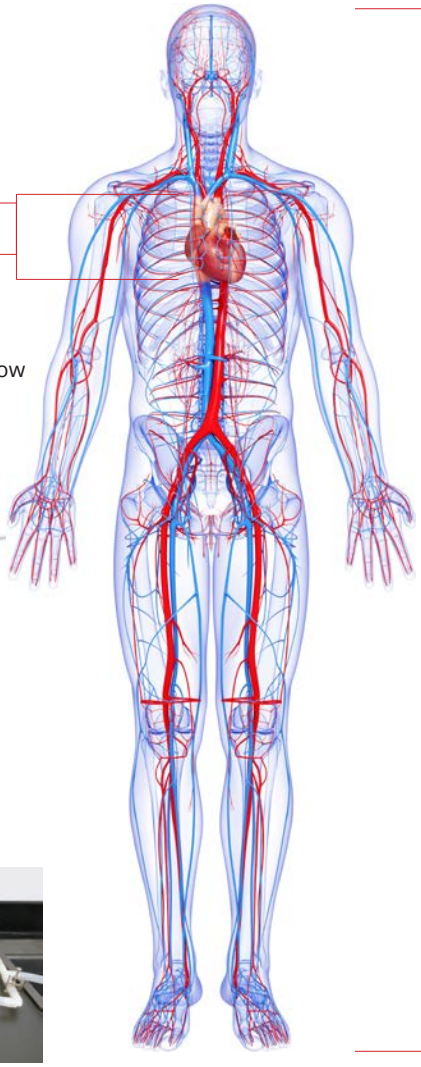
Testing Repair Devices

ViVitro Labs Inc.
First in Cardiovascular Device Testing

Testing Repair Devices with ViVitro Equipment



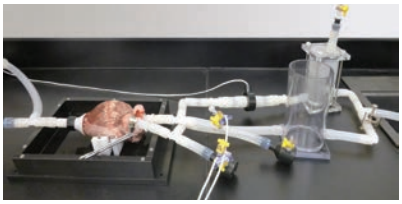
Heart

Pulse Duplicator

- Highly Repeatable
- Precise control of Pressure and Flow

Ex Vivo

- Exact Anatomy
- Simplified Animal Model



Vascular System

Endovascular Simulator

- Highly Repeatable
- Precise control of Pressure and Flow

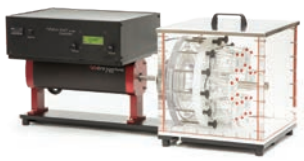
Durability / Fatigue Testing

HiCycle

500 - 1650 BPM

Real-Time Wear Tester (RWT)

0 - 200 BPM



Equipment Relationship Matrix

	Pulse Duplicator	Ex Vivo	Endovascular Simulator	HiCycle	Real-Time Wear Tester
Valvular Repair	✓	✓	✓	✓	✓
Left Atrial Appendage Closure Devices	✓	✓	✓	✓	✓
Shunt Devices	✓	✓	✓	✓	✓
Occluder and Closure Devices	✓	✓	✓	✓	✓
Mechanical Circulatory Support	✓	✓			✓
Electrophysiology		✓			
Stents and Coils			✓		
Embolic/Distal Protection			✓	✓	✓
Clinical Care Devices			✓	✓	✓
Catheters and Delivery Systems			✓		
Accessory Devices		✓	✓		

Valvular Repair

With the explosion of transcatheter valve replacement devices comes a corresponding surge of valvular repair devices. Many are focused on the mitral valve, but technologies exist for all valves in the heart. Such devices are popular because they allow for multiple treatment options before a valve is completely replaced. The devices fall into the following broad categories: annuloplasty rings, annular remodeling, chordal repair, and edge to edge devices. ViVitro Labs offers a variety of design specific verification or validation testing solutions in accordance with ISO 5910.

Use the Pulse Duplicator or Ex Vivo simulator to simulate the function of the heart:

The ViVitro Pulse Duplicator simulates the function of the heart (left or right) by generating pulsatile flow through prosthetic heart valves placed in the Model Heart (Left or Right). Powered by the ViVitro SuperPump, it is composed of the ViVitro Model Heart (Left or Right), SuperPump, Flow Measuring System and ViViTest data acquisition system.

For many of these devices the native anatomy found in an Ex Vivo simulator is very appealing as it makes for a more convenient and controlled platform compared with animal models.

For some designs the Pulse Duplicator may be a better option as mock silicone leaflets or explanted valves can be placed in the system. Compared with the Ex Vivo simulator this option is less physiological, but more convenient and controlled.

The delivery system can be tested using the **Endovascular Simulator**.

See additional details in the catheter section.

