

**Confidential**

**Internal Laboratory Test Report 8 Nov 2016**

**An Experiment to Determine Proof of Concept of a Novel Junctional Hemorrhage Control Device for Use in the Individual First Aid Using the Wake Forest University Hemostasis Model in Unembalmed Human Cadavers with Vascular Pressure**

**Introduction**

Approximately 80 percent of potentially survivable casualties on today's battlefield nevertheless result in mortality due to uncontrolled hemorrhage. Devices that control hemorrhage on the battlefield early in the continuum of care may likely increase the survivability of combat casualties.<sup>1</sup> The object of this study is to test the feasibility of the Junctional Hemorrhage Control Plate (JHCP), a device developed by Combat Medical Systems to be carried in the Individual First Aid Kit (IFAK), and Combat Lifesaver (CLS) bags for temporarily control of junctional hemorrhage. The JHCP is used in conjunction with the **Tactical Mechanical Tourniquet (TMT)** to control hemorrhage in compressible, non-tourniquetable regions.

**Methods**

The Wake Forest University human cadaver hemostasis model was used to test the efficacy of the JHCP. This testing platform uses a pulsatile peristaltic pump to produce realistic constant blood flow within the arteries of a fresh unembalmed human cadaver. Testing hemostatic devices and procedures using intact fresh human tissue has some advantages over alternative live tissue models when a mechanical device is employed to reduce arterial flow rates.

Authentic human anatomy is an important requirement for validating the efficacy of hemorrhage control devices when an external control device is applied to control flow in the external iliac artery at or above the inguinal ligament where peripheral limb tourniquet application cannot be used. In this feasibility study, one fresh human cadaver was used with peristaltic tubing ~~was~~ inserted and sealed within the thoracic aorta. An external peristaltic pump was used to deliver fluid through arteries in the descending abdomen, pelvis and limbs of the cadaver with a constant peristaltic speed and constant arterial flow rate consistent with physiological levels. The right popliteal artery was cut in order to observe dynamic changes in downstream arterial flow rates from fluid pumped through the thigh before, during and after the application of hemorrhage control devices with constant peristaltic pumping. The successful application was measured by arresting of flow through the external iliac artery by observing the flow rate at the exposed popliteal artery.

**Results:**

The human hemostatic testing model developed at the Wake Forest University School of Medicine was used to demonstrate the capacity of the JHCP to stop arterial flow when applied to the external iliac artery. The JHCP completely stopped blood flow and arterial pressure with only 4 turns of the device when the device was applied to the surface of the cadaver just above the

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<sup>1</sup> Holcomb JB, McMullin NR, Pearse L, et al. Causes of death in U.S. Special Operations Forces in the global war on terrorism: 2001–2004. *Ann Surg.* 2007;245:986–991.

inguinal ligament. The JHCP controlled arterial flow through the external iliac in 2 tests on one human cadaver.

**Conclusion:**

The JHCP effectively stopped flow in the external iliac artery. The JHCP is a device that could potentially control hemorrhage in junctional regions. The device warrants further development and studies.



JHCP Base Plate



JHCP attached to Tactical Mechanical Tourniquet for application