REC0810 REV 9 OBSERVATION FORM

Complaint ID	Initials
To be completed by BONESUPPORT.	

1 Instructions

- This form shall be filled in with the known observation data, as soon as any BONESUPPORT employee or any of its representatives becomes aware of an observation on BONESUPPORT's marketed devices.
- If the issue date is different than the notified date, the notified date shall be noted in "Notified date".
- All observations shall be sent to BONESUPPORT AB within 5 days, see BONESUPPORT's address below.
- All potential safety observations shall be sent to BONESUPPORT AB immediately! (without any delay that could not be justified.)
- Note ! if the answer is YES on any of the following questions the complaint details section below, then it can be considered a safety observation: Section 3, Patient affected, and any question in section 3.2
- Questions shall be directed to the contact persons indicated below under contacts.

BONESUPPORT AB	Customer Service
Scheelevägen 19 | Ideon Science Park SE-223 70 LUND, SWEDEN Phone + 46 46 286 53 70 | Fax + 46 46 286 53 71	Phone + 46 46 286 53 70 e-mail orderbox@bonesupport.com

2 Observation Information

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:

3 Observation Details

Date of observation/incident/event:

Observation description:

Date of implantation/use:

Patient affected:

☐ Yes ☐ No ☐ Not known

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

3.1 Patient Data

Patient history, including pre-existing Medical Conditions, Other relevant data, Tests/Laboratory data:

Date of birth:

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 Signature

(Issue Date / Signature of the preparer)