JOSEPH LAMELAS® Atrial Lift System

THE JOSEPH LAMELAS ATRIAL LIFT SYSTEM DEVICE IS A SET OF FOUR TYPES OF DISPOSABLE SURGICAL INSTRUMENT COMPONENTS PACKAGED TOGETHER AS A SYSTEM FOR USE AS A SINGLE SURGICAL INSTRUMENT FOR ATRIAL WALL TISSUE RETRACTION.

The Joseph Lamelas Atrial Lift System device is comprised of:

(A) 1 Stabilization Post,

(B) 1 Insertion Tip,

(C) 3 Support Blades
(sizes: small, medium and large)

(D) 3 Flexible Blades
(sizes: small, medium and large).

A
S-POST®

B
BULLET®

C
S-BLADE®

D
VISOR®

S-POST® DETERMINING OPTIMAL INSERTION SITE

Once atriotomy has been achieved, determine the optimal size and orientation of the S-Blade required by grasping S-Blade component at clamp platform **(Figure 1)** found on either side of S-Post engagement receptacle.

Place S-Blade within atrium (on inferior side of atrial septum) to establish optimal blade size and orientation.

Once optimal blade size and angle has been established, locate intercostal space (lateral to sternum) that correlates with optimal S-Post insertion placement site. Mark optimal S-Post placement site.

Make skin incision at desired S-Post placement site.

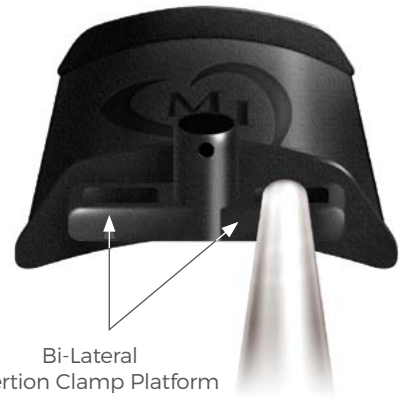


Figure 1

Caution: Careful assessment of underlying vascular anatomy (RIMA) must be taken into consideration prior to S-Post placement and insertion site decision.

S-POST® PREPARATION AND INSERTION

Engage Bullet to S-Post by depressing actuator button on S-Post handle **(Figure 2A)** to deactivate locking pin mechanism on shaft. Slide Bullet onto S-Post **(Figure 2B)**, align pin on shaft with pin hole on Bullet.

Release actuator button **(Figure 3A)** to activate locking pin **(Figure 3B)**.

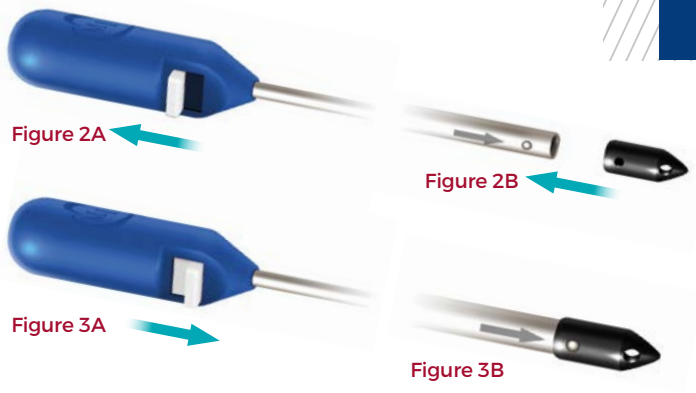
Ensure Bullet to S-Post union is secure.

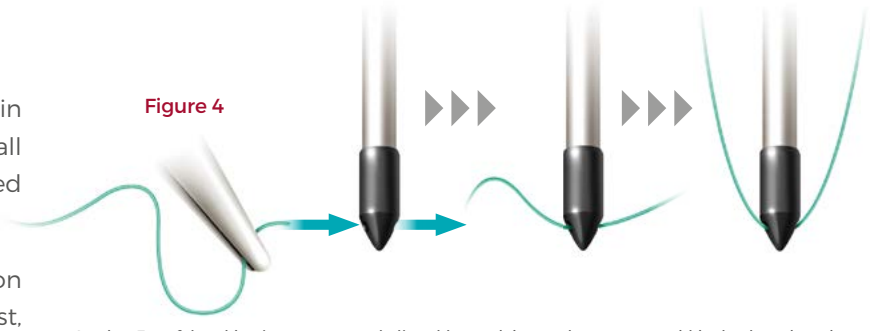
Place a suture tie through the eyelet found on the tip of the Bullet **(Figure 4)**.

