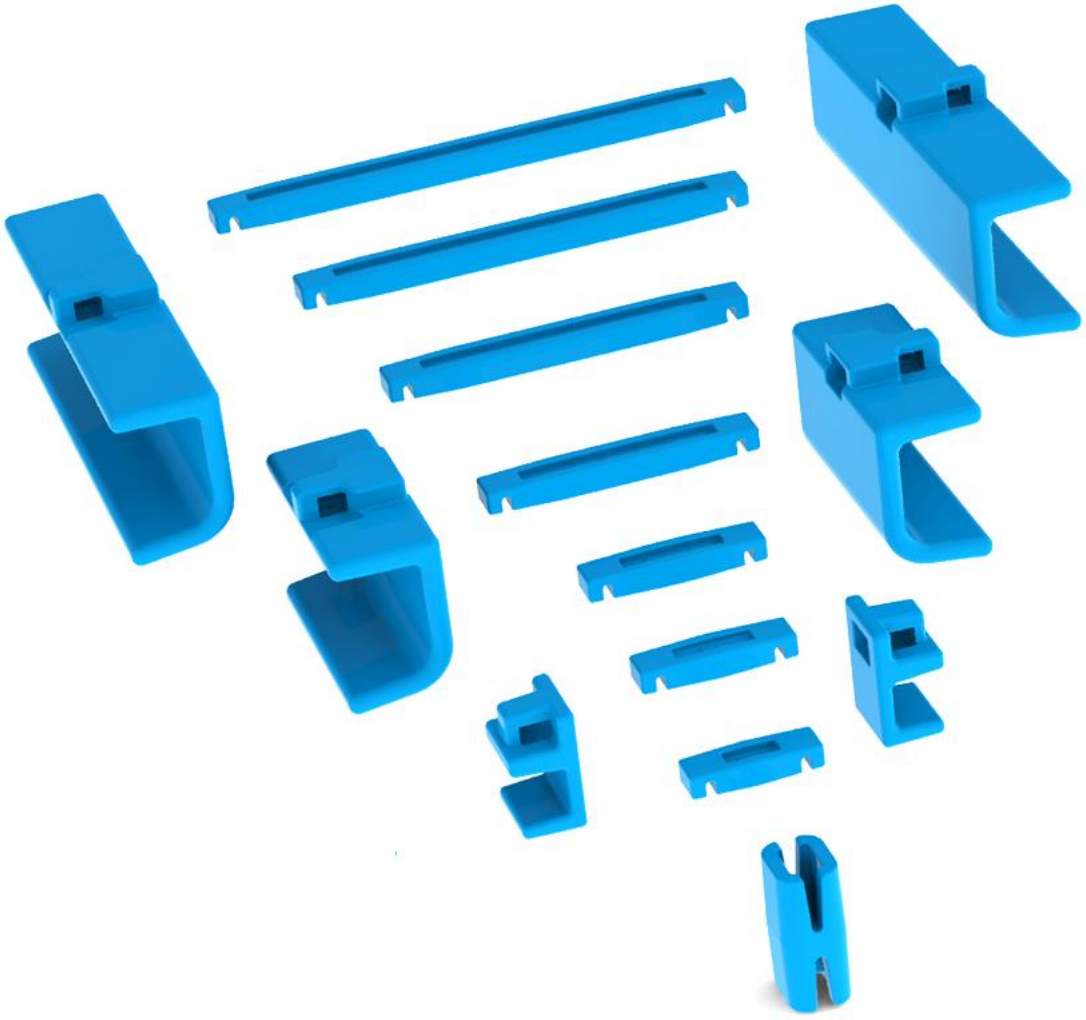
# BlueBridge



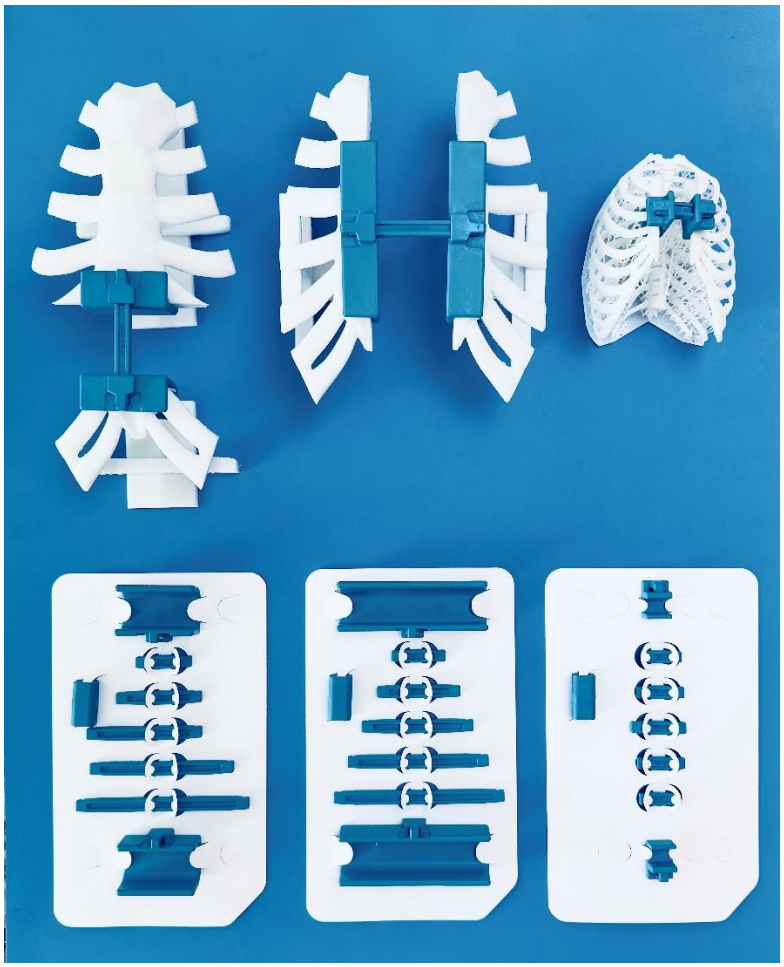
## Open Chest Management System

THORACIC INNOVATIONS

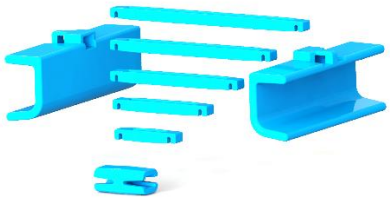
Cardiothoracic surgery is a constantly evolving specialty focused on finding solutions to restore or replace heart function and reestablish cardiovascular health. It involves complex procedures performed on critically ill patients, requiring a high level of care during and after surgery. There is a constant need to adapt and evolve surgical instruments, devices and drugs to effectively manage these critically ill patients.

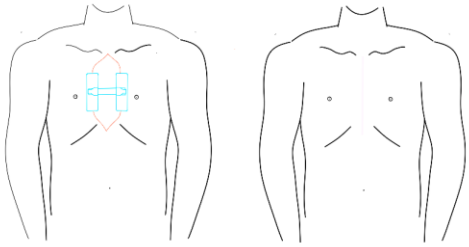
Immediately after cardiothoracic surgery, the heart muscle may not immediately recover its function and may require additional time to restore contractility. *Adequate space is essential for proper diastolic filling*, which may be compromised by mediastinum edema and early approximation of the sternum. In such cases, leaving the chest open with a sterile cover and *delaying sternal closure* becomes a necessary and ***lifesaving intervention***. By postponing the closure, surgeons allow time for the patient's physiological conditions to stabilize, correct fluid imbalance, reduce edema of the mediastinum, and reduce pressure on the heart and lungs. Adequate space is essential for heart filling during diastole, which may be compromised by mediastinum edema and premature approximation of the sternum. The sternum can be safely closed once the heart's function has recovered, fluid imbalances are resolved, and hemodynamic stability is achieved.

The BlueBridge open chest management system ensures safe maintenance of the chest cavity in an open position following surgery. We have developed three kits designed to provide customizable options for all patient populations and various clinical scenarios.

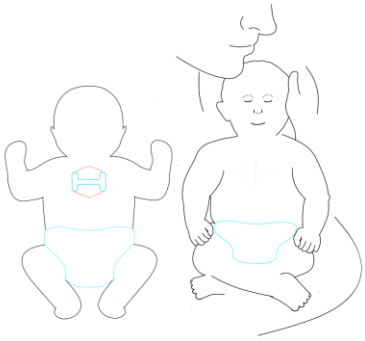


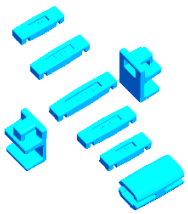
Adult Cardiac



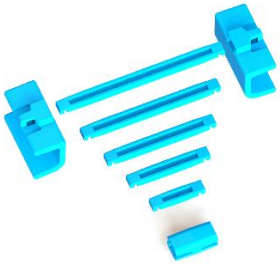


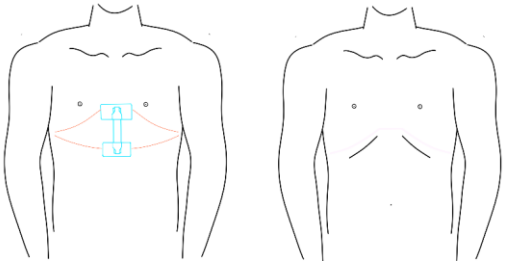
Neonatal Peds Cardiac



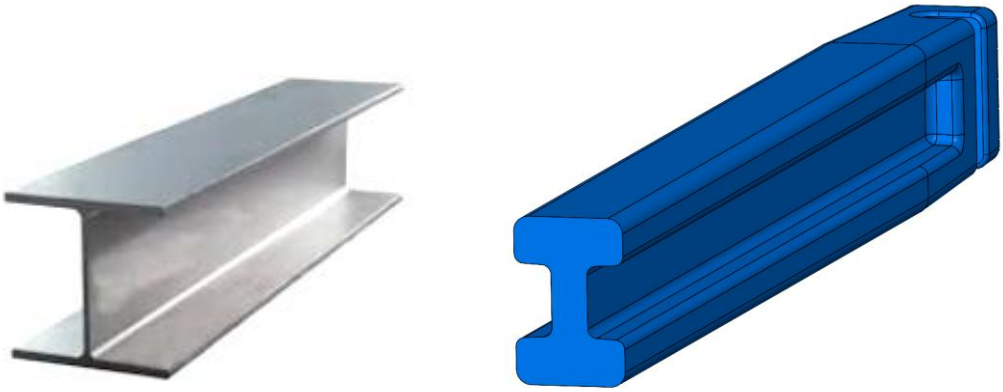


Adult Thoracic





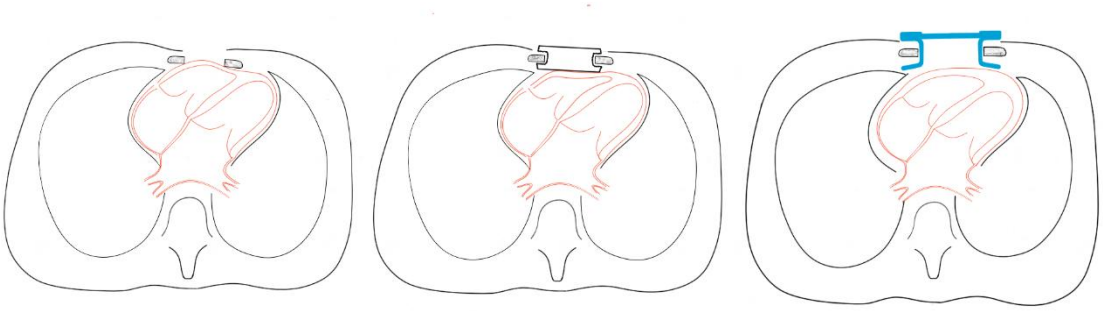
The open chest management system is designed to stabilize the chest cavity in the open position. It functions *similarly to a retractor but with a much lower profile*. This design allows for sterile coverage and effective drainage of the mediastinum. The system is constructed from IXEF, a highly resilient fiberglass-reinforced polymer. We utilize an i-beam cross-section to neutralize stress forces and withstand the loads required to maintain chest stability in the open position.



The i-beam design is a structural engineering innovation that maximizes mechanical strength while minimizing material usage. Its distinctive cross-sectional shape—comprising a central vertical web and horizontal flanges at the top and bottom—efficiently distributes stress and resists bending under load. The vertical web provides rigidity to counter shear forces, while the flanges handle compressive and tensile stresses, making the I-beam exceptionally strong and stable.

IXEF is a high-performance para-polymer known for its exceptional mechanical properties and versatility. This fiberglass-reinforced polyarylamide combines the strength and stiffness of metal with the lightweight and corrosion-resistant benefits of a polymer. IXEF exhibits outstanding tensile strength and dimensional stability, ensuring reliable performance in challenging environments.

The combination of the i-beam design and the material properties of IXEF provides a smooth surface finish and resilience, to withstand the substantial forces required to stabilize the chest cavity without deformation. The device is partially radiopaque, enabling its position to be verified using standard postoperative chest X-rays.



| FEATURES | STERNUM | SYRINGE | Open Chest Management System(OCMS) |
|---|---|---|---|
| EDGES | Sharp edges – right ventricle injury | Rough and sharp edges - heart and lung injuries | Smooth edges |
| HEART FILLING | Partially preserved | Restricted | Preserved |
| STABILITY | Unstable | Prone to dispacement | Stable |
| X-RAY IMAGING | Not visible | Not visible | Radio-opaque: The position can be verified using X-ray imaging. |

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**1. Instructions for Use**

**Device Identification**

- **Device Name:** BlueBridge - Open Chest Management System.
- **Intended Use and Indications:**
  The BlueBridge - Open Chest Management System is intended to provide chest stabilization when delayed sternum closure is necessary after cardiothoracic surgery. The device stabilizes the chest in open position, functioning similarly to a surgical retractor. Its low-profile design allows sterile coverage and effective drainage of the mediastinum. BlueBridge offers increased space for heart recovery compared to current options, mitigating the risk of right ventricular outflow tract compression or injuries caused by the sharp edges of the hemi-sternum or plastic cut syringes.
- **Regulatory Classification:**
  The device is classified as a Class I medical device under FDA guidelines and is exempt from 510(k) premarket notification (Class Code: GAD – 878.4800). It is non-implantable and, like other

general surgical instruments, it is intended for temporary use for twenty-four hours. The device is manufactured from a super-resilient, biocompatible polymer (IXEF PARA GS 1022), sterilized by gamma irradiation, and packaged in a double-barrier sterile pouch.

- **Key Features:**
    - Single-use, sterile, and biocompatible, adjustable to accommodate different chest dimensions.
    - Partially radiopaque for identification and position tracking during postoperative chest X-rays or CT scans.
    - Intended for use exclusively by cardiothoracic surgeons with knowledge and expertise in cardiothoracic surgery.

**Contraindications:**
The device is contraindicated for patients with:

- Anatomically abnormal sternums.
- Sternum instability or multiple sternum fractures where the device cannot achieve stable positioning.

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**Instructions for Use**

**Device Overview:**
The BlueBridge kit includes components that allow manual customization of size and shape based on the required separation between the sternum edges. It features:

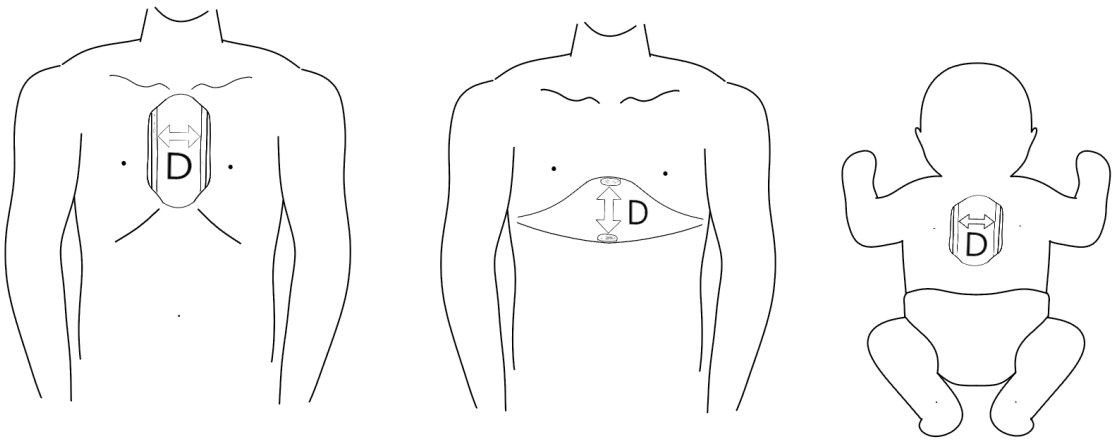
- Sternum plates that interface with the edges of the sternum.
- Different size separation bars. The extremities of the bar will interconnect with the two respective plates.
- Rounded edges to minimize injury to the heart, lungs, and mediastinal structures.
- Super-resilient, biocompatible materials capable of withstanding chest cavity forces.

**Steps for Use**

1. **Pre-Use Inspection:**
    - Verify the integrity of the packaging to ensure sterility.
    - Check the expiration date on the package label.
    - Confirm the indication for delayed sternum closure, such as biventricular dysfunction, right ventricular dysfunction, left ventricular dysfunction, bleeding, arrhythmias, central ECMO cannulation, central ventricular assist devices, severe mediastinum edema, chest cavity content cavity mismatch after heart or lung transplantation.

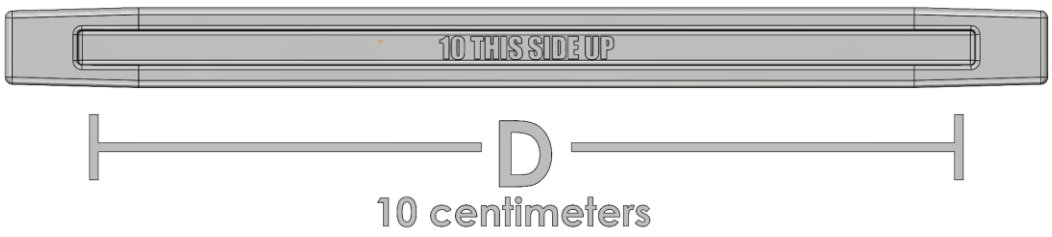
2. **Sizing:**

    - Measure the required distance “D” between the sternum edges represented in figure 1. The distance represents the desired distance of the sternum edges with the chest in open position.




    - **Fig.1-** Distance “D”-represents the desired distance between the sternum edges when the chest cavity is left open. Adult cardiac surgery (left), thoracic surgery(middle), and Neonatal surgery (right)

    - Select an appropriate bar from the kit based on the measurement of distance D(Fig. 2). Note: The reference number on the bar indicates an estimated size in cm but does not represent the final separation distance created by the assembled device.




    - Fig.2- Selection of the bar based on measurement of estimation of the distance between the sternum edges.

3. **Assembly:**

    - Assemble the device outside the surgical field immediately before placement to avoid mechanical issues or accidental loss of components.

    - Connect the bar to the plates by inserting each bar end into the corresponding slot on the plates. Ensure the debossed label, "This Side Up," on the bar faces upward. Fully insert each bar end until it reaches the slot's end (Fig. 3).

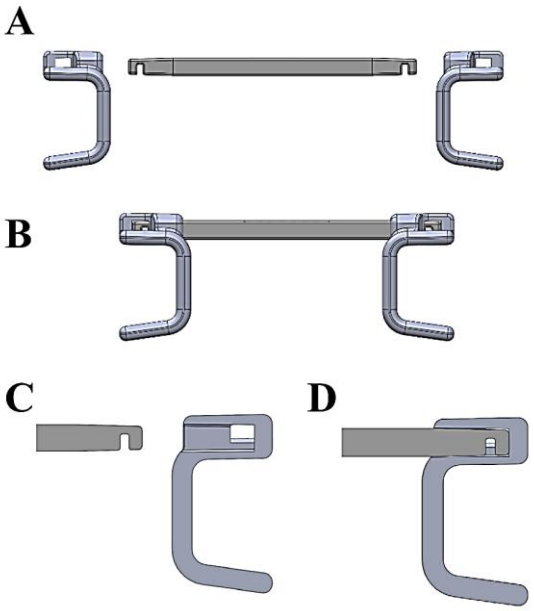
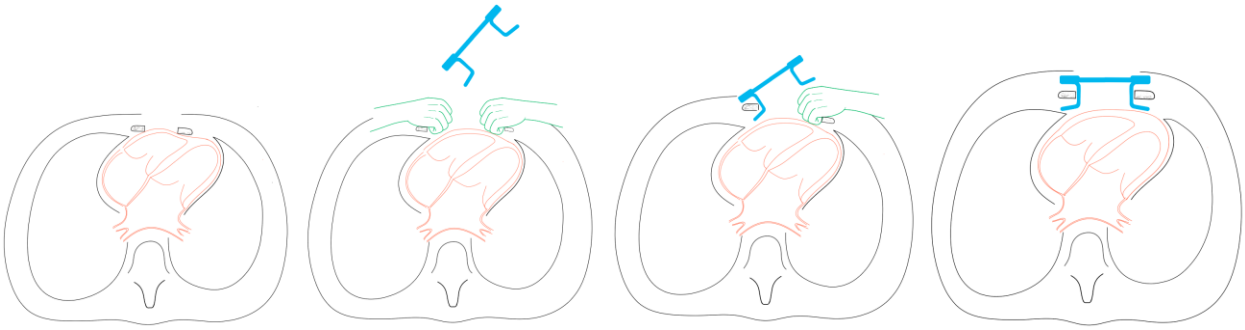



Figure 3. Sternum Spacer Assembly - A. Image of the separated components of the sternum spacer. The "C" shaped components on the left and right are referred to as the plates, and the middle component is referred to as the separation bar, which will include several sizes. B. Image of the device assembled by sliding the extremities of the separation bar between the two spacer plates that will be in contact with the sternum. C. Image of the cross-section of the interlocking mechanism of the device, unassembled. D. Image of the interlocking mechanism assembled and demonstrating the aperture left for placement of wire to further stabilize the device.

4. **Placement and removal:**



- Placement- Manually pull the sternum edges apart to create enough space to place the device in position. Removal- Manually pull the sternum edges apart to give space for the removal of the device
- Securing the device- thread a 0.8mm sternum wire through the channels at the slot ends. Twist the wire ends gently to secure the bar and plates together.
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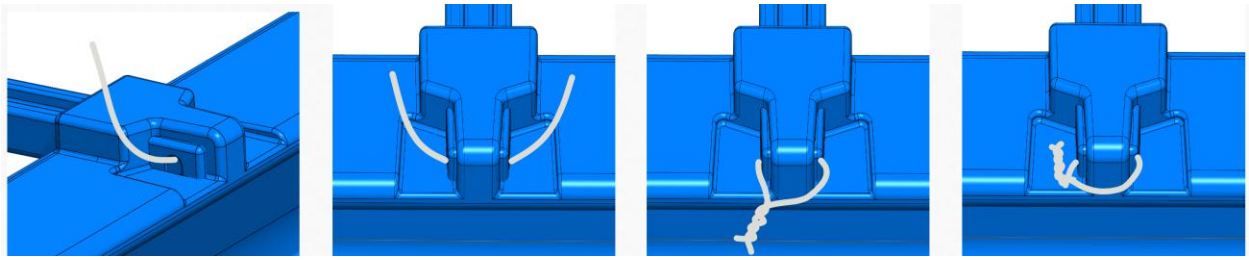
- In adult cardiac patients who require the 10 cm separation bar, have a BMI over 40, or show any signs of bar deformation, we recommend using two sternum spacers—one positioned at the top and one at the base of the sternum.



- Additional stabilization can be achieved with intercostal or periosteal sutures or wires, as per the surgeon's preference.

5. **Size Adjustment (if required):**
    - To change the device size, remove it from the chest, disassemble it by cutting the wires, and detach the plates from the bar ends. Reassemble using a different-sized bar.
6. **Emergency Removal:**
    - The entire device can be removed or repositioned to allow access to the heart and mediastinal structures.
    - Do not attempt to disassemble the device while it is in the patient. Remove it entirely from the chest cavity before reconfiguration.

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**Storage:**
Store the device in clean, dry, and ventilated areas designated for sterile surgical instruments or devices.

**Disposal:**
The device is for single use only and should not be re-sterilized or reused.