

Dear Colleague:

Following the recent TCT meeting and as 2008 comes to a close, this is a good chance to reflect on some of the important new data. Accordingly, we offer thoughts on the following topics:

- Percutaneous Coronary Intervention (PCI) in the Treatment of Patients with Coronary Artery Disease
- Drug-Eluting Stent (DES) Safety
- Dual Anti-platelet Therapy with DES
- 2008 DES Product Landscape

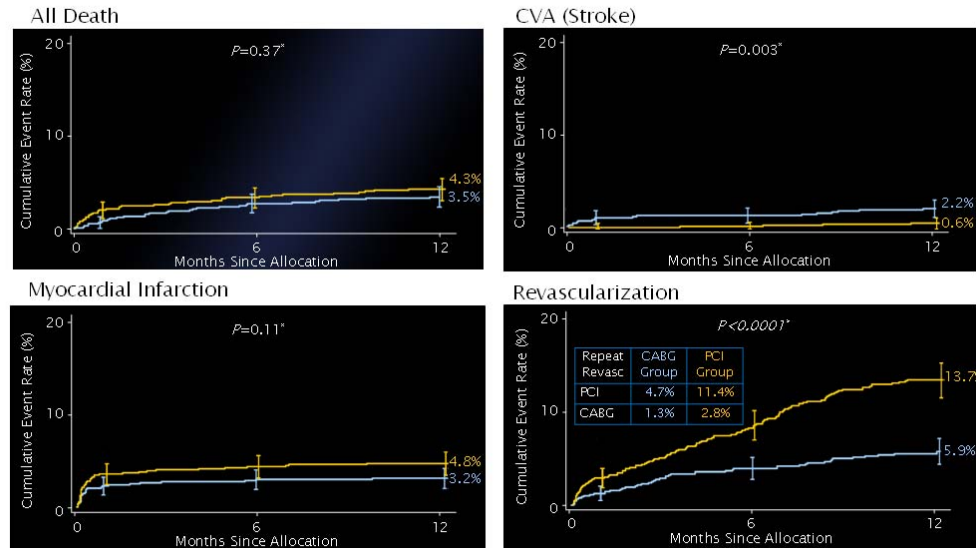
### **PCI in Patients with Coronary Artery Disease**

The COURAGE trial demonstrated that pre-emptive PCI with bare metal stents (BMS) offered no reduction in death and myocardial infarction (MI) compared to a strategy of initial optimal medical therapy (OMT) in patients with generally **mild stable angina** (40% class 0-1) who had access to PCI for progressive symptoms<sup>1</sup>. PCI was used in 30% of OMT patients who crossed-over to PCI at a mean of 11 months. The PCI arm did show initial improvement in quality of life, particularly in patients with more baseline angina, but pre-emptive PCI was not cost-effective in the overall COURAGE population<sup>2,3</sup>. In addition, the COURAGE nuclear sub-study showed that patients who had ischemia of >10% of the LV myocardium had reduced death and MI after PCI<sup>4</sup>. The recommendation for PCI in patients with medically refractory, progressive, or life-style limiting angina, as well as those with significant amounts of ischemic myocardium on nuclear scanning, closely parallel the established indications for PCI in the AHA/ACC/SCAI/ESC Guidelines<sup>5,6</sup>.

The question of whether PCI with the TAXUS<sup>®</sup> Express<sup>®</sup> Stent would be non-inferior to CABG in patients with **left main and/or 3 vessel disease** was examined in the SYNTAX trial<sup>7</sup>. The 12 month outcomes (*Exhibit 1*) were presented at ESC and TCT 2008 and the trial demonstrated:

- Comparable overall safety outcomes (Death, CVA, MI,) in CABG and PCI patients (7.7 vs 7.6 %, p=0.98)
- Significantly higher rate of revascularization in the PCI group (13.7 vs 5.9 %, p<0.001)
- Significantly higher rate of CVA in the CABG group (2.2 vs 0.6%, p=0.003)

- Overall MACCE in the PCI group was higher (17.8 vs 12.1%, p=0.002) due to an excess of repeat revascularization compared with CABG causing the study to miss its overall non-inferiority primary endpoint for 12 month MACCE



Event Rate  $\pm$  1.5 SE, \*Fisher exact test  
 ITT population

■ CABG (N=897) ■ TAXUS® Express® Stent (N=903)

### Exhibit 1: SYNTAX Trial 12 Month Adverse Events

The SYNTAX Score™ is a new, innovative tool to describe the complexity of the coronary vasculature<sup>8</sup>. The SYNTAX Score is a good predictor of MACCE, particularly in PCI patients<sup>9</sup>.

