

AbClo

Abdominal Fascia Closure Device

Contents: 1 unit

2 Rectus Muscle Splints (RMS), 1 Circumferential Dynamic Retainer (CDR), 1 Tensioner Gauge System, 1 Inflation Bulb

Intended Use:

- The AbClo Abdominal Fascia Closure Device is an external non-invasive abdominal closure system.
- The AbClo Abdominal Fascia Closure Device is intended to stabilize and/or facilitate **gradual** fascial closure of midline abdominal defects.



Cautions

- Must not be left on for more than 29 days
- Non-sterile / Do not sterilize
- Single-patient use product not to be reused due to effect on performance, cross contamination, and risk of infection

Indications for use:

- Indicated for adult use only
- Support and stabilize the abdominal wall
- Prevent loss of domain in open abdomen (Laparostomy) patients.
- Prevent abdominal fascia damage
- Prevent lateral retraction of abdominal wall fascia in open abdomen (Laparostomy) patients
- Facilitate primary closure of abdominal wall fascia

Contraindications:

- Pediatric use

AbClo Rectus Muscle Splints (x2)

Key: Parts

Cross Bar

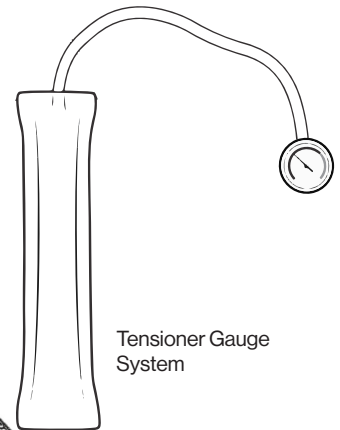
Under Pad

Tensioner Tab

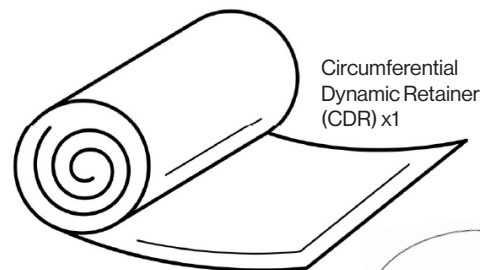
Tensioner Cleat

Tension Dial

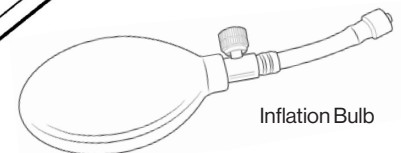
Rectus Muscle Splint (RMS) x2



Tensioner Gauge System



Circumferential Dynamic Retainer (CDR) x1



Inflation Bulb



InventoRR M.D. Inc.
46 Riviera Dr., Markham, ON, Canada L3R 5M1

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contact@abclomedical.com

Made in Canada

REF ABCLO001



Not made with natural rubber latex.

