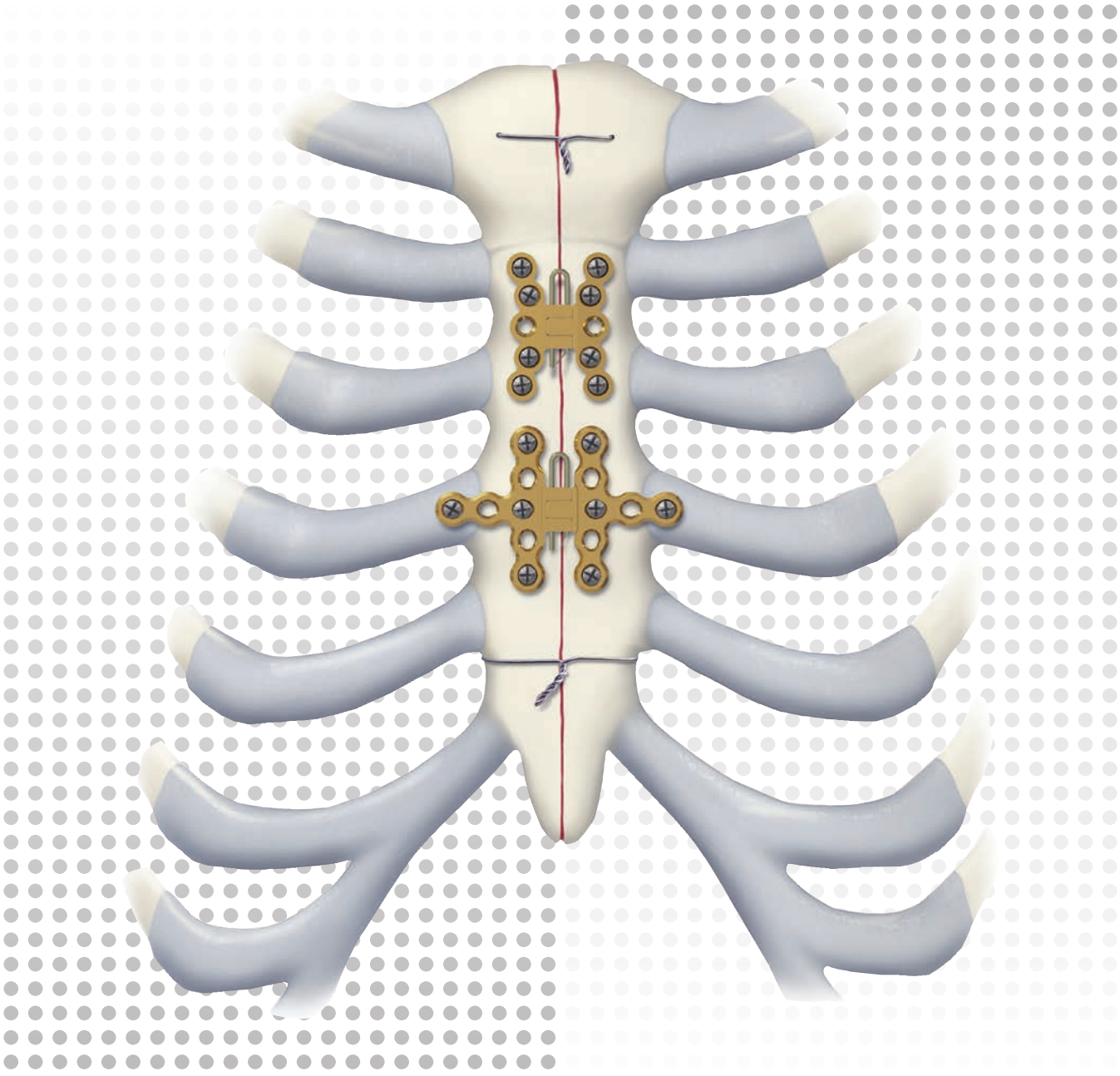
Titanium Sternal Fixation System

For Internal Fixation of the Sternum

Surgical Technique



AO approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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Titanium Sternal Fixation System

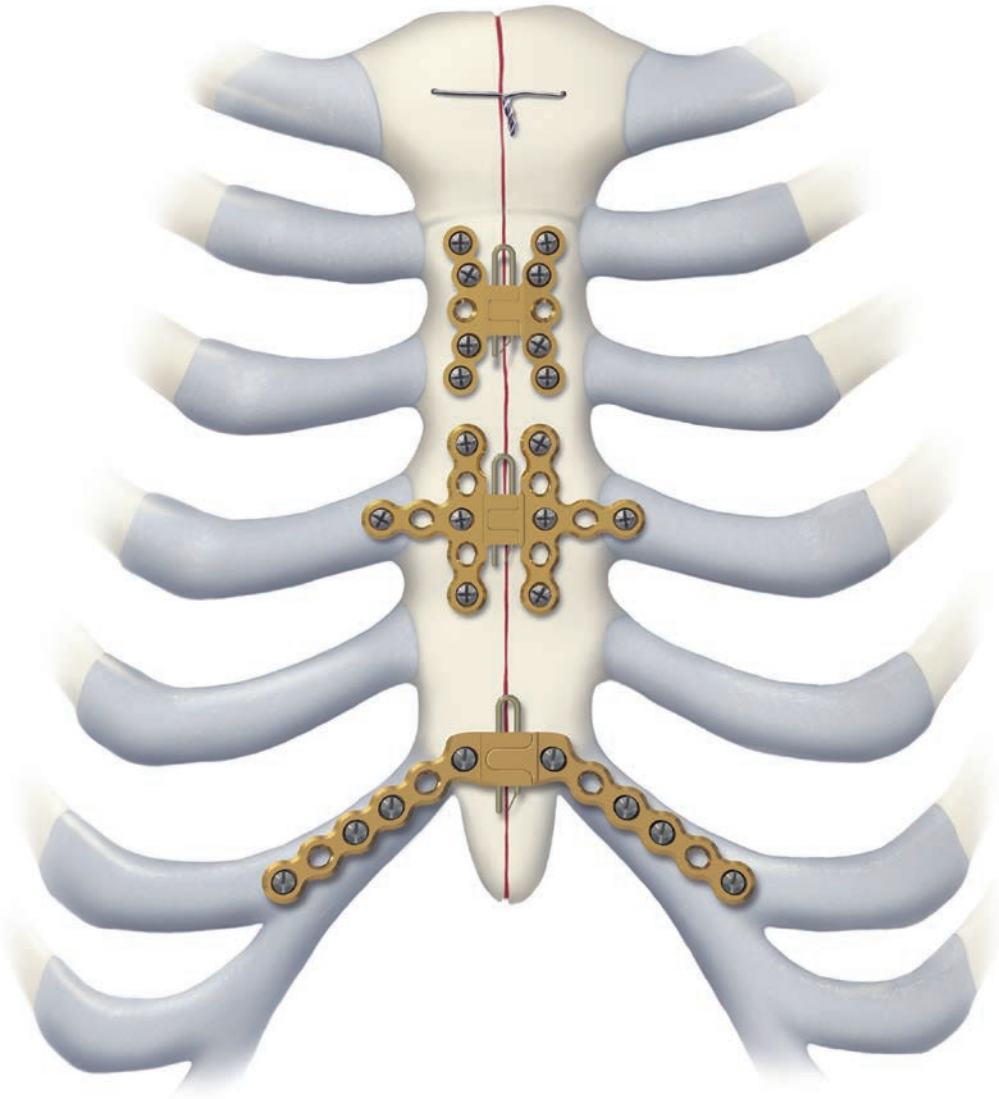
For internal fixation of the sternum

The DePuy Synthes Titanium Sternal Fixation System provides internal fixation of the sternum following a sternotomy or fracture of the sternum.

