SAM®
MEDICAL

NEW PRODUCT INTRODUCTION

COMING JANUARY 18

POSITION.
ALIGN.
VENT.

SAM ThoraSite®

KEY TERMS

- **Thoracostomy:** A small incision of the chest wall.
- **Pleural Space:** A thin fluid filled space that surrounds the lungs, separating the lungs from surrounding structures.
- **Intercostal Space (ICS):** The space between two ribs.
- **Axilla:** The region under the shoulder joint where the arm connects to the shoulder (commonly referred to as the armpit).
- **Iliac Crest:** The most prominent portion of the hip bone or bony pelvis.

WHY THORASITE?

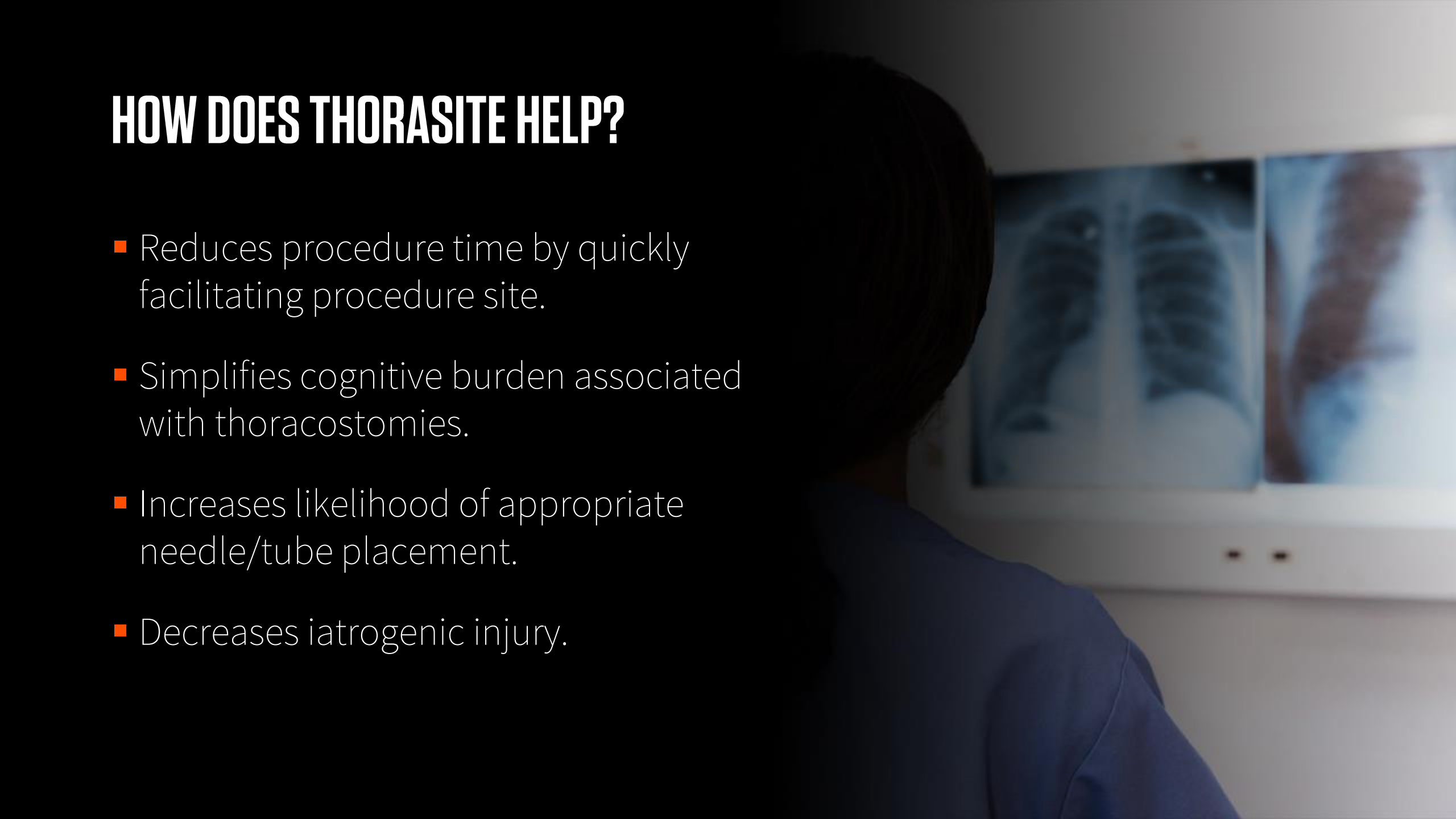
WHAT ARE WE TREATING?

