

# LABELING

## **IBI Therapy™ Ablation Catheter**

### **CAUTION:**

- Read completely and understand these directions prior to use.
- United States Law restricts this device to sale by or on the order of a physician.

### **DESCRIPTION:**

The IBI Therapy™ Ablation Catheter is a sterile, single use catheter with one 4mm ablation electrode at the tip and three 2mm diagnostic electrodes. The catheter includes a temperature sensor in the tip electrode for temperature monitoring and the handle is equipped with a steering mechanism to deflect the distal tip of the catheter. The catheter is available with various distal curve configurations; the curve is indicated on the catheter label.

### **INDICATIONS:**

The IBI Therapy™ Cardiac Ablation System is indicated for mapping and for use with a compatible RF generator for: interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia; the treatment of AV nodal re-entrant tachycardia (AVNRT); or creation of complete AV nodal block in patients with a difficult to control ventricular response to an atrial arrhythmia.

### **CONTRAINDICATIONS:**

Do not use the IBI Therapy™ Ablation Catheter:

- In patients with active systemic infection
- Via the retrograde transaortic approach in patients with aortic valve replacement.
- Via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.

### **WARNINGS:**

- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency catheter ablation in a fully equipped electrophysiology laboratory.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an 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 have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women. 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.
- Vascular perforation is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Use both fluoroscopy and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation. Do not force the catheter to advance or withdraw when resistance is encountered.
- Patients undergoing left-sided ablation procedures should be closely monitored during the post-ablation period for clinical manifestations of embolic events including infarction and stroke.
- Pacemakers and implantable cardioverter/defibrillators can adversely be affected by RF signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate ICDs as they could discharge and injure the patient or be damaged by the ablation procedure, c) exercise extreme caution during ablation when in close proximity to permanent pacing or defibrillation leads, and d) perform complete implantable device analysis on all patients after ablation
- 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 antegrade conduction closely during RF power delivery

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- The long-term risks of RF ablation lesions have not been established, particularly with respect to lesions placed in proximity to the specialized conduction system.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- When using an EP recording system, the equipment must be front-end isolated, or have an isolated patient cable.

### PRECAUTIONS:

- 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.
- Use non-flammable agents for cleaning and disinfections. To maintain optimal patient safety and electrode catheter integrity, do not wipe the catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be adversely affected.
- Needle monitoring electrodes are not recommended.
- Position connecting cables such that contact with patient or other leads is avoided.
- Desired ablation parameters must be set by the user; otherwise, the default values will be used.
- The catheter impedance display of the Cardiac Ablation Generator 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.
- Regularly inspect and test re-usable cables and accessories.

### CLINICAL STUDIES

The Therapy™ Ablation catheter was studied in 159 patients undergoing RF ablation. The Therapy™ Cardiac Ablation System using the Therapy™ Ablation Catheter was evaluated in a prospective, non-randomized, multicenter clinical study for the treatment of supraventricular tachycardias (SVT). The objective of the clinical study was to demonstrate the safety and effectiveness of the Therapy™ Cardiac Ablation System for the treatment of SVT based primarily on three objective performance criteria (OPC). The OPCs which specified acceptable limits for acute success, chronic success and major complications were consistent with FDA guidance documents regarding the evaluation of cardiac ablation catheters.

For AV Nodal Re-entrant Tachycardia (AVNRT) and Accessory Pathway (AP) treatments, "Acute success" was defined as the inability to induce the targeted arrhythmia within 60 minutes of ablation. For complete heart block patients, acute success was defined as the presence of complete AV block, as shown on a 12-lead electrocardiogram.

For all patients, "Chronic success" was defined as the absence of recurrence of the target arrhythmia over a 3-month period following an acute success. In addition, the complete block had to be demonstrated on a 12-lead electrocardiogram for complete AV block patients and no evidence of recurrent pre-excitation had to be demonstrated for manifest AP patients. Adverse events were classified according to FDA's recommended definitions.

Data collection included basic demographics, presenting signs and symptoms, characteristics of the index arrhythmia, procedural parameters (ablation duration, impedance, power and temperature), cardiac medications, treatment outcome, adverse events and assessments for recurrence of the treated arrhythmia. Patients were evaluated one and three months after the initial ablation procedure.

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165 patients were initially enrolled and 6 were discontinued as they did not meet the inclusion criteria. Of the 159 subjects enrolled in the study, one received a diagnostic procedure only, leaving a total of 158 subjects undergoing ablation therapy.

Among the 159 patients enrolled, 114 (71.7%) were female and 45 (28.3%) were male. The average age ( $\pm$ SD) of all treated patients was 55.7 ( $\pm$ 15.5). The majority (67.3%) of patients were treated for AVNRT. All patients had symptomatic arrhythmias at the time of ablation.

