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Niobe® magnetic guidance system for coronary interventions

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UPDATE PRIORITISING SUMMARY

REGISTER ID: **000146**

NAME OF TECHNOLOGY: **NIOBE®**

PURPOSE AND TARGET GROUP: **MAGNETIC NAVIGATION GUIDANCE SYSTEM FOR PERCUTANEOUS CORONARY INTERVENTIONS IN PATIENTS WITH CARDIAC ARRHYTHMIAS**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

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
United States	✓		
Germany	✓		

IMPACT SUMMARY:

Stereotaxis Inc. has recently received FDA approval for the Niobe® magnetic guidance system for use in patients requiring percutaneous coronary interventions. It is currently not available in Australia

BACKGROUND

An arrhythmia is an abnormal rhythm of the heart, which occurs as a result of the disruption of the electrical signals responsible for the normal pumping of the heart muscle. Arrhythmias result in disturbances of the heart's contractile patterns, either pumping too fast, too slow or irregularly, causing the heart to pump less effectively and resulting in inadequate blood flow to the body.

An atrial arrhythmia is an abnormal rhythm that develops in the upper chambers (atria) of the heart. Atrial fibrillation occurs when the atria contract in a rapid and irregular fashion, interfering with the ability of the atria to empty blood into the ventricles that pump blood to the body. Atrial fibrillation may lead to heart failure and may increase the risk of blood clot formation which, in turn may lead to an increased risk of stroke (Beers and Berkow 1999).

Electrophysiologic cardiac mapping studies are invasive tests in which a small electrode catheter is inserted through the groin or neck of the patient into the heart. Cardiac mapping may be performed to locate cardiac arrhythmias and directly measure the electrical activity from various regions in the heart. The physician stimulates the atria or ventricles of the heart electrically to determine response. These studies are performed for both diagnostic and therapeutic purposes. Determining the exact location of an arrhythmia is a pre-requisite for understanding the pathophysiological mechanisms that underlie the arrhythmia and allows for the evaluation of the effect of drugs, as well as facilitating surgical catheter-ablation procedures.
Manually controlled catheters and guidewires used in conventional eclectrophysiologic studies of patients with cardiac arrhythmias may have inherent functional limitations. It has been suggested that manual control of the distal tip becomes increasingly difficult as blood vessels become smaller and less accessible (Ernst et al 2003 and Faddis et el, 2003).

The Niobe® Magnetic Navigation System is an interventional workstation for the navigation of catheters or guidewires through tissue to designated target sites in the right and left cardiac and coronary vasculature. The system uses computer-controlled permanent magnets for orienting the tip of the magnetically adapted interventional device. The Niobe® allows for continuous, 360°, omni–directional control, irrespective of the number of turns or the distance the distal tip must travel to reach its target (Stereotaxis 2005).

The Niobe® is intended for use in patients to treat cardiac arrhythmias such as atrial fibrillation. It may also be of use in patients with difficult lesions, where it is difficult to manually place guidewires or catheters.

The system employs an arrangement of magnets that create a 360° magnetic field around the patient to *orient* or *steer* the tip of a magnetic device in the desired direction. Magnets are placed at the tip of the catheters and guide wires, which are inserted into the arteries. The opposing magnetic field immediately surrounding the patient on the catheterisation table is used to align the catheter's magnet. The physician then uses the device to pinpoint the affected area and guide the catheter to the location. This new way of "steering" catheters differs from the more traditional method of manually twisting, turning and pushing the catheter through the arteries. In addition, the Niobe® can be operated via remote control, thereby reducing physician exposure to radiation.

CLINICAL NEED AND BURDEN OF DISEASE

In 2002-3 there were a total of 36,657 hospital separations for principal diagnosis (I48) of atrial fibrillation and flutter, and a total of 7,043 separations for principal diagnosis (I49) of other cardiac arrhythmias (AIHW 2005).

DIFFUSION

The Niobe® device may receive wide acceptance from interventional radiologists as it overcomes limitations of manual navigation. The manufacturer claims that the device is more flexible and also results in reduced radiation exposure for health professionals (Stereotaxis 2005). The Niobe® is currently unavailable in Australia.

COMPARATORS

For cardiac mapping, standard electrophysiological studies are performed where the operator manually navigates the catheter towards the heart under fluoroscopic guidance.

There are several different options for the treatment of symptomatic arrhythmias depending on the type of arrhythmia, the severity of symptoms experienced, and the presence of other conditions such as diabetes, kidney failure or heart failure. Treatments may include lifestyle

modification and medication or cardioversion, when a small electrical shock is delivered to the heart through the chest to stop certain very fast arrhythmias such as atrial fibrillation, supraventricular tachycardia, or sinus tachycardia. Surgical treatment for arrhythmias is usually performed when all other treatment options have failed. One such treatment is surgical ablation. This is a major surgical procedure, requiring general anaesthesia where the chest is opened exposing the heart, the site of the arrhythmia located and the arrhythmia is eliminated by either radiofrequency ablation or cryoablation. Other surgical therapies for the treatment of atrial fibrillation include the implantation of a pacemaker or an implantable converter defibrillator.

EFFECTIVENESS AND SAFETY ISSUES

Faddis et al (2003) evaluated the safety and effectiveness of the Niobe® (level IV intervention evidence) for intracardiac navigation, recording and pacing. The primary endpoint was the successful navigation and recording of ten specific target points within the right atrium (RA) and right ventricle (RV) in 20 patients. The secondary endpoint was the measurement of stimulation thresholds with the magnetic catheter within the RA and RV. The safety of the Niobe® was assessed by echocardiographic evaluation immediately before and after catheter navigation, in addition to assessing patient recovery from the procedure 7 to 10 days later in a telephone interview. Navigation success was assessed both fluoroscopically and electrophysiologically. After enrolling 20 patients, the trial was expanded to include navigation to left atrial and ventricular sites and the ablation of supraventricular tachycardia (SVT): this study reports on the first seven of these patients.

Catheter navigation was successful in 213 of 215 attempted sites. In a subset of five patients, intracardiac electrograms and stimulation thresholds recorded at the high RA and RV apex with both the Niobe® catheter and a standard ablation catheter resulted in no significant difference between the two with respect to electrogram amplitudes and stimulation thresholds. Ablation of arrhythmias with the Niobe® was performed successfully in the seven patients with SVT with no complications. In relation to safety, echocardiograms performed after magnetic navigation showed that there were no cardiac structural abnormalities caused by the procedure. No adverse events occurred at the time of procedure or were reported during the follow-up phone interview (Faddis et al, 2003).

In a study of 42 patients (level IV intervention evidence) with atrioventricular nodal re-entrant tachycardia (AVNRT), the Niobe® was used to perform magnetic catheter ablation (Ernst et al 2004). In this study each patient initially received a standard electrophysiological study to identify and confirm the underlying tachycardia before magnetic mapping and ablation with the Niobe® was performed. All 42 patients underwent successful remote-controlled mapping and catheter ablation with the Niobe®. Slow pathway modulation (n=27) or ablation (n=15) was performed with a mean number of 7.2 ± 4.7 radiofrequency current applications. Repeated control stimulation failed to induce AVNRT in all patients. No complications occurred during the follow up period of 112 ± 48 days.

COST IMPACT

No information regarding the cost of the device or the cost of cardiac mapping and ablation procedures with the Niobe®, compared to conventional cardiac electrophysiologic studies was available at the time of writing this summary (despite several attempts to contact the manufacturer).

The current Medicare Benefits Schedule (MBS) fees for cardiac electrophysiological studies (item numbers 38209 and 38212) are $700.00 and $1,164 respectively. There were a total of 4,513 procedures performed between July 2003 and June 2000, resulting in a total $2,953,116 Medicare contribution (Health Insurance Commission 2005). The MBS fees for arrhythmia ablation for item numbers 38287, 38290 and 38293 are $1,780, $2,267 and $2,433

respectively. Medicare contributed a total of $3,190,288 for the 2,255 procedures performed for these item numbers between July 2003 and June 2004 (Health Insurance Commission 2005).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

APRIL 2005 - CONCLUSION:

Based on the lack of good quality studies comparing the performance of the Niobe® with standard cardiac mapping and ablation devices,it is recommended that the this technology be monitored.

