

Supplementary Table 1: Summary of completed and ongoing trials. This table provides an overview of device therapies, completed and ongoing trials, main results, patient characteristics, and mechanisms.

PRESSURE SENSOR MONITORING DEVICES										
Trial	Name Of Device	Mechanism	Study Design	Comparison Arm	Patient Characteristics	Major Exclusion Criteria	Primary Outcomes	Main Results	FDA Approval & Year	European Agency Approval (CE Mark)
MONITOR-HF, n=348 ¹	CARDIOMEMS™-HF system (Abbot)	Paperclip-sized pressure monitor placed into the pulmonary artery via catheter. Uses radiofrequency to transmit data, no battery.	Randomized	GDMT alone	- NYHA III - HFHs within 12 months prior to enrollment - no exclusion based on LVEF	- major CV event 60d prior to enrollment - severe valve disorder requiring surgery - eGFR <25 - life expectancy <1yr from non-cardiac cause	- mean change in KCCQ 12 months	At 12 months: - KCCQ improved - HFHs reduced - time to first HFHs reduced - all-cause mortality unchanged - PA pressure reduced - NT-proBNP reduced	Y (2014)	Y
CHAMPION, n=550 ²	CARDIOMEMS™-HF system (Abbot)	See above	Randomized	GDMT alone	- NYHA III - HFHs within 12 months prior to enrollment - no exclusion based on LVEF	- major CV event 30d prior to enrollment - eGFR <25 - severe pulmonary disease (e.g. COPD)	- rate of HFHs at 6 months - rate of device-related adverse events - rate of device-related failure (i.e. inability to sense PA pressures)	- HFHs reduced at 6 months At a mean follow-up of 15 months: - 98.6% free from device-related adverse events - no device failures - days alive outside hospital increased - PA pressures reduced - MWLHF improvement	Y (2014)	Y
GUIDE-HF, n=1000 ³	CARDIOMEMS™-HF system (Abbot)	See above	Randomized	GDMT alone	- NYHA II-IV - HFHs within 12 months prior to enrollment and/or elevated NT-proBNP - 53% EF <40%	- major CV event 30d prior to enrollment - eGFR <25 - severe pulmonary disease (e.g. COPD)	- composite of all-cause mortality and cumulative HF events at 12 months, classified by LVEF categories	Pre-COVID-19 timeline: - no change in all-cause mortality - HFHs reduced in HFrEF group, but not statistically significant in HFpEF group - PA pressures reduced	Y (2014)	Y
PROACTIVE-HF, n=425 ⁴	Cordella™ Pulmonary Artery Sensor System and Heart Failure System (Endotronix)	Pressure monitor placed into pulmonary artery via catheter. Includes comprehensive digital HF management technology that measures, records, and transmits vital signs (blood pressure, heart rate, weight, oxygen saturations) and PAP data from the patients' home to the clinical teams for proactive	Non-randomized	n/a	- NYHA III - HFHs within 12 months prior to enrollment and/or elevated NT-proBNP	- major CV event 30d prior to enrollment - eGFR <25 - severe pulmonary disease (e.g. COPD)	- 6-month incidence of HFH or all-cause mortality compared to a performance goal - 6-month freedom from device or system-complications (DSRC) and pressure sensor failure	- Reduced composite primary event rate of HFH or all-cause mortality - >99% freedom from device or system complications - NYHA class improvement - KCCQ improvement - 6MWT improvement - PA pressure improvement	Y (premarket 2024)	N

		management								
PROACTIVE-HF-2 (NCT05934487)	Cordella™ Pulmonary Artery Sensor System and Heart Failure System (Endotronic)	See above	Randomized (3 arms)	Treatment Arm (Cohort 1) Active Control Arm (Cohort 2) Crossover Arm (Cohort 3)	- NYHA II (randomized arm) or NYHA II (single arm) - will include both HFrEF and HFpEF - HFH within 12 months prior to enrollment - elevated NT-proBNP	- major CV event 90d prior to enrollment - eGFR <20 - severe untreated valvular disease - severe pulmonary disease (e.g. COPD) - life expectancy <2 years from non-cardiac cause	At 12 & 24 months: - composite HF event or death - HFHs - freedom from device/system related complication - freedom from pressure sensor failure	Ongoing	Y (premarket 2024)	N
COMPASS-HF, n=274 ⁵	CHRONICLE Implantable Continuous Hemodynamic Monitor (Medtronic)	Implantable device similar to size of pacemaker generator, with transvenous pressure sensor ending in RV. Continuously measures RV pressures and pressure rate of change to estimate PA pressures	Randomized	Underwent CHRONICLE implantation but no review of data for the 6 months of study	- NYHA III-IV regardless of EF - HFH within 6 months prior to enrollment	- major CV event 90d prior to enrollment - Cr >3.5 - severe pulmonary disease - PAH - life expectancy <6mo from non-cardiac cause	At 6 months: - HF-related events (hospitalizations, ER or urgent care visits) - freedom from system-related complications - freedom from pressure sensor failure	At 6 months: - no difference in HF-related events (did not meet primary efficacy endpoint) - 8% system-related complications (met safety endpoint) - HFH reduced in CHRONICLE group (in retrospective analysis)	N	N
REDUCEhf, n=400 ² *Trial recruitment stopped early (designed to have n=1300) ⁶	CHRONICLE-ICD, n=400 (59)	See above	Randomized	Underwent CHRONICLE implantation but no review of data for the 12 months of study	- NYHA II-III - average EF 23% - HFH within 12 months prior to enrollment - indication from primary ICD	- major CV event 30d prior to enrollment - eGFR <25 - severe pulmonary disease (e.g. COPD)	At 12 months: - HF-related events (hospitalizations, ER or urgent care visits) - freedom from system-related complications	At 12 months: - no difference in HF-related events (did not meet primary efficacy endpoint) - 9% system-related complications (met safety endpoint)	N	N
VECTOR-HF, n=30 ⁷	V-LAP™ (Vectorious Medical Technologies)	Implantable left atrial pressure sensor that is leadless, and placed transeptally via right heart catheterization. Consists of external reader unit and software.	Non-randomized	n/a	- NYHA III - average EF 34%	- major CV event 90d prior to enrollment - severe untreated valve disease - life expectancy <12mo - CVA, TIA, or DVT 6mo prior to enrollment	At 3 months: - successful implantation and pressure measurements - freedom from study-related major adverse cardiac/neurological events	At 3 months: - 30 out of 30 successful implantation and measurements - no major adverse events At 12 months: - No difference in HFH - 6MWT improvement - NYHA class improvement - No difference in KCCQ - No difference in NT-proBNP	N	N
MITRAL VALVE DEVICES										
Trial	Name Of Device	Mechanism	Study Design	Comparison Arm	Patient Characteristics		Primary Outcomes	Main Results	FDA Approval & Year	European Agency Approval (CE Mark)
COAPT, n=614 ^{8,9}	MitraClip™ (Abbott)	Percutaneous Edge to edge mitral valve repair to improve	RCT	GDMT alone	- NYHA II-IV (ambulatory) - EF 20-50%	- major CV event or procedure 30d prior to enrollment	- HFH or death	2yr analysis: reduced HFH and death 5yr analysis: same as above	Y (2013)	Y

		MR			(mean EF 31%) - moderate-severe MR (3-4+)	- severe right-sided congestive heart failure - MV area <4cm ² - COPD on oxygen				
MITRA-FR, n=307 ¹⁰	MitraClip™ (Abbott)	See above	Randomized	GDMT Alone	- NYHA II-IV - EF 15-40% - severe secondary MR	- primary MR - eligible for MV surgery - PCI 30d prior to enrollment - MI 90d prior to enrollment - life expectancy <12mo	Composite outcome at 12 months: - death or unplanned HFH	No difference	Y (2013)	Y
RESHAPE-HF2, n=506 ¹¹	MitraClip™ (Abbott)	See above	Randomized	GDMT alone	- NYHA II-IV - EF 20-50% - HFH in 12 months preceding randomization or elevated proBNP - moderate-severe secondary MR	- major CV event or procedure 90d prior to enrollment - CRT implantation 90d prior to enrollment - primary MR	- Composite of HFH and CV death at 24 months - HFH at 24 months - change in baseline KCCQ score at 12 months	Ongoing (recruitment ended in Apr 2024)	Y (2013)	Y
EVOLVE-MR (n=174)*estimated (NCT03705312)	MitraClip™ (Abbott)	See above	Randomized	GDMT alone	- NYHA II-IV - EF >20% - moderate secondary MR (2-3+)	- severe MR - untreated significant CAD - MV area <4cm ²	- Change in LVEDV at 12 months - Change in 6MWT at 12 months	Ongoing	Y (2013)	Y
CLASP IID, n=300, ¹²	PASCAL™ (Edwards Lifesciences)	Percutaneous Edge to edge mitral valve repair to improve PRIMARY MR	Randomized	MitraClip™ + MitraClip™	- NYHA II-IV - EF >20% - 3-4+ secondary MR - HFH in 12 months prior to randomization or elevated proBNP	- MV anatomy not suitable for either device - untreated significant CAD - any prior MV intervention - severe AS, AR, or carotid stenosis	- Major adverse events - MR improvement	PASCAL non-inferior to MitraClip at 1yr	Y (2022)	Y
CLASP IIF (NCT03706833)	PASCAL™ (Edwards Lifesciences)	Percutaneous Edge to edge mitral valve repair to improve SECONDARY MR	Randomized	MitraClip™ + GDMT	- NYHA II-IV - EF >20% - 3-4+ secondary MR - HFH in 12 months prior to study or elevated proBNP	- MV anatomy not suitable for either device - untreated significant CAD - any prior MV intervention - severe AS, AR, or carotid stenosis	n/a	Ongoing	Y (2022)	Y
REDUCE FMR, n=120 ¹³	Carillon® mitral contour system (Cardiac Dimensions)	Indirect mitral annuloplasty system (cinches MV to reduce A-P diameter)	Randomized	Sham (procedure without device placement)	- NYHA II-IV - EF <50% - symptomatic secondary MR 2+ or greater	- hospitalization for MI in 90d prior to enrollment - presence of CRT - eGFR <30	- MR volume/severity - LV volumes	Reduced MR and LV volumes at 1yr	N	Y
EMPOWER (2018-ongoing) n=300 *estimated (NCT03142152)	Carillon® mitral contour system (Cardiac Dimensions)	Indirect mitral annuloplasty system (cinches MV to reduce A-P diameter)	Randomized	Sham (procedure without device placement)	- NYHA II-IV - EF <50% - symptomatic secondary MR 1+ or greater - HFH in 6 months prior to study or elevated proBNP	- presence of CRT or class I indication for CRT - severe AS - severe MAC - life expectancy <12mo	- Freedom from MAE at 30 days - hierarchical composite endpoint of death, transplant or LVAD, percutaneous or surgical mitral valve intervention, HFH, Improvement in KCCQ, and improvement in six-minute walk distance at 24 months	Ongoing	N	Y
Intrepid	Transcatheter	Transcatheter Mitral	Non-	None	- NYHA II-IV	- prior valve surgery	- Procedural outcomes,	At 30 days:	N	N

transfemoral TMVR early feasibility study, n=15 ¹⁴	Mitral valve replacement (Medtronic)	valve replacement to address MR	randomized		- EF >25% - MR 3-4+	- MI or CVA 90d prior to enrollment - Cr > 2.5	adverse events, MR/echo, HF functional outcomes	- Improved NYHA class - Improved KCCQ - Improved 6MWT		
APOLLO, n=1056 *estimated (NCT03242642)	Transcatheter Mitral valve replacement (Medtronic)	Transcatheter Mitral valve replacement to address MR	Non-randomized	none	- EF >25% - moderate-severe symptomatic MR	- prior MV procedure - prohibitive MAC	- All-cause mortality - HFH	Ongoing	N	N
SUMMIT, n=958 *estimated ¹⁵	Tendyne Transcatheter Mitral valve Implantation (Abbott)	Transcatheter Mitral valve replacement to address MR	Randomized (4 cohorts)	MitraClip™	- NYHA II-IV - EF >25% - 3-4+ secondary MR	- prior MV procedure - severe TR - AV disease requiring intervention - life expectancy <12mo	- Survival free of HFH at 12 months	Ongoing	N	Y
ENCIRCLE, n=900 *estimated (NCT04153292)	Sapien™ M3 Transcatheter Mitral valve replacement (Edwards Lifesciences)	Transcatheter Mitral valve replacement to address MR	Non-randomized	None	- NYHA II-IV - EF >25% - MR 3+ or greater	- inadequate anatomy of MV or presence of other device precluding deployment - MI or PCI 30d prior to enrollment	- Non-hierarchical composite of death and HFH	Ongoing	Y (2021)	N
HighLife TSMVR Feasibility Study, n=30 ¹⁶	HighLife Trans-Septal Mitral Valve Replacement (HighLife SAS)	Transcatheter, transseptal Mitral valve replacement to address MR	Non-randomized	None	- NYHA II-IV - EF >25% - MR 3+ or greater (90% secondary MR)	- CVA or TIA 30d prior to enrollment - severe carotid artery stenosis - life expectancy <12mo - PPM or CRT in 90d prior to enrollment	- Freedom from MAE at 30 days - device implantation success	30 days: 83% device success 1 year: high technical success rate, excellent valve function, no left ventricular outflow tract obstruction, and no need for mitral valve reintervention.	N	N
TIARA-I, n=27 *estimated (NCT02276547)	Neovasc Tiara Mitral Transcatheter Heart Valve with the Tiara Transapical Delivery System (Neovasc)	Transcatheter Mitral valve replacement to address MR	Non-randomized	None	- NYHA III-IV - EF not specified - severe symptomatic MR (stage D)	- unsuitable cardiac structure - degenerative MR deemed to be suitable for surgery	- Freedom From All-cause Mortality and MAE at 30 days	Ongoing	N	N
Cephea Early Feasibility Study, n=30 *estimated (NCT05061004)	Cephea Mitral Valve System (Abbott)	percutaneous transvenous transseptal valve replacement technology	Non-randomized	none	MR ≥ Grade III and/or severe stenosis (mitral valve area ≤ 1.5cm ²) LVEF ≥ 30%	- Prior surgical or interventional treatment that interferes with the Cephea valve delivery or function	- Freedom from all-cause mortality at 30 days - Reduction of MR to ≤ Grade I	Ongoing	N	N
