Surgical Technique

Fortilink®-TC

with TiPlus Technology

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1. Introduction

1.1. Device description

The Fortilink-TC Ti (*Figure 1*) is an interbody fusion device intended for the lumbar spine (L2-S1) in patients with degenerative disc diseases. The Fortilink-TC Ti interbody fusion devices are with SLM (selective laser melting) and are built up from implant grade titanium alloy (Ti6Al4V). The Fortilink-TC Ti has an open mesh structure and a bone window both designed to allow bone ingrowth and facilitate fusion. The banana shaped design is intended to provide primary stability and increase the intervertebral height.

The Fortilink-TC Ti will be used in combination with:

- Dedicated instrument set (see surgical technique for Catalogue Instruments)
- General instruments typically used in spinal surgery (including rongeurs, forceps)

Further copies of the surgical technique and instructions for use can be requested at BAAT Medical Products BV.

Figure 1. Fortilink®-TC with TiPlus Technology

1.2. Intended purpose

The Fortilink-TC Ti is indicated for transforaminal interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

1.3. Clinical benefits

The following benefits to the patient are intended to be achieved with the Fortilink-TC Ti:

- Decrease back pain, as assessed using the Visual Analogue Scale (VAS)
- Clinical improvement, as assessed using the Oswestry Disability Index (ODI)
- Facilitate fusion, assessed by fusion rates in radiological follow-up images
- Increase in intervertebral height, indirectly assessed by pre- versus post-operative patient functionality (ODI) and pain scores (VAS)

1.4. Indications

Degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

1.5. Contraindications

- Active systemic infection or an active infection at the operative site
- A demonstrated allergy or sensitivity to any of the implant materials
- Severe osteoporosis
- Primary or metastatic tumors affecting the spine
- Conditions that may place excessive stresses on bones and the implants, including but not limited to morbid obesity, or other degenerative diseases
- Patients whose ability to follow postoperative restrictions, precautions and rehabilitation programs is limited
- Fractures, severe deformities or a severe instability in the area of surgery
- A medical or surgical situation that would preclude the benefit of surgery
- Pregnancy

1.6. Sterility

The implant is delivered sterile packed. The devices are sterilized by irradiation. Do not re-use or re-sterilize the implants in this system, as adequate mechanical performance, biocompatibility and sterility cannot be guaranteed.

1.7. Material specification

The implants are manufactured from implant grade titanium alloy Ti6Al4V ELI (ASTM F3001).

1.8. Warnings and precautions

INTENDED USERS

Prior to use the surgeon must become familiar with the device system and the surgical procedure. Use surgical instrumentation, accessories, and surgical technique guide provided with this device system. The implantation of the IBF device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PATIENT EDUCATION

Preoperative

The patient should understand that stress on an implant could involve more than weight bearing. In the absence of solid bony union, patient weight alone, muscular forces associated with moving, or repeated stresses of apparent relatively small magnitude, can compromise the implant. Patients should be fully informed of these risks prior to and following surgery.

Postoperative

The surgeon should provide clear directions, warnings and must obtain verification of patient understanding for patient post-operative compliance.

- Partial- or non-weight bearing may be recommended or required to achieve firm bone union.
- Warn patient against smoking, consuming alcohol, and/or taking steroids, non-steroidal anti-inflammatory agents and aspirin or other drugs not prescribed by the physician.
- Warn patient against sudden changes in position, strenuous activity or falls that may cause additional injury and advice that the patient seek medical opinion before entering environments in which this might occur.
- Warn patient to consult the surgeon in the event of malfunction of the device or changes in its performance that may affect safety.
- If appropriate, restrict patient's mobility to allow bony union.
- If nonunion occurs, the surgeon may revise or remove the system.

READ THE INSTRUCTIONS

All users are expected to read the instructions for use that accompany all devices being utilized with these implants.

PATIENT SELECTION

- Avoid patients not meeting the criteria described in the indications.
- Avoid patients with conditions that may predispose to a possible poor result or adverse effect.

IMPACT RISK

No implant system can withstand the forces of sudden dynamic loads such as falls or other accidents.

SINGLE USE ONLY

Do not re-use or re-sterilize the implants in this system, as adequate mechanical performance, biocompatibility and sterility cannot be guaranteed.

