Australian Government
Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network
ANZHSN
AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summaries

C-Port® Distal Anastomosis System

March 2006

ASERNIP-S
Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

Royal Australasian College of Surgeons

Electronic copies can be obtained from http://www.horizonscanning.gov.au

Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

The production of this Horizon scanning prioritising summary 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.

This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

Name of Technology:

C-Port® Distal Anastomosis System (Cardica, Inc., Redwood City, CA, USA).

Purpose and Target Group:

The C-Port Distal Anastomosis System is designed to facilitate end-to-side distal anastomosis of blood vessels during on- or off-pump coronary artery bypass (CABG) surgery (Cardica 2006). The C-Port System aims to improve outcomes in CABG patients by decreasing the time required to complete anastomoses and improving the quality and consistency of anastomoses (Cardica 2006).

Stage of Development (in Australia):

☐ Experimental

☐ Investigational

☐ Nearly established

☐ Established

☐ Established but changed indication or modification of technique

☐ Should be taken out of use

☑ Not yet emerged in Australia

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Europe		✓	
Middle East		✓	
Canada		✓	

Despite 510(k) approval in the United States and CE mark in Europe, the paucity of studies suggest that the C-Port System is still experimental.

Impact Summary:

Background

Coronary artery disease, also called coronary heart disease, develops when atherosclerotic plaque builds up inside the walls of the coronary arteries that supply blood to the muscular

tissue of the heart. Atherosclerotic build up results in narrowing of the affected coronary arteries. Significant narrowing of these arteries by 50% to 70% leads to insufficient supply of blood and oxygen to the heart muscle in the vicinity of the arteries, especially during times of stress and exercise (Heart Foundation 2004; Answers 2006). This reduced blood flow leads to chest pain (angina) (Heart Foundation 2004). When narrowed arteries are completely blocked by a blood clot, a heart attack ensues (Answers 2006).

Sufferers of coronary artery disease may be treated with a variety of therapies depending on the stage of the disease and the age of the patient (Cardica 2006). However, in patients with advanced coronary artery disease, such as those with multi-vessel coronary artery disease, surgery remains the most effective treatment option (Cardica 2006). CABG, is performed in patients with the aim of relieving angina, improving survival and improving the function of the heart muscle by creating new routes around the narrowed or blocked arteries and restoring adequate blood flow (MedicineNet 2002; Answers 2006).

During CABG surgery the surgeon cuts the sternum (breastbone) of the patient and opens up the chest (MedicineNet 2002; Answers 2006). The procedure is performed either by stopping the heart and placing the patient on cardio-pulmonary bypass (on-pump CABG) or using stabilising devices (not all are suction, some are pressure clamps) to hold the artery in place (MedicineNet 2002; Answers 2006). The vessels most commonly used to create new routes around blocked coronary arteries are the long saphenous vein from the leg and the left internal mammary artery from the chest (Answers 2006). The saphenous vein is reversed such that the valves do not interfere with the forward flow of blood (Answers 2006). The graft technique involves sewing the graft to the native coronary artery past the point of blockage (distal anastomosis) and attaching the other end of the vein graft to the aorta (proximal anastomosis) (MedicineNet 2002). Hand-sewn anastomoses are considered the gold standard in CABG procedures because they provide excellent results, despite being technically demanding (Matschke *et al.* 2005; Cardica 2006).

The C-Port System is an automated alternative to hand-sewn anastomoses (Cardica 2006). The System achieves end-to-side distal anastomoses using miniature stainless steel staples to attach the bypass vessel to the coronary artery downstream of the point of blockage or narrowing (Cardica 2006). The staples of the C-Port System replace the individual sutures to produce a compliant anastomosis, giving the anastomosis the ability to adapt in response to changes in blood flow or pressure (Cardica 2006).

Clinical Need and Burden of Disease

According to the Australian Heart Foundation, coronary artery disease, stroke and vascular disease are epidemic despite death rates falling in recent times, with approximately 3.67 million Australians affected (Heart Foundation 2004). Factors that increase the risk of developing these cardiovascular diseases include obesity, insufficient physical activity, high blood cholesterol, hypertension, smoking and excessive consumption of alcohol and diabetes (Heart Foundation 2004). In Australia, coronary artery disease is the country's

biggest killer and was responsible for approximately 38% of all deaths in 2002 (Heart Foundation 2004).

