

# 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 The Tether Controlled Access Program.

- 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 ZimVie Spine Medical Education Team and memorandum signed prior to access.
- Sales representatives must be trained on The Tether by the ZimVie 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

|  |                   |  |
|--|-------------------|--|
| The Tether - Reimbursement Services Program                          | 800-275-9634      | <a href="mailto:tether@mcra.com">tether@mcra.com</a>                           |
| Medical Education (Surgeon Training)                                 | Francisco Arteaga | <a href="mailto:francisco.arteaga@zimvie.com">francisco.arteaga@zimvie.com</a> |
| Sales Education (Representative Training)                            | Dan Voss          | <a href="mailto:dan.voss@zimvie.com">dan.voss@zimvie.com</a>                   |
| Clinical Affairs (IRB Support)                                       | Monica Barascout  | <a href="mailto:monica.barascout@zimvie.com">monica.barascout@zimvie.com</a>   |
| Product Marketing  | Hayley Hendrix    | <a href="mailto:hayley.hendrix@zimvie.com">hayley.hendrix@zimvie.com</a>       |
| Development Senior Engineer  | Randy Mast        | <a href="mailto:randall.mast@zimvie.com">randall.mast@zimvie.com</a>           |
| Sales Support / Field Inventory Control (Ordering/Inventory Support) | Philip Lapuente   | <a href="mailto:philip.lapuente@zimvie.com">philip.lapuente@zimvie.com</a>     |

## 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 completed filled out planning guide (page 2) 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 corporate distribution center. Failure to promptly return unused inventory will result in immediate loss of access to The Tether and potential disciplinary action.

## 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:**

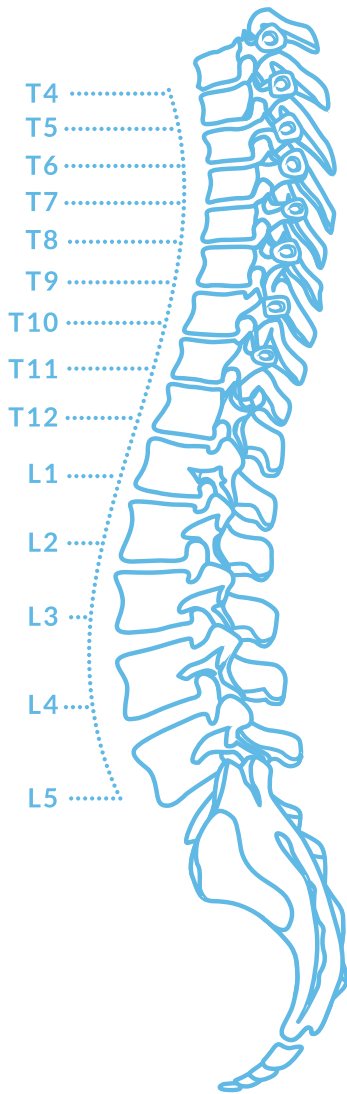
Surgeon Name (required)

Sales Representative Name (required)

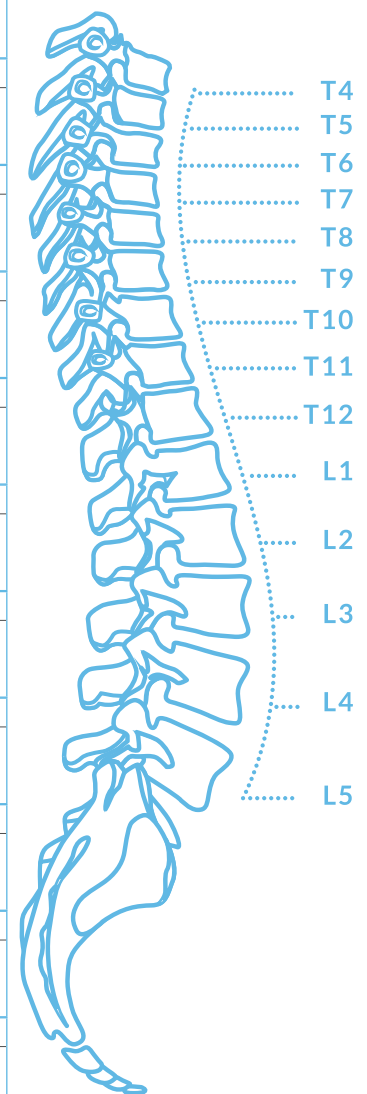
Surgery Date (required)

| Instrument Kit Requested (Select 1 of the Instrument Kit 1's)  | Implant Kit (Select only 1 of the Implant Kits)   |
|--|---|
| <input type="checkbox"/> Instrument Kit 1 – Cannulated: PCR200H1101<br>OR<br><input type="checkbox"/> Instrument Kit 1 – Non-Cannulated: PCR200H1102<br>AND<br><input type="checkbox"/> Instrument Kit 2: PCR200H2101<br>AND<br><input type="checkbox"/> Anchor Implant Kit: PCR200H3101 | <input type="checkbox"/> 5.5 mm Primary / 6.0 Backup Screw Implant Kit: PCR200H3102<br>OR<br><input type="checkbox"/> 6.0 mm Primary / 6.5 Backup Screw Implant Kit: PCR200H3103<br>OR<br><input type="checkbox"/> 6.5 mm Primary / 7.0 Backup Screw Implant Kit: PCR200H3104<br>OR<br><input type="checkbox"/> 7.0 mm Primary Screw Implant Kit: PCR200H3105 |

Left  
 Thoracic  Lumbar



Right  
 Thoracic  Lumbar



|            |  |
|------------|--|
| <b>T4</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T5</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T6</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T7</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T8</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T9</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T10</b> | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T11</b> | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>T12</b> | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>L1</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>L2</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>L3</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>L4</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |
| <b>L5</b>  | 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<br>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<br><input type="checkbox"/> 30 mm <input type="checkbox"/> 32.5 mm <input type="checkbox"/> 35 mm <input type="checkbox"/> 37.5 mm<br><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 |