Australian Government

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Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

National Horizon Scanning Unit
Horizon scanning prioritising summary

Volume 6, Number 9:

PoleStar N-10: Intraoperative MRI for neurosurgical procedures.

August 2004

AHTA

Adelaide Health Technology Assessment

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

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PRIORITISING SUMMARY

REGISTER ID: **000117**

NAME OF TECHNOLOGY: **POLESTAR N-10 INTRAOPERATIVE MRI**

PURPOSE AND TARGET GROUP: **INTERVENTIONAL AND INTRAOPERATIVE MAGNETIC RESONANCE IMAGING FOR NEUROSURGICAL PROCEDURES**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐ Yes
☒ No

ARTG number

☐ Not applicable

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

Odin Technologies Ltd manufacture the PoleStar™ N10, which is distributed by Medtronic Surgical Navigation Technologies, for the purpose of intraoperative magnetic resonance imaging (MRI) during neurosurgical procedures. This device received 510 (k) approval from the United States Food and Drug Administration but currently does not have approval from the Australian Therapeutic Goods Administration.

BACKGROUND

The PoleStar™ N10 system is a compact MRI unit designed for use in normal operating theatres, to provide intra-operative MRI (iMRI) images during cranial surgery. The scanner is portable and when not in use can be stored in a shielded iron cabinet. The scanner consists of two parallel vertical discs embedded together with the gradient and radio frequency transmitter coils. The vertical discs contain ceramic magnets that are spaced 25cm apart, connected by a U-shaped arm. This arm can be moved up and down and in and out once the patient is immobilised. In addition, the system has a computer for controlling image acquisition and navigation and an infrared camera for tracking patient reference markers. The magnetic field strength is 0.12 Tesla (T) and the 5-Gauss line is measured approximately 1.5m away from the centre of the magnetic field (Levivier et al 2003; Schulder & Carmel 2003). The benefit of the low field strength is that surgical instruments do not need to be MRI compatible. However, the low field strength results in longer scan times, lower image resolution and a limited field of view, which may be problematic for deep seated lesions (Scott 2004). For intra-operative use, the device is wheeled into position under a regular operating table. An adjacent room houses the computer, cooler and gradients, although once the system is turned on it is operated completely from within the operating room. A receiving coil is placed on the patient's head and images are acquired (Figures 1 and 2) (Levivier et al 2003; Schulder & Carmel 2003). The PoleStar system is able to acquire 2D single-slice, multi-slice and 3D volume images. The device does not alter the normal work flow of the operating theatre and once the unit is stored, the operating theatre may be used for other surgical procedures (FDA, 2004).

Figure 1

PoleStar™ N10 docked to a regular operating table, with storage cabinet, infrared cameras for optical navigation
(Printed with permission: Odin Technologies)

Figure 2

Patient's head in place between the two parallel discs, with receiving coil placed on head
(Printed with permission: Odin Technologies)

CLINICAL NEED AND BURDEN OF DISEASE

In Australia, the total number of newly diagnosed cases of brain carcinoma was 1,354 in the year 2000, with an age-specific rate of 7.1 per 100,000 and an age-standardised mortality rate of 6 per 100,000 in the year 2000 (AIHW 2004). The total number of public hospital separations in Australia for craniotomy was 8,817 during the year 2001-02 (AR-DRG numbers B02A, B02B and B02C). In addition the number of public hospital separations for nervous system neoplasms (AR-DRG numbers B66A and B66B) were 5,611 for the same time period. The number of MRI scans of the head required for the further investigation of carcinoma of the brain, skull base or pituitary were 7,487 for the period July 2002 to June 2003 (reported by the HIC in private hospitals for the MBS item numbers 63100, 63103 and 63109). The number of MRI scans of the head for the exclusion of specified conditions, for carcinoma of the brain, skull base or pituitary (MBS item numbers 63000, 63003 and 63009) were 17,972 for the same time period. This number may be reduced if MRI scans were conducted intra-operatively.

DIFFUSION

There are currently no PoleStar™ N10 systems installed in Australia, however Medtronic Australia are conducting discussions with two Australian hospitals interested in purchasing the more recent model, the PoleStar™ N20 system. In the United States there are currently 20 hospitals operating the PoleStar™ N10 system with another five pending. There are seven additional systems installed in European hospitals (personal communication, Market Development Manager, Medtronic Surgical Navigation Technologies).

