Next Generation MICS Instrumentation

PRODUCT OVERVIEW

User Reference Guide
This information is intended to provide an overview of the products and their use. Please refer to the instructions for use provided with the product for complete information.
Dr. Joseph Lamelas, an internationally recognized pioneer of minimally invasive cardiac surgery (MICS), has dedicated the past 14 years to developing new and innovative concepts for the advancement of the MICS field.

Leveraging a background of over 17,000 cardiac surgeries - 7,000 of which using a MICS approach - Dr. Lamelas developed the Miami Method technique along with the Miami Instruments facilitating and exposure product lines, designed to enhance patient safety, procedural efficacy and surgeon reproducibility in MICS.

His techniques have proved instrumental for repairing simple congenital cardiac defects, removal of cardiac tumors, aortic valve surgery, mitral valve surgery, double and triple valve surgery, as well as replacing the ascending aorta and aortic root, without splitting the sternum.
MIAMI METHOD EXPOSURE PRODUCTS

Designed to maximize efficiency, access and exposure.

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CUFF™ AORTIC ROOT EXPOSURE DEVICE ----------------------- 15

MIAMI METHOD FACILITATING PRODUCTS

Designed to enhance comfort, control, ease of use, access, and efficiency.

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JOSEPH LAMELAS INTERCOSTAL RETRACTOR SYSTEM™

The Joseph Lamelas Intercostal Retractor System product is a reusable thoracotomy retractor system. The individual accessory components include a retractor rack, 4 different sized paired blade set options, 2 different sized double swivel blade options and a custom sterilization tray.

The parallel retractor arms are double-hinged and are permanently fixed to the rack housing (Figure 1).

Each paired blade set (Figure 2) consists of 1 Solid and 1 Cut-out blade body configuration. The 2 different sized double-swivel blades (Figure 3) consist of 1 individual size option per package.

Incorporated within the distal segment of the retractor arms (Figure 4) are engagement sockets for attaching: (A) retractor blade mount pins, and (B) accessory mount pins (such as the Suture Belt™ device).

The sterilization tray (Figure 5) is comprised of a lid and a base component. The sterilization tray base has been preconfigured with receiving slots for the rack and blade components.
RETRACTOR ARM HINGE ADJUSTMENT

The arm segment hinge screws are preset in the most pliable setting. Arm segment joint pliability can be adjusted to a more rigid setting by tightening the hinge screws to the desired rigidity as determined by the user. Use the 2mm Hex Key to rotate the hinge screws to adjust the desired joint pliability setting (Figure 6).

To tighten:
Rotate the hinge screw clockwise for more rigid joint setting.

To loosen:
Rotate the hinge screw counterclockwise for more pliable joint setting.

Make hinge adjustments prior to cleaning and sterilization. The 2mm Hex Key is not intended for use on the sterile field. Do not store the 2mm Hex Key in sterilization tray. Do not sterilize the 2mm Hex Key.

BLADE ATTACHMENT AND DETACHMENT

Blade Attachment
Attach the blades to the retractor rack by sliding the blade mount pin into the retractor rack arm (Figure 7).

Blade Detachment
Remove the blades from the retractor rack by sliding the blade mount pin out of the retractor rack arm (Figure 8).
GENERAL THORACOTOMY RETRACTION

Insert the appropriately sized retractor blades, one at a time, into the thoracotomy and engage the ribs (Figure 9).

With the blades touching each other and the retractor arms in the completely closed position, attach the retractor rack to the blades (Figure 10).

Turn the retractor knob clockwise to open the retractor and spread the thoracotomy (Figure 11).

Upon completion of procedure, depress the release lever to close the retractor (Figure 12).

Remove the retractor blades from within the thoracotomy.
INDICATIONS: The Joseph Lamelas INTERCOSTAL RETRACTOR SYSTEM product is intended to provide surgical access for minimally invasive cardiothoracic procedures by retraction of soft and bony tissue.

CONTRAINDICATIONS: This device is not intended to be used in sternotomy applications.

WARNINGS AND PRECAUTIONS: Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of any procedure based on their own medical training and experience, and the type of surgical procedure. Refer to the product Instructions for Use manual (IFU) for cleaning, sterilization and maintenance information.

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

NOTE: This device is not intended to be used in either full or mini sternotomy applications. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.
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).

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.

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 CO₂ 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).

If CO₂ disbursement is desired, attach CO₂ line to infusion port located posterior to actuator button on handle (Figure 8).

**VISOR PREPARATION**

Hold Visor in proper orientation (Figure 9).

Locate interlocking cut-outs on lateral wings of Visor (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.

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).
VISOR ENGAGEMENT

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

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).
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.

