

Boston  
Scientific

**SYNERGY™**

Everolimus-Eluting Platinum Chromium Coronary Stent System

HEALTH  
WITH CONFIDENCE

*Because you never know when life will become complex*

Ch  
Pr

# SYNERGY™

Everolimus-Eluting Platinum Chromium Coronary Stent System

## Designed to HEAL

Attributes work together, synergistically, to promote optimal healing within the vessel<sup>1</sup>

ข้อที่ 4 ✓

Synchrony™ Bioabsorbable Polymer Coating is applied only to the abluminal side of the stent to stimulate healthy endothelialization

ข้อที่ 1 ✓

Thin, round stent struts

*Polymer is gone when it's no longer needed, shortly after the drug is completely eluted at 3 months<sup>2</sup>*

1. Eppinger M, PhD. Impact of Polymer Type and Location on Stent Thrombogenicity and Endothelial Cell Coverage. *EuroPCR 2013*.  
2. Chen YL, PhD., Foss A, PhD., Eppinger M, PhD, et al. Characterization of In Vivo PCL/DL-Lactide-co-glycolic acid Bioabsorption from a Drug-Eluting Stent. *EuroPCR 2012*.  
\* Among Boston Scientific Corporation stents. Data on file at Boston Scientific Corporation.  
† Data on file at Boston Scientific Corporation.

**Unmatched acute performance  
which may reduce procedure times†**

Short red tip improves tip flexibility and visibility

ข้อที่ 2 ✓

Lowest stent profile\*

Bi-Segment™ Inner Lumen  
Catheter to provide  
outstanding flexibility  
and pushability†

ข้อที่ 3 ✓

Dual-layer PEBA™ Balloon  
for optimal compliance and  
minimal balloon growth

Monorail™ Port

*Laser-cut hypotube for improved pushability  
and trackability†*

Dr. Pr.

# SYNERGY™

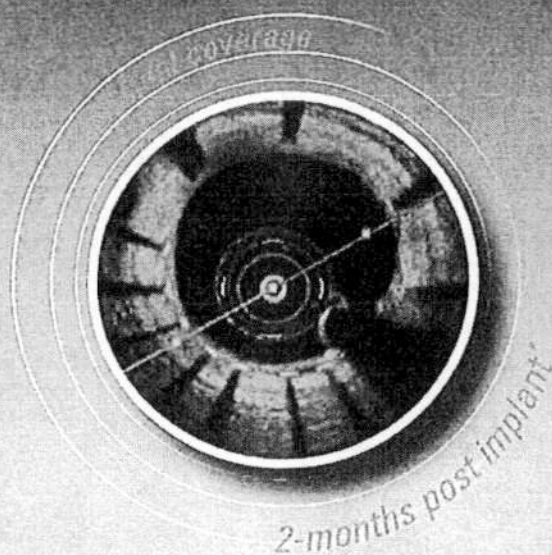
Everolimus-Eluting Platinum Chromium Coronary Stent System

## Early Healing

### In a complex patient

#### 3-month DAPT labeling:

- In selected patients, it may be reasonable to interrupt or discontinue P2Y<sub>12</sub> inhibitor therapy after 3 months<sup>†</sup>
- This reduction in DAPT could minimize medication costs, complications, and improve patient satisfaction

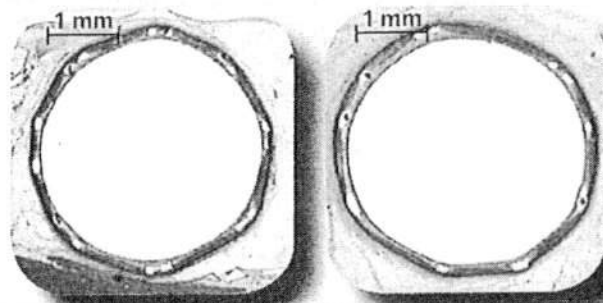


### In prevention of late stent failure

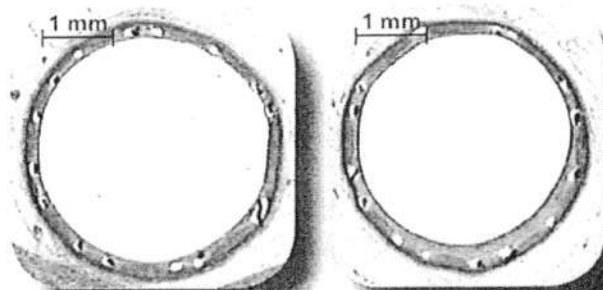
#### Complete endothelialization by 30 days<sup>3</sup>

Similar vascular response to SYNERGY Stent and OMEGA™ Bare Metal Stent (BMS) at 3 months<sup>†</sup>

SYNERGY Stent



OMEGA BMS



30 Days

90 Days

*Pro On*

<sup>3</sup> Wilson G, MD. ACC 2011.

