

	Days Post-Op										Total
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	
Tethering	0	0	0	0	1	0	0	0	0	0	1
Skin and subcutaneous tissue disorders	1	7	0	0	0	0	0	0	0	0	8
Drainage	0	1	0	0	0	0	0	0	0	0	1
Erythema multiforme	1	2	0	0	0	0	0	0	0	0	3
Pruritus	0	3	0	0	0	0	0	0	0	0	3
Rash acneiform	0	1	0	0	0	0	0	0	0	0	1
Surgical and medical procedures	0	1	0	0	0	0	0	0	0	0	1
Yellow discharge	0	1	0	0	0	0	0	0	0	0	1
Vascular disorders	8	2	0	0	0	0	0	0	0	0	10
Flushing	1	0	0	0	0	0	0	0	0	0	1
Hematoma	7	2	0	0	0	0	0	0	0	0	9

†Defined as Remotely/Possible/Probable and Unknown.
Adverse events with missing date are analyzed as relative day 1.
Source: Tables Safety by Severity-Timecourse_FAS.sas; Analyzed: 09JUN2024

Table 38: All Procedure Related Adverse Events by AE Code and Severity – Primary Analysis Set

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All Events	158	87.8%	18	10.0%	4	2.2%	180
General disorders and administration site conditions	88	96.7%	3	3.3%	0	0.0%	91
Fatigue	2	100.0%	0	0.0%	0	0.0%	2
Heat sensation	1	100.0%	0	0.0%	0	0.0%	1
Infusion site extravasation	1	100.0%	0	0.0%	0	0.0%	1
Injection site reaction	11	100.0%	0	0.0%	0	0.0%	11
Localized edema	35	94.6%	2	5.4%	0	0.0%	37
Non-cardiac chest pain	1	100.0%	0	0.0%	0	0.0%	1
Pain	37	97.4%	1	2.6%	0	0.0%	38
Injury, poisoning and procedural complications	48	77.4%	11	17.7%	3	4.8%	62
Bruising	45	78.9%	9	15.8%	3	5.3%	57
Burn	2	50.0%	2	50.0%	0	0.0%	4
postoperative hemorrhage	1	100.0%	0	0.0%	0	0.0%	1
Musculoskeletal and connective tissue disorders	1	100.0%	0	0.0%	0	0.0%	1
Pain in extremity	1	100.0%	0	0.0%	0	0.0%	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0.0%	3	75.0%	1	25.0%	4
Local recurrence	0	0.0%	3	100.0%	0	0.0%	3
Metastatic breast cancer	0	0.0%	0	0.0%	1	100.0%	1
Reproductive system and breast disorders	3	100.0%	0	0.0%	0	0.0%	3
Breast twitches	1	100.0%	0	0.0%	0	0.0%	1
Dimpling	1	100.0%	0	0.0%	0	0.0%	1
Tethering	1	100.0%	0	0.0%	0	0.0%	1
Skin and subcutaneous tissue disorders	8	100.0%	0	0.0%	0	0.0%	8

Drainage	1	100.0%	0	0.0%	0	0.0%	1
Erythema multiforme	3	100.0%	0	0.0%	0	0.0%	3
Pruritus	3	100.0%	0	0.0%	0	0.0%	3
Rash acneiform	1	100.0%	0	0.0%	0	0.0%	1
Surgical and medical procedures	1	100.0%	0	0.0%	0	0.0%	1
Yellow discharge	1	100.0%	0	0.0%	0	0.0%	1
Vascular disorders	9	90.0%	1	10.0%	0	0.0%	10
Flushing	1	100.0%	0	0.0%	0	0.0%	1
Hematoma	8	88.9%	1	11.1%	0	0.0%	9

*Percentage of total events. †Defined as Remotely/Possible/Probable and Unknown.

Source: Tables Safety by Severity-Timecourse_FAS.sas; Analyzed: 09JUN2024

Table 39: All Serious Adverse Events by High and Low Terms – Primary Analysis Set (N=194)

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
All Events	127	59	30.4%	9.9%	31.5%	14.2%	37.7%
Blood and lymphatic system disorders	4	4	2.1%	1.0%	2.5%	3.3%	5.7%
Anemia	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
Febrile Neutropenia	2	2	1.0%	0.5%	1.2%	2.7%	3.9%
Leukocytosis	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Cardiac disorders	18	13	6.7%	1.6%	7.7%	4.2%	11.9%
Acute coronary syndrome	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Aortic valve disease	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Atrial fibrillation	2	2	1.0%	0.0%	0.6%	0.0%	3.0%
Atrioventricular Block Complete	1	1	0.5%	0.0%	0.6%	0.0%	3.1%
Cardiac arrest	2	2	1.0%	0.0%	1.2%	0.0%	3.9%
Chest pain - cardiac	2	1	0.5%	0.0%	0.7%	0.0%	3.5%
Heart failure	5	4	2.1%	0.5%	2.5%	2.7%	5.5%
Myocardial infarction	2	2	1.0%	0.5%	1.2%	2.8%	3.8%
Palpitations	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Sick sinus syndrome	1	1	0.5%	0.0%	0.6%	0.0%	3.3%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
Ear and labyrinth disorders	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Vestibular Disorder	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Gastrointestinal disorders	10	9	4.6%	1.1%	5.9%	3.3%	10.0%
Abdominal pain	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
Colitis	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Constipation	2	2	1.0%	0.5%	1.2%	2.7%	3.9%
Duodenal hemorrhage	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Dysphagia	1	1	0.5%	0.0%	0.7%	0.0%	3.8%
Obstruction gastric	2	1	0.5%	0.0%	0.6%	0.0%	3.3%
Sigmoid diverticulitis	1	1	0.5%	0.0%	0.8%	0.0%	4.0%
Small intestinal obstruction	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
General disorders and administration site conditions	8	6	3.1%	0.6%	3.8%	2.8%	7.3%
COVID	3	2	1.0%	0.0%	1.4%	0.0%	4.3%
Death NOS	3	3	1.5%	0.0%	1.9%	0.0%	4.8%
Edema limbs	1	1	0.5%	0.0%	0.7%	0.0%	3.6%
Multi-organ failure	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
Infections and infestations	16	13	6.7%	2.7%	6.5%	5.5%	10.4%
Endocarditis infective	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Lung infection	5	5	2.6%	0.0%	2.1%	0.0%	5.4%
Sepsis	3	3	1.5%	0.6%	2.0%	2.8%	5.0%
Skin infection	4	3	1.5%	1.6%	1.6%	4.1%	4.1%
Upper respiratory infection	1	1	0.5%	0.0%	0.8%	0.0%	3.9%
Urinary tract infection	2	2	1.0%	0.5%	1.1%	2.7%	3.5%
Injury, poisoning and procedural complications	4	4	2.1%	0.6%	1.9%	2.9%	4.9%
Fall	2	2	1.0%	0.0%	0.7%	0.0%	3.5%
Fracture	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Hip fracture	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
Metabolism and nutrition disorders	3	3	1.5%	0.5%	1.2%	2.7%	3.8%
Hypercalcemia	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Hypokalemia	1	1	0.5%	0.0%	0.0%	0.0%	0.0%
Malnutrition	1	1	0.5%	0.0%	0.7%	0.0%	3.4%
Musculoskeletal and connective tissue disorders	2	2	1.0%	0.0%	1.3%	0.0%	4.2%
Arthritis	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Rhabdomyolysis	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21	20	10.3%	1.6%	11.4%	4.1%	16.3%
Acute Myeloid Leukemia	1	1	0.5%	0.0%	0.6%	0.0%	3.3%
DCIS Left Breast	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Diffuse Metastatic disease to the bones	1	1	0.5%	0.0%	0.7%	0.0%	3.4%

