

FIRE1

Percutaneous Insertion of a Volume Sensor Heart Failure Management Device

March 2025

Our Mission and Vision

1

Empowering patients with heart failure to get their “*normal*” back

2

Revolutionizing heart failure management as Continuous Glucose Monitoring did for diabetes

FDA Breakthrough Device Designation and Total Product Lifecycle (TAP) Participant





Heart Failure

One of the biggest unsolved problems in healthcare

1 in 5 people will suffer from Heart Failure (HF)

Biggest cause of hospitalization in >65-year-olds

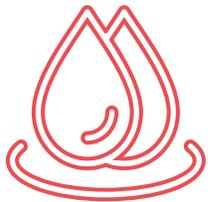
Devastating impact on quality of life

Heart Failure is projected to grow **by 46% from 2012 to 2030 in the US***



Volume accumulation drives symptoms, hospitalizations and death via “congestion”

Heart failure is a challenge of volume management

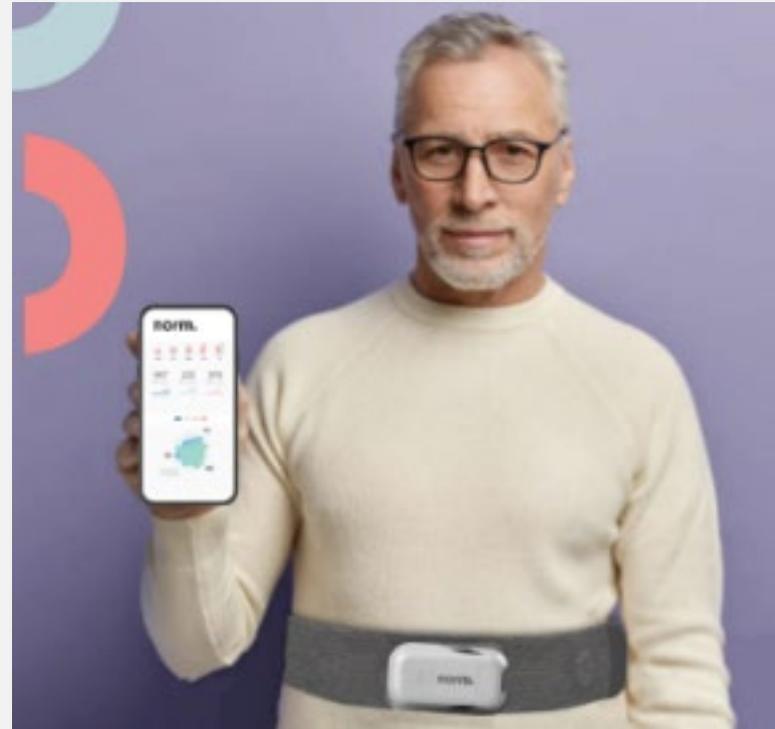
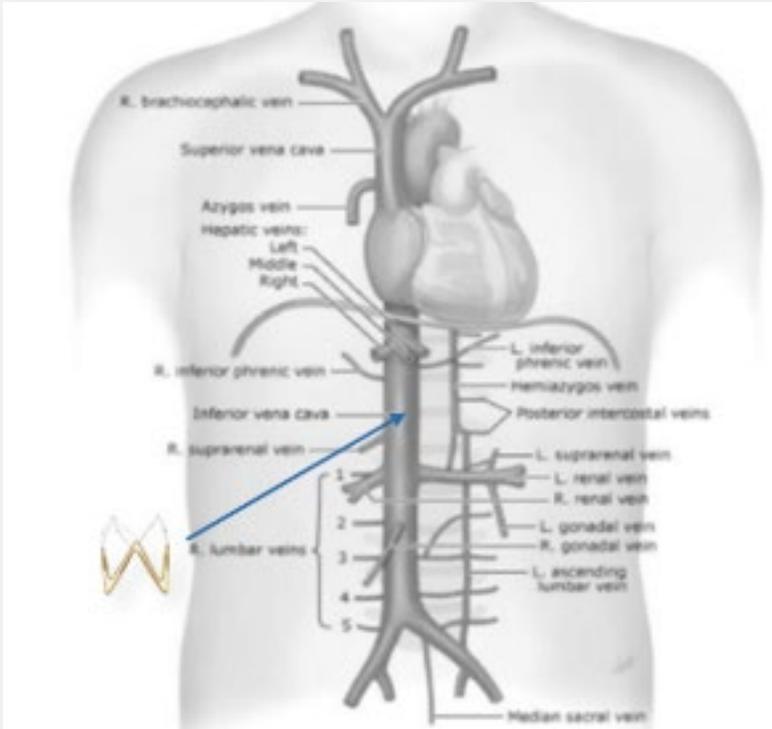


