ASUGI
Azienda Sanitaria Universitaria Giuliano Isontina
REGIONE AUTONOMA FRIULI VENEZIA GIULIA

INFORMATION FOR PATIENTS UNDERGOING PACEMAKER IMPLANTATION (PM)

Azienda Sanitaria Universitaria Giuliano Isontina

PURPOSE OF THE PROCEDURE

The application of a cardiac stimulator, or pacemaker (PM), allows to

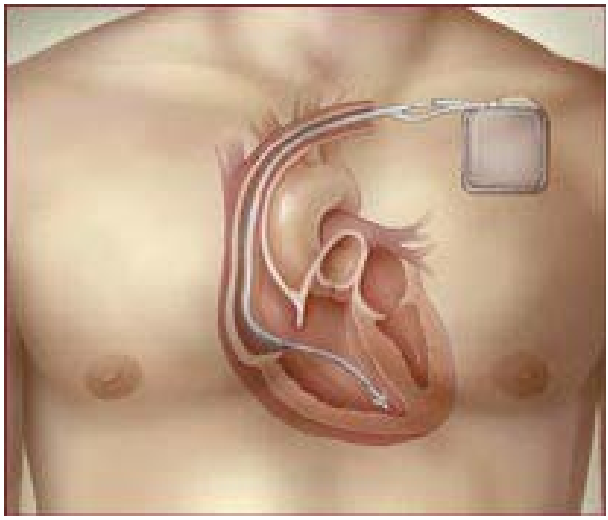
- correct or prevent disorders (fainting, dizziness, asthenia) due to a pathological slowing of the heart rate or
- reduce the risks related to the use of certain medicines necessary for other pathologies (tachycardia, angina, etc.);
- it has no effect on symptoms or pathologies not deriving from the slowing down of cardiac electrical activity.

DESCRIPTION OF THE PROCEDURE

The PM is a small device and consists of a battery and an electronic circuit, connected to the heart through 1 or 2 electrical wires called leads, placed through the venous system.

The operation is performed under local anesthesia and usually lasts between 30 and 90 minutes. Discharge from hospital usually takes place 24 hours after the operation. The operation begins with a skin incision of about 4 - 6 cm, generally under the left clavicle, which serves to prepare a space ("pocket") under the skin for housing the device.

From here the electrocatheters are then inserted through one or more veins and will be positioned inside the heart under radiological control.



Subsequently some electrical measurements are performed, the electrodes are connected to the stimulator and finally some subcutaneous and cutaneous stitches are performed to close the wound.

POSSIBLE COMPLICATIONS

Possible complications of the treatment are divided into intraoperative and postoperative.

The most frequent **intra-operative** complications include pocket bleeding, pneumothorax, coronary sinus lesions, blood effusion in the pericardium, severe arrhythmias (bradycardia or tachycardia). The treatment of these complications can include additional interventions, even invasive, which can prolong the subsequent hospitalization.

Sporadic cases of death during the procedure have been described in medical literature.

The most frequent **post-operative** complications (occurring in the days or weeks following the procedure) include serum-blood effusion in the subcutaneous pocket, erosion of the skin overlying the stimulator or the leads, thrombosis of the arm veins, localized or systemic infections, displacement of the leads from their initial location with the need for repositioning of the same

Incidence of complications are shown below according to data from medical literature (1st column) and in our Center in 2018 (2nd column).

Type of implantation	% in literature data	% in our Center
Atrial/ventricular electrode dislocation	1 - 18%	**3.5%**
Pneumothorax	1,1 – 2.25%	**0.5%**
Pocket hematoma	0.5 – 4.58%	**0.23%**
Infection/decubitus	0.5 – 2.27%	**0.5%**
Pericardial effusion	0.1 – 0.8%	**0 %**
Subclavian vein thrombosis	0.44 – 0.7%	**0 %**
Transient lesion of the cardiac veins	2.5 - 6%	**0%**
Other pocket revision needs (e.g. tenderness without infection)	unknown	**0.5 %**
Patient death		**no one**

Although the devices are subject to very rigorous checks, they can be subject to potential malfunctions (e.g. premature battery discharge, electrode breakage) which make it necessary to replace them. This happens very rarely and interventions are timely, especially in remotely monitored patients.

