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REFLECT™ SCOLIOSIS CORRECTION SYSTEM

05/2023

IMPORTANT INFORMATION ON THE REFLECT™ SCOLIOSIS CORRECTION SYSTEM

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Humanitarian Device. Authorized by Federal law for use in skeletally immature patients who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, who have a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or are intolerant to brace wear. The effectiveness of this device for this use has not been demonstrated.

WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON REFLECT™ SCOLIOSIS CORRECTION SYSTEM

DESCRIPTION
The REFLECT™ Scoliosis Correction System is a non-fusion spinal implant system that 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 REFLECT™ monoaxial screws and locking caps. One or two cords may be used per curve. Single or dual staples provide additional fixation of screws to vertebral bodies and are intended for anterior use only. The screws are placed anteriorly (lateral) in the vertebral bodies to be corrected. The cord is available in varied lengths and two diameters to accommodate patient anatomy. The cord is placed into the screws and secured with locking caps. Manual surgical instruments allow for tensioning of the implant assembly to provide corrective forces.

The REFLECT™ cord is manufactured from polyethylene terephthalate (PET). REFLECT™ screws, locking cap, staples, and the disposable collet on the REFLECT™ cord, are composed of titanium alloy per ASTM F136. REFLECT™ screws are available with hydroxyapatite (HA) coating per ASTM F1185.

INDICATIONS
The REFLECT™ Scoliosis Correction System is indicated for skeletally immature patients who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, who have a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or are intolerant to brace wear.

CONTRAINDICATIONS
The REFLECT™ Scoliosis Correction System should not be implanted in patients with the following conditions:
1. Presence of any systemic infection, local infection, or skin compromise at the surgical site;
2. Prior spinal surgery at the level(s) to be treated;
3. Known poor bone quality defined as a T-score -1.5 or less;
4. Skeletal maturity;
5. Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patient unwillingness or inability to cooperate with post-operative care instructions.

WARNINGS
The appearance of new or increasing angulation between adjacent screws on radiographic imaging may indicate cord breakage. Cord breakage may be associated with loss of correction, overcorrection, or may have no clinical significance.

When tensioning the construct, special consideration should be given to patients with considerable growth remaining (e.g. open triradiate cartilage), lower magnitude Cobb angles, and/or high flexibility as excessive tension may increase the risk of overcorrection.

The implant components of this system are manufactured from titanium alloy, hydroxyapatite (screw coating), and PET. Mixing of titanium alloy and stainless steel implants may result in galvanic corrosion, and is not recommended for metallurgical, mechanical and functional reasons.

The system should not be used with implants or instruments from any other manufacturer. Specialized instruments available for use with this system are designed to aid in proper surgical technique. Improper surgical technique, including selection, placement, tensioning, or securing of implants, may result in unusual stresses or conditions that reduce implant life and/or result in poor performance.

Surgical instruments are subject to wear with normal usage. Instruments experiencing extensive use are more susceptible to damage or wear, and may no longer perform as intended. Instruments should not be modified and should only be used as described in the surgical technique. Check instruments prior to surgery to ensure they are functioning properly and are not bent or damaged.

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. The treating surgeon should have extensive knowledge of vertebral anatomy, scoliosis curve correction, spinal biomechanics, and growth modulation principles, as well as the surgical technique and surgical instruments for proper device implantation.

Extreme caution must be taken to avoid damage to vessels, spinal cord, or lungs during placement of instruments and implants. Special care should be taken at vertebral levels T5 and higher.

The implanting surgeon should carefully consider the levels of implantation, implant selection, implant placement, cord tension, and curve correction most suitable for the patient's age, size, weight, height, potential growth, and skeletal maturity.

The patient must be adequately instructed as to the risks and benefits of surgery in general, anesthesia, spine surgery, REFLECT™ surgery, and alternative treatments; and should be supplied with post-operative care and management instructions. Non-compliance with post-operative instructions could lead to poor results, including implant failure. Since pediatric patients may have additional growth potential following surgery, the likelihood of a subsequent removal and/or revision surgery is greater than it would be in adult patients.

The REFLECT™ cord includes a pre-assembled collet that mates with the cord tensioner. During surgery, after tensioning of the cord, the collet is removed and discarded, and is not implanted into the patient. Do not leave the collet on an implanted cord.

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 re-implanted; even if the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Prior to surgery, ensure that all implants and instruments are available. Inspect all instruments for damage and ensure they are functioning. Damaged instruments should not be used in surgery.

PREOPERATIVE PROCEDURE
The surgeon is responsible for being familiar with the REFLECT™ system and its indications, contraindications, device/procedure risks, and surgical technique to ensure proper treatment, patient selection, and postoperative care. The selected patient must be appropriate for surgery with REFLECT™ based on critical factors including preoperative curvature (Cobb angle), curve flexibility, curve type and location, skeletal maturity, and anticipated growth. Patient anatomy should be evaluated to plan implant placement and the appropriate surgical technique.

Inspect all implants and instruments prior to use. Ensure that instruments are functioning and replace any components as necessary. The use of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments. Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization of surgical instruments is required. Even with correct use, care and maintenance, instruments should not be expected to last indefinitely. This is particularly true for sharp instruments such as drills, driving instruments such as drivers, and instruments subjected to high loads or impaction forces. Instruments may break or malfunction, particularly when they are corroded, damaged, nicked or scratched.

OPERATIVE PROCEDURE
Refer to the REFLECT™ Scoliosis Correction System surgical technique manual for step-by-step instructions on implanting or removing the device. Patients are typically placed in the lateral decubitus position with the convex side of the curve facing upwards. The most common curves are convex on the right side, with the patient in a left lateral decubitus position. Standard anesthesia protocols should be used. A single lung ventilation technique may be used if necessary for surgical exposure. Staples are recommended at all treated levels. Standard techniques may be used for wound closure and dressing.

POSTOPERATIVE CARE
It is recommended that patients follow all postoperative instructions provided by care providers including those regarding medication, wound care, home care, and activity restrictions. Failure to follow these instructions could lead to impaired wound healing, injury to anatomic structures, or failure to correct the scoliotic curve. Bracing may be used for up to six months after surgery depending on patient factors such as bone quality and activity levels. Bracing may provide additional support for patients who are overcorrecting, or who have suspected or confirmed cord breakage. The use of REFLECT™ does not preclude the need to brace compensatory curves.

POTENTIAL COMPLICATIONS
Below is a list of potential adverse effects (i.e., complications) associated with the use of the device.

Potential Device- or Procedure-Related Adverse Events (AEs)
- Overcorrection of the coronal deformity, potentially requiring revision or removal of implants
- Inadequate curve correction
- Loss of curve correction
- Development of new curves above and/or below the instrumented levels
- Trunk imbalance
- Worsening of existing deformities in non-tethered spine segments
- Unintended spontaneous fusion at the instrumented levels
- Pulmonary complications including atelactasis, pneumonia or adverse events related to temporary single lung ventilation
- Anesthesia complications
- Wound infection, superficial or deep
- Wound dehiscence
- Damage to surrounding organs and structures including blood vessels, spinal cord, nerves, lungs, or vertebral bodies
- Vascular complications including bleeding, hemorrhage, or vascular damage leading to anemia or requiring blood transfusion
- Neurologic complications including damage to neurological structures, cerebrospinal fluid leakage, or meningocele
- Problems during device placement including anatomic/technical difficulty and device-sizing issues
- Loosening or migration of the implants
- Bending, fracturing, fraying, kinking, loosening, or breaking of any or all implant components
- Fretting and crevice corrosion at interfaces between components
- Pain, discomfort, or abnormal sensations due to device presence

Systemic AEs
- Deep vein thrombosis
- Pulmonary embolism
- Atelectasis, pneumonia
- Cardiovascular
- Dysphagia
- Dysphonia
- Gastrointestinal (ileus, ulceration, bleeding, malnutrition)
- Foreign body reaction
- Pressure sores
- Genitourinary (infection, urinary retention)
- Infection (systemic)
- Hematologic
- Endocrine/metabolic
- Hepatobiliary
- Immunologic
- Gynecologic
- Ophthalmologic
- Psychological
- Surgical procedure (non-spinal)
- Wound infection (non-spinal)
- Death

MRI SAFETY INFORMATION
The REFLECT™ System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the REFLECT™ system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING
REFLECT™ implants may be provided sterile or nonsterile, except REFLECT™ PET cords and HA-coated implants, which are only available sterile. REFLECT™ instruments are provided nonsterile, except for the MIS Compressor Tube, which is only available sterile, and the MIS Compressor Threaded Shaft and Tube End Cap, which are offered sterile or nonsterile.

Sterile implants and instruments are supplied pre-packaged and are sterilized 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.

Implants and instruments provided nonsterile must be steam sterilized prior to use, as described in the STERILIZATION section below. Instruments must be cleaned prior to sterilization, 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. Nonworking or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING
Implants should not be cleaned. 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 use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water (deionized water or reverse osmosis water) should be used for final rinsing to eliminate mineral deposits on instruments.

The following cleaning methods should be observed when cleaning instruments before or 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. Detach all handles, remove driver sleeves, and disassemble the MIS Compressor; refer to the REFLECT™ Surgical Technique for detailed instructions.
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 the detergent 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 long, narrow, bristled brush (e.g. 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 for a minimum of 30 seconds.
9. Prepare Enzol® (or a similar enzymatic detergent) per the detergent 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 purified water (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 the 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
REFLECT™ implants may be provided sterile or nonsterile, except REFLECT™ PET cords and HA-coated implants, which are only available sterile. REFLECT™ instruments are provided nonsterile, except for the MIS Compressor Tube, which is only available sterile, and the MIS Compressor Threaded Shaft and Tube End Cap, which are offered sterile or nonsterile.

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 Tyvek pouch, single Tyvek pouch with inner tube, or single Tyvek pouch in an outer container. The single or double Tyvek pouch is the sterile barrier for sterile products. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments are steam sterilized as described below, and steam sterilization has 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 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 (perforated metal case with inner trays and/or modules):
- Recommended sterilization parameters are listed in the table below.
- Only rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- The container must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- Sterilization trays must be thoroughly cleaned and pass visual inspection for cleanliness before being loaded. If trays do not pass visual inspection, the cleaning process must be repeated and the trays must again undergo and pass visual inspection.
- 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 these devices. The sterilizer must be properly installed, maintained, and calibrated.

Always immediately clean and re-sterilize instruments that have been used in surgery. This process must be performed before handling or (if applicable) returning to Globus Medical.

SUMMARY OF NON-CLINICAL INFORMATION
A number of non-clinical mechanical tests were performed on the REFLECT™ system, including static and dynamic tension bending, creep, stress relaxation, and wear, and all testing passed the pre-determined acceptance criteria where applicable.

SUMMARY OF CLINICAL INFORMATION
Clinical Data Overview
Clinical data was collected to assess the safety and probable benefit of the REFLECT™ system in twenty (N=20) subjects with idiopathic scoliosis. Data was obtained from a single-site study in which Globus implants were used for scoliosis correction. An ongoing prospective investigator-initiated Investigational Device Exemption (IDE) study was conducted, as approved by the site's Institutional Review Board (IRB). All study subjects were previously treated using CREO® (K124058) and TRANSITION® (K073439) components FDA-cleared for spinal fusion. The REFLECT™ cord is the same cord used in TRANSITION® implants, except that it has a pre-assembled collet for tensioning, and REFLECT™ screws have the same design as CREO® screws but with a more rounded opening for the cord. The main curve Cobb angle was the primary outcome measure. Radiographic images were assessed by independent radiographic evaluators to determine Cobb angle, screw loosening/breakage, and cord breakage. Adverse Events (AEs) were reported by the investigators and assessed by an independent Clinical Events Committee (CEC).

Enrollment Criteria

Inclusion Criteria
- Males or females 8 to 16 years old at time of enrollment (inclusive)
- Diagnosis of idiopathic scoliosis
- Sanders stage of less than or equal to 4
- Thoracic curve of greater than or equal to 35° and less than or equal to 60°
- Lumbar curve less than 35°
- Subject has already been identified for and recommended to have surgical intervention
- Spina bifida occulta is permitted

Exclusion Criteria
- Pregnancy (current)
- Prior spinal or chest surgery
- MRI abnormalities (including syrinx greater than 4mm, Chiari malformation, or tethered cord)
- Neuromuscular, thoracogenic, cardiogenic scoliosis, or any other non-idiopathic scoliosis
- Associated syndrome, including Marfan Disease or Neurofibromatosis
- Sanders stage greater than 4
- Thoracic curve less than 35° or greater than 60°
- Lumbar curve greater than or equal to 35°
- Unable or unwilling to firmly commit to returning for required follow-up visits
- Investigator judgement that the subject/family may not be a candidate for the intervention

Safety and Probable Benefit Assessments

Safety was evaluated through analysis of all AEs reported and assessed by each investigator. All AEs were also assessed and adjudicated by an independent CEC. The primary probable risk was assessed by evaluating all reported safety data. The study did not include hypothesis-driven safety endpoints. The investigator ranked each AE by type, severity (e.g., Serious Adverse Event (SAE)), and relationship to the device- and/or procedure. AEs were collected based on a complete review of each subject's medical record at the study site.

Probable benefit was assessed by measurement of coronal curve correction (Cobb angle) on post-operative radiographs. A subject was considered a success if the Cobb angle of their major curve was less than 40 degrees at 24 months following treatment (Month 24) with the REFLECT™ Scoliosis Correction System. Success rates at 12 months following treatment (Month 12) were also assessed.

All treated subjects (N=20) were included in the safety and probable benefit analysis population. All subjects (20/20) have reached 12-month follow-up, with 85% (17/20) having completed their Month 24 follow-up visit.

Study Population Demographics and Baseline Parameters

A total of 20 subjects were enrolled in this study and had evaluable data. Study population demographics and baseline characteristics are shown in **Table 1**. The majority of subjects were female (16/20, 80%), and the mean age was 12.3 years. All subjects were skeletally immature at the time of surgery, as assessed by Sanders Stage or Risser Score. More than half of the subjects (13/20, 65%) had baseline major curves with a measured Cobb angle between 45 and 65 degrees.

Table 1. Demographics and Baseline Parameters for Study Subjects

Demographic Measure		Value/N (%)
Subjects		20
Gender	Female	16 (80%)
	Male	4 (20%)
Age at time of surgery	Mean (SD)	12.3 (1.9)
	Min, Max	9.0, 16.4
Height (cm)	Mean (SD)	155.6 (12.4)
Weight (kg)	Mean (SD)	46.4 (13.8)
BMI	Mean (SD)	18.9 (4.2)
FEV1 (L)	Mean (SD)	2.2 (0.5)
FVC (L)	Mean (SD)	2.6 (0.6)
Risser Score	0	15 (75%)
	1	1 (5%)
	2	2 (10%)
	3	0
	4	0
	5	0
	NR	2 (10%)
Sanders Stage	0	0
	1	0
	2	2 (10%)
	3	10 (50%)
	4	8 (40%)
	5	0
	6	0
	7	0
	NR	0
Cobb Angle	30°-44°	7 (35%)
	45°-65°	13 (65%)

Safety Results

Total AEs

A total of 148 AEs were reported in the 20 subjects. These AEs are summarized in **Table 2**, and the majority of AEs were non-SAEs; 6 subjects (6/20, 30%) experienced an AE classified as an SAE following treatment with the REFLECT™ Scoliosis Correction System.

Table 2. AE Summary (N=20 subjects)

Adverse Events	All AEs	Non-SAEs	SAEs
Number of Events, N (% of events)	148	142/148 (95.9%)	6/148 (4.1%)
Number of Subjects with AE, N (% of subjects)	20	14/20 (70%)	6/20 (30%)

AEs Categorized by Relationship

A listing of AEs by relationship/category is presented in **Table 3**. The most common AEs include Respiratory - Diminished Bases/Sounds/Capacity (15/20, 75%), Gastrointestinal (13/20, 65%), Pain - Thorax (12/20, 60%), Pain - Upper Extremities (7/20, 35%), and Respiratory - Pneumothorax (7/20, 35%).

Table 3. Adverse Events

Adverse Event Category	Number of AEs (N)	Number of Subjects with AE [N (%)]	Days to AE [Mean (range)]
Cardiovascular	1	1 (5%)	1 (1, 1)
Dysesthesia - Thorax	1	1 (5%)	21 (21, 21)
Gastrointestinal	17	13 (65%)	3 (0, 20)
Infection - Other	3	3 (15%)	48 (6, 94)
Muscle Spasms	2	2 (10%)	22 (5, 38)
Musculoskeletal	4	4 (20%)	249 (1, 699)
Neurological Focal - Other	1	1 (5%)	23 (23, 23)
Other	4	2 (10%)	24 (1, 86)
Pain - Back	8	6 (30%)	179 (1, 807)
Pain - Hip	2	2 (10%)	219 (66, 372)
Pain - Lower Extremities	3	2 (10%)	59 (36, 85)
Pain - Other	2	1 (5%)	26 (4, 48)
Pain - Thorax	15	12 (60%)	10 (0, 85)
Pain - Upper Extremities	8	7 (35%)	79 (0, 372)
Paresthesia - Lower Extremities	1	1 (5%)	21 (21, 21)
Paresthesia - Other	4	4 (20%)	22 (1, 43)
Paresthesia - Upper Extremities	1	1 (5%)	5 (5, 5)
Psychological	1	1 (5%)	12 (12, 12)
Radiographic - Suspected Screw/Staple Issue	1	1 (5%)	386 (386, 386)
Radiographic - Suspected Cord Finding	4	4 (20%)	650 (363, 765)
Respiratory - Atelectasis	4	4 (20%)	2 (1, 3)
Respiratory - Congestion/Cough	6	5 (25%)	10 (0, 51)
Respiratory - Diminished Bases/Sounds/Capacity	24	15 (75%)	6 (0, 49)
Respiratory - Pleural Effusion/Edema	6	6 (30%)	2 (1, 6)
Respiratory - Pneumothorax	7	7 (35%)	1 (0, 3)
Respiratory - Other	4	4 (20%)	1 (0, 1)
Surgery - Index Levels	6	6 (30%)	499 (253, 755)
Trauma	2	2 (10%)	80 (44, 115)
Wound Issue	6	5 (25%)	401 (9, 807)

AEs Categorized by Relatedness

All AEs in the clinical study that were categorized as related to the device or procedure are listed in **Table 4**. A total of 106 device- or procedure-related AEs were identified. The most common device- or procedure-related AE was Respiratory – Diminished Bases/Sounds/Capacity observed in 75% (15/20) subjects.

Table 4. Adverse Events Related to Device or Procedure

Adverse Event Category	Number of AEs (N)	Number of Subjects with AE [N (%)]	Days to AE [Mean (range)]
Cardiovascular	1	1 (5%)	1
Dysesthesia - Thorax	1	1 (5%)	21
Gastrointestinal	14	12 (60%)	2 (0, 8)
Muscle spasms	2	2 (10%)	22 (5, 38)
Musculoskeletal	1	1 (5%)	1
Other	3	2 (10%)	3 (1, 7)
Pain - Back	2	2 (10%)	1 (1, 1)
Pain - Other	1	1 (5%)	4
Pain - Thorax	13	11 (55%)	4 (0, 43)
Pain - Upper extremities	1	1 (5%)	0
Paresthesia - Other	2	2 (10%)	11 (1, 21)
Radiographic - Suspected Screw/Staple Finding	1	1 (5%)	386
Radiographic - Suspected Cord Finding	4	4 (20%)	650 (363, 765)
Respiratory - Atelectasis	4	4 (20%)	2 (1, 3)
Respiratory - Congestion/Cough	5	5 (25%)	2 (0, 6)
Respiratory - Diminished Bases/Sounds/Capacity	22	15 (75%)	2 (0, 23)
Respiratory - Pleural Effusion/Edema	6	6 (30%)	2 (1, 6)
Respiratory - Pneumothorax	7	7 (35%)	1 (0, 3)
Respiratory - Other	4	4 (20%)	1 (0, 1)
Surgery - Index Levels	6	6 (30%)	499 (253, 755)
Wound Issue	6	5 (25%)	401 (9, 807)

Serious AEs

There were 6 SAEs reported during the study and all resulted in secondary surgery, as shown in **Table 5**. Four subjects had a suspected cord breakage (4/20, 20%), one subject's curve progressed (1/20, 5%), and one subject had overcorrection (1/20, 5%).

Table 5. Adverse Events Classified as Serious Adverse Events (SAEs)

Adverse Event	Total Events (N)	SAEs (N)	SAEs Requiring Secondary Surgery	Subjects with SAE [N (% of 20)]	Days to SAE [Mean (range)]
Progression of Instrumented Curve	1	1	1	1 (5%)	755
Overcorrection of Instrumented Curve	1	1	1	1 (5%)	519
Suspected Cord Break	4	4	4	4 (20%)	429 (253, 720)
Total	**6**	**6**	**6**	**6 (30%)**	**499 (253, 755)**

Secondary Surgeries

All secondary surgeries are listed in **Table 6**. Secondary surgeries were classified as Revision, Reoperation, or Removal. Revision (e.g., cord adjustment) surgery is a procedure in which the cord is removed, replaced and re-tensioned. Reoperation (e.g., posterior spinal fusion) involves conversion to a fusion construct using pedicle screws and rods, and may or may not involve removal of all implants. Removal is defined as removal of some or all of the original implants. Cord adjustment surgery provides the potential benefit of arresting curve progression and avoiding fusion surgery.

A total of 6 subjects (6/20, 30%) underwent secondary surgery involving the originally treated levels. One subject (1/20, 5%) with curve progression and four subjects (4/20, 20%) with suspected cord breakages had a reoperation to convert to posterior spinal fusion, and one subject (1/20, 5%) with overcorrection of their curve underwent partial implant removal/revision without posterior fusion.

Table 6. Secondary Surgeries Listing*

Revision Subject #	Secondary Surgery Type	Levels Treated	Months to Secondary Surgery	AE Term and Description
1	Reoperation (Fusion)	T7-L1	37	Tether breakage between T11-T12. Breakage assumed based on increased screw angulation and increased Cobb angle. Underwent posterior spinal fusion from T4-L2 with pedicle screws, hooks, and cobalt chrome rods.
2	Reoperation (Fusion)	T6-T12	18	Tether failure at T10-T11. Underwent posterior spinal fusion.
3	Reoperation (Fusion)	T5-T11	30	Implant re-operation. Progression of curve without evidence of cord breakage. Underwent posterior spinal fusion from T5-L3 with pedicle screws, hooks, and cobalt chrome rods.
4	Reoperation (Fusion)	T6-T11	22	Tether breakage at T7-T8 and at T8-T9. Underwent posterior spinal fusion from T2-T12 with pedicle screws, hooks and rods.
5	Removal/ Revision (removed some implants)	T6-L1	18	Overcorrection of curve. Underwent removal of the cord and screws at T10, T11, T12 and L1; staples remained in place. REFLECT™ device remains implanted at T6, T7, T8 and T9.
6	Reoperation (Fusion)	T5-T12	21	Tether breakage at T10-T11. Breakage assumed based on increased screw angulation and increased Cobb angle. Underwent posterior spinal fusion from T4-L2 with pedicle screws, hooks, and cobalt chrome rods.

*T=Thoracic spine; L=Lumbar spine

Probable Benefit Results

The primary probable benefit endpoint of this single-arm study was based on Cobb angle measurement of the subject's major coronal curve at Month 24. Individual subject success was defined as a major curve less than or equal to 40 degrees at Month 24. For Cobb angle measurements, the superior and inferior end vertebrae of the curve were determined pre-operatively and held constant across all timepoints for direct comparison.

Mean Cobb Angle Correction

The change in Cobb angle from baseline (Pre-Op) to Month 12 and Month 24 is described in **Table 7**. At Month 12, the mean major Cobb angle compared to baseline improved 21.9% from 48.0 degrees to 26.1 degrees. At Month 24, the mean major Cobb angle compared to baseline improved 21.2% from 48.0 degrees to 26.8 degrees.

Table 7. Change in Cobb Angle from Baseline at Month 12 and Month 24

Cohort	N	Cobb Angle				
		Pre-Op (N=20)	Month 12 (N=20)		Month 24 (N=17)	
		Mean (SD) [min, max]	Mean (SD) [min, max]	Δ (%Δ)	Mean (SD) [min, max]	Δ (%Δ)
All subjects	20	48.0 (8.1) [34.1, 62.4]	26.1 (8.6) [6.1, 47.7]	21.9 (45.2%)	26.8 (11.3) [3.5, 47.3]	21.2 (44.7%)

Individual Subject Probable Benefit Success

Individual subject success was defined as achievement of a Cobb angle less than or equal to 40 degrees at Month 24. Fifteen (15) out of 17 subjects with Month 24 data (88.2%) met the success criteria in this study. Success rates at Month 12 and Month 24 stratified by pre-operative Cobb angle are provided in **Table 8**.

Table 8. Overall Study Success (Cobb Angle Less Than or Equal to 40 degrees) at Month 12 and Month 24 by Pre-operative Cobb Angle

Cohort	N	Success % (n/N)		Last Visit Cobb Angle (n, %)
		Month 12	Month 24	
All subjects	20	95% (19/20)	88.2% (15/17)	< 30° (12, 70.6%) < 35° (14, 82.4%) < 40° (15, 88.2%)
Pre-Op Cobb < 45°	7	85.7% (6/7)	100% (6/6)	< 30° (5, 83.3%) < 35° (6, 100%) < 40° (6, 100%)
Pre-Op Cobb ≥ 45°	13	100% (13/13)	81.8% (9/11)	< 30° (7, 63.6%) < 35° (8, 72.7%) < 40° (9, 81.8%)

Sensitivity analyses were also performed to determine how the results were affected by changing the Cobb angle reduction threshold for the probable benefit success endpoint, as shown in **Table 8**. For all treated subjects, the probable benefit success rates were 82.4% (14/20) and 70.6% (12/20) when success is defined as a major Cobb angle of less than 35 degrees and 30 degrees, respectively.

Results were further stratified for subjects with pre-op Cobb angles less than 45 degrees (N=7) and greater than or equal to 45 degrees (N=13), respectively. For subjects with pre-op Cobb angles less than 45 degrees, probable benefit success rates were 100%, 100%, and 83.3% based on a major Cobb angle of less than 40 degrees, 35 degrees, and 30 degrees, respectively, at Month 24. For subjects with pre-op Cobb angles greater than or equal to 45 degrees, probable benefit success rates were 81.8%, 72.7%, and 63.6% based on a major Cobb angle of less than 40 degrees, 35 degrees, and 30 degrees, respectively, at Month 24.

