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SYNERGY™ II

MONORAIL™

Everolimus-Eluting Platinum Chromium Coronary Stent System

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The SYNERGY II Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY II Stent System) is a device/drug combination product comprised of two regulated components: a device (coronary stent system) and a drug product (a formulation of everolimus contained in a biodegradable polymer coating). SYNERGY II is uniquely designed with a low initial polymer load, abluminal coating and bioabsorbable polymer which may reduce the risk of thrombosis and the need for prolonged dual antiplatelet therapy. The characteristics of the SYNERGY II Stent System are described in Table 1. SYNERGY II Stent System Product Description.

Table 1. SYNERGY II Stent System Product Description

Characteristic	SYNERGY II Stent System
Available stent lengths (mm)	8, 12, 16, 20, 24, 28, 32, 38
Available stent diameters (mm)	2.25, 2.50, 2.75, 3.00, 3.50, 4.00
Stent material	Platinum Chromium (PtCr) Alloy
Drug product	An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm² of total stent surface area and a maximum nominal polymer content of 351 µg and drug content of 287 µg on the largest stent (4.00 x 38 mm)
Delivery system effective length	144 cm
Delivery system Y-adapter ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤ 0.014 in (0.36 mm).
Average stent length change upon deployment at nominal diameter	Small Vessel (SV) average: -0.15 mm Workhorse (WH) average: -0.20 mm Large Vessel (LV) average: 0.15 mm
Stent delivery balloon	A compliant balloon, with two radiopaque markers nominally 0.4 mm longer than the stent at each end.
Balloon inflation pressure	Nominal inflation pressure: 11 atm (1117 kPa) Rated burst pressure: 2.25 - 2.75 mm: 18 atm (1827 kPa) 3.00 - 4.00 mm: 16 atm (1620 kPa)
Guide catheter inner diameter	≥ 0.056 in (1.42 mm)
Catheter shaft outer diameter	Proximal: 2.1F (0.70 mm) Distal: 2.25 - 2.75 mm: 2.6F (0.90 mm) 3.00 mm: • 8 - 28 mm: 2.6F (0.90 mm) • 32 - 38 mm: 2.7F (0.95 mm) 3.50 mm: • 8 - 20 mm: 2.6F (0.90 mm) • 24 - 38 mm: 2.7F (0.95 mm) 4.00 mm: 2.7F (0.95 mm)
Stent strut thickness	2.25 - 2.75 mm: 0.074 mm 3.00 - 3.50 mm: 0.079 mm 4.00 mm: 0.081 mm

Device Component Description

The SYNERGY II Stent System consists of a platinum chromium stent platform with an abluminal drug/polymer coating mounted onto a Monorail Delivery System.

The SYNERGY II stent is available in 3 stent models each designed for specific diameters as follows:

- Small Vessel (SV): 2.25, 2.50 and 2.75 mm
- Workhorse (WH): 3.00 and 3.50 mm
- Large Vessel (LV): 4.00 mm

Contents

Qty	Material
One (1)	SYNERGY II Stent System
Two (2)	CLIPIT™ Hypotube Clips
One (1)	Flushing needle with Luer fitting

Drug Eluting Coating Description

The SYNERGY II stent is a stent with a drug/polymer coating. The coating is comprised of a polymer matrix that contains an active pharmaceutical ingredient.

See Everolimus and Polymer Carrier sections for descriptions of drug and polymer, respectively.

Everolimus

Everolimus is the active pharmaceutical ingredient in the SYNERGY II stent.

The everolimus chemical name is 42-O-(2-hydroxyethyl)-rapamycin, and its chemical structure is shown below in Figure 1.

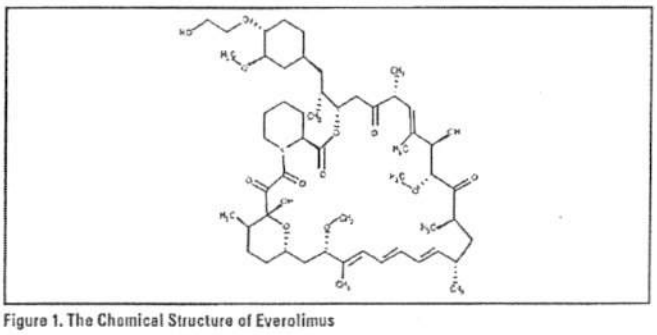

Figure 1. The Chemical Structure of Everolimus

Polymer Carrier

The SYNERGY™ II stent is coated on the abluminal stent surface with a biodegradable drug matrix. The biodegradable drug matrix is composed of PLGA [poly(DL-lactide-co-glycolide)] mixed with everolimus. The chemical structure of PLGA is shown below in Figure 2.

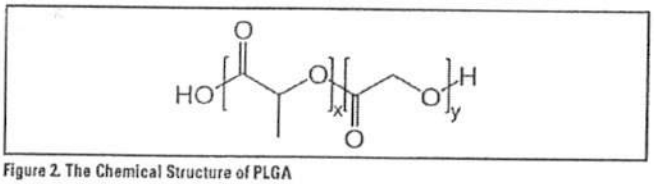

Figure 2. The Chemical Structure of PLGA

Product Matrix

Table 2. SYNERGY II Stent System Product Matrix and Everolimus Content

UPN Number	Nominal Expanded Inner Diameter (mm)	Nominal Unexpanded Stent Length (mm)	Nominal Everolimus Content (µg)
H7493926208220	2.25	8	38.9
H7493926208250	2.50	8	38.9
H7493926208270	2.75	8	38.9
H7493926208300	3.00	8	46.5
H7493926208350	3.50	8	46.5
H7493926208400	4.00	8	67.5
H7493926212220	2.25	12	58.3
H7493926212250	2.50	12	58.3
H7493926212270	2.75	12	58.3
H7493926212300	3.00	12	66.3
H7493926212350	3.50	12	66.3
H7493926212400	4.00	12	96.2
H7493926216220	2.25	16	77.6
H7493926216250	2.50	16	77.6
H7493926216270	2.75	16	77.6
H7493926216300	3.00	16	92.7
H7493926216350	3.50	16	92.7
H7493926216400	4.00	16	124.8
H7493926220220	2.25	20	96.9
H7493926220250	2.50	20	96.9
H7493926220270	2.75	20	96.9
H7493926220300	3.00	20	112.5
H7493926220350	3.50	20	112.5
H7493926220400	4.00	20	153.5
H7493926224220	2.25	24	121.1
H7493926224250	2.50	24	121.1
H7493926224270	2.75	24	121.1
H7493926224300	3.00	24	132.3
H7493926224350	3.50	24	132.3
H7493926224400	4.00	24	182.2
H7493926228220	2.25	28	140.5
H7493926228250	2.50	28	140.5
H7493926228270	2.75	28	140.5
H7493926228300	3.00	28	158.7
H7493926228350	3.50	28	158.7
H7493926228400	4.00	28	210.8
H7493926232220	2.25	32	159.8
H7493926232250	2.50	32	159.8
H7493926232270	2.75	32	159.8
H7493926232300	3.00	32	178.5
H7493926232350	3.50	32	178.5
H7493926232400	4.00	32	239.5
H7493926238220	2.25	38	188.9
H7493926238250	2.50	38	188.9
H7493926238270	2.75	38	188.9
H7493926238300	3.00	38	211.8
H7493926238350	3.50	38	211.8
H7493926238400	4.00	38	287.2

INTENDED USE/INDICATIONS FOR USE

The SYNERGY II Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo native coronary artery lesions. The treated lesion length should be less than the nominal stent length (8 mm, 12 mm, 16 mm, 20 mm, 24 mm, 28 mm, 32 mm and 38 mm) with a reference vessel diameter of 2.25 mm - 4.0 mm.

CONTRAINDICATIONS

Use of the SYNERGY II Stent System is contraindicated in patients with the following:

- Known hypersensitivity to platinum, the platinum chromium alloy, or similar alloy types such as stainless steel.
- Known hypersensitivity to everolimus or structurally related compounds.
- Known hypersensitivity to the polymer or its individual components (see details in **Polymer Carrier**).
- Known severe reaction to contrast agents that cannot be adequately pre-medicated prior to the SYNERGY II stent placement procedure.

Coronary artery stenting is contraindicated for use in the following:

- Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

WARNINGS

- This product should not be used in patients who are not likely to comply with recommended anti-platelet therapy.
- To maintain sterility, the package should not be opened or damaged prior to use. The package should be opened as described in **Operational Instructions**.
- The use of this product carries the risks associated with coronary artery stenting, including stent thrombosis, vascular complications, and/or bleeding events.

- Patients with known hypersensitivity to platinum or stainless steel may suffer an allergic reaction to this implant.

PRECAUTIONS

General Precautions

- Only physicians who have received adequate training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft (CABG) surgery is readily available.
- Potential interactions of the SYNERGY™ II stent with other drug-eluting or coated stents have not been evaluated.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of coronary stents is unknown at present.
- Consideration should be given to the risks and benefits of use in patients with a history of severe reaction to contrast agents.
- Do not expose the stent delivery system to organic solvents such as alcohol or detergents.
- Care should be taken to control the position of the guide catheter tip during stent delivery, deployment, and balloon withdrawal. Before withdrawing the stent delivery system (SDS), visually confirm complete balloon deflation by fluoroscopy (see Table 3., Representative System Deflation Times). Failure to do so may cause increased SDS withdrawal forces and result in guide catheter movement into the vessel and subsequent arterial damage.
- Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglyceride levels.

Stent System Handling (also see, Operational Instructions)

- For single use only. Do not resterilize or reuse this product. Note product "Use By" date and do not use after the "Use By" date.
- The SYNERGY II stent and its delivery system are designed for use as a unit. The stent is not to be removed from its delivery balloon. The stent is not designed to be crimped onto another balloon. Removing the stent from its delivery balloon may damage the stent and coating and/or lead to stent embolization.
- Prior to angioplasty, carefully examine all equipment to be used during the procedure including the dilatation catheter to verify proper function.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery balloon. This is most important during catheter removal from packaging, placement over the guidewire, and advancement through the hemostatic valve and guide catheter hub.
- Excessive manipulation or handling may cause coating damage, contamination, or dislodgment of the stent from the delivery balloon.
- Use only the appropriate balloon inflation media (see Operational Instructions, Balloon Preparation). DO NOT use air or any gas medium to inflate the balloon.
- In the event that the SYNERGY II stent is not deployed, follow product return procedures and avoid handling of the stent with bare hands.
- Stent contact with any fluid prior to placement is not recommended as there is a possibility of drug release. However, if it is absolutely necessary to flush or soak the stent with sterile/isotonic saline, contact time should be limited (1 minute maximum).

Stent Placement

Preparation

- DO NOT PREPARE OR PRE-INFLATE BALLOON PRIOR TO STENT DEPLOYMENT OTHER THAN AS DIRECTED. Use the balloon purging technique described in Operational Instructions, Balloon Preparation.
- If unusual resistance is felt at any time during lesion access before stent implantation, the stent system and guide catheter should be removed as a single unit (see Stent System Removal - Pre-deployment and Stent System Removal - Post-deployment).
- An unexpanded stent should be introduced into the coronary arteries one time only. An unexpanded stent should not be subsequently moved in and out through the distal end of the guide catheter as stent or coating damage or stent dislodgment from the balloon may occur.

Placement

- The vessel should be pre-dilated with an appropriately sized balloon. Failure to do so may increase the risk of placement difficulty and procedural complications.
- Do not expand the stent if it is not properly positioned in the vessel (see Precautions, Stent System Removal - Pre-deployment).
- Balloon pressures should be monitored during inflation. Do not exceed the rated burst pressure as indicated on the product label (see Table 4., SYNERGY II Compliance Chart). Use of pressures higher than specified on the product label may result in a ruptured balloon or shaft. This may result in potential intimal damage, dissection or vessel rupture.
- The stent inner diameter should approximate 1.1 times the distal reference vessel diameter.
- Placement of the stent has the potential to compromise side branch patency if stenting near a side branch.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should generally be stented first, followed by stenting of the more proximal lesion(s). Stenting in this order avoids the requirement to cross the proximal stent when placing the distal stent and reduces the chances of the stent dislodgment.

Stent System Removal - Pre-deployment

- If unusual resistance is felt at any time during lesion access before stent implantation, the stent system and the guide catheter should be removed as a single unit (see note below).
- Do not attempt to pull an unexpanded stent back into the guide catheter, as stent or coating damage or stent dislodgment from the balloon may occur.
- Stent retrieval methods (use of additional wires, snares, and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma, or pseudoaneurysm.

Note: When removing the entire stent system and guide catheter as a single unit the following steps should be executed in the order indicated under direct visualization using fluoroscopy.

- If greater than usual resistance is felt during delivery system withdrawal, pay particular attention to guide catheter position. In some cases it may be necessary to pull back slightly on the guide catheter in order to prevent deep seating (unplanned advancement) of the guide catheter and subsequent vessel damage. In cases where unplanned guide catheter movement has occurred, angiographic assessment of the coronary tree should be undertaken to ensure that there is no damage to the coronary vasculature.
- Maintain guidewire placement across the lesion during the entire removal process. Carefully pull back the stent system until the proximal balloon marker of the stent system is just distal to the guide catheter distal tip.
- The stent system and the guide catheter should be pulled back as a single unit until the tip of the guide catheter is just distal to the arterial sheath, allowing the guide catheter to straighten. Carefully retract the un-deployed stent into the tip of the guide catheter and remove the stent system and the guide catheter from the patient again as a single unit while leaving the guidewire across the lesion.

Stent System Removal - Post-deployment

- Following stent placement, confirm complete balloon deflation (Table 3., Representative System Deflation Times).
- If greater than usual resistance is felt during delivery system withdrawal, pay particular attention to guide catheter position. In some cases it may be necessary to pull back slightly on the guide catheter in order to prevent deep seating (unplanned advancement) of the guide catheter and subsequent vessel damage. In cases where unplanned guide catheter movement has occurred, angiographic assessment of the coronary tree should be undertaken to ensure that there is no damage to the coronary vasculature.

- If greater than usual resistance is felt during delivery system withdrawal into the guide catheter, the stent system and guide catheter should be removed as a single unit (see note in above section).

Table 3. Representative System Deflation Times (seconds)

Balloon Length / Diameter	8 mm	12 mm	16 mm	20 mm	24 mm	28 mm	32 mm	38 mm
2.25 mm	≤ 16	≤ 16	≤ 16	≤ 16	≤ 16	≤ 16	≤ 16	≤ 21
2.50 mm								
2.75 mm								
3.00 mm					≤ 21	≤ 21	≤ 21	≤ 30
3.50 mm								
4.00 mm				≤ 21				

Post-Procedure

- Care must be exercised when crossing a newly deployed stent with ancillary devices to avoid disrupting the stent placement, apposition, geometry, and/or coating.

If the patient requires Magnetic Resonance Imaging (MRI), see Magnetic Resonance Imaging.

Brachytherapy

The safety and effectiveness of the SYNERGY™ II stent in patients with prior brachytherapy of the target lesion have not been established.

The safety and effectiveness of the use of brachytherapy to treat in-stent restenosis in the SYNERGY II stent has not been established.

Both vascular brachytherapy and the SYNERGY II stent alter arterial remodeling. The interaction, if any, between these two treatments has not been determined.

Magnetic Resonance Imaging (MRI)

Through non-clinical testing, the SYNERGY II stent has been shown to be MR Conditional (poses no known hazards under specified conditions). The conditions are as follows:

- Field strengths of 3.0 and 1.5 Tesla with
  - Static magnetic field gradient < 11 T/m (extrapolated).
  - Product of static magnetic field and static magnetic field gradient < 25 T²/m (extrapolated).
- A calculated rate of change of magnetic field (dB/dt) of 60 T/s or less.
- A maximum whole body averaged specific absorption rate (SAR) of lower than 2.0 W/kg for a total active MR scan time (with RF exposure) of 15 minutes or less. The SYNERGY II stent should not migrate in this MRI environment. MR imaging within these conditions may be performed immediately following the implantation of the stent. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 123 MHz in a 3.0 Tesla Magnetom Trio™, Siemens Medical Solutions MR system, software version Numaris/4, syngo™ MR A30A. The stents were in a location and orientation in the phantom that produced the worst case Radio Frequency (RF) heating. RF power was applied for 15 minutes and the measured conductivity of the phantom material was about 0.49 S/m. The phantom average SAR calculated using calorimetry was 2.3 W/kg. The maximal in-vitro temperature rise was calculated as 2.6°C when the local SAR was scaled to 2.0 W/kg for a measured stent length up to 74 mm. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises: for landmarks at the chest level, the calculated temperature rise was 2.6°C with a calculated uncertainty upper bound temperature of 4.7°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

1.5 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla Intera™ Philips Medical Systems, software version Release 12.6.1.3, 2010-12-02 whole body coil MR scanner. The stents were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes and the measured conductivity of the phantom material was about 0.50 S/m. The phantom average SAR calculated using calorimetry was 2.3 W/kg. The maximal in-vitro temperature rise was calculated as 2.6°C when the local SAR was scaled to 2.0 W/kg for a measured stent length up to 74 mm. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises: for landmarks at the chest level, the calculated temperature rise was 2.6°C with an uncertainty upper bound temperature of 4.8°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

In vivo, local SAR depends on MR Field strength and may be different than the estimated whole body averaged SAR, due to body composition, stent position within the imaging field, and scanner used, thereby affecting the actual temperature rise. No tests have been performed on possible nerve or other tissue stimulation possible to be activated by strong gradient magnetic fields and resulting induced voltages.

Image Artifact Information

The calculated image artifact extends approximately 7 mm from the perimeter of the device diameter and 5 mm beyond each end of the length of the stent when scanned in non-clinical testing using a Spin Echo sequence. With a Gradient Echo sequence the calculated image artifact extends 7 mm beyond the perimeter of the diameter and 6 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Intera (Achieva Upgrade), Philips Medical Solutions, software version Release 2.6.3.5 2009-10-12 MR system with a transmit/receive head coil. This testing was completed using ASTM F2119-07 test method.

Pre- and Post-Procedure Antiplatelet Regimen

The device carries an associated risk of acute, subacute, or late thrombosis, vascular complications, and/or bleeding events. Therefore, the patient should be carefully selected, and a $P2Y_{12}$ inhibitor (i.e., clopidogrel, ticlopidine, prasugrel, or ticagrelor) must be prescribed post procedure to reduce risk of thrombosis. Aspirin must be administered concomitantly with $P2Y_{12}$ inhibitor, and then continued indefinitely to reduce the risk of thrombosis. SYNERGY II is designed with a low initial polymer load, abluminal coating and bioabsorbable polymer which may reduce the risk of thrombosis and the need for prolonged dual antiplatelet therapy. It is strongly advised that the treating physician consider the European Society of Cardiology recommendations (or other applicable country guidelines) for antiplatelet therapy pre– and post–procedure to reduce the risk of thrombosis. In selected patients, it may be reasonable to interrupt or discontinue $P2Y_{12}$ inhibitor therapy after 3 months.

It is very important that the patient be compliant with the post-procedural antiplatelet recommendations. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, myocardial infarction, or death. This should be carefully considered by the treating physicians prior to Percutaneous Coronary Intervention (PCI) for patients who may require premature cessation of antiplatelet therapy, e.g., for surgical or dental procedures. Patients who require premature discontinuation of antiplatelet therapy due to significant active bleeding or the expectation of significant active bleeding should be monitored carefully for cardiac events and once stabilised have their antiplatelet therapy restarted without unnecessary delay.

Drug Interactions

When taken orally, everolimus is extensively metabolized by the cytochrome P4503A4 (CYP3A4) in the gut wall and liver and is a substrate for the countertransporter P-glycoprotein. Therefore, absorption and subsequent elimination of everolimus may be influenced by drugs that affect these pathways. Concurrent treatment with strong 3A4 inhibitors and inducers is not recommended unless the benefits outweigh the risk. Inhibitors of P-glycoprotein may decrease the efflux of everolimus from intestinal cells and increase everolimus blood concentrations. In vitro, everolimus was a competitive inhibitor of CYP3A4 and of CYP2D6, potentially increasing the concentrations of drugs eliminated by these enzymes. Thus, caution should be exercised when coadministering everolimus with 3A4 and 2D6 substrates with a

narrow therapeutic index. Everolimus has also been shown to reduce the clearance of some prescription medications when it was administered orally along with cyclosporine (CsA).

Everolimus, when prescribed as an oral medication, may interact with the following drugs or substances.

Note: The list below describes interactions for orally administrated everolimus at significantly higher doses than are present on the SYNERGY™ II Stent System. Interactions observed at these higher, oral doses may not be relevant to the SYNERGY II Stent System.

- CYP3A4 isozyme inhibitors (ketoconazole, itraconazole, ritonavir, erythromycin, clarithromycin, fluconazole, calcium channel blockers)
- Inducers of CYP3A4 isozyme (rifampicin, rifabutin, carbamazepin, phenobarbital, phenytoin)
- Antibiotics (Ciprofloxacin, ofloxacin)
- Glucocorticoids
- HMGCoA reductase inhibitors (simvastatin, lovastatin)
- Digoxin
- Cisapride (theoretical potential interaction)
- Sildenafil (Viagra™) (theoretical potential interaction)
- Antihistaminics (terfonadine, astemizole)
- Grapefruit juice

Because systemic everolimus levels are below the lower limit of detection in pre-clinical studies after two days, formal drug interaction studies have not been performed with SYNERGY II Stent System. Therefore, due consideration should be given to the potential for both systemic and local drug interactions in the vessel wall when deciding to place the SYNERGY II stent in a subject taking a drug with known interaction with everolimus.