MIXING WITH OTHER DEVICES

Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

INSTRUMENTS

Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. Surgeons must verify that the instruments are in good condition and in operating order prior to use during surgery.

INSERTION INSTRUMENTS

For implant insertion, use only the instruments provided. Using other instruments to insert the implant could result in implant damage.

CLEANING AND STERILIZATION
Implants are provided sterile. Reusable instruments are provided non-sterile. For specific cleaning and sterilization instructions, refer to the instructions for use provided with the device or contact RTI Surgical.

PACKAGING INTEGRITY
Inspect the product, including all packaging and labeling materials carefully:
• Do not use past expiration date specified on the product label.
• Do not use if the implant or packaging is damaged or unintentionally opened before use.
• Do not use if there are discrepancies in label information.

DISC SPACE PREPARATION
Care should be taken to avoid pushing the shaver too far in the interspace and cutting through the annulus.
Care should be taken when first rotating the shavers to not force them into the bony endplates, increasing the risk of subsidence. If the shaver catches, drop down one size and proceed.

ENDPLATE PREPARATION
Appropriate removal of the cartilaginous layers of the endplates is important for the vascularization of the bone graft. However, make sure to clean the endplates carefully and maintain the integrity of the underlying bony endplate, as damage of the endplate can lead to implant subsidence.

DISTRACTION
Adequate distraction is one of the preconditions for the primary stability of the implant; it is critical to ensure that the segment is not over distracted to avoid damage of ligaments and/or endplates.

SIZE SELECTION
Select the trial spacer that adequately fills the disc space and provides restoration of disc height. The trial spacer should require minimal force to insert, yet fit snugly within the disc space. Sequentially increase the trial spacer size until the appropriate height is determined. Using the trial spacer as a guide, verify that appropriate height restoration is achieved with lateral fluoroscopy. Select the appropriate implant size.
Using an implant smaller or larger than the size trialed could lead to implant failure.
Preoperative planning and patient anatomy should be considered when selecting implant size and supplemental internal fixation. The physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the device.

SIZE CORRESPONDANCE
The relation of the size of the trial spacers to the size of the implants must be taken into account.

PRODUCT AVAILABILITY
It must be ascertained that the implant is available in all sizes in the range that is appropriate for the patient before starting the procedure in order to make sure that the optimal size, which is determined intraoperatively with the trial sizers, will be available.

IMPLANT PLACEMENT
The cage has teeth to maximize primary stability, however make sure the soft tissue and dura are adequately retracted when inserting the implant to avoid damage from contact with the cage (in particular the teeth). Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.

Goals for final implant placement:
1. Midline placement
2. Anterior half of vertebral body

3. Long axis of implant parallel to coronal plane 4. Snug fit utilizing the natural distraction/ compression forces of the spine
IMPLANT INSERTION Do not use the inserter to apply lateral force or torque to the implant as it may cause damage to the implant.
SUPPLEMENTAL FIXATION Interbody fusion devices are designed to withstand full load-bearing until bony union of the spinal segment(s) normally occurs. To ensure load-bearing capability, supplemental fixation is required for use with these devices.
LOAD-BEARING While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. These implants can break when subjected to the increased loading associated with delayed union or nonunion. Typically, internal fixation devices are load-sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, an implant could eventually break due to fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant.
EXPLANTATION After implantation of an interbody fusion device and identification of the presence of fusion, only the supplemental fixation components should be removed.
COMORBIDITIES Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.
PREVIOUS SURGERY Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
INSTRUMENT WEAR Instruments are subject to damage during use as well as long-term potentially damaging effects such as wear. Damage may result in significant risks to safety and/or inability to function as intended.
INSTRUMENT FRAGMENTS If instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the surgeon's responsibility to carefully consider the risks and benefits of retrieving the fragments. If the fragment is retained in the patient, it is recommended that the surgeon advise the patient of specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.
IMPLANT HANDLING Correct handling of the implant is extremely important. Alterations will produce internal stresses which may lead to eventual breakage of the implant. An explanted implant should never be re-implanted. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
RADIOGRAPHIC VERIFICATION Verify the final implant placement with anterior/posterior and lateral fluoroscopy images.

MRI SAFETY INFORMATION

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial gradient magnetic field of 720-Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (per pulse sequence).

