

A person wearing a light-colored, patterned short-sleeved shirt is riding a bicycle on a sandy beach. The background shows the ocean and a clear sky. The image is overlaid with a semi-transparent white filter.

Understanding your therapy.

PACEMAKER

Patient Guide

For over 50 years, we have been helping to improve the quality of life of patients around the world. Working closely with physicians and medical professionals, we develop innovative and meaningful health care solutions.

We are proud of our heritage and groundbreaking research, allowing us to develop the world's smallest transvenous pacemaker¹, just one example of our commitment to innovation.

Through the daily effort and dedication put into our work, we have the opportunity to improve and save lives. This is our driving force, and what we look forward to every day.

1. Dual chamber pacemaker: 8 cc ; Single chamber pacemaker: 7.5 cc

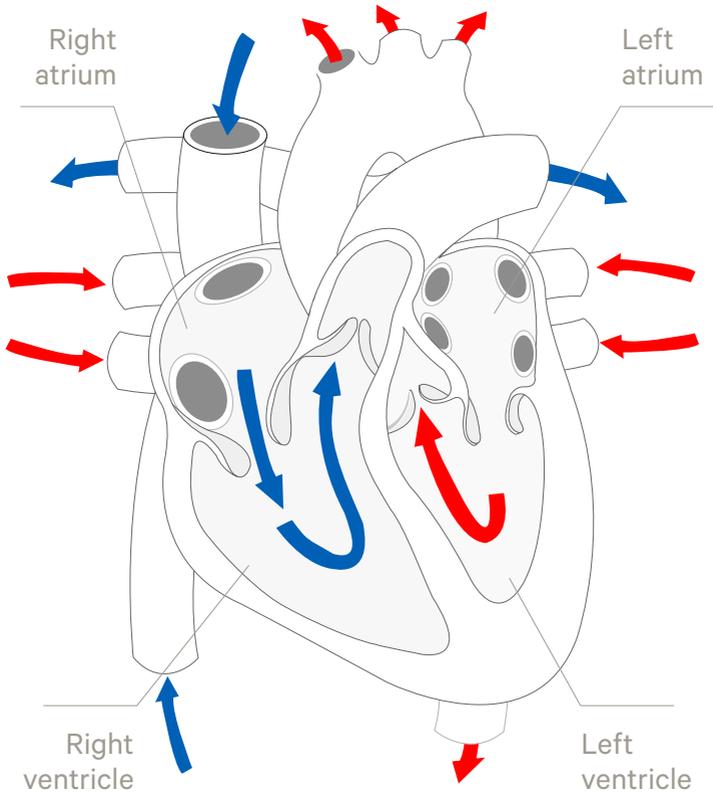
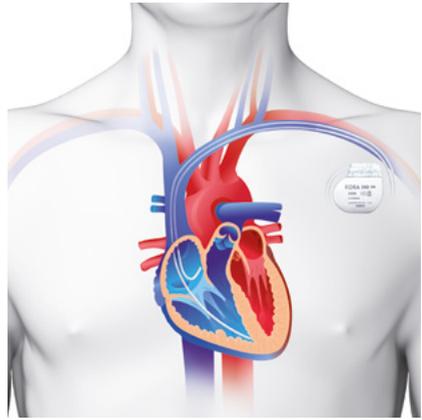
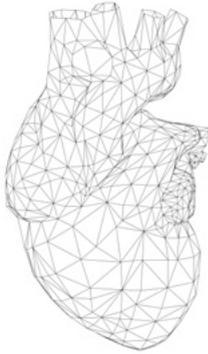
Leading a normal life with a pacemaker.

Hundreds of thousands of people throughout the world experience the benefits of a pacemaker. They lead perfectly normal professional, social and personal lives.

Now that you have a pacemaker, you understandably may want to know more about how the heart works, the pacemaker itself, how it was implanted and how it will affect your daily life.

This booklet will try to answer many of the questions you may have. If you have further questions about your individual circumstances, your doctor will be able to give you more specific answers.

