Intermacs
Adverse Event

Adverse Event Status

Please enter the date of the event you are reporting:

Please enter a label describing this event:
## Rehospitalization

<table>
<thead>
<tr>
<th><strong>Was there an occurrence of rehospitalization?</strong></th>
<th>☐ Yes</th>
<th>☐ No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is this rehospitalization at your hospital?</strong></td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
</tbody>
</table>

| **Date of admission**<br>MM/DD/YYYY | ✔ | Unknown |
| **Discharge Date**<br>MM/DD/YYYY | ✔ | Unknown |

Date of transplant, death or explant for recovery will be considered the date of discharge.

| **Primary reason for rehospitalization** | ☐ Anticoagulation adjustment | ☐ Arterial Non-CNS Thrombo-embolism | ☐ Cardiac Arrhythmia | ☐ Cardiac Tamponade | ☐ Catastrophe (i.e. weather) | ☐ Device Malfunction | ☐ Diagnostic Procedure | ☐ Explant | ☐ Fever without known cause | ☐ Fluid Overload | ☐ Gastroenteritis | ☐ GI Disorder | ☐ Hematological | ☐ Hematoma | ☐ Hemolysis | ☐ Hepatic Dysfunction | ☐ Hypertension | ☐ Limb vascular complication | ☐ Major Bleeding | ☐ Major Infection | ☐ Metabolic/Electrolyte Disturbance | ☐ Myocardial Infarction | ☐ Neurological Dysfunction | ☐ Pericardial Fluid Collection | ☐ Planned medical management | ☐ Planned Procedure | ☐ Pneumonia | ☐ Psychiatric Episode | ☐ Pulmonary Embolism/Hemorrhage | ☐ Pulmonary, Other | ☐ Renal Dysfunction | ☐ Respiratory Failure | ☐ Right Heart Failure | ☐ Syncope without known cause | ☐ Transplant | ☐ Trauma/Accident |
Venous Thromboembolic Event
Wound Complication
Wound Dehiscence
Unknown
Other, specify

Rehospitalization intervention
☐ Surgical Procedure
☐ Heart Cath
☐ Invasive Cardiac Procedures (Other than Heart Cath)
☐ Transplantation
☐ None
☐ Unknown
☐ Other

Type of surgical procedure
☐ Device related operation
☐ Other Cardiac Surgical Procedure
☐ Non Cardiac Surgical Procedure
☐ Other procedure
☐ Unknown

Type of other cardiac procedure
☐ Reoperation for Bleeding within 48 hours of implant
☐ Reoperation for Bleeding and/or tamponade > 48 hours
☐ Surgical Drainage of pericardial effusion
☐ Aortic Valve Surgery - Replacement - Biological
☐ Aortic Valve Surgery - Replacement - Mechanical
☐ Aortic Valve Procedure
☐ Mitral Valve Surgery - Repair
☐ Mitral Valve Surgery - Replacement - Biological
☐ Mitral Valve Surgery - Replacement - Mechanical
☐ Tricuspid Valve Surgery - Repair - DeVega
☐ Tricuspid Valve Surgery - Repair - Ring
☐ Tricuspid Valve Surgery - Repair - Other
☐ Tricuspid Valve Surgery – Replacement - Biological
☐ Tricuspid Valve Surgery – Replacement - Mechanical
☐ Tricuspid Valve Surgery – Excision
☐ Pulmonary Valve Surgery - Repair
☐ Pulmonary Valve Surgery – Replacement - Biological
☐ Pulmonary Valve Surgery – Replacement - Mechanical
☐ Aneursyomectomy
☐ Mitraclip
☐ TAVR
☐ Arrhythmia Surgery (Ablation)
☐ Ligation of Left Atrial Appendage
☐ Unknown
☐ Other, specify

Type of procedure (non cardiac surgical procedure)

Type of Invasive Cardiac Procedure (Other than Heart Cath)

Enter PA systolic pressure

Enter PA diastolic pressure
### Clinical Observations

<table>
<thead>
<tr>
<th>Clinical Observation</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Systolic blood pressure</strong></td>
<td>mmHg</td>
</tr>
<tr>
<td><strong>Diastolic blood pressure</strong></td>
<td>mmHg</td>
</tr>
<tr>
<td><strong>Mean arterial blood pressure</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Has the patient experienced a Neurological Event since time of implant?</strong></td>
<td>Yes/No/Unknown</td>
</tr>
</tbody>
</table>

**Note:** This applies only to patients who have had a CVA, TIA or Anoxic Brain Injury.

**Modified Rankin Scale:**

- 0 - No symptoms at all
- 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
- 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- 3 - Moderate disability: requiring some help, but able to walk without assistance.
- 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- 6 - Dead

Please [click here](#) for further instruction on administering the Modified Rankin Scale in Appendix I.
# Infection

<table>
<thead>
<tr>
<th>Was there a major infection?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is this a MCS related or Non-MCS related infection?</th>
<th>MCS related</th>
<th>Non-MCS related</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MCS Related Infections: Select all that apply</th>
</tr>
</thead>
</table>

- **Percutaneous lead site infection**
  - A positive culture from the skin surrounding the percutaneous lead when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy. The percutaneous lead exit site is preserved. The gram stain of the skin specimen at the driveline exit site will contain white blood cells (i.e. positive sign for inflammation).

- **Infection of blood-contacting surfaces of an implantable component (device endocarditis)**
  - Infection of blood-contacting internal surfaces of the MCS device including inflow/outflow grafts: documented by positive blood cultures or radiographic or echocardiographic evidence of vegetation in blood flow path of the pump coupled with the need to treat with anti-microbial therapy.

- **Unknown**

<table>
<thead>
<tr>
<th>Other, Specify</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Percutaneous lead site infection: Select one</th>
</tr>
</thead>
</table>

- **Superficial percutaneous lead infection**
  - A positive culture from the skin surrounding the percutaneous lead when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy. The percutaneous lead exit site is preserved. The gram stain of the skin specimen at the driveline exit site will contain white blood cells (i.e. positive sign for inflammation).

- **Deep percutaneous lead infection**
  - A positive culture from the driveline exit site deep to the epithelium, when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need for microbial therapy.

