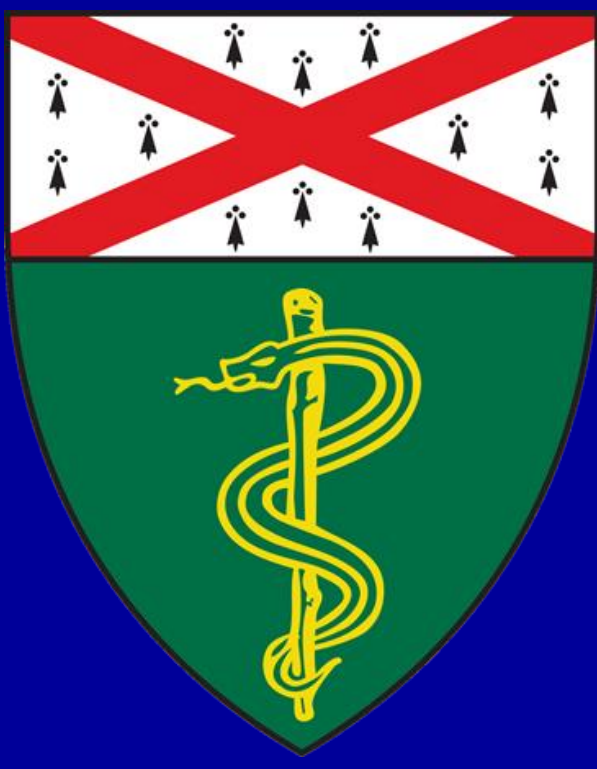




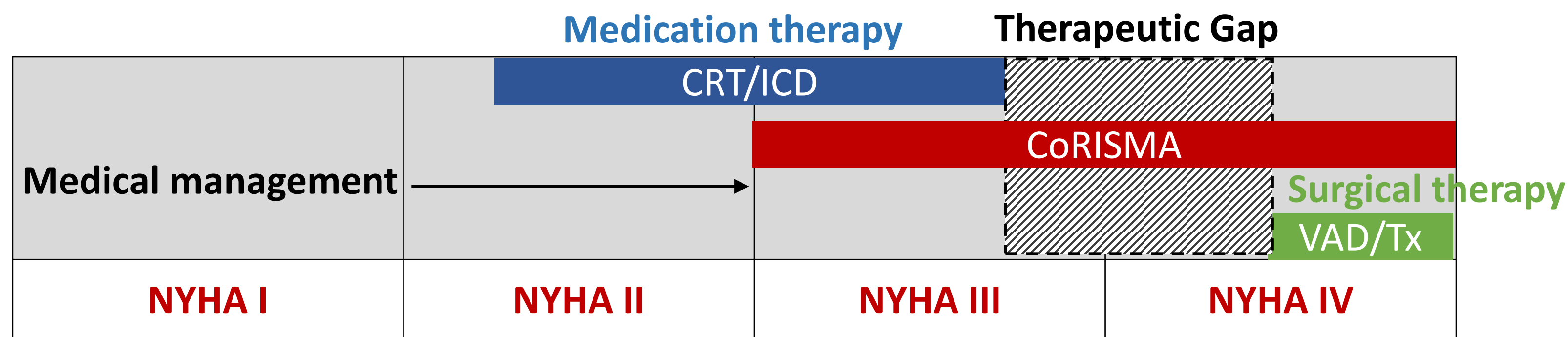
A Co-Rhythmic, Isolable, Self-Maintenance, Assist (CoRISMA) Device for Class III Heart Failure

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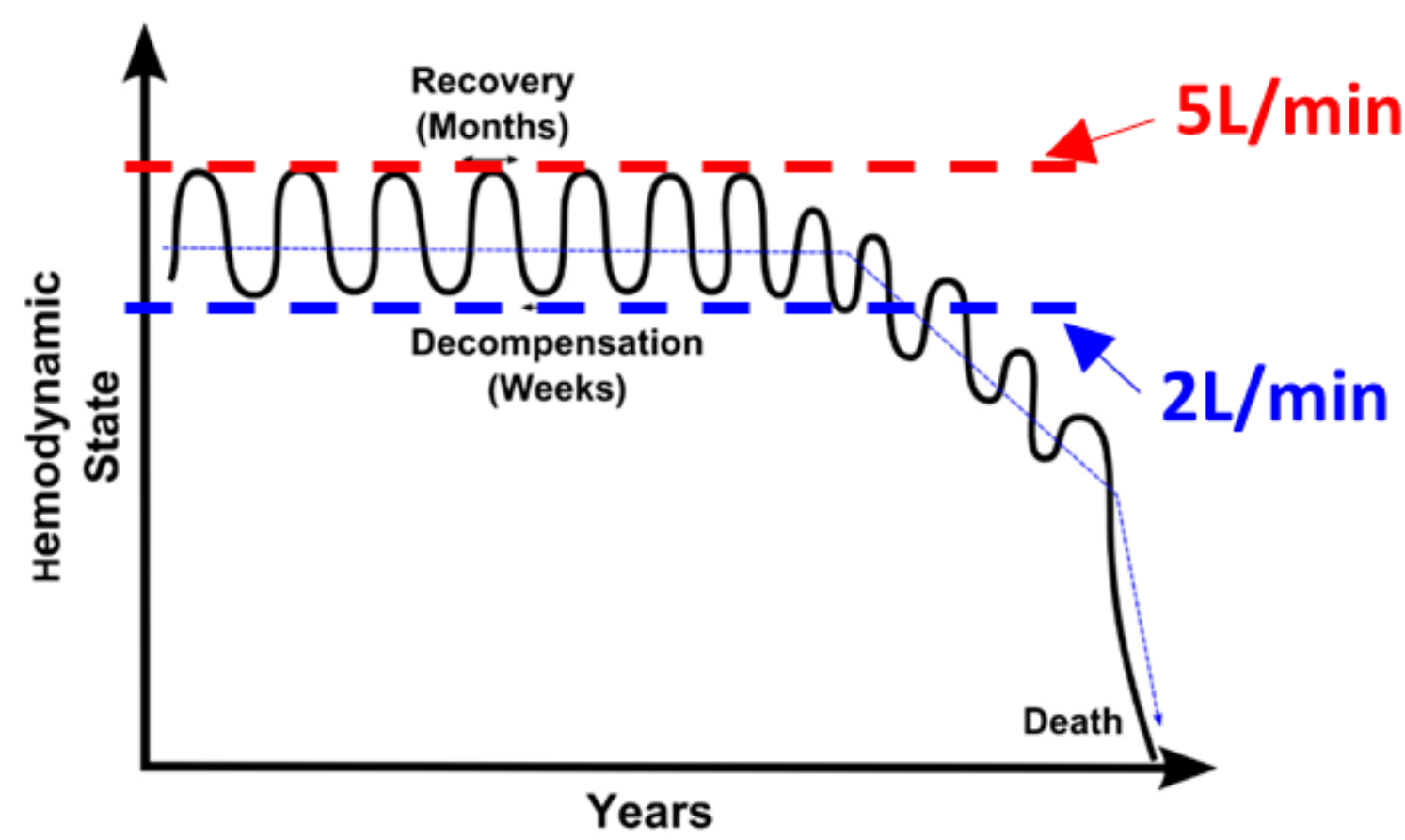
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BACKGROUND



- Approximately 5.1 million Americans over the age of 20 suffer from some degree of heart failure
- About 15-30% of this population meets the current criteria for VAD or transplantation (Tx)
- Current LVAD therapy, which provides full circulatory support, comes at the price of invasiveness, 24-hour care, infection, bleeding, thrombosis, and reduced quality of life



Symptoms of class III heart failure patients are rather periodic, being in a decompensated state for weeks recovery state for months

Characteristics for class III heart failure patients

Mechanical circulatory support for class III heart failure will be acceptable if it is devoid of any adverse events associated with current LVAD devices. Long blood paths, lack of regular maintenance in a pump bathed in blood and tethered operation may account for some of the adverse events witnessed in current LVADs such as stroke, pump thrombosis and infections.

PROPOSAL

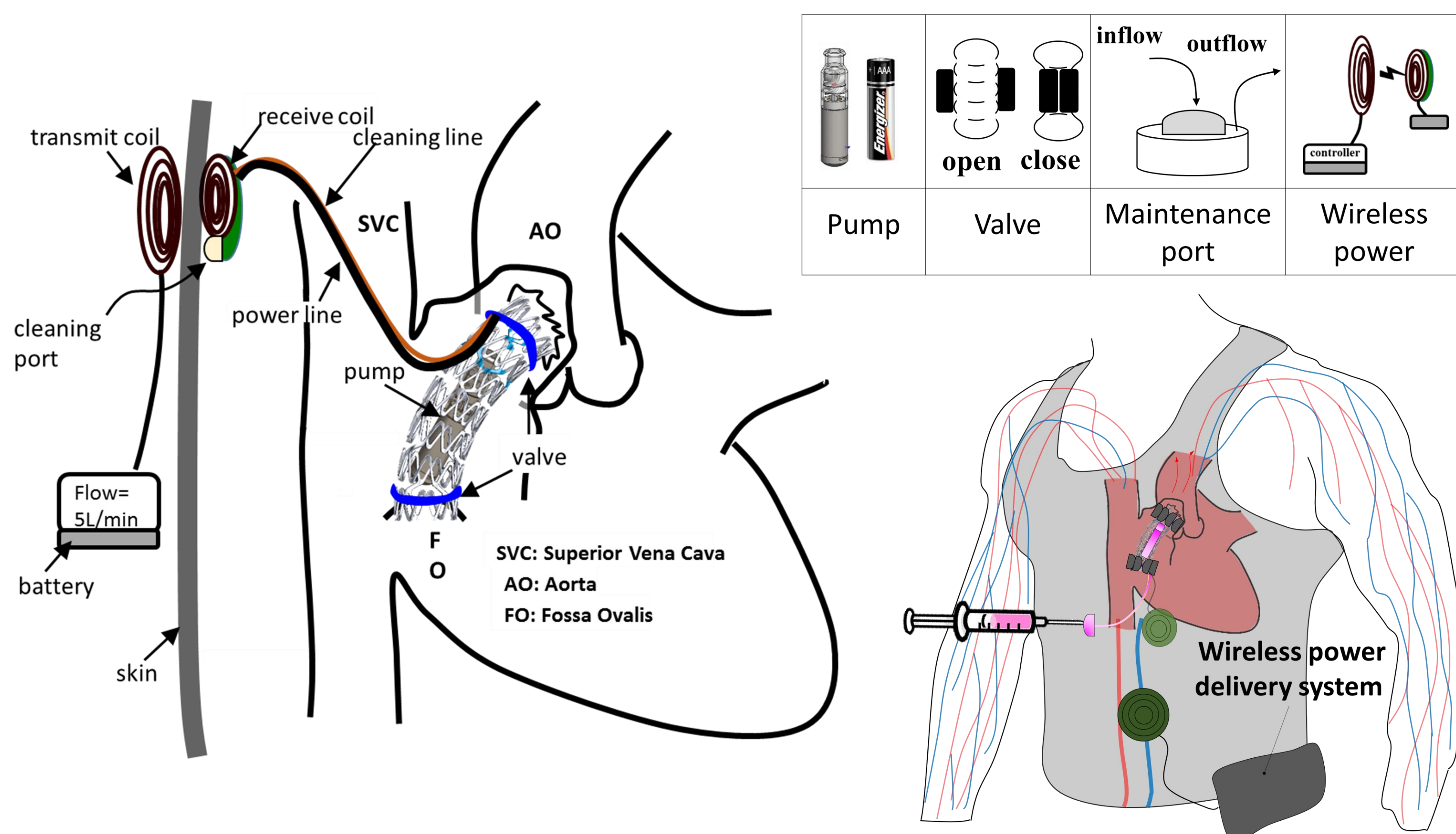
Co
Rhythmic
Isolable
Self
Maintenance
Assist

A minimally invasive support system that can be turned off and isolated from the circulation switched on during hemodynamics stability and during decompensation

An intra-cardiac device with ability to isolate and clean the interior of the pump, powered without driveline is presented.

METHOD

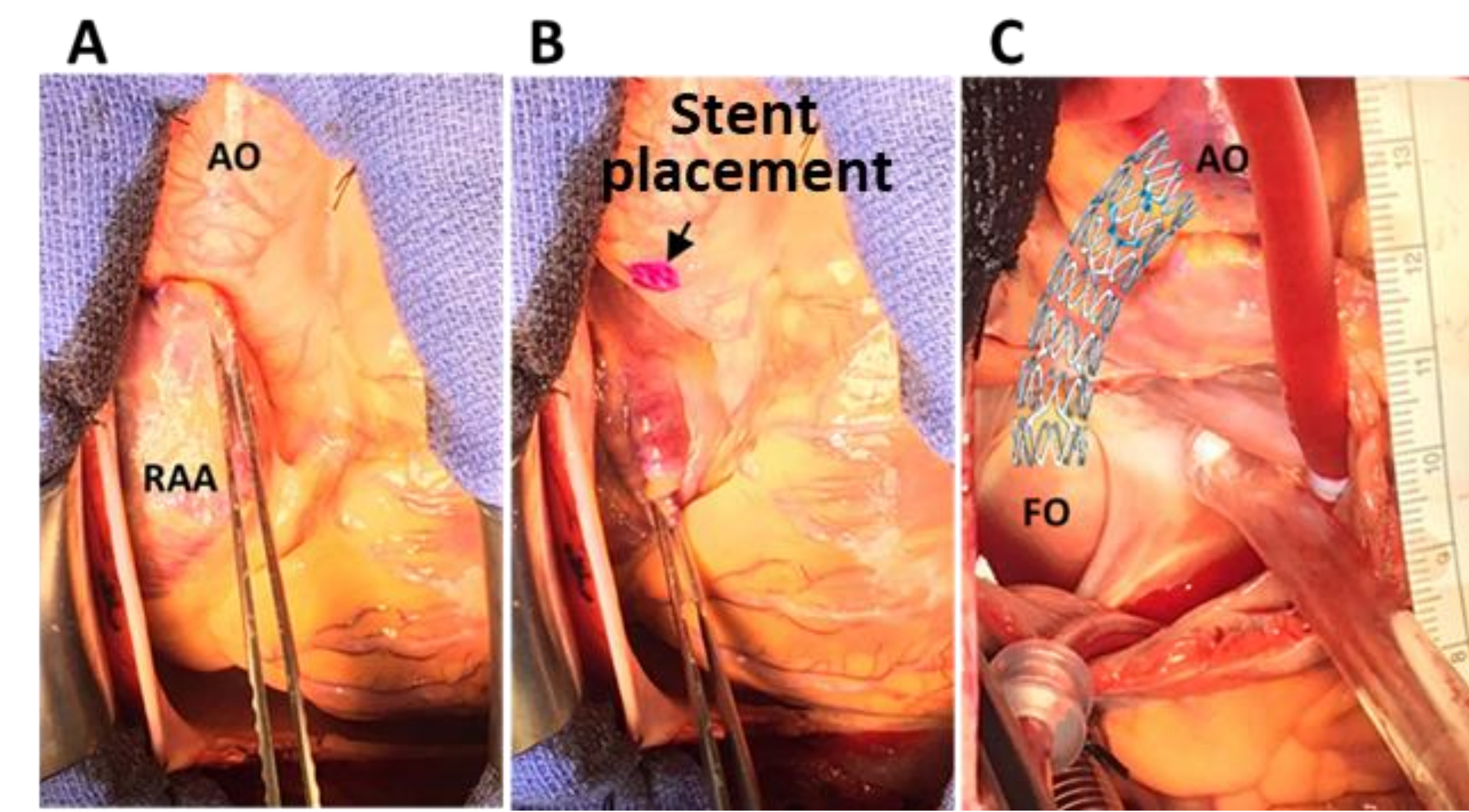
CoRISMA device



- An endovascularly deployable, on-demand cardiac support device
- No clot formation with its ability to periodically clean and maintain the pump
- Total implantability has the potential to offer better quality of life and acceptability for the early stage class III heart failure patients

CoRISMA is a device for Class III heart failure with direct placement from fossa ovalis to aorta. The on-demand device is compactly integrated system with an axial pump the size of AAA battery, valve, pump maintenance port, and wireless power transfer system.

CoRISMA deployment



(A) Relationship between right atrial appendage (RAA) and ascending aorta (AO). (B) Marked site where the stent will pierce ascending aorta (C) Superimposed stent from Fossa ovalis (FO) to aorta in an right atriotomy view.

A deliberate trans-aortic to right atrial covered stent connected to left atrium via fossa ovalis is designed to carry a pump capable of pumping 5 Lt/min. This stent is isolated from circulation using inflow and outflow valve controlled electromagnetically, a hermitically sealed purge system allows periodic cleaning with proteolytic enzymes of the interior (3-7 cc volume), this can be accessed transcutaneously via a hypodermic needle. Keeping in mind that Class III heart failure patient may not need a continuous operation of the pump, the isolation and maintenance is particularly attractive.

