The Heart Laser™ CO_2 TMR System
PLC Medical Systems, Inc.

Information for Use

Table of Contents

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The Heart Laser™ CO_2 TMR System
Information for Use

Caution: Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner). Federal law further restricts the use of this device to practitioners who have been trained in laser heart surgery including laser system calibration and operation.

Caution: Use of this device is restricted to patients who have signed a consent form to ensure that the risks associated with TMR have been fully explained and understood.

1. DEVICE DESCRIPTION

The Heart Laser™ CO_2 TMR System (The Heart Laser System) is a 1000 watt, fast axial flow, CO_2 laser, operated in a pulsed-only mode, producing pulses of 10 to 99 milliseconds at 8 to 80 Joules. The energy is delivered directly to the heart through a seven mirror articulated arm terminated with a 125 millimeter focal length hand piece producing an approximately 1 mm diameter hole. The CO_2 laser beam is combined with a helium-neon (visible) laser beam as it exits the laser tube to facilitate aiming.

The Heart Laser System is a pulsed, ECG synchronized 10.6 μm CO_2 laser intended for use in transmyocardial revascularization. The 1000 watt laser is set to deliver a maximum power of 800 watts in pulses 10 to 99 msec long at energies of 8 to 80 joules. Laser energy is delivered to the tissue through an articulated arm terminated with a single use, sterile, handpiece.

The laser housing contains all systems components, including the laser head, cooling system, power supply, and computer. All laser functions are controlled from the computer touch screen. The computer interfaces directly with the system H/P Model 78352C ECG monitor to trigger laser actuation at the peak of the R-wave. Laser pulse and ECG signals are displayed on the touch screen to allow the operator to see the timing of the laser pulse in relation to the R-wave.

The sterile disposable TMR kit contains a straight and right-angle handpieces to access different sections of the myocardium.

2. INDICATIONS FOR USAGE

Transmyocardial revascularization with The Heart Laser System is indicated for the treatment in patients with stable angina (Canadian Cardiovascular Society class 3 or 4) refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis not amenable to direct coronary revascularization.

3. CONTRAINDICATIONS

No contraindications known.

4. WARNINGS and PRECAUTIONS

UNSTABLE ANGINA WAS ASSOCIATED WITH 22% PERI-OPERATIVE MORTALITY COMPARED TO 1% IN PATIENTS WITH STABLE ANGINA.

In the randomized clinical study involving 151 TMR surgeries, patients were classified as stable or unstable angina (requiring IV anti-anginal medication) based on the two weeks preceding surgery. Peri-operative mortality (surgery + 30 days thereafter) was 1% (1/102) in the absence of unstable angina compared to 22% (11/49) when the patient suffered from unstable angina.

Right ventricular wall, septal ischemia - TMR with The Heart Laser System should not be used on patients with myocardial ischemia limited to the right ventricular wall and/or interventricular septum due to access limitations with TMR.

Laser pulse timing – The laser pulse needs to be timed at the peak of the R-wave. Do not operate The Heart Laser without proper placement of ECG electrodes.

Explosions or fire hazard - Do not operate the Heart Laser in the presence of flammable gases, anesthetics, cleaning agents, combustible materials, or other volatile substances. **Explosions or fire can result.**

- Combustible or flammable materials *(for example surgical drapes, gowns or gauze)* in the surgical field may be ignited by CO_2 radiation unless they are kept wet or moistened.
- Surround the surgical field with wet towels or wet gauze.
- Modify all other flammable materials to make them fire-retardant *(for example flame resistant surgical drapes and gowns).*
- Minimize oxygen exposure as oxygen increases the combustibility of materials exposed to CO_2 laser radiation.
- Do not use plastic or rubber endotracheal tubes as they are highly flammable. Use fireproof endotracheal tubes or protect the endotracheal tube from laser energy.

Laser radiation - The Heart Laser System is a Class IV laser product.

- Avoid exposure to laser radiation at all times during the installation and operation of the laser as direct or reflected radiation may damage skin or eyes.
- DO NOT LOOK DIRECTLY INTO THE CO_2 LASER BEAM (not visible) or the helium-neon laser aiming beam as either can cause permanent ocular damage.
- Protect the patient's eyes by covering them with wet gauze.
- All operating room personnel must wear protective eyewear with a minimum optical density of 5 at a wavelength of 10.6 μm when The Heart Laser System is in use.
- Do not use shiny metallic surfaces within the operative field which may reflect the laser beam. Use instruments with a dull, anodized, or ebonized finish near the laser beam.

Physician Training

- The Heart Laser System should only be used by properly trained surgeons (see Section 11.3 Operator Training).

Handling and Sterilization

- The TMR kit is **for single use only. Do not re-sterilize or reuse**.

- Inspect sealed sterile package before opening. If seal is broken, contents may not be sterile and may cause infection in the patient
- After use, handle and dispose of TMR kit as appropriate for a biohazard.
- Clean exterior panels of laser of bio-contaminants following surgery.
- Use only medical grade CO_2 for the purge gas to prevent possible bio-contamination.

Precautions During TMR

- Transmural penetration by the CO_2 laser should be confirmed by transesophageal echocardiography (see section 6. CLINICAL STUDIES)

5. ADVERSE EVENTS

5.1 Observed Adverse Events

Since the beginning of the clinical studies in the U.S. in 1990, a total of 650 patients have been treated with The Heart Laser System. The randomized trial of TMR using The Heart Laser System versus medical management (MM) involved 192 patients who were followed for a total of 140 patient-years. These 192 patients are the focus of the analyses shown hereafter. However, the incidence of adverse advents in the 458 remaining patients was similar.

There were no intra-operative deaths in the TMR group, but one patient died in cardiogenic shock (day 5 post procedure), one of cardiac arrest (day 9), and one with an acute myocardial infarction (day 12). There were also three deaths in the MM group two from acute myocardial infarction (days 13 and 24 after enrollment), and one from coronary artery disease (day 30). Nine of the patients who received TMR treatment after they failed medical management (crossover patients) died. Three died with ventricular fibrillation (two on day 0 and one on day 2), one with an acute myocardial infarction (day 7), two with strokes (day 7 and day 14), one in cardiogenic shock (day 9), one with low cardiac output (day 11), and one died a cardiac death of unknown cause (day 7).

All deaths and other adverse events were reviewed by an independent Data and Safety Monitoring Board (DSMB) for severity and relation to the procedure (TMR). Table 5.1 shows the incidence of major adverse events which were judged by the DSMB as probably or possibly related to TMR from the Phase III trial.

Table 5.1. Incidence of Major Cardiac Adverse Events
All patients in the Phase III Randomized Trial (N=192)

Cardiac Related Event	TMR assigned (N=91)		Crossovers (N=60)		MM (N=101)
	Day 1-30	Month 1-12[a]	Day 1-30	Month 1-12[a]	Month 1-12[a]
Acute myocardial infarction	6.6%	7.7%	6.7%	6.7%	11.9%
Arrhythmia: Atrial	2.2%	2.2%	5.0%	5.0%	-
Arrhythmia: Ventricular[b]	9.9%	9.9%	11.7%	11.7%	-
Cardiogenic Shock/Low outlput	3.3%	3.3%	6.7%	6.7%	-
Chest Pain	1.1%	1.1%	-	-	1.0%
Congestive heart failure	11.0%	11.0%	5.0%	5.0%	9.9%
Laser Hit – Mitral Regurgitation	1.1%	1.1%	1.7%	1.7%	-
Left Ventricular Bleeding	1.1%	1.1%	1.7%	1.7%	-
Mitral Valve Regurgitation	-	1.1%	-	-	-
Pericardial Tamponade	-	-	1.7%	1.7%	-
Pericarditis	-	1.1%	-	-	-
Ruptured Left Ventricle	-	-	1.7%	1.7%	-
Unstable Angina	1.1%	2.2%	3.3%	5.0%	69.3%

[a] *Includes first month (days 1-30). Average duration of follow-up was 10.4 mos for the 91 TMR patients, 8.7 mos for the 60 crossover patients, and 7.2 mos for the 101 MM patients*
[b] *One patient had 2 events – a peri-operative event and a long-term event*

Adverse events judged by the DSMB to be not related to the TMR procedure were reported in 1% to 8% of the patients including anemia, cancer, cerebrovascular accident, edema, GI complications, hemothorax, hyperglycemia, hypotension, infection, pleural effusion, pulmonary complications, renal complications, and syncope.

5.2 Potential Adverse Events

Adverse events potentially associated with the use of TMR include (in alphabetical order):

- Acute Myocardial Infarction
- Accidental Laser Hit
- Arrhythmia
- Congestive Heart Failure
- Conduction Pathway Injury
- Cerebrovascular Accident
- Death
- Mitral Valve Damage
- Pulmonary Complications
- Unstable Angina

6. CLINICAL STUDIES

Study: TMR using The Heart Laser System versus Medical Management for the treatment of patients with chronic stable angina not amenable to direct revascularization.

Objective: The objective was to compare TMR using The Heart Laser System to medical management for the treatment of patients who were not candidates for conventional CABG or PTCA revascularization procedures and had class III/IV angina refractory to medical treatment.

Methods: The clinical trial was a controlled, 1:1 randomized concurrent study between TMR therapy using The Heart Laser System and medical treatment alone. Patients were randomized to

receive either TMR or continued medical therapy. Transesophageal echocardiography (TEE) was performed to assess regional wall abnormalities, mitral valve anatomy, and confirm transmural penetration by the CO_2 laser.

The protocol included a cross-over clause which permitted patients randomized to the continued Medical Management group to receive the TMR treatment once medical therapy had failed. Medical management failure was defined as the occurrence of an unstable angina event requiring ICU hospitalization for at least 48 hours with IV anti-anginal medication.

Endpoints: The objective of the study was to compare TMR and Medical Management patient groups. The study endpoints were:

- Change in number of myocardial segments with stress-induced ischemia as measured by standardized nuclear imaging studies
- Change in angina class as measured by the Canadian Cardiovascular Society Angina classification system.

Additionally, quality of life, cardioactive medications usage, mortality, and morbidity were monitored throughout the study. All adverse events observed during the randomized study were reviewed and analyzed by the Data Safety Monitoring Board (DSMB), an independent panel of experienced physicians.

Compliance: Patients were followed for 12 months with evaluations at 3, 6 and 12 months. The overall study compliance was 92%.

Population: Patient enrollment in the randomized clinical trial occurred at 12 investigational sites and involved a total of 192 patients randomized to the TMR group (91) or the medical management group (101). Six additional patients were enrolled and randomized to TMR. They are not included in this analysis because they either did not receive TMR treatment (5) or were considered a protocol deviation (1). The protocol deviation involved a patient on IV nitrates at the time of enrollment. This patient died peri-operatively.

Patient characteristics at baseline were similar between the clinical sites and between the randomized study groups. More than half (58%) of the patients were classified as high-risk patients[1].

Demographics	Medical History	Cardiac Status	Risk Factors
• Female 21%	• AMI: 80%	• Class 4 Angina: 66%	• Hypertension: 64%
• Age: 61±10 years	• Arrhythmia: 20%	• Class 3 Angina: 34%	• Diabetes: 45%
	• CHF: 34%	• Unstable Angina: 10%	• High Cholesterol: 61%
	• CVA-TIA: 16%	• LVEF (%): 50±11	• Current Smoker: 8%
	• Prior CABG: 92%	• LVEF ≤ 45%: 33%	
	• Prior PTCA: 50%		
	• Cardiac Arrest 5%		
	• COPD 8%		
	• Renal Disease,10%		

[1] Higgins T, Estaphanos: Stratification of morbidity and mortality by preoperative risk factor in coronary artery bypass patients. JAMA 1992; 267: 2344-8.

Treatment: The average TMR procedure resulted in the creation of 36±13 laser channels with 30±8 channels successfully reaching the left ventricular cavity. On average, The Heart Laser was set to deliver 41±17 Joules per pulse. The TMR procedure was associated with a median ICU length of stay of 2 days and a median hospital length of stay of 7 days.

Results:

Table 6.1 Summary of Study Safety Findings

All patients in the Phase III Randomized Trial (N=192), Percent and 95% [confidence intervals]

Incidence [95% Confidence Interval]	TMR Treatment (N=91)		Medical Management (N=101)		Difference TMR – Med. Mgt.	
Adverse Events Incidence at 12 Month Follow-Up [1]						
Acute myocarial infarction	11%	[4%,18%]	22%	[8%,36%]	-11%	[-25%,3%]
Congestive heart failure	16%	[8%,24%]	23%	[7%,39%]	-7%	[-21%,7%]
Unstable Angina	14%	[7%,21%]	75%	[66%,84%]	61%*	[-72%,-50%]
Survival at Follow-Up[a] (Freedom from death)						
1-Year Survival	85%	[78%,92%]	79%	[65%,94%]	+6%	[-8%,20%]
2-Year Survival	81%	[72%,90%]	---	---	---	---
Event Free Survival at Follow-Up[a] (Freedom from death, Unstable angina, and Class 4 angina)						
1-Year Survival	69%	[60%,79%]	15%	[8%,22%]	+54%	[42%,66%]

[a] *Survival analyses conducted using Kaplan-Meier estimator*

* *Difference statistically significant (p≤0.05) by Chi-square.*

Table 6.2 Summary of Study Effectiveness Findings

All patients in the Phase III Randomized Trial (N=192), Percent and [95% confidence intervals]

Incidence or Mean ± Std Dev [95% Confidence Interval]	TMR Treatment (N=91)		Medical Management (N=101)		Difference TMR – Med. Mgt.	
Angina Pectoris – Success Rate at Follow-Up[a]						
Baseline to 3 Month Change	67% (52/78)	[55%,79%]	6% (4/64)	[2%,16%]	+61%*	[49%,73%]
Baseline to 12 Month Change	72% (44/61)	[60%,84%]	13% (3/23)	[5%,27%]	+59%*	[41%,77%]
Quality of Life – Change in Seattle Angina Questionnaire Scores at Follow-Up[b]						
Baseline to 3 Month Change	+170%	[138%,201%]	+7%	[-9%,23%]	+163%*	[128%,198%]
Baseline to 12 Month Change	+143%	[112%,174%]	+39%	[13%,65%]	+104%*	[50%,158%]
Left Heart SPECT -Change in Number of Ischemic Perfusion Defects at Follow-Up						
Baseline to 3 Month Change	-1.5 ± 3.4	(N=50)	+0.8 ± 3.0	(N=38)	-2.3*	[-3.7,-0.9]
Baseline to 12 Month Change	-1.4 ± 3.4	(N=38)	+1.3 ± 2.3	(N=13)	-2.7*	[-4.7,-0.7]

[a] *Therapy success = Decrease of at least 2 CCS angina classes between baseline and follow-up*

[b] *Average of 5 standard Seattle Angina Questionnaire indices*

* *Difference statistically significant (p≤0.05) by t-test.*

Based on the last available follow-up assessment, 66 percent (52/79) of the patients in the TMR group were considered angina successes. Of these 52 patients, the use of cardioactive medications (beta blockers, calcium channel blockers or nitrates) were decreased in 31 to 42 percent, or unchanged in 52 to 40 percent.

In the randomized clinical study involving 151 TMR surgeries, patients were classified as stable or unstable angina (requiring IV anti-anginal medication) based on the two weeks preceding surgery.

Peri-operative mortality (surgery + 30 days thereafter) was 1% (1/102) in the absence of unstable angina compared to 22% (11/49) when the patient met the definition for unstable angina.

7. PATIENT SELECTION AND TREATMENT

7.1 Specific Patient Populations

The safety and effectiveness of The Heart Laser System has not been established for the following specific populations:

- patients under the age of 18;
- patients who are pregnant or undergoing labor and delivery;
- nursing mothers;
- patients suffering from active hepatic disease, renal failure, cancer or major infection;
- patients with a left ventricular ejection fraction less than <20%;
- patients undergoing CABG/PTCA revascularization.

8. PATIENT COUNSELING INFORMATION

This device is restricted to use in patients who sign an informed consent to ensure that the risks associated with TMR have been fully explained to and understood by the patient.

Patients should be advised that any reduction of angina will occur gradually, that they will continue on their antianginal medications, and that the need for these medications will be re-evaluated at subsequent visits.

Patients should be advised of the risks of the procedure including the possibility of:

- recurrence of angina;
- progression of myocardial ischemia;
- worsening heart failure;
- cardiac arrhythmia;
- death.
-

9. CONFORMANCE TO STANDARDS

The Heart Laser has been tested to and conforms with the requirements of the following domestic and international standards:

- IEC601-1 Medical Electrical Equipment, General Requirements for Safety
- IEC601-2-22 Medical Electrical Equipment, Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment.

10. HOW SUPPLIED

10.1 Packaging

The Heart Laser System consists of the laser unit and the sterile, disposable, TMR kit.

- The 2000 lb laser is initially installed in the Hospital by PLC personnel.
- The single-use TMR kits are supplied sterile for every TMR case. Sterility may be compromised if the package is opened or damaged

10.2 Storage

The storage life of the TMR kit is one year from date of sterilization.

10.3 Accessories

The TMR kit includes:

Straight Handpiece (2)
Right Handpiece (2)
Laser Arm Drape (1)
Heart Diagram (2)
Non-toxic marker (1)
Mirror Swab (30)
Plastic Trays (3)

11. CLINICIAN USE INFORMATION

11.1 Patient Informed Consent

In addition to the standard surgical consent, PLC Medical Systems requires an additional consent form to be signed by each patient to ensure that the risks associated with TMR have been fully explained to the patient.

11.2 Operator's Manual

Operating instruction for the laser unit is contained in the ***Heart Laser TMR System Operator's Manual*** which includes seven sections describing operator safety, a detailed device description, unpacking and installation procedures, system operation, accessories, and preventive maintenance. It also contains four appendices which describe the energy meter calibration procedure, the warranty, a bibliography of articles relevant to TMR, and a list of sales/service contacts.

It is Essential that the Operator's Manual, especially those parts dealing with laser safety be read and understood before operating, maintaining and servicing this system. Failure to operate The Heart Laser System in accordance with the Operator's Manual may result in serious injury.

11.3 Operator Training

Federal law restricts the use of this device to practitioners who have been trained in laser heart surgery including laser system calibration and operation. Operator training for use of The Heart Laser System must include training in the use of the laser system and sterile disposable kit as well as appropriate clinical training.

Laser Training:

The American Society For Laser Medicine And Surgery offers the *following Standards of Practice for the Use of Lasers in Medicine and Surgery*:

Hospital privileges are, and must remain, the responsibility of the hospital governing board. Those requesting privileges to use lasers shall meet all the standards of the hospital with regard to board certification, board eligibility, special training, ethical character, good standing, judgment, indications for application, etc. In addition, the following laser training and experience are recommended:

- The individual should review the pertinent literature and audiovisual aids, and should attend laser training courses devoted to teaching of laser principles and safety. These courses should include basic laser physics, laser-tissue interactions, discussion of the clinical specialty field, and hands-on experience with lasers.
- The individual should have spent time with an experienced operator in the specialty area involved. It is essential that the individual see and document actual clinical applications of the laser in the outpatient or hospital setting as appropriate to the procedures in which the training is conducted.
- The individual should work closely with the biomedical engineering personnel.

Clinical Training:

Use of The Heart Laser System should only be undertaken by personnel trained in accordance with the PLC Medical Systems Training - Continuing Education Program. Comprehensive training program which includes:

- Surgical/clinical training for surgeons at Regional Training Centers, while the hospital nursing staff will receive on-site inservice training. For the initial clinical cases, new Heart Laser users will receive clinical support for patient selection and for TMR surgeries. Finally, PLC staff will conduct early follow-up visits to maximize the likelihood of positive initial clinical experience with TMR using The Heart Laser.
- An extensive continuing education program for existing clinical sites: This program will continuously improve the quality of TMR care through regular on-site in-service training and ongoing communication with Heart Laser users.
- A complete emergency clinical support program: PLC staff will work with the TMR Advisory Board, which will be composed of 5 experienced TMR users, to respond to any TMR related requests for emergency assistance.

Further information about training can be obtained from your PLC Medical Systems, Inc. representative at 800-232-8422.

11.4 Mechanism of Action

The mechanism(s) whereby TMR relieves angina is not known. In addition to possible contribution of placebo effect, current theories include:

- Increased perfusion of myocardium via the channels created;
- Increased collaterization via angiogenesis;
- Symptom reduction resulting from disruption of pain fiber function;
- Possible microinfarcts to the myocardium.

12. PATIENT'S MANUAL

The brochure "Is TMR For You?" provides general information to the potential patient regarding the risks and benefits associated with the TMR treatment.

---------- end of device labeling ----------

REVOLUTIONARY
NEW HEART
TREATMENT

Is TMR For You?

Is TMR

Many heart patients suffer from severe chest pain (angina). If your doctor determines that you are not a candidate for conventional therapy such as coronary artery bypass surgery (CABG), angioplasty, and drug (medical management) therapy, your doctor may recommend that you are a candidate for a new surgical procedure: Transmyocardial Laser Revascularization (TMR).

The information provided in this brochure is designed to assist you in learning more about TMR, and to help you become better informed about your possible treatment options.

For You?

TMR is an approved treatment for patients whose current medical therapy no longer relieves their severe stable angina, but are not in need of emergency treatment. If your doctor has recommended that you have TMR surgery then you will be asked to sign an additional informed consent to undergo this procedure. It is important that you understand the risks and benefits of this new procedure and that you discuss these with your doctor.

At this time it is not understood how TMR relieves chest pain. Current theories that are under investigation include:

- *increases blood flow to the heart muscle;*
- *increases growth of new small blood vessels;*
- *reduces perception of pain from angina;*

Is TMR For You?

What is TMR?

TMR is performed using a high-energy, computer-controlled carbon dioxide (CO_2) laser. Using the laser, approximately 20 to 40 small channels, each about 1mm in diameter, are created from the outside to the inside of your heart. Each channel is created in less than 50 milliseconds. Because the procedure is performed through a small opening in the chest while your heart is beating, no heart-lung machine is required. After reviewing your medical history and the results of preliminary tests, your doctor may recommend TMR as a treatment option for you.

Could I be a candidate for TMR?

TMR candidates frequently suffer from severe chest pain (angina) despite taking medication, and are often severely limited in performing their daily activities. Patients who are candidates for TMR are those for whom coronary artery bypass surgery or angioplasty is no longer an option to treat their disease. Symptoms may be so severe that patients may even be awakened at night by chest pain. After carefully reviewing your current health and medical history, your doctor will discuss with you whether or not you may be a candidate for TMR.

What kind of tests are required to assess whether or not I am a candidate?

In order to determine if you may benefit from TMR, your doctor will probably ask that you undergo a few tests. These tests may include coronary angiography, which will provide x-ray images of the blood vessels (coronary arteries) supplying blood to the heart. You may also undergo nuclear imaging studies, which measure blood flow to your heart muscle and the pumping function of your heart. Both of these tests will help to characterize the areas of your heart that may benefit from TMR channels. You should discuss with your doctor which tests will be necessary to evaluate your particular case.

The Procedure

1. *Once a small incision is made between your ribs to expose the heart muscle, a laser handpiece is then positioned on the outside of the oxygen-deprived area of the heart.*

2. *Approximately 20 to 40 channels, each about 1mm wide, are created through the heart muscle into the inside of the heart chamber. The number of channels will be determined by the size of the oxygen-deprived areas of your heart and will be decided during the procedure by your physician. The laser is automatically matched with your heartbeat and triggered to fire a very thin beam of light when the heart is filled with blood. The blood acts as a backstop for the laser energy and prevents the damaging of other tissue in the heart.*

3. *Clinical evidence suggests that the outside of the channel seals within minutes. At this time, it is not understood how TMR relieves chest pain. Please refer to page 2 for the current theories.*

How is TMR performed?

TMR is performed through a small incision on the left side of your chest between your ribs. The procedure is performed without have to stop your heart or having to place you on a heart-lung bypass machine.

What are the Possible Benefits and risks of TMR?

While there is no guarantee that TMR will improve your symptoms or the functioning of your heart, studies to date suggest that the possible benefits of TMR can include:

- relief of chest pain
- improvement in quality of life
- improvement in myocardial blood flow
- reduction in the number of hospital admissions for heart-related problems.

Possible risks of TMR can include:

- recurrence of angina
- progression of myocardial ischemia
- damage to mitral valve
- worsening heart failure
- cardiac arrhythmia
- death

How long does the TMR procedure take?

The surgery typically takes from one to two hours. Your doctor can give you more specific information for your particular case.

How long will I be in the hospital following TMR?

The median hospital stay for patients who have undergone TMR is about seven days. Following surgery, you can expect to spend about two days in the intensive care unit (ICU) or cardiac care unit (CCU) until your doctor feels that you have recovered enough from surgery to move into another area of the hospital. The length of your hospital stay will depend largely on your individual speed of recovery from surgery and your doctor's evaluation of your overall physical condition.

The Procedure

How long after surgery can I resume "normal" levels of activity?

Following TMR, you should consult with your doctor regarding your level of activity. Many patients are able to resume normal levels of activity within weeks. Your ability to return to your normal daily activity levels depends on how you personally feel, and how well your chest incision is healing, and the advice of your doctor. While some patients have not felt any improvement, many have experienced a continuing improvement in their level of activity in the months following TMR. A supervised cardiac rehabilitation program is always helpful in guiding you and helping you progress to a complete and full recovery.

Will I continue to take any medications following TMR?

As with any surgical procedure, you will likely be required to take medications following surgery. Your doctor should discuss with you which medications are appropriate for your care and for how long you should continue those medications.

Can I expect an immediate improvement in my health following TMR?

Results of TMR vary for each individual. Most individuals feel relief from anginal symptoms soon, while other patients begin to notice an improvement in their symptoms in the weeks following surgery. Although some patients noticed no improvement at all, evaluation of the impact of angina on patients' lives for twelve months after surgery shows that most patients do realize a benefit. Your doctor can assist you in evaluating your progress and physical health following TMR.

Is TMR For You?

If you think TMR may be the right treatment for you, please contact your doctor. You may also consult PLC's web site, at **plcmed.com**, to locate a clinical site in your area. TMR using the PLC System has been used to treat approximately 4,000 patients at 100 heart centers in 30 countries around the world.

This booklet is not intended as a substitute for professional medical care and advice. Only your doctor can diagnose and recommend treatment for heart disease.

Caution: Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Provided with the compliments of PLC Medical Systems, Inc.

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Doc. Number 1165.001