I.	How does the heart work?	7
1.	Anatomy of the heart	7
2.	Electrical conduction in the heart	8
3.	Abnormal rhythms	8
II.	About your pacemaker	11
1.	Pacing therapy system	11
2.	Role of the pacing system	12
3.	Types of pacing systems	13
4.	Replacement	13
III.	How the pacemaker is implanted	15
1.	The implant procedure	15
2.	After implantation	16
3.	Follow-up visits	17
IV.	Living with your pacemaker	19
1.	Electrical equipment	19
2.	Medical procedures	20
3.	Daily life	22
V.	Questions you may have	24
VI.	Glossary of terms	26



i. How does the heart work?

1. Anatomy of the heart

The heart is an organ responsible for blood circulation. It distributes blood throughout the body via a network of arteries and veins, thus supplying tissues with oxygen and other nutrients.

A healthy heart is slightly larger than a clenched fist, and is capable of beating over 100,000 times a day at a rate of about 70 beats per minute. In one day, the heart pumps more than 1,760 gallons (7,000 litres) of blood through approximately 11,800 miles (19,000 km) of circulatory system.

The heart is divided into four chambers:

Two upper chambers known as atria and two lower chambers known as ventricles.

The blood enters the heart through the right atrium. From here it travels to the right ventricle and is pumped into the pulmonary artery.

The pulmonary arteries carry the blood to the lungs where it is oxygenated. Blood flows back to the left side of the heart after being oxygenated (the left atrium and then the left ventricle), and is then pumped throughout the circulatory system.

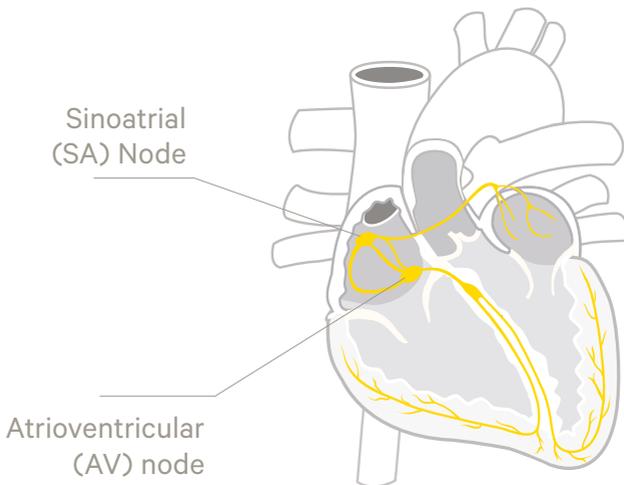
If you place your finger on the inner side of your wrist you will feel your pulse, following contractions of the heart.

2. Electrical conduction in the heart

Contraction of the heart muscle occurs automatically and is triggered by an electrical impulse.

This impulse is created by a specific group of cells located in the right atrium.

Electrical impulses start at the SA node and move through the atrium to the AV node. The AV node controls the release of the impulse, allowing it to travel through the ventricles.



3. Abnormal rhythms

When the electrical impulse or the conduction pathways responsible for transmitting the impulse across the cardiac muscle are disrupted, the heart rate either slows down, speeds up, or the rhythm may become irregular.

This can cause symptoms such as fainting, dizziness and fatigue.

The two most common heart rhythm conditions are:

- Tachyarrhythmia: when the heart beats too fast
- Bradycardia: when the heart beats too slowly. This disorder may require implantation of a pacemaker.

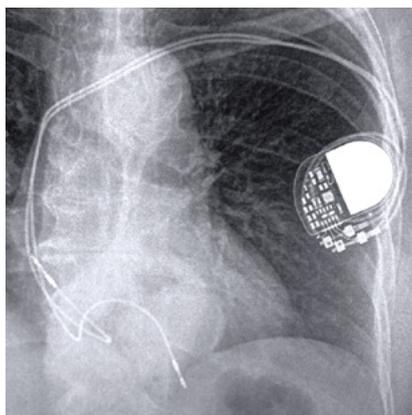
BRADYCARDIA

Your heart normally beats between 60 and 80 times a minute. A rate lower than 60 beats per minute is normal only if you are resting, asleep, or very physically fit. A heart rate below 60 beats per minute is called bradycardia. An abnormally slow heart rate or a very long pause between beats can cause tiredness, dizziness, and blackouts. When bradycardia is diagnosed in isolation, this condition is normally treated with a pacemaker.

