New Devices for Heart Failure

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Conflict of Interest Disclosures

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Devices for Heart Failure

Heart Failure Stage

ICD
CRT(D)

Hemodynamic monitoring
Cardiac Contractility Modulation
Baroreflex Activation Therapy
Interatrial Shunt Devices (HFpEF)
Percutaneous MV repair
Percutaneous Ventricular Restoration
Novel Ultrafiltration Systems

Decongestion Devices
Temporary MCS
Durable MCS

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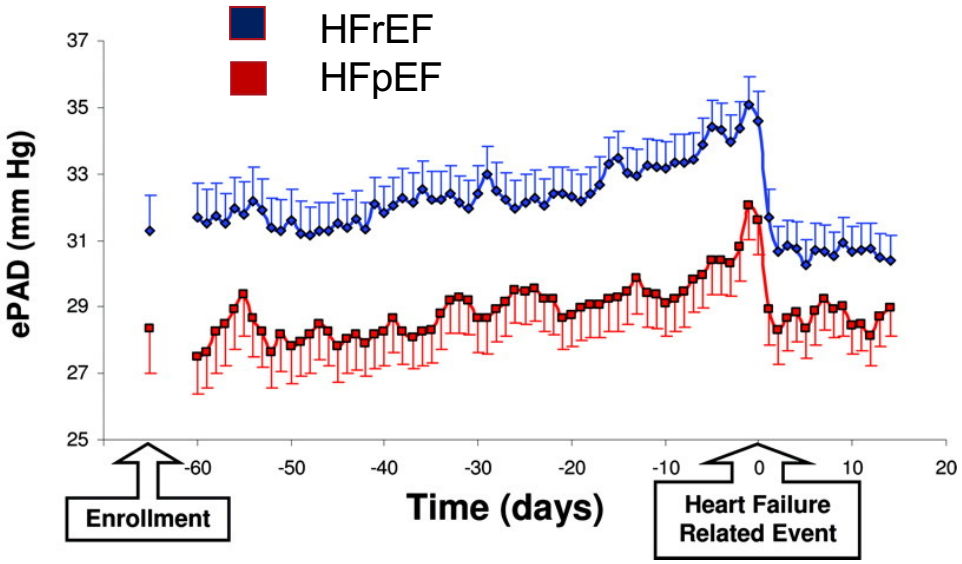
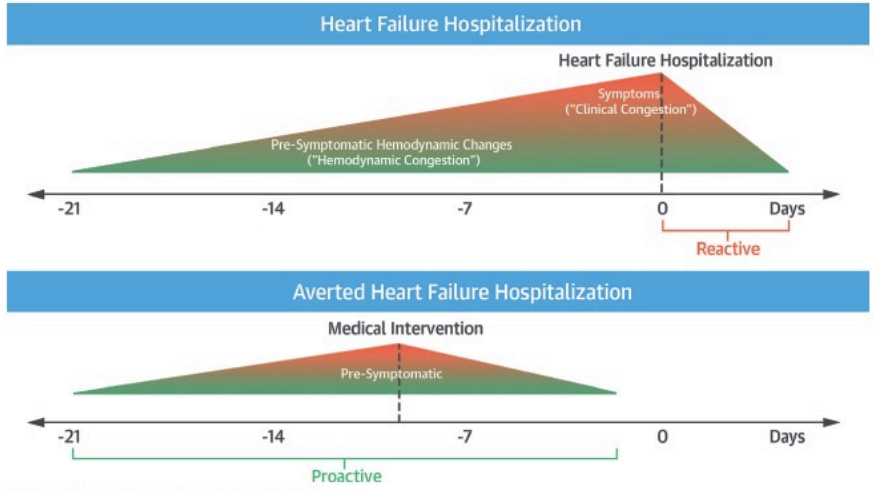
Temporary MCS
Durable MCS

Hemodynamic Congestion Anticipates Clinical Congestion in Heart Failure

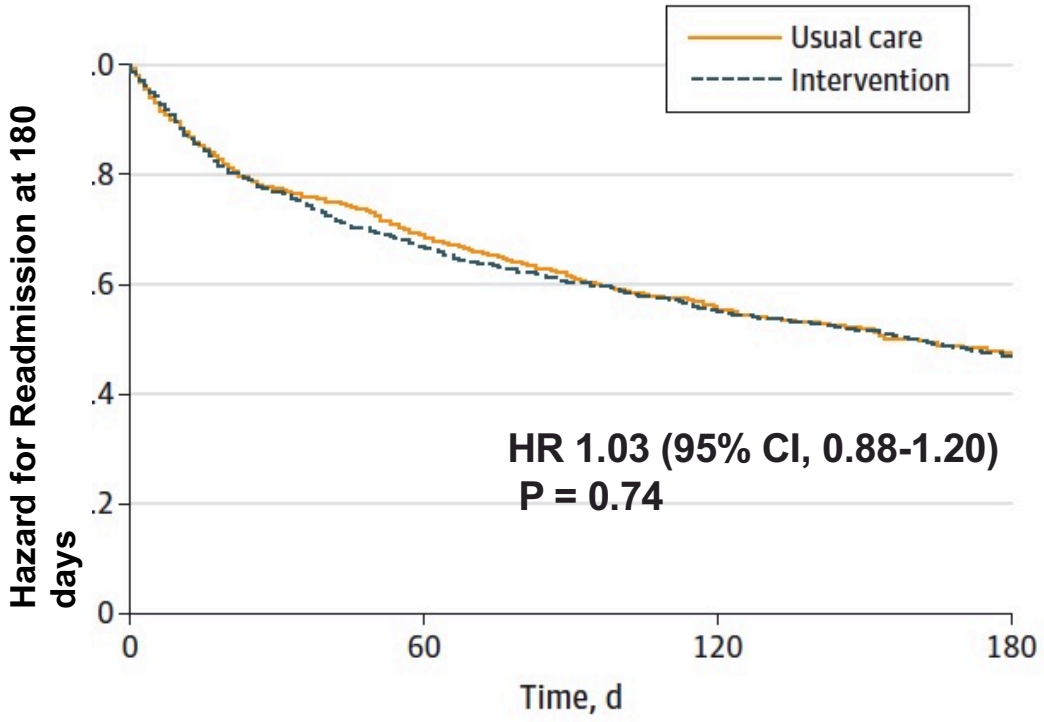




PAP increases days to weeks prior to a heart failure hospitalization providing a window in which to reduce PAP and improve outcomes

Zile et al. Circulation. 2008 Sep 30;118(14):1433-41
Abraham WT, et al. J Am Coll Cardiol 2017; 70(3): 389-98

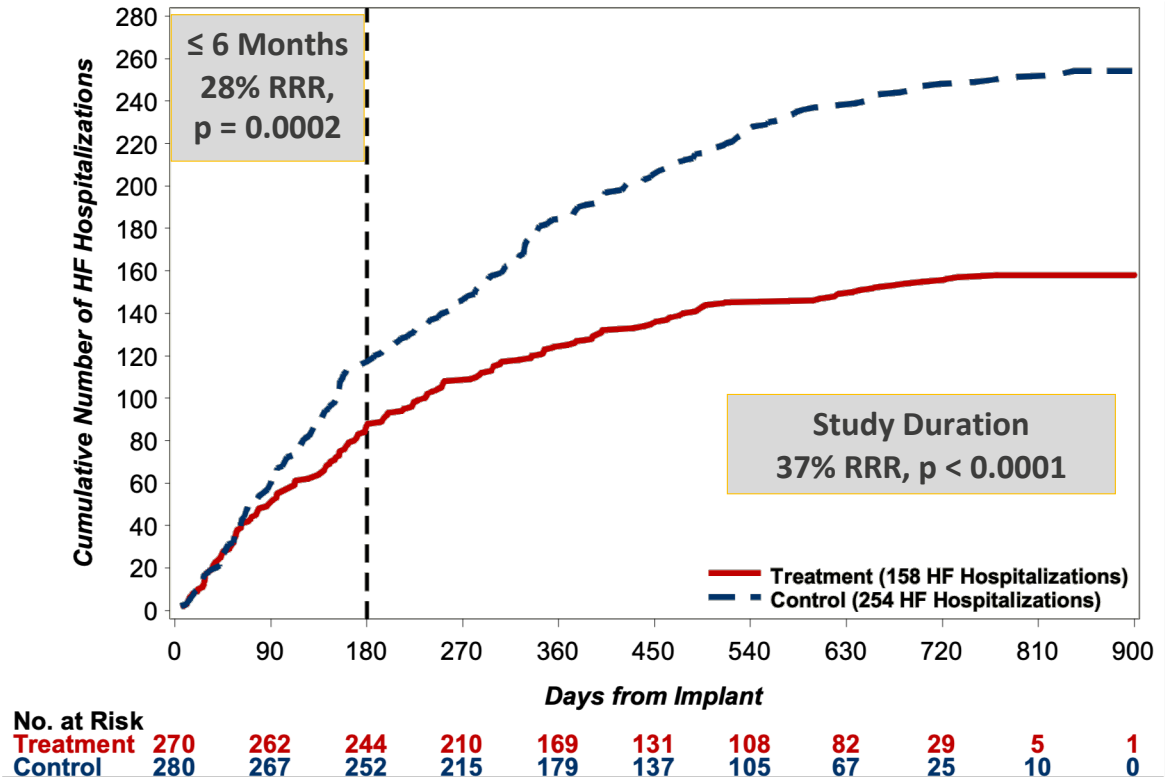
Telemonitoring of Weight and Vital Signs does not Reduce Readmissions or Mortality (BEAT-HF)

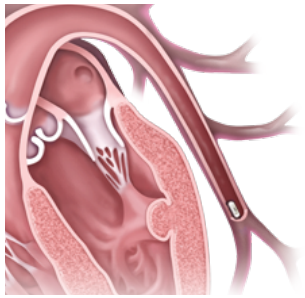


Concordant findings from Tele-HF, TIM-HF, WISH

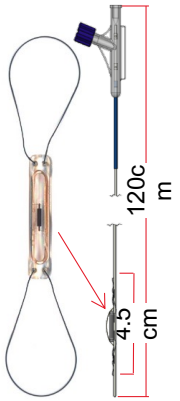
Ong MK et al. JAMA Intern Med. 2016;176:310-318.

CHAMPION: Reduction in HF Hospitalizations with Wireless PAP Monitoring





FDA Approval May 2014 for NYHA III + prior HFH

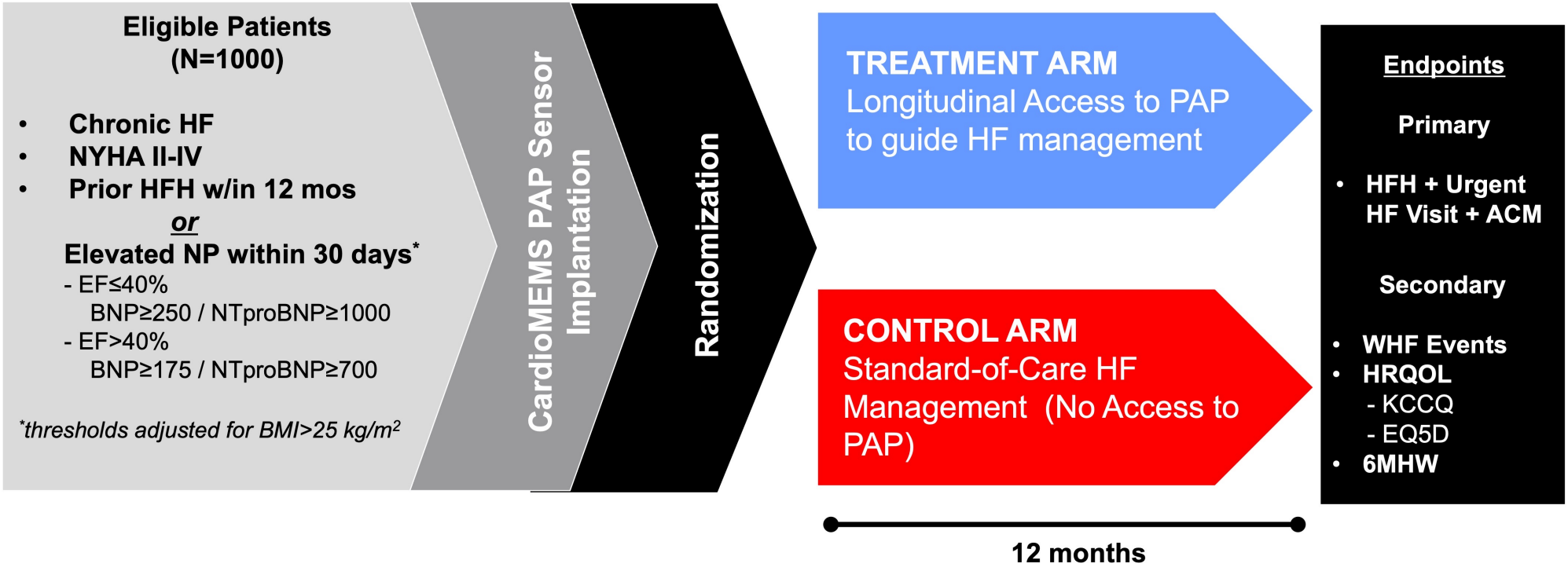


ACC/AHA/HFSA 2022 HF Guideline

COR: Class 2b
LOE: B-R
Uncertain Value

Abraham WT, et al. Lancet, 2011;377:658-666
Heidenreich P, et al. Circulation 2022

GUIDE-HF Trial

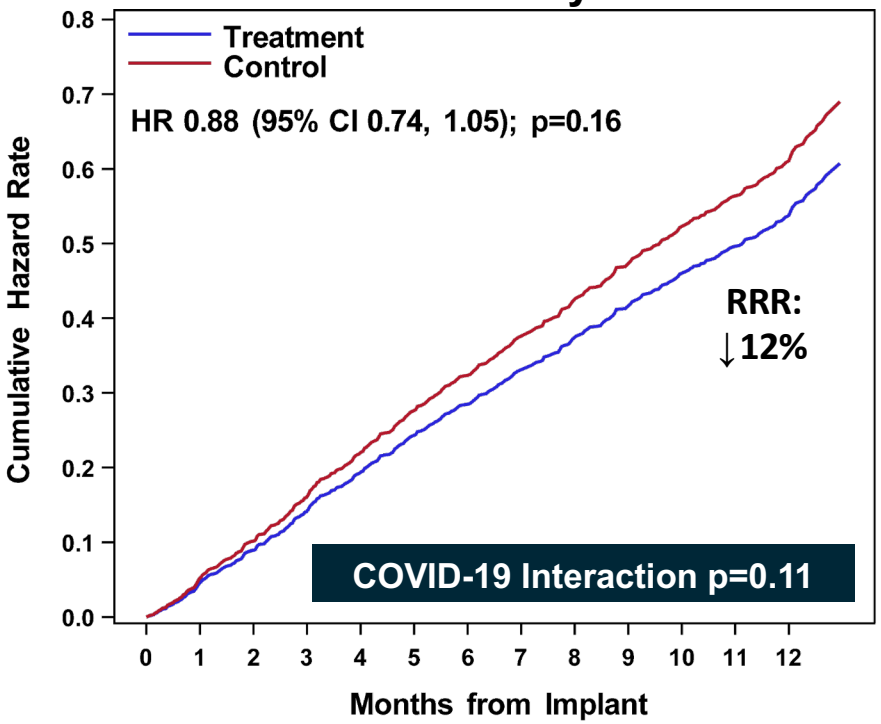


Lindenfeld et al. Am Heart J 2019

GUIDE-HF Primary Endpoint

(All-Cause Mortality, HF Hospitalizations, Urgent HF Visits)

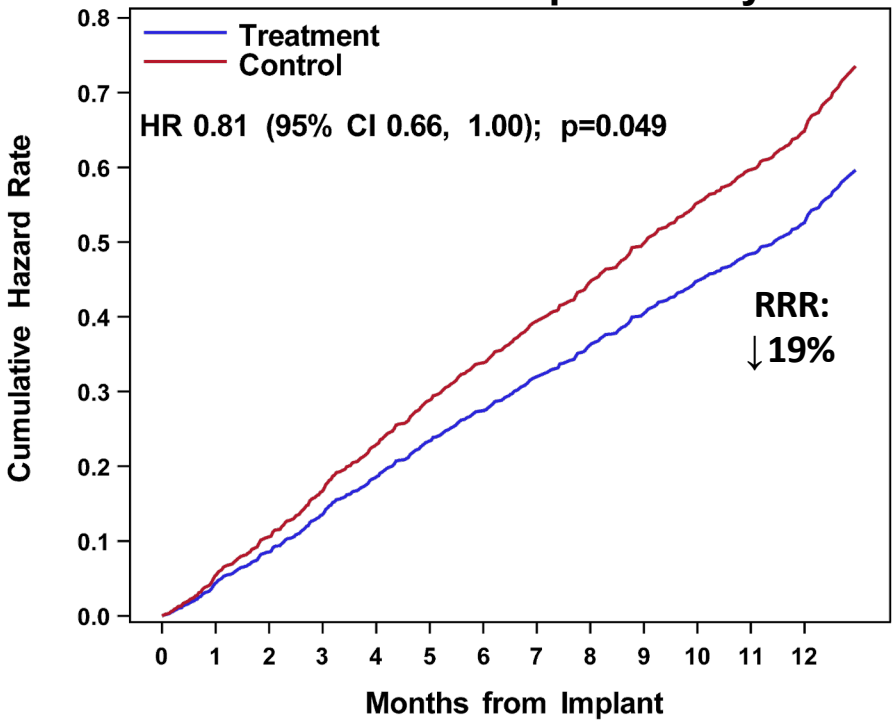
Overall Analysis



No. At Risk

Treatment	497	496	491	486	480	473	468	465	456	447	441	422	193
Control	503	500	494	488	482	476	468	463	459	456	442	434	180

Pre-COVID-19 Impact Analysis



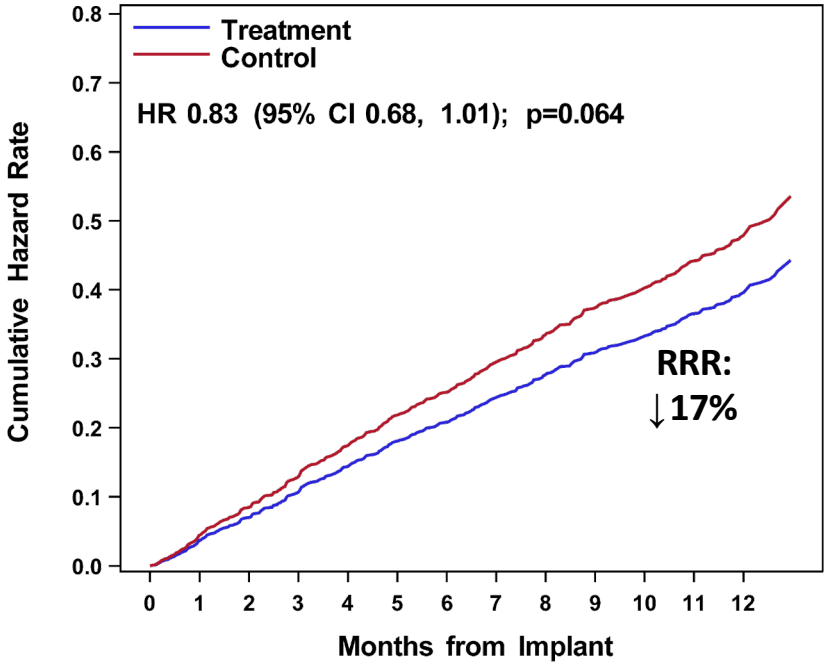
No. At Risk

Treatment	497	496	491	459	404	360	328	290	251	216	182	155	58
Control	503	500	494	459	405	365	335	303	272	237	200	172	59

Lindenfeld J. et al. Lancet 2021

GUIDE-HF: Heart Failure Hospitalizations

Overall Analysis



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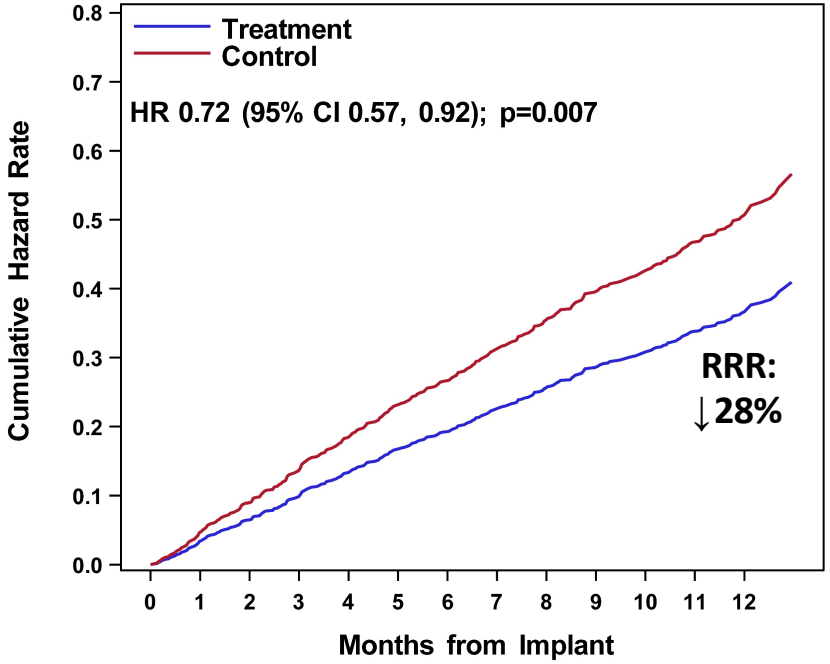