ThoraSite is used when treating life threatening chest injuries or maladies.

Common injuries include collapsed lungs and sucking chest wounds, such as ones caused by stabbings or gunshots.

HOW DOES THORASITE HELP?

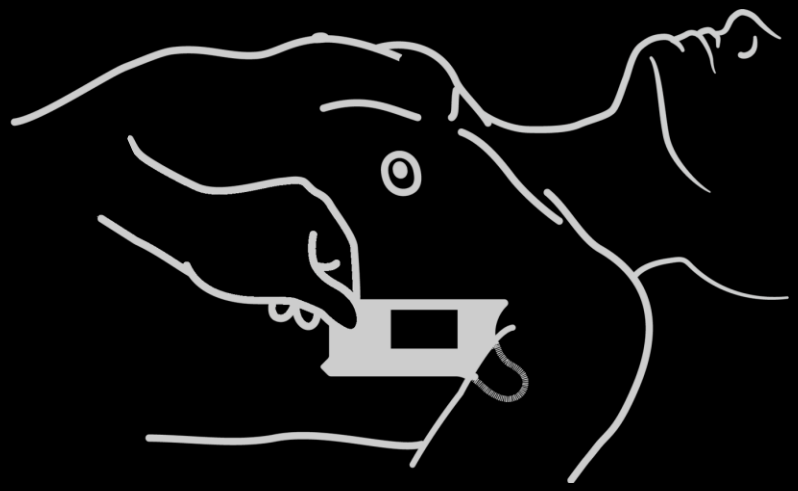
- Reduces procedure time by quickly facilitating procedure site.
- Simplifies cognitive burden associated with thoracostomies.
- Increases likelihood of appropriate needle/tube placement.
- Decreases iatrogenic injury.



SAM THORASITE

PRODUCT DESCRIPTION

ThoraSite is an anatomical landmark guide, designed to provide a safer approach to the pleural space by pinpointing the procedure site. The device aids in identifying the appropriate intercostal space for lateral thoracostomies and similar procedures.



PRODUCT USE

Indication for Use

- Indicated for use by trained professionals following their standard of care to treat patients with pneumothorax, hemothorax and similar conditions requiring a thoracostomy.

