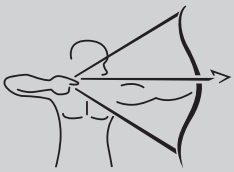
Micro
Interventional
Devices, Inc.™



Micro Interventional Devices, Inc.

MIA™-T

Percutaneous Tricuspid Annuloplasty System

Instructions for Use

REF **MIA-T**

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1.0 HOW SUPPLIED

1.1. CONTENTS: The MIA- T™ Percutaneous Tricuspid Annuloplasty System (MIA-T) consists of (1) one MIA Steerable Guiding Sheath, (1) one MIA Primary Anchor Delivery Catheter, (6) six MIA Secondary Anchor Delivery Catheters, (1) one MIA Suture Lock Catheter and (1) one MIA Suture Cutting Catheter.

2.0 OVERVIEW

MIA-T is used to place a permanent cardiac suture implant into the heart of patients who suffer from severe, symptomatic tricuspid regurgitation (TR), for the purpose of plicating tricuspid valve tissue and reconfiguring abnormal valve geometry that is causing dysfunction. The implanted system is composed of tissue anchors connected by suture and a suture lock. The anchors, when properly deployed, act through the exclusion of a discrete portion of the posterior circumference (annulus) of the tricuspid valve (replicating the surgical bicuspidization technique), and therefore, producing a decrease in the size of the valve orifice. Micro Interventional Devices (MID) has developed the MIA-T procedure that allows the physician to implant the components of MIA-T using a closed chest, beating heart, transcatheter technique via the jugular vein. MIA-T is designed for use only by qualified medical professionals, under sterile conditions, with appropriate anesthesia and monitoring, in a catheterization laboratory or hybrid room or equivalent facility, for the treatment of certain cases of TR with specific architectural, anatomic, and clinical abnormalities.

The MIA T:

- Does not require cardiopulmonary bypass;
- May result in reduction of the tricuspid valve regurgitation, primarily as a result of a decrease in tricuspid valve area and circumference, which may result in improved symptoms, functional capacity and quality of life;
- Is a less invasive treatment than surgical repair or replacement and eliminates substantial risk from open-chest surgery with cardiopulmonary bypass

3.0 SYSTEM DESCRIPTION

MIA-T is a single-patient use, disposable system composed of a series of delivery catheters that deploy proprietary PolyCor™ anchors into the cardiac tissue and ultimately effect a plication of the native valve annulus once a suture lock is deployed to maintain tissue apposition. The PolyCor anchors are polypropylene and developed specifically for soft-tissue. Polycor anchors will be referred to as “anchor(s)” in this IFU. The MIA-T implant consists of a series of anchors connected by the polypropylene surgical suture made to the U.S.P standard. After being deployed into tissue, the anchors are approximated by applying tension to the suture. The anchors are secured after the desired anchor and tissue approximation has been completed with the Suture Lock (Figure 3).

MIA-T is composed of a Primary Anchor Delivery Catheter (Figure 1) that deploys a Primary Anchor (Figure 2), and multiple Secondary Anchor Delivery Catheters (Figure 1) that each deploy a Secondary Anchor (Figure 2). These anchors are connected by a 2-0 (3 metric), 250cm long, blue, non-absorbable polypropylene monofilament surgical suture made to the U.S.P. standard to create the MIA Implant (Figure 3). Both Primary and Secondary Anchors have radiopaque elements that are visible on fluoroscopy and also contain polypropylene spunbond mesh. The Primary and Secondary Anchor Delivery Catheters are used in conjunction with the Steerable Guiding Sheath in order to reach target anchor deployment site locations. The Suture Lock Catheter (Figure 4) is applied to approximate the deployed anchors and plicate annular tissue to reduce annular dimensions and reduce or eliminate valve regurgitation. Once the Suture Lock (Figure 3) has been deployed, the Suture Cutting Catheter (Figure 5) is used to disengage the MIA-T Implant from the excess suture.

The Primary and Secondary Anchor Delivery Catheters are comprised of a bidirectional, steerable catheter, a rigid Anchor Housing located at the distal end of the catheter that holds a single anchor, stabilization pins (Figure 6), and a handle that connects to the proximal end of the catheter (Figure 7). The handle contains the blue deflection collar, the white stabilization pin knob, the safety and the deployment button (Figure 7 and Figure 8). The blue deflection collar controls the deflection of the catheter from -90 degrees to +90 degrees. The white stabilization pin knob actuates the stabilization pins that are utilized to maintain apposition and proper orientation to the annular tissue during anchor deployment (Figure 6). The safety prevents accidental deployment of the anchor and must be disengaged by sliding the safety proximally prior to actuation of the deployment button (Figure 8). After disengaging the safety, the deployment button is actuated by pressing down to deploy the anchor into the tissue (Figure 8).