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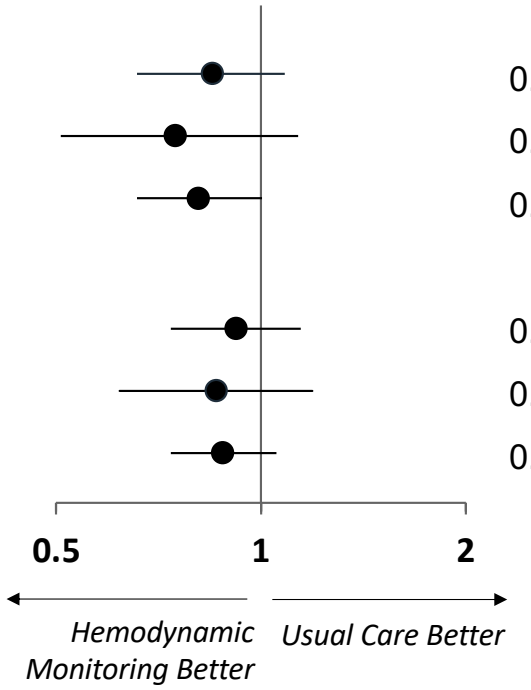
Lindenfeld J. et al. Lancet 2021

Treatment Effect According to Enrollment Stratum
Primary Study Composite

	Treatment Events (rate/100 pt-yr) (N=497)	Control Events (rate/100 pt-yr) (N=503)	HR (95% CI)	$P_{interaction}$
Pre-COVID Analysis				
HFH in year prior	133 (74.7)	166 (88.0)	0.85 (0.66-1.08)	
Elevated NP only	44 (32.9)	58 (43.6)	0.75 (0.51-1.13)	0.58
Overall	177 (55.3)	224 (68.2)	0.81 (0.66-1.0)	
Full Study Duration				
HFH in year prior	181 (75.7)	212 (82.0)	0.92 (0.74-1.14)	
Elevated NP only	72 (35.0)	77 (40.9)	0.86 (0.62-1.19)	0.71
Overall	253 (56.3)	289 (64.0)	0.88 (0.74-1.05)	

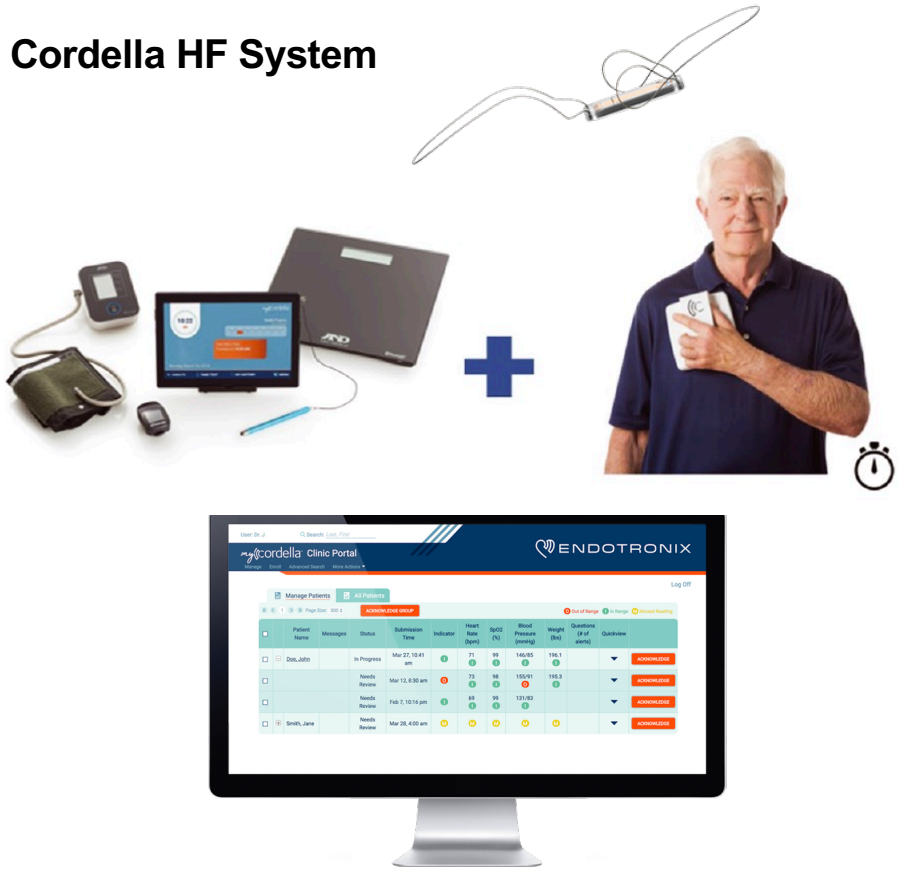


Expanded FDA approval for NYHA 2 and Elevated NP without prior HFH in February 2022

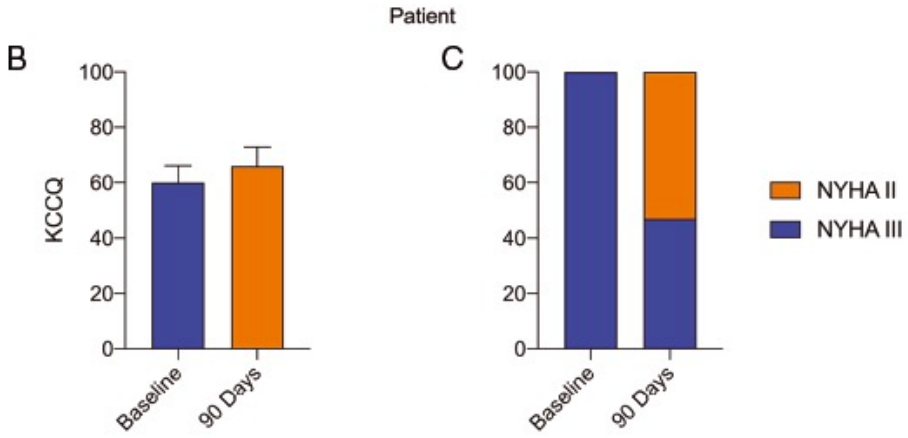
Desai AS, et al. THT 2022

Alternative PAP Monitoring Systems in Development

Cordella HF System



SIRONA-HF (N=15)



