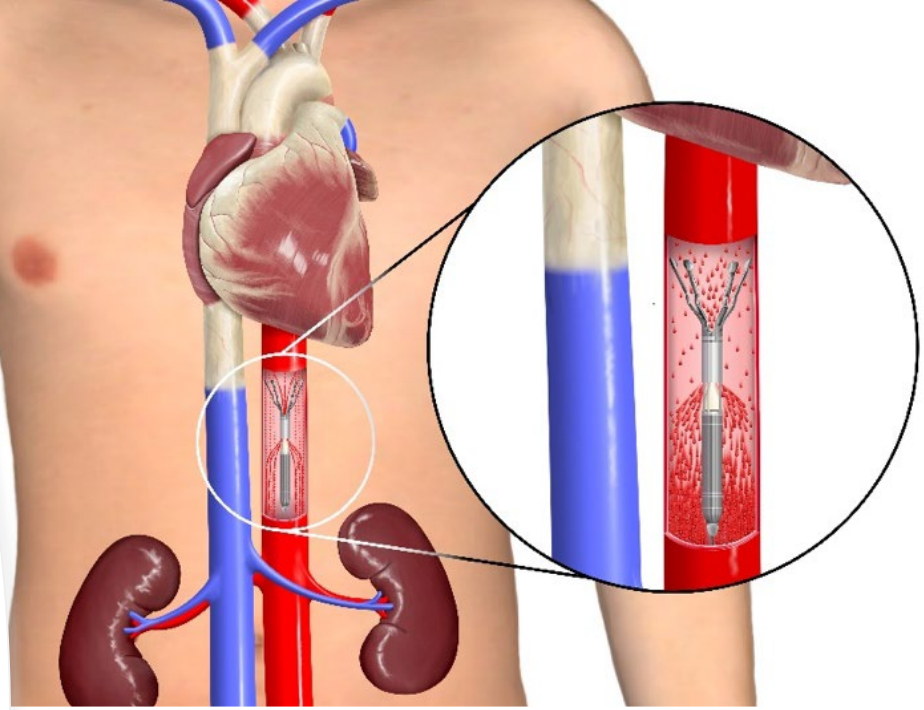
Aortix™

Insertion of Percutaneous Mechanical Circulatory Support Device into Thoracic Aorta

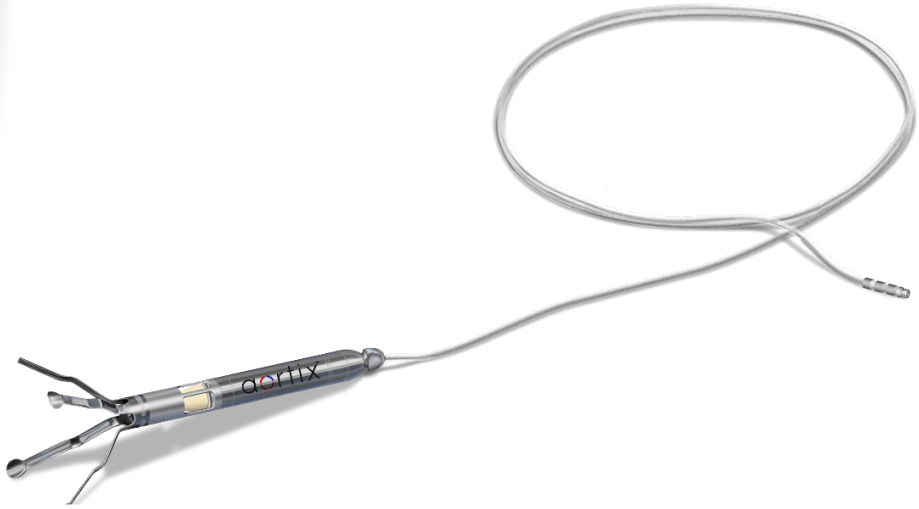
ICD-10 C&M Committee Meeting
March 7-8, 2023

Aortix™ Overview



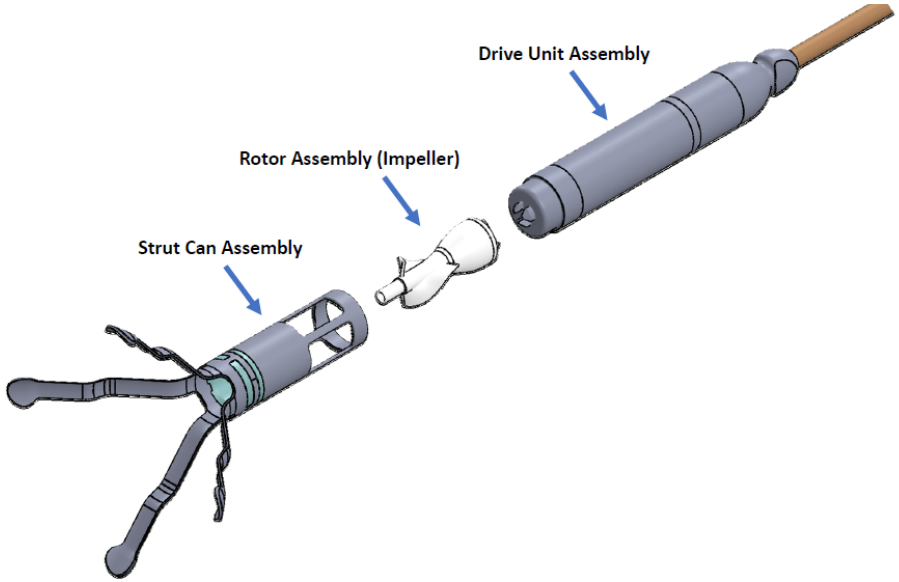
Aortix™ is a circulatory support device for chronic heart failure patients on medical management who have been hospitalized for acute decompensated heart failure (ADHF) and are resistant to diuretic therapy. Aortix™ may aid in the treatment of ADHF by providing cardiac and renal circulatory support to decrease congestion and improve renal function resulting in increased urine output and reduced fluid overload.

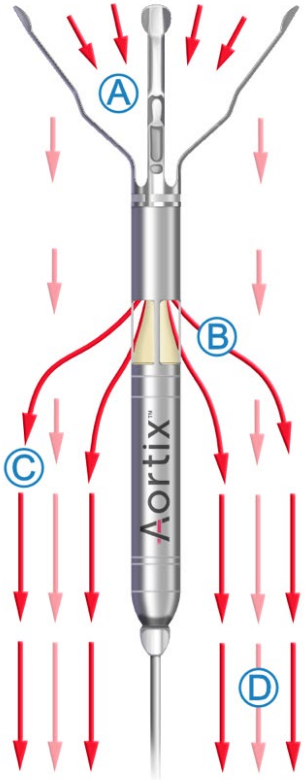
- Percutaneous mechanical circulatory support device
- Continuous flow impeller pump
- Placed in the descending thoracic aorta via the femoral artery
- Inpatient setting
- Implanted in the cardiac cath lab/OR, used for up to 7 days, then removed in the cardiac cath lab/OR
- During therapy, only the 2 mm power lead exits the femoral arteriotomy



Aortix™ Mechanism Of Action

Aortix™ is a continuous flow axial flow pump design that harnesses fluid entrainment to pump blood without the need of a valve, which allows for intra-aortic placement and physiologically natural delivery of therapy.





A A portion of the native flow enters the pump at the inlet

B The flow is accelerated in the pump and exits the device in high velocity jets directed downstream

C The high velocity jets entrain the native flow, transferring momentum and energy to it

D The result is a net increase in overall velocity and aortic flow

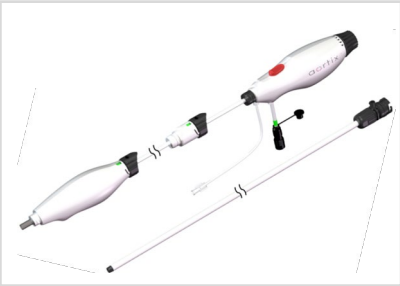
The implantable portion of the system is the Aortix™ pump consisting of the pump body and a thin power lead. The pump body includes the motor, the rotor assembly (impeller) and the struts for localizing and centering the pump in the aorta.

