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The Capnospot® Device - Improving Trauma Care

Clinical Implementation Guideline

Objectives

- Understand the role of Capnospot® pneumothorax decompression indicator in the treatment of tension pneumothorax
- Identify the signs and symptoms of tension pneumothorax in the self-ventilating patient
- Identify the signs and symptoms of tension pneumothorax in the patient who is receiving positive pressure or mechanical ventilation
- Landmark the 2nd intercostal space, midclavicular line
- Landmark the 4th/5th intercostal space, anterior axillary line
- Insertion of a needle decompression device with Capnospot® visual indicator
- Observing for signs and symptoms of clinical improvement after relief of tension pneumothorax with Capnospot® visual indicator
- Troubleshooting the Capnospot® indicator and identification of catheter failure

The Why of the Capnospot® Decompression Indicator

- Patients arrived in the trauma bay looking like this!
- If this is what happens at leading medical centers, what happens in other places
- What is the Pre-Hospital solution? Is there a better way

The Clinical Problem: Tension Pneumothorax

- **100%** fatality rate if not treated immediately
- **30%** of ***preventable*** trauma mortalities occur from tension pneumothorax [1]
- Civilian Incidence “unclear” [2]

  Somewhere between 1% - 20%
- DOD ~3-4% of all combat mortalities[1]
- Prehospital Decompression Reduces 24-hour Mortality by 25%[2]

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1. J. J. McPherson, D. S. Feigin, R. F. Bellamy, Prevalence of Tension Pneumothorax in Fatally Wounded Combat Casualties, *J. Trauma Inj. Infect. Crit. Care* **60**, 573–578 (2006).
2. Muchnok D, Vargo A, Deeb AP, Guyette FX, Brown JB. Association of Prehospital Needle Decompression With Mortality Among Injured Patients Requiring Emergency Chest Decompression. JAMA Surg. 2022 Oct 1;157(10):934-940. doi: 10.1001/jamasurg.2022.3552. PMID: 35976642; PMCID: PMC9386601.

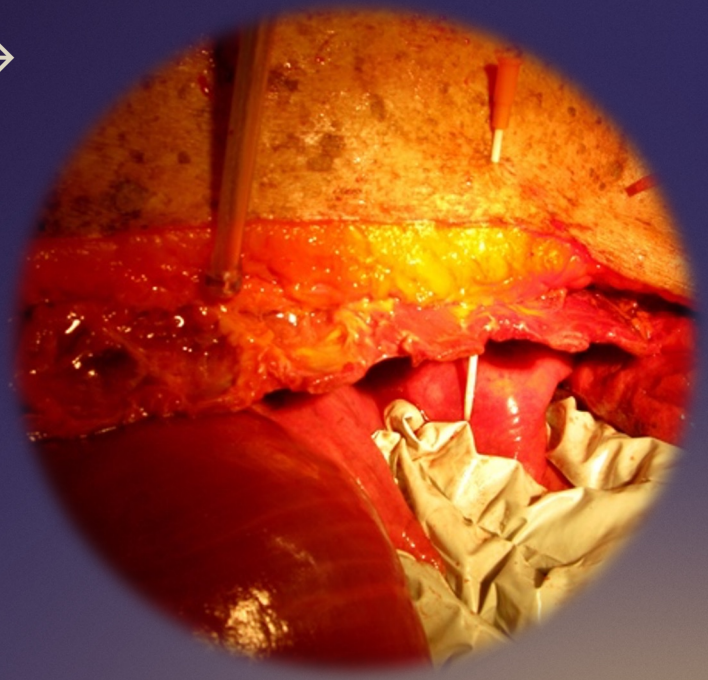
The Current Standard of Care Fails Often

- **Thoracostomy catheter decompresses air in the thoracic cavity**
- *Gold Standard = Listen for a “gush of air”*
- *Clinician: “Wait… did it work?”*
- **Needle Thoracostomy failure rate of 20-50%[3-4]**

3. J. M. Aho, C. A. Thiels, M. M. El Khatib, D. S. Ubl, D. V Laan, K. S. Berns, E. B. Habermann, S. P. Zietlow, M. D. Zielinski, Needle thoracostomy: Clinical effectiveness is improved using a longer angiocatheter., J. Trauma Acute Care Surg. 80, 272–7 (2016).
4. D. V Laan, T. D. N. Vu, C. A. Thiels, T. K. Pandian, H. J. Schiller, M. H. Murad, J. M. Aho, Chest wall thickness and decompression failure: A systematic review and meta-analysis comparing anatomic locations in needle thoracostomy., Injury 47, 797–804 (2016).

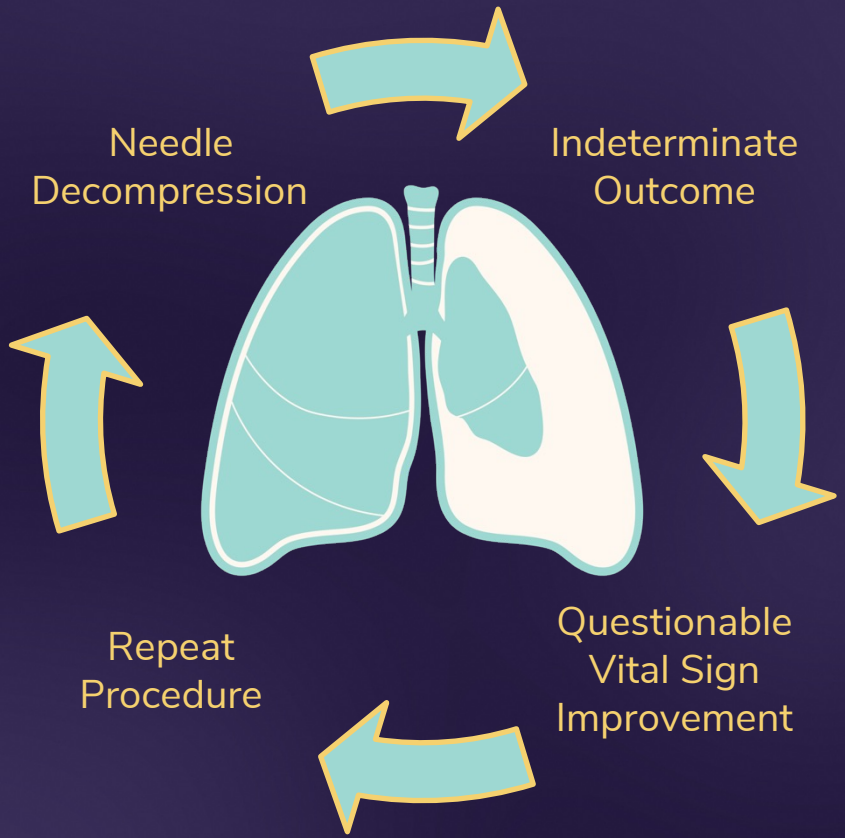
Why is the Failure Rate so High?

- The catheters are not large enough – 18ga → 16ga → 14ga → 10ga?
- Catheters are not long enough – 5 cm → 8 cm
- The chest is too thick! - 2nd ICS → 4th/5th MAL/AAL
- Training issues & “High Acuity, Low Occurrence Procedure”
- Failure Rate remains in most series 20-50% [3-4]
- Hearing a “gush of air” as confirmation of correct placement and relief of a tension pneumothorax



3. J. M. Aho, C. A. Thiels, M. M. El Khatib, D. S. Ubl, D. V Laan, K. S. Berns, E. B. Habermann, S. P. Zietlow, M. D. Zielinski, Needle thoracostomy: Clinical effectiveness is improved using a longer angiocatheter., J. Trauma Acute Care Surg. 80, 272–7 (2016).
4. D. V Laan, T. D. N. Vu, C. A. Thiels, T. K. Pandian, H. J. Schiller, M. H. Murad, J. M. Aho, Chest wall thickness and decompression failure: A systematic review and meta-analysis comparing anatomic locations in needle thoracostomy., Injury 47, 797–804 (2016).

