REPORT
Undesirable event

Please, kindly send the form to the below adress or fax it:

SPINEWAY

7 Allée Moulin Berger, 69130 Ecully - France
Email : **quality@spineway.com**
Fax : **+33-(0) 4 78 38 10 17**

Frame reserved to Spineway

N°

Receipt by

Date

Reporter identification

Name:

First name:

Position/Occupation:

Company:

Address:

Email :

Phone:

Fax :

The Medical Device

Product type (screw, hook, cage, etc):

Reference:

Lot n°:

What is the purpose? (Then, fill the corresponding part)

- A complaint related to requirements specified by Spineway ('defective packaging', etc…)
- A claim (undesirable event related to a product during or after implantation)

The complaint

Description:

Origin of the complaint (surgeon, hospital; join the report) :

The claim

Name of the operative surgeon:

Hospital/ clinic name :

Hospital/ clinic town :

Date of the operation:

Patient's sex:
Male Female

Patient's weight:

Patient's height:

Patient's age:

Explant date
(for implants only)

When did the problem occur?
- At the reception control
- Before surgery
- During surgery
- After surgery

Circumstances / description / pathology / level :

Clinical consequences:

Remedial actions taken:

Other relevant documents (Operating report, X ray ...)

Returned product

Is the product available for inspection?
Yes No
If Yes: send it to Spineway if possible.
Please, indicate if the product has been disinfected before sending.

Medical devices vigilance

Is the event refers to the medical devices vigilance?
Yes No

Is a competent authority informed?
Yes No

Competent authority (name) :

According to french regulation 'loi n°78-17 du 6 janvier 1978' related to named fils, you have access and a rectification right to these datas.