NICE advice

Neo Pedicle Screw System for spinal fusion surgery

Medtech innovation briefing
Published: 13 June 2017

www.nice.org.uk/guidance/mib108

Summary

- The **technology** described in this briefing is the Neo Pedicle Screw System. It is a set of single-use instruments and implantable screws and rods used for spinal fusion surgery in adults.
- The **innovative aspects** are that it contains fewer components in fewer trays than standard instrument sets. This is designed to provide the same function as a standard system but take up less storage space. By using fewer instruments and fewer screws it could potentially streamline surgery. It also has a proprietary soft-tissue protector that covers the screws from sterilisation until contact with the pedicle, which is designed to reduce the risk of infection.
- The intended **place in therapy** is instead of single-use and reusable pedicle screw systems during spinal fusion surgery in adults.
- No publically available **evidence** was found about the use of the Neo Pedicle Screw System.

- **A key uncertainty** is the lack of technical success or efficacy evidence. Studies assessing length of surgery, implant failure rates, rates of successful correction and maintenance of deformity, rates of infection, and functionality compared with other pedicle screw systems would be beneficial.
- The **cost** of the Neo Pedicle Screw System is £1,880 for a single-level system (excluding VAT). This includes training by the distributor, which is minimal. The **resource impact** would be similar to standard care but with a potential reduction in costs, space and instruments needed.

The technology

The Neo Pedicle Screw System (PSS; Neo Medical) is a sterile, single-use pedicle screw system designed for use during spinal fusion surgery in adults. It comprises several differently sized rods, 14 screws, 5 core instruments and several smaller tools. Two rods are used per surgery to stabilise the vertebrae. The screws are long-arm, fenestrated, polyaxial (with monoplanar conversion option), double-threaded and self-tapping as standard.

The 5 core instruments are:

- an awl for breaking the cortical bone in open surgery
- a stefi to measure which screw is needed
- a screwdriver and a T-Handle
- a rod holder for use during minimally invasive surgery.

The system also includes:

- 4 spring steel guide wires to help place the screws
- a pedicle probe
- a rod measurer
- a counter-torque to help with tightening
- a screw-tower removal tool (the rods are delivered through screw towers into the screw head deep in the tissue, and tightened in place with set screws)

- a removable screw-tower to replace an original tower if needed.

Spinal fusion surgery uses bone grafts to make a bridge between adjacent vertebrae to strengthen the spine. It is used to treat back or leg pain caused by pressure on the nerves of the spine, from conditions such as degenerative disc disease or trauma. Bone grafts can be taken from the person's own bone at the surgical site, or donated or artificial bone can be used. Screws and rods are used to strengthen the graft.

The Neo PSS allows the placement of single-use screws into the pedicle of the vertebral body. The screws are placed at multiple spine segments around the bone graft and act as anchor points for the rods. This stabilises the segments of vertebrae that are being fused.

After the vertebrae have fused the screws and rods are normally left in place, unless the surgeon decides that removal is more beneficial. The manufacturer provides a revision kit for this additional surgery if needed, which includes 4 small revision screws, a screwdriver, a counter-torque and a removable screw-tower.

Innovations

The potential innovations are that Neo PSS contains fewer components in fewer trays than standard instrument sets. For example, some pedicle screw systems can contain over 400 screws; the Neo PSS contains only 14 screws while aiming to provide similar functionality. This is designed to take up less storage space and, by using fewer instruments and fewer screws, to potentially streamline surgery. The screws in the Neo PSS are also covered with a plastic sheath which keeps the screws sterile until contact with the pedicle. This is designed to minimise the risk of infection.

Current NHS pathway or current care pathway

Spinal fusion surgery can be used to treat low back pain caused by severe degenerative disc changes, by fusing 1 or 2 levels of the lower spine. It is usually only done after 6 to 12 months of non-surgical treatment.

The NICE guideline on low back pain and sciatica in over 16s recommends that spinal fusion surgery should not be used for this indication unless in a randomised controlled trial. NICE interventional procedure guidance on lateral interbody fusion in the lumbar spine notes that it has serious but well recognised complications, so should only be done by an experienced surgeon for people with life-limiting symptoms that have not responded

to medical management.

Current spinal fusion surgery uses larger single-use and reusable pedicle screw systems to implant the screws. The screws and instruments in reusable systems must be repeatedly sterilised and have a limited shelf-life. The Neo PSS would be used as an alternative to these single-use or reusable systems.

NICE is aware of the following CE-marked device that appears to fulfil a similar function to the Neo PSS:

- SteriSpine (Safe Orthopaedics).

Population, setting and intended user

The Neo PSS is intended for use during spinal fusion surgery for degenerative disc disease, spondylolisthesis, trauma, spinal stenosis, tumour, pseudoarthrosis or failed previous spinal fusion. In 2009/10, over 4,000 spinal fusion operations were done in the NHS. This was a 14% increase on the previous year (Rushton et al. 2015). By 2012/13, this had increased further to 6,500 operations (Greenwood et al. 2016).