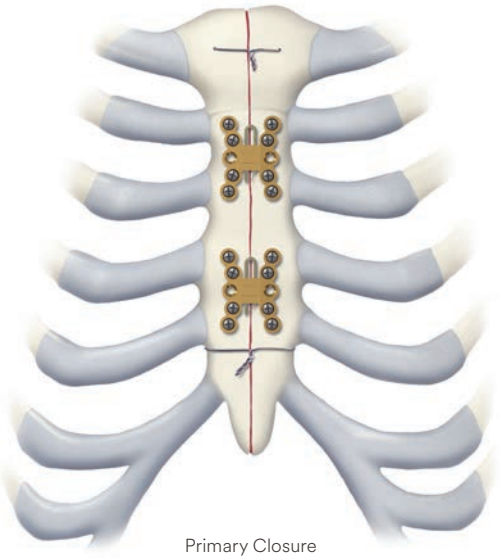
Variety of sternal plates

Different titanium plates according to the anatomical structures and patient's need are available:

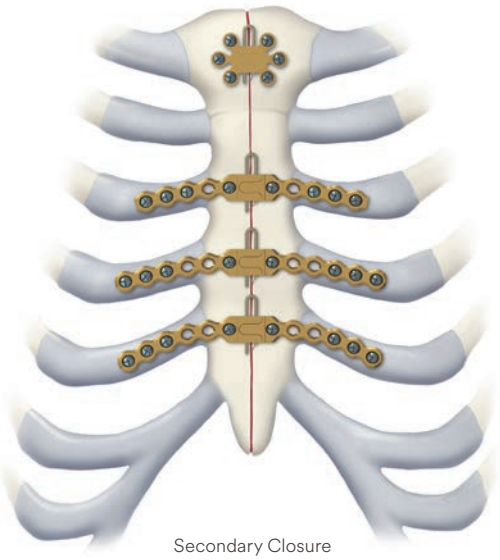
- Sternal body plates
- Star-shaped and H-shaped locking plates for fixation of the manubrium
- Titanium sternal locking straight plate without pin for transverse fractures*
- Straight locking plates for a sternal rib-to-rib fixation



*Contraindicated for use in cardiac patients due to the potential delay if emergent re-entry is required.



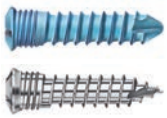
Primary Closure



Secondary Closure

Self-tapping and self-drilling locking screws

Both self-tapping (blue) and self-drilling (silver) locking screws are available.

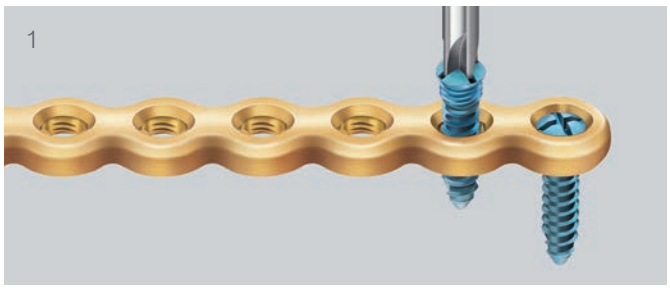


Self-Tapping

Self-Drilling

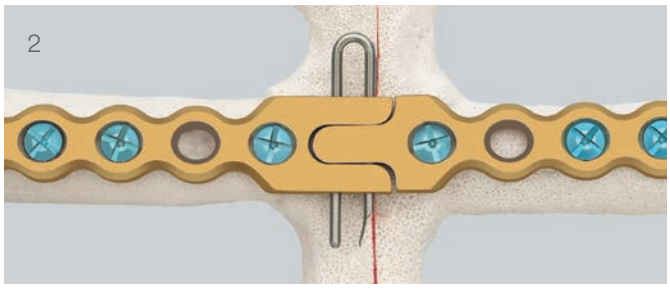
Plate – Screw Locking

The plate functions like an external fixator, applied internally. The screwhead of the sternal locking screws locks into the threaded plate hole to provide fixation (1).



Emergency release pin on plates*

Most plates consist of two parts joined by a U-shaped release pin in the cross section. The release pin allows sternal reentry in cardiac emergency cases (2).



Intended Use, Indications, Contraindications, Warnings and MRI Information can be found in the corresponding system Instructions for Use.

*Except Sternal Locking Plate 2.4, straight, without Emergency Release Pin, 13 holes, Pure Titanium (460.046), which is contraindicated for use in cardiac patients due to the potential delay if emergent re-entry is required.

The AO Principles of Fracture Management

Mission

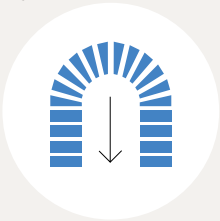
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

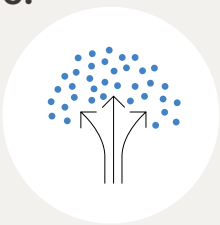
Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

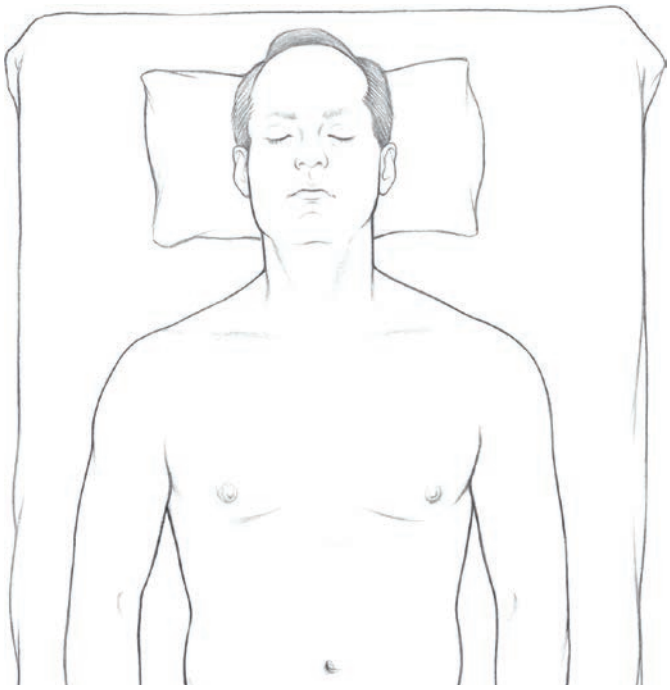
4.

