Bard electrophysiology

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Stinger™/Stinger™ M/Stinger™ S Ablation Catheter Information for Use

BARD

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Read this document in its entirety prior to use.

Single Use.

Sterile, non-pyrogenic unless package opened or damaged.

Caution: Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

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1. DEVICE DESCRIPTION:

The Bard Electrophysiology Stinger™/Stinger™ M/Stinger™ S Ablation catheter is a radiopaque, flexible, insulated catheter with a polymer shaft. The catheter handle has a slider mechanism which, when moved forward or back from the neutral position, results in curvature of the distal tip. The Stinger™/Stinger™ M/Stinger™ S Ablation catheter is available in six (6) different curve configurations designated "A" through "F" and are available as shown in Figure 1.

Stinger Item No.	Stinger S Item No.	Stinger M Item No.	French Size	Poles	Spacing (mm)	Curve Type	Curve	Color
210001	210001S	210001M	7F	Quadpolar	2,5,2	A		Yellow
210002	210002S	210002M	7F	Quadpolar	2,5,2	B		Red
210003	210003S	210003M	7F	Quadpolar	2,5,2	C		Green
210004	210004S	210004M	7F	Quadpolar	2,5,2	D		Blue
210005	210005S	210005M	7F	Quadpolar	2,5,2	E		White
210006	210006S	210006M	7F	Quadpolar	2,5,2	F		Orange

Figure 1

For ablation, the distal tip delivers up to 50W of radiofrequency (RF) energy when used in conjunction with a compatible RF generator. Refer to Section 10, Directions for Use, for the specifications of a compatible generator.

2. INDICATIONS AND USAGE

The Stinger™/Stinger™ M/Stinger™ S Ablation catheter is indicated for creating focal endocardial lesions during cardiac ablation procedures to treat arrhythmias; and for cardiac electrophysiological mapping and delivering diagnostic pacing stimuli.

3. 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.

4. WARNINGS AND PRECAUTIONS

Warnings

- **This device should only be used by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies, catheter ablation, and temporary pacing.**
- **The risk 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 electrophysiological procedures.**
- **Patients having modification of the AV node or ablation of septal accessory pathways are at risk for inadvertent AV block. It is prudent to use lower initial power in these patients and to monitor anterior conduction during RF power delivery.**
- **Do not use excessive force to advance or withdraw the catheter when resistance is encountered because tissue damage or perforation could occur.**
- **Careful consideration should be given for the use of the catheter in pregnant women. Catheter ablation procedures present the potential for significant x-ray exposure to the patient and laboratory staff. Steps should be taken to minimize exposure.**
- **Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. Thus, it is important to:**
  - **have temporary external sources of pacing available during ablation,**
  - **temporarily reprogram the pacing device minimum output or 000 mode to minimize risk of inappropriate pacing,**
  - **perform complete pacing analysis post ablation, and**
  - **use extreme caution during ablation when in close proximity to implanted cardioverter/defibrillator during delivery of RF energy.**
- **Patients having left-sided ablation should be monitored post ablation for clinical manifestations of myocardial infarction or stroke.**
- **All catheter adjustments should be done under fluoroscopic guidance.**
- **Use only with the appropriate Bard TempLink™ Extension Cable. Use of another cable may pose a serious safety risk.**

Precautions

- **Do not ablate through the proximal (ring) electrodes. This catheter is designed for ablation through the distal tip only.**
- **Excessive bending or kinking of the electrode catheter may cause damage to internal wires.**
- **Avoid submerging the catheter handle in any solution.**
- **If sudden dramatic impedance rise is observed during ablation, examine the catheter tip for coagulum. If coagulum is present, carefully remove the substance from the catheter tip. If the distal tip appears to be loose or if there is movement of any proximal ring after cleaning, do not use the catheter.**
- **Ensure that the catheter tip has been returned to the neutral position 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.**

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5. ADVERSE EVENTS

The Stinger™ Ablation catheter was studied in 251 patients undergoing electrophysiologic (EP) mapping and RF catheter ablation for the treatment of atrioventricular (AV) accessory pathways that support arrhythmia; treatment of AV nodal re-entrant tachycardia; ablation of the AV junction in patients with symptomatic drug resistant tachycardias.

