

Hydrophilic Gel for endoprothetics of
human soft tissues
Incident and Malfunction Report for Medical Device

*Designed for Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)*

How to Submit the
Report:

Once information about
incident became known,
completed forms should
be faxed or emailed
within 48 hours to:

EMAIL:
safety@losdeline.com

FAX:
+420228882910

or

mailed to:

BIOTRH s.r.o.
Department of Clinical
Trials and Vigilance

Lyčkovo náměstí
508/7
Karlín, 186 00
Prague
Czech Republic

NOTE:

Submission of this report does not, in itself, represent a conclusion or constitute an admission by the manufacturer and / or authorized Representative / Healthcare Professional 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) or medical personnel caused or contributed to the alleged death or deterioration in the state of the health of any person.

CONTACT DETAILS OF REPORT SUBMITTER:

Organization Name: _____

Contact Person Name: _____

Address: _____

Country: _____

Postal code: _____

City: _____

Phone: _____

Fax: _____

Email: _____

Type of report:

Initial	<input type="checkbox"/>	Does the incident represent a serious public health threat? <input type="checkbox"/> Yes <input type="checkbox"/> No
Follow-UP	<input type="checkbox"/>	
Initial and Follow-UP	<input type="checkbox"/>	

Please put "X" at appropriate section of table

Classification of Incident

Death	<input type="checkbox"/>
Unanticipated Serious Deterioration in State of Health	<input type="checkbox"/>
All other reportable incidents	<input type="checkbox"/>
DEVICE MALFUNCTION <i>(please go to page # 5)</i>	<input type="checkbox"/>

Please put "X" at appropriate section of table

STATUS OF ENTITY \ PERSON WHICH SUBMIT REPORT

Authorised Representative within EEA and Switzerland and Turkey	<input type="checkbox"/>
Physician or hospital administrative person	<input type="checkbox"/>
Local country dealer \ partner	<input type="checkbox"/>
Member of country regulatory agency	<input type="checkbox"/>
Other person	<input type="checkbox"/>

Please put "X" at appropriate section of table

Healthcare Facility Information:

Facility Name: _____

Contact Person Name: _____

Address: _____

Country: _____

Postal code: _____

City: _____

Phone: _____

Fax: _____

Email _____

Details of Physician Who Used Device:

Facility Name
(if other from above): _____

First Name: _____

Second Name: _____

Address: _____

Country: _____

Postal code: _____

City: _____

Phone: _____

Fax: _____

Email: _____

Incident Details:

Date the incident occurred: □□/□□/20□□ (DD/MM/YYYY)	Date when reporting person was aware about incident: □□/□□/20□□ (DD/MM/YYYY)	Date when physician was aware about incident: □□/□□/20□□ (DD/MM/YYYY)	LOT# □□□□□
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Patient Details:

Gender M <input type="checkbox"/> F <input type="checkbox"/>	Age □□	Weight □□ Kg	
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Injections Details:

Date administration: Day / Month / Year	Site (s) of injection: (write name of body part)	Volume of injection(s): ml	Box(s)#
□□/□□/20□□			□□□□□
□□/□□/20□□			□□□□□
□□/□□/20□□			□□□□□

Medical Device Information ↗:

Type of Devices Used:	Comments
Los Deline 100 g <input type="checkbox"/>	_____
Los Deline 25 g <input type="checkbox"/>	_____
Device LOT# □□□□□□□□	_____
Date of Manufacture □□/□□/20□□	_____
Date of Expiration □□/□□/20□□	_____
(If several type of devices used please write comments)	_____

Medical narrative of Incident including outcome:

NOTE: If Device Malfunction Occurred You Must Complete Next Page

Was Any Device Malfunction Occurred?: Yes No

Remedial action taken relevant to the care of the patient

Device Malfunction Report Form

Malfunction Description

When was malfunction of device occurred relevant to injection?

- Before
- After
- Same Time

Was malfunction of device posed any risk to patient?

- Yes
- No

Was device used according to the instruction?

- Yes
- No

If "No", Please Write Comments

Comments on Device Improper Use

NOTE: If there is no free place, write on additional pages