



iTClamp Hemorrhage Control System – Military White Paper



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Introduction

Innovative Trauma Care, Inc. (“iTraumaCare™”) is developing and marketing point of injury solutions to address the common causes of preventable death in traumatic injury scenarios. Founded and incorporated in Edmonton, Canada in 2010, with Commercial headquarters in San Antonio, Texas

ABSTRACT

Innovative Trauma Care’s iTClamp 50’s addresses the main cause of preventable death; hemorrhage, in a few seconds in all environments and phases of care. This invaluable tool will allow treatment of bleeding to occur much faster than is currently possible with existing technologies: in Care Under Fire, CBRN environments, in moving vehicles/helicopters, and during mass casualty triage.

PROBLEM STATEMENT

In recent military operations, uncontrolled hemorrhage was the primary cause of battlefield death (1). Early control of bleeding is critical to survival (2). In particular, junctional hemorrhage, which is not amenable to tourniquet use, is a leading cause of preventable death among Canadian / U.S. soldiers (1, 3, 4). A recent study examining preventable death on the battlefield from 2001-2011 indicates that 91% of battlefield deaths are due to uncontrolled hemorrhage, of which 32.7% (n = 290) could have been prevented with a device that effectively treated junctional (19.2%) and extremity bleeding (13.5%) (1).

Currently, bleeding is controlled by the use of tourniquets, direct pressure, and wound packing (with or without hemostatic agents). These take time to apply, are difficult to maintain during transport, and require extensive training. In field use tourniquets can break down (6) and were found to be ineffective in 83% of cases (distal pulses present) and inappropriately used on venous injuries in 83% (5).

PROPOSED SOLUTION

INTRODUCTION OF SOLUTION

The iTClamp 50, Innovative Trauma Care’s first product, is a temporary wound closure device to control severe bleeding within seconds of application to a penetrating injury.

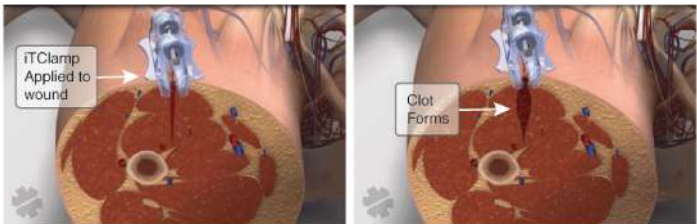


Figure 1: Illustration of iTClamp mechanism of action

Figures one and two illustrate the effectiveness and mechanism of action of the iTClamp in a commonly fatal groin injury. The iTClamp has temporarily closed the wound, creating a hematoma within the wound pocket, which remains contained and does not extend through surrounding tissue. Once the pressure in the hematoma equalizes with the bleeding source, the blood flow is stopped and the clot begins to form, temporizing until surgical repair.

The iTClamp is cleared by the FDA for the control of severe hemorrhage in the extremities, axilla and groin.

APPLICATION OF SOLUTION

The iTClamp50 presents the following benefits to soldier:

- **Effective:** 100% survival in lethal groin injury model

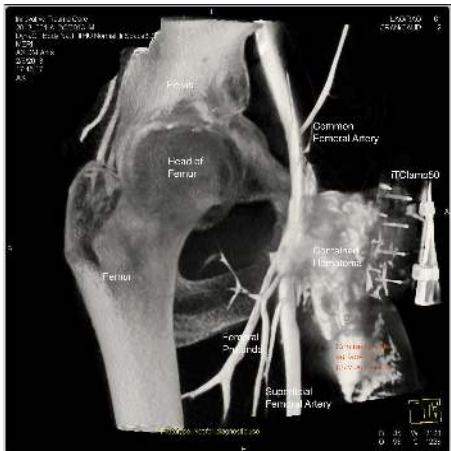


Figure 2: Angiography of re-perfused cadaveric model with penetrating injury (6 mm arteriotomy) to the femoral artery just distal to inguinal ligament.



- **Versatile:** stop bleeding in compressible areas
- **“Care Under Fire”** option: 3-5 seconds to apply
- **Minimal pain:** rated as 1/10 on a pain scale
- **Light (1 oz),** portable, accessible
- **One-handed** for self-application and allows positive control of weapon during application
 - Single gross motor motion: allows application when stress levels are high
 - Maintains distal perfusion if there is a partial arterial injury or collateral flow
 - Can be applied over most clothing without using treatment time to expose the wound

For medics the benefits of using the iTClamp50 are:

- Does not increase scene times
- Eliminate 3 minutes of manual pressure after wound packing
- Frees up the medic’s hands to take care of other critical injuries
- Can be applied during casualty evacuation (in a moving ambulance or helicopter)
- Can be incorporated into mass casualty triage: applied during initial assessments
- Can be used by CBRN teams in contaminated environments

In the field hospital the benefits of the iTClamp are:

- Decrease time spent in trauma room
- Can be used during CT scan and serves as a wound marker on the skin
- Application by non-physicians during primary and secondary surveys

LIMITATIONS:

The iTClamp is limited to wounds where skin edges can be approximated and only works in compressible areas of the body. Tourniquets will still be required for amputations and hemostatic agents may still be needed to pack wounds with large cavities.

FUTURE DIRECTION

The iTClamp will continue to evolve to become lighter, easier to use, and provide a broader range of applications and with a lower profile so that protective equipment can be worn over top.

CONCLUSION

The main advantages to the iTClamp are its small size/weight, speed of application, versatility, and ease of use under austere conditions while not creating any additional damage or pain. The iTClamp can be used in conjunction with hemostatic agents. Two iTClamps should be placed in a soldier’s individual first aid kit to deal with an entry and an exit wound. The iTClamp might not be the only device used to treat a casualty but it should be the first one used in most cases.



Appendices

Appendix A – Scenarios

- a. During a hostage rescue in a foreign country, several members of the elite force are wounded from hostile gunfire. One member in the lead assault team goes down from a massively bleeding groin wound. The other wounded soldiers continue to fight through to secure the hostages. A follow on team applies an iTClamp to the groin wound while the medic in the lead team places clamps on the bleeding extremities of the wounded assaulters.
- b. On a routine convoy in Afghanistan, the lead vehicle is hit with a roadside bomb. There is no hostile fire. The other vehicles form a secure perimeter and look for secondary explosives as well as the bomber. The rescue of the survivors is time sensitive knowing that another device could take out the rescuers. To minimize time on the “X”, iTClamps are placed on bleeding wounds and the wounded are dragged a distance to a secure casualty collection point.
- c. A medevac Blackhawk helicopter is called into a hot zone to rapidly extract a critically wounded soldier. The helicopter hovers just above the ground for the few seconds it takes to load the casualty and then rapidly takes off. There was no time for a handover and the medic on board must treat multiple extremity gunshot wounds in a confined space using night vision goggles in a moving helicopter. He feels for the gunshot wounds and controls bleeding with multiple iTClamps and manual pressure.

Appendix B – References

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