

Screening Log - Pedimacs 06/24/2020

Implant Date

Inclusion: Patient must meet all inclusion criteria:

- Patient less than 19 years of age at time of implant
- Patient receives a mechanical circulatory support device (MCSD) which is FDA approved
- Implanted on or after September 19, 2012 (The device does not need to be the first implant for the patient)
- Patient signed informed consent for the registry

Exclusion: Any exclusion will disqualify the patient for entry into PEDIMACS®

- Patient 19 years or older at time of implant (patient should be enrolled in INTERMACS)
- Patient receives an (MCSD) which is not FDA approved
- Patient is incarcerated (prisoner)
- Patient did not sign the informed consent

Device type

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

Device brand

- Berlin Heart EXCOR (paracorporeal)
- HeartWare HVAD
- HeartMate II LVAS
- HeartMate III
- HeartMate IP
- HeartMate VE
- HeartMate XVE
- Micromed DeBakey VAD - Child
- Novacor PC
- Novacor PCq
- Thoratec IVAD
- Thoratec PVAD
- Abiomed AB5000
- Abiomed BVS 5000
- Thoratec Centrimag (Levitronix)
- Thoratec Pedimag
- TandemHeart
- Biomedicus
- Maquet Rotaflow
- Sorin Revolution
- Abiomed Impella 2.5
- Abiomed Impella 5.0
- Abiomed Impella CP
- Abiomed Impella RP
- Other, Specify

Specify brand

Device brand (RVAD)**Specify brand (RVAD)****Age Range**

- 0 to 2
 3 to 4
 5 to 9
 10 to 12
 13 to 15
 16 to 18

Race

- American Indian or Alaska Native
 Asian
 African-American or Black
 Hawaiian or other Pacific Islander
 White
 Unknown / Undisclosed
 Other / none of the above

Ethnicity: Hispanic or Latino

- Yes
 No
 Unknown

Gender

- Male
 Female
 Unknown

Did death occur within 2 days post implant?

- Yes
 No

Is this VAD an investigational device?

- Yes
 No

Is patient involved in a VAD related study?

- Yes
 No
 Unknown

What is the name of the study?**Is this an industry sponsored post approval study?**

- Yes
 No
 Unknown