Daig Corporation

a St. Jude Medical company

Livewire TC™
Steerable Electrophysiology Catheter

INSTRUCTIONS FOR USE

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1 DEVICE DESCRIPTION

The Daig LivewireTC™ Steerable Electrophysiology Catheter (Livewire Catheter) is a flexible electrode catheter which records electrophysiological activity from the heart and transmits radio frequency (RF) current to the catheter tip electrode for ablation purposes. The catheter is constructed of a radiopaque polyurethane shaft and platinum electrodes. All electrodes may be used for recording and stimulation, but only the tip electrodes may be used to deliver RF energy. The remote control handle located at the proximal end of the catheter deflects distal the tip of the catheter.

The Livewire Catheter must be used with a dispersive pad (reference electrode), and a compatible RF generator with the following specifications:

- A thermocouple (for temperature measurement)
- Maximum temperature limit - 100°C
- Modes - Temperature control and monitoring and power control.
- Maximum output - 50 watts
- RF output frequency - 450–550 KHz
- Impedance range - 40–250Ω

2 INDICATIONS AND USAGE

The Livewire Catheter is indicated for cardiac electrophysiological 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.

3 CONTRAINDICATIONS

Do not use this device:

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

4 WARNINGS AND PRECAUTIONS

Warning

- **Do not ablate from within a 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.
- **Stroke or myocardial infarction** may occur in patients undergoing **left-sided ablation procedures**. Patients should be closely monitored during the post-ablation period for clinical manifestations of embolic events.
- **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

- **Complete AV block** can occur when ablating septal accessory pathways or in the treatment of AVNRT. Closely monitor AV conduction during RF energy delivery and immediately terminate energy delivery if partial or complete AV block is observed.

- **Minimize X-ray exposure** – 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.

- **X-ray exposure to children** – 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.

- **Pregnancy** – Careful consideration should be given to the use of this device in pregnant women because of the dose-related risk for somatic and genetic effects of x-ray exposure.

- **Training** – Cardiac ablation procedures should be performed only by appropriately trained personnel in a fully equipped electrophysiology laboratory (see section 10).

- **Instructions for Use** – Do not attempt to operate the Livewire Catheter before completely reading and understanding the applicable directions for use.
- **Long-term risks of RF ablation** – 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.

4.1 Precautions Specific to the Livewire Catheter

- Do not use the Livewire Catheter for long term pacing.

- Use only Daig Electrophysiology connector cables with the Livewire Catheter since patient or operator injury may occur if incompatible cables are used.

4.2 Handling and Sterilization Precautions

- The Livewire is for SINGLE USE ONLY. Do not resterilize or reuse.
- Do not use the Livewire Catheter after the expiration date because the device performance may no longer be acceptable and/or the device may no longer be sterile.
- Inspect the packaging and catheter prior to use. If the package or the catheter appears damaged, do not use and contact your local Daig representative.
- Do not allow moisture to contact the connector as equipment malfunction or operator injury may occur.

4.3 Precautions During Catheter Use

- The patient should not contact grounded metal surfaces. 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 (μA) under any circumstances.
- Do not use excessive force to advance or withdraw the catheter. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Do not insert or withdraw the catheter without straightening the catheter tip (pulling the thumb knob back)
- Do not use the catheter if the small vent area at the connector end of the handpiece is clogged since air may be forced into the catheter lumen and into the bloodstream.
- Use both fluoroscopy and electrograms to monitor the advancement the catheter to the area of the endocardium under investigation to avoid vascular or cardiac damage.

4.4 Environmental and EMI

- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- During ablation procedures, this catheter is used in conjunction with an RF generator. Electromagnetic interference (EMI) produced by the radiofrequency (RF) generator during the delivery of RF power may adversely affect the performance of other equipment.

4.5 Precautions During Ablation

- Do not increase power before checking for lead connection and appropriate dispersive electrode application. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned.
- Do not deliver RF energy with catheter outside the target site. The RF generator can deliver significant electrical energy and may cause patient or operator injury.

