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Advancing science for life™

# SYNERGY™ XD

**Everolimus-Eluting Platinum Chromium Coronary Stent System**

## Delivering More.

Xtra Deliverability. Optimal Healing.

# SYNERGY™ XD

**Everolimus-Eluting Platinum Chromium Coronary Stent System**

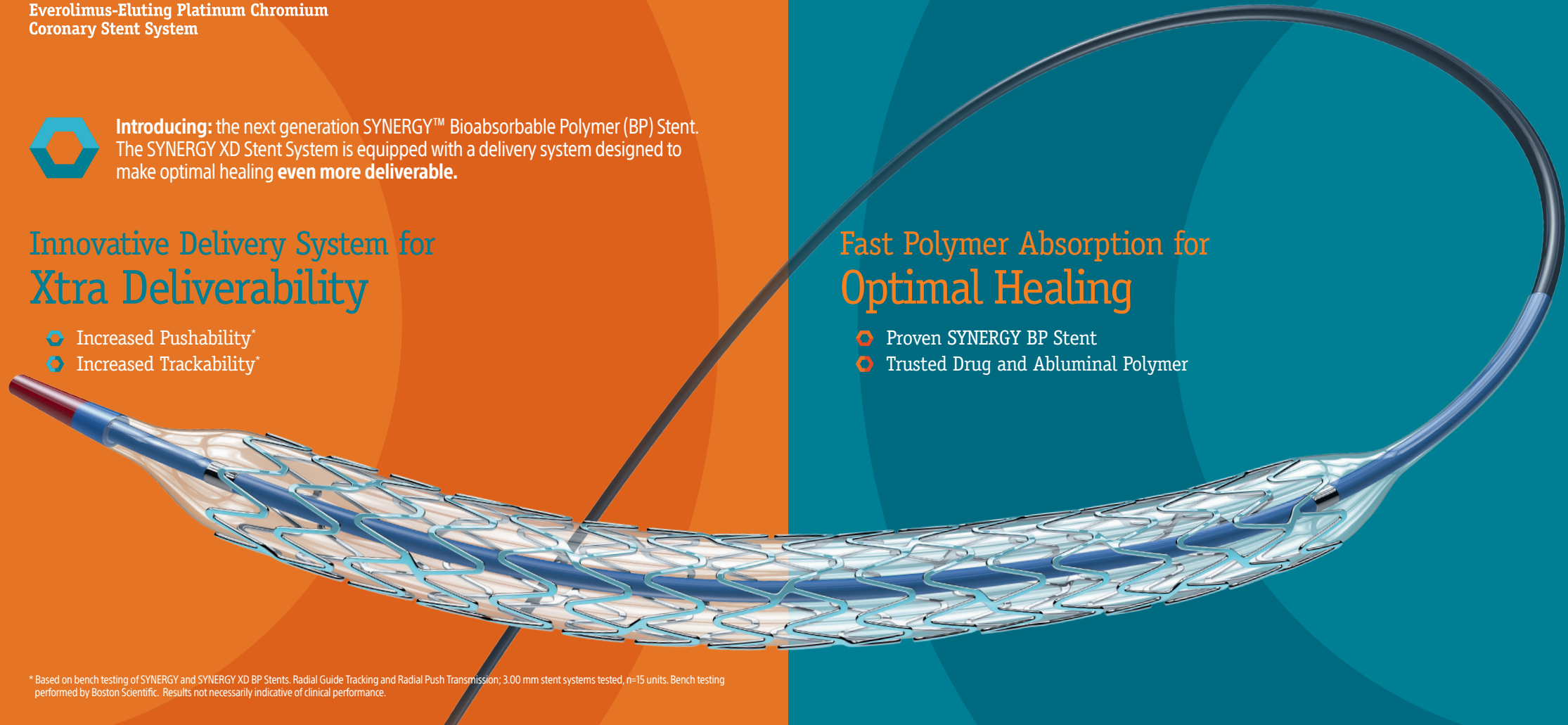
**Introducing:** the next generation SYNERGY™ Bioabsorbable Polymer (BP) Stent. The SYNERGY XD Stent System is equipped with a delivery system designed to make optimal healing **even more deliverable.**

