SynCardia temporary Total Artificial Heart (TAH-t)

Instructions for Use with the Companion 2 Driver System

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C2-900001-EN Rev 004
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Chapter 1. Device Description

The SynCardia™ TAH-t Companion 2 Driver System (TAH-t System) (Figure 1-1) is comprised of the SynCardia™ temporary Total Artificial Heart (TAH-t) and the Companion 2 Driver and includes a Hospital Cart and Caddy.

Figure 1-1 - TAH-t System

The SynCardia™ temporary Total Artificial Heart (TAH-t) (Figure 1-2) is an implantable pulsatile biventricular device that replaces a patient’s native ventricles and valves and pumps blood to both the pulmonary and systemic circulation.
The Companion 2 Driver System (Figure 1-3) is a multi-component electro-mechanical unit designed to provide pneumatic power to the implanted TAH-t. The Companion 2 Driver System includes a Driver, a Hospital Cart, and a Caddy.
1.1 The Implantable TAH-t

The implantable TAH-t consists of two artificial ventricles, each made of a semi-rigid polyurethane housing with four flexible polyurethane diaphragms separating the blood chamber from the air chamber. The diaphragms allow the artificial ventricle to fill and then eject blood when compressed by air from the external driver. Valves, mounted in the inflow and outflow ports of each artificial ventricle, control the direction of blood flow. The maximum dynamic stroke volume of each ventricle allows for generating a flow rate up to 9.5 liters per minute.

The left artificial ventricle is connected via the left atrial inflow connector to the left atrium, and via the aortic outflow connector to the aorta. The right artificial ventricle is connected via the right atrial inflow connector to the right atrium and via the pulmonary artery outflow connector to the pulmonary artery. The cannula from each artificial ventricle driveline is tunneled through the chest wall. The cannulae of the right and left artificial ventricles are attached to seven-foot pneumatic drivelines that connect to the driver.

1.2 TAH-t Theory of Operation

Blood enters the TAH-t through the patient’s native atria, passing through an inflow cuff that has been anastomosed to the atrium at the level of the atrioventricular valve annulus. The cuff attaches to the rigid housing of the TAH-t via an inflow valve that allows blood to enter the polyurethane ventricle.

Pulses of air generated by an external driver and delivered by a driveline distend the ventricle diaphragm and expel blood from the ventricle through an outflow valve into an outflow graft anastomosed to the aorta or pulmonary artery. The TAH-t will fully support the patient’s circulation.

The basic concept for utilizing the TAH-t is “partial fill, full eject.” A graphic representation of a typical pressure curve for the pulse of air delivered to the TAH-t ventricle is shown in Figure 1-4 below.
The pressure waveform contains features that are indicative of the implanted TAH-t performance during systole. The initial segment of the pressure waveform (A to B) communicates a quick rise in pressure as the air side of the ventricle is pressurized until the drive pressure overcomes the afterload pressure and the outflow valve is opened.

During the period between B and C, air continues to enter the air chamber of the ventricle as the diaphragm moves to eject blood, resulting in a sharply reduced rate of pressurization when compared to the front edge.

When the diaphragm is unable to move further, the pressure increases as air continues to enter the isovolumetric air chamber of the ventricle, resulting in a display of a “full eject” flag, indicated by the region from C to D. The Driver then begins diastole, pressure in the air chamber is vented, and the waveform moves towards the starting pressure line on the X-axis.

Reduction of the systolic drive pressure results in reduced cardiac output and increased venous pressures, as the pressure produced by the driver does not exceed the afterload pressure of the patient. Full ejection increases organ perfusion and diminishes blood stasis. Full ejection of the left ventricle is generally achieved by providing a drive pressure that is 30 – 40 mmHg higher than the aortic pressure.

The “partial fill” portion of the operating concept is derived from the Frank-Starling mechanism, which states that the heart has the intrinsic capability of increasing its force of contraction, and therefore its stroke volume, in response to an increase in venous return. The Frank-Starling principle is based on the length-tension relationship within the ventricle. If ventricular end diastolic volume (preload) is increased, it follows that ventricular fiber
length is also increased, resulting in an increased ‘tension’ of the muscle. In this way, cardiac output is directly related to venous return, the most important determining factor of preload.

When the heart rate is constant, cardiac output is directly related to preload, up to a certain point. An increase in preload will increase the cardiac output until very high end diastolic volumes are reached. At this point cardiac output will not increase with any further increase in preload, and may even decrease after a certain preload is reached.

In the TAH-t, the Starling mechanism is implemented by balancing three other parameters: heart rate, percent systole, and vacuum. By reserving a space within the ventricle that is not used when the patient is at rest, the venous return may increase, which results in a higher stroke volume. As long as volume overload is avoided, the TAH-t can behave along a Starling curve with venous return translated into increased cardiac output.

The fill volumes are established using the flow waveform generated during diastole, as depicted in Figure 1-5. The initial part of the curve, (A to B) is characterized by a rapid movement of air as the pressure in the air chamber of the TAH-t is relieved and the outflow valve closes. The inflow valve opens at point B and blood enters the blood chamber of the ventricle, while air is exhausted from the ventricle.

![Figure 1-5 – Typical Flow Waveform for the TAH-t](image)

The duration of the period indicated from B to C, D or E, prior to initiation of systole, is indicative of whether the device is partial or full filling the ventricle. It is this region that is measured to determine the fill volume of the ventricle. Integrating the area under the flow curve once the inflow valve has opened provides the stroke volume of the ventricle, provided...
that full ejection has occurred. The fill volume multiplied by the heart rate provides the device cardiac output.

Full filling of the ventricle is represented by an abrupt mid-diastolic drop of flow rate to zero, as indicated by point C. Increasing the heart rate will increase the cardiac output, but will also decrease the blood fill volume by decreasing the amount of time allowed for filling the ventricle. Adjustment of the percent systole control will vary the time of the cardiac cycle that the device remains in systole. Modification of the percent systole can be used to optimize the filling time of the ventricle. The vacuum control provides another means to control ventricular filling such that increasing the negative diastolic pressure will result in increased ventricular filling.
1.3 The Companion 2 Driver System

The Companion 2 Driver System operates and monitors the TAH-t throughout the TAH-t implantation, surgical recovery phase in the ICU and step-down units and also the ambulatory phases of patient support. The Companion 2 Driver System includes a Driver, a Hospital Cart and a Caddy,

- The Driver powers the TAH-t and docks into the Hospital Cart or Caddy. Data from the TAH-t and the patient are monitored non-invasively by the Driver so there are no electrical connections to the patient.

- The Hospital Cart is a large cart with wheels, into which the Driver docks. It is intended for use in the hospital during the TAH-t implant procedure and subsequent surgical recovery phase.

- The Driver System Caddy is a small cart with wheels into which the Driver docks for use inside the hospital. It is designed to facilitate mobility of ambulatory patients within the hospital.

See the SynCardia Companion 2 Driver System Operator Manual for detailed information on the Companion 2 Driver System.
Chapter 2. Indications for Use

2.1 The TAH-t System is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

2.2 The TAH-t System is intended in-hospital use, during and after surgical implantation of the TAH-t.
Chapter 3. Contraindications

The TAH-t System is contraindicated for use in:

- Patients who are not cardiac transplant eligible.

- Patients who do not have sufficient space in the chest area vacated by the natural ventricles. Generally this includes patients who have body surface areas <1.7m², or who have a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging (CT scan) < 10 cm.

- Patients who cannot be adequately anticoagulated on the TAH-t.
Chapter 4. Warnings

4.1 Setup and operation of the TAH-t System should only be performed by personnel trained and certified in accordance with the SynCardia training program. A thorough understanding of the technical principles, clinical applications, and risks associated with the device is necessary. Prior to use, refer to the SynCardia Companion 2 Driver System Operator Manual.

4.2 Sterile components of the TAH-t are intended for single use only. Do not use if the package is opened or damaged. Do not re-sterilize or reuse.

4.3 Safe use of the TAH-t System has not been established in pregnant patients.

4.4 Do not subject patients implanted with the TAH-t to magnetic resonance imaging (MRI) scans.

4.5 Do not use the TAH-t System if the implantable artificial ventricles cannot fit in the chest area vacated by the natural ventricles. Compression of the inferior vena cava and left pulmonary vein are possible consequences.

4.6 Do not allow any catheter to get near the inflow valves of the TAH-t. If a catheter migrates into an inflow valve, the valve could become stuck, limiting flow. Confirm the position of the catheter by x-ray after catheter insertion and repeat an x-ray immediately if any unexplained sudden drop in cardiac output occurs. A percutaneously inserted central catheter may migrate into the inflow valve when the patient raises his or her arm.

4.7 There is a potential for air embolism. De-air the artificial ventricles to minimize the possibility of air inadvertently entering the device.

4.8 Do not allow the external drivelines to become kinked. If there is any low cardiac output alarm, inspect the external drivelines for kinking.

4.9 A reduction in the maximum stroke volume on the external driver monitoring computer to below 30 milliliters may indicate a failure of one of the diaphragms in a ventricle of the TAH-t.

4.10 Do not administer CPR to TAH-t patients. Defibrillation and CPR are ineffective on patients implanted with the TAH-t.
Chapter 5. Precautions

5.1 Surgical, nursing, and perfusion staff responsible for the SynCardia TAH-t program at each hospital must complete the SynCardia TAH-t Training program.

5.2 The SynCardia TAH-t and Drivelines are provided sterile; caution must be taken in opening the package. Do NOT resterilize. Do NOT use if package is damaged. Storage temperature for the drivelines is 10 - 50°C.

5.3 Measures should be taken to prevent infection or sepsis. Use strict aseptic techniques during implantation.

5.4 The outflow grafts must be pre-clotted before use.

5.5 Do not use an antifibrinolitic agent like Amicar with an active clotting agent like FEIBA.

5.6 Use only water-soluble antiseptic cleaners around the exit site. Ointments may delay tissue in-growth around the driveline cannulae.

5.7 Each Driver contains two independent compressor subassemblies, each capable of providing independent support for operation of the TAH-t. Hospitals and patients supported with the Driver must have an additional Driver available as a backup to be used in the event of a failure of the primary Driver.

Personnel should be trained how to exchange the primary Driver with a backup Driver in the event of system failure. The backup Driver should be connected as quickly as possible. This procedure is for emergency use only. See SynCardia Companion 2 Driver System Operator Manual, Chapter 17, Switching to Companion 2 Backup Driver.

5.8 The TAH-t System contains ferro-magnetic metal components. Do NOT perform MRI imaging procedures on patients implanted with the TAH-t.

5.9 Manage the exit site in accordance with hospital procedures.

5.10 Monitor cardiac output when closing the chest. A reduction in TAH-t output while closing the chest may indicate inflow obstruction. Reposition the TAH-t ventricles by anchoring to a rib or moving it into the left pleural space.

5.11 A sudden reduction in TAH-t flow may be caused by a kink in the pneumatic drivelines, or some inflow obstruction to the TAH-t, such as tamponade. Check and correct any kink in the drivelines.

5.12 Do not administer CPR to TAH-t patients. Defibrillation or CPR will not be effective.
5.13 Flows should be kept at a reasonable output so that proper washing of the ventricles is established.

5.14 The level of anticoagulation will vary depending on the patient’s coagulation status. Typically, patients supported with the TAH-t require systemic antithrombotics similar to those used for patients with mechanical valves.
Chapter 6. Summary of Studies

6.1 TAH-t with CSS Console

The multi-center (5) clinical study was conducted of the TAH-t with a large external driver, the Circulatory Support System (CSS) Console. The purpose of the study was to evaluate the device combination as a bridge to cardiac transplantation in transplant-eligible patients at risk of imminent death from biventricular failure.

Ninety-five patients (ages 16-67) were implanted with the TAH-t; 81 (70 males, 11 females) met all inclusion/exclusion criteria and were designated the core implant group. All patients were in NYHA Class IV at time of enrollment. Additional characteristics of the core implant group at the time of entry into the study are:

- 15 patients were on heart-lung machine/ECMO support,
- 51 patients had central venous pressure > 18 mmHg,
- 11 patients had right ventricular ejection fraction < 20%, and
- all patients had relative or absolute contraindications to VAD support, as evidenced by refractory arrhythmias or unresuscitable cardiac arrest (25), hypokinetic right/left/global ventricles (23), aortic regurgitation, stenosis or prosthesis (13), massive myocardial infarction or direct myocardial injury that affects technical insertion of a VAD through the left ventricle (10), failure to wean from cardiopulmonary bypass with biventricular injury (4), left, right ventricular or mural thrombus (3) or septal defect (3).

All patients were on maximal medical therapy and at imminent risk of death before a donor heart could be obtained.

6.1.1 Trial Success

Treatment success was defined as patients who, at 30 days post transplant, were: 1) alive; 2) NYHA Class I or II, 3) ambulatory; 4) not ventilator dependent; and 5) not on dialysis.

Trial success was achieved in 56 (69%) of the 81 core patients. Sixty-four of the 81 core patients (79%) reached transplant after a mean time of 79 days (range 1-414). Fifty-eight (72%) survived to 30 days post transplant.

6.1.2 Hemodynamics

The hemodynamic performance of the TAH-t was assessed through a comparison of pre- and post-implant values of cardiac index, systolic arterial blood pressure, and central venous pressure. Hemodynamic indices were effectively restored to near normal
values. Average cardiac index increased from 1.9 to 3.0 L/min/m², average systolic blood pressure increased from 93mmHg to 120mmHg, and average CVP decreased from 20mmHg to 14mmHg.

The average perfusion pressure (mean aortic pressure minus CVP) increased from 49mmHg to 63mmHg, which was associated with recovery of renal and hepatic function.

6.1.3 Adverse Events

Adverse events collected for all 81 core patients while on the TAH-t System are presented in descending order in Table 6-1. The adverse events represent 17.6 device years of experience for an overall event rate of 1.9 events per month while on the device awaiting transplant.

### Table 6-1

**Incidence of Adverse Events in Core Patients During Device Implantation, in Decreasing Order of Frequency**

(*Represents 17.6 years or 6411 days on the device*)

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Number of Events</th>
<th>Number (%) of Patients n=81</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Adverse Event</td>
<td>400</td>
<td>76 (93.8%)</td>
</tr>
<tr>
<td>Infection</td>
<td>125</td>
<td>58 (71.6%)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>55</td>
<td>34 (42.0%)</td>
</tr>
<tr>
<td>Respiratory Dysfunction</td>
<td>44</td>
<td>24 (29.6%)</td>
</tr>
<tr>
<td>Hepatic Dysfunction</td>
<td>30</td>
<td>29 (35.8%)</td>
</tr>
<tr>
<td>Neurological Event</td>
<td>26</td>
<td>20 (24.7%)</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>23</td>
<td>21 (25.9%)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>18</td>
<td>17 (21.0%)</td>
</tr>
<tr>
<td>Device Malfunction</td>
<td>18</td>
<td>15 (18.5%)</td>
</tr>
<tr>
<td>Peripheral Thromboembolism</td>
<td>14</td>
<td>9 (11.1%)</td>
</tr>
<tr>
<td>Reduced Blood Pressure</td>
<td>13</td>
<td>12 (14.8%)</td>
</tr>
<tr>
<td>Reduced Cardiac Index</td>
<td>11</td>
<td>7 (8.6%)</td>
</tr>
<tr>
<td>Technical/Procedural</td>
<td>11</td>
<td>3 (3.7%)</td>
</tr>
<tr>
<td>Fit Complication</td>
<td>5</td>
<td>5 (6.2%)</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>3</td>
<td>3 (3.7%)</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>3</td>
<td>3 (3.7%)</td>
</tr>
</tbody>
</table>
6.2 TAH-t Reliability

Reliability testing was conducted to determine with reasonable assurance how long a device would perform as intended, without failure.

Three separate sets of in vitro reliability testing were conducted. In one test, four TAH-t units were run for a period of 180 days. During this time, there were no failures or abnormalities observed.

In a second in vitro reliability trial, four TAH-t units were tested in a “run to failure” study design. After 35 months of testing, there were no failures or abnormalities observed.

A third test was initiated using three TAH-t units which had exceeded their three-year sterilization expiration date. This provided information about the effects of long-term storage on the fatigue resistance properties of the TAH-t. After 24 months of testing, there were no failures or abnormalities observed.

In conclusion, a total of 11 units were run for various lengths of time over six years with no device-related failures. The cumulative number of days used for calculation was 6715, and there were no failures or signs of appreciable wear observed. When the 11 units are used to calculate reliability with a 90% confidence, the reliability at 30, 60 and 365 days is as reported in the Table 6-2.

<table>
<thead>
<tr>
<th># days run</th>
<th>MTBF</th>
<th>Reliability in number of days run</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>30</td>
</tr>
<tr>
<td>6715</td>
<td>2916</td>
<td>0.99</td>
</tr>
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</table>
Chapter 7. Implant Procedures

Patients are prepared for the implant pursuant to standard hospital procedures for any cardiac surgery. An arterial line, a central line, and standard artificial ventilation are required prior to the start of surgery. Transesophageal echocardiography is recommended.

7.1 Materials Needed but not Provided

The following materials are needed for the surgery but are not provided by SynCardia. They are typically ordered and maintained by the implanting hospital.

- *Three 15 by 20 centimeter sheets of membrane (e.g., Gore-Tex®)* are used to create a neo-pericardium to prevent adhesions.

- *Teflon felt buttress strips* are cut to approximately 10-12 mm in width and are generally 10 cm in length. It usually takes at least two of these to extend around the entire atrial cuff. (See Section 7.3, Removal of Native Ventricles)

- *Surgical sealant* is used to coat the outflow grafts.

7.2 Preparation

7.2.1 Pass each sterile TAH-t component onto the sterile field by opening the non-sterile outer bag and dropping or passing the sterile inner bag using sterile technique.

7.2.2 After a standard median sternotomy is performed and before starting heparin,

(1) Prepare the arterial outflow connectors,

(2) Trim atrial inflow connectors to appropriate size, and

(3) Tunnel the artificial ventricle conduits through the skin.

7.2.3 Apply surgical sealant to the two arterial outflow connectors. This is done before cannulation so that there is plenty of time for the outflow connectors to dry before use.

7.2.4 Trim the two inflow connectors. Cut the edges of the atrial quick connects for the atrial anastomoses to a radius extending out from the connector for 5-7 mm. Cut in a completely circular fashion. Then stretch and invert them.

7.2.5 Pass the cannulae through their subcutaneous pathways before heparinization of the patient. Position the left ventricle cannula in the epigastrium at the level of the midclavicular line and approximately 2 inches below the costal margin. Make a
Semicircular skin flap incision on the left midclavicular line approximately 5 to 10 cm below the costal margin.

7.2.6 Place a long clamp through the subcutaneous tissue, rectus fascia, rectus muscle, and into the chest as a chest tube would be placed. Use a similar approach to place the cannula for the prosthetic right ventricle, approximately 4 to 5 cm medial to the left ventricle cannula so that no necrosis between the two exit sites will result.

7.2.7 Enlarge the pathway by opening the clamp and inserting a one-inch Penrose drain through the pathway. Place the end of the cannula in the Penrose drain and advance approximately 8-10 cm. Pull the Penrose drains through the pathway that delivers the cannula. Position the artificial ventricles laterally to the wound and cover with a towel while the rest of the procedure takes place. This provides ample opportunity for small bleeders in the cannula pathway to clot.

7.3 Removal of the Native Ventricles

7.3.1 Cannulation of the aorta and both superior and inferior venae cavae is done in a standard fashion. Umbilical tape chokers are used on the cavae. Dissection around the aorta and pulmonary artery is limited to the proximal portion of the aorta in anticipation of transplantation, thus leaving some untouched areas that will not be very fibrotic. Cardiopulmonary bypass is instituted and the heart is fibrillated. Total bypass is instituted by pulling on the choker tapes.

7.3.2 The heart is fibrillated and excision of the ventricles is begun. The excision is different from that used for transplantation. It seeks to preserve the annulus of both the tricuspid and mitral valves. Thus, an incision is made on the ventricular side of the AV groove of the right ventricle (Figure 7-1).

Figure 7-1 - First Incision of Ventricle Excision
7.3.3 Incision can be done with a knife and extended with a knife or scissors. It is extended anteriorly across the right ventricular outflow tract and just proximally to the pulmonary valve. Posteriorly, it is extended to the interventricular septum and across the septum, staying on the left side of the arterioventricular (AV) groove and preserving the entirety of the mitral annulus. The anterior and posterior lines of incision are dissected apart from each other out to the level of the pulmonary bifurcation.

7.3.4 Trim the excess muscle on the right and left sides down to near the AV valves. All chordae are trimmed away, and a 2 mm edge of valve tissue along with the annulus is left intact. The atrial cuff generally extends 1 cm beyond the AV valves and consists of residual ventricular muscle and fat in the AV groove. The portion of the cuff in the left ventricular outflow tract consists of the residual anterior leaflet of the mitral valve and some aortic tissue. Most of the aortic tissue is trimmed away; however, some is left intact because it may present strong tissue for the sewing of the inflow connector. The great vessels are then separated from the remaining ventricular myocardium above the valvular level. The great vessels are separated from each other (Figure 7-2).
7.3.5 Over-sew the coronary sinus entrance into the right atrium (Figure 7-3). This prevents backflow of blood through the coronary sinus and out to the cut vessels on the AV groove.

Figure 7-3 - Ligate Coronary Sinus

7.3.6 Three 15 by 20 cm sheets of membrane are used to create a neo-pericardium to prevent adhesions. On the right side, a sheet is anchored with non-absorbable suture to the pericardial reflection at the level of the superior vena cava, pulmonary veins and inferior vena cava. On the left side, a second sheet is sutured to the pericardial reflection just anterior to the left pulmonary veins. On the diaphragmatic side, a third sheet is sutured so as to cover the entire diaphragmatic pericardial surface. The three sheets are then folded upon themselves to keep them out of the operative field while the TAH-t is implanted.
7.4 Preparing the Atria

7.4.1 The outer walls of the entire right and left atrial cuff complex are encircled with Teflon felt buttresses. These are placed in such a way that they can be used for strengthening the anastomosis to the inflow connector and also to tamponade and control all possible bleeding from the AV groove portion of the connectors. These are cut to approximately 10-12 mm in width and are generally 10 cm in length. It most often takes at least two of these to extend around the entire atrial cuff. They are placed on the outer edge of the cuff and sewn in place with a running 3-0 polypropylene (Figure 7-4). A long needle (MH needle) is used to accomplish this and, after completing this, the left and right atrial cuffs are surrounded by Teflon felt buttresses.

