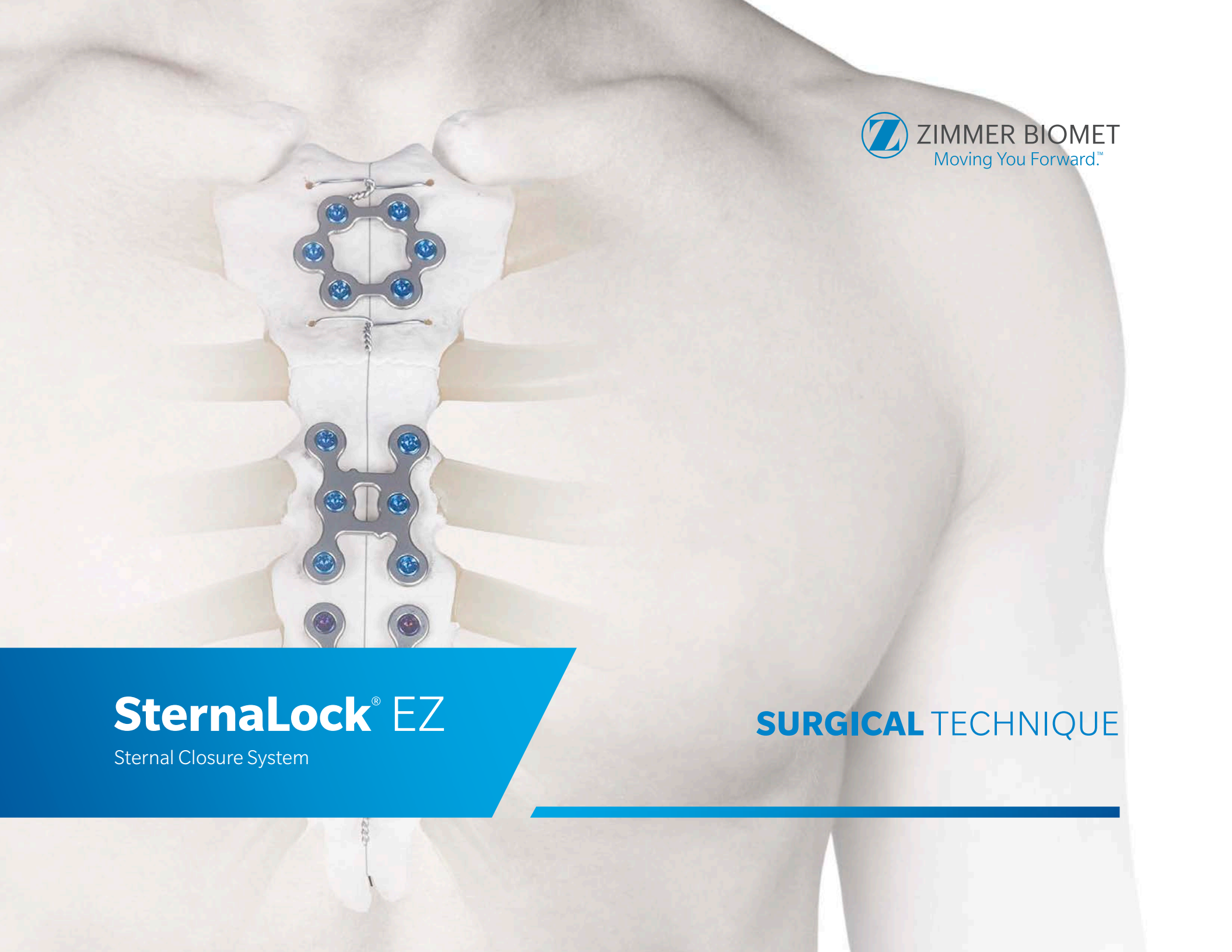


ZIMMER BIOMET
Moving You Forward.™

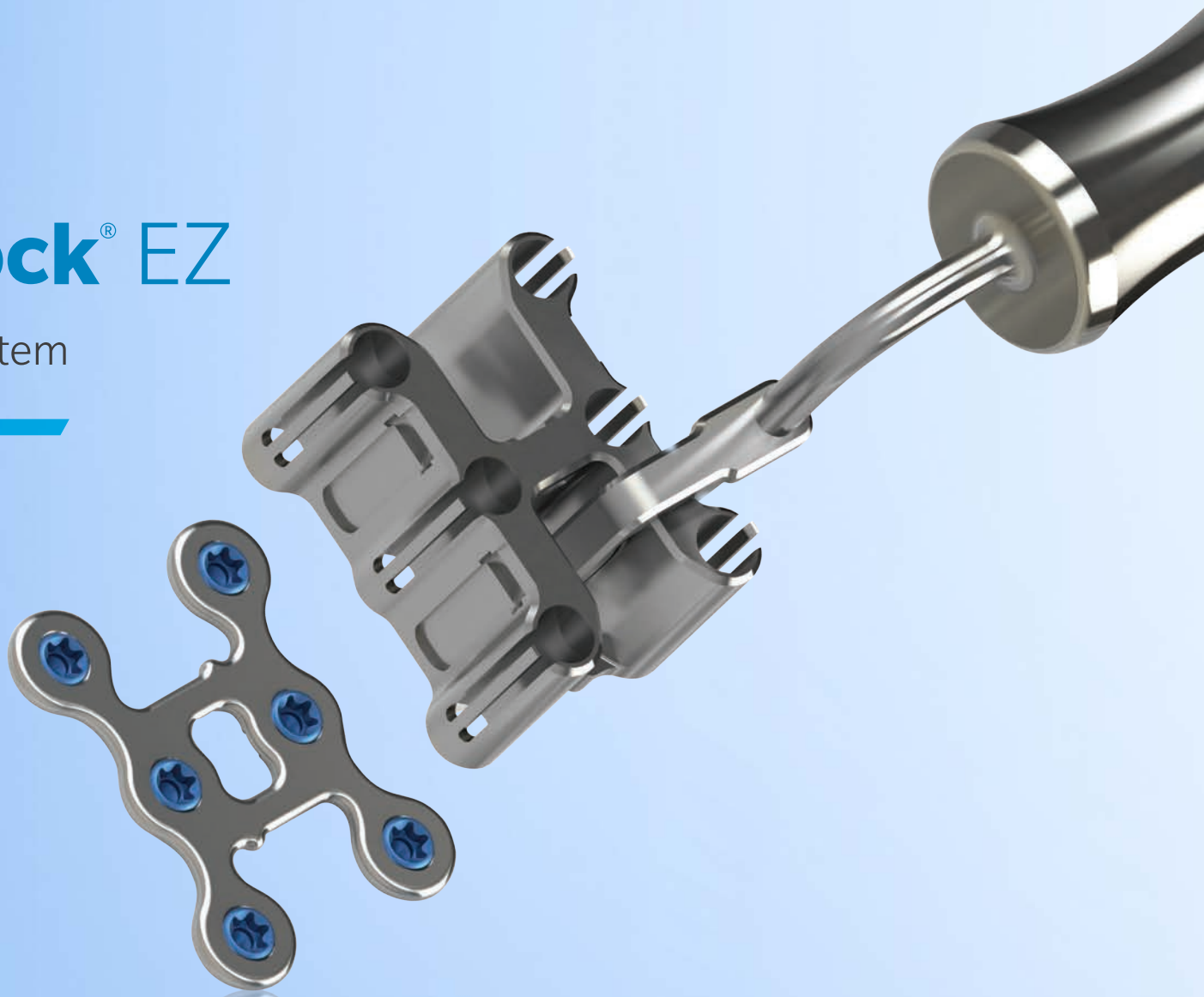
SternaLock® EZ

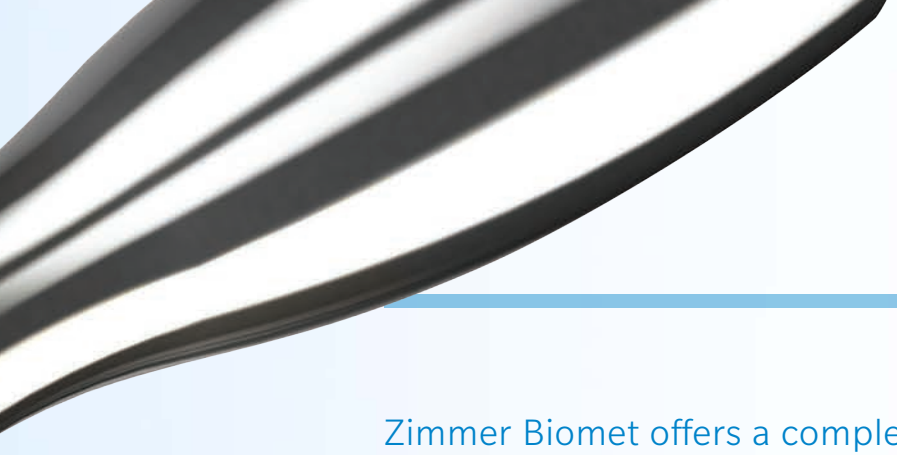
Sternal Closure System

SURGICAL TECHNIQUE

SternaLock® EZ

Sternal Closure 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.

SternaLock EZ Sternal Closure System is unique to the industry. With innovative instrumentation, the system enables the surgeon to achieve plate placement with speed, precision, and efficiency.[1]

The system is contained in one comprehensive case with multiple plate configurations and necessary instrumentation to successfully perform the procedure. The system is comprised of multiple ultrathin plate configurations which are applied post-sternotomy.

Indications

The SternaLock EZ Sternal Closure System is indicated for use in the stabilization and fixation of fractures of the chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, trauma, or planned osteotomies.[2]

1. Jace Medical - Speed of Plate/Screw Fixation Test Report • 2. IFU.0002 Rev B Low Profile Sternal Closure System IFU

1. Sternum and Plate Preparation

Inspect the anterior surface of the sternum where plate placement is desired. Provisional plates can be used to determine plate location. Dissect soft tissue from the surface of the sternum to allow visualization of the bone where the plates will reside.

Note: Remove all tissue from the anterior sternum in the areas where the plates will be placed. Bony calluses, if present, should be avoided, or removed from the midline and sternal surface to allow for proper anatomical reduction and plate placement.

Contouring plates should be avoided if possible. If contouring is required, use the Plate Bending Pliers to contour the plate(s). Contoured/bent plates are not compatible with the implant positioners.

Note: Only bend plates in one direction and avoid small radius bends. Do not reverse bend plates or bend through screw holes. Doing so may lead to failure of the device.

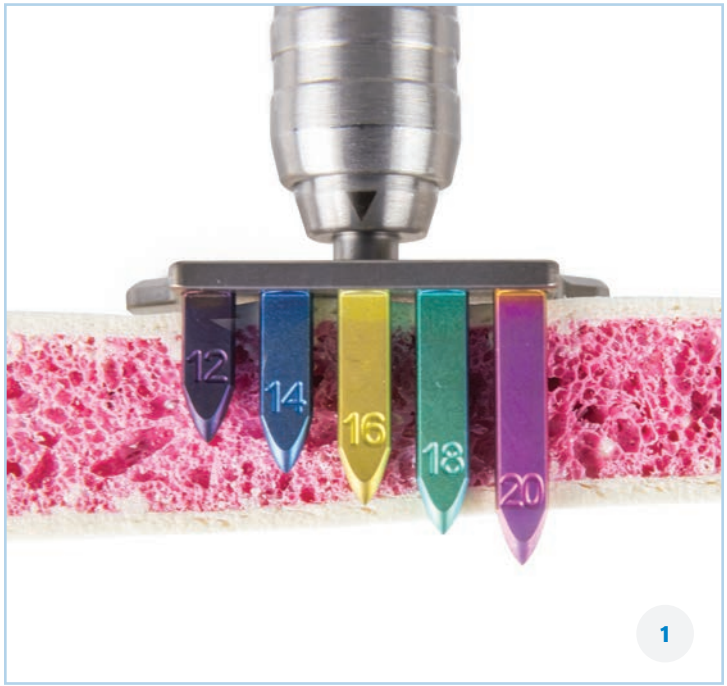
Note: Inspect plates after bending for deformation such as bent screw holes or dents/notches. Do not use plates that contain these deformities as they may lead to failure of the device.

