CARILLON® Mitral Contour System™ (XE2)

Instructions for Use

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ORIGINAL

INSTRUCTIONS FOR USE
Cardiac Dimensions®, Inc. CARILLON® Mitral Contour System™ (XE2)

I. System Description

The Cardiac Dimensions®, Inc. CARILLON® Mitral Contour System™ (XE2) is a class III medical device and consists of the following components:

1) A proprietary implant intended for permanent placement in the coronary sinus (CS)/great cardiac vein (GCV)
2) A catheter-based delivery system which consists of a custom curved 9F (3.0mm outer diameter) delivery catheter and a handle assembly

The implant is attached to the handle assembly and is delivered through the delivery catheter to the coronary vein along the posterolateral aspect of the mitral annulus. The implant is designed to re-shape the mitral annulus in order to reduce annular dilation and mitral regurgitation.

The specific components of the CARILLON® Mitral Contour System™ are described as follows.

- **Implant**

  The XE2 implant is made of nitinol and titanium and is manufactured in different lengths and with different anchor sizes to accommodate individual venous anatomy. 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 1.1). The implant is designed to be deployed, tensioned, and secured in the coronary vein.

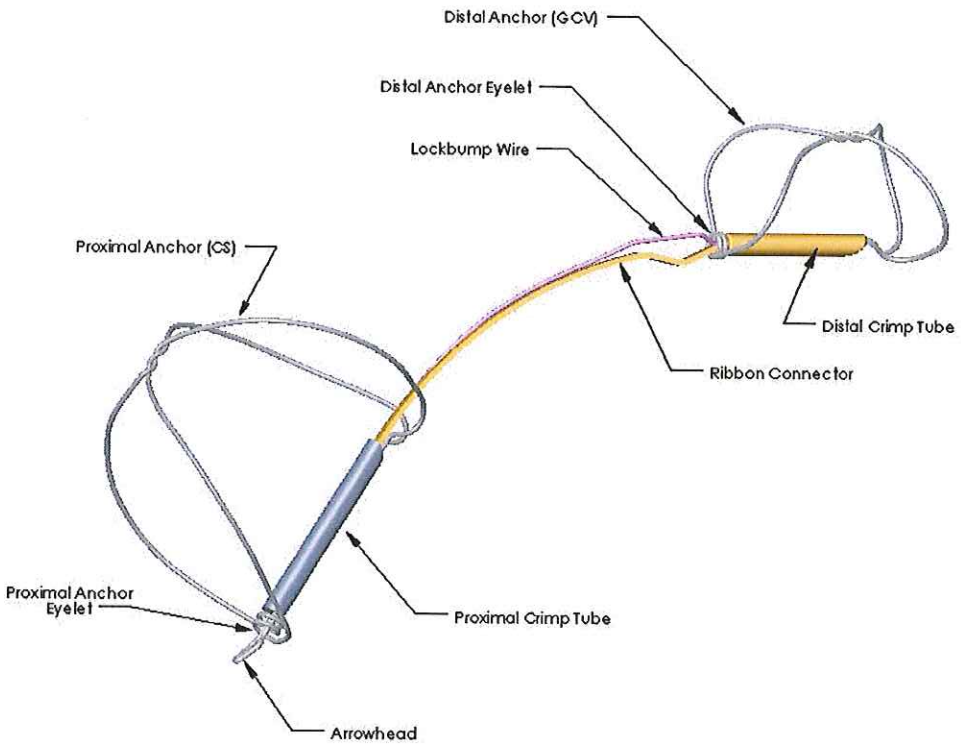


Figure 1.1: CARILLON® XE2 Implant

ORIGINAL

- **Delivery System**

  Delivery Catheter:

  The delivery catheter facilitates percutaneous entry of a marker 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 9F (3.0 mm) outer diameter and 70 cm effective length. 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 (Figure 1.2).

