ARTHROSAMID®

Incident Report Form - In relation to intra-articular injection of Arthrosamid

All pages should be emailed to **complaints@Contura.com and the local distributor** within **24** hours of knowledge of the incident.

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

1. Patient

Year of Birth: _____ Sex: Female ☐ Male ☐

2. Indication

Knee osteoarthritis: Yes ☐ No ☐ Other: _____

3. Treatment details

Date of treatment: : _____ LOT no.: _____ Total volume injected _____ mL

Prophylactic antibiotics: Yes ☐ No ☐

4. Details of complication

Description of complication: _____

_____

Onset date of complication: _____ Hospitalization required: Yes ☐ No ☐

(Day/Month/Year)

Severity of symptoms: Mild ☐ Moderate ☐ Severe ☐

Treatment: _____

Antibiotics: Yes ☐ No ☐

Other treatment: Yes ☐ No ☐

If yes, please describe the treatment (drug, surgery etc.): _____

_____

_____

(Day/Month/Year) *Signature*

5. Relevant Medical History

Prior to treatment

Active skin disease or infection present at or near the injection site?	Yes ☐	No ☐
Joint infected or severely inflamed?	Yes ☐	No ☐
Patient has previously received treatment with a different non-absorbable injectable/implant?	Yes ☐	No ☐
Patient has received a knee alloplasty or has any foreign material in the knee?	Yes ☐	No ☐
Patient has undergone knee arthroscopy within the last 6 months?	Yes ☐	No ☐
Hemophilia patient or patient in uncontrolled anticoagulant treatment?	Yes ☐	No ☐
Patient has been treated with corticosteroids within the last 3 months?	Yes ☐	No ☐
Patient has autoimmune disorders?	Yes ☐	No ☐
Patient has uncontrolled diabetes?	Yes ☐	No ☐
Degradable intra-articular injectable such as hyaluronic acid present?	Yes ☐	No ☐

If yes, how long time since last injection: _____

Other relevant medical history: _____

_____

6. Details of follow-up

Resolution of complication

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

If not, comments: _____

Is any further medical follow-up required? Yes ☐ No ☐

If yes, please specify: _____

Please attach any additional relevant information.

7. Details of injecting physician:

Name of physician: _____

Clinic: _____

Address of clinic: _____

Profession (speciality): _____

Telephone number: _____

E-mail: _____

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

Patient's initials: _____

Malfunction Report

This malfunction concerns

Medical Device	***Lot no. / Serial no.***	***Device should always be returned to enable root cause analysis:***
☐ Arthrosamid® 1 mL ☐ Arthrosamid® 6-Pack, 6x1 mL		☐ 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 injection procedure
☐ During injection procedure
☐ After injection 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 Arthrosamid®

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.