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

[1] Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

1. Position patient

Position the patient with the arms tucked along the sides. Avoid placing arms at 90° on arm boards, as this makes chest closure difficult.



2. Debride (for secondary closure of the sternum)

Remove existing wires. Debride the involved sternal edges until they are free of devitalized tissue and down to bleeding tissue. Hemostasis should be obtained.

A curette can be used to remove any nonviable cartilaginous rib.

▲ Precaution:

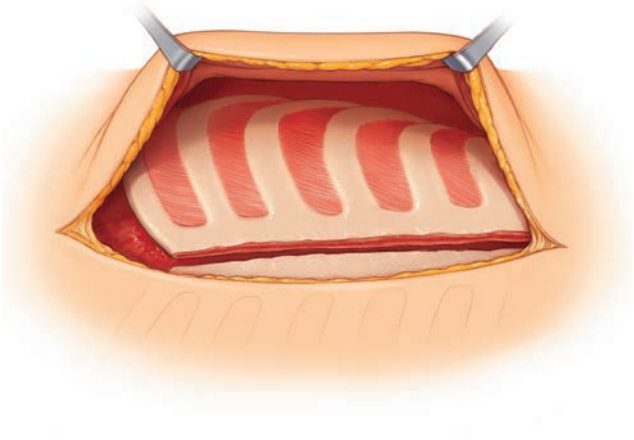
A sternal bone specimen should be sent to pathology to assess for osteomyelitis. Antibiotic treatment should be based on the identification of pathogens from bone cultures at the time of bone biopsy or debridement. Bone cultures are obtained first, then suspected pathogens are covered by initiation of a parenteral antimicrobial treatment.

3. Expose ribs laterally, if necessary

Beginning medially, elevate the pectoralis major muscles with overlying soft tissue attached to create flaps and permit later approximation in the midline.

It is usually not necessary to perform a second incision at the shoulder to release the pectoral muscle insertion.

Following debridement and muscle elevation, pulse lavage the entire surgical site with an adequate volume of saline with antibiotics.



4. Determine sternal edge thickness

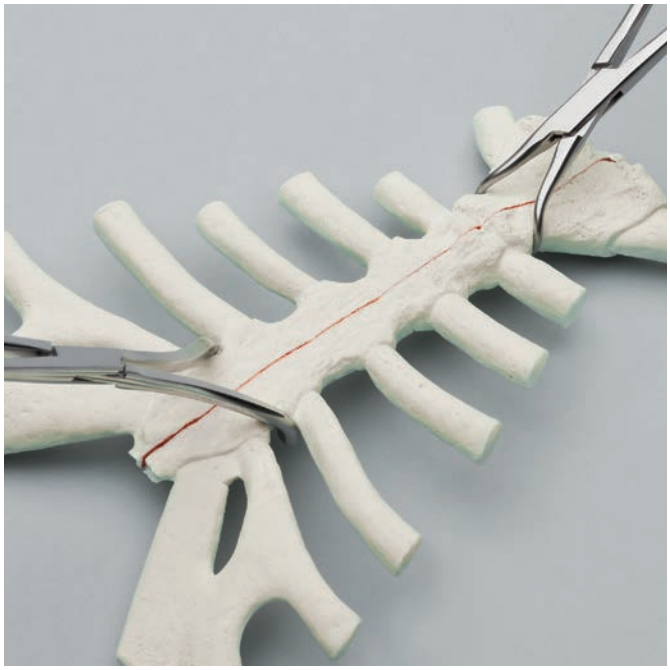
Instrument	
319.110	Depth Gauge for Screws ∅ 1.5 and 2.0 mm, measuring range up to 26 mm
Alternative instruments	
03.501.074	Universal Calliper
03.501.065	Calliper

Using the depth gauge, determine the thickness of the sternal edges adjacent to each rib where a plate may be placed.

Add 3 mm to the thickness of the sternal edge to account for the plate thickness and to determine the appropriate length drill bit with stop.

5. Reduce sternum

Instruments	
398.903	Sternal Reduction Forceps, angled, with ratchet lock
398.985	Reduction Forceps with Points, ratchet lock, length 180 mm
Alternative instrument	
398.902	Sternal Reduction Forceps



Reduce the sternum using reduction forceps on both the superior and inferior aspects of the sternum.

When placing the forceps, care should be taken to avoid the intercostal and mammary vessels and nerves.

■ Note:

Sternum can also be reduced with stainless steel surgical wire, if desired.

▲ Precaution:

Avoid direct contact of stainless steel wires with titanium implants to avoid galvanic corrosion.

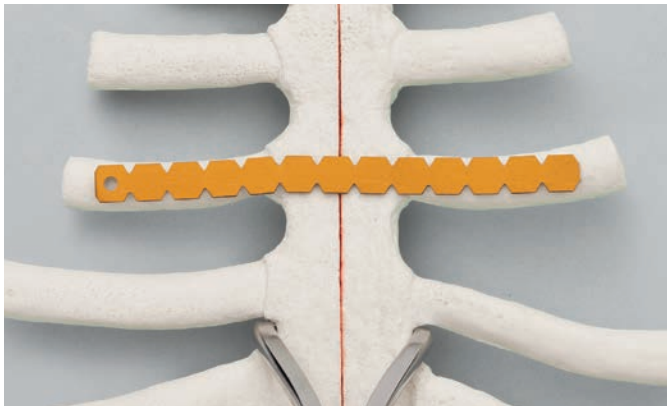
6. Cut and contour bending template

Instruments

329.400	Bending Template for Reconstruction Plates 2.4 to 4.0, length 295 mm

Cut the bending template to a length that allows placement of a minimum of four screws on each side of the fracture/osteotomy line.

Contour the bending template to the sternum and ribs.



7. Select and size plate

Instrument	
391.967	Shortcut 2.4/THORP, without rasp, required in pairs

Alternative instrument	
391.990	Cutting Pliers for Plates and Rods

Select the appropriate shape and length titanium sternal locking plate. Center the release pin on the sternum with sufficient plate length on each side to allow a minimum of four locking screws on each side.

The plate can be cut to length, if necessary, using the Shortcut plate cutters.

- Push the cutters from the opposite sides over the plate.
- Discs must show no distance to each other.
- Close handles with one hand.

As an alternative, cutting pliers for plates and rods may be used.

■ Note:

All steps of preparation and implantation of the Sternal Locking Plate have to be done, whenever possible, with the assembled plate. Do not disassemble the plate by pulling out the Emergency Release Pin.

▲ Precaution:

Select a plate with sufficient length to allow for a minimum of four screws on each side.

8. Contour plate

Instrument	
329.142	Bending Pliers with Nose, for Pure Titanium Plates 2.4 and 2.7

Alternative instruments	
391.963	Universal Bending Pliers, length 165 mm

Orient the plate so that the titanium emergency release pin is parallel to the midline of the sternum. The closed end of the emergency release pin should be oriented cranially. Contour the plate to match the bending template. The top side of the plate is etched with the part number, and the holes are countersunk to allow the screws to seat fully. Ensure that the plate is oriented properly when bending (etched side facing up).

Use the bending pliers with nose to make in-plane bends first, followed by out-of-plane bends.

■ Note:

Be aware that performing bends in reverse order might not result in optimal contouring.

Contour the plate with the emergency release pin inserted. If the emergency release pin interferes with the bending tool, it can be removed and must be replaced with a new pin.

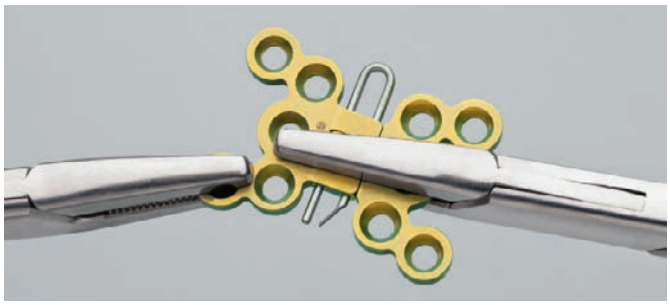
■ Note:

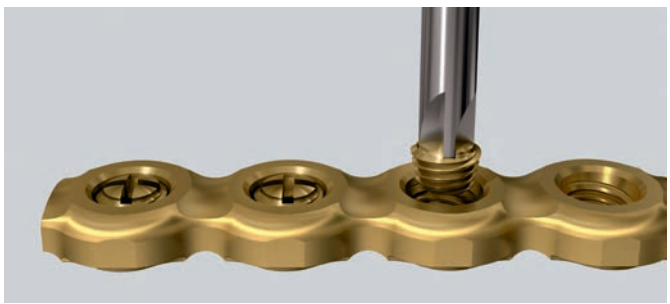
Be careful not to deform the pin section of the plate halves while contouring. If this portion of the plate is bent, the plate could break or the emergency release pin could become stuck in the plate.

Check the plate against the bending template to ensure it has the correct shape.

■ Note:

The smaller sternal body plates can be bent with universal bending pliers.





▲ Precautions:

- Use bending screws for severe bends to prevent plate hole deformation while contouring the plate. Bending screws may be left in place if they cannot be removed. However, DePuy Synthes recommends the use of at least four screws per side/per plate for sternal osteotomies with this system.
- Avoid excessive and reverse bending as it may weaken the plate and lead to premature implant failure.

9. Position plate

Position the plate to allow placement of a minimum of four screws on each side of the fracture/osteotomy line.

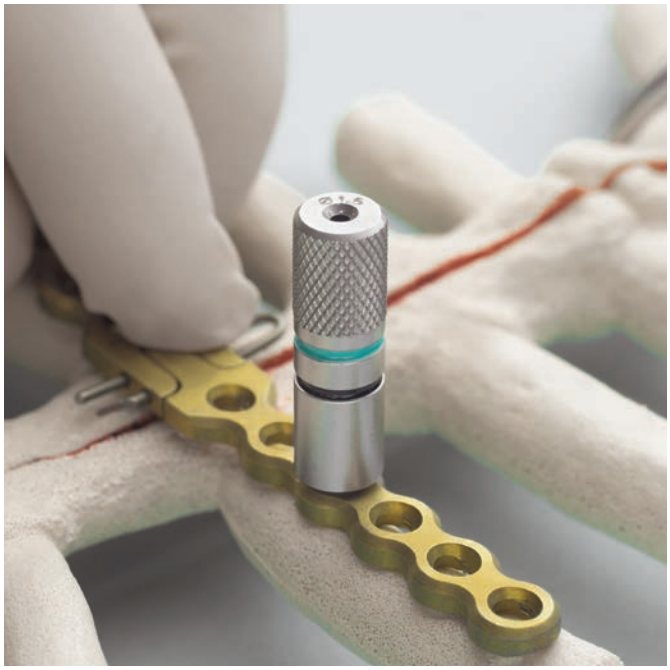
For sternal locking straight plates, position the plate on the superior portion of the rib to avoid the intercostal vessels and nerves during drilling.

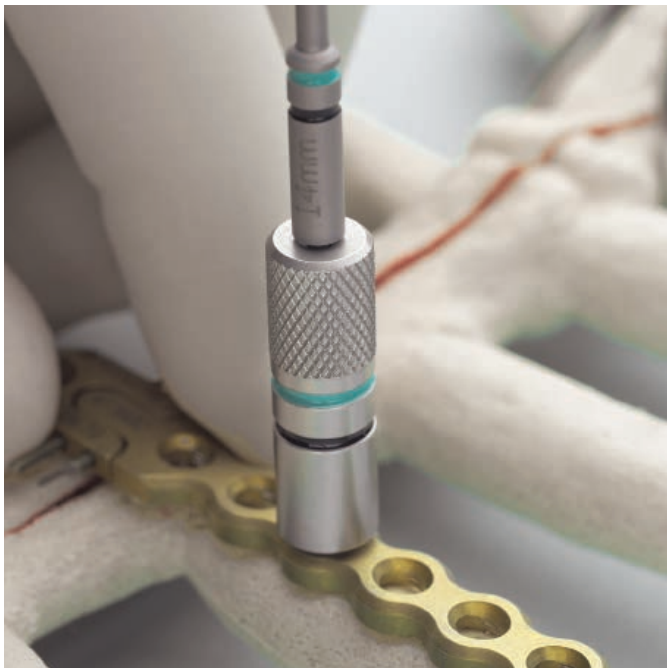
▲ Precautions:

- In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy.
- Use a minimum of four screws per side/per plate for sternal osteotomies with this system.

10. Drill

Instruments	
03.501.008– 03.501.018	Drill Bit ∅ 1.5 mm with Stop, length 82/8–18 mm, 2-flute, for J-Latch Coupling
03.501.000	Drill Guide 1.5, with thread, for Sternal Locking Plates





■ Note:

The alternative technique with self-drilling screws can be used (see section Alternative Technique with Self-drilling Screws).

Insert the 1.5 mm threaded drill guide into the plate to ensure the locking screw will be aligned with the plate hole.

For the sternum, use the drill bit with stop of the proper length as determined in step 4. Drill bits with stop are available in lengths ranging from 8 mm to 18 mm, in 2 mm increments, matching the locking screw lengths.

▲ Precautions:

- Do not drill any deeper than determined in step 4 to avoid the risk of pneumothorax.
- Do not drill in the region above the internal mammary arteries.
- Irrigate during drilling to avoid thermal damage to the bone.
- Drilling speed should never exceed 1800 rpm. Higher speeds can result in thermal necrosis of the bone and increased hole diameter and may lead to unstable fixation.
- Recognize that the thickness of the adjacent ribs may be less than the sternal edge.
- For sternal screws, drill bicortically.
- For rib screws, drill bicortically wherever possible.

Remove the 1.5 threaded drill guide.

11. Select and insert first self-tapping screw

Instruments	
313.940	Screwdriver, cruciform, with Holding Sleeve, for Cortex Screws ∅ 2.4 mm
319.110	Depth Gauge for Screws ∅ 1.5 and 2.0 mm, measuring range up to 26 mm
Optional instruments	
311.023	Ratcheting Screwdriver Handle, with Hexagonal Coupling
313.939	Screwdriver Shaft 2.4/3.0, cruciform, not self-holding, with Hexagonal Coupling
313.970	Holding Sleeve, for Nos. 313.960 and 314.448
03.501.056	Lag Tool

Determine the depth of the drilled hole using the depth gauge through the plate to confirm the appropriate screw length.

Be careful not to extend the tip of the depth gauge past the posterior cortex of the sternum/rib.

Select the proper length ∅ 3.0 mm titanium locking screw.

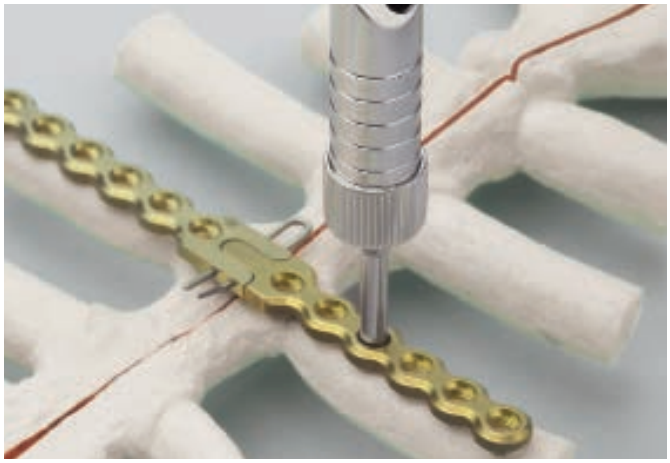
▲ Precaution:

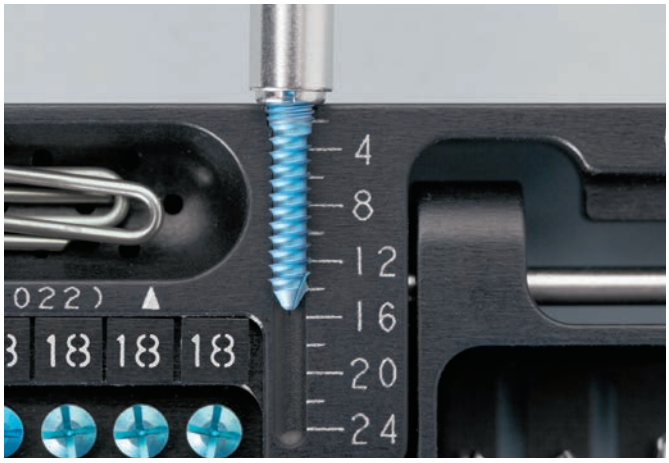
The screw should be no longer than necessary to engage the posterior cortex, to avoid deeper injury.
The tip of the screw should not extend more than 0.5 mm beyond the posterior cortex to avoid the risk of pneumothorax.

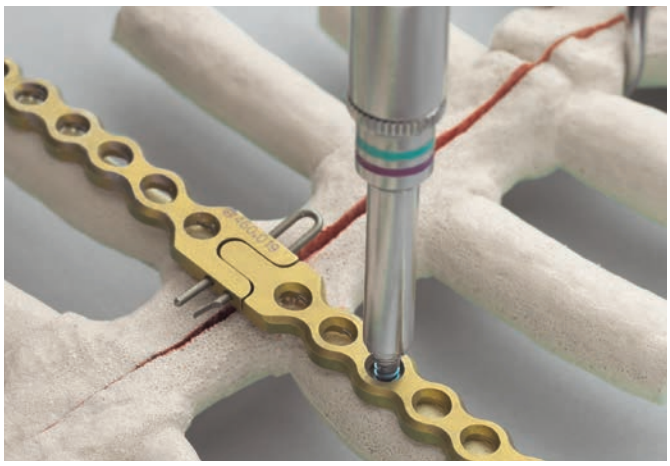
■ Note:

Screw length can be determined using the screw length indicator on the module. Optionally available Lag Tool (03.501.056) can be used to achieve plate to bone reduction. Please see Lag Tool reference guide (036.001.400) for more details.

Insert the locking screw through the plate and tighten until secure.







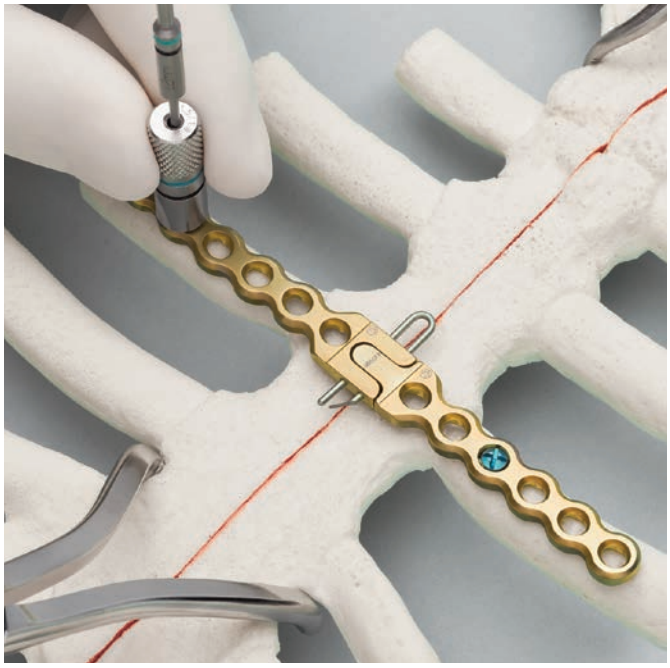
12. Drill and place remaining screws

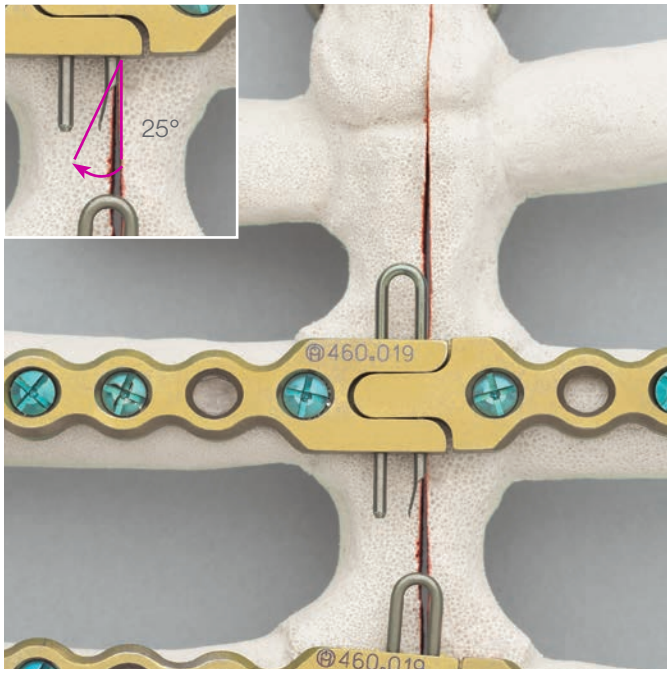
Insert a second screw on the opposite side of the fracture/osteotomy line following steps 10 and 11. Insert all remaining screws in the same manner.

After the plate has been fixated to the sternum/ribs, it is important to verify that the prong is bent medially to educe risk of migration of the pin.

▲ Precaution:

Avoid over-bending of the flat prong (>25°), as this can lead to breakage or inability to remove the pin for emergency reentry.





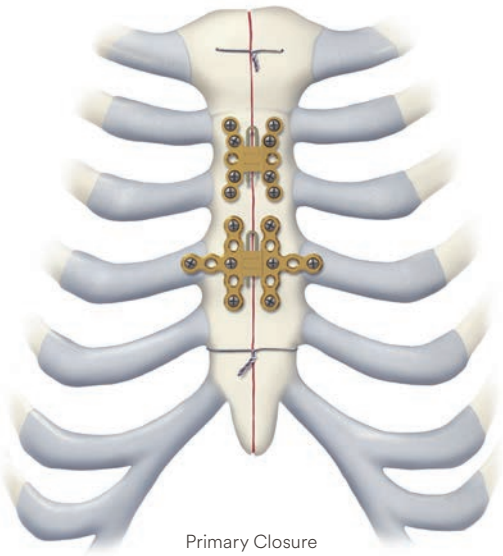
13. Insert remaining plates

Place remaining plates following steps 6 through 12.

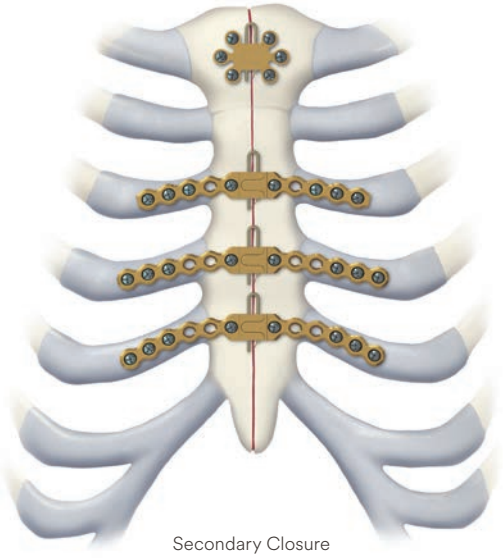
For secondary closure: A minimum of three plates is recommended following a full sternotomy and reconstruction.

▲ Precautions:

- For primary closure: If one plate is used in combination with stainless steel surgical wires, at least four wires should be used for closure of a full sternotomy. If two plates are used in combination with stainless steel wires, a minimum of two wires should be used.
- Avoid direct contact of stainless steel wires with titanium implants to prevent galvanic corrosion.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
- Irrigate and apply suction for removal of debris potentially generated during implantation.



Primary Closure



Secondary Closure

14. Manubrium plate (optional)

Instrument	
391.963	Universal Bending Pliers, length 165 mm

A plate can be placed on the manubrium if needed. Several star-shaped and H-shaped plates are available for placement on the manubrium. Follow guidelines in steps 7 through 12 to place this plate.

For manubrium plates, insert screws bi-cortically when possible. Mono-cortical placement of screws may be used according to surgeon preference.

The manubrium plates can be bent with universal bending pliers.

The H-shaped and star-shaped plates are intended only for use on the manubrium.

15. Closure and postoperative considerations

Standard sternal postoperative considerations are recommended for six weeks after surgery, including:

- Patient should not lift more than 10 lbs (4.5 kg).
- Patient should not raise arms greater than 90°.
- Patient should press a pillow against his/her chest in the event of a strong cough.
- Do not pull or lift the patient by the arms.
- Avoid trunk twisting.
- Avoid contact sports or other activities where there is a potential for high velocity impacts.

■ Note:

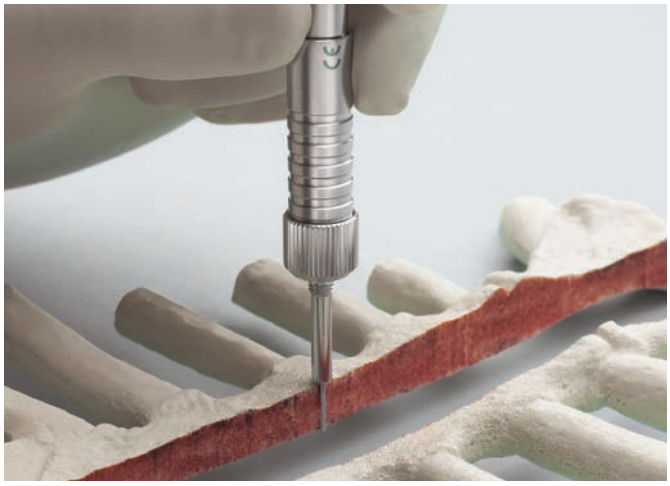
Do not pull or lift the patient by the arms for 6 weeks.
Do not raise arms higher than 90° at shoulder level.

Alternative Technique with Self-drilling Screws

Self-drilling locking screws are available as an alternative to the self-tapping locking screws.

1. Determine sternal edge thickness and position plate

Determine the sternal edge thickness and position the plate as described in steps 1 to 9 of the surgical technique.