Patient empowerment

The world's first direct measure of intravascular volume status



reddot winner 2024



The sensor is deployed in the Inferior Vena Cava (IVC)

Our software applications empower the patient and enable Clinician-Directed Patient Self Management

Our algorithms identify clinically relevant trends and escalate to the Clinical Teams only when necessary

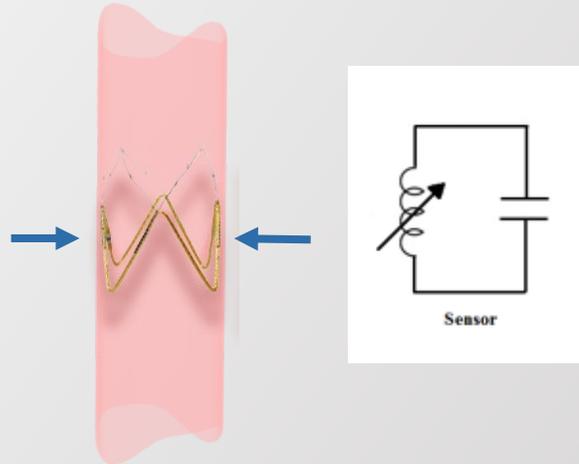
NORM™ system uses resonant circuit technology for management

Magnetic Field



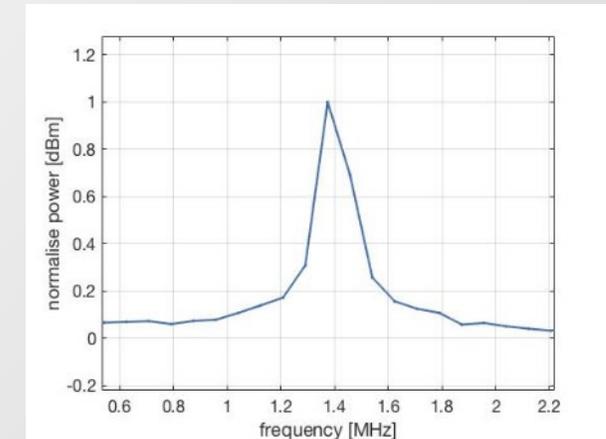
Belt creates magnetic field
to charge sensor