- Avoid use of electrodes and probes of monitoring and stimulating devices which 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 cutoff (impedance or temperature), the catheter must be withdrawn and the tip electrode cleaned of coagulum before RF current 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.
- Discontinue ablation immediately and replace catheter if tip temperature fails to rise during ablation (temperature sensing model).
- The temperature sensing model of the catheter measures electrode tip temperature, not tissue temperature. If the generator does not display temperature (temperature sensing model), verify that the appropriate cable is plugged into the generator. If temperature still is not displayed, there may be a malfunction in the temperature sensing system which must be corrected prior to applying RF power.

5 ADVERSE EVENTS

5.1 Observed Adverse Events

The Livewire Catheter was studied in 329 patients undergoing electrophysiologic (EP) mapping and ablation in two clinical studies: 236 patients using an investigational RF generator and 93 patients using a commercially available generator. Of the 329, eleven patients were not treated with the Livewire Catheter due to either investigational generator issues (9) or non-availability of catheter accessories (2). There was 1 major (atrial perforation) and no minor adverse events in these 11 patients. These 11 patients were excluded from further adverse event analysis. The 318 patients included 10 patients treated for typical atrial flutter.

The number of patients with adverse events (major or minor) was 9 of 226 (4.0

%) in the study using the investigational generator and 2 of 92 (2.2%) in the study using the commercially available generator.

Table 1. Observed Adverse Events

All Patients Treated (N=318), includes 10 patients with atrial flutter

Adverse Event Category Description	Total No. of Pts. Experiencing Adverse Events	% of Pts Experiencing Adverse Events [95% C.I.]
Major; Heart block (requiring a pacemaker)	4	1.3% [0.3%, 3.2%]
Minor (included puncture site bleeding, pericardial effusion, left bundle branch block, transient complete heart block, and first degree atrioventricular block)*	7	2.2% [0.9%, 4.5%]

** Patients with both minor and major adverse events (N=2) were counted only as major adverse events.*

C.I. – Confidence intervals by the exact (binomial) method

5.2 Potential Adverse Events

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

Catheterization/catheter procedure related:

- air embolism
- arrhythmias
- AV fistula
- cardiac perforation
- hemothorax
- nerve palsy or weakness
- pneumothorax
- pseudoaneurysm
- tamponade
- thrombi
- thromboembolism
- thrombosis
- valvular damage
- vascular bleeding/local hematomas
- vasovagal reactions
- visual blurring

RF ablation related:

- cardiac perforation/tamponade
- cardiac thromboembolism
- cerebrovascular accident (CVA)
- chest pain/discomfort
- complete heart block
- coronary artery dissection
- coronary artery spasm
- coronary artery thrombosis
- pericarditis
- transient ischemic attack (TIA)
- valvular damage
- ventricular tachyarrhythmia

6 CLINICAL STUDIES

A prospective, multicenter (10 centers, 7 in the United States and 3 in Canada) study was conducted of radio frequency (RF) ablation of atrioventricular (AV) accessory pathways (AP) associated with tachycardia, AV nodal re-entrant tachycardia (AVNRT), or creation of complete AV nodal block in patients with difficult to control ventricular response to an atrial arrhythmia.

Methods: Acute success was defined as ablation of the target site and elimination of the arrhythmia with no recurrence before patient discharge. Recurrence-free survival to 12 months was assessed.

Patients Studied: The Livewire Catheter was studied with a commercially available generator (N = 93), and with an investigational RF generator, (N = 236) for patients undergoing EP mapping and RF ablation for supraventricular tachycardia (SVT). The closed loop temperature control mode was used for 92 of the patients. The procedure was aborted in 11 patients and 10 patients were found to be in typical atrial flutter. Acute effectiveness was thus assessed in 308 patients.

Results: The patients ranged in age from 11 to 84 years (mean 44 years) and included 183/329 females (56%). The acute success rate for all arrhythmias was 201 of 216 (93%) in the study using the investigational generator and 86 of 92 (93%) in the study using the commercially available generator. The difference between the results for the two generators is 0 % with a 95% confidence interval of [-9%, 8%], so the results for the two generators have been combined. Table 2 shows patient age, enrollment and acute success by indication.