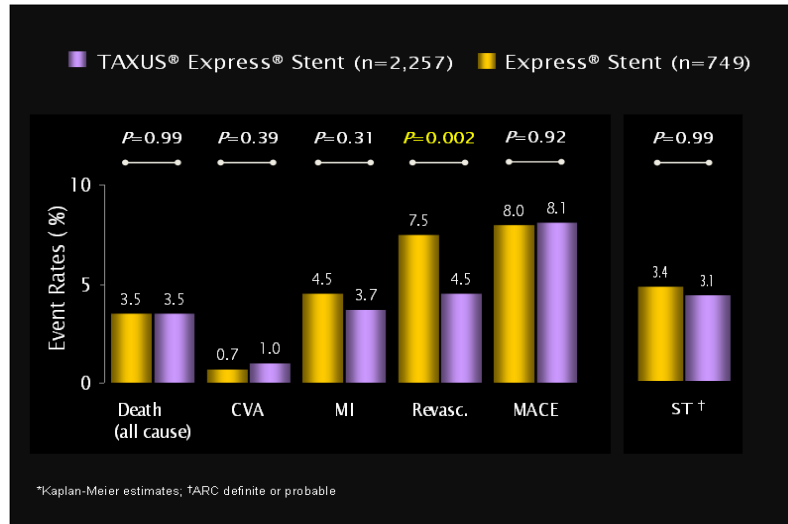
- The SYNTAX trial showed that PCI patients with low or intermediate raw SYNTAX Scores<sup>9</sup> (the lowest two terciles in the trial) have comparable 12-month MACCE rates to CABG patients with adverse outcomes increasing with higher SYNTAX Scores in the PCI group

When this resource becomes available for the entire clinical community, we anticipate the SYNTAX Score becoming an important tool for physicians in assessing complexity and risk for patients undergoing PCI, much as the euroSCORE and Parsonnet scores are for surgical patients.

The question of DES vs BMS in **acute myocardial infarction** was addressed by the HORIZONS trial, whose 12 month results were presented at TCT 2008<sup>10</sup>. This trial which was conducted by the Cardiovascular Research Foundation and funded in part by Boston Scientific, looked at more than 3,000 acute myocardial infarction (AMI) patients randomized to either the TAXUS® Express® Stent or BMS. This trial demonstrated:

The safety and effectiveness of the TAXUS® Express® Stent System have not been established in the following patient populations: lesions located in the unprotected left main coronary artery, patients with multi-vessel disease or in patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow. The TAXUS Express Stent System has not been specifically indicated for patients with diabetes. The PROMUS® Stent is a private-labeled XIENCE V™ Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies.

- A significant reduction with the TAXUS<sup>®</sup> Express<sup>®</sup> Stent in both ischemic TLR (the Primary Efficacy Endpoint) (4.5% vs. 7.5%. p=0.002) at 12 months and in-stent angiographic restenosis (8.3% vs. 21.0%, p<0.0001) at 13 months
- No increase in mortality, stent thrombosis or combined MACE (8.1 vs 8.0%, p=0.92) with the TAXUS<sup>®</sup> Express<sup>®</sup> Stent (*MACE is defined as all cause death, reinfarction, stent thrombosis (ARC definite or probable or stroke)*)



**Exhibit 2: HORIZONS Trial One Year Endpoints**

These findings parallel the recent publication that showed DES-treated patients at 2-years had significantly less repeat revascularization and also a trend toward less recurrent MI in propensity-matched BMS-treated AMI patients<sup>11</sup>.

