

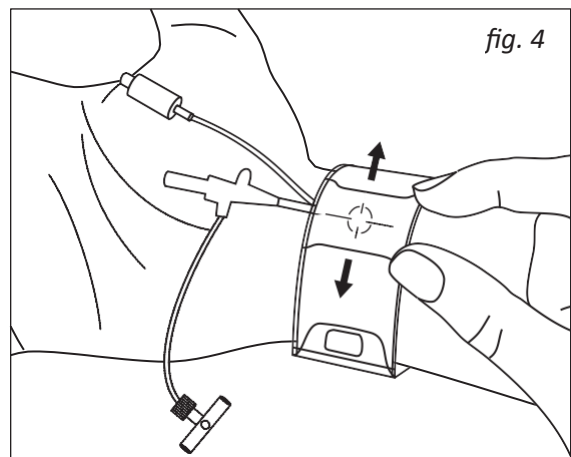
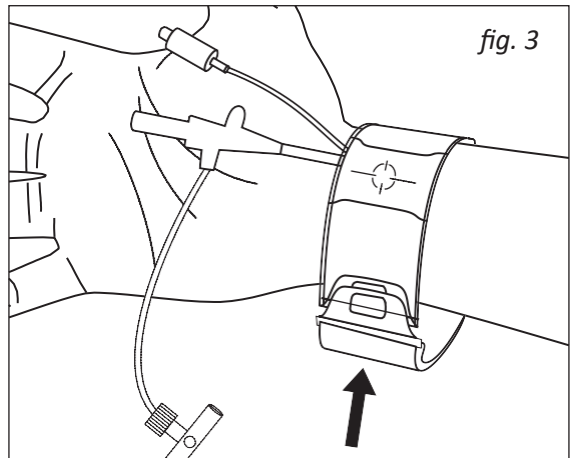
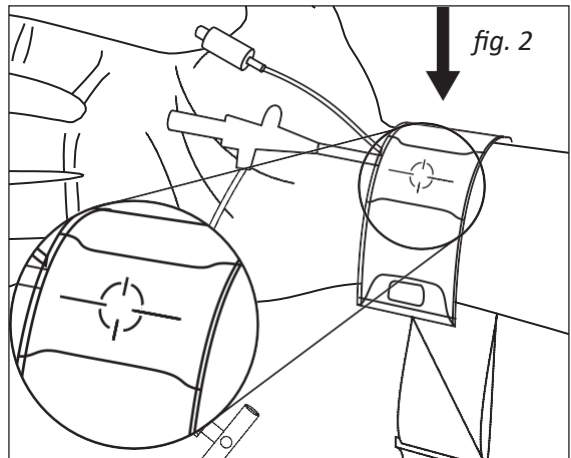
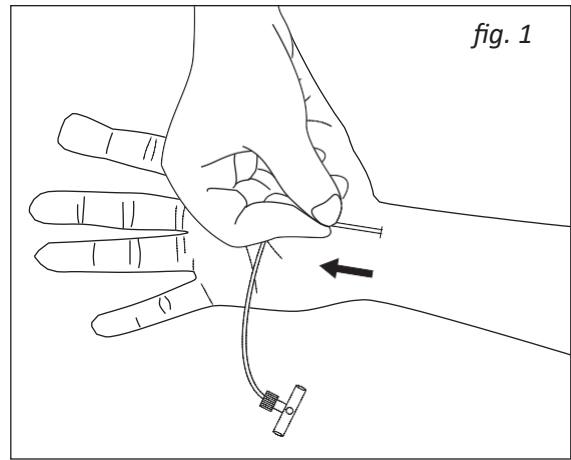
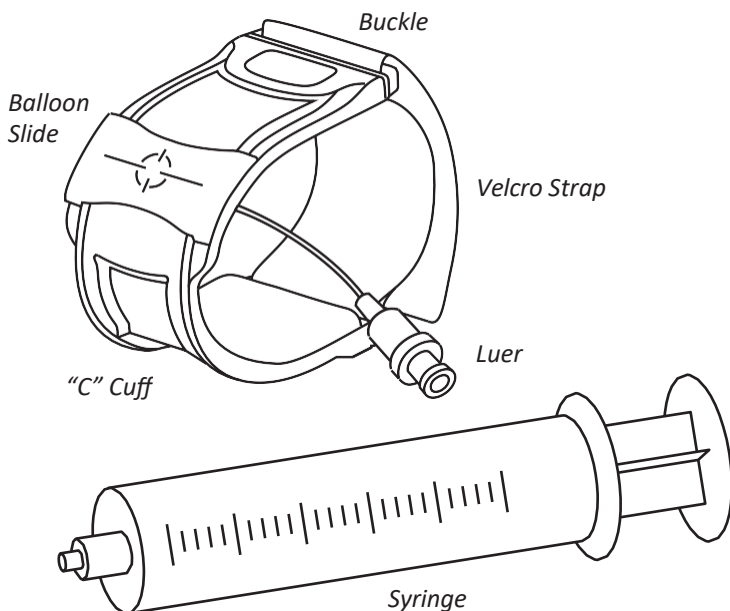
ARC™

