



Total Artificial Heart (TAH) System

***ICD-10-PCS Code Change Request
March 9, 2021***

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Background

- **More than 100,000 patients with heart failure (HF) progress to end-stage HF (Stage D) in the US every year¹**
 - **Heart Failure Diagnosis Codes:**
 - I50.814 Right heart failure due to left heart failure
 - I50.82 Biventricular heart failure
 - I50.84 End stage heart failure
- **There is a huge unmet need for heart transplantation because of donor organ shortage that has not changed over the past 2 decades²**
- **The shortage of heart donors fueled the development of Left Ventricular Assist Devices (LVADS) and Total Artificial Hearts (TAH)**
- **The need for TAHs has been viewed as the "holy grail" by cardiac surgeons since the 1950's**

1. Kalogeropoulos AP, Samman-Tahhan A, Hedley JS, et al. Progression to Stage D Heart Failure Among Outpatients With Stage C Heart Failure and Reduced Ejection Fraction. JACC Heart Fail. 2017 Jul;5(7):528-537.

2. The Journal of Heart and Lung Transplantation. 2019, Volume 38 Issue 10 Pages 1056-1066.

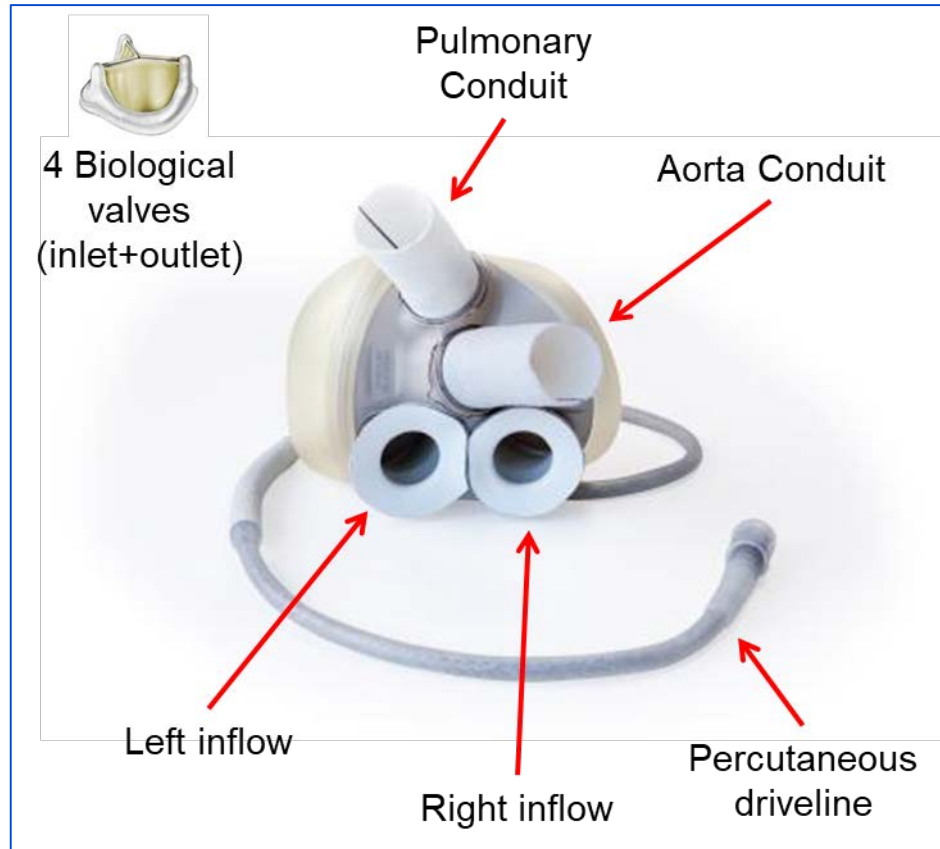
Current Available Treatments for Biventricular Heart Failure

- There are 2 fundamentally different TAH systems:
 - Pneumatic TAH (**SynCardia**) (SynCardia Systems, LLC, Tucson, AZ)
 - FDA approved (P030011) in 2004. It is a pneumatically driven pulsatile system indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.
 - Autoregulated, Electrohydraulic TAH (**Carmat TAH**) (Carmat SA, Vélizy, France)
 - An integrated auto-regulated and electro-hydraulically driven biocompatible, pulsatile, system intended for full cardiac support in adult patients and is currently in an FDA approved EFS study for transplantable eligible patients (IDE G180184, NCT 04117295).
 - Intent to provide a long-term alternative to transplant.

Feature	SynCardia TAH	Carmat TAH
Mode of actuation	<i>External pneumatic drivers</i>	<i>Internal electro-hydraulic pumps</i>
Blood contact	<i>Synthetic surfaces</i>	<i>Bioprosthetic surfaces</i>
Valves	<i>4 mechanical valves</i>	<i>4 biological valves</i>
Blood flow regulation	<i>Limited and manual</i>	<i>Autoregulated by the device</i>

Autoregulated Electrohydraulic TAH System

Fully Implantable Prosthesis

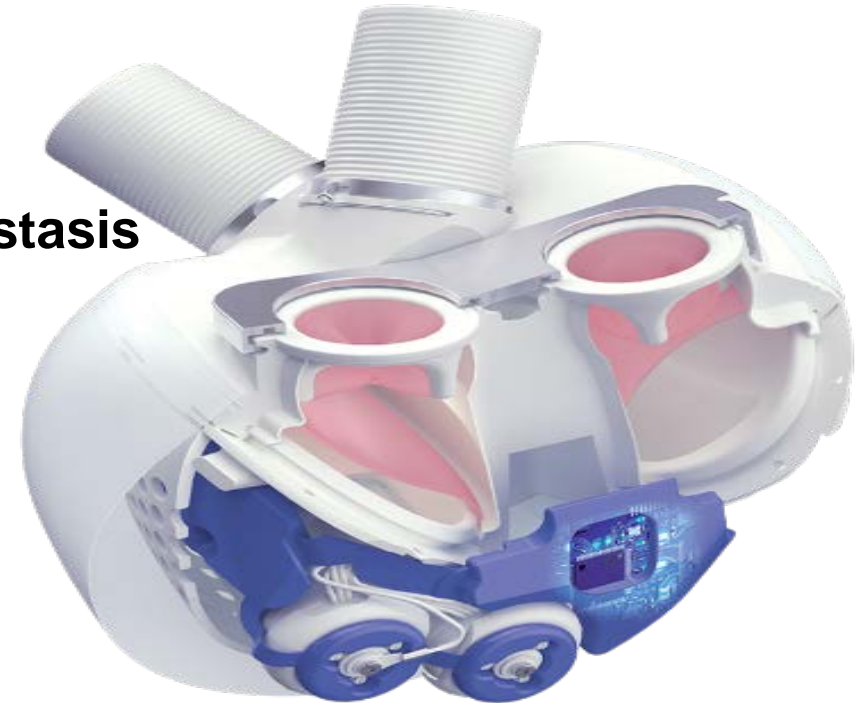


External Equipment



Hemocompatibility Features

- **Biological contact surfaces**
 - 4 biological valves
 - 2 hybrid membranes
- **Minimized shear-stress to prevent hemolysis**
- **Fill-to-empty displacement pump to avoid blood stasis**

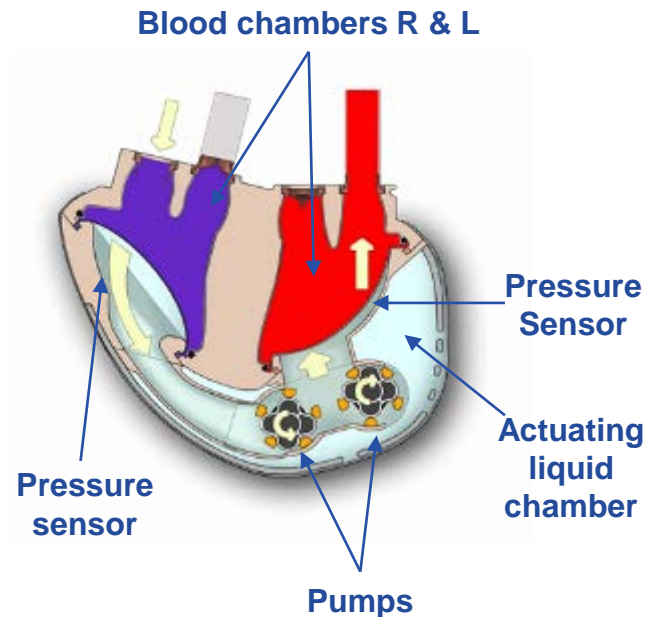


Smadja DM, et al.: Bioprosthetic Total Artificial Heart Induces a Profile of Acquired Hemocompatibility With Membranes Recellularization. *Journal of the American College of Cardiology* 2017;70:404-6.
Smadja DM, et al. Autoregulation of Pulsatile Bioprosthetic Total Artificial Heart is Involved in Endothelial Homeostasis Preservation. *Thromb Haemost.* 2020 Sep;120(9):1313-1322
Richez U, et al. Hemocompatibility and safety of the Carmat Total Artificial Heart hybrid membrane. *Heliyon.* 2019 Dec 8;5(12):e02914
Vincent F et al. Arterial pulsatility and circulating von Willebrand factor in patients on mechanical circulatory support. *J Am Coll Cardiol* 2018;71:2106–18.
Latrémouille C, et al. A bioprosthetic total artificial heart for end-stage heart failure: Results from a pilot study. *J Heart Lung Transplant.* 2018 Jan;37(1):33-37

How Does the Electrohydraulic Autoregulated TAH work?

Principle

Volumetric electrically driven pumps move the actuating silicon liquid within the bag to activate the hybrid membranes allowing the blood to enter and leave the chambers.

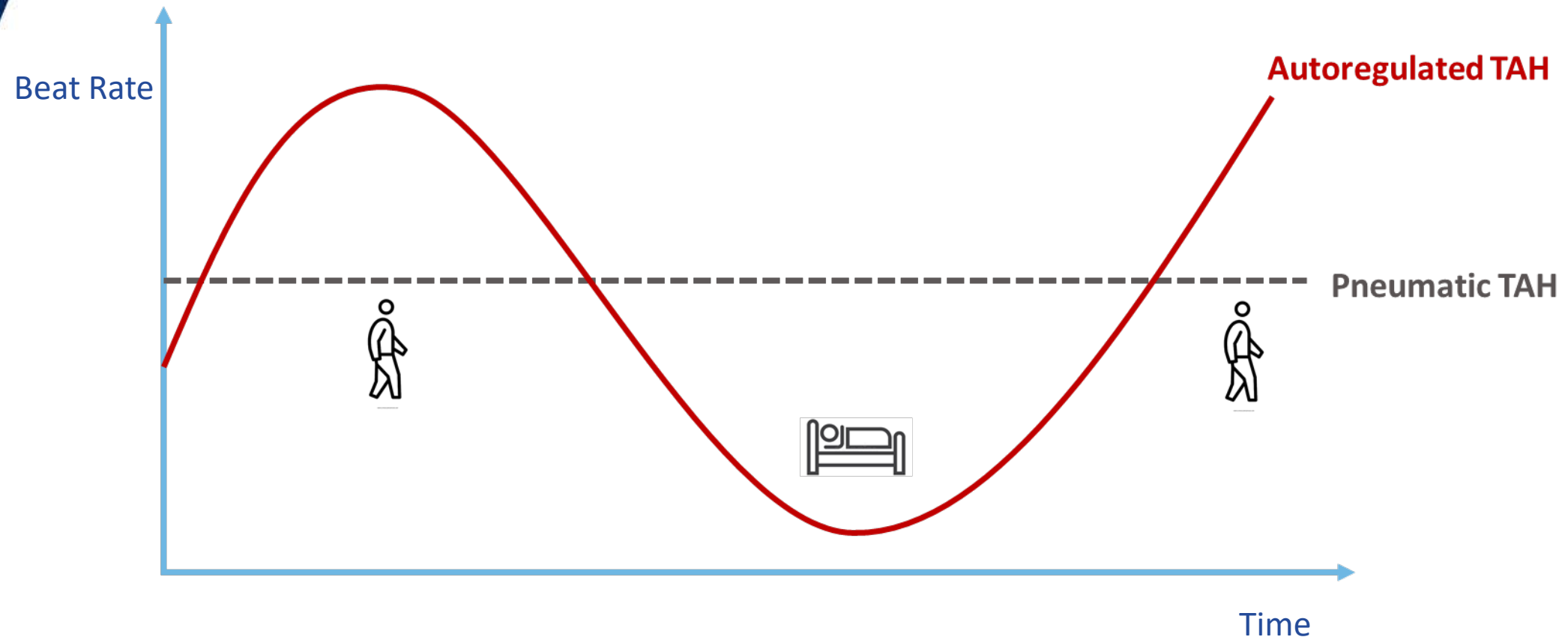


Autoregulation (same as human heart)

- 1) Pressure sensors detect pre-load (blood return to the heart)
- 2) High preload → acceleration of pumps (↑beat rate) → flow ↑
- 3) Ultrasound sensors detect membrane position to ensure full ejection at every beat

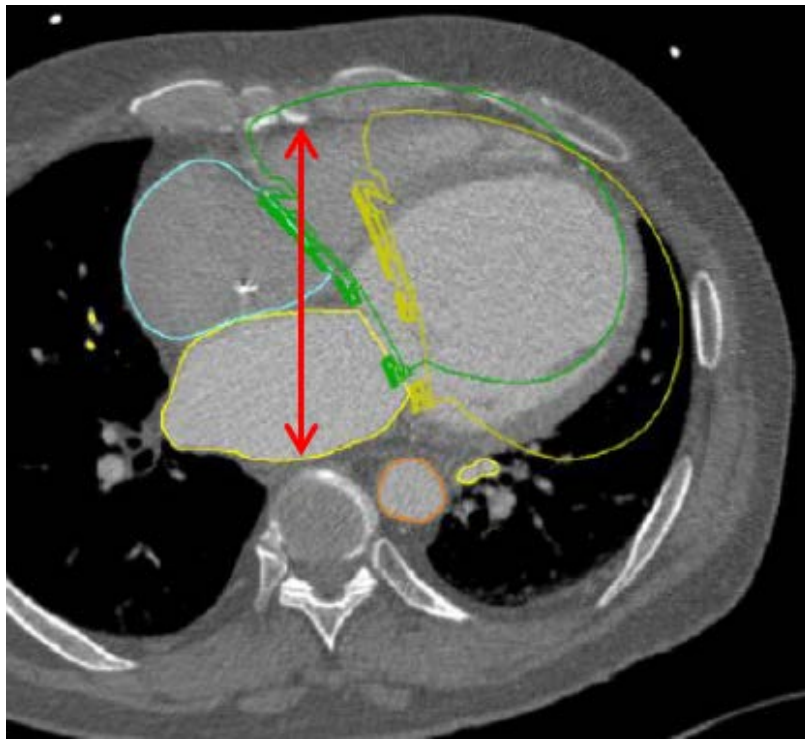
Starts in the operating room with immediate restoration of physiological pressures and flow, reproduction of the circadian rhythm and automatic adaptation of cardiac output to patient physiological needs.

Two Categories of TAH

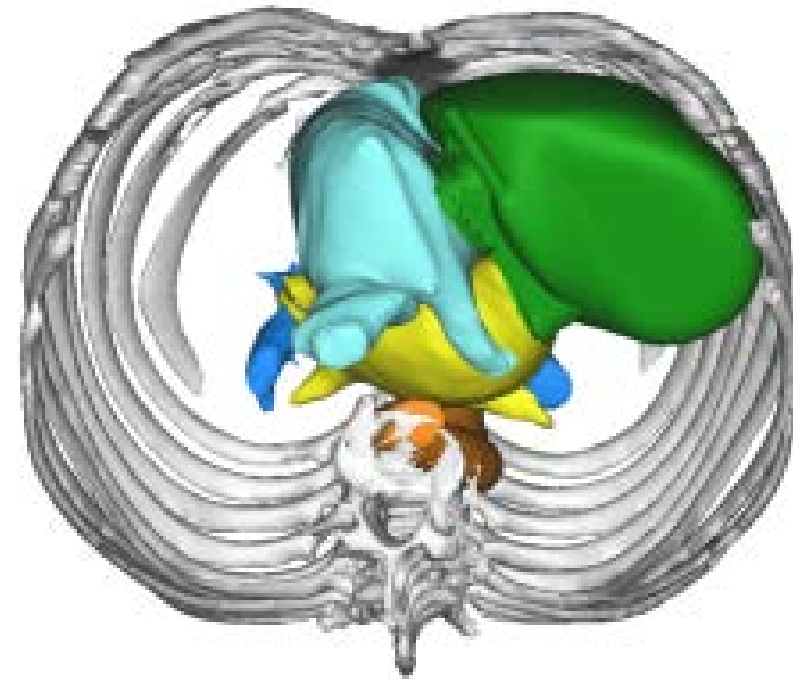


Anatomic fit assessment

- Virtual implant techniques are used to ensure that the device fits in adult patients
- The most important measure is the spine-sternum distance at the level of the mitral valve; a minimal distance of 12cm is advised.

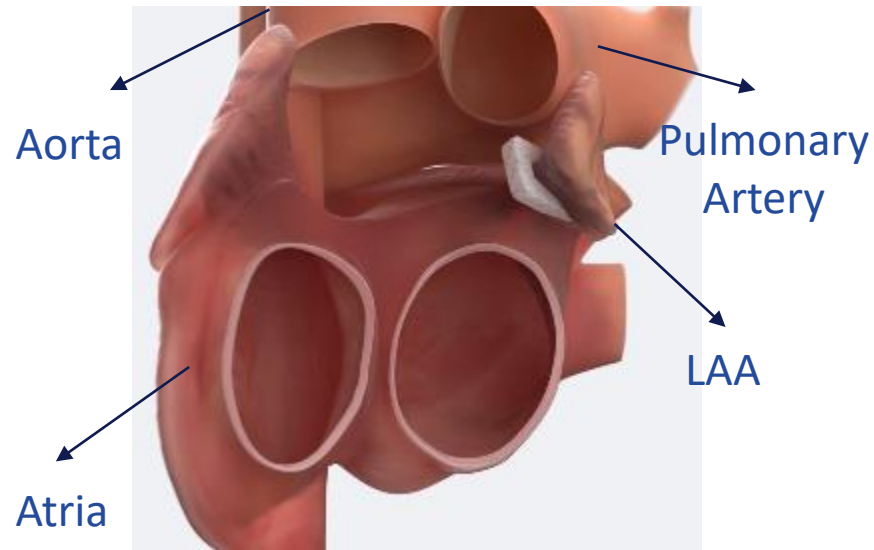


Spine-sternum distance

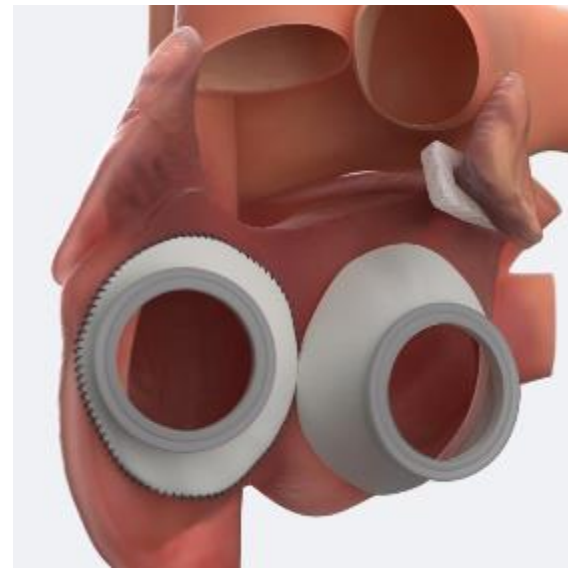


Implant Procedure

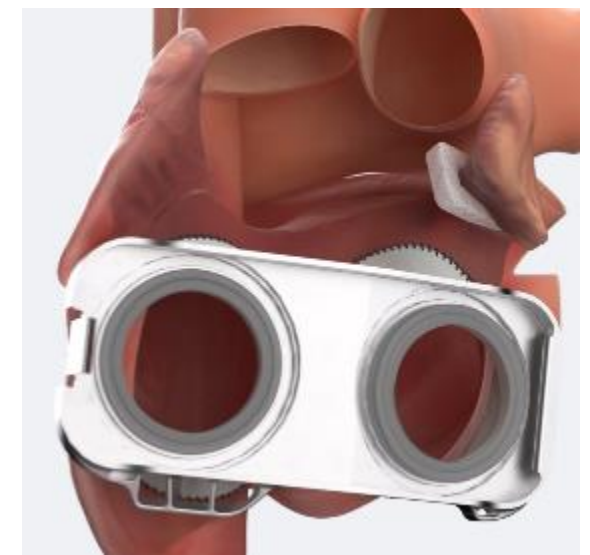
- The Carmat TAH is implanted in the orthotopic position during standard elective open-heart surgery using cardiopulmonary bypass.



Similar to a heart transplant procedure, the native ventricles are excised up to the left and right atrioventricular junctions. Ligation of LAA* is recommended.



Bioprosthesis flanges with a circular central opening reinforced by a silicon ring are cut and sutured onto the mitral and tricuspid valve orifices.



The flanges are connected to a single titanium interface device with two central openings.

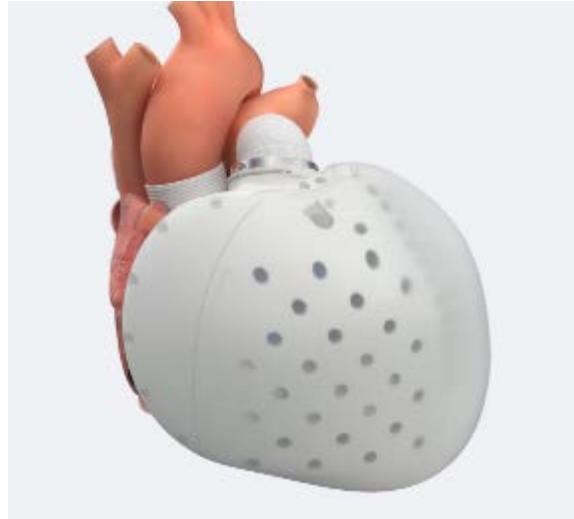
*Left Atrial Appendage

Carpentier A, et al.: First clinical use of a bioprosthesis total artificial heart: report of two cases. The Lancet 2015;386(10003):1556-63.

Implant Procedure (cont.)



The Carmat TAH, with the inflow valves in place, is then positioned and secured with a click onto the interface device



Next, the pulmonary conduit with outflow valve is sutured to the distal pulmonary artery. Finally, the aortic conduit containing the outflow valve is sutured to the distal aorta.



The percutaneous driveline is tunneled to exit the skin at the lower right abdominal quadrant and then connected to the controller and hospital care console.

Out of US Bridge to Transplant Experience

7 Patients

- Age 35-60
- Average support duration 173 days
- 5 patients were discharged from hospital with TAH implanted
- These 5 patients received donor hearts after average support duration 224 days
- Transplant procedure survival was 100%, one-year post-transplant survival 80%

Adverse Event	Percentage of patients
Bleeding requiring re-operation	29%
Pericardial Fluid Collection requiring intervention	14%
Gastro-intestinal bleeding	0%
Pump thrombosis	0%
Hemolysis	0%
Transient Ischemic Attack	0%
Ischemic stroke	0%
Hemorrhagic stroke	0%
Arterial NonCNS Thromboembolism	0%
Major Infection	57%
Percutaneous driveline infection	0%
Hepatic Dysfunction	29%
Renal Dysfunction	43%
Respiratory Failure	14%

Clinical Outcomes and Safety Profile

CE Mark Study

Comparative outcomes @ 6 months						
	Hospital discharge	Survival rate	Bleeding – reoperation	Stroke	Gastrointestinal bleeding	Driveline infection
CARMAT	73%	73%	9%	0%	0%	0%
SynCardia*	24%	54% - 62%	41%	23%	20%	22%
BIVAD**	n/a	46% - 68%	n/a	7%	7%	7%
LVAD***	n/a	90% - 92%	14%	8%	8%	10%

* Kirklin JK *et al.*, JHLT 2018;37:685-691. Arabia F *et al.*, JHLT, 2018;37:1304–1312. Demondion P *et al.*, EJCS. 2013 Nov;44(5):843-8

** Lavee J *et al.*, JHLT 2018;37:1399–1402. Arabia F *et al.*, ATS 2018;105:548–56

*** Strueber M *et al.* JACC 2011;57:1375–82. Netuka I *et al.*, JACC 2015;66:2579–89

Carmat TAH in the US

- Implantation will be performed in US heart transplantation sites in FDA IDE studies beginning in 2021
- First study is to demonstrate safety and efficacy of Carmat TAH in 10 transplant-eligible patients at 7 sites
- CMS has approved coverage of the device and related routine items and services (IDE Category B)

Site of Service and Naming

- Carmat TAH implantation procedure is similar to heart-transplantation
 - CARMAT TAH is performed in the **hospital inpatient setting**
- A coder would find the TAH system identified in the **Operative Report**.
 - If the implanted heart system is not identified in the Operative Note, coders should query the surgeon.
- Naming Conventions: The **Carmat TAH** other names:
 - **Carmat**
 - **Aeson**
 - Carmat TAH
 - Carmat device
 - Carmat Heart
 - C-TAH, Bioprosthetic autoregulated artificial heart
 - Pulsatile Bioprosthetic Total Artificial Heart
 - Carmat physiologic heart replacement therapy
 - CARMAT PHRT
 - Bioprosthetic TAH

Summary

- **Carmat TAH system**
 - Has unique features including hemocompatibility, autoregulation and silent electro-hydraulics resulting in an automatic adaptation of cardiac output to patient physiological needs
 - Is associated with promising clinical outcomes and safety profile
 - Is indicated and available for the replacement of the native heart ventricles in adult transplantable eligible patients with end-stage heart failure requiring biventricular support in an Early Feasibility Study (IDE: G180184)
- Current ICD-10-PCS codes do not allow providers to distinguish between the different **pneumatic** and **autoregulated electrohydraulic** total artificial hearts
- Consequently, existing codes do not enable distinct identification of autoregulated electrohydraulic TAH cases to track utilization, safety and effectiveness.
- Carmat TAH implantations will be performed in clinical studies at US heart transplant sites beginning in 2021 for the replacement of the native heart ventricles in adult transplantable eligible patients with end-stage heart failure requiring biventricular support