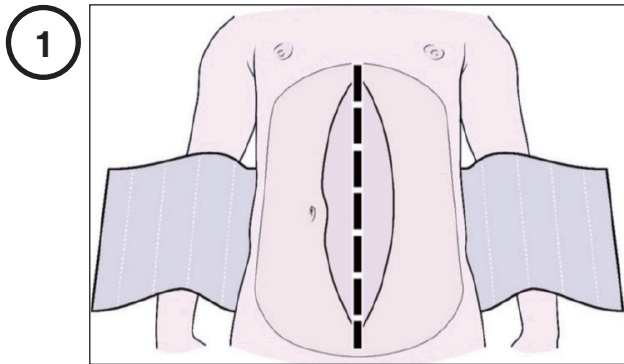


Rx Only

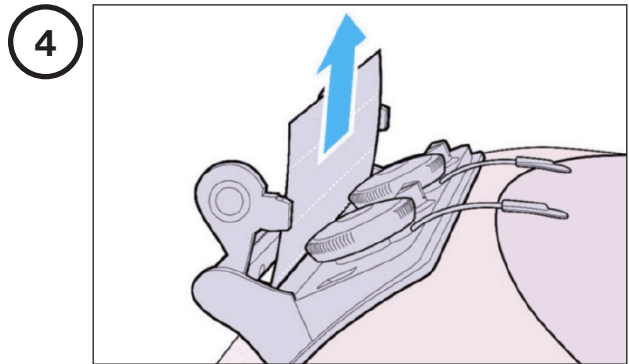
Patents:
www.abclomedical.com/patents

Instructions For Use

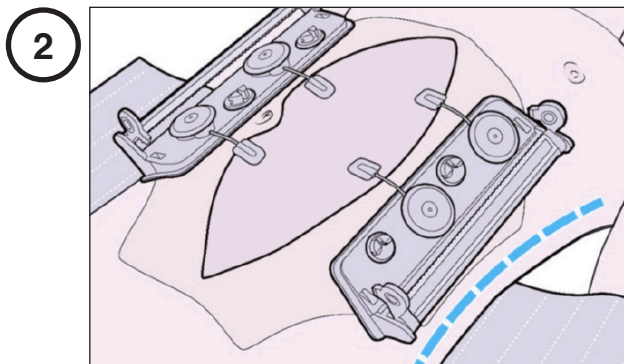
- Placement of AbClo requires two people, one individual for each Rectus Muscle Splint
- Placement is always on top of Temporary Abdominal Coverage (TAC) device, with or without NPWT
- Place Circumferential Dynamic Retainer (CDR) around the patient's torso and centred along the spine
- NOTE: Rectus Muscle Splints (RMS) are not to be placed directly on an ostomy / stoma / appliance (Circumferential Dynamic Retainer can be cut to accommodate)
- Place additional skin protection padding, under the RMS, to prevent damage to the skin.
- From steps 2 onward ensure that both RMS are stabilized and held in position as the tensioners are placed and adjusted.



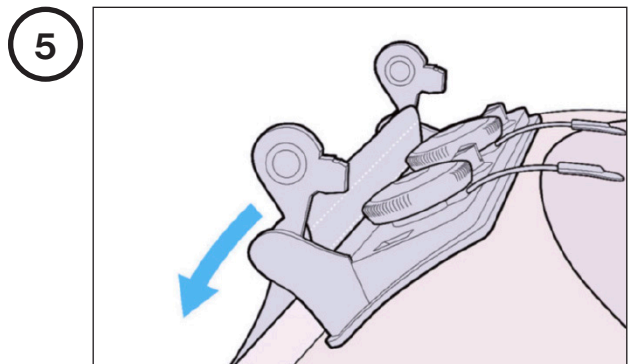
1 Position the CDR around the patient's torso and centred along the spine, leaving a free end on each side of the patient.



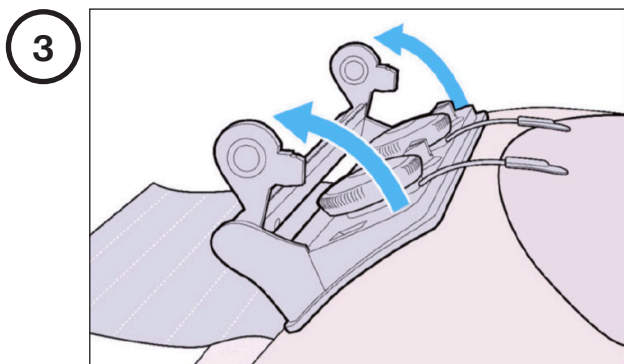
4 Feed the CDR through the opening of the RMS on both sides of the fascial defect. Grasp the leading edge of the CDR and apply tension by pulling until resistance is met. Confirm correct placement of the RMS at the Anterior Axillary Line on both sides of the fascial defect. On both sides of the fascial defect, tension the CDR by pulling straight until the CDR is taut.



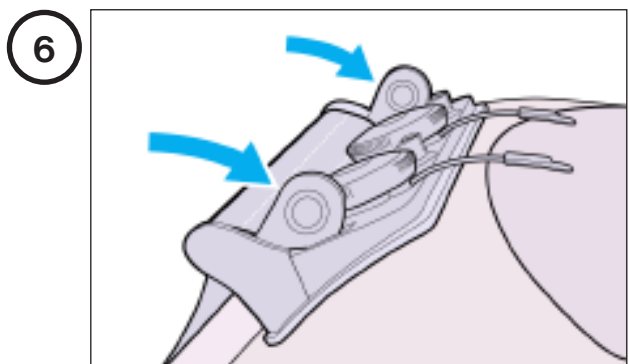
2 Position the RMS with the Tensioning Dial edge adjacent and parallel to the fascial defect with the outer edge aligned with the anterior axillary line.



5 While securely holding the RMS, fold the CDR back and posterolaterally, gently push it against the Locking Strip (hook and loop system) to secure it in place. Confirm proper placement and parallel alignment of the RMS.

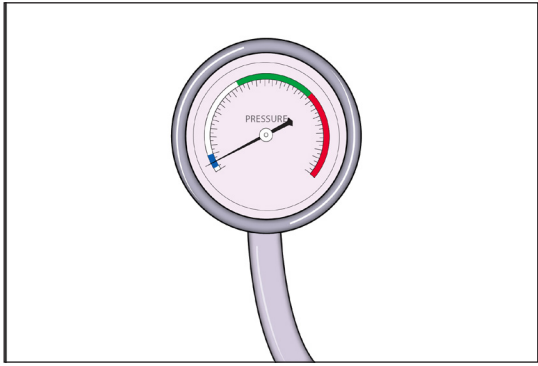


3 Open the Cross Bar to allow for the insertion of the CDR into the opening between the Cross Bar and the locking strips of the RMS.



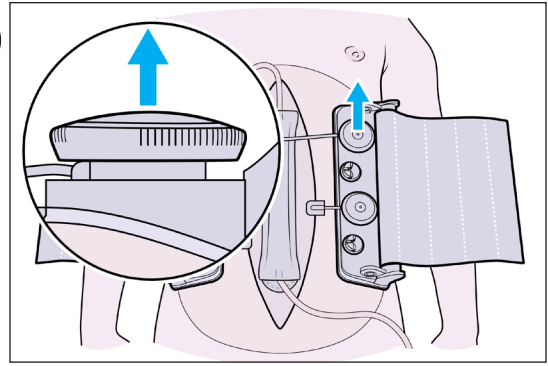
6 Push the Cross Bar down and lock it into place in the aligned slots. Ensuring it is secure.

7



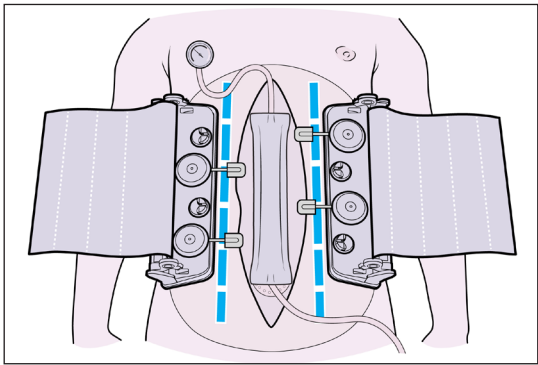
Ensure the Tensioner Gauge System is reading, at rest (ie without any external pressure on it), in the blue range. If it is not in the blue range please follow steps in Appendix A, Adjusting Resting Tensioner Gauge, before continuing.

10



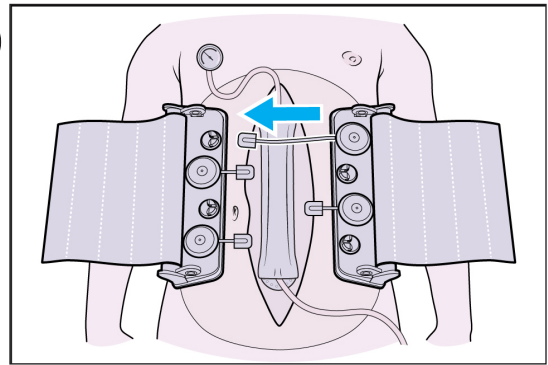
Holding the RMS securely, pull up on the most proximal Tensioning Dial releasing the Tensioner for extraction.

8



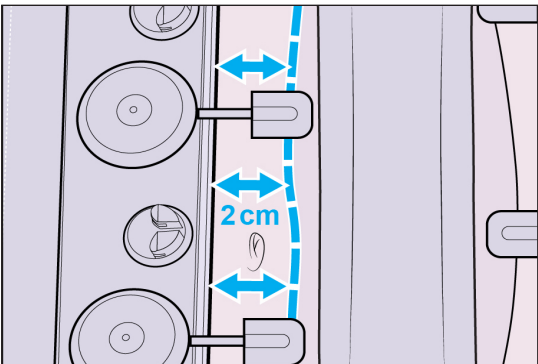
Place Tensioner Gauge System Balloon along the center of the patient on top of TAC device. Ensure the Tensioner Gauge System doesn't interfere with the TAC devices operation. Simultaneously advance both RMS devices towards the fascial defect, creating dynamic tension on the CDR.

