SPEAR®

SIMPLIFIED PNEUMOTHORAX EMERGENCY AIR RELEASE

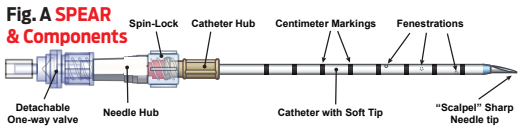
10ga x 3.75 in. • REF 10-0051 • NSN: 6515-01-699-4360

ZZ-1018 • REV051823

STERILE R | MD | Instructions For Use | USA Only | NOT MADE WITH NATURAL RUBBER LATEX | Rx ONLY | MADE IN AMERICA

NORTH AMERICAN RESCUE®
www.NARescue.com • 888.689.6277
35 Tedwall Ct. Greer, SC 29650 USA

Fig. A SPEAR & Components



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

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:
- Not intended for treatment of simple pneumothorax or hemothorax
- Not intended for treatment of simple barotrauma

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

Disposal:
The SPEAR® 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 placement is the preferred location to avoid 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 SPEAR® 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 SPEAR® 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.

(Continued on reverse side)

- 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.

Fig. B Lateral Approach

5th Intercostal space on anterior axillary line (right lateral illustrated)

OR

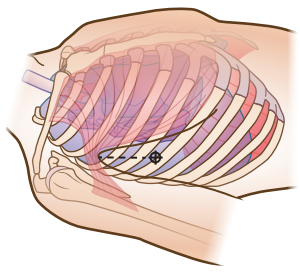
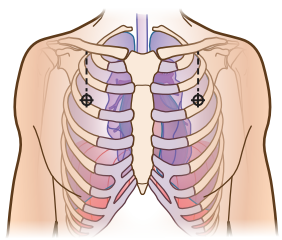


Fig. C Anterior Approach

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 SPEAR® from case (by grasping and gently pulling proximal end of SPEAR®)
5. Insert SPEAR® through skin targeting selected rib (below level of intended insertion site). Place needle tip against exterior rib and confirm position. Direct SPEAR® superiorly over rib and into thoracic cavity - while ensuring perpendicular positioning in relation to thoracic cavity. Penetrate thoracic cavity (extending SPEAR® approximately 3 cm beyond exterior of targeted rib). STOP advancing the needle, and direct needle tip toward middle of clavicle (tension may release at this point)
6. Release catheter from needle by disconnecting Spin Lock (1/4 turn)
7. Advance ONLY the catheter toward middle of clavicle using needle as stationary guide
8. Remove needle only when catheter has been fully inserted (tension may release at this point)

9. If indicated, attach one-way valve to catheter (supplied at proximal end of needle)
10. Secure catheter (as directed by organizational protocol)
11. 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

PATENTS: 10926063 (U.S.)
D584410-S (U.S.)
001013940-0002 (EU)
90010139400002 (GB)

Harmonized Standard Symbols:

REF Device Part Number	Single Use
LOT Lot Number	Do Not Resterilize
Expiration Date	Consult Instructions for Use
Date of Manufacture	Prescription Device
Manufacturer	Made in America
Do Not Use if Package is Damaged	Not Made with Natural Rubber Latex
STERILE R Sterile Symbol	MD Medical Device
Single Sterile Barrier System	

See Reverse for more information