Patient Name: _____ **VAD Implant Date:** _____

VAD Adverse Events

Indicate any Adverse Events (AE) that occur by checking the box and entering the date.

Scan or click the QR code to visit the VAD Adverse Events webpage.

Hematologic Events

- ☐ Neurological Dysfunction _____
- ☐ Bleeding _____
- ☐ Hemolysis _____

Device Related Events

- ☐ Pump Thrombosis _____
- ☐ Device Malfunction _____

Infection Events

- ☐ Device-Specific Infections _____
- ☐ Non-Device Related Infections _____

End-Organ Failure Events

- ☐ Right Heart Dysfunction _____ (Biventricular Circulation Only)
- ☐ Renal Dysfunction _____
- ☐ Hepatic Dysfunction _____
- ☐ Respiratory Dysfunction _____
- ☐ Vasoplegia _____

Gastrointestinal Events

- ☐ Feeding Intolerance _____
- ☐ Chylothorax _____
- ☐ Necrotizing Enterocolitis (NEC) _____

Inadequate Support

- ☐ Inadequate Hemodynamics After VAD _____
- ☐ Fontan Venous Failure After SVAD _____

Other Events

- ☐ Arrhythmia _____
- ☐ Vascular Injury _____

Top ACTION Registry AEs

Bleeding

Grade 2 &3 bleeding are only collected if patient is >72 hrs post-op.

Grade 2: Bleeding requiring local therapy (e.g., packing, hemostatic agents)
Grade 3: Bleeding requiring PRBC transfusion due to bleeding event, new chest tube or anticoagulation held for >24 hrs after starting
Grade 4: Bleeding leading to invasive procedure anytime after leaving OR

Neurological

*Identified anytime during VAD support. Presentation may be **Overt** (symptoms present) or **Covert** (no exam findings).*

Grade 2: Neurological event requiring no modification in patient management (e.g. no antiepileptic started, no discontinuation or addition of an antithrombotic agent or no change in transplant listing status)
Grade 3: Neurological event resulting in 1 or more of the following modifications in patient management:

- New antiepileptic medication initiated
- Discontinuation of any antithrombotic therapy for >24 hours or addition of a new antithrombotic agent.
- Change in transplant listing status

Grade 4: Neurosurgical or interventional procedure performed

Hemolysis

Plasma free >50, LDH>3X with no other cause. Moderate hemolyzed cells on visualization.

Grade 2: Isolated lab criteria without other clinical findings
Grade 3: Lab criteria met and 1 or more of the following:

- anemia requiring transfusions
- external device component exchange to treat hemolysis

Grade 4: Surgical exchange of an internal component or AKI requiring RRT due to hemolysis

Device Malfunction

Identified as any time the device doesn't meet the manufacturer's specs (excluding routine maintenance). Report all malfunction AEs, even if due to user error or human factors.

Grade 2: Device is functioning properly but either:

- Non-routine alarm or change of power source
- Non -routine replacement or repair of external component

Grade 3: Device not working properly but no clinical symptoms

- Non-routine change of external component of paracorporeal device or intracorporeal pump component

Grade 4:

- Device not working, with symptoms, requiring an external component exchange
- Device not working, with symptoms or internal component exchange (symptoms may or may not be present)

Note: See VAD AE Definintions document for complete details.