Surgical Technique

Fortilink®-L

with TiPlus Technology

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1. Introduction

1.1. Device description

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

The Fortilink-L 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®-L with TiPlus Technology

1.2. Intended purpose

The Fortilink-L Ti is indicated for lateral 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-L 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, as measured by increase in post-operative disc height on radiological imaging

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.

NEUROMONITORING

Free-run EMG and SEPP should be employed during disc preparation.

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 the distributor.

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 cutting through the anterior 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.
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).

<u>RF Heating</u>
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.

<u>Artifact</u>
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
- Visceral injury
- 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 disc level following proper patient positioning, neuromonitoring and tissue retraction utilizing an appropriate lateral access system.

NEUROMONITORING
Free-run EMG and SEPP should be employed during disc preparation.

2.2. Disc space preparation

Perform annulotomy and remove disc material from the disc space following preferred methods. De-bulk the disc and prepare the end plates with appropriate instrumentation.

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.

DISC SPACE PREPARATION
Care should be taken to avoid cutting through the anterior 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.

2.3. Implant selection

Trial spacers are available to provide guidance prior to implant selection and are used in conjunction with the Hudson T-handle. The height of the trial spacer matches the height of the corresponding implant. 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. Using the trial spacer as a guide, verify that appropriate height restoration is achieved with anterior/posterior (A/P) and lateral fluoroscopy. Depth markings on the trial spacer can be seen under fluoroscopy to determine proper implant length (*Figure 2*). The first marking on all trial spacers is 40mm, with subsequent markings every 5mm (up to 55mm). Select the appropriate implant size.
Using an implant 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.

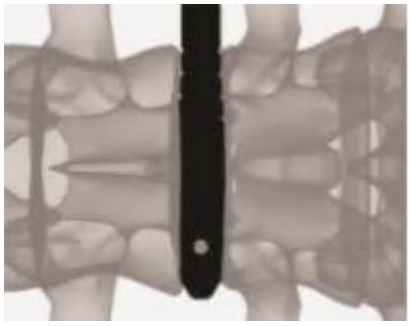

Figure 2

2.4. Implant preparation and insertion

Pack the implant with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

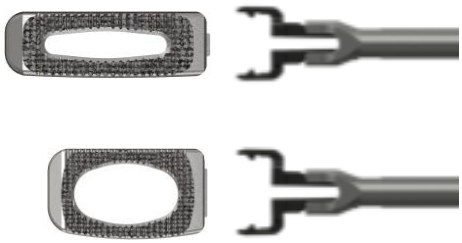

Figure 3

Inserter forks are provided for each implant width (*Figure 3*). Select the appropriate fork and attach to the correct inserter housing.

To assemble, press the button on the housing (*Figure 4A*) and insert the shaft of the fork until it stops. Align the pins with the slots in the housing (*Figure 4B*). While guiding the pins into the slot, rotate the knob clockwise until a click is heard or the fork is fully seated (*Figure 4C*). To prepare for implant, rotate the knob counterclockwise lightly against the hard stop. Place the implant within the fork tip and fully tighten the knob.

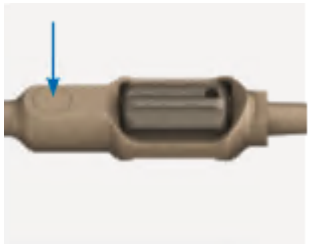

Figure 4A

Figure 4B

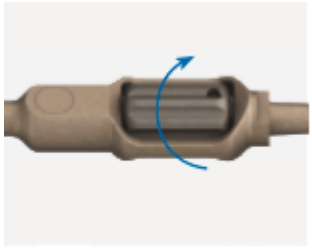

Figure 4C

Attach a T-handle to the back end of the inserter.

With the implant attached to the inserter, tap the implant to the final desired depth.

Detach the inserter from the implant by turning the thumb knob counterclockwise until the positive stop is felt to release the implant.

