Adverse Events and Device Deficiency Sheet

Study ID: H-34 Q1 2022

Device Deficiency												
Patient ID	**Onset date**	**Name of medical device**	**Components**	**Classification of deficiency**	**Description of deficiency and action taken**	**Could the deficiency have led to a SAE?**	**Notes**	**Initial/Follow-up**	**Clinical Dept.Revision**	**Date of communication to PMS**	**Date of PMS reply**	**PMS feedback**

	Role	**Requested to:**
Written by: Lisa Ciuffarin	AJCL	
Approved by: Federica Azzimonti	RMCL	

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Adverse Events

Patient ID		Report type	Initial Report Date	Report Date	Date of Onset	Date of Study Team Aware	Time team became aware (24 hr clock)	Title of clinical study	Protocol ID	Name of the healthcare facility	Name of the Principal Investigator	Name of the medical device involved	Components involved	ID number of study subject	Age	Gender	Attribution within the clinical investigation	Adverse Event (diagnosis, if known, or signs/ symptoms)	Event narrative	Admission date (dd/mmm/yyyy)	Discharge date (dd/mmm/yyyy)	Classification of the adverse event	Outcome of the event	Relevant concomitant drugs and date of administration	Detail all possible and suspected causes including relevant medical history	Current clinical status	Severity	Causality: relationship to study medical device	Causality: relationship to study procedure	Expectedness	Action taken	Detailed treatment	Was the device permanently removed?	Attachments: Relevant Medical History	Attachments: Relevant Medical Records	Attachments: Laboratory Results	Attachments: Imaging Methods (e.g., X-ray, CT-scan)	Attachments: Other	Submitter	Name of submitter	Notes	Status	Initial / Follow-up	communicated to PMS	If Yes, date	Date of reply	Device relationship for PMS dept	Relationship to Procedure for PMS Dept	Complaint	Further evaluation performed	Final decision/communication on relationship and expectdness
101	9	Initial & Final	07/12/2021	07/12/2021	01/12/2021	01/12/2021	08:00	DELTA Revision study	H-34	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	Jerzy Bialecki	Delta Revision Cup	Delta Revision Cup, Hemispherical module, Bone screws, insert	101 - 9	60	Male	Treatment Group	Cup loosening	Early postoperative cup loosening,	19-Nov-2021	19-Nov-2021	Medical or surgical intervention required to prevent any of the above	Ongoing	None	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.	Patient undergone revision surgery at 2021-12-03, with cup and stem reimplantation.	Severe	Not Related	Not Related	N/A	Not pharmacological	Revision surgery with cup and stem removal. Reimplantation Trident Multihole cup with augment and Restoration stem.	Yes	None	None	None	Available	None	Investigator	Pawel Bartosz	N/A	Valid	Initial	Yes	09/12/2021	10/12/2021					
101	10	Initial	19/01/2022	19/01/2022	14/01/2022	14/01/2022	08:51	DELTA Revision study	H-34	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	Jerzy Bialecki	N/A	N/A	101 - 10	76	Male	Treatment Group	Dyspnoea, fluid collection in lungs	Chronic heart failure exacerbation	30-Dec-2021	30-Dec-2021	Hospitalization or prolongation of hospitalization	Ongoing	Furosemid 40mg 2xday from 14.01.2022.	Chronic heart failure	Good	Moderate	Not Related	Not Related	N/A	Pharmacological		No	None	None	None	None	None	Investigator	Pawel Bartosz	N/A	Draft	Initial	No					
101	5	Initial	03/02/2022	03/02/2022	20/10/2021	20/10/2021	00:00	DELTA Revision study	H-34	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	Jerzy Bialecki	Revision Hip /Anca	Stem17mm/200mm	101 - 5	76	Female	Treatment Group	Intraoperative fracture of femur shaft	The femur shaft was weakened beacuse of prevous use of metal loop;	18-Oct-2021	27-Oct-2021	Hospitalization or prolongation of hospitalization	Ongoing	NA	The femur shaft was weakened beacuse of previous use of metal loop; 25 years ago THA of both hips, 2011- revision of right hipEcofic;	On the first control visit 22 Nov 2021 patient is walking with 2 crutches;	Severe	Not Related	Not Related	Anticipated	Other intraoperative reduction and fixation of the fracture		No	None	None	None	None	None	Investigator	Julia Macias	N/A	Draft	Initial	No					

	Role:	Date:	Signature:
Written by: Lisa Ciuffarin	AJCL		
Approved by: Federica Azzimonti	RMCL		