The Thrombi-Pad™ 3x3 is supplied sterile for single use only. Do not re-sterilize.

Do not use Thrombi-Pad™ 3x3 as a replacement for absorbable hemostats. This product contains non-absorbable materials and is not intended to be left in the body.

PRECAUTIONS
Do not use the Thrombi-Pad™ 3x3 if the packaging has been damaged.

The safety and effectiveness of the Thrombi-Pad™ 3x3 have not been established in children and pregnant women.

The Thrombi-Pad™ 3x3 should not be used in the presence of infection. It should be used with caution in contaminated areas of the body.

ADVERSE EVENTS
A recognized rare potential reaction associated with the use of bovine-derived thrombin is the development of inhibitory antibodies, which interferes with hemostasis.

INDICATIONS
The Thrombi-Pad™ 3x3 is applied topically and is indicated as a trauma dressing for temporary control of moderate to severely bleeding wounds and for the control of surface bleeding from vascular access sites and percutaneous catheters and tubes.

CONTRAINDICATIONS
The Thrombi-Pad™ 3x3 is contraindicated in persons with known sensitivity to bovine-derived materials.

WARNINGS
Do not place the Thrombi-Pad™ 3x3 into blood vessels. Extensive intravascular clotting and even death may result.

WARNING: SEVERE BLEEDING AND THROMBOSIS COMPLICATIONS
- THROMBIN-JMI can cause fatal severe bleeding or thrombosis. Thrombosis may result from the development of antibodies against bovine thrombin. Bleeding may result from the development of antibodies against factor V. These may cross-react with human factor V and lead to its deficiency.
- Do not re-expose patients to THROMBIN-JMI if there are known or suspected antibodies to bovine thrombin and/or factor V.
- Monitor patients for abnormal coagulation laboratory values, bleeding, or thrombosis.