The Primary Anchor Delivery Catheter is loaded with the Primary Anchor attached to the surgical suture manufactured to the U.S.P standard (Figure 2). The Secondary Anchor Delivery Catheters are loaded with Secondary Anchors with eyelets (Figures 2 and 3). After Primary Anchor deployment, the suture attached to the Primary Anchor is threaded through the eyelet of each Secondary Anchor and is pulled through a lumen of each Secondary Anchor Delivery Catheter by pulling on the snare (Figure 9) using the snare grip (Figure 8) prior to insertion of the Secondary Anchor Delivery Catheter through the Steerable Guiding Sheath.

Each Secondary Anchor is deployed at a 10mm distance from the previously deployed anchor using the Secondary Anchor Delivery Catheters (Figure 1). However, the first two anchors in the implant pattern and the final two anchors in the implant pattern are deployed at a distance of 5mm apart. Once the final anchor has been deployed, the Suture Lock Catheter (Figure 4) is used to apply tension to the suture, approximate the anchors, and deploy the MIA Suture Lock to secure the plication (Figure 3). A MIA Suture Cutting Catheter (Figure 5) is then used to cut the excess suture from the implant.

A catheterization laboratory table-mounted Stabilization Unit is available as an accessory.

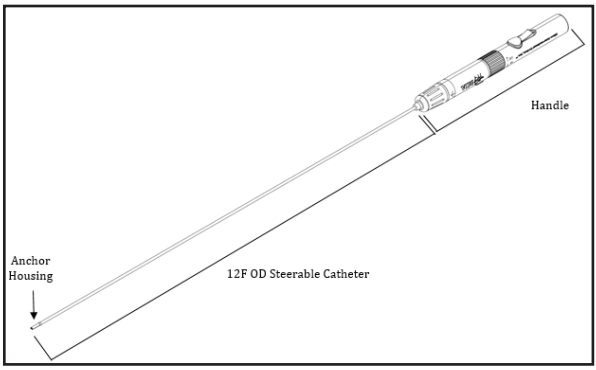


Figure 1. Primary and Secondary Anchor Delivery Catheters

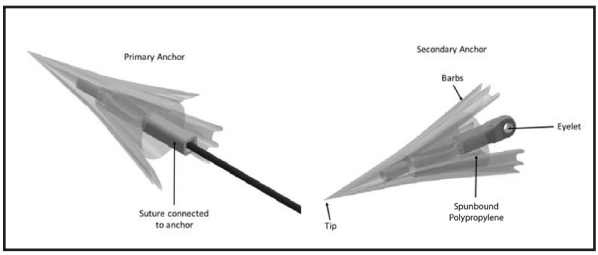


Figure 2. Primary Anchor (left) and Secondary Anchor (Right)

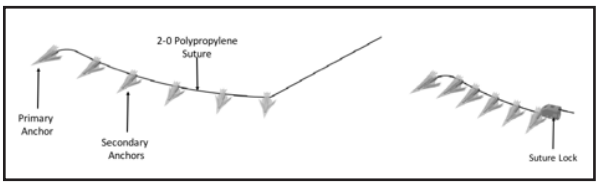


Figure 3. Anchors and Suture Pre-Tensioning (Left) and Post-Tensioning and Suture Lock Application (Right)

