Serious Adverse Event Report

Event 01-Sep-2023 - report of 16-Dec-2024 - 10:18 UTC, revision 1

Initial Report Date	16-Dec-2024
Date of this report	16-Dec-2024
Investigator/reporter	Pawel Bartosz
Study Protocol (Id and Title)	H-34 - DELTA Revision study
Site Information	101 - Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Patient ID	10
Event onset	01-Sep-2023
Report type	Final
Date of Study Team Aware	16-Dec-2024 11:15
Title of clinical study	H-34 - DELTA Revision study
Name of the healthcare facility	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Name of the Principal Investigator	Jerzy Białecki
Name of the medical device involved	N/A
Components involved	N/A
ID number of study subject	101 - 10
Age	78
Gender	Male
Attribution within the clinical investigation	TreatmentGroup
Adverse Event (diagnosis, if known, or	death

signs/symptoms)	
Event narrative	no-surgery related
Admission date (dd-mmm-yyyy)	
Discharge date (dd-mmm-yyyy)	
Classification of the adverse event	Death
Outcome of the event	Died
Relevant concomitant drugs and date of administration	
Detail all possible and suspected causes including relevant medical histor	
Current clinical status	
Severity	Severe
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	NA
Action taken	UnknownAtTimeOfReport
Was the device permanently removed?	No
Detailed treatment	
Relevant medical history	None
Relevant medical records	None
Laboratory Results	None
Imaging Methods (e.g., X-ray, CT-scan)	None

Other (please specify)	None
Submitter	Investigator
Name of submitter	Pawel Bartosz

LimeS CLINICAL DATABASE

Clinical Study: H-34 DELTA Revision study
Patient ID: 101/10
Form: Adverse event

Date	Time	User	Values
16-Dec-2024	10:18:34 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- ReportType: value **Final** - Initial Report Date: value **16-Dec-2024** - Report Date: value **16-Dec-2024** - Date of Study Team Aware: value **16-Dec-2024** - Time team became aware (24 hr clock): value **11:15:00** - Title of clinical study: value **DELTA Revision study** - Protocol ID: value **H-34** - Name of the healthcare facility: value **Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP** - Name of the Principal Investigator: value **Jerzy Białecki** - Name of the medical device involved: value **<empty>** - IsMedicalDeviceNameNA: value **True** - Components involved:

			value **<empty>** - IsMedicalDeviceComponentsNA: value **True** - ID number of study subject: value **101 - 10** - Age: value **78** - Gender: value **Male** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **death** - Event narrative: value **no-surgery related** - Admission date (dd-mmm-yyyy): value **<empty>** - IsEventInformationAdmissionDateNA: value **True** - Discharge date (dd-mmm-yyyy): value **<empty>** - IsEventInformationDischargeDateNA: value **True** - Classification of the adverse event: value **Death** - Outcome of the event: value **Died** - Outcome / Recovered date: value **<empty>** - Outcome / Recovered with sequalae date: value **<empty>** - Outcome / Fatal date: value **<empty>** - Relevant concomitant drugs and date of administration:

			value **<empty>** - Detail all possible and suspected causes including relevant medical history: value **<empty>** - Current clinical status: value **<empty>** - Severity: value **Severe** - Causality: relationship to study medical device: value **NotRelated** - Causality: relationship to study procedure: value **NotRelated** - Expectedness: value **NA** - Action taken: value **UnknownAtTimeOfReport** - Was the device permanently removed?: value **False** - If yes, then please specify date of removal surgery: value **<empty>** - Action taken regarding study device / Other: value **<empty>** - Detailed treatment: value **<empty>** - Attachments / Relevant medical history: value **False** - Attachments / Relevant medical records: value **False** - Attachments / Laboratory Results: value **False** - Attachments / Imaging Methods (e.g., X-ray, CT-scan): value **False** - Attachments / Other: value **False** - Attachments / Other / Specify:

			value **<empty>** - Submitter: value **Investigator** - Name of submitter: value **Pawel Bartosz** - Event Onset: value **01-Sep-2023** - Serious Event: value **True** - Id: value **1139** - Notes: value **<empty>**