PATIENT INFORMATION

REFLECT™

SCOLIOSIS CORRECTION SYSTEM

Life moves us

GLOBUS MEDICAL

REFLECT™ Scoliosis Correction System

Patient Information

This brochure explains the probable benefits and potential risks associated with the REFLECT™ Scoliosis Correction System and provides answers to frequently asked questions. If you have questions after reading this brochure, you should talk to your doctor.

The decision to receive medical treatment is individual to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment, or outcome as surgical techniques vary and complications may occur. It is important to discuss scoliosis correction surgery with your doctor to decide whether this treatment option is right for you.

This brochure is intended to be an educational resource only and is not meant to be a warranty, or to replace a conversation between you and your doctor or member of their health care team. Please consult your doctor for a complete list of indications, contraindications, warnings, precautions, clinical results, and other important medical information related to this procedure.

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.

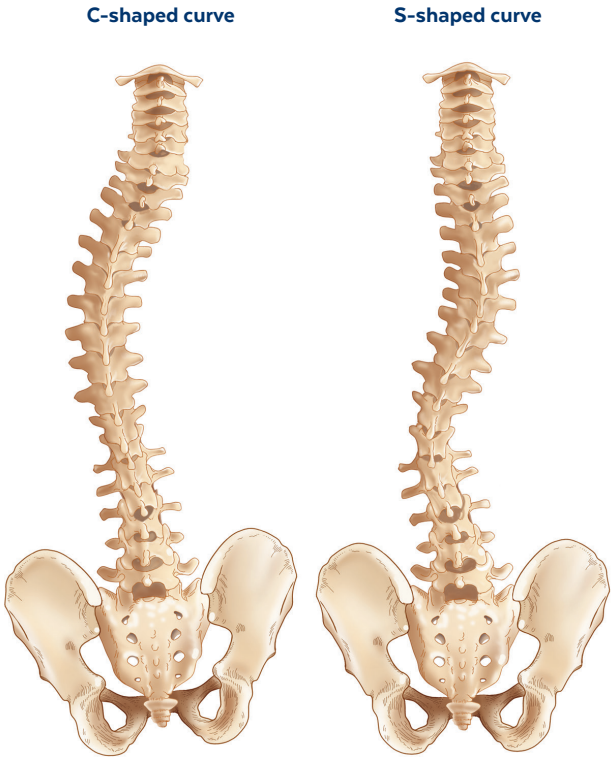
***CAUTION**: Federal (USA) law restricts this device to sale by or on the order of a physician.*

Table of Contents

What is Scoliosis?

Scoliosis is a condition where the spine is curved side-to-side. A spine with scoliosis has an “S” or “C” shape rather than appearing as a straight line on an X-ray, and the bones of the spine (vertebrae) may be rotated. The curvature may make the shoulders, hips or waist appear uneven. The rib cage may stick out more on one side of the back than the other. Scoliosis may be found during a scoliosis screening test at school, or during a regular physical exam.

The curvature may worsen over time and treatment may be necessary to slow or stop the curve from progressing. If left untreated, severe scoliosis could cause long term health consequences, including difficulty breathing, heart problems, and pain. The most common type of scoliosis is idiopathic, meaning the cause is unknown.



How is Scoliosis Typically Treated?

Treatment options for scoliosis depend on the severity of the curve and include watching the curve over time, bracing, and surgery. Watching or observing is recommended for mild curves or those that are not worsening. Bracing is recommended for more moderate curves. Surgery is recommended for patients with severe curves that continue to worsen. The goal of surgical treatment is to reduce (correct) the spinal curvature and prevent further progression. The most common surgical treatment for scoliosis is called spinal fusion, in which rigid metal implants are used to hold the spine in the corrected position.

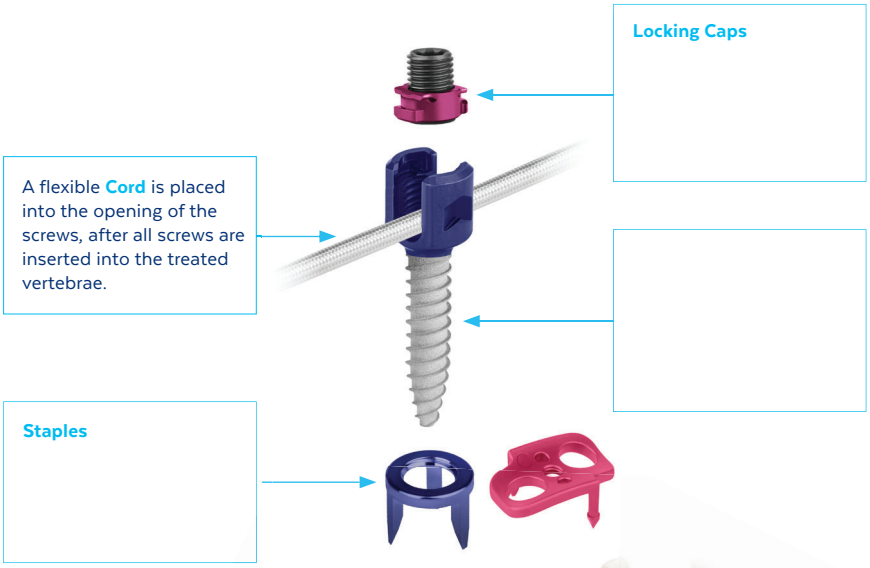
REFLECT™ Scoliosis Correction System

The REFLECT™ Scoliosis Correction System is a treatment option for scoliosis correction that allows the spine to move and grow. Unlike rigid metal rods used for spinal fusion, REFLECT™ uses a flexible, durable cord that allows for scoliosis correction through natural patient growth, known as growth modulation. The flexible cord is placed on the tall side of the curve and tensioned, which allows the short side to continue to grow and straighten the curve over time. The patient's own growth is used to help repair the spinal curvature.

REFLECT™ is part of a special category of medical devices, known as a Humanitarian Use Device. It is specially approved for young patients with idiopathic scoliosis who have a significant amount of growth remaining. REFLECT™ has not been proven to help all cases of scoliosis; instead it has been shown to have probable benefits in these patients.

REFLECT™ Implants

The REFLECT™ system has four unique implants that serve different functions, as shown below. The screws, locking caps, and staples are made from metal (titanium alloy). The flexible cord is made from a polymer material called polyethylene-terephthalate (PET). Both of these materials are commonly used in medical devices.



Who Can Be Treated with REFLECT™?

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.

Who Should Not Be Treated with REFLECT™?

Patients with the following conditions should not be treated with REFLECT™:

- Any type of infection, or if the skin around the operative area is irritated or damaged;
- Previous surgery of the spine where the scoliotic curve is located;
- Soft or less dense bone and a bone density T-score of -1.5 or less;
- Skeletally mature with no remaining growth;
- Allergy to titanium alloy or polymer (PET);
- Other medical or physical conditions that would prevent spinal surgery, such as issues with blood flow or breathing, or that would prevent a benefit from surgery.

What is Done During Surgery with REFLECT™?

REFLECT™ surgery is typically performed while the patient is under general anesthesia and positioned on their side. The surgeon makes a few incisions along the patient's side or between the ribs. The lung is moved out of the way to see the spine. The surgeon uses special tools to place screws and staples into the spine. The cord is inserted into the screws and tightened (tensioned) with a special tool. Locking caps are used to secure the cord within the screws. The surgeon then closes the incisions.

Clinical Data Summary

A clinical study in the United States evaluated 20 subjects with scoliosis who underwent treatment with study devices using the "growth modulation" technique. The study included 16 girls and 4 boys who were 12 years old on average. The severity of the spinal curvature is measured on X-rays as a Cobb angle, in degrees. Subjects with scoliosis have a Cobb angle that is more than 10°. Subjects in this study had an average Cobb angle of 48.0° that improved to 26.8°, which is a 44.7% reduction in the size of the curve. When surveyed, subjects reported improvement in self-image and satisfaction after undergoing the procedure.

