Serious Adverse Event Report

Event 22-Jan-2025 - report of 23-Jan-2025 - 15:10 UTC, revision 1

Initial Report Date	23-Jan-2025
Date of this report	23-Jan-2025
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	31
Event onset	22-Jan-2025
Report type	Initial
Date of Study Team Aware	22-Jan-2025 12:00
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 - 31
Age	74
Gender	Female
Attribution within the clinical investigation	TreatmentGroup
Adverse Event (diagnosis, if known, or	femur fracture at the cement removal

signs/symptoms)	
Event narrative	due to osteoporotic bone during cement removal femur fracuter appear
Admission date (dd-mmm-yyyy)	
Discharge date (dd-mmm-yyyy)	
Classification of the adverse event	Hospitalization
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	vit D3, 23.01.2025
Detail all possible and suspected causes including relevant medical histor	osteoporosis of femoral bone
Current clinical status	healing
Severity	Moderate
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	NA
Action taken	Other
Was the device permanently removed?	No
Detailed treatment	ORIF with plate and long stem fixation
Relevant medical history	None
Relevant medical records	None
Laboratory Results	None
Imaging Methods (e.g., X-ray, CT-scan)	Available

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

LimeS CLINICAL DATABASE

Clinical Study: H-34 DELTA Revision study
Patient ID: 101/31
Form: Adverse event

Date	Time	User	Values
23-Jan-2025	15:09:59 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- ReportType: value **Initial** - Initial Report Date: value **23-Jan-2025** - Report Date: value **23-Jan-2025** - Date of Study Team Aware: value **22-Jan-2025** - Time team became aware (24 hr clock): value **12:00:00** - 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 - 31** - Age: value **74** - Gender: value **Female** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **femur fracture at the cement removal** - Event narrative: value **due to osteoporotic bone during cement removal femur fracuter appear** - 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 **Hospitalization** - Outcome of the event: value **Ongoing** - 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 **vit D3, 23.01.2025** - Detail all possible and suspected causes including relevant medical history: value **osteoporosis of femoral bone** - Current clinical status: value **healing** - Severity: value **Moderate** - Causality: relationship to study medical device: value **NotRelated** - Causality: relationship to study procedure: value **NotRelated** - Expectedness: value **NA** - Action taken: value **Other** - 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 **ORIF with plate and long stem fixation** - 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 **True** - Attachments / Other: value **False**

			- Attachments / Other / Specify: value **<empty>** - Submitter: value **Investigator** - Name of submitter: value **Pawel Bartosz** - Event Onset: value **22-Jan-2025** - Serious Event: value **True** - Id: value **1144** - Notes: value **<empty>**