Patient and Family
Information Guide

The Tether™

Vertebral Body
Tethering System

ZimVie

ZimVie SURGICAL SOLUTIONS

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Humanitarian Device. Authorized by Federal law for use in the treatment of skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with 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 be intolerant to brace wear. The effectiveness of this device for this use has not been demonstrated.

CAUTION: Federal (U.S.A.) law restricts these products to sale by or on the order of a doctor.

The Tether™

Vertebral Body Tethering System

This guide explains probable benefits and potential risks associated with having surgery using The Tether™ and answers questions you may have about vertebral body tethering and scoliosis. If you have any questions after reading this guide, you should talk to your doctor.

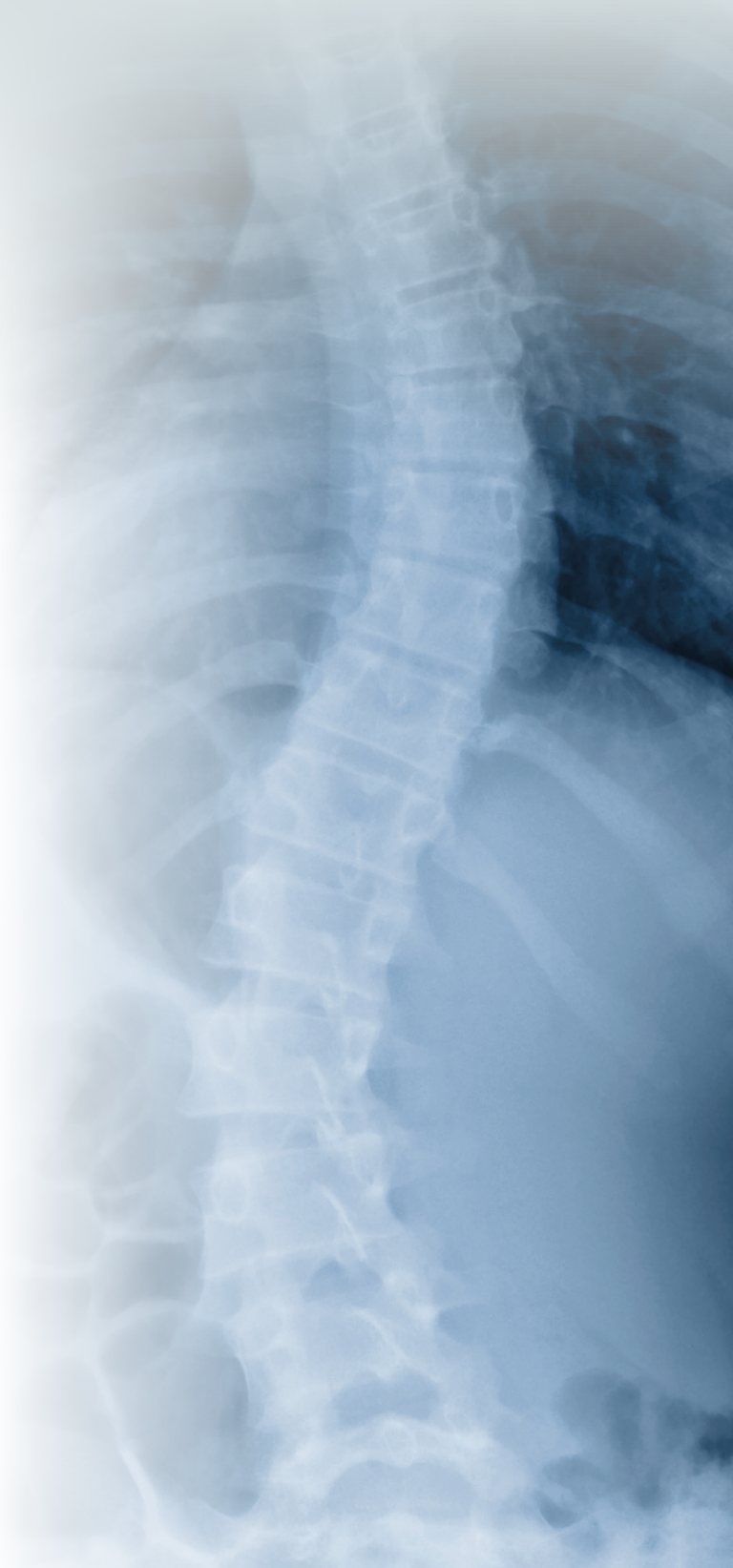
Reading this guide should not take the place of talking with a doctor.

What is Scoliosis?

Scoliosis is a sideways curvature of the spine. While the cause of the curvature is sometimes known, the most common form of scoliosis is idiopathic, which means that the cause is unknown. On an x-ray, the spine of a person with scoliosis looks more like an "S" or a "C" than a straight line. These curves can make the person's shoulders, hips, or waist appear uneven. In some cases, the curve may get worse over time. In these cases, it may be recommended to wear a brace or have surgery to prevent it from getting worse and to straighten the spine.

Scoliosis may be treated with different types of therapies, including physical therapy, bracing, and surgical fusion. Bracing is generally recommended as a first treatment to try to keep a curve from increasing over time and in some cases provides improvement. If bracing is not successful and the curve is continuing to progress, surgery may be necessary. If the curve is not treated and it continues to grow, it may impact the patient far beyond the visible unevenness. For example, the patient may have increased daily pain and lung capacity can be reduced due to the large curve, limiting the space to take a breath.

You should talk with your doctor about the risks and benefits of all available treatments to fully understand your options.



Treatment with The Tether™ – Vertebral Body Tethering System

If you are reading this brochure, your doctor has probably talked to you about The Tether as a potential treatment option for you. The Tether is different than typical scoliosis surgery, called a "spinal fusion," which involves implanting stiff metal rods along either side of your spine to straighten the undesirable curves. Rather than stiff metal rods, The Tether uses a very strong and durable, yet flexible cord to pull on the outside of the scoliosis curve to straighten out the spine. The system permanently straightens your spine using your own growth process. This process is called "growth modulation." The bones, or "vertebrae" in a scoliotic spine are wedge shaped, tall on one side and short on the other. When the vertebrae are pulled by the cord, it puts pressure on the tall side of the vertebrae on the outside of the curve. This pressure slows the growth on the tall side of the vertebrae, so that the short side can grow and catch up. After surgery, the spine may continue to straighten even more over time as you grow.

The Tether is also different from other surgical treatments for scoliosis — e.g. spinal fusion — because the spine is still able to bend and flex, rather than being fixed in place with the stiff metal rods used for spinal fusion. However, when it comes to The Tether, it is important to be treated while you are still growing, so that the implants can allow the spine to correct itself over time.

The Tether is a special category of medical device called a Humanitarian Use Device. This means that the device is specially approved for idiopathic scoliosis in young people who have scoliosis with a significant amount of growth remaining. This is a rare condition and The Tether has not been approved to help all cases of scoliosis.

The Tether has been shown to have a probable benefit. The Tether is the only medical device available that treats scoliosis while a person is actively growing and uses their own growth to correct their curve.

The Tether™ – Vertebral Body Tethering System is made up of three different parts that are used together. Each part has a different role:

TETHER COMPONENT	IMAGE	PURPOSE
The Tether Support Anchor		Circular implants placed against vertebrae to provide additional support for the bone screw.
Strong Tether Implant Assembly		The bone screws are placed into the vertebrae to capture the cord and allow the surgeon to pull each individual vertebra. The set screw (shown assembled into the top of the screw) captures the cord within the U-shaped head of the bone screw to maintain tension along the cord. Maintaining this tension is important for maintaining the surgeon's correction of the scoliotic curve.
Motion Preserving Tether Cord		After all of the screws are inserted, a cord is placed into the U-shaped head on the top of the screws.

The bone screws, set screws, and anchors are made out of titanium alloys that are common for use as spine implants. The Tether cord is made of a polymer, Sulene® PET (polyethylene-terephthalate) that your surgeon will trim based on your spine length and the size of the area to be treated. Together, these implants make up The Tether and allow your surgeon to treat your scoliosis.

When should The Tether™ – Vertebral Body Tethering System be used?

The Tether is indicated to treat skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30° to 65° whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear.

When should The Tether not be used?

The Tether should not be implanted if:

1. You have any type of infection, or if the skin on your back, or sides of your ribs and stomach, are irritated, cut or damaged.
2. You have had a previous surgery at the spinal levels where you have a scoliotic curve.
3. Your bone is soft, and clinically measured to have a T-score (bone density measurement) of -1.5 or less.
4. You are skeletally mature and have no spinal growth remaining.
5. You have any other medical or surgical condition which would not allow you to have spinal surgery, such as a problem with your blood flowing too much or too little, allergies to the implant materials, and/or an unwillingness or inability to cooperate with instructions from your doctor after surgery.

How The Tether is implanted

The surgery to implant The Tether is typically performed while you are under anesthesia and lying on your side. On the day of surgery, your doctor will first make 3-4 small to moderate incisions along your side. For thoracic curves these incisions are made in the space between your ribs. The surgeon will then gently move the closest lung out of the way, if necessary to see the affected vertebrae. The surgeon will then use specially designed instruments to place The Tether support anchors and strong Tether implant assembly in the affected vertebrae. Next the surgeon will insert the strong, motion-preserving Tether cord through one of the incisions and place it along the U-shaped heads of each bone screw. The doctor will tighten the cord between each screw in a process called "tensioning" and use set screws to secure the cord in place. Finally, the surgeon will withdraw the instruments used to manipulate the implants and close the individual incision sites.

Potential Benefits of The Tether™ Vertebral Body Tethering System

When compared with traditional spinal fusion treatment options:

- The Tether is designed to allow for motion at the levels treated.
- There may be smaller incisions required with The Tether surgical technique (less scarring).
- There may be less muscle and soft tissue disruption with The Tether surgical technique allowing for a shorter hospital stay and quicker return to normal activities including sports.

However, note that since this is a Humanitarian Use Device, The Tether has not been shown to help all cases of scoliosis. Instead, The Tether has been shown to have a probable benefit. Talk with your doctor about tethering procedures, what published literature is available, and the outcomes for other patients.

Clinical Data Summary

Spinal tethering is being studied in a 57-patient clinical trial of scoliosis patients. In this trial, one subject was found to not be eligible for the study, thus this subject was included in the safety analysis, but excluded from other analyses. This study included 48 girls and 8 boys who had a spinal tethering surgery when they were around 12 years old. Their tethering was done using a different, but similar device that was modified from the original version. The implants you may receive are new devices made specifically to be used in smaller patients. The patients enrolled in this study will see their doctor regularly for follow up appointments until they are fully grown (approximately 18 years old).

Results

- A Cobb angle is a measurement of the curvature of the spine in degrees and is commonly used evaluate the severity of a particular case of scoliosis. The Cobb angle in scoliosis patients is a minimum of 10°. The

patients in the study experienced an average of 50% reduction in The Cobb angle of their curve. These reductions ranged from 40.4° to 17.6°. On average, patients in this study saw the Cobb angle of their curve reduce by more than 50%, from 40.4° to 17.6°.

- Patients also saw a reduction in the size of their rib hump prominence from an average of 13.6° to 8.7°. Following surgery fewer patients on average reported unlevel shoulders and unlevel hips.
- When asked survey questions about their quality of life and physical functioning after surgery, patients rated their quality of life as 90.8% of maximum and physical function as 92.0% of maximum.
- When asked survey questions about their self-image and satisfaction, patients rated their self-image as a 4.4 out of 5 and satisfaction with the procedure as a 4.6

out of 5.

Complications

Spine surgery is serious, and complications are possible. The most common complications seen in this study were back pain, overcorrection of the curve, nausea/vomiting, pain in the arms or legs, the need for additional surgery, and temporary numbness along the side of the chest or hip. Overcorrection occurs following surgery when the curve becomes perfectly straight and then keeps correcting in the opposite direction. Your doctor will monitor your curve carefully with x-rays to determine if overcorrection is happening. If the overcorrection gets too large, an additional surgery can be performed to treat this problem by loosening or cutting the cord. This surgery is often less invasive than the original surgery and has a quicker recovery time.

In this study eight (8) of the fifty-seven (57) patients had an additional surgery. Five (5) of the eight (8) patients had surgery to fix over corrections, one surgery was performed because the cord broke before the patient finished growing, one surgery was due to the patient developing a new curve in another area of her spine, and one surgery was due to a slippage in the spine that was unrelated to the tethering procedure and caused the spinal canal to narrow.

Conclusions

This study shows that there is a likely benefit of surgery with The Tether, however complications are possible. Should you have more questions,

Potential Risks and Adverse Events

Complications may occur when you are treated with The Tether, as with any surgery. Possible complications may include those listed below, but there may be others that haven't been seen to date. Please ask your doctor if you are experiencing or have questions about the following risks:

Risks specific to the The Tether™– Vertebral Body Tethering System or surgery:

- 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 atelectasis, 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, bending, 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
- Material sensitivity reactions and/or particulate wear debris

Risks from any surgery:

- Deep vein thrombosis
- Pulmonary embolism
- Atelectasis, pneumonia
- Cardiac AEs
- 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

There is also the risk that the surgery may not be effective in correcting the spinal curve or may cause worsening of the curve. If this occurs, you may need another surgery to help you feel better.

A full list of risks is provided in the package insert for the device, which your doctor has received. Please ask your doctor for more information about any additional risks that could be related to your planned surgery.

There may be other potential adverse events that are unforeseen at this time.

Frequently Asked Questions

What is the post-op recovery period?

Most patients spend one day in an intensive care unit and four (4) more days in the hospital. Pain medication is prescribed when you leave the hospital, but most patients find they only need this for a week or two. These recovery times depend on how well you do during surgery and whether or not you have complications. Ask your doctor about the appropriate recovery period for you.

How active can I be after Surgery?

As long as you are healing well, it is possible that you can go back to physical activity and playing sports in four (4) weeks with your doctor's permission. Before returning to these activities, it is important to consult with your doctor to make sure this is appropriate as everyone recovers differently. Your doctor will tell you what types of exercise and sports you can play and when you can start. You should pace yourself with resuming activities as you feel better and refrain from strenuous activity until your doctor clears you for that level of physical activity.

How soon can I return to school or work?

Most patients go back to school after two (2) weeks. Your doctor will let you know when it is safe to do so.

What if I have pain after surgery?

Immediately after surgery, the recovery process can be uncomfortable. However, if you experience pain, inform your doctor.

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

Just as some people have adverse reactions to certain foods, some people may have a reaction to other materials like certain metals. If you are aware of any adverse or allergic reactions to titanium alloy, it is important that you make sure your doctor is aware before surgery. If you believe you are having a reaction after surgery, you should inform your doctor immediately.

Can I walk through metal detectors or security with The Tether™ – Vertebral Body Tethering System?

Yes. You may walk through metal detectors or security scan with The Tether. Implants made from titanium alloy do not typically set off airport security. However, the Transportation Security Administration (TSA) rules state, "TSA Security Officers will need to resolve all alarms associated with metal implants."

Always follow the medical advice of your doctors and specialists.

Learn more about The Tether
at **MyScoliosis.com**

Manufactured by:
Zimmer Biomet Spine, Inc.
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ZimVie
Restoring Daily Life®

RISKS: Common post-operative surgical risks include overcorrection of instrumented curve, cord breakage, nausea, vomiting, and bone screw migration.

CONTRAINDICATIONS: The Tether is not appropriate for patients who have reached skeletal maturity, have poor bone quality, or who have a systemic or local infection at the surgical site.

Indications, contraindications, warnings, precautions, and the directions for use can be found in the product's Instructions For Use (IFU) manual.

Not an actual patient. Results are not necessarily typical, indicative, or representative of all recipient patients. Results will vary due to health, weight, activity and other variables. Not all patients are candidates for this product and/ or procedure. Only a medical professional can determine the treatment appropriate for your specific condition. Appropriate post-operative activities will differ from patient to patient. Talk to your surgeon about whether vertebral tethering is right for you and the risks of the procedure, including the risks of infection, implant wear, loosening, breakage or failure, any of which can require additional surgery. For additional information or to find a surgeon near you, visit www.myscoliosis.com.