AQUAMID®

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 to the local distributor within 48 hours.
For malfunction of medical device please go to page 3.

1. PATIENT DETAILS

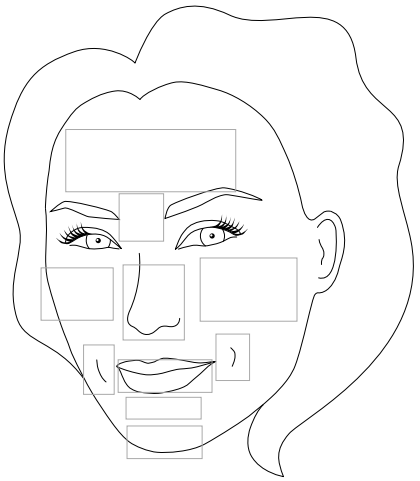
Initials: _____ Sex: Female ☐ Male ☐

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

2. PROCEDURE DETAILS

Injections	1st	2nd	3rd	4th
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:				

Please also indicate the site of injection on the drawing.



Product (please indicate which has been used)

Aquamid®				
Aquamid® Reconstruction				

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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.

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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 prefilled syringe		☐ Device enclosed ☐ Device sent separately
Aquamid® Reconstruction Hydrogel, 1 mL pre-filled syringe		☐ Device enclosed ☐ 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 accidently 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.

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Reset Form

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