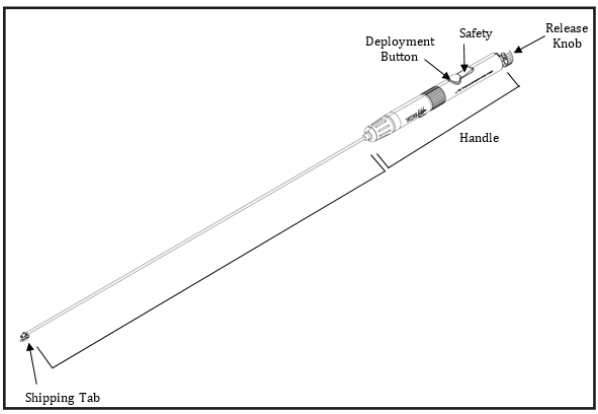


Figure 4. Suture Lock Catheter

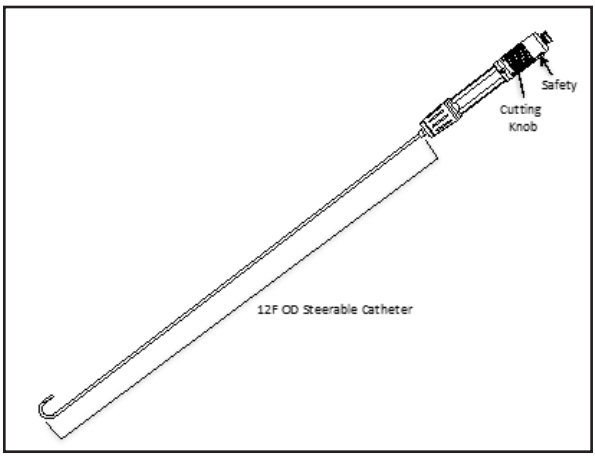


Figure 5. Suture Cutting Catheter

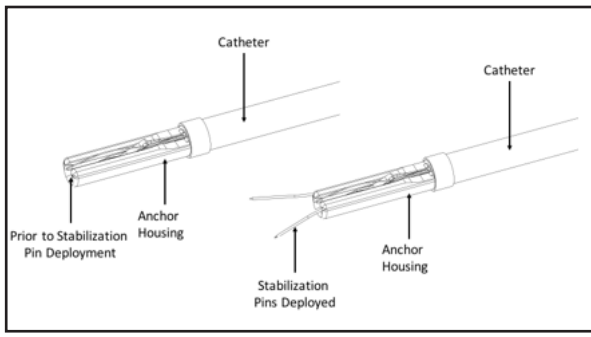


Figure 6. Stabilization Pins Pre-Deployment (Left) and Deployed (Right)

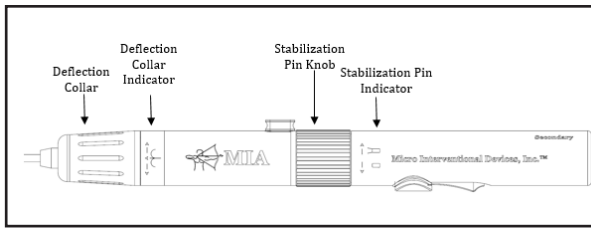


Figure 7. Delivery System Handle

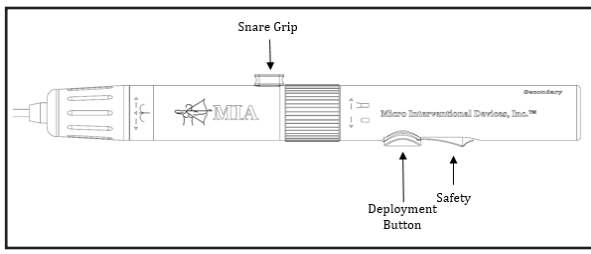


Figure 8. Deployment Button, Safety and Snare Grip

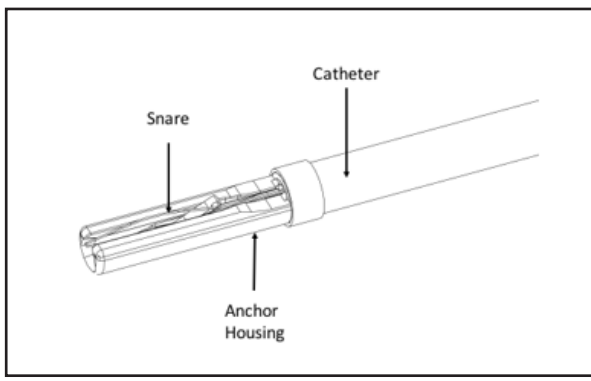


Figure 9. Anchor Housing and Snare

4.0 INDICATIONS FOR USE

The MIA-T Percutaneous Tricuspid Annuloplasty System is intended to reduce the symptoms associated with functional tricuspid regurgitation through annular tissue plication.

MIA-T is indicated for use in symptomatic, high-risk surgical patients suffering from moderate to severe tricuspid valve insufficiency and who are deemed to be candidates for tricuspid valve repair with the MIA-T System by the local Heart Team.

MIA-T is designed for use only by qualified interventional cardiologists familiar with and trained in transcatheter structural heart repair techniques, under sterile conditions, with appropriate anesthesia and monitoring, in a cardiac catheterization laboratory or hybrid room, for the treatment of moderate- to severe functional tricuspid regurgitation.

5.0 CONTRAINDICATIONS

MIA-T is contraindicated in patients with:

- Previous tricuspid valve repair or replacement.
- Trans-tricuspid pacemaker or defibrillator leads which impinge on the tricuspid valve leaflet as evaluated by echocardiography.
- Large pericardial effusion.
- Hemodynamic instability: systolic blood pressure <90mmHg without reduction of afterload, shock, need for inotropic medication or IABP.
- Tricuspid endocarditis.
- Organic tricuspid disease.
- Need for left-sided or pulmonary valve correction.
- Contraindication or known allergy to device's materials (platinum, stainless steel, polypropylene, Polyether ether ketone, aspirin, anti- coagulation therapy or contrast media that cannot be adequately premedicated
- Significant annular calcification.

6.0 WARNINGS

DO NOT use a MIA catheter if the expiration date has elapsed, as either sterility or performance may be compromised.

DO NOT use a MIA catheter if the sterile barrier of the packaging has previously been broken, damaged or if the contents of the package appear to be damaged or defective. There are no data to support the sterility of the catheter if the package is damaged.