The 3.5mm Self-Drilling Locking Screw is available in 6 lengths. The screws are color coded to identify the length.

- 10mm - MINT
- 12mm - PURPLE
- 14mm - BLUE
- 16mm - GOLD
- 18mm - GREEN
- 20mm - MAGENTA

Place the Screw Depth Guide on the edge of the sternum at the desired location of each plate (figure 1). Select the longest screw that does not protrude past the posterior cortex.

Note: The Screw Depth Guide includes the thickness of the plate. Do not add to the indicated size.



Screw Depth Guide against sternum. 16 is the appropriate length in this example.

2. Implant Positioner Loading

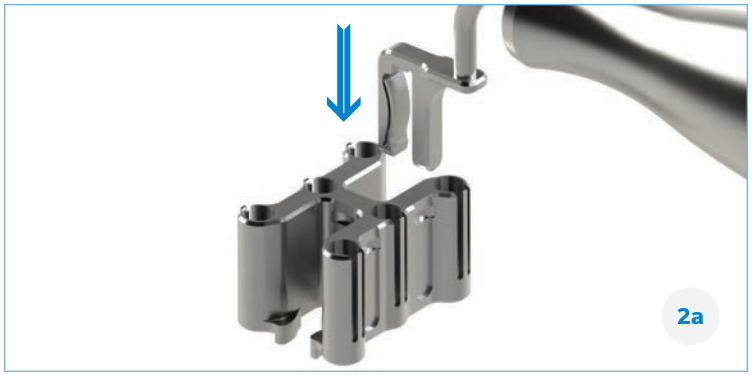
Connect the Implant Positioner Handle to the Implant Positioner by aligning the handle with the attachment feature on the Implant Positioner. Push down on the handle until fully engaged.

Align the Implant Positioner with the corresponding plate and push down. Ensure the arrows and laser markings on the plate are facing down onto the bone (figure 2a).

Note: Do not use the Implant Positioners with plates that have been contoured/bent.

After determining the proper screw length and preloading the plate, insert one of the 3.5mm Self-Drilling Locking Screws into each hole located at the top of the Implant Positioner (figure 2b). Press the screw into the Implant Positioner until the head of the screw is flush with the top of the Implant Positioner.

Note: Use only the plates and screws provided with the SternaLock EZ Sternal Closure System.



Screws loaded into Implant Positioner

3. Plate Placement

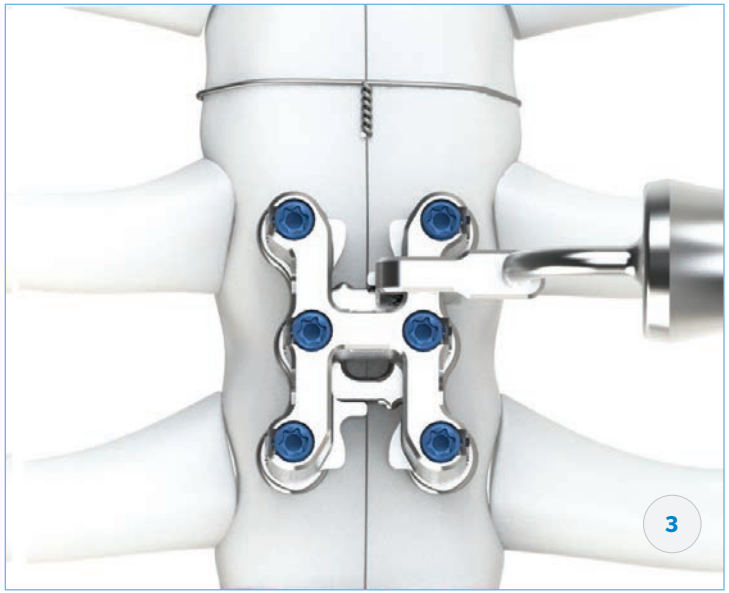
If using more than one plate, start with the most distal plate and proceed sequentially towards the manubrium.

For plate placement, the medial edges of the sternum must be brought together and held in complete approximation. Reduction is achieved using stainless steel wires.

Caution: Avoid contact between the plates and stainless steel wires.

Position the plate lightly on the mid-line of the sternum. The Implant Positioner should be placed directly over the mid-line incision of the sternum with equal portions of the sternal bone on the right and left sides of the device.

Note: Do not impact the Implant Positioner.



Ladder Plate with Cable

4. Screw Fixation with Implant Positioners

Screw placement is achieved using a battery-operated driver with AO adapter fitted with the provided Torque Limiter and silver 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, applying firm downward pressure, while using the other hand to drive the screws (figure 4a).

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.

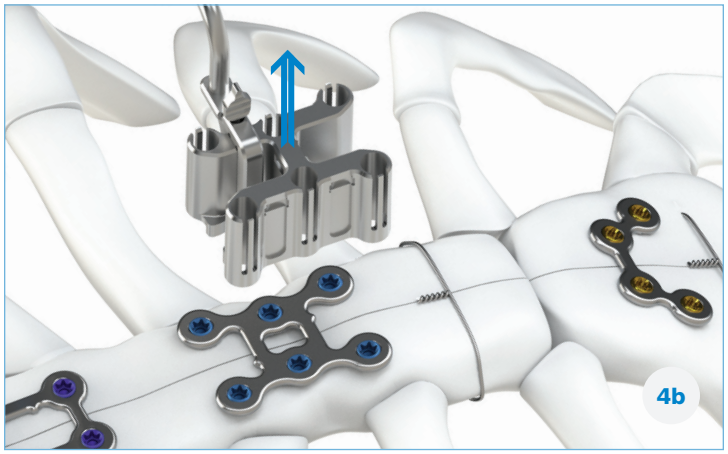
The Torque Limiter will engage once the screws have locked into the plate – as evidenced by an audible click emanating from the Torque Limiter.

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 screws in the Implant Positioner. Double check alignment between the Implant Positioner and the midline of the sternum before driving the next screw. Drive the remaining screws using a criss-cross pattern.

Once screw placement is completed, lift the Implant Positioner off the plate (figure 4b).

NOTE: Ensure screws are fully seated in the plate and are engaged in the bone. Screws should not be placed in the intercostal space or cartilaginous tissue.



5. Screw Fixation with Single Implant Positioners (Optional)

Connect the Quick Connect Handle to the Single Implant Positioner by aligning the handle with the attachment feature on the Single Implant Positioner.

Use the Screw Depth Guide to determine the proper screw length and insert the 3.5mm Self-Drilling Locking Screw into the hole located at the top of the Single Implant Positioner. Press the screw into the Single Implant Positioner until the head of the screw is flush with the top of the Single Implant Positioner.

Align the Single Implant Positioner over a screw hole and push down to connect the positioner to the plate (figure 5a). Ensure the arrows and laser markings on the plate are facing down onto the bone.

NOTE: Do not fully seat the first screw in the plate. Doing so may cause the plate to spin and could damage the instrument.

Drive the first screw using battery-operated driver with AO adapter fitted with the provided Torque Limiter and silver T15 Hexalobe Driver (figure 5b). Ensure the Single Implant Positioner is parallel to the axis of the hole while driving the screw. Do not fully seat the first screw in the plate. Once screw placement is completed, lift the Single Implant Positioner off of the plate.

All subsequent screws can be fully seated in the plate.

Fully seat the first screw and any partially seated screw using the T15 Hexalobe Driver.

