**Please fill out one separate Adverse Event form for each Adverse Event!**

**1. General Information**: Event Onset Date: \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Day Month Year

**Event Occurred:** □ Intraprocedural □ Pre-discharge □Post-discharge

**Event Type:** □ SAE □ SADE □ AE □ ADE □ UADE

**\*Event is related to:** □ Procedure □ Comorbidities □ Device Malfunction □ Other:

**2. Adverse Event Description**: Code: (Please check only one)

**CARDIAC EVENTS:**

* MYOCARDIAL INFARCTION
* ARRHYTHMIA WITHOUT PACEMAKER REQUIRED
* ARRHYTHMIA WITH PACEMAKER DUE TO AV BLOCK
* ARRHYTHMIA WITH PACEMAKER NOT DUE TO AV BLOCK
* CARDIAC ARREST
* CARDIAC TAMPONADE
* ENDOCARDITIS
* PERICARDIAL EFFUSION DRAINED
* PERICARDIAL EFFUSION NOT DRAINED
* PERICARDITIS
* SUDDEN DEATH
* HEMODYNAMIC COLLAPSE

**RENAL EVENTS:**

* RENAL INUFFICIENCY
* RENAL FAILURE REQUIRING TEMPORARY DIALYSIS (<30 DAYS)
* RENAL FAILURE REQUIRING PERMANENT DIALYSIS (>30 DAYS)

Max Creatinine \_\_\_\_\_mg/dL \_\_\_\_\_UMOl/

If difference is an increase of at least 0.5 mg/dl (44mmol/L) compared to Baseline

GFR\_\_\_\_\_\_\_\_\_ mL/min

**PULMONARY EVENTS:**

* PNEUMOTHORAX
* PLEURAL EFFUSION DRAINED
* PLEURAL EFFUSION NOT DRAINED
* RESPIRATORY COMP / FAILURE
* PNEUMONIA
* PULMONARY EMBOLISM

**NEUROLOGICAL EVENTS:**

* NEUROLOGICAL EVENT SEVERE NOT A STROKE
* NEUROLOGICAL EVENT MINOR NOT A STROKE
* HEMORRHAGIC STROKE SEVERE
* NON-HEMORRHAGIC STROKE
* STROKE – CAUSE UNKNOWN
* SYNCOPE
* TRANSITORY PSYCHOTIC SYNDROME
* TRANSIENT ISCHEMIC ATTACK (TIA)

**GASTRO INSTUNAL EVENTS:**

* ULCER
* PERFORATION
* ISCHEMIC BOWL
* OTHER
* SPECIFY: \_\_\_\_\_\_

**HEMATOLOGICAL DISORDERS: see VARC definition**

* MAJOR BLEEDING EVENT (transfusion > 2 units)
* LIFE-THREATENING BLEEDING EVENT (transfusion >4 units)
* COAGULOPATHY / HEMATOLOGICAL DISORDER – THROMBOSIS
* COAGULOPATHY / HEMATOLOGICAL DISORDER - HIT
* HEMOLYSIS

**THROMBOEMBOLIC EVENT**

(Other than heart)

* OCULAR THROMBUS
* RENAL THROMBUS
* GASTRO-INTESTINAL THROMBUS
* SPLENETIC THROMBUS
* CARDIAC THROMBUS
* HEPATIC THROMBUS
* ARM THROMBUS
* LEG THROMBUS
* NEUROLOGICAL
* THROMBUS IN OTHER LOCATION

Lab results before initiating event driven anticoagulation:

PTT sec

INR

Platelet cells/mm3

**MISCELLANEOUS:**

* BONE FRACTURE
* CANCER NEW DIAGNOSED
* CANCER EXPECTED
* DRUG REACTION
* INFLAMMATION/INFECTION
* METABOLIC COMPLICATION
* SEPSIS DUE TO PROLONGED HOSPITAL STAY
* SEPSIS AFTER DISCHARGE
* SUICIDE
* MULTIPLE ORGAN FAILURE
* THORACIC WOUND COMP.
* URINARY TRACT INFECTION
* VISION DISORDER
* OTHER

SPECIFY:

**3. Adverse Event Treatment/Intervention**

* None
* Medical Therapy
* Surgical Intervention
* Hospital Readmission
* Transfusion
* Other:

**4. Event Severity**

* Minor
* Mild
* Major

**5. Outcome**

* Resolved
* Resolved with sequelea
* On-going
* Death (Add death form if death is selected.)

**6. Narrative**: Please describe the event and its course etc:

|  |  |  |  |
| --- | --- | --- | --- |
| My signature indicates that to the best of my knowledge all information entered on Form 6 is correct. | | | Date |
|  |  |  | |
|  |  | **\_\_ \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_** | |
| *Investigator’s Signature* |  | mmm dd yyyy | |