The Tether™

Vertebral Body Tethering System

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℞ only

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.

Commonly Used Symbols for Medical Devices
Note: Refer to the individual package label for symbols applicable to the product.

SYMBOL	DEFINITION
	Manufacturer
	Date of manufacture
	Use by date
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
Ø	Diameter
	Consult instructions for use
	Caution: Consult accompanying documents
MR	MR conditional
NON STERILE	Non-sterile
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
QTY	Quantity per package
LOT	Batch code
REF	Reference
EC REP	Authorized representative in the European Community
℞ only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

DEVICE DESCRIPTION

The Tether™ – Vertebral Body Tethering System is a non-fusion spinal device intended for treatment of idiopathic scoliosis. Anchors and vertebral body screws are placed laterally from a thoracoscopic or thoracotomy approach into the vertebral body on the convex side of a spinal deformity. A SULENE® polyethylene terephthalate (PET) tensioning cord is secured to the vertebral body screws with set screws to connect the levels of the construct. The device provides a lateral tension band across the convex side of the spine that, on insertion and tensioning, partially corrects the curvature, and subsequently can arrest or correct the deformity through modulation of remaining spinal growth. In addition, the subject system includes instrumentation for insertion, manipulation, and removal of the implants.

MATERIALS

The Tether™ - Vertebral Body Tethering System is manufactured from:

- Anchors: Ti 6Al-4V ELI titanium alloy per ASTM F136
- Set Screws: Ti 6Al-4V ELI titanium alloy per ASTM F136
- Bone Screws: Ti 6Al-7Nb titanium alloy per ISO 5832-11 with an hydroxyapatite coating per ISO 13779-2
- Cord: Sulene® PET (polyethylene-terephthalate)
- Instruments and Cases: Generally comprised of aluminum, stainless steel, titanium alloy, and/or polymeric materials

INDICATIONS FOR USE

The Tether™ - Vertebral Body Tethering System is indicated for 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.

CONTRAINDICATIONS

The Tether™ - Vertebral Body Tethering System should not be implanted in patients with the following conditions:

1. Presence of any systemic infection, local infection, or skin compromise at the surgical site;
2. Prior spinal surgery at the level(s) to be treated;
3. Known poor bone quality defined as a T-score -1.5 or less;
4. Skeletal maturity;
5. Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patients unwillingness or inability to cooperate with post-operative care instructions.

PREOPERATIVE PROCEDURE

The surgeon is responsible for being familiar with the indications, contraindications, system/procedure risks, and surgical technique to ensure proper treatment, patient selection, and postoperative care when using The Tether™ - Vertebral Body Tethering System. The patient must be an acceptable surgical risk, and appropriate for vertebral body tethering based on consideration of various factors such as preoperative Cobb angle, curve flexibility, curve type(s), curve location(s), skeletal maturity, and anticipated growth, among others. Examination and evaluation of the individual patient anatomy is necessary to plan the appropriate surgical procedure and technique. Due to smaller vertebral body size and variable venous anatomy, caution should be observed if extending instrumentation proximal to T5.

Zimmer Biomet Spine does not specify the maximum number of times a re-usable instrument may be re-used. The useful life of these instruments is highly dependent on a number of factors including the frequency and manner in which they are used and the handling they experience in between uses. Inspection and, where appropriate, functional testing prior to instrument use is the best way to determine whether or not an individual device should be used. Review and inspect all instrumentation and implants prior to use. Replace or add any needed components for the planned surgery.

Use of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments. Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, instruments should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.

OPERATIVE PROCEDURE

For surgical placement of The Tether™ - Vertebral Body Tethering System, patients are positioned in the lateral decubitus position with the convex side of the curve to be instrumented facing upwards. As most idiopathic thoracic curves are convex towards the right side, a left lateral decubitus position will be the most common position utilized for instrumentation of thoracic curves. For recommended surgical site preparation, positioning, and technique details, please see the Surgical Technique Guide. For thoracoscopic surgery, standard anesthesia protocol should be observed. However, it is recommended to use a single lung ventilation technique such as a double-lumen endotracheal tube to aid surgical exposure if necessary. Anchor use is recommended at all levels. Consideration should be given to the osseous structure at each level to determine if both a bone screw and anchor are needed to adequately support the construct and anticipated loads. Please refer to the Surgical Technique Guide if implant removal is required (including revision). Close wound(s) and apply wound dressing using standard techniques.

POSTOPERATIVE CARE

It is critical that patients follow all postoperative instructions provided by care providers including recommendations regarding medications, home care, surgical wound dressings and activity limitations. The patient must be warned to avoid falls or sudden jolts. Failure to follow postoperative instructions could lead to impaired wound healing, injury to neurologic structures or failure to achieve desired curve correction.

Optional protective bracing may be used for up to six months after surgery depending on patient factors such as bone quality and activity levels. Bracing may provide additional support for patients who are overcorrecting or have a suspected or confirmed cord break. Use of The Tether does not preclude the need to brace compensatory curves.

WARNINGS

1. Do not rotate the screw counterclockwise after insertion. This will reduce stability of the implant in the vertebral body.
2. New or increasing coronal angulation between consecutive screws as seen on radiographs may indicate tether breakage. Tether breakage may be associated with loss of correction, overcorrection or may have no clinical significance.
3. Never use titanium alloy(s) with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
4. When tensioning the construct, special consideration should be given to patients with considerable growth remaining (e.g. open triradiate cartilage), lower magnitude Cobb angles, and/or high flexibility as excessive tension may increase the risk of overcorrection.
5. The Tether™ - Vertebral Body Tethering System must not be used with vertebral components or instruments from other manufacturers. Specialized instruments are designed for Zimmer Biomet Spine implant systems to aid in proper implantation. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure.
6. Surgical instruments are subject to wear with normal usage. Instruments with cutting functions or points may become dull with normal use and no longer perform as intended. Instruments that have experienced extensive use are susceptible to fracture.
7. Do not modify instruments. Do not notch, bend, or reshape instruments. Notches, scratches or other damage and/or wear in the instrument occurring during surgery may contribute to breakage. Do not use an instrument that has become bent from its original shape as this will affect the performance of the instrument. Bent instruments should be disposed of by a Zimmer Biomet Spine representative or according to hospital procedures.
8. The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments.
9. Proper handling of the instruments and implants before and during the operation is crucial. Do not apply excessive force; misuse can damage instruments or implants.

PRECAUTIONS

1. Due to smaller vertebral body size and variable vascular anatomy, caution should be observed if extending instrumentation proximal to T5.
2. Care should be taken when using instruments over a guidewire to avoid unintentional advancement of the guidewire which could result in damage to vessels, spinal cord, or lungs.
3. Extreme caution must be taken to avoid damage to vessels, spinal cord, or lungs during placement of instruments and implants.
4. The Tether™ - Vertebral Body Tethering System is intended to be used by surgeons specialized in spinal surgery with thorough knowledge of vertebral anatomy, regional vertebral morphology, and biomechanical principles of the spine. The surgical procedure is technically demanding and presents a risk of serious injury to the patient. It is advised that the surgeon also be thoroughly familiar with the surgical techniques, equipment, and instruments related to the use of the device. The surgical technique guide may be obtained by contacting Zimmer Biomet Spine Customer Service (contact information is provided below).
5. Risks associated with spine surgery, neurosurgery, general surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is recommended that the advantages and disadvantages of using The Tether™ - Vertebral Body Tethering System, as well as alternative treatment methods, are explained to the patient.
6. The cord implant is made up of three-segments: The Introduction Zone, the Working Zone, and the Functional Zone. Only the Functional Zone may be implanted into the patient.
7. Correct selection and placement of the implants is critical. Implant selection must be based upon the levels to be treated as well as the patient's weight and height.
8. Perform a careful preoperative review to be sure that all necessary implant components are available and that the instrument set is complete and in working order prior to initiating surgery.

9. Before use, inspect all instrumentation for possible damage, wear, or non-function. Damaged or defective instruments should not be used or processed. Contact your local Zimmer Biomet Spine representative or distributor for repair or replacement.
10. Do not reuse single-use devices such as implants. While a single-use device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the single-use device. Do not treat patients with single-use devices that have been in contact with a different patient.
11. All trial, packaging, and instrument components must be removed prior to closing the surgical site.
12. Unless otherwise indicated, instruments are supplied NON-STERILE and must be thoroughly cleaned and sterilized prior to use. Instruments that are not clean may not be effectively sterilized.
13. Automated cleaning using a washer/disinfector alone may not be effective for complex orthopaedic instruments with lumens, cannulations, blind holes, mated surfaces and other features.
14. Do not clean soiled instruments while in polymer or metal trays.

MRI SAFETY INFORMATION

Non-clinical testing and electromagnetic simulations demonstrated that The Tether™ - Vertebral Body Tethering System is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla only.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system.
- When other methods of supplemental fixation are used, also follow the MR conditional labeling for the additional components.

Under the scan conditions defined, The Tether™ - Vertebral Body Tethering System is expected to produce a maximum temperature rise less than 2.5ºC after 15-minutes of continuous scanning.

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. In non-clinical testing, the shape of the expected artifact follows the approximate contour of The Tether™ - Vertebral Body Tethering System and extends radially up to 43 mm from the implant in tests performed in accordance with ASTM F2119.

POSSIBLE COMPLICATIONS

Below is a list of the potential adverse effects (i.e., complications) associated with the use of the device.

Potential Device or Procedure-related Adverse Events (AEs)

- 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

Systemic AEs

- 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

For the specific adverse events that occurred in the clinical study, please see the “Summary of Clinical Experience” section below.

PACKAGING

Non-sterile components are packaged in metal sterilization cases and/or sealed polyethylene bags. Sterile implants will be packaged individually or with other components. Sterile packaging will include double pouches or blisters and shrink-wrapped boxes. The sterile packaging has been designed to maintain sterility unless the package has been opened or damaged or the seal is otherwise broken. Check packages to ensure all components are intact upon receipt. Check all sets and confirm that all instruments and implants

are present. Inspect all set components for functionality to ensure there is no damage prior to use. Immediately return any damaged packages or products to the manufacturer without using them.

HANDLING AND STORAGE

The Tether™ - Vertebral Body Tethering System implants and instruments must be handled, stored, and opened in such a way that they are protected from inadvertent damage or contamination. The sterile implants of The Tether™ - Vertebral Body Tethering System have a shelf life of five years. The aging process has no observed effect on the mechanical performance of the materials. Verify the proper function of the specialized surgical instruments needed for The Tether™ - Vertebral Body Tethering System prior to every surgical procedure.

RESPONSIBILITIES OF THE USER

Cleaning

The health care facility is responsible to ensure that conditions essential to safe handling and cleaning can be achieved. ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance. Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Care should be taken to avoid penetrating or cutting injuries. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers. Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.

Sterilization

The health care facility is responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities provides guidelines for preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

CARE AND HANDLING OF INSTRUMENTS

Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including, but not limited to, the following: prolonged use; misuse; and rough or improper handling. Care must be taken to avoid compromising the performance of the surgical instruments and instrument cases. To minimize damage and risk of injury, the following should be done:

- Visually inspect the instrument case and instruments for damage upon receipt and after each use and cleaning. Instruments in need of repair should be returned to the manufacturer. Instruments returned to Zimmer Biomet Spine or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities provides guidelines for return or contact Zimmer Biomet Spine and/or your distributor for further instruction.
- Only use an instrument for its intended purpose.
- When handling sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
- Alkaline detergents with pH ≤ 12 may be used to clean stainless steel and polymer instruments; however, it is critical that alkaline cleaning agents are thoroughly neutralized and rinsed from devices. The use of alkaline cleaning agents might be corrosive to the surface of aluminum and titanium instruments. Drill bits, reamers, rasps and other cutting devices should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Do not stack instruments or place heavy instruments on top of delicate devices.
- Saline and cleaning agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
- Descaling agents that include morpholine should not be used in steam sterilizers. These agents leave residue which can damage polymer instruments over time. Steam Sterilizers should be descaled in accordance with the manufacturer's instructions.
- Repeated processing according to these instructions has minimal effect on reusable manual instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
- Polymers used in instrument sets can be sterilized using steam/moist heat. If polymer surfaces turn "chalky," show excessive surface damage (e.g. crazing or delamination), or if polymer devices show excessive distortion or are visibly warped, they should be replaced. Notify your Zimmer Biomet Spine representative if polymer devices need to be replaced.
- Most currently available polymers will not withstand conditions in washers/sterilizers that operate at temperatures equal to or greater than 141°C / 285°F, and use live-steam jets as cleaning features. Severe surface damage to polymer instruments may occur under these conditions.
- Stainless steel instruments may be treated with rust removal agents approved for surgical instruments if needed.
- Titanium and titanium alloy instruments are especially susceptible to discoloration from steam impurities and detergent residues which form multi-colored surface layers of oxide deposits. Upon repeated sterilization, these oxide layers, while not harmful to the patient, may become dark and obscure graduation marks, item and lot numbers, and other stamped or etched information. Acidic, anti-corrosion agents may be used to remove this discoloration as needed.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments.

CLEANING

Implants

Implants should not be cleaned. The Tether™ - Vertebral Body Tethering System bone screws, set screws, and cord are provided sterile. The anchors must be sterilized before use. If an implant is soiled and/or contaminated, it should be discarded according to standard biohazard disposal procedures. All implants must be inspected prior to use for damage or wear. If damage or wear is noted, do not use and contact customer service or your Zimmer Biomet Spine representative for a replacement.

Instruments
The Tether™ - Vertebral Body Tethering System instruments are supplied non-sterile and must be sterilized before use. Before sterilization, instruments must be cleaned using the following procedures:

Caution: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments. Such cleaning solutions should not be used unless instructed in the Surgical Technique Guide.

Note: *Some instruments require disassembly prior to cleaning.*

A. Point-of-Use Preparation for Reprocessing
Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Note: *Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.*

For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk. Do not place soiled instruments back into the instrument case.

B. Preparation before Cleaning
Where applicable, multi-component instruments must be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components. If a part is lost, notify your Zimmer Biomet Spine representative when the instrument set is returned.

C. Preparation of Cleaning Agents
Neutral pH, enzymatic, and alkaline cleaning agents with low foaming surfactants are recommended. Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing. Only agents with proven efficacy (FDA approved, VAH listed, or CE mark) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, Zimmer Biomet Spine does not recommend any specific brand. Agents used during the validation of these processing instructions are: Steris®, Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner, Prolystica® 2X Concentrate Neutral Detergent, neodisher® FA Alkaline Detergent, and neodisher® Z Acid Neutralizer. All cleaning agents should be prepared at the use dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents. Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments and to ensure correct concentration. Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Note: *It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically for breakdown of fecal matter or other organic contaminants and may not be suitable for use with orthopaedic instruments.*

D. Cleaning Instructions
1. Completely submerge the instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak and sonicate for 10 minutes at 40-50 kHz. If using enzymatic cleaning agents, use a soft nylon bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush (i.e. pipe cleaner).

   Note: *Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.*

   Note: *While cleaning the cord tensioner, move the tensioner rack in and out while removing soil. Continue cleaning steps with the tensioner rack in the fully out position. See The Tether™ - Vertebral Body Tethering System Surgical Technique Guide for images.*

   Note: *Ensure the Anchor Inserter is fully disassembled to allow for adequate cleaning.*

2. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.

3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The minimum parameters in Tables 1 and 2 are essential for thorough cleaning

   Note: *The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g. CE mark, FDA clearance/approval, and validation according to ISO 15883) should be used.*

Table 1 - Typical U.S. Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	2-minute prewash with cold tap water
2	20-second enzyme spray with hot tap water
3	1-minute enzyme soak
4	15-second cold tap water rinse (X2)
5	2-minute detergent wash with hot tap water (64-66°C/146-150°F)
6	15-second hot tap water rinse
7	2-minute thermal rinse (80-93°C/176-200°F)
8	10-second purified water rinse with optional lubricant (64-66°C/146-150°F)
9	7- to 30-minute hot air dry (116°C/240°F)

Table 2 - Typical European Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	5-minute pre-rinse with cold tap water
2	10-minute alkaline cleaning agent wash at 55°C
3	2-minute rinse with neutralizer
4	1-minute rinse with cold tap water
5	Cleaning at 93°C with hot purified water until A0 3000 is reached (approximately 10 minutes)
6	40-minute hot air drying at 110°C

4. Proceed to Inspection, Maintenance, Testing and Lubrication.

INSPECTION, MAINTENANCE, TESTING AND LUBRICATION

1. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
2. Visually inspect for completeness, damage and/or excessive wear.

   Note: *If damage or wear is noted that may compromise the function of the instrument, contact your Zimmer Biomet Spine Representative for a replacement.*
3. Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
4. If necessary, hinged, rotating, or articulating instruments can be lubricated with an instrument product (e.g. Instrument Milk or equivalent lubricant) specifically designed for compatibility with steam sterilization.

   Note: *Lubricants not specifically designed for compatibility with steam sterilization should not be used because they may: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.*
5. Check instruments with long slender features (particularly rotating instruments) for distortion.
6. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

STERILIZATION PACKAGING AND CONTAINERS

Packaging Individual Instruments

- Single devices should be packaged in a medical grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in Table 3. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.
- Standard medical grade, steam sterilization wrap may be used to package individual instruments. The package should be prepared using the AAMI double wrap or equivalent method.

  Note: *If sterilization wraps are used, they must be free of detergent residues. Reusable wraps are not recommended.*

  Note: *The torque-limiting T-handle is intended for return to Zimmer Biomet Spine for recalibration after 25 cleaning cycles, or 6 months.*

Packaging Instrument Sets in Rigid Trays and Cases with Lids

- Safety Precaution: The total weight of a wrapped instrument tray or case should not exceed 11.4kg / 25lbs. Instrument cases may be placed in an approved sterilization container (e.g. Aesculap®) with gasketed lids at the user's discretion. The total weight of the instrument set, case, and sterilization container, must not exceed 11.4kg / 25lbs (other local limits below 25 lbs. may apply).
- Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
- Trays and cases with lids may also be placed in an approved sterilization container with gasketed lid for sterilization.
- Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.
- Areas designated for specific devices shall contain only devices specifically intended for these areas.

STERILIZATION

The non-sterile instruments and implants (anchors) of The Tether™ - Vertebral Body Tethering System system must be sterilized prior to use. The recommended sterilization process for the instruments and implants is steam autoclave sterilization, using the parameters listed in the table below. Use of an FDA-cleared wrap is recommended to maintain sterility prior to use. The recommended sterilization cycles have been validated to assure a Sterility Assurance Level of at least 10^{-6} SAL. All packaging materials must be removed prior to sterilization.

- Flash (immediate-use) steam sterilization is not recommended.
- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be defined by the hospital's internal procedures.
- Steam sterilizer manufacturer recommendations should always be followed. When steam sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contract with all surfaces.
- See Table 3 for recommended minimum steam sterilization parameters that have been validated to provide a 10^{-6} sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table.

  Note: *The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.*

Table 3 – Recommended Steam Sterilization Parameters

Cycle Type	Temp.	Container	Exposure Time	Minimum Dry Time[1]	Minimum Cool Time[2]
PreVacuum	132°C/ 270°F	Rigid	8 minutes	45 minutes	30 minutes
		Wrap	4 minutes		
U.K. PreVacuum	134°C/ 273°F	Rigid	8 minutes		
		Wrap	3 minutes		

1. Drying times vary according to load size and should be increased for larger loads.
2. Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

These steam autoclave sterilization cycles and associated dry times are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature) and drying times. Sterile packaged components are sterilized by exposure to a minimum dose of 20-kGy gamma radiation, according to individual component labeling.

Zimmer Biomet Spine does not recommend stacking of trays during the sterilization process. Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

STORAGE AND SHELF LIFE

- Sterile, packaged items should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Care must be exercised in handling of wrapped cases or individual instruments to prevent damage to the sterile barrier.
- The health care facility should establish a shelf life for sterilized instrumentation based upon the type of sterile wrap or rigid container used and the recommendations of the sterile wrap or rigid container manufacturer.
- Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

  Note: *If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackaged and sterilized.*

  Note: *If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set resterilized.*

SUMMARY OF NON-CLINICAL INFORMATION

A number of non-clinical tests were conducted on The Tether™ - Vertebral Body Tethering System, including static and dynamic tension bending, static axial grip, creep, stress relaxation and wear testing. All tests passed pre-determined acceptance criteria.

SUMMARY OF CLINICAL EXPERIENCE

Clinical Data Overview

Zimmer Biomet Spine conducted a single-center, non-randomized, clinical study under Investigational Device Exemption (IDE) application G150001 in fifty-seven (57) subjects. The purpose of this study was to assess the safety and probable benefit of the device in subjects with idiopathic scoliosis. Spinal tethering subjects were retrospectively evaluated for clinical and radiographic outcomes and were then prospectively followed until 30 out of 57 (47.4%) reached skeletal maturity by the time of database lock. All subjects were surgically treated utilizing components of the Dynesys® Top-Loading Spinal System which is cleared for spinal fusion (K133164). The Tether™ - Vertebral Body Tethering System includes similar components, but differs from the Dynesys® System in that screws have a lower profile head. A common primary assessment collected for all subjects was curve magnitude as determined by Cobb angle. Radiographic images were analyzed using a single core laboratory for assessment of coronal Cobb angle, device loosening, and device breakage. AEs were also reported and assessed by each investigator.

Enrollment Criteria

The following enrollment criteria were utilized to select subjects for this IDE study.

Inclusion Criteria

Enrollment was limited to subjects who met the following inclusion criteria:

- Pediatric subjects at least 10 years of age on the day of surgery who met the following criteria:
  - Diagnosis of idiopathic scoliosis
  - Failure of brace treatment (as defined by greater than 5 degrees of progression and/or intolerance to brace wear)
  - Treatment with an anterior vertebral body tethering procedure for idiopathic scoliosis via thoracoscopic access or mini-thoracotomy
  - Lenke type 1 curve with a lumbar modifier of A or B
  - Pre-operative major curve Cobb angle ≥ 30 degrees and ≤ 65 degrees
  - Pre-operative thoracic scoliometer reading ≤ 20 degrees
  - Structural, thoracic curve corrected to ≤ 30 degrees pre-operatively on supine or standing side bending radiographs
  - Sanders stage ≤ 5 or Risser sign of ≤ 3 at the time of surgery
  - No additional procedures for treatment of idiopathic scoliosis other than tether re-tensioning
- Consent/assent to participation in a prospective surveillance study and demonstration of English proficiency

Exclusion Criteria

Subjects were not permitted to enroll if they met any of the following exclusion criteria:

- Prior spine surgery or additional spine surgery defined as:
  - Vertebral body stapling
  - Surgery to correct a Lenke 1 curve following an initial AVBT procedure
  - Instrumentation of vertebral bodies in conjunction with the initial AVBT procedure using surgical approaches other than thoracoscopic access or mini-thoracotomy
- Pregnancy
- Inability or unwillingness to return for prospective follow-up visit(s)
- Major psychiatric disorders (as defined in DSM-5)
- History of substance abuse (as defined in DSM-5)
- Wards of the court
- Enrollment in an active drug or device trial that is more than minimal risk and where participation in the trial would confound the measurements for the present study
- Enrollment in a device trial for efficacy of a musculoskeletal device and where participation in the trial would confound the measurements for the present study
- Less than 30 days from completion of another clinical trial of more than minimal risk or for assessment safety and efficacy
- Investigator deems the subject as unwilling/incapable of participating

Safety and Probable Benefit Assessments

Safety was evaluated through an analysis of all AEs reported and assessed by each investigator. All AEs were also assessed and adjudicated by an independent AE Adjudication Committee (AEAC). The IDE study did not include hypothesis-driven safety endpoints. Investigators ranked each AE by type (Unanticipated Adverse Device Effect [UADE], seriousness (e.g., Serious Adverse Event [SAE]), and relationship (e.g., device- and/or procedure-related). AEs were collected based on a complete review of each subject's medical record at the study site.

Probable benefit was assessed by measurement of coronal curve correction on post-operative radiographs. A subject was considered a success if the Cobb angle of their major curve reduced to less than or equal to 40 degrees at 24 months following treatment with The Tether™ – Vertebral Body Tethering System.

All subjects treated with The Tether™ – Vertebral Body Tethering System (N=57) were included in the safety analysis population. One subject treated with the device was later found to be outside of the eligibility criteria (Lenke type 3 curve), and consequently, was excluded from the probable benefit analysis population (N=56).

Study Population Demographics and Baseline Parameters
At the time of database lock, 57 subjects were enrolled and had evaluable data. Study population demographics are presented in Table 4. The majority of subjects were female (49/57, 86.0%), and the mean age at time of surgery was 12.4 years.

Table 4: Demographic Information for Study Subjects

Demographics/Patient Details		N (%)
Subjects		57
Sex	Female	49 (86.0%)
	Male	8 (14.0%)
Age at Surgery	Mean (SD)	12.4 (1.3)
	Min, Max	10.1, 15.0

Table 5 presents baseline information for the study population. Subjects were skeletally immature as assessed by either Risser Score (Risser 1958) or Sanders Stage (Sanders 2008). A total of 43 subjects (43/57, 75.4%) had baseline major curves with a measured Cobb angle between 30 to 44 degrees, of which 31.6% (18/57) were between 40 to 44 degrees. Fourteen (14) subjects (14/57, 24.6%) had baseline major curves with a measured Cobb angle between 45 to 65 degrees.

Table 5: Baseline Information for Study Subjects

Preoperative Patient Characteristic		Value/N
Total Number of Subjects		57
Height (cm) – Mean (SD)		155.4 (10.6)
Weight (kg) – Mean (SD)		44.2 (9.7)
BMI – Mean (SD)		18.1 (2.6)
FEV1 – Mean (SD)		2.27 (0.46)
FVC – Mean (SD)		2.67 (0.55)
Risser Score*	0	39 (68.4%)
	1	9 (15.8%)
	2	5 (8.8%)
	3	1 (1.8%)
	4	1 (1.8%)
	NR	2 (3.5%)
Sanders Stage*	0	0
	1	0
	2	8 (14.0%)
	3	20 (35.1%)
	4	7 (12.3%)
	5	2 (3.5%)
	NR	20 (35.1%)
Cobb Angle	30° – 44°	43 (75.4%)
	45° – 65°	14 (24.6%)

*Values from Imaging Core lab. NR=Not reported.

Safety Results

Total AEs
One hundred and thirty-two (132) AEs were identified in 49 of the 57 subjects in the study population. These events are summarized in Table 6 and are classified as serious AEs (SAEs) or non-serious adverse events (Non-SAEs). In total, nine (9) SAEs (6.8% of 132 total events) were reported in eight (8) out of 57 subjects (14.0%) treated with The Tether™ - Vertebral Body Tethering System.

Table 6: Clinical Study AE Summary

Events	All AEs	Non-SAEs	SAEs
Number of Events N (% of events)	132	123/132 (93.2%)	9/132 (6.8%)
Number of subjects with an event N (% of subjects)	49*	49/57 (86.0%)	8/57 (14.0%)

*Eight subjects did not experience any adverse events.

AEs Categorized by Relationship
A listing of all AEs by preferred term reported in this IDE study is presented in Table 7. The most common AEs reported by number of subjects experiencing an event include back pain (14/57, 24.6%), overcorrection of the instrumented curve (12/57, 21.1%), nausea/vomiting (12/57, 21.1%) and extremity pain (12/57, 21.1%).

Table 7: All IDE Study AEs

AE Preferred Term	Number of Events (N)	Number of Subjects with Event [N (%)]	Days to Event [Mean (range)]
Abrasion	1	1 (1.8)	5 (5, 5)
Acidosis	1	1 (1.8)	0 (0, 0)
Anemia	2	2 (3.5)	1 (1, 1)
Asthma	1	1 (1.8)	311 (311, 311)
Atelectasis	8	8 (14.0)	1 (0, 4)
Back Pain	15	14 (24.6)	789 (35, 1844)
Bone Screw Migration	3	3 (5.3)	934 (692, 1128)
Bradycardia	1	1 (1.8)	0 (0, 0)
Breast Pain	1	1 (1.8)	1309 (1309, 1309)
Buttock Pain	1	1 (1.8)	365 (365, 365)
Chest wall pain	3	3 (5.3)	979 (204, 1681)
Constipation	1	1 (1.8)	2 (2, 2)
Cord break	8	8 (14.0)	1212 (769, 1954)
Definite cord break	1	1 (1.8)	960 (960, 960)
Suspected cord break	7	7 (12.3)	1248 (769, 1954)
Development of new curve	2	2 (3.5)	597 (576, 617)
Dysesthesia	1	1 (1.8)	311 (311, 311)
Dyspnea	2	2 (3.5)	1188 (1051, 1324)
Endocrine disorders	1	1 (1.8)	491 (491, 491)
Extremity Pain	12	12 (21.1)	817 (39, 1840)
Flank Pain	1	1 (1.8)	343 (343, 343)
Fracture	1	1 (1.8)	1051 (1051, 1051)
Gastrointestinal disorders: Crohn's disease	1	1 (1.8)	1930 (1930, 1930)
Hair loss	1	1 (1.8)	26 (26, 26)
Hip deformity	1	1 (1.8)	489 (489, 489)
Hyperchloremia & hypocalcemia	1	1 (1.8)	1 (1, 1)
Ileus	1	1 (1.8)	579 (579, 579)
Intraoperative hemorrhage	1	1 (1.8)	576 (576, 576)
Low Back Pain	1	1 (1.8)	84 (84, 84)
Myalgia	1	1 (1.8)	89 (89, 89)
Nausea / Vomiting	12	12 (21.1)	2 (1, 3)
Neck Pain	2	2 (3.5)	432 (423, 440)
Overcorrection of Instrumented Curve	13	12 (21.1)	648 (290, 1691)
Overcorrection resulting in revision	6	5 (8.8)	613 (290, 1691)
Overcorrection w/ no revision	7	7 (12.3)	678 (364, 1128)
Paresthesia	8	6 (10.5)	409 (7, 1137)
Perioperative peripheral nerve injury	2	2 (3.5)	46 (0, 91)
Pleural Effusion	3	3 (5.3)	146 (1, 433)
Pneumonitis	1	1 (1.8)	63 (63, 63)

AE Preferred Term	Number of Events (N)	Number of Subjects with Event [N (%)]	Days to Event [Mean (range)]
Pneumothorax	5	5 (8.8)	0 (0, 1)
Respiratory disorders: bronchitis	1	1 (1.8)	248 (248, 248)
Spondylolisthesis	1	1 (1.8)	174 (174, 174)
Sympathetic Dysfunction	1	1 (1.8)	1 (1, 1)
Vertebral Disc Degeneration	1	1 (1.8)	311 (311, 311)
Worsening of pre-existing secondary curve	1	1 (1.8)	310 (310, 310)
Wound complication	1	1 (1.8)	7 (7, 7)
Wrist Fracture	1	1 (1.8)	195 (195, 195)

AEs Categorized by Relatedness

All AEs reported in the clinical study that were categorized as related to the device or procedure are listed in Table 8. Twenty-four (24) device-related AEs were identified in 23 out of 57 subjects (40.4%). The most common device or procedure-related AEs by subject occurrence include overcorrection of the instrumented curve (12/57, 21.1%), nausea/vomiting (12/57, 21.1%) and definite or suspected cord breakage (8/57, 14.0%).

Table 8: Clinical Study AEs Related to Device or Procedure

Adverse Event	Number of Events	Number of subjects with Event (%)	Days to Event [Mean (range, if applicable)]
Acidosis	1	1 (1.8)	0
Anemia	2	2 (3.5)	1
Bone screw migration	3	3 (5.3)	934 (692, 1128)
Bradycardia	1	1 (1.8)	0
Cord break definite	1	1 (1.8)	960
Cord break suspected	7	7 (12.3)	1248 (769, 1954)
Development of new curve	2	2 (3.5)	597 (576, 617)
Hyperchloremia & hypocalcemia	1	1 (1.8)	1
Intraoperative hemorrhage	1	1 (1.8)	579 (revision)
Nausea/vomiting	12	12 (21.1)	2 (1, 3)
Overcorrection of instrumented curve	13	12 (21.1)	648 (290, 1691)
Overcorrection requiring revision	6	5 (8.8)	613 (290, 1691)
Overcorrection/ no revision	7	7 (12.3)	678 (364, 1128)
Perioperative peripheral nerve injury	1	1 (1.8)	0
Pleural effusion	3	3 (5.3)	146 (1, 433)
Pneumothorax*	5	5 (8.8)	0 (0, 1)
Sympathetic dysfunction	1	1 (1.8)	1
Transfusion Requirement	8	8 (14.0)	0 (0, 1)
Worsening of pre-existing secondary curve	1	1 (1.8)	310

*No interventions required

AEs Categorized by Seriousness

Nine (9) SAEs were reported as described in Table 9 below. Overcorrection of the major curve following AVBT which required additional spinal surgery was the most common SAE type, and accounted for 6 of the 9 total SAEs. Only one (definite) cord breakage resulted in a reoperation SAE and none of the screw migration events required reoperation.

The applicant considered any major curve that corrected to any degree in the opposite direction of the original convexity to be overcorrected. Seven overcorrection AEs did not require secondary surgery based on curve magnitude (<10 degrees, N=3; 11-20 degrees, N=3; 24 degrees, N=1), and the subject's skeletal maturity status. These subjects have been monitored with radiographs at subsequent follow-up visits.

Table 9: Summary of All Adverse Events (AEs) Classified as Serious Adverse Events (SAEs)

Adverse Event	Number of Events (N)	SAEs* (N)	SAEs requiring Secondary Surgeries	Subjects with SAE [N (% of 57)]	Days to SAE [Mean (range, if applicable)]
Overcorrection of Instrumented Curve	13	6	6	5 (8.8%)	612.8 (290, 1691)
Definite cord break	1	1	1	1 (1.8%)	960
Development of new curve	1	1	1	1 (1.8%)	576
Spondylolis-thesis**	1	1	1	1 (1.8%)	174.0
Bone screw migration	3	0	0	0	934 (692, 1128)
Suspected cord break	7	0	0	0	1248 (769, 1954)
Total	**26**	**9**	**9**	**8**	**–**

*SAEs captured in G150001 include both device-related events and non-device-related AEs which led to a serious deterioration in the health of the subject that:

- Resulted in a life-threatening illness or injury
- Resulted in a permanent impairment of a body structure or a body function
- Resulted in subject hospitalization or prolongation of existing hospitalization
- Resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function
- Results in fetal distress, fetal death or a congenital or abnormality/birth defect

**Late-occurring SAE observed at non-index levels and not related to AVBT procedure

Secondary Surgeries

Overall, there have been nine (9) secondary surgeries affecting eight (8) subjects. The most common reason for secondary surgery was overcorrection (6/9, 66.7%). Table 10 below lists the secondary surgeries performed in the study.

The applicant classified secondary surgeries into two groups – Revision and Reoperation. Revisions are defined as secondary surgeries involving modification of The Tether™ – Vertebral Body Tethering System (e.g., expanding the tether to additional vertebral levels, replacing a tether cord, surgically severing a cord). Reoperations are defined as secondary surgeries which involve implantation of a different spinal device or fusion surgery. Seven (7) of the secondary surgeries were classified as revisions and two were identified as reoperations. There was, therefore, an overall 14.0% subsequent surgery rate comprised of a revision rate of 12.3% (7/57) and a reoperation rate of 3.5% (2/57). Note that one subject underwent both a revision and reoperation procedure.

Overcorrection of instrumented curves occurred on average 665.6 days post-operatively (about 22 months) with a range between 290 and 1691 days (9.5-55.6 months). The revision procedures for overcorrection included:

- Cutting the tether cord (N=2)
- Cutting the tether cord and screw removal and/or replacement (N=2)
- Cutting the tether cord and screw loosening and re-tightening (N=2)

Revisions to either replace, remove, or add tether device components provide these subjects the potential benefit of arrest of curve progression and avoidance of fusion later in life. One study subject required a fusion reoperation for treatment of progressive overcorrection after one revision procedure, and one tether extension reoperation, failed to limit curve progression.

Table 10: Secondary Surgery Listing*

Revision Subject	Secondary Surgery Type	Months to Secondary Surgery	Cause (Preferred Term) & Event Description *T: Thoracic Spine. L: Lumbar Spine. S: Sacral Spine
1	Revision	25	Overcorrection of instrumented curve, Tether was cut at the T5-T6, T9-T10, T10-T11, T11-T12 interspaces. A T5 screw was removed.
2	Revision	21	Overcorrection of instrumented curve, Tether was cut between T9-T10, T10-T11, and T11-T12.
3	Revision	14	Overcorrection of instrumented curve. Surgery to fix over- correction. Tether was cut between L1 and L2. Screws were loosened then tightened at L1, T12, T11.
4	Revision	26	Overcorrection of instrumented curve, Tether was cut between T11-T12 and T12-L1. Screws and tether were removed and replaced from T7-T11.
4	Reoperation	60	Overcorrection of instrumented curve. Posterior spinal fusion T8-L2 was performed.
5	Revision	51	Definite Cord Breakage. Treatment initiated with bracing, but progression of curve led to replacement of the AVBT (T5-T12) and placement of an additional screw at L1.
6	Reoperation	41	Spondylolisthesis (unrelated). Treatment with L5 laminectomy, posterior spinal instrumentation and transforaminal L5-S1 interbody fusion.
7	Revision	27	Development of new curve. AVBT added from T12 to L3.
8	Reoperation	17	Overcorrection of instrumented curve. When curve overcorrection reached -20 degrees a tether cutting procedure was recommended and took place at 9 months post-operatively.

Probable Benefit Results

The primary probable benefit endpoint of this single-arm study was defined based on the Cobb angle measurement of the subject's major coronal curve at 24 months post-procedure. Individual subject success was defined as a major curve less than or equal to 40 degrees at 24 months post-surgery.

Mean Cobb Angle Correction

Table 11 describes the change in Cobb angle from baseline, at the 24-month timepoint, and for the last follow-up visit at or beyond 24 months. The mean main Cobb angle improved 65% from 40.4 degrees to 14.3 degrees at 24 months. At the last available follow-up visit after surgery (at or beyond 24 months), the mean main Cobb angle correction was maintained or improved compared to pre-operative baseline curve magnitude with correction from 40.4 degrees to 17.6 degrees (56.4% curve improvement).

Table 11: Change in Cobb Angle from Baseline at 24 months and Last Visit

Cohort	N	Cobb Angle*				
		Preop (N=56)	24 months (N=44)		Last visit ≥ 24 months† (N=56)	
		Mean (sd)* [min, max]	Mean (sd)* [min, max]	Δ (%Δ)	Mean (sd)* [min, max]	Δ (%Δ)
All Subjects	56	40.4 (6.7) [29,56]	14.3 (8.8) [1,30]	26.1 (64.6%)	17.6 (14.7) [-29,41]	22.8 (56.2%)

*Measurement of the major thoracic (MT) Cobb angle where the superior end vertebra and the inferior end vertebra are defined at pre-op and held constant across all timepoints.

† Mean follow-up of 49.8 months at last radiograph.

Individual Subject Probable Benefit Success

Individual subject success was defined as achievement of a Cobb angle less than or equal to 40 degrees at 24 months post-surgery. Forty three (43) out of 44 subjects with 24-month data (97.7%) met the success criteria in this study. At the last follow-up visit greater than 24 months, 52 out of 56 subjects (92.8%) had a coronal Cobb angle of less than 40 degrees (Table 12).

Table 12: Overall Study Success (Cobb Angle Less Than or Equal to 40 Degrees at 24 Months Post-Op and Most Recent Visit by Pre-operative Cobb Angle

Cohort	N	Success % (n/N)		Last Visit Cobb Angle (n, %)
		Visit at 24 months	Last visit ≥ 24 months	
All subjects	56	97.7% (43/44)	92.8% (52/56)	< 30° (43, 76.7%) < 35° (48, 85.7%) < 40° (52, 92.8%)
Pre-Op Cobb < 45°	43	97.3% (36/37)	90.6% (39/43)	< 30° (35, 81.4%) < 35° (38, 88.3%) < 40° (39, 90.6%)
Pre-Op Cobb ≥ 45°	13	100% (7/7)	100% (13/13)	< 30° (8, 61.5%) < 35° (10, 76.9%) < 40° (13, 100%)

Sensitivity analyses were also conducted to determine how the results were affected by changing the threshold for Cobb angle reduction for the probable benefit success endpoint. For all treated subjects, the success rates are 85.7% (48/56) and 76.7% (43/56) when the probable benefit success is defined as a major Cobb angle of less than 35 degrees and 30 degrees, respectively, at a subject's last follow-up visit.

The probable benefit results were further stratified for those subjects with pre-op Cobb angles less than 45 degrees (N=43) and pre-op Cobb angles of greater than or equal to 45 degrees (N=13), respectively. For subjects with pre-op Cobb angles less than 45 degrees, probable benefit success rates were 90.6%, 88.3% and 81.4% based on probable benefit success defined as a major Cobb angle of less than 40 degrees, 35 degrees and 30 degrees, respectively, at a subject's last follow-up visit. For subjects with pre-op Cobb angles greater than 45 degrees probable benefit success rates were 100.0%, 76.9% and 61.5% based on probable benefit success as defined as a major Cobb angle of less than 40 degrees, 35 degrees and 30 degrees, respectively, at a subject's last follow-up visit.

Three subjects with a last visit beyond 24 months had curves greater than 40 degrees and did not meet the individual subject success endpoint. In addition, one subject, while meeting the 24-month Cobb angle success criterion, required a revision procedure and subsequent fusion for overcorrection, and therefore was a treatment failure.

Improvement in Axial Trunk Rotation

Pre-operatively, the mean measurement in the thoracic region was 13.6 ± 3.9 degrees and 6.9 ± 3.0 degrees in the thoracolumbar region. At the last visit timepoint, the mean thoracic measurement was 8.7 ± 4.8 degrees and the mean thoracolumbar measurement was 3.8 ± 3.5 degrees. Although there is a scoliometer measurement error range of 5 degrees (Cote 1998), there appeared to be overall improvement in the mean thoracic and thoracolumbar axial trunk rotation of 4.9 degrees and 3.1 degrees, respectively, equating to 36% and 45% rotational reductions, respectively.

Maintenance of Growth Through Instrumented Levels

Total vertical thoracic spine length increased between baseline and the last visit by 24.8 mm on average, showing continued spinal growth following vertebral tethering.

Improvement in Patient Reported Outcomes and Quality of Life

Patient-reported outcomes and quality of life assessments performed in the clinical study include the Adolescent Pediatric Pain Tool (APPT), Pediatric Quality of Life Inventory (PedsQL™), and the Scoliosis Research Society outcomes questionnaire (SRS-22). Overall, the results of these assessments are positive and indicate overall patient satisfaction and improvement in function with AVBT.

However, some uncertainty in these assessments arises from the retrospective study design. The applicant presented the patient-reported and quality of life outcomes from the 24-month post-operative timepoint through the last available visit/skeletal

maturity. However, there are no baseline data for APPT, PedsQL and SRS-22 as these assessments were not part of the applicant's standard-of-care assessments.

Spinal Alignment

Spinal alignment was evaluated at each post-operative timepoint and consisted of measurements of thoracic kyphosis, lumbar lordosis, sagittal balance, coronal balance, and total vertical spine length. On standing full-spine/pelvis EOS images, sagittal balance was measured by the distance between a C7 plumb line and the postero-superior aspect of the S1 vertebral body. Displacement of the C7 plumb line anterior to the sacral reference reflects positive sagittal balance and displacement posterior to the sacral reference reflects negative sagittal balance. Coronal balance was measured by the distance between a C7 plumb line and the central sacral vertical line (CSVL). Table 13 below summarizes radiographic parameters examined in the clinical study:

Table 13: Summary of Radiographic Measures in Subjects at ≥ 24 Months Post-Tether (Measures reported as mean (SD))

Follow-up	N	Thoracic kyphosis (º)	Lumbar lordosis (º)	Sagittal balance (mm)*	Coronal balance (mm)**	Total vertical thoracic spine length (mm)
Pre-op	54	15.8 (10.1)	52.2 (11.5)	1.5 (26.6)	2.1 (15)	246.4 (19.3)
LV ≥ 2 years†	**56**	**19.4 (12.9)**	**54.9 (11.9)**	**-10.1 (33.1)**	**-2.1 (15.8)**	**271.2 (19.7)**

*Sagittal balance: positive value indicates anterior shift; negative value indicates posterior shift.

**Coronal balance: positive value indicates right coronal shift; negative value indicates left coronal shift.

† Mean follow-up of 49.8 months. "LV" refers to last visit.

Overall Conclusions

The data in this HDE application support the reasonable assurance of safety and probable benefit of The Tether™ – Vertebral Body Tethering System when used in accordance with the indications for use. This device can be considered safe for its intended use, based upon consideration of the types of SAEs, device- and procedure-related AEs, and subsequent surgical procedures reported. The probable benefit success rate, defined as maintenance of the Cobb angle of the major curve less than or equal to 40 degrees, is equal to or greater than 92.8% at or beyond 24-months. This probable benefit endpoint is considered representative of the likelihood of avoidance of the need for spinal fusion during this time period. The benefit of a device which avoids spinal fusion during the study time period but does not preclude treatment with spinal fusion if needed in the future, is considered to outweigh the higher rate of subsequent surgical intervention when compared to posterior spinal instrumentation and fusion.

References

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- Sanders JO et al.. "Predicting scoliosis progression from skeletal maturity: a simplified classification during adolescence." *The Journal of Bone and Joint Surgery*. 2008: 90(3), 540-553.

PRODUCT COMPLAINTS

Communicate suspected deficiencies in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance directly to Zimmer Biomet Spine (email: spinecomplaints@zimmerbiomet.com, phone: +1 844.557.7463). When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, and the patient case number. Sterilize and return all component(s) to your local Zimmer Biomet Spine representative or distributor. Notify Zimmer Biomet Spine immediately of an incident resulting in patient death or serious injury.

FURTHER INFORMATION

If further directions regarding proper use of the instruments is desired, contact Zimmer Biomet Spine, Inc., Customer Service by email: usbrocustomerservice@zimmerbiomet.com, Tel: +1 800.447.3625, Fax: +1 866.973.9072.

