

Prof Ribichini is providing this presentation
on behalf of Volcano Europe



Volcano & Philips Stronger Together

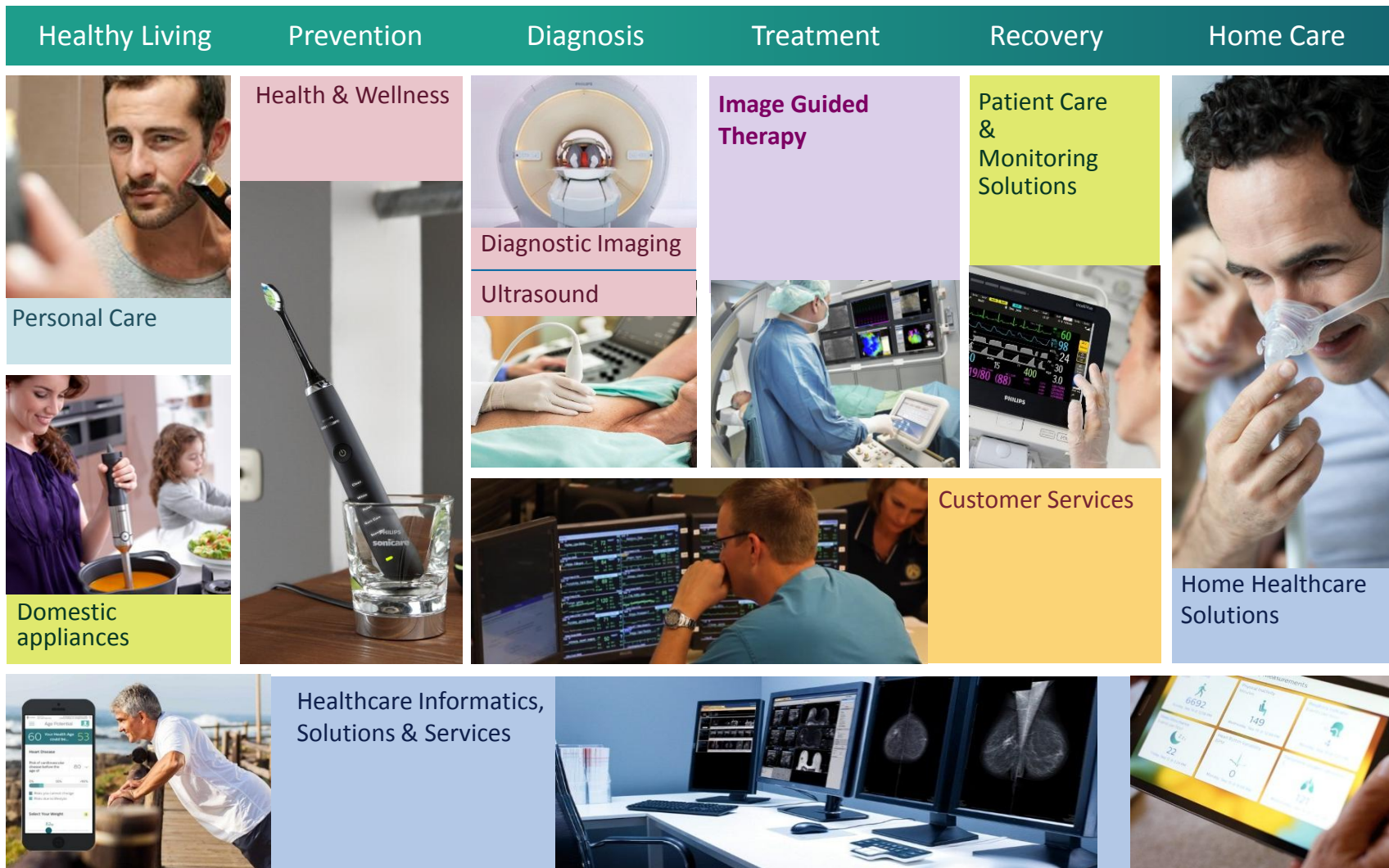
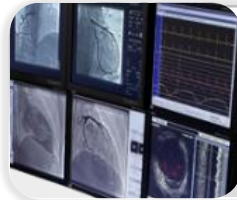


Image Guided Therapy (Volcano) Solutions

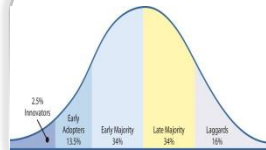
Continuum Of Care



Empowering physicians to choose from an array of precise diagnostic and guidance tools supported by clinical and economic evidence



Improving efficiency in the modern interventional suite by simplifying and increasing access to intravascular imaging and functional management