RF Heating

In non-clinical testing, the device can produce a temperature rise of less than or equal to 6.0 degrees C using an MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes (per pulse sequence) of scanning in a 3-Tesla MR system.
The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. In all cases, the healthcare professional is responsible for the MR conditions, MR imaging quality and patient safety. Any safety issues or major image artefacts should be reported.

DISPOSAL

The products must be disposed according to local regulations.

1.9. Potential adverse effects

The same medical/surgical conditions or complications that apply to any surgical procedure may also occur during or following implantation of this device system. The surgeon is responsible for informing the patient of the potential risks associated with treatment, including complications and adverse reactions. The surgeon may need to perform additional surgery to address any complications or adverse reactions, which may or may not be device related.

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery include:

- Implant component fracture
- Migration, dislocation, or subsidence of the implant
- Loss of fixation
- Pseudoarthrosis (i.e., non-union)
- Fracture of the vertebra
- Neurological injury
- Cardiovascular complications
- Infection
- Allergic reaction
- Pulmonary embolism
- Pneumonia
- Adjacent segment disease
- Heterotrophic ossification
- Bone erosion
- Epidural scarring

2. Surgical technique

2.1. Exposure of disc level

Access the operative site and retract tissues using preferred instruments to permit visualization of the target disc space.

2.2. Laminectomy/Laminotomy, Facetectomy and discectomy

Perform a conventional laminotomy, decompressing the thecal sac and nerve roots above and below the target disc space. Complete a direct decompression using a combination of laminotomy, facetectomy and foraminotomy.

Perform an annulotomy and remove disc material from the disc space.

INSTRUMENTS
Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. Surgeons must verify that the instruments are in good condition and in operating order prior to use during surgery.

2.3. Distraction

Use pedicle screws implanted above and below the disc space (*Figure 2*) for distraction.

Figure 2

Alternatively, paddle distractors may be used to initially distract the work space. This facilitates disc removal and placement of larger paddle distractors and/or shavers.

Using the paddle distractors, the resected space is sequentially distracted until the optimal height is achieved, indirectly decompressing nerve roots by restoring foraminal height.

DISTRACTION
Adequate distraction is one of the preconditions for the primary stability of the implant; it is critical to ensure that the segment is not over distracted to avoid damage of ligaments and/or endplates.

2.4. Disc space preparation

Rotate the shaver clockwise and counterclockwise to further remove disc material and cartilaginous endplate. Care should be taken to avoid pushing the shaver too far in the interspace and cutting through the anterior or lateral annulus. Remove loose tissue with pituitary rongeurs.

DISC SPACE PREPARATION
Care should be taken to avoid pushing the shaver too far in the interspace and cutting through the annulus.
Care should be taken when first rotating the shavers to not force them into the bony endplates, increasing the risk of subsidence. If the shaver catches, drop down one size and proceed.

2.5. Endplate preparation

Prepare the endplates following preferred technique. The rotating shavers should be used to safely remove as much of the lateral disc as possible. Straight and angled curettes and rasps are used to finish removing the cartilaginous endplates and perforate the bony endplates to expose bleeding bone (*Figure 3*).

Figure 3

ENDPLATE PREPARATION
Appropriate removal of the cartilaginous layers of the endplates is important for the vascularization of the bone graft. However, make sure to clean the endplates carefully and maintain the integrity of the underlying bony endplate, as damage of the endplate can lead to implant subsidence.

2.6. Implant selection

Trial spacers are available to provide guidance prior to implant selection. For an overview of the available trial spacers, see ‘Catalogue instruments’.

Lordotic trial spacers and implants are available and can be found in ‘Catalogue implants’ and ‘Catalogue instruments’.

SIZE SELECTION
Select the trial spacer that adequately fills the disc space and provides restoration of disc height. The trial spacer should require minimal force to insert, yet fit snugly within the disc space. Sequentially increase the trial spacer size until the appropriate height is determined (*Figure 4*). Using the trial spacer as a guide, verify that appropriate height restoration is achieved with lateral fluoroscopy. Select the appropriate implant size.
Using an implant smaller or larger than the size trialed could lead to implant failure.
Preoperative planning and patient anatomy should be considered when selecting implant size and supplemental internal fixation. The physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the device.

