

BIOPATCH®

Protective Disk with CHG

STERILE EO












Manufactured for
ETHICON, INC.
Somerville, NJ 08876 USA
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U.S. customers: to order product call
1-800-255-2500;
for product quality and
technical questions call
1-877-384-4266.

ETHICON™

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Labeling Symbols

	Do not reuse		Do not re-sterilize
	Caution! See instructions for use		Do not use if package is damaged
	Batch code		Use by
	Catalogue number		Manufacturer
	Temperature limitation 59°F 15°C to 86°F 30°C		
	Sterilized using ethylene oxide		
	Caution: Federal (USA) law restricts this device to sale by or on the order of the physician or practitioner.		

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

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.

Directions For Use

1. Prepare the skin surrounding the percutaneous device 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) and month (2 digits). The product expires after the last day of the month indicated.
- Do not re-sterilize. 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 re-sterilize.