Boston Scientific
Advancing science for life™

SYNERGY™ XD

Everolimus-Eluting Platinum Chromium Coronary Stent System

Delivering More:
The First and Only
48 mm
DES in the U.S.

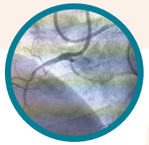
Designed for Complex Cases

The SYNERGY™ XD 48mm BP Stent features a fast-absorbing polymer for **optimal healing.**

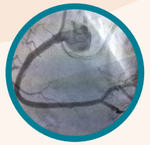
- Proven SYNERGY BP Stent
- Trusted drug and abluminal bioabsorbable polymer

Excellent Conformability

Minimizes Vessel Straightening



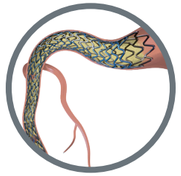
Baseline†



SYNERGY 48 mm in RCA – Post PCI†

Exceptional Overexpansion up to 5.75 mm*

Enables Natural Vessel Tapering



* The labeled dilation limit of the 4.0-5.0 mm stent diameters is 5.75 mm. Please see the SYNERGY XD DFU for dilation limits for all diameters.
† Images courtesy of Belfast City Hospital

Procedural Efficiency

Reduced Treatment Cost
utilizing one stent vs. two

Reduced Procedure Time
due to efficiency of single long stent

Reduced Radiation
exposure and contrast[1]

Over the course of a year, using a SYNERGY XD 48 mm instead of two overlapping stents in just 10% of PCIs could save*[2]:

More than **$50,000**

Over **13 hours** in procedure time

More than **3.5 L** of contrast

* Assumes 1,000 PCIs annually
1. Patted et al. *Cardiol Res.* 2018;9(6):350-357.
2. Jurado-Román A et al. *Cardiovasc Revasc Med.* 2019 Aug; 20(8):681-686.

Quality Outcomes for Patients

EVOLVE 48 Clinical Trial

1-year results with the **SYNERGY 48 mm** BP Stent[3*]:

- 100 patients across 15 sites in U.S., Europe and New Zealand
- 100% B2/C lesions
- 27% diabetes mellitus

4.1% TLF

0% ARC Def/Prob ST

100% Technical and Clinical Procedure Success

Significantly Lower MACE at 3-Years

With a single stent vs. overlapping stents in the SIRTAX Trial[4†].

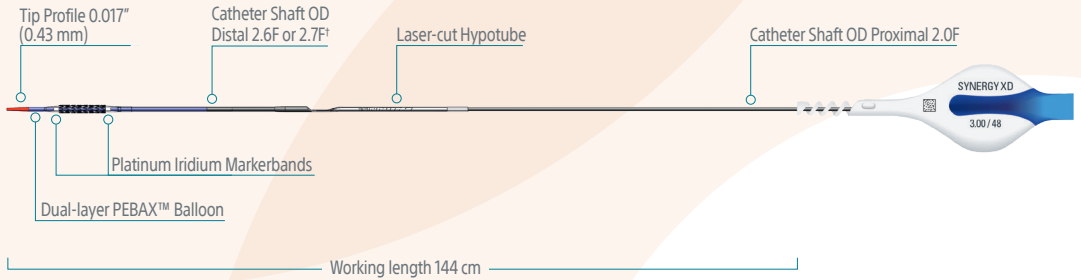
1.8x In MACE ($p<0.01$)

1.7x In MI‡

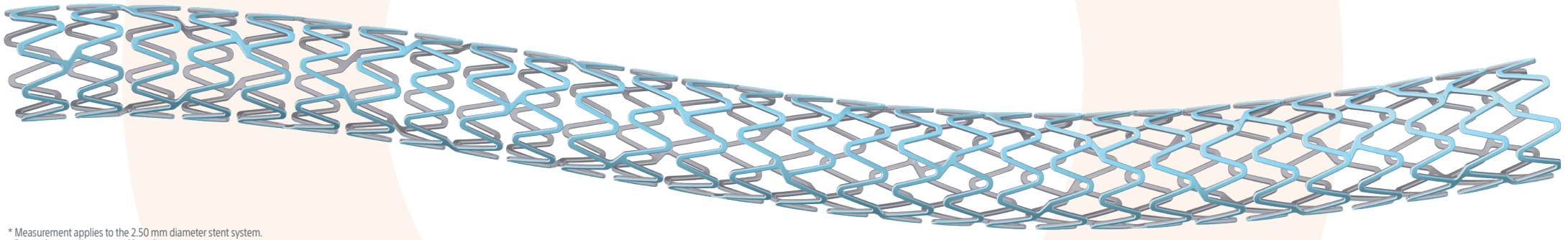
1.4x In ST‡

* Clinical data conducted with SYNERGY 48 mm, SYNERGY XD's predecessor device, which can be used to illustrate SYNERGY XD 48 mm clinical data.
† SYNERGY XD was not evaluated in this trial
‡ Not statistically significant
3. SYNERGY XD Stent System DFU.
4. Raber L et al. *J Am Coll Cardiol.* 2010; 55(12):1178-88.

Ordering Information



	STENT LENGTH (mm)										
Ø (mm)	8	12	16	20	24	28	32	38	48	Expansion Limit
2.25	H7493941808220	H7493941812220	H7493941816220	H7493941820220	H7493941824220	H7493941828220	H7493941832220	H7493941838220		3.50
2.50	H7493941808250	H7493941812250	H7493941816250	H7493941820250	H7493941824250	H7493941828250	H7493941832250	H7493941838250	H7493941848250	3.50
2.75	H7493941808270	H7493941812270	H7493941816270	H7493941820270	H7493941824270	H7493941828270	H7493941832270	H7493941838270	H7493941848270	3.50
3.00	H7493941808300	H7493941812300	H7493941816300	H7493941820300	H7493941824300	H7493941828300	H7493941832300	H7493941838300	H7493941848300	4.25
3.50	H7493941808350	H7493941812350	H7493941816350	H7493941820350	H7493941824350	H7493941828350	H7493941832350	H7493941838350	H7493941848350	4.25
4.00	H7493941808400	H7493941812400	H7493941816400	H7493941820400	H7493941824400	H7493941828400	H7493941832400	H7493941838400	H7493941848400	5.75
4.50		H7493941812450	H7493941816450	H7493941820450	H7493941824450	H7493941828450	H7493941832450			5.75
5.00		H7493941812500	H7493941816500	H7493941820500	H7493941824500	H7493941828500	H7493941832500			5.75



* Measurement applies to the 2.50 mm diameter stent system.
† Dependent on diameter and length

SYNERGY XD Everolimus-Eluting Platinum Chromium Coronary Stent System

Intended Use/Indications for Use: The SYNERGY™ XD Everolimus-Eluting Platinum Chromium Coronary Stent System is indicated for improving luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation MI or documented silent ischemia due to atherosclerotic lesions in native coronary arteries ≥ 2.25 mm to ≤ 5.0 mm in diameter in lesions ≤ 44 mm in length. **Contraindications:** Use of the SYNERGY XD Everolimus-Eluting Platinum Chromium Coronary Stent System is contraindicated in patients with known hypersensitivity to: • 316L stainless steel, platinum, chromium, iron, nickel or molybdenum • Everolimus or structurally-related compounds • The polymer or their individual components. Coronary artery stenting is contraindicated for use in: • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device. • Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. **Warnings:** • To maintain sterility, the inner package should not be opened or damaged prior to use. • The use of this product carries the risks associated with coronary artery stenting, including stent thrombosis, vascular complications, and/or bleeding events. • This product should not be used in patients who are not likely to comply with recommended antiplatelet therapy. **General Precautions:** • Careful consideration should be given to the risks and benefits of use in patients with history of severe reaction to contrast agents. • Stent thrombosis is a rare event and is frequently associated with myocardial infarction (MI) or death. In the clinical trials analysed to date, differences in the incidence of stent thrombosis have not been associated with an increased risk of cardiac death, MI, or all-cause mortality. • When DES are used outside the specified indications for Use, patient outcomes may differ from the results observed in the EVOLVE clinical trials. • Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI or death. When treating such patients, physicians should be aware of this increased risk and consider available data and the limitations of such data. • Orally-administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglyceride levels. **Pre- and Post-Procedure Antiplatelet Regimen:** The optimal duration of antiplatelet therapy, specifically P2Y12 inhibitor therapy is unknown and DES thrombosis may still occur despite continued therapy beyond current professional society guidelines. **Oral Antiplatelet Therapy:** Continuation of combination treatment with aspirin and a P2Y12 inhibitor after PCI appears to reduce major adverse cardiac events. On the basis of randomized clinical trial protocols and the 2016 ACC/AHA guidelines recommend aspirin 81 mg daily should be given indefinitely after PCI. In patients who are not at high risk of bleeding, a P2Y12 inhibitor should be given daily for at least 6 months in stable ischemic heart disease patients and for at least 12 months in acute coronary syndrome (ACS) patients. Full guidelines are provided at the following website: http://content.onlinejacc.org. It is very important that the patient is compliant with the post-procedural antiplatelet recommendations. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, MI or death. Prior to PCI, if a surgical or dental procedure is anticipated that requires early discontinuation of antiplatelet therapy, the interventional cardiologist and patient should carefully consider whether a DES and its associated recommended antiplatelet therapy is the appropriate PCI choice. **Pediatric Use:** The safety and effectiveness of the SYNERGY Stent in pediatric patients have not been established. **Lesion/Vessel Characteristics:** The safety and effectiveness of the SYNERGY Stent have not been established in the cerebral, carotid, or peripheral vasculature or in the following patient populations: • Patients with vessel thrombus at the lesion site. • Patients with coronary artery reference vessel diameters < 2.25 or > 5.00 mm. • Patients with coronary artery lesions longer than 44 mm or requiring more than one SYNERGY Stent. • Patients with lesions located in saphenous vein grafts, in the left main coronary artery, ostial lesions, or complex bifurcation (e.g. bifurcation lesion requiring treatment with more than one stent). • Patients with diffuse disease or reduced blood flow distal to the identified lesions. • Patients with a recent acute ST elevation myocardial infarction where there is evidence of thrombus or poor flow. • Patients with in-stent restenosis. • Patients with a chronic total occlusion. • Patients with 3 vessel disease. **Magnetic Resonance Imaging (MRI) Safety Information:** Non-clinical testing has demonstrated that the SYNERGY XD Stent is MR Conditional for single and overlapped conditions up to 94 mm. A patient with this device can be safely scanned in a Magnetic Resonance system meeting the following conditions: • Static magnetic field of 3.0 and 1.5 Tesla only • Maximum spatial gradient magnetic field of 2300 gauss/cm (23 T/m) • Maximum Magnetic Resonance system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W kg (Normal Operating Mode). Under the scan conditions defined above, the SYNERGY XD Stent is expected to produce a maximum temperature rise of 5˚C or less after 15 minutes of continuous scanning. MR Image quality may be compromised if the area of interest is within the lumen or relatively near the stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of the stent. The image artifact extends approximately 1 cm from the stent when scanned in non-clinical MR testing specified in ASTM F2119-07. The artifact does obscure the device lumen. Image artifact was minimized using the spin echo sequence versus gradient echo. **Potential Adverse Events:** Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to: • Abrupt stent closure • Allergic reaction to anti-coagulant and/or antiplatelet therapy, contrast medium, or stent materials • Angina • Arrhythmias, including ventricular fibrillation and ventricular tachycardia and heart block • Cardiogenic shock/pulmonary edema • Death • Embolization (air, tissue or thrombotic material or material from device(s) used in the procedure), including stent embolization or migration • Heart failure • Hemorrhage, which may require transfusion; including bleeding and hematoma • Hypotension/hypertension • Infection, local or systemic; including fever and pyrogen reaction • Myocardial ischemia or infarction • Pain, chest or access site • Pericardial effusion or cardiac tamponade • Renal insufficiency or failure • Respiratory failure • Restenosis or aneurysm of stented segment • Stent deformation, collapse, or fracture • Stent thrombosis/occlusion • Stroke/cerebrovascular accident/transient ischemic attack • Vessel trauma requiring surgical repair or reintervention; including coronary, femoral or radial artery spasm, dissection; occlusion, perforation, rupture, or pseudoaneurysm. Zortress™, the oral formulation of everolimus developed by Novartis Pharmaceuticals Corporation, has been evaluated in clinical trials and is approved in the United States for the prevention of organ rejection in adult kidney transplant recipients at the dose of 1.5 mg/day. Outside the U.S., Zortress is sold under the brand name, Certican™, in more than 70 countries. Everolimus is also approved in the United States under the name of Afinitor™ for patients with advanced renal cell carcinoma (cancer), after failure of treatment with sunitinib or sorafenib, at doses of 5 to 20 mg/day when taken by mouth. The following list includes the known risks of everolimus at the oral doses listed above. The amount of drug that circulates in the bloodstream following implantation of a SYNERGY™ Stent is several folds lower than that obtained with oral doses (1.5 mg to 20 mg/day). • Abdominal pain • Anemia • Angioedema • Anorexia • Asthenia • Constipation • Cough • Delayed wound healing/fluid accumulation • Diarrhea • Dyslipidemia (including hyperlipidemia and hypercholesterolemia) • Dysgeusia • Dyspepsia • Dyspnea • Dysuria • Dry skin • Edema (peripheral) • Epistaxis • Fatigue • Headache • Hematuria • Hyperglycemia (may include new onset of diabetes) • Hyperkalemia • Hyperlipidemia • Hypertension • Hypokalemia • Hypomagnesemia • Hypophosphatemia • Increased serum creatinine • Infections and serious infections: bacterial, viral, fungal, and protozoal infections (may include herpes virus infection, polyoma virus infection which may be associated with BK virus associated nephropathy, and/or other opportunistic infections) • Insomnia • Interaction with strong inhibitors and inducers of CYP3A4 • Leukopenia • Lymphoma and other malignancies (including skin cancer) • Male infertility (azospermia and/or oligospermia) • Mucosal inflammation (including oral ulceration and oral mucositis) • Nausea • Neutropenia • Non-infectious pneumonitis • Pain; extremity, incision site and procedural, back, chest, musculoskeletal • Proteinuria • Pruritus • Pyrexia • Rash • Stomatitis • Thrombocytopenia • Thrombotic microangiopathy (TMA/Thro mbotic thrombocytopenic purpura (TTP)/Hemolytic uremic syndrome (HUS) • Tremor • Upper respiratory tract infection • Urinary tract infection • Vomiting. Live vaccines should be avoided and close contact with those that have had live vaccines should be avoided. Fetal harm can occur when administered to a pregnant woman. There may be other potential adverse events that are unforeseen at this time. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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