<sup>†</sup> Image provided by Jose M. De la Torre Hernandez, MD, PhD. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

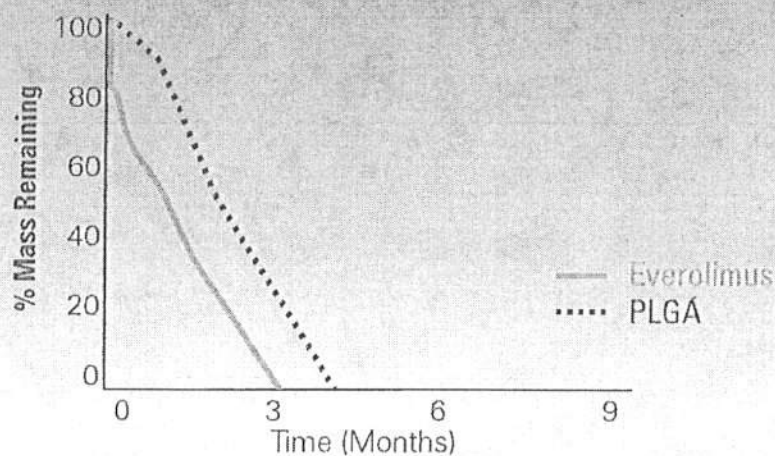
<sup>1</sup> See Directions for Use.

<sup>†</sup> Data on file at Boston Scientific Corporation.

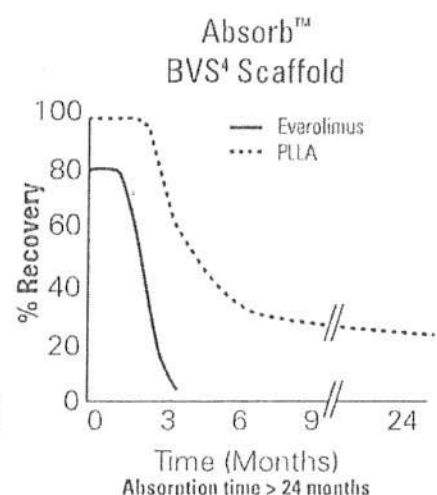
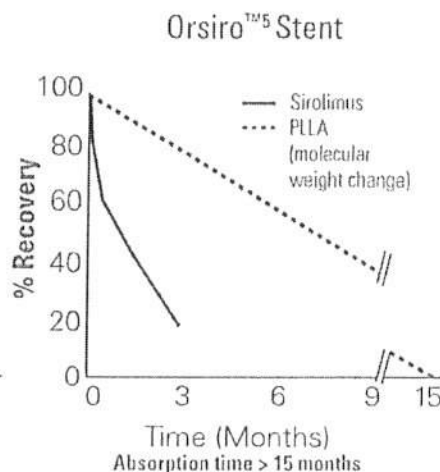
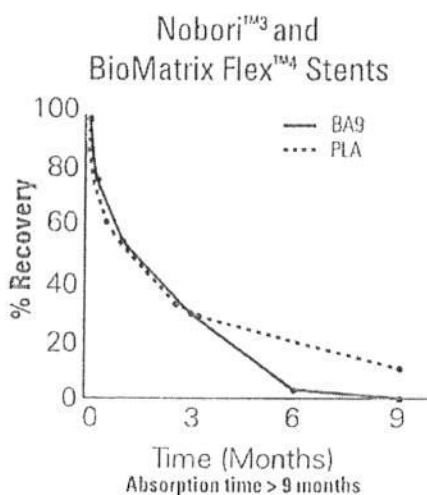
# Freedom from Long-Term Polymer Exposure

SYNERGY™ Stent offers peace of mind knowing that the polymer is gone shortly after the drug is completely eluted at 3 months<sup>1</sup>

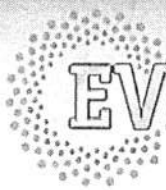
## Synchronous Drug Elution and Polymer Absorption\*



