

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 stabilization 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:

22/12/2021 | 15:54 CET
DocuSigned by:
Written by: Lisa Ciuffarin AJCL

Lisa Ciuffarin
Signer Name: Lisa Ciuffarin
Signing Reason: I am the author of this document
Signing Time: 22/12/2021 | 15:53 CET
205C1223BA1F4EDB99C6206245B0C4464

23/12/2021 | 10:10 CET
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Approved by: Federica Azzimonti RMCL

Federica Azzimonti
Signer Name: Federica Azzimonti
Signing Reason: I approve this document
Signing Time: 23/12/2021 | 10:10 CET
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Role **Requested to:**

22/12/2021 | 15:54 CE

Written by: Lisa Ciuffari

AJCL

Requested to:

—Signed by:

Signer Name: Lisa Ciuffarin
Signing Reason: I am the author of this document
Signing Time: 22/12/2021 | 15:54 CET
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CET

23/12/2021 | 10:10

Approved by: Federica Azzimoni

RMGL

DocuSigned

 Signer Name: Federica Azzimonti
Signing Reason: I approve this document
Signing Time: 23/12/2021 | 10:10 CET
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