Adverse Event - Pedimacs

Rehospitalization

Was there an occurrence of rehospitalization?
- Yes
- No

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
- Other, specify
- Pericardial Fluid Collection
- Planned medical management
- Planned Procedure
- Pneumonia
- Psychiatric Episode
- Pulmonary Embolism/Hemorrhage
- Pulmonary, Other
- Renal Dysfunction
- Respiratory Failure
- Right Heart Failure
- Social Issues / Disposition (Foster Care / Eviction)
- Syncope without known cause
- Transplant
- Trauma/Accident
Rehospitalization intervention

- None
- Transplantation
- Surgical Procedure
- Heart Cath
- Invasive Cardiac Procedures (Other than Heart Cath)
- 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 - Repair (no valve closure)
- Aortic Valve Surgery - Repair with valve closure
- Aortic Valve Surgery - Replacement - Biological
- Aortic Valve Surgery - Replacement - Mechanical
- 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
- Pulmonary Valve Surgery - Repair
- Pulmonary Valve Surgery – Replacement - Biological
- Pulmonary Valve Surgery – Replacement - Mechanical
- Other, specify
- Unknown

Type of procedure (non cardiac surgical procedure)

Other procedure

- Intubation and Vent support
- Dialysis
- Bronchoscopy
- Other, specify

Type of Invasive Cardiac Procedure (Other than Heart Cath)

Enter PA systolic pressure: mmHg

ST= Unknown
- Not Done
Enter PA diastolic pressure ____ mmHg
ST= ● Unknown
  ○ Not Done

Enter PCW pressure ____ mmHg
ST= ● Unknown
  ○ Not Done

Enter Cardiac output ____ L/min
ST= ● Unknown
  ○ Not Done

Clinical Observations

Systolic blood pressure ____ mmHg
ST= ● Unknown
  ○ Not done

Diastolic blood pressure ____ mmHg
ST= ● Unknown
  ○ Not done

Mean Arterial Blood Pressure (MAP) ____ mmHg
ST= ● Unknown
  ○ Not done

Did patient receive new IV or oral medications to treat hypertension? ○ Yes
  ○ No
  ○ Unknown

Has the patient experienced a Neurological Event since time of implant? ○ Yes
  ○ No
  ○ Unknown

If yes, please enter the Modified Rankin 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
  ○ Not Done
# Adverse Event - Pedimacs

## Infection

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was there a major infection?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Date of onset</td>
<td></td>
</tr>
<tr>
<td>ST= Unknown</td>
<td></td>
</tr>
<tr>
<td>Did this infection contribute to death?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Location of patient</td>
<td>In hospital, Out of hospital, Unknown</td>
</tr>
<tr>
<td>Location of infection</td>
<td>Pump / related - Drive Line, Pump / related - Exit Cannula, Pump / related - Pump Pocket, Pump / related - Pump Interior, Positive Blood cultures, Line Sepsis, Pulmonary, Urinary Tract, Mediastinum, Peripheral Wound, GI, Unknown, Other, specify</td>
</tr>
<tr>
<td>Type of infection</td>
<td>Bacterial, Fungal, Viral, Protozoan, Unknown</td>
</tr>
<tr>
<td>Intervention</td>
<td>Drug therapy only: Oral, Drug therapy only: IV, Surgical and drug therapy, Surgical therapy only, Unknown</td>
</tr>
<tr>
<td>Is this a Device Related Event?</td>
<td>Yes, No</td>
</tr>
</tbody>
</table>
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 (select all that apply):
- Hydroxychloroquine
- Azithromycin
- Immunoglobulin
- Anti-viral therapy
- None
- Other, Specify

Anti-viral therapy, specify:

If yes, did the patient have an associated bacterial lung infection?  
- Yes
- No
- Unknown
## Adverse Event - Pedimacs

**Bleeding** *(Transfusions for anemia and hemolysis are not considered bleeding events)*

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was there a Major Bleeding Event?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Date of bleeding episode onset</td>
<td>[ ] Unknown</td>
</tr>
<tr>
<td>Location of patient</td>
<td>In hospital, Out of hospital, Unknown</td>
</tr>
<tr>
<td>Did the major bleeding episode result in one or more of the following</td>
<td>Episode resulted in Death, Episode resulted in re-intervention, Episode resulted in hospitalization, Episode resulted in transfusion</td>
</tr>
<tr>
<td>Total units PRBC's (Enter total number of cc's received for this bleeding episode)</td>
<td>[ ] Unknown</td>
</tr>
<tr>
<td>Date of first transfusion for this episode</td>
<td>[ ] Unknown</td>
</tr>
<tr>
<td>Source/cause/location of bleeding</td>
<td>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, 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, Other, specify</td>
</tr>
<tr>
<td>Heparin levels</td>
<td>[ ] Unknown</td>
</tr>
<tr>
<td>INR</td>
<td>[ ] Not Done</td>
</tr>
</tbody>
</table>

6/17/2020

Adverse Event Bleeding
Adverse Event Bleeding

ST=  
- Unknown
- Not Done

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

**Is this a Device Related Event?**
- Yes
- No
# Adverse Event - Pedimacs

## Neuro

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was there a neurological dysfunction?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Date of onset</td>
<td>ST= Unknown</td>
</tr>
<tr>
<td>Location of patient</td>
<td>In hospital, Out of hospital, Unknown</td>
</tr>
<tr>
<td>Neurological dysfunction categories</td>
<td>TIA, CVA, Seizure, Encephalopathy, Infarction Seen by Imaging, without Clinical Findings of TIA/Stroke, Extra-axial Bleeding Seen by imaging study, Confusion, None</td>
</tr>
<tr>
<td>Type of CVA</td>
<td>Ischemic / Embolism, Hemorrhagic, Other</td>
</tr>
<tr>
<td>Stroke severity</td>
<td>Left sided weakness, Right sided weakness, Left sided paralysis, Right sided paralysis, Speech deficit, Altered mental status, Coma, Other, specify</td>
</tr>
<tr>
<td>Is this a Device Related Event?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Seizure Type</td>
<td>Generalized, Focal</td>
</tr>
<tr>
<td>Encephalopathy type</td>
<td>Metabolic, Anoxic, Traumatic, Other</td>
</tr>
<tr>
<td>Did this Neurological Dysfunction Adverse Event contribute to the patient's death?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Method of diagnosis of CNS event</td>
<td>CT</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticoagulant therapy at time of event</td>
<td>Warfarin</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>Yes</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified Rankin Scale</td>
<td>0 - No symptoms at all</td>
</tr>
</tbody>
</table>
- 1 - No Significant disability
- 2 - Slight disability
- 3 - Moderate disability
- 4 - Moderately severe disability
- 5 - Severe disability
- 6 - Dead

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

## Device Malf/Failure and/or Pump Thrombus

<table>
<thead>
<tr>
<th>Was there a device malfunction / failure and / or a pump thrombus?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
</tr>
</tbody>
</table>

### Description of Malfunction


### Date of onset


### Device Type

<table>
<thead>
<tr>
<th>Location of patient</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>In hospital</td>
<td></td>
</tr>
<tr>
<td>Out of hospital</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
</tr>
</tbody>
</table>

## Thrombus Event

### Did the patient experience a thrombus event (suspected or confirmed)?

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

### 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?

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

### 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**
- 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

<table>
<thead>
<tr>
<th>Patient Outcome</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td></td>
</tr>
<tr>
<td>Serious Injury</td>
<td></td>
</tr>
<tr>
<td>Urgent Transplantation</td>
<td></td>
</tr>
<tr>
<td>Explant Without Replacement</td>
<td></td>
</tr>
<tr>
<td>Exchange</td>
<td></td>
</tr>
<tr>
<td>Breach of Integrity of Drive Line that Required Repair</td>
<td></td>
</tr>
<tr>
<td>Other Surgical Procedure</td>
<td></td>
</tr>
<tr>
<td>None of the Above</td>
<td></td>
</tr>
</tbody>
</table>

### Causative or contributing factors to the Device Malfunction

<table>
<thead>
<tr>
<th>Causative or contributing factors to the Device Malfunction</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Accident</td>
<td></td>
</tr>
<tr>
<td>Patient Non-Compliance</td>
<td></td>
</tr>
<tr>
<td>Sub Therapeutic Anticoagulation</td>
<td></td>
</tr>
<tr>
<td>Prothrombotic States</td>
<td></td>
</tr>
<tr>
<td>End of Component Expected Life</td>
<td></td>
</tr>
<tr>
<td>Technical and/or Procedural Issues (e.g. cannula or graft malposition or kinking)</td>
<td></td>
</tr>
<tr>
<td>No Cause Identified</td>
<td></td>
</tr>
</tbody>
</table>
## Adverse Event - Pedimacs

### Additional Adverse Events

- **Were there any additional adverse events?**
  - [ ] Yes
  - [x] 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
- [ ] OP
- [ ] 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
<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>Event Date</th>
<th>ST=</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric Episode</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dialysis duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak creatinine measurement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intubation duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was a tracheotomy performed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial Non-CNS Thromboembolism</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Date

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

Confirmation source
- Standard clinical and laboratory testing
- Operative findings
- Autopsy findings
- 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

Venous Thromboembolism Event
- Deep Vein thrombosis
- Pulmonary Embolus
- Other, specify
- Unknown
- None

Enter deep vein thrombosis date

Enter pulmonary embolus date

Enter other date
**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
- No
- Unknown

**Date**

ST= Unknown

**Enter location:**

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

---

**Other Events**

- Yes
- No
- Unknown

**Description**


**Event Date**

ST= Unknown
Adverse Event - Pedimacs

**Explant**

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

Explant date  

ST=  
- Unknown

Device explanted  
- LVAD

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  
- 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
## Adverse Event - Pedimacs