## Polymer Absorption Rates in Perspective



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# EVOLVE II Clinical Trial

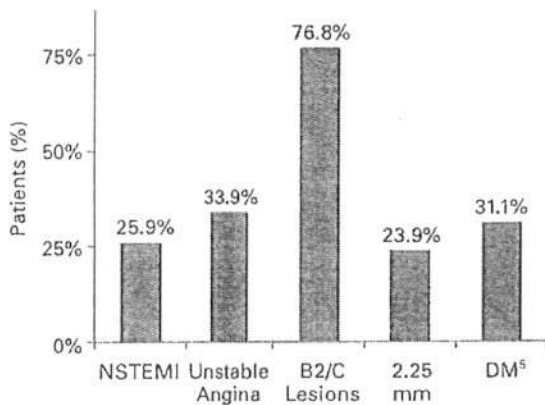
## SYNERGY™ STENT

**Broadest and most complex patient population ever studied in a U.S. Pivotal Trial**

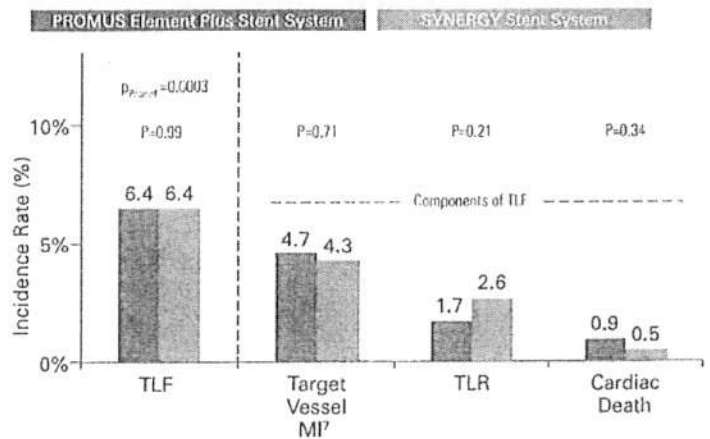
### EVOLVE II Clinical Trial<sup>4</sup> Study Overview:

Patients (1,684) were randomized 1:1 to SYNERGY or PROMUS Element™ Plus Stent Systems with ≤3 native coronary artery lesions in ≤2 major epicardial vessels; lesion length ≤34 mm, RVD ≥2.25 to ≤4.0 mm, %DS ≥ 50 to <100 (excluded LM disease, SVG, CTO, or recent STEMI)

### EVOLVE II Clinical Trial A More Complex Study<sup>4</sup>

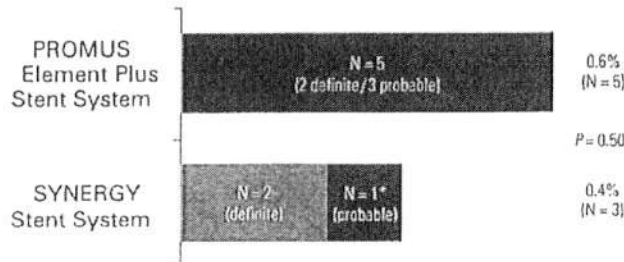


### Primary Endpoint of Target Lesion Failure<sup>6</sup> (TLF) Met



**ZERO definite ST events in SYNERGY arm after 24 hours<sup>4</sup>**

### Stent Thrombosis (ST) (Definite/Probable) Through 12-Months<sup>4</sup>



\*Occurred on day 6. ST rates were equivalent when analyzed in an intent-to-treat or per protocol manner.

Acute (≤1 day)      Sub-Acute (2–30 days)      Late (30 days–1 year)

4. EVOLVE II Clinical Trial presented by Dean Keech, MD at AHA 2014. 1,684 patients were randomized 1:1 to SYNERGY or PROMUS Element™ Plus Stent Systems. Graph shows TLF Per Protocol (PP) and MI, TLR, CD shown for the Intent-to-Treat (ITT) population. ITT TLF for SYNERGY Stent = 6.7% and for PROMUS Element Stent = 6.4%, respectively (p=0.0005 for non-inferiority). The SYNERGY Stent is an investigational device and not for sale in the U.S. or Japan.

5. Medically-Treated Diabetes Mellitus

6. TLF: ischemia-driven TLR, MI related to the target vessel, or any cardiac death. To conclude non-inferiority, the primary endpoint was required to have been met in both intent-to-treat and per protocol patient populations.

7. Per protocol spontaneous MI is defined as rise and/or fall of cardiac biomarkers with one value >99th percentile of the URL = with evidence of myocardial ischemia. Peri-PCI MI is defined as one of the following: i) biomarker elevations within 48 hours of PCI (based on CK-MB >3X URL), ii) new pathological Q waves, or iii) autopsy evidence of acute MI.

