AccuCinch® Ventricular Restoration System

Instructions for Use

CAUTION--Investigational device. Limited by United States law to investigational use.

WARNING: Exclusively for Clinical Investigations. Read all instructions before use. Failure to adhere to instructions, warnings and precautions may lead to device damage, patient injury or death.

INTENDED USE AND INDICATIONS

The AccuCinch® Ventricular Restoration System is indicated for the treatment of Heart Failure, with or without functional mitral regurgitation, in patients with dilated cardiomyopathy of ischemic or non-ischemic etiology.

CONTRAINDICATIONS

The AccuCinch® Ventricular Restoration System is contraindicated in patients with:

1. Known hypersensitivity to implant materials
2. Anatomy that is not compatible with the Ventricular Restoration System
3. Active endocarditis
4. Patients who cannot tolerate procedural anticoagulation

WARNINGS

- AccuCinch catheters are provided sterile and are single patient use only. Do not re-sterilize or re-use.
- AccuCinch accessories, (except for the Reusable Bar and Weight Set and Table Clamp), are provided sterile and are single patient use only. Do not re-sterilize or reuse.
- The AccuCinch Reusable Bar and Weight Set is provided non-sterile is re-sterilizable and re-usable.
- The Table Clamp is provided non-sterile and remains outside the sterile field during use.
- Do not use the AccuCinch System components or accessories if the packaging is compromised. If there is damage to the packaging, the device may not function as intended. If there are holes or tears in the pouch, contents may not be sterile.
- Do not use the AccuCinch System components or accessories if the expiration date has passed; contents may not be sterile or function as intended.
- Use of the AccuCinch System carries the risks associated with percutaneous cardiac interventions and open-heart surgery.
- Patients with allergic reactions to nickel may have an allergic response to the AccuCinch Implant.
- Ensure AccuCinch catheters are adequately flushed with heparinized saline. Ensure a continuous pressurized heparinized saline flush is maintained through the Guide and TracCath for the entire procedure to prevent thrombus formation. An inadequate flush rate may lead to thrombus formation.

PRECAUTIONS

- Store in a cool, dry place.
- Products should be handled using aseptic technique.
- The outer pouch of the catheters is not a sterile barrier. The inner pouch within the outer pouch is the sterile barrier. The outside surface of the inner pouch is NOT sterile. Only the contents of the inner pouch should be considered sterile.
- Only physicians who have received adequate training in cardiac intervention and the AccuCinch System should perform this procedure.
- During insertion and removal, support the Guide internally with the Guide Pigtail or Cut Catheter.
- Remove catheters or other devices slowly from Guide and TracCath. Rapid removal may draw air through passive valves and/or damage the valve.
- The AccuCinch procedure should only be performed at hospitals where emergency cardiac surgery can be readily performed.
- Catheter manipulations should be performed under fluoroscopic guidance. Excessive manipulation may cause damage to the catheters or cardiovascular structures. If strong resistance is felt during manipulation of the catheters, further manipulation should be avoided until the cause of resistance has been determined and resolved.
- After use, discard single patient use AccuCinch catheters and accessories per catheterization lab procedure regarding potential biohazardous materials. After use, clean and re-sterilize the Reusable Bar and Weight Set per instruction in **Table 5** at the end of this IFU.

POTENTIAL RISKS

Risks associated with standard cardiac catheterization, and the use of anesthesia, may include, but are not limited to the following:

- Acute coronary occlusion
- Allergic reaction to antithrombotic therapy or contrast medium or anesthesia
- Allergic/immunologic reaction to the implant
- Anemia
- Aneurysm
- Angina
- Aortic dissection
- Aortic valve insufficiency
- Aortic valve thrombosis/occlusion

- Aortic valve trauma
- Arrhythmias including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Arteriovenous fistula
- Arthralgia
- Atrial fibrillation/Atrial flutter
- Bleeding or bruising
- Blood loss requiring blood transfusion
- Cardiac arrest
- Cardiogenic shock/Pulmonary edema
- Cerebrovascular accident (including stroke, TIA)
- Cognitive impairment
- Conduction disturbance including AV block requiring pacemaker
- Death
- Device malfunction requiring intervention/conversion to open heart surgery
- Emboli (air, tissue, thrombotic or device materials)
- Endocarditis
- Esophageal damage or rupture
- GI symptoms
- Headache
- Heart failure
- Hematologic dyscrasia
- Hematoma
- Hemolysis
- Hemorrhage
- Hypertension/Hypotension
- Infection and/or pain at access site
- Infection, fever
- Infection, systemic/Sepsis
- Ionizing radiation risks
- Ischemia, limb
- Left ventricular outflow tract (LVOT) obstruction
- Mitral valve apparatus damage
- Mitral valve stenosis
- Myalgia
- Myocardial infarction, acute or chronic
- Perforation or Rupture of cardiac structure
- Pericardial effusion/cardiac tamponade
- Pericarditis
- Peripheral nerve injury/paralysis
- Pleural effusion
- Pneumonia
- Pneumothorax
- Postoperative encephalopathy
- Pseudoaneurysm
- Renal insufficiency/failure
- Respiratory insufficiency/failure
- Shock
- Syncope
- Thrombocytopenia
- Vasovagal response
- Vessel spasm
- Vessel thrombosis/occlusion
- Vessel trauma requiring surgical repair or intervention
- Worsening mitral regurgitation or heart failure

PATIENT COUNSELING

Short-term anticoagulation therapy may be necessary after AccuCinch Ventricular Restoration. A three-month course of dual antiplatelet therapy or combined anti-platelet/anti-coagulant is recommended. Physician discretion is warranted in prescribing the best course based on the patient pre-existing conditions. Prescribe anticoagulation and other medical therapy per institutional guidelines.

All patients should be advised to limit strenuous physical activity for at least the first month post-procedure or longer if warranted.

Physicians should consider the following when counseling patients about the AccuCinch Ventricular Restoration System and procedure:

-Discuss the risks associated with the AccuCinch Implant placement
-Discuss the risk/benefit considerations for the patient

PACKAGING, STERILIZATION & STORAGE

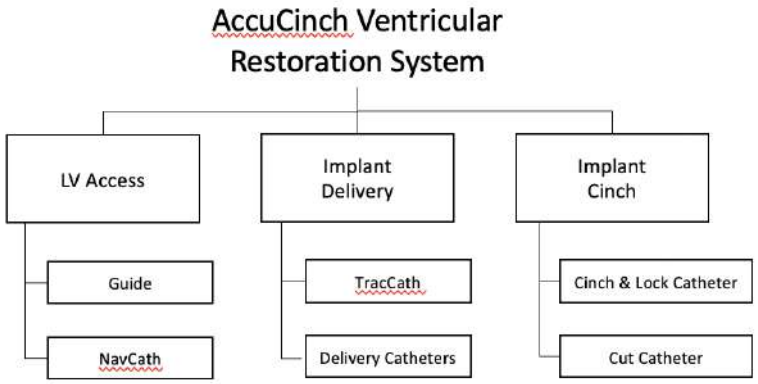
All components of the AccuCinch System, including accessory components (except the Reusable Bar and Weight Set and Table Clamp accessories) are supplied sterile for single-use only and must not be re-sterilized. The AccuCinch components undergo multiple bioburden reduction cycles and 100% EO sterilization during manufacturing. The Reusable Bar and Weight Set accessories are provided non-sterile and must be autoclave sterilized prior to use using the parameters listed in **Table 5.**

The AccuCinch System is to be stored as specified on the unit labels. Performance verification of the system components has been qualified when the devices are stored as specified on the respective unit labeling.

The AccuCinch Implant can be removed using standard surgical techniques (and/or according to applicable study protocols) and all AccuCinch Ventricular Restoration System catheters and components can be disposed of according to institutional guidelines (and/or applicable study protocols).

OVERVIEW PROCEDURE STEPS AND PRIMARY COMPONENTS DESCRIPTION

The AccuCinch procedure employs a catheter-based delivery system to implant and cinch the AccuCinch device into the base of the left ventricle (LV) to reduce dilation and enable remodeling, thereby improving heart failure symptoms and patient's quality of life. The procedure is comprised of three overall procedural steps: LV access, Implant Delivery, and Implant Cinch. The LV access step utilizes two catheters: Guide and NavCath. The AccuCinch Implant Delivery uses two additional catheter types: TracCath and Delivery Catheters. The AccuCinch Implant Cinch is achieved with two additional catheters: Cinch & Lock Catheter and Cut Catheter.

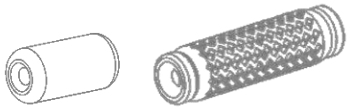


ACCUCINCH IMPLANT DESCRIPTION

The AccuCinch Implant components include a Cable, Anchors, Sliders and a Lock. The Anchors are implanted into the posterior wall of the left ventricle **(Figure 1),** approximately 10 – 20mm below the mitral valve plane, and approximately 11mm apart.

- **Cable –** a Cable is used to couple the Anchors together and to transmit tension along the length of the series of Anchors. The Cable is compatible with each of the catheter-based delivery components to allow repeated device exchanges over one Cable.
- **Anchor –** a radiopaque pre-formed wire deployed from the Delivery Catheter. Each Anchor is preloaded into a Delivery Catheter tip. The **Primary Anchor** is the first Anchor deployed and has the Cable permanently attached to its eyelet. Subsequent Anchors, called **Secondary Anchors,** are configured to allow the Cable to freely pass through the eyelet and are threaded onto the Cable just before delivery. Secondary Anchors additionally include a flexible polymer collar attached at the intersection of the Anchor legs to maintain a closed eyelet. Anchors are deployed sequentially around the subvalvular space. The Implant is comprised of one Primary Anchor followed by up to 15 Secondary Anchors depending on the size of the ventricle. Once the Implant is in place, the Anchors are pulled closer to one another by tensioning the Cable. See **Table 1.**
- **Slider** – a radiopaque cylinder with a center lumen that is placed over the Cable in between Anchors, distributing the load among the Anchors. There are two types of Sliders, Bare Sliders and Covered Sliders. Bare Sliders, which are shorter and uncovered, are deployed at the proximal and distal ends of the Implant. Covered Sliders, which are longer and covered with a polymer, are deployed in the central region of the Implant. See **Table 1**.
- **Lock** – the final proximal component comprised of a radiopaque tube and plug, is configured to secure the Cable, thereby permanently maintaining the configuration of the AccuCinch Implant. See **Table 1**.

Table 1. Components and Materials Used in AccuCinch Implant

Component	Material	Illustration
AccuCinch Implant	(details below)	
Anchor (with Collar)	Primary Anchor: Nitinol Secondary Anchor: Nitinol plus Collar Collar: Polyester, impregnated with Polytetrafluoroethylene (PTFE)	
Cable	Ultra-high molecular weight polyethylene (UHMWPE)	(no separate Cable image)
Slider	Bare: Nitinol Covered: Nitinol plus Polyester	
Lock	Nitinol	

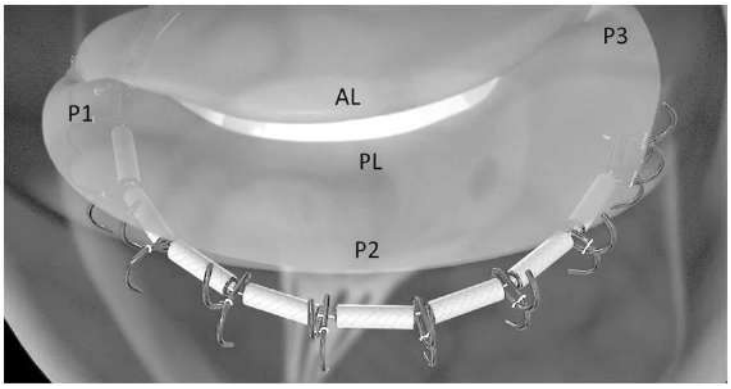


Figure 1: AccuCinch Implant at LV Posterior Wall (AL, PL: anterior and posterior leaflets of mitral valve. P1, P2, P3: posterior leaflet segments)

ACCUCINCH DELIVERY SYSTEM DESCRIPTION

The AccuCinch Delivery System consists of the following catheter-based delivery components:

- **Guide** – a shaped catheter (O.D. 18 F/6.0 mm, Working Length 100 cm) to provide access to the anterior aspect of the sub-valvular space. The Guide orients, directs, and provides support for the other AccuCinch System catheters. A deflectable section near the distal end allows the operator to adjust the Guide curvature using the proximal deflection knob at the handle. The Guide is available in several shapes to accommodate anatomical variations among patients. Refer to **Table 2** below for Guide selection. See **Figure 2.**

Table 2: Guide Selection Recommendations

Guide Shape	Description	Recommended Usage
Shape 23	Standard Shape	Fits most anatomies
Shape 22	Elongated Curvature	Accommodates enlarged aortic root diameters
Shape 20	Angled Curvature	Accommodates increased angles between ascending aorta and mitral valve plane compared to the Standard Shape
Shape 27	Higher Angled Curvature	Accommodates further increased angle between ascending aorta and mitral valve plane compared to the Angled Curvature shape
Shape 26	Narrow Curvature	Accommodates narrowed aortic arch

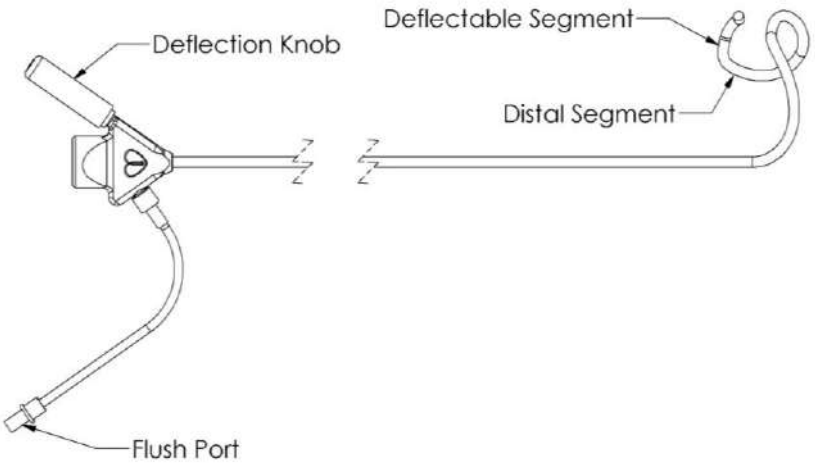


Figure 2. Guide

- **NavCath** – a navigation catheter (compatible with 0.035" O.D. guidewire) to access the sub-valvular space and facilitate guide wire placement between the chordae tendineae and the endocardium. The NavCath tracks within the Guide and accommodates a guide wire within its lumen. See **Figures 3a and 3b**.

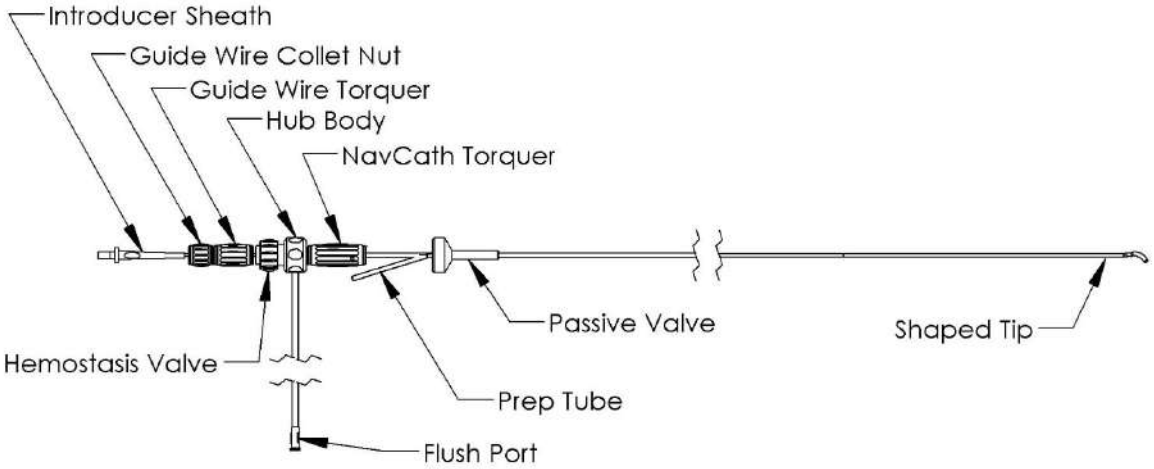


Figure 3a. NavCath (Passive Valve)

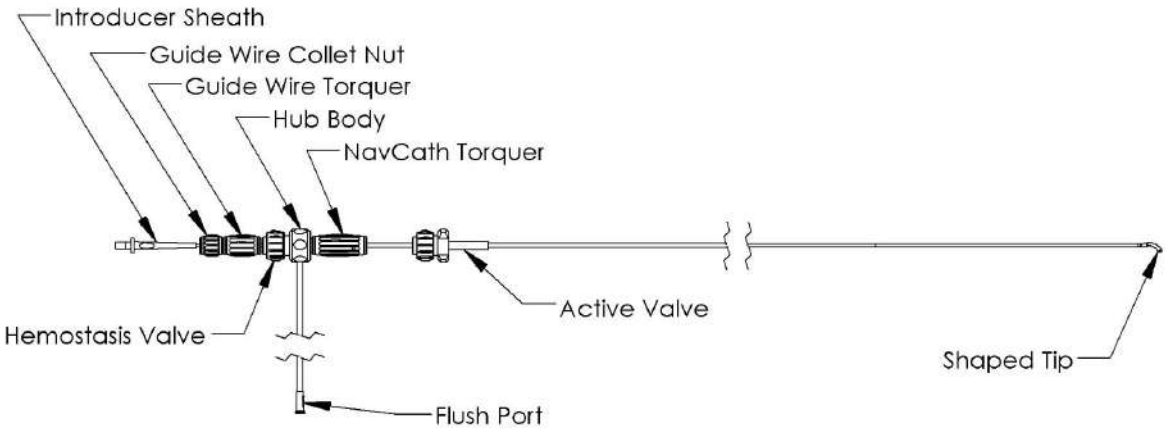


Figure 3b. NavCath (Active Valve)

- **TracCath** – a catheter (compatible with 0.018" O.D. guidewire) to facilitate consistent and accurate placement of the Anchors. The TracCath tracks within the Guide. It consists of both an Outer TracCath with a series of windows and an Inner TracCath with a single window. By aligning the windows of these two, the operator controls positioning of the Delivery Catheters and Anchor deployments. See **Figure 4**.

