



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **National Horizon Scanning Unit**

## **Horizon scanning prioritising summaries**

**Paclitaxel-eluting coronary stents to  
improve coronary artery function and  
prevent restenosis, following coronary  
angioplasty.**

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The production of these *Horizon scanning prioritising summaries* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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# PRIORITISING SUMMARY

**REGISTER ID:** 0000012

**NAME OF TECHNOLOGY:** PACLITAXEL-ELUTING CORONARY STENTS

**PURPOSE AND TARGET GROUP:** TO IMPROVE CORONARY ARTERY FUNCTION AND PREVENT RESTENOSIS, FOLLOWING CORONARY ANGIOPLASTY.

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |  |   |
|--|---|
| <input type="checkbox"/> Yet to emerge                 | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental                  | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational               | <input type="checkbox"/> Should be taken out of use   |
| <input checked="" type="checkbox"/> Nearly established |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |   |       |
|---|---|-------|
| <input checked="" type="checkbox"/> Yes | ARTG number                             | 95263 |
| <input type="checkbox"/> No             | <input type="checkbox"/> Not applicable |       |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
SCORE trial, 17 sites	✓		
TAXUS-I, Germany	✓		
TAXUS-II, Italy	✓		
ASPECT, Asia	✓		
ELUTES, Europe	✓		
DELIVER, USA	✓		
Australia		✓	

## IMPACT SUMMARY:

The Cook Group Incorporated provides paclitaxel-eluting coronary stents with the aim of reducing restenosis after coronary angioplasty. Restenosis is the narrowing of a structure (usually a coronary artery) following the removal or a reduction of a previous narrowing. Paclitaxel is a drug that inhibits cell growth. Stents that elute paclitaxel are therefore designed to reduce the risk of restenosis or narrowing. The technology is available through private and public hospitals for patients with cardiovascular disease who require either coronary artery bypass surgery or coronary angioplasty.

In 2000-01 there were 157,899 hospitalisations for coronary heart disease in Australia. This was 36% of all hospitalisations for cardiovascular conditions (AIHW, 2003). In 2000, 21,874 coronary angioplasty procedures were performed and coronary stents were inserted in 19,333 of these (88%) (AIHW, 2003).

Preliminary trial data are encouraging. Paclitaxel-eluting coronary stents appear to significantly reduce restenosis, neointimal hyperplasia and 30-day major adverse cardiac

events (MACE) rates when compared to bare metal stents and may therefore have a significant clinical impact. However, lack of safety data on vascular cytotoxicity and thrombosis and a lack of long-term effectiveness data (eg restenosis) are issues that need to be resolved.

Paclitaxel-TAXUS coronary stents (38001, Sponser Boston Scientific Pty Ltd) has TGA approval (ARTG No 95263).

#### **CONCLUSION:**

Based on the Level II evidence and given that the level of clinical need in the community and the apparent short-term effectiveness of the procedure, it is expected that paclitaxel-eluting stents will diffuse- or are diffusing- rapidly throughout the Australian health system.

#### **HEALTHPACT ACTION:**

Therefore it is recommended that this technology be referred to MSAC for a full HTA.

#### **SOURCES OF FURTHER INFORMATION:**

Evaluation of ASPECT trial (RCT, 177 enrolled patients: bare stents (placebo) vs Paclitaxel stents).

Hong, M. K., Mintz, G. S. et al (2003). 'Paclitaxel coating reduces in-stent intimal hyperplasia in human coronary arteries: a serial volumetric intravascular ultrasound analysis from the Asian Paclitaxel-Eluting Stent Clinical Trial (ASPECT)', *Circulation*, 107 (4), 517-520.

Park, S. J., Shim, W. H. et al (2003). 'A paclitaxel-eluting stent for the prevention of coronary restenosis', *N Engl J Med*, 348 (16), 1537-1545.

(Studies by Hong et al and Park et al duplicate publication of same research data)

Mintz, G. S., Tinana, A. et al (2003). 'Impact of preinterventional arterial remodeling on neointimal hyperplasia after implantation of (non-polymer-encapsulated) paclitaxel-coated stents: a serial volumetric intravascular ultrasound analysis from the ASian Paclitaxel-Eluting Stent Clinical Trial (ASPECT)', *Circulation*, 108 (11), 1295-1298.

Evaluation of TAXUS-I, -II and -III

TAXUS-I: RCT, 61 patients enrolled: bare stents vs coated stents.

TAXUS-II: RCT, 536 patients enrolled in 38 centres: bare stents vs TAXUS-SR (slow release) and TAXUS-MR (moderate release).

TAXUS-III: Case series 28 patients

Bullesfeld, L., Gerckens, U. et al (2003). 'Long-term evaluation of paclitaxel-coated stents for treatment of native coronary lesions First results of both the clinical and angiographic 18 month follow-up of TAXUS I', *Z Kardiol*, 92 (10), 825-832.

Colombo, A., Drzewiecki, J. et al (2003). 'Randomized study to assess the effectiveness of slow- and moderate-release polymer-based paclitaxel-eluting stents for coronary artery lesions', *Circulation*, 108 (7), 788-794.

Grube, E., Silber, S. et al (2003). 'TAXUS I: six- and twelve-month results from a randomized, double-blind trial on a slow-release paclitaxel-eluting stent for de novo coronary lesions', *Circulation*, 107 (1), 38-42.

Tanabe, K., Serruys, P. W. et al (2003). 'TAXUS III Trial: in-stent restenosis treated with stent-based delivery of paclitaxel incorporated in a slow-release polymer formulation', *Circulation*, 107 (4), 559-564.

#### **SEARCH CRITERIA TO BE USED:**

Coronary Angiography

Coronary Disease/pathology/radiography/\*therapy

Coronary Restenosis/\*prevention & control/radiography/ultrasonography

Coronary Arteriosclerosis/\*surgery

Angioplasty, Transluminal, Percutaneous Coronary  
Angiogenesis Inhibitors/administration & dosage/adverse effects/\*therapeutic use  
Hyperplasia/prevention & control/ultrasonography  
Paclitaxel/administration & dosage/adverse effects/\*therapeutic use  
Stents  
Coated Materials, Biocompatible/\*administration & dosage  
Drug Implants/\*administration & dosage/adverse effects