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Australia and New Zealand Horizon Scanning Network

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National Horizon Scanning Unit
Horizon scanning prioritising summary

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Thoratec heartmate® left ventricular assist device: For patients with heart failure who are ineligible for heart transplantation.

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PRIORITISING SUMMARY

REGISTER ID: **0000048**

NAME OF TECHNOLOGY: **THORATEC HEARTMATE® LEFT VENTRICULAR ASSIST DEVICE**

PURPOSE AND TARGET GROUP: **PATIENTS WITH HEART FAILURE WHO ARE INELIGIBLE FOR HEART TRANSPLANTATION**

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	51280
☐	No	☒	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States (REMATCH)	✓		✓
Case series, Australia	✓		
United States (economic)	✓		

IMPACT SUMMARY:

Heart failure occurs when the heart is unable to pump blood adequately to the rest of the body. The gold standard treatment for heart failure is heart transplantation however, due to a shortage of donor organs, waiting lists are long and many patients die before receiving a transplant (Rose et al 2001). The number of heart transplants conducted in Australia for the period January 1- December 31 2002 was 74. The number of patients who died while on the heart transplantation list was 10 between July 2002 – June 2003 (Australian and New Zealand Organ Donation Registry 2003). In Australia, heart failure occurs predominantly amongst those aged 75 and over and accounted for 40,942 hospitalisations and 2,612 deaths, during the period 2000-01 (AIHW 2003).

The Thoratec Corporation manufacture left ventricular assist devices (LVAD), which are generally used as a bridge to heart transplantation. The technology is available through Australian public and private hospitals for use in patients awaiting heart transplantation. The Thoratec ventricular assist device (Product number 102757) has TGA approval (ARTG No 51280). The number of claims processed by the HIC for the Medical Benefit Schedule numbers 38615 and 38618 (insertion of left ventricular assist device) were 18 for the period July 2002- June 2003.

LVADs receive blood from the left ventricle, then pump it into the aorta, utilising either an external or internal power source. The Thoratec LVAD pump and power source is externalised giving the patient limited mobility and is not ideal for out-patients. This device

also carries a high risk of infection and anticoagulation is required to prevent thromboembolism. In comparison, the Thoratec Heartmate® LVAD has an internalised pump and power source and is equipped with portable controllers to facilitate patient mobility, allowing patients to be discharged from hospital. A risk of infection may still exist, although anticoagulants are not required (Nemeh & Smedira, 2003).

Both types of LVAD can be used as a bridge to transplantation, however, the FDA (USA) recently extended the approval of the Heartmate® LVAD to allow for permanent use in patients who are ineligible for heart transplant. Criteria for these patients included class IV heart failure for ≥ 90 days despite medical therapy, a left ventricular ejection fraction of 25% or less, or peak oxygen consumption of no more than 12 ml/kg body weight/minute. The Heartmate® LVAD is not currently listed on the Australian TGA.

Rose et al (2001) conducted a randomised controlled trial of 129 patients who were ineligible for heart transplantation, 68 were assigned to receive a LVAD (Heartmate®) and 61 received optimal medical therapy. The rates of survival were 52% and 25% at one year follow-up (p=0.002) and 23% and 8% at two year follow-up (p=0.09), in the LVAD and medical therapy groups respectively. That is, there was approximately twice the survival benefit with Heartmate® at 1 year and three times the benefit at 2 years when compared to optimal medical therapy. However the frequency of serious adverse events such as bleeding, infection and device malfunction of the device in the device group was 2.4 times (95% CI, 1.9 –3.0) that of the medical therapy group. Wood et al (2001) conducted a small Australian case series. Three patients actively listed for transplantation were implanted with a Heartmate® LVAD. No deaths were recorded; patients were discharged from hospital between 24 and 45 days post-implantation; and were supported by Heartmate® for a total of 327 days.

The estimated cost of a heart transplant is A$35,000 with yearly ongoing costs of approximately A$15-20,000. No economic studies have been conducted in Australia to evaluate the cost-effectiveness of permanently implanted LVADs, however the cost of the Heartmate® device is estimated to be A$92,000 (US$65,000) with additional hospitalisation costs. Data on the lifetime of the device and potential cost-savings from patient survival are not currently available.

CONCLUSION:

Level II evidence indicates apparent survival benefits for the small target population (70 heart failure patients awaiting transplantation in Australia at January 2003, as well as the proportion ineligible for transplantation). It is expected that Heartmate® LVAD will diffuse rapidly throughout the Australian health system.

HEALTHPACT ACTION:

Therefore it is recommended that a Horizon Scanning report be conducted.

SOURCES OF FURTHER INFORMATION:

Transplant data from http://www.anzdata.org.au/ANZOD/Updates/waitinglist2003-01.htm

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C.A. Wood, C.A., Hayes, H.M. et al (2001). 'Can long term VAD patients be successfully managed in the community?', Abstract presented to the ASM of the Cardiac Society of Australia and New Zealand.

SEARCH CRITERIA TO BE USED:

Heart Diseases/*mortality/*surgery
*Heart-Assist Devices
*Heart Transplantation
Cardiac Surgical Procedures
Heart Failure, Congestive/*surgery/mortality/therapy
Prognosis
Risk Factors
Survival Rate