PATIENT INFORMATION

ADULT SCOLIOSIS

INFORMATION ABOUT ADULT SCOLIOSIS, SYMPTOMS, AND TREATMENT OPTIONS

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Outside the US Only

GLOBUS MEDICAL

Adult Scoliosis

Patient Information

This brochure will help you understand more about:

- **Anatomy of the spine**
- **Information about scoliosis**
- **What to expect from surgery**

The decision to receive medical treatment is individualized 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 can occur. It is important to discuss the viability of treatment with your physician to decide which 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 a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results and other important medical information that pertains to surgical treatment .

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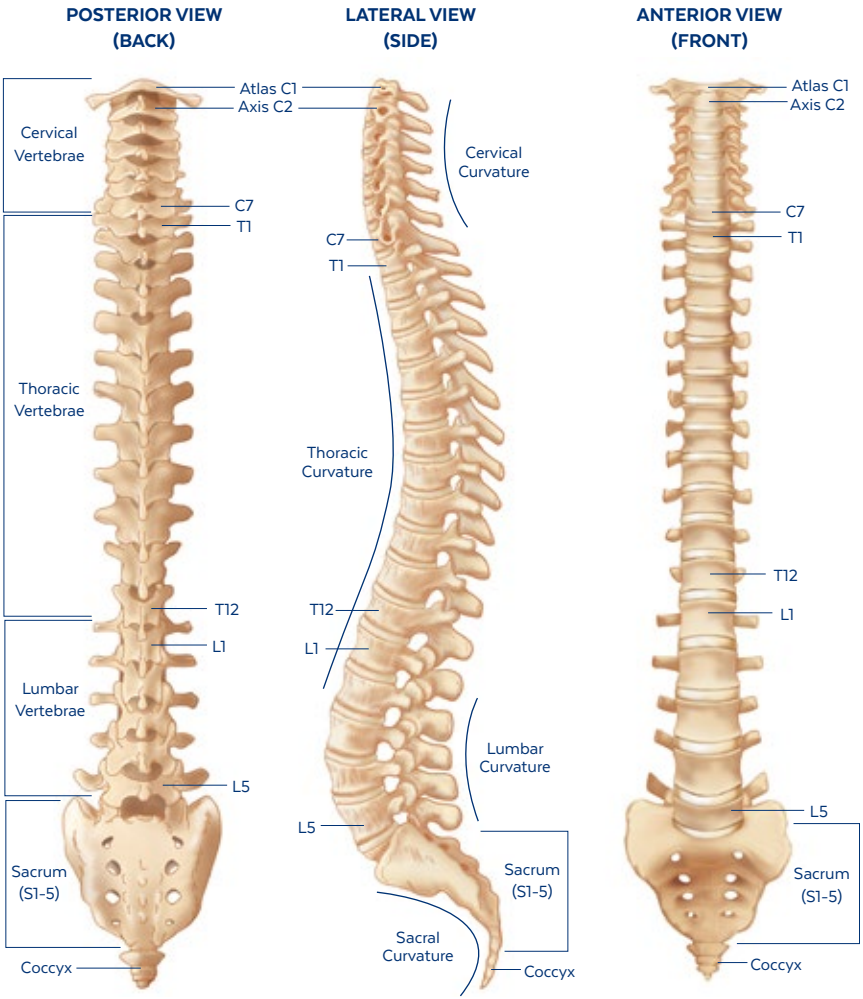
Anatomy of the Spine

The spine is one of the most important structures in the human body. It supports much of the body's weight and protects the spinal cord, which carries information from the brain to the rest of the body. The spine is strong yet flexible, allowing for a wide range of movements.

To understand scoliosis, you must first understand what a healthy spine looks like.



