Adverse Events

Device Malfunction

Was there a device malfunction:
- ❍ Yes
- ❍ No
- ❍ Unknown

Date of event: _____

Was there a device malfunction:
- ❍ In hospital
- ❍ Out of hospital
- ❍ Unknown

Major pump unit involved:
Check all the apply
- ❑ Blood Pump
- ❑ Drive Unit Failure
- ❑ External Control System Failure

Suspected device Thrombosis:
- ❍ Yes
- ❍ No
- ❍ 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: _____

Specific component affected:
Check all the apply
- ❑ External Battery Malfunction specify: _____
- ❑ Internal Battery Malfunction specify: _____
- ❑ External Controller Malfunction specify: _____
- ❑ Internal Controller Malfunction specify: _____
- ❑ Driveline Malfunction specify: _____
- ❑ Inflow Graft Malfunction/Malposition specify: _____
- ❑ Outflow Graft Malfunction/Malposition specify: _____
- ❑ Pump Drive Unit Malfunction specify: _____
- ❑ Inflow Valve specify: _____
- ❑ Outflow Valve specify: _____
- ❑ Volume Compensator Malfunction specify: _____
- ❑ Other Component Malfunction, specify specify: _____

Device malfunction intervention:
Check all that apply

- ❑ Replacement of External Battery
- ❑ Replacement of Internal Battery
- ❑ Replacement of External Controller
- ❑ Replacement of Internal Controller
- ❑ Replacement of Driveline
- ❑ Replacement of Inflow Graft
- ❑ Replacement of Outflow Graft
- ❑ Replacement of Pump
- ❑ Repair of Driveline
- ❑ Replacement of Pump Valve
- ❑ Replacement of Volume Compensator
- ❑ Replacement of Other Component specify: _____
- ❑ Switch from Vented Electric to Pneumatic-mode
- ❑ Other Interventions specify: _____
- ❑ None
- ❑ Unknown

Surgical procedure required:

- ❍ Yes
- ❍ No
- ❍ Unknown

Device explanted:

- ❍ Yes
- ❍ No
- ❍ Unknown

Did this device malfunction adverse event cause patient's death:

- ❍ Yes
- ❍ No
- ❍ Unknown

Causative or contributing factors to the Device Malfunction:
Check all that apply

- ❑ Patient/Device Interaction
- ❑ Medical Management (interaction between health system and patient)
- ❑ Primary Device Malfunction
- ❑ Patient/Disease Related
- ❑ End of Pump Life
- ❑ No specific contributing cause identified

Major Infection

Was there a major infection:

- ❍ Yes
- ❍ No
- ❍ Unknown

Date infection first diagnosed:

Percutaneous Driveline Infection:

- ❍ Yes
- ❍ No
- ❍ Unknown

Location:

- ❍ Superficial Infection
- ❍ Deep Infection

Pocket Infection:

- ❍ Yes
- ❍ No
- ❍ Unknown

Pump and/or Cannula Infection:

- ❍ Yes
- ❍ No
- ❍ Unknown

Predominant organism causing infection: Genus Species:

- ❑ ACINETOBACTER spp
- ❑ ASPERGILLUS
  - ❍ Aspergillus fumigatus
  - ❍ Aspergillus spp
- ❑ BACTEROIDES
  - ❍ Bacteroides spp
  - ❍ Bacteroides fragilis
- ❑ BACILLUS spp
- ❑ CANDIDA
  - ❍ Candida spp
  - ❍ Candida albicans
  - ❍ Candida glabrata
- ❑ CLOSTRIDIUM
  - ❍ Clostridium spp
  - ❍ Clostridium perfringens
- ❑ CORYNEBACTERIUM spp
- ❑ ENTEROBACTER
  - ❍ Enterobacter spp
  - ❍ Enterobacter cloacae
  - ❍ Enterobacter aerogenes
- ❑ ENTEROCOCCUS
  - ❍ Enterococcus spp
  - ❍ Enterococcus faecalis
  - ❍ Enterococcus faecalis VRE
  - ❍ Enterococcus faecium
  - ❍ Enterococcus faecium VRE
- ❑ ESCHERICHIA COLI
- ❑ KLEBSIELLA
  - ❍ Klebsiella spp
  - ❍ Klebsiella pneumoniae
  - ❍ Klebsiella pneumoniae KPC
  - ❍ Klebsiella oxytoca
- ❑ PROTEUS
  - ❍ Proteus spp
  - ❍ Proteus mirabilis
  - ❍ Proteus vulgaris
- ❑ PSEUDOMONAS
  - ❍ Pseudomonas spp
  - ❍ Pseudomonas aeruginosa
- ❑ SERRATIA
  - ❍ Serratia spp
  - ❍ Serratia liquefaciens
  - ❍ Serratia marcescens
- ❑ STAPHYLOCCUS
  - ❍ Staphylococcus aureus (MSSA)
  - ❍ Staphylococcus aureus (MRSA)

- ❍ Staphylococcus Lugdunensis
- ❍ Staphylococcus Warneri
- ❍ Staphylococcus epidermidis
- ❍ Staphylococcus coag-neg, not epidermidis

❑ STENOTROPHOMONAS
- ❍ Stenotrophomonas spp
- ❍ Stenotrophomonas maltophilia

❑ STREPTOCOCCUS
- ❍ Streptococcus spp
- ❍ Streptococcus constellatus group
- ❍ Streptococcus Group B/agalactiae
- ❍ Streptococcus Group C/G
- ❍ Streptococcus Group A/Strep pyogenes
- ❍ Streptococcus pneumonia

❑ OTHER, SPECIFY _____

VAD-related infective endocarditis:

❍ Yes
❍ No
❍ Unknown

Genus Species:

❑ ACINETOBACTER spp

❑ ASPERGILLUS
- ❍ Aspergillus fumigatus
- ❍ Aspergillus spp

❑ BACTEROIDES
- ❍ Bacteroides spp
- ❍ Bacteroides fragilis

❑ BACILLUS spp

❑ CANDIDA
- ❍ Candida spp
- ❍ Candida albicans
- ❍ Candida glabrata

❑ CLOSTRIDIUM
- ❍ Clostridium spp
- ❍ Clostridium perfringens

❑ CORYNEBACTERIUM spp

❑ ENTEROBACTER
- ❍ Enterobacter spp
- ❍ Enterobacter cloacae
- ❍ Enterobacter aerogenes

❑ ENTEROCOCCUS
- ❍ Enterococcus spp
- ❍ Enterococcus faecalis
- ❍ Enterococcus faecalis VRE
- ❍ Enterococcus faecium
- ❍ Enterococcus faecium VRE

❑ ESCHERICHIA COLI

❑ KLEBSIELLA
- ❍ Klebsiella spp
- ❍ Klebsiella pneumoniae
- ❍ Klebsiella pneumoniae KPC
- ❍ Klebsiella oxytoca

❑ PROTEUS

- ❍ Proteus spp
- ❍ Proteus mirabilis
- ❍ Proteus vulgaris

❑ PSEUDOMONAS
- ❍ Pseudomonas spp
- ❍ Pseudomonas aeruginosa

❑ SERRATIA
- ❍ Serratia spp
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- ❍ Streptococcus constellatus group
- ❍ Streptococcus Group B/agalactiae
- ❍ Streptococcus Group C/G
- ❍ Streptococcus Group A/Strep pyogenes
- ❍ Streptococcus pneumonia

❑ OTHER, SPECIFY _____

Bloodstream infection:
- ❍ Yes
- ❍ No
- ❍ Unknown

CVC present:
- ❍ Yes
- ❍ No
- ❍ Unknown

Were there other devices or lines present when the blood cultures were reported positive?:
- ❍ Yes
- ❍ No
- ❍ Unknown

Please list devices:
- ❑ Haemodialysis ports
- ❑ Short term catheter
- ❑ Long term catheter
- ❑ AV fistula
- ❑ Intracardiac devices
- ❑ Pacemaker
- ❑ ICD
- ❑ Other Intravascular catheters
- ❑ PIC/PICC lines
- ❑ Orthopedic prosthesis
- ❑ Hips/knees
- ❑ Other specify: _____

Mediastinitis:

- ❍ Yes
- ❍ No
- ❍ Unknown

Were blood cultures positive with event:

- ❍ Yes
- ❍ No
- ❍ Unknown

Genus Species:

