



ADOLESCENT IDIOPATHIC SCOLIOSIS

INFORMATION ABOUT SCOLIOSIS, ITS SYMPTOMS, AND TREATMENT OPTIONS

Adolescent Idiopathic Scoliosis

Patient Information

This brochure will help you understand more about:

- ▶ **Anatomy of the spine**
- ▶ **Scoliosis, its symptoms, and treatment options**
- ▶ **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.



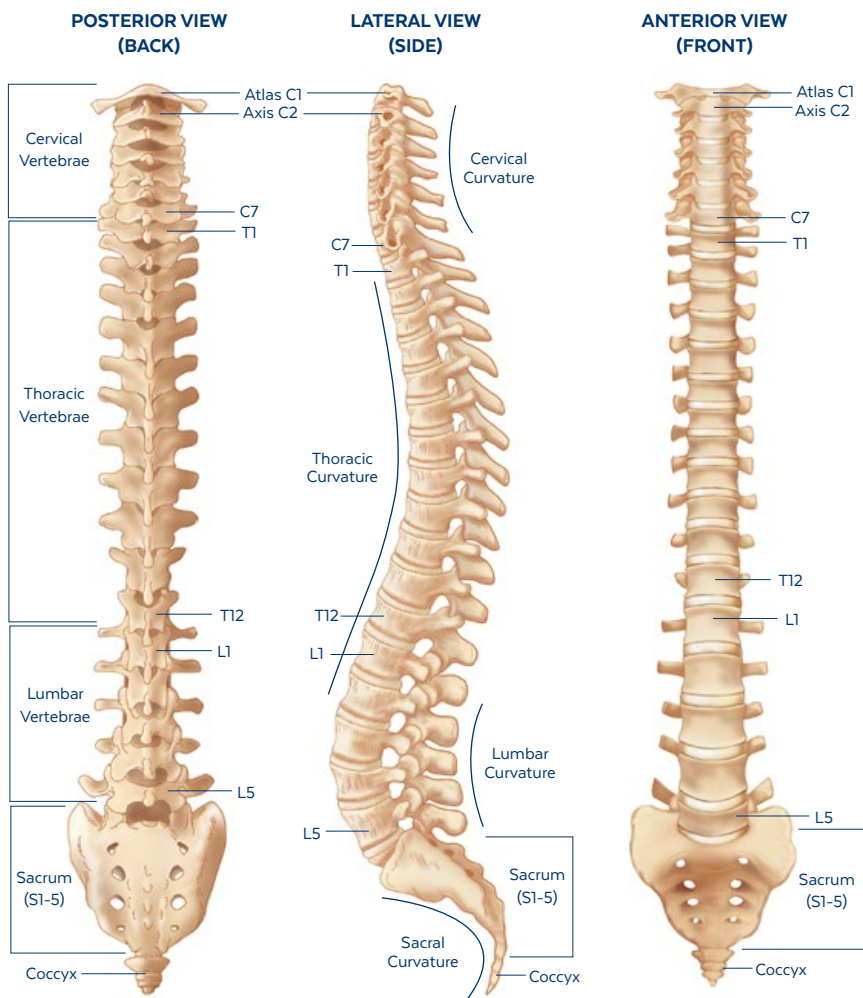
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Anatomy of the Spine

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.



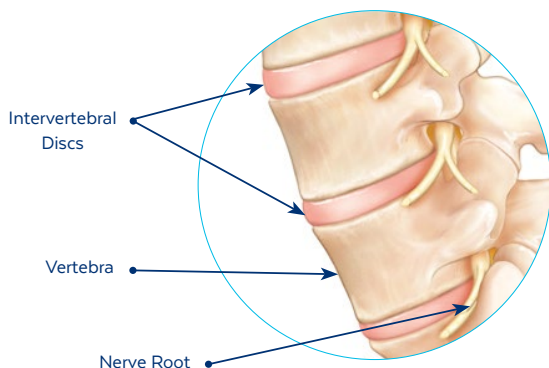
The spine is made up of vertebrae (bones) and is divided into three distinct regions:

- ▶ **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, 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. Each individual vertebra is separated by intervertebral discs, which act as cushions or shock absorbers between the vertebrae.



What is Scoliosis?

Approximately 2%-3% of the population is diagnosed with scoliosis.¹ While scoliosis may occur at any age, Adolescent Idiopathic Scoliosis (AIS) is the most common type and typically occurs between the ages of 10 and 18 years old. The term “idiopathic” means the cause is unknown.

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.

There is ongoing research into the potential causes of scoliosis, including genetics, soft tissue disorders, and abnormalities in the central nervous system.

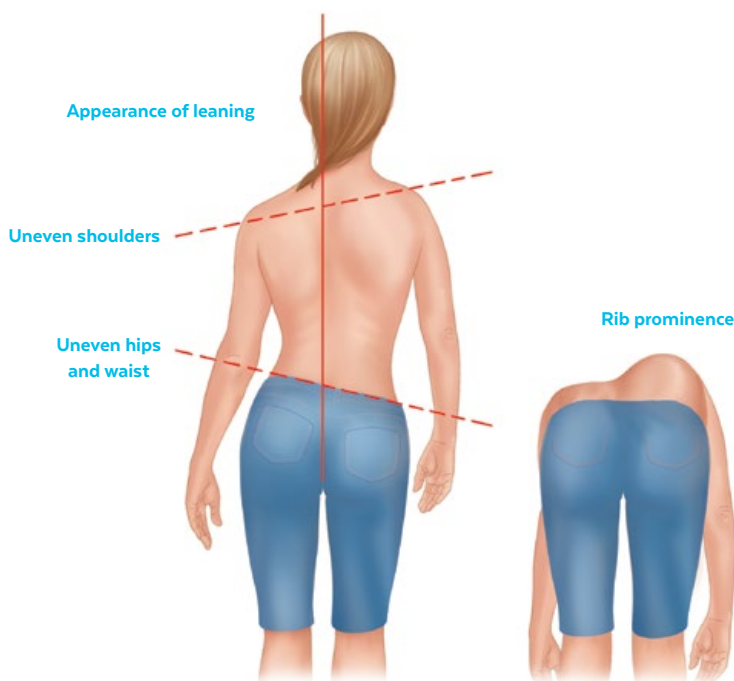


¹ National Scoliosis Foundation. Information and Support. Cited 28 Aug 2019. Available online at: <http://www.scoliosis.org/info.php>.

What are the Symptoms of Scoliosis?

For many patients, AIS is a painless condition. However, there are several warning signs a healthcare professional uses to help determine if a patient has scoliosis. The most common signs of scoliosis include the following:

- ▶ Uneven shoulders and/or shoulder blades
- ▶ Uneven hips and waist
- ▶ Appearance of leaning
- ▶ Head is not centered over the body
- ▶ A rib prominence (raised area) on the side of the spine, that is most noticeable when bending forward



How is Scoliosis Diagnosed?

The diagnosis typically begins with a complete history followed by a thorough physical examination. A healthcare professional examines the spine and looks 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

Treating scoliosis must consider the severity of the curve, the age and state of physical maturity, and the location of the curve. Treatment options range from observation, bracing, and casting to surgery.

Observation

Observation is appropriate for mild size curves that have a low risk of progression when the patient is still growing, or for moderate size curves when growth is complete.² Your doctor will make recommendations regarding the need for X-rays and how often to be seen based on the progression of the curve.

Bracing

Bracing is appropriate for moderate size curves in growing children to help prevent further progression of the curve while growth of the spine remains. The goal of bracing is not to correct the curve, but to prevent further progression into more severe curves.² Your doctor will advise you on which brace is most effective in managing the curve. There are two types of bracing that are often recommended: the Wilmington Brace and the Boston Brace.



Surgical Treatment

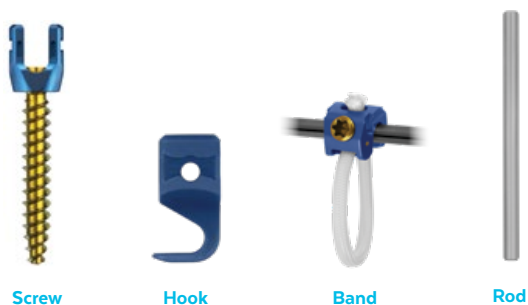
Surgical treatment is reserved for moderate to severe size curves. It may be recommended when the curve continues to progress and there is significant growth left in the spine, or brace treatment has failed. The goals of surgical treatment are to prevent curve progression and to obtain curve correction.

² Scoliosis Research Society 2019. Available online at: <http://www.srs.org>.

Surgical Treatment

Spinal Fusion

The most common surgical treatment for scoliosis is spinal fusion (joining of bones). In this procedure, implants such as screws, hooks, and/or polyester bands are used in conjunction with rods and are attached to the spine in a corrected position until the vertebrae are fused.



To help stabilize the spine in a posterior approach, screws are placed on each side of the vertebrae in the part of the bone called the pedicle (bony tube that connects the back of the vertebra to the front). Hooks or polyester bands may also be used in conjunction with screws, and are placed around the pedicle or around the part of the bone called the lamina.



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

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



Non-Fusion

Another surgical option is a non-fusion spinal procedure. This procedure uses a flexible, durable, and biocompatible polymer cord, in conjunction with hydroxyapatite (HA) coated (coating designed to facilitate bony attachment) screws, to help preserve motion and allow future modulated (adjusted) growth.

A flexible cord is secured to the convex (outward curving) side of the spinal curve using HA coated bone screws. During surgery, the surgeon applies tension to the cord. The tension applied to the cord limits the growth on the convex side of the curve and allows more growth on the concave side. As the patient continues to grow, the curve straightens over time after the surgery.



Polyethylene Terephthalate (PET) Cord



Hydroxyapatite (HA) coated screw



Surgical Treatment (Cont'd)

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

Implant Type

Fusion



Implant Name*

CREO®

REVERE®

SILC®

Nonfusion



REFLECT®

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), 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 can I expect with my recovery?

Although recovery time varies among patients, many are in the hospital for 1-2 weeks, out of school for 2-6 weeks, and may return to activities as soon as 2-9 months after surgery.

It is the surgeon's goal for the patient to return to their 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?

Fusion Devices

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.

Nonfusion Devices

The expected lifetime of these devices is difficult to determine but it is not indefinite. While these devices are made of synthetic materials and are designed to survive the life of the patient, there are many factors which may affect the device lifetime. Therefore, these devices cannot be expected to indefinitely withstand the applied loads of the spine.

Can I have an MRI after the devices are implanted?

These devices have not been evaluated for safety and compatibility in the MR environment. These devices 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, congenital abnormality, tumors, inadequate pedicles, tissue deficits, vertebral fractures, certain allergies, rheumatoid arthritis, osteopenia, osteoporosis, or cancer, or are obese, pregnant, mentally ill, or diabetic. 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, reduced spinal growth, abnormal sensations, decrease in bone density or bone fracture, and allergic reaction to implant material.

Other adverse effects that may be associated with any spinal surgical procedure include non-union or delayed union, pain, secondary surgery, bleeding, infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, 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.

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	

Scoliosis: Fast Facts

- Scoliosis is the most commonly diagnosed spinal imbalance.¹
- The condition causes the spine to abnormally curve sideways, into an “S” or “C” shape.¹
- Scoliosis affects 2%-3% of the population.²
- The condition can affect people of any age, but the most common age of onset is between the ages of 10 and 18.²
- Approximately 30% of AIS patients have a family history of scoliosis.¹
- Although girls and boys are diagnosed with scoliosis in equal numbers, girls are eight times more likely to have a curve that progresses and requires treatment.²
- Common signs and symptoms include uneven shoulders, ribs, hips, or waist, one shoulder blade more prominent than the other, rib prominence, or one arm hanging lower than the other.¹
- In 85% of cases, the cause of scoliosis is unknown; this is called idiopathic scoliosis.²



Resources

SCOLIOSIS RESEARCH SOCIETY (SRS)

www.srs.org

THE GERMAN SOCIETY FOR ORTHOPAEDICS AND TRAUMA (DGOU)

dgou.de/dgou/

THE GERMAN SPINE SOCIETY (DWG)

www.dwg.org

INTERNATIONAL RESEARCH SOCIETY FOR SPINAL DEFORMITIES (IRSSD)

www.liv.ac.uk/HumanAnatomy/phd/irssd

THE SCOLIOSIS ASSOCIATION, INC.

www.scoliosis-assoc.org

SOCIETY ON SPINAL ORTHOPEDIC AND REHABILITATION TREATMENT (SOSORT)

www.sosort.org

CURVY GIRLS SCOLIOSIS

www.curvygirlsscoliosis.com

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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