

SternaLock® Blu



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The SternaLock® Blu system

Indicated for stabilization and fixation of fractures of the anterior chest wall following a sternotomy or stern reconstructive procedures.

Clinical Outcomes**

SternaLock Blu vs. Wire

- Improved Healing¹
- Fewer Sternal Complications¹
- Improved Patient Recovery¹
- Economically Dominant Solutions¹

Mechanical Performance

SternaLock Blu vs. Wire

- Increased Mechanical Stability²
- Increased Strength²
- Reduced Sternal Separation²



****Clinical outcomes results are based off the SternaLock Blu Study**

SternaLock Blu Brochure (00-3265).

1. CR 0712S (Clinical Study Report) SternaLock Blu Study, 2014-15, an evaluation of rigid plate fixation in supporting bone healing: a prospective, multi-center trial of 236 total patients undergoing full midline sternotomy.

2. Internal Testing Report, LT1533, Comparison of SternaLock 360 and wires in lateral testing

System Overview

Product Container



SternaLock Blu Container



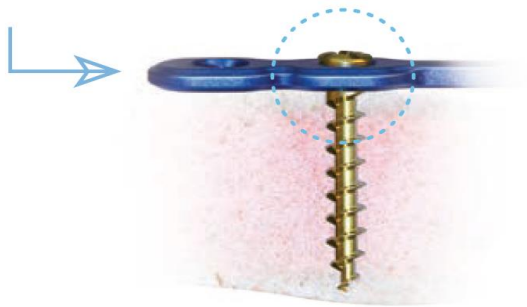
SternaLock Blu Implant Tray

SternaLock Blu Brochure (00-3265).

Plates

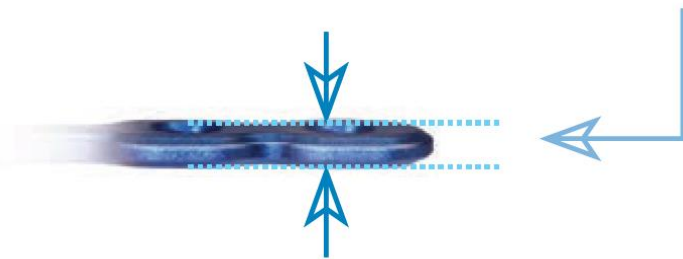
Innovative Locking Technology

Screw heads lock into the plate while the tip engages the posterior cortex of the sternum.



Low Profile Implant Design

The low profile of 1.6mm plates allow for the plate to be easily contoured to sternum and limited palpability.



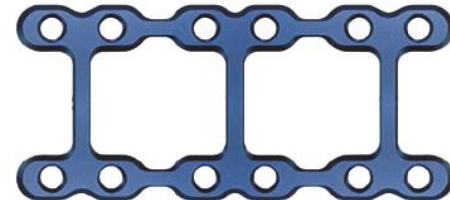
Variety of Plate Designs



4-Hole, L Plate, 100°
73-2643



8-Hole, X Plate
73-2623



12-Hole, Wide Ladder Plate
71-2634



4-Hole, Square Plate
73-2622



12-Hole, Ladder Plate
73-2632

Useful for mini-
sternotomies



8-Hole, JL Plate
73-2645

Use these plates ONLY
for mini-thoracotomies



4-Hole, Straight Plate
73-2636

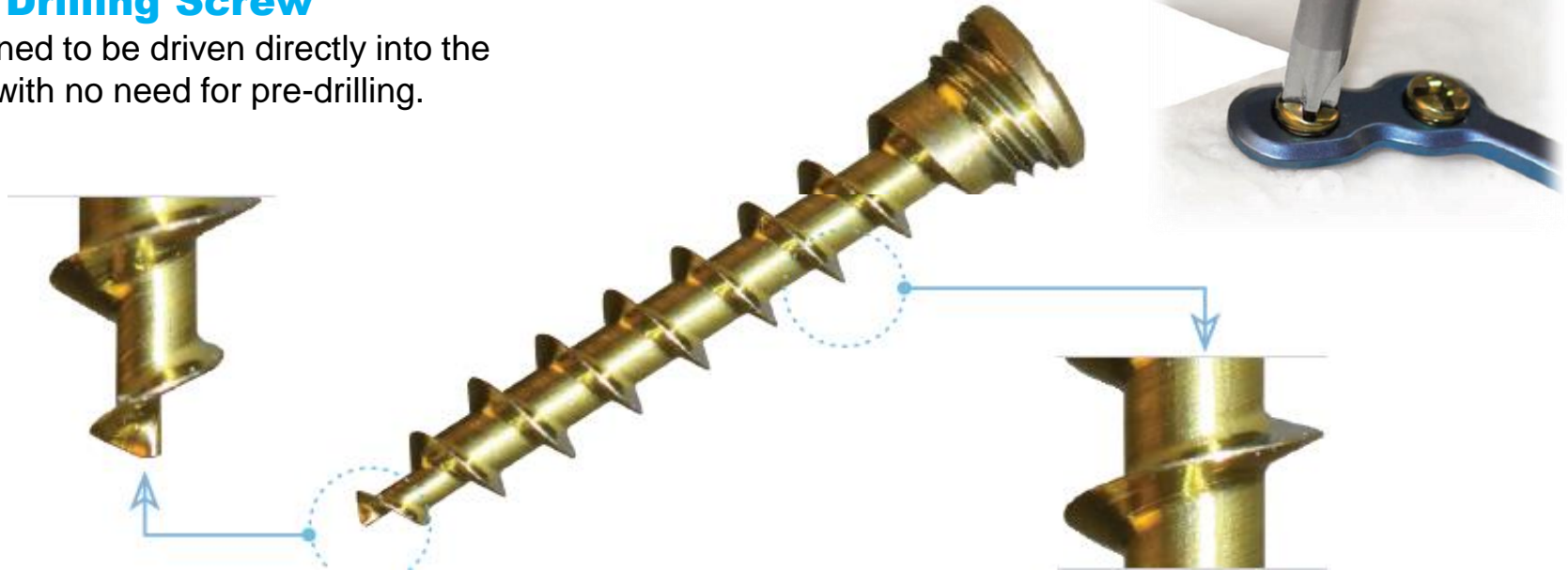


8-Hole, Straight Plate
SP-1952

Screws

Self Drilling Screw

Designed to be driven directly into the bone with no need for pre-drilling.



Cancellous Screw Design

Deeper screw threads provide optimal engagement into the cancellous bone of the chest wall.

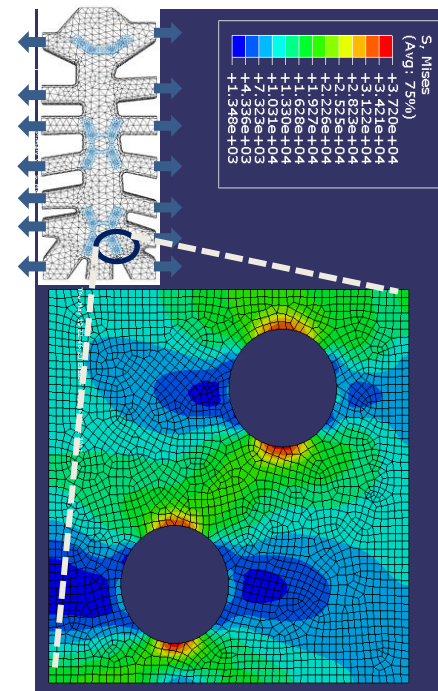
Cancellous Screw Features

- Longer thread depth (.635 mm)
- Longer thread pitch (1.6mm)
- Narrower minor diameter (1.3mm)
- Larger major diameter (2.4mm)
- Sizes: 8, 10, 12, 14, 16, 18 & 20mm

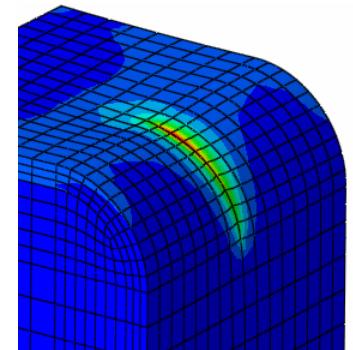
Engineering Performance into Rigid Sternal Fixation

