

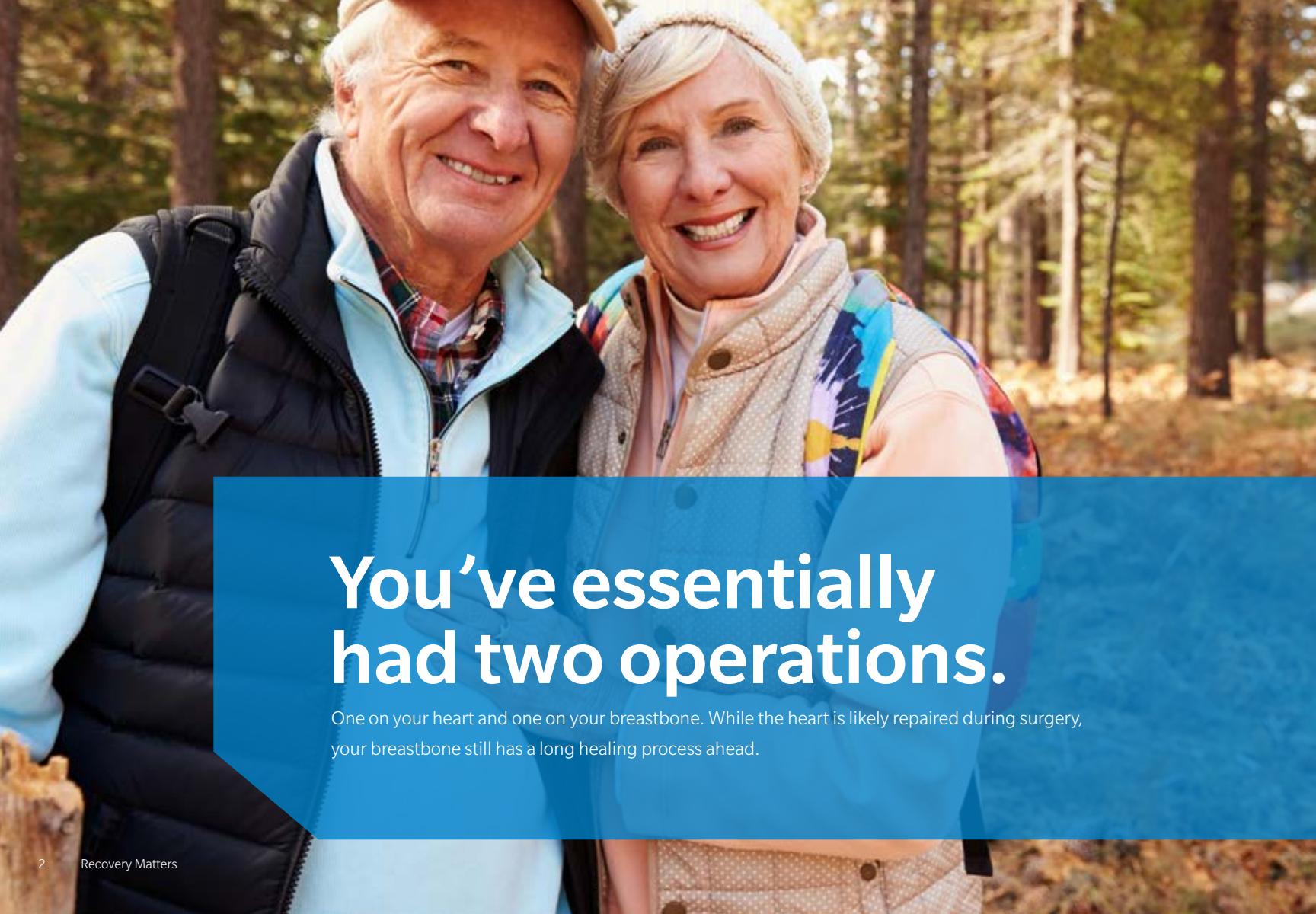


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A photograph of a smiling senior couple walking hand-in-hand on a sandy beach. The man is on the left, wearing a light-colored zip-up sweater over a collared shirt and khaki pants. The woman is on the right, wearing a blue scarf, a light-colored cardigan over a blue top, and jeans. They are walking towards the right side of the frame, with hills and a body of water in the background.