As with any spinal surgery, complications can occur. The most common reported complications in this study were respiratory (breathing), gastrointestinal (stomach), back and upper arm pain, and additional surgery. If the curve worsens, the cord may not be tight enough or may break before the patient finishes growing. If the curve is corrected too far in the other direction (overcorrection), the cord may need to be loosened or replaced. In either case, additional surgery may be necessary to adjust the cord, remove the cord, or to have a spinal fusion if necessary. A total of 6 subjects out of 20 in the study had additional surgery. One subject with curve progression and 4 subjects with possibly broken cords had fusion surgery; and one subject with overcorrection had some of their implants removed without fusion.

The clinical study shows that there is a likely benefit to surgery with REFLECT™ to treat scoliosis, however complications may occur. Talk to your doctor about any other questions that you may have about the clinical study and the results.

Potential Adverse Effects

As with any surgical procedure, complications may occur during or after surgery with REFLECT™. Potential complications include those listed below, but other complications may occur that are unknown at this time. Please talk to your doctor if you have questions or do not understand any of the possible complications listed below.

- Implant malposition, loosening, migration, or breakage
- Loss of fixation or cord tension
- Change in spinal curvature, loss of correction, or overcorrection
- Development of new spinal curvature(s)
- Need for additional surgical intervention
- Technical issues with device placement, sizing, or tensioning
- Trunk imbalance
- Unintended spontaneous fusion
- Reactions to anesthesia
- Tissue sensitivity or allergic reactions to implant materials or wear debris
- Device placement issues including sizing and anatomic variation
- Wound complications including dehiscence, superficial or deep infection
- Damage to surrounding anatomy, including the lungs, spinal cord, nerves, blood vessels, or vertebrae
- Pulmonary complications related to chest tube placement and lung ventilation during surgery, including atelectasis, plural effusion, or pneumothorax
- Neurologic complications, including cerebrospinal fluid leakage, meningocele, loss of neurological function, paralysis, dysesthesia, hyperesthesia, paresthesia, or radiculopathy

- Vascular complications including hematoma, hemorrhage, bleeding, or vascular damage, leading to anemia or blood transfusion
- Pain, discomfort or abnormal sensations due to the presence of implants
- Pulmonary embolism
- Deep vein thrombosis
- Pneumonia
- Dysphagia or dysphonia
- Gastrointestinal complications including Ileus, gastritis, bleeding, or bowel obstruction
- Urogenital complications including infection or urinary retention
- Foreign body reaction
- Cardiovascular
- Hematologic
- Endocrine/metabolic
- Hepatobiliary
- Immunologic
- Gynecologic
- Opthalmologic
- Psychological
- Systemic infection
- Death

Frequently Asked Questions

How long is the post-op recovery period?

Recovery time varies between patients and depends on how the surgery goes and if there are any complications. Most patients are in the hospital for a few days. Ask your doctor about your expected recovery time.

When can I return to school or work?

You can expect to return to school or work approximately 2 to 4 weeks after surgery, depending on your recovery. Ask your doctor about when it is safe for you to do so.

When can I return to sports, dance, and other physical activities?

You may be able to return to activities approximately 4 to 8 weeks after surgery, depending on your recovery. It is important that you talk to your doctor before resuming any activities, to be sure that you are healing well and that it is appropriate for you.

How will the implants affect my mobility?

Unlike spinal fusion with metal rods, REFLECT™ uses a flexible polymer cord that does not prevent movement of the spine. Mobility may vary between patients, so ask your doctor how these implants may affect you.

What if I have pain after my surgery?

Some pain is expected when recovering from surgery. If you experience pain, contact your doctor. Pain medication may be prescribed for the first week or two after surgery.

What if I have an adverse reaction to the implant materials after surgery?

Some people may have an adverse reaction to implant materials such as metals. If you are aware of any allergic reactions to titanium alloy, make sure to inform your doctor prior to surgery. If you believe you are having a reaction after the surgery, contact your doctor immediately.

Will I set off a metal detector at an airport or through security?

No. You may walk through metal detectors or security scanners with REFLECT™ implants in your body. Implants made from titanium alloy do not typically set off metal detectors.

More Information

For more information about the REFLECT™ Scoliosis Correction System, please contact Globus Medical Customer Service at 610.930.1800. Refer to the REFLECT™ Surgical Technique for complete indications, contraindications, warnings, precautions, and instructions for use.

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.

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