5.1 Observed Adverse Events

Major and minor adverse events were classified according to FDA's recommended definitions for evaluating ablation safety. A total of 13 major adverse events were reported for 11 patients. These events included transient complete heart block and transient heart block, first degree AV block, tamponade from RV perforation, cardiac arrest, pericardial effusion, heart failure, CVA, atrial lead microdisplacement, acute renal failure, pneumonia, fever, and a sudden onset of severe back, chest and upper abdominal discomfort.

Adverse Events - Major, Procedural Minor and Deaths
Population: All Patients Enrolled (N=251)

	Number of Events	Number Of Patients	Percent Of Patients
Major Events	13	11/251	4.4%
Procedural Minor Events	37	29/251	11%
Patients Deaths	3	3/251	1.2%

Three (3) patients died during the study. None of the deaths were considered related to the use of the study device.

A total of 37 minor procedural adverse events (as summarized in the table below) were reported for 29 patients:

Procedural Adverse Events
Population: All Patients Enrolled (N=251)

COSTART Terms	Number of Occurrences
Abnormal ECG	1
Abnormal Vision	1
Application Site Reaction	1
Asthenia	1
Back Pain	1
Bundle Branch Block	1
Chest Pain	6
Dizziness	1
Ecchymosis	1
Fever	2
Injection Site Pain, Hemorrhage or Mass	8
Nausea (with or without vomiting)	3
Neck Pain	1
Pain	1
Syncope (vasovagal)	7
Ventricular Arrhythmia	1
Total:	**37**

5.2 Anticipated Adverse Events

Adverse events (in alphabetical order) which may be associated with catheterization and ablation include, but are not limited to:

- anaphylaxis (allergic reaction) with breathing problems, drop in blood pressure and possibly death
- angina (chest discomfort)
- arrhythmia (irregular heartbeat)
- arterial/venous thrombosis (clot formation on the inside wall of the artery at the entry site)
- AV fistula (a communication between the artery and vein at the site of catheter insertion)
- back pain and/or groin pain
- cardiac perforation (hole in the lining of the heart)
- hematoma formation (bruise or bleeding into body tissue) in groin area
- hypotension (fall in blood pressure)
- infection
- myocardial infarction (heart attack)
- pericardial effusion or cardiac tamponade (collection of blood in lining of the heart)
- pneumothorax (an accumulation of air or gas in the pleural space)
- significant blood loss which may lead to blood transfusion
- skins burns (injury to the skin caused by the electrical current)
- thrombotic events including stroke and pulmonary emboli
- unintentional complete heart block requiring a pacemaker
- vessel wall or valvular trauma which may lead to surgical repair

6. CLINICAL STUDIES

The Stinger™ Ablation catheter, used in conjunction with related accessory devices, was evaluated in a clinical study with the EPT-1000 TC RF generator for the treatment of supraventricular tachycardias (SVT).

Study Design

The Stinger™ Ablation catheter was evaluated in a prospective, multicenter trial. Acute success was defined as the proportion of patients where treatment with the study device was able to: 1) eliminate the functioning of aberrant pathways in patients with symptomatic SVT caused by accessory pathways, 2) eliminate the functioning of aberrant pathways in patients with symptomatic SVT caused by AVNRT, 3) ablate the AV node for control of a rapid ventricular response in patients with symptomatic, drug resistant tachycardias.

Long-term (Chronic) success was defined as the proportion of acute success patients, who, at a minimum of 3 months post ablation, continue to have:

- absence of symptoms related to the index arrhythmia; or
- effective AV block.

Patients Studied
- **Patients Enrolled in Study** 251
  - Patients Discontinued Prior to Study 4
    - target arrhythmia non-inducible 3
    - target arrhythmia non indicated 1
  - **Patients Treated in Study** 247

Demographics

Patient Demographics
Population: All Patients with Treatment Attempted
N=247
Males 68% (167) / Females 32% (80)

	N	Mean	Std. Dev.	Minimum	Maximum	Median
Age (years)	247	51.3	15.9	18.0	90.0	50.0
Duration of SVT Symptoms (years)	244	13.6	13.6	0.0	69.9	9.6
Frequency of SVT Symptoms (times/year)	224	99.6	238.4	0.1	1826.3	12.0
No. of SVT Episodes (In Last 6 months)	212	28.1	76.7	0.0	600.0	6.0
No. of Hospital Visits (In Last 6 months)	247	1.1	1.3	0.0	8.0	1.0

Number of Arrhythmia Types Treated

	Percent of Patients N=247	Number of Arrhythmias N=251
Accessory Pathway - Concealed	10%	25
Accessory Pathway - Non-concealed	10%	25
Accessory Pathway - both types	1%	3
AVNRT	66%	163
AV Node Ablation for Rate Control	14%	35

Note: 4 patients had both an Accessory Pathway and AVNRT treated.

Procedure Data

Energy was almost always delivered using the constant temperature mode. Catheters were most often exchanged due to needing a different catheter curve (63%, 41/65 energy deliveries). The reason for terminating the energy delivery was usually based on the desired time interval being achieved (56%, 882/1588).

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ENERGY / TEMPERATURE / PROCEDURE TIME

mean number of energy deliveries per patient	6.5 ± 6.2	
mean duration per delivery	43.3 ± 29.2	seconds
mean duration for all of the deliveries in a single procedure	283.4 ±280.2	seconds
temperature setting	61.2 ± 5.2	°C
actual delivered temperature	55.7 ± 7.2	°C.
mean ablation (procedure) time	63.2 ± 62.5	minutes
mean fluoroscopy time	24.4 ± 22.1	minutes

Acute and Long-Term Effectiveness

Of the 247 patients treated with the Stinger™ Ablation Catheter, acute success was achieved in 230 patients (93%). There were a total of 17 acute failures of which 12 procedures were completed with a non-protocol device, no energy was delivered in 4 procedures due to RF generator malfunction, and the study device was not used in 1 patient due to the patient's tortuous anatomy.

Success Results for Specific Arrhythmias

	Total*	Accessory Pathway	AVNRT	AV Node	>1 Type
Acute Success	93% 230/247 CI: 89% 96%	88% 43/49	95% 151/159	91% 32/35	100% 4/4
Long-Term Success at 3 Months	97% 219/226** CI: 95% 99%	93% 38/41	97% 146/150	100% 31/31	100% 4/4

Table entries show % (number success/number evaluated)

* Exact 95% confidence intervals (CI) based on the binominal distribution

** Four (4) patients not evaluated for long-term success due to 1 death and 3 lost-to-follow-up prior to 3 months.

Antiarrhythmic Medications: For this study, a medication was considered antiarrhythmic if it was given specifically for treatment of the patient's arrhythmia.

Antiarrhythmic Medications

	% of Patients Prior to Ablation		% of Patients @ 3 Months	
All	68%	(156/230)	11%	(25/226)
Accessory Pathways	53%	(23/43)	5%	(2/41)
AVNRT	68%	(102/151)	7%	(11/150)
AV Node	88%	(28/32)	39%	(12/31)
>1 Type	75%	(3/4)	0%	(0/4)

7. PATIENT TREATMENT

7.1 *Pre-Procedure and Post-Procedure*

The patient should be prepped for the ablation according to the standard practice at the clinical site, for example:

a) discontinue antiarrhythmic drugs at least 5 half-lives prior to the ablation procedure,
b) anticoagulation therapy such as heparin, and
c) a baseline electrophysiological study documenting the presence of the arrhythmia.

7.2 *Choosing Temperature or Power Control Mode*

Please refer to the Directions for Use of a compatible RF generator for information in choosing between temperature or power control modes.

7.3 *Specific Patient Populations*

The safety and effectiveness of the Stinger™ Ablation Catheter has not been studied in:

* Asymptomatic patients; and
* Patients who are pregnant.

8. PATIENT COUNSELING INFORMATION

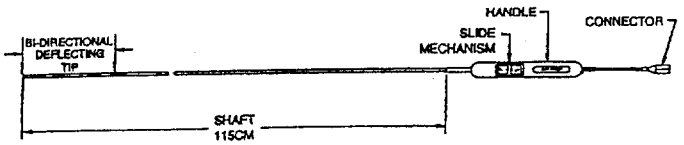
Patients may require anticoagulation and/or antiplatelet therapy for an indefinite period based on the patient's condition.

9. HOW SUPPLIED

The Stinger™/Stinger™ M/Stinger™ S Ablation Catheter is provided sterile (EO). The device is a 7F catheter with a usable length of 115 +2/-5cm, and the following features:

Curve Types:	A, B, C, D, E, & F
Tip Electrode:	4mm
Connector Type:	10 Pin
Spacing:	2mm/5mm/2mm

Following is a diagram of the Stinger™/Stinger™ M/Stinger™ S Ablation Catheter.



9.1 Packaging

The Stinger™/Stinger™ M/Stinger™ S Ablation Catheter is supplied STERILE. The tip of the catheter is secured in a protective tube to keep it straight. The catheter is positioned in a PVC tray with a PVC lid holding it in the tray. The tray with lid is placed in a pouch and sealed. The sealed pouch is placed in a folding carton. Both the pouch and the folding carton are labeled sterile unless the package is damaged or open.

9.2 Storage

The Stinger™/Stinger™ M/Stinger™ S Ablation Catheter must be stored in a cool, dry place. Storage temperature should be between 0° and 45°C.

9.3 Shelf-Life

The Stinger™/Stinger™ M Ablation Catheter has an expiration date of three (3) years. The Stinger™ S has an expiration date of one (1) year.

10. DIRECTIONS FOR USE

10.1 Physician Training

Physicians must be familiar with the techniques and appropriately trained for cardiac mapping and ablation procedures. All mapping and ablation procedures must be performed in a fully-equipped electrophysiology laboratory.

10.2 Compatible RF Generator and Accessories

The Stinger™/Stinger™ M/Stinger™ S Ablation Catheter should be used only with a legally marketed RF generator which has been shown to be safe and effective for cardiac ablation. The Stinger™/Stinger™ M/Stinger™ S Ablation Catheter is to be used with the appropriate Bard TempLink™/TempLink™ M Extension Cable.

Specifications for Compatible RF Generators:

Generator	Specification
Thermometry	Stinger/TempLink – Stinger S/TempLink With thermocouple temperature sensor Stinger M/TempLink M – With thermistor temperature sensor
Temperature Limit, Maximum	95°C
Modes: (must operate in all 3 modes)	Temperature Control Temperature Monitoring Power Control
Maximum Output Power	50 Watts
RF Output Frequency	450kHz - 550kHz
Impedance Cut-off	High: 300 ohms Low: 50 Ohms

Refer to the manufacturer's manual for detailed generator operating instructions for RF catheter ablation with a compatible generator.

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Accessories

The Bard Electrophysiology TempLink™ Extension Cable was designed for use with the Stinger™ /Stinger™ S Ablation Catheter.

The Bard Electrophysiology TempLink™ M Extension Cable was designed for use with the Stinger™ M Ablation Catheter.

10.3 Handling and Preparation

Prior to use, inspect the packaging. Do not use if open or damaged.

Using aseptic technique, remove the catheter from its package and place it in a sterile working area. Inspect the catheter carefully for electrode integrity and overall condition.

10.4 Instructions for Use

1. Inspect the packaging carefully for overall condition. Do not use if the package is open or damaged.
2. Inspect the electrode carefully for integrity and overall condition. If damaged, do not use.
3. Insert the catheter by using a standard percutaneous catheter introducer.
4. The electrode should be passed from a peripheral vessel to the desired intracardiac position under fluoroscopic guidance.
5. The catheter tip can be deflected by advancing or retracting the slider mechanism on the handle from the neutral position. When the slider mechanism is in the neutral position, the tip is approximately straight.

An issued or revision date and a revision number for these instructions are included for the user's information on the last page directly beneath the address and telephone number of Bard Electrophysiology. In the event two years have elapsed between the date and product use, the user should contact Bard Electrophysiology to see if additional information is available.

Patent(s) Pending.

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