ELECTRA

5-6 DÉCEMBRE 2024

HOTEL VILLA MASSALIA,
MARSEILLE I FRANCE

18èmes journées françaises
pratiques de rythmologie
& de stimulation cardiaque

WWW.CONGRES-ELECTRA.COM

2004 - 2024
20 ans
ELECTRA

Futur de la stimulation cardiaque

J Taieb

Centre Hospitalier du Pays d'Aix

Liens d’interet

Sponsoring Abott, Boston, Biotronik, Medtronic, Microport


FUTURE
PRESENT


La meilleure façon
de prédire l'avenir,
c'est de l'inventer
ABRAHAM LINCOLN

Avancées récentes

PMK + Sonde: Physiologique

Médecins => industriel

VD
OD VD
Sinus coronaire
Voies de conduction : his, branches gauche

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PMK sans sonde: Ergonomique

Industriels => médecins

- Miniaturisation capsule VVI
- KT+ Fixation intracardiaque

Direction

PMK + Sonde: Physiologique

Médecins => industriel

VD
OD VD
Sinus coronaire
Voies de conduction : his, branches gauche

Faciliter la stimulation physiologique

PMK sans sonde: Ergonomique

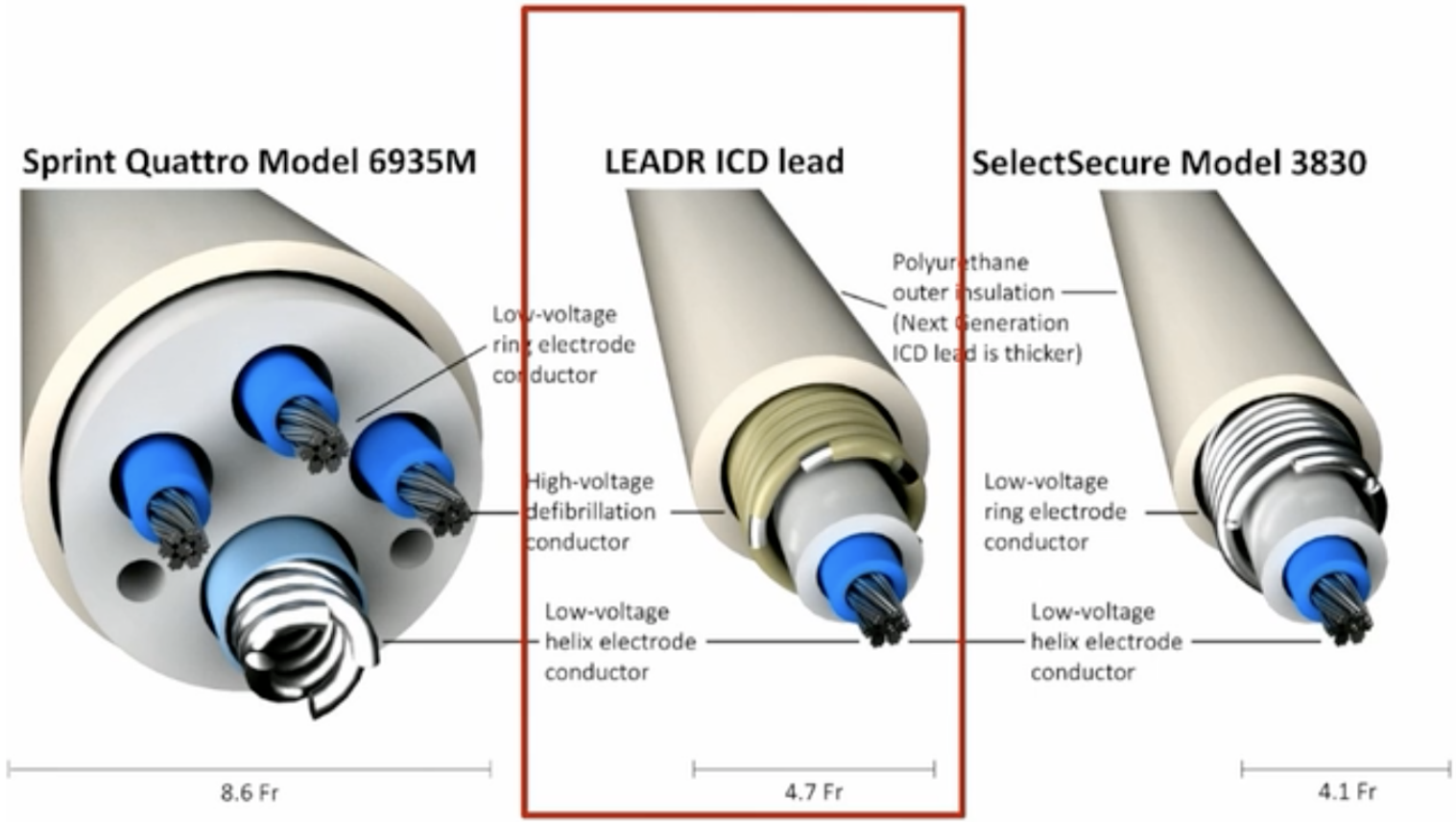
Industriels => médecins

- Miniaturisation capsule VVI
- KT+ Fixation intracardiaque

Coupler à stimulation physiologique A, VD, VG

stimulation physiologique pour tous

Lumenless ICD lead



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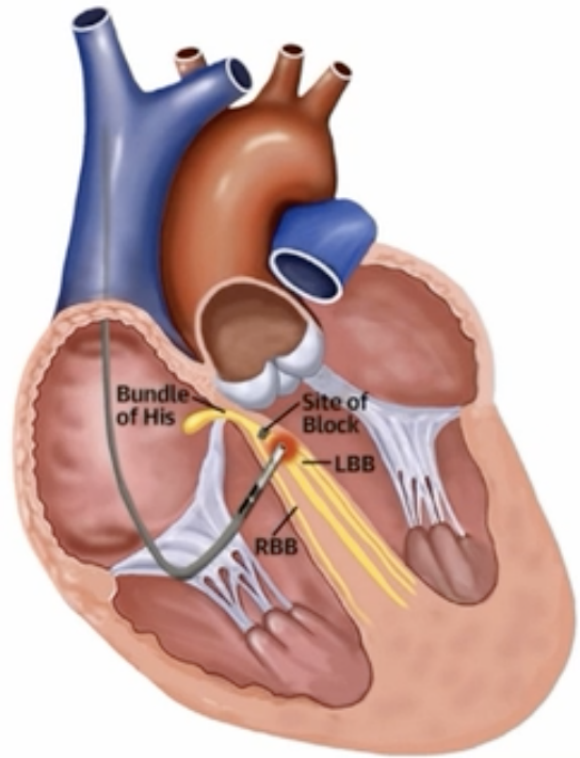


NIH U.S. National Library of Medicine

ClinicalTrials.gov

LEADR study

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	500 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	**Lead** EvaluAtion for Defibrillation and Reliability (LEADR)
Actual Study Start Date :	June 21, 2021
Estimated Primary Completion Date :	December 30, 2023