2. Select and insert first screw

Instrument	
313.940	Screwdriver, cruciform, with Holding Sleeve, for Cortex Screws ∅ 2.4 mm
Optional instrument	
03.501.056	Lag Tool

Select the proper length ∅ 3.0 mm titanium sternal self-drilling locking screw based on sternal edge thickness determination as described in step 4.

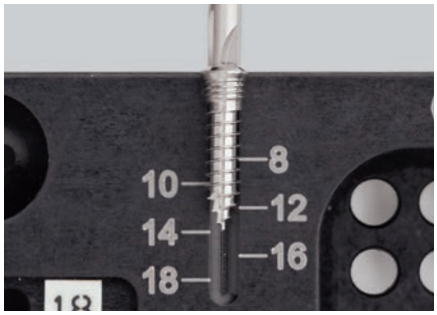
▲ Precautions:

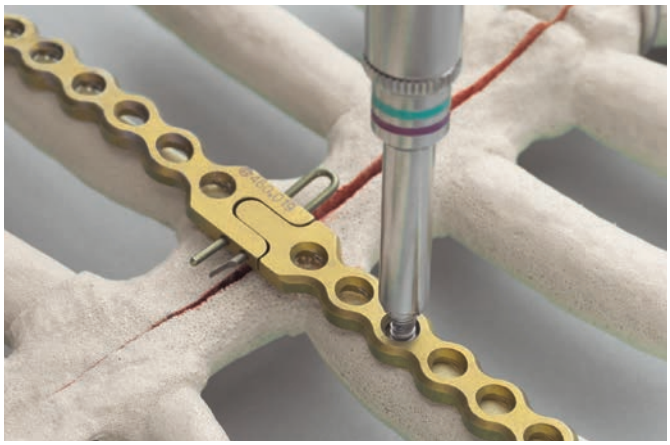
- The self-drilling locking screw should be inserted perpendicular to the plate and the screw axis should be aligned with the thread axis of the plate hole.
- The self-drilling locking screw should be no longer than necessary to engage the posterior cortex, to avoid deeper injury. The tip of the screw should not extend more than 0.5 mm beyond the posterior cortex.
  In the area of the ribs, predrilling may facilitate the determination of the appropriate screw length.

Insert the sternal locking screw through the plate and tighten until secure.

■ Note:

Screw length can be determined using the screw length indicator on the module. Optionally available Lag Tool (03.501.056) can be used to achieve plate to bone reduction. Please see Lag Tool reference guide (036.001.400) for more details.





▲ Precautions:

- Recognize that the thickness of the adjacent ribs may be less than the sternal edge.
- Screw lengths 14 mm and longer should not be used in the area of the ribs.
- For sternal screws, insert bicortically. For rib screws, insert bicortically whenever possible.
- Do not insert screws any deeper than necessary, to avoid the risk of pneumothorax.
- Do not insert screws in the region above the internal mammary arteries.
- After surgery, routinely perform a chest x-ray to exclude the possibility of a pneumothorax.

3. Place remaining screws

Insert a second sternal self-drilling locking screw on the opposite side of the fracture/osteotomy line following steps 1 to 2 of the alternative technique with self-drilling screws. Insert all remaining sternal self-drilling locking screws in the same manner.

Complete the procedure following steps 13 through 15 of the surgical technique.

Emergency Reentry

Remove emergency release pin

Remove the emergency release pins from the plates.

▲ Precaution:

Discard the pins. Pins must not be reused.

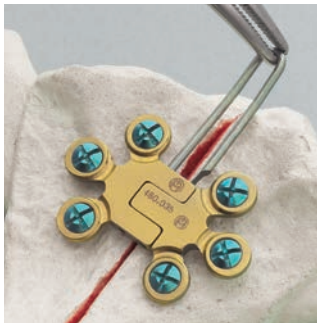
Separate the two plate halves to open the sternum.

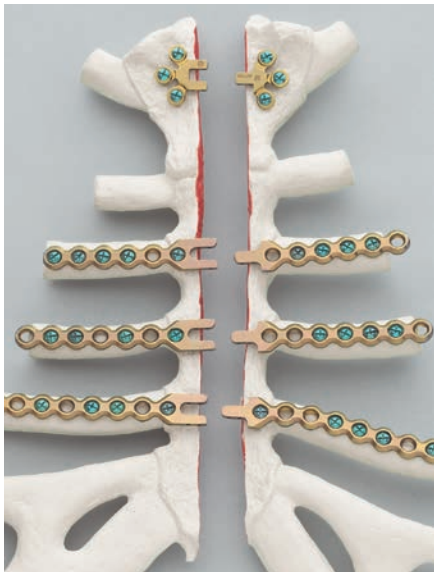
■ Note:

Plate and screw removal is necessary for re-entry with the Sternal Locking Plate 2.4, straight, without emergency release pin or if sternal bony fusion has occurred.
To facilitate plate and screw removal, the DePuy Synthes Universal Screw Removal Set may be used.

▲ Precaution:

Irrigate and apply suction for removal of debris potentially generated during explantation.





Insert emergency release pin

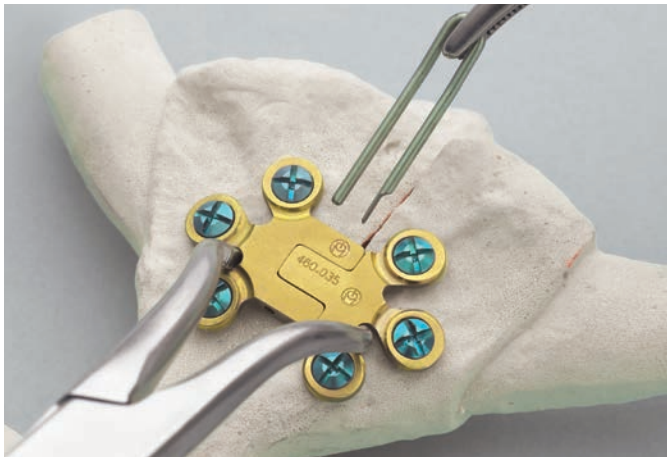
To reclose the sternum, a forceps or reduction instrument may be used to return the plate halves to their original positions. Remove any soft tissue that could reduce the risk of them from interdigitating properly.

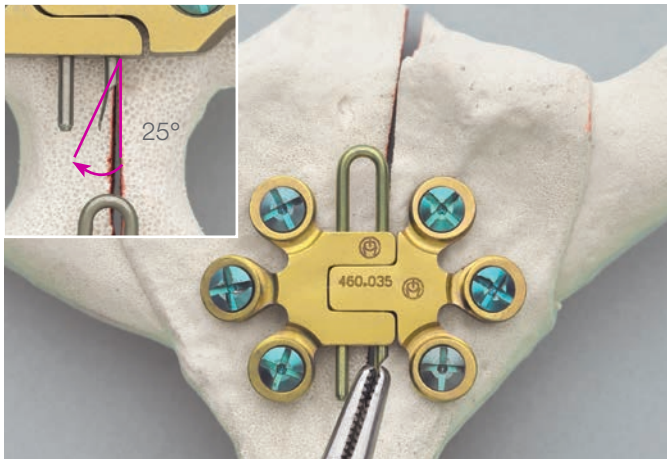
Once the plate halves are coupled, insert a new titanium emergency release pin. The closed end of the emergency release pin should be oriented cranially with the sloped bend oriented anteriorly.

▲ Precautions:

- Avoid over-bending of the flat prong (>25°), as this can lead to breakage or inability to remove the pin for emergency reentry.
- Bend the flat prong on the pin medially 20°–25°, to reduce the chance of pin migration.

If pin cannot be replaced into the existing implant, remove the implant and replace.





Implants

Titanium Sternal Locking Body Plates

460.037	Sternal Locking Plate 2.4, X-shaped, 5+5 holes, Pure Titanium
460.038	Sternal Locking Plate 2.4, Double-T-shaped, 7+7 holes, Pure Titanium
460.039	Sternal Locking Plate 2.4, angle-shaped, 12 holes, Pure Titanium
460.040	Sternal Locking Plate 2.4, X-shaped, wide, 5+5 holes, Pure Titanium

Titanium Sternal Locking Straight Plates

460.045	Sternal Locking Plate 2.4, straight, 8 holes, Pure Titanium
460.019	Sternal Locking Plate 2.4, straight, 12 holes, Pure Titanium
460.023	Sternal Locking Plate 2.4, straight, 20 holes, Pure Titanium
460.024S	Sternal Locking Plate 2.4, straight, 30 holes, Pure Titanium, sterile
460.046*	Sternal Locking Plate 2.4, straight, 13 holes, without Emergency Release Pin, Pure Titanium
460.048S	Sternal Locking Plate 2.4, Double-T-shaped, 9+9 holes, Pure Titanium, sterile

For sterile implants add suffix “S”.
* Contraindicated for use in cardiac patients, due to the potential delay if emergent re-entry is required.

Titanium Sternal Locking Manubrium Plates

460.027	Sternal Locking H-Plate 2.4, small, 4+4 holes, Pure Titanium	
460.028	Sternal Locking H-Plate 2.4, large, 4+4 holes, Pure Titanium	
460.035	Sternal Locking Plate 2.4, star-shaped, 3+3 holes, Pure Titanium	
460.036	Sternal Locking Plate 2.4, star-shaped, 6+6 holes, Pure Titanium	
460.022	Emergency Release Pin (TAN)	

For sterile implants add suffix “S”.

Instruments

Sterile Primary Kits

460.146S	Sternal Primary Kit, X-Plates and Sternal UniLOCK Screws ∅ 3.0 mm, self-drilling, length 12 mm, sterile Contains 2 X-plates and 16 screws For sternal thicknesses of 9 –10 mm
460.147S	Sternal Primary Kit, X-Plates and Sternal UniLOCK Screws ∅ 3.0 mm, self-drilling, length 14 mm, sterile Contains 2 X-plates and 16 screws For sternal thicknesses of 11–12 mm
460.148S	Sternal Primary Kit, X-Plates and Sternal UniLOCK Screws ∅ 3.0 mm, self-drilling, length 16 mm, sterile Contains 2 X-plates and 16 screws For sternal thicknesses of 13–15 mm

Sterile Manubrium Kits

460.172S	Sternal Manubrium Kit, H-Plate, large and Sternal UniLOCK Screws ∅ 3.0 mm, self-drilling, length 14 mm, sterile Contains 1 H-plate and 8 screws
460.173S	Sternal Manubrium Kit, H-Plate, large and Sternal UniLOCK Screws ∅ 3.0 mm, self-drilling, length 16 mm, sterile Contains 1 H-plate and 8 screws

■ Note:

Please refer to Sterile Kits brochure (036.001.340) for additional information.

Titanium Sternal Locking Screws

Sternal UniLOCK self-tapping screws, ∅ 3.0 mm

Art. No.	Length
413.578	8 mm
413.580	10 mm
413.582	12 mm
413.584	14 mm
413.586	16 mm
413.588	18 mm

Sternal UniLOCK self-drilling screws, ∅ 3.0 mm

Art. No.	Length
04.501.110	10 mm
04.501.112	12 mm
04.501.114	14 mm
04.501.116	16 mm
04.501.118	18 mm
04.501.120	20 mm

Bending screw

497.689	Bending Screw for UniLOCK Reconstruction Plates

For sterile screws add suffix “S”.
For screws in packs of 5, add suffix “.05”.

Instruments for preparation and insertion of the implants are available:

398.902	Sternal Reduction Forceps

398.903	Sternal Reduction Forceps, angled, with ratchet lock

398.985	Reduction Forceps, ratchet lock, length 180 mm

399.980	Reduction Forceps, large, with Points, ratchet lock, length 205 mm

329.400	Bending Template for Reconstruction Plates 2.4 to 4.0, length 295 mm

391.967	Shortcut 2.4/THORP, without rasp, required in pairs

329.142	Bending Pliers with Nose, for Pure Titanium Plates 2.4 and 2.7

391.963	Universal Bending Pliers, length 165 mm

03.501.000	Drill Guide 1.5, with thread, for Sternal Locking Plates

Drill Bit ∅ 1.5 mm, with Stop, 2-flute, for J-Latch Coupling

Art. No.	Length/Stop
03.501.008	82/ 8 mm
03.501.010	82/10 mm
03.501.012	82/12 mm
03.501.014	82/14 mm
03.501.016	82/16 mm
03.501.018	82/18 mm

03.501.065	Calliper

03.501.074	Universal Calliper

319.110	Depth Gauge for Screws ∅ 1.5 and 2.0 mm, measuring range up to 26 mm	
313.940	Screwdriver, cruciform, with Holding Sleeve, for Cortex Screws ∅ 2.4 mm	
311.006	Handle, medium, with Hexagonal Coupling	 for position only
311.007	Handle, large, with Hexagonal Coupling	
311.023	Ratcheting Screwdriver Handle, with Hexagonal Coupling	

03.503.072	Screwdriver Shaft MatrixMANDIBLE, long, self-holding, for Hexagonal Coupling	
03.503.073	MatrixMANDIBLE Screwdriver, self-holding	
313.960	Screwdriver, cruciform, not self-holding, for Cortex Screws ∅ 2.4 mm	
313.970	Holding Sleeve, for Nos. 313.960 and 314.448	
03.501.056	Lag Tool	
305.695	Insert for Module, for Bending Screw ∅ 4.0 mm	
391.990	Cutting Pliers for Plates and Rods	

Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.
Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.
All Surgical Techniques are available as PDF files at www.depuysynthes.com/ifu

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