

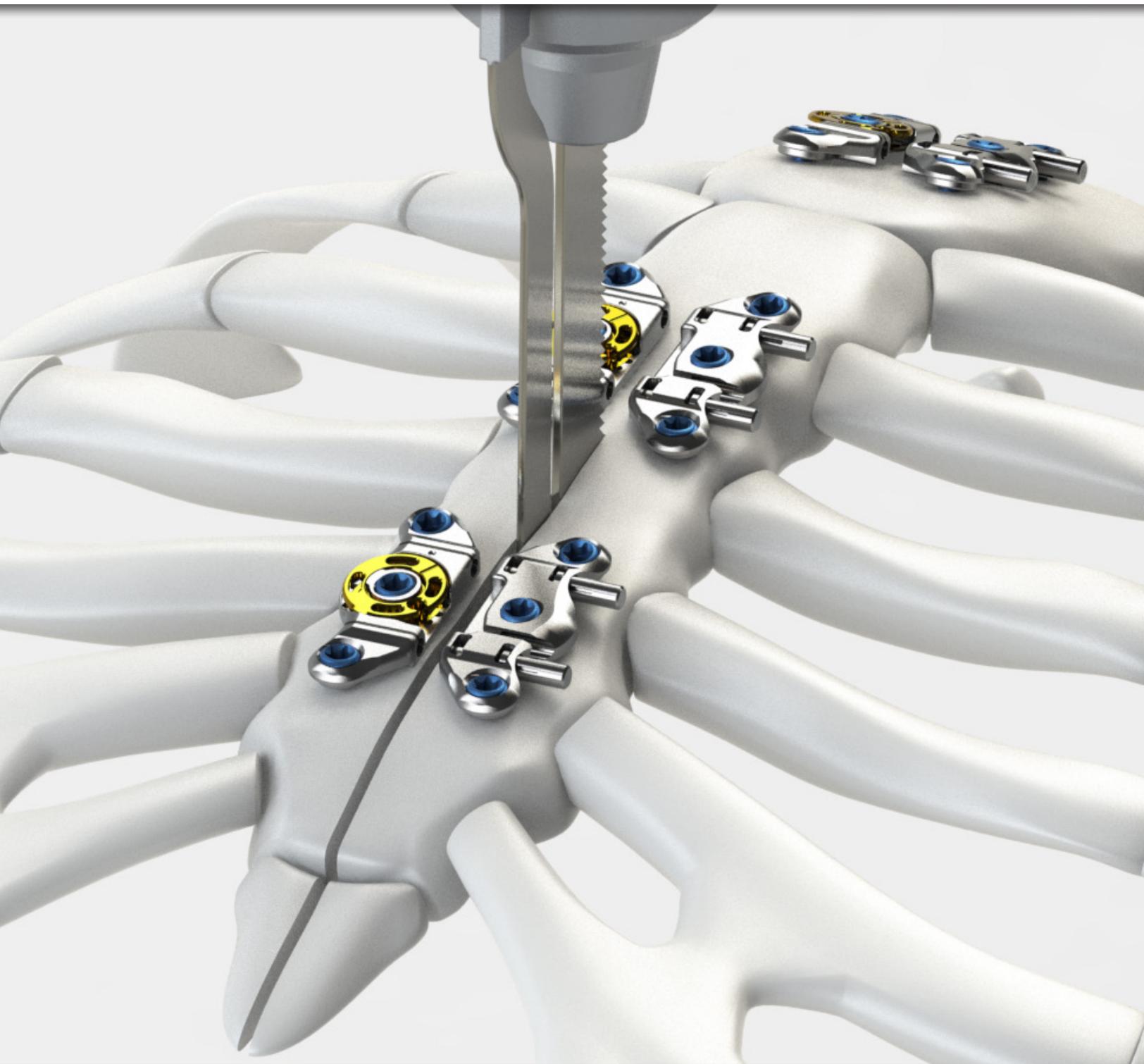
The Grand Pre™

sternal closure system



JACE

MEDICAL



SURGICAL TECHNIQUE

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System Overview

JACE Medical's Grand Pre™ sternal closure system is unique to the industry. With a revolutionary implant design and innovative instrumentation, the system enables the surgeon to achieve plate placement prior to or after sternotomy.

The system is contained in one comprehensive case with one size of implant and necessary instrumentation to successfully perform the procedure.

Indications

The Sternal Closure System is intended for use in stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

Soft Tissue Dissection

- Dissect soft tissue from the surface of the sternum to allow visualization of the bone.

note: → Bony calluses, if present, should be avoided, or removed from the midline and sternal surface to allow for proper anatomical reduction and plate placement.

