Lima Corporate Orthopaedic motion	CLINICAL INVESTIGATION REPORT			
	Department	**Rep. Nr**	**Date**	**Rev.**
	Clinical Research	01	11-Dec-23	1.0

Study Title	**An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision acetabular cup.**
Short Title	**DELTA REVISION CUP**
Protocol ID	**H-34**
Product	**CE marked DELTA Revision acetabular cup**
Study Phase	**Enrollment**
Subject Population	49
Sponsor	**Limacorporate Spa** Via Nazionale 52, 33030, Villanova di San Daniele (UD), Italy
Sponsor representative	**Federica Azzimonti** Clinical Research Manager, Limacorporate S.p.A.
Principal Investigator	**Dr. Jerzy Bialecki** Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP in Otwock, Poland
Sub-Investigator(s)	**Dr. Julia Macias** **Dr. Pawel Bartosz** Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP in Otwock, Poland
Statistical Analysis	**Intermediate statistical analysis:** Limacorporate S.p.A.

Clinical investigation identified as H-34 and entitled “An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA

Revision acetabular cup” has been conducted in accordance with ISO 14155:2020 “Clinical investigation of medical devices for human subjects — Good Clinical Practice” and with the ethical principles of the Declaration of Helsinki.

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List of Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
BMI	Body-Mass Index
eCRF	electronic Case Report Form
FU	Follow-Up
HHS	Harris Hip Score
ISO	International Organization for Standardization
OHS	Oxford Hip Score
ROM	Range of Motion
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SD	Standard Deviation
THA	Total Hip Arthroplasty
UHMWPE	Ultra High Molecular Weight Polyethylene
USADE	Unexpected Serious Adverse Device Effect

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1.0 SUMMARY

Name of sponsor/Company	Limacorporate S.p.A
Study ID	H-34
Study title	An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision acetabular cup.
Name of study product	CE marked DELTA Revision acetabular cup
Investigators & study site(s)	Dr. Jerzy Bialecki Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP in Otwock, Poland
Publication (reference)	N/A
Study period:	Date of first enrolment: 14/09/2021 Date of last enrolment: N/A Current phase: enrollment
Objectives:	Primary objective - To assess the clinical outcomes of the DELTA Revision acetabular cup used in real life settings over a period of 2 years Secondary objectives - To assess the radiographical and clinical outcomes of the DELTA Revision acetabular cup used in real life settings over a period of 2 years -To evaluate the safety profile of the DELTA Revision acetabular cup used in real life settings over a period of 5 years - To describe baseline data (demographic data, primary diagnosis, aetiology, affected side, type of surgery and intra-operative data) of patients with Delta Revision acetabular cup
Criteria for evaluation/Endpoints:	**Primary endpoint:** - The evaluation of Harris Hip Score (HHS) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant. **Secondary endpoints:** - Evaluation of Range of Motion (ROM) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year and 2 years after the implant;

	- Evaluation of Oxford Hip Score (OHS) at pre-operative visit, intraoperatively/discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after the implant; - Survivorship of the implant (Kaplan-Meier estimate) at 2 years of follow-up after surgery; - Radiographic implant evaluation and stability assessment of the DELTA Revision acetabular cup at the following timepoints: at discharge, 2 months, 6 months, 1 year, and 2 years after the implant - Incidence, type and severity of all the Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Device Effects (ADEs) and Serious Adverse Device Effects (SADEs) at intraoperatively, discharge, 2 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after the implant.
Number of patients:	Planned sample size: 49 Enrolled: 21 Completed: 0
Inclusion and exclusion criteria:	**Inclusion criteria:** Patients must meet the following criteria for study entry: 1. Male or female. 2. Age ≥ 18 years old. 3. All patients must give written informed consent approved by the study site's Institutional Review Board (IRB)/Ethical Committee (EC). 4. Adult patients in whom a decision has already been made to perform a total hip arthroplasty with DELTA Revision acetabular cup as per indication for use. The decision to implant DELTA Revision acetabular cup must be taken prior to, and independently from the decision to enroll the patient. This decision should be made in accordance with routine clinical practice at the study site concerned. 5. Patient is able to comply with the protocol **Exclusion criteria:** A patient will not be included in the study if they meet any of the following criteria: 1. Adult patients with any DELTA Revision acetabular cup contraindication for use as reported in the current local Instruction for use. 2. For female patients, current pregnancy and/or lactation or planning a pregnancy.
Statistical methods:	An internal statistical analysis was performed on all collected data, using Microsoft® Excel.
Date of the report:	11 December 2023

2.0 INTRODUCTION

H-34 is a post-marketing, prospective, observational, monocentric, longitudinal cohort clinical study that aims at collecting clinical, patient-reported and radiographic early outcomes after total hip arthroplasty (THA) with DELTA Revision acetabular cup. The study is being carried out at the Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP in Otwock, Poland. Data are being collected prospectively and following hospital standard of care. Every patient is followed from preoperative visit up to 5 years after surgery.

Study population consist of 49 patients in need for a hip revision surgery and deemed suitable for receiving a DELTA Revision acetabular cup. The expected enrollment period is 30 months. So far, 23 patients have been screened and 21 patients have been enrolled, of which 5 performed the 2-year follow-up visit.

Study visits are performed according to the local standard of care. Timelines and temporal windows are the following:

- Pre-operative visit
- Intraoperative visit
- Discharge visit
- Follow-Up 2 months: ± 30 days
- Follow-Up 6 months: ± 60 days
- Follow-Up 12 months: ± 6 months
- Follow-Up 24 months: ± 6 months
- Survival Follow-Up visit at 3,4 and 5 years: ± 6 months

Relevant data will be captured on an eCRF. These data will be transmitted to the sponsor for analysis, will be anonymous and will be identified by a patient number. As this study is non-interventional, all data collected will be in accordance with the practice of clinicians implanting DELTA Revision acetabular cup.

At pre-operative, intra-operative, discharge and each follow-up visit, the following information will be collected:

- Medical history and demographic data (only at pre-operative visit);
- Primary diagnosis and physical examination (only at pre-operative visit);
- Surgical data (only at intra-operative visit);
- X-rays as per standard care;
- Radiographic evaluation;
- Clinical assessment (HHS, ROM, OHS);
- Assessment of type, nature and severity of any DD, AE, ADE, SAE and SADE;
- Survivorship of implant.

The study is still in the enrollment phase and this intermediate clinical study report is based on eCRF data extraction performed on the 11th of December 2023.

3.0 RESULTS

3.1 Study Flowchart

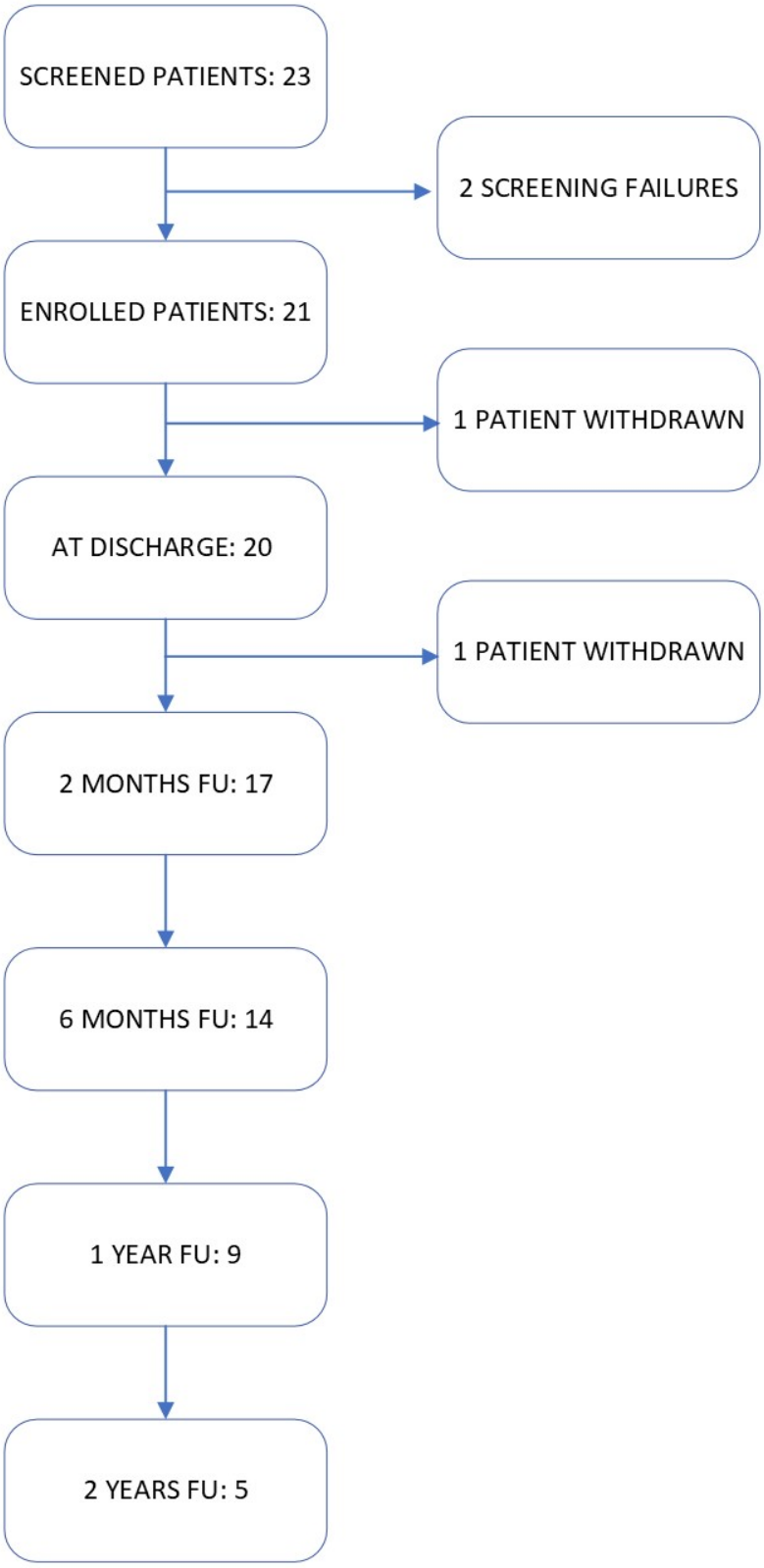

Figure 1 Study flowchart

3.2 Patient population and preoperative data

Variable	N	Mean	SD	Min	Max	Median
Pt enrolled	21					
Weight (kg)	21	78	14	57	110	79
Height (cm)	21	168	10	152	189	167
BMI (kg/m^2)	21	28	4	22	35	27.3
Age (years)	21	64	13	40	87	68

Table 1 Demographics of study population.

Variable	n	%
Gender	**21**	
Female	12	57
Male	9	43
Race	**21**	
White	21	100
Working status	**21**	
Retired	10	48
Not Working	8	38
Active	2	10
Missing data	1	5
Activity level	**21**	
Sedentary	17	81
Normal	3	14
Intense	0	0
Missing Data	1	5
Smoking habits	**21**	
No smoking	16	76
Smoking, daily	5	24
Alcohol drinking	**21**	
No alcohol	20	95
Alcohol drinking, occasionally	1	
Alcohol drinking, daily		
Concomitant medication	**21**	
Yes	15	71
No	5	
-	1	

Table 2 Gender, working status, activity level, smoking and drinking habits, concomitant medications of study population.

Variable	n	%
Affected side	**21**	
Left	11	52.4
Right	10	47.6
Primary diagnosis	**21**	
Presence of bone stock of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum	10	47.6
Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure	9	42.9
Clinical management problem where arthrodesis or alternative reconstruction techniques are less likely to achieve satisfactory results	2	9.5
Previous hip surgeries on the affected side	**21**	
Yes	21	100
No	0	0
Previous hip treatments or surgeries on the contralateral side	**21**	
Yes	8	38.1
No	13	61.9
Description of pain	**21**	
No pain	3	14.3
Unable to describe	0	0
At rest	4	19
Occasional start-up pain	4	19
Always start-up pain	6	28.6
With every movement	3	14.3
-	1	4.8
Pain therapy	**21**	
None	7	33.3
NSAIDs, occasionally	3	14.3
NSAIDs, regularly	4	19
Steroids, occasionally	0	0
Steroids, regularly	0	0
Opiates, occasionally	3	14.3
Opiates, regularly	4	19
Osteoporosis	**21**	
Yes	0	0
No	20	95.2
-	1	4.8

Table 3 Preoperative assessment of study population.

3.3 Intraoperative data

3.3.1 Surgery data

Variable	n	%
Surgical approach	**21**	
Postero-lateral	21	100
Anesthesia	**21**	
Subarachnoid	19	90.5
General	2	9.5
Intraoperative complications	**21**	
No	19	90.5
Yes, not implant-related	2	9.5
Antibiotic prophylaxis	**21**	
Yes	21	100
No	0	0
Antithrombotic prophylaxis	**21**	
Yes	21	100
No	0	0
Antihemorrhagic prophylaxis	**21**	
Yes	12	57.1
No	8	38.1

Table 4 Surgical data of study population with regard to surgical approach, anesthesia, intraoperative complications and prophylaxis therapy.

Variable	n	Mean	SD	Min	Max	Median
Surgery time	21	158	37	105	235	155
Intraoperative hematocrit	21	41	4	32	50	41
Immediate postoperative hematocrit	21	31	5	23	39	31

Table 5 Surgery data of study population in terms of surgery time and hematocrit (intraoperative and postoperative).

Variable	n	%
Bone stock quality - acetabulum	**21**	
Normal	2	9.5
Porotic	17	81
Sclerotic	2	9.5
Bone grafting	**21**	
Yes	16	76.2
No	5	23.8
Graft material	**21**	
Allograft chips	8	38.1
Autograft	1	4.8
Other	8	38.1
-	4	19

Table 6 bone stock quality and bone grafting on the acetabular side of study population.

Variable	n	%
Bone stock quality - femur	**21**	
Normal	10	47.6
Porotic	10	47.6
Sclerotic	1	4.8
Bone grafting	**21**	
Yes	1	4.8
No	20	95.2
Graft material	**21**	
-	20	95.2
Other	1	4.8

Table 7 Bone stock quality and bone grafting on the femoral side of study population.

3.3.2 Implant information

Variable	n	%	Variable	n	%
Cup type	**21**		**Cup liner material**	**21**	
DELTA-REVISION	14	66.7	Neutral UHMWPE X-LIMA + Ti6Al4V	2	9.5
DELTA-REVISION+TT HEMISPHERIC MODULE ECC. 12	5	23.8	Neutral UHMWPE X-LIMA + Ti6Al4V w/ angled 10° spacer	1	4.8
DELTA-REVISION+TT HEMISPHERIC MODULE ECC. 18	1	4.8	Neutral UHMWPE X-LIMA + Ti6Al4V w/ angled 20° spacer	1	4.8
-	1	4.8	Protruded UHMWPE X-LIMA + Ti6Al4V	7	33.3
Cup diameter	**21**		Protruded UHMWPE X-LIMA + Ti6Al4V w/ neutral spacer	3	14.3
50 mm	1	4.8	Protruded UHMWPE X-LIMA + Ti6Al4V w/ neutral +5 spacer	1	4.8
54 mm	4	19	Protruded UHMWPE X-LIMA + Ti6Al4V w/ angled 20° spacer	4	19
58 mm	6	28.6	-	2	9.5
62 mm	5	23.8	**Cup liner size**	**21**	
66 mm	4	19	ID 32 mm-MEDIUM	10	47.6
-	1	4.8	ID 32 mm-LARGE	1	4.8
Cup cement	**21**		ID 36 mm-LARGE	8	38.1
No	21		-	2	9.5

Table 8 Implant details of the acetabular side of study population.

