Serious Adverse Event Report

Event 09-May-2024 - report of 16-Dec-2024 - 09:48 UTC, revision 2

Initial Report Date	24-Jun-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	27
Event onset	09-May-2024
Report type	Initial
Date of Study Team Aware	09-May-2024 09:00
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 - 27
Age	61
Gender	Female
Attribution within the clinical investigation	TreatmentGroup
Adverse Event (diagnosis, if known, or	right peronal nerv palsy after surgery

signs/symptoms)	
Event narrative	In postoperative USG no nerve damage, probably becouse of 1,5 cm limb elongation
Admission date (dd-mmm-yyyy)	07-May-2024
Discharge date (dd-mmm-yyyy)	22-May-2024
Classification of the adverse event	Disability
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	galantamin 5mg daily for 3 weeks
Detail all possible and suspected causes including relevant medical histor	previous surgery and hard scar around the hip could lead to nerve pulling and nerve palsy
Current clinical status	slight better function of right foot At the postoperative control, 17.10.2024, full function recovery of the peroneal nerve palsy.
Severity	Moderate
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	NA
Action taken	Both
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: 101/27
Form: Adverse event

Date	Time	User	Values
16-Dec-2024	09:48:17 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Name of the medical device involved: from **<empty>** to **<empty>** - Components involved: from **<empty>** to **<empty>** - Current clinical status: from **slight better function of right foot** to **slight better function of right foot** **At the postoperative control, 17.10.2024, full function recovery of the peroneal nerve palsy.** - Action taken regarding study device / Other: from **<empty>** to **<empty>** - Notes: from **<empty>** to **<empty>**
24-Jun-2024	11:55:19 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- ReportType: value **Initial** - Initial Report Date: value **24-Jun-2024** - Report Date: value **24-Jun-2024**

			- Date of Study Team Aware: value **09-May-2024** - Time team became aware (24 hr clock): value **09:00:00** - 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 - 27** - Age: value **61** - Gender: value **Female** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **right peronal nerv palsy after surgery** - Event narrative: value **In postoperative USG no nerve damage, probably becouse of 1,5 cm limb elongation**

			- Admission date (dd-mmm-yyyy): value **07-May-2024** - IsEventInformationAdmissionDateNA: value **False** - Discharge date (dd-mmm-yyyy): value **22-May-2024** - IsEventInformationDischargeDateNA: value **False** - Classification of the adverse event: value **Disability** - 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 **galantamin 5mg daily for 3 weeks** - Detail all possible and suspected causes including relevant medical history: value **previous surgery and hard scar around the hip could lead to nerve pulling and nerve palsy** - Current clinical status: value **slight better function of right foot** - Severity: value **Moderate** - Causality: relationship to study medical device: value **NotRelated** - Causality: relationship to study procedure: value **NotRelated** - Expectedness: value **NA** - Action taken:

			value **Both** - 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 **09-May-2024** - Serious Event: value **True** - Id: value **1128** - Notes: value **<empty>**