DO NOT handle the Primary Anchor Delivery Catheter, Secondary Anchor Delivery Catheters, Suture Lock Catheter or the Suture Cutting Catheter without ensuring the safeties on the handles are in the ON position.

DO NOT release the safety feature to the OFF position by sliding the safety proximally or attempt to press the deployment button until the catheters are in the desired position for deployment.

DO NOT look into the distal end of the Primary Anchor Delivery Catheter, Secondary Anchor Delivery Catheters, Suture Lock Catheter or the Suture Cutting Catheter or point the catheters at another individual.

DO NOT deploy a PolyCor Anchor without maintaining proper alignment and exerting sufficient steady pressure against the tissue during deployment.

DO NOT re-sterilize or re-use a MIA catheter or the MIA implant as each catheter component is intended for single-patient-use. There are no data to support the sterility, nonpyrogenicity, and functionality of the catheters after reprocessing.

DO NOT deploy an anchor in a location where damage to the AV Node, Right Coronary Artery, Coronary Sinus, Bundle of His, Aorta, Aortic Valve, Circumflex Artery or other important anatomic structure may result.

DO NOT deploy an anchor in a location where the tissue is less than 16 mm thick.

DO NOT attempt to deploy an anchor at a location where another anchor has been previously deployed.

DO NOT apply significant tension to the suture after anchor deployment to prevent the deployed anchor from being pulled out of the tissue.

DO NOT use MIA-T in patients with trans-tricuspid pacemaker or defibrillator leads that impinge on the tricuspid valve leaflet as evaluated by echocardiography.

DO NOT deploy a delivery catheter with less than 60 degree angulation to the annular plane in order to avoid penetration of the atrial wall.

Patients with the following conditions may have an increased risk of having a serious adverse event or a poor outcome. This may be avoided with preoperative evaluation and proper device usage:

- Known or suspected unstable angina or recent myocardial infarction
- Active infection due to risk of sepsis or other post-procedural infection
- Recent cerebrovascular accident due to risk of recurrent stroke
- Severe right heart dilatation or dysfunction
- Severe pulmonary hypertension

7.0 POTENTIAL RISKS

Potential risks and foreseeable adverse events associated with the MIA Percutaneous Tricuspid Annuloplasty System and the procedure to implant the MIA-T device include (but are not limited to) the following:

Adverse tissue response	Nausea and vomiting
Allergic skin reaction	Nerve or organ damage
Annular tear	Pericardial effusion
Bleeding	Pleural Effusion
Cardiac tamponade	Pneumonia
Damage to coronary arteries	Pulmonary embolism
Device detachment	Post-op delirium
Device malfunction or failure	Reaction to anesthetics or medications

Failure of proper device deployment	Renal insufficiency
Failure of tissue plication with device	Rupture or puncture of the heart wall
Fever	Stroke
Heart failure, worsening heart failure	Temporary or permanent damage to the heart's electrical conduction system, potentially requiring a pacemaker
Hematoma	Thrombosis and thromboembolism
Hemolysis	Valve stenosis
Hydrothorax	Vessel spasm
Infection including endocarditis	Worsening coronary artery stenosis
Irregular heart rhythms, arrhythmia	Worsening valve regurgitation
Myocardial infarction	

8.0 PRECAUTIONS

Prior to use, inspect each MIA-T component to ensure that sterile packaging has not been damaged or compromised during shipment.

MIA-T components are packaged and shipped in the ready-to-deploy condition. Inappropriate use can lead to serious injury.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

9.0 DIMENSIONS

Product Code	Component	Dimension
MIA-T	MIA-Tricuspid System	
MIA1356SG	MIA Steerable Guiding Sheath	13.8F ID, 17F OD, 56cm usable length
MIA1277P	MIA Primary Anchor Delivery Catheter	12F OD, 77cm usable length
MIA1277S	MIA Secondary Anchor Delivery Catheter	12F OD, 77cm usable length
MIA1277SL	MIA Suture Lock Catheter	13.5F OD, 77cm usable length
MIA1277SC	MIA Suture Cutting Catheter	12F OD, 77cm usable length

10.0 THE MIA-T CLINICAL PROCEDURE

The following instructions provide directions for the use of MIA-T as part of a transcatheter tricuspid bicuspidization procedure via a transjugular approach plicating the posterior annulus. These instructions augment but do not replace conventional interventional and medical protocols for interventional access, imaging, patient management and transcatheter tricuspid annuloplasty procedures, nor do they eliminate the need for formal training in the execution of interventional procedures in which MIA-T is used.

The following procedural steps are listed numerically for ease of reference and as a guide to the general procedural progression.

10.1 MIA-T Components

1. The 12F Primary Anchor Delivery Catheter, Secondary Anchor Delivery Catheters, Suture Lock Catheter, and Suture Cutting Catheter are designed for use in conjunction with the 13.8F Steerable Guiding Sheath

   Note: See Steerable Guiding Sheath Instructions for Use for more information.

