

InnoSEAL Hemostatic Pad

Important



Prior to use, read and follow the instruction for use, cautions, and precautions. Failure to do so may result complications.

Rx Only. Topical Use Only.

■ DEVICE DESCRIPTION

InnoSEAL Hemostatic Pad is a hydrophilic lyophilized sponge pad for local management of bleeding wound made of proprietary formulation of Chitosan and catechol conjugated Chitosan which are biocompatible. InnoSEAL Hemostatic Pad applied topically as an adjunct to manual compression. InnoSEAL Hemostatic Pad is a single use device individually packaged by PET mold and Aluminum lid and sterilized with gamma irradiation. A box contains 10 single use pads.

■ INTENDED USE

InnoSEAL Hemostatic Pad is intended for the local management of bleeding wounds and for the promotion of rapid control of bleeding. InnoSEAL Hemostatic Pad is intended for use under the care of a healthcare professional.

The dressing is indicated for following wounds; lacerations, abrasions, and the skin surface puncture sites for vascular procedures, percutaneous catheters/tubes.

■ COMPLICATIONS

Complications may include, but are not limited to; Bleeding, Hematoma, Pseudoaneurysm, Rash, Swelling.

■ PRECAUTION

- Not for intravascular use.
- Do not use if the seal is broken or damaged.
- The InnoSEAL Hemostatic Pad is supplied as sterile, single-use.
Do not re-use. Do not attempt to re-sterilize.
- The InnoSEAL Hemostatic Pad is non-absorbable pad.
- Do not touch InnoSEAL Hemostatic Pad with wet gloves or expose InnoSEAL Hemostatic Pad to liquid. Absorption of the liquid will cause the destruction of InnoSEAL Hemostatic Pad.

■ INSTRUCTION FOR USE

- Apply pressure proximal to wound site.
- Place InnoSEAL Hemostatic Pad to the cleaned wound and apply a clean sterile gauze over the InnoSEAL Hemostatic Pad. Either side of InnoSEAL Hemostatic Pad can be used.
When using more than one InnoSEAL Hemostatic Pad, each InnoSEAL Hemostatic Pad should be overlapped.

- Gradually release proximal pressure to permit a small amount of blood to contact InnoSEAL Hemostatic Pad.
- Apply continuous pressure over the InnoSEAL Hemostatic Pad while maintaining proximal hold.
- Slowly release proximal hold while maintaining contact over the InnoSEAL Hemostatic Pad until hemostasis is achieved.
- Once hemostasis has been confirmed, apply choice of adhesive bandage directly on the skin over the InnoSEAL Hemostatic Pad access site.

■ DIRECTIONS FOR REMOVAL

- After bleeding stops completely, soak InnoSEAL Hemostatic Pad with water and gently remove.
- If desired, the pad and adhesive bandage maybe left in place for up to 24 hours.

CAUTION



- Do not leave the pad and adhesive bandage applied for more than 24 hours. Skin irritation may result.
- When removing the InnoSEAL Hemostatic Pad and the adhesive bandage, do not disrupt the clot by physical manipulation. If the pad adheres to the wound site, irrigate the pad with water and carefully remove it.

■ STORAGE & SHELF LIFE

Store at controlled room temperature, 15°C to 30°C (59°F to 86°F).
 InnoSEAL Hemostatic Pad shelf life is 3 years from manufacturing date.
 See product label for expiration date.

■ SYMBOL REFERENCE

Symbol	Description	Symbol	Description
	Consult instruction for use		Keep away from sunlight
	Caution		Temperature limitation
	Used by date		Sterilized using irradiation
	Do not reuse		Do not re-sterilize
	Batch code		Catalogue number
	Manufacturer		Do not use if package is damaged

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