ZIMMER BIOMET

SternaLock® XP

Rigid Fixation System

SURGICAL TECHNIQUE

SternaLock® XP

Rigid Fixation System

Zimmer Biomet offers a complete selection of sternal-closure options based on the complexity of the procedure, a patient's needs or your closure preference. Whether you're performing minimally-invasive surgery, addressing the requirements of an osteoporotic patient or dealing with several high-risk factors, Zimmer Biomet offers an answer.

The SternaLock XP Rigid Fixation System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures. The system is intended for use in patients with normal and/or poor bone quality.[1]

1. SternaLock XP IFU (formerly Thorecon) 436-502 Rev. B, August 2019.

SternaLock XP

Rigid Fixation System

SternaLock XP Features

Ease of Use

Disposable single use sterile system

Innovative Amorphous Cable

Expands when tensioned to increase surface area[1]

Stronger and More Rigid Closure

Designed to enhance stability and strength of traditional sternal closure technique[2]

Osteoporotic Indications

Intended for use in patients with normal and/or poor bone quality[2]

1. Data on file - TR17063
2. SternaLock XP IFU (formerly Thorecon) 436-502 Rev. B, August 2019.

SternaLock XP

Surgical Technique

Surgical Technique shown is not applicable to the Tower Plate. Please reference the Mini-Thoracotomy Plate Surgical Technique (MKT940016).

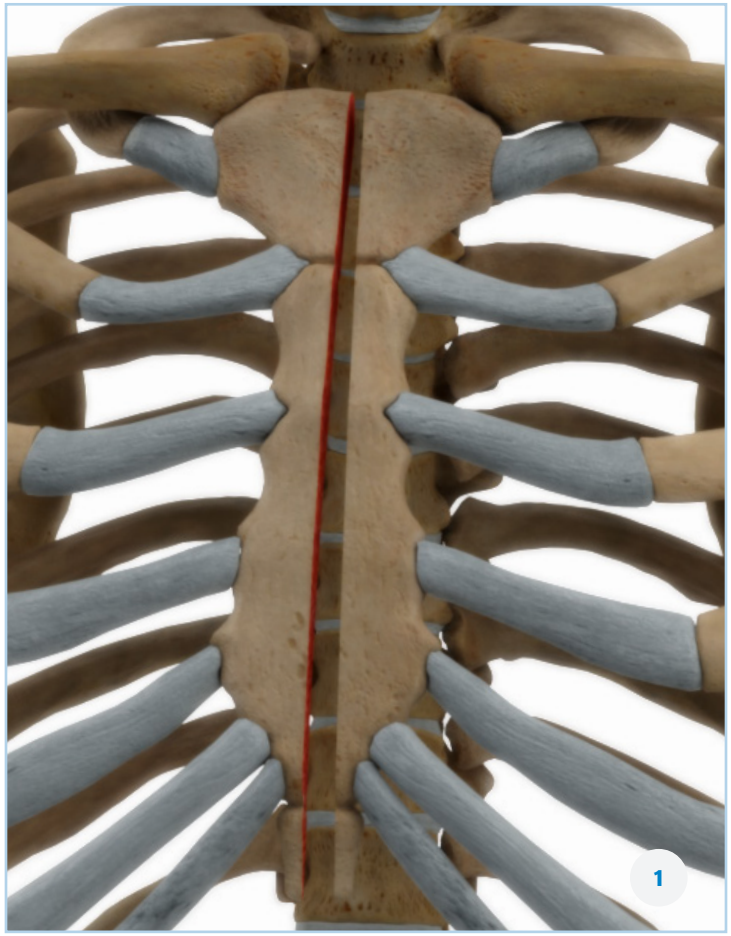
1. Exposure

Beginning medially, dissect all soft tissue from the surface of the sternum to allow for complete visualization; this may decrease the likelihood of an off-midline sternotomy. Optimally, the costal cartilage on both sides of the sternum is revealed. Perform a sternotomy (Figure 1).

FOR SECONDARY CLOSURE OF THE STERNUM

Remove existing wires. Debride the involved sternal edges until they are free of devitalized tissues and hemostasis has been obtained. To allow for proper anatomical reduction and plate placement, bony calluses should also be removed from the midline and sternal surface (in addition to sternal soft tissue dissection in a revision surgery). A rib curette may be used to remove any nonviable cartilaginous rib tissue.

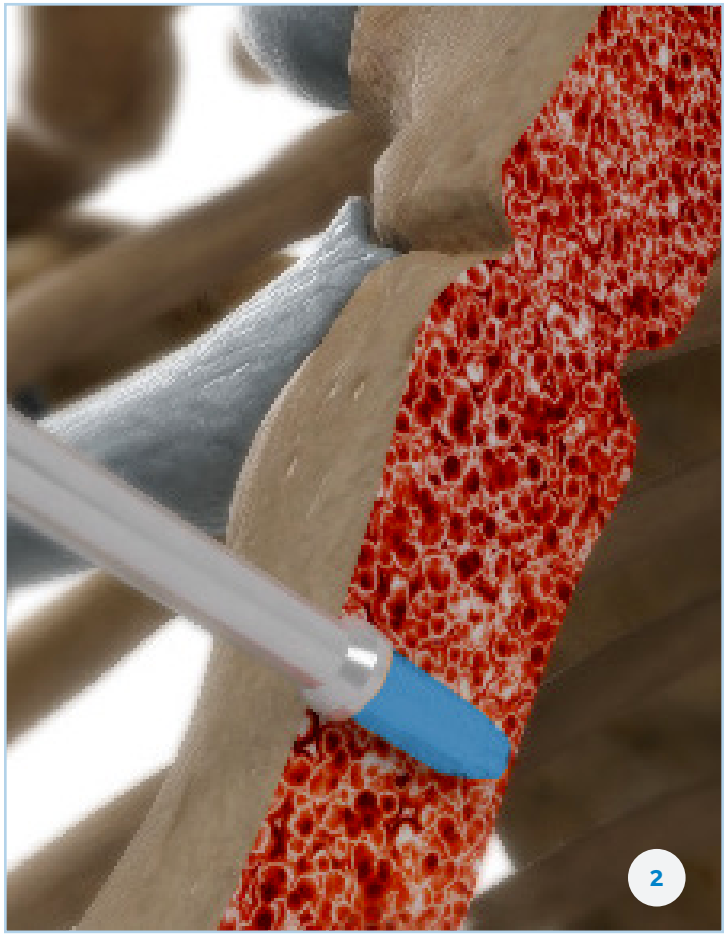
Note: A sternal bone specimen should be sent to pathology to assess for osteomyelitis and to microbiology for culturing This may help the infectious disease consultant determine the appropriate antibiotic treatment if necessary.


1

2. Screw Verification

14mm screws are provided per procedural pack. Confirm 14mm screw lengths are appropriate by using the 14mm screw length indicator edge on the Torque Limiting Driver to measure the thickness of the sternal edge. (Figure 2). If leading edge of the torque driver protrudes past the posterior sternal edge, a 10mm screw should be used in this area of the sternum.

Alternate screw options are available in separate packages, including 2.7mm (standard) and 3.0mm (rescue) diameters, in lengths of both 10mm & 14mm.

