# Cardiac Pathways Corporation

## *Chilli® Cooled Ablation System*

## *Information for Use*

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# *Chilli® Cooled Ablation System*

**Caution: Federal law restricts this device to sale by or on the order of a physician.**

## 1 DEVICE DESCRIPTION

The Chilli® Cooled Ablation System (Chilli Cooled Ablation System) includes the Chilli Cooled Ablation Catheter (Chilli Catheter) and the Model 8004 Radiofrequency Generator and Pump System (Model 8004 RF Generator). The Chilli Catheter has a distal electrode segment and a proximal handle that are connected by a torquable catheter shaft. The electrode segment houses the tip electrode, the ring electrodes, and the temperature monitoring electrodes. The handle includes the electrical connector for the electrode wires, a knob used to deflect the tip, and two luer fittings used to connect the catheter to the fluid pump on the Model 8004 RF Generator and the fluid collection bag, respectively. The pullwire, electrode lead wires, and two lumens carrying cooling fluid pass through the shaft. The fluid pump on the Model 8004 RF Generator circulates cooling fluid through two lumens joined at the tip (see section 9. How Supplied).

## 2 INDICATIONS AND USAGE

The Chilli Cooled Ablation System is indicated for:

- cardiac electrophysiological mapping;
- delivering diagnostic pacing stimuli; and
- radiofrequency ablation of mappable ventricular tachycardias attributable to ischemic heart disease or cardiomyopathy in patients who have failed drug therapy.

## 3 CONTRAINDICATIONS

Do not use this device in the following patients:

- patients with active systemic infection
- patients with a mechanical prosthetic heart valve through which the catheter must pass
- patients with left ventricular thrombus; or with left atrial thrombus or myxoma via the transseptal approach
- patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation

## 4 WARNINGS and PRECAUTIONS

- **Need for adjunctive therapy** – Do not ablate arrhythmias in patients with unablatable ventricular tachycardia and/or ventricular fibrillation without additional standard therapy such as an implantable cardioverter/defibrillator (ICD).
- **Hemodynamic instability** – Patients with severe hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution.

- **Do not ablate from within a coronary artery** as the resulting myocardial injury can be fatal. Adequate fluoroscopic visualization is necessary during the transaortic approach to avoid placement of the ablation catheter in the coronary vasculature.

- **Closely monitor patients following left-sided ablation procedures** until they are fully conscious and have been evaluated for embolic stroke or myocardial infarction.

- **Precautions in patients with implantable pacemakers and implantable cardioverter/ defibrillators (ICDs):**
  - Deactivate ICDs as they could discharge and injure the patient or be damaged by the ablation procedure
  - Have temporary external sources of pacing and defibrillation available
  - Do not apply RF energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function
  - Perform a complete analysis of the implanted device function after ablation

- **Complete AV block** can occur when ablating near the AV node (septal anatomical sites). Closely monitor AV conduction during RF energy delivery and immediately terminate energy delivery if partial or complete AV block is observed.

- **Closely monitor AV conduction when ablating near the AV node** (AV septum) and immediately terminate energy delivery if partial or complete AV block is observed.

- **Minimize X-ray exposure** – Significant x-ray exposure can result in acute radiation injury as well as dose-related risk for somatic and genetic effects. Take all appropriate measures to minimize x-ray exposure to both patients and clinical staff.

- **X-ray exposure to children** – The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children.

- **Pregnancy** – Careful consideration should be given to the use of this device in pregnant women because of the risk of significant exposure to x-rays.

- **Training** – Cardiac ablation procedures should be performed only by appropriately trained personnel in a fully equipped electrophysiology laboratory (see section 10).

- **Instructions for Use** – Do not attempt to operate the Chilli Cooled Ablation System before completely reading and understanding the applicable directions for use.

- **Long-term risks of RF ablation** – The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown.

### *4.1 Precautions Specific to the Chilli Cooled Ablation System*

- Use the Chilli Catheter only with the Model 8004 RF Generator

- Always verify that the syringe, tubing, and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or death.

- Use only dispersive electrodes that meet or exceed ANSI/AAMI requirements (HF18) and follow the dispersive (grounding) electrode manufacturer's instructions for use.

- Do not use impedance cut-off settings greater than 200 Ohms or temperature cut-off settings of 100° C or greater because those settings have not been studied.

- The displayed temperature is not the temperature of the tissue. It is the temperature of the cooled electrode only and does not represent tissue temperature.

### *4.2 Handling and Sterilization Precautions*

- The Chilli Catheter is for SINGLE USE ONLY. Do not resterilize or reuse.

- Do not use the Chilli Catheter after the expiration date because the device performance may no longer be acceptable and/or the device may no longer be sterile.

- Inspect the packaging and catheter prior to use. If the package or the catheter appears damaged, do not use and contact your local Cardiac Pathways representative.

- Do not kink the Chilli Catheter, expose it to organic solvents such as alcohol or immerse the handle or cable connector in fluids.

### *4.3 Environmental and EMI Precautions*

- Do not use the Chilli Cooled Ablation System in the proximity of magnetic resonance imaging (MRI) equipment because the MRI equipment may adversely impact the function of the Model 8004 RF Generator and the ablation system may adversely impact the image quality.

- Electromagnetic interference (EMI) produced by the Model 8004 RF Generator during the delivery of RF power may adversely affect the performance of other equipment.

### *4.4 Precautions During Catheter Use*

- Do not allow the patient to contact grounded metal surfaces. Leakage current from any device connected to the patient must not exceed 10 microAmps under any circumstances. To prevent patient injury or death, use only isolated amplifiers, pacing equipment, and ECG equipment.

- Do not use excessive force to advance or withdraw the catheter. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.

- Do not insert or withdraw the catheter without straightening the catheter tip (pushing the thumb knob toward the shaft).

- Use both fluoroscopy and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid vascular or cardiac damage.

### *4.5 Precautions During Ablation*

- Do not increase power before checking for lead connection and appropriate dispersive electrode application. Verify effective contact between the patient and the dispersive electrode whenever the patient is repositioned.

- Do not deliver RF energy with the catheter outside the target site. The Model 8004 RF Generator can deliver significant electrical energy and may cause patient or operator injury.

- Avoid use of electrodes and probes of monitoring and stimulating devices that could provide paths for high frequency current. Reduce the burn hazard by placing the electrodes and probes as far away as possible from the ablation site and the dispersive electrode.

- In the event of a generator cutoff (impedance or temperature), the catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is re-applied. Use only sterile saline and gauze pad to clean the tip.

- Do not scrub or twist the tip electrode as damage may cause catheter failure or patient injury.

## 5 ADVERSE EVENTS

The Chilli Cooled Ablation System was used in the treatment of patients undergoing electrophysiologic (EP) mapping and RF catheter ablation for the treatment of ventricular tachycardia attributable to ischemic heart disease or cardiomyopathy. Although 188 patients were enrolled in the clinical studies, only 150 patients received ablation therapy using the Chilli Cooled Ablation System. The assessment of adverse events is based on all 150 patients. Patients were followed for 8 ± 5 months (mean ± S.D.); the longest follow-up was 24 months.

## *5.1 Observed Adverse Events*

**Table 1. Adverse Events That Occurred or Began Within Seven Days After Ablation**
**All patients treated with Chilli Catheters, N = 150**

| Adverse Event Category<br>Description | Total No. of Pts. Experiencing Adverse Events (N = 150) | No. of Adverse Events resulting in death (N= 150) | % of Pts Experiencing Adverse Events [95% C.I.] |
|---|---|---|---|
| Major | 16 | | 10.7% [6.2, 16.7] |
| Cerebrovascular accident/ transient ischemic attack | 4 † | 1 † | 2.7% [0.7, 6.7] |
| Cardiac perforation | 4 † | 1 † | 2.7% [0.7, 6.7] |
| Acute myocardial infarction | 1 † | 1 † | 0.7% [0.0, 3.7] |
| Post-operative, cardiogenic shock | 1 | 1 | 1.3% [0.2, 4.7] |
| Post-operative, cardiogenic shock, and aortic valve injury | 1 † | 1 † | 0.7% [0.0, 3.7] |
| Cardiac insufficiency | 1 | 1 | 0.7% [0.0, 3.7] |
| Electromechanical dissociation | 1 | 0 | 0.7% [0.0, 3.7] |
| Third-degree heart block | 4 ‡ | 0 | 1.3% [0.2, 4.7] |
| Pneumonia | 1 | 0 | 0.7% [0.0, 3.7] |
| Minor* | 7 | 0 | 4.7% [1.9, 9.4] |

* Patients with both minor and major adverse events were counted only as major adverse events.

† IDMC classified these events and deaths as possibly procedure-related.

‡ Two of the four instances of complete heart block were anticipated prior to the procedure and not classified as adverse events by the IDMC.

[95% C.I.] = 95% confidence intervals by the exact method.

**Major adverse events** were defined as any complication requiring an invasive intervention or prolonging or requiring a new hospitalization. Table 1 presents the observed adverse events for the 150 patients. An Independent Data Monitoring Committee (IDMC) also reviewed and classified events and deaths.

Major adverse events were reported in 28 of 150 patients (19%), 16 of which occurred or began within the first 7 days after ablation.

Of the 26 total deaths, six occurred or may have been related to adverse events that began within seven days of the ablation procedure (Table 1), and 20 occurred later. Of the 20 late deaths, end stage congestive heart failure was the cause in eight patients, end-stage ischemic heart disease and arrhythmias in six patients, ischemic heart disease in two patients, and non-cardiac causes in three patients.

**Minor adverse events** were defined as those in which an observation was made or a medication was prescribed, but hospitalization was not required or prolonged. Seven minor adverse events occurred within seven days of ablation. The adverse events included transient loss of a lower extremity pulse, distal femoral artery dissection with pseudoaneurysm,

defibrillation skin burns, dysarthria and diplopia attributed to sedation, transient lower extremity weakness attributed to sedation, chronic arterio-venous fistula, and left arm pain.

### *5.2 Potential Adverse Events*

Adverse events (in alphabetical order) which may be associated with catheterization and ablation include:

***Catheterization/catheter procedure related*:**

- air embolism
- arrhythmias
- AV fistula
- cardiac perforation
- hemothorax
- nerve palsy or weakness
- pneumothorax
- pseudoaneurysm
- tamponade
- thrombi
- thromboembolism
- thrombosis
- valvular damage
- vascular bleeding/local hematoma
- vasovagal reactions
- visual blurring

***RF ablation related*:**

- cardiac perforation/tamponade
- cardiac thromboembolism
- cerebrovascular accident (CVA)
- chest pain/discomfort
- complete heart block
- coronary artery spasm
- coronary artery thrombosis
- defibrillation skin burn
- distal aortic/coronary artery dissection
- pericarditis
- transient ischemic attack (TIA)
- valvular damage
- ventricular tachyarrhythmia

## 6 CLINICAL STUDIES

A total of 188 patients were involved in clinical studies of the Chilli Cooled Ablation System. All patients had ischemic heart disease or cardiomyopathy and had experienced a minimum of two episodes of spontaneous ventricular tachycardia (VT) in the two months prior to



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enrollment. Of the 188 patients, 107 were enrolled in the Randomized Trial and 81 in other studies.