Estimated Study Completion Date :	April 30, 2024

Recruiting

Lead EvaluAtion for Defibrillation and Reliability (LEADR) / Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing (LEADR LBBAP)

ClinicalTrials.gov ID NCT04863664

Sponsor Medtronic Cardiac Rhythm and Heart Failure

Information provided by Medtronic Cardiac Rhythm and Heart Failure (Responsible Party)

Last Update Posted 2024-11-27

Study Overview

Brief Summary

The **LEADR** study is designed to assess the safety and efficacy of the Next Generation ICD lead.

The **LEADR LBBAP** study is being conducted under the existing US FDA Investigational Device Exemption (IDE) for the Next Generation ICD Lead and is designed to confirm the safety and defibrillation efficacy of the Next Generation ICD Lead when placed in the **LBBAP** location in ICD and LOT-CRT patient population.

Detailed Description

The LEADR and LEADR LBBAP studies will enroll subjects who are indicated to receive an implantable single or dual chamber ICD, or CRT-D, and who meet all of the inclusion criteria and none of the exclusion criteria. Subjects will receive an investigational Next Generation ICD Lead. Subjects in the LEADR study will be followed for at least 18 months following Next Generation ICD Lead implantation in a septal (non-LBBAP) or apical implant location. Enrollment in the LEADR study has been completed (675 subjects enrolled). Subjects in the LEADR LBBAP study will be followed for at least 3 months (ICD-indicated subjects) or 6 months (CRT-indicated subjects) following Next Generation ICD Lead implantation in an LBBAP implant location.

