

OCCLUDER AND CLOSURE DEVICE TESTING

ViVitro Labs has significant experience providing testing products and services for occluder and closure device testing applications such as:

- ASD - Atrial Septal Defect
- PFO - Patent Foramen Ovale
- VSD - Ventricular Septal Defect
- PDA - Patent Ductus Arteriosus
- PVL - Paravalvular Leakage Device
- LAA - Left Atrial Appendage
- Shunt devices and others

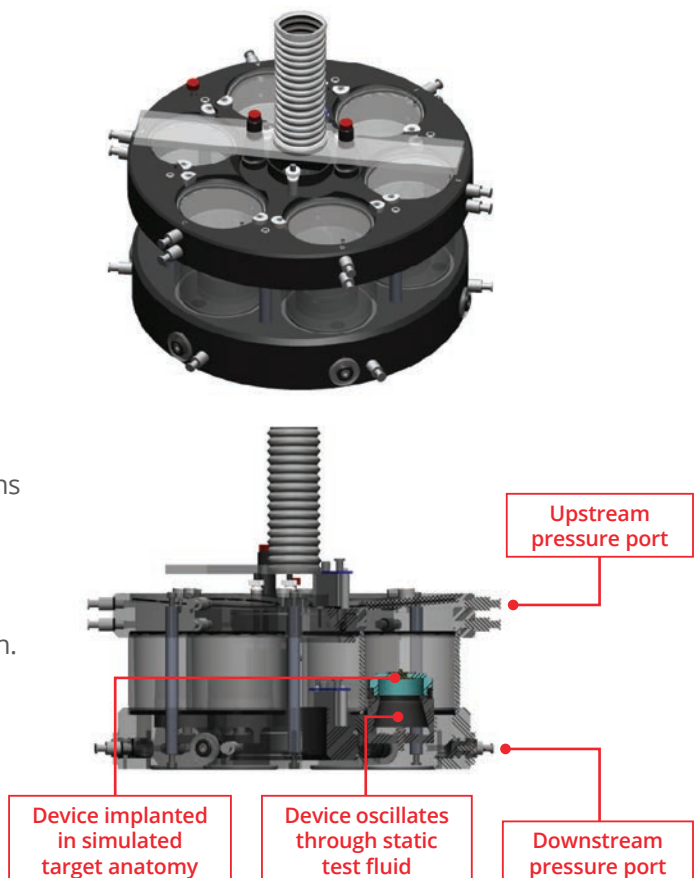
We offer the following tests and services for Occluders and Closure Devices:

Durability Testing

Durability testing is required by regulatory agencies to prove that devices will remain functional during their anticipated lifetime. Occluder and closure device samples can undergo millions of simulated cardiac cycles in a short period of time using the ViVitro Labs HiCycle or Real-Time Wear Tester.

Devices will be deployed into simulated reconstructions of native anatomy and can be tested with or without simulated endothelialization. Peak differential pressures across the device can be set to match the intended cardiac pressures of the deployment location.

No ISO standard currently exists for these devices, however, based on the ISO 5840 standard we recommend using 400 million cycles, or the equivalent of 10 years in vivo use.



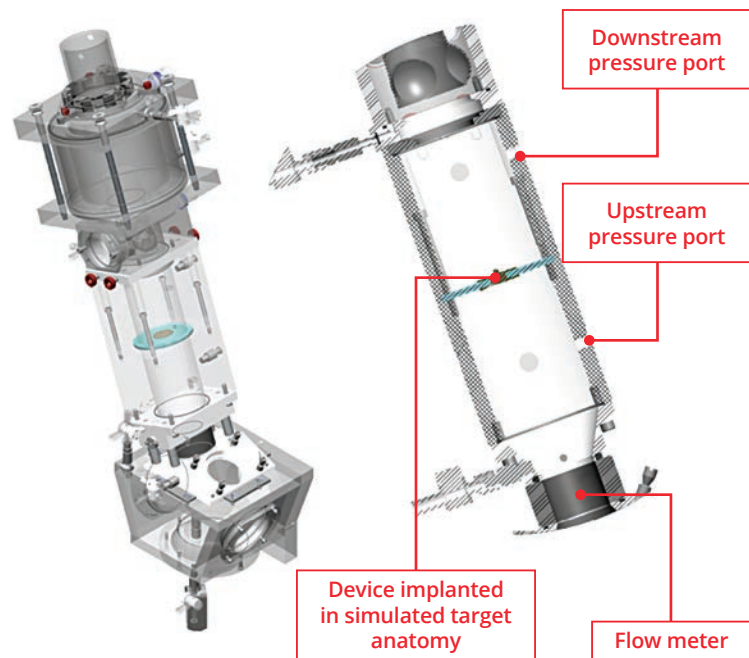
Hydrodynamic Testing

We can provide pressure, flow and high-speed data documenting the performance of an occluder using the ViVitro Labs Pulse Duplicator.

Pulsatile flows simulate the intended deployment location for occluder and closure devices. Steady flow applications can also be re-created to better understand the fundamental operation of devices.

Tests may include:

- Device deformation assessment
- Short-term and long-term pressurization
- Migration resistance testing
- Leakage testing
- Device performance based on defect size



Customized Testing

Leveraging 30 years of expertise in testing of medical devices, ViVitro Labs can design customized testing to mitigate any unique device risks. Our broad experience in standards for valves, stents, and VADs combined with membership in ISO technical committees enables us to customize protocols that meet evolving regulatory requirements.

To learn more about the Occluder and closure device samples, please contact ViVitro +1 (250) 388-3531 or info@vivitrolabs.com