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CORVIA MEDICAL FACT SHEET

CORVIA® ATRIAL SHUNT SYSTEM

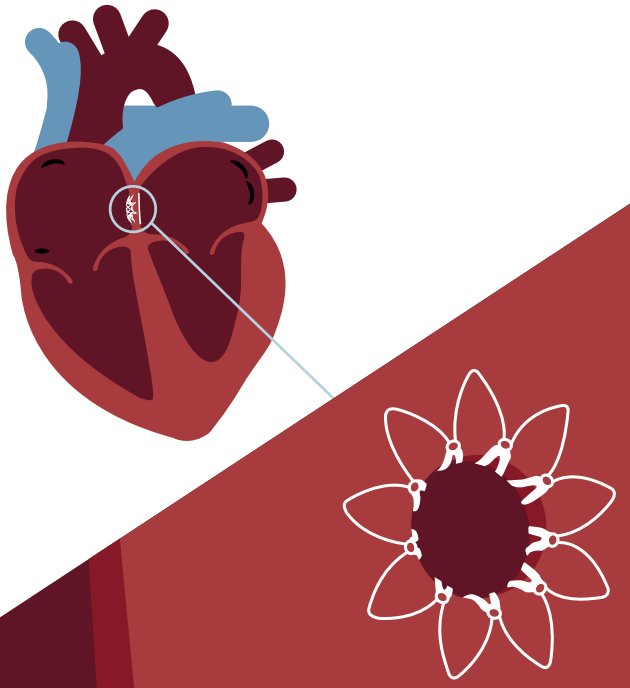
THE DEVICE — The Corvia Atrial Shunt is a novel, minimally invasive cardiac implant for patients suffering from symptomatic Heart Failure (HF). Designed to reduce elevated Left Atrial Pressure (LAP), the Corvia Atrial Shunt offers the most advanced therapeutic option for the more than 50% of HF patients 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 contributor 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 (a recent study revealed that almost half of HF patients are non-compliant with their prescribed medications).[1]
- Therapy is not dependent upon daily pressure monitoring

HOW IT WORKS

During a catheter-based, one-time 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, to lower left atrial and pulmonary pressures. By facilitating continuous and dynamic decompression of the left atrium, the Corvia Atrial Shunt has been shown to reduce HF hospitalizations and improve HF symptoms and quality of life.[2,3]



HEART FAILURE

26 million people have heart failure worldwide.[4]

By 2030, that number will increase by almost 50%,[5] to nearly **38 million**

HEART FAILURE DEFINITION

HF is a condition in which a heart is unable to pump sufficiently to meet the needs of the body. 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 in the limbs and feet (peripheral edema), lungs (pulmonary edema), abdomen (ascites), and the liver.

TYPES OF HEART FAILURE

There are two types of HF, heart failure with reduced ejection fraction (HFrEF) and heart failure with preserved ejection fraction (HFpEF). The heart's ejection fraction (EF) is a measurement of the amount of blood pumped out of the heart during a single heartbeat, and is given as a percentage, with normal ranging from 50% to 75%.

- **Heart Failure with preserved Ejection Fraction (HFpEF; EF ≥50%) or Heart Failure with mid-range Ejection Fraction (HFmrEF; EF 40-49%)**. HFpEF or HFmrEF occurs when the muscles of the left atrium (LA) and ventricle (LV) become stiffer and are unable to relax normally. As a result, blood cannot easily exit the LA into the LV with each heartbeat, causing high pressure inside the lungs and left heart chambers.
- **Heart Failure with reduced Ejection Fraction (HFrEF; EF <40%)**. HFrEF occurs when the heart walls become thinner and lose their ability to contract effectively. As a result, the heart cannot pump with sufficient force to push enough blood out of the LV and into circulation, causing high pressure inside the lungs and left heart chambers.

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 stomach
- 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.[6] 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.

>50% of heart failure patients have HFpEF.[7]

More than half of all HF patients have HFpEF,[7] and that number is increasing, driven by population aging and other common risk factors such as obesity and hypertension.

HEART FAILURE STATISTICS

10 million | Europeans have HF;[8] and over 1.3 million new diagnoses are reported each year in Europe[9]

~3.3 million

Germans have HF[10]

1 in 5

The lifetime risk of developing heart failure[11]

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.[12-14]

~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[15]

€8 Billion

The estimated cost of heart failure in Germany in 2019[16]

CLINICAL EVIDENCE

CLINICAL RESULTS

The Corvia Atrial Shunt is the most clinically studied interatrial shunt for the reduction of left atrial pressure (LAP) in HFpEF/HFmrEF patients. It has been implanted in over 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[17]
- 69% of patients were free from heart failure hospitalizations 3 years after device implantation[17]
- Significant improvement in HF symptom severity, with 65% of patients in New York Heart Association (NYHA) Class I or II at 3 years[17]

SURVIVAL

- 87% survival at 3 years[18]

SAFETY

- 98% freedom from cerebrovascular events (stroke) at 3 years[18]
- 100% patency (blood flow from the left to the right atrium) at 1 year[19-21]
- No reports of implant removal, closure or thrombosis up to 8 years[22]

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 in August 2020, and results of this landmark trial are pending.

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-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**.

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MKT0571 (EN) Rev01 2021-05

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.