



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 AI-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 tests<sup>1</sup>**
- » **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

- » 16 company-sponsored clinical trials and registries addressing accuracy and outcomes
- » 100+ investigator-initiated studies
- » 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 cancelled<sup>4</sup>



**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



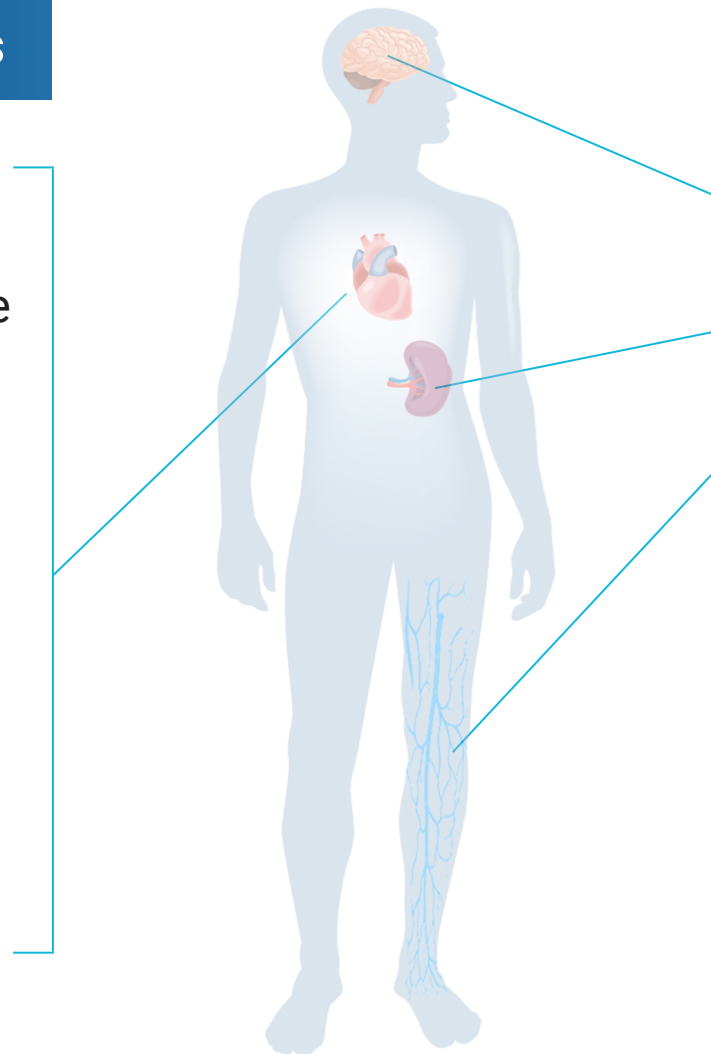
HeartFlow is committed to ongoing research and is interested in exploring the use of  $\text{FFR}_{\text{CT}}$  in these populations:

## Coronary Applications

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

## Other Applications

- Neurovascular
- Renovascular
- PAD

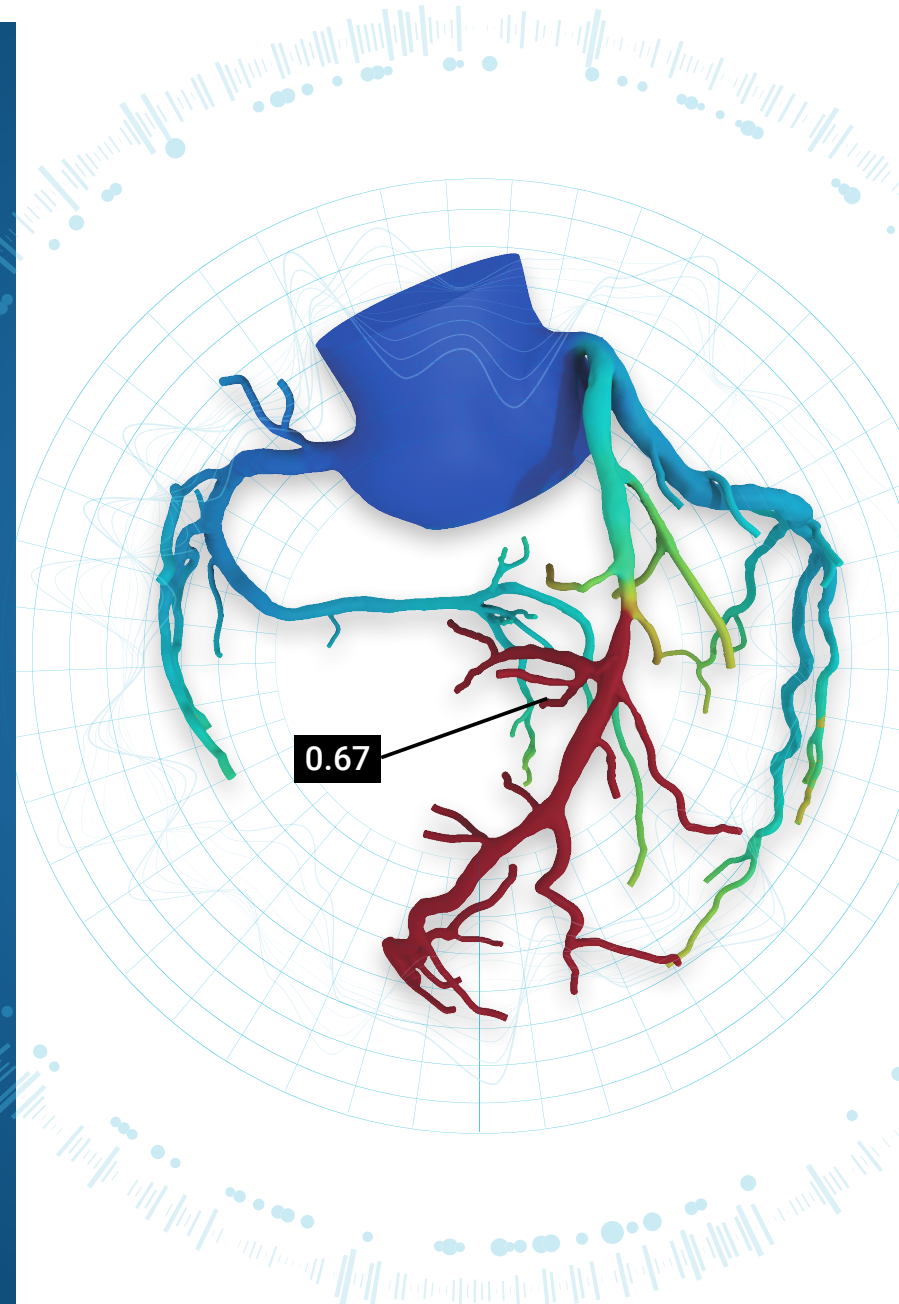




# Best-in-class Technology



- » Patient-specific Interactive 3D Model
- » Best-in-class medical image analysis
- » Advanced deep learning (AI) methodology to precisely extract coronary anatomy
- » AI 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

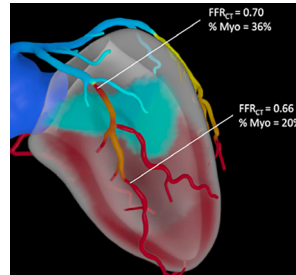
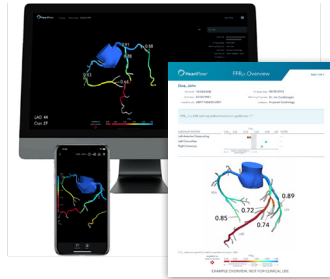


As CAD diagnosis increasingly moves to a CTA-led pathway, HeartFlow is developing a comprehensive, integrated solution to help physicians deliver precise, personalized diagnoses and optimize treatment for their patients.

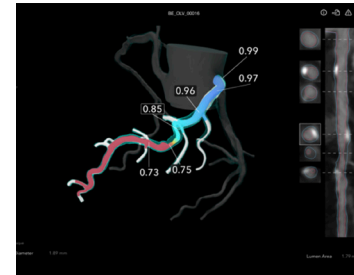
## Anatomic Stenosis\*



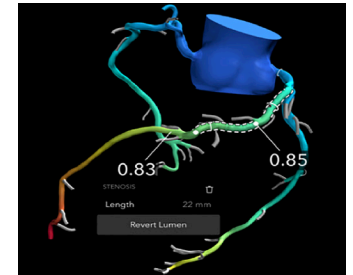
## Physiology & Myocardial Blood Flow^



## Plaque\*



## Intervention Planning



Diagnosis

Treatment Optimization

Risk and Prognosis

\* Currently in development and not available for clinical use. ^ Images not representative of actual product.



# Outstanding Customer Experience



\*Median turnaround time. March 2021

# About HeartFlow



- » Secured regulatory clearance to commercialize first-of-kind, AI-enabled, non-invasive diagnostic simulation of  $\text{FFR}_{\text{CT}}$   
(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
- » 90,000+ patients have received a HeartFlow Analysis
- » Adopted by more than 400 hospitals worldwide, including 80% of the top 50 heart hospitals in the US<sup>7</sup>

## REFERENCES

1. Nørgaard, et al. Euro J Radiol 2015. Jung, et al. Euro Heart J 2008. Melikian, et al. JACC Cardiovasc Interv 2010. Koo, et al. JACC 2011. Min, et al. J Am Med Assoc 2012. Nørgaard, et al. JACC 2014. Danad, et al. JAMA Cardiol 2017. Driessen, et al. JACC 2019.
2. Data on file at HeartFlow. November 2020.
3. Driessen, et al. J Am Coll Cardiol 2019. Nørgaard, et al. J Am Cardiol 2014.
4. Douglas, et al. J Am Coll Cardiol 2016.
5. Curzen, et al. TCTConnect 2020.
6. Karády, et al. JAMA Network Open 2020.
7. Top 50 Heart Hospitals as designated by US News and World Report, 2020-2021.

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