

SternaLock® 360

Sternal Closure System

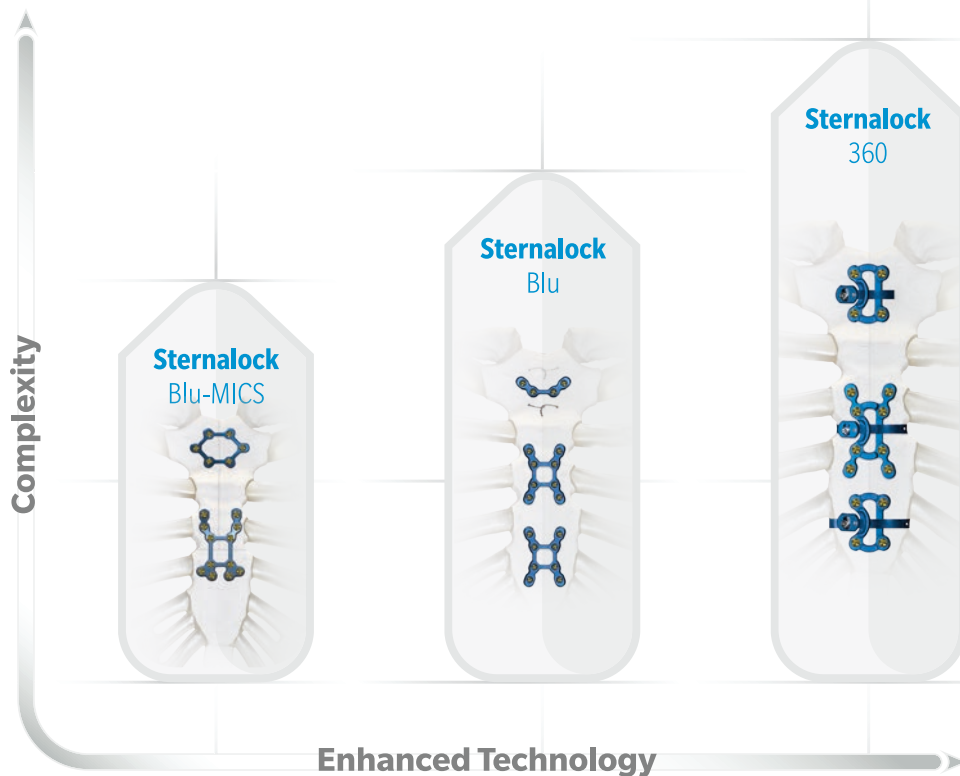


THORACIC

The right clinical system for the right patient.

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® 360 Sternal Closure System approximates, compresses and rigidly fixates the sternum. Each implant is a plate and band combination that provides 360-degree compression of the sternum. With a wider band, the SternaLock 360 system reduces sternal cut through and helps provide a lasting solution for patients with normal and poor bone quality.



Osteoporotic Solution

The SternaLock 360 Sternal Closure System is indicated for use in the stabilization and fixation of fractures of the sternum including sternal fixation following sternotomy and sternal reconstructive procedures, to promote fusion.

1 One system

to **approximate, compress** and **rigidly fixate** the sternum

2 Reduced sternal cut through²

3 Sternal closure system

for patients with normal and poor bone such as **osteoporotic bone**¹

4 Sterile packaged* for increased OR efficiencies

SternaLock 360 vs. Wire

- Increased mechanical stability¹
- Increased strength¹
- Reduced sternal separation¹
- Reduced sternal cut through²
- Promotes fusion in patients with normal and poor bone³



¹Internal Testing Report, LT1533, Comparison of SternaLock 360 and wires in lateral testing • ²Internal Testing Report, LT1496, Lateral compression force comparison between wires and SternaLock 360 • ³SternaLock 360, IFU 01-50-1585. • Benchtop testing may not be indicative of clinical performance. *Only the SternaLock 360 implants are sterile packaged

1 One system to approximate, compress and rigidly fixate the sternum

Finite Element Analysis (FEA)¹ demonstrated benefits of adding cerclage to rigid fixation to more evenly distribute the load. FEA models the mechanical performance of a device using a computer. Cerclage alone did not perform as well as SternaLock Blu or SternaLock 360.

Approximation

Gradual approximation for patients with poor bone

Uniform Compression

Ability to adjust the amount of compression

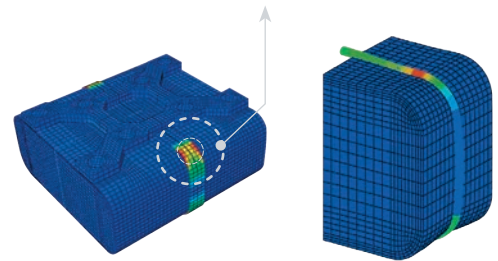
Activate Device Lock and Cut the Band

Band Width

Width of the band and material impact performance of sternal closure device



4.5x Less Stress on the Bone with SternaLock 360 compared to wires



Finite Element Analysis (FEA)

Illustrating more even load of distribution with the SternaLock 360 band compared to wire cerclage which results in reduced sternal cut through.

