B|BRAUN
SHARING EXPERTISE

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Вих. № 3045
від 19.12.2023р.

У Державну службу
з лікарських засобів та контролю
за наркотиками

Ми, компанія ТОВ «Б. Браун Медікал Україна», яка уповноважена представляти інтереси компанії «Б. Браун Мельзунген АГ», Німеччина в Україні, висловлюємо Вам свою повагу та щодо медичного виробу Easypump II LT номер за каталогом 4540014, серії 22B18GEA71 повідомляємо наступне:

Стосовно даного медичного виробу компанією 12.06.2023 р. було отримано скаргу на підтікання помпи. Зі слів медичного персоналу: «Онкологічний хворий проходив хіміотерапію з використанням помпи Easypump II LT номер за каталогом 4540014, серії 22B18GEA71. В помпу введено препарат (фторурацил – 3600 мг (72 мл) + натрію хлорид 0,9% – 388 мл) та встановлено пацієнту, після чого він повертається додому до закінчення інфузії. По поверненню в клініку пацієнт поскаржився на підтікання лікарського засобу.

Компанією було проінформовано про даний випадок 06.12.2023р та відразу ж розпочато розгляд скарги. Виробником надано первинний звіт, його копію надаємо у вкладці.

В разі отримання доповнень чи додаткової інформації від виробника нами буде подано оновлення. Пацієнт почуває себе добре та продовжує лікування.

З повагою,

Фазівець з якості, Уповноважена особа з якості,
ризиків, управління скаргами
ТОВ «Б.Браун Медікал Україна» Денис А.В.

Директор
ТОВ «Б.Браун Медікал Україна» Шаповалов А.Б.

м2 Держлікслужба
№19390/0/08-23 від 25.12.2023
001.3

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)
Ukraine MoH

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident
N/A

d Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a Date of submission: 2023-12-15 (e.g. 2012-10-23)

b Date of incident (e.g. 2012-10-23): 2023-11-20 to 2023-11-20

c Manufacturer awareness date: 2023-12-06 (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
2024-02-08 (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: Distributor

b Manufacturer's reference number for this incident
400633046

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 B. Braun Melsungen AG		
b	Single registration number		
c	Contact's first name Stephan	d	Contact's last name Krause
e	Email stephan.krause@bbraun.com	f	Phone +49 5661-71-1339
g	Country DE - Germany		
h	Street Carl-Braun-Strasse	i	Street number 1
j	Address complement	k	PO Box
l	City name Melsungen	m	Postal code 34212
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 B.Braun Medical Ukraine		
b	Contact's first name Olha	c	Contact's last name Cherneha
d	Email olga.chernega@bbraun.com	e	Phone +380674016602
f	Country UA - Ukraine		
g	Street Boulevard Vaclav Havel 6 "Z"	h	Street number
i	Address complement	j	PO Box
k	City name Kyiv	l	Postal code 03124

Section 2: Medical device information

2.1 Unique Device Identification (UDI)

a	UDI device identifier/Eudamed ID: Unknown	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

2.3 Description of device and commercial information

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

Easypump® II LT

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

Elastomeric Infusion Pumps

c	Model	d	Catalogue/reference number: 4540014
e	Serial number	f	Lot/batch number: 22B18GEA71
g	Software version	h	Firmware version
i	Device manufacturing date (e.g. 2012-10-23)	j	Device expiry date (e.g. 2012-10-23)
k	Date when device was implanted (e.g. 2012-10-23) to	l	Date when device was explanted (e.g. 2012-10-23) to

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		
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	IVDD
○ active implant	○ IVD Annex II List A
○ class III	○ IVD Annex II List B
◉ class IIb	○ IVD devices for self-testing
○ class IIa	○ IVD general
○ class I	
○ class Is	
○ class Im	
○ class Ism	
○ custom-made	

c

MDR	Type (Multiple choice)	IVDR	Type (Multiple choice)
○ class III	☐ implantable	○ class D	☐ self-testing
○ class IIb	☐ active device	○ class C	☐ near-patient testing
○ class IIa	☐ intended to administer and/or remove a medicinal product	○ class B	☐ professional testing
○ class I	☐ sterile conditions	○ class A	☐ companion diagnostic
	☐ measuring function		☐ reagent
	☐ reusable surgical instruments		☐ software
	☐ software		☐ instrument
	☐ systems		☐ sterile conditions
	☐ procedure packs		
	☐ custom-made		
	☐ non-medical purpose		

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:

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)

Description of event: "Chemo Leakage."

"An oncological patient is undergoing chemotherapy treatment. The drug(fluorouracil - 3600 mg (72 ml) + sodium chloride 0.9% - 388 ml) was introduced into the pump and administered to the patient. The patient returns home before the end of the infusion. The patient's complaint about the pump leaking."

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 A050401	Code	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

c What is the current location of the device?

- ○ Healthcare facility/carer
- ○ Distributor
- ○ Patient/user
- ○ Discarded
- ○ In transit to manufacturer
- ○ Remains implanted
- ○ Manufacturer
- ◉ 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 single use medical device
- ○ Reuse of a reusable medical device
- ○ Re-serviced/refurbished/fully refurbished
- ○ Problem noted prior use
- ○ Other:

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

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 E2403	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code F26	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
LISOD - Isreal Oncology Hospital

c Healthcare facility report number (if applicable)

d	Contact's first name: Svitlana Matviychuk	e	Contact's last name: +380503827215
f	Email	g	Phone
h	Country		
i	Street: st. A. Malyshko	j	Street number: 27
k	Address complement	l	PO Box
m	City name: Kiev region, p. Plyuty	n	Postal code: 08720

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

The complaint is under evaluation.
A follow-up report will be provided after the examination results are available.

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

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:

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	Code	Code	Code	Code	Code	Code	Code

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

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

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

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	2023-01-01		2022-01-01		2021-01-01		2020-01-01	
End date								
	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								
EEA + CH + TR								
World								

d

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

Section 5: General comments

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

Medical device name

Easypump® II LT

Basic UDI-DI	Unknown		
UDI device identifier	Unknown	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	E2403							
IMDRF health impact codes	F26							
IMDRF Medical device problem codes	A050401							
IMDRF Component codes								
IMDRF Cause investigation: Type of investigation								
IMDRF Cause investigation: Investigation findings.								
IMDRF Cause investigation: Investigation conclusion.								

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

Sabine Rothhämel-Korbach Digital unterschrieben von Sabine Rothhämel-Korbach Datum: 2023.12.15 10:02:49 +01'00'

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