- **Unknown**

<table>
<thead>
<tr>
<th>Infection of external surfaces of an implantable component: Select all that apply</th>
</tr>
</thead>
</table>

- **Pump / related - Exit Cannula**
- **Pump / related - Pump Pocket**
- **Pump / related - transcutaneous power element**
- **Pump / related - implantable battery**
- **Unknown**

<table>
<thead>
<tr>
<th>Infection of external surfaces of an implantable component: Was the patient treated with anti-microbial therapy?</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>If yes, select route</th>
</tr>
</thead>
</table>

- **IV**
- **Oral**
- **Topical**
- **Unknown**

<table>
<thead>
<tr>
<th>Percutaneous lead site infection: Was the patient treated with anti-microbial therapy?</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Other, Specify</th>
</tr>
</thead>
</table>

10/29/21
<table>
<thead>
<tr>
<th>Patient treated with anti-microbial therapy?</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, select route</td>
<td>□ IV</td>
<td>□ Oral</td>
</tr>
</tbody>
</table>

Infection of blood-contacting surfaces of an implantable component (device endocarditis): Was the patient treated with anti-microbial therapy?
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, select route</td>
<td>□ IV</td>
<td>□ Oral</td>
</tr>
</tbody>
</table>

MCS related - Other, specify: Was the patient treated with anti-microbial therapy?
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, select route</td>
<td>□ IV</td>
<td>□ Oral</td>
</tr>
</tbody>
</table>

Non-MCS Related Infections: Select all that apply
- □ Infective Endocarditis  Non-MCS related (Positive blood cultures and echocardiography findings for mass or vegetation only on native valves, ICD, or pacemaker leads)
- □ Bloodstream Infection  Positive blood cultures with no other source identified; Bloodstream infection: non-VAD site or central venous catheter-related (definition from the Centers for Disease Control/National Healthcare Safety Network)
- □ Mediastinitis
- □ Sepsis  Life-threatening organ dysfunction caused by a dysregulated host response to infection with: Evidence of systemic involvement by infection, manifested by need to treat with anti-microbial therapy and positive blood cultures and/or two of the following: (PaO2/FiO2 < 400 or respiratory rate = 22/min or ventilated respiratory support, Hypotension with systolic BP < 100 mmHg or MAP = 65 mmHg, Platelet count < 150 or elevated prothrombin time or fibrinogen degradation products, Bilirubin (serum) > 50% above baseline, Altered mental status (Glasgow score < 15), Creatinine (serum) > 50% above baseline, Need for intravenous vasoconstricting agents)
- □ Localized non-MCS infection  Infection localized to a site not involving the MCS device or components (e.g., pneumonia, urinary tract infection, cholecystitis, diverticulitis, dental abscess) coupled with the need to treat with anti-microbial therapy. A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures
- □ Other, Specify
- □ Unknown

Infective Endocarditis: Was the patient treated with anti-microbial therapy?
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, select route</td>
<td>□ IV</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Options</td>
<td>Notes</td>
</tr>
<tr>
<td>----------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td><strong>BSI: Was the patient treated with anti-microbial therapy?</strong></td>
<td>Yes, No, Unknown</td>
<td></td>
</tr>
<tr>
<td><strong>If yes, select route</strong></td>
<td>IV, Oral, Topical, Unknown</td>
<td></td>
</tr>
<tr>
<td><strong>Mediastinitis: Select subtype</strong></td>
<td>Procedure-related mediastinitis, Non-MCS related mediastinitis, Superficial mediastinal or thoracotomy wound infection</td>
<td>Mediastinitis definitively owing to another cause e.g., esophageal perforation during endoscopy, contiguous with empyema.</td>
</tr>
<tr>
<td><strong>Mediastinitis: Was the patient treated with anti-microbial therapy?</strong></td>
<td>Yes, No, Unknown</td>
<td></td>
</tr>
<tr>
<td><strong>If yes, select route</strong></td>
<td>IV, Oral, Topical, Unknown</td>
<td></td>
</tr>
<tr>
<td><strong>Sepsis: Was the patient treated with anti-microbial therapy?</strong></td>
<td>Yes, No, Unknown</td>
<td></td>
</tr>
<tr>
<td><strong>If yes, select route</strong></td>
<td>IV, Oral, Topical, Unknown</td>
<td></td>
</tr>
<tr>
<td><strong>Localized non-MCS Infection: Select all that apply</strong></td>
<td>Pneumonia, Tracheobronchitis, Urinary Tract, Thoracotomy incision, Peripheral Wound, GI, Other, Specify</td>
<td></td>
</tr>
<tr>
<td><strong>Localized non-MCS device infection: Was the patient treated with anti-microbial therapy?</strong></td>
<td>Yes, No, Unknown</td>
<td></td>
</tr>
</tbody>
</table>
If yes, select route
- IV
- Oral
- Topical
- Unknown

Non-MCS related - Other, specify: Was the patient treated with anti-microbial therapy?
- Yes
- No
- Unknown

If yes, select route
- IV
- Oral
- Topical
- Unknown

Date of onset
- MM/DD/YYYY

ST = Unknown

Did this infection contribute to death?
- Yes
- No
- Unknown

The association of the infection event should be classified as
- Patient related: e.g., non-adherence or poor management of driveline exit site or indwelling catheters, IV drug abuse, aspiration
- Management related: e.g., improper tunneling, contamination of the intraoperative site, prolonged intubation
- Device related: e.g., device endocarditis diagnosed by radiological examination or detection of pannus within the conduits or device
- No association identified

Location of patient
- In hospital
- Out of hospital
- Unknown

Type of infection
- Bacterial
- Fungal
- Viral
- Protozoan
- Unknown

Bacterial: Select one
- Gram positive
- Gram negative
- Other, Specify

Gram positive
- Enterococcus
- Staphylococcus, Methicillin Resistant
- Staphylococcus, Methicillin Sensitive
- Streptococcus
- Other, Specify

Gram negative
- Citrobacter
- Enterobacter
- Enterobacteriaceae
- Escherichia
- Haemophilus
<table>
<thead>
<tr>
<th>Option</th>
<th>Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klebsiella</td>
<td></td>
</tr>
<tr>
<td>Moraxella</td>
<td></td>
</tr>
<tr>
<td>Pseudomonas</td>
<td></td>
</tr>
<tr>
<td>Serratia</td>
<td></td>
</tr>
<tr>
<td>Other, Specify</td>
<td></td>
</tr>
</tbody>
</table>

**Was surgery an intervention for this AE?**
- Yes
- No
- Unknown

**Did the patient test positive for COVID-19?**
- Yes
- No
- Unknown

**If yes, select all symptoms that apply**
- Cough
- Diarrhea
- Fever
- Anosmia (loss of sense of smell)
- Sore Throat
- Difficulty Breathing
- None
- Other, Specify

**If yes, select all interventions that apply**
- Intubation
- New Inotropes
- ECMO
- Dialysis
- RVAD
- None
- Other, Specify

**If yes, select all therapies the patient received**
- Hydroxychloroquine
- Azithromycin
- Immunoglobulin
- Anti-viral therapy
- Steroids
- Convalescent Plasma
- Interlukin 6 inhibitor
- None
- Other, Specify

**Anti-viral therapy, specify:**

**If yes, did the patient have an associated bacterial lung infection?**
- Yes
- No
- Unknown
Intermacs

**Adverse Event**

**Bleeding**

Transfusions for anemia and hemolysis are not considered bleeding events

<table>
<thead>
<tr>
<th>Was there a major bleeding event?</th>
<th>○ Yes</th>
<th>○ No</th>
<th>○ Unknown</th>
</tr>
</thead>
</table>