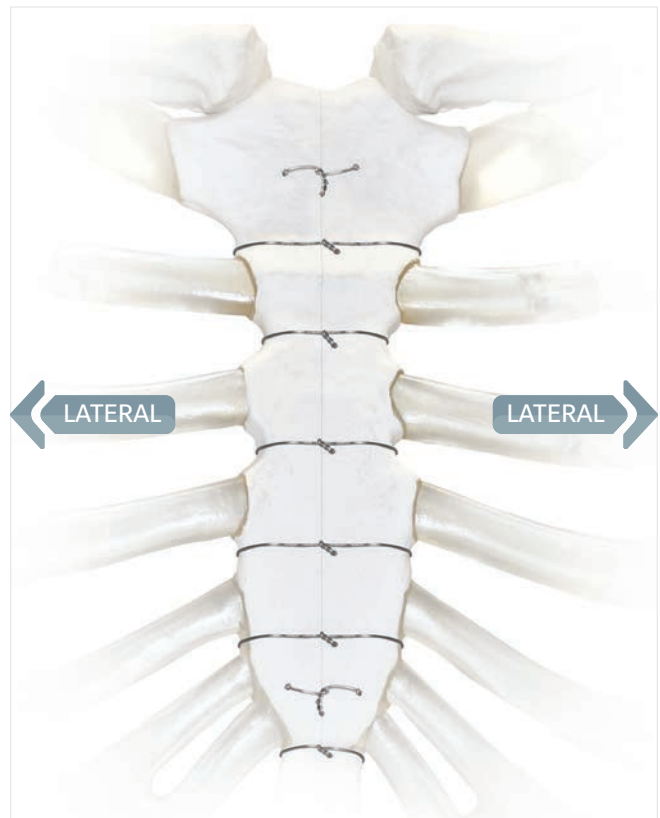
Cerclage and Rigid Fixation

Adding cerclage to rigid fixation more evenly distribute the load. This is important for patients with poor bone quality and lowers the load in cancellous bone.

¹FEA SL360 Design Team Review Slides. Data on file.

2 Reduced sternal cut through⁵

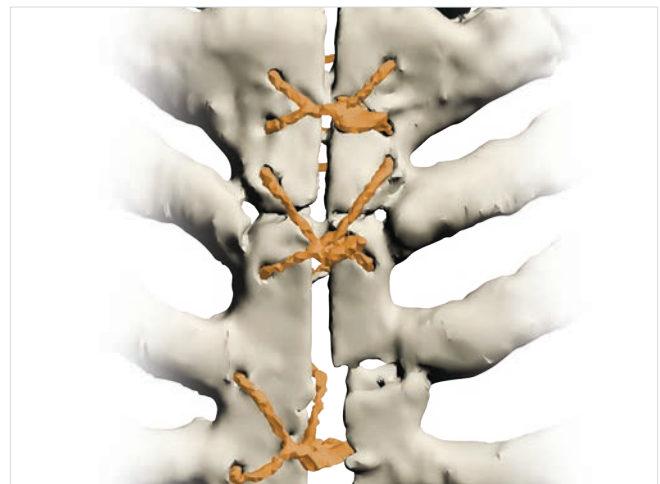
Mechanical Testing¹⁻⁵ demonstrated reduced sternal cut through compared to wire cerclage.



- SternaLock 360 is stronger than wire cerclage in an osteoporotic model.
- The cerclage band is more effective at maintaining sternal compression compared to wire cerclage.
- SternaLock 360 can withstand higher loads compared to wire cerclage for a prolonged period of time.

¹LT1338 Lateral Displacement of Wire Closure Static Report. • ²LT1341 Lateral Fatigue Report Wires. • ³LT1403 Lateral Fatigue Report SternaLock 360. • ⁴LT1406 Lateral Displacement Test SternaLock 360 Report. • ⁵LT1496 SternaLock 360 Compression Testing. • ⁶An Evaluation of Rigid Sternal Fixation in Supporting Bone Healing and Improving Postoperative Recovery. NCT01783483.

*Three-month CT scan using wire closure is not a representative outcome for every wire closure patient.



