERSE EVENTS IN 13 PATIENTS WHILE USING CENTRAL VENOUS CATHETERS IMPREGNATED WITH CHLORHEXIDINE.

Clinical Trial Results

A controlled, randomized, clinical trial consisting of 687 subjects with 1699 central venous or arterial catheter insertion sites was conducted at two centers.[1]

Results showed that the use of BIOPATCH® resulted in a statistically significant 44% reduction in the incidence of local infection ($p \leq 0.0001$).

Table 1: Summary of local infections in 1401 evaluable lines

	No Local Infection # of lines (%)	Local Infection # of lines (%)	Total
BIOPATCH®	556 (83.6%)	109 (16.4%)	665
Control	520 (70.7%)	216 (29.3%)	736
Total	1076	325	1401

Results also showed that the use of BIOPATCH® resulted in a statistically significant 60% reduction in the incidence of catheter-related blood stream infections ($p=0.026$).

Table 2: Summary of catheter-related blood stream infections (CRBSI) in 589 evaluable subjects

	No CRBSI Frequency (%)	CRBSI[1] Frequency (%)	Total
BIOPATCH®	288 (97.6%)	7 (2.4%)	295
Control	276 (93.9%)	18 (6.1%)	294
Total	564	25	589

[1]Clinical diagnosis based on positive blood cultures and DNA typing.

Results of this study also showed that use of BIOPATCH® resulted in statistically significant reduction in skin colonization of microorganisms commonly associated with CRBSI ($p \leq 0.05$). Patients randomized to the BIOPATCH® Treatment Group experienced no serious device-related adverse events.

Information regarding the use of BIOPATCH® on patients <16 years of age is limited. A study performed on 16 patients, ages 3 days to 15 years, was performed to evaluate the effectiveness of BIOPATCH® in the management of insertion or exit sites of indwelling CVCs. No cases of catheter-related infections were reported during the course of the trial. Compared to the institution's standard therapy, BIOPATCH® resulted in better appearance of entrance/exit sites in 56% of cases ($p=0.002$); less irritation of entrance/exit sites in 50% of cases ($p=0.011$); better entrance/exit site protection in 94% of cases ($p<0.001$). BIOPATCH® was the preference of the investigators over standard therapy in 81% of cases ($p<0.001$).

[1]*Maki DG, Mermel L, Genthner D, Hua S, Chiacchierini RP: An evaluation of BIOPATCH® Antimicrobial Dressing compared to routine standard of care in the prevention of catheter-related blood stream infection. Ethicon, Inc. 2000.*

Directions For Use

1. Prepare the insertion site according to hospital protocol.
2. Remove BIOPATCH® from the sterile package using aseptic technique.
3. Place BIOPATCH® around the device, making sure the BLUE PRINTED side is facing upward. The WHITE foam side releases the Chlorhexidine Gluconate (CHG) and should be in contact with the patient's skin.
4. In order to ensure easy removal when used with a film dressing, place BIOPATCH® around the device site in such a way that the device rests upon the slit portion of the BIOPATCH®. The edges of the radial slit must be pushed together and remain in contact to maximize efficacy.
5. Secure the device and BIOPATCH® to the skin. Ensure complete contact between the skin and BIOPATCH®.
6. Change the patch as necessary, in accordance with facility protocol; dressing changes should occur at a minimum of every 7 days. Dressing changes will be needed more frequently with highly exuding wounds.
7. To remove the transparent film dressing, pick up the corner of the dressing and stretch the dressing away from the device, holding the device in place. (Dressing will partially lift.) Peel back until resistance is felt. Repeatedly stretch and peel as necessary until the dressing is removed.
8. BIOPATCH® will remain attached to the transparent film dressing, so removal will be simultaneous.

Storage Information

- Store between 15°C and 30°C (59°F and 86°F).
- It is to be stored in its original packaging.
- Expiration date of the product is indicated as year (4 digits), month (2 digits) and day (2 digits).
- Do not resterilize. Discard all open and unused portions of the device.
- Do not use if the package is opened or damaged. Do not use if seal is broken or compromised.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

NOTE: Over time, the BIOPATCH® may turn yellow in color. This coloration does not reduce the antimicrobial efficacy of the dressing.

