Supplementary Material

Primary End Point
Mediastinitis/sternal instability 30 (± 5).

Secondary End Point
Mediastinitis/sternal instability of 60 (± 5) days, pneumonia until to maximum 30 days after the primary sternum closure.

Definition 1
Superficial Surgical Site Infection
Involves only skin and subcutaneous tissue of the incision and patient has at least one of the following:

- Purulent drainage from the superficial incision
- Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
- At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat.

Mediastinitis
At least one of the following criteria:

Criterion 1: Patient has organisms cultured from mediastinal tissue or fluid obtained during a surgical operation or needle aspiration.

Criterion 2: Patient has evidence of mediastinitis seen during a surgical operation or histopathologic examination.

Criterion 3: Patient has at least one of the following signs or symptoms with no other recognized cause:

- Fever >38°C, chest pain, sternal instability
- And at least one of the following:
  - Purulent discharge from mediastinal area
  - Organisms cultured from blood or discharge from mediastinal area
  - Mediastinal widening on X-ray.

Pneumonia
One chest radiograph with at least one of the following:

- New onset or worsening cough, or dyspnea, or tachypnea
- Rales or bronchial breath sounds
- Worsening gas exchange (e.g., O₂ desaturations (PaO₂/FiO₂ ≤ 240), increased oxygen requirements, or increased ventilation demand).

Definition 2

Adverse event: An adverse event is any untoward medical occurrence in a subject.

Adverse event occurred: Perioperatively means after surgery within 24 hours.

Serious Adverse Event
An adverse event that:

- Led to a death
- Led to a serious deterioration in the health of the subject that:
  - Resulted in a life-threatening illness or injury
  - Required inpatient hospitalization or prolongation of existing hospitalization
  - Resulted in medical or surgical intervention to prevent permanent impairment to body structure or body function medical or surgical intervention
- Led to fetal distress, fetal death, or a congenital abnormality
- Might have led to death or a serious deterioration in health had suitable action or intervention not taken place.
- This includes but is not limited to:
  - A malfunction of a device such that it has to be modified or temporarily/permanently taken out of service.

Deterioration in device characteristics or performance found on examination of the device.

Relation to Device/Adverse Event Device Causality

Unanticipated Device-Related Adverse Event
Any undesirable clinical occurrence in a subject considered to be device related and not listed in the device technical manuals (or not listed in the appropriate section on the adverse-event case report form).

Adverse Device Effect
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.

Note 2: This definition includes any event that is a result of a user error.