



Welcome to Clinical Training for use of the iTClamp (an Innovative Trauma Care product)

The Hemorrhage Problem

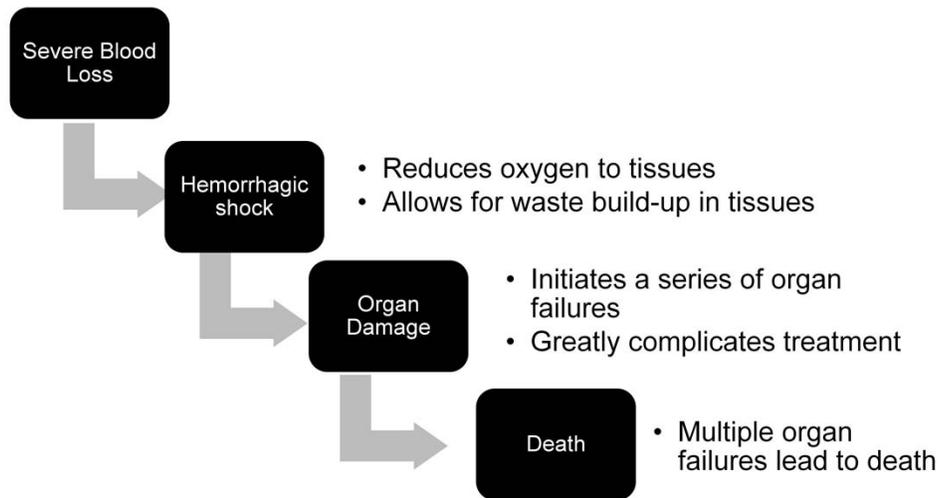
- Severe bleeding is the leading cause of preventable death in traumatic injuries.
 - Blunt force trauma (MVA)
 - Penetrating wounds (gun, knife)
 - Battlefield Injuries
- Current research indicates stopping hemorrhage early is critical to good outcomes
 - Reduces occurrence of coagulopathy
 - Reduces downstream complications and cost
 - Improved survival rates if hemorrhage is controlled prior to onset of shock

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Severe bleeding or hemorrhage is a leading cause of death in both civilian and military settings. In fact, up to 40% of civilian trauma death are attributable to hemorrhage.

Early hemorrhage control is critical to survival of trauma patients because “every red blood cell counts”. Early hemorrhage control reduces negative outcomes such as the occurrence of coagulopathy or impaired blood coagulation.

Hemorrhagic Shock Cascade



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In the most basic assessment hemorrhage initiates a cascade through a series of events which ultimately lead to death. Specifically, once the body enters into hemorrhagic shock, damage begins to occur at the cellular level through hypoxia and acidosis. Left unchecked this damage can lead to organ damage, failure and ultimately death. Interrupting the cascade is critical to the successful management of the patient and, if done early in the course of this cascade, ideally before shock even develops, the better the patient's outcome and less cost to the system for their care. However, management is not as simple as just "filling" up the system with fluid and blood to reverse the damage from shock.

Complications of Hemorrhage

Bleeding

- Reduced body temperature (hypothermia)
- Reduced tissue perfusion (hypoperfusion)

Hypoperfusion

- Low tissue oxygen (hypoxia)
- Anaerobic metabolism producing lactic acid (acidosis)

Acidosis and Hypothermia

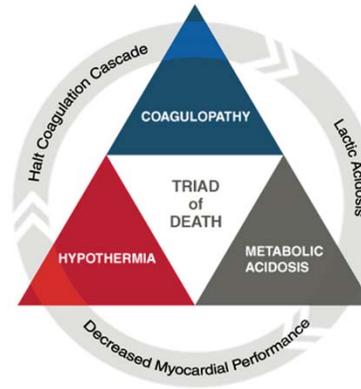
- Disrupts body's coagulation function (coagulopathy)
- Completes the Triad of Death

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Significant blood loss is associated with coagulopathy (impaired blood coagulation). Coagulopathy forms one part of the lethal triad of death. Severe hemorrhage reduces the circulating blood volume which leads to a reduction in core body temperature (hypothermia) and hypoperfusion of the tissues. Hypoperfusion causes the tissues to become hypoxic and respire anaerobically producing lactic acid (metabolic acidosis). Combined hypothermia and acidosis have a deleterious effect on coagulation. Together coagulopathy, acidosis and hypothermia form a vicious cycle that spirals towards death.

