



**Tracking Form for Applicants for New Technology Add-on Payments under
the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal
Year (FY) 2012**

1. Technology Name: AxiaLIF[®] 2-Level System
2. Manufacturer Name: TranS1[®], Inc.
3. Trade Brand of Technology: AxiaLIF[®] 2L+[™]
4. Brief Description of Service or Device:

The TranS1 AxiaLIF[®] 2L+[™] System is an implantable spinal fixation system, delivered through a pre-sacral approach, intended to facilitate spinal fusion by axial stabilization of the anterior lumbar spine.

Newness Criterion

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the Medicare severity diagnosis related groups (MS-DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

January 21, 2010 (K092124)
6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation for any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

Yes. After FDA clearance the product was only available to a small number of surgeons as part of a Limited Market Release program to gain industry feedback on the system before full market release. Full market launch occurred in July 2010.
7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?
 - a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

81.08: Lumbar and lumbosacral fusion, posterior technique

- b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage for more information.) We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment.

N/A

8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage for more information.)

No

Cost Criterion

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by MS-DRG. The most recent version of Table 10 can be downloaded at: <http://www.cms.hhs.gov/AcuteInpatientPPS/10FR/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1227460&intNumPerPage=10>.

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

The anticipated standardized charge for AxiaLIF 2L+ is \$92,572.

9. **A.** What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)?

B. What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology, clearly showing which components are the “new” ones).

10. List the Medicare severity diagnosis-related groups (MS-DRGs) to which cases involving this new technology will most likely be assigned.

459: Spinal Fusion Except Cervical W MCC
460: Spinal Fusion Except Cervical WO MCC

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2012 (by MS-DRG)?

Approximately 200 cases

Clinical Improvement Criterion

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services.

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

- a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

The use of AxiaLIF® 2L+™ to create fusion conditions at L4-L5-S1 offers patients a minimally invasive, biomechanically robust alternative to traditional lumbar fusion. Traditional open anterior/posterior approaches require dissection, retraction, and mobilization of soft tissues and important structures, including nerve roots, major vessels, annuli, ligaments, and abdominal viscera. The annulotomy and ligamentous disruption could reduce the stability of the construct. Using AxiaLIF® 2L+™, the lumbar spine is accessed through an axial channel in the sacrum. This atraumatic tissue plane alleviates the need for the surgeon to cut through supporting muscles and ligaments, thus reducing post-operative pain and the prospect of complications. There will be smaller incisions, no bone removal and no nerve manipulation. The axial fixation rod provides a biomechanical advantage due to proximity of the implant to the bending axis of the spine and alignment with the compression moments of the vertebral bodies, thus reducing ROM significantly and achieving indirect decompression through distraction of the disc space. AxiaLIF® 2L+™ represents a substantial clinical improvement from other traditional fusion procedures in that it reduces morbidity and has reduced risk of injuring vital organs and important intrinsic stabilizing structures, with a lower complication profile than traditional open fusion techniques.

- b. List all published peer-reviewed articles relevant to the new service or technology.

There have been a number of publications that discuss the theoretical biomechanical advantage of an axial implant when used to stabilize the L5-S1 or L4-S1 spinal segments. Clinical evidence shows the transsacral rod with paracoccygeal approach has advantages over other approaches because of its preservation of muscles, ligaments and annulus. Patients recover faster and have less risk of long-term complications. Below is a summary of representative publications regarding benefits of the AxiaLIF® approach:

Reference:
Alegre, Gary M. et al. S1 Screw bending moment with posterior spinal instrumentation across the lumbosacral junction after unilateral iliac crest harvest. Spine 2001; 26: 1950-1955.
Summary:
<p>A biomechanical evaluation comparing fixation across the lumbosacral joint in a synthetic model. The key points of this paper were listed as follows:</p> <p><i>An anterior L5-S1 strut significantly decreases the flexion-extension moment on S1 screws in a long posterior construct except when the construct is extended posteriorly beyond S1 bilaterally with either S2 screws or an S2 screw and an iliac bolt.</i></p> <p><i>Iliac bolt instrumentation decreases the S1 screw flexion-extension moment significantly more than an anterior L5-S1 strut.</i></p> <p><i>Although there appears to be no biomechanical advantage in using an iliac bolt over an S2 screw, the former is technically simpler to instrument, avoids endangering vital anatomic structures, and provides superior bony purchase.</i></p>
Reference:
Akeson, Burak et al. Biomechanical evaluation of paracococcygeal transsacral fixation. J. Spinal Disord Tech 2008; 21(1): 39-44.
Summary:
<p>A biomechanical study using human cadaveric spine to evaluate biomechanics of paracoccygeal transsacral rod fixation. Transsacral fixation via posterior and paracoccygeal approaches are not new and are described in literature. Preservation of supporting structures gives paracoccygeal approaches a biomechanical advantage. Transsacral rod fixation “provides strong ligamentotaxis due to intact annulus. Standalone transsacral rod is able to reduce ROM significantly and achieve indirect compression by distracting L5-S1 disc space.” Additional posterior facet screws or pedicle screws recommended as adjunct for greater stability with use of transsacral rod.</p>
Reference:
Anand N., Rosemann R., Khalsa B., Baron E.M., Mid-term to long-term clinical and functional outcomes of minimally invasive correction and fusion for adults with scoliosis. Neurosurg Focus, 2010. 28 (3): E6.
Summary:
<p>Assessment of operative outcomes of 28 adult patients with scoliosis who were treated surgically with MIS correction and fusion over 3 or more levels. Patients underwent a single or a combination of XLIF, DLIF or AxialIF. Seventeen patients underwent the AxialIF procedure at L5-S1 or L4-S1. Complications included transient dyesthesia (17, recovered within 6 weeks), quadriceps palsy (2, recovered within 6 months), retrocapsular renal hematoma (1, no untoward sequelae) and unrelated cerebral hemorrhage (1, no long term sequelae). There was one case noted of screw fracture (L-2) and another of screw prominence due to insadequate contouring of the rod (T-12). Saggital balance correction was excellent, no pseudoarthrosis at L5-S1 was observed, and no sacral stress fractures or sacral screw loosening were noted. The author concluded “Circumferential MIS correction and fusion for adult scoliosis represents a newer method of achieving long-term outcomes similar to those obtained with open methodolgies in</p>