8. Meredith T. AM, MEdS, PhD. PCR 2014. Only the "full dose" SYNERGY Stent results are shown.

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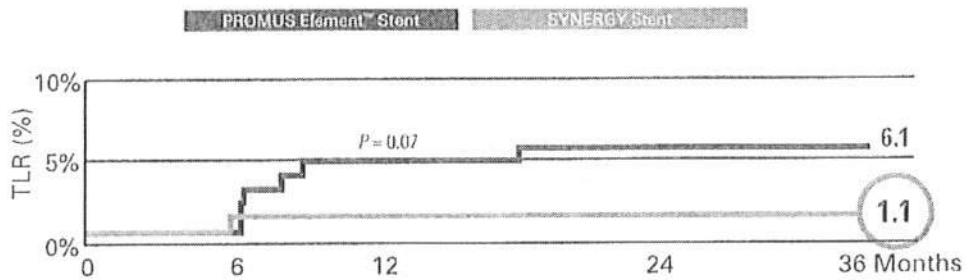
# EVOLVE Clinical Trial

## SYNERGY™ STENT

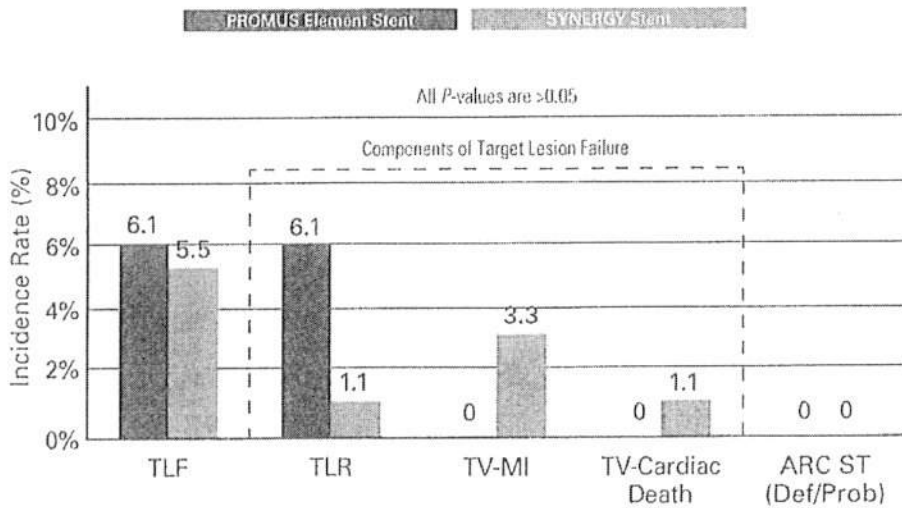
### Outstanding Safety and Efficacy at 3-Years

