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NeuroForm2™ microdelivery stent system for the treatment of cerebral aneurysms.

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PRIORITISING SUMMARY

REGISTER ID: **000101**

NAME OF TECHNOLOGY: **NEUROFORM2™ MICRODELIVERY STENT SYSTEM**

PURPOSE AND TARGET GROUP: **TREATMENT OF CEREBRAL ANEURYSM**

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:

Boston Scientific provides the Neuroform 2™ Microdelivery Stent System with the aim of treating wide-necked cerebral aneurysms. The technology is currently available in both public and private hospitals in Australia. Although in the process of current conformity assessment by the Australian Therapeutic Goods Association, the device is available for use under the special access, Category A conditions set out by the Australian Therapeutic Goods Association. The predicate device, Neuroform™ Microdelivery Stent System, was listed on the TGA in June 2003. Approval to market the device in the United States was granted in September 2002 (FDA 2002a)

BACKGROUND

A cerebral aneurysm is the dilation, bulging or ballooning out of part of the wall of a vein or artery in the brain. The disorder may result from congenital defects or from other conditions such as high blood pressure, atherosclerosis (the build-up of fatty deposits in the arteries), or head trauma (NINDS 2003).

Rupture of a cerebral aneurysm usually results in bleeding in the brain, causing a hemorrhagic stroke. In addition, blood may leak into the area surrounding the brain and develop into an intracranial haematoma. Rebleeding, hydrocephalus (the excessive accumulation of cerebrospinal fluid), vasospasm (spasm of the blood vessels), or additional aneurysms may also occur (NINDS 2003).

Emergency treatment for individuals with a ruptured cerebral aneurysm generally includes restoring deteriorating respiration and reducing intracranial pressure. Surgery is usually performed within the first 3 days to clip the ruptured aneurysm and to reduce the risk of rebleeding. When aneurysms are discovered before rupture occurs, microcoil thrombosis or balloon embolisation may be performed on patients for whom open surgery is inadvisable. During these procedures, a catheter is inserted through an artery to travel up to the brain. Once the catheter reaches the aneurysm, tiny balloons or coils are used to block blood flow through the aneurysm. The advantage of coiling is that the coils can be placed from within the vessel. A limitation of coiling wide-necked aneurysms is achieving and maintaining sufficiently dense coil packing of the aneurysm to permanently exclude blood flow (FDA 2002b).

The Neuroform2™ Microdelivery Stent System (Figure 1) is designed to prevent the rupture of an aneurysm in the brain. The delivery system carries and delivers the stent to the aneurysm site, where it is placed across the neck of the aneurysm. When the stent expands in place to conform to the inside of the artery wall, the delivery catheter is withdrawn. Another catheter is then passed through one of the small openings in the mesh of the stent and slides small embolic coils through this second catheter into the aneurysm. The coils block blood from entering the aneurysm, to help prevent the aneurysm from rupturing, and the stent keeps the coils from falling out of the aneurysm sac (FDA 2002c).

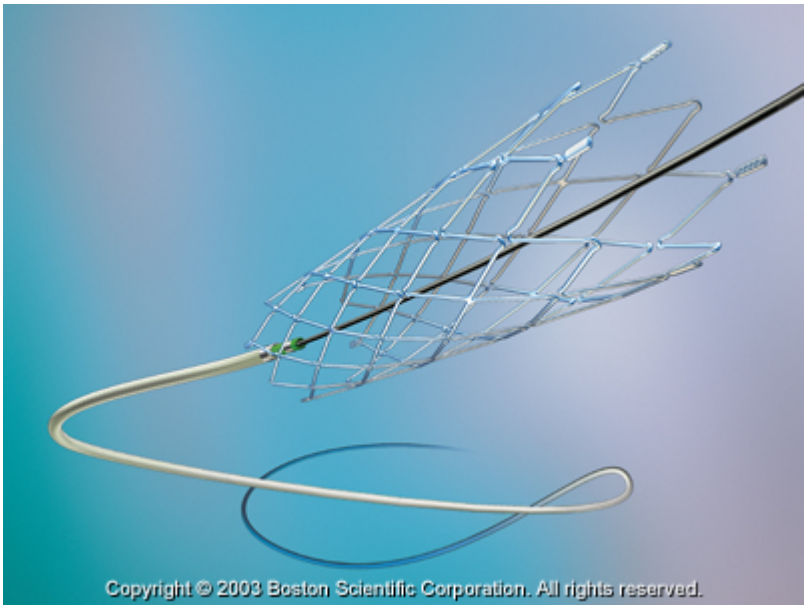

Figure 1 The Neuroform2™ Microdelivery Stent System (Printed with permission, Boston Scientific 2004)

The Neuroform2™ Microdelivery Stent System is indicated for use with embolic coils for the treatment of wide neck intracranial aneurysms that cannot be treated by placing a metal clip around the aneurysm neck (surgical clipping). Wide neck aneurysms are defined as having a neck of ≥ 4mm or a dome-to-neck ratio <2 (FDA 2002b). The Neuroform2™ is contraindicated in patients who cannot take antiplatelet and/or anticoagulation drugs for the prevention of blood clotting.

