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Department of Health and Ageing

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

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Artificial invertebral disc: For the replacement of degenerative lumbar or cervical discs in patients suffering disabling, chronic pain.

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PRIORITISING SUMMARY

REGISTER ID: **0000014**

NAME OF TECHNOLOGY: **ARTIFICIAL INVERTEBRAL DISC**

PURPOSE AND TARGET GROUP: **REPLACEMENT OF DEGENERATIVE LUMBAR OR CERVICAL DISCS IN PATIENTS SUFFERING DISABLING, CHRONIC PAIN**

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	40374, 90217
☐	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
USA, RCT (SB Charite III)	✓		
Korea, Case series	✓		
USA, Case series (SB Charite III)	✓		
Germany, Case series (SB Charite III)	✓		
USA, RCT (ProDisc)	✓		
France, Case series (ProDisc)	✓		

IMPACT SUMMARY:

Several companies are marketing artificial invertebral prostheses with the aim of replacing degenerate lumbar or cervical discs. These companies include Taylor Bryant P/L (ProDisc®), Medtronic Sofamor Danek Aust Pty Ltd (Bryan and Prestige cervical disc systems) and Waldemar Link GmbH and Co (SB Charité III). None of these devices have FDA approval. Two devices have TGA approval in Australia:

a. The artificial cervical disc system (product ID:162167, Orthopedic Internal Fixation Systems, Spinal) sponsored by Medtronic Sofamor Danek Aust Pty Ltd (ARTG Number: 40374)
b. Prodisc (various sizes) (Product ID: 160268, Orthopedic Internal Fixation Systems, Spinal) sponsored by Taylor Bryant P/L (ARTG Number: 90217).

An artificial disc consists of two endplates made from cobalt chromium alloy, coated with titanium. The endplates attach to the vertebral body by anchoring teeth. A polyethylene sliding core is placed between the endplates and acts as a cushion, mimicking normal physiological movement. The prostheses are contraindicated in patients with oesteoporosis, oesteopenia, joint ankylosis and greater than Grade 1 spondylolisthesis. Complications that

may be associated with artificial disc replacement are breakage of the metal plate, dislocation of the implant and infection.

Delamarter et al (2003) conducted a randomised controlled trial (RCT), with 35 patients randomised to have the ProDisc prosthesis implanted and 18 patients randomised to conventional fusion surgery. At six months follow-up, disc replacement patients reported a significant reduction in pain and disability ($p<0.05$) when compared to the patients who had undergone fusion surgery, however the relative improvement on the Visual Analogue Scale was the same for both groups. Greater motion at L4-L5 was reported for disc replacement patients ($p<0.05$).

McAfee et al (2003) conducted an RCT, with 41 patients randomised to have the SB Charite III prosthesis implanted and 19 patients randomised to conventional fusion therapy. At a mean of two years follow-up, disc replacement patients had an Oswestry Disability Index (ODI) before sugery of 50.0 ± 14.3 and 25.0 ± 20.1 post-surgery ($p<0.001$). Conventional fusion patients had an ODI of 45.9 ± 10.4 before surgery and 23.5 ± 17.2 after surgery ($p<0.001$), indicating that the two procedures are comparable.

It is difficult to estimate the current clinical need in Australia for this procedure, as indicated patients may include those unable to undergo conventional surgery such as spinal fusion, discetomy or spinal bone graft, as well as patients who are currently managed by non-operative strategies such as medication and physiotherapy for pain relief.
The number of claims processed by the HIC for MBS item numbers 48639-48640 (discetomy), 48642-48651 (spinal bone graft) and 48654-48675 (spinal fusion) were 208, 1,611 and 1,192 respectively, for the period July 2002 – June 2003.

CONCLUSION:

Level II and Level IV evidence indicates that the implantation of artificial vertebral discs appears to be of potential benefit. Several trials are ongoing in the United States and Europe. At completion of these trials it is expected that this technology will diffuse into the Australian health system, given that the TGA has approved two of these devices.

HEALTHPACT ACTION:

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

SOURCES OF FURTHER INFORMATION:

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Buttner-Janz, K., Hahn, S. et al (2002). '[Basic principles of successful implantation of the SB Charite model LINK intervertebral disk endoprosthesis]', *Orthopade,* 31 (5), 441-453.

Delamarter, R. B., Fribourg, D. M. et al (2003). 'ProDisc Artificial Total Lumbar Disc Replacement: Introduction and Early Results From the United States Clinical Trial', *Spine,* 28 (20), S167-175.

Hochschuler, S. H., Ohnmeiss, D. D. et al (2002). 'Artificial disc: preliminary results of a prospective study in the United States', *Eur Spine J,* 11 (Suppl 2), S106-110.

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Husson, J. L., Korge, A. et al (2003). 'A memory coiling spiral as nucleus pulposus prosthesis: concept, specifications, bench testing, and first clinical results', *J Spinal Disord Tech,* 16 (4), 405-411.

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Kotani, Y., Abumi, K. et al (2002). 'Artificial intervertebral disc replacement using bioactive three-dimensional fabric: design, development, and preliminary animal study', *Spine*, 27 (9), 929-935; discussion 935-926.

McAfee, P. C., Cunningham, B. W. et al (2003a). 'Analysis of porous ingrowth in intervertebral disc prostheses: a nonhuman primate model', *Spine*, 28 (4), 332-340.

McAfee, P. C., Fedder, I. L. et al (2003b). 'Experimental Design of Total Disk Replacement-Experience with a Prospective Randomized Study of the SB Charite', *Spine*, 28 (20), S153-162.

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Takahata, M., Kotani, Y. et al (2003). 'Bone ingrowth fixation of artificial intervertebral disc consisting of bioceramic-coated three-dimensional fabric', *Spine*, 28 (7), 637-644; discussion 644.

Tropiano, P., Huang, R. C. et al (2003). 'Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year', *J Spinal Disord Tech*, 16 (4), 362-368.

van Ooij, A., Oner, F. C. & Verbout, A. J. (2003). 'Complications of artificial disc replacement: a report of 27 patients with the SB Charite disc', *J Spinal Disord Tech*, 16 (4), 369-383.

Wigfield, C. C., Gill, S. S. et al (2002). 'The new Frenchay artificial cervical joint: results from a two-year pilot study', *Spine*, 27 (22), 2446-2452.

SEARCH CRITERIA TO BE USED:

Arthroplasty, Replacement/*instrumentation/methods
MH - Back Pain/diagnosis/etiology/surgery
Intervertebral Disk Displacement/complications/*diagnosis/*surgery
Intervertebral Disk/radiography/surgery
*Joint Prosthesis
Lumbar Vertebrae/*surgery
Pain Measurement/methods
Spinal Fusion/methods
Spinal Osteophytosis/complications/*diagnosis/*surgery
Arthroplasty, Replacement/*instrumentation/methods
Back Pain/etiology/surgery
Prosthesis Design