CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician

DESCRIPTION: The TranS1 AxiaLIF® and/or AxiaLIF Plus System is a multi-component system including instrumentation made of biocompatible materials such as titanium alloy, stainless steel, and Nitinol and implants made of titanium alloy.

CONTENTS: Implants: AxiaLIF1L, 2L, 1L+ and 2L+ Implants (various sizes: L5-S1, L4-L5, L5, and S1) and Fixation Rod (various sizes), and a Distraction Rod (one size)

AxiaLIF and/or AxiaLIF Plus Reusable Instruments: Guide Pin Introducer, Stylet Handle, Guide Pin Handle, 12mm Dilator Sheath, Bone Graft Inserter, Material Inserter, 6mm Dilator, 8mm Dilator, 10mm Dilator, 12mm Dilator, Slap Hammer, 2-Level 7.5mm Twist Drill, 2-Level 9.0mm Twist Drill, 10.5mm Cannulated Twist Drill, 9.0mm Cannulated Twist Drill, 7.5mm Measuring Drill, 7.5mm Measuring Dilator, Exchange Bushing (various angles), Tubular Retractors (various angles), L4/ L5 Dilator Trials (various sizes), L5 Dilator Trials (various sizes), Dual Driver with Retention Tube and Offset Ratcheting T-Handle, L4/L5 Driver, Distraction Driver with Counter Torque Tube, Fixation Rod Driver with Retention Tube, Rod Driver (AxiaLIF 1L), Rod Driver (AxiaLIF 2L), Plug Driver (AxiaLIF 1L/2L) and Instrument Rack.

AxiaLIF Single Use Instruments: Guide Pin Introducer, Stylet Handle, Guide Pin Handle, Beveled Guide Pin, Guide Pin Ex- tension, 10mm Dilator Sheath, 12mm Dilator Sheath, Radial Cutters (various sizes), Tissue Extractors, Bone Graft Inserter, Material Inserters, 2L+ Guide Wire, Fixation Wires, Sterile 2 Pack Tissue Extractors Kit, Sterile 4 Pack Tissue Extractors Kit, Flat Disc Cutters Kit, Rasp Cutters Kit, and Conformable Tip Tubular Retractor (CTTR) Kit.

INTENDED USE and INDICATIONS for the United States:
AxiaLIF and/or AxiaLIF Plus System is intended to provide anterior stabilization of the L5-S1 or L4-S1 spinal segment(s) as an adjunct to spinal fusion. The AxiaLIF Plus System is indicated for patients requiring fusion to treat pseudoarthrosis (unsuccessful previous fusion), spinal stenosis, spondylolisthesis (Grade 1 or 2 if single-level; Grade 1 if two-level), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 in conjunction with use of legally marketed posterior fixation such as facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF.

CONTRAINDICATIONS: Coagulopathy; bowel disease including any condition that may make the likelihood of adhesions of the bowel to the sacrum more likely (e.g. Crohn's, ulcerative colitis); pregnancy; scoliosis that extends to the treated level(s); sacral agenesis; severe spondylolisthesis (L5-S1: >grade 2 or L4-L5: >grade 1); tumor; prior radiation treatment to the sacral or presacral anatomy; trauma. Do not use with facet screws when correction of spinal stenosis requires removal of significant portions of the lamina or any portion of the facets.

WARNINGS:

The safety and effectiveness of this device has not been established in patients with osteoporosis. The AxiaLIF Implant is used for anterior stabilization but may not remain stable in patients with osteoporosis (defined as a bone density z-score of < - 1.5).

The most frequently stated risks are: bowel injury and associated presacral or disc infection, or intraoperative hypotension. Other risks based upon rarely reported incidents include: general infection, vascular injury, superficial wound infection, presacral hematoma, device subsidence requiring treatment, implant migration, graft protrusion, sacral fracture, and ureter injury. Finally there may be risks from surgery including: bleeding (including occult during and after surgery), neurological damage, damage to soft tissue, spinal cord impingement or damage, loss of bowel or bladder function, loss of erectile or ejaculatory function, meningitis, pain, or anesthesia complications. The safety and effectiveness of this device has not been evaluated in patients with spondylolysis. Pedicle screw systems, not facet screws, should be considered when there is degenerative disease of the facets with instability. The risks associated with the implant include: breakage of the implants, loosening or expulsion of the implants possibly causing

delayed nerve root impingement or damage, fracture of osseous structures, and bursitis. There may be pain, discomfort or abnormal sensations due to the presence of the device. There may be risks associated with harvesting autologous grafts such as pain at the donor site, infection, herniation, and fracture. There may be nonunion or delayed union of fusion with the autologous graft.

PRECAUTIONS:

• Single use risk is limited to the utilization of all instrumentation labeled and marked single use, but used multiple times. Single use sterile instrumentation is clearly labeled as such and should be used in the manner consistent to its labeling. Re-cleaning and re-use of single use instrumentation is not recommended. Some single use devices contain areas that will be difficult to clean after use, which may inhibit re-sterilization. In addition, the function and integrity of single use devices may degrade after more than one use and cannot be guaranteed to perform as intended.

Preoperative: Portions of this system are supplied non-sterile and need to be cleaned and sterilized according to the CLEANING AND STERILIZATION section of this insert. Care should be taken during the pre-operative preparation to evaluate the ability to achieve a desirable implant trajectory that allows the device to be fully contained within the vertebral bodies without protrusion anterior or posterior. The provided templates should be used. Severe angulation of the vertebral bodies may make achievement of an effective trajectory difficult. Preoperative planning should include identification of any pre-existing adhesions of the bowel to the sacrum or aberrant anatomy such as vessels crossing the Sacrum (MRI view to tip of coccyx is recommended per established surgical technique). A bowel perforation could occur during creation of the presacral channel if there is an adhesion of the bowel to the sacrum. Unusual bleeding could occur if a vessel crossing the sacrum is injured. Radiolucencies have been observed around the implant in patients where posterior pedicle screw fixation was secured and spanned only from L4 to S1. Segmental posterior screw fixation at L4, L5 and S1 is recommended.

Physicians using the AxiaLIF and/or AxiaLIF Plus System should have significant experience in spinal surgery, including spinal fusion procedues. Physicians should not independently use the AxiaLIF System prior to participation in specific training on its use.

- Intraoperative: All steps of the procedure should be followed as per the "Surgical Technique". All steps in this technique require the use of active or real time fluoroscopy. Refer to "Surgical Technique" for proper implant sizing. Risk of fluctuation in blood pressure exists in any surgery where instruments are introduced through tubes. Rapid introduction of instruments should be avoided in order to minimize introduction of excessive pressure or air into the disc space. As with any surgical procedure, careful patient monitoring is required to minimize risk. As with any surgical procedure, there is some risk that instrumentation will fail to perform as expected or may result in an unretrievable device fragments.
- Postoperative: Risk of occult bleeding exists during and after the procedure. As with all surgical procedures, careful patient monitoring is required to minimize this risk. Following the procedure the patient should be monitored until released for any effects of the procedure. Specifically, patients should be monitored for any sign of potential bowel perforation that include but may not be limited to: severe abdominal pain, blood in stool, fever, and/or elevated white cell counts. In the event that a bowel injury is present, a colorectal surgeon should be consulted. Treatment may range from antibiotics alone (if the injury is small and detected early) to laparascopic repair of the injury or in instances where a bowel injury is more significant or detected later, the patient may require general antibiotics, gram negative specific antibiotics and possibly a temporary diverting colostomy. The patient should adhere to post-operative instructions as provided by physician.
- Revision of the AxiaLIF and/or AxiaLIF Plus system should not include the use of anterior plates.
- AxiaLIF and/or AxiaLIF Plus has not been evaluated for safety and compatibility in the MR environment. AxiaLIF and/or AxiaLIF Plus has not been tested for heating or migration in the MR environment.

ADDITIONAL MATERIALS: Inflation syringe, 20 F Foley Catheter, graft material (such as autograft, autologous blood mixed and/or Demineralized Bone Material (DBM)), Wire Driver (optional), bone void filler (optional-to be used only as indicated to fill void in bone and is not indicated as part of the primary fusion construct-see product labeling for details)

CLEANING AND STERILIZATION:

• Implants Sterilized by Gamma irradiation. Verify package integrity prior to use.

