

SAM[®] Junctional Tourniquet (SJT)



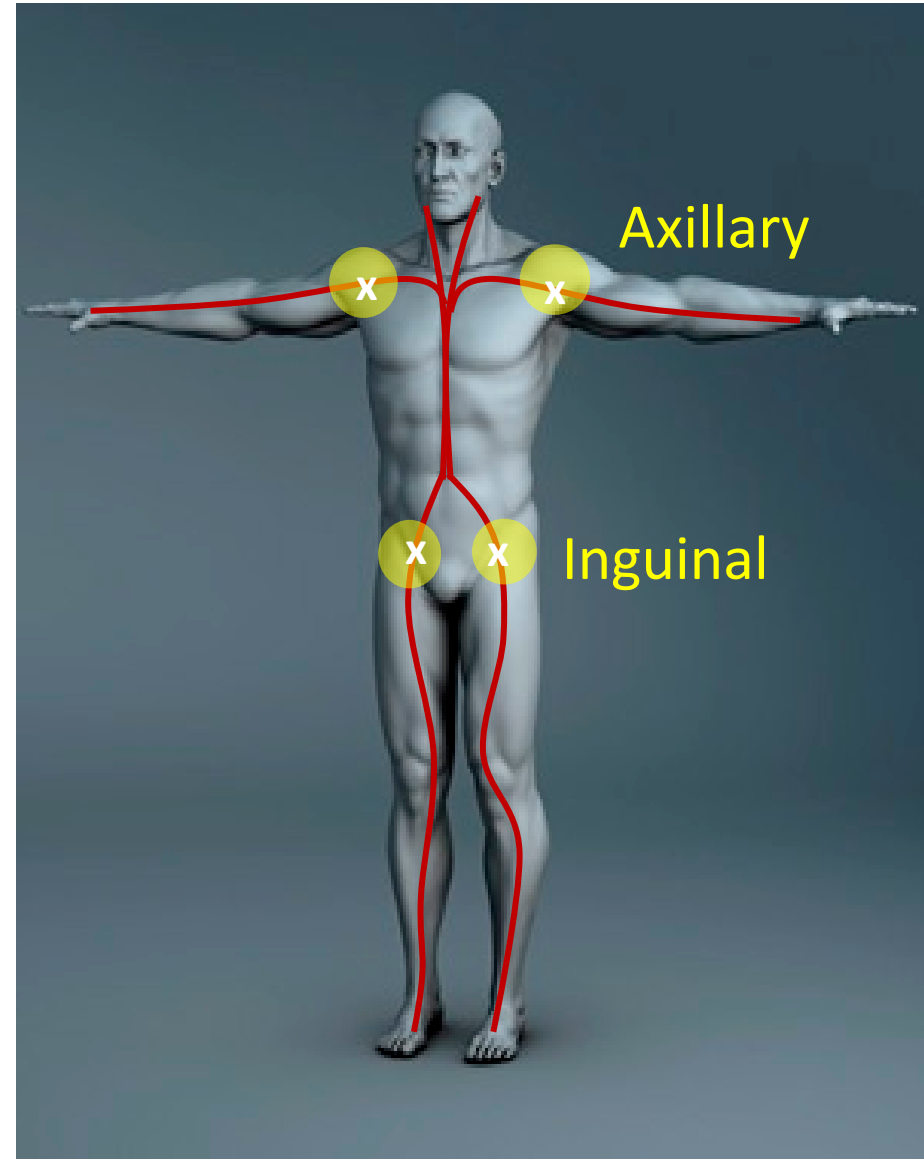
SAM Medical Products

- Developer and Manufacturer of devices for prehospital trauma care:
 - SAM Splint
 - Chest Seal
 - Hemostatic Dressing
 - Pelvic Sling



Junctional Tourniquets

- Compressible, but non-tourniquetable hemorrhage
 - Junction of torso with legs, arms
 - On injury site or proximal arterial occlusion



SJT background

- Military defined clinical need and method (medic)
- Call for industry to translate into a mechanical / commercialized device.
- High incidence of pelvic fractures associated with high amputations due to IED.
- Combine existing Pelvic Sling with Pneumatic Pressure Point = SAM Junctional Tourniquet

SJT description



Deflated: Low profile, low cube, stores flat.



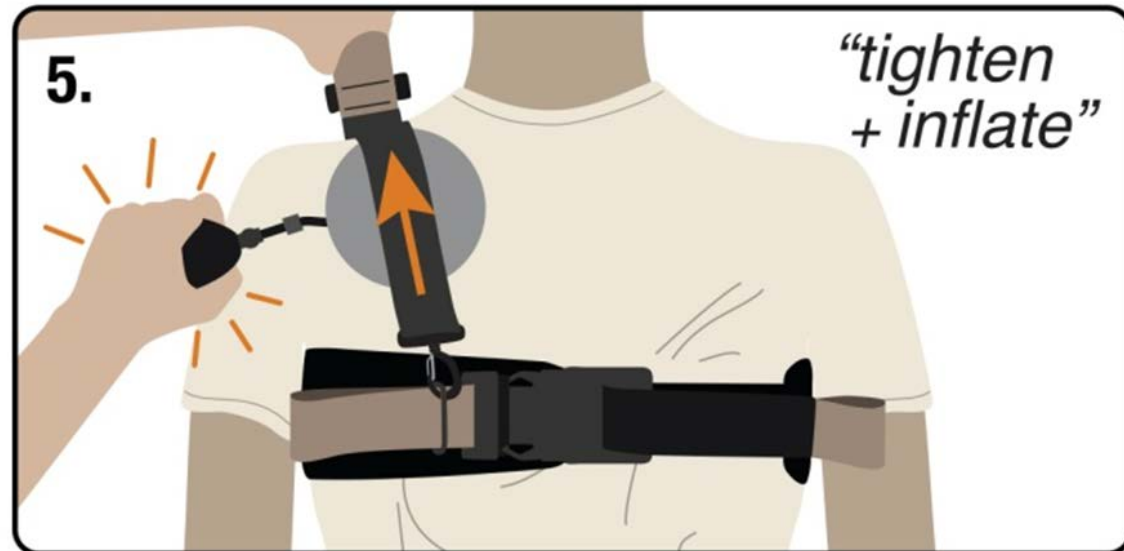
Partially inflated: The average pressure to occlude a femoral artery in mannequin and cadaver model testing.



