

The Tether™ Vertebral Body Tethering System Planning Guide

Mandatory Requirements

The below requirements must be met prior to accessing The Tether System. Please allow 2-3 days after the last item is submitted for the controlled access team to file and approve all documents before inventory can be ordered/released per DD2992.

- Surgeon must submit and have an IRB approval or appropriate local committee approval at the hospital where The Tether cases are being performed prior to access.
- Surgeon must be trained on The Tether by the Zimmer Biomet Spine Medical Education Team and memorandum signed prior to access.
- Sales representatives must be trained on The Tether by the Zimmer Biomet Spine Sales Education Team and memorandum signed prior to access and support.
- Distributor must read and sign the memorandum of understanding for the Tether Controlled Access Process/Program prior to access and support.

Key Contacts

Medical Education (Surgeon Training):	Francisco Arteaga	francisco.arteaga@zimmerbiomet.com
Sales Education (Representative Training):	Dan Voss	dan.voss@zimmerbiomet.com
Clinical Affairs (IRB Support):	Adam Burnett	adam.burnett@zimmerbiomet.com
Marketing/R+D (Technical Product Questions):		
Product Manager	Cara Johnson	cara.johnson@zimmerbiomet.com
Development Senior Engineer	Tom Serra	thomas.serra@zimmerbiomet.com
Sales Support / Field Inventory Control (Ordering/Inventory Support):		
	Jacob Burch	jacob.burch@zimmerbiomet.com
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Tether Planning Steps (filling out the planning sheet):

1. Above mandatory requirements must be fulfilled.
2. Review films/surgical plan with surgeon to identify curves and pre-identify screw needs before inventory can be ordered.
3. Select Left/Right curve and whether Thoracic/Lumbar curve.
4. Select screw diameter and length for levels being treated.
5. Submit filled out planning guide along with ImplantBase order to Sales Support to be reviewed and inventory shipped.
6. If subsequent cases are not already scheduled within 2 days of this case with an implant planning sheet and ImplantBase order submitted with surgery date, then you must return inventory to MMO. Failure to promptly return unused inventory will result in immediate loss of access to The Tether and potential disciplinary action.

Instrument Kit Requested (Must select 1 of the Instrument Kit 1's, and Instrument Kit 2):	Implant Kit Requested (Select the Anchor Implant if required and only 1 of the Implant Kits)
<input type="checkbox"/> Instrument Kit 1 – Cannulated: PCR200H1101 OR	<input type="checkbox"/> Anchor Implant Kit: PCR200H3101 AND
<input type="checkbox"/> Instrument Kit 1 – Non-Cannulated: PCR200H1102 AND	<input type="checkbox"/> 5.5 mm Primary / 6.0 Backup Screw Implant Kit: PCR200H3102 OR
<input type="checkbox"/> Instrument Kit 2: PCR200H2101	<input type="checkbox"/> 6.0 mm Primary / 6.5 Backup Screw Implant Kit: PCR200H3103 OR
	<input type="checkbox"/> 6.5 mm Primary / 7.0 Backup Screw Implant Kit: PCR200H3104

Implant planning criteria per level:

- Primary Screw Diameter: 1 screw diameter per level
- Primary Screw Lengths: 3 lengths per level (1 primary, 2 alternative lengths)

Note: Per the kit configurations, you will receive qty. 1 of the diameter above the primary diameter screw size selected (i.e. If your primary screw diameter is 6.0 mm then you will receive qty. 1 of each 6.5 mm screw lengths as backup/rescue screws). Please utilize and reference the surgical technique for kit configurations.

Reminder: Only 1 implant kit is allowed to be ordered, hence why this implant planning sheet is critical and mandatory to fill out, to ensure case needs are met, the surgeon understands the kit configurations, and the restricted/limited inventory is being managed, used and returned appropriately.

Failure to promptly return unused inventory will result in immediate loss of access to The Tether.

Mandatory to provide the following:

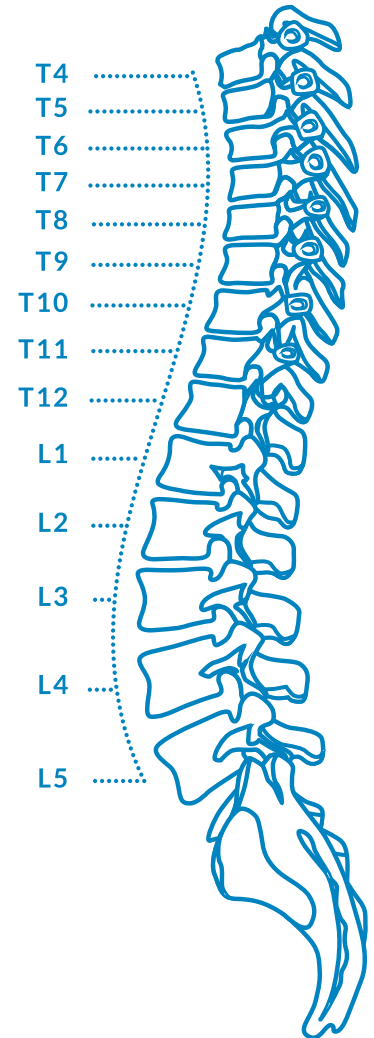
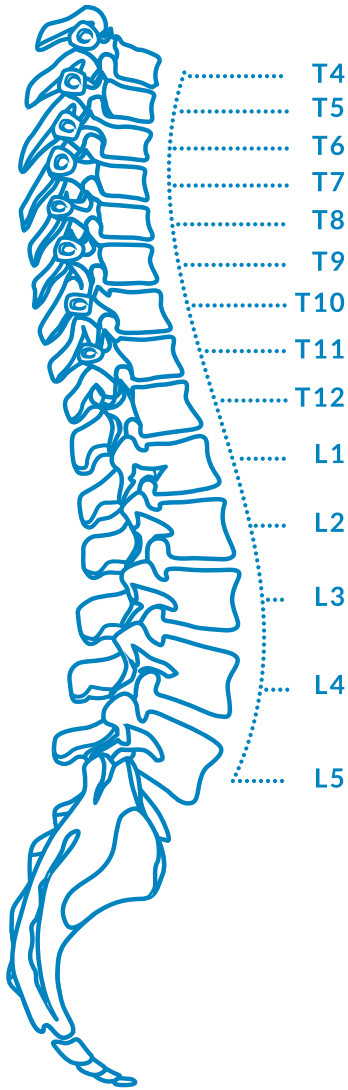
Surgeon Name (required)

Sales Representative Name (required)

Surgery Date (required)

Right
 Thoracic Lumbar

Left
 Thoracic Lumbar



Qty. 2 The Tether Cord 300 mm (PN:204H0300)

T4	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T5	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T6	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T7	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T8	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T9	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T10	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T11	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
T12	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
L1	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
L2	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
L3	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
L4	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm
L5	Primary Screw Diameter: <input type="checkbox"/> 5.5 mm <input type="checkbox"/> 6.0 mm <input type="checkbox"/> 6.5 mm <input type="checkbox"/> 7.0 mm
	Primary Screw Length(s): <input type="checkbox"/> 20 mm <input type="checkbox"/> 22.5 mm <input type="checkbox"/> 25 mm <input type="checkbox"/> 27.5 mm <input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm <input type="checkbox"/> 40 mm <input type="checkbox"/> 42.5 mm <input type="checkbox"/> 45 mm <input type="checkbox"/> 47.5 mm <input type="checkbox"/> 50 mm