Use in Special Populations:

Pregnancy

This product has not been tested in pregnant women or in men intending to father children; effects on the developing foetus have not been studied. While there is no contraindication, the risks and reproductive effects are unknown. It is not recommended that the SYNERGY II Stent System be used in women attempting to conceive, or who are pregnant.

Use of Multiple Stents

Potential interactions of the SYNERGY II stent with other drug-eluting or coated stents have not been evaluated in vivo. Patients should be treated with no more than 2 planned SYNERGY II stents. Additional stents may be placed if bailout stenting is required. The use of multiple drug-eluting stents will expose the patient to larger amounts of drug and polymer.

When more than one stent is required and results in stent-to-stent contact, stent materials should be of similar composition to avoid the possibility of corrosion due to the presence of dissimilar metals in a conducting medium. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion, though in vitro tests to assess stent-to-stent contact using a platinum chromium alloy stent in combination with a 316L stainless steel or cobalt-chromium alloy stent suggest there is no increased risk of corrosion with this pair. If more than one SYNERGY II stent is needed to cover the lesion, it is suggested that, to avoid the potential for gap restenosis, the stents be adequately overlapped (with a minimum of 2 mm overlap).

Drug Information:

Mechanism of Action

The mechanism by which the SYNERGY II stent inhibits neointimal growth has not been established. At the cellular level, everolimus inhibits growth factor-stimulated cell proliferation. At the molecular level, everolimus forms a complex with the cytoplasmic protein FKBP-12 (FK 506 Binding Protein). This complex binds to and interferes with FRAP (FKBP-12 Rapamycin Associated Protein), also known as mTOR (mammalian Target of Rapamycin), leading to inhibition of cell metabolism, growth and proliferation by arresting the cell cycle at the late G1 stage.

Drug Interactions

See Precautions, Drug Interactions.

Carcinogenicity, Genotoxicity, and Reproductive Toxicology

Carcinogenicity, genotoxicity, and reproductive toxicology of SYNERGY II stent were not evaluated. However, testing has been completed on PROMUS (Xience V™). PROMUS (Xience V) and SYNERGY II use the same drug (everolimus) and release profile. A 26-week carcinogenicity study was conducted to evaluate the carcinogenic potential of PROMUS (Xience V) everolimus-eluting stents following subcutaneous implantation in transgenic mice. During the course of the study, there were no abnormal clinical observations that suggested a carcinogenic effect of the test group PROMUS (Xience V). The test group did not demonstrate an increased incidence of neoplastic lesions when compared to the negative control group. However, the positive control and the experimental positive control groups demonstrated notable increases in the incidence of neoplastic lesions compared to either the test or the negative control group. Based on the results of this study, the PROMUS (Xience V) stent does not appear to be carcinogenic when implanted in transgenic mice for 26 weeks.

In addition, a reproductive toxicity (teratology) study was conducted to demonstrate that implantation of PROMUS (Xience V) stents in female Sprague-Dawley rats does not affect their fertility or reproductive capability and shows a lack of any reproductive toxicity on their offspring. The PROMUS (Xience V) stent did not affect the fertility or reproductive capability of female Sprague-Dawley rats. There was no statistical difference between the test article PROMUS (Xience V) stent and the control system in terms of any of the evaluated parameters. The test article had no effect on litter size and caused no increase of in utero mortality. Additionally, the PROMUS (Xience V) stent did not cause any reproductive toxicity in the offspring in this study.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) which may be associated with the implantation of a coronary stent in a native coronary artery include those risks associated with percutaneous transluminal coronary angioplasty as well as additional risks related to the use of the stent as listed below.

- Abrupt stent closure
- Acute myocardial infarction
- Allergic reaction to anti-coagulant and/or antiplatelet therapy, contrast medium, or stent materials
- Angina
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia
- Arteriovenous fistula
- Bleeding
- Cardiac tamponade
- Cardiogenic shock/pulmonary edema
- Coronary aneurysm
- Death
- Dissection
- Emboli, distal (air, tissue, or thrombotic material or material from device(s) used in the procedure)
- Heart failure
- Hematoma
- Hemorrhage, which may require transfusion
- Hypotension/hypertension
- Infection, local or systemic
- Ischemia, myocardial
- Pain, access site
- Perforation or rupture of coronary artery
- Pericardial effusion
- Pseudoaneurysm, femoral
- Renal insufficiency or failure
- Respiratory failure
- Restenosis of stented segment

- Stent deformation
- Stent embolization or migration
- Stent fracture
- Stent thrombosis/vessel occlusion
- Stroke/cerebrovascular accident/transient ischemic attack
- Total occlusion of coronary artery
- Vessel spasm
- Vessel trauma requiring surgical repair or reintervention

Adverse events associated with daily oral administration of everolimus (or potential adverse events not captured above, that may be unique to the everolimus drug coating):

- Abdominal pain
- Acne
- Allergic/immunologic reaction to drug (everolimus or structurally related compounds) or the polymer stent coating or its individual components (see **Drug Component Description**)
- Anemia
- Coagulopathy
- Diarrhea
- Edema
- Hemolysis
- Hypercholesterolemia
- Hyperlipidemia
- Hypertension
- Hypertriglyceridemia
- Hypogonadism male
- Leukopenia
- Liver function test abnormal
- Lymphocele
- Myalgia/Arthralgia
- Nausea
- Pain
- Pneumonia
- Pyelonephritis
- Rash
- Renal tubular necrosis
- Sepsis
- Surgical wound complication
- Thrombocytopenia
- Urinary tract infection
- Venous thromboembolism
- Viral, bacterial, and fungal infections
- Vomiting
- Wound infection

There may be other potential adverse events that are unforeseen at this time.

HOW SUPPLIED

Non-pyrogenic.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Keep dry and protect from light.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

Store product in outer carton until ready for use.

DO NOT REMOVE FROM FOIL POUCH UNTIL READY TO USE.

THE FOIL POUCH IS NOT A STERILE BARRIER.

Do not store devices where they are directly exposed to organic solvents or ionizing radiation.

The foil pouch contains nitrogen gas (N_2) and desiccant as a storage medium.

OPERATIONAL INSTRUCTIONS

Device Selection

Select device(s) with nominal stent length(s) and diameter(s) appropriate for the lesion.

Inspection Prior to Use

Check foil pouch for "Use By" date. Carefully inspect the foil pouch and the sterile package before opening. Do not use the product after the "Use By" date. If the integrity of the foil pouch or the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package), contact your local Boston Scientific representative for return information. Do not use if any defects are noted.

