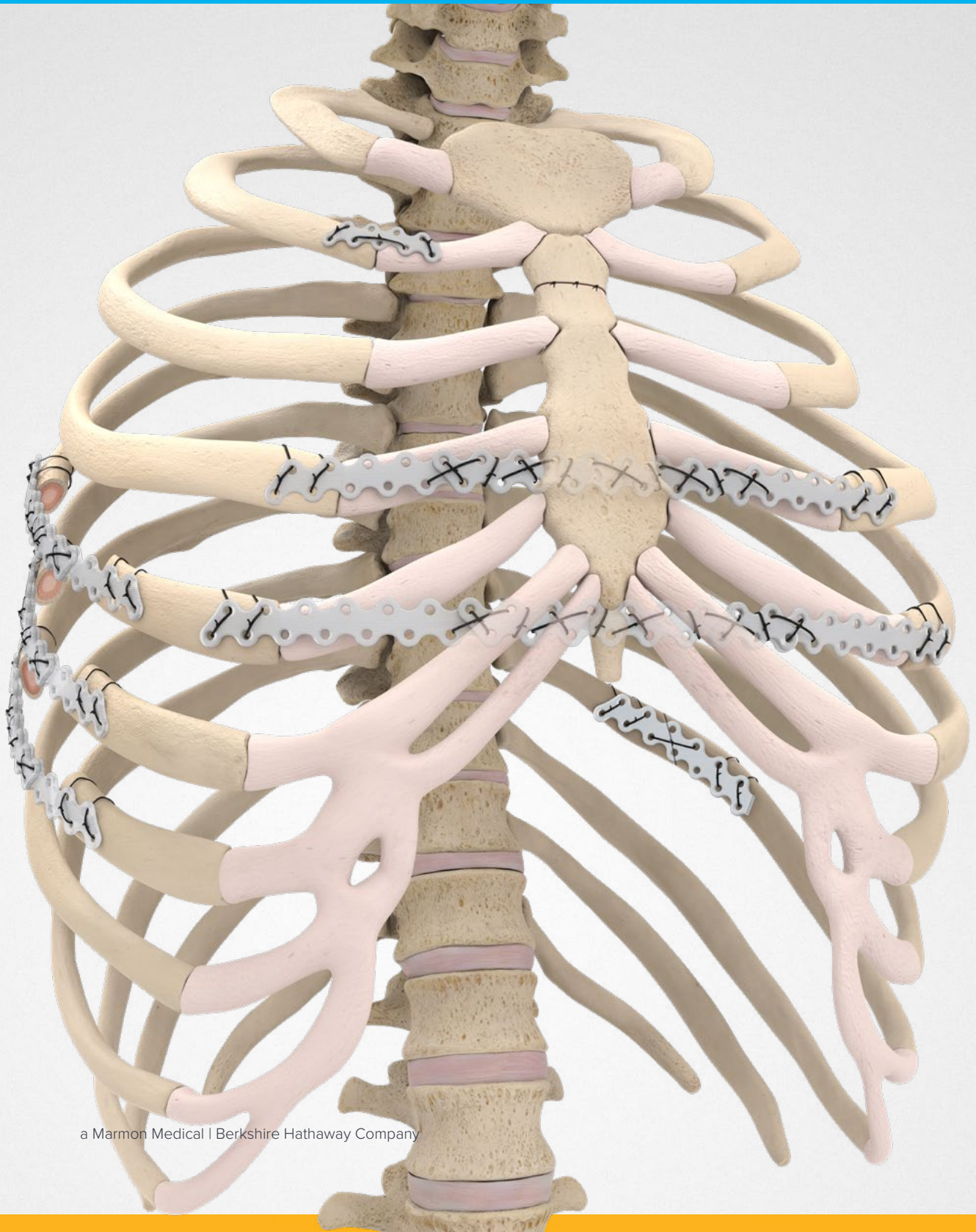


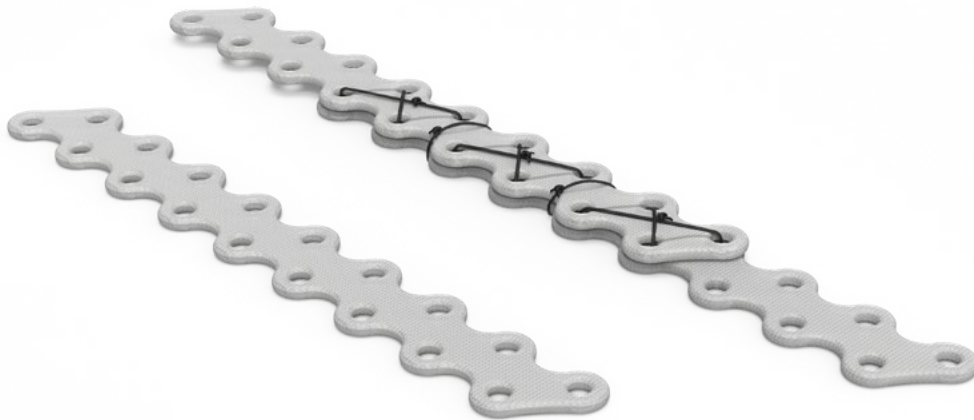
Surgical Technique



Acumed® is a global leader of innovative orthopaedic and medical solutions.



We are dedicated to developing products, service methods, and approaches that improve patient care.



Chest Wall Reconstruction

Acumed's BioBridge® Resorbable Chest Wall Stabilization Plate is a versatile, nonpermanent solution for chest wall stabilization. It was specifically designed to offer strength that exceeds typical chest wall loading¹ and a resorption time that outlasts typical bone healing time¹.

Indications for Use

In the presence of appropriate additional immobilization or fixation, indicated for maintaining the alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), as well as trauma and reconstructive procedures. Specifically, BioBridge can also be used on metacarpus, proximal and middle phalangeal bones, as well as long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax.

	Definition