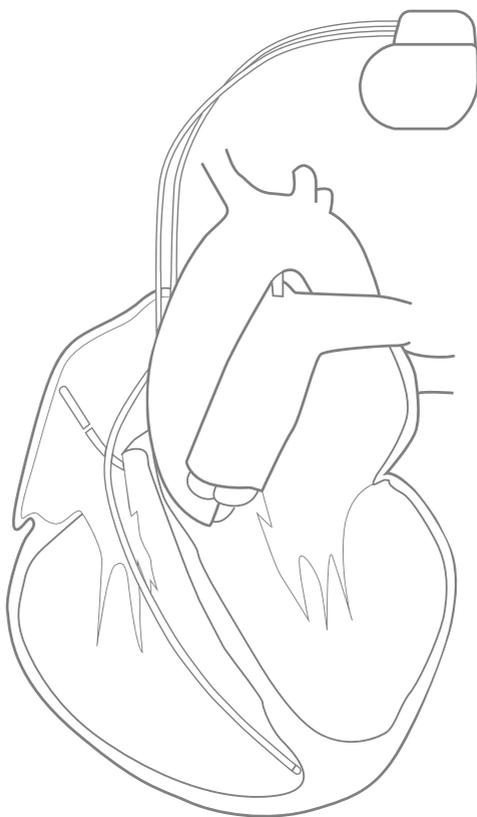
There are two causes for an abnormally slow heart rate:

- The SA node may fire too slowly (sick sinus syndrome), or
- The electrical signal cannot get through the AV node from the atrium to the ventricles (AV block).

A



B



II. About your pacemaker

1. Pacing therapy system

Pacemakers are like miniaturized computers used to monitor your heart's natural beat. If necessary, they will provide extra stimulation, generating an electrical impulse, which compensates for your heart's deficiency.

A. Pacemaker

A pacemaker consists of a sophisticated electronic circuit that monitors and analyzes each heartbeat and, if necessary, delivers imperceptibly small charge impulses to regulate the heart's activity. It contains a lithium battery for supply of power.

The pacemaker memory keeps a record of the heart's activity.

This data will be analyzed by your doctor, who will be able to tell how your heart and pacemaker have been behaving since your last check-up. Using this information, the doctor can decide whether or not to continue with the treatment.

B. Leads: one or two leads

Leads carry the electrical impulses to the heart. They are made from fine flexible insulated wire and link the pacemaker to the heart.

C. Programmer

Your doctor will “communicate” with the pacemaker using a device called a programmer.



Cardiologists will use the programmer to adjust your pacemaker’s settings painlessly, with no need for surgery.

2. Role of the pacing system

Your pacing system (pacemaker + lead) is able to sense and pace your heart.

- **Sensing:** monitoring the natural electrical activity of the heart. If the pacemaker senses a natural heartbeat, it will not deliver a pacing impulse.
- **Pacing:** sending an electrical impulse to your heart through a pacing lead.
- Most people do not feel the pacing impulses when they are delivered.

3. Types of pacing systems

Depending on your heart condition, your doctor will prescribe you a pacemaker that may have one of the following functions:

- **Single chamber stimulation:** one lead, inserted into the right atrium or ventricle.
- **Dual chamber stimulation:** one lead inserted into the atrium and another in the ventricle.
- **Rate responsive stimulation:** the pacemaker detects when you are exercising and delivers more frequent stimulation to keep up with the exercise.

Your doctor will choose the pacemaker system that best fits your needs.

4. Replacement

Pacemakers undergo strict manufacturing procedures and pass all reliability tests. The time before a replacement is required will depend on the pacemaker settings and on your individual case.

Once the battery of your pacemaker has reached its end of life the device needs to be replaced while the leads usually stay in place.



III. How the pacemaker is implanted

1. The implant procedure

Implanting a pacemaker is a quick and simple operation. It takes place in the hospital under either general or local anesthetic.

First, your doctor will make a small incision just below your collarbone, on the left or right side of your chest.

The doctor inserts the lead into a vein in the area beneath the collarbone and advances through to the relevant chamber of the heart (atrium or ventricle) using radioscopic control. Then, a series of electrical measurements is carried out to ensure that the lead is correctly inserted.

Next, the pacemaker is connected to the lead(s) and inserted into the body, usually just below the collarbone. Your doctor will determine where to implant the pacemaker depending on your body shape and lifestyle. The incision is stitched up and protected with a dressing.

Once the implantation is completed you will stay under observation. After 8 to 10 days, your stitches will be removed and the scar will be checked. Your doctor will make arrangements for future check-ups.

2. After implantation

After your pacemaker is implanted, you will be given an identification card containing information on the doctors monitoring your pacemaker and its leads.

Keep the card with you at all times: it contains critical information.

When you fully recover from the operation, you should return to your normal activities; the pacemaker should not interfere with your lifestyle. Your health allowing, all aspects of daily life are possible, including physical exercise and sex.

Tell your doctor immediately in case of redness, swelling, warmth, or drainage from your incisions. This may indicate an infection, and could be serious.

Contact your doctor

- if your arm becomes swollen,
- if pain persists after initial healing of your incision, or
- if you develop a fever

Pain can indicate the need to contact your physician as soon as possible. Don't wait until your next check-up.

3. Follow-up visits

Make regular appointments with your doctor. These visits are necessary to check your pacemaker, and to adjust its settings if your condition changes. Your doctor will know when your pacemaker needs to be replaced. There is no need to worry about this as the batteries used in pacemakers last for years and run down very gradually.

Most medical treatments do not harm pacemakers. However, some treatments can affect their functioning.

If you consult a doctor, dentist, physiotherapist or any other health professional, always tell them that you have a pacemaker, even if the reason for your visit is unrelated.



iv. Living with your pacemaker

1. Electrical equipment

Pacemakers are electronic devices. Therefore, some equipment may temporarily disrupt their operation.

Your pacemaker is protected from electrical interference, household electrical appliances and office equipment:

- Radios, stereo systems, televisions, VCR's, DVD, (game consoles) and remote controls
- Microwave ovens, electric ovens, toasters, blenders, refrigerators
- Vacuum cleaners, washing machines, driers, electric blankets, radiators
- Electric razors, hair-driers, electric toothbrush (some electric razors, hair – driers and electric toothbrush may disturb the pacemaker)
- Cars (including keyless entry), lawn mowers, snow blowers
- Personal computers (including WIFI and bluetooth systems), photocopiers, fax machines, pagers, walkie-talkies
- Hearing aids (Hearing Aids with transmitting necklace loops should be maintain at 15 cm distance between the pacemaker and the portion of the hearing aid necklace)
- Electric sockets and cables, Saw (hand-held, table), Hand drill.

Some electrical equipment can interfere with pacemakers. If you experience any unusual feelings such as lightheadedness or dizziness when you are near any of the following equipment, move away at once and inform your doctor about the incident.

BE CAREFUL, KEEP YOUR DISTANCE FROM:

- Relay stations for television, radio and radar
- Mobile phones: maintain a distance of at least 6 inches (15 cm) from the implanted pacemaker. (Domestic cordless telephones present no risk)
- Airport security systems may interact with pacemakers: walk directly through and do not remain near an Electronic Article Surveillance (including hand held scanner and full body scanner), however an alarm can be initiated.
- Anti-theft barriers in stores: crossing of these barriers is not dangerous, however repeated crossing or prolonged exposure should be avoided
- Defective electrical equipment (short circuits)
- Induction hotplates may disturb the functioning of some pacemaker models
- High voltage industrial machines
- High voltage transformers

THE FOLLOWING SHOULD BE AVOIDED:

- Electric arc welding
- Equipment containing powerful magnets
- Devices involving conduction of electricity through the body

These lists are not exhaustive, if in doubt, ask your doctor.

