Adverse Events and Device Deficiency Sheet

Study ID: H-34

Adverse Events															COMMUNICATION TO PMS		PMS feedback					
Patient ID	**Onset date**	**End date**	**Description**	**Seriousness**	**Outcome**	**Maximum intensity**	**Therapy medication**	**Device relationship for PI**	**Medical device information**	**Notes**	**Relationship to Procedure**	**Expectdness**	**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**
101/09	01/12/2021	10/12/2021	Early postoperative cup loosening. Probable cause is technical mistake at first operation with Delta Revision implantation. Too proximal cup implantation and not sufficient cup hook stablization at the ischial bone. Second cause could be wrong position of stable stem, various position in femur.	Seriousness	Ongoing	Severe	None	not related	Delta Revision Cup, Hemispherical module, Bone screw, insert have been removed	Revision surgery with cup and stem removal. Reimplantation Trident Multihole cup with augment and Restoration stem	not related	N/A	Valid	Initial and final	SAE has been communicated to PMS	09/12/2021	10/12/2021					

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