



INCIDENT REPORT FORM  
&  
MALFUNCTION REPORT FORM

# INCIDENT REPORT FORM

Once knowledge of incident or malfunction is known this report should be faxed or e-mailed to the local distributor within 48 hours. For malfunction of medical device please go to page 3.

## 1. PATIENT DETAILS

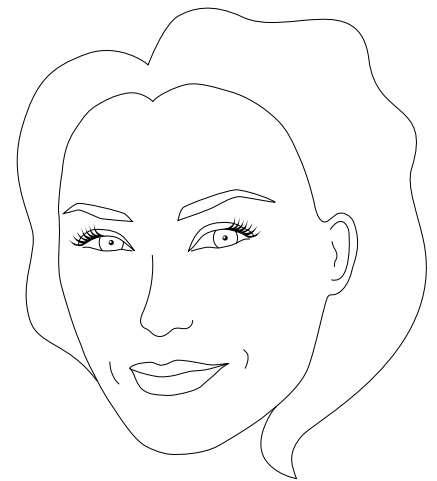
Initials: \_\_\_\_\_ Sex: Female  Male

Date of Birth: \_\_\_\_\_  
(Day/Month/Year)

## 2. PROCEDURE DETAILS

Injections	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>
Date of administration (Day/Month/Year)				
Batch no.				
Volume injected				
<b>Site of injection</b>				
Lip augmentation				
Naso labial folds				
Mento labial folds				
Cheekbones				
Forehead including glabella				
Molar/chin				
Nasal area				
Other, please specify:				
<b>Product</b> (please indicate which has been used)				
Aquamid®				
Aquamid® Reconstruction				

Please also indicate the site of injection on the drawing.



## 3. DETAILS OF COMPLICATIONS

(Please fill in clinical details for the complication)

Description of complication: \_\_\_\_\_  
\_\_\_\_\_

Onset date of complication: \_\_\_\_\_ Number of days after injection: \_\_\_\_\_  
(Day/Month/Year)

Severity: Mild  Moderate  Severe  Very Severe

Antibiotic treatment administered: Yes  No

Other treatment administered: Yes  No

If yes, please give details regarding:

Drug/generic name of product: \_\_\_\_\_

Dosage: \_\_\_\_\_

Duration of treatment: \_\_\_\_\_

Comments: \_\_\_\_\_

Patient's initials: \_\_\_\_\_

## 4. RELEVANT MEDICAL HISTORY

### Prior to injection

- Was the patient under treatment with antibiotics? Yes  No   
 If yes, what product, dosage, indication: \_\_\_\_\_
- Was the patient under treatment with corticosteroids? Yes  No   
 If yes, what product: \_\_\_\_\_
- Had the patient been injected with other fillers? Yes  No   
 If yes, please specify product, amount, site, date of injection: \_\_\_\_\_
- Does the patient have recurrent herpes? Yes  No
- Did the patient have active herpes? Yes  No
- Does the patient have untreated acne? Yes  No
- Did the patient have any active skin disease? Yes  No
- Did the patient undergo surgery or dental work within 3 months prior to injection? Yes  No   
 If yes, please specify: \_\_\_\_\_
- Does the patient suffer from autoimmune disease? Yes  No
- Does the patient suffer from any other diagnosed disease? Yes  No   
 If yes, please specify: \_\_\_\_\_
- Was the patient pregnant or breast-feeding? Yes  No
- Did the patient experience periodical swelling or oedema? Yes  No   
 If yes, please specify: \_\_\_\_\_
- Other, please specify: \_\_\_\_\_

### Post-injection

- Did the patient undergo surgery, dental work or other aesthetic treatment within 6 months after injection? Yes  No   
 If yes, please specify: \_\_\_\_\_
- Is the patient pregnant or breast-feeding? Yes  No
- Does the patient experience periodical swelling or oedema? Yes  No   
 If yes, please specify: \_\_\_\_\_

## 5. DETAILS OF FOLLOW-UP

### Resolution of complication

- Total recovery  (Day/month/year) \_\_\_\_\_ Comments: \_\_\_\_\_
- Partial recovery  (Day/month/year) \_\_\_\_\_ Comments: \_\_\_\_\_
- Is any further medical follow-up required? Yes  No   
 If yes, please specify: \_\_\_\_\_
- Do you need any further medical advice from Contura? Yes  No   
 If yes, please specify: \_\_\_\_\_

## 6. DETAILS OF INJECTING DOCTOR

- Name of Doctor: \_\_\_\_\_
- Clinic: \_\_\_\_\_
- Address of clinic: \_\_\_\_\_  
 \_\_\_\_\_
- Profession (speciality): \_\_\_\_\_
- Telephone number: \_\_\_\_\_ Fax number: \_\_\_\_\_
- E-mail: \_\_\_\_\_
- Date reported: \_\_\_\_\_  
 (Day/month/year)

Please attach any additional relevant information.

Please consult the Aquamid® Complication Management Protocol.

# MALFUNCTION REPORT FORM

To be completed when medical device malfunctions

## 1. THIS MALFUNCTION CONCERNS

Medical device	Lot no.	Device should always be returned to enable root cause analysis	
Aquamid® Hydrogel, 1 mL pre-filled syringe		<input type="checkbox"/> Device enclosed	<input type="checkbox"/> Device sent separately
Aquamid® Reconstruction Hydrogel, 1 mL pre-filled syringe		<input type="checkbox"/> Device enclosed	<input type="checkbox"/> Device sent separately

Malfunction description: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Date of malfunction \_\_\_\_\_ (Day/month/year) Did malfunction happen

Before injection procedure   
 During injection procedure   
 After injection procedure

Was there any risk to patient due to malfunction? No  Yes  If yes, please describe \_\_\_\_\_  
 \_\_\_\_\_

Was the device handled in accordance with Instruction For Use? Yes  No  If no, please describe  
 E.g. was accidentally crushed during handling \_\_\_\_\_  
 \_\_\_\_\_

If an incident occurred due to malfunction, please complete the section for incident in this form, page 1.

## 2. PROCEDURE FOR THE RETURN OF MALFUNCTIONS OF AQUAMID DEVICES

All products that have been used or unpacked must be packed with a biohazard warning before returning in order to reduce possible infection risks. It is important to record the batch number and always send the device including the Syringe Malfunction Report Form. This enables device tracking and production identification. Preferably return syringes in the original blister and carton.

## 3. DETAILS OF INJECTING DOCTOR

Name of Doctor: \_\_\_\_\_  
 Clinic: \_\_\_\_\_  
 Address of clinic: \_\_\_\_\_  
 \_\_\_\_\_  
 Profession (specialty): \_\_\_\_\_  
 Telephone number: \_\_\_\_\_ Fax number: \_\_\_\_\_  
 E-mail: \_\_\_\_\_  
 Date reported: \_\_\_\_\_ (Day/month/year)

Please attach any additional relevant information.