ANSM - Agence nationale de sécurité du médicament et des produits de santé	**Form 5**
Clinical investigation involving a medical device or an in vitro diagnostic medical device	
Vigilance report : Initial report	

Articles L. 1123-10 and R. 1123-39 to 1123- 44, R. 1123-48 and R. 1123-54 of the public health code

Suspected unexpected serious adverse effect

Serious adverse event possibly related to the procedure for implementation of the medical device

To be sent

By email *(preferred) to:*	EC.DM-COS@ansm.sante.fr *(in the subject line, type in "VIGILANCE" and the number assigned by the ANSM (French Health Product Safety Agency) during registration of the application for marketing authorization and opinion)*
By mail to:	**Agence nationale de sécurité du médicament et des produits de santé (ANSM)** **Direction des dispositifs médicaux thérapeutiques et des cosmétiques** **Essais cliniques** **143-147 Boulevard Anatole France** **93285 Saint-Denis cedex**
By fax to:	33 01.55.87.37.17 (Send to the attention of ANSM/DMTCOS)

This section for ANSM only

Date received of the report : / /

Registration number: / / /ei

Clinical investigation identification

Clinical investigation registration number from the ANSM:

Code number of the Clinical investigation assigned by the sponsor, version and date:

Full title of the biomedical research:

Code number identifying the Clinical investigation participant:

Patient initials: Surname initial: First name initial:

Gender: F: M: Date of birth: / / and/or Age: years

Medical device used:

Common device name (for example: arterial stent):
Trade name (if CE mark):
Model: Version (including software):
Serial no.: Batch no.:
Reason for which the device was used in this patient:
How the device was used:

Starting date of this device utilization : / /

Termination date of this device utilization : / /
Was there "unblinding"? yes no N/A
If yes, results:

Other treatments:

Concomitant drug therapy and non-drug treatments (dosage, date treatment began, etc.):

Information about the suspicion of serious adverse effects or events:

Complete description including signs and/or symptoms, organ affected, severity, and the criteria that qualifies the effect as serious; if necessary, explain the diagnosis:

Description of the adverse effect or event:

Date of 1st onset / /

End date / / or duration (specify time period):

What were the consequences when the device was suspended and, if applicable, when the device was reintroduced:

Place of occurrence (research centre, hospital, day hospital, home, nursing home, etc.)

Follow-up will be mentioned (information related to recovery and possible after-effects (sequels), additional tests and if necessary, specific treatments required and their results).

Death give the cause:

Any additional information about a possible cause/effect relationship, especially including any information resulting from an eventual autopsy or other post-mortem tests (including the medical examiner report) when they are available:

Important details factors that can help in the evaluation of the case : related pathologies (can have a causal

relationship with the serious adverse event - SAE), Medical and family histories; results obtained through special investigations:

_____

Possible Cause/Effect Relationship

Imputability estimate

- ***by the sponsor:***

- to MD: certain likely possible
not likely

- **to the procedure for implementation of the MD:**
certain: likely: possible: not likely:

- ***by the investigator (only in the case of a discrepancy between the sponsor and investigator):***

- to MD: certain likely possible
not likely

- **to the procedure for implementation of the DM:**
certain: likely: possible: not likely:

Important comments:

Identification of the reporter

- Name of person to be contacted:
- Address:
- Telephone number:

Administrative and sponsor information

Date of report by the sponsor: / /
Origin of the effect/event:
a) biomedical investigation :
b) scientific literature (provide a copy):
c) spontaneous notifications :
d) other health/registry authority:
Date on which the sponsor first became aware of the adverse event:
/ /
Country in which the event occurred:
Sponsor name:
Sponsor address:

Person delegated by the sponsor to submit the report
- Name of the person :
- Address:
- Telephone number:
- Fax number:

Case ID number assigned by the sponsor:

Attach a copy of the Serious Adverse Event (SAE) report form filled out by the investigator.
Attach a copy of the hospital report if available

Date: / / Sponsor signature:

Name: Title :