



Australian Government
Medical Services Advisory Committee

Public Summary Document

Application 1661 - Implantation of minimally invasive interspinous decompression spacers for moderate degenerative lumbar spinal stenosis

Applicant: Boston Scientific Pty Ltd

Date of MSAC consideration: 83rd MSAC Meeting, 25-26 November 2021

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of minimally invasive interspinous decompression spacers (IDS) for the treatment of moderate degenerative lumbar spinal stenosis (LSS) with or without low-grade spondylolisthesis was received from Boston Scientific Australia Pty Ltd by the Department of Health.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support public funding for the implantation of minimally invasive IDS for moderate degenerative LSS, because the evidence did not support the effectiveness claims compared with alternative treatment options. MSAC considered there may be a clinical place for this therapy, but noted the complexity in defining the appropriate patient population who may benefit. MSAC advised that the clinical trial evidence for the efficacy of the spacers was of low certainty, had uncertain inclusion criteria, and omitted a primary clinical outcome of walking ability. MSAC advised that comparative safety was also uncertain, including over the longer-term. For these reasons, MSAC also considered that the related economic evaluation was insufficiently supported.

Consumer summary
<p>Boston Scientific applied for public funding via the Medical Benefits Schedule (MBS) for implanting minimally invasive interspinous decompression spacers for the treatment of moderate degenerative lumbar spinal stenosis with or without low grade spondylolisthesis.</p> <p>The spinal canal is the channel in each vertebral bone (bones of the spine) through which the spinal cord runs. Spinal canal stenosis is the narrowing of the spinal canal, which can put</p>

Consumer summary

pressure on the spinal cord or the nerves that go from the spinal cord to the muscles. It is a common condition, mostly occurring in the lower back (lumbar spine). It is caused by age-related degenerative changes. It classically causes pain or discomfort in the buttocks, thighs, and or calves brought on by standing and walking, and this is relieved by sitting or leaning forwards. Limited walking ability is the dominant complaint. While commonly seen on imaging in older people, only about one in five people with lumbar canal stenosis on imaging will have symptoms. Spondylolisthesis is a condition that occurs when one vertebra shifts forward on the vertebra below it.

Interspinous decompression spacers are inserted between the part of the vertebrae nearest the skin using minimally invasive surgery methods. The spacers stabilise, and increase the distance between, the vertebrae. There are several interspinous decompression spacers registered for use in Australia, with some used along with decompression surgery (where a small portion of the vertebral bone is removed i.e. laminectomy). Spinal fusion may also be performed with decompression, which is surgery to join two or more vertebrae into one single structure. This stops movement between the bones to prevent back pain. This assessment also included a comparison of interspinous decompression spacers against conservative care, which consisted of non-surgical approaches including physical therapy, pain medications (non-steroidal anti-inflammatory drugs and mild opioids) and epidural steroid injections.

MSAC considered there was uncertainty about the place of interspinous decompression spacers within the clinical care pathway. MSAC acknowledged that IDSs may benefit people with specific symptoms (or symptom complex), particularly when compared to non-surgical treatment. However, MSAC considered that the information provided did not demonstrate that using interspinous decompression spacers is safer and more effective than other treatment options. MSAC also considered that the proposed fee for the surgery was not sufficiently justified.

MSAC's advice to the Commonwealth Minister for Health

MSAC did not support creating new MBS items for implanting interspinous decompression spacers. MSAC was not convinced that IDSs are as safe and effective as other lumbar spinal stenosis treatments and was uncertain about whether interspinous decompression spacers were good value for money.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted this application, from Boston Scientific, requested MBS listing of minimally invasive IDSs for the treatment of moderate degenerative LSS with or without low grade spondylolisthesis. MSAC noted that the Superior IDS, which is manufactured by the applicant, is the only one listed on the Australian Register of Therapeutic Goods.

MSAC noted there have been two previous applications to MSAC for IDS devices: application 1099 in 2007 and application 1422 in 2017. Both applications were not supported by MSAC due to insufficient evidence for effectiveness. Among these proposed devices, only the X-STOP® was, like Superior, a minimally invasive standalone implant that does not require extensive open surgery. The other devices are designed to be used in conjunction with surgical spinal decompression. The nominated population for the current application is similar to that for the X-STOP device : skeletally mature patients with neurogenic intermittent claudication secondary to a diagnosis of moderate degenerative LSS, with or without grade 1 spondylolisthesis (on a scale of

1 to 4), whose impaired physical function or pain are relieved in flexion. Patients must have undergone at least 6 months of non-operative treatment.

MSAC recalled in assessing Application 1422 in 2017, it had concerns as to whether decompression and fusion was any better than decompression alone, and so had queried whether decompression and fusion should be funded on the MBS and requested an in-depth review of the evidence for decompression and fusion ([MSAC 1422 Public Summary Document](#), p2).

MSAC noted the conflicting views in the consultation feedback from the Neuromodulation Society of Australia and New Zealand (NSANZ) and Spine Society of Australia (SSA), which was also noted in the pre-MSAC response. MSAC considered that wider consultation input from other medical practitioners (e.g. general practitioners and rheumatologists etc) would be informative.

MSAC noted the X-STOP device has been withdrawn from the market, which the applicant claimed was due to commercial reasons. MSAC also noted the editorial cited in the commentary which suggested that it was due to poor long-term outcomes along with a relatively high rate of complications.

MSAC noted that the applicant-developed assessment report (ADAR) proposed two new MBS items, covering procedures for one and two lumbar motion segments, respectively. MSAC agreed with ESC that the proposed item descriptors should specify that the service should be restricted to those aged 45 years and older. However, MSAC noted that moderate LSS is common, the presenting patients' symptoms are heterogenous and that it is difficult to determine the correlation between radiological degree of stenosis and clinical severity of spinal canal stenosis, with neurological and claudication symptoms being the most relevant. This makes it difficult to categorically define an eligible population for IDS. However, MSAC considered that the patient group specified in the MBS items was not specific enough, and that the item descriptors needed to be more clinically defined, including specifying the symptom complex that would make patients with moderate LSS eligible (such as neurogenic claudication¹ for at least 3 months with pain being relieved in sitting or lumbar flexion) and include definition of "mild spondylolisthesis". Arising from this item descriptor specificity, and the large list of contraindications that would make patients ineligible, MSAC considered that the patient group who would be eligible for this procedure would likely be small.

MSAC noted that, in the clinical care pathway, conservative care (including watchful waiting) is required for 6 months before surgical approaches (spinal fusion, or decompression with or without spinal fusion) can be undertaken. The Superior device addresses moderate LSS, which traditionally requires indirect compression surgery or a laminectomy, in a minimally invasive approach. MSAC noted there is a considerable overlap between the use of the Superior device and the comparators in the clinical care pathway. Therefore, MSAC considered the clinical place of this therapy to be variable and, ultimately, patient-dependent.

MSAC noted the IDS is designed for treating neurological claudication symptoms, and like most surgical interventions for this condition, IDS does not prevent further deterioration, treat the underlying cause, or stop progression at other vertebral levels. As a result, MSAC considered the device to be a temporising bridge to laminectomy or fusion surgery, rather than a replacement for either procedure. MSAC noted that conservative therapy is typically not very effective, though many patients will get better over time without surgery.

¹ Neurogenic claudication is defined as pain, numbness and/or fatigue below the gluteal line with or without back pain (if back pain is present, leg pain is greater than back pain) that is precipitated by walking and alleviated by sitting or other posture of lumbar flexion.

Regarding the proposed fee, MSAC considered that the proposed percutaneous implantation procedure would require less time than the comparator open surgical procedure on which the fee is based. MSAC considered that a lower cost than open surgery was reasonable for IDS if the procedure takes less time. MSAC noted the applicant's pre-MSAC response that they would be happy to work with the Department to set an appropriate fee.

MSAC considered the stated comparator and clinical place for IDS to be a complex issue. MSAC noted the Ratified PICO included a weighted comparator of decompression with or without spinal fusion. The SSA disagreed with the comparator, stating that this group of patients would not have any surgical intervention (for further detail see Section 9), and IDS would not be indicated in these patients. MSAC agreed with ESC that, if this is the case, IDS may be a second-line treatment before decompression with or without fusion, so a more appropriate comparator may be conservative care, or a weighted comparator comprised of conservative care and decompression with or without spinal fusion.

MSAC noted the evidence base consisted of six randomised controlled trials and none compared Superior with the comparator. One trial compared Superior with the withdrawn X-STOP device and reached a conclusion of non-inferiority, which was used to justify non-inferiority with decompression with/without fusion surgery. However, MSAC agreed with ESC that comparisons between the Superior and X-STOP devices may not be sufficient to justify the safety and effectiveness of Superior versus the comparator. MSAC also agreed with ESC that the clinical trial evidence was of low certainty and had a high risk of bias in multiple domains, in particular the issues associated with the evidence base was largely unblinded and the primary outcome across trials was a patient-reported (subjective) measure. MSAC also considered that walking ability is a key primary clinical outcome, yet it was not included as a primary outcome in these trials (walking distance is captured as a single item within the ZCQ as part of the 5-item physical function subscale, which was a secondary outcome in two trials but data for walking distance were not reported separately).

Regarding comparative safety, MSAC noted the evidence suggested that:

- there was a higher rate of spinous process fractures for IDS compared to surgical decompression alone. The applicant acknowledged this, stating that the rate could be under-reported as it reflects acute, operative fractures only. MSAC noted the rates of other adverse events favour IDS, supporting the claim of non-inferior safety, but considered the long-term safety (based on the safety and effectiveness of X-STOP) to be uncertain. MSAC also noted if reoperation rates are included as a safety outcome then IDS had inferior safety compared with decompression alone (see below)
- IDS has superior safety compared to surgical decompression plus spinal fusion; however, long-term outcomes were not reported, so are uncertain.

Regarding clinical effectiveness, MSAC noted the evidence suggested that:

- there was no significant difference in patient reported outcomes but the rate of reoperation for treatment failure favours surgical decompression over 2-year trial follow-up (and over 4-year follow-up in Deyo 2013). The pre-MSAC response acknowledged that the rate of reoperation was higher for IDS, but claimed that 70–80% of patients avoid further surgery and IDSs are less invasive. MSAC considered there was insufficient evidence to justify this claim.
- there appears to be no significant difference in outcomes when comparing IDS to surgical decompression plus spinal fusion; however, the evidence was limited, and the rate of reoperation was not reported.

MSAC considered the supplementary comparison of IDS versus conservative care, informed from two trials (none were placebo-controlled trials with blinded participants). MSAC considered that,

based on low certainty evidence, IDS showed superior effectiveness in all Zurich Claudication Questionnaire (ZCQ) subscales, including physical function and patient satisfaction, symptom severity and visual analogue scale (VAS) back pain. IDS showed inferior safety compared to conservative care. The commentary noted the trials were poorly reported and there was a high risk of bias for some outcomes, particularly reoperation. MSAC considered this reduced confidence in the findings and economic evaluation using these data.

MSAC noted the ADAR used a cost-minimisation analysis (CMA), rather than a cost-utility analysis (CUA) as suggested by the PICO Advisory Sub-Committee (PASC). A CMA was provided based on the non-inferiority claims and, according to the applicant's pre-MSAC response, it would have been too difficult to do a full CUA as it would have involved an assumption-heavy, scenario-based approach. However, MSAC considered that non-inferiority was not satisfied, and therefore a CUA should have been used due to concerns about safety and effectiveness.

The result of the CMA was a cost reduction, but MSAC considered there to be a lot of uncertainty in the drivers of that reduction. The two major drivers of costs, as demonstrated in the commentary's sensitivity analyses, were the rate of fusion plus decompression surgery in the eligible population, and the reoperation rates (modelled over 5 years). The base case rate of fusion (25%) in the comparator, which MSAC considered to drive the cost neutrality in the base-case model, was based on the opinion of a single clinical expert. MSAC noted the pre-MSAC response that, with the 10% price discount of the prostheses (proposed in the pre-ESC response), the break-even concomitant fusion rate would reduce from 25% to 7.9%. However, MSAC considered the use of fusion is variable due to clinician preference and opinion; therefore, reliance on a single clinical opinion leads to high uncertainty. MSAC considered that if the device is only used in patients who do not require fusion, it will not be a cost-saving procedure.

MSAC also noted the ADAR included a supplementary CUA comparing IDS to extended conservative care. The key inputs were an annualised reoperation rate of 9.5% for IDS (also used in the ADAR's base-case CMA model) compared to 0% for conservative care. MSAC considered the incremental cost-effectiveness ratios (ICERs) of IDS (under alternate scenarios) compared to conservative treatment to be relatively low. MSAC also noted the sensitivity analysis demonstrated that using alternative sources of utility inputs had a large effect on the ICER.

MSAC noted that, consistent with the economic analysis, the financial estimates to the MBS (and to the Australian healthcare system) were sensitive to the comparator and the weighting given to fusion, and that cost savings to the MBS will be less if the rate of fusion is lower.

Overall, MSAC considered there to be uncertainty over the appropriate position of IDS within the clinical care pathway. MSAC acknowledged that IDS may benefit patients with specific symptoms (or specific symptom complex), particularly when compared to conservative therapy, but noted it was difficult to define an appropriate patient population. MSAC noted that Schizas grading² of severity of LSS may be a useful tool to ensure patients selected for IDS are most likely to benefit (consistent with the upcoming SUcCeSS trial³; see below). Grades C or D on the Schizas grading system indicate occlusion of the central canal (i.e. absent cerebrospinal fluid) at the level or levels they want to treat, on T2-weighted MRI or CT myelogram if no MRI or it is contraindicated. MSAC advised that the clinical trial evidence for the efficacy of IDS was of low certainty and had uncertain inclusion criteria. MSAC also advised that the evidence omitted a key primary clinical outcome of walking ability. MSAC advised that the comparative safety of IDS was uncertain, including over the longer term. Generally, MSAC considered the benefits of IDS compared to

² Schizas C, Theumann N, Burn A, Tansey R, Wardlaw D, Smith FW, Kulik G. Qualitative grading of severity of lumbar spinal stenosis based on the morphology of the dural sac on magnetic resonance images. *Spine (Phila Pa 1976)*. 2010 Oct 1;35(21):1919-24.

³ Anderson DB, Ferreira ML, Harris IA, et al. SUcCeSS, SUrgery for Spinal Stenosis: protocol of a randomised, placebo controlled trial. *BMJ Open* 2019;9:e024944. doi:10.1136/bmjopen-2018-024944

alternative treatment options were uncertain. For these reasons, MSAC considered the related economic evaluation was not sufficiently supported.

MSAC considered that any resubmission would need to provide higher quality evidence to address these issues, and also take into account that evidence for any benefit of decompression and decompression plus fusion over conservative treatment is at present uncertain (see below).

Other discussion

MSAC noted that Cochrane reviews from Machado et al (2016)⁴ and Zaina (2016)⁵ suggest there are no clear benefits of surgery compared to non-surgical treatment, while an additional trial by Delitto et al. (2015)⁶ showed there are no benefits of surgery over conservative treatment. Thus, MSAC considered there to be uncertainty about the comparative benefit of any type of surgical LSS treatment, when considering the potential risk of harm. In particular, MSAC considered that decompression and fusion has not been shown to be superior over decompression alone but may increase the risks. This made it difficult to assess the value proposition of IDS versus surgical comparators already funded on the MBS.

MSAC noted that the Surgery for Spinal Stenosis trial (SUcceSS; [ANZCTR12617000884303](https://www.anzctrn12617000884303)) was an upcoming randomised placebo-controlled trial comparing surgical decompression versus placebo surgery on walking capacity and function (primary outcomes) over 2 years in patients with LSS. MSAC noted key inclusion criteria were neurogenic claudication for at least 3 months and patients having grades C or D stenosis as defined by Schizas (2010). MSAC considered it might be informative to see these results when available.

4. Background

MSAC has considered IDS devices on two previous occasions, neither of which were recommended for funding through the MBS.

MSAC Application 1099 assessed the safety, effectiveness and cost-effectiveness of a number of lumbar non-fusion posterior stabilisation devices compared to decompression surgery alone and decompression surgery with or without spinal fusion.

MSAC Application 1422 looked specifically at the safety, effectiveness and cost-effectiveness of using the Coflex interlaminar stabilisation device in combination with decompression, compared to decompression combined with fusion surgery.

These applications differ from the current ADAR in that the included devices were predominately used in conjunction with decompression and the patient population included patients with more severe LSS and higher-grade spondylolisthesis. Key matters of concern are summarised in Table 1.

⁴ Machado GC, Ferreira PH, Yoo RIJ, Harris IA, Pinheiro MB, Koes BW, van Tulder MW, Rzewuska M, Maher CG, Ferreira ML (2016). Surgical options for lumbar spinal stenosis. Cochrane Database of Systematic Reviews, Issue 11. Art. No.: CD012421. DOI: 10.1002/14651858.CD012421. Accessed 20 December 2021.

⁵ Zaina F, et al. (2016). Surgical versus non-surgical treatment for lumbar spinal stenosis. Cochrane Database of Systematic Reviews, Issue 1. Art. No.: CD010264. DOI: 10.1002/14651858.CD010264.pub2

⁶ Delitto A, Piva SR, Moore CG, Fritz JM, Wisniewski SR, Josbeno DA, Fye M, Welch WC. Surgery versus nonsurgical treatment of lumbar spinal stenosis: a randomized trial. *Ann Intern Med.* 2015 Apr 7;162(7):465-73.

Table 1 Summary of key matters of concern

Component	Matter of concern	How the current assessment report addresses it
Cost considerations MSAC 1099 PSD	There was insufficient information on which to base a cost-effectiveness analysis. Non-fusion devices were estimated to cost \$7,634 more per person than decompression surgery alone, and \$10,875 less per person than fusion surgery (PSD, p.2).	Not adequately addressed. There is substantial new clinical evidence presented however a cost-effectiveness analysis is not presented for the main comparator (laminectomy ± fusion).
Comparator MSAC 1422 PSD	MSAC noted that the submission only compared use of the device to decompression with fusion for people with lumbar spinal stenosis. MSAC noted that the PASC had asked that use of the device also be compared with decompression alone because of uncertainty about whether outcomes in people undergoing decompression and fusion were any better than outcomes in people undergoing decompression alone (PSD, p.2). MSAC queried whether decompression and fusion should be funded on the MBS and requested an in-depth review of the evidence for decompression and fusion (PSD, p.2).	Not adequately addressed The comparator is decompression with or without fusion. The final PICO summary table for the current application did specify 'a weighted comparator of laminectomy with or without spinal fusion' but also made the following statement 'PASC considered that the justification of whether or not spinal fusion surgery as a standalone procedure was an appropriate comparator should also be considered in the assessment report.' (Ratified PICO Confirmation Application 1661 , p.10).
Clinical effectiveness MSAC 1422 PSD	MSAC had several concerns about the quality of the IDE trial including that the study was unblinded and that study outcomes may have been selectively reported. Given the uncertainty around clinical effectiveness, MSAC was unable to support the listing of the use of this device. (PSD, p.2)	Addressed There is now a larger body of clinical trial evidence although the evidence remains largely unblinded and at high risk of bias.
Device differences MSAC 1422 PSD	ESC noted the applicant's argument that the device differed from other similar devices because it is implanted between the lamina and spinous processes (interlaminar) rather than between the spinous processes only (interspinous). However, ESC noted that in a previous application (Application 1099) the Coflex device was considered to be similar to interspinous devices. ESC also noted that clinical expert feedback suggested the terms interlaminar and interspinous are interchangeable in the context of non-fusion surgery (PSD, p.8).	Addressed The Applicant has included evidence from both interlaminar devices (Coflex) and interspinous devices and claimed they are equivalent. Nevertheless, the commentary considers this a relevant concern and notes that the X-STOP device for which the most evidence is presented has been withdrawn from the market due to poor long term outcomes.

MSAC = Medical Services Advisory Committee; PASC = PICO Advisory Sub-committee; PICO = population, intervention, comparator, outcome; PSD = Public Summary Document.

Source: Commentary, Table 1

5. Prerequisites to implementation of any funding advice

The proposed technology includes a device (Superion) that is included in the ARTG: 334411, effective 17/04/2020 (spacer); and 333162, effective 2/04/2020 (kit). No other stand-alone IDS is currently included in the ARTG.

The device is not currently listed on the Prosthesis List but an application will be made.

Boston Scientific will require all clinicians seeking to deliver Superior to have completed a two-day BioSkills Education Course. It is anticipated that the device would be inserted by interventional pain physicians whereas the comparator is undertaken by neurosurgeons or orthopaedic surgeons.

6. Proposal for public funding

The applicant is requesting two new MBS items (Table 2).

Although the Superior device is the only minimally invasive IDS currently included in the ARTG, the proposed medical service is device agnostic for the implantation of any minimally invasive interspinous decompression spacer that meets the item descriptor. The percutaneous implantation procedure can be performed by an interventional pain specialist in an admitted day surgery setting. An anaesthetist may be required to administer and monitor patient sedation. In the event of treatment failure, the device can be removed in the same manner and setting as it was implanted.

The commentary considered that the ADAR proposed MBS descriptor is less stringent than the population defined in the PICO. The ADAR has noted that MSAC ‘may prefer to include a precise description of “moderate LSS” in the MBS item descriptor.’ A more precise definition may specify moderate LSS as a compression ratio of 1/3 to 2/3 (33-66%) and the degree of spondylolisthesis as <25% shifting of a vertebral body⁷. A measure of functional impairment could be considered (e.g. Zurich Claudication Questionnaire [ZCQ] score of >2.5) as suggested in consultation feedback from the SSA). In the pre-ESC response, the applicant stated the proposed item descriptor is briefer because the indication is described in more detail in the instruction for use (IFU) for the Superior device. The applicant stated it is willing to accept MSAC’s advice regarding the appropriate level of detail to include in the MBS item descriptor.

Table 2 Proposed MBS items

Category 3 – THERAPEUTIC PROCEDURES
<p>MBS item *XXXX</p> <p>MINIMALLY INVASIVE INTERSPINOUS DECOMPRESSION SPACER, insertion, removal or replacement of, to alleviate pain in patients with:</p> <ul style="list-style-type: none"> • Moderate lumbar spinal stenosis - one lumbar motion segment. • After failure of conservative management for at least 6 months. • Moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion. • With or without low-grade spondylolisthesis. <p>Not being a service associated with a service to which item 51011, 51012, 51013, 51014 or 51015 applies.</p> <p>Multiple Services Rule (Anaes.) (Assist.)</p>
<p>Fee: \$789.35</p>
<p>MBS item *XXXX</p> <p>MINIMALLY INVASIVE INTERSPINOUS DECOMPRESSION SPACER, insertion, removal or replacement of, to alleviate pain in patients with:</p> <ul style="list-style-type: none"> • Moderate lumbar spinal stenosis - two lumbar motion segments. • After failure of conservative management for at least 6 months. • Moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion. • With or without low-grade spondylolisthesis. <p>Not being a service associated with a service to which item 51011, 51012, 51013, 51014 or 51015 applies.</p> <p>Multiple Services Rule (Anaes.) (Assist.)</p>
<p>Fee: \$1,184.03</p>

Source: Commentary, Table 2

⁷ Deer TR et al. (2019). The MIST guidelines: the Lumbar Spinal Stenosis Consensus Group guidelines for minimally invasive spine treatment. *Pain Practice*, **19**(3): 250-274.

The fees estimated for the proposed item descriptors for IDS insertion (one or two levels) are based on MBS item 51020 (simple fixation of part of one vertebra or simple interspinous wiring between two adjacent vertebral levels). It is further specified that the item should not be associated with a decompression service (items 51011, 51012, 51013, 51014 or 51015).

The ADAR stated that IDS percutaneous implantation is commonly provided under local anaesthesia with conscious sedation. An anaesthetist may be required to provide the appropriate level of sedation. However, in the key IDE study this was not the case. An open approach was used in the majority of patients (53% open vs. 47% percutaneous) and most patients underwent general anaesthesia (82%) with 13% having the device inserted under conscious sedation. The pre-ESC response commented that the relatively high rate of general anaesthesia in the IDE trial was due to the investigators being predominantly surgeons, whereas in Australian clinical practice implantation would be predominantly done by interventionalists/pain specialists and performed in day surgery.

The commentary stated that the fee was not justified any further in the ADAR; however, a percutaneous procedure may require less time than the open procedure on which the fee is based. The pre-ESC response considered the proposed fee is reasonable, because although the proposed service is less invasive than the benchmark procedure, it involves a similar degree of technical complexity. The pre-ESC response stated technical complexity does not always correlate with invasiveness, due to complexities around access and visualisation for minimally invasive procedures.

Pain Specialists will primarily perform this procedure, with orthopaedic, spine, and neurosurgeons being a smaller group of treating physicians.

It is expected that patients will require one medical service per lifetime. However, additional services for revision or removal of the device may be required if complications arise postoperatively. Based on current utilisation of one and two-level laminectomies (MBS items 51011 and 51012), the Applicant expects that approximately 31% of patients eligible for the proposed device will be implanted at two levels.

The procedure will be performed at a private or public day surgery clinic on admitted patients.

7. Population

The population defined in the ratified PICO Confirmation and the ADAR is consistent with the indications of the FDA-IDE trial:

Skeletally mature patients with all of the following:

- neurogenic intermittent claudication secondary to a diagnosis of moderate degenerative lumbar spinal stenosis*, with or without grade 1 spondylolisthesis (on a scale of 1 to 4⁸), confirmed by x-ray, magnetic resonance imaging (MRI) and/or computed tomography (CT) evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal or foraminal narrowing.
- impaired physical function and experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, who have undergone at least 6 months of non-operative treatment.

⁸ Classification of spondylolisthesis is based on the degree of shifting of one vertebral body anteriorly or posteriorly relative to an adjacent vertebral body in the spine as follows: grade 1 is shifting of <25%; grade 2 is 25–50%; grade 3 is 50–75%; grade 4 is 75–100% (grade 5, spondyloptosis, is >100%) (Deer et al. 2019)

- an indication for treatment at no more than two levels, from L1 to L5.

*Defined as a 25-50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared with the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:

- evidence of thecal sac and/or cauda equina compression
- evidence of nerve root displacement or compression by either osseous or non-osseous elements
- evidence of hypertrophic facets with canal encroachment

AND the following clinical symptoms:

- moderately impaired physical function (≥ 2 of the Zurich Claudication Questionnaire)
- ability to sit for 50 minutes without pain and to walk ≥ 15.2 metres⁹.

PASC noted the difficulty of defining what constitutes moderate LSS in terms of radiologic and clinical criteria given the current lack of universally agreed diagnostic criteria and the lack of correlation between radiologic and clinical symptoms and signs of LSS in many patients. This is further complicated in cases with co-existing low-grade lumbar spondylolisthesis.

As specified in the population description, the proposed technology follows a trial of unsuccessful conservative treatment, and patients will have had the source of their pain verified through clinical assessment, plain radiography, MRI and discography where appropriate. The proposed intervention is to be used as an alternative to existing surgical approaches, specified as decompression with or without fusion. The main difference in the patient pathway is that the intervention is minimally invasive, so patients are anticipated to have no, or shorter, hospitalisations, fewer complications and little or no rehabilitation.

Although IDS is a replacement for surgery, some patients will require a revision due to failed treatment and therefore may have the comparator treatment after unsuccessful IDS treatment. There is also the possibility that a minimally invasive option may expand the patient population and therefore IDS is an additional option following failed conservative treatment for patients who are not eligible for, or prefer not to undergo, surgical treatment. This population was considered in the ADAR supplementary analysis.

The ADAR addressed the population as specified in the ratified PICO Confirmation.

8. Comparator

The comparator in the ADAR is:

- a weighted comparator of laminectomy with or without spinal fusion
- supplementary comparison with conservative care.

The aim of decompression is to alleviate pain caused by compression of a nerve; laminectomy involves removal of a portion of bone over the nerve root. Minimally invasive approaches have been developed, although the ADAR stated that uptake has been low due to lack of evidence on their benefits.

The aim of fusion surgery is to use a bone graft to fuse the vertebrae superior and inferior to a disc. Bone grafts can be either autologous (harvested from the patient's own pelvic bone) or an allograft (from a bone bank). Recently, bone morphogenetic protein products have also been

⁹ Equivalent to 50 feet

used. There are a number of different methods of performing fusion surgery, including anterior or posterior lumbar intervertebral body fusion and posterolateral fusion. Instrumentation is used to facilitate the fusion by providing stability. There are three types of spinal instrumentation: pedicle screws, anterior interbody cages, and posterior lumbar cages. Fusion surgery is only occasionally performed without prior decompression, and fusion surgery alone was therefore excluded from the assessment (although it remains in the clinical algorithm).

The relevant MBS item numbers for decompression are MBS items 51011 (one segment) and 51012 (two segments) based on its TGA-approved indication. For patients who require posterolateral spinal fusion without instrumentation in combination with a decompression procedure, MBS items 51031 (one segment) and 51032 (two segments) may be selected. For posterolateral spinal fusion with instrumentation, an additional item can be selected from MBS items 51020 (simple fixation), 51021 (one segment) and 51022 (two segments), as described below (Table 3).

Table 3 Comparator MBS items

Decompression
<p>51011 Spinal decompression or exposure via partial or total laminectomy, partial vertebrectomy or posterior spinal release, one motion segment, not being a service associated with a service to which item 51012, 51013, 51014 or 51015 applies Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,458.45 Benefit: 75% = \$1,093.85</p>
<p>51012 Spinal decompression or exposure via partial or total laminectomy, partial vertebrectomy or posterior spinal release, 2 motion segments, not being a service associated with a service to which item 51011, 51013, 51014 or 51015 applies Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,944.40 Benefit: 75% = \$1,458.30</p>
Spinal fusion
<p>51031 Spine, posterior and/or posterolateral bone graft to, one motion segment, not being a service associated with a service to which item 51032, 51033, 51034, 51035 or 51036 applies Multiple Operation Rule (Anaes.) (Assist.) Fee: \$956.50 Benefit: 75% = \$717.40</p>
<p>51032 Spine, posterior and/or posterolateral bone graft to, 2 motion segments, not being a service associated with a service to which item 51031, 51033, 51034, 51035 or 51036 applies Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,147.85 Benefit: 75% = \$860.90</p>
Instrumentation
<p>51020 Simple fixation of part of one vertebra (not motion segment) including pars interarticularis, spinous process or pedicle, or simple interspinous wiring between 2 adjacent vertebral levels, not being a service associated with: (a) interspinous dynamic stabilisation devices; or (b) a service to which item 51021, 51022, 51023, 51024, 51025 or 51026 applies Multiple Operation Rule (Anaes.) (Assist.) Fee: \$777.70 Benefit: 75% = \$583.30</p>

<p>51021</p> <p>Fixation of motion segment with vertebral body screw, pedicle screw or hook instrumentation including sublaminar tapes or wires, one motion segment, not being a service associated with a service to which item 51020, 51022, 51023, 51024, 51025 or 51026 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,301.70 Benefit: 75% = \$976.30</p>
<p>51022</p> <p>Fixation of motion segment with vertebral body screw, pedicle screw or hook instrumentation including sublaminar tapes or wires, 2 motion segments, not being a service associated with a service to which item 51020, 51021, 51023, 51024, 51025 or 51026 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,619.20 Benefit: 75% = \$1,214.40</p>

Source: Commentary, Table 3

A weighted comparator of laminectomy with or without spinal fusion is consistent with the Ratified PICO. However, the text of the Ratified PICO Confirmation states that PASC noted “that there is no clear consensus regarding the indications for fusion surgery in the presence of LSS. The presence of unstable spondylolisthesis is potentially a contraindication for the Superior procedure, in which case the use of a weighted comparator of open spinal decompression with or without spinal fusion may not be appropriate. Even though fusion is being performed in increasing numbers of patients in Australia, this does not constitute support for fusion in the proposed population as the factors contributing to these surgical decisions are unclear” (PICO Confirmation, p.12). Figure 1 of the Ratified PICO shows a continuum of care for patients with LSS and suggests that the patients eligible for Superior do not overlap with patients eligible for fusion surgery. The comparator in the Ratified PICO may be appropriate; however, this depends on the weighting given to fusion surgery and the justification for this. Fusion surgery is likely to be undertaken in the eligible population, but there is a high variability in its use¹⁰ and evidence suggesting a lack of value.

The supplementary comparison was not specified in the Ratified PICO Confirmation, but the text stated “PASC noted that continued conservative management may be a more appropriate comparator for the device given that the SSA considered that the patient group suggested as being eligible for the device is considered to have very mild LSS, which is not usually treated with surgery. The claim would then be one of superiority of the Superior device relative to conservative treatment. PASC considered that the justification of whether or not conservative management was an appropriate comparator should be considered in the assessment report” (PICO Confirmation, p12).

In the pre-ESC response, the applicant acknowledged lack of high quality, locally-relevant and current data to inform the proportion of patients receiving decompression (25% in the base case), though regarded the 0% proposed by the SSA to be highly unlikely.

9. Summary of public consultation input

The Department received targeted consultation responses from the NSANZ and the SSA, and also three responses from device manufacturers to public consultation on this application. No consumer feedback/consumer comments were received for this application.

¹⁰ <https://www.safetyandquality.gov.au/our-work/healthcare-variation/atlas-2017/atlas-2017-4-surgical-interventions>

Responses from the NSANZ and device manufacturers were supportive of the application.

The SSA raised several concerns regarding the proposed intervention. The SSA considered the proposed population too broad, as it includes patients with mild and tolerable LSS who would not warrant invasive interventions and would benefit from conservative care. The SSA considered that the proposed comparators were not appropriate to the proposed intervention. The SSA considered that: decompression by laminectomy (removal of a lumbar lamina) is uncommonly performed by modern spine surgeons in isolation but usually as part of a reconstructive procedure as most patients have instability; and fusion surgery is for significant instability, which Superion would not be indicated for. The SSA suggested including patient assessed functional status in the outcomes and queried whether sufficient evidence was currently available to demonstrate the benefit of the proposed intervention.

The public consultation responses from device manufacturers supported the application and suggested that the proposed medical service should be device agnostic.

10. Characteristics of the evidence base

The characteristics of the evidence base are summarised in Table 4. There were no applicability concerns with the trial populations, which were consistent with the request for funding.

A range of devices were used across the trials (X-STOP in six trials, Coflex in one trial, Aperius in one trial, Superion in one trial). X-STOP is inserted using an open approach and requires an incision of approximately 1-inch¹¹; this may not be considered minimally invasive. Coflex is an interlaminar device and differs in design and mechanism to interspinous spacers; it also requires open surgery. Aperius is a percutaneous device. Therefore, of the included devices, only Aperius is inserted in the same minimally invasive approach as Superion (i.e., percutaneously) although the proposed MBS item does not specify the minimally invasive approach. Coflex is the only device (other than Superion) currently registered on the ARTG; however, it is usually used in combination with decompression and is described on the ARTG as a fixation device for 'permanent implantation between the spinous processes.' The included study used Coflex in a standalone procedure.

Five trials compared IDS with decompression, one trial compared IDS with decompression plus fusion and two trials compared IDS with conservative treatment (supplementary analysis). None of these trials used the Superion device. The single Superion study (the IDE Study) compared Superion with X-STOP and is used to provide evidence that the two devices are non-inferior, in order to support the applicability of the evidence comparing IDS with decompression. X-STOP has been withdrawn from the market due to lack of efficacy in longer term follow up and relatively high complication rates¹². The pre-ESC response stated that it understands Medtronic withdrew the X-STOP device from the US market for commercial reasons, rather than due to lack of efficacy and high complication rates.

The evidence for the comparators did not raise applicability concerns, although a minimally invasive decompression approach, which was used in Lønne (2015)¹³, is less common in Australia.

¹¹ Deer TR et al. (2019). The MIST guidelines: the Lumbar Spinal Stenosis Consensus Group guidelines for minimally invasive spine treatment. *Pain Practice*, **19**(3): 250-274.

¹² Gala RJ, Russo GS, Whang PG (2017). Interspinous implants to treat spinal stenosis. *Curr Rev Musculoskelet Med*, **10**:182-188

¹³ Lønne G, et al. (2015). Comparing Cost-effectiveness of X-Stop With Minimally Invasive Decompression in Lumbar Spinal Stenosis. *Spine*, **40**(8): 514-520.

Table 4 Key features of the included evidence for IDS

Reference N	Design/duration <i>Risk of Bias</i>	Patient population	Outcome(s)	Use in modelled evaluation
IDS vs decompression				
FELIX (Moojen, 2015) ¹⁴ IDS (Coflex) = 80 D = 79	RCT, DB, MC (Netherlands, 15 hospitals) / 24 months <i>High</i>	Patients with NIC (at least 3 months) due to 1- or 2-level degenerative LSS after failed conservative care who are indicated for surgery. Patients with degenerative spondylolisthesis > grade 1 were excluded. Age: 40 to 85 years	<u>Primary:</u> ZCQ <u>Secondary:</u> MRDQ VAS back and leg pain SF-36 HADS SWT Costs/EuroQol Complications and reoperations	To support the non-inferiority in terms of efficacy and safety
Lønne (2015) IDS (X-STOP) = 40 MID = 41	RCT, MC (6 Norwegian hospitals) (2007-2011) / 24 months <i>High</i>	Patients with NIC (within 250 m walking distance for at least 6 months) due to 1 or 2-level LSS after failed conservative care. Patients were included if relieved through spinal flexion. Patients with degenerative spondylolisthesis > grade 1 were excluded Age: 50 to 85 years	<u>Primary:</u> ZCQ <u>Secondary:</u> ODI EQ-5D NRS-11 back and leg pain Complications and reoperations	To support the non-inferiority in terms of efficacy and safety
Strömqvist (2015) ¹⁵ IDS (X-STOP) = 50 D = 50	RCT, MC (3 Swedish spine centres) / 24 months <i>High</i>	Patients with NIC (at least 6 months) due to 1- or 2-level LSS. Patients were included if relieved through spinal flexion. Patients with degenerative spondylolisthesis > grade 1 were excluded Age: 49 to 89 years	<u>Primary:</u> ZCQ <u>Secondary:</u> SF-36 VAS back and leg pain Complications and reoperations	To support the non-inferiority in terms of efficacy and safety
NICE (Meyer, 2018) ¹⁶ IDS (Aperius) = 82 D = 81	RCT, OL, MC (19 international sites) / 24 months <i>High</i>	Patients with NIC (at least 6 weeks) due to degenerative LSS. Patients were included if relieved through spinal flexion. Patients with degenerative spondylolisthesis > grade 1 were excluded	<u>Primary:</u> ZCQ <u>Secondary:</u> SF-36 VAS back and leg pain SAEs Complications and reoperations	To support the non-inferiority in terms of efficacy and safety

¹⁴ Moojen WA et al. (2015) IPD without bony decompression versus conventional surgical decompression for lumbar spinal stenosis: 2-year results of a double-blind randomized controlled trial. *Eur Spine J*, **24**:2295–2305.

¹⁵ Strömqvist B et al. (2013). X-Stop Versus Decompressive Surgery for Lumbar Neurogenic Intermittent Claudication. *Spine*, **38**(17): 1436-1442.

¹⁶ Meyer B et al. (2018). Percutaneous Interspinous Spacer vs Decompression in Patients with Neurogenic Claudication: An Alternative in Selected Patients? *Neurosurgery*, **82**(5): 621-629.

Reference N	Design/duration Risk of Bias	Patient population	Outcome(s)	Use in modelled evaluation
CELAX (Borg, 2021) ¹⁷ IDS (X-STOP) = 21 D = 26	RCT, OL, MC (3 UK centres) (2010-2014) / 24 months <i>High</i>	Patients with NIC (at least 6 months) due to 1- or 2-level degenerative LSS after failed conservative care for 6 months. Patients were included if relieved through spinal flexion. Patients with degenerative spondylolisthesis ≥ grade 2 were excluded	<u>Primary:</u> Cost EQ-5D <u>Secondary:</u> ODI ZCQ QBPS	To support the non-inferiority in terms of efficacy and safety
Meta-analysis – procedural complications	Included CELAX, Lønne (2015), FELIX, Strömqvist (2013), N=372			Not used
Meta-analysis - reoperation	Included CELAX, Lønne (2015), NICE, FELIX, Strömqvist (2013), N=528			Not used
IDS vs decompression with fusion				
Azzazi (2010) ¹⁸ IDS (X-STOP) = 30 D + Fusion = 30	RCT (Egypt) / 24 months <i>High</i>	Patients with lumbar canal stenosis and degenerative spondylolisthesis or retrolisthesis (grade 1), lateral and/or central spinal stenosis after failed conservative care for 3 months	VAS back and leg pain ODI Complications	To support the non-inferiority in terms of efficacy and safety
IDS (Superion) vs IDS (X-STOP)				
Superion IDE study (Patel 2015a) ¹⁹ IDS (Superion) = 190 IDS (X-STOP) = 201	RCT, MC (29 sites) (2008-2011) / 24 months <i>High</i>	Patients with NIC due to 1- or 2-level moderate LSS after failed conservative care for 6 months Patients with degenerative spondylolisthesis > grade 1 were excluded Age: ≥45 years	<u>Primary:</u> Composite <u>Secondary:</u> VAS back and leg pain ODI AEs Complications and reoperations	To support clinical claim of non-inferiority for Superion and X-STOP
IDS vs conservative care				
Zucherman (2005) ²⁰ IDS (X-STOP) = 100 conservative care (non-operative) = 91	RCT, MC (9 US sites) (2000-2001) / 24 months <i>High</i>	Patients with NIC due to 1- or 2-level LSS and who have completed 6 months of conservative care. Patients were included if relieved through spinal flexion. Patients with degenerative spondylolisthesis > grade 1 were excluded Age: ≥50 years	<u>Primary:</u> ZCQ <u>Other:</u> Radiological analysis Safety/ complications	Yes To support clinical claim of superiority vs conservative care, and CUA approach

¹⁷ Borg A et al (2021). A randomized controlled trial of the X-STOP interspinous distractor device versus laminectomy for lumbar spinal stenosis with 2-year quality-of-life and cost-effectiveness outcomes. *J Neurosurg Spine*, 2021 Feb **2**:1-9.

¹⁸ Azzazi A, Elhawary Y (2010). Dynamic Stabilization Using X-STOP Versus Transpedicular Screw Fixation in the Treatment of Lumbar Canal Stenosis; Comparative Study of the Clinical Outcome. *Neurosurgery Quarterly*, 20(3): 165-169.

¹⁹ Patel VV et al. (2015a). Superion Interspinous Process Spacer for Intermittent Neurogenic Claudication Secondary to Moderate Lumbar Spinal Stenosis: Two-Year Results from a Randomized Controlled FDA-IDE Pivotal Trial. *Spine*, **40**(5), 275-282.

²⁰ Zucherman JF et al. (2005). A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: Two-year follow-up results. *Spine*, **30**(12), 1351-1358.

Reference N	Design/duration Risk of Bias	Patient population	Outcome(s)	Use in modelled evaluation
Puzzilli (2014) ²¹ IDS (X-STOP) = 422 conservative care (non-operative) = 120	RCT, MC (2005-2009) / 84 months <i>High</i>	Patients with NIC due to 1- or 2-level degenerative lumbar spine disease LSS who have failed 6 months of conservative care. Patients with degenerative spondylolisthesis > grade 1 were excluded. Age: ≥18 years	ZCQ VAS Radiological analysis Complications	Yes To support clinical claim of superiority vs conservative care, and CUA approach

AE, adverse event; CUA, cost utility analysis; D, Decompression; DB, double blind; EQ-5D, EuroQol 5-dimensional questionnaire; HADS, Hospital Anxiety Depression Scale; IDS, interspinous decompression spacer; LSS, lumbar spinal stenosis; MC, multicentre; MID, minimally invasive decompression; MRDQ, Modified Roland Disability Questionnaire for sciatica; NIC, neurogenic intermittent claudication; NRS-11, Numerical Rating Scale 11; ODI, Oswestry Disability Index; OL, open-label (unblinded); QBPDS, Quebec Back Pain Disability Scale; RCT, randomised controlled trial; SAE, serious adverse event; SF-36, Medical Outcome Study 36-item short-form Generated Health Survey; SWT, Shuttle Walking Test; VAS, Visual Analogue Scale; ZCQ, Zurich Claudication Questionnaire.

Source: Commentary, Table 4

11. Comparative safety

IDS versus decompression

Spinous process fractures

There was a higher rate of operative spinous process fractures in patients treated with IDS (3.31%) compared with surgical decompression (0.0%) (RD [95% CI] 0.03 [-0.00, 0.06], $p=0.05$) (Table 5). The overall rate of spinous process fractures is likely to be underreported in these trials because the spinous process fractures reported are only those observed during device placement and/or in the immediate post-operative period. Lønne (2015) reported an additional late fracture in the IDS arm. Fractures can be occult and/or develop during follow-up. The rate of spinous process fractures reported reflects acute, operative fractures only; the rate of occult and long-term fractures is not reported.

Table 5 Rate of spinous process fractures in RCTs of IDS versus decompression

Trial ID	IDS	Decompression	OR [95% CI]	RR [95% CI]	RD [95% CI]
	n /N (%)	n /N (%)	< 1 favours IDS	< 1 favours IDS	< 0 favours IDS
CELAX	1/21 (4.76%)	0/26 (0.00%)	3.88 [0.15, 100.23]	3.68 [0.16, 85.98]	0.05 [-0.04, 0.13]
Lønne (2015)	1/40 (2.50%)	0/41 (0.00%)	3.15 [0.12, 79.69]	3.07 [0.13, 73.28]	0.03 [-0.02, 0.07]
FELIX	3/70 (4.29%)	0/75 (0.00%)	7.83 [0.40, 154.35]	7.49 [0.39, 142.51]	0.04 [0.00, 0.09]
Strömquist (2013)	1/50 (2.00%)	0/50 (0.00%)	3.06 [0.12, 76.95]	3.00 [0.13, 71.92]	0.02 [-0.02, 0.06]
Pooled	6/181 (3.31%)	0/192 (0.00%)	4.25 [0.87, 20.69], $p=0.07$	4.09 [0.87, 19.34], $p=0.08$	0.03 [-0.00, 0.06], $p=0.05$

CI, confidence interval; IDS, interspinous decompression spacer; OR, odds ratio; RD, risk difference; RR, relative risk, **bold** = statistically significant.

Source: Commentary, Table 5

²¹ Puzzilli F et al. (2014). Interspinous spacer decompression (X-STOP) for lumbar spinal stenosis and degenerative disk disease: A multicenter study with a minimum 3-year follow-up. *Clinical Neurology and Neurosurgery*, **124**: 166-174.

Procedural complications

Procedural complications include spinous process fractures reported during device placement and/or in the immediate post-operative period. There was a lower rate of complications in patients treated with IDS (4.42%) compared with surgical decompression (8.33%) (RD [95% CI] -0.03 [-0.08, 0.01], $p=0.15$). Where spinous process fractures are excluded, the difference becomes significant, favouring IDS (-0.07 [-0.12, -0.03], $p=0.002$).

Table 6 Rate of complications in RCTs of IDS versus decompression

Trial ID	IDS	Decompression	OR [95% CI]	RR [95% CI]	RD [95% CI]
	n /N (%)	n /N (%)	< 1 favours IDS	< 1 favours IDS	< 0 favours IDS
CELAX	2/21 (9.52%)	5/26 (19.23%)	0.44 [0.08, 2.55]	0.50 [0.11, 2.30]	-0.10 [-0.30, 0.11]
Lønne (2015)	1/40 (2.50%)	2/41 (4.88%) ^a	0.50 [0.04, 5.74]	0.51 [0.05, 5.43]	-0.02 [-0.11, 0.06]
FELIX	4/70 (5.71%) ^b	6/75 (8.00%)	0.70 [0.19, 2.58]	0.71 [0.21, 2.43]	-0.02 [-0.11, 0.06]
Strömqvist (2013)	1/50 (2.00%)	3/50 (6.00%)	0.32 [0.03, 3.18]	0.33 [0.04, 3.10]	-0.04 [-0.12, 0.04]
Pooled	8/181 (4.42%)	16/192 (8.33%)	0.53 [0.22, 1.28], $p=0.16$	0.56 [0.24, 1.27], $p=0.16$	-0.03 [-0.08, 0.01], $p=0.15$

CI, confidence interval; IDS, interspinous decompression spacer; OR, odds ratio; RD, risk difference; RR, relative risk.

^a This only include operative complications. There were an additional 3 haematomas observed postoperatively.

^b The study states 5 complications, but describes 4.

Source: Commentary, Table 6

The IDS arms were generally open surgery under general anaesthesia, which differs from the request for public funding; therefore, the applicability of these findings should be considered. A minimally invasive percutaneous approach may result in different rates of complications and different types of complications.

Summary

Collectively, these data support a clinical conclusion of non-inferior safety for IDS compared to decompression surgery. These data support a clinical conclusion of at least non-inferior operative safety; however, no data have been presented to make any conclusions on long-term safety.

Where reoperation rates are considered (presented in effectiveness), the data no longer support a claim of non-inferiority.

IDS versus decompression plus fusion

Procedural complications

IDS is associated with a statistically significantly lower rate of procedural complications (10.0%) compared with decompression plus fusion (46.7%) (RD [95% CI] -0.37 [-0.59, -0.14]).

Table 7 Rates of complications in the RCT of IDS vs. decompression plus fusion

Trial ID	IDS	Decompression plus fusion	OR [95% CI] < 1 favours IDS	RR [95% CI] < 1 favours IDS	RD [95% CI] < 0 favours IDS
	n /N (%)	n /N (%)			
Azzazi (2010)	3/30 (10.00%)	14/30 (46.67%)	0.13 [0.03, 0.51], p=0.004	0.21 [0.07, 0.67], p=0.008	-0.37 [-0.59, -0.14], p=0.0006

IDS, interspinous decompression spacer; OR, odds ratio; RD, risk difference; RR, relative risk.

Bold = statistically significant

Source: Commentary, Table 7

IDS has superior safety compared with decompression plus fusion on the basis of procedural complications. Long-term outcomes and reoperation rates were not presented.

IDS (Superion) versus IDS (X-STOP)

Spinous process fracture and device migration

Although there were some numerical differences between Superion and X-STOP in rates of spinous process fracture and device migration, these differences were not significant, with the exception of device migration, which reached borderline significance.

Table 8 Rate of spinous process fractures, device migration and device subsidence in RCTs of Superion versus X-STOP

IDE Study - outcome	Superion	X-STOP	OR [95% CI] < 1 favours Superion	RR [95% CI] < 1 favours Superion	RD [95% CI] < 0 favours Superion
	n /N (%)	n /N (%)			
Spinous process fracture (day of surgery)	4/190 (2.1%)	2/190 (1.0%)	2.14 [0.39, 11.82], p=0.38	2.12 [0.39, 11.42], p=0.38	0.01 [-0.013, 0.035], p=0.38
Spinous process fracture (total to 24 months)	22/190 (11.58%)	13/201 (6.47%)	1.89 [0.92, 3.88], p=0.08	1.79 [0.93, 3.45], p=0.08	0.05 [0.01, 0.10], p=0.08
Device migration or dislodgment	2/190 (1.05%)	9/201 (4.48%)	0.23 [0.05, 1.06], p=0.06	0.24 [0.05, 1.0], p=0.06	-0.03 [-0.07, -0.00], p=0.04
Device subsidence	4/190 (2.1%)	0/201	Not evaluable	Not evaluable	0.02 [0.00, 0.04], p=0.07

CI, confidence interval; IDS, interspinous decompression spacer; OR, odds ratio; RD, risk difference; RR, relative risk.

Bold = statistically significant.

Source: Commentary, Table 8

Complications

The rates of complications in the Superior IDE study were similar for Superior (13.7%) and X-STOP (16.9%) (RD [95% CI] -0.03 [-0.10, 0.04]).

Table 9 Major complication rates in the RCT of Superior IDE study to 24-months

Trial ID	Superior	X-STOP	OR [95% CI]	RR [95% CI]	RD [95% CI]
	n /N (%)	n /N (%)	< 1 favours Superior	< 1 favours Superior	< 0 favours Superior
IDE Study	26/190 (13.68%)	34/201 (16.92%)	0.78 [0.45, 1.36], p=0.38	0.81 [0.51, 1.30], p=0.38	-0.03 [-0.10, 0.04], p=0.37

CI, confidence interval; OR, odds ratio; RD, risk difference; RR, relative risk.
Source: Commentary, Table 9

Summary

Collectively, these data support a clinical conclusion of non-inferior safety for indirect decompression using Superior compared to X-STOP. It is noted that X-STOP has been withdrawn from the market.

12. Comparative effectiveness

IDS versus decompression

Oswestry Disability Index (ODI)

Two trials (Lønne (2015) and CELAX) reported data on change in ODI score from baseline to 24 months. The CELAX study showed very little change from baseline to 24 months in patients treated with decompression. The mean difference favoured IDS but did not reach the (minimal clinically important difference (MCID) value of 12.8. The difference in ODI scores between trial arms at 2 years in the Lønne study (2015) was 4.07 (95% CI, - 3.45 to 11.59; p=0.285), which was not significantly different.

Table 10 ODI score: Results of IDS vs. decompression across the included RCTs

Trial ID	IDS				Decompression				MD (< 0 favours IDS)
	n /N (%)	Baseline mean (SD)	Endpoint mean (SD)	Mean change (SD)	n /N (%)	Baseline mean (SD)	Endpoint mean (SD)	Mean change (SD)	
Lønne (2015)	40/44 (91%)	32.9 (2.7)	14.3 (2.7)	-18.6 (3.7)	41/46 (89%)	33.8 (2.5)	18.4 (2.6)	-15.4 (3.5)	-3.2
CELAX	21/22 (95%)	49 (NR)	38 (NR)	-11 (NR)	26/27 (96%)	45 (NR)	44 (NR)	-1 (NR)	-10.0

IDS, interspinous decompression spacer; MD, mean difference; NR, not reported; ODI, Oswestry Disability Index; SD, standard deviation.
Note: A lower ODI represents less disability.
Source: Commentary, Table 10

Zurich Claudication Questionnaire (ZCQ)

Four trials (Lønne (2015), Strömqvist (2013), NICE and CELAX) reported data on mean difference in ZCQ scores. Mean difference in symptom severity at 24 months for IDS compared to decompression ranged from -0.20 to -0.05. None reached the MCID value of 0.75 and this difference is likely to be both statistically and clinically insignificant. Mean difference in physical function score ranged from -0.18 to 0.27. None reached the MCID of 0.60 and the differences are likely to be both statistically and clinically insignificant.

Two trials reported overall ZCQ success (Table 11); no significant differences were found between IDS and decompression.

Table 11 Overall ZCQ success: Results of IDS vs. decompression across included RCTs

Trial ID	IDS	Decompression	OR [95% CI]	RR [95% CI]	RD [95% CI]
	n /N (%)	n /N (%)	> 1 favours IDS	> 1 favours IDS	> 0 favours IDS
FELIX	69/80 (86.25%)	60/79 (75.95%)	1.99 [0.88, 4.51], p=0.10	1.14 [0.98, 1.32], p=0.10	0.10 [-0.02, 0.22], p=0.09
NICE	39/72 (54.2%)	44/73 (60.3%)	0.78 [0.40, 1.51], p=0.46	0.90 [0.68, 1.19], p=0.46	-0.06 [-0.22, 0.10], p=0.43

CI, confidence interval; IDS, interspinous decompression spacer; OR, odds ratio; RD, risk difference; RR, relative risk; ZCQ, Zurich Claudication Questionnaire.

Note: ZCQ "success" is defined as improvement in at least 2/3 subscales; "success" on the symptom severity scale and physical function scale was defined as a decrease of ≥ 0.5 points. A score of less than 2.5 on the patient satisfaction subscale was defined as "success".

Source: Commentary, Table 11

VAS leg and back pain

Three studies reported data on visual analogue scale (VAS) leg and back pain (Felix, Strömqvist (2013) and NICE). Mean difference in back pain ranged from -5.0 to 10.0, and mean difference in leg pain from -7.0 to 7.0. There was no statistically significant difference between groups at any time point in Strömqvist (2013), FELIX or NICE. The PICO Confirmation specified an MCID of >20 mm improvement in pain score.

Table 12 VAS leg and back pain scores: Results of the IDS vs. decompression included RCTs

Trial ID	IDS			Decompression			MD (< 0 favours IDS) ^d
	Baseline mean (SD)	Endpoint mean (SD)	Mean change (SD)	Baseline mean (SD)	Endpoint mean (SD)	Mean change (SD)	
Back pain							
FELIX	50 (NR)	36 (NR)	-14 (NR)	52 (NR)	28 (NR)	-24 (NR)	10.00
Strömqvist (2013)	58 (27.0)	34 (32.0)	-24 (NR)	60 (26.0)	23 (29.0)	-37 (NR)	13.00
NICE ^c	40 (23.3)	21.7 (20.2)	-18.3 (NR)	43.8 (19.7)	30.5 (24.3)	-13.3 (NR)	-5.00
Leg pain							
FELIX	52 (NR)	21 (NR)	-31 (NR)	58 (NR)	26 (NR)	-32 (NR)	1.00
Strömqvist (2013) ^a	57 (30.0)	25 (32.0)	-32 (NR)	58 (31.0)	19 (25.0)	-39 (NR)	7.00
Strömqvist (2013) ^b	60 (28.0)	21 (28.0)	-39 (NR)	53 (29.0)	21 (28.0)	-32 (NR)	-7.00
NICE ^c	79.3 (13.1)	21.7 (24.9)	-57.6 (NR)	80.4 (13.2)	26.6 (25.9)	-53.8 (NR)	-3.80

IDS, interspinous decompression spacer; NR, not reported; MD, mean difference; SD, standard deviation; VAS, visual analogue scale.

Note: A lower VAS represents less pain.

a Left leg pain

b Right leg pain

c The outcomes for the NICE trial were multiplied by 10.

d Note that for most studies, mean change was calculated post hoc by subtracting baseline scores for the final scores. Confidence intervals were infrequently reported.

Source: Commentary, Table 12

Reoperations

The reoperation rate was reported in all included studies. The ADAR presented the overall reoperation rate, which includes post-operative complications requiring reoperation and treatment failure (worsened or persistent symptoms) leading to reoperation. This analysis includes both a primary safety outcome (number of reoperations, removals or revisions) and a primary effectiveness outcome (new or persistent worsened neurological deficit at the index level[s]). The ADAR included reoperations in effectiveness, hence this is retained in the executive summary text, but the findings are reflected in the conclusion for both safety and effectiveness. As an effectiveness outcome, reoperations due to treatment failure are more relevant and are presented here. Complications requiring reoperation were more common in the decompression arms of the trials (due to dural tears), whereas reoperations for treatment failure were more common in the ICD arms of the trials. The meta-analysis demonstrated a benefit in favour of decompression against IDS at 17% difference in absolute risk (RD [95% CI] 0.17 [0.11, 0.23]), which was statistically significant ($P < 0.0001$) (Figure 1). Where reported, reoperations due to treatment failure were most commonly decompression for the IDS arm and extended decompression for the decompression arm. No device revisions were reported. This suggests that for more than 20% of patients, the IDS device is a bridge to decompression rather than a replacement.

Table 13 Rate of reoperations (treatment failure) in the RCTs of IDS vs. decompression trials

Trial ID	IDS	Decompression	OR [95% CI] < 1 favours IDS	RR [95% CI] < 1 favours IDS	RD [95% CI] < 0 favours IDS
	n /N (%)	n /N (%)			
CELAX	4/21 (19.05%)	0/26 (0%)	NC	NC	NC
Lønne (2015)	10/40 (25.0%)	2/41 (4.88%)	6.50 [1.32, 31.91]	5.13 [1.20, 21.94]	0.20 [0.05, 0.36]
NICE	12/79 (15.19%)	4/76 (5.26%)	3.22 [0.99, 10.49]	2.89 [0.97, 8.56]	0.10 [0.00, 0.20]
FELIX	23/70 (32.86%)	6/75 (8.00%)	5.63 [2.13, 14.87]	4.11 [1.78, 9.49]	0.25 [0.12, 0.38]
Strömquist (2013)	13/50 (26.00%)	3/50 (6.00%)	5.50 [1.46, 20.76]	4.33 [1.31, 14.28]	0.20 [0.06, 0.34]
Pooled	62/260 (23.8%)	15/268 (5.60%)	5.14 [2.85, 9.30]	4.07 [2.40, 6.90]	0.17 [0.11, 0.23]

CI, confidence interval; IDS, interspinous decompression spacer; OR, odds ratio; RD, risk difference; RR, relative risk.

Bold = statistically significant

Source: Commentary, Table 13

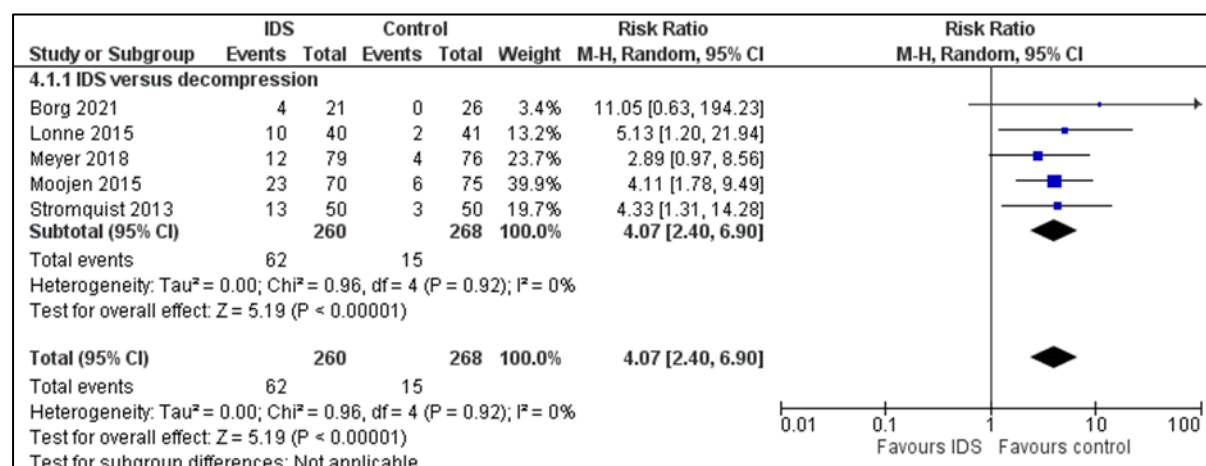


Figure 1 Rate of reoperations due to treatment failure in the RCTs of IDS vs. decompression trials

Source: Commentary, Figure 1

EQ-5D

The European Quality of Life Five Dimension (EQ-5D) was reported in two studies: Lønne (2015) and CELAX. In both cases, the change from baseline in both arms exceeded the MCID of 0.19 reported by Burgstaller (2020) but the difference between arms did not.

Table 14 EQ-5D scores: Results of the IDS vs. decompression included RCTs

Trial ID	IDS			Decompression			MD (>0 favours IDS) ^a
	Baseline mean (SD)	Endpoint mean (SD)	Mean change (SD)	Baseline mean (SD)	Endpoint mean (SD)	Mean change (SD)	
Lønne (2015)	0.409 (0.05)	0.73 (0.05)	0.321 (NR)	0.42 (0.05)	0.688 (0.04)	0.268 (NR)	0.053
CELAX	0.2 (NR)	0.45 (NR)	0.25 (NR)	0.29 (NR)	0.58 (NR)	0.29 (NR)	-0.040

IDS, interspinous decompression spacer; NA, not applicable; NR, not reported; MD, mean difference; SD, standard deviation.

^a Note that for most studies, mean change was calculated post hoc by subtracting baseline scores for the final scores. Confidence intervals were infrequently reported.

Bold = change exceeds MCID of 0.19.

Source: Commentary, Table 14

Summary

The primary effectiveness outcomes for disability and functional status and pain intensity did not demonstrate any statistically or clinically significant differences between IDS and decompression at the 24-month follow-up period for any measure in any trial, although there were improvements from baseline to 2 years in most measures across both arms of the trials. Quality of life, measured by the EQ-5D had similar results with no significant difference between arms. Overall, on these measures, the data suggest that IDS is non-inferior to decompression.

Reoperation rates due to treatment failure consistently favoured decompression. Therefore, IDS may be inferior to decompression with respect to clinical efficacy on the basis of a higher rate of treatment failure leading to reoperation.

IDS versus decompression plus fusion

Oswestry Disability Index (ODI)

Azazzi (2010) presented the number of patients showing >25% improvement in ODI at 24-month follow-up. The difference between groups was non-significant.

Table 15 Improvement in ODI score >25%: IDS vs. decompression plus fusion

Trial ID	IDS	D + F	OR [95% CI]	RR [95% CI]	RD [95% CI]
	n /N (%)	n /N (%)	> 1 favours IDS	> 1 favours IDS	> 0 favours IDS
Azazzi (2010)	27/30 (90.0%)	24/30 (80.0%)	2.25 [0.51, 9.99], p=0.29	1.13 [0.91, 1.39], p=0.28	0.10 [-0.08, 0.28], p=0.27

CI, confidence interval; D+F, decompression plus fusion; IDS, interspinous decompression spacer; ODI, Oswestry Disability Index; OR, odds ratio; RD, risk difference; RR, relative risk.

Source: Commentary, Table 15

VAS leg and back pain

Azazzi (2010) presented the number of patients showing >25% improvement in VAS leg and back pain at 24-month follow-up. The difference between groups was non-significant.

Table 16 VAS leg and back pain: IDS vs. decompression plus fusion

Trial ID	IDS	D + F	OR [95% CI]	RR [95% CI]	RD [95% CI]
	n /N (%)	n /N (%)	> 1 favours IDS	> 1 favours IDS	> 0 favours IDS
Back pain					
Azazzi (2010)	27/30 (90.0%)	24/30 (80.0%)	2.25 [0.51, 9.99], p=0.29	0.12 [0.91, 1.39], p=0.28	0.10 [-0.08, 0.28], p=0.27
Leg pain					
Azazzi (2010)	26/30 (86.7%)	23/30 (76.7%)	1.98 [0.51, 7.64], p=0.32	1.13 [0.89, 1.44], p=0.32	-0.02 [-0.10, 0.30], p=0.31

CI, confidence interval; D+F, decompression plus fusion; IDS, interspinous decompression spacer; OR, odds ratio; RD, risk difference; RR, relative risk; VAS, visual analogue scale.

Source: Commentary, Table 16

Summary

IDS did not differ from decompression plus fusion on the outcomes reported; however, the evidence for this comparison was limited. Reoperation rates were not reported.

IDS (Superion) versus IDS (X-STOP)

The Superion IDE study reported on ‘composite clinical success’ (CCS) as an endpoint; this was a composite of clinical efficacy (ZCQ success), absence of subsequent treatments (e.g., epidurals, rhizotomy, and spinal cord stimulators), neurological success, safety (absence of device revision or removal), and absence of implant or procedure-related complications (absence of dislodgement, migration, spinous process fracture, or serious device-related adverse events).

The pre-specified non-inferiority margin was 10% for the overall subject success rate. Non-inferiority of Superion was established compared to X-STOP in the modified intention-to-treat (mITT) cohort with rates of 52% and 50% (with a Bayesian Posterior Probability > 0.958), respectively. The four components also demonstrated non-inferiority (Table 17).

Table 17 Composite clinical success and its components: Results of the Superion IDE study

Outcome measure	Superion	X-STOP	OR [95% CI]	RR [95% CI]	RD [95% CI]
	n /N (%)	n /N (%)	> 1 favours Superion	> 1 favours Superion	> 0 favours Superion
CCS	95/183 (51.9%)	93/187 (49.7%)	1.09 [0.73, 1.64], p=0.67	1.04 [0.85, 1.28], p=0.67	0.02 [-0.08, 0.12], p=0.67
Clinical success (2/3 ZCQ Domains)	107/131 (81.7%)	116/133 (87.2%)	0.65 [0.33, 1.28], p=0.22	0.94 [0.84, 1.04], p=0.22	-0.06 [-0.14, 0.03], p=0.21
No reoperations & revisions	152/190 (80.0%)	174/207 (86.6%)	0.76 [0.45, 1.27], p=0.29	0.95 [0.87, 1.04], p=0.29	-0.04 [-0.12, 0.04], p=0.29
No major related complications	164/190 (86.3%)	166/201 (82.6%)	1.33 [0.77, 2.31], p=0.31	1.05 [0.96, 1.14], p=0.31	0.04 [-0.04, 0.11], p=0.31
No additional treatments	165/190 (87%)	167/201 (83%)	1.34 [0.77, 2.35], p=0.30	1.05 [0.96, 1.14], p=0.30	0.04 [-0.03, 0.11], p=0.30

CCS, composite clinical success; CI, confidence interval; OR, odds ratio; RD, risk difference; RR, relative risk; ZCQ, Zurich Claudication Questionnaire.

Source: Commentary, Table 17

There was no statistically significant difference between X-STOP and Superion in ODI success (improvement of at least 15 points) at 24 months. There was no statistically significant difference between X-STOP and Superion in VAS back and leg pain success (improvement of at least 20 mm) at 24-months.

Collectively, the data support a clinical conclusion of non-inferiority with respect to clinical efficacy for indirect decompression using Superion and X-STOP devices.

IDS versus conservative care (supplementary analysis)

Patient reported outcomes

There were statistically and clinically significant differences in ZCQ scores favouring IDS over conservative care. For ZCQ success, the meta-analysis demonstrated a statistically significant

benefit in favour of IDS versus conservative care for all ZCQ sub-scales ranging from 40% difference in absolute risk for both physical function and patient satisfaction (RD [95% CI] 0.40 [0.32, 0.49]) to a 43% difference in absolute risk for symptom severity (RD [95% CI] 0.43 [0.35, 0.51] ($p < 0.00001$)). VAS back pain was reported in one study (Puzzilli, 2014): the mean change of -46.0 favoured IDS. The two trials (Zucherman, 2005 and Puzzilli, 2014) were poorly reported and have different follow-up periods; however, measured patient reported outcomes were superior for IDS.

Surgical reoperations

Surgical reoperations were best reported in Puzzilli (2014). There was a lower rate of reoperations due to symptoms in the IDS arm compared with the conservative care arm; however, when reoperations for any cause were included, the difference was no longer statistically significant. The additional reoperations were due to dislocation (both symptomatic and asymptomatic). The reporting in Zucherman (2005) was unclear but the reoperation rate significantly favoured IDS. However, it should be noted that although titled 'reoperation,' these are index operations for the conservative care arm.

Table 18 Rate of reoperations in the RCTs of IDS vs. conservative care

Trial ID, reoperation cause	IDS	Conservative care	OR [95% CI] < 1 favours IDS	RR [95% CI] < 1 favours IDS	RD [95% CI] < 0 favours IDS
	n /N (%)	n /N (%)			
Puzzilli (2014) – due to symptoms	24/422 (5.69%)	20/120 (16.67%)	0.30 [0.16, 0.57], p=0.0002	0.34 [0.20, 0.60], p=0.0002	-0.11 [-0.18, -0.04], p=0.002
Puzzilli (2014) – any cause	52/422 (12.80%)	20/120 (16.67%)	0.73 [0.42, 1.28], p=0.28	0.77 [0.48, 1.23], p=0.27	-0.04 [-0.11, 0.04], p=0.30
Zucherman (2005) – due to symptoms	6/96 (6.25%)	24/87 (27.59%)	0.17 [0.07, 0.45], p=0.0003	0.23 [0.10, 0.53], p=0.0006	-0.21 [-0.68, 0.26], p=0.37
Zucherman (2005) – ADAR reported measure unclear	10/96 (10.42%)	30/87 (34.48%)	0.22 [0.10, 0.49], p=0.0002	0.30 [0.16, 0.58], p=0.0003	-0.24 [-0.71, 0.23], p=0.32

CI, confidence interval; IDS, interspinous decompression spacer; OR, odds ratio; RCT, randomised controlled trial; RD, risk difference; RR, relative risk.

Source: Commentary, Table 18

Overall, the clinical claim of superiority of IDS over conservative care is supported for both safety and effectiveness. However, the evidence for this comparison is limited and subject to a higher risk of bias due to an unblinded comparison.

Clinical claim

Safety

- The data support a conclusion of at least non-inferior (and possibly superior safety) for IDS compared to surgical decompression.
- If reoperation rates are included as a safety outcome (as per the PICO Confirmation), then IDS potentially has inferior safety compared with decompression for this measure.
- IDS has superior safety compared with decompression plus fusion on the basis of procedural complications, though long-term outcomes were not presented.

- The data support a conclusion of non-inferior safety for indirect decompression using Superior compared to X-STOP.

Effectiveness

- The data suggest that IDS is non-inferior to decompression for most effectiveness outcomes, except for reoperation rates (where there is a benefit for decompression). Collectively, these data support a clinical conclusion of non-inferiority or inferiority with respect to clinical efficacy for IDS compared to decompression.
- The data suggest that IDS provides no clinically significant benefit over decompression plus fusion surgery, though reoperation rates were not reported.
- The data support a conclusion of non-inferiority for the comparison of Superior and X-STOP devices. X-STOP devices have been removed from the market due to poor long-term outcomes.

The ADAR made a claim of at least non-inferior safety (based on reduced overall complications) and non-inferior effectiveness in which case a cost-minimisation analysis (CMA) would be appropriate. However, the commentary considered the non-inferiority conclusion is not satisfied for reoperation rates, which reflects effectiveness (new or persistent worsened neurological deficit at the index level) and safety (number of reoperations, need for subsequent intervention).

13. Economic evaluation

Primary analysis

Three of the included randomised controlled trials (CELAX, NICE and Lønne [2015]) in the main comparison included trial-based economic analyses. Across all three studies, the costs of IDS were higher than decompression and the utility gain was non-significant. None compared IDS with decompression weighted with fusion.

The ADAR presented a cost comparison of IDS versus decompression surgery ± spinal fusion, based on a hybrid method of Diagnosis-Related Group (DRG)-based costings and study-based length of stay values. A modelling component is included in which the costs of reoperations following the index operation are quantified.

The cost minimisation approach was justified in the ADAR on the basis of the clinical evaluation demonstrating non-inferiority and the cost of the IDS procedure being lower than the comparator (\$Redacted vs \$21,134). The commentary stated that neither of these assumptions hold. The clinical conclusions do not support a claim of non-inferiority. Furthermore, the lower procedure cost of IDS is dependent on the rate of fusion (assumed as 25% in the ADAR). When compared with decompression alone, IDS has a higher procedure cost (\$Redacted for IDS vs \$15,590 for laminectomy).

The two major translation issues are the rate of fusion plus decompression surgery in the eligible population and the reoperation rates. The applicant applied a rate of 25% decompression plus fusion based on the opinion of a one clinical expert (an Australian surgeon). It is known that use of fusion is often due to clinician preference and opinions and therefore the use of a single clinical opinion leads to high uncertainty. Given the uncertainty about the clinical indications, clinical value and appropriate rate of fusion surgery for the patient population, the economic evaluation should consider a range of values including no fusion.

The applicant chose not to use the meta-analysis of reoperation rates performed in Section B for the economic model, justifying this on the basis of heterogeneity and limited applicability (as the studies included comparison to decompression only). This justification is not considered

sufficient. The meta-analysis had an I² value of 0% suggesting insignificant heterogeneity, while uncertainty about the clinical place of fusion has been raised throughout the assessment. However, the values selected are similar to the meta-analysis. Reoperation rates are assumed to plateau after 3 years for both arms. There is some justification for this based on the IDE data, however the evidence is limited.

Table 19 Summary of the economic evaluation – 5-year cost comparison between IDS and surgical decompression ± spinal fusion

Perspective	Australian healthcare system
Population	Moderate LSS at 1-2 lumbar motion segments, with or without low-grade spondylolisthesis, who have failed a trial of conservative management lasting at least 6 months.
Comparator	Decompression with or without spinal fusion
Type of economic evaluation	Cost comparison (IDS demonstrated to be cost saving). Quantification of QALY gains with potentially superior safety profile is unnecessary
Sources of evidence	Reoperation rates = Superior IDE study, Deyo (2013) Cost inputs = Derived using relevant MBS fees and other resource costs, Machado (2017)
Time horizon	5 years
Outcomes	Not relevant
Methods used	Cost comparison with 5-year modelling of reoperation incidence
Health states	Not relevant
Cycle length	1 year
Discount rate	5%
Software	Microsoft Excel

Source: Commentary, Table 19

The base case is presented in Table 20. No indirect or out-of-pocket costs are included in this analysis (e.g., lost work time, travel and accommodation costs for the patients and their carers). This is likely to bias against IDS in the current analysis.

Table 20 Cost comparison between IDS and decompression ± spinal fusion (index operations only) – base case

Resource item / cost variable	IDS	Decompression ± spinal fusion		Source (see Section C.5)
		Decompression alone	Decompression plus fusion	
Total, per procedure	\$Redacted	\$15,589.67	\$37,767.60	Machado (2017) and Gilmore (2016) The IDS cost derived from the proposed prosthesis / relevant MBS costs. 50% of patients requiring weekly physiotherapy to 6 weeks for IDS and 12 weeks for conventional surgery (at \$64.20 per session; MBS item 10960).
% with concomitant fusion	–	25%		Australian expert opinion This assumption is tested in sensitivity analyses
Mean cost, per procedure	\$Redacted	\$21,134.16 (cost Δ = \$Redacted)		Calculated.

IDS, interspinous decompression spacer.

Source: Commentary, Table 20

Sensitivity analyses are presented in Table 21. The cost benefits for IDS in the base case analysis become smaller when a higher reoperation rate is applied. Additional sensitivity results conducted in the commentary were most sensitive to the proportion undergoing fusion at the index comparator procedure (Table 21).

Table 21 Sensitivity analysis: modelled cost analysis of IDS versus decompression ± spinal fusion, 5 years discounted at 5% pa

Variable tested	Alternative input	IDS, total cost	Decompression ± spinal fusion, total cost	Difference
Base case	–	\$Redacted	\$24,309	-\$Redacted
Superior IDE study and Deyo 2013 ²² (reoperation rates IDS vs comparator 9.5% vs 4.5% pa plateauing at 25.8% vs 15% after 3 years)	No plateauing	\$Redacted	\$25,788	-\$Redacted
	No plateauing, only for conventional surgery	\$Redacted	\$25,788	-\$Redacted
	Superior IDE study adjusted subgroup (14.7% for IDS; plateau after 3 years)	\$Redacted	\$24,309	-\$Redacted
	US Medicare data review (Deyo 2013; 21% for IDS, plateauing after 3 years)	\$Redacted	\$24,309	-\$Redacted
	Meta-analysis of reoperations due to treatment failure (Table 13) 23.8% IDS vs 5.6% decompression (± fusion – assume the same rate)	\$Redacted	\$22,533	-\$Redacted
	Meta-analysis of reoperations due to treatment failure (Table 13) with rates inflated to 3-years: 35.7% IDS vs 8.4% decompression (± fusion – assume the same rate)	\$Redacted	\$23,214	\$Redacted
Index comparator patients undergoing decompression + fusion (base case 25%)	0% concomitant fusion, arguably representing best practice in the target population	\$Redacted	\$18,527	\$Redacted
	13.6%, approximate threshold value	\$Redacted	\$21,673	\$Redacted
	22%, Atlas of Variation (ACSQHC 2017) ²³	\$Redacted	\$23,615	-\$Redacted
Proportion of reoperation patients undergoing fusion (base case, assumes 50%)	32.7%, from IDE study proportion of Superior reoperation patients undergoing fusion	\$Redacted	\$23,851	-\$Redacted

IDS, interspinous decompression spacer.

Source: Commentary, Table 21

The most important assumption for the comparator cost values is the proportion of people in the comparator group undergoing fusion at the index surgery. The (one-way) sensitivity analysis

²² Deyo RA, et al. (2013). Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. *Spine*, **38**(10): 865-872.

²³ Australian Commission on Safety and Quality in Health Care (ACSQHC) 2017. [The second Australian atlas of healthcare variation](#), viewed 28 February 2021.

suggests a cost neutral threshold of around 13.6%. Other factors affecting the relative costs include the proportion expected to undergo reoperation, which is higher for the IDS group compared to the comparator, and the proportion undergoing fusion at a subsequent reoperation. Using the reoperation rates from the meta-analysis in Table 13 (23.8% IDS vs 5.6% decompression, not inflated over time), IDS is cost-saving when the rate of index fusion in the comparator is above 20%; the breakeven threshold is 19.5%.

In the pre-ESC response, the applicant proposed reducing the device cost by 10% to **\$Redacted** per unit, to be cost-neutral even if the rate of fusion in the comparator arm was as low as 7.9%, and giving a total cost saving over five years of **\$Redacted**.

Supplementary analysis

The ADAR's supplementary analysis provides a cost-utility analysis comparing IDS to continued (and unsuccessful) conservative management, for a subpopulation in whom more invasive surgery is limited by factors such as extensive comorbidities. The supplementary analysis makes use of existing literature, though the statistical strength of the employed utility data is somewhat undermined by a small sample size. This limits the strength of the ADAR conclusion of an ICER less than \$50,000 per quality-adjusted life year gained. The commentary noted that the references cited on conservative therapy are outdated, many of them are guidelines produced by surgical societies and some have little relevance. Two key references are a 2016 Cochrane review², which failed to find evidence for the benefits of surgery compared with conservative therapy, and a recently published clinical practice guideline on non-surgical interventions²⁴. Analysis of the comparative effectiveness of conservative care is provided above. The results of the supplementary CUA are provided below (Table 22).

²⁴ Bussieres A, et al. (2021) Non-surgical interventions for lumbar spinal stenosis leading to neurogenic claudication: A clinical practice guideline. *J Pain*, **12**:S1526-5900(21)00188-7

Table 22 Incremental cost-effectiveness ratios of IDSs versus extended conservative care, 5 years discounted at 5% pa

Model outputs	Treatment arms		Difference
	IDS	Conservative care	
Revision as patients require reoperation in the IDS arm			
Costs	\$Redacted	\$Redacted	\$Redacted
QALYs	2.01	0.91	1.11
Incremental cost-effectiveness ratio:			\$Redacted ¹
Explantation as patients require reoperation in the IDS arm			
Costs	\$Redacted	\$Redacted	\$Redacted
QALYs	1.81	0.91	0.90
Incremental cost-effectiveness ratio:			\$Redacted ¹

Abbreviation: IDS, interspinous decompression spacer.

Note: All calculations can be found in the provided Excel model.

Source: ADAR Supplementary analysis, Table 28

The redacted values correspond to the following ranges:

¹ \$15,000 to <\$25,000 per QALY gained

The results of sensitivity analyses are provided below (Table 23). The ADAR noted that a wide range of scenarios are considered; while some fluctuations in the ICER are expectedly demonstrated, this is not to the extent that the base case conclusion is overturned. As expected, the utility inputs are associated with high impacts on the ICER; the application of a highly conservative estimate²⁵ (a post-surgical utility gain of 0.14 vs 0.25 in the base case) increased the ICER to \$25,000 to <\$35,000 per QALY gained. The commentary considered that the supplementary CUA demonstrated IDS to be cost-effective (incremental cost per QALY gained of <\$19,000 under a range of scenarios) when compared with extended conservative care.

²⁵ Skidmore G, et al. (2011). Cost-effectiveness of the X-STOP® interspinous spacer for lumbar spinal stenosis. *Spine*, **36**(5): E345-56.

Table 23 Sensitivity analysis – a modelled CUA of IDS versus extended conservative care (revision as reoperation scenario), 5 years discounted at 5% pa

Variable tested	Alternative input	Incremental cost	Incremental QALY	ICER
Base case	–	\$Redacted	1.11	\$Redacted ¹
Cost inputs				
Number of hospitalisation days for IDS (50% requiring an overnight stay in base case)	Same day	\$Redacted	1.11	\$Redacted ²
	100% overnight stay	\$Redacted	1.11	\$Redacted ¹
Additional ongoing “background” cost (\$0)	\$1000 per year for IDS only	\$Redacted	1.11	\$Redacted ¹
	\$2000 per year for IDS only	\$Redacted	1.11	\$Redacted ¹
	\$1000 per year for conservative care only	\$Redacted	1.11	\$Redacted ²
	\$2000 per year for conservative care only	\$Redacted	1.11	\$Redacted ²
Cost of reoperation (\$3,220.72)	As per index surgery	\$Redacted	1.11	\$Redacted ¹
Utility inputs				
Pre-/post surgery (0.20 & 0.25; Borg 2021, EQ-5D)	Skidmore 2011 (0.62 & 0.76; SF-36)	\$Redacted	0.62	\$Redacted ³
Utility gain with extended conservative care (nil)	0.016 vs baseline (Parker 2015)	\$Redacted	1.03	\$Redacted ¹
	0.04 vs baseline (Skidmore 2011)	\$Redacted	0.92	\$Redacted ¹
Reoperation rates				
Superior IDE study (9.5% pa plateauing at 25.8% after 3 years)	9.5% pa, no plateauing	\$Redacted	1.11	\$Redacted ¹
	Superior IDE study adjusted subgroup (14.7%; plateau after 3 years)	\$Redacted	1.11	\$Redacted ¹
	US Medicare data review (Deyo 2013; 21% plateauing after 3 years)	\$Redacted	1.11	\$Redacted ¹

Abbreviation: ICER, incremental cost-effectiveness ratio; IDS, interspinous decompression spacer; QALY, quality adjusted life year.

Source: ADAR Supplementary analysis, Table 30.

The redacted values correspond to the following ranges:

¹ \$15,000 to <\$25,000 per QALY gained

² \$5,000 to <\$15,000 per QALY gained

³ \$25,000 to <\$35,000 per QALY gained

The commentary considered that comparison to continued conservative treatment is important, as there will be a subset of the LSS population for whom surgery is not a feasible option. The costs are taken from the main analysis and, owing to the need for follow-up post IDS, the marginal cost of extended conservative management is assigned a zero value. The ICER increases with alternative utility inputs from Skidmore (2011), demonstrating a sensitivity to the utility values used. The change in utility from baseline to 12 and 24 months post-operation in the study by Borg (2021) does not reach significance, likely due to the small sample size in this study.

In the pre-ESC response, the 10% price reduction improved the base case ICER from \$15,000 to <\$25,000 per QALY gain to \$5,000 to <\$15,000 per QALY gain for revision or explantation as reoperation scenarios, respectively

14. Financial/budgetary impacts

The ADAR used an epidemiological approach, based on MBS utilisation, to define the potential population with LSS confined to two levels who undergo decompression. The ADAR then used a market-based approach to estimate uptake within this population. The commentary stated that issues affecting the certainty of the financial analysis reflect those discussed in the economic evaluation, because the economic evaluation was a cost analysis and therefore the same assumptions underpin both sections. As the sensitivity analysis conducted demonstrated a cost-neutral threshold of 13% of patients undergoing fusion at the index operation, this value has been added to the financial analysis. No other sensitivity analysis has been conducted and none was presented in the ADAR.

The financial implications to the MBS resulting from the proposed listing of IDS in the base case are summarised in Table 24. The financial implications in a sensitivity analysis in which the index rate of fusion is lowered from 25% to 13% are presented in Table 25. Both analyses suggest a saving to the MBS due to the substitution of surgical procedures, which have a higher cost, by IDS. IDS is assumed to be used once per patient per lifetime and no revisions, replacements or removals were included in the analysis.

Table 24 Net financial implications of IDS to the MBS – base case 25% index fusion

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated use and cost of the proposed health technology					
Number of people eligible for IDS (decompression ± spinal fusion (1 or 2 levels))	Redacted ¹	Redacted ¹	Redacted ¹	Redacted ¹	Redacted ¹
Number of people who receive IDS	Redacted ²	Redacted ²	Redacted ²	Redacted ²	Redacted ²
Cost to the MBS (75% benefit)	\$Redacted ³	\$Redacted ⁵	\$Redacted ⁵	\$Redacted ⁶	\$Redacted ⁶
Cost to the MBS of change in use of associated services (anaesthesia)	\$Redacted ³	\$Redacted ³	\$Redacted ³	\$Redacted ³	\$Redacted ⁴
Change in use and cost of other health technologies					
Change in use of decompression due to substitution and reoperation	-Redacted ²	-Redacted ²	-Redacted ²	-Redacted ²	-Redacted ²
Cost to the MBS of change in use of decompression due to substitution and reoperation	-\$Redacted ⁴	-\$Redacted ⁴	-\$Redacted ⁵	-\$Redacted ⁶	-\$Redacted ⁷
Change in use of decompression + spinal fusion due to substitution and reoperation	-Redacted ⁸	-Redacted ⁸	-Redacted ²	-Redacted ²	-Redacted ²
Cost of change in use of decompression + spinal fusion due to substitution and reoperation	-\$Redacted ³	-\$Redacted ⁴	-\$Redacted ⁴	-\$Redacted ⁵	-\$Redacted ⁵
Net change in costs to the MBS (75% benefit)	-\$Redacted ⁴	-\$Redacted ⁶	-\$Redacted ⁷	-\$Redacted ⁹	-\$Redacted ¹⁰
Net financial impact to the MBS (75% benefit)	-\$Redacted³	-\$Redacted⁴	-\$Redacted⁵	-\$Redacted⁵	-\$Redacted⁶

IDS, interspinous decompression spacer; MBS, Medicare Benefits Schedule.

Source: Commentary, Table 22

The redacted values correspond to the following ranges:

¹ 10,000 to <20,000

² 500 to <5,000

³ < \$1 million

⁴ \$1 million to <\$2 million

⁵ \$2 million to <\$3 million

⁶ \$3 million to <\$4 million

⁷ \$4 million to <\$5 million

⁸ < 500⁹ \$5 million to <\$6 million

¹⁰ \$6 million to <\$7 million

Table 25 Net financial implications of IDS to the MBS – sensitivity analysis 13% index fusion

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated use and cost of the proposed health technology					
Number of people eligible for IDS (decompression ± spinal fusion (1 or 2 levels))	Redacted ¹	Redacted ¹	Redacted ¹	Redacted ¹	Redacted ¹
Number of people who receive IDS	Redacted ²	Redacted ²	Redacted ²	Redacted ²	Redacted ²
Cost to the MBS (75% benefit)	\$Redacted ⁴	\$Redacted ⁴	\$Redacted ⁵	\$Redacted ⁵	\$Redacted ⁶
Cost to the MBS of change in use of associated services (anaesthesia)	\$Redacted ⁴	\$Redacted ⁴	\$Redacted ⁴	\$Redacted ⁴	\$Redacted ⁴
Change in use and cost of other health technologies					
Change in use of decompression due to substitution and reoperation	-Redacted ²	-Redacted ²	-Redacted ²	-Redacted ²	-Redacted ²
Cost to the MBS of change in use of decompression due to substitution and reoperation	-\$Redacted ⁵	-\$Redacted ⁵	-\$Redacted ⁶	-\$Redacted ⁷	-\$Redacted ⁸
Change in use of decompression + spinal fusion due to substitution and reoperation	-Redacted ³	-Redacted ³	-Redacted ³	-Redacted ³	-Redacted ³
Cost of change in use of decompression + spinal fusion due to substitution and reoperation	-\$Redacted ⁴	-\$Redacted ⁴	-\$Redacted ⁴	-\$Redacted ⁴	-\$Redacted ⁵
Net change in costs to the MBS (75% benefit)	-\$Redacted ⁵	-\$Redacted ⁶	-\$Redacted ⁷	-\$Redacted ⁸	-\$Redacted ⁹
Net financial impact to the MBS (75% benefit)	-\$Redacted⁴	-\$Redacted⁵	-\$Redacted⁵	-\$Redacted⁵	-\$Redacted⁶

IDS, interspinous decompression spacer; MBS, Medicare Benefits Schedule.

Source: Commentary, Table 23

The redacted values correspond to the following ranges:

¹ 10,000 to <20,000

² 500 to <5,000

³ < 500

⁴ < \$1 million

⁵ \$1 million to <\$2 million

⁶ \$2 million to <\$3 million

⁷ \$3 million to <\$4 million

⁸ \$4 million to <\$5 million

⁹ \$5 million to <\$6 million

Although a net cost saving to MBS is suggested, the high-cost component of the proposed medical service is not the service but the prostheses. The financial implications for the Australian healthcare system are presented in Table 26 (base case) and Table 27 (sensitivity analysis). Consistent with the economic analysis, the cost-saving presented in the base case is not predicted in the sensitivity analysis.

The inclusion of the decompression ineligible population (presented as supplementary analysis) increases costs to the MBS without any offsets and therefore any addition of patients from this population increases both the predicted financial impact to the MBS and the predicted overall financial implications.

No out-of-pocket costs were discussed in the ADAR.

The pre-ESC response revised financial estimates (with a 10% discount on the device cost) are included in Table 26.

Table 26 Net financial implications of the proposed listing of IDS to the Australian healthcare system – base case 25% index fusion

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Net financial implications of the proposed listing of IDS on hospital resource use					
Other hospital costs with IDS, total	\$1,707,482	\$3,037,546	\$4,409,998	\$5,824,839	\$7,282,067
Changes in other hospital costs (via reduction in decompression ± spinal fusion)	-\$11,694,207	-\$20,310,064	-\$28,908,046	-\$37,876,314	-\$47,112,282
Net financial implications	-\$9,986,725	-\$17,272,518	-\$24,498,047	-\$32,051,476	-\$39,830,215
Net financial implications of the proposed listing of IDS in terms of prostheses costs					
Prosthesis costs with IDS, total	\$Redacted ¹	\$Redacted ²	\$Redacted ³	\$Redacted ⁴	\$Redacted ⁵
Changes in prosthesis (via reduction in spinal fusion)	-\$Redacted ⁶	-\$Redacted ⁷	-\$Redacted ⁸	-\$Redacted ¹	-\$Redacted ¹
Net financial implications	\$Redacted ⁹	\$Redacted ¹	\$Redacted ²	\$Redacted ²	\$Redacted ³
Net financial implications of the proposed listing of IDS to the Australian healthcare system					
IDS costs, all resource items	\$Redacted ¹	\$Redacted ²	\$Redacted ³	\$Redacted ⁴	\$Redacted ¹⁰
Changes in overall healthcare costs, including prosthesis (via reduction in decompression ± spinal fusion)	-\$Redacted ¹	-\$Redacted ²	-\$Redacted ⁴	-\$Redacted ⁵	- \$Redacted ¹⁰
Net financial implications	- \$Redacted ¹¹	- \$Redacted ¹²	-\$ Redacted ¹³	-\$Redacted ⁷	-\$ Redacted ¹⁴
Revised in pre-ESC response to reflect 10% discount					
IDS costs, all resource items	\$Redacted ¹	\$Redacted ²	\$Redacted ³	\$Redacted ⁴	\$Redacted ⁵
Changes in overall healthcare costs, including prosthesis (via reduction in decompression ± spinal fusion)	-\$Redacted ¹	-\$Redacted ²	-\$Redacted ⁴	-\$Redacted ⁵	- \$Redacted ¹⁰
Net financial implications	-\$Redacted ⁶	-\$Redacted ⁷	-\$Redacted	-\$Redacted ¹	-\$Redacted ¹

IDS, interspinous decompression spacer; MBS, Medicare Benefits Schedule

Source: Commentary, Table 24 and Table 4, pre-ESC response

The redacted values correspond to the following ranges:

- ¹ \$10 million to <\$20 million
- ² \$20 million to <\$30 million
- ³ \$30 million to <\$40 million
- ⁴ \$40 million to <\$50 million
- ⁵ \$50 million to <\$60 million
- ⁶ \$3 million to <\$4 million
- ⁷ \$6 million to <\$7 million
- ⁸ \$9 million to <\$10 million
- ⁹ \$8 million to <\$9 million
- ¹⁰ \$60 million to <\$70 million
- ¹¹ \$2 million to <\$3 million
- ¹² \$4 million to <\$5 million
- ¹³ \$5 million to <\$6 million
- ¹⁴ \$7 million to <\$8 million

Table 27 Net financial implications of the proposed listing of IDS to the Australian healthcare system – sensitivity analysis 13% index fusion

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Net financial implications of the proposed listing of IDS on hospital resource use					
Other hospital costs with IDS, total	\$1,471,967	\$2,618,574	\$3,801,723	\$5,021,413	\$6,277,644
Changes in other hospital costs (via reduction in decompression ± spinal fusion)	-\$9,444,097	-\$16,375,271	-\$23,275,218	-\$30,478,562	-\$37,896,865
Net financial implications	-\$7,972,130	-\$13,756,697	-\$19,473,495	-\$25,457,150	-\$31,619,221
Net financial implications of the proposed listing of IDS in terms of prostheses costs					
Prosthesis costs with IDS, total	\$Redacted ¹	\$Redacted ¹	\$Redacted ²	\$Redacted ³	\$Redacted ⁴
Changes in prosthesis (via reduction in spinal fusion)	-\$Redacted ⁵	-\$Redacted ⁶	-\$Redacted ⁷	-\$Redacted ⁸	-\$Redacted ⁹
Net financial implications	\$Redacted ¹⁰	\$Redacted ¹	\$Redacted ²	\$Redacted ²	\$Redacted ³
Net financial implications of the proposed listing of IDS to the Australian healthcare system					
IDS costs, all resource items	\$Redacted ¹	\$Redacted ²	\$Redacted ³	\$Redacted ⁴	\$Redacted ¹¹
Changes in overall healthcare costs, including prosthesis (via reduction in decompression ± spinal fusion)	-\$Redacted ¹	-\$Redacted ²	-\$Redacted ³	-\$Redacted ³	-\$Redacted ⁴
Net financial implications	-\$Redacted ¹²	\$Redacted ¹²	\$Redacted ⁵	\$Redacted ⁶	\$Redacted ⁷

IDS, interspinous decompression spacer; MBS, Medicare Benefits Schedule

Source: Commentary, Table 25

The redacted values correspond to the following ranges:

¹ \$10 million to <\$20 million

² \$20 million to <\$30 million

³ \$30 million to <\$40 million

⁴ \$40 million to <\$50 million

⁵ \$1 million to <\$2 million

⁶ \$2 million to <\$3 million

⁷ \$3 million to <\$4 million

⁸ \$5 million to <\$6 million

⁹ \$6 million to <\$7 million

¹⁰ \$8 million to <\$9 million

¹¹ \$50 million to <\$60 million

¹² < \$1 million

15. Other relevant information

Nil

16. Key issues from ESC to MSAC

ESC key issue	ESC advice to MSAC
Non-inferiority clinical claim against decompression ± fusion	The ADAR made a clinical claim of at least non-inferior safety (possibly superior) and non-inferior efficacy for IDS compared to decompression with or without fusion. This may not be reasonable because reoperation rates do not support these claims. This discrepancy had flow on effects to the model selection in the economic evaluation.
Uncertain comparator	The appropriate proportion of fusion in the comparator is uncertain, which is a key driver in the economic evaluation (primary analysis). In addition, it was noted that IDS may be a second-line treatment before decompression with or without fusion, which would make

	conservative care a more appropriate comparator (included in the supplementary analysis), or a weighted comparator comprised of conservative care and decompression with or without spinal fusion; a cost-utility analysis with all comparators would be informative.
Item descriptor: population definition and fee	<p>The item descriptor should specify:</p> <ul style="list-style-type: none"> • the degree of spondylolisthesis as less than 25% shifting of a vertebral body • clinical signs of compression, based on clinical and radiological evidence of any one of the following: the thecal sac and/or cauda equina compression; nerve root displacement or compression by either osseous or non-osseous elements; hypertrophic facets with canal encroachment • the eligible population as those aged 45 years and older. <p>It is not appropriate to include a precise description of moderate lumbar spinal stenosis (LSS) as a compression ratio of 33–66% is unlikely to be seen over only one or two segments.</p> <p>Additional justification is required for the MBS fee, which is based on an existing MBS fee for an open procedure. The proposed percutaneous implantation procedure would require less time than the open procedure on which the fee is based, so will have a lower cost.</p>
Restriction of clinical providers	<p>The device should be restricted to use by clinicians who are trained in selecting appropriate patients and implanting the device.</p> <p>If the device is implemented in Australia, it should be considered as part of a surgical intervention set for LSS.</p>

ESC discussion

ESC noted that this application was for Medicare Benefits Schedule (MBS) listing of the implantation of minimally invasive interspinous decompression spacer (IDS) devices for one- or two-level lumbar spinal stenosis (LSS). ESC noted that an application will be made to list an IDS device, the Superior Indirect Decompression System, on the Protheses List (PL). Currently, IDS devices are not broadly used in Australia.

ESC noted that there have been two previous applications to MSAC for IDS devices: application 1099 in 2007 and application 1422 in 2017. Both applications were not supported by MSAC because there was insufficient evidence for their effectiveness. ESC noted that only one of the previously proposed devices, the X-STOP®, was similar to the Superior device; that is, a minimally invasive standalone implant that does not require open surgery. The other devices were designed to be used in conjunction with surgical decompression. The population nominated for the X-STOP device is similar to that for the current application.

ESC noted that the X-STOP device has been withdrawn from the market. The commentary stated that this was due to poor results in long-term follow-up and raised concern that comparisons between the Superior and X-STOP devices may not be sufficient to justify the safety and effectiveness of Superior vs. the comparator. ESC raised concern whether the X-STOP device was withdrawn due to safety concerns and if that was so, considered that more data on this would be informative. ESC noted that the pre-ESC response stated that the X-STOP device was withdrawn from the US market because it was not commercially viable for the company. ESC noted that the commentary referenced an editorial²⁶ as the source of its information, not a direct study.

ESC noted that the applicant is proposing two new MBS items, covering procedures for one and two lumbar motion segments respectively.

ESC noted that the population defined in the item descriptor was consistent with the inclusion criteria of the Investigational Device Exemption (FDA-IDE, i.e. IDE) randomised control trial (RCT)

²⁶ Gala RJ, Russo GS, Whang PG (2017). Interspinous implants to treat spinal stenosis. *Curr Rev Musculoskelet Med*, **10**:182-188.

and Australian Instructions for Use (IFU) approved by the Therapeutic Goods Administration (TGA). ESC noted the complexities associated with the population as discussed at PASC.

ESC considered that it would not be appropriate to include a precise description of moderate LSS as a compression ratio of 1/3 to 2/3 (33–66%) in the item descriptor, as it would be unusual to see a compression ratio this high over only one or two motion segments. However, ESC considered that certain requirements for clinical signs of compression, based on various conditions, should be considered, such as clinical and radiological evidence of any one of the following: the thecal sac and/or cauda equina compression; nerve root displacement or compression by either osseous or non-osseous elements; hypertrophic facets with canal encroachments. ESC also considered that it would not be appropriate to include a measure of functional impairment such as a Zurich Claudication Questionnaire (ZCQ) score of greater than 2.5 (as suggested by the Spine Society of Australia [SSA]), because the ZCQ is subjective and not broadly used in Australia.

ESC considered that, consistent with the IDE trial, the item descriptor should also specify:

- the degree of degenerative spondylolisthesis as less than 25% shifting of a vertebral body (i.e. grade 1 or low grade spondylolisthesis)
- clinical signs of compression, based on clinical and radiological evidence of any one of the following: the thecal sac and/or cauda equina compression; nerve root displacement or compression by either osseous or non-osseous elements; hypertrophic facets with canal encroachments
- the eligible population as those aged 45 years and older.

ESC confirmed the remaining criteria in the proposed item descriptor were appropriate, including the requirement for failure of conservative management for at least 6 months.

In addition, ESC advised that the item should be restricted to certain providers, as it necessitates a surgical approach that requires skill to ensure the device is placed in the correct position. ESC considered that if the device is implemented in Australia, it should be considered as part of a surgical intervention set for LSS.

Regarding the proposed fee, ESC considered that the proposed percutaneous implantation procedure would require less time than the open procedure on which the fee is based; ESC considered that a lower cost than open surgery was reasonable for IDS if the procedure takes less time.

ESC noted that, in the clinical care pathway, conservative care is needed for 6 months before surgical approaches (spinal fusion, or decompression with or without spinal fusion) can be undertaken. The Superion device addresses moderate LSS, which traditionally requires indirect compression surgery or a laminectomy, in a minimally invasive approach. However, ESC also noted that after the device is inserted, the disease might continue to progress to a severity that requires a laminectomy or fusion surgery, which was not reflected in the clinical management algorithm. Thus, ESC considered the clinical place of this therapy was a complex issue.

ESC noted that a weighted comparator of surgical decompression with or without spinal fusion was consistent with the Ratified PICO. ESC agreed with the commentary and considered that the weighting given to fusion surgery and its justification based on a single clinical expert is uncertain. ESC advised that clinical practice should determine the appropriate proportion of fusion in the comparator.

In addition, ESC noted the Spine Society of Australia (SSA) had disagreed with the comparator, stating that this group of patients would not have any surgical intervention. ESC also noted that decompression is commonly performed as part of reconstruction surgery (and not in isolation) as most patients have vertebral instability, and IDS would not be indicated in these patients. ESC

considered that, if this is the case, IDS may be a second-line treatment before decompression with or without surgery (i.e. bridge to surgery, rather than a replacement) therefore a more appropriate comparator may be conservative care (included in the ADAR's supplementary analysis), or a weighted comparator comprised of conservative care and decompression with or without spinal fusion.

ESC noted that the ADAR appropriately included the comparison to conservative care in the submission (in a supplementary analysis). The ADAR considered that PASC suggested this group would be a subpopulation with mild disease ineligible for surgery according to clinical practice. Rather the applicant considered that this population are those who cannot undergo surgery due to the risk of complications and extensive recovery time but will only be a small subgroup. ESC considered that due to the complexities associated with the comparator and clinical place, that this supplementary comparison may still be a relevant comparison for MSAC to consider.

ESC noted that the applicant-developed assessment report (ADAR) included six clinical trials that compared IDS separately against surgical decompression, and surgical decompression plus spinal fusion. As none of these studies included the Superior device, ESC noted the ADAR addressed this applicability concern by including a trial comparing the Superior vs. X-STOP IDS devices. The trial populations were predominantly in patients aged 40 years and over. All studies were defined for moderate LSS at one or two levels and provided trial follow-up data to two years, with one providing up to five years. ESC considered that all trials had a high risk of bias in multiple domains, but acknowledged that it is a challenge to conduct a very high quality RCT comparing a minimally invasive surgery with open surgery.

ESC considered the clinical claim for at least non-inferior and possibly superior safety of indirect compression with IDS compared with surgical decompression with or without fusion. Open surgery has a higher rate of complications such as infections. ESC noted the data suggested clinical conclusions of:

- at least non-inferior safety for IDS compared to decompression surgery alone, though no long-term safety data were presented. ESC noted that the commentary did not agree with the claim of non-inferior safety as the reoperation rate was higher (i.e. inferior) in IDS than decompression surgery alone; ESC considered that there was uncertainty around this result
- superior safety for IDS compared to decompression surgery plus fusion surgery; however, long-term outcomes and reoperation rates were not reported
- non-inferior safety for Superior compared to X-STOP IDS devices.

Regarding the clinical claim of non-inferior effectiveness, ESC noted that the data suggested:

- that IDS provided a numerical benefit over decompression surgery for most effectiveness outcomes, except for visual analogue scale (VAS) back and leg pain (where the results are inconsistent), ZCQ (where the results for physical function and patient satisfaction were mixed), and reoperation rates (where there is a benefit for decompression); the data also may suggest a clinical conclusion of non-inferiority with respect to clinically efficacy,
- that IDS provides a numerical benefit over decompression plus fusion surgery for all effectiveness outcomes; the data also may suggest a clinical conclusion of non-inferiority with respect to clinical efficacy
- a clinical conclusion of non-inferiority with respect to clinical efficacy for Superior and X-STOP devices.

ESC considered that the ADAR's clinical claim of at least non-inferior safety (possibly superior) and non-inferior efficacy may not be reasonable because reoperation rates do not support these conclusions.

ESC considered the supplementary comparison of IDS vs. conservative care, informed from two trials. ESC considered that IDS showed superior effectiveness in all ZCQ subscales, including physical function and patient satisfaction, symptom severity and VAS back pain. IDS showed inferior safety compared to conservative care. The commentary noted that the trials were poorly reported and there was a high risk of bias for some outcomes, particularly reoperation. ESC considered that this did not change the direction of superiority, though it reduced confidence in the findings, and the economic evaluation using these data.

ESC noted that the economic model for the primary analysis did not align with the Ratified PICO. PASC had advised that a cost-utility analysis (CUA) would be the most appropriate, but the ADAR provided a cost-minimisation analysis (CMA) on the basis of the non-inferiority claim and considered that quantifying the benefits associated with health-related quality of life may introduce model-related uncertainties. ESC considered that the claim of non-inferiority for safety and efficacy may not be reasonable, and therefore a CUA may be warranted. In addition, ESC considered that a CUA would be achievable as the necessary inputs for IDS versus decompression alone and decompression plus fusion surgery were available – that is, incremental costs and quality-adjusted life year (QALY) gains (for lower complications) and losses (for higher reoperation). ESC considered that the timing of QALY gains and losses should be examined, as it noted that both the IDS device and laminectomy were shown to have a statistically significant benefit at 6 months post-operation; however, while laminectomy sustained its significant benefit at 12- and 24-months post-operation, the IDS device (X-STOP) did not and appeared to have a waning effect.

ESC noted the key inputs for the CMA were the rate of fusion plus decompression surgery in the eligible population and the reoperation rates, modelled over five years. The base case rate of fusion (25%) in the comparator was based on the opinion of a single clinical expert. ESC agreed with the commentary and noted that the use of fusion is variable due to clinician preference and opinion; therefore, the use of a single clinical opinion leads to high uncertainty. ESC considered that the rationale of the ADAR to not use the meta-analysis of reoperation rates provided in the clinical evidence for the economic model on the basis of heterogeneity and limited applicability was not well justified.

ESC noted that, when compared with decompression surgery alone (i.e. laminectomy), IDS has a higher procedure cost (see Table 20). ESC also noted that when the weighting with concomitant fusion and reoperation rates are included (which include concomitant fusion), that IDS was cost saving compared with decompression weighted with concomitant fusion (see Table 21).

ESC also noted that the commentary included additional sensitivity analysis using the meta-analysis of reoperations due to treatment failure (rather than using the Superior IDE study). At the lower limit of reoperation rates the total cost of IDS was \$1,226 less than the cost of decompression with or without spinal fusion; however, at the higher limit of reoperation rates, the total cost of IDS was \$210 more. ESC also noted that as the percentage of patients who have decompression plus fusion surgery increases, the cost savings of IDS also increase, with a break-even point demonstrated at 13.6% of patients undergoing decompression plus fusion. In addition, the commentary's sensitivity analysis using 0% concomitant fusion (i.e. decompression alone) which it considered may represent best clinical practice in the target population resulted in additional cost of **\$Redacted**. Overall, ESC considered that the cost neutrality associated with the ADARs base-case model was driven by the rate of fusion in the comparator.

In addition, ESC noted that the ADAR included a supplementary cost-utility analysis (CUA) comparing IDS to extended conservative care. The key inputs were an annualised reoperation rate of 9.5% for IDS (also used in the ADARs base case CMA model) compared to 0% for conservative care. As discussed above, ESC considered that the reoperation rates for IDS were not well justified. ESC noted the incremental cost-effectiveness ratios (ICERs) under the two

alternative scenarios of revision only and when patients were assumed to undergo explantation were \$15,000 to <\$25,000 and \$15,000 to <\$25,000, respectively. ESC noted that sensitivity analysis demonstrated using alternative sources of utility inputs had a large effect on the ICER, but that these remained under \$50,000 per QALY.

ESC noted consistent with the economic analysis, the financial estimates to the MBS (and more broadly to the to the Australian healthcare system) were sensitive to the comparator and the weighting given to fusion, and that cost savings to the MBS will be less if this lower. ESC noted cost savings were estimated to the MBS under the sensitivity analysis using the modelled cost neutral position of 13% for index fusion but queried if this scenario would align with clinical practice. In addition, ESC considered that the MBS offsets may not be realised if the comparator was conservative care or included a proportion of conservative care, where surgical approaches are not supplemented, and this increases costs without any offset.

The ESC noted no consumer feedback was received for the ADAR. ESC raised consumer issues noting most primary outcomes were patient-reported outcomes and subjective. ESC noted the pre-ESC response indicated that the patient-reported efficacy outcomes already accounted for the impact of revision surgery. ESC also noted a quality issue with the evidence for IDS reoperations. The ADAR stated that 3.7% of patients who participated in a phone survey underwent revision surgery or a reoperation during a 6–12-month follow-up period. However, the ADAR noted that the low rate of revision may have been due to compliant patients with better outcomes being more likely to participate in follow-up surveys. This suggests that there may be data missing for a large group of the population who have received IDS. ESC also considered that involving affected people (i.e. consumers) to identify the outcomes of importance would improve the data.

17. Applicant comments on MSAC's Public Summary Document

The applicant is disappointed with MSAC's decision not to recommend an MBS listing for the implantation of minimally invasive interspinous decompression spacers. We believe there remains a strong clinical need for non-surgical treatment options for patients suffering from moderate degenerative lumbar spinal stenosis.

The applicant would also like to specifically address the Spine Society of Australia (SSA) comment that “the proposed population too broad, as it includes patients with mild and tolerable LSS who would not warrant invasive interventions and would benefit from conservative care” (page 13). We believe this statement reflects a misunderstanding / misinterpretation of the PICO by the SSA. The indication requested in the application consisted of patients with moderate LSS, and specifically excluded patients with mild LSS.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website:
[visit the MSAC website](#)