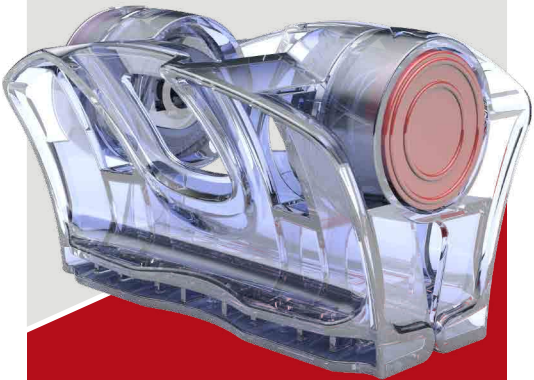
iTClamp®



DIRECTIONS FOR USE

iTraumaCare®
INNOVATIVE TRAUMA CARE®
iTraumaCare.com

iTClamp®

DESCRIPTION: The iTClamp® quickly controls critical bleeding by closing the skin to create a temporary, contained hematoma until surgical repair. The iTClamp® is a self-locking trauma clamp with needles that penetrate the skin to evert the skin edges between pressure bars of the device and anchor it to the skin to reduce slippage and leakage. Pressure is evenly distributed across the bars, which seal the skin over a wound. An adjustable locking mechanism increases or decreases pressure across the wound to achieve a fluid tight seal.

INDICATIONS FOR USE:
The iTClamp® device is indicated for use as an acute skin closure device for short-term soft tissue approximation to inhibit severe bleeding in trauma wounds, lacerations, junctional bleeds, or surgical incisions.

CONTRAINDICATIONS FOR USE: ⚠
The iTClamp® is contraindicated where skin approximation cannot be obtained (for example, large skin defects under high tension).

WARNINGS: ⚠

- This device is intended for temporary use only; use beyond 24 hours has not been studied.
- Patients must be seen promptly by medical personnel for device removal and surgical wound closure. Follow standard wound care practices to treat the wound after device removal.
- Only use device as directed to avoid needle stick injury. Follow standard sharps precautions to minimize risk of needle stick injury.
- Do not use where delicate structures

are near the skin surface, within 10 mm, such as the orbits of the eye.

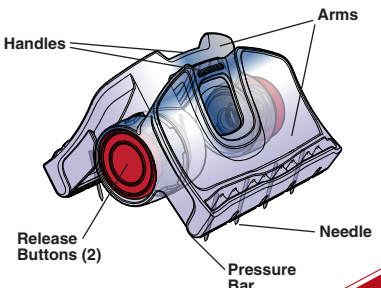
- Will not control hemorrhage in non-compressible sites, such as the abdominal and chest cavities.
- Ensure personal protective equipment is utilized to protect against potential splashing of blood during application.
- When used to control hemorrhage in the neck, consider the need for appropriate airway management as per local protocols under medical direction
- The iTClamp has not been specifically tested for pediatric use
- Subgaleal scalp hematoma (localized collection of blood) is a potentially life threatening complication due to scalp trauma in children less than 2 years of age.

RxOnly

Caution: Federal (USA) law restricts this device to sale by order of a physician.

PRECAUTIONS:

- Single-use, disposable device; not for reuse. Reuse of device may cause cross contamination, leading to patient risk and complication(s).
- iTClamp® is provided sterile (sterilized by EtO). Do not use if sterility seal has been tampered with or packaging is damaged, or after expiration date.
- Not compatible with Magnetic Resonance Imaging (MRI) procedures.
- Dispose of the device in accordance with local guidelines for biohazard sharps.
- The device and/or component(s) are not made from natural rubber, latex free.
- Non-DEHP, nonpyrogenic in unopened, undamaged package.



DIRECTIONS FOR USE:

The iTClamp® controls bleeding by sealing the skin closed to create a temporary pool of blood (hematoma) under pressure. This permits formation of a stable clot until surgical repair can be obtained.

EACH TACTICAL iTCLAMP® DEVICE PACKAGE CONTAINS ONLY:

- 1 Tactical iTClamp® (P/N 9600)
- 1 Device Casing
- Availble in boxes of 10 that include 1 Directions for Use (P/N 8102)

IMPORTANT:

1. Application of iTClamp® should only be performed by personnel trained and experienced with use and handling of the device.
2. Personnel using iTClamp® device should read package insert and corresponding product information and **Directions for Use** prior to using the product.
3. Follow local protocols for hemorrhage control, including wound packing

4. Training sessions, demo applications, training materials and additional documentation for use of device can be obtained by contacting a distributor, iTraumaCare representative, or through the iTraumaCare web site, iTraumaCare.com.

