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Australia and New Zealand Horizon Scanning Network

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AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Paracor HeartNet™ cardiac restraint device

August 2008



**Australian
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and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID

S000087

**NAME OF TECHNOLOGY
DEVICE**

PARACOR HEARTNET™ CARDIAC RESTRAINT

PURPOSE AND TARGET GROUP

**PATIENTS WITH HEART FAILURE IN WHOM
STANDARD THERAPY HAS FAILED TO HALT DISEASE
PROGRESSION**

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|--|
| <input checked="" 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 type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
 No
 Not applicable

INTERNATIONAL UTILISATION

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

IMPACT SUMMARY

Paracor Medical Inc. (Sunnyvale, CA, USA) provides the Paracor HeartNet™ Elastic Restraint Device, which is designed to apply gentle mechanical support to a failing heart. It may be used in patients with heart failure in whom standard medical and device therapy has failed to halt the progression of the disease.

BACKGROUND

Heart failure is a progressive condition in which the heart loses its ability to adequately contract and supply enough blood to meet the body's needs. Typical symptoms of heart failure include tiredness, shortness of breath and fluid build-up in the ankles and legs. The condition can be caused by a number of factors including heart valve disease, high blood pressure, infection or heart muscle scarring following a heart attack (McMurray & Stewart 2000). Heart failure is associated with left ventricular (LV) remodelling, which involves rearrangement of the shape and dimensions of the heart. Specifically, LV remodelling is characterised by dilatation, changes in sphericity, wall thinning, functional mitral valve regurgitation and increased wall stress. This process may initially be a compensatory mechanism, but in the long term the remodelling worsens contractile dysfunction (Carraway & Rayburn 2007).

Medical therapy for heart failure includes the use of drugs such as β -blockers and angiotensin-converting enzyme inhibitors, which can attenuate neurohormonal changes and LV remodelling. Surgery (such as revascularisation surgery or mitral valve repair when there is a correctable problem causing the heart failure) or devices (such as ventricular assist devices or implantable defibrillators to assist or maintain the pumping of the heart) may also be used (Remme et al 2005). However, despite optimal medical and device management, some patients continue to experience progression of heart failure. Several new devices have been designed to halt this progression by interrupting and reversing the process of LV remodelling (Carraway & Rayburn 2007).

In the 1980s, studies were performed which wrapped the latissimus dorsi muscle (located in the lateral mid-back region) around the failing heart in an attempt to improve function. These studies found that passive containment of the ventricles could alter the sphericity and dilatation associated with LV remodelling and reduce wall stress, thus preventing and partially reversing the process of ventricular remodelling (Carraway & Rayburn 2007). These principles led to the development of synthetic ventricular containment devices, including the Acorn CorCap™ Cardiac Support Device (Acorn Cardiovascular, Inc., St Paul, MN, USA) and the Paracor HeartNet Elastic Restraint Device. CorCap, a mesh device made from polyethylene terephthalate fibres that is surgically placed around the ventricles, was a predecessor to HeartNet and has been more extensively studied (Carraway & Rayburn 2007). However, the Corcap has thus far failed to gain United States Food and Drug Administration (FDA) approval because of flaws in the pivotal trial (Wood 2006).

The newer Paracor HeartNet device has several advantages over CorCap. Unlike the non-elastic construction of the CorCap, the HeartNet is made of nitinol mesh, which is both compliant and elastic. The relatively large compliance range of the HeartNet device reduces the likelihood of the heart becoming too constricted, while the elasticity may provide some beneficial positive epicardial pressure. The HeartNet is delivered under general anaesthetic through a minimal access thoracotomy (keyhole surgery), unlike the CorCap which required median sternotomy (open chest surgery) for placement (Klodell et al 2007; Wood 2006). The overall aim of the HeartNet device is to conform to the epicardial surface of the right and left ventricles, to support the heart throughout the

cardiac cycle and to offload the ventricles and reduce wall stress (ClinicalTrials.org 2008).

