Adverse Event

Adverse Event Status

Please enter the date of the event you are reporting:

Please enter a label describing this event:

Adverse Event

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Infection

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

Date of onset
MM/DD/YYYY

ST= ○Unknown

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

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

Location of infection
Check all that apply
- ☐ 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

Was drug therapy an intervention for this AE?
- ○ Yes
- ○ No
- ○ Unknown

If yes, what was the route?
- ○IV
- ○Oral
- ○Topical
- ○Unknown

Was surgery an intervention for this AE?
- ○ Yes
- ○ No
- ○ Unknown

Adverse Event

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Bleeding

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

Date of bleeding episode onset
MM/DD/YYYY

ST= ○Unknown

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

Did the major bleeding episode result in one or more of the following
Select all that apply
- ☐ Episode resulted in Death
- ☐ Episode resulted in re-operation
- ☐ Episode resulted in rehospitalization
- ☐ Episode resulted in transfusion

Total units PRBC

ST= ○Unknown

Date of first transfusion for this episode
MM/DD/YYYY

ST= ○Unknown

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

INR

ST= ○Unknown

○Not Done

Anticoagulant therapy at time of event
Check all that apply
- ☐ Warfarin
- ☐ Heparin
- ☐ Lovenox
- ☐ Aspirin
- ☐ Dipyridamole

- [ ] Clopidogrel (plavix)
- [ ] Argatroban
- [ ] Bivalirudin
- [ ] Fondaparinux
- [ ] Dextran
- [ ] Ticlopidine
- [ ] Hirudin
- [ ] Lepirudin
- [ ] Ximelagatran
- [ ] None
- [ ] Other, specify

Adverse Event

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Neuro

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

Date of onset
MM/DD/YYYY

ST= ○Unknown

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

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

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

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

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
Select all that apply
- ☐ Right hemisphere: frontal
- ☐ Right hemisphere: temporal
- ☐ Right hemisphere: occipital
- ☐ Right hemisphere: parietal
- ☐ Right hemisphere: unspecified
- ☐ Left hemisphere: frontal
- ☐ Left hemisphere: temporal
- ☐ Left hemisphere: occipital
- ☐ Left hemisphere: parietal
- ☐ Left hemisphere: unspecified
- ☐ Bilateral: frontal

- [ ] Bilateral: temporal
- [ ] Bilateral: occipital
- [ ] Bilateral: parietal
- [ ] Occipital
- [ ] Brain stem
- [ ] Cerebellar
- [ ] Thalamic
- [ ] Unknown
- [ ] Other, specify

Method of diagnosis of CNS event

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

Anticoagulant therapy at time of event

Select all that apply

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

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

Note: This applies only to patients who have had a CVA, TIA or Anoxic Brain Injury.

- ○ Yes
- ○ No
- ○ Unknown

If yes, provide 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

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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
MM/DD/YYYY

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

Description of Malfunction
Please briefly describe this device malfunction including what happened, what component was involved, method of diagnosis, intervention(s) if any, and the result.

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?
(Check all that apply)
- ☐ 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?
(Check all that apply)
- ☐ Treatment with intravenous anticoagulation (e.g. heparin)
- ☐ Intravenous thrombolytic (e.g. TPA)
- ☐ Intravenous antiplatelet therapy (e.g. eptifibatide)

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

Please select method of confirmation:
(Check all that apply)
- ☐ Imaging Study
- ☐ Visual Inspection
- ☐ Manufacturer's Report

Was there a device Malfunction?
Did the patient experience a device malfunction (failure of one or more of the components of the MCSD system which either directly causes or could potentially induce a state of inadequate circulatory support or death)?
- ○ 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 / Driver
- ○ Yes
- ○ No

Controller / Driver Component(s)
- ☐ Primary System Failure (running in backup mode)
- ☐ Complete System Failure (primary and backup failure)
- ☐ Power Cable (attached to controller)
- ☐ Power Connectors (attached to controller)

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 Body (including bearings and rotor)
- ☐ Driveline
- ☐ Inflow Cannula
- ☐ Outflow Graft (including bend relief)

Controller (RVAD)
- ○ Yes
- ○ No

- ☐ Primary System Failure (running in backup mode)
- ☐ Complete System Failure (primary and backup failure)
- ☐ Power Cable (attached to controller)
- ☐ Power Connectors (attached to controller)

Peripherals (RVAD)
- ○ Yes
- ○ No

- ☐ External Battery
- ☐ Cell Battery (in controller)
- ☐ Power Module
- ☐ Patient Cable
- ☐ System Monitor / Display
- ☐ Battery Charger
- ☐ Battery Clip

Outcomes of Device Adverse Event

Malfunction / Failure and/or Pump Thrombus

Patient Outcome
(Check all that apply)
- ☐ 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
(Check all that apply)

- ☐ Patient Accident
- ☐ Patient Non-Compliance
- ☐ Sub Therapeutic Anticoagulation
- ☐ Prothrombotic States
- ☐ End of Component Expected Life
- ☐ Technical/Procedural Issues (e.g. cannula or graft malposition or kinking)
- ☐ No Cause Identified

Adverse Event

Delete Adverse Event Form

Other Adverse Events

Were there any other adverse events?
- ○ Yes
- ○ No

Cardiac Arrhythmia
Did a documented arrhythmia result in clinical compromise?
- ○ 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
Did a pericardial effusion that required drainage occur?
- ○ Yes
- ○ No
- ○ Unknown

Event Date
MM/DD/YYYY

ST= ○Unknown

Signs of tamponade
- ○ Yes
- ○ No
- ○ Unknown

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

Hepatic Dysfunction
Did Clinical evidence of liver dysfunction occur beyond 14 days post-implant?
- ○ 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
MM/DD/YYYY

ST= ○Unknown

Myocardial Infarction
Did a myocardial infarction occur?
- ○ Yes
- ○ No
- ○ Unknown

Event Date
MM/DD/YYYY

ST= ○Unknown

Psychiatric Episode
Did a disturbance in thinking, emotion or behaviour that required intervention occur in patient?

○ Yes
○ No
○ Unknown

Event Date
MM/DD/YYYY

ST= ○Unknown

Renal Dysfunction
Did renal dysfunction (by definition) occur?

○ Yes
○ No
○ Unknown

Event Date
MM/DD/YYYY

ST= ○Unknown

Dialysis duration

days

ST= ○Unknown
○Not Done
○Ongoing

Peak creatinine measurement

mg/dL

ST= ○Unknown
○Not Done

Respiratory Failure
Did an impairment of respiratory function requiring intubation or mechanical ventilation occur?

○ Yes
○ No
○ Unknown

Event Date
MM/DD/YYYY

ST= ○Unknown
○Ongoing

Intubation duration

days

ST= ○Unknown
○Ongoing

Was a trachoetomy performed?

○ Yes
○ No
○ Unknown

Arterial Non-CNS Thromboembolism
Did an acute perfusion deficit in any non-cerebrovascular organ system occur?

○ Yes
○ No
○ Unknown

Date
MM/DD/YYYY

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
Check all that apply

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

Venous Thromboembolism Event
Evidence of Venous Thromboemoblic event
Check all that apply

☐ Deep Vein thrombosis
☐ Pulmonary Embolis
☐ Other, specify
☐ Unknown
☐ None

Enter deep vein thrombosis date
MM/DD/YYYY

ST= ○Unknown

Enter pulmonary embolus date
MM/DD/YYYY

ST= ○Unknown

Enter other date
MM/DD/YYYY

ST= ○Unknown

Anticoagulant therapy at time of event
Check all that apply

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

Wound Dehiscence
Did a disruption of the apposed surfaces of surgical incision require surgical repair?

- ○ Yes
- ◉ No
- ○ Unknown

Date
MM/DD/YYYY

ST= ○Unknown

Enter location:

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

Other Events
Did any Other Major Serious Adverse Event occur?

- ○ Yes
- ◉ No
- ○ Unknown

Description
Other Major Serious Adverse Event. An event that causes clinically relevant changes in the patient's health (e.g. cancer).

Event Date
MM/DD/YYYY

ST= ○Unknown

Adverse Event

In Progress | Event Date : 8/8/2014 | Delete Adverse Event Form | Print this Form

Explant

Implied Complete

Explant: For Device Exchange, Recovery, or Transplant
- ○ Yes
- ◉ No

Explant date

ST= ○Unknown

Device explanted

○LVAD

Explant reason

○Transplant
○Device Malfunction - Elective
○Device Malfunction - Emergent
○Device Thrombosis - Elective
○Device Thrombosis - Emergent
○Infection - Emergent
○Infection - Elective
○Ventricular Recovery - Device removed
○Ventricular Recovery - Device not removed but turned off
○Device removed (or turned off) for reasons other than recovery, transplant, or death, Specify

Transplant date

ST= ○Unknown

Waitlist ID

Pump Thrombosis
Did the pump have evidence of pump thrombosis?
- ○ Yes
- ○ No
- ○ Unknown

Exchanged Device FDA IDE Trial
If device was exchanged, was the new device part of an FDA IDE trial?
- ○ Yes
- ○ No
- ○ Unknown

Name of FDA IDE Trial

Adverse Event

In Progress | Event Date : 8/8/2014 | Delete Adverse Event Form | Print this Form

Death

Implied Complete

Did the patient die?
- ○ Yes
- ◉ No

Death date
MM/DD/YYYY

ST= ○Unknown

Was device functioning normally?
- ○ Yes
- ○ No
- ○ Unknown

Associated Operation
Was there an operation associated with the device malfunction?
- ○ 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
- ○ Out of hospital
- ○ Unknown

Timing of death
- ○ Expected
- ○ Unexpected
- ○ Unknown

Primary cause of death
- ○Respiratory: Venous Thromboembolism Event
- ○Respiratory: Respiratory Failure
- ○Respiratory: Pulmonary: Other, specify
- ○Circulatory: Arterial Non-CNS Thromboembolism
- ○Circulatory: Myocardial Infarction
- ○Circulatory: Myocardial Rupture
- ○Circulatory: Ruptured Aortic aneurysm
- ○Circulatory: Right Heart Failure
- ○Circulatory: Major Bleeding
- ○Circulatory: Cardiac Arrhythmia
- ○Circulatory: Hemolysis
- ○Circulatory: Hypertension
- ○Circulatory: Other, Specify
- ○Circulatory: Sudden unexplained death
- ○Circulatory: CHF
- ○Circulatory: Heart Disease
- ○Circulatory: End Stage Cardiomyopathy
- ○Circulatory: End Stage Ischemic Cardiomyopathy
- ○Circulatory: Pericardial Fluid Collection (effusion)
- ○Digestive (Intestinal or GI/GU): Hepatic Dysfunction
- ○Digestive (Intestinal or GI/GU): Renal Dysfunction
- ○Digestive (Intestinal or GI/GU): GI Disorder

○Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder
○Digestive (Intestinal or GI/GU): Pancreatitis
○Nervous System: Neurological Dysfunction
○Psychiatric Episode/Suicide
○Major Infection
○Device Malfunction
○Multiple System Organ Failure (MSOF)
○Withdrawal of Support, specify
○Cancer
○Wound Dehiscence
○Trauma/accident, specify
○Endocrine
○Hematological
○Other, specify

Select type of cancer

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

Specify support withdrawn

Specify