### Drug-Eluting Stent Safety

The concerns surrounding the suggestion of a 0.5%/year increase in DES vs BMS mortality from the original (2003-2004) SCAAR data<sup>12</sup>, have now been further studied. The newer (2003-2005) SCAAR data<sup>13</sup>, which had DES penetration levels in excess of 50% compared to 20-30% in the original data, shows no such effect suggesting that the original SCAAR findings were a consequence of incomplete adjustment for the significantly higher baseline risk of the highly selected DES patients. Moreover, a number of other large propensity-matched registries and a meta-analysis of 162,000 patients presented by Gregg W. Stone, MD at ACC 2008, actually support a significant ~20% *reduction* in mortality favoring DES compared to BMS-treated patients in real world use<sup>14</sup>.

The safety and effectiveness of the TAXUS<sup>®</sup> Express<sup>®</sup> Stent System have not been established in the following patient populations: lesions located in the unprotected left main coronary artery, patients with multi-vessel disease or in patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow. The TAXUS Express Stent System has not been specifically indicated for patients with diabetes. The PROMUS<sup>®</sup> Stent is a private-labeled XIENCE V<sup>™</sup> Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies.

Additional data were released during 2008 concerning DES thrombosis. Virtually all of the randomized trials between DES and BMS have shown near-identical stent thrombosis rates in the first year<sup>15</sup>. The previous concerns about increased very late stent thrombosis (VLST- stent thrombosis after 1 year) appear to result from the use of the protocol definitions.<sup>16</sup> The definitions exclude thrombosis events taking place after a repeat revascularization and skewed the data in favor of the BMS arm. Once **ARC (Definite/Probable) definitions**<sup>17</sup> are applied, which include all stent thrombosis events, there is at most a small (0.1% or 1 in 1,000) and statistically non-significant ( $p=0.40$ ) difference in annual VLST between the TAXUS<sup>®</sup> Express<sup>®</sup> Stent and BMS<sup>18</sup>.

### **Dual Anti-platelet Therapy**

**Prolonged DAPT** seems to provide very similar benefit in late outcomes for DES and BMS patients<sup>19</sup>. This finding suggests that the early benefits of DAPT related to protection of incomplete or delayed DES healing, may be distinguished from any late benefits of sustained DAPT related to protection against background natural history-driven atherosclerotic events<sup>20</sup>. This question is to be investigated in the upcoming 20,000+ patient industry-sponsored DAPT trial, which will compare 30 versus 12 months durations of DAPT treatment in a broad patient population treated with both BMS and DES.

### **2008 Drug-Eluting Stent Product Landscape**

Until early 2008, there were only two approved DES in the U.S. market; the **Cypher<sup>®</sup> Sirolimus-Eluting Stent** (Cordis, launched in 2003), and the **TAXUS<sup>®</sup> Express<sup>®</sup> Paclitaxel-Eluting Stent** (Boston Scientific, launched in 2004). In early 2008, the **Endeavor<sup>®</sup> Zotarolimus-Eluting Stent** (Medtronic) was launched followed in mid-2008 by the Everolimus-Eluting Stent marketed as **Xience V<sup>™</sup>** (Abbott) and **PROMUS<sup>®</sup>** (Boston Scientific), and most recently the **TAXUS<sup>®</sup> Liberté<sup>®</sup> Paclitaxel-Eluting Stent** (Boston Scientific).

Historically in terms of **anti-restenotic efficacy**, published models<sup>21</sup> predict very similar angiographic and clinical restenosis rates for DES with a mean late loss of 0.2-0.4 mm. This has been observed for the Cypher Stent and TAXUS Express Stent in the broad real-world experience and in the REALITY trial<sup>22</sup>.

The SPIRIT III trial<sup>23</sup> comparing the TAXUS Express Stent to the **Xience V / PROMUS Stent** demonstrated:

- Low late loss (0.14mm in segment late loss at 8 months) for the Xience V / PROMUS stent
- Numerically lower ischemia-driven TLR for the XIENCE V / PROMUS Stent vs the TAXUS Express Stent at 1-year (5.6 vs 3.3%,  $p=0.09$ ) and 2-years (6.9 vs 4.3%,  $p=0.07$ )

The safety and effectiveness of the TAXUS<sup>®</sup> Express<sup>®</sup> Stent System have not been established in the following patient populations: lesions located in the unprotected left main coronary artery, patients with multi-vessel disease or in patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow. The TAXUS Express Stent System has not been specifically indicated for patients with diabetes. The PROMUS<sup>®</sup> Stent is a private-labeled XIENCE V<sup>™</sup> Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies.

