MEDSOURCE

[redacted]

12ga x 3.25 inch ***Needle Decompression Kit***

REF	LOT
MS-87012	XXXXXXXX

Manufacturing Date YYYYMMDD

Expiry Date YYYYMMDD

Manufactured For:

MedSource
8600 Shelby Court,
Chanhassen, MN 55317, USA

MSL-REG-LQR-9343

N. Code : HP/DEVICE/MFG/MD/2018/000093
AW/IFU_NI, Rev.03

MD STERILE EO

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.

Rx ONLY
MADE IN INDIA
NOT MADE WITH NATURAL RUBBER LATEX

Warning:
Tension Pneumothorax is cirticial 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 any avoiding the cardiac box, avoiding internal organs. Improper use may result in a tension pneumothorax.

Continually monitor patient for:
- Potential bleeding from site
- Potential local hematoma.
- 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

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 midclavicular 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 in intact, Remove the red cap by rotating and pulling the cap away from the case.

Fig. 1

4. Remove the Decompression Needle from case.
5. The skin over the superior border of the third rib, midclavicular line, and direct it into the intercostal space at a 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. Monitor the patient for any continued occurrences of respiratory distress.

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