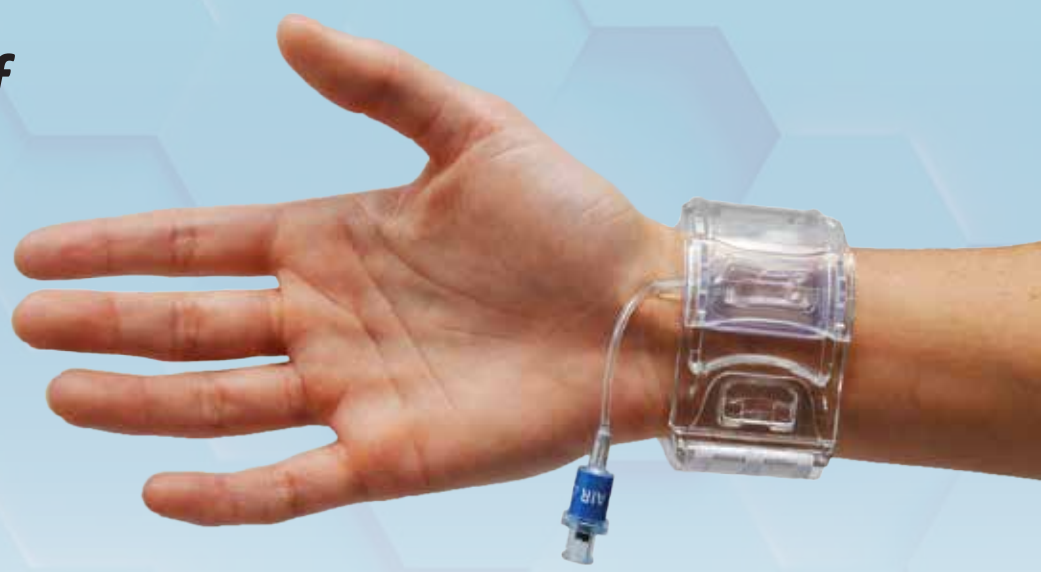
ARC
Adjustable Radial Cuff



ARC Adjustable Radial Cuff Application Guidelines*

1. Peel open sterile package from side with chevron seal and open onto sterile field.

2. After the procedure, ensure access site is clean and dry, clear sheath with flush solution, and withdraw the sheath approximately 1 inch (2-3 cm).

3. With patient's palm facing up, orient device with compression balloon on top and balloon port pointed towards thumb. Gently slide "C" cuff portion of the device over the wrist from the thumb side. Ensure the target area of the compression balloon and reticle are placed directly over sheath access site.

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

4. Holding ARC in-place, clasp the buckle into place around the patient's wrist. Move balloon slide laterally or medially from top of device as needed to ensure optimal placement over radial artery.

5. Holding compression balloon in place with one hand, connect the Velcro™ strap into top of "C" cuff portion of device. Pull Velcro™ strap perpendicular to wrist until device is taut around the wrist. Secure end of Velcro™ strap to the bottom of the device.

6. Attach the luer lock syringe to the inflation port of the compression balloon and inflate to (15 cc's) while slowly removing the sheath.

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

7. Withdraw air from balloon (1cc per second) while observing the access site for bleeding through compression balloon window. When flash is observed, inject 4 cc's of air into balloon until bleeding stops.

8. Confirm "Patent Hemostasis". Adjust compression balloon pressure to provide appropriate hemostasis, and pulse distal to access site.

Notes: The minimum pressure necessary should be used. Ideally a residual radial pulse should be palpable while occluding the ulnar artery (Allen's Test) and a minimally affected radial pulse waveform should be visible on a plethysmograph with O2 saturation remaining normal if monitoring with an oximeter. (Barbeau Test)1,2

If there is an absence of radial blood flow, lowered O2 saturation or diminished radial pulse wave form, the volume in the balloon should be lowered to the point where the wave form returns and there is evidence of antegrade radial blood flow.

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.

1. Barbeau GR, Arsenault F, Dugas L, et al. Evaluation of the ulnopalmar arterial arches with pulse oximetry and plethysmography. Am Heart J.2OO4 Mar; 147 (3):489-93.
2. Patel T, Garzona C, Patel's Atlas of Transradial Intervention: The Basics 1st Edition. 2007
3. Tremmel, J. Launching a Successful Transradial Program. J Invasive Cardio; 21: Suppl A, 5A-10A

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ARC Adjustable Radial Cuff Management and Removal Guidelines*(3)

Recommendations: A thumb or index finger oximeter or plethysmograph should be attached and monitored to maintain patent hemostasis.

1. Initial placement of the access site should be monitored for a minimum of 60 minutes prior to the removal of air from the ARC device.

2. Vital signs per a physician's orders.

Note: Upon patient arrival, refer to patient's chart for initial ARC balloon volume.

Estimated total recovery time 2 hours (post-diagnostic) or 4 hours (post-interventional procedures)

For interventional cases where additional anticoagulation is used, extend recovery time.

3. Assess bleeding, swelling and radial pulse of access site upon arrival and every 15 minutes.

Ensure ARC device is securely fastened.

Instruct patient not to move wrist; may use immobilizer if patient is non-compliant.

4. If there is no bleeding at the site, remove 1-2 cc's air volume with syringe every 15 minutes as ordered by a physician.

5. If bleeding occurs, inject additional air with the syringe until the bleeding stops. Do not exceed 18 cc's.

6. Before removing the ARC device, confirm bleeding has stopped.

7. After fully deflated, leave the ARC device in place for an additional 15 minutes before removal.

8. Unfasten Velcro™ strap and pull through "C" cuff portion of ARC device. Lift and roll balloon slowly off access site.

9. If bleeding occurs hold manual pressure or reapply ARC device until bleeding stops.

10. Remove the ARC device and apply a sterile protective covering over access site.

Note: Evaluate access site 1 hour post- ARC device removal. When Discharging the patient, include instructions to limit movement (no flexion/extension) of wrist for 24 hours.

** Note: The application and removal guidelines outlined in this document are based on the compilation of best practices and TZ Medical internal testing. ARC Adjustable Radial Cuff application and removal should be consistent and in accordance with the needs of the provider(s) and the patient. Balloon volumes, compression pressures and compression time may differ due to the patient's individual therapeutic condition, anticoagulation and the size of the access site puncture. The access site should be checked frequently for complications and the ARC adjusted accordingly.*

For Rx only:

Before using, refer to Instructions for Use for indications, contraindications, as well as additional warnings and precautions.

1. Barbeau GR, Arsenault F, Dugas L, et al. Evaluation of the ulnopalmar arterial arches with pulse oximetry and plethysmography. Am Heart J.2OO4 Mar; 147 (3):489-93.
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