The ATLAS Trial results with the **TAXUS® Liberté® Stent** demonstrated:

- A successful transfer of the same drug and polymer combination to an advanced stent design in the drug-eluting stent era
- Numerically lower MACE, TVR, TLR, MI, and stent thrombosis as compared to the TAXUS® Express® Stent despite a more complex patient population
- A statistical reduction in TVR (9.1% vs. 6.1%,  $p=0.0178$ ) between 9 months and 3 years in the TAXUS Liberté Stent vs the TAXUS Express Stent

The **TAXUS® Express® Atom™** marked a significant milestone in product launches as it is the first small vessel DES approved for stent vessels as small as 2.25mm.

The **Endeavor®** Stent demonstrated<sup>25-28</sup>:

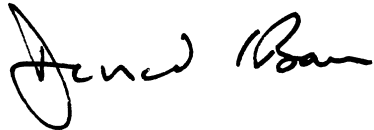
- A mean in-stent late loss of 0.67 mm with significantly higher angiographic and IVUS restenosis than TAXUS Express Stent
- The angiographic cohort showed a significantly higher TLR (9.2 vs 3.1%,  $p=0.045$ ) at 2 years follow-up
- SORT-OUT III trial showed that the Endeavor Stent had 4-times the TLR rate of the Cypher® Stent at 10 months ( $p<0.0001$ ) and had a significantly higher rate of definite ST at 9 months ( $p=0.02$ ).
- In Endeavor IV 2-year data, the Endeavor Stent had a trend towards less VLST in year two, but no lower cumulative definite or probable ST through 2 years than the TAXUS Express Stent (1.1 vs 0.9% for TAXUS Stent,  $p=1.0$ ).

Given that all of the present DES have excellent safety performance, it is very difficult to make meaningful safety comparisons, especially in low frequency events such as VLST (roughly 0.3%/year), in the absence of thousands of patients followed for many years (as in the 8,800 patient PROTECT study comparing the Endeavor Stent to the Cypher Stent). All DES approved in the US thus carry the same recommendations for 12 months of DAPT in patients who are able to tolerate DAPT. All DES are also being treated as a class in the DAPT study to examine the benefits of 30 vs 12 months of DAPT in DES and BMS.

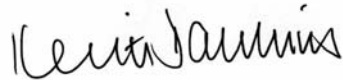
In summary, there are important new data about DES that suggest:

- AMI patients studied in the HORIZONS trial that received a TAXUS® Express® Stent showed a significant reduction in ischemic TLR with no significant difference in mortality, ST, or combined MACE at 12 months
- No increase in mortality of DES vs. BMS
- No significant increase in VLST vs BMS using the ARC (Definite + Probable) definitions
- All current DES are safe and have the same DAPT requirements

We hope that these perspectives will be useful in your clinical practice.



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Cypher is a trademark of Cordis Corp.  
 Endeavor is a trademark of Medtronic Vascular

The safety and effectiveness of the TAXUS® Express® Stent System have not been established in the following patient populations: lesions located in the unprotected left main coronary artery, patients with multi-vessel disease or in patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow. The TAXUS Express Stent System has not been specifically indicated for patients with diabetes. The PROMUS® Stent is a private-labeled XIENCE V™ Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies.

# TAXUS® Express® Stent System Abbreviated Statement

## Indications

The TAXUS Express2 Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of *de novo* lesions  $\leq 28$  mm in length in native coronary arteries  $\geq 2.25$  to  $\leq 4.0$  mm in diameter, and within bare metal stent restenotic lesions  $\geq 2.5$  to  $\leq 3.75$  mm in diameter and  $\leq 28$  mm in length.

## Contraindications

Use of the TAXUS Express2 Paclitaxel-Eluting Coronary Stent System is contraindicated in patients with:

- Known hypersensitivity to paclitaxel or structurally-related compounds.
  - Known hypersensitivity to the polymer or its individual components (see details in TAXUS Express2 Stent System DFU).
- Coronary Artery Stenting is contraindicated for use in:
- Patients who can not 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

- To maintain sterility, the inner package should not be opened or damaged prior to use.
- The use of this product carries the risks associated with coronary artery stenting, including subacute thrombosis, vascular complications, and/or bleeding events.
- Patients with known hypersensitivity to 316L stainless steel may suffer an allergic reaction to this implant.
- This product should not be used in patients who are not likely to comply with recommended antiplatelet therapy.

## Potential Adverse Effects

Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to: Aneurysm, Arrhythmias, Bleeding complications, Death, Distal Emboli, Emergent CABG, Myocardial Infarction, Myocardial Ischemia, Occlusion, Stent Delivery Failures, Target Lesion Revascularization, Thrombosis, Vascular complications, Vessel Dissection.

Potential adverse events not captured above that may be unique to the paclitaxel drug coating:

Alopecia, Allergic reaction to the drug or the polymer, Anemia, Blood product transfusion, Gastrointestinal symptoms, Hematologic dyscrasia, Hepatic enzyme changes, Histologic changes in vessel wall, including inflammation, cellular damage or necrosis, Myalgia/Arthralgia, Peripheral neuropathy.

## The safety and effectiveness of the TAXUS™ Express® Stent have not been established in the cerebral, carotid, or peripheral vasculature or the following patient populations:

- Patients with vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters  $< 2.25$  or  $> 4.0$  mm.
- Patients with coronary artery lesions longer than 28 mm or requiring more than one TAXUS stent
- Patients with lesions located in the saphenous vein grafts, in the unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or poor flow distal to the identified lesions.
- Patients with tortuous vessels ( $>60$  degrees) in the region of the obstruction or proximal to the lesion.
- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with moderate or severe calcification in the lesion or a chronic total occlusion.
- Patients with multi-vessel disease.

Prior to use, please see the complete "Directions for Use" at [www.Taxus-stent.com](http://www.Taxus-stent.com) for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

## Cautions

Federal law restricts this product to sale by or on the order of a physician.

# TAXUS® Liberté® Stent System Abbreviated Statement

## PRESCRIPTIVE INFORMATION

Prior to use, please see the complete "Directions For Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

## Indications

The TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of *de novo* lesions in native coronary arteries  $\geq 2.5$  to  $\leq 4.0$  mm in diameter in lesions  $\leq 28$  mm in length.

## Contraindications

Use of the TAXUS Liberté® Paclitaxel-Eluting Coronary Stent System is contraindicated in patients with known hypersensitivity to 316L Stainless Steel, to paclitaxel or structurally related compounds, or known hypersensitivity to the polymer or its individual components. Coronary Artery Stenting is contraindicated for use in patients who cannot receive recommended antiplatelet therapy and/or anticoagulant therapy or patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

## WARNINGS

The use of this product carries the risks associated with coronary artery stenting, including subacute thrombosis, vascular complications, and/or bleeding events. This product should not be used in patients not likely to comply with recommended antiplatelet therapy.

## PRECAUTIONS

Stent thrombosis is a low frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis is frequently associated with myocardial infarction (MI) or death. In the TAXUS® clinical trials analyzed to date, the differences in the incidence of stent thrombosis observed with the TAXUS® Stent compared to bare-metal stents have not been associated with an increased risk of cardiac death, myocardial infarction, or all-cause mortality. When drug-eluting stents are used outside the specified indications for use, patient outcomes may differ from the results observed in the pivotal clinical trials. • Compared to use within the specified indications for use, the use of drug-eluting stents in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, myocardial infarction, or death.

## POTENTIAL ADVERSE EVENTS

Potential adverse events which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to:

Aneurysm • Arrhythmias • Bleeding Complications • Death, Distal Emboli • Emergent CABG • Myocardial Infarction • Myocardial Ischemia • Occlusion • Stent Delivery Failures • Target Lesion Revascularization • Thrombosis • Vascular Complications • Vessel Dissection.

Potential adverse events not captured above that may be unique to the paclitaxel drug coating:

Alopecia • Allergic reaction to the drug or the polymer • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage or necrosis • Myalgia/Arthralgia • Peripheral neuropathy.

