Adverse Event Status

Please enter the date of the event you are reporting:

Please enter a label describing this event:

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[PediMACS]
# Adverse Event - Pedimacs 03/25/2022

## 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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field</th>
<th>Input</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of admission</td>
<td></td>
<td>ST= Unknown</td>
</tr>
<tr>
<td>Discharge Date</td>
<td></td>
<td>ST= Unknown</td>
</tr>
</tbody>
</table>

## 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
### Adverse Event Rehospitalization

- [ ] Unknown
- [ ] Venous Thromboembolic Event
- [ ] Wound Complication
- [ ] Wound Dehiscence

#### 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)

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

#### Other procedure

- [ ] Unknown
- [ ] Not Done

#### Type of Invasive Cardiac Procedure (Other than Heart Cath)

- [ ]

#### Enter PA systolic pressure

- [ ] mmHg
### Enter PA diastolic pressure

<table>
<thead>
<tr>
<th>mmHg</th>
</tr>
</thead>
</table>

- **ST**:
  - Unknown
  - Not Done

### Enter PCW pressure

<table>
<thead>
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<th>mmHg</th>
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</thead>
</table>

- **ST**:  
  - Unknown
  - Not Done

### Enter Cardiac output

<table>
<thead>
<tr>
<th>L/min</th>
</tr>
</thead>
</table>

- **ST**:  
  - Unknown
  - Not Done

### Clinical Observations

#### Systolic blood pressure

<table>
<thead>
<tr>
<th>mmHg</th>
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</thead>
</table>

- **ST**:  
  - Unknown
  - Not done

#### Diastolic blood pressure

<table>
<thead>
<tr>
<th>mmHg</th>
</tr>
</thead>
</table>

- **ST**:  
  - Unknown
  - Not done

#### Mean Arterial Blood Pressure (MAP)

<table>
<thead>
<tr>
<th>mmHg</th>
</tr>
</thead>
</table>

- **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 03/25/2022

Infection

Was there a major infection?
- Yes
- No
- Unknown

Date of onset
- [ ]

ST= [ ] Unknown

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

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

Location of infection
- 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

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

Intervention
- Drug therapy only: Oral
- Drug therapy only: IV
- Surgical and drug therapy
- Surgical therapy only
- Unknown

Is this a Device Related Event?
- Yes
- No
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the patient test positive for COVID-19?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>If yes, select all symptoms that apply:</td>
<td>Cough, Diarrhea, Fever, Anosmia (loss of sense of smell), Sore Throat, Difficulty Breathing, None, Other, Specify</td>
</tr>
<tr>
<td>If yes, select all interventions that apply:</td>
<td>Intubation, New Inotropes, ECMO, Dialysis, RVAD, None, Other, Specify</td>
</tr>
<tr>
<td>If yes, select all therapies the patient received (select all that apply):</td>
<td>Hydroxychloroquine, Azithromycin, Immunoglobulin, Anti-viral therapy, None, Other, Specify</td>
</tr>
<tr>
<td>Anti-viral therapy, specify:</td>
<td></td>
</tr>
<tr>
<td>If yes, did the patient have an associated bacterial lung infection?</td>
<td>Yes, No, Unknown</td>
</tr>
</tbody>
</table>
## 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></td>
</tr>
<tr>
<td>ST=</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></td>
</tr>
<tr>
<td>ST=</td>
<td>Unknown</td>
</tr>
<tr>
<td>Date of first transfusion for this episode</td>
<td></td>
</tr>
<tr>
<td>ST=</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></td>
</tr>
<tr>
<td>ST=</td>
<td>Unknown, Not Done</td>
</tr>
<tr>
<td>INR</td>
<td></td>
</tr>
</tbody>
</table>
### 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 03/25/2022

## Neuro

<table>
<thead>
<tr>
<th>Was there a neurological dysfunction?</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

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

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

## Neurological dysfunction categories

- TIA
- CVA
- Seizure
- Encephalopathy
- Infarction Seen by Imaging, without Clinical Findings of TIA/Stroke
- Extra-axial Bleeding Seen by imaging study
- Confusion
- None

### 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

<table>
<thead>
<tr>
<th>Is this a Device Related Event?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### Seizure Type

- Generalized
- Focal

### Encephalopathy type

- Metabolic
- Anoxic
- Traumatic
- Other

<table>
<thead>
<tr>
<th>Did this Neurological Dysfunction Adverse Event contribute to the patient's death?</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>


| 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 |
|                                      | □ Subdural |
|                                      | □ Spinal cord |
|                                      | □ Unknown |
|                                      | □ Other, specify |

| Method of diagnosis of CNS event      | □ CT |
|                                      | □ MRI |
|                                      | □ Angiogram |
|                                      | □ Clinical |
|                                      | □ EEG |
|                                      | □ Ultrasound |
|                                      | □ 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 |

| Hypertension                          | □ Yes |
|                                       | □ No |
|                                       | □ Unknown |

| Modified Rankin Scale                  | □ 0 - No symptoms at all |
1 - No Significant disability
2 - Slight disability
3 - Moderate disability
4 - Moderately severe disability
5 - Severe disability
6 - Dead

