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# Horizon Scanning Technology Prioritising Summary

## Spinal interbody fusion with Hydrosorb™ cages

February 2005  
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**ASERNIPs**

**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**

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**DISCLAIMER:** This report is based on information available at the time of research and cannot be expected to cover any developments arising from subsequent improvements to 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.

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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.

This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

**Name of Technology:**

Spinal interbody fusion with Hydrosorb™ cages

**Purpose and Target Group:**

Hydrosorb™ cages are a polylactide resorbable platform, which promotes spinal fusion by maintaining the relative position of bone grafting materials and to assist in maintaining the space between vertebral bodies in conjunction with a rigid fixation. Once fusion has occurred the bioresorbable implants are absorbed by the body (<http://macropore.com>). It may therefore promote spinal fusion between the vertebrae when vertebral discs are damaged after trauma, disease, or age-related degeneration.

**Stage of Development (in Australia):**

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged

**International Utilisation:**

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
United States		✓	

**Impact Summary:*****Background***

Arthrodesis, the fusion of bones across a joint space, is the treatment for a variety of spinal disorders. Traditionally, the most effective technique for achieving fusion has involved placing an autogenous bone graft between adjacent bone surfaces. The autogenous bone graft then matures, often fusing the surfaces together (Heiple *et al.* 1987). However, when bone grafts are used alone they have been associated with a significant incidence of collapse and pseudarthrosis (Couture *et al.* 2004).

Intervertebral cages have been designed to stabilise the spine by providing support between the vertebrae. When used in conjunction with bone autograft or allograft, fusion can occur using the intervertebral cage as a scaffold. These cages have traditionally been made out of titanium or stainless steel; however, the detrimental long-term effects of indwelling spinal instrumentation such as the persistent risk of infection, together with the inability to assess fusion radiographically, prompted the development of spacers from other materials (Lanman *et al.* 2004, Lippman *et al.* 2004).

Hydrosorb™ bioabsorbable spacers are made from a ratio of 70:30 poly[L-lactide-co-D, L-lactide], and are characterised by a degradation time of 18 to 36 months (Couture *et al.* 2004). Hydrosorb™ cages provide immediate postoperative stability but permit controlled load sharing over time due to the gradual degradation of the implant. There appears to be no significant inflammatory response or foreign body reaction and fusion status is easily monitored due to the radiolucent properties of the implant (Toth *et al.* 2002, Robbins *et al.* 2004). Hydrosorb™ Bioabsorbable implants can also be used in conjunction with bone morphogenetic protein (BMP) and bone grafts.

### ***Clinical Need and Burden of Disease***

Back and disc problems are a significant cause of ill health within the community, with increased prevalence in the older adult. Figures from the Australian Bureau of Statistics show that 16% of 16-24 year olds and 32% of 55-64 year olds have required medical attention for back and disc problems between July 2002 and June 2003 (<http://www.abs.gov.au>). Back and disc problems including spinal canal stenosis, cause patients substantial discomfort and subsequently impact heavily on employment and social activities (<http://www.digital-doc.com/neckpain.htm>).

### ***Estimated Speed, Geographic and Practitioner Use Patterns of Diffusion in the Health System***

Over 100 patients in the United States have reportedly been treated with Hydrosorb™ cages, since May 2001. In January 2003, Macropore Biosurgery Inc. received CE mark approval to market Hydrosorb™ Telamon resorbable lumbar spine cages in Europe (Business Wire, 2003). In August 2004, CE mark approval was granted to Macropore Biosurgery Inc. to market Hydrosorb™ Cornerstone HSR, a resorbable cervical interbody device in Europe (<http://www.obgyn.net>). These spine products are manufactured by Macropore Biosurgery and are co-developed, marketed and distributed throughout Europe by Medtronic Sofamor Dantek (<http://www.macropore.com>).

