1. DEVICE DESCRIPTION

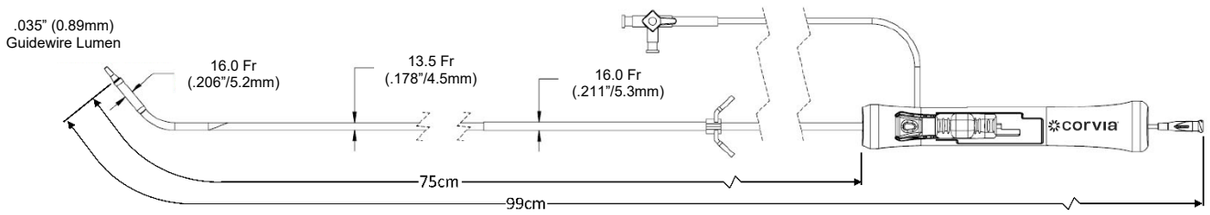
The Corvia Atrial Shunt System consists of a permanent implant pre-loaded onto a delivery system. The implant is placed across the interatrial septum using a percutaneous transvenous approach.

1.1 Intended Use

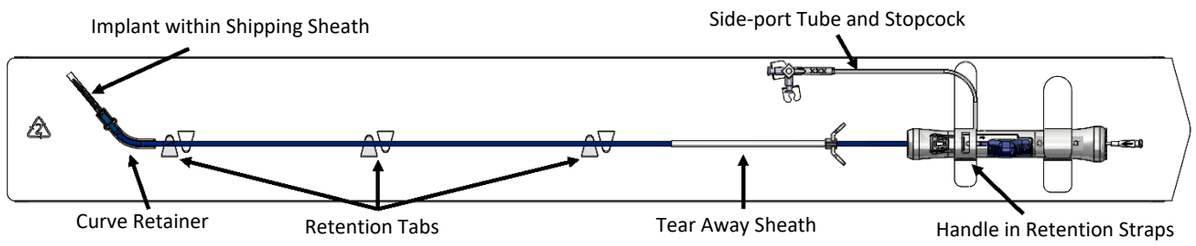
The Corvia Atrial Shunt System is a permanent implant and associated delivery system to reduce left atrial pressure (LAP) by creating an atrial septal shunt.

1.2 Delivery System

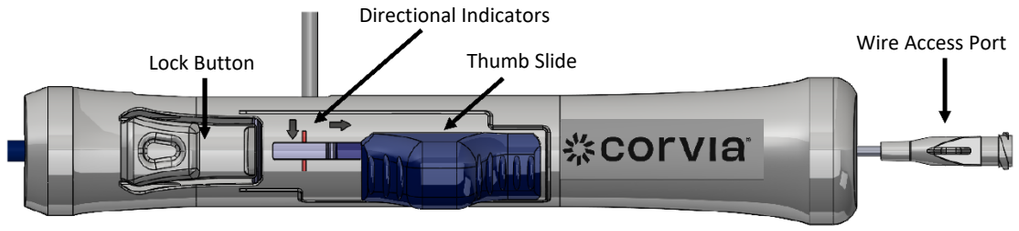
The delivery system is designed to deploy the implant. The delivery system consists of an outer delivery catheter, inner catheter and proximal handle. The delivery system is an over-the-wire (OTW) design, that is 0.89mm (0.035") guidewire compatible. The approximate working length is 75 cm (30"). The delivery system is compatible with a 5.3mm (16 Fr) introducer sheath. The inner and outer catheters both have radiopaque marker bands near the distal tip. The handle features a thumb slide with safety stops for controlled implant deployment.



Corvia Atrial Shunt System Dimensions



Packaged Delivery System



Delivery System Handle

1.3 Implant

The implant is made of nickel-titanium alloy metal that is formed into a self-expanding double-disc design with an open "barrel" in the center. Each disk of the implant is multi-legged and the left atrial disk has a tantalum radiopaque marker at the end of each leg. The overall diameter is approximately 20mm (0.79") and the barrel opening is 8mm (0.315") diameter. In the setting of elevated left atrial pressure greater than right atrial pressure, the barrel allows left to right blood flow. The implant comes pre-loaded in the shipping sheath on the delivery system.

Implant

2. INDICATIONS FOR USE

The Corvia Atrial Shunt System 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 mildly-reduced ejection fraction (HFmrEF) with elevated left atrial pressures, who remain symptomatic despite guideline directed medical therapy.

