



INTENDED USE AND INDICATION

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.

PRECAUTION

- Rx only : U.S. federal law restricts this device to sale to or on the order of a licensed health care professional
- Topical use only
- Single use. Do not re-sterilize or re-use
- Please see the Instruction For Use prior to use



InnoSEAL
HEMOSTATIC PAD
INNOVATIONS IN BLOOD TECHNOLOGY

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Innovative Hemostatic Pad that Controls Bleeding through Electrostatic Interaction and Interfacial Coating

HOW SUPPLIED

Supplied in sterile, single use package. Sterile if package is unopened or undamaged.

Description	Size	Quantity	Item #
InnoSEAL Hemostatic Pad	5 x 3 cm (2.0 x 1.2inch)	1 box of 10	IS-H-01-10
	2 x 2 cm (0.8 x 0.8inch)	1 box of 10	IS-H-01-20

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Distributed by **InnoTherapy America, Inc.**

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Manufactured by **InnoTherapy Inc.**

<http://www.innotherapy.com>



Discovery of hemostatic material derived from mussel-inspired technology

InnoTherapy develops hemostatic devices inspired by diverse adhesive property that nature provides.

INTRODUCING InnoSEAL HEMOSTATIC PAD

InnoSEAL is a hemostatic pad composed of chemically modified biopolymers and it works independently from classical coagulation pathway.



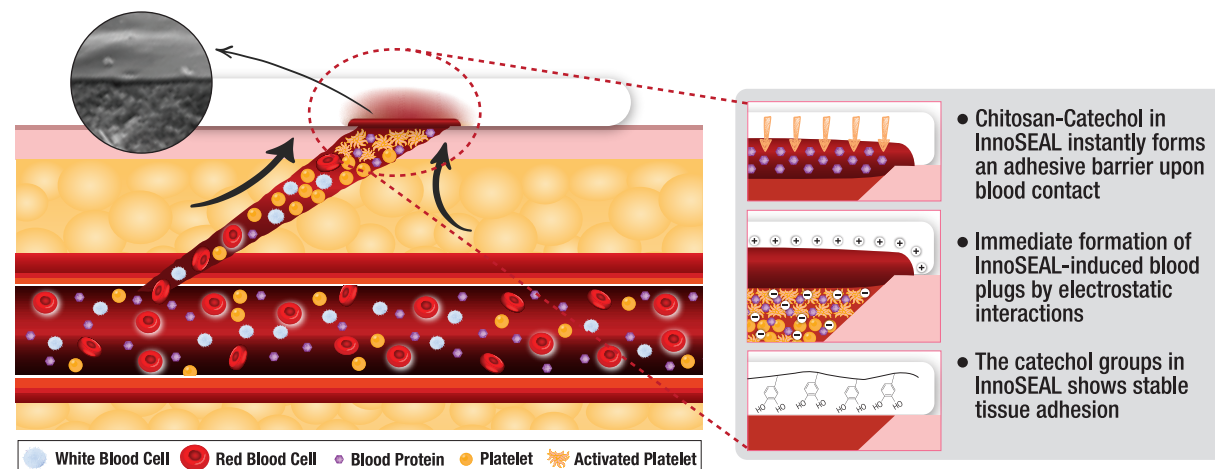
TYPICAL PROCEDURES

- Angiography including coronary angiography and neuroangiography
- Percutaneous coronary intervention
- Angioplasty
- Hepatic chemoembolization
- Surface bleeding during the implant and removal of various devices
- Skin biopsies and Any other surface hemorrhage

MECHANISM

InnoSEAL Hemostatic Pad accelerates hemostasis by ^{[1],[2]}

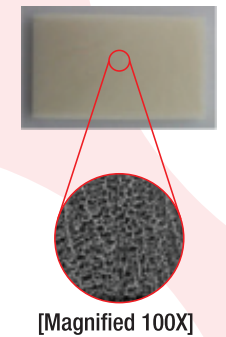
- 1) Formation of stable hemostatic barrier
- 2) Hemagglutination by electrostatic interaction between hemostatic material and blood components



FEATURES AND BENEFITS

- Accelerates clot formation and maintains stable clot
- Works independently from clotting cascade
- Massively porous sponge pad absorbs bleeding
- Less compression time when used as an adjunct to manual compression
- Odorless. Easy to use, fold, or cut
- Non-woven soft pad conforms to all wound surfaces
- Easily removable

[Either side of the pad can be used]



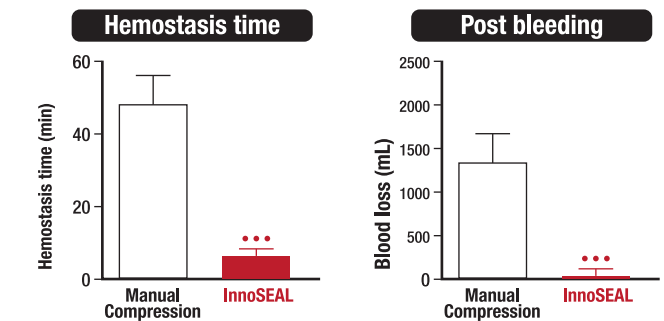
HEMOSTATIC EFFICACY

InnoSEAL Hemostatic Pad achieved superior hemostasis in various nonclinical studies including massive bleeding model

Hemostatic efficacy in comparison with standard manual compression

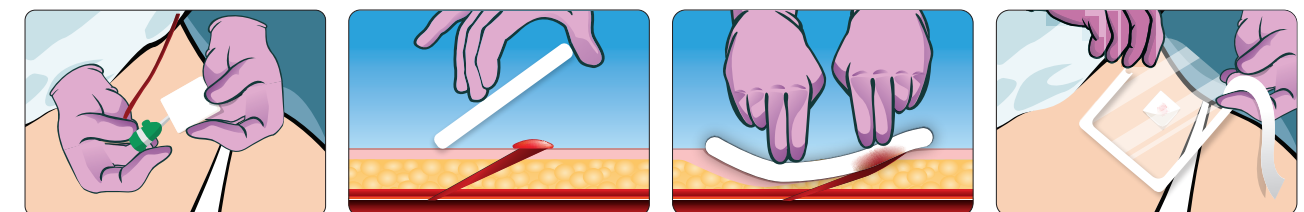
- Hemostasis in 5 minutes
- Significant less post treatment bleeding

* Femoral Artery Injury swine model study ^[3]



APPLICATION AND REMOVAL GUIDE

- Apply pressure proximal to wound site
- Place InnoSEAL Hemostatic Pad to the cleaned wound and apply a sterile gauze over the pad.
- Gradually release proximal pressure to permit a small amount of blood to contact InnoSEAL Hemostatic Pad.
- Apply continuous pressure over the 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.



- 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.