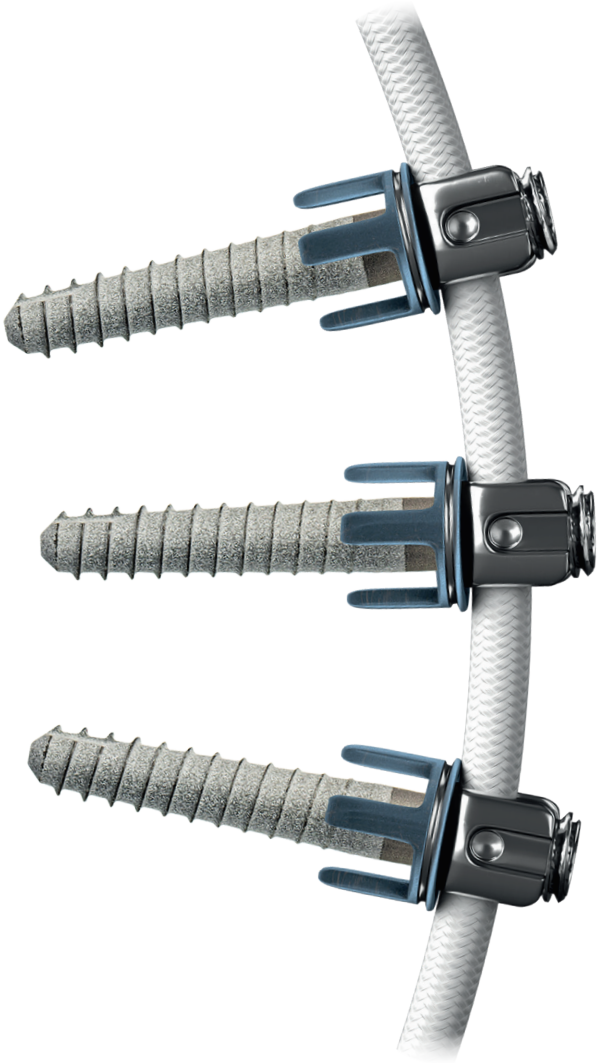
A new choice for
idiopathic scoliosis surgery

The Tether™

Vertebral Body Tethering System



ZimVie

Treatment options for paediatric patients suffering from idiopathic scoliosis are limited.

For patients with progressive scoliosis that have failed bracing or become intolerant to brace wear, the most common surgical option is spinal fusion.

While spinal fusion has proven to be a successful treatment option, it is not without its drawbacks. Reported clinical challenges include limited motion and arrested growth at the levels treated, and disc degeneration in adulthood at adjacent levels.[1-2]

For patients that would otherwise be treated with spinal fusion, The Tether Vertebral Body Tethering System may now offer an alternative option.

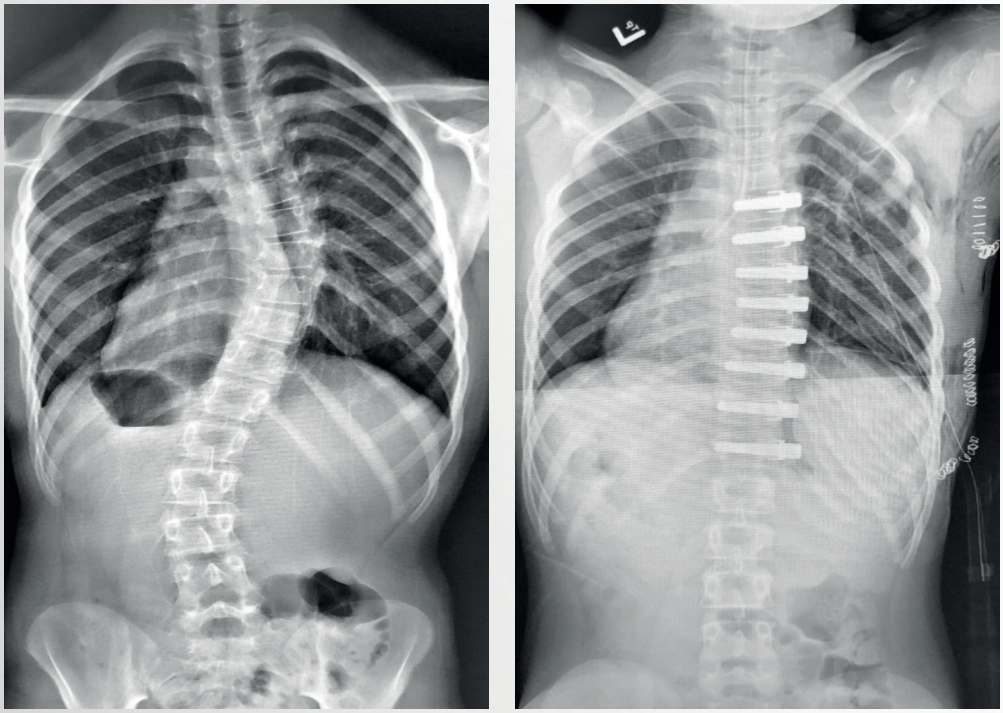
Why Vertebral Body Tethering?

Vertebral Body Tethering is an innovative treatment option for idiopathic scoliosis that is designed to correct and prevent spinal curve progression.

Unlike spinal fusion, Vertebral Body Tethering replaces stiff metal rods with a flexible cord designed to offer greater post-operative mobility, continued spinal growth and secondary curve correction based on the Heuter-Volkmann Law.[3,4]

As spinal mobility is inherent to the concept of Vertebral Body Tethering, it is intended to allow paediatric patients to continue or return to activities that might otherwise be difficult following spinal fusion.

Vertebral Body Tethering is also typically performed via a less invasive thoracoscopic approach, associated with shorter operating times, reduced intraoperative blood loss, and quicker return to normal activities.[5,6]



Before

After

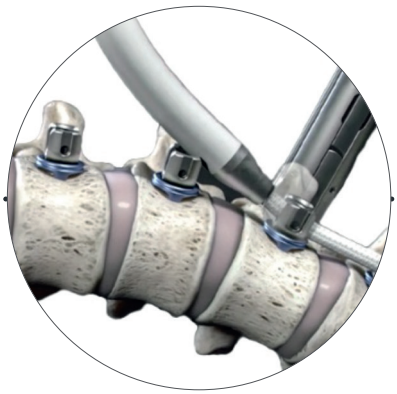
Surgery is performed via a **minimally invasive** thoracoscopic approach.

How does The Tether work?

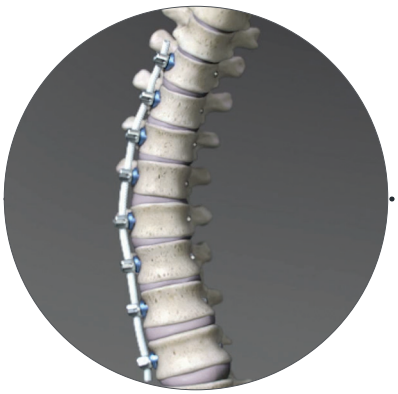
The Tether is intended to treat skeletally immature patients with a main thoracic curve (Lenke Type 1) with a major Cobb angle of 30° to 65° whose osseous structure is dimensionally adequate to accommodate screw fixation.

Pre-op

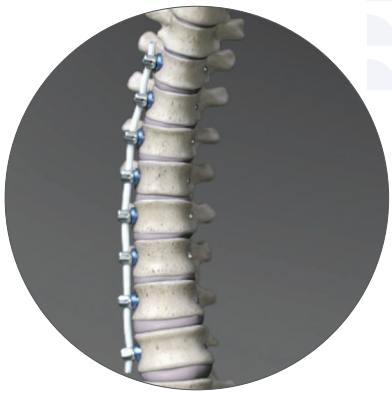
Anchor
An anchor and bone screw are placed on the convex side of each vertebral level of the deformity.



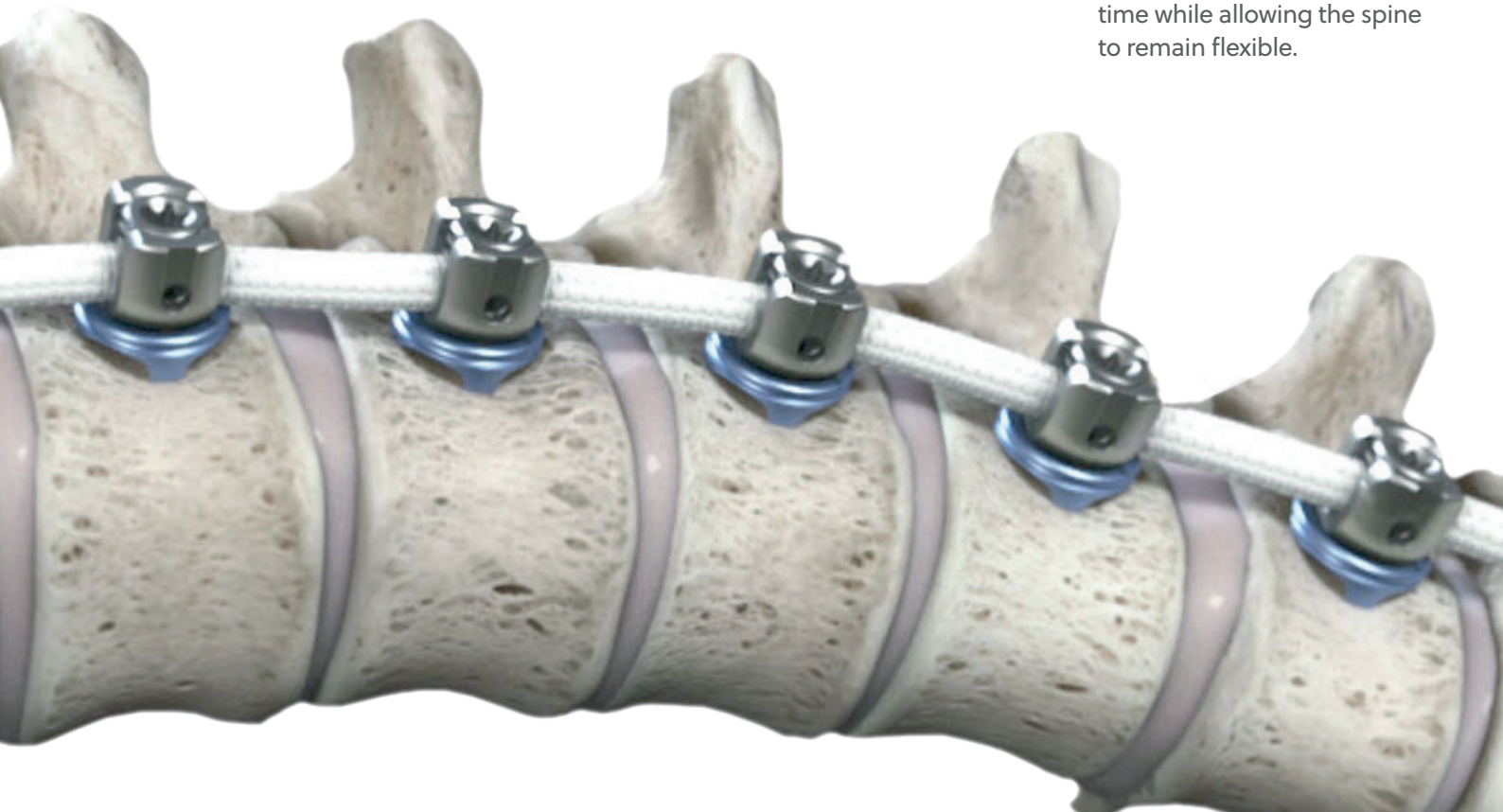
Cord
A strong and flexible polyethylene terephthalate cord is tensioned and secured to connect the levels of the construct.



Immediate post-op
The resulting construct creates a lateral tension band parallel to the curve that is designed to provide initial correction and prevent spinal curve progression.

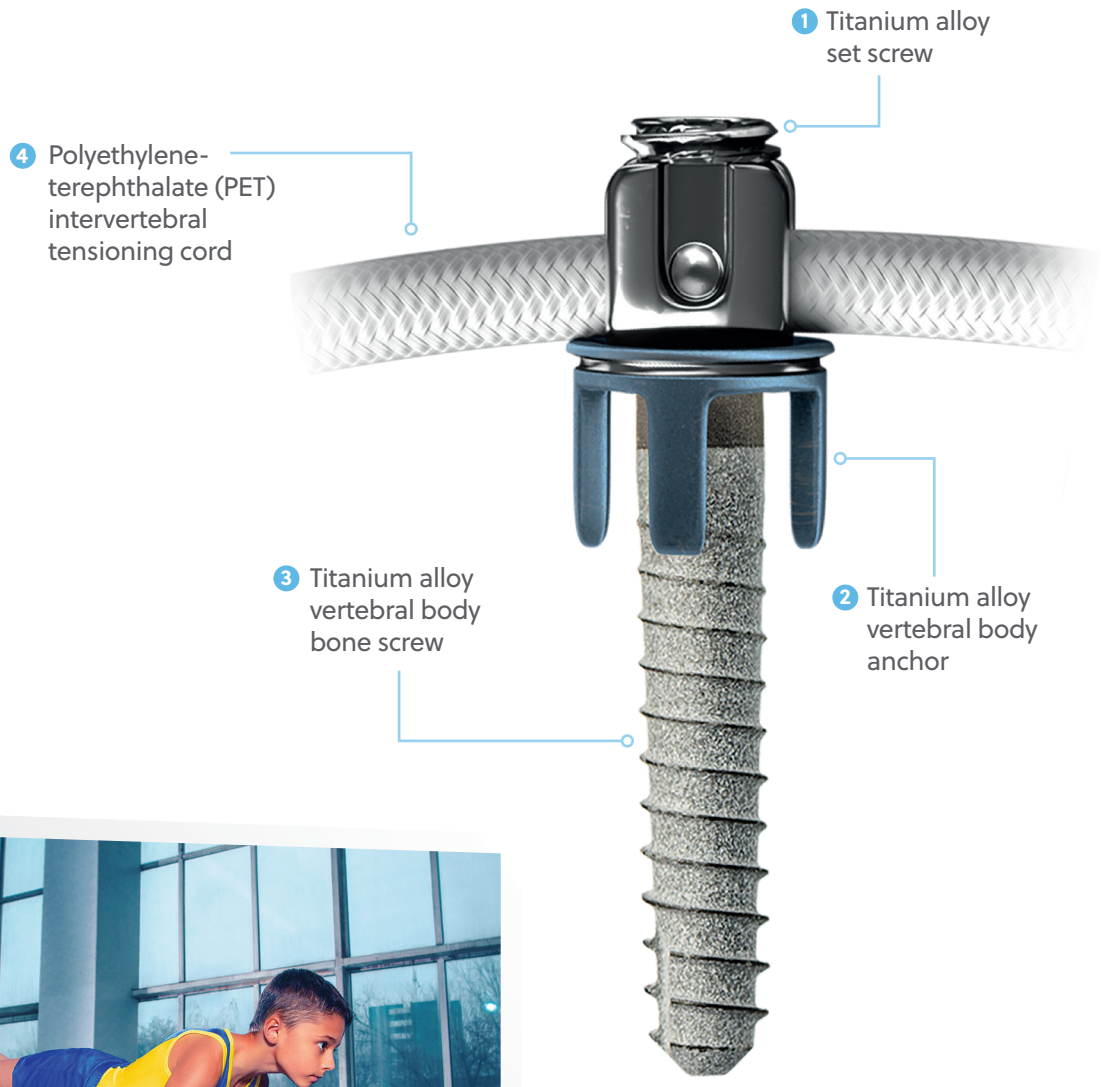


Growth
The residual compressive forces of The Tether are intended to modulate future growth via the Hueter-Volkmann Law[3], providing additional correction over time while allowing the spine to remain flexible.



About The Tether

The Tether instrumentation has been designed to accommodate both a thoracoscopic approach or a mini open procedure (thoracotomy), as per surgeon preference.



The Tether comprises of four main components:

1. Set Screw

- Reverse buttress thread to minimize risk of loosening
- T20 drive feature to maximize instrument endurance.

2. Bone Screw

- Top loading design for ease of cord insertion
- Cannulated. Allows insertion over a guide-wire, if preferred
- HA coated to improve bony contact and adherence[7]
- Designed to fit smallest anatomies. Available in Ø5.5, Ø6.0, Ø6.5 and Ø7.0 and lengths from 20 mm to 60 mm in 2.5 mm increments
- Tip designed to allow bicortical purchase

3. Body Anchor

- Three straight tines to increase construct stability
- Single anchor accommodates all bone screw diameters

4. Tensioning Cord

- Flexible cord made of polyethylene-terephthalate (PET)
- Different, easily identifiable, zones in the cord designed to facilitate insertion and preserve implant performance

Patient selection

When determining the suitability of The Tether for a patient that has failed or become intolerant to bracing, consideration should be given to a number of criteria:

- Type of scoliosis
- Pre-operative Cobb angle
- Curve type(s)
- Spine flexibility
- Skeletal maturity
- Anticipated growth potential

Clinical Outcomes

As with any emerging treatment concept, the clinical evidence for Anterior Vertebral Body Tethering (AVBT) remains limited. However, ZimVie conducted a single-center, non-randomized, Food and Drug Administration (FDA) Investigational Device Exemption (IDE) study[8] to assess the safety and probable benefit of AVBT. A first-generation spinal tethering device equivalent to The Tether was used to treat 57 skeletally immature patients with idiopathic scoliosis.

Assessment of Safety

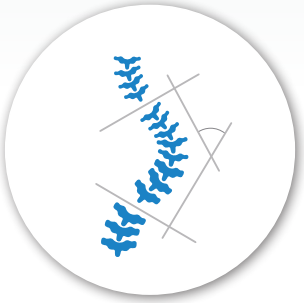
- The most commonly reported device or procedure-related adverse events (AEs) were overcorrection of the instrumented curve (21%; 12 patients) and definite or suspected cord breakage (14%; 8 patients).
- Nine (9) AEs in 8 patients (14%) were deemed serious (SAEs).
- Nine (9) secondary surgeries were required in 8 patients (6 overcorrection, 1 cord break, 1 progression of new curve, and 1 lumbar spondylolisthesis).
- 1/57 patients (1.7%) required conversion to fusion within the study period.

Patient Satisfaction and Self-Image

SRS-22 self-assessments of function, pain, self-image, and mental health indicated overall patient satisfaction and positive outcomes following AVBT.

> To ensure the safe and effective use of The Tether, ZimVie offers a programme of medical education training via the ZimVie Institute. Additional information and details of training modalities can be found at **www.MyScoliosis.com**

Assessment of probable benefit and physical outcomes from the FDA IDE study



- The average main thoracic Cobb angle **improved from 40.4° before surgery to 14.3°** at 24 months post-op (65% improvement).

- **Scoliometer measurements showed 36% and 45% improvements** in axial trunk rotation of the thoracic and thoracolumbar regions, respectively, from preop to last visit (mean 51.3 months).

- **100% of patients with pre-op Cobb angle >45° were considered a study success,** defined as major Cobb angle of ≤ 40° at 24 months post-op.

> The success rate at the last visit (mean 49.8 months) was 92.8%.

