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Symmetry™ Bypass Connector: 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):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number	
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

St. Jude Medical has developed the Symmetry™ Bypass Connector device with the aim of attaching saphenous vein grafts to the aorta. The device is not available in Australia. It is approved for use in the United States and internationally. It was approved for use in Europe in May 2000 and by the FDA (US) in May, 2001.

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.

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). It is not clear whether the cost may be offset by shorter operating times or improved outcomes.

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).

It is important to note that a class action is currently being prepared in the US in regards to adverse outcomes suffered as a result of having had the device implanted (On-line Legal Services Ltd).

CONCLUSION:

There is a high level of evidence available (level II) assessing the effectiveness of the Symmetry™ Bypass Connector, however there is a level of concern regarding the safety of this device with a class action in progress in the United States.

HEALTHPACT ACTION:

It is therefore recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

Carrel, T.P, Eckstein, F.S, Englberger, L., Windecker, S., Meier, B. (2003)'Pitfalls and key lessons with the symmetry proximal anastomotic device in coronary artery bypass surgery.' *Ann Thorac Surg*, 75:1434-6

Cavendish, J. J., Penny, W. F. et al (2004). 'Severe ostial saphenous vein graft disease leading to acute coronary syndromes following proximal aorto-saphenous anastomoses with the symmetry bypass connector device: is it a suture device or a "stent"?', *J Am Coll Cardiol*, 42(1), 133-139.

Eckstein, F. S., Bonilla, L. F. et al (2002a). 'First clinical results with a new mechanical connector for distal coronary artery anastomoses in CABG', *Circulation*, 106 (12 Suppl 1), I1-4.

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Katariya, K., Yassin, S. et al (2004). 'Initial experience with sutureless proximal anastomoses performed with a mechanical connector leading to clampless off-pump coronary artery bypass surgery', *Ann Thorac Surg*, 77 (2), 563-568.

Mack, M. J., Emery, R. W. et al (2003). 'Initial experience with proximal anastomoses performed with a mechanical connector', *Ann Thorac Surg*, 75 (6), 1866-1870; discussion 1870-1861.

Reuthebuch, O., Kadner, A., Turina, M. (2003)'Early bypass occlusion with the aortic connector device.' *Heart Surg forum*, 6 Suppl 1:S19

Traverse, J. H., Mooney, M. R. et al (2003). 'Clinical, angiographic, and interventional follow-up of patients with aortic-saphenous vein graft connectors', *Circulation*, 108 (4), 452-456.

On-line Legal Services Ltd [Internet]. Available from: http://www.bigclassaction.com/class_action/symmetry.html [Accessed 11th February 2004].

SEARCH CRITERIA TO BE USED:

Anastomosis, Surgical/instrumentation
Aorta/surgery
Coronary Disease/*etiology
Postoperative Complications
Saphenous Vein/surgery/*transplantation
*Stents
Suture Techniques/*instrumentation
Vascular Surgical Procedures/instrumentation
Angioplasty, Transluminal, Percutaneous Coronary
*Blood Vessel Prosthesis
Coronary Angiography
Coronary Artery Bypass
Coronary Restenosis
Myocardial Infarction/diagnosis/therapy
Aorta, Thoracic/surgery
*Blood Vessel Prosthesis