CLINICAL NEED AND BURDEN OF DISEASE

The lifetime risk of developing heart failure has been estimated at around 20% for people in Western countries (AIHW 2004). There are no Australian data on the incidence of heart failure; however, based on self-reports from the 2004–05 National Health Survey, it is estimated that 263,000 Australians have chronic heart failure (~1.3% of the population). The actual incidence could be higher as the diagnosis is commonly missed in patients with a mild form of the disease (AIHW 2006). In Australia, heart failure was responsible for 41,425 hospitalisations in the 2003–04 period (0.6% of all hospitalisations) and 2,279 deaths in 2004 (1.7% of all deaths) (AIHW 2006). While the heart failure death rates fell by 43.3% among males and 41.5% among females from 1991 to 2002, the incidence of the disease in the population is likely to be increasing. This expected increase is partly related to the wider use of sensitive diagnostic technology and the improved rates of survival after heart attack and heart failure, as well as the increasing age of the population and the increased prevalence of diabetes and obesity (AIHW 2004). The disease is a major burden on the Australian community because of the lower quality of life and premature death among those affected with heart failure, and the associated high cost of care (AIHW 2004). While newer data are not yet available, in 1993–4 the total health system cost of heart failure in Australia was AU\$411 million (Mathers and Penm 1999).

DIFFUSION

An FDA-approved safety and feasibility trial of the Paracor HeartNet device was recently conducted in the United States, with a subsequent trial in the United States and Germany. The device is not yet available in Australia, and is not approved by the Australian Therapeutic Goods Administration.

COMPARATORS

Current therapy for heart failure may consist of:

- non-pharmacological management (for example, general advice and exercise training)
- medical therapy (for example, β -blockers and angiotensin-converting enzyme inhibitors which can attenuate neurohormonal changes and LV remodelling)
- device therapy and surgery (for example, revascularisation surgery or mitral valve repair, LV assist devices, implantable defibrillators, or cardiac resynchronisation therapy)
- heart transplantation (a final option for patients with end-stage disease) (Carraway & Rayburn 2007; Klodell et al 2007; Remme et al 2005).

Devices to prevent LV remodelling are emerging as alternative treatment options when optimal medical therapy has failed. In addition to the Paracor HeartNet device, these devices include:

- Acorn CorCap (Acorn Cardiovascular, Inc., St Paul, MN) (polyethylene terephthalate fibre mesh placed around the ventricles)
- Myocor® Myosplint™ and Myocor® Coapsys® (Myocor® Inc., Maple Grove, MN, USA)) (two epicardial pads positioned on the heart's surface and connected by transventricular splints or a cord that passes through the LV) (Carraway & Rayburn 2007).

SAFETY AND EFFECTIVENESS ISSUES

Two case series using the Paracor HeartNet device have been published by the same study group. The first (Klodell et al 2007) included patients from five US sites, while the second (Klodell et al 2008) included 12 United States and five European sites. Both studies included patients with New York Heart Association (NYHA) functional class II or III heart failure who had received optimal medical or device therapy for ≥ 3 months. Patients who had undergone previous cardiac operations or who had NYHA functional class IV heart failure were excluded from both studies. Klodell et al (2007) included 21 patients (18 males and 3 females; 7/21 NYHA class II and 14/21 class III) while the later study (Klodell et al 2008) included 51 patients (48 males and 3 females; 18/51 NYHA class II and 33/51 class III). As the two case series have the same study design, outcome measures and length of follow-up, and similar results, it appeared likely that the patients from the Klodell et al (2007) study were all included in the larger Klodell et al (2008) study population. Thus, only the safety and effectiveness results of the more comprehensive 2008 study were reported, which was a consecutive series of the first 51 patients implanted with the device worldwide. Patients in this later study had a mean age of 52.3 years (range 30.4 to 72.6) and a mean duration of heart failure of 6.2 years (range 0.3 to 18.8) (Klondel et al 2008).

The procedure in the studies consisted of a left anterior minithoracotomy incision made slightly lower than the apex of the heart. The pericardium was then opened and suspended, the 'introducer' sheath of the HeartNet device inserted into the pericardium and expanded (to maintain stable access to the pericardial space), and its position confirmed. The delivery system of the HeartNet device was then advanced through the introducer using fluoroscopic guidance. The apex of the heart was grasped with a suction cup while the HeartNet mesh was inserted and deployed. The delivery system was then removed, the position of the mesh confirmed, the pericardium was released and the wound closed (Klodell et al 2008).

Safety:

In the study by Klodell et al (2008) adverse events included reoperation for bleeding (one event [in 1/51 patients]), arrhythmia/bradycardia (abnormally slow heart rate)/tachycardia (abnormally fast heart rate) (17 events [14/51 patients]), heart wall lacerations (two events, one of which led to abortion of the procedure [2/51 patients]), inflammation of the pericardium (one event [1/51 patients]), worsening heart failure episodes (11 events [4/51 patients], of which three patients progressed to decompensated heart failure between 4 and 22 months after implantation), anaemia (three events [2/51 patients]), obtundation (reduced consciousness) (one event [1/51 patients]), phrenic nerve injury (two events [2/51 patients]), stroke/transient ischaemic attack (two events [1/51 patients]), shortness

of breath (one event [1/51 patients]), pleural effusion (fluid collection around the lung) (four events [3/51 patients]), collapsed lung (one event [1/51 patients]), respiratory failure/pneumonia/atelectasis (collapsed lung due to blockage of a bronchus) (two events [2/51 patients]), empyema (pus accumulation in the chest) (one event [1/51 patients]) and kidney insufficiency/failure/compromise (two events [2/51 patients]). Deaths occurred in 2/51 patients within 30 days of the procedure due to pneumonia progressing to multisystem organ failure, and occurred in one patient eight months after the implant procedure (Klodell et al 2008).

Efficacy:

Fifty of 51 patients had a successful implantation in the study by Klodell et al (2008). The mean operation time (skin incision to skin closure) was 77.7 minutes (standard deviation (SD) 39.9; range 26.0 to 233.0) and mean implantation time was 19.8 minutes (SD 21.6; range 4.0 to 108.0). The mean intensive care unit stay was 2.9 days (SD 3.0; range 1.0 to 16.0) and the mean hospital stay was 8.0 days (SD 5.0; range 3.0 to 29.0). At the 6-month follow-up, there was a significant improvement in the 6-minute walk test (mean increase of 65.7.0 m from the baseline value [$P=0.002$; $n=36$]) and the Minnesota Living with Heart Failure questionnaire (mean decrease (improvement) of 15.7 from the baseline value [$P=0.002$; $n=26$]). The peak volume of oxygen use did not change significantly from baseline, whereas several echocardiographic parameters were significantly improved. Significant decreases from baseline were noted in the following echocardiographic parameters: 1) LV end-diastolic dimension (decreased 3 mm; $P=0.038$; $n=39$); 2) end-diastolic volume (decreased 25.7 cm³; $P=0.025$; $n=39$); 3) end-systolic volume (decreased 23.5 cm³; $P=0.37$; $n=39$); 4) LV mass (decreased 23.1 g; $P=0.046$; $n=39$). The 6-months data shows large losses to follow up, the reasons for which are not stated (Klodell et al 2008).

COST IMPACT

There are no cost-effectiveness studies on the use of the Paracor HeartNet cardiac restraint device for heart failure. The Medicare Benefits Schedule reimbursement fees for insertion of other devices for heart failure therapy are listed in table 1. If the HeartNet is shown to be safe and effective, its introduction could lead to a reduction in the use of some of these other procedures.

It should be noted that in addition to the procedural fees related to insertion of devices (such as defibrillators and cardiac resynchronization therapy devices), the cost of the devices themselves is often as high as \$AU50,000–\$AU60,000, depending on sophistication.

Table 1: Medicare Benefits Schedule of fees for insertion of devices currently used in heart failure therapy (Medicare Australia 2008):

Description	Item number	Fee (AUD)	Number of Claims (July 2006 to June 2007)
PERMANENT CARDIAC SYNCRONISATION DEVICE, insertion, removal or replacement of, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of	38365	\$230.70	282

the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120ms.			
PERMANENT TRANSVENOUS LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of through the coronary sinus, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120ms. Where the service includes right heart catheterisation and any associated venogram of left ventricular veins. Not being a service associated with a service to which items 38200 and 35200 apply	38368	\$1,105.90	496
PERMANENT CARDIAC SYNCHRONISATION DEVICE CAPABLE OF DEFIBRILLATION, insertion, removal or replacement of, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120ms.	38371	\$259.95	150
AUTOMATIC DEFIBRILLATOR, insertion of patches for, or insertion of transvenous endocardial defibrillation electrodes for, primary prevention of sudden cardiac death in: - patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or - patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy. Not being a service associated with a service to which item 38213 applies	38384	\$950.65	201
AUTOMATIC DEFIBRILLATOR GENERATOR, insertion or replacement of for, primary prevention of sudden cardiac death in: - patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or - patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy. Not being a service associated with a service to which item 38213 applies, not for defibrillators capable of cardiac resynchronisation therapy	38387	\$259.95	158
LEFT OR RIGHT VENTRICULAR ASSIST DEVICE, insertion of	38615	\$1,383.55	15
LEFT AND RIGHT VENTRICULAR ASSIST DEVICE, insertion of	38618	\$1,724.50	12
PERMANENT LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of via open thoracotomy, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: - sinus rhythm - a left ventricular ejection fraction of less than or equal to 35% - a QRS duration greater than or equal to 120ms.	38654	\$1,105.90	13

NYHF = New York Heart Failure

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

- 1) Some of the authors of the included study (Klodell et al 2008) received grant support or consulting fees from Paracor, indicating a potential conflict of interest.
- 2) A randomised controlled trial on the use of the Paracor HeartNet device is in progress, titled the 'Prospective evaluation of elastic restraint to lessen the effects of heart failure (PEERLESS-HF) trial' (ClinicalTrials.gov Identifier NCT00382863). The purpose of the study is to compare the outcomes of patients with a HeartNet device who are receiving optimal medical and device therapy with those of patients receiving optimal medical and device therapy alone (control group) after six months of follow-up. Study outcome measures include peak volume of oxygen use, 6-minute walk distance, quality of life assessment (Minnesota Living with Heart Failure questionnaire) and safety. The study commenced in 2006 and the estimated completion date is 2010. Study participants are currently being recruited, and the estimated enrolment is 272 participants (ClinicalTrials.gov 2008).
- 3) If inserted through a minimally invasive thoracotomy, the Paracor HeartNet device cannot be used after previous cardiac surgery (for example, coronary artery bypass surgery). Many patients with heart failure will have had previous cardiac surgery, and this is an important contraindication to its use. This makes the device not applicable to this cohort of patients.

SUMMARY OF FINDINGS

The cardiac restraint devices such as the Paracor HeartNet potentially offer a novel method of preventing and partially reversing the LV remodelling associated with progressive heart failure (Carraway & Rayburn 2007). The device has the potential to benefit a very large number of patients; however, at present, there is insufficient high level evidence on the HeartNet device to determine its safety and effectiveness in heart failure patients. The published case series study (Klodell et al 2008) showed that the HeartNet device could be successfully implanted in 98% of cases. Intraoperative lacerations occurred in 2 of 51 cases and there were several serious postoperative adverse events, including two deaths within 30 days of the procedure. While some adverse events can be expected with any surgery in this moderate to severely ill patient population, further studies are required to compare this safety data with that of alternative procedures. The efficacy data from the case series study was limited by large losses to follow-up at 6 months. However, the study showed that the HeartNet device can produce statistically significant improvements in several clinical and functional parameters, including the 6-minute walk test, the Minnesota Living with Heart Failure questionnaire, LV end-diastolic dimension, end-diastolic volume, end-systolic volume and LV mass. The decrease in LV mass indicates that reverse remodelling is possible using the HeartNet. Further high level evidence is required to confirm these improvements.

HEALTHPACT ACTION

Comparative studies are necessary to determine the true effectiveness of the HeartNet relative to other treatment options for patients with heart failure. Due to the potential benefit of the device, and the likelihood of randomised controlled trials being published in the future, it is recommended that HeartNet be monitored for 24 months.

NUMBER OF STUDIES INCLUDED

Total number of studies 1
Level IV intervention evidence

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

HeartNet OR Paracor