RECOVERY MATTERS™

SternaLock® Blu Patient Education



You've essentially had two operations.

One on your heart and one on your breastbone. While the heart is likely repaired during surgery, your breastbone still has a long healing process ahead.

Table of Contents

Patient Risk Information	4
What to Know Before Open-Heart Surgery	6-8
What Happens During Open-Heart Surgery	10
What to Expect After Open-Heart Surgery	12
Recovery Timeline	14
About Bone Healing	16

Appointment Log

Please be certain to take this log book to all appointments.

Date and time of _____

Date and time of _____

Name of healthcare professional _____

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Notes for this appointment _____

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What are the risks associated with sternal closure?¹⁰

To help minimize risk it is always important to follow your surgeon's sternal precautions. Sternal precautions are preventative guidelines provided by your surgeon to protect the breastbone and help reduce breastbone complications.

While uncommon, breastbone complications can occur during and after surgery.

Patient Risk Information

Breastbone complications include, but are not limited to:

- ◆ Poor bone conditions causing the plates or screws to fracture
- ◆ Incomplete bone healing or delayed healing
- ◆ Allergic reaction to metal plates and screws
- ◆ Decrease in bone density
- ◆ Shifting, bending, breaking or loosening of plates and screws
- ◆ Pain, discomfort, abnormal sensation, or palpability due to the presence of the plates and screws
- ◆ Inflammation around the fracture site and/or the plates or screws
- ◆ Poor healing of the bone
- ◆ Decomposition of bone
- ◆ Improper selection of screws that are too long for the thickness of the breastbone may protrude to the interior of the chest

Apart from the adverse effects there are always possible breastbone complications of any surgical procedure such as, but not limited to, infection, nerve or soft tissue (non-bone) damage, and pain which may or may not be related to the implant. Implanted metal plates and screws cannot replace normal healthy bone, and the device can break, bend or be damaged as a result of stress, activity, load bearing or inadequate bone healing. Continue with regular postoperative follow-up examinations as long as the plates and screws remain implanted.

You are not a candidate for sternal plating if you have the following:

- ◆ Current, active infection
- ◆ Specific metal allergy or sensitivities
- ◆ Mental condition preventing compliance with postoperative care instructions

History of Breastbone Closure

Each year in the United States, more than 700,000 people undergo open-heart surgery via sternotomy. The sternotomy is the most commonly used incision in heart surgery and is often referred to as “cracking the chest.” This term refers to the breastbone (sternum) being cut down the middle to allow for access to the heart. Unlike nearly every other broken bone in the body, where metal plates and screws are used to increase stability and promote bone healing, wrapping surgical grade wire around the breastbone remains the primary technique for holding the bone pieces together. In some instances, use of wires has resulted in significant movement of the breastbone,^{1,2} and did not provide enough stability to support the bone.³ If this occurs, the bones may not heal back together and breastbone complications such as infection, pain, or delayed bone healing may occur.^{2,3,4,5}

What is wire closure?

Traditional closure of the breastbone after open-heart surgery is done by wrapping surgical grade stainless steel wire around and through the bone halves and twisting them together to tighten; similar to using a twist tie. Most surgeons who use wires will use multiple and place them along the length of the sternum, in between the ribs.

What is rigid fixation?

Rigid fixation is the use of metal plates and screws to stabilize fractured (broken) bones. If a broken bone cannot easily be casted, such as the chest wall, (also called the breastbone or sternum), rigid fixation can be used to stabilize the bone fragments. Despite the adoption of rigid fixation techniques in nearly every other bone; wire closure remains the predominant method of sternal closure.^{6,7,8,9}

What is SternalLock® Blu?

SternalLock Blu is a rigid fixation system of metal plates and screws for use in sternal closure or sternal reconstruction procedures. These plates and screws are intended to remain implanted permanently, unless complications arise, such as infection, or re-access to the heart is necessary. The plates and screws provide added stability to the breastbone to help facilitate the bone healing process after it is cut open for heart surgery. If reoperation on your heart is necessary, the plates can be cut for re-accessing the heart.¹⁰

What is the SternalLock® Blu Study?

Rigid fixation is used to repair many bone fractures (bones broken by injury), except a sternotomy, which is the sawing of the breastbone in half to access the heart. As a leader in the musculoskeletal space, Zimmer Biomet recognized an opportunity to expand the benefits of rigid fixation to patients undergoing heart surgery.

The SternalLock Blu Study was designed by a team of heart surgeons and health economic researchers, and compared the outcomes following sternal closure of patients with SternalLock Blu versus wire closure. The study analyzed a total of 236 patients (116 SternalLock Blu patients and 120 wire closure patients), undergoing elective heart surgery from 12 different hospitals in the United States. Patient were followed for 6 months to evaluate healing, clinical outcomes and costs.^{11,12,13}

Patients treated with SternalLock Blu plates and screws had improved sternal healing, fewer sternal complications and improved recovery as compared to patients treated with wire closure following open-heart surgery.^{11,12}



HEALING MATTERS

Patients treated with SternalLock® Blu experienced improved and faster healing at 3 and 6 months.^{11, 12}

**2.6x more patients healed
at 3 months**



COMPLICATIONS MATTER

Patients treated with SternalLock Blu experienced fewer sternal complications.^{11, 12}