![Figure 7-4 - Atrial Sutures](image_url)
7.4.2 The atrial inflow connector is sewn first. It is inverted and placed inside the left atrial cuff on the lateral wall. 3-0 polypropylene is used with an MH needle with a running stitch, taking care to tailor the atrial cuff and the inflow connector into a single hemostatic suture line. The suture line includes both free walls of the atrium, buttressed with Teflon felt in the atrial septum, which has no buttressing material. A similar procedure is done with the right inflow connector. The connector is inverted and placed in the atrium, the suture line is run, and after completing both suture lines, the inflow connectors are returned to their normal positions (Figure 7-5).

![Figure 7-5 - Inflow Connector Inverted For Suturing (left), Finished Normal Position (right)](image-url)
7.4.3 Check for hemostasis with the plastic leak tester made to fit within the inflow connector (Figure 7-6). A syringe (60-100 cc) is used to inject saline into a three-way stopcock connected with the tester to test the left atrial suture line. The surgeon places his hand posterior to the left atrium and compresses the right and left pulmonary veins, while the assistant injects saline mixed with a small amount of blood into the left atrium. An alternative test medium is methylene blue. Observe for leaks. A dental tool is used to break the seal between the tester and connector. If there are any leaks, sutures are placed at this time. On the right side, fluid is simply injected into the right atrium under pressure, since the inferior and superior venae cavae are already obstructed by the caval tapes. Again, closure of leaks with a 3-0 MH polypropylene suture is done at this time.
7.5 Outflow Connectors

7.5.1 Great vessel connections are made. The pulmonary artery anastomosis is made first. The lengths of the outflow connectors are determined by placing the artificial ventricles in position within the pericardial cavity. Place the outflow connector between the aortic or pulmonic valve and its respective great vessel and measure the distance. Cut outflow connectors to the appropriate lengths, usually 3 to 5 cm.

7.5.2 The pulmonary artery anastomosis is made with a running 4-0 polypropylene suture in an end-to-end fashion, beginning with the lateral wall and running the back wall of the anastomosis from the inside (Figure 7-7).

![Figure 7-7 - Aorta (left) and Pulmonary Artery (right) Outflow Connector Suturing](image-url)
7.5.3 A similar anastomosis is made with the aortic suture line (Figure 7-7). Then, the outflow connector leak tester is inserted into the aortic outflow connector. Saline is injected under pressure, observed for leaks, and then any leaks are closed with a 4-0 polypropylene suture. The pulmonary artery needs to be cross-clamped in order to test the integrity of the pulmonary artery-to-connector anastomosis. The pulmonary artery/aortic tester is the same, but smaller, than the one utilized for the atrial inflow connector (Figure 7-8).

Figure 7-8 - Aorta (left) and Pulmonary Artery (right) Leak Testers
7.6 Connect Ventricles

7.6.1 Once adequate hemostasis of all suture lines is established, placement of the ventricles begins. First, the left ventricle is connected (Figure 7-9).

Figure 7-9 - Connect Ventricles

7.6.2 Grasp the left inflow connector with two large Mayo clamps placed side by side, with a good hold of the connector. The opposite side of the plastic fitting for the connector of the left ventricle is placed within the connector, and the operator pulls with the Mayo clamps and pushes the left ventricle into the inflow connector. The position in which the heart sits for the duration of the support of the patient is determined by the orientation of the left ventricle as it is placed into the left atrial inflow connector. Therefore, a careful assessment of exactly where the aortic outflow connector will connect to the left ventricle and the anticipated position of the left ventricle should be made before the connection of the atrial inflow connector is completed. Snap on the aortic outflow connector, taking care not to twist the connector or aorta. While this is being done, fill the left ventricle with saline through the aortic valve as well as the outflow connector. Once the connection is made, place the patient in a steep Trendelenburg position, and place large vent sites in the highest point of the aortic outflow connector and the aorta for removal of air.
7.6.3 Connect the right ventricle. Make the atrial connection first, again taking care with the orientation of the right ventricle, so that the direction of flow from the outlet valve is appropriate for the anatomy of the patient. After the atrial connection is made, make the pulmonary outflow connection, again, taking care not to twist. Before connecting the pulmonary outflow connector graft, remove the chokers on the superior and inferior venae cavae. This allows a flow of blood into the right atrium and the right ventricle, and flushes air out as the connection to the pulmonary artery is made (Figure 7-10).

Figure 7-10 - TAH-t Final Position

7.6.4 Prepare the Driver prior to surgery as described in Section 8.2, "Readying the Companion 2 Driver for Clinical Use."

7.6.5 Perform Start Up of the Companion Driver System as described in Section 8.3, "TAH-t Startup Procedure."

7.6.6 Attach the drivelines to the Driver.

7.6.7 Verify that the following parameters are programmed into the Driver:
  - Rate: 1x
  - % Systole: 50
  - LDP: 180 mmHg
• RDP: 60 mmHg
• Right/Left Vacuum: 0 mmHg

7.6.8 Place the patient in a steep Trendelenburg position and slowly ventilate the lungs.

7.6.9 De-air both the left and right ventricles by delivering a single pulse from the Driver at the set pressure and vacuum. (Companion 2 operator presses the 1x button on the Driver for each pulse). Alternately, the rate can be set to a value desired by the surgeon to complete the de-airing process.