Triad of Death

- Significant blood loss is associated with coagulopathy
 - 25% of trauma patients arriving in the ED have an established coagulopathy*
- Even with adequate fluid resuscitation patients with the lethal triad are
 - More susceptible to late mortality and multiple organ failure**



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*Brohi et al. 2003 J. Trauma

**Kauver et al. 2006 J. Trauma

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Potential Civilian Applications

- Sports injuries
- Polytrauma
- Stabbings
- Gunshot wounds
- Tactical situations
- Explosions
- Mass casualties
- Falls
- Agricultural/Industrial injuries



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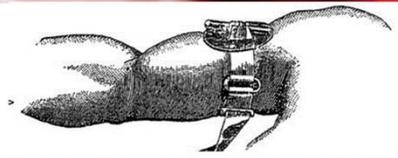
Current Hemorrhage Control Technology

The same “technology” has been used for thousands of years

- Direct pressure
- Tourniquets
- Gauze for packing wounds

New Technology Breakthroughs

- Hemostatic (clotting) agents
- Tranexamic Acid
- Combat Ready Clamp/JETT
- Abdominal Tourniquets

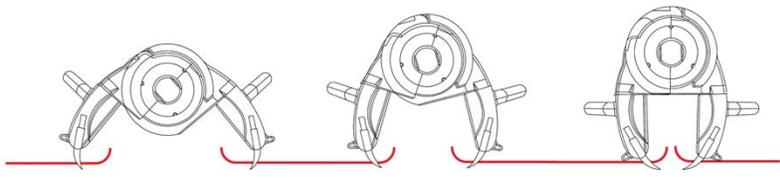


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In spite of the prevalence of trauma in the world of medicine, we are still using technologies that have been in use for literally thousands of years. Tourniquets, bandages, and gauze are mainstays, supplemented by clotting agents.

 **– the Solution**

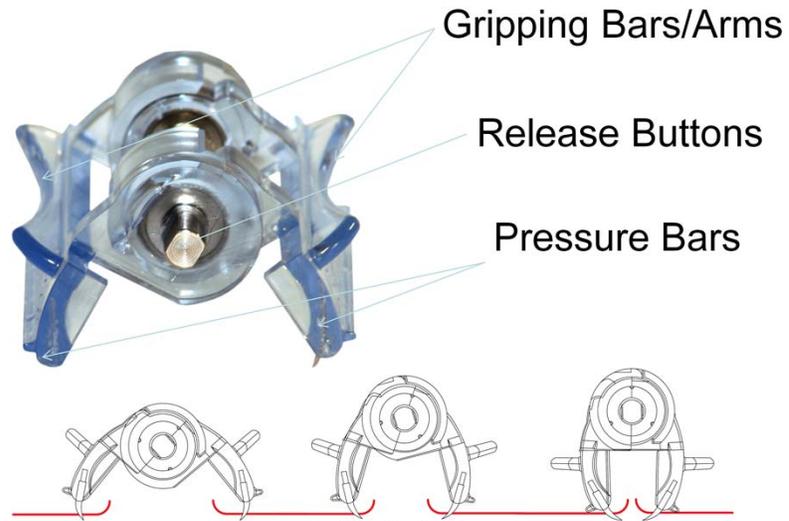
The iTClamp™ by Innovative Trauma Care instantly controls critical bleeding by sealing the skin closed to create a temporary pool of blood under pressure. This forms a stable clot until surgical repair.



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The ITClamp is a wound closure device designed to achieve rapid control of critical bleeding

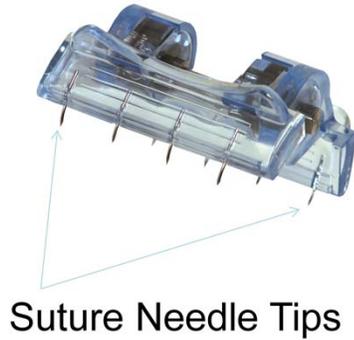
Device Components



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The iTClamp has two gripping bars/arms, two pressure bars, and two release buttons

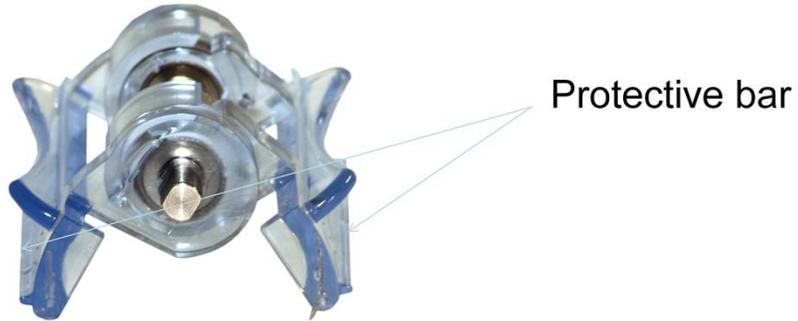
Device Components



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Suture needle tips at the base of the device are designed to grip the skin.
The wound access window allows visualization of the wound through the device.

Needle Tip Safety

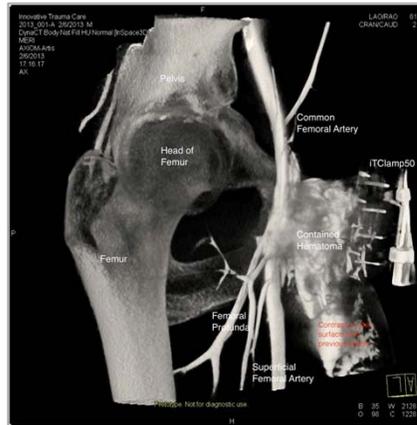


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A protective bar on each pressure bar protects fingers from coming into contact with the needle tips.

How It Works

Once the ITClamp closes the wound, a temporary, contained hematoma forms under the skin, which remains in place until definitive surgical repair is available.



6mm arteriotomy of the femoral artery in a cadaver model; pressure injected contrast; distal perfusion is maintained.

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How does it work?

iTClamp™ 50

Indications:

- The iTClamp 50 device is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla and inguinal areas.

Contraindications:

- The iTClamp50 is contraindicated where skin approximation cannot be obtained (for example, large skin defects under high tension).

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The iTClamp is indicated for use in trauma wounds, junctional bleeds, lacerations and surgical incisions.



To apply the ITClamp, always use standard precautions to protect against body fluid exposure.

The labeled side of the device package is the top.

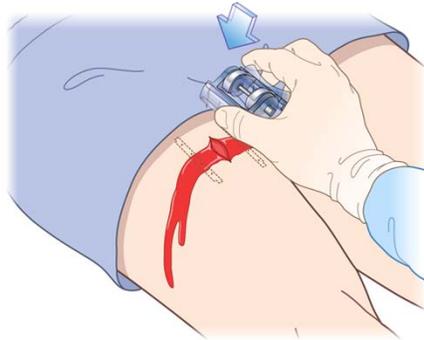
Always bring the device into close proximity to the wound prior to opening the package to avoid needle stick injury.

Open the sterile package by flipping up one or both tabs on the top half of the package.

With one hand, remove the device from the package by lifting it straight up out of the package.

Device Application

Align needle tips along wound edges



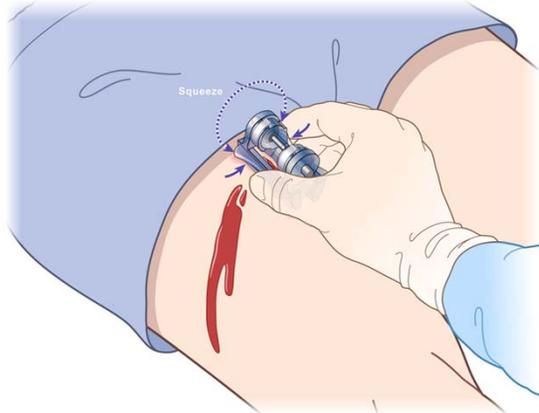
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Align the needle tips of the ITClamp parallel to (or alongside) edges of the wound.

