SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Product Generic Name:	Drug-Eluting Coronary Stent System (NIQ)
Product Trade Name:	TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire)
Applicant's Name and Address:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
Premarket Approval Application (PMA) Number:	P030025
Date of Panel Recommendation:	November 20, 2003
Date of Notice of Approval to Applicant:	March 4, 2004

II. INDICATIONS FOR USE

The TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of de novo lesions ≤ 28mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter.

III. 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 **Section V – Product Description**, below)

Coronary Artery Stenting is contraindicated for use in:

- Patients in whom anti-platelet and/or anticoagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

9

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the TAXUS Express² Paclitaxel-Eluting Coronary Stent System labeling.

V. PRODUCT DESCRIPTION

The TAXUS Express² Stent System is a device / drug combination product comprised of two regulated components: a device (Express² Coronary Stent System) and a drug component (a formulation of paclitaxel contained in a polymer coating). The characteristics of the TAXUS Express² Stent System are described in **Table 1**.

Table 1. TAXUS Express² Stent System Product Description

	TAXUS Express² Monorail (MR) Stent Delivery System	**TAXUS Express²** Over-The-Wire (OTW) Stent Delivery System
Available Stent Lengths (mm)	8, 12, 16, 20, 24, 28, 32	8, 12, 16, 20, 24, 28, 32
Available Stent Diameters (mm)	2.50, 2.75, 3.00, 3.50	2.50, 2.75, 3.00, 3.50
Stent Material	A 316L surgical grade stainless steel Express stent	
Drug Component	A conformal coating of a polymer carrier loaded with 1 μg/mm² paclitaxel in a slow release (SR)* formulation applied to the stent with a maximum nominal drug content of 209 μg on the largest stent (3.50x32mm).	
Delivery System Working Length	140 cm	135 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".	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤ 0.014".
Stent Delivery Balloon	A compliant balloon, nominally 0.3 mm longer than the stent, with two radiopaque markers.	
Balloon Inflation Pressure	Nominal Inflation Pressure: 9 ATM; Rated Burst Inflation Pressure: 18 ATM	
Guide Catheter Inner Diameter	≥ 0.058"	≥ 0.066"
Catheter Shaft Outer Diameter	1.8F proximally, 2.7F distally (Ø up to 3.0mm, and 8-20 mm long stents with Ø > 3.0mm) 2.0F proximally, 2.7F distally (24-32mm long stents with Ø > 3.0mm)	3.2F proximally, 2.7F distally

* release rate is a function of weight/weight ratio of polymer and drug, and (SR) is the formulation that was studied clinically and is used in the marketed product

A. Device Component Description

The device component consists of the Express™ stent pre-mounted onto a stent delivery system (SDS); either the Express²™ Over-the-Wire (OTW) delivery system, or the Express²™ Monorail (MR) delivery system. The Express² OTW and MR delivery systems were previously approved for

10

deployment of the uncoated Express stent in P020009 (approved September 11, 2002).

The 2.5-3.5mm diameter 316L stainless steel stents use one design. The same stent is crimped on various size delivery catheter balloons, which are sized from 2.5 to 3.5mm. Because the identical stent component is used for the entire 2.5-3.5mm diameter range, the total drug per stent is a function of stent length, irrespective of stent diameter.

The Express² Delivery Catheters were not used in the pivotal clinical trial (TAXUS IV). The TAXUS IV trial used the Express Delivery Catheters. The only differences between the Express and the Express² versions of the delivery catheters are that: (1) the Express² catheter changed one of the shaft materials to another material that was used in other components of the original Express delivery catheter shaft; and (2) the Express² manifold was molded slightly differently to allow better retention in the packaging. This PMA requested approval of only the Express² OTW and MR delivery systems for use in delivering the TAXUS Express stent. Appropriate pre-clinical testing was provided to support the Express² stent delivery system, and acute (30 day) safety and performance data was submitted March 1, 2004 (TAXUS V trial, 1167 patients) to support the clinical safety of the TAXUS Express stent mounted on the Express² catheter design.

B. Drug Component Description

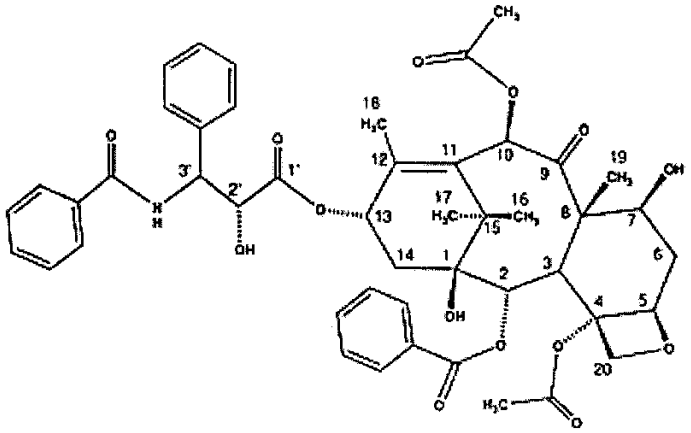
The drug component of the TAXUS Express² Paclitaxel-eluting Coronary Stent System (referred to as the TAXUS Express Stent) consists of paclitaxel (the active ingredient) and Translute™ polymer carrier (the inactive ingredient).

B1. Paclitaxel

The active pharmaceutical ingredient in the TAXUS Express Stent is paclitaxel. It is a white powder, isolated from a spectrum of Taxus species and hybrids. The Chemical name of paclitaxel is: Benzenepropanoic acid, β-(benzoylamino)-α-hydroxy-,6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, [2aR-[2aα,4β,4aβ,6β,9α (αR*, βS*),11α,12α,12aα,12bα]]-.

The chemical structure of paclitaxel is shown below.

Figure 1. The Chemical Structure of Paclitaxel

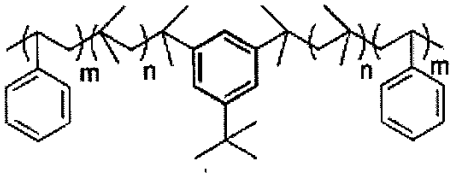


Paclitaxel is a diterpenoid with a characteristic taxane skeleton of 20 carbon atoms, a molecular weight of 853.91 g/mol and a molecular formula of C47H51NO14. It is highly lipophilic, insoluble in water, but freely soluble in methanol, ethanol, chloroform, ethyl acetate and dimethyl sulfoxide.

B2. Inactive Ingredients

The only inactive ingredient in the TAXUS Express stent is SIBS [poly(styrene-b-isobutylene-b-styrene)], a tri-block copolymer (trade name: Translute™), that is composed of styrene and isobutylene units built on 1,3-di(2-methoxy-2-propyl)-5-tert-butylbenzene. It is an hydrophobic elastomeric copolymer with a molecular weight (Mn-number average molecular weight) of 80,000 to 130,000 g/mol and a polydispersity index of 1.0 to 2.0. The polymer is mixed with the drug paclitaxel and then applied to the stents. There is no primer or topcoat layer. The drug/polymer coating is adhered to the entire surface (i.e., luminal and abluminal) of the stent. The structural formula for the polymer is shown below.

Figure 2. The Chemical Structure of SIBS [poly(styrene-b-isobutylene-b-styrene)]



m = repeating units of styrene
n = repeating units of isobutylene

Product Matrix and Paclitaxel Content

Table 2. TAXUS™ Express²™ Stent System Product Matrix and Paclitaxel Content

Product Code MR	Product Code OTW	Nominal Expanded Stent Inner Diameter (mm)	Nominal Un-expanded Stent Length (mm)	Nominal Paclitaxel Content (μg)
H7493897008250	H7493896808250	2.50	8	50
H7493897008270	H7493896808270	2.75	8	50
H7493897008300	H7493896808300	3.00	8	50
H7493897008350	H7493896808350	3.50	8	50
H7493897012250	H7493896812250	2.50	12	79
H7493897012270	H7493896812270	2.75	12	79
H7493897012300	H7493896812300	3.00	12	79
H7493897012350	H7493896812350	3.50	12	79
H7493897016250	H7493896816250	2.50	16	108
H7493897016270	H7493896816270	2.75	16	108
H7493897016300	H7493896816300	3.00	16	108
H7493897016350	H7493896816350	3.50	16	108
H7493897020250	H7493896820250	2.50	20	137
H7493897020270	H7493896820270	2.75	20	137
H7493897020300	H7493896820300	3.00	20	137
H7493897020350	H7493896820350	3.50	20	137
H7493897024250	H7493896824250	2.50	24	151
H7493897024270	H7493896824270	2.75	24	151
H7493897024300	H7493896824300	3.00	24	151
H7493897024350	H7493896824350	3.50	24	151
H7493897028270	H7493896828270	2.75	28	180
H7493897028300	H7493896828300	3.00	28	180
H7493897028350	H7493896828350	3.50	28	180
H7493897032270	H7493896832270	2.75	32	209
H7493897032300	H7493896832300	3.00	32	209
H7493897032350	H7493896832350	3.50	32	209

13

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