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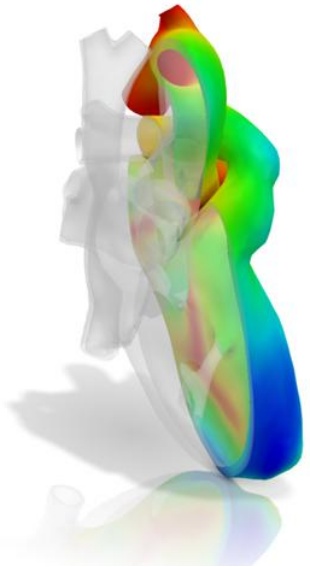
The Living Heart Project

May 2014



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Did you know?

Key problem:
The lack of realistic human models limits ability to predict device behavior under realistic use conditions.

Ultimately, 95% of all new devices, are not tested in a human environment before approval. Growth in recalls suggests room for improvement.

FDA Manufacturer and User Facility Device Experience Database

4,000

The number of devices cleared each year under the 510(k) system

$3.2b

1.25%

The percentage of devices approved under the more stringent system that requires human testing

$800k

Cost to FDA per device when utilizing human testing

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Did you know?

Worldwide

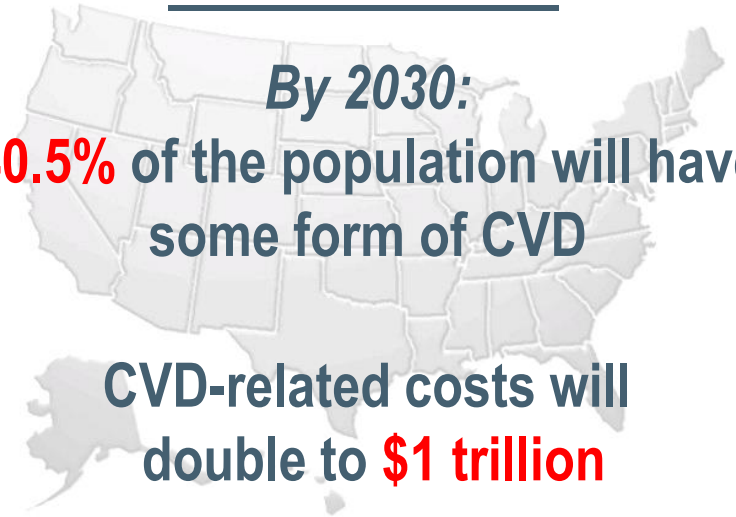
Today, CVDs are the #1 cause of death

By 2030:

CVD-related deaths will reach 23.3 million each year

World Health Organization

United States



By 2030:

40.5% of the population will have some form of CVD

CVD-related costs will double to $1 trillion

American Heart Association

FDA Manufacturer and User Facility Device Experience Database

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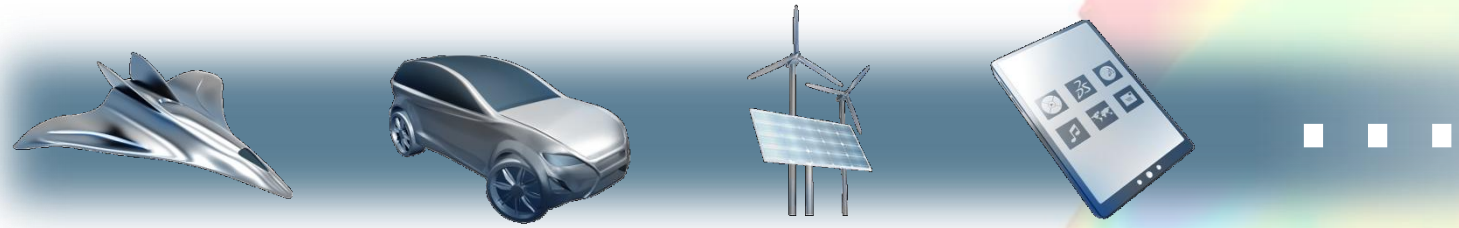
What if doctors could rely on the same incredible 3D modeling and realistic simulation technology that

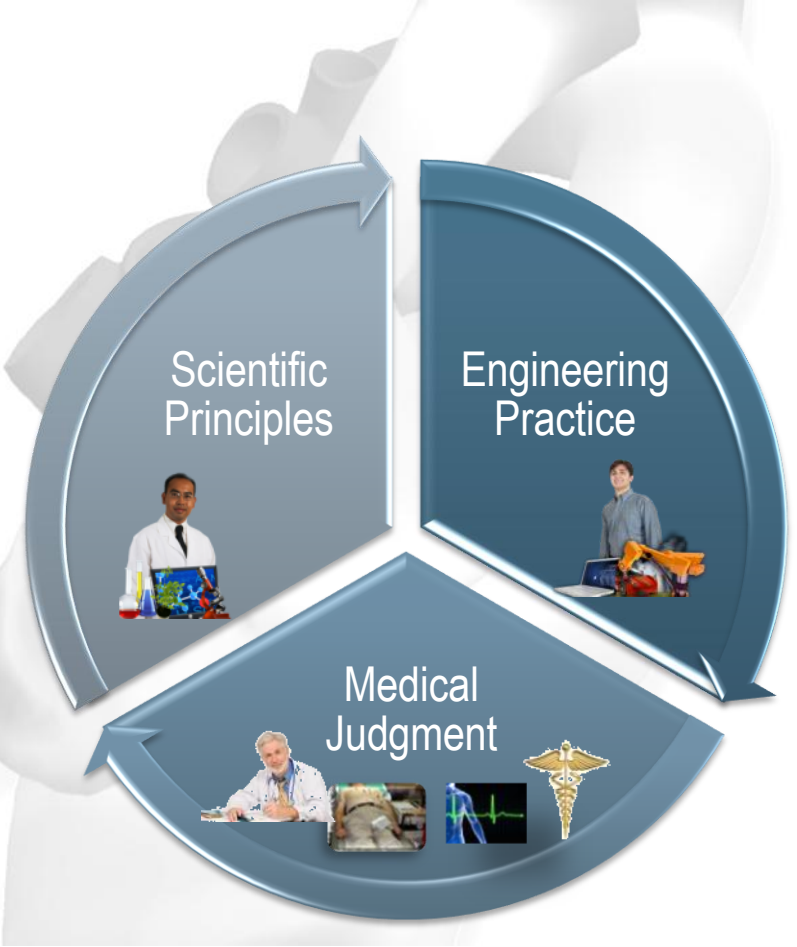


have used for decades to virtually design and test products for optimal performance, quality, and safety?

The Living Heart Project

Mission

Through 3D Modeling & simulation, connect the individual efforts of leading cardiovascular researchers, device developers, and medical practitioners with the goal of advancing computational science to revolutionize bio-sciences and cardiovascular medicine.



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The Living Heart Project - Objectives

Improved designs and faster approval of advanced medical devices

Provision of fundamental insight into the heart's function

Accurate computational models to accelerate translation of research innovation directly into clinical practice

Advancement of personalized, interventional patient care through the usage of "validated" models as practical guides

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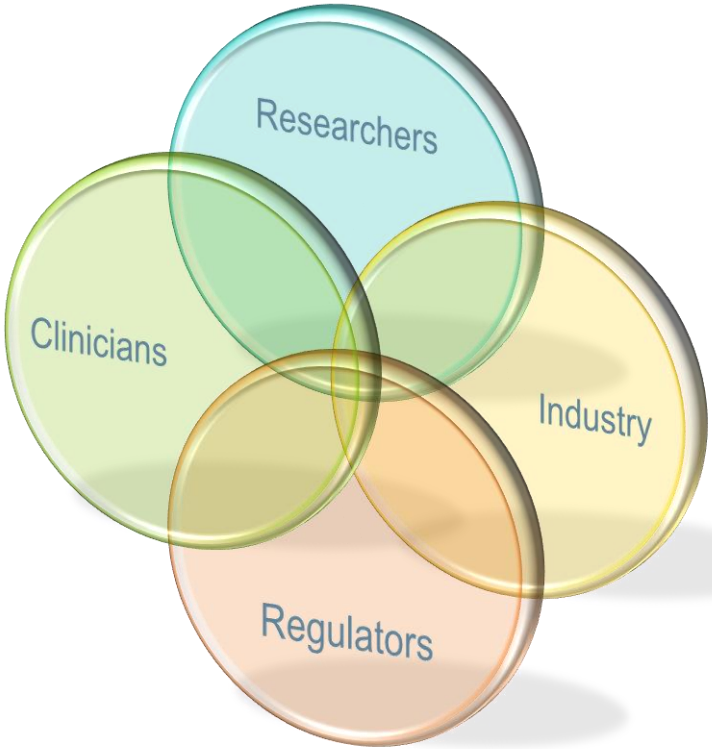
Project Stakeholders

