

Fact Sheet:

SynCardia temporary Total Artificial Heart

Overview

- World's first and only FDA, Health Canada and CE approved Total Artificial Heart
- Nearly 1,700 implants of the Total Artificial Heart, account for over 580 patient years of life on the device
- Originally used as a permanent replacement heart, the SynCardia Total Artificial Heart is currently approved as a bridge to transplant for patients dying from end-stage heart failure affecting both ventricles (biventricular failure).

Approvals

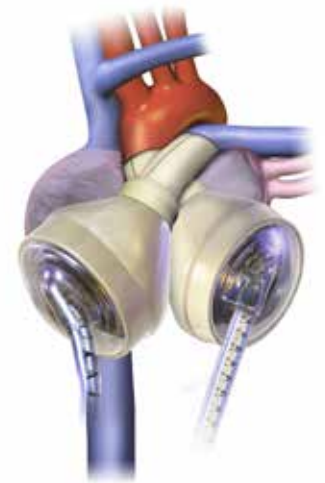
- FDA approval: Oct. 15, 2004 (following a 10-year pivotal clinical study)
- CE Mark: May 16, 2005
- Health Canada: Oct. 27, 2005

Features

- The Total Artificial Heart is the only device that eliminates the symptoms and source of end-stage biventricular failure.
- Similar to a heart transplant, the Total Artificial Heart replaces both failing heart ventricles and the four native heart valves.
- Only device that pumps up to 9.5 L/min through both ventricles
- This high volume of safe blood flow helps vital organs recover faster, helping make patients better transplant candidates.
- Unique partial fill/full eject design allows the patient's body to determine blood flow based on activity level

Reliability: 30 Years of Use

- Diaphragm has a failure rate of less than 1% over with 1,700 implants (3,400 diaphragms)
- No motors or electronics of any type inside the body
- All electronics are located outside the body in the pneumatic driver, which powers the SynCardia Total Artificial Heart and monitors blood flow



SynCardia Total Artificial Heart

Weight: 160 grams

Stroke volume: 70 ml



SynCardia Total Artificial Heart

No internal electronics required



1992 E. Silverlake Rd.
520-547-7461
Tucson, AZ 85713
www.syncardia.com