2. The 12F Primary Anchor Delivery Catheter and Secondary Anchor Delivery Catheters are 77cm in usable length.

   NOTE: The 13.8F Steerable Guiding Sheath is 56cm in usable length, allowing the MIA Primary and Secondary Delivery Catheters to extend approximately 6 cm out from the distal end of the Steerable Guiding Sheath when fully inserted.

3. The Primary Anchor Delivery Catheter deploys one Primary Anchor (Figure 2). The distal end of the catheter has a 22mm rigid section that will not bend.
4. Each Secondary Anchor Delivery Catheter deploys one Secondary Anchor (Figure 2). The distal end of the catheter has a 22mm rigid section that will not bend.
5. The Suture Lock Catheter deploys a 5mm long Suture Lock to approximate the anchors and plicate the tissue after deployment of the anchors around the posterior tricuspid annulus.
6. The 12F Suture Cutting Catheter is used to cut the suture free from the implant after deployment of the MIA Suture Lock.

10.2 ACCESS CONSIDERATIONS

1. Obtain access to the jugular vein using conventional techniques.
2. Insert the Steerable Guiding Sheath with dilator per the Steerable Guiding Sheath Instructions for Use. Position the Steerable Guiding Sheath in the right atrium.

   NOTE: There is an optional step to insert and lock the handle of the Steerable Guiding Sheath into the accessory Stabilization Unit. Consult the MIA Stabilization Unit Instructions for Use if using this accessory.

   NOTE: It is recommended to place a steerable coronary guidewire into the right coronary artery to provide a fluoroscopic and echocardiographic reference prior to Primary Anchor Delivery Catheter positioning and deployment.

10.3 PREPARATION

1. Using fluoroscopy, insert the Primary Anchor Delivery Catheter that is already loaded with the primary anchor through the Steerable Guiding Sheath until the anchor housing located at the distal end of the Primary Anchor Delivery Catheter is observed to extend beyond the distal tip of the Steerable Guiding Sheath.

   NOTE: During insertion, ensure that the Deployment Button on the Primary Anchor Delivery Catheter (Figure 8) is positioned opposite the flush port of the Steerable Guiding Sheath when the Steerable Guiding Sheath is directed to the intended deployment site of the anchor.

   NOTE: There is an optional step to rest the handle of the Primary Delivery Catheter handle on the proximal clamp of the accessory Stabilization Unit. Consult MIA Stabilization Unit Instructions for Use if using this accessory.

2. Advance, deflect, and manipulate the bidirectional Primary Anchor Delivery Catheter by rotating the blue deflection collar (Figure 5) and moving the Primary Anchor Delivery Catheter until it is in apposition with the tissue at target site one located slightly anterior to the Anteroposterior commissure on the tricuspid annulus. If necessary, deflect and advance the Steerable Guiding Sheath while manipulating the Primary Anchor Delivery Catheter to better achieve the desired orientation on the annulus.

   NOTE: It is recommended that the anchors are deployed around the posterior portion of the tricuspid annulus starting with deployment of the primary anchor at or slightly anterior to the Anteroposterior (AP) Commissure. The first secondary anchor should be deployed at approximately 5mm from the primary anchor. The subsequent secondary anchors should be deployed at 10mm increments along the posterior annulus terminating at or slightly septal to the Posteroseptal (PS) commissure. The last two secondary anchors should be deployed at approximately 5mm apart.

10.4 PRIMARY ANCHOR DEPLOYMENTS

1. Ensure that the distal tip of the Primary Anchor Delivery Catheter is positioned against the annulus at the deployment site, achieving a synchronized movement of the Primary Anchor Delivery Catheter and the tissue that is visible on imaging.

   NOTE: The anchor housing that houses the PolyCor anchor will be visible on fluoroscopy and echocardiography. These imaging modalities, including 3D echocardiography, should be used to confirm the deployment location prior to anchor deployment.

2. Exert sufficient pressure on the Primary Anchor Delivery Catheter to maintain full apposition between the distal tip of the Primary Anchor Delivery Catheter and the annular tissue.
3. Once in apposition, rotate the white stabilization pin knob on the Primary Anchor Delivery Catheter handle (Figure 5) clockwise to extend the stabilization pins into the tissue.
4. Confirm on imaging that the distal tip of the Primary Anchor Delivery Catheter is in apposition with the deployment site and that the angle of deployment will direct the anchor into annular and myocardial tissue and avoid non-target anatomic structures. The recommended angle of deployment is between 60 and 90 degrees to the annular plane.

   NOTE: If the distal tip of the Primary Anchor Delivery Catheter is not in proper orientation with respect to the annulus, deflect and manipulate the Primary Anchor Delivery Catheter to achieve a perpendicular orientation with the plane of the annulus while maintaining apposition with the tissue prior to releasing the stabilization pins.

