ITClamp™ 50

The ITClamp™50 is a wound/skin closure device that controls bleeding by closing the skin creating a temporary contained hematoma until surgical repair can take place. It is a self-locking surgical clamp with suture needles that penetrate the skin, everting the skin edges and anchoring it to the skin. Pressure is evenly distributed across the bars sealing the skin over the wound, while the adjustable locking mechanism increases or decreases pressure across the wound to achieve a tight seal and wound closure.

INDICATIONS FOR USE:

The ITClamp™50 device is intended for acute short term use to control severe bleeding in trauma wounds, lacerations (including scalp lacerations) and junctional bleeds.

CONTRAINDICATIONS FOR USE:

The ITClamp50 is contraindicated

- where skin approximation cannot be obtained (for example, large skin defects under high tension)
- bleeding from dialysis shunts

WARNINGS:

• Only use device as directed to avoid needle stick injury.
• Do not use over the orbit of the eye.
• This device is intended for temporary use only due to the increased risk of infection caused by dirty wounds.

PRECAUTIONS:

• Duration of use < 24 hours.
• Single-use, disposable device; not for reuse. Re-use may cause cross contamination, leading to patient risk and complication(s).
• ITClamp™50 is provided sterile. Do not use if sterility seal has been tampered with or packaging is damaged.
• 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
• Not compatible with Magnetic Resonance Imaging (MRI) procedures.

DIRECTIONS FOR USE:

The ITClamp™ 50 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.

APPLICATION DURATION OF USE 24 HOURS (One-handed operation):
1. Open the package by pulling forward on the outer tabs.
2. Remove the device from the package by lifting up, taking care not to close the device until it has been applied to the wound.
3. If the device has inadvertently closed, push the side buttons inward with one hand, and pull the device open with the other hand.
4. Locate the wound edges (fig 1).

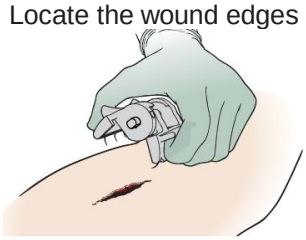


FIGURE 1

5. 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 2).

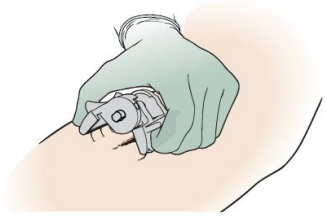


FIGURE 2

6. Press the arms of device together to close the device. Device seal will break with pressure (fig 3).

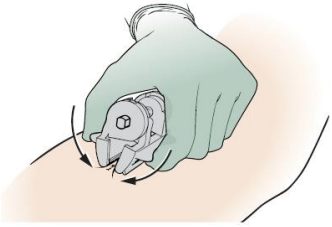


FIGURE 3

7. Ensure the entire wound is sealed and bleeding stops (fig 4).

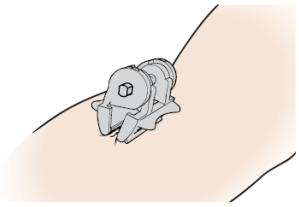


FIGURE 4

8. 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.

NOTE: 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 instructions and reapply.

REMOVAL FROM SKIN (Two-handed operation):
1. Holding the device by the arms, press the device closed (fig 5).

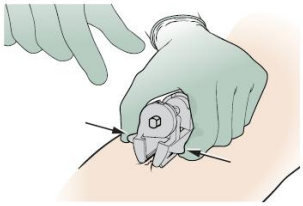


FIGURE 5

2. While maintaining pressure on the arms, press the release buttons with your other hand (fig 6).

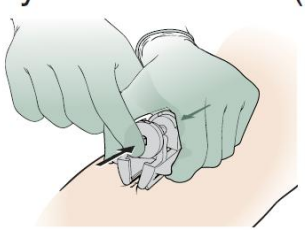
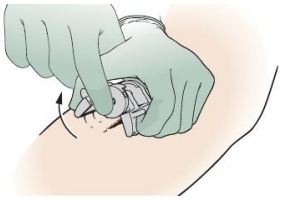
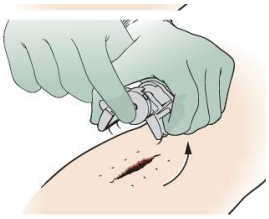


FIGURE 6

3. While pressing the release buttons, pull the arms to open the device and rotate the needles out of the wound (fig 7 and 8).





FIGURES 7 & 8

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

NOTES: Consultation with a Medical Professional is recommended prior to device removal. If the device is being removed for readjustment purposes only, it is ready to reapply at this point.

Reference

Innovative Trauma Care. (2012). *ITClamp 50* (8100-CE-EN Rev A). Retrieved from Medidyne: http://medidyne.dk/wp-content/uploads/itclamp/UK_ITC_DFU_3x6%208100-CE-EN.pdf