3. CONTRAINDICATIONS

- Hypertrophic obstructive cardiomyopathy, constrictive pericarditis, cardiac amyloidosis or other infiltrative cardiomyopathy (e.g., hemochromatosis, sarcoidosis)
- Patients who cannot tolerate procedural anticoagulation or a post-procedure anti-platelet regimen, or with a documented coagulopathy
- Significant right ventricular dysfunction
- Significant pulmonary vascular disease
- Implanted cardiac rhythm management (CRM) device.

4. CLINICAL BENEFITS

Evidence of clinical benefit for heart failure patients treated with the Corvia Atrial Shunt System is supported by clinical results from the REDUCE LAP-HF, REDUCE LAP-HF I and REDUCE LAP-HF II studies as summarized below:

- Reduction in number of Heart Failure (HF) events
- Reduction in HF symptoms
- Improved exercise tolerance
- Improved quality of life

5. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

The summary of safety and clinical performance (SSCP) is intended to provide public access to clinical data and other relevant information about the safety and clinical performance of a specific medical device. The Basic UDI-DI is the unique identifier of a device and can be used to locate the SSCP for the Corvia Atrial Shunt System in EUDAMED (European Database on Medical Devices). The database can be accessed using the following link: https://ec.europa.eu/tools/eudamed.

The Basic UDI-DI for the Corvia Atrial Shunt System is 0863788000400209EM

6. WARNINGS

6.1 Do not implant in patients with:

- Recent history of deep vein thrombosis (DVT), pulmonary emboli, stroke or transient ischemic attack (TIA)
- Hemodynamically significant mitral, tricuspid or aortic valve disease
- Echocardiographic evidence of intra-cardiac mass, thrombus or vegetation
- Evidence of intracardiac, inferior vena cava, or femoral venous thrombus
- Existing or surgically closed atrial septal defects.

6.2 Right ventricular dysfunction can be identified by one or more of the following: TAPSE < 1.4 cm, RV size ≥ LV size or RV fractional area change < 35%.

6.3 Patients with significant pulmonary vascular disease are optimally diagnosed under exercise conditions; peak exercise pulmonary vascular resistance (PVR) > 1.75 Wood units indicates significant pulmonary vascular disease.

6.4 Patients with a history of incident atrial fibrillation or flutter should be treated per anticoagulation guidelines unless otherwise indicated, to minimize the risk for paradoxical embolus and potential ischemic events, including MI and stroke.

6.5 Patients with hypersensitivity to nickel, titanium or tantalum may have an allergic reaction

- Additional information is provided in Section 11.

6.6 The device is only to be used by physicians trained in its use

- Perform the procedure only at hospitals where interventional cardiology expertise and facilities are readily available, and transport to surgery can be achieved in an emergency.
- Only physicians trained by Corvia Medical to use the Corvia Atrial Shunt System and experienced in transseptal puncture and percutaneous structural heart procedures should use the device.

6.7 Do not attempt to repair or reuse damaged product

- Do not reuse or re-sterilize product. The device has been designed and tested for single use only and reuse of any component of the system can lead to serious injury, including death. Re-sterilization and subsequent re-use of the delivery system may potentially reduce the strength of bonds in the delivery system leading to catheter fracture.
- Proprietary equipment is required to load the implant into the delivery system without damaging it. Re-loading a previously deployed implant may cause device malformation or fracture.

6.8 Avoid mal-deployment of the implant

- Use echocardiographic imaging to ensure successful deployment of the implant. If echo imaging is inadequate, use fluoroscopy imaging with contrast injections as needed to visualize the delivery system, implant and the surrounding anatomy.

6.9 Remove mal-deployed implants

- Do not withdraw a mal-deployed implant or partially deployed implant through intra-cardiac structures unless it is contained within a sheath. Moving an uncontained implant may damage vascular, valvular, and/or other cardiac structures, or result in other patient injury.
- A mal-deployed implant may disrupt critical hemodynamic functions. Physicians must be prepared to remove mal-deployed implants.

7. PRECAUTIONS

7.1 Clinical Evidence

- Clinical trial use has been limited to patients with hemodynamic measurements demonstrating right atrial pressure (RAP) < 15 mmHg and a pressure gradient with pulmonary capillary wedge pressure (PCWP) > right atrial pressure (RAP) by at least 5 mmHg.
- The safety and effectiveness of the Corvia Atrial Shunt System has not been established in patients who are younger than 40 years old or women of childbearing potential.

