

## Cardiology

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### Information and patient consent form **Implantation of a Micra transcatheter pacemaker**

Dear patient,

Your doctor has determined, that your pulse is too slow, which caused your symptoms or that it is not possible for you to achieve a rapid pulse with medication without a pacemaker, which is why he advised the implantation of a pacemaker.

#### **The Micra pacemaker system:**

The Micra pacemaker system consists only of the Micra pacemaker, which is about the size of a large vitamin capsule and is implanted directly into your heart. The implantation of a pacemaker electrode is not necessary. A catheter (a long, thin tube) is inserted into a vein in your groin, passes through the bloodstream and placed in your heart. The Micra pacemaker helps your heart beat regularly. A pacemaker electrode that transmits electrical signals is not necessary as the Micra pacemaker is located directly in your heart.



Micra pacemaker (no pacemaker electrode) = the Micra pacemaker system

#### A common pacemaker system

In most common pacemaker systems, a pacemaker (about the size of a tea bag) is implanted under your skin in the upper breast area. During the intervention, a small incision is made in your upper breast area and a pacemaker electrode is inserted into your heart via a vein in your shoulder. The pacemaker-electrode is a small insulated wire that conducts electrical signals from the pacemaker to the heart, helping it to beat regularly.

<u>Standard Pacemaker + Pacing Lead</u>	<u>Micra Pacemaker</u>
	

### **Before implantation of the pacemaker**

You will be first asked questions, after which it will be decided whether you are suitable for an implantation of the Micra Pacemaker. If you are suitable and agree with it, you will be asked to sign this declaration of consent.

### **During the operation**

The surgical procedures for the Micra pacemaker differ from those for other pacemaker systems.

At the beginning of the implantation, your doctor may give you blood thinning medication. A catheter (a long, thin tube) is inserted into a vein in your groin, passes through the bloodstream and placed in your heart. Your doctor will use this catheter to insert the Micra pacemaker into your heart. The implantation of the Micra pacemaker is monitored by fluoroscopy images (similar to X-ray images), while the device is moved through the blood vessels to your heart. Your doctor will take pictures of it. If the doctor finds a suitable location in your heart, the catheter is removed and the Micra pacemaker remains in your heart.

Although you may be awake during the procedure, you will feel only slight pain. Trained Medtronic staff (or staff selected by Medtronic) may be present during implantation or follow-up examinations. With a programming device (an external computer) they communicate with your pacemaker. These activities are carried out under the careful supervision of your doctor. After the implantation procedure, you may experience pain in the groin area where the catheter was inserted and you may have to stay in the hospital for one day or several days.

Your doctor may also choose not to insert the Micra pacemaker if it does not ideally stimulate your heart. In such a case, the doctor will offer you a more suitable alternative treatment method.

It is expected that the battery of the Micra pacemaker lasts about six to ten years. After this time has elapsed, another procedure may be necessary to replace the pacemaker. This applies to you when a Micra pacemaker is implanted and when you receive a pacemaker available on the market that is available for patients who need a pacemaker due to a specific indication. However, scar tissue may be formed around the Micra pacemaker over time, making it difficult to remove it. Your doctor may then decide to leave the Micra pacemaker inserted in your heart, although a new pacemaker would be needed.

The procedure or examination is performed under X-ray radiation. Consequently there is a certain radiation exposure, that however is kept as low as possible. Based on general considerations, in case of pregnancy this kind of examination should only be performed in emergency cases.

### **After the procedure (before discharge from hospital):**

The following measures will be carried out in this examination:

- Checking the device with the programming device and storing the information collected
- Storage of the electrical data of the device
- X-ray examination of the device
- Short walking test in the hallway

### **Potential complications:**

The use of the Micra-pacemaker can lead to undesirable effects, or discomfort.

As with any product, new, previously unknown side effects can occur when using the Micra pacemaker.

Many of the risks associated with the implantation of the Micra pacemaker are the same as those associated with the implantation of usual pacemakers. The general risks and side effects of an operation can also occur.

If you are or become pregnant, you should inform your doctor immediately about it. There may be risks for you and your unborn child that have not yet been researched. Exposure to radiation can lead to miscarriages, birth defects or other unforeseen problems.

### **Space for a sketch / personal notes:**

**Please contact us,**

if you do not understand something or if something seems to be important that was not mentioned in this document or in the personal consultation with your doctor.

**Declaration of consent**

Dr. med. ....

held an informed consent discussion with me. I have understood the information provided to me and could make all the pertinent questions. After sufficient time to think and answering of all my questions I hereby declare myself ready for the proposed therapy. I express my consent for any follow-up procedures that may become necessary.

Signature of patient: \_\_\_\_\_

Signature of doctor: \_\_\_\_\_

Place and date: \_\_\_\_\_

**Consent to data collection and evaluation**

I agree with the collection and analysis of scientific data of my treatment in an encrypted, electronic form. If necessary, the traceability of data for quality assurance is ensured. We assure you with an unrestricted right of access to inspect the data archived about you.

Signature of patient: \_\_\_\_\_

Place and date: \_\_\_\_\_