2. Medical procedures

Some medical procedures should not be performed on anyone with a pacemaker. Before any medical procedure, please inform your doctor that you have an implanted pacemaker and show him your pacemaker ID card.

Most medical and dental procedures will not interfere with your pacemaker. These procedures include:

- Diagnostic x-rays, such as chest, dental, CT, scans, or mammograms.
- Dental procedures to clean or repair teeth.

Other medical procedures or devices may produce a high level of disturbance that could seriously affect the function of your pacemaker. Be sure to discuss their risks and benefits with your doctor.

Some procedures can be carried out with proper precautions (the equipment should not be placed directly over the pacemaker):

- Transcutaneous electrical nerve stimulation (TENS).
- Lithotripsy (the use of shock waves to break up kidney and gall stones inside your body),
- Electrocautery (this is an electronic device used to stop bleeding during surgery),
- Diathermy (this equipment uses an electric field to apply heat to tissues, such as muscle)
- Radiation therapy
- Therapeutic ultrasound
- Magnetic resonance imaging (MRI)

MRI is a medical imaging technique that uses magnetic fields to create images of the body. You can undergo an MRI as long as you are implanted with a MicroPort CRM MR conditional pacing system. Your pacemaker ID card specifies the model of your implanted device and lead(s).

The MicroPort CRM MR conditional pacing systems were designed, tested and approved to be used safely with MRI scanners.

MRI procedures may potentially affect the functioning of your pacemaker if you are not implanted with a MicroPort CRM MR conditional pacing system, which could result in cardiac tissue heating, inappropriate pacing, and dangerous arrhythmias.

Prior to an MRI scan, your doctor will verify that you meet the patient eligibility requirements, and ensure that your MRI feature is programmed to ON.

The radiologist may need to talk to your cardiologist before performing the MRI procedure; showing your pacemaker ID card may be helpful.

During the MRI scan, you are continuously monitored to ensure your safety.

After leaving the MRI scan, your device switches back automatically to its normal configuration. Thanks to the unique automatic MRI mode, there is no need to return to your cardiologist to reconfigure your device after your MRI scan.

3. Daily life

Eating and drinking *(including alcohol)*

There are no restrictions related to the pacemaker.

Sport

Health allowing, and if your doctor agrees, no restrictions exist. However, blows to the pacemaker should be avoided, as should prolonged exposure of the implant region to sunlight.

Driving

No restrictions. However, avoid touching the engine or electrical system under the hood. Seat belts are safe to wear.

For information about driving restrictions, please refer to the local authorities and always follow your doctor's recommendations.

Traveling

No restrictions. However, because airport security gates may result in an alarm, you should present your pacemaker identification card to the official beforehand.

Work

There are no restrictions provided that you follow the recommendations given in this booklet. If your work environment contains a lot of electrical equipment or if your job involves a lot of physical effort, consult your doctor.

Checking your pacemaker

Your pacemaker is designed to be highly reliable. It includes a battery and the electronic circuitry is designed to provide you with years of service. How long the pacemaker lasts depends on the specific model your doctor has chosen for you.

Checking your pacemaker can be accomplished in a number of ways. The easiest method is to take your pulse daily for one full minute. It is best to take your pulse at the same time every day, so that your pulse does not vary because of physical activity.

v. Questions you may have

— Why do I need a pacemaker?

A pacemaker is an implanted device that helps to control abnormal heart rhythms. It is used to treat problems with the rate or rhythm of the heartbeat that may cause symptoms including fatigue, shortness of breath, and dizziness. The most common medical condition requiring a pacemaker is called 'Bradycardia', meaning that the natural rhythm of the heart is too slow.

— Is it safe to have an MRI?

You can safely undergo an MRI scan as long as you are implanted with a MicroPort CRM MR conditional pacing system. This system was designed, tested and approved for safe usage with MRI scanners.

An MRI procedure may potentially disturb the function of your pacemaker if you are not implanted with a MicroPort CRM MR conditional pacing system.

Please show your pacemaker ID card to your doctor, as this specifies the model of your implanted device and lead(s).

— Can I use electric devices such as a microwave oven?

Yes, you can use household electrical appliances and office equipment. For more details see the ‘Living with your pacemaker’ chapter, under the ‘Electrical equipment’ heading on page 19.

— How often will my doctor need to check my pacemaker?

Will my pacemaker need to be replaced?

Your doctor will inform you about the next follow up required to check your pacemaker and adjust its settings for any changes in your condition. It is important to always keep these appointments.

During regular follow up visits, your doctor will let you know if your pacemaker needs to be replaced. Replacement time depends on several factors (type of pacemaker, the heart condition and the frequency of pacing).

If you have any additional questions, or would like more information about your pacemaker, contact your pacemaker specialist.

vi. **Glossary** of terms

Arrhythmia

An abnormal cardiac rhythm.

Asystole

A failure of the heart to beat or contract at a time when it should have.

Atrium/Atria

The top or 'collecting' chambers of the heart. There are two atria, the right atrium and the left atrium.

AV node

Also known as the 'atrioventricular node', this is a special conduction centre in the heart. It is located between the two lower chambers (ventricles) of the heart and receives the electrical impulse from the upper chambers (atria) of the heart and passes it downward into the lower chambers (ventricles).

Blood pressure

The pressure of blood against the walls of the blood vessels. This term is normally used to refer to arterial blood pressure. It is determined by the force of the heartbeat, the resistance to the flow of blood in the arteries, the elasticity of the vessel walls, and blood thickness. Blood pressure is expressed as a ratio, i.e., 120/80. The first number represents the systolic pressure (see 'Systole') and the second, the diastolic pressure (see 'Diastole'). Both are recorded in millimeters of mercury. Strenuous physical activity, excitement, nervous tension, or fright can raise the systolic pressure.

Bradycardia

A heart rate of less than 60 beats per minute. This can be quite normal while at rest or sleeping, or in especially

physically fit people. It may also be caused by the sinoatrial node working too slowly or blockage of the electrical pathways in the heart. (See ‘Sinoatrial node’).

Bundle branch block

A blockage of one of the specialized conducting pathways within the lower chambers of the heart.

Bundle of HIS

Also called common bundle or AV bundle. A bundle of specialized muscle fibers responsible for conducting impulses from the AV node to the lower chambers of the heart. Named after Wilhelm His, a German medical scientist.

Capture

When a pacemaker impulse or discharge succeeds in causing both cavities of the heart to beat or contract.

Cardiac insufficiency

Inability of the heart to pump adequately.

Causes shortness of breath, fluid retention, etc.

Cardiac output

The amount of blood pumped by the heart per minute.

Catheterization

In cardiology, the process of examining the heart by means of introducing a thin tube (catheter) into a vein or artery and passing it into the heart. The pacemaker lead inserted through the vein for pacing is a type of catheter.

Circuitry

The electrical portion of your pacemaker designed to pace the heart at a pre-established rate, and with a demand pacemaker, to sense your natural rhythm.

Coronary arteries

The arteries that supply blood to the heart muscle itself.

Depolarization

Electrical activity spreading through the heart, causing it to contract or beat.

Diastole

Relaxation of the heart between contractions.

Ectopic

Electrical stimulation of cardiac contractions beginning at a point other than the sinoatrial (SA) node.

Electrocardiogram

Often called EKG or ECG, electrocardiograms are graphic records of the electrical currents produced by the heart.

