ASUGI
Azienda Sanitaria Universitaria Giuliano Isontina
REGIONE AUTONOMA FRIULI VENEZIA GIULIA

INFORMATION FOR PATIENTS UNDERGOING REVISION OR REPLACEMENT OF PACEMAKER OR IMPLANTABLE DEFIBRILLATOR

Azienda Sanitaria Universitaria Giuliano Isontina

PURPOSE OF THE PROCEDURE

Revision or replacement of the device is necessary for the following reason:

- low battery charge or malfunctioning
- it is necessary to replace or reposition non-functioning electrodes
- the evolution of the pathology or technological-scientific knowledge suggest the opportunity to modify the stimulation system ("upgrading") by adding electrodes and positioning a different generator
- it is necessary to intervene surgically at the level of the pocket (decubitus plasty, emptying of the hematoma, etc.)

DESCRIPTION OF THE PROCEDURE

The intervention usually lasts between **20-30 min (replacement of generators) to 60-90 minutes (revision/repositioning of the electrodes)**.

Discharge from hospital takes place on the same day in case of generator replacement or pocket revision; after 24 hours in case of replacement/repositioning of the electrodes.

The operation will take place in an operating room, under local anesthesia: the pocket of the generator will be opened and the latter will be disconnected from the connection with the old electrode/s, and replaced with a new device, if necessary. In case of only replacement of the generator or in case of only revision of the surgical wound, the pocket is sutured and you are immediately discharged from hospital.

If the spontaneous heartbeat is too slow during the operation, **it may be**

indicated to apply a temporary pacemaker through a venipuncture (under local anesthesia) in the groin. The temporary stimulator will be removed at the end of the procedure but it will be advisable for you to remain in bed for a few hours to avoid bleeding at the puncture site. In this case you will be discharged from hospital in the late afternoon. If it is necessary to replace a malfunctioning catheter or insert an additional electrode catheter to allow the new generator to best perform its functions (upgrading), a vein must be identified for placement of the lead in the heart, as happened with the previous implantation. These maneuvers will take place under radioscopic control. If the electrode catheters have difficulty advancing inside the vein in the direction of the heart, some contrast agent could be introduced into the circulation.
After verifying the functioning of the system, the wound will be closed with stitches.

POSSIBLE COMPLICATIONS

Possible complications of the treatment are divided into intraoperative and postoperative and are different depending on whether electrodes are positioned/replaced or only the generator pocket is opened.
The most frequent **intra-operative** complications include pocket bleeding and excessive heart slowing before placing the new device; if new leads are placed, the risks are similar to those of a first pacemaker or defibrillator implantation (pneumothorax, coronary sinus lesions in resynchronization devices, blood effusion in the pericardium). 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 after the procedure) include serum-blood effusion in the subcutaneous pocket, erosion of the skin overlying the stimulator or the leads, if new electrodes are placed, also systemic thrombosis of the arm veins, displacement of the leads from their initial location with the need to reposition them.

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

Pocket replacement/revision	**% in literature data**	**% in our Center**
Pocket hematoma	0.5 – 4.58%	**0.23%**
Infection/decubitus	0.5 – 2.27%	**0.5%**
Vascular lesions if it requires stimulation from the femoral vein	0.1	**no one**
Leads addition	**% in literature data**	**% in our Center**
Atrial/ventricular electrode dislocation	1 - 18%	**1.14/3.8%**
Pneumothorax	1.1 – 2.25%	**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%	**3.1%**
Other pocket revision needs (e.g. pain without infection)	unknown	**0.47%**
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 due to low battery charge or suboptimal functioning of the currently implanted device.

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 is still the need for periodic checks (1-2/year) which must be carried out in our or another electrostimulation center authorized for PM control.

In the event of a single discharge from the ICD felt by the patient, the appearance of pain with swelling or redness in the pocket, it is necessary to promptly contact the Pacemaker Clinic; in the event of repeated and/or frequent shocks or syncope, it is essential to immediately contact the nearest Emergency Room.

As after the implantation, exposure to strong magnetic fields, in

particular used for diagnosis or therapy, must always be reported, even after the replacement of the device, in order to evaluate the feasibility and methods of performing the diagnostic test (for example nuclear magnetic resonance) or treatment (magnetotherapy, neuro-muscular stimulation). The presence of unused but not extracted (abandoned) electrodes can further limit the possibility of performing diagnostic investigations (e.g. Magnetic Resonance).

After the replacement, the same driving and sporting activity restrictions apply as before.

FORESEEABLE OUTCOMES OF NON-TREATMENT

I have been explained that if I decide **NOT** to undergo the procedure, I am exposed to the risks related to the

- Device battery running out soon
- The lack of benefits of a replacement of non-functioning or insufficient electrodes for the necessary stimulation system
- The risks related to the non-treatment of the wound that needs revision (for bleeding, hematoma, erosion, etc.)

SCARS

Scars are represented by a further surgical scar, above or near the previous one (4-6 cm long).

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.

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

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

DIAGNOSTIC AND INTERVENTIONAL ELECTROPHYSIOLOGY UNIT
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