

Adjudicated Clinical Events

Parameter	ABLATE Cumulative to 30 Days N=51		ABLATE AF Cumulative to 30 Days N=13		ABLATE+ABLATE AF Cumulative to 30 Days N=64		ABLATE Cumulative to 6 mos. N=51	
	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event
Any Adverse Event	160	92.2% (47/51)	47	84.6% (11/13)	207	90.6% (58/64)	188	94.1% (48/51)
Blood and lymphatic system disorders	22	37.3% (19/51)	7	53.8% (7/13)	29	40.6% (26/64)	23	37.3% (19/51)
Anaemia	16	29.4% (15/51)	4	30.8% (4/13)	20	29.7% (19/64)	17	31.4% (16/51)
Coagulopathy	5	9.8% (5/51)	0	0.0% (0/13)	5	7.8% (5/64)	5	9.8% (5/51)
Thrombocytopenia	1	2.0% (1/51)	3	23.1% (3/13)	4	6.3% (4/64)	1	2.0% (1/51)
Cardiac disorders	35	58.8% (30/51)	3	15.4% (2/13)	38	50.0% (32/64)	41	62.7% (32/51)
Atrial rupture	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Atrioventricular block	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Atrioventricular block first degree	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Atrioventricular block second degree	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Bradycardia	13	25.5% (13/51)	1	7.7% (1/13)	14	21.9% (14/64)	13	25.5% (13/51)
Cardiac arrest	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	0	0.0% (0/51)
Cardiac failure congestive	4	7.8% (4/51)	1	15.4% (2/13)	5	7.8% (5/64)	7	13.7% (7/51)
Cardiac tamponade	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Cardiogenic shock	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Mitral valve incompetence	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	2	3.9% (2/51)
Nodal arrhythmia	3	5.9% (3/51)	0	0.0% (0/13)	3	4.7% (3/64)	3	5.9% (3/51)
Nodal rhythm	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Pericardial effusion	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Sick sinus syndrome	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)

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	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event
Sinus arrest	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Sinus bradycardia	3	5.9% (3/51)	0	0.0% (0/13)	3	4.7% (3/64)	4	7.8% (4/51)
Gastrointestinal disorders	3	5.9% (3/51)	2	15.4% (2/13)	5	7.8% (5/64)	3	5.9% (3/51)
Colonic pseudo-obstruction	1	2.0% (1/51)	1	7.7% (1/13)	2	3.1% (2/64)	1	2.0% (1/51)
Haematochezia	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Ileus	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	0	0.0% (0/51)
Small intestinal obstruction	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
General disorders and administration site conditions	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Adverse drug reaction	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Multi-organ failure	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Hepatobiliary disorders	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Cholecystitis	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	0	0.0% (0/51)
Hyperbilirubinaemia	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Infections and infestations	19	21.6% (11/51)	5	23.1% (3/13)	24	21.9% (14/64)	25	27.5% (14/51)
Bacteraemia	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Breast abscess	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Bronchitis	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Candidiasis	4	7.8% (4/51)	0	0.0% (0/13)	4	6.3% (4/64)	4	7.8% (4/51)
Cellulitis	1	2.0% (1/51)	1	7.7% (1/13)	2	3.1% (2/64)	1	2.0% (1/51)
Pneumonia	5	9.8% (5/51)	0	0.0% (0/13)	5	7.8% (5/64)	6	11.8% (6/51)
Respiratory tract infection	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	0	0.0% (0/51)
Sepsis	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	1	2.0% (1/51)

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	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event	# of Evts	% (n/N) of Pts with Event
Staphylococcal bacteraemia	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Staphylococcal infection	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	0	0.0% (0/51)
Upper respiratory tract infection	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Urinary tract infection	3	5.9% (3/51)	1	7.7% (1/13)	4	6.3% (4/64)	6	11.8% (6/51)
Wound infection	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Injury, poisoning and procedural complications	8	13.7% (7/51)	5	30.8% (4/13)	13	17.2% (11/64)	9	13.7% (7/51)
Agitation postoperative	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	0	0.0% (0/51)
Anemia postoperative	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	0	0.0% (0/51)
Atrial rupture	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Brachial plexus injury	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Cardiac procedure complication	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Cardiac vein perforation	0	0.0% (0/51)	1	7.7% (1/13)	1	1.6% (1/64)	0	0.0% (0/51)
Confusion postoperative	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Fall	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Lead dislodgement	0	0.0% (0/51)	2	15.4% (2/13)	2	3.1% (2/64)	0	0.0% (0/51)
Subcutaneous emphysema	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Vena cava injury	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Venous injury	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Investigations	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Urine analysis abnormal	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Metabolism and nutrition disorders	12	21.6% (11/51)	2	15.4% (2/13)	14	20.3% (13/64)	12	21.6% (11/51)
Hyperglycaemia	9	15.7% (8/51)	2	15.4% (2/13)	11	15.6% (10/64)	9	15.7% (8/51)

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Hypoglycaemia	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Hyponatraemia	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Musculoskeletal and connective tissue disorders	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Critical illness polyneuropathy	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	2	3.9% (2/51)
Bladder neoplasm	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Prostate cancer	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Nervous system disorders	2	3.9% (2/51)	1	7.7% (1/13)	3	4.7% (3/64)	4	7.8% (4/51)
Cerebrovascular accident	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Encephalopathy	1	2.0% (1/51)	1	7.7% (1/13)	2	3.1% (2/64)	1	2.0% (1/51)
Haemorrhage intracranial	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Transient ischaemic attack	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)
Renal and urinary disorders	7	13.7% (7/51)	2	15.4% (2/13)	9	14.1% (9/64)	7	13.7% (7/51)
Renal failure	6	11.8% (6/51)	1	7.7% (1/13)	7	10.9% (7/64)	6	11.8% (6/51)
Urinary retention	1	2.0% (1/51)	1	7.7% (1/13)	2	3.1% (2/64)	1	2.0% (1/51)
Respiratory, thoracic and mediastinal disorders	27	41.2% (21/51)	9	46.2% (6/13)	36	42.2% (27/64)	35	47.1% (24/51)
Haemothorax	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Nocturnal dyspnoea	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Pleural effusion	15	27.5% (14/51)	5	23.1% (3/13)	20	26.6% (17/64)	20	31.4% (16/51)
Pneumothorax	2	3.9% (2/51)	1	7.7% (1/13)	3	4.7% (3/64)	3	5.9% (3/51)
Pulmonary oedema	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	1	2.0% (1/51)

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Respiratory failure	8	15.7% (8/51)	3	23.1% (3/13)	11	17.2% (11/64)	9	17.6% (9/51)
Skin and subcutaneous tissue disorders	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Decubitus ulcer	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Vascular disorders	19	31.4% (16/51)	11	53.8% (7/13)	30	35.9% (23/64)	20	33.3% (17/51)
Deep vein thrombosis	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Embolism	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Haemorrhage	13	23.5% (12/51)	5	38.5% (5/13)	18	26.6% (17/64)	13	23.5% (12/51)
Hypertension	1	2.0% (1/51)	3	23.1% (3/13)	4	6.3% (4/64)	1	2.0% (1/51)
Hypotension	2	3.9% (2/51)	3	23.1% (3/13)	5	7.8% (5/64)	3	5.9% (3/51)
Thrombophlebitis	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Device Related Adverse Event	0	0.0% (0/51)	0	0.0% (0/13)	0	0.0% (0/64)	0	0.0% (0/51)
AF Procedure Related Adverse Event	8	15.7% (8/51)	0	0.0% (0/13)	8	12.5% (8/64)	8	15.7% (8/51)
Cardiac disorders	6	11.8% (6/51)	0	0.0% (0/13)	6	9.4% (6/64)	6	11.8% (6/51)
Atrial rupture	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Atrioventricular block	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Atrioventricular block first degree	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Atrioventricular block second degree	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Bradycardia	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Injury, poisoning and procedural complications	2	3.9% (2/51)	0	0.0% (0/13)	2	3.1% (2/64)	2	3.9% (2/51)
Vena cava injury	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)
Venous injury	1	2.0% (1/51)	0	0.0% (0/13)	1	1.6% (1/64)	1	2.0% (1/51)