B|BRAUN
SHARING EXPERTISE

ТОВ «Б. БРАУН МЕДІКАЛ УКРАЇНА»

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Вих. № 1048
Від 29.06.2021

Державна служба України з лікарських засобів та контролю за наркотиками

Шановні колеги!

Компанія **ТОВ «Б. Браун Медікал Україна»,** яка є Уповноваженим представником в Україні виробника **Б.Браун Медікал АГ, Швейцарія** повідомляємо наступне:

Компанією було отримано повідомлення від виробника щодо передбачуваних побічних реакцій на медичний виріб: Пронтосан, розчин для іригації ран, (клас ризику – III) в Швейцарії.

Продукт	Пронтосан, розчин для іригації ран
Номер серії:	невідомо
Опис	У пацієнта була рана глибиною 1 см (розміром із головку шпильки), яку зрошували розчином для зрошення ран пронтосаном. Згідно з заявою пацієнта, рану промили 40 мл Prontosan за допомогою гудзикової канюлі. Згодом пацієнт страждав від печіння, екстремального відчуття тиску, невеликого набряку, сильного почервоніння на передпліччі, набряку кисті, а також болю. Його рука була на третину більша за звичайну. Через набряк була потрібна операція на руці. Для попередження можливого некрозу тканин був встановлений дренаж. При зрошенні ран та порожнин порожнини слід стежити за тим, щоб розчин не вводився або не вводився в тканину під тиском, а також щоб гарантували дренаж постійно. Якщо на зрошувальний канал застосовується тиск, і розчин не можна стікати, можуть спостерігатися такі побічні ефекти, як набряки. Крім того, 40 мл - це занадто багато для маленької ранки. Тому помилка у використанні є найбільш вірогідною першопричиною набряку та наслідком хірургічного втручання. Однак остаточного твердження від медичного працівника щодо помилки у використанні немає.
Дата фіксації	11.06.2021

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Вищезазначені реакції є передбачуваними і зазначені в інструкції з використання медичного виробу.

Звіти щодо дослідження цих повідомлень виробником надаємо.

З повагою,

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

Уповноважена особа з якості
ТОВ «Б.Браун Медікал Україна» Денис А.В.

Виконавець: Денис А.В.
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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)

BfArM Bundesinstitut für Arzneimittel und Medizinprodukte

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident

d Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a Date of submission: 2021-06-25 (e.g. 2012-10-23)

b Date of incident (e.g. 2012-10-23): 2021-06-02 to 2021-06-09

c Manufacturer awareness date: 2021-06-11 (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

CC 400517262

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 Medical AG			
b	Single registration number			
c	Contact's first name Seraphina	d	Contact's last name Weibel	
e	Email seraphina.weibel@bbraun.com	f	Phone +41 58 258 52 60	
g	Country CH - Switzerland			
h	Street Seesatz	i	Street number 17	
j	Address complement	k	PO Box	
l	City name Sempach	m	Postal code 6204	
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 AG		
b	Contact's first name Seraphina	c	Contact's last name Weibel
d	Email seraphina.weibel@bbraun.com	e	Phone +41 58 258 52 60
f	Country CH - Switzerland		
g	Street Seesatz	h	Street number 17
i	Address complement	j	PO Box
k	City name Sempach	l	Postal code 6204

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)

Prontosan

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

Prontosan Wound Irrigation Solution

c	Model	d	Catalogue/reference number
e	Serial number	f	Lot/batch number
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	0344	2113812CE01
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: AR, CL, CO, PE, MX, PY, ZA, EC, MY, MT, SV, NA, LU, M

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)

A patient had a 1cm deep wound (the size of a pinhead), which was irrigated with Prontosan Wound Irrigation Solution. According to patient's statement the wound was flushed with 40ml Prontosan with a button cannula. Afterwards, the patient suffered from burning sensation, extreme feeling of pressure, small edema, extreme redness on the forearm, swelling of the hand as well as pain. His hand was a third larger than normal. Because of the edema, surgery was needed on the hand. A drain was placed to prevent possible tissue necrosis.

