

SENZA-RCT: SAFETY PROFILE EQUIVALENT TO TRADITIONAL SCS¹

	HF10 THERAPY		TRADITIONAL SCS	
	Number of SAEs	# (%) Subjects with SAEs (N=10)	Number of SAEs	# (%) Subjects with SAEs (N=97)
Study related serious adverse events (SAEs)	5	4 (4.0%)	8	7 (7.2%)
Study related SAEs (including neurological deficit)	0	0 (0.0%)	0	0 (0.0%)
SAEs by outcome				
Unanticipated device related SAEs	0	0 (0.0%)	0	0 (0.0%)
Deaths*	1	1 (1.0%)	1	1 (1.0%)

* HF10 therapy subject death due to hepatocellular carcinoma at month 13; traditional SCS subject death due to myocardial infarction during IPG implant procedure.