19th Cardiovascular Summit
TCTAP 2014

Contemporary Stent Designs: How to Customize It to Make It Better?

Real World Practice Sharing
(Promus Premier)

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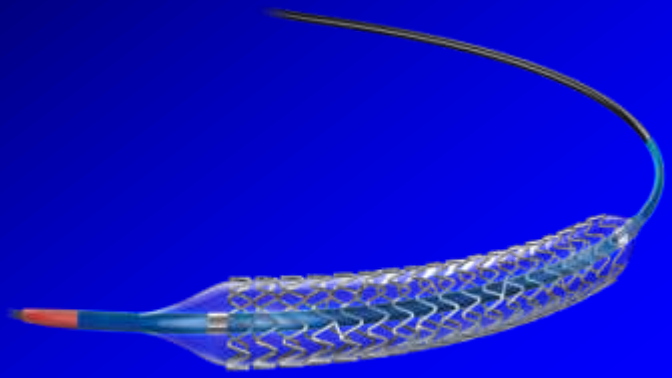
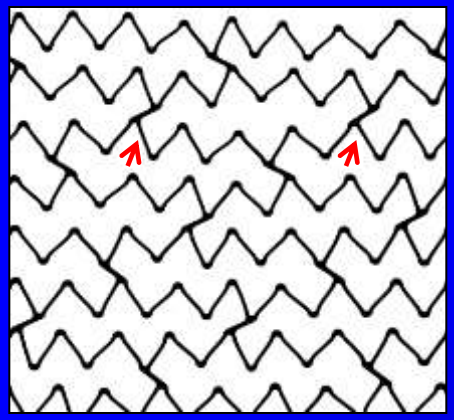
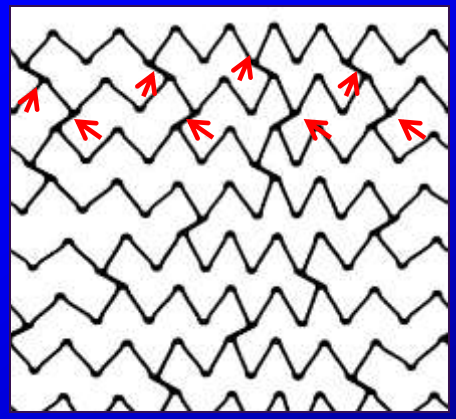
Promus PREMIER™ Stent

- Promus PREMIER utilises the same platinum chromium alloy, stent geometry, drug and polymer as the Promus ELEMENT Stent



- Increased resistance to longitudinal compression: Connectors added to the 2 most proximal stent segments of the small workhorse (2.50-2.75mm), workhorse (3.0-3.5 mm) and large vessel (4.0 mm) stent



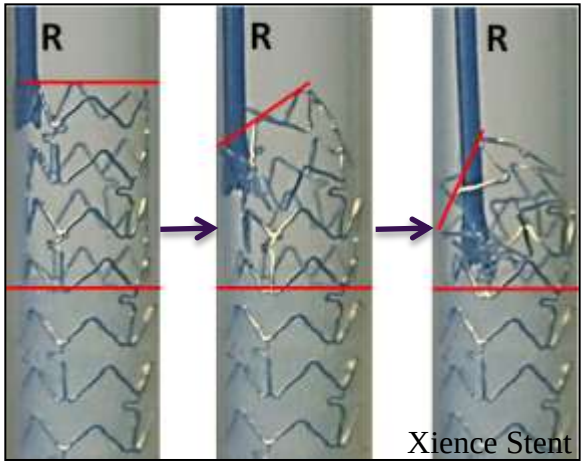


- Delivery system includes a shorter catheter tip to improve tip flexibility, PTFE hypotube coating to reduce friction and a red tip to improve visibility when loading the SDS on a guidewire

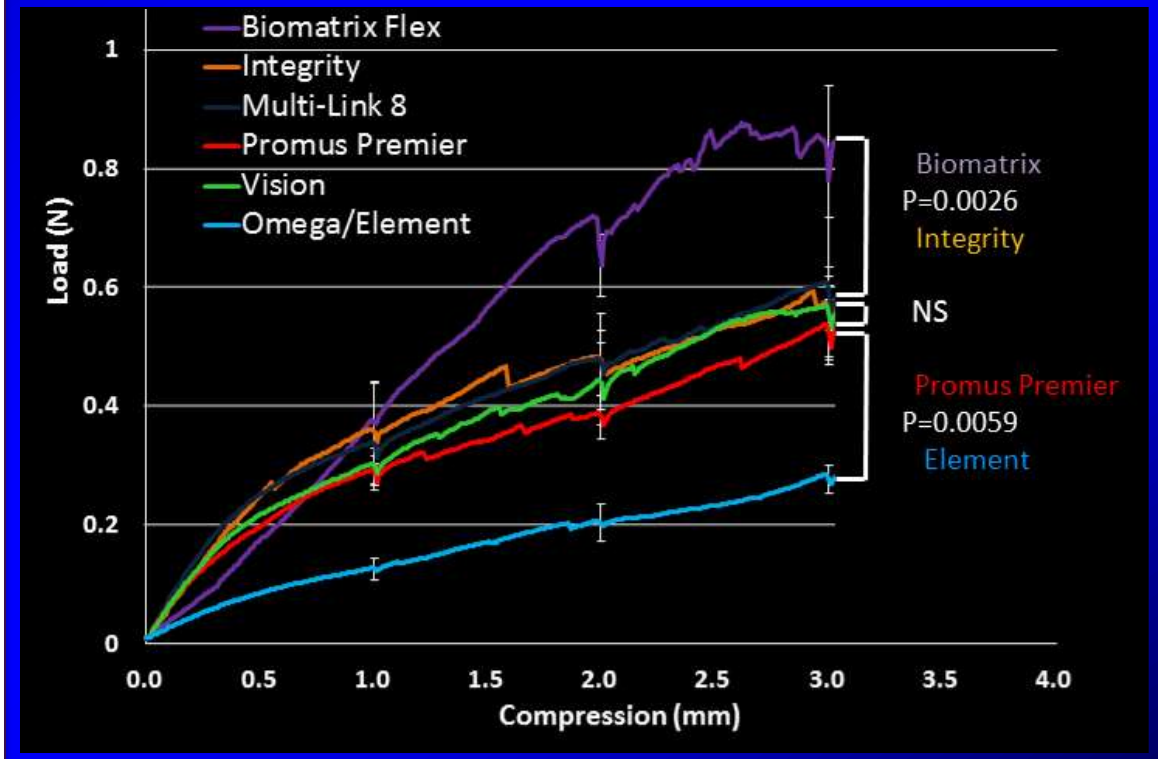
Element/OMEGA/ION design	Promus PREMIER design
The 2.5, 2.75, 3.0 , 3.5 and 4.0 mm stents have 2 connectors between segments at the proximal end	The 2.5, 2.75, 3.0 and 3.5 mm stents have 4 connectors between segments at the proximal end; the 4.0 mm stent has 5 connectors

PREMIER™ Resistance to Compression Similar to Xience™ and Resolute™

Tested in a second generation bench test designed to mimic clinical longitudinal stent distortion (point compression with 0.5N force)



Stent is fixed distally (below red line) and malapposed proximally → Instron applies 0.5N force via a rod → Stent is compressed on side of force and displaced → Instron measures force and distance compressed



Ormiston et al CRT 2013

NG PROMUS Clinical Trial: 30-Day Clinical Outcomes

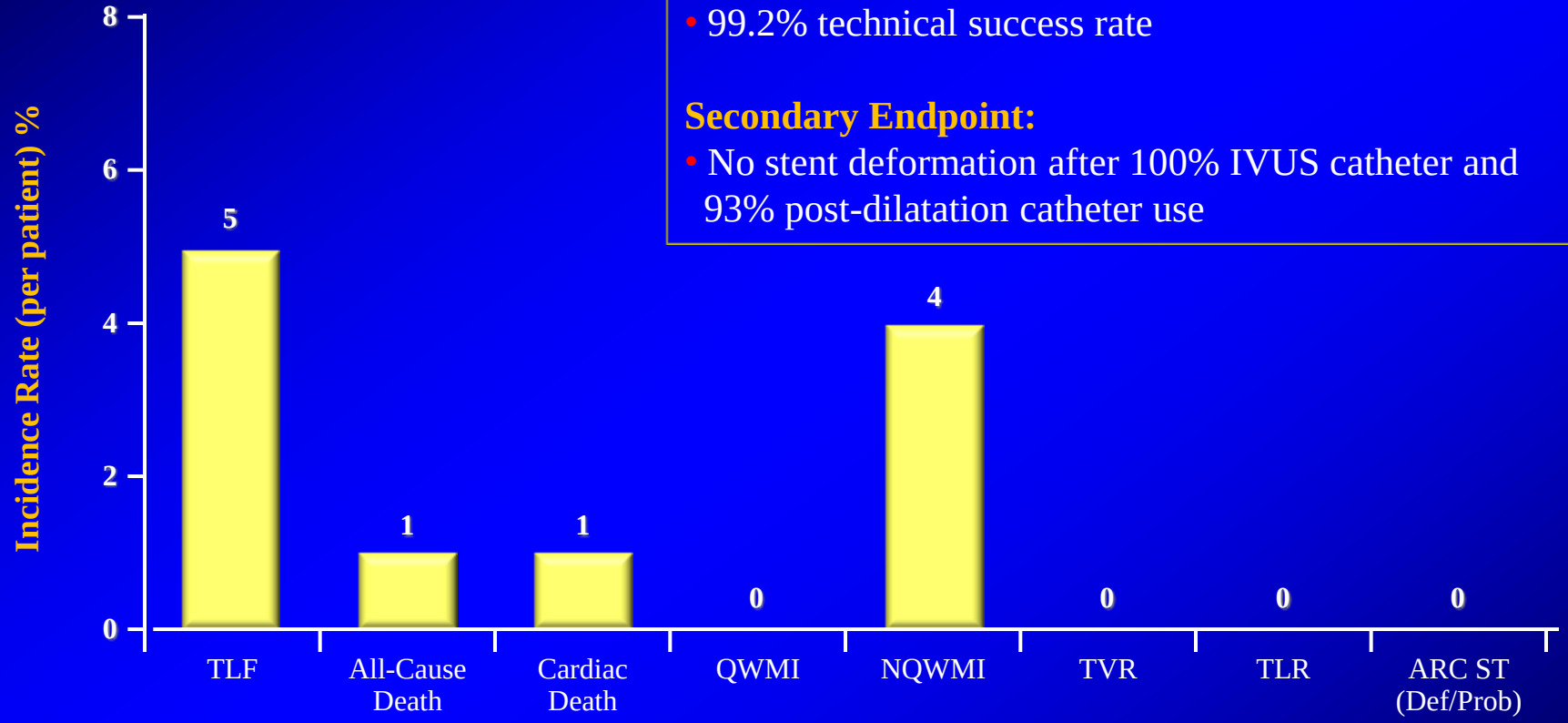
(100 patients enrolled in 9 sites (New Zealand, Singapore, Australia)

Primary Endpoint:

- 99.2% technical success rate

Secondary Endpoint:

- No stent deformation after 100% IVUS catheter and 93% post-dilatation catheter use



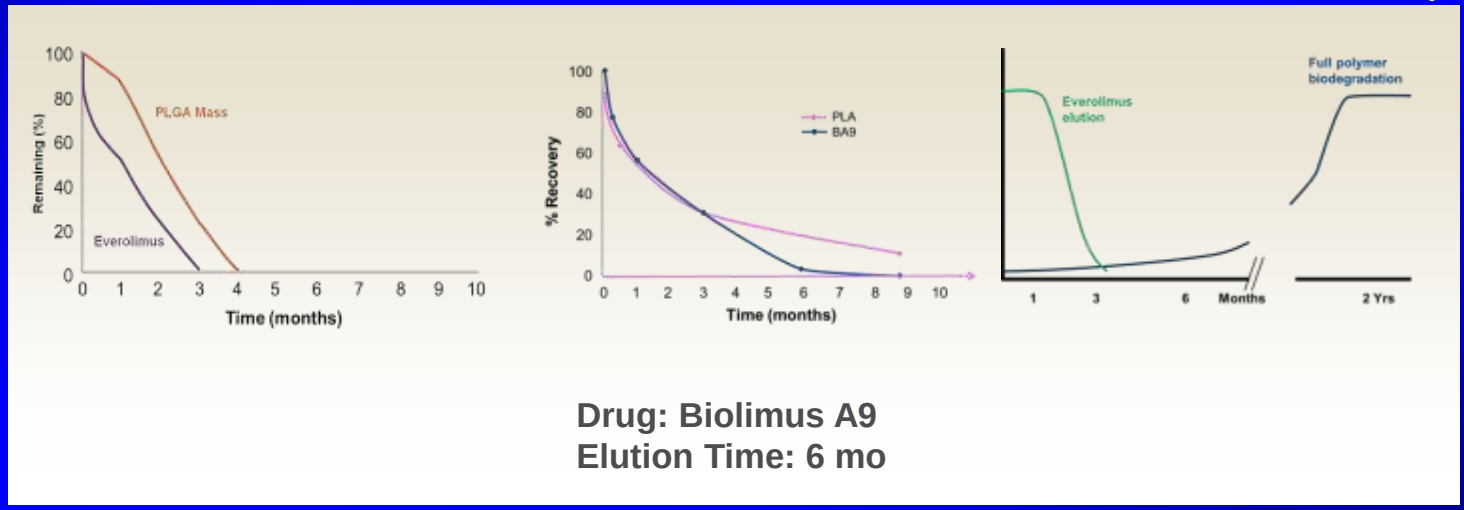
SYNERGY™ vs Promus PREMIER™
Everolimus-Eluting Platinum Chromium Coronary Stent System

- Biodegradable polymer
- Thinner struts
- Shorter tip

Bioabsorbable Coatings in Perspective

Relative Polymer and Drug Absorption Profiles

Bioabsorbable Polymer-Coated Stents			Bioabsorbable Scaffold
SYNERGY™	**Nobori™ and BioMatrix Flex™**	**Orsiro™**	**Absorb™ BVS**
Polymer: PLGA Absorption Time: **3-4 mo**	Polymer: PLA Absorption Time: >9 mo	Polymer: PLLA Absorption Time: >12 mo	Scaffold: PLLA Polymer: PDLLA Absorption Time: >2 yrs

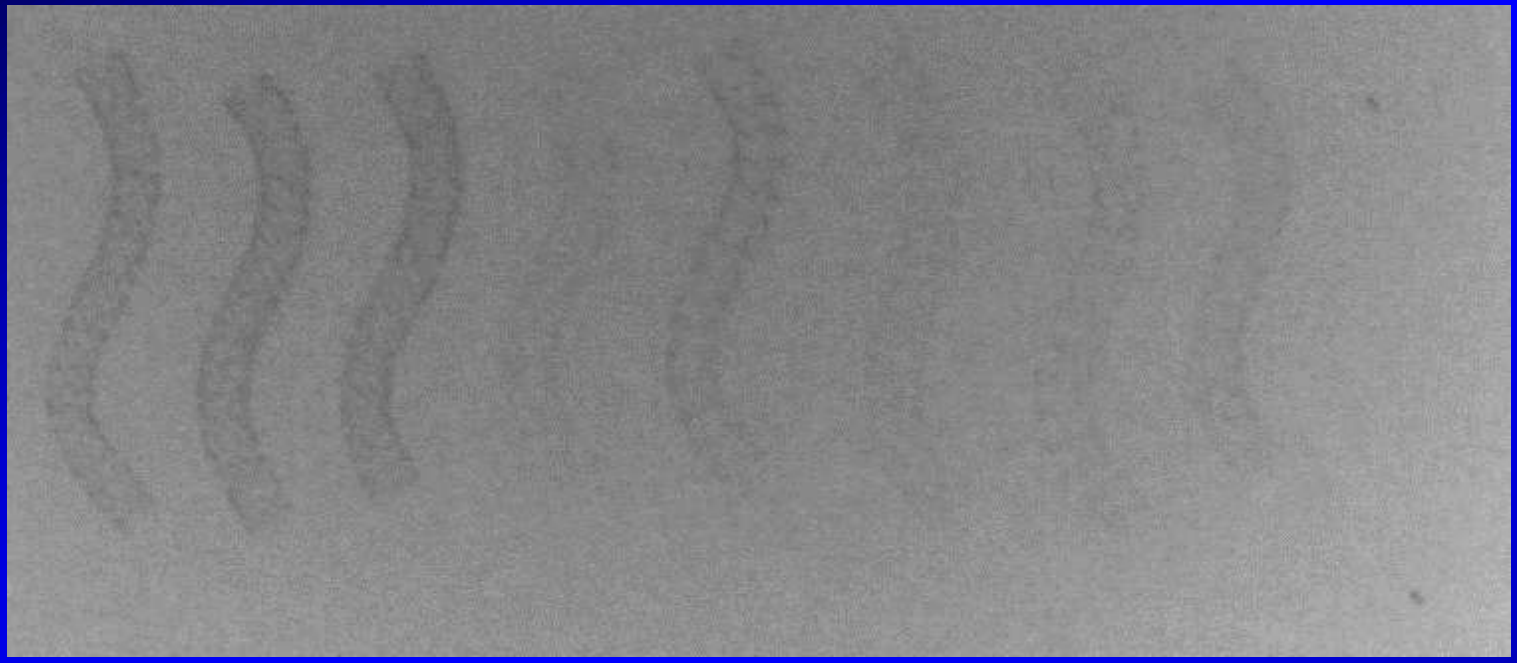


Drug: Biolimus A9
Elution Time: 6 mo

SYNERGY has the Only Polymer to Absorb Shortly After Drug Elution Ends at 3 Months

SYNERGY™ II Stent

Even with Thin Struts the High Density of Platinum Chromium Allows for Greater Visibility*



	SYNERGY II Stent	Promus PREMIER™ Stent	PROMUS Element™ Stent	Resolute Integrity™ Stent	XIENCE™ Xpedition Stent	BioMatrix™ Stent	Nobori™ Stent	Orsiro™ Stent	ABSORB™ BVS Stent
Alloy	PtCr	PtCr	PtCr	CoNi	CoCr	Stainless Steel	Stainless Steel	CoCr	PLLA Polymer
Strut Thickness	74 µm*	81 µm	81 µm	89 µm	81 µm	120 µm	120 µm	60 µm	150 µm

*Strut thickness for small vessel model is 74µm, Workhorse model is 79µm and large vessel is 81µm.

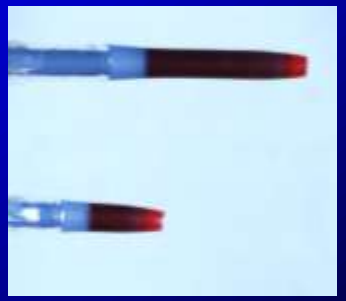
SYNERGY™ II Stent System
Delivery System Overview

- Hypotube extends into midshaft to exit port to improve pushability
  - 10% longer than existing BSC monorail hypotube designs
- Additional length laser cut to maintain midshaft flexibility
  - Variable pitch intermittent laser cuts (~360 cuts over 100mm length)
- Low profile
- Shorter, more flexible tip

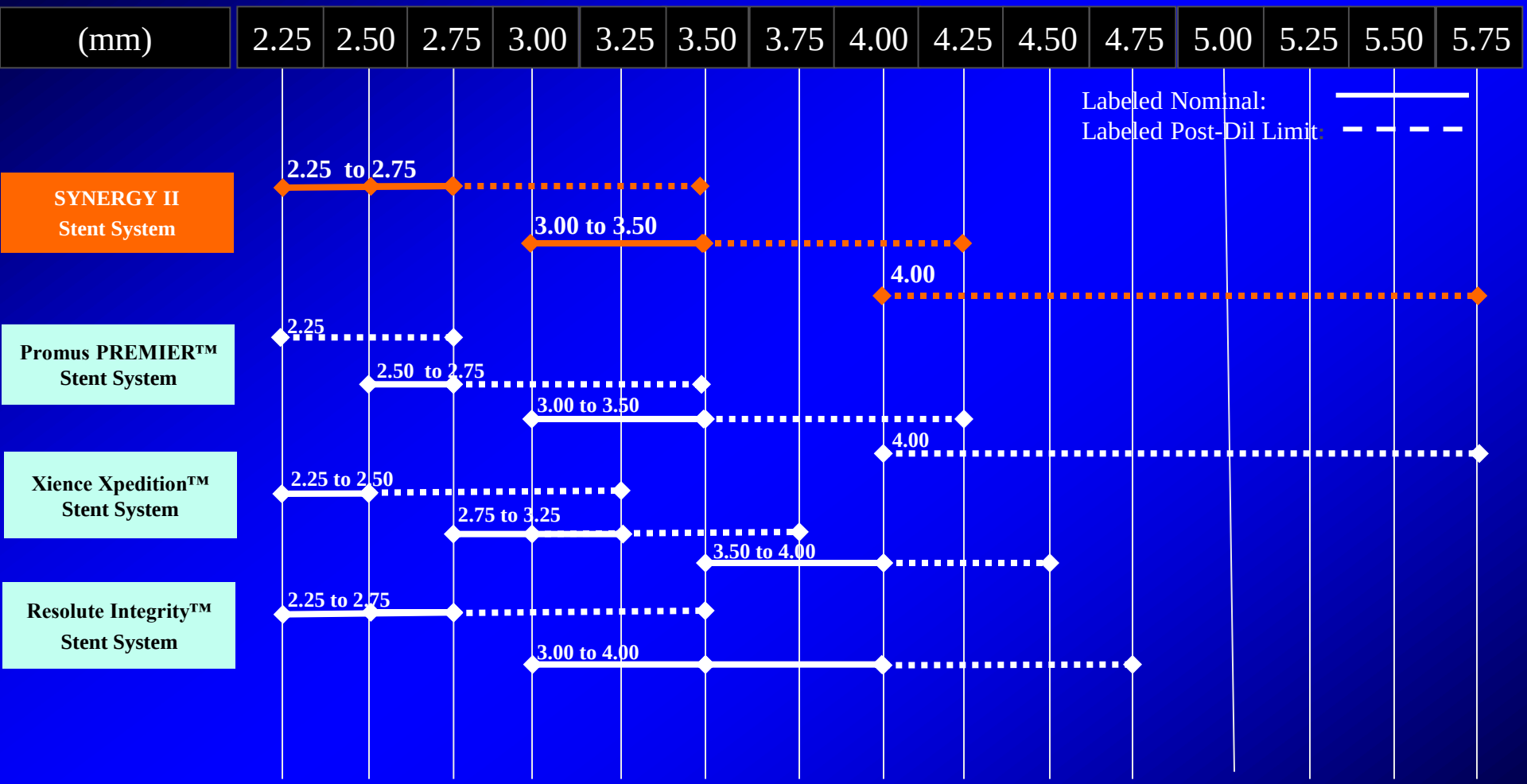
Polarized View: Variable Pitch Laser-Cuts