### Death

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the patient die?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Death date</td>
<td>Unknown</td>
</tr>
<tr>
<td>Was device functioning normally?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Associated Operation</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Post mortem device explant?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Did the device go to the manufacturer?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Location of death</td>
<td>In hospital, Long term care facility, Home/Residence, Out of hospital, Other, Unknown</td>
</tr>
<tr>
<td>Did COVID-19 contribute to death?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>Primary cause of death</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>☐ Respiratory: Venous Thromboembolism Event</td>
<td></td>
</tr>
<tr>
<td>☐ Respiratory: Respiratory Failure</td>
<td></td>
</tr>
<tr>
<td>☐ Respiratory: COVID-19</td>
<td></td>
</tr>
<tr>
<td>☐ Respiratory: Pulmonary: Other, specify</td>
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</tr>
<tr>
<td>☐ Circulatory: Arterial Non-CNS Thromboembolism</td>
<td></td>
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<tr>
<td>☐ Circulatory: Myocardial Infarction</td>
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<tr>
<td>☐ Circulatory: Myocardial Rupture</td>
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<tr>
<td>☐ Circulatory: Ruptured Aortic aneurysm</td>
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<tr>
<td>☐ Circulatory: Right Heart Failure</td>
<td></td>
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<tr>
<td>☐ Circulatory: Major Bleeding</td>
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<tr>
<td>☐ Circulatory: Cardiac Arrhythmia</td>
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<tr>
<td>☐ Circulatory: Hemolysis</td>
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<tr>
<td>☐ Circulatory: Hypertension</td>
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<tr>
<td>☐ Circulatory: Other, Specify</td>
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<tr>
<td>☐ Circulatory: Sudden unexplained death</td>
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<tr>
<td>☐ Circulatory: CHF</td>
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<tr>
<td>☐ Circulatory: Heart Disease</td>
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<tr>
<td>☐ Circulatory: End Stage Cardiomyopathy</td>
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<tr>
<td>☐ Circulatory: End Stage Ischemic Cardiomyopathy</td>
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<tr>
<td>☐ Circulatory: Pericardial Fluid Collection (effusion)</td>
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<tr>
<td>☐ Digestive (Intestinal or GI/GU): Hepatic Dysfunction</td>
<td></td>
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<tr>
<td>☐ Digestive (Intestinal or GI/GU): Renal Dysfunction</td>
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<tr>
<td>☐ Digestive (Intestinal or GI/GU): GI Disorder</td>
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</tr>
<tr>
<td>☐ Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder</td>
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<tr>
<td>☐ Digestive (Intestinal or GI/GU): Pancreatitis</td>
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<tr>
<td>☐ Nervous System: Neurological Dysfunction</td>
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<tr>
<td>☐ Psychiatric Episode/Suicide</td>
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<tr>
<td>☐ Major Infection</td>
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<tr>
<td>☐ Device Malfunction</td>
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<tr>
<td>☐ Multiple System Organ Failure (MSOF)</td>
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<tr>
<td>☐ Withdrawal of Support, specify</td>
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</tr>
<tr>
<td>☐ Cancer</td>
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<tr>
<td>☐ Wound Dehiscence</td>
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<tr>
<td>☐ Trauma/accident, specify</td>
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<tr>
<td>☐ Endocrine</td>
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<tr>
<td>☐ Hematological</td>
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<table>
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<tr>
<th>Select type of cancer</th>
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<tbody>
<tr>
<td>☐ CNS</td>
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<tr>
<td>☐ GI</td>
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<tr>
<td>☐ Lymph</td>
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<tr>
<td>☐ ENT</td>
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<tr>
<td>☐ Pulmonary</td>
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<tr>
<td>☐ Renal</td>
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<tr>
<td>☐ Breast</td>
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<td>☐ Reproductive</td>
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<tr>
<td>☐ Skin</td>
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<tr>
<td>☐ Other</td>
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<tr>
<td>☐ Unknown</td>
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</table>

<table>
<thead>
<tr>
<th>Specify support withdrawn</th>
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</thead>
</table>
Specify
# Adverse Event

## Extracorporeal / Paracorporeal Pump Change

| Was there an extracorporeal pump/component exchange? | ○ Yes  
| ○ No |

| Pump/Component Exchange Date: |       |
| ST= ○ Unknown |

| Device Type: | ○ LVAD  
| ○ RVAD  
| ○ BIVAD |

| Component Exchanged: | ○ Pump  
| ○ Inflow Cannula Parts (not requiring OR visit)  
| ○ Outflow Cannula Parts (not requiring OR visit)  
| ○ Driving Tube Connector  
| ○ Other, specify |

| RVAD Component Exchanged: | ○ Pump  
| ○ Inflow Cannula Parts (not requiring OR visit)  
| ○ Outflow Cannula Parts (not requiring OR visit)  
| ○ Driving Tube Connector  
| ○ Other, specify |

| Reason for Exchange | ○ 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 |