Transcatheter LV Restoration: The AccuCinch® Ventricular Restoration System

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Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

AFFILIATION/FINANCIAL RELATIONSHIP
Consulting Fees/Honoraria

COMPANIES
- Abbott Vascular
- Ancora Heart
- Boston Scientific
- Edwards LifeSciences
- Medtronic

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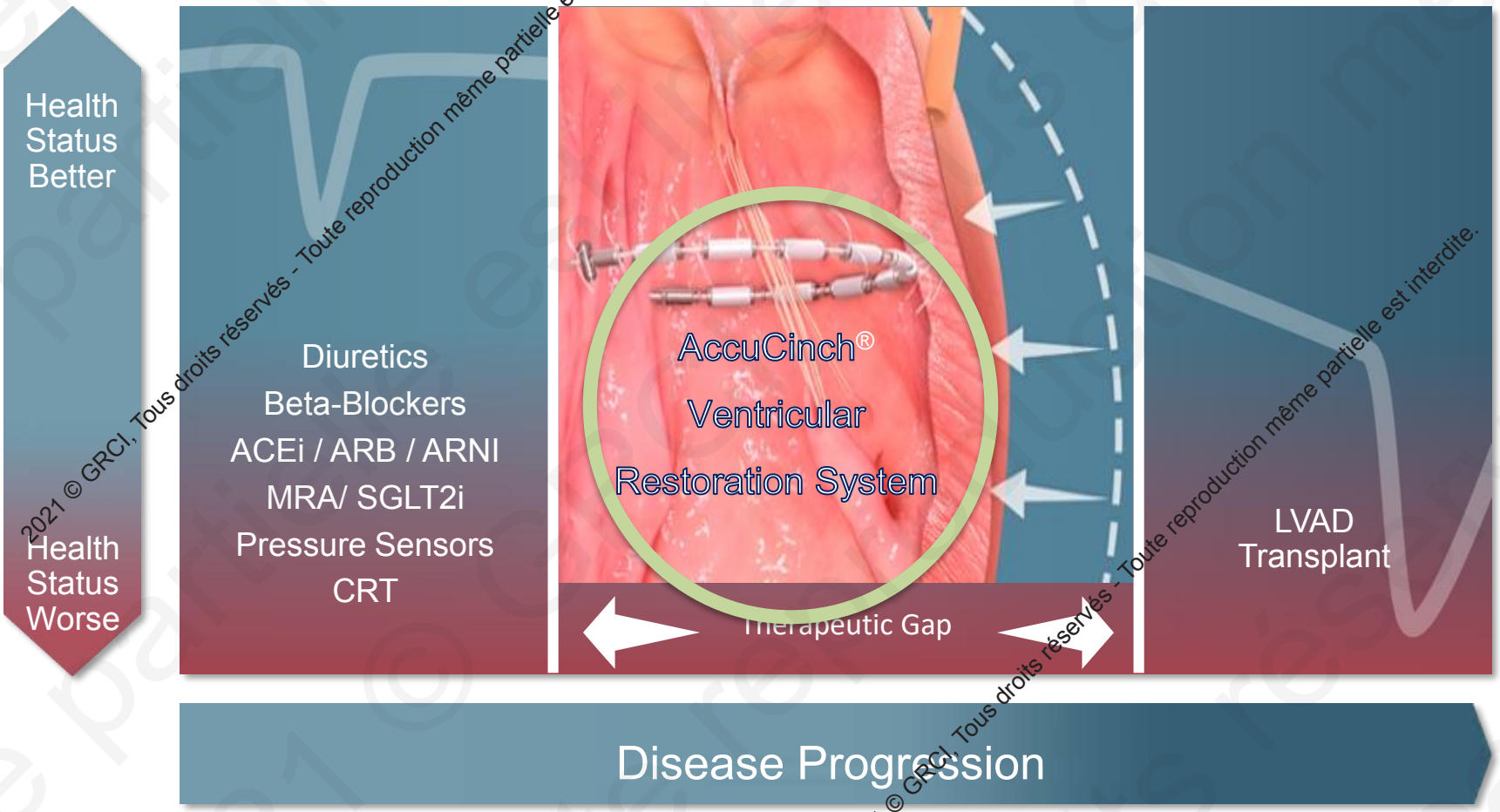
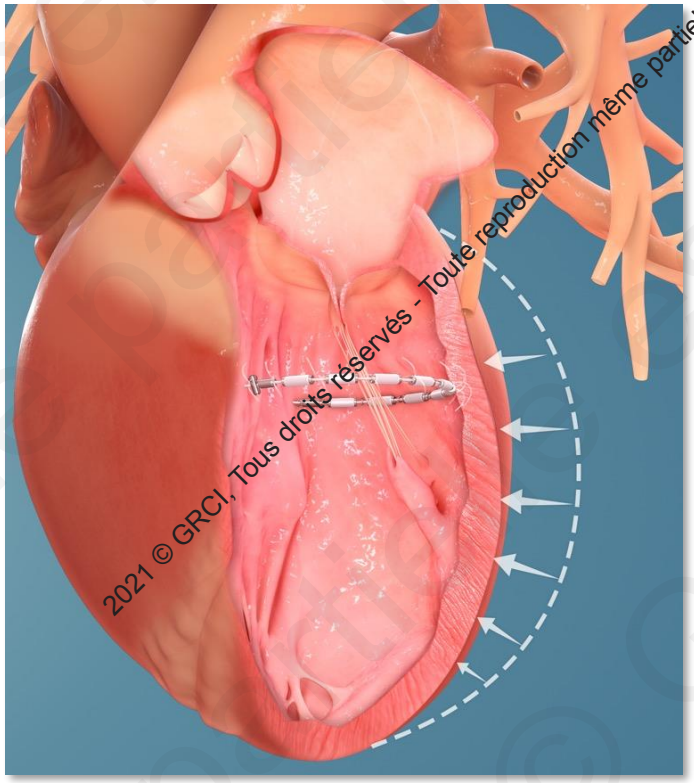
Therapeutic Gap in the Treatment of HFrEF



AccuCinch® Ventricular Restoration System

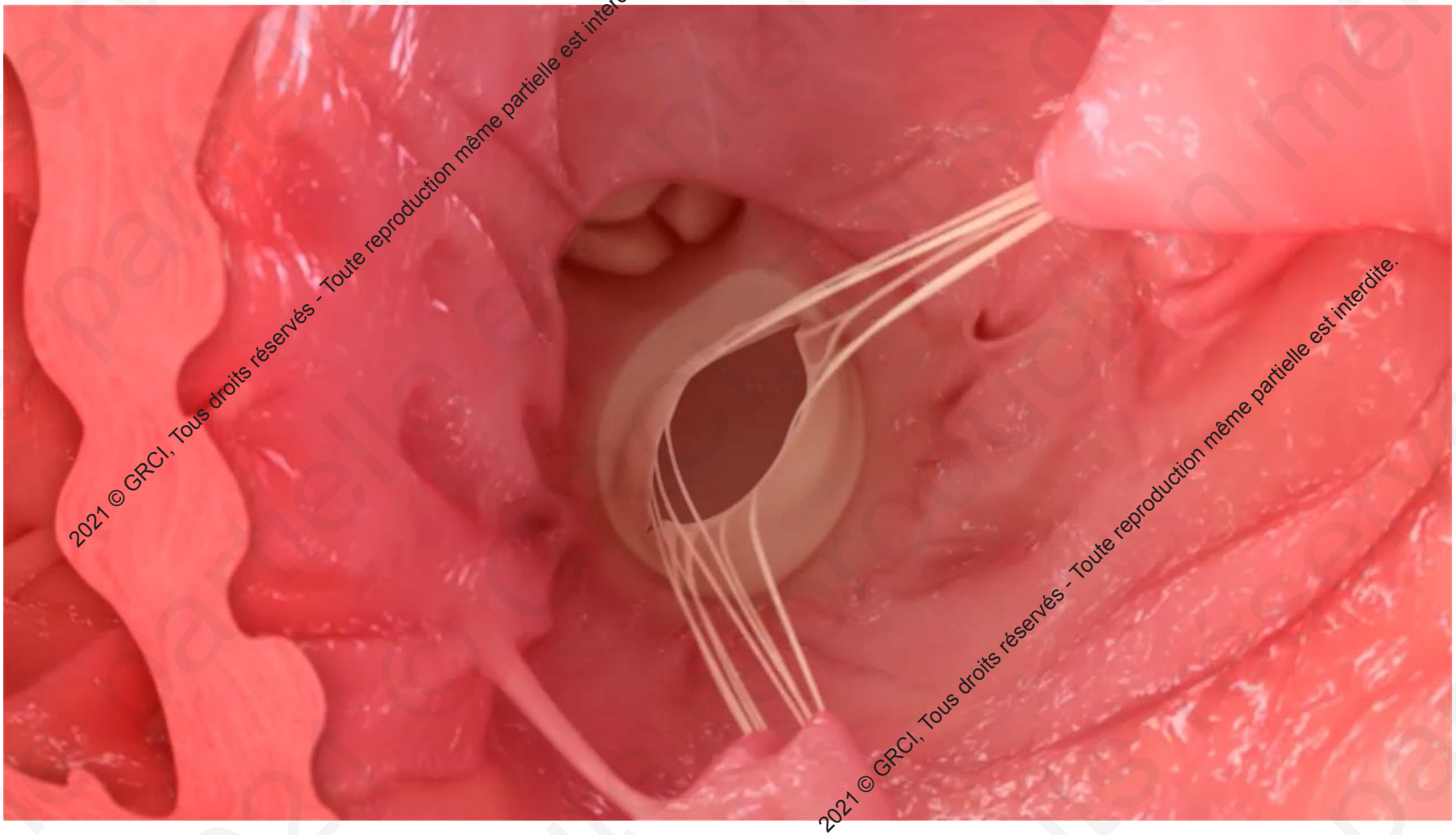


Transcatheter, device therapy intended to restore, support and strengthen the dilated left ventricle

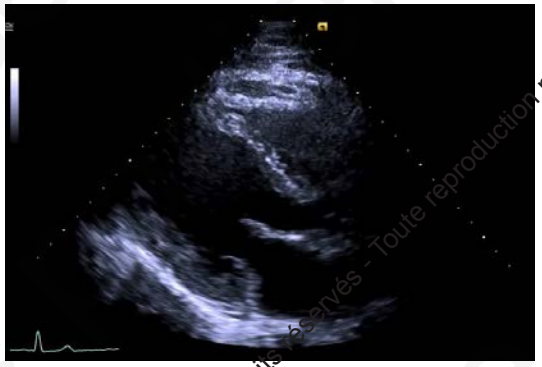
Reduces LV dimensions and LV wall stress and may initiate a biologic process of reverse-remodeling to improve myocardial contractility and overall cardiac function

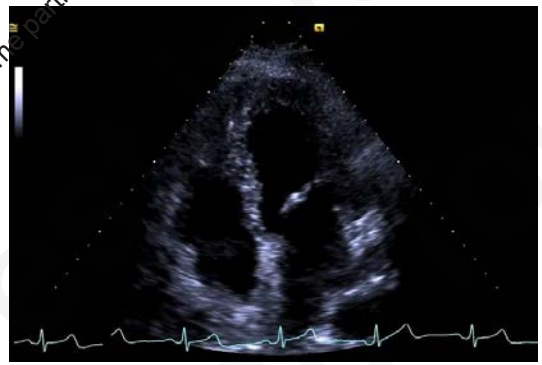
CAUTION -- Investigational device. Limited by United States law to investigational use
WARNING – Exclusively for Clinical Investigations

AccuCinch® System – Procedure



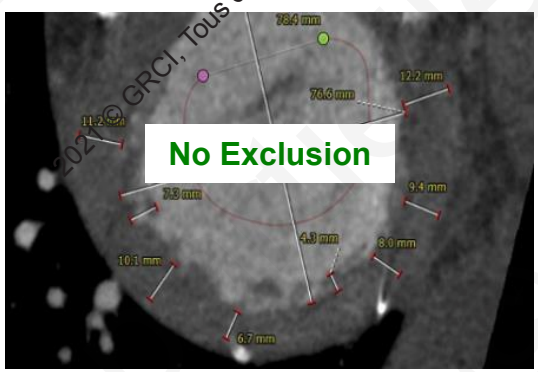
Screening – Imaging

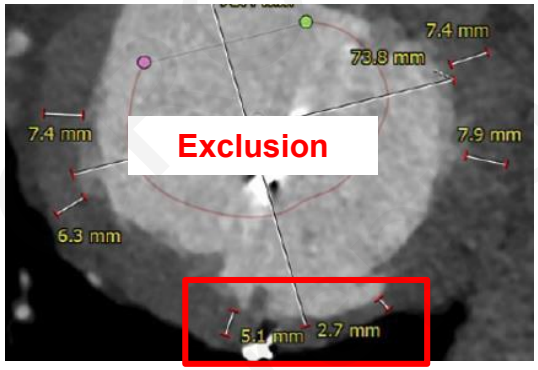




Transthoracic Echocardiography

Inclusion Criteria:
LVEF 20-40%
LVEDD ≥ 55 mm
MR ≤ 2+





Thin LV Wall

Full Gated Cardiac CT with Contrast

LV Wall Thickness Criteria: **~6 mm**

Core lab analyzed

Screening – Optimization of GDMT

What Medications are Required?

- ☑ ACEi / ARB / ARNI
- ☑ Beta-blocker
- ☑ MRA
- ☑ Ivabradine (when indicated)
- ☑ Vasodilators (when indicated)
- ☑ SGLT2i (recommended, not yet required)

What Dosage is Required (and for How Long)?

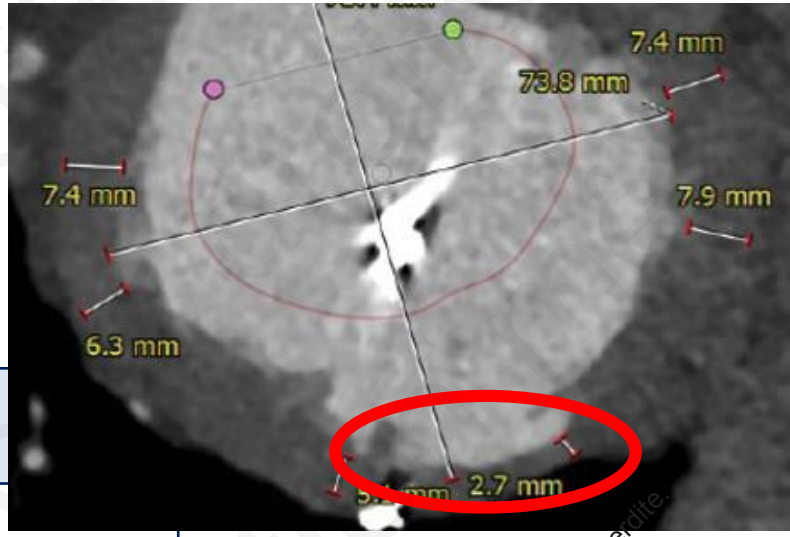
- ☑ Maximum dose or maximally tolerated dose
- ☑ Stable* for at least 30 days

What Documentation is Required?

- ☑ Reason for why not on the Rx or why not at max dose
- ☑ Documentation from the medical record for each reason

*Stable = Dosage change does not exceed 100% increase or 50% decrease in total dose OR there is a dose-for-dose equivalent change within medication class

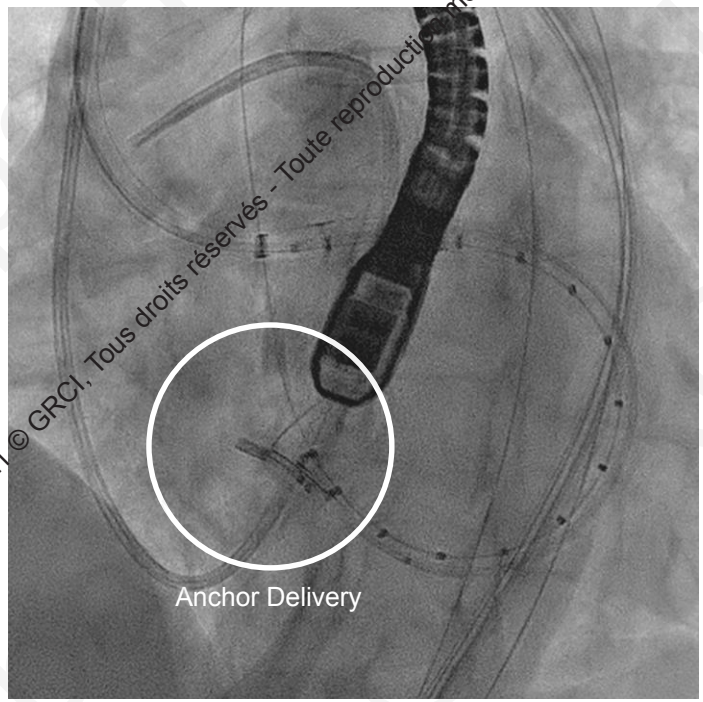
Screening – Failure

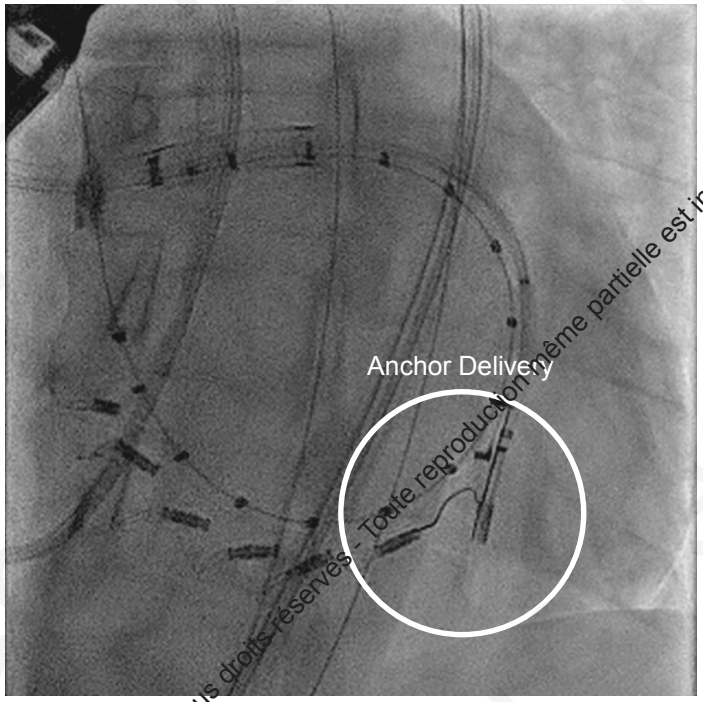


Most Common Screen Failures

- ☑ Anatomical (Thin Walls, Femoral Access…)
- ☑ LVEDD ≤ 55 mm
- ☑ EF (out of range)
- ☑ Moderate/Severe Aortic Valve Stenosis/Prosthesis
- ☑ Severe MR – TR
- ☑ Prior Surgical Valve Intervention
- ☑ Consent Withdrawn