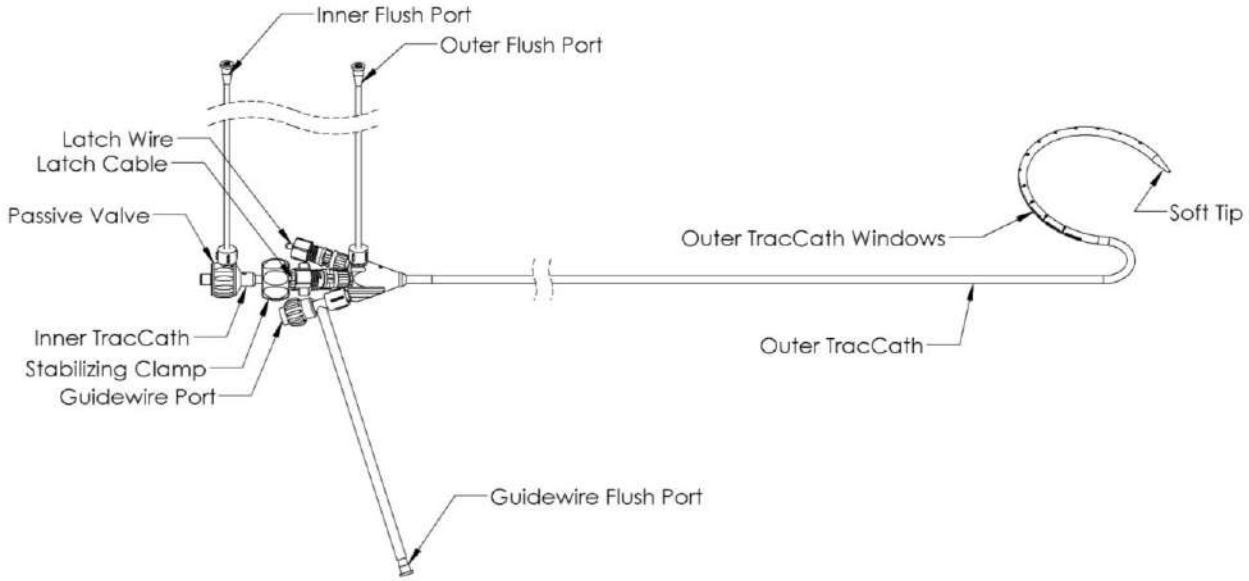


Figure 4. TracCath

- **Delivery Catheters** (Primary Delivery Catheter and Secondary Delivery Catheters) **–** All of the Delivery Catheters track within the TracCath and exit through a selected window in order to deliver each Anchor sequentially into the myocardium (from distal to proximal locations).
    - The Primary Delivery Catheter (PDC) is supplied pre-loaded with an Anchor and the attached Cable. See Figures **5a** and **5b**.

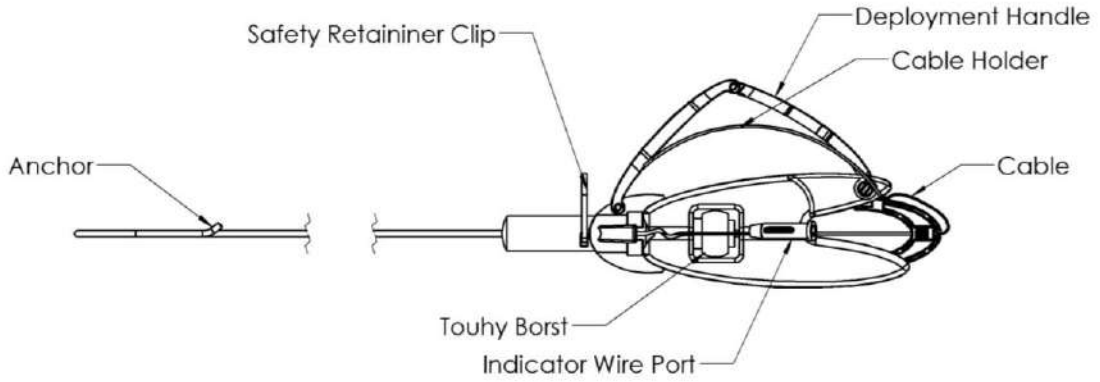


Figure 5a. Primary Delivery Catheter V1

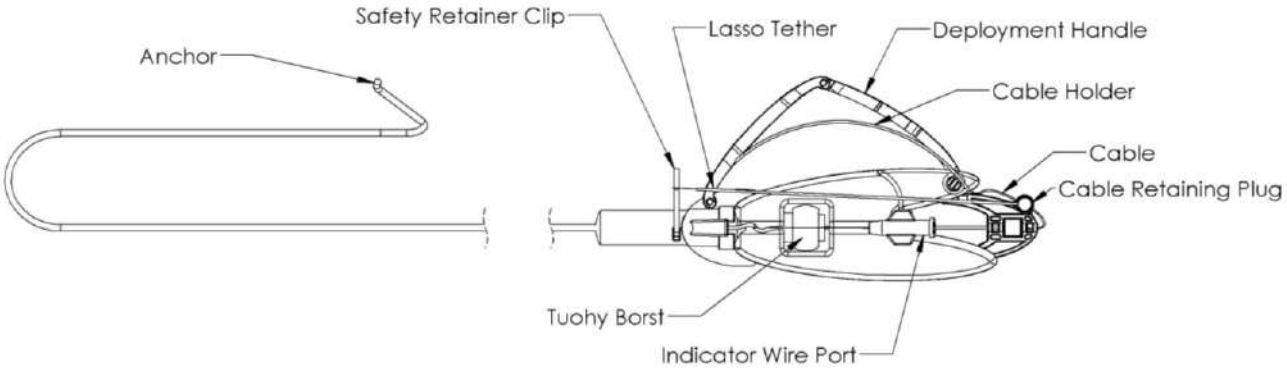


Figure 5b. Primary Delivery Catheter V2

- Secondary Delivery Catheters (SDC) are supplied pre-loaded with Anchors only. Secondary Delivery Catheters are available in two shapes, Distal and Proximal.
  - Distal Secondary Delivery Catheters are used for the majority of the Implant.
  - Proximal Secondary Delivery Catheters may be used for approximately the last up to 6 deployments as necessary based on ventricle shape and Anchor orientation. See **Figures 5c and 5d**.

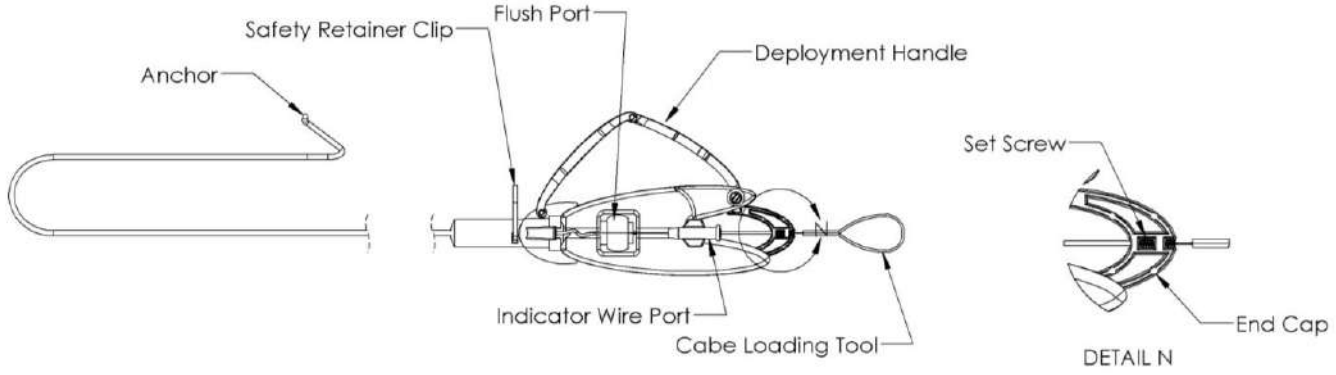


Figure 5c. Secondary Delivery Catheter V1

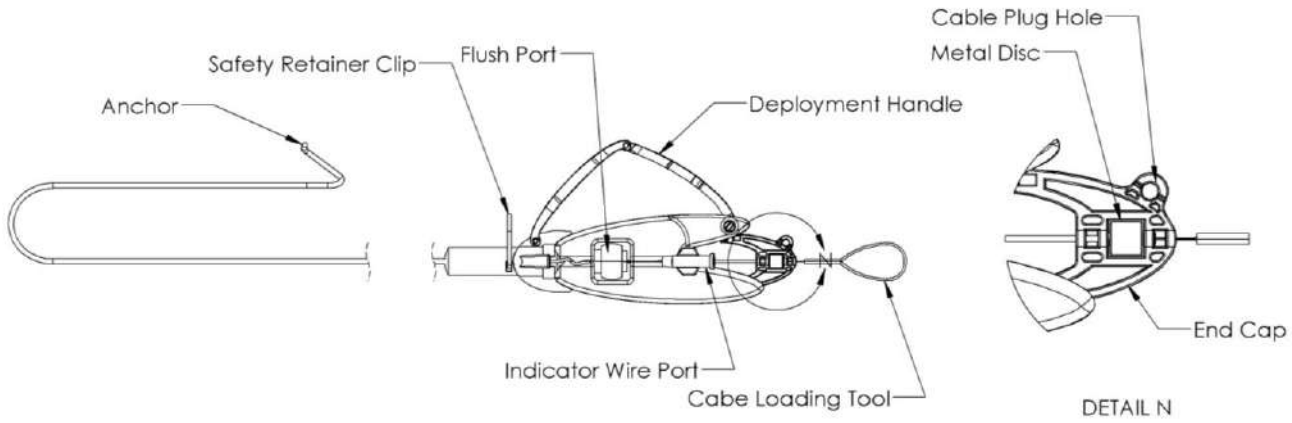


Figure 5d. Secondary Delivery Catheter V2

- **Cinch and Lock Catheter –** a catheter that tracks over the Cable within the Guide to the final Anchor placed, enabling controlled tensioning of the Cable and deployment of the Lock. The handle of the catheter provides controls for Cable tensioning and Lock engagement. See **Figure 6**.