NOTE: Ensure screws are fully seated in the plate and are engaged in the bone. Screws should not be placed in the intercostal space or cartilaginous tissue.

6. Screw Fixation with Double Implant Positioners (Optional)

Connect the Quick Connect Handle to the Double Implant Positioner by aligning the handle with the attachment feature on the Double Implant Positioner.

Use the Screw Depth Guide to determine the proper screw length and insert the 3.5mm Self-Drilling Locking Screws into the hole located at the top of the Double Implant Positioner. Press the screw into the Double Implant Positioner until the head of the screw is flush with the top of the Double Implant Positioner.

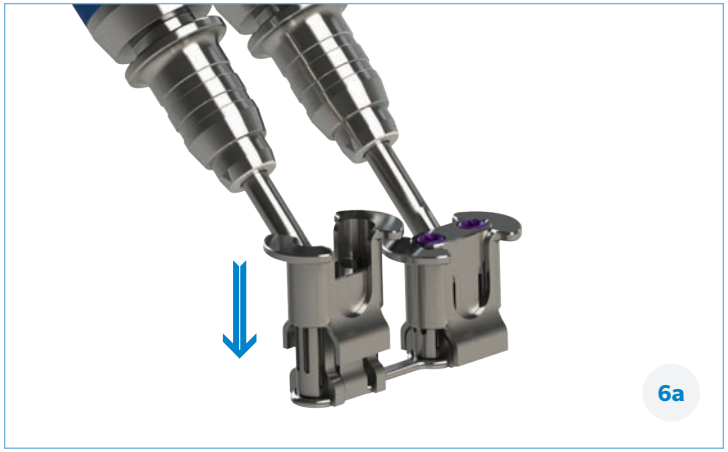
Pull the collar up and push down on the handle until the Double Implant Positioner is fully engaged with the plate (figure 6a).

NOTE: Do not use the Double Implant Positioners to bend plates

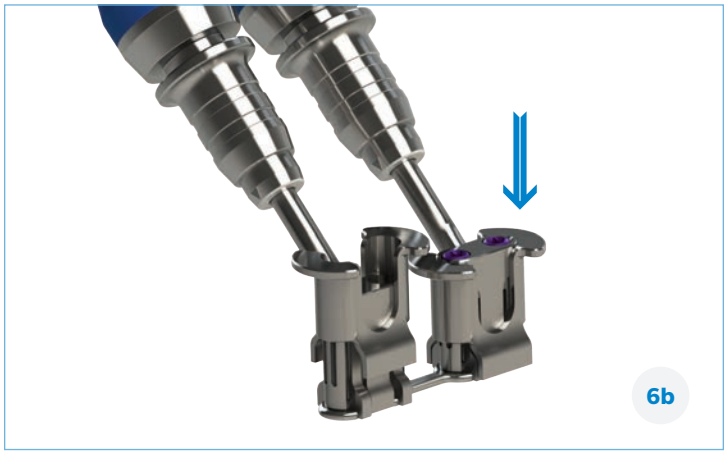
Push the collar down to lock the Double Implant Positioner to the plate (figure 6b). Ensure the arrows and laser markings on the plate are facing down onto the bone.

Drive the first screw using battery-operated driver with AO adapter fitted with the provided Torque Limiter and silver T15 Hexalobe Driver (figure 6b). Once screw placement is completed, pull the collar up and remove the Double Implant Positioner from the plate.

NOTE: Ensure screws are fully seated in the plate and are engaged in the bone. Screws should not be placed in the intercostal space or cartilaginous tissue.



6a



6b

7. Screw Fixation without Implant Positioners

Manual screw fixation is required if the plate(s) have been contoured. Screw fixation without Implant Positioners is achieved using a quick connect handle and gold Retaining T15 Hexalobe Driver. Connect the male end of the gold Retaining T15 Hexalobe Driver to the Quick Connect Handle.

Press the gold Retaining T15 Hexalobe Driver firmly into the head of the desired length screw.

