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| **MEDDEV 2.7/3 SAE Report Table v2** |
| **EUDAMED - ID:** |   |
| **Title of Clinical Investigation:** |   |
| **CIP Number:** |   |
| **Contact person**(Name, Address, E-Mail, Telephone Number) |   |   |   |   |   |   |   |   |   | **Device type:** |   |
| **MS+NCA Reference Numbers**for all participating Countries: |   | **Reference Member State:** |   |
| **No. of Patientsenrolled to date total**: |   |   | **No. of Patientsenrolled to date** (date of report) **per country**: |   |   |   |   |   | **No. of Invest.Devicesused to date total:** |   |   | **No. of Invest.Devicesused to date per country:** |   |   |
| **Date of Report:** | dd/mm/yyyy |
| **Status: A, M**, **U** | **Date Sponsor received Report of SAE (dd/mm/yyyy)** | **Countrycode** | **Study Center** | **Patient ID Code** | **SAE ID Code** | **Date of Procedure/ First Use (dd/mm/yyyy)** | **Date of Event Onset (dd/mm/yyyy)** | **SAE OR Dev. Def.** | **Description of event** | **action/ treatment/patient outcome** | **Relationshipto Procedure:**not related **OR** unlikely **OR** possible **OR** probable **OR** causal relationship | **Relationship to Investigational Device:**not related **OR** unlikely **OR** possible **OR** probable **OR** causal relationship | **Unanticipated SADE:** Yes **OR** No | **Treatment Arm:** Investigational Device/Control Group/blinded/n.a. | **Event Status:** Resolved/Resolved with Sequelae/Ongoing/Death | **Date of Event Resolution (dd/mm/yyyy)** |
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Link to the current [Medical Devices Sector Directives](https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en)