Variable	n	%
Head type	**21**	
Modular	19	90.5
-	2	9.5
Head material	**21**	
Biolox (r) Delta	15	71.4
Biolox (r) Delta + Ti6Al4V	1	4.8
CoCrMo Taper 12/14	2	9.5
CoCrMo Taper 14/16	1	4.8
-	2	9.5
Head diameter	**21**	**100**
32 mm	11	52.4
36 mm	8	38.1
-	2	9.5
Head size	**21**	
S	6	28.6
M	4	19
L	7	33.3
XL	2	9.5
-	2	9.5

Table 9 Implant details of the femoral head of study population.

Variable	n	%
Stem type	**21**	
H-MAX S standard	2	9.5
Modulus-R	2	9.5
Modulus Taper B	3	14.3
Revision	4	19
Competitor (no Lima)	10	47.6

Table 10 Implant used on the femoral side of study population.

3.4 Efficacy analysis

3.4.1 Clinical results

3.4.1.1 Clinical results – Harris Hip Score (HHS)

Time point	n	Mean	SD	Min	Max	Median
Preoperative	21	38.6	15.7	12	64	41
2 months FU	17	60.6	12.7	42	80	56
6 months FU	14	73.9	15.5	45	94	74.5
1 year FU	9	84.3	12.7	65	97	89
2 years FU	5	77	13.8	57	93	79

Table 11 Change in HHS from preoperative (baseline) to 2-year follow-up

	Preoperative		2 months FU		6 months FU		1 year FU		2 years FU	
Total score description	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Very poor	20	95.2	9	52,9	3	21.4	0	0	1	20
Poor	1	4.8	1	5,9	1	7.1	2	22.2	0	0
Fair	0	0	6	35,3	5	35.7	1	11.1	2	40
Good	0	0	1	5,9	1	7.1	2	22.2	1	20
Excellent	0	0	0	0,0	4	28,6.	4	44.4	1	20

Table 12 Change in total score description of HHS from preoperative (baseline) to 2-year follow-up.

3.4.1.2 Clinical results – Oxford Hip Score (OHS)

Time point	n	Mean	SD	Min	Max	Median
Preoperative	21	19.7	8.9	3	37	21
2 months FU	17	30.9	7.6	17	43	33
6 months FU	14	38.6	5.8	28	47	38.5
1 year FU	9	41.2	6.3	28	48	42
2 years FU	5	39.4	8.5	25	46	42

Table 13 Change in OHS from preoperative (baseline) to 2-year follow-up.

	Preoperative		2 months FU		6 months FU		1 year FU		2 years FU	
Total score description	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Very poor	0	0	0	0	0	0	0	0.	0	0
Poor	17	81	7	41.2	0	0	0	0.	1	20
Fair	2	9.5	2	11.8	3	2.4	1	11.1	0	0
Good	2	9.5	6	35.3	6	42.9	2	22.2	1	20
Excellent	0	0	2	11.8	5	35.7	6	66.7	3	60

Table 14 Change in total score description of OHS from preoperative (baseline) to 2-year follow-up.

3.4.2 Radiographic results

3.4.2.1 Preoperative radiographic evaluation

Variable	n	%
Varus/valgus deformity	21	
Neutral	19	90.5
Varus	2	9.5
Valgus	0	0
Osteoarthritis severity	21	
Grade I	11	52.4
Grade II	2	9.5
Grade III	0	0
Grade IV	4	19
-	4	19
Presence of osteophytes	21	
Yes	1	4.8
No	17	81
Missing Data	3	14.3

Presence of cysts	21	
Yes	1	4.8
No	17	81
Missing Data	3	14.3
Sclerosis	21	
None	15	71.4
Slight	4	19
Moderate	2	9.5