Once released, remove the inserter from the disc space.

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

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.

2.5. Radiographic verification

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

2.6. 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.

Supplemental pedicle fixation may be achieved using a posterior pedicle screw system.

2.7. Removal (if necessary)

For removal of the implant, attach the slap hammer to the end of the inserter.

Ensuring the appropriate sized forks are assembled to the inserter housing (as in Step 4, 'Implant preparation and insertion'), slide the forks into the slots of the implant and fully tighten the thumb knob on the inserter. Using the slap hammer, carefully back-slap the implant from the disc space.

3. Catalogue implants

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-L-1440-08-0L	Fortilink-L Ti 14x40x08-0L	14	40	8	0	1
77-L-1440-09-0L	Fortilink-L Ti 14x40x09-0L	14	40	9	0	1
77-L-1440-11-0L	Fortilink-L Ti 14x40x11-0L	14	40	11	0	1
77-L-1440-13-0L	Fortilink-L Ti 14x40x13-0L	14	40	13	0	1
77-L-1440-15-0L	Fortilink-L Ti 14x40x15-0L	14	40	15	0	1
77-L-1440-09-6L	Fortilink-L Ti 14x40x09-6L	14	40	9	6	1
77-L-1440-11-6L	Fortilink-L Ti 14x40x11-6L	14	40	11	6	1
77-L-1440-13-6L	Fortilink-L Ti 14x40x13-6L	14	40	13	6	1
77-L-1440-15-6L	Fortilink-L Ti 14x40x15-6L	14	40	15	6	1
77-L-1445-08-0L	Fortilink-L Ti 14x45x08-0L	14	45	8	0	1
77-L-1445-09-0L	Fortilink-L Ti 14x45x09-0L	14	45	9	0	1
77-L-1445-11-0L	Fortilink-L Ti 14x45x11-0L	14	45	11	0	1
77-L-1445-13-0L	Fortilink-L Ti 14x45x13-0L	14	45	13	0	1
77-L-1445-15-0L	Fortilink-L Ti 14x45x15-0L	14	45	15	0	1
77-L-1445-09-6L	Fortilink-L Ti 14x45x09-6L	14	45	9	6	1
77-L-1445-11-6L	Fortilink-L Ti 14x45x11-6L	14	45	11	6	1
77-L-1445-13-6L	Fortilink-L Ti 14x45x13-6L	14	45	13	6	1
77-L-1445-15-6L	Fortilink-L Ti 14x45x15-6L	14	45	15	6	1
77-L-1450-08-0L	Fortilink-L Ti 14x50x08-0L	14	50	8	0	1
77-L-1450-09-0L	Fortilink-L Ti 14x50x09-0L	14	50	9	0	1
77-L-1450-11-0L	Fortilink-L Ti 14x50x11-0L	14	50	11	0	1
77-L-1450-13-0L	Fortilink-L Ti 14x50x13-0L	14	50	13	0	1
77-L-1450-15-0L	Fortilink-L Ti 14x50x15-0L	14	50	15	0	1
77-L-1450-09-6L	Fortilink-L Ti 14x50x09-6L	14	50	9	6	1
77-L-1450-11-6L	Fortilink-L Ti 14x50x11-6L	14	50	11	6	1
77-L-1450-13-6L	Fortilink-L Ti 14x50x13-6L	14	50	13	6	1
77-L-1450-15-6L	Fortilink-L Ti 14x50x15-6L	14	50	15	6	1
77-L-1455-09-0L	Fortilink-L Ti 14x55x09-0L	14	55	9	0	1
77-L-1455-11-0L	Fortilink-L Ti 14x55x11-0L	14	55	11	0	1
77-L-1455-13-0L	Fortilink-L Ti 14x55x13-0L	14	55	13	0	1
77-L-1455-15-0L	Fortilink-L Ti 14x55x15-0L	14	55	15	0	1
77-L-1455-09-6L	Fortilink-L Ti 14x55x09-6L	14	55	9	6	1
77-L-1455-11-6L	Fortilink-L Ti 14x55x11-6L	14	55	11	6	1
77-L-1455-13-6L	Fortilink-L Ti 14x55x13-6L	14	55	13	6	1
77-L-1455-15-6L	Fortilink-L Ti 14x55x15-6L	14	55	15	6	1
77-L-1840-09-6L	Fortilink-L Ti 18x40x09-6L	18	40	9	6	1
77-L-1840-11-6L	Fortilink-L Ti 18x40x11-6L	18	40	11	6	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-L-1840-13-6L	Fortilink-L Ti 18x40x13-6L	18	40	13	6	1
77-L-1840-15-6L	Fortilink-L Ti 18x40x15-6L	18	40	15	6	1
77-L-1845-08-0L	Fortilink-L Ti 18x45x08-0L	18	45	8	0	1
77-L-1845-09-0L	Fortilink-L Ti 18x45x09-0L	18	45	9	0	1
77-L-1845-11-0L	Fortilink-L Ti 18x45x11-0L	18	45	11	0	1
77-L-1845-13-0L	Fortilink-L Ti 18x45x13-0L	18	45	13	0	1
77-L-1845-15-0L	Fortilink-L Ti 18x45x15-0L	18	45	15	0	1
77-L-1845-09-6L	Fortilink-L Ti 18x45x09-6L	18	45	9	6	1
77-L-1845-11-6L	Fortilink-L Ti 18x45x11-6L	18	45	11	6	1
77-L-1845-13-6L	Fortilink-L Ti 18x45x13-6L	18	45	13	6	1
77-L-1845-15-6L	Fortilink-L Ti 18x45x15-6L	18	45	15	6	1
77-L-1845-11-12L	Fortilink-L Ti 18x45x11-12L	18	45	11	12	1
77-L-1845-13-12L	Fortilink-L Ti 18x45x13-12L	18	45	13	12	1
77-L-1845-15-12L	Fortilink-L Ti 18x45x15-12L	18	45	15	12	1
77-L-1850-08-0L	Fortilink-L Ti 18x50x08-0L	18	50	8	0	1
77-L-1850-09-0L	Fortilink-L Ti 18x50x09-0L	18	50	9	0	1
77-L-1850-11-0L	Fortilink-L Ti 18x50x11-0L	18	50	11	0	1
77-L-1850-13-0L	Fortilink-L Ti 18x50x13-0L	18	50	13	0	1
77-L-1850-15-0L	Fortilink-L Ti 18x50x15-0L	18	50	15	0	1
77-L-1850-09-6L	Fortilink-L Ti 18x50x09-6L	18	50	9	6	1
77-L-1850-11-6L	Fortilink-L Ti 18x50x11-6L	18	50	11	6	1
77-L-1850-13-6L	Fortilink-L Ti 18x50x13-6L	18	50	13	6	1
77-L-1850-15-6L	Fortilink-L Ti 18x50x15-6L	18	50	15	6	1
77-L-1850-11-12L	Fortilink-L Ti 18x50x11-12L	18	50	11	12	1
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77-L-1855-11-0L	Fortilink-L Ti 18x55x11-0L	18	55	11	0	1
77-L-1855-13-0L	Fortilink-L Ti 18x55x13-0L	18	55	13	0	1
77-L-1855-15-0L	Fortilink-L Ti 18x55x15-0L	18	55	15	0	1
77-L-1855-09-6L	Fortilink-L Ti 18x55x09-6L	18	55	9	6	1
77-L-1855-11-6L	Fortilink-L Ti 18x55x11-6L	18	55	11	6	1
77-L-1855-13-6L	Fortilink-L Ti 18x55x13-6L	18	55	13	6	1
77-L-1855-15-6L	Fortilink-L Ti 18x55x15-6L	18	55	15	6	1
77-L-1855-11-12L	Fortilink-L Ti 18x55x11-12L	18	55	11	12	1
77-L-1855-13-12L	Fortilink-L Ti 18x55x13-12L	18	55	13	12	1
77-L-1855-15-12L	Fortilink-L Ti 18x55x15-12L	18	55	15	12	1
77-L-1860-09-0L	Fortilink-L Ti 18x60x09-0L	18	60	9	0	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-L-1860-11-0L	Fortilink-L Ti 18x60x11-0L	18	60	11	0	1
77-L-1860-13-0L	Fortilink-L Ti 18x60x13-0L	18	60	13	0	1
77-L-1860-15-0L	Fortilink-L Ti 18x60x15-0L	18	60	15	0	1
77-L-1860-09-6L	Fortilink-L Ti 18x60x09-6L	18	60	9	6	1
77-L-1860-11-6L	Fortilink-L Ti 18x60x11-6L	18	60	11	6	1
77-L-1860-13-6L	Fortilink-L Ti 18x60x13-6L	18	60	13	6	1
77-L-1860-15-6L	Fortilink-L Ti 18x60x15-6L	18	60	15	6	1
77-L-1860-11-12L	Fortilink-L Ti 18x60x11-12L	18	60	11	12	1
77-L-1860-13-12L	Fortilink-L Ti 18x60x13-12L	18	60	13	12	1
77-L-1860-15-12L	Fortilink-L Ti 18x60x15-12L	18	60	15	12	1
77-L-2245-08-0L	Fortilink-L Ti 22x45x08-0L	22	45	8	0	1
77-L-2245-09-0L	Fortilink-L Ti 22x45x09-0L	22	45	9	0	1
77-L-2245-11-0L	Fortilink-L Ti 22x45x11-0L	22	45	11	0	1
77-L-2245-13-0L	Fortilink-L Ti 22x45x13-0L	22	45	13	0	1
77-L-2245-15-0L	Fortilink-L Ti 22x45x15-0L	22	45	15	0	1
77-L-2245-09-6L	Fortilink-L Ti 22x45x09-6L	22	45	9	6	1
77-L-2245-11-6L	Fortilink-L Ti 22x45x11-6L	22	45	11	6	1
77-L-2245-13-6L	Fortilink-L Ti 22x45x13-6L	22	45	13	6	1
77-L-2245-15-6L	Fortilink-L Ti 22x45x15-6L	22	45	15	6	1
77-L-2245-11-12L	Fortilink-L Ti 22x45x11-12L	22	45	11	12	1
77-L-2245-13-12L	Fortilink-L Ti 22x45x13-12L	22	45	13	12	1
77-L-2245-15-12L	Fortilink-L Ti 22x45x15-12L	22	45	15	12	1
77-L-2250-08-0L	Fortilink-L Ti 22x50x08-0L	22	50	8	0	1
77-L-2250-09-0L	Fortilink-L Ti 22x50x09-0L	22	50	9	0	1
77-L-2250-11-0L	Fortilink-L Ti 22x50x11-0L	22	50	11	0	1
77-L-2250-13-0L	Fortilink-L Ti 22x50x13-0L	22	50	13	0	1
77-L-2250-15-0L	Fortilink-L Ti 22x50x15-0L	22	50	15	0	1
77-L-2250-09-6L	Fortilink-L Ti 22x50x09-6L	22	50	9	6	1
77-L-2250-11-6L	Fortilink-L Ti 22x50x11-6L	22	50	11	6	1
77-L-2250-13-6L	Fortilink-L Ti 22x50x13-6L	22	50	13	6	1
77-L-2250-15-6L	Fortilink-L Ti 22x50x15-6L	22	50	15	6	1
77-L-2250-11-12L	Fortilink-L Ti 22x50x11-12L	22	50	11	12	1
77-L-2250-13-12L	Fortilink-L Ti 22x50x13-12L	22	50	13	12	1
77-L-2250-15-12L	Fortilink-L Ti 22x50x15-12L	22	50	15	12	1
77-L-2255-08-0L	Fortilink-L Ti 22x55x08-0L	22	55	8	0	1
77-L-2255-09-0L	Fortilink-L Ti 22x55x09-0L	22	55	9	0	1
77-L-2255-11-0L	Fortilink-L Ti 22x55x11-0L	22	55	11	0	1