If yes, Select Type

- ○ Type 1  Bleeding that is not actionable and does not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a healthcare professional; may include episodes leading to self-discontinuation of medical therapy by the patient without consulting a healthcare professional. This type is not relevant during a hospitalization
- ○ Type 2  Any overt, actionable sign of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for Type 3, 4, or 5 but does meet at least one of the following criteria: 1. Requiring non-surgical, medical intervention by a healthcare professional, 2. Leading to hospitalization or increased level of care, 3. Prompting evaluation
- ○ Type 3a  Overt bleeding accompanied by hemoglobin drop of 3 to < 5g/dl or (1.86-3.1 mmol/liter SI units) (provided hemoglobin drop is related to bleed)
- ○ Type 3b  Overt bleeding plus hemoglobin drop 5 g/dl (3.1 mmol/liter) or greater (provided hemoglobin drop is related to bleed)
- ○ Type 4  VAD implantation-related bleeding (includes concomitant cardiac or non-cardiac surgical procedures)
- ○ Type 5  Fatal bleeding

Type 2: select all that apply

- ○ Requiring non-surgical, medical intervention by a healthcare professional
- ○ Leading to hospitalization or increased level of care
- ○ Prompting evaluation

Type 3b: select all that apply

- ○ Cardiac tamponade
- ○ Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid)
- ○ Bleeding requiring intravenous vasoactive agents

Type 4: select all that apply

- ○ Reoperation after the closure of incision or incisions used to implant the VAD to control bleeding
- ○ >= 50 kg: >= 4U PRBC within any 48 hours during the first 7 days post-implant
- ○ < 50 kg: >= 20 cm3/kg PRBC within any 24 hours during the first 7 days post-implant
- ○ Chest tube output > 2 liters within 24 hours

Type 5: select one

- ○ Type 5a: Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious
- ○ Type 5b: Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation
- ○ Unknown

Source/cause/location of bleeding

- ○ Mediastinal: chest wall
- ○ Mediastinal: outflow-aorta anastomosis
- ○ Mediastinal: outflow conduit
- ○ Mediastinal: inflow conduit
Date of bleeding episode onset

ST = Unknown

Location of patient
○ In hospital
○ Out of hospital
○ Unknown

Anticoagulant therapy at time of event
Select all that apply
○ Warfarin
○ Heparin
○ Lovenox
○ Aspirin
○ Dipyridamole
○ Clopidogrel (plavix)
○ Argatroban
○ Bivalirudin
○ Fondaparinux
○ Dextran
○ Ticlopidine
○ Hirudin
○ Lepirudin
○ Ximelagatran
○ None
○ Other, specify

The association of the bleeding event should be classified as
Select one
○ Patient related e.g., coagulopathy unrelated to surgical technique such as
  non-adherence with anti-coagulation medication resulting in an inappropriately
  high level of anti-coagulation, hepatic failure
○ Management related e.g., related to surgical technique; hypertension;
  bleeding in the setting of inappropriate levels of anti-coagulation or to
  mismanagement of anti-coagulants
○ Device related e.g., bleeding from the outflow graft, apical connector, or
  other internal components
○ No association identified
Was there a neurological dysfunction?

- Yes
- No
- Unknown

Select type

- Type 1 - Overt CNS injury
  - Acutely symptomatic brain or spinal cord injury
- Type 2 - Covert CNS injury
  - Acutely asymptomatic brain or spinal cord injury detected by neuroimaging
- Type 3 - Neurologic dysfunction (acutely symptomatic) without CNS injury
  - Include seizures here

Type 1: select subtype

- Type 1a - Ischemic stroke
  - Sudden onset of neurologic signs or symptoms fitting a focal or multifocal vascular territory within the brain, spinal cord, or retina
- Type 1ah - Ischemic stroke with hemorrhagic conversion
  - Ischemic stroke includes hemorrhagic conversions
- Type 1b - Symptomatic intracerebral hemorrhage
  - Rapidly developing neurologic signs and symptoms (focal or global) caused by an intraparenchymal, intraventricular, spinal cord, or retinal collection of blood, not caused by trauma
- Type 1c - Symptomatic subarachnoid hemorrhage
  - Rapidly developing neurologic signs or symptoms (focal or global) and/or headache caused by bleeding into the sub-arachnoid space, not caused by trauma
- Type 1d - Stroke, not otherwise specified
  - An episode of acute focal neurologic signs or symptoms and/or headache presumed to be caused by CNS ischemia or CNS hemorrhage, persisting 24 hours or until death, but without sufficient evidence to be classified as one of the above (i.e., no neuroimaging performed)
- Type 1e - Symptomatic hypoxic-ischemic injury
  - Non-focal (global) neurologic signs or symptoms due to diffuse brain, spinal cord, or retinal cell death (confirmed by pathology or neuroimaging) in a non-vascular distribution, attributable to hypotension and/or hypoxia
- Type 1f - Symptomatic subdural hemorrhage
  - An episode of acute focal neurologic signs or symptoms and/or headache accompanied by evidence of bleeding into the subdural space
  - Unknown

Type 2: select subtype

- Type 2a - Covert CNS infarction
  - Brain, spinal cord or retinal cell death attributable to focal or multifocal ischemia on the basis of neurological imaging or pathologic evidence of CNS infarction, without a history of acute neurologic symptoms consistent with the lesion location
- Type 2ah - Covert CNS infarction with hemorrhagic conversion
- Type 2b - Covert CNS hemorrhage
  - Neuroimaging or pathologic evidence of CNS hemorrhage within the brain parenchyma, subarachnoid space, subdural space, ventricular system
  - Unknown

Type 3: select subtype

- Type 3a - TIA
  -Transient focal neurologic signs or symptoms (lasting < 24 hours presumed to be owing to the focal brain, spinal cord, or retinal ischemia, but without evidence of acute infarction by neuroimaging or pathologic evidence of CNS infarction, or in the absence of imaging)
- Type 3b - Delirium without CNS injury
  - Transient non-focal global neurologic signs or symptoms (variable duration) without evidence of cell death by neuroimaging or pathologic injury
- Seizure
Type 1a: select one

- **Persist for 24 hours or until death**: With pathology or neuroimaging evidence that demonstrates either (a) CNS infarction in the corresponding vascular territory (with or without hemorrhage) or (b) Absence of other apparent causes (including hemorrhage), even if no evidence of acute ischemia in the corresponding vascular territory is detected.

- **Symptoms lasting < 24 hours**: With pathology or neuroimaging confirmation of CNS infarction in the corresponding vascular territory. Note: when CNS infarction location does not match the transient symptoms, the event would be classified as covert CNS infarction (Type 2a) and a TIA (Type 3a), but not an ischemic stroke. Signs and symptoms consistent with stroke typically include an acute onset of one of the following: focal weakness and/or numbness, impaired language production or comprehension, homonymous hemianopia or quadrantanopia, diplopia, altitudinal monocular blindness, hemispatial neglect, dysarthria, vertigo, or ataxia. For pediatric patients, generalized symptoms such as seizure, irritability, or altered wakefulness may be accepted as confirmation of acute stroke if imaging or pathology demonstrates previously undocumented CNS infarction.

Note: This only applies to patients who have a CVA, TIA, or Anoxic Brain Injury. You must complete this section at the time of event and throughout the patient’s complete STS Intermacs® lifespan.

**Modified Rankin Scale**

Please click here for further instruction on administering the Modified Rankin Scale in Appendix I.

- **0** - No symptoms at all
- **1** - No Significant disability: despite symptoms: able to carry out all usual duties and activities
- **2** - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- **3** - Moderate disability: requiring some help, but able to walk without assistance.
- **4** - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- **5** - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- **6** - Dead
- **Not Documented**
- **Not Done**

**NIH Stroke Scale**

Please click here for further instruction on administering the Modified Rankin Scale in Appendix I.

