

Issues in HEMORRHAGE CONTROL

Uncontrolled hemorrhage is a significant cause of mortality worldwide.

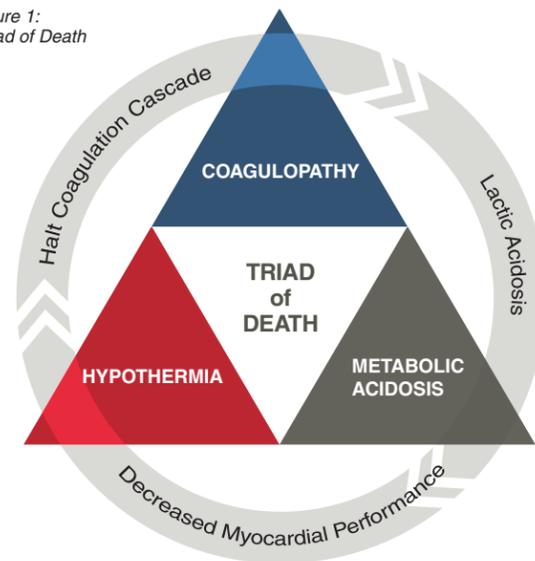
Up to 40 percent of civilian trauma deaths are attributable to hemorrhage, second only to Central Nervous System injury.^{1,2} Furthermore, hemorrhage is the primary cause of acute death (within 24 hours) in trauma patients.¹ Early and effective control of hemorrhage is critical to survival of the trauma patient.

EVERY RED BLOOD CELL COUNTS

In the pre-hospital setting, hemorrhage control is a priority because “every red blood cell counts.”³ Significant blood losses are associated with coagulopathy (impaired blood coagulation). In fact, approximately 25 percent of trauma patients arriving in emergency departments have an established coagulopathy.⁴ Coagulopathy combined with hypothermia and acidosis forms the lethal triad of death (see figure 1).

Even with adequate fluid resuscitation, when the lethal triad is present patients are more susceptible to late mortality and multiple organ failure.² To further complicate matters, significant blood loss can lead to hemorrhagic shock – “a pathophysiologic state in which the circulatory system is unable to perfuse tissues and meet oxygen demand adequately.”⁵ In severe shock, a rapid immune response produces large quantities of inflammatory mediators, cytokines, and reactive oxygen species. This dysfunctional inflammatory response leads to secondary organ damage, multiple organ failure and subsequent death.⁶ Therefore, early control of hemorrhage is not only important to prevent death but also to reduce the harmful consequences associated with inflammation and shock.

figure 1:
Triad of Death



HEMORRHAGE IS A LEADING CAUSE OF PREVENTABLE DEATH

Recently, significant advances have been made in the field of pre-hospital hemorrhage control, particularly in military-based medical research. Similar to civilian settings, hemorrhage is a leading cause of preventable death in casualties and significant resources have been invested in researching new solutions.⁷ Now in addition to direct pressure, first responders have access to limb tourniquets, hemostatic agents, and systemic agents such as tranexamic acid.⁶

Still, additional innovative solutions are needed to control bleeding in the field – specific areas such as the scalp and junctional areas (groin, armpits, neck) are not amenable to tourniquets. Direct pressure takes a first-responder out of the game by requiring them to exclusively focus on one patient. Solutions that can be applied quickly and effectively allow

medics and first responders to address other critical medical needs or provide care to other injured patients. In the pre-hospital setting, new products need to be fast, effective, easily applied and removed, intuitive, stable, lightweight and transportable.

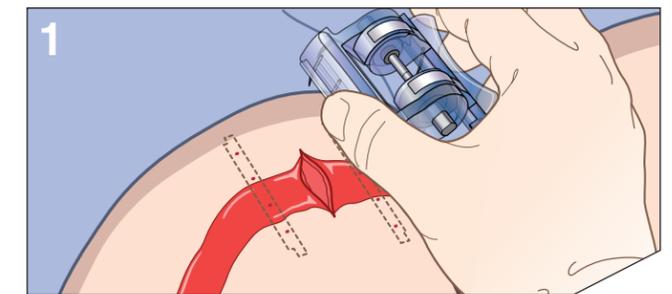
STOP THE BLEEDING!

There are several innovations on the horizon that hold promise to address these needs, such as the iTClamp™ Hemorrhage Control System. The iTClamp, developed by a Canadian trauma surgeon who served in Afghanistan, is a 2x2 inch, less than 2 ounce single use, disposable plastic device with surgical needles and two pressure bars to create a fluid tight seal across the wound edges in seconds. This allows a hematoma (pool of blood) to form in a contained space. As the pressure in the hematoma increases, there is no further flow into the space and a stable blood clot forms until the patient’s wound can be surgically addressed. The iTClamp is available in Europe and Canada and is pending regulatory approval in the US.

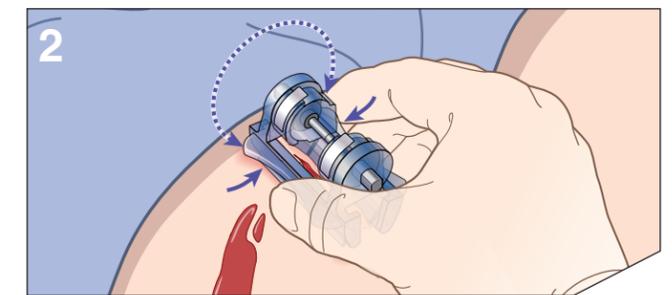
Addressing the solvable problem of uncontrolled hemorrhage is a priority in saving lives, and with today’s available technology, promising technology to come, and an industry wide commitment to finding answers, we can lower the number of preventable deaths due to hemorrhage in the US and beyond.

- **UP TO 40 PERCENT** of civilian trauma deaths are attributable to hemorrhage
- **APPROXIMATELY 25 PERCENT** of trauma patients arriving in emergency departments have an established coagulopathy
- **Coagulopathy** combined with hypothermia and acidosis forms the lethal “triad of death”

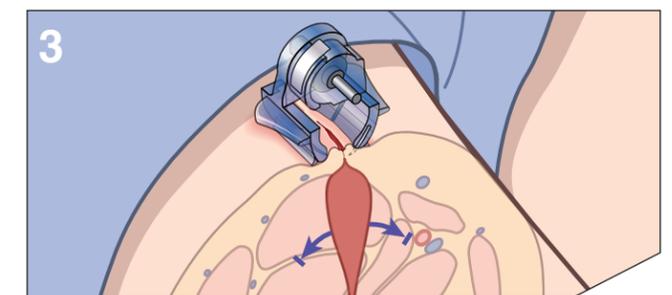
HOW THE iTCLAMP™ WORKS



Device is applied to wound



Wound is sealed



Clot forms under skin

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 **iTClamp™**
HEMORRHAGE
CONTROL SYSTEM



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