TRICUSPID VALVE DEVICES TRIAL	NAME OF DEVICE	Mechanism	STUDY DESIGN	COMPARISON ARM	Patient Characteristics		PRIMARY OUTCOMES	MAIN RESULTS	FDA Approval	European Agency Approval (CE Mark)
TRILUMINATE Pivotal n=350 ¹⁷	TriClip™ Transcatheter Tricuspid Valve Repair system (Abbott Structural Heart)	Percutaneous transcatheter edge-to-edge repair (TEER) to reduce TR	Randomized	Medical therapy alone	- NYHA II-IV - severe TR	- tricuspid valve anatomy not suitable for device - presence of leads or devices interfering with device - MI or PCI 30d prior to enrollment	hierarchical composite: - death from any cause or tricuspid-valve surgery - hospitalization for HF - improvement in QOL measured by KCCQ	At 1 year: - No difference in HFH or mortality - Improved KCCQ - improved severity of TR	Y (2024)	Y

TRISCEND, n=176 ¹⁸	EVOQUE™ Tricuspid Valve Replacement System (Edwards)	Percutaneous tricuspid valve replacement	Non-randomized	None	- Symptomatic (75% NYHA III-IV) - severe TR (88%)	- tricuspid valve anatomy not suitable - planned cardiac surgery in next 12mo	- All-cause mortality - HFH, - non-elective TV re-intervention - NYHA class - 6MWT - KCCQ	At 1 year: - Reduced HFHs - Reduced TR severity - Improved NYHA class - Improved KCCQ - Improved 6MWT	Y (2024)	Y
TRISCEND II, n=150 ¹⁹	Percutaneous tricuspid valve replacement (Edwards)	Percutaneous tricuspid valve replacement	Randomized	GDMT alone	n/a	- tricuspid valve anatomy not suitable - planned cardiac surgery in next 12mo	n/a	At 6 months: - Reduced TR severity - Improved NYHA class, KCCQ, 6MWT	Y (2024)	Y
Edwards Cardioband Tricuspid Valve Reconstruction System Early Feasibility study, n=37 ²⁰	Cardioband Tricuspid Valve Reconstruction System (Edwards Lifesciences)	Treatment of functional TR via annular reduction	Non-randomized	None	- NYHA III-IV (65%) - severe TR	- PCI in 30d prior to enrollment - severe AS, AR, MR - significant untreated CAD	- major adverse events - intraprocedural success - echocardiographic parameters of TR - clinical and quality-of-life measures	At 1 year: - reduced TR severity - Improved NYHA class, KCCQ - no change in 6MWT - 8% cardiovascular mortality	N	Y
TTVR Early Feasibility Study, n=15 *estimated (NCT04433065)	Intrepid transcatheter tricuspid valve replacement (TTVR) system (Medtronic)	Intrepid transcatheter tricuspid valve replacement (TTVR) system intended for transfemoral access to deliver a self-expanding bioprosthetic valve within the tricuspid valve.	Non-randomized	None	- EF >30%	- significant untreated CAD - presence of inferior vena cava filter - evidence of severe RV dysfunction on echo - tricuspid valve anatomy not suitable	Rate of implant or delivery related serious adverse events at 30 days	Ongoing	N	N
AORTIC VALVE DEVICES TRIAL	NAME OF DEVICE	Mechanism	STUDY DESIGN	COMPARISON ARM	Patient Characteristics		PRIMARY OUTCOME	MAIN RESULT		
PARTNER 1, n=699 ²¹	SAPIENT™ heart-valve system (Edwards Lifesciences)	Transcatheter, transfemoral access aortic-valve replacement treats AS by displacing and functionally replacing native valve with a bioprosthetic valve.	Randomized	SAVR	- NYHA II-IV - EF >20% (mean 53%) - Severe AS - high surgical risk	- bicuspid or non-calcified valve - CAD requiring revascularization - severe MR or AR - Cr > 3 - MI 30d prior to enrollment	- All-cause mortality at 12 months	- TAVR non-inferior to SAVR all-cause mortality at 30d and 12mo	Y (2011)	Y
PARTNER 2, n=2032 ²²	SAPIEN XT™ heart-valve system (Edwards Lifesciences)	See above; different structure/dimensions of frame, and lower profile delivery catheter	Randomized	SAVR	- NYHA II-IV - EF > 20% (mean EF 56%) - intermediate surgical risk - severe AS	- bicuspid or non-calcified valve - CAD requiring revascularization - severe MR or AR - Cr > 3 - MI 30d prior to enrollment	- All-cause mortality or disabling stroke at 2 years	- TAVR non-inferior to SAVR for all-cause mortality and disabling stroke at 2 years - Transfemoral TAVR (as opposed to transthoracic) had fewer deaths/strokes compared to SAVR	Y (2011)	Y
PARTNER 3, n=1000 ²³	SAPIEN 3™ system (Edwards Lifesciences)	See above	Randomized	SAVR	- NYHA II-IV or asymptomatic with EF <50% - EF > 30%	- bicuspid or non-calcified valve - CAD requiring revascularization	- composite of death from any cause, stroke, or rehospitalization at 12 months	- Rate of death from any cause, stroke, or rehospitalization at 12 months was significantly lower among TAVR group vs SAVR	Y (2011)	Y

