Fortilink®-A

with TiPlus™ Technology

SURGICAL TECHNIQUE

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INTRODUCTION

Device description

The Fortilink-A TiPlus implant (Figure 1) is an interbody fusion device intended for the lumbar spine (L2-S1) in patients with degenerative disc diseases. The Fortilink-A TiPlus interbody fusion devices are manufactured with SLM (selective laser melting) and are built up from implant grade titanium alloy (Ti6Al4V). The Fortilink-A TiPlus implant 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 and lordosis.
The Fortilink-A TiPlus implant will be used in combination with:

- Dedicated instrument set
- General instruments typically used in spinal surgery (including rongeurs, forceps)

Further copies of the surgical technique and instructions for use can be requested at the distributor.

Figure 1
Fortilink®-A with TiPlus™ Technology

Intended purpose

The Fortilink-A TiPlus implant is indicated for anterior 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 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 FDA-cleared 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. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior FDA-cleared supplemental fixation.

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

Clinical benefits

The following benefits to the patient are intended to be achieved with the Fortilink-A TiPlus implant:

- 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
- Increase in lordosis, as measured by increase in post-operative lordosis on radiological imaging

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.

Material specification

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

SURGICAL TECHNIQUE

Patient positioning

The patient should be placed in a supine position appropriate for an anterior approach. For anterior approach to the lower lumbar levels, position the patient in a slight Trendelenburg position.

Exposure of disc level

Locate the correct operative disc level and make an incision location by taking a lateral X-ray (fluoroscopic view) while holding a straight metal instrument at the side of the patient (Figure 2). This ensures that the incision and exposure will allow direct visualization into the disc space. Expose the operative disc level and retract tissues using appropriate instrumentation. Retract and protect the great vessels to allow complete exposure and visualization of the operative site.

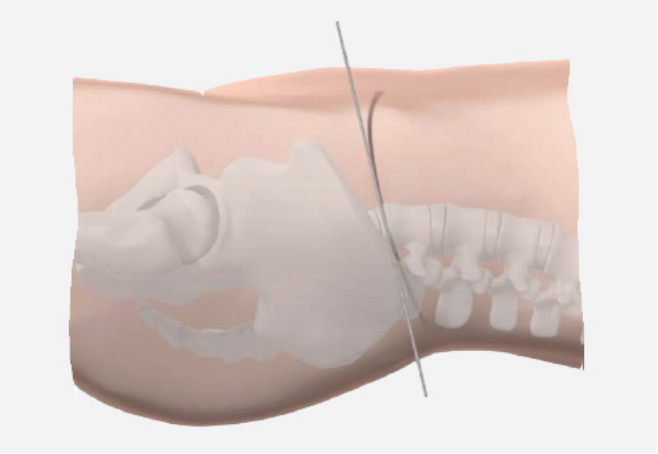

Figure 2

Discectomy and endplate preparation

Perform a complete discectomy using 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 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

Spreaders may be used to distract the disc space. A smaller width of the spreader may be inserted first to aid in distraction of the disc space. After initial distraction, turn the spreader 90 degrees to the full spreader height to distract the disc space.

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.

Implant selection

Trial spacers are available to provide guidance prior to implant selection. For an overview of the available trial spacers, see 'Ordering guide'.

SIZE SELECTION

Select an appropriate size detachable trial head and assemble it to the trial shaft handle by threading the trial handle clockwise until the positive stop is reached (Figure 3). Trial markings indicate footprint size, height and angle of lordosis. The trial spacer should require minimum force to insert yet fit snugly within the disc space (Figure 4). Sequentially increase the trial spacer size until the appropriate fit 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.

Insert the trial into the annulotomy window. Check fit and positioning with anterior/posterior (A/P) and lateral fluoroscopy. Repeat until the desired fit is achieved to identify the optimal trial profile.

Figure 3

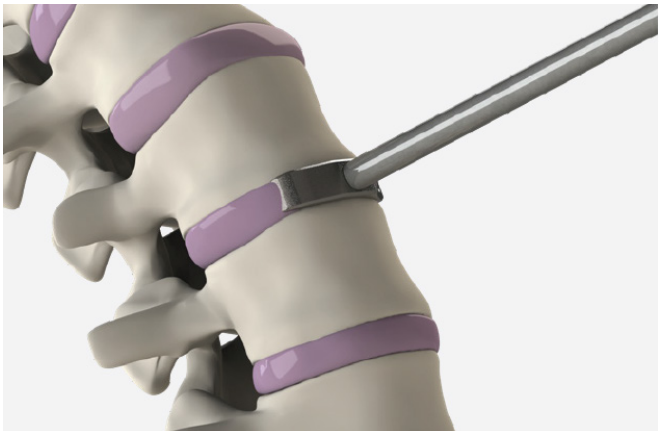

Figure 4

Implant preparation

Select the implant based upon the trial sizing. The Fortilink-A trials are sized line-to-line to the implant. The implants are available in different lordotic degrees and sizes, see 'Ordering guide'.

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

Inserter preparation

Both anterolateral and straight inserters are available to aid with insertion for specific approaches (Figure 5). Each inserter type has their specific inner shaft and external housing.

