Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2.1

European Union Medical Devices Vigilance System

Section 1: Administrative information

1.1 Corresponding competent authority

a Name of receiving national competent authority (NCA)

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident

unknown

d Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a Date of submission: 2024-03-01 (e.g. 2012-10-23)

b Date of incident (e.g. 2012-10-23): 2022-07-27 to 2022-07-27

c Manufacturer awareness date: 2022-10-12 (e.g. 2012-10-23)

d Type of report

- ○ Initial
- ○ Follow up
- ○ Combined initial and final
- ◉ Final (Reportable incident)
- ○ Final (Non-reportable incident)

e In case of initial and follow-up reports, please indicate the expected date of the next report

(e.g. 2012-10-23)

f Classification of incident

- ○ Serious public health threat
- ○ Death
- ○ Unanticipated serious deterioration in state of health
- ◉ All other reportable incidents

1.3 Submitter information

1.3.1 Submitter of the report

a

◉ Manufacturer ○ Authorised representative ○ Other, please specify

b Manufacturer's reference number for this incident

279/22

c	If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted - NCA's local reference number - EUDAMED's reference number - Manufacturer's reference number		
d	If this incident is covered under an FSCA, please provide the relevant numbers: - NCA's local FSCA reference number - EUDAMED's FSCA reference number - Manufacturer's FSCA reference number		
e	Periodic Summary Report (PSR) ID		
f	If the incident occurred within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation		
1.3.2	**Manufacturer information**		
a	Manufacturer organisation name Limacorporate S.p.A.		
b	Single registration number		
c	Contact's first name Federica	d	Contact's last name Malvaso
e	Email medicalcomplaints@limacorporate.com	f	Phone +39 0432945511
g	Country IT - Italy		
h	Street via Nazionale	i	Street number 52
j	Address complement	k	PO Box
l	City name Villanova di San Daniele - Udine	m	Postal code 33038
1.3.3	**Authorised representative information**		
a	Authorised representative organisation name		
b	Single Registration Number		
c	Contact's first name	d	Contact's last name
e	Email	f	Phone
g	Country		

h	Street	**i**	Street number
j	Address complement	**k**	PO Box
l	City name	**m**	Postal code

1.3.4	**Submitter's details if not also manufacturer or authorised representative**

a	Registered commercial name of company Limacorporate S.p.A.		
b	Contact's first name Federica	**c**	Contact's last name Malvaso
d	Email medicalcomplaints@limacorporate.com	**e**	Phone +39 0432945511
f	Country IT - Italy		
g	Street via Nazionale	**h**	Street number 52
i	Address complement	**j**	PO Box
k	City name Villanova di San Daniele - Udine	**l**	Postal code 33038

Section 2: Medical device information

2.1 Unique Device Identification (UDI)

a	UDI device identifier/Eudamed ID: 08033390010351	b	UDI production identifier: Unknown
c	Basic UDI-DI/Eudamed-DI: Unknown	d	Unit of use UDI-DI:

2.2 Categorisation of device

a Medical device terminology

○ EMDN ◉ GMDN ○ UMDNS(ECRI) ○ GIVD/EDMS ○ Other, please specify:

b Medical device nomenclature code: 60516

2.3 Description of device and commercial information

a Medical device name (brand/trade /proprietary or common name)

DELTA-REVISION ACET.CUP Ø50MM

b Nomenclature text/Description of the device and its intended use

REVISION SURGERY UNCEMENTED ACETABULAR CUPS

c	Model: 5533.21.050	d	Catalogue/reference number:
e	Serial number:	f	Lot/batch number: 1908345
g	Software version:	h	Firmware version:
i	Device manufacturing date (e.g. 2012-10-23): 2019-07-22	j	Device expiry date (e.g. 2012-10-23): 2024-07-31
k	Date when device was implanted (e.g. 2012-10-23): 2022-04-26 to 2022-04-26	l	Date when device was explanted (e.g. 2012-10-23): 2022-07-27 to 2022-07-27

m If precise implant/explant dates are unknown, provide the duration of implantation

Number of years: Number of months: Number of days:

n	Implant facility:	o	Explant facility:

p

	Notified body (NB) ID number(s) (if applicable)	Notified body (NB) certificate number(s) of device (if applicable)
1	0123	G7 18 02 75731 056
2		

q Please indicate the date of one of the following:

○ First declaration of conformity
○ The device first CE marked
○ First placed on the market
○ First put into service
○ If software, date first made available

Year: Month:

2.4 Risk class of device when placed on market

a

◯ This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD

b

MDD/AIMDD

- ◯ active implant
- ◉ class III
- ◯ class IIb
- ◯ class IIa
- ◯ class I
- ◯ class Is
- ◯ class Im
- ◯ class Ism
- ◯ custom-made

IVDD

- ◯ IVD Annex II List A
- ◯ IVD Annex II List B
- ◯ IVD devices for self-testing
- ◯ IVD general

c

MDR

- ◯ class III
- ◯ class IIb
- ◯ class IIa
- ◯ class I

Type (Multiple choice)

- ☐ implantable
- ☐ active device
- ☐ intended to administer and/or remove a medicinal product
- ☐ sterile conditions
- ☐ measuring function
- ☐ reusable surgical instruments
- ☐ software
- ☐ systems
- ☐ procedure packs
- ☐ custom-made
- ☐ non-medical purpose

IVDR

- ◯ class D
- ◯ class C
- ◯ class B
- ◯ class A

Type (Multiple choice)

- ☐ self-testing
- ☐ near-patient testing
- ☐ professional testing
- ☐ companion diagnostic
- ☐ reagent
- ☐ software
- ☐ instrument
- ☐ sterile conditions

2.5 Market distribution of device (region/country)

(according to the best knowledge of the manufacturer)

a

☐ All EEA, Switzerland and Turkey

☒ AT	☐ BE	☐ BG	☐ CH	☒ CY	☐ CZ	☒ DE	☐ DK	☐ EE	☒ ES	☐ FI	☒ FR	☒ GB
☒ GR	☒ HR	☐ HU	☐ IE	☐ IS	☒ IT	☐ LI	☐ LT	☐ LU	☐ LV	☐ MT	☐ NL	☐ NO
☒ PL	☐ PT	☐ RO	☐ SE	☐ SI	☐ SK	☒ TR						

Others: BOSNIA AND HERZEGOVINA BRAZIL EGYPT JORDAN L

2.6 Use of accessories, associated devices or other devices

a

Relevant accessories used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

b

Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

3.1 Nature of incident

a Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

Left hip revision surgery due to dislocation of the femoral head (FEM. MODULAR HEAD - M Ø32MM, product code 5010.42.322, lot n. 2183496, ster. 2100324) from its position, performed on 27th July 2022. According to the available information, the patient felt pain when standing up of bed.
The previous surgery took place on 26th April 2022 and was a revision surgery of competitor's implants.
The complaint source reported that the suspected cause is an initial migration of the acetabular cup (DELTA-REVISION ACET.CUP Ø50MM, product code 5533.21.050, lot n.1908345, ster.1900270).
Patient is female, 40 years old, BMI: 27.3, sedentary.

3.2 Medical device problem information

a IMDRF Medical device problem codes (Annex A)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code: A01	Code: A051201	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Number of patients involved: 1

c What is the current location of the device?

- ○ Healthcare facility/carer
- ○ Patient/user
- ○ In transit to manufacturer
- ○ Manufacturer
- ○ Distributor
- ○ Discarded
- ○ Remains implanted
- ◉ Unknown
- ○ Other:

d Operator of device at the time of the incident

- ○ Healthcare professional
- ○ Patient/lay user
- ○ Other, please describe

e Usage of device (as intended)

- ◉ Initial use
- ○ Reuse of a reusable medical device
- ○ Problem noted prior use
- ○ Reuse of a single use medical device
- ○ Re-serviced/refurbished/fully refurbished
- ○ Other:

f Remedial actions taken by healthcare facility, patient or user subsequent to the incident

Revision surgery

3.3 Patient information

a IMDRF 'Health Effect' terms and codes (Annex E, F)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Age of patient at the time of the incident
years | months | days

c Gender ○ Female ○ Male ○ Unknown ○ Not applicable

d Body weight (kg)

e List any of the patient's prior health condition or medication that may be relevant to this incident

3.4 Initial reporter (can be healthcare professional of facility, patient, lay user)

a Role of initial reporter
◉ Healthcare professional ○ Patient ○ Lay user ○ Other, please specify

b Name of healthcare facility where incident occurred
Samodzielny Publiczny Szpital Kliniczny Konarskiego Otwock

c Healthcare facility report number (if applicable)

d	Contact's first name	**e**	Contact's last name
f	Email	**g**	Phone
h	Country: PL - Poland		
i	Street	**j**	Street number
k	Address complement	**l**	PO Box
m	City name	**n**	Postal code

Section 4: Manufacturer analysis

4.1 Manufacturer's preliminary comments

a	For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer's investigation
b	Initial actions (corrective and/or preventive) implemented by the manufacturer
c	What further investigations do you intend in view of reaching final conclusions?

