

XPLORE-2 TIMELINE

	Study Periods	Screening	Treatment		Follow Up				
	Visit	1: Baseline	2: Intra-op	3: Day 1	4: Day 7 Discharge	5: 6 weeks	6: Month 3	7: Month 6	8-12: 12, 24, 36, 48, 60 months
	Time (days)	> 30 days	Day 0	1 Day	m +/- 2 days	6 weeks +/- 7 days	3 months +/- 7 days	6 months +/- 14 days	12,24,36,48,60 months +/- 30 days
Clinical Examinations	Patient information & consent	X							
	Medical history	X							
	Demographics	X							
	In-/Exclusion criteria	X	X						
	Height & Weight	X			X	X	X	X	X
	Physical examination	X		X	X	X	X	X	X
	Vital Signs	X		X	X	X	X	X	X
	Medication	X		X	X	X	X	X	X
	NYHA score	X					X	X	X
Diagnostic Tests	Laboratory tests	X		X				X	X
	Pregnancy test	X	X						X (up to 24 months)
	ECG	X			X	X	X	X	X
	Echocardiography (TTE)	X			X	X	X	X	X
Post-op variables	Implantation of device		X						
	Adverse effects		X	X	X	X	X	X	X