• AxiaLIF Single Use Instrumentation: Sterilized by Ethylene Oxide. Verify package integrity prior to use.

• AxiaLIF Reusable: Non-Sterile: To be Sterilized Before Use

Prior to beginning the procedure, ensure all instruments are clean and sterile. (Especially the lateral cross holes in the L4/L5 and L5 Dilator Trials)

CLEANING INSTRUCTIONS for use or reuse of AxiaLIF and/or AxiaLIF Plus Reusables:

(Note: Only the AxiaLIF and/or AxiaLIF Plus Reusables may be sterilized for reuse. Do not reuse the Implants or AxiaLIF Single Use instruments)

CLEANING INSTRUCTIONS (Combination Manual and Automatic)	
Point of Use	
1	Remove visible debris using a disposable cloth from surfaces, crevices, mating surfaces, cannulas, joints and all other hard-to-clean features.
Preparation for Decontamination	
2	Instruments designed be assembled at use should be disassembled prior to cleaning
Manual Cleaning	
3	Rinse using cool tap water
4	Soak for a minimum of 1 minute in Enzymatic Cleaning Solution
5	Use a surgical scrub brush to remove visible debris, paying attention to hard to reach areas (i.e. crevices, lumens, mated surfaces, connectors) and actuating any moving components. If necessary, lumens should be cleaned with a long, narrow brush.
6	Rinse thoroughly with water for a minimum of 30 seconds
7	Place devices in automatic washer such that design features are accessible to cleaning and allow for proper drainage
Automated Cleaning	
8	Run the automatic wash cycle - Minimum cycle parameters: • 2 minute prewash with cold tap water • 2 minute Enzyme Wash with hot tap water, including two 15-second cold tap water rinses • 2 minute detergent wash MINIMUM (60C MINIMUM) • 1 minute hot tap water rinse • 12 minute hot air dry (80C MINIMUM)
Maintenance and Inspection	
9	Visually inspect the instruments to ensure there is no visible contamination; if contamination is present, repeat the cleaning process
10	Visually inspect for damage and wear; if instrument is damaged, contact your TranS1 representative for a replacement
Packaging	
11	Instruments should be placed in the appropriate sterilization case in the designated location for each instrument. Single-use or damaged/non-functional instruments should be returned to your TranS1 representative for replacement
12	Wrap the autoclave case using FDA-cleared wrap

STERILIZATION INSTRUCTIONS (for Reusable items only)

- Place the devices directly in the autoclave tray.
- Wrap in FDA-cleared sterilizer wrap.
- Deviations from the recommended cleaning and sterilization are not advised. If deviations are made, it is the responsibility of the user to qualify the deviation.

STERILIZATION INSTRUCTIONS (STEAM)	
Type/Cycle	Pre-Vac / Full Cycle
Exposure Time	Four (4) minutes
Temperature	132°C
Dry Time	Twenty (20) minutes

INSPECTION PRIOR TO USE: All system components should be carefully examined for defects and/or damage.
Extraction of AxiaLIF implants:
In the event that the AxiaLIF implant needs to be removed, contact TranS1 for instructions.

PRODUCT COMPLAINTS: Any user of this product, who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or TranS1. If any of the devices ever "malfunctions", or is suspected of doing so and/or may have caused or contributed to death or serious injury of a patient, the distributor or TranS1 should be notified immediately by telephone, or written/email correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

Package Symbol Definitions:

RxOnly	FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN		SINGLE USE DEVICE, DO NOT REUSE
	CONSULT ACCOMPANYING PACKAGE INSERT FOR LABELING INDICATIONS	NON STERILE	DEVICES ARE SUPPLIED NON-STERILE
	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE
LOT	LOT NUMBER		EXPIRATION DATE
STERILE R	STERILIZED BY GAMMA IRRADIATION	STERILE EO	STERILIZED BY ETHYLENE OXIDE
REF	REFERENCE/CATALOG NUMBER		

IN UNITED STATES:
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