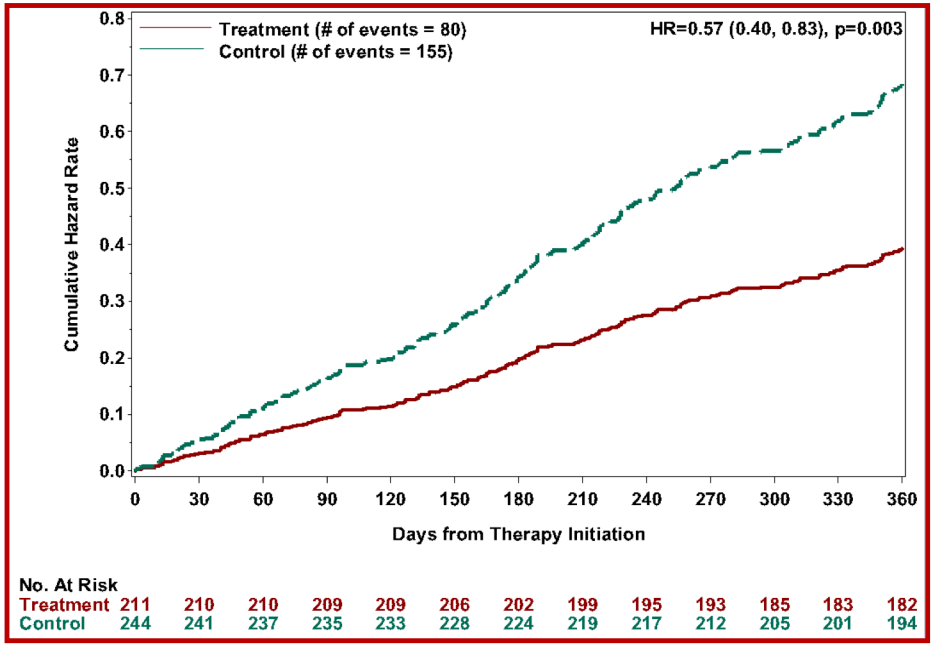
PROACTIVE-HF Trial Ongoing

Mullens W, et al. Eur J Heart Fail 2020

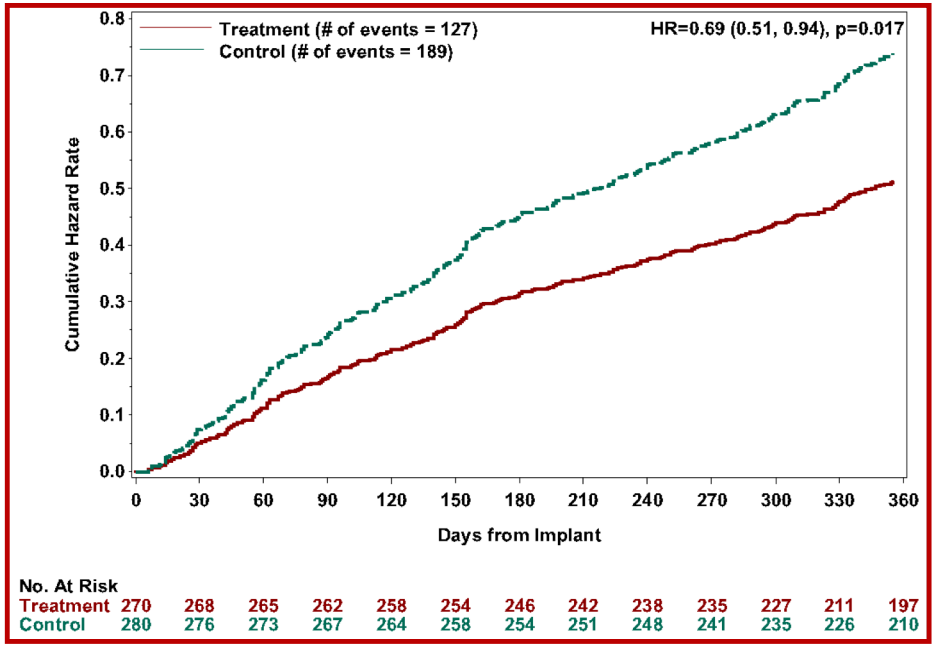
LA Pressure Monitoring

Cumulative Hazard HFH at 12 Months in LAPTOP-HF

LAPTOP-HF



CHAMPION



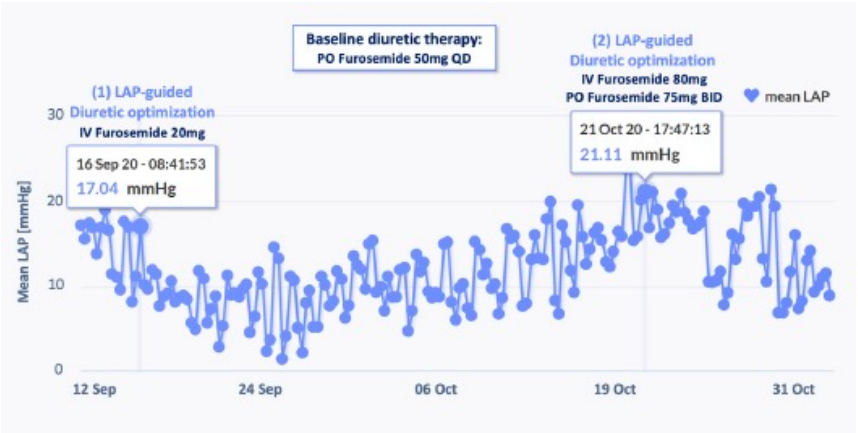
Abraham WT, et al. Lancet 2011

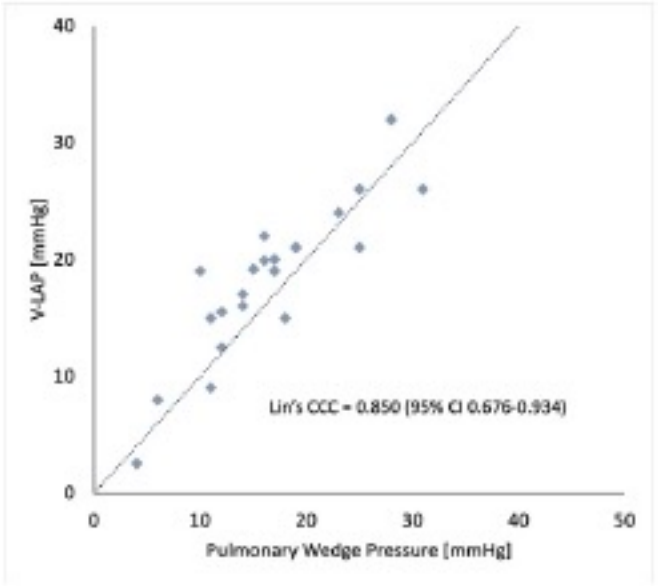
Abraham WT HFSA LBCT 2016

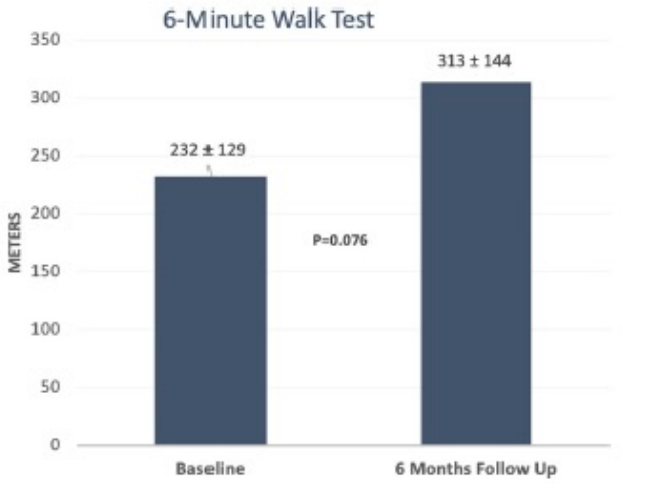
Abraham WT and Perl L, J Am Coll Cardiol 2017; 70: 389-98