Warning	Indicates critical information about a potential serious outcome to the patient or the user.
Caution	Indicates instructions that must be followed in order to ensure the proper use of the device.
Note	Indicates information requiring special attention.



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System Features

Chest Wall Reconstruction
Reconstruction technique² provides long-term chest wall stability through bone healing and/or soft tissue scarring

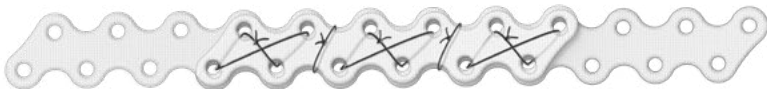


Customizable Solution
BioBridge® is flexible and can be stacked or trimmed for increased rigidity and/or length



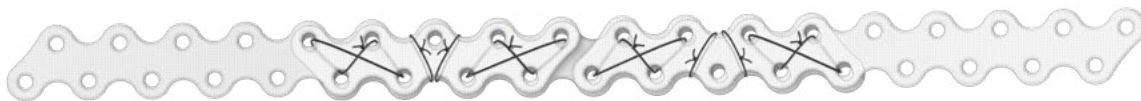
Side view

Doublet



Top view

Triplet



Chest Wall Reconstruction Technique

Clinical Summary of Chest Wall Resections

Indication for chest wall resection can include chest wall tumors (benign and malignant), radiation necrosis, contiguous lung or breast cancer, and lung/chest wall infections.^{4,7} The locations of resections vary, but have been shown to occur more commonly in ribs than the sternum (Table 1).

