

# Instructions for Use

CryoCor™

 CRYOBLATOR™

10F Cryoablation Catheter

Model 1205, 1207

## DEVICE DESCRIPTION

The CryoCor CryoBlator 10F Cryoablation Catheter is a single use, 10F, uni-directional steerable ablation catheter, specifically designed for the treatment of cardiac arrhythmias. The flexible distal section can be deflected by displacement of an integral tendon controlled by a lever on the handle. A variable manual locking feature or “brake” is provided to lock or hold the deflection angle. The proximal shaft is more rigid to allow torque transmission to the distal end of the shaft. A metal end-tip provides therapy delivery. Target tissue in contact with the tip is ablated by cooling achieved via the vaporization of refrigerant fluids inside the catheter tip assembly. A temperature sensor, located within the tip, provides temperature monitoring during therapy delivery. The tip, along with an additional 1.3mm wide band electrode spaced 3 mm proximal to the tip, also has the ability to collect intracardiac electrograms for mapping procedures. The catheter is connected to the CryoCor Cryoablation Console, Model 2020, via three quick-connect receptacles: one for refrigerant gas, a second for pressure monitoring inside the tip and a third for electrical signal transmission.

## INDICATIONS

The CryoCor Cryoablation System’s intended use is in the Ablation of Isthmus-dependent Atrial Flutter in patients 18 years of age or older.

## CONTRAINDICATIONS

- Do not use this device:
- in patients with active systemic infection
- in patients with intracardiac mural thrombus
- in patients with cryoglobulinemia

## Potential Adverse Events

- Vaso-vagal syncope
- Perforation or damage to the peripheral vasculature or heart
- Bleeding
- Infection
- Initiation of life threatening arrhythmias
- Thrombus or embolus
- Pericarditis
- Myocardial infarction
- Ablation beyond the targeted tissue
- Death
- catheter rupture and release of refrigerant

## WARNINGS

- The CryoCor Cryoablation Console is capable of delivering significant cryoablation therapy. When operating, do not touch the catheter tip because operator injury may occur.
- The CryoCor CryoBlator 10F Cryoablation Catheter is disposable and intended for single use. Do not re-sterilize or reuse. This may result in a loss of cryoablation, electrical and mechanical function and could cause patient injury and/or death.
- Use only isolated ECG amplifiers with the CryoCor Cryoablation System. Leakage current from a connected device to the patient must not exceed 10 microamps (µA).
- If the catheter develops a leak, patient injury or death may occur.
- Caution should be used when delivering cryotherapy as structures located beyond the target tissue may be affected.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force or torque to advance, withdraw, or manipulate the catheter.

## RISKS

### Potential Risks Associated with Placement and Catheter Manipulation

- Vaso-vagal syncope
- Perforation or damage to vasculature
- Bleeding
- Infection
- Initiation of arrhythmias
- Thrombotic and/or embolic events (including air emboli)
- Death
- Myocardial infarction

### Potential Risks Associated with Pulmonary Vein Ablation

The known risks of pulmonary vein ablation from RF and other energy sources, including cryoablation, include the following:

- Phrenic nerve damage and resultant diaphragmatic paralysis
- Pericarditis
- Pulmonary vein stenosis (heat-based therapies only)
- Esophageal Fistula (heat-based therapies only)

### Potential Risks Unique to the Cryoablation Procedure

There is one identified potential risk unique to pulmonary vein cryoablation procedures, namely catheter rupture and release of refrigerant gas.

## PRECAUTIONS

- Patients undergoing left-sided ablation procedures should be closely monitored during post-ablation period for clinical manifestations of infarction.
- Anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- The sterile packaging and catheter should be visually inspected prior to use. Inspect for holes in the packaging and compromise to the seal prior to opening and removal of catheter. If damaged, do not use. Inspect the catheter for damage to the shaft, exposed wire(s) or tubing and damaged connectors.
- Do not attempt to operate the Cryoablation System before thoroughly reading the Operators Manual.
- The LCD on the Console should be monitored during therapy delivery.
- Excessive bending or kinking of the catheter shaft and/or flex interconnect may damage internal components. Manual pre-bending of the distal curve can damage the steering and/or deployment mechanism and may lead to patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of catheter ablation in a fully equipped electrophysiology laboratory.
- It is important that the physician determines, assesses and communicates to each individual patient all foreseeable risks of a cardiac ablation procedure.
- The CryoCor Cryoablation Console is intended for use only with CryoCor Cryoablation Catheters and accessories. The safety of use with other electrophysiology catheters and accessories has not been assessed.
- Prior to delivery of ablation therapy, ensure catheter tip is beyond the end of the sheath.
- Do not articulate the catheter when the articulation segment is constrained within the sheath, as articulation function may be compromised.

## DIRECTIONS FOR USE

### Preparing the CryoCor CryoBlator 10F Cryoablation Catheter

1. Using sterile technique, remove the catheter from the package and place in a sterile work area.
2. Visually inspect the catheter carefully for integrity (cuts, punctures) and overall condition. If damaged, do not use: return to CryoCor.
3. Manipulate handle to confirm steering function.
4. Maintain the black plastic end cap on the main gas connector whenever the catheter is not connected to the Console.

### Insertion and Placement of CryoCor CryoBlator 10F Cryoablation Catheter

1. Create appropriate vascular access site to introduce catheter to reach desired locations within the heart.
  - Right Atrium: Approach through the femoral vein utilizing standard 10F or larger percutaneous hemostasis sheath.
  - Left Atrium: Approach transseptally from the right atrium through fossa ovalis utilizing a Brockenbrough-type needle and transseptal sheath (10F or larger).
2. Ensuring that the tip of the catheter is in its relaxed or non-articulated position, advance the catheter through the vasculature and into the desired area of the heart under fluoroscopic guidance. Use the lever control on the catheter to facilitate positioning of the catheter tip.

*NOTE: During manipulation, the catheter may be disconnected from the control arm of the Console in order to avoid twisting and tangling of cables and connections.*

### Connect Catheter To Console

*NOTE: The control arm on the Console is non-sterile. Ensure that, when making or breaking connection to the control arm, care is taken to avoid contact with the Console.*

1. Twist and remove the black plastic end cap from the main gas connector on the proximal end of the catheter and let it hang by the metal chain.
2. Remove black precooler plug from the precooler receptacle located on the control arm of the Console.
3. Align the gas connector with the mating receptacle on the control arm of the Console (non-sterile) and push the gas connector in until it latches. To disconnect, grasp the black sleeve on the connector and pull back until the connector disengages. Following disconnection of the gas connector, replace the plastic end cap to avoid contamination within the sterile field and replace precooler plug on control arm.

*NOTE: This connection is not keyed and can rotate freely.*
4. Locate the Luer at the proximal end of the catheter and align it with the mating receptacle at the end of the console arm. Grasp the body of the Luer and twist until a snug connection has been made. To disconnect, grasp the body of the Luer and twist the Luer fitting counter clockwise until the Luer is disconnected.
5. Locate the electrical connector and attach it to the receptacle located on the distal end of the control arm of the Console by aligning the key on the connector with the key indicator on the receptacle while pushing together until connector has latched.

*NOTE: If the physician chooses to disconnect the sensor cable from the console once it has been connected, care must be taken not to contaminate the sterile field by the now contaminated end of the sensor cable. Disconnection of the sensor cable at the catheter end prevents contamination. For removal of the sensor cable, grasp the gray sleeve on the connector and pull back until the connector disengages from the receptacle.*

## THERAPY DELIVERY

1. Prior to delivery of ablation therapy, ensure that the catheter tip is in direct contact with the target tissue.
2. During therapy delivery, the catheter tip will become attached to the target tissue. Do not attempt to manipulate or move the catheter tip during therapy delivery.
3. Following therapy delivery, do not manipulate the catheter tip until the “Wait to Remove Catheter” message on the Console LCD has disappeared. This provides sufficient time for the catheter tip to thaw and detach itself from the target tissue.

## POST-PROCEDURE CATHETER REMOVAL

1. Prior to removing the CryoCor CryoBlator 10F Cryoablation Catheter, ensure that the catheter is in its relaxed or non-articulated position.
2. Slowly withdraw the catheter from the patient. Should any resistance be encountered withdrawing the catheter into the sheath, the catheter and the sheath should be removed as a single unit.”
3. Remove the hemostasis or transseptal sheath, and follow standard practice for management of the insertion site.
4. Follow standard practice for disposal of used medical devices.

## STORAGE AND HANDLING

Store in a cool, dark, dry place.

## SPECIFICATIONS

Catheter Diameter ..... 10F (3.3mm)

Usable Length--

Model:  -05: 95 cm

Model:  -07: 97 cm

Tip Length ..... 6.5 mm

Articulation Segment Length--

Model:  -05: 5 cm

Model:  -07: 7 cm

Deflection Angle ..... >180° (uni-directional)

Band Electrode Width ..... 1.3 mm

Band Electrode Spacing (from tip) ..... 3 mm



 CRYOBLATOR™

10F Cryoablation Catheter

Model 1205, 1207

One sterile CryoCor CryoBlator 10F Cryoablation Catheter

Non-pyrogenic

No warranty implied

Contents are for single use. Do not attempt to resterilize.

Read instructions prior to use.

Sterilization: Radiation

**Caution: Federal (USA) law restricts this device to use by or on the order of a physician.**

Manufactured by:

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