— Show less

Official Title

Lead EvaluAtion for Defibrillation and Reliability (**LEADR**) / Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing (**LEADR LBBAP**)

Study Start (Actual)
2021-06-21

Primary Completion (Estimated)
2025-07-31

Study Completion (Estimated)
2027-11-30

Enrollment (Estimated)
975

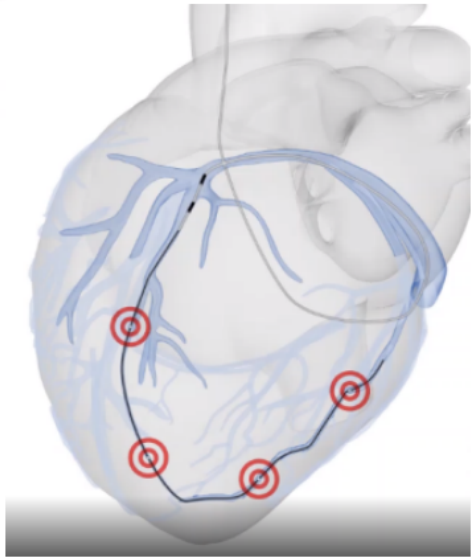
Study Type
Interventional

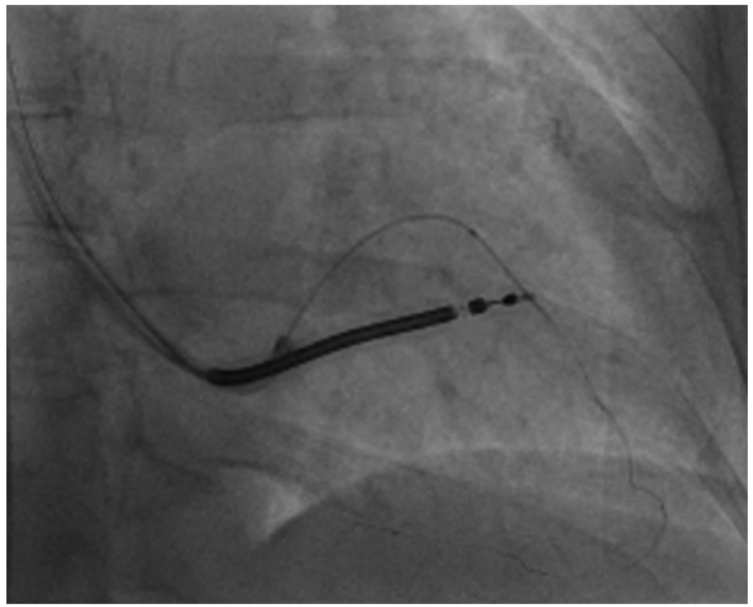
Phase
Not Applicable

AXONE lead (Microport)

Quadripolar ultrathin LV lead (1,2F) guided by a micro-catheter to navigate through very thin coronary veins, giving more options for pacing sites, and allowing multiple zone pacing.

Axone diameter
0.4 mm / 1.2 Fr





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ClinicalTrials.gov

ASTRAL 4LV

Detailed Description:

This is a interventional, pivotal, prospective, single arm, open label, multicenter, international trial.

The device under investigation is the Axone system, consisting of:

- Axone 4LV: an ultrathin, lumenless, quadripolar, IS4-compatible lead designed for left ventricular pacing for cardiac resynchronization therapy (CRT).
- Axone µGuide: a dedicated, permanently implantable micro catheter designed for implantation of the Axone 4LV lead.

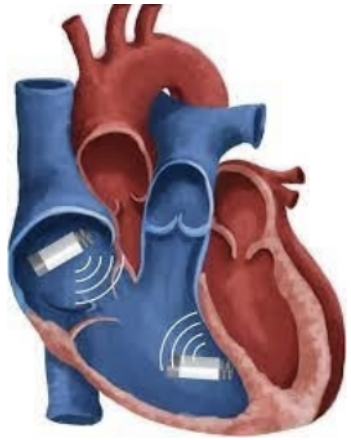
The primary endpoint data will be used to support CE marking of the Axone system.

The primary endpoints will be evaluated at 6 months post-implantation. Subjects will be followed-up at 6 weeks, 3 months, 6 months, 12 months post-implantation, then yearly until 4 years post-implantation.

Study Design Go to

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	152 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Assessment of the Axone Micro Quadripolar Lead for Enhanced Cardiac Resynchronization Therapy
Actual Study Start Date :	December 3, 2020
Estimated Primary Completion Date :	July 2022
Estimated Study Completion Date :	December 2025

Aveir DR



i2i (implant to implant) communication

CAUTION: The Aveir™ DR dual-chamber leadless pacemaker is an investigational device limited by Federal (U.S.) local law and Medical Device Regulation for investigational use only.