Table 2. Patient Age and Acute Success by Indication
All Patients Treated for SVT (N=308)

Arrhythmia	Age, mean (range)	Success (%) [95% CI]
AVNRT	46 (11, 78)	156/163 (96%) [91%, 98%]
AP	36 (12, 66)	99/112 (88%) [82%, 94%]
AV nodal	57 (22, 84)	31/33 (94%) [80%, 99%]
All arrhythmias	44 (11, 84)	286/308 (93%) [89%, 95%]

C.I. – Confidence intervals by the exact (binomial) method

Of the 201 patients successfully treated with the investigational generator, follow-up data was available for 195. Of these 195 patients, recurrence was reported in 41 (21%), and 16 (8%) were lost to follow-up by 12 months. Table 3 shows the recurrence free survival to 12 months.

Table 3. Recurrence-free survival (Kaplan-Meier Estimates)
Patients Successfully Treated with follow-up (N=195*)

Follow-up Time	Cumulative Survival [95% CI]	Number Remaining
One Month	92% [88%, 96%]	179
Three Months	87% [82%, 91%]	164
Six Months	82% [77%, 88%]	150
Twelve Months	77% [70%, 83%]	98

C.I. – Confidence intervals from the Kaplan Meier estimates

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

Antiplatelet or Anticoagulation Use

To avoid thromboemboli, intravenous heparin is used when entering the left heart during ablation, and many physicians prescribe aspirin, less often warfarin, for about 3 months afterward. No consensus yet exists about the need for short–term anticoagulation after ablation.

Left Heart Insertion

During the clinical study, systemic anticoagulation before intracardiac RF catheter ablation in the left heart was typically an initial intravenous heparin bolus

of 3000 - 5000 Units. Anticoagulation was maintained with an intravenous heparin drip or additional periodic intravenous boluses of heparin as necessary.

Right Heart Insertion

During the clinical study, systemic anticoagulation was variable for patients undergoing intracardiac RF catheter ablation in the right heart. If used, systemic anticoagulation in the clinical study before ablation was typically an initial intravenous heparin bolus of 2000 - 5000 Units. For some patients, anticoagulation was maintained by intravenous heparin drip or additional periodic intravenous boluses.

Choosing Temperature or Power Control Mode

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

7.2 Specific Patient Populations

The safety and effectiveness of cardiac ablation has not been established in:

- Asymptomatic patients;
- patients who are pregnant; or
- nursing mothers.

8 PATIENT COUNSELING INFORMATION

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

9 SUGGESTED DIRECTIONS FOR USE

9.1 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.

9.2 Directions for Use

1. Use a Daig Fast–Cath™ Introducer to insert the Livewire Catheter.
2. Always use fluoroscopy when positioning the electrode catheter.
3. Use only a Daig Electrophysiology ablation extension cable to connect the Livewire Catheter to the appropriate electrode interface in the electrophysiology lab.
4. To record intracardiac electrograms, connect extension cable to catheter. Observe polarity of proximal end connector pins of extension cable when connecting to an ECG amplifier of your choice.

5. To use this device for temporary pacing, connect extension cable to catheter. Observe polarity of proximal end connector pins of extension cable when connecting to an external pulse generator of your choice.
6. To use this device for RF ablation without temperature monitoring, connect extension cable to catheter. Observe polarity of proximal end connector pins of extension cable when connecting to an ECG amplifier of your choice. Determine the exact location of the ablation site using the physicians clinical experience with electrophysiological and fluoroscopic guidance and mapping techniques. Connect the proximal end connector of the extension cable to the compatible RF generator previously described in these instructions.
7. When using the Livewire Catheters with the temperature monitoring feature, a six conductor ablation extension cable (blue) must be used.
8. Consult the compatible RF generator instructions for use for the proper Connection of the patient grounding plate.
9. To manipulate the tip portion of this catheter, rotate the control collar located in the handle of the catheter.
10. Always use fluoroscopy when manipulating tip of catheter.
11. Always straighten catheter tip before removing catheter from patient.

9.3 Compatible RF Generators and Accessories

The Livewire Catheter should be used only with a RF generator which has been shown to be safe and effective for cardiac ablation.

Table 4. Specifications for a Compatible RF Generator:

PARAMETER	SPECIFICATION
Thermometry	Thermocouple
Temperature Limit, maximum	100°C
Modes: (must operate in all 3 modes)	1. Temperature Control 2. Temperature Monitoring 3. Power Control
Maximum Output Power	50 Watts
RF output frequency	450 kHz - 550 kHz
Impedance cut-off	high: 250Ω low: 40Ω

Refer to the RF generator manual for detailed generator operating instructions for RF catheter ablation.

Accessories:

Use only the appropriate Daig extension cable with Redel 14-pin connector to connect to a compatible RF generator.

10 HOW SUPPLIED

The Livewire Catheter is only available with temperature sensing. All catheters use a 4mm tip electrode, Redel 14–pin connector, and standard 2–5–2(mm) spacing. The Livewire TC™ Catheter is available in one of the following six curve styles: Small Curl, Medium Curl, Large Curl, Small Sweep, Medium Sweep & Large Sweep.

10.1 Packaging

The Livewire Catheter is supplied STERILE. The catheter is placed into a thermoformed plastic tray designed to protect the catheter during handling. The tray is placed into a Tyvek® and Mylar® pouch and heat sealed.

10.2 Storage and Shelf–Life

The catheters must be stored in a cool, dark, dry place.

All catheters are labeled with a three year expiration date.

10.3 Warranty and Replacement Policy

Daig Corporation does not warrant or guarantee the Livewire Catheter. Please see the enclosed "Warranty Card" for further information. Also, please see the following labeling sections for information concerning the performance of this device: Contraindications, Warnings and Precautions, and Adverse Events.

DAIG CORPORATION
14901 DeVeau Place
Minnetonka, MN 55345–2126 USA

PH: (800) 328–3873
In MN, call: (612) 933–4700
FAX: (612) 933–0307

ST. JUDE MEDICAL EUROPE, INC.
Arianelaan 5
1200 Brussels
Belgium

PH: 32 2 774 68 11
FAX: 32 2 772 83 84

40841 Rev. Preliminary D
11/19/98

U.S. Patent Nos. 5,395,328 & 5,395,329

Information for Patients Considering Ablation Treatments of Heart Rhythm Problems

This booklet provides an overview of catheter ablation procedures for the treatment of SVT.

You should consult your physician for a complete explanation of this procedure.

Daig Corporation
14901 DeVeau Place
Minnetonka, MN 55345
800-328-3873 or 612-933-4700

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INTRODUCTION

Your doctor has told you that you may benefit from a catheter ablation procedure. This booklet was designed to provide you with an overview of this procedure and address many of the questions you may have. However, as with all medical procedures, you should consult your physician for a complete explanation of this procedure.

HOW THE HEART WORKS

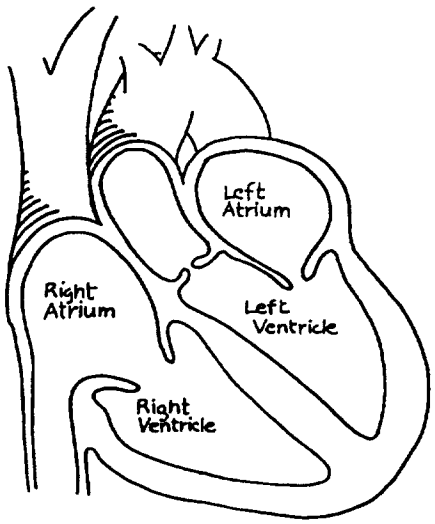
Before discussing the specifics of catheter ablation procedures, you will need to know a little about how the heart works.

The heart is a hollow, muscular organ that pumps blood throughout the body. This is an important function as blood contains both the oxygen and nutrients your body needs to work properly. Blood is pumped from the heart when it contracts (beats). This contraction occurs when the heart muscle is stimulated by an electrical impulse, either naturally or from an external source. To do all of this, your heart has plumbing and wiring, just like your home.