### Ordering Information

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<td>MI-ALS-001</td>
<td>Box of 6 sterile pouches 3 Sizes JOSEPH LAMELAS ATRIAL LIFT SYSTEM per sterile pouch</td>
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### Device Specifications

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<td>BULLET (Insertion Tip)</td>
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<td>0.61</td>
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**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.
COLLAR™ PAPILLARY MUSCLE EXPOSURE DEVICE

The Collar device is a flexible surgical retractor designed to retract valve leaflet tissue when inserted within the valve annulus.

The device consists of a main body component (Figure 1A) which extends laterally to become the retraction wings. The distal tips of the retraction wings (Figure 1B) are bifurcated for additional tissue traction. The posterior aspect of the device has circumferential traction raisings, a stiffening rib (Figure 1C) along the superior border and a stabilization flange (Figure 1D) along the inferior border.

The Collar device is available in 2 sizes (small and large) which are packaged together in a disposable set.

PREPARATION FOR INSERTION

Roll the lateral wings of the appropriately sized Collar device inwards in compliance with the pre-formed curvature (Figure 2).

Grasp the overlapping wings with an insertion clamp so that the device may be inserted into the annulus in compliance with the marking arrows for insertion direction (Figure 3).

INSERTION AND DEPLOYMENT

Insert the rolled device within the valve leaflets (Figure 4).

Release the device from the insertion clamp and allow the lateral wings to unfurl within the annulus to provide leaflet retraction (Figure 5).
REPOSITIONING

To reposition the device for optimal retraction orientation, grasp the distal wing tips and pull them toward one another until they overlap. Rotate the Collar device to the desired position within the annulus (Figure 6).

![Figure 6]

REMOVAL

To remove the Collar device, grasp the distal end of one of the wing tips and pull the tip through the center towards the opposing side in an overlapping manner (Figure 7A). Remove the Collar device from within the annulus by pulling the entire device outward (Figure 7B).

![Figure 7A](image1)
![Figure 7B](image2)

Ordering Information

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<td>MI-COTIE-001</td>
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Device Specifications

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<td>COLLAR PAPILLARY MUSCLE EXPOSURE DEVICE (Large)</td>
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INDICATIONS: The COLLAR device is intended for use to retract valve leaflet tissue during specific 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. 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.
MIAMI METHOD EXPOSURE PRODUCTS™

CUFTM AORTIC ROOT EXPOSURE DEVICE

The Cuff device is a flexible surgical retractor designed for exposure and access purposes when inserted into the aortic root and used to retract aortic wall tissue.

The device consists of a main body component (Figure 1A) with retraction wings which are two-tiered and extend laterally (Figure 1B). The posterior aspect of the device has a stabilization flange (Figure 1C) along the inferior border. Two alignment suture eyelet holes (Figure 1D) can be found within the medial portion of the stabilization flange.

The Cuff device is available in 3 different sizes that are packaged together as a disposable set.

The following table provides general guidance on sizing parameters.

<table>
<thead>
<tr>
<th>Aortic Annular Dimension</th>
<th>Corresponding Size</th>
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<tr>
<td>&lt; 19mm – 23mm</td>
<td>Small</td>
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<tr>
<td>23mm – 25mm</td>
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<tr>
<td>25mm – 29mm &gt;</td>
<td>Large</td>
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</table>

Note: The sizing decision should be determined and confirmed by visual inspection.

SITE PREPARATION

Prior to device insertion, placement of retraction sutures at the apex of the commissures is recommended (Figure 2).

PREPARATION FOR INSERTION

After excising the valve leaflets and thoroughly debriding the annulus, roll the lateral wings of the appropriately sized Cuff device inwards in compliance with the pre-formed curvature (Figure 3).

Grasp the overlapping wings with an insertion clamp so that the device may be inserted into the aortic root in compliance the marking arrows for insertion direction (Figure 4).
**Positioning and Insertion**

Position the device so that the suture eyelet holes on the stabilization flange are in alignment with the left–non commissure. Thread the left non commissural suture upward through the alignment eyelet holes (Figure 5A) to guide the device during insertion. Insert the rolled device within the aortic root (Figure 5B).

**Seating and Securing**

Release the device from the insertion clamp and allow the lateral wings to unfurl within the aortic root to provide circumferential aortic wall retraction (Figure 6).

Place a rubber catheter or tube (to be used as a Rummel-style tourniquet) over the alignment suture (Figure 7A). Cinch the tube down and clamp the proximal end (Figure 7B) to retain the device in optimal orientation within the aortic root.