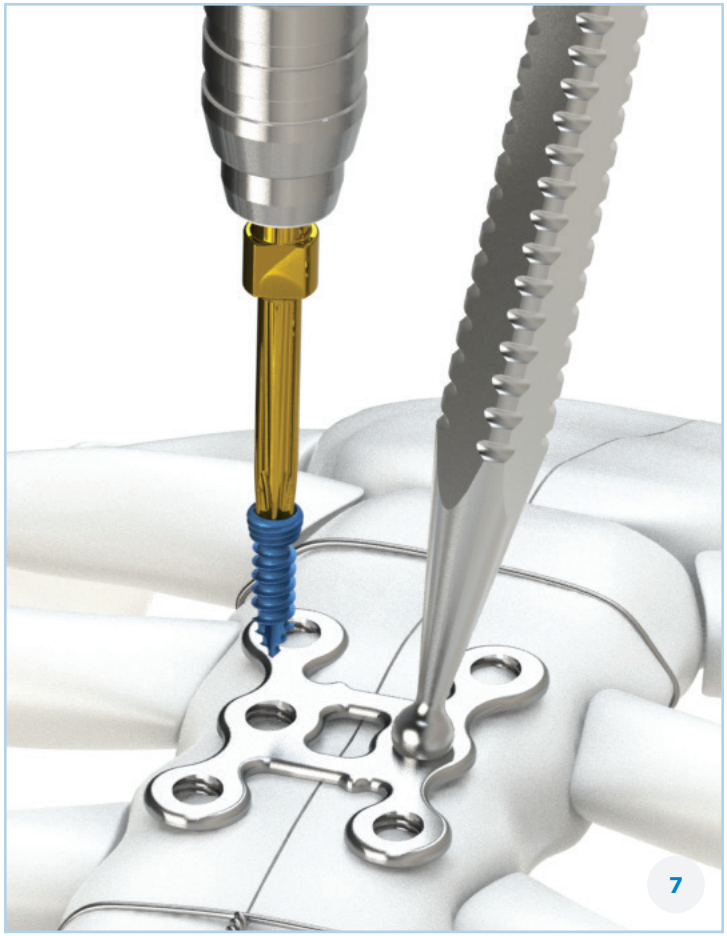
Ensure the arrows and laser markings on the plate are facing down onto the bone. Start by driving one of the screws until fully seated in the plate. Double check alignment between the plate and the midline of the sternum before driving the next screw. Drive the remaining screws using a criss-cross pattern.

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.

The Plate Holder may be used to stabilize the plate during Screw Fixation.

NOTE: Place the screw parallel to the axis of the hole. Failure to do so may result in cross threading which may lead to failure of the device.

NOTE: Ensure screws are fully seated in the plate and are engaged in the bone. Screws should not be placed in the intercostal space or cartilaginous tissue.



Emergent Re-entry

If emergent reentry is required, the plates allow for rapid access to the chest cavity.

Using the Plate Cutter, cut the horizontal cross bars/struts of each plate as well as any corresponding wires if present (figure 8).

Following the emergent reentry procedure, removal of the plates will be necessary. Use a silver T15 Hexalobe Driver connected to a Quick Connect Handle for complete removal of the plates and screws. Loosen all of the screws first, and then remove the plate from the sternum.

If new plates are utilized for subsequent closure, ensure that the plates are positioned over virgin bone to allow for secure screw purchase.


8

Product Information

Implants & Screws

Product Information - Implants

V Plate, 4 Holes
115.101.04

H Plate, 6 Holes
115.102.06

Box Plate
115.103.04

O Plate, 6 Holes
115.104.06

V Junction Plate, 10 Holes
115.105.10

Box Junction
Plate, 10 Holes
115.106.10

O Junction
Plate, 12 Holes
115.107.12

Double V Plate, 8 Holes
115.109.08

Manubrium Plate, 10 Holes
115.110.10

Bridge H Plate, 6 Holes
115.202.06

Bridge Box Plate, 4 Holes
115.203.04

Ladder Plate,
Narrow, 12 Holes
115.301.12

Ladder Plate,
Wide, 16 Holes
115.302.16

Straight Plate, 4 Holes
115.401.04

Straight Plate, 6 Holes
115.402.06

Items not to scale.

Product Information - Implants

Straight Plate,
8 Holes
115.403.08

Straight Plate, 12 Holes
115.405.12

Straight Plate, 16 Holes
115.406.16

Straight Plate, 24 Holes
115.407.24

T Plate, 7 Holes
115.501.07

Double T Plate, 14 Holes
115.502.14

V Plate, 8 Holes
115.503.08

Y Plate, 12 Holes, Narrow
115.504.12

Y Plate, 12 Holes, Wide
115.505.12

V Plate, 4 Holes, Concave
115.601.04

H Plate, 6 Holes, Concave
115.602.06

Box Plate, 4 Holes, Concave
115.603.04

O Plate, 6 Holes, Concave
115.604.06

Straight Plate,
4 Holes, Concave
115.461.04

Box Plate, 4 Holes, Convex
115.703.04

Items not to scale.

Product Information - Screws

3.5mm x 10mm
Self-Drilling Locking Screw
100.035.10

3.5mm x 12mm
Self-Drilling Locking Screw
100.035.12

3.5mm x 14mm
Self-Drilling Locking Screw
100.035.14

3.5mm x 16mm
Self-Drilling Locking Screw
100.035.16

3.5mm x 18mm
Self-Drilling Locking Screw
100.035.18

3.5mm x 20mm
Self-Drilling Locking Screw
100.035.20

Items not to scale.

Product Information

Instruments

Product Information - Instruments

Screw Depth Guide
201.025.00

Torque Limiter, AO Connection
201.047.00

T15 Hexalobe Driver
201.047.15

Quick Connect Handle
201.050.00

Implant Positioner Handle
215.010.01

Retaining T15 Hexalobe Driver (Gold)
215.010.15

Single Implant Positioner
215.010.11

Double Implant Positioner
215.010.12

Items not to scale.

Product Information - Instruments

Plate Bender Pliers
215.010.30

Reconstruction Plate Bending Plier
215.010.35

Plate Cutter
215.010.40

Plate Holder
215.010.50

Bone Reduction Clamp
215.010.55

V Plate, 4 Holes Implant Positioner
215.101.04

H Plate, 6 Holes Implant Positioner
215.102.06

Items not to scale.

Product Information - Instruments

Box Plate, 4 Holes Implant Positioner
215.103.04

O Plate, 6 Holes Implant Positioner
215.104.06

Bridge H Plate,
6 Holes Implant Positioner
215.202.06

Box Plate, 4 Holes,
Convex Implant Positioner
215.703.04

V Plate, 4 Hole,
Concave Implant Positioner
215.601.04

H Plate, 6 Holes,
Concave Implant Positioner
215.602.06

Box Plate, 4 Holes,
Concave Implant Positioner
215.603.04

O Plate, 6 Holes,
Concave Implant Positioner
215.604.06

Items not to scale.

SternaLock EZ

Sterna Closure Set Layout

Items not to scale.

Clinical Set - Sterilization Tray and Caddies

SternaLock EZ
Sternal Closure System Base
315.010.00

SternaLock EZ Sternal
Closure System Lid
315.010.20

Screw Caddy
315.010.30

Plate Caddy
315.010.40

Specialty
Plate Caddy*
315.010.50

Implant
Positioner Caddy
315.110.00

Items not to scale.

*Specialty Plate Caddy available upon request.

SternaLock EZ

Reconstruction Tray

Recon Set - Sterilization Tray and Caddies

Reconstruction Base
315.110.00

Reconstruction Lid
315.110.20

Screw Caddy
315.010.30

Implant
Positioner Caddy
315.110.00

Plate Caddy
315.010.40

Reconstruction Plate Caddy
315.110.40

Items not to scale.

For more information on the SternaLock® EZ Sternal Closure System and other solutions, please contact us at:

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SternaLock EZ (formerly JACE Low Profile) Sternal Closure System is manufactured by

JACE MEDICAL

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