AccuCinch® System – Procedure – Implant Delivery





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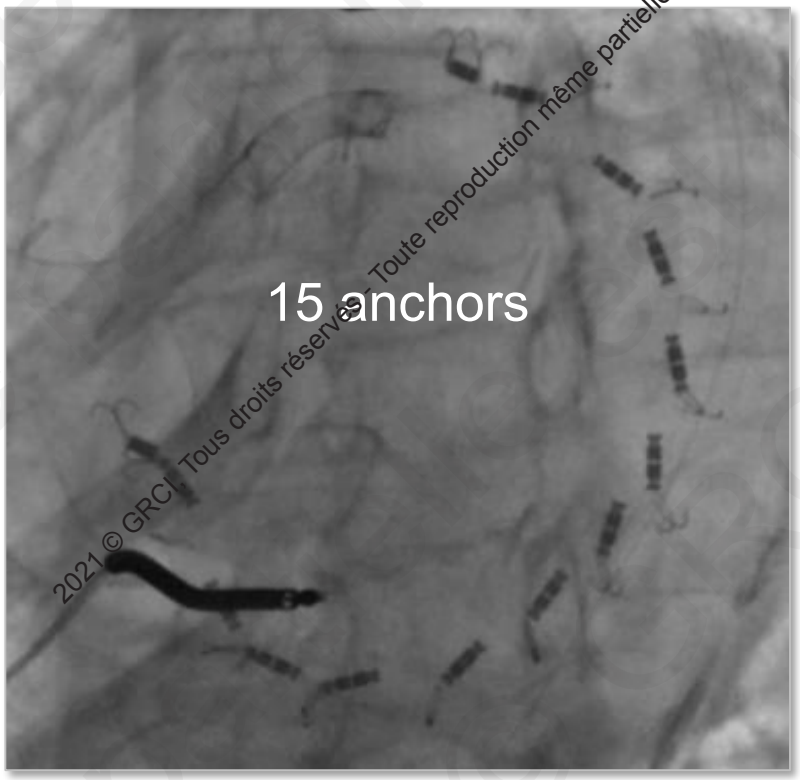
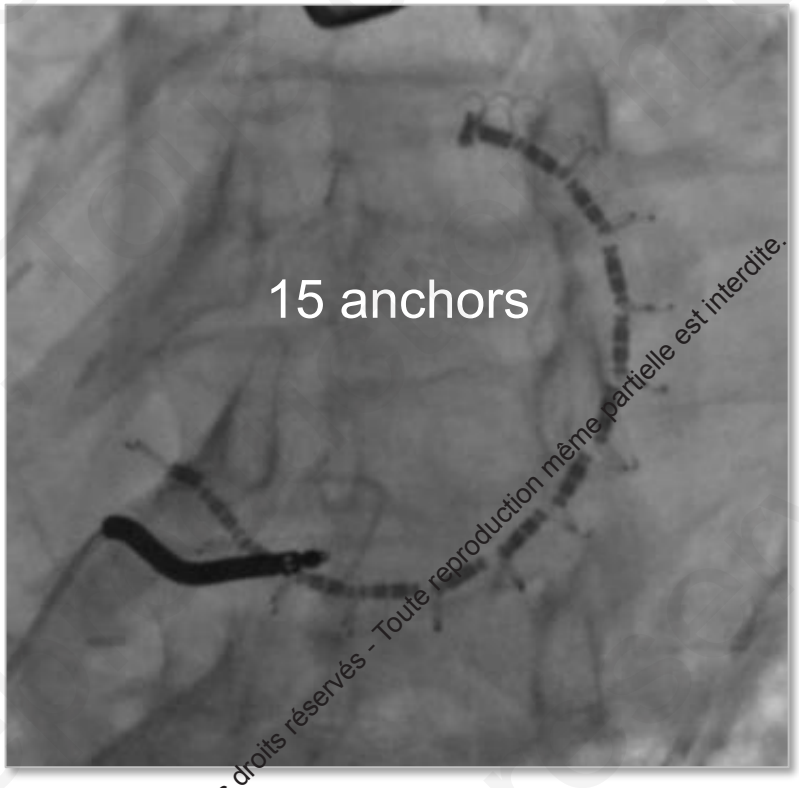
AccuCinch® System – Procedure – Cinching