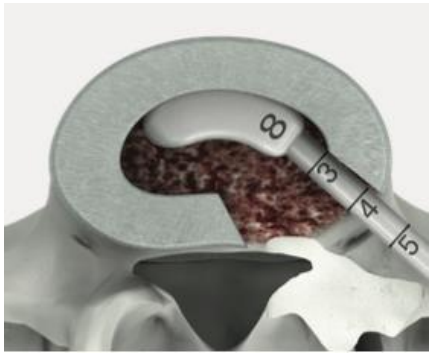

Figure 4

The height of the lollipop trial spacers is 0.8mm lower than the corresponding implant, sized to midline of implant valley and teeth (*Figure 5*).

Figure 5

2.7. Implant preparation and insertion

Pack the implant with autogenous and/or allogenic bone graft (*Figure 6*). Thread the implant onto the inserter until the foot of the instrument is flush with the implant body.

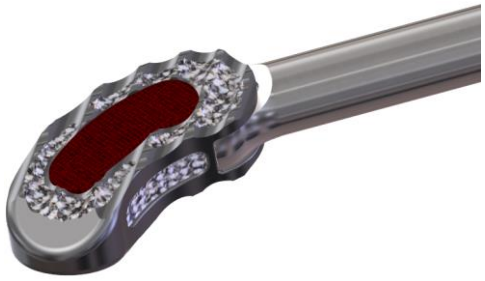

Figure 6

INSERTION INSTRUMENTS
For implant insertion, use only the instruments provided. Using other instruments to insert the implant could result in implant damage.

If necessary, the thecal sac and inferior nerve root may be gently retracted medially with a nerve root retractor.

IMPLANT PLACEMENT
The cage has teeth to maximize primary stability, however make sure the soft tissue and dura are adequately retracted when inserting the implant to avoid damage from contact with the cage (in particular the teeth). Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.

With the implant attached to the inserter, place the tip of the implant at the prepared opening and tap it into the prepared space. The bullet-shaped tip assists in distraction and insertion. Follow the natural curve of the vertebral space in guiding the implant into place (*Figure 7*).

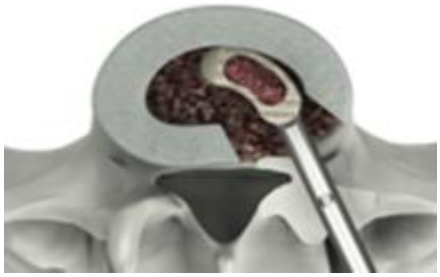

Figure 7

IMPLANT INSERTION
Do not use the inserter to apply lateral force or torque to the implant as it may cause damage to the implant.

Unscrew the inserter from the implant to disengage the inserter from the implant.

Using a positioning tamp, guide the implant to the proper position (*Figures 8A and 8B*). The angled teeth tread and custom tamps are designed to help guide the implant to the final position as described below. The curved implant shape matches the contour of the vertebral body.

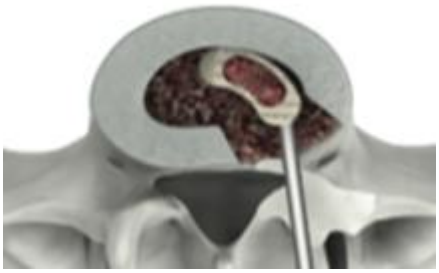

Figure 8A

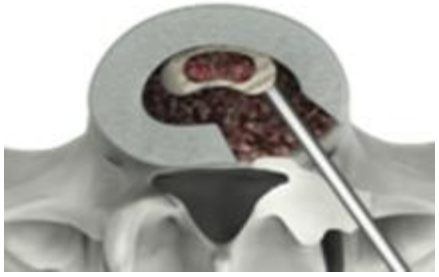

Figure 8B

Goals for final implant placement:
1. Midline placement
2. Anterior half of vertebral body
3. Long axis of implant parallel to coronal plane
4. Snug fit utilizing the natural distraction/compression forces of the spine

2.8. Fixation options

SUPPLEMENTAL FIXATION
Interbody fusion devices are designed to withstand full load-bearing until bony union of the spinal segment(s) normally occurs. To ensure load-bearing capability, supplemental fixation is required for use with these devices.