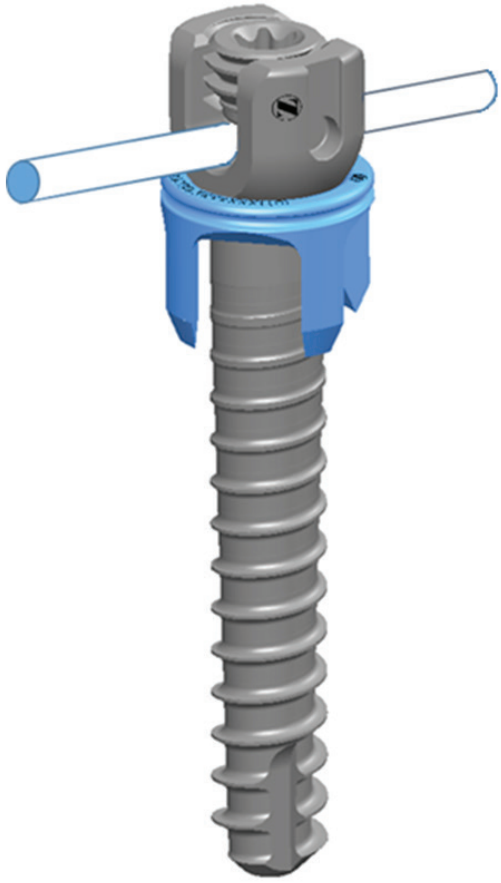
CAUTION: Federal Law (USA) restricts this device to use on the order of a physician.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product label.

ZIMMER BIOMET
Your progress. Our promise.®

The Tether™
Vertebral Body Tethering System

Surgical Technique Guide



Federal (USA) law restricts this device to sale by or on the order of a physician. ℞ only

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.

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

IMPORTANT INFORMATION ON THE TETHER™ – VERTEBRAL BODY TETHERING SYSTEM

DEVICE DESCRIPTION

The Tether™ – Vertebral Body Tethering System is a non-fusion spinal device intended for treatment of idiopathic scoliosis. Anchors and vertebral body screws are placed laterally from a thoracoscopic or thoracotomy approach into the vertebral body on the convex side of a spinal deformity. A SULENE® polyethylene terephthalate (PET) tensioning cord is secured to the vertebral body screws with set screws to connect the levels of the construct. The device provides a lateral tension band across the convex side of the spine that, on insertion and tensioning, partially corrects the curvature, and subsequently can arrest or correct the deformity through modulation of remaining spinal growth. In addition, the subject system includes instrumentation for insertion, manipulation, and removal of the implants.

MATERIALS

The Tether™ - Vertebral Body Tethering System is manufactured from:

- Anchors: Ti 6Al-4V ELI titanium alloy per ASTM F136
- Set Screws: Ti 6Al-4V ELI titanium alloy per ASTM F136
- Bone Screws: Ti 6Al-7Nb titanium alloy per ISO 5832-11 with an hydroxyapatite coating per ISO 13779-2
- Cord: Sulene® PET (polyethylene-terephthalate)
- Instruments and Cases: Generally comprised of aluminum, stainless steel, titanium alloy, and/or polymeric materials

INDICATIONS FOR USE

The Tether™ - Vertebral Body Tethering System is indicated for 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.

CONTRAINDICATIONS

The Tether™ - Vertebral Body Tethering System should not be implanted in patients with the following conditions:

- Presence of any systemic infection, local infection, or skin compromise at the surgical site;
- Prior spinal surgery at the level(s) to be treated;
- Known poor bone quality defined as a T-score -1.5 or less;
- Skeletal maturity;
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patients unwillingness or inability to cooperate with post-operative care instructions.

SUMMARY OF CLINICAL EXPERIENCE

For a summary of clinical experience. please reference the system's Instructions for Use (IFU).

PREOPERATIVE PROCEDURE

The surgeon is responsible for being familiar with the indications, contraindications, system/procedure risks, and surgical technique to ensure proper treatment, patient selection, and postoperative care when using The Tether™ - Vertebral Body Tethering System. The patient must be an acceptable surgical risk, and appropriate for vertebral body tethering based on consideration of various factors such as preoperative Cobb angle, curve flexibility, curve type(s), curve location(s), skeletal maturity, and anticipated growth, among others. Examination and evaluation of the individual patient anatomy is necessary to plan the appropriate surgical procedure and technique. Due to smaller vertebral body size and variable venous anatomy, caution should be observed if extending instrumentation proximal to T5.

Zimmer Biomet Spine does not specify the maximum number of times a re-usable instrument may be re-used. The useful life of these instruments is highly dependent on a number of factors including the frequency and manner in which they are used and the handling they experience in between uses. Inspection and, where appropriate, functional testing prior to instrument use is the best way to determine whether or not an individual device should be used. Review and inspect all instrumentation and implants prior to use. Replace or add any needed components for the planned surgery.

Use of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments. Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, instruments should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.

OPERATIVE PROCEDURE

For surgical placement of The Tether™ - Vertebral Body Tethering System, patients are positioned in the lateral decubitus position with the convex side of the curve to be instrumented facing upwards. As most idiopathic thoracic curves are convex towards the right side, a left lateral decubitus position will be the most common position utilized for instrumentation of thoracic curves. For recommended surgical site preparation, positioning, and technique details, please see the Surgical Technique Guide. For thoracoscopic surgery, standard anesthesia protocol should be observed. However, it is recommended to use a single lung ventilation technique such as a double-lumen endotracheal tube to aid surgical exposure if necessary. Anchor use is recommended at all levels. Consideration should be given to the osseous structure at each level to determine if both a bone screw and anchor are needed to adequately support the construct and anticipated loads. Please refer to the Surgical Technique Guide if implant removal is required (including revision). Close wound(s) and apply wound dressing using standard techniques.

POSTOPERATIVE CARE

It is critical that patients follow all postoperative instructions provided by care providers including recommendations regarding medications, home care, surgical wound dressings and activity limitations. The patient must be warned to avoid falls or sudden jolts. Failure to follow postoperative instructions could lead to impaired wound healing, injury to neurologic structures or failure to achieve desired curve correction.

Optional protective bracing may be used for up to six months after surgery depending on patient factors such as bone quality and activity levels. Bracing may provide additional support for patients who are overcorrecting or have a suspected or confirmed cord break. Use of The Tether does not preclude the need to brace compensatory curves.

WARNINGS

- Do not rotate the screw counterclockwise after insertion. This will reduce stability of the implant in the vertebral body.
- New or increasing coronal angulation between consecutive screws as seen on radiographs may indicate tether breakage. Tether breakage may be associated with loss of correction, overcorrection or may have no clinical significance.
- Never use titanium alloy(s) with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
- When tensioning the construct, special consideration should be given to patients with considerable growth remaining (e.g. open triradiate cartilage), lower magnitude Cobb angles, and/or high flexibility as excessive tension may increase the risk of overcorrection.
- The Tether™ - Vertebral Body Tethering System must not be used with vertebral components or instruments from other manufacturers. Specialized instruments are designed for Zimmer Biomet Spine implant systems to aid in proper implantation. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure.
- Surgical instruments are subject to wear with normal usage. Instruments with cutting functions or points may become dull with normal use and no longer perform as intended. Instruments that have experienced extensive use are susceptible to fracture.
- Do not modify instruments. Do not notch, bend, or reshape instruments. Notches, scratches or other damage and/or wear in the instrument occurring during surgery may contribute to breakage. Do not use an instrument that has become bent from its original shape as this will affect the performance of the instrument. Bent instruments should be disposed of by a Zimmer Biomet Spine representative or according to hospital procedures.
- The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments.
- Proper handling of the instruments and implants before and during the operation is crucial. Do not apply excessive force; misuse can damage instruments or implants.

PRECAUTIONS

- Due to smaller vertebral body size and variable vascular anatomy, caution should be observed if extending instrumentation proximal to T5.
- Care should be taken when using instruments over a guidewire to avoid unintentional advancement of the guidewire which could result in damage to vessels, spinal cord, or lungs.
- Extreme caution must be taken to avoid damage to vessels, spinal cord, or lungs during placement of instruments and implants.
- The Tether™ - Vertebral Body Tethering System is intended to be used by surgeons specialized in spinal surgery with thorough knowledge of vertebral anatomy, regional vertebral morphology, and biomechanical principles of the spine. The surgical procedure is technically demanding and presents a risk of serious injury to the patient. It is advised that the surgeon also be thoroughly familiar with the surgical techniques, equipment, and instruments related to the use of the device. The surgical technique guide may be obtained by contacting Zimmer Biomet Spine Customer Service (contact information is provided below).
- Risks associated with spine surgery, neurosurgery, general surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is recommended that the advantages and disadvantages of using The Tether™ - Vertebral Body Tethering System, as well as alternative treatment methods, are explained to the patient.
- The cord implant is made up of three-segments: The Introduction Zone, the Working Zone, and the Functional Zone. Only the Functional Zone may be implanted into the patient.
- Correct selection and placement of the implants is critical. Implant selection must be based upon the levels to be treated as well as the patient's weight and height.
- Perform a careful preoperative review to be sure that all necessary implant components are available and that the instrument set is complete and in working order prior to initiating surgery.
- Before use, inspect all instrumentation for possible damage, wear, or non-function. Damaged or defective instruments should not be used or processed. Contact your local Zimmer Biomet Spine representative or distributor for repair or replacement.
- Do not reuse single-use devices such as implants. While a single-use device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the single-use device. Do not treat patients with single-use devices that have been in contact with a different patient.
- All trial, packaging, and instrument components must be removed prior to closing the surgical site.
- Unless otherwise indicated, instruments are supplied NON-STERILE and must be thoroughly cleaned and sterilized prior to use. Instruments that are not clean may not be effectively sterilized.
- Automated cleaning using a washer/disinfector alone may not be effective for complex orthopaedic instruments with lumens, cannulations, blind holes, mated surfaces and other features.
- Do not clean soiled instruments while in polymer or metal trays.

SYSTEM OVERVIEW

Implants

The Tether™ – Vertebral Body Tethering System is comprised of four main components—a titanium alloy vertebral body anchor; a cannulated, hydroxyapatite-coated, vertebral body bone screw; a polyethylene-terephthalate (PET) intervertebral tensioning cord; and a titanium set screw (Figure 1).

The Tether™ – Vertebral Body Tethering System is intended to treat skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis.

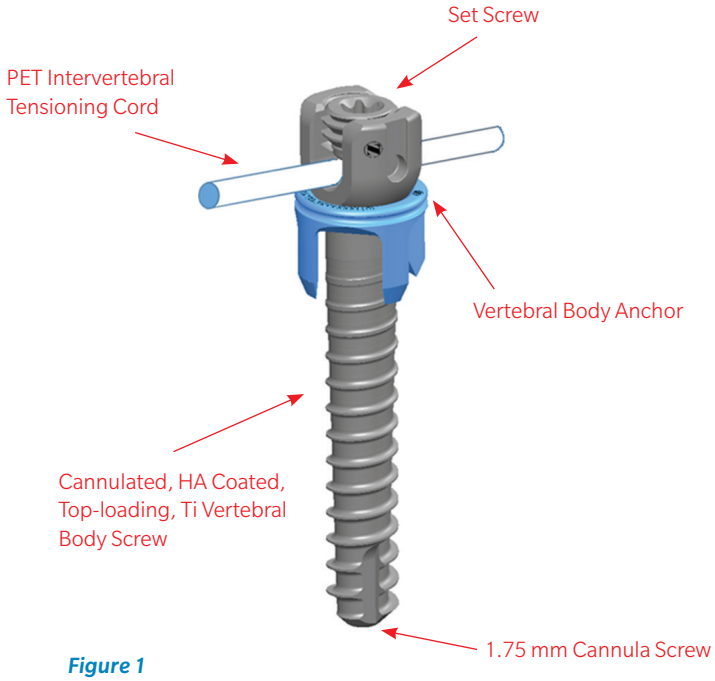


Figure 1
Implant components

Implant Components

Vertebral Body Anchor

The vertebral body anchors accommodate each vertebral body bone screw diameter offered in The Tether™ – Vertebral Body Tethering System. These anchors feature three straight tines designed to add greater stability to the construct (Figure 2).

Figure 2
Vertebral body anchor

Vertebral Body Bone Screw

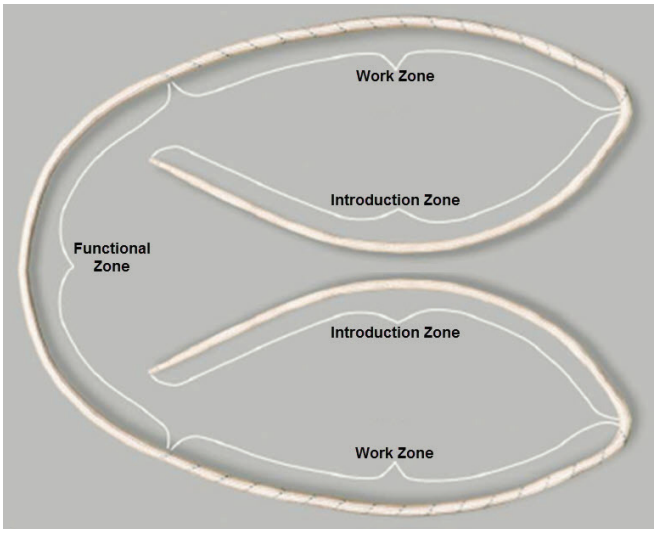
The vertebral body bone screw is available in 5.5 mm, 6.0 mm, 6.5 mm, and 7.0 mm diameters and includes lengths from 20 mm to 50 mm, in 2.5 mm increments. The screw is made from titanium alloy and features a top-loading design, for ease of cord insertion. The vertebral body bone screws also include a 1.75 mm cannula screw, for use with an optional 1.45 mm diameter guidewire. The vertebral body bone screw features an outer layer of hydroxyapatite (Figure 3).

Figure 3
Vertebral body bone screw

Cord

The flexible polyethylene-terephthalate (PET) intervertebral tensioning cord is used in conjunction with the other implants in the system, to apply compressive forces across the convexity of a scoliotic curve.

The cord features a central functional zone, two peripheral working zones, and introduction zones on the ends of the cord. The introduction zone is designed to help start threading the cord to the extension spring tube and the tensioner. The working zone is intended for use in capturing, manipulating, and tensioning the overall cord. The central functional zone is placed within the tulip heads of the vertebral body bone screw and is part of the final implant construct. Do not use the introduction or working zone sections of the cord in the final construct (Figure 4).



PET cord

Set Screw

The titanium alloy set screw features a customized T20 hexalobe interface and a reverse buttress thread form (Figure 5). It is used to secure the cord in the vertebral body screw saddle of the tulip head.

Caution: *Only use the torque-limiting T-handle with the set screw driver to introduce and tighten the set screws.*

Caution: *Repetitive adjustment of the set screw is not recommended, nor is adjustment of the set screw after final tightening has been performed.*

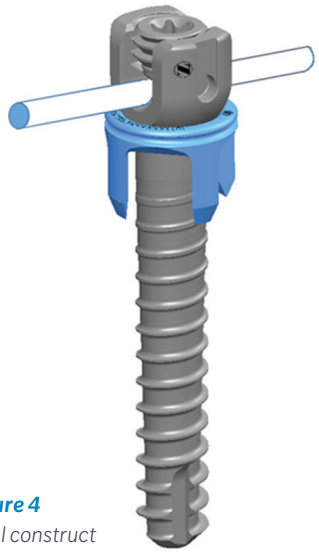


Figure 4
Final construct

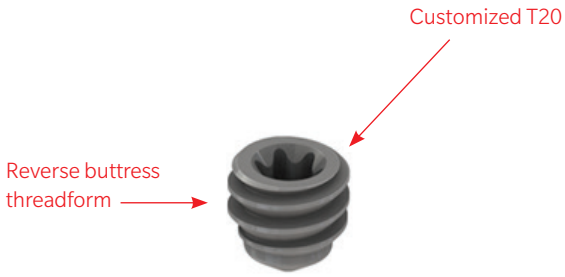


Figure 5
Set screw

INSTRUMENTS

All-Through-One (ATO) Instrument:

Anchor Inserter Inner Sleeve

Anchor Inserter Outer Sleeve and Handle

Awl

Awl Long

Anchor Inserter 90° Handle

Ratcheting Handle, Palm (x1)

Taps (Cannulated)

5.0 mm
5.5 mm
6.0 mm
6.5 mm
7.0 mm

Taps (Non-Cannulated)

4.5 mm
5.0 mm
5.5 mm
6.0 mm
6.5 mm
7.0 mm

Sounding Probes (x2)

Screwdrivers (x2)

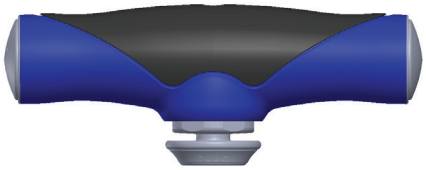
Ratcheting Handle (x1)

Set Screw driver (x2)

Counter-Tensioner (x2)

Cord Alignment Rod (x2)

Torque-limiting Handle (50 in-lb) (x2)



Cord Tensioner (x2)

Extension Spring Tube Short

Extension Spring Tube Long

Fine Adjustment Knob

SURGICAL TECHNIQUE

Preoperative planning – It is highly recommended that surgeons take ample opportunity to plan their approach, including implant dimensions and level selection, using the most recent and best quality imaging studies they have available. Accuracy of implant placement and selection is highly dependent upon this preoperative planning process. It is also imperative that vertebral body screw dimensions be planned prior to surgery.

The patient must be an acceptable surgical risk and appropriate for vertebral body tethering based on consideration factors such as preoperative Cobb angle, curve flexibility, curve type(s), curve location(s), skeletal maturity, and anticipated growth, among others.

Constructs should extend from the cephalad vertebra to the caudal vertebra of the curve to be surgically corrected. However, due to smaller vertebral body size and variable venous anatomy, caution should be observed if extending instrumentation proximal to T5.

PATIENT POSITIONING

- Place the patient in a lateral decubitus position, with the convex side of the curve to be instrumented facing upwards. As most idiopathic thoracic curves are convex towards the right side, a left lateral decubitus position will be the most common position utilized for instrumentation of thoracic curves.
- It is important to securely maintain the patient in a fully lateral position on a radiolucent OR table at all times. This may be achieved with the use of lateral positioning accessories or taping the patient directly to the table.

It is essential to have thoracotomy instruments in the OR, during a vertebral body tethering procedure. This is done as a precautionary measure, should an unexpected need for a thoracotomy arise.

Both thoracoscopic and thoracotomy techniques are accepted access techniques for vertebral body tethering surgery. For thoracoscopic surgery, a standard anesthesia protocol should be observed. However, it is recommended to use a single lung ventilation technique such as a double-lumen endotracheal tube to aid surgical exposure.

PRE-SURGICAL INSTRUMENT ASSEMBLY

The All-Through-One (ATO) instrument is intended to provide the surgeon with the ability to implant the vertebral body anchor, prepare the site and insert the vertebral body bone screw, through a single cannulated instrument. This allows for more precise, deliberate, and consistent implant placement than freehand insertion using separate instruments.

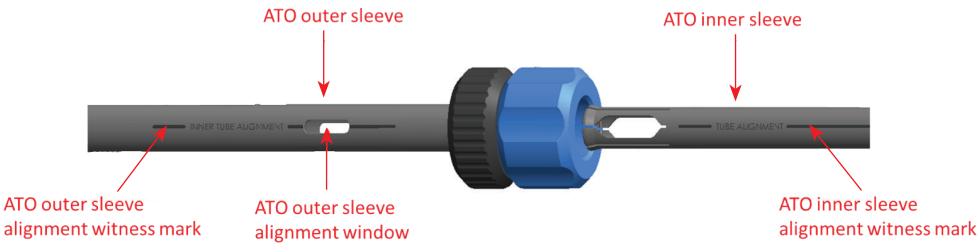


Figure 6
ATO assembly

Figure 7
ATO sleeve alignment

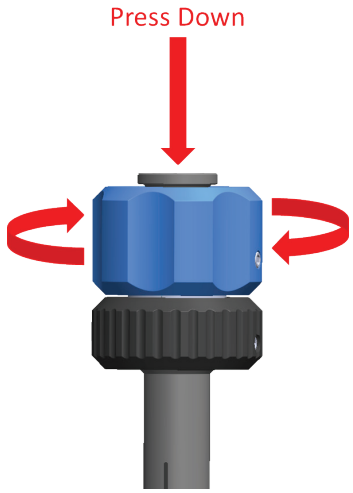


Figure 8
ATO sleeve engagement

ALL-THROUGH-ONE (ATO) AND AWL ASSEMBLY

- Insert ATO inner sleeve into the ATO outer sleeve (Figure 6).
- When these instruments are properly aligned, the witness mark on the outer sleeve shaft will be aligned with the witness mark on the inner sleeve, when observed through the alignment window (Figure 7).
- Once properly aligned, press on the proximal end of the ATO inner sleeve and simultaneously rotate the blue collar on the ATO outer sleeve in a counter-clockwise fashion (Figure 8). When done properly, the inner sleeve will be captured by the outer sleeve and the inner sleeve will begin to progress forward.

PRE-SURGICAL INSTRUMENT ASSEMBLY *(continued)*

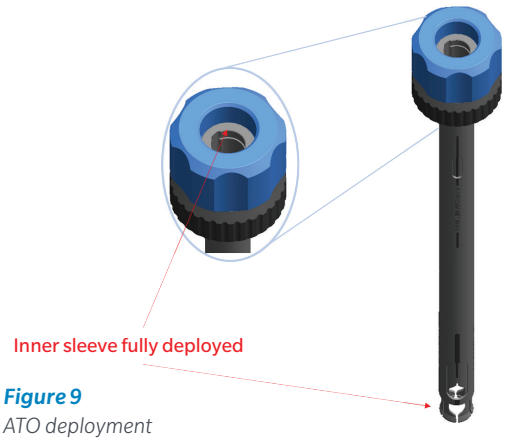


Figure 9
ATO deployment

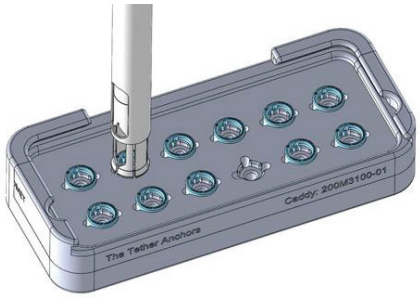


Figure 10
Capture anchor in caddy

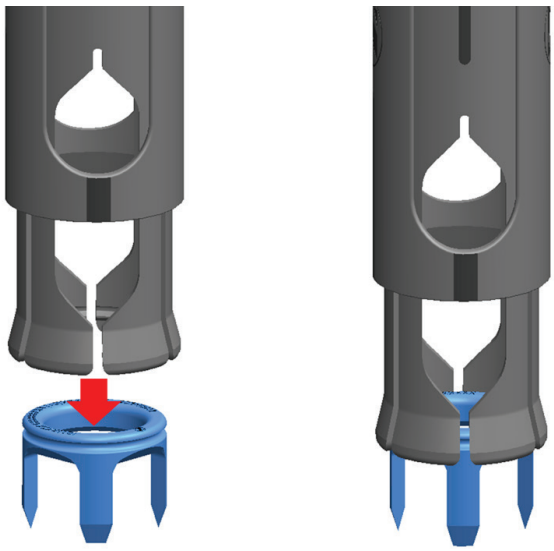


Figure 11
Initial capture of anchor

ALL-THROUGH-ONE (ATO) AND AWL ASSEMBLY *(continued)*

- Once the ATO inner and outer sleeves are provisionally assembled, turn the ATO's blue collar counter-clockwise until the distal end of the inner sleeve is fully deployed (Figure 9). When the distal end of the ATO's inner sleeve is fully deployed, it is ready to accept and provisionally capture the anchor implant.
- Remove the anchor implant caddy lid and press the distal end of the ATO over the anchor implant, while the implant remains seated in the caddy (Figure 10).
- Press downward until the end of the ATO captures and retains the anchor. An audible and tactile response should be observed when the distal end of the ATO properly captures the anchor (Figure 11).

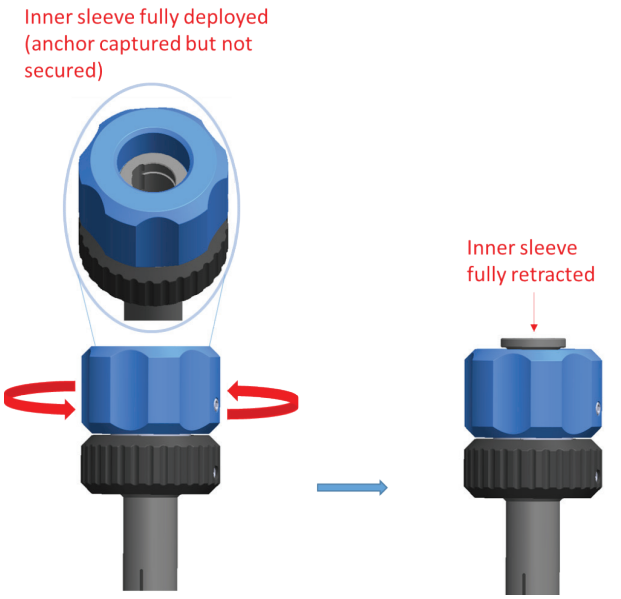


Figure 12
Anchor retraction and retention

Figure 13
Anchor fully captured, and sleeve fully retracted

- Once the anchor is provisionally captured, rotate the blue collar of the ATO in a clockwise fashion—this will retract the distal end of the inner sleeve and fully secure the anchor to the ATO instrument (Figures 12 and 13). Do not force the ATO's blue dial.

There are two awls available in the system—a long awl with a sharp tip that measures 27 mm in length, and a shorter version with a tip that measures 17 mm in length. Both awls feature two retention posts on the proximal ends of each instrument and are found just beyond the strike pad/dial. Prior to using the long awl, the surgeon should be sure to thoroughly assess the size of the vertebral body to ensure that it is adequate to accommodate the longer length of this instrument's tip.

PRE-SURGICAL INSTRUMENT ASSEMBLY *(continued)*

Figure 14
Short awl

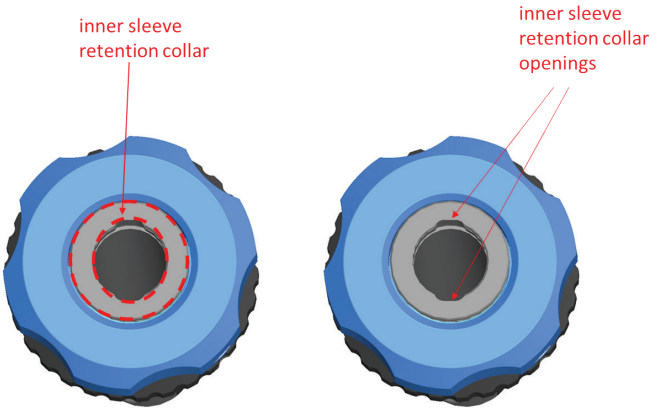


Figure 15
Inner sleeve retention collar

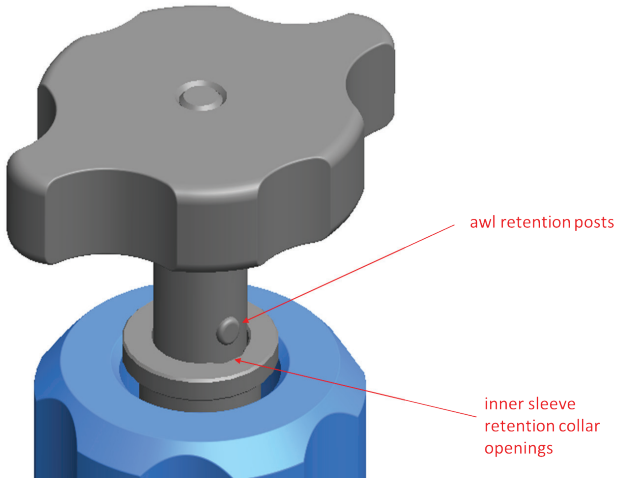


Figure 16
ATO and awl assembly

ALL-THROUGH-ONE (ATO) AND AWL ASSEMBLY *(continued)*

- The retention posts are designed to interface with the retention collar of the ATO's inner sleeve (Figure 14).
- The retention collar features an oblong opening that will accommodate the retention posts when properly aligned (Figure 15).
- Insert the distal tip of the selected awl into the proximal cannula of the ATO instrument. If the strike pad/dial of the awl does not come to rest immediately next to the blue dial of the ATO, do not attempt to force the awl into place. The retention posts of the awl need to be properly aligned with the oblong opening of the ATO retention collar (Figure 16). Hold both instruments upright and rotate the strike pad/dial until the awl falls into place.

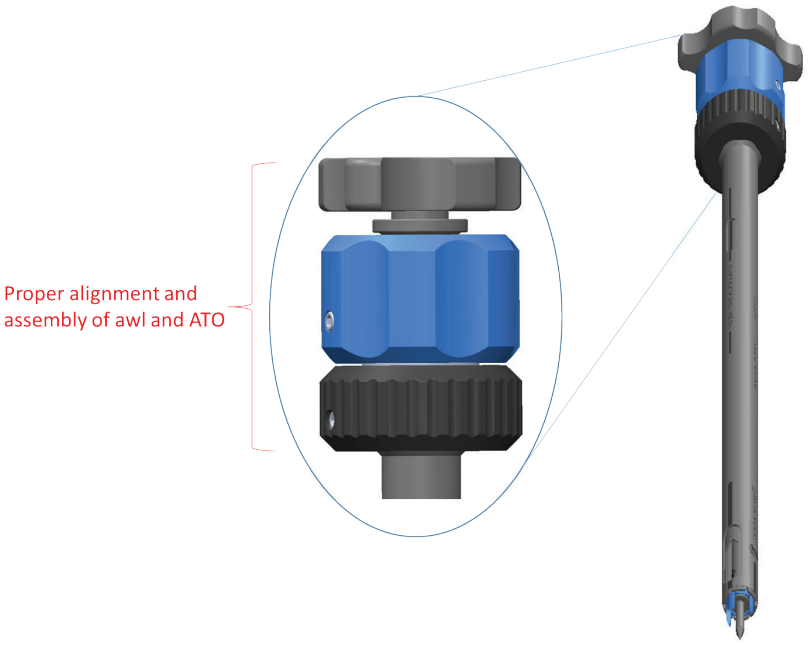


Figure 17
Complete ATO, anchor, and awl assembly

- The ATO is now properly assembled with the awl and anchor implant and is ready for insertion (Figure 17).

PRE-SURGICAL INSTRUMENT ASSEMBLY *(continued)*

Figure 18
Tap and ratcheting handle assembly

RATCHETING HANDLE WITH TAP

- After selecting the appropriate tap, insert its ¼" square proximal end into the distal recess of the ratcheting handle until it is captured. If the tap does not fully seat, rotate the shaft of the tap slightly during insertion. While still holding the ratcheting handle, tug on the tap to ensure that it is properly secured (Figure 18).

Figure 19
Screwdriver and ratcheting handle assembly

RATCHETING HANDLE WITH SCREWDRIVER

- Insert the ¼" proximal end of the screwdriver into the distal recess of the ratcheting handle until it is captured. If the screwdriver does not fully seat, rotate the shaft of the screwdriver slightly during insertion. While still holding the ratcheting handle, tug on the screwdriver to ensure that it is properly secured (Figure 19).

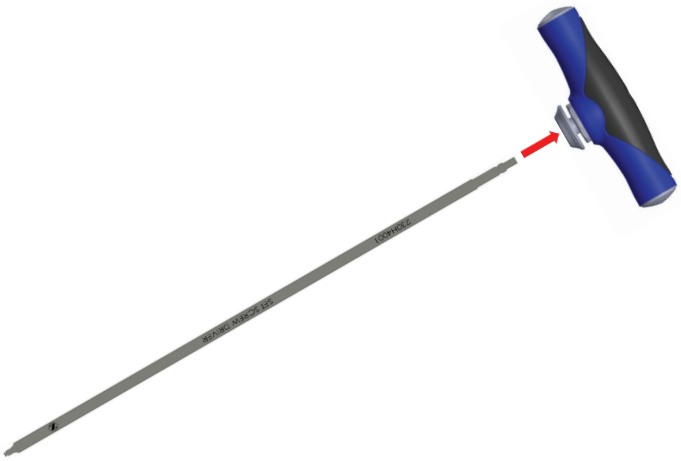


Figure 20
Set screw driver and torque-limiting T-handle assembly

TORQUE-LIMITING T-HANDLE WITH T20 SET SCREW DRIVER

- Insert the proximal end of the T20 set screw driver into the distal recess of the T-handle. Simply insert the set screw driver until it is captured by the T-handle. If the set screw driver will not fully seat, rotate the shaft of the set screw driver during insertion. While still holding the T-handle, tug on the set screw driver to ensure that it is properly secured (Figure 20).

  Note: *The torque-limiting T-handle is intended for return to Zimmer Biomet Spine and recalibration after 25 cleaning cycles, or 6 months.*

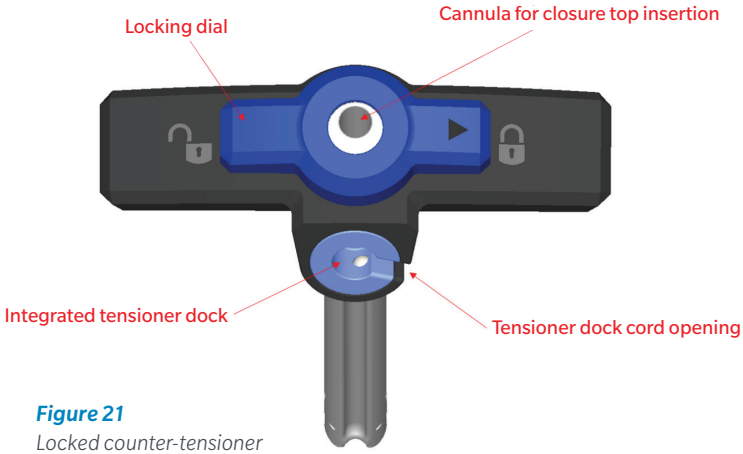


Figure 21
Locked counter-tensioner

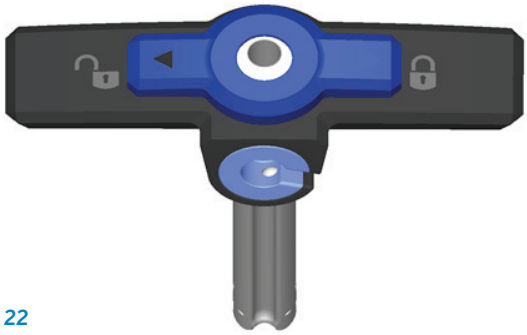


Figure 22
Unlocked counter-tensioner

COUNTER-TENSIONER

- The counter-tensioner is used to capture an implanted screw and assist with the cord tensioning and capture processes. The counter-tensioner features a cannula for introducing a set screw to the vertebral body bone screw, to secure the cord (Figure 21).
- Before attempting to attach the counter-tensioner to a screw implant, ensure that the locking dial on the T-handle of the counter-tensioner is in the unlocked position (Figure 22).
- The cord may be tensioned using the integrated tensioning port on the counter-tensioner's handle, or the counter-tensioner may be used in conjunction with the extension spring tube.

PRE-SURGICAL INSTRUMENT ASSEMBLY *(continued)*

Figure 23
Extension spring tube

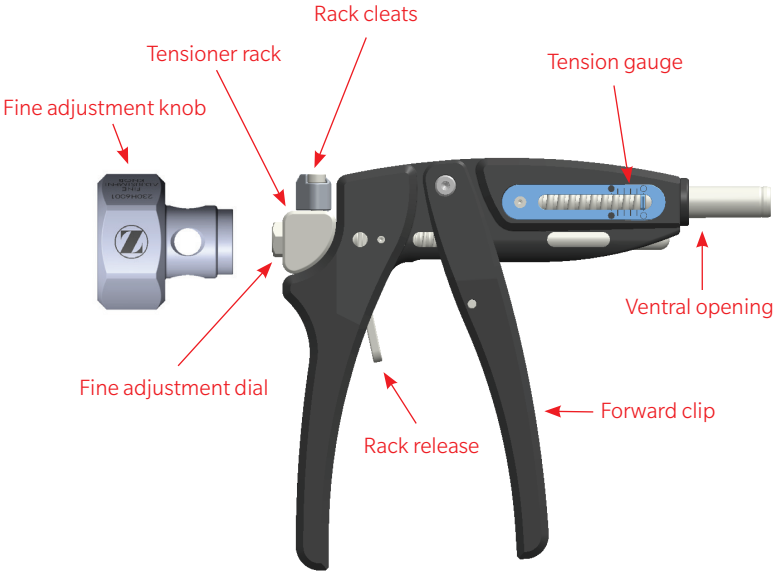


Figure 24
Tensioner

EXTENSION SPRING TUBE, LONG

- The extension spring tube eliminates the need to feed the cord through a port and into the dock of the counter-tensioner to tension the construct. The extension spring tube is typically inserted through the most caudal 15 mm port. Never tension the cord through the extension spring tube without the distal end of the tube first resting against the most caudal counter-tensioner (Figure 23).

TENSIONER

- The tensioner is used to tension the cord along the implant construct. The tensioner can either be used in conjunction with the extension spring tube and a counter-tensioner, or with only a counter-tensioner. The tensioner features a ventral opening through which the cord is passed (Figure 24).

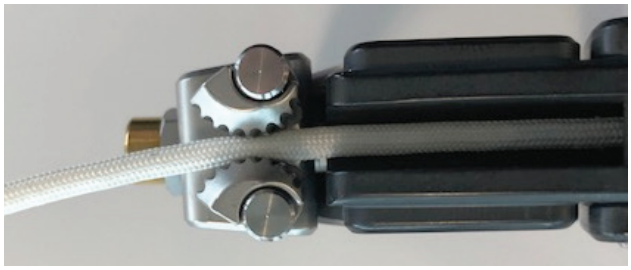


Figure 25
Tensioner rack and cleat capture of cord

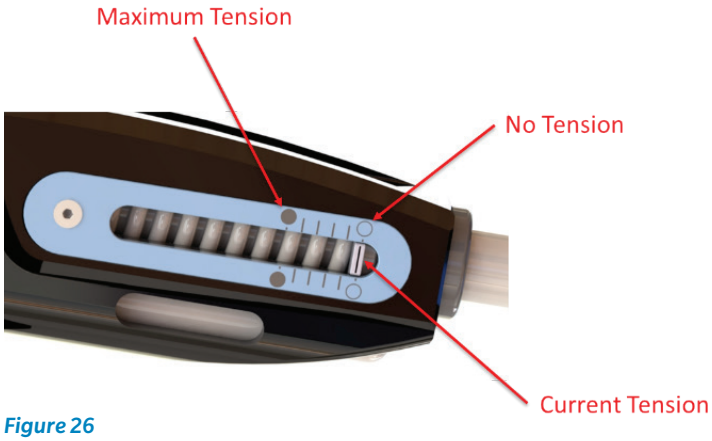


Figure 26
Tension gauge

- Once the cord exits the body of the tensioner it is placed into the cleats of the tensioner's rack (Figure 25). This will secure the cord in place so that it may be tensioned.
- Tensioning is performed by squeezing the forward grip of the tensioner. If preferred, the surgeon may utilize the fine adjustment knob to add or reduce tension in a more precise manner than squeezing the grip of the tensioner. Place the fine adjustment knob on the back of the tensioner's rack and rotate clockwise for additional tension and counter-clockwise to reduce tension.
- The tensioner features a gauge that indicates the achieved proximal tension, but is not a direct indicator of tension across the implant construct (Figure 26). Tension on the cord at the implant construct will vary depending on whether the extension spring tube, or the counter-tensioner is being utilized to tension. The extension spring tube applies greater tension. Do not exceed the maximum tension marker when tensioning the cord.
- It is recommended to use the fine adjustment knob, to relieve tension along the cord, before pressing the silver tensioner release. This will help prevent the tensioner rack from rebounding as the release is depressed and the cord is relieved of tension.

SURGICAL APPROACH

NON-SCREW DELIVERY INSTRUMENTATION PORTS

Screw Insertion Portal Preparation

Once the patient is properly positioned, identification of the entry portals for screw insertion should be done prior to preparation and draping. This is done to ensure proper visualization of each vertebral body to be instrumented. The entry points for screw insertion can be estimated from posterior-anterior and lateral fluoroscopy images, taking care to align the fluoroscopy between each image, so that a perfectly orthogonal view of the vertebra is obtained. The portal sites for screw insertion are typically in the posterior-axillary line.

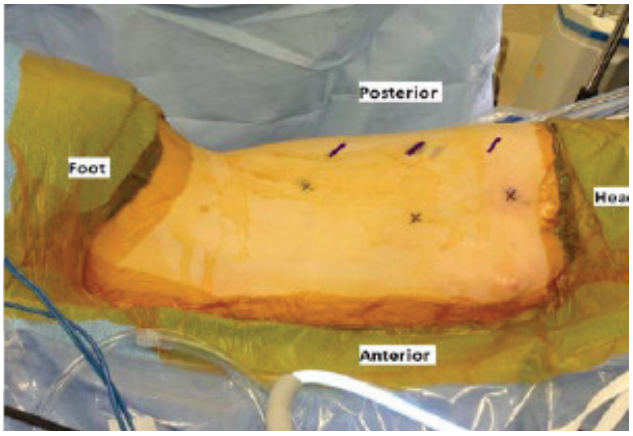


Figure 27
Trocar and port preparation

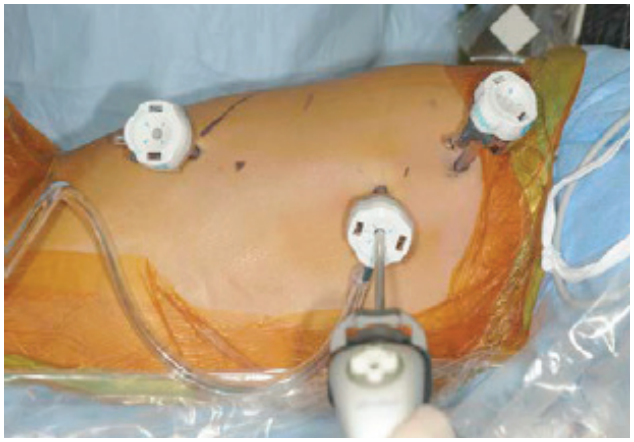


Figure 28
Ports inserted

THOROSCOPY PORTAL PREPARATION AND INSERTION

- Insert two to three thoracoscopic ports in the anterior axillary line, through the intercostal spaces spanning the curve to be addressed with The Tether™ – Vertebral Body Tethering System. These ports may be used for harmonic scalpel and thoracoscopic camera introduction, as well as lung retraction. These instruments may be moved between ports; throughout the procedure as necessary. Confirm the vertebral body level using C-arm fluoroscopy in the anterior/posterior (A/P) view (Figures 27 and 28).
- Using the harmonic scalpel, incise the parietal pleura longitudinally and identify the segmental vessels along the vertebrae to be instrumented. Coagulate the segmental vessels and expose the lateral aspect of the vertebral bodies intended for instrumentation. Some surgeons choose to dissect anterior to the rib heads, in a circumferential fashion. Others choose to expose posterior to the rib head, to maintain anterior-posterior orientation, noting the proximity of the posterior wall of the vertebral body and the spinal canal. Dissection should be conducted in a sequential fashion along the length of the spinal curvature that is to be instrumented and ultimately tethered. Dissect the pleura off the lateral aspect of the vertebral bodies intended for instrumentation.

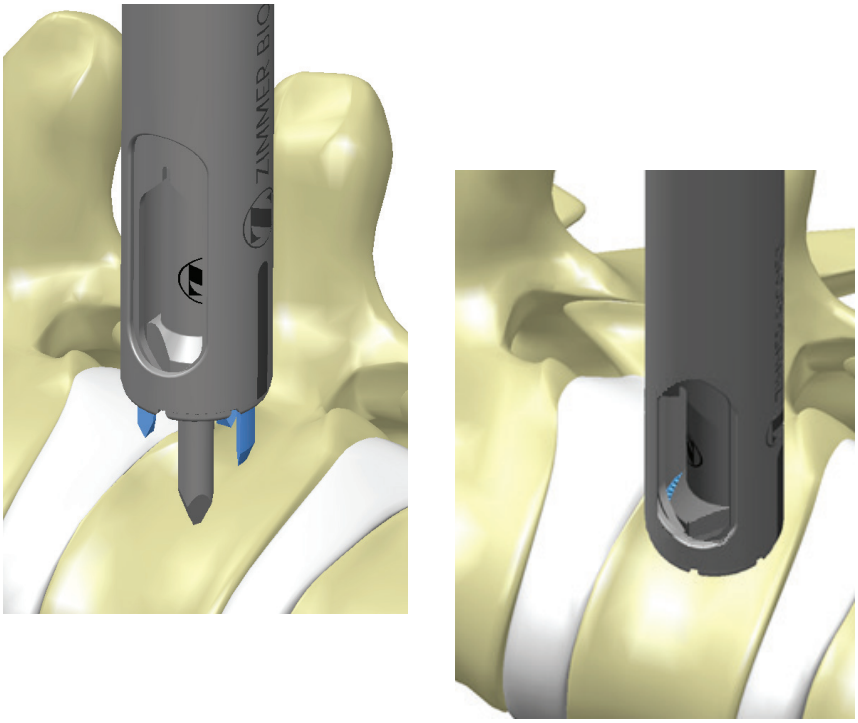


Figure 29
Anchor insertion and initial screw pilot hole

ANCHOR INSERTION

- Introduce a port overlaying the most cephalad or caudal vertebral body to be instrumented and ultimately tethered. After each vertebral level is instrumented, the ports may be moved as necessary to the adjacent intercostal spaces, to facilitate ideal implant placement.
- With the anchor firmly secured and the appropriate awl fully inserted and retained, use the ATO to approach either the most cephalad or caudal vertebra to be instrumented, via a port marked preoperatively along the posterior-axillary line. Targeting the lateral aspect of the vertebral body, place the awl tip and anchor along the lateral body and confirm their exact position with A/P and lateral fluoroscopy. Care should be taken to ensure that the tip of the awl will travel parallel to the vertebral end plate at the level being instrumented. Introduce the awl and anchor into the lateral vertebral body, by gently impacting the awl's strike pad/dial with a mallet.
- The proper positioning of the awl and anchor should be well visualized with a thoracoscope (Figure 29). Care must be taken to ensure that the awl tip and the anchor tines remain anterior to the rib head, to ensure that neither encroaches upon the neural foramen. Keep the anchor tines from violating the disc space or the vertebral endplate.

SURGICAL APPROACH *(continued)*

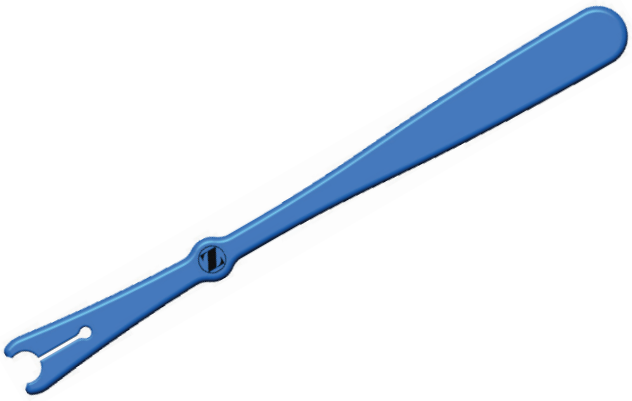


Figure 30
Anchor inserter 90° handle

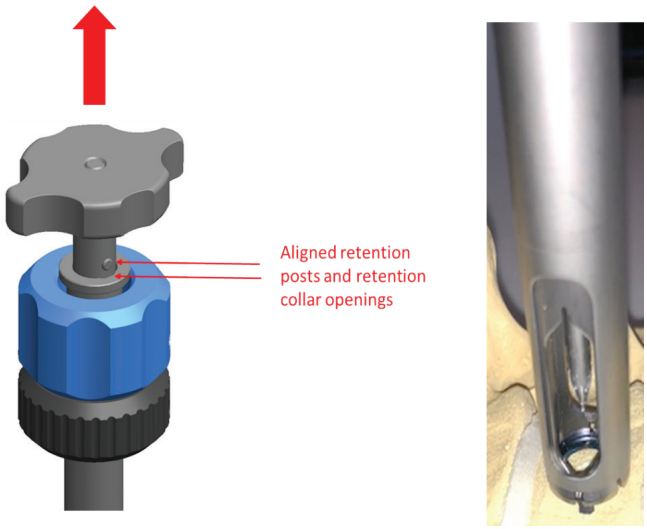


Figure 31
Remove awl from ATO

- Modulate anchor placement, depending upon the region of the spine being instrumented and the sagittal alignment presented by the patient in preoperative imaging. To recreate kyphosis, or reduce lordosis along the construct, place the anchor as far forward along the anterior column as deemed safe. Conversely, place the anchor towards the posterior column of the vertebra, if it is determined that a reduction in kyphosis or the introduction of lordosis is needed. Take care to ensure that the tines of the anchor and the tip of the awl do not encroach upon the intervertebral foramen, when placing the anchor along the posterior aspect of the vertebral body.
- Proper positioning of the anchor should be confirmed via C-arm fluoroscopy in both A/P and lateral views.
- Depending on surgeon preference, the radiolucent anchor inserter 90° handle can be used to hold the ATO, while using fluoroscopic imaging (Figure 30).
- Once the anchor and awl are fully seated and their positioning is confirmed via fluoroscopy, remove the awl by pulling back on the strike pad/dial, until the retention posts of the awl rest against the retention collar of the ATO's inner cannula. Then turn the strike pad/dial, until the retention posts find the proper alignment with the oblong opening in the ATO inner sleeve's retention collar. At this point the awl can be fully removed (Figure 31).

Figure 32
Proximal integrated tap depth gauges

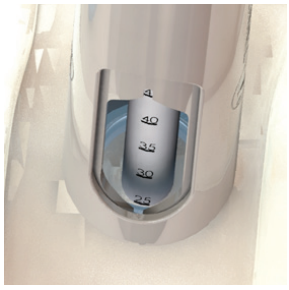


Figure 33
Distal integrated tap depth gauges

Figure 34
Tapping through ATO

SCREW PREPARATION AND INSERTION

- There are distance gauges on the proximal and distal ends of the tap (Figures 32 and 33). The proximal gauge works in conjunction with the ATO instrument's inner sleeve to show the depth that the tap has been inserted into bone.
- Insert the appropriate tap through the ATO cannula until it comes to rest against the opening in the vertebral body's lateral cortex, created by the awl tip (Figure 34).
- Rotate the ratcheting handle in a clockwise fashion, to progress the tap forward and into the bone. Using fluoroscopy for guidance, the tap should be advanced from the convexity of the curve toward the concavity, across the anterolateral aspect of the vertebral body. Care should be taken to ensure that the progression of the tap is completely parallel to the endplates of the vertebral body being instrumented.
- Careful bi-cortical purchase is desired when placing final instrumentation. After reaching the desired depth with the tap, confirm it's positioning with both A/P and lateral fluoroscopy. Once the desired positioning has been confirmed, rotate the ratcheting handle counter-clockwise to back the tap out of the bone.

SURGICAL APPROACH *(continued)*

Figure 35
Sounding probe

Figure 36
Screwdriver and screw assembly

- A ball-tipped sounding probe may be used to manually inspect the preparation site (Figure 35). There are markings on the distal end of the probe that indicate the depth to which it is inserted. These markings work in a similar fashion to the distal markings on the tap. Once preparing the vertebra for screw insertion is complete, the appropriate length screw can be selected.
- To secure the screw to the screwdriver, firmly seat the tip into the tulip of the vertebral body bone screw (Figure 36). Push forward on the screwdriver's dial and rotate the dial clockwise, until the screw is secured.

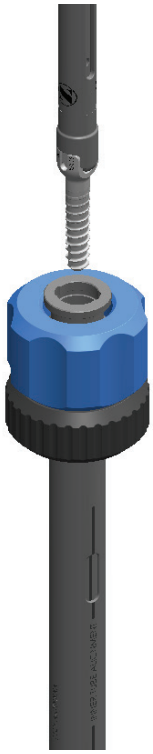


Figure 37
Screw insertion through ATO

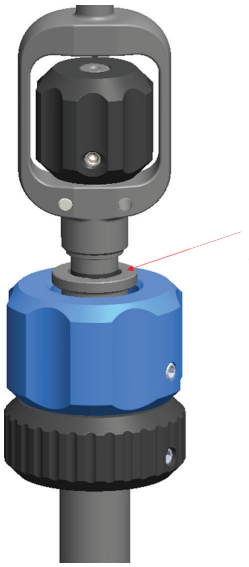


Figure 38
Screw insertion

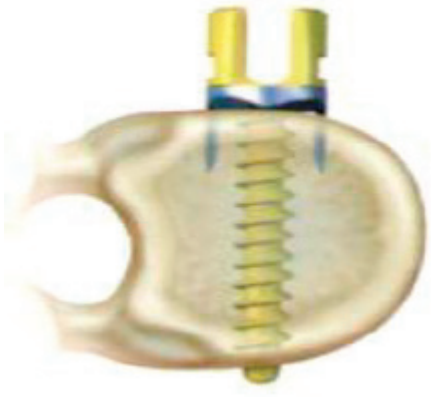


Figure 39
Bi-cortical screw placement

SCREW PREPARATION AND INSERTION *(continued)*

- Insert the screw and distal inserter end into the ATO cannula, until it comes to rest at the entry point into bone previously prepared by the awl and tap (Figure 37).
- Rotate the ratcheting handle clockwise, until the witness mark on the screwdriver meets the retention collar of the ATO inner sleeve (Figure 38). Do not over-insert the screw.
- Careful bi-cortical purchase is recommended for the placement of each screw (Figure 39). Fluoroscopy and thoracoscopic guidance should be used during the screw insertion process, to ensure that proper alignment and placement is achieved.

SURGICAL APPROACH *(continued)*

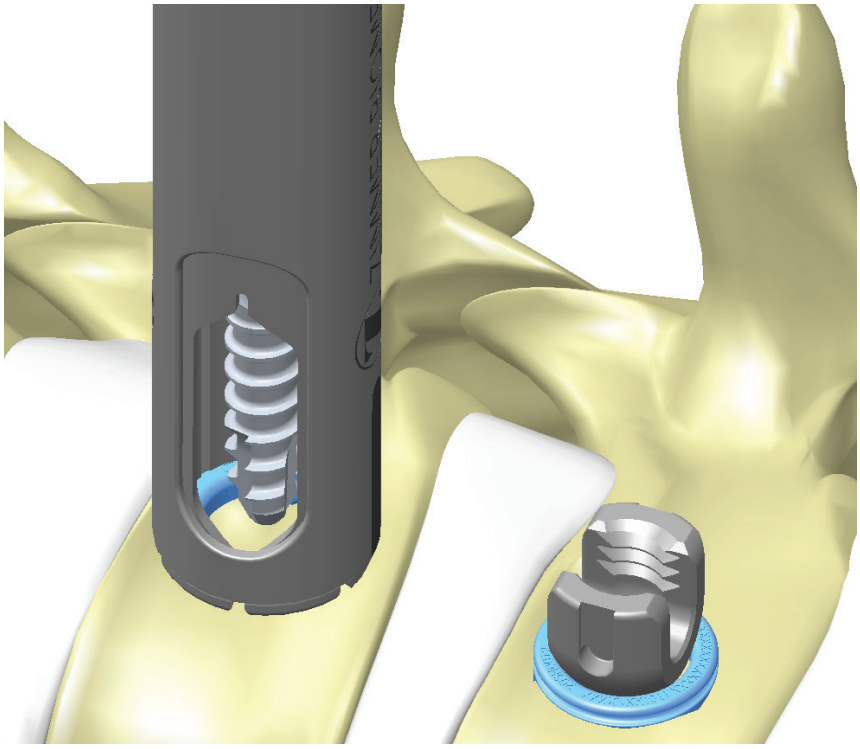


Figure 40
Subsequent screw placement

- Subsequent screws are placed in a similar manner in the vertebral bodies intended for instrumentation (Figure 40).

  Note: *Usually, 3 intercostal punctures are performed for each port's skin incision—each intercostal puncture corresponds to the placement of a screw. This process involves the removal of the trocar at the initial port site and then inserting it, through the same skin incision, to the next lower interspace. When a thoracotomy is performed, the most distal screws can be placed via the thoracotomy incision.*

- Once all screws are placed, each screw is checked for proper positioning using C-arm fluoroscopy in A/P and lateral views.

- If no anchor is placed at any vertebral level, the awl can be used in a free-hand fashion. In these instances, tap insertion depth should be determined using the distal markings on the instrument.

- K-wires are available to assist with freehand introduction of a tap and the implant itself.

  Note: *In the event that a thoracic construct should need to span the diaphragm, a small opening in the diaphragm is made and the cord is passed through that opening. Care should be taken to ensure that the opening made in the diaphragm is minimal and co-axial to the eventual path of the cord, once it is tensioned. This will prevent a widening of the diaphragm opening or bunching of the diaphragm tissue against the vertebral body. Consideration should also be given to closing the diaphragmatic opening.*

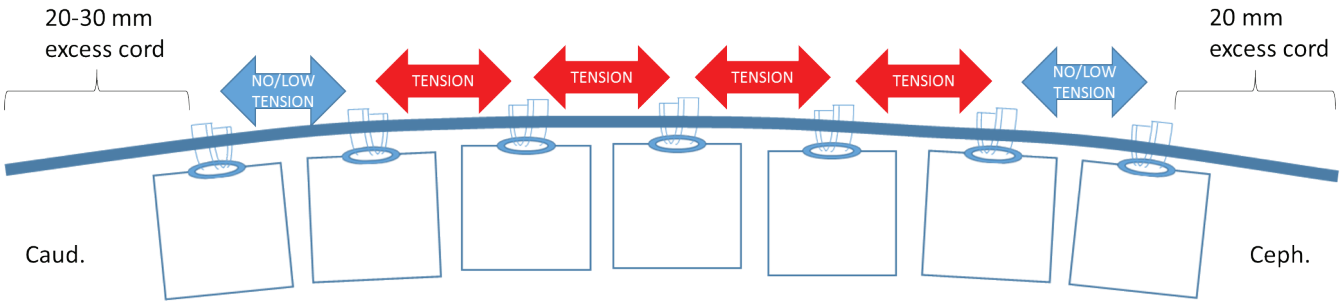


Figure 41
Selective tensioning

PLACEMENT AND TENSIONING OF THE FLEXIBLE PET CORD

Tensioning will provide an initial correction of the curve being treated, but more importantly it will allow for growth modulation at the levels instrumented. The amount of tension needed will vary from patient to patient and ultimately be dependent on a multitude of factors including preoperative Cobb angle, curve flexibility, curve type(s), curve location(s), skeletal maturity, and anticipated growth, among others. The forces applied to the different levels should be such that tensioning and the resulting growth modulation will be able to achieve the desired correction over time.

There are two strategies for tensioning along a tethering construct:

1. Sequential (or segmental) tensioning, where tensioning is performed one motion segment at a time
2. Multi-segment tensioning, where more than one segment is tensioned at the same time.

Once all desired screws have been inserted, introduce the cord to the thorax. Some surgeons may find that first passing the cord through the extension spring tube, then inserting the distal end of both the cord and the tube through the caudal 15 mm port simplifies the insertion process.

Once this has been done, use either the cord alignment rod or an endoscopic grasper to pull a sufficient working length of cord through the distal tip of the extension spring tube, so that it may be laid into the screw tulip heads. Similarly, the cord alignment rod or an endoscopic grasper may then be used to seat the cord into the tulip heads of the screw.

It is important to leave 20 mm of excess tether beyond the most cranial screw and 20 to 30 mm beyond the most caudal screw. This is done to provide the ability to make subsequent surgical adjustments, should the patient show signs of overcorrection post-operatively.

- To accommodate the patient's future growth, prevent overcorrection, and reduce the risk of screw plowing, take care to gently tension the cord at the most cranial and caudal motion segments (Figure 41).
- When tensioning the construct, special consideration should be given to patients with considerable growth remaining (e.g. open triradiate cartilage), lower Cobb angles, or high flexibility as excessive tension may increase the risk of overcorrection.

SURGICAL APPROACH *(continued)*

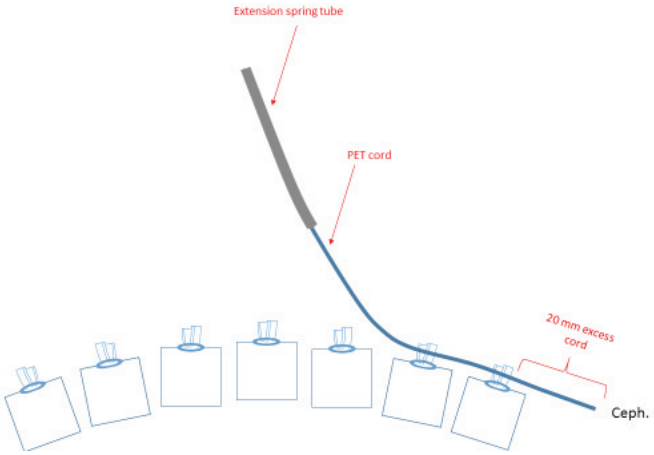


Figure 42
Initial cord placement in screw heads

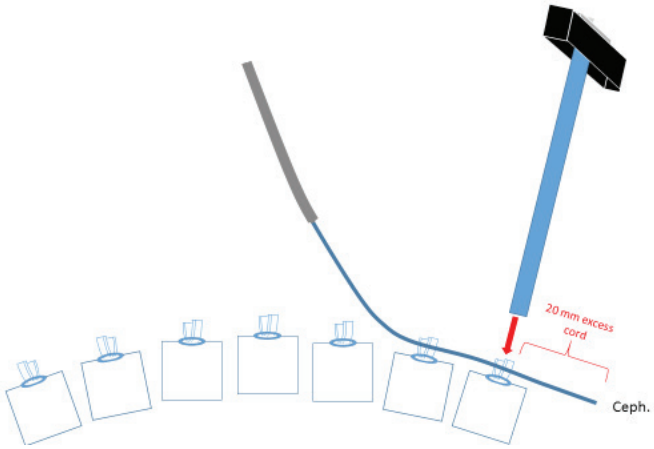


Figure 43
Initial counter-tensioner introduction

OPTION 1: SEQUENTIAL (OR SEGMENTAL) TENSIONING

- Using the cord and tube introduction method previously described, use an endoscopic grasper, or the cord alignment rod, to seat the cord along the first two proximal screws in the construct (Figure 42).
- Introduce the first counter-tensioner to the thoracic cavity via the most cephalad port, to capture the cord and the most cranial screw (Figure 43). Ensure that the dial on the tensioner is in the unlocked position before attempting to secure it to the screw.

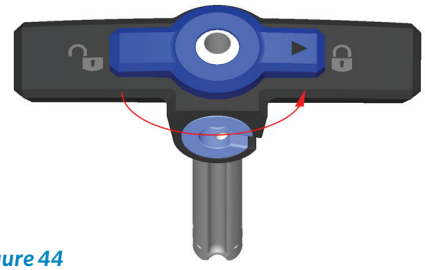


Figure 44
Locking counter-tensioner

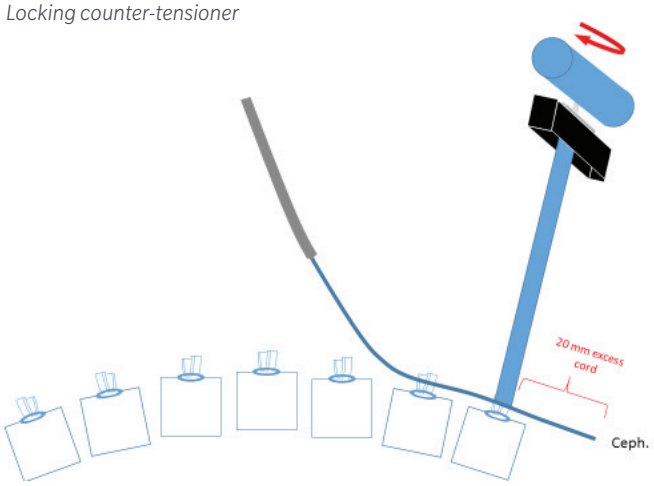


Figure 45
Locking first set screw

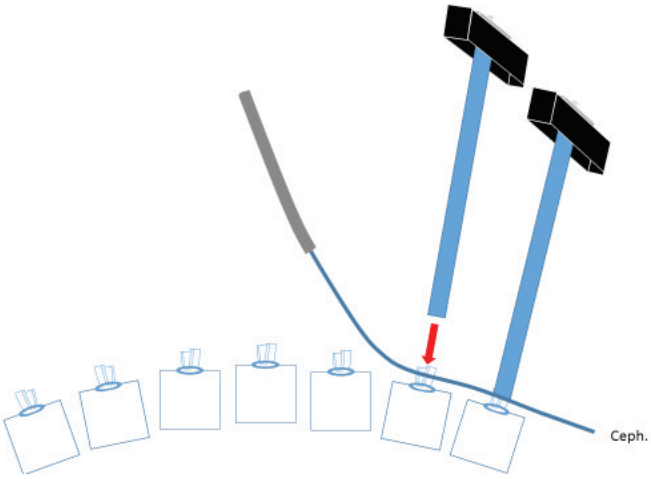


Figure 46
Securing second counter-tensioner

OPTION 1: SEQUENTIAL (OR SEGMENTAL) TENSIONING *(continued)*

- Once the distal end of the counter-tensioner is provisionally seated over the tulip head of the most cranial screw, turn the locking dial on the T-handle of the counter-tensioner, to lock the instrument in place (Figure 44).
- Introduce a set screw through the counter-tensioner's cannula using the set screw driver and T-handle. Secure the cord by first tightening the set screw at the most cranial level of the construct. Once the set screw is secured, final tighten it by rotating the T-handle clockwise, until an audible and tactile response is observed (Figure 45). Remove the set screw driver by withdrawing it from the counter-tensioner's cannula.
- Leaving the first counter-tensioner in place, introduce a second counter-tensioner to the thoracic cavity via a 15 mm port at the next caudal intercostal space. Secure the counter-tensioner to the second most cranial screw and lock it in place (Figure 46). Slide the distal end of the extension spring tube along the cord so that it rests against the caudal counter-tensioner.

SURGICAL APPROACH *(continued)*

Figure 47
Cord insertion through tensioner

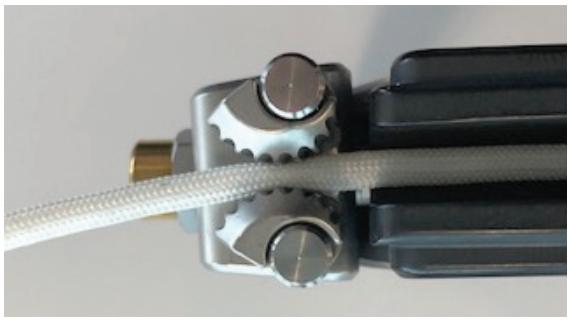


Figure 48
Capture cord with tensioner rack cleats

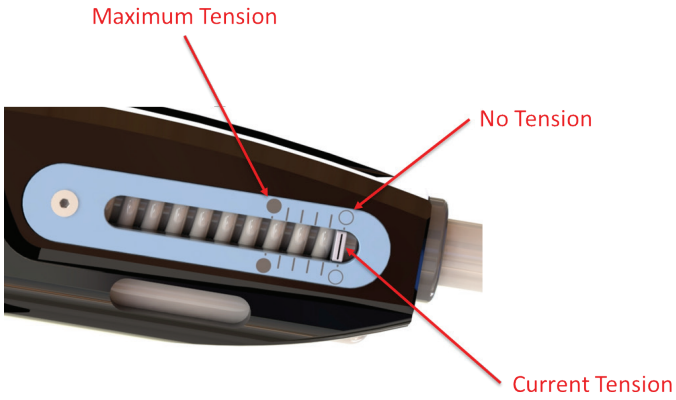


Figure 49
Tensioner gauge

- Now feed the cord through the ventral port of the tensioner (Figure 47).
- Once the end of the cord emerges from the tensioner, slide the tensioner along the cord until the tensioner's ventral aspect makes contact with the tube's proximal opening. Pull the remaining slack out of the cord and feed the cord through the tensioner's cleats, so that it is secured into place and retained by the cleats (Figure 48).
- The tensioner features a gauge that indicates the achieved proximal tension, but is not a direct indicator of tension across the implant construct (Figure 26). Tension on the cord, at the implant construct, will vary depending on whether the extension spring tube or the counter-tensioner is being utilized to tension. The extension spring tube applies greater tension. Do not exceed the maximum tension marker when tensioning the cord (Figure 49).

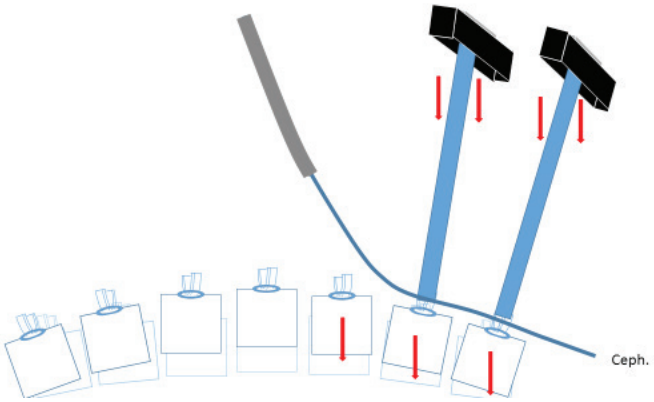


Figure 50
Lateral translation using counter-tensioners

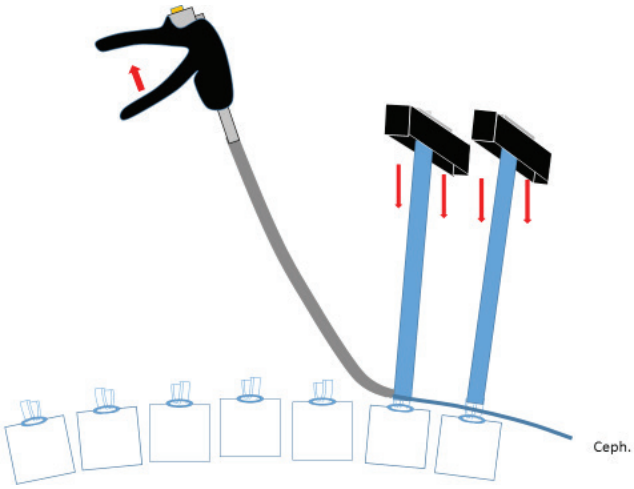


Figure 51
Tension the first segment

OPTION 1: SEQUENTIAL (OR SEGMENTAL) TENSIONING *(continued)*

- By applying gentle downward force to the counter-tensioners during the tensioning process, the surgeon can translate the spine and reduce coronal deformity. This will help increase the likelihood of reaching the desired level of correction, without reaching the tensioner's limit (Figure 50).
- Apply gentle downward force to the counter-tensioners to translate the spine and reduce the coronal deformity before tensioning begins. Tension the cord by squeezing the handles of the tensioner until the desired correction has been achieved. Gently tension the first segment to prevent over correction and to avoid screw plowing (Figure 51).

  Note: *The fine adjustment knob may be utilized to add or reduce tension in a more precise manner, rather than squeezing the grip of the tensioner. Place the fine adjustment knob on the back of the tensioner's rack and rotate clockwise for additional tension or counter-clockwise to reduce tension.*

SURGICAL APPROACH *(continued)*

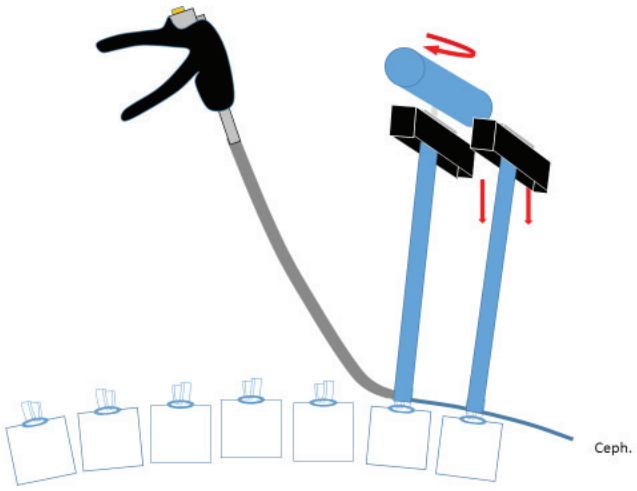


Figure 52
Final tighten first segment

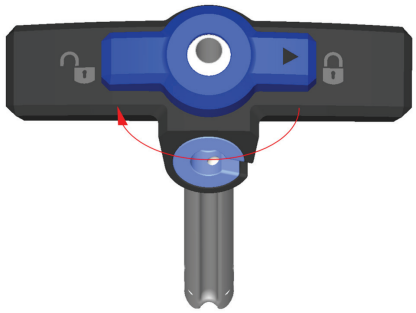


Figure 53
Unlock counter-tensioner

- Using the torque-limiting T-handle and the set screw driver, introduce the set screw to the most caudal counter-tensioner. Turn the torque-limiting T-handle clockwise until a tactile and auditory response is observed, indicating that the set screw has been final tightened (Figure 52). Press the silver release trigger on the tensioner and disengage the cord from the tensioner cleats. Back the distal end of the extension spring tube away from the caudal counter-tensioner. Remove the set screw driver from the most caudal counter-tensioner's cannula.

  Caution: *Do not provisionally introduce a set screw to the cannula of the caudal counter-tensioner before tensioning. Similarly, do not provisionally thread a set screw into the tulip of the vertebral body bone screw, before tensioning. The cord should be tensioned until the desired correction is achieved, or the tension limit is met on the tensioner's gauge, and only then should a set screw be introduced to the construct.*

- Unlock the most cranial counter-tensioner via the locking dial on the counter-tensioner's T-handle (Figure 53). Withdraw the most cranial counter-tensioner from the cranial port.
- Prior to construct finalization, cut the excess cord using the harmonic scalpel, taking care to ensure that there is approximately 20 mm of cord left above the most cephalad screw.

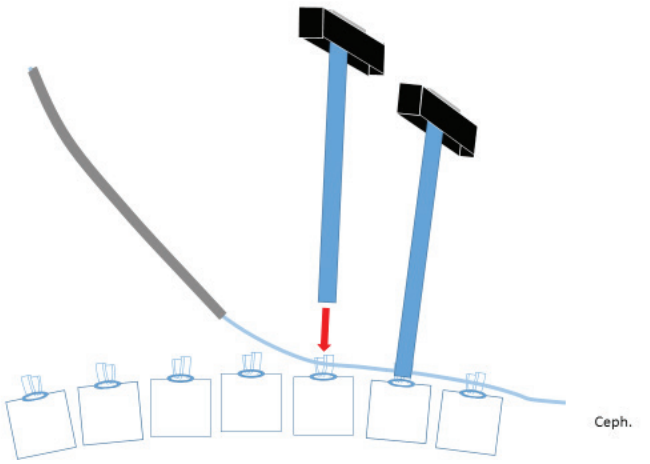


Figure 54
Setting up second segment

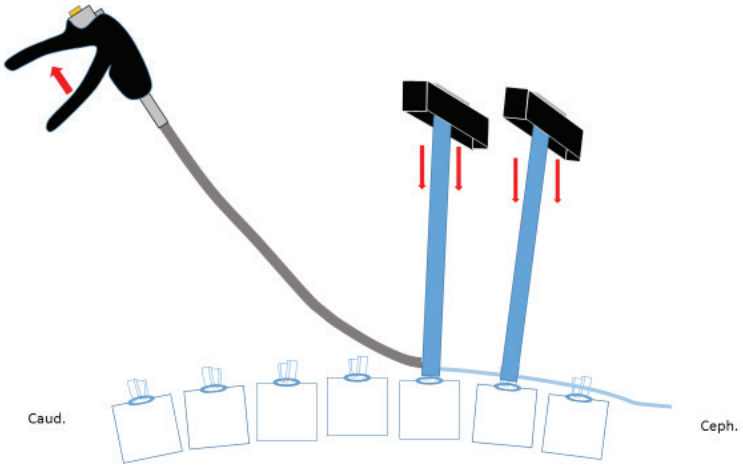


Figure 55
Tensioning across second segment

OPTION 1: SEQUENTIAL (OR SEGMENTAL) TENSIONING *(continued)*

- Introduce a port to the next intercostal space and use it to introduce the counter-tensioner to the next caudal screw. Place the distal end of the counter-tensioner over the next caudal screw in the construct and lock it into place, using the locking dial on the counter-tensioner's T-handle (Figure 54). With the cord still passed through the extension spring tube and provisionally captured by the tensioner, seat the distal end of the extension spring tube against the most caudal counter-tensioner. Next, ensure that the mouth of the tensioner is seated against the proximal opening of the extension spring tube, pull any slack out of the cord, and adjust the cord's placement in the tensioner's cleats as necessary.
- Apply gentle downward force to the counter-tensioners to translate the spine and reduce the coronal deformity before tensioning begins.
- Tension the cord by squeezing the handles of the tensioner, until the desired correction has been achieved, or the gauge on the tensioner shows that maximum tension has been reached (Figure 55). Using the torque-limiting T-handle and the set screw driver, introduce the set screw to the most caudal counter-tensioner.

SURGICAL APPROACH *(continued)*

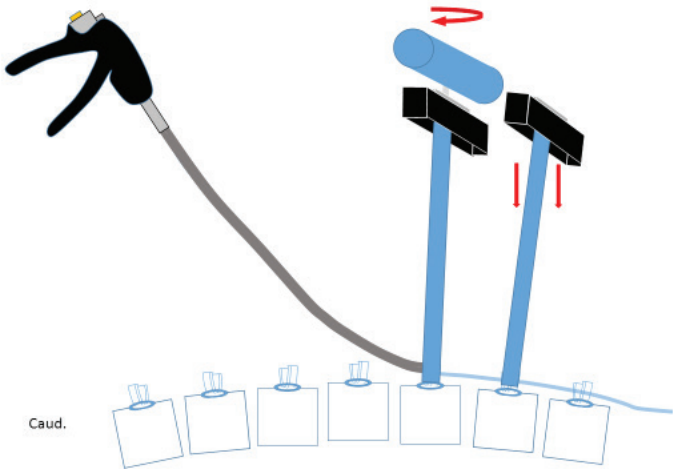


Figure 56
Final tightening second segment.

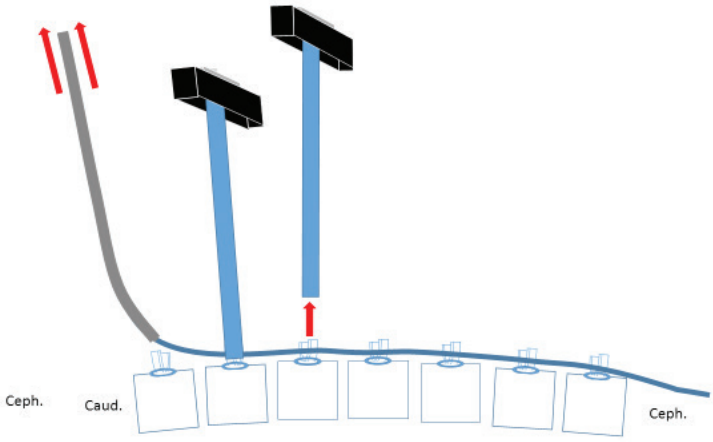


Figure 57
Remove counter-tensioner

- Using a set screw driver, introduce a set screw to the caudal screw via the caudal counter-tensioner's cannula. Turn the T-handle clockwise until a tactile and auditory response are observed. This will indicate that the set screw has been final tightened (Figure 56). Press the silver release trigger on the tensioner and disengage the cord from the tensioner cleats. Back the distal end of the extension spring tube away from the caudal counter-tensioner. Remove the set screw driver from the most caudal counter-tensioner's cannula. Unlock the most cranial counter-tensioner, via the locking dial on the counter-tensioner's T-handle. Withdraw the most cranial counter-tensioner from the cranial port.
- Repeat this process of sequential tensioning until the cord has been tensioned and secured in the second to last screw of the construct. Once tensioning has been completed from the most cephalad screw to the second most caudal screw, finalize the construct.
- Back the distal end of the extension spring tube away from the caudal counter-tensioner and withdraw the extension spring tube completely from the thorax. Unlock the most cranial counter-tensioner, via the locking dial on the counter-tensioner's T-handle. Withdraw the most cranial counter-tensioner from the cranial port (Figure 57).

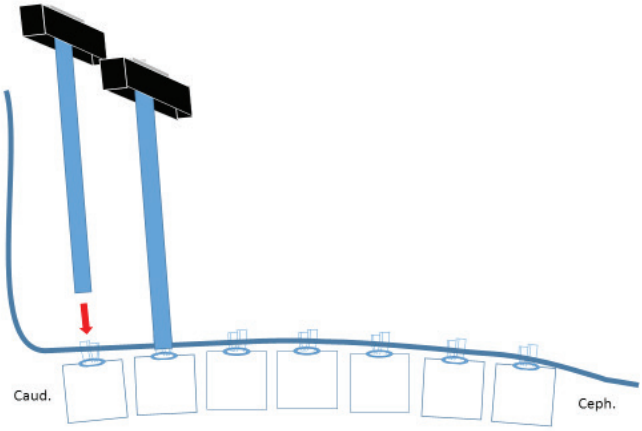


Figure 58
Placing final counter tensioner

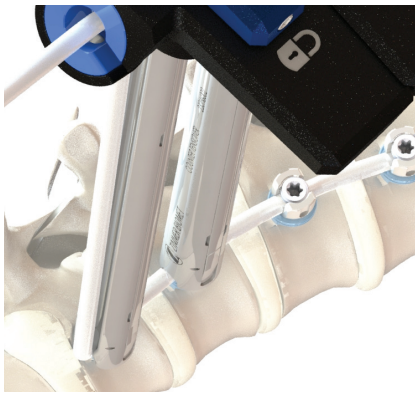


Figure 59
Preparing to final tension last segment

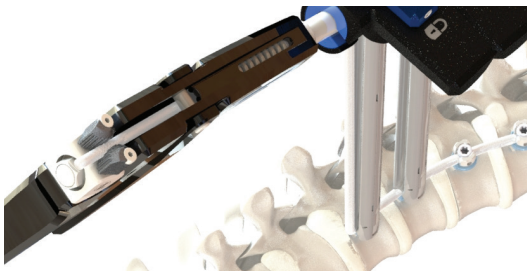


Figure 60
Tensioning final segment

OPTION 1: SEQUENTIAL (OR SEGMENTAL) TENSIONING *(continued)*

- Using the endoscopic grasper, seat the cord in the tulip of the most caudal screw. Then introduce the counter-tensioner to the thorax to capture the most caudal screw. Place the distal end of the counter-tensioner over the most caudal screw in the construct and lock it into place, using the locking dial on the counter-tensioner's T-handle (Figure 58).
- Run the cord up the caudal aspect of the most caudal counter-tensioner and out through the same port that this counter-tensioner is passing through. Lace the cord through the radial opening in the handle dock of the counter-tensioner. The distal end of the cord should now be passed through the ventral opening of the tensioner, until it exits at the back of the tensioner (Figure 59).
- While still holding the end of the cord, slide the tensioner to the integrated dock on the counter-tensioner, and then seat the ventral port into the dock. Pull the distal end of the cord taut and seat the cord in the grasping cleats of the tensioner instrument (Figure 60).

SURGICAL APPROACH *(continued)*

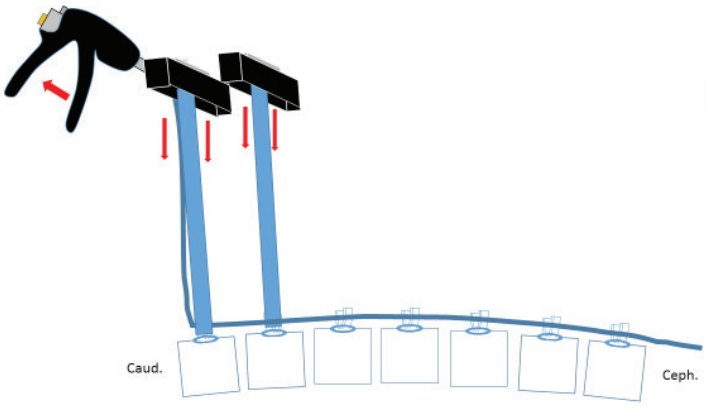


Figure 61
Finalize the caudal aspect of the construct

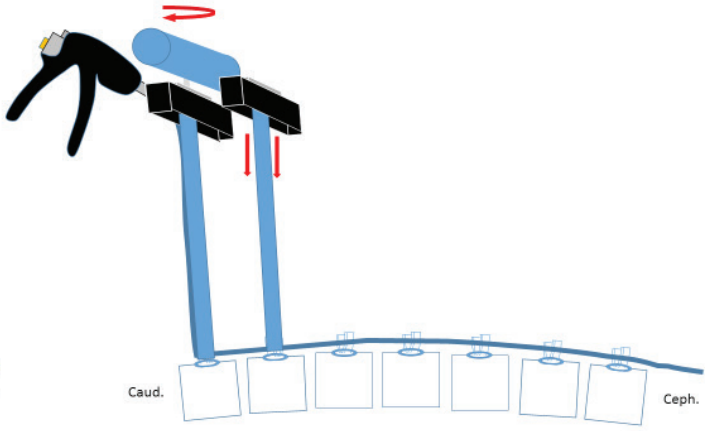


Figure 62
Final tensioning of caudal segment

- Apply gentle downward force to the counter-tensioners, to translate the spine and reduce the coronal deformity before tensioning begins. Squeeze the handles of the tensioner until the desired correction has been achieved. This last segment should be very gently tensioned, in order to prevent over correction and to avoid screw plowing (Figure 61).

  Note: *The fine adjustment knob may be utilized to add or reduce tension in a more precise manner, rather than squeezing the grip of the tensioner. Place the fine adjustment knob on the back of the tensioner's rack and rotate clockwise for additional tension or counter-clockwise to reduce tension.*

- While maintaining downward pressure, introduce a set screw to the last screw via the caudal counter-tensioner's cannula. Rotate the T-handle until a tactile and auditory response is observed, indicating that the set screw has been final tightened (Figure 62). Withdraw the T-handle and set screw driver from the most caudal counter-tensioner and then remove both counter-tensioners.

- Now that the construct has been finalized, cut the excess cord using the harmonic scalpel, taking care to ensure that there is approximately 20-30 mm of cord left beyond the final caudal screw in the construct.

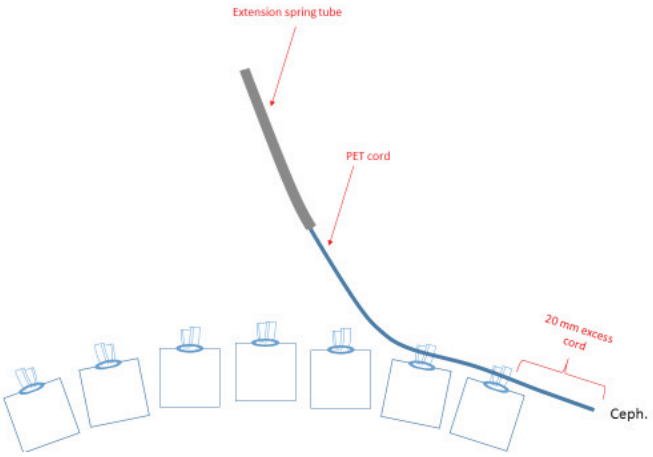


Figure 63
Seating cord

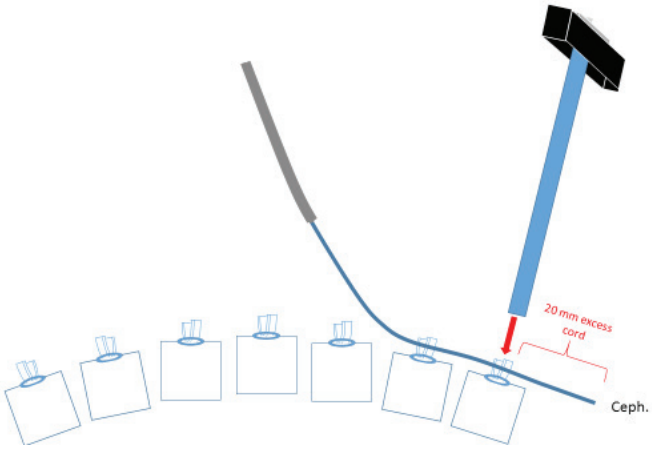


Figure 64
Introduce first counter-tensioner

OPTION 2: MULTI-SEGMENT TENSIONING

- After seating all of the screws, using the cord and tube introduction method previously described, select an endoscopic grasper or the cord alignment rod to seat the cord along the first two proximal screws in the construct (Figure 63).
- Introduce the counter-tensioner to the thoracic cavity via the most cephalad port, in order to capture the cord and the most cephalad screw (Figure 64). Ensure that the dial on the tensioner is in the unlocked position before attempting to secure it to the screw.

SURGICAL APPROACH *(continued)*

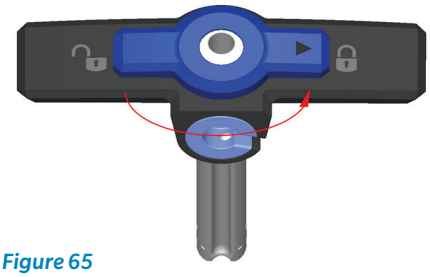


Figure 65
Secure first counter-tensioner

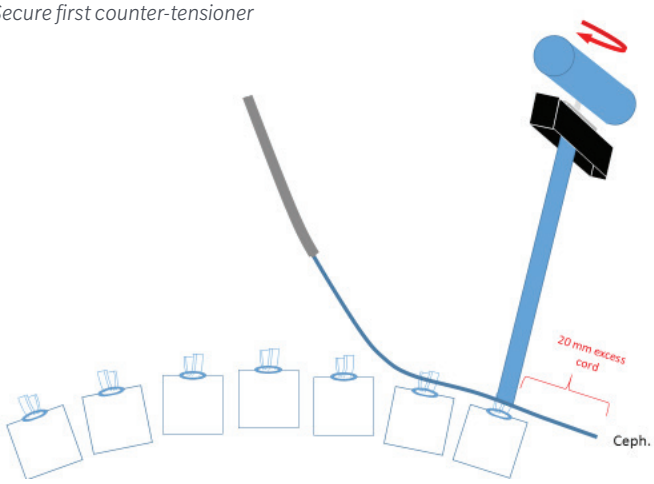


Figure 66
Secure the first set screw

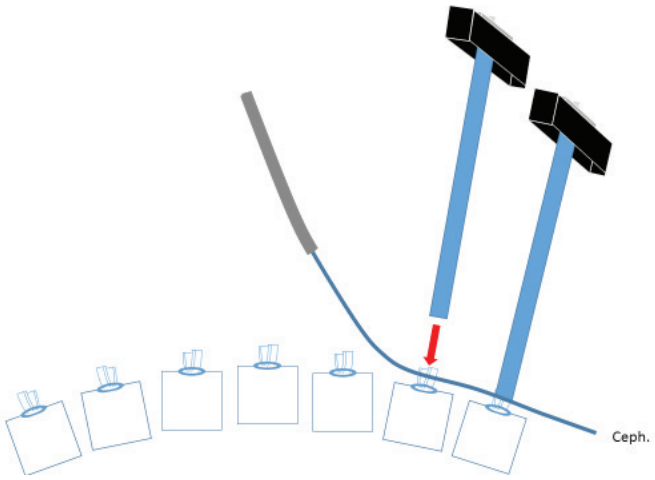


Figure 67
Secure the second counter-tensioner

OPTION 2: MULTI-SEGMENT TENSIONING *(continued)*

- Once the distal end of the counter-tensioner is provisionally seated over the tulip head of the second most cranial screw, turn the locking dial on the T-handle of the counter-tensioner, to lock it in place (Figure 65).
- Introduce a set screw through the counter-tensioner's cannula using the set screw driver and T-handle. Secure the cord by final tightening the set screw at the most cranial level of the construct. Once the set screw is secured, final tighten it by rotating the T-handle clockwise, until an audible and tactile response is observed. Remove the set screw driver by withdrawing it from the counter-tensioner's cannula (Figure 66).
- Prior to construct finalization, cut the excess cord using the harmonic scalpel, taking care to ensure that there is approximately 20 mm of cord left above the most cephalad screw.
- Leaving the first counter-tensioner in place, introduce a second counter-tensioner to the thoracic cavity via a 15 mm port at the next caudal intercostal space. Secure the counter-tensioner to the second most cranial screw and lock it in place (Figure 67). Slide the distal end of the extension spring tube along the cord until it rests against the caudal counter-tensioner.

Figure 68
Cord insertion through tensioner

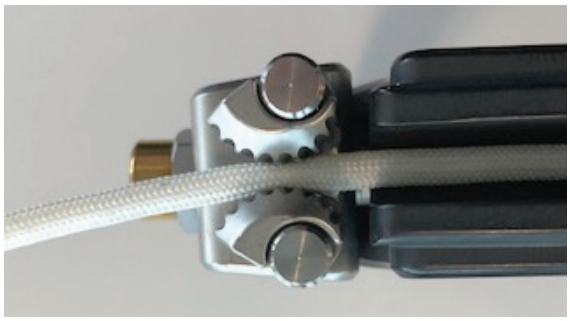


Figure 69
Capture cord with tensioner rack cleats

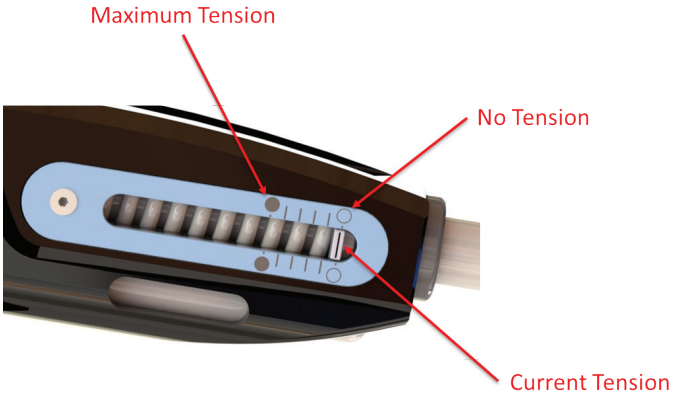


Figure 70
Tensioner gauge

- Feed the cord through the ventral port of the tensioner (Figure 68).
- Once the end of the cord emerges from the tensioner, slide the tensioner along the cord until the tensioner's ventral aspect makes contact with the tube's proximal opening. Pull remaining slack out of the cord and feed the cord through the tensioner's cleats, so that it is secured into place and retained by the cleats (Figure 69).
- The tensioner features a gauge that indicates the extent to which the instrument has created proximal tension and is not a direct indicator of tension across the implant construct (Figure 26). The tension on the cord at the implant construct will vary depending on whether the extension spring tube, or the counter-tensioner is being utilized to tension. The extension spring tube applies greater tension. Do not exceed the maximum tension marker when tensioning the cord (Figure 70).
- As noted previously, when tensioning the construct special consideration should be given to patients with considerable growth remaining (e.g. open triradiate cartilage), lower Cobb angles, or high flexibility as excessive tension may increase the risk of overcorrection.

SURGICAL APPROACH *(continued)*

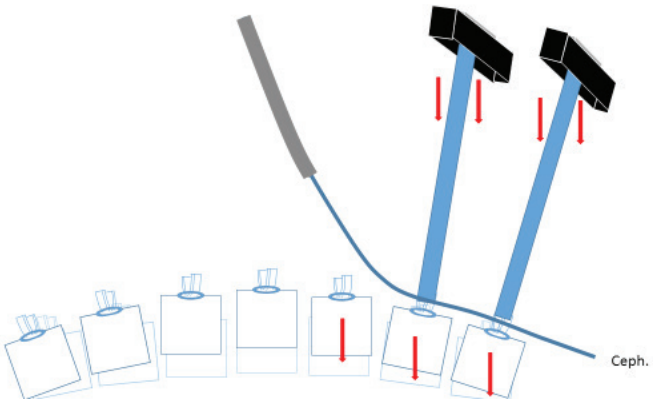


Figure 71
Lateral translation using counter-tensioners

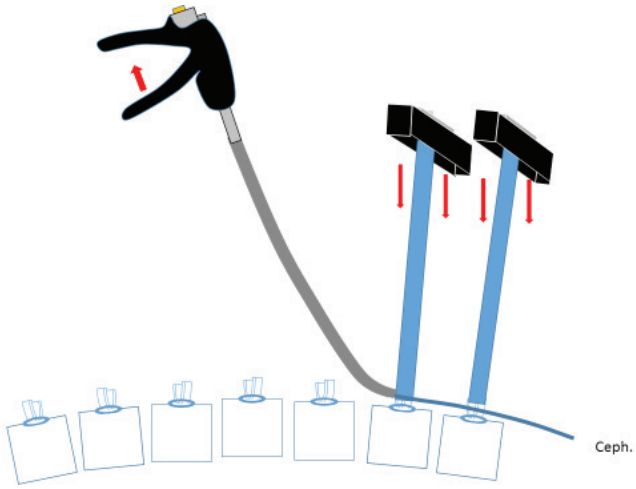


Figure 72
Tensioning first segment

OPTION 2: MULTI-SEGMENT TENSIONING *(continued)*

- By applying gentle downward force to the counter-tensioners during the tensioning process, the surgeon can translate the spine and reduce the coronal deformity before tensioning begins. This will help increase the likelihood of reaching the desired level of correction, without reaching the tensioner's limit (Figure 71).
- Apply gentle downward force to the counter-tensioners to translate the spine and reduce the coronal deformity before tensioning begins. Squeeze the handles of the tensioner until the desired correction has been achieved. This first segment should be very gently tensioned in order to prevent over correction and to avoid screw plowing (Figure 72).

  Note: *The fine adjustment knob may be utilized to add or reduce tension in a more precise manner, rather than squeezing the grip of the tensioner. Place the fine adjustment knob on the back of the tensioner's rack and rotate clockwise for additional tension or counter-clockwise to reduce tension.*

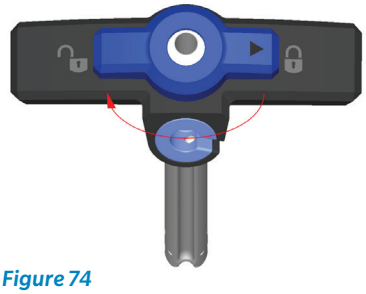


Figure 74
Unlock counter-tensioner

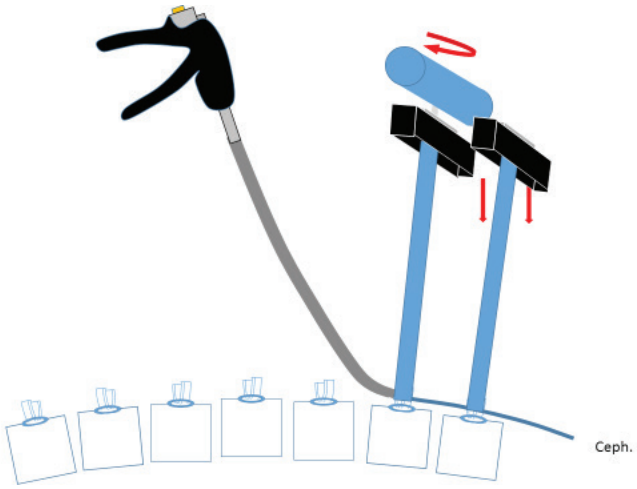


Figure 73
Final tighten the first segment

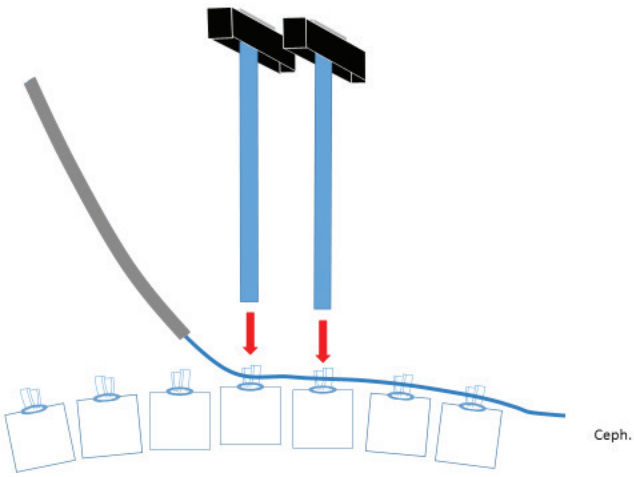


Figure 75
Place counter tensioners along apex

- Using the torque-limiting T-handle and the set screw driver, introduce the set screw to the most caudal counter-tensioner. Turn the torque-limiting T-handle clockwise until a tactile and auditory response is observed, indicating that the set screw has been final tightened (Figure 73). Press the silver release trigger on the tensioner and disengage the cord from the tensioner cleats. Back the distal end of the extension spring tube away from the caudal counter-tensioner. Remove the set screw driver from the most caudal counter-tensioner's cannula.
- Unlock both counter-tensioners via the locking dial on their respective T-handles. Withdraw both counter-tensioners from their respective ports (Figure 74).
- The two counter-tensioners should now be introduced to the thoracic cavity via 15 mm ports at intercostal spaces over the apex of the scoliotic curve. If the curve features a single apical vertebra, rather than an apical disc, place the counter-tensioners at the apical vertebra and the vertebra immediately superior to the apex. Secure the counter-tensioners by locking them into place (Figure 75). Once the counter-tensioners are secured, bring the distal end of the extension spring tube to rest against the caudal counter-tensioner.

SURGICAL APPROACH *(continued)*

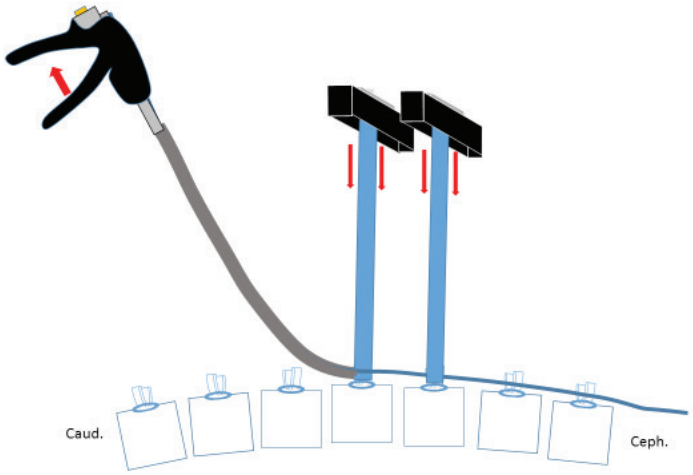


Figure 76
Multi-segment tensioning

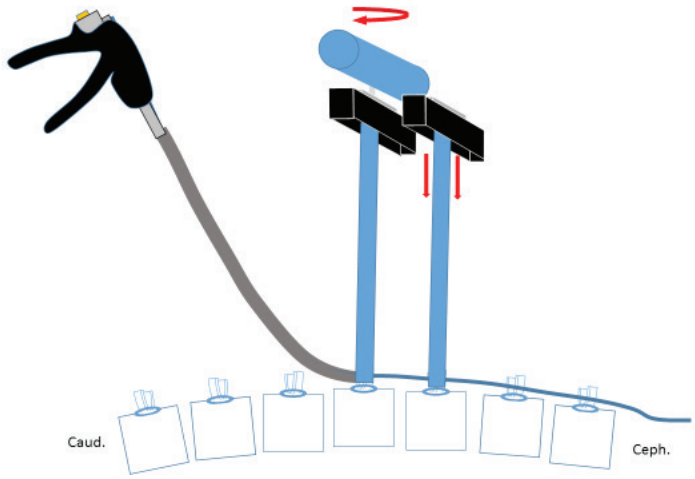


Figure 77
Finalize the first segments of the construct

OPTION 2: MULTI-SEGMENT TENSIONING *(continued)*

- Apply gentle downward force to the counter-tensioners to translate the spine and reduce the coronal deformity before tensioning begins.
- Squeeze the handles of the tensioner until the desired correction has been achieved, or the tension gauge shows that maximum tension has been reached (Figure 76).
- Using the torque-limiting T-handle and the set screw driver, introduce the set screw to the most caudal counter-tensioner. Turn the torque-limiting T-handle clockwise until a tactile and auditory response is observed, indicating that the set screw has been final tightened (Figure 77).

  Caution: *Do not provisionally introduce a set screw to either counter-tensioner cannulas before tensioning. Similarly, do not provisionally thread a set screw into the tulip of either vertebral body bone screw before tensioning. The cord should be tensioned until the desired correction is achieved, or the tension limit is met on the tensioner's gauge, and only then should a set screw be introduced to the construct.*

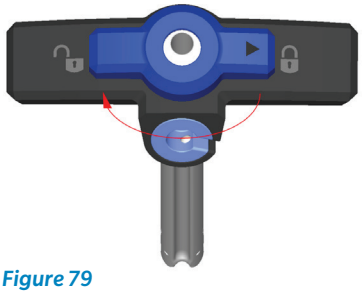


Figure 79
Unlock counter-tensioner

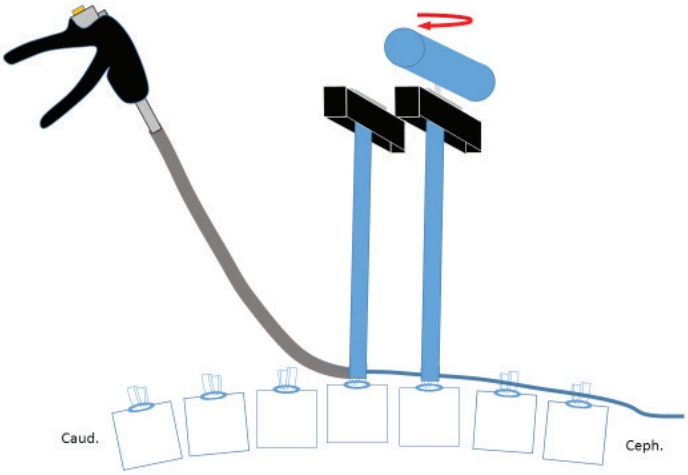


Figure 78
Final tightening of set screw

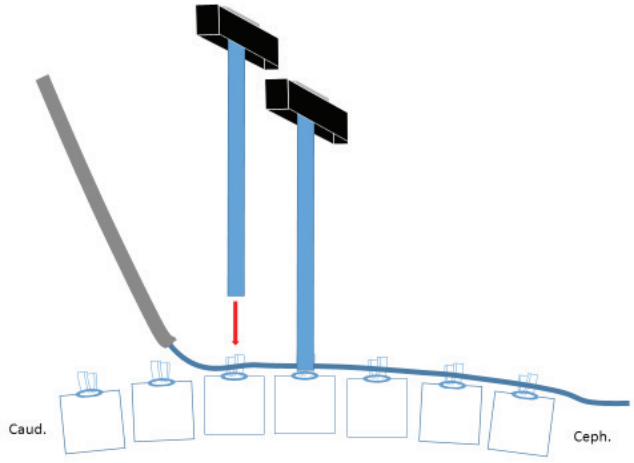


Figure 80
Introduce counter-tensioner to next caudal screw

- Using the torque-limiting T-handle and the set screw driver, introduce the set screw to the most cephalad counter-tensioner. Turn the torque-limiting T-handle clockwise until a tactile and auditory response is observed, indicating that the set screw has been final tightened.
- Press the silver release trigger on the tensioner and disengage the cord from the tensioner cleats. Back the distal end of the extension spring tube away from the caudal counter-tensioner. Remove the set screw driver from the most cephalad counter-tensioner's cannula (Figure 78).
- Unlock the most cranial counter-tensioner via the locking dial on the counter-tensioner's T-handle. Withdraw the most cranial counter-tensioner from the cranial port (Figure 79).
- Introduce a 15 mm port to the next intercostal space that provides access to the vertebra caudal to the apical vertebra. Use this new port to introduce the counter-tensioner to the next caudal screw (Figure 80). Place the distal end of the counter-tensioner over this screw and lock it into place, using the locking dial on the counter-tensioner's T-handle. With the cord still passed through the extension spring tube and provisionally captured by the tensioner, seat the distal end of the extension spring tube against the most caudal counter-tensioner. Ensure that the mouth of the tensioner is seated against the proximal opening of the extension spring tube, pull any slack out of the cord, and adjust the cord's placement in the tensioner's cleats as necessary.

SURGICAL APPROACH *(continued)*

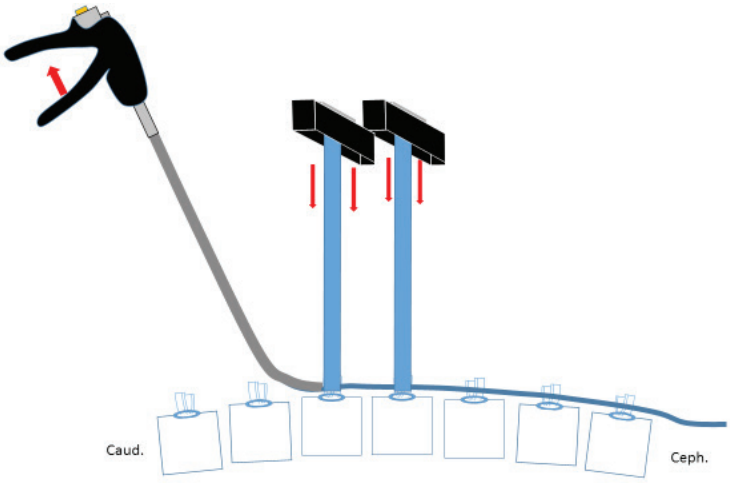


Figure 81
Tension segmentally caudal to apex

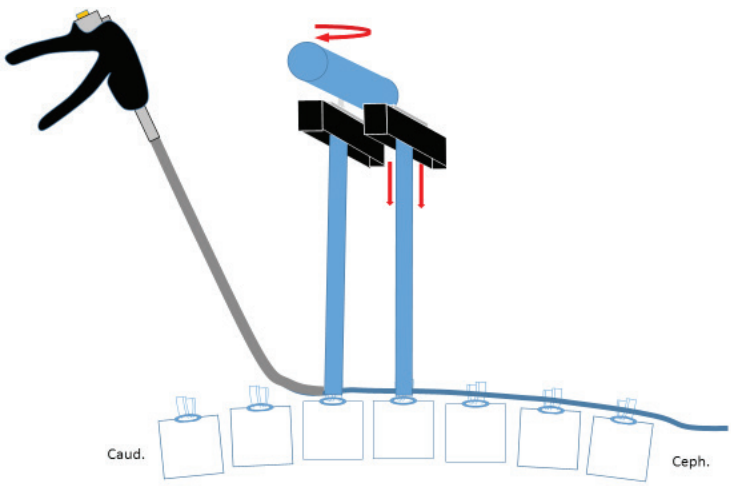


Figure 82
Finalize segment caudal to apex

OPTION 2: MULTI-SEGMENT TENSIONING *(continued)*

- Apply gentle downward force to the counter-tensioners to translate the spine and reduce the coronal deformity before tensioning begins.
- Now tension the cord by squeezing the handles of the tensioner until the desired correction has been achieved, or the witness mark shows that maximum tension has been reached. Using the torque-limiting blue T-handle and the set screw driver, introduce the set screw to the most caudal counter-tensioner (Figure 81).
- Using a set screw driver, introduce a set screw to the caudal screw via the caudal counter-tensioner's cannula. Turn the T-handle clockwise until a tactile and auditory response is observed. This will indicate that the set screw has been final tightened. Remove the set screw driver from the most caudal counter-tensioner's cannula. Unlock the most cranial counter-tensioner, via the locking dial on the counter-tensioner's T-handle. Withdraw the most cranial counter-tensioner from the cranial port (Figure 82).
- Repeat this process of sequential tensioning until the cord has been tensioned and secured in the second-to-last screw of the construct. Finalize the construct once tensioning has been completed from the most cephalad screw to the second most caudal screw.

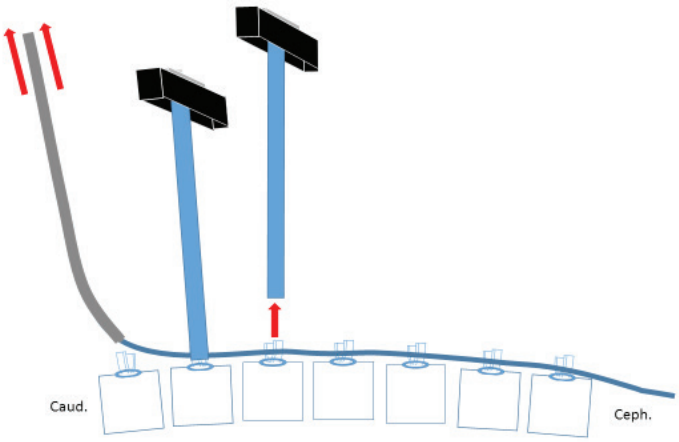


Figure 83
Remove cephalad counter-torque

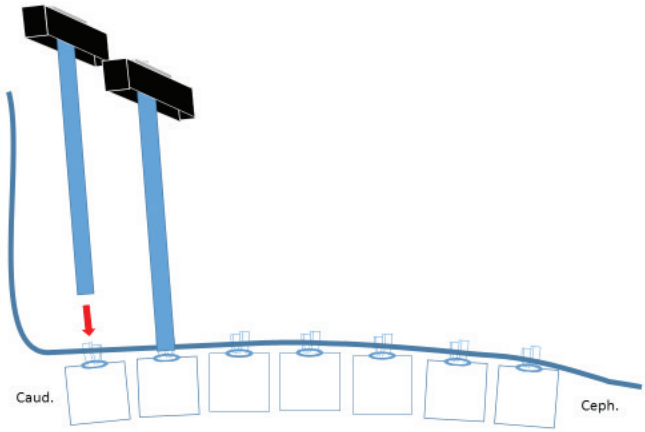


Figure 84
Place counter-tensioner at caudal vetrebral body bone screw

- Back the distal end of the extension spring tube away from the caudal counter-tensioner and withdraw the extension spring tube from the thorax. Unlock the most cranial counter-tensioner, via the locking dial on the counter-tensioner's T-handle. Withdraw the most cranial counter-tensioner from the cranial port (Figure 83).
- Using the endoscopic grasper, seat the cord in the tulip of the most caudal screw. Then introduce the counter-tensioner to the thorax to capture the most caudal screw. Place the distal end of the counter-tensioner over the most caudal screw in the construct and lock it in place, using the locking dial on the counter-tensioner's T-handle (Figure 84).

