

SAM XT EXTREMITY TOURNIQUET

PRODUCT FAMILY TECHNICAL DATA SHEET

Finished Product Description

The SAM[®] Extremity Tourniquet Product Family is available in three colors and is designed to fit patient limbs with a circumference of between 5.5 in (13.9 cm) and 35 in (88.9 cm). The SAM[®] Extremity Tourniquets are composed of lightweight bonded fabrics, durable nylon polymers, aluminum and an acetal copolymer buckle with stainless steel springs. The SAM[®] Extremity Tourniquet is provided with printed instructions for use included in the packaging.

The SAM[®] Extremity Tourniquet includes a pre-tensioning buckle that addresses a current capability gap identified by the military community among competitor products – Slack Control. The TRUFORCE[™] Buckle locks into the belt when sufficient circumferential force is applied establishing a consistent baseline tension of the SAM[®] Extremity Tourniquet prior to final tightening with the windlass to achieve hemorrhage control. The TRUFORCE[™] Buckle includes a tab to unlock the buckle for readjustment or removal. The TRUFLEX[™] Plate is made of a flexible nylon polymer that allows fitment around differing anatomical sizes. The C-Hooks found on the TRUFLEX[™] Plate have an intuitive angular design making windlass locking easier and more efficient. The Time Band is made of weather resistant fabric providing a very conspicuous location to mark the time when the SAM[®] Extremity Tourniquet was applied to alert clinical personnel how long the device has been in place.

The SAM[®] Extremity Tourniquet is labeled as Single Use with the Do Not Reuse symbol both on the product and in the IFU. After use dispose of per healthcare facility protocol for biological waste.

Material Technical Data

Belt Materials

- Strap: Webbing, Nylon, Black
- Thread: Bonded Nylon Twist, Black
- Hook and Loop Fastener: Nylon, Black
- Contrast: Night vision optimized

TRUFORCE Buckle

- Frame and Slider: Acetal Copolymer, Hi-Viz Orange, Hi-Viz Blue and Tactical Black
- Springs: 17-7 Stainless Steel

TRUFLEX Plate

- Nylon polymer, Hi-Viz Orange, Hi-Viz Blue and Tactical Black

Windlass

- 6061-T6 aluminum with low-slip diamond knurling

Time Band

- Fabric: Weather resistant acrylic adhesive, nylon webbing with hook & loop
- Contrast: Night vision optimized, amenable to recording application time with ink

Labeling

- Instructions for Use: Included within the packaging and at sammedical.com/eIFU

Packaging

- Single Use Only, dispose of used device per healthcare facility biohazard protocol
- Wrapping: Individually with 60-gauge Polyolefin Shrink-wrap
- Dimensions: 2.0 in (5.1 cm) H x 1.5 in (3.8 cm) W x 7.25 in (18.4 cm) L
- Weight Each: 3.8 oz (108 g)
- Case Amount: 25

Compliance

- CE Marked, Self-Certified with Declaration of Conformity
- ISO 13485:2016 MDSAP Certified
- EN ISO 13485:2016 Quality Management System Certified
- Authorized Representative – Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, NL
- NSN#: 6515-01-670-2240 (Tactical Black)

SAM® Extremity Tourniquet Product Family Listing

Part Number	Description
XT600-BL-EN	SAM® Extremity Tourniquet, Hi-Viz Blue
XT600-OR-EN	SAM® Extremity Tourniquet, Hi-Viz Orange
XT600-BK-EN	SAM® Extremity Tourniquet, Tactical Black

SAM® Extremity Tourniquet Patents Pending**United States**

14/324,672

15/297,937

Europe

15746775.4

PCT

PCT/US15/12296

PCT/US2017/057195