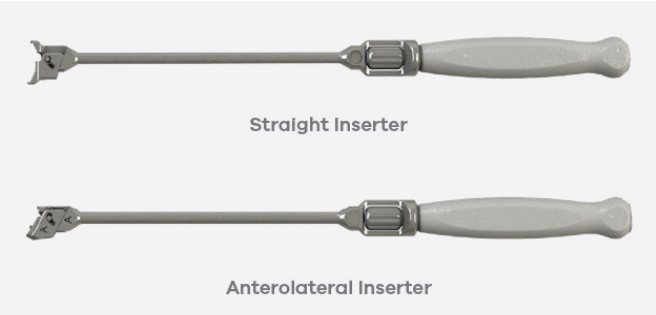

Figure 5

Inserter assembly

To assemble, insert the inner shaft into the housing (Figure 6A), depress the button (Figure 6B) and push shaft within housing until a positive stop is felt. With the jaws facing you, align the inner shaft jaw flat and housing jaw flat (Figure 7), rotate the knob clockwise until the shaft is fully seated (Figure 6C).

Verify the labeling on the inner shaft is the same when assembling to the housing ("S" indicates straight inserter and "A" indicates the anterolateral inserter).

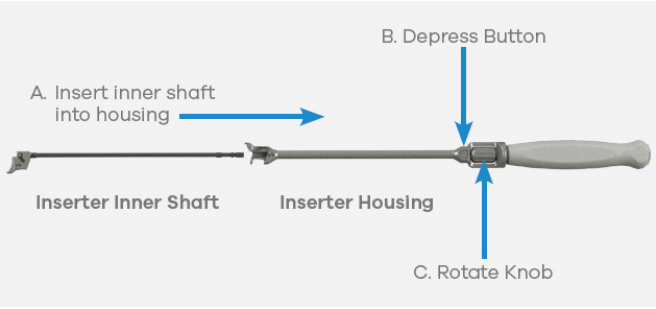

Figure 6

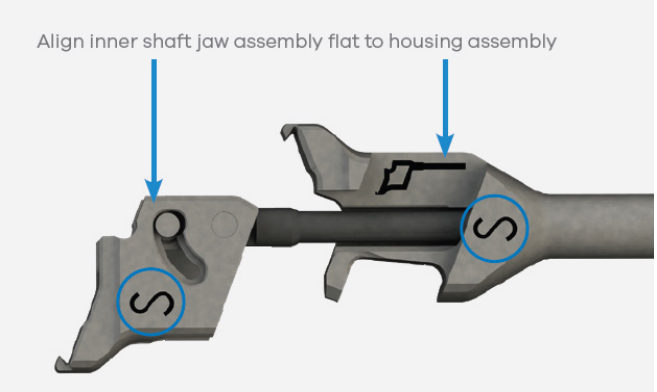

Figure 7

Inserter and implant loading

Rotate inserter knob counterclockwise until positive stop is felt, visually confirm distal end is fully open (Figure 8).

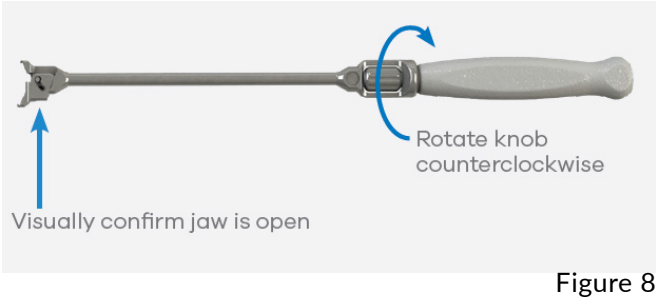

Figure 8

Attach the selected implant to the inserter by placing the inserter jaw into the recessed implant pocket (Figure 9). Rotate the knob clockwise until a positive stop is reached. Verify the implant is fully attached to inserter before inserting into the disc space (Figure 10). Insert the implant into the desired position as determined by direct visualized and lateral fluoroscopy.

If fine adjustments are needed for final placement of the implant, the tamp may be used to aid in final positioning of the implant (Figure 11). When using the tamp, always ensure that it is docked within the inserter geometry for direct tamping and if corner tamping is required, ensure that the cup portion of the tamp is at the corner of the implant. Always use gentle force when tamping.

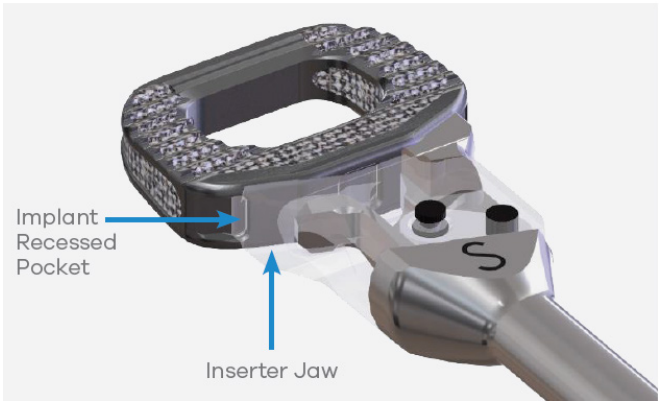

Figure 9

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.