					(mean EF 65%) - low surgical risk - Severe AS	- severe MR or AR - Cr > 3 - MI 30d prior to enrollment				
TAVR UNLOAD, n=178 ²⁴	SAPIEN 3™ system (Edwards Lifesciences)	See above	Randomized	Surveillance group on GDMT alone	- NYHA II-IV - EF 20-50% - moderate AS - intermediate surgical risk	- major CV event 14d prior to enrollment - eGFR <20 - life expectancy <1yr from non-cardiac cause		- In moderate AS, TAVR is not superior to AS surveillance in morbidity or mortality		
The Evolut Low Risk Trial (Medtronic Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients), n=1414 ²⁵	CoreValve™, Evolut R™, or Evolut PRO™ valve (Medtronic)	See above	Randomized	SAVR	- NYHA I-IV - mean EF 61% - low surgical risk - severe AS or asymptomatic with very severe AS	- coronary stent placement 180d prior to enrollment - life expectancy <2yr from non-cardiac cause	- all-cause mortality or disabling stroke at 2 years	- TAVR non-inferior to SAVR for all-cause mortality and disabling stroke at 2 years - higher rate of pacemaker placement in TAVR group	Y (2015)	Y
PORTICO NG Study n=120, ²⁶	Navitor™ Transcatheter Heart Valve (Abbott)	See above	Non-randomized	None	- NYHA II-IV - mean EF 60% - Severe AS	- coronary procedure 30d prior to enrollment - life expectancy <1yr from non-cardiac cause	- all-cause mortality at 30d, 1yr, 5yrs - moderate or worse paravalvular leak at 30d	- at 1 year, 4% all-cause mortality, and 0.8% disabling stroke - at 1 year, 1% of moderate or worse paravalvular leak - 15% required pacemaker	Y (2023)	Y
Evolut™ EXPAND TAVR II Pivotal Trial, n=650 *estimated (NCT05149755)	Evolut™ PRO+ TAVR System, or Evolut™ FX TAVR System (Medtronic)	See above	Randomized	GDMT alone	- NYHA II-IV - EF 20- 60% - moderate AS	- age <65 - class I indication for cardiac surgery	- composite all-cause mortality, HFH, or medical instability leading to AV intervention at 2 years - MAE at 30 days	Ongoing	N	N
ENVISION IDE Trial, n=1500 *estimated (NCT05932615)	Navitor™ TAVI System (Abbott)	See above	Randomized	Any commercially available transcatheter AV system	- NYHA II-IV - EF >30% - low-intermediate surgical risk - severe AS	- coronary procedure 30d prior to enrollment - life expectancy <2yr - severe MR	- composite of all-cause mortality or stroke at 12 months	Ongoing	N	N
The JenaValve ALIGN-AR Pivotal Trial (ALIGN-AR), n=180 ²⁷	JenaValve Trilogly Heart Valve System (JenaValve Technology, Inc.)	Valve-anchoring system independent of aortic cusp calcification to reduce AR	Non-randomized	None	- NYHA II-IV - EF >25% (mean EF 55%) - moderate to severe AR - high surgical risk	- moderate MR or worse - coronary disease intervention 30d prior or planned within 12mo after procedure - severe RV dysfunction	- composite of all-cause mortality, stroke, major bleeding, device complications, kidney injury, vascular injury, pacemaker requirement - all-cause mortality at 1 year	- primary efficacy endpoint achieved (8% mortality) at 1 year - primary safety endpoint achieved (events in 27%) at 1 year - new pacemaker requirement in 24%	N	Y
J-Valve TF Early Feasibility Study, n=25 (NCT06034028)	J-Valve TF System (JC Medical, Inc.)	Self-expanding valve with anchors for the aortic valve leaflets to reduce AR	Non-randomized	None	- NYHA II-IV - EF > 25% - severe (3+) native AR	- anatomic criteria e.g. bicuspid AV, ascending aortic dilatation, aorto-iliac disease	- freedom from death or disabling stroke at 30d		N	N
BAROREFLEX ACTIVATION THERAPY TRIAL										
	NAME OF DEVICE	Mechanism	STUDY DESIGN	COMPARISON ARM	Patient Characteristics		PRIMARY OUTCOME	MAIN RESULT	FDA Approval	European Agency Approval

										(CE Mark)
HOPE4HF, n=146 ²⁸	BaroStim (CXRx)	Electrical stimulation of carotid baroreceptors to modulate sympathomimetic pathway of HF and reduce sympathetic tone	Randomized	GDMT Alone	- NYHA III - EF<35%	- ACS, CVA, syncope, or ICD therapy, PPM 90d prior to enrollment - BMI >40 - life expectancy <12mo	NYHA class, MLWHFQ QoL score, and 6MWT	At 6 months: - improved NYHA class, MLWHF QoL Score, 6MWT - improved NT-proBNP - 97% MANCE free rate	Y	Y
BEAT-HF, n=408 ²⁹	BaroStim (CVRx)	See above	Randomized	GDMT alone	- NYHA III (95%) - EF <35%	- ACS, CVA, TIA, or PCI 90d prior to enrollment - receiving CRT or class I indication for CRT - BMI >40	NYHA class, MLWHFQ QoL score, and 6MWT	At 6 months: - improved NYHA class, MLWHF QoL Score, 6MWT - improved NT-proBNP - 97% MANCE free rate	Y	Y