SYNERGY Catheter Tip

SYNERGY II Catheter Tip

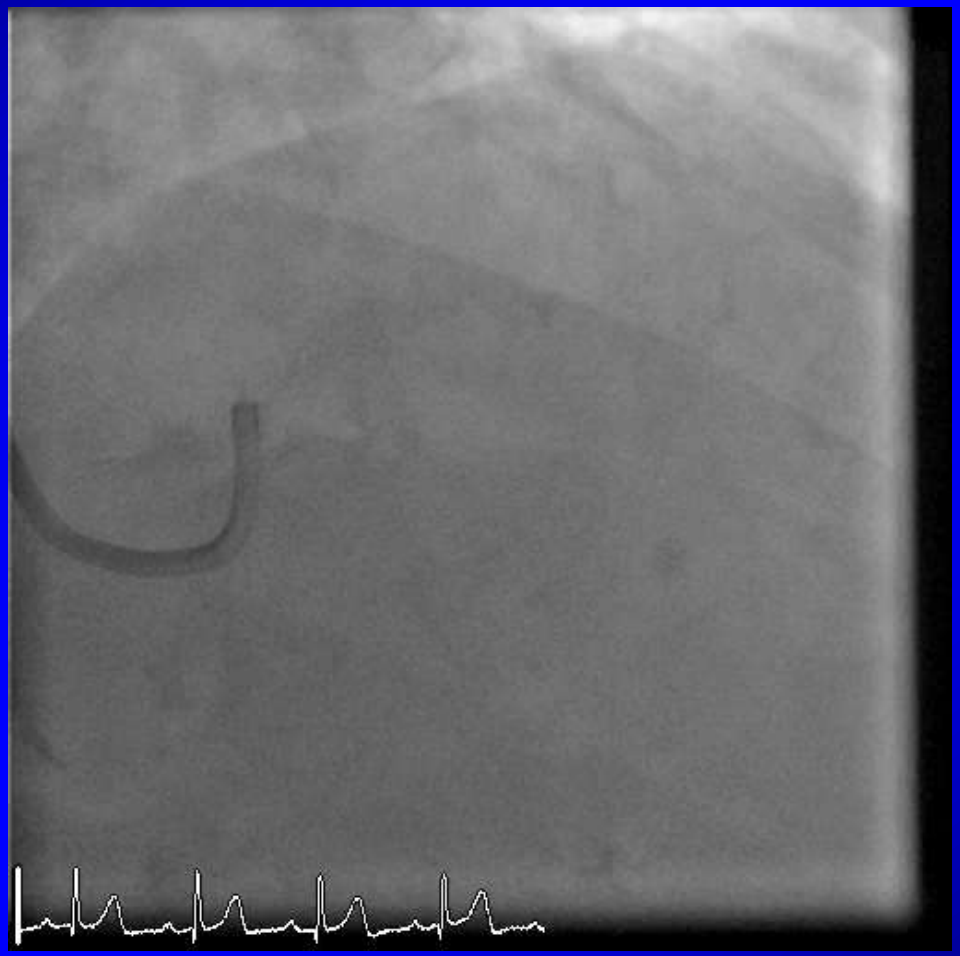


SYNERGY™ II Stent System
Labeled Post-Dilatation Limits*

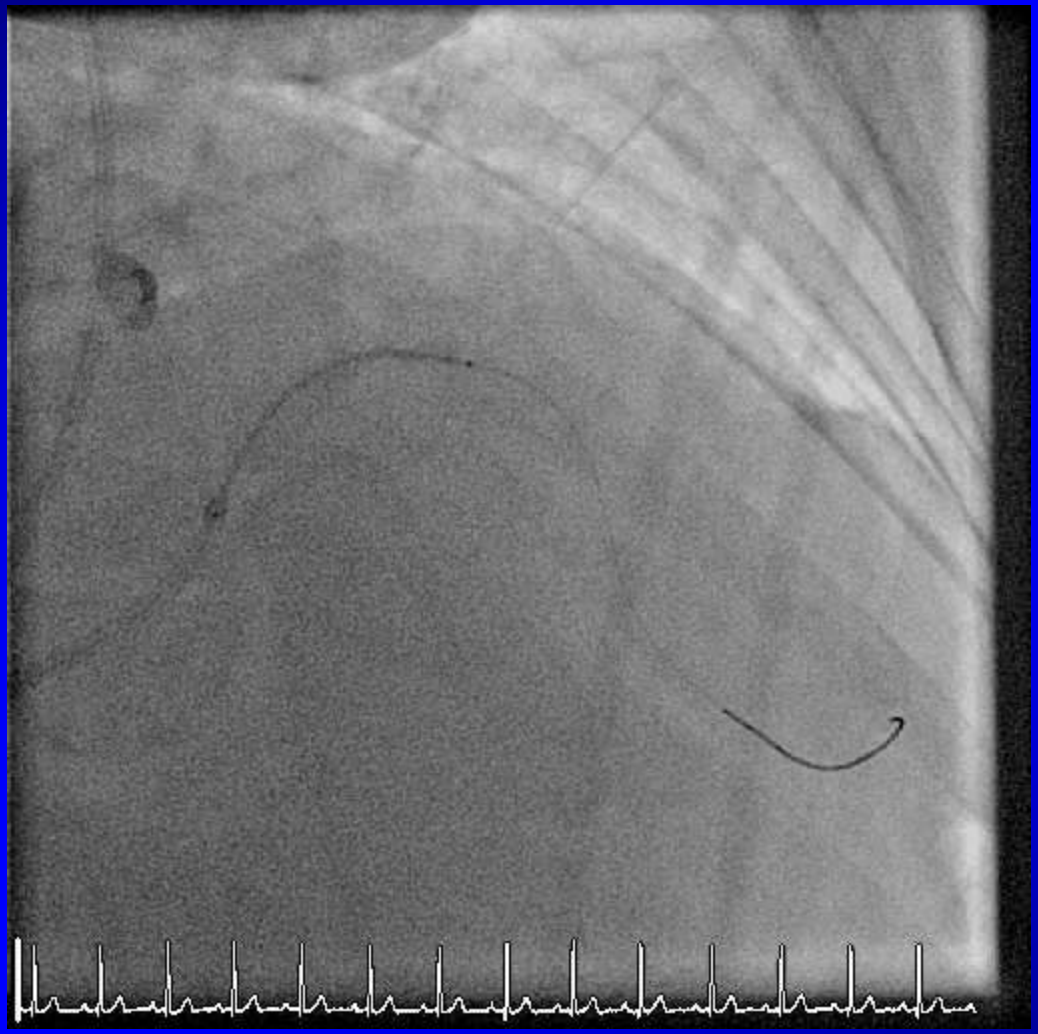


Case Example

- F/72 CVRF hypertension, hyperlipidemia
- Angina pectoris. MPI showed mid LAD ischemia



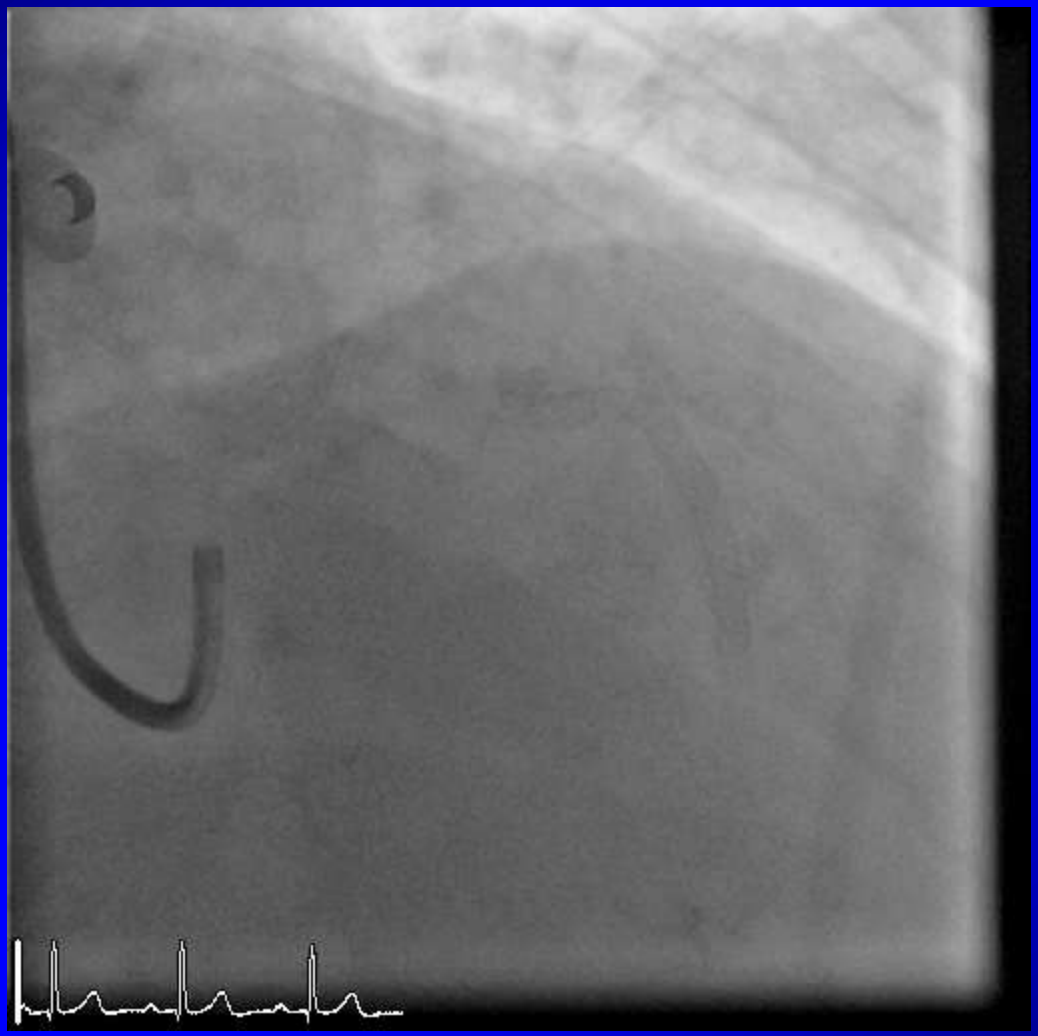
PROMUS PREMIER™ Case Study



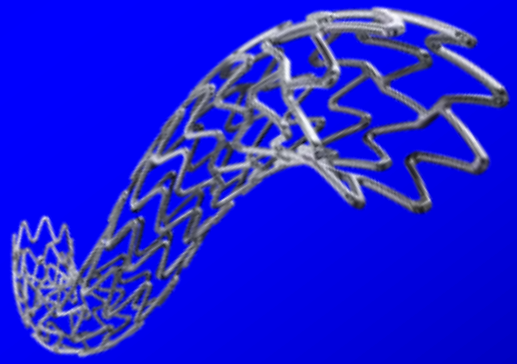
Premier 2.25x32mm Stent

PROMUS PREMIER™ Case Study

PROMUS PREMIER™ Case Study

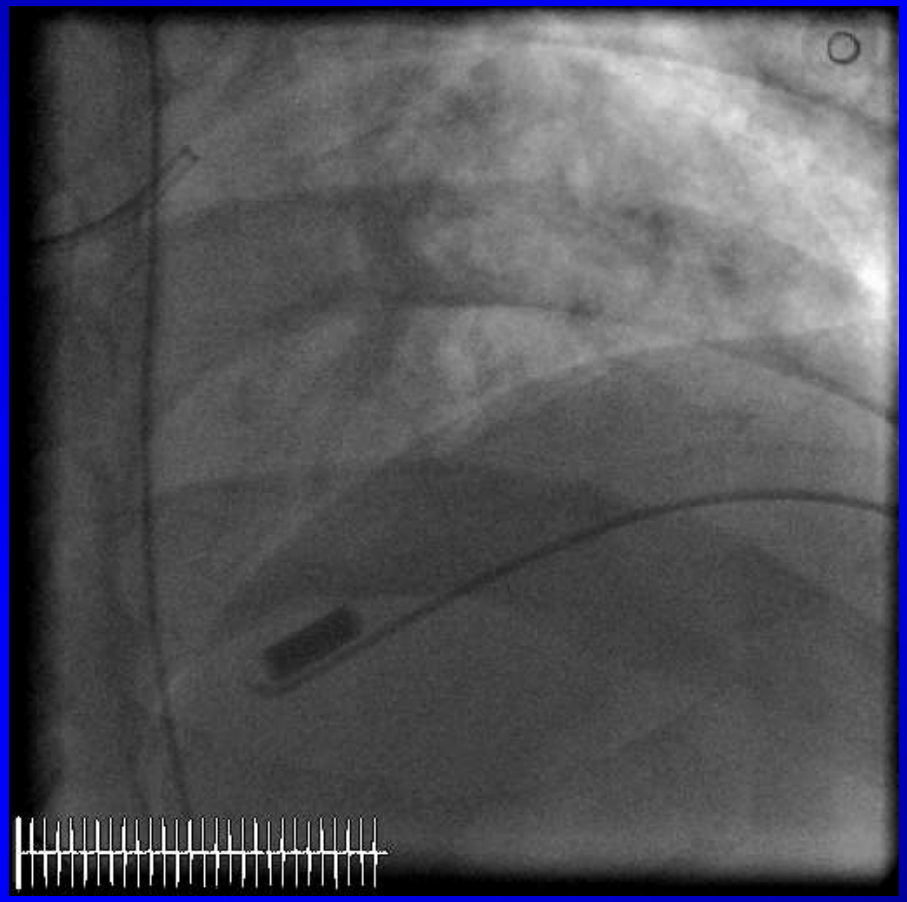


SYNERGY™ Stent: Introduced to Singapore on Christmas Day 2012

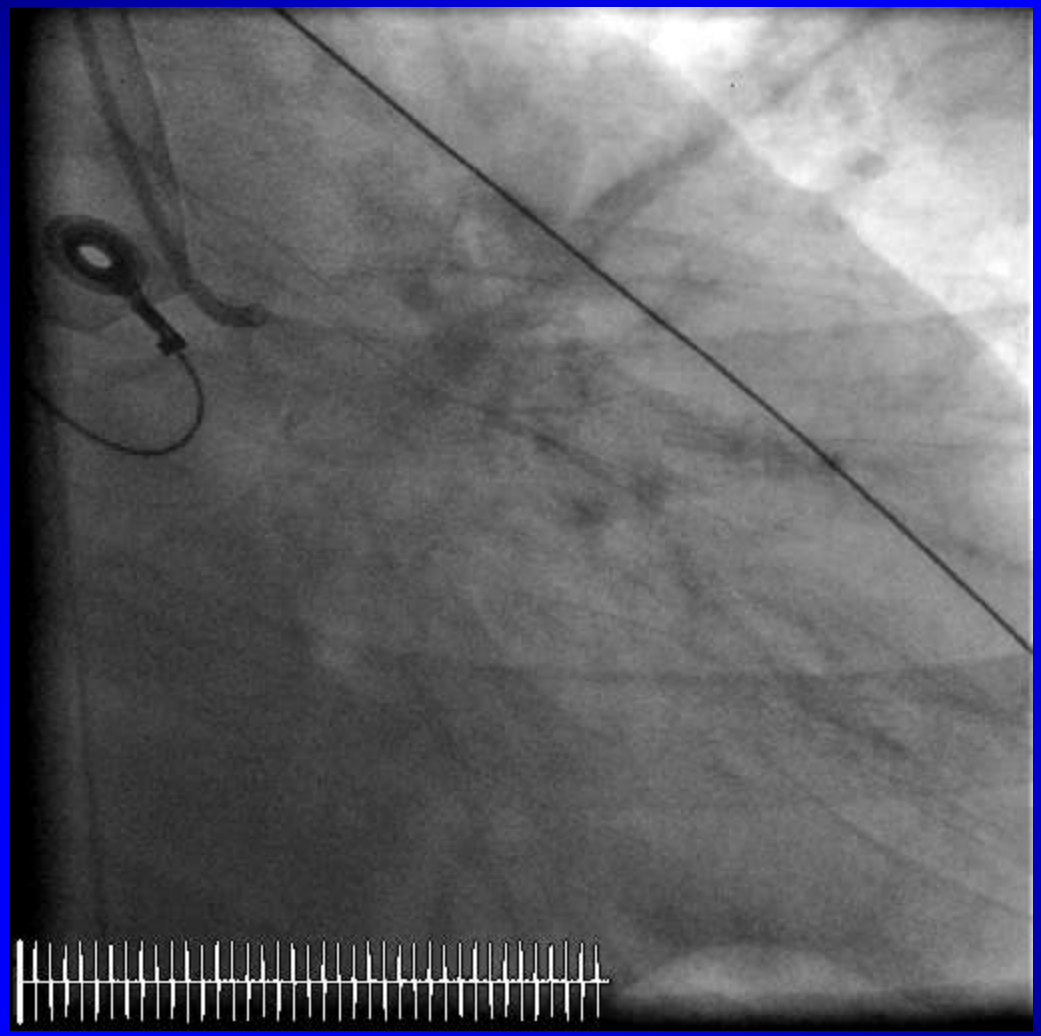


Case Example

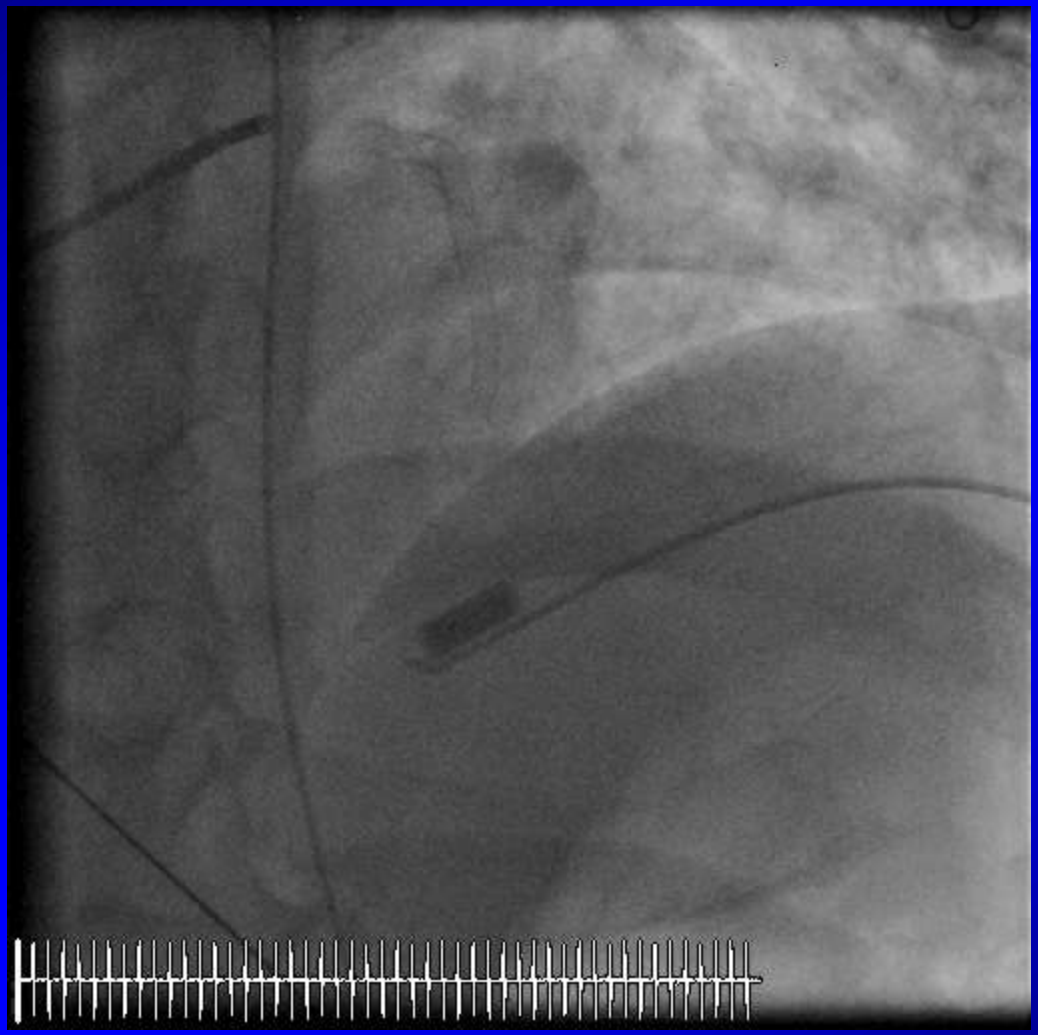
- 47-yr-old man. VF collapse from anterior MI while playing badminton.
- CPR and DC shock enroute to hospital in ambulance
- In cardiogenic shock



Two CoCR Stents Implanted in LAD Artery



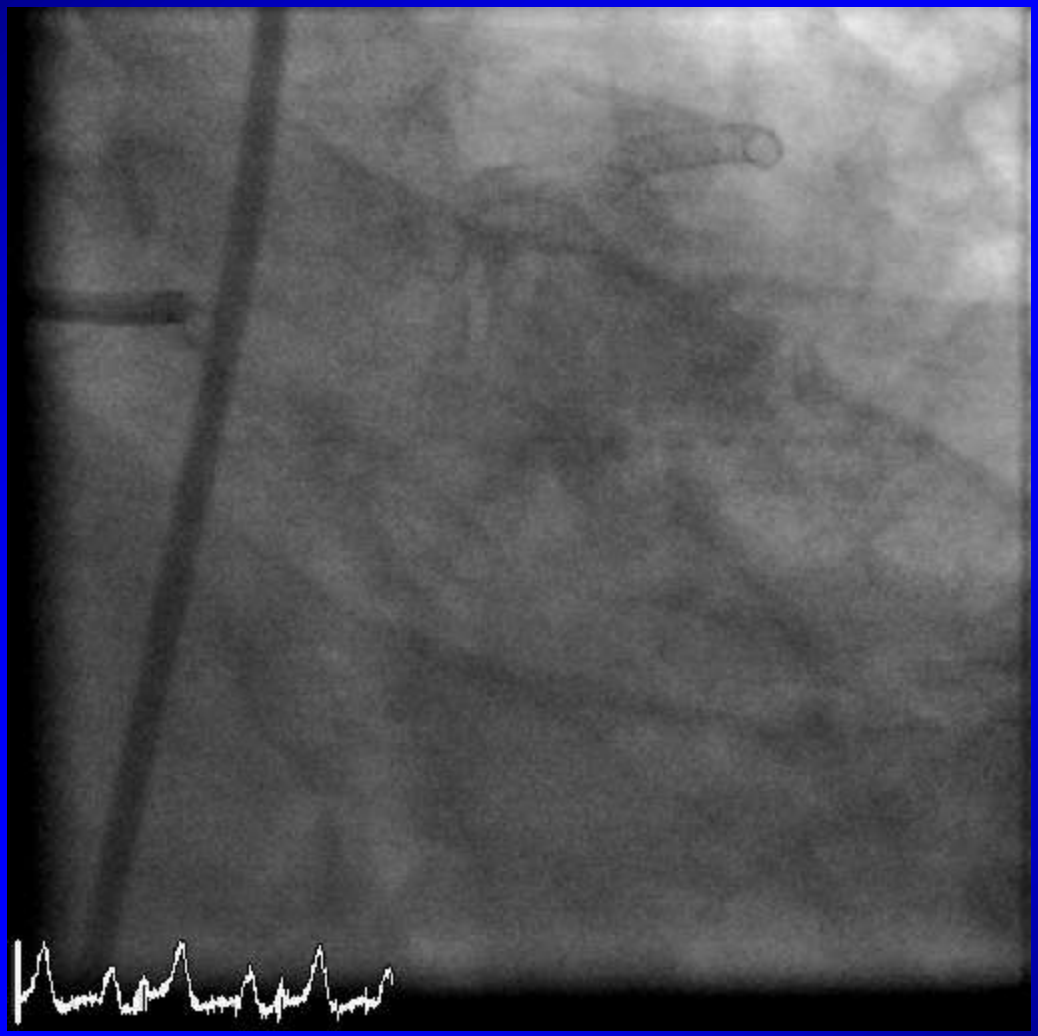
Final Angiography Results



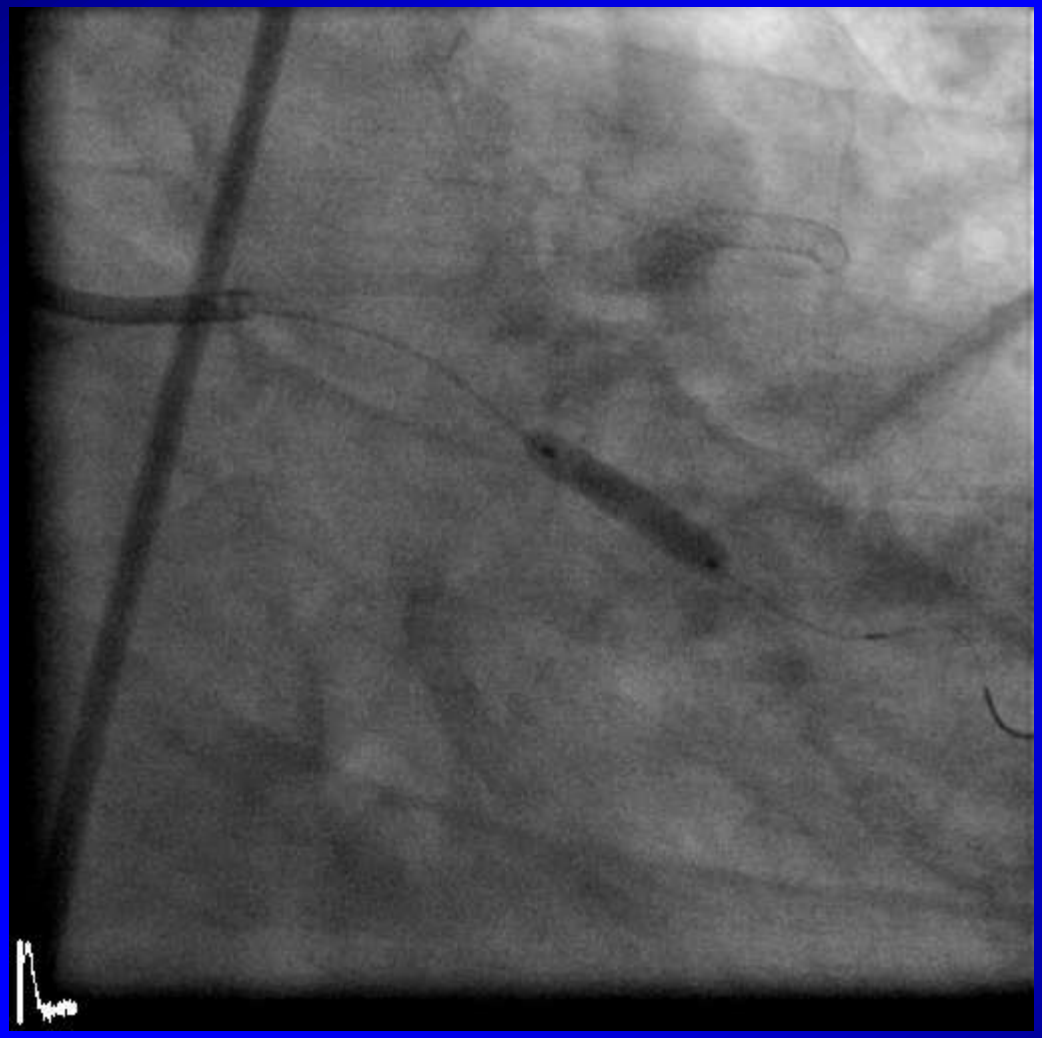
Clinical Course

- Intra-aortic balloon pump
- Hypothermia therapy
- Stayed in CCU for a week
- Discharged on Day 13. Full neurological recovery
- Two-dimensional echocardiogram showed mild left ventricular systolic dysfunction. LVEF 42%

Elective Staged PCI to LCx

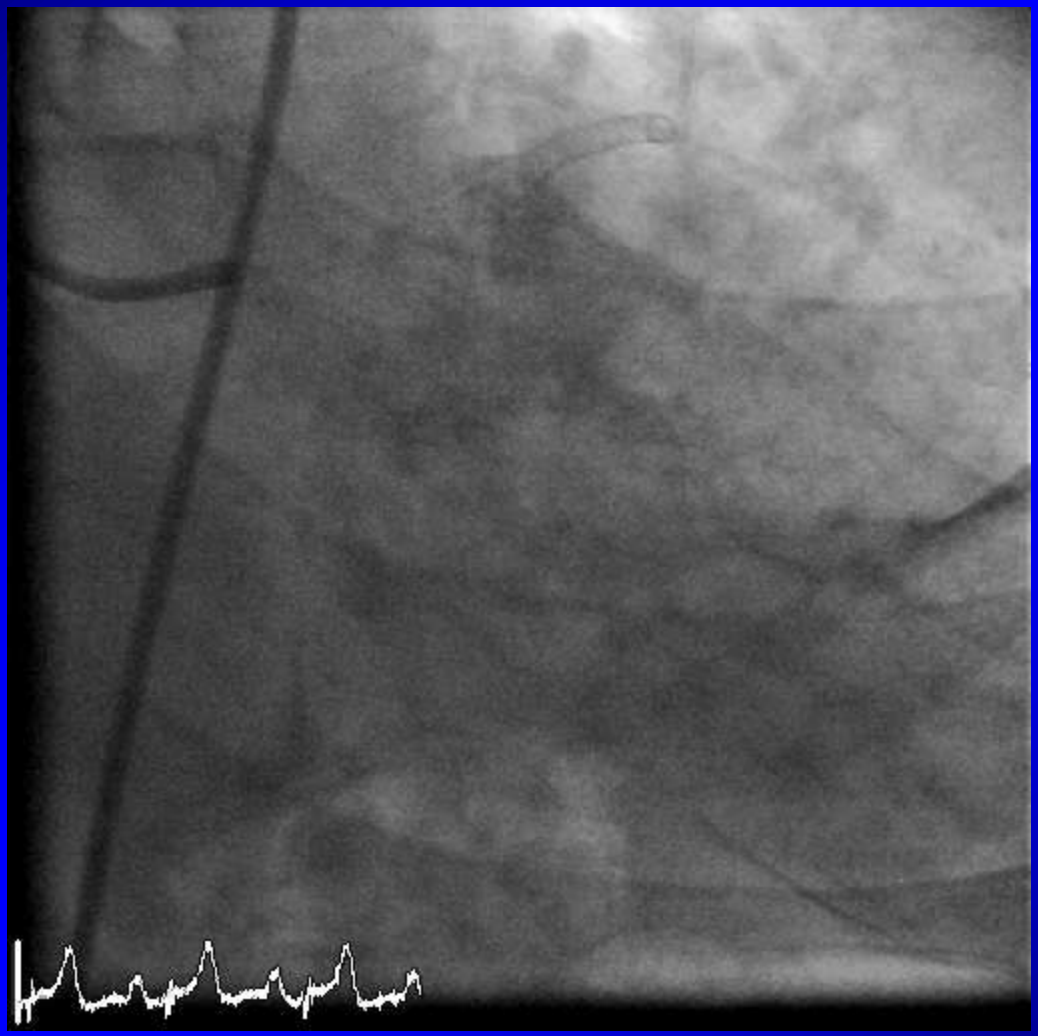


SYNERGY™ Case Study

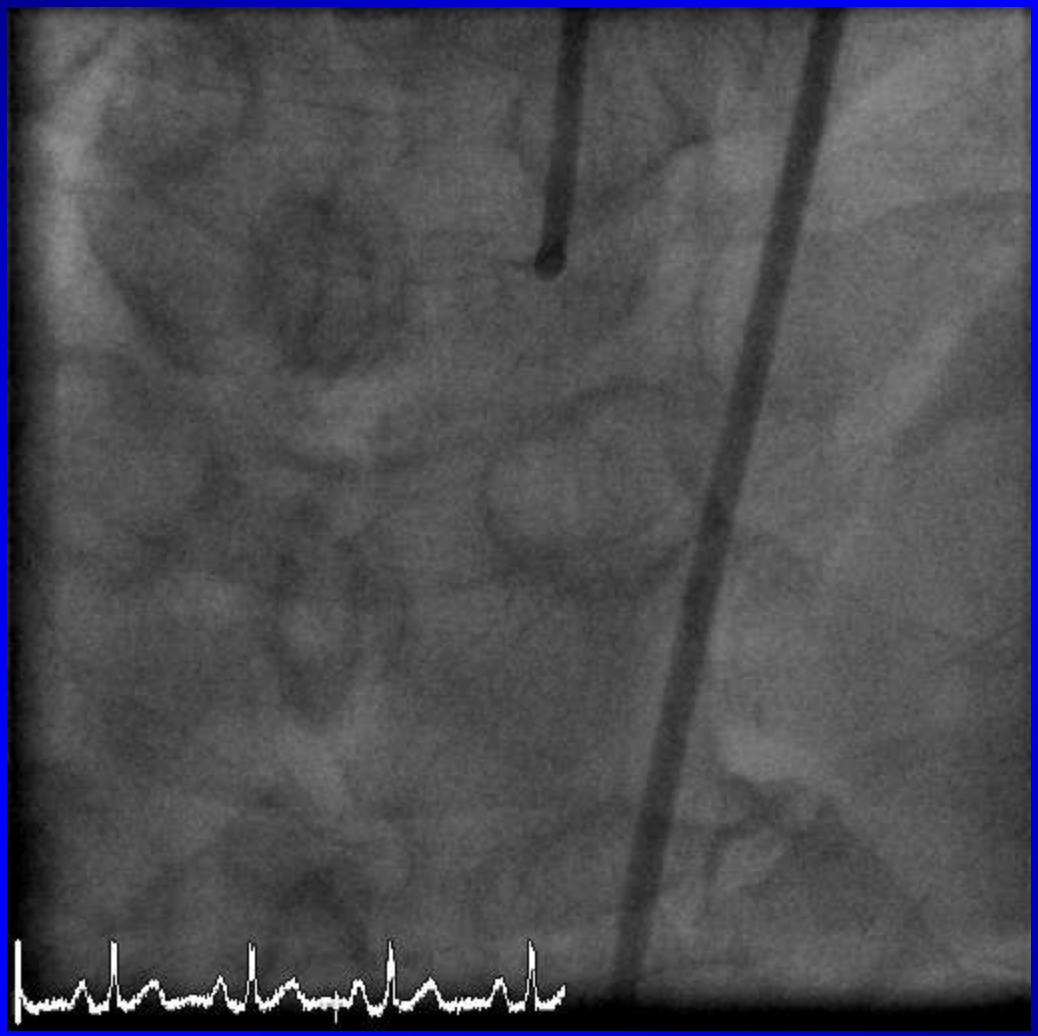


Synergy ™ 2.75x16mm Stent

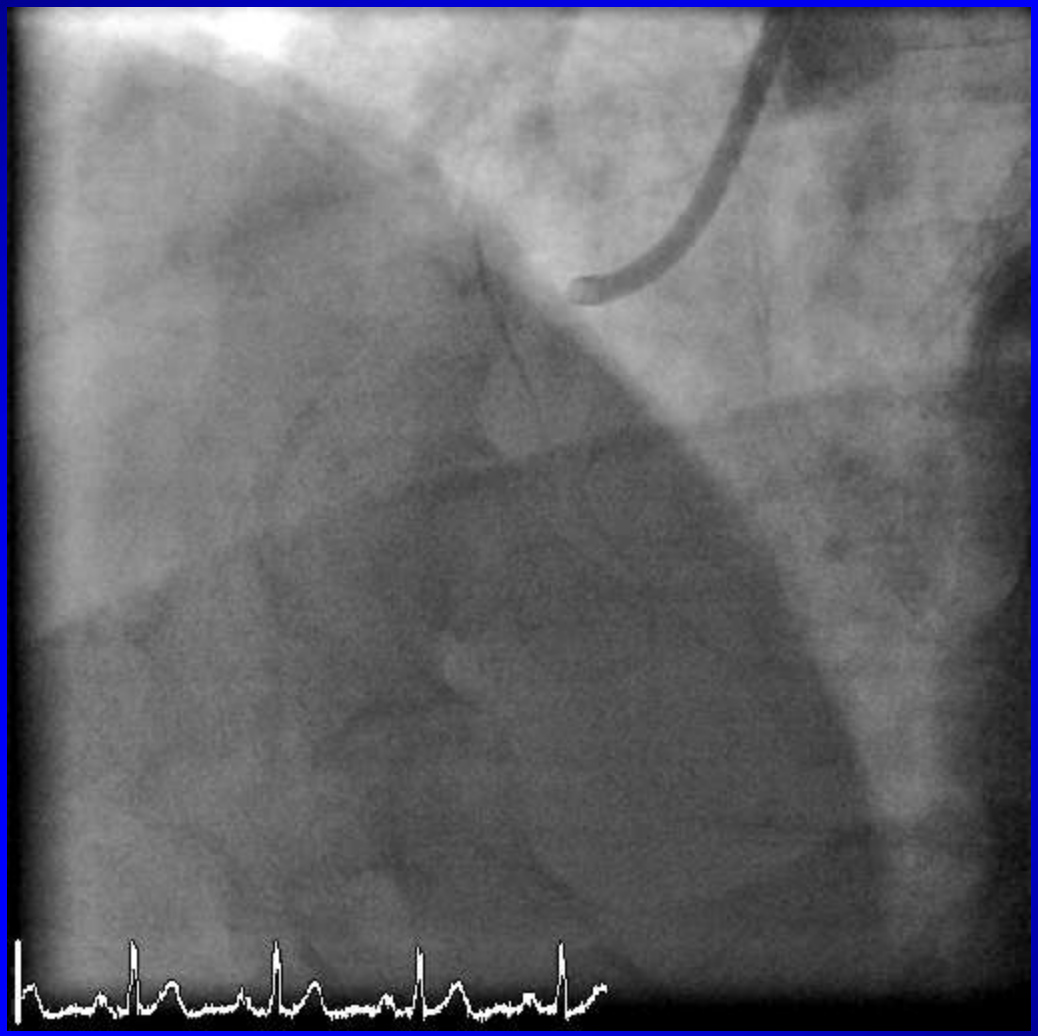
SYNERGY™ Case Study



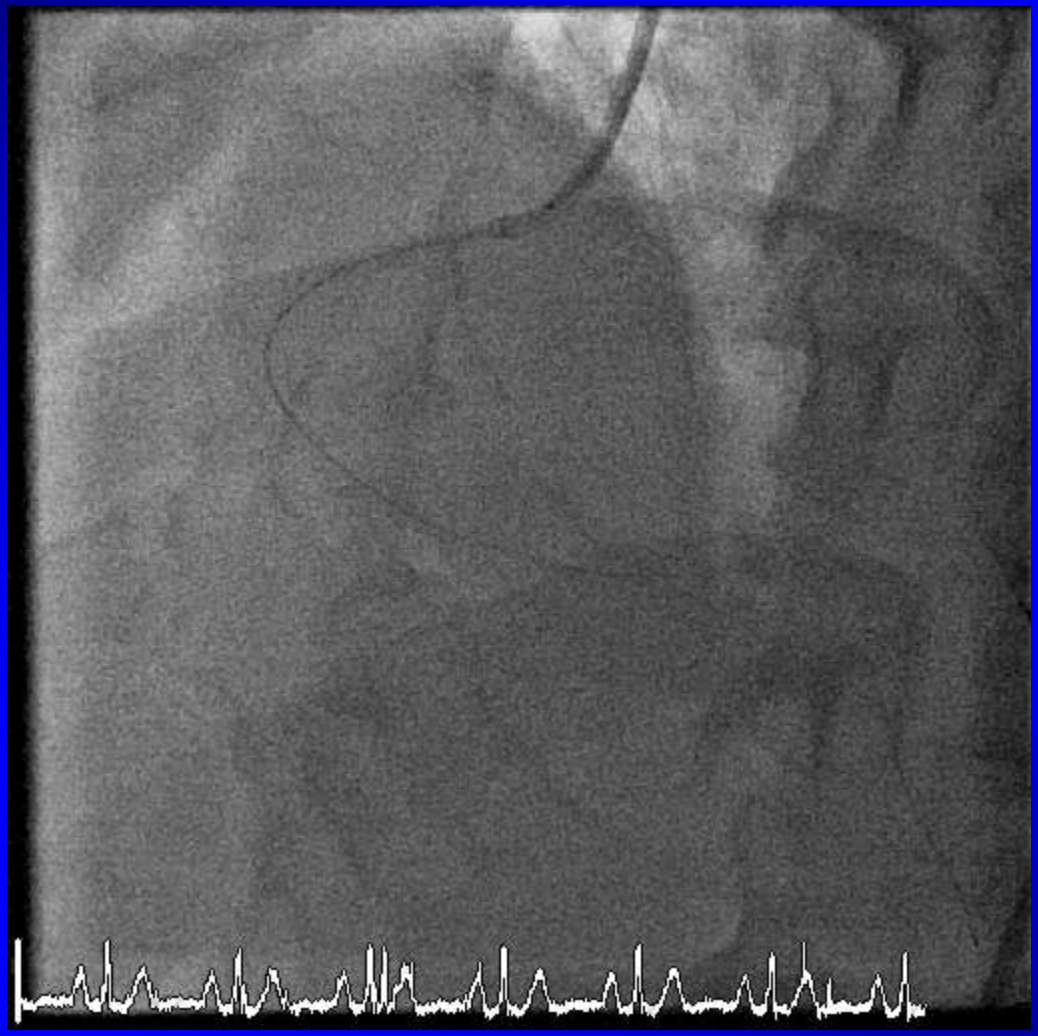
SYNERGY™ Case Study



SYNERGY™ Case Study

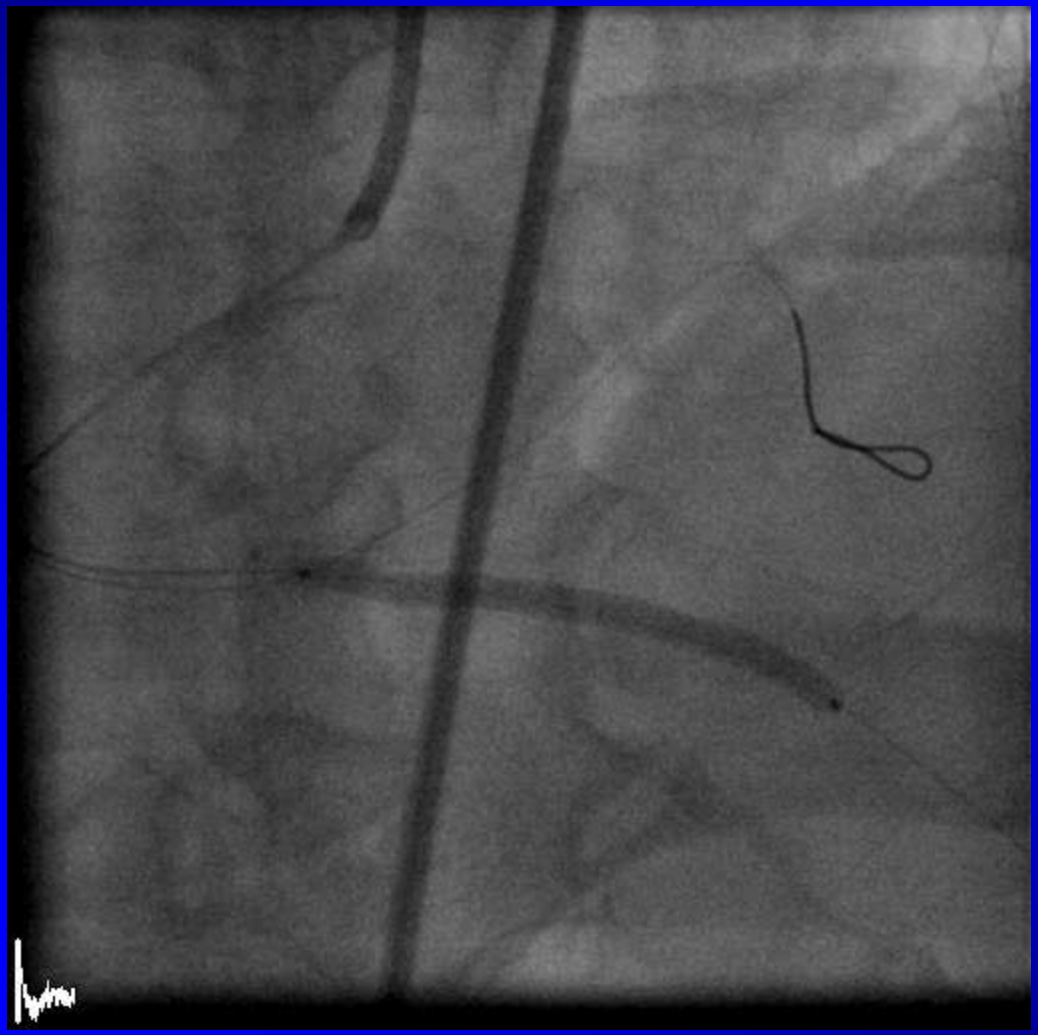


SYNERGY™ Case Study



SYNERGY™ 2.25x38mm stent

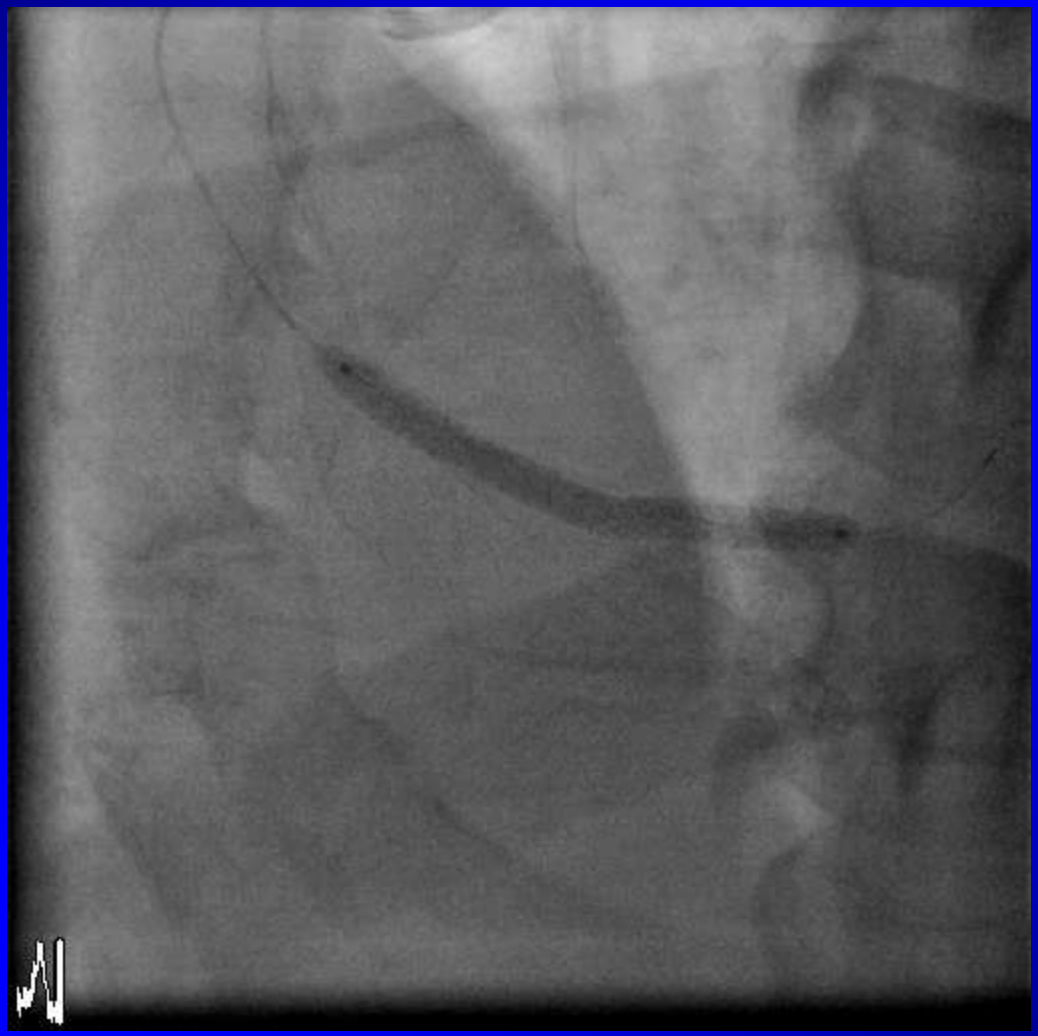
SYNERGY™ Case Study



SYNERGY™ Case Study

SYNERGY™ 3.0x38mm stent

SYNERGY™ Case Study



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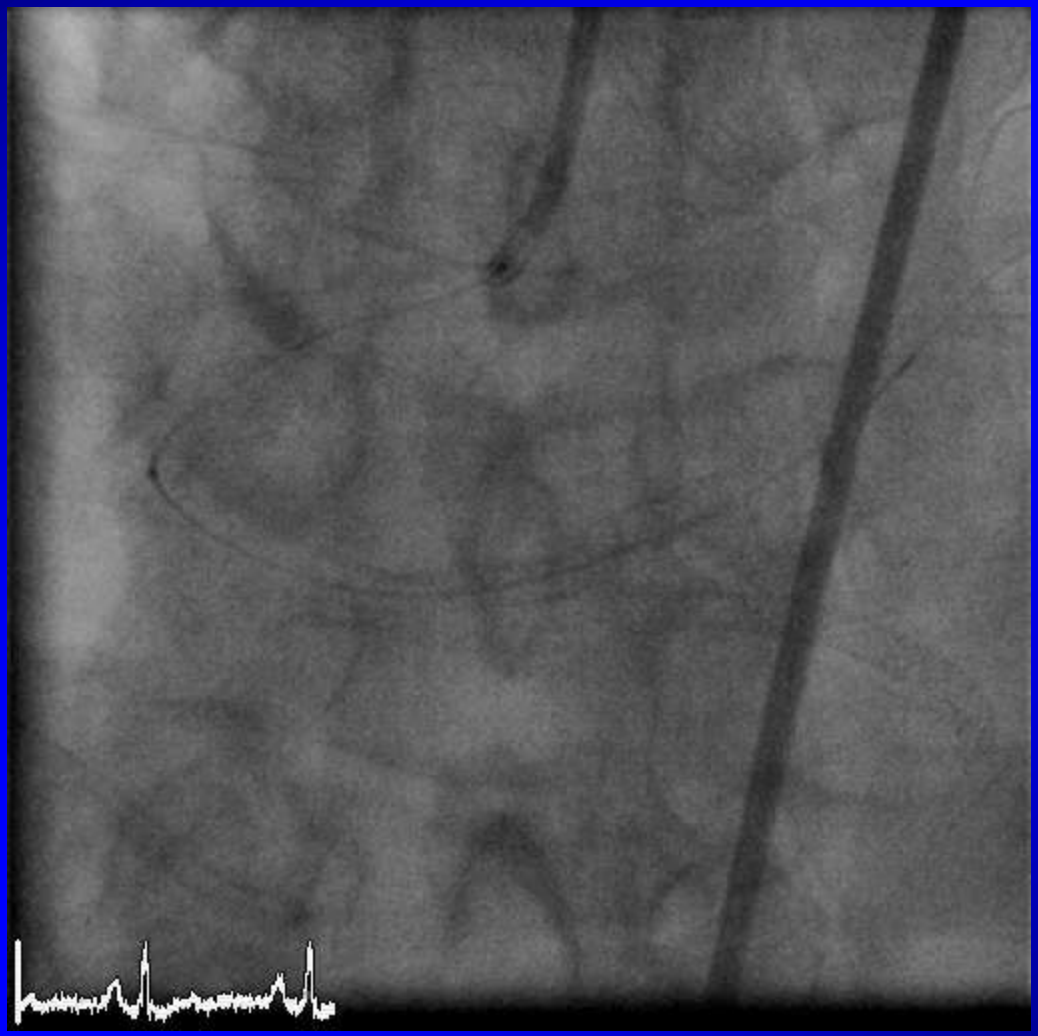
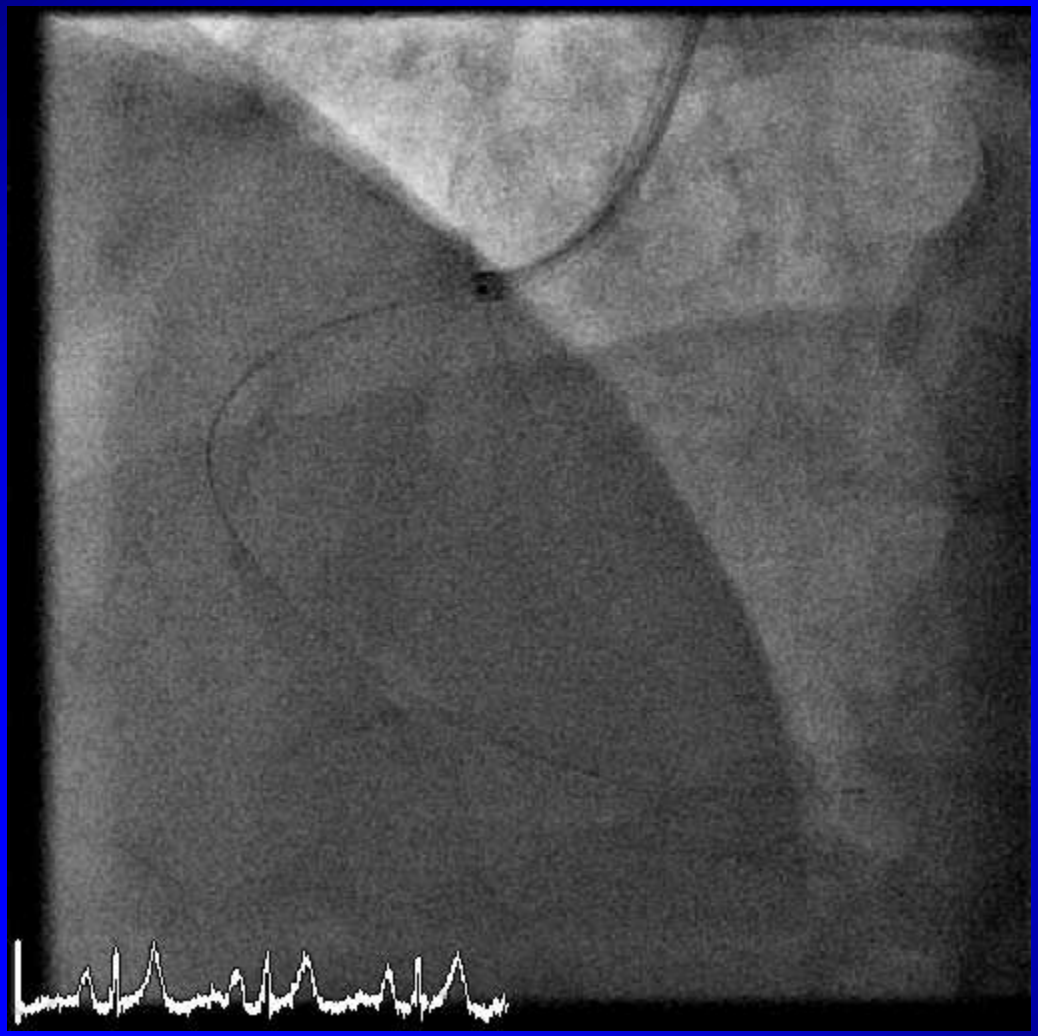
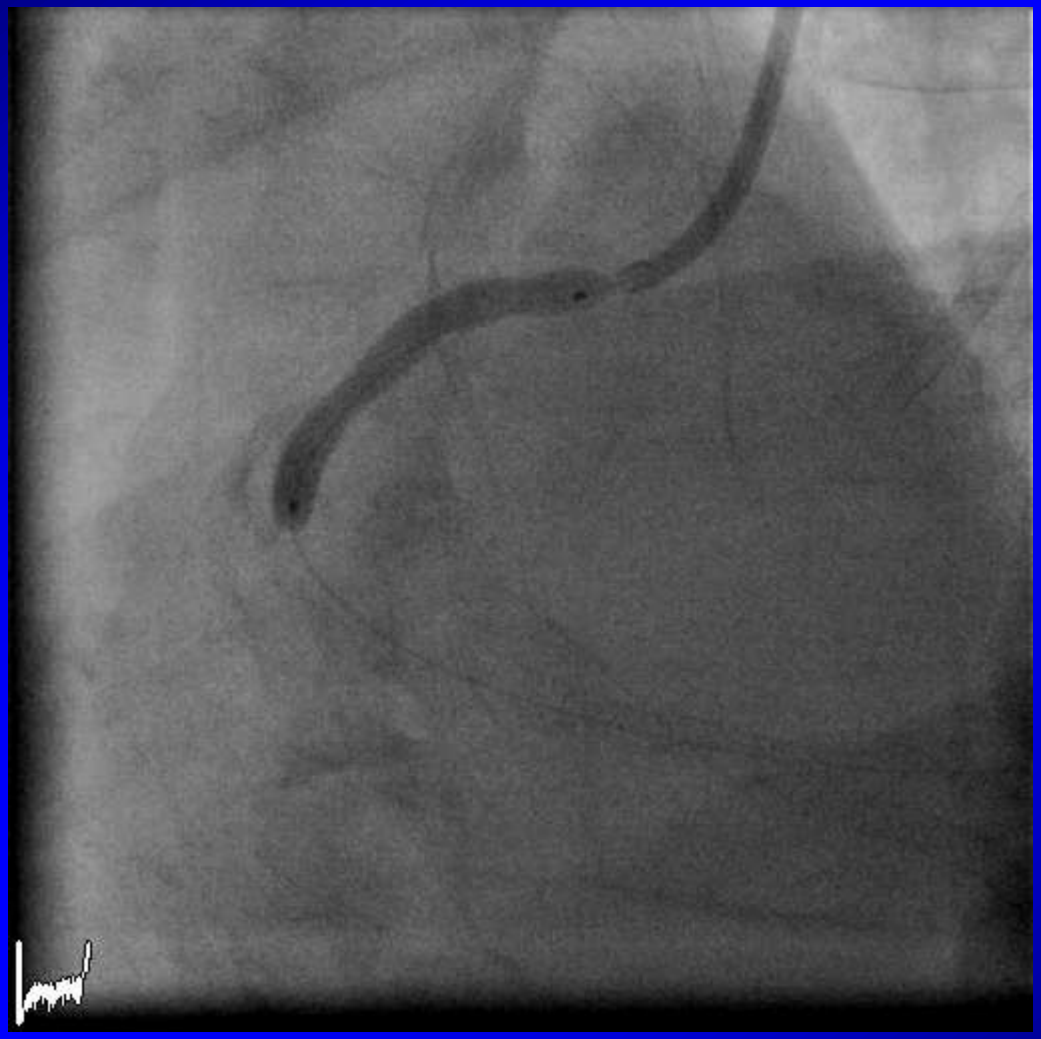


SYNERGY™ Case Study



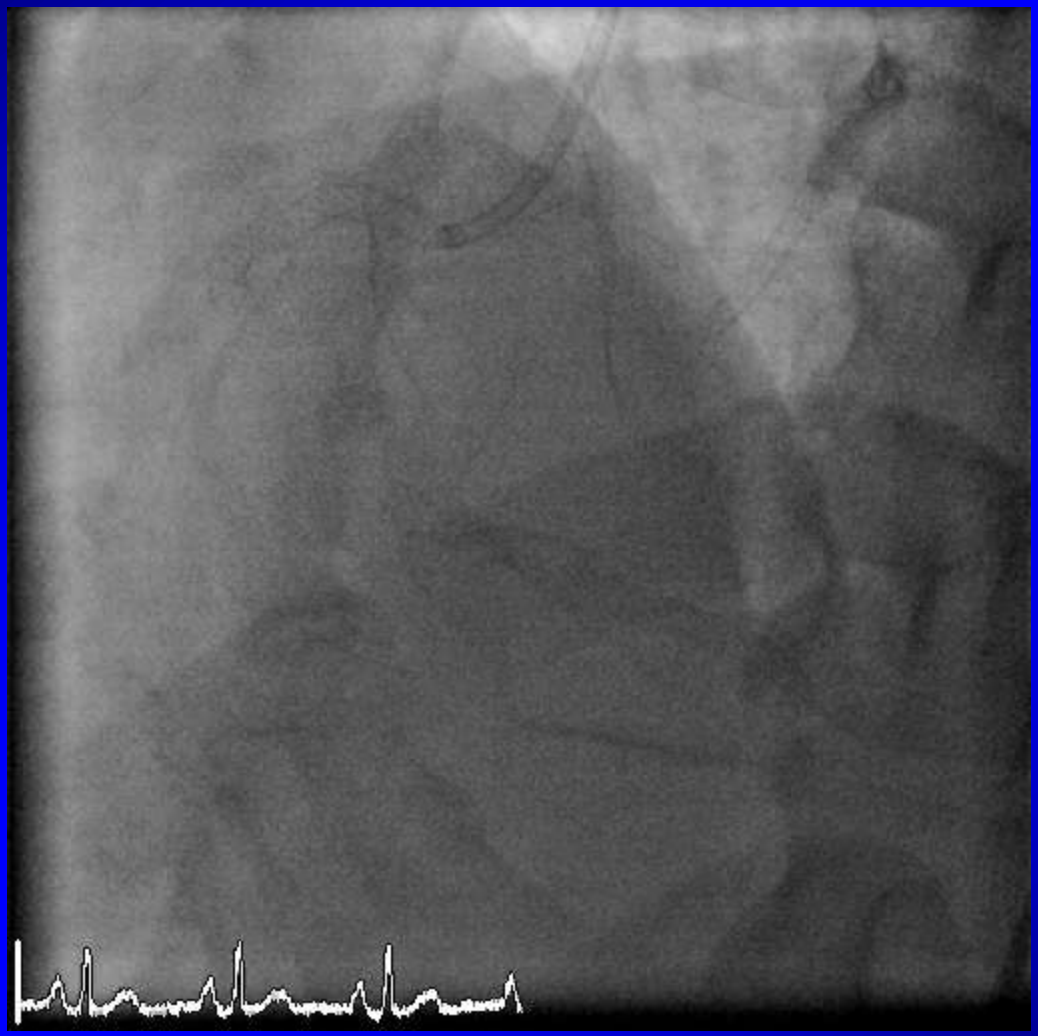
SYNERGY™ 3.5x38mm stent

SYNERGY™ Case Study

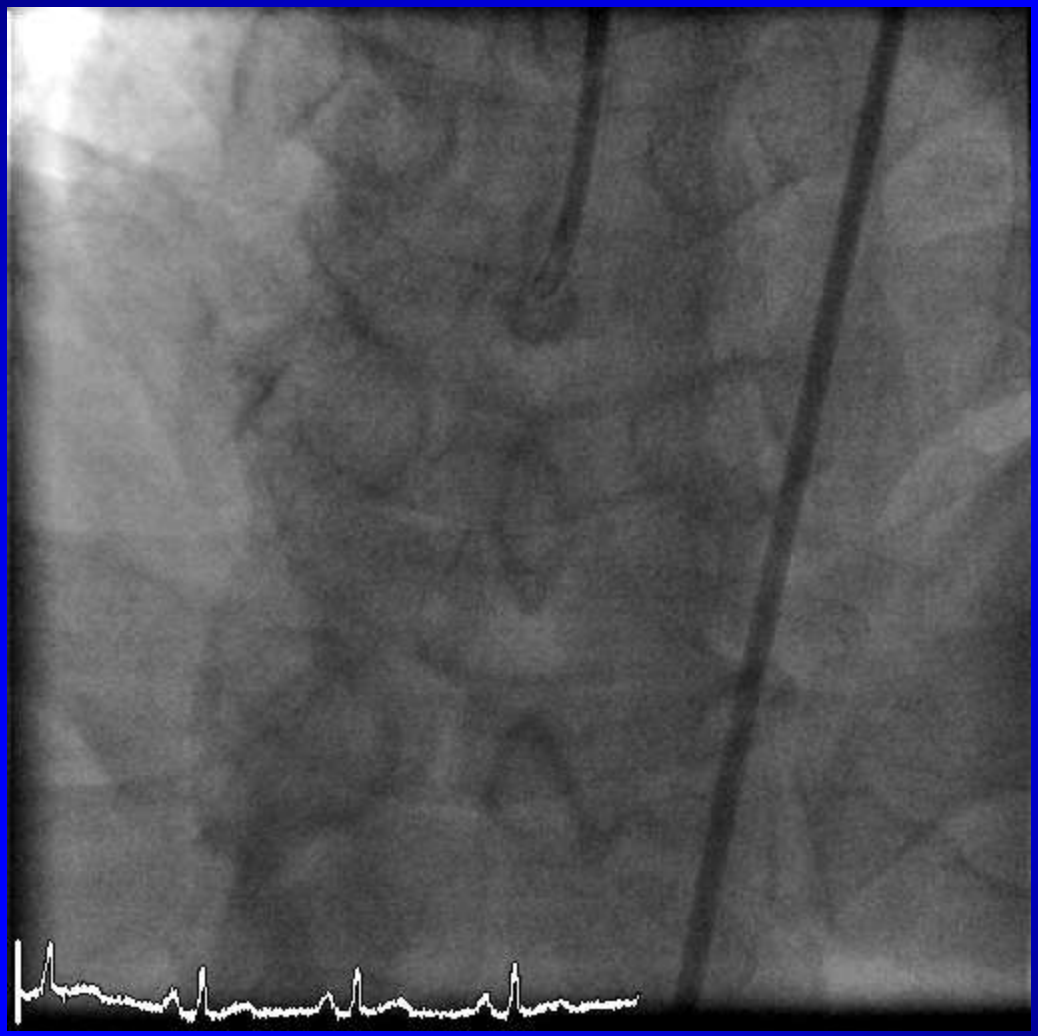


Post-dilation Sapphire NC 3.5x18mm balloon

SYNERGY™ Case Study



SYNERGY™ Case Study



Conclusions

- Modification of stent geometry and design answers clinical needs for improved longitudinal strength and reduced risk of stent deformation. Thinner stent struts and stent delivery system enhances deliverability and flexibility but with ? reduced radiopacity

- Bioabsorbable polymer design potentially enhances the safety of Synergy™ DES with no risk of chronic inflammation and late stent thrombosis. Allows for shortened duration of dual antiplatelet therapy but this needs to be validated in clinical studies

- Early experience with Synergy™ suggests comparable efficacy to other drug-eluting stents with no safety concerns related to the novel stent design and biodegradable polymer

Thank You