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

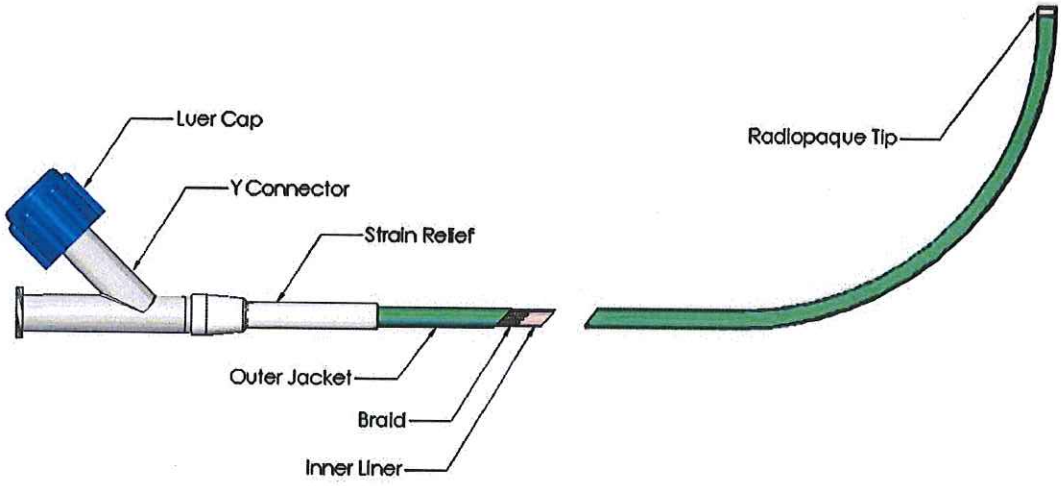


Figure 1.2: CARILLON® Delivery Catheter

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 1.3). 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.

- 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. The release safety must be removed prior to decoupling the implant from the handle assembly.

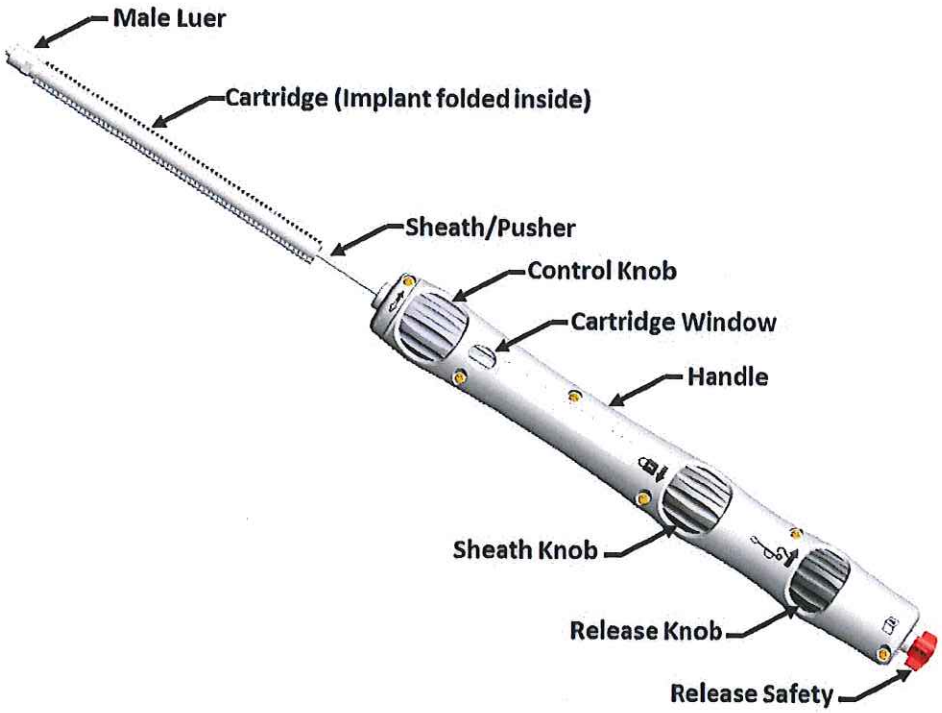


Figure 1.3: CARILLON® Handle Assembly

II. Indications for Use

The CARILLON® Mitral Contour System™ is indicated for use in patients with functional mitral regurgitation.

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 a mitral annuloplasty ring implant

IV. User Requirements

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 system.

Implant placement should only be performed at institutions where emergency surgery can be readily arranged.

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 DA twist, recapture and remove the entire implant. See Step 5 – Implant Recapture.
- 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.
- 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, recapture and remove the implant. Confirm a return to baseline arterial dimensions.

VI. Risks

The CARILLON® Mitral Contour System™ procedure will require coronary angiography and, as such, the risks associated with the CARILLON® Mitral Contour System™ procedure include those risks associated with diagnostic coronary angiography as well as those risks associated with the delivery, permanent placement, and recapture of the CARILLON® implant in the coronary venous system.