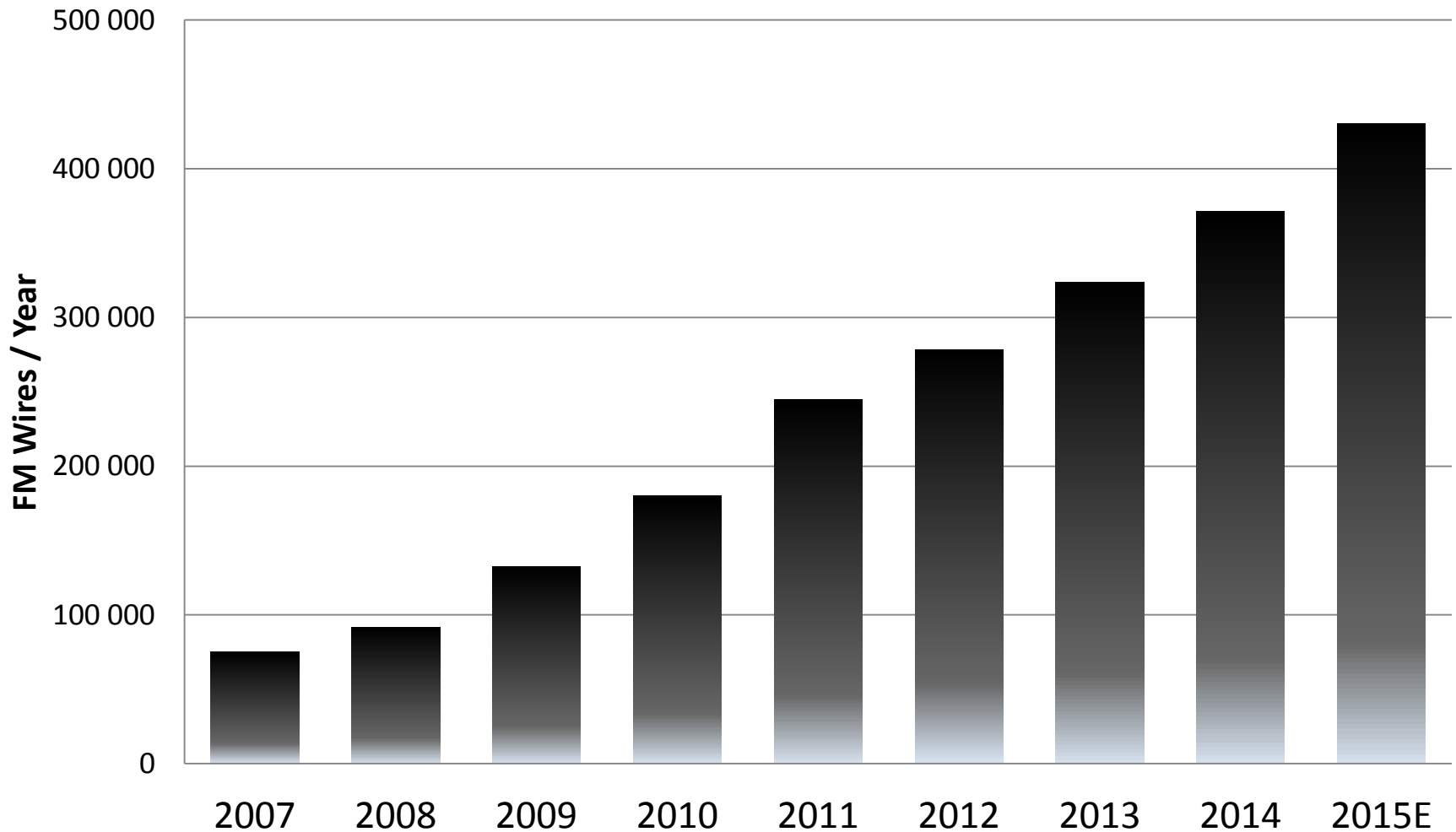


Identify opportunities to align clinical adoption with the available level of evidence



Innovation to address clinical utility & needs

FFR Use Has Grown Tremendously...



...On the Back of Strong Guidelines Support...

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

	Class ^a	Level ^b
FFR-guided PCI is recommended for detection of ischaemia-related lesion(s) when objective evidence of vessel-related ischaemia is not available.	I	A
FFR-guided PCI in patients with multivessel disease.	IIa	B

- **CLASS IIa Level of Evidence A:** FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD. (p32)