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: A2303	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: 1

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

Because of the edema, surgical intervention was necessary for the hand to prevent possible tissue necrosis. Therefore, a drain was placed.

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: E2338	Code: E2326	Code: E2325	Code:	Code:	Code:
IMDRF 'Health impact' codes (Annex F)	Code: F1901	Code: F23	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

c Healthcare facility report number (if applicable)

d	Contact's first name	**e**	Contact's last name
f	Email	**g**	Phone

h Country
DE - Germany

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

When irrigating wounds and wound cavities, it has to be ensured, that the solution is not introduced or injected into the tissue under pressure as well as that drainage is guaranteed at all times. If pressure is applied to the irrigation channel and the solution is not allowed to drain, the reported adverse effects such as edema may occur. Furthermore, 40ml is too much for the small wound. Therefore, an use error is the most probable root cause for the edema and the resulted surgical intervention. However, there is no final statement available from the healthcare professional regarding the use error.

b Initial actions (corrective and/or preventive) implemented by the manufacturer

There are no corrective and preventive actions impelmented. Wound irrigating is regarded as standard procedure. The instruction for use states that the product is not for infusion or injection. When applying too much pressure during wound irrigating and no drainage is guaranteed, edemas may occur because solution is not allowed to drain correctly.

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

This report has been identified as B. Braun Medical AG internal report number CC 400517262.

The instructions for use of the product have been checked and the following side effects are listed:
"In very rare cases, there may be a mild burning sensation after application of Prontosan, but this usually dissipates after a few minutes. Prontosan can cause allergic reactions such as itching (urticatia) and rashes (exanthema). In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported."..."General safety instructions: For external use only. Do not use for infusion or injection. Do not swallow."

According to the description of the application of the Prontosan Wound Irrigation Solution by the healthcare professional, it is assumed that too much pressure was applied during wound irrigation. Therefore, B. Braun Medical AG assumes a use error resulting in surgical intervention to prevent tissue necrosis. However, no statement from the healthcare professional was received to confirm this hypothesis.
The product quantities sold in 2020 for Prontosan Solution were over 4.7 million. So far, this is the first complaint regarding use error due to too much pressure during wound irrigation. Hence, no negative trend can be observed.
This is an isolated case (not a repeated complaint).

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:

Risk-Analysis Document has been checked:
RA-400403-505 Version 15
Nr. 5 Incorrect application of product: Rinsing volume or pressure too low to remove wound coating
Nr. 7 Intravenous application of the product LC: Infusion or injection: Clear indication of application area on label and in

instructions for use, product used by qualified personel. Nr. 8 Biological Safety contains Local skin irritations or allergic reactions Nr. 9 Wrong application of the product: Every bottle is deliverd with an instruction for use. No update of the Risk Analysis is necessary.

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: B11	Code: B12	Code: B13	Code: B17	Code	Code	Code	Code

IMDRF Cause investigation: Investigation findings (Annex C)	Code: C13	Code: C19	Code	Code	Code	Code

IMDRF Cause investigation: Investigation conclusion (Annex D)	Code: D1101	Code: D1102	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 sample is available. Therefore, no analytical testing is possible.
Correct application is cleary stated in the IfU. Since there is no trend, no further actions are initated at the moment.

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	2021-01-01		2020-01-01		2019-01-01		2018-01-01	
End date	2021-05-30		2020-12-31		2019-12-31		2018-12-31	
	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	1	232,292	0	610,442	0	589,800	0	562,720
EEA + CH + TR	0	1,012,896	0	2,426,249	0	2,324,051	0	1,091,168
World	0	1,966,483	0	4,715,767	0	4,877,970	0	4,421,593

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

Prontosan

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	E2338	E2326	E2325					
IMDRF health impact codes	F1901	F23						
IMDRF Medical device problem codes	A2303							
IMDRF Component codes								
IMDRF Cause investigation: Type of investigation	B11	B12	B13	B17				
IMDRF Cause investigation: Investigation findings.	C13	C19						
IMDRF Cause investigation: Investigation conclusion.	D1101	D1102						

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

schesech — Digital unterschrieben von schesech Datum: 2021.06.25 15:06:24 +02'00'

