

# Electrophysiology Products

## Corporate Overview

# Redefining EP...Together



# EP...Redefining Ablation Technology

Boston  
Scientific

## Leader in Performance EP Catheters\*

- Broad Rx and Dx Catheter product line
- Blazer™ Temperature Ablation Catheter family



## Portfolio of Ablation Technology defining the new 'gold standard' of expectations

- First family of catheters designed to give multi-dimensional information in real time
- Designed to deliver unparalleled clarity for therapeutic and diagnostic decisions

**INTELLATIP™**  
Multi-Sense Ablation Technology

## Rhythmia™ acquisition provides strategic entry into Mapping & Navigation segment



## Acquisition of Bard EP builds larger, stronger global commercial footprint

## Invested in Clinical Trials

- ZERO AF clinical trial (A-Fib)
- Block CTI clinical trial (A-Flutter)



Main Menu

\* Domestic

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# Why Bard Electrophysiology?

## Diagnostic Catheters

### PRE-ACQUISITION

Explorer 360™/Explorer ST™ Fixed-Curve Dx Catheters  
Blazer® Dx-20 Duodecapolar Diagnostic Catheter  
StereoCath-Dx™ Steerable Diagnostic Catheter  
Polaris Dx™ Steerable Diagnostic Catheter  
Polaris X™ Steerable Diagnostic Catheter  
Constellation® Diagnostic Mapping Catheter  
Ultra ICE™ Imaging Catheter  
IntellaMap Orion™ High-Res Mapping Catheter

### POST-ACQUISITION

Blazer® Dx-20 Duodecapolar Diagnostic Catheter  
StereoCath-Dx™ Steerable Diagnostic Catheter  
Polaris X™ Steerable Diagnostic Catheter  
Constellation® Diagnostic Mapping Catheter  
Ultra ICE™ Imaging Catheter  
IntellaMap Orion™ High-Res Mapping Catheter  
WovenFlexie™ Fixed Curve Diagnostic Catheter  
Viking™ Fixed-Curve Diagnostic Catheter  
Tango® Stabilene™ Fixed-Curve Diagnostic Catheter  
Dynamic Tip™ CS Steerable Diagnostic Catheter  
Dynamic XT™ CS Steerable Diagnostic Catheter  
Radia™ Steerable Mapping Catheter  
EP•XT™ CS Steerable Diagnostic Catheter  
Orbiter™ PV Advanced Mapping Catheter  
Orbiter™ ST Steerable Mapping Catheter

## Access Products

### PRE-ACQUISITION

Heartspan™ Braided Fixed-Curve Introducer Sheath  
Heartspan™ Transseptal Needle  
Zurpaz™ 8.5F Steerable Introducer Sheath  
PeriVac™ Pericardiocentesis Kit

### POST-ACQUISITION

Heartspan™ Braided Fixed-Curve Introducer Sheath  
Zurpaz™ 8.5F Steerable Introducer Sheath  
PeriVac™ Pericardiocentesis Kit  
TSX™ Transseptal Needle  
DiRex™ Steerable Sheath

# Why Bard Electrophysiology?

## Capital Equipment

### PRE-ACQUISITION

Rhythmia™ Mapping System  
Maestro 3000® Cardiac Ablation System  
CiruCool® Pump  
iLab® Ultrasound Imaging System

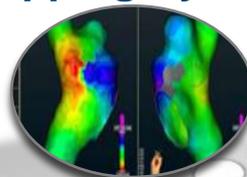
### POST-ACQUISITION

Rhythmia™ Mapping System  
Maestro 3000® Cardiac Ablation System  
CiruCool® Pump  
iLab® Ultrasound Imaging System  
LabSystem™ PRO EP Recording System  
MicroPace StimCor™ Stimulator



# Boston Scientific Electrophysiology Surrounding the EP Customer

## Rhythmia™ Mapping System



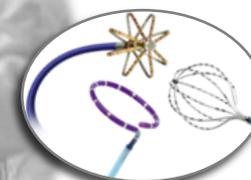
## IntellaTip MiFi™ XP



## Refreshed Core EP



## EP Systems



## Mapping Catheters



## Open-Irrigation



## Intracardiac Access

# Full Suite of Technology Solutions

# Product Overview

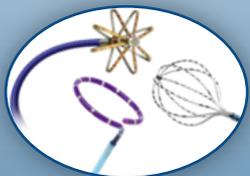
## Full Suite of Technology Solutions

Boston  
Scientific

### DIAGNOSING Cardiac Arrhythmias



Diagnostic Catheters

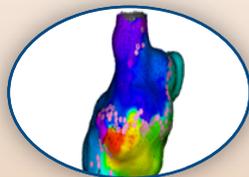


Advanced Mapping Catheters



EP  
Systems

### VISUALIZING Cardiac Anatomy



Rhythmia™  
Mapping System



iLab™ Ultrasound  
Imaging System



Ultra ICE™  
Imaging Catheter

### ACCESSING Cardiac Anatomy



Fixed Curve  
Sheaths



Steerable  
Sheaths



Transseptal  
Access

### TREATING Cardiac Arrhythmias



Blazer™  
Catheter Family



Chilli II™ Cooled  
Ablation System



Blazer Open-Irrigated  
Catheter\*

\*Not available for sale in the US

### REDEFINING Electrophysiology



IntellaTip MiFi™ XP  
Ablation Catheter



Rhythmia™  
Mapping System



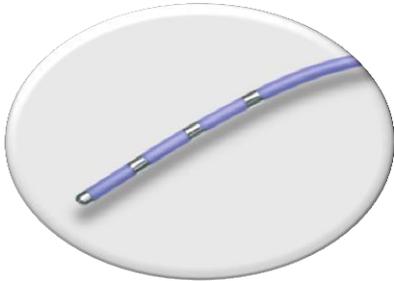
EP New Products  
and Pipeline

Investigational devices. Limited by federal law to investigational use only. Not available for sale.

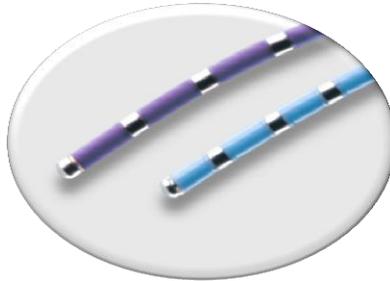
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## Fixed Curve Diagnostic Catheters

## Steerable Diagnostic Catheters



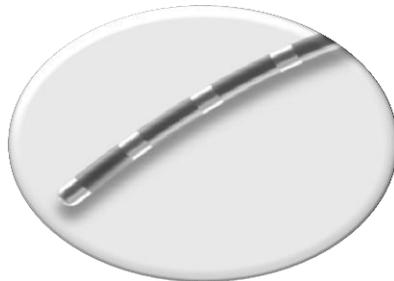
Tango™ Stabilene™  
Diagnostic Catheter



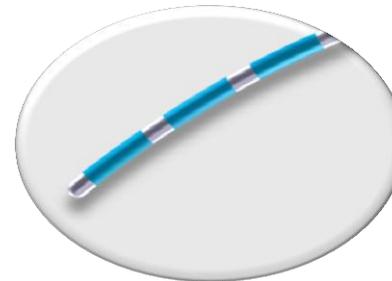
Viking™ Diagnostic  
Catheter



Viking™  
Soft Tip Diagnostic  
Catheter



Woven Diagnostic  
Catheter



WovenFlexie™  
Diagnostic Catheter

## Fixed Curve Diagnostic Catheters

## Steerable Diagnostic Catheters



Blazer™ Dx-20  
Bidirectional Duodecapolar  
Diagnostic Catheter



Dynamic Tip™  
Steerable  
Catheter



Dynamic XT  
Steerable  
Catheter



EP•XT™  
Steerable  
Catheter



Orbiter™ ST  
20-Pole  
Steerable Catheter



Polaris X™  
Steerable  
Decapolar  
Mapping Catheter

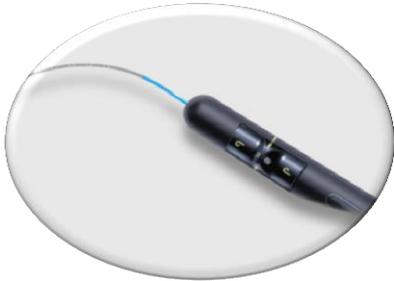


Radia™  
Bidirectional  
Diagnostic Catheter

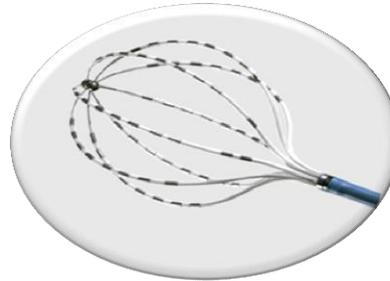


StereoCath-Dx™  
Bidirectional  
Steerable  
Diagnostic Catheter

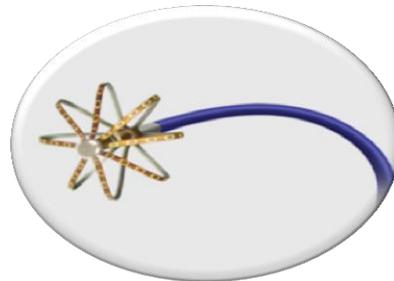
## Advanced Mapping Catheters



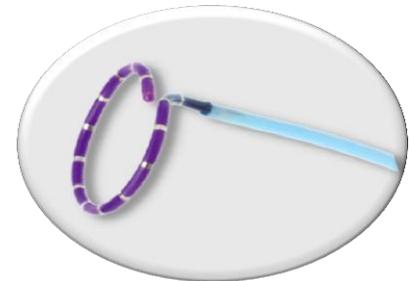
CONFORMA™  
Bidirectional  
Diagnostic  
Catheter



Constellation™  
Mapping  
Catheter



IntellaMap Orion™  
Mapping  
Catheter



Orbiter™ PV  
Variable Loop  
Mapping Catheter

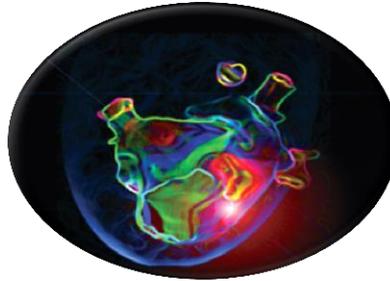
## Recording Systems



LabSystem™ PRO  
EP Recording System



CLEARSIGN™  
Amplifier



EPLogix™ Mapping  
and  
Analysis Suite



EPLink™ H.I.S.  
Interface



MicroPace  
StimCor™



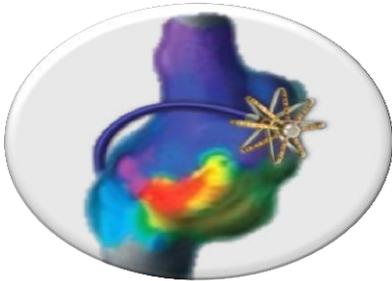
MicroPace  
StimLab™ Bedside  
Interface

## RF Generator



Maestro 3000™ Cardiac  
Ablation Generator

## Mapping and Ultrasound



Rhythmia™  
Mapping System



iLab™  
Ultrasound  
Imaging System



Ultra ICE™  
Imaging Catheter

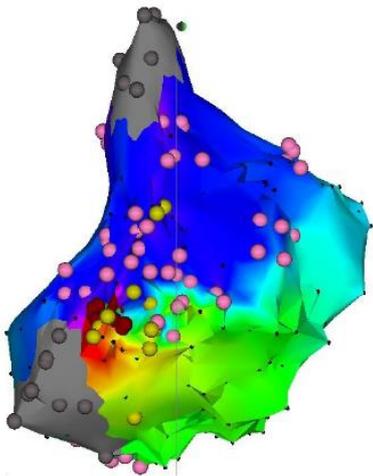
# Visualizing Cardiac Arrhythmias Increase EP Lab Productivity

The Rhythmia™ Mapping System delivers highly detailed maps in less time than conventional systems

## J&J Carto® XP System

Mapped Points: 253

Mapping Time: 38 minutes

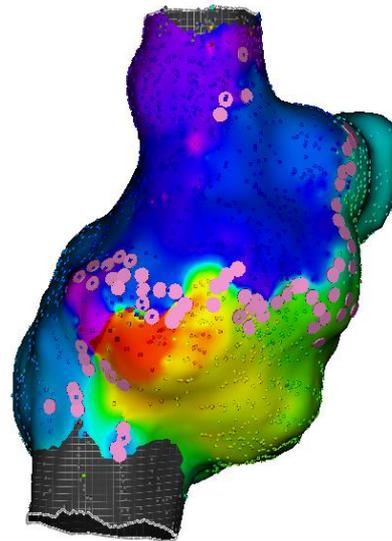


Long process in which physician must manually accept each map point

## Rhythmia Mapping System

Mapped Points: 3,658

Mapping Time: 11 minutes



Proprietary algorithm sorts input from 64-pole basket in real time

More points = superior electrical information and more well-defined maps

**Time Savings** from faster map creation and **improved clarity of diagnosis**

# Visualizing Cardiac Arrhythmias Map the Heart in 1/3 of the Time

## Journal of Interventional Cardiac Electrophysiology Time & Density Comparison<sup>2</sup>

148 Data Points



Manual Mapping Mode with  
Conventional Ablation Catheter\*

979 Data Points



Manual Mapping Mode with  
IntellaMap Orion™ Catheter\*\*

3,566 Data Points



Continuous Mapping Mode with  
IntellaMap Orion Catheter

- \* Comparable to standard mapping on conventional systems
- \*\* Comparable to multi-electrode mapping on conventional systems

<sup>2</sup>Ptaszek L, Chalhoub F, Perna F, Beinart R, Barrett C, Danik S, Heist EK, Ruskin J, Mansour M, Rapid acquisition of high-resolution electroanatomical mapping using a novel multi-electrode mapping system. *J Interv Card Electrophysiol*. 2012 Nov 22.

