

CLAMP







RATCHET DRIVEN HEMOSTATIC CLAMP

SIZE: 2.3×1.7×1 in Weight: 36 g

Description

Ratchet Driven Hemostatic Clamp rapidly controls severe bleeding by closing the skin to create a temporary, contained hematoma until surgical repair. Ratchet Driven Hemostatic Clamp is a self-locking surgical clamp with suture needles that penetrate the skin to evert the skin edges between the pressure bars of the device and anchor it to the skin to reduce slippage and leakage. Pressure is evenly distributed across the pressure bars, sealing the skin over the wound. An adjustable locking mechanism can increase or decrease pressure across the wound to achieve a fluid-tight seal.







Detailed display











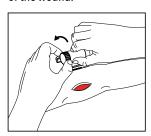
Application

STEP 1

Remove the device from the package.

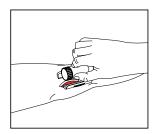
STEP 2

Identify the wound edges, then rotate the knob as indicated by the arrow in the diagram. Adjust the angle to a suitable degree depending on the size of the wound.



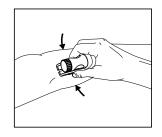
STEP 3

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.



STEP 4

Press the device arms together to close it, ensuring complete wound sealing and cessation of bleeding.



NOTE

1. More than one device may be required.

STEP 5

A gauze or compression wrap can be wrapped around the device and wound to shield the device and enhance pressure on the wound, thereby restricting hematoma expansion.

Removal

STEP 1

Hold the device and rotate the knob according to the diagram.



STEP 2

Rotate the knob while removing the needles from the wound, smoothly remove the device.



STEP 3

Dispose of the device following local guidelines for biohazardous sharps.

NOTES

1. This device is designed for temporary use only.

2.Patients should be promptly examined by medical personnel for device removal and surgical wound closure.3.If the device is removed solely for

3.If the device is removed solely for readjustment purposes, it can be reapplied at this time.



WARNINGS:

- $\bullet \ \, \text{This device is intended for temporary use only; use beyond three hours has not been studied.}$
- Patients must be promptly examined by medical personnel for device removal and surgical wound closure.
- Use the device only as directed to avoid needle stick injury.
- Do not use where delicate structures are within 10 mm of the skin surface, 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.

PRECAUTIONS:

- This device is single-use and disposable; it is not intended for reuse. Reusing the device may lead to cross-contamination, posing risks and complications to patients.
- The iTClampTM50 is provided sterile (sterilized by EtO). Do not use if the sterility seal has been tampered with or if the packaging is damaged.
- This device is not compatible with Magnetic Resonance Imaging (MRI) procedures.
- Dispose of the device following local guidelines for biohazard sharps.
- The device and/or its components are not made from natural rubber and are latex-free.





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