National Institute for Health and Clinical Excellence

191/2– Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication
Consultation Comments table

IPAC date: 9th September 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	for those suffering from Central Canal Stenosis and not for those with lateral recess stenosis	Thank you for your comment. The guidance will not be changed as the Committee was advised otherwise.
2	Consultee 2 NHS Professional British Pain Society	**1**	Interspinous distraction is a procedure of limited efficacy as well as time-limited effects. Â The porcedure should not be regarded as a definitive treatment as is clearly stated in the guidance.	Thank you for your comment. Section 1.1 of the guidance will be changed.
3	Consultee 1 NHS Professional	**2.1**	Current treatment still carries a signifcant incidence of recurrence of symptoms	Thank you for your comment. Section 2.1 of the guidance is intended to be a summary of the current treatments used and does not provide a description of their risk and benefits.

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4	Consultee 2 NHS Professional British Pain Society	**2.1**	Indication: Interspinous distraction can be performed under local anaesthetsia/conscious sedation and does not necessarily require the administartion of general anasethesia. A number of patients presenting with claudication are elderly and may be unfit for a general anaesthetic and the surgery of decompression. In view of the above, the guidance should clarify that this porcedure should be primarily recommended for the following group of patients • Unable to tolerate a general anaesthetic and formal decompression because of age/associated morbidities. • Patients presenting with primarily with claudication symptoms as opposed to back pain • A time limited improvement in walking distance/relief from claudication distance is the aim	Thank you for your comment. It is not within the remit of the IP Programme to provide a detailed referral protocol. Section 2.2.1 of the guidance clarifies the aim of the procedure as being relief of pain on standing or walking.
5	Consultee 1 NHS Professional	**2.2**	Is it a DCS procedure? What happens if implant gets infected?	Thank you for your comment. This is beyond the remit of the guidance.
6	Consultee 2 NHS Professional British Pain Society	**2.2**	None	Thank you for your comment.

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7	Consultee 2 NHS Professional British Pain Society	**2.3**	The available RCT compares interspinous distraction to conservative treatement interspinous distration is shown to be superior. It should be noted that, exercise and ultrasound apart, consevative treatment has limited efficacy/ evidence in claudication (Goren et al Efficacy of exercise and ultrasound in patients with lumbar spinal stenosis: a prospective randomized controlled trial. Â Clinical rehabilitation July 2010:24:7623-31. Tran de QH, Duong S, Finlaysson RJ. Lumbar Spine Stenosis: a brief review of the non surgical mangement Can J Anaesth 2010 Jul vol (57) & 694-703. The study therefore compares a new therapy to an existing therapy that is clearly not the current gold standard for treatment. The definitive trial should compare interspinous distraction against bony decompression. The Felix Trial Group (Moojen et al. The Felix-trial. Double-blind randomization of interspinous implant or bony decompression for treatment of spinal stenosis related intermittent neurogenic claudication. BMC Musculoskelet Disord.2010: 11 100) have published a portocol of such a study.	Thank you for your comment. The IP programme does not compare the efficacy and safety of interventions against comparator interventions.
8	Consultee 3 SURGIC Manufacturer	**2.3**	There are a number of studies that are not included in your report. I would also like to draw your attention to the RCT in the US comparing Coflex to PLIF - 384 patients at 21 centres have been treated so far. Publication is planned for 2012. In addition, the results of a German RCT comparing decompression	Thank you for your comment. The consultee refers to a non peer-reviewed study. The NICE IP methods guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee.

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			alone to decompression plus Coflex, will be presented later this year. Adelt et al. (2007) Coflex Interspinous Stabilisation: Clinical and Radiographic Results from an International Multicentre Retrospective Study. Paradigm Spine Journal Adelt et al. (2010) Das interspinöse U-implantat (Später Coflex). Orthopäde Vol. 39, p. 595-601 Arrotegui I. (2010) Coflex Device for Lumbar Disc Surgery: Avoid the Last Step: Lumbar Instability. Spanish Journal of Surgical Research. Vol 13, No. 1, p. 7-11 Errico T et al. (2009) Survivorship of Coflex Interlaminar-Interspinous Implant. SAS Journal Vol 3, Issue 2, p. 59-67 Kong E et al. (2007) One Year Outcome Evaluation after Interspinous Implantation for Degenerative Spinal Stenosis with Segmental Instability. Journal of Korean Medical Science Vol 22 (2) p330- Nachanakian A et al. (2010) Posterior dynamic stabilisation. Pan Arab Journal of Neurosurgery Vol 14, No 1, p. 33-37. Trautwein F et al. (2010) Determination of the in vivo posterior loading environment of the	This study is published in a manufacturer-funded journal. This study is not published in English. This study was identified in the post-consultation literature search and will be included in appendix A of the overview. This study was identified in the post-consultation literature search and will be included in table 2 of the overview. This article is in table 2 of the overview. This study was identified in the post-consultation literature search and will be included in appendix A of the overview. Outcomes in this study are biomechanical, rather than clinical. Outcomes in this study are biomechanical, rather than clinical. This study is in vitro and outcomes are biomechanical, rather than clinical.

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			Coflex interlaminar-interspinous implant. The Spine Journal Vol 10, p. 244-251. Tsai K et al. (2006) A Biomechanical Evaluation of an Interspinous Device (Coflex Device) used to Stabilize the Lumbar Spine. Journal of Surgical Orthopaedic AdvancesVol 17, p. 1049-1056. Wilke H et al. (2008) Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure. European Spine Journal. Vol 17, p. 1049-1056 Wilke H et al. (2010) Biomechanik der intersinosen platzhalter. Orthopäde Vol 39, p. 565-572. **Posters/meeting abstracts:** Bertagnoli R. (2010) Functional dynamic stabilisation in lumbar spinal stenosis with COFLEX interspinous implant - Min. 3-year results. SAS/DWG. Bertagnoli R. (2006) Coflex Interspinous Implant: Motion Preservation Treatment in Lumbar degenerative Stenosis Patients - Min 1-Y. Results. Global Symposium on Motion Preservation Technology. Hossain-Ibrahim D. and Shad A. (2009) Maintenance of Foraminal Height after Lumbar Decompression with Coflex	This study is not published in English. Evidence from posters or meeting abstracts is not normally included in the evidence presented to the Committee.

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			Interspinous Stabilisation Improves Leg and Back Pain as well as Quality of Life. SAS. Kamal T et al. (2010) 2 years follow up for Coflex@ inter-spinous dynamic stabilization device. A prospective analysis. Britspine. Sinigaglia R et al. Short Term Results and Gait Analysis in Severe Multilevel Lumbar Spinal Stenosis Treated with Decompression and Interspinous Distraction.	
9	Consultee 2 NHS Professional British Pain Society	**2.4**	Safety: Interspinous distraction is a relatively safe procedure. Complications that have not been mentioned are erosion of the implant through the skin and new onset radiculopathy (Bowers et al Neurosurg focus June 2010:28:6ppE8)	Thank you for your comment. This study was identified in the post-consultation literature search and will be included in table 2 of the overview.

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10	Consultee 4 BUPA	**2.5.1**	Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. Bupa is uncomfortable with the draft recommendation that normal arrangements are appropriate. We appreciate that you deal with generic procedures so have to give blanket recommendations, but we note that their are several implants which can be used for this procedure and that the amount and quality of evidence supporting the safety and efficacy of the various products is very different. The range runs from RCT to unpublished accounts. Efficacy and need for re- operation seems to vary. Thus our comment on 2.5.1 is that it should alert patients to the need to ask their surgeon how well proven the implant he intends to use is, making it clear that they are aware that some are still relatively early in development so their performance is unknown.	Thank you for your comment. Section 2.2.3 of the guidance will be changed.
11	Consultee 2 NHS Professional British Pain Society	**2.5**	None	Thank you for your comment.
12	Consultee 3 SURGIC Manufacturer	**2.5**	This warning to patients can be applied to all interventions, but with most interspinous implants, the procedure does not cause problems for further surgery due its minimally invasive technique.	Thank you for your comment.

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13	Consultee 1 NHS Professional	**general**	Lumbar canal stenosis is known to be of 2 typesCentral and lateral. It does make sense that patients with central canal stenosis maybenfit temporarily from the that procedure .Eventually, their symptoms Â will recur as the main pathological process is dynamic with ongoing degenrative changes involving the facet joints and ligamentum flavum. For patiets with lateral spinal stenosis which may be having (lateral recess stenosis) , the procedure is unlikely to be useful for them as putting an interspinous spacer would not decompress the nerve root in the lateral recess which is the gutter where the nerve root resides before it enters into the foramen. Patients who are undergoing this procedure should be warned in advance that it is a temporaryprocedure not addressing the original pathological process.	Thank you for your comment. The Committee considered it but decided not to change the guidance.