The potential risks associated with the CARILLON® Mitral Contour System™ procedure include, but are not limited to:

- Allergic reaction
- Angina pectoris
- Aortic stenosis
- Bleeding
- Cardiac arrhythmia
- Cardiac tamponade
- Carotid artery trauma
- Chronic nerve damage
- Death
- Denudation of venous tissue

- Dissection, perforation, or rupture of a coronary vessel
- Embolism of air, tissue, device or thrombus
- Hematoma
- Hemodynamic deterioration
- Implant fracture
- Inability to permanently place the implant
- Infection
- Inflammation
- Lack of mitral regurgitation reduction
- Loss of mitral regurgitation reduction
- Mitral stenosis
- Myocardial infarction
- Myocardial ischemia
- Occlusion of a coronary vessel
- Pericardial effusion
- Pneumothorax
- Prolonged exposure to fluoroscopic radiation
- Renal failure
- Stroke
- Surgical removal of the implant
- Tissue necrosis
- Tissue penetration
- Transient ischemic attack
- Vasovagal reaction
- Vessel erosion
- Vessel spasm

VII. Precautions

General Precautions

- Store all CARILLON® Mitral Contour System™ components in their shelf boxes in a location that is cool and dry.
- Inspect packaging prior to use. Do not use a component if its peel pouch is damaged or opened or if the contents appear to be damaged.

- **For SINGLE USE ONLY.** Do not re-sterilize or reuse the implant, delivery catheter, or handle assembly. Resterilization or cleaning may impair performance of the CARILLON® Mitral Contour System™. Reuse may result in implant fracture or deformation. Reuse may also compromise deployment, recapture and anchor locking strength. Do not autoclave.
- 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

- 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. With respect to coronary sinus interventions, a waiting period of three - six (3 - 6) months post-implant is recommended to allow for full encapsulation of the implant.
- Patients with known conduction system disease, especially left bundle branch block, should be considered for temporary transvenous RV 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 mitral regurgitation reduction.

Precautions Specific to Implant Procedure

- Implant placement should only be performed at institutions where emergency cardiac surgery can be readily arranged.
- Only cannulate the right internal jugular vein for introducing the CARILLON® Mitral Contour System™.
- The distal end of the distal anchor must 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 9F delivery catheter over a 7F outer diameter catheter such as a multi-purpose angiographic (MPA) diagnostic catheter or deflectable catheter.
- Follow standard interventional cardiology anticoagulation protocols when using the CARILLON® Mitral Contour System™.
- Minimize bending 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 which may compromise the integrity of 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 MR is not reduced, if final location of the implant is not in the intended coronary sinus anatomy, or if implant anchor wireforms appear severely misshaped.
- Do not reuse a delivery catheter, handle assembly, or implant for an additional implant procedure attempt.

Precautions Specific to Post-Procedure Care

- Employ proper access site management post procedure and post hospital discharge to prevent infection.

VIII. Implant Procedure

WARNING: If the patient experiences prolonged third degree A-V block or asystole at any point during the procedure, terminate the procedure.

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 9F vascular introducer sheath. Do not use a different vein for access.

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

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

2. Coronary Venous Access

a. Attach a rotating hemostatic valve (RHV) to a 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 hydrophilic guidewire or other soft tip guidewire through the RHV and into the 7F diagnostic catheter.

c. Attach a rotating hemostatic valve to the straight port of the 9F (3.0 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 9F delivery catheter.

e. Insert the entire access assembly through the 9F venous introducer sheath.

f. Cannulate the coronary sinus (CS) using the telescoping system of the 9F delivery catheter, 7F shaped diagnostic catheter, and soft tip guidewire. Use the venous phase of a previous arteriogram as a guide to the CS ostium.

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

h. Advance the 7F diagnostic catheter over the guidewire to the GCV/AIV junction.

i. Advance the 9F delivery catheter over the 7F diagnostic catheter to the GCV/AIV junction.

j. Remove the 7F diagnostic catheter and guidewire from the 9F delivery catheter.

k. Confirm bleed back through the 9F delivery catheter, indicating a luminal position of the catheter tip. If necessary, withdraw the delivery catheter until bleed back occurs.

l. As an alternative coronary sinus access method, load a 7F (2.3 mm) outside diameter deflectable catheter (with or without guidewire lumen) through the RHV into the 9F delivery catheter. Cannulate the CS with the 7F deflectable catheter (and guidewire, if present). Advance the 7F deflectable catheter (over the guidewire, if present) to the GCV/AIV junction. Advance the 9F delivery catheter over the 7F deflectable catheter to the GCV/AIV junction. Remove the 7F deflectable catheter (and guidewire, if present) from the 9F delivery catheter. Confirm bleed back through the 9F delivery catheter, indicating a luminal position of the catheter tip. If necessary, withdraw the delivery catheter until bleed back occurs.

3. Implant Target Location and Implant Selection

a. Advance a graded marker wire or marker catheter (e.g., a 5F (1.7 mm) outer diameter centimeter sizing catheter or similar device) through the RHV and to the tip of the 9F delivery catheter for vein length and diameter measurements.

b. Perform a small volume, low-pressure contrast venogram through the 9F delivery catheter to verify that the catheter tip is not located in a vein side branch or occluding the vein lumen. Retract the 9F delivery catheter, if necessary. If the catheter position is appropriate, perform and record a contrast venogram through the delivery catheter to note 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.

   If the CS ostium is inadequately visualized with the venogram performed from the GCV, consider repeating the venogram with the 9F delivery catheter in the CS.

   Alternatively, perform the CS venogram in the LAO caudal projection prior to cannulation of the GCV. After the CS venogram, continue to cannulate the GCV as described in section 2.

c. If the 9F delivery catheter needs to be advanced in order to be closer to the GCV/AIV junction, first remove the graded marker device and reinsert the 7F diagnostic catheter and guidewire (or 7F deflectable catheter (and guidewire, if present)) into the 9F delivery catheter. Always advance the 9F delivery catheter over a 7F diagnostic or deflectable catheter.

> **CAUTION: Always advance the 9F delivery catheter over a 7F diagnostic or deflectable catheter.**

d. Perform arteriograms, as needed, with the graded marker device positioned in the 9F delivery catheter to determine the relationship of the coronary arteries to the CS/GCV. Remove the graded marker device.

e. Implant target zones are determined by considering available vein length, vein geometry, location of venous side branches, location of coronary arteries, and location of coronary artery stents.

f. 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 2 cm distal anchor target zone. If venograms from complementary projections suggest ovalized vein, consider averaging vein diameters from these complementary projections to account for asymmetric venous anatomy. Determine the CS diameter at two positions on either side of the proximal anchor apex target position and compute the average of these two measurements. Consider marking the monitor screen or using anatomical landmarks to indicate the distal anchor and proximal anchor targets.

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.