Table 15 Preoperative radiografic assessment

3.4.2.2 Postoperative radiographic evaluation

	Immediate postoperative		2 months FU		6 months FU		12 months FU		24 months FU	
Variable	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Acetabular component migration	**20**		**17**		**14**		**9**		**5**	
Absent	19	95	17	100	14	100	9	100	5	100
Present	1	5	0	0	0	0	0	0	0	0

Table 16 Postoperative assessment of acetabular radiographic migration

		Zone 1		Zone 2		Zone 3	
Immediate postoperative	**Radiolucent lines**	**n**	**%**	**n**	**%**	**n**	**%**
	None	16	80	15	75	19	95
	<1 mm	0	0	0	0	0	0
	≥1 to <2 mm	0	0	2	10	0	0
	≥ 2 to < 3 mm	0	0	0	0	0	0
	≥3 to <4 mm	0	0	1	5	0	0
	≥ 4 mm	4	20	2	10	1	5
2 months FU	**Radiolucent lines**	**n**	**%**	**n**	**%**	**n**	**%**
	None	11	65	14	82	16	94
	<1 mm	0	0	0	0	1	6
	≥1 to <2 mm	0	0	2	12	0	0
	≥ 2 to < 3 mm	0	0	0	0	0	0
	≥3 to <4 mm	2	12	0	0	0	0
	≥ 4 mm	4	24	1	6	0	0
6 months FU	**Radiolucent lines**	**n**	**%**	**n**	**%**	**n**	**%**
	None	14	100	9	64	13	93
	<1 mm	0	0	0	0	0	0
	≥1 to <2 mm	0	0	3	21	0	0
	≥2 to <3 mm	0	0	1	7	1	7
	≥3 to <4 mm	0	0	0	0	0	0
	≥ 4 mm	0	0	1	7	0	0
1 year FU	**Radiolucent lines**	**n**	**%**	**n**	**%**	**n**	**%**
	None	8	89	7	78	9	100
	<1 mm	0	0	0	0	0	0

2 years FU	≥1 to <2 mm	1	11	1	11	0	0
	≥2 to <3 mm	0	0	0	0	0	0
	≥3 to <4 mm	0	0	0	0	0	0
	≥ 4 mm	0	0	1	11	0	0
	Radiolucent lines	**n**	**%**	**n**	**%**	**n**	**%**
	None	5	100	4	80	4	80
	<1 mm	0	0	0	0	0	0
	≥1 to <2 mm	0	0	0	0	1	20
	≥2 to <3 mm	0	0	1	20	0	0
	≥3 to <4 mm	0	0	0	0	0	0
	≥ 4 mm	0	0	0	0	0	0

Table 17 Postoperative assessment of radiolucent lines on the acetabular cup

		Zone 1		Zone 2		Zone 3	
Immediate postoperative	**Osteolysis acetabular component**	**n**	**%**	**n**	**%**	**n**	**%**
	None	18	90	18	90	19	95
	1 mm	0	0	0	0	0	0
	2 mm	0	0	1	5	0	0
	> 2mm	2	10	1	5	0	0
2 months FU	**Osteolysis acetabular component**	**n**	**%**	**n**	**%**	**n**	**%**
	None	13	76	16	94	17	100
	1 mm	0	0	0	0	0	0
	2 mm	0	0	0	0	0	0
	> 2mm	4	24	1	6	0	0
6 months FU	**Osteolysis acetabular component**	**n**	**%**	**n**	**%**	**n**	**%**
	None	13	93	11	79	13	93
	1 mm	0	0	0	0	0	0
	2 mm	1	7	2	14	0	0
	> 2mm	0	0	1	7	1	7
1 year FU	**Osteolysis acetabular component**	**n**	**%**	**n**	**%**	**n**	**%**
	None	8	89	8	89	9	100
	1 mm	1	11	1	11	0	0
	2 mm	0	0	0	0	0	0
	> 2mm	0	0	0	0	0	0
2 years FU	**Osteolysis acetabular component**	**n**	**%**	**n**	**%**	**n**	**%**
	None	5	100	5	100	5	100
	1 mm	0	0	0	0	0	0
	2 mm	0	0	0	0	0	0
	> 2mm	0	0	0	0	0	0

Table 18 Postoperative assessment of osteolysis on the acetabular cup

	Immediate postoperative		2 months FU		6 months FU		1 year FU		2 years FU	
Variable	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Presence of Distal Femoral Component Migration/Subsidence	**20**		**17**		**14**		**9**		**5**	
Absent (<5 mm)	20	100	17	100	14	100	9	100	5	100
Present (>5 mm)	0	0	0	0	0	0	0	0	0	0
Presence of any Periprosthetic Fracture	**20**		**17**		**14**		**9**		**5**	
Absent	17	85	17	100	14	100	9	100	5	100
Present	3	15	0	0	0	0	0	0	0	0
Type of periprosthetic fractur	**3**		-		-		-		-	
Type A	2	66,7								
Type B1	1	33,3								
Dislocation	**20**		**17**		**14**		**9**		**5**	
Absent	20	100	17	100	14	100	9	100	5	100
Loosening	**20**		**17**		**14**		**9**		**5**	
Absent	20	100	17	100	14	100	9	100	5	100
Bone remodellingCortical Hypertrophy	**20**		**17**		**14**		**9**		**5**	
Absent	20	100	17	100	13	92.9	9	100	5	100
Present	0	0	0	0	1*	7.1	0	0	0	0
Bone remodelingStress Shielding	**20**		**17**		**13**		**9**		**5**	
Absent	20	100	17	100	13	100	9	100	5	100
Present	0	0	0	0	0	0	0	0	0	0

*New bone appear in the zone 2 of acetabulum

Table 19 Postoperative radiographic assessment (presence of distant femoral component migration/subsidence, presence of periprosthetic fractures, dislocation, loosening, bone remodeling cortical hypertrophy/stress shielding).

	Immediate postoperative		2 months FU		6 months FU		1 year FU		2 years FU	
Variable	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Heterotopic Ossification	**20**		**17**		**14**		**9**		**5**	
Grade 0	18	90	12	70.6	9	64.3	6	66.7	2	40
Grade 1	2	10	5	29.4	5	35.7	2	22.2	2	40
Grade 2	0	0	0	0	0	0	1	11.1	1	20
Infection	**20**		**17**		**14**		**9**		**5**	
Absent	20	100	17	100	14	100	9	100	5	100
Presence of Hardware Failure	**20**		**17**		**14**		**9**		**5**	
Absent	20	100	0	0	14	100	9	100	5	100
Presence of cysts	**20**		**17**		**14**		**9**		**5**	
Absent	20	100	17	100	14	100	9	100	5	100
Presence of osteophytes	**20**		**16**		**14**		**9**		**5**	
Absent	20	100	16	100	14	100	9	100	5	100

Presence of Sclerosis Calcifications	20		17		14		9		5	
Absent	20	100	17	100	13	92.9	9	100	5	100
Present	0	0	0	0	1	7.1	0	0	0	0

Table 20 Postoperative radiographic assessment (heterotopic ossification, infection, presence of hardware failure, cysts, osteophytes, sclerosis/calcifications).

3.5 Safety analysis

3.5.1 Adverse events reporting

Adverse events	n	%	Seriousness type	n	%
Total adverse events	8		Death	0	0
Serious	6	75	Life-threatening	0	0
			Hospitalization or prolongation of hospitalization	4	66.7
			Permanent impairment	0	0
			Medical or surgical intervention required to prevent any of the above	2	33.3
Not serious	2	25			
Severity	**n**	**%**	**Outcome of the event**	**n**	**%**
Mild	1	12.5	Recovered	5	62.5
Moderate	4	50	Ongoing	3	37.5
Severe	3	37.5			
Causality: relationship to study medical device	**n**	**%**	**Causality: relationship to study procedure**	**n**	**%**
Not Related	7	87.5	Not Related	5	62.5
Possible	0	0	Possible	1	12.5
Probable	1	12.5	Probable	1	12.5
Causal relationship (related)	0	0	Causal relationship (related)	1	12.5

Table 21 Adverse events occurred (seriousness, severity, causal relationship with study medical device and study procedure, outcome of the event).