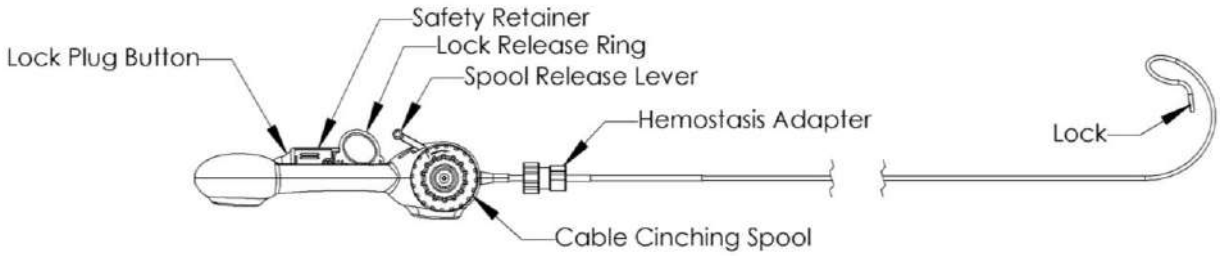


Figure 6. Cinch and Lock Catheter

- **Cut Catheter** – a catheter that tracks over the Cable within the Guide to the Lock, enabling final cutting of the excess portion of the Cable proximal to the Lock. See **Figure 7**.

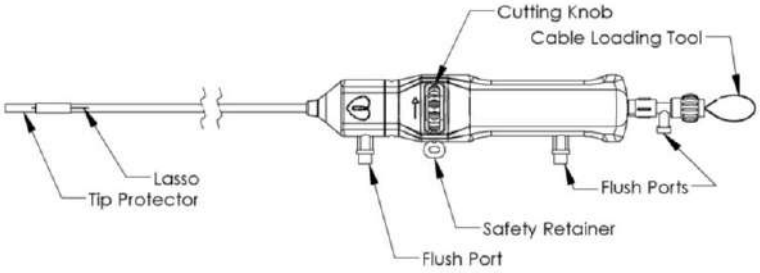


Figure 7. Cut Catheter

Optional/Occasional Use components:

- **Primary Anchor Retrieval Catheter –** The Primary Anchor Retrieval Catheter (PARC) is a general purpose catheter used mainly to capture a Primary Anchor if for any reason it is not satisfactorily secured to the myocardium after deployment. The PARC is tracked within the TracCath to the unsecured Anchor. Once the catheter tip envelops the eyelet of the unsecured Anchor, the Cable is used to stow and draw the Anchor into the PARC lumen. Upon withdrawal of the PARC from the TracCath, the Anchor is removed from the body. The PARC catheter may also be used for Slider tensioning, to reduce friction on the Cable during TracCath removal, or for swapping of the Inner TracCath, as necessary. See **Figure 8**.

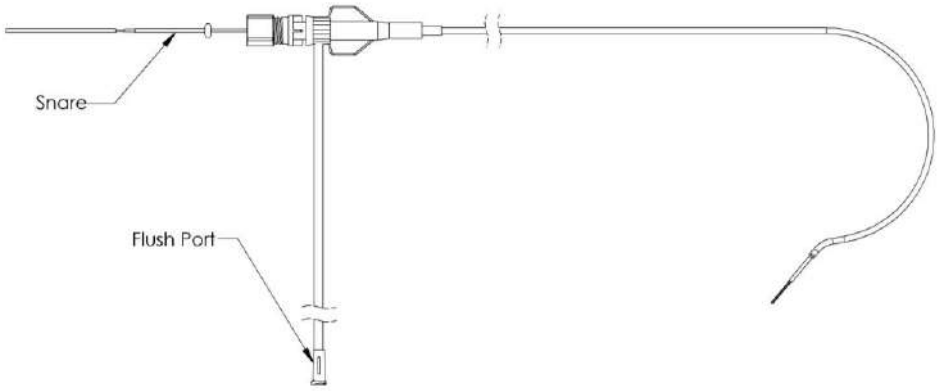


Figure 8: Primary Anchor Retrieval Catheter

- **Flexible Lock Catheter –** In the event the Implant must be terminated prior to completion (eg: due to hemodynamic instability, or if the Implant should be locked without cinching, e.g., insecure anchors in 2 or more adjacent windows or 4 or more total loose anchors) the Flexible Lock Catheter may be used to safely lock the Implant in place at any time during the procedure. Similar in design to the Cinch and Lock Catheter, this catheter can track over the Cable within the Guide and contact the most proximal Anchor of the Implant. The added flexibility of this catheter allows tracking around the subvavlular space to contact the most proximal Anchor regardless of its distance from the Guide. The handle of the catheter provides controls for removing slack from the Cable, Lock plug insertion and Lock release. **The Flexible Lock Catheter should NOT be used for cinching the Implant.** See **Figure 9**.

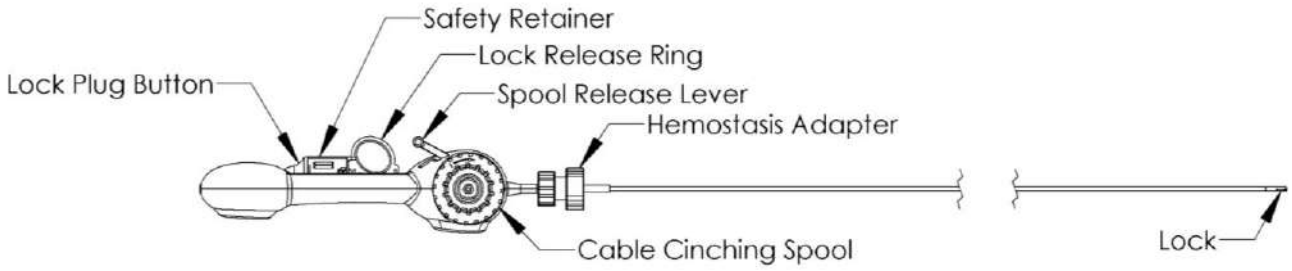


Figure 9: Flexible Lock Catheter

ADDITIONAL INFORMATION: IMPLANT LENGTH

In the AccuCinch Implant the number of Anchors placed along the free wall during a procedure to is a function of LV size, with larger ventricles receiving more anchors and smaller ventricles fewer anchors. The number of Anchors to be implanted is determined using the TracCath, as described in procedure steps below. At the end of the procedure, the Implant is cinched and locked in place in order to reduce LV diameter. **Table 3** describes the nominal number of anchors and AccuCinch Implant length corresponding to the TracCath markers. The Implant lengths and reductions shown are approximate. Lengths can vary as a function of anatomical shape and condition – e.g. whether circular or oval, a prior history of MI, or the presence or absence of trabeculations.

Table 3. AccuCinch size, Implant length and expected left ventricular (LV) reduction

TracCath Radiopaque Markers	Anchors	Nominal AccuCinch Implant Length & Reduction				Nominal LVEDD Reduction (mm)
		Pre-Cinch Length (mm)	Length Reduction (mm)	Reduction (%)	Post-Cinch Length (mm)	
11	11	100	25	25%	75	8 – 12 mm
12	12	112	29	26%	82	
13	13	123	34	27%	90	
14	14	135	38	28%	97	

15	15	146	42	29%	104	
16	16	158	47	30%	111	

SUMMARY PROCEDURE DESCRIPTION:

The AccuCinch Implant begins with deployment of the Primary Anchor which has the Cable attached to its eyelet. All subsequent Implant components are placed over this Cable. Delivery Catheters pre-loaded with Anchors are sequentially tracked up the TracCath and positioned out each TracCath window and into tissue, where the Anchors are then deployed. The Primary Anchor is followed by a Bare Slider. Then a Secondary Anchor is placed followed by a Covered Slider. Secondary Anchors and Covered Sliders are placed alternately until the final TracCath window is reached. In the final TracCath window a Secondary Anchor is placed followed by a final Bare Slider and then a final Secondary Anchor. The Implant is then cinched and secured with the Lock, as shown in **Figure 10**.

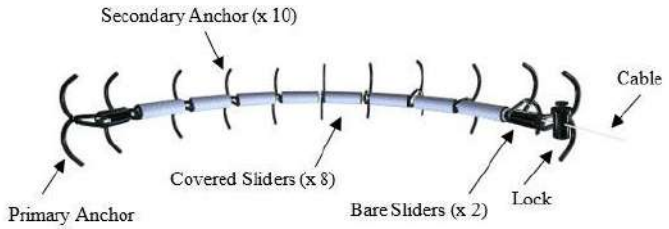


Figure 10. Complete 11 Anchor AccuCinch Implant

The size and nominal quantity of each catheter used in a standard AccuCinch procedure is listed in **Table 4** below.

Table 4. Catheter Diameters and Quantities

Component	Size (OD)	Qty/Procedure
Guide	18 F	1
NavCath	8 F	1
TracCath	14 F	1
Primary Delivery Catheter	7 F	1
Secondary Delivery Catheter	7 F	10 – 15
Cinch & Lock Catheter	11 F	1
Cut Catheter	11 F	1

The AccuCinch System is used with the following accessory components:

- **AccuCinch Accessories:**
  - Guide Pigtail (6 F)
  - **Reusable** Bar and Weight Set or **Disposable** Bar and Weight Set
  - Table Clamp
  - Indicator Wire: OEM NeoWire, Soft Light Guidewire (0.014”, 180 cm (NiTi)), used with the Delivery Catheters to indicate proper depth prior to the Anchors’ deployment. Manufactured for Ancora Heart by Hereaeus.
- Required accessories (not included):
  - 20F Introducer sheath **(GORE® DrySeal** or equivalent)
  - 5-6 Fr Pigtail catheter
  - Non-Hydrophilic Coated Guidewire (0.035", minimum 180 cm length, J-tip)
  - **Boston Scientific V-18 ControlWire™ Guidewire** – A guidewire (0.018”, 300 cm length) that allows the TracCath to safely advanced around the subvalvular space.
  - **Terumo Radiofocus® Guidewire** – A guidewire (0.035”, 180 cm length, 1.5 mm radius J tip) used with the NavCath to access the subvalvular space.
  - **Cook Amplatz** extra stiff non-hydrophilic guidewire (0.035”, 260 cm length) or equivalent
- Additional accessories (not included):
  - Percutaneous Closure Device, 2 each, Abbott ProGlide or equivalent, (unless a surgical cutdown and repair is performed).

- Prep Table (2 m long x 1 m wide)
- Bowl (large) to submerge GW + small bowl for heparinized saline (Prep Table)
- Bowl (large) to submerge GW + small bowl for heparinized saline (Patient Table)
- Surgical Towels
- 4" x 4" (10 x 10 cm) Sterile Gauze (Prep Table, Patient Table)
- Syringes (10 ml, 60 ml, 10 ml angiography control)
- 3 Port Manifold (Optional)
- Short extension lines
- 3-Way Stopcocks
- Pressurized IV line with normal saline (0.9%), heparinized per institutional standard
- Contrast Medium

All AccuCinch devices including AccuCinch accessory components (except the Reusable Bar and Weight Set which may be re-sterilized, and the Table Clamp, which remains outside the sterile field and is not sterilized) are provided sterile, non-pyrogenic, and intended for single use only.

PREPARE CABLE WEIGHT AND BAR SET (REUSABLE OR DISPOSABLE)

Prior to starting the AccuCinch procedure, prepare the Bar and Weight Set using preparation steps listed later in this IFU.

NOTE: One of two Bar and Weight sets will be supplied, either reusable or disposable. Follow the instructions appropriate for the set supplied.

ACCUCINCH VENTRICULAR RESTORATION PROCEDURE

NOTE: HEPARIN SHOULD BE ADMINISTERED THROUGHOUT THE PROCEDURE

CATHETER PREPARATION

1. All catheters should be flushed and wiped with heparinized saline prior to use. Specific prep steps are listed as needed for each catheter.

ACCESS THE LEFT VENTRICLE

2. Place the introducer sheath into the selected femoral artery per standard catheterization lab procedure.

WARNING: The AccuCinch® device requires the use of a large bore Introducer Sheath (20F). Utilization of vascular closure devices or a surgical cutdown and vascular repair are recommended for safe access site management.

3. Load the pigtail over a 0.035" J tip guidewire and advance into the left ventricle. Retract the guidewire.

4. Insert an exchange length 0.035" Extra Stiff, J tip guidewire into left ventricle then withdraw the pigtail.

GUIDE PREPARATION AND USAGE

5. Attach a pressurized heparinized saline line to the Guide flush port and flush the Guide.

6. With the flush line open, load the Guide Pigtail into the Guide and slowly advance until the tapered section of the Guide Pigtail is distal of the Guide tip and creates a smooth transition between the components. Flush may be turned off until just prior to insertion.

WARNING: Ensure Guide is clear of air prior to insertion.

7. With the flush turned on advance the Guide with Guide Pigtail over the guidewire into the left ventricle until the Guide has entered the left ventricular outflow tract (LVOT). Retract the guidewire and Guide Pigtail to the descending aorta.

WARNING: Moving the Guide without support may result in kinking.

8. Visualize the sub-valvular space with a contrast injection through the Guide.

9. In the Long Axis view, position the Guide distal segment parallel to, and just below the mitral valve (MV). Use deflection, by rotating the deflection knob counterclockwise, as needed.

10. In the Short Axis view, position the Guide distal segment along the anterolateral wall and in the sub-valvular space behind chordae tendineae. Identify the position of the LVOT and the junction with the ventricular wall in the Short Axis view and confirm desired position using fluoroscopy with contrast injection through the Guide.

11. Using TEE, perform a second confirmation of the Guide position, measure the distance from MV to Guide center, and assess aortic valve regurgitation (AR). Guide manipulations such as advancing and retracting should be used as appropriate.

12. Withdraw and remove the guidewire and Guide Pigtail.

NOTE: Final position should be verified in both Long Axis and Short Axis views before proceeding, as catheter manipulation in one view may affect positioning in the other view. If satisfactory positioning cannot be achieved, remove the Guide and insert a different shape of Guide. Refer to Table 1 for Guide selection recommendations.

WARNING: Ensure a continuous pressurized heparinized saline flush is maintained through the Guide for the entire procedure to prevent thrombus formation.

NAVCATH PREPARATION AND USAGE

13. Retract the Guide Wire Collet Nut prior to flushing. Load the 0.035", 1.5mm radius J-tip guidewire through NavCath until the J-tip is just outside tip of NavCath, then the tighten Guide Wire Collet Nut.

14. Depending on which NavCath is being used, follow steps **14a** or **14b**.

14a. Using NavCath (Passive Valve), slide the Passive Valve over the NavCath tip and J-tip of guidewire and insert the Passive Valve into the Guide. Allow any trapped air to bleed out of the Passive Valve through the prep tube before removing the prep tube.

14b. Using NavCath (Active Valve), slide the Active Valve over the NavCath tip and J-tip of guidewire and insert the Active Valve into the Guide. Loosen the Active Valve to allow any trapped air to bleed out of it, then lightly tighten the Active Valve to obtain hemostasis.

WARNING: Do not retract the guidewire completely into the NavCath. If it is necessary to extend the guidewire from the NavCath tip, ensure the NavCath tip is oriented away from myocardium. Extending the guidewire out of the tip while the NavCath tip is directed at tissue may result in ventricular perforation.

15. Advance the tip of the NavCath until it is aligned with the tip of the Guide.

16. In the Long Axis view, orient the NavCath toward the subannular groove (junction of left ventricle and mitral valve annulus) using the NavCath Torquer, then extend the guidewire until it meets an obstruction (guidewire will deflect). Fix the guidewire and advance the NavCath. Continue to orient the NavCath and advance the guidewire/NavCath around the sub-valvular space until the tip exits the outflow tract and re-crosses the aortic arch.

17. In the Short Axis view, confirm the desired NavCath and wire position and verify unrestricted MV leaflet motion with TEE assessment. Optionally assess position using fluoroscopy with a contrast injection through the Guide. If NavCath position is suboptimal (ie: not positioned behind all chordae tendineae), retract the NavCath and guidewire to the Guide and repeat step **16**. Repeat position and verification steps until the desired position of the NavCath behind chordae tendineae is achieved.

WARNING: Failure to verify proper position of the NavCath and guidewire may result in chordae tendineae damage, tissue damage, tissue perforation, worsening mitral regurgitation, or compromise proper Anchor implantation.

18. Remove the 0.035" guidewire.

19. Insert a 0.018" guidewire into NavCath (Introducer Sheath should be used to insert guidewire through the Guide Wire Collet Nut) and advance the wire beyond the NavCath distal tip; stop prior to the femoral bifurcation.

20. Remove the NavCath from the Guide, while maintaining 0.018" guidewire position.

TRACCATH PREPARATION AND USAGE

21. Attach a pressurized, heparinized saline flush line to the Inner TracCath Flush Port, the Outer TracCath Flush Port and the TracCath Guidewire Flush Port.

22. Backload the 0.018" guidewire into the TracCath.

23. In the Long Axis view, advance the TracCath to the distal curve of the Guide and verify Guide and guidewire position.

WARNING: Ensure a continuous pressurized heparinized saline flush is maintained through the Inner TracCath, the Outer TracCath, and the TracCath Guidewire lumen for the entire procedure to prevent thrombus formation.

24. Advance the TracCath and position the TracCath so that the distal most window is in position to deploy the Primary Anchor. Use the Short Axis view to confirm the distal window position.

25. In the Long Axis view, position the TracCath parallel to the mitral annulus.

26. Confirm desired TracCath position, AR severity, and verify unrestricted MV leaflet motion with TEE. Optionally assess position using fluoroscopy with a contrast injection through the TracCath.