COMPARATORS

Magnetic resonance imaging (MRI) is used to view internal structures, particularly soft tissues such as the brain. Conventional diagnostic MR images have high contrast resolution and fast imaging and are able to generate a homogenous, high strength magnetic field (Scott 2004). Conventional MRI or computed tomography (CT) scans are used pre-operatively as a diagnostic tool and to mark the location and borders of brain tumours. However, when the skull and dura mater are opened during surgery, the brain tissue may shift, making the pre-operative images unreliable. Conventional MRI or CT scans may also be utilised after surgery to confirm the complete resection of tumour (StealthStation 2004).

EFFECTIVENESS AND SAFETY ISSUES

Two large case series (Level IV evidence) have been conducted using the PoleStar™ N10 system (Kanner et al 2002; Schulder & Carmel 2003). The study conducted by Kanner et al (2002) reported on 70 neurological procedures, including 38 craniotomies, 15 brain biopsies, nine trans-sphenoidal approaches and one drainage of a subdural haematoma. The median intraoperative imaging time for craniotomy was 36 mins (range 7.5-60.5), for biopsy was 21.5 mins (range 12.5-48.5) and trans-sphenoidal approaches was 19 mins (range 11.5-36). The median total operative time for craniotomy was 295 mins (range 87-505), for biopsy was 108 mins (range 60-220) and trans-sphenoidal approaches was 113 mins (range 85-164).

Conventional MRI confirmed radical resection post-operatively in 28 patients after craniotomy and a subtotal resection was confirmed in eight craniotomies and two biopsies. Complications included one (1.4%) case of aseptic meningitis and one case of temporary intraoperative failure of the anaesthesia unit. The neuro-navigational portion of the surgery was aborted in 7/70 (10%) of cases, three of these were due to the obesity of the patients (they could not fit in the apparatus). The study conducted by Schulder and Carmel (2003) reported on 112 patients who underwent neurological procedures including craniotomy, brain biopsy and trans-sphenoidal approaches. Intraoperative imaging resulted in additional tumour removal in 40/112 (36%) patients. In addition, the aim of surgery was confirmed early in 35/112 (31%) patients, which may have avoided additional dissection around the brain. iMRI could not be utilised in two patients with skull based lesions due to their inability to fit in the apparatus (obesity). The additional time per operation when using the iMRI was an average of 1.6 hours (range 0.5 – 4). The mean number of scans per operative session was 3.2 (range 2-9). Five patients (4.5%) developed post-operative complications: 2/112 (1.8%) with a haematoma, 1/112 (0.9%) cerebral infarction and 2/112 (1.8%) temporary weakness or numbness in the arm.

COST IMPACT

The current listed price for the PoleStar™ N20 is US$1.6 million (approximately AUD$2.2 million) (personal communication, Market Development Manager, Medtronic Surgical Navigation Technologies). The price of a mobile radiofrequency shielding system is approximately US$80,000 (AUD $110,000) (Levivier et al 2003). The current cost of conducting an MRI scan of the head for the further investigation, or the exclusion of specified conditions, for carcinoma of the brain, skull base or pituitary (MBS item numbers 63100, 63103, 63109, 63000, 63003 and 63009) is $475 per scan.

No cost-effectiveness studies have been conducted on PoleStar™ N10. A study by Schulder and Carmel (2003) compared the first 58 patients to receive neurosurgery with the PoleStar™ N10 system to 76 patients with matched diagnoses, who received conventional care. The post-operative length of stay in intensive care for iMRI patients was 3.3 days compared to 3.8 days for the non-iMRI group ($p = 0.21$). However, the total hospital length of stay was significantly shorter in the iMRI group (5.1 days) compared to the non-iMRI group (9.4 days), ($p = 0.001$). Overall total costs for the iMRI group were not significantly reduced due to the increased operating theatre time (an average of 1.6 additional hours).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

This summary indicates that the PoleStar iMRI is costly and would be used sparingly for this particular patient group.

HEALTHPACT ACTION:

Queensland HTA are currently conducting a full HTA on all types of iMRI, therefore it is recommended that this technology be referred to Queensland HTA.

SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA TO BE USED:

Brain Mapping/methods
Neurosurgical Procedures/adverse effects/instrumentation
Stereotaxic Techniques
Magnetic Resonance Imaging/*methods/*instrumentation/economics
Neuronavigation/*methods/*instrumentation
Operating Rooms
Biopsy/instrumentation/methods
Brain/pathology/surgery
Motor Cortex/*anatomy & histology/*surgery
Brain Neoplasms/pathology/*surgery
Craniotomy/instrumentation
Glioma/pathology/*surgery/*diagnosis/economics
*Neurosurgical Procedures/economics/trends
Adenoma/pathology/*surgery
Meningeal Neoplasms/pathology/*surgery
Meningioma/pathology/*surgery
Pituitary Neoplasms/pathology/*surgery