Boston Scientific

# SYNERGY™ SHIELD

**MONORAIL™**

Everolimus-Eluting Platinum Chromium Coronary Stent System


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# SYNERGY™ SHIELD

**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.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

**REUSE WARNING**

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.

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.

**DEVICE DESCRIPTION**

The SYNERGY SHIELD Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY SHIELD 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 SHIELD 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 SHIELD Stent System are described in Table 1. SYNERGY SHIELD Stent System Product Description.

**Table 1. SYNERGY SHIELD Stent System Product Description**

| Characteristic | SYNERGY SHIELD Stent System |
|---|---|
| Available Stent Lengths (mm) | 8, 12, 16, 20, 24, 28, 32, 38, 48* |
| Available Stent Diameters (mm) | 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50** and 5.00** |
| 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 $mm^2$ of total stent surface area and a maximum nominal polymer content of 444 µg and drug content of 364 µg on the largest stent (4.00 mm x 48 mm) |
| Delivery System Effective Length | 144 cm |
| Delivery System Port | Single access port to inflation lumen.<br>Guidewire exit port is located approximately 26 cm from tip.<br>Designed for guidewire ≤ 0.014 in (0.36 mm). |
| Average Stent Length Change Upon Deployment at Nominal Diameter | Small Vessel (SV) average: -0.10 mm<br>Workhorse (WH) average: -0.20 mm<br>Large Vessel (LV) average: 0.20 mm |
| Stent Delivery Balloon | A 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)<br>Rated burst pressure:<br>2.25 mm - 2.75 mm: 18 atm (1827 kPa)<br>3.00 mm - 5.00 mm: 16 atm (1620 kPa) |
| Guide Catheter Compatibility (ID) | 2.25 mm - 4.00 mm ≥ 5F (0.056 inches/1.42 mm)<br>4.50 mm - 5.00 mm ≥ 6F (0.070 inches/1.78 mm) |
| Catheter Shaft Outer Diameter | Proximal: 2.1F (0.70 mm)<br>Distal:<br>2.25 mm - 2.75 mm: 2.6F (0.89mm)<br>3.00 mm:<br>• 8 mm - 28 mm: 2.6F (0.89 mm)<br>• 32 mm - 48 mm: 2.7F (0.92 mm)<br>3.50 mm:<br>• 8 mm - 20 mm: 2.6F (0.89 mm)<br>• 24 mm - 48 mm: 2.7F (0.92 mm)<br>4.00 mm - 5.00 mm: 2.7F (0.92 mm) |
| Stent Strut Thickness | 2.25 mm - 2.75 mm: 0.074 mm<br>3.00 mm - 3.50 mm: 0.079 mm<br>4.00 mm - 5.00 mm: 0.081 mm |

*The 48 mm length is not available in 2.25 mm, 4.50 mm, or 5.00 mm diameters.

**The 4.50 mm and 5.00 mm diameter is not available in 8 mm, 38 mm, or 48 mm lengths.

**Device Component Description**

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

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

- Small Vessel (SV): 2.25 mm, 2.50 mm and 2.75 mm
- Workhorse (WH): 3.00 mm and 3.50 mm
- Large Vessel (LV): 4.00 mm, 4.50 mm and 5.00 mm

**Contents**

| Quantity | Material |
|---|---|
| One (1) | SYNERGY SHIELD Stent System |

**Drug-Eluting Coating Description**

The SYNERGY SHIELD 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 SHIELD Stent.

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

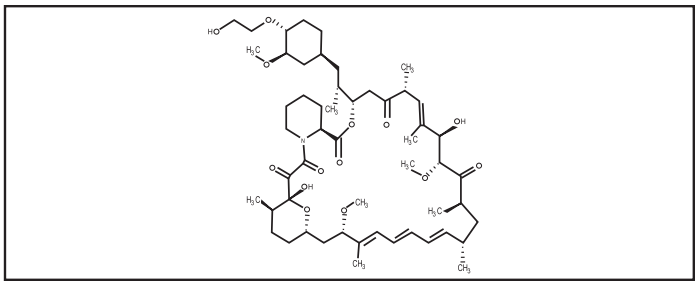

**Figure 1. The Chemical Structure of Everolimus**

**Polymer Carrier**

The SYNERGY SHIELD 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.

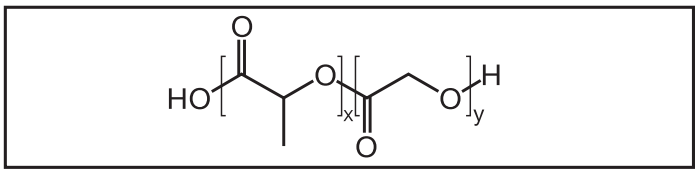

**Figure 2. The Chemical Structure of PLGA**

**Operating Principle**

The vascular access site is prepared according to standard practice and the lesion is then prepared, for example with a pre-dilation catheter.

The SYNERGY SHIELD device is prepared and the proximal end of the guidewire is inserted through the distal tip. The distal section of the SYNERGY SHIELD device is dual lumen and coaxial - the inner lumen is the guidewire lumen for the delivery system and the outer lumen is used for inflation and deflation of the balloon. The delivery system is advanced over the guidewire and through a guide catheter to the target lesion. The location of the balloon and stent is monitored using fluoroscopy via the radiopaque stent component and marker bands.

When the target lesion is reached, the balloon is expanded using an inflation device to deploy the drug-coated stent. The inflation device is attached to the manifold port via a stopcock. Diluted contrast media passes through the manifold and single-lumen hypotube to the distal section of the delivery system. Once the stent is deployed, the delivery system with deflated balloon is retrieved back through the guide catheter and over the guidewire. Stent apposition is assessed using intravascular imaging and post-dilation is completed if required.

The abluminal stent polymer coating elutes the Everolimus drug for the purpose of limiting restenosis which could occur as the tissue responds to the newly placed stent. After the drug is eluted and the polymer is absorbed, the stent scaffold remains, providing long-term mechanical support to the vessel.

**Materials**

The SYNERGY SHIELD Stent is comprised of a platinum chromium stent platform with an everolimus drug and polymer coating (approximately 1 µg of everolimus per $mm^2$ of total stent surface area and a maximum nominal polymer content of 444 µg and drug content of 364 µg on the largest stent (4.00 mm x 48 mm)).

The stent implant composition includes the following materials - patients with known hypersensitivity to these materials may suffer an allergic reaction to this implant as described in the **Warnings** section:

Platinum: 33 %

Chromium: 18 %

Iron: 37 %

Nickel: 9 %

Molybdenum: 2.63 %

The delivery catheter is comprised of a proximal stainless steel hypotube and hydrophilic coated distal polymer shaft. The distal portion of the catheter has two platinum iridium marker bands for radiopacity. SYNERGY SHIELD has a polymer inner component and polymer balloon.

Contains cobalt: The stainless steel hypotube is a metal alloy that contains cobalt (CAS No. 7440-48-4; EN No. 231-158-0, which is defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1 % weight by weight). Current scientific evidence supports that metal alloys containing cobalt used in medical devices, do not cause an increased risk of cancer or adverse reproductive effects.

**Non-Pyrogenic**

SYNERGY SHIELD Everolimus-Eluting Platinum Chromium Coronary Stent System is sterile, non-pyrogenic in unopened, undamaged packaging.

**User Information**

Only physicians who are experienced in percutaneous coronary interventions should perform implantation of the stent.

**Product Matrix**

**Table 2. SYNERGY SHIELD Stent System Product Matrix and Everolimus Content**

| UPN Number | Nominal Expanded Inner Diameter (mm) | Nominal Unexpanded Stent Length (mm) | Nominal Everolimus Content (µg) |
|---|---|---|---|
| H7493966608220 | 2.25 | 8 | 38.9 |
| H7493966608250 | 2.50 | 8 | 38.9 |
| H7493966608270 | 2.75 | 8 | 38.9 |
| H7493966608300 | 3.00 | 8 | 46.5 |
| H7493966608350 | 3.50 | 8 | 46.5 |
| H7493966608400 | 4.00 | 8 | 67.5 |
| H7493966612220 | 2.25 | 12 | 58.3 |
| H7493966612250 | 2.50 | 12 | 58.3 |
| H7493966612270 | 2.75 | 12 | 58.3 |
| H7493966612300 | 3.00 | 12 | 66.3 |
| H7493966612350 | 3.50 | 12 | 66.3 |
| H7493966612400 | 4.00 | 12 | 96.2 |
| H7493966612450 | 4.50 | 12 | 96.2 |
| H7493966612500 | 5.00 | 12 | 96.2 |
| H7493966616220 | 2.25 | 16 | 77.6 |
| H7493966616250 | 2.50 | 16 | 77.6 |
| H7493966616270 | 2.75 | 16 | 77.6 |
| H7493966616300 | 3.00 | 16 | 92.7 |
| H7493966616350 | 3.50 | 16 | 92.7 |
| H7493966616400 | 4.00 | 16 | 124.8 |
| H7493966616450 | 4.50 | 16 | 124.8 |

| UPN Number | Nominal Expanded Inner Diameter (mm) | Nominal Unexpanded Stent Length (mm) | Nominal Everolimus Content (µg) |
|---|---|---|---|
| H7493966616500 | 5.00 | 16 | 124.8 |
| H7493966620220 | 2.25 | 20 | 96.9 |
| H7493966620250 | 2.50 | 20 | 96.9 |
| H7493966620270 | 2.75 | 20 | 96.9 |
| H7493966620300 | 3.00 | 20 | 112.5 |
| H7493966620350 | 3.50 | 20 | 112.5 |
| H7493966620400 | 4.00 | 20 | 153.5 |
| H7493966620450 | 4.50 | 20 | 153.5 |
| H7493966620500 | 5.00 | 20 | 153.5 |
| H7493966624220 | 2.25 | 24 | 121.1 |
| H7493966624250 | 2.50 | 24 | 121.1 |
| H7493966624270 | 2.75 | 24 | 121.1 |
| H7493966624300 | 3.00 | 24 | 132.3 |
| H7493966624350 | 3.50 | 24 | 132.3 |
| H7493966624400 | 4.00 | 24 | 182.2 |
| H7493966624450 | 4.50 | 24 | 182.2 |
| H7493966624500 | 5.00 | 24 | 182.2 |
| H7493966628220 | 2.25 | 28 | 140.5 |
| H7493966628250 | 2.50 | 28 | 140.5 |
| H7493966628270 | 2.75 | 28 | 140.5 |
| H7493966628300 | 3.00 | 28 | 158.7 |
| H7493966628350 | 3.50 | 28 | 158.7 |
| H7493966628400 | 4.00 | 28 | 210.8 |
| H7493966628450 | 4.50 | 28 | 210.8 |
| H7493966628500 | 5.00 | 28 | 210.8 |
| H7493966632220 | 2.25 | 32 | 159.8 |
| H7493966632250 | 2.50 | 32 | 159.8 |
| H7493966632270 | 2.75 | 32 | 159.8 |
| H7493966632300 | 3.00 | 32 | 178.5 |
| H7493966632350 | 3.50 | 32 | 178.5 |
| H7493966632400 | 4.00 | 32 | 239.5 |
| H7493966632450 | 4.50 | 32 | 239.5 |
| H7493966632500 | 5.00 | 32 | 239.5 |
| H7493966638220 | 2.25 | 38 | 188.9 |
| H7493966638250 | 2.50 | 38 | 188.9 |
| H7493966638270 | 2.75 | 38 | 188.9 |
| H7493966638300 | 3.00 | 38 | 211.6 |
| H7493966638350 | 3.50 | 38 | 211.6 |
| H7493966638400 | 4.00 | 38 | 287.2 |
| H7493966648250 | 2.50 | 48 | 237.2 |
| H7493966648270 | 2.75 | 48 | 237.2 |
| H7493966648300 | 3.00 | 48 | 271.0 |
| H7493966648350 | 3.50 | 48 | 271.0 |
| H7493966648400 | 4.00 | 48 | 363.6 |

**INTENDED USE/ INDICATIONS FOR USE**

The SYNERGY SHIELD Stent System is intended to improve luminal diameter in native coronary arteries with discrete, de novo stenosis in patients with symptomatic ischemic heart disease; including those with acute coronary syndromes (acute myocardial infarction and unstable angina), diabetes mellitus, renal failure or who are at a high risk of bleeding.

The SYNERGY SHIELD Stent System is also indicated for use in the following coronary lesion types:

- Bifurcation
- Ostial
- Unprotected left main
- Total occlusion
- In-stent restenosis
- Saphenous vein graft
- Multi-vessel disease

The treated lesion length should be less than the nominal stent length with a reference vessel diameter of 2.25 mm - 5.00 mm

**Clinical Benefit Statement**

The clinical benefit of the SYNERGY SHIELD Stent System is sustained improvement of myocardial perfusion as a result of improved luminal diameter in coronary arteries.

**Summary of Safety and Clinical Performance**

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed).

**CONTRAINDICATIONS**

Use of the SYNERGY SHIELD 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 SHIELD Stent placement procedure.

Coronary artery stenting is contraindicated for use in the following:

- Patients who cannot receive recommended antiplatelet 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 stainless steel, platinum, chromium, iron, nickel or molybdenum, may suffer an allergic reaction to this implant.

**PRECAUTIONS**

**General Precautions**

- Only physicians who are experienced in percutaneous coronary interventions should perform implantation of the stent.
- Stent placement should only be performed at medical facilities where emergency open-heart surgery is readily available.
- The Heart Team, potentially made up of clinical or non-invasive cardiologists, cardiac surgeons and interventional cardiologists, can be utilized to provide a balanced, multidisciplinary decision-making process on optimal patient care for complex pathologies in accordance with current ESC and/or other local guidelines.
- Potential interactions of the SYNERGY SHIELD Stent with other drug-eluting or coated stents have not been evaluated.
- Subsequent restenosis may require repeat dilation of the arterial segment containing the stent. The long-term outcome following repeat dilation 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. Ensure balloon is fully deflated before delivery system withdrawal. Larger and longer balloons will take more time to deflate than smaller and shorter balloons. Allow adequate time, at least 30 seconds, for complete balloon deflation. Before withdrawing the stent delivery system visually confirm complete balloon deflation using fluoroscopy. Failure to do so may cause increased SDS withdrawal forces and result in guide catheter movement into the vessel and subsequent arterial damage.
- Physicians should consider reference vessel diameter taper when choosing a long stent.
- Used devices may pose a biohazard risk and must be handled and disposed of properly.

