

The SYNERGY™ Coronary Stent System: An innovative stent designed for improved healing and better clinical outcomes of patients with complex coronary artery disease

SYNERGY[™] is a next generation everolimus-eluting stent system with a unique bioabsorbable polymer coating. It is the only drug-eluting stent (DES) with a polymer to absorb shortly after drug elution ends at three months. SYNERGY's unique stent architecture and polymer/drug coating are designed for optimal healing in patients with complex coronary artery disease.

SYNERGY provides freedom from long-term polymer exposure

- In a DES, the polymer's sole role is to provide a mechanically stable matrix for the drug and modulate drug release into the vessel wall. Remaining polymer after drug release ends is a redundant design component.
- Newer generation durable polymers, i.e. those that are coating the stent permanently, are still a source of inflammation, neoatherosclerosis and thrombosis risk.¹ In addition, all polymer coatings have the potential to be damaged and permanent polymers remain forever.
- SYNERGY's bioabsorbable coating offers highly synchronous absorption of the drug and polymer: The polymer is designed to be gone when it is no longer needed after drug elution ends at three months, leaving a passive platinum Chromium bare metal stent surface to optimise healing.
- The SYNERGY[™] stent is the latest innovation in Boston Scientific's stent portfolio. With the only polymer to absorb shortly after drug elution ends at three months, SYNERGY[™] represents a significant advancement in stent engineering designed for improved safety in the treatment of people with complex coronary artery disease.

Fast healing through the unique bioabsorbable polymer coating

- The polymer coating is ultra-thin and applied only on the abluminal side, i.e. the outer surface, of the stent to minimise the polymer load with the potential to offer faster and more complete vessel healing after stent implantation. The synchronous drug and polymer absorption has been shown to significantly improve endothelialisation, the healing process of tissue regrowth over the stent to prevent thrombosis following stent implantation.² In preclinical studies, endothelial coverage was achieved by 30 days.³
- This technology with a low initial polymer load, abluminal coating and bioabsorbable polymer of SYNERGY[™] has the potential to optimise vessel healing, reduce the risk of thrombosis and the need for prolonged dual antiplatelet therapy. In selected patients, it may be reasonable to interrupt or discontinue dual antiplatelet therapy after three months.⁴



SYNERGY's customised stent architecture provides strength and flexibility where it matters

- SYNERGY[™] is built on the well-proven platinum chromium alloy. Its customised stent architecture provides flexibility without compromising strength: SYNERGY's thin, round struts and four connectors on the two most proximal segments add axial robustness while the 2 connector design within the stent body maintain flexibility and conformability to reduce the risk of stent fracture and vessel straightening.
- SYNERGY[™] uses everolimus, the market leading drug, with a similar everolimus dose and release profile as Boston Scientific's well-proven PROMUS[™] and PROMUS Element[™] stents.

Improved deliverability: Effective even for complex cases to access and treat challenging lesions

- SYNERGY[™] is a drug-eluting stent which can be delivered very easily so challenging lesions can also be accessed and treated effectively.
- SYNERGY[™] comes with a new delivery system with a laser-cut hypotube for improved pushability during the procedure, and also confident delivery even in complex cases.
- The SYNERGY[™] catheter has <1mm profiles and has a more flexible tip.
- Efficient and short procedure time: In 500 cases during early evaluation of SYNERGY[™], two thirds of procedures were completed in less than 30 minutes which may also speak for the exceptional deliverability of the stent.⁵

A wealth of scientific data to demonstrate improved clinical outcomes with SYNERGYTM

- SYNERGY[™] is supported by a rigorous clinical programme.⁶ Two-year follow-up data from the EVOLVE trial showed a target lesion revascularisation (TLR) rate of 1.1 percent and a stent thrombosis rate of 0.0 percent.⁷
- The pivotal EVOLVE II trial completed enrolment in August 2013. In this global, multicentre, randomised, controlled trial 1,684 patients in 125 sites worldwide were enrolled.
- In addition, SYNERGY[™] is being studied in a comprehensive research programme with more than 25,000 patients around the world, providing further robust scientific evidence on the safety and efficacy of the stent in a broad patient population. A number of independent, real-world studies investigate SYNERGY[™] across the full spectrum of cardiovascular disease complexity. Additional studies to assess outcomes, including the potential for reduced dual antiplatelet therapy, are expected to be supported by Boston Scientific.

For additional information, please visit <u>www.bostonscientific.com</u>.



Media contact

Simonetta Balbi Group Manager Europe PR and Corporate Communication **Boston Scientific Corporation** +39 338 79 36 422 (mobile) balbis@bsci.com

REFERENCES

- ³ Presented by Gregory J. Wilson, MD, ACC 2011. Boston Scientific data on file. ⁴ SYNERGYTM Directions for Use, Boston Scientific.
- ⁵ Boston Scientific: data on file.

⁷ EVOLVE 2-Year Clinical Results: Presented by Ian T. Meredith, MD, EuroPCR 2013.

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found with product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations. This information does not constitute medical or legal advice, and Boston Scientific makes no representation or warranty regarding this information or its completeness, accuracy or timeliness. Accordingly, Boston Scientific strongly recommends that you consult with your physician on all matters pertaining to your health or to address any questions.

All cited trademarks are the property of their respective owners.

©2014 Boston Scientific Corporation or its affiliates. All rights reserved.

SH-222104-AA JAN2014

¹ Keith Dawkins. Bioerodable Polymer Stents: Synergy and the EVOLVE trial. http://icimeeting.com/wp-content/uploads/2013/12/1910 dawkins A monsmallpdf.com .pdf. Accessed on 23 January 2014. ² Presented by Mike Eppihimer, PhD, Boston Scientific, PCR 2013; Eppihimer et al. Circ Cardiovasc

Interv. 2013;6:370-377.

⁶ Ian T. Meredith et al. J Am Coll Cardiol. 2012;59(15):1362-1370.