Resection Location	Rate
Anterior Ribs	33%
Anterolateral Ribs	20%
Lateral Ribs	19%
Posterior Ribs	13%
Posterolateral Ribs	13%
Sternum – Upper	8%
Sternum – Mid	2%
Sternum – Lower	2%

Table 1: Summary of resection location in 200-patient study (Mansour et al.)⁶

Mansour et al. summarized the optimal chest wall resection and reconstruction as having three tenets:

- ▶ Sufficient amount of tissue must be resected to remove all devitalized tissue.
- ▶ In large chest wall resections, chest wall replacement must be performed to restore the rigid chest wall to prevent physiologic flail.
- ▶ Healthy soft tissue coverage is essential to seal the pleural space, to protect the thoracic viscera and great vessels, and to prevent infection.

When chest wall dynamics are not compromised (i.e., no flail chest), reconstruction may not be required.³ However, even when chest wall continuity is maintained, reconstruction may be desired to enhance cosmesis and protect underlying structures.^{6,7,9}

When chest wall dynamics are compromised, reconstruction to restore chest wall rigidity is often recommended.^{1,3-4, 6-9}

In a review of 101 chest wall reconstruction cases comparing autogenous and prosthetic repair (i.e., mesh), it was noted that ventilator use was 5 times more frequent in patients who had autogenous reconstruction alone. Hospital stay was also prolonged for these patients.⁵

Guidelines for Reconstruction

A 3D reconstruction CT scan is used to determine the size, location, and extent of the resection and reconstruction that is needed for each patient. The reconstruction method depends primarily on location and size of the resection. For example, smaller resections (<5 cm) or resections under the scapula (ribs 1–3) usually do not require reconstruction.

Larger or more anterior chest wall defects are more likely to require material implants to prevent lung herniation or flail chest, and to restore a natural cosmetic shape.

Chest Wall Reconstruction Technique [continued]

The technique described here is preferred for three primary benefits:

- ▶ The BioBridge plate provides a dynamic support for reconstruction.
- ▶ Bovine pericardium maintains a watertight seal of the chest and provides a scaffold for tissue ingrowth.
- ▶ The reconstruction material absorbs, remodels, and is replaced by normal soft tissue.

To start, all devitalized tissue is removed. In cases of malignant tumor removal, it is recommended that, at minimum, an additional 4 cm margin grossly free of the tumor be resected.¹

Preparation of BioBridge Plates

Prepare for the reconstruction by measuring the chest wall defect. When planning the length of the plate, measure the distance between the planned anchor ribs bilaterally and account for at least four holes (1 cm) overlap with the rib at each anchor point. Use a non-absorbable suture no smaller than a USP size two.

If the defect is larger than 8 cm, BioBridge plates can be stacked in either a “doublet” or “triplet” configuration and sutured together to form one long stabilizer. When stacking, overlap at least four holes and ensure each overlapping hole is sutured together, then add suture around the scallops in the plate to ensure a rigid construct (Figure 1).

Important: The stacked stabilizer must be rigid. If the final construct is loose, remove any loose sutures and re-tie them. Add BioBridge plates if additional stiffness is necessary.

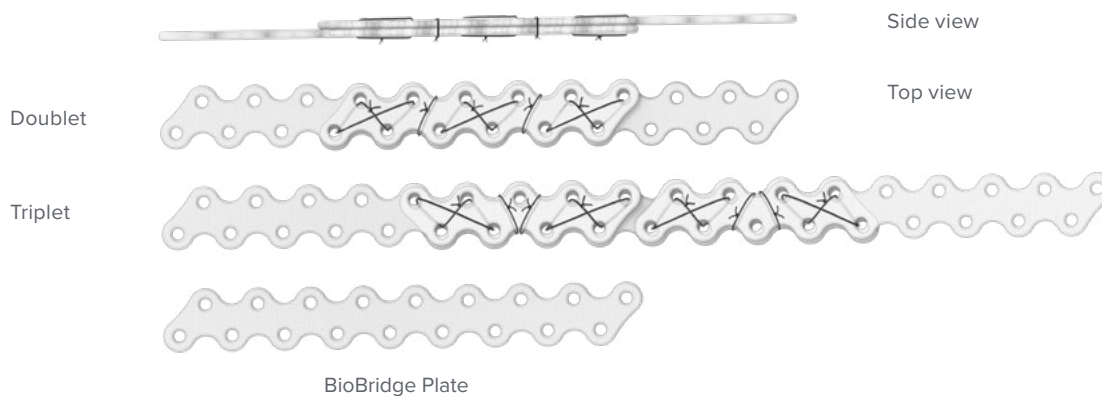


Figure 1: BioBridge doublet and triplet

- ▶ Two stacked plates (doublet) sutured together to form one longer stabilizer, minimum 8-hole overlap (12-hole overlap shown here).
- ▶ Suture through the holes and around the scallops of the plates in order to achieve a tight stabilizer construct.

Chest Wall Reconstruction Technique [continued]

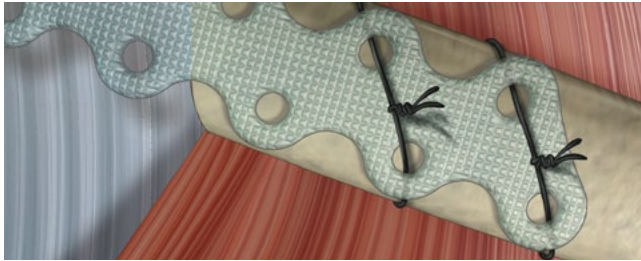


Figure 2: Minimum of two sutures at each anchoring point

Installation

Anchor each end of the plate or stabilizer with at least two sutures running through the top and bottom holes of the BioBridge and around the rib (Figure 2). Alternatively, suture may be passed through the ribs. An example of a bioresorbable reconstruction using BioBridge is shown in Figure 3. In this case, each resected rib is bridged and a perpendicular BioBridge triplet is used to add stability.

Note: In very large resections involving multiple rib levels, a more rigid construct may be needed in place of the resorbable plates (i.e., metal struts or a methyl methacrylate sandwich).