The Plumbing

Your home no doubt has a plumbing system, which includes sinks, a water heater, pipes, etc. Your heart also has a plumbing system. Instead of sinks, your heart has four compartments, or chambers. These four chambers work together to pump blood throughout the body. The upper two chambers are called the left and right atria (singular: atrium) and the two lower chambers are called the left and right ventricles (see Figure 1).

- Figure 1 -



The atria receive blood from the body, and the ventricles pump blood out to the body. Normally both atria contract (or pump) at approximately the same time, and then both ventricles contract together a short time later.

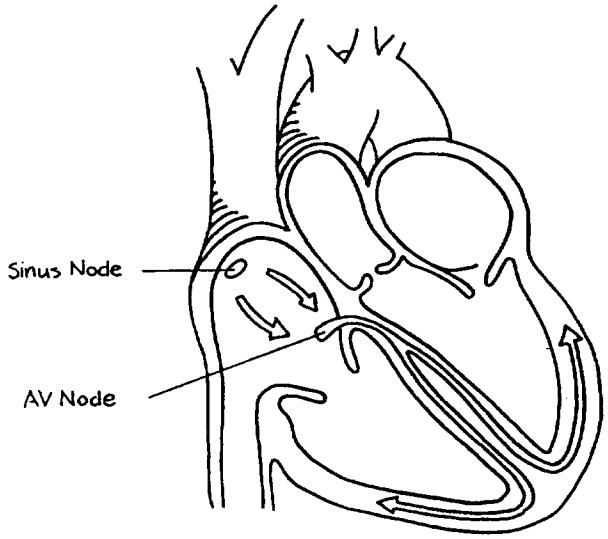
The Wiring

Your home also has an electrical system. So does your heart. The heart depends on its electrical system to stimulate it to contract properly. This system directs electrical impulses through the heart in an organized fashion. Each part of the heart contracts when an impulse reaches it, and each normal heartbeat starts at the sinus node, or SA node (see Figure 2).

The sinus node is a group of special heart cells located in the right atrium. Normally the sinus node generates an electrical impulse at the proper time for each heartbeat. Therefore, the sinus node is the heart's "natural pacemaker" as it controls the normal heart rate.

From the sinus node the electrical impulse travels throughout the atria, causing them to contract and squeeze blood into the ventricles.

- Figure 2 -



From the atria, the electrical impulse travels to the atrioventricular node (or AV node), which is located between the atria and the ventricles. The AV node provides the only normal path for the impulse to travel from the atria to the ventricles. This is because there is a layer of tissue between the atria and ventricles that does not conduct electrical impulses. The AV node sends the impulse to the ventricles at the proper time. This impulse stimulates the ventricles to contract and pump blood efficiently to the body.

WHAT HAPPENS WHEN THERE IS SOMETHING WRONG WITH THE WIRING?

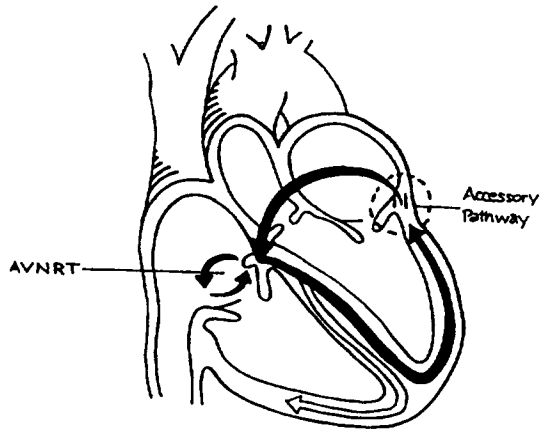
If the wiring in your house were installed incorrectly it would not function properly. It might even be dangerous. The same is true if there is a problem with the wiring in your heart. Abnormal heart wiring can cause abnormal heart rhythms, or arrhythmia. This usually results in a change in the rate at which the heartbeats.

