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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.

Instructions for Use

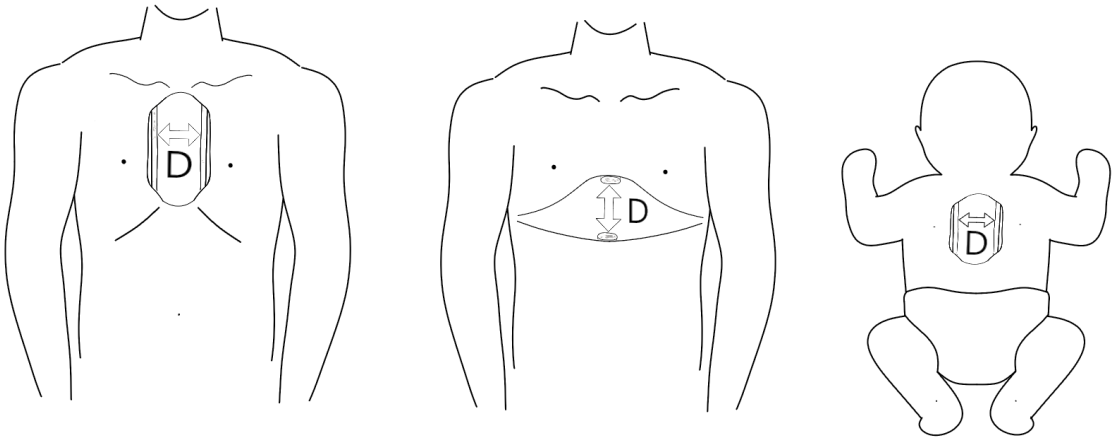
Device Overview:
The BlueBridge kit includes components that allow manual customization of size and shape based on the required separation between the sternum edges. It features:

- Sternum plates that interface with the edges of the sternum.

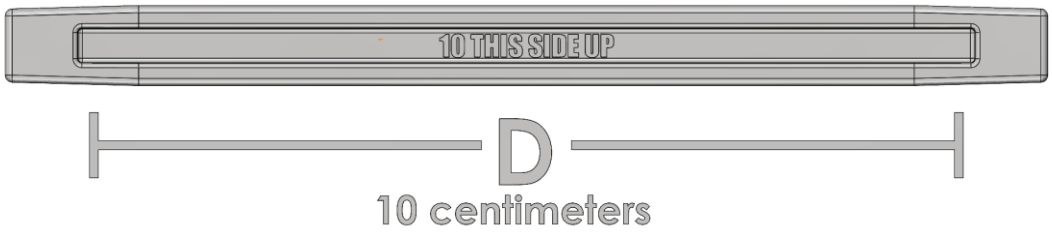
- Different size separation bars. The extremities of the bar will interconnect with the two respective plates.
- Rounded edges to minimize injury to the heart, lungs, and mediastinal structures.
- Super-resilient, biocompatible materials capable of withstanding chest cavity forces.

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).

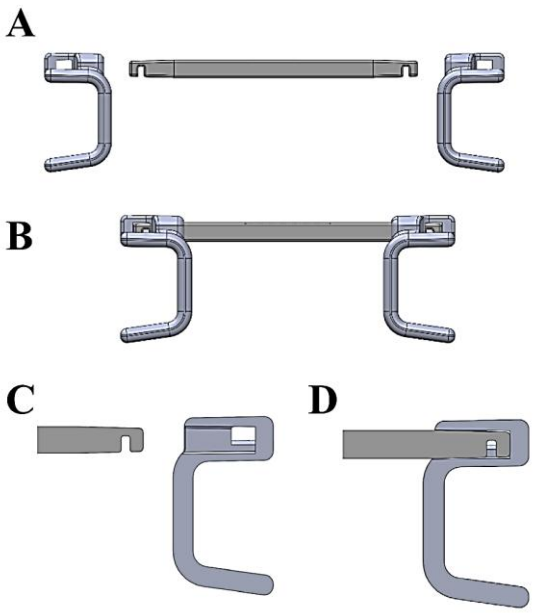
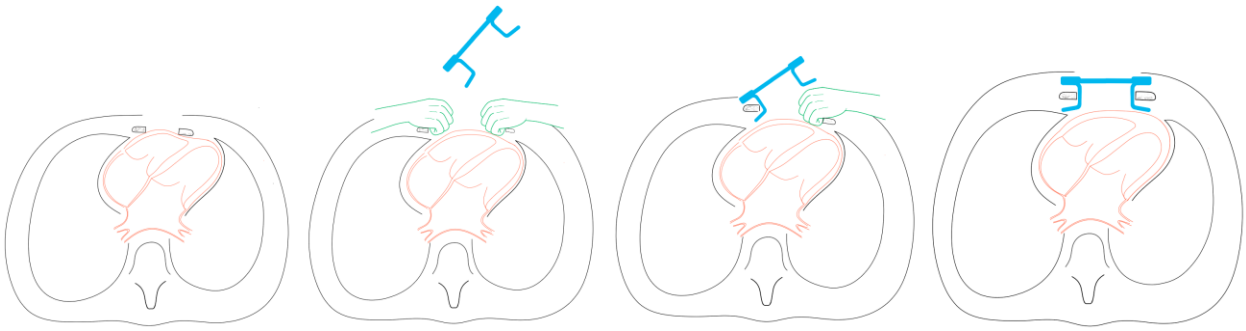
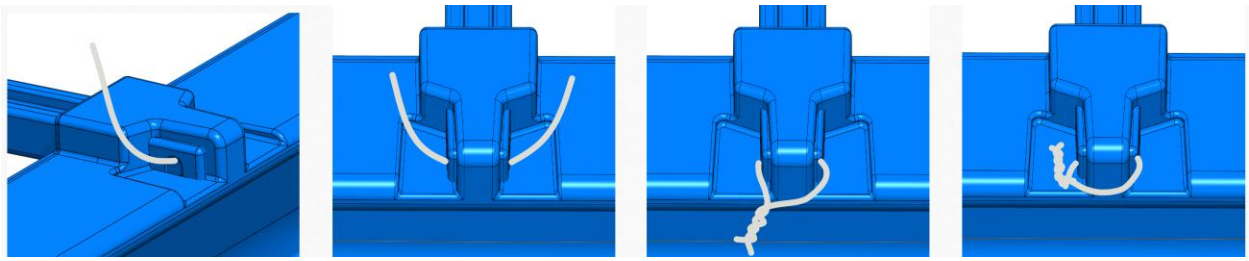


Figure 3. Sternum Spacer Assembly - A. Image of the separated components of the sternum spacer. The “C” shaped components on the left and right are referred to as the plates, and the middle component is referred to as the separation bar, which will include several sizes. B. Image of the device assembled 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:**
    - Position one plate against the right sternum edge first. Pull the sternum edges apart to create enough space to carefully position the left plate against the left sternum edge.



    - Once the device is inserted into both plates, 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.
    - 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.

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.