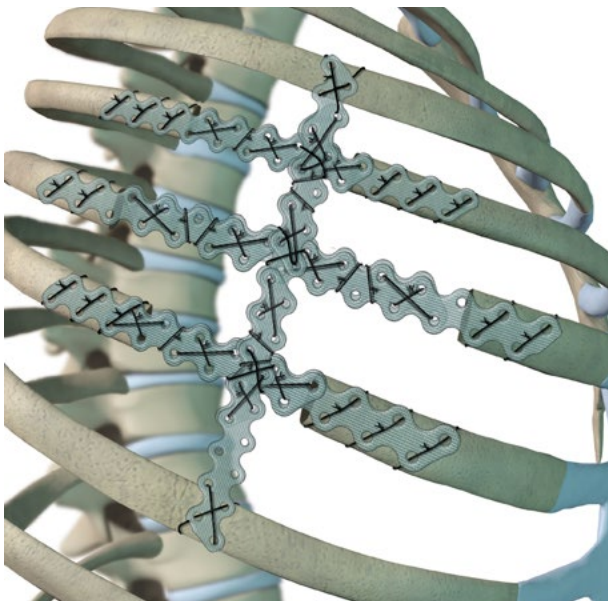


Figure 3: Reconstruction of resection site

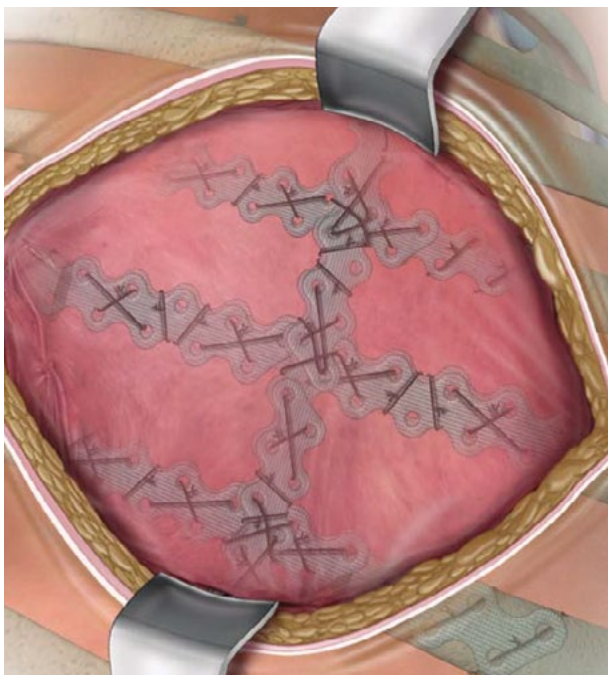


Figure 4: Pericardial patch is secured in place

Once the desired reconstruction is achieved, the bovine pericardium is stretched over the defect and sutured to the chest wall muscle and ribs. The pericardial patch is tightened, like a drum, creating a seal and preventing paradoxical motion of the chest wall (Figure 4).

In the case of a full-thickness (including soft tissue) chest wall reconstruction, a muscle flap is preferred to provide viable tissue to cover the reconstruction material and prevent infection. Table 2 contains types of muscle flaps used in chest wall reconstruction and associated frequencies of use. A plastic surgeon should be consulted when a muscle flap may be necessary for reconstruction.

Chest Wall Reconstruction Technique [continued]

Autogenous Tissue Replacement	Rate
Pedicle Flap	48%
Free Flap	9%
Latissimus Muscle	20%
TRAM	17%
Pectoralis Muscle	16%
Serratus Muscle	9%
Deltoid Muscle	2%
Trapezius Muscle	2%
Omentum	10%
STSG	12%

Table 2: Muscle flap type and frequency (Mansour et al)⁶

Complications	Rate
Respiratory	24%
Seroma	7%
Wound Infection	5%
Arrhythmia	3%
Hemorrhage	2%
Myocardial Infarction	2%
Prolonged Air Leak	1%
Other	3%

Table 3: Complications reported from chest wall reconstruction³

Closure and Follow Up

Following chest wall reconstruction, pain management is typically achieved with an epidural catheter. Jackson-Pratt (JP) drains are usually used above the reconstruction material to prevent seromas. When fluid drainage is less than 50 cc in a 24-hour period, the drain is removed. Some patients may be sent home with a JP drain. Pain medications are typically needed 4–6 weeks postoperative. Patients should limit lifting over 20 lb and additional restrictions may be needed if muscle flaps are used.

Complications

Complications relating to chest wall resection and reconstruction can be significant and should be understood before performing the resection. Deschamps et al. found that 46% of patients experienced complications. A summary of complications related to chest wall reconstruction is provided in Table 3. Note that these complications are not specific to the method discussed here.

Conclusion

Chest wall reconstructions are complex procedures requiring individualized solutions and an experienced team. The use of biomaterials such as the BioBridge plate and bovine pericardium, and free, or pedicled muscle flaps, offers a distinctive solution that is dynamic and customizable. This technique can provide long-term stability, a dynamic, watertight seal, and a restored chest wall at the site of the defect that allows for the eventual incorporation of normal tissue.

Pectus Deformity Repair Technique



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The goal of this monograph is to describe a novel technique to help stabilize the sternum posteriorly after a modified Ravitch repair for pectus defects.

BioBridge is composed of absorbable material that is used to enhance the stability of the sternum at the time of an open repair. This technique provides stability through the timed support of the sternal repair with the goal of obtaining long-term stability through the natural healing of tissue and cartilage, thus preventing recurrence of the pectus deformity.

This document is intended for support and educational purposes and is not to be used in any other capacity. All questions regarding surgical implantation of this product should be directed to a licensed medical professional familiar with Acute Innovations products. In addition, consult the product's 'Instructions for Use' for more detailed information.

Pectus Deformity Repair Technique [continued]

For years, the open Ravitch repair has been the standard surgical procedure for repair of pectus deformities. Recently, a resorbable BioBridge plate was developed that can be used to help stabilize the sternum at the time of the open pectus repair. The plate maintains full strength for 180 days and is absorbed in 2–3 years, thus avoiding a second procedure.

This modified Ravitch repair involves excising the deformed cartilage, usually three through seven bilaterally, while preserving the perichondrium. An anterior wedge osteotomy of the sternum is performed just below the angle of Louis, which corrects the sternum deformity. The BioBridge is used to reinforce the sternum posteriorly and is anchored, on either side, to the anterior aspect of the ribs, usually the fourth and/or fifth.

The following technique describes a modified Ravitch procedure using the BioBridge Resorbable Chest Wall Stabilization Plate.



Figure 1: Preoperative pectus defect

Preoperative Patient Evaluation

Evaluation of a patient with a pectus deformity includes a CT scan of the chest with calculation of a Pectus Index (PI) and documentation of sternal symmetry, a 2-D echocardiogram to access right ventricular function, and pulmonary function tests to rule out primary lung disease. The patient's symptoms in regards to pain, exercise capability, and breathing difficulty should be detailed.

Note: Calculation of the pectus index (by a chest CT scan) and sternal symmetry is needed to determine if an open or closed (Nuss) procedure is most appropriate.

Note: BioBridge is to be used in addition to the Ravitch procedure and is not intended to replace a metal strut alone.

Recommended Preoperative Checklist

- ▶ Suture: A non-absorbable suture, USP size two with a CTX needle
- ▶ Redo sternal saw: For anterior wedge osteotomy of the sternum
- ▶ BioBridge plates: The number of plates needed depends on the width of the patient's chest cavity and on the preoperative severity of the defect. At least six plates should be available
- ▶ Periosteal elevators: For removing costal cartilage from within the perichondrium

Caution: In preparation for the procedure, it is recommended that the OR personnel be trained on the technique for stacking and suturing the BioBridge plates together (Figure 4) and on the equipment necessary for the procedure.

Pectus Deformity Repair Technique [continued]

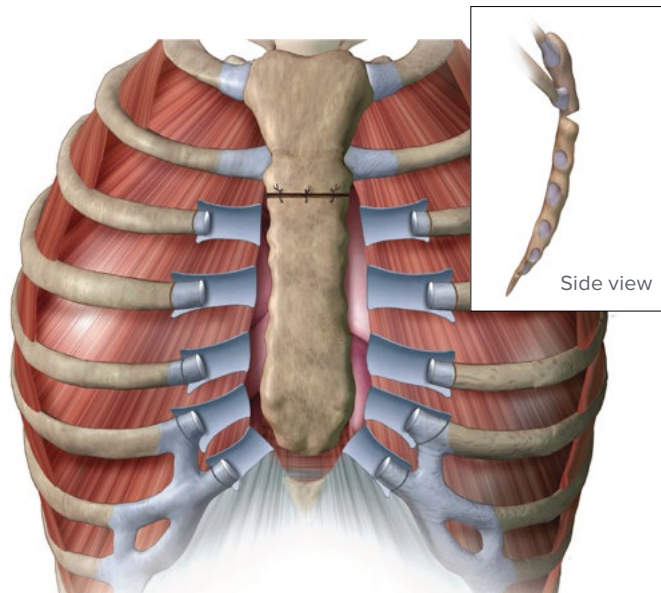


Figure 2: Cartilage removed, perichondrium preserved, and wedge osteotomy sutured

Incision

For males, create a vertical midline incision from the fourth rib to the xiphoid. For females, an inframammary incision is used. Using electrocautery, the pectoralis major muscles are dissected free from the chest wall and sternum so that abnormal cartilage may be identified for removal.

Remove Costal Cartilage

Once the sternum and costal cartilage are visualized, remove the cartilage where the defect begins. Remove the cartilage in a subchondral plane to preserve the perichondrium from the sternum to the ribs. Separate the perichondrium from the sternal edge and detach the xiphoid from the sternum, keeping the rectus muscles attached to the xiphoid (Figure 2).

