BIOMONITOR III

Cardiac Monitor

Patient Information

Information about the Device

Your physician has recommended you the implantation of a cardiac monitor. It is possible that your heart is beating too fast, too slowly, too infrequently, or too irregularly. The BIOMONITOR III device can record cardiac rhythm disturbances and provide diagnostic data to the physician thus helping in the diagnosis of your illness.

The Device

BIOMONITOR III is a cardiac monitor, which is usually implanted on the left above your heart. The device senses the heart rhythm. If the device detects an abnormality in your heart rhythm, an ECG is recorded and stored. The cardiac monitor monitors your cardiac rhythm around the clock.

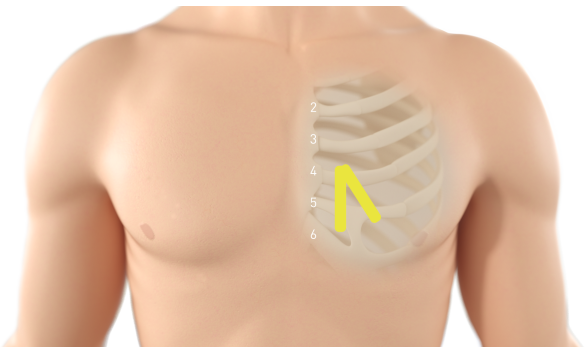

Fig. 1: Schematic diagram of the device in the body.
The device can be inserted in various positions.

Triggering of Recordings using the Remote Assistant III

You may receive a Remote Assistant III after the implantation. Using the Remote Assistant III, you can start the recording of an ECG at the touch of a button. If you experience symptoms such as dizziness and trigger the recording of an ECG, your physician can find a link between your heart rhythms and your symptoms on the basis of this data. Your physician will discuss the exact use of the Remote Assistant III with you.

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Monitoring with Home Monitoring

The data that was recorded and stored by your device must be forwarded to your physician. To ensure that this data transfer takes place quickly and regularly, the device enables monitoring via Home Monitoring. The data of the device is transferred to a transmitter, the CardioMessenger. The transmitter then sends the daily recordings to your physician. Your physician thereby receives information on your heart rhythm, which can help in the diagnosis and targeted treatment of the illness. In addition to this, data about your device, such as the charging status of the battery, is sent to your physician.

Biocompatibility of the Device

The device contains the following materials that come into contact with your body:

- Titanium, iridium
- Silicone

Please inform your physician if you are allergic to any of these substances.

There are no additional material residues that pose a risk after implantation.

After Implantation

Possible Complications

BIOTRONIK has taken steps to minimize any residual risk. In spite of this, the following complications may arise after implantation:

- Foreign body rejection phenomena against the device
- Tissue reaction to the device
- Migration of the device in the body
- Accumulation of fluid in the device pocket
- Transdermal erosion
- Hemorrhage
- Infections

General Behavioral Information for Implanted Patients

The device has been developed in such a way that it does not limit your normal habits. However, since it is an implanted device near your heart, you should follow these instructions:

- Contact your physician in case of any doubts about or problems with your implanted device.
- Carry your patient ID card with you at all times.
- Be careful to avoid any impact on your implanted device.
- Avoid areas marked with the following warning symbol:

- Avoid any pressures above normal levels, such as those exposed to when scuba diving.
- Mobile metal detectors may interfere with your implanted device. Show your patient ID card and ask to be hand-searched.
- Quickly pass through electronic anti-theft alarm systems at storefronts.
- Electrical devices create electromagnetic fields that may interfere with your implanted device. The implanted device is designed to be almost unaffected by electromagnetic fields, though it is impossible to be absolutely sure that it will not be affected. Always follow the instructions of the manufacturer.
- Avoid any work involving electrical welding or exposure to high voltages.
- Stay away from industrial plants that generate strong magnetic fields due to high-energy electrical currents.
- Avoid direct contact with electrical currents. In case you receive an electric shock, check that your implanted device is still functioning correctly.
- Always use and carry yout cellular phone on the side of the body that is opposite of the implanted device.

Follow-up Care

Your physician will call you regularly or as needed for follow-ups. This follow-up care is important to check the state of your implanted device, i.e., to check its effectiveness and remaining service time. In addition, your physician can also decide on further treatment on the basis of these examinations.

Follow-up intervals

Follow-ups must be carried out at regular intervals. The follow-up intervals for you will be set individually by your physician as appropriate.

BIOTRONIK recommends the following intervals:

- Following the ingrowth phase, approximately 3 months after implantation, the first follow-up should be carried out by the physician.
- In-office follow-ups should be carried out once a year, with a maximum interval of 12 months between each meeting.

Follow-up with BIOTRONIK Home Monitoring

The implanted device allows additional monitoring via the Home Monitoring system.

Your physician will decide whether the data provided by the Home Monitoring system is sufficient to make a judgment on your clinical status and on the condition of your implanted device. If the provided data is insufficient, an in-office follow-up must be carried out.

Get in touch with your physician if your symptoms should recur or deteriorate, even if you are using Home Monitoring.

Medical Examinations and Treatments

The use of certain procedures in the medical diagnosis and treatment may lead to damage to the device or pose a risk to the patient. Therefore, certain safety precautions must be observed and implemented here.

Show your patient ID card before undergoing any medical examination or treatment.

Your medical specialists can evaluate whether your device system is suitable for the examination and whether safety measures need to be taken when conducting your treatment.

The following procedures must be avoided:

- Hyperbaric oxygen therapy (high-pressure chamber treatments)

Special precautions should be taken when using the following procedures:

- External defibrillation
- High-frequency surgical procedures such as electrocautery (obliteration of blood vessels) and high-frequency ablation (obliteration of tissue)
- Shortwave and microwave therapy
- Radiation therapy
- Therapeutic ultrasound
- Lithotripsy (kidney stone fragmentation)
- Magnetic resonance imaging

Incidents

In certain circumstances, the data of your implanted device may not be transferred to the CardioMessenger.

- Check whether the distance from the CardioMessenger is too large and reduce the distance.
- Check whether the battery of the CardioMessenger is charged.

If you should detect any anomaly or experience an incident with your implanted device, please inform:

- Your physician
- The manufacturer BIOTRONIK (biotronik.com)
- The Therapeutic Goods Administration (TGA) (tga.gov.au)

Service Time

The service time of the cardiac monitor cannot be determined as a general rule. The exact service time of the implanted device depends on how many recordings have been stored and transferred by your device.

The average service time for the implanted device is 48 months (reference value).

The battery status is transmitted regularly to your physician via the Home Monitoring function or checked during the follow-ups. Your physician will initiate necessary measures towards the end of service.

Validity of this Patient Information Sheet

Please check regularly on the internet for any updated editions of this information sheet at:

biotronik.com/en-au/patients

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