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

DESCRIPTION: This product is designed to stabilize the facet joint and to create a 360º fusion construct when used in conjunction with the AxiaLIF® System or any legally marketed anterior fusion product. The facet screws have washers and are cannulated with cancellous threads and may be provided with or without a lag. The screws and washers are made of medical grade titanium alloy (ASTM F-136 and ISO 5832-3).

CONTENTS: Implants: 2 Facet Screws with washers, Single Use Sterile Instruments: Guide Pin Handle, 2 Guide Pins, Dilator Sheath, Facet Drill, Bone Graft Inserter Tube, Bone Graft Inserter Rod, 2 K-Wires. Reusable Instruments: Dilator, Ratcheting Palm Handle Tap, Screw Driver, Screw Retention Pin, Retention Rod Removal Tool, Tamp, Rasp. Optional Instruments: Reusable – Mini T Ratcheting Handle, Single Use - Smooth Sheath, Bone Graft Inserter Rod, Bone Graft Inserter Tube, Anesthetic Delivery Tool.

INDICATIONS: The TranS1 Facet Screws are to supplement legally marketed anterior fusion products in order to create an anterior / posterior fixation construct as an aid to fusion.

The facet screws may be implanted using a transfacetpedicular technique. The screws are inserted bilaterally through the superior side of the facet, across the facet joint (usually) at a single level and into the pedicle. Bone graft must be used.

The system is indicated for the posterior surgical treatment at L3-S1 (inclusive) spinal levels for the following: Spondylolisthesis; Spondylolysis; Pseudarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

CONTRAINDICATIONS: The contraindications include but are not limited to: Facet Screws should not be used when the correction of spinal stenosis requires the removal of significant portions of the lamina of any portion of the facets. Active infection process of significant risk of infection (immunocompromised). Signs of local inflammation. Fever or leukocytes. Morbid obesity. Pregnancy. Mental Illness. Grossly distorted anatomy caused by congenital abnormalities. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such at the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation in the WBC differential count. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condidtion may limit the degree of obtainable correction and/or the amount of mechanical fixation. Suspected or documented metal allergy or intolerance. Any case where metals must be mixed from different components. Any case where the implant components selected for use would be too large or too small to achieve a successful result. Any case where a bone graft and fusion is unnecessary or where fracture healing is not required. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition. Any patient in which implant utilization would interfere with anatomical structures or physiological performance. Any patient unwilling to follow post-operative instructions. Any case not described in the indications.

WARNINGS and 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. The re-use of single use devices has not been evaluated and therefore the manufacturer does not recommend reuse of items labeled for single use. 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 multiple uses and cannot be guaranteed to perform as intended.

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. Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of

implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing. A higher risk of device loosening, bending, or breaking exists with fractures involving severe comminution, displacement, or other difficult medical situations. These devices can break when subjected to the increased loading associated with delayed union, or nonunion. Internal fixation appliances are load sharing devices, which stabilize and hold a
spinal segment in alignment until healing occurs. If healing is delayed, or does not occur, the implant will eventually loosen, bend, or break. Loads on the device produced by load bearing, and the patient's activity level will dictate the longevity of the implant. Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn can enhance fatigue fractures of implants. Thus, every effort should be made to use compatible metals and alloys in conjunction with each other. Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone even after healing has occurred. If a device remains implanted after complete healing, it may increase the risk of refracture in an active individual. Therefore, these devices are temporary and may be removed after completing their intended function-aiding in the bone graft healing process. The surgeon should weigh the risk versus benefit when deciding whether to remove an implant. Implant removal should be followed by adequate postoperative management. If the patient is older and has a low activity level, the surgeon may elect not to remove the implant, thus eliminating the risks associated with a second surgery.

Physicians using the Facet Screws should have significant experience in spinal surgery, including spinal fusion

POSSIBLE ADVERSE EVENTS: All of the adverse events associated with general surgery or spinal fusion surgery are possible. With instrumentation, a listing of possible adverse events includes but is not limited to: Early or late loosening of any or all of the components. Disassembly, bending, and/or breakage of any or all of the components. Foreign body (allergic) reaction to implants, debris, corrosion products including metallosis, staining, tumor formation, and/or auto-immune disease. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments. Post-operative change in spinal curvature, loss of correction, height, and/or reduction. Infection. Dural tears. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy and/or the development or continuation of pain, numbness, neuroma, or tingling sensation. Cauda equine syndrome, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis. Urinary retention or loss of bladder control or other types of urological system compromise. Scar formation possibly causing neurological compromise around nerves and/or pain. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, spinous process, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Non-union (or pseudarthrosis). Delayed union. Mal-union. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform activities of daily living. Bone loss or decrease in bone density, possibly caused by stress shielding. Graft donor site complications including pain, fracture, or wound healing problems. Herniated nucleus pulposus, disc disruption or degeneration. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise. Reproductive system compromise such as sterility, loss of consortium, and sexual dysfunction. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc. Change in mental status. Death. Additional surgery may be necessary to correct some of these adverse events.

CAUTION: Preoperative: Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided. Care should be used in handling and storing of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally

assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The Facet Screws are not to be combined with the components from another manufacturer. Different metal types should never be used together. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of unexpected need.

Intraoperative: Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

Caution: Do not overtap or use a screw that is too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. Bone graft may be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.

Postoperative: The physician's postoperative directions and warnings to the patient, and the corresponding patient compli- ance, are extremely important. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage during rehabilitation may be increased if the patient is active, debilitated, or demented. The patient should be warned to avoid falls or sudden jolts. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nico- tine products, or to consume alcohol or non-steroidals or anti-inflammatory medications during the bone graft healing process. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for the permanent restriction in motion. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device should be revised and/or removed before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high risk patients. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the Facet Screws should never be reused under any circumstances.

ADDITIONAL MATERIALS: Wire Driver

INSPECTION PRIOR TO USE: Carefully examine for defects. Verify package integrity prior to use. Do no use instruments and/or implants if there are visible defects.

PACKAGING: Packages for each of the components should be intact upon receipt. All sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or product should not be used and should be returned to TranS1.

Prior to beginning the procedure, ensure all instruments are clean and sterile.

CLEANING AND DECONTAMINATION: Certain instruments may require dismantling before cleaning. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

CLEANING INSTRUCTIONS

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: Unless marked sterile and clearly labeled as such, the Facet Screws described in this insert are provided non-sterile and must be sterilized prior to use. If the components described in this insert are sterilized by the hospital in a tray or case, they should be sterilized in the tray or case provided by TranS1. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below: Note: The following note applies to the process parameter identified with the ** below: For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

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

All Steps Must Be Completed Using Fluoroscopic Guidance: See Surgical Technique For Detailed Instructions

REFERENCES: The physician should consult literature on current minimally invasive spine surgery.

EXTRACTION OF IMPLANTS: In the event that the Facet Screw 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, 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		

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