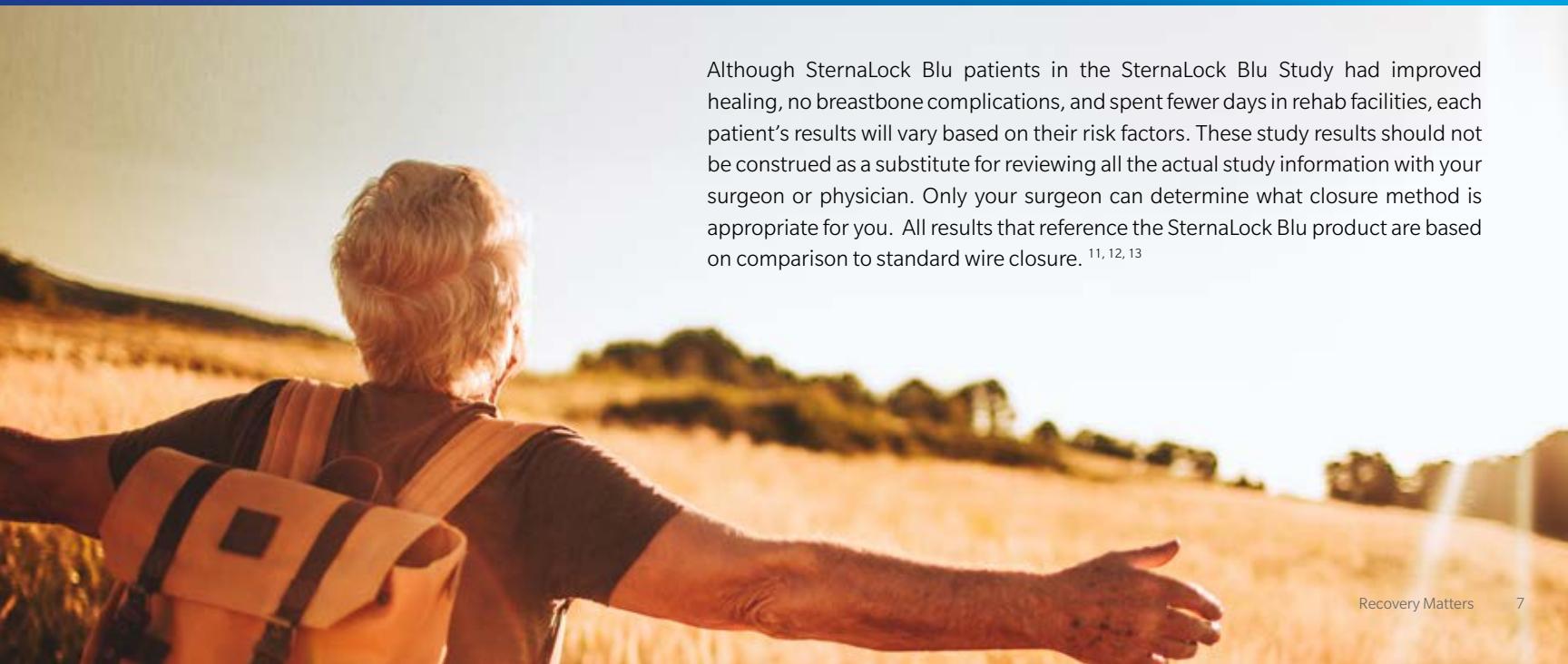
**0% vs. 5% sternal
complication rate**



RECOVERY MATTERS

Patients treated with SternalLock Blu spent fewer days in rehab hospitals or skilled nursing facilities.^{11, 12, 13}

**237 total fewer days in rehab
and recovery**



Although SternalLock Blu patients in the SternalLock Blu Study had improved healing, no breastbone complications, and spent fewer days in rehab facilities, each patient's results will vary based on their risk factors. These study results should not be construed as a substitute for reviewing all the actual study information with your surgeon or physician. Only your surgeon can determine what closure method is appropriate for you. All results that reference the SternalLock Blu product are based on comparison to standard wire closure.^{11, 12, 13}



What to know about open-heart surgery

Before surgery

For several weeks leading up to surgery, your doctor may ask you to quit smoking and eliminate alcohol use. This will help keep your immune system strong and improve liver function for a quicker post-surgical healing process.¹⁶ Some patient risk factors that affect breastbone healing include age, smoking and BMI.¹⁷ A heart surgeon may choose an improved method of breastbone closure, such as SternalLock Blu, to help promote improved healing.

It is important to ask your surgeon about what method of closure will be used on your breastbone. While your heart is likely repaired during surgery, your breastbone takes time to heal. The stability of your breastbone can influence your recovery. Greater stability allows the blood vessels to grow across the fracture, which is the key to carrying blood and nutrients to the bone. If those vessels keep breaking due to movement, it will take much longer for the bone to heal, potentially preventing healing from occurring.¹⁸

Preparing for hospital admission

Your doctor may instruct you not to eat or drink anything for a time period before your surgery. You must have an empty stomach going into surgery. Remember to bring all your regular medications to the hospital, even those that you were instructed to discontinue before surgery. You'll be more comfortable if you remember to bring a lightweight robe, a nightshirt, slippers with nonskid soles, toiletries, glasses, etc.¹⁹

The admitting nurse will take you to your room and familiarize you with the hospital surroundings. There are numerous forms you will sign upon admission. The details may vary slightly from one hospital to the next, but certain forms are standard. To verify information about your health that you have already provided, the nurse and admitting staff may ask you several questions that you've probably answered before.^{14, 19}

Identify a point of contact¹⁹

Make sure to identify a point of contact to make medical decisions on your behalf and help relay your results to family members and friends. This person should also understand your sternal precautions and activity limitations to help you with your recovery at home. Sternal precautions are preventative guidelines provided by your surgeon to protect the breastbone and reduce complications during the recovery process.

Before surgery, be sure to consider the support system you have at home. You will benefit greatly if you have some assistance for the first several weeks with cooking, bathing, housekeeping, errands, etc.

The hospital discharge planner, occupational therapist, and social worker can help you explore all your options for having assistance at home. You might discuss a home healthcare professional, visiting nurse, or other help. If an adequate support system at home is not available, you may want to consider going to a rehabilitation facility or nursing home during recovery.