APPLICATION

5. Open the package by peeling off the package lid using the pull tab (fig 1).

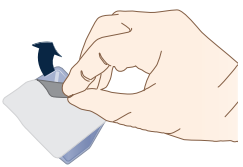


FIGURE 1

6. Pull the device to remove it from the package (fig 2).

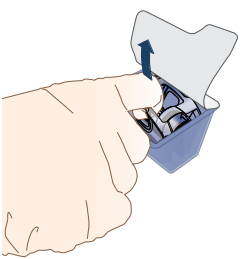


FIGURE 2

7. Prepare the device for use by pinching together the device handles to open the device (fig 3).

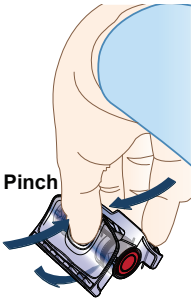


FIGURE 3

NOTE: Ensure the device is fully open before applying the device.

8. Locate the wound edges (fig 4).

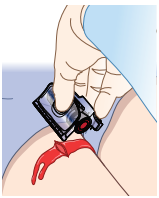


FIGURE 4

9. Align the device parallel to the length of wound edge. Position the needles about 1-2 cm (0.5-1 in.) from the wound edge on either side (fig 5). Keep hands clear of the wound area while applying the device.

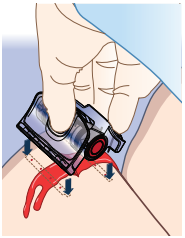


FIGURE 5

10. Press the arms of device together to close the device (fig 6).

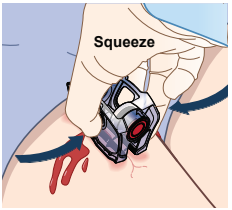


FIGURE 6

11. Ensure the entire wound is sealed and bleeding stops (fig 7).

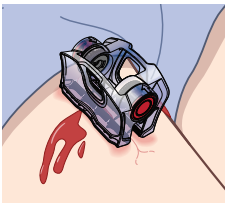


FIGURE 7

12. A gauze or compression wrap can be placed around the device on the wound to protect the device and increase pressure on the wound to limit hematoma expansion. Additional hemorrhage control measures may be required in the presence of an expanding hematoma.

NOTE: For wounds larger than 2 inches (50mm) more than one device may be required.

IF BLEEDING CONTINUES:

a. If bleeding continues while the device is in the correct position, close the device more firmly by applying further pressure to the

arms of the device.

b. If bleeding continues because the wound is too large, apply a second device to the open section.

c. If bleeding continues because the device is not positioned correctly, remove the device according to the instructions and reapply.

REMOVAL FROM SKIN

1. Hold the device handles (fig 8).

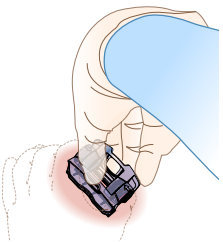


FIGURE 8

2. With your other hand (fig 9), press the release buttons.

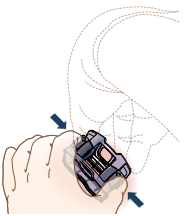


FIGURE 9

3. While pressing the release buttons, pinch the device handles to open the device and rotate the needles out of the wound (fig 10).

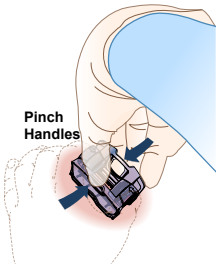
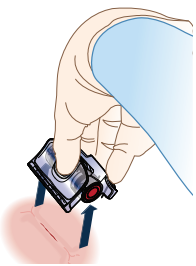


FIGURE 10

4. Remove the device (fig 11).



5. Dispose of the device in accordance with local guidelines for biohazard sharps.

NOTES: This device is intended for temporary use only. Patients must be seen promptly by medical personnel for device removal and surgical wound closure. If the device is being removed for readjustment purposes only, it is ready to reapply at this point.

PRECAUTIONS:

Health Hazard

This device contains stainless steel needles, which may contain cobalt at greater than 0.1% weight by weight (w/w). Cobalt is identified by ECHA Annex VI as a Category 1B carcinogenic, mutagenic and reprotoxic substance.

SERIOUS INCIDENTS OR ADVERSE EVENTS:

Report any serious incident that has occured in relation to the iTClamp to Innovative Trauma Care and the Competent Authority of the Member State in which the user and/or patient is established.

A list of Competent Authorities is available from the European Medicines Agency.

ema.europe.eu

FOR TRAINING DEVICE ONLY P/N 9200

TRAINER RESET INSTRUCTONS

1. Hold the device handles (fig 12).With your other hand, press the release buttons.

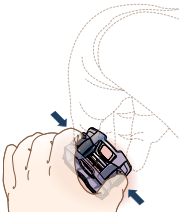


FIGURE 12

2. While pressing the release buttons, pinch the device handles to fully open the device (fig 13).

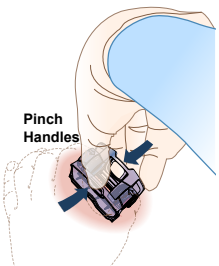


FIGURE 13

3. When the device is fully opened, the buttons will reach a point where they can be pressed in another 2-3 mm. While holding the buttons in this position, rotate the device closed (fig 14). The buttons will stay in place if the device has been reset successfully.