ST= Not Documented
Not Done

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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**
- [ ] 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>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Death</td>
</tr>
<tr>
<td>☐ Serious Injury</td>
</tr>
<tr>
<td>☐ Urgent Transplantation</td>
</tr>
<tr>
<td>☐ Explant Without Replacement</td>
</tr>
<tr>
<td>☐ Exchange</td>
</tr>
<tr>
<td>☐ Breach of Integrity of Drive Line that Required Repair</td>
</tr>
<tr>
<td>☐ Other Surgical Procedure</td>
</tr>
<tr>
<td>☐ None of the Above</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>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Patient Accident</td>
</tr>
<tr>
<td>☐ Patient Non-Compliance</td>
</tr>
<tr>
<td>☐ Sub Therapeutic Anticoagulation</td>
</tr>
<tr>
<td>☐ Prothrombotic States</td>
</tr>
<tr>
<td>☐ End of Component Expected Life</td>
</tr>
<tr>
<td>☐ Technical and/or Procedural Issues (e.g. cannula or graft malposition or kinking)</td>
</tr>
<tr>
<td>☐ No Cause Identified</td>
</tr>
</tbody>
</table>

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[PediMACS]
## Additional Adverse Events

### Cardiac Arrhythmia
- **Were there any additional adverse events?**
  - Yes
  - No
- **Event Date**
  - [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
- **Were there any additional adverse events?**
  - Yes
  - No
  - Unknown
- **Event Date**
  - [Date]
  - ST= Unknown

### Signs of tamponade
- **Were there any additional adverse events?**
  - Yes
  - No
  - Unknown

### Method of drainage
- **Were there any additional adverse events?**
  - OP
  - Cath
  - Unknown

### Hepatic Dysfunction
- **Were there any additional adverse events?**
  - Yes
  - No
  - Unknown
- **Total bilirubin measurement**
  - [Value] mg/dL
  - ST= Unknown
  - Not Done
- **SGOT / AST measurement**
  - [Value] u/L
  - ST= Unknown
  - Not Done
- **SGPT / ALT measurement**
  - [Value] u/L
  - ST= Unknown
  - Not Done
- **Event Date**
  - [Date]
  - ST= Unknown
<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
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</thead>
<tbody>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td></td>
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</tr>
<tr>
<td>Event Date</td>
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<td><strong>Psychiatric Episode</strong></td>
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<td>Event Date</td>
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<tr>
<td>ST= Unknown</td>
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</tr>
<tr>
<td><strong>Renal Dysfunction</strong></td>
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<tr>
<td>Event Date</td>
<td></td>
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<tr>
<td>Dialysis duration</td>
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<td>ST= Unknown</td>
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<tr>
<td>Peak creatinine measurement</td>
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<tr>
<td>ST= Unknown</td>
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<td></td>
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<tr>
<td><strong>Respiratory Failure</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Event Date</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Intubation duration</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>ST= Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was a tracheotomy performed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial Non-CNS Thromboembolism</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST= Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Date

ST= ☐ Unknown

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

Venous Thromboembolism Event

☒ Deep Vein thrombosis
☒ Pulmonary Embolus
☐ Other, specify
☐ Unknown
☐ None

Enter deep vein thrombosis date

ST= ☐ Unknown

Enter pulmonary embolus date

ST= ☐ Unknown

Enter other date

ST= ☐ Unknown
<table>
<thead>
<tr>
<th>Anticoagulant therapy at time of event</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heparin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lovenox</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Dipyridamole</td>
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</tr>
<tr>
<td>Clopidogrel (plavix)</td>
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</tr>
<tr>
<td>Argatroban</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bivalirudin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fondaparinux</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Dextran</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ticlopidine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hirudin</td>
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<td>Lepirudin</td>
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<tr>
<td>Ximelagatran</td>
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<tr>
<td>Other, specify</td>
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<tr>
<th>Wound Dehiscence</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>Date</td>
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<tr>
<td>ST=</td>
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<tr>
<th>Enter location:</th>
<th>Sternum</th>
<th>Driveline Sites</th>
<th>Site of thoracotomy</th>
<th>Other, specify</th>
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</table>

<table>
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<tr>
<th>Other Events</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
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</thead>
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<tr>
<td>Description</td>
<td></td>
<td></td>
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<tr>
<td>Event Date</td>
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<td>ST=</td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
</tbody>
</table>
Adverse Event - Pedimacs 03/25/2022

Explant

Was Device Explanted for any reason (includes exchanges or "turned off")?

- Yes
- No

Explant date

ST= Unknown

Device explanted

- LVAD

Patient's Home Street Address

ST= Unknown

Patient's Home City

ST= Unknown

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
Patient's Home Zip Code

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**
Death

Did the patient die?  
- Yes
- No

Death date
- Unknown

Patient's Home Street Address
- Unknown

Patient's Home City
- Unknown

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
Adverse Event Death

- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Palau
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virgin Islands
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming
- Alberta
- Ontario
- Nova Scotia
- British Columbia
- Manitoba
- Quebec
- New Brunswick
- Prince Edward Island
- Saskatchewan
- Newfoundland and Labrador
- Unknown

**Patient’s Home Zip Code**

ST= Unknown

**Was device functioning normally?**

- Yes
- No
- Unknown

**Associated Operation**

- Yes
- No
- Unknown

**Post mortem device explant?**

- Yes
- No
- Unknown
**Did the device go to the manufacturer?**
- Yes
- No
- Unknown

**Location of death**
- In hospital
- Long term care facility
- Home/Residence
- Out of hospital, Other
- Unknown

**Did COVID-19 contribute to death?**
- Yes
- No
- Unknown

**Primary cause of death**
- Respiratory: Venous Thromboembolism Event
- Respiratory: Respiratory Failure
- Respiratory: COVID-19
- 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
Adverse Event - Pedimacs 03/25/2022

**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

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