Material Required (not included in stent system package)

Quantity	Material
1	Guide catheter with ≥ 0.058 in (1.42 mm) inner diameter
2-3	20-mL (cc) syringe
1000 u / 500 cc	Normal heparinised saline
1	≤ 0.014 in (0.36 mm) guidewire
1	Rotating hemostatic valve
1	Diluted contrast medium 1:1 with normal heparinised saline
1	Inflation device (with luer fitting)
1	Torque device (optional)
1	Pre-deployment dilatation catheter
1	Three-way stopcock
1	Appropriate arterial sheath

Preparation

Package Removal

Step	Action
1.	Open the outer box to reveal the foil pouch and carefully inspect the foil pouch for damage.
2.	Carefully open the foil pouch by tearing along the tear strip as indicated on the foil pouch to access the sterile barrier package containing the stent delivery system.
3.	Carefully inspect the sterile barrier package for damage.
4.	Carefully peel open the sterile barrier using aseptic techniques and extract the stent delivery system.
5.	Carefully remove the stent delivery system from its protective tubing for preparation of the delivery system. Do not bend or kink the device during removal.
6.	Remove the product mandrel and stent protector by grasping the catheter just proximal to the stent (at the proximal balloon bond site) and, with the other hand, grasp the stent protector and gently remove distally.
7.	Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
8.	The catheter may be coiled once and secured using the CLIPIT™ Hypotube Clip provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT Hypotube Clip; the CLIPIT Hypotube Clip is not intended for the distal end of the catheter.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the CLIPIT Hypotube Clip.

Guidewire Lumen Flush

Step	Action
1.	Flush stent system guidewire lumen with normal heparinised saline using the flushing needle supplied for the Monorail™ Delivery System at the distal end.
2.	Verify that the stent is positioned between the proximal and distal balloon markers. Check for bends, kinks and other damage. Do not use if any defects are noted.

Note: Use caution while flushing guidewire lumen with flushing needle to avoid damage to catheter tip.

Note: Avoid manipulation of the stent during flushing of the guidewire lumen, as this may disrupt the placement of the stent on the balloon.

Note: Stent contact with any fluid is not recommended as there is a possibility of initiating drug release. However, if it is absolutely necessary to flush the stent with saline, contact time should be limited (1 minute maximum).

Balloon Preparation

Step	Action
1.	Prepare inflation device/syringe with diluted contrast medium.
2.	Attach inflation device/syringe to stopcock; attach to inflation port. Do not bend the hypotube when connecting to inflation device/syringe.
3.	With tip down, orient stent system vertically.
4.	Open stopcock to stent system; pull negative pressure for 15 seconds; release to neutral for contrast fill.
5.	Close stopcock to stent system; purge inflation device/syringe of all air.
6.	Repeat steps 4 through 6 until all air is expelled. If bubbles persist, do not use product.
7.	If a syringe was used, attach a prepared inflation device to stopcock.
8.	Open stopcock to stent system.
9.	Leave on neutral.

Delivery Procedure

Step	Action
1.	Prepare the vascular access site according to standard practice.
2.	Predilate the lesion/vessel with appropriate diameter balloon.
3.	Maintain neutral pressure on inflation device attached to stent system.
4.	Backload stent system onto proximal portion of guidewire while maintaining guidewire position across target lesion.
5.	Fully open rotating hemostatic valve to allow for easy passage of the stent and prevent damage to the stent.
6.	Carefully advance the stent system into the hub of the guide catheter. Be sure to keep the hypotube straight. Ensure guide catheter stability before advancing the stent system into the coronary artery.

Note: If unusual resistance is felt before the stent exits the guide catheter, do not force passage. Resistance may indicate a problem. Use of excessive force may result in stent damage or stent dislodgment from the balloon. Maintain guidewire placement across the lesion, and remove the stent system and guide catheter as a single unit.

7.	Advance the stent system over the guidewire to target lesion under direct fluoroscopic visualisation. Use the proximal and distal radiopaque balloon markers as a reference point. Fully cover the entire lesion and balloon treated area. The stent should adequately cover healthy vessel proximal and distal to the lesion. If the position of the stent is not optimal, it should be carefully repositioned or removed (see also Precautions, Stent System Removal - Pre-deployment). The inside edges of the marker bands indicate both the stent edges and balloon shoulders. Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.

Note: If unusual resistance is felt at any time during lesion access before stent implantation, the stent system and the guide catheter should be removed as a single unit (see also **Precautions, Stent System Removal - Pre-deployment**). Once the stent delivery system has been removed, do not reuse.

8.	Sufficiently tighten the rotating hemostatic valve. The stent is now ready to be deployed.

Deployment Procedure

Step	Action
1.	Inflate the delivery system expanding the stent to a minimum pressure of 11 atm - 1117 kPa. Higher pressure may be necessary to optimise stent apposition to the arterial wall. Accepted practice generally targets an initial deployment pressure that would achieve a stent inner diameter of about 1.1 times the distal reference vessel diameter (see Table 4.). Balloon pressure must not exceed rated burst pressure of 18 atm - 1827 kPa for the 2.25–2.75 mm sizes and 16 atm - 1620 kPa for the 3.00-4.00 mm sizes (see Table 4.).
2.	Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3.	Deflate balloon by pulling negative pressure on inflation device until balloon is fully deflated.
4.	Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stenosed arterial segment should be covered by the stent. Fluoroscopic visualisation during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the artery wall.
5.	If stent sizing/apposition requires optimisation, readvance the stent system balloon, or another high-pressure, non-compliant balloon catheter of the appropriate size, to the stented area using standard angioplasty techniques.
6.	Inflate the balloon to the desired pressure while observing under fluoroscopy. Deflate the balloon (refer to product labeling and/or see Balloon Compliance Chart supplied with device).
7.	If more than one SYNERGY™ II stent is needed to cover the lesion and balloon treated area, it is suggested that, to avoid the potential for gap restenosis, the stents be adequately overlapped. To ensure that there are no gaps between stents, the balloon marker bands of the second SYNERGY II stent should be positioned inside of the deployed stent prior to expansion.
8.	Reconfirm stent position and angiographic result. Repeat inflations until optimal stent deployment is achieved, or remove stent delivery system for larger post-dilatation balloon catheter.

Removal Procedure and Completion

Step	Action
1.	Ensure balloon is fully deflated before delivery system withdrawal.
2.	Fully open rotating hemostatic valve.
3.	While maintaining guidewire position and negative pressure on inflation device, withdraw delivery system.
4.	The Monorail Delivery System may be coiled once and secured using the CLIPIT™ Hypotube Clip (see **Package Removal**).
5.	Repeat angiography to assess the stented area.
6.	If an adequate expansion has not been obtained, exchange back to the original stent delivery catheter or exchange to another balloon catheter of appropriate balloon diameter to achieve proper stent apposition to the vessel wall.

- The stent delivery balloon may be used for post-dilatation up to stent diameters indicated on the compliance chart (Table 4).
- A post-dilatation balloon catheter may be used to expand the stent up to the post-dilatation limits indicated in the following table.

Pre-

Post-Deployment Dilatation of Stented Segments

Precaution: Do not dilate the stent beyond the limit tabulated below.

Nominal Stent Diameter (ID)	Post-Dilatation Limits (ID)*
2.25 mm, 2.50 mm, 2.75 mm	3.50 mm
3.00 mm, 3.50 mm	4.25 mm
4.00 mm	5.75 mm

*Max Stent Inner Diameter

Note: All efforts should be taken to assure that the stent is not underdilated. If the deployed stent size is still inadequate with respect to vessel diameter, or if full contact with the vessel wall is not achieved, a larger post-dilatation balloon catheter may be used to expand the stent further. The balloon should be centered within the stent and should not extend outside of the stented region.

Note: Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent placement, apposition, geometry, and/or coating. If recrossing with a guidewire, the stented segment should be recrossed carefully with a prolapsed tip to avoid dislodging the stent.

