

SWAT-T Durability

September 17th, 2014

Background

Prior to the SWAT-T release in 2009, testing included deformation well past TQ pressures. The SWAT-T was allowed to return to its normal size/shape. This cycle was then repeated for 5,000 revolutions, and no wear on materials or memory to deformation was documented. The elastomer and packaging facilities are state of the art facilities (Quality Management Systems - ISO 9001:2008). The final stop in the manufacturing process, prides itself as a National Institute for the Severely Handicapped facility (with current large US military contracts). They incorporate multiple stringent quality control stops making a defective device extremely unlikely.

Data:

TEMS Solutions polled several of its resellers and training companies (n=9). Response rate was 89%, and results were gathered as per Chart 1. Questions were asked concerning usage rates, durability and safety.

Conclusion:

This is considered to be a sampling of what training companies and end-users should expect with the SWAT-T. Note: When not in training, the SWAT-T is a <u>one-time use device</u> and ideally is left in its packaging (protecting from UV exposure) until usage. Training devices are not recommended to be stowed or carried for field emergency usage.

In the 32,956 recorded applications in this study, the SWAT-T had **zero** first time failures. Of the training companies that reuse their devices, there were 2 breakages out of 32,956 due to a sharp object or glass (one of these was on a markedly old device). Of the training companies that reuse their devices, there were 4 breakages with devices that were "markedly old," out of 32,956 applications. From this data it is expected that likelihood of device breakage is less than 0.00012%, or 1 in 8,239 - this is with re-used devices, **not** with first time applications. It is a statistical improbability that a device would break during first time usage, and a statistical impossibility that 2 devices could fail in the same time/event, **unless** they were improperly used.

In a class by itself, the SWAT-T is a low cost trauma multi-tool, and not simply a tourniquet. The SWAT-T is a durable medical device. Instructions on the packaging and Internet training videos aid those in using the SWAT-T - as a primary or back-up tourniquet, pressure dressing or elastic wrap. Independent human trials compared the SWAT-T to the gold standard military windlass tourniquets and found the SWAT-T to be safer and more effective.

SWAT-T Durability	Number of SWAT-T uses	New: 1st time; 1st application breakage	Used: any breakage, any condition	Are the SWAT-Ts applied in training to full occlusion	Any injuries encountered	Scenario work
STS Consulting	3,000	Never	-1 after puncture from piece of glass (old TQ with many uses) -1 during application, it was one of our oldest (used so much you could no longer read any of the writing - really worn)	Yes	No	Human patient actors and Simulators. We use them in all the bleeding scenarios and have even placed them in simulated blood and then handed them to the students to use to show them they still work when wet.
Force Pro	4,200	Never	None	Yes	No	Yes, FMP with various training models
Urban Shield	1,000	Never	None	Yes	No	Yes, FMP scenarios
Rescue Essentials	3,700	Never	None	Yes	No	Yes, FMP scenarios
International School of Tactical Medicine	15,600	Never	3 breaks due to excessive repeated use in training evolutions	Yes	No	Yes, Extensive FMP scenarios
Z-medica	1,000	Never	1- sharp object	Yes	No	Yes, manikin training
Medicine in Bad Places	2,000	Never	Never	Yes	No	Yes
TEMS Solutions - DPD, NPD, SOMA, SOCM	2,000	Never	None	Yes	No	Yes, FMP scenarios
Studies 2013, 2012, 2012,	334	None reported	None reported	Yes	No	No - study
2009	62	None reported	None reported	Yes	None reported	No - study
2008	60	None	None	Yes	No	No - study

CHART 1