Needle Decompression: The Field Hamster Wheel



Overview of the Capnospot® Visual Indicator

- The pneumothorax contains CO_2.
- Indicates **visually** if decompression was successful or not within seconds, allowing immediate adjustment of the catheter[5]
- **Objective** confirmation of decompression by detecting CO2 from the pneumothorax and showing an obvious color change to the operator[5]
- Compatible with all decompression devices and is easy to attach with a standard Luer fitting. Small, lightweight, and compact, and functions in low-light environments[5]

5. Aho JME, Sackner-Bernstein J, Mcdougall V. 510(K) *SUMMARY ADMINISTRATIVE INFORMATION Date of Summary Preparation: March 28 Th.* Vol 6.

Signs and Symptoms of a Tension Pneumothorax in a Self Ventilating Patient

Tension pneumothorax detected via advanced imaging, clinical suspicion, or known traumatic injury to the chest, back, or abdomen, with severe or progressive respiratory distress associated with **at least one or more of the following signs and symptoms[6,7]:**

- **Severe or progressive tachypnea**
- **Severe or progressive dyspnea**
- **Tachycardia**
- **SpO_2 < 90%**
- **Absent or diminished lung sounds on the affected side**
- **Hypotension**
- **Persistent loss of consciousness**
- **Traumatic cardiac arrest without obviously fatal wounds**

6. Butler F, Holcomb J, Shackelford S, et al. *Management of Suspected Tension Pneumothorax in Tactical Combat Casualty Care TCCC Guidelines Change* 17-02. Accessed April 9, 2024. https://www.jsomonline.org/Updates/2018219Butler.pdf
7. Leigh-Smith S, Harris T. Tension pneumothorax - Time for a re-think? *Emergency Medicine Journal*. 2005;22(1):8-16. doi:10.1136/emj.2003.010421

Signs and Symptoms of a Tension Pneumothorax in a Patient Receiving Positive Pressure or Mechanical Ventilation

Tension pneumothorax detected via advanced imaging, clinical suspicion, or known traumatic injury to the chest, back, or abdomen, and **at least two or more of the following symptoms presenting with a rapid onset[6,7]:**

- **Severe and progressive respiratory distress in the conscious self-ventilating patient (CPAP or Bi-level Ventilation)**
- **Severe or progressive tachypnea during administration of CPAP or Bi-Level Ventilation**
- **Tachycardia**
- **$SpO_2 < 90\%$**
- **Hypotension**

6. Butler F, Holcomb J, Shackelford S, et al. *Management of Suspected Tension Pneumothorax in Tactical Combat Casualty Care TCCC Guidelines Change 17-02.* Accessed April 9, 2024. https://www.jsomonline.org/Updates/2018219Butler.pdf
7. Leigh-Smith S, Harris T. Tension pneumothorax - Time for a re-think? *Emergency Medicine Journal*. 2005;22(1):8-16. doi:10.1136/emj.2003.010421

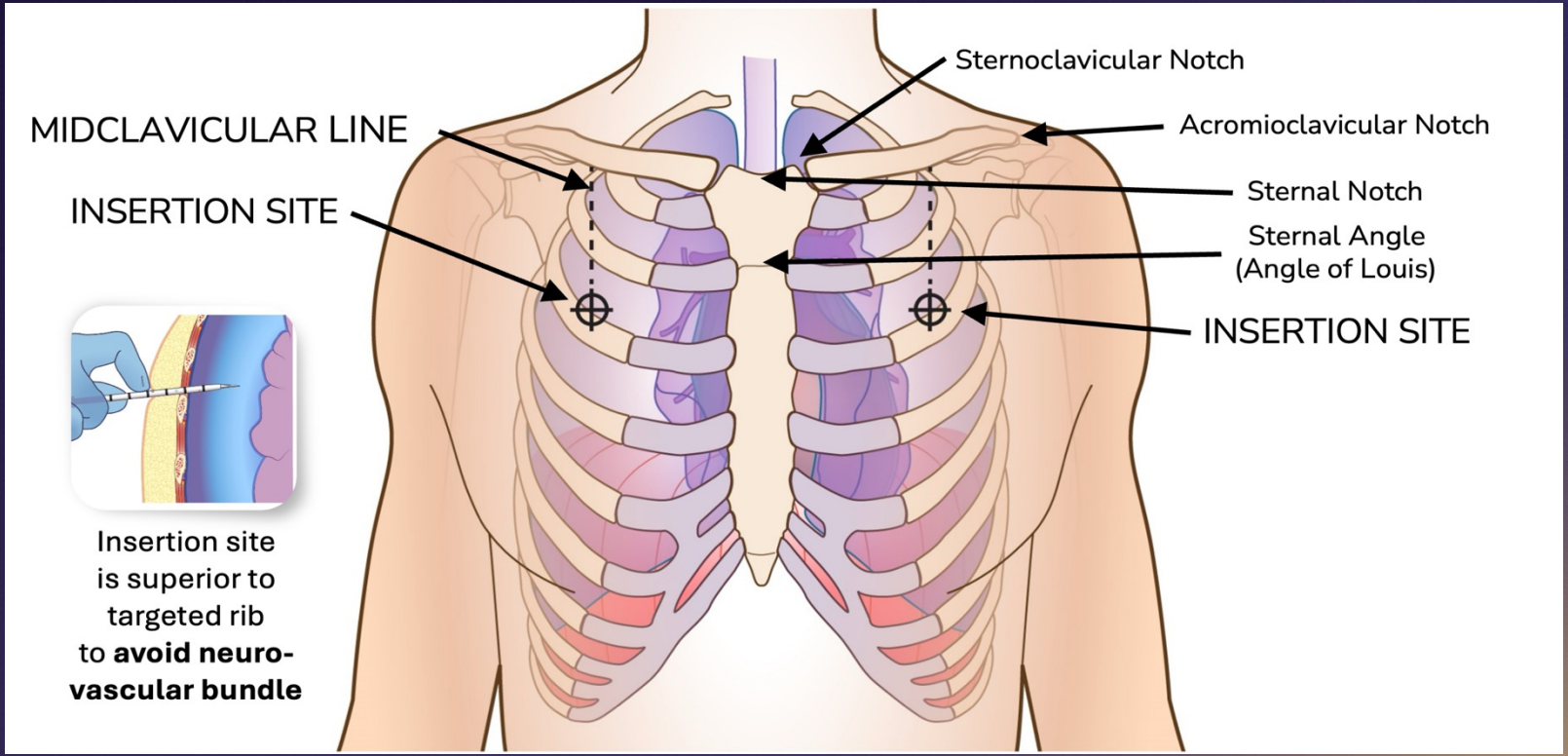
Signs and Symptoms of a Tension Pneumothorax in a Patient Receiving Positive Pressure or Mechanical Ventilation (*continued*)

- Decrease of compliance during ventilation
- Acutely increased or progressive ventilatory requirements
- Subcutaneous emphysema
- Absent or diminished lung sounds on the affected side
- Loss of consciousness (while receiving CPAP or Bi-level Ventilation)
- Cardiac arrest without other known etiology

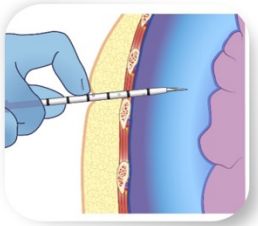
6. Butler F, Holcomb J, Shackelford S, et al. *Management of Suspected Tension Pneumothorax in Tactical Combat Casualty Care TCCC Guidelines Change 17-02*. Accessed April 9, 2024. https://www.jsomonline.org/Updates/2018219Butler.pdf
7. Leigh-Smith S, Harris T. Tension pneumothorax - Time for a re-think? *Emergency Medicine Journal*. 2005;22(1):8-16. doi:10.1136/emj.2003.010421