- Less sternal separation with plates
- Plate and screw designed to distribute load across sternum¹
- Locking screw fixation provides the greatest advantage over conventional screw fixation in poor quality bone²

FEA studies show offsetting screws on X plate help reduce stress gradient¹



With rigid fixation, stress dispersed more optimally over wider region of bone

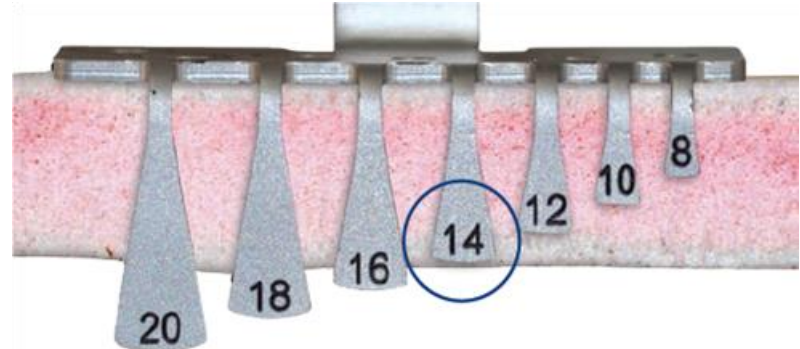


With wires, high stress on localized region of bone

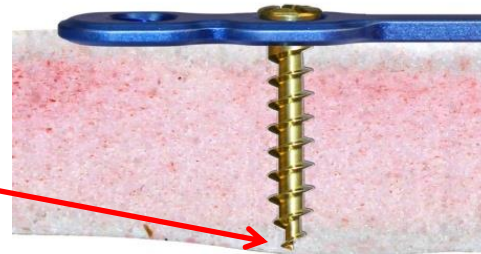
1. Price et al. Design Study on the Stability and Safety of Median Sternotomy Fixation. American Biomechanical Society. 2012
2. LCP Large Fragment Locking Compression Plate

Instrumentation

Screw Sizer



Ensure the tip of the screw engages the posterior cortical table



Simple tool that helps disarm the concern of selecting the right size screw

**2mm has been added to the screw length marking which is the measurement shown on the screw sizer. The screw sizer is to be utilized as a guideline for screw determination. Surgeons must determine screw size based on patient anatomy.*

Alternate Methods of Estimating Screw Size



Ruler

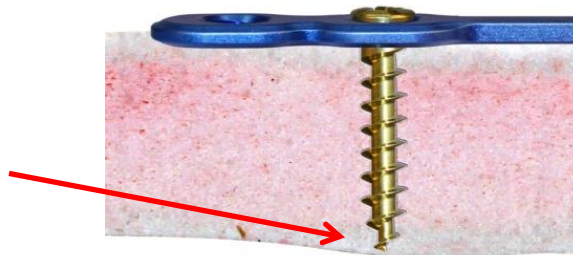
**2mm should be added to the screw length to account for plate thickness.*



Caliper

**2mm has been added to the screw length marking which is the measurement shown on the caliper.*

Ensure the tip of the screw engages the posterior cortical table



The caliper and ruler are to be utilized as a guideline for screw determination. Surgeons must determine screw size based on patient anatomy.

SternaLock Blu Instrumentation



**Large Plate and
Wire Cutter**
P/N: 51-0960



**2.0/2.4 Screw
Driver Handle**
01-7600



Power Driver™
50-1000



Power Driver™
Battery 50-1010



**Standard Plate
Bender 01-9728**



**Beuse Plate
Holding Forceps**
01-9095



Plate Holding Wand
P/N: 24-1186

*Instrument not standard in SternaLock Blu set, available upon request.

Forceps



**Bone Reduction Forceps,
Narrow**
P/N: 73-2596



Wide Reduction Forceps
P/N: 73-2597



Reduction Forceps
P/N 01-2595



Reduction Forceps
P/N 24-1112

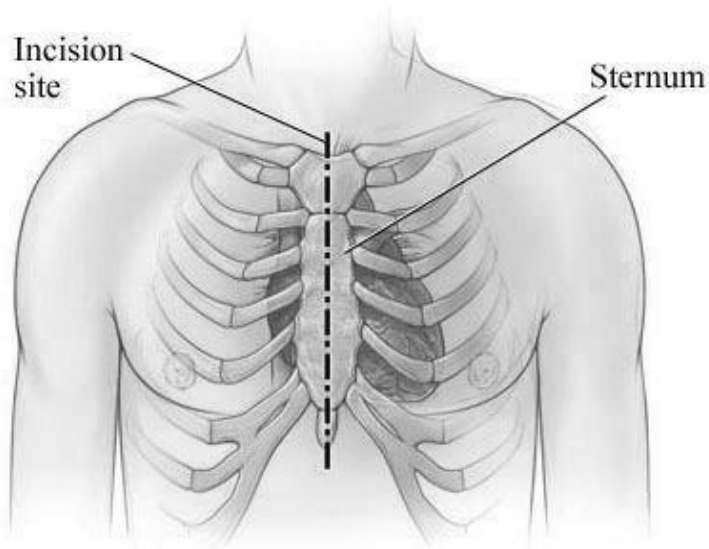
Surgical Technique

SternaLock Blu® Technique

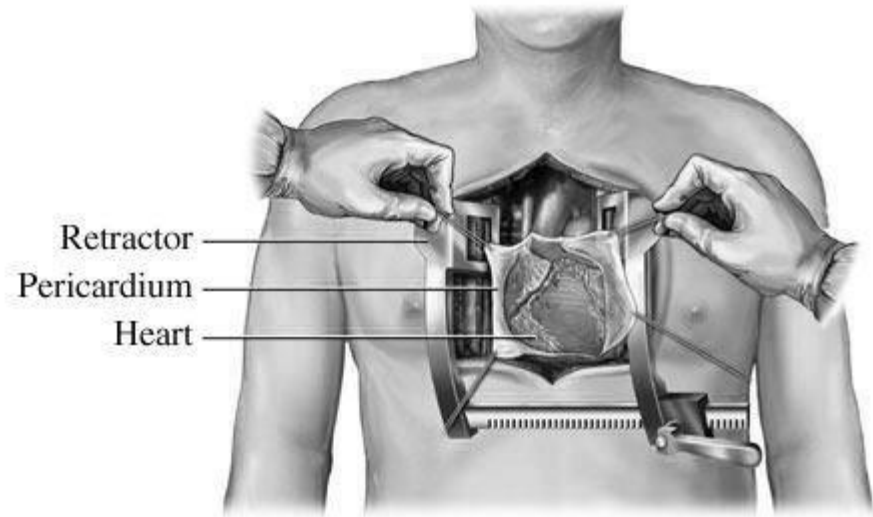
- 1) Sternotomy & Bone Assessment
- 2) Muscle Dissection
- 3) Measure Sternal Depth & Select Screws
- 4) Reduce Sternum
- 5) Select, Contour & Fixate Plates to Sternum

Sternotomy & Bone Assessment

1. Complete Midline Sternotomy



2. Carefully retract the sternum



3. Examine sternum after procedure

- Remove sternal retractor
- Identify transverse fractures
- Assess bone quality

- **Caliper:** takes into consideration the plate thickness
- **Ruler:** add 2 mm to measurement

Muscle Dissection

Dissect Muscle (Pectoralis Major)

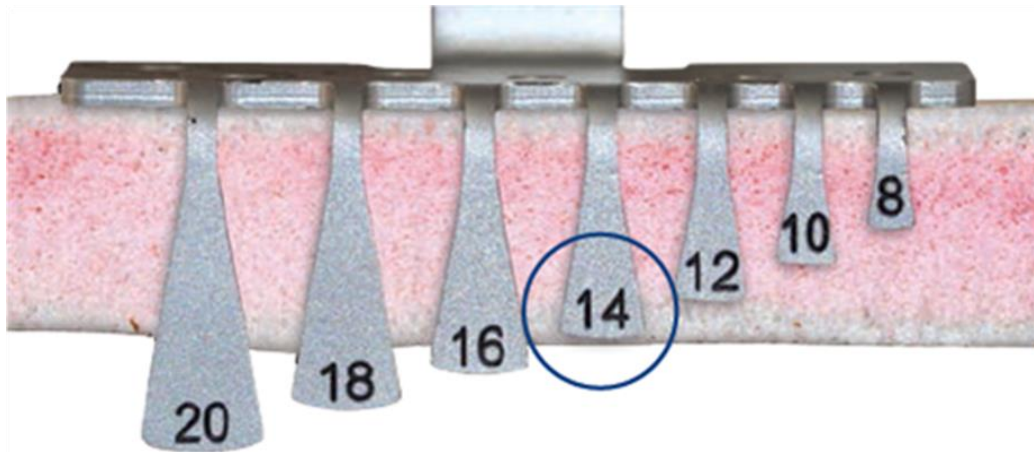
- Only dissect the Pectoralis Major at the anticipated plate locations
- Do not strip down to the periosteum as this is essential nutrients for the bone to heal.



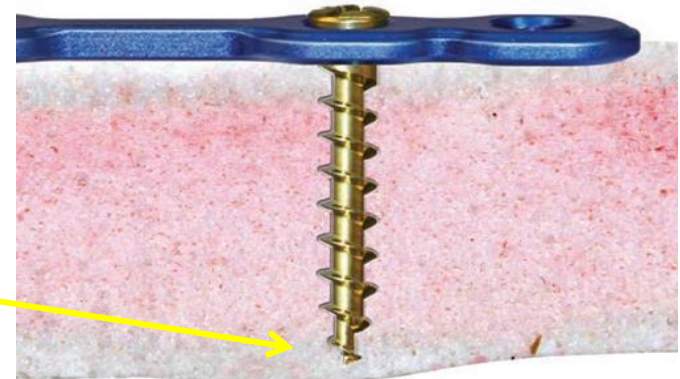
Measure Sternal Depth & Select Screws

Measure sternal depth after procedure

- Ensure the tip of the screw engages the posterior cortical table
- Select screw sizes based on bi-cortical depth measurements



Bi-cortical
engagement



Reduce Sternum

Use sternal wires or reduction forceps to align segments

- If reducing with Stainless steel wires, then place wires at manubrium and xiphoid
- When reducing the sternum, place the bone reduction forceps (P/N 73-2596 and/or P/N 73-2597) in intercostal spaces. These instruments are intended to go around the sternum.
- If small amount of reduction is still needed, then use the sharp tipped reduction forceps (P/N 01-2595 and/or P/N 24-1112) in the intercostal space.
- Consider plate placement in relation to the stainless steel wires



Select, Contour & Fixate Plates to Sternum

1. Select plate configuration

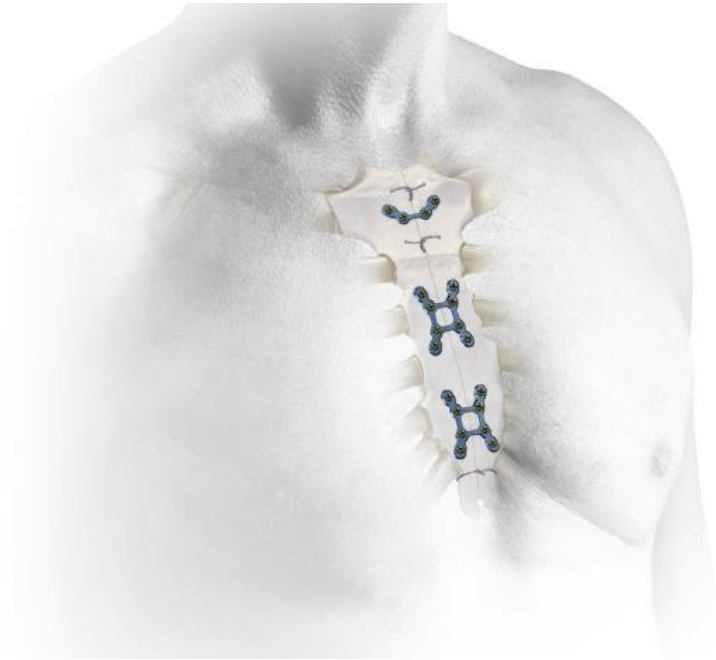
- Recommended Configuration: “L-plate” at Manubrium, “X-plate” at Body and “X-plate” as inferior as possible towards the Xiphoid

2. Contour plates to patients anatomy

- *Caution: avoid multiple bends at same point as this will fatigue the metal*

3. Fixate plates to the sternum

- Position each plate on bone such that cuttable cross-section spans sternotomy
- Place first screw perpendicular to the plate and don't fully seat the first screw to avoid plate rotation
- Place remaining screws
- Fully seat first screw into the plate



Re-Entry

Emergency

- Use the double-action wire cutters
- Cross-section of plate can be cut with standard cutter found in operating room

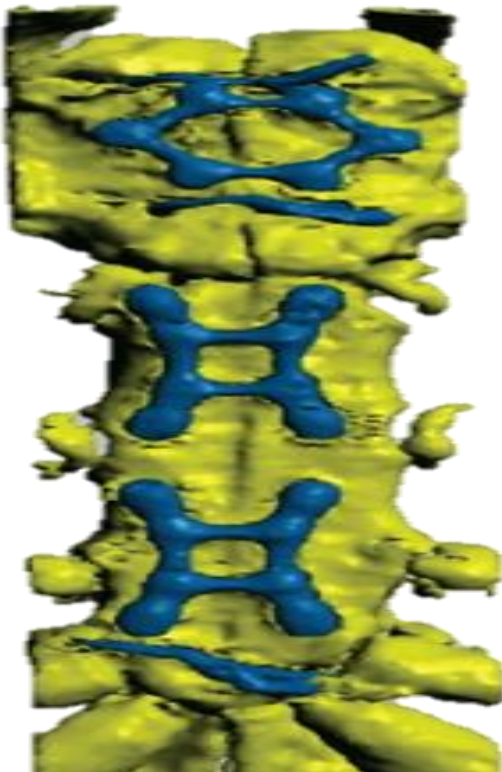
Planned

- Remove screws
- Remove plates

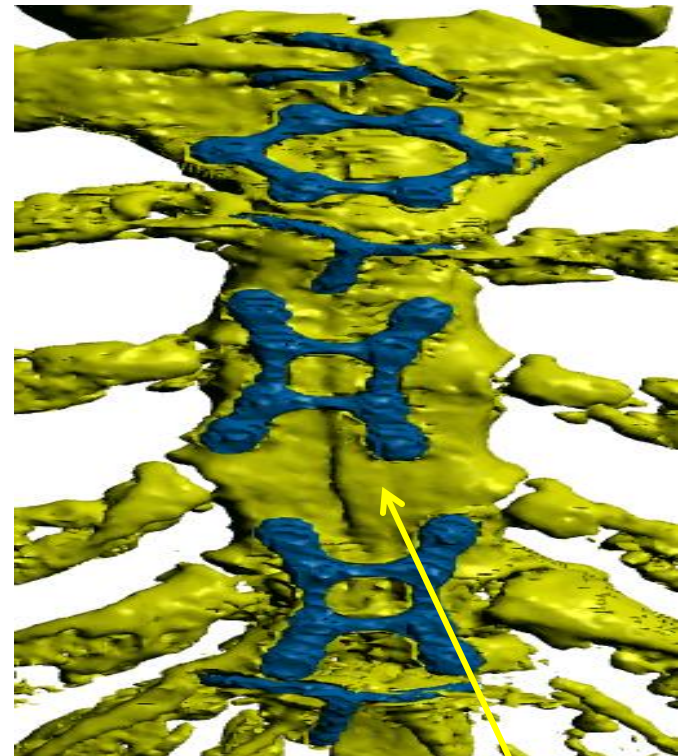
Always train the post-op staff on emergent re-entry procedure