Resonant Circuit



Sensor geometry Δ
▶ inductance Δ
▶ resonant frequency Δ

Frequency Change



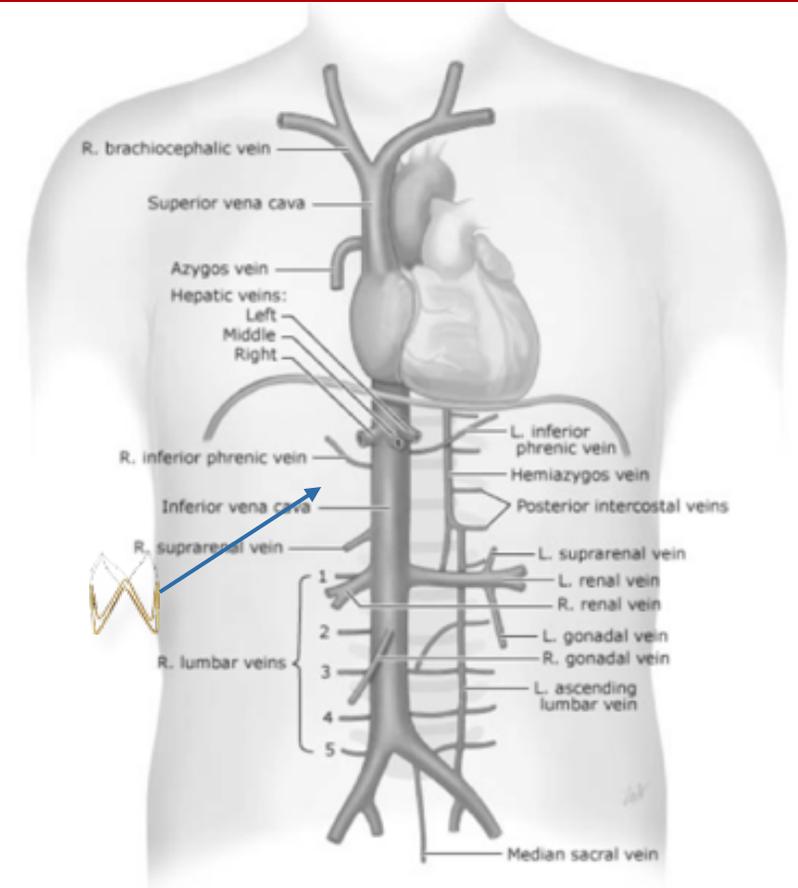
Resonant frequency Δ
▶ IVC metric Δ

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

Why the IVC?

- 70% of blood is in the veins – most of it in the venous reservoir of the abdomen
- The IVC is the 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
- The IVC is a compliant vessel that buffers volume shifts to maintain cardiac preload
- IVC volume assessment is already included in Echo guidelines (IVC size increases and collapsibility)

Placed in the Inferior Vena Cava (IVC)



Volume ≠ Pressure

Unique advantages of volume monitoring



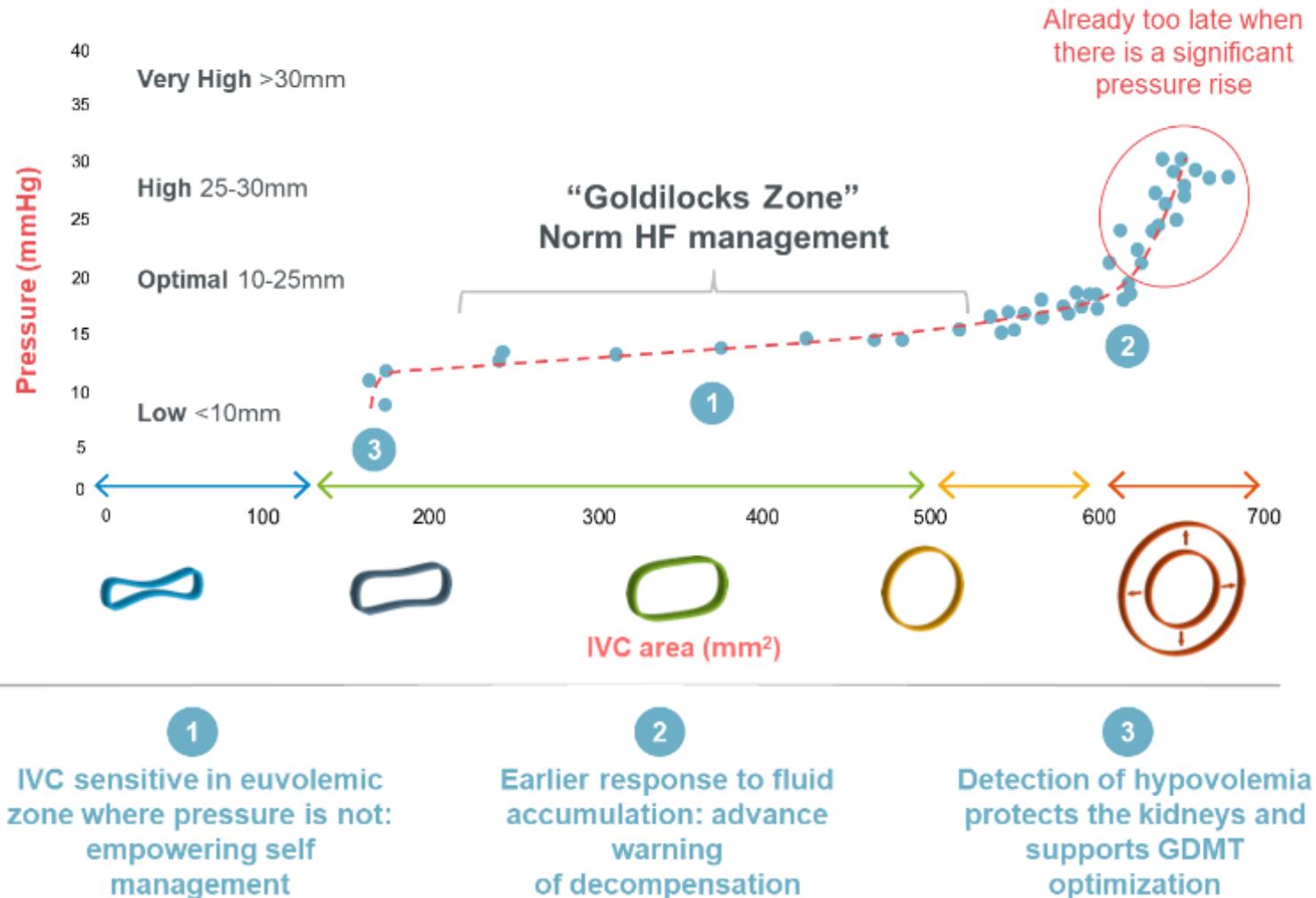
Implant procedure performed outside the heart