2.9. Radiographic verification

RADIOGRAPHIC VERIFICATION
Verify the final implant placement with anterior/posterior and lateral fluoroscopy images.

2.10. Removal (if necessary)

For removal of the Fortilink-TC implant, use an appropriate removal tool. Thread the removal tool into any hole on the implant, and attach the slap hammer to aid in removal.

3. Catalogue implants

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-TC-1026-07-0L	Fortilink-TC Ti 10x26x07-0L	10	26	7	0	1
77-TC-1026-08-0L	Fortilink-TC Ti 10x26x08-0L	10	26	8	0	1
77-TC-1026-09-0L	Fortilink-TC Ti 10x26x09-0L	10	26	9	0	1
77-TC-1026-10-0L	Fortilink-TC Ti 10x26x10-0L	10	26	10	0	1
77-TC-1026-11-0L	Fortilink-TC Ti 10x26x11-0L	10	26	11	0	1
77-TC-1026-12-0L	Fortilink-TC Ti 10x26x12-0L	10	26	12	0	1
77-TC-1026-13-0L	Fortilink-TC Ti 10x26x13-0L	10	26	13	0	1
77-TC-1026-14-0L	Fortilink-TC Ti 10x26x14-0L	10	26	14	0	1
77-TC-1026-15-0L	Fortilink-TC Ti 10x26x15-0L	10	26	15	0	1
77-TC-1026-07-6L	Fortilink-TC Ti 10x26x07-6L	10	26	7	6	1
77-TC-1026-08-6L	Fortilink-TC Ti 10x26x08-6L	10	26	8	6	1
77-TC-1026-09-6L	Fortilink-TC Ti 10x26x09-6L	10	26	9	6	1
77-TC-1026-10-6L	Fortilink-TC Ti 10x26x10-6L	10	26	10	6	1
77-TC-1026-11-6L	Fortilink-TC Ti 10x26x11-6L	10	26	11	6	1
77-TC-1026-12-6L	Fortilink-TC Ti 10x26x12-6L	10	26	12	6	1
77-TC-1026-13-6L	Fortilink-TC Ti 10x26x13-6L	10	26	13	6	1
77-TC-1026-14-6L	Fortilink-TC Ti 10x26x14-6L	10	26	14	6	1
77-TC-1026-15-6L	Fortilink-TC Ti 10x26x15-6L	10	26	15	6	1
77-TC-1026-08-12L	Fortilink-TC Ti 10x26x08-12L	10	26	8	12	1
77-TC-1026-09-12L	Fortilink-TC Ti 10x26x09-12L	10	26	9	12	1
77-TC-1026-10-12L	Fortilink-TC Ti 10x26x10-12L	10	26	10	12	1
77-TC-1026-11-12L	Fortilink-TC Ti 10x26x11-12L	10	26	11	12	1
77-TC-1026-12-12L	Fortilink-TC Ti 10x26x12-12L	10	26	12	12	1
77-TC-1026-13-12L	Fortilink-TC Ti 10x26x13-12L	10	26	13	12	1
77-TC-1026-14-12L	Fortilink-TC Ti 10x26x14-12L	10	26	14	12	1
77-TC-1026-15-12L	Fortilink-TC Ti 10x26x15-12L	10	26	15	12	1
77-TC-1027-07-0L	Fortilink-TC Ti 10x27x07-0L	10	27	7	0	1
77-TC-1027-08-0L	Fortilink-TC Ti 10x27x08-0L	10	27	8	0	1
77-TC-1027-09-0L	Fortilink-TC Ti 10x27x09-0L	10	27	9	0	1
77-TC-1027-10-0L	Fortilink-TC Ti 10x27x10-0L	10	27	10	0	1
77-TC-1027-11-0L	Fortilink-TC Ti 10x27x11-0L	10	27	11	0	1
77-TC-1027-12-0L	Fortilink-TC Ti 10x27x12-0L	10	27	12	0	1
77-TC-1027-13-0L	Fortilink-TC Ti 10x27x13-0L	10	27	13	0	1
77-TC-1027-14-0L	Fortilink-TC Ti 10x27x14-0L	10	27	14	0	1
77-TC-1027-15-0L	Fortilink-TC Ti 10x27x15-0L	10	27	15	0	1
77-TC-1027-07-6L	Fortilink-TC Ti 10x27x07-6L	10	27	7	6	1
77-TC-1027-08-6L	Fortilink-TC Ti 10x27x08-6L	10	27	8	6	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
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77-TC-1027-10-6L	Fortilink-TC Ti 10x27x10-6L	10	27	10	6	1
77-TC-1027-11-6L	Fortilink-TC Ti 10x27x11-6L	10	27	11	6	1
77-TC-1027-12-6L	Fortilink-TC Ti 10x27x12-6L	10	27	12	6	1
77-TC-1027-13-6L	Fortilink-TC Ti 10x27x13-6L	10	27	13	6	1
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77-TC-1027-08-12L	Fortilink-TC Ti 10x27x08-12L	10	27	8	12	1
77-TC-1027-09-12L	Fortilink-TC Ti 10x27x09-12L	10	27	9	12	1
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77-TC-1027-14-12L	Fortilink-TC Ti 10x27x14-12L	10	27	14	12	1