Device Application

Insert needles alongside wound edges.

Close clamp



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Gently insert needles insert the needles

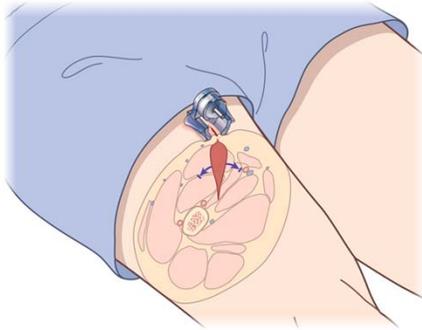
Close clamp by squeezing gripping bars/arms together. The device seal will break once pressure is applied to the arms.

Once it is closed, the device will automatically lock into place.

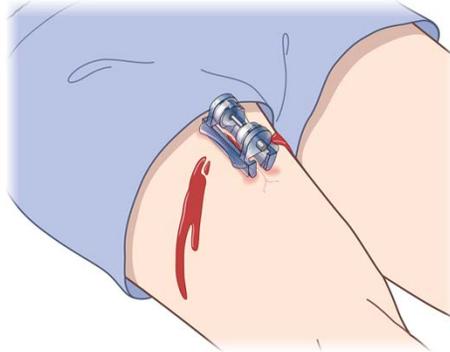
The pressure bars on the ITClamp assure a fluid-tight seal.

Device Application

Hematoma forms



Bleeding stops



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Once the clamp is closed, a temporary, contained hematoma forms under the skin, and stops bleeding.

Additional Bleeding Control

- If bleeding continues:
 - Close device more firmly
 - Place additional devices for larger wounds
 - Remove, reposition & reapply device

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If the wound continues to bleed after the ITClamp is applied, there are several options:

Close device more firmly by applying additional pressure to device arms

Use additional devices for larger wounds: if the wound is larger/longer than a single ITClamp, additional clamps should be placed to close the entire wound.

If necessary, remove and reapply the ITClamp

Adjuncts with iTClamp to improve Bleeding Control

- Wound packing
- Hemostatic agents
- Compression wraps

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The iTClamp can be used in conjunction with other hemorrhage control interventions.

Wound packing: If desired, wound packing may be done before the iTClamp is placed on a wound.

Hemostatic agents: The iTClamp may be placed on a wound that has a hemostatic agent applied. The hemostatic agent does not have to be removed.

Binding/wrapping: If desired, additional compression binding/wrapping may be placed over the iTClamp after it has been applied on a wound. This action will protect the clamp and may provide additional compression to the wound, limiting hematoma formation.

Device Removal



Release Buttons

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The release buttons on either side of the iTClamp may be used to open the device for removal or repositioning

iTClamp Removal/Repositioning

Use the release buttons to open the device if:

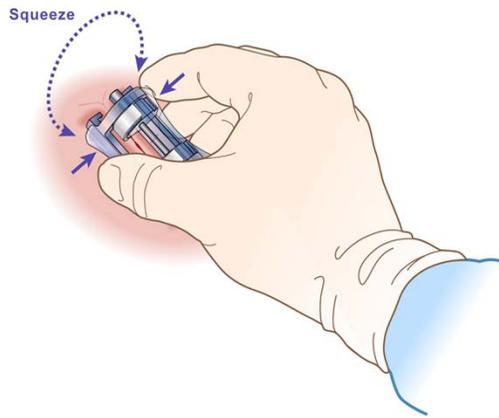
- The device was inadvertently closed prior to placement
- The device was positioned incorrectly
- Surgical intervention is available and the patient is ready for definitive wound repair

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The release buttons on either side of the iTClamp may be used to open the device:

1. If the device is inadvertently closed prior to placement
2. If the device has been positioned incorrectly
3. If definitive care is available and the patient is ready for surgical repair of the wound

