DI123A-EN (Rev K)	TRANSITION® STABILIZATION SYSTEM
04/2025	**IMPORTANT INFORMATION ON THE TRANSITION® STABILIZATION SYSTEM**

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For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

WITHIN THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE TRANSITION® STABILIZATION SYSTEM

DESCRIPTION

The TRANSITION® Stabilization System implants include pedicle screws and implant assemblies which are provided pre-assembled or can be assembled intraoperatively.

TRANSITION® pedicle screws are coated with hydroxyapatite (HA). Either TRANSITION® HA-coated pedicle screws or specified REVERE® pedicle screws may be used in conjunction with the implant assemblies. Specifically, REVERE® polyaxial (solid, cannulated and dual outer diameter) screws and monoaxial screws 6.5mm diameter and larger, and 35mm length and larger, may be used with the TRANSITION® implant assemblies.

Implant assemblies consist of a polyethylene terepthalate (PET) cord, polycarbonate urethane (PCU) spacers and bumpers, and titanium alloy spools, end spools and set screw ends. The cord passes through the entire implant such that the spools are positioned to sit within the screw heads and the spacer sits between the spools. The end spool includes one end of the secured cord. The bumper followed by a set screw end is positioned at the other end of the cord.

Implant assemblies are available in single or multi-level configurations. TRANSITION® locking caps or REVERE® locking caps with inner set screws are used to rigidly connect the pedicle screws to the implant assemblies.TRANSITION® implants are available in a variety of sizes to accommodate varied patient anatomy.

TRANSITION® implants are manufactured from titanium alloy Ti6Al4V (ASTM F136) or Ti6Al7Nb (ASTM F1295), polyethylene terepthalate (PET), and/or polycarbonate urethane (PCU). Titanium alloy TRANSITION® screws are hydroxyapatite (HA) coated (ASTM F1185).

INDICATIONS

The TRANSITION® Stabilization System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar and sacral spine in skeletally mature patients: Grade I degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudoarthrosis).

In addition, the TRANSITION® Stabilization System is indicated for use in patients: who are receiving fusions with autogenous graft only; who are having the device fixed or attached to the lumbar or sacral spine; and who are having the device removed after the development of a solid fusion mass.

TRANSITION® is only indicated for use when fusion with autogenous bone graft is being performed at all instrumented levels.

CONTRAINDICATIONS

Contraindications of the TRANSITION® Stabilization System are similar to other commercially available posterior spinal fixation systems. Contraindications include but are not limited to the following:

- Active systemic or local infection.
- Obesity
- Pregnancy
- Mental Illness
- Severe osteoporosis or osteopenia
- Sensitivities/allergy to metals, polymers, polyurethane, polycarbonate urethane and polyethylene terapththalate
- Patient unwilling or unable to follow postoperative instructions
- Soft tissue deficit not allowing sound closure
- Any medical or physical condition that would preclude the potential benefit of spinal implant surgery
- Congenital abnormalities, tumors or other conditions that would prevent secure component fixation that has the potential to decrease the useful life of the device
- Any medical or mental condition which could exclude the patient at high risk from surgery of this severity
- Inadequate pedicles of the thoracic, lumbar, and sacral spine, such that anchorage of the implant is not possible

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

Patients who smoke have been shown to have an increased incidence of non-union or pseudarthrosis. These patients should be informed of this increased risk and counseled to discontinue tobacco use prior to and immediately after surgery.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Loosening, disassembly, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Loss of fixation
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction
- Urinary retention or loss of bladder control or other types of disorders of the urogenital system
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
- Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
- Pain or discomfort
- Bursitis
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Difficulty removing the hydroxyapatite coated screws resulting in high removal torques and potential complications in revision procedures
- Bone graft donor site pain, fracture, and/or delayed wound healing
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Death

WARNINGS

The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with autogenous bone graft is being performed at all instrumented levels.

The safety and effectiveness of the TRANSITION® System has not been established for spinal indications beyond those stated in the Indications section.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

• device component fracture,

• loss of fixation,

• non-union,

• allergic reaction or metal sensitivity,

• fracture of the vertebrae,

• neurological injury, and

• vascular or visceral injury.

Implanting metals and alloys in the human body subjects them to an aggressive chemical environment of salts, acids and proteins which can cause corrosion. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components from different manufacturers is not recommended, for metallurgical, mechanical and functional reasons. Specifically, do not use the TRANSITION® System with components from other manufacturers or with components or in ways not described in the TRANSITION® System surgical technique manual.

PRECAUTIONS

The implantation of screw and rod systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative planning and patient anatomy should be considered when selecting rod assemblies, and screw diameter and length. Please refer to the surgical technique manual for a detailed explanation of implant selection.

Implants must be handled and stored to avoid damage. Implants should be protected from damage including scratches, nicks and corrosive environments. All components should be inspected for damage prior to use. Aseptic handling is to be observed during the implantation. Implants removed from a patient should never be re-sterilized or reused.

The patient must be adequately instructed as to the risks and limitations of this system, and should be supplied with postoperative care and management instructions. Postoperative care and patient activity must be planned in such a way to avoid excess loading of the spinal column. Excessive loads or delayed or non-union may result in implant failure. The patient should be advised that non-compliance with post-operative instructions could lead to poor results, including implant failure.

Implant removal is recommended after fusion has occurred. The surgeon and patient need to weigh the risks and benefits when deciding whether to remove the implants.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.