

Supplementary Appendix

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Table S1: 6-month clinically relevant measures of response by sex

Endpoint Results	Female			Male			Female / Male Interaction p-value
	BAT + GDMT (N=23)	GDMT Alone (N=26)	Difference	BAT + GDMT (N=97)	GDMT Alone (N=99)	Difference	
6MHW	44 ± 45	-32 ± 118	81*	50 ± 71	-1.5 ± 78	55*	0.33
NYHA Improvement ≥ 1 Class	70%	27%	43%*	64%	32%	32%*	0.46
MLWHF QoL Score	-34 ± 27	-9.0 ± 23	-23*	-18 ± 24	-5.5 ± 19	-12*	0.10
Clinically Relevant Responder							
6MHW>10%	70%	20%	50%*	60%	34%	26%*	0.13
QoL>5 Points	78%	54%	24%	66%	41%	25%*	0.87
NYHA Improvement ≥1 Class	70%	27%	43%*	64%	32%	32%*	0.46
Clinically relevant response in ≥ 2	87%	28%	59%*	68%	29%	39%*	0.15
Clinically relevant response in all 3	35%	4%	31%*	28%	9%	19%*	0.31
Super Responder							
6MHW>20%	39%	20%	19%	33%	18%	15%*	0.84
QoL>10 Points	78%	42%	36%*	57%	34%	23%*	0.34
NYHA Improvement to Class I	22%	4%	18%	14%	2%	12%*	0.91
Super response in ≥ 2	43%	8%	35%*	24%	11%	13%*	0.21

* p-value<0.05

Table S2: System or procedure-related MANCE-free rates within 6 months of implant by sex

	Total Number of Subjects	Number of Subjects MANCE-Free Rate	MANCE-Free Rate	Interaction P-value
Male	101	98	97%	0.57
Female	24	23	96%	

Table S3: System or procedure-related MANCE events within 6 months

MANCE Event	Gender	Event	Days since Implant	Intervention	Outcome	Procedure Related	System Related
Acute Decompensated HF	Male	Acute decompensated heart failure	1	HF medications change or administration: IV administered; Hospital visit or admission	Recovered, no residual effects	Related	Not related
Infection Requiring Explant	Female	Postoperative Wound Infection	6	Other medication change or administration; Change to Neo System: Surgical Intervention; Hospital visit or admission	Recovered, no residual effects	Related	Related
	Male	Device Infection	25	Other medication change or administration; Diagnostic testing: Wound culture of right neck drainage; Change to Neo System: Surgical Intervention; Hospital visit or admission	Recovered, no residual effects	Related	Related
Stroke	Male	Acute left-sided CVA	11	Diagnostic testing: Head CT; Hospital visit or admission	Recovered, with residual effects	Related	Not related

Table S4: Serious related adverse events in the first six months post implant by sex

Relation	Female	Male
	N=24 Implants	N=101 Implants
System	0 (0%)	0 (0%)
Procedure	1 (4%)	5 (5%)
System and Procedure	1 (4%)	1 (1%)
Total	1 (4%)	6 (6%)