Sternal Elevation

Create an anterior wedge sternal osteotomy below the angle of Louis to overcorrect the sternum anteriorly. U-stitches are used across the sternum osteotomy to stabilize the position.



Figure 3: Sternum after freeing the cartilage

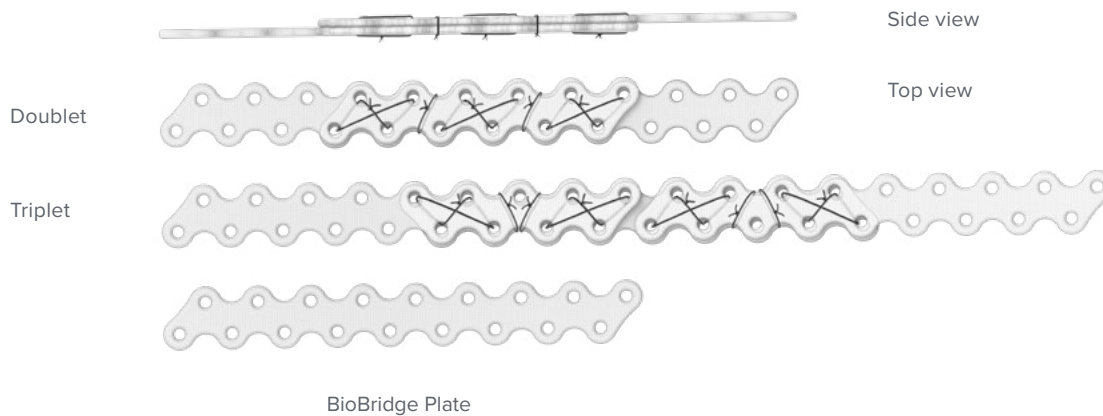
Pectus Deformity Repair Technique [continued]

Preparation of BioBridge Plates

BioBridge plates are sutured together to create a stabilizer of appropriate length. When planning the length of the stabilizer, measure the distance between the planned anchor ribs bilaterally and account for at least four holes (1 cm) overlap with the rib at each anchor point. Use non-absorbable sutures to stack two or three BioBridge plates together as a “doublet” or “triplet” stabilizer.

When stacking, overlap at least four holes to ensure each overlapping hole is sutured together, then add suture around the scallops in the plate to ensure a rigid construct (Figure 4).

Important: The stacked stabilizer must be rigid. If the final construct is loose, remove any loose sutures and re-tie them. Add BioBridge plates if additional stiffness is necessary.



Pectus Deformity Repair Technique [continued]

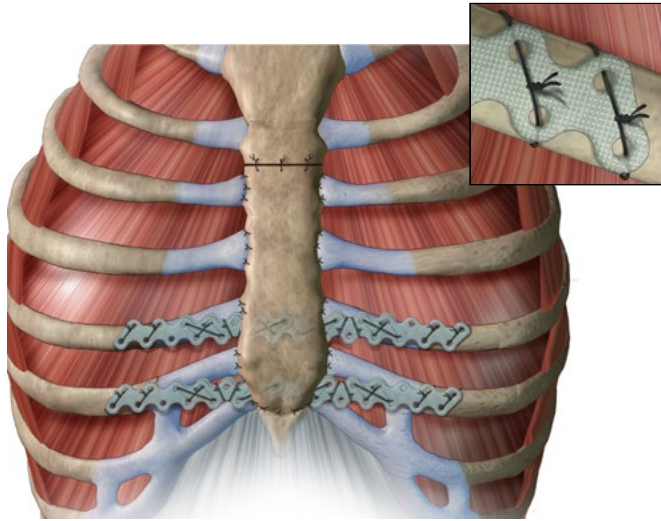


Figure 5: BioBridge stabilizers installed, inset showing suture at anchor points

Installation

Place the BioBridge stabilizer posterior to the sternum and anchor each end anteriorly on the ribs. Secure the BioBridge stabilizer by passing the CTX suture needle through the superior and inferior holes of the plate. Then wrap the suture around the rib posteriorly and anteriorly and through the intercostal muscles using a figure of eight or simple interrupted suture. Additional suture may be wrapped around the BioBridge plate and bone to add stability. Test the rigidity of the supported sternum. An additional BioBridge stabilizer may need to be added to increase rigidity (Figure 5).