Best Practices

Appropriate Technique

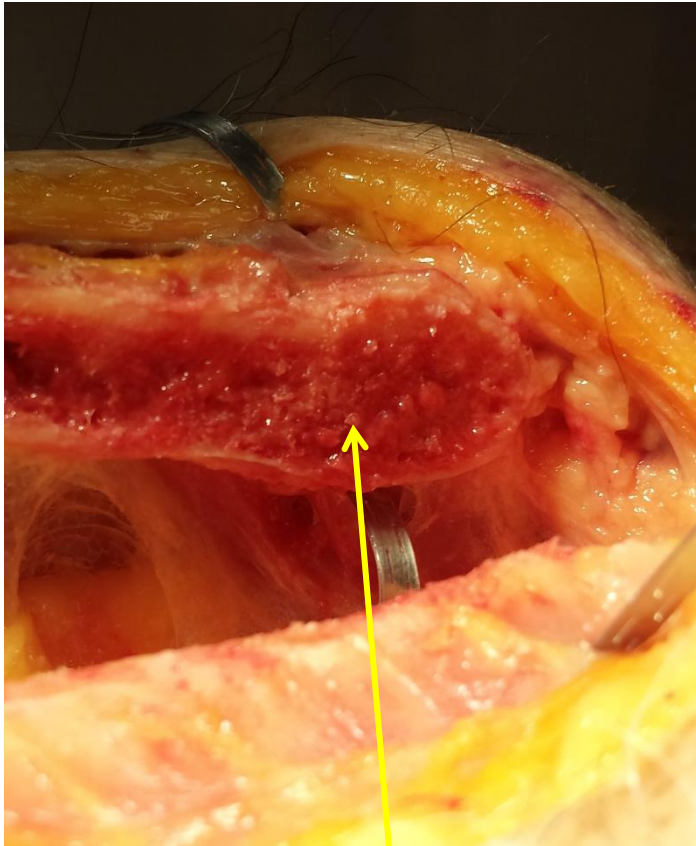


Inappropriate Technique



Off mid-line

Good Bone Quality



Poor Bone Quality

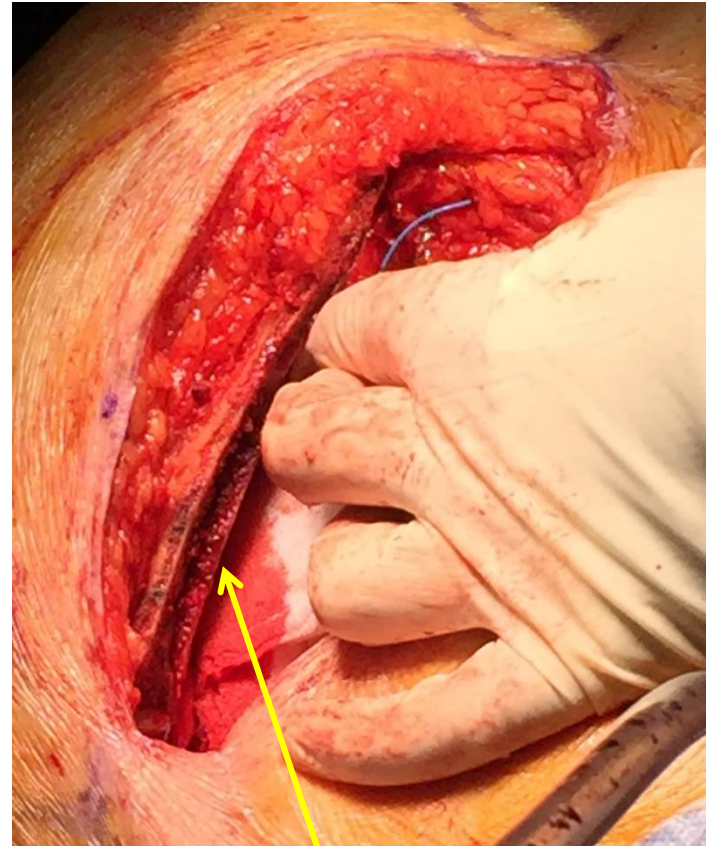
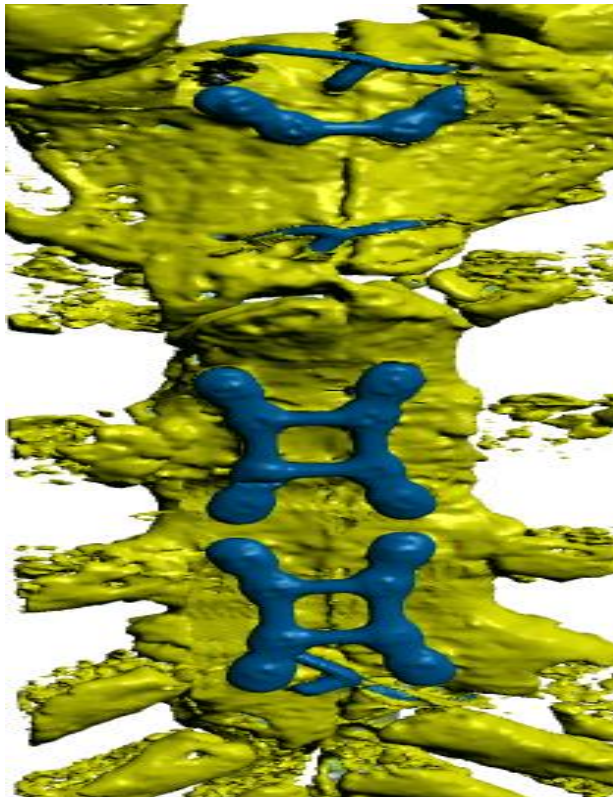
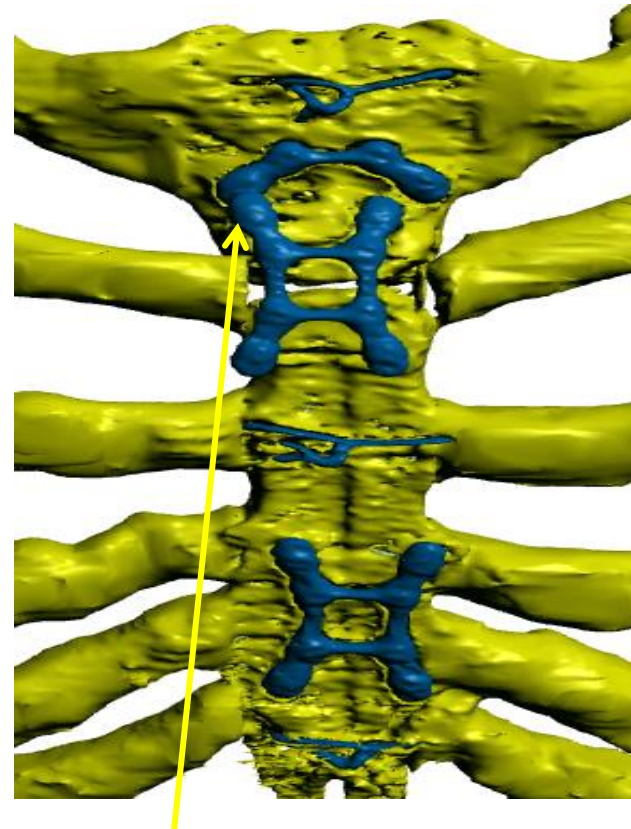


Plate Placement

Appropriate Technique



Inappropriate Technique



"X" plate on sternal body is also placed incorrectly over the sternal manubrial joint.

Screws Gaining Purchase Into Bone

Appropriate Technique

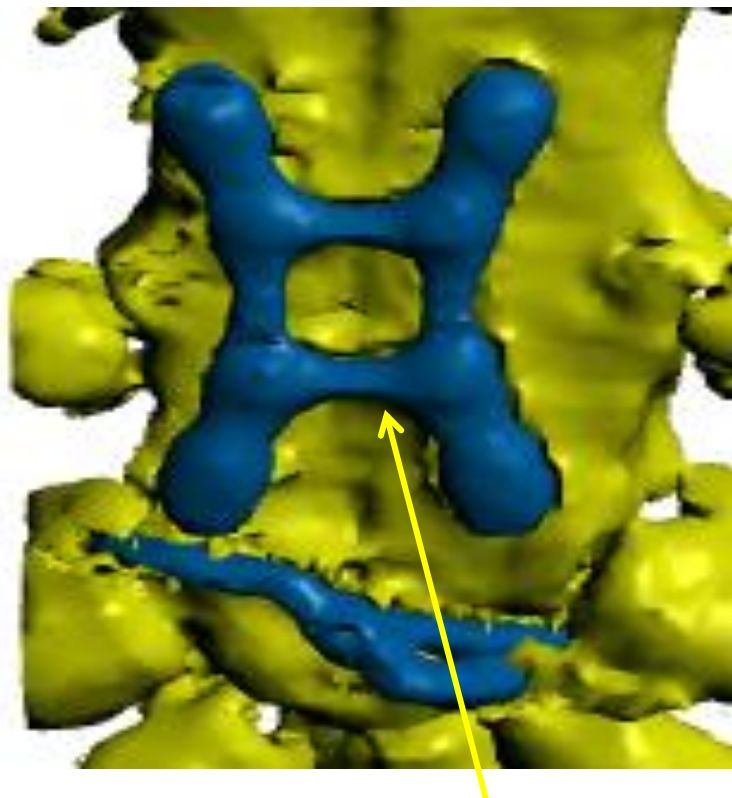
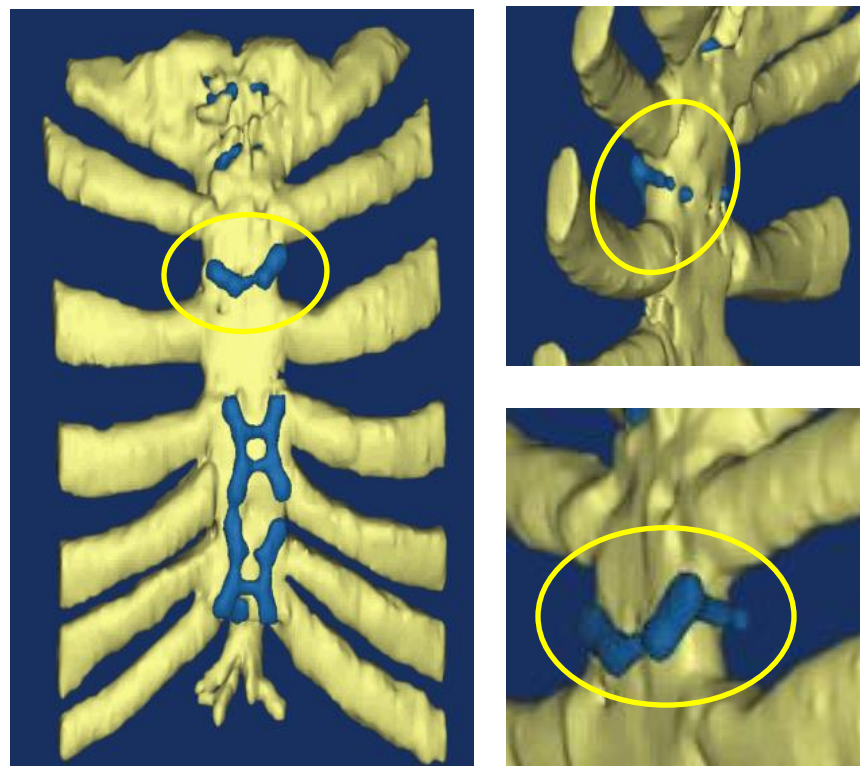


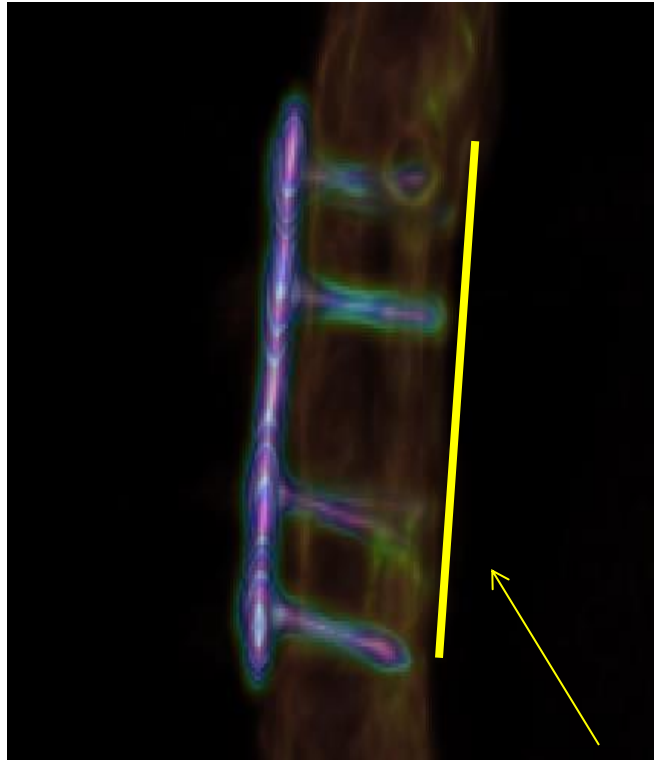
Plate centered over the midline and screws are gaining purchase into bone.

Inappropriate Technique



"L" plate not centered over midline and screws in intercostal space.

