

# RESHAPING THE VENTRICLE: CORCINCH AND THE GEOMETRY REVOLUTION

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April 16<sup>th</sup>, 2026

# HEART FAILURE STATISTICS, 2025

- 1.2 million primary HF hospitalizations, 2022
- 45% of cardiovascular deaths due to Heart Failure, 2022
  
- Approximately 1 in 4 individuals will develop HF in their lifetime
- Approximately 6.7 millions Americans over the age of 20 have HF
- 8.7 million - 2030, 10.3 million - 2040, 11.4 million - 2050
  
- 2020, Direct medical cost, 32 billion, Indirect medical cost, 14 billion
- Projected medical cost 2050, 142 billion
  
- 1- year mortality rate of 13.5% in ambulatory adults
- 1 year post discharge mortality rate is 35% in patients greater than 65 years old

# REVERSE REMODELING, A GOAL FOR HF THERAPY

STATE-OF-THE-ART PAPER

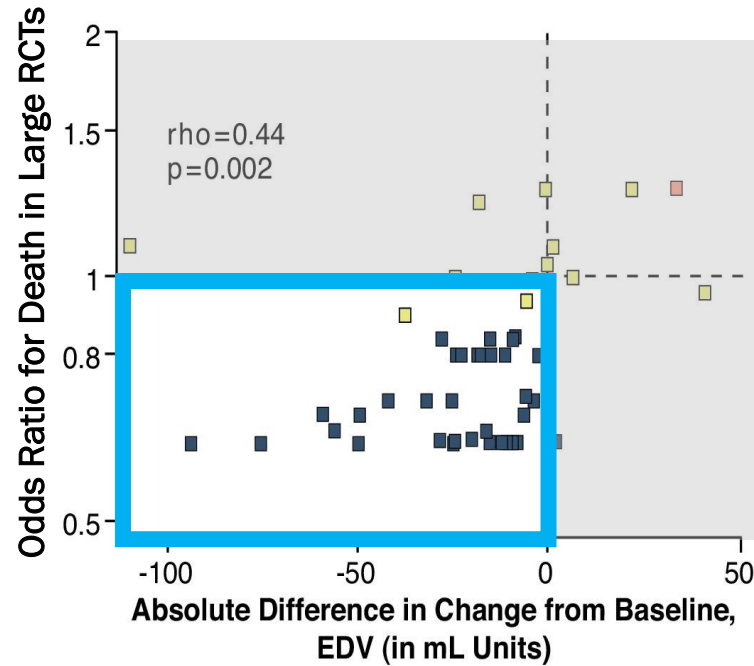
## Left Ventricular Remodeling in Heart Failure

Current Concepts in Clinical Significance and Assessment

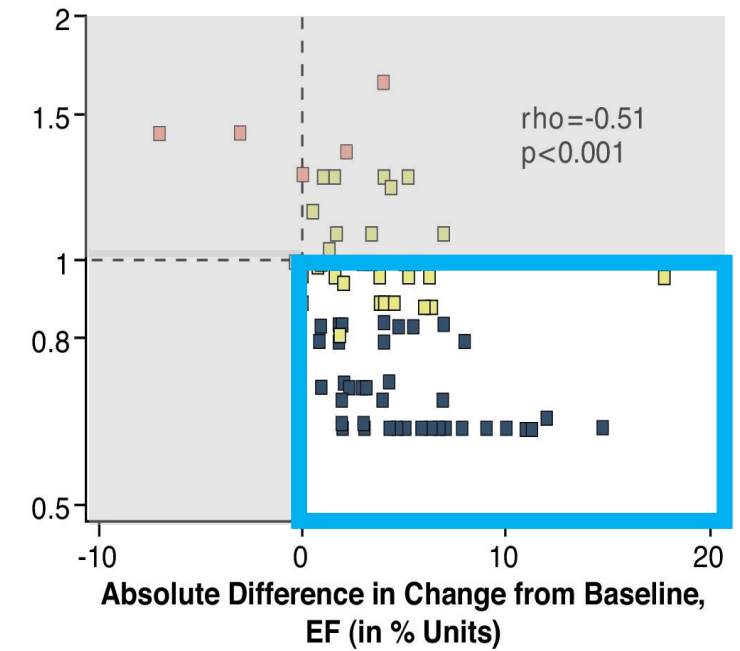
Marvin A. Konstam, MD, Daniel G. Kramer, MD, Ayan R. Patel, MD,  
Martin S. Maron, MD, James E. Udelson, MD

Boston, Massachusetts

*LV volume stands out among surrogate markers as strongly correlating with the impact of a particular drug or device therapy on patient survival.*

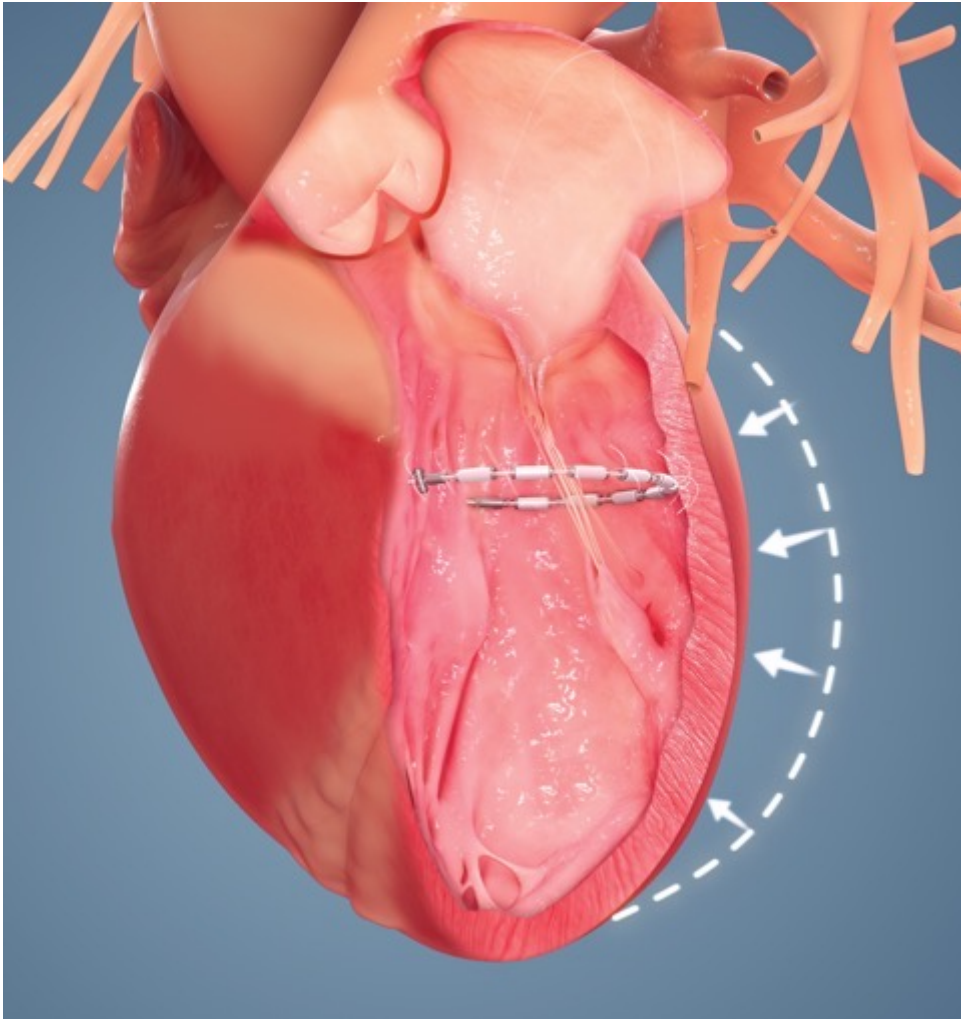


Reduced LVEDV (mL)



Increased LVEF (%)

# ACCUCINCH- DIRECT REDUCTION OF LV SIZE



## APPROACH:

Transcatheter device to treat the dilated left ventricle (LV)

## MECHANISM:

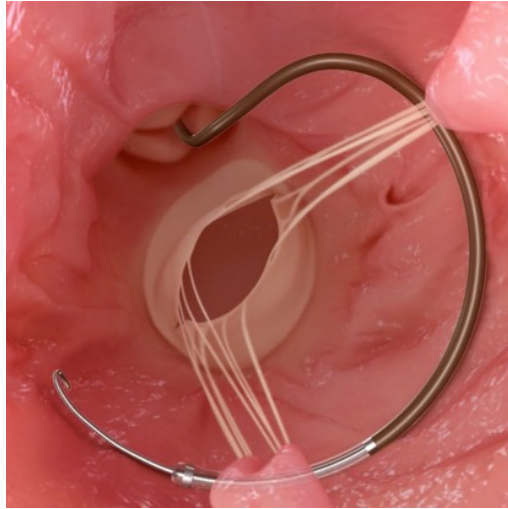
LV size reduction → LV wall stress reduction → Initiation of biological reverse remodeling

## GOAL:

Improve quality of life, functional capacity, HF hospitalization rate, and life expectancy