## PRECAUTIONS – LESION/ESSEL CHARACTERISTICS

The safety and effectiveness of the TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System have not been established in the cerebral, carotid, or peripheral vasculature or patients with:

Vessel thrombus at the lesion site; coronary artery reference vessel diameters  $< 2.5$  mm or  $> 4.0$  mm; coronary artery lesions longer than 28mm or requiring more than one TAXUS® stent; diffuse disease or poor flow distal to the identified lesions; tortuous vessels ( $>60$  degrees) in the region of the obstruction or proximal to the lesion; a recent acute myocardial infarction; moderate or severe calcification in the lesion or a chronic total occlusion; multi-vessel disease; lesions located in saphenous vein grafts, in an unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation; lesions with in-stent restenosis; lesions where there is evidence of thrombus or poor flow; pediatric patients.

## CAUTION

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

# PROMUS™ Stent System Abbreviated Statement

## INDICATIONS

The PROMUS™ Everolimus Eluting Coronary 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 (length  $\leq 28$  mm) with a reference vessel diameter of 2.5 mm - 4.0 mm.

## CONTRAINDICATIONS

The PROMUS™ Everolimus Eluting Coronary Stent System is contraindicated for use in:

- Patients in whom anti-platelet and / or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Patients with a known hypersensitivity or contraindication to everolimus, cobalt, chromium, nickel, tungsten, acrylic and fluoro – polymers may have an allergic reaction to this implant; therefore, the implant is not recommended for such patients.

## WARNINGS

- Long term outcome for this permanent implant containing polymers and everolimus is unknown at present.
- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and / or bleeding events.
- Oral administration of everolimus in combination with cyclosporine have been associated with increased serum cholesterol and triglycerides. Therefore, patients should be monitored for changes in lipid profiles.
- Persons allergic to L-605 cobalt chromium alloy, acrylic or fluoro – polymers, or everolimus may suffer an allergic reaction to this implant.

## PRECAUTIONS

- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- The extent of the patient's exposure to drug and polymer is directly related to the number of stents implanted. A patient can receive up to 4 PROMUS™ Everolimus Eluting Coronary Stents depending on the number of vessels treated and the lesion length.

## 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.

## ADVERSE EVENTS

Adverse events may be associated with the use of a coronary stent in native coronary arteries.

Abrupt closure, Acute myocardial infarction, Allergic reaction to contrast, Aneurysm, Arterial perforation, Arterial rupture, Arteriovenous fistula, Arrhythmias, including atrial and ventricular, Bleeding complications, which may require transfusion, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery, Distal emboli (air, tissue or thrombotic), Drug reactions to anti-platelet agents / contrast medium, Emergent or non-emergent Coronary Artery Bypass Graft Surgery, Fever, Hypertension / Hypertension, Hypersensitivity reactions, Infection and pain at insertion site, Injury to the coronary artery, Ischemia, myocardial, Myelosuppression, Nausea and vomiting, Palpitations, Peripheral ischemia (due to vascular or nerve injury), Pseudoaneurysm, Restenosis of stented segment, Stroke / cerebrovascular accident (CVA), Total occlusion of coronary artery, Unstable or stable angina pectoris, Vascular complications, including entry site which, may require vessel repair, Ventricular arrhythmias including ventricular fibrillation and ventricular tachycardia, Vessel dissection

Adverse events associated with daily oral administration of everolimus:

Abdominal pain, Acne, Anemia, Coagulopathy, Diarrhea, Edema, Hemolysis, Hypercholesterolemia, Hyperlipidemia, Hypertension, Hypertriglyceridemia, Hypogonadism male, Leukopenia, Liver function test abnormal, Lymphocyte, Myalgia, Nausea, Pain, Pneumonia, Pylonephritis, Rash, Renal tubular necrosis, Sepsis, Surgical wound complication, Thrombocytopenia, Urinary tract infection, Venous thromboembolism, Viral, bacterial and fungal infections, Vomiting, Wound infection

Prior to use, please see the full "Instructions for Use" supplied with the PROMUS Everolimus-Eluting Coronary Stent System. Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

The safety and effectiveness of the TAXUS® Express® Stent System have not been established in the following patient populations: lesions located in the unprotected left main coronary artery, patients with multi-vessel disease or in patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow. The TAXUS Express Stent System has not been specifically indicated for patients with diabetes. The PROMUS® Stent is a private-labeled XIENCE V™ Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies.