

SAM[®]
MEDICAL

POSITION.
ALIGN.
VENT.



SAMThoraSite®

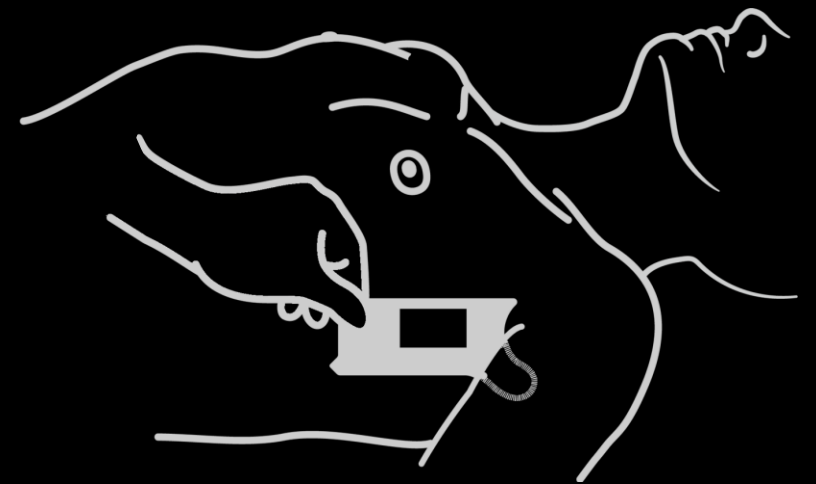
KEY TERMS

- **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 (i.e. armpit).
- **Iliac Crest:** The most prominent portion of the hip bone or bony pelvis.

SAM THORASITE

PRODUCT DESCRIPTION

SAM ThoraSite is an anatomical landmark guide, designed to provide a safer approach to the pleural space by pinpointing the procedure site.^{1,2} 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.
- SAM ThoraSite is non-sterile and intended to be single use.

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 those caused by stabbings or gunshots.



HOW DOES THORASITE HELP?

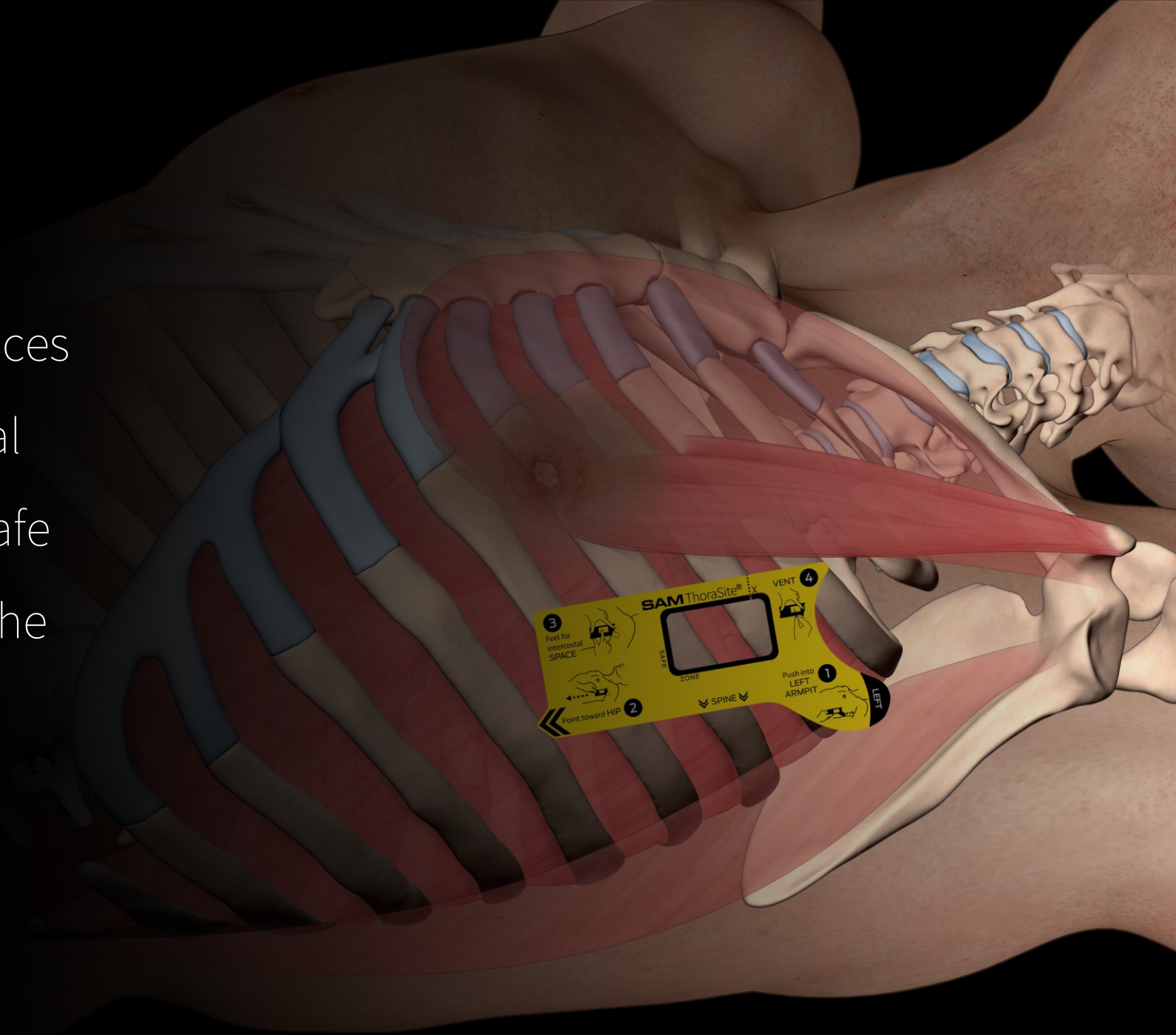
- Facilitates rapid identification of landmarks & procedure site.
- Simplifies cognitive burden associated with thoracostomies.
- Increases likelihood of appropriate needle/tube placement.¹
- Decreases potential of iatrogenic injury.²