**Preparing for Removal**

After all of the annular sutures have been placed, and prior to prosthesis seating, removal of the CUFF device is recommended. To prepare for removal of the Cuff device, unclamp then remove the tourniquet catheter/tube. Grasp at least 2 suture pairs covering the distal end of 1 of the wing tips, pull the sutures away from the tip to create an opening for removing the device from behind the sutures (Figure 8A).

Bend the corresponding wing tip down (Figure 8B). Place the sutures behind the tip (Figure 8C). Repeat the step with the other wing tip.

*Note: Ensure that the inferior border of the Cuff device is positioned so that it lies on the plane above the apex of the commissures.*
INDICATIONS: The CUFF device is intended for use to retract aortic wall tissue during specific 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.

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.

REMOVAL FROM AORTIC ROOT

To remove the device from within the aortic root, grasp both of the lateral wing tips (Figure 9A) and bring the tips towards the opposing sides in an overlapping manner (Figure 9B). Pull the entire device upward and out of the aortic root (Figure 9C).

REMOVAL FROM THE FIELD

To remove the device from behind the annular sutures, unclamp 1 of the wing tips to allow the device to unfurl (Figure 10A), pass the device through the opening between suture pairs (Figure 10B) and rotate the device into the center of the suture cluster (Figure 10C). Slide the device up and off the commissural suture while removing it from within the thoracic cavity. Prior to prosthesis seating, remove the commissural suture from within the center of the suture cluster and reposition as necessary.

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<td>MI-CUFF-001</td>
<td>Box of 6 pouches 3 Sizes CUFF AORTIC ROOT EXPOSURE DEVICE per pouch</td>
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Device Specifications

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<th>Description</th>
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<th>C (cm)</th>
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<td>CUFF (Large)</td>
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INDICATIONS: The CUFF device is intended for use to retract aortic wall tissue during specific 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.

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.

CUFF™ AORTIC ROOT EXPOSURE DEVICE
The Suture Belt device is a circumferential surgical suture organizer that mounts to a retractor rack prior to use.

The Suture Belt device (Figure 1) is a disposable product and is available in 1 model: MI-ISBA-001.

The device incorporates a rigid base frame with 24 flexible holding plug inserts (Figure 1A) that receive and retain suture pairs. Suture retention is achieved by pressing the suture strands into the compression slots (Figure 1B) found between the rigid base frame and flexible holding plug inserts. The rigid base frame consists of 2 hinged halves (Figure 1C) which allow for angle adjustment of the individual segments. The attachment arms (Figure 1D) allow the device to be mounted to the retractor arms. The device is secured into the desired orientation and segment angle positioning by tightening the immobilizing thumb screws (Figure 1E). Two spacer components (Figure 1F) allow the attachment arm height to be adjusted.

**DEVICE ATTACHMENT**

Attach the Suture Belt device to the retractor rack by sliding the attachment arm mount pins into the retractor arm mount pin sockets (Figure 2).
If the Suture Belt device does not sit on the desired plane, due to the distal segments of the retractor arms being on uneven planes, use the spacer components to adjust the height of the attachment arms (Figures 3A and 3B).

Note: Placement of a retrieval suture through the spacer eyelet is recommended (Figure 3C).
DEVICE ATTACHMENT

Position the Suture Belt device in the desired orientation above the retractor. Adjust the angle of the individual segmented halves to their respective desired planes (Figure 4A).

Tighten the thumb screws to immobilize the individual segments and the entire device in their respective desired positions (Figure 4B).

SUTURE MANAGEMENT

After a suture has been placed in the target site, bring both ends of the suture to the corresponding flexible holding plug insert (Figure 5A). Separate the ends and place the desired retraction tension on the suture (Figure 5B). Secure 1 strand per compression slot (Figure 5C).

Insert and remove surgical sutures from within the compression slots as needed.

When the device is no longer needed, remove the Suture Belt from the retractor rack by disengaging the attachment arm mount pins (or spacer component mount pins) from within the retractor arm mount pin sockets.

Dispose of used product in accordance with established hospital protocols for biohazard.

Ordering Information

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Device Specifications

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<td>SUTURE BELT (Spacer Component)</td>
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PREPARING THE SUTURE LOOP

Prior to use, visually inspect the product to verify that it has not been damaged. If the package or product is damaged, DO NOT USE.

Pull the suture loop tab to enlarge the suture loop to the desired size (Figure 2A).

Clamp the proximal end of the tube with a small hemostat to immobilize and retain the enlarged suture loop (Figure 2B).

Remove and discard the suture loop tab prior to use (Figure 2C).
DELIVERING THE SUTURE LOOP

Once the desired knot location has been established, pass the 2 arms of the target suture through the suture loop (Figure 3).