BATwire Implant Kit (NCT04600791)	BaroStim (CVRx)	See above	Non-randomized	None	- ambulatory - BMI <40 - suitable carotid anatomy	- ACS, CVA, TIA, or PCI 90d prior to enrollment - clinically significant structural heart disease	- serious adverse events between implant and 30 days post-implant - 6MWT at 6 months	Ongoing	N	N
VAGAL NERVE STIMULATION TRIAL	NAME OF DEVICE	Mechanism	STUDY DESIGN	COMPARISON ARM	Patient Characteristics		PRIMARY OUTCOMES	MAIN RESULTS	FDA Approval	European Agency Approval (CE Mark)
ANTHEM-HF, n=60 ³⁰	Demipulse Model 103 pulse generator and PerenniaFLEX Model 304 lead; (Cyberonics™)	Reduce sympathetic overactivity and enhance parasympathetic activity, reducing cardiac workload	Mixed (randomized and non-randomized analyses)	- Right vs left vagal nerve implant - self comparison within whole group	- NYHA II-III - EF<40% - on GDMT	n/a	- incidence of procedure and device-related adverse events (safety endpoint) - changes in LVEF and LVESV at 6 month (efficacy endpoint)	At 6 months: - LVEF improvement - NYHA class improvement - 6MWT improvement - 1 device-related death	***FDA approved for epilepsy	Y
ANTHEM-HFpEF, n=532 ³¹	VNS device (LivaNova VNS Therapy® system)	See above	Randomized	n/a	n/a	- ACS in 90d prior to enrollment - severe valve disease requiring surgery - eGFR <30 - life expectancy <12mo	n/a	Trial terminated, results not yet published	N	Y
ANTHEM-HFpEF, n=52 ³²	VNS device (LivaNova VNS Therapy® system)	See above	Non-randomized	None	- NYHA II-III, - EF ≥40% - on GDMT	- ACS in 90d prior to enrollment - severe valve disease requiring surgery - eGFR <30 - life expectancy <12mo	- Incidence of procedure and device-related complications at 12 months	At 12 months: - no device-related malfunctions or unexpected device-related adverse events - NYHA class improvement - LVEF remained preserved/slightly reduced - No change in NT-pro-BNP	N	Y
INOVATE-HF, n=707 ³³	VNS device (BioControl CardioFit system)	See above	Randomized	GDMT alone	- NYHA class III - EF ≤35%	- ACS 90d prior to enrollment - Cr >3	- composite of death from any cause or first event for worsening HF	At 16 months (median): - no difference in composite of death or HF exacerbation	N	N

TRIAL	NAME OF DEVICE	Mechanism	STUDY DESIGN	COMPARISON ARM	Patient Characteristics		PRIMARY OUTCOMES	MAIN RESULTS	FDA Approval	European Agency Approval (CE Mark)
REBALANCE-HF, n=100 ³⁷	Splanchnic ablation for volume management (SAVM) (Satera System, Axon Therapies)	Interrupt splanchnic nerve signaling by delivering radiofrequency energy through an intravascular catheter to redistribute volume within splanchnic vasculature	Randomized	Sham control	- symptomatic HFpEF (EF ≥ 50%) - elevated PCWP at rest or exertion (≥ 25 mmHg) - evidence of diastolic dysfunction via echocardiography	- MI, PCI, or CRT 90d prior to enrollment - EF <40% in 3yrs prior to enrollment - BMI >45 - systolic BP <100mmHg - eGFR <25	- primary efficacy endpoint: change in mean PCWP at 1 month - primary safety endpoint: device- or procedure-related serious adverse events at 1 month	At 1 month: - 1 safety event (worsening HF event) - reduced PCWP during exercise At 12 months: - NYHA class improvement - KCCQ improvement - 6MWT improvement - NT-proBNP unchanged	N	N
SPLANCHNIC III (NCT04575428)	Splanchnic nerve block (Duke University)	Unilateral celiac plexus block with botulinum toxin to redistribute splanchnic volume	Non-randomized	none	- NYHA stage II-IV, (Class C-D) - History of HFH or ER visit or iv diuretic use in last 12 months - no LVEF criteria	- severe valve disease requiring intervention - STEMI or type I NSTEMI 7d prior to enrollment - anticoagulation agents at time of procedure	- peak exercise PCWP at 4 weeks - peak PA pressure at 4 weeks - absence of nerve block-associated complications at 8 weeks	n/a	N	N
CARDIAC CONTRACTILITY MODULATION (CCM)										
TRIAL	NAME OF DEVICE	Mechanism	STUDY DESIGN	COMPARISON ARM	Patient Characteristics		PRIMARY OUTCOMES	MAIN RESULTS	FDA Approval	European Agency Approval (CE Mark)