An arrhythmia may first be noticed as a skipping or fluttering sensation in the chest (palpitation) or it may cause light-headedness, fainting, chest pain, or shortness of breath. Occasionally, arrhythmias may go unnoticed and are only detected by an electrocardiogram (ECG).

Some arrhythmias are merely an annoyance. However, others can be serious and can result in heartbeats that are too fast or too slow to pump blood effectively to the body.

A common type of arrhythmia is called supraventricular tachycardia, or SVT. In this type of arrhythmia the atria beat too fast, often causing the ventricles to also beat too quickly. Three common types or causes of SVT are described in the following pages.

- *Figure 3* -



Wolff-Parkinson-White (WPW) Syndrome

Wolff-Parkinson-White Syndrome is a common cause of SVT. In WPW there is extra tissue connecting the atria and ventricles. This extra tissue is a "short circuit" between these chambers. It provides an extra pathway for electrical impulses to be conducted through the tissue which normally blocks electrical impulses between the atria and ventricles. This short circuit is called an **accessory pathway**, and it allows electrical impulses to travel between the atria and the ventricles without going through the AV node.

In WPW an SVT is usually started when an impulse travels down the AV node to the ventricles, and then up through the "short circuit" tissue to the atria. This impulse can then travel through the atria and down the AV node before the sinus node can start the next heartbeat. If the impulse continues to travel in this repeating, circular pattern, it can cause the heart to beat very rapidly.

AV Nodal Reentrant Tachycardia (AVNRT)

AVNRT is another common form of SVT. In AVNRT there is an extra electrical pathway in or near the AV node. If an electrical impulse is conducted in this pathway, it may direct the impulse through both the AV node and the extra pathway in a repeating, circular pattern. This causes the atria and ventricles to contract with each cycle of this circular pattern, resulting in a rapid heartbeat.

Rapid AV Nodal Conduction

In some SVTs the atria may spontaneously generate multiple rapid impulses. Many of these impulses can travel through the AV node to the ventricles in an erratic manner. As a result, the heart rhythm can be irregular and rapid. If this happens, the heart will pump blood inefficiently.

TREATING SVT

There are several ways to treat SVT, including antiarrhythmic medications, surgery, and ablation.

Antiarrhythmic medications
change how your heart's electrical system works. They can help prevent abnormal heartbeats from starting or being sustained.

Heart surgery
is rarely performed for the treatment of SVT. During such an operation, surgeons either cut or remove extra electrical pathways causing the arrhythmia.

Catheter ablation
is another procedure in which the extra electrical pathway(s) causing your arrhythmia is disrupted or destroyed.

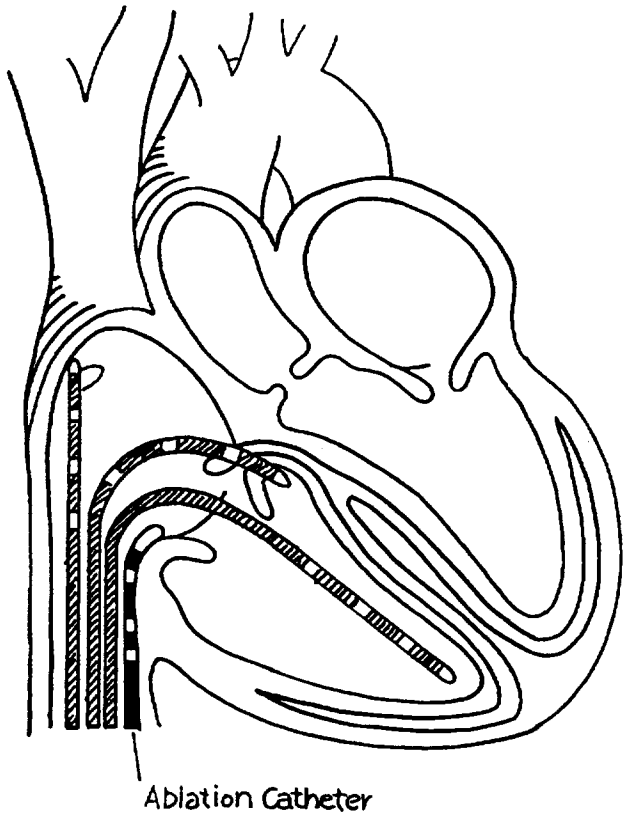
Which Procedure Is "Best"?