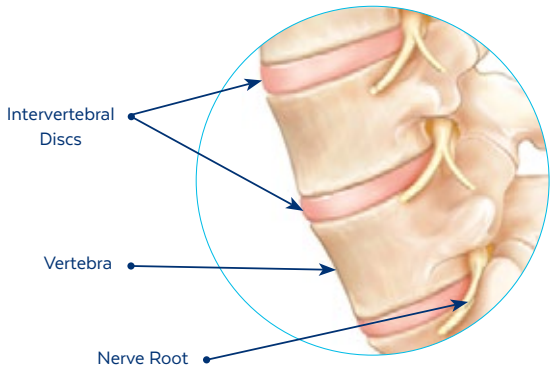
The spine is made up of vertebrae (bones) and is divided into three distinct regions:

- **Cervical spine**: The cervical spine is your neck. It starts at the base of your skull and contains seven vertebrae.
- **Thoracic spine**: The thoracic spine is your mid-back. It contains 12 vertebrae that connect to the ribs and sternum, making this portion very stable.
- **Lumbar spine**: The lumbar spine is your lower back. It contains five vertebrae which are the largest and strongest, and carries most of your body weight.

Below the lumbar spine is the sacrum, which is comprised of five fused vertebrae. At the end of the spine is the coccyx or the tailbone.

From behind, the healthy spine appears to be straight. However, when viewed from the side, the spine is naturally curved inward and outward which allows the spine to support more weight.

The vertebrae bear the weight of the upper body and provide points of attachment for muscles and ligaments. They also protect the spinal canal (cavity that runs through each of the vertebrae and contains the spinal cord) and provide exit points for spinal nerves. The individual vertebrae are separated by intervertebral discs, which act as cushions or shock absorbers between the vertebral bodies.



What is Adult Scoliosis?

Scoliosis is an abnormal sideways curvature of the spine. When a healthy spine is viewed from the back, it appears to be straight. However, patients with scoliosis have curves that look like a “C” (one curve) or an “S” (two curves) when viewed from the back on an x-ray .

Approximately 2%-3% of the population is diagnosed with scoliosis.[1] Although scoliosis can occur at any age, it most frequently develops in children between 10 and 18 years old. Scoliosis that occurs or is diagnosed in adulthood is an entirely different condition, since the causes of scoliosis and the treatment goals are different.

What are the Causes of Adult Scoliosis?

There are many different causes of scoliosis in adults. The most common causes include:

Adolescent scoliosis of the Adult (AsA)

Scoliosis that was present during adolescence and then worsened during adulthood. This type of scoliosis is often idiopathic (of unknown cause) and is known as adolescent scoliosis of the adult (ASA).

De Novo degeneration scoliosis (DDS)

Scoliosis that began in adulthood due to degenerative changes in the spine, causing a deformity to develop. This type of scoliosis is known as de novo degeneration scoliosis (DDS).

What are the Symptoms of Adult Scoliosis?

Unlike adolescents with scoliosis who rarely complain of pain, adult patients with scoliosis present with a variety of symptoms including:

Low back pain and stiffness

Numbness, weakness, and cramping due to pinched spinal nerves. These symptoms are caused by degeneration of the discs and joints leading to narrowing of openings in the spine (spinal stenosis).

Loss of sagittal balance which causes the patient to compensate by bending their hips and knees to try and maintain balance, which can cause muscle fatigue (tiredness).

How is Scoliosis Diagnosed?

The diagnosis typically begins with a complete history followed by a thorough physical and neurologic examination. A healthcare professional will examine the spine and look for any signs of scoliosis.

X-rays may be taken in order to evaluate any tilt or rotation of the vertebrae causing a curvature. X-rays allow the doctor to confirm the diagnosis, monitor the degree and severity of the curve, and to assess the patient's skeletal maturity.

Posterior view (back)

Lateral view (side)

General Treatment Options

In most cases of adult scoliosis, non-operative treatment is preferred. This can include periodic observation, pain relievers, physical therapy and exercise.

Surgical treatment may be needed for patients who have failed non-operative treatment, based on the following:

- Back pain
- Progressive leg pain or neurologic (nerve) deficit
- Spinal imbalance with muscle fatigue
- Curve progression
- Progressive pulmonary compromise
- Severe deformity

The goals of surgery are to restore spinal balance, reduce pain and discomfort, and maintain corrected alignment by fusing and stabilizing the spine.

Surgical Treatment

How is Surgery Performed?

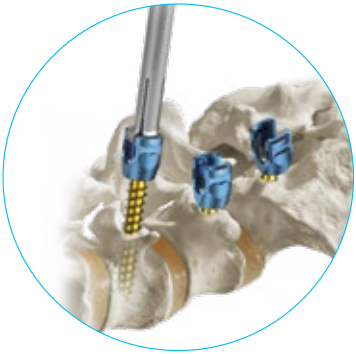
The surgeon may use a posterior approach (from the back) or an anterior approach (from the front) to access the spine.

To help stabilize the spine, screws are placed on each side of the vertebrae into the pedicles. Hooks or bands may also be used together with screws, and are placed around the pedicle or the lamina. Screws, hooks, bands and various connectors are inserted where needed.

Hook

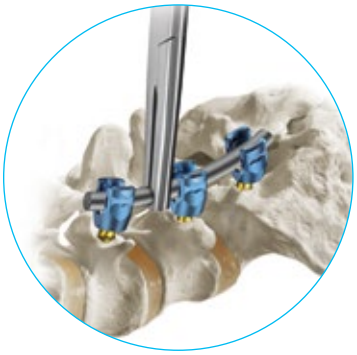
Screw

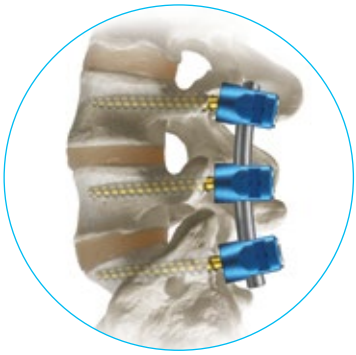
Band



Rods are then placed and secured in the screw heads, connecting neighboring vertebrae. The rods are shaped to match the desired corrected curvature of the spine and are connected to the screws and/or hooks and other implants.

Rod



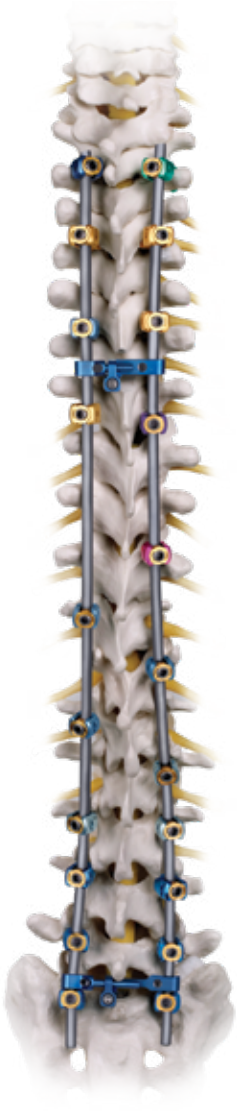


Surgical Treatment (Cont'd)

How is Surgery Performed? (Cont'd)

Bone graft material is placed around the final assembly and as the spine heals, spinal fusion is accomplished by bone growth between the vertebrae. This bone growth permanently fixes the spine in the desired position.

The implants hold the spine in the corrected position while the spine fuses.



Globus Medical offers a variety of implants for the surgical treatment of adult scoliosis.

Implant Type	**Implant Name***
Spine Stabilization Systems for Adult Scoliosis	CREO® REVERE® PROTEX® SILC®

Visit Globus Medical's website at https://www.globusmedical.com/international/
**These products may not be available in your region.*

These implants are composed of titanium alloys, polyetheretherketone (PEEK), commercially pure titanium, tantalum, stainless steel, hydroxyapatite, polyethylene terephthalate (PET), polycarbonate urethane (PCU), and/or cobalt chromium alloy. These materials are biocompatible and have a history of clinical use. If you have an allergy to any of these materials, please consult with your physician.

Frequently Asked Questions

What should I expect with my recovery?

Surgical treatment for scoliosis may help you return to normal activities. Patients may notice improvement of some or all symptoms, and pain from surgery may diminish between 2 to 4 weeks after surgery. However, recovery time varies among patients.