Recommended Positioning of Capnospot® Visual Indicator with Decompression Device

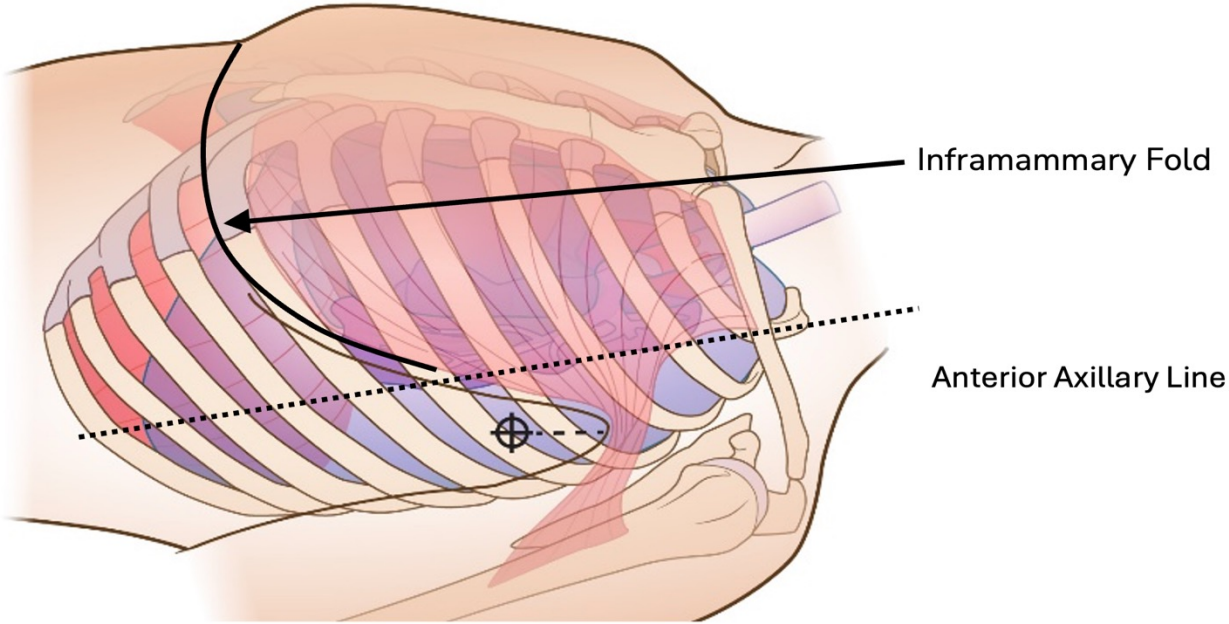
Identifying the 2nd Intercostal Space, Mid Clavicular Line



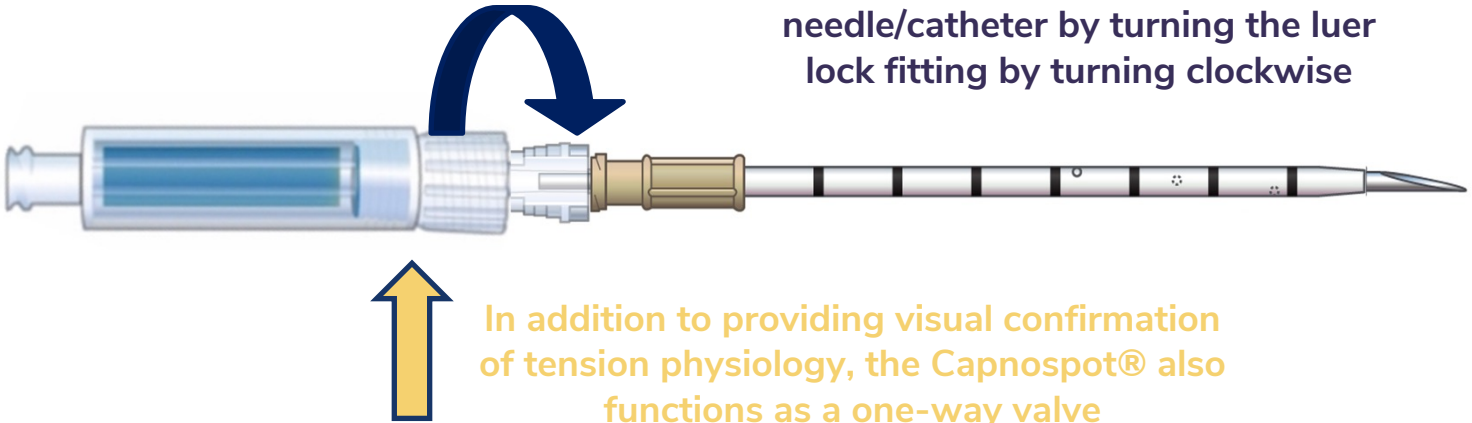
Identifying the 4th/5th Intercostal Space, Anterior Axillary Line



Insertion site is superior to targeted rib to **avoid neuro-vascular bundle**



Prepare Equipment

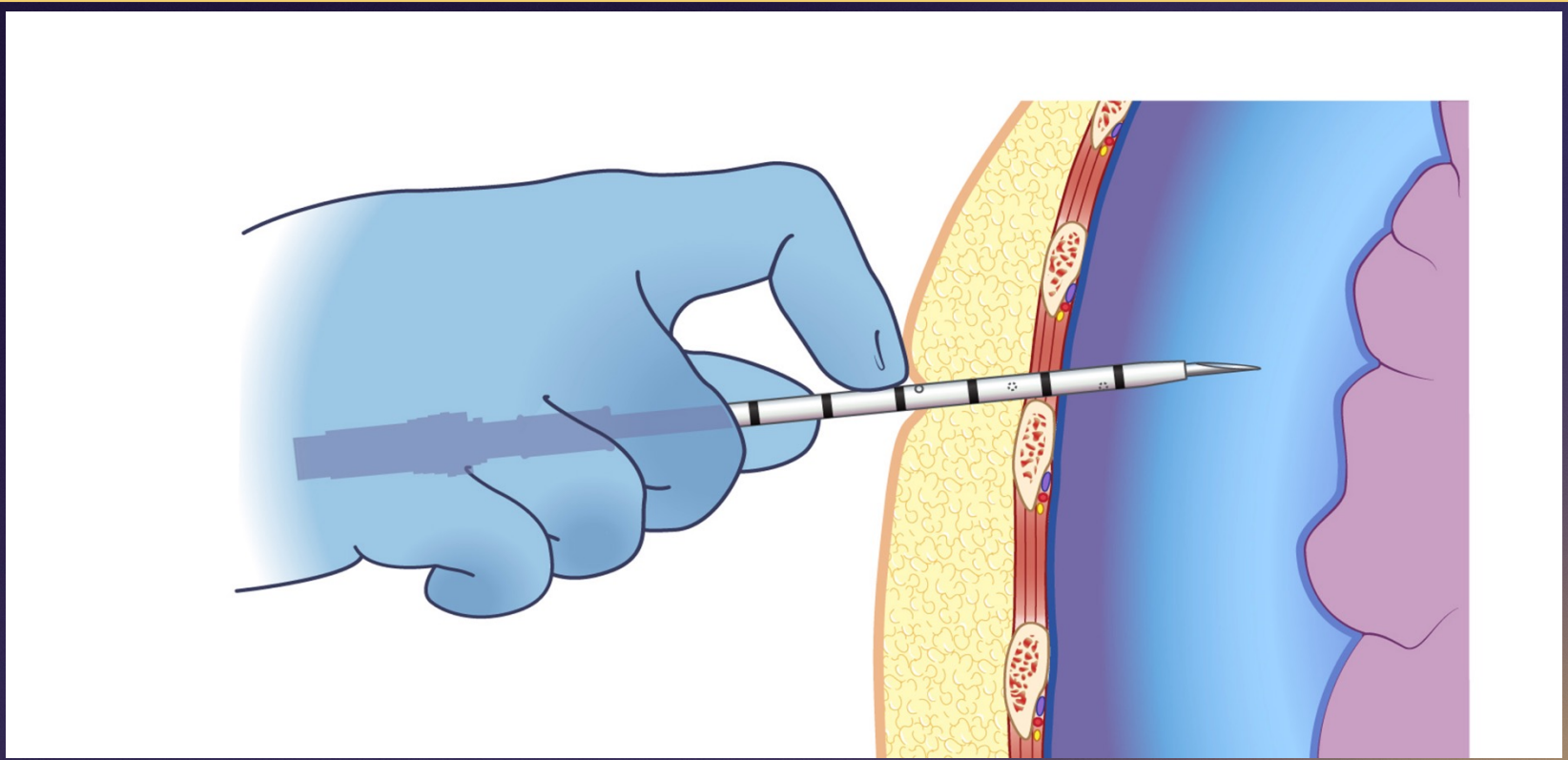


Affix Capnospot® to decompression needle/catheter by turning the luer lock fitting by turning clockwise