Fully extended: ~3 seconds to full inflation and maximum compression.



SJT description

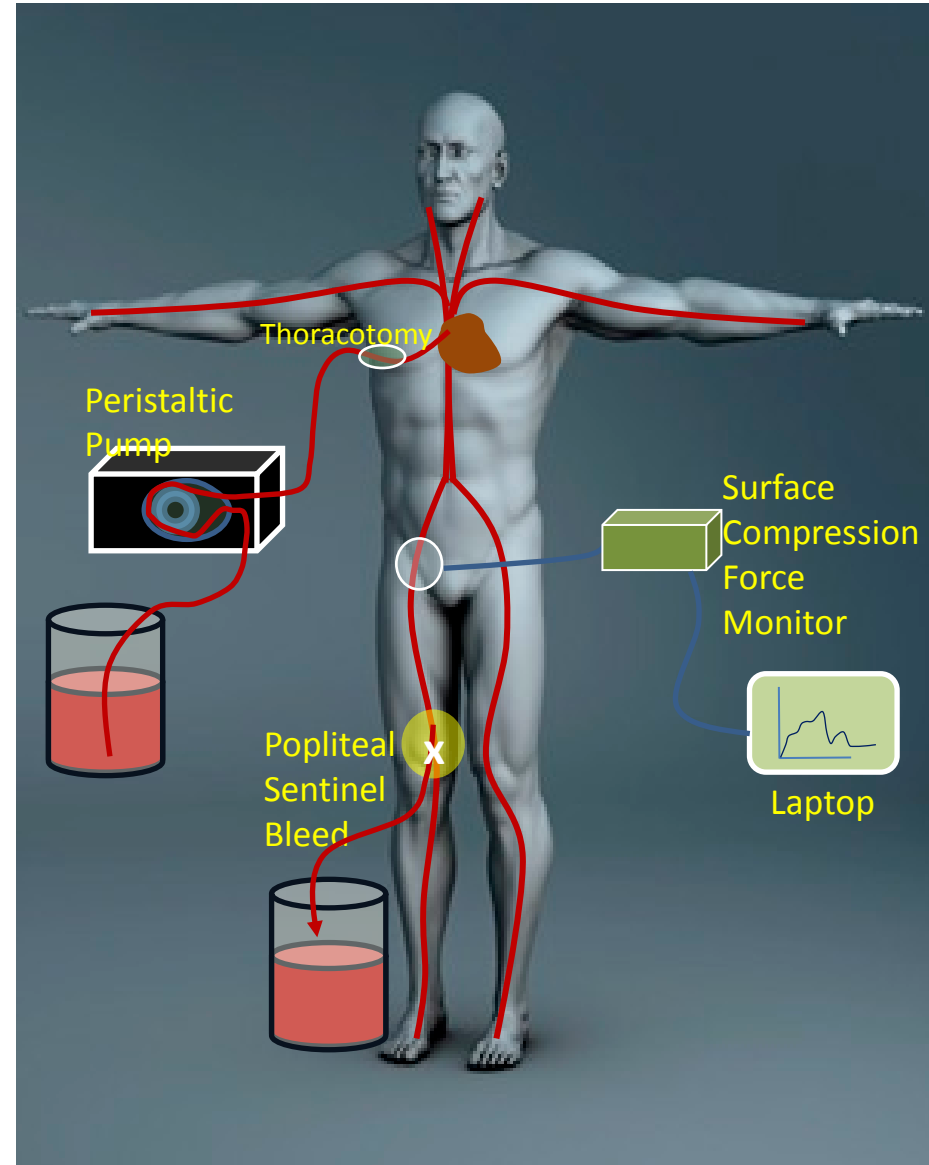


Regulatory Strategy

- FDA Cleared Indications (K123694, K131561):
 - To control difficult bleeds in the inguinal area.
 - To immobilize a pelvic fracture
 - To control difficult bleeds in the axilla area.
- Predicates: CRoC, SAM Sling
- Product code DXC: Vascular clamp; Class II; Rx
- CRoC predicates: Vascular access / Cath lab device - Compressar

Clearance Testing

- Safety:
 - Biocompatibility
 - Robustness (over 4 hr use period and shelf life)
- Performance
 - Human Simulation Comparative Study (USAISR)
 - Human Cadaver (Wake Forest University)
 - Why no swine?



Subsequent Testing

- Human Volunteer perfusion (Oregon Health Sciences University)
- 6 comparative military studies:
 - Medic usability and efficacy testing
 - US, Norwegian, Israeli
- Case Reports

In the Field



Challenges

- User at Point of Injury is not a doctor.
Implications:
 - Device must be physically simple/intuitive/familiar.
 - Directions, indications, contraindications must minimize decision tree.
- Translating military requirements to civilian population.
 - Bariatric / Geriatric / Pediatric

Contact

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