   NOTE: If the orientation of the stabilization pins suggests that the anchor may be deployed into a non-target anatomic structure, rotate the white stabilization pin knob on the Primary Anchor Delivery Catheter handle counterclockwise to retract the stabilization pins from the tissue and reposition the Primary Anchor Delivery Catheter on the annulus.

   NOTE: **DO NOT** deploy an anchor in a location where damage to the AV Node, Right Coronary Artery, Coronary Sinus, Bundle of His, Aorta, Aortic Valve, Circumflex Artery or other important anatomic structure may result.

   NOTE: **DO NOT** deploy an anchor in a location where the tissue is less than 16 mm thick.

NOTE: **DO NOT** deploy an anchor in a location where another anchor has previously been deployed.

NOTE: **DO NOT** deploy an anchor at a location or deployment angle where penetration of the atrial wall could occur, as this may cause pericardial effusion and/or cardiac tamponade per Figure 10.

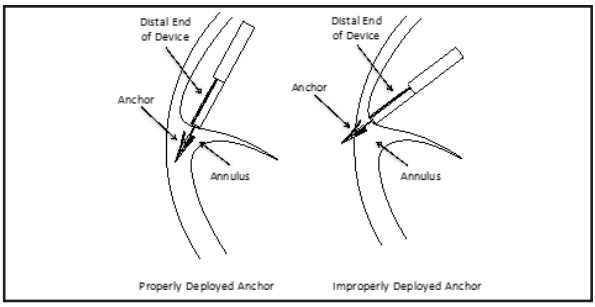


Figure 10. Proper and Improper Anchor Deployment Angulations Relative to Tissue

5. While maintaining apposition and appropriate orientation with the tissue, release the safety and press the deployment button on the handle to deploy the anchor into the annulus at the target site.
6. Rotate the white stabilization pin knob on the Primary Anchor Delivery Catheter handle counterclockwise to retract the stabilization pins from the tissue.
7. Straighten the Primary Anchor Delivery Catheter.

   NOTE: If the Stabilization Unit was used during the procedure (optional step), remove the handle of the Primary Anchor Delivery Catheter from the accessory Stabilization Unit.

8. Remove the Primary Anchor Delivery Catheter over the suture and from the Steerable Guiding Sheath and leave the Steerable Guiding Sheath and 250 cm length of suture in situ.

   NOTE: The Primary anchor is connected to 250cm of suture. Avoid applying significant tension to the suture to prevent the deployed anchor from being pulled out of the tissue when removing the Primary Anchor Delivery Catheter.

10.5 SECONDARY ANCHOR DEPLOYMENTS

1. Retrieve a Secondary Anchor Delivery Catheter loaded with a secondary anchor.
2. Position the Secondary Anchor Delivery Catheter so that the snare grip on the handle and the anchor are facing up.
3. Thread the proximal end of the 250 cm length 2-0 suture from right to left through the eyelet of the anchor while the tip of the anchor is pointing away from the user.
4. Backload 2-4cm of the proximal end of the 250 cm long suture through the Snare (Figure 7) of the Secondary Anchor Delivery Catheter.
5. Pull on the Snare Grip (Figure 8) to pull the suture through the length of the Primary Anchor Delivery Catheter.
6. Disconnect the Snare from the suture.
7. Gently pull the suture taut to remove any slack while inserting the Secondary Anchor Delivery Catheter through the Steerable Guiding Sheath and into the right atrium.

   Note: During insertion, ensure that the Deployment Button on the Secondary Anchor Delivery Catheter is positioned opposite the flush port of the Steerable Guiding Sheath while the Steerable Guiding Sheath is directed toward the next deployment site.

   NOTE: Maintain 2N of tension on the suture while advancing the Secondary Delivery Catheter through the Steerable Guiding Sheath.

   NOTE: Avoid applying tension greater than 2N to the suture in order to prevent the primary anchor from being pulled out of the tissue when inserting or removing the Secondary Anchor Delivery Catheter.

   NOTE: There is an optional step to rest the handle of the Secondary Anchor Delivery Catheter handle on the proximal clamp of the accessory Stabilization Unit. Consult the MIA Stabilization Unit Instructions for Use if using this accessory.

8. Advance, deflect and manipulate the MIA Secondary Anchor Delivery Catheter with the blue deflection collar until it is in apposition with the tissue at deployment site two, located approximately 5 mm posterior (towards the PS commissure) to the deployment site of the primary anchor on the tricuspid annulus. If necessary, deflect and advance the Steerable Guiding Sheath while manipulating the Primary Anchor Delivery Catheter to better achieve the desired orientation on the annulus.

   NOTE: It is recommended that each new anchor be deployed at a distance of 10 mm from the previously deployed anchor with the exception of the first two and last two of anchors being deployed at a distance of 5mm.

NOTE: Do not rotate the Primary Anchor Delivery Catheter more than 90 degrees in each direction.