Send as XML file — Submit XML by Email

Send as PDF file — Submit PDF by Email

4.1 a - For initial and follow-up reports: preliminary results and conclusions of manufacturer's investigation

When irrigating wounds and wound cavities, it has to be ensured, that the solution is not introduced or injected into the tissue under pressure as well as that drainage is guaranteed at all times. If pressure is applied to the irrigation channel and the solution is not allowed to drain, the reported adverse effects such as edema may occur. Furthermore, 40ml is too much for the small wound. Therefore, an use error is the most probable root cause for the edema and the resulted surgical intervention. However, there is no final statement available from the healthcare professional regarding the use error.

4.1 b - Initial actions (corrective and/or preventive) implemented by the manufacturer

There are no corrective and preventive actions impelmented. Wound irrigating is regarded as standard procedure. The instruction for use states that the product is not for infusion or injection. When applying too much pressure during wound irrigating and no drainage is guaranteed, edemas may occur because solution is not allowed to drain correctly.

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

This report has been identified as B. Braun Medical AG internal report number CC 400517262.

The instructions for use of the product have been checked and the following side effects are listed:
"In very rare cases, there may be a mild burning sensation after application of Prontosan, but this usually dissipates after a few minutes. Prontosan can cause allergic reactions such as itching (urticatia) and rashes (exanthema). In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported."..."General safety instructions: For external use only. Do not use for infusion or injection. Do not swallow."

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The product quantities sold in 2020 for Prontosan Solution were over 4.7 million. So far, this is the first complaint regarding use error due to too much pressure during wound irrigation. Hence, no negative trend can be observed.
This is an isolated case (not a repeated complaint).

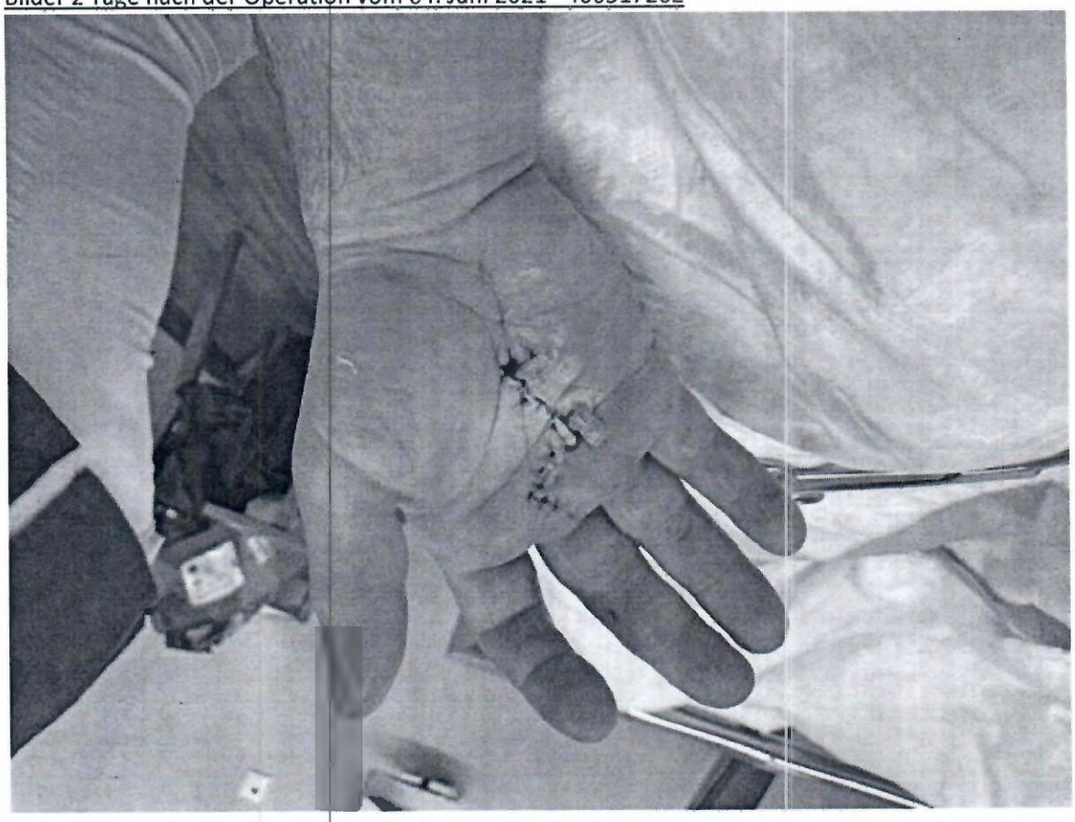
4.2 d - Results of the assessment:

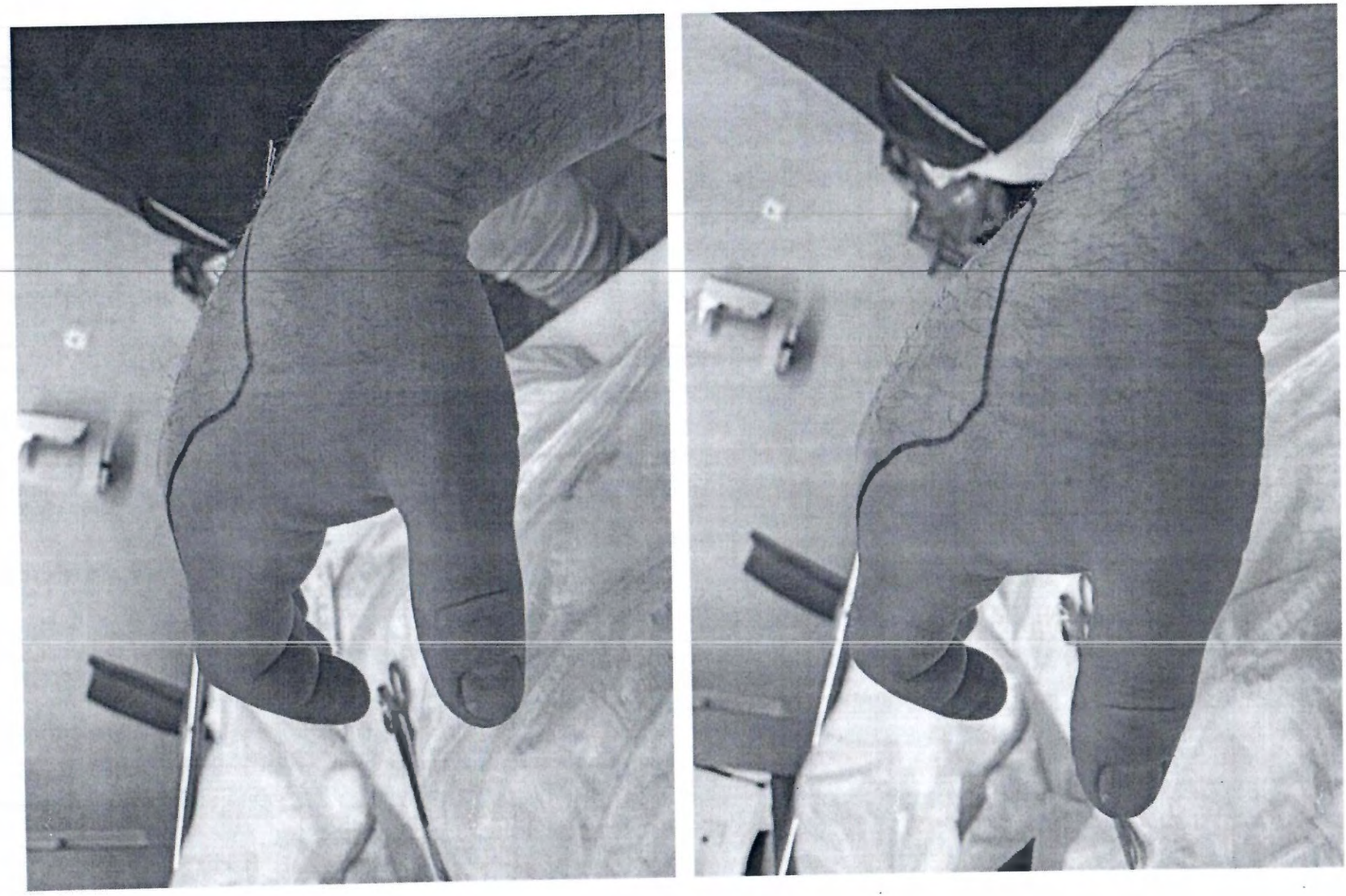
Risk-Analysis Document has been checked:
RA-400403-505 Version 15
Nr. 5 Incorrect application of product: Rinsing volume or pressure too low to remove wound coating
Nr. 7 Intravenous application of the product LC: Infusion or injection: Clear indication of application area on label and in instructions for use, product used by qualified personel.
Nr. 8 Biological Safety contains Local skin irritations or allergic reactions
Nr. 9 Wrong application of the product: Every bottle is deliverd with an instruction for use.
No update of the Risk Analysis is necessary.

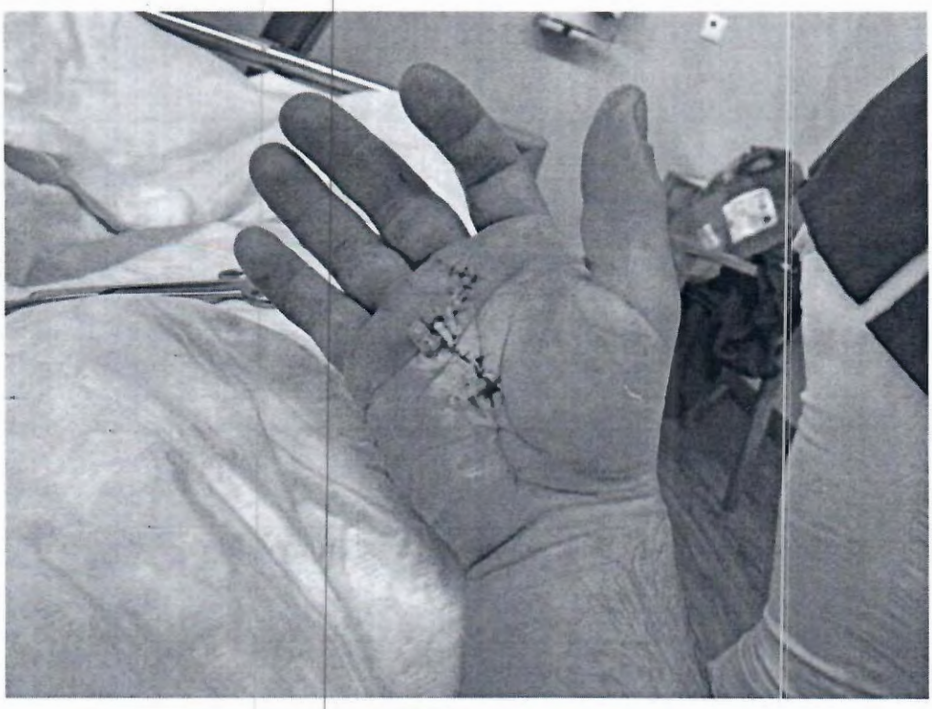
4.2 g - Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)

No sample is available. Therefore, no analytical testing is possible.
Correct application is cleary stated in the IfU. Since there is no trend, no further actions are initated at the moment.

