



Title	Spinal Implants: DR8™ Pedicle Screw System
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Reference	Technology Review Report, 016/08. http://medicaldev.moh.gov.my/uploads/16.spinal.pdf

Aim

To determine the safety, effectiveness, and cost effectiveness of the DR8™ Pedicle Screw System for spinal implants.

Further research/reviews required

Further clinical research is warranted.

Conclusions and results

No scientific evidence was retrieved on the DR8™ Pedicle Screw System. The titanium screws and rods conformed to a grade of Ti-6Al-4V or UNS R56401. Titanium screws underwent mechanical testing and conformed to required standards.

The evidence was insufficient to support the safety, effectiveness, and cost effectiveness of the DR8™ Pedicle Screw System.

Recommendations

Based on this review, the DR8™ Pedicle Screw System cannot be recommended for use until further evidence is obtained on its safety and effectiveness.

Methods

A literature search included the following electronic databases: MEDLINE, Cochrane Library, Science Direct, EBSCOhost, and general databases, eg, Google and Yahoo.

All relevant literature was critically appraised using Critical Appraisal Skills Programme (CASP) checklists, and evidence was graded according to the US/Canadian Preventive Services Task Force Levels of Evidence (Harris 2001).

Regarding effectiveness, this review included only human studies. Only randomized controlled trials and systematic reviews of randomized controlled trials were included. Animal studies and observational studies were excluded.

Regarding safety assessment, all studies on the DR8™ Pedicle Screw were included.