11



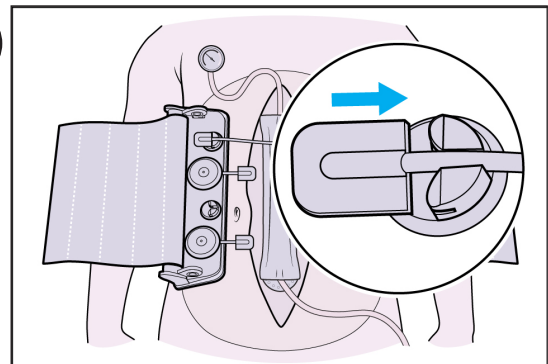
Pull the Tensioner across the facial defect and position it in the corresponding Cleat on the opposite RMS.

9



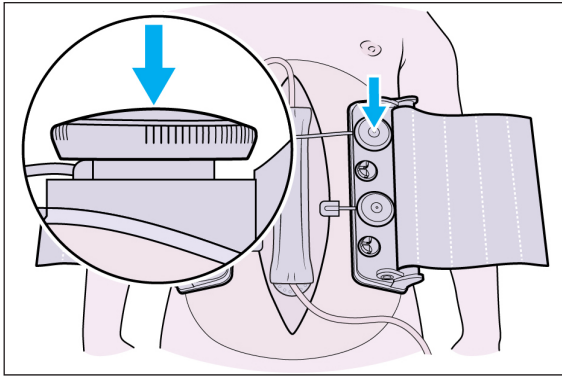
Bring each RMS to a tensioned resting position parallel to the fascial defect edge and approximately 2cm (a thumb's width) from it.

12



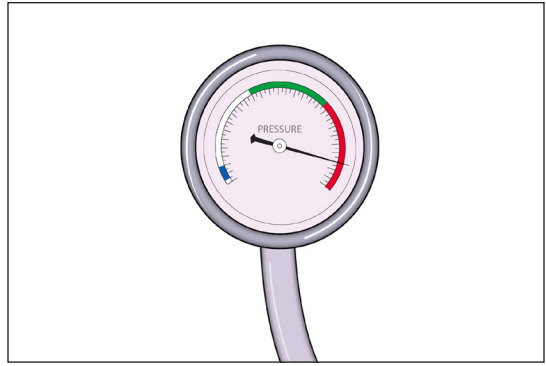
Ensure the Tensioner is fit into it's corresponding Cleat.

13



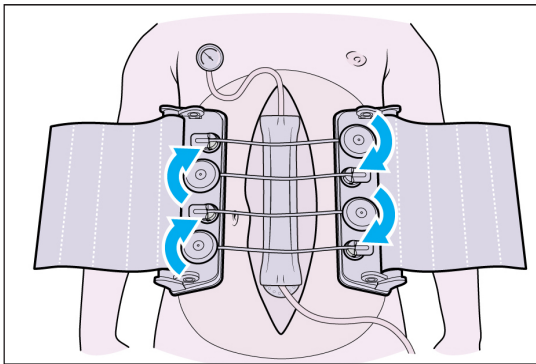
Push down on the Tensioning Dial to engage it and rotate clockwise to wind the tensioner until taut. Repeat with remaining tensioners alternating top and bottom.

14C



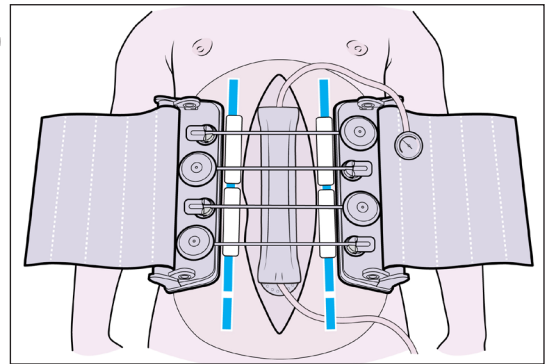
If Gauge reading exceeds the green zone and enters the red zone gradually loosen the Tensioners equally, by pulling up on the Tensioning Dial to release them (as shown in step 10), until the gauge returns to green zone. Ensure Tensioning Dials are pushed down and engaged after returning to the green zone.

14A



In unison, tension both sides equally while maintaining parallel alignment with the fascial defect. Ensure that each Tensioner Tab remains secure in its Cleat. (Note that the sequence of Tensioner installation and tightening should keep the RMS parallel).

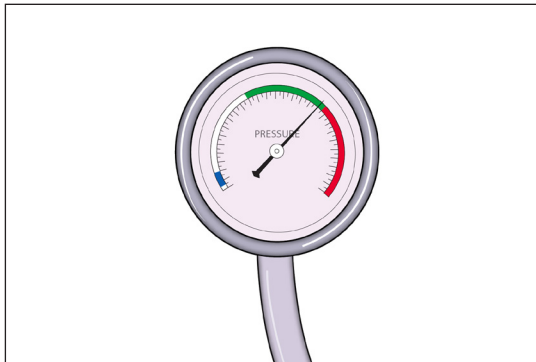
15



Inspect the RMS for tautness, placement, parallel position and distance from fascial defect. Position gauze packs (padding) to prevent tensioners from coming in contact with abdominal viscera or TAC device material.

Velcro gauge to CDR for safe placement.

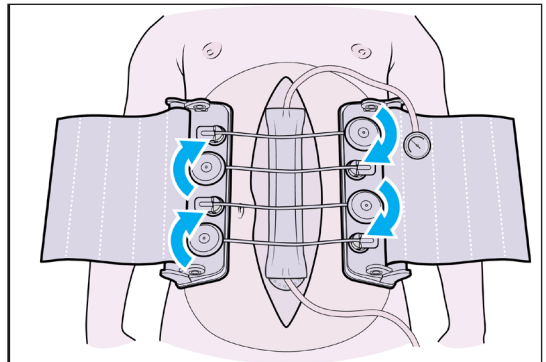
14B



Apply tension equally until gauge, on the Tensioner Gauge System, reads in the green zone.

Fluctuation is expected with patients respiratory movements. Gauge reading should stay in green zone on patient exhale.

16



Tensioner Gauge System monitoring and adjustment

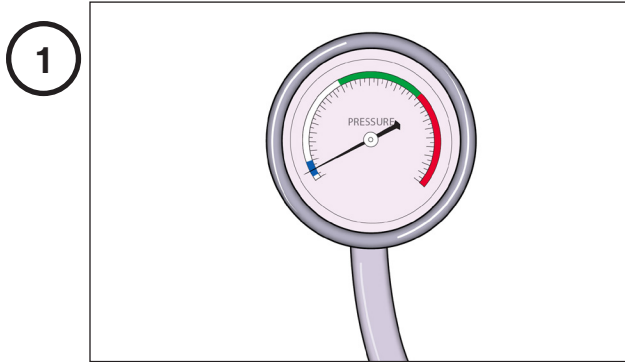
Monitor Tension Gauge to ensure gauge is in green zone. If gauge in Red Zone decrease tension (as shown in step 14C). If gauge is below green zone (ie in blue or white zones) increase tension by equally tensioning RMS with Tensioning Dial's (as show in steps 14A & 14B). Note that the sequence of Tensioner installation and tightening should keep the RMS parallel.

Post Installation Assessment -

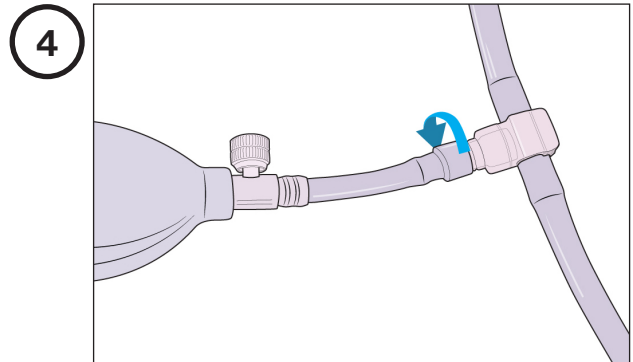
- Reassess AbCLO RMS position and the status of the skin. Adjust to ensure parallel positioning of RMS is maintained and apply padding to skin as required.
- Monitor intra abdominal pressure following institutional protocols . If pressure rises above acceptable levels loosen or remove AbClo as required.
- Support tensioners with gauze (padding) to prevent friction between the tensioners and the TAC material.

