Preliminary Results from the Early Feasibility Study of the FIRE1 System in Heart Failure Patients

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CRF THT

Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Abbott, Abiomed
Medical Advisory Board	Leviticus, Livemetric, Revamp

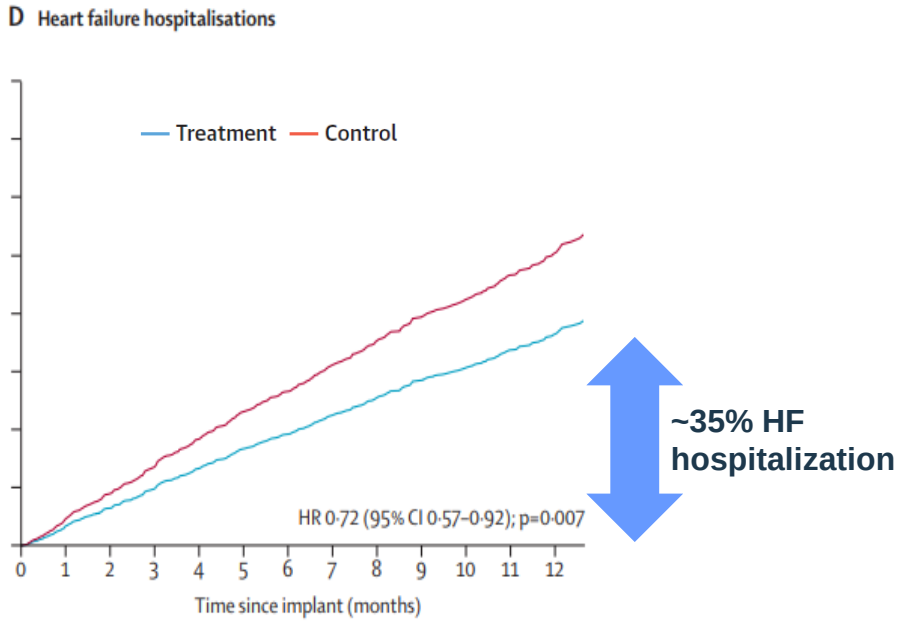
All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

The FIRE1™ System is investigational, not approved in the US. The following data and analyses have not been reviewed by any regulatory bodies, including FDA.

Introduction

- Heart failure affects approximately 6.2 million adults in the United States.
- Despite advancements in treatment, heart failure remains a leading cause of morbidity and mortality, contributing to 1 in 9 deaths in the US.
- Invasive hemodynamic monitoring has been shown to decrease decompensations and improve quality of life, however heart failure hospitalizations remain high.

*Statistics from American Heart Association, Centers for Disease Control and Prevention 2023



Lindenfeld, Lancet 2021

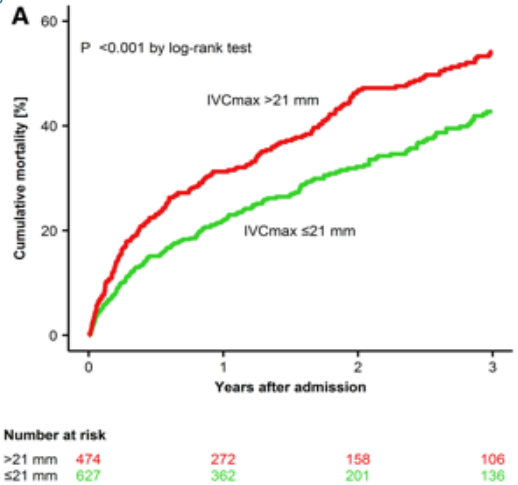
To manage volume you need to measure volume
The best place to measure volume….

Why the Inferior Vena Cava (IVC)?