You and your doctor should decide which is the best treatment for your particular arrhythmia, after discussing the risks and benefits of each.

HOW DOES CATHETER ABLATION WORK?

During catheter ablation, doctors insert several special long, flexible tubes with wires called electrode catheters into the heart (see Figure 4). Some of these can be used to study your arrhythmia. However, one of these catheters will be used for the actual ablation. One catheter your doctor may select for this ablation treatment is called the Livewire TC™ ablation catheter and is made by Daig Corporation, Minnetonka, Minnesota. Your physician will position the ablation catheter so that it lies on or very close to the abnormal tissue. High-frequency electrical energy is then delivered through the ablation catheter to this tissue. The small area of heart tissue under the tip of the ablation catheter is heated by this high-frequency energy, destroying the tissue. As a result, this tissue is no longer capable of conducting or sustaining the SVT.

239 ***- Figure 4 -***



240 **WHAT CAN I EXPECT DURING THE PROCEDURE?**

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Catheter ablation is done in a specially equipped room, called an Electrophysiology Laboratory (EP Lab). Sometimes these procedures are performed in a Cardiac Catheterization Laboratory (Cath Lab).

Normally you'll be taken to the EP Lab on a movable bed, then shifted onto a x-ray table. This special table is moveable and has a large x-ray camera over it. There is other equipment in an EP Lab, including viewing screens, heart monitors, emergency equipment, etc. Once on the x-ray table several types of monitoring equipment will be connected to you. You will then be covered with a sterile drape.

There are usually several EP Lab staff present during the procedure, including one or more electrophysiologists (a cardiologist with special training), nurses, and technicians.

A nurse will shave and cleanse the area where the catheters will be inserted. In most cases this will be the groin or neck area. To numb the area, a local anesthetic is injected into the skin with a tiny needle.

A small intravenous needle ("IV line") will be inserted into a vein in your arm. This allows drugs to be injected directly into the vein, if necessary.

Many times you will be awake during the procedure, although medication is often given to help you relax and be comfortable. However, you may fall asleep during the procedure. The staff will be monitoring you constantly.

A small incision is made in the numbed skin, again usually in the groin or neck area. A needle is used to puncture the blood vessel (usually a vein, but sometimes an artery) into which an ablation and /or electrode catheter will be inserted.

One or more electrode catheters are inserted into your blood vessels and advanced toward your heart, while the staff follows the catheter(s) progress on a x-ray viewing screen.

These electrode catheters can be used to sense electrical activity in various areas of your heart and measure how fast these impulses travel. The electrode catheters can also be used to deliver tiny electrical impulses to stimulate your heart to contract - you should not feel these impulses. By doing so, doctors often attempt to start (or induce) your SVT so they can understand and decide how best to treat it. If you feel the same symptoms you experienced when the arrhythmia

occurred previously, you should let the EP Lab staff know.

Often these induced arrhythmias will stop by themselves. However, if an arrhythmia persists or is very rapid, it may make you faint for a moment. If such an arrhythmia happens, your doctor may decide to deliver an electric shock to your heart in order to stop the abnormal heart rhythm. If you were not in an EP Lab, these arrhythmias could be very dangerous, perhaps even life-threatening. However, well-trained personnel in the EP Lab have the equipment and medications necessary to respond to these arrhythmias.

The catheter ablation procedure is usually not painful. However, you may feel some pressure at the site(s) where the catheters are inserted. It is also not unusual to experience some mild chest discomfort during the application of the high-frequency energy during the ablation.

Most catheter ablation procedures are completed within two hours. However, a complete procedure can last up to six hours or more. It is therefore possible that you may feel tired and uncomfortable after lying still for such a lengthy period of time.

WHAT CAN I EXPECT AFTER THE PROCEDURE?

All the catheters will be removed at the conclusion of the procedure. Firm pressure will be applied at the catheter insertion sites for several minutes in order to prevent bleeding. In some cases a few stitches will be used to close the skin at these locations. A bandage dressing will also be applied.

Much of the monitoring equipment will be disconnected from you. However, sometimes some of this equipment will remain connected until you have been transported to a recovery area or your hospital room. The IV line in your arm is often left in place.

Once in the recovery area or your room you will be required to lie flat and still for several hours. You should avoid lifting and bending your leg(s) where the catheters were inserted. This will provide the punctured blood vessels an opportunity to close more completely.

Typically a nurse will follow your progress for several hours by checking your pulse, blood pressure, and the catheter insertion sites. If you notice bleeding or feel pain at these insertion sites, or if you feel your heart beating rapidly, you should immediately notify the nurse.

Sometimes you will be allowed to go home the same day as the procedure. However, you may be required to stay in the hospital overnight. Your heart may be monitored with an ECG until you go home. You should make arrangements for someone to take you home from the hospital.

After you return home you should limit your activity for several days. All vigorous physical exertion and strain (such as lifting heavy objects) should be avoided. In addition, you should carefully follow your doctor's instructions regarding which medications to take.

You should leave the bandage dressing in place until the next day, or as instructed by your doctor or nurse. They will also tell you how long you should wait after returning home before bathing.

It is not unusual for there to be a bruise or small lump where the catheters were inserted. This will usually disappear in a week or two. However, it is unusual for this site(s) to become warm to the touch, tender, painful, or for any swelling to increase after you return home. It would also be unusual for you to develop a fever, or experience a recurrence of your rapid heart rhythm, chest pain, dizziness, or shortness of breath. If any of these occur you should contact your doctor immediately.

WHAT ARE THE RISKS?

Ablation is a procedure that requires the insertion of catheters *into* the body. It therefore does involve some risk.

Some patients can have bleeding, swelling, or bruising where the catheters were inserted. Serious complications do sometimes occur. These include infection, damage to your heart and/or blood vessels, and blood clots. Deaths are very rare during these procedures.

It is also possible that the heart's normal electrical system could be damaged during this procedure. If this occurs, an artificial pacemaker implant may be necessary.

Most patients who undergo catheter ablation do not experience complications. However, you should be aware of the risks. If you should have any questions about the potential risks, you should ask your doctor.

WHAT ARE THE POTENTIAL BENEFITS?

Catheter ablation may permanently cure your arrhythmia and may allow you to avoid taking medications while resuming a normal lifestyle.

GLOSSARY

Arrhythmia – abnormal heart rhythm.

Accessory pathway – an abnormal, extra electrical pathway between the upper and lower chambers of the heart.

Artificial pacemaker - a device often implanted in the body that delivers regular electrical impulses to the heart when the heart's normal electrical system fails.

Atrium - (pl: atria) upper chamber of the heart. There is one on the right side of the heart and one on the left side. These chambers receive blood from the rest of the body.

AV node – group of specialized cells that lies between the atria and the ventricles. The heart's electrical impulse normally passes through these cells on its way to the ventricles.

AV nodal reentrant tachycardia (AVNRT) – very rapid heart rate that is caused by an abnormal pathway close to the AV node.

Catheter ablation - non-surgical technique that disrupts (destroys) parts of the abnormal electrical pathway that is causing an arrhythmia.

Electrocardiogram – test that records the electrical activity of the heart. Often called an ECG or EKG.

Electrophysiology study – heart rhythm study. Often called an EP study.

Sinus node - group of specialized cells in the right atrium. Normally these cells act as the heart's "natural pacemaker", setting the pace for the heartbeat.

Supraventricular tachycardia (SVT) – very rapid heart rate that begins in the heart's upper chambers.

Tachycardia – rapid heart rate.

Ventricle - lower chamber of the heart. There is one on the right side of the heart and one on the left side. These chambers pump blood out of the heart.

Wolff-Parkinson-White (WPW) syndrome – a condition in which a very rapid heart rate is caused by an abnormal extra pathway between the upper and lower chambers of the heart.