

National Institute for Health and Care Excellence

IP1339 – Percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture

Consultation Comments table

IPAC date: 8 September 2016

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Manufacturer	4 and 5	<p>Dear Madam, Dear Sir,</p> <p>I would like to inform that 4 new publications are available on our technology SpineJack:</p> <ul style="list-style-type: none"> - Vanni 2016 - J Spine Surg 2016;2(1):13-20 - "Third-generation percutaneous vertebral augmentation systems" - Noriega 2016 - Osteoporos Int (2016) 27:2047-2055 - Safety and clinical performance of kyphoplasty and SpineJack® procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study - Lin 2016 - World Neurosurg. 90: 391-396 - Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: a 1-Year Follow-up Study - Noriega 2016 - Turk Neurosurg, DOI: 10.5137/1019-5149.JTN.12294-14.1 - Long-Term Benefits of Percutaneous Anatomical Restoration of Vertebral Compression Fractures Linked to Malignancy <p>I remain at your disposal for any further information.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment and for sending us references of new publications.</p> <p>The Vanni (2016) paper is a review of the percutaneous vertebral augmentation systems available for the treatment of osteoporotic vertebral fractures. Therefore it has not been included in the overview.</p> <p>The first Noriega (2016) paper has been added to the main extraction table (table 2).</p> <p>The Lin (2016) paper has been added to table 2.</p>

				The second Noriega (2016) paper has been added to table 2.
2	Consultee 2 Professional organisation Society of British Neurological Surgeons	General	My colleague [REDACTED] very kindly reviewed the document. He has experience in the device described as well as Vertebroplasty and Balloon Kyphoplasty.	Thank you for your comment.
3	Consultee 2 Professional organisation Society of British Neurological Surgeons	5	The safety aspects are agreed.	Thank you for your comment.
4	Consultee 2 Professional organisation Society of British Neurological Surgeons	4	The efficacy of the procedure is comparable but not significantly better than Kyphoplasty. The evidence indicated in the document is not disputed.	Thank you for your comment.
5	Consultee 2 Professional organisation Society of British Neurological Surgeons	General	The cost of the procedure is more than the alternative methods. In the current financial climate, the increased cost is not justified in relation to the clinical efficacy and outcome. More evidence is clearly required.	Thank you for your comment. Cost-effectiveness is not part of the remit of the IP Programme. NICE encourages further research into all procedures on which it produces guidance.

6	Consultee 2 Professional organisation Society of British Neurological Surgeons	1.1	The normal arrangement for audit and governance is agreed.	Thank you for your comment. The consulted agrees with main recommendation.
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"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."