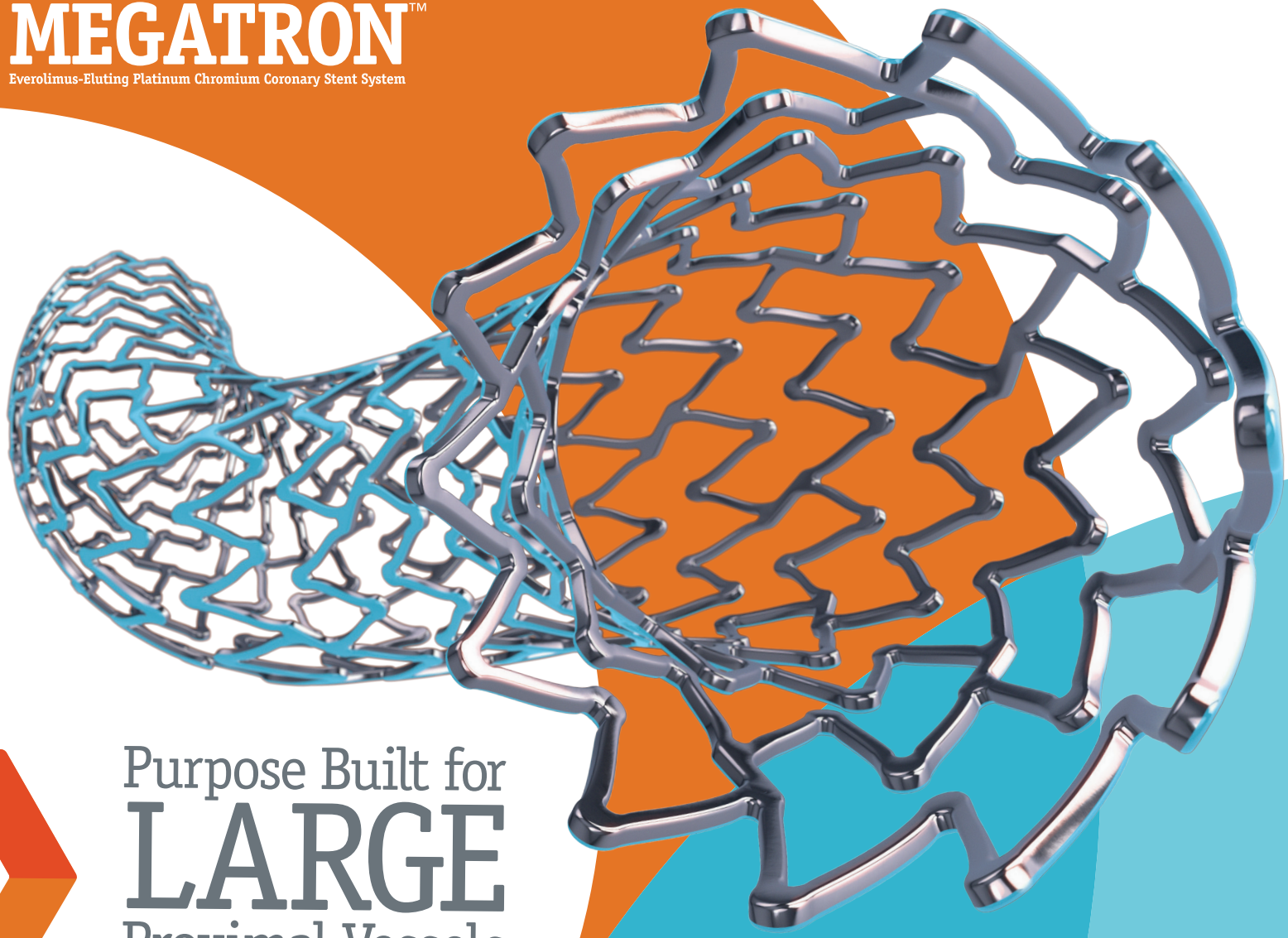
Boston Scientific

Advancing science for life™

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System

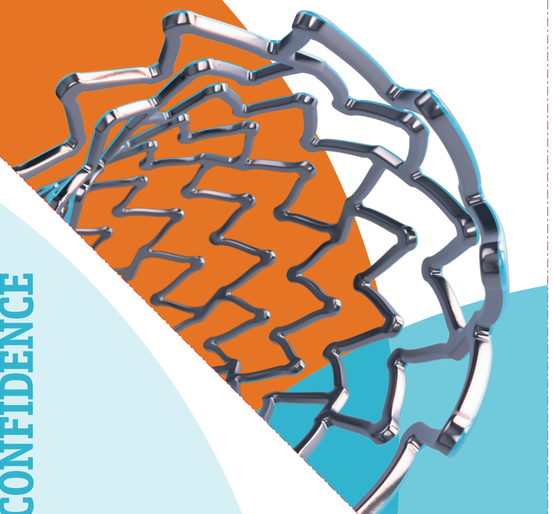


Purpose Built for LARGE Proximal Vessels

Mega Strength, Optimal Healing.