**Stent System Handling (also see, Operational Instructions)**

- Note product "Use By" date and do not use after the "Use By" date.
- The SYNERGY SHIELD 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 dilation catheter to verify proper function.
- Excessive handling can cause catheter damage such as delivery system kinking, shaft rupture or separation which may necessitate additional procedures. Do not bend or kink the device during removal from the packaging.
- 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.
- Improper handling before or during deployment, or interaction with ancillary intravascular devices or subsequent intravascular procedures may lead to stent deformation, collapse, fracture, or device separation. Stent deformation, collapse, fracture, or separation may potentially result in embolization/migration, vessel injury, restenosis, or stent thrombosis. Use caution to avoid stent damage during and after implantation.
- 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 SHIELD Stent is not expanded, 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**

- PREPARE THE BALLOON PRIOR TO STENT DEPLOYMENT AS DIRECTED. DO NOT PRE-INFLATE THE BALLOON PRIOR TO STENT DEPLOYMENT. 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, see **Precautions, Stent System Removal - Pre-deployment for directions**.
- An unexpanded stent should be introduced into the coronary arteries **one time only**. An unexpanded stent should not be used after being moved in and out through the distal end of the guide catheter as stent or coating damage or stent dislodgment from the delivery balloon may occur.

**Placement**

- The target lesion 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 3. SYNERGY SHIELD 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, taking into consideration vessel taper.
- Placement of the stent has the potential to compromise neighboring side branch patency.
- Stent implantation may cause dissection of the vessel distal and/or proximal to the stented portion which may lead to acute vessel closure requiring additional intervention (e.g. further dilation, placement of additional stents, or coronary artery bypass grafting (CABG) surgery).
- When treating multiple lesions in the same vessel, the distal lesion should 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 stent dislodgment or deformation.
- When treating coronary bifurcation lesions, care must be exercised to access the secondary vessel via the repeating open cells in the body of the stent within the primary vessel.

**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 for instructions on this removal method).
- Retraction of an unexpanded stent back into the guide catheter could result in stent or coating damage or stent dislodgment from the balloon. If retraction of the unexpanded stent back into the guide catheter is required, ensure that the guide catheter is coaxially aligned with the stent system and cautiously withdraw the stent system into the guide catheter using direct fluoroscopic visualization.

- Stent retrieval methods (use of additional wires, snares, and/or forceps) may result in additional trauma to the vascular access 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 proximal coronary tree should be undertaken to ensure 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. Ensure balloon is fully deflated before delivery system withdrawal.

**Note:** Larger and longer balloons will take more time to deflate than smaller and shorter balloons. Allow adequate time, at least 30 seconds, for balloon deflation. Before withdrawing the stent delivery system visually confirm complete balloon deflation 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 there is no damage to the coronary vasculature.
- If greater than usual resistance is felt during delivery system withdrawal into the guide catheter, see **Precautions, Stent System Removal - Pre-deployment for directions**.

**Post-Procedure**

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

**Brachytherapy**

- The safety and effectiveness of the SYNERGY SHIELD 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 SHIELD Stent has not been established.

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

**Magnetic Resonance Imaging (MRI) Safety Information**

Non-clinical testing has demonstrated that the SYNERGY Shield 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. Failure to follow these conditions may result in injury to the patient. If information about a specific parameter is not included, there are no conditions associated with that parameter.

- Static magnetic field of 3.0 Tesla 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)
- Scanner Type: Horizonal, Cylindrical bore
- Maximum gradient slew rate per axis [T/m/s]: max. 80 mT/m/ms (1.5 T), 200 mT/m/ms (3.0 T)
- RF Excitation: CP (Circular Polarization) 90
- RF Transmit/ Receive Coil Type: Integrated Whole-Body Transmit/Receive Coil
- Scan Duration: Up to 15 minutes of continuous RF (a sequence or back-to-back series scan without breaks), followed by 5 minutes of cooling.

Under the scan conditions defined above, the SYNERGY Shield 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.

**Individualization of Patient Treatment**

The SYNERGY SHIELD Stent is designed with an abluminal coating and low initial bioabsorbable polymer load which may reduce the risk of thrombosis and the need for prolonged dual antiplatelet therapy (DAPT). However, the device still carries an associated risk of acute, sub-acute or late thrombosis, vascular complications, and/or bleeding events. Therefore, patients should be carefully selected, and appropriate antithrombotic and dual antiplatelet therapy are required during the procedure. Post-procedure, antiplatelet therapy consistent with the standard of care is required, taking into account patient factors such as bleeding risk, acuity of presentation, medication tolerance, and any other relevant patient characteristics.

Physicians should use the information from the large body of clinical evidence for everolimus-eluting stents, coupled with current literature on drug-eluting stents, current European Society of Cardiology recommendation (or other applicable country guidelines) and the specific needs of the individual patient to determine the specific antiplatelet/anticoagulation regimen to be used for their patients in general practice.

It is very important that the patient be compliant with all post-procedural antiplatelet medications prescribed by their physician.

**Use in High Bleeding Risk Patients**

In selected higher risk patients where the physician determines that the risks outweigh the benefits of continued DAPT, it may be reasonable to interrupt or discontinue therapy after 1 month of DAPT based on the low stent thrombosis rates and no observed increased risk of stent thrombosis demonstrated in the current literature. Patients who require premature discontinuation of antiplatelet therapy should be monitored closely and have their antiplatelet therapy restarted as soon as possible per the discretion of their treating physician.

