טופס הסכמה: השתלת קוצב דיפריברילטור

CONSENT FORM: ICD (IMPLANTABLE CARDIOVERTER DEFRIBRILLATOR) IMPLANTATION

Cardioverter defibrillator implantation (hereafter: "the instrument") is intended to protect the patient from rapid rhythm disturbances that are liable to endanger his life.
The implantation consists of the insertion of electrodes through veins into the heart under x-ray guidance, or insertion of electrodes under the skin. The implanted electrodes are connected to a pacemaker under the skin.
During the implantation rhythm disturbances will be caused intentionally, aimed at examining the effectiveness of the instrument. Their cessation by means of electric shock causes discomfort and is liable to be painful.
The treatment is usually carried out under local anesthesia with or without giving a sedative.

Name of Patient: _____ _____ _____ _____
Last Name First Name Father's Name ID No.

I hereby declare and confirm that I received a detailed verbal explanation from:
Dr. _____ _____
Last Name First Name
regarding the need for the **implantation of a cardioverter defibrillator** (hereafter "the primary treatment").
It has been explained to me that in most cases after implantation of the instrument, the appearance of a rhythm disturbances will be avoided.
I hereby declare and confirm that I have received an explanation regarding the side effects of the primary treatment, including: pain and discomfort in the region of the implantation of the instrument, which is liable to disturb movements of the hand on the side of the implantation.

I have also received an explanation regarding the possible risks and complications of the primary treatment including:

- damage to the pleura (covering of the lung) and the possibility of puncture of the lung by a needle, which sometimes requires insertion of a drain into the chest cavity
- perforation of the heart wall that is liable, rarely, to cause significant leakage of blood that will require drainage of the pericardial cavity by needle puncture and sometimes an urgent operation.
- displacement of one of the electrodes that will require a repeat procedure to replace it correctly.
- bleeding at the site of the implant that may sometimes require opening and drainage.
- infection in the region of the procedure that is liable to warrant removal of the appliance and sometimes also prolonged antibiotic treatment.
- falls in blood pressure during the process that are liable to cause reduced blood flow to the brain and rarely damage such as a cerebrovascular accident (CVA).
- deterioration of congestive cardiac failure , including the possibility of pulmonary edema that is liable to require a respirator during or after the procedure.

It has been explained to me that after the implantation , a number of complications over the passage of years related to living with the instrument are possible, including:

- fractures in the electrodes or in their casing that will require repeating the operation.

- technical faults in the instrument itself that are liable, rarely, to lead to the need for its replacement.
- the electric shock given by the instrument is liable to give pain and is liable in certain cases to be given without a rhythm disturbance due to incorrect identification by the instrument.

The frequency of each of the above complications is relatively low. In rare cases these complications are liable to cause death.
I hereby give my consent to perform the primary treatment.
I also hereby declare and confirm that I received an explanation and understand the possibility that during the primary treatment the need to extend or modify it, or perform additional or different procedures, may arise, in order to save my life or prevent physical harm, including additional surgical procedures that cannot be fully or definitely predicted at this time, but whose significance has been made clear to me. I, therefore, also give my consent to such an extension, modification or performance of different or additional procedures, including additional surgical procedures, which the institution's physicians deem essential or necessary during the primary treatment.
I also consent to carrying out local anesthesia and general sedation after I have received an explanation that sedative medications are liable to cause, rarely, disturbances of breathing and of heart function especially in patients with respiratory or heart disease, and the possible risk of an allergic reaction of varying degrees to the local anesthetic substances.
If performance of the examination under general anesthesia is decided on, I will receive an explanation regarding the anesthesia from an anesthesiologist.

I know and agree that the primary treatment and any other procedure will be performed by whoever is designated to do so, according to the institutional procedures and directives, and that there is no guarantee that they will be performed, fully or in part, by a certain person, as long as they are performed according to the institution's standard degree of responsibility and according to the law.

_____ _____ _____
Date Time Patient's Signature

_____ _____
Name of Guardian (Relationship) Guardian's Signature (for incompetent, minor or mentally ill patients)

I hereby confirm that I provided the patient / the patient's guardian* with a detailed verbal explanation of all the abovementioned, as required, and that he/she signed the consent form in my presence after I was convinced that he/she fully understood my explanations.

_____ _____ _____
Name of Physician Physician's Signature License No.

* Cross out irrelevant option.