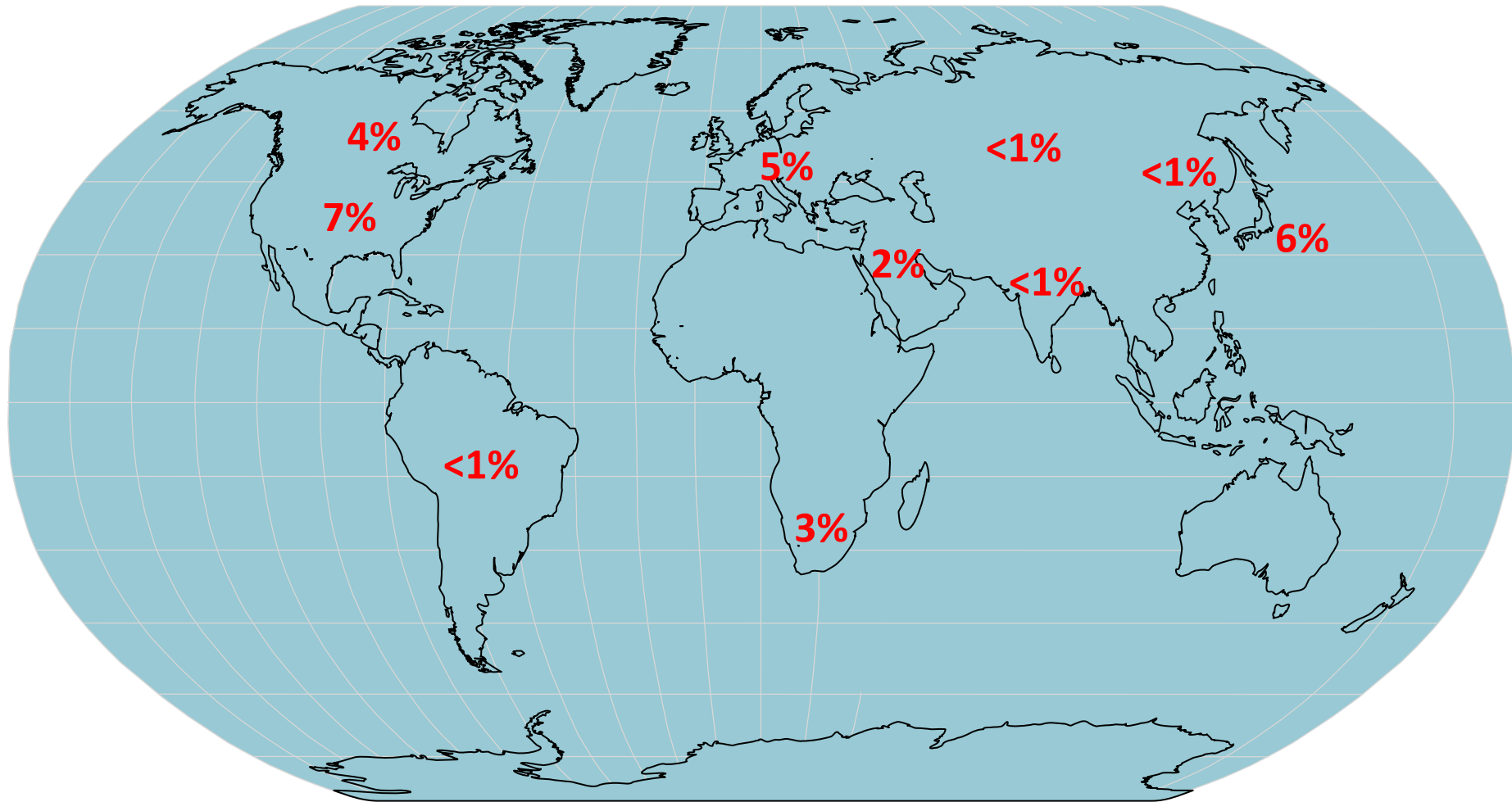
ACCF/AHA/SCAI Practice Guideline

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: Executive Summary

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

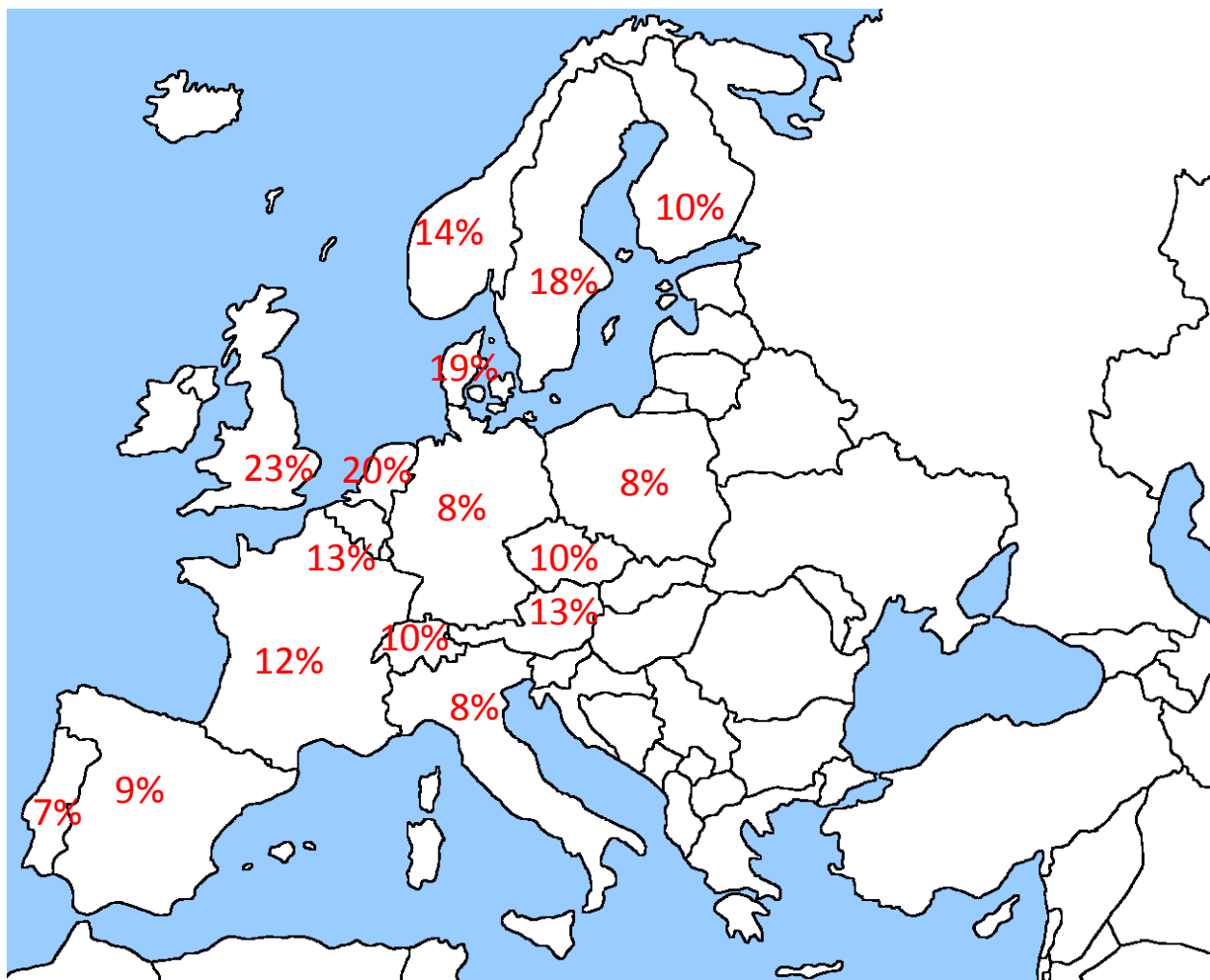
- Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS); European Association for Percutaneous Cardiovascular Interventions (EAPCI), Wijns W et al. Guidelines on myocardial revascularization. Eur Heart J. 2010 Oct;31(20):2501-55.
- Levine GN, et al. 2011 ACCF/AHA/SCAI Guideline for PCI: Executive Summary. Circulation 2011;124:2574-2609

Physiology Use is Still Globally Limited* (%FFR of Diagnostic Catheterization)

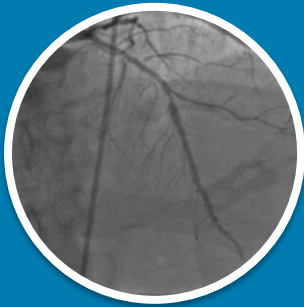


Physiology Use in Western Europe*

(%FFR Penetration vs PCI: 11%)

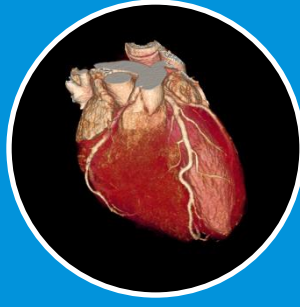


Innovation to Address Clinical Needs



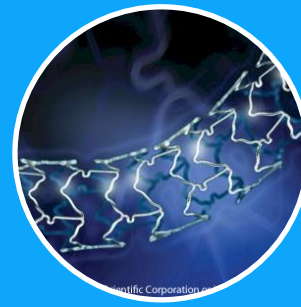
Diagnostic Angio with Obstructive Disease

- Treatment decisions are often determined by angiography alone, with or without non-invasive tests



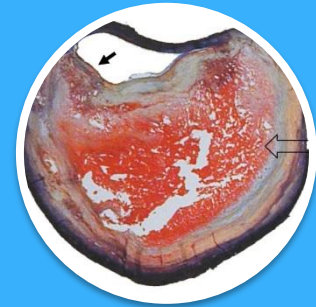
Diagnostic Angio without Obstructive Disease

