

Leadless Pacing

DATA COLLECTION TOOL

Site: _____

Study Number: _____

Date of birth: _____

Gender: Male Female

Leadless Pacing

- 1. Cardiac Diagnosis**
- 2. Rhythm Diagnosis**
- 3. Indication for Leadless Pacing**
- 4. Prior Cardiac surgical procedures**
 - Yes
 - i. State type and dates**
 - No
- 5. Reported Genetic mutations**
 - Yes
 - i. State type**
 - No
- 6. Channelopathy**
 - Yes
 - i. State type**
 - No
- 7. Previous Cardiac Rhythm Device**
 - Yes
 - i. Indication for previous Cardiac Rhythm Device**
 - No
- 8. Prior to Leadless Pacemaker:**
 - **ECG results**
 - **Ambulatory monitoring results**
 - i. Longest Pause:**
 - 1. Sinus**
 - 2. Atrioventricular block**
 - ii. Average Heart Rate**
 - iii. Minimum heart rate**
 - iv. Maximum heart rate**
 - **Other monitoring results**
- 9. Autonomic Nervous System testing**
 - Yes
 - i. Type and results**
 - No
- 10. Symptoms prior to Leadless Pacemaker (list each one and its frequency and duration)**
- 11. Medications at time of Leadless pacemaker implantation**
 - **Name and dose**
- 12. Implant Characteristics**

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- **General Anesthesia:**
- [] Yes
 - i. **State type**
- [] No.
 - i. **State Type (Sedation)**

13. Physician

- **Single**
- **More than one physician**
- **Pediatric electrophysiologist**
- **Pediatric and adult electrophysiologist**
- **Adult electrophysiologist**
- **Interventional Cardiologist assisting**
 - i. [] Yes
 - ii. [] No

14. Hospital

- **Children's Hospital**
- **Adult Hospital**

15. Age at Leadless pacemaker implantation: (years)

16. Weight at Leadless pacemaker implantation: (lb)

17. Height at Leadless pacemaker implantation: (cm)

18. Body surface area at Leadless pacemaker implantation: (m²)

19. Prior imaging for femoral vein size : state type and results

20. Prior imaging for right ventricular size: state type and results

21. Echocardiographic results prior to Leadless pacemaker implantation

22. Additional operative or interventional procedure at time of Leadless pacemaker implantation: state type and result

23. Angiographic Femoral vein size: (mm)

24. Angiographic Iliac vein size: (mm)

25. Angiographic IVC size: (mm)

26. Presence of tricuspid valve abnormalities on echocardiogram at time of implant:

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- i. Yes
 - 1. **State type and severity**
- ii. No

27. Utilization of echocardiogram during implantation

- i. Yes
- ii. No

28. Leadless pacemaker implantation procedure total duration _____ in minutes

29. Additional interventional or operative procedures at implant of Leadless pacemaker

- i. Yes
 - 1. **State type and result**
- ii. No

30. Leadless Pacemaker implantation site:

- RV apex
- RV high septum
- RV mid septum
- RV apex
- Other

-specify

31. Number of Leadless Pacemaker tines engaged at implantation

32. Number of Leadless Pacemaker attempts prior to permanent fixation

33. Was Device retrieval with snare or other mechanism necessary?

- i. Yes
 - 1. **State type and outcome**
- ii. No

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34. Fluoroscopy time during implantation of Leadless pacemaker (minutes)

35. Vessel sizes

- **Femoral vein size (mm)**
- **Iliac vein size (mm)**
- **IVC (mm)**

36. Which femoral vein utilized

- **Right**
- **Left**

37. Suture material and method for femoral vein closure

38. Right ventricular volume measurement at time of Leadless pacemaker implantation

- **Absolute in (cc)**
- **Indexed to BSA : (Cc/m²)**
- **State method of measurement**

39. Echocardiographic right ventricular dimension measurement at time of Leadless pacemaker implantation

- **End diastolic (mm)**
- **End systolic (mm)**
- **Fractional area of change (%)**

40. Echocardiographic left ventricular dimensions and function

- **EF(%) and method of measurement**
- **Shortening fraction (%)**
- **End diastolic (mm)**
- **End systolic (mm)**

41. Chest roentgenogram reports after Leadless pacemaker implantation

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42. Echocardiogram reports prior to Leadless pacemaker implantation

43. Complications during procedure

44. Recovery unit after implantation of Leadless pacemaker

45. Days of hospitalization after implantation of leadless pacemaker

46. Prophylactic antibiotic use for implantation of leadless pacemaker

i. Yes

1. State type and duration

ii. No

47. Complications during follow -up in the study period

- Vessel**
- Cardiac**
- Non -cardiac**
- Device Embolization**
- Thromboembolic phenomenon**
- Non procedure related**
- Respiratory**
- Valvular**
- Death**
- Bleeding**
- Hematoma**
- Infection**
- Other**

48. Recommendation to take SBE prophylaxis after leadless pacemaker

i. Yes

1. State duration

ii. No

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- 49. Leadless pacemaker programmed parameters at implantation**
- 50. Leadless pacemaker electrical parameters at implantation**
- 51. Leadless pacemaker electrical parameters at each follow up**
- 52. Leadless pacemaker programmed parameters at each follow up**
- 53. Percentage of ventricular pacing at each follow up**
- 54. Chest roentgenogram reports after Leadless pacemaker implantation**
- 55. Echocardiogram reports after Leadless pacemaker implantation**
- 56. ECG parameters after Leadless pacemaker implantation**
- 57. Ambulatory monitoring results after Leadless pacemaker implantation**
- 58. Symptoms prior to Leadless Pacemaker (list each one and its frequency and duration)**
- 59. Medications after Leadless pacemaker implantation**
 - Name and dose**
- 60. Date of each follow up during study period**
- 61. Date of death and/or transplantation if applicable**