SYNERGY SHIELD Stent can be used with acceptable safety in patients with recommended shorter DAPT treatment post stent implantation due to high risk of bleeding after careful consideration and risk benefit discussion with the patient. While global definitions of High Bleeding Risk are not present, the 2017 European Society of Cardiology (ESC) focused update on DAPT in coronary artery disease developed in collaboration with European Association for Cardio-Thoracic Surgery (EACTS) provides guidance on validated risk scores for DAPT decision-making. Risk scores consider hemoglobin, white blood count, age (>75), renal function and history of prior bleeding.

**Drug Interactions**

Possible interactions of everolimus from SYNERGY SHIELD Stent System with concomitantly administered medications have not been formally investigated. Drug interactions of systemic therapeutic levels of everolimus with possible concomitant medications are outlined in the labeling for finished pharmaceuticals containing everolimus, such as Afinitor™ or Certican™. Given that the amount of everolimus loaded onto each SYNERGY SHIELD Stent is 4-55 times lower than the daily dose used in transplant and cancer patients and systemic everolimus levels are below the limit of detection in preclinical studies after two days, drug interactions are unlikely to be detectable. This is reinforced since systemic levels of everolimus were found to be close to or below limit of quantitation of 0.2 ng/ml beyond 48 hours post-stent placement in clinical trials.

**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 fetus have not been studied. While there is no contraindication, the risks and reproductive effects are unknown. It is not recommended that the SYNERGY SHIELD Stent System be used in women attempting to conceive, or who are pregnant.

**Use of Multiple Stents**

Potential interactions of the SYNERGY SHIELD 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 SHIELD 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 SHIELD 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**

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. The mechanism by which the SYNERGY SHIELD Stent inhibits neointimal growth has not been established.

**Drug Interactions**

See **Precautions, Drug Interactions.**

**Carcinogenicity, Genotoxicity, and Reproductive Toxicity**

The SYNERGY SHIELD Stent was found to be non-genotoxic in both in vitro and in vivo genotoxicity tests. Carcinogenicity and reproductive toxicity of SYNERGY SHIELD Stent were not evaluated. However, testing has been completed on PROMUS™ (Xience V™). PROMUS (Xience V) and SYNERGY SHIELD 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 coronary vessel include those risks associated with percutaneous transluminal coronary angioplasty as well as additional risks related to the use of the stent as listed below.

- Allergic or adverse reaction (including medications, anesthesia, contrast, or device materials)
- Angina
- Arrhythmias, including ventricular fibrillation, ventricular tachycardia and heart block
- Bleeding including hemorrhage or hematoma (possibly requiring transfusion or additional intervention)
- Cardiac failure leading to low cardiac output (cardiogenic shock) or pulmonary edema
- Death
- Emboli (including air, tissue, thrombus, or device materials)
- Fever and pyrogen reaction
- Heart failure
- Hypotension/hypertension
- Infection, local or systemic
- Myocardial infarction
- Pain or inflammation
- Pericarditis, pericardial effusion, or tamponade
- Radiation injury
- Renal insufficiency or failure
- Respiratory insufficiency or failure
- Restenosis or late acquired malapposition of treated segment
- Stent placement issues including geographic miss, malapposition, migration, or embolization
- Stent thrombosis / vessel occlusion
- Stroke/cerebrovascular accident/transient ischemic attack
- Vessel injury (including access-site) such as spasm, lymphatic problems, pseudoaneurysm, arteriovenous fistula, trauma, dissection, occlusion, perforation, and rupture

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) can be found in the labeling for finished pharmaceuticals containing everolimus, such as Afinitor or Certican

**HOW SUPPLIED**

**Device Details**

The SYNERGY SHIELD Stent System is supplied:

- Sterile, using an ethylene oxide (EO) process.
- Non-pyrogenic in unopened, undamaged packaging.

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

If damage is found, call your Boston Scientific representative.

**Handling and Storage**

Keep dry and protect from light.

Recommended Storage 25ºC (77ºF);

excursions permitted to 15ºC - 30ºC

Store product in outer carton until ready for use.

DO NOT REMOVE FROM FOIL POUCH UNTIL READY FOR 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 ($N_2$) 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. Do not use the product after the ``Use By'' date. Carefully inspect the foil pouch and the sterile package before opening. 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.

**Additional Items for Safe Use (not included in stent system package)**

| Quantity | Material |
|---|---|
| 1 | Appropriate guide catheter (see Table 1. SYNERGY SHIELD Stent System Product Description) |
| 2-3 | 20-mL (cc) syringe |
| 1000 u/500 cc | Heparinized normal saline |
| 1 | ≤ 0.014 in (0.36 mm) guidewire |
| 1 | Rotating hemostatic valve |
| 1 | Diluted contrast medium 1:1 with heparinized normal saline |
| 1 | Inflation device (with luer fitting) |
| 1 | Torque device (optional) |
| 1 | Pre-deployment dilation 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 protector, and with the other hand, grasp the distal end of the stent protector and gently remove.
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.

**Guidewire Lumen Flush**

**Step Action**

1. Flush stent system guidewire lumen with heparinized normal saline 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 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 or soak the stent with sterile/isotonic saline, contact time should be limited (1 minute maximum).

**Procedure**

**Balloon Preparation**

**Step Action**

1. Prepare inflation device/syringe with diluted contrast medium.
2. For treatment of occluded vessels, contrast visualization of the distal vessel to confirm position of guidewire within the lumen is recommended.
3. Attach inflation device/syringe to stopcock; attach to inflation port. Do not bend the hypotube when connecting to inflation device/syringe.
4. With tip down, orient stent system vertically.
5. Open stopcock to stent system; pull negative pressure for 15 seconds; release to neutral for contrast fill.
6. Close stopcock to stent system; purge inflation device/syringe of all air.
7. Repeat steps 5 through 7 until all air is expelled. If bubbles persist, do not use product.
8. If a syringe was used, attach a prepared inflation device to stopcock.
9. Open stopcock to stent system.
10. Leave at atmospheric pressure (neutral).

**Delivery Procedure**

**Step Action**

1. Prepare the vascular access site according to standard practice.

**Note:** If a guide catheter extension is used, consideration should be given to the appropriate guide catheter compatibility (see Table 1. SYNERGY SHIELD Stent System Product Description), as a larger guide catheter may be required. Use of guide catheter extension devices reduces the lumen available for catheter manipulation.

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, see **Precautions, Stent System Removal - Pre-deployment** for directions.

7. Advance the stent system over the guidewire to target lesion using direct fluoroscopic visualization. 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, see Precautions, Stent System Removal - Pre-deployment for directions. 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 optimize 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 3. SYNERGY SHIELD Compliance Chart). Balloon pressure must not exceed rated burst pressure of 18 atm (1827 kPa) for the 2.25 mm - 2.75 mm sizes and 16 atm (1620 kPa) for the 3.00 mm - 5.00 mm sizes (see Table 3. SYNERGY SHIELD Compliance Chart).
2. Maintain inflation pressure for 15 seconds to 30 seconds for full expansion of the stent.

3. Deflate balloon by pulling negative pressure on inflation device until balloon is fully deflated. Ensure balloon is fully deflated before delivery system withdrawal. Larger and longer balloons will take more time to deflate than smaller and shorter balloons. Allow adequate time, at least 30 seconds, for balloon deflation. Before withdrawing the stent delivery system visually confirm complete balloon deflation using fluoroscopy.
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 visualization 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 diameters. Optimal expansion requires that the stent be in full contact with the artery wall. Stent wall apposition should be verified through intravascular imaging.
5. If stent sizing/apposition requires optimization, readvance the stent system balloon, or another high-pressure balloon catheter of the appropriate size, to the stented area using standard angioplasty techniques.
6. Inflate the balloon to the desired pressure while observing using fluoroscopy (refer to product labeling and/or Table 3. SYNERGY SHIELD Compliance Chart). Deflate the balloon. Ensure balloon is fully deflated before delivery system withdrawal. Larger and longer balloons will take more time to deflate than smaller and shorter balloons. Allow adequate time, at least 30 seconds, for balloon deflation. Before withdrawing the stent delivery system or post-dilation balloon catheter visually confirm complete balloon deflation using fluoroscopy.
7. If more than one SYNERGY SHIELD 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 SHIELD 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 exchange the stent delivery system with a larger post-dilation balloon catheter.

**Removal Procedure and Completion**

**Step Action**

1. Ensure balloon is fully deflated before delivery system withdrawal. Larger and longer balloons will take more time to deflate than smaller and shorter balloons. Allow adequate time, at least 30 seconds, for balloon deflation. Before withdrawing the stent delivery system or post-dilation balloon catheter visually confirm complete balloon deflation using fluoroscopy.
2. Fully open rotating hemostatic valve.
3. While maintaining guidewire position and negative pressure on inflation device, withdraw delivery system.
4. Repeat angiography to assess the stented area.
5. If an adequate expansion has not been obtained, exchange back to the original stent delivery catheter or exchange to another balloon catheter of appropriate diameter to achieve proper stent apposition to the vessel wall.
   - The stent delivery balloon may be used for post-dilation up to stent diameters indicated on the compliance chart (see Table 3. SYNERGY SHIELD Compliance Chart).
   - A post-dilation balloon catheter may be used to expand the stent up to the post-dilation limits indicated in the following table

**Post-Deployment Dilation of Stented Segments**

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

| Nominal Stent Diameter (ID) | Post-Dilation 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, 4.50 mm, 5.00 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-dilation 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. For in-stent restenosis, where details of the original stent are known, the expanded inner diameter of the new stent should not exceed the dilation limits of the original stent. Where details of the original stent are not known, the expanded inner diameter of the new stent should not exceed the reference vessel diameter.

**Note:** In calcified lesions ensure balloon expansion in the distal stented segment fully apposes the stent to the vessel wall (particularly with non-compliant balloons).

**Note:** Care must be exercised when crossing a newly deployed stent with an intravascular 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.

6. Complete angiographic confirmation, remove interventional equipment, and close vascular access site according to standard practice.

**Instructions for Simultaneous Use of Two Devices in a Guide Catheter (Kissing Balloon Technique)**

6F (1.78 mm) compatibility: Any combination of one SYNERGY SHIELD Stent (2.25 mm to 5.00 mm) and one balloon catheter (NC EMERGE™ 3.25 mm x 20 mm or smaller*), can be used simultaneously within a 6F Guide Catheter (min ID 1.78 mm / 0.070 inch).

* or other Boston Scientific coronary balloon catheter with the same shaft outer dimensions

The technique can be performed as per the sequence listed below:

1. Prepare the vascular access site according to standard practice and track the guidewires to the target sites in the main vessel and side branch.
2. Advance the SYNERGY SHIELD Stent System over the guidewire to the target lesion as described in the **Operational Instructions.**
3. Advance the balloon catheter to the side branch target site over the guidewire as described in the balloon catheter IFU.
4. Perform the Kissing Balloon Technique according to standard practice. Allow adequate time for complete balloon deflation.
5. While maintaining guidewire position, remove the side branch balloon catheter as described in the balloon catheter IFU.
6. While maintaining guidewire position, withdraw the SYNERGY SHIELD Stent System into the guide catheter as described in the **Operational Instructions**. If greater than usual resistance is felt during withdrawal of SYNERGY SHIELD into the guide catheter, see **Precautions, Stent System Removal - Pre-deployment** for directions.
7. Repeat angiography to assess the stented area. If an adequate SYNERGY SHIELD Stent expansion has not been obtained, see **Operational Instructions - Removal Procedure and Completion** for directions.
8. Complete angiographic confirmation, remove the guidewires, and close vascular access site according to standard practice.

**Note:** Consideration should be given to the appropriate guide catheter compatibility if utilizing two SYNERGY SHIELD devices within the one guide catheter, as a larger guide catheter may be required.

**Note:** Use of guide catheter extension devices reduces the lumen available for catheter manipulation.

**Disposal**

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

**Post-Procedure**

It is very important that the patient be compliant with post-procedural antiplatelet recommendations given by their physician.

- If the patient requires MRI imaging, see **Magnetic Resonance Imaging (MRI)**.
- Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

**Implantable Device Patient Information**

Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

**IN VITRO INFORMATION**

**SYNERGY SHIELD Stent System Compliance**

**Table 3. SYNERGY SHIELD Compliance Chart**

| Pressure atm - kPa | Stent I.D. (mm) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2.25 | 2.50 | 2.75 | 3.00 | 3.50 | 4.00 | 4.50 | 5.00 |
| 8 - 814 | --- | 2.35 | 2.57 | 2.89 | 3.30 | 3.81 | 4.11 | 4.62 |
| 9 - 910 | 2.13 | 2.42 | 2.65 | 2.96 | 3.40 | 3.91 | 4.24 | 4.73 |
| 10 - 1014 | 2.19 | 2.48 | 2.72 | 3.02 | 3.48 | 3.98 | 4.35 | 4.85 |
| 11 - 1117 | 2.24 | 2.54 | 2.79 | 3.08 | 3.55 | 4.06 | 4.46 | 4.95 |
| 12 - 1213 | 2.28 | 2.59 | 2.85 | 3.13 | 3.61 | 4.12 | 4.54 | 5.03 |
| 13 - 1317 | 2.31 | 2.63 | 2.89 | 3.17 | 3.66 | 4.17 | 4.61 | 5.11 |
| 14 - 1420 | 2.35 | 2.67 | 2.93 | 3.20 | 3.70 | 4.22 | 4.68 | 5.17 |
| 15 - 1517 | 2.37 | 2.70 | 2.96 | 3.24 | 3.74 | 4.26 | 4.73 | 5.22 |
| 16 - 1620 | 2.40 | 2.73 | 3.00 | 3.27* | 3.79* | 4.30* | 4.78* | 5.28* |
| 17 - 1724 | 2.43 | 2.76 | 3.03 | 3.32 | 3.83 | 4.36 | 4.83 | 5.34 |
| 18 - 1827 | 2.45* | 2.79* | 3.06* | 3.37 | 3.87 | 4.42 | 4.89 | 5.39 |
| 19 - 1924 | 2.48 | 2.82 | 3.10 | 3.43 | 3.93 | 4.52 | 4.96 | 5.45 |
| 20 - 2027 | 2.51 | 2.85 | 3.13 | 3.49 | 3.99 | --- | 5.04 | 5.50 |
| 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 I.D. (mm) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2.25 | 2.50 | 2.75 | 3.00 | 3.50 | 4.00 | 4.50 | 5.00 |
| 8 - 814 | --- | 2.51 | 2.73 | 3.05 | 3.46 | 3.99 | 4.29 | 4.79 |
| 9 - 910 | 2.29 | 2.58 | 2.81 | 3.12 | 3.56 | 4.09 | 4.42 | 4.91 |
| 10 - 1014 | 2.35 | 2.64 | 2.88 | 3.18 | 3.64 | 4.16 | 4.52 | 5.03 |
| 11 - 1117 | 2.40 | 2.70 | 2.95 | 3.24 | 3.71 | 4.24 | 4.63 | 5.12 |
| 12 - 1213 | 2.44 | 2.75 | 3.01 | 3.29 | 3.77 | 4.30 | 4.71 | 5.20 |
| 13 - 1317 | 2.47 | 2.79 | 3.05 | 3.33 | 3.82 | 4.35 | 4.79 | 5.28 |
| 14 - 1420 | 2.51 | 2.83 | 3.09 | 3.36 | 3.86 | 4.40 | 4.85 | 5.34 |
| 15 - 1517 | 2.53 | 2.86 | 3.12 | 3.40 | 3.90 | 4.44 | 4.90 | 5.40 |
| 16 - 1620 | 2.56 | 2.89 | 3.16 | 3.43* | 3.95* | 4.48* | 4.95* | 5.46* |
| 17 - 1724 | 2.59 | 2.92 | 3.19 | 3.48 | 3.99 | 4.54 | 5.01 | 5.51 |
| 18 - 1827 | 2.61* | 2.95* | 3.22* | 3.53 | 4.03 | 4.60 | 5.07 | 5.57 |
| 19 - 1924 | 2.64 | 2.98 | 3.26 | 3.59 | 4.09 | 4.70 | 5.14 | 5.62 |
| 20 - 2027 | 2.67 | 3.01 | 3.29 | 3.65 | 4.15 | --- | 5.22 | 5.68 |
| 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