Implant Positioner Loading

- Connect the Quick Connect Handle to the Implant Positioner by aligning the etched triangle on the Quick Connect Handle with the flat side on the Implant Positioner. Pull back the collar on the Quick Connect Handle and fully advance the handle over the AO connection on the Implant Positioner. Once fully engaged, release the collar on the Quick Connect Handle (figure 1).

note: → Use care when loading the Implant Positioner to avoid the periosteal spikes.

- Preload the Grand Pre Implant Positioner with two corresponding plate halves – the Ratchet Wheel Plate and the Shear Bar Plate (figure 2).

note: → Each plate half is designed to only mate with one side of the Implant Positioner. Assemble plate halves ensuring the plates are positioned with the flat surface of the plates facing outward (figure 2).

- Depress and hold the blue quick release buttons while inserting the plates into the pockets. When the plates are fully seated, release the quick release buttons. The plates should now be held securely in position.



figure 1:

Quick Connect Handle connection to Implant Positioner



figure 2:

Implants loaded into Implant Positioner



Shear Bar Plate
100.033.01



Ratchet Wheel Plate
100.033.02



Implant Positioner
201.047.47



Quick Connect Handle
201.050.00

The Grand Pre™

- Following preloading of plates, insert six of the blue 3.5mm x 14mm Self-Drilling Locking Screws into the holes located at the top of the Implant Positioner (figure 3). Once the screws are in place, use the Screw Plunger to ensure their correct position within the barrel (figure 4).

note: → Use only the plates and screws provided with the Grand Pre sternal closure kit.



figure 3: Implants loaded into Implant Positioner



figure 4: Ensure screw placement with Screw Plunger



3.5mm x 14mm
Self-Drilling Locking Screw
100.035.14



Screw Plunger
201.047.06



Implant Positioner
201.047.47



Quick Connect Handle
201.050.00

Plate Placement Prior to Sternotomy

- Depending on the length of the sternum, one to three Grand Pre implants are likely to be utilized.
- Orient the handle laterally and position the plates lightly on the midline of the center of the sternum (figure 5).
- The Implant Positioner should be placed directly over the midline of the sternum with equal portions of the sternal bone on the right and left sides of the device.
- Once the target position is achieved, apply downward pressure on the Implant Positioner engaging the periosteal spikes on the face of the instrument. The spikes are intended to stabilize the position of the Implant Positioner on the sternum prior to screw deployment.

note: → Do not impact the Implant Positioner.

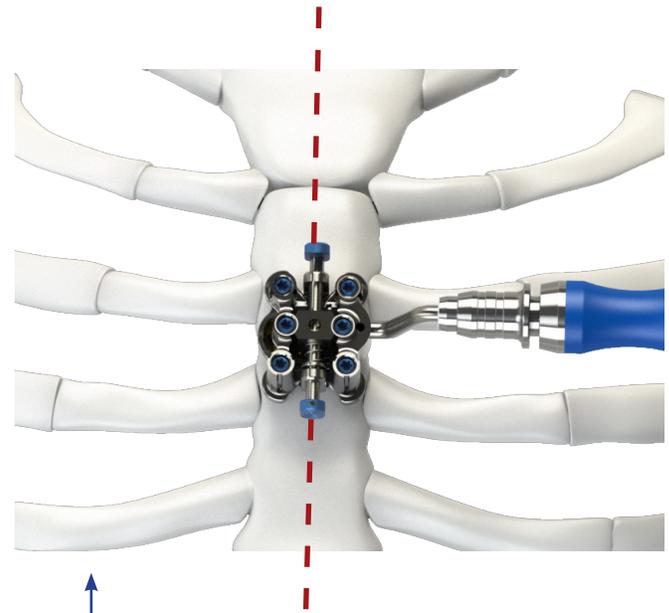


figure 5: Plate placement - Red dashed line indicates midline of sternum



Implant Positioner
201.047.47



Quick Connect Handle
201.050.00

Screw Fixation

- Screw placement is achieved using a battery-operated driver with AO adapter fitted with the provided Torque Limiter and T15 Hexalobe Driver. Connect the male end of the Torque Limiter to the AO adapter on the battery-operated driver.
- With one hand, or the aid of an assistant, hold the Implant Positioner in place while using the other hand to drive the screws (*figure 6*).
- The Torque Limiter will engage once the screws have locked into the plates – as evidenced by an audible click emanating from the Torque Limiter.

note: → The Torque Limiter must be used when inserting screws with a power driver. A 1000-1500 RPM battery-operated power driver is recommended.

- Start by driving one of the center screws in the Implant Positioner. Double check alignment between the Implant Positioner and the midline of the sternum before driving the next center screw. Drive the remaining four oblique screws using a criss-cross pattern.
- Once screw placement is completed, depress the blue quick release buttons on the Implant Positioner to disengage the plates (*figure 7*).

note: → Ensure screws are fully seated in plate.

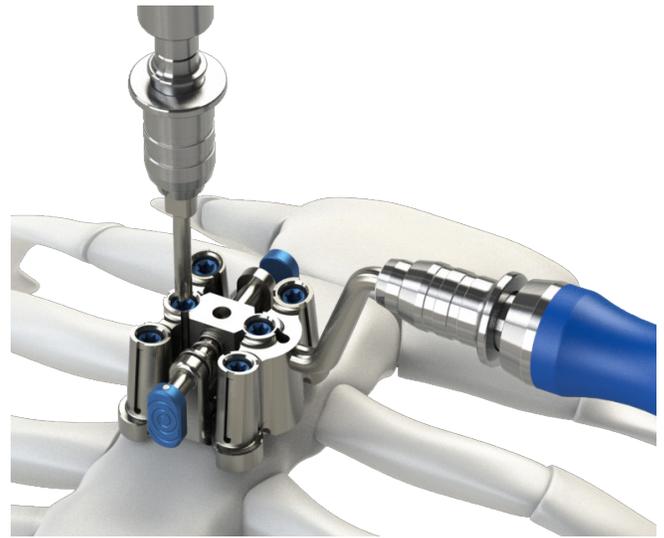


figure 6: Screw insertion



figure 7: Implants affixed to bone



3.5mm x 14mm
Self-Drilling Locking Screw
100.035.14



Torque Limiter
201.047.00



T15 Hexalobe Driver
201.047.15



Implant Positioner
201.047.47



Quick Connect Handle
201.050.00

Sternotomy

- Execute the sternotomy down the midline of the sternum cutting between the Grand Pre plates (*figure 8*).

Caution:

- » **Avoid saw contact with the Grand Pre implants when performing sternotomy.**
 - » **Check the posterior side of the sternum to ensure the screws did not breach the posterior aspect of the sternum.**
- Proceed with normal retraction and complete the intended surgical procedure.

