Carillon Mitral Contour System®

Instructions for Use

Issue Date: 2023-07-27

CE 0344

STERILE PRODUCT– DO NOT RESTERILIZE – SINGLE USE ONLY

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INSTRUCTIONS FOR USE

Carillon Mitral Contour System

I. Intended Purpose

The Carillon Mitral Contour System is intended to reduce secondary mitral regurgitation within 12 months of implantation.

II. Indication

The Carillon Mitral Contour System is indicated for use in patients with secondary (functional) mitral regurgitation who are symptomatic (NYHA Grade ≥ 2) despite treatment with guideline directed medical therapy.

Carillon Mitral Contour System implantation can be considered in case of:

- Presence of symptomatic secondary mitral regurgitation not corrected by conventional guideline directed treatment; and
- Presence of annulus dilatation as primary contributor to the significant MR; and
- Absence of mitral valve leaflet abnormalities where the effect of the abnormalities outweighs any beneficial effects of (partial) annulus reduction achieved by the Carillon implant.

III. Contraindications

The Carillon Mitral Contour System is contraindicated for use in:

- Patients with existing devices in the CS/GCV
- Patients who have had a mitral valve replacement or have a mitral annuloplasty ring implant

IV. Intended Users

The Carillon Mitral Contour System is intended for use only by physicians who have expertise in the techniques of vascular catheterizations and who have been trained on the proper use of the Carillon Mitral Contour System. The implant procedure should be conducted in a location where cardiac catheterizations are intended to be performed.

The decision to implant the Carillon Mitral Contour System should be determined by a multidisciplinary and specialized heart team.

Any serious incident that has occurred in relation to Carillon Mitral Contour System should be reported to a Cardiac Dimensions representative or directly to complaints@cardiacdimensions.com, and, if deemed appropriate, the competent authority of the European Union Member State in which the user and/or patient is established. Cardiac Dimensions is available to assist in determining if the incident is considered serious and device related.

V. Warnings

- If the patient experiences prolonged third-degree A-V block or asystole at any point during the procedure, terminate the procedure.
- If the distal anchor struts are inadvertently collapsed by over advancement of the delivery catheter to the distal anchor twist, recapture and remove the entire implant. See Section 5 – Implant Recapture under IX Implant Procedure.
- The implant cannot be recaptured with the handle assembly once it is decoupled from the handle assembly.
- If, at any point during the procedure, a coronary venogram demonstrates evidence of a clinically significant venous dissection in the implant target zone, terminate the implant procedure and monitor the patient.
- If, at any point during the procedure, a coronary venogram or echocardiogram demonstrates evidence of a clinically significant venous perforation, terminate the implant procedure. Monitor the patient for pericardial effusion and assess the need for pericardial drainage.

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- If clinically significant denuded venous tissue is observed on a component of the Carillon Mitral Contour System following implant recapture, terminate the implant procedure. Monitor the patient for pericardial effusion.
- If placement of the implant causes a significant change in the electrocardiogram (ECG), recapture and remove the implant.
- If placement of the implant causes a significant reduction in the coronary arterial dimensions of a clinically significant artery and unresponsive to intracoronary nitroglycerine, then recapture and remove the implant. Confirm a return to baseline arterial dimensions.

VI. Residual Risks and Undesirable Side Effects

Potential complications, residual risks, and undesirable side effects associated with the use of the Carillon Mitral Contour System are listed below. Those which have occurred during clinical trials conducted using the Carillon Mitral Contour System are identified by an *. Additional information on Carillon Mitral Contour System clinical study results and risk analyses is in the Summary of Safety and Clinical Performance (SSCP) available on the European database on medical devices (EUDAMED) https://ec.europa.eu/tools/eudamed and on the Cardiac Dimensions website https://cardiacdimensions.com/SSCP.

Allergic Reaction*

Angina Pectoris

Cardiac Arrhythmia*

Cardiac Tamponade

Carotid Artery Trauma

Contrast-Induced Renal Insufficiency/Failure*

Death*

Denudation of Venous Tissue

Dissection of a Coronary Vessel

Hematoma / Hypovolemic Shock

Infection

Inflammation

Mitral Stenosis

Myocardial Infarction*

Myocardial Injury*

Myocardial Ischemia

Occlusion of a Coronary Vessel / Venous Embolism

Perforation or Rupture of a Coronary Vessel

Pericardial Effusion*

Stroke

Tissue Erosion

Tissue Necrosis

Tissue Penetration

Transient Ischemic Attack

Valve Entanglement / Coronary Sinus Occlusion

Worsening Heart Failure

VII. Precautions

General Precautions

- Store all Carillon Mitral Contour System components in their original unopened shelf boxes in a location that is cool, dry, and away from direct sunlight.
- Inspect packaging prior to use. Do not use a component if its peel pouch is damaged or opened.
- Do not use a component if it appears to be damaged.

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- **For SINGLE USE ONLY.** Do not re-sterilize and reuse the implant, delivery catheter, sizing catheter, or handle assembly.
- Recapture of the implant can impair the performance of the implant and delivery catheter. Reuse may result in inability to deploy the implant, inability to recapture the implant, a compromise in implant function, and implant fracture.
- Use the product prior to the “Use By” date shown on the device labeling.
- Use sterile technique when handling the Carillon Mitral Contour System.

Precautions Specific to Patient Selection

- The Carillon Mitral Contour System is recommended for use when a multi-disciplinary and specialized heart team determines that a reduction in regurgitant volume can be reasonably expected within 12 months of implantation. The expected reduction in regurgitant volume can be inferred from previous study data.
- Patients with a history of atrial fibrillation should undergo a trans-esophageal echo prior to the procedure to rule-out left atrial appendage clot to minimize the risk of thrombo-embolism caused by the tissue plication.
- Patients with nickel, titanium or nickel/titanium (nitinol) sensitivity may have a reaction to the implant.
- Permanent placement of the implant may affect future cardiac procedures such as percutaneous coronary intervention or placement of a pacing lead through the coronary sinus for resynchronization therapy.
- Patients with known conduction system disease, especially left bundle branch block, should be considered for temporary transvenous right ventricular pacing prior to cannulation of the coronary sinus.
- Patients with a left dominant or co-dominant coronary artery circulation may be more likely to experience acute transient coronary artery compression during the procedure.
- Patients who have significant mitral annular calcification may be less likely to have a reduction in mitral regurgitation.
- Patients with non-compaction cardiomyopathy may be more likely to have hyperdynamic venous compression (when any portion of the coronary sinus vein lumen fully contracts during the cardiac cycle) and hyperdynamic venous compression may be more likely to cause implant anchor wire fracture.

Precautions Specific to Implant Procedure

- Implant placement should only be performed at institutions where emergency cardiac surgery can be readily arranged (either within the implanting institution, or via patient transport to an alternate institution with emergency surgery capability).
- The Carillon Mitral Contour System should be introduced through the right internal jugular vein and should not be introduced through a femoral vein, the right subclavian vein, or the left internal jugular vein.
- Patients may have a coronary artery near the great cardiac vein which can lead to acute coronary compromise during deployment of the Carillon implant, which can lead to subsequent recapture of the implant.
- The distal end of the distal anchor must be able to be placed at least 9 cm from the CS ostium.
- Ensure accurate sizing of the coronary vein and appropriate implant selection.
- Do not advance or withdraw the Carillon Mitral Contour System when resistance is met. Determine the cause of the resistance through fluoroscopic examination or other means.
- Always advance the Carillon delivery catheter over a 6F or 7F outer diameter catheter such as a multi-purpose angiographic diagnostic catheter or deflectable catheter. NOTE: A 7F catheter is preferred to a 6F as it minimizes the luminal transition between the diagnostic catheter and the Carillon delivery catheter.
- Follow standard interventional cardiology anticoagulation protocols when using the Carillon Mitral Contour System.