4.2 Cause investigation and conclusion

a	**For Final (Reportable incident):** Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

The Device History Records of the involved lot numbers were checked with the following results:
- No pre-existing anomaly on the 100 FEM. MODULAR HEADS - M Ø32MM, product code 5010.42.322, lot n. 2183496, ster. 2100324 was detected,
- No pre-existing anomaly on the 6 DELTA-REVISION ACET.CUPS Ø50MM, product code 5533.21.050, lot n.1908345, ster.1900270 was detected.
This is the first and only complaint registered on these lot numbers (2183496, 1908345).

The available x-rays images were analyzed by a medical consultant, with the following result:
"Both X-rays are dated 4th June 2022, at 15.32. At least on x-ray #1 definitive loosening of the cup is evident. On both xrays the cup definitely is placed in a wrong position, much too vertical with the hook outside the position it is supposed to be. The augment is not at the correct position. Additional Dislocation such is not surprising. As there is no previous xray I cannot comment, whether the cup has been misplaced from the beginning (what I would suspect) or it dislocated during mobilization. Probably a combination of both. Anyway revision is required, with correcting the obvious failures."

The medical expert also noted that the two x-rays are both dated 4th June 2022, but show two different hips, one with wings, another one without and the stems appear also different in their position. Both the x-rays showed however a wrong positioning of the cups.

No further clarifications were available about the x-rays/x-rays dates provided by the complaint source.

To complete the analysis, previous x-rays were also requested to the complaint source. X-rays taken after the previous surgery were received and shared with the medical consultant. He commented:
"The additional x-rays, dated 27th April, seem to be the ones performed immediately after the revision of the competitors implant, as evidenced by the visible drainage. On those x-rays it is clearly visible, that the cup has been placed in a wrong position from the very beginning, with the hook completely off the correct position. There are some wings visible, but obviously partially removed. The Cup is much to vertical and such it is not surprising that dislocation occurred as visualized on the x-ray dated 4th June 2022. This malposition of the cup has been the reason for the next revision on July27."

The involved devices were not available to be returned to LimaCorporate for analysis, therefore no specific analysis could be performed on them.

Based on the available information and investigation performed, we can state that:
- No pre-existing anomalies were detected by the check of the Device History Records, thus the components had been manufactured up to specifications and in line with the relevant checks and tests,
- The analysis of the x-rays taken before the revision surgery, confirmed that the acetabular cup appears loose and in a suboptimal position. The analyses of the x-rays taken after the previous surgery suggest that the acetabular cup was in fact implanted in a suboptimal position.

In conclusion, based on the analyses performed, the cause of the revision surgery reported does not seem to be product-related and surgical factors might have contributed.

PMS Data
Based on LimaCorporate PMS data, we estimate a revision rate of the Delta Revision acetabular cups (family codes 5533.21.xxx) of about 0.16%. None of these complaints was classified as product related.

b	**For Final (Non-reportable incident):** Fill out rationale for why this is considered not reportable
c	Is root cause confirmed? (•) Yes ( ) No
d	Has the risk assessment been reviewed? (•) Yes ( ) No If 'No', rationale for no review required:
	If the risk assessment has been reviewed, is it still adequate? ( ) Yes ( ) No Results of the assessment:
the risk is already included in the relevant risk management file the risk is acceptable according to Limacorporate risk evaluation criteria	

e IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

Coding with IMDRF terms is a mandatory requirement.	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code B14	Code B15	Code B17	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation findings (Annex C)	Code C07	Code C19	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation conclusion (Annex D)	Code D10	Code D15	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

f IMDRF Component codes (Annex G)

Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Component' codes (Annex G)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

g Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)

(For a FSCA, fill in the FSCA form)

No corrective action needed following this complaint. LimaCorporate will continue monitoring the market to promptly detect any further similar event.

h Time schedule for the implementation of the identified actions

i Final comments from the manufacturer on cause investigation and conclusion

4.3 Similar incidents (for Final (Reportable incident))

4.3.1 Use of IMDRF terms and codes for identifying similar incidents

a Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes
Tick-mark which code or combination of codes were used for identifying similar incidents.

	Choice 1
IMDRF code relating to most relevant 'Medical device problem' (Annex A)	☒
IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')	☐

☐ Other – enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used

4.3.2 Use of in-house terms/codes for identifying similar incidents (only for transition period)

a If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.

	Choice 1	
Code/term for most relevant medical device problem	Code	
	Term	
Code/term for most relevant root cause evaluation	Code	
	Term	

☐ Other – enter description of what similar incidents are based on and the rationale why the above codes were not used

4.3.3 Number of similar incidents and devices on the market

a Indicate on which basis similar incidents were identified regarding the device or device variant:

○ Model ○ Software ○ Lot/Batch ○ Product platform ◉ Other variant

Details of the selection made above

Delta Revision acetabular cups (family codes 5533.21.xxx)

b Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate):

- ○ Devices placed on the market or put into service
- ◉ Units distributed within each time period
- ○ Number of tests performed
- ○ Number of episodes of use (for reusable devices)
- ○ Active installed base
- ○ Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
- ○ Number of devices implanted
- ○ Other -describe

c Enter the number of similar incidents and devices on the market for the indicated time periods

You must use yearly time periods unless:

A: a different time period has been specified by the European vigilance Working Group

B: the device has not been on the European market for more than three years

	Time period (N) Year to date = incident year (e.g. 2012-10-23)		Time period (N-1) calendar year one year before incident (e.g. 2012-10-23)		Time period (N-2) calendar year two years before incident (e.g. 2012-10-23)		Time period (N-3) calendar year three years before incident (e.g. 2012-10-23)	
Start date	2022-01-01		2021-01-01		2020-01-01		2019-01-01	
End date	2022-12-31		2021-12-31		2020-12-31		2019-12-31	
	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market
Country of incident	2	15						
EEA + CH + TR	2	19						
World	2	29						

d Comments on how similar incidents and associated number of devices on the market were determined

The number of incidents is the number of post operative complaints registered by LimaCorporate within the indicated timeframes, concerning revision surgeries of Delta Revision acetabular cups (family codes 5533.21.xxx) due to loosening.
The number of devices on the market is the number of Delta Revision cups sold within the indicated timeframes.
When considering the number of post-operative incidents in comparison to the quantities on the market per each timeframe, it should be taken into account that the complaints notified within each time period might involve devices sold in the previous years as well.

Section 5: General comments

Coded summary of report (will be auto populated from previous selections)

Medical device name

DELTA-REVISION ACET.CUP Ø50MM

Basic UDI-DI	Unknown		
UDI device identifier	08033390010351	UDI production identifier	Unknown

IMDRF adverse event reporting terms and codes

IMDRF=International Medical Device Regulators Forum. Coding with IMDRF terms is a mandatory requirement.

IMDRF clinical signs, symptoms, conditions codes								
IMDRF health impact codes								
IMDRF Medical device problem codes	A01	A051201						
IMDRF Component codes								
IMDRF Cause investigation: Type of investigation	B14	B15	B17					
IMDRF Cause investigation: Investigation findings.	C07	C19						
IMDRF Cause investigation: Investigation conclusion.	D10	D15						

Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

Before signing and submitting

Check the form | Save as PDF

Date

Signature/Digital Signature

federica.malvaso@limacorporate.com Firmato digitalmente da federica.malvaso@limacorporate.com Data: 2024.03.01 16:43:28 +01'00'

Send as XML file — Submit XML by Email

Send as PDF file — Submit PDF by Email

3.1 a - Provide a comprehensive description of the incident

Left hip revision surgery due to dislocation of the femoral head (FEM. MODULAR HEAD - M Ø32MM, product code 5010.42.322, lot n. 2183496, ster. 2100324) from its position, performed on 27th July 2022. According to the available information, the patient felt pain when standing up of bed.
The previous surgery took place on 26th April 2022 and was a revision surgery of competitor's implants.
The complaint source reported that the suspected cause is an initial migration of the acetabular cup (DELTA-REVISION ACET.CUP Ø50MM, product code 5533.21.050, lot n.1908345, ster.1900270).
Patient is female, 40 years old, BMI: 27.3, sedentary.

4.2 a - Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

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In conclusion, based on the analyses performed, the cause of the revision surgery reported does not seem to be product-related and surgical factors might have contributed.

PMS Data
Based on LimaCorporate PMS data, we estimate a revision rate of the Delta Revision acetabular cups (family codes 5533.21.xxx) of about 0.16%. None of these complaints was classified as product related.

4.2 h - Time schedule for the implementation of the identified actions

No corrective action needed following this complaint. LimaCorporate will continue monitoring the market to promptly detect any further similar event.

4.3.3 d - Comments on how similar incidents and associated number of devices on the market were determined

The number of incidents is the number of post operative complaints registered by LimaCorporate within the indicated timeframes, concerning revision surgeries of Delta Revision acetabular cups (family codes 5533.21.xxx) due to loosening.
The number of devices on the market is the number of Delta Revision cups sold within the indicated timeframes.
When considering the number of post-operative incidents in comparison to the quantities on the market per each timeframe, it

should be taken into account that the complaints notified within each time period might involve devices sold in the previous years as well.