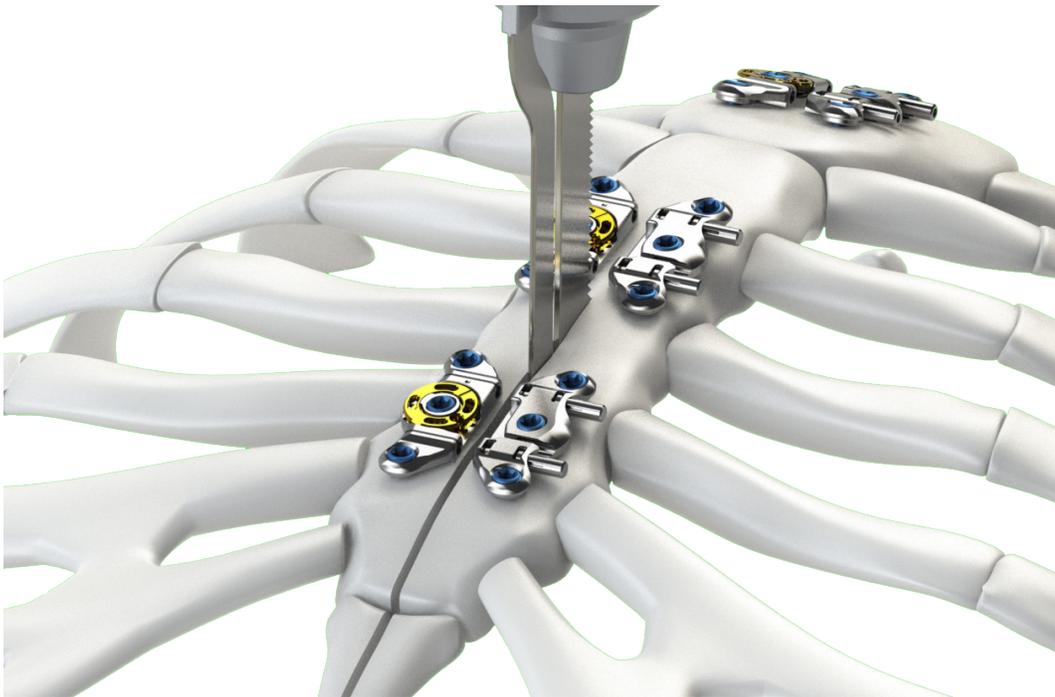


figure 8: Sternotomy performed between Grand Pre implants

Sternal Reduction

- Insert the vertical barbell end of the Locking Element into the Posi-Lock™ Ratchet Wheel capture receptacle (*figure 9*). Gently pull on the opposite end of the Locking Element to ensure that it is properly seated into the ratchet wheel capture receptacle. To ensure complete capture of the Locking Element, place the Ratchet Driver securely onto the Posi-Lock™ Ratchet Wheel and gently turn the wheel clockwise one click. Repeat this step if multiple Grand Pre implants are being utilized.
- Gross sternum reduction can be achieved by placing hands on the ribcage and applying medial pressure.
- Once gross sternum reduction is achieved, place the Locking Element into the capture slot in the opposing Shear Bar Plate (*figure 10*). Ensure that it is securely seated in the capture slot. Repeat this step if multiple Grand Pre implants are being utilized.

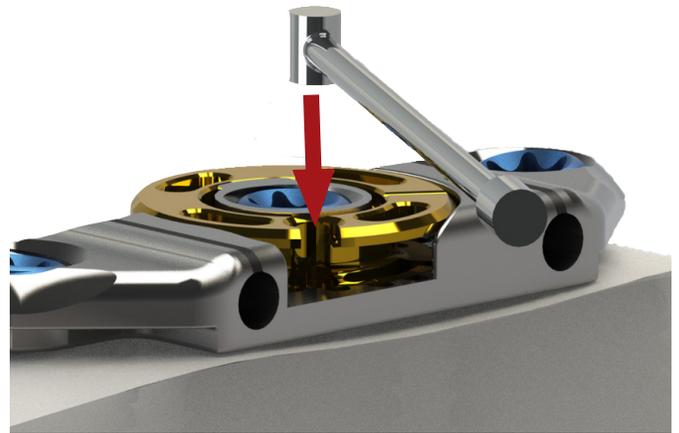


figure 9: Locking Element inserted into Ratchet Wheel

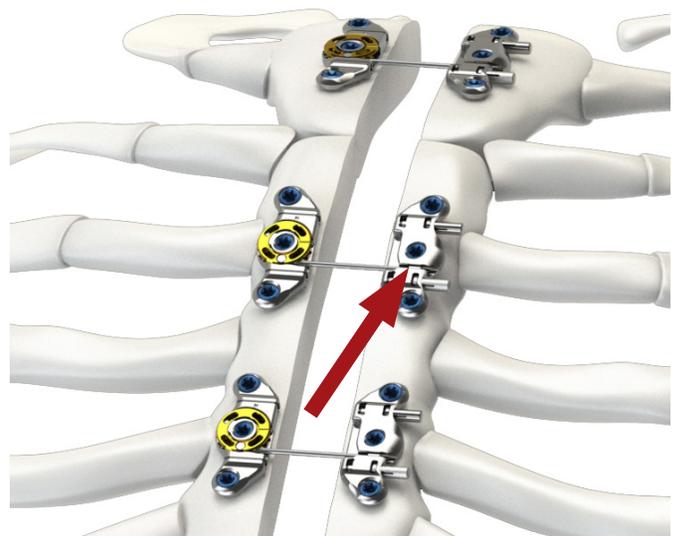


figure 10: Locking Element inserted into Shear Bar Plate slot



Shear Bar Plate
100.033.01



Ratchet Wheel Plate
100.033.02



Locking Element
101.012.32



Ratchet Wheel Driver
201.033.00



Quick Connect Handle
201.050.00

Shear Bar Deployment

- Deploy all Shear Bars manually by pushing on the end of the Shear Bar with a finger. When deployed manually, a tactile click may be felt when the Shear Bar is fully deployed. If access is difficult due to soft tissue, the Shear Bar Pusher may be used (*figure 11*).
- Check to ensure the Shear Bars are fully deployed. Full deployment is indicated when the barbs of the Shear Bar are visible through the open window in the Shear Bar Plate (*figure 12*).

Caution: Ensure Shear Bars are fully deployed.

