

## DEVICE LABELING

### Cardima REVELATION<sup>®</sup> Tx Cardiac Ablation System

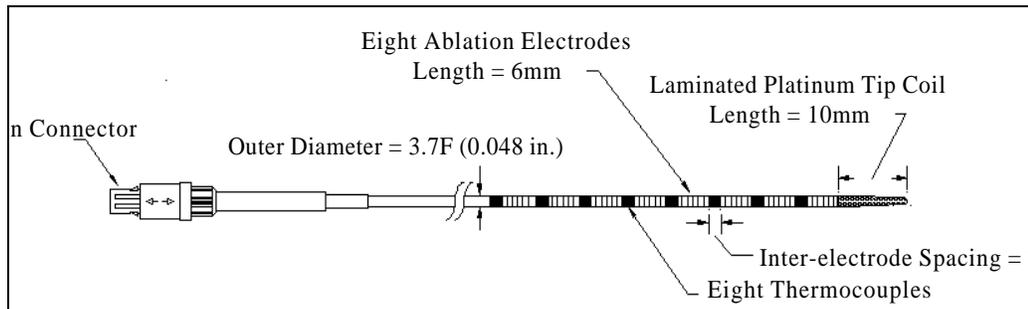
**STERILE** **R** Contents sterile in unopened, undamaged package

 **CAUTION:** This device is intended for one use only. Do not re-sterilize or re-use the device.

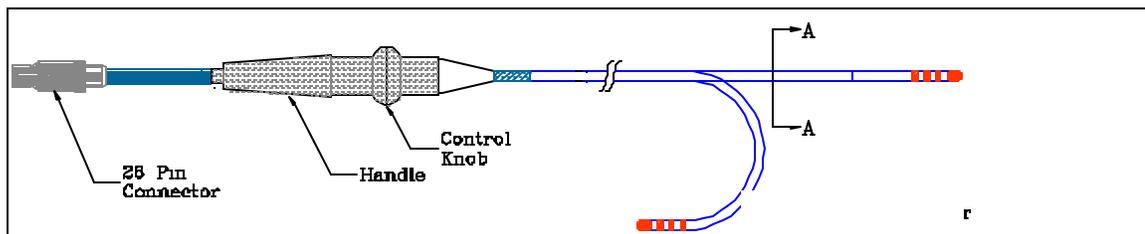
**CAUTION:** Federal (U.S.A) Law restricts this device to sale by, or on the order of a physician.

### Description

The Cardima<sup>®</sup> REVELATION<sup>®</sup> Tx Microcatheter System consists of a single use, steerable, eight-electrode ablation microcatheter (3.7F), the REVELATION<sup>®</sup> Tx, with an atraumatic, flexible, non-electrically active tip, and a single use, deflectable NavAblator<sup>™</sup> "hot tip" (4mm) ablation catheter (8F) with an electrically active tip. Both catheters incorporate thermocouple sensors for temperature feedback.



**Figure 1, Cardima REVELATION<sup>®</sup> Tx Microcatheter**



**Figure 2, Cardima<sup>®</sup> NavAblator<sup>™</sup>**

**Intended Use**

The Cardima<sup>®</sup> Inc., REVELATION<sup>®</sup> Tx Microcatheter RF Ablation System is indicated for the treatment of Atrial Fibrillation in patients with drug refractory paroxysmal atrial fibrillation by creating a set of continuous linear lesions along the lateral and septal walls and along the isthmus in the right atrium.

The REVLATION<sup>®</sup> Tx is intended for the creation of continuous linear lesions for the purpose of interrupting arrhythmia pathways.

The NavAblator<sup>™</sup> is intended for the creation of linear lesions at the isthmus for the purpose of interrupting arrhythmia pathways.

**Contraindications**

?? This procedure is contraindicated in patients with active systemic infection.

?? The catheters in this system should not be used to create lesions in conditions where the catheter would be unsafe (e.g., intracardiac thrombus).

**Warnings**

- This device is not intended for ablation from within the coronary vasculature.
- Use of RF energy may interfere with proper function of pacemakers and implantable cardioverter/defibrillators. Refer to PPM/ICD manufacturer's instruction on use of RF energy with these devices mentioned.
- Never advance or retract device against unknown resistance or damage to device or its components may occur.
- Improper handling or use including reuse of this device may result in device failure and/or possible complications.

**Precautions**

- Catheter placement should be accomplished under fluoroscopic imaging.
- The long-term risks of fluoroscopic exposure have not been established.
- The long-term risks of radiofrequency ablation have not been established.
- Use in conjunction with the Tx SELECT<sup>™</sup> switchbox and Tx Catheter Cable. (See technical specification and requirements)
- Excessive bending or kinking of the device may cause damage to the device or its components.
- Always consult the RF-Generator Operating Manual and follow precautions prior to delivery of RF-Energy.

- The safety and effectiveness of the use of this system in treating children or pregnant women have not been established.
- This device should only be used by physicians thoroughly trained in the techniques of transvenous intracardiac studies and/or electrophysiology studies.

## Technical Specifications And Requirements

### Cardima REVELATION<sup>®</sup> Tx Dimensional Specifications

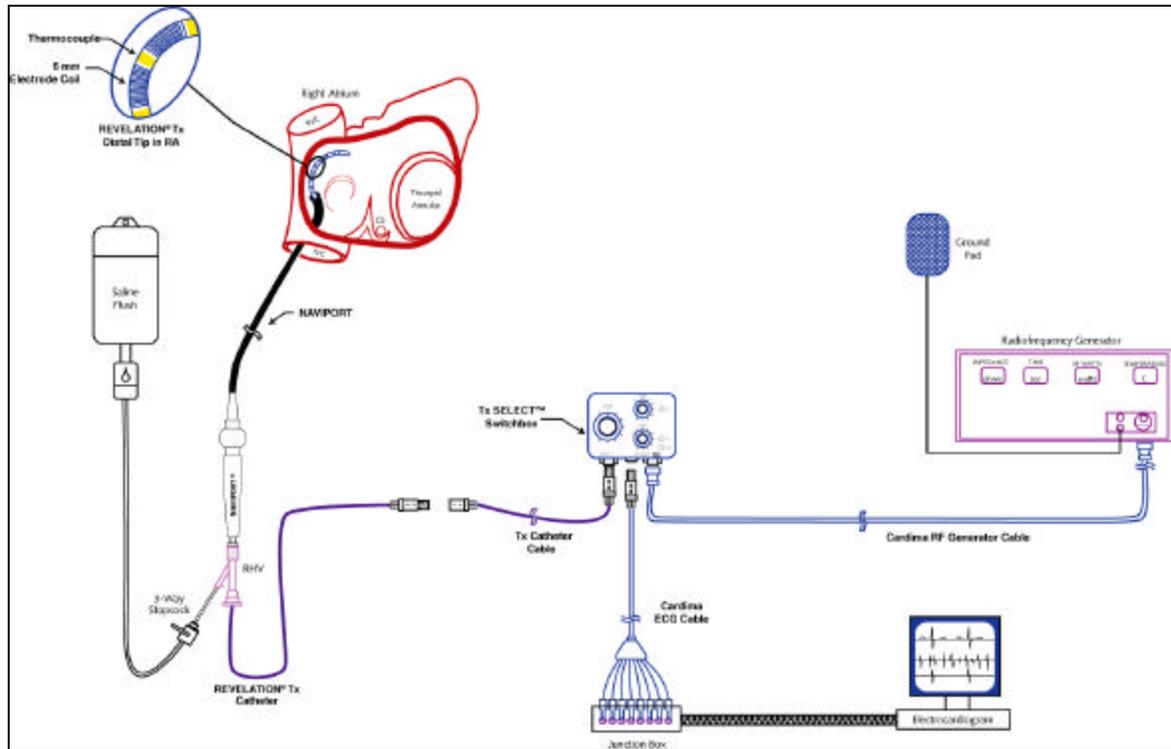
Description	REVELATION <sup>®</sup> Tx	NavAblator <sup>™</sup>
Nominal Electrode Region Diameter	3.7 F, .048", 1.2 mm	8 F, 0.105", 2.7 mm
Nominal Proximal Shaft Diameter	3.5 F, .045", 1.1 mm	8 F, 0.105", 2.7 mm
Nominal Curve Reach	n/a	30 mm (01-044001, 01-044007, 01-044013) 40 mm (01-044002, 01-044008, 01-044014)
Working Length	150 cm	90 cm (01-044001, 01-044002) 110 cm (01-044007, 01-044008) 125 cm (01-044013, 01-044014)
Tip Coil Length	1.0 cm	n/a
Number of Electrodes	8	4 (1 ablation, 3 mapping)
Electrode Material	Platinum	Platinum
Ablation Electrode Length	6 mm	4 mm
Mapping Electrode Length	6mm	1.5 mm
Interelectrode Spacing	2 mm	2 mm
Connectors: Quantity	1	1
Switchbox Requirements (not included)	Tx SELECT <sup>™</sup> Switchbox	
Connecting Cable (not included)	Tx Catheter Cable, Tx ECG Cable	