**INFORMATION TO BRIEF THE PATIENT**

Physicians should consider the following in counseling patients about this product:

- Discuss the risks and benefits including review of potential adverse events listed in this document, both for SYNERGY SHIELD and for other interventional treatments likely to be employed.
- Discuss patient allergies, in particular the risk for patients who may be allergic to antiplatelet therapy, or to the stent components including everolimus, polymer, stainless steel, iron, nickel, molybdenum, chromium and/or platinum.
- Discuss the risks and benefits of antiplatelet therapy including risk of thromboembolism should the patient discontinue use.
- Discuss the conditions under which the patient can safely undergo MRI scanning (1.5 T and 3 T) after implant of a SYNERGY SHIELD Stent.
- Discuss post-procedure instructions, including any follow-up appointments, lifestyle changes, medications, and home-care or rehabilitation guidelines.
- Instruct the patient to contact their healthcare provider if they develop any symptoms post-procedure, especially chest pain or access site pain or bleeding.
- Provide the patient with the completed implant card and advise the patient to carry the card with them at all times.
- Instruct the patient to present the implant card to their healthcare professionals (doctors, dentist, technicians) so they can take the necessary precautions.

**Expected Lifetime**

Inform the patient that the stent is a permanent implant – after the drug is eluted and the polymer is absorbed, the metallic stent scaffold remains. The stent scaffold has been tested for structural integrity (fracture resistance) for a minimum of 10 years; however, the materials of the stent scaffold are nonbiodegradable and are intended to last for the lifetime of the patient.

**Note:** It is estimated that the everolimus drug will be released into the surrounding arterial tissue for approximately 3 months following stent implantation. The bioabsorbable polymer is eliminated from the body as carbon dioxide and water through natural metabolic mechanisms. In vivo studies support that the polymer degradation is essentially complete by 4 months.

**WARRANTY**

For device warranty information, visit (www.bostonscientific.com/warranty).



**SYMBOL DEFINITIONS**

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document

Contents
Contenido
Contenu
Conteúdo

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Endereço do Patrocinador Australiano

ARG

Argentina Local Contact
Contacto local en Argentina
Contact local en Argentine
Contacto local na Argentina

ID

Maximum Stent Inner Diameter
Diámetro interno máximo del stent
Diamètre interne maximum du stent
Diâmetro Interno Máximo do Stent

GC R

Recommended Guide Catheter
Catéter guía recomendado
Cathéter guide recommandé
Cateter-guia Recomendado

GW R

Recommended Guidewire
Guía recomendada
Guide recommandé
Fio-guia Recomendado

RH

Protect from Humidity
Proteger de la humedad
Protéger de l'humidité
Proteger da humidade

30 °C
15 °C
25°C R

Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F).
Almacenar a 25 °C (77 °F); se permiten intervalos de temperatura entre 15 y 30 °C (59 - 86 °F).
Conserver à 25 °C (77 °F) ; variations permises entre 15 et 30 °C (59 à 86 °F)
Armazene a 25°C (77°F); são permitidas variações entre 15 e 30°C (59-86°F).

Do not open foil pouch until ready for use.
No abra el envase de papel de aluminio hasta que esté listo para su uso.
N'ouvrir la poche en aluminium qu'au moment de l'utilisation.
Não abra a bolsa de alumínio até estar pronto para utilizar.

Open Here
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EC REP

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**Galway IRELAND**

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