27. Assess length of Implant – ie: number of Anchors to be implanted – along the free wall by counting the number of radiopaque markers from the distal end of the TracCath to the Guide tip, as depicted in **Figure 11**. The radiopaque markers on the Outer TracCath are spaced approximately every 11mm. The first marker is placed at the junction of the free wall and septum under P3. Then the number of Anchors to be implanted is determined by counting the number of radiopaque markers from the distal end of the TracCath to the Guide Tip. The number of markers corresponds to the number of Anchors of the Implant. **Figure 11** shows sizing for a 12 Anchor Implant. **Table 3** describes the nominal number of Anchors and AccuCinch Implant length corresponding to the TracCath markers.

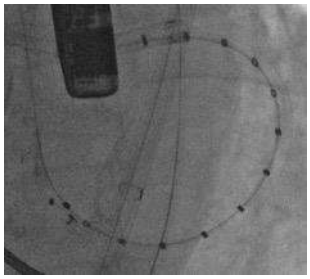
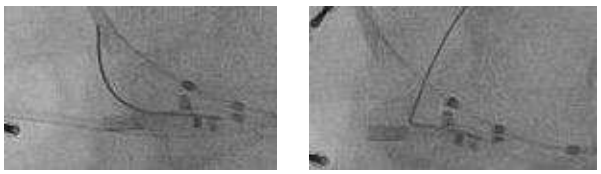


Figure 11: TracCath positioned along Basal LV Free Wall

PRIMARY DELIVERY CATHETER (PDC) PREPARATION AND PRIMARY ANCHOR DEPLOYMENT

28. For the first (distal) Anchor deployment, use a Primary Delivery Catheter (PDC).

29. Load the Indicator Wire into the Indicator Wire port, verify tip extension, place torquer on the Indicator Wire, and then retract tip into Indicator Wire lumen.
30. Remove Cable retainer and release Cable.
31. Align the Inner TracCath markers with the markers on the first window of the Outer TracCath.
32. Insert and advance the PDC into the TracCath until the PDC Tip aligns with the proximal Inner Window radiopaque marker. Depending on which PDC is being used, follow steps **32a** or **32b**.
32a. For PDC V1, remove the Safety Retainer Clip from the PDC Handle.
32b. For PDC V2, remove the Cable Retaining Plug first, then the Lasso Tether and Safety Retainer Clip from the PDC Handle.
33. Advance the Indicator Wire until it exits the TracCath, clear of latches and other obstructions, then continue to extend the Indicator Wire to assess TracCath apposition.
34. Advance the PDC until the Indicator Wire signals appropriate depth (approximately 6 mm depth in tissue), denoted as an Indicator Wire deflection of 90 – 120 degrees to the PDC shaft. See **Figure 12** below.



Prior to Deployment Signal Deployment Signal

Figure 12: Indicator Wire Signal

WARNING: Extending the Delivery Catheter tip too far may result in ventricular perforation.

35. Stabilize the PDC to the TracCath, depending on which PDC is being used, follow steps **35a** or **35b**.
35a. For PDC V1, apply constant and gentle tension to the Cable, and depress the Deployment Handle until the Primary Anchor has been deployed.
35b. For PDC V2, do not apply Cable tension, depress the Deployment Handle until the Primary Anchor has been deployed.
36. Release the Deployment Handle, ensure there is no Cable tension, slowly retract the PDC approximately 2cm, retract the Indicator Wire.
37. Verify that the Primary Anchor remains in a stable position of sufficient myocardial depth and appropriate angulation using fluoroscopy. Stability is denoted by Anchor motion during the cardiac cycle that is planar, without a rotational component. Monitor for ventricular septal defects or pericardial effusion with TEE.
38. Carefully withdraw the PDC from the TracCath.
39. After each catheter exchange, wipe Cable with heparinized saline

NOTE: If primary Anchor position is unsatisfactory, proceed per below instructions, under optional Retrieve Primary Anchor section.

SECONDARY DELIVERY CATHETER (SDC) PREPARATION AND INTERMEDIATE ANCHOR DEPLOYMENTS

40. Secondary Delivery Catheter preparation is the same as the Primary Delivery Catheter preparation.

NOTE: Prior to each Delivery Catheter insertion, verify TracCath position in the Short Axis view and parallel alignment of the Guide and TracCath to the mitral annulus in the Long Axis view, or by TEE approximately every 3 Windows, or as necessary. Adjust the Guide or TracCath as necessary.

41. Load a Slider onto the Cable (Use a Bare Slider for the first and last positions and Covered Sliders for all intermediate positions), then thread the Cable through the SDC.
42. With constant Cable tension, advance Slider and SDC into the TracCath and continue to advance until the Slider exits the Inner Window.
43. Release Cable tension and withdraw SDC back into the Window.
44. Adjust the Inner TracCath to the next position, one window proximal.
45. Remove the Safety Retainer Clip from the SDC Handle. Apply constant tension to the Cable to remove slack.
46. Advance SDC until the SDC tip aligns with the proximal Inner Window radiopaque marker. Extend the Indicator Wire until it exits the TracCath, clear of latches and other obstructions, then continue to extend the Indicator Wire to assess TracCath apposition.
47. Advance the SDC until it exits the TracCath, then release the Cable tension.
48. Advance the SDC until the Indicator Wire signals appropriate depth (approximately 6mm), denoted as an Indicator Wire deflection of 90 – 120 degrees to the SDC shaft.
49. Stabilize the SDC to the TracCath, depending on which SDC is being used, follow steps **49a** or **49b**.
49a. For SDC V1, apply constant Cable tension, then depress the Deployment Handle until the Anchor has been deployed.
49b. For SDC V2, depress the Deployment Handle until the Anchor has been deployed; constant Cable tension is optional during Anchor deployment.
50. Release the Deployment Handle, ensure there is no Cable tension, slowly retract the SDC approximately 2cm, retract the Indicator Wire.
51. Verify that the Anchor remains in a stable position of sufficient endocardial depth and angulation using fluoroscopy. Stability is denoted by Anchor motion during the cardiac cycle that is planar, without a rotational component. Monitor for ventricular septal defects, or pericardial effusion with TEE.
52. Carefully withdraw the SDC from the TracCath.

NOTE: Secondary Anchors cannot be retrieved once deployed. If Secondary Anchor position is unsatisfactory, proceed per below instructions, under optional Secure Intermediate Anchor section:

53. Repeat steps **41-52** until all intermediate Anchors are deployed from all desired windows.

DEPLOYMENT OF FINAL ANCHOR

54. Repeat steps **41-43** using a Bare Slider.
55. Adjust the Inner TracCath to the proximal end of the final window.
56. Repeat step **45-46**.
57. Advance the SDC until the tip exits the TracCath and the Cable is in the SDC tip slot, release Cable tension.
58. Repeat steps **48-52**.

TRACCATH REMOVAL

59. To reduce friction on the Cable during TracCath removal, the PARC may be loaded over Cable and advanced into TracCath.
60. Completely release the latches by retracting the Latchwire and Latchcable (**Figure 7**).
61. Tension the Cable to help separate the released latches from the Implant without disrupting the Anchors (Cable tension should be released once TracCath latches release from Implant)**.**
62. Retract the distal TracCath section to the Guide tip, without introducing cinch to the Implant.
63. Slowly withdraw the TracCath completely from the Guide, verifying Cinch is not introduced to the Implant. Manipulate the Guide as necessary to prevent forward movement of the Guide Tip as the TracCath is removed.
64. After the TracCath has been completely removed from the Guide, perform a Short Axis fluoroscopic image with breath-hold at end expiration. Monitor for significant changes to blood pressure, MV leaflet motion, MR and AR with TEE.

WARNING: Failure to prevent the Guide from moving forward may result in Anchor malposition or dislodgement from the myocardium.

Note: If resistance is met, slightly advance and retract the TracCath and Guide until the TracCath can be smoothly withdrawn.

CINCH AND LOCK CATHETER PREPARATION AND CINCHING THE IMPLANT

65. Flush the Cinch and Lock Catheter tip with heparinized saline, then remove the safety cap from the tip.
66. Thread the Cable through the Cinch and Lock Catheter.
67. While pinning the Cable, insert Cinch and Lock Catheter into the Guide through the hemostasis valve.
68. Apply slight tension on the Cable until a slight deflection is noted on the Guide Tip, then advance the Cinch and Lock Catheter to the Guide Tip.
69. Thread the Cable through the Hemostasis Adaptor on the Cinch and Lock Catheter and advance the Adaptor into the Guide hemostasis valve and lightly tighten.
70. With slight tension on the Cable advance the Cinch and Lock Catheter to the most proximal Anchor.
71. Wrap the Cable around the Cable Cinching Spool in the clockwise direction (3 to 5 times) and secure into the Cable Retainer, then tighten the Hemostasis Adapter.
72. Rotate the Cable Cinching Spool in the clockwise direction to tension the Cable, pausing after every 3-5 clicks to allow the tension in the Cable to distribute throughout the Implant.
73. Continue cinching until the gaps between the Sliders are 1mm or less throughout the Implant (**Figure 13**).

Note: During cinching, use fluoroscopy to assess cinching progress and spacing between Sliders.