Adjustable Radial Cuff

Instructions for Use

1. Peel package from upper edge and open onto sterile field.
2. After the procedure, ensure access site is clean and dry, and clear sheath with flush solution, withdrawing the sheath approximately 1 inch (2-3 cm). (See fig. 1)
3. With patient's palm facing up, orient device with compression balloon on top and balloon port pointed towards thumb. Gently slide "C" portion of the device over the wrist from the thumb side. Ensure the target area of the compression balloon is placed directly over sheath access site. (See fig. 2)
4. Holding ARC™ in place, clasp the buckle into place around the patient's wrist. (See fig. 3). Move balloon slide laterally or medially from top of device as needed to ensure optimal placement over radial artery. (See fig. 4)

Warning: The device must be placed differently when used on the left or right wrist. For right wrist ensure the balloon port of the device is facing the patient palm.



5. Holding compression balloon pressure in place with one hand, connect the Velcro™ strap perpendicular to wrist until device is taut around the wrist. (See fig. 5) Secure end of Velcro™ strap to the bottom of the device.

6. Attach the syringe to the inflation port of the compression balloon and inflate (suggested 15 ml). (See fig. 6)

Caution: Over injection may be painful to the patient and cause damage to compression balloon.

Warning: Check to make sure you are injecting into compression balloon and not sheath side port or through any other device.

Note: ARC™ device utilizes a standard luer lock syringe to inflate and deflate compression balloon.

7. Remove sheath, confirm there is no bleeding from the access site by viewing site through compression balloon window. If bleeding is observed, inject more air into balloon until bleeding stops. (See fig. 7)

8. Adjust compression balloon pressure to provide appropriate hemostasis, and pulse distal to access site. (Figure 8)

Notes: The minimum pressure necessary should be used. Ideally a residual pulse should be palpable while occluding the ulnar artery (Allen's Test) and a minimally affected pulse waveform should be visible on a plethysmograph with O2 saturation remaining normal if monitoring with an oximeter. (See fig. 8)

Warning: If it is necessary to totally occlude the radial artery to achieve hemostasis, the artery should not be occluded for more than 10-15 minutes before flow is restored.

9. Once total hemostasis has been established, removal of the ARC™ device should be performed in accordance with your facility's postcare procedures.

Device Removal Recommendation:

Remove air from compression balloon slowly and observe hemostasis at access site until device is loosened. If bleeding is observed, retighten device to the original pressure until bleeding stops. If there is no bleeding noted, dry the access area and apply sterile dressing in accordance with facility policy.

Note: If oozing occurs, a standard pressure dressing should be applied to assist in achieving hemostasis. Assure patency.

