Informed Consent Form

Official Study Title:

Electronic Device Implantation Through Remote Guidance

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INFORMED CONSENT FORM

Informed consent form for participation in the research project " Electronic Device Implantation Through Remote Guidance"

• PURPOSE OF THE STUDY: Implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) are essential tools for managing patients at risk of life-threatening arrhythmias and heart failure. This study aims to evaluate the feasibility and safety of performing these implantations under remote guidance by a biomedical engineer (Field Clinical Specialist - FCS) through a dedicated telemedicine system. The main objectives are: to compare the procedural duration and outcomes between remote and standard FCS support; to assess any differences in fluoroscopy time, device functionality, and adverse events; and to confirm the reliability of device parameters at follow-up.

• PROCEDURES: This is a prospective, randomized pilot study conducted at the “Magna Graecia” University and at University Hospital "Annunziata" of Cosenza. Patients undergoing ICD or CRT-D implantation will be randomly assigned to a procedure with an on-site or remote FCS. The procedure will follow standard protocols, with real-time audiovisual communication guiding the steps of device implantation and programming. There are no additional risks to patients compared to standard procedures.

• CONFIDENTIALITY: Data will be processed in accordance with Article 13 of EU Regulation 2016/679 (GDPR) and the relevant Italian legislation. The Data Controller is the Cardiology Department of the University of Calabria. All data will be collected anonymously and used exclusively for scientific research purposes. Participant anonymity will be ensured by restricting data access to authorized research staff only.

• VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW: Participation in this study is entirely voluntary. You have the right to refuse participation or withdraw at any time without giving any reason. There will be no consequences for your medical care.

• DISSEMINATION OF RESULTS: The results of this study will be published in scientific journals and/or presented at national and international conferences. At the end of the study, participants may request access to study results from the investigators or attend a dedicated dissemination session.

• ETHICS COMMITTEE APPROVAL: This study has been approved by the Ethics Committee of the Cardiology Department of the University of Calabria.

By signing this form, I declare:

- That I have read this document carefully;

- That I have been informed about the purpose and objectives of the study;

- That I have had the opportunity to ask questions and received clear answers;

- That I have received sufficient guarantees on the confidentiality of the information collected during the study;

- That I am aware I can withdraw at any time;

- That I freely give my consent to participate in this study.

Date: _____ Participant's signature: _____

I, the undersigned, declare:

- That I have received complete and clear information and understood the information sheet;

- That I have had the opportunity to ask questions and received satisfactory answers;

I acknowledge that:

- Participation in the study is entirely voluntary;

- I am free to withdraw at any time without justification;

- The study has been approved by the Ethics Committee;

- Data will be handled in compliance with EU Regulation No. 679/2016.

Therefore, I DECLARE:

☐ I wish to participate in the study ☐ I do not wish to participate in the study

_____ _____ _____

Full name in block letters | Participant's signature | Date

_____ _____ _____

Impartial witness (if applicable) | Participant's signature | Date

(only if the patient is unable to write)

DECLARATION OF THE INVESTIGATOR ENROLLING THE PATIENT

I declare that I have provided the patient with full and detailed explanations regarding the nature, objectives, procedures, and duration of the study.

I also declare that I have given the patient the information sheet and a signed and dated copy of this Informed Consent Form.

_____ _____ _____

Investigator's full name (block letters) | Signature | Date