Improvement in Patient Reported Outcomes

Patient-reported outcomes included the Scoliosis Research Society (SRS) outcomes questionnaire (SRS-30). Overall outcomes are positive and show improvement in self-image and patient satisfaction with treatment.

Spinal Alignment

Spinal alignment was measured on radiographs at each timepoint, in terms of thoracic kyphosis, lumbar lordosis, sagittal balance, coronal balance, and total vertical thoracic spine length. On standing images, sagittal balance was measured by the distance between the C7 plumb line and the posterior S1 vertebral body; anterior displacement of the plumb line corresponds to positive sagittal balance, and posterior displacement corresponds to negative sagittal balance. Coronal balance was measured by the distance between a C7 plumb line and the central sacral vertical line (CSVL); plumb line right of the CSVL corresponds to positive coronal balance and left corresponds to negative coronal balance. Radiographic parameters at each time point are summarized for all subjects in **Table 9**.

Table 9. Radiographic Data by Timepoint [mean (SD)]

Timepoint	N	Thoracic Kyphosis (°)	Lumbar Lordosis (°)	Sagittal Balance (mm)*	Coronal Balance (mm)**	Total Vertical Thoracic Spine Length (mm)
Pre-op	20	15.6 (10.4)	50.7 (7.1)	-5.7 (26.0)	8.1 (17.0)	204.8 (16.9)
Month 12	20	18.4 (8.1)	48.9 (7.6)	-2.4 (31.1)	-0.1 (14.7)	220.4 (16.0)
Month 24	17	19.6 (9.2)	48.5 (8.5)	7.0 (24.2)	-3.6 (14.9)	223.8 (11.4)

*Sagittal balance: positive value indicates anterior shift; negative indicates posterior shift.
**Coronal balance: positive value indicates right coronal shift; negative value indicates left coronal shift.

Overall Conclusions

The reported clinical data and analysis support the reasonable assurance of safety and probable benefit of the REFLECT™ Scoliosis Correction System when used in accordance with the indications for use. This device can be considered safe for its intended use, based upon consideration of the types of serious AEs, device-related and procedure-related AEs, and subsequent surgical procedures reported. The probable benefit success rate, defined as maintenance of a Cobb angle less than 40 degrees, is 88.2% at Month 24. This probable benefit endpoint is considered representative of the likelihood of avoidance of the need for spinal fusion during this time period. The benefit of a device which avoids spinal fusion during the study time period but does not preclude treatment with spinal fusion if needed, is considered to outweigh the higher rate of subsequent surgical intervention when compared to posterior spinal instrumentation and fusion.

References

1. Risser JC. The iliac apophysis: An invaluable sign in the management of scoliosis. *Clinical Orthopedics* 1958, 11:111-119.
2. Sanders JO, Khoury JG, Kishan S, Browne RH, Mooney JF 3rd, Arnold KD, McConnell SJ, Bauman JA, Finegold DN. Predicting scoliosis progression from skeletal maturity: A simplified classification during adolescence. *JBJS* 2008, 90(3):540-553.

Product Complaints

Immediately report any issues related to product quality, identity, durability, reliability, safety, effectiveness or performance to Globus Medical at 1-866-GLOBUS1 (456-2871) or by email at complaints@globusmedical.com. Include the name, part number, lot number for all relevant components (if available), and a description of the complaint, as well as the name and contact information of the person reporting the complaint. Notify Globus immediately of an incident that results in death or serious injury. Complaints may also be reported directly to Medwatch at http://www.fda.gov/medwatch.

In the event that device removal is necessary, return the device to Globus Medical. Sterilize the explanted device, place in a plastic bag, and return the device, along with complaint information as described above, to: Globus Medical, Inc., Attn: Clinical Affairs REFLECT™ Explant, Valley Forge Business Center, 2560 General Armistead Blvd, Audubon, PA 19403.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		