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- Minimize bending or rotating of the handle assembly and delivery catheter during the advancement, delivery, deployment, and recapture of the implant.
- Do not place an implant in a location within the CS/GCV where it might interact with a coronary artery stent.
- Use coronary angiography to check for coronary artery obstruction as part of the implant procedure.
- Confirm both anchors are locked prior to decoupling the implant from the handle assembly.
- Consider recapturing and removing the implant if the final location of the implant is not in the intended coronary sinus anatomy, if the anchors do not lock, or if implant anchor wire-forms appear severely misshaped.
- Do not reuse a delivery catheter, handle assembly, or implant for an additional implant procedure attempt.
- Implant retrieval methods (i.e., use of wires or snares) after the implant is decoupled from the handle assembly have not been assessed and may result in trauma to the coronary vasculature and/or the vascular access site.

Precautions Specific to Post-Procedure Care

- Employ proper access site management post procedure and post hospital discharge to prevent infection.
- Encapsulation of the implant should be considered prior to conducting future coronary sinus interventions.
- If the patient requires post-procedure imaging see Section XI, Magnetic Resonance Imaging (MRI) Compatibility.

VIII. System Description and Characteristics

The Cardiac Dimensions Carillon Mitral Contour System (CMCS) is a medical device and consists of the following components:

1) Carillon Mitral Contour System with Implant/Handle. A proprietary implant ("Carillon implant") intended for permanent placement in the coronary sinus and great cardiac vein (CS/GCV), preloaded into a handle assembly.
2) Carillon Curved Delivery Catheter. A curved delivery catheter ("Carillon delivery catheter") as an accessory to the implant/handle assembly for cannulation of the CS and precise placement of the implant.
3) Carillon Sizing Catheter. A sizing catheter to enable the physician to estimate the overall CS/GCV dimensions so that an appropriately sized implant may be selected.

The Carillon implant is advanced through the Carillon delivery catheter to the coronary vein along the posterolateral aspect of the mitral annulus.

The specific components of the Carillon Mitral Contour System are described in detail as follows.

- **Implant**

  The Carillon implant is made of nitinol (nickel/titanium alloy) and pure titanium and is manufactured in different lengths and with different anchor sizes to accommodate individual venous anatomy. The implant contains up to 1,260 mg of nitinol and up to 180 mg of pure titanium (or less, depending on the implant size). The implant is composed of a distal anchor (positioned in the GCV), proximal anchor (positioned in the CS), ribbon connector (joining the anchors), proximal crimp tube, and distal crimp tube. The lock bump and arrowhead help secure their respective eyelets in the locked position (Figure 1). The implant is designed to be deployed, tensioned, and secured in the coronary vein.

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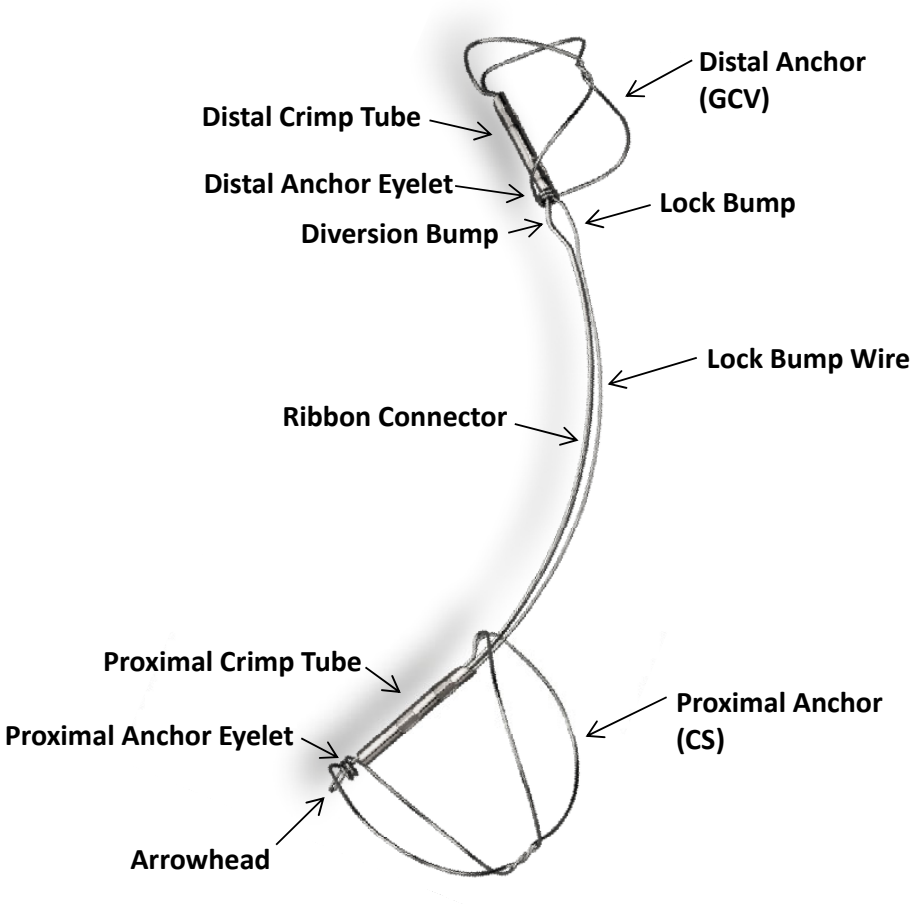

Figure 1: Carillon Implant Illustration

- **Delivery System**

  Carillon Curved Delivery Catheter:

  The delivery catheter (Figure 2) facilitates percutaneous entry of the sizing catheter, attachment of the cartridge, delivery of the implant, engagement of the locking mechanism of the distal anchor, and recapture of the implant (if necessary).

  The delivery catheter is composed of a metal braid reinforced polymer sheath with a luer “Y” connector and will withstand a maximum of 1700 KPa (246 psi) injection pressure. The catheter tip is radiopaque. The delivery catheter is curved at its distal end and has a 3.2 mm outer diameter and 70 cm effective length (Figure 2). The inside diameter is 2.5 mm and will accept a 0.035” (0.89 mm) guidewire or a 7F (2.3 mm) outer diameter diagnostic or deflectable catheter.

  The straight port is used for advancement and removal of the sizing catheter and introduction of the implant. The side port may be used for injection of a radiopaque contrast medium.

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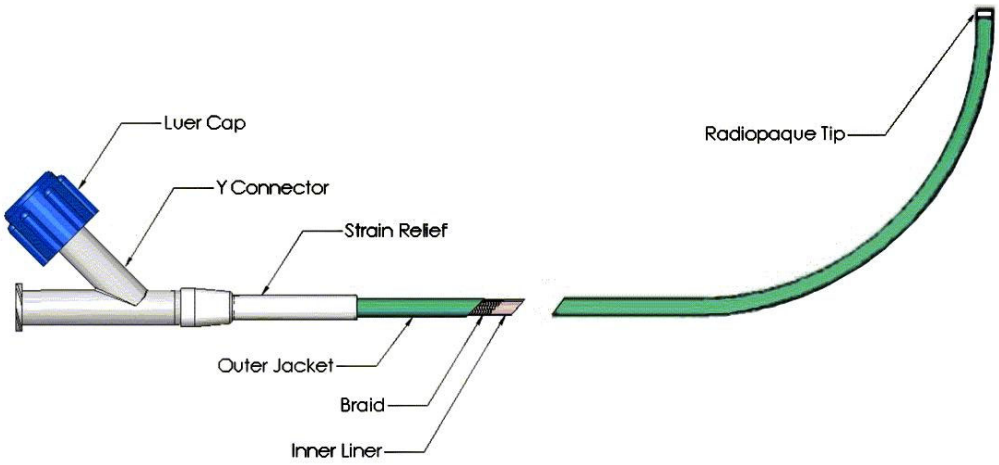

Figure 2: Carillon Delivery Catheter Illustration

Carillon Implant/Handle Assembly:

The handle assembly is composed of a cartridge, a sheath/pusher assembly and a handle assembly with cartridge window, rotating knobs, and release safety (Figure 3). The distal end of the cartridge (male luer) connects to the luer fitting of the straight port on the proximal end of the delivery catheter and should only be connected to the Carillon delivery catheter.

- In its packaging, the cartridge contains the implant, which is folded in the unlocked position within the cartridge lumen. It also houses the distal portion of the sheath/pusher assembly, which is connected to the implant. During delivery, the implant is manually pushed from the cartridge into the delivery catheter.
- The sheath/pusher assembly is composed of a lock wire and tether wire, a pusher, and a polymeric sheath for locking the proximal anchor. The combination of the pusher and wires aid in the placement, deployment, and decoupling of the implant from the handle assembly. They provide a mechanism for assuring that the implant is connected to the handle assembly until the appropriate time for decoupling (using the release safety & release knob).
- The handle facilitates deployment, locking, decoupling, and recapture of the implant. This is accomplished by rotating knobs that enable controlled movements of the delivery catheter, the implant, the sheath/pusher, and the decoupling mechanism. A release safety is provided to prevent inadvertent release / decoupling of the implant.

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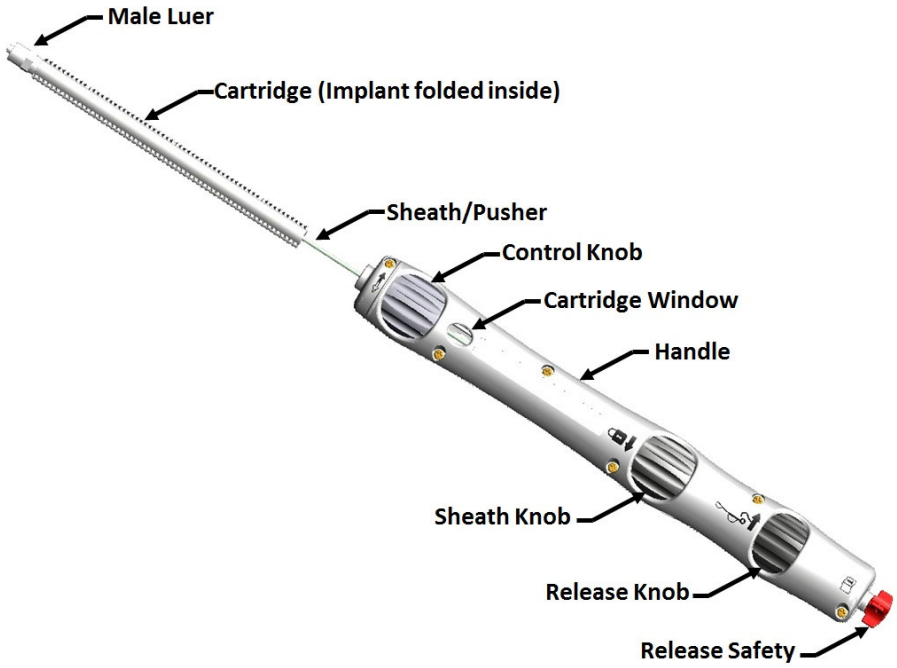

Figure 3: Carillon Implant/Handle Assembly Illustration

- **Carillon Sizing Catheter**

  The Carillon Sizing Catheter is used to estimate the overall CS/GCV dimensions so that an appropriately sized implant may be selected. The sizing catheter is inserted into the delivery catheter and advanced until the most distal marker band is aligned with the radiopaque marker at the tip of the delivery catheter. Venous size estimates are then determined by the physician using venograms captured with fluoroscopy.

  The sizing catheter consists of polymer shaft, a hub with a luer connector at the proximal end, a polymer strain relief, radiopaque marker bands, and a clear distal sleeve covering the marker bands (Figure 4).

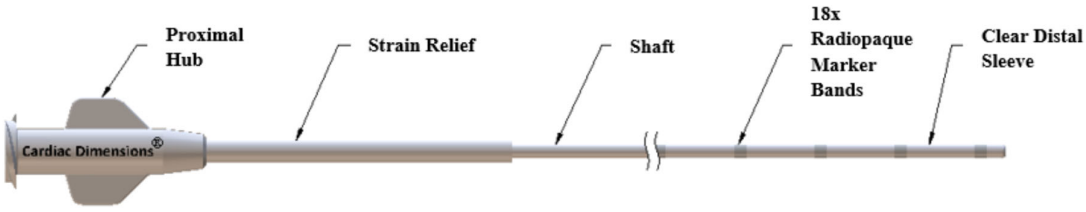

Figure 4: Carillon Sizing Catheter Illustration

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IX. Implant Procedure

WARNING: If a catheter inadvertently enters the ventricle and the patient experiences prolonged third-degree A-V block or asystole at any point during the procedure, the procedure should be terminated.

1. Procedure Preparation

a. Perform a procedure baseline echocardiogram.

b. Cannulate a peripheral artery with a vascular introducer sheath for coronary artery injections.

c. Cannulate the right internal jugular vein with a 10F vascular introducer sheath. Do not use a different vein for access as the additional vasculature curvature may impact implant delivery or recapture.

d. Administer heparin to the patient and maintain adequate heparinization throughout the procedure according to standard interventional cardiology anticoagulation protocols for diagnostic catheterization procedures.

e. Perform baseline left and right coronary arteriograms to:

   i. Evaluate relevant arterial disease
   ii. Record the baseline arterial dimensions and flow patterns
   iii. Record the CS ostium location during the venous phase of the injection
   iv. Assess the venous dimensions to ensure it is not atretic and incapable of accommodating a Carillon device.

2. Coronary Venous Access

a. Attach a rotating hemostatic valve (RHV) to a 6F (2.0 mm) or 7F (2.3 mm) outer diameter shaped diagnostic catheter (e.g., MPA-1 or MPA-2) and flush the catheter with heparinized saline.

b. Insert a 0.035” (0.89 mm) soft tip guidewire through the RHV and into the diagnostic catheter.

c. Attach a rotating hemostatic valve to the straight port of the Carillon (3.2 mm) outer diameter delivery catheter and flush the catheter with heparinized saline.

d. Insert and advance the diagnostic catheter/wire assembly through the RHV on the Carillon delivery catheter.

e. Insert the entire access assembly through the 10F venous introducer sheath.

f. Cannulate the coronary sinus (CS) using the telescoping system of the Carillon delivery catheter, 6F or 7F shaped diagnostic catheter, and soft tip guidewire. Use the venous phase of a previous arteriogram as an angiographic guide for cannulation of the CS ostium.

g. Advance the guidewire through the CS and GCV into the anterior interventricular vein (AIV).

h. Advance the diagnostic catheter over the guidewire to the GCV/AIV junction.

i. Advance the Carillon delivery catheter over the diagnostic catheter to the GCV/AIV junction.

j. Remove the diagnostic catheter and guidewire from the Carillon delivery catheter.

k. Confirm bleed back through the Carillon delivery catheter, indicating a luminal position of the catheter tip. If necessary, withdraw the delivery catheter until bleed back occurs.

l. When cannulation of the coronary sinus using a diagnostic catheter is not possible, load a 7F (2.3 mm) outside diameter deflectable catheter through the RHV into the Carillon delivery catheter. Cannulate the CS with the 7F deflectable catheter. If the tip of the delivery catheter is causing venous wall tenting, then retract the delivery catheter to expose the deflectable tip catheter. Advance the 7F deflectable catheter to the GCV/AIV junction. Advance the Carillon delivery catheter over the 7F deflectable catheter to the GCV/AIV junction. Remove the 7F deflectable catheter from the Carillon delivery catheter. Confirm bleed back through the Carillon delivery catheter, indicating a luminal position of the catheter tip. If necessary, withdraw the delivery catheter until bleed back occurs.

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3. Implant Target Location and Implant Selection

a. Carefully remove the sizing catheter from its packaging to avoid kinking. Advance the sizing catheter through the RHV and align its distal radiopaque band with the delivery catheter distal radiopaque band.

b. Perform a small volume, low-pressure contrast venogram through the Carillon delivery catheter to verify that the catheter tip is not located in a vein side branch or occluding the vein lumen. Retract the Carillon delivery catheter, if necessary. If the catheter position is appropriate, perform and record a contrast venogram through the delivery catheter to opacify the venous anatomy, noting the position of the GCV/AIV junction, the CS ostium, and to determine the combined length of the CS/GCV. Venograms should be recorded in projections sufficient to visualize vein geometry. Consider LAO/caudal, RAO/caudal and AP/caudal. The final arteriogram and venogram should be in the LAO/caudal (or AP/caudal) position such that the fluoroscopy screen can be marked for anchor positioning. The table or image intensifier should not be moved until the Carillon Mitral Contour System has been completely unsheathed and locked.

c. If the CS ostium is inadequately visualized with the venogram performed from the GCV, consider repeating the venogram with the Carillon delivery catheter in the CS.

d. If the Carillon delivery catheter needs to be advanced in order to be closer to the GCV/AIV junction, first remove the sizing catheter and reinsert the diagnostic catheter and guidewire (or deflectable catheter) into the Carillon delivery catheter. Do not advance a stiff wire, diagnostic catheter, or deflectable catheter tip out of the Carillon delivery catheter into the GCV. Instead, retract the Carillon delivery catheter to expose the working length of the smaller catheter. Then advance the smaller catheter to the AIV junction, advance the Carillon delivery catheter over the smaller catheter to the AIV, and remove the smaller catheter. Reinsert the sizing catheter and align its distal radiopaque band with the delivery catheter distal radiopaque band.

CAUTION: Always advance the Carillon delivery catheter over a 6F or 7F diagnostic or deflectable catheter.

e. Perform arteriograms, in RAO and LAO caudal views with the sizing catheter positioned in the Carillon delivery catheter to determine the relationship of the coronary arteries to the CS/GCV. Loosen the RHV and remove the sizing catheter.

f. Implant target zones are determined by considering available vein length, vein geometry, location of venous side branches, venous valves, venous tortuosity, dynamic venous compression, location of coronary arteries, and location of coronary artery stents.

g. Use the fluoroscopic projection and venogram frame or frames yielding the largest vein diameters to measure the vein diameters in the implant target zones. Compute the average of 3 equally spaced diameter measurements to determine the average GCV diameter in the 1.5 cm - 2 cm distal anchor target zone (Figure 5). If venograms from complementary projections suggest an ovalized vein, consider averaging vein diameters from these complementary projections to account for asymmetric venous anatomy. Determine the CS diameter at three positions over a 2 cm proximal anchor target zone. Mark the monitor screen (Figure 6) to indicate the distal anchor and proximal anchor targets.

NOTE: Do not move the table or the image intensifier once the monitor screen has been marked or ensure that the table and image intensifier can be returned to the precise position as present when the monitor is marked. Consider using anatomical landmarks to aid in returning the table and image intensifier to the original location, when necessary.

i. Do not place a distal anchor in a vein segment with an average diameter of less than 3.5 mm.

ii. Do not place a proximal anchor apex at a vein location with a diameter of greater than 13.5 mm.

iii. The distal end of the distal anchor must be placed at least 9 cm from the CS ostium.

CAUTION: If the delivery catheter causes a localized vein distention, do not measure the vein diameter at the distended location.

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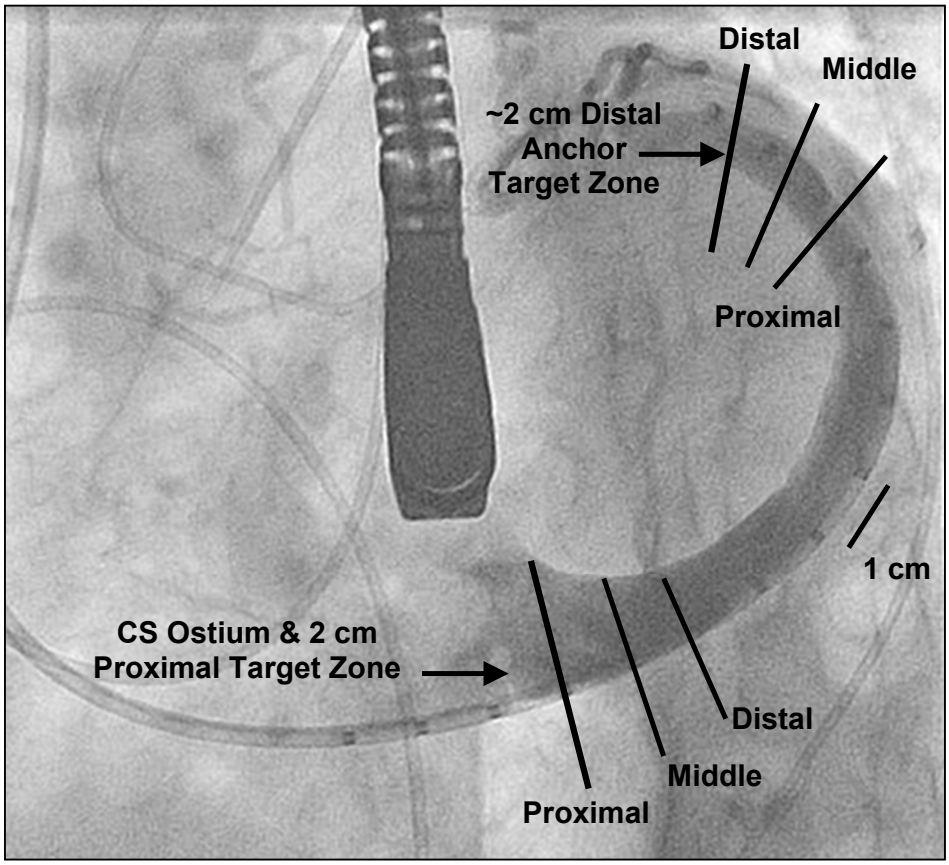

