

AbClo

Instructions for Use

REF ABCLO001

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Intended Use:

- The AbClo is indicated for use in reducing or assisting with the closure of full-thickness wounds of the skin for midline abdominal defects.

Product Description

- The AbClo is a non-sterile, single-use device, which contains the following:
- 2 Rectus Muscle Splints (RMS) 1 Circumferential Dynamic Retainer (CDR)
- 1 Tensioner Gauge System
- 1 Inflation Bulb
- 1 Instructions for Use



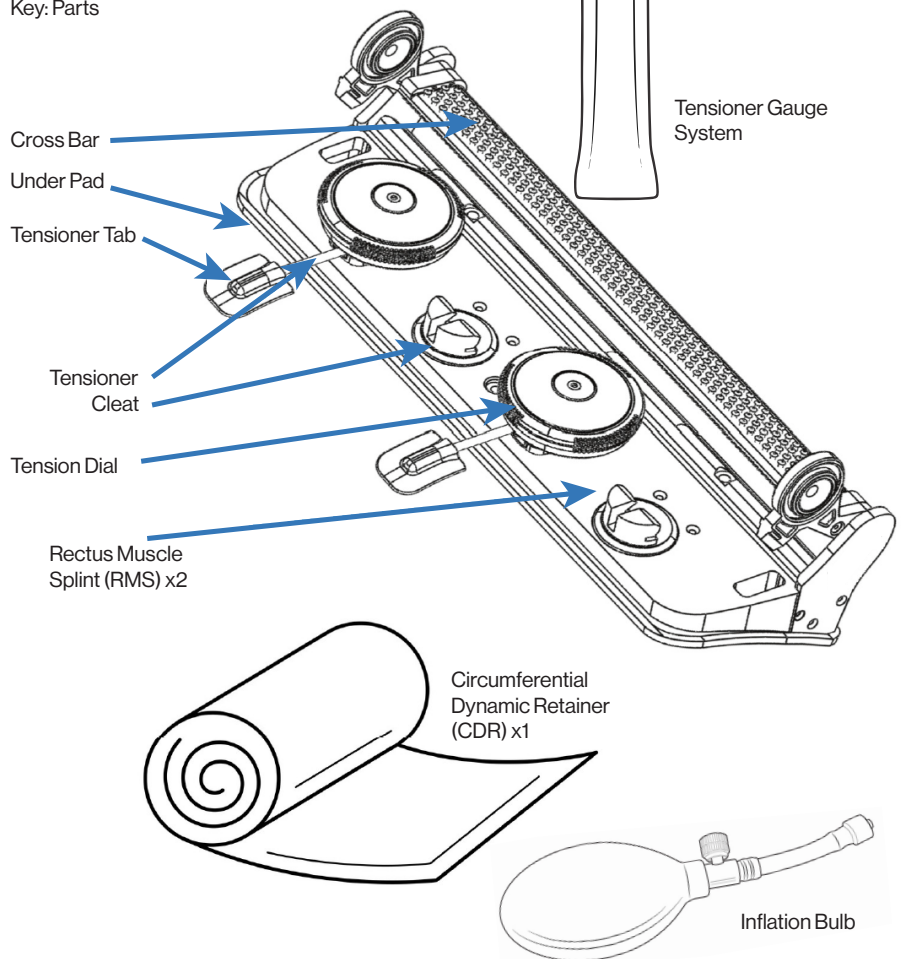
Cautions

- Do not use for more than 29 days.
- For single use only. Not to be reused due to effect on performance, cross contamination, and risk of infection.
- Do not sterilize.
- Not intended for pediatric use.
- Not intended for use in patients with spine instability.

Notes:

- Read all instructions for use before using.
- For use by healthcare professionals only.

Key: Parts



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contact@abclomedical.com

Made in Canada



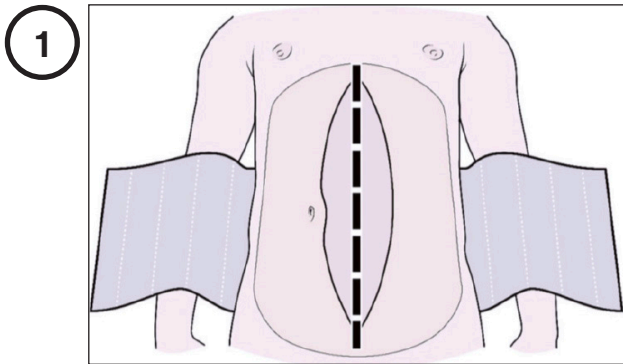
Not made with
natural rubber latex.