# Visualizing Cardiac Arrhythmias

## Every Minute Counts

The Rhythmia™ Mapping System could potentially reduce case mapping time by **30-60 minutes**



### POTENTIAL TIME & COST SAVINGS<sup>2</sup>

- Reduced overtime and other operational expenses
- Shorter, more predictable case times
- Increased lab throughput
- Reduced exposure to fluoroscopy
- Reduction in the number of pre-procedure tests (CT & MRI)

<sup>2</sup>Ptaszek L, Chalhoub F, Perna F, Beinart R, Barrett C, Danik S, Heist EK, Ruskin J, Mansour M, Rapid acquisition of high-resolution electroanatomical mapping using a novel multi-electrode mapping system. *J Interv Card Electrophysiol.* 2012 Nov 22.

# Visualizing Cardiac Arrhythmias

## The Impact on Your Bottom Line

What is **30-60 minutes** Worth to Your Lab?

Mapping Time Reduction	30 Minutes	60 Minutes
# of Procedures/Year	200	200
Lab Cost Savings/Year	<b>+\$227,340</b>	<b>+\$454,680</b>
Lab Time Savings/Year	<b>+100 hours</b>	<b>+200 hours</b>

 Assumes base lab cost per minute<sup>3</sup> = \$37.80

*System price break-even point can be realized  
within less than two years.\**

<sup>3</sup>BSC internal analysis based on 2012 MedPAR weighted average procedure costs for DRG's 250 and 251, The Advisory Board Company, and BSC customer interviews.

\*Based on assumptions listed above, which may vary.

## Introducer Sheaths



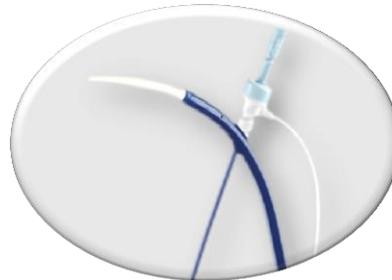
Channel  
Steerable Sheath



DiRex™  
Steerable Sheath

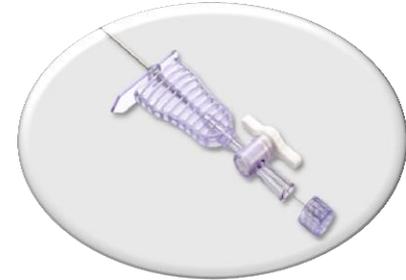


Zurpaz™ 8.5F  
Steerable Sheath



HeartSpan™  
Fixed Curve  
Braided Transseptal  
Sheath

## Transseptal Needle



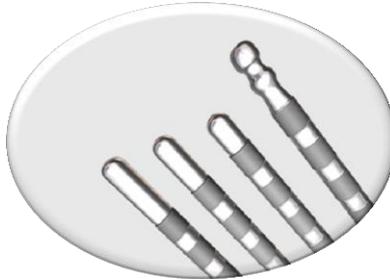
TSX™  
Transseptal Needle

## Blazer Family

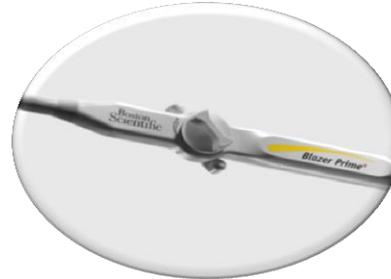
### Small Tip



Blazer™ II  
Temperature Ablation  
Catheter



Blazer™ II HTD  
Temperature  
Ablation Catheter



Blazer Prime™  
Temperature  
Ablation  
Catheter Family

### Large Tip

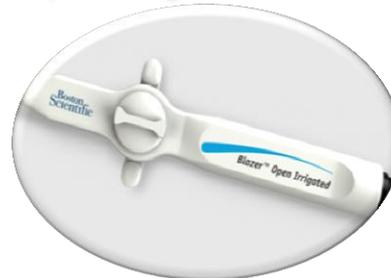


Blazer™ II XP  
Temperature  
Ablation Catheter



Blazer Prime™ XP  
Temperature  
Ablation  
Catheter Family

### Open-Irrigated



Blazer™  
Open-Irrigated  
Ablation Catheter\*

## IntellaTip™



IntellaTip MiFi™ XP  
Catheter

## Cooled Ablation



Chilli II™  
Cooled  
Ablation Catheter

# Treating Cardiac Arrhythmias Multi-sense Ablation Technology

## IntellaTip MiFi™ XP Catheter Unique Design

### 3 Sophisticated Mini-Electrodes

- Enable localized recording of a small area
- Deliver signals of unparalleled clarity
- Allow multiple channels for highly localized EGMs

**INTELLATIP™**  
Multi-Sense Ablation Technology



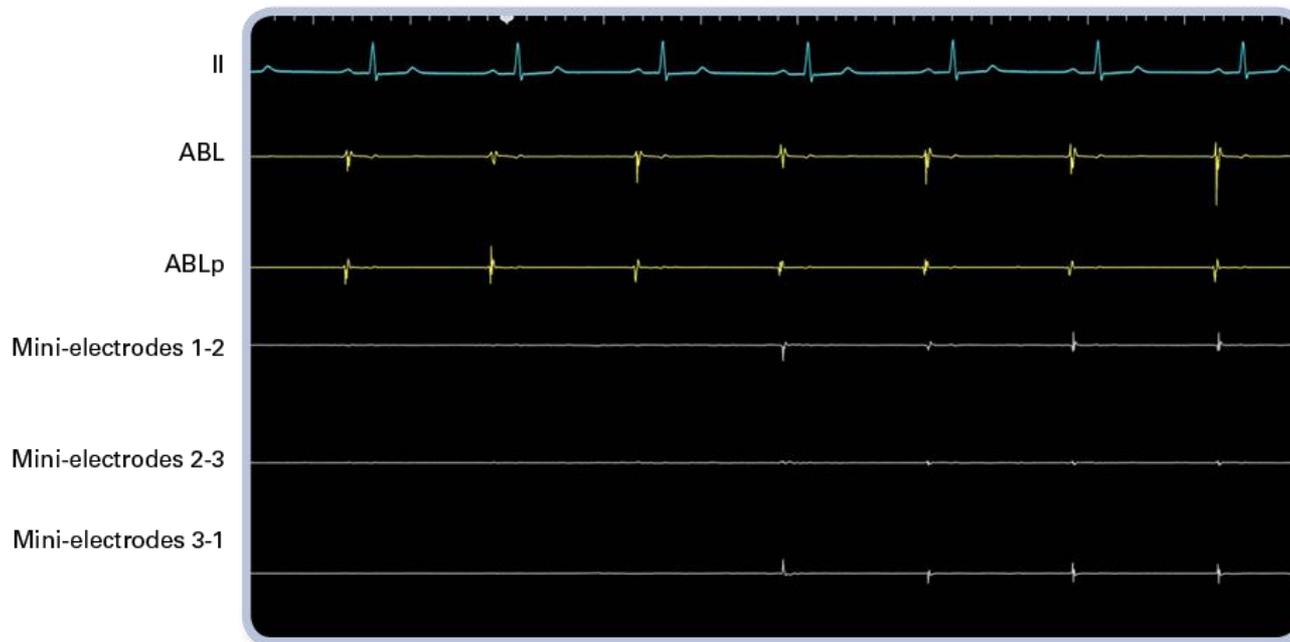
Next

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# Treating Cardiac Arrhythmias

## Accurate EGM Localization

- EGMs with mini-electrodes provide accurate information of tip location
- Mini-electrode electrograms clearly demonstrate when the tip enters the RA from the SVC<sup>1</sup>



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# Treating Cardiac Arrhythmias

## IntellaTip MiFi™ XP System Components

### IntellaTip MiFi™ XP Temperature Ablation Catheter



### Cables & Accessories



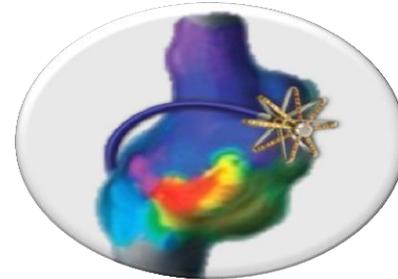
# Redefining Electrophysiology 2013 New Products Launched

## IntellaTip MiFi



IntellaTip MiFi XP Catheter

## Rhythmia

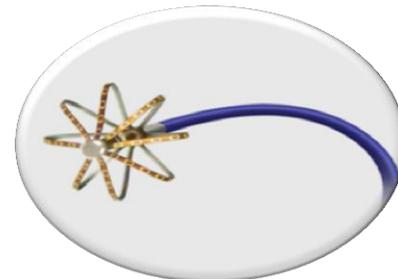


Rhythmia™  
Mapping System

## Zurpaz



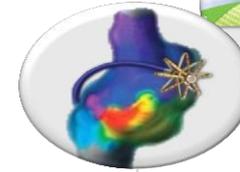
Zurpaz™ 8.5F  
Steerable Sheath



IntellaMap Orion™  
Mapping Catheter

Next

# Redefining Electrophysiology 2014 Product Pipeline



**OUS Launch**  
IntellaTip  
MiFi™ XP  
Catheters\*

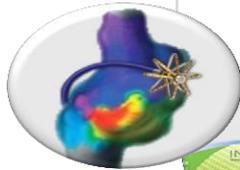
**OUS Launch**  
OI System

**OUS Launch**  
IntellaTip MiFi™ OI  
Catheters\*  
**OUS Launch**  
Rhythmia™ Gen 1

**OUS Launch**  
IntellaNav  
MiFi™ OI  
Catheters\*

**US Launch**  
Rhythmia™  
Gen 1  
**US Launch**  
OI System

**US Launch**  
IntellaNav XP



**Next**

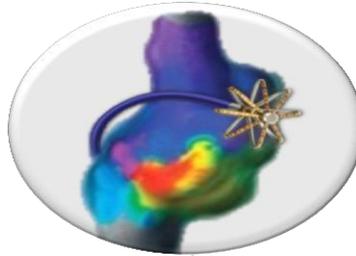
**Main Menu**

\*Investigation device limited by federal law to investigational use only. Not available for sale in the US. The Blazer OI Ablation catheter has received CE Mark approval.

# Redefining Electrophysiology 2015 Product Pipeline



*OUS/US Launch*  
**LabSystem PRO  
NextGen**



*OUS/US Launch*  
**Rhythmia Gen 2**



*US Launch*  
**IntellaTip MiFi™ OI  
Catheters\***



*OUS Launch*  
**IntellaNav XP**



*OUS/US Launch*  
**IntellaMap Gen 2**

\*Investigation device limited by federal law to investigational use only. Not available for sale in the US. The Blazer OI Ablation catheter has received CE Mark approval.