# ACCUCINCH PROCEDURE, 3 STEPS

## ACCESS

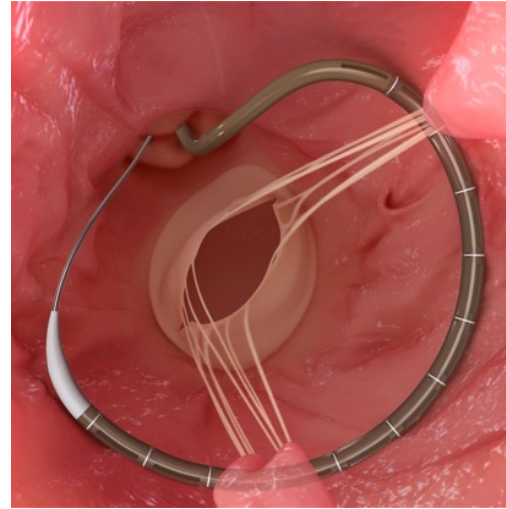


LV ACCESS USING  
THE ACCUCINCH  
**GUIDE CATHETER**

LV FREE WALL  
GUIDEWIRE  
PLACEMENT WITH  
THE ACCUCINCH

**NAVCATH**

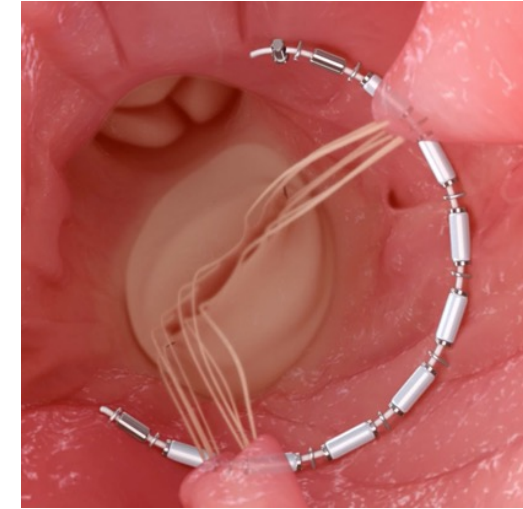
## DELIVERY



ADVANCEMENT  
OF THE  
ACCUCINCH  
**TRACCATH**

DELIVERY OF THE  
ACCUCINCH  
IMPLANT

## CINCH

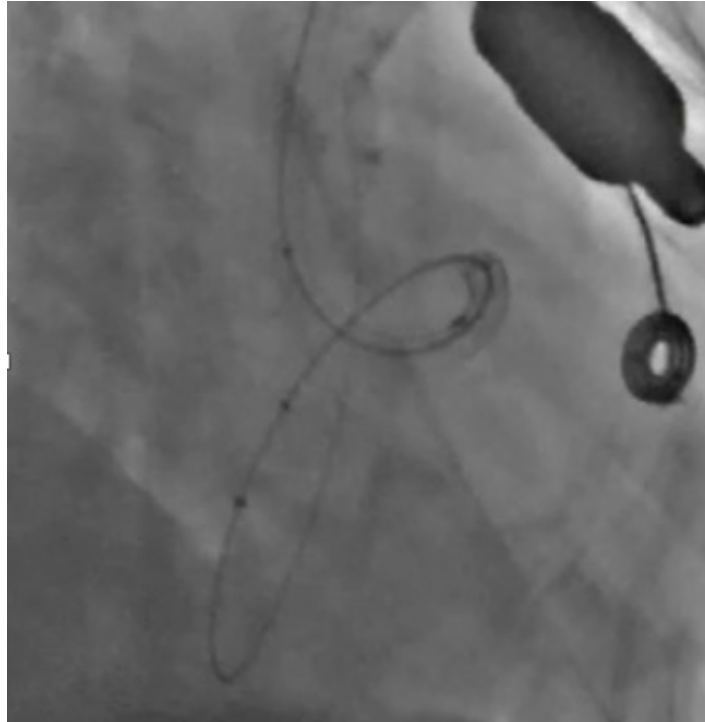


COMPLETION OF  
THE ACCUCINCH  
PROCEDURE BY  
**CINCHING** AND  
ACUTELY  
REDUCING THE  
SIZE OF THE LEFT  
VENTRICLE

# ACCESS

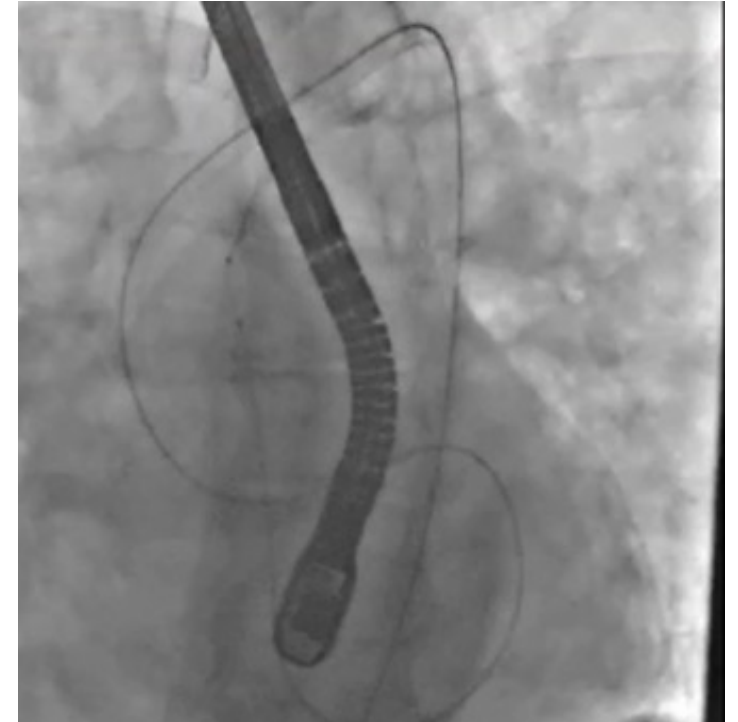


**Guide Catheter**  
position in the LV,  
relative to the MV



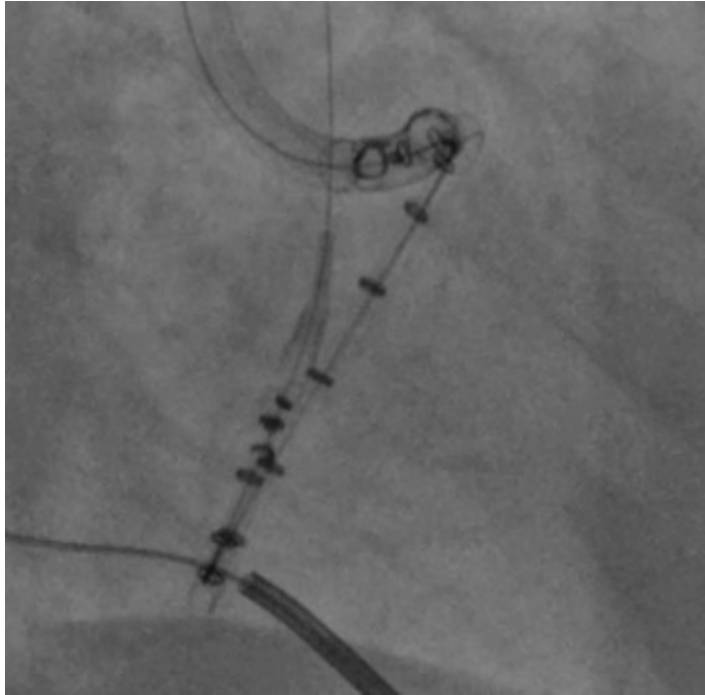
Circumferential wiring  
of the LV, facilitated  
by the **NavCath**

