



Thrombix® Topical Hemostat Silver

Ordering Information

MODEL	DESCRIPTOR
3100	Thrombix® Silver Topical Hemostat

Packaged in quantities of 25 units per box. Individual units are not sold separately.

Thrombix topical hemostat is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

INDICATIONS The Thrombix Silver topical hemostat is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes. Thrombix Silver contains silver chloride to prevent microorganisms commonly encountered in the clinical setting from colonizing on the pad.

CONTRAINDICATIONS The Thrombix Silver topical hemostat is contraindicated in persons with known sensitivity to bovine-derived materials. (IFU for reference attached)

Microorganism Kill Rate¹

D-Stat Silver was exposed to a wide breadth of microorganisms and demonstrated a kill rate of 99.99% or greater for all organisms tested. This in vitro data demonstrates the effect of the antimicrobial agent based on bench testing after 24 hours of contact time with the chosen microbial cultures. These results also pertain to Thrombix Silver Topical Hemostat since it contains the same formulation as D-Stat Silver.

Microorganism	GRAM STAIN	KILL RATE
Staphylococcus aureus (MRSA)	+	99.999%
Staphylococcus epidermidis (MRSE)	+	99.999%
Pseudomonas aeruginosa	-	99.99%
Enterococcus faecalis (VRE)	+	99.999%
Escherichia coli	-	99.999%
Klebsiella pneumoniae	-	99.999%
Candida albicans	+	99.999%

Zone of Inhibition¹

D-Stat Silver was placed on growth mediums cultured with a variety of microorganisms. A zone of inhibition was observed around D-Stat Silver and measured. This distinct area of no microorganism growth occurs as a result of the diffusion of ionic silver from D-Stat, and demonstrates the antimicrobial properties of silver chloride.

Zone of Inhibition Results (Reported in mm)*



*Product sample reconstituted with 1ml of sterile water

References:

Representative test samples from the D-Stat Silver product family (Dry, Wrap and Thrombix Silver) demonstrated an antimicrobial effect in these
laboratory tests. Data on file. Laboratory test results may not be indicative of clinical performance.

Please see instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

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.. 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.

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