7.2 Handling Precautions

- Inspect package before opening. Do not use if pouch seal is opened, broken or damaged as contents may no longer be sterile.
- Inspect implant and delivery system prior to patient use. Do not use if product appears to be damaged.
- Do not modify the device. Modification may result in damage to product and/or patient injury.
- Do not use if unable to flush delivery system.
- Do not perform power injections through delivery system.
- Do not use after labeled expiration date.

7.3 Procedural Precautions

- Prophylaxis for bacterial endocarditis should be considered per institutional guidelines.
- Patients should be anticoagulated throughout the procedure, recommended ACT >250 seconds.
- The device is designed to be used with fluoroscopic and echocardiographic imaging guidance.
- The patient's venous vasculature should be sufficient to accommodate the 16 Fr sheath which provides access for the 16 Fr delivery system.
- Retrieval equipment, such as long, large diameter sheaths, additional 0.035" (0.89mm) guidewires, loop snares, and retrieval baskets must be available in case there is need for implant removal.
- Use a J-tip guidewire; a straight tipped guidewire risks puncture of cardiac structures, a curly tipped guidewire risks entanglement with the implant.
- Avoid interaction with intracardiac leads. The guidewire and the transseptal puncture catheter may interact with previously implanted cardiac devices such as intracardiac leads in the right atrium. If this occurs, delivery of the device may result in entrapment of the lead against the septal wall. Intracardiac lead entrapment may result in:
  - Release of thrombus and/or vegetation from the surface of the intracardiac lead
  - Tricuspid regurgitation from tension on right ventricular intracardiac leads

  - Lead malfunction
  - Difficult future lead exchange
- Patients with pre-existing devices in the right atrium and septum should be carefully evaluated before implantation of the Corvia Atrial Shunt to ensure proper positioning and deployment and to avoid adverse interactions with other devices. To avoid lead entrapment:
  - Be aware of any cardiac leads and locate all leads with fluoroscopic and echocardiographic imaging before initiating the transseptal procedure.
  - Check lead connectivity and tricuspid valve function before the procedure.
  - Use fluoroscopic and echocardiographic imaging to avoid lead interactions during transseptal puncture preparation, implant introduction and prior to implant deployment.
- If a lead is entrapped:
  - Check lead connectivity
  - Check tricuspid valve function after the procedure
- Avoid transseptal puncture in thick sections of the atrial septum >6mm.
- Do not deploy the implant in a PFO tunnel.
- Do not advance delivery system if significant resistance is met. Remove entire system, immediately flush with heparinized saline and determine cause before proceeding.
  - Carefully replace the curve retainer and shipping sheath
  - Fully retract the thumb slide to deploy the implant into the shipping sheath
  - Inspect the system and implant if the curve retainer and shipping sheath are available
  - Re-flush the system with heparinized saline if reintroducing the system
  - Do not use the system if damaged or unable to flush
- If excessive resistance to moving the thumb slide is encountered, do not use excessive force on the delivery system handle when delivering the implant. If significant resistance is met, stop, assess the cause and if needed remove entire system.
  - Severe angulation of the delivery system with the handle will increase resistance and may interfere with implant delivery.
  - Do not hold the delivery system shaft while deploying the implant as this may lead to implant migration relative to the septum and may contribute to mal-deployment.
  - If at any time the Corvia Atrial Shunt System is or appears to be malfunctioning, recapture the left atrium (LA) legs if deployed and remove the delivery system from the patient. After evaluating the patient's anatomy, a new system may be used to complete the procedure.
- Do not apply excessive tension to the side-arm or apply tension to the side-arm at extreme angles. If a side-arm is pulled off the delivery system, the system should be replaced to prevent blood loss or air ingress. The device must be removed, and a new system may be used to complete the procedure.
- If the delivery system is removed prior to implant deployment, immediately flush with heparinized saline through the wire access and side ports.
  - Do not reuse system if the left atrial legs have been deployed and recaptured.
  - Do not use the system if damaged or unable to flush.
- To reduce the potential of thrombus formation associated with the implant, do not reverse heparin at the end of the implant procedure.
- Remove all femoral catheters, introducers, sheaths, and accessories from the patient at the conclusion of the procedure in the Cath Lab. Late removal of access catheters risks thrombus accumulation and increases the risk of patient injury.

7.4 Post Implant Precautions

Short-term anticoagulation or antiplatelet therapy may be necessary after placement of the implant. Prescribe medical therapy per institutional and practice guidelines.

Medication	Patient Population	Post-Procedure
Dual anti-platelet therapy (DAPT) – Aspirin and clopidogrel	Patients not currently taking an oral anticoagulant (OAC)	Post-procedure: aspirin 75 – 325 mg daily and clopidogrel 75 mg daily for 6 months
Oral anticoagulant (OAC)	Patients currently prescribed and taking warfarin or OAC	Post-procedure: Resume OAC and forgo administration of clopidogrel

Medication	Patient Population	Post-Procedure
	Implanted patients diagnosed with atrial fibrillation	Evaluate risk of stroke using CHA_2DS_2-VASc Score & initiate OAC according to atrial fibrillation practice guidelines
Subacute bacterial endocarditis (SBE) prophylaxis	Implanted patients	Antibiotic prophylaxis, such as prior to dental or interventional procedures should be considered for patients at risk for endocarditis per institutional guidelines

7.5 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 5 mm 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.

8. POTENTIAL ADVERSE EVENTS

Procedural complications and long-term risks associated with Corvia Atrial Shunt System and similar devices in which permanent implants are placed on the atrial septum using a cardiac catheterization procedure include the following:

- Access site injury, pseudoaneurysm or hematoma
- Adverse anesthesia reaction
- Adverse contrast agent reaction
- Allergic reaction to implant
- Apnea
- Arrhythmias
- Bleeding, with possible need for blood transfusion
- Blood clot
- Cardiac arrest, myocardial infarction or angina
- Chest pain
- Constipation (procedural risk)
- Death
- Decreased cardiac output
- Device embolization, whole or partial
- Device fracture
- Dyspnea
- Endocarditis
- Erosion of vessel or myocardium
- Fever
- Gastro-esophageal perforation or other injury associated with transesophageal echocardiography
- Headache, migraine
- Hemolysis
- Hypotension or hypertension
- Infection, including sepsis
- Intervention or surgery to remove a mal-deployed or embolized device
- Intracardiac lead entrapment causing device malfunction, valve dysfunction or difficulty to exchange lead
- Pain or nerve damage at access site
- Paradoxical embolism
- Perforation of vessel or myocardium
- Pleural effusion or irritation of lungs
- Reduced L→R shunting or occlusion of implant
- Renal insufficiency, injury or failure
- Right heart failure with or without worsening tricuspid regurgitation
- Stroke or transient ischemic attack
- Systemic embolization (air, tissue or thrombus)
- Tamponade or pericardial effusion
- Thrombosis
- Urinary retention (procedural risk)
- Worsening heart failure

9. HOW SUPPLIED

9.1 Contents

One (1) Corvia Atrial Shunt Delivery System with Corvia Atrial Shunt Implant

9.2 Sterile

The medical device is sterilized by ethylene oxide. The implant and delivery system are supplied sterile and nonpyrogenic. The implant is pre-loaded onto the delivery system and is packaged in a peelable pouch. The pouch is contained in a shelf box bearing an identity label and a tamper evident seal.

This is a single use device that cannot be reused on another patient. Changes in mechanical, physical and chemical characteristics from repeated use, cleaning or resterilization will compromise the integrity of the design and materials, leading to contamination and diminished safety and performance of the device. Absence of original labeling may lead to misuse; absence of original packaging may lead to device damage or loss of sterility.

9.3 Storage

The Corvia Atrial Shunt System should be stored in the labeled box at 10°C - 25°C (50°F - 77°F) in a cool, dry, dark and contamination-free area.

10. DIRECTIONS FOR USE

10.1 Required Materials

Quantity	Item
1	Corvia Atrial Shunt System
1	Introducer Sheath, ≥ 16F (5.3mm)
1	0.035” (0.89mm) J-tip guidewire, exchange length, extra stiff
1	Transseptal puncture kit
1	6mm (0.236”) non-compliant balloon catheter, 0.035” (0.89mm) guidewire compatible (if needed for dilatation of the septal wall prior to implant)
	Various long (>65cm), large diameter sheaths, additional 0.035” (0.89mm) guidewires, retrieval snares and baskets for potential device removal

10.2 Preparation

10.2.1 Check expiry date and condition of package.

10.2.2 Remove product from double pouch in an aseptic manner and place the delivery system and package insert within sterile field.