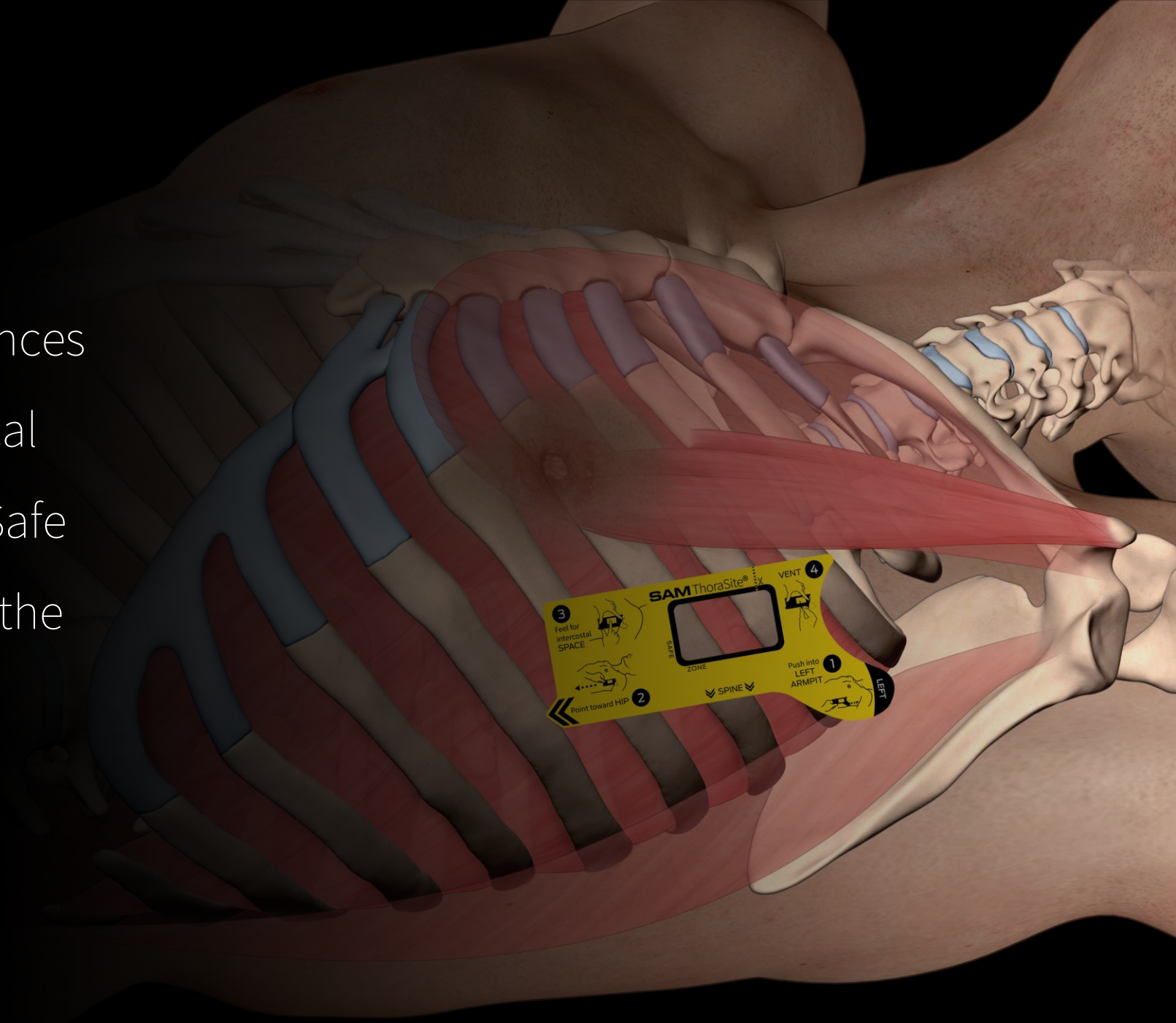
Intended Use

- An anatomical location aid to identify an appropriate location for lateral thoracostomies in adult and adolescent patients. Not intended for pediatric, or neonatal use.
- ThoraSite is non- sterile and intended to be single use.

DEVICE DESIGN

DESIGN RATIONALE

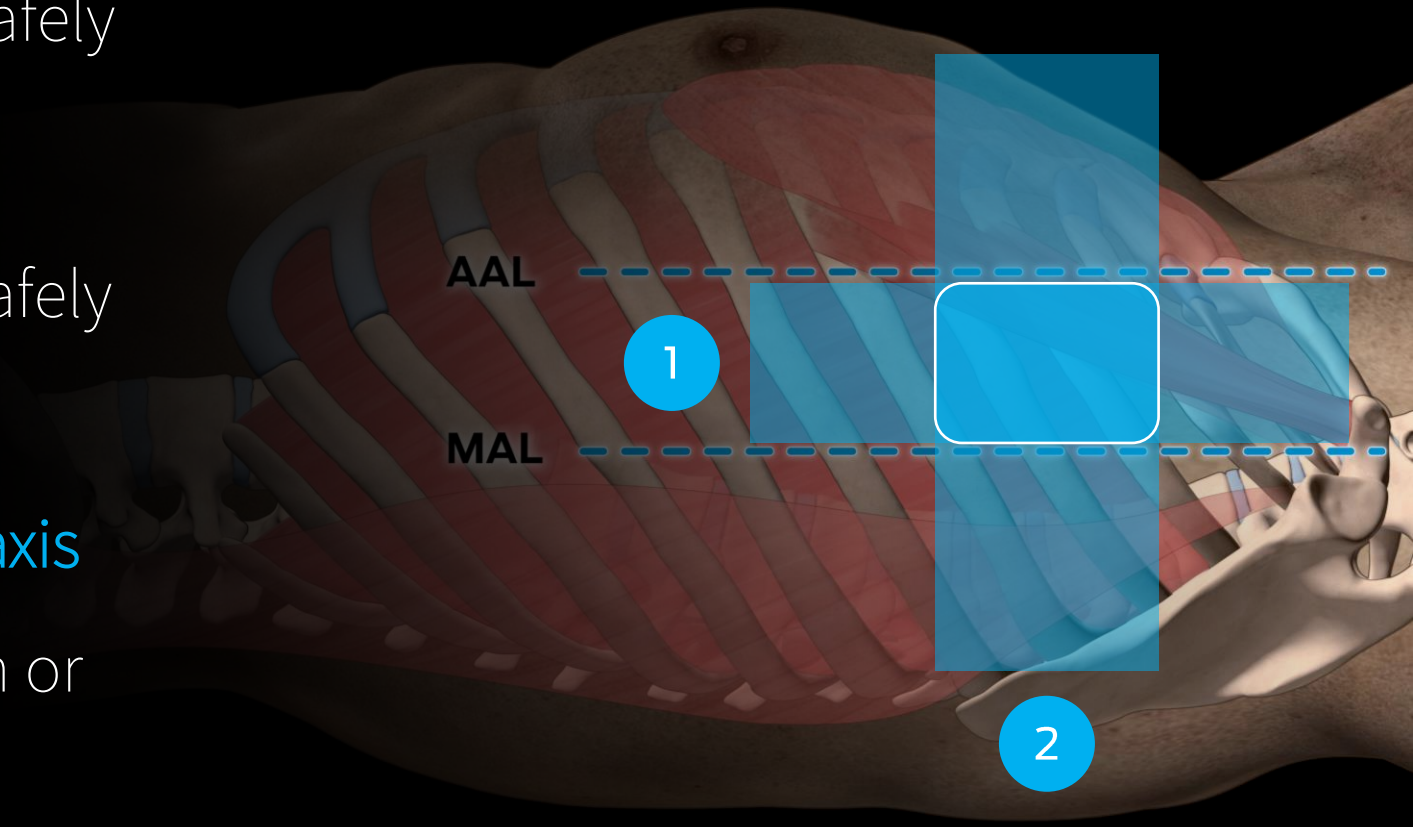
The patented design references the patient's own anatomical landmarks to position the Safe Zone Window directly over the ideal procedure site.