- Patients are sometimes told the angina-like symptoms they experience are “definitely” not their heart



PCI Guidance for Stable Angina

- Justification to treat may be subjected to FFR, but which lesions get treated are still often driven by angiography



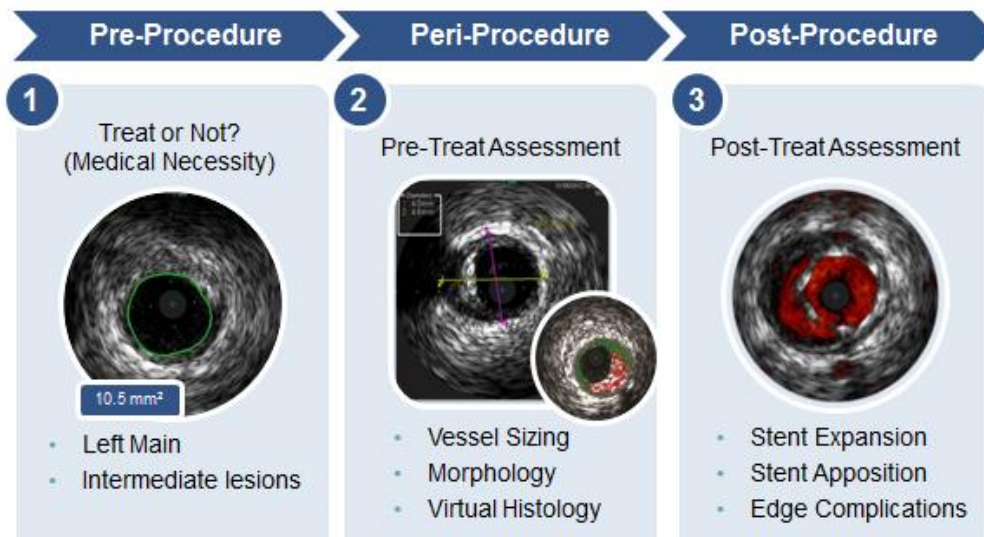
PCI Guidance for Acute Coronary Syndrome (ACS)

- Non-culprit disease is sometimes submitted to non-invasive testing or staged to determine significance

Advancing the Tools (Wires, Software, Systems)

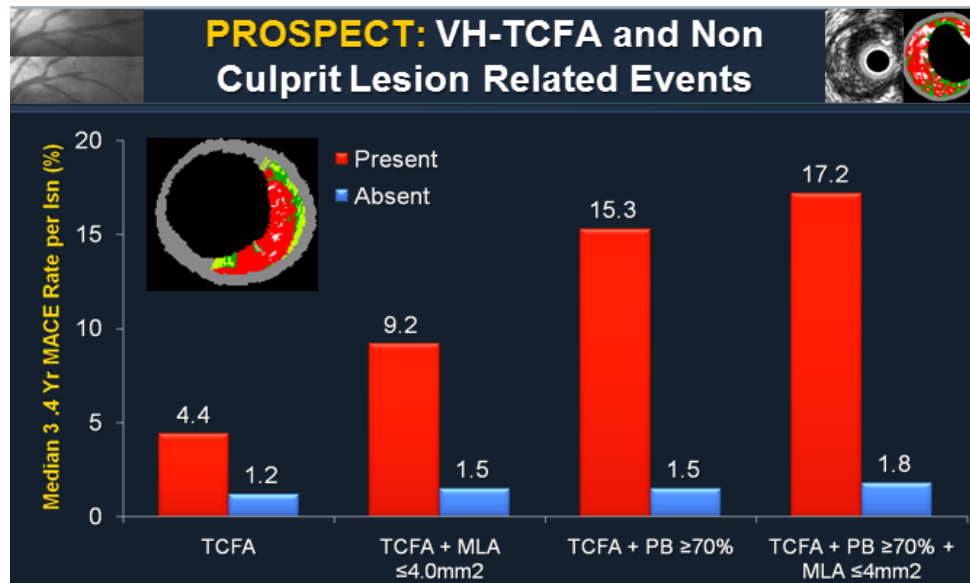
Advancing the Science (Targeted Clinical Programs)