77-TC-1027-15-12L	Fortilink-TC Ti 10x27x15-12L	10	27	15	12	1
77-TC-1032-07-0L	Fortilink-TC Ti 10x32x07-0L	10	32	7	0	1
77-TC-1032-08-0L	Fortilink-TC Ti 10x32x08-0L	10	32	8	0	1
77-TC-1032-09-0L	Fortilink-TC Ti 10x32x09-0L	10	32	9	0	1
77-TC-1032-10-0L	Fortilink-TC Ti 10x32x10-0L	10	32	10	0	1
77-TC-1032-11-0L	Fortilink-TC Ti 10x32x11-0L	10	32	11	0	1
77-TC-1032-12-0L	Fortilink-TC Ti 10x32x12-0L	10	32	12	0	1
77-TC-1032-13-0L	Fortilink-TC Ti 10x32x13-0L	10	32	13	0	1
77-TC-1032-14-0L	Fortilink-TC Ti 10x32x14-0L	10	32	14	0	1
77-TC-1032-15-0L	Fortilink-TC Ti 10x32x15-0L	10	32	15	0	1
77-TC-1032-07-6L	Fortilink-TC Ti 10x32x07-6L	10	32	7	6	1
77-TC-1032-08-6L	Fortilink-TC Ti 10x32x08-6L	10	32	8	6	1
77-TC-1032-09-6L	Fortilink-TC Ti 10x32x09-6L	10	32	9	6	1
77-TC-1032-10-6L	Fortilink-TC Ti 10x32x10-6L	10	32	10	6	1
77-TC-1032-11-6L	Fortilink-TC Ti 10x32x11-6L	10	32	11	6	1
77-TC-1032-12-6L	Fortilink-TC Ti 10x32x12-6L	10	32	12	6	1
77-TC-1032-13-6L	Fortilink-TC Ti 10x32x13-6L	10	32	13	6	1
77-TC-1032-14-6L	Fortilink-TC Ti 10x32x14-6L	10	32	14	6	1
77-TC-1032-15-6L	Fortilink-TC Ti 10x32x15-6L	10	32	15	6	1
77-TC-1032-08-12L	Fortilink-TC Ti 10x32x08-12L	10	32	8	12	1
77-TC-1032-09-12L	Fortilink-TC Ti 10x32x09-12L	10	32	9	12	1
77-TC-1032-10-12L	Fortilink-TC Ti 10x32x10-12L	10	32	10	12	1
77-TC-1032-11-12L	Fortilink-TC Ti 10x32x11-12L	10	32	11	12	1
77-TC-1032-12-12L	Fortilink-TC Ti 10x32x12-12L	10	32	12	12	1
77-TC-1032-13-12L	Fortilink-TC Ti 10x32x13-12L	10	32	13	12	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-TC-1032-14-12L	Fortilink-TC Ti 10x32x14-12L	10	32	14	12	1
77-TC-1032-15-12L	Fortilink-TC Ti 10x32x15-12L	10	32	15	12	1
77-TC-1036-07-0L	Fortilink-TC Ti 10x36x07-0L	10	36	7	0	1
77-TC-1036-08-0L	Fortilink-TC Ti 10x36x08-0L	10	36	8	0	1
77-TC-1036-09-0L	Fortilink-TC Ti 10x36x09-0L	10	36	9	0	1
77-TC-1036-10-0L	Fortilink-TC Ti 10x36x10-0L	10	36	10	0	1
77-TC-1036-11-0L	Fortilink-TC Ti 10x36x11-0L	10	36	11	0	1
77-TC-1036-12-0L	Fortilink-TC Ti 10x36x12-0L	10	36	12	0	1
77-TC-1036-13-0L	Fortilink-TC Ti 10x36x13-0L	10	36	13	0	1
77-TC-1036-14-0L	Fortilink-TC Ti 10x36x14-0L	10	36	14	0	1
77-TC-1036-15-0L	Fortilink-TC Ti 10x36x15-0L	10	36	15	0	1
77-TC-1036-07-6L	Fortilink-TC Ti 10x36x07-6L	10	36	7	6	1
77-TC-1036-08-6L	Fortilink-TC Ti 10x36x08-6L	10	36	8	6	1
77-TC-1036-09-6L	Fortilink-TC Ti 10x36x09-6L	10	36	9	6	1
77-TC-1036-10-6L	Fortilink-TC Ti 10x36x10-6L	10	36	10	6	1
77-TC-1036-11-6L	Fortilink-TC Ti 10x36x11-6L	10	36	11	6	1
77-TC-1036-12-6L	Fortilink-TC Ti 10x36x12-6L	10	36	12	6	1
77-TC-1036-13-6L	Fortilink-TC Ti 10x36x13-6L	10	36	13	6	1
77-TC-1036-14-6L	Fortilink-TC Ti 10x36x14-6L	10	36	14	6	1
77-TC-1036-15-6L	Fortilink-TC Ti 10x36x15-6L	10	36	15	6	1
77-TC-1036-09-12L	Fortilink-TC Ti 10x36x09-12L	10	36	9	12	1
77-TC-1036-10-12L	Fortilink-TC Ti 10x36x10-12L	10	36	10	12	1
77-TC-1036-11-12L	Fortilink-TC Ti 10x36x11-12L	10	36	11	12	1
77-TC-1036-12-12L	Fortilink-TC Ti 10x36x12-12L	10	36	12	12	1
77-TC-1036-13-12L	Fortilink-TC Ti 10x36x13-12L	10	36	13	12	1
77-TC-1036-14-12L	Fortilink-TC Ti 10x36x14-12L	10	36	14	12	1
77-TC-1036-15-12L	Fortilink-TC Ti 10x36x15-12L	10	36	15	12	1

