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Horizon scanning prioritising summary

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Symmetry™ Bypass Connector: Update: To facilitate the attachment of saphenous vein grafts to the aorta in patients undergoing coronary artery bypass surgery.

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PRIORITISING SUMMARY

REGISTER ID: **0000065**

NAME OF TECHNOLOGY: **SYMMETRY™ BYPASS CONNECTOR**

PURPOSE AND TARGET GROUP: **TO FACILITATE THE ATTACHMENT OF SAPHENOUS VEIN GRAFTS TO THE AORTA IN PATIENTS UNDERGOING CORONARY ARTERY BYPASS SURGERY**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☐ Yet to emerge
- ☐ Experimental
- ☒ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☒ Yes
- ☐ No

ARTG number

At the time of writing the prioritising summary the Symmetry™ device was approved for use in the Australian market by the Therapeutic Goods Administration (personal communication, St Jude Medical), however the evaluators cannot determine the ARTG number for this device.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		
Switzerland	✓		

IMPACT SUMMARY:

This summary provides a 12 month update on the Symmetry™ Bypass Connector manufactured by St. Jude Medical. The original Prioritising Summary for this device was compiled in February 2004.

BACKGROUND

The Symmetry™ Bypass is a mechanical device that facilitates the attachment of saphenous vein grafts to the aorta without requiring aortic clamping during off-pump coronary artery bypass surgery (OPCAB), thereby reducing aortic manipulation. Reduced manipulation of the ascending aorta during coronary artery bypass graft (CABG) surgery has been described as the most important factor in reducing neurologic complications such as the risk of embolism (Eckstein et al. 2001). The Symmetry™ Bypass device consists of an aortic cutter, a delivery system to implant the saphenous vein graft to the aortic wall and a self-expanding nickel-titanium connector.

CLINICAL NEED AND BURDEN OF DISEASE

In 2000-01 the total number of coronary artery bypass graft surgeries performed in Australian hospitals (AR-DRG numbers F05A, F05B, F06A, F06B) was 13,985 (AIHW 2004). The cost of the device in 2003 was $US 450 (Mack et al. 2003). At the time of preparing the original summary it was not clear whether the cost of using the device could be potentially offset by shorter operating times or improved outcomes.

DIFFUSION

At the time of writing the prioritising summary the Symmetry™ device was approved for use in the Australian market by the Therapeutic Goods Administration (St Jude Medical company representative, personal communication).

COMPARATORS

Aortic clamps are used in both on-pump and off pump CABG procedures to restrict blood flow to the area where grafts will be placed.

EFFECTIVENESS AND SAFETY ISSUES

A Swiss study of 20 consecutive patients (level IV evidence) who received at least one saphenous vein graft anastomosis using the Symmetry™ Bypass Connector (for a total of 34 vein grafts) reported no postoperative neurologic complications such as stroke, delirium, impaired levels of consciousness or major neuropsychological deficits. Time to complete the new mechanical anastomoses was less than 10 seconds in all cases. There was one case of intraoperative device failure that resulted in an aortic injury, which caused leakage but did not require suturing. In this case, the anastomosis was completed with suturing and the aorta had to be clamped. There were no cardiac-related events or angina at three month follow up. Exercise tolerance tests and stress electrocardiograms were negative in all patients (Eckstein et al. 2001). Two additional studies of 66 patients by the same authors report similar results (Eckstein et al 2002a, Eckstein et al 2002b). Two of the authors disclosed a financial relationship with St. Jude Medical.

One study of 67 patients (level IV evidence) at two US institutions found that the Symmetry™ Bypass Connector successfully anastomosed 138 of 139 saphenous vein grafts to the aorta with one misdeployment of the device requiring arterial clamping and suturing. Six anastomoses (4.3%) required an additional suture. The authors also report problems with device pre-deployment in 7% of the grafts and attribute this to human error. The authors reported no operative mortality, myocardial events or stroke. Six month follow up of 94% of the patients resulted in two patients requiring stenting because of total occlusion of the connector-saphenous vein graft (Mack et al. 2003).

Despite the studies above that reporting apparently successful *short-term* outcomes there is current concern regarding the occlusion of saphenous vein grafts placed using the Symmetry™ Bypass Connector. A US narrative review of 320 implanted devices in 121 patients undergoing CABG surgery between January and December 2002, found five patients with acute coronary syndrome within 6 months. Eleven saphenous vein grafts were either totally occluded or severely compromised (Cavendish et al. 2004). The authors cite two further studies that report adverse outcomes. The first reported 10% of patients developing clinical problems, and up to 38% with evidence of saphenous vein graft stenosis, in a randomised trial comparing the device to hand-sewn techniques (Carrel et al. 2003). The subsequent study reported 11% of patients with saphenous vein graft failure (Reuthebuch et al. 2003).

COST IMPACT

At time of writing the original Symmetry™ prioritising summary there were no data on cost impact.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were raised at the time of preparing the original prioritising summary.

OTHER ISSUES

A class action was being prepared in the US in regards to adverse outcomes suffered as a result of having had the device implanted (Accessed 11th February 2004, http://www.bigclassaction.com/class_action/symmetry.html).

RECOMMENDATION:

HealthPACT recommended monitoring the Symmetry™ device for outcomes of the class action in 2004.

HEALTHPACT ACTION: UPDATE 2005

Given the withdrawal of the Symmetry™ device, the ongoing litigation and the number of reported adverse events it is recommended that this technology be archived.

12 MONTH UPDATE **APRIL 2005**

In September 2004 St Jude Medical announced a voluntary withdrawal of the Symmetry™ device effective as of January 2005 (St Jude Medical 2005). As of February 25, 2005, sixteen lawsuits were pending against the company. In addition, a number of persons have made a claim against the company involving the Symmetry device without filing a lawsuit (Internet Bankruptcy Library 2005).

Four studies have been published since the original prioritising summary was presented to HealthPACT in January 2004 (Dietrich et al 2005, Wiklund et al 2005, Bergsland et al 2004 and Melero et al 2004). Two randomised controlled trials (Intervention II evidence), a comparative study (intervention III-2 evidence) and a case series (intervention IV) report the use of the Symmetry™ in a total of 96 patients. The longest follow up period was 12 months in one of the RCTs and ≤ six months in three of the remaining studies.

The two RCTs and the controlled trial reported increased occlusion rates in patients who had undergone bypass with the Symmetry™ compared to control groups. The case series study in three patients reported evidence of anastomotic neointimal hyperplasia.

An online search of the Manufacturer User Facility and Distributor Experience (MAUDE) database operated by the United States Food and Drug Administration found a total of 234 adverse events with the Symmetry between January 2002 and June 2005 (United States Food and Drug Administration). The two most frequently reported events were stenosis and occlusion/thrombus.

Given the withdrawal of the Symmetry™ device, the ongoing litigation and the number of reported adverse events it is recommended that this technology be archived.

SOURCES OF FURTHER INFORMATION:

Bergsland, J., Hol, P. K. et al (2004). 'Intraoperative and intermediate-term angiographic results of coronary artery bypass surgery with Symmetry proximal anastomotic device', *J Thorac Cardiovasc Surg*, 128 (5), 718-723.

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Melero, J. M., Porras, C. et al (2004). 'Severe stenosis of anastomoses by using the symmetry aortic connector system', *Ann Thorac Surg*, 78 (5), 1831-1833.

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Wiklund, L., Bonilla, L. F. & Berglin, E. (2005). 'A new mechanical connector for distal coronary artery anastomoses in coronary artery bypass grafting: a randomized, controlled study', *J Thorac Cardiovasc Surg*, 129 (1), 146-150.