7.6.10 Agitate the ventricles, as well as the atria, to facilitate removal of air from the system. Use transesophageal echocardiography to help determine when the device has been completely de-aired.

7.6.11 As air is slowly removed from the TAH-t, and when directed by the surgeon, increase the pumping rate by pressing the rate “+” button to begin pumping at 40 bpm. Generally, this process takes about 10 minutes and should be done with patience and attention, to remove air from the artificial ventricles before the TAH-t takes over from the heart-lung machine. Decrease flow on the heart-lung machine temporarily to help move air through the lungs and into the TAH-t. Once satisfied that all the air is out of the TAH-t, close the vent sites, and begin full pumping at a rate of 120 bpm as the patient is weaned off the heart-lung machine.

7.6.12 The patient should be kept in steep Trendelenburg for an additional 15-20 minutes to ensure that any remaining air in the system does not cause neurologic complications. The stroke volumes will be low until the patient is completely weaned off cardiopulmonary bypass. As the perfusionist begins to slow venous return, TAH-t filling should increase.

7.6.13 As the table is flattened out, try to position the ventricles within the mediastinum. The pleura on both sides should not be opened and the pericardium should be left intact for closure.

7.6.14 In smaller patients, there may be a need to force the right ventricle under the left edge of the sternum. Care should be taken to examine the left pulmonary veins and the inferior vena cava for evidence of compression. This is facilitated with transesophageal echo.

7.6.15 Check for hemostasis. After protamine has been administered and hemostasis obtained, use towel clips to perform a trial closure of the sternum. If the fit of the device is judged to be adequate by hemodynamic stability and by transesophageal echo examination of the caval and pulmonary venous flows, reopen the chest and bring together the edges of the Gore-Tex sheets to form a tent or
neo-pericardium. Take care to make a loose fit, without impinging upon the cavae and placing tension on the device. Prior to closure of the cephalic part of the neo-pericardium, pass a rectangular piece of Gore-Tex membrane around the proximal ascending aorta and anchor with non-absorbable suture. This provides a surgical plane at explant between the aorta and pulmonary artery to facilitate encircling and cross clamping the aorta.

7.6.16 Place one chest tube in the neo-pericardium and a second in the native pericardial space. Irrigate with antibiotic solution before closure. Close the sternum and remaining incision in a routine fashion. Check device output, central venous pressure, and device filling when the chest is closed, because chest closure may alter the anatomy, causing pressure on the left pulmonary veins, inferior vena cava, and occasionally the right pulmonary veins. If decreased flow is noted, reopen the chest and make changes in the position of the device. One possible change is to mobilize the diaphragmatic attachment of the pericardium, allowing the device to sit more leftward in the chest. This requires opening the left pleura, allowing the TAH-t to slightly migrate into the left pleural space. If decreased flow is still observed, the right ventricle may need to be anchored to a rib, using umbilical tape (Figure 7-11).

Figure 7-11 - Solution to a Fit Problem
Chapter 8. Companion 2 Driver System

The SynCardia Companion 2 Driver System Operator Manual contains detailed information on the setup and operation of the Companion 2 Driver System. It contains the following sections:

- Device Description
- Indications for Use
- Contraindications
- Warnings
- Precautions
- Companion 2 Driver
- Hospital Cart
- Driver Caddy
- Operating Modes – Surgical (O.R.) Environment
- Operating Modes – I.C.U. Environment
- Operating Modes – Ambulatory Mode
- List of Symbols
- Companion 2 Driver Operating Cautions
- Power Management
- Alarms and Notification
- Switching to Backup Companion 2 Driver
- Switching from the SynCardia CSS Console to the Companion 2 Driver System
- Switching from Companion 2 Driver System to the SynCardia CSS Console
- Switching from Companion 2 Driver System to the Freedom Driver System
- Equipment Maintenance and Care
- Unpacking and System Setup
- Companion 2 Driver System Specifications
8.1 Companion 2 Driver Operation Dos and Don’ts

- **Do** set backup Driver parameters to the same values as the primary Driver.

- **Do** keep wheel casters locked except for transport.

- **Do** connect the A/C power cord only to grounded mains outlets with ratings that match those given on the device identification label. Only connect the mains input of these components to suitable mains outlets complying with the electrical safety regulations of the respective country of use.

- **Do** protect all components from exposure to dampness and moisture. Do not store the Companion 2 Driver System in damp rooms.

- **Do** protect all components against temperatures lower than 10°C (50°F) and above 30°C (95°F), as well as against sudden temperature changes and overheating. Avoid exposing the components to direct heat radiation.

- **Do** protect all Companion 2 Driver System components against interference from strong electromagnetic fields (as generated by mobile/cell phones, magnetic resonance tomography equipment, etc.). This also applies to the Batteries not currently connected.

- **Do** ensure that the Companion 2 Driver System always receives an adequate amount of power. **Never disconnect both Batteries from the Driver at the same time.** Recharge depleted Batteries immediately.

- **Do** use only the power cords and Batteries supplied with the Companion 2 Driver System. Do not connect the Companion 2 Driver System to multiple-outlet adapters or mains extension cables.

- **Do** make sure that the Driver is not covered by textiles, clothing or similar items.

- **Do** protect all components against dirt and contamination (IP30 rating). Prevent foreign objects from falling or working their way into the connectors and ventilation slits.

- **Do** use only Batteries that you know are in full working order. Immediately replace Batteries that are not working correctly.

- **Do** protect the components against mechanical shocks, and ensure that they are not dropped.

- **Do** keep a backup Companion 2 Driver System ready for use and near the patient at all times.
- **Do not** operate or adjust the Companion 2 Driver System without proper training.

