Boston Scientific

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2015-01
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Chilli II®
Cooled Ablation Catheter

TABLE OF CONTENTS

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Carefully read all instructions prior to use; including the Boston Scientific Corporation (BSC) Operators Manuals for the Model 8005 Pump and associated compatible, BSC radiofrequency (RF) Generator/Controller. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Chilli II Cooled Ablation System includes the Chilli II Cooled Ablation Catheter (Chilli II Catheter) (Figure 1) and the Model 8005 Pump (CircuCool® Pump) with a compatible BSC RF Cardiac Ablation Controller (henceforth, referred to as the Controller). The appropriate accompanying Operator's Manuals must be consulted and reviewed for all equipment in use.

The Chilli II Catheter has a distal electrode segment (Figure 2) and a proximal handle that are connected by a torquable catheter shaft. The electrode segment is comprised of a tip electrode and ring electrodes. The tip electrode has an embedded temperature sensor and delivers RF energy for cardiac ablation. The ring electrodes record ECG signals for mapping and deliver stimulus for pacing. The handle includes the electrical connector for the cable connection to the RF Cardiac Ablation Pod (henceforth, referred to as the Pod) and two luer fittings used to connect the catheter to the fluid pump. The steering assembly, electrode lead wires, and two lumens carrying cooling fluid reside within the catheter shaft.

The Chilli II Catheter incorporates a closed-loop cooling mechanism capable of removing heat from the tip/tissue interface. The Pump circulates cooling fluid through the two lumens without infusing it into the heart. Two luer connections at the proximal end of the handle provide the connection for the cooling fluid to flow to and from the catheter tip via the pump and corresponding tubing kit. Fluid flow through the tip during ablation provides cooling of the tip. The catheter is shown in Figure 1 (below). Figure 5 (page 5) provides a connectivity diagram for the BSC Cardiac Ablation System with 8005 system.

The Chilli II Catheter has high torque characteristics. The degree of tip deflection of the Chilli II Catheter is controlled by the Steering Knob on the catheter handle. Rotating the entire handle to the right or left rotates the catheter tip clockwise or counter-clockwise, respectively (as viewed from the proximal end of the catheter shaft). Once the catheter is positioned, the tension control knob on the handle of the catheter locks the curve into place.

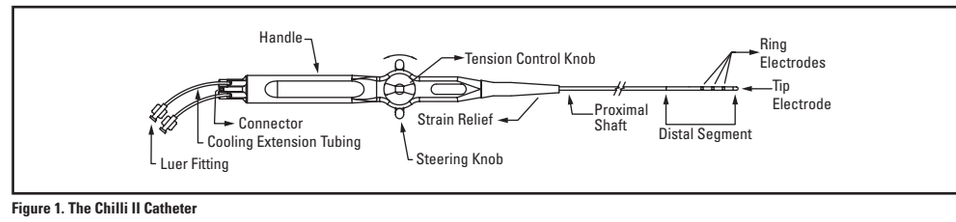

Figure 1. The Chilli II Catheter

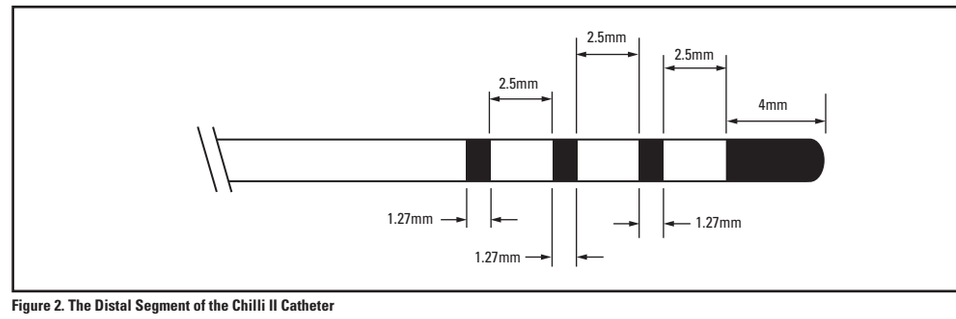

Figure 2. The Distal Segment of the Chilli II Catheter

INDICATIONS FOR USE

The Chilli II 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

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.

WARNINGS

Before using, inspect for physical damage, including electrical insulation on the cables and the catheter shaft. Replace damaged equipment.

Care must be taken to ensure that any equipment used in connection with the BSC catheters be type CF, be defibrillation proof, and meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use.

No modification of this equipment is allowed.

Maximum Catheter Rated Voltage: 178 Vrms (251 Vpk)

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 arrhythmias in patients with unablatable ventricular tachycardia and/or ventricular fibrillation without additional standard therapy such as an implantable cardioverter/defibrillator (ICD).

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.

Do not ablate from the 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.

The Chilli II® Catheter should be used only by physicians fully trained in cardiac electrophysiology.

Ablation in contact with any other electrodes alters the function of the catheter and can lead to thrombus, coagulum, or char formation.

At no time should a Chilli II Catheter be advanced or withdrawn when resistance is felt, without determining the cause. Vascular perforation is a risk with any intracardiac catheter.

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

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.

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

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.

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

- Do not wipe this catheter with organic solvents such as alcohol, or immerse the handle cable connector in fluids.
- Excessive curves or kinking of the catheter may damage internal components and affect steering performance.
- The Chilli II Catheter is not intended to be used with a RF generator output setting exceeding 50 watts or 500 Volts peak.
- Do not allow the patient to contact grounded metal surface.
- The RF Generator must only be used in Power Control Mode.
- Electrical recording or stimulation equipment must be isolated and in compliance with relevant EN 60601-1 requirements for intended use. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes under any circumstances.
- Do not use the Chilli II® Cooled Ablation System in the proximity of magnetic resonance imaging (MRI) equipment because the MRI equipment may adversely impact the function of a RF generator and the ablation system may adversely impact the image quality.
- Use only dispersive electrodes that meet or exceed EN 60601-1 requirements and follow the dispersive (grounding) electrode manufacturer's instructions for use.
- 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 use impedance cut-off setting greater than 200 Ohms or temperature cut-off settings of 100 °C or greater because those settings have not been studied.
- Use both fluoroscopy and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid vascular damage, cardiac perforation or tamponade.
- 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.
- Do not deliver RF energy with the catheter outside the target site. RF Generators 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 cut-off (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.
- The Chilli II Catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than 1 1/2 full rotations (540°). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall, before resuming rotation of the handle and catheter shaft.
- Do not insert or withdraw the catheter without straightening the catheter tip (returning the steering lever to neutral position).
- In the event of a suspected failure of the integrity of fluid flow through the catheter, the procedure should be stopped, and both the catheter and the tubing kit should be replaced, primed, and then reinserted. If there is any abnormality of the integrity of fluid flow through the catheter, the catheter should be replaced by a different catheter.
- Do not use the Chilli II Catheter after the expiration date because the device performance may no longer be acceptable and/or the device may no longer be sterile.

HOW SUPPLIED

Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Operating Environment

Ambient Temperature: 10 °C to 40 °C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C

Relative Humidity: 30% to 85%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 20 °C to 30 °C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

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 (The Chilli I Cooled Ablation Catheter and Model 8004 RF Generator and Pump System). 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

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-operative cardiogenic shock, & 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]

All patients treated with Chilli Catheters, N = 150
* 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: 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 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: 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:

Catherization/Ablation Procedure Related

- air embolism
- arrhythmias
- AV fistula
- cardiac perforation
- cardiac/respiratory arrest
- hemorrhage

- hemothorax
- hypotension
- nerve palsy or weakness
- pleuritis
- pulmonary edema
- pneumothorax
- pseudoaneurysm
- sinus or AV node injury
- 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

CLINICAL STUDIES

The clinical studies reported here were conducted using the Chilli™ Cooled Ablation System before the introduction of the Chilli II® Catheter model. 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

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%]

Percent [95% Confidence Interval], (Numerator/Denominator)
All patients enrolled (N = 107)
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 3 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).

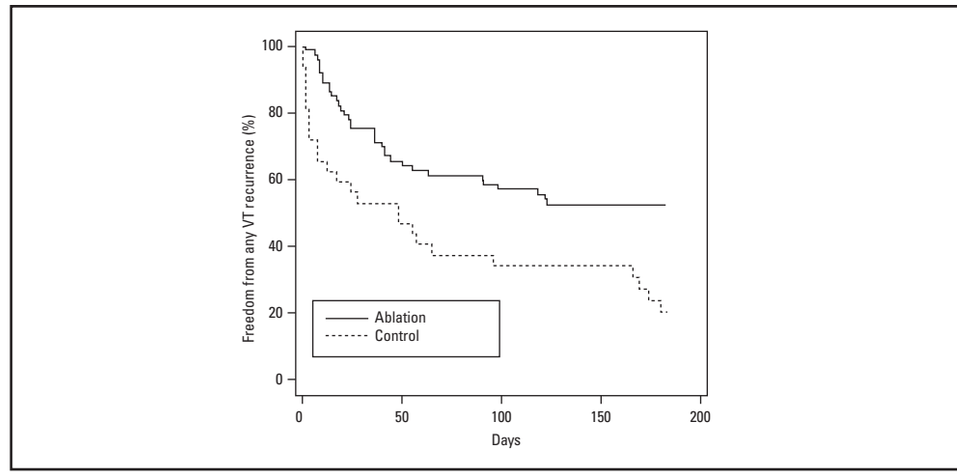

Figure 3. Freedom from VT Recurrence by Treatment*
All patients in the Randomized Trial, N = 107

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 Ablations 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

CHILLI VT POST APPROVAL STUDY (CHILLI VT PAS)

A post approval study (PAS) was conducted to further assess the safety and effectiveness of the Chilli Cooled Ablation System. The objective of this study was to confirm the safety and effectiveness of the Chilli Cooled Ablation System for the treatment of mappable VT in subjects with ischemic heart disease or non-ischemic cardiomyopathy who failed drug therapy. The Chilli VT PAS was conducted using the Chilli Cooled Ablation Catheter and Model 8004 RF Generator and Pump System or Model 8005 Pump. Study endpoints included Freedom from recurrence of any VT at six months, Freedom from Major Adverse Events and Reduction in VT episode density. Clinical data from the subjects were collected from the time of the ablation (Index) procedure and again at six months following the Index procedure. Clinical data were collected on 182 subjects. The analysis was performed on an Intent-To-Treat (ITT) basis so included the entire subject population (N = 182).

***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).

Baseline demographics for the Chilli VT PAS are presented below.

Table 4. Baseline Demographics For Chilli VT Pas

Baseline Demographic	Number (%)
Previous VT ablation	62/182 (34.1%)
Previous ICD	142/182 (78.0%)
Failed amiodarone	141/182 (77.5%)
Failed other AADs	165/182 (90.7%)
Ischemic Heart Disease	123/182 (67.6%)
Non-Ischemic Cardiomyopathy	42/182 (23.1%)
Bundle branch reentry tachycardia	8/116 (6.9%)
MI ≤ 6 weeks before the procedure	10/172 (5.8%)
NYHA Class IV heart failure	8/172 (4.7%)
Heart transplant list candidate	15/172 (8.7%)
Limited life expectancy (terminal illness)	1/172 (0.6%)
Ejection Fraction (%) Mean ± Std. Dev N	 31.7±15.2 162
Number of medications previously failed Mean ± Std. Dev Median Min-Max N	 3.0±1.6 3.0 0.0-8.0 182

Table 5 presents the procedure-related Major Adverse Event Rate. Major adverse events that occurred within seven days of the Index procedure, or the period of hospitalization if extended beyond seven days, were reported. *It should be noted that a recurrence of VT was not counted nor reported as an AE since it was a primary study endpoint.* Seventeen (17) subjects experienced a procedure-related Major Adverse Event. Freedom from Major Complications was observed in 90.7% of the subjects.

Table 5. Procedure-Related Major Adverse Event Rate (N=182)

Overall	One-Sided Exact 95% CI Upper Limit	One-Sided Normal 95% CI Upper Limit	[1] Objective Performance Criteria (OPC)
17/182 (9.3%)	13.7%	12.9%	13.8%

[1]OPC is the percentage of patients who experienced procedure related adverse events as prospectively established from the Investigational Device Exemption (IDE) clinical study.

Table 6 presents a summary of the deaths experienced in Chilli VT PAS as compared to the Chilli IDE study. Eighteen (18) deaths occurred in the 182 subjects enrolled in the Chilli VT PAS.