- 70% of blood is in the veins – most of it in the veins of the abdomen
- Largest vein in the body
- Returns majority of the blood to the heart
- The intravascular storage vessels (e.g. splanchnic veins) feed into the IVC
- Is a compliant vessel that buffers volume changes to maintain cardiac preload
- Already in Echo guidelines and used in the ICU

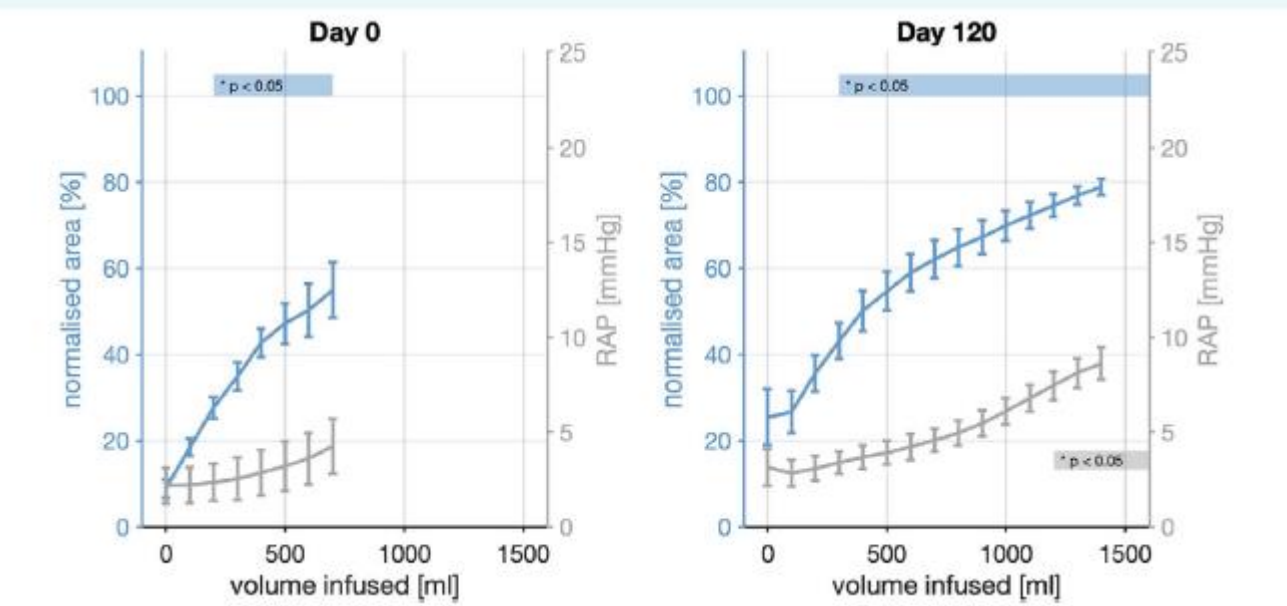
Large IVC diameters are prognostic in HF

Acute HF (n=1101)[1]



Jobs et al., Heart Vessels (2017)