In addition to providing visual confirmation of tension physiology, the Capnospot® also functions as a one-way valve

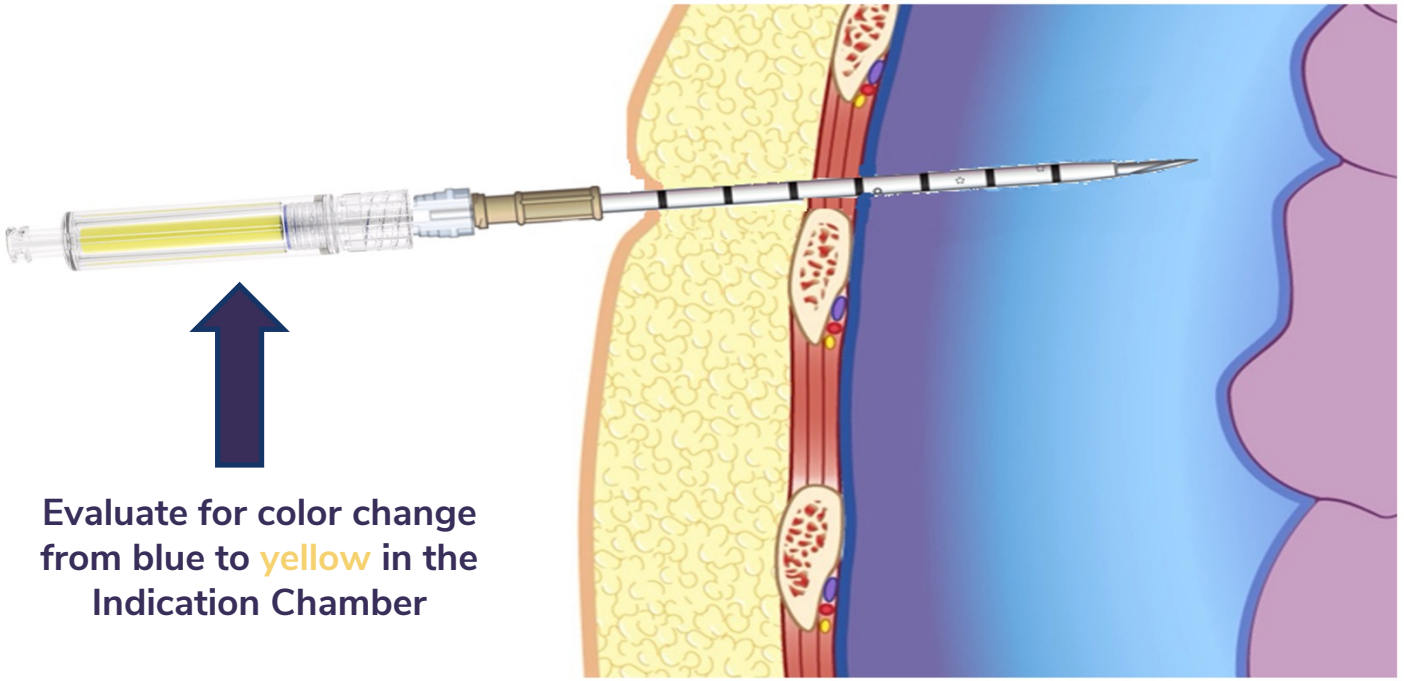
5. Aho JME, Sackner-Bernstein J, Mcdougall V. 510(K) SUMMARY ADMINISTRATIVE INFORMATION Date of Summary Preparation: March 28 Th. Vol 6.

Insert the Decompression Device With Capnospot Affixed to Needle



5. Aho JME, Sackner-Bernstein J, Mcdougall V. 510(K) *SUMMARY ADMINISTRATIVE INFORMATION* Date of Summary Preparation: March 28 Th. Vol 6.

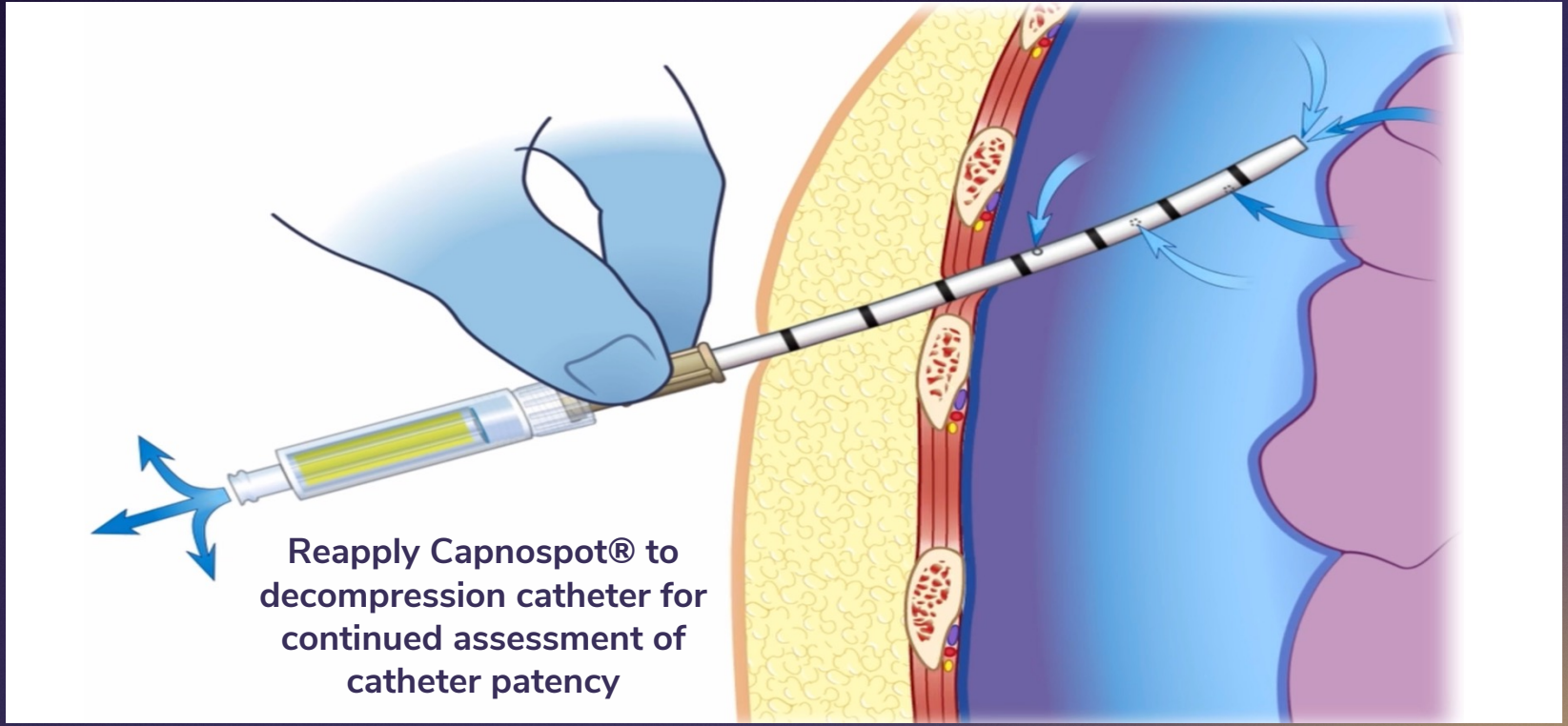
Advancing the Decompression Device



Evaluate for color change from blue to yellow in the Indication Chamber

5. Aho JME, Sackner-Bernstein J, Mcdougall V. 510(K) SUMMARY ADMINISTRATIVE INFORMATION Date of Summary Preparation: March 28 Th. Vol 6.

