INCIDENT ANALYSIS FORM

Please note that this document will be used in the further administrative process of investigating product safety. Please note that all items in this checklist must be filled. If you do not have the information, tick the box "No".

Name entity/person reporting of the incident

_____

Signature _____ **Date** _____

Address _____

_____

Email _____

1. Data on the primary injection procedure	
Serial number(s) and/or lot/batch number(s) ☐ YES	NO ☐
Person who conducted a primary injection Name _____ Qualification _____ Clinic _____ Has the doctor been trained to work with the product? Date & Place of Training /	NO ☐

_____	
Date of the procedure ☐ YES	NO ☐
2. Patient Selection	
Data of preoperative (before primary implantation) examination of the patient – medical history ☐ YES (provide a copy as an attachment to this document)	NO ☐
Test results (according to Instruction for Use, before contouring procedure a patient has to be examined: blood analysis, AIDS, Hbs Ag, Anti HVC, RW test, ECG, coagulogram, urine test, ultrasound in a case of breast procedure) ☐ YES (provide a copy as an attachment to this document)	NO ☐
Signed Informed consent (according to Instruction for Use, doctor should inform the patient about expected results, possible adverse events/ effects or complications before procedure. A written informed consent for body treatment procedure should be obtained before procedure.) ☐ YES (provide a copy as an attachment to this document)	NO ☐

Photo documentation: before/after (according to Instruction for Use, the detailed photographic documentation must be the part of medical documentation in accordance with local legislation.) ☐ YES (provide a copy as an attachment to this document)	NO ☐
Diagnosis, Indications for use of the product in a particular patient ☐ YES _____ _____ _____ _____ _____	NO ☐
3. Procedure of injection	
Accreditation of the clinic ☐ YES _____ _____ _____ _____ _____ _____	NO ☐
Which zone was the product injected ☐ YES _____ _____ _____ _____ _____ _____	NO ☐
Volume injected ☐ YES	NO ☐

What post-treatment recommendations were given to patient ☐ YES _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	NO ☐
Follow up visits data ☐ YES (provide a copy as an attachment to this document)	NO ☐
4. Incident related actions (Primary doctor)	
Date of the first symptoms (complaints) manifestation ☐ YES	NO ☐
Date of contacting the primary doctor after the onset of symptoms ☐ YES	NO ☐
Diagnosis, first aid ☐ YES _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	NO ☐

_____ _____ _____ _____ _____ _____	
What examination was performed ☐ YES _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	NO ☐
Results of the examination (Blood tests, ultrasound, MRI, bacterial culture tests, histopathological examination) ☐ YES (provide a copy as an attachment to this document)	NO ☐
Diagnosis after examination ☐ YES _____ _____ _____ _____ _____ _____	NO ☐

Information on the treatment actions taken by primary doctor (If the operation was performed - provide a copy of the results of bacteriological and histological examination.) ☐ YES _____	NO ☐
Whether the primary doctor involved other specialists to consult ☐ YES (provide a copy as an attachment to this document)	NO ☐
5. Incident related actions (Third party doctor)	
Date of referral to a third party doctor (clinic) ☐ YES	NO ☐

The reason why the patient went to a third party doctor (clinic) ☐ YES _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	NO ☐
What examination was performed ☐ YES _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	NO ☐
Results of the examination (Blood tests, ultrasound, MRI, bacterial culture tests, histopathological examination) ☐ YES (provide a copy as an attachment to this document)	NO ☐
Diagnosis after examination ☐ YES _____ _____ _____ _____ _____ _____	NO ☐

Information on the treatment actions taken by third party doctor (If the operation was performed - provide a copy of the results of bacteriological and histological examination.) ☐ YES _____	NO ☐