Early and long-term data demonstrates exceptional results.<sup>8</sup>

#### 0% TLR from 6 Months to 3-Years<sup>8</sup>



#### 1.1% TLR and 0% ARC ST at 3-Years<sup>8</sup>

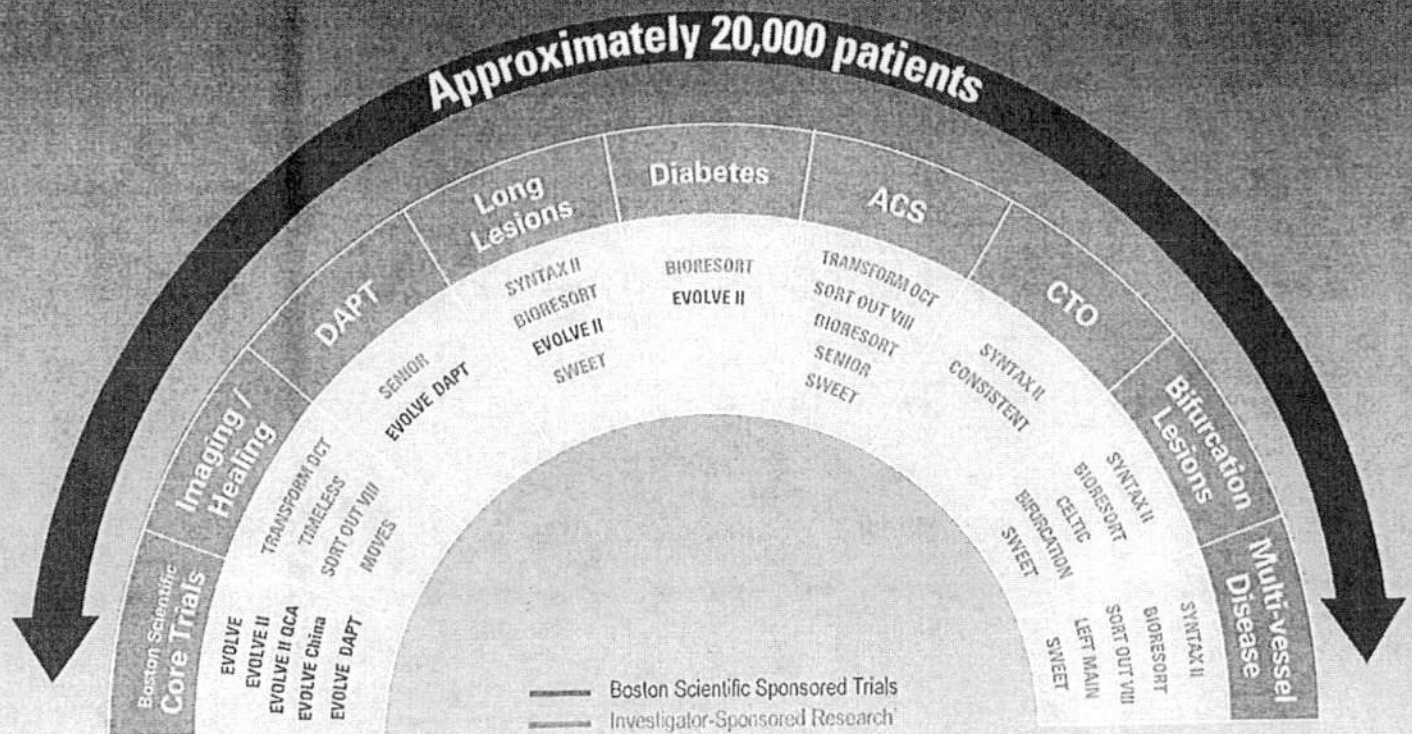


One NQMI in the SYNERGY group was periprocedural. The remaining 2 NQMI in the SYNERGY arm were considered unrelated to the study device: one at day 317 due to anemia and a major GI bleed, and one at day 364 subsequent to respiratory failure in a patient with severe COPD—enzymes were checked indicating that a NQMI had occurred. The one death was of an unknown cause at day 472 and adjudicated as a Cardiac Death, Safety Population.

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# SYNERGY™ Stent Clinical Program and Research\*

Addressing full spectrum of cardiovascular disease complexity



## SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System

MONORAIL™ CATHETER — PRODUCT ORDERING INFORMATION

ø (mm)	STENT LENGTH (mm)								Overexpansion Capabilities
	8	12	16	20	24	28	32	38	
2.25	H7493926208220	H7493926212220	H7493926216220	H7493926220220	H7493926224220	H7493926228220	H749392632220	H749392638220	3.50
2.50	H7493926208250	H7493926212250	H7493926216250	H7493926220250	H7493926224250	H7493926228250	H749392632250	H749392638250	3.50
2.75	H7493926208270	H7493926212270	H7493926216270	H7493926220270	H7493926224270	H7493926228270	H749392632270	H749392638270	3.50
3.00	H7493926208300	H7493926212300	H7493926216300	H7493926220300	H7493926224300	H7493926228300	H749392632300	H749392638300	4.25
3.50	H7493926208350	H7493926212350	H7493926216350	H7493926220350	H7493926224350	H7493926228350	H749392632350	H749392638350	4.25
4.00	H7493926208400	H7493926212400	H7493926216400	H7493926220400	H7493926224400	H7493926228400	H749392632400	H749392638400	5.75

\* Boston Scientific is not responsible for the collection, analysis or reporting of the investigator-sponsored research output which is the sole responsibility of the investigators. Boston Scientific's involvement in investigator-sponsored research is limited to providing financial support for research that advances medical and scientific knowledge about our products.