SURGICAL APPROACH *(continued)*

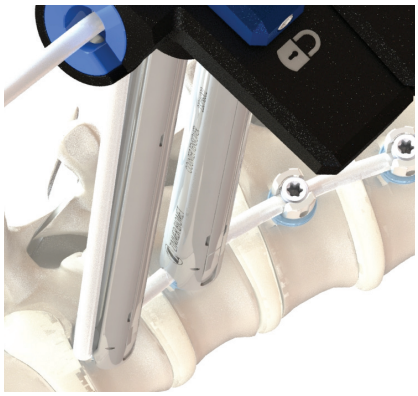


Figure 85
Prepare to final tension the last segment

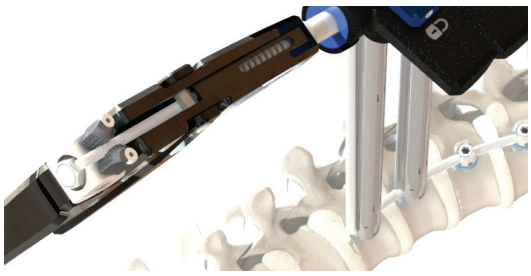


Figure 86
Tension the final segment

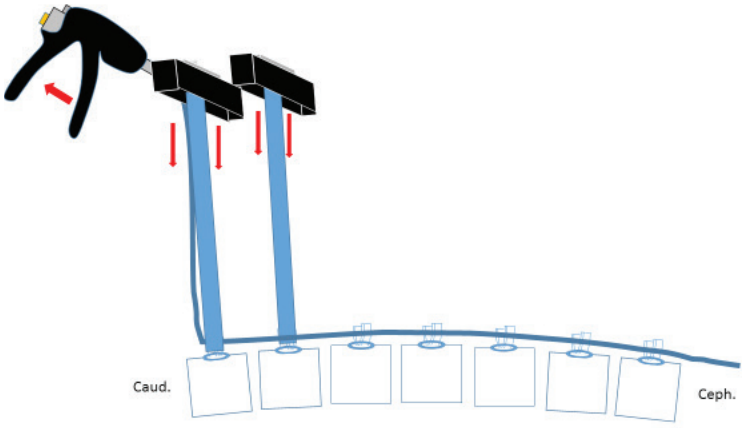


Figure 87
Tension caudal aspect of construct

OPTION 2: MULTI-SEGMENT TENSIONING *(continued)*

- Run the cord up the caudal aspect of the counter-tensioner and out through the same port that the counter-tensioner is passing through. The cord should be laced through the radial opening in the handle dock of the counter-tensioner. Pass the distal end of the cord through the ventral opening of the tensioner, until it exits at the back of the tensioner (Figure 85).
- While still holding the end of the cord, slide the tensioner to the integrated dock on the counter-tensioner, and then seat the ventral port into the dock. Pull the distal end of the cord taut and seat the cord in the grasping cleats of the tensioner instrument (Figure 86).
- Apply gentle downward force to the counter-tensioners, to translate the spine and reduce the coronal deformity before tensioning begins. Now tension the cord by squeezing the handles of the tensioner until the desired correction has been achieved. This last segment should be very gently tensioned, in order to prevent over correction and to avoid screw plowing (Figure 87).

  Note: *The fine adjustment knob may be utilized to add or reduce tension in a more precise manner, rather than squeezing the grip of the tensioner. Place the fine adjustment knob on the back of the tensioner's rack and rotate clockwise for additional tension or counter-clockwise to reduce tension.*

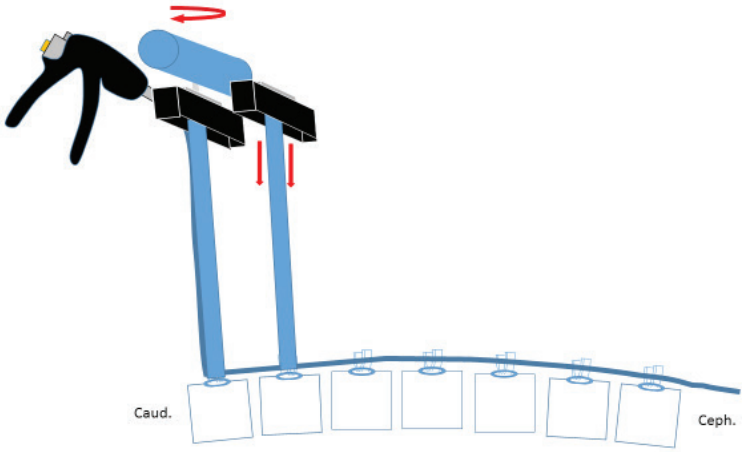


Figure 88
Finalize caudal segment

Figure 89
Tensioner rack fully extended

- While maintaining this downward pressure, introduce a set screw to the last screw via the caudal counter-tensioner's cannula. Rotate the T-handle until a tactile and auditory response is observed, indicating that the set screw has been final tightened (Figure 88). Withdraw the T-handle and set screw driver from the most caudal counter-tensioner and then remove both counter-tensioners.
- Now that the construct has been finalized, cut the excess cord using the harmonic scalpel, taking care to ensure that there is approximately 20-30 mm of cord left beyond the most caudal screw in the construct.

CLOSURE

- The wound is closed using standard techniques.

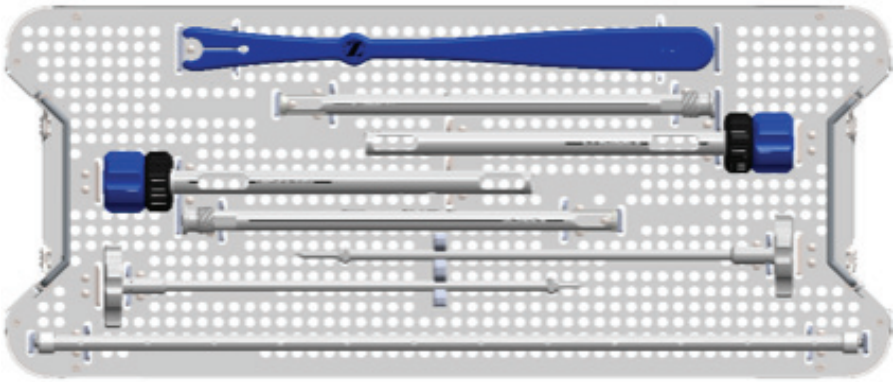
REVISION/REMOVAL

- Introduce the counter-tensioner to the desired screw. Use the T-handle and set screw driver to loosen the set screw and remove. Introduce the screwdriver to the thorax, through a 15 mm trocar to remove the screw in a freehand fashion. The staple may be removed by an endoscopic grasper, or via the ATO.

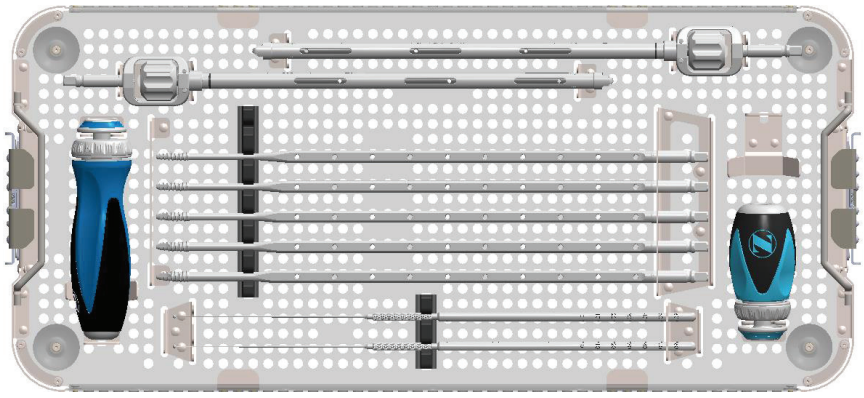
SPECIAL CLEANING INSTRUCTIONS FOR TENSIONER

- Work the rack in and out while manually cleaning the tensioner. The tensioner rack should be fully extended during automated cleaning (Figure 89).

KIT CONTENTS



Upper



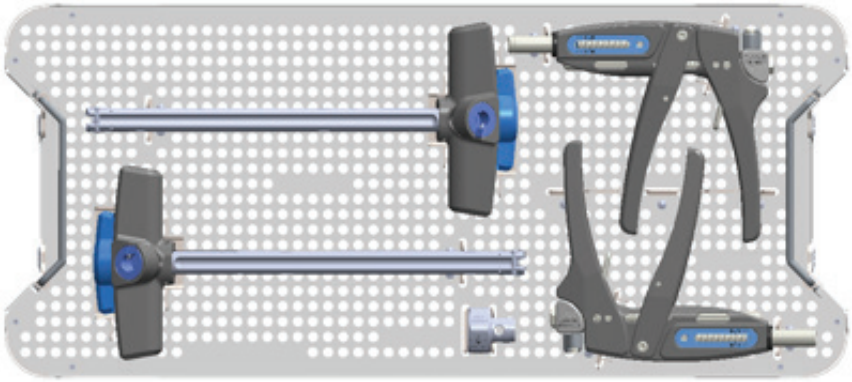
Lower

The Tether Instrument Kit 1 - Cannulated
Kit Number: PCR200H1101

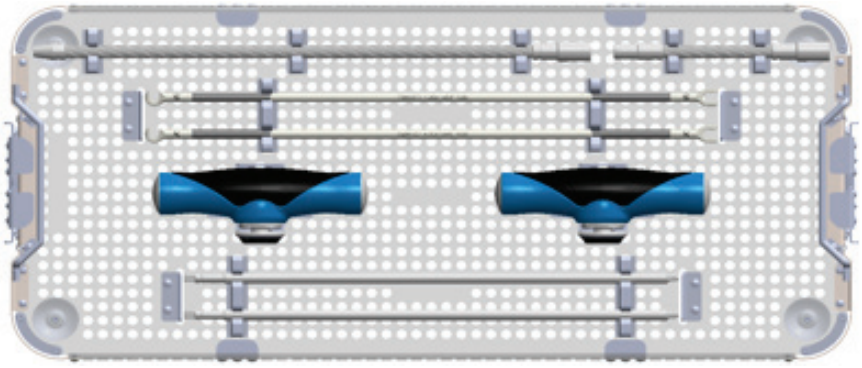
DESCRIPTION	QTY	PART NUMBER
Ratcheting Handle	1	230H5502
Ratcheting Handle, Palm	1	230H5503
5.0 mm Tap, Cannulated	1	230H2050
5.5 mm Tap, Cannulated	1	230H2055
6.0 mm Tap, Cannulated	1	230H2060
6.5 mm Tap, Cannulated	1	230H2065
7.0 mm Tap, Cannulated	1	230H2070
Screwdriver	2	230H4002
Sounder	2	230H3003
Anchor Inserter 90° Handle	1	230H1010
Anchor Inserter Outer Sleeve	2	230H2001
Anchor Inserter Inner Sleeve	2	230H2002
Awl	1	230H1004
Awl Long	1	230H1006
K-wire Dispenser	1	230H3304
K-wire	15	230H3301

The Tether Instrument Kit 1 – Non-cannulated
Kit Number: PCR200H1102

DESCRIPTION	QTY	PART NUMBER
Ratcheting Handle	1	230H5502
Ratcheting Handle, Palm	1	230H5503
4.5 mm Tap, Non-Cannulated	1	230H2145
5.0 mm Tap, Non-Cannulated	1	230H2150
5.5 mm Tap, Non-Cannulated	1	230H2155
6.0 mm Tap, Non-Cannulated	1	230H2160
6.5 mm Tap, Non-Cannulated	1	230H2165
7.0 mm Tap, Non-Cannulated	1	230H2170
Screwdriver	2	230H4002
Sounder	2	230H3003
Anchor Inserter 90° Handle	1	230H1010
Anchor Inserter Outer Sleeve	2	230H2001
Anchor Inserter Inner Sleeve	2	230H2002
Awl	1	230H1004
Awl Long	1	230H1006



Upper

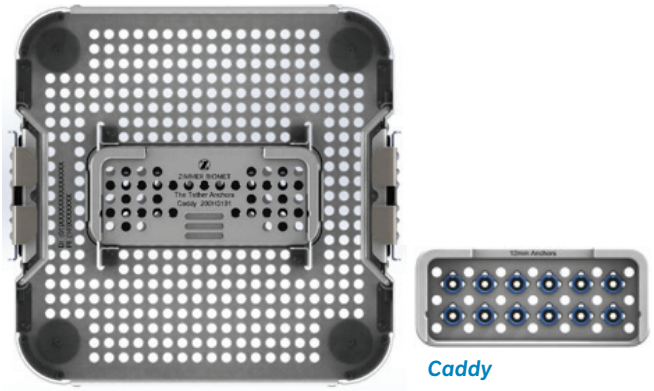


Lower

The Tether Instrument Kit 2
Kit Number: PCR200H2101

DESCRIPTION	QTY	PART NUMBER
Torque-Limiting Handle	2	230H5501
Set Screw Driver	2	230H4001
Cord Alignment Rod	2	230H4004
Extension Spring Tube Long	1	230H6007
Extension Spring Tube Short	1	230H6008
Counter-Tensioner	2	230H6002
Cord Tensioner	2	230H6003
Fine Adjustment Knob	1	230H6001

KIT CONTENTS *(continued)*



Caddy

Implant Kit 1 – Vertebral Body Anchors
Kit Number: PCR200H3101

DESCRIPTION	QTY	PART NUMBER
12 mm Vertebral Body Anchor	12	203H0012

Implant Kit 2 – Vertebral Body Bone Screws
Kit Number: PCR200H3102

The Vertebral Body Assembly includes a Bone Screw and a Set Screw. All implants are sterile packaged.

DESCRIPTION	QTY	PART NUMBER
300 mm Flexible PET Cord	2	204H0300
ø5.5 mm x 20 mm Vertebral Body Assembly	1	211H5520
ø5.5 mm x 22.5 mm Vertebral Body Assembly	2	211H5522
ø5.5 mm x 25 mm Vertebral Body Assembly	4	211H5525
ø5.5 mm x 27.5 mm Vertebral Body Assembly	6	211H5527
ø5.5 mm x 30 mm Vertebral Body Assembly	6	211H5530
ø5.5 mm x 32.5 mm Vertebral Body Assembly	6	211H5532
ø5.5 mm x 35 mm Vertebral Body Assembly	6	211H5535
ø5.5 mm x 37.5 mm Vertebral Body Assembly	6	211H5537
ø5.5 mm x 40 mm Vertebral Body Assembly	6	211H5540
ø5.5 mm x 42.5 mm Vertebral Body Assembly	4	211H5542
ø5.5 mm x 45 mm Vertebral Body Assembly	2	211H5545
ø5.5 mm x 47.5 mm Vertebral Body Assembly	2	211H5547
ø5.5 mm x 50 mm Vertebral Body Assembly	2	211H5550
ø6.0 mm x 20 mm Vertebral Body Assembly	1	211H6020
ø6.0 mm x 22.5 mm Vertebral Body Assembly	2	211H6022
ø6.0 mm x 25 mm Vertebral Body Assembly	2	211H6025
ø6.0 mm x 27.5 mm Vertebral Body Assembly	3	211H6027
ø6.0 mm x 30 mm Vertebral Body Assembly	3	211H6030
ø6.0 mm x 32.5 mm Vertebral Body Assembly	4	211H6032
ø6.0 mm x 35 mm Vertebral Body Assembly	4	211H6035
ø6.0 mm x 37.5 mm Vertebral Body Assembly	3	211H6037
ø6.0 mm x 40 mm Vertebral Body Assembly	3	211H6040
ø6.0 mm x 42.5 mm Vertebral Body Assembly	2	211H6042
ø6.0 mm x 45 mm Vertebral Body Assembly	2	211H6045

Implant Kit 3 - Vertebral Body Bone Screws
Kit Number: PCR200H3103

The Vertebral Body Assembly includes a Bone Screw and a Set Screw. All implants are sterile packaged.

DESCRIPTION	QTY	PART NUMBER
300 mm Flexible PET Cord	2	204H0300
ø5.5 mm x 20 mm Vertebral Body Assembly	1	211H5520
ø5.5 mm x 22.5 mm Vertebral Body Assembly	1	211H5522
ø5.5 mm x 25 mm Vertebral Body Assembly	1	211H5525
ø5.5 mm x 27.5 mm Vertebral Body Assembly	1	211H5527
ø5.5 mm x 30 mm Vertebral Body Assembly	1	211H5530
ø5.5 mm x 32.5 mm Vertebral Body Assembly	1	211H5532
ø5.5 mm x 35 mm Vertebral Body Assembly	1	211H5535
ø5.5 mm x 37.5 mm Vertebral Body Assembly	1	211H5537
ø5.5 mm x 40 mm Vertebral Body Assembly	1	211H5540
ø6.0 mm x 20 mm Vertebral Body Assembly	1	211H6020
ø6.0 mm x 22.5 mm Vertebral Body Assembly	2	211H6022
ø6.0 mm x 25 mm Vertebral Body Assembly	4	211H6025
ø6.0 mm x 27.5 mm Vertebral Body Assembly	6	211H6027
ø6.0 mm x 30 mm Vertebral Body Assembly	6	211H6030
ø6.0 mm x 32.5 mm Vertebral Body Assembly	6	211H6032
ø6.0 mm x 35 mm Vertebral Body Assembly	6	211H6035
ø6.0 mm x 37.5 mm Vertebral Body Assembly	6	211H6037
ø6.0 mm x 40 mm Vertebral Body Assembly	6	211H6040
ø6.0 mm x 42.5 mm Vertebral Body Assembly	4	211H6042
ø6.0 mm x 45 mm Vertebral Body Assembly	2	211H6045
ø6.0 mm x 47.5 mm Vertebral Body Assembly	2	211H6047
ø6.0 mm x 50 mm Vertebral Body Assembly	2	211H6050
ø6.5 mm x 20 mm Vertebral Body Assembly	1	211H6520
ø6.5 mm x 22.5 mm Vertebral Body Assembly	1	211H6522
ø6.5 mm x 25 mm Vertebral Body Assembly	2	211H6525
ø6.5 mm x 27.5 mm Vertebral Body Assembly	2	211H6527
ø6.5 mm x 30 mm Vertebral Body Assembly	2	211H6530
ø6.5 mm x 32.5 mm Vertebral Body Assembly	2	211H6532
ø6.5 mm x 35 mm Vertebral Body Assembly	2	211H6535
ø6.5 mm x 37.5 mm Vertebral Body Assembly	2	211H6537
ø6.5 mm x 40 mm Vertebral Body Assembly	2	211H6540
ø6.5 mm x 42.5 mm Vertebral Body Assembly	2	211H6542
ø6.5 mm x 45 mm Vertebral Body Assembly	1	211H6545
ø6.5 mm x 47.5 mm Vertebral Body Assembly	1	211H6547
ø6.5 mm x 50 mm Vertebral Body Assembly	1	211H6550

Implant Kit 4 - Vertebral Body Bone Screws
Kit Number: PCR200H3104

The Vertebral Body Assembly includes a Bone Screw and a Set Screw. All implants are sterile packaged.

DESCRIPTION	QTY	PART NUMBER
300 mm Flexible PET Cord	2	204H0300
ø6.0 mm x 20 mm Vertebral Body Assembly	1	211H6020
ø6.0 mm x 22.5 mm Vertebral Body Assembly	1	211H6022
ø6.0 mm x 25 mm Vertebral Body Assembly	1	211H6025
ø6.0 mm x 27.5 mm Vertebral Body Assembly	1	211H6027
ø6.0 mm x 30 mm Vertebral Body Assembly	1	211H6030
ø6.0 mm x 32.5 mm Vertebral Body Assembly	1	211H6032
ø6.0 mm x 35 mm Vertebral Body Assembly	1	211H6035
ø6.0 mm x 37.5 mm Vertebral Body Assembly	1	211H6037
ø6.0 mm x 40 mm Vertebral Body Assembly	1	211H6040
ø6.5 mm x 20 mm Vertebral Body Assembly	1	211H6520
ø6.5 mm x 22.5 mm Vertebral Body Assembly	2	211H6522
ø6.5 mm x 25 mm Vertebral Body Assembly	4	211H6525
ø6.5 mm x 27.5 mm Vertebral Body Assembly	6	211H6527
ø6.5 mm x 30 mm Vertebral Body Assembly	6	211H6530
ø6.5 mm x 32.5 mm Vertebral Body Assembly	6	211H6532
ø6.5 mm x 35 mm Vertebral Body Assembly	6	211H6535
ø6.5 mm x 37.5 mm Vertebral Body Assembly	6	211H6537
ø6.5 mm x 40 mm Vertebral Body Assembly	6	211H6540
ø6.5 mm x 42.5 mm Vertebral Body Assembly	4	211H6542
ø6.5 mm x 45 mm Vertebral Body Assembly	2	211H6545
ø6.5 mm x 47.5 mm Vertebral Body Assembly	2	211H6547
ø6.5 mm x 50 mm Vertebral Body Assembly	2	211H6550
ø7.0 mm x 22.5 mm Vertebral Body Assembly	1	211H7022
ø7.0 mm x 25 mm Vertebral Body Assembly	1	211H7025
ø7.0 mm x 27.5 mm Vertebral Body Assembly	1	211H7027
ø7.0 mm x 30 mm Vertebral Body Assembly	2	211H7030
ø7.0 mm x 32.5 mm Vertebral Body Assembly	2	211H7032
ø7.0 mm x 35 mm Vertebral Body Assembly	2	211H7035
ø7.0 mm x 37.5 mm Vertebral Body Assembly	2	211H7037
ø7.0 mm x 40 mm Vertebral Body Assembly	2	211H7040
ø7.0 mm x 42.5 mm Vertebral Body Assembly	1	211H7042
ø7.0 mm x 45 mm Vertebral Body Assembly	1	211H7045
ø7.0 mm x 47.5 mm Vertebral Body Assembly	1	211H7047
ø7.0 mm x 50 mm Vertebral Body Assembly	1	211H7050

Implant Kit 5 - Vertebral Body Bone Screws
Kit Number: PCR200H3105

The Vertebral Body Assembly includes a Bone Screw and a Set Screw. All implants are sterile packaged.

DESCRIPTION	QTY	PART NUMBER
300 mm Flexible PET Cord	2	204H0300
ø6.5 mm x 20 mm Vertebral Body Assembly	1	211H6520
ø6.5 mm x 22.5 mm Vertebral Body Assembly	2	211H6522
ø6.5 mm x 25 mm Vertebral Body Assembly	2	211H6525
ø6.5 mm x 27.5 mm Vertebral Body Assembly	3	211H6527
ø6.5 mm x 30 mm Vertebral Body Assembly	3	211H6530
ø6.5 mm x 32.5 mm Vertebral Body Assembly	4	211H6532
ø6.5 mm x 35 mm Vertebral Body Assembly	4	211H6535
ø6.5 mm x 37.5 mm Vertebral Body Assembly	3	211H6537
ø6.5 mm x 40 mm Vertebral Body Assembly	3	211H6540
ø6.5 mm x 42.5 mm Vertebral Body Assembly	2	211H6542
ø6.5 mm x 45 mm Vertebral Body Assembly	2	211H6545
ø7.0 mm x 20 mm Vertebral Body Assembly	1	211H7020
ø7.0 mm x 22.5 mm Vertebral Body Assembly	2	211H7022
ø7.0 mm x 25 mm Vertebral Body Assembly	4	211H7025
ø7.0 mm x 27.5 mm Vertebral Body Assembly	6	211H7027
ø7.0 mm x 30 mm Vertebral Body Assembly	6	211H7030
ø7.0 mm x 32.5 mm Vertebral Body Assembly	6	211H7032
ø7.0 mm x 35 mm Vertebral Body Assembly	6	211H7035
ø7.0 mm x 37.5 mm Vertebral Body Assembly	6	211H7037
ø7.0 mm x 40 mm Vertebral Body Assembly	6	211H7040
ø7.0 mm x 42.5 mm Vertebral Body Assembly	4	211H7042
ø7.0 mm x 45 mm Vertebral Body Assembly	2	211H7045
ø7.0 mm x 47.5 mm Vertebral Body Assembly	2	211H7047
ø7.0 mm x 50 mm Vertebral Body Assembly	2	211H7050

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