

SOFTSEAL[®]-STF

INSTRUCTIONS FOR USE SOFTSEAL[®]- STF TOPICAL HEMOSTATIC PAD

Rx Topical use only

DESCRIPTION

SoftSeal[®]- STF is a soft, non-woven chitosan fiber pad. The chitosan in SoftSeal[®] is a highly purified derivative of crab chitin. The SoftSeal[®]- STF pad is individually packaged in a foil pouch and sterilized using gamma irradiation.

INDICATIONS

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

PRECAUTIONS

- SoftSeal[®]- STF 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. Store at controlled room temperature, 15°C to 30°C (59°F to 86°F). 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).
- No known contraindications.

COMPLICATIONS

Complications may include, but are not limited to:

- Bleeding
- Pseudoaneurysm
- Swelling
- Hematoma
- Rash

HOW SUPPLIED

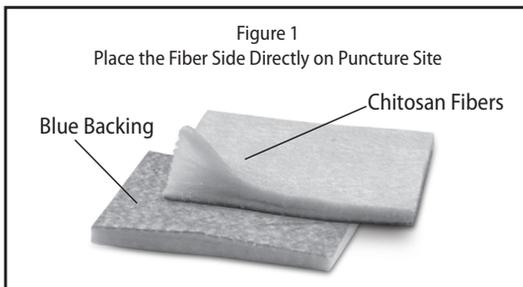
SoftSeal®- STF pads are individually wrapped, provided sterile and not made with latex. The pads are sterilized by gamma irradiation. Do not reuse. Do not re-sterilize. Store pads at controlled room temperature, 15°C to 30°C (59°F to 86°F).

- SoftSeal®- STF Topical Hemostatic Pad
- 20 - Individually Wrapped Pads Per Bag



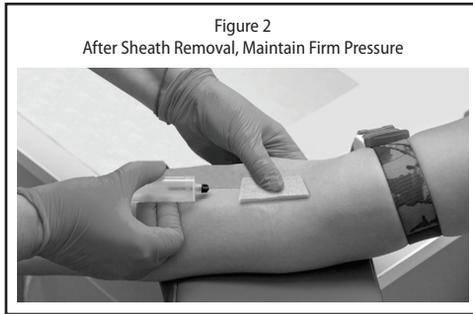
APPLICATION

1. Open the SoftSeal®- STF pouch into a sterile field.
2. Cover puncture site with a SoftSeal®- STF pad, blue side up, and apply firm pressure.



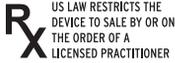
3. Pad may be placed over sheath hub prior to removal or placed directly over puncture site after sheath is removed. Remove sheath following hospital protocol.

4. After sheath removal, maintain firm pressure.



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

LABELING SYMBOLS



Manufactured by
Chitogen Inc.

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Reference 2150 2110-ART Rev M