<table>
<thead>
<tr>
<th>Complication</th>
<th>Grade IVb</th>
<th>Grade IVa</th>
<th>Grade IVb</th>
<th>Grade IVa</th>
<th>Grade IVb</th>
<th>Grade IVa</th>
<th>Grade IVb</th>
<th>Grade IVa</th>
</tr>
</thead>
<tbody>
<tr>
<td>New onset of atrial fibrillation/flutter (AF) requiring medical treatment or</td>
<td>Intervention required (e.g. opening of wound, percutaneous drainage)</td>
<td>Intervention required (e.g. opening of wound, percutaneous drainage)</td>
<td>Intervention required (e.g. opening of wound, percutaneous drainage)</td>
<td>Intervention required (e.g. opening of wound, percutaneous drainage)</td>
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<td>Intervention required (e.g. opening of wound, percutaneous drainage)</td>
</tr>
<tr>
<td>cardioversion; does not include recurrence of AF that was present preoperatively</td>
<td>NPO. Requiring nasogastric intubation, and prokinetics (e.g. Maxeran, Gravol)</td>
<td>NPO. Requiring nasogastric intubation, and prokinetics (e.g. Maxeran, Gravol)</td>
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</tr>
<tr>
<td>Symptomatic and requiring drugs and non-invasive ventilation (e.g. BiPAP) for &lt;24 hrs</td>
<td>Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)</td>
<td>Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)</td>
<td>Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)</td>
<td>Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)</td>
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<td>Associated with single organ failure (e.g. CHF, hypotension, syncope, shock)</td>
</tr>
<tr>
<td>Intervention required (e.g. opening of wound, percutaneous drainage) without GA</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
<td>Converting after correction of electrolytes; no other intervention required</td>
</tr>
<tr>
<td>Symptomatic, requiring a cardio-version or a device (e.g., pacemaker)</td>
<td>Loss of integrity or viability of conduit due to ischemia or dehiscence</td>
<td>Loss of integrity or viability of conduit due to ischemia or dehiscence</td>
<td>Loss of integrity or viability of conduit due to ischemia or dehiscence</td>
<td>Loss of integrity or viability of conduit due to ischemia or dehiscence</td>
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<td>Loss of integrity or viability of conduit due to ischemia or dehiscence</td>
<td>Loss of integrity or viability of conduit due to ischemia or dehiscence</td>
</tr>
<tr>
<td>Surgical intervention performed under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
<td>Operative intervention required under general anaesthesia</td>
</tr>
<tr>
<td>Endoscopic, radiological or bedside interventions performed</td>
<td>Venous Thrombosis</td>
<td>Venous Thrombosis</td>
<td>Venous Thrombosis</td>
<td>Venous Thrombosis</td>
<td>Venous Thrombosis</td>
<td>Venous Thrombosis</td>
<td>Venous Thrombosis</td>
<td>Venous Thrombosis</td>
</tr>
<tr>
<td>Transfusion, PPI infusion, or other medical therapy</td>
<td>(Cardiovascular)</td>
<td>(Cardiovascular)</td>
<td>(Cardiovascular)</td>
<td>(Cardiovascular)</td>
<td>(Cardiovascular)</td>
<td>(Cardiovascular)</td>
<td>(Cardiovascular)</td>
<td>(Cardiovascular)</td>
</tr>
<tr>
<td>Requiring percutaneous coronary intervention (PCI)</td>
<td>Concomitant multiorgan complications</td>
<td>Concomitant multiorgan complications</td>
<td>Concomitant multiorgan complications</td>
<td>Concomitant multiorgan complications</td>
<td>Concomitant multiorgan complications</td>
<td>Concomitant multiorgan complications</td>
<td>Concomitant multiorgan complications</td>
<td>Concomitant multiorgan complications</td>
</tr>
<tr>
<td>Non-occlusive, requires no therapy</td>
<td>Requires anti-coagulation</td>
<td>Requires anti-coagulation</td>
<td>Requires anti-coagulation</td>
<td>Requires anti-coagulation</td>
<td>Requires anti-coagulation</td>
<td>Requires anti-coagulation</td>
<td>Requires anti-coagulation</td>
<td>Requires anti-coagulation</td>
</tr>
<tr>
<td>Bleeding that starts in the gastrointestinal tract</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
</tr>
<tr>
<td>Requires anti-diarrhoeal treatment</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
<td>Requires surgical repair</td>
</tr>
<tr>
<td>Ventricular Arrhythmia</td>
<td>Medical therapy added</td>
<td>Medical therapy added</td>
<td>Medical therapy added</td>
<td>Medical therapy added</td>
<td>Medical therapy added</td>
<td>Medical therapy added</td>
<td>Medical therapy added</td>
<td>Medical therapy added</td>
</tr>
<tr>
<td>Confusion/Delirium</td>
<td>Leads to multiple organ failure</td>
<td>Leads to multiple organ failure</td>
<td>Leads to multiple organ failure</td>
<td>Leads to multiple organ failure</td>
<td>Leads to multiple organ failure</td>
<td>Leads to multiple organ failure</td>
<td>Leads to multiple organ failure</td>
<td>Leads to multiple organ failure</td>
</tr>
<tr>
<td>Death</td>
<td>Death</td>
<td>Death</td>
<td>Death</td>
<td>Death</td>
<td>Death</td>
<td>Death</td>
<td>Death</td>
<td>Death</td>
</tr>
</tbody>
</table>

Table 1: AEs harmonized with CATS database
<table>
<thead>
<tr>
<th>Severity Level</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>No complications or co-morbidities.</td>
</tr>
<tr>
<td>Grade II</td>
<td>One major complication or co-morbidities.</td>
</tr>
<tr>
<td>Grade IIIa</td>
<td>One major complication or co-morbidities with life-threatening consequences.</td>
</tr>
<tr>
<td>Grade IIIb</td>
<td>One major complication or co-morbidities with life-threatening consequences, leading to single organ failure.</td>
</tr>
<tr>
<td>Grade IVa</td>
<td>One major complication or co-morbidities with life-threatening consequences, requiring reoperation.</td>
</tr>
<tr>
<td>Grade IVb</td>
<td>Two major complications or co-morbidities with life-threatening consequences.</td>
</tr>
<tr>
<td>Grade V</td>
<td>Three or more major complications or co-morbidities with life-threatening consequences.</td>
</tr>
</tbody>
</table>

**Examples of Major Complications**

- **Acute Respiratory Distress Syndrome (ARDS)**
  - Severe (PaO2/FIO2 ≤100 mmHg)

- **Urological Complications**
  - Urinary Retention
  - Urinary Tract Infection (UTI)

- **Pulmonary Complications**
  - Bronchopleural Fistula
  - Pneumonia
  - Pneumothorax Requiring Chest Tube Insertion

- **Cardiovascular Complications**
  - Multisystem Organ Failure
  - Ventilator > 48 Hours

- **Other Complications**
  - Leukopenia (<4000 WBC/mm³) or Leukocytosis (≥12,000 WBC/mm³)
  - New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements

**Diagnosis and Management**

<table>
<thead>
<tr>
<th>Event</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchopleural Fistula</td>
<td>Bronchoscopy performed to confirm diagnosis and manage as appropriate.</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Evaluation of infectious agents and supportive care as needed.</td>
</tr>
<tr>
<td>Pneumothorax Requiring Chest Tube Insertion</td>
<td>Thoracentesis or chest tube insertion performed as needed.</td>
</tr>
<tr>
<td>Other Pulmonary Event</td>
<td>Evaluation and management as indicated.</td>
</tr>
<tr>
<td>Life-threatening organ failure present</td>
<td>Physician institutes appropriate antimicrobial therapy.</td>
</tr>
</tbody>
</table>

**Urinary Tract Infections**

- **Bacterial Infection**
  - A urine culture of > 100,000 colonies/ml urine with no more than two species of organisms. Signs and symptoms suggestive of an infection. Dipstick test positive for leukocyte esterase and/or nitrate.
  - Two urine cultures with repeated isolation of the same uropathogen with >100,000 colonies/ml urine in non-foul smelling urine.

**Renal Function**

- **Acute Renal Failure**
  - Occurrences: Progressive Renal Insufficiency
  - **Severity Levels**
    - Type I: Transient injury requiring no therapy; Dietary modification allowed.
    - Type II: Transient injury requiring dialysis; Physician institutes appropriate therapy.
    - Type III: Chronic injury; Physician institutes appropriate therapy.

**Additional Events**

- **Subcutaneous Emphysema**
  - Occurrences: Requiring medical therapy only.

**Additional Medical Interventions**

- **Dialysis**
  - Occurrences: Requiring dialysis.

**Complications Requiring Intervention**

- **Recurrent Laryngeal Nerve Injury**
  - Occurrences: Requiring surgical, radiological, endoscopic intervention, or multi-therapy intervention (does not require general anaesthesia).

**Life-threatening Conditions**

- **Septic Shock**
  - Occurrences: Life-threatening; debilitating; organ failure present.

**Severe Complications**

- **Seizure**
  - Occurrences: Life-threatening; debilitating; organ failure present.

- **Death**
  - Occurrences: Life-threatening; debilitating; organ failure present.

**Recovery and Discharge**

- **Urinary Retention**
  - Occurrences: Requiring reinsertion of urinary catheter, delaying discharge or discharge with urinary catheter.

**Surgical Events**

- **Unexpected Return to the OR**
  - Occurrences: Indicate whether the patient had an unplanned invasive procedure after surgery.

**Miscellaneous Events**

- **Occasions: Bronchopleural Fistula**
- **Occasions: Pneumonia**
- **Occasions: Pneumothorax Requiring Chest Tube Insertion**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Minor</td>
</tr>
<tr>
<td>II</td>
<td>Moderate</td>
</tr>
<tr>
<td>IIIa</td>
<td>Major Urgent</td>
</tr>
<tr>
<td>IIIb</td>
<td>Life-threatening</td>
</tr>
<tr>
<td>IVa</td>
<td>Life-threatening</td>
</tr>
<tr>
<td>IVb</td>
<td>Life-threatening</td>
</tr>
<tr>
<td>V</td>
<td>Life-threatening</td>
</tr>
</tbody>
</table>

- **Grade I**: Minor complications (e.g., superficial incisional SSI).
- **Grade II**: Moderate complications (e.g., organ space SSI).
- **Grade III**: Major urgent complications (e.g., surgical intervention under general anesthesia).
- **Grade IV**: Life-threatening complications (e.g., tracheostomy due to life-threatening consequences).
- **Grade V**: Life-threatening complications with organ failure.

**Surgical, radiological, endoscopic intervention, or multi-therapy intervention (does not require general anaesthesia)**

- **Grants**:
  - Grade IIIa: Transfusion, evacuation or aspiration.
  - Grade IIIb: Opening of wound at bedside.

**Concomitant multiorgan complications**

- **Grants**:
  - Grade IIIa: Transient or equivocal, no therapy added.
  - Grade IIIb: Concomitant multiorgan complications.

**Unstable Arrhythmia**

- **Grants**:
  - Grade IIIa: Prolonged Length of Stay.
  - Grade IIIb: Thoracic Wound Dehiscence*.

**Infections**

- **Grants**:
  - Grade IIIa: Unplanned Reoperation.
  - Grade IIIb: Airway (LMA), nasotracheal tube, etc.
  - Grade IVa: Any readmission (to the same or another hospital), for any reason, within 30 days of the principal surgical procedure, a percutaneous procedure performed at bedside or surgical procedure, a percutaneous procedure performed at bedside or surgery.

**Concomitant Procedures**

- **Grants**:
  - Grade IIIa: Unplanned transfer of the patient to the ICU due to deterioration in the condition of the patient.
  - Grade IIIb: Patient required a tracheostomy in the postoperative period whether or not a tracheobronchial injury occurred.

**Unplanned Invasive Procedures**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned transfer of the patient to the ICU owing to deterioration in the condition.
  - Grade IIIb: Patient was reintubated during the initial postoperative period.

**Surgical Events**

- **Grants**:
  - Grade IIIa: Indicate whether a tracheobronchial injury occurred.
  - Grade IIIb: Indicate whether the patient experienced any other surgical events in the post-operative period requiring a procedure with general anesthesia.

**Surgical Site Infections (SSIs)**

- **Deep Incision SSI**: An infection that occurs within 30 days after the operation and involves only skin or subcutaneous tissue of the incision and at least one of the following:
  - Purulent drainage
  - Positive culture
  - Organisms seen on Gram stain of unspun urine
  - Signs and symptoms should be reported within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent.

- **Superficial Incisional SSI**: An infection that occurs within 30 days after the operation and involves only skin or subcutaneous tissue of the incision and at least one of the following:
  - Purulent drainage, with or without laboratory confirmation
  - Signs and symptoms should be reported within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent.

- **Abdominal site**: Refers primarily to loss of the integrity of fascial closure (or whatever closure was used) with contamination or infection.

**Organ Space SSI**

- **Grants**:
  - Grade IIIa: The spontaneous reopening of a previously surgically closed wound that occurs within 30 days after the surgery.
  - Grade IIIb: The occurrence of organ space SSI.

**Wound/Diaphragm**

- **Grants**:
  - Grade IIIa: Any complication, Grade IIIb or above that resulted in tracheostomy.
  - Grade IIIb: Any complication, Grade IVb or above that resulted in tracheostomy.

**Concomitant Procedures**

- **Grants**:
  - Grade IIIa: Indicate if the patient had an unplanned invasive procedure after the index procedure, a percutaneous procedure performed at bedside or surgical procedure, a percutaneous procedure performed at bedside or surgery.
  - Grade IIIb: Indicate if the patient had an unplanned invasive procedure after the index procedure, a percutaneous procedure performed at bedside or surgical procedure, a percutaneous procedure performed at bedside or surgery.

**Other Medical Events**

- **Grants**:
  - Grade IIIa: Indicate whether the patient experienced any other medical events in the post-operative period requiring a procedure with general anesthesia.
  - Grade IIIb: Indicate whether the patient experienced any other medical events in the post-operative period requiring a procedure with general anesthesia.

**Medical Therapy**

- **Grants**:
  - Grade IIIa: Indicate if the patient had an unplanned invasive procedure after the index procedure, a percutaneous procedure performed at bedside or surgical procedure, a percutaneous procedure performed at bedside or surgery.
  - Grade IIIb: Indicate if the patient had an unplanned invasive procedure after the index procedure, a percutaneous procedure performed at bedside or surgical procedure, a percutaneous procedure performed at bedside or surgery.

**Inpatient Stay**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned transfer of the patient to the ICU owing to deterioration in the condition.
  - Grade IIIb: Patient was reintubated during the initial postoperative period.

**Return to the Operating Room**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned return to the operating room for any concurrent procedure performed; This return must be within the 30 day postoperative period.
  - Grade IIIb: Indicate whether there was an unplanned return to the operating room for any concurrent procedure performed; This return must be within the 30 day postoperative period.

**Infection**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned transfer of the patient to the ICU owing to deterioration in the condition.
  - Grade IIIb: Patient was reintubated during the initial postoperative period.

**Unplanned Admission**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned transfer of the patient to the ICU owing to deterioration in the condition.
  - Grade IIIb: Patient was reintubated during the initial postoperative period.

**Return to the Operating Room**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned return to the operating room for any concurrent procedure performed; This return must be within the 30 day postoperative period.
  - Grade IIIb: Indicate whether there was an unplanned return to the operating room for any concurrent procedure performed; This return must be within the 30 day postoperative period.

**Infection**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned transfer of the patient to the ICU owing to deterioration in the condition.
  - Grade IIIb: Patient was reintubated during the initial postoperative period.

**Unplanned Admission**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned transfer of the patient to the ICU owing to deterioration in the condition.
  - Grade IIIb: Patient was reintubated during the initial postoperative period.

**Return to the Operating Room**

- **Grants**:
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  - Grade IIIb: Indicate whether there was an unplanned return to the operating room for any concurrent procedure performed; This return must be within the 30 day postoperative period.

**Infection**

- **Grants**:
  - Grade IIIa: Indicate whether there was an unplanned transfer of the patient to the ICU owing to deterioration in the condition.
  - Grade IIIb: Patient was reintubated during the initial postoperative period.