

SYNERGY'S CLINICAL PROGRESS

SYNERGY CE MARK TRIAL OVERVIEW

Enrollment and follow-up in the 30-patient long-term support CE Mark trial is ongoing. Data to-date have provided proof-of-concept that partial circulatory support (PCS) can provide statistically significant and sustained improvements in hemodynamics in patients with chronic heart failure. The baseline demographic and hemodynamic data are provided in the charts below:

PATIENT DEMOGRAPHICS (n=26)

Age	Mean: 55 years	Range: 34–69
Gender	21 Males 5 Females	
INTERMACS Profile	INTERMACS 2: 1 INTERMACS 3: 1 INTERMACS 4: 24	
Heart Failure Etiology	21 Ischemic Cardiomyopathy 5 Non-ischemic Cardiomyopathy	
Body Surface Area	Mean: 1.9 M ²	Range: 1.6–2.3
AICD	17 patients	
Mitral Regurgitation (≥ 2+)	15 patients	
Diabetes	6 patients	
Creatinine	Mean: 1.4 mg/dl Normal: <1.5	Range: 0.8–2.6
B-type Natriuretic Peptides (NT-proBNP)	Mean: 6,383 pg/ml Normal: <125	Range: 789–21,359

BASELINE HEMODYNAMICS (n=26)

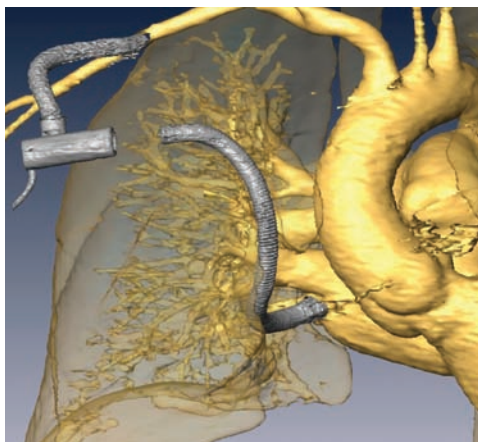
	Mean	Range
LV Ejection Fraction (%)	22	10–46
LV End Diastolic Dimension (cm)	6.9	5.4–9.2
Heart Rate (bpm)	78	50–112
Mean Blood Pressure (mmHg)	76	58–100
Mean Pulmonary Artery Pressure (mmHg)	37	15–56
Pulmonary Capillary Wedge Pressure (mmHg)	27	18–43
Pulmonary Vascular Resistance (W)	2.6	1.0–5.8
Cardiac Index (L/min/m ²)	2.0	1.3–3.7

SUMMARY OF CLINICAL EXPERIENCE

- To-date, 26 patients have been implanted
- >2,600 cumulative days on device support
- Longest patient supported for 260+ days
- Device is implanted during a 150 minute off-pump procedure
- Recovery pattern is ~2-4 days in the ICU and discharged in ~19 days
- Significant and sustained improvements in hemodynamics have been observed
- Patients were able to manage the external components
- In the event of pump stoppage, patients are supported by native heart function

SUCCESSFUL IMPLANTATION VIA MINI-THORACOTOMY PROCEDURE

The ongoing CE Mark trial utilizes a minimally invasive implantation procedure, without cardiopulmonary bypass. The implantation entails surgical placement of the inflow cannula into the left atrium via a right mini-thoracotomy, and surgical anastomosis of the outflow graft to the subclavian artery, through the micro-pump pocket.



Implanted Synergy System: 3D CT Scans

NOTE: Non-reinforced section of the inflow cannula (at micro-pump connection) is not visible on right CT Scan

CLINICAL DATA

Patients implanted with the Synergy micro-pump thus far have experienced clinical improvements, including significant long-term hemodynamic improvements. Activation of the micro-pump resulted in increases in patients' cardiac output (CO) and cardiac index (CI), as well as decreases in pulmonary capillary wedge pressure (PCWP) and maintained or improved renal function. Collectively, clinical trial data thus far indicate that when used in the target population, long-term PCS provided by Synergy results in clinically meaningful improvements in hemodynamics that correlate with preserved (or improved) end-organ function, improved exercise tolerance and improved quality of life. Results from the first patient to receive PCS with the Synergy micro-pump were published by B. Meyns, et. al., in the *European Heart Journal* in May 2008. Long-term data detailing Synergy's hemodynamic benefits were published by B. Meyns, et. al., in the *Journal of the American College of Cardiology* in June 2009.

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