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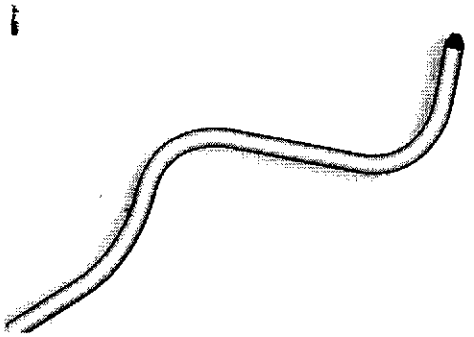

AESCULA™ LV
Model 1055K

Unipolar, Silicone, Titanium Nitride Left Heart Lead

USER'S MANUAL

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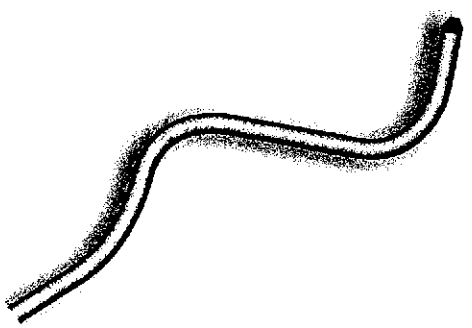

AESCULA™ LV
Model 1055K

Unipolar, Silicone, Titanium Nitride Left Heart Lead

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

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DESCRIPTION

The Aescula™ LV Model 1055K lead is a silicone-insulated left heart lead with a Titanium Nitride (TiN) coated platinum-iridium electrode, designed for use with implantable pulse generators for long-term cardiac pacing. The distal portion of the tip is preshaped by the silicone insulation into an "s-curve" to provide passive fixation.

The lead length is 75 centimeters, and the minimum recommended lead introducer size is 7.0 French. The lead complies with IS-1 connector standard ISO 5841-3.

The Aescula LV Model 1055K lead is a unipolar lead, having one conductor that terminates at the tip electrode.

Features of the Aescula LV Model 1055K lead include:

- Passive Fixation – incorporating an s-shaped curve designed to stabilize the lead in the vein.
- Fast-Pass® Coating – creates a lubricious surface.

INDICATIONS AND USAGE

The Aescula™ LV Model 1055K lead has application as part of a St. Jude Medical® biventricular system.

Contraindications

The Aescula™ lead is contraindicated in patients:

- Who are unable to undergo an emergent thoracotomy procedure, and
- With coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

WARNINGS AND PRECAUTIONS

Lead Selection

- Before opening the lead package, confirm that it is compatible with the pulse generator to be implanted.
- *Ventricular leads with polished platinum tip electrodes.* Pairing the Model 1055K ventricular lead with a polished platinum tip electrode lead may create a source impedance mismatch that could adversely affect sensing. Therefore, in the use of these leads, evaluate adequate sensing performance at the time of implant.

Storage and Handling

- For single use only.
- Do not sterilize the lead using an autoclave, gamma radiation, or ultrasonics; if sterilization is required, see page 8.
- Do not stretch, crush, kink or bend the lead. Leads may be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- Do not bring the lead into contact with sharp objects that could puncture or otherwise compromise the insulation.
- Handle the lead only with powderless, sterile surgical gloves.
- Avoid handling the lead with any surgical tools such as hemostats, clamps or forceps.
- Leads have an electrostatic attraction for particulate matter; do not expose them to lint, dust or other such materials.
- Avoid touching or handling the lead tip electrode itself.
- Do not immerse the lead body in mineral oil, silicone oil or any liquid other than sterile saline or injectable fluid.

- Do not immerse the tip electrode in any fluid prior to implantation.

Lead Implantation

- Lead implantation should be performed only when proper emergency facilities for cardioversion and/or defibrillation are available.
- The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.
- During this procedure it is advisable to also have echocardiographic equipment available.
- If subclavian venipuncture is used for lead introduction, it is important to insert the lead as lateral as possible during entry of the lead into the vein.
- Do not slide the suture sleeve over the connector pin sealing rings. This could result in damage to the lead.
- Failure to use the suture sleeve to secure the lead may result in lead dislodgment or in damage to the lead's insulation and/or conductor coil.

Potential Adverse Events

Potential adverse events associated with the use of transvenous leads include:

- Body rejection phenomena
- Cardiac/coronary sinus dissection
- Cardiac/coronary sinus perforation
- Cardiac tamponade
- Coronary sinus or cardiac vein thrombosis
- Death
- Endocarditis
- Excessive bleeding
- Hematoma/seroma
- Induced atrial or ventricular arrhythmias
- Infection
- Lead dislodgement
- Local tissue reaction; formation of fibrotic tissue
- Loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead
- Myocardial irritability
- Myopotential sensing
- Pectoral/diaphragmatic/phrenic nerve stimulation
- Pericardial effusion
- Pericardial rub
- Pneumothorax/hemothorax
- Pulmonary edema
- Rise in threshold and exit block
- Thrombolytic or air embolism
- Valve damage.

Performance of a coronary sinus venogram is unique to lead placement in the cardiac venous system, and carries risks.

Potential complications reported with direct subclavian venipuncture include hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage, and rarely death.

Clinical Study

A prospective, randomized, controlled, multi-center clinical trial conducted at 49 participating sites (44 in the US, 5 in Canada) compared the safety and effectiveness results for patients receiving the Frontier Model 5508 pulse generator and the Aescula 1055K Left Heart Lead to those receiving legally marketed right ventricular pulse generators and standard leads fol-

lowing an AV node ablation for chronic atrial fibrillation. Chronic AF is defined as persisting without interruption for at least one month. The study's cumulative implant duration was 4,684 months with a mean of 13.0 ± 9.6 months (range of 0.1 to 35.7 months). Two hundred and six (206) patients underwent successful LV lead placement. The cumulative duration in BV, LV and Roll-in groups was 3,129 months.

For this randomized study, the key inclusion criteria were:

- Patients who underwent complete AV node ablation for chronic atrial fibrillation (defined as persisting without interruption for at least one month) resulting in complete AV block,
- Patients who were on a stable medical therapy regimen, and
- Patients who were able to complete the six-minute walk with the only limiting factor(s) being fatigue and/or shortness of breath.

Key study exclusion criteria were:

- Patients who were classified as NYHA Class IV,
- Patients who could walk more than 450 meters in a six-minute walk test,
- Patients who had an implanted ICD or were considered for implant of an ICD,
- Patients with prosthetic valve replacements,
- Patients with severe musculoskeletal disorder(s), and
- Patients who could not independently comprehend and complete the quality of life questionnaire.

The overall study population included 361 patients. One hundred and forty-six (146) were randomized to BV and 106 were randomized to RV. In addition, 53 were randomized to LV pacing under a previous revision of the investigational plan. Fifty-six (56) were "roll-in" patients (non-randomized) and received the biventricular pacing system (Frontier pulse generator and Aescula lead system). All patients underwent implantation of a permanent pacemaker following an elective AV node ablation for chronic atrial fibrillation. The mean age was 69.23 ± 9.98 years and the population was 34.3% female and 65.7% male. Fifteen percent (15%) of the patients had no heart failure symptoms or were NYHA Class I, 48% were NYHA Class II, and 37% were NYHA Class III prior to implant. Safety data from all patients who underwent an attempted implant were reported.

Study Results

There were three primary safety objectives related to the Aescula Model 1055K Left Heart Lead. The results are outlined below.

Primary Objectives

1. Freedom from Aescula lead-related complications through six months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from Aescula lead related complication for the BV group through six months will not be less than 75%.

Results: There were 25 Aescula lead related complications in 24 patients through 6-months follow-up. The freedom from Aescula lead related complications was 88.2% with a lower bound of 84.4%. Table 1 outlines the Aescula lead related complications during the trial and all implant dissection and perforation events. A complication is an adverse event that was resolved invasively or resulted in the termination of the procedure, while an observation is an adverse event that was resolved without invasive procedures.

Event	BV, LV, and Roll-In (N = 254)*			
	# of Events	# of Patients	% of Patients	Events/ Device-Months†
LV Lead Related	**25**	**24‡**	**9.4**	**0.0080**
Acute LV Lead Dislodgement	9	9	3.5	0.0029
Diaphragmatic Stimulation	6	6	2.4	0.0019
High LV Pacing Threshold at Implant, Later System Revised	6	6	2.4	0.0019
LV Lead Loss of Capture	3	3	1.2	0.0010
Pectoral Stimulation	1	1	0.4	0.0003
Implant Dissection and Perforation Complications	**11**	**10‡**	**3.9**	**0.0035**
CS Dissection at Implant	7	6	2.4	0.0022
CS Perforation at Implant	3	3	1.2	0.0010
Cardiac Tamponade at Implant	1	1	0.4	0.0003

Table 1. Aescula lead-related complications and implant dissection and perforation events

* Aescula lead-related complications based on total number of procedures (N = 254).

† Events per Device-Month calculated as number of events divided by the total device cumulative duration in months in BV, LV, and Roll-in group. The cumulative duration in months in these groups was 3,129 months.

‡ One patient may have more than one event.

Note: Three additional events of CS Dissection at Implant in three patients were classified as observations.

2. Rate of successful implantation of the Aescula lead

Objective: The lower bound of the one-sided 95% confidence interval of the successful implantation rate of the Aescula lead for the BV group will not be less than 80%.

Results: One hundred and forty-six (146) patients randomized to BV underwent attempted implants. One hundred and twenty-five (125) were successfully implanted. The rate of successful implant of the Aescula lead was 86% with a lower bound of 81%.

3. Aescula lead pacing threshold at 6-months

Objective: The upper bound of the one-sided 95% confidence interval of the mean capture threshold will not be greater than 3.0 V for the BV group at 6-months

Results: The pacing threshold at 6-months for the BV group was 2.27 V ± 1.66 V with an upper bound of 2.53 V.

Conformance to Standards

The lead complies with IS-1 connector standard ISO 5841-3.

How Supplied

The Model 1055K Lead is packaged one per package in a sterile package. Each package contains:

- One passive-fixation pacing lead with suture sleeve attached
- One vein lifter
- One funnel
- Six (6) 0.014" stainless steel stylets with colors designating the degree of firmness:

A Patient's Guide to Understanding Cardiac Biventricular Devices

ST. JUDE MEDICAL

A Patient's Guide to Understanding Cardiac Biventricular Devices

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Your Contact and Device Information

Have your doctor or nurse complete the information on this page before you go home from the hospital.

Physician Name_____

Phone Number_____

Address_____

_____

Hospital Name_____

Phone Number_____

Address_____

_____

Device Model Number_____

Serial Number_____

Date Implanted_____

Understanding Your Device

You have just received—or you're about to receive—a remarkable little device that can improve your quality of your life and may even save your life. It's called a "pulse generator," but it's also known as a "biventricular device" or a "cardiac pacemaker." It helps to keep your heart pumping regularly and on time.

Invented in the 1950s, these amazing devices—about the size of a silver dollar—send small pulses of electricity to the heart to help it beat normally. The devices are run by tiny computer chips and sophisticated software. They are powered by batteries that last for years.

This booklet will answer many of your questions about your pulse generator. It will also tell you how the surgery is done and how to prepare for it. You'll also find out what happens after the operation, and how to avoid problems when you're living with your device.

A cardiac biventricular device is different from a standard pacemaker because its two leads are implanted into both the right and left ventricles. This means that the device can be used to stimulate both lower heart

chambers to support the pumping of blood from the heart.

After reading this booklet, if you still have questions, discuss them with your doctor.

If you come across a word you do not understand, you can find its definition in the Glossary on page 33.

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The Healthy Heart

Why is the heart sometimes called a pump?

Your heart's job is to deliver oxygen and nutrients to all the organs and tissues of your body. Your heart does this by pumping blood from the lungs (where it picks up oxygen) to all the areas in your body (where it drops the oxygen off). The heart then pumps blood back to your lungs, completing the loop that keeps you alive day and night year after year.

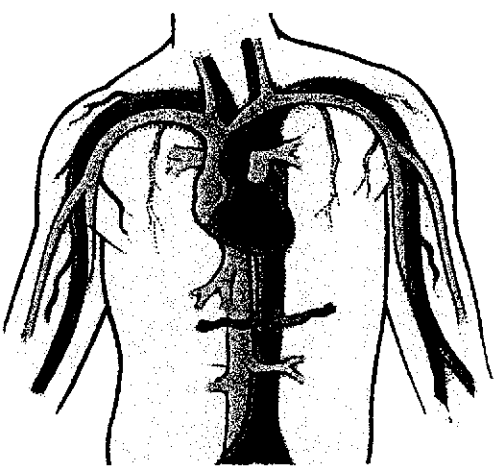

Figure 1. Blood flow through the heart.

What does the heart look like?

Your heart is divided into four connected *chambers*, each with a part to play in pumping blood. Oxygen-poor blood from the body enters the heart at the *right atrium.*

When the atrium is full, it pumps the blood into the chamber below it, the *right ventricle*. This larger chamber squeezes the blood out of the heart and into a blood vessel called the *pulmonary artery* that takes the blood to the lungs.

After picking up oxygen, the blood returns to the heart through the *pulmonary veins* into the *left atrium.* When the left atrium is full, it pumps the blood into the large chamber below it. The *left ventricle* then uses its strong muscles to pump blood into the body.

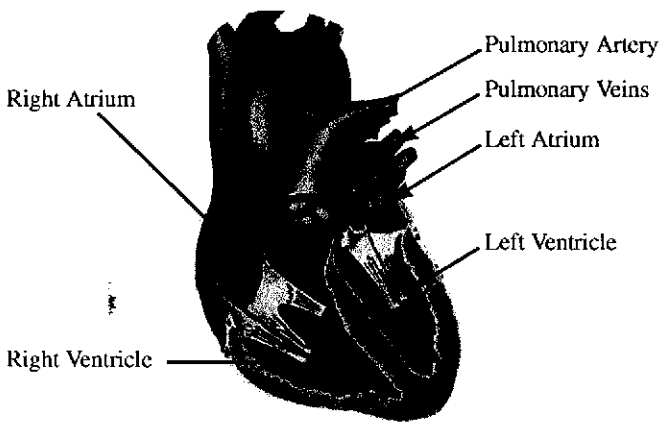

Figure 2. A typical heart.

How does the heart beat?

The millions of cells in your heart react to small *pulses* of electricity. Your heart makes its own electrical pulses in a special area at the upper part of the heart called the *Sinoatrial Node* or *SA Node (see below).*

How often does the heart beat?

A normal heart beats 60 to 100 times each minute, regularly and in *rhythm*, so the time between each heartbeat is roughly the same. Depending on the body's need for oxygen, the heart can beat faster or slower. Your body tells your heart how much oxygen it needs.

What is the Sinoatrial (SA) Node?

The SA Node is a cluster of specialized cells in the atrium that produces tiny electrical signals and sends them to the rest of the heart.

The SA Node senses when the atrium fills with blood and sends out an electrical pulse that causes the muscles in the atrium to contract. This *contraction* pushes the blood in the atrium down into the ventricle.

What is the AV Node?

The *AV Node* or *Atrioventricular Node* is another specialized cell cluster, located between the atrium and the ventricle. It holds the pulse for just a few hundredths of a second before releasing it into the ventricle. The result is that the atrium beats first, pushing blood into the ventricle, and then the ventricle beats after it has been filled with the blood from the atrium.

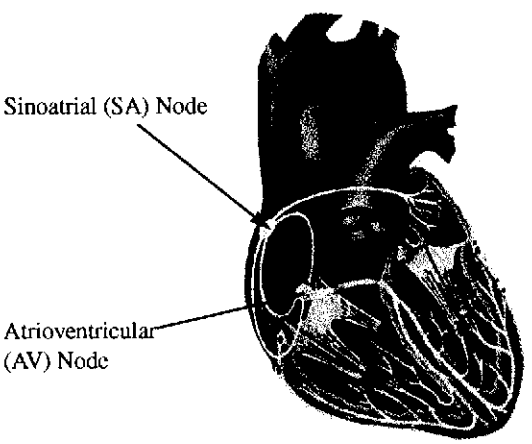

Figure 3. The Sinoatrial (SA) Node and Atrioventricular (AV) Node.

Arrhythmias

What is an arrhythmia?

An *arrhythmia* (pronounced "a-RITH-me-a") is any abnormal heart rhythm. It could be irregular, too fast, or too slow.

What are the different kinds of arrhythmia?

Too Slow—Bradycardia

Bradycardia means "slow heart." A heart that beats too slowly all the time can make a person tired, dizzy, or light-headed because a slow heart is not pumping enough blood to provide the body with as much oxygen as it needs. A *pulse generator* can be used to make a person's heart beat normally.

Too Fast—Tachycardia

Tachycardia means "fast heart." If the heart beats too fast all the time, its chambers may not fill completely with blood. The heart will not be able to pump enough oxygen to the body and the result will be dizziness, fainting, and even cardiac arrest. Some tachycardias occur in the top chambers of the heart and some occur in the lower portion.

Ventricular Fibrillation

This is the most serious kind of arrhythmia, where the heart's electrical signals aren't timed correctly and start in the ventricle instead of the SA Node. The result is that the heart "fibrillates" or quivers instead of beating regularly. A fibrillating heart pumps very little blood to the body, and a person in ventricular *fibrillation* quickly loses consciousness. Untreated ventricular fibrillation can be fatal.

To treat ventricular fibrillation, doctors use *de-fibrillation*, which is a large electrical shock to the heart that returns the heart to its normal rhythm. The shock can come from a machine with large paddles, or it can come from an *ICD* (Implantable Cardioverter-Defibrillator) implanted within the body.

Atrial Fibrillation

This is the most common arrhythmia in older people. In atrial fibrillation, the upper chambers of the heart are quivering (or "fibrillating") and the signals sent to the lower chambers are irregular and erratic. Some people may not feel any effects of atrial fibrillation. But in many people, this arrhythmia causes a feeling of pounding or

fluttering in the chest. It may make people feel tired, sluggish, dizzy, or short of breath.

More serious is the fact that atrial fibrillation can cause a blood clot inside the heart that can flow to any part of the body, where it can cause a stroke or embolism.

Doctors can treat atrial fibrillation with a combination of surgery, medications, and defibrillation. Pulse generators can also be used to treat some patients with atrial fibrillation, depending on the cause and type of arrhythmia.

Asynchrony

Besides beating too fast or too slow, the heart can also beat irregularly. For example, one side of the heart may contract sooner than the other side. When this happens, blood and oxygen are not delivered fast enough to the body and the pumping mechanism begins to fail. If blood is not pumped out of the lungs and the body, it backs up, causing congestion like a traffic jam.

This can lead to a serious condition called *congestive heart failure.* This condition is usually treated with drugs, but in some cases, a special kind of pulse generator can be used to help in the treatment.

What causes arrhythmias?

Many conditions and substances affect the heart's rhythm. Diseases like diabetes, hypertension, heart disease, chronic obstructive pulmonary disease, and hyperthyroidism can cause arrhythmias. Alcohol and certain drugs can cause arrhythmias, and so can drug withdrawal. Some people are born with hearts prone to arrhythmias. Some people have their heart's electrical system damaged by a heart attack or poisons. Even emotional swings, caffeine, and pregnancy affect the heart. Finding the cause of an arrhythmia is important because the treatment depends on the cause. Your doctor may order tests and procedures to diagnose the cause of your arrhythmia.

Some Basic Facts About Pulse Generators

What is a pulse generator?

A pulse generator can recognize a problem with your heart's rhythm and send out its own electrical pulse to make your heart beat regularly and on time. (A pulse generator *generates* or makes a pulse.) It is made up of computer chips and a small, but long-lived battery in a sealed case.

The pulse generator is surgically implanted in the upper chest or abdomen. (The operation is described on page 15.) The pulse it generates is sent through special wires called *leads*, normally placed inside the heart. The lead also helps the pulse generator sense the heart's rhythm. This is important because the device must send out its pulse at a precise moment.

What is a cardiac biventricular device?

Some St. Jude Medical pulse generators have three leads: one in the right atrium, one in the right ventricle and one in the left ventricle. These can help the left and right ventricle beat at the same time for those people whose left and right sides may not beat together.

The pulse generators described above can also be *rate-modulated*. That means the pulse generator can speed up when the

patient becomes more active and slow down when the patient is resting. Also known as "rate-responsive" or "rate-adaptive," this type of pulse generator has a sensor so it knows when the patient is moving. For example, a rate-modulated pulse generator will speed up when a person jogs. When the person stops to rest, the pulse generator slows the heart rate.

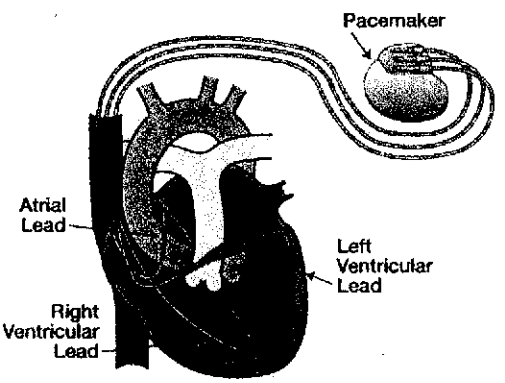

Figure 4. A pulse generator system.

Why do I need a pulse generator?

If you have a slow or abnormal heart rate that causes fainting, dizziness, tiredness, shortness of breath, palpitations, or loss of consciousness, you may need a pulse generator. In many cases, a pulse generator can help your heart beat properly.

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How does the pulse generator know when to pulse?

The pulse generator can sense the heart's rhythm. Pulse generators can be "programmed" to either send out a pulse or to wait for the heart to beat on its own. Some pulse generators also sense the patient's activity — for example, climbing stairs or exercising — so that it can speed up or slow down the heart rate.

After a pulse generator is inside the body, its settings can still be changed. Doctors and clinicians "talk" to it with a *programmer.* This is a computer with a wand that sends signals through the body to the pulse generator. The procedure is painless. The programmer also displays information the pulse generator has collected about the heart.

What does a pulse feel like?	Most people can't feel it at all. The electrical pulse of a pulse generator is very small. If you do feel a pulse, your doctor or clinician may change the settings to make you more comfortable.
What happens when the battery runs down?	A pulse generator normally lasts from five to ten years. How long it lasts depends on the type of battery, how often it sends a pulse, the patient's medical condition, and other factors. The battery does not suddenly stop working. It gradually runs down over a period of months, usually with more than enough time to schedule a replacement. Doctors and clinicians check the battery at each follow-up visit. When the battery energy gets low, the pulse generator has to be replaced with a new one, and you must have another operation.
What happens if your lead needs to be replaced?	If your lead needs to be replaced, surgery is required to replace it.

Risks and Benefits

Pulse generators are not a cure for heart disease. They don't treat the causes of slow or irregular heartbeats. But because they can keep the heart pumping for years, pulse generators can greatly improve the quality of life for people with arrhythmias.

What are the benefits of having a pulse generator?

A pulse generator improves the ability of the heart to pump regularly and on time. Some people must rely completely on the pulse generator to make the heart beat.

Many patients get relief from symptoms such as light-headedness, dizziness, and fainting. Some people feel they have more energy.

A pulse generator also gives many patients "peace of mind." They feel safer because the pulse generator can keep their hearts beating.

What are the risks of having a pulse generator?

A small number of patients develop complications from the operation to implant the pulse generator and the leads in the body. These can include infection, a reaction to a drug used during surgery, blood loss, or damage to a blood vessel, the heart wall, or other organ. These complications can usually be corrected or cured.

After the surgery, you may feel some discomfort or feel tired, but these feelings only last a short time. Some patients, however, may continue to feel a bit uncomfortable in the area where the pulse generator was implanted.

Modern pulse generators have many safety features. Sometimes, a pulse generator may not act properly because it is being affected by outside sources of electromagnetic energy. (This is discussed on page 25.)

It is also possible for the tip of the lead to shift in the heart so that the pulse is no longer effective. Very rarely, the device may slip out of the "pocket" in the chest. (See the section on surgery below.)

Finally, remember these are man-made devices. It is important to monitor the device regularly with follow-up visits as often as your doctor recommends.

Contact your doctor if:

- You notice you are tired, short of breath or your heart rate is changing.
- Symptoms you had before the pulse generator was implanted seem to return.

Surgery for the Pulse Generator

What will the operation be like?

Surgery to implant a pulse generator is routine. In many cases, the operation takes one to two hours, and patients go home the same day.

However, each patient is unique, and the surgery will differ from person to person.

The following sections discuss what generally happens to patients during a pulse generator operation. Your doctor will give you details about what will happen during your own surgery.

What happens before the operation?

Before the surgery, your doctor will tell you how to prepare for the operation. You may have to stop taking one or more of your medications beforehand. Usually, patients are asked not to drink or eat for several hours before the operation. A technician may take a blood sample. Some doctors will also ask patients to complete insurance and other forms.

What happens on the day of the operation?

You will be taken to an operating room where a nurse or clinician will shave and wash your upper chest or abdomen. You may have an IV (*intravenous*) line placed in your arm and a blood pressure cuff around your arm. ECG (*electrocardiogram*) electrodes will be placed on various parts of your body.

Most patients stay awake for the procedure, and receive a shot of a *local anesthetic* to numb the area where the pulse generator will be placed. If you are going to be given *general anesthetic*, an anesthesiologist will give you medications to put you to sleep.

What happens during the surgery?

After the skin of the shoulder or chest is cleaned and numbed with an anesthetic, the doctor makes a cut through the skin about one to two inches long. The doctor then finds a vein and threads the lead directly into the heart, using a fluoroscope to see where it will go. You should not feel the leads in your heart.

The doctor then makes a small "pocket" under the skin. The doctor fits the pulse generator into the pocket and connects it to the leads. The pulse generator is then tested to make sure it is working properly.

You may feel some pressure while the pulse generator and leads are being inserted. If you begin to feel increased discomfort, let the doctor know immediately.

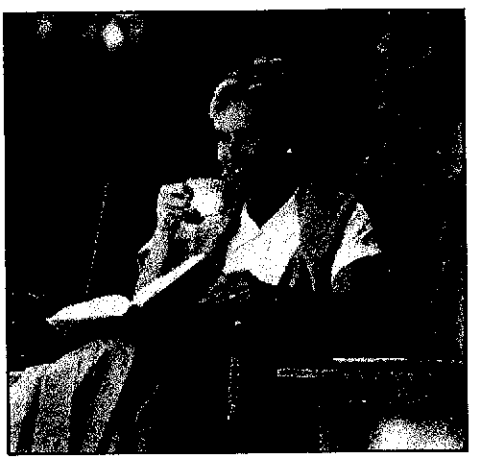
What happens after surgery?

You will be taken to a recovery room where nurses will look after you to make sure you are doing well. You may feel some soreness where the pulse generator was implanted. You will be given pain medication if you need it.

Later on, the doctor or clinician will test your pulse generator to make sure it is working properly.

Many patients go home the same day. Other patients may need longer to recover and will stay overnight before going home.

Coming Home After Surgery



What will happen when I get home from the hospital?

For the first few days or weeks after your operation, you will need to recover. The wound should gradually heal. You should feel better. At first, you may be aware of the pulse generator, but after a while you will not notice it.

Right after the operation, you should:

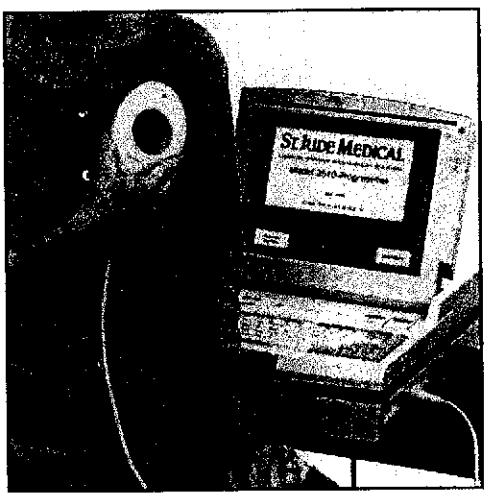
- Keep the wound clean and dry. If you notice that the wound is red, hot, swollen, more painful or starts to drain fluid, call your doctor immediately.

- Follow the instructions about bathing, changing the wound dressing and resuming activities.
- Use only gentle movements with the arm closest to the pulse generator. Avoid stretching, lifting, and sudden, jerky movements. As you heal, gradually increase the use of your arm.
- Do not play with or move the pulse generator under your skin. Try not to hit it or bump into it.
- Keep your doctor appointments.
- Keep your pacemaker identification card with you at all times.
- If your symptoms do not improve, call your doctor. Do not wait for a follow-up visit.

What happens at follow-up visit?

A follow-up visit normally takes place in a doctor's office or in a clinic. The visit is painless. After a brief physical examination, the clinician or doctor usually attaches ECG electrodes to your chest. They will then place the wand over your chest and use the *programmer* (the computer that talks to the pulse generator) to display and print out information about your heart and the pulse generator. With this information, the doctor can check the settings on the pulse generator. If any changes are needed, they can be

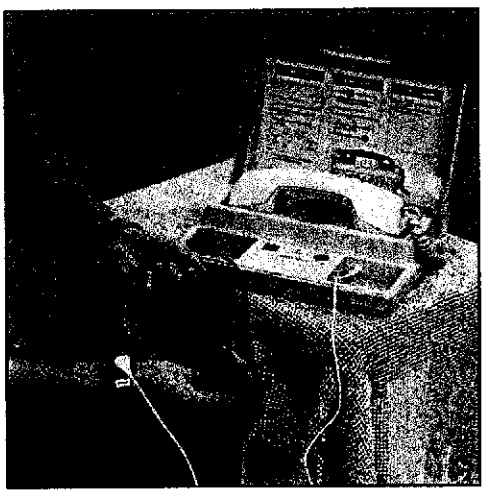
done right away. They will also check your pulse generator's battery.



Be sure to tell your doctor or clinician about any problems you may be having with the pulse generator, your heart or your health in general. It's also a good time to ask questions about your pulse generator.

What is remote monitoring?

Remote monitoring is the use of a telephone or computer to send information to the doctor about your pulse generator. Some doctors ask patients to "phone in" information instead of coming in for a follow-up visit. Many doctors use remote monitoring along with visits to the clinic.



There are a number of different systems for remote monitoring. They are all fairly easy to use. Some are held over the pulse generator and then held over the phone. Some use computers and modems to send in the information. Your doctor will give you instructions on how to use phone monitoring.

When can I get back to my old life?

Each person's recovery period is different, but eventually, you may be able to return to your normal life with very few changes.

Your wound should be completely healed before you return to your usual daily activities. Talk to your doctor about how soon you can return to work, drive your car, begin exercising, or go away on a trip.

Living with Your Pulse Generator

What is a Pulse Generator Identification Card?

This card lets everyone know that you have a pulse generator. It contains information on the type of pulse generator you have and other important information. If you're ever in a medical emergency, this card will give emergency personnel critical data that could save your life. Keep it with you at all times.

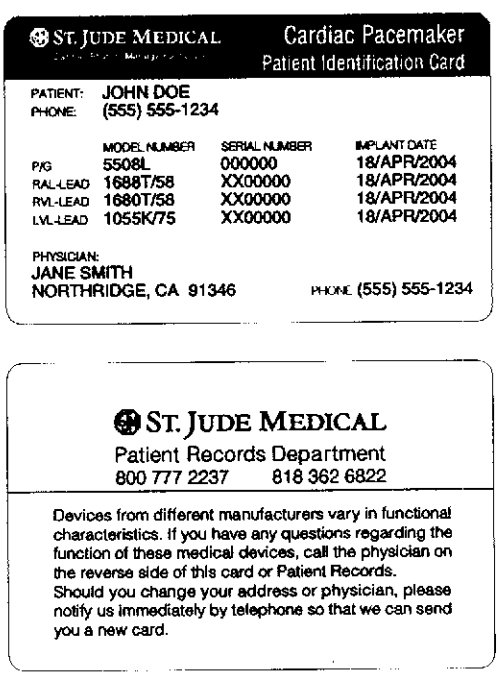


Figure 5. Example of a typical St. Jude Medical Pulse Generator Identification Card.

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Will a pulse generator limit the things I do?

One of the reasons for getting a pulse generator is to help you lead a fuller life. At home, most people will have no restrictions on their activity. If you work with heavy electrical equipment that causes *EMI,* tell your doctor.

Precautions and Warnings

What is EMI?

EMI means *electromagnetic interference.* Certain types of electrical or magnetic energy can interfere with your pulse generator's operation. You should do your best to avoid some major causes of EMI, explained below.

What causes EMI?

EMI or electromagnetic interference can be caused by:

- Electrical appliances in poor condition or not grounded correctly
- Electrical equipment that produces a great deal of energy, like industrial generators

- High-voltage transmission lines and equipment, arc or resistance welders, induction furnaces.
- Communication equipment, such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters.
- Metal detectors and security systems used in stores and airports.
- Magnetic resonance imaging (MRI) scans, which can severely damage your device when you are in or near an MRI room.
- Transcutaneous Electrical Nerve Stimulation (TENS) units, which are electrical nerve and muscle stimulators.
- Therapeutic radiation, such as cancer radiation therapy.
- Electrosurgical cautery, which can inhibit the operation of your device.

What should I do if I am near a source of EMI?

In most cases, you can just walk away from the EMI source or turn it off. At airports, show the security personnel your pulse generator identification card so that you do not have to walk through the metal detector.

If you feel symptoms after being near an EMI source, contact your doctor.

What electrical equipment is safe to use?

Most home appliances in good working order and properly grounded are safe to use. This includes microwave ovens, blenders, toasters, electric knives, televisions, VCRs, electric blankets, stoves and garage door openers.

Office equipment and most medical equipment is also safe to use. The pulse generator will work properly during chest and dental x-rays, diagnostic ultrasound, CT scan, mammography, and fluoroscopy.

What if I am going into a hospital or clinic?

Tell the hospital personnel that you have a pulse generator before you undergo any medical or dental procedure or test.

Do not enter areas that have a "no pacer" symbol posted.

Talk to your doctor if you have to undergo the following medical procedures:

- Electrosurgery
- Electrocautery
- Lithotripsy
- Radiation therapy.

Do not undergo any diathermy procedure, even if your pacemaker has been turned off. It could cause damage to the tissue around the implanted electrodes, or permanent damage to the pulse generator.

External defibrillator paddles should not be placed directly on your device or leads. Carry your identification card at all times so emergency personnel are aware of your device if necessary.

Will a cellular phone interfere with my pulse generator?

You can use a cellular phone without any problems with most St. Jude Medical pulse generators. Contact St. Jude Medical for more information about using a cellular phone.

What about security systems?

Security systems, like the ones used at entrances, exits, or checkout counters are also sources of EMI. When you enter or leave a place with security system, walk through the entrance or exit at a normal pace. Do not linger in these areas.

Are there any precautions I need to take at home?

It is safest to live in a home that has a properly grounded electrical system, so

three-prong plugs fit right into the wall. Poor grounding can cause EMI. An evaluation of wiring by an electrician, particularly in older homes, would identify any improper grounding.

Keep your tools and appliances in good running order. Don't use products with breaks in the power cords. If you're fixing your car, remember that your car's electrical system (alternators, high-tension ignition wires, spark plugs, and coil wires) can be a source of EMI.

Some stereo speakers contain large magnets which can interfere with pulse generators.

Electric razors, vibrators, or handtools held directly over the pulse generator may affect its operation. Some pulse generators respond to pressure, so your doctor may tell you to avoid sleeping on the pulse generator.

Do not manipulate your implanted pulse generator since it may result in lead damage or lead displacement.

What about sports and recreation?

In most cases, your pulse generator will not limit your fun. However, avoid rough contact sports that might damage your pulse generator—like football, soccer or rugby. It's also best to avoid activities that involve severe shaking, like horseback riding or

bumper cars. Depending on the programming of your device, this type of activity may inappropriately cause a temporary increase in the rate of pacing. Strenuous or repetitive upper-body exercise, like weight lifting or softball, can in some cases affect your pulse generator or leads.

Before you begin any vigorous exercise or activity, talk to your doctor.

What precautions should I take at work?

If you work near large sources of EMI (see list above), you should discuss this with your doctor and employer. You may be able to limit your exposure to these sources.

Magnets, large heaters, and radio transmitters can also cause EMI.

Work that involves severe shaking or physical contact should also be avoided.

Other Questions?

If you have any other questions or would like more information about your pulse generator, call Technical Services at the phone numbers below.

In North America:

1-818-362-6822

1-800-722-3774
(toll-free in North America)

1-818-362-7182 (FAX)

Glossary

Anesthetic	A substance that produces numbness or sleep.
Arrhythmia	An abnormal rhythm of the heart.
Atrioventricular (AV) Node	The small mass of special tissue that delays the energy pulse traveling from the SA Node to the lower chambers (ventricles) of the heart.
Atrial	Relating to the atrium.
Atrium	One of the two upper chambers of the heart, the right atrium and the left atrium. These chambers receive blood from the body and pump it to the ventricles, the lower chambers of the heart. (Plural = *Atria*)
Biventricular Pacing Therapy	See "Cardiac Biventricular Pacing."
Bradycardia	An abnormally slow heart rate.
Cardiac Biventricular Pacing	A system comprising a device and leads that enables simultaneous pacing of the left and right ventricles.

Chamber	One of the four areas in the heart that fill with blood before contracting during the heartbeat. The four chambers are: right atrium, left atrium, right ventricle, and left ventricle.
Congestive Heart Failure	The failure of the heart to pump enough blood to the rest of body, resulting in congestion of blood in the lungs and tissues.
Contraction	Heartbeat. A squeezing of the heart muscle that forces blood out of the heart.
Defibrillation	The use of electric shock to correct rapid heartbeats, usually tachycardia or fibrillation. Defibrillators can be paddles on the outside of the chest or small internal electrodes placed directly on the heart.
Dual-Chamber Pulse Generator	A pulse generator with two leads, usually connected to the right atrium and right ventricle.
Electrocardiogram	Often called an EKG or ECG, it is a recording of the electrical activity of the heart.

Electromagnetic Interference	Also known as EMI, this is magnetic or electrical interference from machines or devices which can interrupt the normal operation of a pulse generator.
Electrophysiologist	A doctor who specializes in diseases of the electrical system of the heart.
EMI	See "Electromagnetic Interference."
Fibrillation	An arrhythmia in which the heart quivers rapidly. Atrial fibrillation occurs in the atrium and is usually not life-threatening. Ventricular fibrillation occurs in the ventricles and can be fatal.
General Anesthetic	A medication or group of medications that will make the patient unconscious during surgery.
ICD	Implantable Cardioverter-Defibrillator; an implanted pulse generator used to treat ventricular fibrillation and tachycardia by delivering electrical shocks directly to the heart.
Intravenous (IV)	Inside a vein.
Lead	A special wire connected to the pulse generator and placed inside the heart.