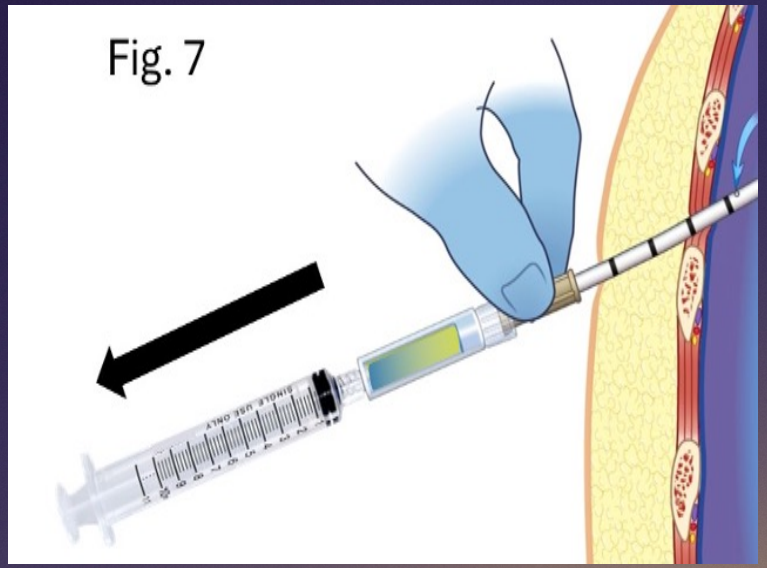
Continued Monitoring of Catheter Patency and Patient Improvement



5. Aho JME, Sackner-Bernstein J, Mcdougall V. 510(K) SUMMARY ADMINISTRATIVE INFORMATION Date of Summary Preparation: March 28 Th. Vol 6.

Trouble Shooting Capnospot and Evaluating Catheter Patency

If the Capnospot® color-changing indicator presents a blue color, attach a 10mL syringe to the female luer connection of the Capnospot® device and attempt to aspirate air. If the Capnospot® indicator chamber does not change to a yellow color or air cannot be aspirated without resistance, evaluate the catheter for displacement or obstruction.



5. Aho JME, Sackner-Bernstein J, Mcdougall V. 510(K) SUMMARY ADMINISTRATIVE INFORMATION Date of Summary Preparation: March 28 Th. Vol 6.

THANK YOU

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Tension Pneumothorax Management with Capnospot® Clinical Procedural Guide

Purpose:

To provide procedural guidance for needle thoracostomy while utilizing the Capnospot®.

1. Indications for Use:

For patients with known or suspected tension pneumothorax. Used for more accurate placement of pneumothorax decompression devices than the current standard of care auditory assessments[1,2].

2. Signs and Symptoms of Tension Pneumothorax:

a. **Self-Ventilating Patients:** Tension pneumothorax detected via advanced imaging, clinical suspicion, or known traumatic injury to the chest, back, or abdomen, with severe or progressive respiratory distress associated with **at least one or more of the following signs and symptoms[3,4]:**

   i. Severe or progressive tachypnea
   ii. Severe or progressive dyspnea
   iii. Tachycardia
   iv. $SpO_2 < 90\%$
   v. Absent or diminished lung sounds on the affected side
   vi. Hypotension
   vii. Persistent loss of consciousness
   viii. Traumatic cardiac arrest without obviously fatal wounds

b. **For Positive Pressure Or Mechanically Ventilated Patients:** Tension pneumothorax detected via advanced imaging, clinical suspicion, or known traumatic injury to the chest, back, or abdomen, and **at least two or more of the following symptoms presenting with a rapid onset[3,4]:**

   i. Severe and progressive respiratory distress in the conscious self-ventilating patient (CPAP or Bi-level Ventilation)
   ii. Severe or progressive tachypnea during administration of CPAP or Bi-Level Ventilation
   iii. Tachycardia
   iv. $SpO_2 < 90\%$

v. Hypotension
vi. Decrease of compliance during ventilation
vii. Acutely increased or progressive ventilatory requirements (e.g. Reduced tidal volume with pressure control or high peak pressure with volume control)
viii. Subcutaneous emphysema
ix. Absent or diminished lung sounds on the affected side
x. Loss of consciousness (while receiving CPAP or Bi-level Ventilation)
xi. Cardiac arrest without other known etiology

3. Identification of Landmarks and Site Preparation for Needle Thoracostomy:

a. 2nd Intercostal Space Midclavicular line:

i. Identification of the sternal notch (Figure 1)
ii. Identification of the sternoclavicular joint (Figure 1)
iii. Identification of the acromioclavicular joint (Figure 1)
iv. Identification of the clavicle mid-point (midclavicular line) (Figure 1.)
v. Identification of the 2nd intercostal space (above the third rib – midclavicular line, at the sternal ridge, or sternal Angle of Louis) (Figure 1)
vi. Identify the intersection between the vertical midclavicular line and a horizontal line running laterally from the Angle of Louis (Figure 1)
vii. Confirm location by firmly palpating the 3rd rib on the midclavicular line (Figure 1)
viii. Cleanse the site by applying antiseptic wipe or solution if available

b. 4th or 5th Intercostal Space Anterior Axillary Line:

i. Identify the Inframammary fold (Figure 2)
ii. Moving laterally, the landmark is immediately behind the edge of the pectoralis major muscle (Figure 2)
iii. Cleanse the site by applying antiseptic wipe or solution if available

4. Prepare Equipment:

a. Affix the Capnospot® male Luer connector to the female Luer connection of an appropriately sized needle decompression device (Figure 3). This device features a built-in one-way valve

Insert the Decompression Device:

a. Penetrate the skin advancing the decompression device at a 90-degree angle through the chest wall just above the rib and into the plural space (Figure 4)[3,4]

b. Advance the catheter through the chest wall until a positive indication of CO_2 is observed via Capnospot® or a "pop" is felt upon entering the plural space[2–6]

c. Hold the decompression device in place for approximately 10 seconds and observe for visible color change in the Capnospot® indication chamber (Figure 5). Even If no observed color change, proceed to step **d**[3–6]

d. Advance the catheter hub of the decompression device over the needle to the plane of the patient's skin [3,4]

e. Remove Capnospot® from the needle of the commercially available (5-8cm, 10 gauge) decompression device and dispose of the needle in an appropriate sharp securement device[3,7,8]

f. Reapply the Capnospot® to the catheter for ongoing assessment of catheter patency based on the color changing indicator (Figure 6)[5]

g. Secure the catheter per institutional policy

5. Monitor Patient for Improvement of Vital Signs:

a. Monitor Capnospot® for continuous confirmation of catheter patency by visualization of a yellow color within color changing indicator[5]

b. Increase in SPO_2; Improvement of patient blood pressure; improvement of tachypnea and shortness of breath[3,4,7]

c. If the Capnospot® color changing indicator presents a blue color, attach a 10mL syringe to the female Luer connection of Capnospot® and attempt to aspirate air. If the Capnospot® does not change to a yellow color or air is unable to be aspirated without resistance, evaluate the catheter for displacement or obstruction (Figure 7)[3–5,7,9]

d. If catheter displacement occurs, evaluate the patient for further clinical deterioration and consider the placement of a second commercially available decompression device with Capnospot® affixed[3–5,9]

e. The Capnospot® may be kept in place to confirm catheter patency until definitive care is reached[5]

