

CASE STUDY

HYPERGRIP CONNECTOR SERIES

SynCardia's Freedom[®] Portable Artificial Heart Driver



- ▶ **Customer:** SynCardia Systems
- ▶ **Location:** Tucson, Arizona
- ▶ **Date:** Nov. 2010

Hypertac delivers high-reliability interconnect solutions to the medical industry. Their interconnect solutions have been used extensively for decades in areas where integrity and reliability are essential to the well-being of a patient. Hypertac contacts, connectors and cable assemblies facilitate medical trends toward less invasive procedures, disposable probes, embedded electronics, high cycle life and sterilization.

BACKGROUND

A recognized leader in the mechanical circulatory support industry, SynCardia Systems of Tucson, Arizona manufactures the SynCardia temporary "Total Artificial Heart" as a bridge to transplant for patients who are dying from end-stage biventricular failure and are on waiting lists for a heart transplant. SynCardia's Total Artificial Heart is the only FDA, Health Canada and CE approved Total Artificial Heart in the world.

SITUATION

- ▶ Shortage of donors require patients to be placed on long waitlists.
- ▶ Mobile lifestyles and quality of life is restricted due to the size, weight and non-portability of life sustaining equipment.
- ▶ Total signal reliability is crucial to development of smaller portable devices.

CHALLENGE

For patients being kept alive by the Total Artificial Heart, their wait for a donor heart has typically been one of forced hospital confinement, tethered to a large power console. SynCardia's "Big Blue" Driver is the only FDA approved driver for powering the Total Artificial Heart in the US, but it is a 418 lb. device.

SynCardia began to develop a suitable portable substitute for Big Blue that would provide patients stability with the opportunity to be discharged from the hospital to live in the comfort and familiarity of their own homes while waiting for donors.

RESULTS

SynCardia is currently conducting an FDA approved clinical study of the portable Freedom driver system. The IDE clinical study is designed to demonstrate the suitability of the Freedom driver as a pneumatic driver for stable Total Artificial Heart patients and can be safely used at home. The Freedom driver has received CE approval for commercial use in Europe.

The interconnect solutions from Hypertac within the Freedom portable driver are a key element in ensuring the reliability and dependability of this SynCardia device that can now make a positive difference in the lives of critical cardiac patients around the world.

SMITHS CONNECTORS

Smiths Connectors is a leading supplier of application-specific, high-reliability electrical interconnect solutions from highly integrated assemblies to microminiature connectors and spring probe contacts. Connectors is comprised of Hypertac, Sabritec and IDI brands, which are synonymous of exceptional performance when critical applications require a technologically advanced, high quality, multi-pin electrical connection to ensure reliability and safety. Alongside Smiths Microwave and Smiths Power,

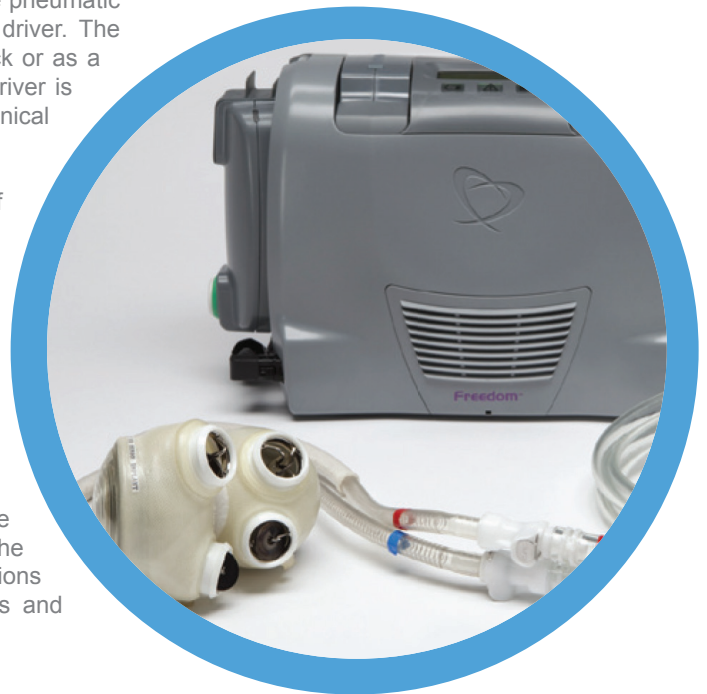
Smiths Connectors is part of the Smiths Interconnect division of Smiths Group www.smiths.com, a global leader in applying advanced technologies for markets in threat and contraband detection, energy, medical devices, communications and engineered components. Smiths Group employs around 23,000 people in more than 50 countries.

SOLUTION

SynCardia's research and development produced the Freedom portable pneumatic driver as an alternative power source to its hospital-based Big Blue driver. The Freedom driver weighs in at 13.5 lbs. and can be placed in a backpack or as a shoulder bag, providing patients hands-free operation. The Freedom driver is currently an FDA approved Investigational Device Exemption (IDE) clinical study in the US.

An issue of paramount concern to SynCardia during the development of the Freedom driver was to make certain that total signal reliability was maintained. This challenge included a critical need for reliable and dependable interconnect systems within the product. SynCardia turned to Hypertac, a proven connector vendor with a track record of success in the medical device industry. Hypertac's specialized design and development of interconnect systems met SynCardia's vital requirements for including color coding, sealing, keying and simple mating action.

Hypertac's design engineers worked closely with the SynCardia team to create an interconnect system of cable assemblies and connectors for the Freedom driver that could confidently deliver complete reliability. The combination of the Hypertac HyperGrip® and D-Series interconnect solutions within the SynCardia Freedom driver addressed the unique demands and requirements of the life-sustaining application.



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