

Document ID	Initials
To be completed by BONESUPPORT.	

Observation Form

1 Instructions

- This form shall be filled in with the known data, as soon as any BONESUPPORT employee, any of its representatives or any medical professional becomes aware of an observation or product feedback on BONESUPPORT's marketed devices.
- Questions shall be directed to complaint@bonesupport.com.
- **After completion of this Observation form, it shall be sent to complaint@bonesupport.com.**

2 Observation Information

Complaint Product feedback

Received by:

Notified date:

Reported by :

User facility Distributor Importer Authority Other

Name:

2.1 Customer

Customer:

Country:

Hospital name:

Hospital address:

Contact person:

Tel:

E-mail:

Fax:

2.2 Product

Article No.:

Name/Description:

Lot No.:

Expiry date:

If Product feedback, continue at section 4 Product Feedback.

3 Observation Details

Date of observation/incident/event:

Observation/incident/event description:

Date of implantation/use:

Patient affected:

Yes No Not known

If NO (patient not affected), continue at section 3.3 Device Observation.

3.1 Patient Data

Patient history, including pre-existing medical conditions, other relevant data, tests/laboratory data (ensure that patient cannot be identified by personal data):

Age:

Weight:

Sex: Female Male

3.2 Patient Observation

Death: Yes (if yes, contact QM within 24 hours) No

Life-threatening: Yes (if yes, contact QM within 24 hours) No

Hospitalization - initial or prolonged: Yes No

Disability or Permanent Damage: Yes No

Description:

Required Intervention to Prevent Permanent Impairment/Damage:

Yes No

Description:

Other serious medical event: Yes No

Description:

Current status of the patient: Fully recovered Still suffering from incident Not known

3.3 Device Observation

Product malfunction:

Yes No

Description:

Damaged packaging:

Yes No

Description:

Incorrect label:

Yes No

Description:

Device incomplete:

Yes No

Component missing:

Device returned to BONESUPPORT AB:

Yes No

When:

3.4 Other relevant information

Other relevant information, e.g. document here the effort when and why full information cannot be obtained:

4 Product Feedback

Product feedback description: