Adverse Event - Pedimacs 11/07/2024

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 11/07/2024

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 11/07/2024

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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 11/07/2024

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 11/07/2024

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 11/07/2024

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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

- [ ] 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 11/07/2024

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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 11/07/2024

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Explant

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

- Yes
- No

Explant date

ST= Unknown

Device explanted

- LVAD
- RVAD
- BIVAD
- TAH

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

If death or transplant occurred post cessation of MCSD support please complete the 1 year post cessation form.

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

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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 11/07/2024

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