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ClinicalTrials.gov

Aveir DR i2i IDE Study

The purpose of this clinical investigation is to evaluate the clinical safety and effectiveness of the Aveir DR Leadless Pacemaker system in a patient population indicated for a DDD(R) pacemaker.

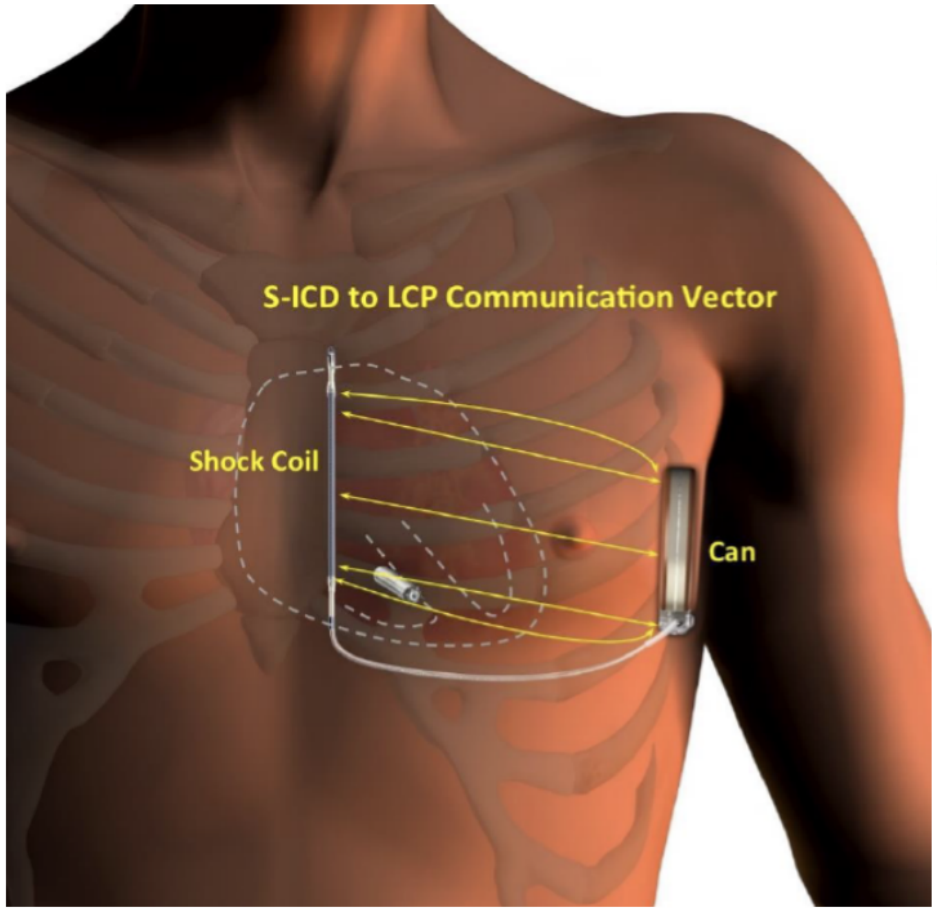
Subjects participating in the study are followed through at least 12 months with data collected at baseline, implant procedure, pre (hospital) discharge, and follow-up at 1 month, 3 months, 6 months, 12 months, and every 6 months thereafter until study completion

Study Design

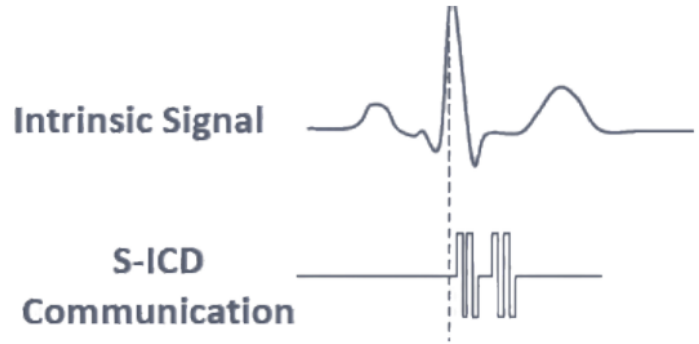
Go to

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	550 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Intervention Model Description:	Prospective, multi-center, international, single-arm, pivotal investigational study
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Aveir Dual-Chamber Leadless **i2i** IDE Study
Actual Study Start Date :	February 3, 2022
Estimated Primary Completion Date :	November 2023
Estimated Study Completion Date :	November 2025

Modular CRM (mCRM)



- All EMBLEM™ S-ICDs can be upgraded and paired with EMPOWER™
- Utilizes existing morphology-based S-ICD algorithms
- Uni-directional device-device communication from S-ICD → LP
- Specific conductive communication protocol



- Coupled to R-wave
- Voltage and pulse width similar to existing lead impedance measurement
- Built-in redundancy

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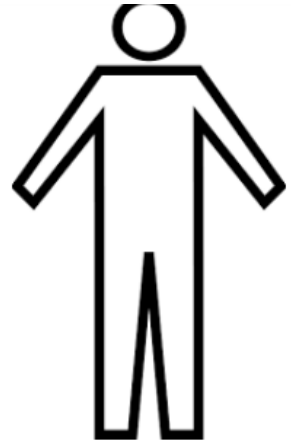
Modular ATP study



Detailed Description:

The MODULAR ATP Clinical Study will enroll subjects with a standard Implantable Cardioverter Defibrillator (ICD) indication applying international practice guidelines, as well as those who already have an implanted S-ICD System and satisfy the inclusion criteria for this study, while not meeting any exclusion criteria. Subjects will be followed for at least 6 months following mCRM Therapy System implantation.

Study Design Go to

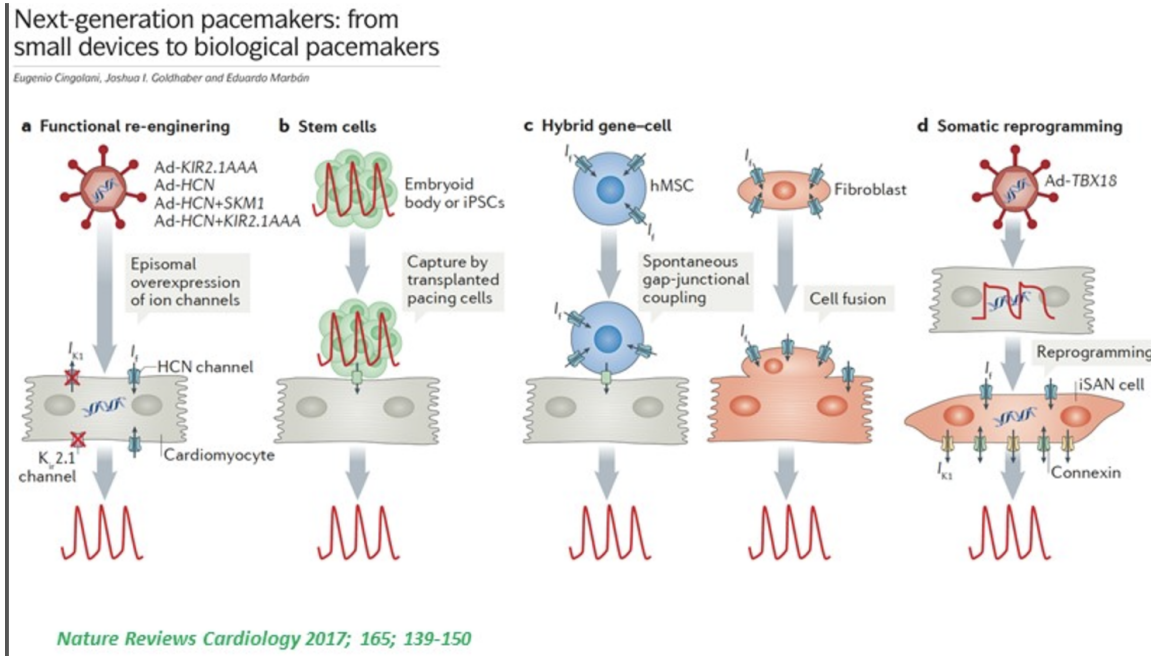
Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	300 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Effectiveness of the EMPOWER™ **Modular** Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing
Actual Study Start Date :	November 30, 2021
Estimated Primary Completion Date :	January 31, 2023
Estimated Study Completion Date :	December 31, 2028

Endpoints: safety, electrical parameters, AV synchrony

Pacemaker biologique

- **Biostimulation**
  - cellules souches => cellule cardiaque
  - transduction du gène Tbx18: converti myocytes atriaux en cellules nodales sino-atriales
  - Régénération cellulaire: protéines recombinantes d'ARN modifiés ou de facteurs de croissance

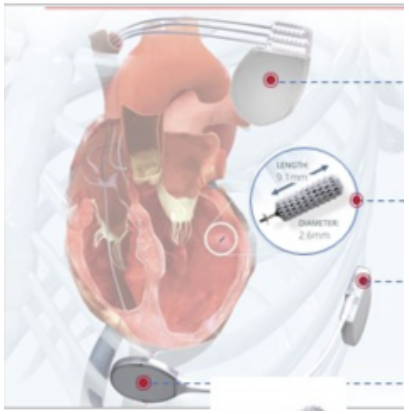
- **Optogénétique**
  - lumière pour contrôler l'activité des cellules modifiées génétiquement



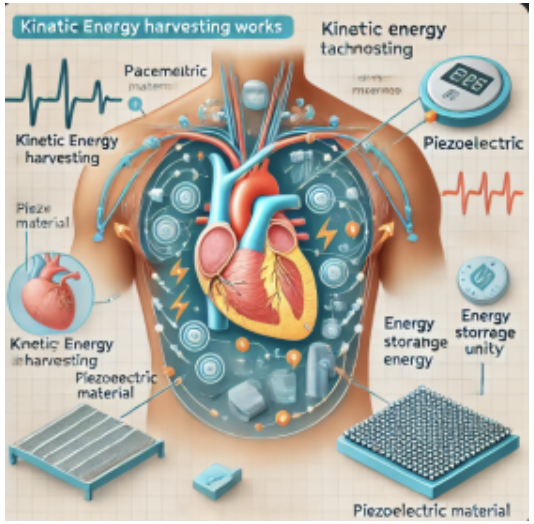
Intelligence artificielle

- Prédiction FA ou TV et ajuster la stimulation pour prévenir ces épisodes+ alerte
- Identification de FA « maligne » à risque thrombogène (fréquence, régularité, morphologie, charge…)
- Analyse fine des signaux (amplitude => forme) : distinguer onde T, onde P, farfield
- Analyse de données capteurs électriques, mécaniques… biologiques ?

Energie



- Isotopique -> lithium
- Le rechargement par induction transcutanée (idem smartphone)
- récupération d'énergie cinétique du corps : harvesting energy
  - la société française **Cairdac** a développé l'**ALPS™** (Autonomous Leadless Pacing System), un pacemaker sans sonde qui utilise une technologie de récupération d'énergie générée par les battements du cœur
  - Intérêt: taille, durée ..
  - Problèmes: stockage, repos, hybride ?



PRESS RELEASE

Mar 31, 2022

CAIRDAC raises €17m to finance the development of ALPS™ the first SELF-SUSTAINABLE LEADLESS PACEMAKER

Elvira-Hernández EA, Romero-García J, Ledezma-Pérez A, et al. Synthesis of ZnO Nanorod Film Deposited by Spraying with Application for Flexible Piezoelectric Energy Harvesting Microdevices. Sensors (Basel) 2020;20:6759.
Gruenwald W, Bhattacharrya M, Jansen D, et al. Electromagnetic Analysis, Characterization and Discussion of Inductive Transmission Parameters for Titanium Based Housing Materials in Active Medical Implantable Devices. Materials (Basel) 2018;11:2089.

Télésurveillance avancée

Nouvelles energies + 5G, les pacemakers => données **en temps réel via smartphone**

L'IA pourrait **anticiper** en analysant des tendances subtiles et alerter

INTERFERENCES

- Filtres avancés et algorithmes de détection qui isolent les fréquences de communication problématiques.
- Adaptation aux interferences par IA
- Protection renforcée pour IRM plus puissante

Vinci va tester des autoroutes rechargeables sur un tronçon de 2 km de l'A10, avec des travaux débutant en novembre 2024

Les normes de protection des pacemakers contre les interférences électromagnétiques (CEM)

Norme ISO 14117 : Protection contre les interférences électromagnétiques

Norme ISO 14708-1 : Exigences générales pour les dispositifs médicaux implantables actifs

Norme IEC 60601-1-2 : Compatibilité électromagnétique pour les dispositifs médicaux

ANSI/AAMI PC69** - Recommandations spécifiques pour les pacemakers et défibrillateurs implantables face aux interférences avec les équipements électriques.

EEE C95.1** - Norme pour la sécurité des expositions humaines aux champs électromagnétiques, spécifiquement dans les applications médicales.

Conclusion

La stimulation du futur devrait etre

- Physiologique et sans sonde
- IA
- PMK biologique
- Telesurveillance
- Energie
- Interferences… normes

…Rôle de l’economie

FIN