NOTE: Maintain slight tension on the suture while locating the deployment site so as not to create a build-up of excess suture in the atrium during manipulations.

NOTE: Once the anchor housing of the Secondary Anchor Delivery Catheter has exited the Steerable Guiding Sheath, **DO NOT** retract the anchor housing into the Steerable Guiding Sheath prior to anchor deployment.

9. Ensure that the distal tip of the Secondary Anchor Delivery Catheter is positioned against the annulus at the deployment site, achieving a synchronized movement of the MIA Secondary Anchor Delivery Catheter and the tissue that is visible on imaging.
10. Exert sufficient pressure on the Secondary Anchor Delivery Catheter to maintain full apposition between the distal tip of the Catheter and the annular tissue.
11. Once in apposition, rotate the white stabilization pin knob on the Secondary Anchor Delivery Catheter handle (Figure 5) clockwise to extend the stabilization pins into the tissue.
12. Confirm on imaging that the distal tip of the Secondary Anchor Delivery Catheter is in apposition with the deployment site, that the angle of deployment will direct the anchor into annular and myocardial tissue and avoid non-target anatomic structures. The recommended angle of deployment is between 60 and 90 degrees to the annular plane.

    NOTE: If the distal tip of the Secondary Anchor Delivery Catheter is not in proper orientation with respect to the annulus, deflect and manipulate the Secondary Anchor Delivery Catheter to achieve a perpendicular orientation with the plane of the annulus while maintaining apposition with the tissue.

    NOTE: If the orientation of the stabilization pins suggests that the anchor may be deployed into non-target anatomic structures, rotate the white stabilization pin knob on the Secondary Anchor Delivery Catheter handle counterclockwise to retract the stabilization pins from the tissue and reposition the Secondary Anchor Delivery Catheter on the annulus.

    NOTE: **DO NOT** deploy an anchor in a location where damage to the AV Node, Right Coronary Artery, Coronary Sinus, Bundle of His, Aorta, Aortic Valve, Circumflex Artery or other important anatomic structure may result.

    NOTE: **DO NOT** deploy an anchor in a location where the tissue is less than 16 mm thick.

    NOTE: **DO NOT** deploy an anchor in a location where another anchor has previously been deployed.

    NOTE: **DO NOT** deploy an anchor at a location or deployment angle where penetration of the atrial wall could occur, as this may cause pericardial effusion and/or cardiac tamponade per Figure 10.

13. While maintaining apposition and appropriate orientation with the tissue, release the safety and press the deployment button to deploy the anchor into the annulus at the target site.
14. Rotate the white stabilization pin knob on the Secondary Anchor Delivery Catheter handle counterclockwise to retract the stabilization pins from the tissue.
15. Straighten the Secondary Anchor Delivery Catheter.

    NOTE: Remove the handle of the Secondary Anchor Delivery Catheter from the accessory Stabilization Unit (optional step if Stabilization Unit was used during the procedure).

16. Remove the Secondary Anchor Delivery Catheter from the Steerable Guiding Sheath, leaving the Steerable Guiding Sheath and 250 cm length of suture in situ.

    NOTE: The secondary anchor is connected to 250cm of suture. Avoid applying significant tension to the suture to prevent the deployed anchor from being pulled out of the tissue when removing the Secondary Anchor Delivery Catheter.

17. Repeat steps one through sixteen in section 9.5 SECONDARY ANCHOR DEPLOYMENTS to deploy additional anchors in sequence at 10 mm intervals on the tricuspid annulus until the array of anchors connected by suture extends from at or anterior to the AP commissure to at or slightly septal to the PS commissure. It is recommended to deploy the final anchor 5mm from the penultimate anchor.

10.6 MIA SUTURE LOCK DEPLOYMENT

1. Remove the shipping tab from the distal end of the Suture Lock Catheter (Figure 6).
2. Backload 2-4cm of the proximal end of the suture through the Snare (Figure 7) of the Suture Lock Catheter.
3. Pull on the Snare Grip (Figure 8) to pull the suture through the length of the Suture Lock Catheter.
4. Disconnect the Snare from the suture.

5. Gently pull the suture taut to ensure that there is no slack in the 250 cm length 2-0 monofilament polypropylene suture.
6. Deflect the Steerable Guiding Sheath 15°- 30° towards the final anchor deployed in section 9.5 SECONDARY ANCHOR DEPLOYMENTS.

   NOTE: **DO NOT** deflect the Steerable Guiding Sheath more than 30° prior to Suture Lock Deployment or release

7. While maintaining 2N of tension on the suture insert the Suture Lock Catheter over the suture and into the Steerable Guiding Sheath with the deployment button on the Suture Lock Catheter oriented 90° clockwise from the Flush Port of the Steerable Guiding Sheath.
8. Advance the Suture Lock Catheter until the distal end of the MIA Suture Lock Catheter is in contact with the final anchor deployed at or adjacent to the PS commissure.
9. Apply tension up to 4N on the suture while advancing the Suture Lock Catheter until the anchors appear to be in apposition and the annular tissue has been plicated as confirmed on imaging.

   NOTE: If the plication obtained on imaging is not ideal, the Suture Lock Catheter may be removed at this time and additional secondary anchors may be deployed per section 8.5.

10. Release the safety and press the deployment button on the Suture Lock Catheter to deploy the suture lock.
11. Rotate the release knob at the proximal end of the Suture Lock Catheter counterclockwise and push forward to release the Suture Lock (Figure 6).
12. Remove the Suture Lock Catheter and discard.

10.7 MIA SUTURE CUTTING

1. Backload 2-4cm of the proximal end of the suture through the Snare of the Suture Cutting Catheter (Figure 7).
2. Pull on the Snare Grip to pull the suture through the length of the Suture Cutting Catheter (Figure 8).
3. Disconnect the Snare from the suture.
4. Gently apply <2N of tension to the suture so as to ensure that there is no slack.
5. Introduce the Suture Cutting Catheter over the suture, through the Steerable Guide Sheath, and into the right atrium while applying ≤2N of tension to the suture to ensure that there is no slack
6. When the tip of the Suture Cutting Catheter is in position adjacent to the Suture Lock, as confirmed on imaging, release the safety and rotate the knob on the handle counter-clockwise to cut the suture.
7. Remove the Suture Cutting Catheter and discard.

10.8 CONFIRM ON IMAGING MODALITIES

1. Confirm the results of the procedure and the reduction in annular dimensions on imaging modalities.

11.0 MIA ACCESSORIES

1. The MIA Stabilization Unit can be used to facilitate Catheter manipulation and procedure steps.

12.0 PRODUCT INFORMATION DISCLOSURE

MID has exercised reasonable care in the manufacturing of this system. MID excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this system, as well as factors relating to the patient, diagnosis treatment, surgical procedures, and other matters beyond the control of MID directly affect this system and the results obtained from its use. MID shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this system. MID neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this system.

13.0 MRI SAFETY INFORMATION

The MIA-T implant is MR conditional. A patient with this device may safety receive MR scans at 3T or less.

14.0 SYSTEM AS SUPPLIED

MIA-T is provided in sterile packaging. The product is sterilized with ethylene oxide and is intended for single patient use only. The MIA catheters and implant cannot be reused. Additional implants are not provided with the device. Do not re-sterilize. Each catheter is packaged in a pouch and display box with Instructions for Use (IFU).

The system and primary packaging are latex-free. Store in a cool, dry place.

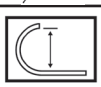
The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI. The Eudamed public website:
https://ec.europa.eu/tools/eudamed

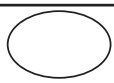
The UDI-DI is 0864821000301

15.0 SYMBOL TRANSLATION BLOCK

Explanation of symbols on package labeling

Refer to the outer package label to see which symbols apply to this product.

SYMBOL	DEFINITION
	MANUFACTURER
	DO NOT REUSE
	DO NOT RESTERILIZE
	CONSULT INSTRUCTIONS FOR USE
	INSTRUCTIONS FOR USE
	DO NOT USE IF PACKAGE IS DAMAGED
	USE-BY
	LOT NUMBER
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	PRODUCT IS IN COMPLIANCE WITH EUROPEAN CONFORMITY
	CATALOGUE NUMBER
	DATE OF MANUFACTURE
	LENGTH
	OUTSIDE DIAMETER
	CURVE
	QUANTITY
	BI-DIRECTIONAL CURVE
	UNI-DIRECTIONAL CURVE
	RIGID SECTION LENGTH
	PACKAGE CONTAINS
	MEDICAL DEVICE

SYMBOL	DEFINITION
	SINGLE STERILE BARRIER SYSTEM
	CAUTION
Rx only	BY PRESCRIPTION ONLY
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	TEMPERATURE LIMIT
STERILE EO	STERILIZED USING ETHYLENE OXIDE
	MR CONDITIONAL

16.0 RETURN OF DEVICES

If any portion of the MIA-T system fails prior to or during a procedure, discontinue use and return it to Micro Interventional Devices, Inc. The devices should be returned to:

Micro Interventional Devices, Inc.™

Taking Aim at Structural Heart Disease

Caufield Place
Suite 102
Newtown, PA 18940
215 600 1270

EC REP Oscor Europe GmbH
Fritz-Vomfelde-Strasse 6
40547 Düsseldorf, Germany

info@microinterventional.com

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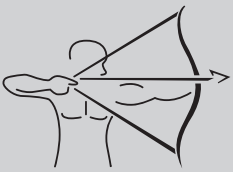
Micro Interventional Devices, Inc.™



Micro Interventional Devices, Inc.
MIA™-T

Micro Interventional Devices
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