Table 6. Patient Death Summary

	Chilli VT PAS	Chilli IDE	
Patient Deaths	**Number (%)**	**Number (%)**	**p-value**
Total	18/182 (9.9%)	11/75 (14.7%)	0.1519
Tachyarrhythmic	8/182 (4.4%)	3/75 (4.0%)	0.4423
Cardiac (non-tachyarrhythmic)	4/182 (2.2%)	7/75 (9.3%)	0.0216
Non-cardiac	4/182 (2.2%)	1/75 (1.3%)	0.3069
Unknown	2/182 (1.1%)	0	0.0775

Table 7 presents the observed VT recurrence rate at the Six Month follow-up visit. Eight (8) of the 182 enrolled subjects were excluded from this analysis: six (6) were lost to follow-up, two (2) subjects died prior to the Six Month follow-up visit; a total of 174 subjects were included in this analysis. The observed VT recurrence rate (57.5%) and the one-sided upper limits exceeded the 54.2% OPC. The differences between the PAS and the original IDE patient population contributed to the increase in the percentage of patients who experienced VT at six months post ablation procedure. The subject population changed significantly in the PAS Study from the original IDE Clinical Study. The enrolled subjects in the PAS Study encompassed a wider inclusion (ischemic or non-ischemic cardiomyopathy), and more pathologic population (terminal end stage treatment for VT) than the patient population of the original IDE study. The inclusion criteria were broader in the PAS study than in the IDE study and therefore the sicker patient was not excluded.

Table 7. VT Recurrence at Six Months

Observed VT Recurrence Rate	One-Sided Exact 95% CI Upper Limit	One-Sided Normal 95% CI Upper Limit	[1] Objective Performance Criteria (OPC)
100/174 (57.5%)	63.8%	63.6%	54.2%

[1]OPC is the percentage of patients who experienced procedure related VT as prospectively established from the Investigational Device Exemption (IDE) clinical study.

Figure 4 presents the Kaplan-Meier Event Free Survival Estimates of the freedom from VT rate and the associated 95% confidence intervals. The event-free survival estimates are reported at interval end and the standard errors are calculated by the Greenwood formula.

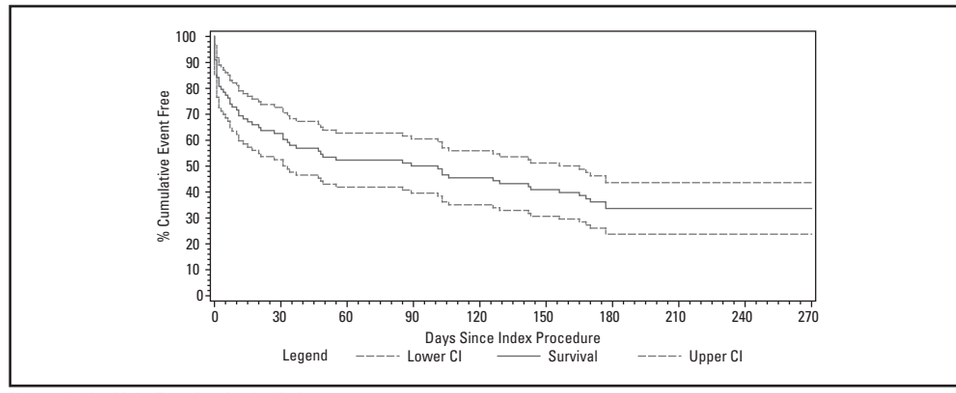

Figure 4. Kaplan-Meier Event Free Survival Estimates

Table 8. Freedom From VT Recurrence At 6 Months

	Interval Ending (Days Post Procedure)						
	0	**7**	**14**	**30**	**90**	**180**	**270**
Entered	174	158	129	123	114	95	58
Censored	0	1	0	1	1	16	55
Events	16	28	6	8	18	21	0
At Risk	174	157.5	129	122.5	113.5	87	30.5
Events/month	480.0	120.0	25.7	15.0	9.0	7.0	0.0
Event-Free	90.8%	74.6%	71.2%	66.5%	56.0%	43.1%	43.1%
Std Error	2.2%	3.3%	3.4%	3.6%	3.8%	3.8%	3.8%

Pre-and post-procedure episode density was analyzed as a measure of clinically meaningful ablation success (**Table 9**). One hundred and forty one subjects (141) had VT episode density data collected both pre-procedure and at Six Months post-procedure, where the VT episode collection methodology that was at least as comprehensive post-procedure as is was pre-procedure.

