CHASE MEDICAL

DISPOSABLE PLATFORM BLADES

Product Code	Description
DPB-8000S	Disposabable Platform Blades (1 Pair)

CHASE MEDICAL

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STERILE EO

Product Description:
The device consists of two Disposable Platform Blades designed to attach to a reusable Activator Drive Mechanism (not included). The Platform Blades in combination with the Activator Drive Mechanism are used to spread the sternum, providing access and direct visualization to the thoracic cavity. The Platform Blades provide a stable mounting surface for the Chase Viper II Heart Stabilizer, Q Base and Chase Viper II Apical Lift, Q Base.

Indications for Use:
● The Platform Blades connected to a reusable Activator Drive Mechanism are intended for use during cardiovascular surgical procedures through a median sternotomy.
● The Platform Blades also allow for the organization of pericardial sutures.

Contraindications:
● This device is not intended for use except as indicated above.

Warnings and Precautions:
● Carefully read instructions prior to use.
● Product is Ethylene Oxide sterilized. **DO NOT REUSE OR RESTERILIZE.** Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
● Proper surgical procedures and techniques are the responsibility of the medical professional. The surgical team must evaluate the appropriateness of the procedure based on their experience. The outcome is dependent on many variables, including patient anatomy, pathology, surgical technique and anesthesia management.
● Although product has been carefully designed, manufactured and inspected or tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the product labeling and in this document provide more detailed information and should be read by the user prior to use of product.
● Suture holder features are designed for "0" size sutures.
● Sterile unless package is opened or damaged.

CAUTION: Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.

Adverse Effects:
None known.

Directions for Use:
1. Inspect the package and product for damage and expiration date. If undamaged and unexpired, open the package and transfer the device onto a sterile field utilizing aseptic techniques.
2. Utilizing aseptic technique, attach the Platform Blades onto a reusable Activator Drive Mechanism, matching the correct left and right blades to the correct drive attachment side (Figure 1). Ensure the blades are fully engaged.
3. Ensure the Platform Blades are properly seated on the sternum.
4. Turn the drive handle counter-clockwise to begin spreading the sternum to the desired opening.
5. If using sutures, insert the sutures into the suture holder slots. Engage only one suture strand per slot to ensure proper hold. Release engaged suture by concurrently pulling back and up on the suture while pulling the suture through the suture holder slot.
6. To remove the Platform Blades from the Activator Drive Mechanism, turn the release latch on each blade in the direction of the arrow and pull each Platform Blade away from the drive mechanism.
7. When finished, discard the Platform Blades according to approved hospital procedures.

The Disposable Platform Blades attach to / detach from a reusable Activator Drive Mechanism (not included) per Figure 1.
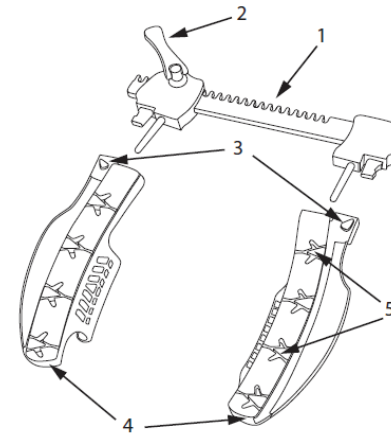

Figure 1

1. Reusable Activator Drive Mechanism (not included)
2. Drive Handle (not included)
3. Platform Blade Release Latch
4. Disposable Platform Blade (Left and Right)
5. Suture Holders

LIMITED WARRANTY AND DISCLAIMER OF LIABILITY

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