PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mdb.gov.my
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SERIOUS ADVERSE EVENTS (SAE) FORM	
Status:	Remarks
Date Sponsor Received Report of SAE (dd/mm/yyyy)	
Country Code	
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 Device Defect.	
Description of Event	
Action / Treatment / Patient Outcome	
Relationship to 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 SAE: 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)	

Note 1: Submission of this report does not, in itself, represent a conclusion by the sponsor or the competent authority that the content of this report is complete or that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Note 2: If additional columns are added to this form (for instance to include the opinion of the investigators), please add them next to the existing columns on the right. This form may be subjected to automatic analysis and addition of columns in between may interfere with automatic analysis. Widening of columns can be applied without alteration of the order.

Note 3: Serious Adverse Event = SAE