

# SAM<sup>®</sup> Junctional Tourniquet (SJT)



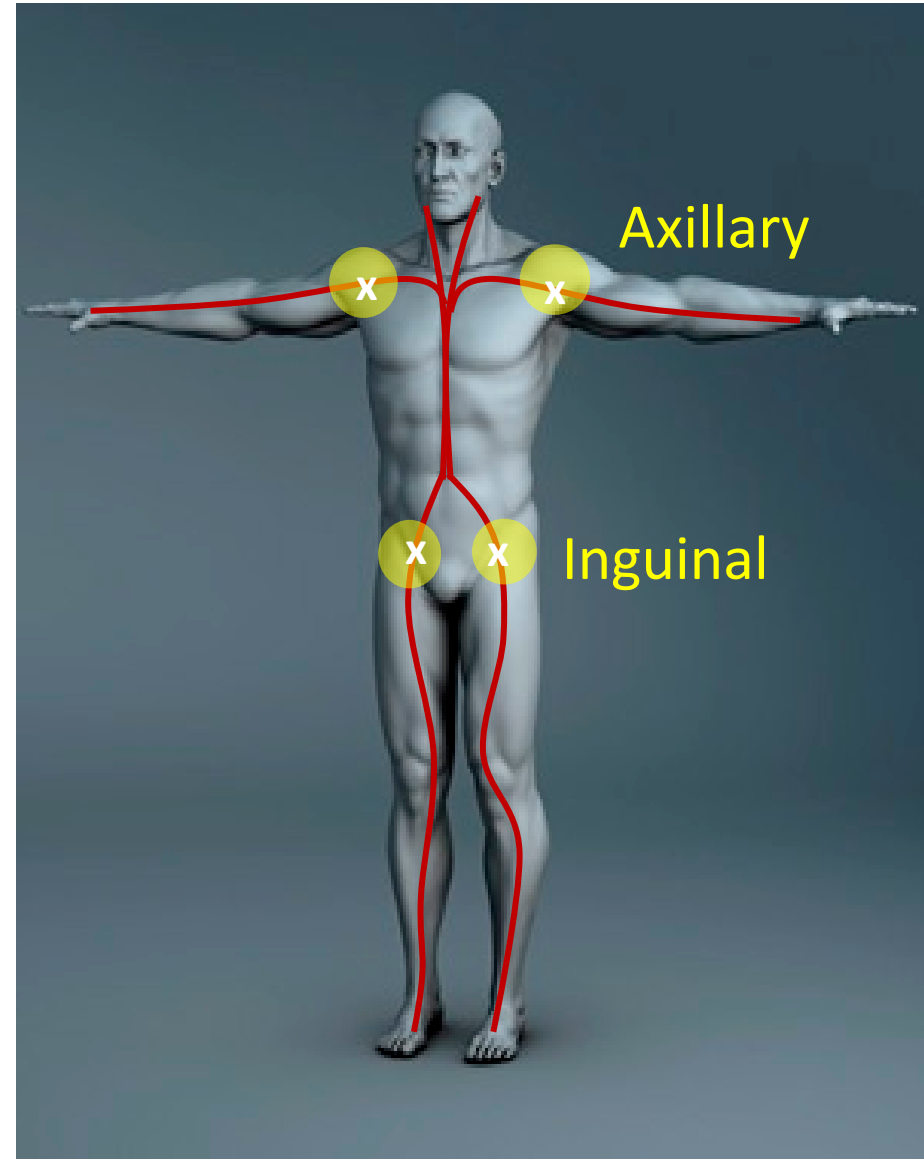
# SAM Medical Products

- 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.



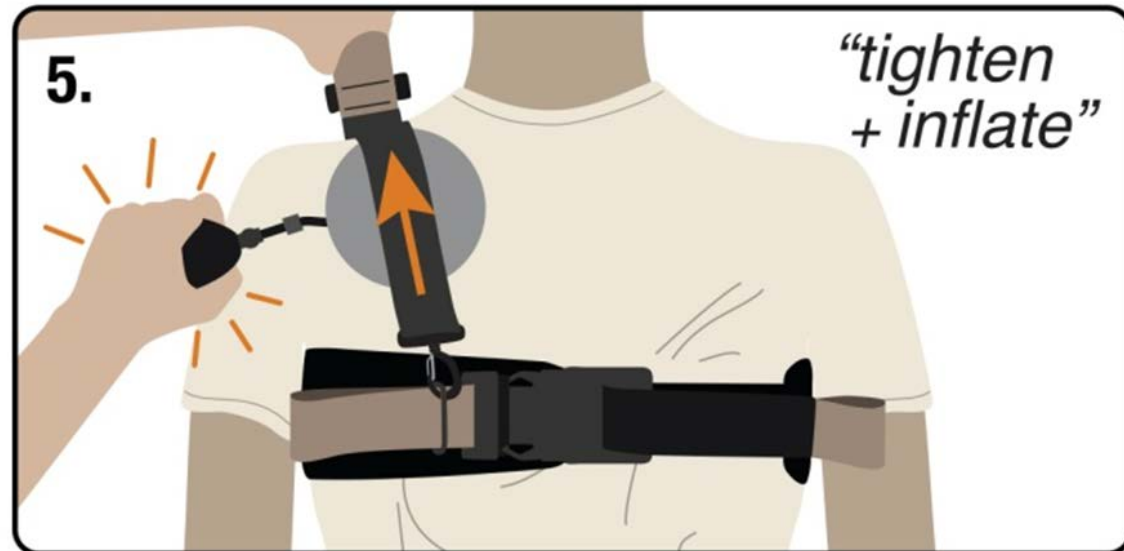
Partially inflated: The average pressure to occlude a femoral artery in mannequin and cadaver model testing.



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



# SJT description

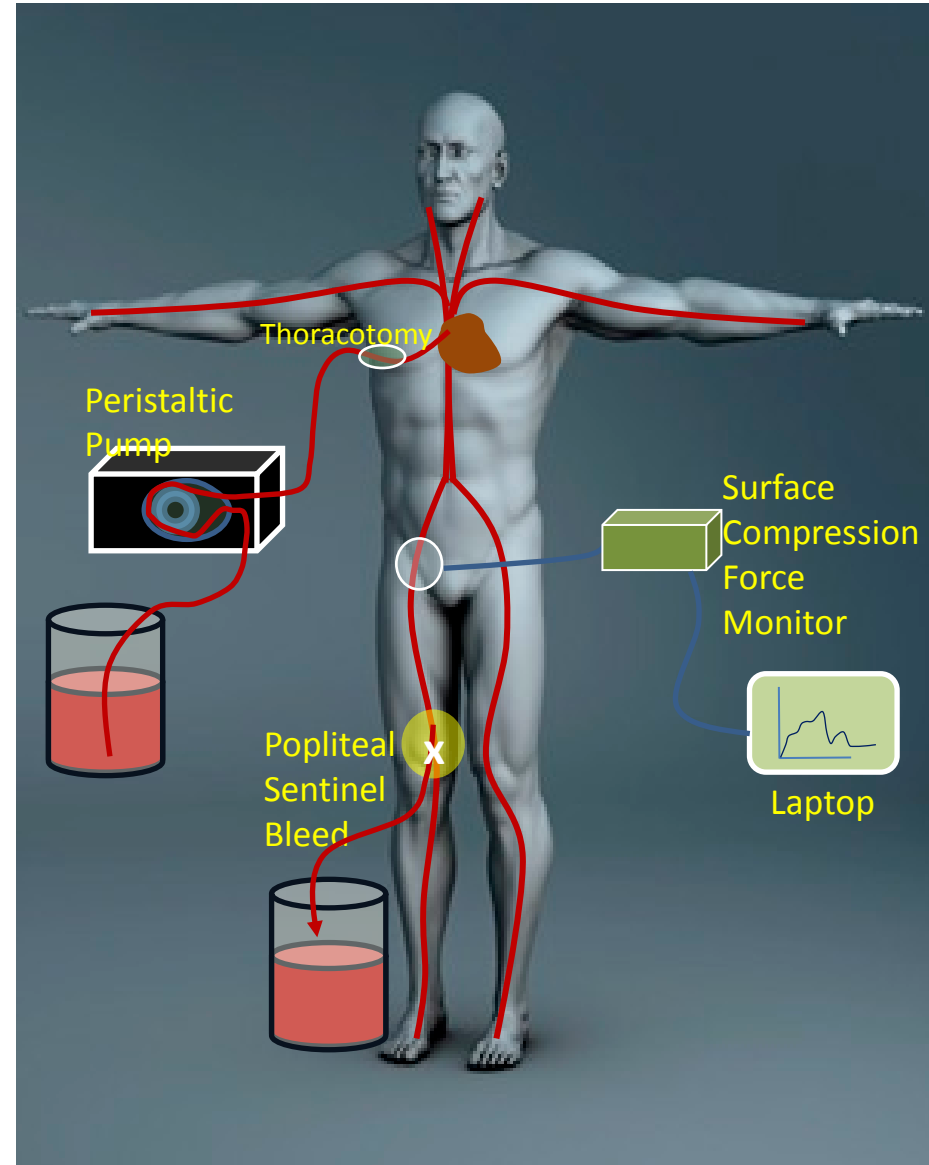


# Regulatory Strategy

- 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