ENGAGING THE SUTURE LOOP

While controlling the target suture with 1 hand, hold the device tip in place (using a forceps with the other hand) at the desired knot location.

Have an assistant unclamp the tube (or wire), then cinch the suture loop around the target suture by pulling back on the tension handle while pushing forward on the tubing (Figure 5).

Re-clamp the proximal end of the tube to retain tension on the tightened suture loop to immobilize the tip at the desired location on the target suture (Figure 6).

Note: The hemostat can alternatively be clamped directly onto the suture loop wire and placed immediately adjacent to the proximal end of the tube.

Place the device tip at the desired knot location on the target suture (Figure 4).
**DELIVERING THE KNOT**

Deliver the first knot throw to the level of the device tip (Figure 7A).

Deliver subsequent throws on top of the previous throws. Make the desired number of throws to complete the knot (Figure 7B).

Note: Standard surgical square knots (alternating throws) is recommended. Do not use excessive downward force when seating the square knots, as excessive downward force may cause the device to shift from optimal target knot location.

**REMOVING THE SUTURE LOOP**

To remove the Tie device for repositioning or disposal, remove the hemostat from the tube (or wire). (Figure 8A).

Pull the tube back to release suture loop tension from around the target suture (Figure 8B).

Reposition the tip of the suture loop from beneath the knot mass (Figure 8C). Reclamp the proximal end of the tube to retain the re-expanded suture loop size. Slide the suture loop over the knot mass and off of the target suture (Figure 8D).

Dispose of used product in accordance with established hospital protocols for biohazards.
INDICATIONS: The TIE device is intended for use to assist in accurate suture knot placement during specific 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.

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.

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**Device Specifications**

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MIAMI METHOD FACILITATING PRODUCTS™

JOSEPH LAMELAS KNOT PUSHER™

The Joseph Lamelas Knot Pusher is a disposable surgical instrument used to advance throws of extracorporeal knots to an intracorporeal surface or object within a small cavity during limited access cardiothoracic procedures.

The Joseph Lamelas Knot Pusher device (Figure 1) is a disposable product and is available in 1 model: MI-KP-001.

Note: Handle the Knot Pusher with care to avoid excessive impact, which could result in damage to the tip.

ENGAGING THE SUTURE

Depress actuator button (Figure 2A) on handle to open suture guide eyelet gate (Figure 2B) for suture engagement.

SECURING THE SUTURE

Release actuator button (Figure 4A) to close suture guide eyelet gate (Figure 4B) and entrap suture within suture guide eyelet (engaged arm).
THROWING THE KNOT

Hand the end of the engaged arm (Figures 5A and 6A) of the suture (stationary arm) to an assistant.

Hold the Knot Pusher in one hand and the free arm (Figures 5B and 6B) of the suture in the other while an assistant maintains relaxed tension on the stationary arm.

Make surgical knot throws according to surgeon discretion.

DELIVERING THE KNOT

Apply relaxed tension to both arms of the suture while advancing the Knot Pusher tip (Figure 7) such that the eyelet is 3 to 5 mm lateral and ahead of the knot vortex (Figure 8), thus, using the suture guide eyelet to pull the knot down toward the seating position.

Note: Saline can be used to lubricate the suture and Knot Pusher tip if needed. Avoid pulling the suture throws down with the eyelet gate.
While applying gentle tension on both ends of the suture arms, pull the throw down to the approximation site (Figure 9). Apply firm lateral tension across the knot vortex with the Knot Pusher suture guide tip until the throw is fully seated (Figure 10).

Note: Excessive tension on the suture may cause the suture to tear through the tissue, escape from the suture guide eyelet, or cause the suture to fracture or break. Avoid seating the suture throws with the eyelet gate.

Retract the Knot Pusher from the cavity while maintaining gentle tension on both arms of the suture. Repeat the previous steps for the desired number of knots. When desired number of knots has been achieved, depress the actuator button on the Knot Pusher handle to open the suture guide eyelet gate and disengage the suture.

**Ordering Information**

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<tr>
<th>Order #</th>
<th>Description</th>
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<tbody>
<tr>
<td>MI-KP-001</td>
<td>Box of 6 pouches Next line: 1 JOSEPH LAMELAS KNOT PUSHER per sterile pouch</td>
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**Device Specifications**

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<th>Description</th>
<th>A (cm)</th>
<th>B (cm)</th>
<th>C (cm)</th>
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<tr>
<td>JOSEPH LAMELAS KNOT PUSHER</td>
<td>38</td>
<td>20</td>
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**INDICATIONS:** The Joseph Lamelas KNOT PUSHER is intended for use to advance throws of extracorporeal knots to an intracorporeal surface or object within a small cavity during limited access cardiothoracic 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. 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.