DEVICE DESIGN

DESIGN RATIONALE

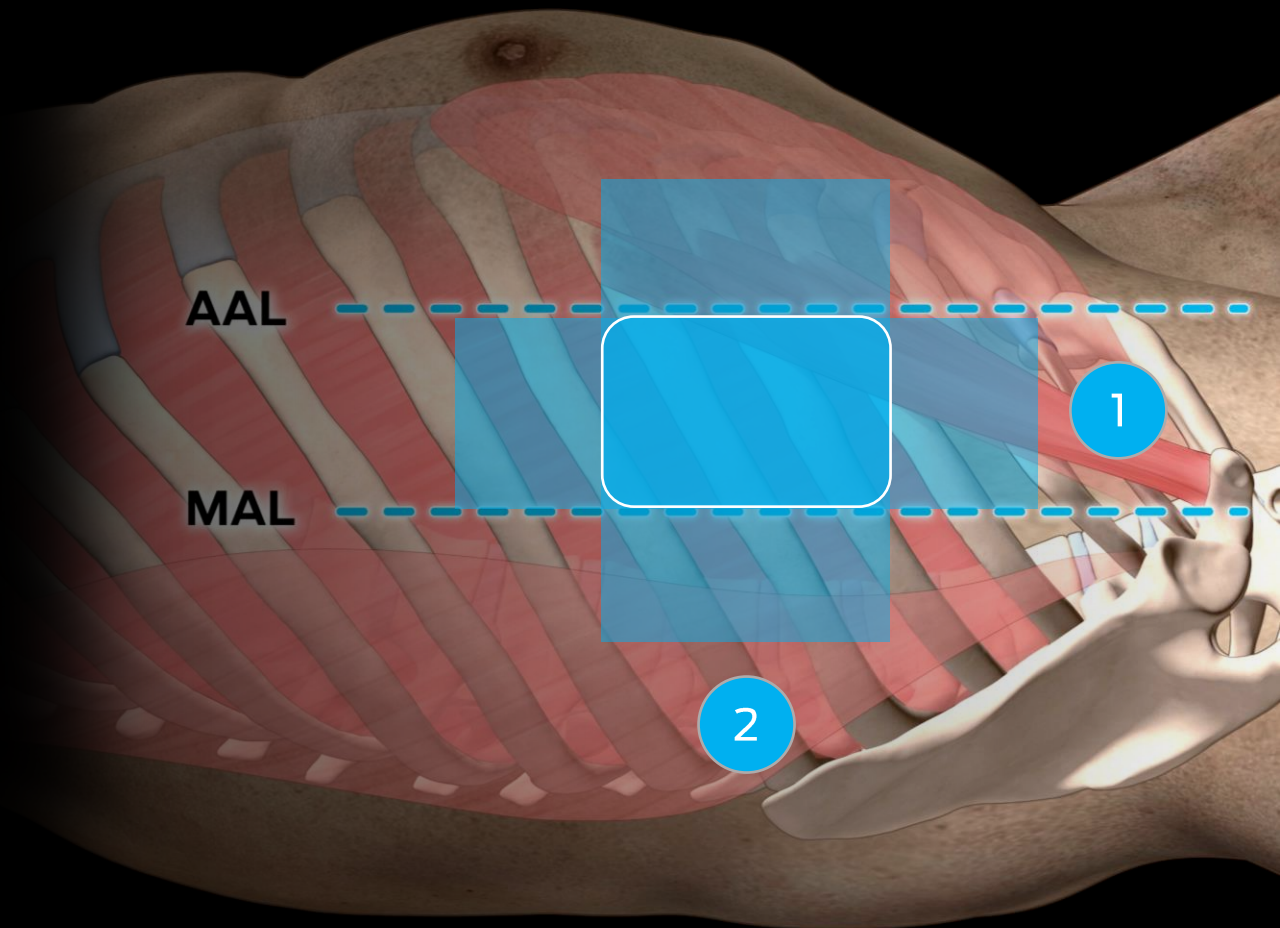
The patented design references the patient's own anatomical landmarks to position the Safe Zone Window directly over the ideal procedure site.



SAFE ZONE PRINCIPLE

The principle 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.



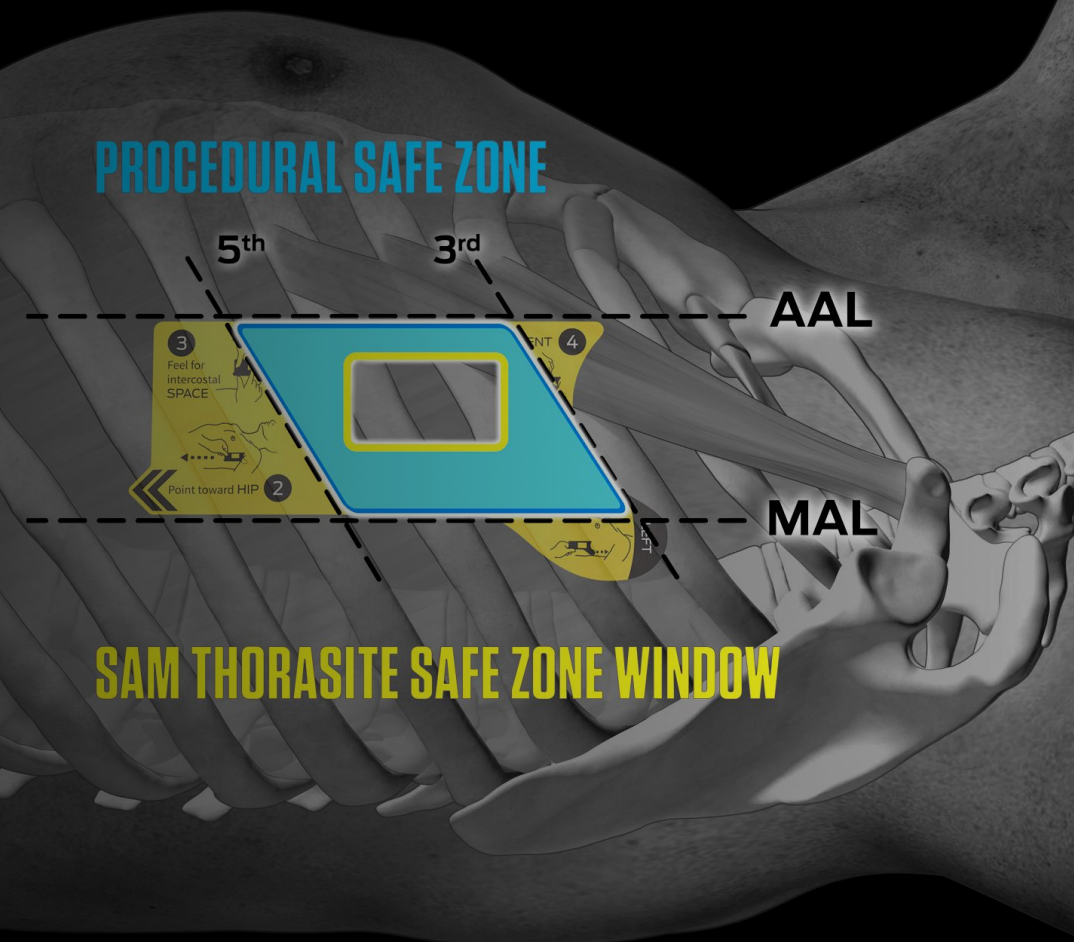
SAFE ZONE vs. SAFE ZONE WINDOW

Safe Zone

- The **Procedural Safe Zone** is between the anterior axillary (AAL) and midaxillary line (MAL) and the 3rd to 5th ICS