- **Do not** use a Driver outside of its planned maintenance cycle.

- **Do not** operate a Driver having only one functional compressor for any longer than is necessary to switch to a back up Driver.

- **Do not** leave the OR with the Driver set to O.R. Mode, because audible alarms are muted, and the system may be stopped by setting the rate to zero.

- **Do not** leave the key in the key switch while the Driver is operating. Remove the key once the Driver is turned on. Store in a location determined by the clinical staff.

- **Do not** use the Driver System in areas with explosive atmospheric conditions.

- **Do not** touch or manipulate the components with pointed or sharp-edged objects (surgical instruments, wire brushes etc.). Also be careful with clothing items, such as sharp-edged belt buckles.

- **Do not** let the Driver come into contact with any chemicals other than those permitted for disinfection.

- **Do not** place other objects on the Driver.

### 8.2 Readying the Companion 2 Driver for Clinical Use

8.2.1 Dock the Driver without External Batteries into the Hospital Cart. If necessary, this may be done with the help of another trained user.

8.2.2 Connect the Hospital Cart to a wall AC power source.

8.2.3 Insert two External Batteries into the Driver.

8.2.4 Connect the Driver to external air. If external air is not available, the Driver will operate with its internal compressors.

8.2.5 Turn the Driver to the ON position using the key, and then remove the key and store in a location determined by the clinical staff.

8.2.6 Immediately upon start-up, the Driver will perform several self-checks to verify that all the internal electronics are functioning properly. The Driver will operate at the default parameters until the software is fully loaded. It will then operate at the previously settings in Ambulatory Mode.

8.2.7 Change from Ambulatory Mode to O.R. Mode using the password.

8.2.8 Perform System Check – Select MENU, SYSTEM, and SYSTEM CHECK, then follow the onscreen prompts.
8.2.9 Enter data for the new patient’s profile.

8.2.10 Set the startup parameters in O.R. Mode to the following values:

- Rate: “--” indicates single pulse mode
- % Systole: 50
- LDP: 180 mmHg
- RDP: 60 mmHg
- Right/Left Vacuum: 0 mmHg
- **NOTE**: When in O.R. Mode, audible alarms are always muted.

8.2.11 Before moving the Driver (and Hospital Cart) to the Operating Room, moisten a clean cloth with an antibacterial agent and wipe down all exterior surfaces of the Hospital Cart.

8.2.12 Do not spray any cleaning agent directly on the Driver or Hospital Cart.

8.1.13 Move the Driver (and Hospital Cart) into the O.R. and plug the Hospital Cart into a wall outlet.

### 8.3 TAH-t Startup Procedures

8.3.1 Position the rear side of the Hospital Cart within driveline length of the patient’s chest.

8.3.2 Lock the casters (wheels).

8.3.3 Verify that the Driver is in O.R. mode with the following values:

- Rate: “--” indicates single pulse mode
- % Systole: 50
- LDP: 180 mmHg
- RDP: 60 mmHg
- Right/Left Vacuum: 0 mmHg
- **NOTE**: When in O.R. Mode, audible alarms are always muted.

8.3.4 Attach drivelines to Driver.

8.3.5 When instructed by the surgeon, deliver a single pulse at the set pressure and vacuum by pressing the 1x button to de-air both the left and right ventricles. Continue to deliver single pulses by pressing the 1x button as directed by the surgeon until all air is out of the system. Alternately, the rate can be set to a value desired by
the surgeon to complete the de-airing process. After ventricles are
de-aired and verified by transesophageal echo, await instructions
from the surgeon to continue.

8.3.6 Following de-airing and when directed by the surgeon, press the
rate “+” button to begin pumping at 40 bpm.

8.3.7 If there is a need to stop the Driver, the drivelines can be
disconnected from the Driver using the single connector to
immediately cease TAH-t pneumatic support. Alternately, the
Driver may be switched to the OFF position, but the System must
complete the boot process before settings can be adjusted.

8.3.8 When the surgeon is ready to wean the patient from
cardiopulmonary bypass, increase the rate to 120 bpm. Pressing
the “+” button will increase rate by 1 BPM. Press and hold the “+”
button to increase rate in 10 BPM increments.

8.3.9 Stroke volumes will be low until the patient is completely weaned
from cardiopulmonary bypass. As the perfusionist begins to slow
venous return, TAH-t filling should increase.

8.3.10 Pneumatic drive ejection pressures should be set to achieve full
ejection. Monitor the pressure tracings displayed on the Hospital
Cart Display to assure the right drive pressure is set to overcome
the pulmonary systolic pressure, and the left drive pressure is set to
overcome the aortic systolic pressure.

8.3.11 The fill volumes will be approximately 45 ± 5 milliliters until volume
is added and vacuum is applied.

8.3.12 Do not apply vacuum until after chest is completely closed.

8.3.13 The TAH-t Rate should be set on the Hospital Cart Display to
achieve a stroke volume between 50 and 60 milliliters. TAH-t Rate
is typically between 110 - 130 bpm.

8.3.14 Prior to moving to ICU, press MENU on the Driver, then MODE and
enter ICU Mode to enable audible alarm functions of the Driver, to
add additional security for changing operating parameters, and to
prevent changes of rate to a single pulse mode or other non-
therapeutic settings (e.g., 40 bpm).

8.3.15 When moving patient to ICU from the OR, the Hospital Cart with the
docked Driver can be placed at the foot of the bed, or the Driver
can be docked into a Driver Caddy, or can be placed on the
patient’s bed.

8.3.16 In ICU, continue to monitor Driver settings to ensure partial fill
volumes and full eject and adjust as necessary.
8.3.17 When the patient is ready to be moved from ICU to the Step Down Unit, change user mode to Ambulatory Mode to prevent unauthorized changes to device settings.
Chapter 9. Explantation Procedures

Explantation of the TAH-t should be handled like any other redo cardiac procedure. Great care should be taken in the separation of the sternum from the TAH-t, the great vessel connector, and the drivelines. Explantation may be easier if the TAH-t is covered with a Gore-Tex membrane.

Initiate cardiopulmonary bypass with dual caval cannulation with tourniquets. Cross-clamp the aorta, and turn off the TAH-t System. Separate the artificial ventricles from the atrial inflow cannula. Amputate the great vessels outflow connectors at the level of the connector/great vessel anastomosis. Transect the artificial ventricles at the base to the cannula connection, and remove the TAH-t from the operating field. Pull the cannulae through the skin. The remaining atria inflow connectors are still in the remaining portion of ventricular muscle where they were initially sutured. Remove them by transecting the AV groove throughout. Trim the remaining atria and great vessels to accept the donor heart.
Chapter 10. System Components

10.1 SynCardia TAH-t System

The TAH-t System is comprised of the following:

- **Implant Kit** - Part # 500101 (Sterile)
  Contains left artificial ventricle, right artificial ventricle, two inflow connectors, two outflow connectors, and an ancillary pack with drivelines, inflow pressure test plug, outflow pressure test plug, locking ties, and two de-airing needles (all sterile). All sterile components are packaged in double aseptic transfer packages.

- **Surgical Spares Kit** - Part # 500177 (Sterile)
  Contains inflow connector, outflow connector, drivelines, inflow pressure test plug, outflow pressure test plug, and locking ties.

- **External Pneumatic Driver:**
  Companion 2 Driver System – Part # 397002-001 (non-sterile).

10.2 Companion 2 Driver System

The Companion 2 Driver System is comprised of the following components:

- Driver (plus one additional backup Driver) – Part # 397002-001
- 2 Batteries (plus two additional Batteries for backup Driver) - Part # 293001-001
- Hospital Cart - Part # C-400002/ Part # 397003-001
- Caddy - Part # C-400003/ Part # 397001-001
- AC Power Cord - Part # 197053
- Pair of Drive Lines - Part # C-400008/ Part # 193002-001
- Optional Hand Pump – Part # 397004
Appendix A - Patient Selection and Management

Management and coordination of successful TAH-t support requires a multidisciplinary team that has experience with circulatory support systems. Teams can include surgeons, cardiologists, heart transplant coordinators, perfusionists, engineers, nurses, cardiac rehabilitation therapists and coagulation specialists.

The following is a report of the experience of one of the largest clinical site users, University Medical Center, Tucson, Arizona.

Patient Selection

Successful bridge to transplant with the TAH-t involves selecting patients who are transplant eligible and who additionally are assessed in two main areas: 1) evaluation of fit of the TAH-t in the patient's chest, and 2) evaluation of the potential for reversal of any end organ dysfunction.

Once the TAH-t is implanted, and there are no fit issues, flow is maximized through the TAH-t.

The TAH-t is generally specified for patients with body surface areas of 1.7 m². At a cardiac index of 2.5 l/min/m², the calculated flow would be 4.25 liters/min. This is the flow used to simulate hypotensive conditions tested during product reliability testing.

With normalized hemodynamics, device outputs remain relatively constant, changing as the CVP fluctuates. This “Starling-like response” (where an increase in CVP fills the TAH-t with more volume, which is ejected on the next beat, increasing device output), requires no controller adjustments. Constant device output and high flow under normal CVP provides washing of the artificial ventricles.

Antithrombotic Therapy

The level of anticoagulation will vary depending on the patient’s coagulation status. Typically, patients supported with the TAH-t require systemic antithrombotics similar to that used for patients with mechanical valves.

Driveline Exit Site Management

Take care to keep driveline exit sites clean and dry. Infections should be treated according to hospital protocol.
Appendix B - Outline of Training Program

Operation of the TAH-t System should only be undertaken by personnel trained in accordance with the SynCardia Certification Program. The program will include the following topics:

(1) Indications and Contraindications
(2) System Overview
(3) Implant Procedures
(4) Operation of the Drive Systems
(5) Explant Procedures
(6) Patient Management
(7) Summary of Clinical Studies
(8) Animal Procedure – a minimum of one implant needs to be performed.
(9) Practical Experience - Physicians will be required to minimally view one live implant procedure or have their first procedure proctored. SynCardia will maintain centers of excellence where surgeons may view implantations. Proctors will be made available by SynCardia for surgical teams during their first case.
(10) Patient Management for Discharge
Appendix C - Materials Matrix

The TAH-t ventricle components are manufactured from the raw materials as defined in Table C-1. The artificial ventricles and drivelines have met the test requirements of ISO 10993, Biological Evaluation of Medical Devices.

Table C-1 - TAH-t Patient Contacting Materials Matrix

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventricle and diaphragm</td>
<td>Segmented polyurethane</td>
</tr>
<tr>
<td></td>
<td>Nylon</td>
</tr>
<tr>
<td>Inflow connector</td>
<td>Segmented polyurethane</td>
</tr>
<tr>
<td></td>
<td>Polyester fabric</td>
</tr>
<tr>
<td>Outflow connector</td>
<td>Segmented polyurethane</td>
</tr>
<tr>
<td></td>
<td>Polyester material</td>
</tr>
<tr>
<td>Valves</td>
<td>Titanium and pyrolitic carbon</td>
</tr>
<tr>
<td></td>
<td>(Medtronic Hall Heart Valves)</td>
</tr>
<tr>
<td>Drivelines</td>
<td>Polyvinyl chloride tubing</td>
</tr>
</tbody>
</table>