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 Summary

Niobe magnetic navigation system for percutaneous coronary interventions

Update: August 2007

AHTA

Adelaide Health Technology Assessment

ISBN
Publications Approval Number:

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

DISCLAIMER: This report is based on information available at the time of research cannot be expected to cover any developments arising from subsequent improvements health technologies. This report is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

The Commonwealth does not guarantee the accuracy, currency or completeness of the information in this report. This report is not intended to be used as medical advice and intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used therapeutic purposes or as a substitute for a health professional's advice. The Commonwealth does not accept any liability for any injury, loss or damage incurred by use of or reliance the information.

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 departments in all states and territories, the Australia and New Zealand governments; and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by Adrian Purins and Professor Janet Hiller from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Discipline of Public Health, Mail Drop 511, University of Adelaide, Adelaide, SA, 5005.

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 electrophysiologic 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.

RECOMMENDATION:

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 following be conducted:

☐ Horizon Scanning Report	☐ Full Health Technology Assessment
☒ Monitor	☐ Archive

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.

Burkhardt, J. D., Saliba, W. I. et al (2006). 'Remote magnetic navigation to map and ablate left coronary cusp ventricular tachycardia', *J Cardiovasc Electrophysiol,* 17 (10), 1142-1144.

Chun, J. K., Ernst, S. et al (2007). 'Remote-controlled catheter ablation of accessory pathways: results from the magnetic laboratory', *Eur Heart J,* 28 (2), 190-195.

Davis, D. R., Tang, A. S. et al (2006). 'Successful ablation of a concealed parahisian accessory pathway using a remote magnetic navigation system following failure by conventional methods', *J Interv Card Electrophysiol,* 16 (3), 149-151.

Ernst, S., Chun, J. K. et al (2007). '"Sequential" Mapping Mimicking "Simultaneous" Mapping Using Magnetic Navigation During Catheter Ablation of Supraventricular Tachycardia: Results of the Single DX Study', *J Cardiovasc Electrophysiol,* 18 Suppl 1, S11-17.

Gallagher, P., Martin, L. et al (2007). 'Initial clinical experience with cardiac resynchronization therapy utilizing a magnetic navigation system', *J Cardiovasc Electrophysiol,* 18 (2), 174-180.

Thornton, A. S. & Jordaens, L. J. (2006). 'Remote magnetic navigation for mapping and ablating right ventricular outflow tract tachycardia', *Heart Rhythm,* 3 (6), 691-696.

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

HEALTH PACT DECISION:

- ☐ Horizon Scanning Report
- ☐ Full Health Technology Assessment
- ☐ Monitor
- ☒ Archive
- ☐ Refer

PRIORITY RATING

- ☐ **High**
- ☐ **Medium**
- ☐ **Low**

MAY 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).

MAY 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.

MAY 2006 – RECOMMENDATION:

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. Therefore, it is recommended that the following be conducted:

☐ Horizon Scanning Report	☐ Full Health Technology Assessment
☐ Monitor	☒ Archive

MAY 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

HEALTH PACT DECISION:

☐ Horizon Scanning Report	☐ Full Health Technology Assessment
☐ Monitor	☐ Archive
☐ Refer	

PRIORITY RATING

☐ **High**	☐ **Medium**	☐ **Low**

AUGUST 2007 UPDATE

AUGUST 2007 - SAFETY AND EFFECTIVENESS ISSUES:

A study investigating the effectiveness of the Niobe magnetic navigation guidance system compared to normal non-magnetic methods of cardiac resynchronisation therapy showed similar performance in most areas and exceeded the performance of non-magnetic techniques in certain circumstances. 102 consecutive patients were analysed with 50 and 52 being assigned non-randomly to magnetic and non-magnetic techniques, respectively (Table 1) (Gallagher et al 2007).

Table 1 Comparison of Niobe vs Non-magnetic guidance

	Niobe placement (n=50)	Non-magnetic placement (n=52)	P value	Similar or Different
Navigation time[1]	98.1 ± 29.1 minutes	91.2 ± 34.2 minutes	.029	Similar
Fluoroscopy time[1]	22.7 ± 15.1 minutes	20.8 ± 11.5 minutes	0.49	Similar
Number of CS vessels tested[1]	1.33 ± 0.6	1.34 ± 0.6	0.95	Similar
CS access + venography times[1]	7.0 ± 7.1 minutes	7.4 ± 4.7 minutes	0.49	Similar
% single CS vessel tested	77%	68%	Not given	Similar
% multiple CS vessel tested	23%	32%	Not given	Similar
LV lead positioning times[1]	10.4 ± 7.6 minutes	18.6 ± 18.9 minutes	0.005	Different (favours Niobe)
LV lead placement time if single CS vessel tested[1]	7.7 ± 6.1 minutes vs	11.2 ± 13.3 minutes	0.045	Different (favours Niobe)
LV lead placement time if multiple vessels tested[1]	16.2 ± 7.7 minutes	36.4 ± 23.4 minutes	0.004	Different (favours Niobe)
IV contrast used[1]	7.4 ± 7.1 cc	22.4 ± 11.4 cc	0.0001	Different (favours Niobe)
0.014" guidewires used [1]	1.08 ± 0.6	2.2 ± 0.5	0.0001	Different (favours Niobe)

1 Values are means ± standard deviation. Adapted from (Gallagher et al 2007).

The authors noted that there is a learning curve associated with the Niobe® device and that as users gain experience they perform procedures with it faster. This adds further significance to the time comparison presented in Table 2 in which the Niobe® out performs the standard practice. It is likely that if the study was performed solely by experienced Niobe® operators even shorter times would have been possible. The time for the learning curve to plateau was approximately 25-30 procedures. Of the patients treated with the Niobe system 92 per cent were available for long term follow-up (3 and 9 months). Of these the LV pacing thresholds were equal or lower in 83 and higher in 13 per cent of patients. Four per cent of patients required reprogramming, and none required lead revision (Gallagher et al 2007) (level III-2 Intervention evidence).

Table 2 Comparison of Sheathed versus Bare wire navigation using Niobe

	Sheathed (n=35)	Bare wire (n=22)	P value	Similar or Different
Total procedure time[1]	98 ± 32 minutes	80 ± 18 minutes	0.029	Different (favours Bare wire)
Fluoroscopy time[1]	23 ± 15 minutes	13 ± 4 minutes	0.0007	Different (favours Bare wire)
LV lead positioning times[1]	10 ± 6 minutes	4 ± 2 minutes	0.015	Different (favours Bare wire)
CS access + CS venography + LV lead placement combined time[1]	18 ± 9 minutes	11 ± 4 minutes	0.0001	Different (favours Bare wire)
Method attempted on	35 patients	22 patients[2]	NA	NA
Method successfully used on	35 of 35 patients[3]	15 of 22 patients	NA	Favours Sheathed

Adapted from (Gallagher et al 2007).
1 Values are means ± standard deviation
2 Attempted on 22 patients with failure and therefore switch to sheathed technique occurring in 7 of these patients: failure due to CS ostial flap (n=2), lead support or advancement issues (n=3), and probing problems (n=2).
3 Includes the 7 patients that the bare wire technique failure occurred in

A study involving 41 patients investigated whether the Niobe® system could perform both the diagnostic and therapeutic roles in the radio frequency ablation of supraventricular tachycardia. The study reported diagnostic success in 37/41 patients (90%; 4 patients were non-inducible due to lack of either an accessory pathway or no dual atrioventricular), and therapeutic success in 34/37 (92%) of successfully diagnosed patients. Due to the ability to remote control the Niobe® system, the operator was exposed to radiation for only one third of the procedure time. The ability of the Niobe® system to store locations previously visited during the procedure also reduced the patient's exposure to radiation from fluoroscopy. The investigators report that the total fluoroscopy time was reduced, compared to published sources, to a median of 3.0 minutes for AV nodal re-entry tachycardia ablation and a median of 6.5 minutes for accessory pathway ablation (Ernst et al 2007)(level III-3 intervention evidence).

Remote controlled ablation of the accessory pathways was investigated using the Niobe® in 59 patients (Chun et al 2007)(level III-3 intervention evidence). The study also reported on the generational advances in the technology of the magnetic catheters; three generations were analysed. The first generation catheter group consisted of 18 patients, the second generation group had 27 patients, and the third generation group had 14 patients. The success rates varied significantly with the evolution of the catheter design, with rates of success reported at 67 per cent for first generation, 85 per cent for second generation, and 92 per cent for third generation magnetic catheter tip designs (Table 3). Although the study was performed sequentially with evolving technology, the patients did not have significantly different baseline characteristics. No complications were observed during the follow-up period (median 351 days).

Table 3 Comparison of three generations of magnetic catheter tips used in accessory pathway ablation

	First Generation	Second Generation	Third generation
Success rate	67%	85%	92%
Median fluoroscopy time (minutes)	21.2	6.5	4.9
Median fluoroscopy dose (μGym^2)	1110	290	129
Mean procedure time (minutes)	217 ± 67	182 ± 68	172 ± 90

Adapted from (Chun et al 2007)

Several single-case case reports using the Niobe® system for unusual or difficult to treat presentations were published during the update period. A patient who had previously undergone three conventional, unsuccessful attempts to correct her arrhythmia was successfully treated using the Niobe® system. The condition was discovered to be a concealed, parahisian accessory pathway. This condition is associated with higher rates of recurrence after treatment and accidental heart block occurring during treatment (Davis et al 2006)(level IV intervention evidence). Another procedure, the treatment of aortic cusp ventricular tachycardia by ablation, normally associated with higher risks due to the difficulty of navigation with conventional catheters was successfully performed with the Niobe® system (Burkhardt et al 2006)(level IV intervention evidence). Another reportedly difficult procedure to perform, ablation in the right ventricular outflow tract, was performed successfully with the Niobe® system. Four patients underwent mapping and subsequent ablation with acute success in four patients and no recurrence in three of the four patients (Thornton & Jordaens 2006)(level IV intervention evidence).

The reports presented show the Niobe® device to equal or exceed the current standard devices used for navigating within patients to remedy heart arrhythmias. There are many reported advantages, such as faster procedure times, lower radiation exposure, and less contrast agent needed. Also it was found that the Niobe® device itself is improving, with newer generations of the device performing better than the earlier.

AUGUST 2007 - COST IMPACT :

No information regarding the cost impact of the Niobe® system was found.

AUGUST 2007 – SUMMARY OF FINDINGS

In the studies reviewed in this update, the Niobe® system performs well compared to conventional techniques, and in some areas exceeds the abilities of current techniques. Despite this there is still not a significant volume of data comparing the Niobe® system to current procedures and there is a lack of consecutive randomised trials with long term outcomes. Cost effectiveness data are not reported in the studies in this update and none were found during literature searches. The studies to date indicate a very positive outlook for the Niobe® system, with shorter procedure times, lower radiation exposures for the patient and practitioner, and the ability to perform conventionally refractive procedures. If the long term patient outcome and cost-effectiveness data, that are currently lacking, are published in the future this will be identified by ongoing horizon scanning activities.

HEALTHPACT ACTION:

Due to the lack of substantial high quality evidence and cost-effectiveness data, and the relatively high cost of the device HealthPACT have recommended that further assessment of this technology is no longer warranted.

NUMBER OF STUDIES INCLUDED

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

AUGUST 2007 - REFERENCES

Burkhardt, J. D., Saliba, W. I. et al (2006). 'Remote magnetic navigation to map and ablate left coronary cusp ventricular tachycardia', *J Cardiovasc Electrophysiol,* 17 (10), 1142-1144.

Chun, J. K., Ernst, S. et al (2007). 'Remote-controlled catheter ablation of accessory pathways: results from the magnetic laboratory', *Eur Heart J,* 28 (2), 190-195.

Davis, D. R., Tang, A. S. et al (2006). 'Successful ablation of a concealed parahisian accessory pathway using a remote magnetic navigation system following failure by conventional methods', *J Interv Card Electrophysiol,* 16 (3), 149-151.

Ernst, S., Chun, J. K. et al (2007). '"Sequential" Mapping Mimicking "Simultaneous" Mapping Using Magnetic Navigation During Catheter Ablation of Supraventricular Tachycardia: Results of the Single DX Study', *J Cardiovasc Electrophysiol,* 18 Suppl 1, S11-17.

Gallagher, P., Martin, L. et al (2007). 'Initial clinical experience with cardiac resynchronization therapy utilizing a magnetic navigation system', *J Cardiovasc Electrophysiol,* 18 (2), 174-180.

Thornton, A. S. & Jordaens, L. J. (2006). 'Remote magnetic navigation for mapping and ablating right ventricular outflow tract tachycardia', *Heart Rhythm,* 3 (6), 691-696.