Table 9. Summary Of VT Episode Density

Statistic	Pre – Procedure	Post-Procedure	Difference	Mean Percentage Change	P-value	
					Paired-t Test	Wilcoxon Signed Rank test
Mean	33.98	4.64	-29.34	86.34%	<0.0001	<0.0001
Std. Dev.	83.26	15.25	84.47			
95% CI[1]	-	-	[-43.3,-15.4]			
Min	0.0	0.0	-745.5			
Max	750.0	126.8	116.5			
N	141	141	141			

N (%) of patients with ≥75% reduction[2]: 80.7% (113/140) [73.2%, 86.9%]
[1] 95% CI was estimated by normal approximation
[2] 95% CI was estimated by exact method

The mean percent change can be affected by outliers so the data was examined to determine how many subjects experienced at least a 75% reduction in episodes to determine if subjects were benefiting from the therapy. This analysis found that 81% of the subjects enrolled experienced at least a 75% reduction in episodes post-procedure compared to episodes pre-procedure.

PATIENT 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 System procedure in the revention of the recurrence of ventricular tachycardia.

PATIENT INFORMATION

A patient information brochure titled "Understanding Arrhythmias" is available through your Boston Scientific representative.

MATERIALS REQUIRED

- Boston Scientific's Chilli II® Catheter
- Commercially available disposable dispersive pads which are in compliance with IEC 60601-1/IEC 60601-2-2.
- Sterile dextrose 5% in water (commercially available)
- 8F (2.67 mm) Venous Introducer Sheath
- The following compatible Boston Scientific RF Generator/Controllers can be used in conjunction with the Chilli II Catheter:

BSC Maestro 4000 Cardiac Ablation Controller and:

- RF Ablation Pod
- 681 Cable
- 8005 Pump (CircuCool Pump)
- Tubing Kit 2104

Or

BSC Maestro 3000® Cardiac Ablation Controller and

- RF Ablation Pod
- 681 Cable
- 8005 Pump (CircuCool Pump)
- Tubing Kit 2104

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 Boston Scientific personnel regarding the Chilli Cooled Ablation system prior to performing the initial case with the system.
- Boston Scientific 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.

CHILLI II CATHETER SETUP AND OPERATION

Note: Operation of the Model 8005 RF Pump is completely described in the Model 8005 Operator's Manual. The operator should read the Operator's Manual prior to using the system.

Note: The operator should read the appropriate operator's manual prior to use. Consult the Operator's Manual for use of the RF Generator in Power Control Mode.

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

1. Connect the patient to an ECG recording system to facilitate arrhythmia monitoring per the standard operating procedure of the electrophysiology lab or manufacturer's operator's manual.

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

2. Attach the dispersive pad per the manufacturer's directions for use.
3. Place an 8F (2.67 mm) venous introducer sheath percutaneously into the vein or artery using the Seldinger technique.
4. Open the Chilli II Catheter package and the Tubing Kit package. Carefully transfer the package contents into the sterile field, maintaining sterile technique.
5. Connect the cooling fluid extension tubes of the Tubing Kit to the respective Pump according to Figure 5 (page 5). Refer to the Instructions provided with the Tubing Kit.
6. Connect the Chilli II Catheter to the Tubing Kit. Care must be taken to ensure all luer fittings are secure to prevent leaking. For the Model 8005 Pump, use **ONLY** sterile, dextrose 5% in water (D5W). For the Model 8005 Pump, 40 mL of sterile D5W are needed to prime the tubing and catheter. No additional fluid is required for the procedure.
7. Before placing the Chilli II Catheter in the sheath, start the pump according to the Operator's Manual provided with the Model 8005 Pump. Check for proper connections, circulation of fluid and lumen patency. Ensure the pump section of tubing is properly seated on the rollers. Completely prime the pump, tube set and catheter for approximately 5 minutes. Check for leaks at the tip of the catheter, at the handle, and at the luer connections. Do not use a Chilli II Catheter that leaks. Assure that fluid flows completely through the catheter to the cooling fluid outlet lumen. Leave the pump on.
8. Under fluoroscopic guidance, insert the catheter into the sheath and advance 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. Ensure that the cable/catheter connection remains dry throughout the procedure.
10. Connect the opposite end of the cable to the Controller according to their respective Operator's Manuals. Refer to Figure 5 (page 5).
11. The degree of tip deflection of the Chilli II Catheter is controlled by the Steering Knob on the catheter handle. If the Steering Knob is turned in a clockwise direction from its neutral position, the tip will curve proportionately depending upon the curve option selected. Turning the Steering Knob in the counter clockwise direction will cause the tip to deflect in the opposite direction. To prevent overstressing the tip, the Steering Knob movement is limited by the handle design. The tension adjust knob may be used when the desired catheter placement is achieved.
12. Determine the area of interest for ablation. Refer to the Operator's Manual for initial cooling system operation.
13. Refer to the Controller Operator's manual for setting ablation parameters.
14. Perform the ablation procedure in accordance with standard medical procedure. Ensure that cooling fluid is circulating throughout the application of RF energy.
15. Fluid should be continuously circulated through the tip. The 8005 Pump will automatically determine the fluid flow rate. Do not attempt to modify the fluid flow rate or any part of the tubing kit.
16. In the event of a suspected failure of the integrity of fluid flow through the catheter, the procedure should be stopped, and both the catheter and the tubing kit should be replaced, primed and then reinserted. If the parameters do not appear normal or if there is any abnormality of the integrity of fluid flow through the catheter, the catheter should be replaced by a different catheter.
17. Withdraw the Chilli II Catheter when the procedure is finished.
18. Dispose of the Chilli II Catheter per hospital procedures.
19. Carefully monitor patient while in recovery to ensure hemostasis is achieved and any complications are immediately treated.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.

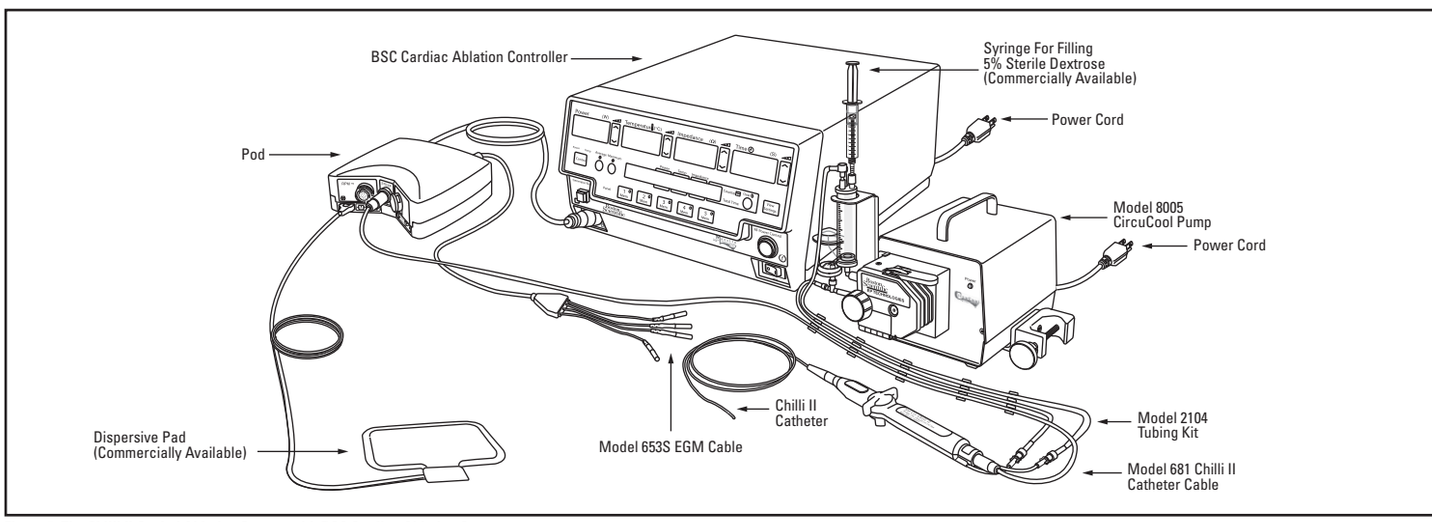

Figure 5. The Chilli II Cooled Ablation System with BSC Cardiac Ablation System

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Do not use if package is damaged.

Recyclable Package

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