# Abbreviated DFUs

# Blazer® II and Blazer® II HTD Temperature Ablation Catheters (US DFU)

## Indication for Use\*

When using the Blazer II Catheter/Blazer II HTD Catheters: The Boston Scientific Cardiac Ablation System is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia.

## Contraindications

The use of the device is contraindicated in patients with active systemic infection. The transeptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

## Warnings

- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
- Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.
- Patients undergoing AV nodal modification or ablation of septal accessory pathways are at risk for inadvertent AV block. It is advisable to use lower initial power in such patients and to monitor anterior conduction closely during RF power delivery.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:
  - a) have temporary external sources of pacing available during ablation,
  - b) temporarily reprogram the pacing system to minimum output or 000 mode to minimize risk of inappropriate pacing,
  - c) exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads, and
  - d) perform complete pacing system analysis on all patients after ablation.
- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.
- During a transaortic approach, adequate fluoroscopic visualization is necessary to avoid placement of the ablation catheter within the coronary vasculature. Catheter placement and RF power application within the coronary artery has been associated with myocardial infarction and death.
- Patients undergoing left-sided ablation procedures should be closely monitored during the post-ablation period for clinical manifestations of infarction.
- The steerable ablation catheter is intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- The use of catheters or cables with unprotected male pin connectors present a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of component with unprotected male pin connectors must exercise caution during device set-up to prevent patient or operator injury.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the vicinity of the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues.

## Precautions

- Before using, inspect for physical damage including electrical insulation on the cables and the catheter shaft. Replace damaged equipment
- The Blazer II Catheter and the Blazer II HTD Catheter are 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.
- Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transeptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamonade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- The sterile packaging and catheter should be inspected prior to use.
- It is recommended not to exceed thirty (30) radiofrequency power applications per catheter.

\* **EU Indication for Use:** The Boston Scientific Cardiac Ablation System is indicated for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia - typically chronic, drug refractory atrial fibrillation.

# Blazer® II and Blazer® II HTD Temperature Ablation Catheters (US DFU)

## Precautions (cont'd)

- The Boston Scientific Blazer II Temperature Ablation Catheter and Blazer II HTD Catheters are intended for use with the EPT-1000™ Cardiac Ablation System Controller and accessories or the Maestro 3000® Controller and accessories only.
- Do not attempt to operate the BSC Cardiac Ablation System before thoroughly reading the Cardiac Ablation Controller Operator's Manual.
- The catheter impedance LED display of the Cardiac Ablation Controller should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and the distal tip of the catheter cleaned to eliminate any coagulum.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered catheter ablation in a fully-equipped electrophysiology laboratory.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.
- The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore 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. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- Read and follow the dispersive indifferent patch (DIP) electrode manufacturer's instructions for use; the use of DIP electrodes which meet or exceed IEC 60601-1/IEC 60601-1-2 requirements is recommended.
- Placement of the DIP electrode on the thigh could be associated with the higher impedance, which could result in automatic RF power shut-off.
- The Cardiac Ablation Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and DIP electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the ablation procedures are performed.
- Electromagnetic interference (EMI) produced by the Cardiac Ablation Controller during the delivery of RF power may adversely affect the performance of other equipment.
- Regularly inspect and test re-usable cables and accessories. The instrument cables and adapter cables may be sterilized only up to ten times by ethylene oxide sterilization.
- Boston Scientific relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the cardiac ablation procedure.

## Adverse Events

- The following adverse events are listed in descending order according to their clinical significance as determined by their severity and frequency (<1% unless otherwise noted with an asterisk). A total of 57 adverse events were observed in the 513 procedures performed during the clinical study.
- Cardiac/Vascular
- Death
- Cardiac Tamponade, Perforation, Pericardial Effusion
- Cerebral Vascular Accident
- Myocardial Infarction
- Endocarditis
- Pulmonary Edema
- Pulmonary Embolism, Venous Thrombus
- \*Puncture Site Hematoma, Ecchymosis (2.1%)
- Aortic Valve Insufficiency/Wall Motion Abnormality
- Arrhythmic
- Permanent Atrioventricular Block
- Ventricular Fibrillation
- \*Non-sustained Ventricular Tachycardia (1.6%)
- Conduction System Abnormalities
- \*Atrial Fibrillation, Flutter, Tachycardia (2.5%)
- Pacemaker Failure-to-sense

# Blazer® II XP Temperature Ablation Catheter (US DFU)

## Indication for Use\*

The Boston Scientific Corporation Blazer II XP Catheter is indicated for use with the BSC high power Cardiac Ablation Controllers (the Maestro 3000® Controller, the EPT-1000XP™ Controller, and the EPT-1000XPT™ Controller) and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older. The BSC high power Cardiac Ablation Controllers and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.

## Contraindications

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma; and
- via the retrograde approach in patients with aortic valve replacement.

## Warnings

- Before operating the device, read these warnings carefully:
- Peri-procedural anti-coagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic, anti-coagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications.
- Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:
  - a. Retain temporary external sources of pacing available during ablation.
  - b. Reprogram the pacing system temporarily to minimum output or 000 mode to minimize risk of inappropriate pacing.
  - c. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.
  - d. Perform complete pacing system analysis on all patients after ablation.
- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power. Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue.
- Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN-60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of thrombus in the left atrial appendage.
- Do not pass the catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve.

\***EU Indication for Use:** The Boston Scientific Cardiac Ablation System is indicated for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia, for treatment of atrial flutter tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia – typically chronic, drug refractory atrial fibrillation.

# Blazer® II XP Temperature Ablation Catheter (US DFU)

## Precautions

- Observe these precautions, before using the device:
- Do not attempt to operate the Controller before thoroughly reading the appropriate BSC high power Cardiac Ablation Controller & Accessories Operator's Manual.
- The Blazer II XP Catheters are intended for use with the BSC high power Controllers and accessories only.
- The Blazer II XP Catheter is highly torqueable. 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 one and one-half times the full rotation (540 degrees). 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.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the technique of RF Powered Catheter Ablation in a fully-equipped electrophysiology laboratory.
- Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize coagulum, it is recommended that the catheter periodically be removed and the distal tip cleaned after each line of block.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiograms (ECG) during radiofrequency power applications.
- When using Blazer II XP Catheters, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of IEC 60601-1/IEC 60601-1-2 be used as the ablation return electrodes or skin burns may result. Use of only one DIP electrode will not allow the operator to fully access the higher power capabilities of the Controller.
- Placement of the DIP electrodes on the thigh could be associated with the higher impedance, which could result in automatic RF power shut-off.
- During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrodes or failure of an electrical lead.
- Do not increase power before checking for obvious defects or misapplication.
- Regularly inspect and test re-usable cables and accessories.

# Blazer® II XP Temperature Ablation Catheter (US DFU)

## Adverse Events

### Potential Adverse Events

Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to:

- allergic reaction (including anaphylaxis)
- angina
- arrhythmias
- arterial or pulmonary embolism
- arterial-venous fistula
- atrioventricular node damage (transient/permanent)
- back pain and/or groin pain
- cardiac perforation
- cardiac respiratory arrest
- catheter entrapment
- cerebral vascular accident
- complete heart block (transient/permanent)
- cerebral vascular accident
- chest pain/discomfort
- complications of sedative agents (e.g. aspiration pneumonia)
- death
- effusion (pericardial/pleural)
- hematoma/bruising
- hemoptysis
- hemorrhage
- hemothorax
- hypotension
- infection
- myocardial infarction
- nerve palsy or weakness
- pericarditis
- phrenic nerve damage/diaphragmatic paralysis
- pleurisy
- pneumothorax
- pulmonary edema
- pseudoaneurysm
- radiation exposure
- sinoatrial node damage
- skin burn (defibrillator/cardioverter/radiation)
- tamponade
- transient ischemic attack (TIA)
- valvular damage
- vasovagal reactions
- visual blurring

# Blazer Prime® HTD Temperature Ablation Catheters (US DFU)

## Indication for Use\*

When using the Blazer Prime HTD Catheter: The Boston Scientific Cardiac Ablation System is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia.

## Contraindications

The use of the device is contraindicated in patients with active systemic infection. The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

## Warnings

- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
- Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.
- Patients undergoing AV nodal modification or ablation of septal accessory pathways are at risk for inadvertent AV block. It is advisable to use lower initial power in such patients and to monitor anterior conduction closely during RF power delivery.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:
  - a. have temporary external sources of pacing available during ablation,
  - b. temporarily reprogram the pacing system to minimum output or 000 mode to minimize risk of inappropriate pacing,
  - c. exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads, and
  - d. perform complete pacing system analysis on all patients after ablation.
- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.
- During a transaortic approach, adequate fluoroscopic visualization is necessary to avoid placement of the ablation catheter within the coronary vasculature. Catheter placement and RF power application within the coronary artery has been associated with myocardial infarction and death.
- Patients undergoing left-sided ablation procedures should be closely monitored during the post-ablation period for clinical manifestations of infarction.
- The steerable ablation catheter is intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- The use of catheters or cables with unprotected male pin connectors present a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the handle or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of component with unprotected male pin connectors must exercise extreme caution during device set-up to prevent patient or operator injury.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the vicinity of the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues.

## Precautions

- Before using, inspect for physical damage including electrical insulation on the cables and the catheter shaft. Replace damaged equipment.
- The Blazer Prime HTD Temperature Ablation Catheter is highly torqueable. Avoid overtorsioning. 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.
- Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- The sterile packaging and catheter should be inspected prior to use.
- It is recommended not to exceed thirty (30) radiofrequency power applications per catheter.

\* **EU Indication For Use:** The Boston Scientific Cardiac Ablation System is indicated for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia - typically chronic, drug refractory atrial fibrillation.

# Blazer Prime® HTD Temperature Ablation Catheters (US DFU)

## Precautions (cont'd)

- The Boston Scientific Blazer Prime HTD Catheter is intended for use with the EPT-1000™ Controller and accessories or the Maestro 3000® Controller and accessories only.
- Do not attempt to operate the BSC Cardiac Ablation System before thoroughly reading the Cardiac Ablation Controller Operator's Manual.
- The catheter impedance LED display of the Cardiac Ablation Controller should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and the distal tip of the catheter cleaned to eliminate any coagulum.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered catheter ablation in a fully equipped electrophysiology laboratory.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.
- The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore 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. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- Read and follow the dispersive indifferent (DIP) electrode manufacturer's instructions for use; the use of DIP electrodes which meet or exceed IEC 60601-1/IEC 60601-1-requirements is recommended.
- Placement of the DIP electrodes on the thigh could be associated with the higher impedance, which could result in automatic RF power shut-off.
- During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- The Cardiac Ablation Controller is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and DIP electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrodes or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the ablation procedures are performed.
- Electromagnetic interference (EMI) produced by the Cardiac Ablation Controller during the delivery of RF power may adversely affect the performance of other equipment.
- Regularly inspect and test re-usable cables and accessories. The instrument cables and adapter cables may be sterilized only up to ten times by ethylene oxide sterilization.
- Boston Scientific relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the cardiac ablation procedure.

## Adverse Events

The following adverse events are listed in descending order according to their clinical significance as determined by their severity and frequency (<1% unless otherwise noted with an asterisk). A total of 57 adverse events were observed in the 513 procedures performed during the clinical study.

- Cardiac/Vascular
- Death
- Cardiac Tamponade, Perforation, Pericardial Effusion
- Cerebral Vascular Accident
- Myocardial Infarction
- Endocarditis
- Pulmonary Edema
- Pulmonary Embolism, Venous Thrombus
- \*Puncture Site Hematoma, Ecchymosis (2.1%)
- Aortic Valve Insufficiency/Wall Motion Abnormality
- Arrhythmic
- Permanent Atrioventricular Block
- Ventricular Fibrillation
- \*Non-sustained Ventricular Tachycardia (1.6%)
- Conduction System Abnormalities
- \*Atrial Fibrillation, Flutter, Tachycardia (2.5%)
- Pacemaker Failure-to-sense

# Blazer Prime® XP Temperature Ablation Catheter (US DFU)

## Indication for Use\*

The Boston Scientific Corporation Blazer Primer XP Catheter is indicated for use with the BSC high power Cardiac Ablation Controllers (the Maestro 3000® Controller, the EPT-1000XP™ Controller, and the EPT-1000XPT™ Controller) and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older.