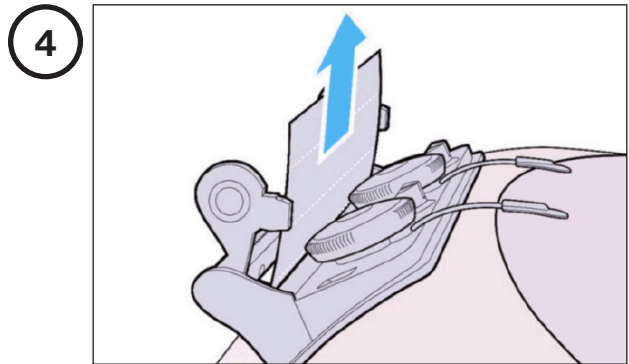
Patents:
www.abclomedical.com/patents

Instructions For Use

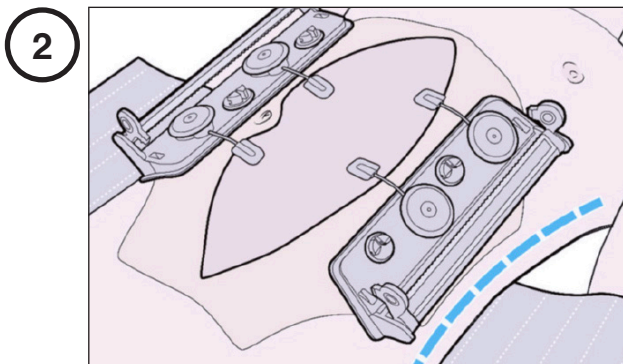
- Placement of AbClo requires two people, one individual for each Rectus Muscle Splint.
- Placement is always on top of Temporary Abdominal Coverage (TAC) device, with or without Negative Pressure Wound Therapy (NPWT).
- Place Circumferential Dynamic Retainer (CDR) around the patient's torso and centered along the spine.
- NOTE: Rectus Muscle Splints (RMS) are not to be placed directly on an ostomy / stoma / appliance
- Place additional skin protection padding under RMS and and/or under CDR 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.



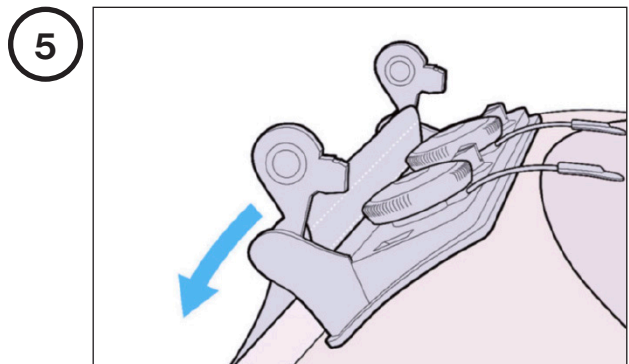
1 Position the CDR around the patient's torso and centered along the spine, leaving a free end on each side of the patient.



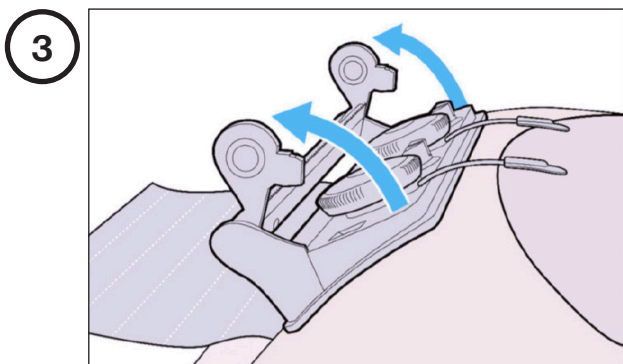
4 Feed the CDR through the opening of the RMS on both sides of the fascial defect. Grasp the leading edge of the CDR and apply tension by pulling until resistance is met. Confirm correct placement of the RMS at the Anterior Axillary Line on both sides of the fascial defect. On both sides of the fascial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