7. Complete angiographic confirmation, remove devices, and close vascular access site according to standard practice.

IN VITRO INFORMATION

SYNERGY™ II Stent System Compliance

Table 4. SYNERGY II Compliance Chart

Pressure atm - kPa	Stent I.D. (mm)					
	2.25	2.50	2.75	3.00	3.50	4.00
8 - 814	---	2.35	2.57	2.89	3.30	3.81
9 - 910	2.13	2.42	2.65	2.96	3.40	3.91
10 - 1014	2.19	2.48	2.72	3.02	3.48	3.98
11 - 1117	2.24	2.54	2.79	3.08	3.55	4.06
12 - 1213	2.28	2.59	2.85	3.13	3.61	4.12
13 - 1317	2.31	2.63	2.89	3.17	3.66	4.17
14 - 1420	2.35	2.67	2.93	3.20	3.70	4.22
15 - 1517	2.37	2.70	2.96	3.24	3.74	4.26
16 - 1620	2.40	2.73	3.00	3.27*	3.79*	4.30*
17 - 1724	2.43	2.76	3.03	3.32	3.83	4.36
18 - 1827	2.45*	2.79*	3.06*	3.37	3.87	4.42
19 - 1924	2.48	2.82	3.10	3.43	3.93	4.52
20 - 2027	2.51	2.85	3.13	3.49	3.99	---
21 - 2130	2.54	2.90	3.19	---	---	---
22 - 2227	2.58	2.95	3.23	---	---	---

*Rated Burst Pressure. DO NOT EXCEED
Nominal Pressure = 11.0 atm - 1117 kPa

Pressure atm - kPa	Stent O.D. (mm)					
	2.25	2.50	2.75	3.00	3.50	4.00
8 - 814	---	2.51	2.73	3.05	3.46	3.99
9 - 910	2.29	2.58	2.81	3.12	3.56	4.09
10 - 1014	2.35	2.64	2.88	3.18	3.64	4.16
11 - 1117	2.40	2.70	2.95	3.24	3.71	4.24
12 - 1213	2.44	2.75	3.01	3.29	3.77	4.30
13 - 1317	2.47	2.79	3.05	3.33	3.82	4.35
14 - 1420	2.51	2.83	3.09	3.36	3.86	4.40
15 - 1517	2.53	2.86	3.12	3.40	3.90	4.44
16 - 1620	2.56	2.89	3.16	3.43*	3.95*	4.48*
17 - 1724	2.59	2.92	3.19	3.48	3.99	4.54
18 - 1827	2.61*	2.95*	3.22*	3.53	4.03	4.60
19 - 1924	2.64	2.98	3.26	3.59	4.09	4.70
20 - 2027	2.67	3.01	3.29	3.65	4.15	---
21 - 2130	2.70	3.06	3.35	---	---	---
22 - 2227	2.74	3.11	3.39	---	---	---

*Rated Burst Pressure. DO NOT EXCEED
Nominal Pressure = 11.0 atm - 1117 kPa

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

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CONTENIDO

SYNERGY™
MONORAIL™
Everolimus-Eluting Platinum Chromium Coronary Stent System

2.25mm x 12mm

Sistema de stent coronario de platino-cromo con liberación de everolimus, Système de stent coronaire en alliage platine-chrome à élution d'évérolimus, Everolimus-abgebendes Platin-Chrom-Koronarstentsystem, Sistema di stent coronarico in platino-cromo a rilascio di everolimus, Everolimus eluerend coronaire-stentsysteem van platina-chroom, Everolimus-eluerende platin-krom koronarstentsystem, Σύστημα στεφανιαίου stent πλατίνας-χρωμίου έκλουσης everolimus, Sistema de Stent Coronário de Crómio e Platina com Eluição de Everolimus, Everolimus-eluerande koronarstentsystem i platina-krom, Everolimus-kibocsátó platina-króm szívkoszorúér-sztentrendszer, Systém chrom-platinového koronárního stentu uvolňujícího everolimus, System stentu wieńcowego ze stopu platyny i chromu uwalniający ewerolimus, Everolimus-avgivande koronarstentsystem av platina/krom, Everolimus Salınımlı Platin Krom Koroner Stent Sistemi

Contents (1)

atm - kPa Pressure		2.25mm Stent I.D.	2.25mm Stent O.D.
8 - 810		--	--
9 - 910		2.13	2.29
10 - 1014		2.19	2.35
11 - 1117	NOMINAL	2.24	2.40
12 - 1213		2.28	2.44
13 - 1317		2.31	2.47
14 - 1420		2.35	2.51
15 - 1517		2.37	2.53
16 - 1620		2.40	2.56
17 - 1724		2.43	2.59
18 - 1827	RATED*	2.45	2.61
19 - 1924		2.48	2.64
20 - 2027		2.51	2.67
21 - 2130		2.54	2.70
22 - 2227		2.58	2.74

*Rated Burst Pressure. DO NOT EXCEED.

GW ≤0.014in (0.36mm) Recommended Guidewire
GC ≥5F (0.056in/1.42mm) Recommended Guide Catheter
ID 3.50mm Maximum Stent Inner Diameter
NE (1) Includes Flushing Needle with Luer Fitting
PL Protect from Light
RH Protect from Humidity
See foil pouch and carton label for Use By date.

GTIN	08714729840985	LOT	12345678
REF Catalog No.	H7493926212220	Use By	2010-12-31
30 °C / 15 °C / 25°C Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F).	Do not open foil pouch until ready for use.	STERILE EO Sterilized using ethylene oxide.	MR Magnetic Resonance Conditional

SYNERGY™ MONORAIL™ 2.25 mm 12 mm (01) 2010-12-31

SYNERGY™ MONORAIL™ 2.25 mm 12 mm

Internal BSC Bar Code
90844266-02K

Boston Scientific
SYNERGY™
2.25mm x 12mm
GTIN 08714729840985
REF H7493926212220
LOT 12345678

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LOT 12345678

(01)08714729840985(17)101231(10)12345678 GS1

CE 0344

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

Label Specification Part Number:90844266-02K

แบบ บ.น.พ. ๑

ใบอนุญาตนำเข้าเครื่องมือแพทย์

ใบอนุญาตที่ 64-2-1-2-0005193

ใบอนุญาตฉบับนี้ให้ไว้แก่

บริษัท บอสตัน ไซเอนทิฟิค (ประเทศไทย) จำกัด

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ สน. 152/2554

เพื่อแสดงว่าเป็นผู้รับอนุญาตนำเข้าเครื่องมือแพทย์ตามมาตรา ๑๗ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

SYNERGY MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System

รายละเอียดเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ณ สถานที่นำเข้าเครื่องมือแพทย์ชื่อ**บริษัท บอสตัน ไซเอนทิฟิค (ประเทศไทย) จำกัด**

ตั้งอยู่เลขที่ 98 สาทร สแควร์ ออฟฟิส ทาวเวอร์ ชั้นที่ 29 ห้องเลขที่ 2907-2911

ตรอก/ซอย - ถนน สาทรเหนือ หมู่ที่ -

ตำบล/แขวง สีลม อำเภอ/เขต บางรัก

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10500 โทรศัพท์ 0 2032 1888 โทรสาร 0 2032 1899