How Supplied

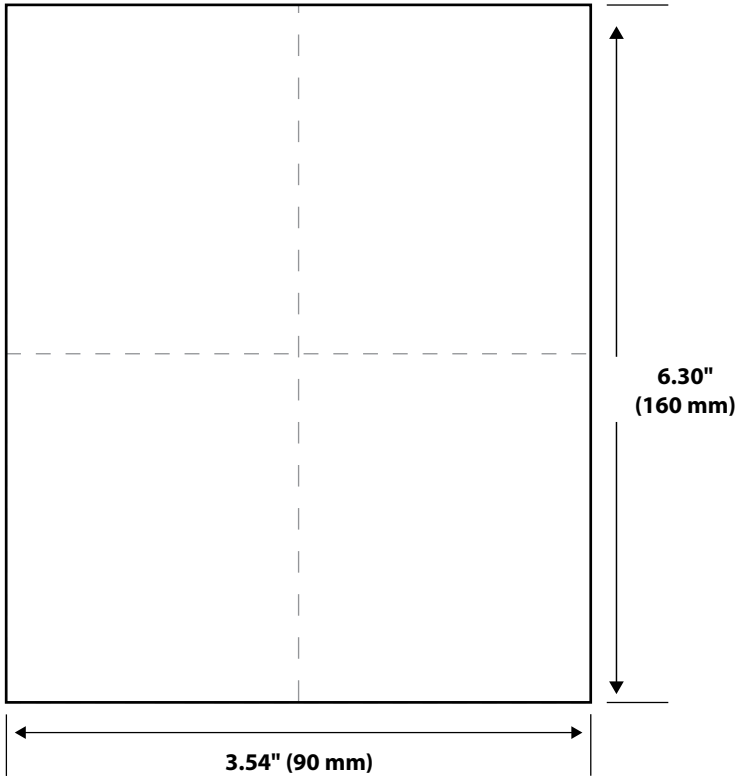
BIOPATCH® is supplied sterile. Each package contains a single disk. BIOPATCH® is intended for single use only.

Do not resterilize.

Product Code Ending	BIOPATCH® Size	Maximum Amount of CHG per Dressing
-150	1" DISK (2.5 cm) 4.0 mm center hole	92 mg
-151	3/4" DISK (1.9 cm) 1.5 mm center hole	53 mg
-152	1" DISK (2.5 cm) 7.0 mm center hole	86.8 mg

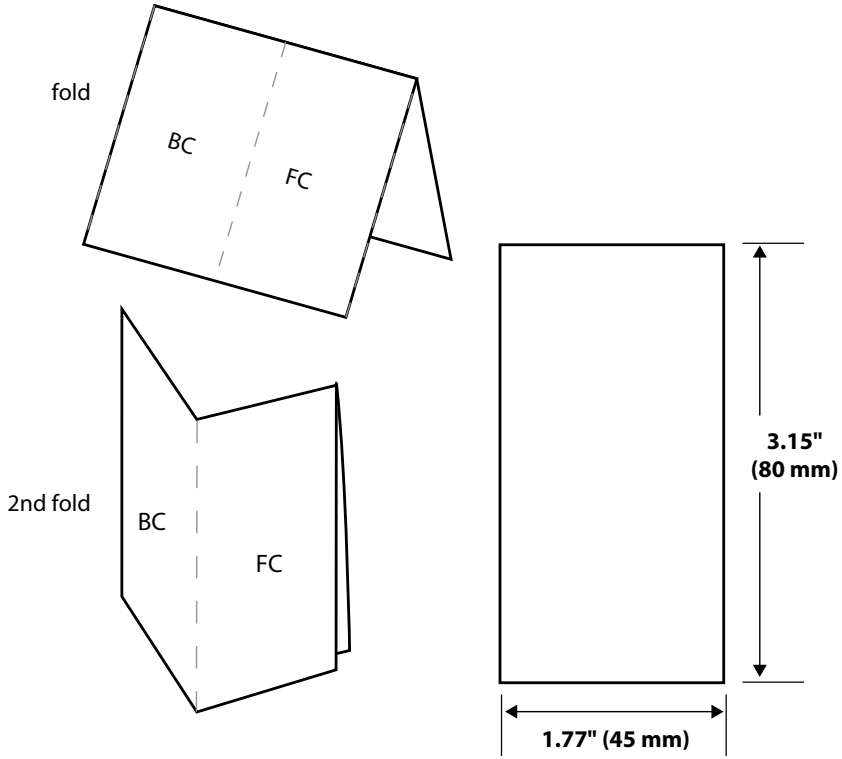
IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



Flat Size

FOLD PATTERN



Folded Size

TITLE	DESCRIPTION	LAB NUMBER	SPECIAL INSTRUCTIONS/COMMENTS	COLORS
BioPatch® US	**MAP IFU**	**LAB0010999v3**	**n/a**	**PMS 287 Blue**

FLAT SIZE	FOLDED SIZE	RMC NUMBER	PAGE COUNT	BINDING	SELF COVER	PLUS COVER	SEALING METHOD	WAFER SEAL
3.54" x 6.30" 90 mm x 160 mm	**1.77" x 3.15" 45 mm x 80 mm**	**10558-731-04**	**2**	**n/a**	[X]	☐	**n/a**	☐

BLEED SIZE .5" (12.7 mm)	.125" (3.175 mm)	NONE	BLEED ALL SIDES	BLEED TOP	BLEED RIGHT	BLEED LEFT	BLEED BOTTOM
☐	☐	[X]	☐	☐	☐	☐	☐

DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.

STOCK
40 opaque white non-glossy

ETHICON