3 Month CT Scan Using Wire Closure^{*6}

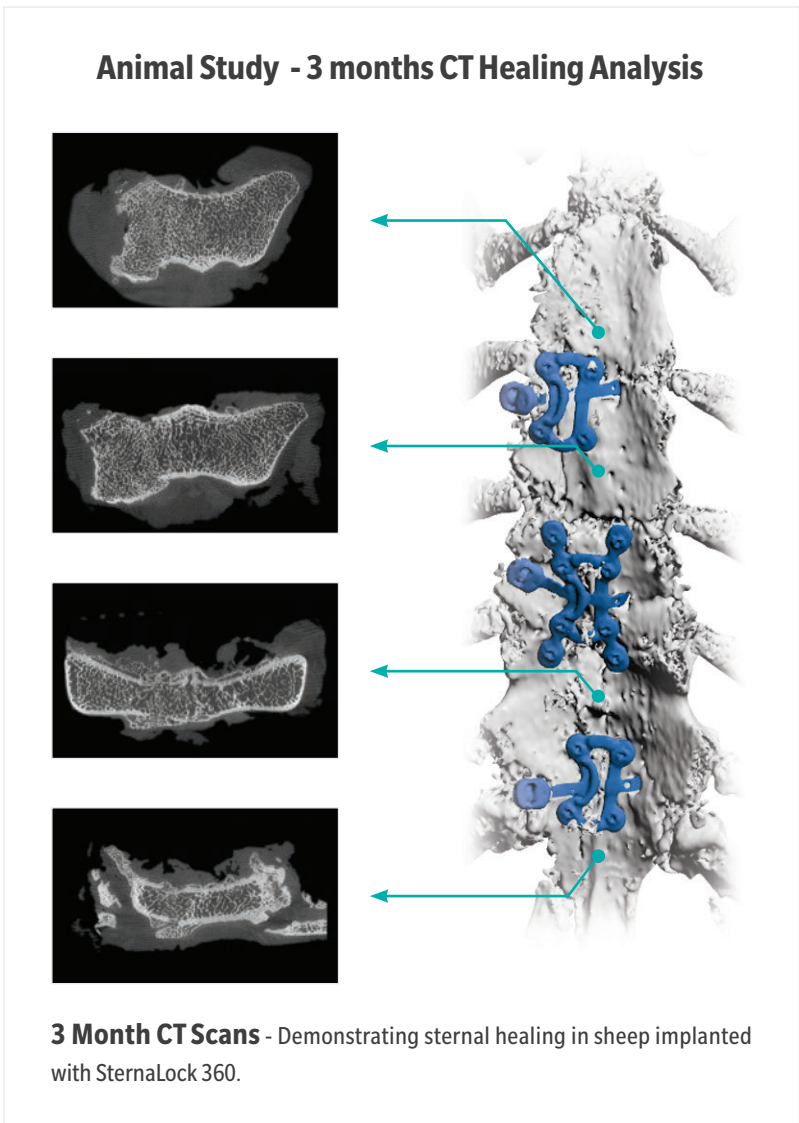
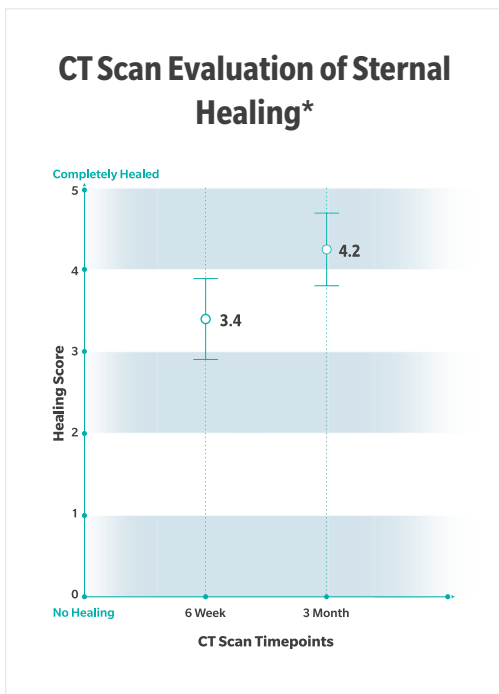
Animal Study¹⁻³ demonstrated rapid bone healing

A sheep model was developed to evaluate the surgical technique, long-term implantation in an animal, sternal healing, biocompatibility and device removal.

Sheep implanted with SternaLock 360 were well healed by three months and had sternums similar to those that had never been cut.

The SternaLock 360 implants were biocompatible, and the tissue response was similar to stainless steel wires.

It was easier to remove the SternaLock 360 band than wire cerclage, which supports that the device could be removed in the case of a future cardiac procedure.



¹SL360 Animal Study Design Team Review Slides. Data on file. • ²BI08S SL360 Sheep Pathology Report. • ³SL 360 AATS Sheep Abstract.

*Method of assessing healing based on criteria in following publication: Evaluation of Sternal Bone Healing with Computed Tomography and a Quantitative Scoring Algorithm. Stacy, et. al. The Open Medical Imaging Journal, 2014, 8, 29-35.

