corvia®

CORVIA MEDICAL FACT SHEET

Note: The Corvia® Atrial Shunt System (IASD® System) is not available for commercial distribution in the United States.

CORVIA® ATRIAL SHUNT SYSTEM

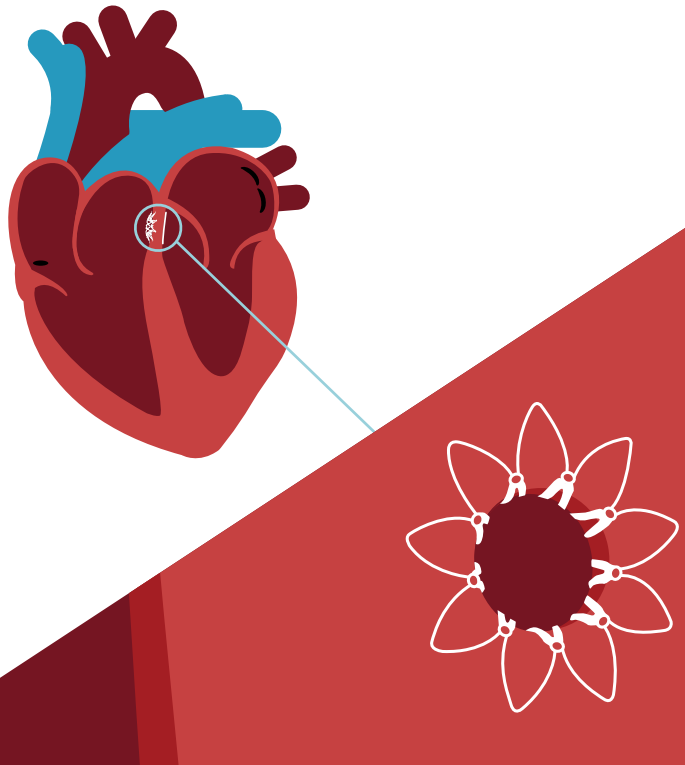
THE DEVICE — The Corvia Atrial Shunt is a novel, minimally invasive cardiac implant for patients suffering from symptomatic heart failure (HF). Designed to reduce elevated Left Atrial Pressure (LAP), the Corvia Atrial Shunt offers a new therapeutic option for the more than 50% of HF patients with an ejection fraction over 40%. These patients previously had no effective treatment options, and often remained symptomatic with a poor quality of life, despite Guideline Directed Medical Therapy (GDMT). The Corvia Atrial Shunt received CE Mark approval in 2016 and was the first commercially available interatrial shunt for HF.

QUICK FACTS

- First therapeutic device designed to directly address elevated LAP, the primary cause of HF symptoms
- Provides continuous and dynamic LAP reduction at any activity level
- Only requires short term dual antiplatelet therapy
- Treatment is less reliant on compliance with medication and diet
- Therapy is not dependent upon daily pressure monitoring

HOW IT WORKS

During a catheter-based, outpatient procedure, an interventional cardiologist or electrophysiologist will insert a catheter into a vein in the groin to access the heart. This catheter is used to create a very small opening in the septum, the heart wall between the right and left atria, the upper chambers of the heart. After this small opening is created, the Corvia Atrial Shunt is implanted, forming a passage between the left and right atria that enables the left atrium to decompress on demand at rest and during physical activity, with the aim of lowering left atrial and pulmonary pressures. By facilitating continuous and dynamic decompression of the left atrium, the Corvia Atrial Shunt therapy aims to improve heart failure symptoms and quality of life, decrease heart failure hospitalizations, and reduce the overall cost of managing heart failure patients.



HEART FAILURE

26 million people have heart failure worldwide.[1]

By 2030, that number will increase by almost 50%,[2] to nearly **38 million**

HEART FAILURE DEFINITION

HF is a pathophysiological state in which cardiac output is insufficient to meet the needs of the body or does so at higher filling pressures. The term "congestive heart failure" is often used, as one of the common symptoms is congestion, or build-up of too much fluid in tissues and veins. Specifically, congestion takes the form of water retention and swelling (edema), both as peripheral edema (causing swollen limbs and feet) and as pulmonary edema (causing breathing difficulty), as well as ascites (swollen abdomen) and liver enlargement.

TYPES OF HEART FAILURE

HF is generally divided into two different syndromes based on ejection fraction (EF), a measurement of how well the heart is pumping blood. Ejection fraction represents the proportion of blood pumped out of the heart during a single contraction and is given as a percentage, with the normal range being between 55 and 75%.

- **Heart Failure with preserved Ejection Fraction (EF >50%; HFpEF) or Heart Failure with mid-range Ejection Fraction (EF 40-49%; HFmrEF)**. HFpEF or HFmrEF occurs when the muscles of the left atrium and ventricle become stiffer and are unable to relax normally. As a result, the left heart cannot fill properly, and the pressure inside the left heart chambers and the lungs increases.
- **Heart Failure with reduced Ejection Fraction (EF <40%; HFrEF)**. HFrEF occurs when the heart loses its ability to contract effectively, meaning the heart cannot pump with sufficient force to push enough blood into circulation, and the pressure inside the left heart chambers and the lungs increases.

SYMPTOMS OF HEART FAILURE

Both types of HF result in similar symptoms, due primarily to elevated LAP, which causes blood to back up into the lungs. Common symptoms include the following:

- Shortness of breath during daily activities
- Having trouble breathing when lying down
- Weight gain with swelling in the feet, legs, ankles, or abdomen
- Generally feeling tired or weak with limited or inability to exercise

THE UNMET CLINICAL NEED

HFpEF and HFmrEF remain among the most significant unmet needs in cardiovascular medicine. While there have been significant advances in the treatment for patients with HFrEF, there previously were no effective treatment options for HFpEF/HFmrEF.[3] Medicines that are effective for treating HFrEF frequently do not work well for HFpEF/HFmrEF, and although they are prescribed to help alleviate symptoms, patients often struggle with daily activities because of breathlessness, fatigue and depression. For many, these symptoms drastically reduce their quality of life and frequently result in hospitalization.

More than half of all HF patients have HFpEF[4], and that number is increasing, driven by population aging and other common risk factors such as obesity and hypertension.

HEART FAILURE STATISTICS

26 million | There are an estimated 26 million people suffering globally from heart failure[1]

~6.2 million

people in the United States have HF; approximately 1 million people are newly diagnosed each year[5]

1 in 5

The lifetime risk of developing heart failure[6]

~7.4 million

Europeans have HF[7]; and over 1.3 million new diagnoses are reported each year in Europe[8]

20-30%

Despite significant advances in HF treatment, mortality post HF hospitalization remains around 10% at 1-month, and the overall HF mortality rate remains 20-30% at 1 year and 75% at 5 years.[9,10,11]

~7 million

HF with preserved (HFpEF) or mid-range ejection fraction (HFmrEF), accounts for over half of all heart failure admissions, affecting approximately 7 million people in the United States and Europe alone[12]

$69.8 billion

The estimated annual cost of heart failure in the US was $30.7 billion in 2012 and costs are estimated to reach $69.8 billion by 2030[5]

CLINICAL EVIDENCE

CLINICAL RESULTS

The Corvia Atrial Shunt is the most clinically studied interatrial shunt for the reduction of left atrial pressure in HFpEF/HFmrEF patients. It has been implanted in nearly 500 patients worldwide and reviewed in over 20 publications. Patients implanted with the device have been followed for more than seven years. Through multiple REDUCE LAP-HF studies around the world, clinical results have consistently demonstrated the safety and efficacy of the device.