10.2.3 Remove the delivery system from the package insert by unlatching the straps and pulling the handle.

Note: *The curve retainer and shipping sheath should remain on the delivery system at this time.*

10.2.4 Inspect implant and delivery system for damage. Do not use if damaged.

10.2.5 Using at least 20ml of heparinized saline, flush delivery system through wire access port and the side port.

10.2.6 Push the thumb slide forward (distal) to the first stop. Translate the slide away from the user over the Left Atrium/Right Atrium stop and continue forward (distal) until the slide clicks into the ‘locked’ position to completely cover the implant with the outer sheath of the delivery system.

10.2.7 Once the implant is covered by the sheath, flush the delivery system again through the wire access port and side port with at least 20ml of heparinized saline.

Note: *Remove, but do not discard the shipping sheath and curve retainer.*

10.3 Implant Placement

10.3.1 Use standard institutional procedures to establish access to the femoral vein and place an introducer sheath.

10.3.2 Using Transesophageal Echocardiography (TEE) and/or Intracardiac Echocardiography (ICE), confirm in multiple views that there is sufficient space to accommodate the implant (20mm (0.79”) deployed diameter) without impinging on adjacent cardiac structures.

Note: *if the patient has pre-existing intracardiac leads, these should be located and checked for thrombus or vegetation.*

10.3.3 Use standard institutional procedures to perform a transseptal puncture of the atrial septum, preferably in the center of the fossa ovalis, guided by echocardiography and fluoroscopy.

***Caution**: Avoid wrapping the guidewire and the transseptal puncture catheter around a intracardiac lead while advancing through the right atrium and in the superior vena cava.*

If a lead appears to move medial to the septum, the guidewire and transseptal catheter must be retracted back in the inferior vena cava, and the advancement of the guidewire and transseptal catheter in the superior vena cava must be repeated.

***Note:** If a PFO is noted or suspected use caution when performing the transseptal puncture: do not wire through the PFO tunnel. A transseptal puncture should be performed to place the guidewire.*

10.3.4 Use standard institutional practice to administer anticoagulant to achieve an activated clotting time (ACT) of >250 seconds. Do not proceed with guidewire insertion until the ACT is at least 250secs.

10.3.5 Insert 0.035" (0.89mm) exchange length J-tip guidewire into the left atrium and into the pulmonary vein. Guidewire placement in the left superior pulmonary vein guides proper delivery system insertion and reduces the risk of implant embolization if mal-deployment occurs.

***Caution:** Do not place the guidewire in the LV or allow the guidewire to migrate into the left ventricle.*

10.3.6 Advance half of the system into the introducer sheath and insert the tear away sheath into the introducer, being sure not to stretch the tear away over the larger tip or curved section of the delivery system. The tear away sheath is used to reduce friction between the delivery system and the introducer sheath.

***Note:** If it becomes necessary during the procedure, the tear away sheath may be removed by pulling apart the two wings and peeling the sheath apart down its length.*

10.3.7 Under fluoroscopic and echocardiographic visualization, carefully advance the delivery system over the guidewire into the left atrium (LA) and position the catheter tip in the mid-LA cavity. Verify position using TEE and/or ICE. If the delivery system cannot cross the septum, it may be removed and immediately flushed, inspected, and reintroduced as per Precautions in section 5.

***Caution:** If an intracardiac lead moves towards the septum during advancement of the Corvia Atrial Shunt delivery system across the right atrium, re-start the procedure with a new transseptal puncture to avoid intracardiac lead interaction.*

10.3.8 Under fluoroscopic and echocardiographic guidance, completely deploy the left atrial legs and barrel of the implant by depressing the locking button and retracting the thumb slide of the handle proximal to the first stop and ensure the red line on the handle is and remains exposed.

***Caution:** Do not use excessive force on the thumb slide of the delivery system handle when delivering the implant. If significant resistance is met, stop, assess the cause, and if needed remove entire system.*

***Note:** Severe angulation of the handle will interfere with implant delivery.*

10.3.9 Under echocardiographic visualization, carefully retract the delivery system until the LA legs make contact with the septum. Verify position of LA legs using echocardiography and fluoroscopy. Next, retract the delivery system to apply a small amount of tension on the septum until the left atrial legs of the implant are verified to be in contact with the septum by echocardiography and visibly are deflecting on the septum by fluoroscopy.

***Note:** A small volume contrast injection through the side-port by a second operator while maintaining tension on the delivery system may be helpful for confirming position by observing contrast in both atria.*

***Caution**: If LA legs do not sit properly against the septum, the LA legs may be re-covered by advancing the delivery system into the left atrium to provide clearance of the LA legs from the septum and then moving the thumb slide forward to cover the legs. If LA legs are deployed and then re-covered, the device must be removed and discarded.*

10.3.10 While maintaining tension on the delivery system and the septal wall, rotate the thumb slide towards the user and retract the thumb slide back (proximal) until the RA legs of the implant are deployed. This releases the implant from the delivery system.

Note: *Deployment of the RA legs fully releases the implant from the delivery system.*

Caution: *Do not hold the delivery system shaft while deploying the implant as this may contribute to mal-deployment.*

Use echocardiography and fluoroscopy to ensure that intra-cardiac leads will not become trapped during release of the RA legs. Releasing the implant with intra-cardiac leads near the landing zone of the implant can result in intra-cardiac lead entrapment.

Failure to confirm and maintain proper positioning of the implant during RA leg deployment may result in implant mal-deployment.

10.3.11 Slowly retract the delivery system into the right atrium while maintaining wire position. When the delivery system is completely in the RA, return the thumb slide to the forward 'locked' position to return the delivery system to the closed position.

10.3.12 Remove half of the delivery system and then slide the tear away sheath from the introducer, before entirely removing the delivery system.

10.3.13 Confirm proper placement of the implant via echo and fluoroscopy. Confirm flow through the implant via echo.

Caution: *If the deployed implant is* ***mal-positioned****, remove the implant percutaneously to avoid damage to device and/or adjacent cardiac structures. If unable to retrieve implant using standard interventional techniques, consider surgery for implant removal.*

If the implant has ***embolized****, it must be removed to avoid disruption of cardiac functions and/or damage to cardiac structures, or other patient injury. If unable to retrieve the implant using standard interventional techniques, perform surgery for implant removal.*

10.3.14 Carefully remove the guidewire, making sure to avoid entanglement of the guidewire with the implant. Use standard institutional practice to complete the procedure. Remove all femoral catheters, introducers, sheaths, and accessories from the patient at the conclusion of the procedure in the Cath Lab.

Caution: *Late removal of access devices risks thrombus accumulation and increases risk of patient injury.*

10.4 Post Procedure and Discharge Instructions

10.4.1 Consider keeping the patient overnight in the hospital for observation.

10.4.2 Short-term anticoagulation therapy may be necessary after placement of the implant. Use standard institutional practice to prescribe anticoagulation and other medical therapy.

10.4.3 An implant card containing information about the implant and imaging is included in the package. Fill out the implant card, provide the card to the patient, instruct the patient to carry the card at all times.

10.4.4 Advise the patient as follows:

- Show the implant card to medical professionals who are not aware of shunt implantation.
- Avoid strenuous physical activity for at least 2 weeks.
- Be diligent with prescribed medications including those for heart failure and anticoagulants.
  - Seek immediate medical attention if you experience sudden increases in heart failure symptom frequency or severity.
  - A pause or stoppage of prescribed anticoagulant therapy may increase the risk of stroke.

10.5 Disposal

10.5.1 The package insert and box are recyclable. Use standard institutional practice and local regulations to dispose of the packaging materials.

10.5.2 Dispose of the delivery system in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of this device.

10.6 Serious Incident Reporting

10.6.1 Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the country in which the device was used.

11. QUALITATIVE AND QUANTITATIVE INFORMATION RELATED TO THE CORVIA ATRIAL SHUNT SYSTEM

11.1 The implant is made of the following materials:

- Nickel-titanium alloy: mass – 0.144g, volume - 0.0232cm^3, surface area - 3.77cm^2
- Tantalum: mass – 0.0047g, volume - 0.00027cm^3, surface area - 0.03cm^2

11.2 One or more components of the delivery system contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:

- Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

12. DEFINITIONS FOR SYMBOLS USED ON LABEL

REF	Catalog Number	Rx	Prescription Only
LOT	Lot Number		Temperature Limitation: Avoid Exposure Beyond 4ºC and 40ºC
SN	Serial Number		Nonpyrogenic
	Use by Date	MR	MR Conditional
https://corviamedical.com/safety-info/	Consult Instructions for Use or Electronic Instructions for Use		Manufacturer
	Do Not Re-use	EC REP	Authorized Representative in the European Community
	Keep Dry	STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged	CE 2797	Notified Body Identification
UDI	Unique Device Identifier	YYYY-MM	Date of Manufacture
MD	Medical Device	UK CA 0086	UKCA Marking
	Contains Hazardous Substances		

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