

Adverse Event v2 08/03/2025 00:00:00

Initial Report Date

21-Jul-2025

Report type

FollowUp

Report Date

21-Jul-2025

Event Onset

08-Mar-2025

Date of Study Team Aware

10-Mar-2025

Time team became aware (24 hr clock)

10-Mar-2025

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 Bialecki

Name of the medical device involved

N/A

Components involved

N/A

Patient 30

ID number of study subject

101 - 30

Age

56

Gender

Female

Attribution within the clinical investigation

TreatmentGroup

Adverse Event (diagnosis, if known, or signs/symptoms)

Dislocation with cemented constrained liner loosening

Event narrative

After 4 weeks during walking patient felt sever hip pain, in control X-ray ita was dislocation with liner loosening

Admission date (dd-mmm-yyyy)

08-Mar-2025

Discharge date (dd-mmm-yyyy)

03-Apr-2025

Is Serious Event

True

Classification of the adverse event

InterventionRequired

Outcome of the event

Recovered

Relevant concomitant drugs and date of administration

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Detail all possible and suspected causes including relevant medical history

Muscle deficiency due to spinal fracture in the history.

Current clinical status

With hip plaster for 6 weeks, walking with walker, after that plaster removal and she is walking with crutches

Severity

Moderate

Causality: relationship to study medical device

NotRelated

Causality: relationship to study procedure

NotRelated

Expectedness

(the assessment of expectedness must be based on the information contained in the approved Investigator Brochure and/or Analysis Report and/or Protocol)

Unanticipated

Action taken

Other

Was the device permanently removed?

No

Detailed treatment

17.03.2025 liner removal, metal spacer angled 20 degree with dual mobility liner

Relevant medical history

None

Patient 30

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