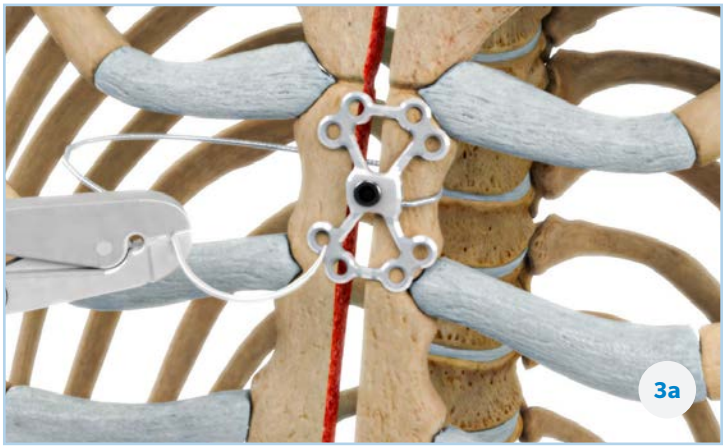


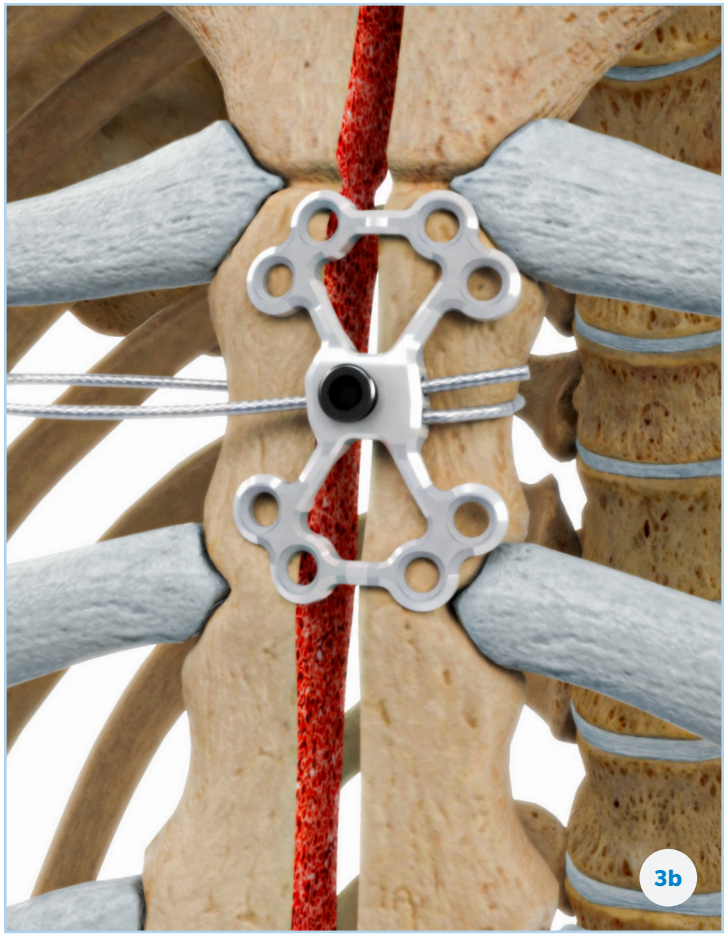
3. Cable Insertion

Once the plate is placed, route the cable around the sternum at the desired location. Cut the leader of the cable to remove the needle, leaving a small amount of leader to help guide the cable through the plate (Figure 3a). Thread the cable through the plate (Figure 3b).

CAUTION: Plates are not intended to be contoured or modified.

CAUTION: When cutting the leader of the cable, there must be a small amount of leader remaining, otherwise the cable could fray and become difficult to pass through the plate and/or cable tensioner.





4. Sternal Approximation

The sternum can be reduced with the assistance of appropriate sized stainless steel sutures or stainless steel sternal cable at the xyphoid and manubrium. During reduction, observe the midline for protruding internal tissue and proper bony alignment. Mid-body sternal approximation can be completed using the included Cable Tensioner.

Note: Sternal approximation and stability must be determined by tactile assessment. Optimal tension is dependent on proper assessment of the patient's bone quality.

CAUTION: Putting dissimilar metals and alloys in contact with each other may be detrimental to the patient and/or function of the implant(s); therefore stainless steel cable or suture wire is recommended.

WARNING: Do not place any SternaLock XP plate over any other implants such as, but not limited to, plates, wires, screws or cables.

5. Cable Tensioning

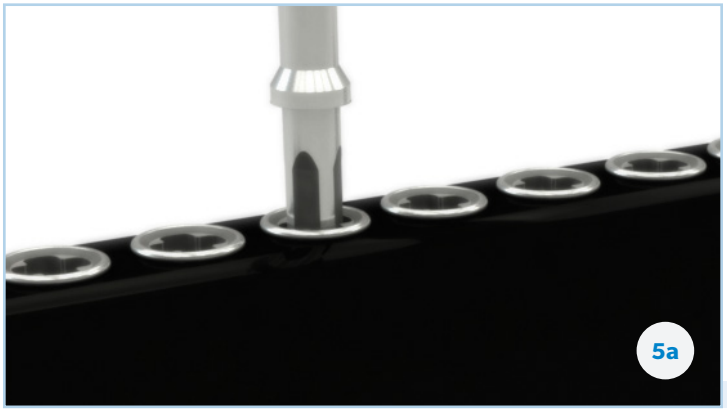
To ensure a clear cable passage through the Cable Tensioner, rotate the handle clockwise until the line on the rear of the tensioner and on the handle are parallel. Pass the cable through the distal tip of the Cable Tensioner and advance the Cable Tensioner against the plate by pulling on the loose end of the cable to remove any slack. Obtain appropriate cable tension by rotating the handle clockwise (Figure 4).

CAUTION: Exercise caution while tensioning the cable. Over-tensioning could result in cable cutting into the bone, or cable breakage.

Note: Simultaneously tension the two cables that are most cephalad and caudal to better approximate the sternal constructs. This assures tension consistency between constructs and provides uniform tension across the sternum.

6. Bone Screw Placement

Using the Torque Limiting Driver's "stab-and-grab" feature, attach the bone screw to the Torque Limiting Driver (Figure 5a) and insert perpendicular through the desired screw hole on the plate. While applying downward force, rotate clockwise to drive the screw into the sternum (Figure 5b).



7. Screw Tightening

Fully seat the screw head into the plate. The screw head will thread into the plate causing the screw to lock to the plate (Figure 6).

