

## Consent form: Electrophysiological Study (EPS) and RF (Radio Frequency) Ablation or Cryoablation

An electrophysiological study is designed to diagnose various kinds of arrhythmia by inserting a catheter through a blood vessel into the cardiac cavity.

Radio Frequency (RF) Ablation or Cryoablation for the treatment of the aforementioned arrhythmias.

The treatment is generally performed under local anesthesia, with or without administration of a sedative.

Patient's  
name:

\_\_\_\_\_

_____	_____	_____	_____
Last name	First name	Father's name	I.D.

I hereby declare and confirm that I received a detailed oral explanation from Dr.

\_\_\_\_\_  
First name and last name

on the need for an Electrophysiological Study and Radio Frequency Ablation or Cryoablation (Hereinafter: "The Primary Procedure"). I was provided with an explanation that in most cases after **Cryoablation** or **RF Ablation** arrhythmias can be prevented.

I hereby declare and confirm that the side effects of the primary procedure were explained to me, including: pain and discomfort at the catheter insertion site.

Also explained to me were the potential risks and complications of the main treatment, including:

- Vascular damage at the catheter insertion site that might, occasionally, result in surgery to repair the damage.
- Damage to the pleura and/or lung perforation if the catheter is inserted through the chest wall veins.
- Perforation of the heart wall that might, on rare occasions, cause significant blood leaks that could require drainage of the pericardium by insertion of a needle and occasionally even emergency surgery.
- Damage to the cardiac conduction system that might result in the need for a permanent pacemaker.

- Traveling of embolisms from the heart to arteries of various distant organs, with the resulting damage that may require immediate treatment including possible surgery.
- Thermal esophageal injury up to the point of the formation of an atrio-esophageal fistula.
- Cerebrovascular accident or brain hemorrhage.
- Damage to the phrenic nerve up to the point of permanent paralysis (phrenic nerve palsy) that can be manifested by shortness of breath, cough, hiccups and chest pain.
- In the case of pulmonary vein ablation, the result might be the occurrence of pulmonary vein stenosis and subsequent chronic damage to the lungs manifested by shortness of breath that might lead to a permanent respiratory disability. This complication might require additional interventions to the pulmonary veins, such as stent implantation and, on rare occasions, pulmonary surgery.

The incidence of each of these complications is relatively low. On extremely rare occasions, these complications may result in death.

I am hereby granting my consent to the primary procedure.

I was informed and I understand that there is a possibility that the scope of the primary procedure might need to be expanded, changed or that other or additional life-saving measures might need to be adopted or aimed to avoiding physical injury, including additional therapeutic actions that cannot be anticipated with certainty or in full, but the significance of which has been clarified to me. As such, I am hereby granting consent to said expansion, change or performance of other or additional procedures, including therapeutic procedures that the hospital doctors believe are necessary or required in the course of the primary procedure.

My consent is hereby granted for the administration of local anesthesia with or without an intravenous injection of sedatives after having received an explanation of the risks and complications of local anesthesia, including varying degrees of allergic reaction to the anesthetics and possible complications of use of sedatives that might, on rare occasions, cause respiratory disorders and disruptions in heart activity, particularly among cardiac patients and patients with respiratory system disorders.

If the decision is made to perform the primary procedure under general anesthesia, I will be given an appropriate explanation of the anesthesia by an anesthesiologist.

I know and agree that the primary intervention and all major procedures will be carried out by the person assigned for this purpose, in accordance with the hospital procedures and instructions, and I was not guaranteed that all or some of the procedures will be performed by a certain person, and pursuant to the procedures being performed with the standard liability of the hospital subject to law, and that the person in charge of surgery will be Dr.:

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First name and last name

Consent remark : \_\_\_\_\_

Site of the consent discussion : \_\_\_\_\_

Persons present during the discussion: \_\_\_\_\_

_____	_____	<b>X</b>
Date	Time	Signature
_____	_____	_____
Guardian's name	Guardian's proximity	Guardian's signature (if the patient is legally incompetent, a minor or mentally ill)

I hereby confirm that I provided an oral explanation to the patient / guardian of the Patient\* about all of the specified above in appropriate detail and that he/she signed the consent before me after I have been convinced that he/she fully understood the explanation.

_____	_____	_____
Physician's name	Physician's signature and stamp	License No.
_____	_____	_____

- Delete the inappropriate