ALTERNATIVES

I have been explained that THERE ARE NO REASONABLE ALTERNATIVES to this treatment in reducing the risks related to excessive slowing of the heart rate.

AFTER THE PROCEDURE

In general, the period necessary for functional recovery is about 15 days in order to allow adequate healing of the surgical wound; the sutures are removed after about 10 days

After discharge from hospital, it is necessary to follow all the prescribed provisions and treatments; in particular, there are periodic checks (1-2/year) which must be done in our or another electrostimulation center authorized to check PMs. In the event of pain with swelling or redness in the pocket, it is necessary to promptly contact the Pacemaker Clinic; in case of syncope it is essential to immediately go to the nearest Emergency Room.

After the implantation of the PM, exposure to strong magnetic fields, in particular used for diagnosis or therapy, must always be reported, in order to evaluate the feasibility and methods of carrying out the diagnostic test (for example nuclear magnetic resonance) or treatment (magnetotherapy, neuromuscular stimulation).

After the implantation of the PM there may be limitations to driving and sporting activity (transient, or permanent but already justified by the underlying pathology, therefore not due to the presence of the device).

FORESEEABLE OUTCOMES OF NON-TREATMENT

I have been explained that if I decide NOT to have the surgery, I am exposed to the risks related to the excessive slowing of the heart rate (asthenia, dizziness, fainting, sometimes death) or there will be no possibility of using some medicines necessary for other pathologies (tachycardia, angina, etc.).

SCARS

Scars are represented by a surgical scar (4-6 cm long) below the left clavicle; you can also see the swelling caused by the device (about 5 mm thick) at the level of the scar.

SPECIAL WARNINGS

ALLERGY TO IODINE

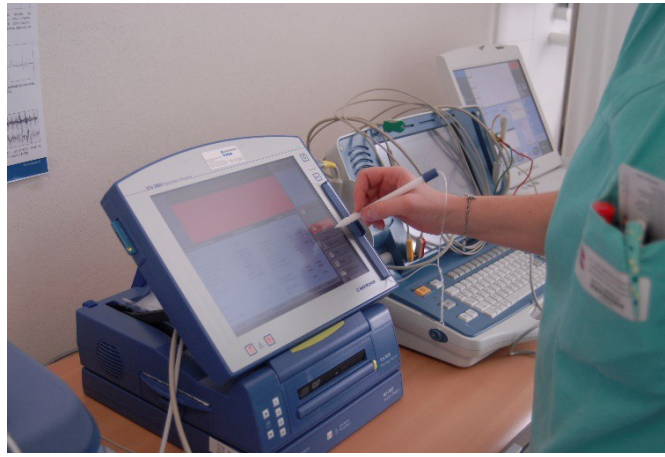
The procedure may include the need to administer a contrast agent containing iodine. Patients with previous allergic episodes following administration of iodine must undergo particular medical treatment (premedication with antihistamines and cortisone) in the previous 24 hours.

ALLERGY TO ANTIBIOTICS

ANTIBIOTICS are given before the procedure and for 24 hours afterward for the prophylaxis of infections. Any allergies to antibiotics must be promptly reported.

PREGNANCY

Due to the use of X-rays, it is necessary to inform the doctors of a possible pregnancy or pregnancy in progress.



A Pacemaker programmer.

THE PROCEDURE WILL BE CARRIED OUT BY ONE OR MORE OF THE FOLLOWING DOCTORS:

- **dr. Massimo Zecchin**
- **dr. Elisabetta Bianco**
- **dr Luca Salvatore**
- **dr. Fulvia Longaro**
- **dr. Cosimo Carriere**

DIAGNOSTIC AND INTERVENTIONAL ELECTROPHYSIOLOGY UNIT
Responsible: dr. M. Zecchin
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Drafted by ASUGI's Communication, External Relations, Press Office, URP on the basis of texts provided by dr. Zecchin of the Cardiolgy Department

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