Safety Results

The ITT data analysis set served as the principal set for the safety analysis (200 treatment subjects (37 from the Active Mode 2 arm and 163 from the Active Mode 1) and 149 control subjects). A total of 114 AEs were reported during the study: 74 AEs experienced by 62 treatment subjects (31.0.%), and 40 AEs experienced by 26 subjects (17.45%) in the control arm. Two (2) AES, both in the control arm, were classified as serious adverse events (SAEs), but were not considered related to the study treatment. There were no SAEs reported in the treatment arms.

49 AEs were considered possibly, probably or definitely related to the study treatment or procedure (41 in the treatment arm, and 8 in the control arm). Device and procedure related AEs reported in the study included abdominal pain, abdominal distension, abdominal discomfort, vomiting, nausea, diarrhea, flatulence and proctalgia. Medical device discomfort events characterized as sensation of vibration were the most commonly reported device related AE, with 18 subjects (11.04%) in the Active Mode 1 arm reporting 20 such events and 1 subject in the Active Mode 2 arm (2.70%) reporting 1 such event (none in the placebo group).

Table 7: Adverse Events by System Organ Class, Preferred Term and Relationship (ITT)

System Organ Class	Preferred Term	Relation to Device	Active (Combined)			Placebo		
			# of reports	# of subjects	Incidence	# of reports	# of subjects	Incidence
Total	Total	Total	41	29	14.50%	8	5	3.36%
		Possibly related	12	7	3.50%	7	4	2.68%
		Probably related	8	6	3.00%	1	1	0.67%
		Related	18	15	7.50%	.	.	.
		Related to procedure	3	2	1.00%	.	.	.
Gastrointestinal disorders	Total	Possibly related	9	5	2.50%	7	4	2.68%
		Probably related	5	5	2.50%	1	1	0.67%
	Abdominal pain	Possibly related	1	1	0.50%	2	2	1.34%
	Vomiting	Possibly related	3	3	1.50%	.	.	.
	Nausea	Possibly related	1	1	0.50%	.	.	.
		Probably related	1	1	0.50%	.	.	.
	Diarrhoea	Possibly related	1	1	0.50%	.	.	.
		Probably related	1	1	0.50%	.	.	.
	Abdominal distension	Possibly related	1	1	0.50%	1	1	0.67%
	Flatulence	Possibly related	1	1	0.50%	.	.	.
	Constipation	Possibly related	1	1	0.50%	.	.	.
	Proctalgia	Possibly related	.	.	.	1	1	0.67%
		Probably related	1	1	0.50%	.	.	.
	Abdominal discomfort	Probably related	2	2	1.00%	.	.	.
	Anorectal discomfort	Possibly related	.	.	.	2	1	0.67%
	Abdominal pain lower	Possibly related	.	.	.	1	1	0.67%
	Abdominal pain upper	Probably related	.	.	.	1	1	0.67%
General disorders and administration site conditions	Total	Possibly related	1	1	0.50%	.	.	.
		Probably related	3	3	1.50%	.	.	.
		Related	16	14	7.00%	.	.	.
		Related to procedure	2	1	0.50%	.	.	.
	Medical device discomfort	Possibly related	1	1	0.50%	.	.	.
		Probably related	3	3	1.50%	.	.	.
		Related	16	14	7.00%	.	.	.
		Related to procedure	1	1	0.50%	.	.	.
	Discomfort	Related to procedure	1	1	0.50%	.	.	.
Reproductive system and breast disorders	Total	Possibly related	1	1	0.50%	.	.	.
	Amenorrhoea	Possibly related	1	1	0.50%	.	.	.
Nervous system disorders	Total	Possibly related	1	1	0.50%	.	.	.
	Headache	Possibly related	1	1	0.50%	.	.	.
Psychiatric disorders	Total	Related	1	1	0.50%	.	.	.
	Sleep disorder	Related	1	1	0.50%	.	.	.
Injury, poisoning and procedural complications	Total	Related	1	1	0.50%	.	.	.
	Intentional device misuse	Related	1	1	0.50%	.	.	.
Investigations	Total	Related to procedure	1	1	0.50%	.	.	.
	Weight decreased	Related to procedure	1	1	0.50%	.	.	.