Final Labeling

CARDIAC PATHWAYS CORPORATION

995 Beneccia Avenue
Sunnyvale, CA 94086
Phone: (408) 737-0505
Fax: (408) 737-1700

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Rev B

Cardiac Pathways Corporation

Chilli® Cooled Ablation System
Chilli® Cooled Ablation System with Tracking

Instructions for Use

Read These Instructions Before Use

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

Table of Contents

1 ice Description

The Chilli® Cooled Ablation System (Chilli Cooled Ablation System) includes the Chilli Cooled Ablation Catheter (Chilli Catheter) or the Chilli Cooled Ablation Catheter with Tracking (Chilli Catheter with Tracking) 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 electrode. The handle includes the electrical connector for the electrode wires, a knob used to deflect the tip, and two luer fitting 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. (See Chapter 8, How Supplied.) The fluid pump on the Model 8004 RF Generator circulates cooling fluid through two lumens joined at the tip. The Chilli Catheter with Tracking comes with three transducers embedded along the shaft. These catheters are to be used with the Arrhythmia Mapping and Tracking System.

2 ications

The Chilli Cooled Ablation System is indicated for:

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

In addition, the Chilli Catheter with Tracking is used with the Arrhythmia Mapping and Tracking System to provide catheter location information.

3 traindications

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 nings 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 Chapter 9).
- **Instructions for Use** – Do not attempt to operate the Chilli Cooled Ablation System before completely reading and understanding the applicable instructions 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.

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 and 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.

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.

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.

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 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 (returning the deflection control knob to the neutral position).
- 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.

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.
- Catheter location information is not available from the Chilli Catheter with Tracking during delivery of RF power.

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. The clinical studies reported here were conducted using the Chilli Cooled Ablation System before the addition of transducers which provide catheter location information. Bench and animal testing were performed to evaluate the location features of the Chilli Catheters with Tracking. 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.

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 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-operativecardiogenic 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 with the first seven days after ablation.

Of the 26 total deaths, six occur 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.

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 [redacted]ical Studies

The clinical studies reported here were conducted using the Chilli Cooled Ablation System before the addition of transducers which provide catheter location information. Bench and animal testing were performed to evaluate the location features of the Chilli Catheters with Tracking. 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 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).

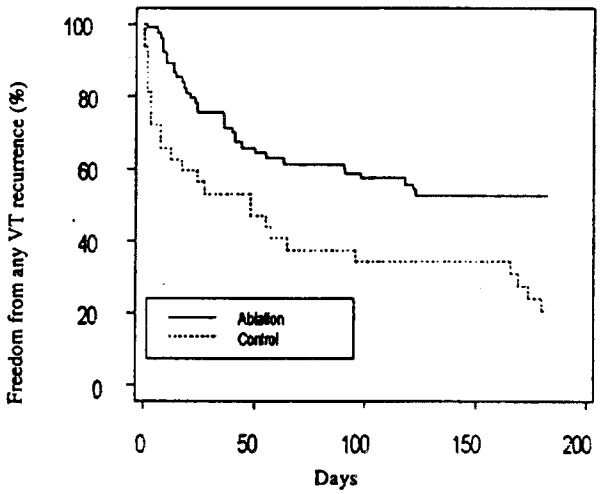

Figure 1. Freedom from VT Recurrence by Treatment*
All patients in the Randomized Trial, N=107

* 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

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 measure]
† Acute success not assessed in five patients
‡ Six-month follow-up not available in 10 patients

7 ent Information

PATIENT SELECTION AND TREATMENT

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 2 1/2 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, was 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.

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
- asymptomatic patients with ventricular tachycardia

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.

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.

Supplied

The Chilli Catheter is available with the following items:

- Bidirectional and unidirectional
- 100, 110, 120 cm lengths
- Curves
  - Without tracking
  - With tracking
- 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, 2062, 2063 EGM/RF Generator Cable or 2053, 2057, 2055 EGM/PAM Junction Box
- Cardiac Pathways Model 2100 Tubing Kit
- Cardiac Pathways Model 2035, 2050 Switch Boxes
- 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.

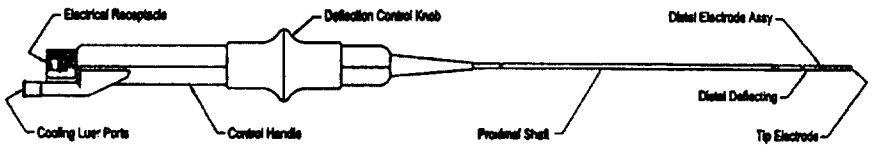

Figure 2. The Chilli Cooled Ablation Catheter

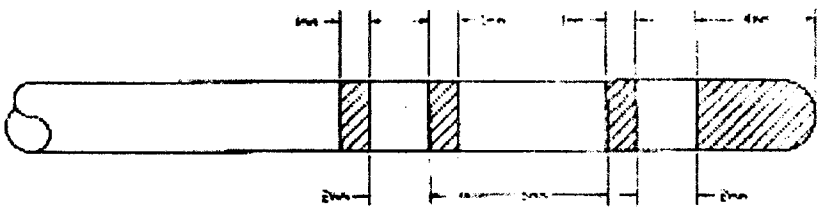

Figure 3. Drawing of the Electrode Spacing

43

The deflection control knob is packaged in the neutral position in which the distal tip and shaft are straight. Pulling the deflection knob away from the catheter shaft causes the tip to deflect in one direction. For catheters with bidirectional deflection, pushing the knob towards the catheter shaft causes the tip to deflect in the opposite direction. 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.

PACKAGING

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

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).

9 ctions for Use

This chapter provides an overview of Directions for Use. Refer to the rest of this manual and the *Model 8004 RF Generator and Pump System Operator's Manual* for complete information.

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.

MATERIALS REQUIRED

- Cardiac Pathways Chilli Catheter
- Cardiac Pathways 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
- To utilize the tracking feature, refer to the Arrhythmia Mapping and Tracking System Operator's Manual for specific materials and instructions

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 Chapters 1 and 8 for a detailed description of the Chilli Catheter.

45

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 Instructions 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.

46

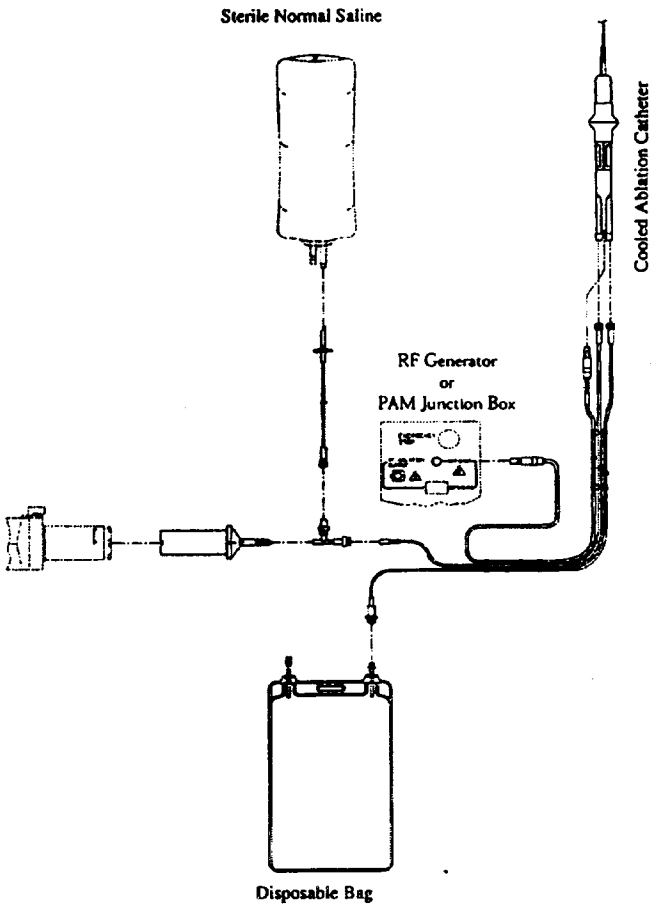

Figure 4. Connection Scheme for Tubing Kit

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, or, for tracking, attach to the appropriate connection on the Position Acquisition Module (PAM) junction box.
11. Use the deflection knob (Figure 2 in Chapter 8) and the handle rotation to position the tip of the catheter in the heart. Pulling the deflection knob backward (toward the operator) will cause the tip to deflect in one direction. For catheters with bidirectional deflection, pushing the deflection knob forward (away from the operator) will deflect the catheter in the opposite direction. In the neutral position, the distal tip and shaft of the catheter straighten. 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.

Cardiac Pathways Corporation
995 Benecia Avenue
Sunnyvale, CA USA 94086
Phone: (408) 737-0505
FAX: (408) 737-1700

Authorized Representative
Cardiac Pathways Corporation (Europe)
P.O. Box 13892
London, N6 5WF
United Kingdom