IVUS / VH in the assessment of coronary lesion



ESC/EACTS Guidelines on myocardial revascularization

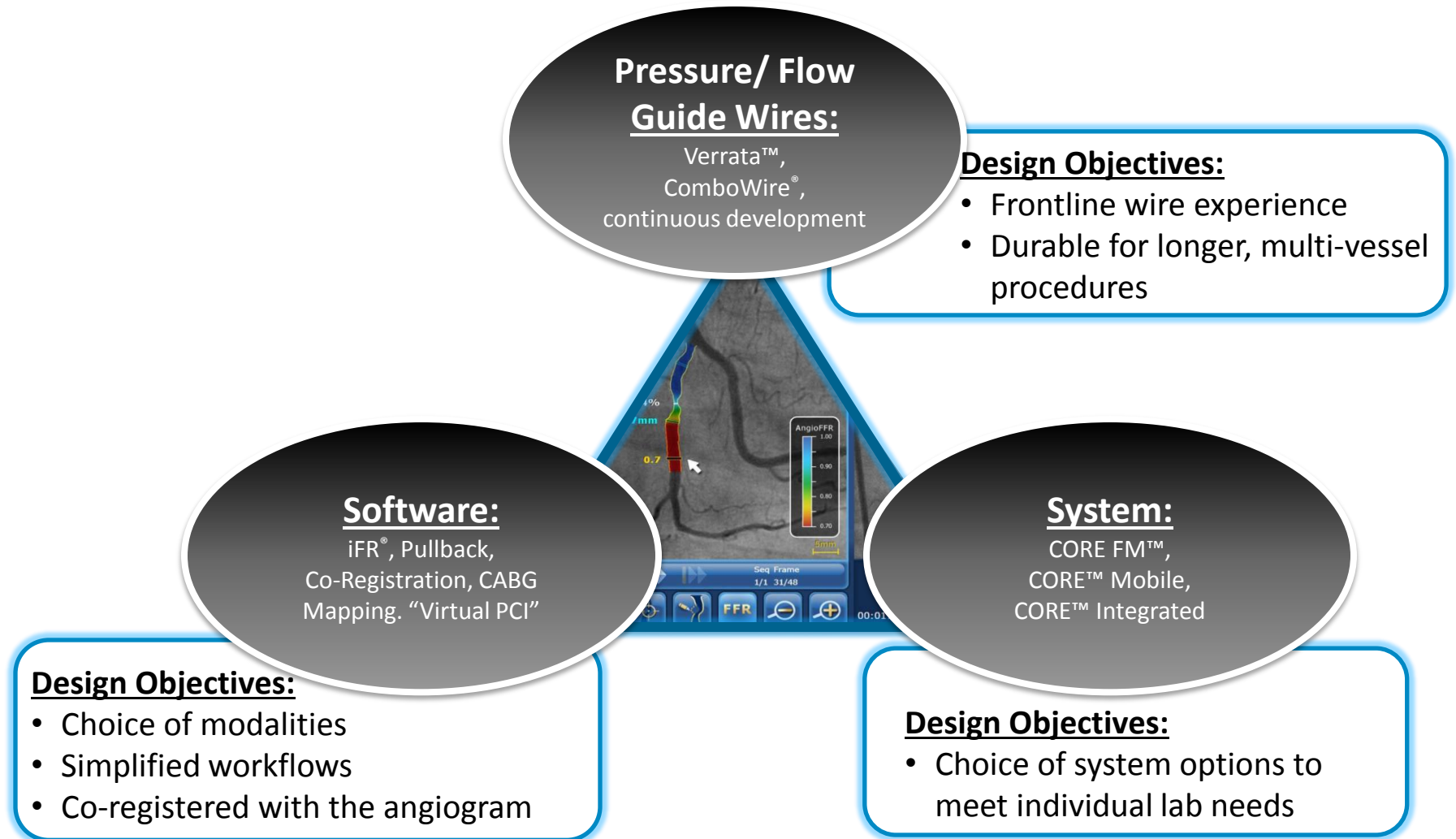
Recommendations	Class	Level
IVUS in selected patients to optimize stent implantation.	IIa	B
IVUS to assess severity and optimize treatment of unprotected left main lesions.	IIa	B
IVUS or OCT to assess mechanisms of stent failure.	IIa	C



PROSPECT Study Published in The New England Journal of Medicine Demonstrates that IVUS and VH® IVUS Technologies Can Assess Risk of a Future Clinical Event Better Than Using Angiography Alone

N Engl J Med 2011;364:226-35

Innovation to Address Clinical Needs

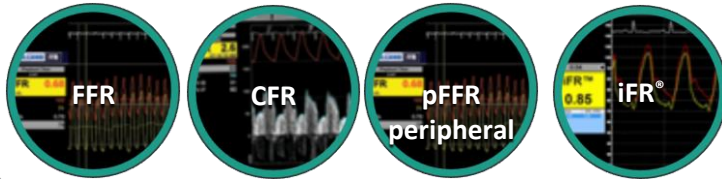


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Volcano Physiology Product Portfolio

Coronary and Peripheral Guide Wires, Hardware and Modalities

Modalities

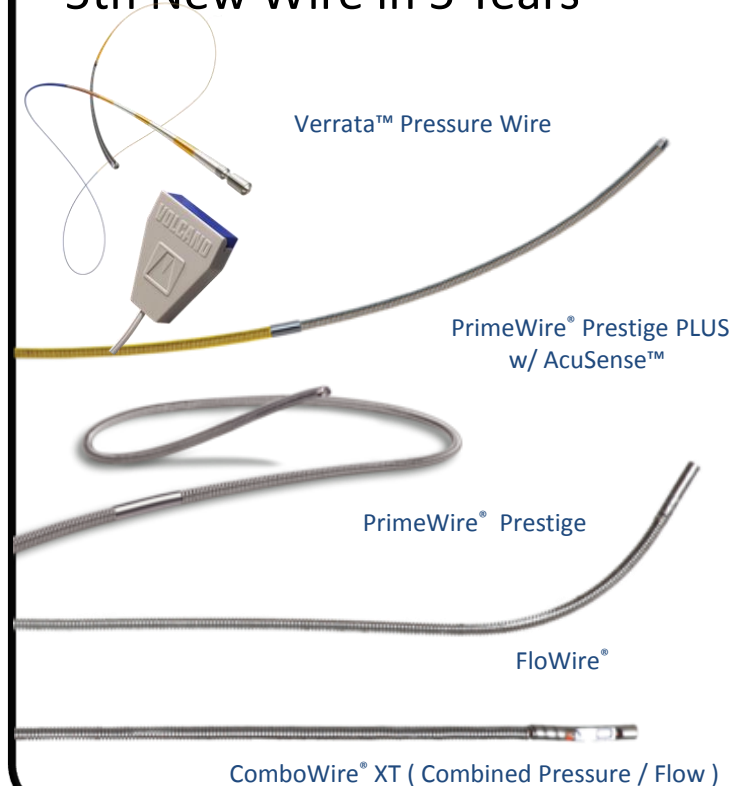


Hardware



Physiology Guide Wires

5th New Wire in 5 Years



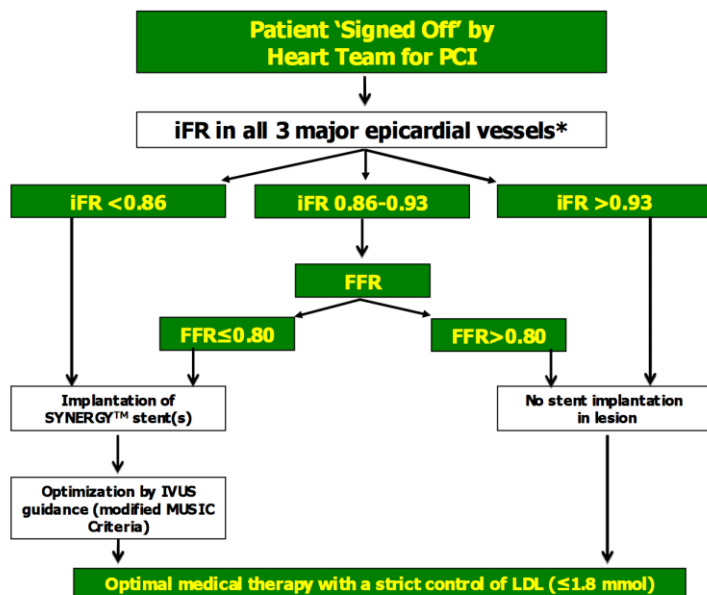
Clinical Investment Enabling Functional Guidance

- Over 4000 patients have been studied with iFR
- Numerous prospective iFR studies have been published in peer-reviewed journals
- More than 1500 equipped with iFR world wide



Major Enrolling Randomized Controlled Trials

Syntax II N=450

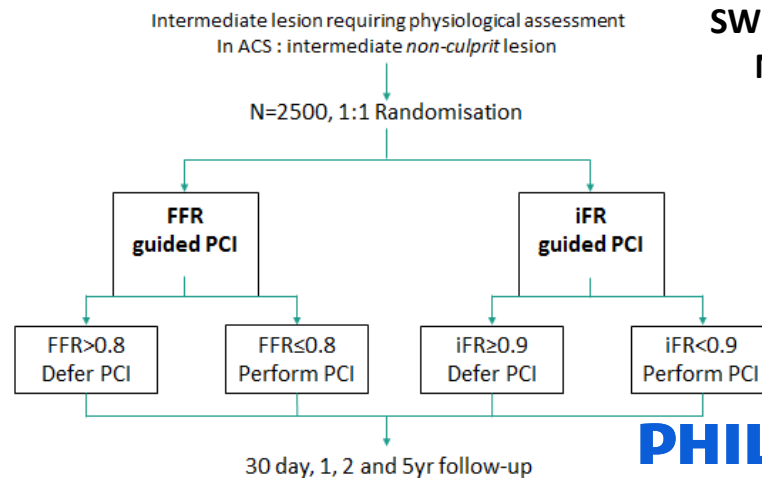


*FFR with adenosine, iFR/FFR in side branches, all at discretion of the operator

DEFINE FLAIR
Functional Lesion Assessment of Intermediate stenosis to guide Revascularisation



SWEDHEART
N= 2500



PHILIPS

Clinical Investment Enabling Functional Guidance

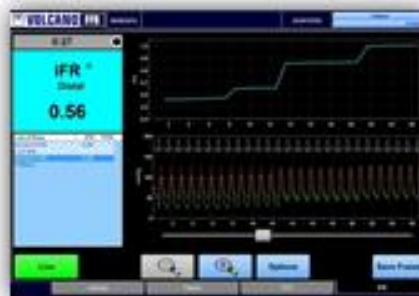
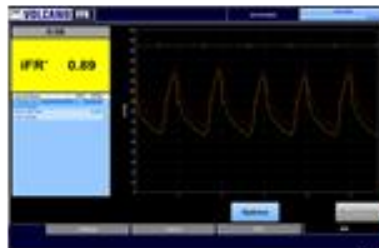
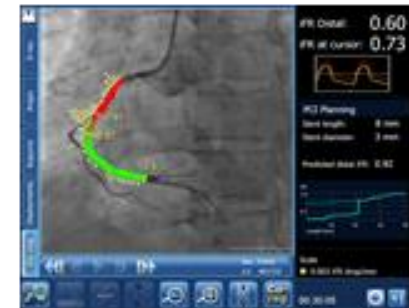
Total N= 10350

Study	Geographies	Patients	Endpoint Summary
ADVISE II [†] (2013)	US, EU, ME	800	<ul style="list-style-type: none"> Diagnostic accuracy of iFR[®]/ FFR 'hybrid approach' Hyperemia savings of 'hybrid approach'
MITNEC* (2013)	Canada	500	<ul style="list-style-type: none"> Diagnostic yield of non-invasive tests vs. FFR Performance of iFR[®] vs. FFR vs. non-invasive tests
ORBITA* (2013)	UK	300	<ul style="list-style-type: none"> Impact of PCI on QOL metrics vs. OMT alone Ability of 'Functional Gain' to predict QOL gains
J-DEFINE* (2013)	Japan	500	<ul style="list-style-type: none"> Practical use and events using 'hybrid' iFR[®] / FFR Mismatch of non-invasive and angio w/ FFR & iFR[®]
SYN	10 prospectives studies including more than 10 000 patients enrolling with iFR		
DEF			
DEFINE FLAIR* (2014)	US, EU, JP, KO, ME, AF	2,500	<ul style="list-style-type: none"> Non-inferiority of iFR[®] vs. FFR (Stable, UA, ACS) Safety of deferral of non-culprit during primary PCI
iFR SWEDEHEART* (2014)	Sweden	2,500	<ul style="list-style-type: none"> Non-inferiority of iFR[®] vs. FFR (Stable, UA, ACS) Predictive value of post-PCI iFR on outcomes
DEFINE Dx [†] (2016)	US, EU	2,000	<ul style="list-style-type: none"> Appropriateness of patients with high risk factors to bypass nuclear and proceed to cath w/FFR
DEFINE PAD [†] (2017)	US	300	<ul style="list-style-type: none"> Ability of pFFR to predict event rates following PAD stenting and atherectomy