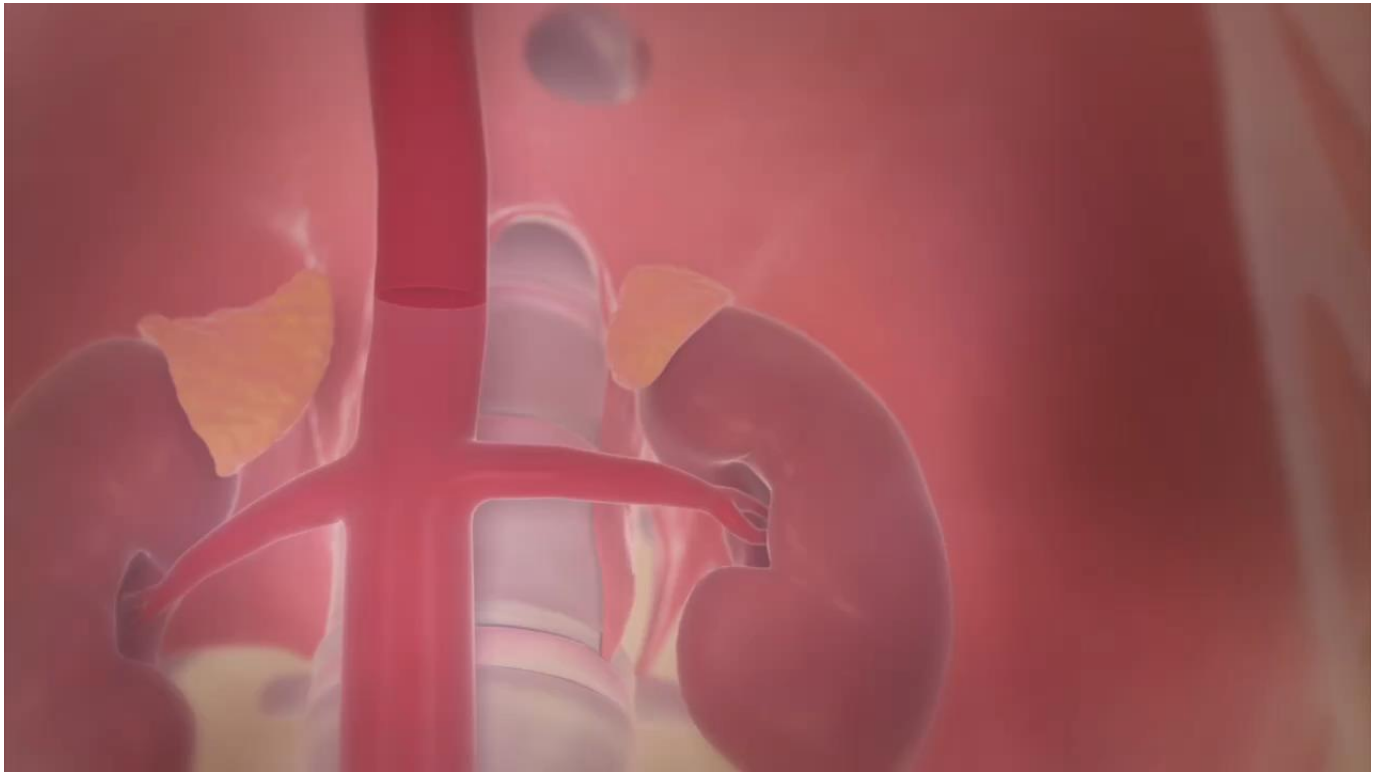
Volume more sensitive than pressure



Change in normalized mean area of the inferior vena cava (blue) occurs earlier than change in right atrial pressure (grey) as a function of infused volume in animal studies

Sheridan, EJHF 2023

FIRE1 System



FUTURE-HF2 Study Design

FUTURE-HF2: prospective, single arm, open label, multi-center EFS of the FIRE1™ System

15 Subjects	**5** Centers

Key Inclusion Criteria

- Adults 18 years or older
- HF hospitalization within prior 12 months
- NT-proBNP >1000pg/ml
- Daily oral loop diuretic 40mg furosemide eq.

Key Exclusion Criteria

- GFR <25 ml/min/1.73m^2
- NYHA Class IV
- Severe tricuspid regurgitation or mechanical valve
- Invasive cardiac surgery or percutaneous intervention in previous 3 months
- LVAD or heart transplantation

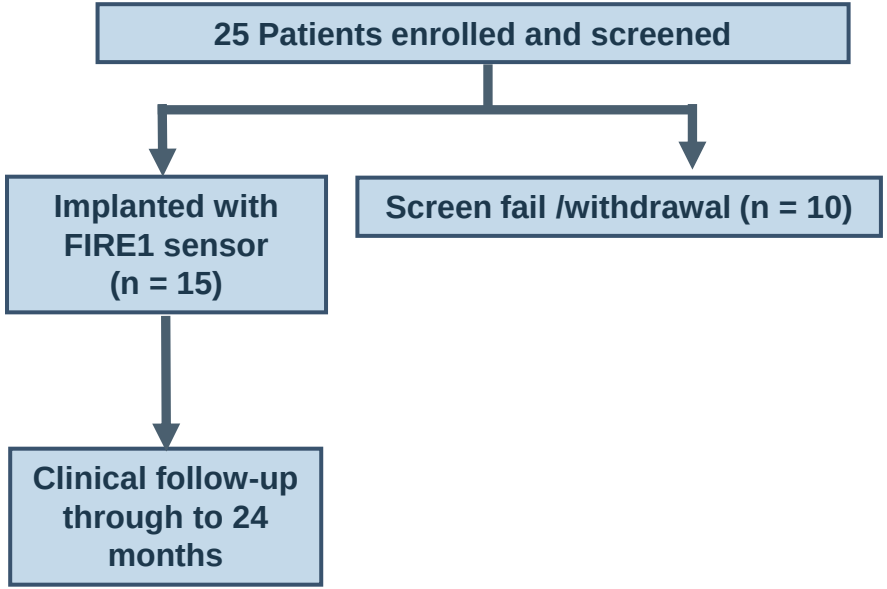
All eligible patients are implanted using standard interventional techniques with the FIRE1 ™ Sensor as outpatient procedure, provided with equipment for home readings, and the clinicians have access to patient sensor data in the cloud based system

