Adverse Event - Intermacs

Adverse Event Status

Please enter the date of the event you are reporting:

Please enter a label describing this event:

Adverse Event - Intermacs

Rehospitalization

Was there an occurrence of rehospitalization?
- Yes
- No

Is this rehospitalization at your hospital?
- 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
- Pericardial Fluid Collection
- Planned medical management
- Planned Procedure
- Pneumonia
- Psychiatric Episode
- Pulmonary Embolism/Hemorrhage
- Pulmonary, Other
- Renal Dysfunction
- Respiratory Failure
- Right Heart Failure
- Syncope without known cause
- Transplant

- Trauma/Accident
- Venous Thromboembolic Event
- Wound Complication
- Wound Dehiscence
- Unknown
- Other, specify

Rehospitalization intervention

- Surgical Procedure
- Heart Cath
- Invasive Cardiac Procedures (Other than Heart Cath)
- Transplantation
- None
- 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
- Unknown
- Other, specify

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

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

Doppler Opening Pressure
ST= Unknown
Not done
Not applicable

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

If yes, you may enter either the Modified Rankin Scale and/or the NIH Stroke 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

NIH Stroke Scale

- 0: No Stroke
- 1-4: Minor Stroke
- 5-15: Moderate Stroke
- 16-20: Moderate to Severe Stroke
- 21-42: Severe Stroke

ST= Not Documented
Not Done

Adverse Event - Intermacs

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

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

Is this a Device Related Event?

- ○ Yes
- ○ No

Adverse Event - Intermacs

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-operation
- Episode resulted in rehospitalization
- Episode resulted in transfusion

Total units PRBC

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
- 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

- [ ] 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 - Intermacs

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
- 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

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
- Unknown
- Other, specify

Method of diagnosis of CNS event

- CT
- MRI
- Angiogram
- Clinical
- 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

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

- Yes
- No
- Unknown

If yes, you may enter either the Modified Rankin Scale and/or the NIH Stroke 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

NIH Stroke Scale

○ 0: No Stroke
○ 1-4: Minor Stroke
○ 5-15: Moderate Stroke
○ 16-20: Moderate to Severe Stroke
○ 21-42: Severe Stroke

ST= ○ Not Documented
○ Not Done

Adverse Event - Intermacs

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 - Intermacs

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
- Surgical intervention
- 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 trachoetomy 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 Embolis
- 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 - Intermacs

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 - Intermacs

Death

Did the patient die?
- Yes
- No

Death date

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
- 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