The BSC high power Cardiac Ablation Controllers and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.

## Contraindications

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma; and
- via the retrograde approach in patients with aortic valve replacement.

## Warnings

Before operating the device, read these warnings carefully:

- Peri-procedural anti-coagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic, anti-coagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications.
- Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:
  - a. Retain temporary external sources of pacing available during ablation.
  - b. Reprogram the pacing system temporarily to minimum output or 000 mode to minimize risk of inappropriate pacing.
  - c. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.
  - d. Perform complete pacing system analysis on all patients after ablation.
- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power. Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue.
- Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN-60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of thrombus in the left atrial appendage.
- Do not pass the catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve.

## Precautions

Observe these precautions, before using the device:

- Do not attempt to operate the Controller before thoroughly reading the appropriate BSC high power Cardiac Ablation Controller & Accessories Operator's Manual.
- The Blazer Prime XP Catheters are intended for use with the BSC high power Controllers and accessories only.
- The Blazer Prime XP Catheter is highly torqueable. 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 one and one-half times the full rotation (540 degrees). 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.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the technique of RF Powered Catheter Ablation in a fully-equipped electrophysiology laboratory.
- Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize coagulum, it is recommended that the catheter periodically be removed and the distal tip cleaned after each line of block.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiograms (ECG) during radiofrequency power applications.
- When using Blazer Prime XP Catheters, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of IEC 60601-1/IEC 60601-1-2 be used as the ablation return electrodes or skin burns may result. Use of only one DIP electrode will not allow the operator to fully access the higher power capabilities of the Controller.
- Placement of the DIP electrodes on the thigh could be associated with the higher impedance, which could result in automatic RF power shut-off.
- During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrodes or failure of an electrical lead.
- Do not increase power before checking for obvious defects or misapplication.
- Regularly inspect and test re-usable cables and accessories.

\* **EU Indication For Use:** The Boston Scientific Cardiac Ablation System is indicated for interruption of accessory atrioventricular conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia, for treatment of atrial flutter tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia – typically chronic, drug refractory atrial fibrillation.

# Blazer Prime® XP Temperature Ablation Catheter (US DFU)

## Adverse Events

### Potential Adverse Events

Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to:

- allergic reaction (including anaphylaxis)
- angina
- arrhythmias
- arterial or pulmonary embolism
- arterial-venous fistula
- atrioventricular node damage (transient/permanent)
- back pain and/or groin pain
- cardiac perforation
- cardiac respiratory arrest
- catheter entrapment
- complete heart block (transient/permanent)
- cerebral vascular accident
- chest pain/discomfort
- complications of sedative agents (e.g. aspiration pneumonia)
- death
- effusion (pericardial/pleural)
- hematoma/bruising
- hemoptysis
- hemorrhage
- hemothorax
- hypotension
- infection
- myocardial infarction
- nerve palsy or weakness
- pericarditis
- phrenic nerve damage/diaphragmatic paralysis
- pleurisy
- pneumothorax
- pulmonary edema
- pseudoaneurysm
- radiation exposure
- sinoatrial node damage
- skin burn (defibrillator/cardioverter/radiation)
- tamponade
- transient ischemic attack (TIA)
- valvular damage
- vasovagal reactions
- visual blurring

# Chilli II® Cooled Ablation Catheter (US DFU)

## Indication 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 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.
- 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 Volts peak.
- Do not allow the patient to contract 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.

\*EU Direction For Use: The Chilli II Catheter is indicated for use in:

- Electrophysiology procedures where recording of intracardiac electrogram information is desired.
- Ablation of cardiac arrhythmias.
- Delivery of pacing stimuli to the heart for the purpose of diagnostic provocative stimulation when connected to a pacing source.

# Chilli II<sup>®</sup> Cooled Ablation Catheter (US DFU)

## Precautions (cont'd)

- 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 to 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.

## 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 the 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.

# Blazer<sup>®</sup> Open-Irrigated Temperature Ablation Catheter (EU DFU)

## INDICATIONS FOR USE

The Blazer Open-Irrigated Ablation Catheter is indicated for use in catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation.

## CONTRAINDICATIONS

The Blazer Open-Irrigated Ablation Catheter is contraindicated for use:

- in patients with active systemic infection;
- in patients with a mechanical prosthetic heart valve through which the catheter must pass;
- in patients with left ventricular thrombus; or with left atrial thrombus or myxoma via the transseptal approach;
- in patients who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation;
- in patients who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach;
- in patients who are hydrodynamically unstable;
- in patients who have myxoma or an intracardiac thrombus;
- in patients who have had a ventriculotomy or atriotomy within the preceding eight weeks.
- via transseptal approach in patients with interatrial baffle or foramen ovale patches;
- via retrograde transaortic approach in patients who have had aortic valve replacement.

## WARNINGS

- Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology and in the techniques of radiofrequency powered catheter mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab.
- Carefully read all ancillary device instructions prior to use, including the Stockert 70 Radiofrequency Generator User Manual (P/N M-5276-205) and the Biosense- Webster CoolFlow Irrigation Pump User Manual (P/N M-5276-323A). Observe all contraindications, warnings, and precautions noted in these directions. Failure to do so may result in patient complications.
- Before using, inspect the Blazer Open-Irrigated Ablation Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that, if used, may cause patient and/or user injury. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed.
- Contents are supplied **STERILE** using an ethylene oxide (EO) process and should be used by the "Use By" date on the device package. Do not use the device if past the "Use By" date. Do not use if sterile barrier is damaged as use of non-sterile devices may result in patient injury. If damage is found, call your Boston Scientific representative.
- Start each radiofrequency application at low power and carefully follow the power titration and the correlating flow rate procedures as specified in the instructions for use. Too rapid an increase in power during ablation, ablating at high power (>30 W) or insufficient flow rate may lead to perforation caused by steam pop, arrhythmias, damage to adjacent structures, and/or embolism.
- Collateral tissue damage is a possibility when using the ablation catheter at the upper power setting (50 W.)
- Collateral tissue damage is a possibility when using the ablation catheter at the upper power setting (50 W) with a duration longer than 60 seconds without moving the tip of the ablation catheter.
- Patients who have had a prior atrial flutter ablation procedure may be at greater risk for perforation and/or pericardial effusion with the use of this catheter system.
- Patients undergoing septal accessory pathway, AV node reentry tachycardia, and/or atrial flutter ablation are at risk for complete AV block which requires the implantation of a temporary and/or permanent pacemaker.
- Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism.
- During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces to minimize the potential for electrical shock.
- Electrodes and stimulating devices can provide paths of high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes as far away as possible from the ablation site and the dispersive indifferent patch (DIP) electrode. Protective impedances may reduce the risk of burns and permit continuous monitoring of the electrocardiogram during energy delivery.
- Before use, ensure irrigation ports are patent by infusing heparinized normal saline through the catheter tubing. Patency of irrigation ports is important to maintain cooling function and minimize risks of coagulum and char that may result in embolism as well as perforation caused by steam pop.
- To avoid systemic thromboemboli, intravenous heparin or an acceptable alternative must be used when entering the left heart during ablation.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. **Blazer™ Open-Irrigated 4**
- Electrical recording or stimulation equipment must be isolated. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes. Care must be taken to ensure that any equipment used in connection with the Boston Scientific Corporation (BSC) catheters be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use to reduce the potential risk of inadvertent electrical shock.
- Stimulation of cardiac tissues caused by pacing stimulus and/or RF energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns.
- Maximum Catheter Rated Voltage: 66.1 Vrms (93.5 Vpk).

# Blazer® Open-Irrigated Temperature Ablation Catheter (EU DFU)

## Warnings (cont'd)

- Warnings for patients with implantable pacemakers and implantable cardioverter/ defibrillators (ICDs):
  - Follow manufacturer guidelines for ICD programming during RF ablation as RF ablation may result in underdetection of VT/VF, inappropriate therapy delivery and/or electrical reset of the device.
  - Temporarily reprogram pacemaker per the manufacturer guidelines as RF ablation may result in electrical reset of the device, inappropriate sensing and/or therapy.
  - 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.
  - Fluoroscopic guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgment.
  - Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function.
  - Remember to reactivate the pulse generator after turning off the radio frequency ablation equipment.
- Do not ablate from within 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.
- During RF ablation, care must be taken not to deliver RF energy on or near the coronary artery even on the right side of the heart, as the resulting myocardial injury can be fatal.
- Ablation in contact with any other electrodes alters the function of the catheter and can lead to thrombus, coagulum, or char formation that may result in embolism.
- At no time should a Blazer™ Open-Irrigated Ablation Catheter be advanced or withdrawn when resistance is felt, without determining the cause. Valve damage, vascular and/or cardiac perforation is a risk with any intracardiac catheter.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is overtorqued and/or positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.
- 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.
- 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.
- In the event of a suspected failure of the integrity of fluid flow through the catheter or the tubing set or if there is a rapid temperature rise of >15°C noted on the generator, the procedure should be stopped, and the catheter withdrawn to reduce the risk of steam pop that could result in adverse events including perforation, embolism or injury to adjacent structures. Both the catheter and the tubing set should be replaced, primed outside the body to reduce risk of air embolism and then reinserted.
- Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.
- Excessive curves or kinking of the catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance and may cause patient injury.
- Manual bending and/or twisting of the distal curve can damage the steering mechanism and cooling lumens and may cause catheter failure and patient injury.
- Do not scrub the tip electrode, doing so may result in irrigation port(s) occlusion and may lead to catheter failure and patient injury.
- Use both fluoroscopy and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade.
- Do not deliver RF energy with the catheter outside the target site. RF generators can deliver significant electrical energy and may cause patient injury.
- 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 reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation.
- Verify effective contact between the patient and the DIP electrode whenever the patient is repositioned as patient movement may disrupt DIP contact resulting in patient injury and/or extended procedure times.
- Always verify that the tubing, catheter and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing and catheter can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system.
- Patients undergoing left sided ablation procedures should be closely monitored during and post procedure for clinical manifestations of infarction, pulmonary vein injury, nerve damage, embolism and/or atrial esophageal fistula.
- Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution.
- This catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death.
- 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.
- Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism.
- If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/or thrombus in the left atrial appendage.
- Guiding catheters and/or long introducer sheaths present the potential for thromboembolic events. Pre-flush and maintain lumen patency with heparinized intravenous infusion.
- Do not wipe this catheter with organic solvents such as alcohol, or immerse the handle cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient.

