



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

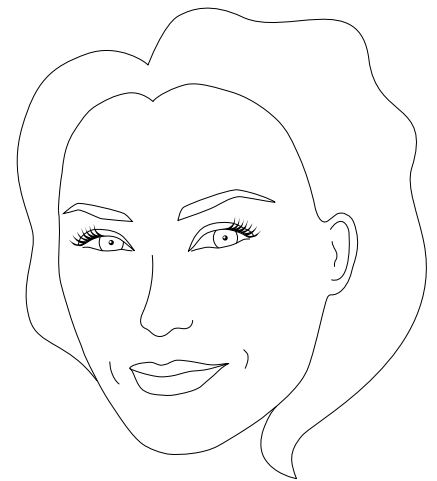
Initials: _____ Sex: Female Male

Date of Birth: _____
(Day/Month/Year)

2. PROCEDURE DETAILS

Injections	1 st	2 nd	3 rd	4 th
Date of administration (Day/Month/Year)				
Batch no.				
Volume injected				
Site of injection				
Lip augmentation				
Naso labial folds				
Mento labial folds				
Cheekbones				
Forehead including glabella				
Molar/chin				
Nasal area				
Other, please specify:				
Product (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 (speciality): _____
 Telephone number: _____ Fax number: _____
 E-mail: _____
 Date reported: _____ (Day/month/year)

Please attach any additional relevant information.