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National Horizon Scanning Unit
Horizon scanning prioritising summary

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Medtronic® InSync® III Biventricular Pacing System: Cardiac resynchronisation therapy in patients with congestive heart failure.

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PRIORITISING SUMMARY

REGISTER ID: **000086**

NAME OF TECHNOLOGY: **MEDTRONIC® INSYNC® III BIVENTRICULAR PACING SYSTEM**

PURPOSE AND TARGET GROUP: **CARDIAC RESYNCHRONISATION THERAPY IN PATIENTS WITH CONGESTIVE HEART FAILURE**

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	79844
☐	No	☐	Not applicable

In addition pre-market approval was given by the Food and Drug Administration in 2003 in the USA.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Austria	✓		
Germany	✓		
Denmark	✓		
Spain	✓		
France	✓		
Italy	✓		
Canada	✓		
Australia		✓	

IMPACT SUMMARY:

The Medtronic® InSync® Biventricular Cardiac Pacing System includes the InSync® Model 8042 Pulse Generator and specialised leads. The Medtronic® InSync® Biventricular Cardiac Pacing System is an implantable atrial biventricular pacing device for cardiac resynchronisation, (biventricular pacing).

Heart failure occurs when the heart is unable to pump blood adequately to the rest of the body, which may lead to the accumulation of fluid in the lungs or legs. Causes of heart failure include chronic hypertension, cardiomyopathy and myocardial infarction. 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).

Previous studies have suggested that cardiac resynchronisation therapy (CRT) achieved through atrial-synchronised biventricular pacing produces clinical benefits in patients with heart failure who have an intraventricular conduction delay (Abraham et al 2002). Cardiac resynchronisation improves a broad range of measures of cardiac function and clinical status in patients with moderate-to-severe heart failure and a prolonged QRS interval. Cardiac resynchronisation has been found to reduce the degree of ventricular dysynchrony (evidenced by a shortened duration of the QRS interval), increase the left ventricular ejection fraction and decrease the left ventricular end-diastolic dimension and magnitude of mitral regurgitation (Abraham et al 2002).

Medtronic® InSync® III Biventricular Cardiac Pacing System delivers electrical pulses to the two sides of the heart, stimulating them to beat in a normal rhythm. During implantation, the resynchronisation device — unlike conventional pacemakers — requires the insertion of an additional pacing lead into the coronary sinus, which is advanced into a cardiac vein to allow pacing of the left ventricle. Resynchronising the contractions of the ventricles can help the heart pump blood throughout the body more efficiently and reduce the symptoms of heart failure. The device is indicated for the reduction of the symptoms of moderate to severe heart failure in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction of ≤35% and a QRS duration ≥ 130ms.

The InSync III differs from earlier models with a new function called "sequential bi-ventricular pacing" which allows a physician to independently program and control the sequence of contractions. Other features of the InSync III include faster programming at implantation and specific diagnostic capabilities that help the physician assess the performance of the device, the heart failure status of the patient and the patient's response to treatment. The device reports up to six months of daily measurements for three heart failure status indicators: the amount of activity a patient does; the resting heart rate and the average variability of the heart rate. These extra features provide an indication of the progress of the patient and allows treatment to be tailored to each patient's individual requirements, and thus may improve quality of life (Medtronic 2004).

A multicenter, non-randomised case series study (level IV evidence) evaluated the clinical safety, performance and efficacy of the InSync® III in 198 patients with symptomatic systolic heart failure and a prolonged QRD complex duration (Mortensen et al 2004). The effectiveness of the InSync® III at baseline, prehospital discharge visit and 1-, 3- and 6-month follow-up visits was evaluated using the New York Heart Association (NYHA) criteria and 6 minute hall walk (MHW) distance (see Appendix A). 86 patients improved their 6 MHW from 339 ± 92 metres at baseline to 422 ± 127 metres at 3 months, $P < 0.001$. 55 patients improved their NYHA class from 3.1 ± 0.5 at baseline to 1.9 ± 0.7, $P < 0.001$. The study reported no device malfunctions. A total of 20 patients experienced 22 complications associated with the biventricular stimulator or lead system that required lead repositioning in ten patients and two lead explantations.

Previous studies of CRT have indicated a reduction in all-cause mortality and heart failure hospitalisation by 40%, which suggests a substantial reduction in the use of medical resources after implantation (Auricchio et al. 2004). In contrast to standard pacemakers, a CRT device has more sophisticated software and hardware that requires more extensive follow-up visits and higher cost. Current technology allows automatic storage of intracardiac electrograms and monitoring of patient's physical activity, as well as heart rate and heart rate variability. A preliminary economic analysis from Germany has concluded that CRT is a cost-effective intervention. The modestly higher upfront cost (+22% compared with medical treatment) due to implantation of a CRT device was offset by a significant decrease in hospitalisation within the first year of treatment (Bantz & Gras 2003). The current cost of the Medtronic® InSync® III

Biventricular Pacing System is $13, 442 (excl. GST) in Australia (Medtronic Customer Service Australia March 17, 2004).

The number of public hospital separations in Australia for patients with heart failure and shock, in 2001-02, was 39,505 (AR-DRG numbers F62A and F62B) (AIHW 2004). The number of hospital separations for Cardiac Pacemaker Implantation in code F12Z in 2001-2 was 8,186 (AIHW 2004). Current MBS item fees for single chamber permanent transvenous electrode, permanent cardiac pacemaker, and dual chamber permanent transvenous electrode (MBS item numbers 38278, 38281, 38284) are $530.80, $212.30, and $695.90.

CONCLUSION:

Cardiac Resynchronisation Therapy (CRT) has recognised benefits for patients with heart failure. If the new biventricular pacing devices are found to be more effective than the existing CRT technologies, it is likely that they will simply replace the current models.

HEALTHPACT ACTION:

It is therefore recommended that this technology be referred to MSAC for a full HTA.

SOURCES OF FURTHER INFORMATION:

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Bantz K, Gras D. Cardiac resynchronization therapy: a model to assess the economical value of this new technology. *Eur Heart J,* 2003; 24: 364.

Medtronic *Newsroom* [Internet]. Available from: http://www.medtronic.com/newsroom/media_kits_InSyncIII.html [Accessed 16th March 2004].

Mortensen, P. T., Sogaard, P. et al (2004). 'Sequential Biventricular Pacing', *Pacing Clin Electrophysiol,* 27 (3), 339-345.

New York Heart Association *New York Heart Association classification for congestive heart failure* [Internet]. New York Heart Association. Available from: http://www.hcoa.org/hcoacme/chf-cme/chf00070.htm [Accessed 1st March 2004].

Willerson, J. T. & Kereiakes, D. J. (2004). 'Cardiac resynchronization therapy: helpful now in selected patients with CHF', *Circulation,* 109 (3), 308-309.

SEARCH CRITERIA TO BE USED:

Cardiac Pacing, Artificial/adverse effects/ methods
Defibrillators, Implantable
Heart Atria/ physiopathology
Heart Failure, Congestive/ physiopathology/ therapy
Heart Ventricles/ physiopathology
Ventricular Dysfunction, Left/physiopathology/therapy

APPENDIX A

NEW YORK HEART ASSOCIATION CLASSIFICATION FOR CONGESTIVE HEART FAILURE

A functional and therapeutic classification for prescription of physical activity for cardiac patients.

Class I: patients with no limitation of activities; they suffer no symptoms from ordinary activities.

Class II: patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion.

Class III: patients with marked limitation of activity; they are comfortable only at rest.

Class IV: patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest.

(New York Heart Association)