# Blazer® Open-Irrigated Temperature Ablation Catheter (EU DFU)

## Warnings (cont'd)

- Pre-procedural anticoagulation therapy is at the discretion of the physician. However, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications. Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- The safety and/or efficacy of epicardial use of the Blazer Open-Irrigated Ablation Catheter has not been evaluated in a clinical trial.
- The transseptal procedure presents the potential risk for an air embolus, which may involve the coronary arteries. Aspiration and flushing of the sheath, dilator, needle and catheter should be performed frequently pre- and during insertion and/ or exchange to minimize this risk.
- Care should be used during multiple sheath/catheter exchanges through the transseptal puncture to avoid causing a residual atrial septal defect that would require repair.
- To avoid patient injury, manipulate the sheath carefully when performing the transseptal puncture especially if the patient has any of the following conditions:
  - Enlarged aortic root
  - Marked right atrial enlargement
  - Small left atrium
  - Marked skeletal deformity or distortion of the thoracic configuration (e.g. scoliosis)

## PRECAUTIONS

- The BSC Blazer Open-Irrigated Ablation Catheter is designed for use with the BSC Model 691 Cable, the Stockert 70 RF Generator (Model S7001 with software version 1.035) or equivalent, the Biosense Webster CoolFlow® Irrigation Pump (Catalog CFP002/Model M-5491-01/02 with software version 1.3) or equivalent, the Biosense Webster CoolFlow Irrigation Tubing Set (Catalog CFT001) or BSC Irrigation Tubing Set (Model 116) or equivalent, and other appropriate interface cables and connectors.
- Do not use the temperature sensor to monitor tissue temperature. The temperature sensor located within the electrode will not reflect either electrode-tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the electrode.
- Electromagnetic interference (EMI) produced by the catheter when used in conjunction with a RF generator during normal operation may adversely affect the performance of other equipment.
- Use only sterile saline and gauze pad to clean the tip.
- The Blazer™ Open-Irrigated Ablation Catheter is not intended to be used with a RF generator output setting exceeding 50 watts or 200 Volts peak.
- The RF generator must only be used in power control.
- Do not use the Blazer Open-Irrigated 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 Indifferent Patch (DIP) electrodes that meet or exceed IEC 60601-1/IEC 60601-1-2 requirements (e.g., Valley Lab Model E7506) and follow the DIP electrode manufacturer's instructions for use. The use of DIP electrodes which meet ANSI/AAMI requirements (HF18) is recommended.
- Apparent low power output, high impedance reading or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrode or failure of an electrical lead.
- The Blazer Open-Irrigated Ablation 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).
- Electrophysiology catheters and systems are intended for use only in x-ray shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines.
- Ensure that the cable/catheter connection remains dry throughout the procedure.
- The Blazer Open-Irrigated Ablation Catheter contains Bis (2-ethyhexyl) phthalate (DEHP). Boston Scientific Corporation (BSC) has assessed the residual patient risk associated with phthalates in this device to be minimal; however, BSC has not assessed the residual patient risk associated with phthalates which may be contained in non-BSC ancillary devices required for use in conjunction with the Blazer Open-Irrigated Ablation Catheter.
- The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
- Patients undergoing a long irrigated ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely.
- Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the dilator or catheter.
- After use, handle and dispose of product and packaging in accordance with hospital biohazard procedure, administrative and/or local government policy.

# Polaris X™ Diagnostic Catheter (US DFU)

## Device Description

The Boston Scientific diagnostic catheters are designed for use in intracardiac pacing and recording only. The catheters have been designed to carry electrical signals for the purpose of endocardial stimulation (pacing) or recording. The Polaris Dx Catheter and the Polaris X Catheter are uni-directional steerable catheters. The curve is actuated by means of a patented thumb-slide (see Figure 1)

## Indications for use

The catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

## Contraindications

Caution should be exercised, in the use of this or any other catheter, in patients with prosthetic valves. Patients with recurrent sepsis or with hypercoagulable state should not be considered candidates for transvascular catheters, since the catheter could serve as a focal point for septic or blood thrombus formation.

## Warnings

- The device(s) should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used.
- Care must be taken to ensure that any equipment used in connection with the BSC Catheters be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with local regulatory requirements for the specified intended use.
- The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets of connectors could result in electrocution of the patient or operator.
- Diagnostic electrophysiology involves x-ray exposure that present the potential risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam and intensity and duration of the fluoroscopic imaging. Steps should be taken to minimize this exposure as much as possible.
- Careful catheter manipulation must be performed to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- This catheter is not indicated for use in Cardiac Ablation or Coronary Artery Mapping.

## Precautions

- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and/or electrical wires, and may cause patient injury.
- Before using, inspect for physical damage, including electrical insulation on the cables and the catheter shaft. Replace damaged equipment.

## Adverse Events

The following potential risks or discomforts may be associated with diagnostic BSC procedure. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

- |   |                           |
|---|---------------------------|
| • Allergic reaction                             | • Myocardial infarction   |
| • Arrhythmias                                   | • Perforation             |
| • Cardiac or respiratory arrest                 | • Pericardial effusion    |
| • Cardiac valve damage                          | • Pericarditis/pleuritis  |
| • Catheter entrapment/entanglement              | • Pneumothorax            |
| • Chest pain                                    | • Pseudoaneurysm          |
| • Damage to vessel intima or cardiac structures | • Pulmonary edema         |
| • Death   | • Sinus or AV node injury |
| • Embolus, air embolus                          | • Stroke                  |
| • Hematoma/ecchymosis                           | • Tamponade               |
| • Hemorrhage                                    | • Thrombosis              |
| • Hypotension                                   | • Vasovagal reaction      |
| • Infection                                     | • X-ray exposure          |

# SteeroCath-Dx™ Steerable Diagnostic Catheter (US DFU)

## INDICATIONS FOR USE

The catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

## CONTRAINDICATIONS

Caution should be exercised, in the use of this or any other catheter, in patients with prosthetic valves. Patients with recurrent sepsis or with hypercoagulable state should not be considered candidates for transvascular catheters, since the catheter could serve as a focal point for septic or blood thrombus formation.

## WARNINGS

- The device(s) should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used.
- Care must be taken to ensure that any equipment used in connection with the BSC Catheters be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with local regulatory requirements for the specified intended use.
- The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets of connectors could result in electrocution of the patient or operator.
- Diagnostic electrophysiology involves x-ray exposure that present the potential risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam and intensity and duration of the fluoroscopic imaging. Steps should be taken to minimize this exposure as much as possible.
- Careful catheter manipulation must be performed to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- This catheter is not indicated for use in Cardiac Ablation or Coronary Artery Mapping.
- No modification of this equipment is allowed.

## PRECAUTIONS

- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and/or electrical wires, and may cause patient injury.
- Before using, inspect for physical damage, including electrical insulation on the cables and the catheter shaft. Replace damaged equipment.

## ADVERSE EVENTS

The following potential risks or discomforts may be associated with diagnostic BSC procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

- Allergic reaction
- Arrhythmias
- Cardiac or respiratory arrest
- Cardiac valve damage
- Catheter entrapment/entanglement
- Chest pain
- Damage to vessel intima or cardiac structures
- Death
- Embolus, air embolus
- Hematoma/ecchymosis
- Hemorrhage
- Hypotension
- Infection
- Myocardial infarction
- Perforation
- Pericardial effusion
- Pericarditis/pleuritis
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Sinus or AV node injury
- Stroke
- Tamponade
- Thrombosis
- Vasovagal reaction
- X-ray exposure

# Blazer® Dx-20 Bidirectional Duodecapolar Diagnostic Catheter (US DFU)

## Indication for Use

The Blazer Dx-20 Catheter is intended for temporary use in electrophysiology studies intracardiac stimulation (pacing) and/or recording of electrical potentials.

## Contraindications

- Caution should be exercised, in the use of these or any other catheters, in patients with prosthetic valves.
- Patients with recurrent sepsis or with hypercoagulable state should not be considered candidates for transvascular catheters, since the catheter could serve as a focal point for septic or blood thrombus formation.
- Care should be taken during placement and removal of this or any diagnostic catheter, so as to avoid disturbing permanent internal pacing/defibrillation leads.
- The Blazer Dx-20 Catheter is contraindicated for transseptal approach in patients with atrial thrombus or myxoma, or interatrial baffle or patch.
- The Blazer Dx-20 Catheter is contraindicated for use from the femoral approach in patients who have vena cava embolic protection filter devices or known femoral thrombus.

## Warnings

- The device(s) should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used.
- Care must be taken to ensure that any equipment used in connection with the BSC Catheter meet IEC 60601-1 electrical safety and IEC 60601-1-2 electromagnetic compatibility requirements, be type CF, be defibrillation proof, system configurations meet IEC 60601-1-1 electrical safety requirements and comply with local regulatory requirements for the specified intended use.
- The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets of connectors could result in electrocution of the patient or operator.
- Do not use Blazer Dx-20 Catheter as an internal defibrillation catheter. Doing so may result in perforation, arrhythmias, embolism, thrombus, and/or patient death.
- Diagnostic electrophysiology involves x-ray exposure that presents the potential risk for somatic and genetic effects to both patients and laboratory staff due to the x-ray beam and intensity and duration of the fluoroscopic imaging. Steps should be taken to minimize this exposure as much as possible.
- Careful catheter manipulation must be performed to avoid cardiac damage, perforation, or tamponade.
- Catheter advancement should be performed under fluoroscopic guidance.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Stimulation of cardiac tissues caused by pacing stimuli may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns.
- Do not use if package is opened or damaged.
- This catheter is not indicated for use in Cardiac Ablation or Coronary Artery Mapping.

## Precautions

- Excessive bending or kinking of the catheter shaft may damage internal wires.
- Manual prebending of the distal curve can damage the steering mechanism and/or electrical wires and may cause patient injury.
- Before using, check shelf life. Do not use catheter after expiration date.

## Adverse Events

The following potential risks or discomforts may be associated with diagnostic BSC procedures. The frequency and severity of these adverse events can vary and may necessitate additional medical intervention, including surgery Allergic reaction, Arrhythmias, Cardiac or respiratory arrest, Cardiac valve damage, Catheter entrapment/entanglement, Chest pain, Damage to vessel intima or cardiac structures, Death, Embolus, air embolus, Hematoma/ecchymosis, Hemorrhage, Hypotension, Infection, Myocardial infarction, Perforation, Pericardial effusion, Pericarditis/pleuritis, Pneumothorax, Pseudoaneurysm, Pulmonary edema, Sinus or AV node injury, Stroke, Tamponade, Thrombosis, Vasovagal reaction, X-ray exposure

# Constellation® Mapping Catheter (US DFU)

## Indication for Use\*

For use in the right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

## Contraindications

**Both the heparin-coated and uncoated version of the Constellation Catheter and the Soft Tip Sheath are contraindicated in patients who cannot be anticoagulated or infused with heparinized saline. Additionally, use of the Constellation Catheter is contraindicated in patients with the following:**

- Permanent leads or prosthetic or stenotic valves present;
- Active systemic infection;
- Echocardiographically-confirmed visual presence of thrombus;
- For whom the inability of obtaining vascular access exists;
- Heparin-induced thrombocytopenia;
- Hemodynamic instability or shock.

## Warnings and Precautions

**The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of atrial arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.**

- This device has not been shown to be safe and effective for use in any cardiac chamber except for the right atrium.
- Maintain activated clotting time (ACT) levels above 300 seconds at all times during the procedure and monitor throughout Constellation Catheter use. Failure to do so may increase the risk of thrombus formation, which could lead to complications.
- Do not leave the catheter in situ more than three hours for the cumulative duration of catheter placement.
- Catheter mapping procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic defects in both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter mapping should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure.

## Precautions Specific to Constellation Catheter

- Preclinical and clinical testing show that small thrombi may attach to the basket and splines at locations where there is an abrupt change in geometry. However, there were no clinical sequelae.
- Ensure the patient is appropriately anticoagulated to ensure thrombus formation is minimized.
- As with percutaneous placement of any large diameter sheath, carefully monitor the vascular puncture site.
- To minimize risk of air embolus, flush the Soft Tip Sheath to remove all air before introduction into vasculature. The introduction of the Constellation Catheter into the Soft Sheath also has the potential to introduce air into the Soft Tip Sheath. Therefore, during the introduction of the Constellation Catheter into the Soft Tip Sheath, again aspirate fluid to expel any air.
- If other catheters are used concurrently with the Constellation Catheter remove those catheters before removing or repositioning the Constellation Catheter.
- The Constellation Catheter is NOT intended for use as an ablation catheter.
- Carefully manipulate the catheter to avoid causing cardiac damage, perforation, or tamponade. Advance the catheter under fluoroscopic guidance. Do not advance or withdraw the catheter against excessive resistance. Do not torque the catheter while it is fully deployed.
- Excessive bending or kinking of the catheter shaft may damage internal wires.
- Manual pre-bending of the distal assembly can damage the basket assembly and may cause patient injury.

## Precautions During Catheter Use

**Cardiac mapping procedures should be performed only by physicians thoroughly trained in the electrophysiologic techniques in a fully equipped electrophysiology laboratory.**

- The soft tip of the Soft Tip Sheath has limited radiopacity. Do not advance against resistance.
- Use only isolated amplifiers, pacing equipment, and ECG equipment or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 microAmps under any circumstances.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Use of components with shrouded pins is highly recommended. Those who use components with unprotected male pin connectors must exercise extreme caution during device setup to prevent patient or operator injury.
- Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, contact your Boston Scientific representative.

## Adverse Events

### Observed Adverse Events

- The Constellation Catheter was studied in 84 patients undergoing electrophysiologic (EP) mapping and ablation. The number of patients with adverse events (major or minor) was 12 of 84 (14.3%). The difference of 14.3% has a 95% confidence interval of (7.2%, 21.4%).

\*EU Indication For Use: Indicated for electrophysiological mapping of cardiac structures, i.e. stimulation and recording, only. The Constellation Mapping Catheter is designed to obtain electrograms in the atrial region of the heart.

# Ultra ICE™ Imaging Catheter (US DFU)

## Intended Use/Indications for Use

The Ultra ICE Rounded Tip Catheter is indicated for enhanced ultrasonic visualization of intracardiac structures.

## Contraindications

- This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization.
- This device is not to be used in the coronary arteries.
- This device is not intended for fetal use.

## Warnings

- DO NOT advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis.
- If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire system simultaneously.
- When utilizing a steerable guide sheath, it is not recommended to articulate the sheath tip beyond 55 degrees. Over articulation may result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.
- Utilizing a fixed curve guide sheath with an angle greater than 55 degrees is not recommended. This could result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.
- A guide sheath with an inner diameter less than 2.84 mm must never be utilized. Utilization of such a guide sheath could cause separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.
- When utilizing the ICE catheter, it is not recommended to place the transducer assembly within the curve of the guide sheath while imaging. This could result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result.

## Precautions

- Contents supplied STERILE using a gamma radiation (Cobalt 60) 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.
- This device should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used.
- After the procedure, inspect the catheter carefully for any damage which may have occurred during use.
- The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Do not attempt to connect the catheter to electronic equipment other than the designated systems.
- Never attempt to attach or detach the catheter while the motor is running. To do so may damage the connector.
- Throughout the procedure anticoagulant therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- Avoid any sharp bends, pinching or crushing of the catheter.
- Do not kink or sharply bend the catheter at any time. This can cause drive cable failure. An insertion angle greater than 45° is considered excessive.
- Turn the MDU "OFF" before withdrawing the imaging catheter, or when advancing the catheter in the body
- Prior to utilizing the ICE catheter, verify there are not kinks in either the ICE catheter or guide sheath. Utilization of a kinked ICE catheter and/or guide sheath could compromise the functionality of the ICE catheter, leading to a device failure.

## Complications

The risks and discomforts involved in imaging cardiac structures include those associated with similar types of diagnostic procedures in the heart. However, any of these risks for discomforts may occur with greater frequency or severity than previously reported. Additionally, these complications may necessitate additional medical treatment including surgical intervention.

- Myocardial infarction
- Abnormal heart rhythms
- Thrombosis
- Hematoma
- Cardiac wall injury including perforation
- Vascular wall injury including perforation
- Infection/discomfort
- Damage to cardiac valvular structures
- Hypotension/Hypertension
- Endocarditis
- Stroke/embolism
- Death
- As with all procedures that utilize the Seldinger Technique for introducing a catheter into an artery, the following complications have been reported:
- Infection and pain in the region of the insertion site
- Hemorrhage
- Arteriovenous Fistula

# HeartSpan™ Braided Fixed Curve Transseptal Sheath (US DFU)

## Indication for Use

For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture.

## Warnings

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged.
- 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. This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy, system performance, or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization, or reuse.
- The device(s) should be used by physicians engaged in the practice of specialized invasive cardiology techniques. Use of the device should be restricted to those physicians specifically trained in the approach to be used.
- When the sheath is left in the vessel, a continuous heparinized infusion under pressure is strongly recommended through the sheath sideport.
- Infusion through the sideport should only be done after all air is removed from the unit.
- Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve components resulting in blood flow through the valve, as well as cause a vacuum which may allow air to enter the sheath.
- Aspiration of the side port is recommended when withdrawing the catheter, probe, or dilator to remove any fibrin deposition which may have accumulated in or on the tip of the sheath.
- Careful sheath manipulation must be performed in the presence of an implantable cardiac device of any kind to minimize the potential to displace or dislodge lead placement.
- Direct percutaneous insertion of the sheath requires the use of the dilator to minimize the potential risk of vessel injury due to a flared tip.
- Fluoroscopic monitoring of the location of the distal tip of the sheath using the radiopaque marker, especially when used in a transseptal approach, is recommended.

## For U.S.-California Only.

### Proposition 65, a State of California voter initiative, requires the following notice:

**WARNING:** This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or defects or other reproductive harm.

## Precautions

- Aspiration and flushing of the sheath, dilator, and catheter should be performed frequently to help minimize the potential for air embolism.
- Indwelling sheaths should be internally supported by a catheter, electrode, or dilator.
- Never advance, torque, or withdraw guidewire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action.
- Use the sideport for injection or aspiration of sheath and sideport assembly. Assure that stopcock is in the closed position after flushing, to prevent back-bleeding.
- The following conditions require that special care be taken when using this product involving the transseptal approach.
  - enlarged aortic root
  - marked right atrial enlargement
  - small left atrium
  - marked distortion of the thoracic configuration (e.g. kyphosis or scoliosis)
- Care should be taken to avoid excessive bending of the sheath and/or dilator before and during use.
- Fluoroscopic procedures involve exposure to ionizing radiation by the patient and staff. Precautions to minimize exposure should be taken and protective equipment should be used.
- Fluoroscopic guidance should be used when advancing the Braided Transseptal Sheath and/or dilator. When advancing the sheath and/or dilator across a valve, a guidewire or pigtail should be used.
- The sheath, dilator, and guidewire are designed for single use only. Reuse may expose the patient to communicable disease and/or injury.
- Arrhythmias may occur during the use of any intracardiac device. Careful monitoring and availability of emergency equipment are mandatory.
- When using the Braided Transseptal Sheath in the presence of radio frequency ablation, care must be taken to assure all ablating elements are outside the sheath.

## Adverse Reactions

Adverse reactions to cannulation of the peripheral vasculature and intracardiac placement of the sheath and dilator may include, but are not limited to:

- infection
- local nerve damage
- perforation
- dissection
- AV fistula formation
- pseudoaneurysm formation
- arrhythmias
- hematoma
- hemorrhage
- thromboembolic events
- catheter entrapment
- valve damage
- pacemaker/defibrillator lead displacement
- air embolus
- vasovagal reaction
- vessel trauma
- vessel spasm
- atrial septal defect
- aortic puncture
- perforation and/or tamponade
- coronary artery spasm and/or damage
- stroke
- myocardial infarction
- pericardial/pleural effusion
- pulmonary edema

# Rhythmia™ Mapping System (US DFU)

## Indications for Use

The Rhythmia Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

## Contraindications

There are no known contraindications.

## Warnings (abbreviated)

General:

- All devices that are connected to the Rhythmia Mapping System must meet IEC 60601-1 requirements and any other relevant safety standards.
- The use of the Rhythmia™ Mapping System with accessories and devices that do not comply with relevant standards may reduce the safety of the system, cause equipment damage or system malfunction, or harm to the patient or user.
- Do not connect life-sustaining pacing through the Rhythmia Mapping System.
- Use the Rhythmia Mapping System only with one of the following RF ablation generators: Maestro®, Stockert™, or IBI™. Compatibility with other RF ablation generators has not been demonstrated.

## Precautions (abbreviated)

- To minimize the risk of electric shock, make sure that electrodes and lead connectors do not contact one another or contact ground.
- To prevent low quality signals from body surface electrodes, properly prepare the skin prior to attaching the electrodes.
- Do not use excessive gel as this may lead to shorts between different electrodes.

# IntellaMap Orion™ Catheter (US DFU)

## Indications for Use

The IntellaMap Orion High-Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

## Contraindications

The Rhythmia Mapping Catheter should not be used in:

- Patients who are not candidates for transvascular catheter procedures.
- Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy.
- Patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside.
- Patients with active systemic infection. Pediatric patients. Pregnant and/or nursing patients.
- Patients with any other condition where catheter manipulation may not be safe.
- The IntellaMap Orion Catheter should not be used for radio frequency (RF) ablation.
- The IntellaMap Orion Catheter should not be used inside an MRI machine.

## Warnings

- Do not allow the handle or cabling to be immersed in fluid.
- Resterilization may damage the device and reuse may increase the risk of cross contamination.
- Do not use the catheter to deliver ablation therapy.
- If resistance is felt during advancement, retraction, articulation, deployment or un-deployment, stop and evaluate device location under fluoroscopy.
- Do not advance or retract the catheter through a sheath when deployed or articulated.
- In order to reduce the risk of clot formation: Maintain an activated clotting time (ACT) of greater than 300 sec. at all times during use of the catheter, and continuously flush the electrode array with saline via the irrigation port at the proximal end.

## Precautions

- To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed.
- Use visualization (such as fluoroscopy) to verify underdeployment.
- Do not articulate the sheath while the catheter array is inside the articulating section.
- Do not deploy or articulate the catheter while the distal end is inside a sheath.
- Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter.
- When pacing, verify desired waveform is observed.
- Federal Law (U.S.A.) restricts the sale of this device by or on the order of a physician only.

## Potential Adverse Events

- Serious adverse events have been reported in the literature in relation to cardiac catheterization including: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism and death.
- Complications reported included also (in alphabetical order): air embolism, arrhythmia, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding and vasovagal reactions.

# IntellaTip MiFi™ XP Temperature Ablation Catheter (US DFU)

## Indications for Use

The Boston Scientific Corporation (BSC) IntellaTip MiFi™ XP Catheter is indicated for use with the BSC Maestro 3000® Controller, and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older. The BSC Controller and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures.

## Contraindications

Do not use this device:

- In patients with active systemic infection; Via the transeptal approach in patients with left atrial thrombus or myxoma; Via the retrograde approach in patients with aortic valve replacement. .

## Warnings

Before operating the device, read these warnings carefully:

- Peri-procedural anti-coagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, during and post-ablation to reduce the incidence of major complications.
- Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals.
- It is important to:
  - a. Retain temporary external sources of pacing available during ablation.
  - b. Reprogram the pacing system temporarily to minimum output or 000 mode to minimize risk of inappropriate pacing.
  - c. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.
  - d. Perform complete pacing system analysis on all patients after ablation.
- Implanted cardioverter/defibrillators should be deactivated during delivery of RF power.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures.
- The potential for catheter entrapment may be increased when the catheter is positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue.
- Care must be taken to ensure that any equipment used in connection with the BSC catheters, be type CF, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.
- Maximum IntellaTip MiFi XP Catheter Rated Voltage: 178 Vrms (251 Vpk). No modification of this equipment is allowed.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of thrombus in the left atrial appendage.
- Do not pass the IntellaTip MiFi XP Catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve.

## Precautions

- The IntellaTip MiFi XP Catheters are intended for use with the BSC Controller and accessories only.
- Overrotating 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 one and one-half times the full rotation (540 degrees).
- 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.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Catheter advancement should be done under fluoroscopic guidance.
- **Do not** use excessive force to advance or withdraw the catheter when resistance is encountered.
- Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury.
- Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize coagulum, it is recommended that the catheter periodically be removed and the distal tip cleaned after each line of block.
- When using the IntellaTip MiFi XP Catheter, it is required that two Dispersive Indifferent Patch (DIP) Electrode Pads satisfying the requirements of IEC 60601-1/IEC 60601-1-2 be used as the ablation return electrodes or skin burns may result.
- Placement of the DIP electrodes on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.
- During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Do not increase power before checking for obvious defects or misapplication..

## Potential Adverse Events

Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to:

- Allergic reaction (including anaphylaxis), angina, arrhythmias, arterial or pulmonary embolism, arterial-venous fistula, atrioventricular node damage (transient/permanent), back pain and/or groin pain, cardiac perforation, cardiac respiratory arrest, catheter entrapment, complete heart block (transient/permanent), cerebral vascular accident, chest pain/discomfort, complications of sedative agents (e.g. aspiration pneumonia), death, effusion (pericardial/pleural), hematoma/bruising, hemoptysis, hemorrhage, hemothorax, hypotension, infection, myocardial infarction, nerve palsy or weakness, pericarditis, phrenic nerve damage/diaphragmatic paralysis, pleurisy, pneumothorax, pulmonary edema, pseudoaneurysm, radiation exposure, sinoatrial node damage, skin burn (defibrillator/cardioverter/radiation), tamponade, transientischemic attack (TIA), valvular damage, vasovagal reactions, visual blurring.

# Zurpaz™ Steerable Sheath (US DFU)

## Indications for Use

The Zurpaz Steerable Sheath is indicated for use when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

## Contraindications

Do not use this device:

- Patients who do not tolerate anticoagulation therapy; Known or suspected atrial myxoma; Recent cerebral vascular accident (CVA); Myocardial infarctions within the last two weeks; Patients with an active infection; Unstable angina; Presence of atrial thrombus; Previous intra-atrial septal patch.

## Warnings

- Do not reuse this device.
- Adverse patient reactions may result from reuse of this device.
- Maintain continuous hemodynamic monitoring throughout the procedure.
- Always observe acceptable hemodynamics prior to advancing the dilator or any other component.
- Always withdraw components/aspirate slowly to minimize the vacuum created during withdrawal.
- From the sideport only – aspirate all air prior to fluid infusion.
- Thermal deformation of the sheath tip may result in patient injury and/or damage to the sheath or to the other devices used concurrently.
- Fibrin may accumulate in or on the sheath tip during the procedure.
- To prevent dislodgement of potential thrombus, aspirate when removing dilator or catheter.
- Maximum in-vivo time: 7 hours.

## Precautions

- Do not attempt to insert a catheter having a distal tip or body size larger than the sheath size indicated.
- The steerable sheath is designed to interlock only with the Zurpaz™ sheath dilator.
- Misuse may result in serious complications. Do not attempt to use a guidewire larger than the maximum diameter specified on the package label.
- During insertion, use caution not to create excessive bends in this device.
- Frequently aspirate and saline flush the sheath to minimize the potential for thrombus formation.
- Do not deflect the device beyond 180° prior to insertion of a catheter.
- Indwelling percutaneous introducer sheaths should always be supported with a catheter.
- Aspirate slowly, only from the sideport. Inject or saline flush only from the sideport.
- Certain conditions may require special consideration when using this product. These may be, but are not limited to Enlarged Aortic Root, Small Left Atrium, Marked Right Atrial Enlargement, Marked Distortion of the Thorax Configuration (i.e. Kyphosis or Scoliosis)

## Potential Adverse Events

Adverse events may vary in severity and may require medical or surgical intervention. These potential adverse events may include, but are not limited to:

- Arrhythmias
- Cardiac tamponade
- Effusion (pericardial)
- Embolism
- Hematoma
- Hemorrhage
- Infection (local/systemic)
- Intimal tear
- Myocardial infarction
- Lead displacement
- Patent foramen ovale (PFO)
- Perforation
- Thrombus formation
- Valvular damage

Please consult the respective manufacturer's labeling for adverse events associated with the use of either cardiovascular catheters and/or endomyocardial biopsy devices.

# Diagnostic Electrode Catheter

## Description

BARD® Electrophysiology's fixed curve diagnostic electrode catheters have an insulated polymer shaft with platinum electrodes located along the distal section of the shaft.

## Indications for use

BARD® Electrophysiology's fixed curve diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

## Contraindications

The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

## Warnings

- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- The risks of using electrophysiology catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection. The induction of an unintended arrhythmia is a known complication.
- This device is for single use only. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- If using an open lumen catheter remove any guidewire / stylette prior to electrical stimulation.

## Precautions

- Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.
- Use only sterile saline or water to wipe this catheter.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.

# Steerable Diagnostic Electrode Catheter

## Description

Bard Electrophysiology Steerable Catheters are radiopaque, flexible, insulated catheters with a polymer shaft. The EP•XT™ Steerable Catheter has a white rotating handle mechanism which provides curve actuation of the distal tip. All other BARD® Steerable Diagnostic Electrode Catheters have a plunger mechanism, which, when moved forward or back, results in curvature of the distal tip.

## Indications for use

Bard Electrophysiology's Steerable Diagnostic Electrode Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

## Contraindications

The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

## Warnings

- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- The risks of using electrophysiology catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection. The induction of an unintended arrhythmia is a known complication.
- This device is for single use only. Resterilization and reuse of this device have not been proven to be effective.
- Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Catheter advancement should be done under fluoroscopic guidance.

## Precautions

- The safety and effectiveness of this device as an ablation catheter have not been established. Therefore, such use is considered investigational.
- Use only sterile saline or water to wipe this catheter.
- Avoid submerging the catheter handle in any solution.
- The catheter is equipped with a cable connector; use with the appropriate BARD® cable.
- Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.

# ORBITER™ PV Steerable Catheter

## DEVICE DESCRIPTION

The BARD® ORBITER™ PV Steerable Catheter is a cardiac diagnostic catheter, which has a variable diameter loop on the distal end of a steerable shaft. The loop is controlled by the thumb-wheel mechanism on the handle, which causes the loop to expand or contract. The tip of the catheter, on which the loop resides, can also be curved in a single direction by pushing or pulling a slide tab on the handle.

## INDICATIONS AND USAGE

Bard Electrophysiology's steerable diagnostic catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

**CONTRAINDICATIONS** The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus). The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement. The retrograde transaortic approach is contraindicated due to the risk of entrapping the tip in the left ventricle.

## WARNINGS

- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies, catheter ablation, and temporary pacing.
- Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- The risks of using electrophysiology catheters include those risks related to heart catheterization such as thromboembolism, perforation, tamponade, pneumothorax, and infection. The induction of an unintended arrhythmia is a known complication of electrophysiologic procedures.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- To place the ORBITER™ PV catheter, torque (or rotate) shaft in a clockwise motion only.
- OPEN LOOP PRIOR TO TRAVERSING SHEATH ! OPEN LOOP PRIOR TO TRAVERSING SHEATH

## PRECAUTIONS

- Do not use excessive force to advance or withdraw the catheter when resistance is encountered because tissue damage or perforation could occur.
- All catheter adjustments should be done under fluoroscopic guidance.
- Use only sterile saline or water to wipe this catheter.
- Excessive bending or kinking of the electrode catheter may cause damage to the catheter, including internal wires.
- Avoid fluid penetration into handle. Do not submerge the handle in any solution.
- Ensure that the loop is fully expanded and the catheter tip has been returned to the neutral position prior to removal from the patient.
- To avoid potential damage to anatomical structures, do not attempt to pull the catheter, or withdraw it with the loop in a contracted state. The loop should be fully expanded prior to removal from the patient.
- After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state and federal laws.

# ORBITER™ ST Steerable Electrode Catheter

# CONFORMA™ Steerable Electrode Catheter

## Description

The BARD® Electrophysiology ORBITER™ ST / CONFORMA™ Steerable Catheter is a radiopaque, flexible, insulated catheter with a polymer shaft and a 2 mm distal tip. The catheter handle has a slider mechanism which, when moved forward or back from the neutral position, results in curvature of the distal tip.

## Indications for use

BARD® Electrophysiology's Steerable Diagnostic Electrode Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

## Contraindications

- The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus).
- The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

## Warnings

- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing. • The risks of using electrophysiology catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection. The induction of an unintended arrhythmia is a known complication.
- This device is for single use only. Resterilization and reuse of this device have not been proven to be effective.
- Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Catheter advancement should be done under fluoroscopic guidance.

## Precautions

- Use only sterile saline or water to wipe this catheter.
- Avoid submerging the catheter handle in any solution.
- The catheter is equipped with a cable connector; use with the appropriate BARD® cable.
- Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.

# RADIA™/ RADIA™ XT Steerable Electrode Catheter

## Description

The BARD® Electrophysiology RADIA™/ RADIA™ XT Steerable Catheter is a radiopaque, flexible, insulated catheter with a polymer shaft and a 2 mm distal tip. The catheter handle has a rotary mechanism which, when rotated from the neutral position, results in curvature of the distal tip.

## Indications for use

BARD® Electrophysiology's steerable diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

## Contraindications

- The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus).
- The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

## Warnings

- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- The risks of using electrophysiology catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection.
- The induction of an unintended arrhythmia is a known complication.
- This device is for single use only. Resterilization and reuse of this device have not been proven to be effective.
- Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Catheter advancement and adjustments should be done under fluoroscopic guidance.

## Precautions

- Use only sterile saline or water to wipe this catheter.
- Avoid submerging the catheter handle in any solution.
- The catheter is equipped with a cable connector; use with the appropriate BARD® cable.
- Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.

# DIREX™ Steerable Sheath

## **Intended Use/Indications for Use**

The DIREX™ Steerable Sheath is intended to facilitate the intracardiac placement of diagnostic and therapeutic devices.

**Refer to the Instructions for Use for the complete List of Adverse Effects, Precautions, and Warning.**

## **Contraindications**

- Known active systemic or local infection
- Known inability to obtain vascular access
- Patients with atrial thrombus or myxoma, or interatrial baffle or patch
- Use of a steerable sheath is contraindicated in patients with obstructed or inadequate vasculature.

## **Warnings**

The steerable sheath must be thoroughly flushed with either saline or heparinized saline and free of air prior to use to avoid air embolism to the patient.

If the patient has left bundle branch block, back up pacing should be readily available during insertion of the steerable sheath assembly. Use of the steerable sheath assembly may cause heart block. Before removing the steerable sheath, straighten the distal section as much as possible to avoid damage during removal. Refer to “Deflecting and straightening the steerable sheath” for instructions.

## **Precautions**

**Transvenous device compatibility:** Use the steerable sheath only with compatible transvenous devices. Use the appropriate size sheath for the size of the transvenous device being utilized. Consequences of using the steerable sheath with incompatible devices may include the inability to deliver the transvenous device or damage to the transvenous device during delivery.

**Do not aspirate steerable sheath with a guidewire in place through the hemostatic valve.**

- Aspiration with a guidewire through the valve may cause air embolism which can result in significant morbidity or death.
- Use the sideport, located at the handle, to inject contrast solution or flush the steerable sheath. The steerable sheath must be thoroughly flushed with either saline or heparinized saline and free of air prior to use to avoid air embolism to the patient.
- Aspiration and flushing of the sheath should be performed frequently to help minimize the potential for air embolism.

# BARD® LABSYSTEM™ PRO EP Recording System

## INDICATIONS FOR USE

The BARD® LABSYSTEM™ PRO EP Recording System is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of intracardiac electrophysiological data.

The BARD® Amplifiers are intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (The BARD® LABSYSTEM™ PRO EP Recording System) that can record and display the information.

## CONTRAINDICATIONS

None known.

## WARNINGS

This equipment is for use only by, and under the supervision of qualified personnel.

The BARD® Amplifiers do not transmit alarms and do not have arrhythmia detection capability. If arrhythmia monitoring is needed use a separate ECG monitor with arrhythmia detection capability.

To avoid electrical safety hazard, please consult Warnings and Precautions (PK5015170)

To avoid stimulation at an undesired pacing site, always be sure the Stim Setup is appropriate before stimulating. Stim Setup, including the stimulator connection settings, is stored with Amplifier Configuration information. Selecting a new Channel Setup could result in a change to the current stimulator pacing site(s). DO NOT stimulate the patient until confirming that the changes to Stim Setup are appropriate. Defibrillation protection of hardware components can only be assured using cables and accessories supplied by Bard.

## PRECAUTIONS

The BARD® LABSYSTEM™ PRO EP Recording System product is provided complete and ready for use. To ensure appropriate/proper compatibility and interface, the installation or connection of additional hardware, software, or updates of any kind to the LABSYSTEM™ PRO EP Recording System platform, other than that which is provided by and/or approved by Bard is prohibited.

# Micropace Cardiac Stimulators

## EPS320B/BT, StimCor™, StimLab™

### Intended Use

The Micropace Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

### Indications for Use

The Stimulator system is an electrical stimulus generator for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

### Contraindications

Do not use the Stimulator system for life support in patients with life-threatening bradycardia; use instead temporary external pacemaker.

### Compatibility

Subject to these requirements, the Micropace Stimulator is intended for use with the following equipment; the user should contact Micropace Pty Ltd for compatibility information prior to use of other equipment:

#### Diagnostic pacing electrode catheters

Currently available legally marketed electrophysiological diagnostic electrode catheters, including those manufactured by Cordis Biosense Webster, Daig, CR Bard, Medtronic and EPT.

#### Ablation electrode catheters

The EPS320 Cardiac Stimulator is tested for use with a number of legally marketed RF ablation catheters. Contact Micropace Pty Ltd for further information (Refer also to "Warnings and Precautions" section below).

#### EP Recording equipment

Computerized EP Recording systems manufactured by Bard Electrophysiology (LabSystem™ Duo™ and LS Pro™) and GE/Prucka (CardioLab 4000, 7000) have been tested for use with the EPS320 Stimulator.

#### RF Ablation Equipment

RF ablation equipment manufactured by EPT (EPT1000XP) and Medtronic (Atakar RF Generator) have been tested for use with the EPS320 Stimulator.

### General Warnings

#### Warning: Stimulator must be used only under supervision by a cardiologist.

Cardiac Diagnostic Stimulators are used in medical procedures, during which intentional or unintentional life-threatening cardiac arrhythmias are likely to occur. To avoid death or injury to patient from arrhythmias, the Stimulator may be used on humans only under the direct supervision by a physician familiar with electrophysiology and the operation of this Stimulator, in an appropriate hospital facility.

The supervising physician must verify all Stimulator settings immediately prior to commencement of pacing, with particular attention to any adaptively calculated S1 pacing interval settings, and in the case of StimLab™, in case settings were altered using the alternate controller.

#### Warning: Installation and use only by qualified personnel.

In order to prevent electrocution hazards or impaired performance of the Stimulator from incorrect installation, only qualified personnel, such as representatives of Micropace Pty Ltd, its authorized distributor or hospital-appointed biomedical engineers, may carry out installation of the Stimulator system and its connection to other equipment.

In order to reduce operator errors, installation, configuration and customer training should be performed in a manner, which allows optimal use of the Stimulator by the user.

#### Warning: Stimulator is not a life support device – operator must have available backup temporary external pacemaker.

To avoid injury to patient from bradycardia, operator must have available a backup temporary external pacemaker. The Stimulator system is a diagnostic tool for provocative electrophysiological testing of the human heart. The Stimulator system is not intended, designed or fit for the purpose of life support. Two levels of backup pacing for bradycardia are provided in case of failure of normal functioning of the Stimulator and are for use in non-life threatening bradycardia; in case of life-threatening bradycardia, pacing with a temporary external pacemaker must be established immediately.

A backup temporary external pacemaker must be immediately available for use in case of the occurrence of a life-threatening bradycardia. It should preferably be connected directly to an intracardiac electrical catheter located in a ventricle, bypassing any switching apparatus in case of failure or inappropriate settings of such switching apparatus..

# Micropace Cardiac Stimulators

## EPS320B/BT, StimCor™, StimLab™

### General Warnings (Continued)

#### **Warning: Stimulator must use isolated mains supply only.**

To avoid electrocution hazards, all parts of the Stimulator, including the computer, monitor and Stimulus Generator Unit must all be connected to the Mains Isolation Transformer and never directly to a mains power outlet.

For StimLab™ and StimCor™, in order to comply with IEC60601-1-1/UL601-1-1 and avoid possibility of patient / operator shock from accidental connection of Stimulator computer parts directly to mains power, ensure that Isolation Transformer has Mains Cord Retaining Bracket MP3181 installed.

For StimLab™, in order to avoid electrocution hazards or loss of normal device function, ensure that the StimLab™ Bedside Remote Controller Station touch screen has its DC Power Plug Cover securely attached by screws, preventing accidental disconnection of its DC power plug and preventing insertion of a mains lead plug; this part must only use low voltage DC power input and must never be connected to mains power.

Provided above isolated mains supply warnings are complied with, the complete StimLab™, StimCor™ or EPS320 system may be located within the patient environment.

#### **Warning: Connect Stimulator system only to legally marketed, mains-isolated electrical equipment.**

To avoid electrocution hazards, the Stimulator system may be connected to other equipment provided the other equipment is also isolated from the mains. It must comply with electrical safety requirements of IEC60601-1 standard or equivalent, is legally marketed in the country and is CE marked for installations in the EU countries.

#### **Warning: Use Stimulator only in ventilated areas and away from flammable gasses.**

To avoid risk of explosion, the Stimulator should only be used in a ventilated area as gasses may be released during charging of backup battery, and should not be used in rooms with flammable anesthesia.

### Warnings Specific to the Micropace Stimulator

#### **Warning: Monitor function of Stimulator and patient's vital signs continuously.**

The Micropace Stimulator may fail to stimulate or unintentionally stimulate the patient through software, hardware or human error. To avoid injury to patient from arrhythmias, monitor the function of Stimulator and patient's vital signs continuously while Stimulator is connected to the patient.

In case of repeated recurrence of unexplained life-threatening arrhythmias despite cardioversion/defibrillation during the use of the Stimulator, disconnect the Stimulator from the patient by unplugging the green Pace Output plug on the front panel in case it has an occult malfunction causing recurrent micro-electrocution or recurrent DC current stimulation.

#### **Warning: Measurements by Stimulator are for information only.**

Measurements displayed by Stimulator, including the Impedance measurement, RR interval and SNRT measurement are for facilitation of use of Stimulator. The user should use third party legally marketed measurement devices independent of the Stimulator to measure these parameters for the purpose of clinical diagnoses.

#### **Warning: When using the optional Four Channel Stimulus Multiplexer Box (SM-Box)**

Product is not suitable for sterilization and must be protected from ingress of fluids

In order to prevent inadvertent or ineffective pacing, the user should always verify the actual channel being paced using independent EP Recording Equipment. If unexpected results are observed or the SM-Box FAULT indicator lights, do not use the SM-Box; if urgent pacing is required, use the Emergency Bypass output socket and pace Ch2 (Ventric), or use Emergency Pacing on the Stimulator.

### Warnings Related to the use of Micropace Stimulator with RF Ablation Equipment

#### **Warning: Use Stimulator only with RF-filtered stimulus connection. (Micropace parts: MP3014, MP3086).**

Use only supplied Stimulus Connection Box (MP3014) or optional Stimulus Multiplexer Box (MP3086) components to connect Stimulator's stimulus output to patient circuits. These components contain RF suppression filters to prevent large RF energies from RF Ablation equipment not equipped with RF filters from reaching the Stimulator output circuits. Use of other, including custom made connectors may bypass RF filtering and potentially lead to repeated alarms and shutdowns of the Stimulator and possible induction of unintended lifethreatening arrhythmias during delivery of RF ablation energy.

The MP3014 and MP3086 components are over voltage protected by gas arrestors for differential voltages > 350VAC. Exposing these components to unfiltered RF ablation energies exceeding this limit (e.g. by direct connection to unfiltered RF Ablation energies > 150W or ablating into > 300 Ohm loads may cause reduction of RF energy available for ablation and overheating and a fire hazard within these components.

#### **Warning: Do not stimulate via ablation electrode during delivery of RF Ablation energy.**

To avoid possibility of unintended arrhythmia induction, do not stimulate myocardium via the ablation electrode during application of RF energy. Efficacy and potential for adverse effects of stimulation of heated myocardium in the process of ablation have not been established.

# Micropace Cardiac Stimulators

## EPS320B/BT, StimCor™, StimLab™

### Precautions:

#### Caution: Precautions during use.

Observe the Stimulator and patients at all times for abnormal function and rectify any problem promptly or disconnect the patient from the Stimulator (by unplugging the green plug from the green PACE OUTPUT socket on the front panel).

Do not use the Stimulator and disconnect it from the patient if it repeatedly switches to Backup Manual mode and displays error messages on the front panel. Contact your Micropace Distributor.

To ensure reliable stimulus capture, set stimulation current according to capture threshold whenever changing stimulation site or catheter. Two times threshold is usually used.

Use of excessive stimulation currents may induce fibrillation and produce misleading results in ventricular stimulation studies.

To reduce chance of accidentally inducing ventricular fibrillation, ensure reliable ECG sensing and use SYNC\_TO function to avoid stimulating in the vulnerable diastolic period where appropriate.

When using ECG-synchronous stimulation, to improve efficacy and prevent unwanted induction of arrhythmias, ensure that the ECG signal and detection of PQRS are satisfactory before and during pacing.

#### Caution: The Stimulus Generator Unit should be charging its backup battery while not in use.

The Micropace stimulator should be connected to external power; its Power switched on at the rear panel switch and in the Standby Mode while not in use to ensure that backup battery remains fully charged.

The Stimulator should be maintained according to "Maintenance" section of this manual.

# CLEARSIGN™ Amplifier IFU

## Indications for Use

- The LABSYSTEM™ PRO EP Recording System is intended for use as a data acquisition tool designed to facilitate the gathering, display, analysis by a physician, and storage of intracardiac electrophysiological data.
- The BARD® CLEARSIGN™ Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the BARD® LABSYSTEM™ PRO EP Recording System) that can record and display the information.

## Contraindications

None known.

## Warnings and Precautions

Refer to the Warnings and Precautions Information Booklet, Bard Part No. PK5015170 for a comprehensive list of warnings and precautions specific to the installation, setup and operation of the BARD® LABSYSTEM™ PRO EP Recording System and BARD® Amplifiers.

## Description

The transseptal needle kit consists of an outer needle cannula and an inner stylet. The needle is comprised of flexible thin walled tubing with an ergonomic hub and stopcock attached to the proximal end. The stylet consists of a solid wire that when inserted in the needle protrudes beyond the distal tip of the cannula.

## Indications for Use

The transseptal needle is used in conjunction with a transseptal catheter and/or introducer to create the puncture in the atrial septum to allow left heart catheterization procedure to occur through the right atrium.

## Contraindications

- Left atrial thrombus or tumor
- Dilated aortic root
- Continual anticoagulation
- Inability to lie flat
- Substantial deformity of the spine or chest
- Marked atrial enlargement
- Distorted anatomy due to congenital heart disease
- Previous intra-septum patch

## Warnings

- Only those physicians who specialize in the practice of invasive cardiology techniques should use this device. The device should be restricted for use by those specialists trained to perform transseptal procedures.
- Maintain continuous pressure monitoring and repeated biplane fluoroscopy during positioning.
- Caution should be used in patients with small left atrium, to avoid left atrial wall puncture.
- The transseptal needle should never be advanced until the catheter is positioned correctly on the atrial septum.
- Always ensure that the transseptal needle has clearly entered the left atrial cavity by confirming distinct left atrial pressure and fluoroscopy of the needle tip before advancing the dilator, sheath or catheter.
- Do not remove a dilator, sheath or catheter that has been inadvertently advanced into the pericardial space until the patient is in surgery.
- Do not reuse this device. The device must be discarded after one use using acceptable medical practices and applicable local, state and federal laws and regulations.
- Follow instructions accompanying the transseptal introducers.

## Precautions

- Store in a cool dry place.
- Inspect all components prior to use.
- If resistance is met while advancing or withdrawing the introducer or guidewire, fluoroscopy should be used to determine the cause.
- Prior to use, ensure the appropriate catheter is being used with the transseptal needle.

## Adverse Events

In addition to the complications associated with any cardiac catheterization, the following could occur during a transseptal catheterization:

- Inferior vena cava puncture
- Aorta puncture
- Atrial free wall puncture
- Coronary sinus puncture
- Arterial embolism from thrombus at the puncture site
- Tamponade
- Residual atrial septal defects
- Atrial arrhythmia

# TSX™ Transseptal Needle and Stylet Set DFU

## Directions for Use

1. To determine the size and location of the left atrial septum, it may be helpful to perform right side angiography.
2. Thoroughly flush the transseptal needle.
3. Inspect all components prior to use for integrity and appropriateness for the particular procedure.
4. The transseptal needle/stylet set is advanced through the transseptal catheter until the tip of the needle is just within the catheter.

**Note:** Ensure the transseptal needle is free to twist and/or rotate without resistance, as it is advanced to this position.

5. Retract the stylet prior to puncturing the interatrial septum.
6. The tip of the transseptal needle is positioned against the interatrial septum.
7. The transseptal needle is advanced through the septum into the left atrium once the correct location is confirmed using fluoroscopy (preferably biplane).
8. The successful puncture into the left atrium is confirmed by observing a left atrial pressure tracing. If an incorrect pressure tracing is observed, a small amount of contrast media is injected to identify the positioning.
9. The transseptal catheter is advanced over the transseptal needle into the left atrium.
10. The transseptal needle is slowly removed.