NavCath position facilitated by  
TEE



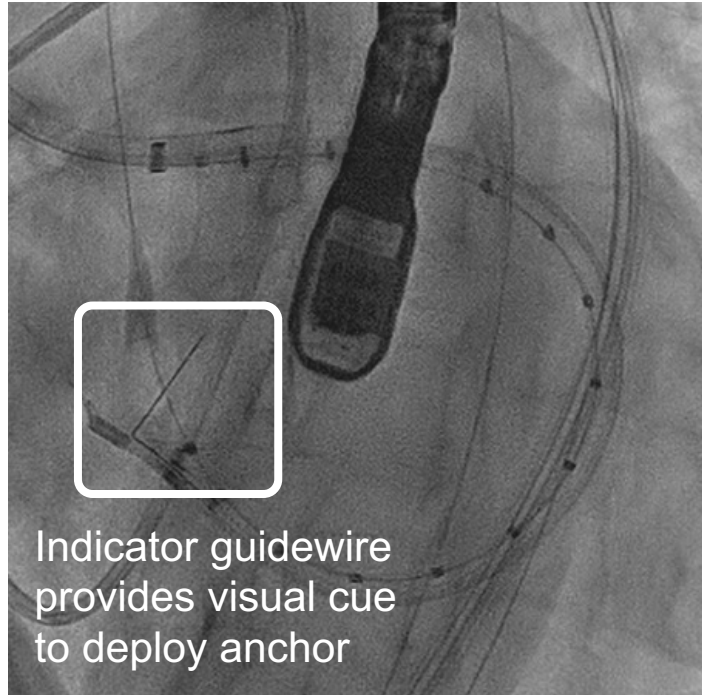
Final position of the  
guidewire, parked in  
the descending aorta

# DELIVERY

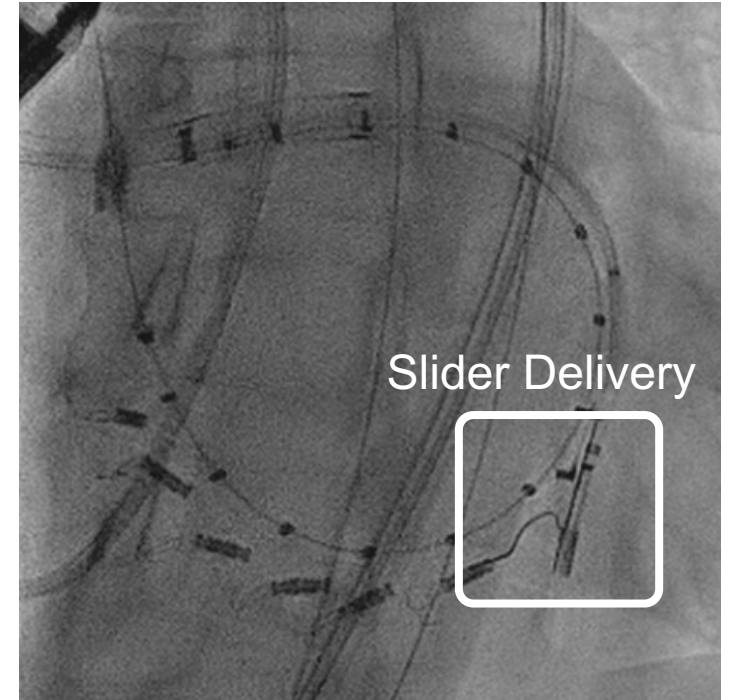


**TracCath** positioned parallel to and ~10 to 15 mm below the mitral plane

TracCath position facilitated by TEE



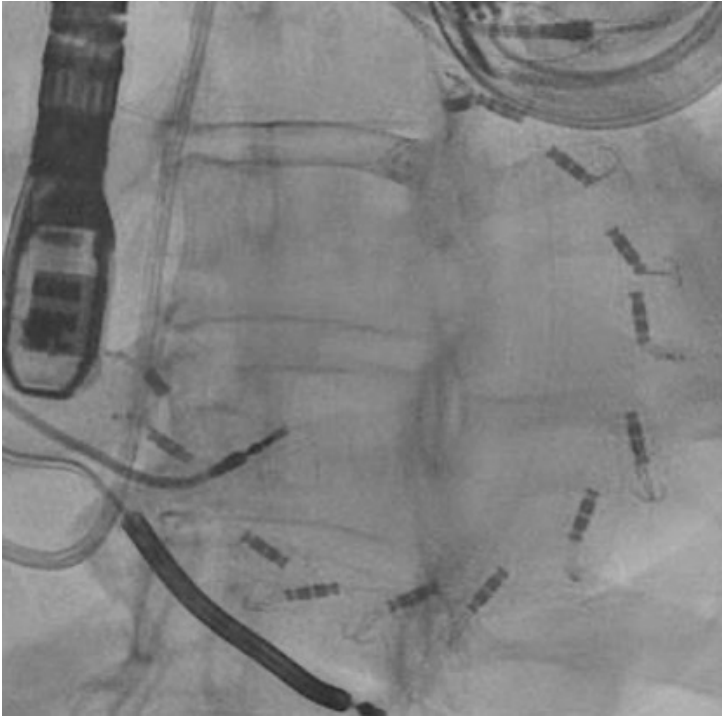
Indicator guidewire provides visual cue to deploy anchor



