Adverse Event - Intermacs

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>Question</th>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was there an occurrence of rehospitalization?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Is this rehospitalization at your hospital?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Date of admission**

ST= Unknown

**Discharge Date**

ST= Unknown

**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
<table>
<thead>
<tr>
<th>Rehospitalization intervention</th>
<th>Surgical Procedure</th>
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<tbody>
<tr>
<td></td>
<td>Heart Cath</td>
</tr>
<tr>
<td></td>
<td>Invasive Cardiac Procedures (Other than Heart Cath)</td>
</tr>
<tr>
<td></td>
<td>Transplantation</td>
</tr>
<tr>
<td></td>
<td>None</td>
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<tr>
<td></td>
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<td></td>
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<table>
<thead>
<tr>
<th>Type of surgical procedure</th>
<th>Device related operation</th>
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<tbody>
<tr>
<td></td>
<td>Other Cardiac Surgical Procedure</td>
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<td></td>
<td>Non Cardiac Surgical Procedure</td>
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<td>Other procedure</td>
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<table>
<thead>
<tr>
<th>Type of other cardiac procedure</th>
<th>Reoperation for Bleeding within 48 hours of implant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reoperation for Bleeding and/or tamponade &gt; 48 hours</td>
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<tr>
<td></td>
<td>Surgical Drainage of pericardial effusion</td>
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<tr>
<td></td>
<td>Aortic Valve Surgery - Repair (no valve closure)</td>
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<td></td>
<td>Aortic Valve Surgery - Repair with valve closure</td>
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<tr>
<td></td>
<td>Aortic Valve Surgery - Replacement - Biological</td>
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<tr>
<td></td>
<td>Aortic Valve Surgery - Replacement - Mechanical</td>
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<td>Mitral Valve Surgery - Repair</td>
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<td>Mitral Valve Surgery - Replacement - Biological</td>
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<td>Tricuspid Valve Surgery - Repair - DeVega</td>
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<td>Tricuspid Valve Surgery - Repair - Ring</td>
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<td>Tricuspid Valve Surgery - Repair - Other</td>
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<td>Tricuspid Valve Surgery – Replacement - Biological</td>
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<td>Tricuspid Valve Surgery – Replacement - Mechanical</td>
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<table>
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<tr>
<th>Type of procedure (non cardiac surgical procedure)</th>
<th>Other procedure</th>
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<tr>
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<td>Intubation and Vent support</td>
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<tr>
<td></td>
<td>Dialysis</td>
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<td>Bronchoscopy</td>
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<td></td>
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<table>
<thead>
<tr>
<th>Type of Invasive Cardiac Procedure (Other than Heart Cath)</th>
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Adverse Event - Rehospitalization

version date: 06/28/2018

3 of 24
Clinical Observations

**Enter PA systolic pressure**

[ ] mmHg

- ST= [ ] Unknown
- ST= [ ] Not Done

**Enter PA diastolic pressure**

[ ] mmHg

- ST= [ ] Unknown
- ST= [ ] Not Done

**Enter PCW pressure**

[ ] mmHg

- ST= [ ] Unknown
- ST= [ ] Not Done

**Enter Cardiac output**

[ ] L/min

- ST= [ ] Unknown
- ST= [ ] Not Done

**Systolic blood pressure**

[ ] mmHg

- ST= [ ] Unknown
- ST= [ ] Not done

**Diastolic blood pressure**

[ ] mmHg

- ST= [ ] Unknown
- ST= [ ] Not done

**Doppler Opening Pressure**

[ ]

- ST= [ ] Unknown
- ST= [ ] Not done
- ST= [ ] Not applicable

**Has the patient experienced a Neurological Event since time of implant?**

- Yes
- No
- Unknown

If yes, you may enter either the Modified Rankin Scale and/or the NIH Stroke Scale.

**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

- ST= [ ] Not Documented
- ST= [ ] Not Done
NIH Stroke Scale

- 0: No Stroke
- 1-4: Minor Stroke
- 5-15: Moderate Stroke
- 16-20: Moderate to Severe Stroke
- 21-42: Severe Stroke

ST= ☐ Not Documented
    ☐ Not Done
### Adverse Event - Infection

<table>
<thead>
<tr>
<th><strong>Was there a major infection?</strong></th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
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<tbody>
<tr>
<td><strong>Date of onset</strong></td>
<td></td>
<td></td>
<td>ST= Unknown</td>
</tr>
<tr>
<td><strong>Did this infection contribute to death?</strong></td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Location of patient</strong></td>
<td>In hospital</td>
<td>Out of hospital</td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Location of infection</strong></td>
<td>Pump / related - Drive Line</td>
<td>Pump / related - Exit Cannula</td>
<td>Pump / related - Pump Pocket</td>
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<tr>
<td><strong>Type of infection</strong></td>
<td>Bacterial</td>
<td>Fungal</td>
<td>Viral</td>
</tr>
<tr>
<td><strong>Was drug therapy an intervention for this AE?</strong></td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
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<tr>
<td><strong>If yes, what was the route?</strong></td>
<td>IV</td>
<td>Oral</td>
<td>Topical</td>
</tr>
<tr>
<td><strong>Was surgery an intervention for this AE?</strong></td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
</tbody>
</table>
Is this a Device Related Event?

- Yes
- No

Adverse Event - Infection

version date: 06/28/2018
### Adverse Event - Intermacs

#### Bleeding

**Was there a Major Bleeding Event?**
- Yes
- No
- Unknown

**Date of bleeding episode onset**

ST = Unknown

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

**Did the major bleeding episode result in one or more of the following**
- Episode resulted in Death
- Episode resulted in re-operation
- Episode resulted in rehospitalization
- Episode resulted in transfusion

**Total units PRBC**

ST = Unknown

**Date of first transfusion for this episode**

ST = Unknown

**Source/cause/location of bleeding**
- Mediastinal: chest wall
- Mediastinal: outflow-aorta anastomosis
- Mediastinal: outflow conduit
- Mediastinal: inflow conduit
- Mediastinal: aortic-venous cannulation site
- Mediastinal: coagulopathy with no surgical site
- Mediastinal: other surgical site
- Pump pocket
- Mediastinal: Unspecified
- Pleural space
- Intra-abdominal
- Retroperitoneal
- Pulmonary
- Device anastomosis
- Urinary tract
- GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel)
- GI: Lower gastrointestinal (colon, rectum, and anus)
- GI: unknown, but guaiac positive stools
- ENT/Dental
- Other, specify

**INR**

ST = Unknown
- Not Done
<table>
<thead>
<tr>
<th>Anticoagulant therapy at time of event</th>
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<tbody>
<tr>
<td>☐ Warfarin</td>
</tr>
<tr>
<td>☐ Heparin</td>
</tr>
<tr>
<td>☐ Lovenox</td>
</tr>
<tr>
<td>☐ Aspirin</td>
</tr>
<tr>
<td>☐ Dipyridamole</td>
</tr>
<tr>
<td>☐ Clopidogrel (plavix)</td>
</tr>
<tr>
<td>☐ Argatroban</td>
</tr>
<tr>
<td>☐ Bivalirudin</td>
</tr>
<tr>
<td>☐ Fondaparinux</td>
</tr>
<tr>
<td>☐ Dextran</td>
</tr>
<tr>
<td>☐ Ticlopidine</td>
</tr>
<tr>
<td>☐ Hirudin</td>
</tr>
<tr>
<td>☐ Lepirudin</td>
</tr>
<tr>
<td>☐ Ximelagatran</td>
</tr>
<tr>
<td>☐ None</td>
</tr>
<tr>
<td>☐ Other, specify</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is this a Device Related Event?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>
## Neuro

**Was there a neurological dysfunction?**
- Yes
- No
- Unknown

**Date of onset**
ST=
- Unknown

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

**Neurological dysfunction categories**
- TIA
- Confusion
- CVA
- Seizure
- Encephalopathy

**Type of CVA**
- Ischemic / Embolism
- Hemorrhagic
- Other

**Stroke severity**
- Left sided weakness
- Right sided weakness
- Left sided paralysis
- Right sided paralysis
- Speech deficit
- Altered mental status
- Coma
- Other, specify

**Is this a Device Related Event?**
- Yes
- No

**Seizure Type**
- Generalized
- Focal

**Encephalopathy type**
- Metabolic
- Anoxic
- Traumatic
- Other

**Did this Neurological Dysfunction Adverse Event contribute to the patient’s death?**
- Yes
- No
- Unknown

**Location of CNS event**
- Right hemisphere: frontal
- Right hemisphere: temporal
| Right hemisphere: occipital |
| Right hemisphere: parietal |
| Right hemisphere: unspecified |
| Left hemisphere: frontal |
| Left hemisphere: temporal |
| Left hemisphere: occipital |
| Left hemisphere: parietal |
| Left hemisphere: unspecified |
| Bilateral: frontal |
| Bilateral: temporal |
| Bilateral: occipital |
| Bilateral: parietal |
| Occipital |
| Brain stem |
| Cerebellar |
| Thalamic |
| Unknown |
| Other, specify |

**Method of diagnosis of CNS event**

- CT
- MRI
- Angiogram
- Clinical
- Unknown
- Other, specify

**Anticoagulant therapy at time of event**

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bivalirudin
- Fondaparinux
- Dextran
- Ticlopidine
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify

**Has the patient experienced a Neurological Event since time of implant?**

- Yes
- No
- Unknown

**Modified Rankin Scale**

- 0 - No symptoms at all
- 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
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5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
6 - Dead

NIH Stroke Scale

0: No Stroke
1-4: Minor Stroke
5-15: Moderate Stroke
16-20: Moderate to Severe Stroke
21-42: Severe Stroke

ST= Not Documented
Not Done
# Device Malf/Failure and/or Pump Thrombus

**Was there a device malfunction / failure and / or a pump thrombus?**
- Yes
- No
- Unknown

**Date of onset**

**Device Type**

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

**Description of Malfunction**

---

# Thrombus Event

**Did the patient experience a thrombus event (suspected or confirmed)?**
- Yes
- No
- Unknown

**Was the suspected or confirmed thrombus associated with one or more of the following signs or symptoms?**
- Hemolysis
- Heart Failure
- Abnormal Pump Parameters
- Stroke
- TIA
- Arterial Non-CNS Thromboembolism
- None
- Other, Specify

**Did the patient have one or more of the following?**
- Treatment with intravenous anticoagulation (e.g. heparin)
- Intravenous thrombolytic (e.g. TPA)
- Intravenous antiplatelet therapy (e.g. eptifibatide)
- Other, Specify

**Was the thrombus event confirmed?**
- Yes
- No
- Unknown

**Please select method of confirmation:**
- Imaging Study
- Visual Inspection
- Manufacturer's Report
Was there a device Malfunction?  
- Yes  
- No  
- Unknown

Please select all of the components that apply

### Pump
- Yes  
- No

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

### 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)

### 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
## Outcomes of Device Adverse Event

### Patient Outcome
- Death
- Serious Injury
- Urgent Transplantation
- Explant Without Replacement
- Exchange
- Breach of Integrity of Drive Line that Required Repair
- Other Surgical Procedure
- None of the Above

### Causative or contributing factors to the Device Malfunction
- Patient Accident
- Patient Non-Compliance
- Sub Therapeutic Anticoagulation
- Prothrombotic States
- End of Component Expected Life
- Technical and/or Procedural Issues (e.g. cannula or graft malposition or kinking)
- No Cause Identified
### Adverse Event - Additional Events

**Were there any additional adverse events?**
- Yes
- No

**Cardiac Arrhythmia**
- Yes
- No
- Unknown

**Event Date**
- ST = Unknown

**Type of cardiac arrhythmia**
- Sustained ventricular arrhythmia requiring defibrillation or cardioversion
- Sustained supraventricular arrhythmia requiring drug treatment or cardioversion
- Unknown

**Pericardial Effusion**
- Yes
- No
- Unknown

**Event Date**
- ST = Unknown

**Signs of tamponade**
- Yes
- No
- Unknown

**Method of drainage**
- Surgical intervention
- Cath
- Unknown

**Hepatic Dysfunction**
- Yes
- No
- Unknown

**Total bilirubin measurement**
- mg/dL
- ST = Unknown
- Not Done

**SGOT // AST measurement**
- u/L
- ST = Unknown
- Not Done

**SGPT // ALT measurement**
- u/L
- ST = Unknown
- Not Done

**Event Date**
- ST = Unknown
**Myocardial Infarction**
- Yes
- No
- Unknown

Event Date

**Psychiatric Episode**
- Yes
- No
- Unknown

Event Date

**Renal Dysfunction**
- Yes
- No
- Unknown

Event Date

Dialysis duration

Peak creatinine measurement

**Respiratory Failure**
- Yes
- No
- Unknown

Event Date

Intubation duration

Was a trachooetomy performed?

**Arterial Non-CNS Thromboembolism**
- Yes
- No
- Unknown
<table>
<thead>
<tr>
<th>Location</th>
<th>Pulmonary</th>
<th>Renal</th>
<th>Hepatic</th>
<th>Splenic</th>
<th>Limb</th>
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<tbody>
<tr>
<td>Confirmation source</td>
<td>Standard clinical and laboratory testing</td>
<td>Operative findings</td>
<td>Autopsy finding</td>
<td>Other</td>
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<tr>
<td>Anticoagulant therapy at time of event</td>
<td>Warfarin</td>
<td>Heparin</td>
<td>Lovenox</td>
<td>Aspirin</td>
<td>Dipyridamole</td>
<td>Clopidogrel (plavix)</td>
<td>Argatroban</td>
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<tr>
<td>Venous Thromboembolism Event</td>
<td>Deep Vein thrombosis</td>
<td>Pulmonary Embolus</td>
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<tr>
<td>Other, specify</td>
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<table>
<thead>
<tr>
<th>Wound Dehiscence</th>
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<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
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<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST= Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enter location:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sternum</td>
</tr>
<tr>
<td>Driveline Sites</td>
</tr>
<tr>
<td>Site of thoracotomy</td>
</tr>
<tr>
<td>Other, specify</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST= Unknown</td>
</tr>
</tbody>
</table>
# Adverse Event - Intermacs

## Explant

**Was Device Explanted for any reason (includes exchanges or "turned off")?**
- [ ] Yes
- [ ] No

**Explant date**

**ST=**  [ ] Unknown

## Device explanted

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

**Explant reasons (check all that apply)**
- [ ] Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- [ ] Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
- [ ] Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
- [ ] Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
- [ ] Infection: Elective (Please fill out Infection form)
- [ ] Infection: Emergent (Please fill out Infection form)
- [ ] Other

## Exchanged Device FDA IDE Trial

**Exchanged Device FDA IDE Trial**
- [ ] Yes
- [ ] No
- [ ] Unknown

**Name of FDA IDE Trial**

**Explant reasons (check all that apply)**
- [ ] Recovery
- [ ] Withdrawal of Support
- [ ] Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- [ ] Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
- [ ] Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
- [ ] Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
- [ ] Infection: Elective (Please fill out Infection form)
- [ ] Infection: Emergent (Please fill out Infection form)
- [ ] Other
**Reasons (check all that apply)**

- Recovery
- Withdrawal of Support
- Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
- Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
- Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
- Infection: Elective (Please fill out Infection form)
- Infection: Emergent (Please fill out Infection form)
- Other

**Evidence of Pump Thrombosis?**

- Yes
- No
- Unknown

**Evidence of Pump Thrombosis?**

- Yes
- No
- Unknown

**Transplant date**

ST= Unknown

**Waitlist ID**
### Death

<table>
<thead>
<tr>
<th>Question</th>
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</thead>
<tbody>
<tr>
<td>Did the patient die?</td>
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<td></td>
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<td>Death date</td>
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<tr>
<td>Was device functioning normally?</td>
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<tr>
<td>Unknown</td>
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<td></td>
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<tr>
<td>Associated Operation</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
<tr>
<td>Post mortem device explant?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the device go to the manufacturer?</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
<tr>
<td>Location of death</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>In hospital</td>
<td></td>
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</tr>
<tr>
<td>Out of hospital</td>
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<td></td>
</tr>
<tr>
<td>Unknown</td>
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</tr>
<tr>
<td>Timing of death</td>
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</tr>
<tr>
<td>Expected</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Unexpected</td>
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</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Primary cause of death

- Respiratory: Venous Thromboembolism Event
- Respiratory: Respiratory Failure
- Respiratory: Pulmonary: Other, specify
- Circulatory: Arterial Non-CNS Thromboembolism
- Circulatory: Myocardial Infarction
- Circulatory: Myocardial Rupture
- Circulatory: Ruptured Aortic aneurysm
- Circulatory: Right Heart Failure
- Circulatory: Major Bleeding
- Circulatory: Cardiac Arrhythmia
- Circulatory: Hemolysis
- Circulatory: Hypertension
- Circulatory: Other, Specify
- Circulatory: Sudden unexplained death
- Circulatory: CHF
- Circulatory: Heart Disease
- Circulatory: End Stage Cardiomyopathy
- Circulatory: End Stage Ischemic Cardiomyopathy
- Circulatory: Pericardial Fluid Collection (effusion)
- Digestive (Intestinal or GI/GU): Hepatic Dysfunction
- Digestive (Intestinal or GI/GU): Renal Dysfunction
- Digestive (Intestinal or GI/GU): GI Disorder
- Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder
- Digestive (Intestinal or GI/GU): Pancreatitis
- Nervous System: Neurological Dysfunction
- Psychiatric Episode/Suicide
- Major Infection
- Device Malfunction
- Multiple System Organ Failure (MSOF)
- Withdrawal of Support, specify
- Cancer
- Wound Dehiscence
- Trauma/accident, specify
- Endocrine
- Hematological
- Other, specify

Select type of cancer

- CNS
- GI
- Lymph
- ENT
- Pulmonary
- Renal
- Breast
- Reproductive
- Skin
- Other
- Unknown

Specify support withdrawn
Specify