What happens during open-heart surgery



After you are admitted to the hospital, you will be prepped for surgery. Using a needle, a small intravenous (IV) tube will be inserted into a vein in your arm. The tube will be used to administer antibiotics, pain medication, and fluids during and after your surgery. About an hour before the operation, your anesthesiologist will talk with you about the type of anesthesia you will receive. You may be lightly sedated before being taken to the operating room.¹⁴

Be aware that the operating room can be a bright, cold, busy and loud place. A nurse will verify your identity and knowledge of the operation. Once the anesthesia takes effect, your surgical site will be sterilized.

During open-heart surgery, the surgeon will access your heart by creating a vertical cut down the center of your chest. In order to get to the heart, the surgeon will saw through the breastbone, also called the sternum. After both of those openings are made, the surgeons will proceed with the heart operation.¹⁴ Open-heart surgery can take approximately 3 to 6 hours depending on the complexity of the procedure.¹⁵

Once the operation is complete, the surgeon will close your breastbone (sternum) with either wires or a rigid fixation system of plates and screws, such as SternaLock Blu.



Recovery after open-heart surgery

Study information presented throughout this timeline is a summary of the Sternalock® Blu Study results and should not be construed as a substitute for reviewing all the actual study information with your physician. All results that reference the Sternalock Blu product are based on comparison to standard wire closure.^{11, 12}

What Can I Expect During Heart Surgery Recovery?

After surgery, you will be moved from the operating room to the Cardiovascular Unit (CVU) or Intensive Care Unit (ICU), until you wake up.²⁰

While your heart is likely repaired during surgery, your breastbone still has a long healing process ahead. The following timeline provides guidance for recovery and potential sternal precautions that your surgeon may enforce. Sternal precautions are preventative guidelines provided by your surgeon to protect the breastbone and reduce complications during the recovery process. Regardless of the method of sternal closure your surgeon chooses to use, there will be activity restrictions during your recovery. Post-operative healing times and ability to return to daily activities vary for each patient; only a physician can determine what activities are acceptable for your recovery.

Risks specific to your heart surgery should be discussed thoroughly with your heart surgeon; as a medical device manufacturer, Zimmer Biomet does not practice medicine. Risks associated specifically with SternalLock® Blu sternal closure include the risk of screw or plate breakage, instrument breakage, and delayed or incomplete bone healing. For more information on risks associated with sternal closure, see page 5. Ask your surgeon about additional risks associated with heart surgery.

Returning to Normal Activities^{14, 20, 21}

During recovery, your surgeon may advise you to increase your activity gradually. Based on your surgeon's guidance, you may choose to do light household chores, such as laundry, shopping, cooking and light gardening. However, it is important that patients do not lift, pull or push objects heavier than their surgeon recommends.

While transitioning back to normal activities, your surgeon may advise that you avoid any activity or position that causes pain or pressure on your chest. Notify your doctor if you have shortness of breath, fatigue, dizziness or other symptoms that cause discomfort.

The SternalLock Blu study followed patients for 6 months and showed that patients treated with SternalLock Blu spent less time in rehab hospitals and skilled nursing facilities.^{11, 12}

Your doctor may recommend a rehab hospital or skilled nursing facility as part of his/her standard discharge orders, regardless of your method of closure. A patient's comfort returning to normal activities may depend on numerous variables including, but not limited to, the method of sternal closure.

Reducing Physical Stress on the Breastbone

To promote breastbone healing, it is important to reduce physical stress during recovery. Following a sternotomy, patients may have an area of the breastbone where the bone did not fully heal back together, called a non-union, which can lead to chronic pain. For instance, when a patient coughs, one side of the breastbone may rub against the other side of the breastbone causing pain. You may hear clicking or popping of the breastbone when you move because of the bone not healing properly.

If you experience discomfort or breastbone popping sensations, contact your doctor.

The SternalLock Blu Study found that 88% of patients treated with SternalLock Blu had no pain at 3 months as compared to 76% of patients treated with wire closure.^{11, 12}

Activity levels and healing times may vary for each patient. Some patients continued to experience some level of pain, regardless of closure method.

Recovery Timeline



Discharge^{20, 21, 22}

At discharge, your surgeon will review sternal precautions you should take to protect your breastbone while healing.

Most patients will go home after the hospital. When you are home, it is important to continue your breathing exercises and remember to stabilize your chest while coughing. Patients requiring additional care may go to a rehab facility instead of their home.

At this time point, surgeons may advise that patients can do the following:

- ✓ Shower carefully but avoid soaking in a bath
- ✓ Avoid stretching or twisting the torso
- ✓ Dress yourself while seated
- ✓ Sleep on back and take caution when getting out of bed



4-6 Weeks After Surgery^{20, 21}

A follow-up appointment with your physician is usually scheduled 4 – 6 weeks after surgery. At this time, most patients are introduced to cardiac rehab and begin to focus on long-term lifestyle changes to facilitate the healing process.

At 6 weeks after surgery, the SternaLock® Blu Study found that 74% of patients treated with SternaLock Blu had no pain at rest versus only 59% of patients treated with wire closure.^{11, 12}

Some patients may continue to experience some level of breastbone (sternum) pain regardless of their closure method.

Intensive Care Unit²⁰

Since your breastbone has been separated and you are recovering from surgery, you will be primarily limited to bed rest in the ICU following surgery.

Most patients are moved to a general care unit the day after surgery but it is common to remain in the ICU for longer.

Hospital Stay²⁰

Following surgery, you will stay in the hospital to continue your recovery until you are ready to go home. During your hospital stay, you will learn ways to improve your recovery, such as managing chest pain while coughing and getting in and out of bed.

Before you can leave the hospital, you must meet several discharge criteria, such as:

- ✓ Stable vital signs
- ✓ Assisted mobility
- ✓ Adequate pain management without IV
- ✓ Sufficient breathing
- ✓ Chest tube removal

At this time point, surgeons may advise that patients can do the following:

- ✓ Perform light housework
- ✓ Climb stairs using railing
- ✓ Ride a stationary bike
- ✓ Reach one arm at a time (not both)
- ✓ Lift small objects less than 10 lbs.

Regardless of how you feel, it is important that you give your body time to heal, before returning to any activities. Always consult your doctor(s) for specific guidance on your level of activity.

6 Weeks After Surgery²¹

Your breastbone is still healing, but most patients can slowly increase their activity level with the guidance of their doctor.

Patients with Sternalock® Blu had less interference with activities and less physical limitations attributed to pain. The Sternalock Blu Study found that at 6 weeks, 70% of scores reported by Sternalock Blu patients indicated they had no difficulty using their arms, compared to 59% of patients who were treated with wire closure.^{20,21}

Activity levels and healing times may vary for each patient. Regardless of how you feel, it is important that you give your body time to heal, before returning to any activities. Always consult your doctor(s) for specific guidance on your level of activity.

At this time point, surgeons may advise that patients can do the following:

- ✓ Return to work with no heavy lifting
- ✓ Drive by yourself
- ✓ Heavy housework
- ✓ Light cardio
- ✓ Resume sexual activity

3 Months After Surgery²¹

As advised by your doctor, you may be able to fully return to routine activities.

At 3 months after surgery, the Sternalock Blu Study found that 41% of Sternalock Blu patients had sufficient bone healing versus only 16% of patients treated with wires.^{11,12}

Activity levels and healing times may vary for each patient. Bone healing time varies and some heart patients may continue to feel pain or discomfort indefinitely.