SAFE ZONE PRINCIPAL

The principal utilizes two axes to safely position the device.

The first axis positions ThoraSite safely between the anterior axillary and midaxillary line, while the second axis aligns the window over the 3rd, 4th or 5th intercostal space.

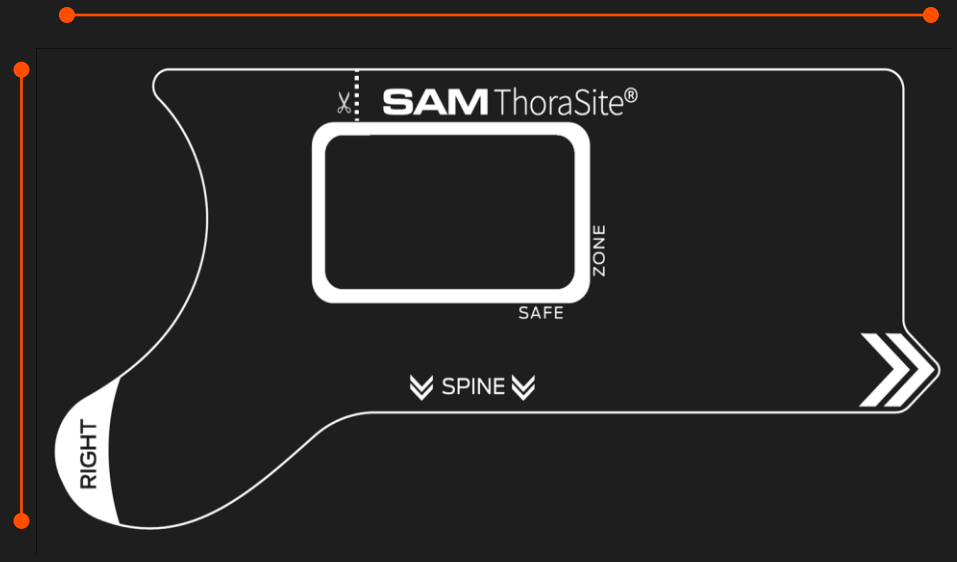


PRODUCT FEATURES

PRODUCT SPECS

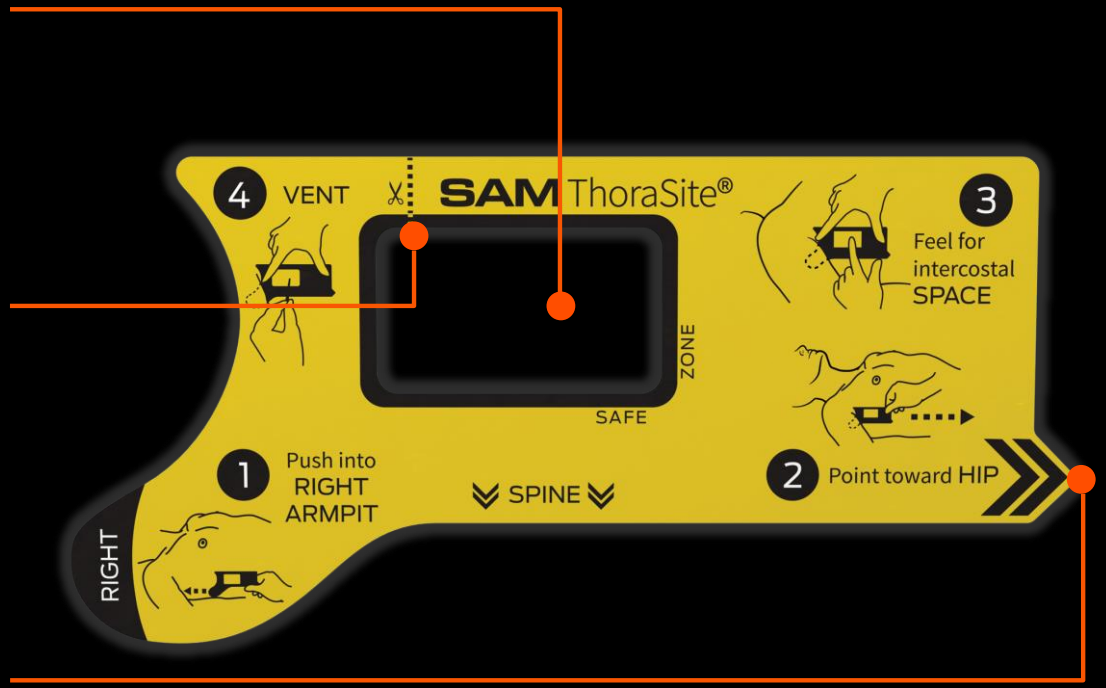
ThoraSite is designed to accommodate a large range of patients' sizes. It is made of a heavyweight cardstock, which is heat treated with a laminate to provide additional durability.

Height | 2.7 in.
Length | 5.6 in.
Weight | .18 oz.



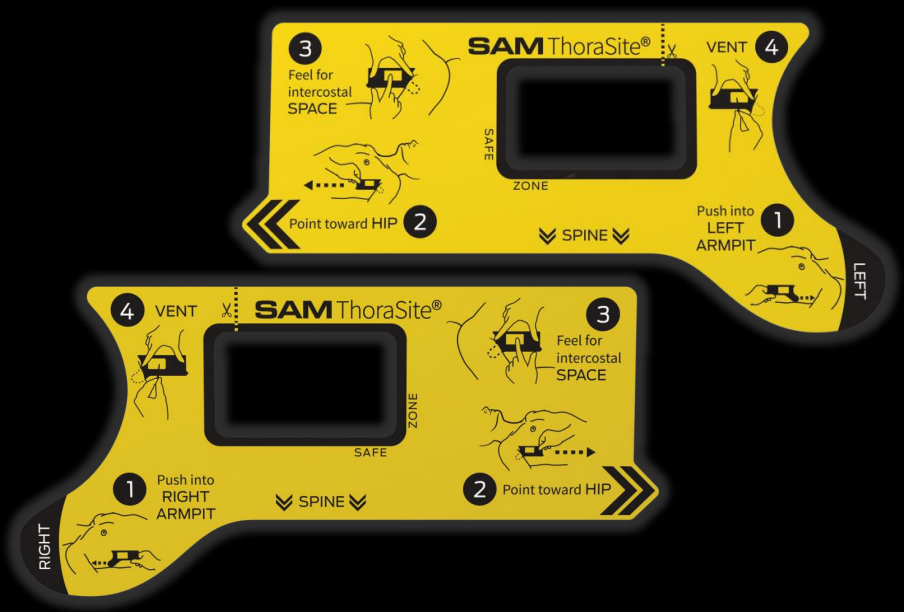
PRODUCT FEATURES

- **Safe Zone Window:** Highlighted alignment area safely guides user to the appropriate procedure site.
- **Perforated Release:** Created for quick removal when discarding to minimize interference with other devices or procedures.
- **Alignment Arrow:** Designed to align the device with the patient's anterior iliac crest/hip.



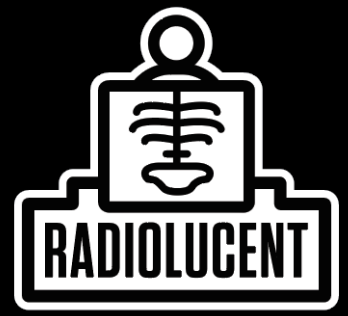
PRODUCT FEATURES (CONT)

- **Axilla Hook:** Developed to be inserted into the patient's axilla for device alignment between the anterior axillary line (AAL) and the midaxillary line (MAL).
- **Bilateral Application:** Dual sided device accommodates procedures on both patients' left and right side.



PRODUCT FEATURES (CONT)

- **Night Vision Optimized:** Developed with HI-VIZ, capabilities the black-yellow contrast is ideal for visibility in low-light or night conditions and is compatible with night vision devices.
- **Radiolucent Material:** Composed of materials compatible with X-rays imaging, eliminating the need for guide removal.



PRODUCT FEATURES (CONT)

- **Durable Flex:** Constructed to bend and adapt to patient anatomy while maintaining the Safe Zone Window spatial integrity.
- **Compact & Compatible:** Easily fits inside IFAKs and is compatible with all thoracostomy devices.

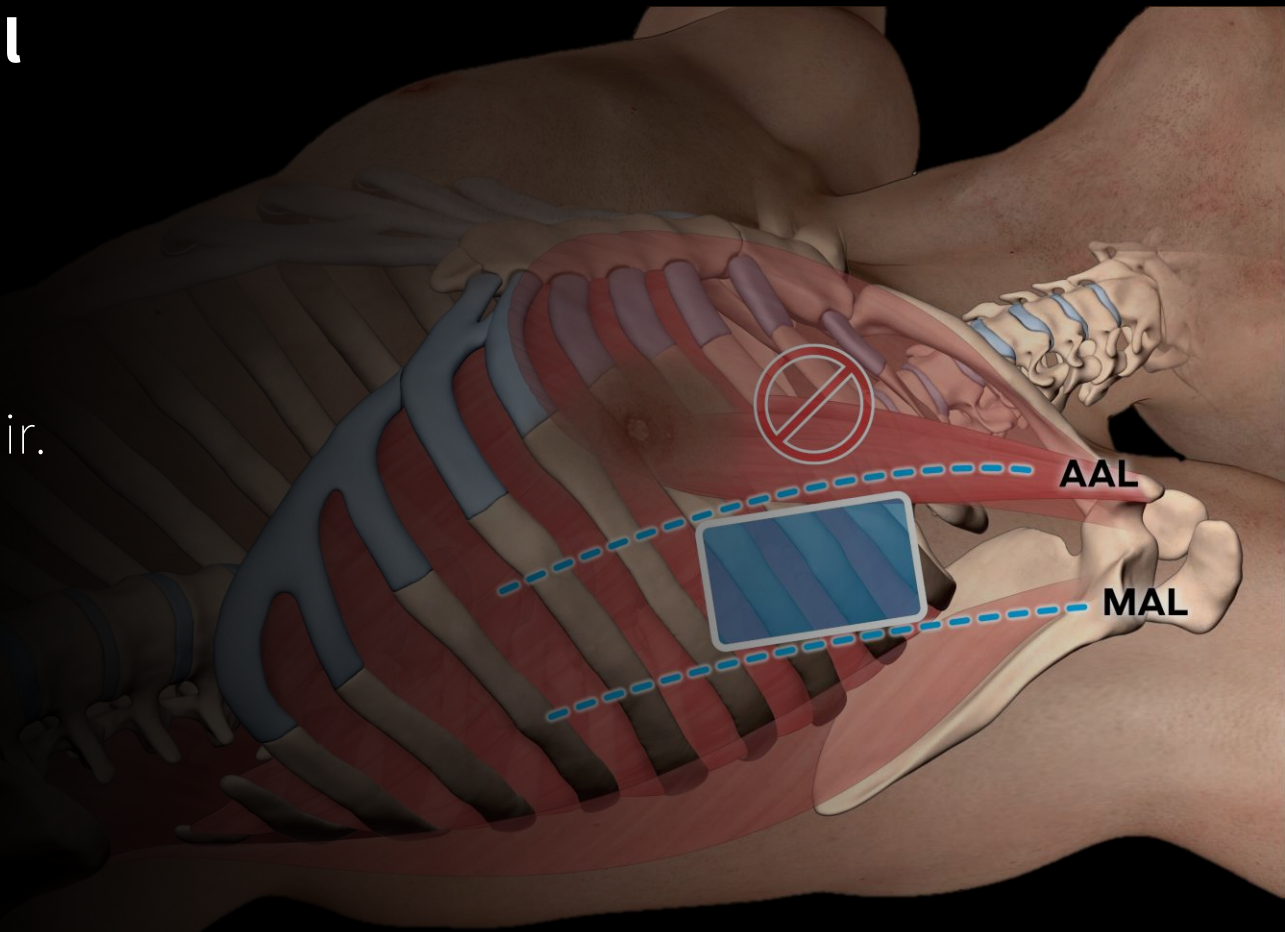
APPLICATION

APPLICATION SITE

ThoraSite is only indicated for a lateral approach.

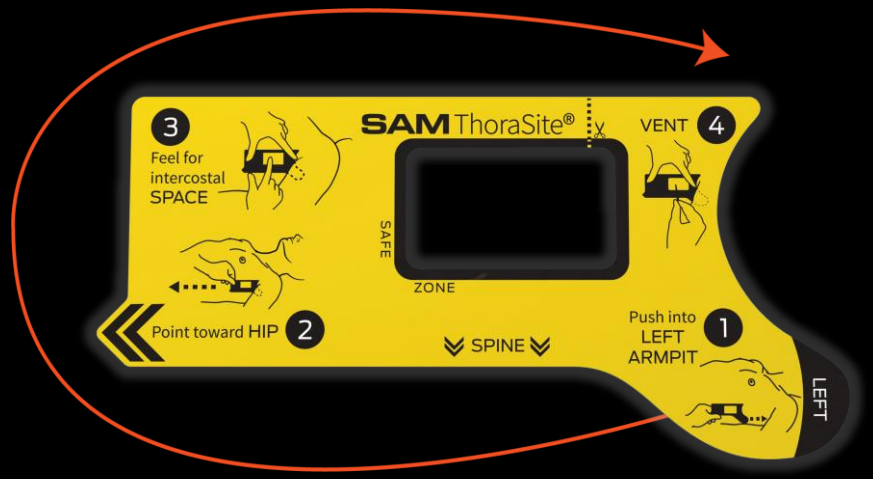
- While the anterior site is most common, it is associated with higher failure rates and only good for needle decompression to remove air.
- Lateral sites have higher success rates and can be used for both needle and tube thoracostomy.

⚠ ThoraSite is not indicated for anterior use.



BILATERAL APPLICATION

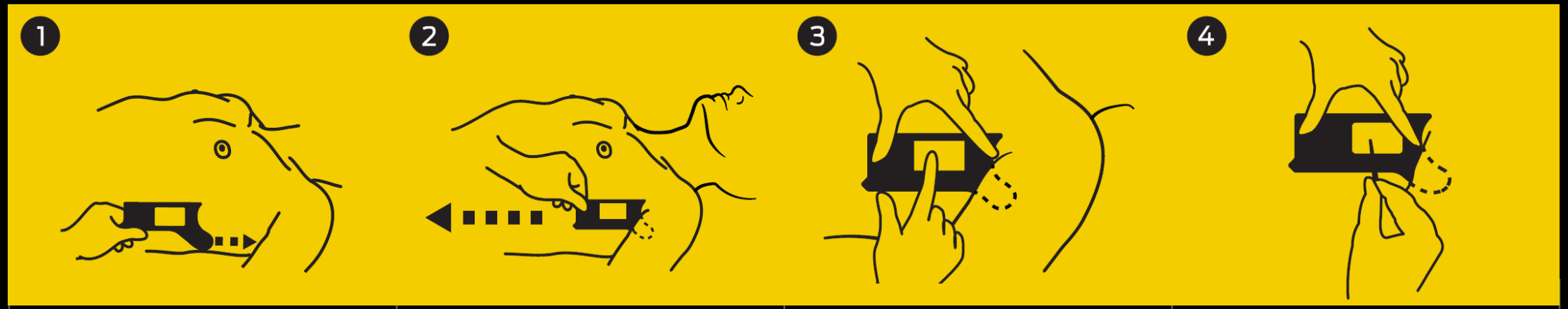
Dual sided device accommodates procedures on both left and right side.



Left | Clockwise Steps

Right | Counterclockwise Steps

INSTRUCTIONS FOR USE



Push Axilla Hook into the armpit until fully inserted into axillary fossa. Note: Keep patient's arm positioned by their side, no greater than 90° upward.	Point Alignment Arrow toward the hip, aligning with iliac crest. Note: Base of the device should be parallel to patient's spine.	Palpate within Safe Zone Window to feel intercostal space (ICS). Note: If two intercostal spaces are identified within the Safe Zone Window, select the upper ICS.	Vent in identified intercostal space within the Safe Zone Window. Note: If ribs cannot be palpated, vent in the center of the Safe Zone Window. If a rib is encountered, redirect above the rib.

PRODUCT LAUNCH

PURCHASING OPTIONS

5pk Bag | TS200-5P-EN

- Case Qty: x5 (25 units)

25pk Box | TS200-25P-EN

- Case Qty: x3 (75 units)

All units come individually bagged in a quick-tear sleeve inside the bulk packaging.

MSRP: $15.00 ea.*

*Device not sold individually

MARKETING COLLATERAL & SUPPORT

- Webpage & Press Kit
- Product Animation Video
- Education & Training Decks
- Sell Sheet & FAQ Sheet
- Social Media Posts
- Press Release

TARGET MARKET

ThoraSite is an expansion of the SAM Respiratory Management Product Line.

Target customers are people providing advanced chest trauma care; in other words, those currently buying SAM Chest Seals.

SUPPORTING TCCC FACTS

- Because of the complications noted at the current site [anterior/midclavicular] for NDC, authors have recommended using the 3rd or 4th ICS at the MAL as an alternate site.[1]
- Moving the decompression site more laterally and slightly inferior to the 4-5th ICS at the anterior axillary line (AAL) would thus be expected to reduce complications resulting from this procedure.[2]
- NDC potentially lifesaving when performed by paramedics in selected civilian trauma patients.[3,4]

INJURY RATES & DATA

- There are an estimated 50,000 needle thoracostomy injuries per year.
- An estimated one in four trauma deaths is directly the result of thoracic injuries, and thoracic trauma is a contributing factor in another 25% of trauma patients who die of their injuries.
- Thoracic trauma is one of the principal causes of combat deaths, making it of great relevance to military combat and operational situations.
- Needle thoracostomies are commonly performed in the prehospital and emergency department setting. The procedure may occur in the operating room or in the emergency department, intensive care unit, or ward.

THORASITE® TREATMENT PRINCIPLES | SUPPORTING LITERATURE

- Kenny L, Teasdale R, Marsh M, McElnay P. Techniques of training in the management of tension pneumothorax: bridging the gap between confidence and competence. Ann Transl Med. 2016;4(12):233. doi:10.21037/atm.2016.05.40

- Goh S, Xu WR, Teo LT. Decompression of tension pneumothoraces in Asian trauma patients: greater success with lateral approach and longer catheter lengths based on computed tomography chest wall measurements. Eur J Trauma Emerg Surg. 2018 Oct;44(5):767-771. doi: 10.1007/s00068-017-0853-z. Epub 2017 Oct 3. PMID: 28975363.

THORASITE® TREATMENT PRINCIPLES | SUPPORTING LITERATURE

- Wernick B, Hon HH, Mubang RN, Cipriano A, Hughes R, Rankin DD, Evans DC, Burfeind WR Jr, Hoey BA, Cipolla J, Galwankar SC, Papadimos TJ, Stawicki SP, Firstenberg MS. Complications of needle thoracostomy: A comprehensive clinical review. Int J Crit Illn Inj Sci. 2015 Jul-Sep;5(3):160-9. doi: 10.4103/2229-5151.164939. PMID: 26557486; PMCID: PMC4613415.

- Beatty, R, Needle Decompression: Size Matters, https://ppemedical.com/, 2018 Dec 6

- Ball CG, Wyrzykowski AD, Kirkpatrick AW, Dente CJ, Nicholas JM, Salomone JP, Rozycki GS, Kortbeek JB, Feliciano DV. Thoracic needle decompression for tension pneumothorax: clinical correlation with catheter length. Can J Surg. 2010 Jun;53(3):184-8. PMID: 20507791; PMCID: PMC2878990.

CITATIONS

1. Riwoe D, Poncia H: Subclavian artery laceration: a serious complication of needle decompression. Emerg Med Australas 2011;23:651-653

2. Inaba K, Branco B, Eckstein M, et al: Optimal positioning for emergent needle thoracostomy: a cadaver-based study. J Trauma 2011;71:1099-1103

3. Davis DP, Pettit K, Rom CD, et al: The safety and efficacy of prehospital needle and tube thoracostomy by aeromedical personnel. Prehosp Emerg Care 2005;9:191-197

4. Eckstein M, Suyehara D: Needle thoracostomy in the prehospital setting. Prehosp Emerg care 1998;2:132-135

SUMMARY

REDUCES PROCEDURE TIME

AIDS IN IDENTIFYING THE APPROPRIATE PROCEDURE SITE

INCREASES LIKELIHOOD OF APPROPRIATE NEEDLE / TUBE PLACEMENT

DECREASES IATROGENIC INJURY

PRODUCT & REGULATORY INFORMATION

U.S. Patent № 10,595,898

ThoraSite is a registered Class 1 device in the United States of America

SAM Medical Products®
12200 SW Tualatin Rd., Ste 200
Tualatin, OR 97062 USA

MD

5-PACK (TS200-5P-EN)
25-PACK (TS200-25P-EN)

ENGINEERED FOR ACCURACY

sammedical.com