## Innovative Delivery System for Xtra Deliverability

- Increased Pushability*
- Increased Trackability*

## Fast Polymer Absorption for Optimal Healing

- Proven SYNERGY BP Stent
- Trusted Drug and Abluminal Polymer



* Based on bench testing of SYNERGY and SYNERGY XD BP Stents. Radial Guide Tracking and Radial Push Transmission; 3.00 mm stent systems tested, n=15 units. Bench testing performed by Boston Scientific. Results not necessarily indicative of clinical performance.

# Xtra Deliverability

## Innovative Delivery System

**Designed for Flexibility**
Short Red Tip and 2-Connector Stent Design

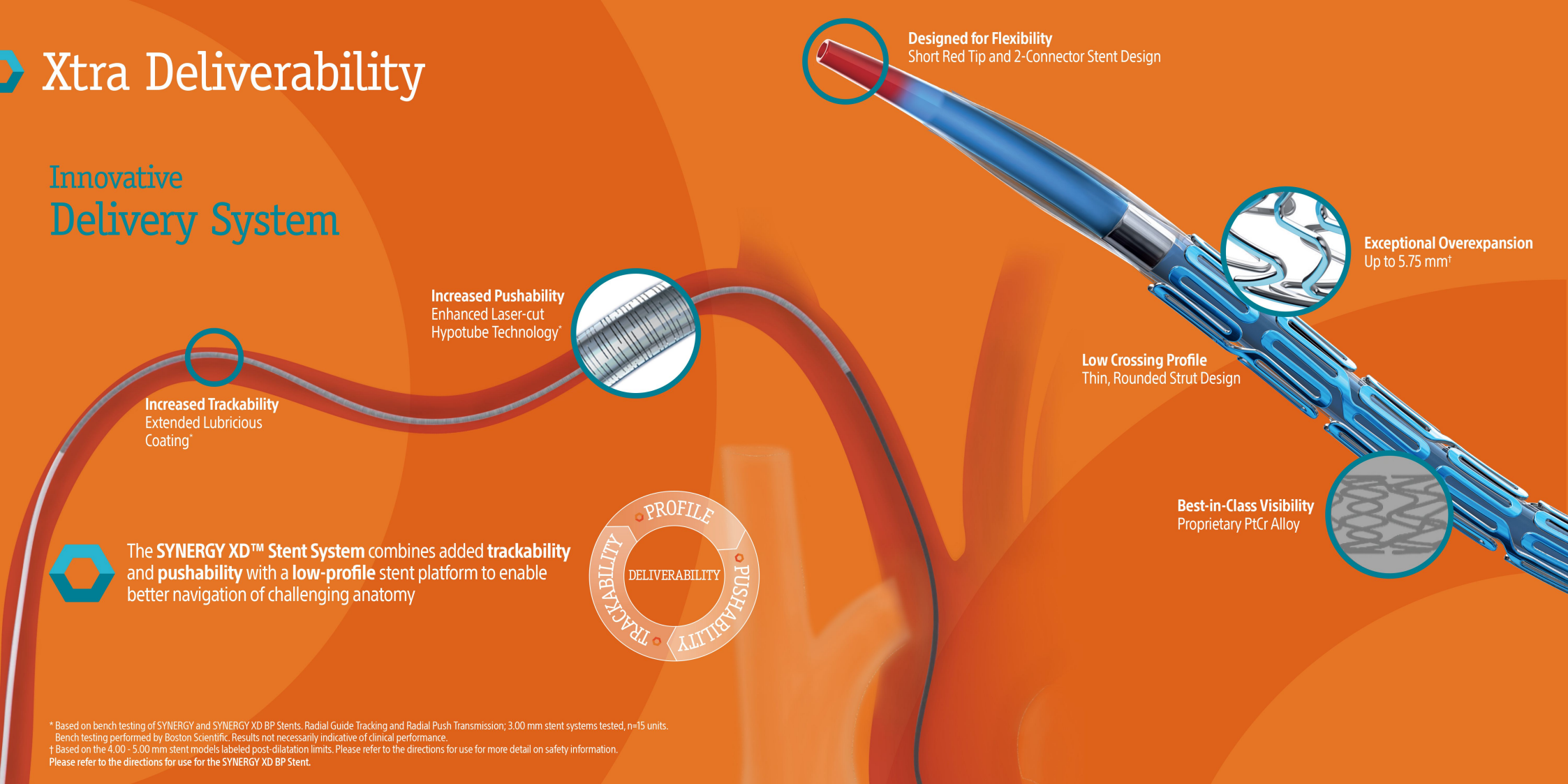
**Exceptional Overexpansion**
Up to 5.75 mm†

**Low Crossing Profile**
Thin, Rounded Strut Design

**Best-in-Class Visibility**
Proprietary PtCr Alloy

**Increased Pushability**
Enhanced Laser-cut Hypotube Technology*

**Increased Trackability**
Extended Lubricious Coating*



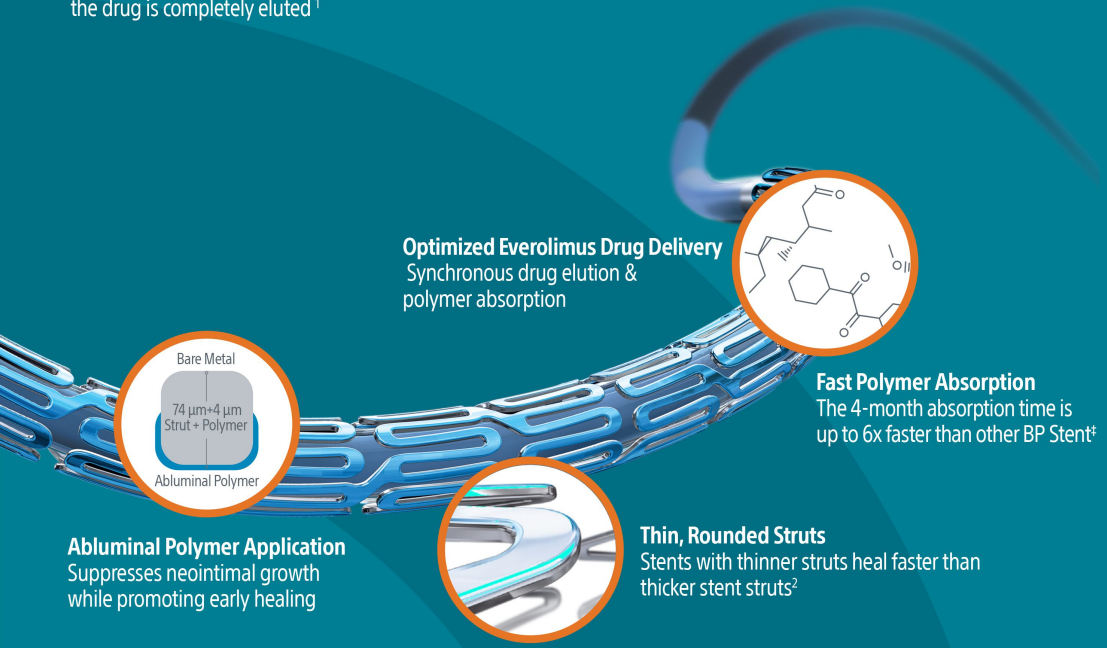

The **SYNERGY XD™ Stent System** combines added **trackability** and **pushability** with a **low-profile** stent platform to enable better navigation of challenging anatomy

* Based on bench testing of SYNERGY and SYNERGY XD BP Stents. Radial Guide Tracking and Radial Push Transmission; 3.00 mm stent systems tested, n=15 units. Bench testing performed by Boston Scientific. Results not necessarily indicative of clinical performance.
† Based on the 4.00 - 5.00 mm stent models labeled post-dilatation limits. Please refer to the directions for use for more detail on safety information.
**Please refer to the directions for use for the SYNERGY XD BP Stent.**