Use the HiCycle or Real-Time Wear Tester (RWT) to determine durability:

The ViVitro HiCycle Durability Tester or Real-Time Wear Tester (RWT) can be used to determine the durability of cardiac devices under physiological loading. Implant Durability/Fatigue can be tested to show the equivalent of 10 years of use.

Left Atrial Appendage Closure Devices

Patients with atrial fibrillation may benefit from closing off the Left Atrial Appendage to prevent thromboembolism and reduce the risk of stroke. There are a host of different designs attempting to mitigate this risk but the majority of transcatheter approaches attempt to seal off the appendage using a barrier. While no standard currently exists for these devices, ViVitro Labs offers solutions for design specific verification or validation testing.

Use the Pulse Duplicator or Ex Vivo Simulator to:

Ensure closure of the Atrial Appendage to prevent thromboembolism

- Implant Diameter Recovery after deployment
- Particle exclusion properties of the sealing surface

Determine hydrodynamic performance of the device under different physiological pressure and flow conditions including:

- Implant embolization
- Migration resistance
- Implant Deployment and Recapture
- Flow characterization/visualization
- Simulated use testing

The delivery system can be tested using the **Endovascular Simulator.**

See additional details in the catheter section.

Use the HiCycle or Real-Time Wear Tester (RWT) to determine durability:

The ViVitro HiCycle Durability Tester and Real-Time Wear Tester (RWT) are used to determine the durability of cardiac devices under physiological loading. Implant Durability/Fatigue can be tested to show the equivalent of 10 years of use.

Shunt Devices

Patients experiencing heart failure with preserved ejection fraction (HFPEF) may experience increased left atrial pressure. One solution to reduce this pressure is to shunt blood between the atria. While no standard currently exists for these devices, ViVitro Labs offers solutions for design specific verification or validation testing.

Use the Pulse Duplicator or Ex Vivo to:

Determine hydrodynamic performance of the device under different physiological pressure and flow conditions including:

- Implant embolization
- Migration resistance
- Implant Deployment and Recapture
- Flow characterization/visualization
- Simulated use testing

The delivery system can be tested using the **Endovascular Simulator**. See additional details below:

Use the HiCycle or Real-Time Wear Tester (RWT) to determine durability:

The ViVitro HiCycle Durability Tester and Real-Time Wear Tester (RWT) are used to determine the durability of cardiac devices under physiological loading. Implant Durability/Fatigue can be tested to show the equivalent of 10 years of use.

Occluder and Closure Devices

Congenital heart defects may leave holes in various locations of the cardiovascular system. Using a transcatheter approach these holes can be plugged by deploying a sealing device into the affected anatomy. This same style of device may also be used to seal paravalvular leaks that occur from valve replacement. While no standard currently exists for these devices, ViVitro Labs offers solutions for design specific verification or validation testing. These devices may include Atrial Septal Defect (ASD), Patent Foramen Ovale (PFO), Ventricular Septal Defect (VSD), Patent Ductus Arteriosus (PDA), Paravalvular Leakage Device (PLD).

Use the Pulse Duplicator or Ex Vivo Simulator to:

Determine hydrodynamic performance of the device under different physiological pressure and flow conditions including:

- Ensure closure of the Atrial Appendage to prevent thromboembolism
- Particle exclusion properties of the sealing surface
- Implant embolization
- Migration resistance
- Implant Deployment and Recapture
- Flow characterization/visualization
- Simulated use testing

The delivery system can be tested using the **Endovascular Simulator**. See additional details below:

Use the HiCycle or Real-Time Wear Tester (RWT) to determine durability:

The ViVitro HiCycle Durability Tester and Real-Time Wear Tester (RWT) are used to determine the durability of cardiac devices under physiological loading. Implant Durability/Fatigue can be tested to show the equivalent of 10 years of use.

Mechanical Circulatory Support

For various reasons patients may require support in perfusing blood through the circulatory system. The most extreme may be a total artificial heart (TAH) for complete heart failure, followed by ventricular assist devices (LVADs/ RVADS/BiVADs), finally to Interaortic pumps. ViVitro Labs can offer various solutions for design specific verification or validation testing in accordance with ISO 14708 and ISO 18242.

Use the Pulse Duplicator or Ex Vivo Simulator for:

- Pump characterization using dynamic (or static) mock circulatory loop. Simulate how support system performance affects the "patient" and how "patient" changes affect support system performance
- Cavitation observation
- Flow characterization/visualization
- Simulated use testing

Use the HiCycle or Real-Time Wear Tester (RWT) to determine durability:

The ViVitro HiCycle Durability Tester and Real-Time Wear Tester (RWT) are used to determine the durability of cardiac devices under physiological loading.

- Long term reliability testing against pulsatile load
- Ingress testing
- Component specific fatigue/durability testing

Electrophysiology

The ViVitro Ex Vivo or EV simulator provide support to assess the performance of catheter based devices during simulated use testing, however they do not simulate electrical responses of the heart.

