Adverse Event - Pedimacs 03/25/2022

Blank View

Adverse Event Status

Please enter the date of the event you are reporting:

Please enter a label describing this event:

Adverse Event - Pedimacs 03/25/2022

Blank View

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

- 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)

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 03/25/2022

Blank View

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

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 03/25/2022

Blank View

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

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-intervention
- ☐ Episode resulted in hospitalization
- ☐ Episode resulted in transfusion

Total units PRBC's (Enter total number of cc's received for this bleeding episode)

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
- ☐ Pleural space
- ☐ Intra-abdominal
- ☐ Retroperitoneal
- ☐ Pulmonary
- ☐ Device anastamosis
- ☐ 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

Heparin levels

ST= ○ Unknown
○ Not Done

INR

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 03/25/2022

Blank View

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
- 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

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
- [ ] 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

Adverse Event - Pedimacs 03/25/2022

Blank View

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

- [ ] Patient Cable
- [ ] System Monitor / Display
- [ ] Battery Charger
- [ ] Battery Clip

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 - Pedimacs 03/25/2022

Blank View

Additional Adverse 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
- 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

Myocardial Infarction
- Yes
- No
- Unknown

Event Date

ST= Unknown

Psychiatric Episode
- Yes
- No
- Unknown

Event Date

ST= Unknown

Renal Dysfunction
- Yes
- No
- Unknown

Event Date

ST= Unknown

Dialysis duration days

ST= Unknown
- Not Done
- Ongoing

Peak creatinine measurement mg/dL

ST= Unknown
- Not Done

Respiratory Failure
- Yes
- No
- Unknown

Event Date

ST= Unknown
- Ongoing

Intubation duration days

ST= Unknown
- Ongoing

Was a tracheotomy performed?
- Yes
- No
- Unknown

Arterial Non-CNS Thromboembolism
- Yes
- No
- Unknown

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

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 03/25/2022

Blank View

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

- Nebraska
- Nevada
- New Hampshire
- 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

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 03/25/2022

Blank View

Death

Did the patient die?
- Yes
- No

Death date

ST= Unknown

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
- Nebraska
- Nevada
- New Hampshire

- 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

Blank View

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