APRIL 2005 - SOURCES OF FURTHER INFORMATION:

AIHW 2005 '*Prinicipal Diagnosis 0203. Interactive national hospital morbidity database'*[Internet] Available from: http://www.aihw.gov.au/cognos/cgi-in/ppdscgi.exe?DC=Q&E=/AHS/principaldiagnosis0203 [Accessed March 02, 2005]

Beers, M.H., Berwkow, R. (1999) The Merck Manual of Diagnosis and Therapy. Merck Research Laboratories.

Ernst, S., Ouyang, F. et al (2004a). 'Initial experience with remote catheter ablation using a novel magnetic navigation system: magnetic remote catheter ablation', *Circulation,* 109 (12), 1472-1475.

Ernst, S., Ouyang, F. et al (2004b). 'Modulation of the slow pathway in the presence of a persistent left superior caval vein using the novel magnetic navigation system Niobe', *Europace,* 6 (1), 10-14.

Faddis, M. N., Blume, W. et al (2002). 'Novel, magnetically guided catheter for endocardial mapping and radiofrequency catheter ablation', *Circulation,* 106 (23), 2980-2985.

Faddis, M. N., Chen, J. et al (2003). 'Magnetic guidance system for cardiac electrophysiology: a prospective trial of safety and efficacy in humans', *J Am Coll Cardiol,* 42 (11), 1952-1958.

Faddis, M. N. & Lindsay, B. D. (2003). 'Magnetic catheter manipulation', *Coron Artery Dis,* 14 (1), 25-27.

Health Insurance Commission (2005) *HIC - Professional - Statistics - Medicare Benefits Schedule (MBS) Item* [Internet] Available from: http://www.hic.gov.au/statistics/dyn_mbs/forms/mbs_tab4.shtml (Accessed March 23, 2005)

SEARCH CRITERIA TO BE USED:

Catheter Ablation/ instrumentation
Fluoroscopy
Heart Catheterization/ instrumentation
Radiography, Interventional

JUNE 2006 UPDATE - EFFECTIVENESS AND SAFETY ISSUES

Since the initial prioritising summary, a number of comparative studies have been published which evaluate the use of the Niobe® magnetic navigation system.

Tsuchida et al (2006) published a comparative study (level III-2 intervention evidence) to evaluate the use of the Niobe® magnetic navigation system (Niobe® MNS) with manual navigation in patients with coronary artery stenoses. Seventeen consecutive patients, who all had documented coronary artery disease and were candidates for percutaneous coronary intervention, underwent both Niobe® MNS and manual navigation procedures in the same coronary vessel. Patients were excluded on the basis of having contraindications to exposure to strong magnetic fields, acute coronary syndrome, evidence of visible thrombus, claustrophobia and end-stage renal disease with serum creatinine ≥ 2.5mg/dl (Tsuchida et al 2006). Following a baseline coronary angiogram, guidewires were advanced using first the Niobe® MNS and then manual navigation. Comparisons were not attempted in totally occluded or severely stenotic (diameter stenosis ≥ 80%) lesions. The endpoint was defined as intraluminal wire position distal to the stenosis (Tsuchida et al 2006). Success was defined as successful guidewire passage with no procedureal events i.e. no clinical perforation or dissection, and post-procedural elevation of creatinine kinase level (Tsuchida et al 2006). Procedure time, contrast amount used, fluoroscopy time and dose/area product (DAP) were all recorded. It is important to note that no vessel had a severe degree of tortuosity.

Procedural and fluoroscopy time were significantly different ($p=0.001$) between Niobe® MNS (median, 120 and 105 seconds respectively) and manual navigation (median, 40 and 38 seconds respectively). Contrast amount and DAP were also significantly different ($p=0.018$ and $p=0.002$ respectively) between Niobe® MNS (median, 13mL and 215Gym² respectively) and manual navigation (median, 9mL and 73Gym² respectively). No complications were documented using either method of navigation. Procedural success was not obtained in two vessels using the Niobe MNS whilst all cases were successful with the use of manual navigation (Tsuchida et al 2006).

A study of 59 patients and 68 lesions (level IV intervention evidence) by Atmakuri et al (2006) evaluated the use of Niobe® MNS during percutaneous coronary intervention (PCI) of tortuous coronary vessels. Patients were eligible for the study if an operator believed that manual navigation of the guidewire would be difficult or impossible, or if previous PCI had been unsuccessful using manual navigation. Outcomes measured were guidewire placement time and success, procedural time, fluoroscopic time, contrast amount and procedural success. The successful placement of guidewire was made in 58 lesions (85%) of which 54 (79%) continued on to successful completion of the procedure. Guidewire placement time, procedural time, fluoroscopic time and contrast amount (reported as median (25^{th}, 75^{th} percentiles)) were 10.5 minutes (6, 18), 64 minutes (41, 76), 30 minutes (15.2, 60.1) and 190mL (140, 270) respectively. The only complication noted was one episode of coronary artery perforation occurring after the lesion was successfully crossed with the Niobe® MNS wire. The guidewire was exchanged with conventional wire over which a stent was placed and perforation occurred after multiple balloon dilations (Atmakuri et al 2006).

The use of a magnetic navigation system in the placing of a left ventricular (LV) pacing lead, with or without a guiding sheath, was investigated by Rivero-Ayerza et al (2006) (level III-2 intervention evidence). In a small population of twenty one consecutive patients enrolled in this study, nine underwent cardiac resynchronization therapy (CRT) using Niobe® MNS. In six of these patients the procedure was performed using a CS guiding sheath. The twelve patients in the control group received conventional CRT. All patients met the standard criteria for CRT. Baseline clinical variables of patients in both groups did not differ significantly (Rivero-Ayerza et al 2006).

No significant difference in mean total procedure time or mean fluoroscopy time was observed between the Niobe® MNS group and the control group, 164 ± 58 minutes vs 144 ± 41 minutes and 28 ± 9 minutes vs 26 ± 12 minutes respectively. In the Niobe® MNS group, the use of a guiding sheath did not alter the mean fluoroscopy time significantly, 24 ± 8 minutes with the guiding sheath vs 35 ± 3 minutes without the guiding sheath. However, the mean procedural time was significantly longer in the group of patients in whom the guiding sheath was not used, 132 ± 26 minutes vs 229 ± 52 minutes, p=0.007. No major complications were observed during or after the procedure (Rivero-Ayerza et al 2006).

In a study to assess the feasibility of magnetic catheter guidance in patients with atrial fibrillation (AF) undergoing circumferential pulmonary vein ablation (CPVA), 40 patients underwent this procedure using Niobe® II MNS (level III-3 intervention evidence) (Pappone et al 2006). A control group of 28 patients, matched for gender, age and clinical characteristics was selected and underwent conventional CPVA ablation (Pappone et al 2006). Remote ablation was achieved in 38 of 40 patients undergoing CPVA using Niobe® II MNS with a median procedure time of 152.5 minutes. Interestingly, the difference in median procedure time between the first 12 patients and the last 28 patients undergoing CPVA using Niobe® II MNS was significantly different, (192.5 minutes vs 148 minutes respectively, p=0.012), indicating a short learning curve. The median ablation time was 49.5 minutes for all 40 patients but, again, was much shorter for the last 28 patients than the first 12 patients (49 minutes vs 70 minutes, p=0.021). Making the assumption that the last 28 patients in the remote ablation group were a more representative sub-population than the first 12 patients, the authors compared the procedural times with those of the control group, 148 and 110 minutes respectively, p<0.001. No acute complications were noted in this study (Pappone et al 2006).