Appendix A:

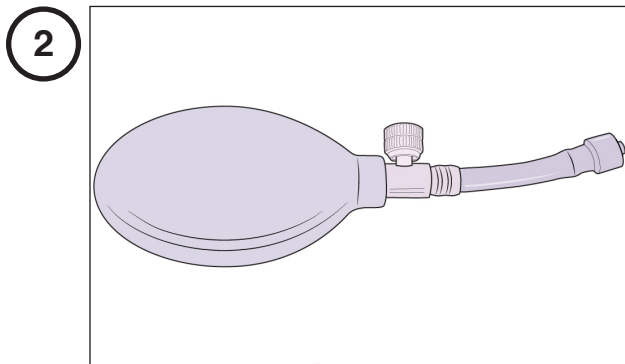
Preparing and Adjusting Tensioner Gauge System



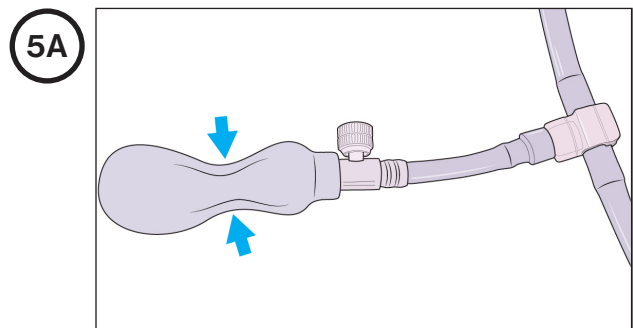
1
If the tensioner gauge isn't in the blue zone at rest; we must adjust it to ensure it is in the blue zone before use.



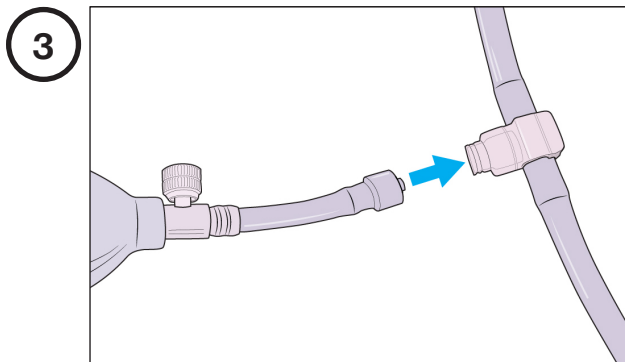
4
Twist to secure connection between Inflation bulb and Tensioner Gauge System.



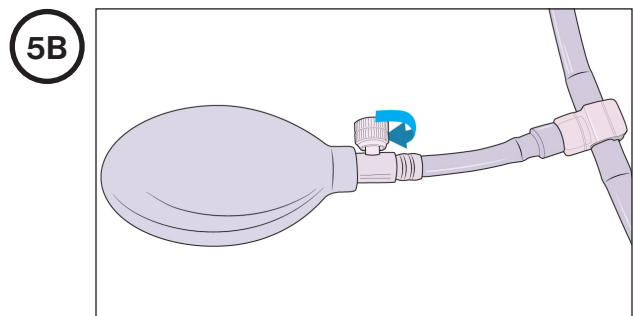
2
Use the Inflation Bulb.



5A
If the Gauge on the Tensioner Gauge System is reading below the blue zone squeeze the Inflation Bulb until gauge reading in the blue zone. Then disconnect the Inflation Bulb and let rest ensuring the Tensioner Gauge System stays unchanged in the blue zone for 5 minutes.



3
Connect the Inflation Bulb to the Tensioner Gauge System at the connection port.



5B
If the Gauge on the Tensioner Gauge System is reading above the blue zone twist the Air Release Valve on the Inflation Bulb until gauge reader decreases into the blue zone. Then disconnect the Inflation Bulb and let rest ensuring the Tensioner Gauge System stays unchanged in the blue zone for 5 minutes.