Safe Zone Window

- ThoaSite's **Safe Zone Window** is positioned within the procedure zone



PRODUCT FEATURES

PRODUCT SPECS

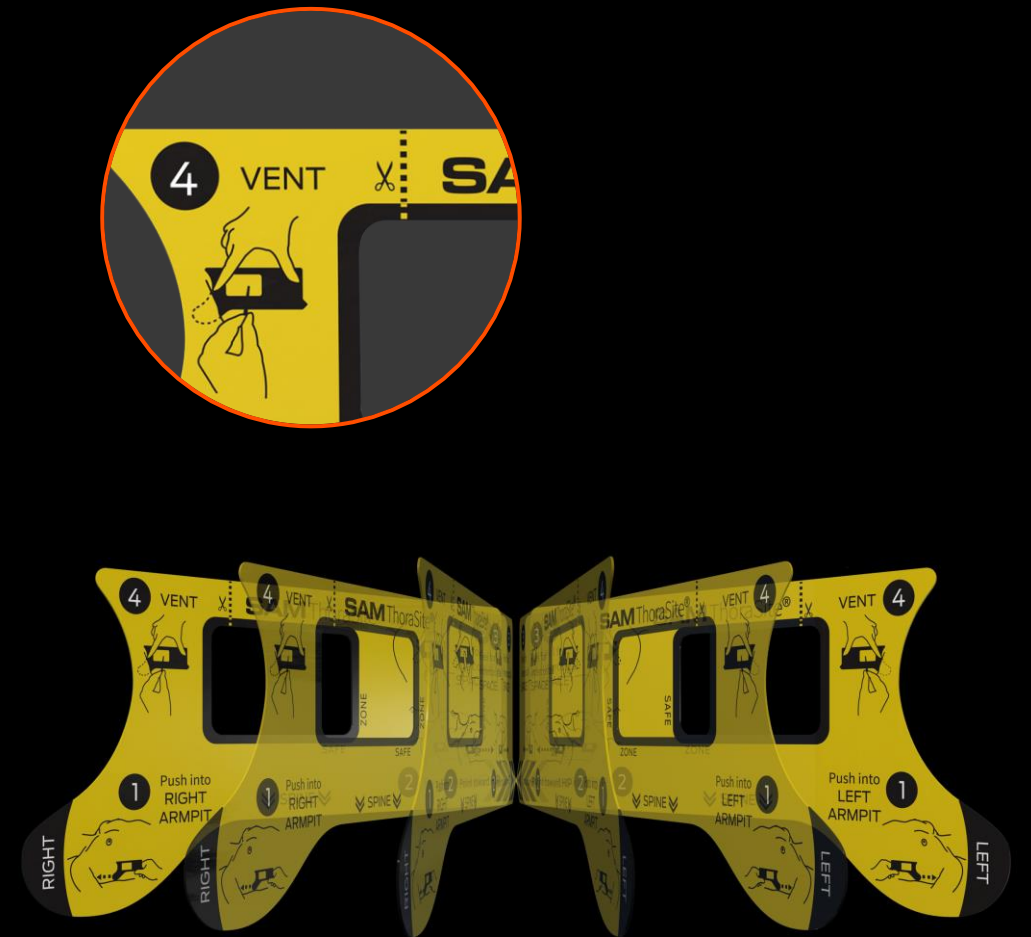
ThoraSite is designed to accommodate a large range of patient sizes. It is made of a heavyweight cardstock, which is laminated to provide additional durability.

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



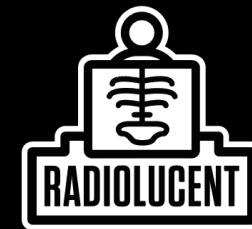
PRODUCT FEATURES (CONT)

- **Perforated Release:** Created for quick removal when discarding to minimize interference with other devices or procedures.
- **Bilateral Application:** Dual-sided device accommodates procedures on both patient's 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-ray 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 thoracostomy devices.



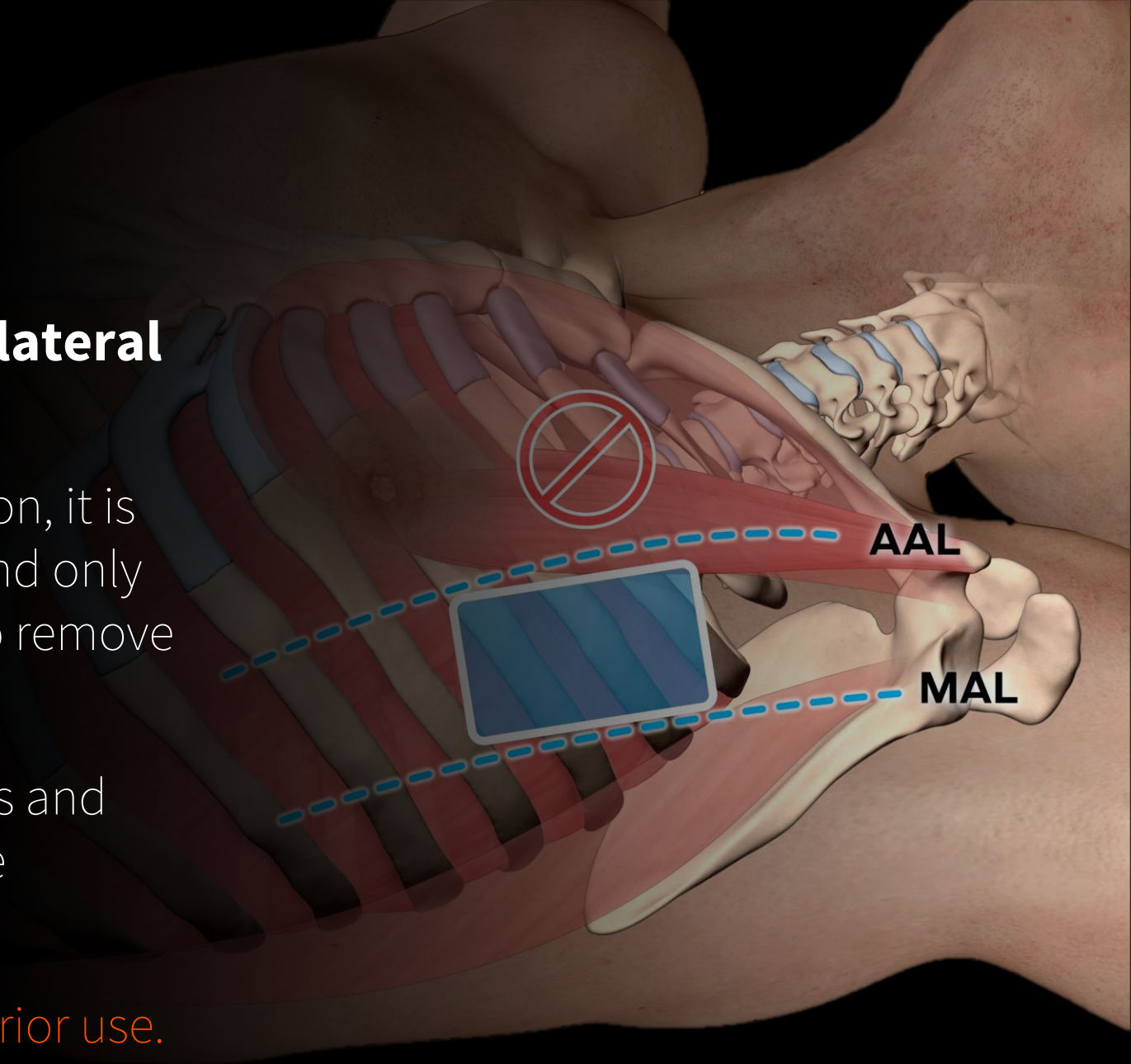
APPLICATION

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 suitable for needle decompression to remove air.
- Lateral sites have higher success rates and can be used for both a needle or tube thoracostomy.

