

# Patient 30

## 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

# Patient 30

## Relevant concomitant drugs and date of administration

## 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