CABG procedures were first performed during the 1960s and is now an established procedure (Davies and Senes 2003). However, CABG procedures are a treatment and not a cure for coronary artery disease (there is currently no cure for coronary artery disease), and repeat procedures are required for some patients (Davies and Senes 2003). Where the procedure is successful, grafts may fail after 10 to 15 years, at which time further surgery or other interventions may be required (Davies and Senes 2003).

In 1999 there were 74 cardiac surgeons operating in 52 hospitals throughout Australia (Davies and Senes 2003). During the same period, approximately 17,321 coronary artery bypass graft procedures were performed, in addition to other cardiac procedures (Davies and Senes 2003). In a time where the health system is experiencing a shortage of health professionals across all areas it is imperative that optimal use of health resources is made. Given the ageing nature of the Australian population, more and more people will be at risk of developing coronary artery disease and as a result more will need treatment for coronary artery disease.

Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System

The United States Food and Drug Administration (FDA) granted marketing approval for the C-Port System in November 2005 (Cardica 2006). The C-Port System has also been approved for marketing and distribution in Europe, the Middle East and Canada (Guidant 2004). Though it has received the CE mark, this does not give any assurance of clinical efficacy.

Existing Comparators

- Endopath™ and Proximate™ linear cutters and staplers (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA).
- U-Clip® Anastomotic Device (Medtronic, Inc., Minneapolis, MN USA).
- Auto Suture Modified VCS™ Clip Applier (US Surgical Corporation, Norwalk, CT, USA).
- Hand-sewn anastomosis.

Estimated Cost Impact

The cost of the C-Port System was not revealed by the searches conducted. The Medicare Benefits Schedule does not list any reimbursements for the use of the C-Port System in CABG procedures. However, the reimbursement fees for CABG procedures range from $1,722 to $2067 depending on the number and type of grafts used (Item Numbers 38497, 38498, 38500, 38501, 38503, and 38504). From July 2004 to June 2005, a total of 5973 claims were made for these Item Numbers.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	1
Case series studies	1

Only one prospective multi-centre case series study published in 2005 was retrieved and forms the basis for the safety and efficacy data on the C-Port System. The study (Matschke *et al.* 2005), carried out in five centres on 130 participants, evaluated intraoperative device performance, incidence of device related adverse events, pre-discharge and 6-month angiographic graft patency and 12-month clinical outcomes for the C-Port System. In the 130 participants, the C-Port System was used to perform vein-to-coronary artery anastomosis as part of elective CABG surgery. The study included in this summary is highlighted in bold in the reference list.

Intraoperative Device Performance

Vein-to-coronary artery anastomoses were successfully achieved using the C-Port System in 119 of the 130 patients. In 11 patients, the procedure was converted to hand-sewn suturing due to inadequate target preparation, inappropriate target vessel selection, or both, rather than technical aspects of the device itself. In an additional three patients inadequate graft blood flow related to poor target vessel runoff necessitated conversion. All conversions to hand-sewn anastomosis were safe and successful. This represents an intraoperative device related failure rate of 8.5%.

No redo operations were required in any of the patients for bleeding or revision of the C-Port anastomoses. Three patients died before discharge of causes that were not related to the device. In two of these patients, patency of the C-Port anastomosis was confirmed. Therefore, 113 patients had received C-Port mediated anastomoses at the time of discharge.

Pre-discharge and 6-Month Angiographic Graft Patency

Prior to discharge, a total of 107 C-Port anastomoses were studied by angiography (n = 104) or computed tomography (CT) (n = 3). One hundred and six (99%) of the anastomoses were patent. In three of these patients, the anastomosis was rated as FitzGibbon B (stenosis reducing the calibre of proximal or distal anastomosis or trunk to less than 50% of the grafted coronary artery). In the remaining 104 patients evaluated by angiography, 96.2% achieved FitzGibbon A classification (excellent graft with unimpaired runoff, freedom of stenosis greater than 50%).

At six months, 105 patients were available for clinical follow-up. Of these, 98% achieved Canadian Cardiovascular Society Class 0 or 1 (Class 0, asymptomatic; Class 1, angina with strenuous exercise), while 99% achieved New York Heart Association Class I or II (Class I, patients with no limitations of activities and asymptomatic whilst performing ordinary activities; Class II, patients with slight, mild limitation of activities and comfortable at rest or with mild exertion). Of the 105 patients, 98 were evaluated by either angiography (n = 89) or CT (n = 9) and 94 (95.9%) had patent anastomoses. Of the 89 patients evaluated by angiography, 82 were classified as FitzGibbon A, three were classified as FitzGibbon B and four were classified as FitzGibbon 0 (occluded).