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
Endometrial Cancer	2	2	1.0%	0.0%	1.2%	0.0%	3.8%
Hepatocellular carcinoma	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Kidney cancer	1	1	0.5%	0.0%	0.8%	0.0%	4.3%
Local recurrence	7	7	3.6%	0.0%	4.7%	0.0%	8.6%
Lung Adenocarcinoma	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Meningioma	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Metastatic breast cancer	1	1	0.5%	0.0%	0.7%	0.0%	3.6%
Non-small cell lung cancer	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Second primary BC	3	3	1.5%	0.0%	0.7%	0.0%	3.7%
Nervous system disorders	12	12	6.2%	3.2%	6.9%	6.1%	10.9%
Altered mental status	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Encephalopathy	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Intracranial hemorrhage	1	1	0.5%	0.5%	0.5%	2.7%	2.7%
Memory impairment	3	3	1.5%	0.5%	1.7%	2.7%	4.3%
Presyncope	1	1	0.5%	0.0%	0.6%	0.0%	3.0%
Stroke	2	2	1.0%	0.5%	1.2%	2.7%	3.9%
Syncope	1	1	0.5%	0.0%	0.7%	0.0%	3.5%
Thoracic stenosis	1	1	0.5%	0.6%	0.6%	2.9%	2.9%
Transient ischemic attacks	1	1	0.5%	0.6%	0.6%	2.8%	2.8%
Renal and urinary disorders	4	4	2.1%	1.1%	2.4%	3.4%	5.5%
Acute kidney injury	4	4	2.1%	1.1%	2.4%	3.4%	5.5%
Respiratory, thoracic and mediastinal disorders	18	12	6.2%	3.2%	5.7%	6.1%	9.4%
Aspiration	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
COPD	1	1	0.5%	0.0%	0.0%	0.0%	0.0%
Dyspnea	5	2	1.0%	0.5%	1.2%	2.6%	3.9%
Emphysema	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Hypoxia	1	1	0.5%	0.5%	0.5%	2.8%	2.8%
Pleural effusion	4	4	2.1%	0.0%	1.3%	0.0%	4.0%
Pulmonary edema	1	1	0.5%	0.0%	0.6%	0.0%	3.1%
Respiratory failure	4	4	2.1%	1.6%	1.6%	4.0%	4.0%
Vascular disorders	6	5	2.6%	1.6%	2.8%	4.1%	5.7%
Bilateral Carotid Stenosis	1	1	0.5%	0.0%	0.6%	0.0%	3.2%
Hypertension	2	2	1.0%	0.0%	1.2%	0.0%	3.7%
Thromboembolic event	3	3	1.5%	1.6%	1.6%	4.1%	4.1%

† Total number of events without regard to length of follow-up.

‡ Number of subjects experiencing event without regard to length of follow-up.

° Percentage of subjects experiencing specific event without regard to length of follow-up.

** Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bound (UB).

Procedure relationship: Remotely, Possible, Probable, Unknown.

Adverse events with missing date are analyzed as relative day 1.

Source: Tables Safety_FAS.sas; Analyzed: 09JUN2024

Table 40: All Serious Adverse Events by AE Code and Timecourse - Primary Analysis Set

	Days Post-Op										
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
All Events	0	1	3	7	12	14	23	25	29	13	127
Blood and lymphatic system disorders	0	0	1	1	0	0	0	0	2	0	4
Anemia	0	0	0	0	0	0	0	0	1	0	1
Febrile Neutropenia	0	0	0	1	0	0	0	0	1	0	2
Leukocytosis	0	0	1	0	0	0	0	0	0	0	1
Cardiac disorders	0	0	0	0	1	2	5	7	1	2	18
Acute coronary syndrome	0	0	0	0	0	0	0	1	0	0	1
Aortic valve disease	0	0	0	0	0	0	1	0	0	0	1
Atrial fibrillation	0	0	0	0	0	0	1	0	0	1	2
Atrioventricular Block Complete	0	0	0	0	0	0	1	0	0	0	1
Cardiac arrest	0	0	0	0	0	0	1	1	0	0	2
Chest pain - cardiac	0	0	0	0	0	0	0	1	0	1	2
Heart failure	0	0	0	0	1	0	1	2	1	0	5
Myocardial infarction	0	0	0	0	0	1	0	1	0	0	2
Palpitations	0	0	0	0	0	1	0	0	0	0	1
Sick sinus syndrome	0	0	0	0	0	0	0	1	0	0	1
Ear and labyrinth disorders	0	0	0	1	0	0	0	0	0	0	1
Vestibular Disorder	0	0	0	1	0	0	0	0	0	0	1
Gastrointestinal disorders	0	0	1	0	1	0	0	4	4	0	10
Abdominal pain	0	0	0	0	0	0	0	1	0	0	1
Colitis	0	0	0	0	1	0	0	0	0	0	1
Constipation	0	0	1	0	0	0	0	0	1	0	2
Duodenal hemorrhage	0	0	0	0	0	0	0	1	0	0	1
Dysphagia	0	0	0	0	0	0	0	0	1	0	1
Obstruction gastric	0	0	0	0	0	0	0	2	0	0	2
Sigmoid diverticulitis	0	0	0	0	0	0	0	0	1	0	1
Small intestinal obstruction	0	0	0	0	0	0	0	0	1	0	1
General disorders and administration site conditions	0	0	0	0	0	1	2	2	3	0	8
COVID	0	0	0	0	0	0	0	1	2	0	3
Death NOS	0	0	0	0	0	0	2	1	0	0	3
Edema limbs	0	0	0	0	0	0	0	0	1	0	1
Multi-organ failure	0	0	0	0	0	1	0	0	0	0	1
Infections and infestations	0	0	0	1	2	2	3	2	4	2	16
Endocarditis infective	0	0	0	0	0	0	1	0	0	0	1
Lung infection	0	0	0	0	0	0	0	2	1	2	5
Sepsis	0	0	0	0	0	1	0	0	2	0	3
Skin infection	0	0	0	1	1	1	1	0	0	0	4
Upper respiratory infection	0	0	0	0	0	0	0	0	1	0	1

	Days Post-Op										
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
Urinary tract infection	0	0	0	0	1	0	1	0	0	0	2
Injury, poisoning and procedural complications	0	0	0	0	0	1	0	1	1	1	4
Fall	0	0	0	0	0	0	0	0	1	1	2
Fracture	0	0	0	0	0	1	0	0	0	0	1
Hip fracture	0	0	0	0	0	0	0	1	0	0	1
Metabolism and nutrition disorders	0	0	0	0	1	0	0	1	0	1	3
Hypercalcemia	0	0	0	0	1	0	0	0	0	0	1
Hypokalemia	0	0	0	0	0	0	0	0	0	1	1
Malnutrition	0	0	0	0	0	0	0	1	0	0	1
Musculoskeletal and connective tissue disorders	0	0	0	0	0	0	0	1	1	0	2
Arthritis	0	0	0	0	0	0	0	0	1	0	1
Rhabdomyolysis	0	0	0	0	0	0	0	1	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	1	1	1	5	4	7	2	21
Acute Myeloid Leukemia	0	0	0	0	0	0	0	1	0	0	1
DCIS Left Breast	0	0	0	0	0	0	1	0	0	0	1
Diffuse Metastatic disease to the bones	0	0	0	0	0	0	0	1	0	0	1
Endometrial Cancer	0	0	0	0	0	0	2	0	0	0	2
Hepatocellular carcinoma	0	0	0	0	0	0	0	1	0	0	1
Kidney cancer	0	0	0	0	0	0	0	0	1	0	1
Local recurrence	0	0	0	0	0	0	2	1	4	0	7
Lung Adenocarcinoma	0	0	0	0	1	0	0	0	0	0	1
Meningioma	0	0	0	1	0	0	0	0	0	0	1
Metastatic breast cancer	0	0	0	0	0	0	0	0	1	0	1
Non-small cell lung cancer	0	0	0	0	0	1	0	0	0	0	1
Second primary BC	0	0	0	0	0	0	0	0	1	2	3
Nervous system disorders	0	0	0	2	2	2	3	0	3	0	12
Altered mental status	0	0	0	0	0	0	0	0	1	0	1
Encephalopathy	0	0	0	0	1	0	0	0	0	0	1
Intracranial hemorrhage	0	0	0	1	0	0	0	0	0	0	1
Memory impairment	0	0	0	0	1	0	2	0	0	0	3
Presyncope	0	0	0	0	0	0	1	0	0	0	1
Stroke	0	0	0	1	0	0	0	0	1	0	2
Syncope	0	0	0	0	0	0	0	0	1	0	1
Thoracic stenosis	0	0	0	0	0	1	0	0	0	0	1
Transient ischemic attacks	0	0	0	0	0	1	0	0	0	0	1
Renal and urinary disorders	0	0	0	0	2	0	0	0	2	0	4
Acute kidney injury	0	0	0	0	2	0	0	0	2	0	4

Respiratory, thoracic and mediastinal disorders	0	1	1	0	1	4	2	3	1	5	18
Aspiration	0	0	0	0	0	1	0	0	0	0	1
COPD	0	0	0	0	0	0	0	0	0	1	1
Dyspnea	0	1	0	0	0	0	0	2	1	1	5
Emphysema	0	0	0	0	0	1	0	0	0	0	1
Hypoxia	0	0	0	0	0	1	0	0	0	0	1
Pleural effusion	0	0	0	0	0	0	1	1	0	2	4
Pulmonary edema	0	0	0	0	0	0	1	0	0	0	1
Respiratory failure	0	0	1	0	1	1	0	0	0	1	4
Vascular disorders	0	0	0	1	1	1	3	0	0	0	6
Bilateral Carotid Stenosis	0	0	0	0	0	0	1	0	0	0	1
Hypertension	0	0	0	0	0	0	2	0	0	0	2
Thromboembolic event	0	0	0	1	1	1	0	0	0	0	3

Adverse events with missing date are analyzed as relative day 1.
Source: Tables Safety by Severity-Timecourse_FAS.sas; Analyzed: 09JUN2024

Table 41: All Serious Adverse Events by Event Code and Severity

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All Events	5	3.9%	35	27.6%	87	68.5%	127
Blood and lymphatic system disorders	0	0.0%	1	25.0%	3	75.0%	4
Anemia	0	0.0%	0	0.0%	1	100.0%	1
Febrile Neutropenia	0	0.0%	0	0.0%	2	100.0%	2
Leukocytosis	0	0.0%	1	100.0%	0	0.0%	1
Cardiac disorders	2	11.1%	3	16.7%	13	72.2%	18
Acute coronary syndrome	1	100.0%	0	0.0%	0	0.0%	1
Aortic valve disease	0	0.0%	0	0.0%	1	100.0%	1
Atrial fibrillation	0	0.0%	1	50.0%	1	50.0%	2
Atrioventricular Block Complete	0	0.0%	0	0.0%	1	100.0%	1
Cardiac arrest	0	0.0%	0	0.0%	2	100.0%	2
Chest pain - cardiac	0	0.0%	0	0.0%	2	100.0%	2
Heart failure	0	0.0%	2	40.0%	3	60.0%	5
Myocardial infarction	0	0.0%	0	0.0%	2	100.0%	2
Palpitations	1	100.0%	0	0.0%	0	0.0%	1
Sick sinus syndrome	0	0.0%	0	0.0%	1	100.0%	1
Ear and labyrinth disorders	0	0.0%	1	100.0%	0	0.0%	1
Vestibular Disorder	0	0.0%	1	100.0%	0	0.0%	1
Gastrointestinal disorders	0	0.0%	3	30.0%	7	70.0%	10
Abdominal pain	0	0.0%	0	0.0%	1	100.0%	1
Colitis	0	0.0%	0	0.0%	1	100.0%	1
Constipation	0	0.0%	0	0.0%	2	100.0%	2

