



# COMPLAINT REPORT

Référence : F3- F

Revision :6, May 9th 2019

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## Reporter

Name :

Hospital / Company :

Country :

Address :

Clinical Contact (if relevant) :

Phone :

e-mail :

## Medical Devices

Product Name :

Serial Number :

### Incident Declaration :

Did the incident lead to, or could it have lead to, directly or indirectly, either of the following:

(a) a death of a patient, user or other person,

(b) a temporary or permanent serious deterioration of a patient's, user's or another person's state of health?

If Yes, send this report to Novacor immediately and not later than 2 days after becoming aware of the incident, for the attention of the Regulatory Affairs Manager

Fax : 33(0) 1 41 39 01 99, e-mail : [qualite@novacor.fr](mailto:qualite@novacor.fr)

Yes  No 

Was the product involved?

(Explain the reasons in the incident description below)

Yes  No 

Was the product returned to NOVACOR?

Yes  No 

Was a vigilance notification made to the local competent authority? If yes, please send a copy as soon as possible.

Yes  No 

## Incident Description

Date of the incident :

Place :

Description :

Reporter signature :

Function :

Date :

This section is to be used by Novacor Q. A.

Services  Products  Quality System

Reception date :

Evaluated by:

Reference: RCL-

Corrective Action N°: