

D-SEAL[®]

INSTRUCTIONS FOR USE D-SEAL[®] TOPICAL HEMOSTATIC PAD

Rx Topical use only

DESCRIPTION

D-Seal[®] is a soft, non-woven chitosan fiber pad. The D-Seal[®] pad is individually packaged in a foil pouch and sterilized using gamma irradiation.

INDICATIONS

D-Seal[®] is indicated for use in the management of bleeding wounds such as percutaneous catheter or tube sites, vascular access sites, or skin lacerations. D-Seal[®] promotes the rapid control of bleeding for patients on hemodialysis and patients on anticoagulation therapy.

COMPLICATIONS

Complications may include, but are not limited to:

- Bleeding
- Pseudoaneurysm
- Swelling
- Hematoma
- Rash

HOW SUPPLIED

D-Seal[®] pads are individually wrapped, provided sterile and not made with latex. The pads are sterilized by gamma irradiation. Do not reuse. Do not re-sterilize. Store pads at controlled room temperature, 15°C to 30°C (59°F to 86°F).

- D-Seal[®] Topical Hemostatic Pads will be delivered in a shelf package for convenient storage.

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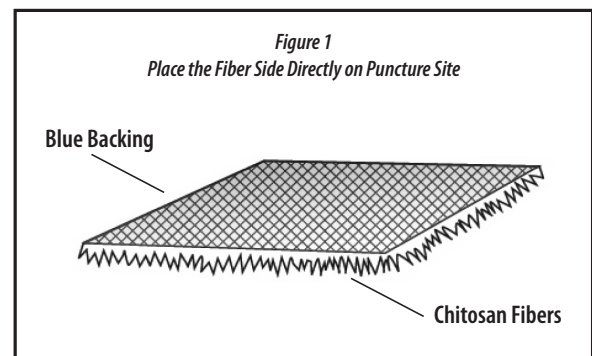
PRECAUTIONS

- D-Seal[®] is intended for use under the direction of a healthcare professional.
- Longer compression time may be necessary for patients who are hypertensive or obese.
- Sterilized by gamma irradiation. For one time use only. Do not re-sterilize. Do not reuse. Do not use if packaging is damaged. **Note:** if the user chooses to use a re-sterilized version of this product (and/ or re-use of product); infection OR degraded performance may occur.
- D-Seal[®] is composed of chitosan, a marine biopolymer. There are no known allergic responses to chitosan unlike the unprocessed chitin which is derived from crab exoskeleton.

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APPLICATION

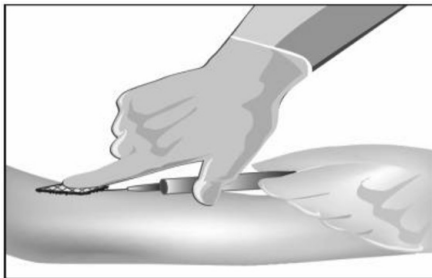
1. Open the D-Seal[®] pouch.
2. Cover puncture site with a D-Seal[®] pad, blue side up, and apply firm pressure.



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3. Pad may be placed over sheath hub prior to removal or placed directly over puncture site after sheath is removed. Remove sheath following clinic protocol.
4. After sheath removal, maintain firm pressure.

*Figure 2
After Sheath Removal, Maintain Firm Pressure*

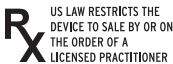


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5. Continue to apply pressure over puncture site until hemostasis is achieved, then slowly release, leaving the D-Seal® pad in place.
6. Place dry gauze over D-Seal® pad and cover with an appropriate dressing.
7. Within 24 hours, soak D-Seal® pad with water and gently remove.

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LABELING SYMBOLS



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Reference 2120, 2150 DWG 2125 Rev D