DI196B-EN (Rev G)	REFLECT™ SCOLIOSIS CORRECTION SYSTEM

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IMPORTANT INFORMATION ON THE REFLECT™ SCOLIOSIS CORRECTION SYSTEM

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

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE REFLECT™ SCOLIOSIS CORRECTION SYSTEM

DESCRIPTION

The REFLECT™ Scoliosis Correction System allows for continued growth and mobility of the entire spine as well as straightening of the spine by holding the segments in a natural anatomic position using non-rigid materials. The system consists of the REFLECT™ cord used in conjunction with CREO™ 4.75 monoaxial screws and locking caps. The size and number of screws are dependent on the length and location of the REFLECT™ cord. Staples may be used to provide additional fixation of screws to vertebral bodies and are intended for anterior use only.

The REFLECT™ cord is available in varied lengths to accommodate patient anatomy and is placed into the screw and secured with a locking cap. Manual surgical instruments allow for tensioning of the implant assembly to provide corrective forces. The REFLECT™ cord is manufactured from polyethylene terephthalate (PET). CREO™ screws are composed of titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138. CREO™ screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Staples are composed of titanium alloy, as specified in ASTM F136 and F1295.

INDICATIONS

The REFLECT™ Scoliosis Correction System is intended to provide spinal alignment and stabilization of the thoracolumbar spine in the treatment of spinal deformity. REFLECT™ implants are indicated for use in the treatment of deformities or curvatures of the spine in skeletally immature patients with adolescent idiopathic scoliosis using growth modulation and in skeletally mature patients with thoracolumbar deformity using correctional stabilization. Screw fixation is achieved using CREO™ monoaxial screws for anterolateral screw fixation (T1-L5). Staples may be used in conjunction with anterolateral screws for additional fixation.

WARNINGS

The safety and effectiveness of the REFLECT™ Scoliosis Correction System has been established only for spinal conditions with significant mechanical instability or deformity including idiopathic scoliosis using growth modulation. The safety and effectiveness of this device for any other conditions are unknown.

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,
- fracture of the vertebrae,
- changes to spinal curvature,
- neurological injury,
- vascular or visceral injury.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from Hydroxyapatite coated titanium alloy, pure titanium, stainless steel and cobalt chromium-molybdenum alloy and PET. Mixing of stainless steel implant components with different metals is not recommended for metallurgical, mechanical and functional reasons.

Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions reducing the service life of the implants.

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury.

PRECAUTIONS

The implantation of the system should be performed only by experienced spinal surgeons 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 screw diameter and length.

Implants must be handled and stored to avoid damage. All components should be inspected for damage prior to use. Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage. When using the device, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

The patient must be adequately instructed as to the risks and limitations of this system, and should be supplied with post-operative care and management instructions. Postoperative care and patient activity must be planned in such a way as to avoid excess loading of the spinal column. Excessive loads 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.

The implanting surgeon should consider carefully the size and type of implants most suitable for the pediatric patient's age, size, weight and skeletal maturity.

Since pediatric patients may have additional growth potential following implant surgery, the likelihood of a subsequent removal and/ or revision surgery is greater than in adult patients.

CONTRAINDICATIONS

Contraindications of the REFLECT™ Scoliosis Correction 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
- Severe osteopenia
- Sensitivities/allergy to metals, polymers such as polyethylene terephthalate
- Patient unwilling or unable to follow postoperative instructions
- 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 have 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
- 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.
- Vertebral fractures
- 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.
- Systemic infection, active respiratory disease or conditions with increased anesthetic risk.

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
- 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, or overcorrection
- 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
- Pain or discomfort
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Muscle impairment
- Cardiac or Respiratory disorder
- Death

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.

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.

REFLECT™ PET cords and 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 or container/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 a 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 are designed 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 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
Steam	Pre-vacuum	134°C (273°F)	3 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.