

AVEIR™ Dual Chamber (DR) Leadless Pacemaker System

Category:

Best Medical Technology

Company Name:

Abbott

Product/Solution Name:

AVEIR™ Dual Chamber (DR) Leadless Pacemaker System

Compound/Tech Name:

AVEIR™ Dual Chamber (DR) Leadless Pacemaker System

Trade Name:

ABT

Corporate Name:

Abbott

Date of Approval:

2023-06-29

Indications:

Cardiac arrhythmia relates to a problem with the rate or rhythm of the heartbeat. During an arrhythmia, the heart can either beat too fast, too slow, or in an irregular or erratic rhythm. This can cause symptoms including dizziness or lightheadedness, chest pain, fatigue or weakness, and fainting spells.

Each year, nearly 454,000 hospitalizations occur in the U.S. for people living with cardiac arrhythmia. Pacemakers are designed to keep the heart beating normally. When it senses the lack of a normal heart rhythm, a pacemaker sends an electrical impulse to the heart to re-establish a normal rhythm.

Abbott's AVEIR™ DR is the world's first dual chamber leadless pacemaker system and is revolutionizing the way physicians treat people with slow or irregular heart rhythms by

using the naturally conductive characteristics of the body's blood and tissue to enable communication between the two implanted devices.

Therapeutic Areas:

AVEIR DR directly supports the cardiology space, as it encompasses the study of the heart and cardiovascular system. The device contributes to the advancements in treating arrhythmias and expands treatment options for millions of people.

General Information File Document upload:

N/A

Background information and need for drug / device:

There is an intense global burden for people living with irregular heart rhythms or cardiac arrhythmias, and it is estimated that 12.1 million people in the United States will have cardiac arrhythmias by 2030. To address heart irregularities, people often turn to pacemakers, implanted devices that help people keep their heart beating at a healthy rate.

Traditional pacemakers are battery-powered devices implanted underneath the skin, in the chest area, that deliver electrical impulses to the heart muscle via thin insulated wires, better known as cardiac leads. As a traditional pacemaker is about the size of a hockey puck, it creates a pocket in the chest that is visible.

Leadless pacemakers work like traditional pacemakers to regulate the heart rate, but they reduce lead- and pocket-related complications, offering more long-term freedom from complications. The minimally invasive procedure typically takes less than an hour and has a shorter recovery time than traditional pacemaker implantations, allowing people to go back to enjoying the things they love.

Since nearly 80% of people who receive a pacemaker need a dual chamber option to pace both atrial and ventricular chambers of the heart, AVEIR DR significantly increases access to leadless pacing for millions of people across the U.S.

Mikey DeTemple, former professional surfer and filmmaker, has faced the challenge of overcoming eight surgeries due to his traditional pacemaker leads breaking as a result from his active lifestyle. On one occasion, the device tore through his chest muscle. Over time he lost sensation in his arm and was unable to move his fingers or make a fist. Today, he's back on the waves, doing what he loves, thanks to receiving the AVEIR DR dual chamber leadless pacemaker in May 2024.

Background File Document upload:

N/A

History of the development of the solution/product:

Manufacturing revolutionary devices presents unique challenges. For nearly a decade, Abbott's CRM business worked to establish game-changing features, the most significant being the i2i communication technology. The team conducted a variety of tests to establish communication between two leadless pacemakers on every heartbeat, with one of the first of these tests occurring in a fish tank. This test mimicked the scenario of having the two leadless pacemakers implanted in the heart within a person's torso. When this early prototype test worked, the team knew the i2i technology was a success, and the system of leadless devices would revolutionize the way irregular heart rhythms are treated.

Externally, Abbott invested in its suppliers and created long-term partnerships to identify and secure the materials needed to produce innovative and high-quality components. For example, because the devices had to be small enough to be placed into the chamber of a heart, the battery, docking mechanism, and titanium external case needed to be a single unit. This required special engineering involving the coordination and cooperation of suppliers as well as revamping Abbott's internal processes.

The company sourced new production and test equipment while training employees on how to produce the devices efficiently and effectively at a high volume. Abbott adapted its entire manufacturing process, test fixtures, and programs for AVEIR DR's unique i2i communication protocol. All of these new processes and equipment are managed by a performance system that leverages the latest Industry 4.0 concepts. This enables Abbott to drive productivity and ensure the highest possible quality. As a last step, Abbott evolved its distribution and customer delivery model to avoid potential shipping and customs delays caused by the new technology included in the breakthrough device.

After its development and clinical trial, Abbott announced late-breaking results at the Heart Rhythm Society's 44th annual meeting in New Orleans on May 20, 2023, from the AVEIR DR i2i Investigational Device Exemption (IDE) study showing that the leadless pacemaker met its three prespecified primary endpoints for safety and performance. The results were simultaneously published in The New England Journal of Medicine.

Additionally, Abbott announced the one-year results from the AVEIR DR i2i Investigational Device Exemption (IDE) study at the Heart Rhythm Society's 45th annual meeting in Boston in May 2024. Results showed:

Physicians demonstrated a 98.7% implant success rate.

The safety endpoint evaluating freedom from device or procedure complications was achieved.

97.6% of patients had freedom from complications.

98.7% of people had successful atrioventricular (AV) synchrony, meaning that the upper and lower chambers of the heart were beating normally, despite different types of underlying slow heart rhythms.

The FDA approved AVEIR DR deeming it safe and effective - on June 29, 2023, making it available for domestic commercial use, and has since been implanted in 46 states across the U.S. AVEIR DR received CE Mark on June 6, 2024, making the medical device available in Europe allowing even more people living with abnormal heart rhythms to enjoy every day without the constant reminder that they have a pacemaker.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

As the world's first dual chamber leadless pacemaker, AVEIR DR has four game-changing features:

UNIQUE TECHNOLOGY: Through novel i2i technology, AVEIR DR delivers beat-to-beat communication between two leadless pacemakers, eliminating the need for wires and solving a major medical challenge. i2i technology uses the naturally conductive characteristics of the body's blood to communicate on every heartbeat between the paired co-implanted devices, ultimately using less battery current than other modes of communication.

LEADLESS DESIGN: While traditional pacemakers are effective for millions of people, approximately 1 in 8 recipients experience complications attributed to the pocket or leads. Since Abbott's leadless pacemakers can be implanted directly within the heart and eliminate cardiac leads, it effectively eradicates pocket and lead-related complications and eliminates arm movement restrictions.

DEVICE SIZE: AVEIR DR is designed to provide the same therapy as a traditional dual chamber pacemaker, but each device is roughly one-tenth the size. AVEIR DR leadless pacemaker system is shorter, smaller, and slimmer than a AAA battery and is implanted directly inside the heart, meaning the system is not visible, there is no scarring, and it offers a quicker recovery period.

FIXATION DESIGN: With a unique helix-based fixation design, AVEIR DR is engineered to be retrievable should a person's therapy needs evolve or the device needs to be replaced in the future. The active fixation helix uses a screw-in mechanism to enable both secure implantation and chronic retrieval. Even more, the helix design enables AVEIR DR to provide real-time mapping capabilities to measure electrical signals within the heart, helping physicians assess accurate device placement and reposition the device, if necessary, before implantation.

AVEIR DR marks a pivotal moment in the history of cardiac rhythm management for physicians and people. By overcoming the long-standing challenges of pacemaker technology, this device sets a new standard for treating arrhythmias.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

CDC Website: https://www.cdc.gov/heartdisease/atrial_fibrillation.htm

FDA Approval Press Release:

<https://abbott.mediaroom.com/2023-07-05-Abbott-Receives-FDA-Approval-for-Worlds-First-Dual-Chamber-Leadless-Pacemaker>

i2i Communication Technology Study:

<https://www.ahajournals.org/doi/10.1161/CIRCEP.122.010909>

6-Month Performance Results in Heart Rhythm Journal:

[https://www.heartrhythmjournal.com/article/S1547-5271\(24\)02525-6/fulltext](https://www.heartrhythmjournal.com/article/S1547-5271(24)02525-6/fulltext)

Late-Breaker Results in The New England Journal of Medicine:

<https://www.nejm.org/doi/full/10.1056/NEJMoa2300080>

References File Document upload:

N/A