



SAM JUNCTIONAL TOURNIQUET

PRODUCT FAMILY TECHNICAL DATA SHEET

Finished Product Description

The SAM® Junctional Tourniquet (SJT) is a non-invasive, circumferential belt with an inflatable Target Compression Device (TCD) engineered to control junctional hemorrhage due to trauma with or without pelvic ring fractures. The SJT immobilizes pelvic fractures by providing controlled circumferential compression. Pelvic fractures are often associated with the traumatic events leading to junctional hemorrhage. SJT can be applied in under 25 seconds, and is designed for upper and lower junctional use, with bilateral capability for lower-extremity application. The SAM® Junctional Tourniquet is used to stabilize pelvic fractures and control a difficult bleed for up to 4 hours, or until the injured patient can be transferred to surgical personnel for definitive care.

Engineered for durability, the SJT was tested to, and met, the relevant MIL-STD-810G standard criteria. The results showed the Target Compression Devices remained functional up to 15,000 ft in an altitude chamber. The TCD utilizes a standard luer lock connection so a syringe can be used to inflate the TCD with water, saline or any other non-compressible fluid. In 2016, the U.S. Army Medical Materiel Agency began fielding the SJT on the battlefield to address traumatic hemorrhage not amenable to control with a standard extremity tourniquet. The SJT is a recommended device by the Committee on Tactical Combat Casualty Care (CoTCCC).

Indications for use

The SAM® Junctional Tourniquet is indicated for battlefield and trauma situations:

- To control difficult bleeds in the inguinal area
- To control difficult bleeds in the axilla area
- To immobilize a pelvic fracture

Material Technical Data

Product Materials

- AUTOSTOP® Buckle: Acetal, Stainless Steel Springs
- Belt and Auxiliary Strap: Nylon and Polypropylene, Acetal/Metal Snap Hooks
- Thread: Bonded Nylon Twist
- Hook and Loop Fastener: Nylon
- TCD: Medical Grade Polyurethane with Polycarbonate base
- TCD Extender: Polycarbonate
- Hand Pump: PVC Free Plastisol
- Bag/pouch: Nylon
- Does not contain natural rubber latex
- Made in the USA

Instructions for Use

- Included within the packaging and at sammedical.com/eIFU
- Single Use Only, dispose of used device per healthcare facility biohazard protocol
- Prescription Use Only in United States

Packaging

- Packaged in a corrugated cardboard box
- Dimensions: 4.75 in (12.1 cm) H x 4.75 in (12.1 cm) W x 8.875 in (22.5 cm) L
- Weight Each (JT400-EN): 24 oz (680 g)
- Weight Each (JT401-EN): 18 oz (510 g)
- Case Amount: 6
- Sterilization Method: Not a sterile device
- Shelf Life: Does not have a defined shelf life

* Size and weight may vary by configuration and/or manufacturing process.

Compliance

- SAM Medical maintains current EN ISO 13485:2016 and ISO 13485:2016/MDSAP certifications from NSAI
- United States of America: Class I medical device, 510(k) K131561. Product Code: DXC
- European Union: Class I medical device, CE Marked, Self-Certified
- Authorized Representative: Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, NL
- NSN#: 6515-01-618-7475 (JT400-EN)

SAM® Junctional Tourniquet Product Family Listing

| Part Number | Description |
|-------------|--|
| JT400-EN | SJT Belt, (2) TCD, Extender, Hand Pump, Auxiliary Strap, IFU |
| JT401-EN | SJT Belt, (1) TCD, Hand Pump, IFU |
| JT402-EN | SJT Trainer |

SAM® Junctional Tourniquet Patents**United States**

8,926,536
 9,028,435
 9,427,238