Corvia® Atrial Shunt System

[Previously known as the Corvia InterAtrial Shunt Device (IASD®) System II]

INFORMATION FOR PATIENTS

This leaflet is intended to help answer questions you may have about your atrial shunt. It provides information on the following:

- What is an atrial shunt, how does it work, and who needs it
- Important safety and follow-up information
- Materials in the atrial shunt
- Who to contact if you have a serious incident related to the shunt
- The symbols on your implant card

This information is a guide. Please talk to your doctor if you have more questions.

ABOUT YOUR ATRIAL SHUNT

What is an Atrial Shunt?

The Corvia Atrial Shunt is a permanent implant designed to reduce left atrial pressure (LAP) by creating a passage that allows blood to flow from the left to the right atrium. An atrial shunt is a small metal scaffold placed in your heart.

Who Needs an Atrial Shunt?

An atrial shunt is used to treat chronic heart failure in patients who have symptoms due to high pressures in their left atrium (the part of the heart that receives oxygenated blood from the lungs). In these patients, the high pressure in the left heart causes blood to back up into the lungs. This can cause shortness of breath, fatigue, and hospital visits due to worsening heart failure.

SAFETY AND FOLLOW-UP INFORMATION

Safety Information

After your atrial shunt procedure, your doctor will recommend the following:

- Avoid strenuous physical activity for at least 2 weeks
- Take your medications as directed
- Seek medical care right away if your heart failure symptoms increase (more frequent or severe)

Some medical procedures require your doctor to take extra precautions. Before you have a medical procedure, tell your doctor that you have an atrial shunt, and show them your Cardiac Implant Card.

Magnetic Resonance Imaging (MRI) Information

An MRI scan is an imaging procedure that uses magnetic fields and radio waves to look inside your body. Your atrial shunt is MR Conditional. This means you can have an MRI scan if certain steps are followed. If an MRI is needed, your doctor must follow safety instructions for this device.

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Healthcare provider instructions are available on the Corvia Medical website:
https://corviamedical.com/corvia-atrial-shunt-system/

You may also share the instructions below:

MRI INFORMATION FOR YOUR DOCTOR

Magnetic Resonance (MR) Imaging Information

Non-clinical testing demonstrated that the Corvia Atrial Shunt is **MR Conditional**. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 tesla and 3 tesla, only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40-T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode)

Under the scan conditions defined, the Corvia Atrial Shunt is expected to produce a maximum temperature rise of 2.4°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Corvia Atrial Shunt extends approximately 5mm from this device when imaged using a gradient echo pulse sequence and a 3 tesla MR system. The device shunt lumen cannot be visualized on T1-weighted, spin echo and gradient echo pulse sequences. The magnetically induced displacement force and magnetically induced torque were tested, and no clinically significant displacement or torque was measured.

Potential Long-Term Risks

While not common, there are potential long-term risks with any implant. Potential risks with your atrial shunt include:

- Atrial shunt moving or breaking after being placed
- A blood clot that forms on or near the atrial shunt and travels through the heart causing a blockage of a blood vessel (called an embolization, infarction with potential stroke)
- A tear or wearing down of the heart wall
- Headache
- Chest pain
- Heart rhythm changes
- Or the atrial shunt becomes blocked over time and there is a return of symptoms

How Long will Your Atrial Shunt Last?

Your atrial shunt is a permanent implant. It does not have a defined time after which it must be removed. It would only be removed if there was a medical reason to do so. Your atrial shunt has passed testing equal to 10 years of real-life heart beating. Talk to your doctor about the risks and benefits of this medical device and any necessary follow-up.

Appointments with Your Doctor

After placement of your atrial shunt, your doctor will schedule follow-up visits to see you. During these visits, your doctor will examine you to make sure that your atrial shunt is working well for you.

IMPLANT MATERIALS

Atrial Shunt Material

Your atrial shunt is mostly made of a nickel titanium (NiTi) alloy (0.144 grams), the same metal used in heart stents and other implants. The atrial shunt has a very small amount of Tantalum (0.005 grams), a metal that allows your doctor to see your atrial shunt on x-ray.

Residuals

Your device was sterilized with ethylene oxide (EO). Remaining EO particles are rarely found at a detectable level on a metal implant.

IN CASE OF SERIOUS INCIDENT

If you have a serious issue with your device, you should tell your doctor right away. Please also report the issue to Corvia Medical, Inc. at the following website: www.corviamedical.com

CAUTION: Investigational Device. Limited by United States law to investigational use. To be used by qualified investigators only. For use in a pre-market clinical investigation only.

The following international symbols are provided on the implant card, on the device package label, and in the instructions for use given to the doctor who places the implant.

IMPLANT CARD SYMBOLS

Explanation of Symbols on the Implant Card

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Patient Name or ID		Medical Device
	Date of Implant		Lot Number
	Healthcare Provider / Institution		Serial Number
	Patient Information Website		Unique Device Identifier
	MR Conditional		Manufacturer

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