Stents and Coils

Stents can be bare metal, covered, drug eluding, or bioresorbable, and have been used in arteries from the cranial to popliteal. They can be used for coronary or a variety of endovascular aneurysm repair (EVAR) including Abdominal Aortic Aneurysm (AAA), thoracic aortic aneurysm (TAA), renal artery aneurysm (RAA), and Iliac artery aneurysm (IAA). Coils can be used for aneurysm closure or occlusion. ViVitro Labs offers solutions for design specific verification or validation testing in accordance with ISO 25539, ISO 12417, ISO 17137.

Our vascular flow platform brings physiological pulsatility to anatomical models for research and development.

Use the Endovascular Simulator to:

Determine hydrodynamic performance of the device under different physiological pressure and flow conditions including:

- Implant embolization
- Migration resistance
- Implant Deployment and Recapture
- Preoperative planning for complex cases
- Flow characterization/visualization
- Simulated use testing

The delivery system can be tested using the **Endovascular Simulator**.

Embolic/Distal Protection

Many studies highlight the importance of embolic protection devices during transcatheter procedures. These devices can be used for cerebral or peripheral protection and capture, and/or to remove debris that becomes dislodged during an interventional procedure. ViVitro Labs offers solutions for design specific verification or validation testing in accordance with ISO 25539-3:2011 Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters.

Use the Endovascular Simulator to:

Determine hydrodynamic performance of the device under different physiological pressure and flow conditions including:

- Ensure coverage of the vessel to prevent thromboembolism
- Particulate capture properties of the sealing surface
- Implant embolization
- Migration resistance
- Implant Deployment and Recapture
- Flow characterization/visualization
- Simulated use testing

The delivery system can be tested using the **Endovascular Simulator**. See additional details below:

Use the HiCycle or Real-Time Wear Tester (RWT) to determine durability:

The ViVitro HiCycle Durability Tester and Real-Time Wear Tester (RWT) are used to determine the durability of cardiac devices under physiological loading.

Clinical Care Devices (Pressure and/or Flow Monitoring)

For many reasons percutaneous measurement of vascular pressure or flow many be useful to patients and clinician. These measurements may be made using a removable catheter or implantable device.

Use the Endovascular Simulator to:

Determine hydrodynamic performance of the device under different physiological pressure and flow conditions including:

- Implant embolization
- Migration resistance
- Implant Deployment and Recapture
- Flow characterization/visualization
- Simulated use testing

The delivery system can be tested using the **Endovascular Simulator**. See additional details below:

Use the HiCycle or Real-Time Wear Tester (RWT) to determine durability:

The ViVitro HiCycle Durability Tester or Real-Time Wear Tester (RWT) can be used to determine the durability of cardiac devices under physiological loading. Implant Durability/Fatigue can be tested to show the equivalent of 10 years of use.

Catheters and Delivery Systems (Active or Passive)

ViVitro Labs offers solutions for design specific verification or validation testing in accordance with ISO 10555. Our vascular flow platform brings physiological pulsatility to anatomical models for research and development for:

Use the Endovascular Simulator to:

Determine hydrodynamic performance of the device under different physiological pressure and flow conditions including:

- Consistent, accurate, and safe contact with the intended anatomic treatment site
- Safe withdrawal of any product components not intended to remain in the body
- Kink Resistance - the endovascular system can bend in order to accommodate the minimum radius or angle to be negotiated during access and delivery
- Pushability – the endovascular system can be pushed or positioned by an operator without bending or buckling.
- Torquability- the endovascular system can provide sufficient rotation to the distal (leading) end to deliver the implant within the anatomy in accordance with the design constraints of the system.
- Trackability - the endovascular system can advance over the recommended guidewire and follow the guidewire tip along the path of the vessel, including in narrow, tortuous vessels.
- Human Factors/Simulated use testing in accordance with (IEC 62366)
- Flow characterization/visualization

Accessory Devices

Closure devices, apex punches

Many of the above procedures use accessory devices (such as closure devices and apex punches) to reduce procedure times or complications. These devices can be tested on their own or in conjunction with their indicated therapy using many of the ViVitro Products. The Ex Vivo Simulator provides a flexible platform to test devices on a beating explanted heart. The Endovascular Simulator allows for deployment into silicone mock or explanted vessels.

Contact Us

To discuss how ViVitro can best assist you in your testing, or for further details, please contact us.

ViVitro Labs Inc.
First in Cardiovascular Device Testing

455 Boleskine Rd., Victoria, BC
V8Z 1E7, Canada
T: 250 388 3531 • F: 250 483 1975

info@ViVitrolabs.com
www.ViVitroLabs.com

Douglas Bigrigg, B.Eng
Major Accounts

Rob Fraser, MSc
Lab Manager

A StarFish™ Company