- ❑ ACINETOBACTER spp
- ❑ ASPERGILLUS
  - ❍ Aspergillus fumigatus
  - ❍ Aspergillus spp
- ❑ BACTEROIDES
  - ❍ Bacteroides spp
  - ❍ Bacteroides fragilis
- ❑ BACILLUS spp
- ❑ CANDIDA
  - ❍ Candida spp
  - ❍ Candida albicans
  - ❍ Candida glabrata
- ❑ CLOSTRIDIUM
  - ❍ Clostridium spp
  - ❍ Clostridium perfringens
- ❑ CORYNEBACTERIUM spp
- ❑ ENTEROBACTER
  - ❍ Enterobacter spp
  - ❍ Enterobacter cloacae
  - ❍ Enterobacter aerogenes
- ❑ ENTEROCOCCUS
  - ❍ Enterococcus spp
  - ❍ Enterococcus faecalis
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- ❑ ESCHERICHIA COLI
- ❑ KLEBSIELLA
  - ❍ Klebsiella spp
  - ❍ Klebsiella pneumoniae
  - ❍ Klebsiella pneumoniae KPC
  - ❍ Klebsiella oxytoca
- ❑ PROTEUS
  - ❍ Proteus spp
  - ❍ Proteus mirabilis
  - ❍ Proteus vulgaris
- ❑ PSEUDOMONAS
  - ❍ Pseudomonas spp
  - ❍ Pseudomonas aeruginosa
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- ❍ Streptococcus constellatus group
- ❍ Streptococcus Group B/agalactiae
- ❍ Streptococcus Group C/G
- ❍ Streptococcus Group A/Strep pyogenes
- ❍ Streptococcus pneumonia

❑ OTHER, SPECIFY _____

Location:

❑ VAD-Pocket Involved
❑ Sternal wound/Bone Involved
❑ Other, Source (eg. Esophageal perforation)

Non VAD related infection:

❍ Yes
❍ No
❍ Unknown

Were blood cultures positive with event:

❍ Yes
❍ No
❍ Unknown

Genus Species:

❑ ACINETOBACTER spp
❑ ASPERGILLUS
- ❍ Aspergillus fumigatus
- ❍ Aspergillus spp

❑ BACTEROIDES
- ❍ Bacteroides spp
- ❍ Bacteroides fragilis

❑ BACILLUS spp
❑ CANDIDA
- ❍ Candida spp
- ❍ Candida albicans
- ❍ Candida glabrata

❑ CLOSTRIDIUM
- ❍ Clostridium spp
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❑ CORYNEBACTERIUM spp
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- ❑ ESCHERICHIA COLI
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  - ❍ Streptococcus constellatus group
  - ❍ Streptococcus Group B/agalactiae
  - ❍ Streptococcus Group C/G
  - ❍ Streptococcus Group A/Strep pyogenes
  - ❍ Streptococcus pneumonia
- ❑ OTHER, SPECIFY _____

Type:

- ❍ Pneumonia/Pulmonary
- ❍ Cholecystitis
- ❍ Urinary Tract Infection
- ❍ Clostridium Difficile
- ❍ Other specify: _____

Was the patient known to be penicillin allergic?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Was the organism susceptible to antibiotic therapy?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Was the antibiotic stopped prematurely?:

- ❍ Yes
- ❍ No
- ❍ Unknown

If yes, please choose why:

- ❍ Renal Impairment
- ❍ Hepatic Impairment
- ❍ Allergy to treatment
- ❍ Intolerant/Patient Refused

Check all the apply:

❑ Amikacin	_____ days
❑ Amphotericin	_____ days
❑ Anidulafungin	_____ days
❑ Aztreonam	_____ days
❑ Caspafungin	_____ days
❑ Cefazolin	_____ days
❑ Cefuroxime	_____ days
❑ Ceftazidime	_____ days
❑ Ceftriaxone	_____ days
❑ Cefepime	_____ days
❑ Ceftaroline	_____ days
❑ Ciprofloxacin	_____ days
❑ Co-amox/Clavulanate	_____ days
❑ Daptomycin	_____ days
❑ Ertapenem	_____ days
❑ Flucloxacillin	_____ days
❑ Fluconazole	_____ days
❑ Gentamicin	_____ days
❑ Levofloxacin	_____ days
❑ Linezolid	_____ days
❑ Meropenem	_____ days
❑ Micafungin	_____ days
❑ Pip/Tazobactam	_____ days
❑ Rifampicin	_____ days
❑ Teicoplanin	_____ days
❑ Ticarcillin/Clavulanate	_____ days
❑ Tigecycline	_____ days
❑ TMP/SMX	_____ days
❑ Vancomycin	_____ days
❑ Voriconazole	_____ days
❑ Other	specify: _____

Did the infection resolve completely?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Did the patient remain on oral or IV antibiotics indefinitely or until heart transplantation?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Was surgery an intervention for this AE?:

- ❍ Yes
- ❍ No
- ❍ Unknown

If yes, what kind of surgical intervention was carried out?:

- ❑ Debridement
- ❑ Irrigation of wound
- ❑ VAC pump
- ❑ Transplantation
- ❑ Replacement of new VAD

- ❑ Re-siting of the driveline
- ❑ Other specify: _____

Replacement:
- ❍ Partial Removal
- ❍ Complete Removal

Did the patient die?:
- ❍ Yes
- ❍ No
- ❍ Unknown

Neurological Dysfunction

Was there a neurological dysfunction?:
- ❍ Yes
- ❍ No
- ❍ Unknown

Date of event:

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

Neurological dysfunction categories:
- ❍ TIA
- ❍ Confusion
- ❍ CVA
- ❍ Seizure
- ❍ Encephalopathy

Type of CVA:
- ❍ Ischemic
- ❍ 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

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: _____

Major Bleeding

Was there a major bleeding event?:

- ❍ Yes
- ❍ No
- ❍ Unknown

AN EPISODE OF SUSPECTED INTERNAL OR EXTERNAL BLEEDING THAT RESULTS IN ONE OR MORE OF THE FOLLOWING:

1. Death,
2. Re-operation,
3. Hospitalization,
4. Transfusion of red blood cells

Date of bleeding episode onset:

Location of patient:

- ❍ In hospital
- ❍ Out 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

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: _____

Did the bleeding episode occur during the 1st 7 days post implant?:
- ❍ Yes
- ❍ No

Did the patient receive more than 4 units during any 24 hour period of the bleeding episode?:
- ❍ Yes
- ❍ No

Did the bleeding episode occur 8 or more days post implant?:
- ❍ Yes
- ❍ No

If yes, did the patient receive 1 Or more units during any 24 hour period of the bleeding episode?:
- ❍ Yes
- ❍ No

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: _____

Death

Is the patient deceased?:
- ❍ Yes
- ❍ No

Death date:

Was device functioning normally:
- ❍ Yes
- ❍ No
- ❍ Unknown

Location of death:

- ❍ In hospital
- ❍ Out 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 Arrythmia
- ❍ Circulatory: Hemolysis
- ❍ Circulatory: Hypertension
- ❍ Circulatory: Other specify: _____
- ❍ Circulatory: Sudden unexplained death
- ❍ Circulatory: CHF
- ❍ Circulatory: Heart Disease
- ❍ Circulatory: End Stage Cardiomyopathy
- ❍ Circulatory: Ischemic Cardiomyopathy
- ❍ Circulatory: Pericardial Fluid Collection
- ❍ Digestive: Hepatic Dysfunction
- ❍ Digestive: Renal Dysfunction
- ❍ Digestive: GI Disorder
- ❍ Digestive: Fluid/Electrolyte Disorder
- ❍ Digestive: Pancreatitis
- ❍ Nervous System: Neurological Dysfunction
- ❍ Psychiatric Episode/Suicide
- ❍ Major Infection
- ❍ Device Malfunction
- ❍ MSOF
- ❍ Withdrawal of Support specify: _____
- ❍ Other: Wound Dehiscence
- ❍ Other: Trauma/accident specify: _____
- ❍ Other: Cancer
- ❍ Endocrine
- ❍ Hemotalogical
- ❍ Other specify: _____
- ❍ Cardiovascular, Other specify: _____

Explant

Explant: For Device Exchange, Recovery or Transplant:

- ❍ Yes
- ❍ No

Device Type:

- ❍ LVAD
- ❍ RVAD
- ❍ Both (in the same OR visit)
- ❍ Total Artificial Heart

Explant date: [ ]

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
- ❍ Other specify: _____

Transplant date: [ ]

Waitlist ID: [ ]

Respiratory Failure

Did an impairment of respiratory function requiring reintubation, tracheostomy, or the inability to discontinue ventilator support within six days post-VAD implant?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Date of event: [ ]

Intubation duration: [ ] days

Was a tracheotomy performed:

- ❍ Yes
- ❍ No
- ❍ Unknown

Right Heart Failure

Did the patient have signs or symptoms of Right Heart Failure?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Date of event: [ ]

Indication of SEVERE RIGHT HEART FAILURE:

Implantation of a right ventricular assist device (RVAD) indicates a SEVERE RIGHT HEART FAILURE

Indication of MODERATE RIGHT HEART FAILURE:

Was the patient on IV inotrope therapy or inhaled nitric oxide at 1 week or more post-implant?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Indication of MILD RIGHT HEART FAILURE: The patient must have experienced at least 2 of the questions listed below to constitute MILD RIGHT HEART FAILURE:

Does the patient show evidence of elevated CVP pressure (dilated IVC, IVS with collapse, physical exam – signs of increased jugular venous pressure)?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Does the patient have a CVP or mean RA Pressure greater than 18 mmHg?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Does the patient have ascites or evidence of moderate to severe peripheral edema?:

- ❍ Yes
- ❍ No
- ❍ Unknown

Does the patient have a CI less than 2.3L/min/M^2 (by Swan)?:

- ❍ Yes
- ❍ No
- ❍ Unknown