Knot the suture ends together.

Place the S-Post / Bullet tip combination within the skin incision, push through the chest wall until S-Post / Bullet tip combination is visualized in thoracic cavity.

Grasp the Bullet tip, depress actuator button on S-Post handle, slide Bullet tip off of the S-Post, and extract from within thoracic cavity.





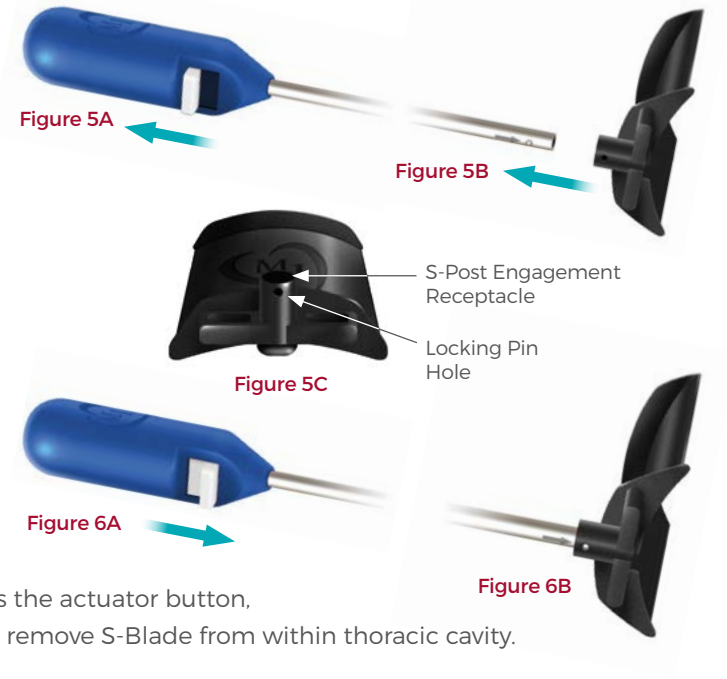
Caution: Forceful pushing (not recommended) could cause injury to the structures within the thoracic cavity. Use caution when pushing the S-Post/Bullet tip combination through the chest wall.

S-BLADE® ATTACHMENT

Place S-Blade within atrium beneath superior atrial wall. Engage S-Post to S-Blade by depressing actuator button on S-Post handle **(Figure 5A)** to deactivate locking pin mechanism, slide S-Post into S-Post engagement receptacle **(Figure 5B)**, align pin on shaft with pin hole on S-Post engagement receptacle **(Figure 5C)**.

Release actuator button **(Figure 6A)** to activate locking pin **(Figure 6B)**. Ensure the S-Blade to S-Post union is secure.

To disengage S-Post from S-Blade for repositioning or disposal purposes, ensure that the S-Blade is alleviated of all weight bearing load and the locking pin is properly aligned within locking pin hole on receptacle.



Grasp the S-Blade at the insertion clamp platform, depress the actuator button, pull the S-Blade downward to disengage from S-Post, and remove S-Blade from within thoracic cavity.

Note: If the actuator button becomes difficult to depress, ensure that the locking pin is properly aligned within locking pin hole on receptacle by slightly rotating the handle back and forth. If the actuator button continues to be difficult to depress, flush a minimum of 30 mL of saline solution through the S-Post shaft using the CO2 infusion/irrigation flush port located on the S-Post handle. Repeat the flushing technique as necessary.

S-POST® STABILIZATION AND CO_2 ATTACHMENT

Attach bed mounted clamp mechanism to S-Post shaft immediately distal to the handle. Determine placement for optimal exposure, tighten bed mounted clamp to secure position **(Figure 7)**.