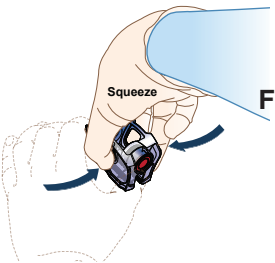


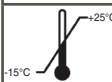
FIGURE 14

NOTE: TRAINER RESET INSTRUCTIONS ARE INTENDED FOR TRAINING DEVICE ONLY (P/N 9200), STERILE DEVICES (P/N 9600) ARE SINGLE USE ONLY

Symbols Used In Labeling

The following symbols may be found on the package labels. These symbols tell you about the proper and safe use of the iTClamp®. Some of these symbols may not have meaning in your region, and are listed for informational purposes only. This table shows what each symbol means.

	Lot Number
	Manufacturer Information
	Date of Manufacture
RxOnly	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.
	Expiry Date
	Sterilized using Ethylene Oxide. Do not use if package is damaged or open.

	Device has not been sterilized; not for clinical use.
	For single patient use only. Do not re-use.
	Consult Directions for Use.
	Authorized Representative in the European Community.
	CE Mark
	Medical Device
	UK Conformity Assessed
	Storage Conditions
	Health Hazard

WARRANTY AND LIMITATION OF LIABILITY

Section 1 Limited Warranty.
iTraumaCare warrants that the Products will conform with iTraumaCare's written product specifications for such Products in all material respects until the expiration date designated therefor on such Products (the "Warranty Period"). The warranty will not apply if the Products have been subjected to physical abuse, misuse, abnormal use, use not consistent with iTraumaCare's published directions and instructions for use, fraud, tampering, unusual physical stress, negligence or accidents. iTraumaCare does not guarantee that the operation of a Product will be uninterrupted or error-free. In the event of breach of warranty during the Warranty Period, iTraumaCare will either repair or replace any Product, provided that (i) Customer notifies iTraumaCare of such nonconformity within thirty (30) days after Customer's receipt of the Product, and (ii) Customer makes the nonconforming Product available to iTraumaCare and, upon iTraumaCare's request, returns it to iTraumaCare's designated facility at iTraumaCare's expense, all in accordance with iTraumaCare directions. Customer will not return any Product to iTraumaCare without having first obtained an RMA, in accordance with the provisions above. If after reasonable efforts, iTraumaCare is unable to repair or replace the nonconforming Product, iTraumaCare may, at its option, refund to Customer the purchase price paid by Customer for such Product in full satisfaction of all claims related to any defects or deficiencies in the Product.

Section 2 Warranty Disclaimer.
EXCEPT FOR ANY EXPRESS WARRANTY (AS PROVIDED ABOVE), ALL ITRAUMACARE PRODUCTS AND SERVICES ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. THE PRODUCTS ARE DESIGNED FOR USE SOLELY BY TRAINED, QUALIFIED AND LICENSED MEDICAL PERSONNEL USING REASONABLE MEDICAL DISCRETION IN EMERGENCY OR MEDICALLY NECESSARY SITUATIONS. ITRAUMACARE DISCLAIMS ANY AND ALL LIABILITY WITH RESPECT TO THE PRODUCTS ARISING FROM ANY USE OF THE PRODUCTS THAT IS NOT CONSISTENT WITH ITRAUMACARE'S PUBLISHED DIRECTIONS OR INSTRUCTIONS FOR USE (DFU/IFU). ITRAUMACARE SPECIFICALLY DISCLAIMS ALL OTHER EXPRESS, IMPLIED OR STATUTORY WARRANTIES, INCLUDING DESIGN WARRANTIES, THE IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY AND NON-INFRINGEMENT. NO PERSON IS AUTHORIZED TO MAKE ANY OTHER WARRANTY OR REPRESENTATION CONCERNING THE PERFORMANCE OF THE PRODUCTS OR SERVICES. BUYER WILL HAVE NO RIGHT TO MAKE OR PASS ON ANY SUCH WARRANTY ON BEHALF OF ITRAUMACARE TO ANY THIRD PARTY.

Section 3 Limitation of Liability.
iTraumaCare's liability for all claims related to or arising out of this Acknowledgment will be limited to a refund or credit to Customer of the purchase price for Products, or to the repair or replacement of Products, at iTraumaCare's option. IN NO EVENT WILL ITRAUMACARE BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION, THE COST OF PROCURING SUBSTITUTE GOODS OR SERVICES, INABILITY TO OBTAIN SUBSTITUTE GOODS OR SERVICES, LOST PROFITS, LOST BUSINESS OPPORTUNITIES, COSTS INCURRED DUE TO DELAY OR FAILURE TO MEET ANY SHIPMENT DATE, REGARDLESS OF THE FORM OF ACTION OR THEORY OF LIABILITY, AND REGARDLESS OF WHETHER ITRAUMACARE HAS BEEN ADVISED OF THE POSSIBLITY OF SUCH DAMAGES.

iTraumaCare®

Manufactured for and Distributed by:
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Made in the United States of America

EMERGENCY NUMBER:
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For further assistance, contact your local iTraumaCare representative:
iTraumaCare.com

RxOnly

EC REP

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