Pre-Cinch

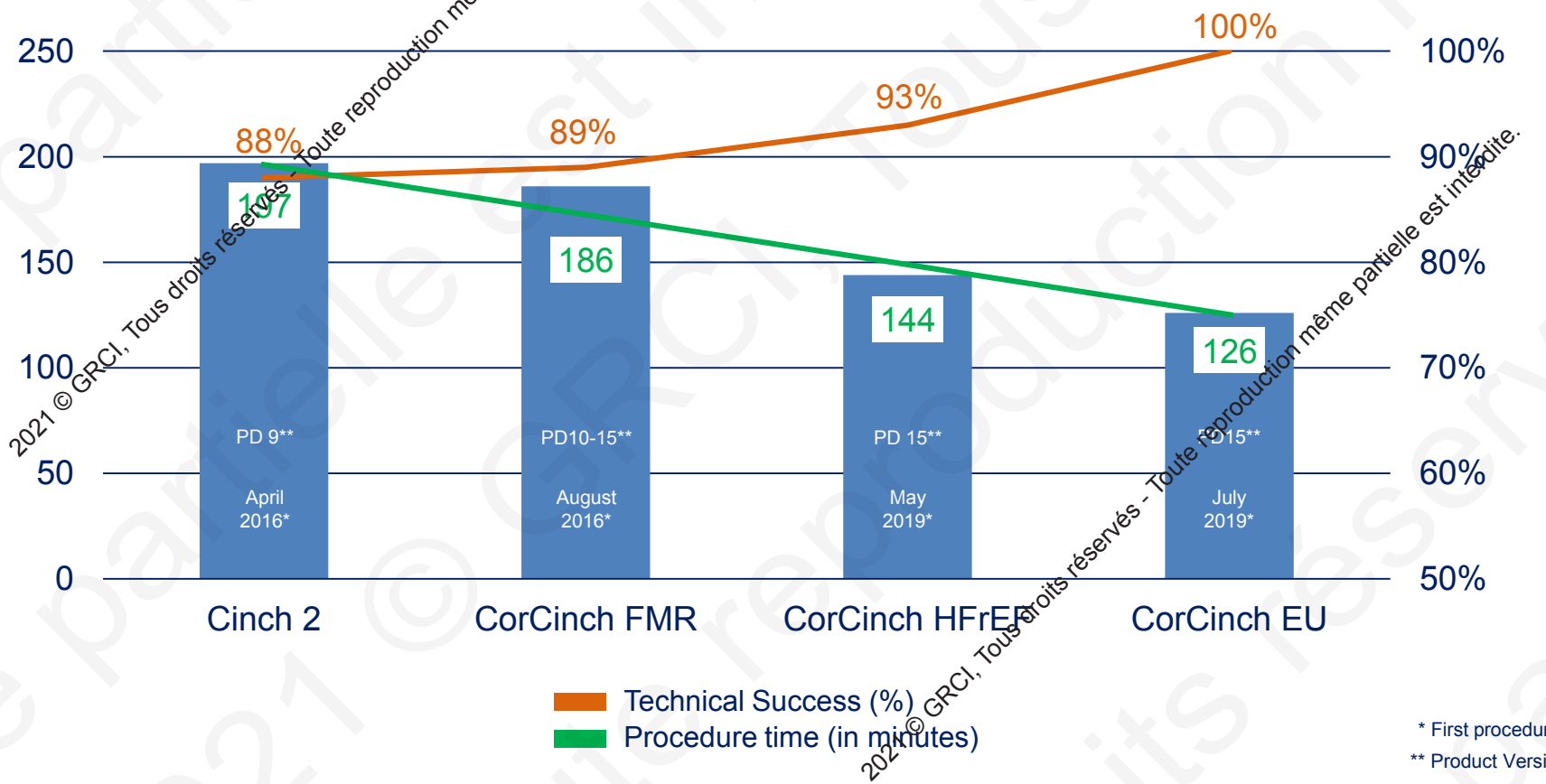


Post-Cinch

Decreasing Procedure Times

VS

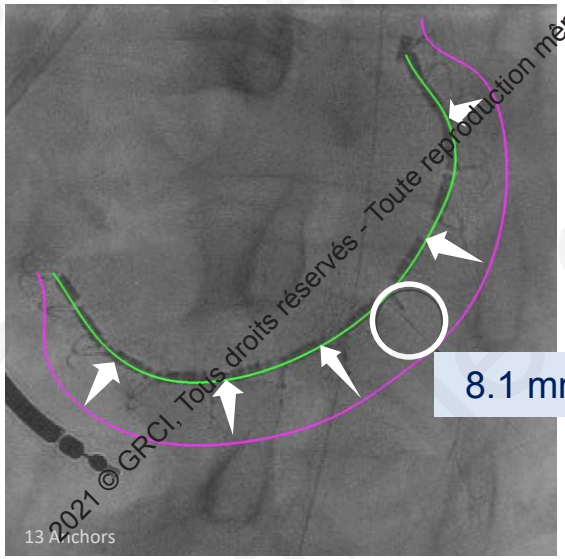
Increasing Technical Success

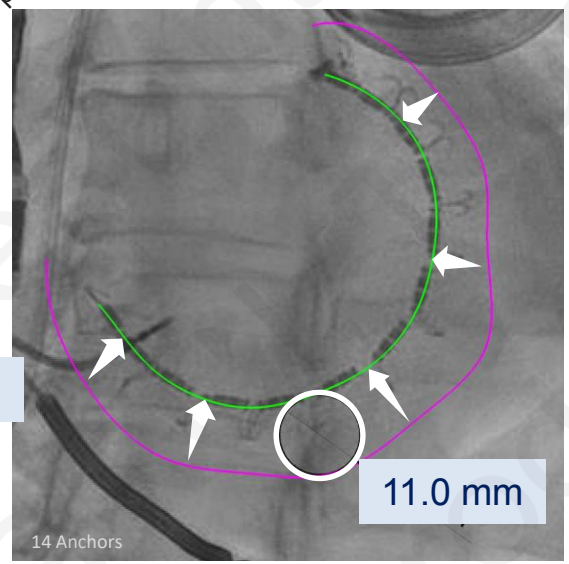


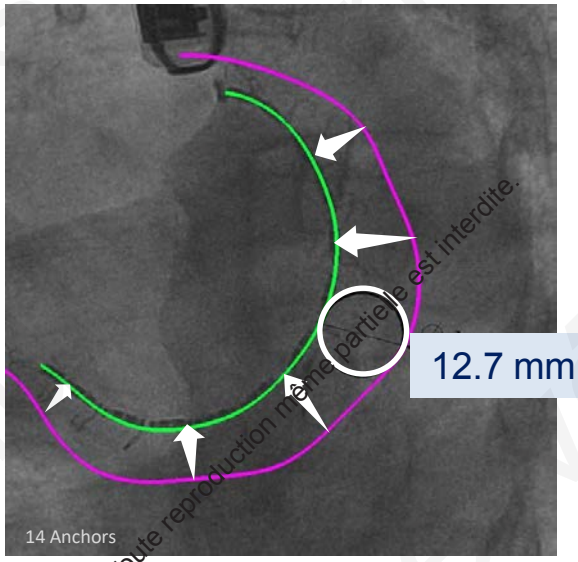
* First procedure

** Product Version

Acute Procedural Results – Reduction in LV Dimensions







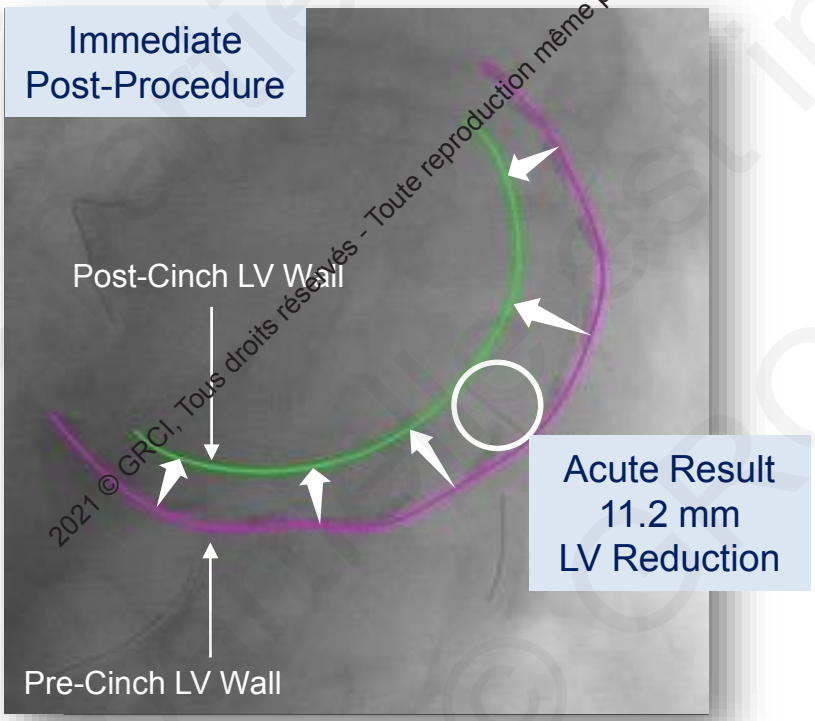
LV Reduction	8.1 mm

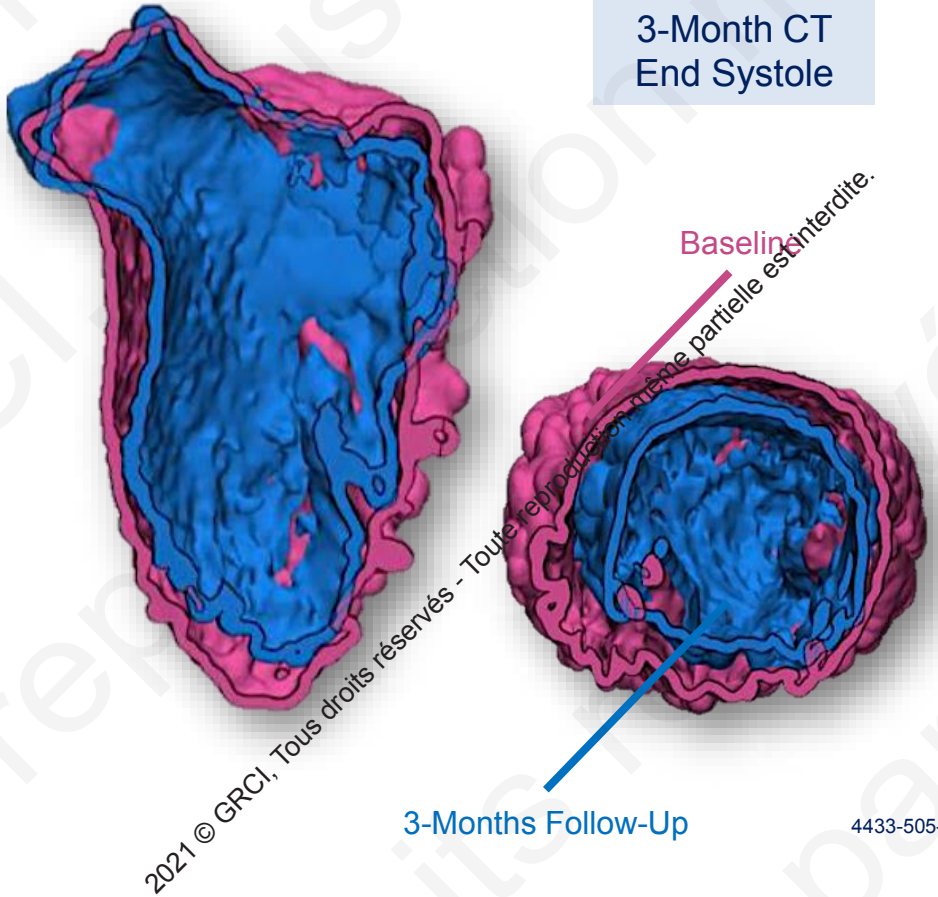
LV Reduction	11.0 mm

LV Reduction	12.7 mm

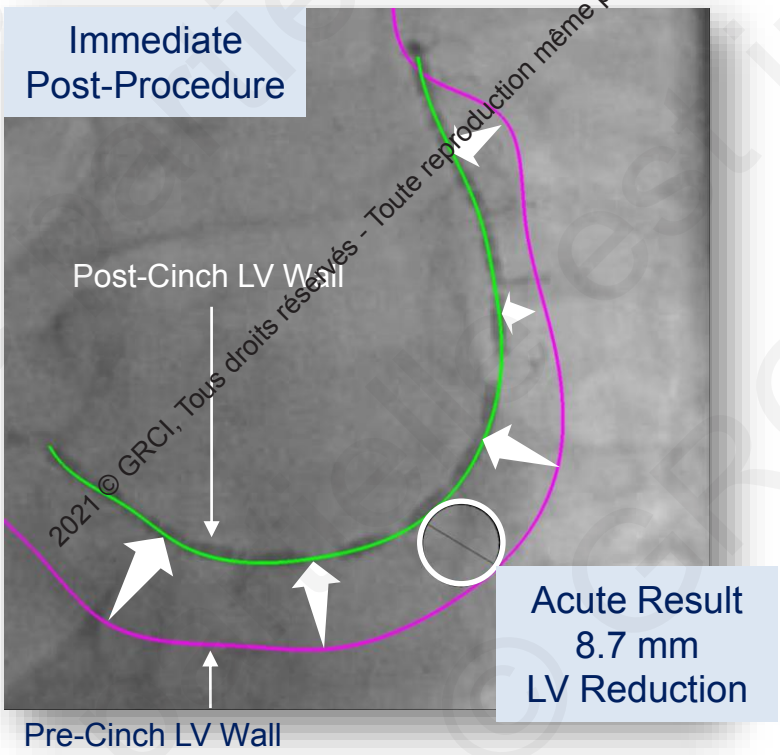
1. 5017-523-101
2. 5017-524-107
3. 5017-519-101

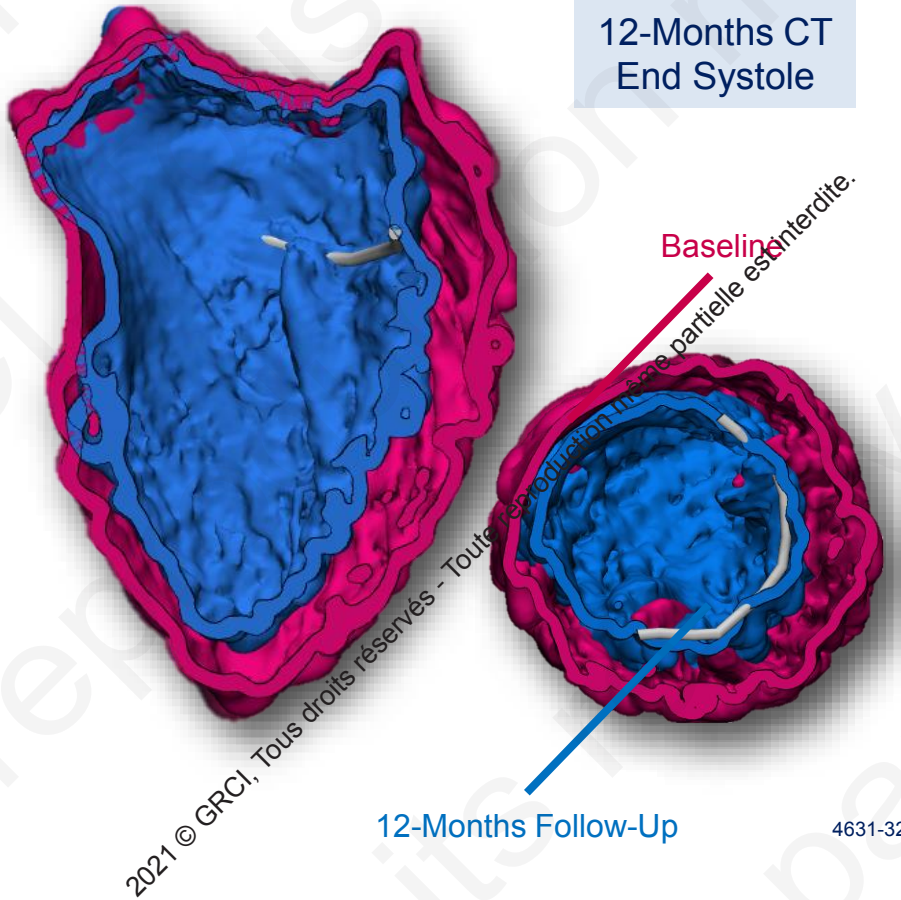
Reduction in LV Volume – Baseline vs. 3-Months





Reduction in LV Volume – Baseline vs. 12-Months





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AccuCinch®
