

CorCap Cardiac Support Device

COMPANY: Acorn Cardiovascular™ is a privately held medical device company located in St. Paul, Minnesota, USA. Incorporated in 1996, Acorn Cardiovascular develops innovative solutions to improve quality of life and survival for heart failure (HF) patients.

PRODUCT: Acorn Cardiovascular developed the CorCap™ Cardiac Support Device (CSD), a proprietary mesh wrap that is implanted around the heart, to provide gentle support. The CorCap CSD is intended to prevent and reverse the progression of heart failure by improving the heart's structure and function, leading to improvements in the quality of a patient's life.

Many heart failure patients develop oversized, dilated hearts as increasing pressure within the heart pushes out against the muscle wall. The CorCap CSD is the first medical device specifically designed to alleviate this pressure, thereby addressing a major contributing factor in heart failure progression.

The CorCap CSD represents the introductory technology in Acorn Cardiovascular's product line focused on addressing a previously unmet need for heart failure patients. It is the only therapy of its kind that has been evaluated in prospective randomized clinical trials.

Since April 1999, more than 315 implants of the CorCap CSD have been performed worldwide. The product has received CE Marking in Europe, and Acorn Cardiovascular plans to seek market clearance in the United States.

CORCAP CSD—RESEARCH AND DESIGN: Acorn Cardiovascular designed the unique material used in the CorCap CSD to conform to and support the heart, while allowing normal cardiac function. To form the CorCap CSD an implant-grade polyethylene terephthalate (PET-polyester) is fabricated into a multifilament mesh knit. The proprietary processing of the device produces a highly biocompatible and durable material, designed and thoroughly tested for permanent implantation without adverse effects.

**PATIENT
POPULATION:**

The majority of patients with heart failure are on an extensive drug regimen to help relieve symptoms and potentially slow the disease. To date, neither drugs nor other medical devices have been effective at halting the eventual progression of this chronic condition. Available options for patients with advancing heart failure — organ transplants, assist devices or artificial hearts — are very limited.

The CorCap CSD has been evaluated in prospective randomized clinical trials for treatment of patients with an enlarged heart and progressive symptoms of heart failure despite optimized drug therapy.

**ANTICIPATED
BENEFITS:**

Improved cardiac structure and function: Clinical trial results indicate that patients treated with the CorCap CSD have sustained improvements in heart size and shape. Other research studies of heart failure populations have indicated that heart size reduction is associated with improvements in clinical outcomes and survival. (Circ 1987;76:44, Circ 1999;89:68)

Enhanced quality of life: Clinical trial results indicate that patients treated with the CorCap CSD have sustained improvements in quality of life, indicated by a reduction in the number of major cardiac procedures and improved quality-of-life test scores by standardized measures.

**ACORN CLINICAL
TRIAL:**

The Acorn Clinical Trial is the most extensive pre-market evaluation of a surgical treatment for heart failure ever undertaken, involving 300 patients at 29 centers across North America. This trial was conducted to evaluate effectiveness of CorCap CSD therapy in the treatment of heart failure patients with an enlarged heart and progressive symptoms despite optimized drug therapy.

CAUTION – The CorCap Cardiac Support Device is limited by United States law to investigational use.

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RESHAPING HEART FAILURE THERAPY