VECTOR-HF

- N=24
- Single Arm, Open Label
- NYHA III + Prior HFH
- Proof-of-concept





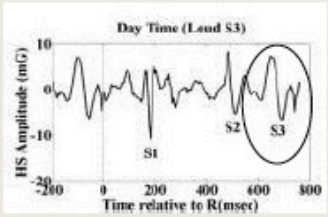


Perl L, et al. J Card Fail 2022; 00:1-10

Device Integrated Sensors: Multiparameter Monitoring

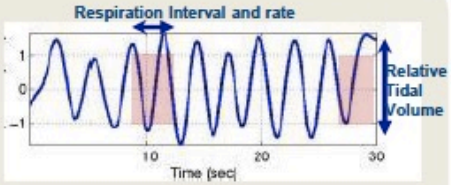
Heart Sounds

Signs of elevated filling pressure (S3)



Respiration

Rapid breathing and reduced tidal volume – shortness of breath



Thoracic Impedance

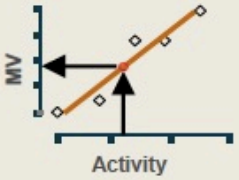
Fluid accumulation and pulmonary edema

Posture

Increased night elevation angle as indicator of Orthopnea or PND

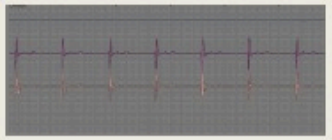
Activity Response

Physiologic changes as a result of activity – such as signs of dyspnea on exertion



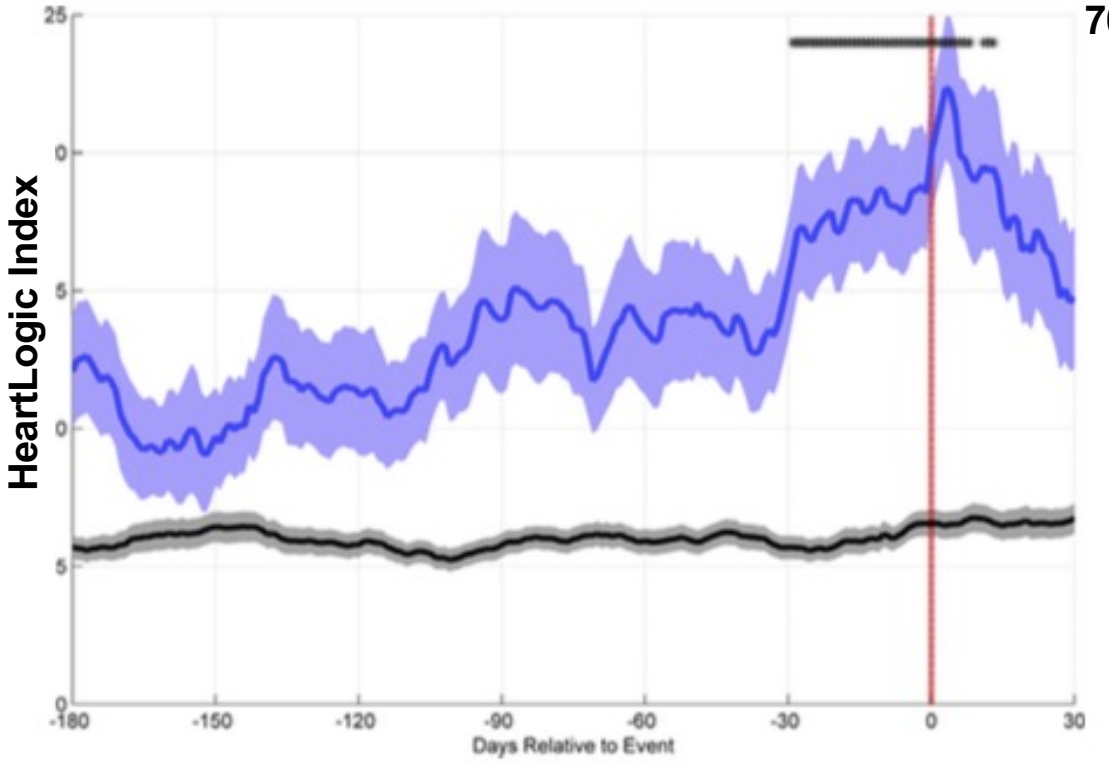
Heart Rate and Arrhythmias

Heart rates as indicator of cardiac status; atrial arrhythmias related to HF status



Multiparameter Monitoring Permits Anticipation of HF Events

MANAGE-HF
Ongoing



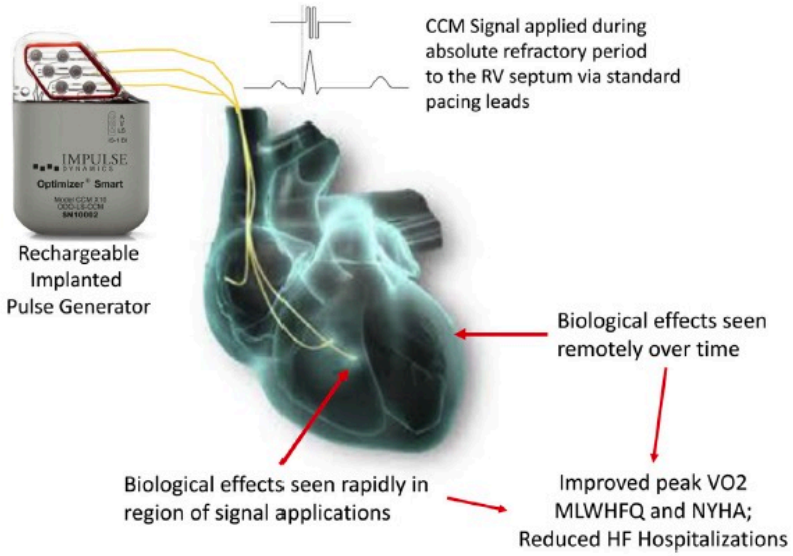
70% Sensitivity for HFE
Median lead time 34d

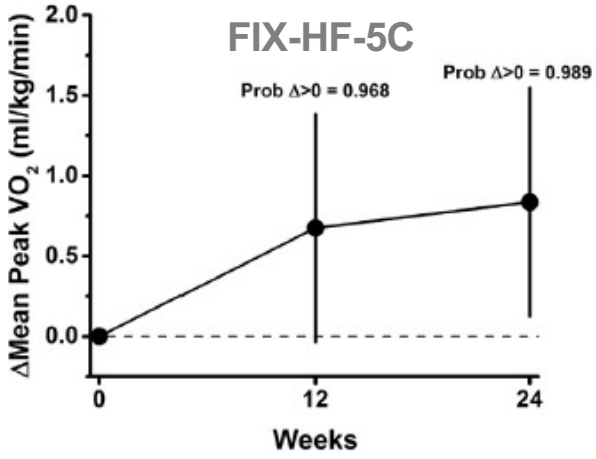
Patient with a HF event

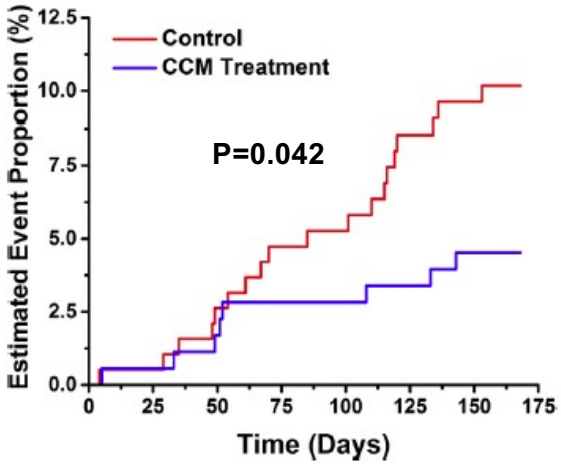
Patients without a HF event

Boehmer JP, et al. J Am Coll Cardiol HF 2017; 5: 216-25

Cardiac Contractility Modulation (CCM)





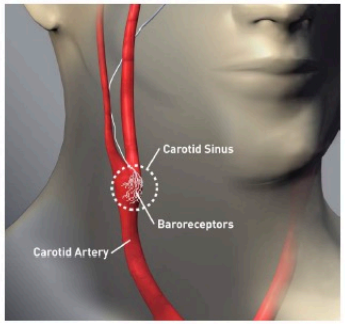


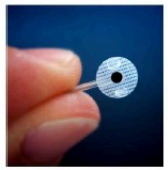
FDA Approved for

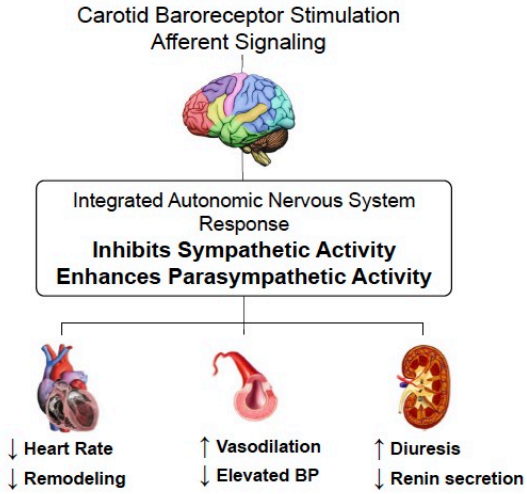
- **NYHA III HF,**
- **EF 25-45%**
- **OMT**
- **Not eligible for CRT**

Abraham WT, et al J Am Coll Cardiol HF 2018

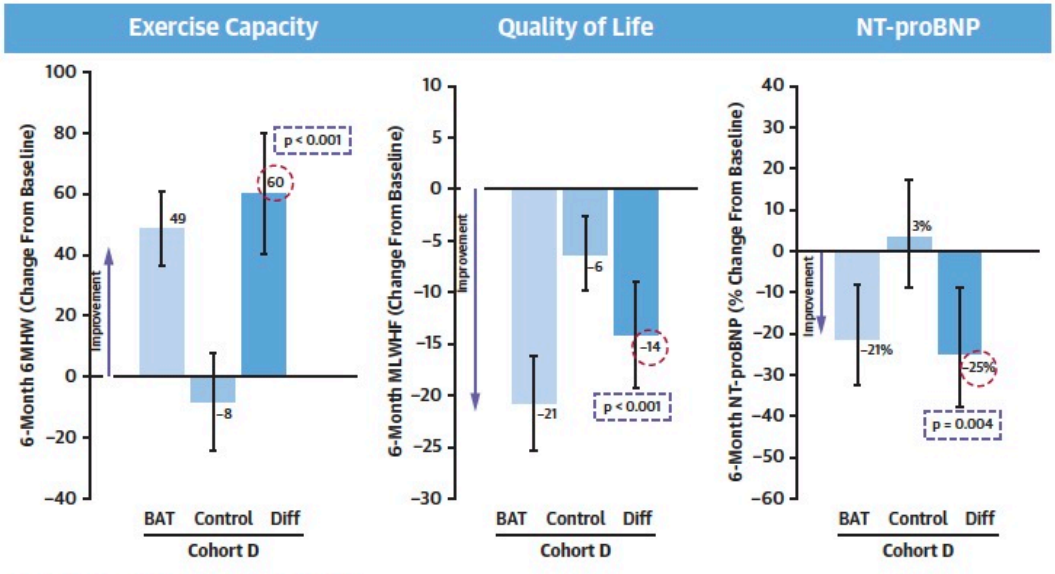
Neuromodulation with Baroreflex Activation Therapy







BeAT-HF Trial (N=408)

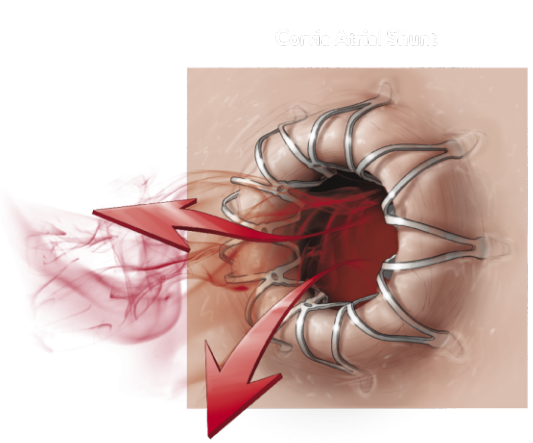


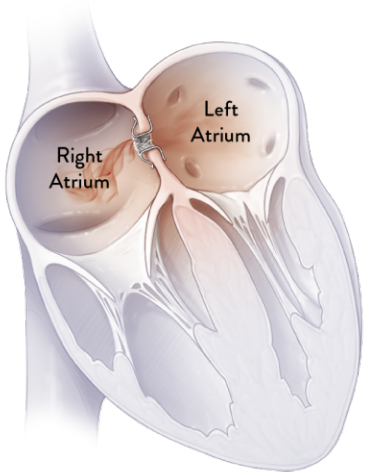
FDA Approved for

- **NYHA III HF**
- **EF <= 35%**
- **NTproBNP < 1600 pg/mL**
- **OMT**
- **Not eligible for CRT**

Zile MR, et al J Am Coll Cardiol 2020

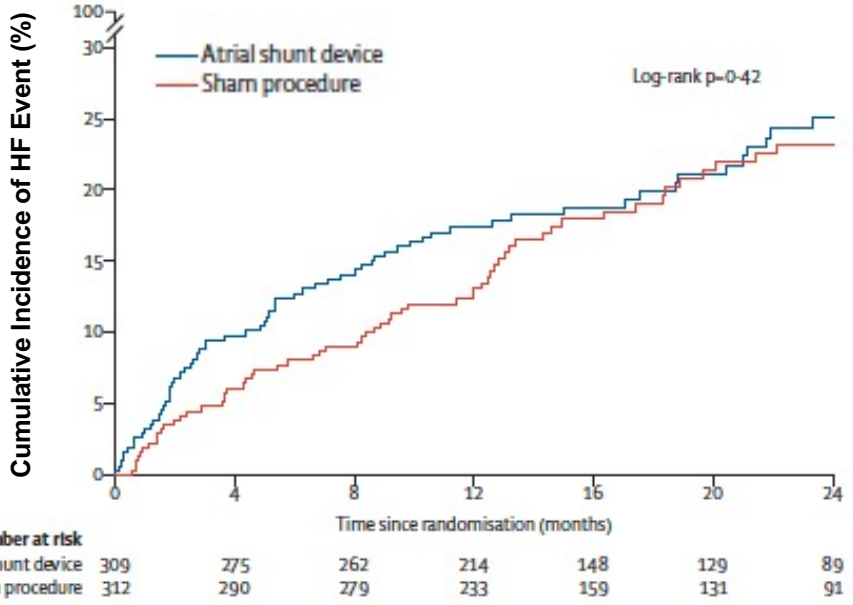
Inter-Atrial Shunt Device for HFpEF





REDUCE-LAP-HF-2 (N=626)

Chronic HF, EF>=40%, Ex PCWP >=25 mm Hg

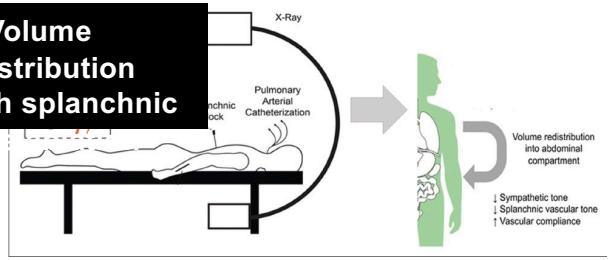


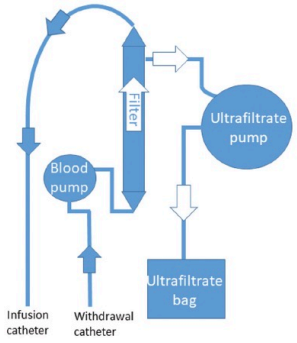
Number at risk							
Atrial shunt device	309	275	262	214	148	129	89
Sham procedure	312	290	279	233	159	131	91

Shah S, et al Lancet 2022

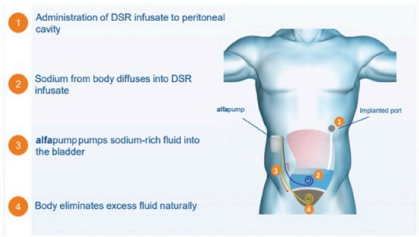
Horizon Therapies for Decongestion in ADHF

Volume redistribution through splanchnic

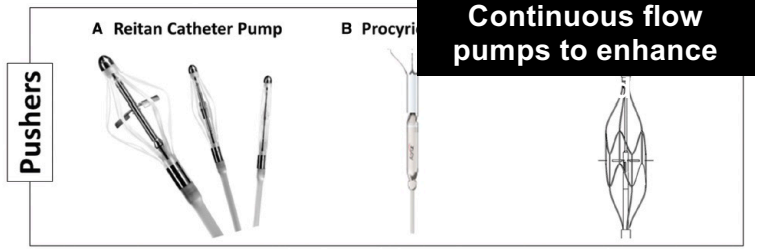


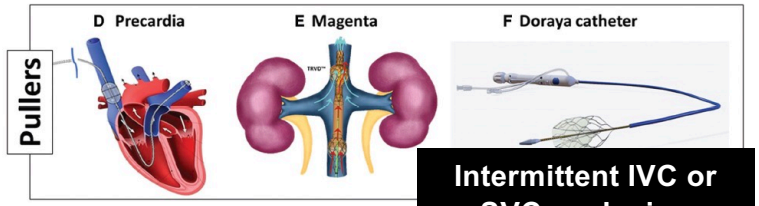


Novel ultrafiltration or peritoneal dialysis systems for volume



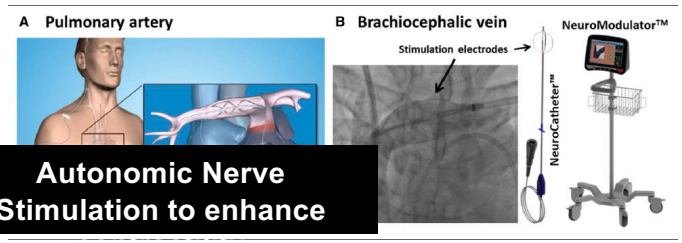
Intra-aortic Continuous flow pumps to enhance



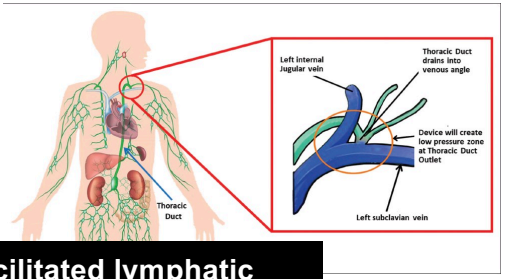


Intermittent IVC or SVC occlusion devices to reduce

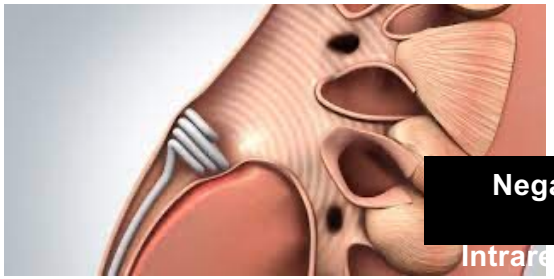
Autonomic Nerve Stimulation to enhance



Acute Heart Failure



Facilitated lymphatic drainage through transcatheter



Negative Pressure Diuresis

Rosenblum H, et al. Circ Heart Fail 2020; 13: e006731

Summary

- Technology for remote hemodynamic monitoring is expanding
- Hemodynamic-guided HF therapy may reduce HF readmissions for selected patients
- Cardiac Contractility Modulation and Baroreflex Activation Therapy may improve functional capacity and quality of life for selected patients who are not candidates for CRT
- Interatrial shunt decompression for HFpEF has not proven effective in initial trials
- Novel devices to facilitate decongestion in acute HF are evolving