- **0-5**
- **6-14**
- **15+**
- **Not Documented**
- **Not Done**

**Date of onset**

MM/DD/YYYY

**Location of patient**

- In hospital
- Out of hospital
- Unknown

**Did this neurological dysfunction adverse event contribute to the patient’s death?**

- Yes
- No
- Unknown

**The association of the neurologic event should be classified as**

- Patient related e.g., documentation of previous carotid or cerebrovascular disease, coagulopathy unrelated to surgical technique such as non-adherence with anti-coagulation medication resulting in an inappropriately high level of...
anticoagulation, related to illicit drug use, non-adherence with other medications, trauma, associated with sepsis

- **Management related**: e.g., over anti-coagulation or associated with the use of accessory assist device, hypotension or hypertension-related to surgical procedure
- **Device related**: e.g., secondary to pump thrombosis or device malfunction
- **No association identified**

### Method of diagnosis of CNS event
- CT
- MRI
- Angiogram
- Clinical
- Unknown
- Other, specify

### Anticoagulant therapy at time of event

**Check all that apply**
- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bivalirudin
- Fondaparinux
- Dextran
- Ticlopidine
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify
### Intermacs Adverse Event

**Device Malf/Failure and/or Pump Thrombus**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was there a device malfunction / failure and / or a pump thrombus?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Was there a device malfunction?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td><strong>If yes, select type</strong></td>
<td>Major Device Malfunction, Minor Device Malfunction, Unknown</td>
</tr>
<tr>
<td>If Major Device Malfunction, check all criteria that apply</td>
<td>Death, Hospitalization, Life-threatening event, Results in significant disability or incapacity, Requires an intervention to prevent impairment/injury, Urgent transplantation listing, Pump replacement, Pump explant, Pump deactivation without explant or partial explant of components, Breach of integrity of percutaneous lead requiring repair, Operation to repair or replace any internal component of the circulatory support system, Procedure to repair or stent an outflow graft, Unknown</td>
</tr>
<tr>
<td>Requires an intervention to prevent impairment/injury, check all criteria that apply</td>
<td>Urgent transplantation listing (please enter explant form and add new device to record exchange), Pump replacement (please enter explant form), Pump explant (please complete explant form and select explant reason: turned off (decommissioned)), Pump deactivation without explant or partial explant of components (please complete explant form and select explant reason: turned off (decommissioned)), Breach of integrity of percutaneous lead requiring repair, Operation to repair or replace any internal component of the circulatory support system, Procedure to repair or stent an outflow graft, Unknown</td>
</tr>
<tr>
<td>Date of Device Malfunction onset</td>
<td>MM/DD/YYYY</td>
</tr>
</tbody>
</table>

**Device Type**

<table>
<thead>
<tr>
<th>Location of patient</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>In hospital</td>
<td>Yes</td>
</tr>
<tr>
<td>Out of hospital</td>
<td>Yes</td>
</tr>
<tr>
<td>Unknown</td>
<td>Yes</td>
</tr>
</tbody>
</table>
## Description of Malfunction
Please briefly describe this device malfunction including what happened, what component was involved, method of diagnosis, intervention(s) if any, and the result.

### Pump
- Yes
- No

### Pump Component(s)
- Pump Body (including bearings and rotor)
- Driveline
- Inflow Cannula
- Outflow Graft (including bend relief)

### Implantable component(s)
- Yes
- No

#### Implantable component(s)
Check all that apply
- Percutaneous driveline
- Implantable batteries
- Other, Specify

### Controller
- Yes
- No

### Controller Component(s)
- Primary System Failure (running in backup mode)
- Complete System Failure (primary and backup failure)
- Power Cable (attached to controller)
- Power Connectors (attached to controller)
- Other, Specify

### Peripherals
- Yes
- No

#### Peripheral Component(s)
- External Battery
- Cell Battery (in controller)
- Power Module
- Patient Cable
- System Monitor / Display
- Battery Charger
- Battery Clip

### Pump (RVAD)
- Yes
- No

### Pump Component(s) (RVAD)
- Pump Body (including bearings and rotor)
- Driveline
- Inflow Cannula
- Outflow Graft (including bend relief)

### Implantable component(s) (RVAD)
- Yes
- No

### Implantable component(s) (RVAD)
- Percutaneous driveline
- Implantable batteries
### Controller (RVAD)
- Yes
- No

### Controller Component(s) (RVAD)
- Primary System Failure (running in backup mode)
- Complete System Failure (primary and backup failure)
- Power Cable (attached to controller)
- Power Connectors (attached to controller)
- Other, Specify

### Peripherals (RVAD)
- Yes
- No

### Peripheral Component(s) (RVAD)
- External Battery
- Cell Battery (in controller)
- Power Module
- Patient Cable
- System Monitor / Display
- Battery Charger
- Battery Clip

### Was there a device thrombus?
- Yes
- No
- Unknown

Device thrombus: Intracorporeal device thrombus represents a special case of major device malfunction and can be categorized as a suspected device thrombus or confirmed device thrombus. Device thrombus will be classified as suspected (see definition below) on the basis of clinical, biochemical, or hemodynamic findings or confirmed (see definition below) on the basis of device inspection or incontrovertible radiologic studies or absence of appropriate Doppler flow signals that confirm thrombus within the device or its conduits that results in or could potentially induce circulatory failure.

### If yes, select type (suspected or confirmed).
- Suspected device thrombus A device-related malfunction in which clinical or MCSD parameters suggest thrombus on the blood-contacting components of the pump, cannula, or grafts
- Confirmed device thrombus A major device-related malfunction in which thrombus is confirmed within the blood-contacting surfaces of device inflow cannula or outflow conduit or grafts. This can be reported through direct visual inspection or by incontrovertible contrast radiographic evidence or by the absence of an appropriate Doppler flow signal that results in or could potentially induce circulatory failure or result in thromboembolism

### If suspected device thrombus, check all signs and symptoms that apply
- Presence of major hemolysis Including elevation of biochemical markers of hemolysis; i.e., lactate dehydrogenase or plasma-free hemoglobin, or clinical evidence of hemolysis; i.e., hemoglobinuria
- Presence of heart failure not explained by structural heart disease
- Abnormal pump parameters consistent with diminished pump output/pump efficiency/pump performance
- Unknown

### If suspected device thrombus, check all events/interventions that apply:
- Death (please complete death form)
- Stroke or TIA (please complete neuro dysfunction adverse event)
- Arterial non-CNS thromboembolism (please complete adverse event form)
- De-novo need for inotrope therapy
- Treatment with intravenous anti-coagulation (i.e., heparin), intravenous...
thrombolytics (i.e., tPA), or intravenous anti-platelet therapy (i.e.,
eptifibatide, tirofiban)

- Pump replacement (please enter explant form and add new device to
  record exchange)
- Pump explantation with or without exchange (please complete explant
  form)
- Pump deactivation without pump removal (please complete explant form
  and select explant reason: turned off (decommissioned))
- Operation to repair or replace any internal component of the circulatory
  support system
- Urgent transplantation listing  Immediate urgent listing for transplant
- Unknown