77-L-2255-13-0L	Fortilink-L Ti 22x55x13-0L	22	55	13	0	1
77-L-2255-15-0L	Fortilink-L Ti 22x55x15-0L	22	55	15	0	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-L-2255-09-6L	Fortilink-L Ti 22x55x09-6L	22	55	9	6	1
77-L-2255-11-6L	Fortilink-L Ti 22x55x11-6L	22	55	11	6	1
77-L-2255-13-6L	Fortilink-L Ti 22x55x13-6L	22	55	13	6	1
77-L-2255-15-6L	Fortilink-L Ti 22x55x15-6L	22	55	15	6	1
77-L-2255-11-12L	Fortilink-L Ti 22x55x11-12L	22	55	11	12	1
77-L-2255-13-12L	Fortilink-L Ti 22x55x13-12L	22	55	13	12	1
77-L-2255-15-12L	Fortilink-L Ti 22x55x15-12L	22	55	15	12	1
77-L-2260-08-0L	Fortilink-L Ti 22x60x08-0L	22	60	8	0	1
77-L-2260-09-0L	Fortilink-L Ti 22x60x09-0L	22	60	9	0	1
77-L-2260-11-0L	Fortilink-L Ti 22x60x11-0L	22	60	11	0	1
77-L-2260-13-0L	Fortilink-L Ti 22x60x13-0L	22	60	13	0	1
77-L-2260-15-0L	Fortilink-L Ti 22x60x15-0L	22	60	15	0	1
77-L-2260-09-6L	Fortilink-L Ti 22x60x09-6L	22	60	9	6	1
77-L-2260-11-6L	Fortilink-L Ti 22x60x11-6L	22	60	11	6	1
77-L-2260-13-6L	Fortilink-L Ti 22x60x13-6L	22	60	13	6	1
77-L-2260-15-6L	Fortilink-L Ti 22x60x15-6L	22	60	15	6	1
77-L-2260-11-12L	Fortilink-L Ti 22x60x11-12L	22	60	11	12	1
77-L-2260-13-12L	Fortilink-L Ti 22x60x13-12L	22	60	13	12	1
77-L-2260-15-12L	Fortilink-L Ti 22x60x15-12L	22	60	15	12	1
77-L-2645-9-6L	Fortilink-L Ti 26x45x9-6L	26	45	9	6	1
77-L-2645-11-6L	Fortilink-L Ti 26x45x11-6L	26	45	11	6	1
77-L-2645-13-6L	Fortilink-L Ti 26x45x13-6L	26	45	13	6	1
77-L-2645-15-6L	Fortilink-L Ti 26x45x15-6L	26	45	15	6	1
77-L-2645-13-12L	Fortilink-L Ti 26x45x13-12L	26	45	13	12	1
77-L-2645-15-12L	Fortilink-L Ti 26x45x15-12L	26	45	15	12	1
77-L-2650-08-0L	Fortilink-L Ti 26x50x08-0L	26	50	8	0	1
77-L-2650-09-0L	Fortilink-L Ti 26x50x09-0L	26	50	9	0	1
77-L-2650-11-0L	Fortilink-L Ti 26x50x11-0L	26	50	11	0	1
77-L-2650-13-0L	Fortilink-L Ti 26x50x13-0L	26	50	13	0	1
77-L-2650-15-0L	Fortilink-L Ti 26x50x15-0L	26	50	15	0	1
77-L-2650-9-6L	Fortilink-L Ti 26x50x9-6L	26	50	9	6	1
77-L-2650-11-6L	Fortilink-L Ti 26x50x11-6L	26	50	11	6	1
77-L-2650-13-6L	Fortilink-L Ti 26x50x13-6L	26	50	13	6	1
77-L-2650-15-6L	Fortilink-L Ti 26x50x15-6L	26	50	15	6	1
77-L-2650-13-12L	Fortilink-L Ti 26x50x13-12L	26	50	13	12	1
77-L-2650-15-12L	Fortilink-L Ti 26x50x15-12L	26	50	15	12	1
77-L-2655-08-0L	Fortilink-L Ti 26x55x08-0L	26	55	8	0	1
77-L-2655-09-0L	Fortilink-L Ti 26x55x09-0L	26	55	9	0	1
77-L-2655-11-0L	Fortilink-L Ti 26x55x11-0L	26	55	11	0	1

