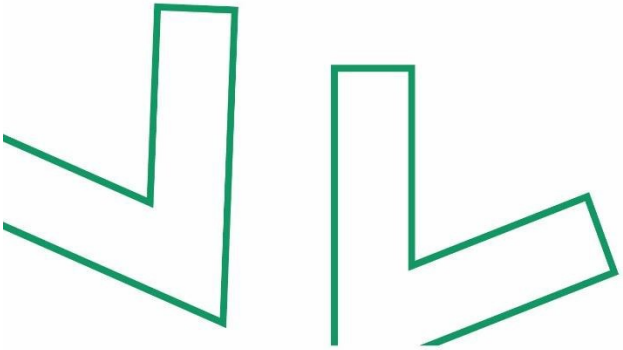
ASUGI
Azienda Sanitaria Universitaria Giuliano Isontina
REGIONE AUTONOMA FRIULI VENEZIA GIULIA

INFORMATION FOR PATIENTS UNDERGOING IMPLANTATION OF TRANSVENOUS IMPLANTABLE DEFIBILLATOR (ICD)



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PURPOSE OF THE PROCEDUR

The defibrillator (Internal Cardioverter-Defibrillator - ICD) is able to treat serious and potentially fatal ventricular arrhythmias (sustained ventricular tachycardia, ventricular fibrillation). If the heart rate slows down, it can also stimulate the heart in the same way as a normal pacemaker.

The ICD is a small device and consists of a battery and an electronic circuit, connected to the heart through 1-2 electric wires (depending on whether it is single-chamber or dual-chamber) called electrocatheters, positioned respectively in the right atrium, in the right ventricle and inside a vein, the coronary sinus, which from the right atrium reaches the external wall of the left ventricle.

The ICD can recognize serious ventricular arrhythmias that can cause sudden death and treat them with:

1) high-energy electric shock, generally used to interrupt more rapid and/or irregular arrhythmias (eg in the case of cardiac arrest due to ventricular fibrillation), perceived as an internal electric shock;

2) brief cardiac stimulation, able to interrupt, in a completely asymptomatic way, less rapid and regular tachycardias.

DESCRIPTION OF THE PROCEDURE

The ICD 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, which are placed through the venous system.

The operation is performed under local anesthesia and usually lasts between 45 and 90 minutes.

Discharge from the 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 collarbone 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.

At the end of the procedure it may be necessary to test the correct functioning of the system, causing a rapid ventricular arrhythmia and verifying that the defibrillator recognizes it and treats it effectively.

In this phase a deep sedation is practiced to avoid unpleasant sensations related to the onset of arrhythmia and the consequent electrical therapy. In this case, a specific informed consent form is delivered for undergoing sedation.

POSSIBLE COMPLICATIONS

The 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 after 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 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).

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**

There is also the risk of inappropriate activation (in particular shocks from the ICD) on arrhythmias that are not really dangerous or not present (e.g. in case of acceleration of the heartbeat to values above normal, non-ventricular arrhythmias, external electromagnetic interference, etc.).

These activations are present in about 10% of patients and can

also be painful, sometimes lead to transient loss of consciousness and require reprogramming of the device (generally without the need for surgery).

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.

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 ICDs.

In the event of a single discharge 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.

After ICD implantation, exposure to strong magnetic fields, especially used for diagnosis or therapy, should always be reported, to assess the feasibility and methods of performing the diagnostic test (for example nuclear magnetic resonance) or treatment (magnetotherapy, neuromuscular stimulation).

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

FORESEEABLE OUTCOMES OF NON-TREATMENT

I have been explained that if I decide **NOT** to undergo the surgery there is no possibility of reducing the risk of sudden death related to my pathology.

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 (10-15 mm thick) at the level of the scar.

SPECIAL WARNINGS

ALLERGY TO IODINE

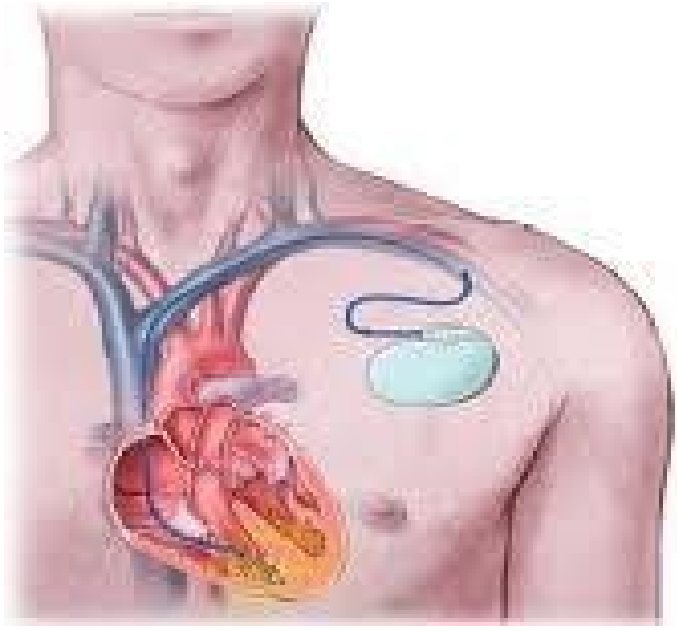
The procedure may include the need to administer a contrast agent containing iodine, not to be used in patients with previous allergic episodes unless after particular medical treatment (pre-medication with antihistamines and cortisone) in the previous 24 hours.

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. Cosimo Carriere**
- **dr. Fulvia Longaro**
- **dr Luca Salvatore**

DIAGNOSTIC AND INTERVENTIONAL ELECTROPHYSIOLOGY UNIT
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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

CARDIOLOGY DEPARTMENT
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Revision 02 November 2022