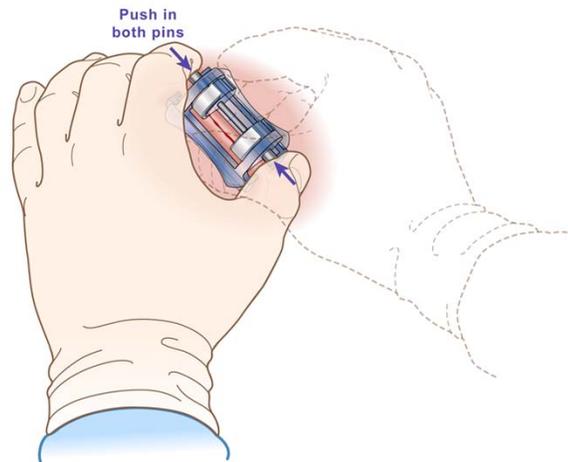
Squeeze clamp to release



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To remove the ITClamp from the wound, hold the device by the gripping bars and squeeze it closed to release the friction in the lock.

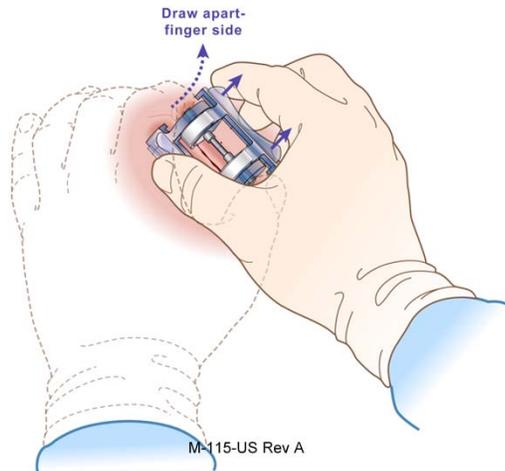
Press BOTH release buttons



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While maintaining pressure on the gripping bars, press the release buttons with your other hand. Note this is a two-handed process.

Pull one of the gripping bars open and rotate the needles out of the wound, one side at a time



While maintaining pressure on the buttons, pull one of the gripping bars open and rotate the needles out of the wound, one side at a time. Only 1 arm will freely rotate.



Dispose of the device in accordance with local guidelines for biohazard sharps. Holding the device by the button during removal minimizes accidental contact with the needles.

iTClamp 50 - Warnings

- This device is intended for temporary use only; use beyond three-hours has not been studied
- Patients must be seen promptly by medical personnel for device removal and surgical wound repair
- Only use device as directed to avoid needle stick injury
- Do not use where delicate structures are near the skin surface, within 10 mm, such as the orbits of the eye
- Will not control hemorrhage in non-compressible sites, such as the abdominal and chest cavities
- Ensure personal protective equipment is utilized to protect against potential splashing of blood during application

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iTClamp™ 50– Cautions

- Single-use, disposable device; not for reuse. Re-use of contents may cause cross contamination, leading to patient risk and complication(s). Can be repositioned.
- iTClamp50 is provided sterile (sterilized by EtO). Do not use if sterility seal has been tampered with or packaging is damaged.
- Not compatible with Magnetic Resonance Imaging (MRI) procedures.
- Dispose of the device in accordance with local guidelines for biohazard sharps.
- The devices and/or component(s) are not made from natural rubber, latex free.

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iTClamp Summary Points

- Indicated for bleeding control in extremities, axilla and inguinal areas
- A hematoma forms under pressure, which stops the bleeding.
- May be used at any site where skin edges can be approximated
- Transport for definitive care

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In summary, the iTClamp is:

- 1) Indicated for temporary bleeding control in extremities, axilla and inguinal areas.
- 2) The device also a hematoma to form under pressure; this functions to control the bleeding
- 3) The iTClamp can be used on any site where the skin edges can be approximated
- 4) The device allows for transport of the patient to definitive care

Questions?

For More Information:

www.itraumacare.com

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For more information, please visit Innovative Trauma Care at www.innovativetraumacare.com.
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