terms of clinical improvement, but has considerably lower morbidity and complication rates. Blood loss and hospital stays are significantly lower than those reported in earlier literature.” “....minimally invasive circumferential deformity correction remains attractive, especially in elderly patients and in patients with medical comorbidities who are being considered for deformity correction, decompression, and fusion.”
Reference:
Erkan S, Wu C, Mehbod AA, Hsu B, Pahl DW, Transfeldt EE: Biomechanical evaluation of a new AxiaLIF technique for two level lumbar fusion. European Spine Journal. 2009 Jun; 18(6): 807-14
Summary:
Biomechanical study of L4-S1 motion segments instrumented with the AxiaLIF II transsacral rod using human cadaveric lumbosacral spine segments from L4 to S1. and non-destructive pure moments in axial torsion, lateral bending, and flexion extension were applied to each specimen following intact, standalone AxiaLIF II, and AxiaLIF II with two posterior fixation options: facet screws and pedicle screws with rods. Range of motion was calculated from the raw data collected with an optical motion tracking system. The author concluded “the standalone rod reduced intact ROM significantly. Supplementary fixations including facet screws and pedicle screws are required to achieve higher construct stability for successful fusion”.
Reference:
Deluzio K., Lucio J., Rodgers W.B.: Value and cost in less invasive spinal fusion surgery: lessons from a community hospital. SAS E-Journal. Volume 4, Issue 2, June 2010, Pages 37-40.
Summary:
Retrospective evaluation of the effect on costs seen at a hospital (16-bed community hospital in a mid-sized American city) associated with the transition from a traditional, open fusion platform to a less destructive surgical approach on a specific intervention and a specific treatment scenario in a selected patient cohort. A hospital cost comparison of the perioperative period was performed between the 2 groups. All patients were treated with an instrumented 2-level lumbar fusion, with one group receiving an open 2-level PLIF and the second group receiving a less disruptive MIS 2-level fusion. The author reported the average length of stay in the MIS group was 49% less than the open group, and the average cost for the surgical procedure and initial hospital stay in the MIS group was 6% less than the open group. During the post-operative period, there was a 76% decrease in the rate of residual events from the open to the less invasive group. For the entire perioperative period there was an average savings of 9.6%. “A nearly 10% reduction in costs, within the first 45 days after an intervention, augurs well for a massive cost savings if implemented on a societal scale.
Reference:
Ledet, Eric H. et al. Biomechanical evaluation of a novel lumbosacral axial fixation device. Journal of Biomechanical Engineering 2005; 127: 929-933.
Summary:
Biomechanical in vitro evaluation of the axial fixation rod in calf spine model. The range of motion, bending stiffness, and axial compressive stiffness were tested for intact and

drilled specimens. Results were compared with literature results for 14 different products. "When compared to existing anterior, posterior, and interbody instrumentation, lateral and sagittal bending stiffness of the axial fixation rod exceeded that of all other interbody devices, while stiffness in extension and axial compression were comparable to plate and rod constructs. Torsional stiffness was comparable to other interbody constructs and slightly lower than plate and rod constructs." "For stabilization of L5-S1, motion segment, axial placement of implants offers potential benefits relative to traditional exposure. The preliminary biomechanical data from this study indicate that the axial fixation rod compares favorably to other devices and may be suitable to reduce pathologic motion at L5-S1, thus promoting bony fusion."

Reference:

Shen, Francis H. et al. Minimally invasive techniques for lumbar interbody fusions. Orthopedic Clinics of North America 2007; 28: 373-386.

Summary:

Overview of various lumbar fusion techniques (including AxiaLIF). AxiaLIF is described as "Axial lumbar interbody fusion". The challenges and advantages of each technique according to the author's view are presented. Regarding AxiaLIF, the author notes that "Conceptually, inter-body fusion with instrumentation placed along the long axis of the spine have appeal from a biomechanical standpoint because of the ability to place instrumentation close to the bending axis of the spine and in line with the compression moments of the vertebral bodies." "This has been recognized for years, and- although not a new concept- para-axial open approaches to the lumbosacral spine have been described through the use of fibular strut graft from L5 to S1." The author concludes that "In the properly selected patient, newer minimal invasive surgical approaches- combined with advanced surgical techniques and implants- may reduce surgical morbidity, decrease the postoperative recovery time, and increase the early postoperative rehabilitation potential."