Pt ID	Adverse Event (diagnosis, if known, or signs/ symptoms)	Event narrative	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?	Outcome of the event	Is the patient still in the study?
101 - 1	Surgery of the controlateral side.	Total hip replacement of rigt hip.			Moderate	Not Related	Not Related	N/A	None		No	Recovered	Yes
101 - 5	Intraoperative fracture of femur shaft	The femur shaft was weakened beacuse of previous use of metal loop;	The femur shaft was weakened beacuse of previous use of metal loop; 25 years ago THA of both hips, 2011- revision of right hipEcofit;	On the first control visit 22 Nov 2021 patient is walking with 2 crutches;	Severe	Not Related	Not Related	N/A	Other intraoperative reduction and fixation of the fracture		No	Recovered	Yes
101 - 9	Cup loosening	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.	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	Recovered	Withdrawn
101 - 10	Dyspnoea, fluid collection in lungs	Chronic heart failure exacerbation	Chronic heart failure	Good	Moderate	Not Related	Not Related	N/A	Pharmacological	Farmacological treatment: Furosemid 40mg 2xday from 14.01.2022 to 18.01.2022. With this treatment we got an improvement.	No	Recovered	Yes
101 - 13	Intraoperative fracture of great trochanter	During the reduction of endoprotsthesis Intraoperatively, it came to fracture of great trochanter . Without dispacement. It was fixed with two Dall- Miles loops.	-	Rehabilitation.	Mild	Not Related	Probable	Anticipated	Not pharmacological	Fracture was fixed with two Dall- Miles loops.	No	Recovered	Yes
101 - 14	Dislocation of left hip	at night, when standing up of bed she felt pain	Suspected cause is initial migration of the cup.	Reoperation is planned.	Severe	Not Related	Possible	Anticipated	Not pharmacological	13.06.2022- reposition of the hip;	No	Ongoing	Withdrawn
101 - 17	Periprosthetic fracture- fracture of right pubis bone	A stress fracture was diagnosed, with possible loosening of the endoprosthesis of the operated hip.	There is a possibility that the connection of screws with the acetabulum is stiff enough to cause a fracture of the pubis bone.	Under the observation.	Moderate	Probable	Causal relationship (related)	Unanticipated	Not pharmacological	Diagnostics of periprosthetic fracture- computed tomography	No	Ongoing	Yes
101 - 24	Intraoperatively, when rotating the femur fracture of greater trochanter was observed	Femur was weakened after removal of Proxima stem.		The fracture was intraoperatively reducted and fixated with 120mm Synthes plate.	Moderate	Not Related	Not Related	N/A	Other intraoperatively fixation of fracture		No	Ongoing	Yes

Table 22 Detailed description of adverse events occurred.

3.5.2 Device deficiency

No device deficiencies were recorded so far.

3.5.3 Device survivorship

As described in Table 22 of the Adverse Events sections, two subjects underwent revision surgery of Delta Revision cup and were thus withdrawn from the study. The serious adverse events that led to a revision surgery occurred to patient 101-9 and 101-14, 2 weeks and 6 weeks after surgery, respectively.

Kaplan-Meier survival analysis has not been performed since this is an intermediate report and the entire observed sample has not fully completed the observational period, yet. To achieve a more accurate survival estimation, this analysis will be carried on at the end of the study.

4.0 SUMMARY AND OUTLOOK

Preliminary results suggest that the treatment with Delta Revision cup results in an improvement of clinical outcomes from preoperative to 2 year-follow-up. This can be observed both for HHS and OHS. No relevant radiographic issues have been identified from the radiographic analysis. Only 2 cases of revision have been recorded so far.

Intermediate Report Approval Page

This intermediate report has been read and approved.

Name and Surname	Signature	Date