

IceCure Medical, Ltd. - ProSense™ System  
 Briefing Document for the General and Plastic Surgery Devices Panel – Appendix A  
 Appendix A: Additional Detail on Reason for Deaths in ICE3 Study

20 deaths occurred within 5 years of treatment with cryoablation. One additional death (1) occurred after the follow-up period (>1825 days post-treatment) and is indicated by an asterisk below.

Patient #	Date of cryoablation	Date of Death	Summary
1	30 Aug 2018	4 Aug 2022	Cause of death: <b>Diffuse Metastatic disease to the bones</b> Metastatic disease in multiple areas, left clavicle, left scapula, spine L5 sacral. Site updated information for survival follow-up. When the subject left the study, went into Hospice. The site was made aware of the subject's death from Hospice. The subject entered hospice on 6/23/22 and was discontinued from the study, subject was followed for survival but passed away on 8/4/22.
2	30 Aug 2018	9 June 2022	Cause of death: <b>Gastric volvulus and cardiopulmonary arrest</b> The patient arrived at the emergency department on 8 June 2022 and was found to have gastric volvulus with partial gastric outlet obstruction. The patient refused surgical intervention and an NG tube and stated she wanted DNR.
3	31 Jan 2019	8 Nov 2021	Cause of death: <b>Unknown cause of death.</b> The site was informed subject was deceased by Medicare when insurance verification was being conducted. No next of kin is listed. The site called other providers and they did not know about the subject being deceased either. Medicare notified the site subject deceased on November 8, 2021.
4	08 Oct 2015	3 Nov 2016	Cause of death: <b>Emphysema.</b> The patient suffered from Emphysema, related to her medical history of COPD, on 10/13/2016 resulting in death on 11/03/2016.
5	08 Aug 2016	12 Jan 2017	Cause of death: <b>Nontraumatic Intracranial Hemorrhage.</b> The patient had Right Temporal craniotomy surgery due to meningioma (28 Dec 2016).
6	26 Jan 2016	28 Mar 2016	Cause of death: The patient passed away on 3/28/2016 due to <b>hypoxic respiratory failure</b> in the setting of squamous cell carcinoma of the cervix.
7	25 Mar 2015	18 May 2021	Cause of death: <b>Respiratory Failure</b> following COVID-19 on 05/18/2021. The patient was supposed to complete 5y FU in March 2020, However, FU was not performed.
8	04 Jun 2015	1 May 2016	Cause of death: <b>Heart failure - grade 5.</b> Death related to heart failure per daughter. The site does not have the exact date of death, the daughter stated May 2016.
9	18 Apr 2016	12 Feb 2021	Cause of death: Diagnosed with <b>Metastatic breast cancer</b> on 10/2020 and was admitted to hospital 11/2020 and died in hospice 2/2021.  Note that the DSMB considered this case as inadequate treatment since the user didn't follow the

Patient #	Date of cryoablation	Date of Death	Summary
			<p>study protocol. However, according to records and event analysis the user covered the tumor with sufficient margins.</p> <p>While not believed to be related to device or procedure, this death was reported to FDA out of conservative interpretation of reporting guidelines.</p>
10	19 Aug 2016	10 Jan 2019	Cause of death: <b>Heart Block Atrioventricular Complete</b>
11	20 Jun 2018	30 Aug 2021	<p>Cause of death: <b>Myocardial Infarction</b></p> <p>The patient's son informed the site that the subject suffered a fatal myocardial infarction in her sleep.</p>
12	16 May 2018	30 Aug 2020	<p>Cause of death: <b>Severe Aortic valve regurgitation.</b></p> <p>The patient was hospitalized for acute infective endocarditis and severe aortic valve regurgitation on 08/21/2020. She expired on 08/30/2020.</p>
13	18 July 2018	8 Sep 2020	<p>Cause of death: <b>Cardiac Arrest</b></p> <p>Cardiac arrest occurred at a local infusion center, the patient was intubated and presumed to have an upper GI bleed as a source of significant hematemesis and subsequent respiratory failure. Resuscitation was attempted.</p>
14	25 Sep 2018	6 Jul 2020	Cause of death: <b>Multi-organ failure</b> – Renal Failure, Hyperkalemia and metabolic acidosis
15	22 Jan 2019	7 Nov 2021	<p>Cause of death: <b>Progression of metastatic endometrial cancer</b></p> <p>Metastatic cancer originates from primary gynecological cancer.</p>
16	07 Dec 2015	31 Dec 2017	<p>Cause of death: <b>Alzheimer's dementia.</b></p> <p>The patient was in hospice and then passed away.</p>
17	09 June 2017	25 Feb 2018	<p>Cause of death: <b>Alzheimer's Dementia.</b></p> <p>The patient was in hospice due to dementia and died in hospice.</p>
18	15 Sep 2017	09 Feb 2021	<p>Cause of death: <b>Lung Infection</b></p> <p>Acute respiratory failure secondary to community-acquired pneumonia.</p>
19	20 Sep 2017	3 Apr 2018	<p>Cause of death: <b>Respiratory Failure</b></p> <p>The patient showed to have an aortic aneurysm but was deemed not a surgical candidate.</p>
20	10 Jan 2018	25 Dec 2021	<p>Cause of death: <b>Unknown cause of death</b></p> <p>The patient died in a nursing home. The specific reason for death is unknown</p>
21	06 Feb 2019	1 Feb 2022	<p>Cause of death: <b>Unknown cause of death</b></p> <p>After multiple attempts to reach the patient or her family, the site discovered an online obituary for the patient. No phone numbers to call to try to get any information about death.</p>