Of the 107 patients enrolled in the Randomized Trial, 75 were assigned to receive RF ablation and 32 to optimized antiarrhythmic drug therapy.

**Acute success** was defined as an inability to induce VT following the ablation procedure. **Chronic success** was defined as freedom from spontaneous recurrence of any VT for six months following ablation.

**Results:** The Randomized Trial was analyzed by intention-to-treat. Table 2 compares chronic success for patients randomized to RF ablation or antiarrhythmic drugs (control).

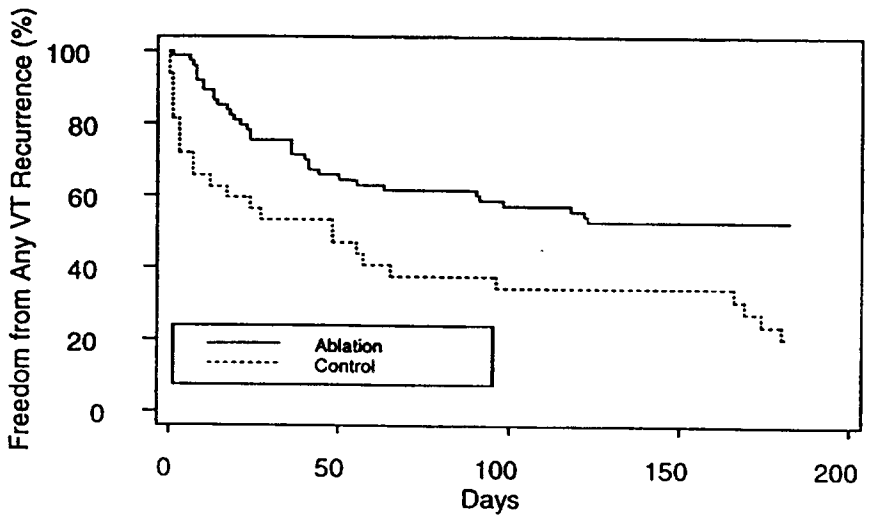
**Table 2. Chronic (6 month) Success in the Randomized Trial**
Percent [95% Confidence Interval], (Numerator/Denominator)
All patients enrolled (N=107)

| Chronic Success | Ablation Patients | Control Patients | Difference |
|---|---|---|---|
| No recurrence of any VT at 6 months | 55% [43%, 66%] (41/75†) | 19% [5.4%, 33%] (6/31††) | 35%* [17%, 53%] |

95% confidence intervals by normal approximation
†Intention-to-treat includes 10 patients randomized to ablation who did not receive ablation treatment
†† One patient was lost to follow-up prior to six months and was excluded from analysis.
* Difference was statistically significant (p<0.005) by Fisher's Exact Test

Figure 1 shows the freedom from recurrence of any VT for both treatment groups in the Randomized Trial. Control patients who crossed over to ablation (N = 17) were censored (removed from the survival analysis).

**Figure 1: Freedom From VT Recurrence by Treatment***
All patients in the Randomized Trial, N=107




* Intention-to-treat includes 10 patients randomized to ablation who did not receive ablation treatment. The difference in VT recurrence was statistically significant by the Gehan test (p <0.001).

A total of 188 patients were enrolled in the studies; data from 150 patients with the Chilli Catheter inserted were analyzed, including 65 of the 75 patients randomized to ablation, 17 of the 32 patients initially randomly assigned to antiarrhythmic drug therapy (control) who crossed over to ablation, 15 of the 18 patients treated for emergency use, and 53 of the 63 patients treated after randomization was discontinued.

Of these 150 patients in whom a Chilli Catheter was inserted, most (127) received ablation treatment on a single occasion, 18 were treated on two occasions, one patient on three occasions, and four received no ablation treatment because the VT could not be mapped. Only the first treatment was considered in the effectiveness analyses. Table 3 lists the number of patients enrolled, treated, and the acute and chronic (six-month) success.

**Table 3. Patient Cohorts and Ablation Success**
All patients treated with the Chilli Cooled Ablation System (N=150)

| Patient Cohort | No. of Patients Ablated | Acute Success | | Chronic Success | |
|---|---|---|---|---|---|
| | | Number | Percent | Number | Percent |
| Randomized to ablation | 65 | 46/65 | 71% [60%, 82%]* | 36/65 | 55% [43%, 68%]* |
| Control cross-over | 17 | 14/17 | 82% [57%, 96%] | 12/17 | 71% [44%, 90%] |
| Emergency use | 15 | 7/10† | 70% [35%, 93%] | 8/15 | 53% [27%, 79%] |
| Nonrandomized | 53 | 42/53 | 79% [68%, 90%] | 22/43‡ | 51% [36%, 66%] |
| Total | 150 | 109/145 | 75% [68%, 82%] | 78/140 | 56% [48%, 64%] |

* [95% confidence intervals by exact method]
† Acute success not assessed in five patients
‡ Six-month follow-up not available in 10 patients

# 7 PATIENT SELECTION AND TREATMENT

## *7.1 Individualization of Treatment*

To screen patients for left ventricular or atrial thrombus or myxoma, it is recommended that patients undergo surface or transesophageal echocardiography or a comparable cardiac imaging study prior to the ablation procedure.

**To avoid thromboemboli, intravenous heparin or an acceptable alternative must be used when entering the left heart during ablation.** During the trial, monitoring of activated clotting time (ACT) was performed as follows:

- The patient's baseline ACT was measured.
- An initial intravenous heparin bolus of 5,000 to 10,000 units was given prior to ablation.
- Heparin was given to prolong the ACT to 2 to 2½ times the baseline value throughout the time the Chilli Catheter remained in the left heart. ACT was measured every 30 to 60 minutes.

Aspirin, and less often warfarin, were given to most patients after ablation. No consensus yet exists about the need for continued anticoagulation or antiplatelet therapy after ablation. In the

clinical studies, the antiplatelet and/or anticoagulation therapy was continued for approximately 3 months following ablation.

### *7.2 Specific Patient Populations*

The safety and effectiveness of cardiac ablation has not been adequately studied in:

- patients who have not failed antiarrhythmic drug therapy;
- patients with idiopathic VT or bundle-branch reentrant tachycardia;
- patients with only unmappable or hemodynamically unstable VT;
- patients who are pregnant; or
- asymptomatic patients with ventricular tachycardia.

## 8 PATIENT COUNSELING INFORMATION

Physicians should consider the following points in counseling the patient about this device:

- Alternative treatments for ventricular tachycardia include antiarrhythmic medications, surgical implantation of an implantable cardioverter defibrillator (ICD), or surgical intervention to remove abnormal heart tissue or disconnect the abnormal pathway.
- Risks of the ablation procedure include bleeding at the catheter insertion site, catheter damage to the heart and blood vessels, blood clots, infection, myocardial infarction, cerebrovascular accident and death.
- A potential benefit of the Chilli Cooled Ablation procedure is the prevention of the recurrence of ventricular tachycardia.

## 9 PATIENT INFORMATION

A patient information brochure (provided to the physician with the Chilli Catheter) contains information for patients considering treatment using the Chilli Cooled Ablation System for ventricular tachycardia.

Additional copies can be obtained from Cardiac Pathways Corporation, 995 Benecia Avenue, Sunnyvale, CA 94086.

## 10 HOW SUPPLIED

The Chilli Catheter is available with the following items:

| | |
|---|---|
| Two curve types: | Model 3005 (standard curve) |
| | Model 3006 (large curve) |
| Tip electrode: | 4 mm tip |
| Spacing: | Standard 2-5-2 spacing (edge-to-edge electrode spacing) |

Cardiac Pathways Model 8004 RF Generator and Pump System

Cardiac Pathways Model 2001, 2002, 2028, 2029 EGM/RF Generator Cable

Cardiac Pathways Model 2100 Tubing Kit

Cardiac Pathways Model 2035 Switch Box

Cardiac Pathways Model 2045 RF Filter Box

A separately packaged EGM cable is required for connecting the catheter to external stimulators, the Model 8004 RF Generator, and electrophysiologic recorders.

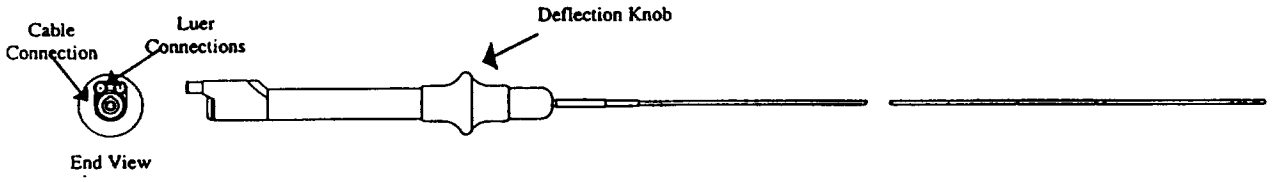



**Figure 2: The Chilli Catheter**

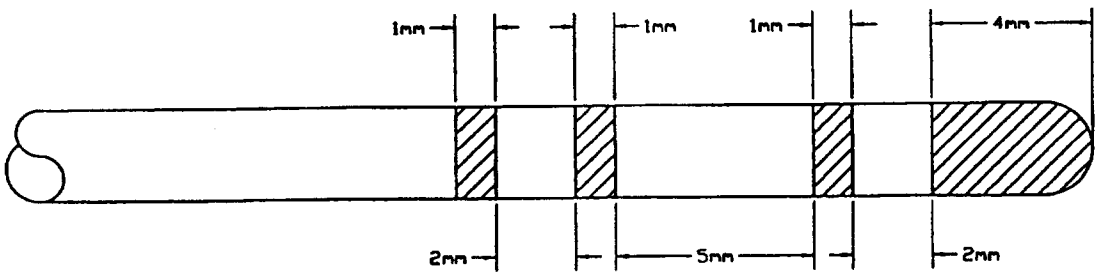



**Figure 3: Drawing of the Distal Catheter Shaft**

Pulling the deflection knob away from the catheter shaft causes the tip to deflect. Pushing the knob towards the catheter shaft straightens the tip. Rotating the entire handle to the left or right rotates the catheter tip in either direction. Fluid for cooling the catheter tip during ablation flows from the pump to the tip through one cooling lumen and back to the collection reservoir through the other cooling lumen.

### *10.1 Packaging*

The Chilli Catheter is supplied STERILE. It has been sterilized with ethylene oxide gas. The catheter is placed into a polystyrene tray designed to restrain the catheter from movement. The tray is sealed in a Tyvek®/Polymylar pouch.

### *10.2 Storage*

The Chilli Catheter must be stored in a cool, dry place. Storage temperature should be between 5° and 25° C (41° and 77° F).

## 11 DIRECTIONS FOR USE

This section provides an overview of Directions for Use – See _____ for complete information.

### *11.1 Physician Training*

- Physicians must be familiar with the techniques and appropriately trained for cardiac mapping and ablation procedures.

- Physicians must have received an in-service from qualified Cardiac Pathways personnel regarding the Chilli Cooled Ablation System prior to performing the initial case with the system.

- Cardiac Pathways personnel must be present during the first two procedures performed with the system to answer any technical questions regarding the system.

- All mapping and ablation procedures must be performed in a fully-equipped electrophysiology laboratory.

### *11.2 Materials Required*

- Cardiac Pathways Model 3005 or 3006 Chilli Catheter
- Cardiac Pathways Model 2001 EGM/RF Generator Cable
- Cardiac Pathways Model 2100 Tubing Kit
- 7F or 8F Venous Introducer Sheath (not included in the packaging)
- Cardiac Pathways Model 8004 RF Generator
- Patient Return Electrode with cord (Pfizer Valleylab, cat. No. E7506)
- Normal saline, sterile

### *11.3 Chilli Catheter Setup and Operation*

Before use, inspect the packaging for any violation of the sterile barrier and inspect the catheter for any defects. Do not use any potentially contaminated or defective equipment.

**Note:** Operation of the Model 8004 RF Generator is completely described in the *Model 8004 Operator's Manual*. The operator should read the Operator's Manual prior to using the system.

See Section 1 for a detailed description of the Chilli Catheter.

### *11.4 Operating Instructions:*

1. Connect the patient to an ECG recording system to facilitate arrhythmia monitoring.

   **Note:** This should be done prior to introducing any intracardiac catheters.

2. Attach the Patient Return Electrode as follows. Clean and dry an area of skin 4 inches x 6 inches in the left subscapular area. Shave hair in the area if necessary. Unwrap the Patient Return Electrode and apply it to the skin with firm pressure, avoiding wrinkles or kinks. Attach the electrode cord to the Reference outlet of the Model 8004 RF Generator.

3. Place a 7F or 8F introducer sheath percutaneously into the femoral or other large vessel using the Seldinger technique.

4. Open the Chilli Catheter package and the Tubing Kit package. Carefully transfer the package contents into the sterile field.

5. Connect the cooling fluid collection bag and extension tubes of the Tubing Kit to the Chilli Catheter and to the Model 8004 RF Generator according to Figure 4. Also refer to the



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Directions for Use provided with the Tubing Kit. Proper sterile technique must be used when assembling the Tubing Kit. Care must be taken to ensure all luer fittings are secure to prevent leaking. For cooling fluid reservoir, use ONLY sterile, 0.9% saline for intravenous injection. 1000 ml will supply 10-20 lesions depending on duration of ablation.

6. Before placing the Chilli Catheter in the sheath, start the pump according to the Operator's Manual provided with the Model 8004 RF Generator. Check for proper connections, circulation of fluid, and lumen patency. Completely prime the syringe, tube set, and catheter. Check for leaks at the tip of the catheter and at the Luer connections. Do not use a Chilli Catheter with leaks. Assure that fluid flows completely through the catheter to the cooling fluid collection bag.

7. Turn the pump off.

8. Under fluoroscopic guidance, insert the Chilli Catheter into the sheath and advance it through the vasculature into the heart.

9. Attach the appropriate EGM cable by pushing the cable connector into the catheter handle. The connector is keyed to ensure that appropriate connections are made between the handle and the cable.

10. Connect the opposite end of the cable to the Model 8004 RF Generator.

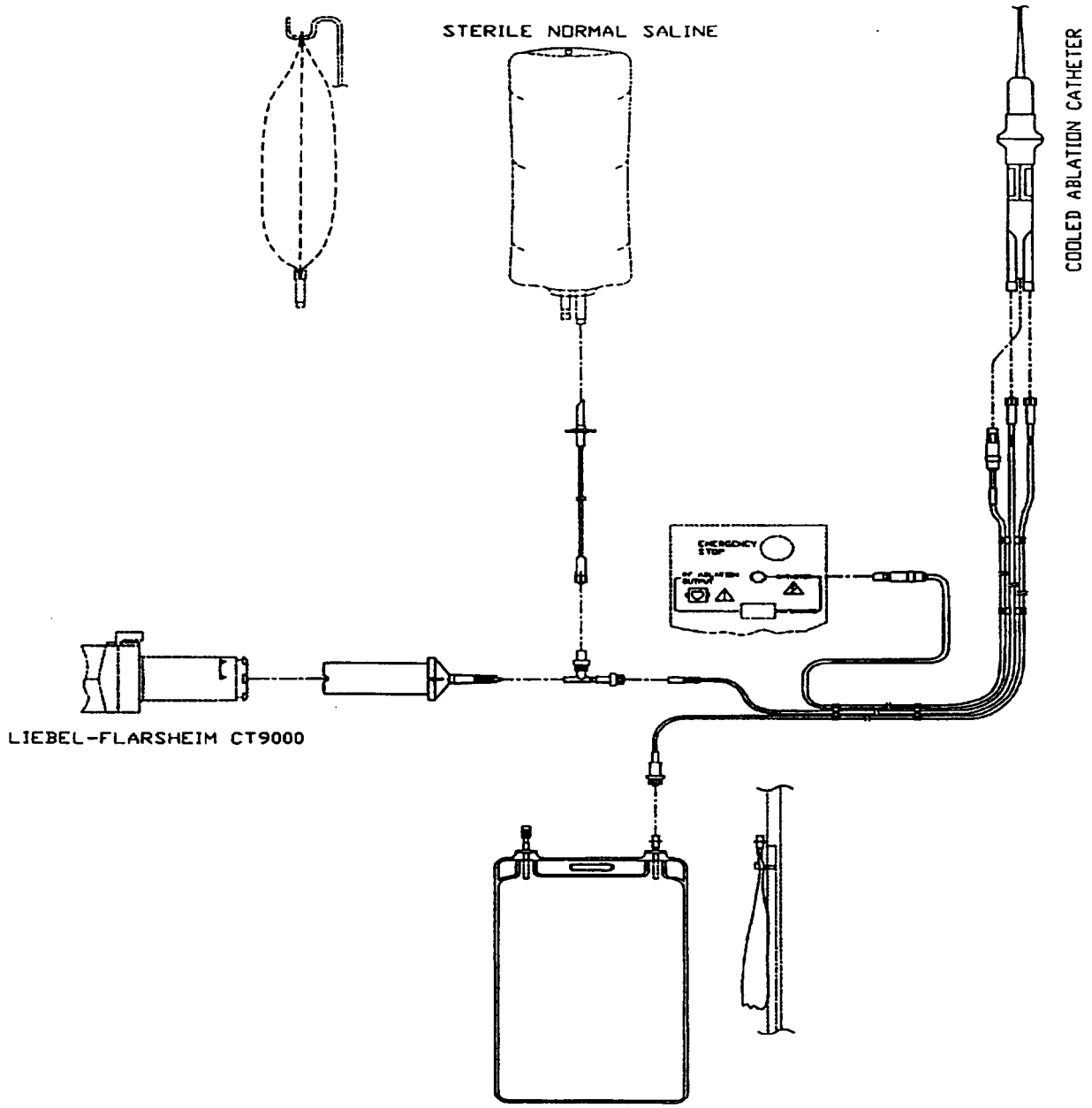


**Figure 4: Connection Scheme for Tubing Kit**

11. Use the deflection knob (Figure 1 in Section 1) and the handle rotation to position the tip of the catheter in the heart. Pulling the deflection knob away from the catheter shaft will cause the tip to deflect. Pushing the deflection knob towards the catheter shaft will straighten the catheter. The catheter should hold the position selected without the need to maintain pressure on the knob. Rotating the entire handle assembly controls the rotation of the catheter tip.

12. Refer to the Model 8004 RF Generator Operator's Manual for setting ablation parameters and for initial cooling system operation (for example, priming the pump).

13. Perform the ablation procedure in accordance with standard medical procedure (Make sure that cooling fluid is circulating throughout the application of RF energy). The pump will

start automatically when the system is enabled. Observe on the Model 8004 RF Generator display a fall in catheter tip temperature. The temperature should fall 6 - 8° C within 15 seconds.

14. The pump will automatically refill when necessary.

---------- end of IFU ----------

# Information For

# Patients Considering

# Heart Ablation

## Cardiac Pathways Corporation

## Chilli Cooled Ablation System

**Cardiac Pathways Corporation**

**995 Benecia Avenue**

**Sunnyvale, CA 94086**

Information for patients considering cooled catheter ablation for ventricular tachycardia

Your doctor has recommended that you have a cooled catheter ablation procedure to treat your abnormal heart rhythm, called ventricular tachycardia (VT). This information is provided to answer many of the questions you and your family may have.

## This booklet contains

Before discussing the details of catheter ablation, it is helpful to understand how the heart works.

## How your heart works

The heart is a hollow, muscular organ made up of four chambers that pump blood through the body in response to signals from the heart's electrical conduction system.

## The circulatory system of the heart

The two upper chambers (atria) collect blood entering the heart. Once full, they squeeze (contract) to force blood into the two lower chambers (ventricles). The ventricles then contract to pump blood to the lungs from the right side of the heart and to the rest of the body from the left side of the heart. (See figure1.)

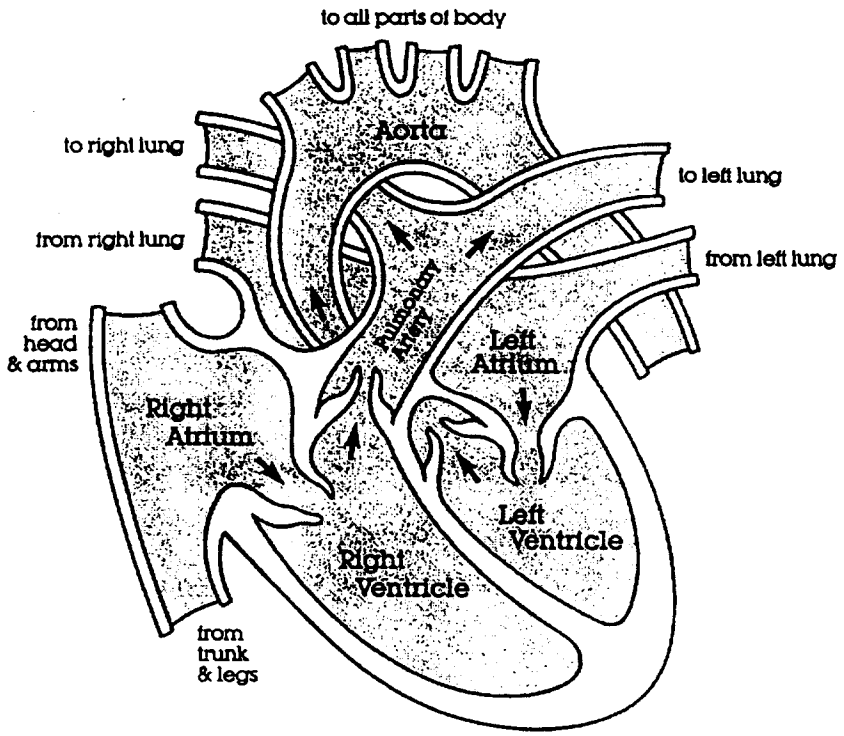


**Figure1. Circulation system of the heart.**



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## The electrical circuit of the heart

Electrical signals travel through the heart along a pathway. This pathway begins in the sinus node, a group of specialized cells that cause the heart to beat at a regular rate and rhythm. In a normal heartbeat, these signals spread across the atria, causing them to contract. The signal slows down briefly at the junction of the atria and ventricles (A-V node) and enters the ventricles through special pathways (bundle branches) that divide into smaller pathways (Purkinje fibers). (See figure2.) The signals then move from cell to cell causing the heart to contract. You can feel this contraction or heartbeat when you take your pulse.

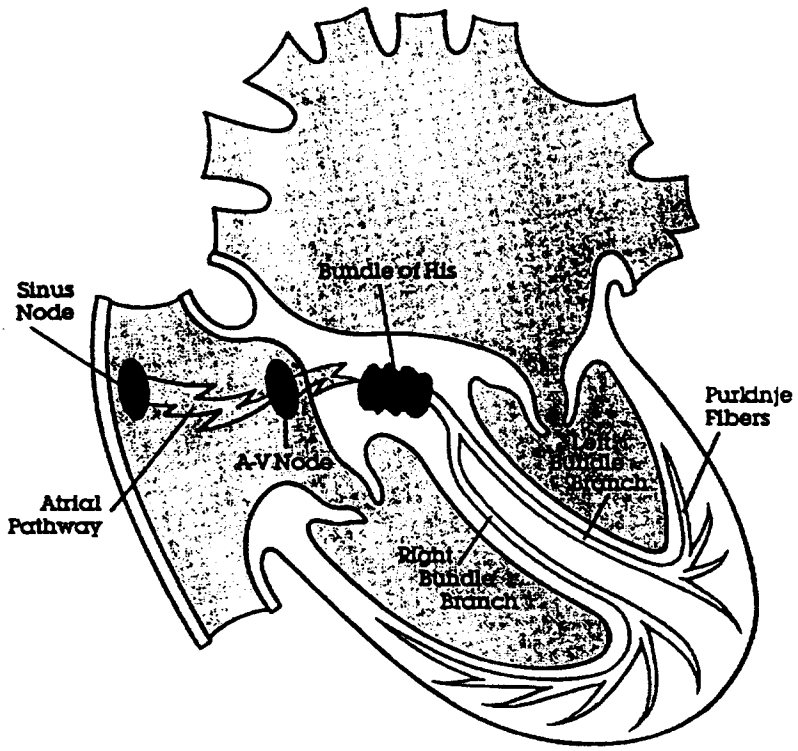


**Figure 2. Electrical pathways of the heart.**

This regular heartbeat is called sinus rhythm. An abnormal heart rate and/or rhythm is called an arrhythmia. It can originate from either the atrium or the ventricle.

## What is ventricular tachycardia (VT)?

VT is an arrhythmia that originates in the ventricles. It often occurs when abnormal electrical pathways exist in the ventricles. These pathways are frequently found in an area of the heart that has been damaged by heart attack or disease. When the electrical signal enters this abnormal pathway, it causes rapid contractions of the ventricles that interfere with the heart's ability to pump blood to the body effectively. You may or may not have symptoms. You may feel skipped beats or a fluttering sensation in your chest (palpitations). VT may cause you to faint, to feel lightheaded, or to feel chest pain or shortness of breath. If VT doesn't stop by itself, it can sometimes result in your heart stopping (cardiac arrest) and death. (See figure 3.)

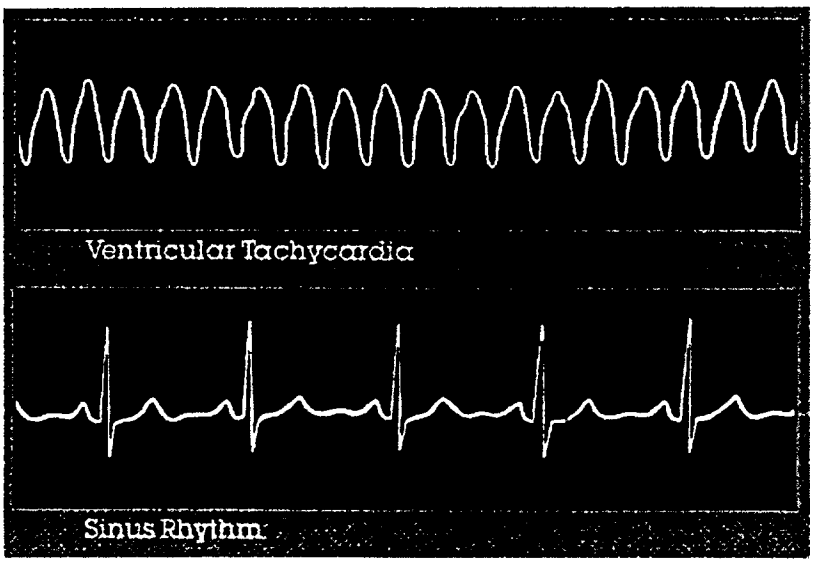


**Figure 3. Electrocardiogram showing normal sinus rhythm and ventricular tachycardia.**

## How is VT treated?

Your doctor will discuss with you the following options to treat your arrhythmia.

**Medications** can be used to change the characteristics of the electrical signals in the heart to help maintain a normal heart rate and rhythm. Mediations are often tried first. These medications must be taken indefinitely, are not always totally effective and may produce side effects. Other methods that are available to treat your arrhythmia require different levels of invasive therapy. Antiarrhythmic drug therapy may be used in combination with all other treatments described.

In some patients, an **implantable cardioverter defibrillator (ICD)** device is surgically placed under the skin of the upper chest. An ICD monitors the heart rate and rhythm and will deliver an electric shock to restore sinus rhythm if an abnormal ventricular rhythm is seen. ICDs have been effective in reducing the incidence of sudden cardiac death. However, they do not prevent the abnormal ventricular rhythm from occurring. Though life-saving, shocks from the ICD can be painful. ICD therapy may be used in conjunction with all other treatments described.

For a small number of patients, **surgery** is an option in order to disconnect the abnormal pathway or to remove the abnormal heart tissue responsible for the arrhythmia. This major heart operation is usually done at the same time as other necessary heart surgery. Although it offers a permanent cure, it is associated with a risk of complications and death.

**Catheter ablation** is a non-surgical option that uses a type of energy called radiofrequency (RF) energy to destroy areas of heart tissue that cause the arrhythmia. The RF energy heats tissue and causes a burn that will block the arrhythmia from traveling down the abnormal pathway. RF energy can be delivered through the Chilli® Cooled Ablation Catheter to the catheter tip. In addition, the Chilli® Cooled Ablation Catheter contains small lumens, or tubes, that deliver a saline solution to cool the tip of the catheter, eliminating excessive heat build-up during delivery of RF energy. This cooling permits RF energy to reach target sites deep within the wall of the heart and to penetrate thick scar tissue. Cooled Catheter Ablation may permanently cure the arrhythmia problem you have been experiencing. (See figure 4.)

**Figure 4. Chilli Cooled Ablation Catheter positioned in the left ventricle.**

## What are the risks of this procedure?

An ablation procedure requires insertion of catheters into the body, and therefore involves some risks. The most common complication is bleeding at the site of catheter insertion. Blood can collect under the skin, causing localized swelling and/or a bruise that heals in a few days. More serious complications occur less frequently. These include damage to the heart and blood vessels caused by the catheters, blood clots, infection, heart attack and stroke. Death can occur. In rare cases, ablation can cause damage to part of the heart's normal conduction system, making placement of a permanent pacemaker necessary.

## What are the potential benefits of this procedure?

Prevention of further episodes of your arrhythmia is possible with the cooled ablation procedure. In a recent study using the Cooled Ablation System, about half of the patients had no recurrence of VT following ablation. Cooling at the target site allows placement of deeper lesions that can penetrate thick ventricular scar

tissue and reach sites deep within the wall of the heart. In many cases, medications for arrhythmia control and their side effects can be avoided completely.

## What happens during the cooled catheter ablation procedure?

Before your ablation, you must have an electrophysiology (EP) study to identify the sites of abnormal conduction causing your VT. If you haven't already had an EP study, your doctor may decide to do both procedures in the same setting. These procedures take place in a specially equipped laboratory where trained personnel work together with your doctor to provide your care. During the procedure, you will be lying on an X-ray table for approximately 2-6 hours, covered with sterile sheets and connected to various heart and blood pressure monitors. The staff will get you positioned as comfortably as possible before the procedure begins. You will be given sedatives to help you relax during the procedure. You will probably not go to sleep, though, so remember it is very important for you to try to remain as still as possible. The staff will monitor your vital signs constantly and will check to see how you are feeling. Medication for discomfort is available, if needed.

The skin of your neck, upper chest, arm or groin will be shaved and cleansed thoroughly. The doctor will numb the catheter insertion sites with a local anesthetic. After inserting the catheters into the vessels, your doctor will use a type of video X-ray machine called a fluoroscope to guide the catheters into the heart. These special catheters are long flexible tubes with wires inside that can conduct electrical signals to and from the heart. The catheters will be used to deliver pacing pulses to start and stop the VT. Once the site of the abnormal electrical pathway is located, the Chilli® Cooled Ablation Catheter is positioned at that site and RF energy is delivered. Each application of energy usually lasts about a minute. Several applications of energy may be required, but the exact number will be determined by your doctor during the procedure. Although the procedure is usually not painful, you may experience some discomfort, described as chest warmth or burning, that goes away immediately when the RF energy is turned off. You may also feel tired and uncomfortable from lying still for a long time. The soreness at the catheter insertion sites will go away over a few days.

Once the ablation procedure is complete, the catheters are removed from your vessels, and firm pressure is applied for about 10-20 minutes until a seal forms at the catheter insertion site. Then you are taken back to your room. You will be asked to lie flat in bed for two to four hours without lifting or bending the leg where the catheters were inserted. Your nurse will check your vital signs and



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puncture sites frequently. You should notify the nurse immediately if you feel sudden pain or if you notice bleeding from any of the catheter insertion sites. Often, patients go home the day after the procedure, but your doctor will make that decision. You will receive specific discharge instructions from your doctor.

## Glossary

**Ablation**-Procedure in which heart tissue is burned to remove the source of the abnormal heart rhythm

**Ablation catheter**-Long, flexible tube that can send and receive electrical impulses from the heart

**Arrhythmia**-Abnormal heart rate or rhythm

**Atria**-Upper chambers of the heart

**Conduction system**-Electrical circuit of the heart

**Electrophysiology study**-A study in which catheters are inserted into the heart to test the electrical conduction system of the heart

**Implantable Cardioverter Defibrillator (ICD)**-An electrical device that is surgically placed in the body to monitor and treat abnormal heart rhythms

**Ventricles**-Lower chambers of the heart

**Ventricular tachycardia(VT)**-Abnormal heart rhythm that originates from the lower chambers of the heart