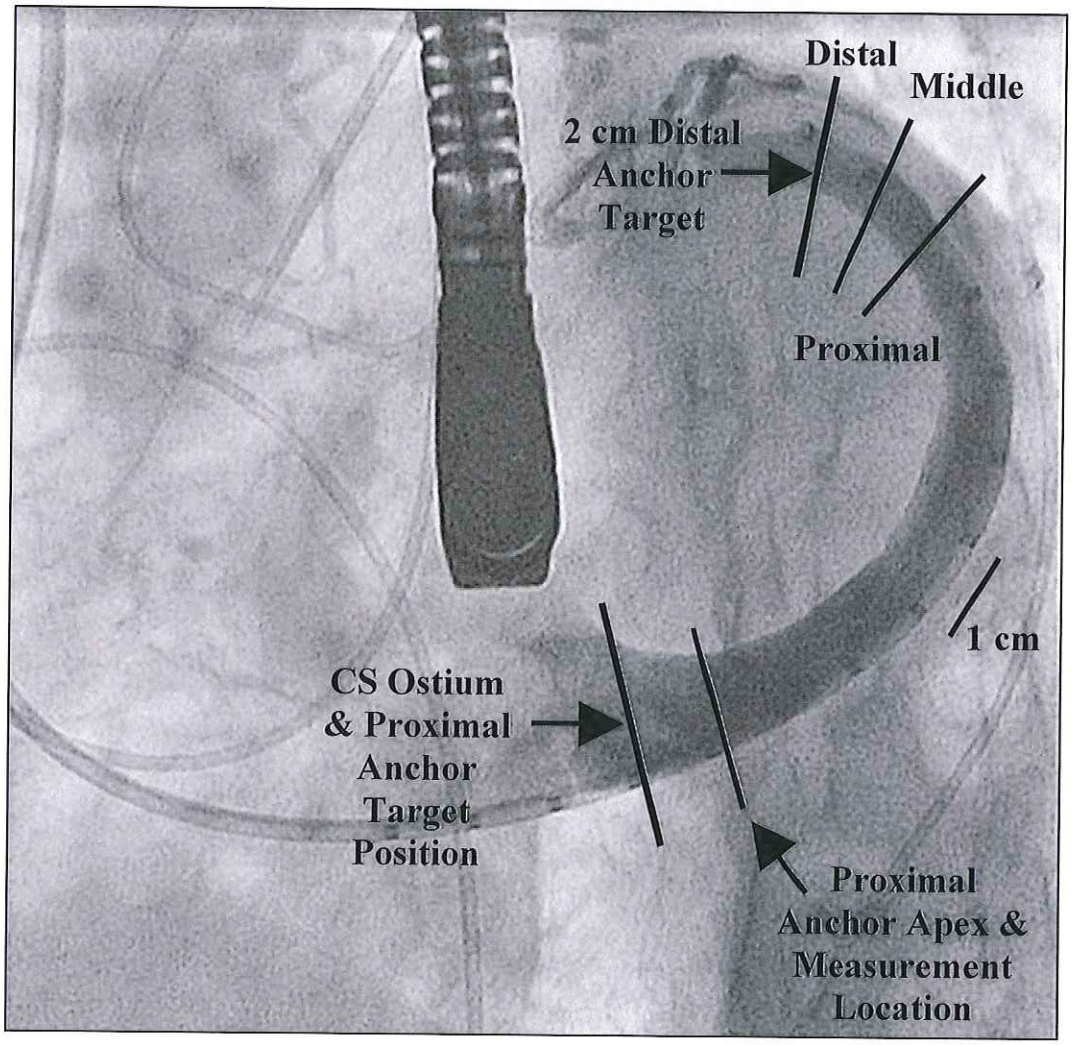


Figure 3.1: GCV/CS Venogram – Vein Sizing

g. 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.

   i. Table 3.1 contains the anchor sizing recommendations. However, individual vein geometry may require the use of an alternative anchor size for a given vein diameter.

   ii. 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 a 80 mm length implant for the first attempt
   - If additional implants attempts are made, either length may be chosen
   - Note that implants with 13 or 14 mm distal anchors are available only in 70 or 80 mm lengths.

Table 3.1: CARILLON® XE2 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. Remove the RHV from the straight port of the 9F delivery catheter and connect the male luer at the distal end of the cartridge to the delivery catheter (Figure 4.1).

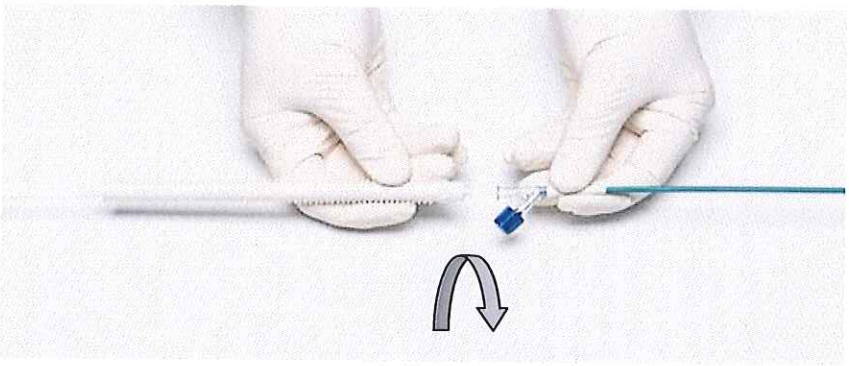


Figure 4.1: Connecting the Cartridge to the Straight Port of the Delivery Catheter

b. 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 so as not to kink the sheath/pusher assembly (Figure 4.2). Continue to advance the sheath/pusher assembly until the handle and cartridge come together.

Figure 4.2: Advancing the Implant into the Delivery Catheter

c. 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. Stop rotating the control knob once the proximal end of the cartridge is visible in the cartridge window (Figure 4.3).

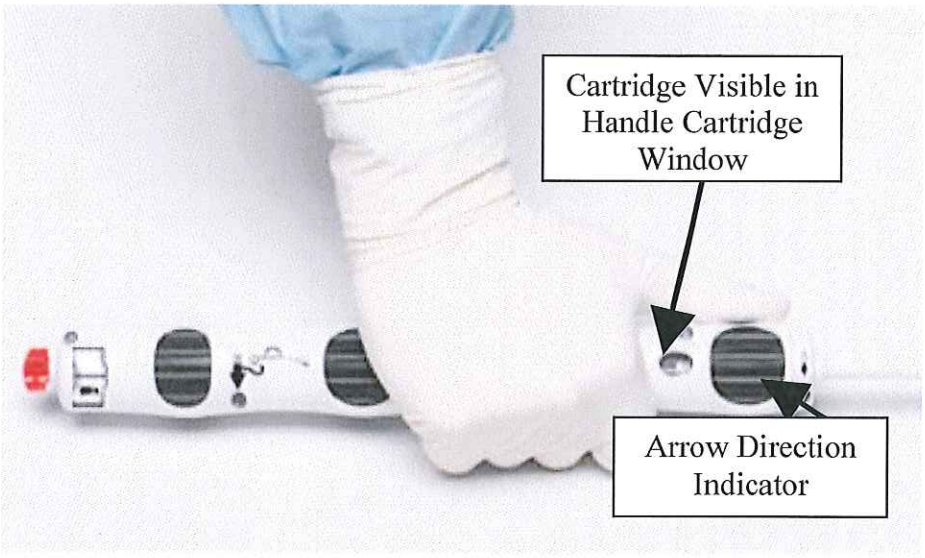


Figure 4.3: Cartridge is Visible in the Handle Cartridge Window

ATTENTION: The remaining Device Implantation steps (d-n) must be performed with fluoroscopic guidance.

d. 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. If necessary, gently pull back on the handle and delivery catheter during rotation of the control knob to accurately deliver the distal anchor to the target location. Continue to rotate the control knob in the same direction until the distal anchor eyelet is completely out of the delivery catheter (Figure 4.4).

Figure 4.4: Rotating the Control Knob to Deploy the Distal Anchor

e. 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 DA twist, recapture and remove the entire implant. See Step 5 – Implant Recapture

f. Perform arteriograms, 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 pulling 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.

g. Retract the delivery catheter to the distal end of the proximal anchor by rotating the control knob in the direction indicated by the black arrow.

h. Place gradual tension on the implant by gently pulling on the handle assembly and/or the 9F delivery catheter while stabilizing the venous introducer sheath. Pull the proximal anchor crimp tube toward the target location in the CS as guided by fluoroscopy and echocardiography. Do not pull the proximal anchor crimp tube into the right atrium. Use the venous phase of the arteriogram to help confirm that the proximal anchor remains in the coronary sinus. Alternatively, inject contrast through the side-port of the delivery catheter to assess the position of the proximal anchor's crimp tube relative to the CS anatomy.

NOTE: Perform arteriograms as needed to assess relevant arterial dimensions and flow. If there is a significant impact on arterial dimensions or flow not relieved by partial release of tension, then release the tension on the implant to restore arterial dimensions. Recapture and remove the implant.

NOTE: If the distal anchor slips during tensioning, recapture and remove the implant (See step 5 – Implant Recapture).

i. While maintaining tension on the handle assembly and/or the 9F 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 the eyelet is out of the delivery catheter or until no more rotations are possible (Figure 4.5).

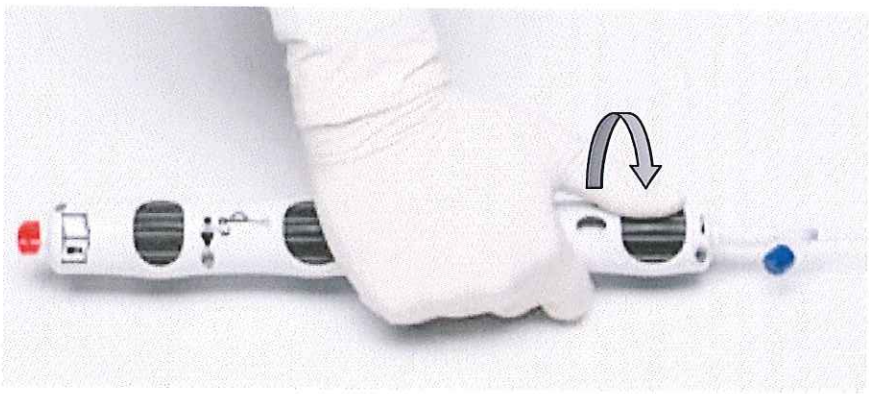


Figure 4.5: Rotating the Control Knob to Deploy the Proximal Anchor

j. Lock the proximal anchor at the CS target location by rotating the sheath knob in the direction indicated by the lock 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. Verify that the proximal anchor eyelet remains against the proximal crimp tube in the locked position. If necessary, rotate the sheath knob in the direction of the lock arrow to advance the sheath again for another attempt at locking (Figure 4.6).

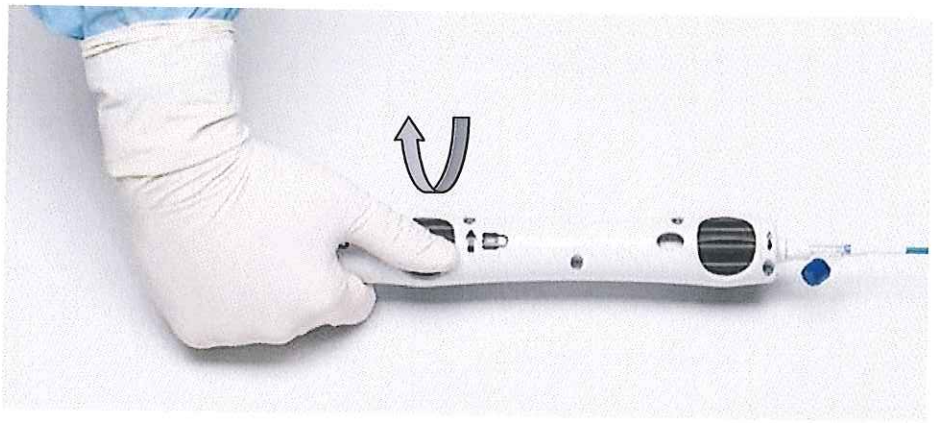


Figure 4.6: Rotating the Sheath Knob to Lock the Proximal Anchor

k. Remove external tension on the system by gently advancing the delivery catheter at the introducer sheath.

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

i. Assess hemodynamics and patient stability.

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

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 4.7 through 4.10.

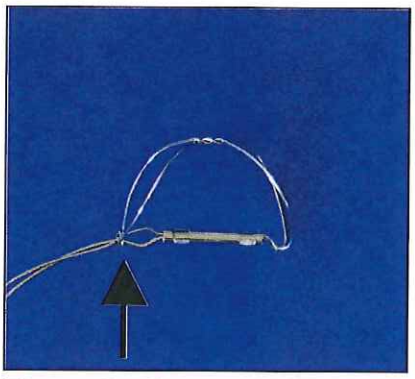


Figure 4.7: Unlocked Distal Anchor

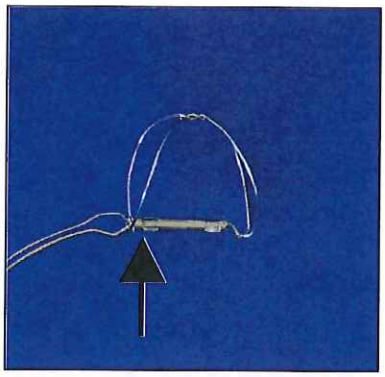


Figure 4.8: Locked Distal Anchor

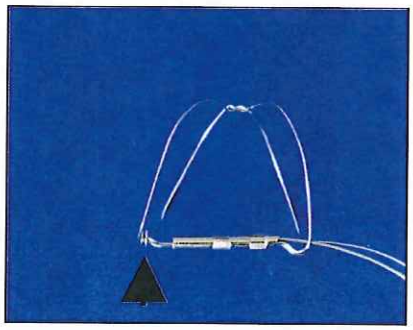


Figure 4.9: Unlocked Proximal Anchor

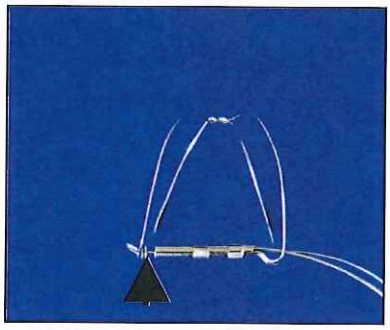


Figure 4.10: Locked Proximal Anchor

iv. Use an echocardiogram to quantify MR reduction.

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

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

m. 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 4.11). Then rotate the release knob in the direction indicated by the decouple arrow until the implant is completely separated from the handle assembly (Figure 4.12).

