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Getting a New Lease on Life

BIOTRONIK

Cardiac Rhythm Therapy

Patient's Manual

Getting a New Lease on Life

with an Implantable Cardioverter-Defibrillator

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Getting a New Lease on Life with an Implantable Cardioverter – Defibrillator

www.biotronik.com

Design, stoffers/steinicke, Berlin

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Introduction

Your physician has recommended that you receive a BIOTRONIK® Implantable Cardioverter-Defibrillator (ICD). The implantation may have taken place already.

Just like the ICD, this brochure aims at giving your life a boost. We explain how your ICD works and the few necessary precautions which will ensure that your new lease on life is a long one.

Please share the information in this brochure with your relatives and friends so that they get the chance to understand your new situation and assist you in adjusting to life with an ICD.

The information in this brochure is not intended as a substitute for regular contact with your physician, whose instructions you should always follow. There is a blank page at the end of this brochure where you can write down any concerns or questions that arise during the time between your follow-up appointments.

The ICD monitors your heartbeat and delivers electrical pulses when necessary. Therefore, it is the primary – and hopefully most frequent – task of the ICD to give you confidence that your heart is not beating too rapidly or too slowly on its own accord. You don't need to be overly careful and can develop your strength through an active lifestyle.

Even when your heart is beating a little too slowly, rapidly or irregularly, the ICD will sense this and, in most cases, be able to prevent worse from happening by delivering weak electrical impulses, which most patients don't even notice.

The most important and, fortunately, least frequently required task of the ICD is the early detection of life-threatening rapid heartbeats or even cardiac fibrillation – which physicians refer to as tachyarrhythmias – and to terminate these by applying strong electrical impulses.

It is an important characteristic of the ICD that even its strongest pulses are far weaker than those applied to the body externally by a physician in the event of an emergency.

A special section of this brochure is aimed at helping you relate to your implant in a positive way. We know that a big change has just occured in your life. Drawing on the experience of hundreds of thousands of people from all over the world, we want to reassure you that the changes you can expect are for the better.

You will learn how to live with a highly advanced piece of technology. Initial insecurity and apprehension will give way to confidence, letting you rest assured that your ICD will always apply the right pulses in critical, perhaps even life-threatening, situations. Secure in this knowledge, you will be able to look confidently to the future.


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Greeting

Dear Reader,

If you are reading this brochure, you probably belong or will belong to the category of people to whom the implantation of a defibrillator was recommended for medical reasons.

You are being presented with a complex piece of technology that may cause you to feel insecure, possibly even afraid. Perhaps in recent years your everyday life has been severely restricted by heart disease, a myocardial infarction, or repeated life-threatening heart rhythm disturbances.

You have undergone many medical examinations and most likely received medication, but without further measures, the threat to your life still remained.

You have to take a break from many of the things you would have liked to do. I was in a similar situation nine years ago.

The decision to have a "defib" implanted offers you the unique opportunity to live a full life again after a relatively short time.

This brochure provides comprehensive information on the latest advances in defibrillator therapy. Its reliability is second to none in the treatment of cardiac disease.

Take the opportunity to talk to other heart patients (for example, members of a support group), speak with your physician about getting accustomed to life with an ICD, and let relatives and friends know what is happening with your medical situation.

You will find that your anxiety and fears will gradually diminish as the quality of your life steadily increases. Once you have become used to the implanted device, the confidence of knowing that a reliable aide is always at hand to assist in emergency situations will be very reassuring to you.

Your ICD will help you get a new lease on life, and you will be able to do more than you ever dared to do before.

I wish you all the best for the future.

Dieter Wetzel, Münster
Chairman Herz in Takt Defi-Liga e.V.
Support group for defibrillator patients


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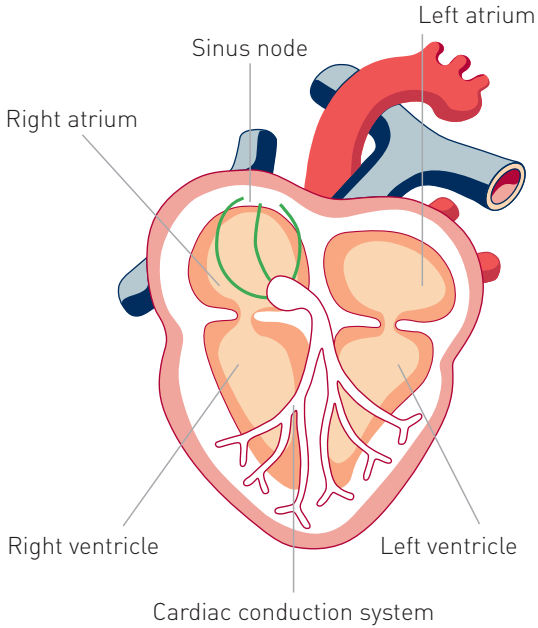
The Heart and Its Natural Rhythm

The heart is a hollow muscle about the size of a fist that pumps blood through the body at a rate of approximately five liters per minute. To achieve this, a healthy person's heart will pump between 60 and 140 times, depending on whether the individual is under exertion or at rest. On average, a human heart beats 100,000 times per day (this translates into about 40 million times per year and almost 3 billion times in a lifetime). Internally, the heart is physically divided into two parts: the left heart and the right heart. Each half consists of an atrium and a ventricle.

The right heart pumps used, dark-red colored blood into the lungs, where the blood is enriched with oxygen again and is then pumped back to the left heart. The left heart pumps unused, light-red colored blood into the main artery, thus supplying the entire body with oxygen.



Anatomy of the heart

Heartbeats are caused by rhythmic contraction of the atria and ventricles. Every muscle fiber of the heart has the strength to contract on its own. The muscle fiber consists of cells, each of which has its own electrical charge. This charge is polarized, or ordered, by an electrical pulse. In a healthy person, this process is generated by a cell cluster inside the heart called the sinus node.

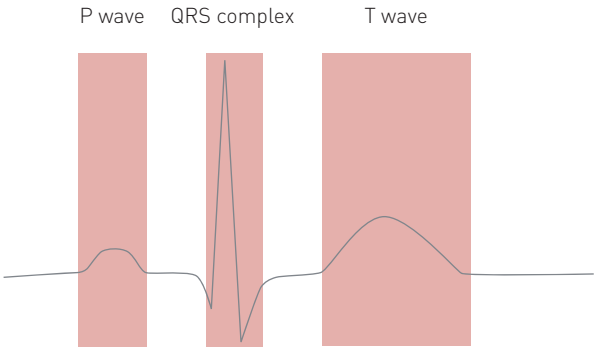
These tiny electrical impulses generated by the sinus node trigger the heartbeat and regulate the sequence of the individual phases. From the node, the impulses flow through conductive tissue, which is embedded in the heart muscle. This tissue is known as the cardiac conduction system.

When the cardiac conduction system is healthy, all impulses reach even the most distant heart muscle cells. This is necessary so that all the muscle fibers contract and relax according to a regular rhythm.

Patient undergoing exercise ECG test

An ECG records both the heart rate (the number of heartbeats per minute) and the muscle contraction sequence during each individual heartbeat.

The analysis of an individual heartbeat, in particular, provides your physician with important indicators about the condition of your heart.



ECG

P wave = atrial contraction

QRS complex = ventricular contraction

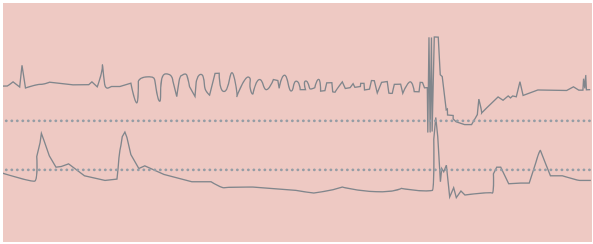
T wave = repolarization

Heart Rhythm Disorders

The heart can beat too slowly or too rapidly, and it can beat regularly or irregularly. However, combinations of these types of deviations can occur.

When a heart beats too slowly: Bradycardia

Bradycardia, or a chronically slow heart rate, was the first heart rhythm disorder to be successfully treated using electrical stimulation. This led to the development of the cardiac pacemaker. However, other complex rhythm disorders exist where a patient has a chronically slow heartbeat, but, at the same time, experiences severe episodes of tachyarrhythmia (ventricular flutter or fibrillation).



When a heart beats too rapidly: Tachycardia

Physicians describe excessively rapid heart rates as tachycardia (general) and tachyarrhythmia. Both words are derived from Greek. "Tachys" means "fast", "cardia" is the heart, and "arrhythmia" denotes an irregular rhythm.

Causes of tachyarrhythmia

Anyone who has suffered previous damage to the heart, had a myocardial infarction, has constricted coronary arteries, or suffers from any other heart disease may be affected by tachyarrhythmia.

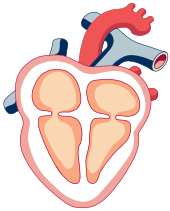
Often, racing of the heart (ventricular flutter or ventricular fibrillation) is caused by an extra-systole. An extrasystole is an additional heartbeat outside the normal rhythm, as if the heart were stumbling. However, this additional heartbeat is not triggered by an impulse from the sinus node; instead, the muscle fiber contracts randomly and on its own accord. In other words, the electricity contained in the individual cells is discharging in a disorderly fashion.

Anyone with a healthy heart can easily cope with an extrasystole. However, in patients with previous heart damage, the sinus node might not be able to "restore order".

As a result, the individual phases of the heart-beat are unable to follow each other in an orderly fashion.

Racing of the heart

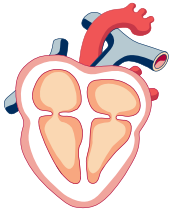
From a medical point of view, racing of the heart is tachycardia. That is to say, the heart is usually still beating regularly, but far too quickly. This results in dizziness and a general sense of weakness.



Heart beating 160 times a minute

Ventricular flutter

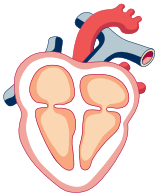
Heart rates that exceed 250 beats per minute are dangerous. This situation is known as ventricular flutter. When ventricular flutter occurs, the ventricles will contract so rapidly that there will barely be enough time for them to fill with blood. The heart will thus be pumping very little blood into the cardiovascular system, causing the person to be close to unconsciousness.



Heart beating 250 times a minute

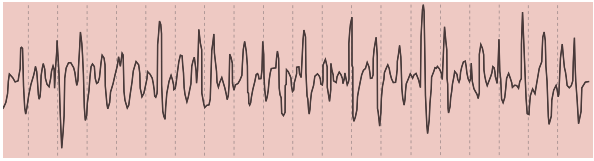
Ventricular fibrillation

Heart rates exceeding 300 beats per minute are life-threatening. This situation is known as ventricular fibrillation. When ventricular fibrillation occurs, the heart muscle will only be able to fibrillate (rapidly contract), and virtually no blood will be pumped into the cardiovascular system. The person will lose consciousness, because no fresh blood will be able to reach the brain. The result may be severe damage to the brain and other organs, and possibly death.



300

Heart beating 300 times a minute

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The ICD – Lifesaving Electrical Impulses

Due to technological advances in medicine, implanting an ICD has become a routine operation. ICD stands for Implantable Cardioverter-Defibrillator. There is no need to remember this specialized terminology, as every physician knows the abbreviation.

The following section explains how the ICD can help you. The individual components of the device will be described later in this manual, in the section on implantation.

Implantable cardioverter-defibrillators have been in existence since 1980. They have significantly broadened the range of treatment for people suffering from tachyarrhythmia. Previously, the only way a physician could prevent the onset of tachyarrhythmia was to prescribe medication. However, not all patients respond well to drugs. The catheter ablation method, which involves removing tissue from certain areas of the ventricle, is also not suitable for all types of patients.

From external electrical shocks to precisely controlled impulses

Treatment with electrical shocks is the most effective way to counteract heart rhythm disturbances. If a heart beats too slowly, for example, even a weak but regular impulse, such as one generated by a pacemaker, will be sufficient to stimulate it.

However, prior to the invention of the ICD, tachycardias such as ventricular fibrillation could only be terminated by a physician applying a strong external electrical shock or by administering emergency medication. Because this kind of ventricular fibrillation is entirely unpredictable, in the past, the patient's only chance of survival was to to have a paramedic provide lifesaving shock treatment with a portable defibrillator immediately. Of course, all this depended on whether the patient's circulation had been kept going until the shock was delivered.

The idea of a physician applying two large metal electrodes to the chest and inducing an electrical shock is understandably a frightening vision for most people. Naturally, the fear that the emergency physician may not arrive in time is even greater.

In order for the ICD to apply lifesaving impulses at the right moment, it must be able to recognize life-threatening heart rates and respond with appropriate electrical impulses. These functional capabilities have been combined with several other therapy functions inside a tiny implant with the help of state-of-the-art microelectronics.

Besides immediate availability, an ICD has another decisive advantage over the application of external electrical shocks: energy is applied directly to the heart precisely where it is required. For this reason, even in worst-case scenarios, the shock induced by an ICD can be kept to one tenth of the electrical shock applied by an external defibrillator.

The ICD: Providing the right stimulus for every situation

The ICD's main task, of course, is to save your life, if it ever becomes necessary. The ICD is designed to quickly terminate ventricular flutter or fibrillation by applying shock impulses, thus saving your life in an emergency. Under no circumstances do you need to fear that the ICD will react to every minor deviation from your natural heart rhythm by applying electrical shocks. On the contrary, weak impulses that are not perceived as painful or regular stimulation by the ICD often prevent the heart from going into ventricular fibrillation.

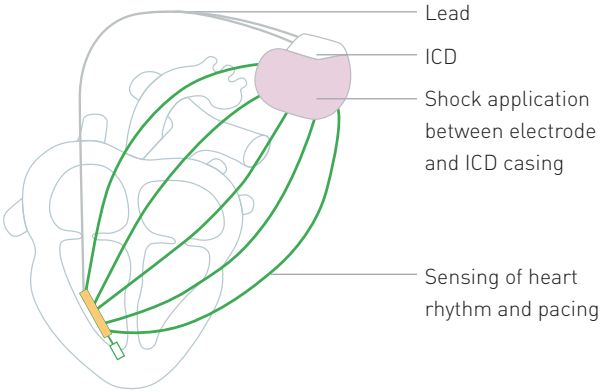
Your physician will program your ICD to your individual needs. This programmability makes it possible for your physician to set the device to best suit the demands of an active lifestyle.

The ICD stores all data related to therapeutic measures along with data about events preceding and following any episodes. These data are then regularly read and evaluated at your follow-up examinations. Let us take a detailed look at the individual levels of therapy provided by the ICD:

Antitachycardia and antibradycardia pacing

Before the heart develops ventricular flutter or fibrillation, it often begins to race. In this case, the ICD delivers weak electrical impulses (antitachycardia pacing) in quick succession. In many cases (60-80%), this stops the heart from racing before ventricular flutter or fibrillation develops.

The ICD also stimulates the heart if it beats too slowly (antibradycardia pacing). This is the type of stimulation provided by a pacemaker.



For patients who require therapy not only in the ventricle but also in the atrium, a special ICD model is available that combines the functions of the ICD with those of a dual-chamber pacemaker.

Cardioversion

Cardioversion is a specific form of defibrillation and serves to restore the normal heart rhythm. If racing of the heart persists despite antitachycardia pacing, or if the situation deteriorates into ventricular flutter, then the next level of therapy will be applied. Cardioversion (changing the heart rhythm) consists of the delivery of a weak electrical shock that is synchronized with the contraction of the ventricles.

Defibrillation

If ventricular flutter occurs, or if previous therapy attempts have not produced the desired effect within a given period of time, then a stronger shock impulse will be delivered, which can usually be relied on to terminate tachyarrhythmia. The energy required for this strong impulse is available in less than ten seconds following the onset of ventricular flutter. Before delivering additional strong shock impulses, your ICD will always check if the tachyarrhythmia still persists.

If no tachyarrhythmia is found, then the ICD will refrain from delivering additional impulses.

Will I feel the impulses?

Antitachycardia and antibradycardia pacing will be delivered virtually unnoticed. However, you will notice that your heartbeats are normal again. Cardioversion and defibrillation can be briefly painful. However, many people lose consciousness before the impulse is delivered and, therefore, do not feel it.

Those who are conscious during the shock delivery describe it as a sharp blow to the chest, with the accompanying pain receding immediately. However, it is possible that the shock may cause chest and arm muscle cramps on the side where the implant is located, resulting in soreness in this area for one or two days afterwards.

This shock impulse is delivered within a fraction of a second, and in the majority of cases terminates the life-threatening arrhythmia. However, if it persists, additional impulses will follow.

Most people who live with an ICD have a positive view of even the strongest impulses, for the simple reason that they are lifesavers. Statistically speaking, the strongest impulses are usually delivered within the first few months after implantation. Later on, the necessity for such a therapeutic measure decreases, so that in the years to follow, many ICD patients do not even require cardioversion or defibrillation.

Who needs an ICD?

Each year, hundreds of thousands of people die of sudden cardiac death in Europe alone. Sudden cardiac death is not always due to myocardial infarction, as is often thought, but it is quite often due to ventricular fibrillation and the resulting cardiovascular arrest. Many people who have died as a result of ventricular fibrillation could still be alive if they had had an ICD to protect them.

Your physician will recommend that you have a defibrillator implanted for example if you have already experienced ventricular fibrillation and have recovered, if treating your tachyarrhythmia with drugs is not proving to be effective, or if you are at risk of suffering a first-time tachyarrhythmia.

Joachim T., engineer from Cologne, born 1947

"When I fell unconscious at home, my wife called the paramedics immediately. I was revived, and later, at the hospital, I got an ICD implanted. Since then, the implant has saved my life twice. You don't forget an experience like that. I'm very thankful that I have the ICD and now I appreciate life more intensively. I enjoy every day of my life and the time that I have with my family and friends."

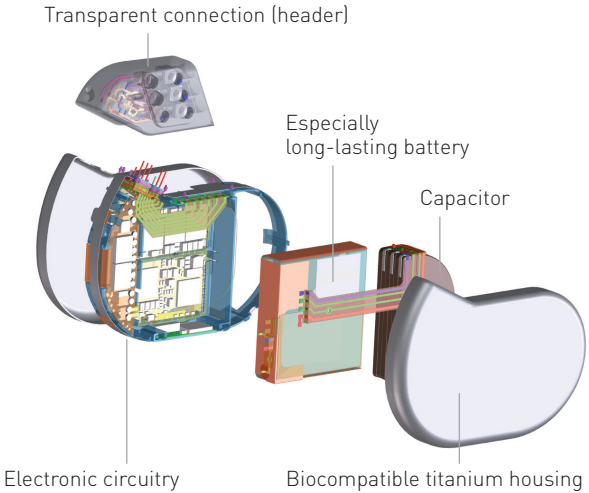
ICD Implantation

Nowadays, thanks to advances in miniaturization and improved lead technology, implanting an ICD is no longer a complicated operation. The devices weigh less than 95 grams and are now just over a centimeter thick.

The ICD's individual components

The titanium housing encapsulates a micro-computer and a long-lasting battery. Titanium is optimal for implants because it is well tolerated by human tissue.

Connectors at the top of the ICD serve to attach one end of each lead to the ICD housing. The other end of the lead is fed into the right heart. The metal part of these leads is made of precious metals such as silver, platinum or iridium. Electrodes at the tip of the lead continuously transmit heart signals to the microcomputer in the ICD. The leads are insulated with tissue-friendly silicone. If necessary, the ICD delivers electrical impulses to the heart via the leads.



The defibrillator

For this purpose, a defibrillation electrode, which delivers shock impulses to the ventricle in the event of an emergency, is integrated in the lead.

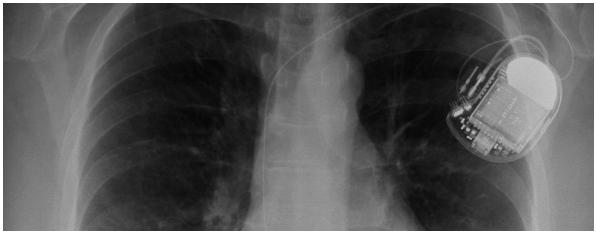
Your physician will use a programmer to set up the ICD to meet your individual requirements. This does not require a cable connection between the programmer and the implanted ICD. Data transfer is wireless (telemetry).Your physician will simply place a programming head on your chest where the implant is located. The programming head and the programmer are connected by a cable.

A minor operation

Implanting an ICD is similar to implanting a pacemaker; it is a routine operation with a low complication rate. The device is usually placed underneath the left chest muscle (submuscular implantation) or just beneath the skin (subcutaneous implantation) in the same area. In rare cases, ICDs are implanted in the stomach region.

The operation is usually performed under local anesthesia instead of the now only seldomly used

general anesthetic. The lead is fed through a vein into the right ventricle and connected to the ICD at its other end. The lead will soon grow into the ventricle's inner wall, without impeding the heart in any way. As blood vessels and the inner wall of the heart are insensitive to pain, you will not feel the lead. Because the lead is fed through a vein underneath the chest muscle, it is not necessary to perform direct heart surgery.



X-ray of an implanted ICD and lead

The operation usually takes only between one and two hours. Finally, while you are still under anesthesia, ventricular fibrillation will be induced artificially, and your ICD will be tested and programmed according to your requirements.

After the implantation, you will probably be kept under close observation for several hours before being transferred to a normal ward. The operation scar will be approximately 10 centimeters long and visually inconspicuous. The rate for complications is very low, at 1–2%.

Precautions immediately after implantation

Immediately after implantation, your priority is to recuperate. The wound will normally heal relatively quickly.

