

SOFTSEAL[®]-STFR

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

Rx Topical use only

DESCRIPTION

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

INDICATIONS

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

PRECAUTIONS

- SoftSeal[®]-STFR 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.
- SoftSeal[®]-STFR 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

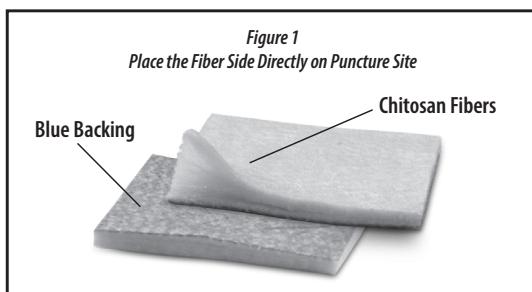
SoftSeal®-STFR pads are individually wrapped, provided sterile and not made with latex. The pads are sterilized by gamma irradiation.

Do not reuse. Do not re-sterilize. Store pads at controlled room temperature, 15°C to 30°C (59°F to 86°F).

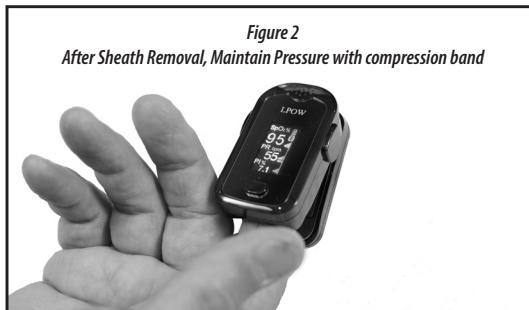
- SoftSeal®-STFR Topical Hemostatic Pads will be delivered in a shelf package for convenient storage.

APPLICATION

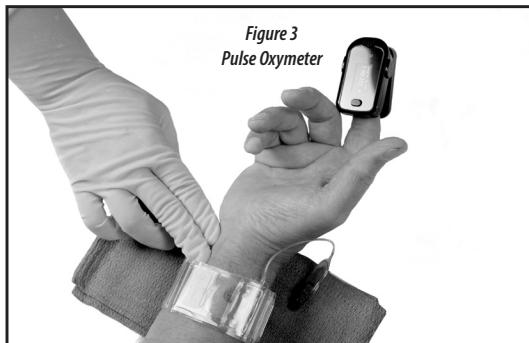
1. Open the SoftSeal®-STFR pouch.
2. Cover puncture site with a SoftSeal®-STFR pad, blue side up, and apply compression band over SoftSeal®-STFR pouch.



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 pressure following compression band instructions.
5. Continue to apply pressure over puncture site until hemostasis is achieved, then slowly release, leaving the SoftSeal®-STFR pad in place.



6. Following compression band instructions, observe for patent hemostasis, then slowly release band.
7. Evaluate radial artery patency using the reverse Barbeau test.
8. Within 24 hours, soak SoftSeal®-STFR pad with water and gently remove.



LABELING SYMBOLS



CONSULT
INSTRUCTIONS
FOR USE



NOT MADE
WITH LATEX



DO NOT
REUSE



LOT NUMBER
EXPRESSED AS:
YYYYMMDD



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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