Common Post-Op Surgical Risks:

- Pain in the back, neck, extremities and chest
- Nausea/vomiting
- Overcorrection of instrumented curve
- Inadequate curve correction
- Cord breakage
- Development of new curves
- Spondylolisthesis
- Bone screw migration
- Numbness or tingling
- Lung collapse or fluid on the lungs

Contraindications: The Tether is not appropriate for patients with the following conditions:

- Presence of any systemic infection, local infection or skin compromise at surgical site
- Prior spinal surgery at level(s) to be treated
- Known poor bone quality defined as a T-score of -1.5 or less
- Skeletal maturity
- Any medical condition which would preclude the potential benefit of spinal surgery

Our complete portfolio of spinal solutions

At ZimVie Spine, we understand Vertebral Body Tethering is a potential option for a subset of scoliosis patients. Thus, we are proud to deliver a complete line of comprehensive spinal solutions that can accommodate patients that might not be eligible for The Tether.

Vital™ Deformity Spinal Fixation System and Vital™ Power Instrument Kit

The Vital Spinal Fixation System addresses the modern demands of surgeons treating complex spinal pathologies. The system is designed to be a comprehensive solution for rigid spinal fixation, from the thoracic spine to the ilium with the possibility to accommodate 5.5 and 6.0 rods and with specific instruments for deformity correction. The addition of powered pedicle preparation is a tremendous benefit to surgeons, as compared to traditional hand-driven pedicle preparation and insertion.

For more information about these options and the rest of ZimVie's spine portfolio, please visit **www.ZimVie.eu/en**

Universal Clamp® Spinal Fixation System

Provides a stable interface between spinal anatomy and the rod through a pedicle-sparing band passage technique. The result is a spinal implant system that is intended to provide segmental stability and allows compression, distraction, derotation and translation while sparing the pedicles and reducing implant/bone contact stress. It can work alongside hooks, screws and wires, enabling surgeons to perform translation, reduction, distraction and compression in situ.

Polaris™ 5.5 Deformity System

This pedicle screw fixation system is well appointed thanks to an efficient combination of Rod Reduction and Vertebral Body Derotation specific instruments. Such combination allows an innovative posterior three-dimensional spinal deformity correction technique.

Polaris™ 4.75 Deformity System

This system is designed to satisfy the need of the smallest anatomies, with universal hooks for costo-transversal fixation, growing rod connectors and iliac saddles the system can help in the most complex cases of the smallest anatomies.

References

1. Pehlivanoglu T, Oltulu I, Erdag Y, et al. Comparison of clinical and functional outcomes of vertebral body tethering to posterior spinal fusion in patients with adolescent idiopathic scoliosis and evaluation of quality of life: preliminary results. Spine Deform 2021;[Online ahead of print]. doi: 10.1007/s43390-021-00323-5.
2. Kepler CK, Meredith DS, Green DW, et al. Long-term outcomes after posterior spine fusion for adolescent idiopathic scoliosis. Curr Opin Pediatr 2012;24(1):68-75.
3. Castro Fp. Adolescent idiopathic scoliosis, bracing, and the Heute-Volkmann principle. Spine J 2003;3(3): 180-185.
4. Miyanji F, Pawelek J, Nasto LA, Rushton P, Simmonds A, Parent S. Safety and efficacy of anterior vertebral body tethering in the treatment of idiopathic scoliosis. Bone Joint J. 2020 Dec;102-B(12):1703-1708.
5. Newton PO, Bartley CE, Bastrom TP, et al. Anterior Spinal Growth Modulation in Skeletally Immature Patients with Idiopathic Scoliosis: A Comparison with Posterior Spinal Fusion at 2 to 5 Years Postoperatively. J Bone Joint Surg Am 2020;102(9):769-777.
6. Baroncini A, Trobisch PD, Berrer A, Kobbe P, Tingart M, Eschweiler J, Da Paz S, Migliorini F. Return to sport and daily life activities after vertebral body tethering for AIS: analysis of the sport activity questionnaire. Eur Spine J. 2021 Jul;30(7):1998-2006.
7. Data on file at Zimmer Biomet – The Tether Surface Coating Review – ETR-00250 – 07Dec2018.
8. The Tether Vertebral Body Tethering System Instructions for Use. IFU0021-0117_Rev 2.

For more information visit ZimVie.com

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