BIOMONITOR IIIm

Cardiac Monitor

Patient Information

Information about the Device

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

The Device

BIOMONITOR IIIm 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.

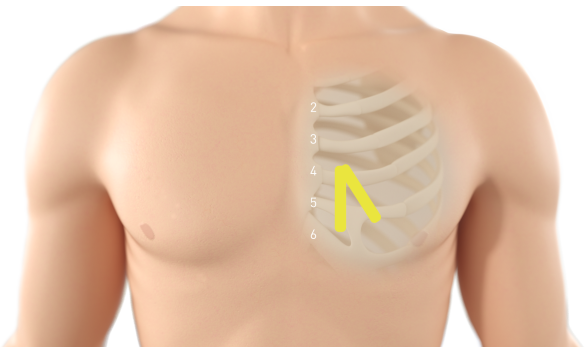

Fig. 1: Schematic diagram of the device in the body.
The device can be inserted in various positions.

Triggering of Recordings using the Remote Assistant III

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

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

Information on How to Behave Directly after the Implantation

In the first weeks after implantation, there is a risk that the implantation scar will get infected.

Please follow the instructions below:

- Do not touch the open implantation site.
- Visit your physician if any of the following anomalies occur:
  - Blood or liquid oozes out of the post-operative scar.
  - The post-operative wound swells up and becomes warm.
  - Fever, chills, or fatigue occur.

General Behavioral Information for Implanted Patients

Overall, the implanted device should not restrict you in your daily activities. However, since it is a device near your heart, you should conduct yourself as follows:

- Contact your physician in case of any doubt about or problems with the implanted device.
- Carry your patient implant card with you at all times.
- Do not move or rotate the device. The movement may detach the device from its intended position and cause it to move within the body.
- Avoid areas marked with the following warning symbol: 
- Magnetic fields may interfere with your device. Do not bring magnets near the device and avoid areas with magnetic fields.

Handling of electrical devices

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.

- Maintain a distance of 15 cm from devices that generate electromagnetic fields.

Follow-up Care

Your physician will call you regularly or as needed for follow-ups. The follow-up is important to check the state of your implanted device, i.e., to check its proper functioning and service time. In addition, your physician can also decide on further treatment based on this follow-up.

Follow-up with BIOTRONIK Home Monitoring

The device system can be remotely monitored by the physician. At BIOTRONIK this function is called Home Monitoring. This allows your medical team to check the state of health of your heart and the condition of the device system continuously, and to identify any anomalies. The data from the device is transferred onto a separate transmitter, the CardioMessenger. The CardioMessenger then sends the encrypted information to your physician.

Your physician will decide whether the data provided by the Home Monitoring system is sufficient to assess your health status and 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 implant 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 during data transfer 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 is 66 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 regularly check the internet for any updated editions of this information sheet at:

  biotronik.com/en-au/patients

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