Innovation to Enable Functional Guidance Providing Choice between FFR



and



iFR®
2013-2014

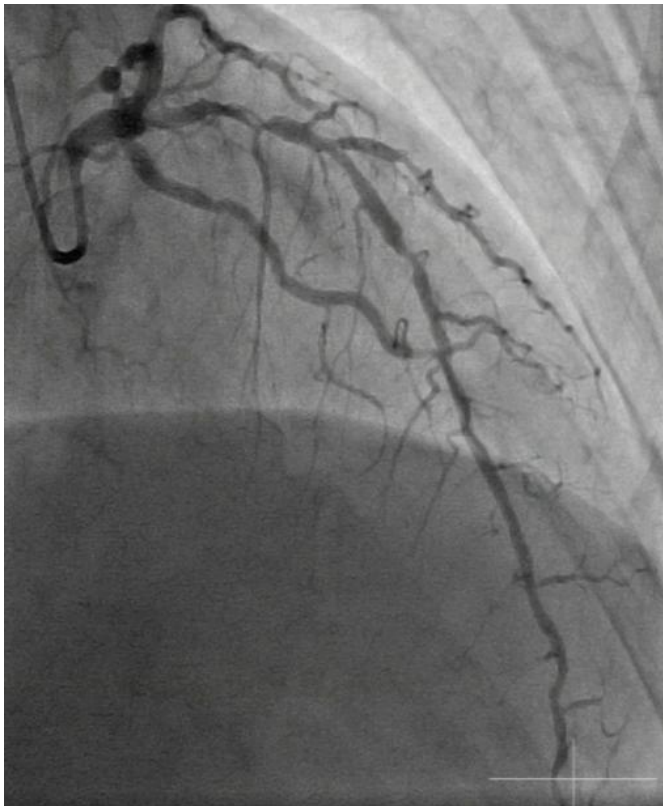
iFR Scout™
2015-2016

iFR® Co-
Reg
2017-2020

A Vision for More Physiologic Guidance: iFR SCOUT

Functionally **Justified** PCI

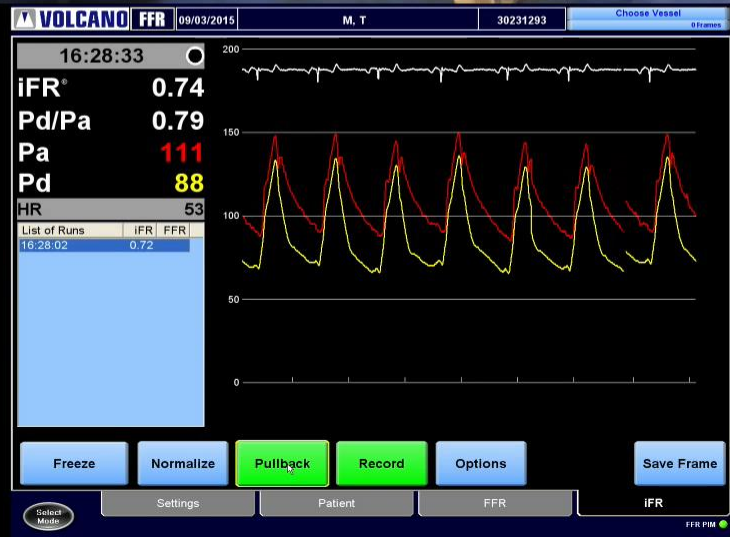
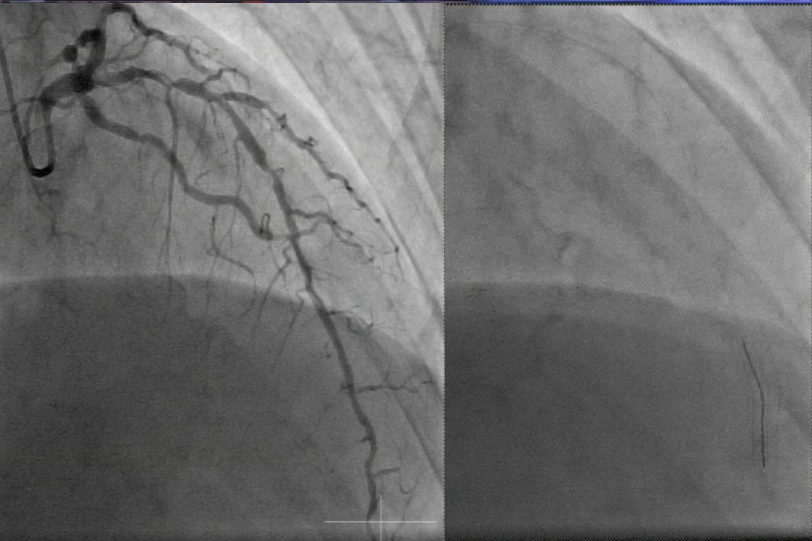
- Is the vessel significant?
 - $\text{FFR} < 0.80$
 - Yes, a stent is needed.



Functionally **Guided** PCI

- Is the Vessel Significant?
 - $\text{FFR} < 0.80$
- Which lesion(s) are significant?
 - Physiologic pullback to identify largest increases?
- How many stents are needed?
- Have the gradients been resolved?
 - Post-PCI iFR measurements.

iFR SCOUT total vessel assessment



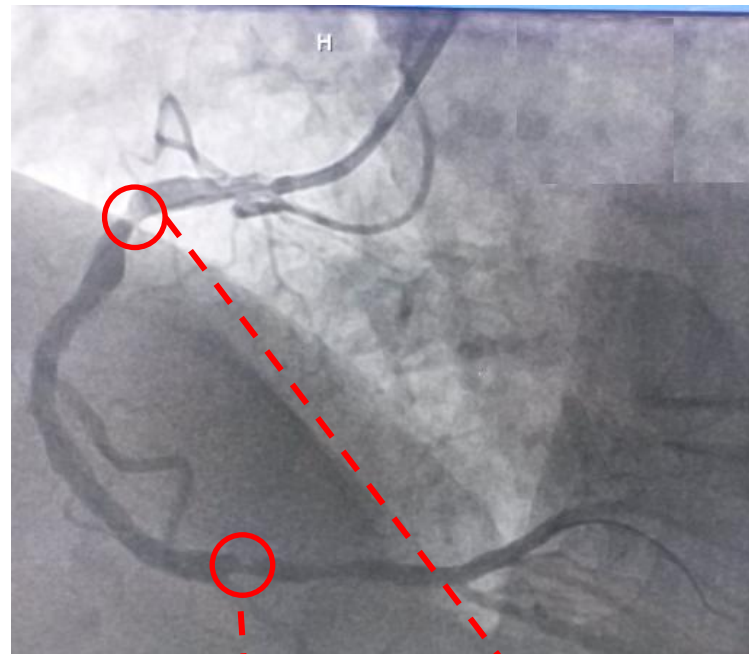
Male 80 Y

New Angina symptoms

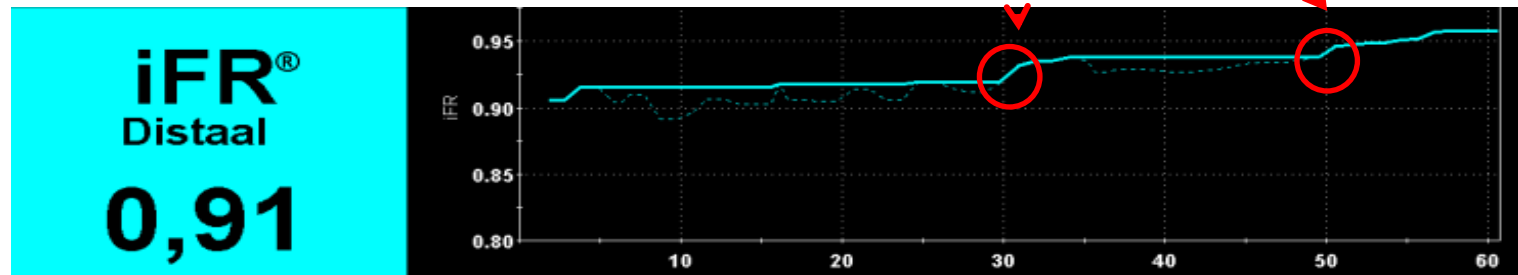
PCI LAD / RCA in 2003

Culprit lesion in LCX treated with PCI

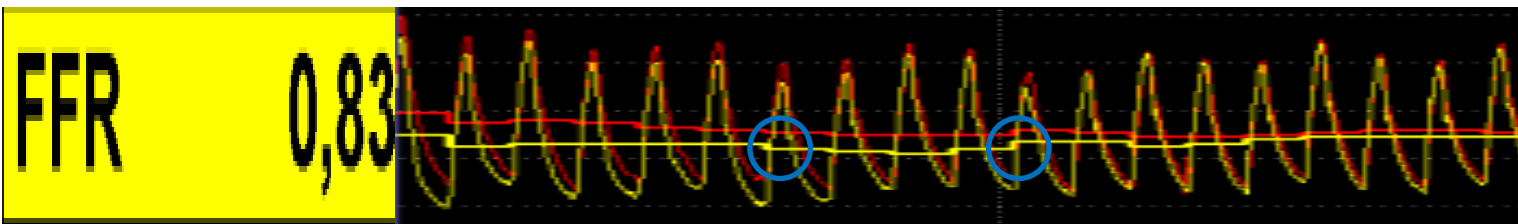
Suspicious RCA disease



iFR Pullback

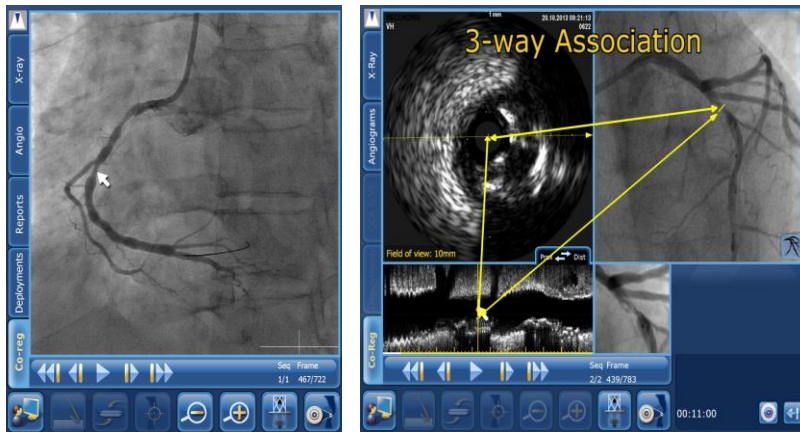


FFR Pullback

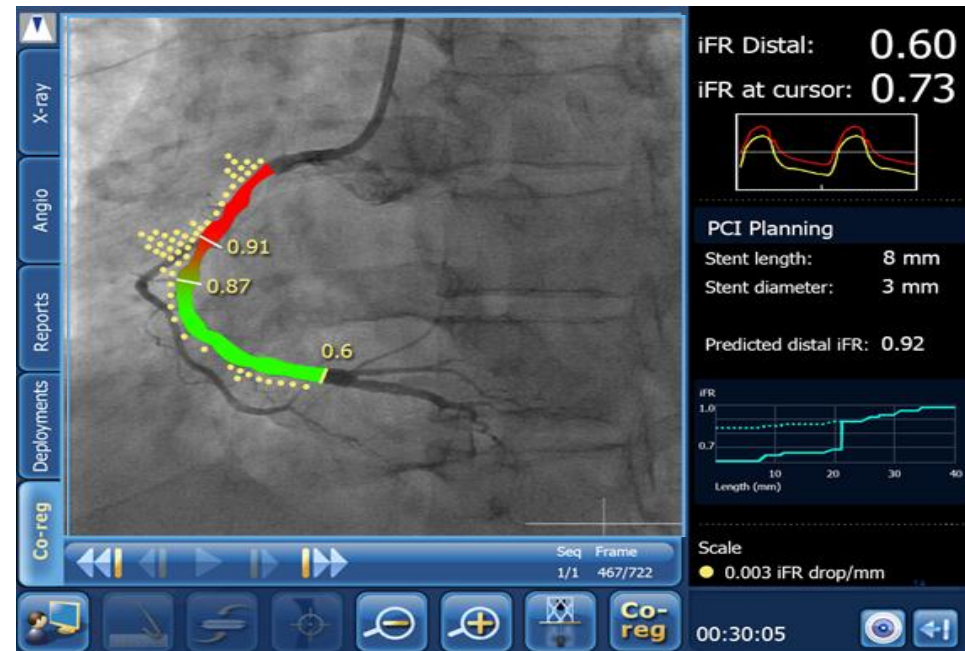
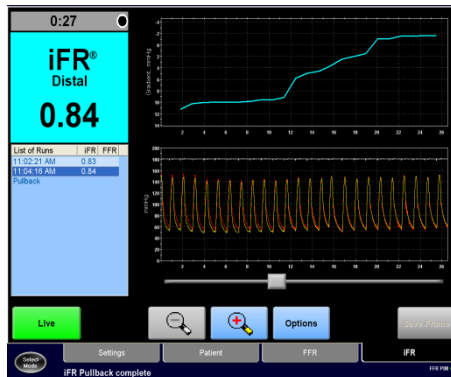


A (Sync)Vision for Functional Guidance*

Anatomy



Physiology



Conclusions

1. Any physiologic assessment (CFR, HSR, BSR, IMR, FFR, iFR or Pd/Pa) is better than angiography alone.
2. Improving 'angiography alone' will be driven by
 - the right clinical investments, the right technical advancements (simpler, easier, faster)
 - robust clinical research based on outcomes
 - and educational initiatives (Courses like ETP)
3. Functionally-guided myocardial revascularization