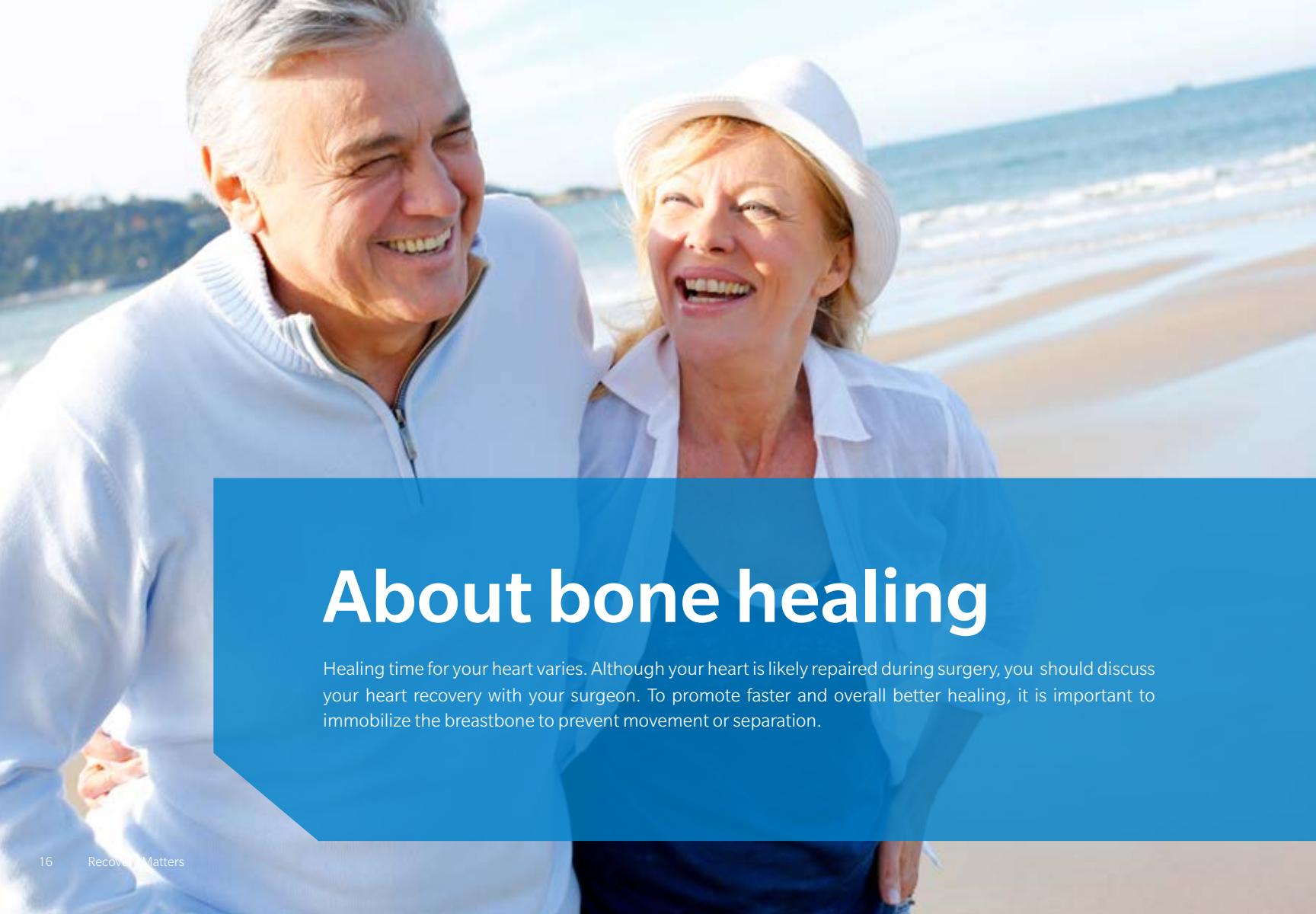
At this time point, surgeons may advise that patients can do the following:

- ✓ Return to work full time
- ✓ Perform heavy housework & gardening
- ✓ Begin to lift more than 10 lbs.
- ✓ Resume normal activities such as biking, jogging or swimming
- ✓ Play sports such as bowling and tennis

6 Months After Surgery^{11,12}

Enhanced stability of the breastbone helps improve sternal healing, which can reduce the risk of sternal complications and lead to improved recovery.²²

At 6 months, the Sternalock Blu Study showed that 0% of the patients treated with Sternalock Blu suffered from breastbone complications versus 5% of patients treated with wires closure.^{11,12}



About bone healing

Healing time for your heart varies. Although your heart is likely repaired during surgery, you should discuss your heart recovery with your surgeon. To promote faster and overall better healing, it is important to immobilize the breastbone to prevent movement or separation.

How long does it take my heart to heal?²³

Healing time for your heart varies. Although your heart is likely repaired during surgery, you should discuss your heart recovery with your surgeon. As for your breastbone, it still has a long healing process ahead. The healing of the breastbone tends to be the slowest part of the recovery process. Patients essentially experience two operations during open-heart surgery; one on the heart and one on the breastbone.

What factors influence breastbone healing? ¹⁷

Age, smoking, and high BMI are risk factors that may significantly influence healing.

As with most surgeries, sternal closure comes with risk, including the risk of infection, implant wear, loosening, screw or plate breakage and delayed or incomplete bone healing. For more information on risks associated with sternal closure using Sternalock® Blu see page 5.

Other factors that can have an impact on how well you heal include:

- ✓ Diabetes
- ✓ Chronic obstructive pulmonary disease (COPD)
- ✓ The use of medications such as steroids or immunosuppressants
- ✓ Osteoporosis

It can take 6 months or more for the bone to completely heal.

How long does it take my breastbone to heal? ^{4,24}

For healing to occur, bones must be brought together and stabilized. The chest wall is constantly in motion with every breath, cough, sneeze, or bend. To promote faster and overall better healing, it is important to immobilize the breastbone to prevent movement or separation.

In the Sternalock Blu Study, patients that received wire closure had slower rates of healing compared to those with Sternalock Blu. At 3 months after surgery, 41% of Sternalock Blu patients had sufficient bone healing versus only 16% of patients treated with wires.^{11,12}

Various things, including your general health, quality of bone, activity level, and adherence to your doctor's instructions, can affect healing times. If non-union (failure of the bone to mend back together) occurs, it may affect healing time considerably.



Know your options

In the SternaLock® Blu Study, patients treated with SternaLock Blu experienced fewer breastbone complications compared to patients with wire closure. Breastbone complications experienced by the wire group included infection and removal for pain.^{11,12}

What risks are associated with sternal closure?

If the breastbone (sternum) does not heal properly, recovery can be delayed or complications can occur. Complications of the breastbone include infection and pain and may lead to reoperation. You may hear clicking of the breastbone when moving.²² If you hear this or experience discomfort in the middle of your chest, contact your surgeon.

In the SternaLock® Blu Study, patients treated with SternaLock Blu experienced fewer breastbone complications compared to patients with wire closure. Breastbone complications experienced by the wire group included infection and removal for pain.^{11, 12}

Possible adverse risks of sternal closure include, but are not limited to risk of infection, implant wear, loosening, screw or plate breakage and delayed or incomplete bone healing. For more information on risks associated with sternal closure using SternaLock Blu see page 5.

How does healing affect pain levels?

Chest pain after heart surgery may be caused by damage to nerves surrounding the breastbone or incision sites. If the breastbone is not immobilized, movement of the chest wall will continue to pinch surrounding nerves, causing chronic pain.

The SternaLock Blu Study followed patients for 6 months after surgery and found that when the breastbone completely healed, there was an 85% chance of being pain free.^{11, 12}



AS PATIENTS HEAL, THE PROBABILITY OF BEING PAIN FREE INCREASES

Bone healing time varies and some heart patients may continue to feel pain or discomfort indefinitely.

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 conditions that a surgeon may encounter and treatment options that may be considered for those conditions.

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 of the procedure and infection, including the risk of implant wear, loosening, screw or plate breakage or incomplete bone healing.

The Sternalock Blu study was funded by Zimmer Biomet.

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