### ***Existing Comparators***

- Autogenous bone graft
- Allogeneic bone graft
- Fusion using titanium or steel cages

### ***Estimated Cost Impact***

The costs associated with this new product are not available. The cost of surgery involving autogenous or allograft bones in Australia is also not available. However, reimbursement fees as stated by the Medicare Benefits Schedule for bone grafts to the spine without internal fixation are approximately \$899 (Item number 48642). The reimbursement for spinal fusion at one level is approximately \$900 (Item number 48660), increasing when more than one level is affected, and internal spinal fixation with a synthetic product is approximately \$470

(Item number 48678). According to the HIC, for the 2003/2004 financial year there were 100 claims to Medicare for bone grafts to the spine, 985 claims for spinal fusions at one or more than one level (Item Numbers 48600, 48663, 48666, 48669, 48672, 48675) and 66 claims for internal spinal fixation with a synthetic product (<http://www.hic.gov.au>).

In 2000, the spinal cage market in the Asia Pacific region, exceeded US\$22.9 million-an increase of 6.9% compared to 1999. Australia, Japan, and South Korea currently account for over 93% of this market, which was forecast to increase at a compound annual growth rate of 8.2%, according to a 2003 millennium research group report (<http://devicelink.com/news/market9.html>).

## ***Efficacy and Safety Issues***

### **List of Studies Found**

Total number of studies	6
Case series studies	6

The studies included in this summary are highlighted in bold in the reference list. Data from four case series are included in this summary. The included studies were chosen for longer follow-up times, comprehensiveness of results and severity of complications.

Kuklo *et al.* (2004) reported continuous bridging bone and hence solid arthrodesis of the interbody space in 34/39 (87.2%) fusion levels. There were 39 fusion levels for a total of 22 patients. Bridging bone was noted as early as 3 months postprocedure with the breadth of the bridging bone seeming to widen over time. At the 12-month follow-up visit, continuous bridging bone was noted in 38/39 (97.4%) fusion levels. This is similar to the 30/31 (96.8%) patients and 42/44 (95.5%) levels that progressed to solid fusion in the case series by Coe *et al.* (2004) and Couture *et al.* (2004) respectively. Lenman *et al.* (2004) reported solid fusion in all 20 patients. SF-36 analysis demonstrated significantly improved 12-month pain ( $p < 0.001$ ) and physical function scores ( $p < 0.039$ ) (Coe *et al.* 2004). At the 3-month follow-up Lanman *et al.* (2004) also reported improvements in physical functioning, general health and bodily pain scores, although they were not significant.

The case series conducted by Kuklo *et al.* (2004) reported a mean operating time of 4.2 hours (range 2.25-8.9 hours). The mean blood loss was 380 ml (range 150-800 ml). The mean hospital stay was 4.7 days (range 3-9 days).

The case series by Lanman *et al.* (2004) reported that one patient in 20 (5%) experienced severe dysphagia postoperatively, resulting in an extended hospital stay of 32 days and requiring a feeding tube until they were able to swallow at one-month postprocedure. One of the 20 (5%) patients also experienced non-union and required a second operation which eventually resulted in fusion.

Kuklo *et al.* (2004) reported no infections, allergic reactions, deep vein thromboses or implant complications; however, there were three neurological changes. Two of the 22 (9.1%) patients experienced transient neuropraxia which self corrected by six weeks, and 1/22 (4.5%) patient had persistent right-sided L-5 neurodynia which required L5-S1 foraminal decompression at 6 months postprocedure. There was one case (4.5%) of intraoperative dural tear which was repaired without sequelae. Similarly, Coe *et al.* (2004) also reported there were no cases of allergic or inflammatory reactions to the polymer but there were four reported complications in three patients. One of 31 (3.2%) patients had superficial wound infection, 1/31 (3.2%) had deep wound infection along with persistent foot drop and another 1/31 (3.2%) patient experienced transient foot drop. One of the 31 (3.2%) patients also developed a non-union and underwent subsequent revision. Couture *et al.* (2004) reported incidental durotomy in 4/15 (15%) patients.