Electrode

The wire connecting the pacemaker (pulse generator) to the heart. It is responsible for carrying the electrical discharge to the heart and the sensor output from electrical activity of the heart back to the pacemaker.

Endocardial

Refers to the inside layer of the heart. An endocardial electrode is one that is inserted via a vein, with the tip contacting the internal surface of the heart.

Epicardial

The outer layer of the heart. An epicardial electrode is one that is attached directly to the heart's outer surface.

Fibrillation

Rapid, uncoordinated contractions of the heart muscle occurring when individual

muscle fibers contract in an independent and irregular sense.

Fibrosis

Scarring of the heart or other organs of the body. Within the electrical portion of the heart this scarring may cause heart block or other rhythm disturbances.

Heart block

A condition where transmission of electrical impulses from the upper chambers of the heart to the lower chambers is partially or completely blocked, resulting in the chambers failing to work in a synchronized way.

Hypertension

An unstable or persistent elevation of blood pressure above the normal range. May eventually lead to an enlarged heart or kidney damage.

Hermetic seal

A process where the battery and circuitry of the pulse generator are sealed within a metal container that cannot be penetrated by body fluids.

Intrinsic rate

Patient's own natural heart rate.

Myocardial infarction

The damage or death of areas of the heart muscle (myocardium) resulting from a reduction in the blood supply reaching that area.

Nitroglycerin

A medication used to relax the muscles in the blood vessels. Often used to relieve attacks of angina pectoris and spasms of the coronary arteries. It is a vasodilator.

Pace

A condition in which a heart beat is initiated by a pacemaker.

PAC

Premature Atrial Contraction; a heartbeat originating early in the upper chambers of the heart (atria). It is considered ectopic since it is not part of the usual conduction pathway.

Programmable pacemaker

A type of pacemaker that can be adjusted from outside of the body using a specific instrument (programmer). The programmer can be used to vary the rate of pacing as well as the electrical output of the pacemaker. This does NOT require surgery.

Pulse

A rhythm in the arteries caused by the contractions of the heart.

Pulse generator

Referring to the entire pacemaker. The circuitry and batteries; together these produce a periodic electrical impulse to the heart.

Purkinje Fibers

Specialized muscle fibers forming a network in the walls of the heart's lower chambers. Believed to be involved in conducting electrical impulses to the muscular walls of the ventricles. These impulses are responsible for contraction of the ventricles.

PVC

Premature Ventricular Contraction; similar to PAC but occurring within the lower chambers of the heart.

Rate response

A function that allows the pacemaker to increase the heart rate during exercise.

Rhythm

A regular and repetitive recurrence of a beat.

SA node

Sinoatrial node, the special nerve centre in the upper right chamber of the heart responsible for initiating each beat.

Sense

The ability of a pacemaker to recognize the electrical impulse of a heart beat.

Septum

A thick muscular wall dividing the heart into right and left.

Sinus rhythm

A typical type of rhythm initiated from the upper chambers of the heart with the electrical impulse passing normally into the lower chambers.

Stimulus

An electrical discharge from the pacemaker to the heart.

Stokes / Adams attacks

Fainting spells associated with a temporary lack of perfusion of blood to the brain. Generally associated with complete heart block.

Systole

The contraction of the heart that forces blood through the arteries.

Syncope

Fainting.

Tachycardia

A rapid heart rate, usually over 100 beats per minute.

Threshold

The lowest amount of electrical energy from a pacemaker stimulus necessary to cause the heart to contract.

Titanium

A type of metal used to make the outer case of the pacemaker.

Transvenous

A type of electrode that is generally endocardial. It is inserted through a vein and passed to the heart, with the tip of the electrode placed in the endocardium.

Transthoracic surgery

When an opening is made between the ribs such that epicardial electrodes can be sewn directly to the outer wall of the left ventricle.

Ventricles

The two lower chambers of the heart. The right ventricle pumps blood to the lungs and the left ventricle pumps blood throughout the body.

Manufactured in Europe by MicroPort CRM.

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