

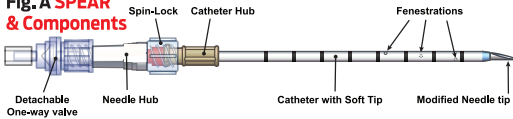


REF PN: 10-0051 • NSN: (Pending)  
10ga X 3.75 in. • Patent Pending



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

**Fig. A SPEAR® & Components**



#### Intended Use:

The NAR SPEAR is intended to be inserted into the pleural space of the chest cavity for emergency relief and temporary management of suspected 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 which, if left untreated, may result in death.

#### Contraindications:

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

**Warranty:** The contents contained herein constitute a medical device, the use of which requires specific education and training. North American Rescue, LLC, warrants this product as merchantable expressly for the indication detailed. North American Rescue disclaims all other implied warranties relating to

this product, to include use beyond this product's identified purpose, and utilization by untrained personnel or legally unauthorized parties.

#### Potential adverse complications:

- Death secondary to cardiac penetration
- Lung injury
- Vascular injury
- Pain
- Bleeding
- Infection
- Injury to local nerves resulting in numbness or paralysis of intercostal muscle
- Laceration of the lung tissue of uninjured lung tissue

#### Disposal:

The NAR 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 protocols. After removal of the needle portion of the device, dispose in a sharps or other appropriate protection device, per medical protocols. Dispose of the catheter portion of the device in accordance with medical protocols. Contact NAR for more information as needed.

#### Warning:

- The NAR 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 physician.
- Inserting the NAR SPEAR through the chest wall of a casualty who has NOT suffered a penetrating chest injury AND in whom the diagnosis of tension pneumothorax has NOT been confirmed may result in the inadvertent puncture of the underlying lung which

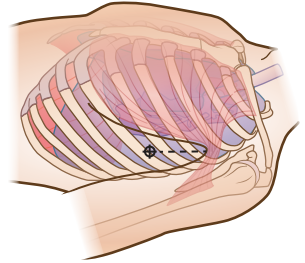
may create a pneumothorax.

- 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**

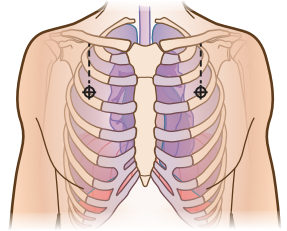
5th Intercostal space  
on anterior axillary line  
(left lateral illustrated)

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 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). 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 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

#### Harmonized Standard Symbols:



Device Part Number



Lot Number



Expiration Date



Date of Manufacture



Manufacturer



Do Not Use if Package is Damaged



Sterile Symbol



Single Use



Do Not Resterilize



Consult Instructions for Use



Prescription Device



Made in America



Not Made with Natural Rubber Latex

See Reverse for more information