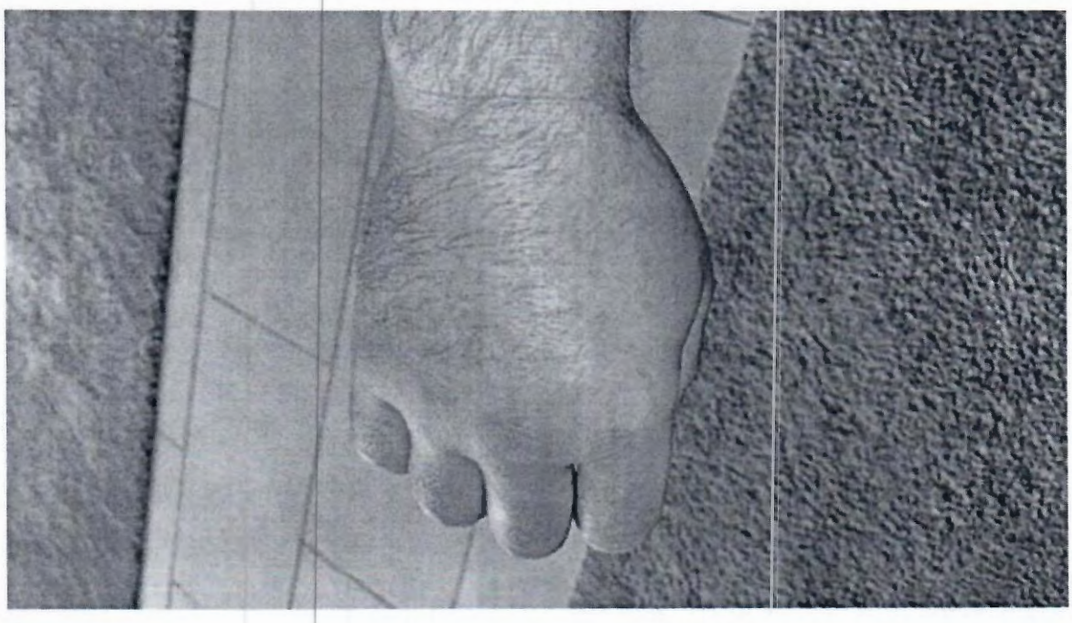
Bilder 2 Tage nach der Operation vom 04. Juni 2021 - 400517262

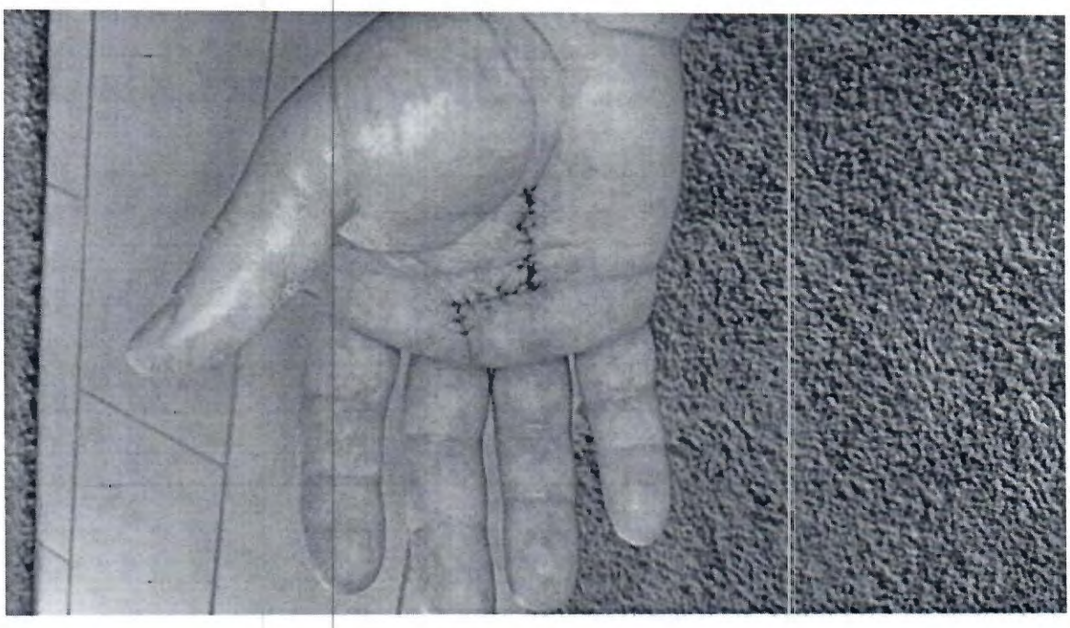






Bilder 8 Tage nach der Operation vom 10. Juni 2021 - 400517262





Bilder nach dem Injizieren und vor der Operation - 400517262