⚠ ThoraSite is not indicated for anterior use.



BILATERAL APPLICATION

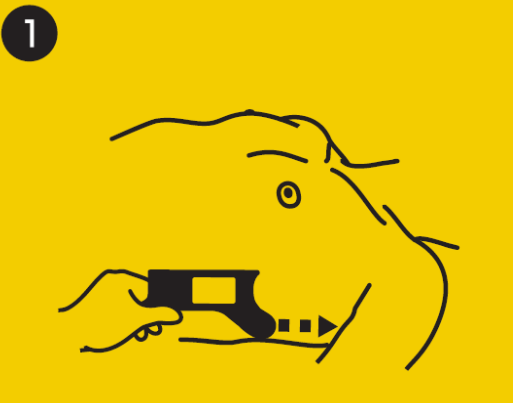
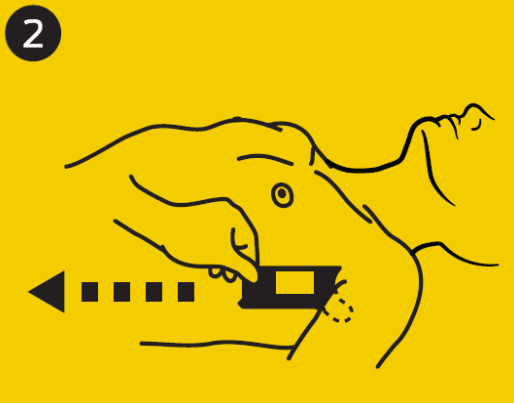
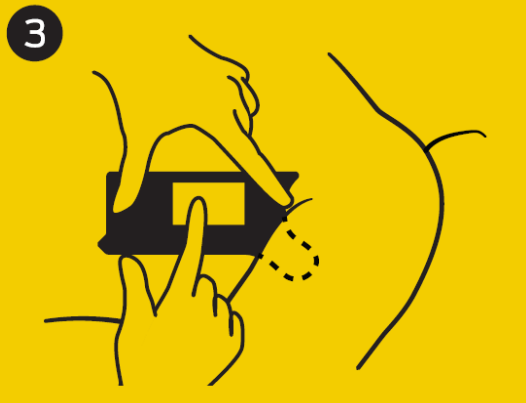

Dual-sided device accommodates procedures on both left and right side.



Left | Clockwise Steps

Right | Counterclockwise Steps

INSTRUCTIONS FOR USE

 <p>1</p>	 <p>2</p>	 <p>3</p>	 <p>4</p>
<p>Push Axilla Hook into the armpit until fully inserted into axillary fossa.</p> <p>Note: Keep patient's arm positioned by their side, no greater than 90° upward.</p>	<p>Point Alignment Arrow toward the hip, aligning with iliac crest.</p> <p>Note: Base of the device should be parallel to patient's spine.</p>	<p>Palpate within Safe Zone Window to feel intercostal space (ICS).</p> <p>Note: If two intercostal spaces are identified within the Safe Zone Window, select the upper ICS.</p>	<p>Vent in identified intercostal space within the Safe Zone Window.</p> <p>Note: If ribs cannot be palpated, vent in the center of the Safe Zone Window. If a rib is encountered, redirect above the rib.</p>

A person is lying on their back, receiving medical training. A person wearing a black glove is applying a SAM thorasite to the chest area. The background is dark and out of focus.

SAM THORASITE TRAINING

SAM[®]
MEDICAL

KEY LANDMARKS

PATIENT CONSIDERATIONS

Surface landmarks change location due to gender, age, body mass, and surgical procedures.



AXILLARY LINES

The Anterior and Mid Axillary lines are often hard to discern due to the uniqueness of each person's body.



AXILLARY LINES

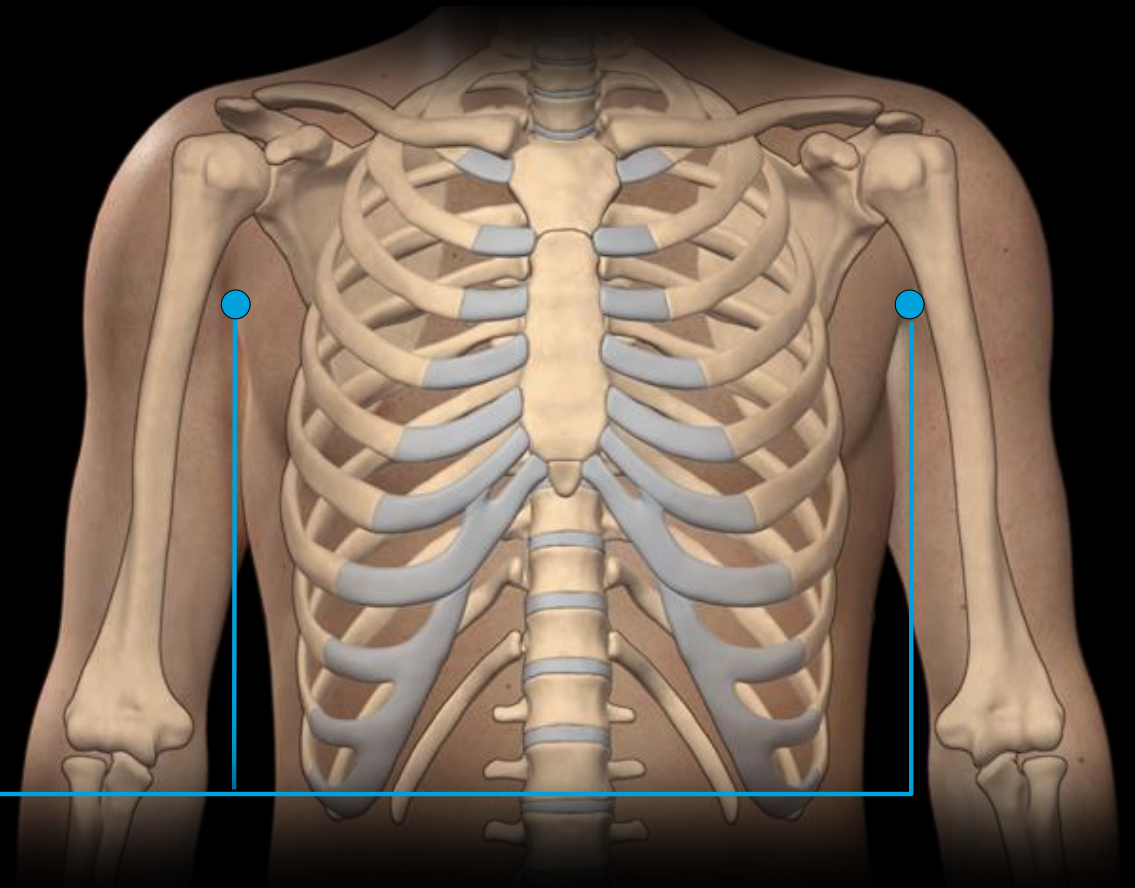
Proper thoracostomy site selection is further complicated due to excessive skin, skin folds, adipose, muscle, breast tissue sag, and nipple location creep.



AXILLA

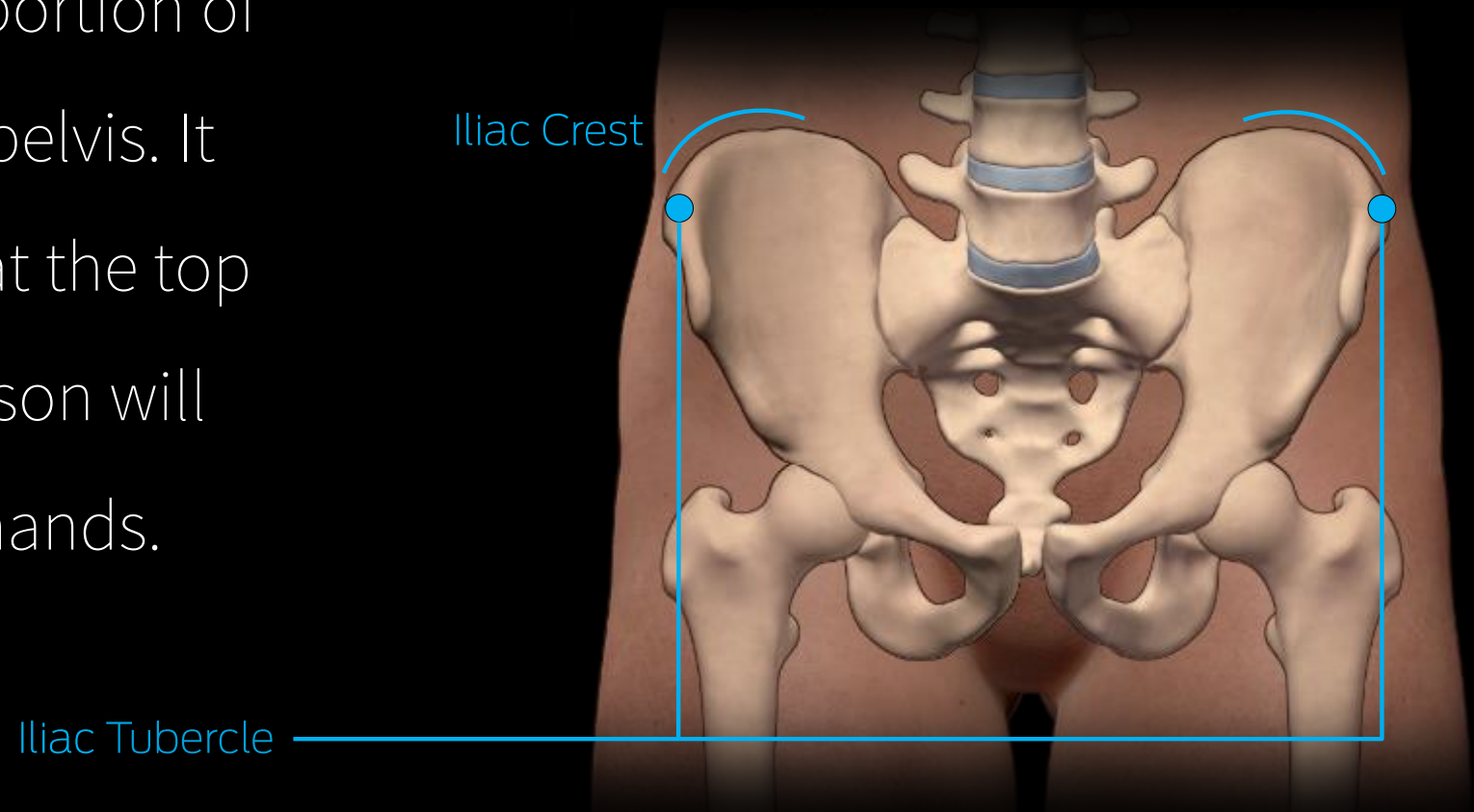
The anatomical region under the shoulder joint where the arm connects to the shoulder.

Axillary Fossa



ILIAC CREST

The most prominent portion of the hip bone or bony pelvis. It is the curved portion at the top of the hip where a person will sometimes rest their hands.



COMMON CHEST MALADIES

KEY TERMS

- **Tension Pneumothorax:** When air is trapped between the pleura and chest wall, a potentially life-threatening condition.
- **Pneumothorax:** The collapse of one or more portions of one or both lungs.