# Optimal Healing

## Fast Absorbing
### Bioabsorbable Polymer Advantage

Unlike permanent polymer DES technology, the SYNERGY XD Bioabsorbable Polymer is gone shortly after the drug is completely eluted [1]




**Optimized Everolimus Drug Delivery**
Synchronous drug elution & polymer absorption

**Fast Polymer Absorption**
The 4-month absorption time is up to 6x faster than other BP Stent‡

**Abluminal Polymer Application**
Suppresses neointimal growth while promoting early healing

**Thin, Rounded Struts**
Stents with thinner struts heal faster than thicker stent struts[2]

‡ Compared to Orsiro BP Stent.


1. Wilson GJ et al. *Catheter Cardiovasc Interv.*
2. Soucy N, Feygin J et al. *EuroIntervention.* 2010 Nov;6(5):630-7.


## Excellent Safety
### & Long Term Outcomes

The SYNERGY BP Stent has been studied in over 35,000 patients across various patient and lesion complexities

Now FDA Approved
HIGH BLEEDING RISK INDICATION
SYNERGY XD Stent

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
EVOLVE Short DAPT Trial**[5]

**ZERO ST**
After patients stopped DAPT at 1-month through 12-months
SENIOR Trial[3]

**RANKED #1**
Lowest relative risk of Def/Prob ST
Kang Network Meta-Analysis[4]

Excellent Results In
**COMPLEX PATIENTS**
Lowest ST rate in statistically more complex patients
Real-World SCAAR Registry[6]

§ The HBR indication excludes the SYNERGY XD 48 mm stent
** 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.


3. Varenne O et al. Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial. *Lancet.* 2018;391(10115):45-50. doi:10.1016/ S0140-6736(17)32713-7.
4. Kang S et al. *J Am Coll Cardiol. Intv.*doi:10.1016/j.jcin.2016.03.038.
5. EVOLVE Short DAPT Subgroup Analyses. Presented by Robert Stoler, MD at ACC 2020.
6. Sarno G et al. *Cathet. Cardiovasc. Intervent.*. doi:10.1002/ccd.27030.

| Ø (mm) | STENT LENGTH (mm) | | | | | | | | | Expansion Limit |
|---|---|---|---|---|---|---|---|---|---|---|
| | 8 | 12 | 16 | 20 | 24 | 28 | 32 | 38 | 48 | |
| 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 |

**SYNERGY™ XD Monorail Coronary Stent System**

**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 atherosderotic lesions in native coronary arteries ≥2.25 mm to ≤5.00 mm in diameter in lesions ≤44 mm in length and for high bleeding risk patients with coronary arteries ≥2.25 mm to ≤5.00 mm in diameter in lesions ≤34 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 (see Section 2.4.2 Polymer Carrier in the eIFU) 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 in the eIFU). **WARNINGS** • To maintain sterility, the 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 during 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 cydosporine 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 trials 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://www.onlinejacc.org Based upon the results of the EVOLVE Short DAPT Study the SYNERGY XD stent can be safely used in conjunction with shortened DAPT in patients at high risk for bleeding. In the EVOLVE Short DAPT Study, high bleeding risk subjects were defined as meeting one or more of the following criteria: ≥75 years of age and, in the opinion of the investigator, the risk of bleeding associated with >3 months of DAPT outweighs the benefit; need for chronic or lifelong anticoagulation, history of major bleeding (severe/life threatening or moderate bleeding based on the GUSTO classification) within 12 months of the index procedure; history of stroke (ischemic or hemorrhagic); renal insufficiency (creatinine ≥2.0 mg/dl) or failure (dialysis dependent); platelet count ≤100,000/µL. 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 44mm 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 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, 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, see Section 7.2, Pharmacokinetics of the eIFU). • Abdominal pain • Anemia • Angioedema • Anorexia • Asthenia • Constipation • Cough • Delayed wound healing/fluid accumulation • Diarrhea • Dyslipidemia (induding 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 (induding skin cancer) • Male infertility (azospermia and/or oligospermia) • Mucosal inflammation (induding 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 dose 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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IC-751701-AB