ENHANCED ARS™ AIR RELEASE SYSTEM

for Needle Decompression

14ga x 3.25" Needle Decompression Kit

REF 10-0063 NSN: PENDING

STERILE R | MD | 2 STERILIZE | Do Not Resterilize | Consult Instructions for Use

REV041724

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Fig. A
ENHANCED ARS & Components

Intended Use:
The ENHANCED 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

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

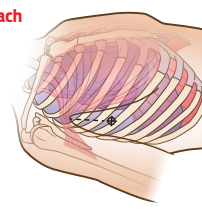
Contraindications:
- Within the European Union (EU), the ENHANCED ARS™ is not indicated for pediatrics and pregnant women due to EU regulatory requirements
- Not intended for treatment of simple pneumothorax, hemothorax or simple barotrauma

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 ENHANCED 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.

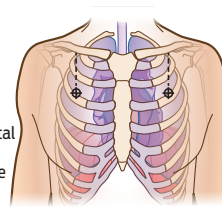
Warning:
- Tension Pneumothorax is a life threatening medical emergency, which if left untreated will result in death. When using anterior approach, ensure placement in 2nd intercostal space perpendicular to and through the anterior chest wall at the mid-clavicular line. Do not place medial to the mid-clavicular 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 ENHANCED 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 ENHANCED 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. B
Lateral Approach
5th Intercostal space on anterior axillary line (right lateral illustrated)



OR

Fig. C
Anterior Approach
2nd intercostal space, mid clavicular line



DIRECTIONS FOR USE

1. **Select Site: See *Fig. B* lateral approach OR *Fig. C* anterior approach**
2. **Cleanse site with antimicrobial solution**
3. **Remove red cap from case with twisting motion (exposing proximal end of needle set)**
4. **Remove ENHANCED ARS™ from case (by grasping and gently pulling proximal end of ENHANCED ARS™)**
5. **Insert ENHANCED ARS™ through skin targeting selected rib (below level of intended insertion site). Place needle tip against exterior rib and confirm position. Direct ENHANCED ARS™ superiorly over rib and into thoracic cavity - while ensuring perpendicular positioning in relation to thoracic cavity. Penetrate thoracic cavity (extending ENHANCED ARS™ approximately 3 cm beyond exterior of targeted rib. Tension may release at this point).**
6. **Stop advancing the needle, and advance ONLY the catheter portion toward the middle of the clavicle using the needle as a guide but avoiding further penetration with the needle.**
7. **Remove needle only when catheter has been fully inserted (tension may release at this point)**
8. **Secure catheter (as directed by organizational protocol)**
9. **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
- Consult Instructions for Use
- Do Not Resterilize
- Single Use
- Do Not Use if Package is Damaged
- STERILE R Sterile Symbol
- Single sterile barrier system
- MD Medical Device
- ℞ ONLY Prescription Device
- TAA TAA Compliant
- Not Made with Natural Rubber Latex

Patents
D584410-S (U.S.),
001013940-0002 (EU),
90010139400002 (GB)