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.

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 resterilized 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.

COMPLICATIONS

Complications may include, but are not limited to:

- Bleeding
- Pseudoaneurysm
- Swelling
- Hematoma
- Rash

HOW SUPPLIED

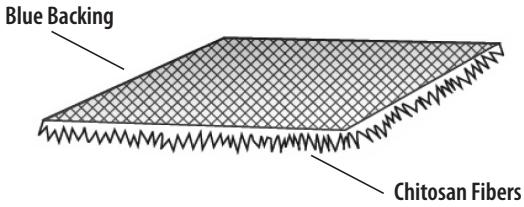
D-Seal™ pads are individually wrapped, provided sterile and not made with latex. The pads are sterilized by gamma irradiation. Do not reuse. Do not re-sterilize. Store pads at controlled room temperature, 15°C to 30°C (59°F to 86°F).

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

APPLICATION

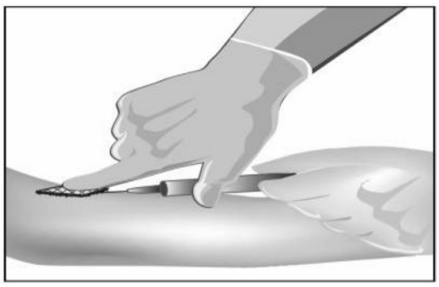
1. Open the D-Seal™ pouch.
2. Cover puncture site with a D-Seal™ pad, blue side up, and apply firm pressure.

Figure 1
Place the Fiber Side Directly on Puncture Site



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



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.

LABELING SYMBOLS

CONSULT INSTRUCTIONS FOR USE

LATEX NOT MADE WITH LATEX

DO NOT REUSE

LOT LOT NUMBER EXPRESSED AS: YYYYMMDD

STERILE R STERILIZED USING IRRADIATION

DO NOT USE IF PACKAGE IS BROKEN

REF CATALOGUE NUMBER

℞ US LAW RESTRICTS THE DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

STORAGE TEMPERATURE RANGE

USE BY DATE: YYYYMMDD

MANUFACTURED BY

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U.S. Patent #8,703,176

Reference 2120, 2150 DWG 2125 Rev C