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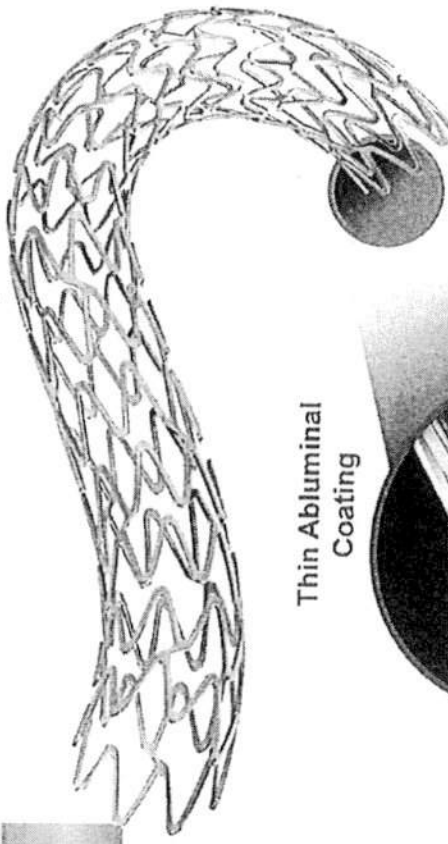


# SYNERGY™ Everolimus-Eluting Stent

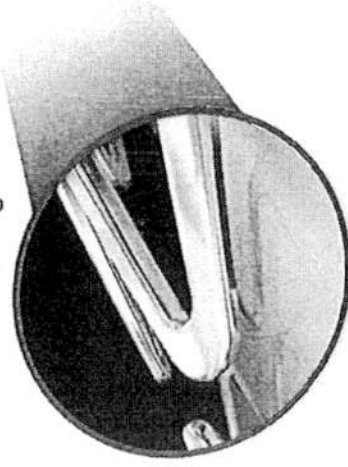
## Product Summary

**Boston Scientific**

Advancing science for life™



Thin Abluminal Coating



### Synchrony™ Bioabsorbable Coating

- Polymer is gone when no longer needed, shortly after completion of drug elution at 3 months (ข้อที่ 4) ✓
- Applied to the abluminal side of the stent, designed for optimal healing
- Providing *Suppression* of neointimal growth at the arterial wall & *Promotion* of healing inside the lumen



**SYNERGY Stent**  
Abluminal PLGA Bioabsorbable Polymer

**Promus PREMIER™ Stent**  
Conformal PVDF Permanent Polymer

\*Stent thickness for small vessel model is 0.0029" (74μm). Workhorse model is 0.0031" (79μm) and large vessel is 0.0032" (81μm). Boston Scientific data on file. © 2018 Boston Scientific. Confidential to the Affiliates. All rights reserved. All trademarks are the property of their respective owners.

Pr. Q

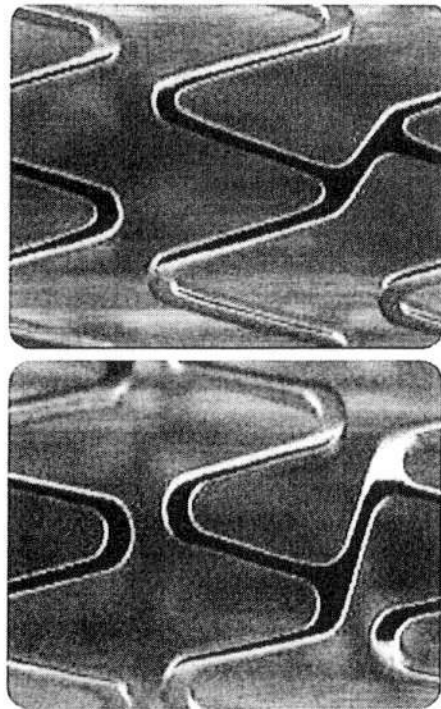
# SYNERGY™ Stent System Enhanced Platform

## Strength and Flexibility Where It Matters

**Boston Scientific**

Advancing science for life™

### Connector Angle Comparison



Promus PREMIER™ Stent

SYNERGY Stent

Strut thickness, peak radius and connector angles designed to improve *crimping profile and deliverability* over

**Promus PREMIER Stent**

### Customized Stent Architecture

Additional connectors on proximal two segments

Robust proximal end for *increased axial strength*<sup>1</sup>



2 connectors throughout body

Overall design maintains *flexibility and conformability*<sup>2</sup> (ข้อที่ 1)

<sup>1</sup> The Small Vessel and Workhorse sizes have 4 connectors on the two most proximal segments. The Large Vessel sizes have 5 connectors on the two most proximal segments.  
<sup>2</sup> Bench testing, 3.0 mm stents performed by Boston Scientific Corporation. Bench test results may not necessarily be indicative of clinical performance. Boston Scientific Data on File.

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## **SYNERGY™ II**

**MONORAIL™**

Everolimus-Eluting Platinum Chromium  
Coronary Stent System

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