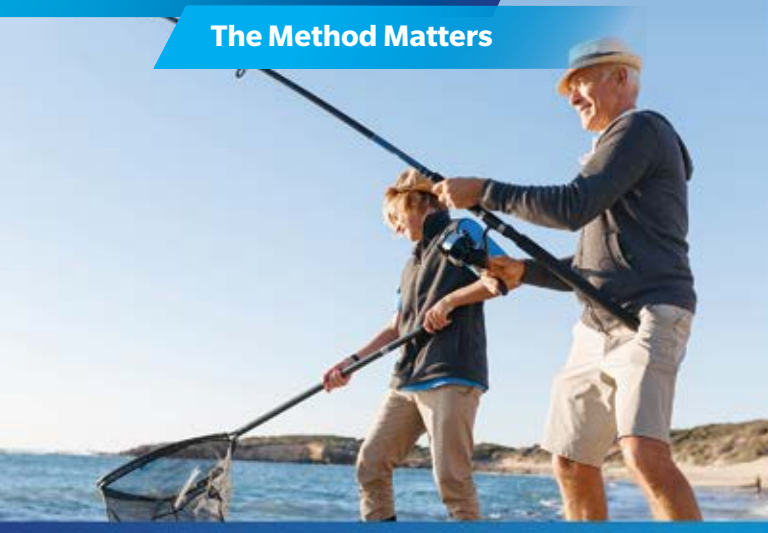
SternaLock® Blu

The Method Matters



YOU'VE ESSENTIALLY HAD TWO OPERATIONS.

One on your heart and one on your breastbone.

Open-heart surgery requires the breastbone (sternum) to be cut down the middle from top to bottom. The breastbone is then spread apart to allow access to the heart.

Surgical grade wire is commonly used to bring the bone back together. This is done by wrapping wires around the bone and then securing them in a twist tie configuration. A more stable alternative to wire closure is rigid fixation with plates and screws. [1,2]

Zimmer Biomet conducted the SternaLock Blu Study to compare bone healing and recovery in patients who received SternaLock Blu rigid fixation closure versus patients who received wire closure. The results showed that 41% of SternaLock Blu patients were healed at 3 months, compared to 16% of patients treated with wire closure. [1,2,3]

Although SternaLock Blu patients in the study had improved healing, no breastbone complications, and spent fewer days in rehab facilities, each patient's results will vary based on risk factors. The study results should not be construed as a substitute for reviewing all of the actual study information with your surgeon. Only your surgeon can determine what closure method is appropriate for you. [1,2,3]

SternaLock® Blu is a rigid fixation system of titanium plates and screws used to stabilize the broken breastbone after open-heart surgery. These plates and screws help reinforce the bone halves to help them heal back together. The implants are permanent and do not need to be removed at a later time. However, if a reoperation on your heart is needed, the plates can be removed for re-entry.[4]

Wire Closure

SternaLock Blu

The information herein is of a general nature and does not represent or constitute medical advice or recommendations and is for general education purposes only. The information includes descriptions of a medical device that a thoracic (heart) surgeon may choose for patients undergoing open-heart surgery.

Zimmer Biomet manufactures medical devices, including metal plates and screws that may be used by your heart surgeon to hold together the sternum (breastbone) after heart surgery. We do not practice medicine; all questions regarding your medical condition must be directed to your doctor(s).

Results with sternum plates and screws (rigid fixation) will vary due to health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Only a medical professional can determine the treatment appropriate for your specific condition. Appropriate post-operative activities will differ from patient to patient. Talk to your surgeon about whether rigid fixation is right for you and the risks associated therewith, including but not limited to the risks of infection, implant wear, loosening, screw or plate breakage or incomplete bone healing. For a complete list of risks associated with Zimmer Biomet's rigid fixation system, see www.SternaLock.com risk page.

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1. CR 0712S (Clinical Study Report) SternaLock Blu Study, 2014-15, an evaluation of rigid plate fixation in supporting bone healing: a prospective, multi-center trial of 236 total patients undergoing full midline sternotomy.

2. CR 0712E (Economic Study Report) SternaLock Blu Study, 2014-15, an evaluation of rigid fixation in supporting bone healing; a prospective, multi-center trial of 236 total patients undergoing full midline sternotomy.

3. SternaLock Blu patients spent a total of 237 total fewer days in rehab hospitals or skilled nursing facilities over 6 months. 705 total days for wire cerclage patients (n=120) vs. 468 total days for SternaLock Blu patients (n=116).

4. SternaLock Blu IFU 01-50-1215