Broad range of physicians who can implant

Allows other interventions



Ambulatory measurements = unique insights e.g., HFpEF



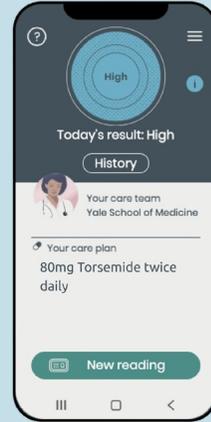
NORM™ patient-centric workflow

Wireless belt and patient self management

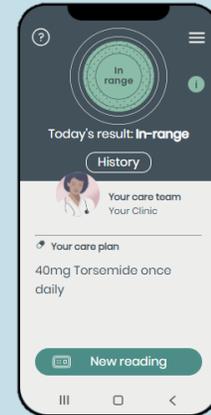
Patient Takes Daily Reading



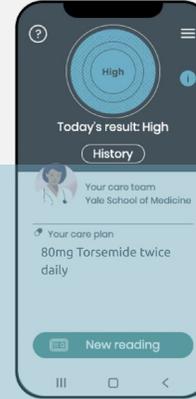
Patient receives elevated dose message



Patient receives standard dose message



If NORM™ signal remains high
Management escalates to HF care team



Reading returns to within range

Significant clinician workload reduction as patient self manages



Clinical results:

Safety and accuracy confirmed

Safety ✓



100%

Procedural success



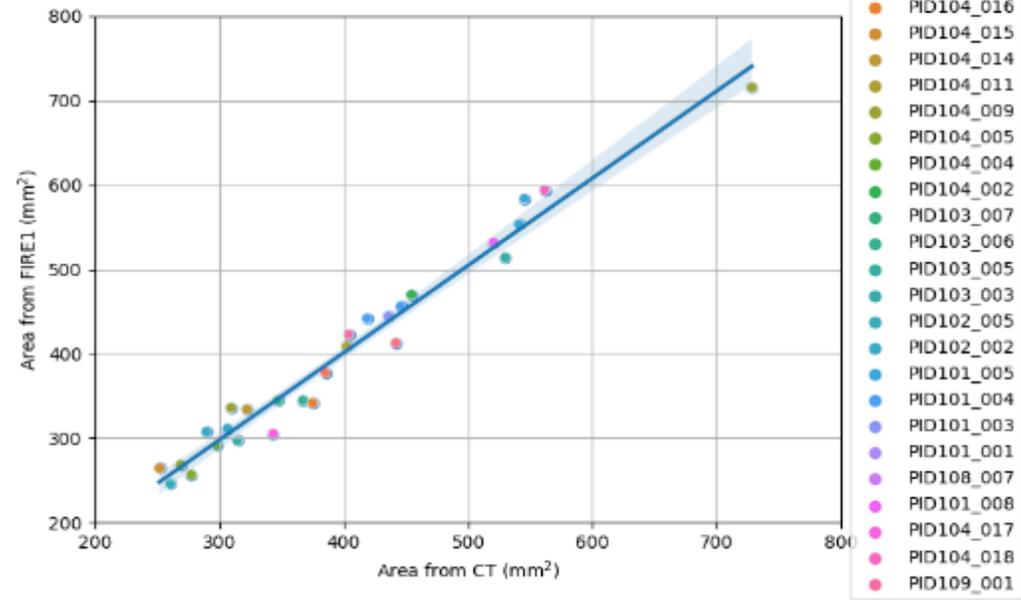
100%

Freedom from sensor /
procedural complications

Data from early studies on file with FIRE1

Accuracy ✓

FIRE1 vs CT Area
 $R^2 = 0.97$



n=29 patients

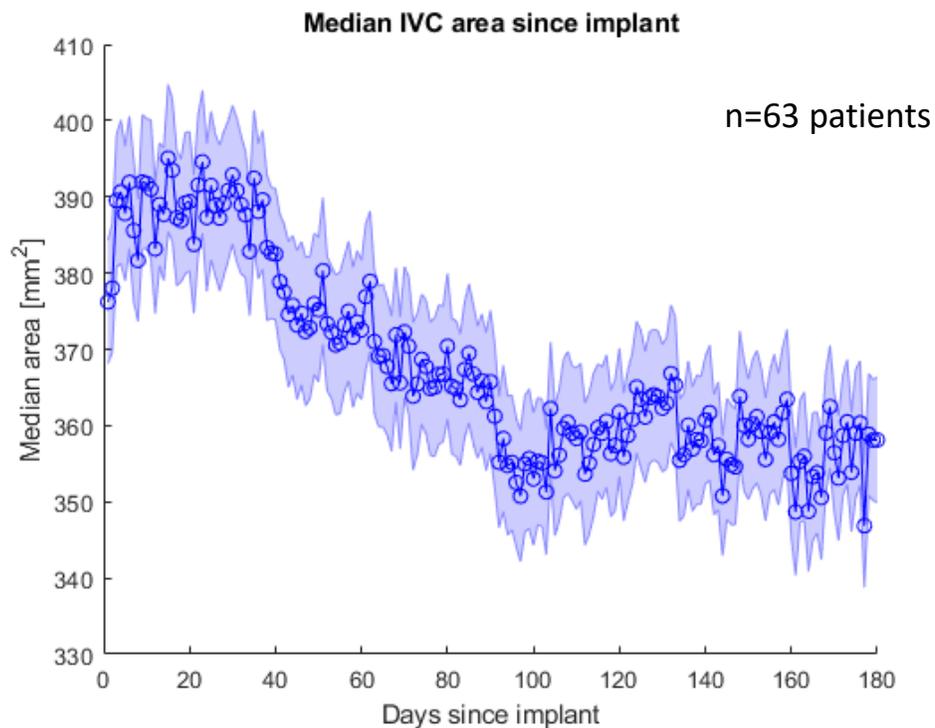
Clinical results:

IVC changes correlate with hospitalization reduction

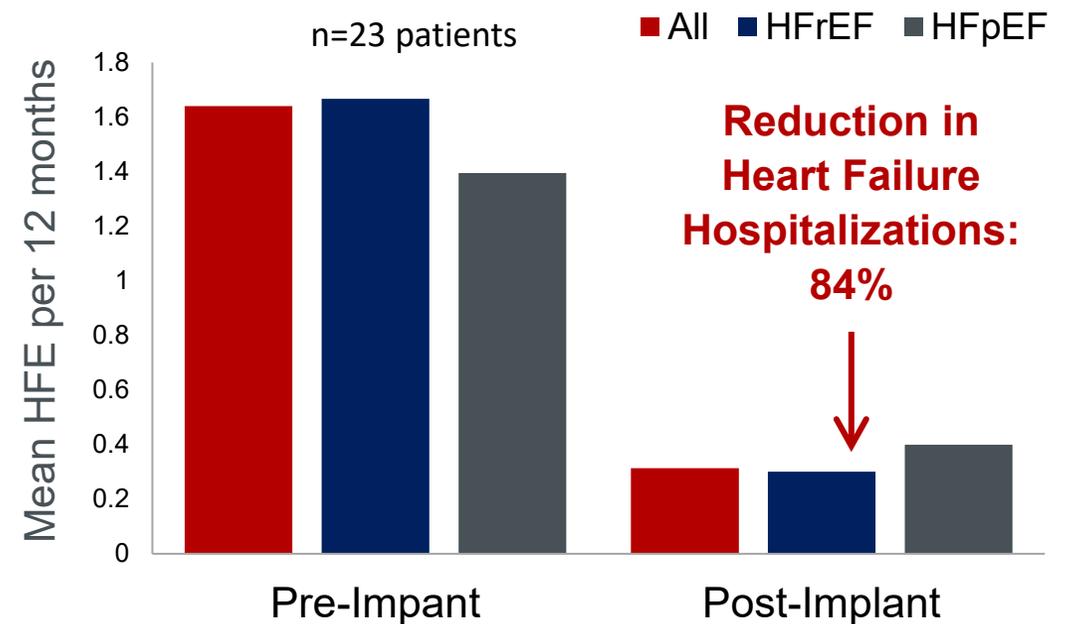
Confirming the unique IVC physiological insight drives...

... pronounced hospitalization reductions

IVC area reduction



Mean Heart Failure Events in 12 months pre and post implant



n=63 patients implanted, 40 patients with 6-month follow-up and 23 patients with 12-month follow-up. Data from early studies on file with FIRE1

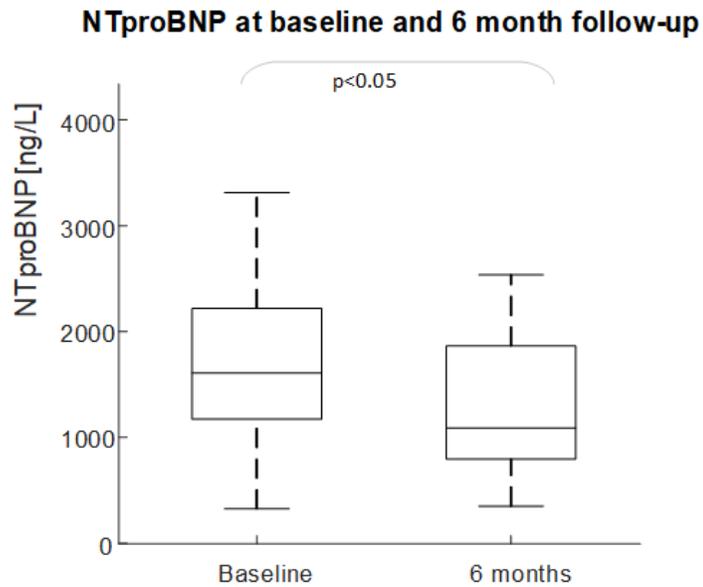
HFrEF: Heart Failure with Reduced Ejection Fraction

HFpEF: Heart Failure with Preserved Ejection Fraction

Clinical Results

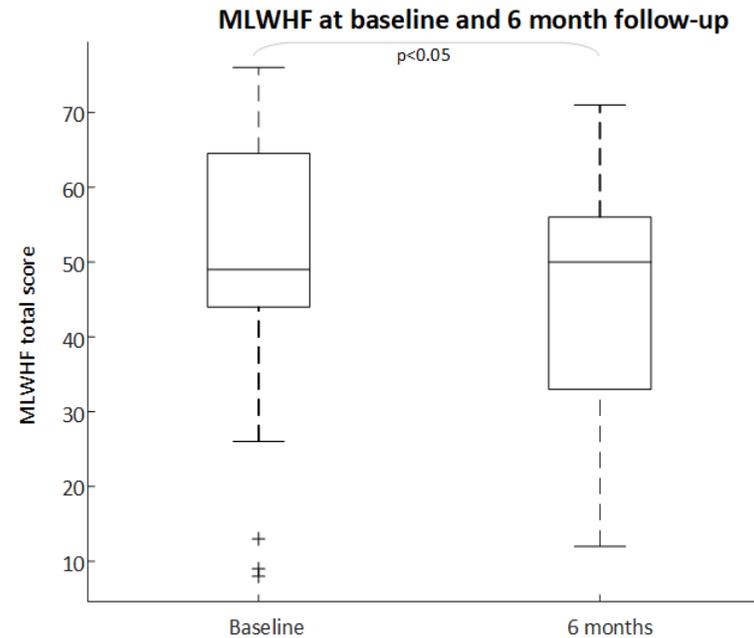
Reinforced by supporting clinical and quality of life metrics

Reduction in NT-Pro BNP



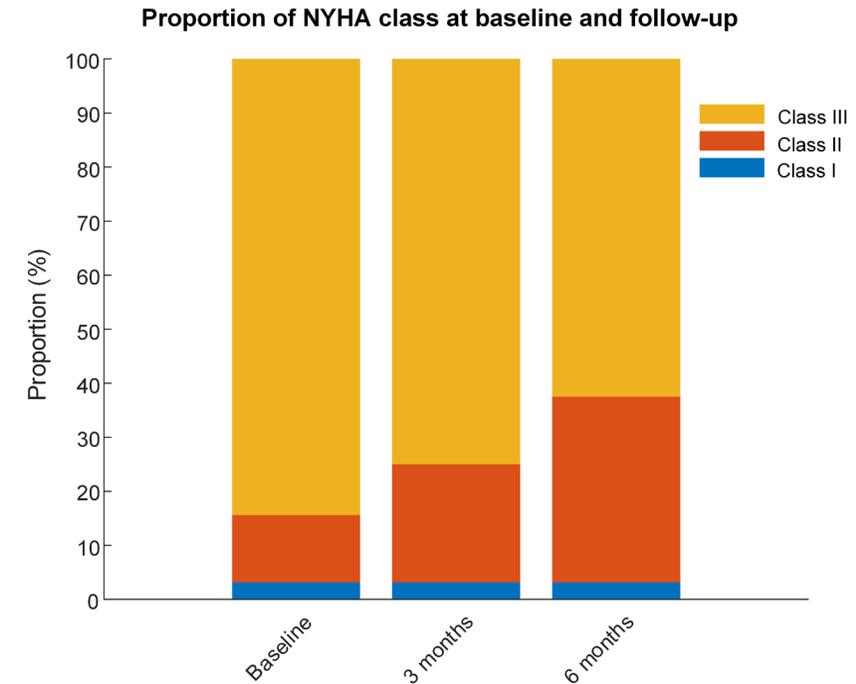
n=47 patients

Improvement in QOL



n=47 patients

Improvement in NYHA Class



n=47 patients

n=47 patients observed to 6-month follow-up. Paired data show a significant improvement ($p<0.05$) in NTproBNP, MLWHF as well as NYHA class between baseline and 6 months.
MLWHF: Minnesota Living with Heart Failure Questionnaire
Data from early studies on file with FIRE1

Randomized Controlled Trial Planned Early 2026

Breakthrough Device Designation and TAP Program ensure smooth development with FDA

Pivotal Trial Design underway

- Discussing an 800 patient, multicenter, prospective, 1:1 randomized, open-label, with blinded adjudication of endpoints design
- 80 to 100 hospitals

While most procedures will be performed outpatient (~85-90%), some will need to be performed during hospital admission (~10-15%)

- Fluid overload identified during implantation (right heart cath) resulted in admission
- Right heart cath on admitted patient shows fluid overload; proactive implantation during admission

Two publications of Early Feasibility Studies

- Safety and Feasibility of an Implanted Inferior Vena Cava Sensor for Accurate Volume Assessment: FUTURE-HF2 Trial - *J Card Fail.* 2024 Sep 28:S1071-9164(24)00377-4.
- "First-in-Human Implantable Inferior Vena Cava Sensor for Remote Care in Heart Failure: FUTURE-HF" In press at *JACC Heart Failure* 2025



Thank you!

norm.