Boston Scientific
Advancing science for life™

TRON™
Coronary Stent System



HEAL
WITH CONFIDENCE

Boston Scientific now offers a portfolio of **SYNERGY BP Stents** with distinct options to optimize performance and enable early healing.

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System

	Stent Length (mm)								
Ø (mm)	8	12	16	20	24	28	32	Overexpansion Capabilities
3.50	H7493942808350	H7493942812350	H7493942816350	H7493942820350	H7493942824350	H7493942828350	H7493942832350	6.0
4.00	H7493942808400	H7493942812400	H7493942816400	H7493942820400	H7493942824400	H7493942828400	H7493942832400	6.0
4.50	H7493942808450	H7493942812450	H7493942816450	H7493942820450	H7493942824450	H7493942828450	H7493942832450	6.0
5.00	H7493942808500	H7493942812500	H7493942816500	H7493942820500	H7493942824500	H7493942828500	H7493942832500	6.0

*Average stent crossing profile measured on the SYNERGY MEGATRON 3.50 mm diameter.

SYNERGY MEGATRON™ Stent

INDICATIONS FOR USE The SYNERGY MEGATRON Everolimus-Eluting Platinum Chromium Coronary Stent System is indicated for improving luminal diameter in patients, including those at high risk for bleeding, 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 ≥3.50 mm to ≤5.00 mm in diameter in lesions ≤28 mm in length. **CONTRAINDICATIONS** Use of the SYNERGY MEGATRON 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 (see Section 2.4.2 Polymer Carrier) 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 (see Section 6.2, Pre- and Post-Procedure Antiplatelet Regimen for more information). **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 analyzed 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 drug eluting stents are used outside the specified Indications for Use, patient outcomes may differ from the results observed during the EVOLVE clinical trials. • Compared to use within the specified Indications for Use, the use of drug eluting stents 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. SYNERGY MEGATRON leverages the clinical data from the EVOLVE Clinical Trial Program. Therefore, the statements below regarding SYNERGY™ also apply to SYNERGY MEGATRON. **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 continuation of 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 trials, the 2016 ACC/AHA guidelines recommend aspirin 81 mg daily be given indefinitely after PCI. In patients who are not at a 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://www.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 MEGATRON 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 <3.50 or >5.00 mm. • Patients with coronary artery lesions longer than 28mm or requiring more than one SYNERGY Stent. • Patients with lesions located in saphenous vein grafts, in the left main coronary artery, ostial location, 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 MEGATRON Stent is MR Conditional for single and overlapped conditions up to 66 mm in 1.5T and 3.0T MR systems. A patient with this device can be safely scanned in a Magnetic Resonance system meeting the following conditions: • Static magnetic field of up to and including 3.0 Tesla • Maximum spatial gradient magnetic field of 2000 gauss/cm (20.0 T/m) for 1.5T systems and 1060 gauss/cm (10.6 T/m) for 3.0T systems • 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 MEGATRON Stent is expected to produce a maximum temperature rise of 5.7oC after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 10 mm from the SYNERGY MEGATRON stent when imaged with a gradient echo pulse sequence and a 3 T MRI system as specified in ASTM F2119-01. 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 artifact does obscure the device lumen. Image artifact was minimized using the spin echo sequence vs. 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, 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 or hematoma • Hypotension/hypertension • Infection, local or systemic, including fever and pyrogen reaction • Myocardial ischemia/infarction • Pain • 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 MEGATRON™ Stent is several folds lower than that obtained with oral doses (1.5 mg to 20 mg/day, see Section 7.2, Pharmacokinetics). • Abdominal pain • Anemia • Angioedema • Anorexia • Asthenia • Constipation • Cough • Delayed wound healing/fluid accumulation • Diarrhea • Dyslipidemia (including hyperlipidemia and hypercholesterolemia) • Dysgeusia • Dyspepsia • Dyspnea • Pyuria • 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 (azoospermia 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/Thrombotic 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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
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Advancing science for life™

Interventional Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

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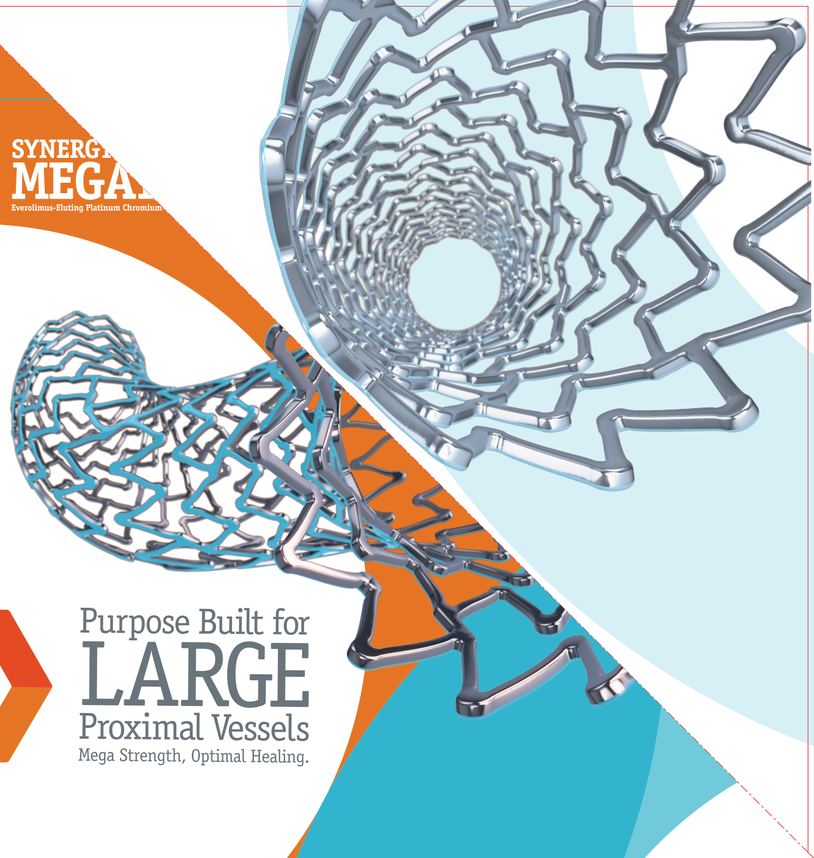
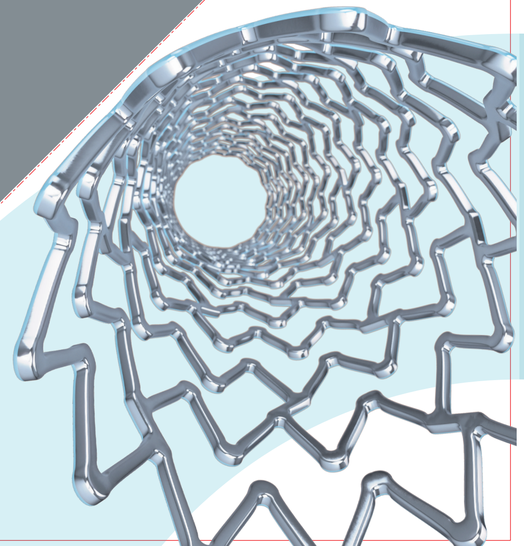
IC-741902-AA-US

SYNERGY
MEGA
Everolimus-Eluting Platinum Chromium



Purpose Built for
LARGE
Proximal Vessels
Mega Strength, Optimal Healing.

folded down



SYNERGY
MEGATRON™
Everolimus-Eluting Platinum Chromium Coronary Stent System

Introducing a new type of stent: SYNERGY MEGATRON is purpose built for large proximal vessels. Available in 3.5 mm–5.0 mm diameters to maximize performance where it is needed most.

Innovative New
Stent Architecture

- Best-in-Class Strength
- Unmatched Overexpansion
- Maximum Visibility
- Uniform Lesion Scaffolding

Trusted
Bioabsorbable Polymer

- Early Healing
- Consistently Low ST Rates
- Shortened DAPT Data
- Proven Long-Term Outcomes

Now FDA Approved
HIGH BLEEDING RISK INDICATION
SYNERGY MEGATRON

The HBR indication is supported by the data from the EVOLVE Short DAPT Trial.

0.2% ST

After patients stopped DAPT at 3-months through 15-months in the **EVOLVE Short DAPT Trial***

* EVOLVE Short DAPT is a prospective, multicenter, single-arm trial defining the safety of 3-month DAPT in subjects at high risk for bleeding undergoing PCI with the SYNERGY BP Stent. Approximately 74% of patients enrolled discontinued DAPT at 3-months. N = 1,396 (patients with respective event or sufficient follow-up). Co-primary endpoints: ARC Def/Prob ST and Death/ MI from 3 -15 months.

Boston Scientific now offers a portfolio of **SYNERGY BP Stents** with distinct options to optimize performance and enable early healing.

HEAL
WITH CONFIDENCE

folded up

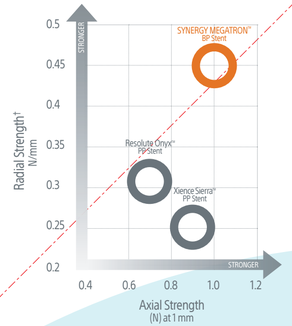
Best-in-Class
Axial & Radial Strength

43% More **axial** strength*

To maintain stent integrity in complex interventions

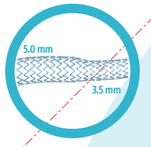
40% More **radial** strength*

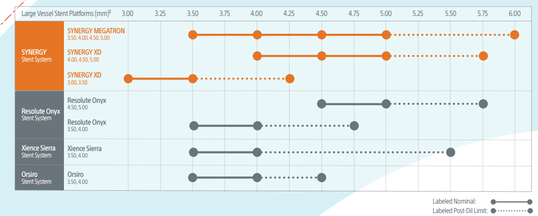
To maintain vessel patency



Unmatched
Overexpansion

A versatile stent model that can expand **2.5 mm, from 3.5 mm to 6.0 mm,** to accommodate wide diameter mismatch.





* SYNERGY MEGATRON 5.0 mm diameter vs. Resolute Onyx 5.0 mm diameter. (N=3 minimum). Bench tests performed by Boston Scientific Corporation. Data on file. Bench test results not necessarily indicative of clinical performance.
† Based on bench test data comparing to largest nominal diameter; 4.0 mm for Xience Sierra and 5.0 mm for SYNERGY MEGATRON and Resolute Onyx. N=3 minimum. Data on file. Bench test results not necessarily indicative of clinical performance.
‡ Expansion information pulled from individual DFU documents for: SYNERGY MEGATRON Stent System, SYNERGY XD Stent System, Resolute Onyx Stent System, Xience Sierra Stent System, Orsiro Stent System.

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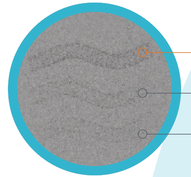
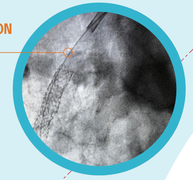
Maximum
Visibility

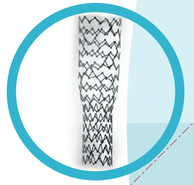
Platinum Chromium (PtCr) Alloy enhances visibility to aid in accurate stent placement





Uniform Lesion
Scaffolding

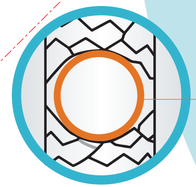
To **maximize** lumen gain



33% **Less Tissue Prolapse**

12-peak stent design to minimize tissue prolapse and maintain lumen diameter††

Large
Side Branch Expansion

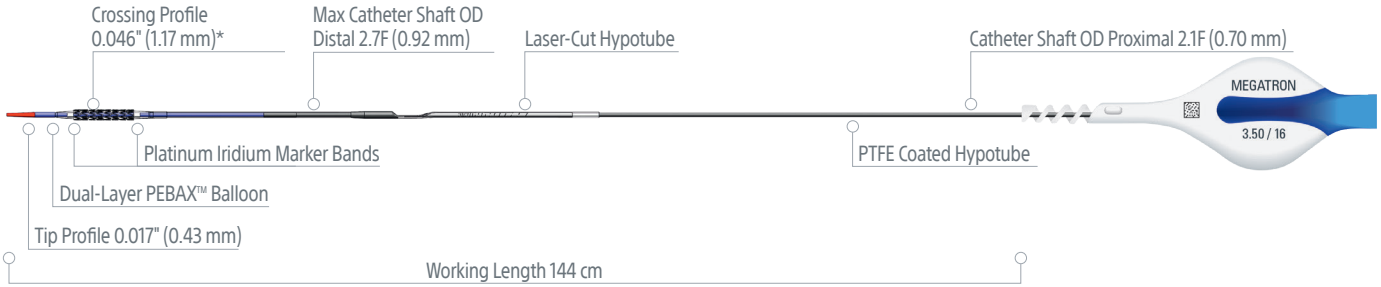


5.0 mm Maximum expanded cell diameter‡‡

§ 3.5 mm stent products tested under 6.0 mm copper phantom to simulate body mass. Bench testing performed by Boston Scientific Corporation. Data on file. Bench test results not necessarily indicative of clinical performance.
** SYNERGY MEGATRON angiography image provided from Golden Jubilee National Hospital.
†† Compared to a 9-peak prototype DES. Bench testing performed by Boston Scientific Corporation. Data on file. Bench test and computational model results may not necessarily be indicative of clinical performance.
‡‡ Based on SYNERGY MEGATRON 5.0 mm diameter. Bench testing performed by Boston Scientific Corporation. Data on file. Bench test results not necessarily indicative of clinical performance.

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System



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*Average stent crossing profile measured on the SYNERGY MEGATRON 3.50 mm diameter.

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Image artifact was minimized using the spin echo sequence vs. 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, 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 or 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 MEGATRON™ Stent is several folds lower than that obtained with oral doses (1.5 mg to 20 mg/day, see Section 7.2, Pharmacokinetics). • 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/Thrombotic 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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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