

Adverse Event Reminders

Appendix A: Adverse Event Definitions

Cardiac Arrhythmia

Did a documented arrhythmia result in clinical compromise since followup/admission?*

YES NO UNK

Event Date:*

mm/dd/yyyy

ST=

Type of cardiac arrhythmia:*

Pericardial Fluid Collection

Did a pericardial effusion that required drainage occur since last INTERMACS report/last followup?:*

YES NO UNK

Event date.:*

mm/dd/yyyy

ST=

Signs of tamponade:*

YES NO UNK

Method of drainage:*

Surgical Intervention Cath Unknown

Hemolysis

Did clinical signs associated with hemolysis (plasma-free hemoglobin PFHgb > 40 mg/dl) occur after the first 72 hours post-implant and since last INTERMACS report/last followup?:*

YES NO UNK

Plasma-free hemoglobin measurement:*

mg/dL

ST=

Hematocrit measurement:*

%

ST=

Patient has Hyperbilirubinemia (Total Bilirubin > 2 mg/dl):*

YES NO UNK

Cause of Hemolysis:*

Other, specify:*

Hepatic Dysfunction

Did Clinical evidence of liver dysfunction since last INTERMACS report/last followup occur beyond 14 days post implant?:*

YES NO UNK

Total bilirubin measurement:*

mg/dL ST=

SGOT/AST measurement:*

u/L ST=

SGPT/ALT measurement:*

u/L ST=

Hypertension

Did onset bp \geq 140mm Hg systolic or 90mm Hg diastolic (Pediatric patient: $>$ 95th percentile, see definition) occur since last INTERMACS report/last followup?:*

YES NO UNK

Systolic bp:*

mm Hg ST=

Diastolic bp:*

mm Hg ST=

Myocardial Infarction

Did a myocardial infarction occur since last INTERMACS report/last followup?:*

YES NO UNK

Date of event:*

mm/dd/yyyy

ST=

Psychiatric Episode

Did a disturbance in thinking, emotion or behavior that required intervention occur in patient since last INTERMACS report/last followup?:*

YES NO UNK

Renal Dysfunction

Did renal dysfunction (by definition) occur since last INTERMACS report/last followup?:*

YES NO UNK

Event date.:*

mm/dd/yyyy

ST=

Dialysis duration:*

weeks

ST=

Peak creatinine measurement:*

mg/dL

ST=

Respiratory Failure

Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last INTERMACS report/last followup?:*

YES NO UNK

Date of event:*

mm/dd/yyyy ST=

Intubation duration:*

days ST=

Was a tracheotomy performed?:*

YES NO UNK

Right Heart Failure

Did symptoms or signs of right heart failure occur requiring RVAD implantation or inotropic therapy at least 14 days post implant and since last update?:*

YES NO UNK

Event date.:*

mm/dd/yyyy ST=

Check all signs/symptoms that apply:*

- CVP > 18 mmHg
- CI < 2.0 L/min/M2
- Ascites
- Peripheral Edema

Arterial Non-CNS Thromboembolism

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last INTERMACS report/last followup?*

YES NO UNK

Date: * mm/dd/yyyy ST=

Location: *

Other acute perfusion deficit: *

Confirmation source: *

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify: *

Venous Thromboembolism Event

Evidence of Venous Thromboembolic event since last INTERMACS report/last followup - check all that apply - :*

- Deep Vein thrombosis
- Pulmonary Embolis
- Other, specify
- Unknown
- None

Specify event: *

Enter deep vein thrombosis date: * mm/dd/yyyy ST=

Enter pulmonary embolis date: * mm/dd/yyyy ST=

Enter other date: * mm/dd/yyyy ST=

Anticoagulant therapy at time of event - check all that apply - :*

- Warfarin
- Heparin
- Lovenox
- Aspirin

- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bilvalirudin
- Fondaparinux
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other

Specify: *

Wound Dehiscence

Did a disruption of the apposed surfaces of surgical incision require surgical repair since last INTERMACS report/last followup? *

YES NO UNK

Date: * mm/dd/yyyy ST=

Other

Did an Other Major Serious Adverse Event occur since last INTERMACS report/last followup? *

YES NO UNK

Other Major Serious Adverse Event since last INTERMACS report/last followup: