Serious Adverse Event Report

Event 31-Mar-2025 - report of 08-May-2025 - 16:44 UTC, revision 1

Initial Report Date	08-May-2025
Date of this report	08-May-2025
Investigator/reporter	Julia Macias
Study Protocol (Id and Title)	H-34 - DELTA Revision study
Site Information	101 - Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Patient ID	28
Event onset	31-Mar-2025
Report type	FollowUp
Date of Study Team Aware	31-Mar-2025 13:30
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	
Components involved	
ID number of study subject	101 - 28
Age	75
Gender	Female
Attribution within the clinical investigation	TreatmentGroup
Adverse Event (diagnosis, if known, or	Periprosthetic Joint Infection- redness around the scar,

signs/symptoms)	
Event narrative	
Admission date (dd-mmm-yyyy)	28-Apr-2025
Discharge date (dd-mmm-yyyy)	
Classification of the adverse event	InterventionRequired
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	
Detail all possible and suspected causes including relevant medical histor	
Current clinical status	
Severity	Moderate
Causality: relationship to study medical device	
Causality: relationship to study procedure	
Expectedness	
Action taken	Other
Was the device permanently removed?	Yes, 29-Apr-2025
Detailed treatment	Revision of the left hip endoprosthesis Corail / Delta Revision. Removal of the endoprosthesis. Removal of extensive inflammatory granulation tissue and necrotic tissues around the acetabulum, hip and right thigh. Implantation of a garamycin sponge (2). Implantation of acetabular cement filling.
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	Julia Macias

LimeS CLINICAL DATABASE

Clinical Study: H-34 DELTA Revision study
Patient ID: 101/28
Form: Adverse event

Date	Time	User	Values
08-May-2025	16:44:17 (UTC)	Julia Macias (maciasjulia@gmail.com)	- ReportType: value **FollowUp** - Initial Report Date: value **08-May-2025** - Report Date: value **08-May-2025** - Date of Study Team Aware: value **31-Mar-2025** - Time team became aware (24 hr clock): value **13:30:00** - 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 **False** - Components involved:

			value **<empty>** - IsMedicalDeviceComponentsNA: value **False** - ID number of study subject: value **101 - 28** - Age: value **75** - Gender: value **Female** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **Periprosthetic Joint Infection- redness around the scar,** - Event narrative: value **<empty>** - Admission date (dd-mmm-yyyy): value **28-Apr-2025** - IsEventInformationAdmissionDateNA: value **False** - Discharge date (dd-mmm-yyyy): value **<empty>** - IsEventInformationDischargeDateNA: value **False** - Classification of the adverse event: value **InterventionRequired** - 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 **<empty>** - Detail all possible and suspected causes including relevant medical history: value **<empty>** - Current clinical status: value **<empty>** - Severity: value **Moderate** - Causality: relationship to study medical device: value **<empty>** - Causality: relationship to study procedure: value **<empty>** - Expectedness: value **<empty>** - Action taken: value **Other** - Was the device permanently removed?: value **True** - If yes, then please specify date of removal surgery: value **29-Apr-2025** - Action taken regarding study device / Other: value **<empty>** - Detailed treatment: value **Revision of the left hip endoprosthesis Corail / Delta Revision. Removal of the endoprosthesis. Removal of extensive inflammatory granulation tissue and necrotic tissues around the acetabulum, hip and right thigh. Implantation of a garamycin sponge (2). Implantation of acetabular cement filling.** - 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 **Julia Macias** - Event Onset: value **31-Mar-2025** - Serious Event: value **True** - Id: value **1195** - Notes: value **<empty>**