MEDSOURCELABS

NIK

Needle Decompression Indicator Kit

INSTRUCTIONS FOR USE

This kit includes:

(1) MedSource Decompression Needle

(1) PDI-001 Pneumeric™ Capnospot™

Biohazard
Destroy by incineration after use

BAA
Buy America Act

MSL-REG-LQR-10721
REV. 0

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PNEUMERIC™ CAPNOSPOT™

Device Description

The Pneumeric™ Capnospot™ Pneumothorax Decompression Indicator is a capnography device that provides objective, real-time feedback during decompressive thoracostomy. Specifically, the device detects the presence of carbon dioxide in the gas from the decompressed pneumothorax, permitting more accurate placement of the needle or thoracostomy device compared to the current standard of care based upon auditory a ssessments. The Pneumeric Capnospot is a therapeutic device intended to guide the placement of pneumothorax decompression needles and thoracostomy devices. The product consists of a cylindrical polycarbonate tube containing a carbon dioxide detecting paper. The device has a male luer connector on the distal end of the device to connect to decompression needles and thoracostomy devices, a diaphragm to prevent backflow of gases, a color changing indicator and a female luer on the proximal end of the device that can be used to connect accessories. The product is shipped non-sterile and labeled for single use only. The device is supplied in a single pack configuration labeled with a QR code linking to an electronic Instructions for Use. Each device is sealed in a foil pouch with a desiccant pack.

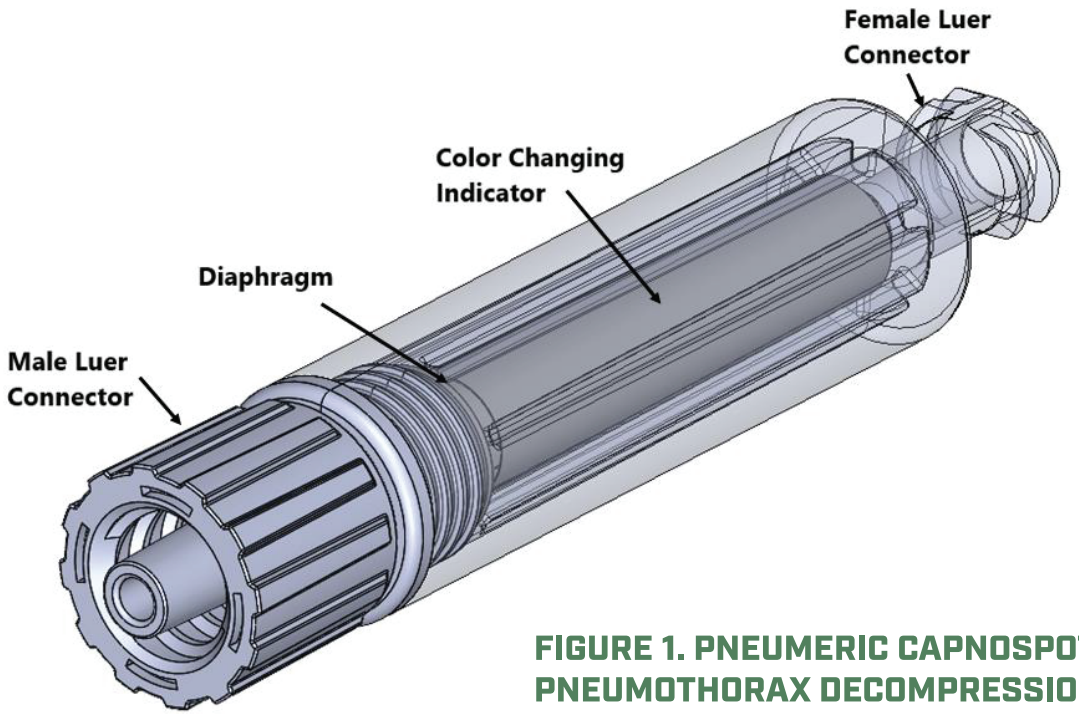


FIGURE 1. PNEUMERIC CAPNOSPOT PNEUMOTHORAX DECOMPRESSION INDICATOR

Indication, Intended Use, and Expected Clinical Benefit

Used for more accurate placement of pneumothorax decompression devices than the current standard of care auditory assessments. The Pneumothorax Decompression Indicator is a colorimetric capnography device indicated to detect the carbon dioxide in the gas passing through the device used to treat pneumothorax with suspected tension physiology.