FUTURE-HF2 Study Design

Objective

- Evaluate the safety of the FIRE1™ Sensor
- Assess performance of the sensor to provide a signal to healthcare team
- Assess the FIRE1™ System including the Monitoring Algorithm & medical management protocol

Patient Flow Diagram



Primary Endpoints

Primary Safety Endpoints (30 days and 3 months)

1. Procedural success defined as Sensor deployment at the intended site without procedural related SAEs (30 days)
2. Freedom from Sensor complications including device migration, clinically significant fracture and/or clinically significant perforation of the IVC or symptomatic caval thrombosis (3 months)

Primary Effectiveness Endpoint (3 months)

1. Device performance defined as an assessment of the ability of the FIRE1™ System to successfully transmit collected data to a secure database (3 months)

All primary safety endpoint events were adjudicated by an independent clinical events committee

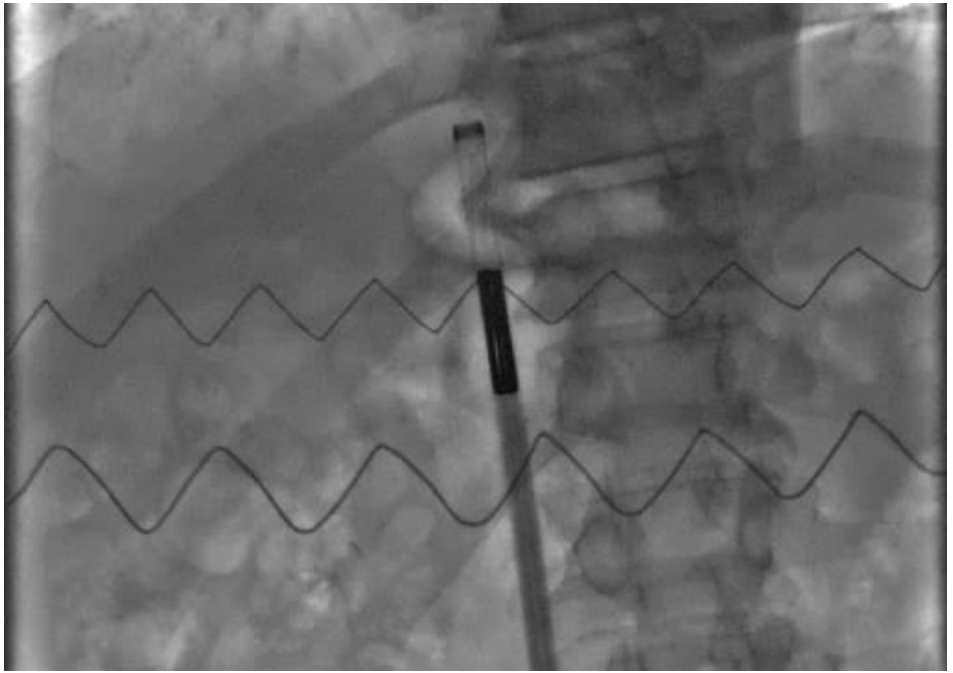
Results: Patient Demographics

Demographics	N = 15
Age (years ± SD)	65.8 ± 12.3
Sex (female, %)	**46.7**
Ethnicity (Hispanic or Latino %)	20
Race (Black or African American %)	20
Body Mass Index (Kg/m² ± SD)	33.2 ± 8.1
Medical History	
# of Heart Failure Hospitalisation in Previous Year (mean ± SD)	**2.5 ± 1.5**
Heart Failure of Dilated Aetiology (%)	40
Primary HF Type - HFrEF (%)	**73.3**
Diabetes (%)	66.6
Arrhythmia (%)	53.3
Stroke (%)	13.3
Hypertension (%)	86.6
Vital Signs and hemodynamic analyses	
Systolic Pressure (mmHg ± SD))	116.7 ± 14.2
Diastolic Pressure (mmHg ± SD)	64.2 ± 11.5
RAP (mmHg ± SD)	14.2 + 5.7
