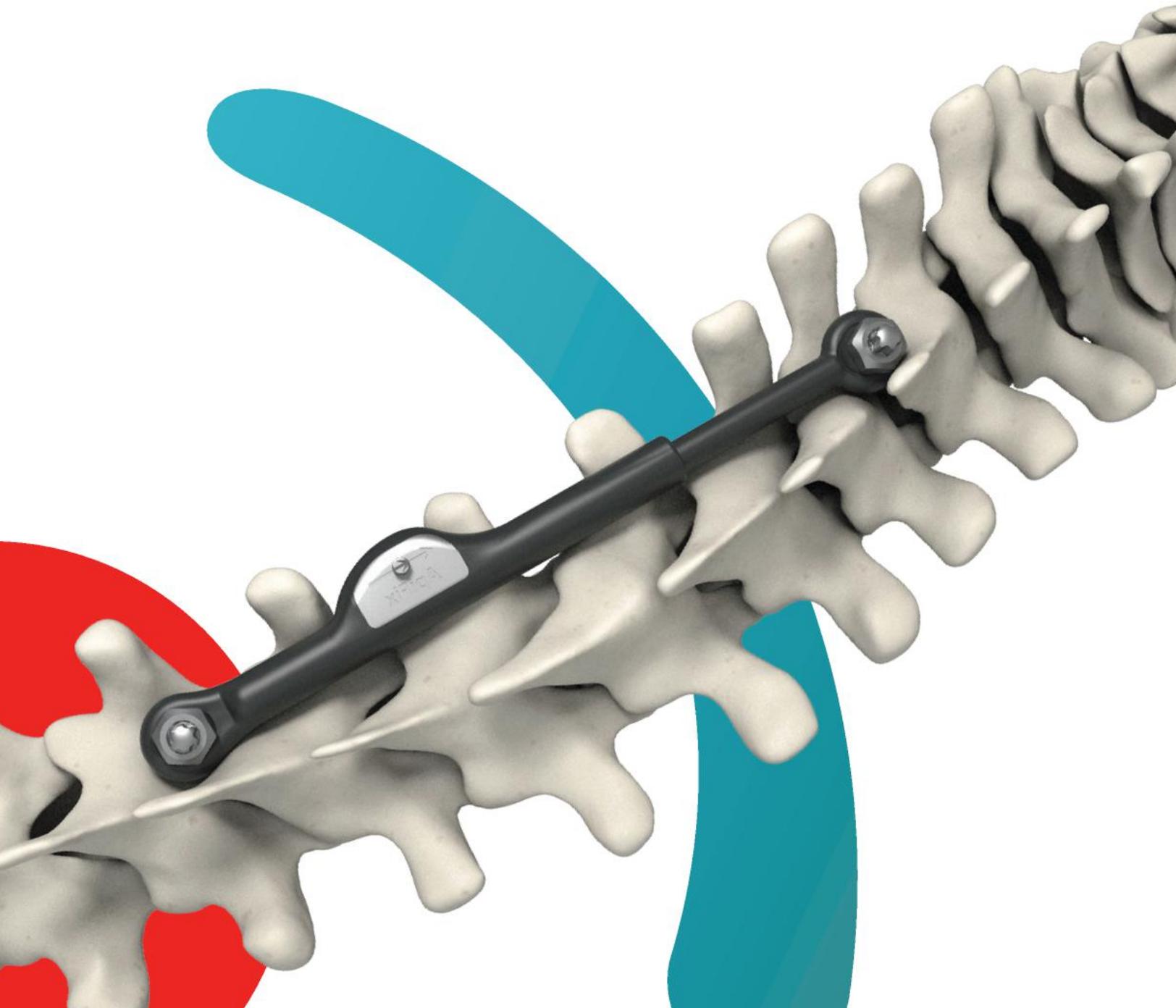


ApiFix

THE INTERNAL BRACE OPTION

MID-C SYSTEM PATIENT GUIDE



CAUTION: Federal law restricts this device to sale by or on the order of a physician.
Humanitarian Device.

Authorized by Federal law for use in the treatment of adolescent idiopathic scoliosis (AIS).
The effectiveness of this device for this use has not been demonstrated.

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GLOSSARY

Cervical – The cervical area of the spine is commonly referred to as the neck.

Cobb Angle – A measure of a curvature in the spine in degree units.

Coccyx – A small triangular bone, commonly referred to as the “tailbone”, located at the bottom of the spine.

Idiopathic – A descriptive term used to indicate that a disease or condition arises spontaneously or from a cause that is unknown.

Lenke Classification - A method of characterizing different x-ray curve patterns in scoliosis

Lumbar – The lumbar area of the spine is in the lower back, where the spine curves inward toward the abdomen.

Major Curve – The largest curve in a spine with scoliosis.

Pressure sores – Areas of damaged skin caused by staying in one position for too long. Also known as “bed sores”.

Risser Scale – A measure of skeletal maturity.

Sacrum – A shield-shaped bony structure that is located at the base of the lumbar vertebrae and that is connected to the pelvis.

Scoliosis – Abnormal, side-ways (lateral) curving of the spine.

Spinal Cord – Group of nerves that runs along spinal column and connects to the brain.

Spinal Instrumentation and Fusion - A procedure where a surgeon uses instruments such as rods, plates, and screws to help bones in the spine to grow together (fuse).

Spontaneous – Occurring without an apparent cause.

Thoracic – The thoracic area of the spine runs from the base of the neck down to the lumbar spine.

Thoracic kyphosis – Thoracic kyphosis is when the thoracic spine curves causing the back to hunch at the shoulders.

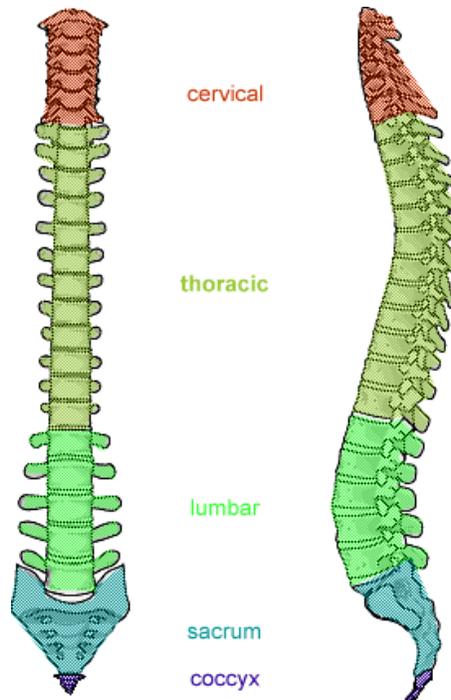
Vertebrae – A series of 33 individual bones that interlock with each other to form the spinal column.

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THE SPINE

The spine, also known as the spinal column, is a column of 26 bones in an adult body — 24 separate vertebrae bones interspaced with cartilage, the sacrum, and coccyx (tailbone). Prior to adolescence, the spine consists of 33 bones because the sacrum's five bones and the coccyx's four do not fuse together until adolescence.

The vertebrae are named by the first letter of their spinal region (C for cervical, T for thoracic, or L for lumbar) and with a number to indicate their position in the spinal region.



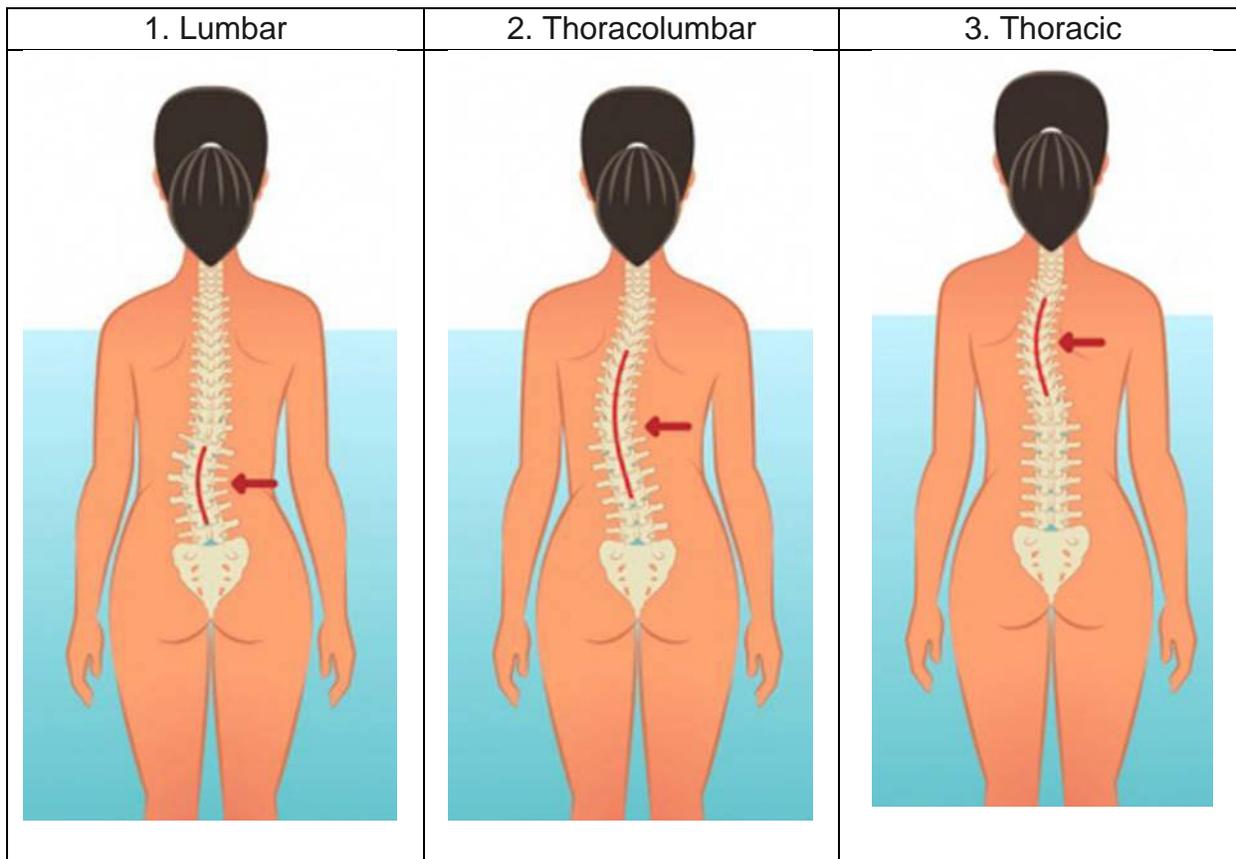
Thin regions of cartilage known as the intervertebral discs are located between the vertebrae of the spine. The vertebrae bones of the spine align so that their vertebral canals form a hollow, bony tube to protect the spinal cord from external damage.

WHAT IS ADOLESCENT IDIOPATHIC SCOLIOSIS (AIS)?

Scoliosis is a medical condition that results in an abnormal curve of the spine. Instead of growing straight, the spine develops a side-to-side curve, usually in an “S” shape. The bones of the spine may also be slightly rotated. Adolescent idiopathic scoliosis (AIS) is an abnormal curvature of the spine that spontaneously appears in late childhood or adolescence due to an unknown cause.

AIS appears during the adolescent growth spurt, a time when children are growing rapidly. In many cases, the abnormal spinal curve is stable. However, in some cases, the curve

will continue to worsen over time.¹ Below are three images showing how AIS affects the spine in the lumbar (image 1), thoracolumbar (image 2), and thoracic (image 3) regions:



Thoracic kyphosis may also be present in AIS patients. Thoracic kyphosis is when the thoracic spine (upper spine) curves causing the back to hunch at the shoulders. An image is provided below:

¹ NIH. U.S. National Library of Medicine. Adolescent idiopathic scoliosis available at: <https://ghr.nlm.nih.gov/condition/adolescent-idiopathic-scoliosis>.



SYMPTOMS OF ADOLESCENT IDIOPATHIC SCOLIOSIS (AIS)

Mild scoliosis generally does not cause pain, problems with movement, or difficulty breathing. It may be diagnosed if it is noticed during a regular physical examination or a scoliosis screening at school. The most common signs of the condition include a tilt or unevenness in the shoulders or waist. A small percentage of affected children develop a more severe spinal curve.

Scoliosis can occur as a feature of other conditions, including a variety of genetic syndromes. However, adolescent idiopathic scoliosis typically occurs by itself, without signs and symptoms affecting other parts of the body.¹

DIAGNOSIS AND TREATMENT OPTIONS

As described above, scoliosis is a condition that causes the spine to curve and is typically detected during a physical examination and imaging. There are several different types of scoliosis that affect children and adolescents, but the most common type is "idiopathic," where the exact cause is not known.

Options for managing AIS include observation with or without physical therapy, use of an external brace, and surgical treatment, typically spinal instrumentation and fusion surgery. Spinal instrumentation and fusion surgery is a surgical procedure that significantly

corrects the scoliosis curve and creates permanent rigidity in a portion of the spine. Some risks associated with spinal fusion include: decreased spinal motion, damage to the other portions of the spine, neurological complications, pain, implant breakage, and the potential need for later surgery.

The intended use of the MID-C System is to correct and stabilize a scoliosis curve without fusion. If curve correction is maintained long term, this device offers the potential to avoid spinal fusion. Potential risks associated with the MID-C System are outlined below.

WHAT IS THE MINIMALLY INVASIVE DEFORMITY CORRECTION (MID-C) SYSTEM?

The MID-C System acts as an “internal brace”. The device is intended to reduce the spinal curve and maintain improvement in the spine without the need for spinal fusion. The implant is attached to the spine with two single screws that are inserted in the vertebrae above and below the major curve. The expandable rod is attached to the screws.

The rod can expand during normal activity or physical therapy where the patient straightens their spine. After the rod extends to a longer position, it will not go back to a shorter position. The expandable rod may continue to be extended until fully expanded.

Implanted MID-C System Illustration



Sample Post-Procedure X-Ray Image of Device



WHO SHOULD BE TREATED WITH THE MID-C SYSTEM?

The MID-C System is indicated for use in adolescents with a significant single major curve of the thoracic or lumbar spine [single curves classified as Lenke 1 or Lenke 5], but not a

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backward curve of the upper back of over 55 degrees as measured from T5 to T12. Patients should also have a Cobb angle of 45 to 60 degrees which reduces to less than or equal to 30 degrees on side-bending x-ray imaging, as the implant is only intended for use in patients with flexible curves.

In addition to reading the information provided below, please speak to your physician to understand the benefits and risks associated with the MID-C System and to find out if you are a candidate for receiving the MID-C System implant.

WHO SHOULD NOT RECEIVE THE MID-C SYSTEM (CONTRAINDICATIONS)?

If you have been diagnosed with or are experiencing any of the following conditions, it is recommended that you do not receive the MID-C System:

- Any type of non-idiopathic scoliosis;
- A backwards curve of the upper back (in excess of 55 degrees measured between T5 to T12);
- Any main thoracic deformity that includes cervical to T2 vertebral levels;
- Known medical or surgical condition which would not allow you to have spinal surgery, such as infection or skin compromise at surgical site;
- Spinal cord abnormalities that require treatment;
- Abnormal function of a body area due to weaker function of the brain, spinal cord, muscles, or nerves; or
- Known poor bone quality. Tell your doctor if you have been diagnosed with a bone condition such as osteoporosis or are prone to fractures.

The surgery should not be performed if you have a known history of a cancerous growth, or any whole body infection, local infection, or skin compromise at the surgical site.

WHAT ARE THE WARNINGS ASSOCIATED WITH THE MID-C SYSTEM?

Your doctor will understand the following warnings associated with the MID-C System and should explain them to you. Ask your doctor if you have any questions or concerns, especially related to the following:

- The safety and compatibility of the MID-C System in the magnetic resonance imaging (MRI) environment is unknown.
- Metallic implants can loosen, fracture, corrode, shift, or cause pain.

WHAT ARE THE PRECAUTIONS ASSOCIATED WITH THE MID-C SYSTEM?

- Safety and probable benefit of the ApiFix MID-C System in skeletally immature patients with a Risser Grade status less than or equal to 1 have not been established.
- Patients implanted with the MID-C System should not participate in contact or high demand sports such as weightlifting, tumbling, gymnastics, rowing, or other high-risk activities.
- Your doctor should weigh the risks and benefits of using the MID-C System if you have been diagnosed with or are experiencing any of the following conditions:
 - Type 1 diabetes;
 - Heart disease or another whole body disease;
 - Bleeding disorder(s);
 - A disease of the nervous system that results in a loss of muscle coordination;
 - Documented HIV or hepatitis infection;
 - Family history of genetic disorders of the nervous system or Marfan's syndrome (a genetic disorder of the connective tissue);
 - Unable to tolerate use of anesthesia;
 - Major psychiatric disorders or a history of substance abuse.

WHAT ARE THE RISKS OF THIS TYPE OF SURGERY?

Spinal implant surgery in general has some risks. They include:

- Blood clot in the leg
- Blood clot in the lung
- Heart problems
- Pneumonia or collapse of lung tissue
- Difficulty swallowing
- Muscle disorders
- Gastrointestinal issues
- Inflammatory reaction to the implant
- Pressure sores
- Genitourinary (urinary tract infection or urine retention)
- Spinal fluid leak
- Chest tube insertion
- Infection (whole body)
- Blood disease
- Issues related to hormones

- Issues related to the liver, gallbladder, bile ducts or bile
- Issues with the immune system
- Issues with the female reproductive organs or breast
- Issues related to the eyes
- Psychological concerns
- Related surgical procedure (non-spinal)
- Wound infection (non-spinal)
- Death

THE MID-C SYSTEM CLINICAL STUDY

ApiFix conducted a prospective, multi-center, non-randomized, open label clinical study in Hungary, Romania, and Israel in twenty (N=20) subjects. The purpose of the study was to assess the safety and probable benefit of the device in AIS patients. In addition, the company also collected data in countries where the device is approved for use. A total of 252 patients outside of the United States (OUS) have been implanted with the MID-C System (as of the time of device approval for use in US). Not all patients treated OUS would have been eligible for treatment in the United States. Some OUS patients were treated with an older version of the device than the one approved for use in the United States.

The available clinical data support the reasonable assurance of safety and probable benefit of the MID-C System when used as instructed. Among all 252 patients, 17.9% had a reoperation, while 12.0% of the Target Population with the MID-C System had a reoperation. The MID-C System is determined to be safe for its indications for use considering the types of adverse events (AEs) observed. In addition, to have achieved the probable benefit of the device, a patient needed to have a major Cobb angle less than or equal to 35 degrees and could not have a curve that worsened compared to when they were treated with the MID-C System. The probable benefit success rate is 75% to 90% for the analysis populations at 24-months. This probable benefit endpoint can be considered representative of likelihood of avoidance of the need for spinal fusion during this time period.

WHAT ARE THE EXPECTED OUTCOMES AND BENEFITS OF THE MID-C SYSTEM?

The main probable benefit of the MID-C System is correction and maintenance of the patient's major spinal curve below the threshold where spinal fusion is indicated to possibly avoid the need for spinal fusion surgery. Based on the data provided, the probable benefit success rate of curve correction and maintenance below 35 degrees is greater than or equal to 75% over the 24-month duration of follow-up. Additionally, the data reports a 4.4% (11 out of 252 patients) rate of conversion to spinal fusion at some point after receiving the MID-C System, which suggests a likely probability of a patient

experiencing the benefit of avoiding spinal fusion. Other, more immediate, benefits include shorter hospitalization, and less blood loss compared to spinal fusion.

WHAT ARE THE POTENTIAL ADVERSE EFFECTS OF THE MID-C SYSTEM?

As with any surgical procedure, complications may occur when you are treated with the MID-C System. During the MID-C System clinical trial, patients in the study reported various health-related problems that could be related to the surgical procedure, the patient's physical health, or the MID-C System itself. Some of these problems were identified earlier in the Risk of Surgery section of this guide. Listed below are various adverse events that could be related to this type of device or the procedure.

- Screw/nut loosening
- Device loosening, shifting, breakage, poor positioning
- Sizing issues
- Technical difficulty with the device or the treatment site
- Inability to implant the device
- Need to correct the device during surgery
- Inadequate curve correction
- Loss of curve correction
- Curve development above and/or below the instrumented levels
- Requirement for subsequent surgical intervention
- Abnormal growth of bone in the non-skeletal tissues
- Trunk imbalance
- Interference with imaging
- Unintended spontaneous fusion
- Bone fracture
- Tearing of, or leakage from, the outer lining of the spine
- Fluid buildup near surgical site, joint inflammation, or grating, crackling or popping sounds and sensations experienced under the skin and joints
- Skin penetration by device
- Wound that does not fully close at the edge
- Bruising under the skin
- Wound infection (at skin level or deeper)
- Neurologic injury during surgery
- Injury to the arteries or veins, excessive blood loss, or low pressure that occur during surgery
- Anesthesia, airway, or ventilation related adverse events
- Nervous system injury
- Injury to internal organs
- Blood transfusion

- Allergic reaction
- Injury to the eye
- Pain (back, surgical site, other)

HOW DO I PREPARE FOR SURGERY?

Please be sure to follow your doctor's guidance as you prepare for surgery. Here is a list of topics that may be covered prior to the surgery:

- Assessment of your current condition and review of all possible options for treating your scoliosis;
- Evaluation of your overall health to ensure that it is safe for you to have surgery;
- Questions about the medicines that you are currently taking to determine if you should stop taking any of them prior to surgery;
- Instructions on drinking or eating the night before surgery;
- Confirmation that you have someone to assist you at home after surgery and that you can easily access important items you will need on a regular basis;
- The benefits of reading and understanding this entire information guide;
- Any additional questions you have about the risks and benefits of this surgery.

WHAT HAPPENS DURING A MID-C SYSTEM SURGERY?

The device is implanted with the patient lying face down under general anesthesia. The surgeon identifies the correct location for implantation using X-ray imaging and gains access to the rear of the spine while the patient is lying on their stomach. The surgeon accesses the major curve through an approximately 10-14 cm incision. Screws are inserted on both sides of the major curve. The MID-C implant is then connected to the screws. Initial curve correction may be done during surgery to initiate the correction process. The incision is then closed per standard surgical technique. The MID-C System implantation procedure usually takes about one hour.

WHAT HAPPENS AFTER MID-C SYSTEM SURGERY (PHYSICAL THERAPY)?

Three weeks after the operation, your physician will instruct you to begin a physical therapy program. The purpose of the program will be to gradually relax the soft tissue and maintain or improve the spinal correction. You, and your physical therapist, and surgeon will work together to design a physical therapy plan that caters to the specific characteristics of your condition. As an example, one option is to base your physical therapy plan on the Schroth method. The Schroth method utilizes breathing techniques, visualization, and corrective exercises designed for muscle activation to improve body awareness and treat patients with AIS. Some exercises used in the Schroth method include: hanging; leaning sideways over a chair back while sitting; side lying on a rolling

pad; standing side bends with a band; sitting in flex; and stretching outward while lying on a chair. You should discuss with your physical therapist and surgeon if any of these exercises are appropriate for you, given the characteristics of your condition. Exercises will most likely be performed two times a day for 3 months. You should not perform exercises that place undue stress on the implanted MID-C System and should consult with your physical therapist about this.

Do not push yourself too hard during physical therapy. If at any point you feel pain, stop the exercise and limit it to an extent that is not painful. If at a certain point you feel that something is uncomfortable with your spine, stop doing the exercises and consult with your physical therapist and/or physician. If the discomfort continues, consult your physician.

Post-operative follow-up visits with your doctor should be scheduled and attended to monitor your condition improvement and maintenance.

As described above, patients implanted with the MID-C System should not participate in contact or high demand sports such as weightlifting, tumbling, gymnastics, rowing, or other high-risk activities.

WHEN SHOULD I CALL THE DOCTOR AFTER SURGERY?

Some pain and discomfort after surgery is normal. Talk to your doctor about when to call regarding problems after surgery.

If you have any worsening of your curve, increased pain, surgical site infection or any other medical issue at any time after surgery, contact your doctor.

TALK TO YOUR DOCTOR

While this brochure is meant to provide you with information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice. If you have any questions about the MID-C System, please call or see your doctor, who is the only one qualified to diagnose and treat your spinal condition. As with any surgical procedure, you should select a doctor who is experienced in performing the specific surgery that you are considering.

If you have specific questions about the MID-C System, or its usefulness in your course of treatment, please contact your doctor. For additional information, please visit www.apifix.com.