Academic and Clinical Researchers, who unlock secrets of basic human anatomy, reveal underlying biophysical mechanisms and develop scientific methodologies to replicate behavior

Biomedical Industry, who develop innovative devices and interventional techniques to treat disease and conduct clinical trials to demonstrate their efficacy

Government Regulators, who balance the benefits and risks of deploying new medical innovations

Medical Professionals, who gain intimate knowledge through clinical observation and the practical use of devices and medical intervention



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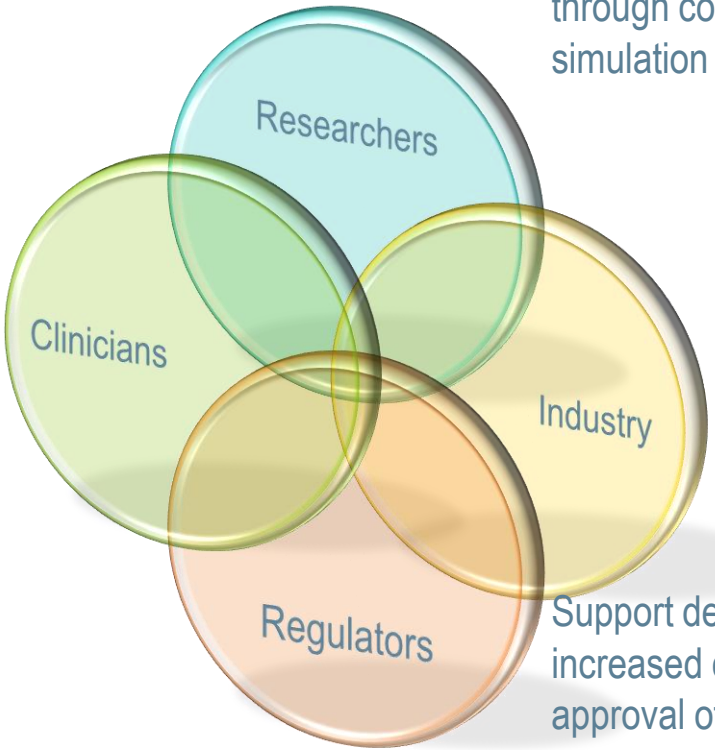
Project Value Proposition

Enabling scientific breakthroughs through collaboration and robust simulation models and tools

More informed patient care through the access to state of the art technologies



Validated virtual testing environment to reduce the cost to deliver safer, more effective medical devices

Support delivery of innovation with increased confidence and efficiency in the approval of medical device submissions

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Project Value Proposition

The Real Winners…

Increased longevity, better quality of life, and more affordable health care!

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Why this Project is Unique

- **Focus**
  - Emphasis exclusively on cardiovascular systems
- **Commitment to commercial solutions**
  - Led by Industry: State-of-the art science
  - Clinically Focused: Solutions to real health problems
  - Results Published: Ensure critical peer review of all project outputs
- **Built on proven technology**
  - Incorporating leading research technology, not-re-inventing it
  - Based on world class products such as Abaqus, Isight, and the new cloud-based 3DEXPERIENCE Platform

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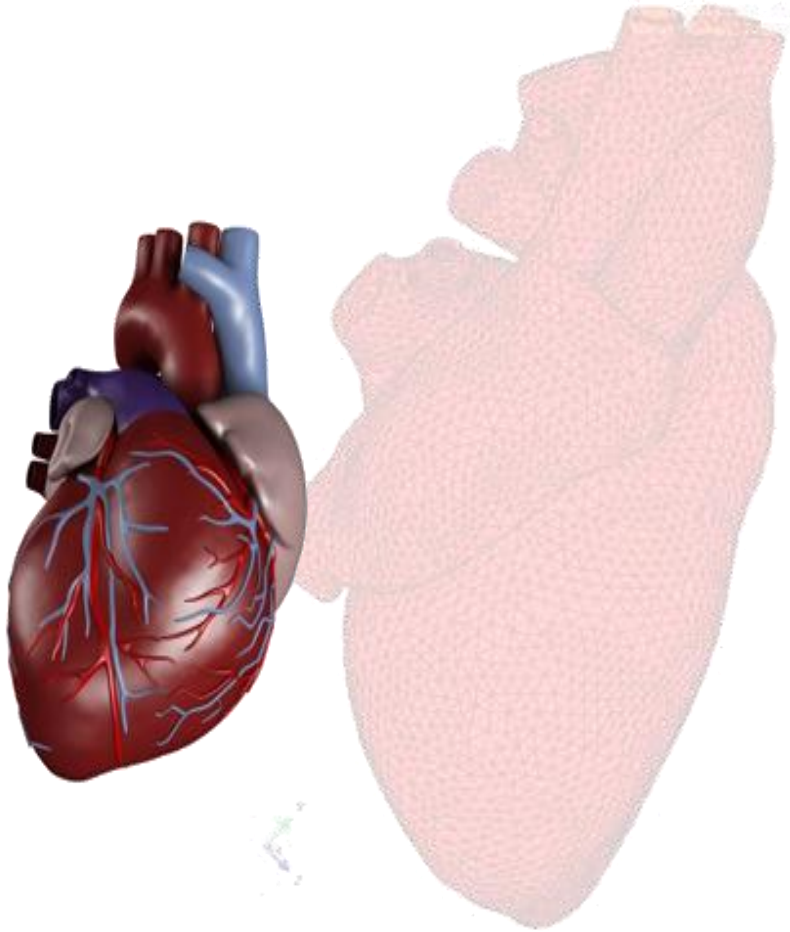
Overview

- A realistic simulation of the human heart couples numerous domains:
  - **Electrical:** electric stimuli causes muscle contraction
  - **Mechanical:** the muscular contractions result in large deformation changes
  - **Fluids:** the mechanically induced volume changes causes blood to flow through the heart and onto the rest of the body



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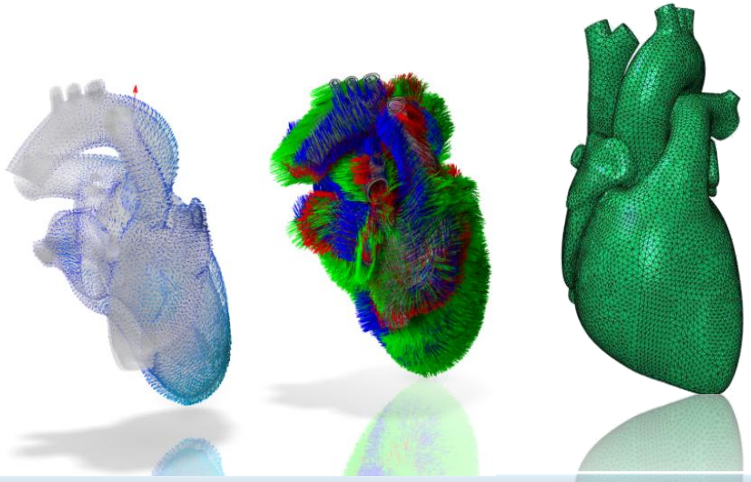
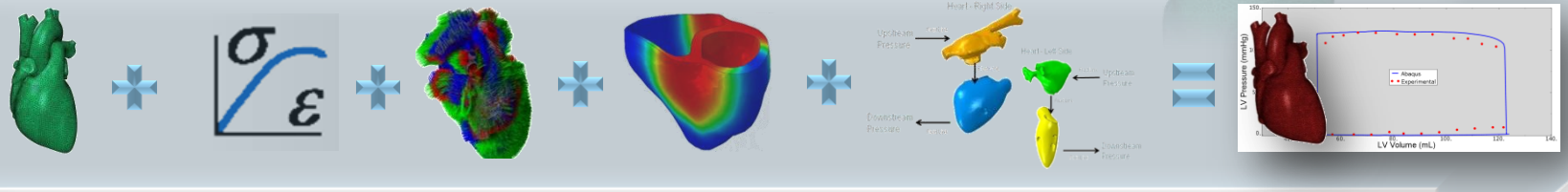
Realistic Heart Simulation



State-of-the-Art Geometry

Detailed Fiber Orientation



Proprietary Material Model

$$\psi_{dev} = \frac{a}{2b}\exp\left[b(I_1-3)\right] + \sum_{i=f,s}\frac{a_i}{2b_i}\left\{\exp\left[b_i(I_{4i}-1)^2\right]-1\right\} + \frac{a_{fs}}{2b_{fs}}\left[\exp\left(b_{fs}I_{8fs}^2\right)-1\right]$$

