



Corvia® Atrial Shunt System (IASD®)

Atrial Shunt

INFORMATION FOR PATIENTS

This leaflet is intended to help answer questions you may have about your atrial shunt. It provides information about your atrial shunt, including a description of the following:

- What your atrial shunt is, what it does, and who needs it
- Important performance, safety and follow-up information
- Materials used to make your atrial shunt
- Who to contact if you have a serious incident related to your device
- The symbols on your implant card

This information is only designed as a guide. Please talk to your doctor if you have questions that are not answered in this leaflet.

ABOUT YOUR ATRIAL SHUNT

What is an Atrial Shunt?

Your atrial shunt is a small metal scaffold placed in your heart. It is a permanent implant designed to decrease pressures in the heart and lungs and therefore reduce breathing difficulty and other heart failure symptoms that often result in hospitalization.

Who Needs an Atrial Shunt?

Atrial shunts are used to treat patients with chronic heart failure who are experiencing symptoms due to high pressures in their left atrium (the chamber of the heart that receives oxygenated blood from the lungs). In these patients, the high pressure in the left atrium causes blood to back up into the lungs, causing shortness of breath, fatigue, and hospitalization due to worsening heart failure.

PERFORMANCE, SAFETY AND FOLLOW-UP INFORMATION

Intended Performance

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. The shunt does not need to be removed unless there is a medical reason to do so.

Safety Information

After your atrial shunt implant procedure, your doctor will advise the following:

- Avoid strenuous physical activity for at least 2 weeks.
- Be diligent with prescribed medications.
- Seek immediate medical attention if you experience sudden increases in heart failure symptom frequency or severity.

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 at organs and structures inside your body. Your atrial shunt is MR Conditional. Patients with an MR Conditional implanted device can undergo an MRI scan if certain steps are followed. If an MRI is needed, your provider must follow the MRI safety instructions for this device.

Healthcare provider instructions are available on the Corvia Medical website:

www.corviamedical.com/treatment/ or you can share this leaflet, which provides instructions below:

Magnetic Resonance (MR) Imaging Information

Non-clinical testing demonstrated that the Corvia Atrial Shunt (IASD) 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.

Potential Long-Term Risks

Potential long-term device risks include movement or fracture after placement, a blood clot that forms on or near the device and travels through the heart causing a blockage of a blood vessel (embolization, infarction with potential stroke), perforation or erosion of the heart wall, headache, chest pain, heart rhythm changes, or gradual implant occlusion and return of symptoms. These risks are uncommon.

How Long will Your Atrial Shunt Last?

Your atrial shunt is a permanent implant and does not have a defined service life after which it must be removed. It would only be removed if there was a medical reason to do so. 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 made out of a nickel titanium (NiTi) alloy, the same metal used in cardiac stents and other implants.

Residuals

Your device was sterilized with ethylene oxide. Ethylene oxide residuals are rarely found at a detectable level on a metal implant.

IN CASE OF SERIOUS INCIDENT

If you encounter a serious incident with your device, you should report it immediately to your doctor. Please also report the incident to Corvia Medical, Inc. at the following website: www.corviamedical.com

CE Mark of Conformity

The following CE Mark of conformity is applicable to this device:



Notified Body ID

The following international symbols are provided on the device packaging and in the instructions for use provided 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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