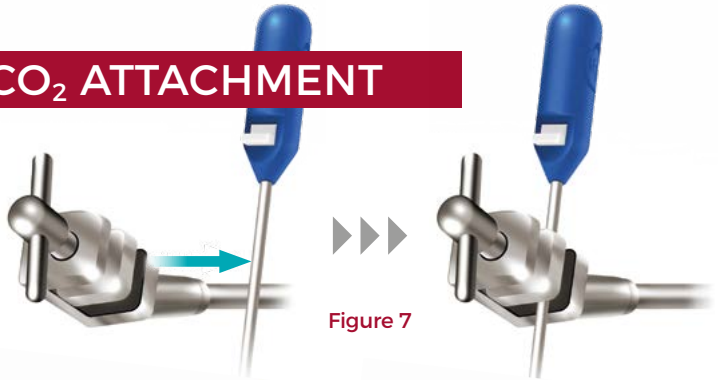


Figure 7

If CO_2 disbursement is desired, attach CO_2 line to infusion port located posterior to actuator button on handle **(Figure 8)**.

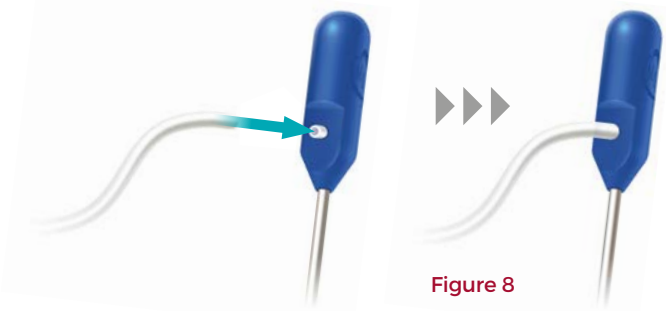


Figure 8

VISOR® PREPARATION

Hold Visor in proper orientation **(Figure 9)**.

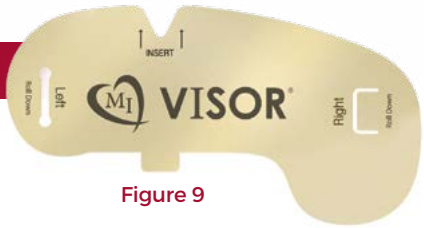


Figure 9

Note: For optimal atrial wall retraction and exposure, corresponding sized flexible intra-atrial exposure blades (Visor) are provided within the sterile package for use with the respective sized Support Blades (S-Blade).

Locate interlocking cut-outs on lateral wings of Visor **(Figure 10)**.

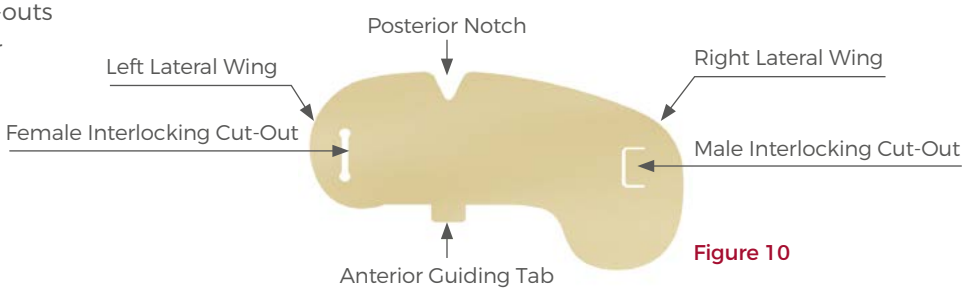


Figure 10

Roll left and right lateral wings downward so the interlocking male and female cut-outs can be engaged **(Figure 11)**.

Note: Ensure that the right wing is positioned on the inside of the left wing after rolling the device.

Figure 11

Locate anterior guiding tab and posterior notch on Visor. Hold rolled Visor such that the anterior guiding tab and posterior notch are centered superiorly. Attach insertion clamp to inferior portion of rolled Visor **(Figure 12)**.

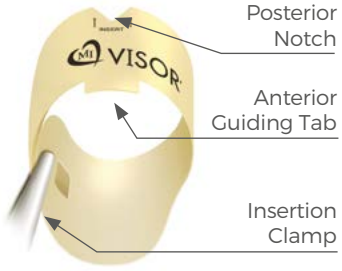


Figure 12

VISOR® ENGAGEMENT

Locate Visor support bracket and bi-lateral stability steps beneath the inferior surface of the S-Blade **(Figure 13)**.