Coe *et al.* (2004) reported a cracked implant immediately after insertion in 1/31 patients (3.2%). Radiographic evaluation by Kuklo *et al.* (2004) also found one of the 22 patients to have a broken screw. At one year follow-up he was asymptomatic with a solid arthrodesis.

There is limited evidence for the safety and efficacy of spinal interbody fusion using Hydrosorb™ cages. The studies conducted suggest Hydrosorb™ cages, in conjunction with bone autograft, may effectively promote spinal interbody fusion. However, with a reported degradation time of 18 to 36 months, there is insufficient data evaluating the long-term safety and efficacy of the Hydrosorb™ cages. Furthermore, with no comparative studies of Hydrosorb cages to bone autograft alone or cages of alternative compositions, product evaluation is difficult to determine.

### 2006 update

A search of relevant databases, online journals and the Internet was conducted in February 2006, following the recommendation in February 2005 that Hydrosorb cages be monitored for assessment in 12 months time. The company which manufactures the Hydrosorb implants (Macropore) has undergone some reorganisation and is now known as MacroPore Biosurgery, a division of Cytori Therapeutics Inc. Hydrosorb implants are currently being marketed exclusively by Medtronic Sofamor Danek. Two new sources of evidence on the safety and efficacy of this intervention have been located in the literature.

Coe & Vaccaro (2005) evaluated the safety and efficacy of the Hydrosorb Mesh (Medtronic Sofamor Danek) in 31 patients requiring transforaminal lumbar interbody fusion. Of these, 27 patients had minimum follow-up of 24 months and were included in the final analysis. Twenty five (92.6%) patients achieved solid fusion while the remaining two patients experienced complications with regards to fusion. One patient (3.7%) did not achieve union as determined by flexion-extension lateral radiographs which was undertaken due to complaints of lower back pain at 9 month post-surgery. This patient has undergone subsequent revision surgery. The other patient who did not achieve successful fusion was initially thought to have solid fusion, however the patient became increasingly symptomatic over 2 years after the procedure. Radiographic and CT scans indicated solid posterolateral fusion but his interbody fusion was not united as revealed by coronal and sagittal CT reconstructions, this patient was scheduled for anterior revision. SF-36 analysis revealed that 16 patients demonstrated a statistically significant improvement in the 12 and 24 months mean pain scores and 24 month mean role physical scores when compared to pre-operative scores (Coe & Vaccaro 2005).

Four post-operative complications were reported in 3/27 patients (11.1%) but none were attributed to the use of the Hydrosorb implant. One patient (3.7%) had a cracked implant immediately after insertion, but there was no evidence of further structural failure and the patient achieved solid fusion in the last follow-up. There were no adverse events directly related to the used of the implants (Coe *et al.* 2005).

Wang & Liu (2005) presented the results of 20 patients who underwent anterior cervical discectomy and fusion with the Cornerstone resorbable interbody implants/spacers (aka Hydrosorb Cornerstone) (Medtronic Sofamor Danek). Nine patients had symptoms of myelopathy pre-treatment, all experienced improvement post-treatment; 4/9 (44%) had near complete resolution of symptoms. Mean Nurick score improved from 2.7 to 1.3 after treatment. Fourteen patients had symptoms of radiculopathy, 9/14 (64%) experienced complete resolution of symptoms, 4/14 (29%) had substantial improvement while 1/14 (7%) had some improvement but with persistent symptoms. SF-36 results showed improvement in all eight profiles of functional health and well-being. Successful fusion was attained in all patients. With regards to intervertebral disc height, a decrease of 9% in interspace height ratio was reported. Lordosis was maintained in all patients at the treated level. No adverse

events relating to the Hydrosorb implant were reported (Wang & Liu 2005).

#### References

- 1) Coe JD and Vaccaro AR. Instrumented transforaminal lumbar interbody fusion with bioresorbable polymer implants and iliac crest autograft. *Spine* 2005;**30**(17S):S76-S83.
- 2) Wang MY and Liu CY. Resorbable polylactic acid interbody spacers with vertebral autograft for anterior cervical discectomy and fusion. *Neurosurgery* 2005;**57**(1):135-140.