CAUTION: Misalignment of the Torque Limiting Driver to the screw head may cause stripping of the screw head. Screws are not intended to be angled.

Note: Screw seating into the plate does not require the Torque Limiting Driver to reach full torque.

Note: Do not fully seat the screw into the plate when using a Power Driver. Fully seating the screws to the plate must be done manually using the Torque Limiting Driver.

8. Cerclage Locking

Insert the Torque Limiting Driver perpendicular into the Cerclage Set Screw. While applying downward force, rotate clockwise to drive the Cerclage Set Screw into the plate until the Torque Limiting Driver audibly clicks indicating desired torque (20in lbs.) is achieved and the Cerclage Set Screw is fully seated (Figure 7).

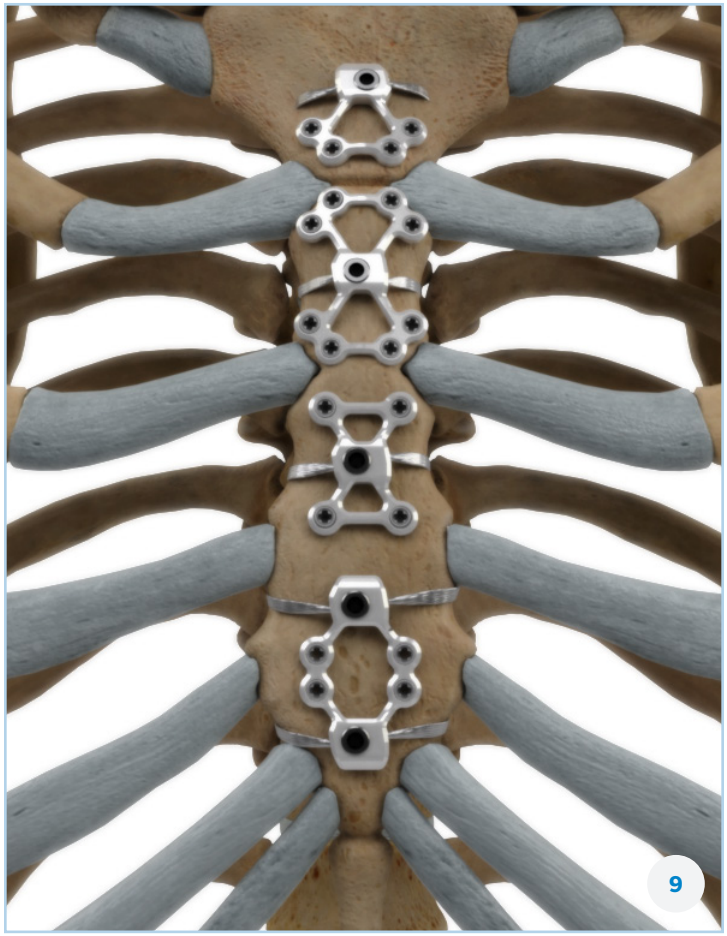
9. Cable Cutting and Tension Removal

Fully insert the Torque Limiting Driver into the hollow tube on the distal tip of the Cable Tensioner (Figure 8a). Gently lever the handle forward until the Cable Tensioner releases from the plate indicating the cable is fully cut flush with the plate (Figure 8b). Once the cable has been cut, remove the Cable Tensioner, Torque Limiting Driver and discard along with remaining cable (Figure 8c).

CAUTION: The cable must only be cut once, flush to the plate, and prior to removing the Cable Tensioner from the device.

10. Complete Construct

It is important to be aware of the overall stability of the closure and use as many plates as necessary to achieve adequate fixation based on a surgeon's assessment for each patient (Figure 9).



11. Closure

After the plate/screw constructs, and all cable or wire (if applicable) are installed in final position, wound closure is performed. Close skin and subcutaneous tissues in standard closing procedure.

Note: Do not pull or lift the patient by the arms. It is also not recommended to raise the arms higher than 90° at shoulder level.

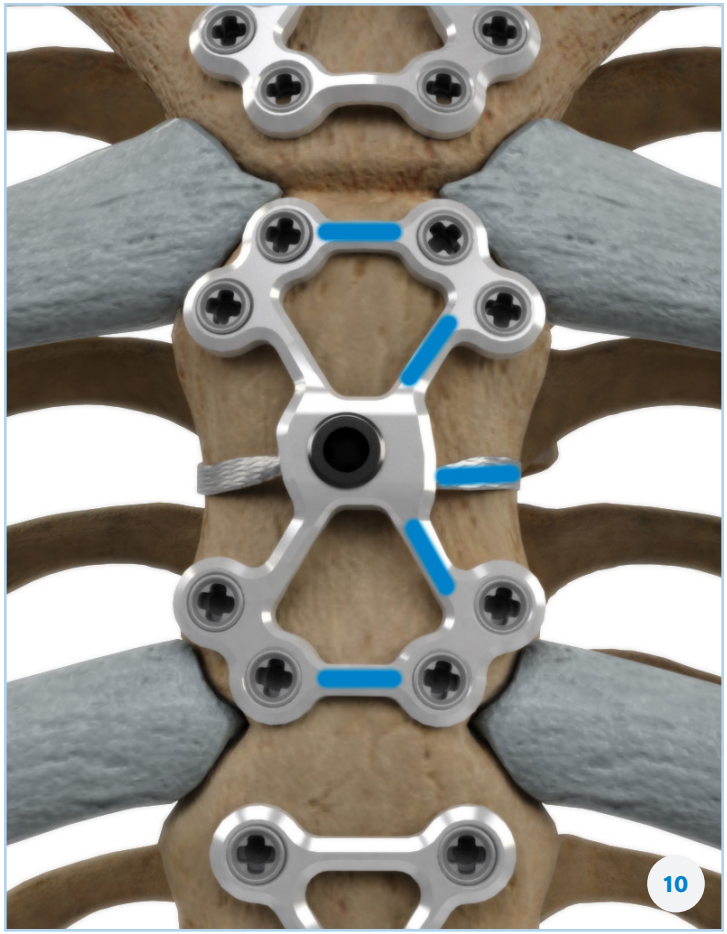
12. Emergent Re-entry/Removal

Extraction (if required)

To remove the bone screws, insert the Torque Driver into the head of the screw and rotate counter-clockwise while exerting downward pressure. Use a cable cutting instrument to cut the cable from the sternum.

Emergent Re-Entry (if required)

First, use a cable cutting instrument to cut the cable. Next, cut the plate through the main support locations (Figure 10; 8 Hole X-Plate shown as example). If needed, follow extraction instructions above.

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SternaLock XP • Implants

94-1200-08: X-Plate Kit

8x 14mm Screws, 1x Cable, 1x Tensioner, 1x Driver

94-1300-04: Double Cable Plate Kit

4x 14mm Screws, 2x Cable, 2x Tensioner, 1x Driver

94-1300-04-S: Double Cable Plate Kit (Sharp)

4x14mm Screws, 2x Cable, 2x Tensioner, 1x Driver

94-1400-04: Box Plate Kit

4x 14mm Screws, 1x Cable, 1x Tensioner, 1x Driver

94-1500-04-S : Auxiliary Plate Kit

4 x 14mm Screws, 1x Cable,1x Tensioner, 1x Driver

94-1600-05: Tower Plate Kit

2x 10mm Screws, 3x 14mm Screws, 1x Cable, 1x Tensioner, 1x Driver

94-1700-10: Ladder Plate Kit

10x 14mm Screws, 2x Cable, 2x Tensioner, 1x Driver

Items not to scale

SternaLock XP • Optional Instrumentation

94-Driver-S: Driver

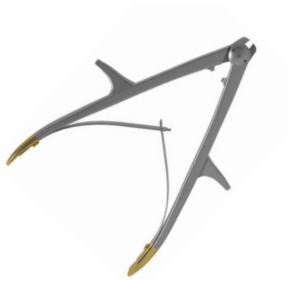
Ordering Qty: 1

94-Tensioner-S: Cable Tensioner

Ordering Qty: 1

94-Platecutter: Plate and Cable Cutter

Ordering Qty: 1



70-2001: ZDrive™ High Torque Driver & Battery

Ordering Qty: 1

73-1195: ZDrive™ Blade, SternaLock XP

Ordering Qty: 1

Items not to scale

SternaLock XP • Additional Sterile Screws

Part Number	Description	Content	
94-27-14-8S	Bone Screw 2.7 x 14mm	8 Pack	 Items not to scale
94-27-10-8S	Bone Screw, 2.7 x 10mm	8 Pack	
94-27-14-6S	Bone Screw 2.7 x 14mm	6 Pack	
94-27-10-6S	Bone Screw, 2.7 x 10mm	6 Pack	
94-27-14-4S	Bone Screw 2.7 x 14mm	4 Pack	
94-27-10-4S	Bone Screw, 2.7 x 10mm	4 Pack	
94-30-14-2S	Bone Screw, 3.0 x 14mm	2 Pack	
94-30-10-2S	Bone Screw, 3.0 x 10mm	2 Pack	

For more information on the SternaLock® XP Rigid Fixation System and other solutions, please contact us at:

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