

sxmu PULSE Mitral

BEATING HEART SIMULATOR

FOR TRANSAPICAL MITRAL VALVE REPLACEMENT

ADVANCED SKILLS & PATIENT LIKE **TRAINING**

The simuPULSE platform simulators have full pulsate movement and flow

FOCUS

· Patient and procedural outcomes

LEARN

- · Outcomes driven implantation with flow and regurgitation

 Advanced procedural imaging protocol
- Tips and tricks

RIGID STRUCTURES

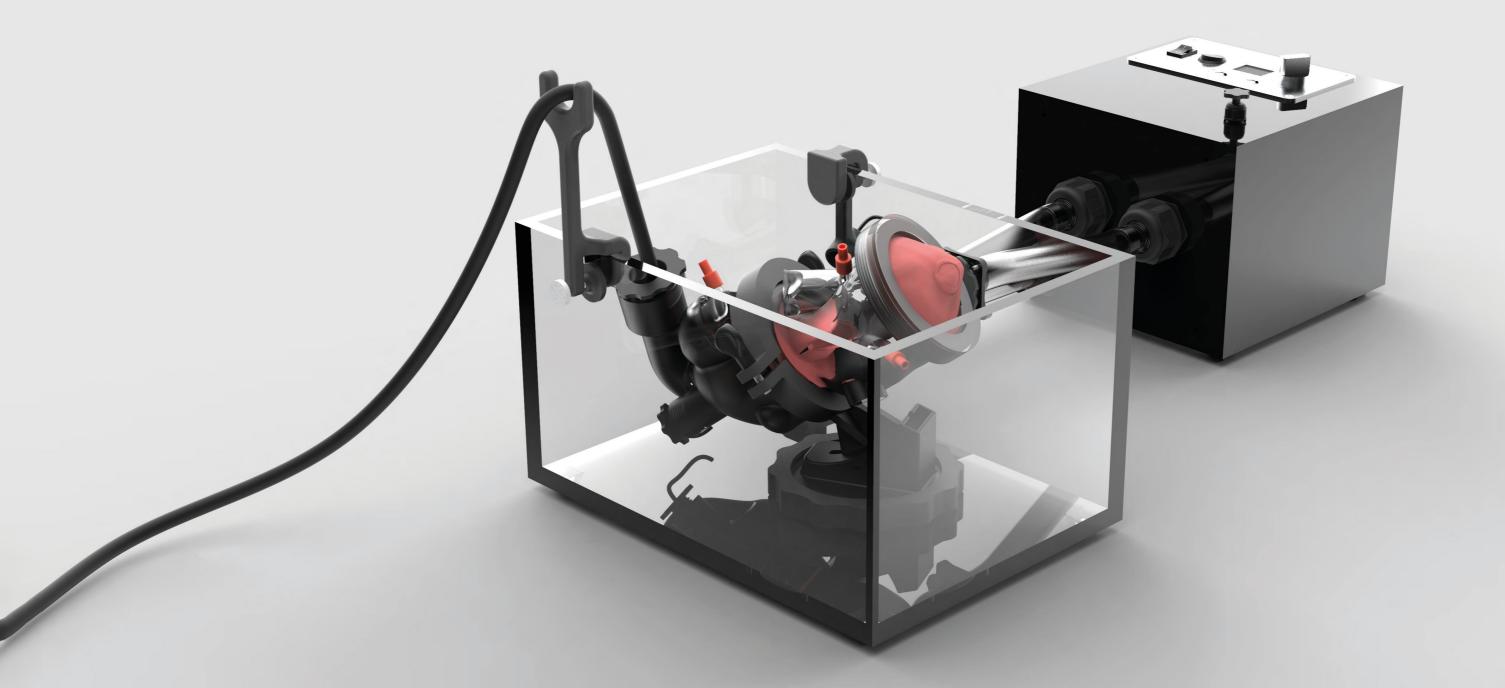
- · Femoral transseptal access
- Transesophageal accessVentricular skeleton
- · Left atrium
- · Left ventricle
- Esophagus

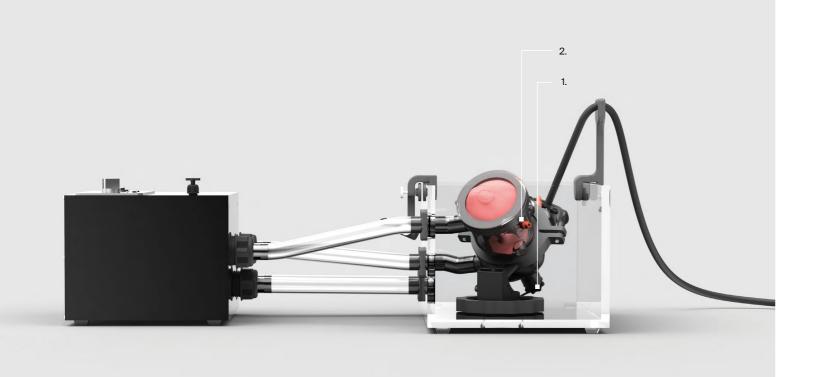
Landmarks representing

- Aortic valve
- · Left atrial appendage

SOFT STRUCTURES

- · Mitral valve and chordae
- LV apex





REAL IMAGING

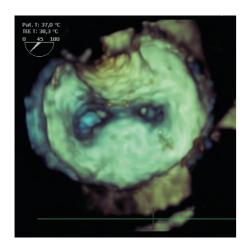
DIRECT CAMERAS & FLUOROSCOPIC GUIDANCE



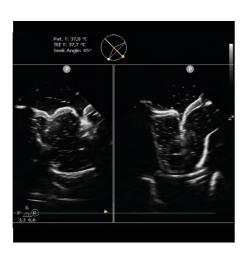
1. Lateral



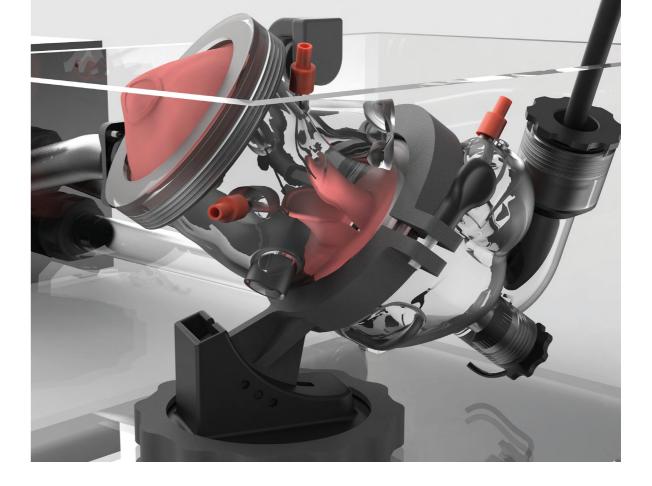
2. Left Ventricular Outflow Tract (LVOT)



3D En-Face Surgical



X-Plane



HUMAN GRADE PLATFORM

MODULAR ANATOMICAL SYSTEM

Complete anatomical representation, human grade and tissue like tactile interaction along the entire implantation pathway.

Designed to generate pressure gradient over Mitral valve to allow realistic behavior of the device. Based on real patients CT, MRI and 3D echo datasets.

SIMULATOR COMPONENTS

Promotes understanding of 3D anatomy from 2D displays with integrated video-camera systems and fine hand-eye coordination.

PULSATILE FLOW EXPERIENCE

- Delivery system and implant maneuvering in wet environment
- Delivery system, implant functions and interaction with moving structures
- · Detailed procedural steps
- · Just like in real patient

MATERIALS

Proprietary materials enhance the pulsating physiological behavior of the Mitral valve. The leaflets treated to be visible under fluoroscopy.

'Friction-less' coating allows smooth introduction and interaction of the device with the components.

TWO PATIENT SCENARIOS

Basic - Common Mitral valve pathologies. Advanced - Challenging Mitral valve anatomies and pathologies.

TECHNICAL FEATURES

PULSATILE SYSTEM

- · Pulsatile portable pump system for hemodynamic heart valve motion
- · Self-adjustable body temperature control (36.7°C)

 Adjustable heart rate between
- 40-80BPM
- Rapid pacing activation mode at constant 120BPM
- · Adjustable pulsatile intensity with 3-settings
- · Adjustable after-load pressure by rail on aquarium

PLUG AND PLAY

No tools required - full system setup ready in under 15 minutes. Just add warm water and it's ready for your device. Quick 2 min reset between the procedures.

POWER SYSTEM

- 12V powered system with socket for various power cables and
- · Worldwide compatible with voltage from 90 to 264V at a frequency from 47 to 63 Hz

SETUP INFO

Electronic IFU documentation with Step-by-Step simulated video user training and guide for simple assembly.

IMAGING CAPABILITIES

- · All components can be used in the cath lab under fluoroscopy
- 2x USB waterproof endoscopic cameras for en-face and lateral view visualization
- · 1x tablet with split screen capabilities for visualization and recording

AQUARIUM

10L - quick water fill container included.

IN THE BAG

All fits into: backpack Total weight: 14kg Dimensions: 50x40x22cm





JOIN THE SIMULANDS REVOLUTION

Our simulator components replicate the characteristics of the human anatomy. The simulators are engineered to reproduce real life haptic interaction of the medical devices within the targeted anatomy, representing true anatomical geometries and trajectories. All of our simulators can be used under real echo and fluroscopic guidance.

SHIFTING THE PARADIGM

From Patient and Animal testing to platforms for R&D and comprehensive Hands-On procedural training using:

Real Devices
Real Imaging
For the Real Heart Team

SIMULANDS systems designed and validated according to **all relevant ISO normative** requirements of clinical and technical equivalence to the human cardiovascular systems.

Our simulators are used for **human factor testing**, usability and ergonomics and meet required benchmarks of various competent authorities, ethics committees and notified bodies (CE, FDA, MDR).

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