Descending Thoracic Aorta:

Aortix™ Tools and Control System

For the Insertion:

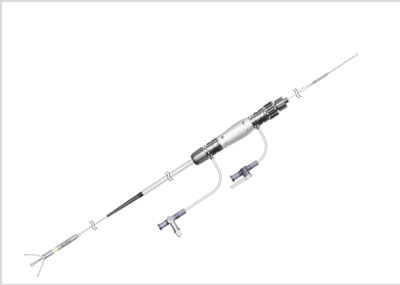
AORTIX™ DELIVERY SYSTEM (ADS)



- Percutaneous delivery
- 18F ID / 21F OD Introducer Sheath
- Aortix™ Delivery Tool supplied containing pump

For the Removal:

AORTIX™ RETRIEVAL SYSTEM (ARS)



- Percutaneous retrieval
- 18F ID / 21F OD Sheath
- Full control of arteriotomy after retrieval

For Monitoring:

AORTIX™ CONTROL SYSTEM (ACS)

- No need for device saline purge (electrical power only)
- Bluetooth communication between Controller and Cradle

Controller

- Connects to power lead of pump
- Provides 2+ hours of battery support
- Visible and audible indicators

Cradle

- Sets pump speed and charges the Controller
- Displays speed, power consumption, battery status, and visual and audible alerts

Summary of Procedural Steps

Insertion:

- Access the femoral artery and place pre-closed sutures at arteriotomy site.
- Advance the introducer sheath/dilator over the guidewire into the femoral artery. Continue to the *descending thoracic aorta*. Place distal tip of the delivery sheath approximately lateral to the superior aspect of the T10 vertebral body.
- Connect delivery system to introducer sheath.
- Advance the non-deployed pump into place using fluoroscopy for guidance.
- Ensure proper position of the Aortix™ pump superior to the renal arteries.
- Deploy Aortix™ pump by retracting Introducer Sheath.
- Withdraw Aortix™ delivery system and introducer sheath using fluoroscopy.
- Achieve hemostasis using previously pre-closed sutures at arteriotomy site.

Removal:

- Fluoroscopy is maintained during entire removal procedure.
- Insert stiffening wire into lumen of power lead.
- Release the knotted sutures at the arteriotomy site.
- Via percutaneous technique or a cutdown, advance the retrieval sheath/dilator over the power lead into the femoral artery. Continue to the descending thoracic aorta.
- While holding the retrieval dilator, advance retrieval sheath over pump.
- Pull pump into retrieval sheath.
- Retrieve the pump via the retrieval sheath.
- Perform closure, achieving hemostasis.

Additional Details

Number of devices inserted? Permanent Implant?

One impeller pump is inserted/implanted. The device is not a permanent implant.

How and where will the procedure/technology be documented in the medical record?

- Cardiac Catheterization laboratory: Cardiac catheterization log, formal cardiac catheterization reports for insertion, revision, and removal.
- Potential operating room: Operative report and operative notes for insertion, revision, and removal.
- Monitoring is performed in intensive care unit, cardiac critical care unit, or intermediate critical care unit. Monitoring will be documented in critical care notes, critical care logs, physician progress notes, and some nursing notes.

Various terms that are used to describe the procedure/technology?

- Continuous flow impeller pump or impeller pump
- Short term external heart assist
- Mechanical Circulatory Support (MCS) or percutaneous Mechanical Circulatory Support (pMCS)

Procedural complications?

As is typical with pMCS devices there have been adverse events reported. In terms of serious, procedural related AEs: bleeding, pump migration, vascular complication/injury.

Aortix™

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