If confirmed device thrombus, check all criteria that apply

- Death
- Hospitalization, emergency room visit or prolongation of hospitalization,
or escalation of the level of care in an ongoing hospitalization  i.e. transfer
to the intensive care unit
- Life-threatening event  i.e., stroke or TIA, cardiac arrest, heart failure,
syncope or near syncopal event, arrhythmia, etc.
- Results in significant disability or incapacity
- Requires an intervention to prevent impairment/injury  Urgent
  transplantation listing (immediate urgent listing for the transplant), Pump
  replacement, Pump explant, Pump deactivation without explant or partial
  explant of components, Breach of integrity of percutaneous lead requiring
  repair, Operation to repair or replace any internal component of the circulatory
  support system, Procedure to repair or stent an outflow graft
- Unknown

Requires an intervention to prevent
impairment/injury, check all criteria that apply

- Urgent transplantation listing (immediate urgent listing for the
  transplant)
- Pump replacement (please enter explant form and add new device to
  record exchange)
- Pump explant (please complete explant form)
- Pump deactivation without explant or partial explant of components
  (please complete explant form and select explant reason: turned off
  (decommissioned))
- Breach of integrity of percutaneous lead requiring repair
- Operation to repair or replace any internal component of the circulatory
  support system
- Procedure to repair or stent an outflow graft
- Unknown

If confirmed device thrombus, check all signs and symptoms and events/interventions
that apply

*Note: Para conduit device thrombus represents a special case of device malfunction whereby thrombus obstructs the
outflow graft from the pump. This should be classified as major if the thrombus directly interferes with pump function
by obstructing flow and if the pump is replaced because of the thrombus. The event should be classified as minor if
there is visible thrombus with the preserved function of the pump but requires surgical intervention. In all instances,
visual confirmation of the thrombus is sufficient for confirmation. **Note: If a suspected device thrombus event is
ultimately confirmed through visual inspection following pump replacement, urgent transplantation or on autopsy
following death, the event may be reclassified to confirmed device thrombus.

- Presence of major hemolysis  including elevation of biochemical markers of
  hemolysis; i.e., lactate dehydrogenase or plasma-free hemoglobin, or clinical
  evidence of hemolysis; i.e., hemoglobinuria
- Presence of heart failure not explained by structural heart disease
- Abnormal pump parameters consistent with diminished pump
  output/pump efficiency/pump performance.
- Arterial non-CNS thromboembolism (please complete adverse event
  form)
- De-novo need for inotrope therapy
- Treatment with intravenous anti-coagulation  i.e., heparin
- Intravenous thrombolytics  i.e., tPA
- Intravenous anti-platelet therapy  i.e., eptifibatide, tirofiban
- Unknown

Date of device thrombus onset

<table>
<thead>
<tr>
<th>MM/DD/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/29/21</td>
</tr>
</tbody>
</table>

Please select method of confirmation:

- Imaging Study
<table>
<thead>
<tr>
<th>The association of the device malfunction / thrombus event should be classified as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Patient related i.e. non-adherence with care of device or instructions for use, or its peripheral components, non-adherence with the anti-coagulation regimen, pro-coagulation abnormalities</td>
</tr>
<tr>
<td>☐ Management related i.e. surgical protocol deviation, sub-optimal anti-coagulation</td>
</tr>
<tr>
<td>☐ Device related i.e. detected in a device at explant or on contrast studies or associated with hemolysis or other controller data consistent with device malfunction</td>
</tr>
<tr>
<td>☐ No association identified</td>
</tr>
</tbody>
</table>

Check all that apply
☒ Visual Inspection
☐ Manufacturer’s Report
Other Adverse Events

Were there any additional adverse events?
- Yes
- No

Cardiac Arrhythmia
Did a documented arrhythmia result in clinical compromise?
- Yes
- No
- Unknown

Date of event
MM/DD/YYYY
ST = Unknown

Cardiac arrhythmia, select type
Any documented arrhythmia that results in clinical compromise (e.g., abnormal VAD function [e.g., diminished VAD flow or suction events], oliguria, pre-syncope or syncope, angina, dyspnea), or requires hospitalization or treatment (drug therapy, defibrillation, cardioversion, ICD therapy [e.g., shock or anti-tachycardia pacing] or arrhythmia ablation procedure). Cardiac arrhythmias are classified as 1 of 2 types:
- Sustained ventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, defibrillation, cardioversion, ICD therapy, or arrhythmia ablation procedure
- Sustained supraventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, cardioversion, ICD therapy, or arrhythmia ablation procedure
- Unknown

The association of the cardiac arrhythmia event should be classified as follows:
- Patient related e.g., recurrence of pre-operative arrhythmia non-adherence with medications
- Management related e.g., related to uncorrected electrolyte imbalance, Swan Ganz malposition, secondary to cardiac tamponade
- Device related e.g., pump malfunction, malposition of pump, or inflow cannula
- No association identified

Respiratory Failure
Impairment of respiratory function requiring reintubation, tracheostomy, or the inability to discontinue ventilatory support within 6 days (144 hours) post-VAD implant. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.

Date of event
MM/DD/YYYY
ST = Unknown
- Ongoing

Was this a prolonged intubation?
Cumulative duration of intubation. Any reintubation except procedures should be documented here. Initial implant intubation including any subsequent intubation will be considered the initial procedure intubation
- Yes
- No
- Unknown

Number of days of intubation
ST: Unknown
- Ongoing

Was there a need for a tracheostomy?
- Yes
- No
Date of tracheostomy
MM/DD/YYYY
ST = Unknown

Was there a need for reintubation?
Any reintubation except procedure should be documented here
○ Yes
○ No
○ Unknown

Date of reintubation
MM/DD/YYYY
ST = Unknown

The association of the respiratory failure event should be classified as follows:
○ Patient related e.g., non-adherence to medical therapy resulting in respiratory failure
○ Management related e.g., inadequate diuretic therapy resulting in respiratory dysfunction
○ Device related e.g., device failure resulting in respiratory dysfunction
○ No association identified

Evidence of Venous Thromboembolic event
☐ Deep Vein thrombosis
☐ Pulmonary Embolism
☐ Other, specify
☐ Unknown
☐ None

Enter deep vein thrombosis date
MM/DD/YYYY
ST = Unknown

Enter pulmonary embolus date
MM/DD/YYYY
ST = Unknown

Enter other date
MM/DD/YYYY
ST = Unknown

Anticoagulant therapy at time of event
☐ Warfarin
☐ Heparin
☐ Lovenox
☐ Aspirin
☐ Dipyridamole
☐ Clopidogrel (plavix)
☐ Argatroban
☐ Bivalirudin
☐ Fondaparinux
☐ Dextran
☐ Ticlopidine
☐ Hirudin
☐ Lepirudin
☐ Ximelagatran
☐ None
☐ Other, specify

Wound Dehiscence ○ Yes
Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

<table>
<thead>
<tr>
<th>Date of event</th>
<th>MM/DD/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST = Unknown</td>
<td></td>
</tr>
</tbody>
</table>

Enter Location

- Sternum
- Driveline Sites
- Site of thoracotomy
- Other, specify

**Arterial non-CNS Thromboembolism**
An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by 1 or more of the following: This definition excludes neurologic events. 1) standard clinical and laboratory testing 2) operative findings and 3) autopsy findings

<table>
<thead>
<tr>
<th>Date of event</th>
<th>MM/DD/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST = Unknown</td>
<td></td>
</tr>
</tbody>
</table>

Location

- Pulmonary
- Renal
- Hepatic
- Splenic
- Limb
- Other
- Unknown

Confirmation source

- Standard clinical and laboratory testing
- Operative findings
- Autopsy finding
- Other
- Unknown

Anticoagulant therapy at time of event

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bivalirudin
- Fondaparinux
- Dextran
- Ticlopidine
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify
### Hypertension
- **New-onset blood pressure elevation greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump).**
- [ ] Yes
- [ ] No
- [ ] Unknown

#### Date of event

<table>
<thead>
<tr>
<th>Date of event</th>
<th>unknown</th>
</tr>
</thead>
</table>

### Hepatic Dysfunction
- **An increase in any two of the following hepatic laboratory values (total bilirubin, AST, and ALT) to a level greater than 3 times the upper limit of normal for the hospital, beyond 14 days post-implant (or if hepatic dysfunction is the primary cause of death).**
- [ ] Yes
- [ ] No
- [ ] Unknown

#### Date of event

<table>
<thead>
<tr>
<th>Date of event</th>
<th>MM/DD/YYYY</th>
<th>unknown</th>
</tr>
</thead>
</table>

#### Total bilirubin measurement
- [ ] Unknown
- [ ] Not Done

#### SGOT // AST measurement
- [ ] Unknown
- [ ] Not Done

#### SGPT // ALT measurement
- [ ] Unknown
- [ ] Not Done

### Psychiatric Episode
- **Disturbance in thinking, emotion or behavior that causes substantial impairment in functioning or marked subjective distress and requires intervention. Intervention is the addition of new psychiatric medication, hospitalization, or referral to a mental health professional for treatment. Suicide is included in this definition.**
- [ ] Yes
- [ ] No
- [ ] Unknown

#### Date of event

<table>
<thead>
<tr>
<th>Date of event</th>
<th>MM/DD/YYYY</th>
<th>unknown</th>
</tr>
</thead>
</table>

#### The psychiatric event should be classified according to the DSM 5 classification: (select one)
- [ ] Axis I: Clinical disorders, including anxiety disorders, mood disorders, schizophrenia and other psychotic disorders.
- [ ] Axis II: Personality disorders and mental retardation.
- [ ] Axis III: General medical conditions.
- [ ] Axis IV: Psychosocial and environmental problems.
- [ ] Unknown

### Pericardial Effusion
- **Did a pericardial effusion that required drainage occur?**
- [ ] Yes
- [ ] No
- [ ] Unknown

#### Date of event

<table>
<thead>
<tr>
<th>Date of event</th>
<th>unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Signs of tamponade</strong></td>
<td>○ Yes</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------</td>
</tr>
<tr>
<td><strong>Method of drainage</strong></td>
<td>○ Surgical intervention</td>
</tr>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td>○ Yes</td>
</tr>
</tbody>
</table>

Did a myocardial infarction occur?

<table>
<thead>
<tr>
<th><strong>Date of event</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ST = ○ Unknown</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Other events** | ○ Yes | ○ No | ○ Unknown |

Did any other major serious adverse event occur?

<table>
<thead>
<tr>
<th><strong>Description</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Major Serious Adverse Event. An event that causes clinically relevant changes in the patient's health (e.g. cancer).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Date of event</strong></th>
<th>MM/DD/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST = ○ Unknown</td>
<td></td>
</tr>
</tbody>
</table>
Intermacs

Adverse Event

Explant

Was device explanted for any reason (includes exchanges or "turned off")?
- Yes
- No

Explant date
ST= Unknown

Device explanted
- LVAD

Did patient suffer major hemolysis related solely to this device?
- Yes
- No
- Unknown

Patient's Home Street Address
ST= Unknown
- Undisclosed

Patient's Home City
ST= Unknown
- Undisclosed

Patient's Home State/Territory/Province
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Federated States of Micronesia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Marshall Islands
- Maryland
- Massachusetts
- Michigan
Patient's Home Zip Code

Explant reason
- Explant - Death
- Explant - Transplanted
- Explant - Exchange
- Explant - No new device
- Turned off (decommissioned)

Explant reasons
- Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
Exchanged Device FDA IDE Trial
If device was exchanged, was the new device part of an FDA IDE trial?
- Yes
- No
- Unknown

Name of FDA IDE Trial

Explant reasons
Check all that apply
- Recovery
- Withdrawal of Support
- Device Malfunction: Elective
- Device Malfunction: Emergent
- Device Thrombosis: Elective
- Device Thrombosis: Emergent
- Infection: Elective
- Infection: Emergent
- Other

Reasons
Check all that apply
- Recovery
- Withdrawal of Support
- Device Malfunction: Elective
- Device Malfunction: Emergent
- Device Thrombosis: Elective
- Device Thrombosis: Emergent
- Infection: Elective
- Infection: Emergent
- Other

Evidence of Pump Thrombosis?
If yes, please fill out the Device Malfunction/Thrombosis form
- Yes
- No
- Unknown

Evidence of Pump Thrombosis?
If yes, please fill out the Device Malfunction/Thrombosis form
- Yes
- No
- Unknown

Transplant date
ST=

Waitlist ID
May enter ‘99999’, when the waitlist ID number is not known.
## Death

**Did the patient die?**
- [ ] Yes
- [ ] No

**Death date**
- **MM/DD/YYYY**
  - ST = Unknown

**Patient’s Home Street Address**
- ST = Unknown
- [ ] Undisclosed

**Patient’s Home City**
- ST = Unknown
- [ ] Undisclosed

**Patient’s Home State/Territory/Province**
- [ ] Alabama
- [ ] Alaska
- [ ] American Samoa
- [ ] Arizona
- [ ] Arkansas
- [ ] California
- [ ] Colorado
- [ ] Connecticut
- [ ] Delaware
- [ ] District of Columbia
- [ ] Federated States of Micronesia
- [ ] Florida
- [ ] Georgia
- [ ] Guam
- [ ] Hawaii
- [ ] Idaho
- [ ] Illinois
- [ ] Indiana
- [ ] Iowa
- [ ] Kansas
- [ ] Kentucky
- [ ] Louisiana
- [ ] Maine
- [ ] Marshall Islands
- [ ] Maryland
- [ ] Massachusetts
- [ ] Michigan
- [ ] Minnesota
- [ ] Mississippi
- [ ] Missouri
- [ ] Montana
- [ ] Nebraska
- [ ] Nevada
- [ ] New Hampshire
Patient's Home Zip Code

ST= Unknown

Was device functioning normally?

- Yes
- No
- Unknown

Associated Operation

Was there an operation associated with the device malfunction?

- Yes
- No
- Unknown

Post mortem device explant?

- Yes
- No
- Unknown

Did the device go to the manufacturer?

