SERIOUS ADVERSE EVENT FORM MEDDEV

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| **Report Type:** | ❑ Initial Report  ❑ Follow-up Report n°………………….. |

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| **GENERAL INFORMATION:** | |
| Number of subjects enrolled to date: |  |
| Number of investigational devices used to date: |  |

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| **MEDICAL DEVICE INFORMATION:** | |  | **SUBJECT INFORMATION:** | |
| Device ID number: |  |  | Subject number: |  |
| Date of first use: |  |  | Age of subject on date of onset: |  |
| Investigational arm  (device/ control group/ blinded/ NA): |  |  | Gender: |  |

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| **DESCRIPTION OF SAE:** *(detailed information can be provided in the narrative)* |  |
| Previously reported as :  (if applicable) |  |
| Criterion for considering the AE as serious. | Adverse event that led to any of the following:  ❑ death  ❑ serious deterioration in the health of the subject, that resulted in any of the following:  ❑ a life-threatening illness or injury  ❑ a permanent impairment of a body structure or a body function  ❑ hospitalization or prolongation of patient hospitalization  ❑ in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function  ❑ chronic disease  ❑ foetal distress, foetal death or a congenital physical or mental impairment or birth defect |
| Date of event onset (yyyy-mm-dd) |  |
| Date of study personnel’s awareness of event (yyyy-mm-dd) |  |
| Intensity / Severity | ❑ mild ❑ moderate ❑ severe |
| Actions taken  *(please provide all actions taken, i.e. diagnostic procedures, treatment, referral to other departments,…)* |  |
| Outcome of the event: | ❑ Resolved, date (yyyy-mm-dd): ………..............................................................  ❑ Resolved with sequelae, date (yyyy-mm-dd): ……….......................................  ❑ Ongoing  ❑ Death, date of death (yyyy-mm-dd): ………......................................................  ❑ Unknown, explain ……………………………………………………………... |
| Changed Outcome of the event in case of Follow-up Report: | ❑ Resolved, date (yyyy-mm-dd): ………..............................................................  ❑ Resolved with sequelae, date (yyyy-mm-dd): ……….......................................  ❑ Ongoing  ❑ Death, date of death (yyyy-mm-dd): ………......................................................  ❑ Unknown, explain ……………………………………………………………... |
| Setting (hospital, home, …): |  |

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| **SAE NARRATIVE:**  *Please describe more in detail the serious adverse event including* ***clinical signs/symptoms*** *and* ***clinical impact*** |
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| **RELEVANT LABORATORY AND DIAGNOSTIC TESTS OR PROCEDURES:** | | |
| **Date (yyyy-mm-dd)** | **Test** | **Results (+ normal range if applicable)**  **Please attach report when possible** |
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| **ASSESSMENT OF CAUSALITY BY (PRINCIPAL) INVESTIGATOR:** | | |
| Is SAE related to the device (i.e. investigational device or the comparator)?  *(see CIP for definition)* | ❑ Not related  ❑ Possibly  ❑ Probably  ❑ Causal relationship | |
| Is SAE related to the investigation procedure?  *(see CIP for definition)* | ❑ Not related  ❑ Possibly  ❑ Probably  ❑ Causal relationship  ❑ Not applicable | |
| Is this event related to a device deficiency?\* | ❑ Yes  ❑ No | If yes, explain:  ............................................................ |
| Is this a Reportable Event?  (Reportable Events are at least possibly related to device, comparator or investigation procedure) | ❑ Yes  ❑ No | Note: For Reportable Events, send form **immediately** to HIRUZ CTU for reporting to FAMHP. |

*\*Device deficiency: inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, use error, or inadequacy in the information supplied by the manufacturer.*

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| **REMARKS:** |
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| **SIGNATURES:** | |
| Report completed by:  Print Name:  Signature: | ..............................................................................  .............................................................................. Date (yyyy-mm-dd): ............................ |
| I have reviewed this serious adverse event report and confirm it is complete and accurate.  Signature of Investigator: .............................................................................. Date (yyyy-mm-dd): ............................ | |

*Only for completion by Coordinating Investigator U(Z) Gent*

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| **ASSESSMENT COORDINATING INVESTIGATOR (or delegate):** | |
| Is SAE related to the device (i.e. investigational device or the comparator)?  *(see CIP for definition)* | ❑ Not related  ❑ Possible related  ❑ Probable related  ❑ Causal relationship |
| Is SAE related to the investigation procedure?  *(see CIP for definition)* | ❑ Not related  ❑ Possible related  ❑ Probable related  ❑ Causal relationship  ❑Not applicable |
| Is the SAE unanticipated?  (e.g. not listed in IB, Instructions for Use) | ❑ Yes, unanticipated  ❑ No  Explain and mention source:........................................................... |
| Is this event related to a device deficiency? | ❑ Yes  ❑ No  If yes, explain:........................................................... |

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| **SIGNATURE COORDINATING INVESTIGATOR:** | |
| I agree with the assessment of this serious adverse event report. | |
| Print Name Coordinating Investigator or delegate:  Signature Coordinating Investigator (or delegate):  Date (yyyy-mm-dd) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_ |