The Neo PSS would most likely be used for skeletally mature patients over the age of 18, who need spinal fusion surgery. The system will most likely be used by spinal, orthopaedic and trauma surgeons and neurosurgeons. In-house training is needed for both surgical and nursing staff before using the system to ensure familiarity with its use. A product specialist from the distributor provides this training as well as advice during surgery if needed.

Costs

Technology costs

A single-level Neo PSS costs £1,880 (excluding VAT), including all components and training. A revision kit to remove the screws and rods costs £220.

Costs of standard care

SteriSpine, a single-use, single-level pedicle screw system, costs £1,995 (excluding VAT). The Revolution pedicle screw system is a minimally invasive reusable system, and costs

£2,300 (excluding VAT).

Resource consequences

The Neo PSS would be used in the same setting by the same surgeons who use existing pedicle screw systems. No additional facilities or products are needed for Neo PSS, and it should need less storage space.

Repeatedly sterilising reusable screw systems can corrode the screws and instruments, which increases the chances of metal fracture and implant failure. A sterile single-use system, such as the Neo PSS, could be cost saving to the NHS if there were a reduced incidence of implant fracture or failure. The screws are supplied in a protective sheath designed to keep them sterile up to the point of insertion which, if it resulted in fewer infections, could reduce the associated costs. There is currently no evidence to support these potential resource benefits.

The Neo PSS is currently being used in 2 NHS trusts.

Regulatory information

The Neo Pedicle Screw System (Neo PSS) was CE marked as a class IIb device in September 2016. It is distributed in the UK by Ovidius Medical.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected

characteristics under the Equality Act 2010).

The manufacturer states that the Neo Pedicle Screw System (Neo PSS) should not be used in children, people who still have general skeletal growth, and people with certain mental health problems. Some mental health problems are common contraindications for spinal fusion surgery because of the extent of self-care needed after surgery. A specialist commentator advised that the consultant surgeon would consider surgery on a case-by-case basis, always acting in the best interests of the patient.

People with mental health problems that affect everyday living may be considered to have a disability, which, along with age, is a protected characteristic under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

No publically available evidence was found on the use of the Neo Pedicle Screw System (Neo PSS).

Overall assessment of the evidence

Evidence of clinical effectiveness would allow for informed clinical or commissioning decisions on the Neo PSS. Primary outcome measures should include rates of successful correction, maintenance of spinal deformity, rates of infection, length of surgery and implant failure rates. Secondary outcome measures should include functional, mobility and quality-of-life measures, and surgeon and theatre staff satisfaction. Ideally, these outcomes should be measured in large samples comparing Neo PSS with other single-use or reusable systems used in the NHS to determine clinical efficacy.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 specialist commentators were familiar with this technology, and 1 had used it once before.

Level of innovation

Two commentators agreed that the Neo Pedicle Screw System (Neo PSS) is a variation on existing technologies, with 1 stating that it provides a single-use disposable option. Another commentator noted that the Neo PSS has some value in reducing the tray space needed during surgery. The commentators felt that little training would be needed to use the system.

Potential patient impact

Two commentators did not expect the Neo PSS to improve patient health outcomes, and none felt that there would be any change to patient experience. Two commentators stated that it could potentially reduce the risk of infection, but evidence from studies would be needed to prove this. One noted that Neo PSS could prevent the incidence of surgery being cancelled because a hole is found in the cover of conventional trays of instruments.

One commentator noted that single-use devices also have the potential advantage of reduced exposure to Creutzfeldt–Jakob disease when used in patients born after 1996 and when there is a breach of the dura mater (outermost membrane that surrounds the spinal cord and brain).

Potential system impact

The commentators did not identify any significant effect on NHS services, facilities and infrastructure. One commentator believed that the Neo PSS could be associated with reduced sterilisation costs, if these are significant, and improved theatre efficiency. Two commentators noted that it needs less storage space than other systems. One stated that using Neo PSS would lead to a lot of disposable packaging needing to be removed after surgery, and that there is a cost associated with this.

The commentators did not see any clear cost savings associated with using the Neo PSS. One felt that in order to identify any cost saving, the cost of sterilising reusable instruments would need to be assessed.

General comments

Two commentators noted that the use of Neo PSS would be limited to straightforward surgeries, because other instruments would be needed for patients with variations to their anatomy, where correction of deformity or bone reduction is needed, or to correct segment deformity.

Two commentators stated that they did not have concerns over how repeated sterilisation procedures may affect the integrity of the instruments; neither had seen evidence to show that sterilisation caused damage or metal fatigue. Another commentator noted that instruments have a stated shelf-life, after which they are disposed of.

Specialist commentators

- Dr Babak Arvin, consultant neurosurgeon, Queens Hospital, Romford. No conflicts of interest declared.
- Dr Navin Furtado, consultant neurosurgeon and spinal surgeon, Queen Elizabeth Hospital, Birmingham. No conflicts of interest declared.
- Dr Alwyn Jones, consultant orthopaedic spinal surgeon, University Hospital of Wales, Cardiff. Consultancy with regards to teaching surgical procedures for Nuvasive Spinal Company.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-2529-2