FIX-HF-5C study, n= 160 ³⁸	OPTIMIZER system (Impulse Dynamics)	Delivers high-voltage, non-excitatory electrical impulses to the RV septum during absolute refractory period in diastole, thus enhancing myocardial function at the cellular level	Randomized	GDMT alone	- NYHA III-IV - EF 25-45% - QRS <130ms	- MI within 90d of enrollment - has potentially correctable cause of HF e.g. valve disorder	- Peak VO2 - proportion of subjects who did not experience either an OPTIMIZER device-related complication or a procedure-related complication by 24 weeks	At 24 weeks: - improvement in peak VO2 difference - improvement in NYHA class, MWLHF, and 6MWT - acceptable safety profile ~10% device-related events - reduced composite CV death and HFH	Y (2019)	Y
Cardio-microcurrent device for chronic heart failure: first-in-human clinical study, n=10 ³⁹	Cardiac microcurrent device (C-MIC; Berlin Heals)	Electrical potential gradient plays a central role in maintaining sufficient myocardial function	Non-randomized	none	- non-ischemic cardiomyopathy - NYHA III - EF < 35%	- previous cardiac procedures - presence of any implantable electronic device (e.g. PPM, ICD)	- feasibility and safety in incidence of adverse events	- no deaths, 1 LV lead misplacement - NYHA class improvement (8 out of 10 pts) - 6MWT improvement - SF-36 questionnaire improvement - LVEF improvement	N	Y

								- LV end-diastolic diameter and LV end-systolic diameter improvement		
C-MIC III, n=92 *estimated (NCT04662034)	Cardiac microcurrent device (C-MIC; Berlin Heals)	See above	randomized	GDMT alone	- NYHA III-IV - EF 25-35%	- has potentially correctable cause of HF e.g. valve disorder - eGFR <45 - Hgb <12 (male) <10 (female) - presence of CRT or indication for CRT	- change in LVEF at 6 months	n/a	N	Y
STRUCTURAL DEVICES TRIAL	NAME OF DEVICE	Mechanism	STUDY DESIGN	COMPARISON ARM	Patient Characteristics		PRIMARY OUTCOMES	MAIN RESULTS	FDA Approval	European Agency Approval (CE Mark)
REDUCE LAP-HF, n=68 ⁴⁰	InterAtrial Shunt Device (Corvia Medical)	Self-expanding metal stent with a double-disc shape and a central opening that creates an inter-atrial communication, in an attempt to decompress the left atrium and reduce pulmonary pressures during exercise	Non-randomized	None	- NYHA II-III - EF ≥40% - PCWP >15 at rest or >25 with exercise	- MI or PCI 90d prior to enrollment - AVR 12mo prior - CRT 6mo prior - MR 3+, TR 2+, AR 2+, or > moderate AS - eGFR <25	- procedure related safety outcomes and MACE at 6 months - change in PCWP at rest or exercise at 6 months - presence of left-to-right atrial shunt at 6 months	At 6 months: - no procedure complications - no MACEs - PCWP improvement at rest and exercise - Cardiac output improvement - NYHA class improvement - 6 MWT improvement - MLWHF score improvement - exercise time improvement	Y	Y
REDUCE LAP-HF I, n=44 ⁴¹	InterAtrial Shunt Device (Corvia Medical)	See above	Randomized	Sham control	- NYHA III-IV - EF ≥40% - PCWP >15 at rest or >25 with exercise	- MI or PCI 90d prior to enrollment - AVR 12mo prior - CRT 6mo prior - MR 3+, TR 2+, AR 2+, or > moderate AS - eGFR <25	- change in exercise PCWP at 1 month - MACE/major renal events at 1 month	At 1 month: - PCWP improvement - no MACE/renal events in intervention group	Y	Y
REDUCE LAP-HF II, n=626 ⁴²	InterAtrial Shunt Device II (Corvia Medical)	See above	Randomized	Sham control	- symptomatic HF - EF ≥40% - PCWP >25 with exercise	- MI or PCI 90d prior to enrollment - AVR 12mo prior - CRT 6mo prior - MR 3+, TR 2+, AR 2+, or > moderate AS - eGFR <25	Composite outcome: - CV death or nonfatal ischemic stroke at 12 months - rate of total HF events at 24 months - change in KCCQ score	- no difference in primary composite outcome (death/HF events/KCCQ score) or in individual components of primary endpoint at 12 or 24 months - no difference between groups in composite safety endpoint	Y	Y
First-in-Human Experience With the V-Wave System, n=38 ⁴³	First-generation V-Wave Interatrial Shunt (V-Wave)	Hourglass-shaped, self-expanding, percutaneously implanted device to shunt blood from left atrium to right atrium	Non-randomized	n/a	- NYHA III despite GDMT - EF >40% - at least 1 HFH within last 12 months - NT-proBNP >1500	- EF <15% - CVA or thromboembolic event 6mo prior to enrollment - eGFR <25	- device- or procedure-related major adverse cardiovascular and neurological events at 3 and 12 months - procedural success, defined as successful device implantation with no periprocedural death	- successful implantation in all patients, 1 periprocedural cardiac tamponade At 12 months: - 50% of shunts had stenosis or occlusion - NYHA class improvement - KCCQ & MLWHF improvement - 6MWT improvement - no change in echo evaluation of left or right sided function	N	Y

