



November 8, 2018

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Subject: Washington State Health Care Authority Draft Technology Report on Sacroiliac Joint Fusion

Dear Mr. Morse:

On behalf of the International Society for Advance of Spine Surgery, we appreciate the opportunity to submit comments regarding the Washington State Health Care Authority (HCA) Draft Evidence Report on Sacroiliac (SI) Joint Fusion Surgery prepared by RTI International–University of North Carolina Evidence-based Practice Center.

We are in general agreement with the authors of the Washington State HCA Draft Evidence Report who conclude that Minimally Invasive Surgery Sacroiliac Joint (MIS SIJ) Fusion procedures provide significant benefit to carefully selected patients. Although we recognize the best available studies utilize one particular device from one manufacturer, ISASS policy does not endorse any specific MIS SIJ System. There are numerous devices available that have received FDA 510(k) clearance for use in minimally invasive joint fusion (MIS SIJ) stabilization. The clinical concept of creating a true arthrodesis (either anatomic or extra-anatomic) across the SI joint have been reported with favorable outcomes at one year¹ which are sustained long term (up to 5 years)^{2 3}. Of importance is the clinically documented opioid reduction for low back pain patients as a result of this procedure, agnostic to the specific MIS SIJ system^{4 5}. ISASS recommends that WSHCA revise the wording in the draft “conclusions and summary of evidence” sections to refer to MIS SIJ Fusion “procedurally” where it currently refers specifically to the “i-Fuse technology.”

¹ Richard A. Kube¹ and Jeffrey M. Muir. Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery *The Open Orthopaedics Journal*, 2016, 10, 679-689

² Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. *Open Orthop J*. 2014;8:375-83. Published 2014 Oct 17. doi:10.2174/1874325001408010375

³ Vanaclocha VV, Verdú-López F, Sánchez-Pardo M, Gozalbes-Esterelles L, Herrera JM, et al. (2014) Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients. *J Spine* 3:185. doi:10.4172/2165-7939.1000185

⁴ Vanaclocha V, Herrera JM, Sáiz-Sapena N, Rivera-Paz M, Verdú-López F. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. *Neurosurgery*. 2018 Jan 1;82(1):48-55. doi: 10.1093/neuros/nyx185.

⁵ Araghi A, Woodruff R, Colle K, et al. Pain and Opioid use Outcomes Following Minimally Invasive Sacroiliac Joint Fusion with Decortication and Bone Grafting: The Evolution Clinical Trial. *Open Orthop J*. 2017;11:1440-1448. Published 2017 Dec 27. doi:10.2174/1874325001711011440

In addition, we also agree with the finding that comparative studies between minimally invasive SI joint fusion and open joint fusion procedures show a preference for the minimally invasive option in terms of improved post-operative pain and shorter length of hospital stay. Equally important is that the current evidence supports that the minimally invasive SI joint fusion procedure is safe and cost effective for pain management and improved quality of life for patients with chronic SI joint dysfunction.

We found the literature search and data extraction that was the basis of this report to be comprehensive; however, we would recommend updated wording in the summary of evidence section and the addition of specific citations within that section (E1.4) as suggested below.

ES 4.1 Summary of the Evidence. Compared to conservative management, minimally invasive SI joint fusion surgery improves pain, physical function and quality of life. The quality of evidence for these findings is moderate for outcomes at 6 months^{1,2} and very low for outcomes between 6 months and 6 years³. Findings are mixed with respect to opioid use (modest reductions in use with low to very low quality of evidence). From both randomized trials, no differences in the rate of serious adverse events exist between surgery and conservative management (low to very low quality of evidence). Blinded randomized trials were not done, but blinding subjects would be challenging as all implant systems are highly radiopaque and obvious on any radiographic study. The incidence of revision surgery is likely no higher than 3.4 percent at 2 years^{4,5} (moderate quality of evidence). Minimally invasive surgery costs \$13,313 per additional quality of life-adjusted year gained compared to conservative management⁶; an amount that most would consider cost-effective. No differences exist between open fusion and conservative management with respect to pain, function, and quality of life, but this conclusion is based on one low quality evidence study⁷. Minimally invasive SI joint fusion improves pain over 2 years^{8,9} or longer^{3,10,11} and is associated with a shorter length of hospital stay compared to open fusion¹². The incidence of adverse events was similar for open fusion and Minimally Invasive SI Joint Fusion,¹² but findings were mixed for the comparative incidence of revision surgery. All findings related to this comparison are based on very low quality of evidence. We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events across the 8 uncontrolled studies evaluating open fusion limits our ability to draw definitive conclusions from this body of evidence. Similarly, the incidence of adverse events and revision surgery reported in the 24 uncontrolled studies of minimally invasive surgery is heterogenous, likely reflecting differences in outcome definitions and ascertainment, but is generally low. The incidence of complications from minimally invasive fusion reported from an analysis of insurance claims is higher than the incidence reported in controlled studies;¹⁴ issues regarding the identified patient population in this analysis¹⁵ make interpretation of this result challenging. The incidence of revision surgery after fusion observed in trials is similar to the incidence reported in post-market surveillance.^{4,5}

We also noted that the WA State Health Authority document cites a rate of adverse events after MIS SIJF of up to 30% in two locations; however, we are not aware of where the 30% figure comes from and believe the figure mischaracterizes the safety of most MIS procedures. Please see the abstracted sections with highlights. We recommend the Health Authority review these statements to ensure they are accurate and provide direct citations in order to allow for proper verification and documentation.

Among the 13 studies evaluating the iFuse Implant System, the frequency of adverse events that were definitely or probably related to the device or procedure ranged from 0 percent to 30 percent. One study retrospectively evaluated the frequency of adverse events after minimally invasive SI joint fusion using a large insurance claims database from 2007 to 2014.³³ Study authors could not report the specific procedures or systems used based on available data. The overall incidence of complications was 13.2 percent at 90 days and 16.4 percent at 6 months among 469 claimants that had received surgery.

Among the 13 studies evaluating the iFuse Implant System, the frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320 (2.8%) underwent a revision and 63% of the revisions occurred within the first year postoperatively.³⁴

Among the 13 studies evaluating the iFuse Implant system, the frequency of adverse events ranged from 0 percent to 91 percent; however, when limited to adverse events definitely or probably related to the device or procedure, the range was from 0 percent to 30 percent. Though a few uncontrolled studies reported a higher frequency than those observed in the 2 RCTs^{15,16} and 1 CCS,¹⁷ most uncontrolled studies reported a similar or lower frequency. The frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320

With the recommended edits and revisions, overall, we support the findings of this evidence report and welcome it as justification for continued research and study of minimally invasive SI joint fusions. Thank you for the opportunity to provide comments and edits and please do not hesitate to contact ISASS with any questions or with follow up at the staff contact below.

Sincerely,



Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force

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Citations

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