12-Month Outcomes of LV Volume Reduction in HFrEF with a Transcatheter Ventricular Restoration System

Demographic Summary

Variable	n=41
Age, years	54.9 ± 12.4 [33 - 77]
Gender, Male	34 (82.9%)
DCMP-Ischemic Etiology	9 (22.0%)
Hypertension	26 (63.4%)
Hyperlipidemia	24 (58.5%)
Atrial Fibrillation	8 (19.5%)
Diabetes	10 (24.4%)
Prior CABG	6 (14.6%)
Prior PCI	7 (17.1%)
Cardiac Rhythm Management Devices	
None	21 (51.2%)
Pacemaker	1 (2.4%)
ICD	11 (26.8%)
CRT	8 (19.5%)
NYHA	n=40
II	22 (55.0%)
III	17 (42.5%)
IV	1 (2.5%)
Prior Stroke	3 (7.3%)
Prior TIA	0 (0.0%)

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Demographic Summary

Screening / Baseline TTE	
LVEF, %	29.0 ± 4.6 [20.7 – 36.7]
MR Grade	
0	14 (34.1%)
1+	18 (43.9%)
2+	9 (22.0%)
≥3+	0 (0.0%)
LVESV, ml	142.6 ± 40.1 [74.2 - 236.9]
LVEDV, ml	200.0 ± 51.1 [101.3 - 302.3]
LVEDs, cm	5.5 ± 0.8 [3.7 - 7.1]
LVEDd, cm	6.5 ± 0.6 [5.0 - 7.9]

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Safety at 6 Months

MAE categories	HF Group (n=41)	
	Definitely Related	Possibly Related
Device-related complications		
Death	0	0
Stroke	0	2
MI	0	0
Need for non-elective cardiovascular surgery for: - pericardial effusion or tamponade - aortic valve damage	 0 0	 0 0
Need for MCS>24 hours for worsening HF	0	0
Acute kidney injury requiring renal replacement therapy	0	0
Procedure-related femoral artery access-related complications		
Need for non-elective cardiovascular surgery for: - femoral artery access events	3	0
Subjects with at least 1 MAE	**5**	

DEVICE-RELATED

Stroke @ day 7 post-implant
- Hospitalized
- Subtherapeutic INR for atrial fibrillation and history sub-apical thrombus

Stroke @ day 72 post-implant (per site report, not adjudicated)
- Diagnosed with vertebrobasilar stroke
- Speech disorder resolved during first days of inpatient treatment

PROCEDURE-RELATED

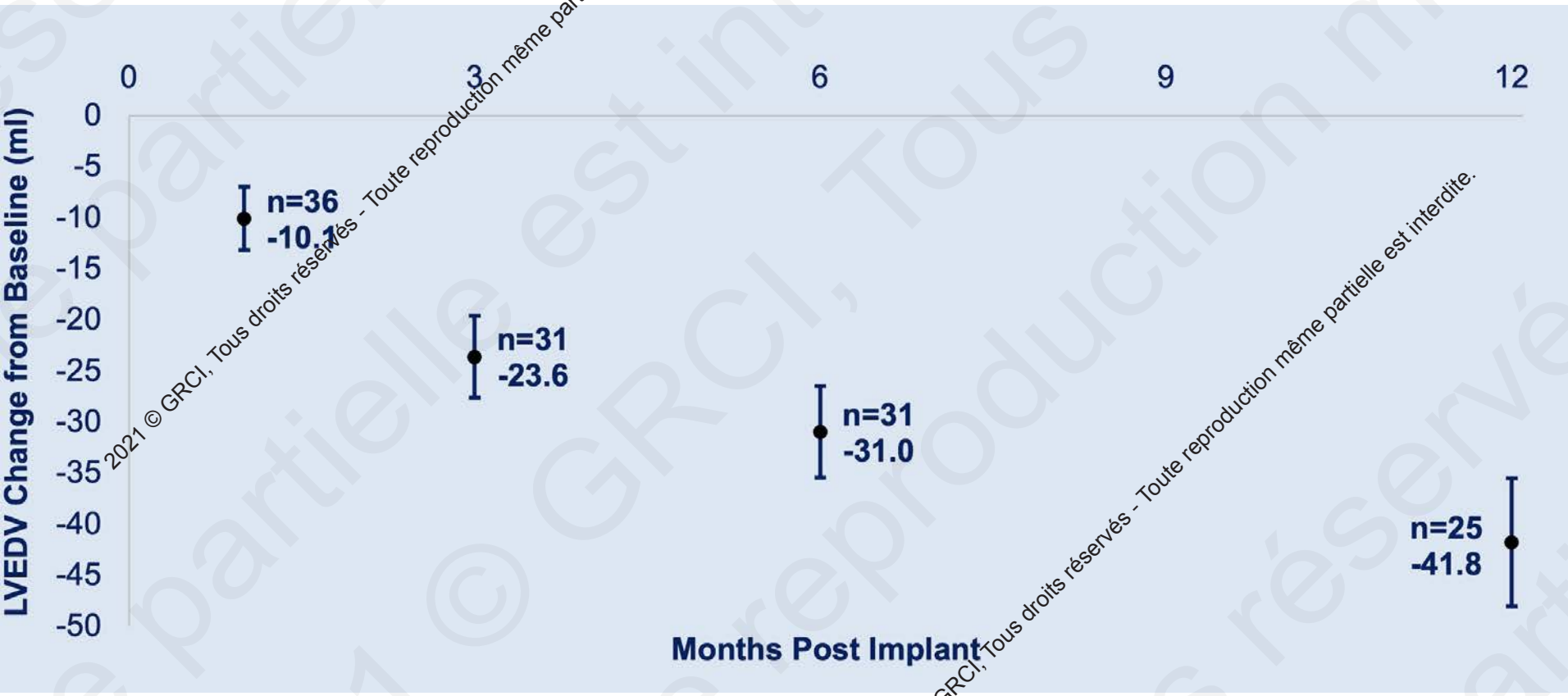
Vascular Complication @ day 1 post-implant
- Percutaneous access with **manual compression** used as closure method (no vessel closure device or surgical cutdown)
- Thrombectomy performed

Vascular Complication @ day 2 post-implant
- Percutaneous access with **manual compression** used as closure method (no vessel closure device or surgical cutdown)
- Pseudoaneurysm noted and treated with FemoStop
- Transfusion and surgical intervention required

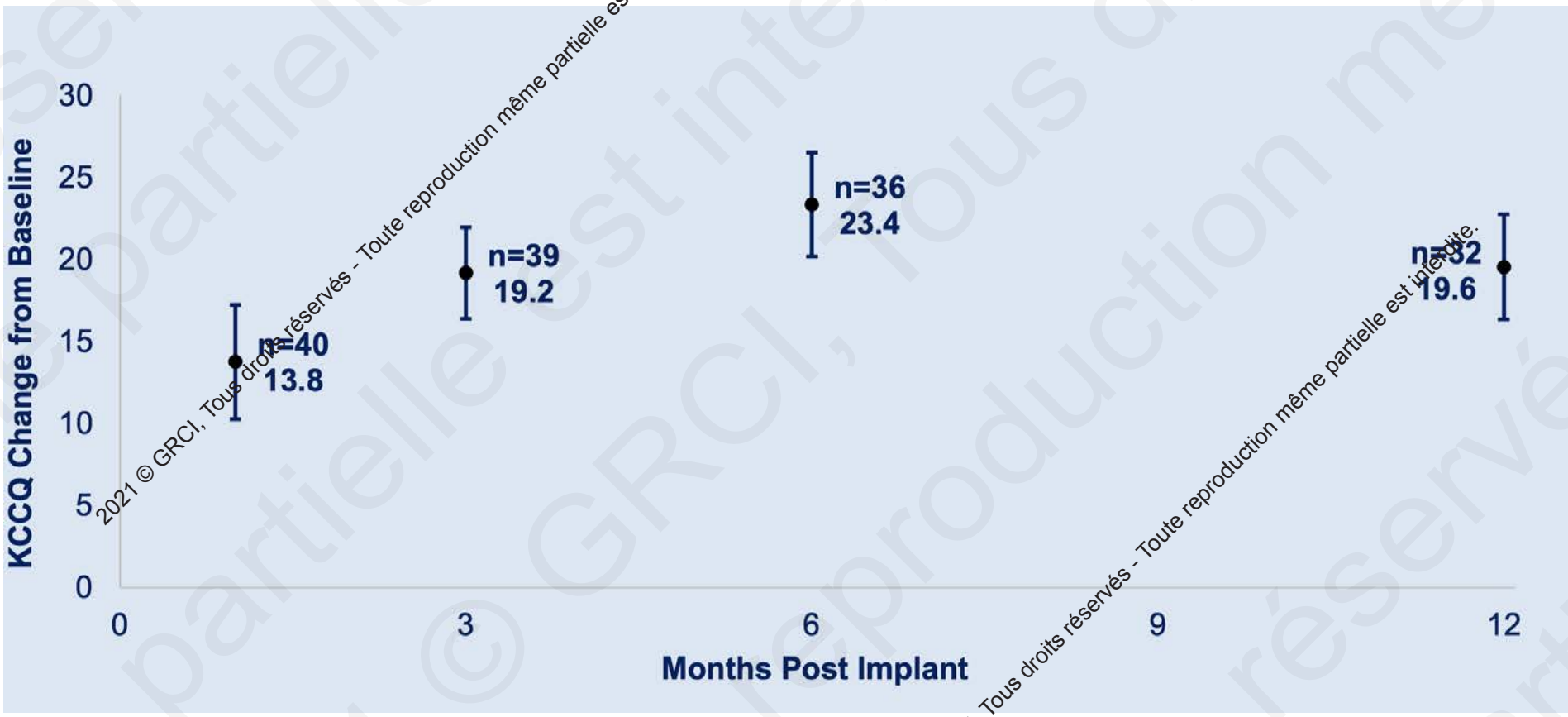
Vascular Complication @ day 2 post-implant
- **Infection** and/or pain at access site
- Treated with antibiotics
- Wound dehiscence and VAC dressing applied

ALL EVENTS RESOLVED W/OUT SEQUALAE
- No additional MAEs in 36 of 41 subjects with 12 mo. follow-up
- 12 mo. f/u for final 5 subjects due November 2021

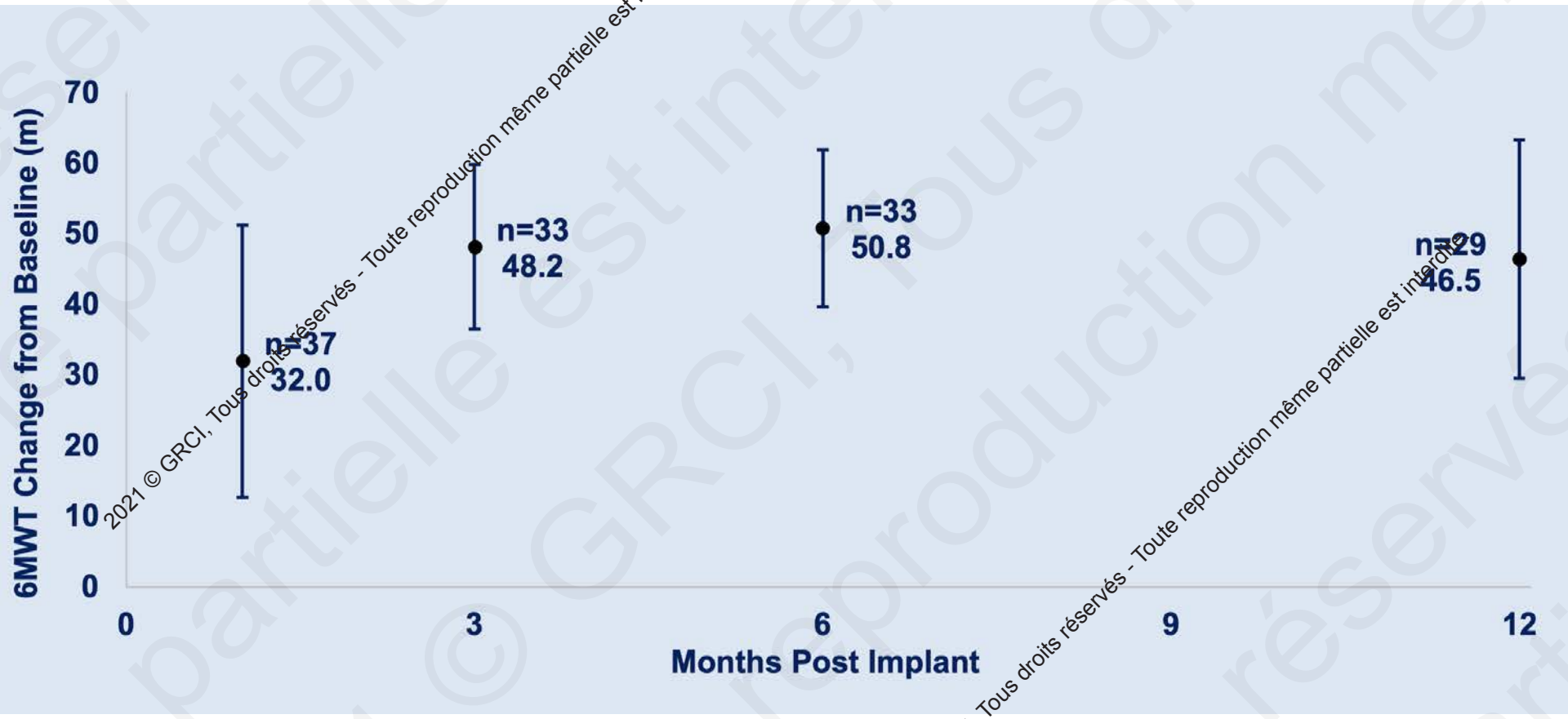
Improvement in LVEDV



Improvement in KCCQ-OS



Improvement in 6MWT



Conclusions

- The AccuCinch Ventricular Restoration System is a novel device-based therapy for HFrEF with a repeatable, predictable procedure and favorable safety profile

- Analysis of early feasibility HF Group data suggests meaningful improvement in KCCQ-OS, 6MWT and LV volumes

- Preliminary results suggest the observed reverse remodeling with the AccuCinch® Ventricular Restoration System may initiate a process of biological reverse remodeling

- Ongoing randomized, controlled CORCINCH-HF pivotal study is currently evaluating the AccuCinch® System in HFrEF who remain symptomatic despite GDMT

The CORCINCH-HF Study – IDE Pivotal Trial

OVERVIEW	**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 guideline-directed medical therapy (GDMT) or GDMT alone **Enrollment**: 400 subjects at up to 80 centers, globally (*US-EU-Eastern*) **Endpoints**: - Safety & efficacy evaluated when 250 subjects reach 6-mo f/u - Safety & efficacy evaluated when 400 subjects reach 12-mo f/u
KEY INCLUSION CRITERIA	**LVEF**: 20-40% **NYHA**: - II (with HF hospitalization in the past 12 months) - III - IV (ambulatory) **LVEDD**: ≥ 55 mm **MR**: ≤2+

CORCINCH HF Study Leadership

Chairman:
Martin Leon, MD

Co-PIs:
Mark Reisman, MD
Ulrich Jorde, MD

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