- Yes
- No
- Unknown
<table>
<thead>
<tr>
<th>Location of death</th>
<th>☐ In hospital</th>
<th>☐ Out of hospital</th>
<th>☐ Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing of death</td>
<td>☐ Expected</td>
<td>☐ Unexpected</td>
<td>☐ Unknown</td>
</tr>
<tr>
<td>Did COVID-19 contribute to death?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ Unknown</td>
</tr>
<tr>
<td>Primary cause of death</td>
<td>☐ Respiratory: Venous Thromboembolism Event</td>
<td>☐ Respiratory: Respiratory Failure</td>
<td>☐ Respiratory: COVID-19</td>
</tr>
<tr>
<td></td>
<td>☐ Respiratory: Pulmonary: Other, specify</td>
<td>☐ Circulatory: Arterial Non-CNS Thromboembolism</td>
<td>☐ Circulatory: Myocardial Infarction</td>
</tr>
<tr>
<td></td>
<td>☐ Circulatory: Myocardial Rupture</td>
<td>☐ Circulatory: Ruptured Aortic aneurysm</td>
<td>☐ Circulatory: Right Heart Failure</td>
</tr>
<tr>
<td></td>
<td>☐ Circulatory: Major Bleeding</td>
<td>☐ Circulatory: Cardiac Arrhythmia</td>
<td>☐ Circulatory: Hemolysis</td>
</tr>
<tr>
<td></td>
<td>☐ Circulatory: Hypertension</td>
<td>☐ Circulatory: Other, Specify</td>
<td>☐ Circulatory: Sudden unexplained death</td>
</tr>
<tr>
<td></td>
<td>☐ Circulatory: CHF</td>
<td>☐ Circulatory: Heart Disease</td>
<td>☐ Circulatory: End Stage Cardiomyopathy</td>
</tr>
<tr>
<td></td>
<td>☐ Circulatory: End Stage Ischemic Cardiomyopathy</td>
<td>☐ Circulatory: Pericardial Fluid Collection (effusion)</td>
<td>☐ Digestive (Intestinal or GI/GU): Hepatic Dysfunction</td>
</tr>
<tr>
<td></td>
<td>☐ Digestive (Intestinal or GI/GU): Renal Dysfunction</td>
<td>☐ Digestive (Intestinal or GI/GU): GI Disorder</td>
<td>☐ Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder</td>
</tr>
<tr>
<td></td>
<td>☐ Digestive (Intestinal or GI/GU): Pancreatitis</td>
<td>☐ Nervous System: Neurological Dysfunction</td>
<td>☐ Psychiatric Episode/Suicide</td>
</tr>
<tr>
<td></td>
<td>☐ Major Infection</td>
<td>☐ Device Malfunction</td>
<td>☐ Withdrawal of Support, specify</td>
</tr>
<tr>
<td></td>
<td>☐ Cancer</td>
<td>☐ Wound Dehiscence</td>
<td>☐ Trauma/accident, specify</td>
</tr>
<tr>
<td></td>
<td>☐ Endocrine</td>
<td>☐ Hematological</td>
<td>☐ Other, specify</td>
</tr>
</tbody>
</table>

| Select type of cancer      | ☐ CNS                       | ☐ GI                         | ☐ Lymph                     |
|                           | ☐ ENT                       | ☐ Pulmonary                  | ☐ Renal                     |
|                           | ☐ Breast                    | ☐ Reproductive               | ☐ Skin                      |
|                           |                            |                               |                            |
Adverse Event Death

- Specify support withdrawn
- Specify

☐ Other
☐ Unknown
Exchange of extracorporeal/paracorporeal pumps and pump components. Please use this form when only extracorporeal/paracorporeal pump components (i.e. cannulaes, and pumps) are exchanged. If components/pump are exchanged in the surgery suite and/or the pump is exchanged to a different device brand (i.e Maquet to Berlin Heart) then please fill out the device explant form and enter a new device and do not fill out this form.

**Extracorporeal / Paracorporeal Pump Change**

**Was there an extracorporeal pump/component exchange?**
- Yes
- No

**Pump/Component Exchange Date:**
Enter exchange date in MMDDYYYY format.

ST= Unknown

**Device Type:**
- LVAD
- RVAD
- BIVAD

**Component Exchanged:**
Select all that apply. Note: not all components are applicable to all devices.
- Pump
- Inflow Cannula Parts (not requiring OR visit)
- Outflow Cannula Parts (not requiring OR visit)
- Driving Tube Connector
- Other, specify

**RVAD Component Exchanged:**
Select all that apply. Note: not all components are applicable to all devices.
- Pump
- Inflow Cannula Parts (not requiring OR visit)
- Outflow Cannula Parts (not requiring OR visit)
- Driving Tube Connector
- Other, specify

**Reason for Exchange**
Select one of the following.
- Thrombus NOT associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters (please enter Device Malfunction Form)
- Upsizing device because of patient growth status
- Other, specify
# Hemolysis

Must be within 30 days of event

<table>
<thead>
<tr>
<th>Was there a hemolysis adverse event?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**If yes, select type**

- **Minor Hemolysis**  A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant in the absence of clinical symptoms or findings of hemolysis or abnormal pump function (see Major Hemolysis for a list of symptoms and findings) and thought not attributable to laboratory error.
- **Major Hemolysis**  A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant and associated with clinical symptoms or findings of hemolysis or abnormal pump function.

**If major hemolysis, select condition**

Major Hemolysis requires the presence of at least one of these conditions Note: Isolated LDH elevations should not be reported as hemolysis if attributable to laboratory error, hepatic or pulmonary dysfunction. If suspected, confirmatory testing of LDH, LDH isoenzymes and plasma-free hemoglobin within 24 hours should be obtained to rule out laboratory error. All causes of hemolysis should be reported regardless of whether they are thought attributable to the device or not.

- **Hemoglobinuria**  tea-colored urine
- **Anemia**  hematocrit <= 25 or hemoglobin <= 8 not explained by chronic illness or usual post-VAD state
- **Hyperbilirubinemia**  total bilirubin above 2 mg/dl, with predominately indirect component
- **Pump malfunction and/or abnormal pump parameters as per section on device malfunction**

The association of the hemolysis event should be classified as (select one):

- **Patient related**  e.g., hematologic abnormalities
- **Management related**  e.g., drug related, secondary pump or IABP related, pump malposition
- **Device related**  e.g., related to pump thrombosis or device malfunction
- **No association identified**

**Date of Event**

| MM/DD/YYYY | ST= | Unknown |

**Please enter the peak Plasma-free hemoglobin (PFH).**

| ST= | Unknown | Not Done |

**What is your hospital's upper limit of the normal range for peak PFH?**

| ST= | Unknown | Not Done |

**Please enter the peak serum lactate dehydrogenase (LDH).**

<p>| ST= | Unknown | Not Done |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>ST.</th>
<th>Unknown</th>
<th>Not Done</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is your hospital’s upper limit of the normal range of LDH?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. HCT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max. HCT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. HGB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max. HGB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Highest Total Bilirubin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Adverse Event

