AIR RELEASE SYSTEM

10ga x 3.25" Needle Decompression Kit

REF ZZ-0298
NSN: 6515-01-673-1701
MD

STERILE R

REV041824

NORTH AMERICAN RESCUE®
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35 Tedwall Ct. • Greer, SC 29650 • USA

Intended Use:
The ARS® is intended to be inserted into the pleural space of the chest cavity for emergency relief and temporary management of tension pneumothorax.

USA Only
NOT MADE WITH NATURAL RUBBER LATEX
℞ ONLY
TAA COMPLIANT

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

Key Word: Tension Pneumothorax: A known life threatening medical emergency where air becomes trapped in the pleural space outside of the lungs leading to inability to expand the lungs and loss of blood return to the heart.

Contraindications:
- Within the European Union (EU), the ARS® is not indicated for pediatrics and pregnant women due to EU regulatory requirements.
- Not intended for treatment of simple pneumothorax, hemothorax or simple barotrauma

Potential adverse complications:
- Incomplete/Inadequate relief of a tension pneumothorax with return of life threatening symptoms • Cardiac injury
- Infection • Injury to local nerves resulting in numbness or paralysis of intercostal muscle • Laceration of the lung tissue of uninjured lung • Lung injury
- Vascular injury • Pain • Bleeding

Disposal:
The ARS® is a single use device and is designed for disposal after use.

Do not attempt to clean or reuse the device, as it may increase the possibility of cross contamination. Dispose of the device in a manner ensuring the isolation of potential substances in accordance with universal precautions. After removal of the needle portion of the device, dispose in a sharps container or other appropriate protection device, per medical protocols. Dispose of the catheter portion of the device in accordance with medical protocols.

Warning:
- Tension Pneumothorax is a life threatening medical emergency, which if left untreated will result in death. Ensure placement in 2nd intercostal space perpendicular to and through the anterior chest wall at the mid-clavicular line. Do not place medial to the mid-clavicular line. This anatomic placement is the preferred placement to avoid inadvertent injury to the cardiac box, avoiding cardiac or vascular structures.
- Use caution to only insert the needle as far as needed to penetrate the pleural cavity
- The ARS® should be used only by persons who have received training on treatment of a tension pneumothorax. Improper use could result in injury to casualty. Use only as directed by your EMS authority or under the supervision of a physician.
- Inserting the ARS® through the chest wall of a casualty who has NOT suffered a penetrating chest injury AND/OR in whom the diagnosis of tension pneumothorax has NOT been confirmed may result in the inadvertent puncture of the underlying lung which may create a pneumothorax.
- Use of this device may result in your contact with contaminated body fluids.
- Contents sterile unless packaging open or damaged. If packaging is opened or damaged DO NOT use device.
- Re-use of this device will degrade the efficacy, resulting in adverse casualty reaction, including potential death.
- Continually monitor casualty to ensure device is functioning per medical protocols.
- In the event of a malfunction, follow local protocols and report any serious incident to North American Rescue or authorized representative and the competent authority of the Member State.

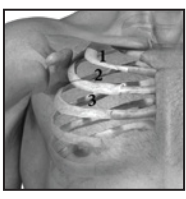

Fig. 1
Note: Numbers Denote Intercostal spaces

DIRECTIONS FOR USE:
1. Select Site: Identify the second intercostal space on the anterior chest at the midclavicular line on the same side as the injury. (Fig. 1)
2. Cleanse site with antimicrobial solution
3. Remove the red cap with a twisting motion
4. Remove the ARS® from case
5. Insert the ARS® into the skin over the superior border of the third rib, mid-clavicular line, and direct it into the 2nd intercostal space at a 90-degree angle to the chest wall. Ensure ARS® entry into the chest is not medial to the mid-clavicular line and not directed toward the heart.
6. Insert the ARS® into the pleural space. Listen for the sudden escape of air as the tension pneumothorax is decompressed. Stop advancing the needle when you feel the needle penetrate the pleural space. Thread the catheter into the pleura while keeping the needle in place.
7. Remove the needle portion of the ARS® and leave the catheter in place. Secure the catheter to the chest as directed by your local protocols.
8. Monitor patient for recurrence of respiratory distress following procedure. Continually assess patient for complications:
   - Hemodynamic instability
   - Respiratory distress
   - Unilateral chest expansion
   - Decreased oxygen saturation
   - Bleeding
   - Catheter occlusion
   - Hematoma

Harmonized Standard Symbols:

REF	Device Part Number
LOT	Lot Number
	Expiration Date
	Date of Manufacture
	Manufacturer
	Do Not Use if Package is Damaged
STERILE R	Sterile Symbol
	Single Use
	Do Not Resterilize
	Consult Instructions for Use
℞ ONLY	Prescription Device
TAA	TAA Compliant
NOT MADE WITH NATURAL RUBBER LATEX	Not Made with Natural Rubber Latex
MD	Medical Device
	Single sterile barrier system

Patents:
D584410-S (U.S.)
001013940-0002 (EU)
9001013940002 (GB)