4. Catalogue instruments

Instruments are manufactured by Pioneer Surgical Technology Inc. and distributed by RTI Surgical, Inc.

Instrument list Fortilink-TC Ti (TLIF)	
Part #	**Description**
30-TCE-INSERTER	INSERTER
30-TCE-INSERTER-CL	INSERTER, MODULAR CLEANING
30-TCE-SLAPHAMMER	SLAP HAMMER
30-TCE-TAMP-C	CRESCENT TAMP
30-CE-TAMP-L	LONG TAMP
30-CE-TAMP-S	STRAIGHT TAMP
30-TCE-TRL1027-10	TRIAL SPACER
30-TCE-TRL1027-11	TRIAL SPACER
30-TCE-TRL1027-12	TRIAL SPACER
30-TCE-TRL1027-13	TRIAL SPACER
30-TCE-TRL1027-14	TRIAL SPACER
30-TCE-TRL1027-15	TRIAL SPACER
30-TCE-TRL1027-7	TRIAL SPACER
30-TCE-TRL1027-8	TRIAL SPACER
30-TCE-TRL1027-9	TRIAL SPACER
30-TCE-TRL-10-6	TRIAL SPACER
30-TCE-TRL-11-6	TRIAL SPACER
30-TCE-TRL-12-6	TRIAL SPACER
30-TCE-TRL-13-6	TRIAL SPACER
30-TCE-TRL-14-6	TRIAL SPACER
30-TCE-TRL-15-6	TRIAL SPACER
30-TCE-TRL-7-6	TRIAL SPACER
30-TCE-TRL-8-6	TRIAL SPACER
30-TCE-TRL-9-6	TRIAL SPACER