EFFICACY

- 75% of patients had an improvement in quality of life at 3 years[13]
- 69% of patients were free from heart failure hospitalizations 3 years after device implantation[13]
- Significant improvement in HF symptom severity, with 65% of patients in New York Heart Association (NYHA) Class I or II at 3 years[13]

SURVIVAL

- 87% survival at 3 years[14]

SAFETY

- 98% freedom from cerebrovascular events (stroke) at 3 years[14]
- 100% patency (blood flow from the left to the right atrium) at 1 year[15,16,17]
- No reports of implanted device removal, closure or thrombosis up to 8 years[18]

CLINICAL INVESTIGATION

Corvia Medical has conducted multiple **REDUCE LAP-HF** studies around the world to evaluate the Corvia Atrial Shunt System for the treatment of HF patients with elevated left atrial pressure who remain symptomatic despite standard GDMT. Studies include the following:

Pilot Study (first in human) n=11

REDUCE LAP-HF (CE Mark study) n=64

REDUCE LAP-HF I (randomized mechanistic study) n=44

REDUCE LAP-HF II* (sham controlled trial) n=626

*Randomization in the global, 626-patient REDUCE LAP-HF II was completed August 2020, and results of this landmark trial are expected late 2021.

ENROLLMENT IS ONGOING IN THE FOLLOWING REDUCE LAP-HF STUDIES:

- **REDUCE LAP-HF III**: A prospective, multicenter, international study to collect post market data in up to 500 consecutive patients treated with the Corvia Atrial Shunt to further evaluate efficacy, safety and quality of life outcomes as a new treatment for patients with heart failure in a "real world" practice setting. This study is currently enrolling patients in Europe.
- **REDUCE LAP-HF IV**: A continued access study designed to generate additional safety and efficacy evidence to support therapy adoption of the Corvia Atrial Shunt. Up to 150 symptomatic heart failure patients with elevated left sided filling pressures despite standard GDMT, will be implanted in the study. The safety and efficacy results will be compared to those from the treatment arm of the REDUCE LAP-HF II study. This study will enroll patients at major centers in North America.
- **REDUCE LAP-HFrEF**: A pilot study (10 patients) to evaluate the safety and performance of the Corvia Atrial Shunt to reduce elevated left atrial pressures in patients with HFrEF who remain symptomatic despite GDMT.

CORVIA MEDICAL

THE COMPANY

Corvia Medical, Inc. is revolutionizing the treatment of heart failure (HF) through novel transcatheter cardiovascular devices. Founded in 2009 and headquartered in Tewksbury, MA, Corvia Medical is dedicated to transforming the standard of care for heart failure treatment, enabling patients to reclaim their lives. Privately held, the company is backed by Third Rock Ventures, General Catalyst Partners, AccelMed, Lumira Ventures, Edwards Lifesciences and an undisclosed strategic investor.

CORVIA MEDICAL & DC DEVICES

Corvia Medical, Inc. was formerly known as DC Devices, Inc. and changed its name to Corvia Medical, Inc. in June 2015.

LEADERSHIP

Corvia Medical's leadership team is comprised of professionals who share a passion and commitment to transform the standard of care for heart failure treatment. Each member of the management team brings extensive experience within the medical device field and a track record of success.

George Fazio
President and Chief Executive Officer

Jan Komtebedde
Senior Vice President and Chief Medical Officer

Ed McNamara
Vice President, R&D and Operations

Kate Stohlman
Vice President, Quality Assurance & Regulatory Affairs

Lisa Ensz
Vice President, Marketing

For more information, visit **www.corviamedical.com** and **treatmyheartfailure.com**.

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FDA warning: The Corvia® Atrial Shunt System is under investigational use and not available for commercial distribution in the United States.

The Corvia Medical InterAtrial Shunt Device (IASD®) System II is indicated for the improvement in quality of life and reduction of heart failure related symptoms and events in patients with heart failure with preserved (HFpEF) or mid-range ejection fraction (HFmrEF) with elevated left atrial pressures, who remain symptomatic despite standard guideline directed medical therapy.