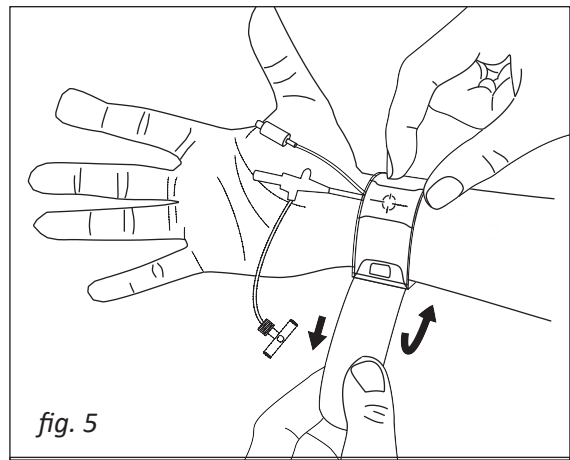


fig. 5

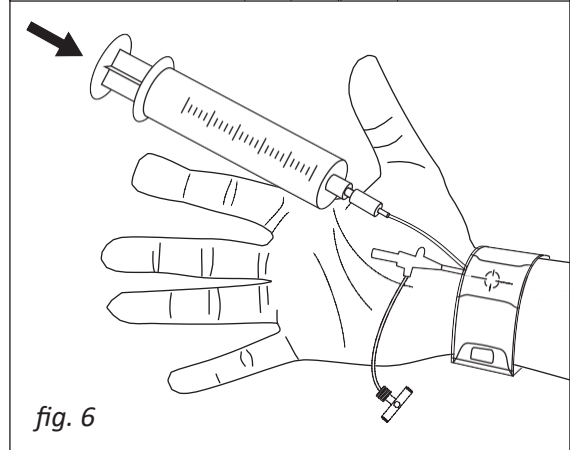


fig. 6

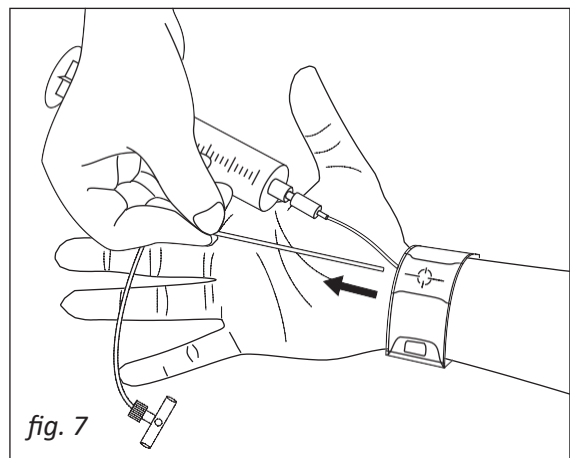


fig. 7

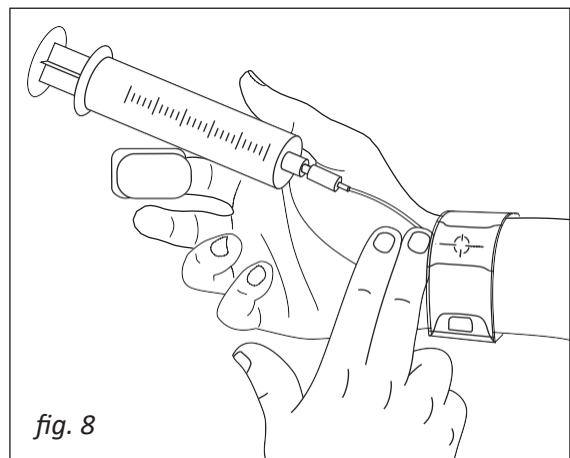


fig. 8

ARC™ (Adjustable Radial Cuff) Device
Manufacturers information
LIMITED WARRANTY

TZ Medical warrants the ARC™ device free from material and workmanship defects until the expiration date is reached. TZ Medical shall not assume liability for consequential, incidental, or special expense directly relating from the product usage. Warranty liability and the buyer's exclusive remedy is expressly limited to replacement of the ARC™ device, used under normal use and service, by the Company as having been defective in materials or workmanship. The buyer is directly obligated to return the device to the Company for examination and replacement.

No employee, representative or agent of TZ Medical has the authority to bind, amend or alter the warranty. Any purported alteration amendments, or implied representation shall not enforceable by the buyer against TZ Medical.

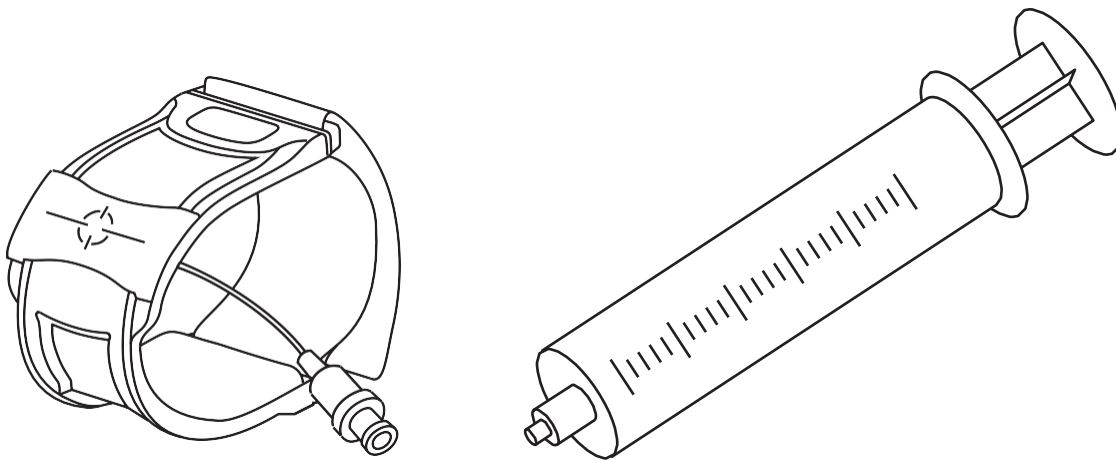
THIS WARRANTY IS IN LIEU OF ANY IMPLIED OR EXPRESSED WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY OR FITNESS FOR ANY OTHER OBLIGATION ON THE PART OF TZ MEDICAL.

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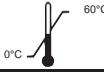

PATENT AND TRADEMARKS

This device may be covered by one or more U.S. or international patents.
ARC™ is a registered trademark of TZ Medical, Inc.

CONTENT



SYMBOLS & GLOSSARY

REF	
 Caution: Rx Only	Caution: Federal Law (US) restricts device sale by or on the order of a physician
CONTENT	Contents of this package
	Compression Assist Device
	Ethylene Oxide Sterilization
	Do not Reuse Single Use only
	Lot number
	Use By date
	Manufacturer
	Keep Dry- Protect from moisture
	Do not use if package is damaged
	Keep out of direct sunlight
	Consult Instructions For Use
	Maximum Temperature. 60°C; Minimum Temperature, 0°C for at least an hour before use
	Complies with Medical Device Directive 93/42/EEC
	Does Not Contain Natural Rubber Latex

Device Description

TZ Medical ARC™ device is a sterile, single use disposable device.

The TZ Medical ARC™ radial artery hemostasis device is a radial compression device consisting of a rigid polycarbonate “C” shaped brace, a flexible strap containing a PVC backing, Velcro™, and two buckles which attach to the ends of the brace, a collapsible bubble fixed to an adjustable slider with a tube and universal luer lock, as well as a low durometer TPE pad opposite of the bubble for patient comfort. Each device also includes a standard male luer locking syringe.

The device comes in three sizes:

Small (#RCB-0047)

Medium (#RCB-0048)

Large (#RCB-0049)

Indications for Use

When applied by a trained health care professional, the TZ Medical ARC™ device is designed to assist in controlled compression hemostasis of the radial artery after a transradial procedure; the device is indicated to compress the radial artery access puncture site in order to achieve hemostasis and maintain patency of the radial artery (patent hemostasis).

Contraindications

Radial Access is contraindicated in patients with an impaired or abnormal Allen’s or Modified Allen’s test (1&2) or patients that do not have two functional arteries (radial and ulnar).

Warning

- Confirm that you are injecting air into the ARC™ device and NOT into the side port of the radial sheath or any other device.
- Over inflation of the balloon (above 20 ml of air) may cause numbness, patient discomfort or RAO (radial artery occlusion).
- Under inflation of the balloon (under 12 ml of air) may affect the device's ability to assist or maintain hemostasis.
- Do not soak or wipe with agents containing organic solvents.
- The patient should not be left unattended while the ARC™ is in use.

Precautions

- USA Caution Federal Law (US) restricts device sale by or on the order of a physician.
- The safety and effectiveness of the ARC™ device has not been fully established for use with children and pregnant women.
- Inspect sealed packaging prior to use. Do not use if original packaging is damaged or opened.
- The ARC™ device is a "SINGLE USE DEVICE", reuse, resterilization or repackaging after cleaning attempts may result in patient infections.
- The device should be used only by clinicians or those properly trained in the use of the device.
- Only use air for inflation. Do not use other media for inflation.
- Depending on patient's condition and the degree of balloon pressure, an adverse event including artery occlusion, hypodermia hematoma, hemorrhage, pain, or numbness may occur. Check the progress of hemostasis and adjust the air pressure according.
- Do not use the air syringe for other purposes than to inflate the ARC™ device. It is not designed for other purposes.
- The ARC™ device can be inflated only by using the air syringe. If other devices are used, adequate air compression cannot be achieved.
- Do not put excessive pressure on the tip of the air syringe; this may result in damage of the tip. If the syringe tip is broken while connected to the ARC™ device, it could cause air leakage and bleeding.
- When connecting the air syringe to the ARC™ device, keep the plunger in place. Releasing the plunger will cause the air to expel from the device. Loss of air compression may cause bleeding.
- While using, be careful not to put excessive load on the balloon that could break it. Be careful that no foreign particles get into the air injection port as this may cause air leakage.
- If there is itching or redness of the skin while compressing, stop using and treat appropriately.
- At extremely low temperature, there is a possibility of damage due to decrease in resistance to shock.
- Take care not to damage the ARC™ device with needle, scissors, and other sharp instruments. This may result in air leakage and bleeding.
- The device should be used immediately after opening the package and disposed of safely and properly after use.
- Care should be taken to prevent infection during manipulation.
- Avoid exposure to water, direct sunlight, extreme temperature, or high humidity during storage.
- Hemostasis times may vary patient to patient dependent on the following:
 - Systolic blood pressure exceeding 160 mmHg.
 - Platelet level less than 250,000 units.
 - Patients currently receiving GPIIb/IIIa or Coumadin.

Adverse Events

Radial access can be associated with problems deriving from puncture, hemostasis or guide management, including, but not limited to hematoma, paresthesia, pseudoaneurysm, arteriovenous fistula, perforation of the artery or radial artery occlusion.

Recommendations

A thumb or index finger oximeter or plethysmograph should be attached and monitored during hemostasis process (2).

Patient Care Recommendations

- Monitor site and patient for 1 hour post device removal.
- Instruct patient not to bend or move wrist for 24 hours post hemostasis.
- Patient should not lift any excessive weight or immerse wrist in water for the first 24 hours post hemostasis.
- Provide patient with facility instructions sheet and review it with patient.

References

1. Barbeau GR, Arsenault F, Dugas L, et al. Evaluation of the ulnopalmar arterial arches with pulse oximetry and plethysmography. *Am Heart J.* 2004 Mar; 147 (3):489-93.
2. Patel T, Garzona C, Patel's Atlas of Transradial Intervention: The Basics 1st Edition. 2007



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