Once the anatomical correction is made, re-attach the xiphoid and the perichondrial beds to the newly positioned sternum (Figures 5 and 6).

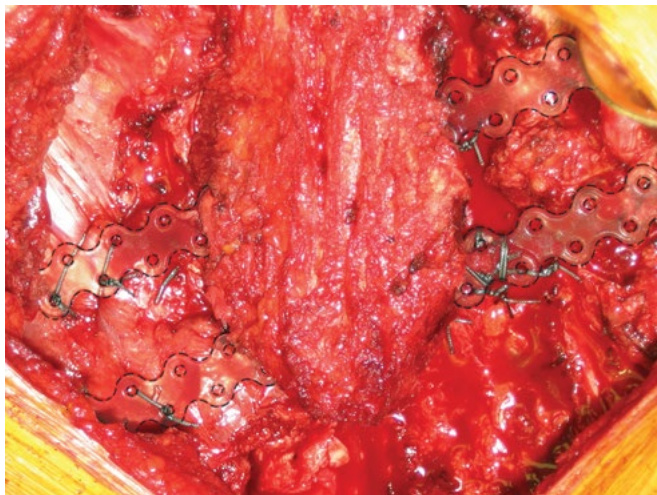


Figure 6: Plates installed and perichondrium re-attached
Note: BioBridge stabilizers are highlighted in this image for visibility

Closure

Reapproximate the pectoralis major muscle and subcutaneous tissues, followed by a subcuticular skin closure. Two 10 mm Jackson-Pratt drains are routinely placed anterior and posterior to the pectoralis muscles. If the pleura is violated a 19 FR Blake is placed in the pleural space (Figure 7).

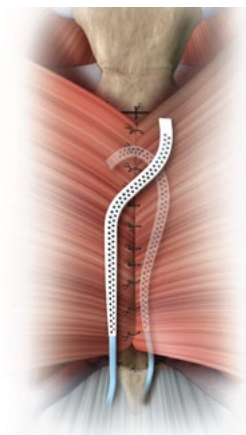


Figure 7: Closure showing placement of drains

Postoperative

An epidural is used for postoperative pain management. The patients are monitored on a regular telemetry floor. All drains are usually removed on postoperative day 3 or 4 in the majority of the patients. If the drainage is excessive, the patient is discharged and monitored until drainage is <50 ml/day. All patients are fitted with a protective shield to protect the soft, anterior chest. The shield is typically worn for 6 to 8 weeks. Follow-up appointments are conducted at 3–4 weeks, 3 months, and 6 months.

Appendix

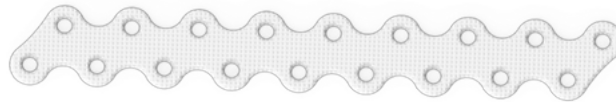
For additional information on the BioBridge Resorbable Chest Wall Stabilization Plate, contact your local Acumed sales representative or visit Acumed.net.

BioBridge Plate Indications

In the presence of appropriate additional immobilization or fixation, indicated for maintaining the alignment and fixation of bone fractures, osteotomies, arthrodeses, or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures.

Specific Indications

- ▶ Metacarpus, proximal, and middle phalangeal bones
- ▶ Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax



Ordering Information



Components

- | | | |
|---|-----------------------------------|---------|
| 1 | 110 mm BioBridge Resorbable Plate | RRP1501 |
|---|-----------------------------------|---------|

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