## Right Heart Failure

<table>
<thead>
<tr>
<th>Was there a Right Heart Failure Adverse Event?</th>
<th>☐ Yes</th>
<th>☐ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MM/DD/YYYY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST= Unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, select type</td>
<td>☐ Early post-implant RHF</td>
<td>☐ Late RHF</td>
</tr>
<tr>
<td>One of the following clinical findings or is associated with one of the following manifestations:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early post-implant RHF: Select category</td>
<td>☐ Need for implantation of a temporary or durable RVAD (including ECMO) within 30 days following LVAD implantation for any duration of time</td>
<td>☐ Initiation or continuation of inotropic or vasopressor support or inhaled nitric oxide after 14 days following LVAD implantation or having to initiate this support within 30 days of implant for a duration of at least 14 days</td>
</tr>
<tr>
<td>If late RHF, select category</td>
<td>☐ Need for implantation of an RVAD (including ECMO) greater than 30 days after an LVAD implantation</td>
<td>This may occur within the index hospitalization for LVAD implant or during subsequent rehospitalization for any diagnosis which resulted in a need for temporary or permanent right-sided mechanical assist devices</td>
</tr>
</tbody>
</table>

The primary diagnosis of right heart failure is made by the presence of at least two of the following clinical findings or is associated with at least one of the following manifestations:

**Initiation or continuation of inotropic or vasopressor support clinical findings**

- ☐ Ascites
- ☐ Functionally limiting peripheral edema >= 2
- ☐ Elevated estimated jugular venous pressure (>= 6cm) at least half way up the neck in an upright patient or hepatomegaly (>= 3cm below costal margin)
- ☐ Elevated measured central venous pressure (CVP) or right atrial pressure (RAP) (>= 16mmHg)

**Initiation or continuation of inotropic or vasopressor support manifestations**

- ☐ Renal failure with serum creatinine > 2x baseline values
- ☐ Liver injury with an elevation of at least 2x upper limit normal in AST/ALT or total bilirubin > 2.0
- ☐ SvO2 < 50%
- ☐ Cardiac index < 2.2 liter/min/m²
- ☐ Reduction in pump flow of > 30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax
- ☐ Elevated lactate > 3.0 mmol/liter

**Death clinical findings**

- ☐ Ascites
<table>
<thead>
<tr>
<th>Check all that are present</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Functionally limiting peripheral edema &gt;= 2</td>
</tr>
<tr>
<td>☐ Elevated estimated jugular venous pressure (&gt;= 6cm) at least half way up the neck in an upright patient or hepatomegaly (&gt;3 cm below costal margin)</td>
</tr>
<tr>
<td>☐ Elevated measured central venous pressure (CVP) or right atrial pressure (RAP) (&gt;= 16mmHg)</td>
</tr>
</tbody>
</table>

**Death manifestations**

<table>
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<tr>
<th>Check all that are present</th>
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<tbody>
<tr>
<td>☐ Renal failure with serum creatinine &gt; 2x baseline values</td>
</tr>
<tr>
<td>☐ Liver injury with an elevation of at least 2x upper limit normal in AST/ALT or total bilirubin &gt; 2.0</td>
</tr>
<tr>
<td>☐ SvO2 &lt; 50%</td>
</tr>
<tr>
<td>☐ Cardiac index &lt; 2.2 liter/min/m2</td>
</tr>
<tr>
<td>☐ Reduction in pump flow of &gt; 30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax</td>
</tr>
<tr>
<td>☐ Elevated lactate &gt; 3.0 mmol/liter</td>
</tr>
</tbody>
</table>

**Hospitalization clinical findings**

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<td>☐ Ascites</td>
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<tr>
<td>☐ Functionally limiting peripheral edema &gt;= 2</td>
</tr>
<tr>
<td>☐ Elevated estimated jugular venous pressure (&gt;= 6cm) at least half way up the neck in an upright patient or hepatomegaly (&gt;3 cm below costal margin)</td>
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**Hospitalization manifestations**

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<td>☐ Reduction in pump flow of &gt; 30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax</td>
</tr>
<tr>
<td>☐ Elevated lactate &gt; 3.0 mmol/liter</td>
</tr>
</tbody>
</table>

**The association of the RHF event should be classified as**

- **Patient related** e.g., pre-implant RHF, volume overload secondary to non-adherence with medical management, severe aortic regurgitation, cardiorenal syndrome, arrhythmia induced, pulmonary disease, elevated pulmonary vascular resistance
- **Management related** e.g., related to implant surgery, volume overload, inotropic agent withdrawal
- **Device related** e.g., associated with Pump malfunction, outflow graft compromise
- **No association identified**
## Adverse Event Renal Dysfunction

<table>
<thead>
<tr>
<th>Was there a Renal Dysfunction adverse event?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, select type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Renal Dysfunction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic Renal Dysfunction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>An increase in serum creatinine of 2 mg/dl or greater above baseline, or requirement for renal replacement therapy, either of which is sustained for at least 90 days</td>
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<td></td>
</tr>
<tr>
<td>If acute, select stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase in serum creatinine to 150% to 199% (1.5 to 1.99x increase compared with baseline) or increase of &gt; 0.3 mg/dl (&gt; 26.4 mmol/liter) or urine output &lt; 0.5 ml/kg/h for &gt; 6 but &lt; 12 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase in serum creatinine to 200% to 299% (2.0 to 2.99x increase compared with baseline) or urine output &lt; 0.5 ml/kg/h for &gt; 12 but &lt; 24 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase in serum creatinine to &gt; 300% (&gt; 3x increase compared with baseline) or serum creatinine of &gt; 4.0 mg/dl (&gt; 354 mmol/liter) with an acute increase of at least 0.5 mg/dl (44 mmol/liter) or urine output &lt; 0.3 ml/kg/h for &gt; 24 hours or anuria for &gt; 12 hours or need for renal replacement therapy (includes dialysis or ultrafiltration) regardless of above criteria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If stage 1, Select all that apply</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase in serum creatinine to 150% to 199% (1.5 to 1.99x increase compared with baseline)</td>
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<tr>
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<td>Urine output &lt; 0.5 ml/kg/h for &gt; 6 but &lt; 12 hours</td>
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<tr>
<td>If stage 2, Select all that apply</td>
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<td>Urine output &lt; 0.5 ml/kg/h for &gt; 12 but &lt; 24 hours</td>
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<tr>
<td>If stage 3, Select all that apply</td>
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<td>Urine output &lt;0.3 ml/kg/h for &gt;24 hours</td>
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<tr>
<td>Anuria for &gt;12 hours</td>
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</tr>
<tr>
<td>Need for renal replacement therapy (includes dialysis or ultrafiltration) regardless of above criteria</td>
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<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Date of event</th>
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<tbody>
<tr>
<td>MM/DD/YYYY</td>
<td></td>
</tr>
<tr>
<td>ST= Unknown</td>
<td></td>
</tr>
</tbody>
</table>

The association of the renal dysfunction event should be classified as follows

- Patient related e.g., non-adherence to medical therapy resulting in renal dysfunction
- Management related e.g., overprescribing of diuretic therapy or administration of renal toxic drugs or contrast agents that result in renal dysfunction
- Device related e.g., device failure resulting in renal dysfunction
- No association identified