

# Chilli II™

Cooled Ablation Catheter

Boston  
Scientific

Cooling Power . . . Contained.

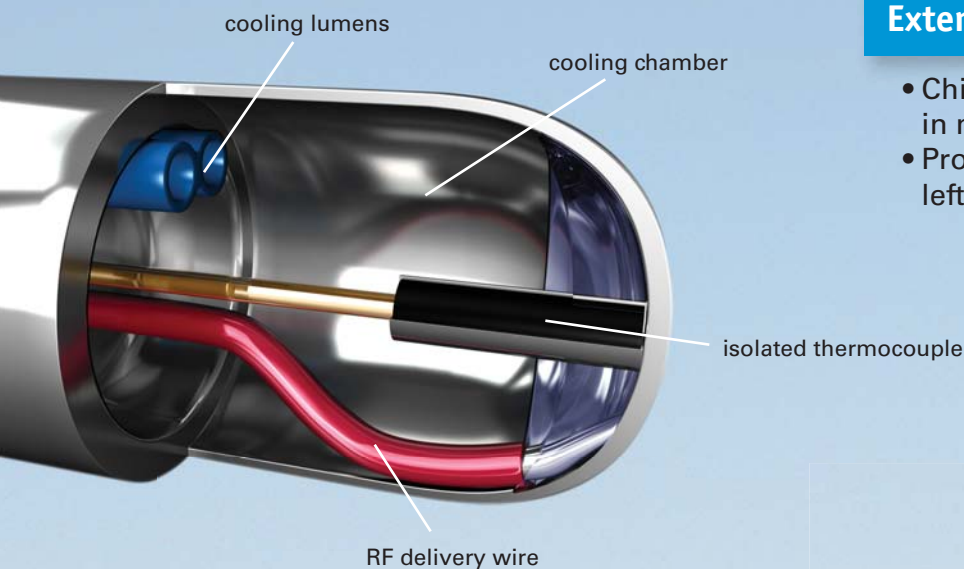


Sid-Cry Chilli II™  
720 Watt, 720 Watt, 720 Watt  
Model 8001, 100, 800000

# Chilli II™ Cooled Ablation Catheter

## Patented Closed-Loop Cooling System Enhances Performance

- No fluid infusion to the patient
- No potential for the impact of a conductive “saline cloud”
- No interference in ICE images
- No open path for air emboli
- No delay in RF delivery



## Extensive History of Safety and Efficacy

- Chilli® Catheters and Chilli II Catheters used in more than 25,000 cases (US)
- Proven safe and effective in challenging left-sided VT applications<sup>1</sup>

## Simple Pump and Fluid Management

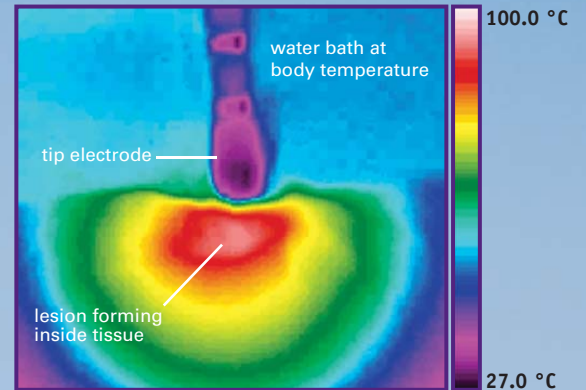
- Featuring the CircuCool® Pump
- Compact, easy-to-use design
- Provides consistent, continuous fluid recirculation
- No need to change or monitor bags and flow rates
- Self-contained, one-piece tubing kit



## Uniform Cooling of Entire Tip Electrode

- Innovative internal cooling system is designed to provide uniform cooling of the *entire* tip electrode and reduce the potential for electrode “hot spots” regardless of contact angle

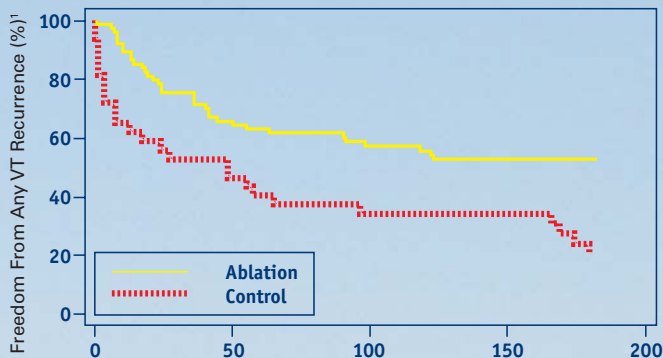
## High Resolution Infrared Thermography of Chilli II Catheter



## Versatility of Cooled Ablation Expands Clinical Options

- Cooling designed to reduce coagulum formation and provide the option to deliver high power
  - Create conventional-sized lesions with the benefit of a cooled tip electrode
  - Create large lesions through the option to deliver high power
  - Create lesions quickly with the delivery of high power for short durations

### Freedom From VT Recurrence by Treatment\* All Patients in the Randomized Trial (n=107)



\* Intention-to-treat includes 10 patients to ablation who did not receive ablation treatment. The difference in VT recurrence was statistically significant by the Gehan test ( $P=0.0009$ ).

## Dependable Blazer™ Catheter Platform

- Familiar handle for comfortable, one-hand operation
- Accurate tip placement through bi-directional steering
- Predictable control for consistent performance



#### INDICATIONS FOR USE:

The Chillii 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:

- 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 patient 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.
- Before using, inspect for physical, 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 EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use.
- 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 Chillii 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 Chillii 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 Chillii 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.
- 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 Chillii 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 Chillii 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 Chillii II Catheter after the expiration date because the device performance may no longer be acceptable and/or the device may no longer be sterile.

#### POTENTIAL ADVERSE EVENTS:

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

Catheterization/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

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician. See the appropriate technical manuals for detailed information regarding instructions for use, indications, contraindications, warnings and precautions, and potential adverse events.

1. Clinical Study SSE Data on file, Boston Scientific Corporation.

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*For more information about  
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Catheters, call Boston Scientific  
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