Incident- / Malfunction Report

Incident

(for Malfunction Report go to page 3)

All pages should be emailed to the local distributor within 48 hours of knowledge of the incident.

Local contact:	Physician's stamp (name + address)

1. Patient Details

Initials: _____ Sex: Female ☐ Male ☐

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

2. Indication

Urinary Incontinence (UI): ☐ Vesicoureteral Reflux (VUR): ☐

3. Treatment details

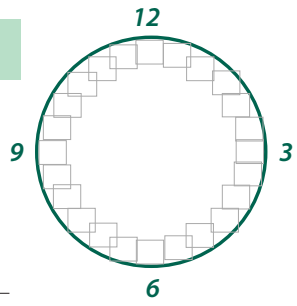
Date of treatment: _____ Lot no.: _____ Total volume injected: _____mL
(Day/Month/Year)

4A. Procedure details for VUR

STING Procedure: ☐ HIT Procedure: ☐ Double-HIT Procedure: ☐

4B. Procedure details for UI

Site of injections (please mark) for UI only:



5. Details of complications

Description of complication: _____

Onset date of complication: _____ Hospitalization required: Yes ☐ No ☐
(Day/Month/Year)

Severity of symptoms: Mild ☐ Moderate ☐ Severe ☐ Serious ☐

Treatment: _____

Antibiotics: Yes ☐ No ☐

Other treatment: Yes ☐ No ☐

If yes, please describe the treatment (drug, (dosage, duration of treatment), surgery, catheter etc.): _____

_____
(Day/Month/Year) *Signature*

Patient's initials: _____

6. Relevant Medical History

Prior to treatment

Did the patient receive pharmacological treatment for urinary incontinence?	Yes ☐	No ☐
Did the patient suffer from Urinary Tract Infection (positive Nephur® stix)?	Yes ☐	No ☐
Did the patient receive treatment for Urinary Tract Infection?	Yes ☐	No ☐
Is the patient known to be allergic or hypersensitive?	Yes ☐	No ☐
Is the patient known to suffer from any connective tissue disease?	Yes ☐	No ☐
Had the patient received previous treatments with radiation in the pelvic floor?	Yes ☐	No ☐
Had the patient undergone previous surgery for the treatment of UI?	Yes ☐	No ☐
Had the patient undergone any previous surgery in the pelvic floor?	Yes ☐	No ☐
If so, please name: _____		
Had the patient non-functional kidney(s)?	Yes ☐	No ☐
Had the patient Ureterocele?	Yes ☐	No ☐
Had the patient Hutch diverticulum?	Yes ☐	No ☐
Had the patient herpes genitalis?	Yes ☐	No ☐
Had the patient urinary refluxing megaureters with distal stenosis?	Yes ☐	No ☐

5. Details of follow-up

Resolution of complication

Total recovery: _____ Comments: _____
(Day/Month/Year)

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: _____

Please attach any additional relevant information.

Details of injecting doctor:

Name of doctor: _____

Clinic: _____

Address of clinic: _____

Profession (speciality): _____

Telephone number: _____

E-mail: _____

Date reported: _____ Signature of doctor: _____
(Day/Month/Year)

Malfunction Report

Treatment of VUR (Vesicoureteral Reflux): ☐ *Treatment of UI* (Urinary Incontinence): ☐

This malfunction concerns

Medical Device	***Lot no. / Serial no.***	***Device should always be returned to enable root cause analysis***
Bulkamid® Hydrogel, 1 mL prefilled syringe		☐ Device enclosed ☐ Device sent separately
Bulkamid® Needle		☐ Device enclosed ☐ Device sent separately
Bulkamid® Rotatable Sheath		☐ Device enclosed ☐ Device sent separately
Whole Bulkamid® Kit		☐ Device enclosed ☐ Device sent separately
Bulkamid® Urethroscope		☐ Device enclosed ☐ Device sent separately

If device is not returned, please clarify why and explain what happened: _____

_____

_____

Malfunction description: _____

_____

_____

_____

Date of malfunction _____ *(Day/Month/Year)*

Did malfunction happen
Before bulking procedure: ☐
During bulking procedure: ☐
After bulking procedure: ☐

Were there any risk to patient due to malfunction? No ☐ Yes ☐ If yes please describe _____

_____

Was the device handled in accordance with instructions for use? (e.g. was accidently dropped on the floor) Yes ☐ No ☐ If no please describe

_____

_____

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

_____ _____

(Day/Month/Year) *Signature*

Procedure for the return of Malfunctions of Bulkamid® Devices

All products that have been used or unpacked in the OR and have not been re-sterilized, must be packed in special yellow bags or boxes for contaminated utensils with biohazard warning before returning in order to indicate possible infection risks. It is important to capture the batch number and always send the device including the Incident - / Malfunction Report Form otherwise it is not possible to find out the cause of the malfunction.

Malfunctions of products from the Bulkamid® Kit, e.g. needles, sheath and syringes must be returned in original kitbox.

Bulkamid® Devices:

BULKAMID® ROTATABLE SHEATH:
The sheath must be packed in material for contaminated products as mentioned above.

BULKAMID® NEEDLE:
The needle must be sent with the protection sheath in place.

BULKAMID® SYRINGE:
The syringe must be sent in original blisterpack.

Bulkamid® Urethroscope:

The optic must be packed and shipped with the protection sheath and preferably in the original shipping box or similar protection. This is to prevent further damage during the transportation. The Incident - / Malfunction Report Form should be included besides the optic. Do not return the metal sterilization container.

Reset form