CLINICAL NEED AND BURDEN OF DISEASE

In 2001-02 there were 833 hospitalisations for cerebral aneurysm (ICC-10-AM code 167.1), (source: Australian Instituted of Health and Welfare, 2004).

DIFFUSION

The Neuroform2™ is currently being used in approximately 20% of cerebral aneurysm procedures in the 10 centres that provide aneurysm services Australia-wide (personal communication, Boston Scientific). Given that there is currently no minimally invasive approach to treating wide neck aneurysms, it is likely that there will be a rapid uptake.

COMPARATORS

Wide-necked aneurysms are often untreatable surgically or endovascularly - with devices that are currently approved for neurovascular use - as the large size of the aneurysm opening does not allow for coils to be placed.

The conventional neurosurgery procedure for aneurysm treatment is clipping, which involves surgically placing a clip over the neck of the aneurysm, thereby isolating the aneurysm from the circulation. This technique involves precise placement of the clip and requires access to the vessel from the outside to completely capture the neck of the aneurysm. However, some wide- necked aneurysms in vessels deep within the brain are not amendable to being treated by open neuro surgery.

EFFECTIVENESS AND SAFETY ISSUES

To date there have been three published case series studies (level IV evidence) with the Neuroform2™ for the treatment of wide-necked aneurysms (Fiorella et al, 2004, Benitez et al, 2004 and Wanke et al, 2004). All of these studies reported short-term outcomes. The occlusion rates from two of these studies are included in the table below.

Table 1. Occlusion rates of wide-necked aneurysms treated with the Neuroform2™

	Occlusion Rate				
Benitez et al, 2004*	100 %	99%	>90%	<90%	0%
(48 cases)	28 (58%)	7 (15%)	4 (8%)	3 (6%)	6 (13%)
Fiorella et al, 2004 (16 cases)	100%	>95%	<95%		
	1 (6%)	4 (25%)	11 (69%)		

* There were another 8 cases where the Neuroform2™ stent was not successfully deployed

In the study by Benitez et al (2004), 56 patients were enrolled, however only 48 (86%) patients with 49 wide-necked aneurysm were successfully treated with Neuroform2™ stents. There were nine different aneurysm locations amongst the study population. This study is the largest series using the Neuroform2™ to date. Mortality and morbidity outcomes from this study include five deaths (8.9%), one which occurred secondary to a stroke after the procedure (1.8%), four thromboembolic events (7%) and two femoral pseudo-aneurysms that required treatment. The overall complication rate was 10.7%.

There are no studies reporting long-term outcomes with the Neuroform2™.

COST IMPACT

An Australian randomised controlled trial (level II evidence) compared the cost and outcome of endovascular procedures (n=10) compared to open neurosurgical procedures (n=12) in the treatment of ruptured intracranial aneurysms (Bairstow et al, 2002). This study found that although endovascular procedures were more expensive in terms of the direct costs of materials used during the procedures, savings in staffing costs, length and cost of

hospitalisation compensated these expenses. The device-related costs for the procedure are dependent on the size and complexity of the aneurysm and the number of coils required. The cost of the stent and coils are approximately AUD$7,500 and $1000 - $1700, respectively (personal communication Boston Scientific).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

There is limited evidence on the use of the Neuroform2™ Microdelivery Stent System, however there is likely to be a high uptake of the technology in a small patient group.

HEALTHPACT ACTION:

Therefore it is recommended that tis technology be referred to MSAC for a full HTA.

SOURCES OF FURTHER INFORMATION:

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Maurice-Williams, R. S. (2004). 'Aneurysm surgery after the International Subarachnoid Aneurysm Trial (ISAT)', *J Neurol Neurosurg Psychiatry*, 75 (6), 807-808.

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Wanke, I., Doerfler, A. et al (2003). 'Treatment of wide-necked intracranial aneurysms with a self-expanding stent system: initial clinical experience', *AJNR Am J Neuroradiol*, 24 (6), 1192-1199.

SEARCH CRITERIA TO BE USED:

Intracranial Aneurysm/mortality/ therapy