Local Anesthetic	A medication used in surgery that numbs only one area of the body while the patient stays awake.
Node	A cluster or a place where things join, for example, the Sinoatrial Node is where many nerves join.
Pacemaker	Another term for *pulse generator.*
Programmer	A special computer designed to communicate with or "program" an implanted pulse generator.
Pulmonary Artery	A blood vessel that carries blood from the right ventricle to the lungs.
Pulmonary Vein	A blood vessel that carries blood from the lungs to the left atrium.
Pulse	A short burst of electricity.
Pulse Generator	A sealed device containing electronic circuitry and a battery, that is designed to send out electrical pulses and correct problems with the heart's rhythm.
Rate-Modulated	A pulse generator that can sense a person's activity and change the heart rate accordingly.

Remote Monitoring	Using a device or machine to transmit information about your pulse generator over a phone line.
Rhythm	The regular beating of your heart.
Sinoatrial (SA) Node	The small mass of special tissue that generates a heartbeat. It is located in the upper right chamber of the heart.
Tachycardia	An abnormally fast heart rate.
Ventricle	The two lower chambers of the heart. These chambers pump the blood out of the heart into the body.
Ventricular	Relating to the ventricle.

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Notes

Notes

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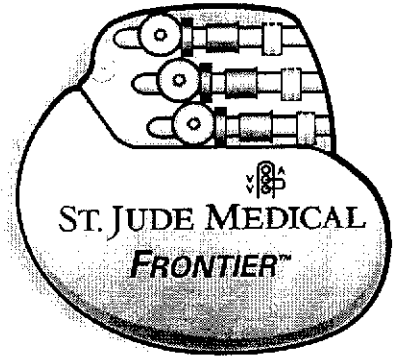

FRONTIER™
Model 5508L

Biventricular Stimulation Device

User's Manual

USER'S MANUAL

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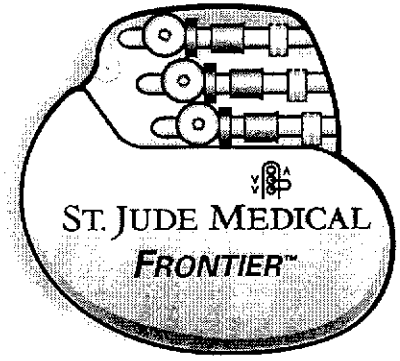

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

FRONTIER™
Model 5508L

Biventricular Stimulation Device

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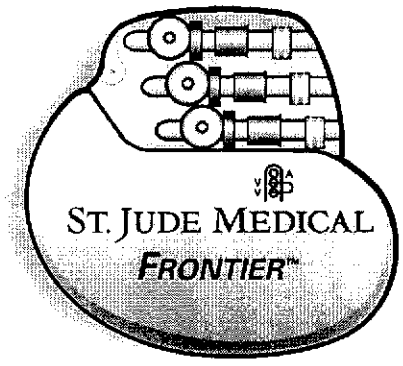

Figure 1. Frontier Model 5508L Cardiac Stimulation Device

DESCRIPTION

The Frontier™ pulse generator is a multi-site, implantable cardiac device with biventricular sensing and stimulation capabilities, intended for use with a St. Jude Medical® left-heart pacing lead.

The Frontier device is equipped with automatic rate-adjusting algorithms, patient safety features, and an extensive offering of diagnostic tools and tests. The Frontier device contains the Omnisense® accelerometer activity sensor to provide rate-modulated operation.

In addition, with the Frontier device, the Model 3510/3500 Programming System offers:

- On-screen Reference Manual
- Floppy disk database interface
- Continuous real-time printing of ECG, EGM, and Markers (only available on the Model 3510 Programmer).

A single setscrew for each lead secures the pin within the connector. The device header accepts unipolar or bipolar IS-1, VS•1, or 3.2 mm leads.

The Frontier device can be programmed with the Model 3510/3500 Programming System with Model 3307 software or higher.

For detailed information on programming, testing, and displaying diagnostic data, refer to the Frontier Ref-

erence Manual or select the HELP button on the Model 3510/3500 Programmer.

Indications and Usage

Implantation of the Frontier™ Biventricular Pacing System is indicated for maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure

Contraindications

Implantation of the Frontier™ Biventricular Pacing System is contraindicated in patients who have been implanted with an implantable cardioverter-defibrillator (ICD)

For specific indications and contraindications associated with individual modes, refer to *Operating Modes* on page 28.

Warnings

To prevent permanent damage to the pulse generator and tissue damage at the electrode/tissue interface:

- ***Electrosurgery.*** Do not use electrosurgical devices in the vicinity of an implanted pulse generator. If electrocautery is necessary, use a bipolar cauterizer or place the indifferent electrode as far from the pulse generator as possible.
- ***Lithotripsy.*** Do not focus a lithotripsy beam within six inches of the pulse generator. Program the device to *Sensor* Off prior to lithotripsy to prevent inappropriate increases in the pacing rate. A thorough assessment of device's function with special attention to the sensor should be performed following exposure to lithotripsy.
- ***Therapeutic Radiation.*** Do not use ionizing radiation in the vicinity of an implanted pulse generator. Radiation therapy may damage the electronic circuitry of the device.
- ***Ultrasound Treatment.*** Do not use therapeutic ultrasound within six inches of the pulse generator.

- ***Ventricular Sensing.*** *Ventricular Sensitivity* should be programmed to the highest setting (lowest sensitivity) that will provide ventricular sensing with adequate sensing margin. Left ventricular lead dislodgement, to a position near the atria, can result in atrial oversensing and ventricular inhibition.

Perform a thorough assessment of the pulse generator's function following exposure to any of the above.

Backup VVI Operation. In rare instances, the Frontier™ device may revert to Backup VVI operation at the programmed settings listed in Table 1. These values are not programmable.

When the device has reverted to Backup VVI operation, the programmer will display a pop-up message indicating that the device is operating at the Backup VVI values. Press [Continue] and follow the on-screen instructions.

Under most conditions, the previously programmed settings can be restored. The programmer will execute a short routine (approximately five minutes) to restore the previously programmed settings. When the routine is complete, a Device Status Report will be generated. This report should be returned to the St. Jude Medical location indicated on the report. Normal follow-up testing should be performed and the restored parameter settings should be reviewed.

Parameter	Value
Mode	VVI
Base Rate	67.5 ppm
Pulse Configuration	Unipolar
Sense Configuration	Unipolar Tip
Pulse Amplitude	4.0 V minimum
Pulse Width	0.6 ms
Refractory Period	320 ms
Sensitivity	2.0 mV

Table 1. Backup VVI Settings

Elective Replacement Indicator (ERI). At ERI, the nominal life of the Frontier device is three months. When the pulse generator exhibits signs of ERI,

described on page 51, it should be replaced expeditiously.

Patient follow-up visits should be scheduled at an appropriate frequency so that ERI can be detected well before End-of-Life (EOL).

PRECAUTIONS

- **For single use only.**

Sterilization

- Do not implant or resterilize a pulse generator that has been contaminated by contact with body fluids.
- Do not resterilize the device more than once.
- Do not implant a device from a damaged package without resterilizing it.
- To sterilize the pulse generator, use ethylene oxide gas at temperatures not exceeding 50° C (122° F), according to the sterilizer manufacturer's instructions. Allow proper aeration per local and national ordinances.[1]
- Do not sterilize the device with an autoclave, steam, gamma radiation, or ultrasonics.
- Resterilization of the Frontier™ device does not change the "use before" date established at the time of manufacture.

Storage and Handling

- ***Mechanical Shock.*** St. Jude Medical® devices are ruggedly constructed. However, if you suspect the device has been damaged, do not implant it; return it to St. Jude Medical.
- ***Temperature.*** Do not subject the device to temperatures above 50° C (122° F) or below –5° C (23° F). Exposure to temperatures below 0° C may cause false ERI indications. Following exposure to extreme temperatures, warm the device to room temperature. If ERI indications are still present, return the device to St. Jude Medical.

1. See also AAMI GVR-1987, *Good Hospital Practice: Ethylene Oxide Gas – Ventilation Recommendations and Safe Use.*

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- *Incineration.* Do not incinerate the device.

Preparation for Implantation

- *Package Label.* Before opening the sterile package, carefully read the label and verify that the package contains the desired device.
- *Verifying Operation.* Before opening the sterile package, verify that the device is operating properly by interrogating it in the package. Remove the magnet and position the Model 3510/3500 Programmer telemetry wand over the package and select "Interrogate." Then, select the "Meas. Data/Diagnostics" tab. The unit's Measured Data should indicate normal voltage and battery status, and the programmed parameters should be identical to the Shipped Settings listed on the package label and in Table 17 on page 54.
- *Package Integrity.* Ensure that the package has not been opened or in any way compromised. If damage is suspected, return it to the manufacturer.
- *"Use Before" Date.* Do not implant the device after the "use before" date printed on the label.

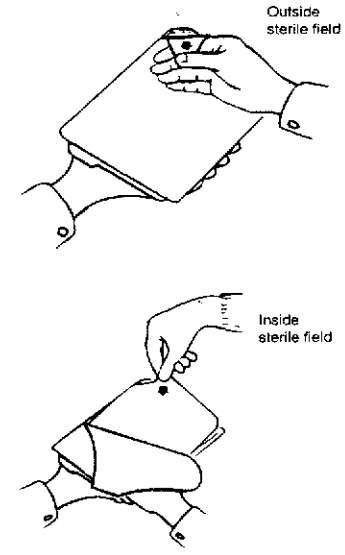

Figure 2. Opening the Sterile Package

- *Opening the Package.* If interrogation of the device in its sterile packaging indicates normal functioning,

remove it from the package. The package's outer tray can be opened in nonsterile surroundings. However, when opening the inner tray, complete sterile technique must be observed (Figure 2).

Pre-Implant Testing

- ***Compatible Leads.*** In the Frontier™ device, use only a St. Jude Medical lead for the left ventricular lead, such as the Aescula™ left heart lead. The device's header accepts unipolar or bipolar IS-1, VS•1, or 3.2 mm leads. Prior to implantation, make sure the leads fit easily and snugly into the pulse generator's header.
- ***Leads Testing with Pacing System Analyzer.*** After implanting the leads, capture and sensing thresholds should be determined with a pacing system analyzer (PSA) before implanting the device. Connect the negative (black) PSA terminal to the portion of the lead terminal pin corresponding to the tip electrode. The positive (red) terminal should be connected to the ring electrode portion of the lead pin for bipolar leads or to an indifferent electrode. For more information on conducting capture and sensing threshold tests, please consult the PSA technical manual.
- ***PSA Adaptor Probes.*** Use only IS-1 PSA cable adaptor probes when testing the pulse generator. Other probes may damage the connector.
- ***Establishing Baseline Ventricular Capture/Sensing Thresholds.*** After the leads have been implanted and before they are connected to the device, separately identify and document the baseline morphology for capture and sensing thresholds for each ventricular lead. Once the baselines are established, determine if the ECG or IEGM recordings can help discriminate biventricular capture, univentricular capture, and native depolarization for each lead. In a biventricular pacing system. the ECG may display two distinct capture loss morphologies, because the left and right chambers often have different pacing thresholds. To ensure that the device is losing capture on both sides of the heart, allow the test to run until a marked change in morphology occurs, indicating capture loss on both sides.
- ***Device Testing with PSA.*** Before implantation of the device, the clinician may wish to test the device

using a compatible PSA with calibrated sensitivity and output settings. When the probe is attached to the pulse generator's connector, the programmed parameters should be identical to the Shipped Settings listed on the package label and in Table 17 on page 54.

Implantation

- ***Ventricular Leads with Polished Platinum Tip Electrodes.*** Pairing the Model 1055K ventricular lead with a polished platinum tip electrode lead may create a source impedance mismatch that could adversely affect sensing. Therefore, in the use of these leads, evaluate adequate sensing performance at the time of implant.
- ***Case Markings.*** Examine the markings on the pulse generator case and verify proper ventricular connection. Ventricular leads can be inserted into either ventricular port.
- ***Setscrew.*** Exercise caution when turning the setscrew, which may be backed out of the connector if turned counter-clockwise for more than two rotations.

Programming

- ***Programmer.*** The Frontier™ cardiac stimulation device can be interrogated and programmed with the Model 3510/3500 Programmer with Model 3307 software or higher version. For a list of programmable parameters and their programmable values, see Table 18 on page 58.
- ***Setting Lead Type.*** When the user interrogates the device for the first time, the programmer will prompt the user to set the *Lead Type*. Because some parameters are determined by the *Lead Type* (for example, *Pulse Configuration)*, the user should set this parameter to Bipolar/Unipolar when the device is implanted. See *Ventricular Lead Selection* on page 43.
- ***Lead Impedance Values.*** Signals to and from the two ventricular leads are joined in the device's connector to form a single ventricular channel. Consequently, lead impedance values displayed on the programmer's Measured Data screen will reflect this dual lead configuration and will likely be less than the value seen in a single lead system.

- *Ventricular Pulse Amplitude* should be set according to the higher capture threshold measurement of the left and right ventricular leads. Typically, capture thresholds are higher in the left ventricle. Ensure that the device is capturing in both left and right ventricles before setting *Ventricular Pulse Amplitude*.
- *Follow-up Capture Threshold Measurements.* Because both ventricular leads are joined in a single ventricular channel, the clinician may be able to determine when capture is occurring in both, one, or no chambers by noting changes in the ECG morphology during a ventricular capture threshold test. See the Frontier Reference Manual for more information.
- *Emergency VVI.* When programming the device to Emergency VVI settings, press the programmer's *Emergency VVI* button only once. Settings for Emergency VVI can be found in the Frontier Reference Manual or by selecting the HELP button on the Model 3510/3500 Programmer.
- *AOO(R), VOO(R), and DOO(R) Modes* are primarily intended for temporary diagnostic use. Long-term use may result in competitive pacing, inducing potentially dangerous arrhythmias.
- *ODO, OVO, and OAO Modes* are not recommended for patients who would be adversely affected by even a short cessation of device function.
- *Noninvasive EP Testing.* Atrial or ventricular tachycardia or fibrillation may occur during noninvasive EP testing. Therefore, (1) closely monitor the patient, and (2) have emergency equipment for cardioversion/defibrillation readily available while conducting EP testing.
- *High-Output Settings.* Programming high-output settings with a high *Base Rate* may shorten the time to ERI.
- *Runaway Protection.* Hardware circuitry in the Frontier device prevents it from stimulating at rates higher than 190 ppm (± 10 ppm).

Environmental and Medical Therapy Hazards

The Frontier™ device is equipped with special shielding and filters that significantly reduce the adverse effects of electromagnetic interference (EMI) on the operation of the device.

Patients should be directed to exercise reasonable caution in avoidance of strong electric or magnetic fields. If the pulse generator inhibits or reverts to asynchronous operation while in the presence of electromagnetic interference (EMI), the patient should move away from the EMI source or turn the source off.

Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the device, including areas protected by a warning notice preventing entry by patients with pulse generators.

Medical Procedures and Environments

In general, patients implanted with the Frontier™ device should not be exposed to hospital equipment that produces high electromagnetic field strength signals, such as diathermy machines and electrosurgical units.

- ***External Defibrillation.*** The electronic circuitry in the pulse generator provides protection from defibrillation discharges. Nevertheless, do not place defibrillator paddles directly over the pulse generator or lead. Following defibrillation, ensure that the pacemaker is operating correctly.
- ***Magnetic Resonance Imaging (MRI).*** Before and after the patient is exposed to MRI, conduct a detailed assessment of the pulse generator. The extremely strong magnetic fields generated during MRI may cause the device to temporarily stimulate in an asynchronous mode (VOO, DOO, or AOO) if *Magnet Response* is set to an option other than Off. If a patient must undergo MRI, before the procedure, program the pulse generator to *Sensor* Off and *Magnet Response* Off.
- ***Ionizing Radiation.*** Therapeutic ionizing radiation (for example, used in linear accelerators and cobalt machines) can permanently damage the device's circuitry. The effect of ionizing radiation is cumulative; the potential for damage to the device is pro-

portional to the patient's total radiation dosage. If the patient must be exposed to ionizing radiation, protect the device during the procedure with local radiation shielding. If tissue near the implant site must be irradiated, it may be necessary to move the device to another area. Before and after exposure to radiation, evaluate the device operation to identify any adverse consequences.

- ***Transcutaneous Electrical Nerve Stimulation (TENS).*** To reduce the possibility of interference with the device function, place the TENS electrodes close to one another and as far from the device as possible. Before allowing unrestricted use of TENS in a home or other setting, screen the patient in a monitored environment for possible interaction.
- ***Therapeutic Diathermy.*** Avoid diathermy, even if the device is programmed off, as it may damage tissue around the implanted electrodes or may permanently damage the pulse generator.
- ***Electrosurgical Cautery*** can induce ventricular arrhythmias and/or fibrillation or may cause asynchronous or inhibited device operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the device and leads as possible. A bipolar cauterizer may minimize these effects. Following electrocautery, conduct a thorough assessment of the device.

Patient Environment

- ***High-Voltage*** transmission lines and equipment, arc or resistance welders, induction furnaces, and similar equipment may generate substantial EMI fields that may interfere with device operation.
- ***Communication Equipment,*** such as microwave transmitters,[2] linear power amplifiers, or high-power amateur transmitters may generate sufficient EMI to interfere with the operation of the pulse generator. Advise patients to move away from this equipment to resume normal pacemaker operation.
- ***Home Appliances*** that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. Elec-

2. Home appliance microwave ovens do not interfere with device operation.

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tric vibrators, razors, and handtools held directly over the pulse generator may disturb its operation.

- ***Twiddler's Syndrome.*** Caution patients against manipulating the implanted pulse generator since it may result in lead damage or lead displacement.
- ***Patient Activities.*** Any activities that involve repetitive impacts or jarring (such as horseback riding, jackhammer use, etc.) may increase the pacing rate when the device's *Sensor* is programmed On. Caution patients against such activity and program *Sensor* parameters with these activities in mind.
- ***Theft Detection Systems.*** Theft detection systems, such as those often located at the entrances and exits of stores and public libraries may disturb the function of the device only if the patient pauses in the path of the beam.

Figure 3. No Pacer Symbol

- ***No Pacer Symbol.*** Caution patients implanted with this device to avoid areas marked with the NO PACER symbol.
- ***Cellular Phones.*** A St. Jude Medical-designed protective filter in the Frontier device prevents cellular phone-generated electromagnetic signals from interfering with the operation of the device.[3]

3. Carrillo R, Williams DB, Traad EA, Schor JS. Electromagnetic filters impeded adverse interference of pacemakers by digital cellular telephones. *JACC* 1996; 27(2A):15A Abstract 901-22.

Type	Description
NADC (TDMA 50)	North American Digital Communications (Time Division Multiple Access 50 Hz)
US (TDMA 11)	Time Division Multiple Access 11 Hz
CDMA	Code Division Multiplex Access
PCS (GSM 1.9 GHz)	Personal Communication Systems (GSM 1.9 GHz)

Table 2. Digital Phones Standards Tested

Clinical tests performed by St. Jude Medical and five independent organizations[4] have documented that devices which incorporate this protective filter are not affected by any known analog cellular phone systems or any of the digital cellular phone technologies listed in Table 2. No special patient precautions are required for patients using analog or digital cellular telephones.

You or your patient may wish to contact Technical Support (page 64) to obtain more information on the interaction of certain cellular phones and this device.

Explantation

- Do not reuse explanted pulse generators and leads.
- Clean explanted equipment with +1% sodium hypochlorite, rinse with water, dry.
- Return the explanted device to the manufacturer.
- Explant the device before cremation of a deceased patient.
- Hex wrenches are available for disconnecting a previously implanted pulse generator from the indwelling leads. To obtain the wrenches, contact your local St. Jude Medical representative.

4. Center for Devices and Radiological Health, FDA, Rockville MD; Medical Devices Bureau of Health, Ottawa, Ontario, Canada; Mount Sinai Medical Center of Greater Miami, Miami Beach FL; Center for Study of Wireless Electromagnetic Compatibility, University of Oklahoma, Norman OK; Qualcomm, Inc., San Diego, CA.

ADVERSE EVENTS

Clinical study of the Frontier™ system began on August 16, 2000. As of August 5, 2003, there were 361 attempted implants in the PAVE (Post-AV Node Ablation Evaluation) study from centers in the United States and Canada with average implant duration of 13.0 months (range: 0.1 - 35.7 months).

Fifty-one deaths occurred throughout the study. Death information was gathered and classified by an independent mortality committee of three practicing physicians according to a published classification scheme. A summary of the death classification is shown in Table 3 on page 14.

Observed Adverse Events

A prospective, randomized, controlled, multi-center clinical trial of patients who had received AV nodal ablation for chronic atrial fibrillation was conducted at 49 participating sites (44 in the US, 5 in Canada). The study compared the safety and effectiveness of biventricular (BV) pacing therapy, using the Frontier™ Model 5508 pulse generator and the Aescula™ 1055K Left Heart Lead (BV treatment group) to traditional right ventricular (RV) pacing therapy (RV control group) using the legally marketed pulse generators and right ventricular leads.

Of a total of 361 attempted implants, 146 patients were randomized to BV pacing, and 106 were randomized to RV pacing. In addition, 53 patients were randomized to left ventricular (LV) pacing under a previous revision of the investigational plan, and 56 were "roll-in" patients (nonrandomized) who received the biventricular pacing system (Frontier pulse generator and Aescula lead system). As per the protocol, their data were only used in the safety endpoint analysis. All of these patients underwent a complete AV nodal ablation procedure. The study's cumulative implant duration for all enrolled patients was 4,684 months with a mean of 13.0 ± 9.6 months (range of 0.1 to 35.7 months). The cumulative duration for investigational patients (BV, LV and Roll-in groups only) was 3,129 months (260.8 years).

Primary Cause	RV (N = 106)	BV (N = 146)	LV (N = 53)	Roll-in (N = 56)	Total (N = 361)
Cardiac: Arrhythmic	1	1	1	0	3
Cardiac: Other	7	3	3	2	15
Cardiac: Unknown	0	1	0	0	1
Non-Cardiac	4	2	5	4	15
Unknown	6	5	3	2	16
Total	18	12	12	8	50*
% Death	17.0	8.2	22.6	14.3	13.8

Table 3. Deaths

* One additional patient was consented, but died prior to any study related procedure.

An adverse event is defined as an unfavorable clinical event, which impacts, or has the potential to impact, the health or safety of a clinical study participant caused by, or associated with, a study device or intervention. An adverse event is classified as a complication when it results in an injury or an invasive intervention (for example, lead repositioning after lead dislodgement) that would not have occurred in the absence of the implanted device and/or system components. An observation is defined as an adverse event that is not associated with injury to the patient or an invasive intervention, but which is associated with the system under investigation, or the programming thereof.

During the entire study period, 170 adverse events were reported including 53 complications and 117 observations. Tables 4 through 6 summarize the complications, and Tables 7 and 8 summarize the observations that occurred during the study. System-related complications and observations are based on patients with investigational systems only (BV, LV, and Roll-in groups, N = 254; RV group, N = 106). Procedure-related complications are based on patients who underwent a study-related procedure, including the AV nodal ablation procedure (BV, LV, Roll-in groups, N = 255; RV group, N = 106).

Events	BV, LV, and Roll-In (N = 254)*			
	# of Events	# of Patients	% of Patients	Events/Device-Months†
LV Lead-Related:	**25**	**24**	**9.4**	**0.0080**
Pectoral Stimulation	1	1	0.4	0.0003
Diaphragmatic Stimulation	6	6	2.4	0.009
Acute LV Lead Dislodgement	9	9	3.5	0.0029
High LV Pacing Threshold at Implant, Later System Revised	6	6	2.4	0.0019
LV Lead Loss of Capture	3	3	1.2	0.0010
RV Lead-Related:	**5**	**4**	**1.6**	**0.0016**
Acute RV Lead Dislodgement	3	2	0.8	0.0010
RV Perforation	1	1	0.4	0.0003
RV Insulation Failure	1	1	0.4	0.0003
Total System-Related	**30**	**27**	**10.6**	**0.0096**

Table 4. System-Related Complications for Investigational Group‡

* System-related complications based on total number of attempted implants (N = 254).

† Events per Device-Month calculated as number of events divided by the total device cumulative duration in months in the BV, LV, and Roll-in groups. The cumulative duration in months in these groups was 3,129 months.

‡ Each patient may have more than one complication in more than one category.

Event	BV, LV, and Roll-In (N = 255)*			
	# of Events	# of Patients	% of Patients	Events/Device-Months†
Procedure-Related:	**17**	**15**	**5.9**	**0.0054**
CS Dissection at Implant	7	7	2.7	0.0022
CS Perforation at Implant	3	3	1.2	0.0010
Pneumothorax at Implant	3	3	1.2	0.0010
Arrhythmia - VT at Implant	1	1	0.4	0.0003
Pulmonary Edema Post-Ablation	1	1	0.4	0.0003
LV Lead Dislodgment During Ablation Procedure	1	1	0.4	0.0003
Cardiac Tamponade at Implant	1	1	0.4	0.0003
Total System-Related and Procedure-Related Complications	**47**	**42**	**16.5**	**0.0150**

Table 5. Procedure-Related Complications for Investigational Group‡

* Procedure-related complications based on total number of procedures (N = 255).

† Events per Device-Month calculated as number of events divided by the total device cumulative duration in months in the BV, LV, and Roll-in groups. The cumulative duration in months in these groups was 3,129 months.

‡ Each patient may have more than one complication in more than one category.

Event	RV (N = 106)			
	# of Events	# of Patients	% of Patients	Events/Device-Months*
Acute RV Lead Dislodgement	1	1	0.9	0.0006
RV Perforation	1	1	0.9	0.0006
RV Lead Fracture	2	2	1.9	0.0013
Infection	1	1	0.9	0.0006
Hematoma	1	1	0.9	0.0006
Total Complications	6	6	5.7	0.0039

Table 6. Complications for Control Group

* Events per Device-Month calculated as number of events divided by the total device cumulative duration in months in the RV group. The cumulative duration for the RV group is 1,555 months.

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Event	BV, LV, and Roll-In (N = 254)*			
	# of Events	# of Patients	% of Patients	Events/Device-Months†
Diaphragmatic Stimulation	22	19	7.5	0.0070
High LV Pacing Threshold	14	14	5.5	0.0045
Pectoral Stimulation	13	11	4.3	0.0042
Hematoma at Implant	8	8	3.1	0.0026
High LV Threshold at Implant	7	7	2.8	0.0022
Fatigue	6	6	2.4	0.0019
Infection	5	5	2.0	0.0016
LV Loss of Capture	4	4	1.6	0.0013
CS Dissection at Implant	3	3	1.2	0.0010
Telemetry Error	3	2	0.8	0.0010
Oversensing	3	3	1.2	0.0010
Thrombosis	2	2	0.8	0.0006
Hypotension	1	1	0.4	0.0003
Palpitation	1	1	0.4	0.0003

Table 7. Observations for Investigational Group† (table footnotes appear on page 20)

Event	BV, LV, and Roll-In (N = 254)*			
	# of Events	# of Patients	% of Patients	Events/Device-Months†
Noise on IEGM	1	1	0.4	0.0003
Arrhythmia - Torsades	1	1	0.4	0.0003
Dyspnea on Exertion	1	1	0.4	0.0003
RV Back-up Pacing Due to PVCs	1	1	0.4	0.0003
Acute LV Lead Dislodgment (minor)	1	1	0.4	0.0003
RV Loss of Capture	1	1	0.4	0.0003
LV Lead Undersensing	1	1	0.4	0.0003
Pneumothorax	1	1	0.4	0.0003
Stuck Stylet	1	1	0.4	0.0003
Syncope	1	1	0.4	0.0003
Total Events	**102**	**74**	**29.1**	**3.2600**

Table 7. Observations for Investigational Group‡ (table footnotes appear on page 20) (continued)

* Observations based on total number of attempted implants (N = 254).

† Events per Device-Month calculated as number of events divided by the total device cumulative duration in months in the BV, LV, and Roll-in groups. The cumulative duration in months in these groups was 3,129 months.

‡ Each patient may have more than one observation in more than one category.

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Event	RV (N = 106)			
	# of Events	# of Patients	% of Patients	Events/Device-Months*
Diaphragmatic Stimulation	1	1	0.9	0.0006
Hematoma at Implant	3	3	2.8	0.0019
Fatigue	1	1	0.9	0.0006
Hypotension	2	2	1.9	0.0013
Palpitation	2	2	1.9	0.0013
Device Site Discomfort	3	3	2.8	0.0019
Bloody Drainage from Incision Site	1	1	0.9	0.0006
High RV Pacing Thresholds	1	1	0.9	0.0006
Presyncope	1	1	0.9	0.0006
Total Observations	**15**	**15**	**14.2**	**0.0096**

Table 8. Observations for Control Group

* Events per Device-Month calculated as number of events divided by the total device cumulative duration in months in the RV group. The cumulative duration for the RV group is 1,555 months.

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Potential Adverse Events

Potential adverse events associated with the use of the transvenous leads and pacing systems include:

- Body rejection phenomena
- Cardiac/coronary sinus dissection
- Cardiac/coronary sinus perforation
- Cardiac tamponade
- Coronary sinus or cardiac vein thrombosis
- Death
- Device migration and pocket erosion
- Endocarditis
- Excessive bleeding
- Hematoma/seroma
- Induced atrial or ventricular arrhythmias
- Infection
- Local tissue reaction; formation of fibrotic tissue
- Loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead
- Myocardial irritability
- Myopotential sensing
- Pectoral/diaphragmatic/phrenic nerve stimulation
- Pericardial effusion
- Pericardial rub
- Pneumothorax/hemothorax
- Pulmonary edema
- Rise in Threshold and Exit Block
- Thrombolytic or air embolism
- Valve damage

The following in addition to the above, are potential complications associated with the use of rate modulated pacing systems.

- Inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity.
- Loss of activity-response due to sensor failure.

Performance of a coronary sinus venogram is unique to lead placement in the cardiac venous system, and carries risks, such as renal failure, cardiac or coronary

sinus dissection, and cardiac or coronary sinus perforation.

Potential complications reported with direct subclavian venipuncture include hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage, and rarely death.

Clinical Study

A prospective, randomized, controlled, multi-center clinical trial conducted at 49 participating sites (44 in the US, 5 in Canada) compared the safety and effectiveness results for patients receiving the Frontier™ Model 5508 pulse generator and the Aescula™ 1055K Left Heart Lead to those receiving legally marketed right ventricular pulse generators and standard leads following an AV nodal ablation for chronic atrial fibrillation. Chronic AF is defined as persisting without interruption for at least one month.

The study's cumulative implant duration for all enrolled patients was 4,684 months with a mean of 13.0 ± 9.6 months (range of 0.1 to 35.7 months). Two hundred and six patients underwent successful LV lead placement. The cumulative duration for all investigational patients (BV, LV and Roll-in groups only) was 3,129 months.

For this randomized study, the key inclusion criteria were:

- Patients who will undergo complete AV nodal ablation for chronic atrial fibrillation (defined as persisting without interruption for at least one month) resulting in complete AV block
- Patients who are on a stable medical therapy regimen, and
- Patients who are able to complete the six-minute walk with the only limiting factor(s) being fatigue and/or shortness of breath.

Key study exclusion criteria were:

- Patients who are classified as NYHA Class IV
- Patients who can walk > 450 meters in six-minute walk test

- Patients who have an implanted ICD or being considered for implant of an ICD
- Patients with prosthetic valve replacements
- Patients with severe musculoskeletal disorder(s). and
- Patients who cannot independently comprehend and complete the quality of life questionnaire.

The overall study population included 361 patients. One hundred and forty-six were randomized to BV, and 106 were randomized to RV. In addition, 53 were randomized to LV pacing under a previous revision of the investigational plan. Fifty-six were "Roll-in" patients (nonrandomized) and received the biventricular pacing system (Frontier pulse generator and Aescula lead system). All patients had permanent pacemaker implant indication following an elective AV nodal ablation for chronic atrial fibrillation. The mean age was 69.2 ± 10.0 years; 34.3% were female and 65.7% were male. Fifteen percent of the patients had no diagnosis of heart failure or were NYHA Class I, 48% were NYHA Class II, and 37% were NYHA Class III prior to implant. Safety data from all patients were reported.

Primary Objectives and Results

1. Freedom from system-related complications through six months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from system-related complications for the BV group will not be less than 70%. A system-related complication was defined as a complication that is caused by a failed pacing system. A pacing system refers to all implanted components, including the pulse generator, leads, and the interaction of these components.

Results: There were 29 system-related complications in 26 patients within six-months follow-up. The freedom from system-related complications is 87.8% with a lower bound of 84.0%. Objective met.

2. Freedom from pulse generator-related complications through six months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from pulse generator-related complications for the BV group through six months will not be less than 90%.

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Results: There were no pulse generator-related complications through six months. The survival rate is 100% with a lower bound of 98.6%. Objective met.

3. Freedom from Aescula™ lead-related complications through six months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from Aescula™ lead-related complication for the BV group through six months will not be less than 75%.

Results: There were 25 Aescula lead-related complications in 24 patients through six months follow-up. The freedom from Aescula lead-related complications is 88.2% with a lower bound of 84.4%. Objective met.

4. Rate of successful implantation of the Aescula™ lead

Objective: The lower bound of the one-sided 95% confidence interval of the successful implantation rate of the Aescula lead for the BV group will not be less than 80%. The success rate was defined as the proportion of patients who received the complete pacing system.

Results: One hundred and forty-six patients randomized to BV underwent attempted implants. One hundred and twenty-five were successfully implanted. The rate of successful implant of the Aescula lead for BV group is 86% with a lower bound of 81%. Objective met.

5. Aescula™ lead pacing threshold at six months

Objective: The upper bound of the one-sided 95% confidence interval of mean capture threshold will not be greater than 3.0 V for the BV group at six months.

Results: The pacing threshold at six months for the BV group is 2.27 V ± 1.66 V with an upper bound of 2.53 V. Objective met.

6. Exercise capacity as measured by distanced walked in six-minute walk test

Objective: To determine if the treatment group (BV) shows a statistically significant improvement over the control group (RV) at the six months follow-up time.

Results: The treatment group (BV) showed statistically significant improvement over the control group (RV) in

distance walked from pre-implant to six months ($p = 0.03$). The BV group also had a greater percentage of patients showing improvements than the RV group ($p = 0.035$). Figure 4 illustrates the improvement in the six-minute walk between BV and RV groups. Table 9 outlines the improvement distribution in the six-minute walk between BV and RV groups.

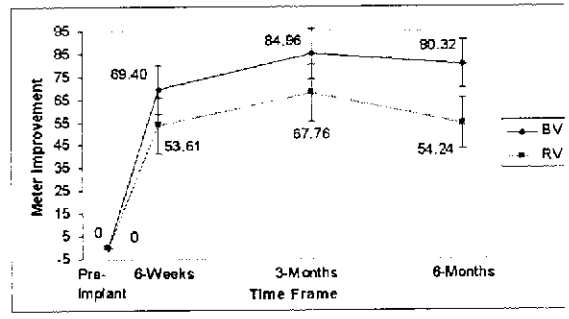

Figure 4. Improvements in Six-Minute Walk Distance in BV and RV Groups ($p = 0.03$)

	RV (N = 66)	BV (N = 84)
Improved (> 5 m)	46 (69.70%)	69 (82.14%)
No Change (-5 to 5 m)	4 (6.06%)	4 (4.76%)
Worsened (< -5 m)	16 (24.24%)	11 (13.10%)

Table 9. Distribution of Improvement in BV and RV Group in Six-Minute Walk ($p = 0.035$)

Secondary Objectives and Results

1. Quality of Life as Measured by SF-36 Score

Objective: To determine if the BV group shows improvement over the RV group at the six-month follow-up in the health-related quality of life as measured by the SF-36 score.

Results: Using the SF-36 Quality-of-Life questionnaire, a standardized measurement of quality of life, the study found that for the six-week to six-month visit time period, the improvement in SF-36 scales was not different between groups.

2. Functional capacity as measured by peak VO_2

Objective: To determine if the BV group shows improvement in functional capacity, as measured by peak VO_2, from the six-week follow-up to the six-month follow-up.

Results: The BV group showed an improvement of 0.86 ml/kg/min in peak VO_2 from six weeks to six months measured during CPX testing ($p = 0.03$). The BV group also had a greater percentage of patients showing improvement in peak VO_2 ($p = 0.02$). Figure 5 illustrates the improvement in peak VO_2 in BV and RV groups. Table 10 outlines the distribution of improvement in peak VO_2 between BV and RV groups.

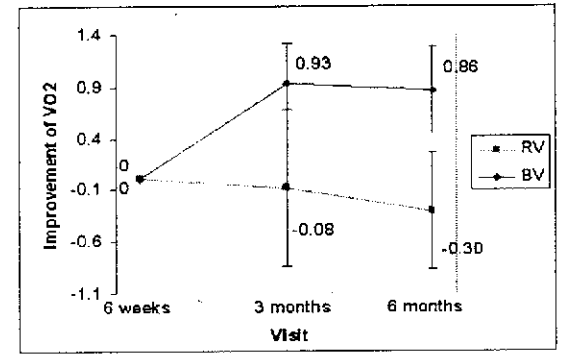

Figure 5. Improvements in Peak VO_2 in BV and RV Groups ($p = 0.03$ Within BV Group)

Change in Peak VO_2 (ml/kg/min)	RV (N = 10)	BV (N = 35)
Improved (> 0.5)	4 (40%)	21 (60.0%)
No Change (-0.5 to 0.5)	0 (0%)	4 (11.4%)
Worsened (< -0.5)	6 (60%)	10 (28.6%)
p-Value Within Group	0.38	0.02

Table 10. Distribution of Improvements in VO_2 in BV and RV groups

Operating Modes

The Frontier™ device is a biventricular stimulation device capable of operating in the following therapy modes. All modes can also be programmed to operate with rate-modulation (R). See *Rate-Modulated Modes* on page 40.

Dual Chamber Modes

DDT

(Dual Chamber Pacing, Sensing, and Triggering)

In this AV-sequential pacing mode, the device generates a pulse at the programmed *Base Rate* either in the absence of intrinsic activity or synchronously with the sensing of a P-wave, R-wave, or both P- and R-waves. The device can also be programmed to adjust its timing according to atrial or ventricular activity and to deliver its pulses solely to the atrium, the ventricles, or to the atrium and ventricles.

When the user programs DDT mode, the programmer displays two additional programmable parameters: *DDT Timing* and *DDT Trigger*.

DDT Timing gives the user the option of using atrial based timing (DDD) or ventricular based timing (DDI).

DDT Trigger gives the user the option of triggering the pulse concurrently with the P-wave, R-wave, or both P- and R-waves, when *DDT Timing* is set to DDD. When *DDT Timing* is set to DDI, the pulse can only be triggered by an R-wave.