LOCKING THE IMPLANT

74. Remove the Safety Retainer on the Cinch and Lock Catheter.
75. Advance the Lock Plug Button until the Plug is fully engaged with the Lock Tube.
76. Place the Spool Release Lever in the disengaged position and fully unwind and release the Cable from the Cable Cinching Spool, then loosen the Hemostasis Adapter.
77. Remove the Lock Release Ring from the handle and pull to release the Lock. If the Lock does not completely release, carefully and slowly advance the Plug Button to release the Lock from the catheter.
78. Remove the Cinch and Lock Catheter.

Note: After the Implant has been released from the Cinch and Lock Catheter, small gaps will appear between Sliders in the mid-region of the Implant. This provides some intentional flexibility to the Implant. See Figure 14.

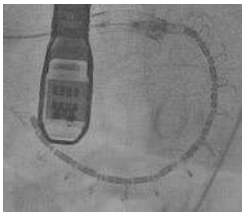


Figure 13: Implant fully cinched.

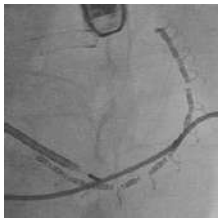


Figure 14: Final Implant with gaps.

CUT CATHETER PREPARATION AND CUTTING EXCESS CABLE

79. Flush the Cut Catheter with heparinized saline through the three flush ports; remove the safety cap from the tip.
80. Load the Cable through the Cut Catheter.
81. Maintain slight tension on the Cable while inserting and advancing the Cut Catheter through the Guide up to the Guide tip.
82. Remove the Safety Retainer from the handle and slightly tension the Cable.
83. Advance until the Cut Catheter tip is flush against the Lock, then slowly rotate the Cutting Knob on the Cut Catheter handle until the Cable is Cut.
84. Verify that the Cable has been cut by lightly pulling on the Cable. If the Cable is not easily withdrawn, it may not be completely severed. Advance the Cutting Knob completely forward then repeat the cutting steps until the Cable has been cut and separated from the Lock Implant.

FINAL VERIFICATION

85. In both the Short Axis and Long Axis views, obtain fluoroscopic images to visualize the final Implant position. This visualization should be performed with breath-hold at end expiration.
86. Before pulling the Guide through the aortic valve, remove all deflection on the Guide by rotating the Deflection Knob clockwise until it stops.
87. Position the Cut Catheter tip a few millimeters inside the Guide Tip and completely remove the Cut Catheter and Guide together from the introducer sheath. Optionally the Cut Catheter may be removed from the Guide and the Guide Pigtail may be reinserted into the Guide for Guide removal. Perform sheath removal and femoral closure per catheterization lab protocol.

RETRIEVE PRIMARY ANCHOR (OPTIONAL)

1. Completely remove the PDC.
2. Load the Cable through the PARC.
3. Advance the PARC to the Primary Anchor while maintaining tension on the Cable.
4. Align and apply the PARC tip to the Primary Anchor.
5. Apply tension on the Cable until the Primary Anchor is completely withdrawn into the PARC.
6. Completely remove the PARC, Cable and Primary Anchor.
7. To continue implantation, prepare a replacement PDC and resume at step **32**.

SECURE INTERMEDIATE ANCHOR (OPTIONAL)

1. Carefully withdraw the SDC from the TracCath.
2. Load a bare Slider onto the Cable.
3. Prepare and load a replacement SDC onto the Cable.
4. Advance the Slider out the Inner Window.
5. Deploy the Anchor as described above out of the same window as the loose Anchor.
6. Load a second bare Slider onto the Cable, followed by a SDC and advance the Slider out of the same window as the previous Anchor.
7. Continue the Implant starting at step **43**.
8. If there are no secure anchors in 2 or more adjacent windows, or 4 or more Anchors in the entire Implant, the Flexible Lock Catheter should be used to remove the slack from the Implant, but the Implant should be locked without cinching. Complete the Implant unless otherwise indicated and then follow the steps in optional Flexible Lock Catheter Preparation and Usage section to Lock without cinching.

FLEXIBLE LOCK CATHETER PREPARATION AND USAGE (OPTIONAL)

1. Flush the Flexible Lock Catheter with heparinized saline through the safety cap and then remove the safety cap .
2. Thread the Cable through the Flexible Lock Catheter.
3. While pinning the Cable, insert the Flexible Lock Catheter into the Guide through the hemostasis valve.
4. Apply slight tension on the Cable until a slight deflection is noted on the Guide Tip, then advance the Flexible Lock Catheter to the Guide Tip.
5. Thread the Cable through the Hemostasis Adapter on the Flexible Lock Catheter and advance the Adapter into the Guide hemostasis valve and lightly tighten.
6. With slight tension on the Cable, advance the Flexible Lock Catheter to the most proximal Anchor.
7. Wrap the Cable around the Cable Cinching Spool in the clockwise direction (3 to 5 times) and secure into the Cable Retainer, then tighten the Hemostasis Adapter.
8. Rotate the Cable Cinching Spool in the clockwise direction until Cable slack is removed, indicated by the Sliders lining up and the gaps between the Sliders and Anchors beginning to reduce. See **Figure 15**.

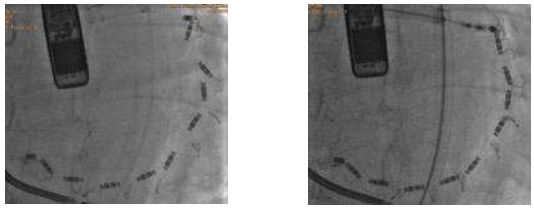


Figure 15: Baseline (left) and Slack Removed in Implant (right)

Note: During slack removal, use fluoroscopy to assess orientation of and spacing between Sliders.

9. Remove the Safety Retainer on the Flexible Lock Catheter.
10. Advance the Lock Plug Button until the Plug is fully engaged with the Lock Tube.
11. Place the Spool Release Lever in the disengaged position and fully unwind the Cable from the Cable Cinching Spool, then loosen the Hemostasis Adapter.
12. Remove the Lock Release Ring from the handle and pull to release the Lock. If the Lock does not completely release, carefully and slowly advance the Plug Button to release the Lock from the catheter.
13. Remove the Flexible Lock Catheter.
14. Continue to step **79**.

REUSABLE BAR AND WEIGHT SET PREPARATION FOR USE

1. Unwrap the sterile components and place into the sterile field using standard procedures.

Note: The Reusable Bar and Weight Set is provided non-sterile and must be autoclave sterilized prior to use using the parameters listed in Table 5.

2. Prior to assembly, visually inspect all components for damage.

3. Cut two pieces from the polymer tube and assemble these onto the hemostat tips as shown in **Figure 16** (Items 1, tube packaged with the Primary Delivery Catheter)

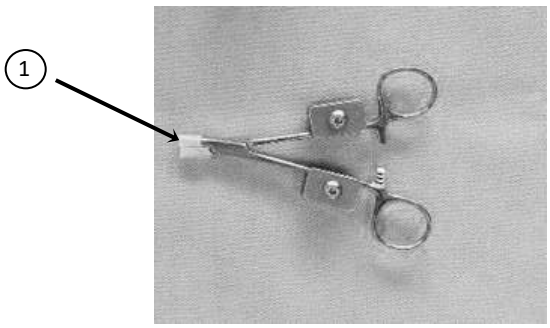


Figure 16: Polymer Tips Assembled onto Hemostat

4. Screw the two long metal bars together (Items 2) and hand tighten.

5. Slide the bar clamp (Item 3) onto the long metal top bar and secure using one of the thumb screws (Item 4).

6. Insert the cross bar (Item 5) into the bar clamp (Item 3) and secure using the remaining thumb screw (Item 4).

7. Refer to **Figure 17** for completed bar set assembly.

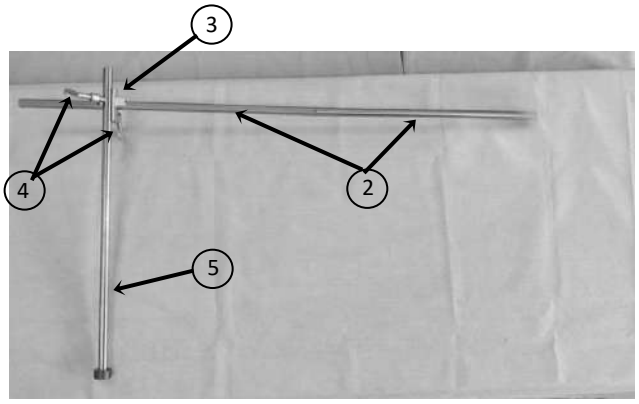


Figure 17: Bar Set, Assembled

8. Slide table clamp (non-sterile) onto the cath lab table rail in the desired location, as shown in **Figure 18**. Tighten the clamp knob. The table clamp is non-sterile. Note: the clamp tightening knob should be facing downward.

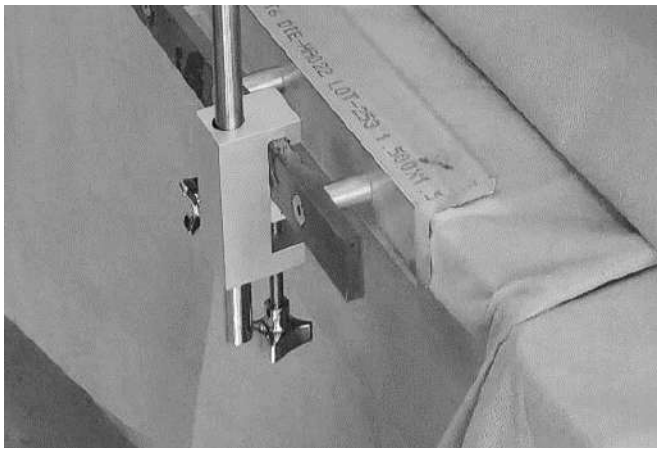


Figure 18: Table Clamp attached to cath lab table rail (shown with Bar Inserted)

9. Pass the end of the long bar opposite the cross bar out of the sterile field to the circulating nurse and insert into the table clamp approximately flush with the clamp bottom, as shown in **Figure 18**.
10. Tighten the clamp knob to secure the bar set to the table clamp. The Bar and Weight Set is ready for use.

DISPOSABLE CABLE WEIGHT AND BAR SET PREPARATION FOR USE

1. Unpackage the sterile components and place into the sterile field using standard procedures.
2. Prior to assembly, visually inspect all components for damage.

Figure 19: Cable Weight

3. Screw the Upper and Lower Rods together and hand tighten (**Figure 20**).
4. Using the thumbscrew, screw the Upper/Lower Rod assembly to the Horizontal Rod, taking care to ensure that the flat surface on the Upper Rod interfaces correctly to the flat surface of the Horizontal Rod (**Figure 21**).
5. Refer to **Figure 22** for completed Cable Bar assembly.

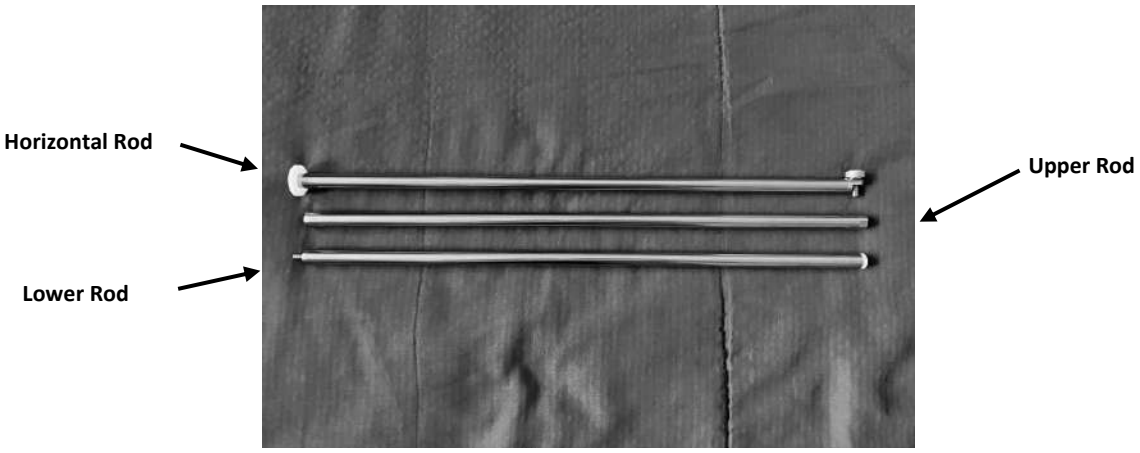


Figure 20: Cable Bar Rod Set

Figure 21: Upper/Horizontal Rod Detail

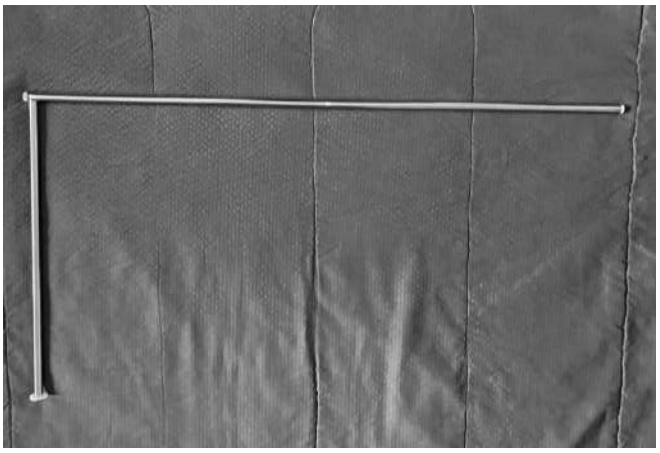


Figure 22: Cable Bar, Assembled

6. Slide table clamp (non-sterile) onto the cath lab table rail in the desired location, as shown in **Figure 23**. Tighten the clamp knob. The table clamp is non-sterile. Note: the clamp tightening knob should be facing downward.

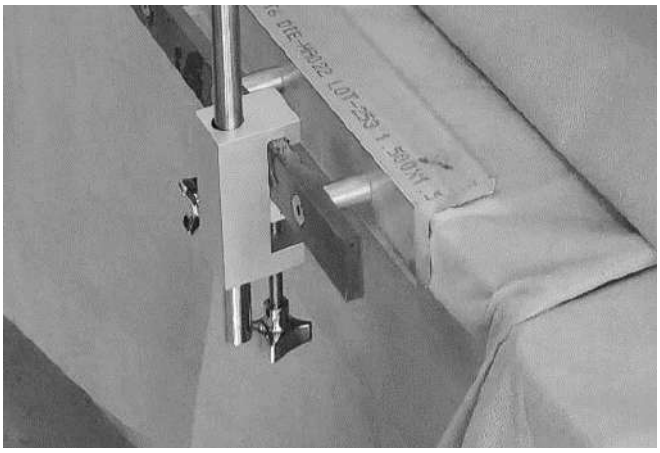


Figure 23: Table Clamp attached to cath lab table rail (shown with Cable Bar Inserted)

7. Pass the long end of the Cable Bar out of the sterile field to the circulating nurse and insert into the table clamp approximately flush with the clamp bottom, as shown in **Figure 23**.
8. Tighten the clamp knob to secure the Cable Bar to the table clamp. The Cable Weight and Bar Set is ready for use.

REUSABLE BAR AND WEIGHT SET STERILIZATION PROCEDURE

REFERENCE DOCUMENTS

- ANSI/ AAMI ST79 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities

EQUIPMENT

- Steam Sterilizer

MATERIAL

- Kimguard KC600
- Leather gloves or equivalent

SAFETY

- All safety measures should be observed at all times.
- Wear leather gloves or equivalent while handling products from the steam sterilizer

PROCEDURE

1. Follow hospital or internal guidelines to clean surgical tools for removal of soil and contaminants.
2. Disassemble the rods from the Bar Set.
3. Remove the clamp from the rod and disassemble the screws from the clamp.
4. Use hex key to slightly loosen the screws on the hemostat to loosen the brackets but do not completely disassemble. Leave tips in place, as shown in the **Figure 24** below.

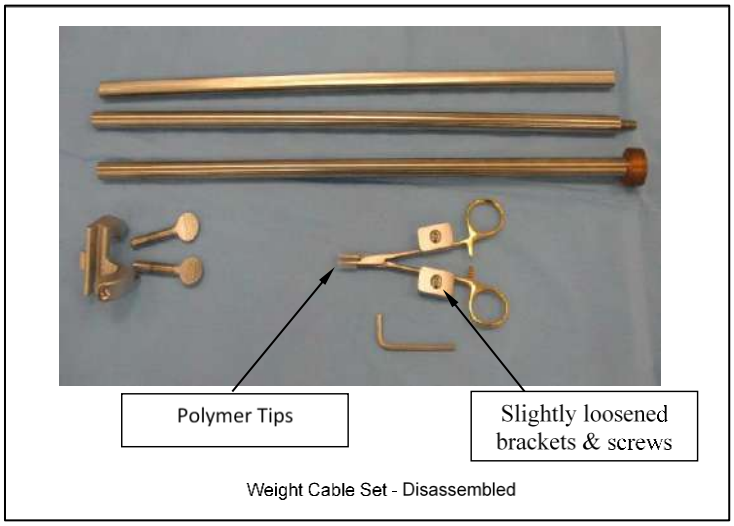


Figure 24. Bar and Weight Set components.

5. Wrap all articles in two layers of 1-ply polypropylene wrap (Kimguard KC600) using sequential envelope folding technique.

6. Follow the listed parameters listed in **Table 5** to sterilize the Bar and Weight Set.
7. After sterilization is complete, visually inspect all wrapped articles for any gross damage.

Table 5. Cable Weight and Bar Set Sterilization Parameters

Sterilizer Type:	Pre-vacuum (Pre-Vac)
Preconditioning Pulses:	4
Minimum Temperature:	132°C
Full Cycle Time:	4 minutes
Minimum Dry Time:	40 minutes (in chamber)

MRI INFORMATION

MR Conditional

MR CONDITIONAL

Non-clinical testing demonstrated that the Accucinch Implant is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the AccuCinch Implant is expected to produce a maximum temperature rise of 2.2°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

ARTIFACT INFORMATION

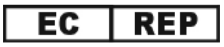
In non-clinical testing, the image artifact caused by the AccuCinch Implant extends approximately 10-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

LABELING SYMBOL DEFINITIONS

	Catalog Number		Do Not Re-use
	Sterilized using Ethylene Oxide		Consult Instructions for Use
	Caution		Use by
	Batch Code		Manufacturer
	Non-pyrogenic		Do not resterilize
	Do not use if package is damaged		Keep dry
	MR Conditional		European Authorized Representative

 Manufacturer:

Ancora Heart, Inc.
4001 Burton Drive
Santa Clara CA 95054 – United States
Telephone: +1 408 727-1105

 EC Authorized Representative:

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