

## **COMMENCE: Adverse Event Form**

Event Number# \_\_\_\_\_

Date of event:     /     /

Date study staff aware of event:     /     /

### **MACE Event List**

- Death from Cardiovascular Cause     *Death from cardiovascular cause is defined as any death for which there is no clearly documented nonvascular cause*
- Peri-operative Myocardial Infarction     *Peri-operative Myocardial Infarction is defined as cTn measurement  $\geq 10 \times 99^{\text{th}}$  percentile upper reference limit (URL) during first 48 hours following CABG, with at least 1 of the following: A) with new pathologic Q waves or new LBBB (Q-wave MI); B) angiographic evidence of new graft or native coronary artery occlusion; or C) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.*
- Non-perioperative Myocardial Infarction     *defined as a detection of rise and/or fall of cTn with at least one value above the 99<sup>th</sup> percentile of the URL more than 48 hours after the surgery, together with evidence of myocardial ischemia with at least 1 of the following: A) symptoms of ischemia; B) ECG changes indicative of new ischemia (new ST-T changes or new LBBB); C) development of pathologic Q waves in the ECG; D) Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality; or E) identification of an intracoronary thrombus by angiography or autopsy.*
- Cerebrovascular Accident     *Stroke is defined as A) new, acute focal neurological deficit thought to be of vascular origin with signs or symptoms lasting >24 hours and confirmed by a neurologist; B) new, focal neurological deficit lasting > 24 hours with imaging evidence of cerebral infarction or intracerebral hemorrhage; C) non-focal encephalopathy lasting >24 hours with imaging evidence of cerebral infarction or intracerebral hemorrhage.*
- Coronary Ischemia     *Recurrent Ischemia after surgery is defined as re-hospitalization for classified unstable angina*
- Target vessel revascularization     *defined as a new CABG procedure or PCI associated with documented ischemia by stress testing (ECG, echocardiography, or nuclear testing), graft failure, new culprit lesion ( $\geq 70\%$  luminal stenosis), or determined by the patient's physician to be clinically indicated.*
- Conversion to sternotomy     *For patients undergoing MICS CABG, the need for doing a sternotomy for any reason (including completing anastomosis, control bleeding, improve hemodynamics).*
- Re-opening for bleeding     *defined as requirement to return to OR for re-opening of sternotomy or MICS CABG incision for any reason, within the same hospital admission as the completed procedure.*
- Other     *Adverse event whether serious, not serious, related not related, expected, not expected that has an untoward medical occurrence or unfavorable and unintended sign in a subject per investigators decision.*

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**Event:**

**EVENT DESCRIPTION**

Event Number# \_\_\_\_\_

Description of Event (attach source documents as relevant)

Interventions/Treatments

Event outcome:     Resolved – date \_\_\_\_\_     Death – date \_\_\_\_\_     Ongoing

Is/was the event serious?                  <sub>0</sub>  N    <sub>1</sub>  Y

Is/was the event unexpected?              <sub>0</sub>  N    <sub>1</sub>  Y

**Assessment by Principal Investigator**

Relationship to study treatment

- Unlikely Related** - no temporal association or the cause of the event has been identified, or the drug, biological or device cannot be implicated
- Possibly Related** - temporal association, but other etiologies are likely to be the cause; however involvement of the drug, biological, or device cannot be excluded.
- Probably Related** - temporal association and other etiologies are possible but unlikely
- Related** - definite association to drug, biological or device is certain

If event is serious, unexpected, and possibly/probably related to study treatment, expedited reporting to Sponsor, REB and appropriate regulatory authorities is required.

\_\_\_\_\_  
Signature of Investigator assessing relationship

\_\_\_\_\_  
Date (dd/mmm/yyyy)

Entry date:        /        /  
                          dd/mmm/yyyy

Entered by: \_\_\_\_\_

Signature: \_\_\_\_\_