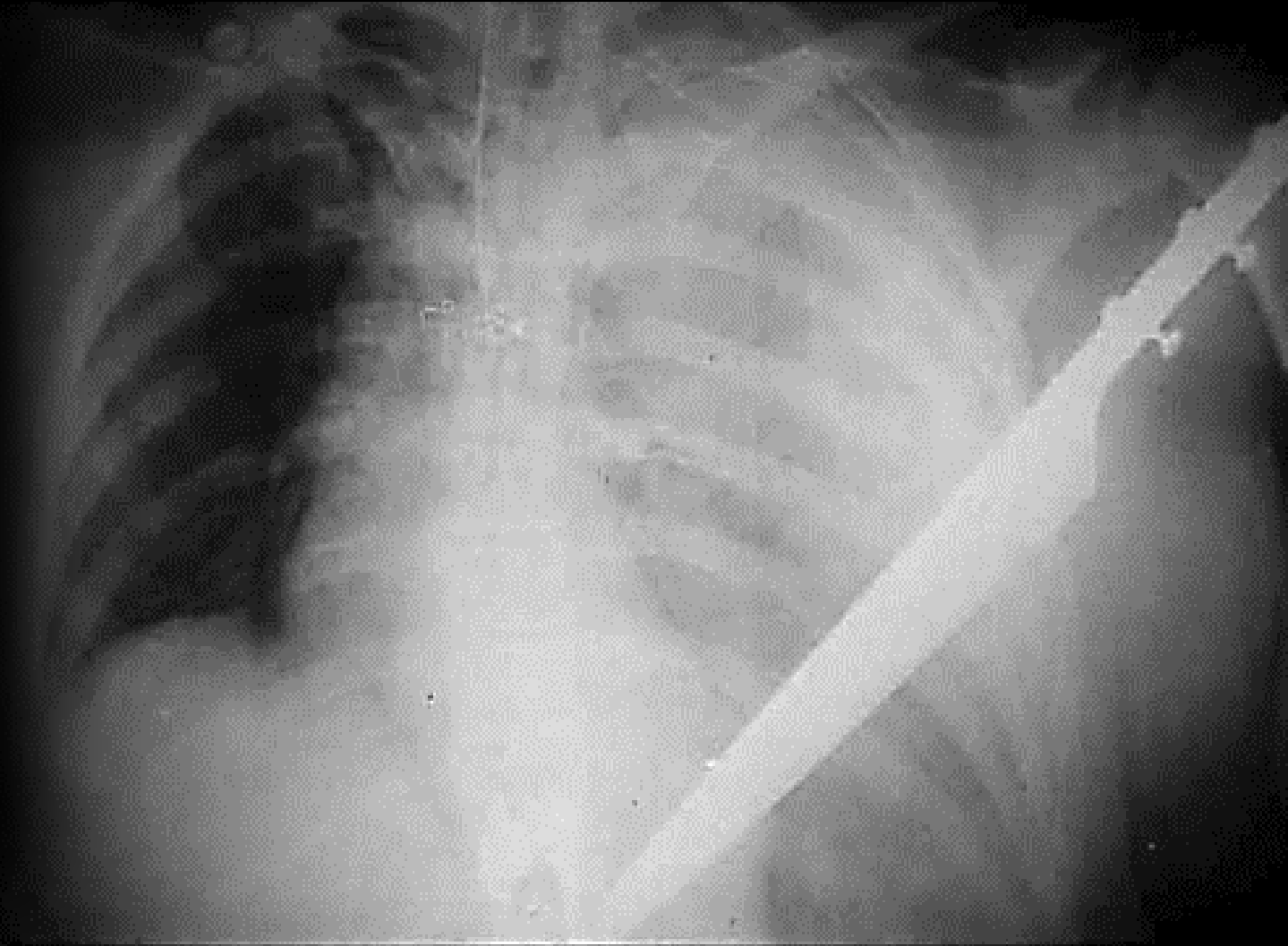


MEDICAL CAUSES

- **Adhesion:** Tissue sticking to other tissue.
- **Bleb:** A collection of air between the Pleura, usually the upper lobe. When ruptured the Bleb causes a pneumothorax.
- **Spontaneous Event:** Sudden onset of a collapsed lung without any apparent cause. Can be caused by tissue rupture, tear, infection, other.
- **Excessive Positive Pressure:** Leading cause is from intubated patient with excessive ventilatory pressure.
- **Over-pressurization:** Blast injuries due to excessive positive and negative pressure gradients.

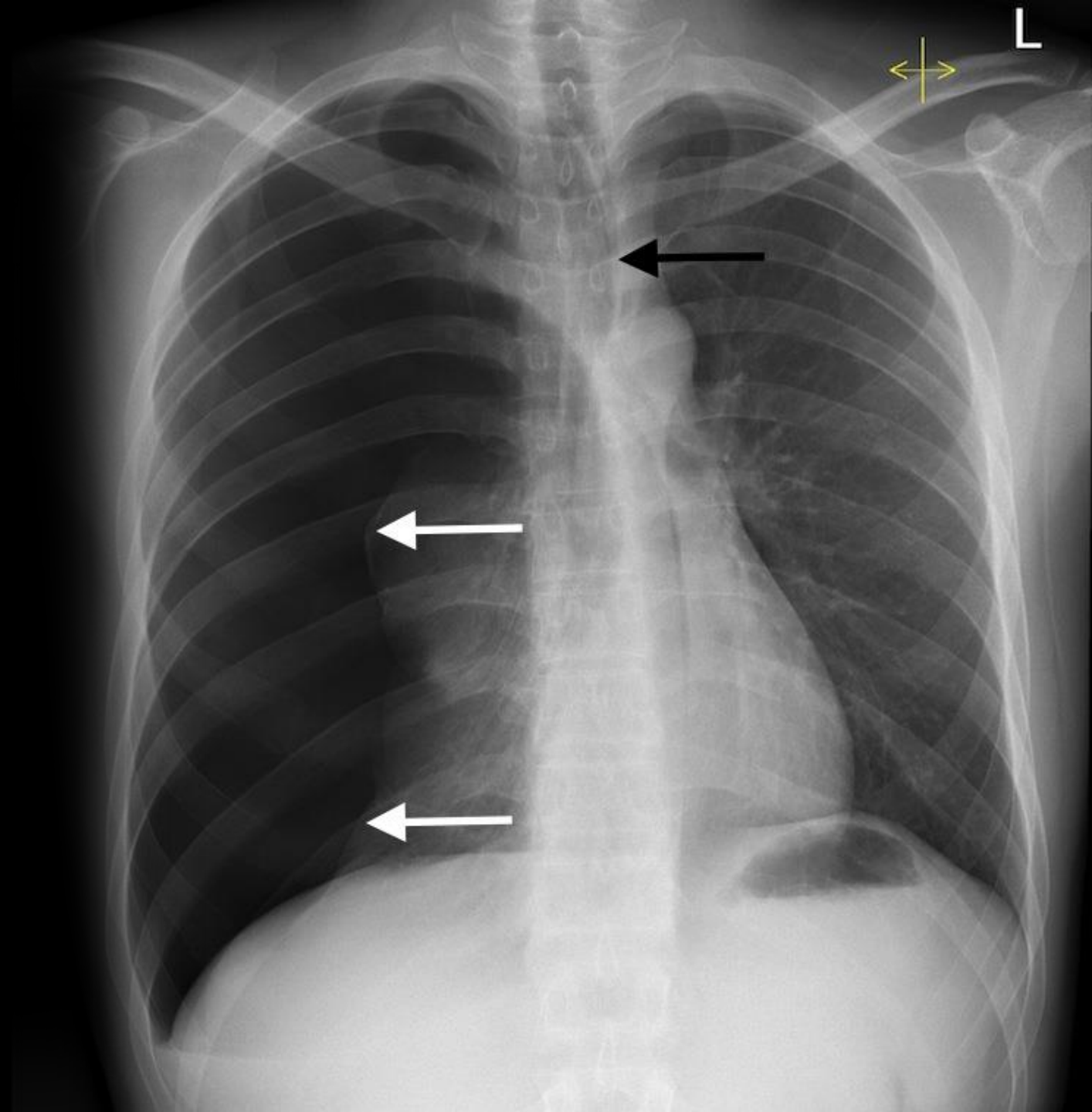
COMMON OPEN

- External Source
 - Bullet, knife, shrapnel
- Blast Injury
 - Shrapnel



COMMON CLOSED

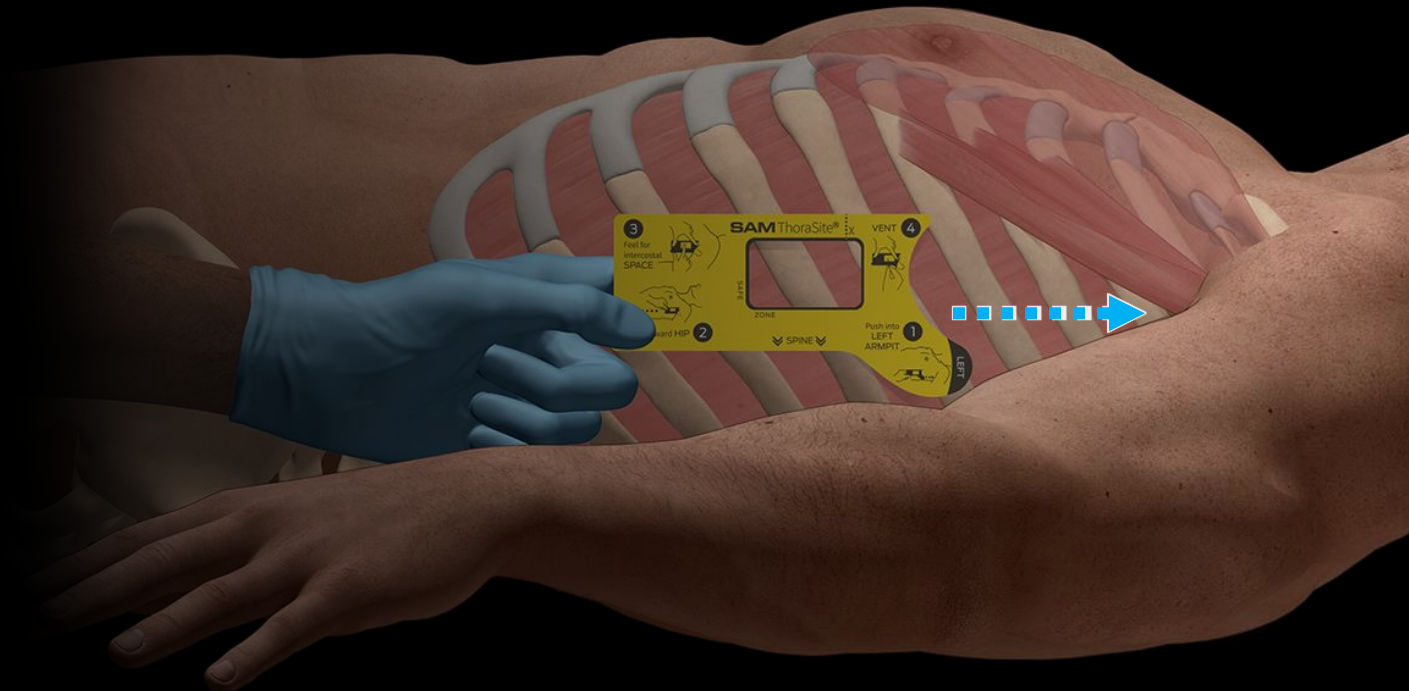
- Blunt Trauma
 - Internal Puncture Injury
 - Rupture
- Penetration Lung Trauma
 - Internal Source (ex: fractured rib)



APPLICATION | TIPS & PEARLS

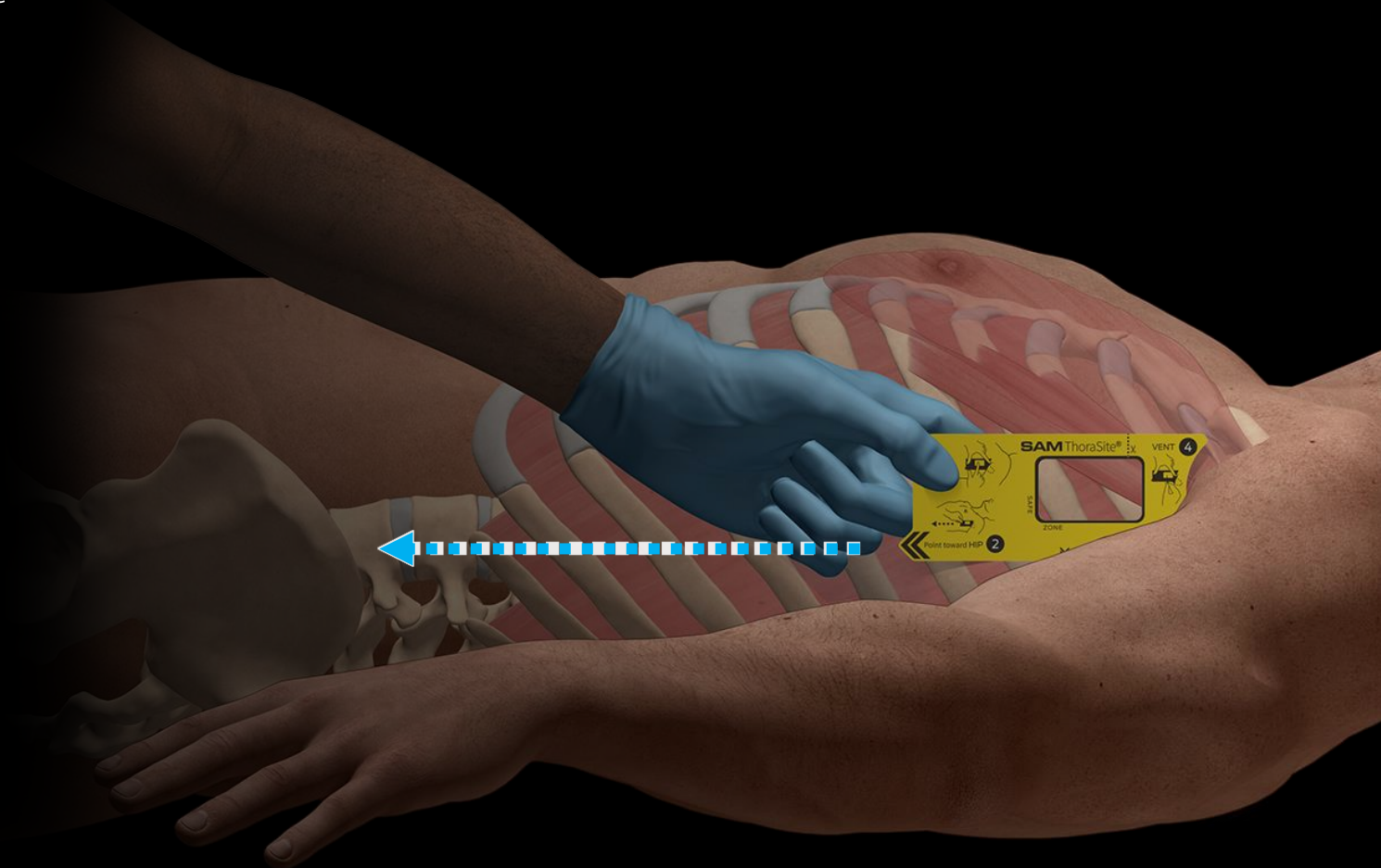
1. POSITION

- Grasp SAM ThoraSite near **2**
- Following the rib cage, push SAM ThoraSite into the Arm Pit until the Axilla Hook is fully inserted into Axillary Fossa



2. ALIGN

- Point SAM ThoraSite's alignment arrow toward the Iliac Crest
- Align the device parallel with the patient's spine



4. VENT

- Within the Safe Zone Window place the needle/tube at the selected Intercostal Space (ICS)

- Hold needle 90° to the chest wall

If unable to palpate the ICS, place needle in the middle of the Safe Zone Window.

If the needle contacts the rib, move the needle over the top into the ICS.



COMMON THORACOSTOMY COMPLICATIONS

- Lack of clinical improvement ³
- Failure to penetrate the plural space – improper needle length ^{2,3,4,}
- Ineffective drainage ³
- Misplaced tubes or needles ⁶
- Iatrogenic injury to other organs or structures ³

RESULTS

- In emergency situations providers often consume valuable time counting ribs. In time-sensitive situations, there needs to be a simplified, efficient solution to identify the appropriate intercostal spaces.
- ThoraSite was developed to address this problem, streamlining lateral thoracostomy procedures.

RESULTS

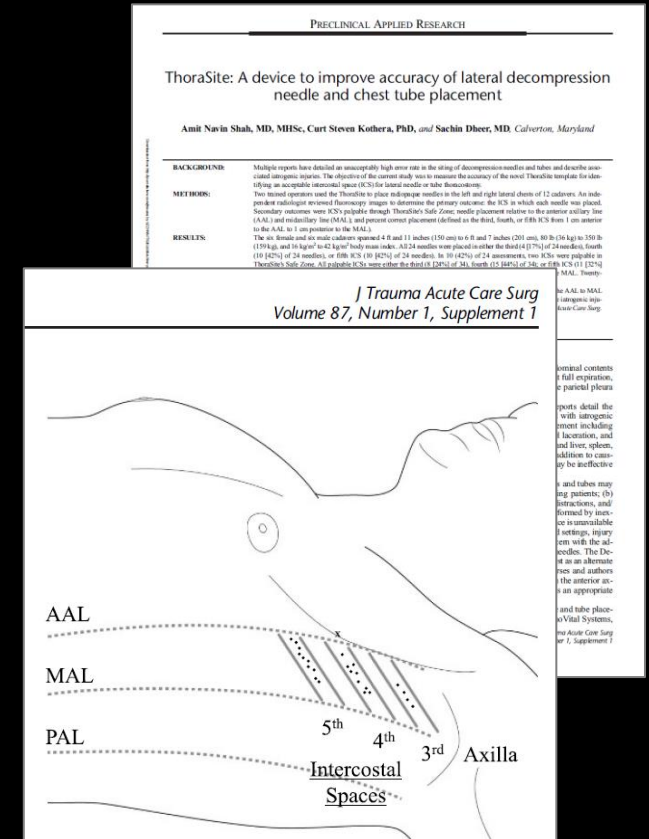
CADAVERIC RESULTS

All needles were placed in either the 3rd, 4th, or 5th ICS.

Ninety-six percent (96%) of needles were accurately placed.

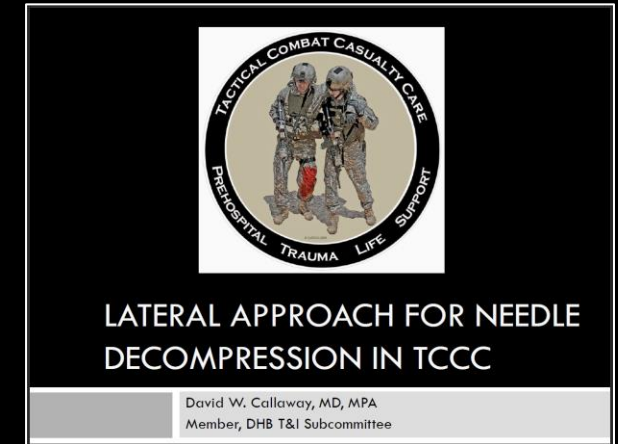
CONCLUSION

ThoraSite use was associated with needle placement in the third, fourth, or fifth ICS in an area roughly spanning the AAL to MAL in anatomically diverse cadavers. By facilitating appropriate needle/tube placement, ThoraSite use may decrease iatrogenic injuries.



SUPPORTING TCCC FACTS

- Because of the complications noted at the current site [anterior/midclavicular] for needle decompression (NDC), authors have recommended using the 3rd or 4th ICS at the MAL as an alternate site.⁷
- Moving the decompression site more laterally and slightly inferior to the 4th-5th ICS at the anterior axillary line (AAL) would thus be expected to reduce complications resulting from this procedure.⁸
- Needle decompression is potentially lifesaving when performed by paramedics in selected civilian trauma patients.^{9, 10}



SUMMARY

FACILITATES QUICK PROCEDURE TIME

AIDS IN IDENTIFYING THE APPROPRIATE PROCEDURE SITE

INCREASES LIKELIHOOD OF APPROPRIATE NEEDLE / TUBE PLACEMENT

DECREASES IATROGENIC INJURY

PURCHASING OPTIONS

Sold in either a 5-Pack bag or 25-Pack box, each device comes individually bagged in a quick-tear sleeve inside the bulk packaging. Currently ThoraSite is not sold individually, and is not intended for individual unit resale.

5 PACK BAG | TS200-5P-EN

- **Description:** Plastic reclosable bag containing five SAM ThoraSite® units and one Instructions for Use (IFU).
- **Case Quantity:** Five 5-Packs
- **NSN:** 6515-01-694-8359



25 PACK BOX | TS200-25P-EN

- **Description:** Lightweight cardboard reclosable carton containing twenty-five SAM ThoraSite® units and one Instructions for Use (IFU).
- **Case Quantity:** Three 25-Packs



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. Shah, Amit Navin MD, MHSc; Kothera, Curt Steven PhD; Dheer, Sachin MD. *ThoraSite: A device to improve accuracy of lateral decompression needle and chest tube placement*. Journal of Trauma and Acute Care Surgery. 2019;87(1S):S128-S131.
2. 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
3. Aylwin CJ, Brohi K, Davies GD, Walsh MS. *Pre-hospital and in-hospital thoracostomy: indications and complications*. Ann R Coll Surg Engl. 2008 Jan;90(1):54-7
4. Kaserer A, Stein P, Simmen HP, Spahn DR, Neuhaus V. *Failure rate of prehospital chest decompression after severe thoracic trauma*. Am J Emerg Med. 2017 Mar;35(3):469-474
5. Escott ME, Gleisberg GR, Kimmel K, Karrer A, Cospers J, Monroe BJ. *Simple thoracostomy. Moving beyond needle decompression in traumatic cardiac arrest*. JEMS. 2014 Apr;39(4):26-32

CITATIONS

6. Carter P, Conroy S, Blakeney J, Sood B. *Identifying the site for intercostal catheter insertion in the emergency department: is clinical examination reliable?* Emerg Med Australas. 2014 Oct;26(5):450-4
7. Riwoe D, Poncia H: *Subclavian artery laceration: a serious complication of needle decompression.* Emerg Med Australas 2011;23:651-653
8. Inaba K, Branco B, Eckstein M, et al: *Optimal positioning for emergent needle thoracostomy: a cadaver-based study.* J Trauma 2011;71:1099-1103
9. 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
10. Eckstein M, Suyehara D: *Needle thoracostomy in the prehospital setting.* Prehosp Emerg care 1998;2:132-13

PRODUCT & REGULATORY INFORMATION

U.S. Patent N^o 10,595,898

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



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



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

sammedical.com

ENGINEERED FOR ACCURACY