Slider Delivery

**Anchor + Slider** delivery sequence repeated until desired implant length reached

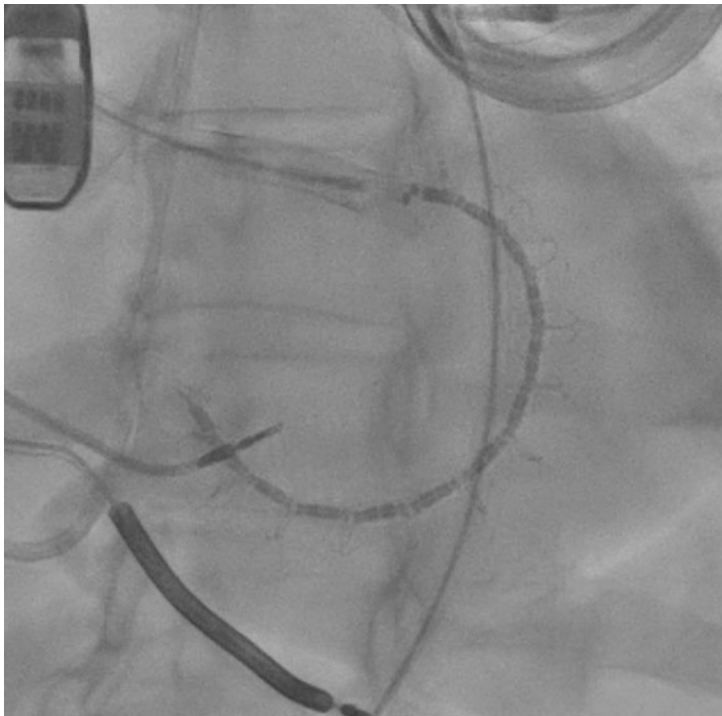
# CINCH



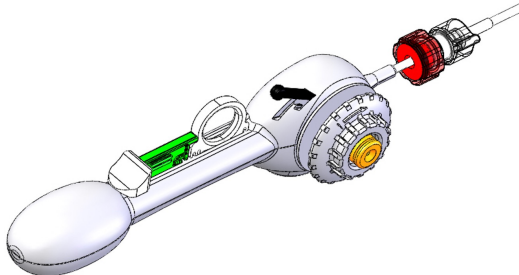
**Pre-Cinch**



**In-Process**



**Complete Cinch**  
(Prior to Lock deployment)



## Transcatheter Left Ventricular Restoration in Patients With Heart Failure

NADIRA HAMID, MD,<sup>1,2</sup> ULRICH P. JORDE, MD,<sup>3,4</sup> MARK REISMAN, MD,<sup>5</sup> AZEEM LATIB, MD,<sup>3,4</sup> D. SCOTT LIM, MD,<sup>6</sup> SUSAN M. JOSEPH, MD,<sup>7</sup> ALENA KURLIANSKAYA, MD, PhD,<sup>8</sup> OLEG POLONETSKY, MD, PhD,<sup>9</sup> PETR NEUZIL, MD, PhD,<sup>9</sup> VIVEK REDDY, MD,<sup>10</sup> JASON FOERST, MD,<sup>11</sup> HEMAL GADA, MD, MBA,<sup>12</sup> KENDRA J. GRUBB, MD, MHA,<sup>13</sup> GUILHERME SILVA, MD,<sup>14</sup> DEAN KEREIAKES, MD,<sup>15</sup> SATYA SHREENIVAS, MD,<sup>15</sup> SEAN PINNEY, MD,<sup>16</sup> GIEDRIUS DAVIDAVICIUS, MD, PhD,<sup>17</sup> PAUL SORAJJA, MD,<sup>18</sup> JOHN P. BOEHMER, MD,<sup>19</sup> FRANZ X. KLEBER, MD, PhD,<sup>20</sup> PATRICK PERIER, MD,<sup>21</sup> NICOLAS M. VAN MIEGHEM, MD, PhD,<sup>22</sup> NICOLAS DUMONTEIL, MD,<sup>23</sup> MARTIN B. LEON, MD,<sup>1,2</sup> AND DANIEL BURKHOFF, MD, PhD<sup>2</sup>

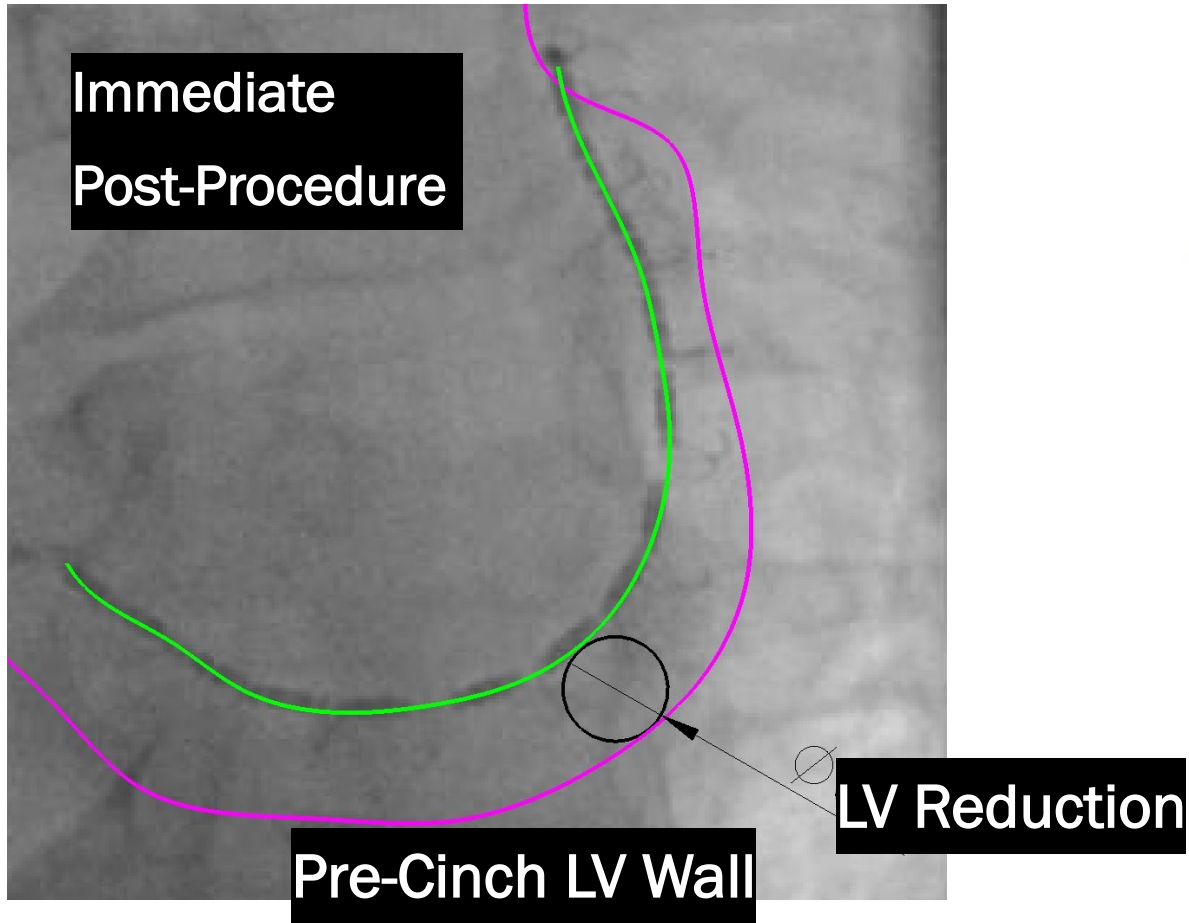
N = 51

LVEF 20-40%

MR grade  $\leq$  2+

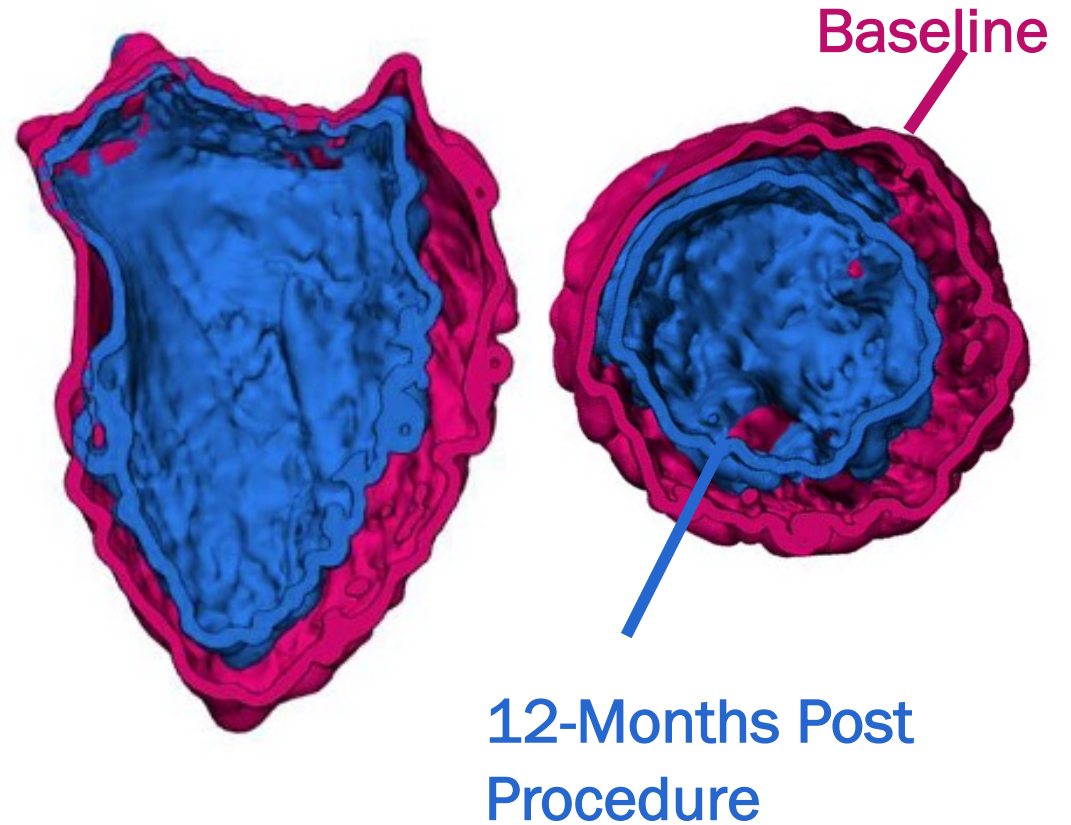
LVEDD > 5.5

# ACUTE LV REDUCTION



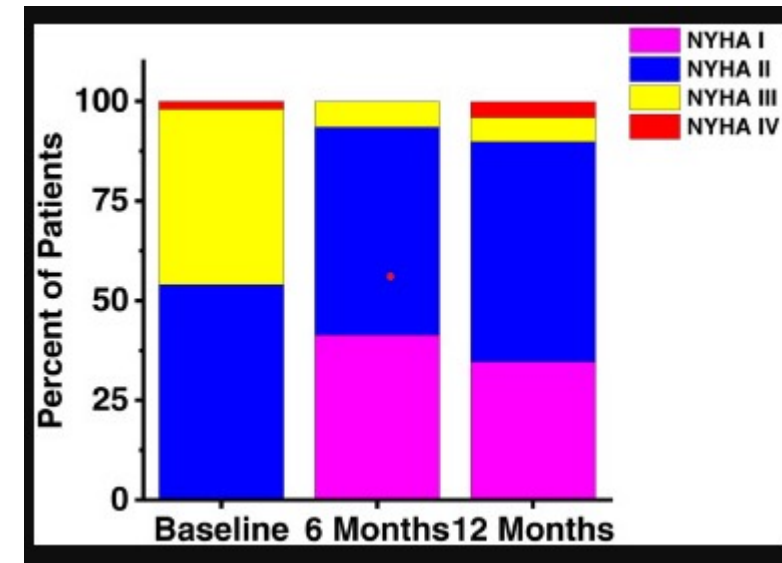
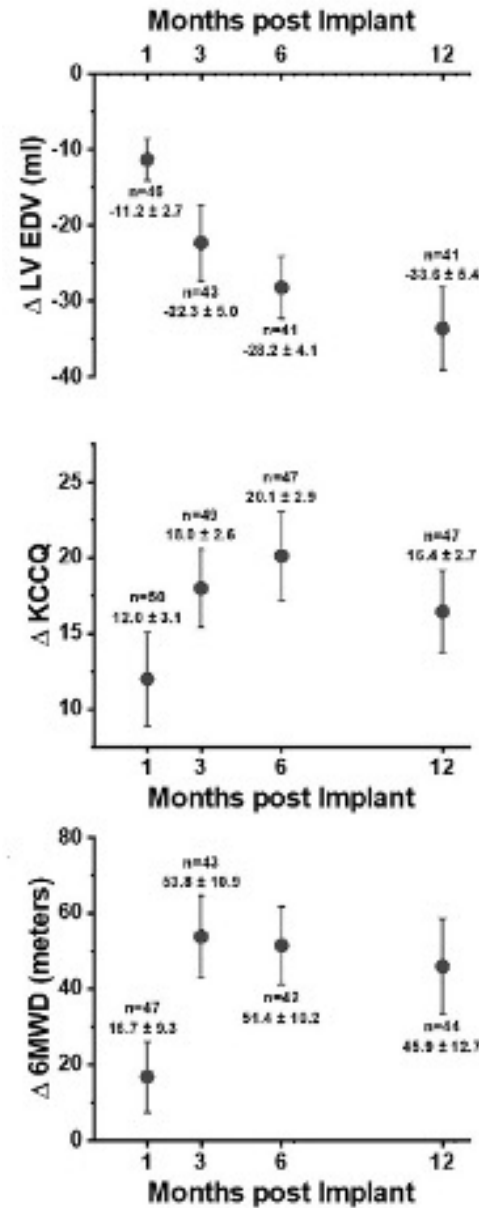
131 mins, 13 anchors, LV reduction 9.3 mm

Cardiac CT



# OUTCOMES AT 1 YEAR

- Progressive reverse remodeling (LVEDV)
- Improvement in LVEF
- Improvement in KCCQ-OS
- Improvement in 6MWT
- Improvement in NYHA



# SAFETY AT 2 YEARS

MAE categories	Definitely Related	Possibly Related
<b>Device related complications</b>		
Death	0	0
Stroke	0	1
MI	0	0
Need for non-elective cardiovascular surgery, pericardial effusion/tamponade	1	0
Need for non-elective cardiovascular surgery, aortic valve damage	0	0
Need for MCS >24 hours for worsening HF	0	0
Acute kidney injury, requiring RRT	0	0
<b>Procedure related femoral artery access-related complications</b>		
Need for non-elective cardiovascular surgery, femoral artery access events	3	0

# PATIENT OUTCOMES AT 2 YEARS

-Heart Transplants, 0

-LVADs, 3

-Deaths, 5

-Significant decrease rate of HF hospitalizations post procedure

-90% survival at 2 years

# OUTCOMES AT 2 YEARS

Improvement of End Diastolic Volume (LVEDV)

-30ml

Improvement of Ejection Fraction (LVEF)

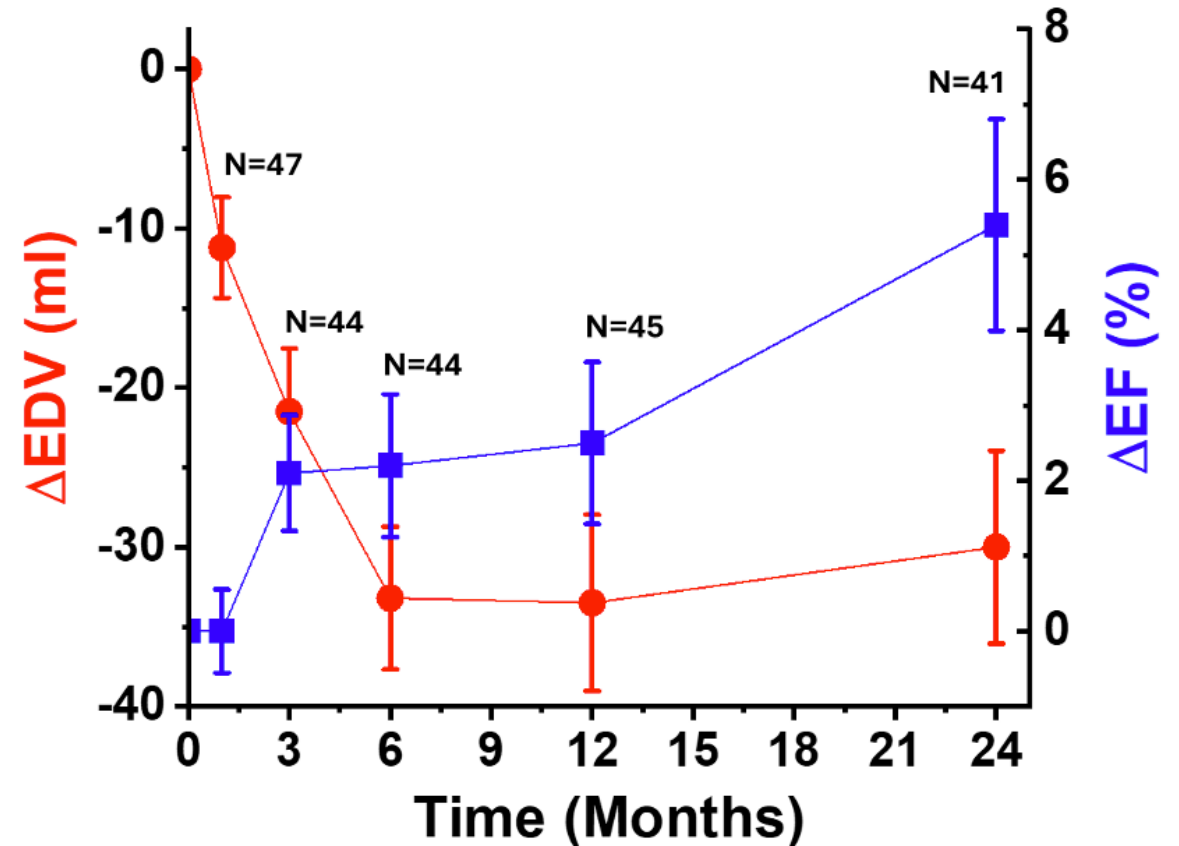
+5.4%

NYHA improved or unchanged

98%

NYHA class improvement  $\geq 1$

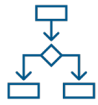
60%



# THE CORCINCH-HF STUDY / IDE PIVOTAL TRIAL ([NCT04331769](https://clinicaltrials.gov/ct2/show/study/NCT04331769))



**DESIGN:** Prospective, randomized, open-label, multi-center clinical safety and efficacy investigation in patients with symptomatic HFrEF



**RANDOMIZATION:** 1:1 - Treatment with the AccuCinch System plus GDMT or GDMT alone



**ENROLLMENT:** 400 randomized subjects at up to 80 centers, globally



**ENDPOINTS:** Safety & efficacy evaluated when 250 subjects reach 6-mo follow-up, and when 400 subjects reach 12-mo follow-up

## KEY ELIGIBILITY CRITERIA

- **LVEF:** 20-40%
- **NYHA:**
  - II with HF hosp. in the past 12 mo.
  - III
  - IV ambulatory
- **LVEDD:**  $\geq 55$  mm
- **MR:**  $\leq 2+$

## Study Leadership

**Chairman:**

Martin Leon, MD

**Co-Principal Investigators:**

Mark Reisman, MD

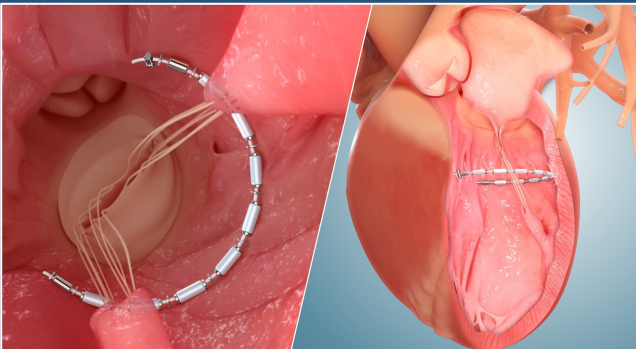
Ulrich Jorde, MD

**Local Principal Investigator: Gerin Stevens, MD**

# WHEN AND WHOM TO CONSIDER FOR THE CORCINCH-HF STUDY

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Adult HFrEF patients  
who remain  
symptomatic despite  
guideline-directed  
medical therapy (GDMT)



- **HF etiology:** Ischemic or non-ischemic
- **Reduced ejection fraction:** LVEF 20 - 40%
- **Dilated left ventricle:** LVEDD  $\geq$  55 mm
- **Non-significant mitral regurgitation:** MR  $\leq$  2+
- **Maximally tolerated GDMT:** 4-Pillar Rx, +/- ICD, CRT and/or TEER
- **Symptomatic:** NYHA II (with recent hospitalization or outpatient intensification of treatment), III, or IV (amb); 6MWT 100 to 450 m

**Local Principal Investigator: Gerin Stevens, MD**

# THANK YOU

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April 16<sup>th</sup>, 2026

END

	<b>n=51</b>	<b>Cardiac Rhythm Management Devices</b>		<b>TTE Measurements</b>	
<b>Age, years</b>	56.3 ± 13.1 [33 - 87]	<b>None</b>	27 (52.9%)	<b>LVEF, %</b>	29.8 ± 5.1 [20.7 – 39.4]
<b>Gender, Male</b>	44 (86.3%)	<b>ICD</b>	14 (27.5%)	<b>MR Grade</b>	
<b>DCM-Ischemic Etiology</b>	13 (25.5%)	<b>CRT</b>	10 (19.6%)	<b>0</b>	
<b>Hypertension</b>	33 (64.7%)	<b>NYHA Classification</b>		none/trace	
<b>Hyperlipidemia</b>	32 (62.7%)	<b>II</b>	27 (54.0%)	1+	17 (33.3%)
<b>Atrial Fibrillation</b>	10 (19.6%)	<b>III</b>	22 (44.0%)	1+ mild-moderate	14 (27.5%)
<b>Diabetes</b>	12 (23.5%)	<b>IV</b>	1 ( 2.0%)	2+	10 (19.6%)
<b>Prior CABG</b>	8 (15.7%)	<b>TTE Measurements</b>		2+ moderate	10 (19.6%)
<b>Prior PCI</b>	9 (17.6%)	<b>LVESV, ml</b>	150.0 ± 47.8 [63.3 – 292.8]	≥3+	0 ( 0.0%)
<b>Prior Stroke</b>	5 (9.8%)	<b>LVEDV, ml</b>	211.5 ± 60.0 [96.5 – 372.3]		
<b>Prior TIA</b>	0 (0.0%)	<b>LVESD, cm</b>	5.6 ± 0.7 [3.7 - 7.1]		
		<b>LVEDD, cm</b>	6.6 ± 0.6 [5.0 - 7.9]		

# HEART FAILURE STATISTICS, 2025

