

## **HeartFlow®**

# Revolutionizing Precision Heart Care



## Ingenuity Applied



HeartFlow brings together human ingenuity and advanced technology to help combat heart disease, the leading cause of death.

HeartFlow's non-invasive, personalized cardiac test provides unprecedented visualization of each patient's coronary arteries, enabling physicians to create more effective treatment plans for their patients.



## Superior Quality



By combining review from trained analysts, who have over 500,000 hours of collective experience, with Al-powered algorithms trained on millions of CT images, HeartFlow is bringing a new level of precision to non-invasive detection of heart disease.

- 2x more likely to identify disease than other tests¹
- » Low false negative and false positive rates reported in real-world clinical use<sup>2</sup>
- "Core Lab" quality control monitoring program with over 10,000 measurements<sup>2</sup>



## Clinical Excellence



Since inception, HeartFlow has been committed to producing comprehensive clinical evidence supporting the diagnostic accuracy, safety, efficacy, cost-effectiveness, and utility of its product portfolio.

With more than 425 publications in prominent peer-reviewed medical journals including *JAMA, JACC, Circulation, the American Journal of Cardiology, and Heart*, the HeartFlow technology has been proven across diverse patient populations. These clinical activities have included a series of large, multi-center global trials.

#### **ROBUST EVIDENCE**

- 3 16 company-sponsored clinical trials and registries addressing accuracy and outcomes
- >> 100+ investigator-initiated studies
- 3 425+ peer-reviewed publications
- Demonstrated safety with long-term data out to 5 years
- Studied in > 10,000 patients

## Exceptional Clinical Results



Time and time again, HeartFlow demonstrates unmatched non-invasive diagnostic performance and accuracy, alongside cost-effectiveness and efficacy.



**83**% of avoidable coronary angiograms cancelled⁴



**40**% reduction in layered testing<sup>5</sup>



Higher diagnostic accuracy than other common non-invasive cardiac tests<sup>3</sup>



**36%** improvement in revascularization efficiency<sup>5</sup>



**Dominates** stress testing and CTA alone in cost-effectiveness analysis, better outcomes at lower costs<sup>6</sup>



\$2.7B annual cost savings delivered to CMS through reduction of invasive diagnostic procedures<sup>4</sup>

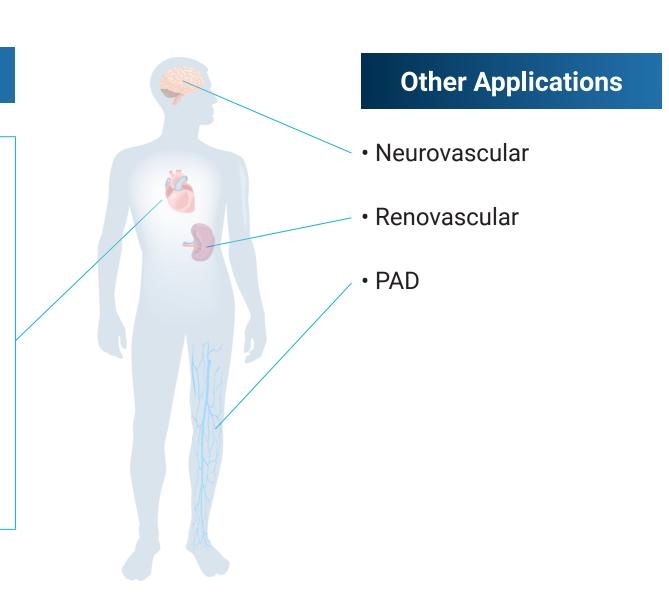
### Areas of Research



HeartFlow is committed to ongoing research and is interested in exploring the use of  $FFR_{CT}$  in these populations:

#### **Coronary Applications**

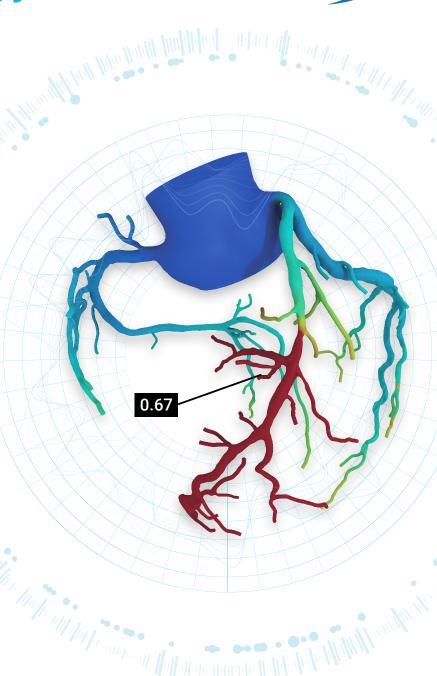
- Pre-TAVR
- Acute Coronary Syndrome (ACS) - NSTEMI
- Heart Transplant
- Emergency Department
- Perioperative Cardiac Evaluation
- Preventative Screening
- Pediatrics



## Best-in-class Technology



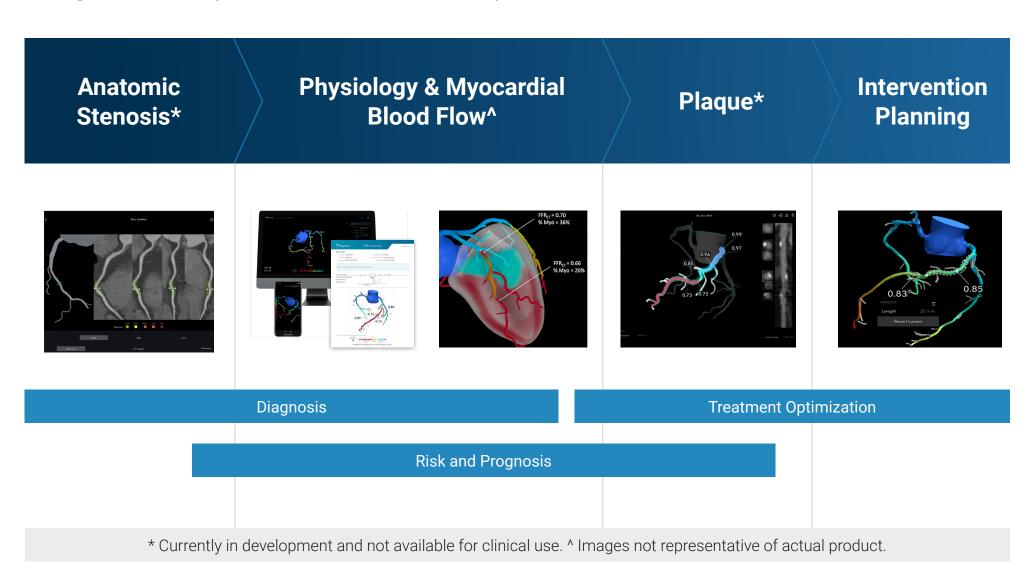
- Patient-specific Interactive 3D Model
- Best-in-class medical image analysis
- Advanced deep learning (AI) methodology to precisely extract coronary anatomy
- Al trained on millions of CT images carefully annotated by expert analysts
- Physics-based computational models assess pressure and flow changes in coronary arteries
- HIPAA and SOC 2 Type II compliant, HITRUST certified
- Secure cloud infrastructure, including encrypted transmission of image data and protected health information (PHI)
- Comprehensive IP portfolio of > 400 issued and allowed patents worldwide, covering innovations in cardiovascular medicine, physiology and bioengineering



## Unparalleled Innovation



As CAD diagnosis increasingly moves to a CTA-led pathway, HeartFlow is developing a comprehensive, integrated solution to help physicians deliver precise, personalized diagnoses and optimize treatment for their patients.



## Outstanding Customer Experience





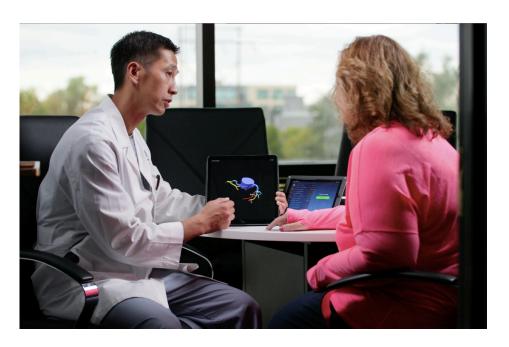
## About HeartFlow



Secured regulatory clearance to commercialize first-of-kind, Al-enabled, non-invasive diagnostic simulation of FFR<sub>CT</sub>

(2011: CE Mark, 2014: US FDA De Novo Clearance, 2016: Japan PMDA approval)

Established Medicare New Technology Ambulatory Payment Classification to reimburse hospitals, effective Jan 1, 2018





- 96% of people in the US have insurance coverage for HeartFlow
- 3 100,000+ patients have received a HeartFlow Analysis
- Adopted by more than 400 hospitals worldwide, including 80% of the top 50 heart hospitals in the US7

#### **REFERENCES**

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