Appropriate Technique



Posterior
Cortex

Inappropriate Technique



Posterior
Cortex

Appropriate Technique

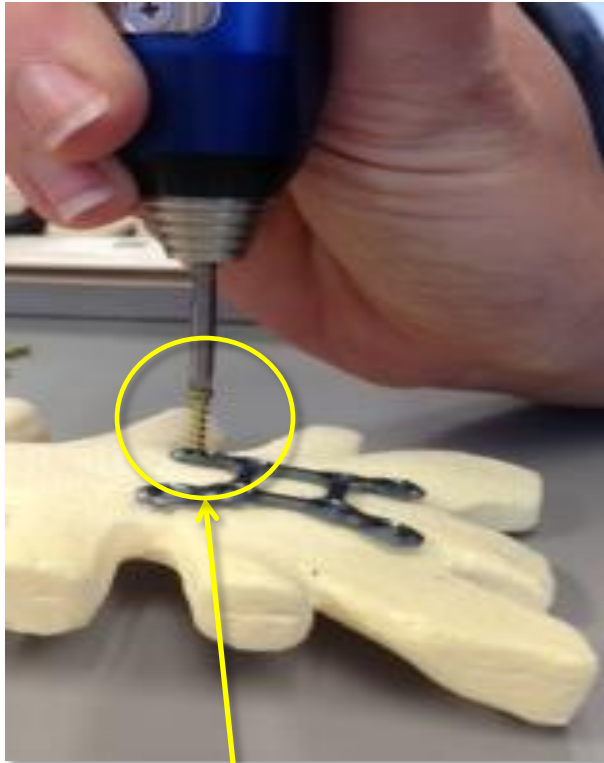


Inappropriate Technique



Plate not
contoured
to bone

Appropriate Technique



Screw is driven straight into the screw hole

Inappropriate Technique



Screw is driven at an angle into the screw hole

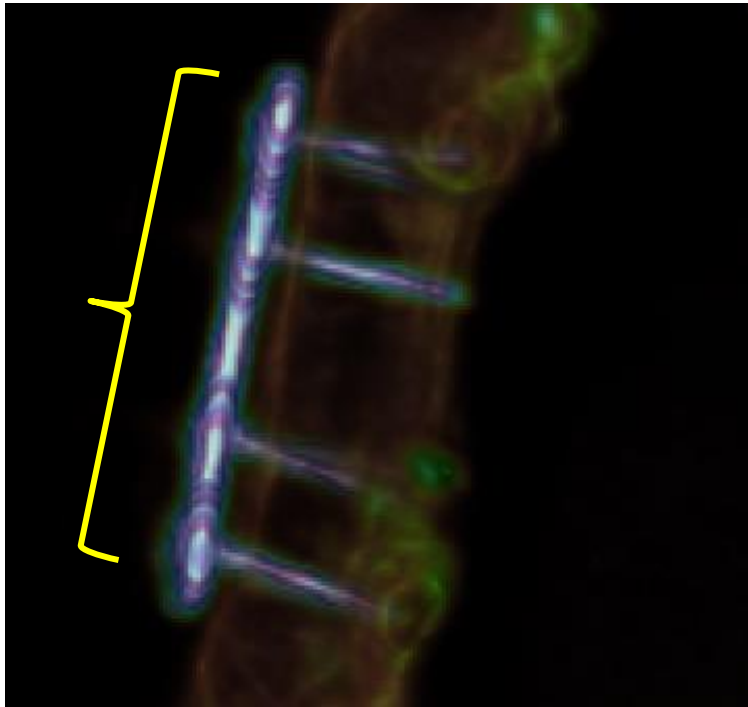
Power Driver



Manual Driver



Appropriate Technique



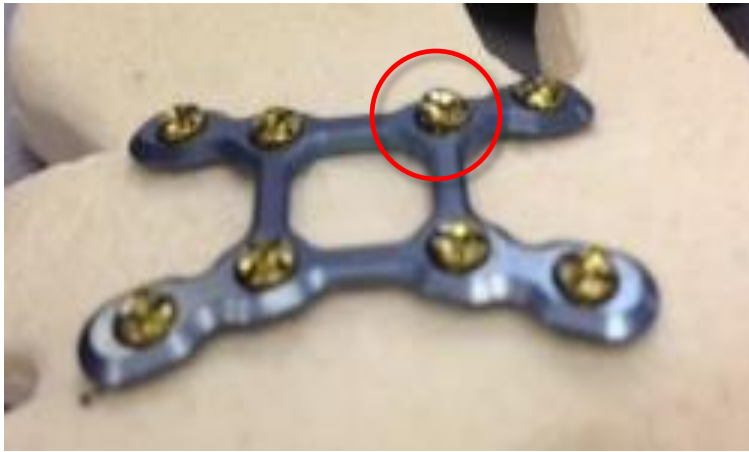
All screws are fully seated and locked.

Inappropriate Technique

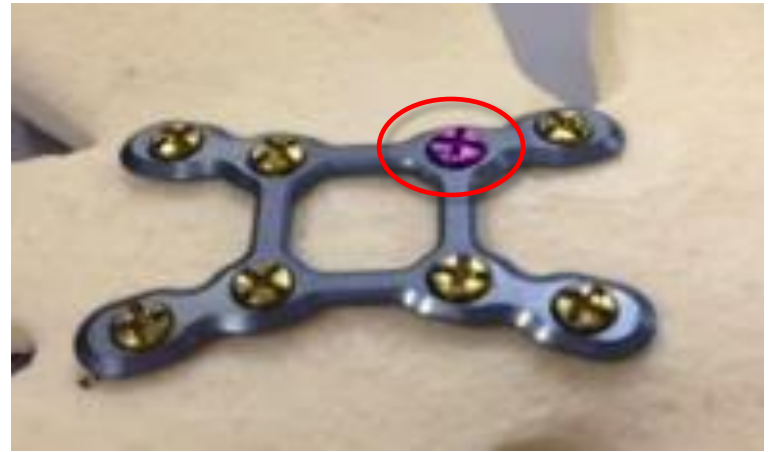


Screws are NOT fully seated and locked

Stripped Screw



Rescue Screw



SternaLock® Blu MICS **Minimally-Invasive Closure Solution**



MICS System

Indications for use:

The stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion.

Product Description:

Rigid fixation and instrument combination will facilitate sternal approximation and stabilization of bony segments for T-cut sternotomies

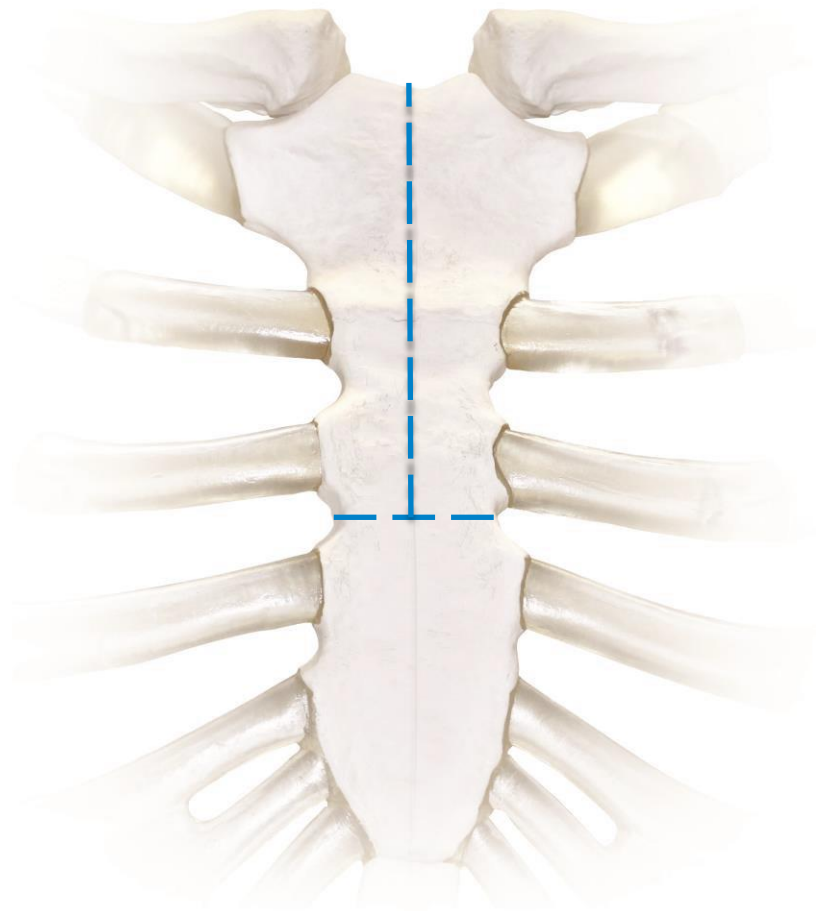


MICS System



Mini-Sternotomy Approaches

- MICS was designed for T cut sternotomy
- Was not designed for J or L cut sternotomies



Product Overview



73-0005
SternaLock Blu
Measuring Caliper



SP-2890
6-Hole Hexagon Plate



SP-3215
60° JL 12-Hole Plate

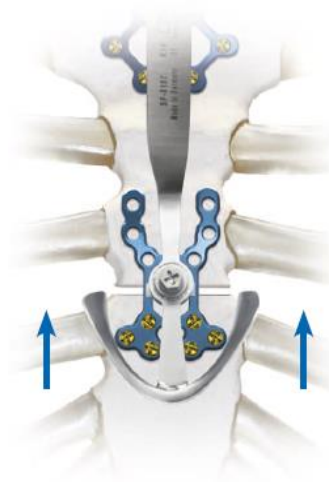


SP-3184-03
Replacement Set Screw

SP-3192
JL Plate Instrument

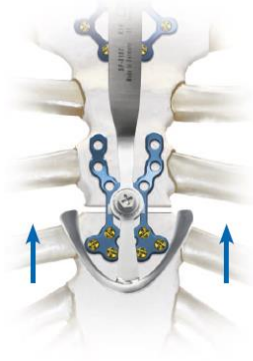
Surgical Guideline

1. Measure manubrium and transverse sternotomy
2. Reduce the superior portion of sternum



Surgical Guideline Pearls

- Assess Bone Quality
- Measuring caliper (73-0005) is needed for bi-cortical screw measurement
- Anterior/Posterior cortex of the superior sternum must be aligned
- Rostro/Caudal alignment of superior sternotomy must be achieved to ensure full approximation of transverse sternotomy
- Position plate on a flat surface when fixating the plate to the instrument, and then turn set screw clockwise to secure plate to the instrument
- Insert screws perpendicular to the plate
- While approximating transverse sternotomy hold approximation force until all the superior screws have been implanted



Available Materials

- Inventory Control Charge Sheet
(Biomet App and Customer Service)
- Technique video
 - Cadaveric Available Now
 - (Biomet University)
- Flier
(Biomet App and Customer Service)



Z Drive

Product Overview

ZDrive to fully seat and lock screws into the plate with increased speed and performance.

- Power tool with consistent speed and performance
- Sterile packaged, single use to increase hospital efficiencies
- Alkaline batteries which means can be shipped overnight



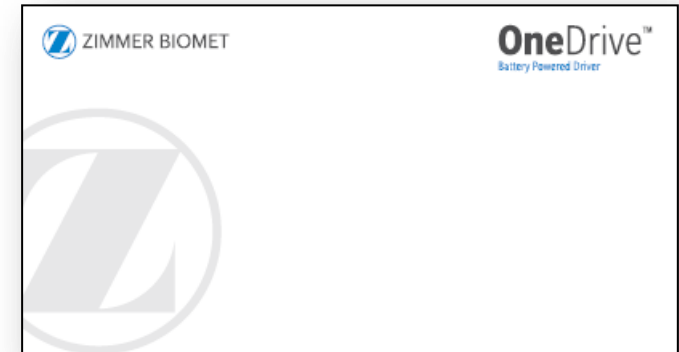
What is the Value?

Surgeon Benefits

- Increased OR Efficiencies with sterile packaged products
- Reduced hospital resources with no sterilization costs
- Consistent performance with single-use instruments
- Increased Speed & Torque compared to PowerDriver¹
- Price is similar to existing solution
- Lot traceability

Sales Rep Benefits

- Supports continuous growth within thoracic business
- Provides a competitive solution
- Improved reliability compared to PowerDriver¹
- Increased Speed to overcome time objection¹
- No increased costs to overcome price objection



1. LT1606 Baseline testing of Power Driver and Kaiser driver functionality (Thoracic Application)

ZDrive versus PowerDriver

	ZDrive ¹	PowerDriver ¹
Torque (in-oz)	124	42
Speed (RPM)	150	99
Insertion Time (sec)	3.8	7.2

*All data is based on the insertion of 20mm Sternalock Blu Screws into 20 Hole Straight Plates in 20 pcf foam



ZDrive compared to the PowerDriver has:

3x more torque for single step locking

2x faster screw delivery

ZDrive Technique

1. Insert Battery



2. Insert Blade



3. Load Screws

4. Apply Downward pressure

- Forward and reverse function when inserting the screws

5. Lock Screws

- While pressing the forward button, rotate driver handle to lock the screws.
- The driver has increased torque, but it is important during the initial cases to still go back and manually lock the screws.

6. Disconnect before disposal



Handling Objections

- Cost
- Time
- “Don’t have problems with wires”
- “I’ll use the system for my next revision”

Handling the cost objection

- Compared to wires it is more – compared to other types of rigid fixation it is significantly less or comparable
- Our customers see tremendous value in the benefits SternaLock provides based off the SternaLock Blu Study (i.e. improved mechanical stability, reduced sternal separation, improved bone healing)!
- Discuss how our surgeon adopters have justified the adoption of SternaLock to their hospitals
- Begin on a limited usage basis
- Cranial closure analogy

Handling the “wires are faster” objection

- Our most experienced surgeon users say that once you complete the learning curve of approximately five cases, the time required to close with SternaLock is either comparable or less than wire
- Emphasize the simplicity of the technique
- Less bleeding
- Propose a hands-on workshop

Handling the “wires are working fine” or “I’m not having any problems” objection

- The results you’re seeing are along the lines with the current standard of care, but what if they could be better?
- The reality of the improved stability will be apparent immediately!
- Our customers see tremendous value in the benefits SternaLock provides based on the Sternalock Blu Study (i.e. improved mechanical stability, reduced sternal separation, improved bone healing)!
- Discuss postoperative follow-up (i.e. cardiologist)
- Cranial closure analogy

Handling the “next revision” objection

- “Although SternaLock is indicated and works well for most revision cases, the bone quality of these patients is often poor. I want your initial experience with the system to be as positive as possible.”
- Close for high risk patient CABG, mini-sternotomy or mini-thoracotomy

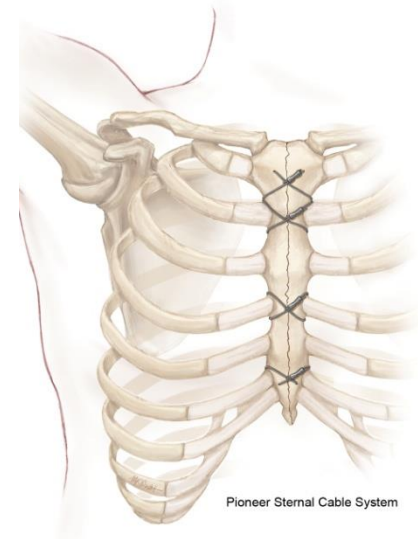
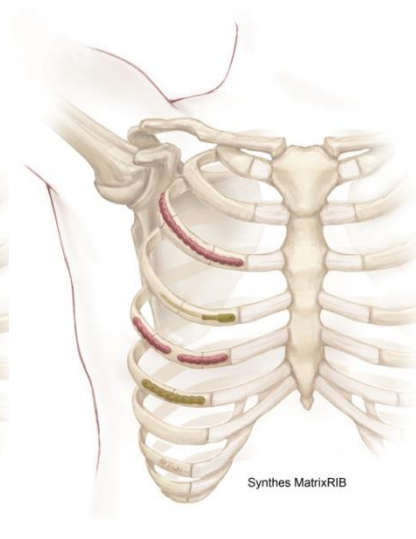
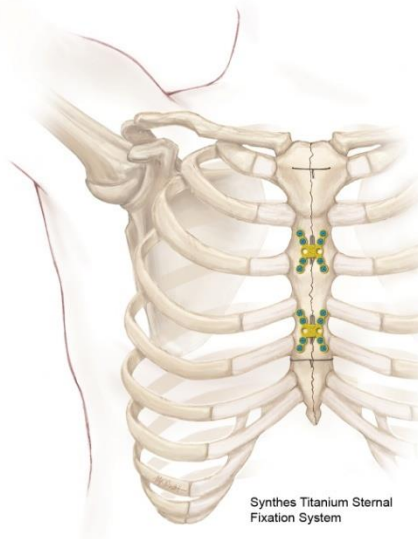
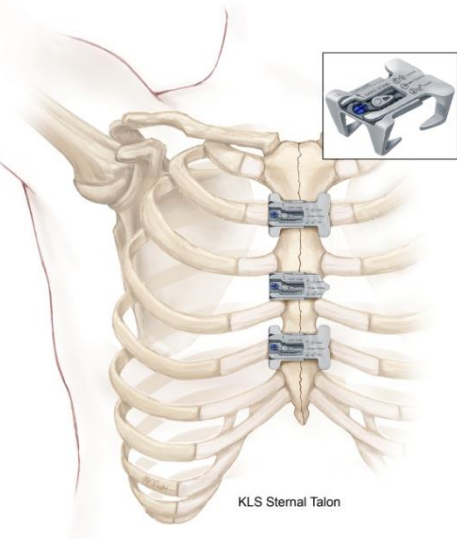
Close for the CABG

- “Do you have any CABGs on the books? Can we bring in the system for that case?”
- Close for high risk patient case
- Offer no charge case as a last resort

Closing for the valve replacement case

- Do you perform a full mid-line sternotomy, mini-sternotomy, or thoracotomy on your AVR and MVR procedures?
- Do you sometimes find it difficult to wire the corner on your mini-sternotomies?
- Do you wire your thoracotomies? Do your patients ever experience pain related to the motion of the ribs that wires allow?
- Do you have any valve replacement cases on the books? Can we bring in the system for that case?

Competitive Products

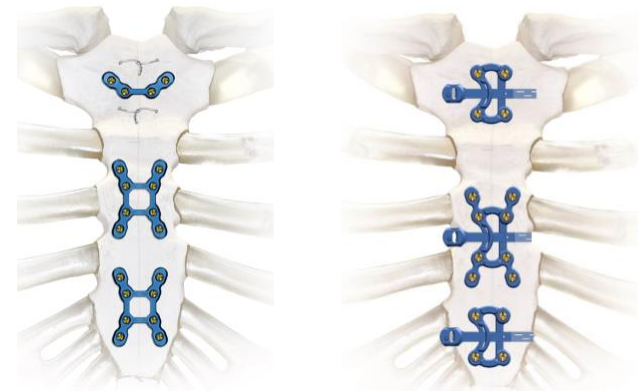


SternaLock

SternaLock Silver, SternaLock Blu and SternaLock 360

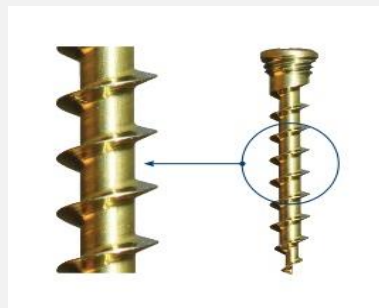
Talking Points

- 3 Generations
- 14+ years of clinical use
- 3 Prospective, Randomized Controlled Trials
- Sell the entire portfolio versus leading with just SternaLock 360
- Significance of cancellous screws



Cancellous Screw vs. Cortical Screw

SternaLock Blu Cancellous Screw¹



KLS Martin Cortical Screw²



Synthes Cortical Screw³



Features

- Longer thread depth (.635mm)
- Longer thread pitch (1.6mm)
 - Narrower minor diameter (1.3mm)
- Larger major diameter (2.4mm)

- Shorter thread depth
- Shorter thread pitch
- Wider minor diameter (2.5mm)
 - Smaller major diameter (2.3mm)

- Shorter thread depth
- Shorter thread pitch (1.0mm)
 - Wider minor diameter (1.5mm)
 - Smaller major diameter (1.8mm)

Thread Depth

Cancellous screws feature greater thread depth to gain deeper purchase into spongy bone.

Cortical screws have shorter depth for less porous bones of the body.

Designed to screw in the bone but do not fully engage in cancellous bone.

Screw Head

Threaded screw head engages into the plate and is a locking mechanism to help prevent screw back out.

TBD

Threads in the screw head are designed to lock the screw into the plate to prevent screw back out, although not preventable with poor bone quality.





Locking Mechanism



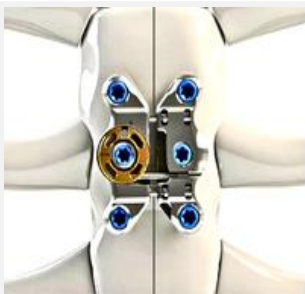
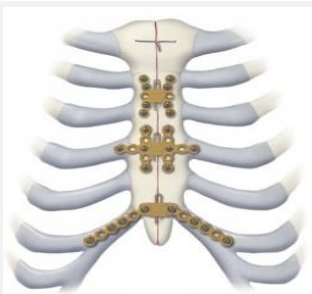
Threaded locking mechanism helps ensure perpendicular insertion of screw and therefore bicortical engagement.

TBD

Locking mechanism at the head of screw.

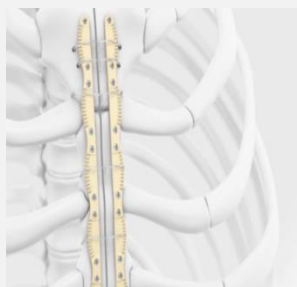


Rigid Fixation Product Analysis	SternaLock Blu ¹	SternaLock 360 ⁴	KLS Plating ²	Pioneer Tritium ⁵	
					
	Product Positioning	Primary closure, High-risk patients, MIS	Only system specifically developed for poor bone	Revisions, Primary Closure, High-risk patients, MIS	Target SLB users, Primary closure
	Plate Profile	1.6mm	2.4mm	2.0mm	1.7mm
	Double-sided Plate	Yes	No	No	No
	Contour Plates	Yes	Yes	Yes	No
	Cuttable Plate	Yes	Yes	Yes	Yes
	Screw Design	Cancellous	Cancellous	Cortical	Cancellous
	Screw Diameters	2.4mm and 2.7mm	2.4mm and 2.7mm	2.3mm and 2.5mm	2.7mm and 3.0mm
	Screw Lengths	8, 10, 12, 14, 16, 18, 20mm	8, 10, 12, 14, 16, 18, 20mm	9, 11, 13, 15, 17mm	10, 12, 14, 16mm
	Cerclage	No	4mm width coated Ti Band	No	1.3mm Ti Cable
	LSP Configuration	\$\$	\$\$\$	\$\$	\$\$
	Randomized Controlled Trials	RESTORE ⁶ , SternaLock Blu Study ⁷	SternaLock 360 Study ⁷	None	None

Rigid Fixation Product Analysis	SternaLock Blu ¹	Jace Anterior Plating ⁸	Jace Grand Pre ⁹	Synthes Plating ³	
					
	Product Positioning	Primary closure, High-risk patients, MIS	Target SLB users, Primary closure	Pre-sternotomy plating system for primary closure	Primary Closure, High risk patients, MIS
	Plate Profile	1.6mm	TBD	TBD	3.0mm
	Double-sided Plate	Yes	No	No	No
	Contour Plates	Yes	No	No	Difficult
	Cuttable Plate	Yes	Yes	Yes	Yes
	Screw Design	Cancellous	Cortical	Cortical	Cortical
	Screw Diameters	2.4mm and 2.7mm	3.5mm	3.5mm	3.0mm
	Screw Lengths	8, 10, 12, 14, 16, 18, 20mm	10, 12, 14, 16, 18, 20mm	12, 14, 16, 18, 20mm	10, 12, 14, 16, 18, 20, 22mm
	Cerclage	No	No	No	No
	LSP Configuration	\$\$	\$\$	\$\$	\$\$\$
	Randomized Controlled Trials	RESTORE ⁶ , SternaLock Blu Study ⁷	None	None	None

Non-Rigid Fixation Product Analysis

KLS LSS¹⁰



Synthes ZipFix¹¹



KLS Talon¹²



AcuTie II¹³



Product Positioning

Primary closure

Primary Closure

Revision, Primary
Closure

Primary Closure

Rigid Fixation

No

No

No

No

Material

PEEK

PEEK

Titanium

Titanium

Cuttable

Yes

Yes

No

Yes

Sizes

Cuttable plates to fit
patients sternum

4mm width band

XS, S, M, L, XS width and
11, 14, 17 and 20 mm depth

TBD

Pricing

\$

\$

\$\$

\$

Clinical Research

TBD

TBD

TBD

TBD

Tritium Pioneer Claims

Focuses on traditional sternal closure techniques by incorporating cerclage cables and cancellous screws with a low profile plate.

Increased Stability

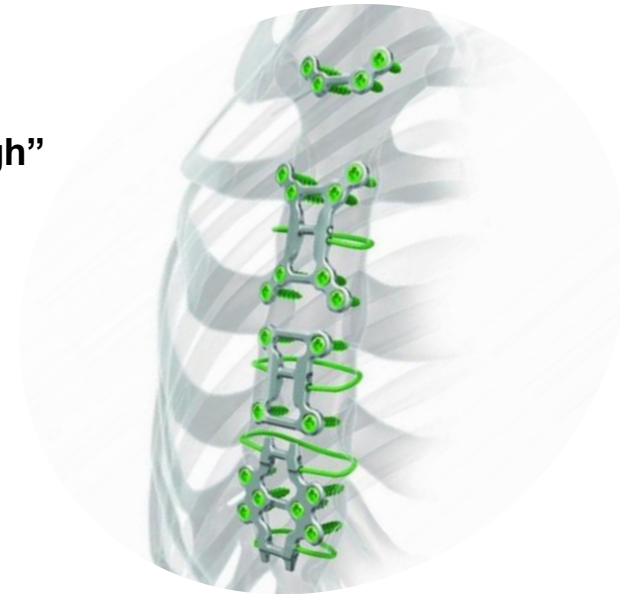
- **Stability in all planes of motion**
- **1.3mm diameter Titanium cable**
- **Sternotomy plates distribute load, reducing risk of “pull-through”**
- 360 cerclage
- Plate and screw thread locking

System Benefits

- **Compression across the osteotomy**
- **Uniquely designed thin plates** for anatomical fit
- Cancellous screws designed for the sternum
- Specially designed instrumentation

O.R. Benefits

- Minimal tissue preparation
- Fewer sizing steps
- Reduced learning curve



Citations

1. SternaLock Blu Brochure (00-3265)
2. KLS Martin Sternal Closure Technique Guide
3. DePuy Synthes Titanium Sternal Fixation Product Brochure
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5. Pioneer Tritium Surgical Technique Guide
6. Raman et al. Sternal Closure with rigid plate fixation versus wire closure: A randomized controlled multi-center trial. *Annals Thor Surg* 2012; 94:1854-61.
7. Allen, K, et al. Randomized, Multicenter Trial Comparing Sternotomy Closure with Rigid Plate Fixation to Wire Cerclage. *The Journal of Thoracic Surgery*. Vol 153, Number 4. Pg 888-896. April 2017
8. Jace Anterior Plating Product Brochure
9. Jace Grand Pre Product Brochure
10. KLS LSS Technique Guide
11. DePuy Synthes Sternal ZipFix Technique Guide
12. KLS Talon Product Brochure
13. Acute AcuTie Product Brochure

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Questions / Discussion