### *Arrhythmias Types Treated*

| Indication              | Number of Patients | Percent |
|-------------------------|--------------------|---------|
| AV Nodal Re-entrant     | 107                | 67.30%  |
| Complete Heart Block    | 32                 | 20.13%  |
| Accessory Pathway (AP)  | 17                 | 10.69%  |
| Non Protocol Arrhythmia | 3                  | 1.89%   |

Energy was applied a total of 947 times with an average of 6.2 ( $\pm$ 7.2) applications per patient. The mean duration of energy delivery per application was 40.9 ( $\pm$ 28.2) seconds at an average temperature of 53.6 ( $\pm$ 6.0) degrees. Mean fluoroscopy time was 13.5 ( $\pm$ 13.7) minutes and mean treatment time was 37.7 ( $\pm$ 35.3) minutes.

### *Objective Performance Criteria*

| Criteria                 | Rate  | 95% CL | Meets OPC? |
|--------------------------|-------|--------|------------|
| Acute Success > 85%      | 90.6% | 86.1%  | Yes        |
| Chronic Success > 80%    | 86.8% | 81.5%  | Yes        |
| Major Complications < 7% | 3.8%  | 6.9%   | Yes        |

### **ADVERSE EVENTS:**

Among the 158 study subjects who underwent RF ablation 8 major complications in 6 subjects were observed within 7 days of the procedure. These included two instances of inadvertent heart block, one instance each of bradycardia, cardiac tamponade, perforation, sepsis, pneumothorax requiring hospitalization and one instance of prolonged hospitalization due to worsening congestive heart failure. One death was observed 22 days following successful ablation in a patient with congestive heart failure. The event was noted to be unrelated to the device or the procedure. There were no unanticipated, serious device-related adverse events.

Catheter placement and RF power application within the coronary vasculature has been associated with the following complications (in alphabetical order):

- Air embolism
- Arrhythmia
- Arterial spasm
- Arterial/venous thrombosis
- AV Fistula
- Back pain
- Blood loss requiring transfusion
- Cardiac perforation
- Cardiac tamponade
- Chest pain

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- Death
- Groin hematoma
- Groin pain
- Hemothorax
- Hypotension
- Infection
- Myocardial infarction
- Pericardial effusion
- Pneumothorax
- Pseudoaneurysm
- Pulmonary Embolism
- Radiation injury
- Skin burns caused by electrical current
- Stroke
- Thrombotic events
- Transient ischemic attack
- Unintended complete heart block requiring pacemaker insertion
- Unintended sinus node dysfunction requiring pacemaker insertion
- Valvular damage (mitral or tricuspid)
- Vascular trauma
- Vasovagal reaction

### **PATIENT SELECTION AND TREATMENT RECOMMENDATIONS:**

The patient should be prepared for the ablation procedure in accordance with standard clinical practice, for example:

- A baseline electrophysiological study documenting the presence of the arrhythmia,
- Discontinuation of antiarrhythmic drugs prior to the ablation procedure, and
- Anticoagulation therapy such as heparin.

The safety and effectiveness of the Therapy™ Ablation Catheter have not been studied in asymptomatic or pregnant patients.

### **DIRECTIONS:**

1. Inspect the catheter package prior to use. Do not use if the package is open or damaged.
2. Remove the catheter from its package. Inspect the electrodes and catheter carefully for integrity, continuity of leads and overall condition.
3. Insert the catheter by using a standard percutaneous catheter introducer.
4. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy.
5. The catheter has a built-in cable connector that must be used with the appropriate interface cable for electrogram recording and radiofrequency ablation. Refer to the RF Generator and/or interface cable instructions for details
6. Connect the appropriate interface cable to the catheter.
7. Observe the polarity of the proximal end connector pins of the patient cable when connecting to an EP recording system.
8. Use care to isolate any unused connector pins. This will reduce the chances of developing accidental current pathways to the heart
9. To manipulate the tip portion of the catheter, push or pull the thumb control located at the distal end of the handle.
10. Always use fluoroscopy when manipulating the tip of catheter.
11. For catheter ablation, refer to the RF Generator Operator's Manual.
12. Always straighten the catheter tip before removing the catheter from the patient.

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### CONNECTION TO OTHER EQUIPMENT:

This device may be connected to a commercially available EP recording system and/or a compatible radio frequency generator using a connection cable with a Redel connector in the pin configuration corresponding to this catheter. The use of cables with shrouded pins is recommended and is required in some countries such as the United States. Such equipment must be "patient isolated", or have an isolated patient cable. The maximum power to be delivered through this catheter is limited to 50 Watts.

### Specifications for Compatible RF Generators:

- Must operate in temperature control mode
- Must limit temperature to 90°C
- Must provide impedance cutoffs (e.g. 25-50 Ohms low and 300 Ohms High)
- Must operate at a frequency between 450 to 550 kHz

### PACKAGING AND SHELF-LIFE:

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the products remain in the unopened package until time of use. Contents are sterile **STERILE | EO** if package is unopened and undamaged. Do not resterilize. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location.

### WARRANTY:

Irvine Biomedical, Inc. (IBI) warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products are set forth in the related "Instructions for Use" that accompany each product. IBI disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. IBI's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. IBI disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. IBI neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete IBI warranty policy available from IBI (1-949-851-3053) or on the back of an IBI invoice.