3 Sternal closure system for patients with poor bone such as osteoporotic bone¹

Sternal Closure With SternaLock 360: First in Man Study¹⁻²

Consistent with the approach of demonstrating the clinical benefits of our technologies, Zimmer Biomet initiated a SternaLock 360 clinical study. The study is being conducted at the University of Cape Town and Groote Schuur Hospital in South Africa - the location of the world's first heart transplant surgery in 1967.

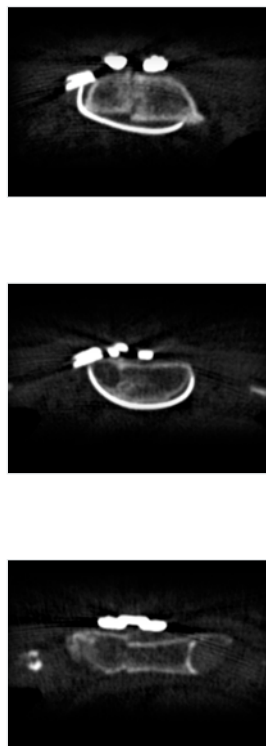
Objective: To evaluate the surgical technique and postoperative outcomes in patients receiving SternaLock 360 or wire cerclage

Design: Randomized, controlled trial (NCT02686099) that includes patients with normal and poor bone quality

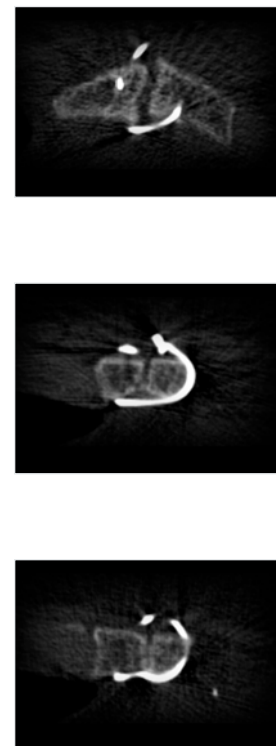
Outcome measures: Bone-quality assessment, with preoperative CT scan and intraoperative assessment

Sternal healing: CT scans at 3 and 6 months

Functional outcomes: Pain, recovery, return to work



3 Month CT Scan SternaLock 360 System



3 Month CT Scan Using Wire Closure*

¹SternaLock 360 Clinical Study Protocol • ²Patient data 06140110 • *Three-month CT scan using wire closure is not a representative outcome for every wire closure patient in clinical trials.

4 Sterile packaged* for increased OR efficiencies.



SternaLock 360 Multi-Implant System
74-0004

*Only the SternaLock 360 implants are sterile packaged
Note: Image is representative of packaging items.

SternaLock Blu Screws

2.4mm Diameter Cancellous Self-Drilling Locking Screws (Gold)



Part No.	Description
73-2408	2.4mm x 8mm
73-2410	2.4mm x 10mm
73-2412	2.4mm x 12mm
73-2414	2.4mm x 14mm
73-2416	2.4mm x 16mm
73-2418	2.4mm x 18mm
73-2420	2.4mm x 20mm

2.7mm Diameter Cancellous Locking Screws (Magenta)



Part No.	Description
73-2708	2.7mm x 8mm
73-2710	2.7mm x 10mm
73-2712	2.7mm x 12mm
73-2714	2.7mm x 14mm
73-2716	2.7mm x 16mm
73-2718	2.7mm x 18mm
73-2720	2.7mm x 20mm

SternaLock 360 Instrumentation



Manubrium Bone Punch
74-1193



Needle Guide
74-1192



Threaded In-situ Benders
74-1195

Instrumentation



Cutters
51-0960



Sizer
73-0006



Manual Driver
01-7600



SternaLock Blu Container*
73-2306

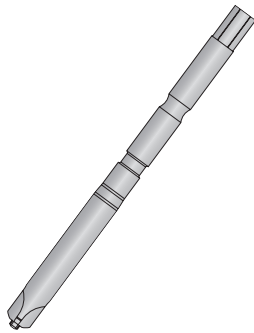
Instrumentation



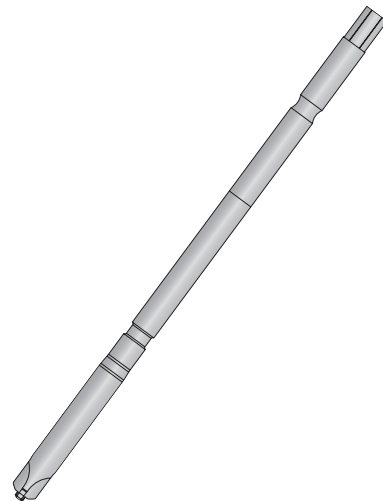
Power Driver™
50-1000



Power Driver Battery
50-1010



Power Driver Blade
73-1191



Standard Blade
73-1194

For more information on SternaLock 360 and other thoracic fixation solutions, please contact us at:

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