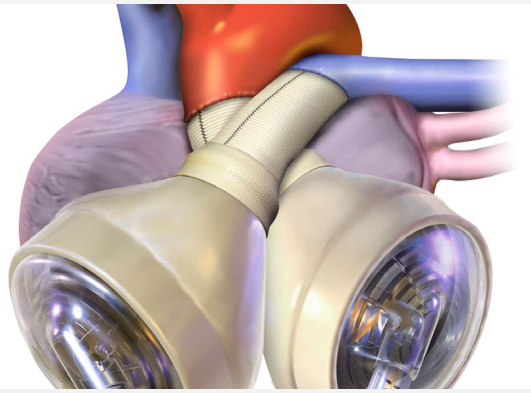
SynCardia
A Picard Medical Company

SAVING LIVES,
ONE HEART AT A TIME

July 11, 2023

SynCardia Updates Total Artificial Heart Labeling with Real World Data



SynCardia Systems, LLC., a Picard Medical Company, today announced that the U.S. Food and Drug Administration (FDA) has approved an update of the SynCardia TAH-t label with real world data further confirming the safety and performance of the Companion 2 Driver.

July 11, 2023, Tucson, AZ. SynCardia Systems, LLC., a Picard Medical Company, today announced that the U.S. Food and Drug Administration (FDA) has approved an update of the SynCardia TAH-t label with real world data further confirming the safety and performance of the Companion 2 Driver.

The supporting data was collected from two post approval studies, including the SynCardia CardioWest TAH-t Post market Surveillance Study (PAS) (NCT00614510) and the SynCardia Companion 2 Driver System Post Approval Study Protocol With INTERMACS™-Based Data Collection (C2 PAS) (NCT01919320). The purpose of both studies was to demonstrate that outcomes of the pivotal clinical trial that was using the Circulatory Support System (CSS) are repeatable across all other hospital using the Companion 2 Driver, following completion of the SynCardia Training Program.

Results obtained from the first 50 patients enrolled in the two post approval studies at newly trained hospitals were compared to the outcomes from the 95 subjects enrolled in the pivotal trial. Up to eight consecutive patients at each newly trained site were included in the comparison.

The comparison showed equal outcomes for Bridge to Transplant (BTT) patients, and for patients at one year post transplant. Results also confirmed the safety and efficacy of the C2 Driver. SynCardia will be updating their IFU to reflect and include this data.

Picard Medical is the parent company of SynCardia Systems, a Tucson, Arizona based leader in mechanical heart replacement technology for patients suffering from end-stage heart failure. SynCardia develops, manufactures, and commercializes the SynCardia Total Artificial Heart (TAH), an implantable system designed to assume the full functions of a failing or failed human heart. It is the first and only FDA approved TAH commercially available in the United States and Canada. With 39 years of clinical use, SynCardia's TAH and its predecessors have been used in over 2,000 implantations across 140 medical centers globally and it is the most widely used and extensively studied TAH in the world.

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#SynCardia

About SynCardia Systems, LLC
Headquartered in Tucson, Ariz., SynCardia manufactures the world's only commercially approved total artificial heart. In clinical use for more than 35 years and with more than 1,800 implants, the SynCardia temporary Total Artificial Heart (TAH) is the most widely used and extensively studied TAH in the world.

By partnering with, training and supporting healthcare teams at more than 140 transplant hospitals and heart failure programs in more than 20 countries, SynCardia helps create better outcomes for critically ill adults and adolescents whose best chance at survival is total heart replacement. When a donor heart isn't an available option, SynCardia provides a new heart without the wait for patients with end-stage heart failure affecting both sides of the heart (biventricular failure).

SynCardia Systems, LLC – a Picard Medical Company
The SynCardia temporary Total Artificial Heart (TAH-t) is a treatment option for cardiac transplant-eligible patients at risk of imminent death from biventricular failure.