The use of the Niobe® MNS in ablation of atrioventricular nodal reentry tachycardia (AVNRT) was compared to the conventional method of ablation (Kerzner et al 2006) (level III-3 intervention evidence). Twenty eight patients who had been identified as having AVNRT in electrophysiological studies as part of another, larger study (Arrhythmia Treatment with a Thermocouple Radiofrequency Ablation Catheter, ATTRAC study), were selected to have ablation of supraventricular tachyarrhythmias using the Niobe® MNS. These subjects were matched to twenty eight patients who were retrospectively identified to have had an ablation of AVNRT using conventional means during the period of enrolment in the ATTRAC study (Kerzner et al 2006). Matching of control patients was based on the attending physician who performed the procedure, gender, and the age of the patient, in this order of priority. Patients who had a second arrhythmia identified during the procedure were excluded from this study (Kerzner et al 2006). The Niobe® MNS approach had similar procedural and fluoroscopy times when compared to the matched controls but had a significantly longer time between insertion of the ablation catheter and placement of the first radiofrequency lesion (23.3 ± 12.0 minutes vs 10.5 ± 13.9 minutes, p=0.0001). The Niobe® MNS group also showed a trend towards a shorter time for which radiofrequency energy was applied (5.2 ± 4.5 minutes vs 8.0 ± 7.2 minutes, p=0.087). No major complications or recurrences were seen in the 3 months of follow up for the Niobe® MNS group (Kerzner et al 2006).

JUNE 2006 – OTHER ISSUES

One of the authors of the study by Tschudia et al (2006) was an employee of Stereotaxis Inc. Since the initial submission of the manuscript by Atmakuri et al (2006), one of the authors has become an employee of Stereotaxis Inc. Stereotaxis Inc. supported the ATTRAC study from which data for the manuscript by Kerzner et al (2006) was extracted.

JUNE 2006 – CONCLUSION:

The studies cited indicate that the Niobe MNS may have clinical use in the percutaneous coronary intervention of tortuous vessels, cardiac resynchronization therapy, and ablation for atrial fibrillation and supraventricular tachyarrhythmias. However, the evidence is not of a high quality, nor do the studies contain large patient numbers, or have long term follow-up.

JUNE 2006 - HEALTHPACT ACTION:

Cardiologists are increasingly using a variety of magnetic guidance systems. For this reason it is recommended that the technology be monitored.

JUNE 2006 - SOURCES OF FURTHER INFORMATION:

Atmakuri, S. R., Lev, E. I., et al. (2006). 'Initial experience with a magnetic navigation system for percutaneous coronary intervention in complex coronary artery lesions.' *Journal of the American College of Cardiology* 47(3), 515-21.
Ernst, S., et al., *Remote catheter ablation of parahisian accessory pathways using a novel magnetic navigation system--a report of two cases.* Journal of Cardiovascular Electrophysiology, 2005. **16**(6): p. 659-62.
Kerzner, R., Sanchez, J. M., et al. (2006). 'Radiofrequency ablation of atrioventricular nodal reentrant tachycardia using a novel magnetic guidance system compared with a conventional approach.' *Heart Rhythm* 3(3), 261-7.
Pappone, C., Vicedomini, G., et al. (2006). 'Robotic magnetic navigation for atrial fibrillation ablation.' *Journal of the American College of Cardiology* 47(7), 1390-400.
Rivero-Ayerza, M., Thornton, A. S., et al. (2006). 'Left ventricular lead placement within a coronary sinus side branch using remote magnetic navigation of a guidewire: a feasibility study.' *Journal of Cardiovascular Electrophysiology* 17(2), 128-33.
Tsuchida, K., Garcia-Garcia, H. M., et al. (2006). 'Guidewire navigation in coronary artery stenoses using a novel magnetic navigation system: first clinical experience.' *Catheterization and Cardiovascular Interventions* 67(3), 356-63.

LIST OF STUDIES INCLUDED

Total number of studies	
Level III-2 intervention evidence	2
Level III-3 intervention evidence	2
Level IV intervention evidence	1