

Innovative Medical Device Proven by the Military Now Available for Civilian Use

The Abdominal Aortic and Junctional Tourniquet – Stabilized (AAJT-S™), was created to provide a solution to control difficult to manage junctional hemorrhage and pelvic bleeding. It has been used in combat^{1,2} and is the only junctional tourniquet to save life in upper³ and lower⁴ junctional bleeding. It is the only truncal tourniquet approved by the FDA and has been shown to be equivalent to Zone 3 REBOA^{5,6}. It also provides for pelvic fracture stabilization.

The AAJT-S™ is a single use, externally applied truncal and junctional tourniquet that utilizes a wedge-shaped bladder to press into the body occluding blood flow through all vasculature under the site of application. It is approved for 1 hour of application on the abdominal site and 4 hours of application on the junctional sites (axilla and groin).

Summary of Referenced literature:

Human Use – Case Studies

The AAT™ (first version of the current device, AAJT-S™) was first applied by the physicians with the United Kingdom Ministry of Defense saving the life of an Afghanistan soldier injured by an Improvised Explosive Device (IED).

- “Abdominal Aortic Tourniquet use in Afghanistan” *Journal of Special Operations Medicine*, Vol 13, Edition 2, Summer 2013, pp 1-2
- Croushorn, J and Calloway, D, “Abdominal Aortic Tourniquet use in Afghanistan” *Journal of Special Operations Medicine*, Vol 13, Edition 2, Summer 2013, p 3

The patient had bilateral lower extremity amputations, pelvic wounds and despite advanced resuscitative interventions (i.e. blood transfusion, Fresh Frozen Plasma, tranexamic acid, mechanical ventilation) he continued to decompensate. The AAT™ was applied and the patient began to improve immediately. He increased end-tidal CO₂ and ultimately survived transport and damage control surgery. At 48 hours he showed no signs of renal failure or bowel ischemia from the application of the AAT™.

The device was placed on two other patients that same year for control of junctional hemorrhage. In both cases the patients survived and showed no complications from placement of the AAT™.

- Croushorn, J et al., “Abdominal Aortic Tourniquet Controls Junctional Hemorrhage From a Gunshot Wound of the Axilla.” *Journal of Special Operations Medicine*, Vol 13, Edition 3, Fall 2013, pp 1-4

This patient arrived in hemorrhagic shock from a single gunshot wound that entered the left posterior upper arm and traversed the axilla destroying 6 cm of brachial artery. He

was bleeding severely from his wounds and continued to decompensate despite rapid initiation of blood transfusion and mechanical ventilation. The AAT™ was applied against the axilla on the affected side, secured around the opposite shoulder and inflated. The article includes x-ray imagery of the patient after the device is applied. The wedge is clearly seen pressing into the chest wall. Soft tissue compression extended up to the clavicle stopping blood flow in the subclavian artery at the mid clavicular site. He survived surgical resuscitation and made a full recovery.

- Croushorn, J et al., “Abdominal Aortic and Junctional Tourniquet Controls Hemorrhage From a Gunshot Wound of the Left Groin.” *Journal of Special Operations Medicine*, Vol 14, Edition 2, Summer 2014, pp 6-8

This patient arrived into an urban emergency department in hemorrhagic shock with a single gun shot wound to the left proximal thigh. A commercially available extremity tourniquet was applied above the point of wounding. Resuscitation continued with blood transfusion and fluid resuscitation. The bleeding resumed and there was not enough room to place a second tourniquet above the first one applied. This prompted the use of the AAT™. This provided for immediate and total hemorrhage control. The patient was resuscitated and transferred to a level 1 trauma center. Vascular surgeons repaired a complete femoral artery transection and the patient survived.

Equivalency of Zone 3 REBOA

Resuscitative Endothelial Balloon Occlusion of the Aorta (REBOA) is an innovative approach in the management of trauma patients. The ability to stop blood flow through the aorta can provide for dramatic physiologic benefits such as increasing the mean arterial pressure (MAP), increasing end tidal CO₂ and conservation of life saving interventions by limiting the circulating volume to the vital organs.

In 2017 the US military conducted two research studies to examine the equivalency of the application of the AAJT-S™ and Zone 3 REBOA. The Institute of Surgical Research and the USAF 59th Medical Wing demonstrated equivalency in safety and efficacy of the two techniques. The military was interested in extending the physiologic benefits of REBOA to the point of wounding. REBOA requires advance provider skills generally limited to physicians. The procedure is typically performed in a hospital with ultrasound guidance. The application of the AAJT-S™ can be applied successfully by individuals without any specific medical training at the point of wounding. It is also less expense and non-invasive.

- Rall, Jason M., et al. “Comparison of Zone 3 Resuscitative Endovascular Balloon Occlusion of the Aorta and the Abdominal Aortic and Junctional Tourniquet in a Model

of Junctional Hemorrhage in Swine." *Journal of Surgical Research*, vol. 226, 2018, pp. 31–39.

The USAF 59th Medical Wing found in this study that the AAJT™ when applied to the abdominal location was equivalent in efficacy and safety to Zone 3 REBOA. The AAJT™ group demonstrated higher mean arterial pressure than the REBOA group. The study found that both techniques achieved statistically similar hemostatic, hemodynamic and metabolic profiles.

References:

1. "Abdominal Aortic Tourniquet use in Afghanistan" *Journal of Special Operations Medicine*, Vol 13, Edition 2, Summer 2013, pp 1-2
2. Croushorn, J and Calloway, D, "Abdominal Aortic Tourniquet use in Afghanistan" *Journal of Special Operations Medicine*, Vol 13, Edition 2, Summer 2013, p 3
3. Croushorn, J et al., "Abdominal Aortic Tourniquet Controls Junctional Hemorrhage From a Gunshot Wound of the Axilla." *Journal of Special Operations Medicine*, Vol 13, Edition 3, Fall 2013, pp 1-4
4. Croushorn, J et al., "Abdominal Aortic and Junctional Tourniquet Controls Hemorrhage From a Gunshot Wound of the Left Groin." *Journal of Special Operations Medicine*, Vol 14, Edition 2, Summer 2014, pp 6-8
5. Rall, Jason M., et al. "Comparison of Zone 3 Resuscitative Endovascular Balloon Occlusion of the Aorta and the Abdominal Aortic and Junctional Tourniquet in a Model of Junctional Hemorrhage in Swine." *Journal of Surgical Research*, vol. 226, 2018, pp. 31–39.
6. Schechtman, David W. MD; Kauvar, David S. MD; De Guzman, Rodolfo; Polykratis, I. Amy BS; Prince, M. Dale BS; Kheirabadi, Bijan S. PhD; Dubick, Michael A. PhD, "Abdominal aortic and junctional tourniquet versus zone III resuscitative endovascular balloon occlusion of the aorta in a swine junctional hemorrhage model," *Journal of Trauma and Acute Care Surgery*: February 2020 - Volume 88 - Issue 2 - p 292-297