Coupled Multi-physics

Valves, Fluid Pressure, …

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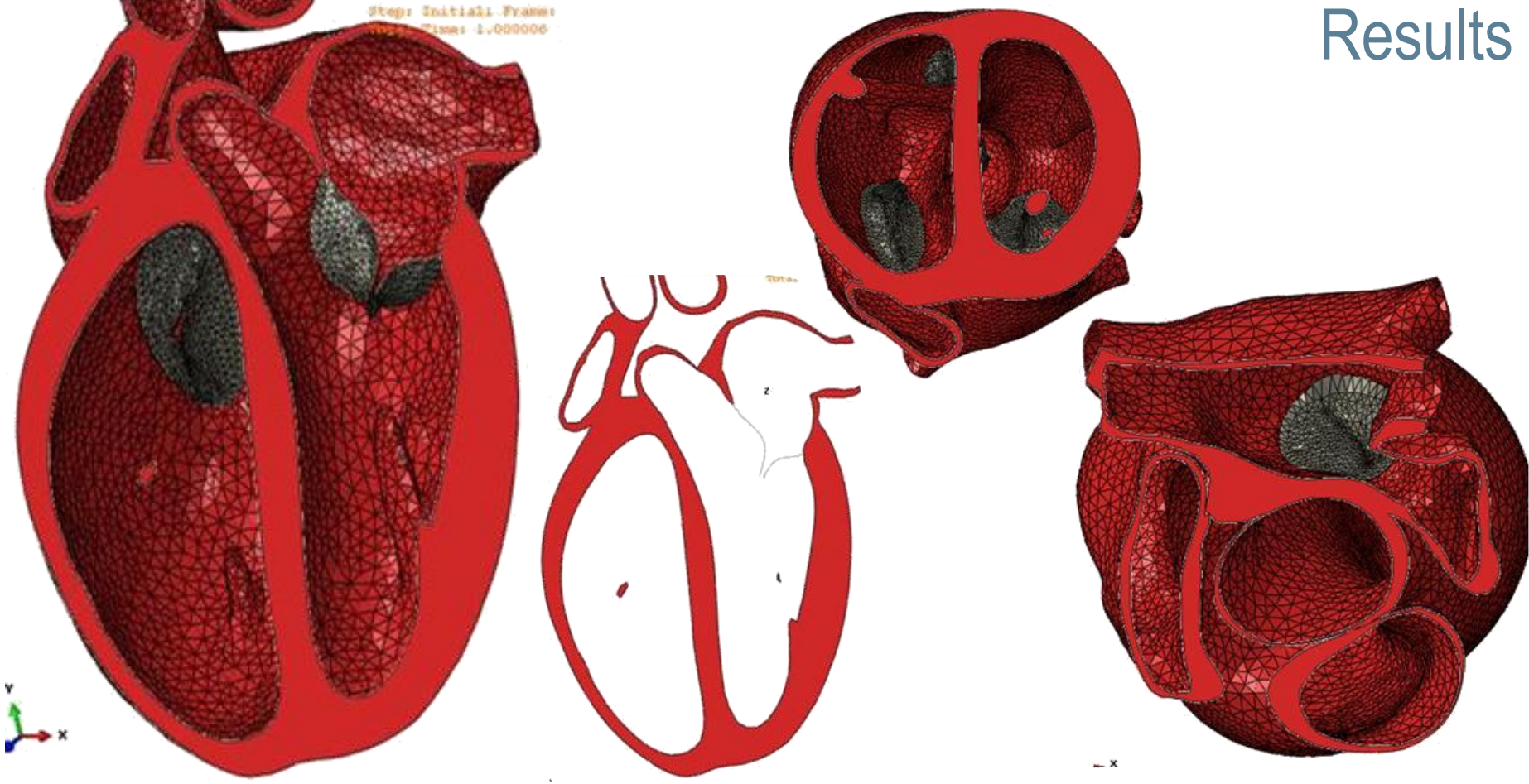
Results