It is the surgeon's goal for the patient to eventually return to his/her preoperative activities. A positive attitude, reasonable expectations and compliance with your doctor's post-surgical instructions may all contribute to a satisfactory outcome.

How long will my implant last?

The device lifetime for these implants is one year in which it is expected that the devices will achieve their intended purpose (support fusion) and maintain performance until fusion occurs. After fusion occurs, the devices are made to survive the life of the patient. These implants can be removed after fusion occurs; however, this is determined by the surgeon and patient.

Can I have an MRI after the devices are implanted?

These devices have not been evaluated for safety and compatibility in the MR environment, and have not been tested for heating or migration in the MR environment.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for these devices if you have an infection, a congenital abnormality, tumors, inadequate pedicles, tissue deficits, vertebral fractures, certain allergies, are obese, pregnant, mentally ill, or diabetic, or if you suffer from rheumatoid arthritis, osteopenia, osteoporosis, or cancer. In addition, a patient whose mental or physical impairment places undue stresses on the implant during healing may be at a higher risk of implant failure.

As with any surgical procedure, complications or adverse effects may occur following the placement of these devices. These can include but are not limited to early or late implant bending, breakage, device fracture or failure, loss of fixation, subsidence, loosening, movement/migration, decrease in bone density or bone fracture, abnormal sensations, and allergic reaction to implant material.

Other adverse effects that may be associated with any spinal surgical procedure include non-union or delayed union, pseudarthrosis, pain, secondary surgery, bleeding, infection, tissue sensitivity, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, joint inflammation, muscle impairment, cardiovascular system compromise, respiratory problems, change in spinal curvature, complications due to bone grafting, reactions to anesthesia, restriction of activities, impotence, sexual dysfunction, paralysis, and death.

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

Contraindications and Adverse Effects (Cont'd)

If you experience a serious adverse effect with your implant, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Other	Report to your local health authority per local guidelines	

References

1. National Scoliosis Foundation. Information and Support. Cited 28 Dec 2011. Available online at: http://www.scoliosis.org/info.php.

Scoliosis Resources

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS (AAOS)

Address: 6300 North River Road
Rosemont, IL 60018
Phone: (847) 823-7186
Website: www.aaos.org

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS (AANS)

Address: 5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: (847) 378-0500
Website: www.aans.org

AMERICAN PHYSICAL THERAPY ASSOCIATION (APTA)

Address: 1111 North Fairfax Street
Alexandria, VA 22314
Phone: (703) 684-2782
Website: www.apta.org

INTERNATIONAL RESEARCH SOCIETY FOR SPINAL DEFORMITIES (IRSSD)

Address: The University of Liverpool
Sherrington Building
Ashton Street
Liverpool L69 3GE UK
Phone: 44 151 794 5502
Website: www.liv.ac.uk/HumanAnatomy/phd/irssd

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

Address: 1 AMS Circle
Bethesda, MD 20892
Phone: (301) 495-4484
Website: www.niams.nih.gov

NATIONAL SCOLIOSIS FOUNDATION (NSF)

Address: 5 Cabot Place
Stoughton, MA 02072
Phone: (800) 673-6922
Website: www.scoliosis.org

NORTH AMERICAN SPINE SOCIETY (NASS)

Address: 22 Calendar Court, 2nd Floor
LaGrange, IL 60525
Phone: (877) 774-6337
Website: www.spine.org

SOCIETY ON SPINAL ORTHOPEDIC AND REHABILITATION TREATMENT (SOSORT)

E-mail: kotwicki@amp.edu.pl
Website: www.sosort.org

SCOLIOSIS RESEARCH SOCIETY (SRS)

Address: 555 East Wells Street, Suite 1100
Milwaukee, WI 53202
Phone: (414) 289-9107
Website: www.srs.org

THE SCOLIOSIS ASSOCIATION, INC.

Address: P.O. Box 811705
Boca Raton, FL 33481
Phone: (561) 994-4435
Website: www.scoliosis-assoc.org5

Notes

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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