Product number	Product name	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-L-2655-13-0L	Fortilink-L Ti 26x55x13-0L	26	55	13	0	1
77-L-2655-15-0L	Fortilink-L Ti 26x55x15-0L	26	55	15	0	1
77-L-2655-9-6L	Fortilink-L Ti 26x55x9-6L	26	55	9	6	1
77-L-2655-11-6L	Fortilink-L Ti 26x55x11-6L	26	55	11	6	1
77-L-2655-13-6L	Fortilink-L Ti 26x55x13-6L	26	55	13	6	1
77-L-2655-15-6L	Fortilink-L Ti 26x55x15-6L	26	55	15	6	1
77-L-2655-13-12L	Fortilink-L Ti 26x55x13-12L	26	55	13	12	1
77-L-2655-15-12L	Fortilink-L Ti 26x55x15-12L	26	55	15	12	1
77-L-2660-08-0L	Fortilink-L Ti 26x60x08-0L	26	60	8	0	1
77-L-2660-09-0L	Fortilink-L Ti 26x60x09-0L	26	60	9	0	1
77-L-2660-11-0L	Fortilink-L Ti 26x60x11-0L	26	60	11	0	1
77-L-2660-13-0L	Fortilink-L Ti 26x60x13-0L	26	60	13	0	1
77-L-2660-15-0L	Fortilink-L Ti 26x60x15-0L	26	60	15	0	1
77-L-2660-9-6L	Fortilink-L Ti 26x60x9-6L	26	60	9	6	1
77-L-2660-11-6L	Fortilink-L Ti 26x60x11-6L	26	60	11	6	1
77-L-2660-13-6L	Fortilink-L Ti 26x60x13-6L	26	60	13	6	1
77-L-2660-15-6L	Fortilink-L Ti 26x60x15-6L	26	60	15	6	1
77-L-2660-13-12L	Fortilink-L Ti 26x60x13-12L	26	60	13	12	1
77-L-2660-15-12L	Fortilink-L Ti 26x60x15-12L	26	60	15	12	1

4. Catalogue instruments

Instruments are manufactured by Pioneer Surgical Technology Inc. and distributed by Surgalign Spine Technologies, Inc.

Instrument list Fortilink-L Ti (LLIF)	
Part #	**Description**
65-LCE-INSERTER2	Straight Inserter, Fortilink L
65-LCE-FORK2-14	Fork, 14mm, Fortilink L Str Inst
65-LCE-FORK2-18	Fork, 18mm, Fortilink L Str Inst
65-LCE-FORK2-22	Fork, 22mm, Fortilink L Str Inst
65-LCE-FORK2-26	Fork, 26mm, Fortilink L Str Inst
65-LCE-TRL14-8	Fortilink-L Trial Spacer 14x8
65-LCE-TRL18-8	Fortilink-L Trial Spacer 18x8
65-LCE-TRL22-8	Fortilink-L Trial Spacer 22x8