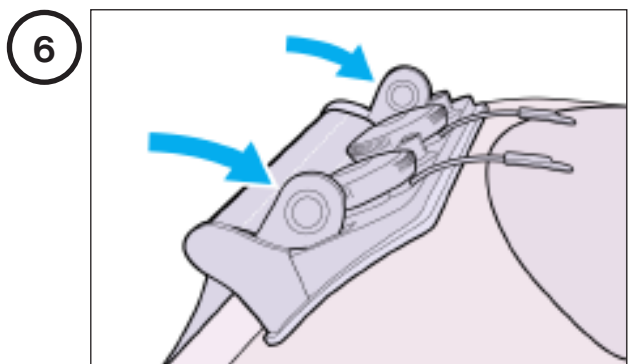
2 Position the RMS with the Tensioning Dial edge adjacent and parallel to the fascial defect with the outer edge aligned with the anterior axillary line.



5 While securely holding the RMS, fold the CDR back and posterior laterally, 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.

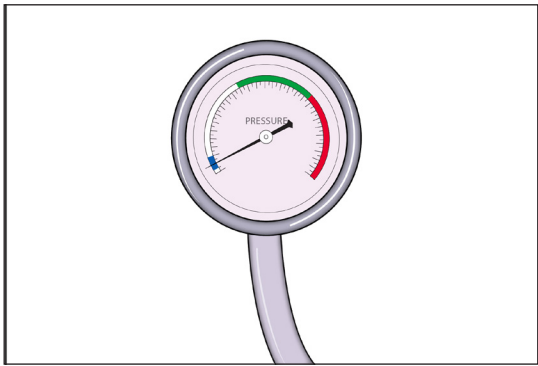


3 Open the Cross Bar to allow for the insertion of the CDR into the opening between the Cross Bar and the locking strips of the RMS.



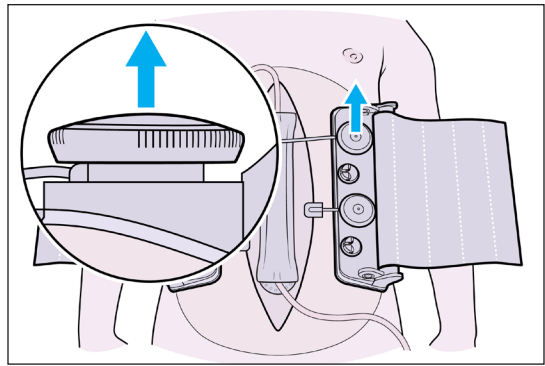
6 Push the Cross Bar down and lock it into place in the aligned slots. Ensure it is secure.

7



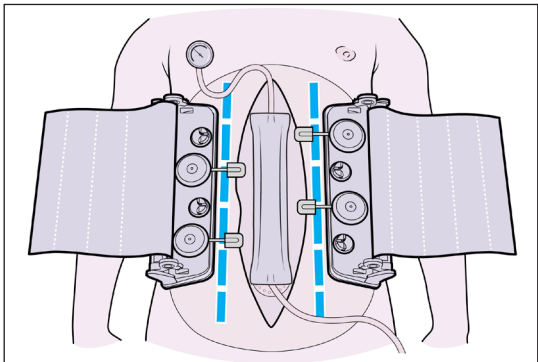
Ensure the Tensioner Gauge System is reading, at rest (i.e., without any external pressure on it), in the blue range. If it is not in the blue range please follow steps in Appendix A, calibrating Resting Tensioner Gauge, before continuing.

10



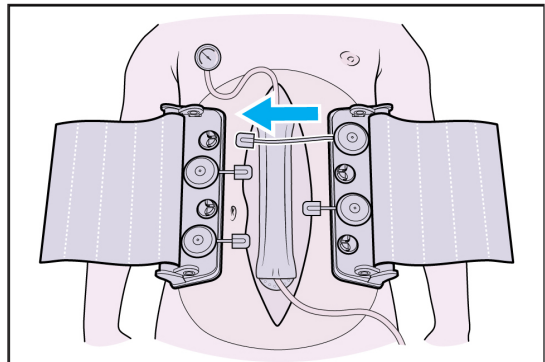
Holding the RMS securely, pull up on the most proximal Tensioning Dial releasing the Tensioner for extraction.

8



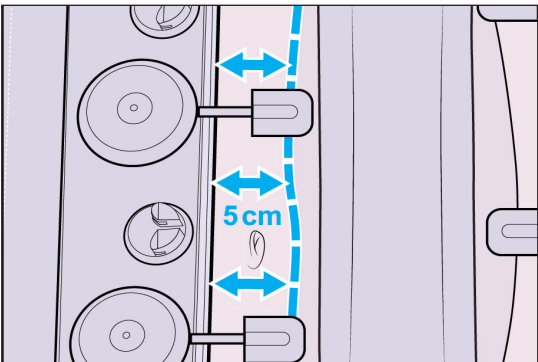
Place Tensioner Gauge System Balloon along the center of the patient on top of TAC device. Ensure the Tensioner Gauge System doesn't interfere with the TAC devices operation. Simultaneously advance both RMS devices towards the fascial defect, creating dynamic tension on the CDR.

11



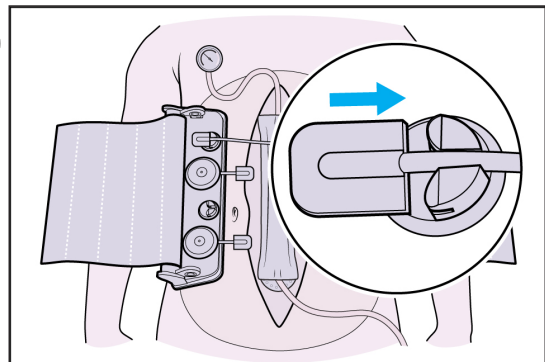
Pull the Tensioner across the facial defect and position it in the corresponding Cleat on the opposite RMS.

9



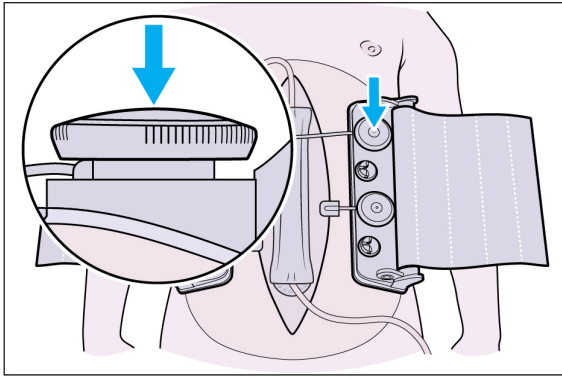
Bring each RMS to a tensioned resting position parallel to the fascial defect edge and approximately 5cm from it.

12



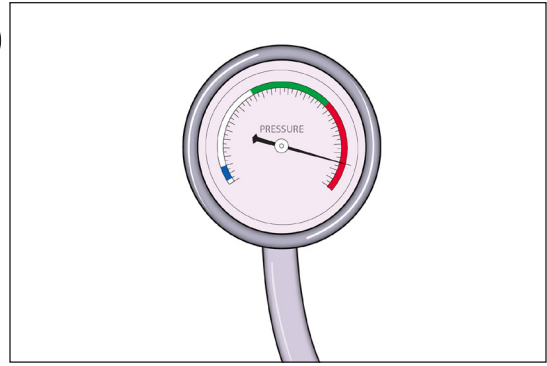
Ensure the Tensioner is fit into its corresponding Cleat.

13



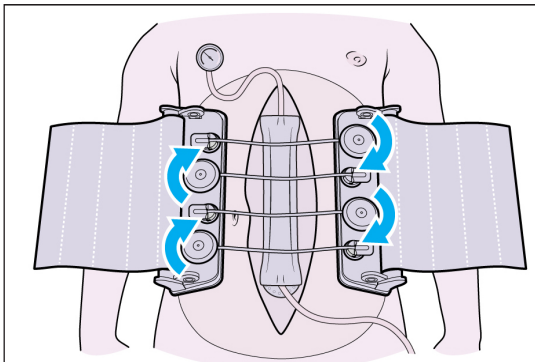
Push the RMS's downwards, into and engaging the Rectus Muscles, and then slightly inwards toward the open abdomen (maintaining 5cm gap from wound edge). Then push down...

14C



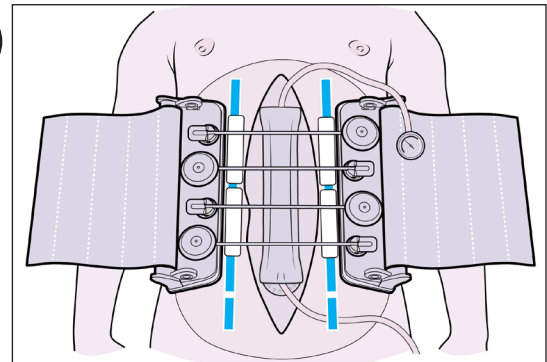
If Gauge reading exceeds the green zone and enters the red zone gradually loosen the Tensioners equally, by pulling up on the Tensioning Dial to release them (as shown in step 10), until the gauge returns to green zone. Ensure Tensioning Dials are pushed down and engaged after returning to the green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

14A



In unison, tension both sides equally while maintaining downwards medial pressure and 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).

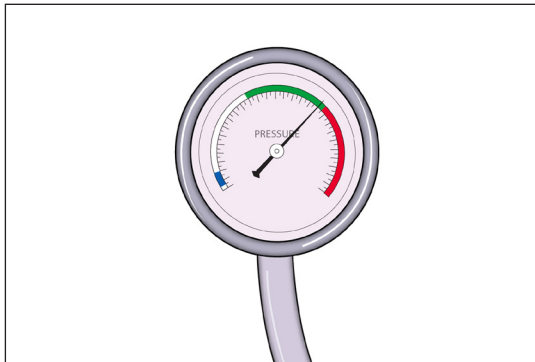
15



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.

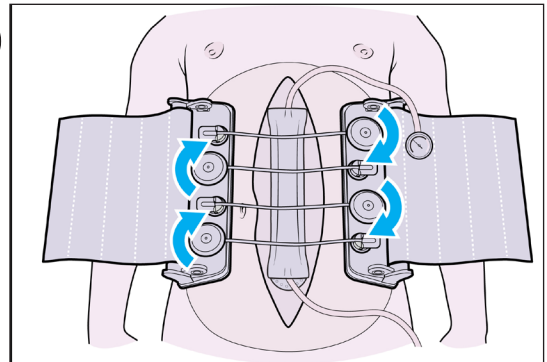
14B



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 exhalation or when the patient exhales.

16



Tensioner Gauge System monitoring and adjustment

Continually monitor Tension Gauge to ensure gauge is in green zone. If gauge is in the Red Zone decrease tension (as shown in step 14C). If gauge is below green zone (i.e., in blue or white zones) increase tension by repeating steps 9- 14B. Note that the sequence of Tensioner installation and tightening should keep the RMS parallel.

Frequently Asked Questions

Who applies the AbClo device to a patient?

A physician prescribes AbClo, and any authorized individual can apply/adjust/monitor the device.

Can the AbClo device be used in conjunction with Negative Wound Pressure Therapy (NWPT) devices?

Yes. Either alone or in combination with NWPT (when used in accordance with the manufacturers instructions), AbClo can be deployed to assist in the primary closure in the Open Abdomen (OA) patient.

Can the AbClo device be used with patients with higher Body Mass Indexes (BMI)? How high a BMI has it been used with effectively?

AbClo can be used effectively in high BMI patients. Larger sized CDR (circumferential dynamic retainer) binders are available for use in these patients. AbClo has been used effectively in patients with a BMI of 61.

Is the AbClo Device reusable?

No, AbClo is not reusable. AbClo can be reused on the same patient.

How do you manage abdominal pressure for the patient with the AbClo device?

Abdominal pressure should be monitored using standard hospital protocols. The AbClo tensioner bag and gauge do not measure abdominal pressure.









If the patient has a Stoma can the AbClo device still be used?

Yes. An opening can be cut in the CDR binder to allow for stoma access.

Does the AbClo device need to be removed from the patient if a second look or follow-up abdominal surgeries are required?

The AbClo device can be removed and replaced to allow for abdominal access.

Explanation of Symbols Used

	Catalogue or model number
	Manufacturer
	Serial number
	Consult instructions for Use
	Caution: Read all warnings and cautions in instructions for use
	Do not reuse
	Nonsterile
Rx Only	Prescription Use Only
	Do not use if package is damaged.

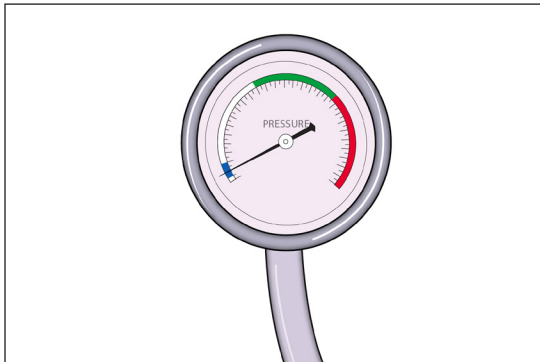
Post Installation Assessment

- Reassess AbClo 4 times per day for 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.
- When removing AbClo pull up on Tensioner Dial's to release the device, then fully disconnect the RMS from the CDR by opening the cross bar. Opening the cross bar is done by pushing in on the tabs on either end of the cross bar and pulling upwards away from the device. When re-applying an AbClo to its original patient always fully remove (including disconnecting the RMS from the CDR) the AbClo and fully re-apply the device according to these instructions for use.
- Always follow complete instructions for use when putting AbClo on a patient.

