Appendix 1. Definition of adverse events

ADVERSE EVENT (AE)
Any untoward medical occurrence in a subject.
NOTE this definition does not imply that there is a relationship between the adverse event
and the device under investigation.

SERIOUS ADVERSE EVENT (SAE)
An adverse event that
a) led to a death,
b) led to a serious deterioration in the health of the subject that
   1) resulted in a life-threatening illness or injury,
   2) resulted in a permanent impairment of a body structure or a body function,
   3) required in-patient hospitalization or prolongation of existing hospitalization,
   4) resulted in medical or surgical intervention to prevent permanent impairment to body
      structure or a body function.
c) led to foetal distress, foetal death or a congenital abnormality or birth defect.

ADVERSE DEVICE EFFECT (ADE)
Any untoward and unintended response to a medical device.
NOTE 1 This definition includes any event resulting from insufficiencies or inadequacies in
the instructions for use or the deployment of the device.

SERIOUS ADVERSE DEVICE EFFECT (SADE)
Adverse device effect that has resulted in any of the consequences characteristic of a serious
adverse event or that might have led to any of these consequences if suitable action had not
been taken or intervention had not been made or if circumstances had been less opportune.

UNANTICIPATED SERIOUS ADVERSE DEVICE EFFECTS (USADE)
Any serious adverse device effect which, by its nature, incidence, severity or outcome, has not
been identified in the anticipated AE’s listed in section 8.1.1.

DEVICE DEFICIENCY
Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors and inadequate labelling.

**USE ERROR**
Act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user. Use error includes slips, lapses and mistakes. An unexpected physiological response of the subject does not itself constitute a use error.

**SEVERITY DEFINITIONS**
The following definitions will be used to determine the severity rating for all adverse events:
Mild: awareness of signs or symptoms, that does not interfere with the subject’s usual activity or is transient that resolved without treatment and with no sequelae.
Moderate: a sign or symptom, which interferes with the subject’s usual activity.
Severe: incapacity with inability to do work or perform usual activities.
### Clavien Dindo Classification

<table>
<thead>
<tr>
<th>Grades</th>
<th>Definition</th>
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<tr>
<td>Grade I:</td>
<td>Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. This grade also includes wound infections opened at the bedside. [Allowed therapeutic regimens are: drugs as anti-emetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy.]</td>
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Grade II: Requiring pharmacological treatment with drugs (other than those noted above) including blood transfusions and total parenteral nutrition

Grade III: Requiring surgical, endoscopic or radiological intervention  
Grade III-a: intervention not under general anaesthesia  
Grade III-b: intervention under general anaesthesia

Grade IV: Life-threatening complication (including CNS complications) requiring HDU/ICU management  
Grade IV-a: single organ dysfunction (includes dialysis)  
Grade IV-b: multi organ dysfunction

Grade V: Death of a patient

Suffix 'd': If the patients suffers from a complication at the time of discharge, the suffix “d” (for ‘disability’) is added to the respective grade of complication.

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1 brain haemorrhage, ischaemic stroke, subarachnoid haemorrhage, but excluding transient ischaemic attacks; HDU, high dependency unit; ICU, intensive care unit.