ชื่อและที่ตั้งของเจ้าของผลิตภัณฑ์

Boston Scientific Corporation 300 Boston Scientific Way Marlborough MA 01752 USA

ใบอนุญาตนำเข้าฉบับนี้ใช้ได้จนถึงวันที่ 31 ธันวาคม พ.ศ. 2568 และให้ใช้เฉพาะสถานที่ซึ่งระบุไว้ในใบอนุญาตเท่านั้น

ออกให้ ณ วันที่ 19 เดือน ตุลาคม พ.ศ 2564

สำนักงานคณะกรรมการอาหารและยา

กระทรวงสาธารณสุข

ผู้อนุญาต

เอกสารแนบท้าย

ใบอนุญาตนำเข้าที่ 64-2-1-2-0005193

รายละเอียดเครื่องมือแพทย์

มีรายละเอียดรายการเครื่องมือแพทย์ หรืออุปกรณ์เสริม ดังนี้

NEWCODE	ชื่อผลิตภัณฑ์	identifier	บริษัทผู้ผลิต	อื่นๆ
6444045000001	SYNERGY MONORAIL 20mm x 3.50mm	H7493926220350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000004	SYNERGY MONORAIL 16 mm x 5.00 mm	H7493926216500	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000005	SYNERGY MONORAIL 20mm x 2.50mm	H7493926220250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000007	SYNERGY MONORAIL 12 mm x 4.50 mm	H7493926212450	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000009	SYNERGY MONORAIL 28 mm x 5.00 mm	H7493926228500	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000011	SYNERGY MONORAIL 8mm x 2.75mm	H7493926208270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000012	SYNERGY MONORAIL 12mm x 3.50mm	H7493926212350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000013	SYNERGY MONORAIL 38mm x 3.50mm	H7493926238350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000015	SYNERGY MONORAIL 20mm x 2.75mm	H7493926220270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000017	SYNERGY MONORAIL 32 mm x 4.50 mm	H7493926232450	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000021	SYNERGY MONORAIL 48mm x 3.00mm	H7493926248300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000022	SYNERGY MONORAIL 38mm x 2.75mm	H7493926238270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000023	SYNERGY MONORAIL 16mm x 2.25mm	H7493926216220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000025	SYNERGY MONORAIL 8mm x 4.00mm	H7493926208400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000027	SYNERGY MONORAIL 24mm x 2.50mm	H7493926224250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
6444045000031	SYNERGY MONORAIL 12 mm x 5.00 mm	H7493926212500	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000032	SYNERGY MONORAIL 20 mm x 4.50 mm	H7493926220450	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000033	SYNERGY MONORAIL 24mm x 3.50mm	H7493926224350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000036	SYNERGY MONORAIL 28 mm x 4.50 mm	H7493926228450	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000037	SYNERGY MONORAIL 38mm x 2.25mm	H7493926238220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000038	SYNERGY MONORAIL 12mm x 2.75mm	H7493926212270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000042	SYNERGY MONORAIL 38mm x 4.00mm	H7493926238400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000045	SYNERGY MONORAIL 28mm x 3.50mm	H7493926228350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000046	SYNERGY MONORAIL 38mm x 2.50mm	H7493926238250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000047	SYNERGY MONORAIL 16mm x 3.50mm	H7493926216350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000050	SYNERGY MONORAIL 16mm x 2.50mm	H7493926216250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000053	SYNERGY MONORAIL 28mm x 2.25mm	H7493926228220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000056	SYNERGY MONORAIL 32mm x 2.75mm	H7493926232270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000059	SYNERGY MONORAIL 48mm x 3.50mm	H7493926248350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000060	SYNERGY MONORAIL 8mm x 2.50mm	H7493926208250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000064	SYNERGY MONORAIL 32mm x 2.50mm	H7493926232250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000069	SYNERGY MONORAIL 24mm x 2.75mm	H7493926224270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000070	SYNERGY MONORAIL 32 mm x 5.00 mm	H7493926232500	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000073	SYNERGY MONORAIL 12mm x 4.00mm	H7493926212400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000075	SYNERGY MONORAIL 16mm x 3.00mm	H7493926216300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
6444045000078	SYNERGY MONORAIL 16mm x 4.00mm	H7493926216400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000079	SYNERGY MONORAIL 20mm x 2.25mm	H7493926220220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000081	SYNERGY MONORAIL 20mm x 4.00mm	H7493926220400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000082	SYNERGY MONORAIL 32mm x 4.00mm	H7493926232400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000084	SYNERGY MONORAIL 28mm x 2.50mm	H7493926228250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000087	SYNERGY MONORAIL 48mm x 4.00mm	H7493926248400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000089	SYNERGY MONORAIL 24 mm x 5.00 mm	H7493926224500	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000090	SYNERGY MONORAIL 32mm x 3.50mm	H7493926232350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000093	SYNERGY MONORAIL 16 mm x 4.50 mm	H7493926216450	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000095	SYNERGY MONORAIL 12mm x 2.25mm	H7493926212220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000096	SYNERGY MONORAIL 48mm x 2.50mm	H7493926248250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000097	SYNERGY MONORAIL 8mm x 3.50mm	H7493926208350	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000101	SYNERGY MONORAIL 24 mm x 4.50 mm	H7493926224450	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000102	SYNERGY MONORAIL 28mm x 3.00mm	H7493926228300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000106	SYNERGY MONORAIL 24mm x 3.00mm	H7493926224300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000107	SYNERGY MONORAIL 24mm x 4.00mm	H7493926224400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000108	SYNERGY MONORAIL 32mm x 2.25mm	H7493926232220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000110	SYNERGY MONORAIL 8mm x 2.25mm	H7493926208220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000111	SYNERGY MONORAIL 8mm x 3.00mm	H7493926208300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000115	SYNERGY MONORAIL 38mm x 3.00mm	H7493926238300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000116	SYNERGY MONORAIL 12mm x 3.00mm	H7493926212300		

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
			BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000118	SYNERGY MONORAIL 20 mm x 5.00 mm	H7493926220500	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000119	SYNERGY MONORAIL 24mm x 2.25mm	H7493926224220	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000121	SYNERGY MONORAIL 28mm x 2.75mm	H7493926228270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000122	SYNERGY MONORAIL 12mm x 2.50mm	H7493926212250	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000124	SYNERGY MONORAIL 32mm x 3.00mm	H7493926232300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000125	SYNERGY MONORAIL 48mm x 2.75 mm	H7493926248270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000128	SYNERGY MONORAIL 16mm x 2.75mm	H7493926216270	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000129	SYNERGY MONORAIL 20mm x 3.00mm	H7493926220300	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-
6444045000130	SYNERGY MONORAIL 28mm x 4.00mm	H7493926228400	BOSTON SCIENTIFIC LIMITED (IRELAND) Ballybrit Business Park Galway IRL	-

EC DESIGN-EXAMINATION CERTIFICATE

Number: 3812454DE32

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough, MA 01752
United States Of America

For the product

SYNERGY™ MONORAIL™ and SYNERGY MEGATRON™ MONORAIL™
Everolimus-Eluting Platinum Chromium Coronary Stent System

Documents, that form the basis of this certificate:

Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 1 July 2014

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 1 July 2014
Revised: 23 September 2019
Reissued: 15 April 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3812454DE32

EC DESIGN-EXAMINATION
MEDICAL DEVICES

SYNERGY™ MONORAIL™ and SYNERGY MEGATRON™ MONORAIL™
Everolimus-Eluting Platinum Chromium Coronary Stent System

Issued to:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States Of America

This certificate covers the following product(s):

Name	Models	Diameters	Lengths
SYNERGY™ MONORAIL™	SV	2.25 mm	8mm to 38 mm
SYNERGY™ MONORAIL™	SV	2.50 mm	8mm to 48 mm
SYNERGY™ MONORAIL™	SV	2.75 mm	8mm to 48 mm
SYNERGY™ MONORAIL™	WH	3.00 mm	8mm to 48 mm
SYNERGY™ MONORAIL™	WH	3.50 mm	8mm to 48 mm
SYNERGY™ MONORAIL™	LV	4.00 mm	8mm to 48 mm
SYNERGY™ MONORAIL™	LV	4.50 mm	12 mm to 32 mm
SYNERGY™ MONORAIL™	LV	5.00 mm	12 mm to 32 mm
SYNERGY MEGATRON™ MONORAIL™	XLV	3.50 mm	8 mm to 32 mm
SYNERGY MEGATRON™ MONORAIL™	XLV	4.00 mm	8 mm to 32 mm
SYNERGY MEGATRON™ MONORAIL™	XLV	4.50 mm	8 mm to 32 mm
SYNERGY MEGATRON™ MONORAIL™	XLV	5.00 mm	8 mm to 32 mm

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3812454DE32

EC DESIGN-EXAMINATION
MEDICAL DEVICES

SYNERGY™ MONORAIL™ and SYNERGY MEGATRON™ MONORAIL™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Issued to:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States Of America

Initial date: 1 July 2014
Revision date: 3 April 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

Boston Scientific

ประเทศไทย

บริษัท บอสตัน ไซเอนทิฟิค (ประเทศไทย) จำกัด (สำนักงานใหญ่)
เลขที่ 98 สาทร สแควร์ ออฟฟิส ทาวเวอร์ ชั้นที่ 29
ห้องเลขที่ 2907-2911 ถนนสาทรเหนือ แขวงสีลม
เขตบางรัก กรุงเทพฯ 10500
โทรศัพท์ : 02 032 1888
โทรสาร : 02 032 1899
www.bostonscientific.com

วันที่ 1 มิถุนายน พ.ศ. 2566

เรียน ผู้เกี่ยวข้อง
เรื่อง รับรองการเป็นตัวแทนจำหน่าย

หนังสือฉบับนี้ เป็นการรับรองว่า บริษัท พีทูพีเฮลแคร์ จำกัด สำนักงานตั้งอยู่เลขที่ 21/264 ซอยบรมราชชนนี 115/1 แขวงศาลาธรรมสพน์ เขตทวีวัฒนา กรุงเทพมหานคร 10170 ได้รับการแต่งตั้งจาก บริษัท บอสตัน ไซเอนทิฟิค (ประเทศไทย) จำกัด ให้เป็นตัวแทนจำหน่ายผลิตภัณฑ์ ภายใต้ชื่อผลิตภัณฑ์ยี่ห้อ BOSTON SCIENTIFIC แต่เพียงผู้เดียว ในประเทศไทย โดยมีรายละเอียดผลิตภัณฑ์ ดังนี้

- ROTALINK BURR
- ROTA WIRE (FLOPPY OR EXTRA SUPPORT)
- NC EMERGE
- PROMUS PREMIER
- OPTICROSS OR OPTICROSS HD
- FLEXTOME
- GUIDEZILLA II
- ACURATE NEO2 AORTIC VALVE
- SLED PULLBACK
- PROMUS ELITE
- ENCORE 26
- ROTAPRO CONSOLE
- SYNERGY MEGATRON
- SENTINEL CEREBRAL PROTECTION SYSTEM
- ROTALINK ADVANCER
- EMERGE
- PROMUS ELEMENT PLUS
- SYNERGY II / SYNERGY XD
- COMET PRESSURE WIRE
- IMPULSE
- LOTUS
- WATCHMAN
- SENTAI GUIDEWIRE FAMILY
- WOLVERINE
- ROTAPRO
- AGENT
- SAFARI2

ขอแสดงความนับถือ
บริษัท บอสตัน ไซเอนทิฟิค (ประเทศไทย) จำกัด

(นางสาวพิลาศลักษณ์ สมุทวนิช)
กรรมการผู้จัดการ

บริษัท พีทูพีเฮลธ์แคร์ จำกัด

สำนักงานใหญ่ : 21/264 ซอยบรมราชชนนี 115/1 แขวงศาลาธรรมสพน์ เขตทวีวัฒนา กรุงเทพฯ 10170
โทร. 0-2405-4863 เลขประจำตัวผู้เสียภาษีอากร 0 1055 62090 40 5

วันที่ 10 เดือน สิงหาคม พ.ศ. 2565

เรื่อง ยืนยันการเป็นตัวแทนจำหน่าย

เรียน คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

บริษัท พีทูพีเฮลธ์แคร์ จำกัด ขอยืนยันว่าบริษัท ฯ ได้รับแต่งตั้งจาก บริษัท บอสตัน ไซเอนทิฟิค (ประเทศไทย) จำกัด ให้เป็นผู้แทนจำหน่ายผลิตภัณฑ์ของ บริษัท บอสตัน ไซเอนทิฟิค (ประเทศไทย) จำกัด

จึงเรียนมาเพื่อทราบ

ขอแสดงความนับถือ
บริษัท พีทูพีเฮลธ์แคร์ จำกัด

นางสาวอรนุช ราษฎร์เหนือ
ผู้รับมอบอำนาจ

ข้อกำหนดและเงื่อนไขเงินฝากออมทรัพย์ Terms and Conditions of Savings Deposit

1. [illegible] This passbook is required when contacting our bank
2. [illegible] This contains only an accounting passbook. The balance shown herein will not be deemed correct unless verified by the corresponding balance shown in the account kept by and at our bank
3. [illegible] The right to funds in this deposit account/passbook is not transferable, nor can it be used as security for a third party **unless written consent is given by the Bank**. The **depositor** may not make any changes on, or tear any pages off of, this passbook
4. [illegible] For withdrawals from this account or the closing of it at any branch, please show proper identification
5. [illegible] In case of loss of this passbook, the account owner must file a police report and notify our bank in writing or via the channels specified at the branch where the account was opened
6. [illegible] An account that has been dormant and has not maintained a minimum balance as specified by our bank will be closed, and/or be subject to a maintenance fee at the rate and in the manner prescribed by our bank

0951004-3-19 (120 ร.) สอบถามข้อมูลเพิ่มเติม K-Contact Center 02-8888888 หรือ www.kasikornbank.com

ธนาคารกสิกรไทย KASIKORNBANK

สำนักงาน OFFICE: สาขา เซ็นทรัล ปิ่นเกล้า

เลขที่บัญชี A/C NO.: 058-3-68091-8

ชื่อ NAME

บจก. ทีทูที เฮลธ์แคร์

เงินฝากที่ได้รับความคุ้มครองจากสถาบันคุ้มครองเงินฝากตามจำนวนที่กำหนดไว้ในกฎหมาย

สาขาผู้ให้บริการ 0758 K0562254 84701271

บัญชีเงินฝากออมทรัพย์

ธนาคารไม่มีนโยบายรับฝากสมุดบัญชีทุกประเภทของลูกค้า