Figure 5: GCV/CS Venogram – Vein Sizing

Figure 6: Example of Marked Monitor Screen for Anchor Placement

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h. Select an appropriate implant based on vein diameters and available vein length. Available vein length is determined by total vein length (CS ostium to GCV/AIV junction), vein diameters, vein geometry, and relevant arterial anatomy. Available vein length may be less than total vein length.

Table 1 contains the anchor sizing recommendations. The recommendations for choosing an implant length are as follows:

- If available vein length is ≤ 12 cm, use a 60 or 70 mm length implant for the first attempt
- If available vein length is ≥ 13 cm, use an 80 mm length implant for the first attempt, unless placement of the distal anchor is less than 12cm from CS ostium (for example, to avoid a coronary artery)
- Note that implants with 13 or 14 mm distal anchors are available only in 70 or 80 mm lengths
- A shorter device may be selected to minimize crossing of the coronary artery, which might include placing the distal anchor at a position in the vein away from the GCV/AIV junction. This may be done provided there is at least 9 cm of vein length from the distal anchor target Zone to the CS ostium. Placing the distal anchor more proximally in this manner may diminish the need for recapture and risk of venous trauma.

Table 1: Carillon Implant Anchor Sizing Recommendations

Average GCV Diameter in the Distal Anchor Target Zone (mm)	Distal Anchor (GCV) Height (mm)	Average CS Diameter in the Proximal Anchor Target Zone (mm)	Proximal Anchor (CS) Height (mm)
3.5 – 3.9	7	6.0 – 6.9	12
4.0 – 4.4	8	7.0 – 7.9	14
4.5 – 4.9	9	8.0 – 8.9	16
5.0 – 5.6	10	9.0 – 10.9	18
5.7 – 6.3	11	11.0 – 13.5	20
6.4 – 7.2	12		
7.3 – 7.8	13		
7.9 – 8.4	14		

4. Device Implantation

a. Carefully remove the handle assembly and cartridge from the packaging tray and do not allow the cartridge to move relative to the handle. Ensure the implant remains sheathed in the cartridge and that it is not advanced out of the cartridge prematurely. If the implant becomes partially unsheathed during handling, that system should be discarded and a new system should be used.

b. After removal of the handle assembly and cartridge from the packaging, rotate the sheath locking knob in a clockwise direction, opposite the black locking arrow (Figure 7), ensuring the proximal locking sheath is fully retracted.

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Figure 7: Counter-Rotating the Sheath Locking Knob

c. Remove the RHV from the straight port of the Carillon delivery catheter and connect the male luer at the distal end of the cartridge to the delivery catheter by rotating the cartridge (Figure 8). Note: Minimize rotating the handle assembly while connecting the cartridge to the handle.

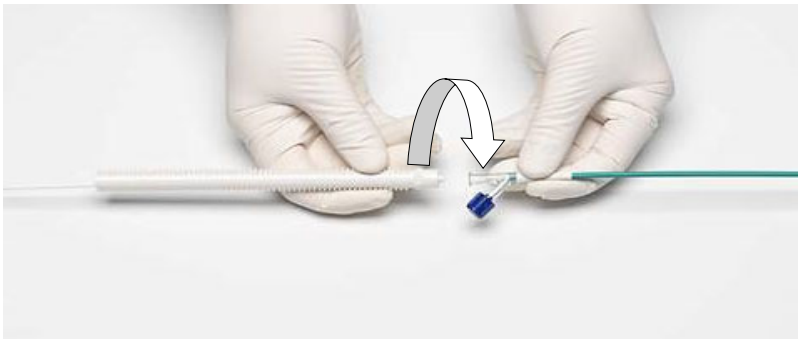

Figure 8: Connecting the Cartridge to the Straight Port of the Delivery Catheter

d. Advance the implant out of the cartridge and into the delivery catheter by manually advancing the sheath/pusher assembly at the proximal end of the cartridge. Push in small increments (1cm - 2 cm increments) so as not to kink the sheath/pusher assembly (Figure 9). Continue to advance the sheath/pusher assembly until the handle and cartridge come together.

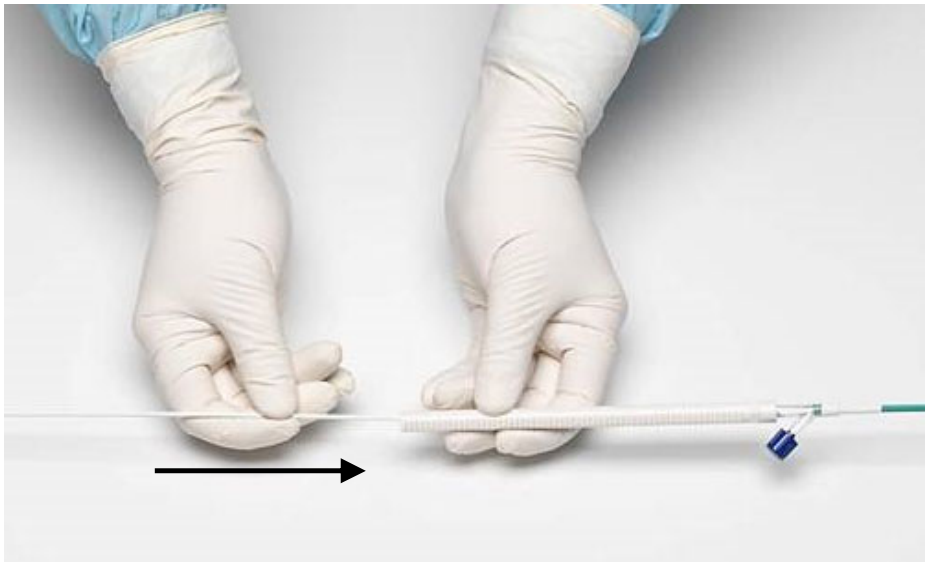

Figure 9: Advancing the Implant into the Delivery Catheter

e. Insert the proximal end of the cartridge into the distal socket of the handle and rotate the control knob in the direction indicated by the black arrow to engage the cartridge. Ensure that the delivery catheter remains in a fixed position at the introducer sheath while rotating

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the control knob and engaging the cartridge. Stop rotating the control knob once the proximal end of the cartridge is visible in the cartridge window (Figure 10).

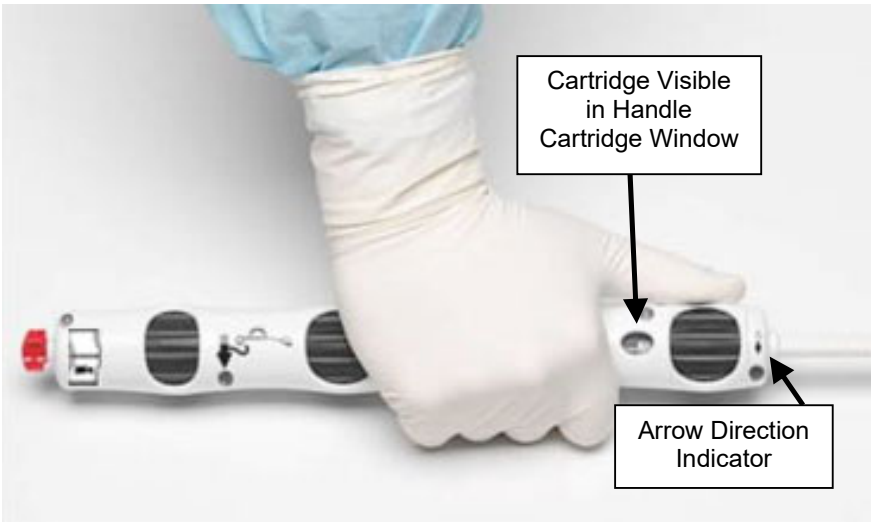

Figure 10: Cartridge is Visible in the Handle Cartridge Window

ATTENTION: The remaining device implantation steps (f-p) must be performed with fluoroscopic guidance.

f. Using fluoroscopy (and/or cinefluoroscopy), confirm correct distal anchor orientation prior to unsheathing the distal anchor from the delivery catheter. The diversion bump should be closer to (and pointing towards) the inner curvature of the delivery catheter (Figure 11a). If the diversion bump is closer to (and pointing towards) the outer curvature of the delivery catheter (Figure 11b), then the distal anchor is incorrectly oriented, and the distal anchor should not be deployed.

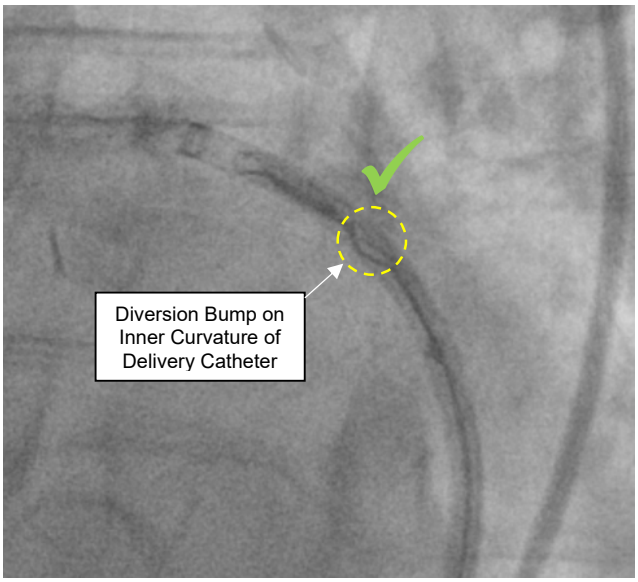

Figure 11a: Correct Distal Anchor Orientation

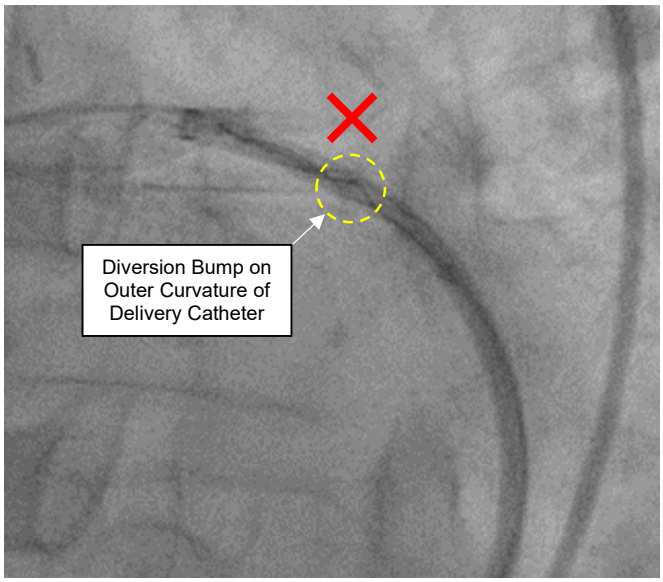

Figure 11b: Incorrect Distal Anchor Orientation

If a distal anchor with incorrect orientation is inadvertently unsheathed from the delivery catheter, recapture the implant. See Step 5 – Implant Recapture.

g. Deploy the distal anchor in the target location in the GCV by rotating the control knob in the direction indicated by the black arrow until the distal anchor is exposed. Typically, it is necessary to gently pull back on the handle and delivery catheter with the left hand during rotation of the control knob to accurately deliver the distal anchor to the target location.

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Continue to rotate the control knob in the same direction until the distal anchor eyelet is completely out of the delivery catheter (Figure 12).

Figure 12: Rotating the Control Knob to Deploy the Distal Anchor

h. Lock the distal anchor at the target location by rotating the control knob in the direction indicated by the white arrow until the delivery catheter pushes the eyelet flush against the distal crimp tube. Retract the delivery catheter by rotating the control knob in the direction indicated by the black arrow to verify that the distal anchor eyelet remains flush against the distal crimp tube in the locked position. If necessary, rotate the control knob in the direction of the white arrow to advance the delivery catheter again for another attempt at locking.

CAUTION: Once the distal anchor is locked, additional rotation of the control knob in the direction of the white arrow will cause the delivery catheter to begin recapturing the anchor.

WARNING: If the distal anchor struts are inadvertently collapsed by over advancement of the delivery catheter to the distal anchor twist, recapture and remove the entire implant. See Step 5 – Implant Recapture

i. Arteriograms may be performed as needed, to assess the arterial dimensions and flow in the region around the implant. If there is a significant impact on arterial dimensions or flow that is not resolved by adjusting tension on the system, recapture and remove the implant (See Step 5 – Implant Recapture).

NOTE: Consider administration of intracoronary nitroglycerine to rule out vessel spasm whenever coronary compromise due to the implant is suspected.

j. Retract the delivery catheter to the distal end of the proximal anchor crimp tube by rotating the control knob in the direction indicated by the black arrow. To ensure the proximal anchor remains sheathed in the delivery catheter, only rotate the control knob until ~2 cm of exposed thread length is visible on the cartridge.

k. Place gradual tension on the implant by gently pulling on the handle assembly and/or the Carillon delivery catheter while stabilizing the venous introducer sheath. Continue slowly pulling tension until the proximal anchor crimp tube is at the proximal anchor target location (demarcated on the fluoroscopy screen) in the CS as guided by fluoroscopy.

l. Do not pull the proximal anchor crimp tube into the right atrium. The venous phase of an arteriogram may help confirm that the proximal anchor remains in the coronary sinus. Alternatively, contrast may be injected through the side-port of the delivery catheter to assess the position of the proximal anchor's crimp tube relative to the CS anatomy. Careful attention must be made to ensure that the tension in the system is not altered during these maneuvers.

NOTE: Before unsheathing and deploying the proximal anchor, perform arteriograms as needed to assess relevant arterial dimensions and flow. If there is a significant impact on arterial dimensions or flow which is not relieved by partial release of tension, then release the tension on the implant to restore arterial dimensions. The implant should then be

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recaptured in accordance with Step 5 – Implant Recapture. If the coronary vessels are obscured by any portion of the Carillon device, consider performing arteriograms in an alternative projection, such as RAO caudal, to adequately visualize coronary vessels and flow. This maneuver requires careful planning to ensure that the location of the table and image intensifier are returned to the same position when returning from the RAO caudal to the LAO caudal position, to allow the proximal anchor to be placed in the intended location.

NOTE: If the distal anchor slips during tensioning, recapture and remove the implant (See step 5 – Implant Recapture). Repositioning of the implant should not be considered. However, a new Carillon Mitral Contour System may be considered if appropriate.

m. While maintaining tension on the handle assembly and/or the Carillon delivery catheter, deploy the proximal anchor at the target position in the CS by rotating the control knob in the direction indicated by the black arrow. Adjust tension as needed to keep the proximal anchor at the target position. Continue to rotate the control knob until no more rotations are possible (Figure 13).

Figure 13: Rotating the Control Knob to Deploy the Proximal Anchor

n. Lock the proximal anchor at the CS target location by rotating the sheath knob in the direction indicated by the locking arrow until the sheath pushes the proximal anchor eyelet flush against the proximal crimp tube. Retract the sheath by rotating the sheath knob in the reverse direction, opposite the locking arrow. Verify that the proximal anchor eyelet remains against the proximal crimp tube in the locked position. To better visualize and confirm proximal anchor locking, consider viewing the proximal anchor in an LAO cranial projection. If necessary, rotate the sheath knob in the direction of the lock arrow to advance the sheath again for another attempt at locking (Figure 14).

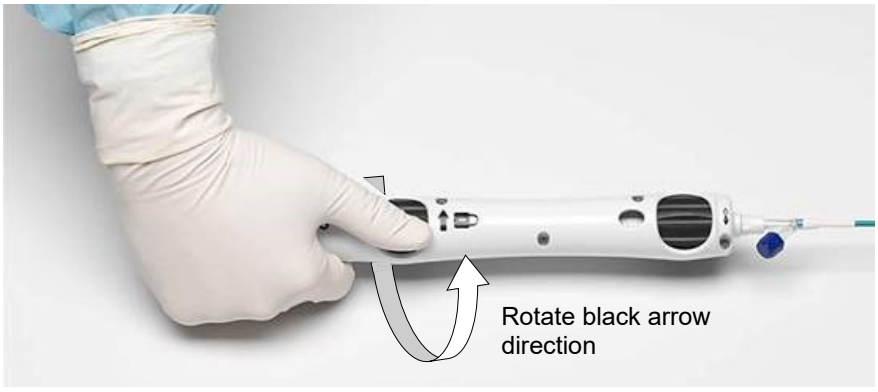

Figure 14: Rotating the Sheath Knob to Lock the Proximal Anchor

o. Remove any external tension on the system by gently advancing the delivery catheter at the introducer sheath. Confirm that when excess external system tension is relieved the implant does not migrate or change position in the CS/GCV.

p. Prior to decoupling the implant from the handle assembly, perform each of the following steps:

   i. Assess hemodynamics and patient stability.

   ii. Perform arteriograms to confirm no significant impact on the left and right coronary arteries.

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WARNING: If placement of the implant causes a significant change in the electrocardiogram (ECG), recapture and remove the implant.

WARNING: If placement of the implant causes a significant reduction in the coronary arterial dimensions of a clinically significant artery, recapture and remove the implant. Confirm a return to baseline arterial dimensions.

iii. Confirm both anchors are locked by utilizing multiple fluoroscopic views.

Examples of locked and unlocked anchors are shown in Figures 15a through 15d.

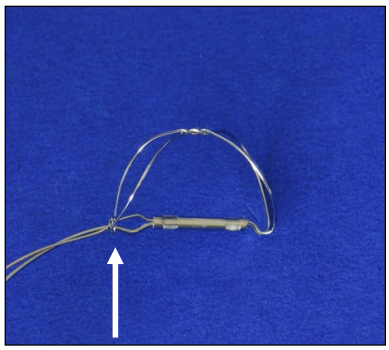

Figure 15a: Unlocked Distal Anchor

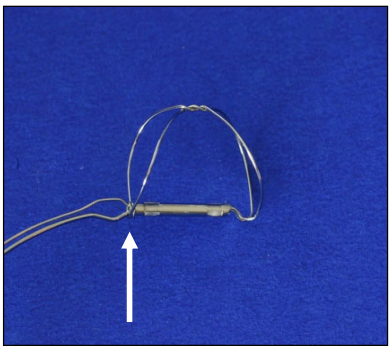

Figure 15b: Locked Distal Anchor

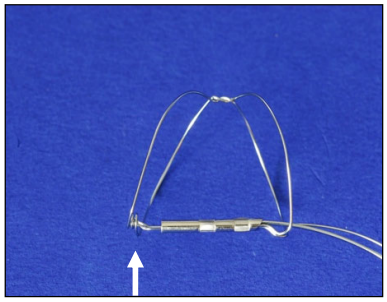

Figure 15c: Unlocked Proximal Anchor

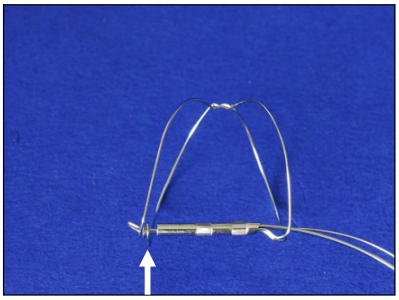

Figure 15d: Locked Proximal Anchor

iv. Echocardiogram may be used to quantify MR reduction.

WARNING: The implant cannot be recaptured with the handle assembly once it is decoupled from the handle assembly.

v. Consider recapturing and removing the implant if the final location of the implant is not in the intended coronary sinus anatomy, or if the implant anchor wireforms appear severely misshaped (See Step 5 – Implant Recapture).

q. To decouple the implant from the delivery system, turn the red release safety in the direction of the arrow and remove the safety from the handle (Figure 16). Then rotate the release knob in the direction indicated by the decouple arrow until the implant is completely separated from the handle assembly (Figure 17).

r. **Note**: Do not rotate the implant release knob in the opposite direction of the arrow at any time during the procedure.

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Figure 16: Rotating and Removing the Release Safety

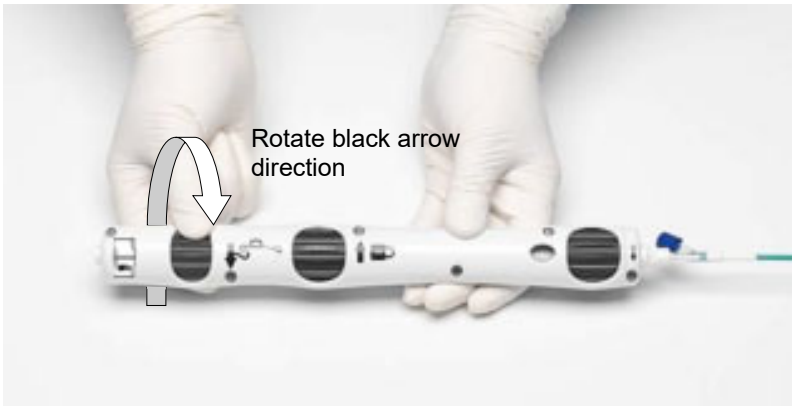

Figure 17: Rotating the Release Knob to Decouple the Implant from the Handle Assembly

s. Withdraw the handle assembly and attached Carillon delivery catheter out of the venous introducer sheath. Do not advance the system once the implant has been decoupled.

t. Remove the delivery system.

5. Implant Recapture

If clinical circumstances warrant, the implant may be recaptured and removed from the coronary vein **prior** to decoupling from the handle assembly. Recapture and remove the implant if implant performance, appearance or final location is unsatisfactory.

a. If the proximal anchor has been deployed, rotate the sheath knob (middle knob) in the direction indicated by the lock arrow until the sheath has pushed the anchor eyelet against the proximal anchor crimp tube. Do not over tighten. Then proceed to (b). If the proximal anchor has not been deployed proceed directly to (d).

b. Rotate the control knob in the direction indicated by the white arrow to advance the Carillon delivery catheter over the proximal anchor wire forms (Figure 18). After capture of the proximal anchor, the system (implant/handle and delivery catheter) should be advanced gently to remove the tension.

c. Next, retract the catheter approximately 1 cm by rotating the control knob in the direction indicated by the black arrow, exposing the tip of the proximal anchor wire forms beyond the tip of the delivery catheter. This is done to “normalize” or remove any inversion of the tip of the delivery catheter prior to capturing the distal anchor.

d. To recapture the distal anchor, rotate the control knob in the direction indicated by the white arrow to advance the Carillon delivery catheter over the remainder of the implant. Prevent excess tension on the system during recapture by manually advancing the delivery catheter at the introducer sheath while rotating the control knob. Tension on the system can be monitored by the location of the proximal anchor crimp tube with respect to cardiac anatomy.

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Figure 18: Rotating the Control Knob to Recapture the Implant

NOTE: If significant resistance is encountered while trying to recapture an anchor, retract the catheter approximately 2 cm from the anchor by rotating the control knob in the direction indicated by the black arrow. Place tension on the handle assembly or Carillon delivery catheter to straighten the angle between the delivery catheter and the anchor. Then rotate the control knob in the direction indicated by the white arrow to advance the delivery catheter to initiate recapture of the anchor. Once the anchor begins to collapse, release the extra tension on the system by manually advancing the delivery catheter at the introducer sheath. Then continue rotating the control knob to complete the recapture.

e. Once the entire implant is inside the Carillon delivery catheter, disconnect the cartridge from the delivery catheter and stabilize the delivery catheter. Pull on the handle assembly to withdraw the implant completely out of the delivery catheter, thus leaving the used delivery catheter in the coronary vein and maintaining coronary venous access. A venogram may be done to assess for a venous dissection. Alternatively, once the entire implant is inside the delivery catheter, withdraw the handle assembly and delivery catheter together through the venous introducer sheath.

WARNING: If a venogram shows evidence of a clinically significant venous dissection or perforation following recapture, do not attempt to place an additional implant.

WARNING: If clinically significant denuded venous tissue is observed on a component of the Carillon Mitral Contour System following recapture, do not attempt to place an additional implant. Monitor the patient for pericardial effusion.

f. If an additional implant procedure attempt is planned, repeat the implant procedure with a new delivery catheter, handle assembly, and implant. Components of the Carillon Mitral Contour System are single use only. If the delivery catheter was left in the coronary vein after recapture, use an appropriate exchange length guidewire (e.g., a 0.035” (0.89 mm) soft tip guidewire) to remove the used catheter and bring in a new Carillon delivery catheter over a diagnostic catheter for the next procedure attempt. Repeat the implant procedure beginning with Section 3.

X. Follow-up Procedures

The following patient assessments are recommended post-implant:

- Chest X-ray or cinefluoroscopy to assess proper position and integrity of the implant
- Echocardiogram to assess left ventricular function and mitral regurgitation
- Echocardiogram to assess potential myocardial ischemia
- Patient history to assess for symptoms of ischemia

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XI. Magnetic Resonance Imaging (MRI) Compatibility: MR Conditional

Non-clinical testing has demonstrated the Carillon Mitral Contour System implant is MR Conditional. A patient with this device can be safely scanned under the following conditions:

- Static magnetic field of 3 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results (including the effect of blood perfusion) indicate the Carillon Mitral Contour System is expected to produce a maximum temperature rise of less than 3.2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Carillon Mitral Contour System when imaged with a gradient echo pulse sequence and a 3 T MR system.

XII. Sterilization

The implant / handle assembly, delivery catheter, and sizing catheter are provided sterile and non-pyrogenic. The delivery catheter and sizing catheter are packaged separately. All system components are sterilized with ethylene oxide and are for SINGLE USE ONLY—DO NOT RESTERILIZE. Do not use if the package is opened or damaged.

XIII. Storage Conditions and Disposal

Store all Carillon Mitral Contour System components in their shelf boxes in a location that is cool, dry, and away from direct sunlight.

Do not use after the use by date.

Institutional procedures and regional specific regulations for post procedure disposal of medical devices contaminated with potentially infectious substances of human origin should be followed.

XIV. Summary of Safety and Clinical Performance

The Summary of Safety and Clinical Performance (SSCP) for the Carillon Mitral Contour System (Unique Device Identification / Basic UDI-DI 081983302CarillonB5) is available on the European database website on medical devices (EUDAMED) https://ec.europa.eu/tools/eudamed and on the Cardiac Dimensions website https://cardiacdimensions.com/SSCP.

XV. Definitions

The symbols used on the Carillon implant / handle assembly and their definitions are listed below:

Symbol	Definition
	Consult instructions for use
	Control symbol
	Lock symbol
	Release symbol

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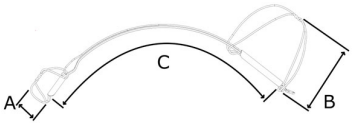
The symbols on the Carillon Mitral Contour System package labels and their definitions are listed below:

Symbol	Definition
	Do not reuse - Single use
	Do not use if package is damaged
	Use-by date
	Sterilized using ethylene oxide
	Lot number / Batch code
	Catalogue number
http://www.cardiacdimensions.com /physicians/instructions-for-use/	Consult electronic instruction for use (eIFU)
	Manufacturer
	MR conditional
	Keep dry
	Keep away from sunlight
	A – Implant Distal Anchor Height B – Implant Proximal Anchor Height C – Implant Overall Length
	Medical Device
	Do not resterilize
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system
	Caution – Consult instructions for use for important cautionary information.
	Importer
	Unique Device Identifier

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Symbol	Definition
	Healthcare institution/provider
	Date of implantation
	Patient information website
	Patient identification
EC REP	Authorized Representative in the European Community / European Union
CH REP	Authorized Representative in Switzerland
CE	Conformité Européenne - product meets the essential requirements of all relevant European Medical Device Directives

XVI. Manufacturer

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Patents: http://www.cardiacdimensions.com/company/IP.html

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