								- decreased mortality and HFHs in patients with patent shunts		
RELIEVE-HF, n=508 ⁴⁴	Ventura Shunt (revised version of the V-wave interatrial shunt)	See above	Randomized	Sham control (right heart catheterization and invasive echo without shunt placement)	- NYHA II-IV on GDMT - at least 1 HFH within last 12 months - NT-proBNP >1500	- Stroke or TIA or DVT within the last 6 months - Moderate to severe aortic or mitral stenosis - eGFR <25 - RV dysfunction (TAPSE <12mm or RVFAC ≤25%) - Left Ventricular End-Diastolic Diameter >8cm	- device-related major adverse cardiovascular or neurologic events at 3 months - hierarchical composite of death from any cause; heart transplant or LVAD; HFH; worsening of outpatient HF events; and change in quality of life (KCCQ)	- no major device-related safety event in either group - no difference in primary composite outcome	N	Y
CorCinch-HFrEF, n=22* estimated (NCT03533517)	AccuCinch Ventricular Restoration System (Ancora Heart Inc.)	catheter-delivered ventriculoplasty system which deploys anchors under the mitral annulus to reduce LV dimensions. Aims to reverse detrimental LV remodeling in cardiomyopathy, and reduce wall tension.	Non-randomized	n/a	- NYHA III-IV (ambulatory) - EF 20-40% - stably on >3 months of GDMT	- MI or PCI 90d prior to enrollment - MR 3+ or severe TR - eGFR <30 - CVA 90d prior to enrollment - life expectancy <12mo	- Device-related or procedure-related major adverse events within 30 days	n/a	N	Y
CorCinch-EU, n=122 *estimated (NCT03183895)	AccuCinch Ventricular Restoration System (Ancora Heart Inc.)	See above	Non-randomized	n/a	- NYHA III-IV (ambulatory) - EF 20-40% - stably on >3 months of GDMT	- non-dilated cardiomyopathy (e.g. HCM) - CVA or MI 30d prior - MV area <4cm ² - any prior MV procedure eGFR <30	- Device-related or procedure-related major adverse events within 30 days	n/a	N	Y
CorCinch-FMR, n=35 *estimated (NCT02806570)	AccuCinch Ventricular Restoration System (Ancora Heart Inc.)	See above	Non-randomized	n/a	- functional MR (at least moderate; 2+) - NYHA II-IV (ambulatory) - EF 20-60% - stably on >1 months of GDMT	- MI, PCI, or carotid surgery 30d prior - moderate or worse AS or AR	- Device-related or procedure-related major adverse events within 30 days	n/a	N	Y
CorCinch-HF, n=400 *estimated (NCT04331769)	AccuCinch Ventricular Restoration System (Ancora Heart Inc.)	See above	Randomized	GDMT	- NYHA II-IV (II only if HFH within last 12 months) - EF 20-40%	- MI, PCI, carotid surgery, or cardiac surgery 90d prior - unsuitable ventricular anatomy - MR 3+, TR 4+, AR 2+ - eGFR <25 - life expectancy <12mo	At 6 months: - Device-related or procedure-related major adverse events - KCCQ change from baseline - 6MWT change from baseline At 1 year: - Device-related or procedure-related major adverse events - hierarchical composite of: all-cause mortality, LVAD/heart transplant, HFHs, KCCQ change	n/a	N	Y
Revivent TC	Revivent TC®	Transcatheter	Non-	n/a	- NYHA	- calcified myocardium in	At 12 months:	At 12 months:	N	Y

System, n=89 ⁴⁵	Transcatheter Ventricular Enhancement System (Bioventrix)	placement of internal and external anchors to exclude scarred myocardium from viable tissue, closing a portion of the LV chamber	randomized		functional class II-IV - EF >15% and ≤45% - MI at least 90 days prior to study - LV anterior/apical dyskinesia	akinetic region - diastolic dysfunction (E/A ratio > 2) - MR 1+ or worse - PPM lead in apical RV - Cr >2 - life expectancy <12mo	- change in LV end systolic/diastolic index - change in LVEF	- LV volumes improved - LVEF improved - NYHA class improvement - MLWHF improvement - 6MWT improvement - 3 procedure-related deaths - proBNP reduction (not statistically significant)		
REVIVE-HF, n=180 (NCT03845127)	Revivent TC® Transcatheter Ventricular Enhancement System (Bioventrix)	See above	Randomized (2:1)	GDMT alone	- similar to above but details not available	- MI 90d prior to enrollment - calcified myocardium in akinetic region - diastolic dysfunction (E/A ratio > 2) - MR 1+ or worse - PPM lead in apical RV - Cr >2 - life expectancy <12mo	- 6MWT at 3 and 6 months	Ongoing	N	Y

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