Contact your physician if anything unusual occurs, for instance if:

- Blood or other fluids exude from the scars and seep through the bandage;

- The wound swells up and becomes unusually warm; or
- After initially improving, the pain worsens again.

On average, you will be in the hospital only for a few days. Before you are discharged, the physician will test your ICD one more time. You will receive a short-term anesthetic, then the physician will induce ventricular fibrillation, which the ICD should terminate immediately.

You should take the following precautions in the period directly after implantation:

Always take the prescribed medication on time and definitely follow your physician's instructions. Avoid any blows to the vicinity of the implanted device. Avoid excessive arm movement, and do not do any heavy lifting. Avoid anything that may constrain the vicinity of the implanted device, such as clothing, belts, suspenders, corsets etc.

ICD patient identification card

You will be given a patient identification card when you are discharged from the hospital. This identification card contains important information for your physician and other medical personnel. The ID card lists dates for future follow-up examinations together with selected data pertaining to your ICD.

- Always carry the ICD patient ID card with you.
- Always show the ID card when you go for medical treatment, even to your dentist.

ICD patient ID card

The owner of this ID card carries an Implantable Cardioverter Defibrillator (ICD) with antibradycardiac and antitachycardiac pacemaker function.

Patientenausweis (ICD)

Der Inhaber dieses Ausweises ist Träger eines implantierbaren Kardioverters/Defibrillators (ICD) mit antibradykarder und antitachykarder Schrittmacherfunktion.

Carte d'identification du patient porteur de DAI

Le possesseur de cette carte est porteur d'un défibrillateur automatique implantable comportant des fonctions stimulateur antibardycardique et antitachycardique.

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Follow-up: An Important Part of Your Therapy

Your first follow-up examination will usually take place one month after the implantation. Your physician will check the set-up of your ICD and make adjustments, if necessary. This does not cause any pain, since the data transfer between the ICD and the programmer is wireless.

Programmer ICS 3000

On the display of the programmer, the physician can see all settings of your ICD, for example, the remaining service life of the battery. Because the ICD stores every therapeutic measure delivered, your physician will know exactly what your heart is doing at the moment an impulse is applied.

- Keep a therapy diary and make a note of every time your ICD applies an impulse. Your physician will be able to compare your notes with the data stored by the ICD for optimal assessment.
- Tell your physician if you believe that you have been receiving unnecessary shocks.

Further follow-ups are conducted at regular intervals. Your physician will let you know when you have your next appointment.

Precautions to Ensure a Long Life with Your ICD

The more confident you feel about living with your ICD, the more it will be able to help you. Therefore, we want to give you our firm assurance that you can always rely on your ICD.

In order to enable the ICD to help you on all accounts, we recommend the following measures:

- Learn what to do when the ICD reacts to ventricular fibrillation.
- Let every physician you consult know that you have an implant.
- Avoid certain electrical devices and processes or employ these only after taking special precautions.

You will see that you need to take far fewer precautions than you might think, and that you will soon adjust to these safety measures.

What to do during ventricular fibrillation and after VF therapy

Be aware that strong arrhythmia can occur at any time and at any place. If it does not stop on its own accord or is not terminated by antitachycardia pacing, then the ICD will deliver a shock impulse in order to bring your heart rhythm back to normal.

If ventricular flutter or fibrillation occurs, take the following precautions:

- Always carry with you the address and phone numbers of your physician and clinic/hospital.
- If tachyarrhythmia becomes imminent (sudden palpitations, dizziness), find a place to sit or lie down. Ask someone to stay with you until the episode is over.
- Ask this person to call the paramedics, should you stay unconscious for more than one minute.

Following therapy for ventricular fibrillation, observe the following:

- Provided that you feel well enough after the episode, there is no need for immediate medical assistance. Even if you experience an episode during the night but still feel well afterwards, it is sufficient to let your physician know the next day.
- You or a relative should inform your physician of each strong pulse delivered by your ICD at the earliest opportunity.
- Describe to your physician what you were doing at the time you received a shock impulse, and how you felt before and afterwards. Also tell your physician if you received a shock impulse but previously felt no noticeable symptoms of arrhythmia.

- Letting your physician know about each shock impulse is important. Your physician can make sure that the device has been appropriately programmed and that it is treating your arrhythmia correctly.
- However, should you receive a series of shocks, or should the symptoms persist, then please call a paramedic or go to a hospital as soon as possible.

Among others, the following medical equipment and technologies should be avoided or used only at the discretion of the physician:

- Magnetic resonance imaging
- Ultrasound and electrical stimulation therapy
- External defibrillation
- High-frequency diathermy
- Radiotherapy
- Lithotripsy (e.g. crushing of kidney stones)
- Electrocautery (obliteration of blood vessels)
- Ablation (obliteration of tissue)
- Hyperbaric oxygen therapy (pressure chamber treatment)

Some ICDs are designed to undergo MR scans under specific conditions. Your ICD patient ID card will indicate if this is the case with your ICD. Please inform your physician of the possibility of undergoing an MR scan.

What to do when you go for medical treatment

Medical technology is progressing all the time, and new medical equipment is constantly being implemented for procedures and treatments. Only your physician can properly assess such new technologies and equipment.

- Let any physician you consult know that you have an ICD.
- Show your ICD patient ID card prior to any kind of treatment so that your physician avoids using any medical equipment that might affect your ICD.

Technical processes and equipment

The ICD is a medical device designed to meet the highest quality and safety standards possible. It has a shield that provides excellent protection against interference from other electrical devices. In order for you to be able to rely on your ICD in every situation, this brochure contains a list of technical processes and equipment that may interfere with ICD functions.

However, do not worry about having to limit the scope of your activities unduly. The technical processes and equipment listed are either hardly ever used in the home or in public areas, or have a low interference potential to begin with.

Beware!

If your job involves dealing with high voltage current or any other kind of complex technology, your place of work may first have to be evaluated for any risks regarding your ICD.

Strong magnetic fields

Avoid environments and situations where you are exposed to strong magnetic fields.

The worst thing that could happen is an interruption of tachyarrhythmia monitoring while you are exposed to strong magnetic fields. As soon as you leave the magnetic field, the functions of the ICD will return to normal.

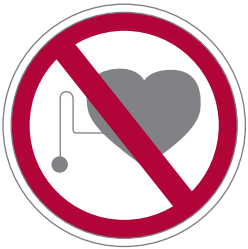
Magnetic fields are especially caused by strong electric currents. You should therefore take precautions when dealing with unfamiliar electrical devices.

You should always keep a safe distance from the following electrical systems or equipment:

- Motor vehicle ignition systems: Always maintain a distance of at least thirty centimeters between the ICD and a running internal combustion engine. The ignition coils operate at very high voltages. However, they only interfere with an ICD at close proximity.
- Loudspeakers: Always maintain a distance of at least thirty centimeters between the ICD and all large loudspeakers.
- Headphones: Keep a distance of at least 3 centimeters between your ICD and headphones such as those of MP3 players.
- Electrically powered tools such as electric drills and cordless electrical screwdrivers: Always maintain a distance of at least thirty centimeters between the ICD and electrically powered tools.

- Amateur and CB radio equipment
- Large-scale radio and TV transmission installations
- Electric welders

Pay attention to manufacturer's instructions that might restrict the use for pacemaker and defibrillator patients and watch out for the following warning sign:



- Prohibited for pacemaker and defibrillator patients

Metal detectors (airports, embassies, etc.)

Metal detectors are used at airports, embassies, and other locations to detect whether someone is carrying dangerous objects. Normally, metal detectors do not affect the functional capability of an ICD. Nevertheless, you should always show your patient ID card to security personnel. You will then be checked using a different method and led around the detector-controlled monitoring area.

Anti-theft devices (department stores, libraries, etc.)

Anti-theft devices, such as those used in department stores, libraries, and other locations, have rarely been known to interfere with the functional capability of an ICD. Nevertheless, such systems possess an interference potential, which may trigger unnecessary therapeutic action.

Take the following precautions:

- Move swiftly past the entry and exit areas of department stores and cashier stations.
- Do not lean on the (sometimes concealed) alarm sensor devices usually installed on both sides of the entry and exit areas.

Mobile and cordless telephones

Reports about electromagnetic interference between mobile/cordless telephones and ICDs are extremely rare. ICDs are sufficiently well shielded against interference due to mobile/cordless telephones.

Nonetheless, please observe the following:

Always hold your mobile/cordless telephone to the ear opposite to the side where the implant is located. Hold the phone at least 15 centimeters away from the ICD.

Some mobile/cordless telephones transmit constant signals as soon as they are switched on, regardless of whether they are being used or not. Therefore, never carry a mobile/cordless telephone in a breast pocket, or attached to a belt within a 15 centimeter radius of the implant. Remember that electromagnetic interference is only temporary. Any such interference will cease, and the functional capabilities of the ICD will return to normal as soon as the mobile/cordless telephone is no longer in the vicinity of the implant.

Christina L., architect from Munich, born 1952

"I got my ICD due to dangerous disturbances in my heart rhythm. The surgeon perfomed a functional test before I left the clinic. That was unpleasant, but afterwards I went home with the confidence that the device was working properly. I felt safe. Now I'm back at work full-time, I play tennis, and I go on vacation twice a year, just as I used to."

A New Lease on Life

You will need time to adjust to a life with an ICD. Most people take about 4 months to learn to lead an active life with an implant. Over time, your initial insecurity and misgivings will subside as you gradually begin to accept the ICD. In fact, most people quickly accept the implant as being a form of life insurance.

An ICD offers you the best chance of surviving a critical episode in an emergency without causing lasting damage to your heart. The ICD is always available and can deliver the right therapy to the correct part of your heart within seconds.

Since ICD patients are less numerous than people with cardiac pacemakers, the implantable defibrillator is still relatively unknown to the general public. This brochure can help you to inform your relatives and friends about your device.

There is no reason why you should have to slow down. The ICD has the best chance of improving your quality of life if it does not occupy your mind all the time. If you ever start to worry about the state of your health, then consider this: you will be able to do things in your life again which would have quite simply been impossible without the ICD.

Overcoming initial psychological setbacks

The intital period after the implantation may not be easy. You will have to learn to accept your device as a part of your body, as an intrinsic element of your life. The physician knows negative emotional reactions to the implant and the disease to be initial problems that are normal.

In the beginning, it may be difficult to be self-confident. Some patients become overly sensitive or even suffer from mild depression.

Some people actually become angry at the implant itself. However, bear in mind that being overly cautious can diminish your ability to enjoy life in the long term.

Negative reactions towards the "foreign object" in your chest shortly after the implantation are normal. In part, they are caused by feeling dependent on the device.

However, surveys on the quality of life experienced by ICD patients have shown that negative reactions of this kind are quite often not really directed at the implant itself. Most often, they are due to the fact that patients are finally coming to terms with their heart problem only after the implantation.

An ICD cannot cure your heart disorder. However, it is a reliable and discreet guardian of your health, and even your life.

Allow yourself to be motivated by the dry words of psychologists that you can look positively to the future:

"A patient can regard his defibrillator as a relatively neutral form of intervention intended to prolong his life while improving its quality, and not as a device on which his whole life should focus in the future." (Herz/Kreislauf 3/97)[1]

[1] Investigations on the quality of life of ICD patients from a medical-psychological point of view. Stankoweit et. al.

Exchanging views and experiences

Many ICD patients welcome the idea of exchanging views and experiences in a support group, where people with similar medical histories can meet. Seeing how others have overcome their initial difficulties and swapping information are a great comfort during the period immediately following the implantation. National heart organizations and some implantation centers both sponsor and support patient organizations of this kind as well as support groups.

"I began to feel more and more secure because the implanted device had successfully dealt with life-threatening heart rhythm disturbances on several occasions. As a result, I realized that I could rely on it completely.

About six months after implantation, I began planning my life again the way I had before. I avoided stressful situations at work and began participating in sports again, such as playing tennis and riding a bicycle.

With the permission of my physician, I can now drive a car again, something I was not allowed to do immediately after the operation.

Now I already have my third device and a new ICD lead. I hardly ever give my ICD any thought and feel quite secure."

Dieter Wetzel, born 1949, ICD patient since 1990

Living a Full Life with an ICD

Depending on your physical abilities and any limitations your physician may advise, you can live a full life provided that you observe a few safety precautions. You can return to your job once you have gotten used to your ICD. Only those few patients whose jobs involve dealing with high voltage or other kinds of complex technology may first have to have their place of work be evaluated for any risks regarding their ICDs.

Driving a car, riding a motorcycle, traveling

Consult your physician as to whether you can drive a car or ride a motorcycle. Normally your physician will advise you not to drive a car for the first six months after the implantation or at least to wait and see how you react to a first shock impulse, after which he will be able to give you further advice.

You may travel freely, but always inform your physician about the duration and type of journey you will be undertaking. Traveling by air, train, or ship poses no problem. If you need addresses of follow-up hospitals and/or physicians either in your country or in foreign countries, e.g. for your vacation, contact

BIOTRONIK
Tel. +49 (0) 30 68905-0
or by e-mail:
patients@biotronik.com

Sports

You can enjoy sports activities such as swimming, sailing, skiing, or cycling after consulting your physician. You should, however, always have somebody accompanying you. The gauge for undertaking sports activities is your overall physical well-being and your physical capabilities and not the fact that you have an ICD. Dangerous sports such as mountain climbing, diving, etc. should be avoided, as tachyarrhythmia can lead to a sudden loss of consciousness, resulting in a dangerous situation, even if someone is with you. Diving is contraindicated due to the high pressures to which the ICD would be exposed.

Swimming, taking a bath or a shower

There are no problems associated with swimming, taking a bath or a shower, as the ICD is hermetically sealed inside your body. The water would not conduct a current, even if a shock impulse occurs. However, you should be aware that you may briefly lose consciousness if an arrhythmia occurs. Therefore, you should only swim when accompanied or where trained lifeguards are on duty and have been informed about your heart condition.

Safety of electrical household appliances

Household activities often involve the use of electrical appliances. Provided that they are in good working order, the following devices will not affect the ICD:

- Electric household appliances
- Radios, TV sets, video equipment, wireless headphones

- Electric blankets
- Ovens, including microwave ovens
- Computers, fax machines, WLAN
- Electric shavers and toothbrushes

Answers to frequently asked questions about the ICD

This section is intended to answer frequently asked questions and address the anxieties often expressed by ICD patients about certain aspects of living with an implant.

We want to help you overcome these anxieties.

Some of the answers will probably sound familiar to you after having read this brochure.

Can other devices cause interference with my ICD?

No electronic appliance except for the programmer used by your physician can change the settings (i.e. the programming) of your ICD. Rarely encountered or easily avoided strong magnetic fields can temporarily interrupt the ICD's ability to monitor tachyarrhythmia.

- Once you are out of range of the magnetic field, the ICD will function normally again.
- Anti-theft devices at departments stores and libraries can cause temporary interference resulting in unnecessary therapeutic measures.
- Move swiftly past the entry and exit areas of department stores and cashier stations. Do not lean on the (sometimes concealed) alarm sensor devices usually installed on both sides of the entry and exit areas.

What will I actually feel of the implanted components of the ICD?

The ICD is located in a skin pocket inside your chest and is visible as a slight elevation. Until you have gotten used to the foreign object in your body, you may be aware of your ICD's presence due to its weight. The leads run underneath your skin from the ICD to the area of your clavicle. They are so thin that you will hardly notice them once your wounds have healed after the operation.

How will I notice the different therapeutic measures delivered by the ICD?

The ICD delivers impulses of varying intensity, according to your requirements. Most arrhythmias can be terminated by weak stimulation, which will pass by unnoticed.

A strong shock impulse is rarely required. In case of severe arrhythmia, most people lose consciousness before the strong shock impulse is delivered and therefore do not feel it. Should you consciously experience a shock impulse, you will feel a sharp blow to the chest with quite intense but brief pain.

Will the ICD cure my heart problem?

Unfortunately, the answer is "no". The ICD cannot cure your heart problem, that is, the cause of your arrhythmia. However, by providing therapy for the arrhythmia, the ICD also provides therapy for the symptoms of your heart problem, allowing you to lead a relatively normal life again without fear of a life-threatening arrhythmia.

Will I still have to take medication once I have an ICD?

This depends entirely on your individual situation, and only your physician can answer this question. Many patients no longer need to take medication all the time after ICD implantation. You may still need to take medication to give your heart some additional support. Medication may also be useful in order to avoid severe arrhythmias and the need for strong shock impulses for a long time, or at least to minimize these. Do not, under any circumstances, make any decisions about your medication on your own. Always follow your physician's instructions.

Can the shock delivered by the ICD be dangerous to another person?

Anybody who is in physical contact with your chest or back when you receive a strong impulse may feel a minor electrical tingling sensation. This is entirely painless and harmless.

People who are informed about your situation will not be frightened by this.

Will the ICD impair my sex life?

There are no restrictions regarding sexual activity. Some ICD patients worry because the heart rate increases during sexual activity. The ICD is programmed to distinguish between a fast heartbeat and tachyarrhythmia.

Will my ICD allow me to die in peace, when the time has come?

Some people are worried that their ICD will not let them die in peace. When a heart no longer has enough strength to continue beating, then no electrical impulse will be able to bring it back to life.

Can I prolong the ICD's service time by taking extra care?

No. In general, the ICD's service time has nothing to do with levels of physical exertion. Being physically active on a regular basis helps decrease the chance of you experiencing a strong arrhythmia.

What is the service time of my ICD, and when will it need to be replaced?

The ICD is equipped with a high-quality, long-lasting battery and has a service time of up to seven years. The more often the ICD is required to apply high-energy impulses, the faster the battery runs out. During your follow-up examinations, your physician will tell how many strong impulses have been delivered and thus determine the battery status. For this reason, keeping your follow-up appointments is a decisive contribution to the reliability of the ICD and can, in effect, save your life.

How is an ICD replaced?

ICD batteries are not replaced. You will receive a brand new ICD before the battery of your ICD is depleted. Your physician will make an incision above the site of the original implantation, remove the old ICD, and replace it with a new one. The leads can usually be kept in place, which is why changing an ICD does not take as long as a first-time implantation.

The Invention of the ICD

A colleague of Prof. M. Mirowski, a U.S. physician, died of sudden cardiac death as a result of ventricular fibrillation in 1967. Prof. Mirowski was deeply affected by the loss of his friend and colleague, and also by the fact that he had not been able to help him. He decided to focus all his efforts on developing a device that would protect people with tachyarrhythmias from sudden cardiac death. This was the birth of the implantable cardioverter-defibrillator (ICD).

In 1980, the first ICD was implanted in the USA. The first implantation in Europe took place in 1984. The technology rapidly improved in the following years. Today, there are hundreds of thousands of people with ICDs throughout the world.

The BIOTRONIK Group

The origins of BIOTRONIK can be traced back to the research activities of the physicist Max Schaldach at the Physical Institute of the Technical University of Berlin. There, the future company founder developed the first German pacemaker.

In 1963, Professor Dr. Schaldach launched the enterprise. Since then, BIOTRONIK has developed into a medical technology company of international significance with research and production facilities all over the world.

Roughly 4,500 highly motivated employees develop and produce systems for bradycardia and tachyarrhythmia therapy, interventional cardiology, and electrophysiology. The long-time experience of the employees, the reliability and efficiency of the products, e.g. pacemakers and implantable defibrillators, have made BIOTRONIK a respected partner for physicians and patients.


BIO

Medical Terms

Antiarrythmic agents: medication to combat rhythm disturbances

Antibradycardia pacing: delivery of electrical impulses to the heart muscle in order to restore a normal heart rhythm (cardiac pacemaker)

Antitachycardia pacing: delivery of electrical impulses to the heart muscle to stop racing of the heart

Arrhythmia: irregular heartbeat

Asystole: cardiac arrest

Atrium: atrial chamber of the heart, i.e. the two upper chambers of the heart. One distinguishes between a left and a right atrium.

Block: temporary or permanent interruption of the electrical conduction within the heart

Bradycardia: abnormally slow heartbeat

Cardiomyopathy: disease affecting the heart muscle

Contraction: contraction of the heart muscle

Coronary arteries: arteries supplying the heart with blood

Defibrillation: delivery of an electrical shock to restore the normal heart rhythm

Diastole: tiring of the heart muscle, brief pause in heart activity

Electrocardiogram (ECG): graph showing electrical heart excitation sequences, on the basis of which a physician can recognize the individual phases of a single heartbeat

Endocardium: inner wall of the heart chambers

Epicardium: outer wall of the heart

Extrasystole: a heartbeat occuring outside the normal rhythm; may trigger racing of the heart or ventricular fibrillation

Hypertension: abnormally high blood pressure

Lead: insulated wire transmitting electrical impulses from the ICD to the heart muscle

Myocardial infarction (heart attack): occurs when an artery that supplies the heart muscle with blood becomes blocked; part of the heart muscle dies off and is replaced by scar tissue

Myocardium: heart muscle

Programmability: ability to change the settings of an ICD using an external device to adapt to individual requirements; possible without surgical intervention

Sinus node: natural cardiac pacemaker cells inside the right atrium

Sinus rhythm: electrical transmission of a pulse which starts in the sinus node, passes through the heart, and is concluded by contraction of the ventricles; is repeated approximately 60 to 80 times a minute

Stimulus: electrical impulse delivered to the heart; causes contraction or terminates tachy-cardia

Syncope: unconsciousness caused by a malfunction of the heart

Systole: contraction of the heart muscle; pumping activity of the heart

Tachycardia: abnormally fast heartbeat, more than 100 heartbeats per minute

Ventricle: chamber in the lower half of the heart

Ventricular: relating to the ventricle