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| ANSM - Agence nationale de sécurité du médicament et des produits de santé | **Form 6** |
| **Clinical investigation involving a medical device or an in vitro diagnostic medical device.** **Vigilance report : additional information, follow-up data** |
| *Articles L. 1123-10 and R. 1123-39 to 1123- 44, R. 1123-48 and R. 1123-54 of the public health code* |
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| **Date of initial report to the ANSM: //** |
| **Suspected unexpected serious adverse effect**  |
| **Serious adverse event possibly related to the procedure for implementation of the medical device**  |

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| **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)* |
| **Par courrier à :** **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** |
| **Par fax :**  01.55.87.37.17 (Spécifier à l’attention de l’ANSM/DMTCOS) |

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| **This section for ANSM only****Date additional report was received: //****Registration number:  ///ei**  |

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| **Clinical investigation identification** Clinical investigation registration number from the ANSM: Code number of the clinical investigation protocol assigned by the sponsor, version and date: Full title of the clinical investigation :  |

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|  Date of the additional information report : // Code number identifying the investigation participant: Patient Initials : Surname initial: First name initial: Gender: F: M: Birthday: // and/or Age: years Follow-up of the previously reported serious adverse effect/event (the possible initiated treatments and the results will be listed):Additional information obtained since the initial report:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*****Do additional data change the assessment of the effect’s or event’s imputability to the device being studied?* yes**: **no:** ***If yes, explain:*****Comments:**  |

Attach a copy of the Serious Adverse Event (SAE) report form filled out by the investigator.Attach a copy of the hospital report if necessary Date: // Sponsor signature: Name: Quality:   |