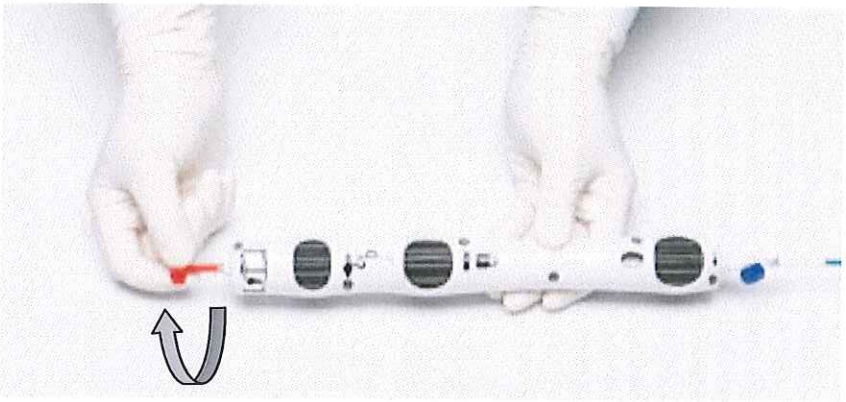


Figure 4.11: Rotating and Removing the Release Safety

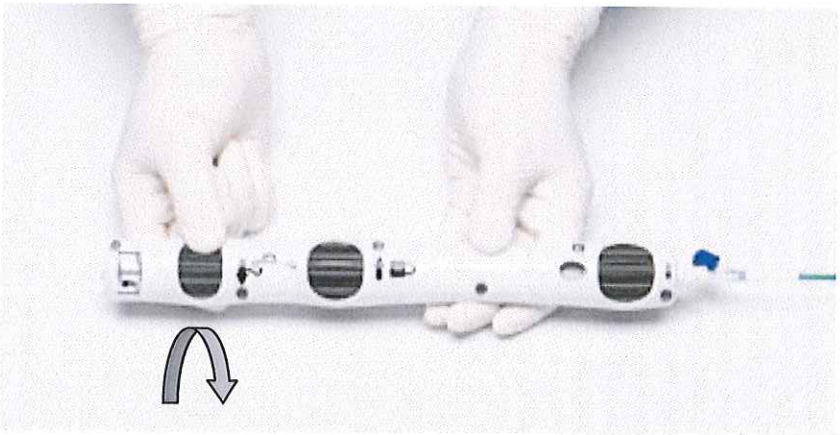


Figure 4.12: Rotating the Release Knob to Decouple the Implant from the Handle Assembly

n. Withdraw the handle assembly and attached 9F delivery catheter out of the venous introducer sheath. Do not advance the system once the implant has been decoupled.

o. 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 in the direction indicated by the lock arrow until the sheath is firmly 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 (b).

b. Rotate the control knob in the direction indicated by the white arrow to advance the 9F delivery catheter over the proximal anchor wires (Figure 5.1). Next, retract the catheter approximately 2 cm by rotating the control knob in the direction indicated by the black arrow. To recapture the distal anchor, rotate the control knob in the direction indicated by the white arrow to advance the 9F 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.

Figure 5.1: 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 9F 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.

c. Once the entire implant is inside the 9F 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. 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.

d. 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 9F delivery catheter over a 7F diagnostic or deflectable catheter for the next procedure attempt. Repeat the implant procedure beginning with Section VIII, 3.

IX. 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 (LV) function and mitral regurgitation
- Electrocardiogram (ECG) to assess potential myocardial infarction
- Patient history to assess for symptoms of ischemia

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

Non-clinical testing has demonstrated the CARILLON® XE2 implant is MR Conditional according to the terminology specified in the ASTM International Standard F2503. It can be safely scanned under the following conditions:

- Static magnetic field of 3.0 Tesla
- Spatial gradient field of 720 Gauss/cm
- Maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning

In non-clinical testing, the CARILLON® XE2 implant produced a temperature rise of less than or equal to 2.3°C at a maximum whole body absorption rate (SAR) of 2.9 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3.0 Tesla (3.0 Tesla/128 MHz, Excite, HDX, Software 14x.M5, General Electric Healthcare, Milwaukee, WI) MR system.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the CARILLON® XE2 implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. Artifacts were in the form of signal voids as follows:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,951 mm^2	384 mm^2	2,279 mm^2	644 mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

X. Sterilization

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

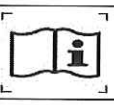
XI. Storage Conditions

Store all CARILLON® Mitral Contour System™ components in their shelf boxes in a location that is cool and dry.

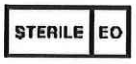
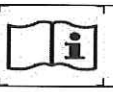
Do not use after expiration date.

XII. Definitions

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

Symbol	Definition
	Caution, see instructions for use
	Control symbol
	Lock symbol
	Release symbol

The symbols used in the product labeling and their definitions are listed below:

Symbol	Definition
	Do not Reuse - Single use
	Do not use if package is damaged
	Use by
	Method of sterilization using ethylene oxide
	Lot number
	Catalogue (Model) Number
	Consult instructions for use
	Manufacturer
	MR Conditional

ORIGINAL

XIII. Manufacturer

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Patent- http://www.cardiacdimensions.com/company/IP.html

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