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Duodenal hemorrhage	0	0.0%	1	100.0%	0	0.0%	1
Dysphagia	0	0.0%	0	0.0%	1	100.0%	1
Obstruction gastric	0	0.0%	0	0.0%	2	100.0%	2
Sigmoid diverticulitis	0	0.0%	1	100.0%	0	0.0%	1
Small intestinal obstruction	0	0.0%	1	100.0%	0	0.0%	1
General disorders and administration site conditions	0	0.0%	1	12.5%	7	87.5%	8
COVID	0	0.0%	1	33.3%	2	66.7%	3
Death NOS	0	0.0%	0	0.0%	3	100.0%	3
Edema limbs	0	0.0%	0	0.0%	1	100.0%	1
Multi-organ failure	0	0.0%	0	0.0%	1	100.0%	1
Infections and infestations	1	6.3%	5	31.3%	10	62.5%	16
Endocarditis infective	0	0.0%	0	0.0%	1	100.0%	1
Lung infection	1	20.0%	1	20.0%	3	60.0%	5
Sepsis	0	0.0%	0	0.0%	3	100.0%	3
Skin infection	0	0.0%	3	75.0%	1	25.0%	4
Upper respiratory infection	0	0.0%	1	100.0%	0	0.0%	1
Urinary tract infection	0	0.0%	0	0.0%	2	100.0%	2
Injury, poisoning and procedural complications	0	0.0%	2	50.0%	2	50.0%	4
Fall	0	0.0%	1	50.0%	1	50.0%	2
Fracture	0	0.0%	1	100.0%	0	0.0%	1
Hip fracture	0	0.0%	0	0.0%	1	100.0%	1
Metabolism and nutrition disorders	0	0.0%	1	33.3%	2	66.7%	3
Hypercalcemia	0	0.0%	0	0.0%	1	100.0%	1
Hypokalemia	0	0.0%	0	0.0%	1	100.0%	1
Malnutrition	0	0.0%	1	100.0%	0	0.0%	1
Musculoskeletal and connective tissue disorders	1	50.0%	0	0.0%	1	50.0%	2
Arthritis	0	0.0%	0	0.0%	1	100.0%	1
Rhabdomyolysis	1	100.0%	0	0.0%	0	0.0%	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0.0%	11	52.4%	10	47.6%	21
Acute Myeloid Leukemia	0	0.0%	0	0.0%	1	100.0%	1
DCIS Left Breast	0	0.0%	0	0.0%	1	100.0%	1
Diffuse Metastatic disease to the bones	0	0.0%	0	0.0%	1	100.0%	1
Endometrial Cancer	0	0.0%	1	50.0%	1	50.0%	2
Hepatocellular carcinoma	0	0.0%	0	0.0%	1	100.0%	1
Kidney cancer	0	0.0%	0	0.0%	1	100.0%	1
Local recurrence	0	0.0%	7	100.0%	0	0.0%	7
Lung Adenocarcinoma	0	0.0%	1	100.0%	0	0.0%	1
Meningioma	0	0.0%	0	0.0%	1	100.0%	1
Metastatic breast cancer	0	0.0%	0	0.0%	1	100.0%	1
Non-small cell lung cancer	0	0.0%	0	0.0%	1	100.0%	1
Second primary BC	0	0.0%	2	66.7%	1	33.3%	3
Nervous system disorders	1	8.3%	2	16.7%	9	75.0%	12
Altered mental status	0	0.0%	0	0.0%	1	100.0%	1

