Serious Adverse Event Report

Event 01-Dec-2021 - report of 04-Nov-2022 - 09:12 UTC, revision 20

Initial Report Date	07-Dec-2021
Date of this report	04-Nov-2022
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	9
Event onset	01-Dec-2021
Report type	Final
Date of Study Team Aware	01-Dec-2021 08:00
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	Delta Revision Cup
Components involved	Delta Revision Cup, Hemispherical module, Bone screws, insert
ID number of study subject	101 - 9
Age	60
Gender	Male
Attribution within the clinical investigation	TreatmentGroup

Adverse Event (diagnosis, if known, or signs/symptoms)	Cup loosening
Event narrative	Early postoperative cup loosening,
Admission date (dd-mmm-yyyy)	19-Nov-2021
Discharge date (dd-mmm-yyyy)	10-Dec-2021
Classification of the adverse event	InterventionRequired
Outcome of the event	Recovered 03-Dec-2021
Relevant concomitant drugs and date of administration	None
Detail all possible and suspected causes including relevant medical histor	Probable cause is technical mistake at first operation with Delta Revision implantation. Too proximal cup implantation and not sufficient cup hook stabilization at the ischial bone. Second cause could be wrong position of stable stem, various position in femur.
Current clinical status	Patient undergone revision surgery at 2021-12-03, with cup and stem reimplantation.
Severity	Severe
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	NA
Action taken	NotPharmacological
Was the device permanently removed?	Yes, 03-Dec-2021
Detailed treatment	Revision surgery with cup and stem removal. Reimplantation Trident Multihole cup with augment and Restoration stem.
Relevant medical history	None

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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: 101/9
Form: Adverse event

Date	Time	User	Values
04-Nov-2022	09:12:58 (UTC)	Julia Macias (maciasjulia@gmail.com)	- .ReportType: from **Initial & Final** to **Final** - Outcome of the event: from **Ongoing** to **Recovered** - Outcome / Recovered date: from **<empty>** to **03-Dec-2021** - Action taken regarding study device / Other: from **<empty>** to **<empty>**
16-Dec-2021	16:29:34 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Admission date (dd-mmm-yyyy): from **<empty>** to **19-Nov-2021** - Discharge date (dd-mmm-yyyy): from **<empty>** to **10-Dec-2021**
16-Dec-2021	16:28:12 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Causality: relationship to study medical device: from **Probable** to **Not Related** - Causality: relationship to study procedure: from **Probable** to **Not Related**

			- Action taken: from **<empty>** to **Not pharmacological** - Action taken regarding study device / Other: from **<empty>** to **<empty>**
09-Dec-2021	15:35:43 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-3.jpg**
09-Dec-2021	15:35:43 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-4.jpg**
09-Dec-2021	15:35:42 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-2.jpg**
09-Dec-2021	15:35:41 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-5.jpg**
09-Dec-2021	15:35:41 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-1.jpg**
09-Dec-2021	15:32:00 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment deleted: **101-9-4.jpg**
09-Dec-2021	15:31:41 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment deleted: **101-9-5.jpg**
09-Dec-2021	15:29:28 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment deleted: **101-9-3.jpg**
09-Dec-2021	14:44:53 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment deleted: **101-9-2.jpg**
09-Dec-2021	14:44:25 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment deleted: **101-9-1.jpg**
07-Dec-2021	22:06:46 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-1.jpg**
07-Dec-2021	22:06:46 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-3.jpg**
07-Dec-2021	22:06:46 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-4.jpg**
07-Dec-2021	22:06:46 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-5.jpg**

07-Dec-2021	22:06:46 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachment added: **101-9-2.jpg**
07-Dec-2021	22:00:43 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Attachments / Relevant medical history: from **True** to **False** - Notes: from **<empty>** to **<empty>**
07-Dec-2021	21:59:43 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- ReportType: value **InitialAndFinal** - Initial Report Date: value **07-Dec-2021** - Report Date: value **07-Dec-2021** - Date of Study Team Aware: value **01-Dec-2021** - Time team became aware (24 hr clock): value **08:00:00** - 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 **Delta Revision Cup** - IsMedicalDeviceNameNA: value **False** - Components involved: value **Delta Revision Cup, Hemispherical module, Bone screws, insert** - IsMedicalDeviceComponentsNA:

			value **False** - ID number of study subject: value **101 - 9** - Age: value **60** - Gender: value **Male** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **Cup loosening** - Event narrative: value **Early postoperative cup loosening,** - Admission date (dd-mmm-yyyy): value **<empty>** - 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 **None** - Detail all possible and suspected causes including relevant medical history:

			value **Probable cause is technical mistake at first operation with Delta Revision implantation. Too proximal cup implantation and not sufficient cup hook stabilization at the ischial bone. Second cause could be wrong position of stable stem, various position in femur.** - Current clinical status: value **Patient undergone revision surgery at 2021-12-03, with cup and stem reimplantation.** - Severity: value **Severe** - Causality: relationship to study medical device: value **Probable** - Causality: relationship to study procedure: value **Probable** - Expectedness: value **NA** - Action taken: value **<empty>** - Was the device permanently removed?: value **True** - If yes, then please specify date of removal surgery: value **03-Dec-2021** - Action taken regarding study device / Other: value **<empty>** - Detailed treatment: value **Revision surgery with cup and stem removal. Reimplantation Trident Multihole cup with augment and Restoration stem.** - Attachments / Relevant medical history: value **True** - 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 **01-Dec-2021** - Serious Event: value **True** - Notes: value **<empty>**