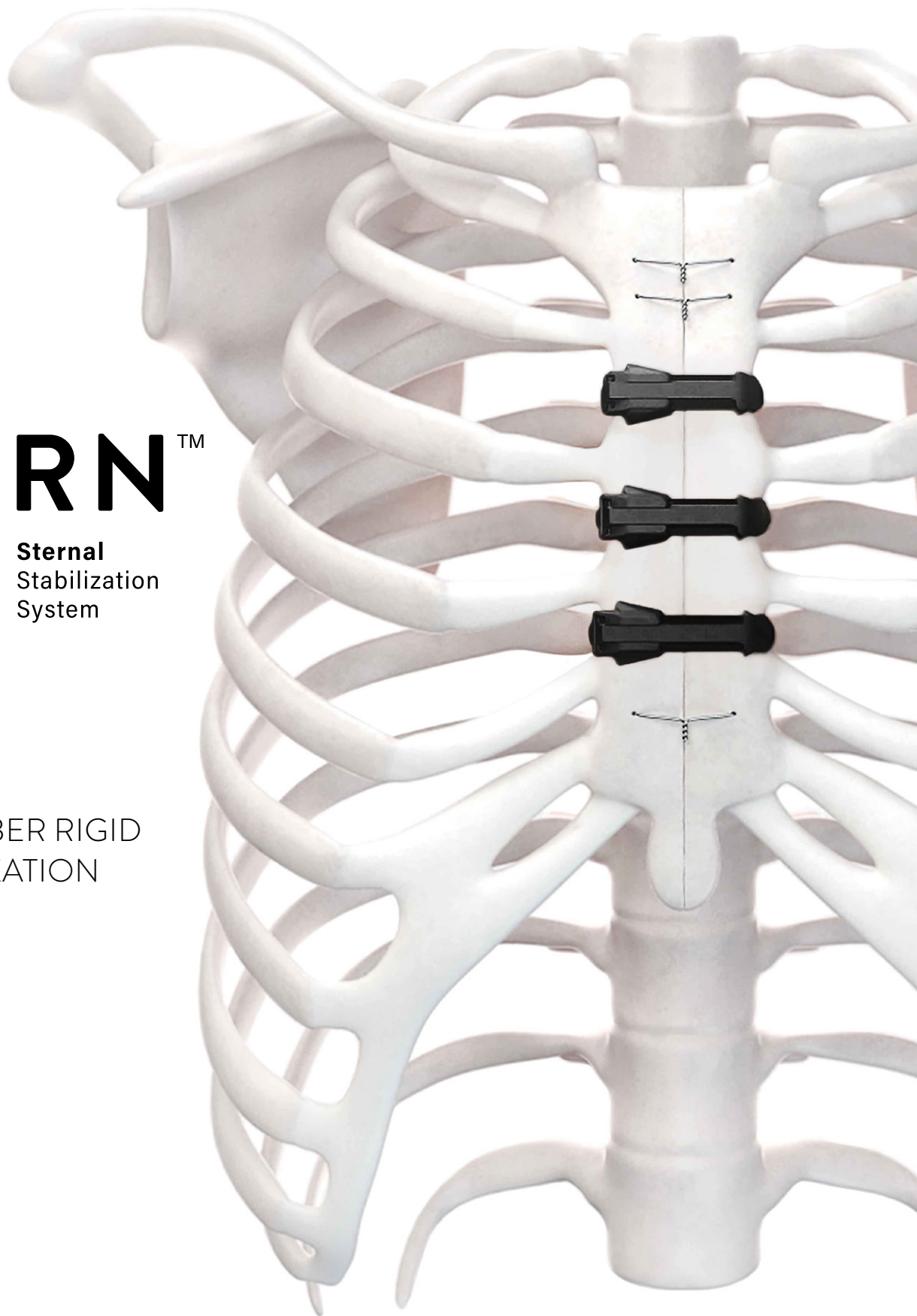


STERNTM FIX Sternal Stabilization System

CARBON FIBER RIGID
STERNAL FIXATION



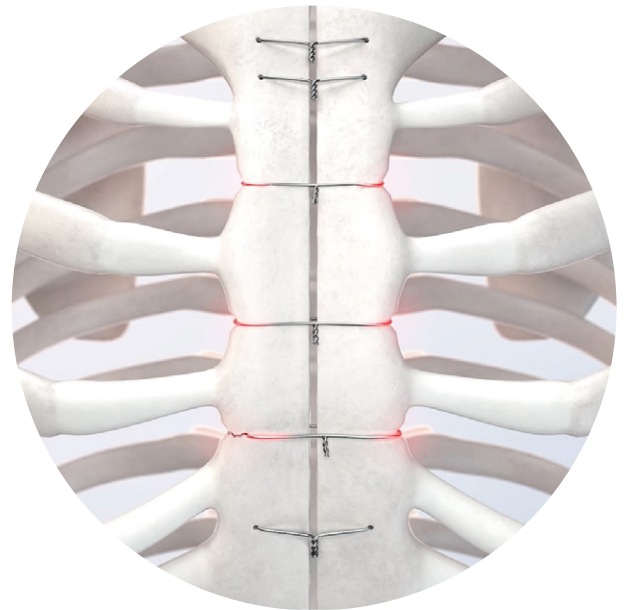
THE PROBLEM: STERNAL INSTABILITY

Despite the adoption of rigid fixation techniques in other surgical disciplines such as Ortho, Spine and Craniomaxillofacial, steel wires cerclage remains the predominant method of sternal closure in Cardiac Surgery.

The risk of using wires is not providing adequate rigid fixation:

- Might loosen or break in case of high forces acting on the sternum (i.e. coughing)
- Can cut-through the bone, especially in weak sternums.

This can also lead to sternal wound complications like sternal **instability**, **dehiscence**, **deep sternal wound infection (DSWI)** or **mediastinitis**, with a higher incidence in high risk patients.^{1, 2, 3, 4}



Deep sternal wound infection (DSWI) represents an important economic factor for the health-care system^{5,6,7}



3x HIGHER COST^{5,7}
for the hospital than
non-infected patients.

Sternal wound complications can imply:

- Extended length of stay (LOS)
- Need for additional surgical procedures.
- Vacuum-assisted wound dressing and antibiotic therapy.

GUIDELINES FROM CARDIAC SURGERY

Guidelines for Perioperative Care in Cardiac Surgery / Enhanced Recovery After Cardiac Surgery Society.⁸

"Recommended the use of rigid sternal fixation to potentially improve or accelerate sternal healing and reduce mediastinal wound complications"

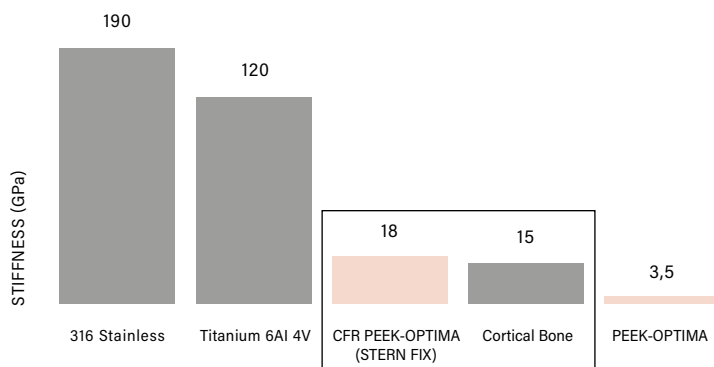
"Most cardiac surgeons use wire cerclage for sternotomy closure because of the perceived low rate of sternal wound complications and low cost of wires. This closure achieves approximation and compression but **does not eliminate side-by-side movement**, and thus **rigid fixation is not achieved with wire cerclage**"

"Rigid sternal fixation has benefits in patients undergoing sternotomy and should be especially considered in individuals at high risk"

THE SOLUTION: AN EASY TO USE & SECURE STERNAL FIXATION

STERN FIX is a unique Carbon Fiber rigid sternal fixation system designed to improve the patient recovery following a sternotomy procedure, while offering an easy-to-use application technique.

STERN FIX is made of a matrix of Carbon Fiber and PEEK (Polyether-ether-ketone) polymer. This matrix is a high-performance material with biocompatible and mechanical properties that provides an alternative to titanium and steel alloys.^{9,10}



Source for metal data: Ratner et al, eds. An Introduction to Materials in Medicine. Elsevier Academic Press.



Excellent material for sternal closure

Carbon Fiber compound closely matches the cortical bone properties, thus reducing the stress and the risk of bone damage at the bone-implant interface. Other implants, such as metallic implants with much higher stiffness than cortical bone may cause severe stress and potential failure.

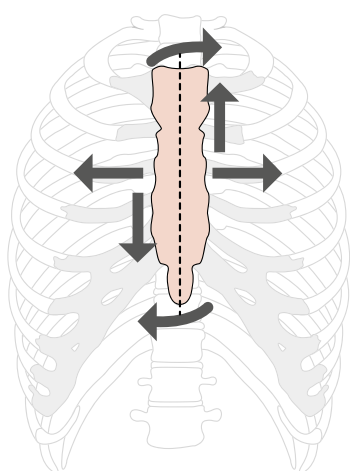
Characteristics of Carbon Fiber reinforced PEEK-OPTIMA™ (CFR PEEK)¹¹

- High compression, strength and durability.
- Stiffness similar to the cortical bone.
- Proven biocompatibility ensures safe and long-term implantation.
- Artifact-free imaging (CT and MRI) for accurate and reliable post-operative monitoring.
- Low coefficient of friction, making it a "slick" material easing insertion into the intercostal spaces.
- No corrosion and no liberation of metal ions.

DESIGNED TO IMPROVE PATIENT RECOVERY

The optimized atraumatic design improves the distribution of the pressure reducing the risk of bone cut-through.

STERN FIX can also be used in partial sternotomies compatible with MICS (Minimal Invasive Cardiac Surgery).



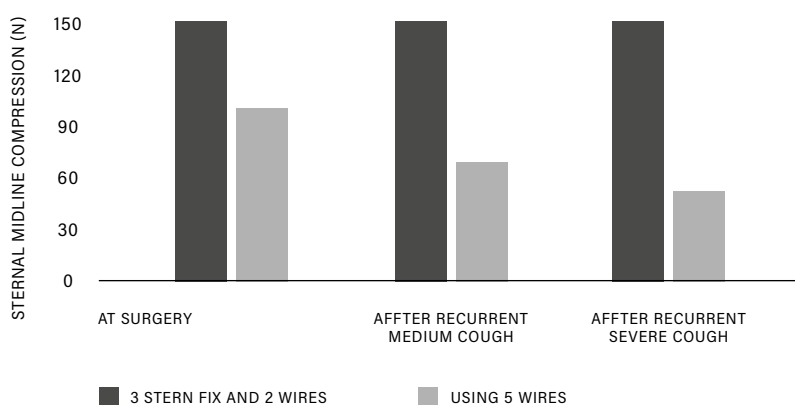
**Multi-axis stability:
optimal stability in all
three planes**



CONTINUOUS STERNAL COMPRESSION

STERNAL UNION

UNDER PRESENCE OF MEDIUM AND SEVERE COUGHING FORCES (225N, 350N).¹²

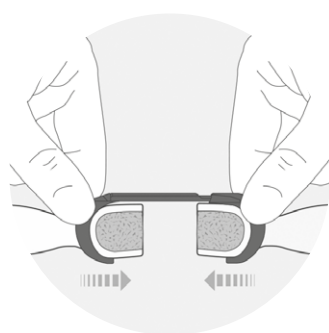


The use of STERN FIX provides a continuous contact between the two halves of the sternum, with a sustained compression strength even when coughing forces are present.

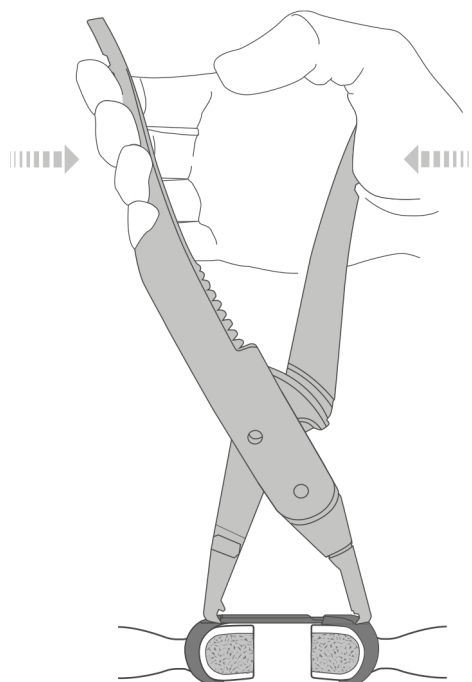
When using traditional wires closure, mechanical testing results showed a significant loss of compression after recurrent severe cough (-46%).¹³