Contraindications

- Uncooperative patient
- When pneumothorax decompression is otherwise contraindicated

Warnings and Precautions

- Read all instructions carefully. Failure to follow instructions may lead to serious medical consequences.
- Only persons having adequate training in pneumothorax decompression techniques should perform procedure.
- Capnospot has not been tested in patients with open pneumothorax, where treatment should be based on accepted guidelines and standard practices.
- Capnospot should be used in combination with clinical assessments and standard practice guidelines.
- Procedure details will vary according to practitioner's clinical judgement.
- Single Use Only.
- Do not use if package is opened or damaged.
- In order to achieve its intended use, Capnospot must be connected to a needle or thoracostomy device (angiocatheter, needle angiocatheter, pigtail thoracostomy catheter, or tube thoracostomy catheter with adapters) with a female luer fitting.
- This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices may result in a bio-incompatibility, infection, or product failure risks to the patient.
- Store between 10°F (-12°C) and 140°F (60°C). Storage for extended periods at temperatures below 10°F (-12°C) or above 140°F (60°C) may reduce shelf life.

Important Risk Information

Potential adverse events associated with the use of Capnospot include:

- Delay of therapy

Disposal

- The carton is recyclable. Dispose of all packaging materials as appropriate.
- Use solid biohazard waste procedures to discard device.

Notice Regarding the Reporting of Adverse Events

Any serious incident that has occurred in relation to Capnospot should be reported to the manufacturer and the competent authority of the EU Member State or other relevant regulatory body in which the user and/or patient is established.

DECOMPRESSION NEEDLE

Contraindications

Not for use in treating simple pneumothorax.
Not indicated for the treatment of simple barotrauma.
Not indicated for pediatric patients.
Not indicated for use in pregnancy.

Warnings

Tension Pneumothorax is a critical condition where air is trapped in the pleural cavity, which if left untreated will result in death. Ensure placement in 2nd intercostal space perpendicular to and through the anterior chest wall lateral to the mid-clavicular line. This anatomic placement will avoid inadvertent injury to the cardiac box, avoiding internal organs. Improper use may result in a tension pneumothorox.

Continually Monitor Patient For:

- Potential bleeding from site
- Potential local hemotoma
- Occlusion or bending of the cannula
- Progressive respiratory distress
- Unilateral decreased chest expansion

Adverse Reaction

Adverse reactions include:

- Pain
- Bleeding
- Infection
- Injury to local nerves resulting in numbness or paralysis of intercostal muscle
- Laceration of the lung tissue of uninjured lung tissue

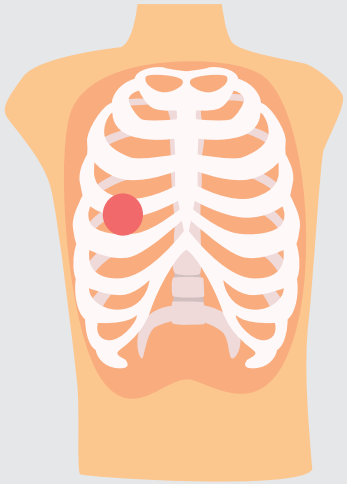
DECOMPRESSION NEEDLE WITH PNEUMERIC™ CAPNOSPOT™

INSTRUCTIONS FOR USE

The Decompression Needle is intended to be inserted into the pleural space of the chest cavity, to act as a mechanism to relieve tension pneumothorax in casualties with progressive respiratory distress, with known or suspected torso trauma.

1. Select Site: Identify the second intercostal space on the anterior chest at the mid-clavicular line on the same side as the injury. (Fig. 1)
2. Clean identified location with an antimicrobial solution.
3. Verify that the seal over the red cap and case is intact. Remove the red cap by rotating and pulling the cap away from the case.
4. Remove the Decompression Needle from case.

FIG. 1



5. The skin over the superior border of the third rib, mid-clavicular line, and direct it into the intercostal space at 90° angle to the chest wall. Ensure Needle Decompression entry into the chest is not medial to the nipple line and not directed toward the heart.

6. Continue to advance the needle into the pleural space. You will hear a sudden escape of air as the tension pneumothorax is released.

7. Remove the needle while leaving the catheter in place and secure the catheter to the patient as directed by your local protocols and training.

8. Locate Pneumeric™ Capnospot™, inspect the pouch, and verify that it is unopened and undamaged. DO NOT use the device if pouch is found opened or damaged.

9. Gently open the pouch by tearing the notch below the seal and inspect the components for damage. DO NOT use the device if damage is evident.

10. The device consists of cylindrical polycarbonate tube with a male luer on the distal end, female luer on the proximal end, and blue indicator paper inside the tube.

11. A minimal amount of green-yellow color in the indicator paper is a normal condition. Do not use the device if majority of the indicator paper is yellow in color.

12. Connect the male luer on the Capnospot™ to the female luer portion of the Decompression Needle device as shown in Figure 2.

NOTE: CAPNOSPOT™ MUST BE CONNECTED TO THORACOSTOMY DEVICE BEFORE PROVIDER ATTEMPTS TO DECOMPRESS PNEUMOTHORAX WITH SUSPECTED TENSION PHYSIOLOGY. ALTERNATIVELY, IF A NEEDLE ANGIOCATHETER IS BEING USED ONCE THE NEEDLE IS REMOVED, CAPNOSPOT™ SHOULD BE PROMPTLY ATTACHED TO THE ANGIOCATHETER.

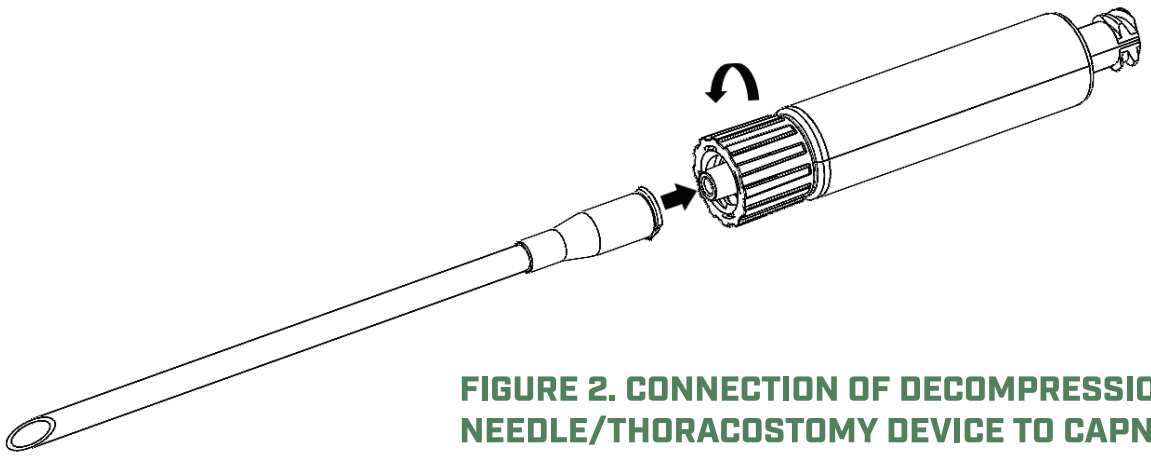


FIGURE 2. CONNECTION OF DECOMPRESSION NEEDLE/THORACOSTOMY DEVICE TO CAPNOSPOT™

13. Observe for color change within 10 seconds. The indicator paper should change from blue to yellow if greater than ambient CO_2 levels are detected. (Fig. 3)

FIG. 3

If the indicator paper is yellow, the device is positioned correctly.

If the indicator paper is blue, reposition the device.

14. If color changes, continue with current clinical care.

15. If no color change occurs, keep the Capnospot™ connected to the needle or thoracostomy device, evaluate the clinical condition, and re-assess if needle decompression is indicated. **Remove decompression needle from the patient and repeat product placement with a new decompression needle and Pneumeric™ Capnospot™.**

MONITOR THE PATIENT THROUGHOUT PROCEDURE FOR ANY CONTINUED OCCURRENCES OF RESPIRATORY DISTRESS.

SYMBOLS


Single Use Only

Country of Manufacture (change "CC" to two letter country code)

Medical Device

Unique Device Identifier

Prescription Only


Manufacturer


Importer


Non-Pyrogenic


Biological Risk


Do Not Use If Package Is Damaged


Date of Manufacture

Do Not Resterilize

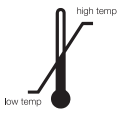

Expiration


Keep Dry

Batch Number


Keep Away From Sunlight


Consult Instructions for Use



Temperature Limitation

Catalog Number

Sterilized with Ethylene Oxide