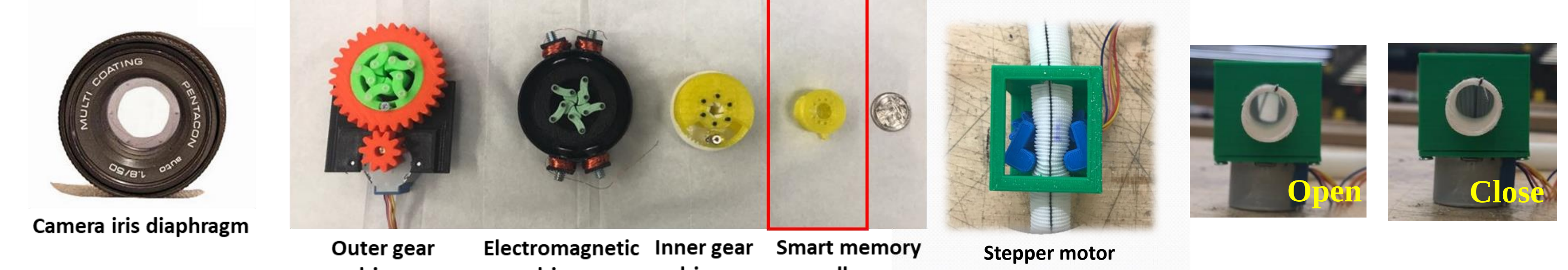
RESULT

Prototype

Pump design

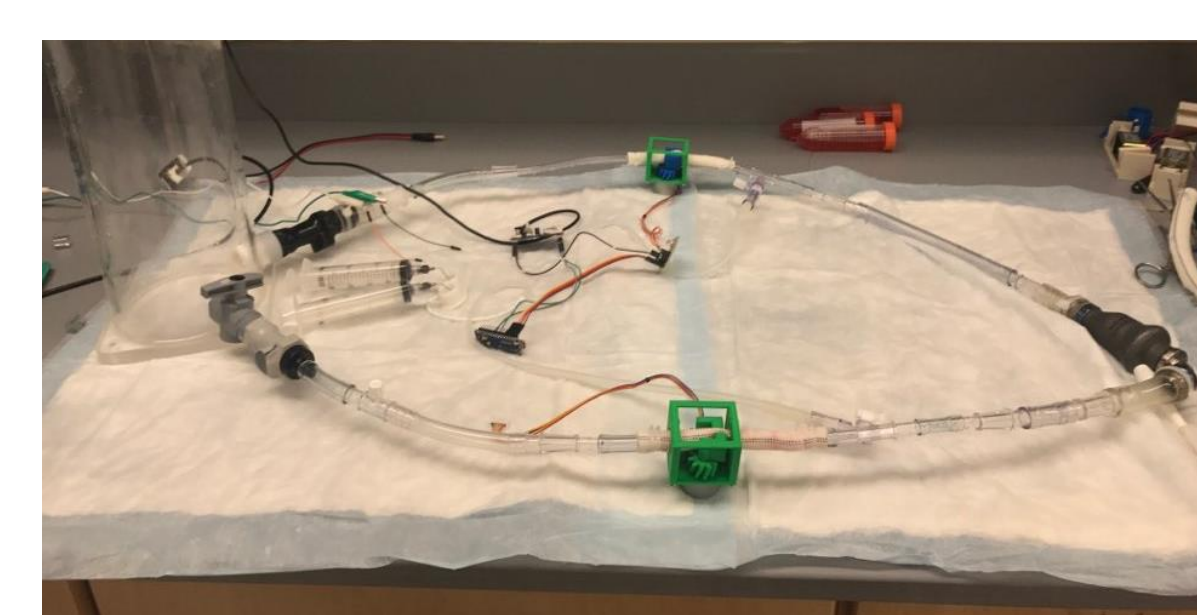
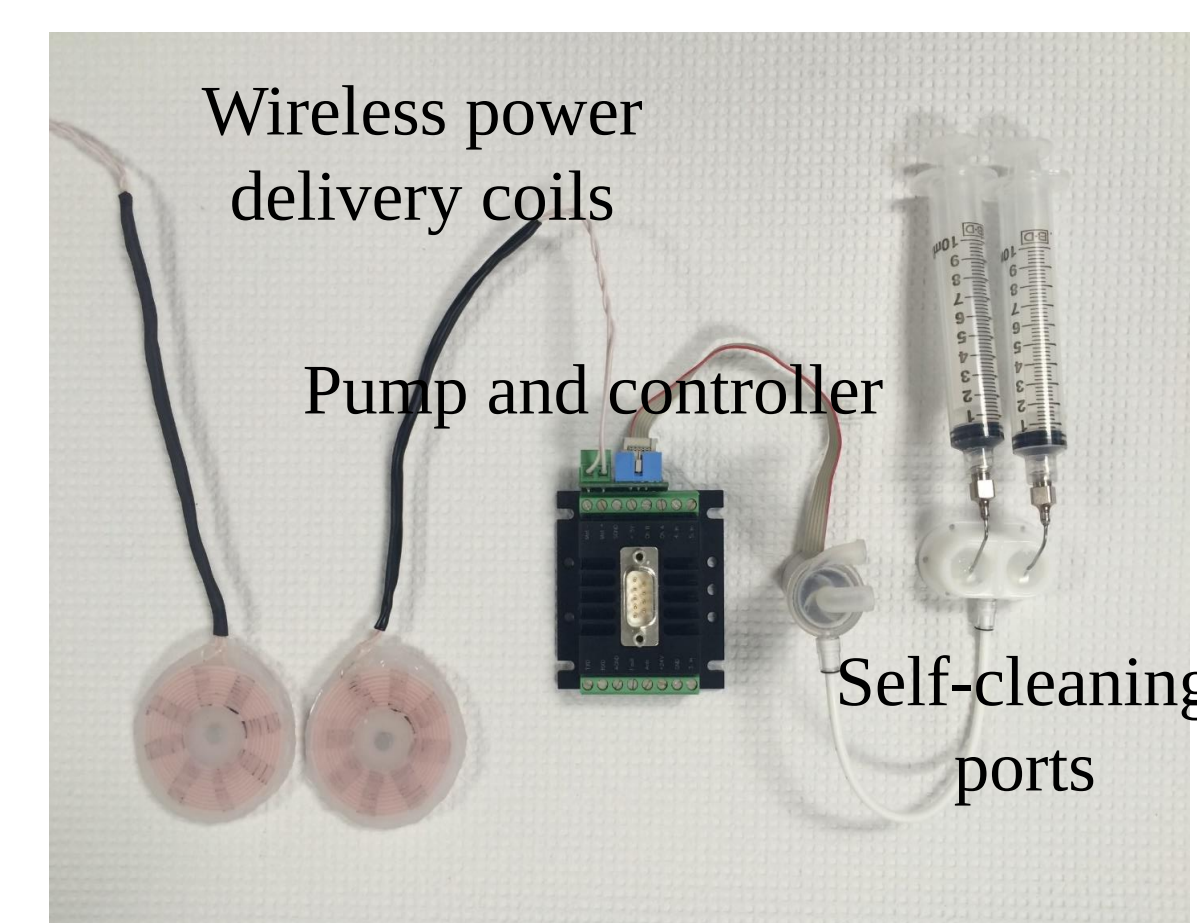


Valve design



- Rapid prototyping with 3D printer and performance evaluation using mock loop
- Pump is endovascularly deployable and valve design is inspired by camera iris diaphragm. The ultimate form and size of the valve are shown in the red box.

Full system configuration



Testing of gear driven maintenance system with commercial pumps.

The entire system could be delivered via 27 French sheath to a human sized circulatory system mannequin via femoral vein. Three topologies were considered for the outflow and inflow valve, including iris type, solenoid and gear driven system. In the final prototype, gear driven system allowed isolation of the pump with minimum power utilization. Pump maintenance system could be accessed and indicator dye clearance could be achieved with ease on repeated occasions. The maintenance system works well with commercially available pumps as well the AAA sized pump that was specifically developed for the CoRISMA device. The gear based seal held strongly in repeated experiments. The pump could produce up to 5 Lt/min of flow with a pump head of 80 mm of Hg.

CONCLUSION

A miniature, intra-cardiac wireless device specifically designed in keeping the need and demand of class III patients was tested in-vitro with excellent functioning. This device has the potential to revolutionize therapy for early stage heart failure patients with minimum adverse events and excellent quality of life.