EASY TO USE

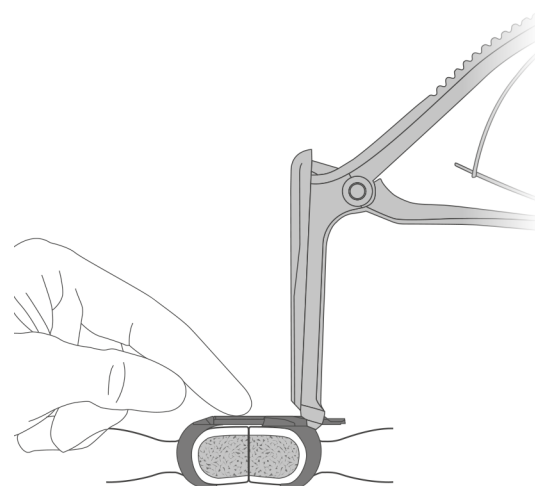
Needle-free implant.
Avoids perforation of
the intercostal fascial.



Place and engage manually
the two product parts.



Torque-limiting forceps to
approximate and adjust
the device.



Cutter for the
excess segment.

CONTROLLED CLOSURE OF THE STERNUM

The torque limiting forceps
incorporates a force limiter,
which can be activated at the surgeon's
discretion, to limit the maximum force
applied in the product tightening.



CLINICAL OUTCOMES

Results of a clinical study to demonstrate the safety and efficacy of STERN FIX; proven sternal stability in all patients, including also high-risk patients who benefited with a significant **PAIN DECREASE** at 6 months follow up.¹⁴

GOOD AESTHETIC RESULT

No protuberances

CT images of a female patient, BMI 17.6 (44kg / 97bs).

STERNAL STABILITY

100% of patients reached the maximum stability (0 in the Sternal Instability Scale).

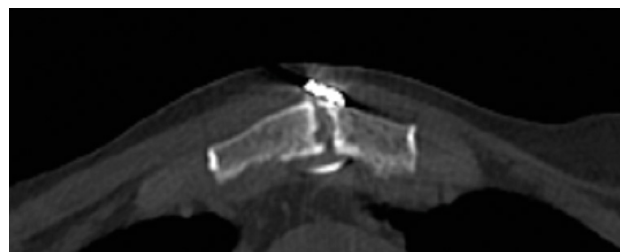
BLEEDING

93% of patients had less bleeding with STERN FIX compared to WIRES.

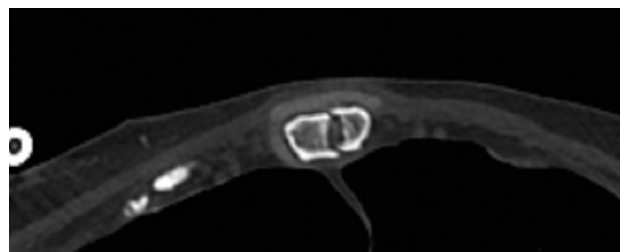
EASY TO REMOVE:

No need to use specific instruments in case of emergency re-entry

Quick re-entry with a standard wire cutting tool.



Steel wires in the manubrium.

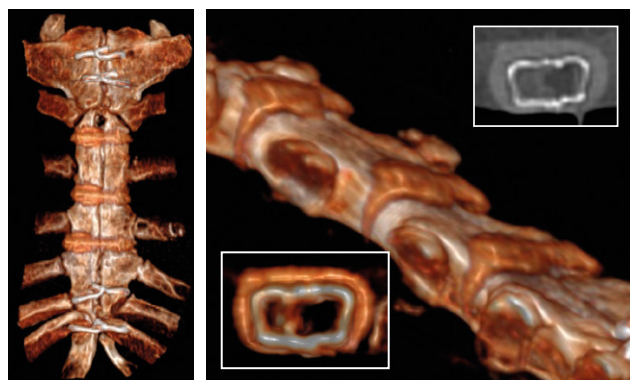


STERN FIX in the intercostal space number 2.

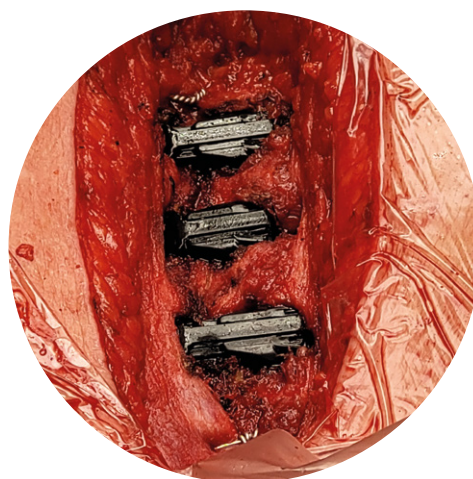
OR TIME



VS



Sternal healing 6 months after surgery was assessed using the Sternal healing Scale¹⁵.

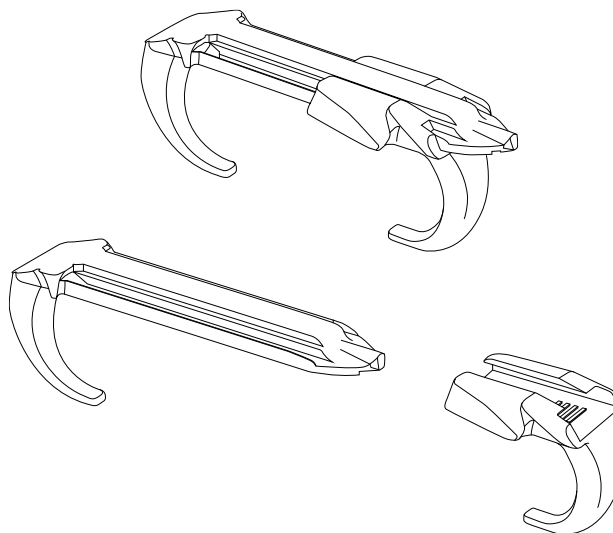


PRODUCT DETAILS

Every **STERN FIX** is sold individually with different sizes. Available in five sizes of curved arm to adjust to the different sternal bone thicknesses, from 9,5 to 17 mm.

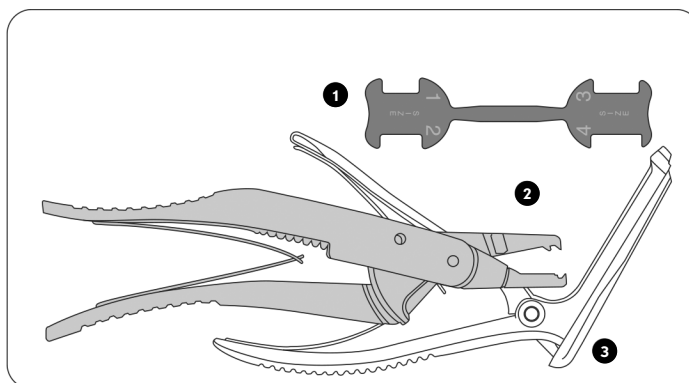
MOST FREQUENT SIZES

SIZE 1	SKU SC010111	STERNAL BONE THICKNESS 9,5 - 11 mm
SIZE 2	SKU SC010222	STERNAL BONE THICKNESS 11- 12,5 mm
SIZE 3	SKU SC010333	STERNAL BONE THICKNESS 12,5 - 14 mm



INSTRUMENT TRAY

- **1 DEPTH GAUGE** (SCI0000)
to select the right size of the device depending on the thickness of the bone.
- **1 FORCEPS** (SCI0501)
to tighten and adjust the device.
- **1 CUTTER** (SCI0700)
to cut the excess segment of the male part once the device has been adjusted.



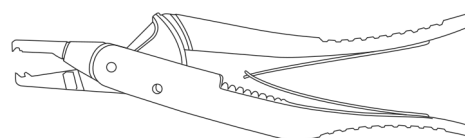
All the instruments are supplied and stored in the instrument tray. This tray is used for storage of the surgical instruments and may be used to contain the instruments during cleaning and sterilization. It is not intended to maintain the instruments sterility by itself once the tray and its contents are sterilized.

For detailed information about the use, limitations and likely risks of the product, please refer to its Instructions for Use

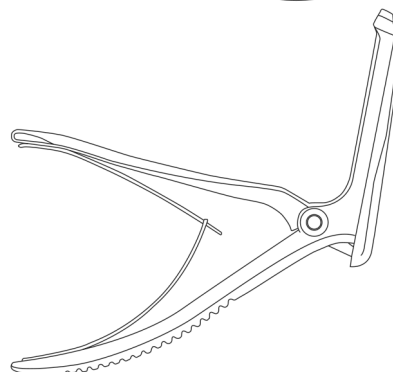
1
DEPTH GAUGE
(SCI0000)



2
FORCEPS
(SCI0501)



3
CUTTER
(SCI0700)



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- ¹³ J. Adams et al., "Comparison of force exerted on the sternum during a sneeze versus during low-, moderate-, and high-intensity bench press resistance exercise with and without the valsalvamanuever in healthy volunteers". *The American Journal of Cardiology.* 2014, vol. 113, no. 6, pp. 1045–1048
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