Left Ventricular Ejection Fraction (% mean ± SD)	38.8 ± 17.7
Laboratory	
Serum Creatinine (µMol/L ± SD)	1.73 ± 0.49
Estimated Glomerular Filtration Rate (mL/min/1.73 m² ± SD)	37.2 + 11.9
N-Terminal Pro-Brain Natriuretic Peptide (ng/L ± SD)	**4540.6 ± 4644.0**
Heart Failure Medication	
Beta-Blocker (%)	86.7
Angiotensin-Converting Enzyme Inhibitor (%)	6.7
Angiotensin Receptor-Neprilysin Inhibitor (%)	53.3
Aldosterone Inhibitor (%)	46.7
Sodium-Glucose Co-Transporter 2 Inhibitor (%)	73.3
Diuretics (%)	**100.00**
Functional Class	
New York Heart Association Functional Class III (%)	**86.7**

Implant Procedure

100% patient procedures utilized:
- Right Heart Cath (RHC)
- Conscious sedation

85% patients implanted as day procedure
- 2 patients (15%) were admitted for IV diuresis and then later successfully discharged home



Primary Safety Endpoint Result

1. Primary safety endpoint (30 days)	Percentage with successful primary safety result (N = 14)
Sensor deployment at the intended site without procedural related SAEs (30 days)	**100%**

To date, 93% of patients have reached 30 day follow up

2. Primary safety endpoint (3 months)	Percentage with successful primary safety result (N = 8)
Freedom from Device Migration (3 months)	**100%**
Freedom from Clinically significant fracture (3 months)	**100%**
Freedom from Clinically Significant perforation of IVC (3 months)	**100%**
Freedom from Symptomatic caval thrombosis (3 months)	**100%**

To date, 53% of patients have reached 3 month follow up

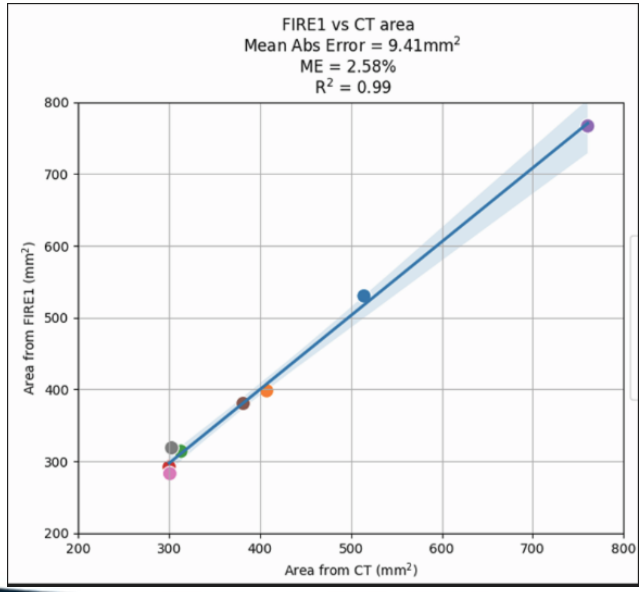
Primary Effectiveness Endpoint Result (3 months)

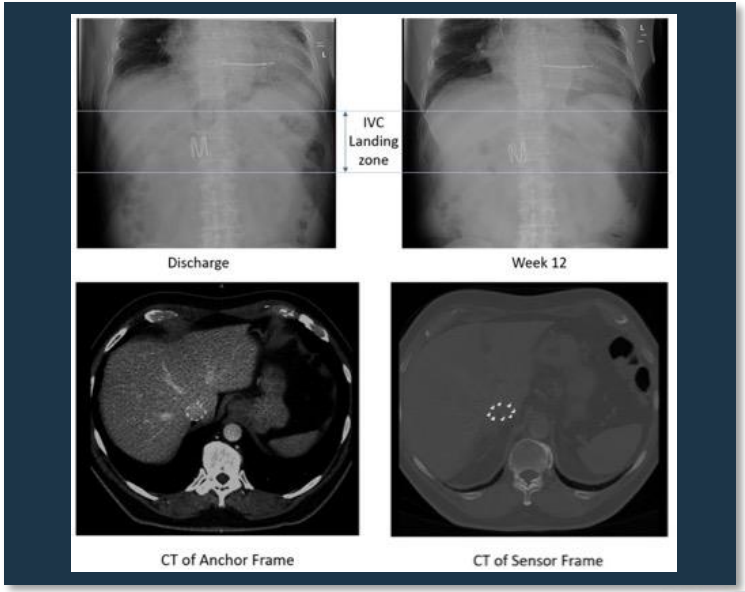
To date, 53% of patients have reached 3 month follow up

Primary effectiveness endpoint	Percentage with a successful primary effectiveness result (N = 8)
Device Performance (ability of the FIRE1™ System to successfully transmit collected data to a secure database)	100%

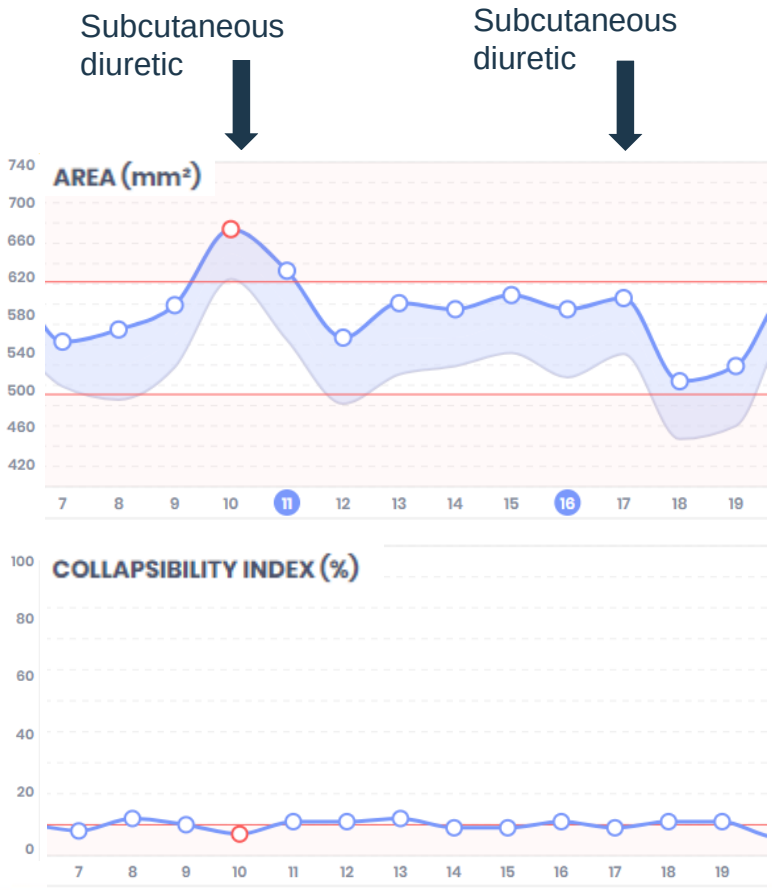
Exploratory Outcomes

- 91% patient adherence to signal transmission (5/7 days)
- FIRE1 accuracy of signal versus CT data





Case Study



Legend:
red lines = pre-set thresholds

Conclusions

Safety

- **100% met their primary safety endpoints (patients who have reached their 30 day & 3 month endpoint)**

Efficacy

- **100% met the primary effectiveness endpoint (patients who have reached their 3 month endpoint)**

FUTURE-HF2 early results are encouraging with all implanted patients continuing clinical follow up

FUTURE-HF2 EFS Investigators

Principal Investigator	Interventional Implanter	Site Name
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Austin Heart
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The University Hospital of Columbia and Cornell

DUKE UNIVERSITY MEDICAL CENTER

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

ROCHESTER REGIONAL HEALTH

Thank you **to all FUTURE HF2 investigators, research staff and patients**