12-Month Clinical Outcome

At 12 months, 107 patients returned for clinical follow-up. Of these, 93% achieved Canadian Cardiovascular Society Class 0 or 1, and 98% were classified as New York Heart Association Class I or II. Aspirin was the only treatment required by 68% of patients. Ninety-one patients underwent a stress electrocardiograph examination, and 93.4% showed no evidence of myocardial ischemia. The C-Port graft was found to be patent in a further three patients who underwent a stress electrocardiograph examination 17 to 20 months postoperatively.

According to researchers, patency of hand-sewn saphenous vein grafts are expected to be 87.9% after 30 days, 84.1% between 3 and 6 months, 82.7% after 12 months and 74.3% between 2 and 5 years (Matschke *et al.* 2005). In this study, C-Port grafts exceeded this benchmark with discharge patency of 99% and 6 month patency of 95.9%.

Safety Issues and Contraindications

At both the 6- and 12-month follow-ups, no major adverse cardiac events (MACE) (myocardial infarction, device related death or need for target vessel revascularisation) were reported. No contraindications for the C-Port System were identified in the literature retrieved.

The 14 patients in which a conversion to hand-sewn anastomosis was performed were also evaluated after 12 months. One patient had died 4 months postoperatively as a result of recurrent strokes, while the remaining patients were well (MACE = 0).

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

The study by Matschke *et al.* (2005) was supported through a research grant from Cardica Inc.

A new version is now available, C-Port xA, for the same intended use as the C-Port System. The new version includes modifications to improve safety and reliability as well as deployment of a greater number of staples to create leak-proof sealing without the need for additional stitches at either end of the anastomosis (Cardica 2006).

Recommendation:

Only one published case series study evaluating the safety and efficacy of the C-Port System was located. The study suggested that the C-Port System may be a safe and effective method of performing vein-to-coronary artery anastomoses, but a head-to-head comparison with hand-sewn anastomosis is needed to confirm this.

☐ Horizon Scanning Report ☐ Full Health Technology Assessment

☐ Monitor ☐ Archive

☑ Refer

ASERNIP-S will produce a broad prioritising summary on all non-robotic anastomotic devices.

References:

Answers. Coronary artery bypass surgery. Answers Corporation. Last updated 2006. http://www.answers.com/topic/coronary-artery-bypass-surgery?method=22 [Accessed February 2006].

Cardica. Cardica: Products overview. Cardica, Inc. Last updated 2006. http://www.cardica.com/Products.php [Accessed February 2006].

Davies and Senes. Cardiac Surgery in Australia 1999. Australian Institute of Health and Welfare and National Heart Foundation Australia. Last updated April 2003. http://www.aihw.gov.au/publications/cvd/csa99/csa99.pdf [Accessed February 2006].

Guidant. Guidant press release: Guidant to distribute new technology to make heart bypass surgery easier to perform. Guidant Corporation. Last updated 2004. http://www.guidant.com/news/400/print_release/CardiacPRCPort.pdf [Accessed February 2006].

Heart Foundation. Heart disease facts. National Heart Foundation Australia. Last updated 2004. http://www.heartfoundation.com.au/index.cfm?page=47 [Accessed February 2006].

Matschke KE, Gummert JF, Demertzis S, Kappert U, Anssar MB, Siclari F, Falk V, Alderman EL, Detter C, Reichenspurner H, Harringer W. The Cardica C-Port System: Clinical and angiographic evaluation of a new device for automated, compliant distal anastomoses in coronary artery bypass grafting surgery - A multicenter prospective clinical trial. *The Journal of Thoracic and Cardiovascular Surgery* 2005; **130**(6): 1645-1652.

MedicineNet. Coronary artery bypass graft surgery (CABG). MedicineNet, Inc. Last updated April 2002. http://www.medicinenet.com/coronary_artery_bypass_graft/article.htm [Accessed February 2006].

Medicare Australia. Last update 2006. http://www9.health.gov.au/mbs/ [Accessed February 2006].

Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, International Network of Agencies for Health Technology Assessment, relevant online journals and the Internet was conducted in February 2006.

Search terms used were: 'C-Port', 'distal anastomosis system', 'Cardica', 'bypass surgery' and 'anastomosis'.

This Horizon Scanning Prioritising Summary was prepared by Mr Luis Zamora from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).