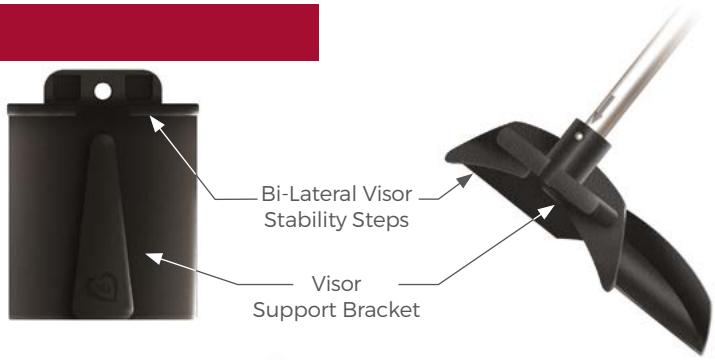


Figure 13

Guide the posterior notch of the Visor midline between the superior surface of the Visor support bracket and the inferior surface of the S-Blade **(Figure 14A)**.

Figure 14A

Figure 14B

Position the rolled Visor such that the posterior notch fully engages with the support bracket attachment structure. The anterior guiding tab should be positioned to fit between the bi-lateral stability steps **(Figure 14B)**.

Disengage clamp from rolled Visor.

VISOR® DEPLOYMENT

To unfurl Visor, locate and individually grasp distal ends of Visor wings **(Figure 15A)**. Push the male interlocking cut-out wing (right) upwards and inwards, while holding female interlocking cut-out wing (left) stationary **(Figure 15B)**.

After male interlocking cut-out becomes disengaged from female cut-out, gently allow wings to unfurl to provide further retraction beneath the lateral aspects of atriotomy **(Figure 15C)**.

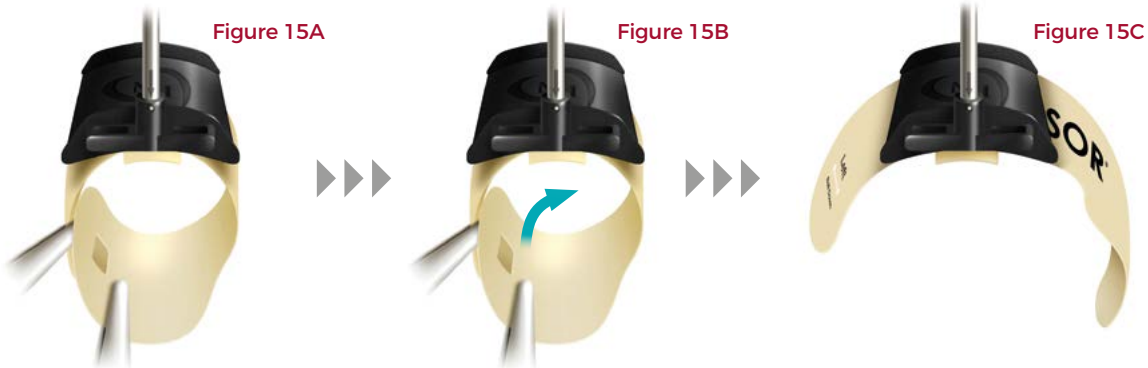


Figure 15A

Figure 15B

Figure 15C

VISOR® DISENGAGEMENT

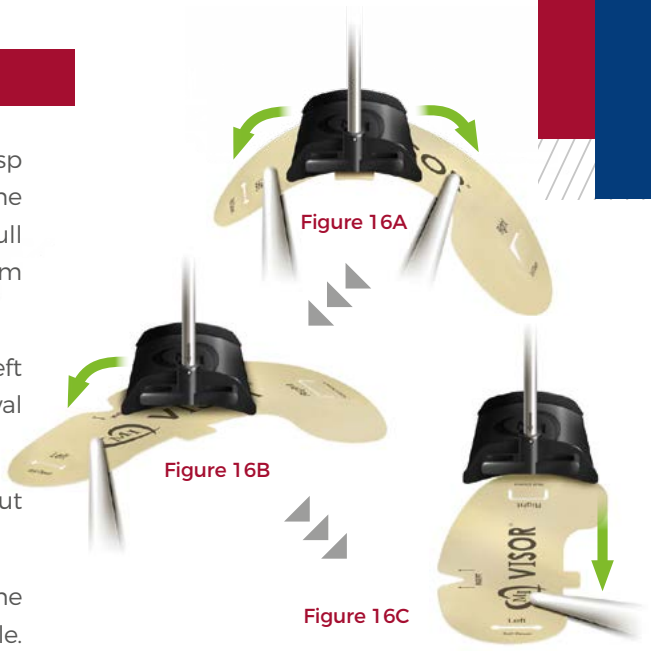
To disengage Visor from S-Blade for repositioning or disposal, grasp both left and right wings just lateral to the lateral aspects of the body of the S-Blade. Using a downward and outward motion, pull both wings until the body of the Visor has been disengaged from behind the stability steps **(Figure 16A)**.

Release the clamp from the right wing, and continue pulling the left wing in a downward and outward motion as it swivels into removal position beneath the S-Blade **(Figure 16B)**.

Remove the Visor from within thoracic cavity by pulling out longitudinally **(Figure 16C)**.

Ensure that the S-Blade is alleviated of all weight bearing load and the locking pin is properly aligned within locking pin hole on receptacle. Grasp the S-Blade at the insertion clamp platform. Depress the actuator button and pull the S-Blade downward to disengage from S-Post. Remove S-Blade from within the thoracic cavity.

Remove S-Post from within the chest wall.



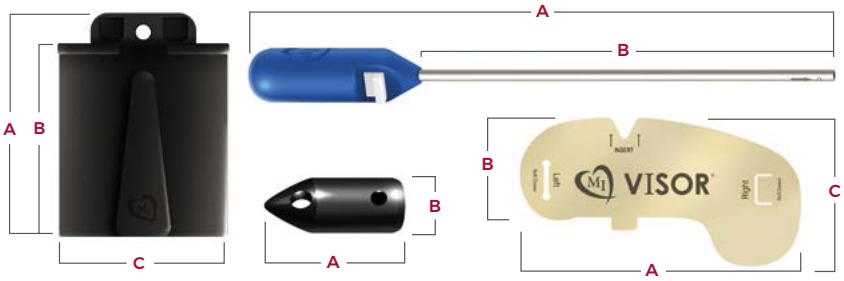
Note: If the actuator button becomes difficult to depress, ensure that the locking pin is properly aligned within locking pin hole on receptacle by slightly rotating the handle back and forth. If the actuator button continues to be difficult to depress, flush a minimum of 30 mL of saline solution through the S-Post shaft using the CO_2 infusion/irrigation flush port located on the S-Post handle. Repeat the flushing technique as necessary.

ORDERING INFORMATION

ORDER #	DESCRIPTION
MI-ALS-001	Box of 6 sterile pouches 3 Sizes JOSEPH LAMELAS ATRIAL LIFT SYSTEM per sterile pouch

DEVICE SPECIFICATIONS

DESCRIPTION	A (CM)	B (CM)	C (CM)
S-POST (Stabilization Post)	22.3	16.3	N/A
S-BLADE (Small Support Blade)	3.65	3	3.4
S-BLADE (Medium Support Blade)	4.65	4	3.4
S-BLADE (Large Support Blade)	6.65	6	3.4
VISOR (Small Flexible Blade)	8.5	3	4.4
VISOR (Medium Flexible Blade)	10.8	4	5.8
VISOR (Large Flexible Blade)	14.5	6	7.9
BULLET (Insertion Tip)	1.85	0.61	N/A



INDICATIONS: The Joseph Lamelas ATRIAL LIFT SYSTEM device is intended for use to retract the atrial wall during limited access cardiac surgical procedures.

CONTRAINDICATIONS: None known.

WARNINGS AND PRECAUTIONS: This device is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not use if package or product is damaged.
Use care to avoid tissue damage while introducing and lifting with Support Blade.
It is the responsibility of the user to dispose of the device in accordance with local regulations and hospital procedures.

For additional information please refer to the Instructions for Use provided with the product.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.