Serious Adverse Event Report

Event 03-Feb-2025 - report of 27-Jun-2025 - 15:18 UTC, revision 5

Initial Report Date	26-Feb-2025
Date of this report	27-Jun-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	30
Event onset	03-Feb-2025
Report type	FollowUp
Date of Study Team Aware	04-Feb-2025 07:30
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	N/A
Components involved	N/A
ID number of study subject	101 - 30
Age	56
Gender	Female
Attribution within the clinical investigation	TreatmentGroup
Adverse Event (diagnosis, if known, or	Dislocation

signs/symptoms)	
Event narrative	Patients after lumbar spine fracture with gluteal paresis, dislocation caused by muscle defficency
Admission date (dd-mmm-yyyy)	03-Feb-2025
Discharge date (dd-mmm-yyyy)	19-Feb-2025
Classification of the adverse event	InterventionRequired
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	None
Detail all possible and suspected causes including relevant medical histor	Gluteal muscle defficency
Current clinical status	Good
Severity	Moderate
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	Unanticipated
Action taken	Other revision surgery with constrainde liner from other company
Was the device permanently removed?	No
Detailed treatment	10.02.2025 surgery: Cementation constrainded liner and body exchange. After one month patient again admitted to our hospital with dislocation. Reoparated at 17.03.2025 liner removal and spacer with 20degree, dual mobility and changed body.
Relevant medical history	None
Relevant medical records	None

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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: 101/30
Form: Adverse event

Date	Time	User	Values
27-Jun-2025	15:18:50 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Detailed treatment: from **10.02.2025 surgery: Cementation constrainded liner and body exchange** to **10.02.2025 surgery: Cementation constrainded liner and body exchange. After one month patient again admitted to our hospital with dislocation. Reoparated at 17.03.2025 liner removal and spacer with 20degree, dual mobility and changed body.**
27-Jun-2025	14:41:08 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Name of the medical device involved: from **<empty>** to **<empty>** - Components involved: from **<empty>** to **<empty>** - Notes: from **<empty>** to **<empty>**
26-Feb-2025	11:34:50 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **druzd4.jpg**
26-Feb-2025	11:34:48 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **druzd3.jpg**
26-Feb-2025	11:25:49 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- ReportType: value **FollowUp** - Initial Report Date: value **26-Feb-2025**

			- Report Date: value **26-Feb-2025** - Date of Study Team Aware: value **04-Feb-2025** - Time team became aware (24 hr clock): value **07:30:00** - 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 **True** - Components involved: value **<empty>** - IsMedicalDeviceComponentsNA: value **True** - ID number of study subject: value **101 - 30** - Age: value **56** - Gender: value **Female** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **Dislocation** - Event narrative:

			value **Patients after lumbar spine fracture with gluteal paresis, dislocation caused by muscle defficency** - Admission date (dd-mmm-yyyy): value **03-Feb-2025** - IsEventInformationAdmissionDateNA: value **False** - Discharge date (dd-mmm-yyyy): value **19-Feb-2025** - 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 **None** - Detail all possible and suspected causes including relevant medical history: value **Gluteal muscle defficency** - Current clinical status: value **Good** - Severity: value **Moderate** - Causality: relationship to study medical device: value **NotRelated** - Causality: relationship to study procedure: value **NotRelated** - Expectedness: value **Unanticipated**

			- 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 **revision surgery with constrainde liner from other company** - Detailed treatment: value **10.02.2025 surgery: Cementation constrainded liner and body exchange** - 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 **03-Feb-2025** - Serious Event: value **True** - Id: value **1146** - Notes:

			value **<empty>**