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Figures

Fig. 1

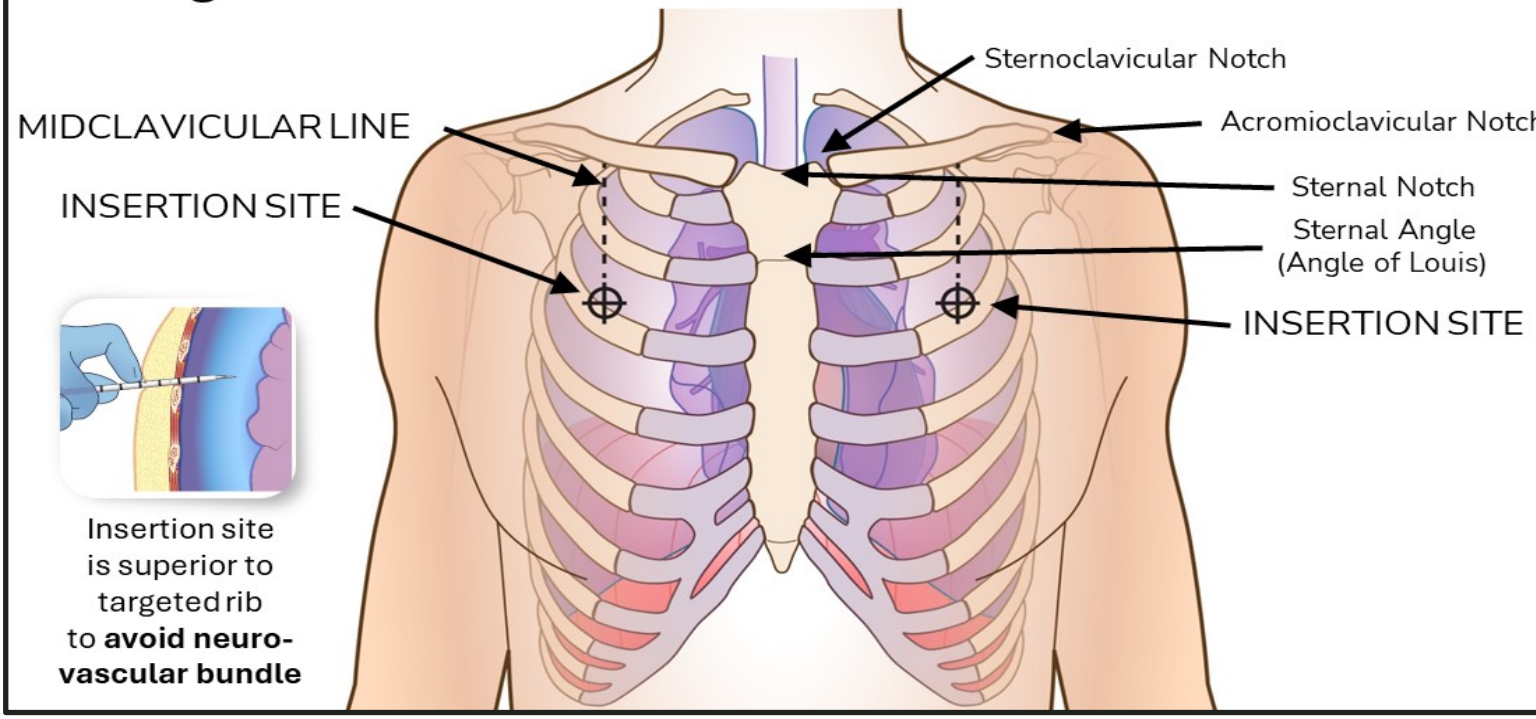

Fig. 2

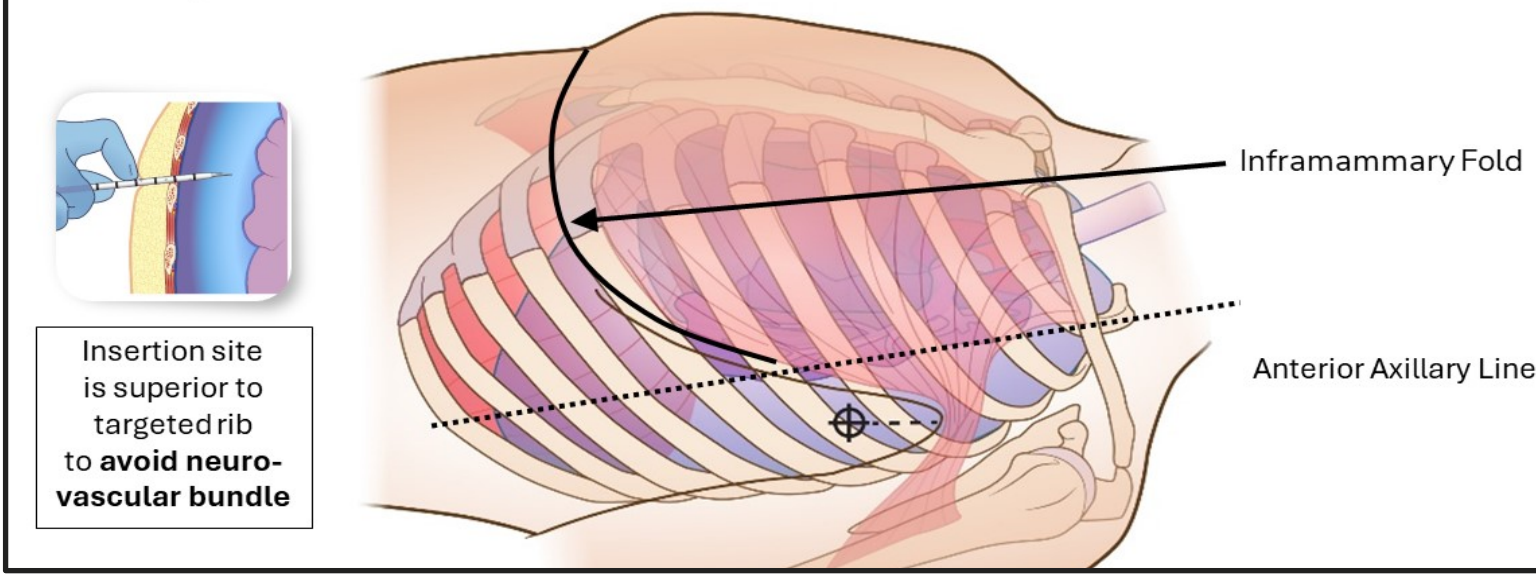

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Fig. 3

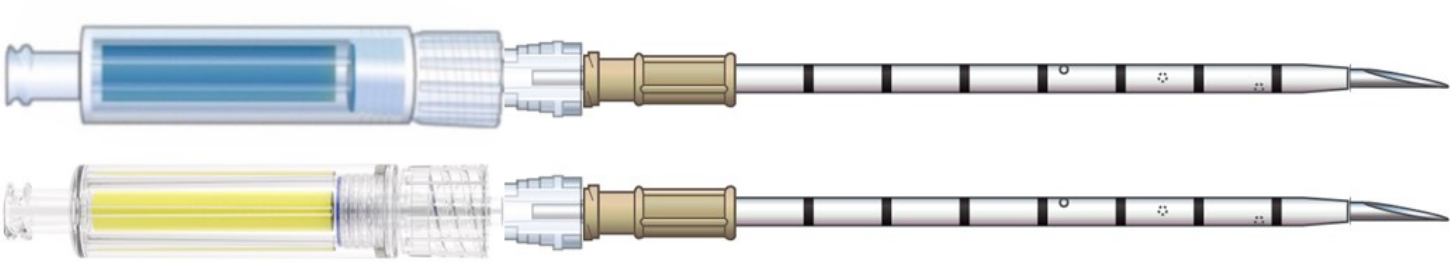

Fig. 4

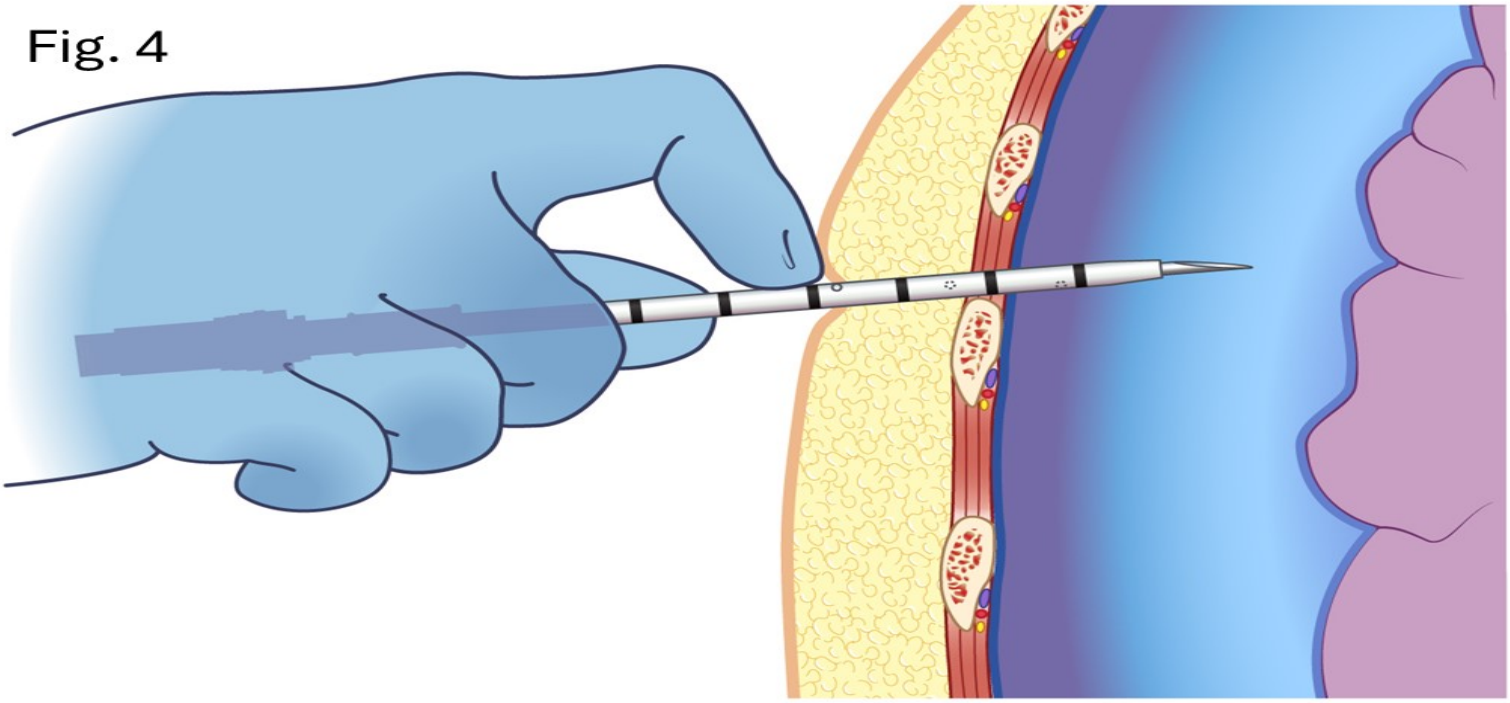

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Fig 5

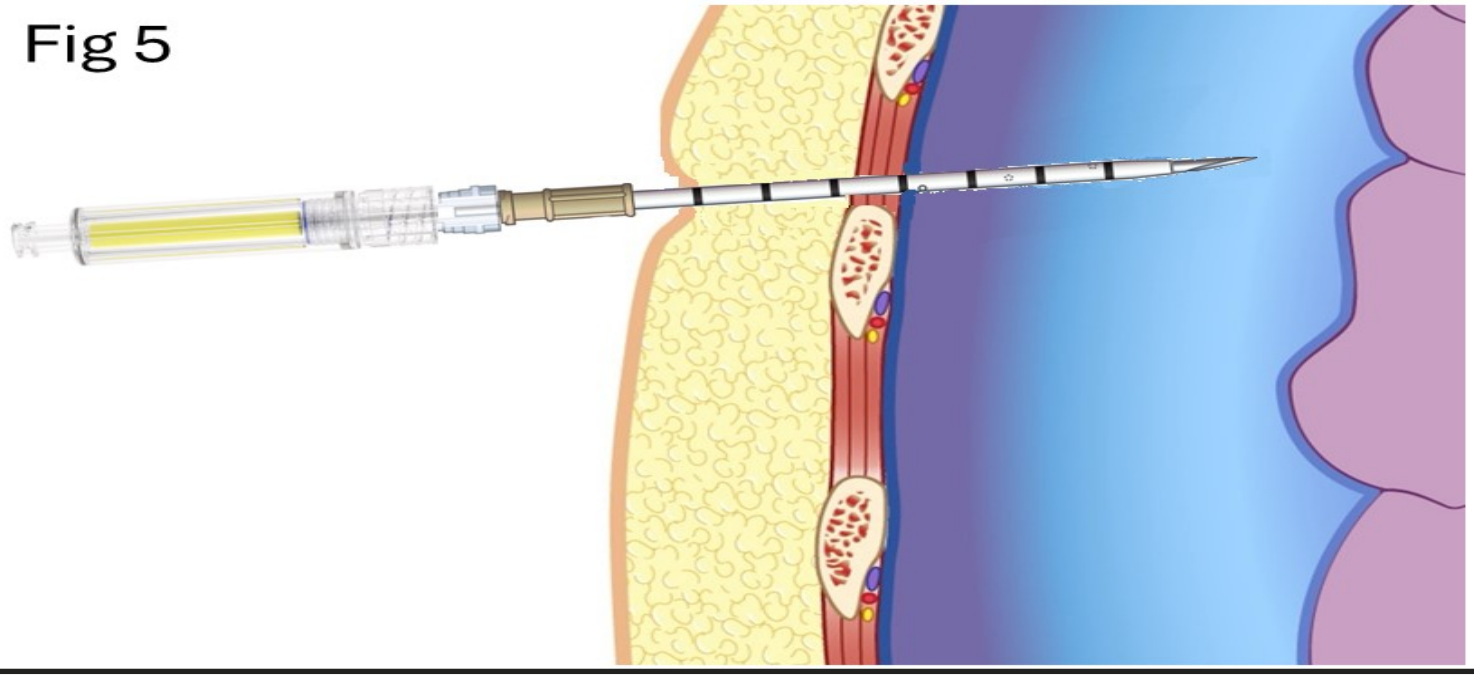

Fig. 6

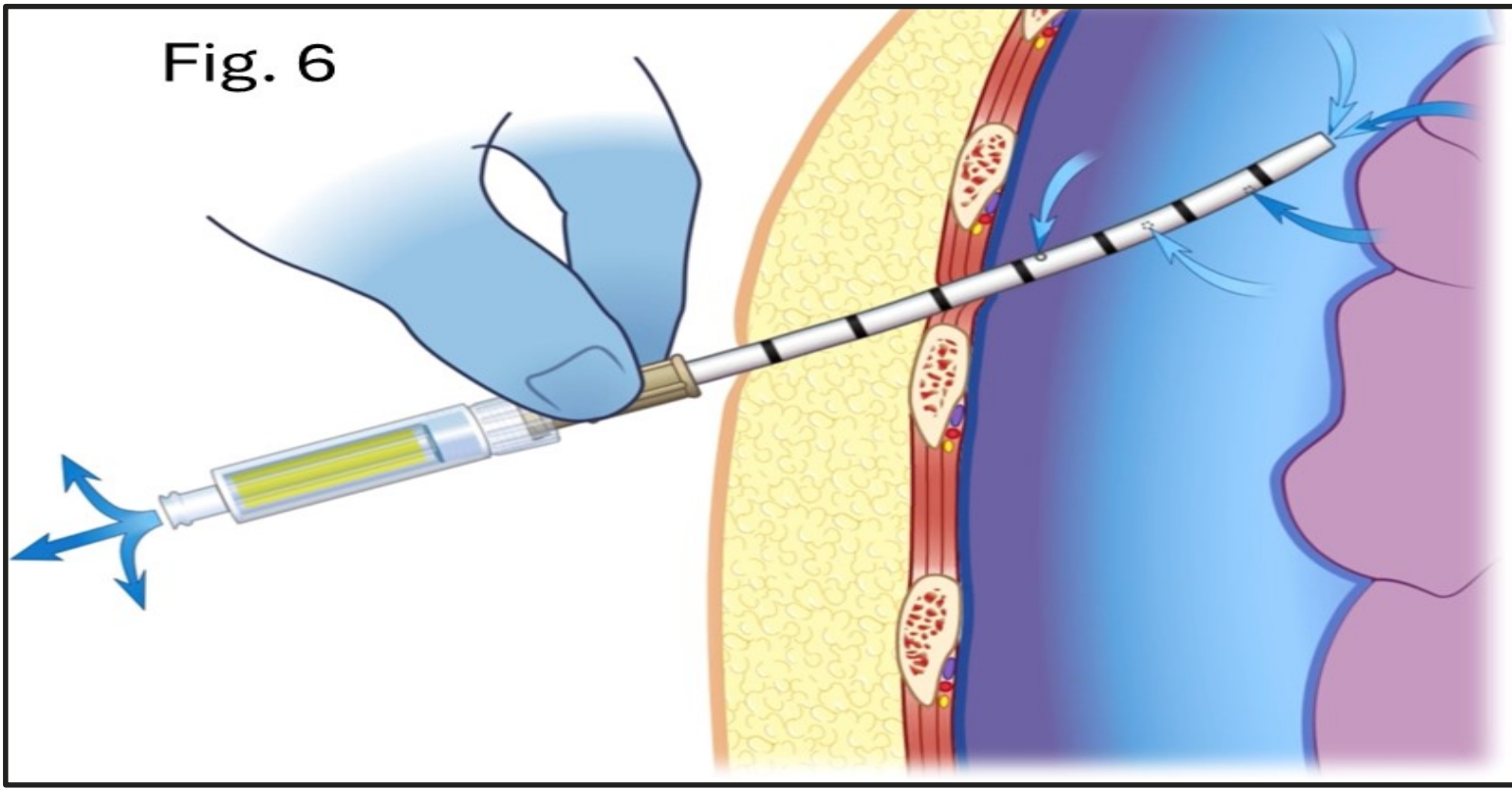

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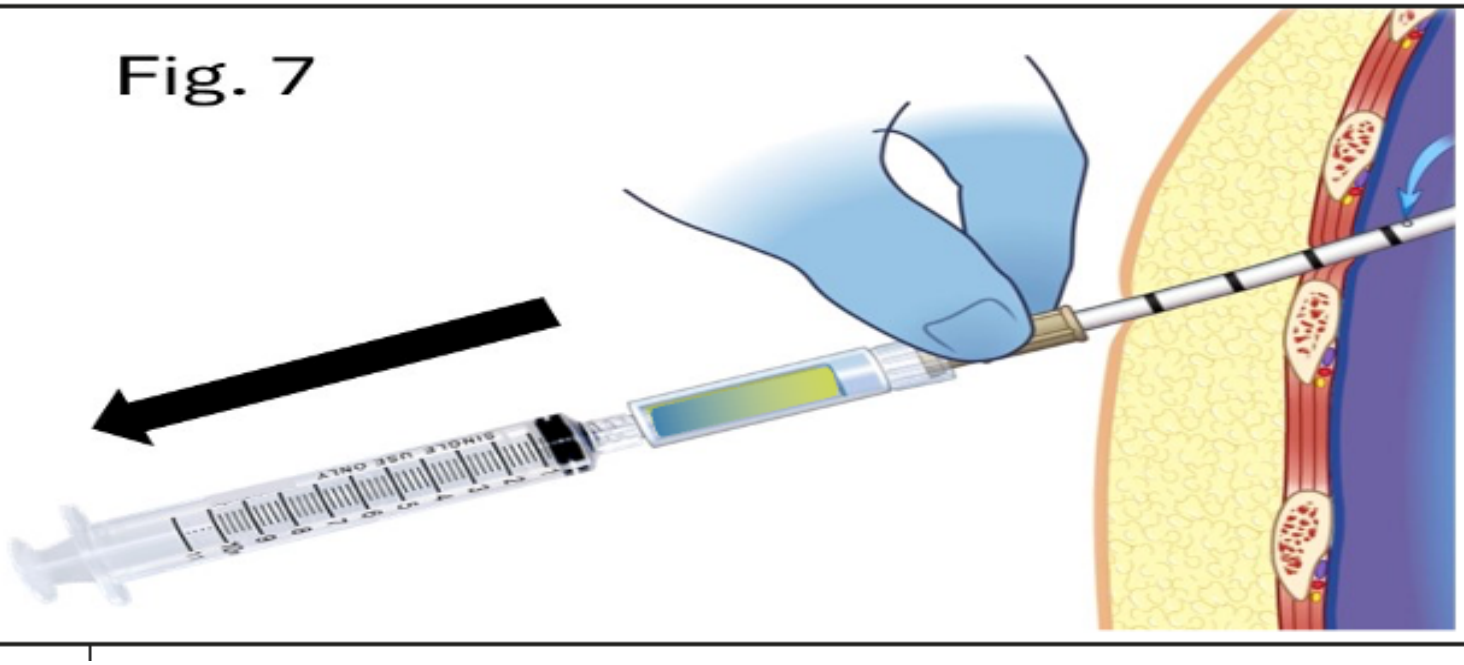
Fig. 7



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3. Butler F, Holcomb J, Shackelford S, et al. *Management of Suspected Tension Pneumothorax in Tactical Combat Casualty Care TCCC Guidelines Change 17-02*. Accessed April 9, 2024. https://www.jsomonline.org/Updates/2018219Butler.pdf
4. Leigh-Smith S, Harris T. Tension pneumothorax - Time for a re-think? *Emergency Medicine Journal*. 2005;22(1):8-16. doi:10.1136/emj.2003.010421
5. Aho JME, Sackner-Bernstein J, Mcdougall V. *510(K) SUMMARY ADMINISTRATIVE INFORMATION Date of Summary Preparation: March 28 Th*. Vol 6.
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Tension Pneumothorax Management with Capnospot®
Competency Evaluation

Date: _____ **Clinician Name:** _____

Performance Criteria	S	U
Uses appropriate PPE		
Verbalizes signs and symptoms of tension pneumothorax in a self-ventilating patient		
Verbalizes the signs and symptoms of tension pneumothorax in patients who are receiving positive pressure or are being mechanically ventilated		
Identifies landmarks and properly locates the 2nd intercostal space at the midclavicular line and preps the site with antiseptic agent		
Identifies landmarks and properly locates the 4th or 5th intercostal space at the anterior axillary line		
Prepares properly sized decompression needle and affixes Capnospot's male Luer connection to the female Luer connection of the decompression device		
Penetrates the skin advancing the decompression device at a 90-degree angle through the chest wall just above the rib and into the plural space		
Advance the catheter through the chest wall until a positive indication of CO2 is observed via Capnospot® or a pop is felt upon entering the plural space		
Hold the decompression device in place for approximately 10 seconds and observe Capnospot® for visible color change in the indication chamber		
Advance the catheter hub of the decompression device to the plane of the patient's skin		
Remove Capnospot® from the needle and dispose the needle in an appropriate sharp securement device		
Reapply the Capnospot to the catheter for ongoing assessment of catheter patency based on the color changing indicator		
Secure the catheter per institutional policy		
Verbalizes continuous evaluation for objective patient improvement via vital signs and catheter patency with Capnospot®		
Demonstrate catheter trouble shooting by aspirating the Capnospot® with a 10mL syringe for suspected catheter failure		
Verbalizes need to perform additional decompression if catheter failure occurs and the patient's clinical condition worsens		
Verbalizes that the catheter and Capnospot® may be kept in place to assess catheter patency until definite care is reached		

Comments: _____

_____

_____

Successful or **Unsuccessful** Demonstration of Competency (**S** or **U**): _____

Evaluator Name: _____

Evaluator Signature: _____