Tx RFG Cables for these commercially available RF Generators:

- Stockert 70 (EP-Shuttle - EU)
- Medtronic Atakr
- Osypka HAT 300 Smart (outside U.S. only)

## Directions

### A. REVELATION<sup>®</sup> Tx System Setup (see Figure 3)



**Figure 3, REVELATION<sup>®</sup> Tx Ablation System Set-up**

1. Attach the RF generator ground pad securely to the patient's skin per manufacturers instructions.
2. Connect the Cardima Tx SELECT<sup>™</sup> Switchbox to the electrocardiograph, pacing stimulator, and RF generator using the appropriate connecting cables as specified in the Cardima Tx SELECT<sup>™</sup> Switchbox Instructions For Use.

*NOTE: Adaptor cables are available for the Stockert 70, Medtronic Atrak and in Europe, the Osypka HAT 300 Smart generator. Please consult a Cardima representative.*

- a. Select the appropriate NAVIPOINT<sup>®</sup> French size, curve reach and length.
- b. Connect an RHV (Rotating Hemostatic Valve) adapter to the NAVIPOINT<sup>®</sup> hub.
- c. Connect a pressurized, heparin/ saline flush bag to the RHV. Maintain a continuous drip.

- d. Introduce an appropriate size angiographic guidewire (e.g., .038") into the NAVIPORT<sup>®</sup>.
4. Prepare the REVELATION<sup>®</sup> Tx catheter for use.
  - a. Flush catheter with a heparin/saline solution while it is still in its protective dispensing coil.
  - b. Remove catheter from dispensing coil and confirm electrode coil integrity.

### **B. Atrial Access**

1. Place the NAVIPORT<sup>®</sup>/guidewire assembly through the introducer sheath and advance to the targeted area into the atrium under fluoroscopic guidance.
2. Remove the guidewire from the NAVIPORT<sup>®</sup>.
3. Place the introducer over distal tip of the REVELATION<sup>®</sup> Tx to cover electrodes, then insert into RHV. Advance the REVELATION<sup>®</sup> Tx through the introducer into the NAVIPORT<sup>®</sup>.
4. Remove or pull back the introducer.
5. Place the REVELATION<sup>®</sup> Tx at the targeted area under fluoroscopic guidance and then connect it to the Cardima REVELATION<sup>®</sup> Tx Catheter Cable.
6. Hand off opposite end (male end) to be connected to switchbox.

### **C. Determination of Catheter/Tissue Contact**

1. Observe the catheter on the fluoroscope to confirm correct positioning.
2. Record bipolar electrical signals from the REVELATION<sup>®</sup> Tx.

In general, sharp electrograms with high frequency components and large relative amplitudes are suggestive of good contact.

### **D. RF Energy Delivery**

1. Consult the appropriate RF generator operating manual before starting, and configure using the following settings:

Control Mode:	Constant Temperature
Set Temperature:	Initially 50° C
Maximum Power:	35 W
Differential Impedance Setting:	Switch on if available and adjust to 20? . If not available, monitor impedance and stop RF energy delivery if impedance increases by more than 20? .
Timer Set:	60 seconds

These settings will allow power to be delivered up to a maximum of 35 W during the course of the burn. RF energy will shutoff automatically after 60 seconds unless the impedance rises to a user-determined level in which case the shutoff will occur immediately.

2. Determine which electrodes will receive RF energy based on the tissue contact assessment. Energy will be delivered to each electrode individually.
3. Set the switchbox to correspond with the electrode receiving energy.
4. If RF energy delivery automatically terminates (due to sudden rise in impedance) before 60 seconds, remove the REVELATION<sup>®</sup> Tx at the completion of the burn line and inspect for coagulum on the electrodes. Loosely adherent coagulum may be carefully cleaned off the catheter electrodes with a saline-soaked 4 x 4 gauze. Do not apply force to the tip coil when wiping the electrodes. If strongly adherent char is not easily wiped off, or if any damage is observed, use another REVELATION<sup>®</sup> Tx catheter.

*NOTE: Following RF ablation electrogram amplitudes should decrease at least 25-50%.*

*Note: To avoid phrenic nerve damage, prior to ablation, pace with a stimulator setting of 10 mA at 2 ms. Palpate the patient for a diaphragmatic stimulation. Do not apply RF energy at any location where diaphragmatic stimulation is detected in this manner.*

5. Repeat steps D2-D4 above for the remaining electrodes with sufficient tissue contact.
6. Repeat section C above to assess changes that have occurred as a result of the RF energy application. Repeat RF energy applications along a given trajectory as necessary. The set temperatures may be increased to a maximum of 60° C at the physician's discretion.
7. Reposition the catheter in the next desired location and repeat sections C and D above until RF lesions are created in all desired trajectories.

*NOTE: If frequent impedance rises during RF delivery are noted and/or an excessive amount of coagulum appears on the electrodes, it may be advisable to reduce the temperature setting or reposition the catheter prior to the next RF application.*

*NOTE: If bi-directional block is not achieved at the isthmus, the NavAblator<sup>™</sup> may be used for this lesion.*

#### **E. NavAblator<sup>™</sup> Preparation**

3. Prepare the NavAblator<sup>™</sup> for use.
  - a. Remove the NavAblator<sup>™</sup> from the sterile package under sterile conditions. As with all medical devices, always inspect prior to use to ensure no damage has occurred during shipping.

- b. Prior to use, activate the deflection mechanism of the catheter by pulling the control knob. Then push the control knob distally to straighten the tip before inserting.
  - c. Place the NavAblator™ through the vascular introducer and advance to the atrium.
4. Set the switchbox to **electrode position 1 only**.
5. Follow the steps in B through D to create a line of block at the isthmus. The duration of RF energy delivery may be increased from 20 to 120 seconds at the physician's discretion.

### **Potential Complications**

Risks to patients include all those risks currently associated with electrophysiology diagnostic procedures and radiofrequency catheter ablation procedures, such as:

- Bleeding
- Cardiac or vessel wall injury or perforation
- Cerebrovascular accident
- Conduction system abnormalities
- Death
- Hematoma at entry site
- Local or systemic infection
- Pericardial effusion
- Permanent atrioventricular block
- Phrenic nerve damage
- Pneumothorax
- Thromboembolic events

### **Reports Of Adverse Events**

Major complication rate associated with this study were 3.4%. Minor complications associated with this study occurred in 26% of the subjects. There were no deaths associated with this study.

## REPORTS OF CLINICAL STUDIES

Clinical studies were conducted of more than 80 subjects treated with the investigational ablation system at approximately 20 investigational sites. The Study Design was a prospective, non-randomized, single arm, controlled study in which the patients serve as their own control. The "control" consisted of a baseline model for each patient based upon the number of symptomatic atrial fibrillation episodes documented by that patient in a 30-day period (before treatment).

The study subjects were required by inclusion criteria to have documented paroxysmal atrial fibrillation that did not respond to antiarrhythmic drugs. If the patient was taking Amiodarone, he or she need be unresponsive (refractory) to that one drug, otherwise, the patient was required to be unresponsive to two antiarrhythmic drugs.

The objective of the study was to determine the safety and effectiveness of the treatment system based upon a reduction in the number of symptomatic AF episodes each patient had during the follow up period compared to the number of episodes the patient had during the baseline period. If the patient was found to have demonstrated a reduction of 50% or more from the reported number of baseline episodes, he was deemed to be a clinical success.

Eligible patients were treated and followed for 24 months, with assessments at 1, 3, and 6, month intervals for the number of symptomatic atrial fibrillation episodes they recorded and transmitted and for the number and type of complications reported during the follow up period.

**Table 1, Mean Episode Reduction**

Number of Episodes	Baseline		3 months		6 months	
	freq	%	freq	%	freq	%
Total	111	100.0	93	100.0	81	100.0
Mean, SD	9.9 ± 8.7		3.9 <sup>b</sup> ± 5.9		1.2 <sup>b</sup> ± 2.0	

<sup>a</sup> p<0.0001, paired t-test

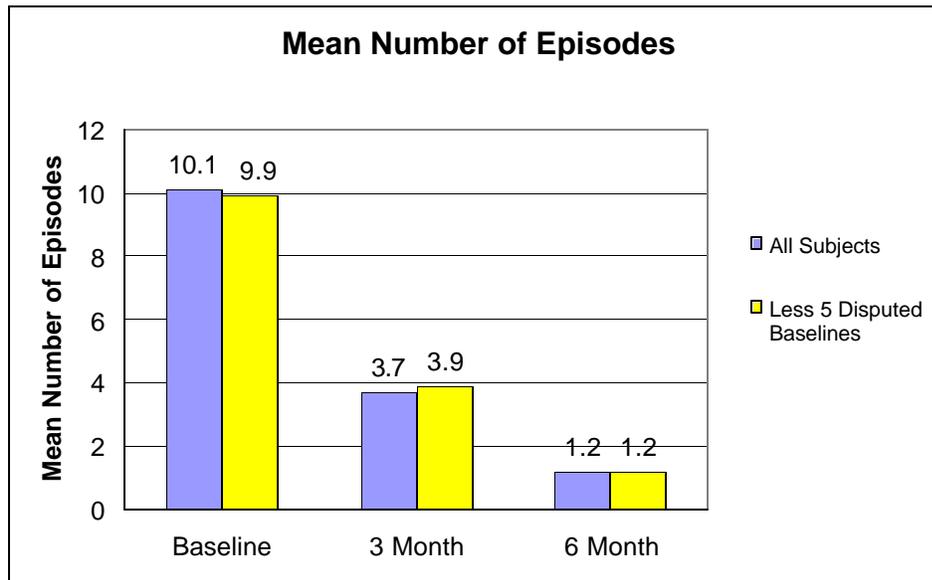
**Table 2, Clinical Success**

Criteria	3 Month (n=93) freq/n (%)	6 Month (n=81) freq/n (%)
# of subjects with Episode Reduction compared to Baseline	76/93 (83.9)	79/81 (97.5)
?50% Reduction <sup>a, c</sup>	58/93 (64.5)	69/81 (85.2)
100% Reduction	33/93 (35.5)	44/81 (54.3)
<50% Reduction <sup>c</sup>	33/93 (35.5 <sup>c</sup> )	12/81 (14.8 <sup>c</sup> )
No Reduction	15/93 (16.1)	2/81 (2.5)
Mean % reduction ± SE	53.1 <sup>b</sup> ± 6.6	82.9 <sup>b</sup> ± 3.0

<sup>a</sup> ? 3-4 baseline episodes <sup>b</sup> p<0.0001

<sup>b</sup> Statistics do not include five subjects with disputed numbers of baseline episodes.

<sup>c</sup> Includes those with "no reduction" as a subset of the <50% reduction group. In the >50% reduction group, those with 100% reduction are included.



### CUSTOMER SERVICE INFORMATION

If you have questions or comments regarding the use of this device, please address them to:

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### **LIMITED WARRANTIES**

Cardima<sup>®</sup>, Inc. warrants that this product is free from defects in original workmanship and materials. Cardima warrants that sterile products will remain sterile for a period of two years as labeled as long as the original packaging remains intact. Cardima<sup>®</sup>'s products are designed for single use only. Cardima<sup>®</sup>'s products are not designed for reuse. If any Cardima<sup>®</sup> product is proved to be defective in original workmanship or original materials, Cardima<sup>®</sup>, in its absolute and sole discretion, will replace or repair any such product, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products that have been used for their normal and intended uses. Cardima<sup>®</sup>'s limited warranty shall NOT apply to Cardima<sup>®</sup> products which have been resterilized, repaired, altered, or modified in any way and shall NOT apply to Cardima<sup>®</sup> products which have been improperly stored or improperly installed, operated or maintained contrary to Cardima<sup>®</sup>'s instructions.

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The buyer's use of the product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

### **PATENT NUMBERS**

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