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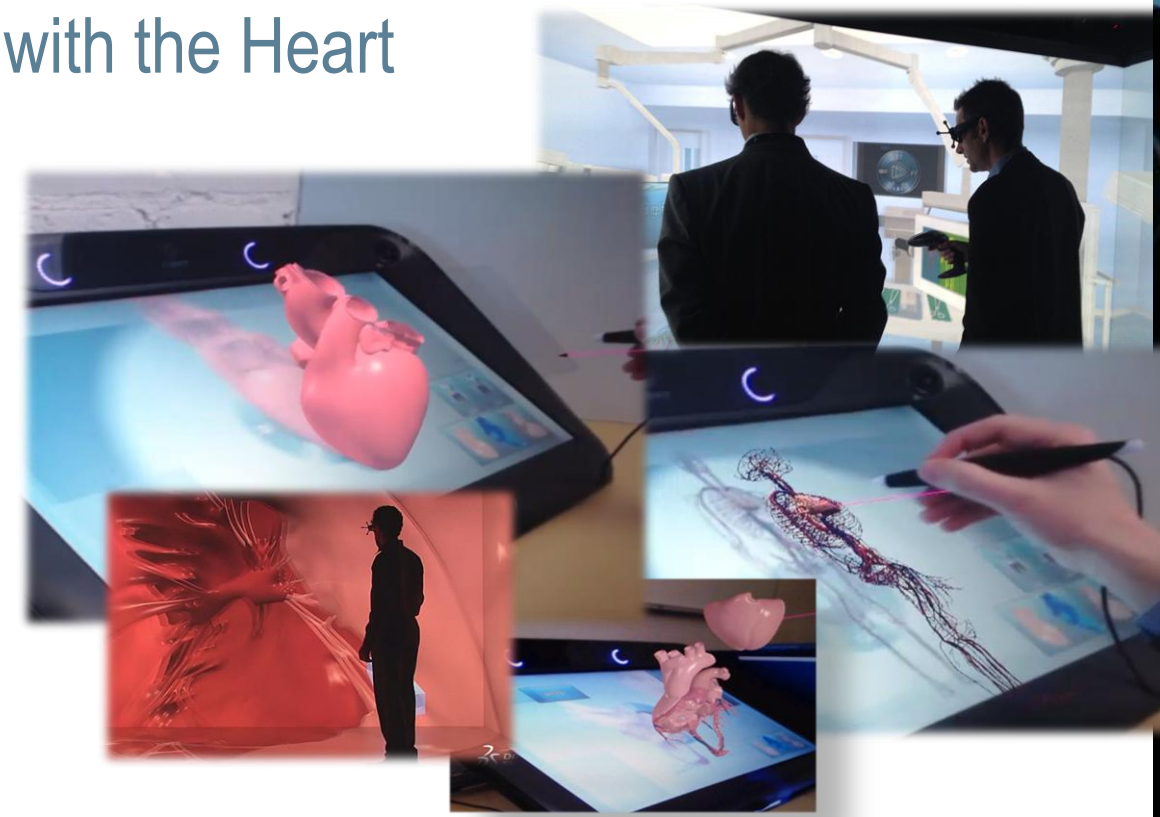
Interactive Experiences with the Heart



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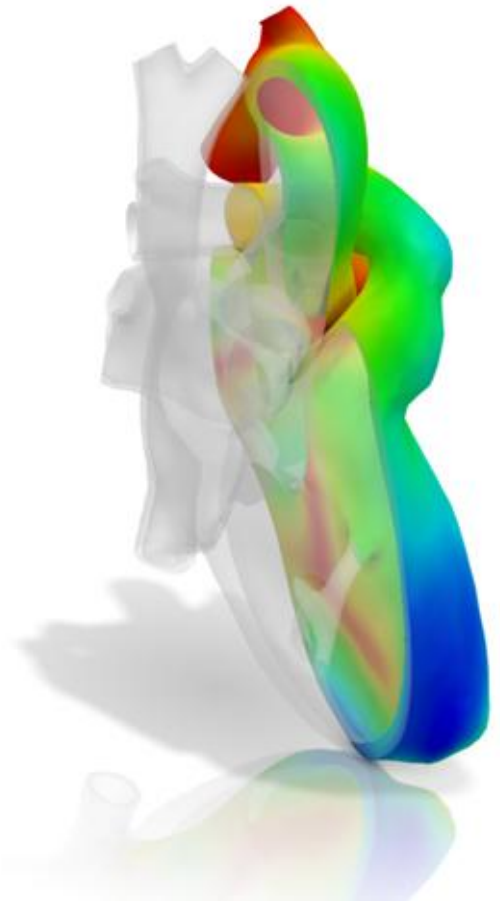
Thank you!

For more information, to join the project or just learn more, please visit:

- www.3ds.com/heart
- The Living Heart Project on LinkedIn



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