Appendix A:

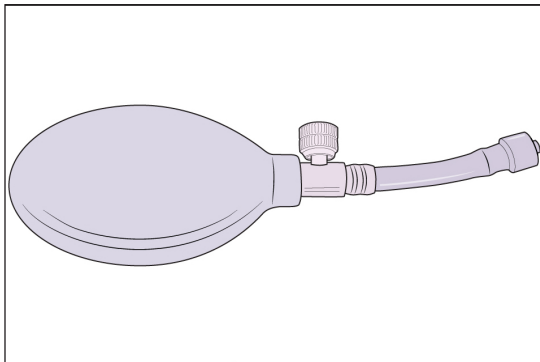
Preparing and Calibrating Tensioner Gauge System

1



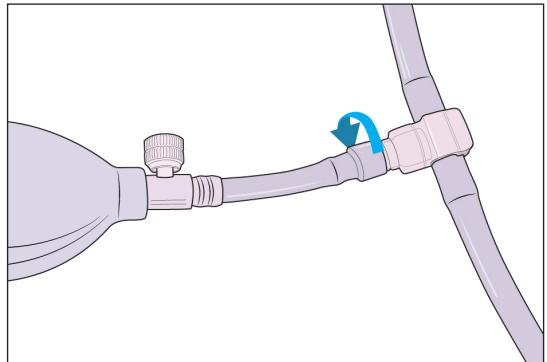
If the tensioner gauge isn't in the blue zone at rest; calibrate it to ensure it is in the blue zone before use.

2



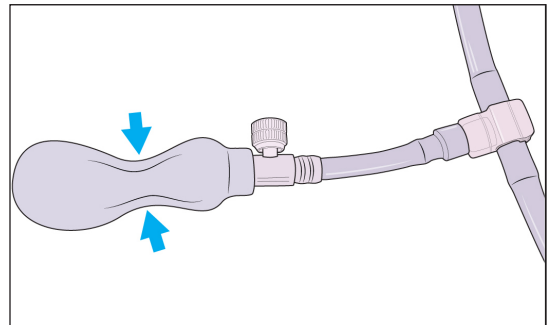
Use the Inflation Bulb.

4



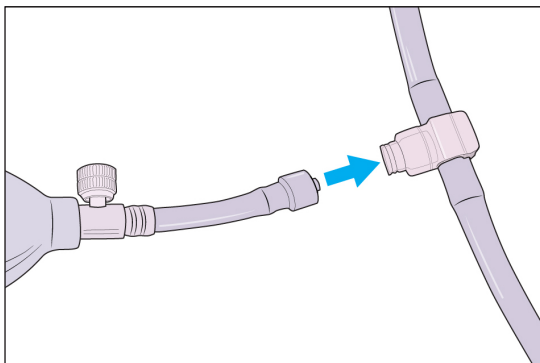
Twist to secure connection between Inflation bulb and Tensioner Gauge System.

5A



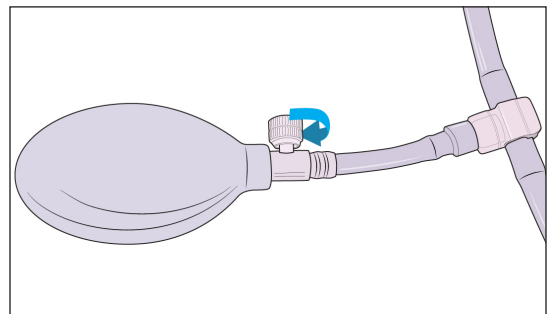
If the Gauge on the Tensioner Gauge System is reading below the blue zone squeeze the Inflation Bulb until gauge reading is in the blue zone. Then disconnect the Inflation Bulb and let rest ensuring the Tensioner Gauge System stays unchanged in the blue zone for 5 minutes.

3



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.

5B



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