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Encephalopathy	0	0.0%	0	0.0%	1	100.0%	1
Intracranial hemorrhage	0	0.0%	0	0.0%	1	100.0%	1
Memory impairment	1	33.3%	0	0.0%	2	66.7%	3
Presyncope	0	0.0%	1	100.0%	0	0.0%	1
Stroke	0	0.0%	1	50.0%	1	50.0%	2
Syncope	0	0.0%	0	0.0%	1	100.0%	1
Thoracic stenosis	0	0.0%	0	0.0%	1	100.0%	1
Transient ischemic attacks	0	0.0%	0	0.0%	1	100.0%	1
Renal and urinary disorders	0	0.0%	1	25.0%	3	75.0%	4
Acute kidney injury	0	0.0%	1	25.0%	3	75.0%	4
Respiratory, thoracic and mediastinal disorders	0	0.0%	2	11.1%	16	88.9%	18
Aspiration	0	0.0%	0	0.0%	1	100.0%	1
COPD	0	0.0%	0	0.0%	1	100.0%	1
Dyspnea	0	0.0%	0	0.0%	5	100.0%	5
Emphysema	0	0.0%	0	0.0%	1	100.0%	1
Hypoxia	0	0.0%	0	0.0%	1	100.0%	1
Pleural effusion	0	0.0%	2	50.0%	2	50.0%	4
Pulmonary edema	0	0.0%	0	0.0%	1	100.0%	1
Respiratory failure	0	0.0%	0	0.0%	4	100.0%	4
Vascular disorders	0	0.0%	2	33.3%	4	66.7%	6
Bilateral Carotid Stenosis	0	0.0%	1	100.0%	0	0.0%	1
Hypertension	0	0.0%	0	0.0%	2	100.0%	2
Thromboembolic event	0	0.0%	1	33.3%	2	66.7%	3

*Percentage of total events.

Source: Tables Safety by Severity-Timecourse_FAS.sas; Analyzed: 09JUN2024

Table 42: All Serious Procedure Related Adverse Events by High and Low Terms – Primary Analysis Set

	ICECURE (N= 194)			Kaplan-Meier**			
	Events†	Subjs‡	%°	Year 2	Year 5	Year 2 1-sided 95% CI UB	Year 5 1-sided 95% CI UB
All Events	4	3	1.5%	0.0%	1.9%	0.0%	4.9%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	3	1.5%	0.0%	1.9%	0.0%	4.9%
Local recurrence	3	3	1.5%	0.0%	1.9%	0.0%	4.9%
Metastatic breast cancer	1	1	0.5%	0.0%	0.7%	0.0%	3.6%

† Total number of events without regard to length of follow-up.
‡ Number of subjects experiencing event without regard to length of follow-up.
° Percentage of subjects experiencing specific event without regard to length of follow-up.
** Kaplan-Meier Estimates at day 365, 730, 1095, 1460, and 1825 with 1-sided 95% CI upper bound (UB).
Procedure relationship: Remotely, Possible, Probable, Unknown.
Adverse events with missing date are analyzed as relative day 1.
Source: Tables Safety_FAS.sas; Analyzed: 09JUN2024

Table 43: All Serious Procedure Related Adverse Events by AE Code and Timecourse – Primary Analysis Set

	Days Post-Op										
	0	1-30	31-60	61-180	181-365	366-730	731-1095	1096-1460	1461-1825	>1825	Total
All Events	0	0	0	0	0	0	2	0	2	0	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	0	0	0	2	0	2	0	4
Local recurrence	0	0	0	0	0	0	2	0	1	0	3
Metastatic breast cancer	0	0	0	0	0	0	0	0	1	0	1

† Defined as Remotely/Possible/Probable and Unknown.
Adverse events with missing date are analyzed as relative day 1.
Source: Tables Safety by Severity-Timecourse_FAS.sas; Analyzed: 09JUN2024

Table 44: All Serious Procedure Related Adverse Events by AE Code and Severity - Primary Analysis Set

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All Events	0	0.0%	3	75.0%	1	25.0%	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0.0%	3	75.0%	1	25.0%	4
Local recurrence	0	0.0%	3	100.0%	0	0.0%	3
Metastatic breast cancer	0	0.0%	0	0.0%	1	100.0%	1

*Percentage of total events. †Defined as Remotely/Possible/Probable and Unknown.
Source: Tables Safety by Severity-Timecourse_FAS.sas; Analyzed: 09JUN2024