#### Ethical Issues:

No issues were identified from the retrieved material.

#### Cultural or Religious Considerations:

No issues were identified from the retrieved material.

#### Other Issues:

It should be noted that Dr Lanman is a paid consultant for Medtronic Sofamor Danek.

#### Recommendation:

Limited evidence exists on the safety and efficacy of Hydrosorb™ cages. Long-term safety and efficacy data from randomised controlled trials will be required before this procedure can be widely accepted. Due to the limited evidence available on this procedure, it is recommended that the following be conducted:

- |  |  |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor      | <input type="checkbox"/> Archive                           |

**2006 Update: There has been substantial amount of research in the area of spinal fusion in the past year. It is expected that further research will be conducted on Hydrosorb due to its high fusion rates and its potential to replace conventional bone grafts. A multi-centre RCT would be essential to verify Hydrosorb fusion rates and to identify any long-term issues. This technology will be monitored for a further 12 months.**

#### References:

Business Wire. Macropore biosurgery receives first European approval in spine industry for hydrosorb resorbable lumbar spine cage. Last updated Jan 2003.

[http://www.findarticles.com/p/articles/mi\\_m0EIN/is\\_2003\\_Jan\\_13/ai\\_96391286](http://www.findarticles.com/p/articles/mi_m0EIN/is_2003_Jan_13/ai_96391286) Last accessed September 2004.

**Coe JD.** Instrumented transforaminal lumbar interbody fusion with bioabsorbable polymer implants and iliac crest autograft. *Neurosurgical Focus* 2004; 16(3):E11

**Couture DE, Branch CL.** Posterior lumbar interbody fusion with bioabsorbable spacers and local autograft in a series of 27 patients. *Neurosurgical Focus* 2004; 16(3):E8.

Heiple KG, Goldberg VM, Powell AE. Biology of cancellous bone grafts. *Orthopedic Clinics in North America* 1987; 18:179-85.

**Kuklo TR, Rosner MK, Polly DW.** Computerized tomography evaluation of a resorbable implant after transforaminal lumbar interbody fusion. *Neurosurgical Focus* 2004; 16(3):E10.

**Lanman TH, Hopkins TJ.** Early findings in a pilot study of anterior cervical interbody fusion which recombinant human bone morphogenetic protein-2 was used with poly (L-lactide-co-D, L-lactide) bioabsorbable implants. *Neurosurgical Focus* 2004; 16(3):E6.

Lippman CR, Hajjar M, Abshire B, Martin G, Engelman RW, Cahill DW. Cervical spine fusion with bioabsorbable cages. *Neurosurgical Focus* 2004; 16(3):E4.

Robbins MM, Vaccaro AR, Madigan L. The use of bioabsorbable implants in spine surgery. *Neurosurgical Focus* 2004; 16(3):E1

Toth JM, Wang M, Scifert JL. Evaluation of 70/30 D,LPla for use as a resorbable interbody fusion cage. *Orthopedics* 2002; 25(Suppl 10):S1131-S1140.

#### **Sources of Further Information:**

Lowe TG and Coe JD. Resorbable polymer implants in unilateral transforaminal lumbar interbody fusion. *Journal of Neurosurgery of the Spine* 2002; 97(4):464-7

Vaccaro AR, Robbins MM, Madigan L, Albert TJ, Smith W, Hilibrand AS. Early findings in a pilot study of anterior cervical fusion in which bioabsorbable interbody spacers were used in the treatment of cervical degenerative disease. *Neurosurgical Focus* 2004; 16(3):E7

#### **Search Criteria:**

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for

Health Technology Assessments, relevant online journals and the Internet was conducted in September 2004.

Search terms used were: 'hydrosorb cages and spinal fusion', 'spinal fusion and absorbable cages', 'hydrosorb cages' and 'bioabsorbable interbody spacers'.

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This Horizon Scanning Prioritising Summary was prepared by Ms Lynette Cufone from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).