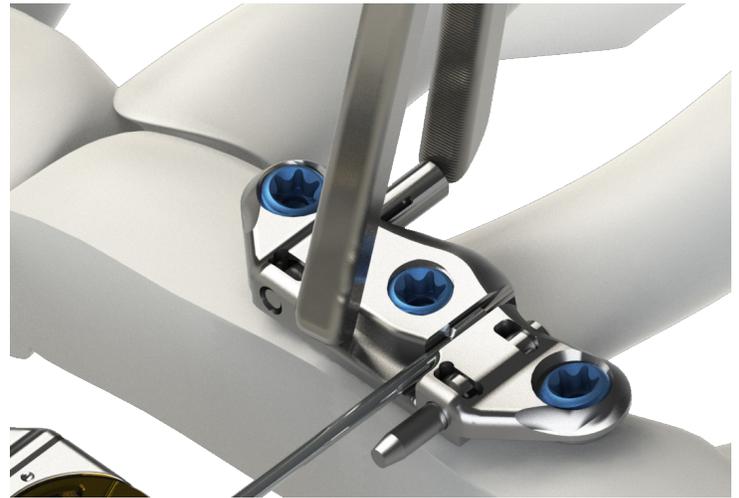


figure 11: Deploy Shear Bars with Shear Bar Pusher

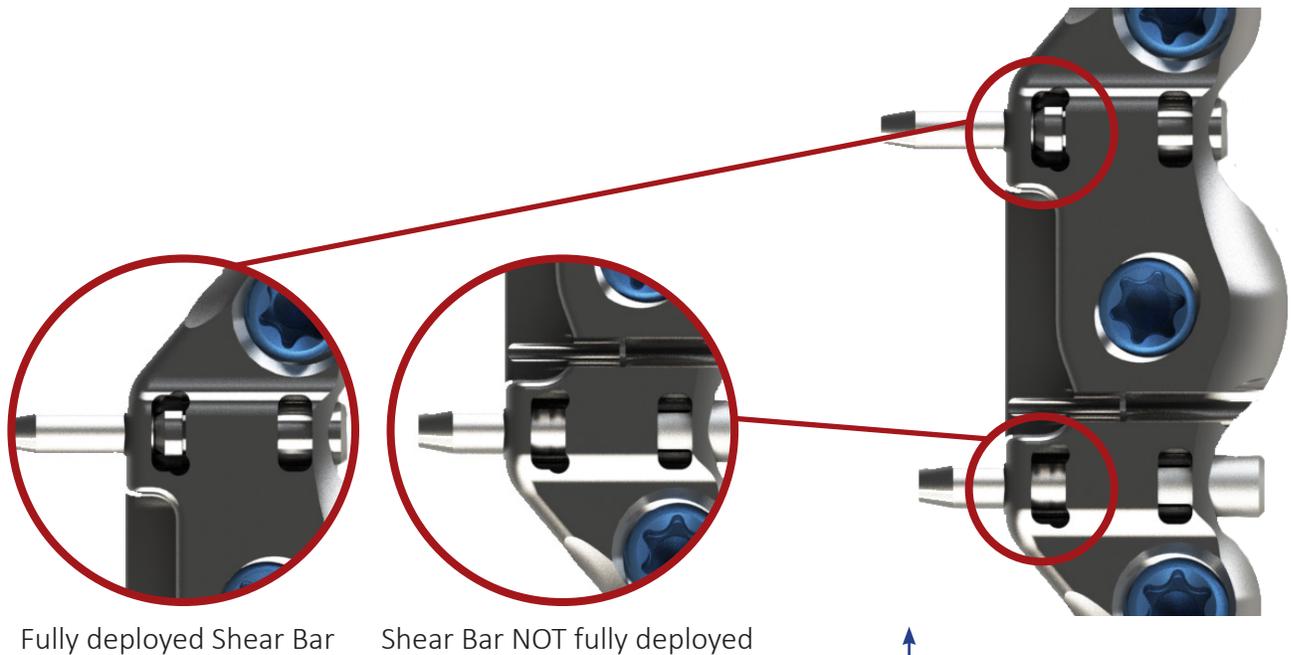


figure 12: Visual Indication of deployed Shear Bars



Shear Bar Plate
100.033.01



Ratchet Wheel Plate
100.033.02



Shear Bar Pusher
201.030.00

Sternal Closure

- Starting with the center construct, place the Ratchet Driver securely onto the Posi-Lock™ Ratchet Wheel (*figure 13*). Gently turn the wheel clockwise until the Shear Bars are approximately 1-3mm from the Ratchet Wheel Plate. A series of tactile clicks will occur as the wheel is advanced. If using multiple plates, repeat this step by incrementally tightening the middle plate first, then the proximal plate, and finally, the distal plate.
- Starting with the center construct, use the Single or Double Alignment Instruments to ensure the Shear Bars are axially aligned with the receptacle in the Ratchet Wheel Plate. The half circle receptacles on the Alignment Instruments are designed to mate with the rounded edges of the plates (*figure 13*).



figure 13: Tighten with Ratchet Wheel Driver

Caution: Avoid excessive prying or force on the plates with the Alignment Instruments.

- Once the Shear Bars are aligned, tighten the Ratchet Wheel until the sternal halves make contact. If using multiple plates, repeat this step by incrementally tightening the middle plate first, then the proximal plate, and finally, the distal plate (*figure 14*).

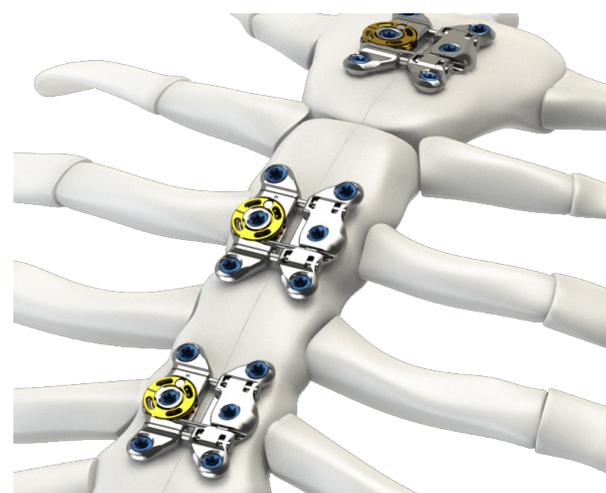


figure 14: Implanted Grand Pre implants

Caution: Do not overtighten the Ratchet Wheel.

- Use the T15 Hexalobe Driver connected to the Quick Connect Handle to confirm screws are properly seated.
- Confirm sternal halves have remained in contact prior to soft tissue closure.
- Complete soft tissue closure in the normal fashion.

note: → Sternal/cerclage wires can also be used in conjunction with Grand Pre implants if desired. Take care to avoid direct contact between sternal/cerclage wire and the titanium Grand Pre system.



Shear Bar Plate
100.033.01



Ratchet Wheel Plate
100.033.02



Ratchet Wheel Driver
201.033.00



Alignment Instrument,
Single End
201.040.10



Alignment Instrument,
Double End
201.040.20



Quick Connect Handle
201.050.00

Emergent Reentry

If emergent reentry is required, the Grand Pre sternal closure system allows for rapid access to the chest cavity.

note: → If bone healing necessitates recutting of the sternum to establish access, removal of the plates will be necessary. Use a T15 Hexalobe Driver for complete removal of the plates and screws. Loosen all of the screws first, and then remove the plate from the sternum.

- Cut the Locking Element(s) with the Wire Cutter (*figure 15*). Cover the Shear Bar portion of the element with a finger or 4x4 pad to ensure that it remains in position after the cut (*figure 16*).

Caution: Ensure residual Locking Element is retained in the Shear Bar Plate.

note: → The Shear Bars do not need to be divided, as they will disengage when the sternal halves are separated.

- Use smooth forceps to remove and discard the cut end of the Locking Element.

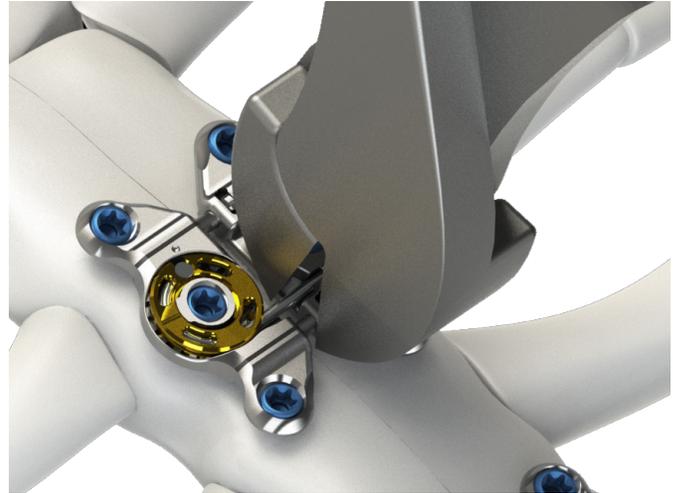


figure 15: Locking Element cut with Wire Cutter

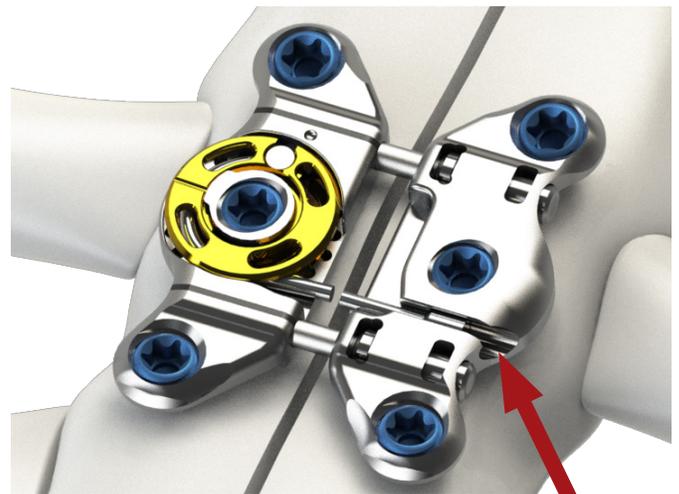


figure 16: Red arrow indicates portion of Shear Bar Plate to cover during cutting



Locking Element
101.012.32



Wire Cutter
201.012.00

Servicing the Posi-Lock™ Ratchet Wheel

- Using the Ratchet Wheel Driver, turn the Ratchet Wheel clockwise one full turn and then ensure that the groove on the wheel is aligned with the dimple on the Ratchet Wheel Plate (*figure 17*).
- Remove the Ratchet Wheel from the plate manually or with the Shear Bar Pusher oriented vertically and using a gentle back and forth upward rocking motion. Carefully remove and discard the coiled Locking Element (*figure 18*).
- Inspect the Ratchet Wheel for damage. Utilize replacement parts in the white Service Caddy if damage is present.

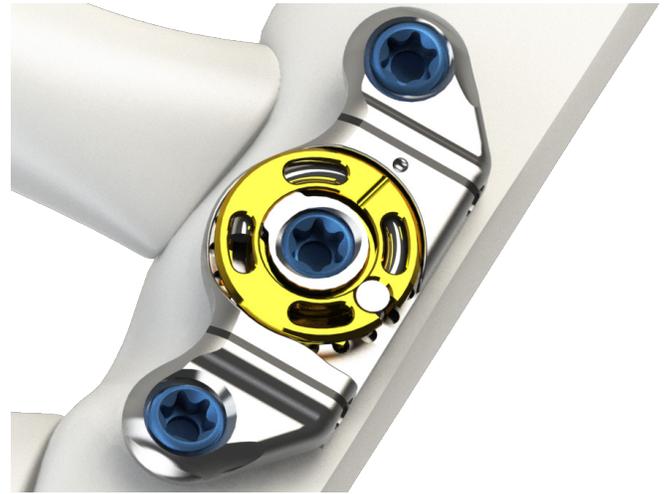


figure 17: Wheel removal position



figure 18: Wheel and Locking Element removal



Ratchet Wheel Plate
100.033.02



Shear Bar Pusher
201.030.00



Ratchet Wheel Driver
201.033.00



Quick Connect Handle
201.050.00

- Reinstall the Ratchet Wheel by aligning the groove on the ratchet wheel with the dimple on the Ratchet Wheel Plate. Using the Ratchet Wheel Driver, rotate the wheel one click clockwise (figure 19). This is the correct orientation for the wheel to accept another Locking Element. Reinstall the Locking Element(s) and close as previously described.
- The Shear Bars can be removed from the Shear Bar Plate if damaged. The Shear Bars are retracted with the Shear Bar Removal Instrument. Insert the Shear Bar Removal Instrument in the Shear Bar Plate window (figure 20). Apply light downward pressure and simultaneously rock the Quick Connect Handle towards the midline of the sternum to unlock the Shear Bar. Manually push the Shear Bar back into the Shear Bar Plate. Utilize replacement parts in the white Service Caddy if damage is present.



figure 19: Ratchet Wheel rotated one click

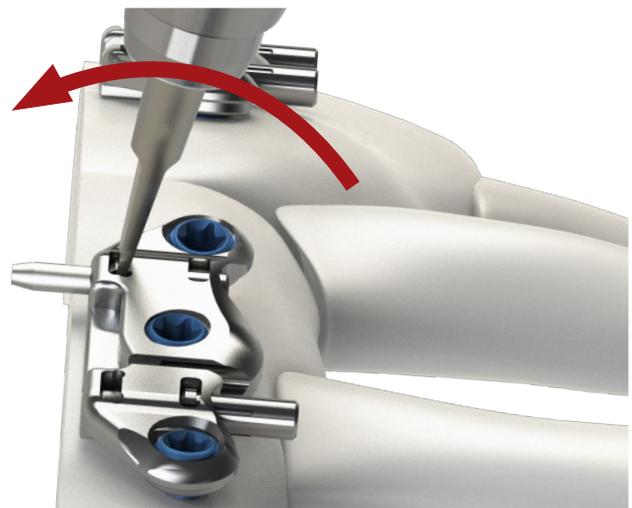


figure 20: Shear Bar Removal Tool



Locking Element
101.012.32



Posi-Lock™
Ratchet Wheel
100.033.00



Shear Bar
100.030.00



Shear Bar Removal
Instrument
201.033.10

Plate Placement Following Sternotomy

- For plate placement following sternotomy, the medial edges of the sternum must be brought together and held into complete approximation. Reduction is achieved using normal methods including stainless steel wires.

note: → It is critical to place and completely close each construct separately starting with the manubrium.

- With approximation achieved, place the preloaded Grand Pre Implant Positioner (see page 5) on the manubrium. Orient the Implant Positioner handle laterally and position the plates lightly on the mid-line of the sternum. The Implant Positioner should be placed directly over the mid-line of the sternum with equal portions of the sternal bone on the right and left sides of the device. Ensure the sternotomy line is centered between the plates. Once the target position is achieved, apply downward pressure on the Implant Positioner engaging the periosteal spikes on the face of the instrument. The spikes are intended to stabilize the position of the Implant Positioner on the sternum prior to screw deployment.

note: → It is critical that the approximation of the sternal halves are in their intended and final position, as the locking screws will secure them precisely where they are held. Apply considerable upward and medial tension to the chest cavity to achieve the correct anatomic position of the sternum.

- Screw placement is achieved using a battery-operated driver with AO adapter fitted with the Torque Limiter and T15 Hexalobe Driver (see page 8). Place considerable upward and medial tension on the wires superior and inferior to the plate to provide counter tension as the screws are placed. With one hand, or the aid of an assistant, hold the Implant Positioner in place while using the other hand to drive the screws. The Torque Limiter will engage once the screws have locked into the plate – as evidenced by an audible click emanating from the Torque Limiter. Start by driving one of the center screws in the Implant Positioner. Double check alignment between the Implant Positioner and the mid-line of the sternum before driving the next center screw. Drive the remaining four oblique screws using a criss-cross pattern.
- Once screw placement is completed, depress the blue quick release buttons on the Implant Positioner to disengage the plates.
- Complete final closure of first implant by following steps outlined in *Sternal Reduction through Sternal Closure* (see pages 10 - 12).

note: → If multiple implants are used, fully close each implant prior to placing subsequent implants.

- Repeat steps outlined in *Plate Placement Following Sternotomy* for each additional implant.



3.5mm x 14mm
Self-Drilling Locking Screw
100.035.14



Ratchet Wheel Plate
100.033.02



Shear Bar Plate
100.033.01



Torque Limiter
201.047.00



T15 Hexalobe Driver
201.047.15



Implant Positioner
201.047.47



Quick Connect Handle
201.050.00

Notes



Product Information

Implants

Item Number	Description
100.030.00	Shear Bar
100.033.00	Ratchet Wheel
100.033.01	Shear Bar Plate
100.033.02	Ratchet Wheel Plate
100.035.14	3.5mm x 14mm Self-Drilling Locking Screw
101.012.32	Locking Element



Shear Bar
100.030.00



Posi-Lock™
Ratchet Wheel
100.033.00



Shear Bar Plate
100.033.01



Ratchet Wheel Plate
100.033.02



3.5mm x 14mm
Self-Drilling Locking Screw
100.035.14



Locking Element
101.012.32

Instruments

Item Number	Description
201.012.00	Wire Cutter
201.030.00	Shear Bar Pusher
201.033.00	Ratchet Wheel Driver
201.033.10	Shear Bar Removal Instrument
201.040.10	Alignment Instrument, Single End
201.040.20	Alignment Instrument, Double End
201.047.00	Torque Limiter, AO Connection
201.047.06	Screw Plunger
201.047.15	T15 Hexalobe Driver
201.047.47	Implant Positioner
201.050.00	Quick Connect Handle

Sterilization Trays

Item Number	Description
301.010.00	Sterilization Base
301.010.10	Sterilization Lid
301.010.15	Sterilization Tray
301.010.20	Sterilization Implant Caddy
301.010.25	Sterilization Service Caddy

Service Items

Item Number	Description
100.030.00	Shear Bar
100.033.00	Posi-Lock™ Ratchet Wheel
100.035.14	3.5mm x 14mm Self-Drilling Locking Screw
101.012.32	Locking Element

Disclaimer: As the manufacturer of the Grand Pre™ sternal closure system, JACE Medical, LLC does not practice medicine and does not recommend this or any other product or surgical technique for use on a specific patient. The surgeon who performs any sternal closure procedure must determine the appropriate closure method and surgical procedure for each individual patient.

IFU and JACE Medical Product Care, Cleaning, and Sterilization instructions are available on the JACE Medical website (www.jacemed.com) or by calling Customer Service at 574.306.0355.

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