Figure 10

Radiographic verification

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

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. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

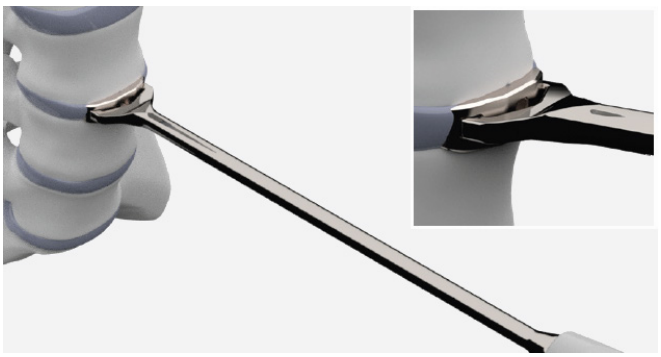
Figure 11

Removal (if necessary)

Assemble the inner jaw to the housing. After assembly (see previous steps), re-engage inserter to the implant. Rotate knob of inserter clockwise for reattachment until positive stop is felt. Attach slap hammer adapter to the inserter. Assemble slap hammer to the slap hammer attachment. Carefully back slap the hammer and remove the implant from the disc space.

ORDERING GUIDE

INSERTER SET - REQUIRED (65-LS-A-INSERTER)

Product number	Product name	Quantity
65-A-INSERTER	Inserter	1
65-A-INSERTER-A	Anterolateral Inserter	1
65-A-SHAFT	Inserter Jaw	1
65-A-SHAFT-A	Anterolateral Inserter Jaw	1
65-A-TAMP	Tamp	1
38-SLAPHAMMER	Slap Hammer, Hudson	1
38-SLAPADAPT	Slap Hammer Adapter, Hudson	1

STANDARD TRIAL SET - 8 & 14 DEGREE (65-LS-A-TRIALS)

Product number	Product name	Quantity
65-A-INSERTER-TRL	Trial Inserter	2
65-A-S08-8L-TRL	Trial Spacer, 32 x 25 x 8mm – 8L	1
65-A-S10-8L-TRL	Trial Spacer, 32 x 25 x 10mm – 8L	1
65-A-S12-8L-TRL	Trial Spacer, 32 x 25 x 12mm – 8L	1
65-A-S14-8L-TRL	Trial Spacer, 32 x 25 x 14mm – 8L	1
65-A-S16-8L-TRL	Trial Spacer, 32 x 25 x 16mm – 8L	1
65-A-S18-8L-TRL	Trial Spacer, 32 x 25 x 18mm – 8L	1
65-A-M08-8L-TRL	Trial Spacer, 36 x 27 x 8mm – 8L	1
65-A-M10-8L-TRL	Trial Spacer, 36 x 27 x 10mm – 8L	1
65-A-M12-8L-TRL	Trial Spacer, 36 x 27 x 12mm – 8L	1
65-A-M14-8L-TRL	Trial Spacer, 36 x 27 x 14mm – 8L	1
65-A-M16-8L-TRL	Trial Spacer, 36 x 27 x 16mm – 8L	1
65-A-M18-8L-TRL	Trial Spacer, 36 x 27 x 18mm – 8L	1
65-A-L08-8L-TRL	Trial Spacer, 40 x 29 x 8mm – 8L	1
65-A-L10-8L-TRL	Trial Spacer, 40 x 29 x 10mm – 8L	1
65-A-L12-8L-TRL	Trial Spacer, 40 x 29 x 12mm – 8L	1
65-A-L14-8L-TRL	Trial Spacer, 40 x 29 x 14mm – 8L	1
65-A-L16-8L-TRL	Trial Spacer, 40 x 29 x 16mm – 8L	1
65-A-L18-8L-TRL	Trial Spacer, 40 x 29 x 18mm – 8L	1
65-A-S10-14L-TRL	Trial Spacer, 32 x 25 x 10mm – 14L	1
65-A-S12-14L-TRL	Trial Spacer, 32 x 25 x 12mm – 14L	1
65-A-S14-14L-TRL	Trial Spacer, 32 x 25 x 14mm – 14L	1
65-A-S16-14L-TRL	Trial Spacer, 32 x 25 x 16mm – 14L	1
65-A-S18-14L-TRL	Trial Spacer, 32 x 25 x 18mm – 14L	1
65-A-M10-14L-TRL	Trial Spacer, 36 x 27 x 10mm – 14L	1
65-A-M12-14L-TRL	Trial Spacer, 36 x 27 x 12mm – 14L	1
65-A-M14-14L-TRL	Trial Spacer, 36 x 27 x 14mm – 14L	1
65-A-M16-14L-TRL	Trial Spacer, 36 x 27 x 16mm – 14L	1
65-A-M18-14L-TRL	Trial Spacer, 36 x 27 x 18mm – 14L	1
65-A-L12-14L-TRL	Trial Spacer, 40 x 29 x 12mm – 14L	1
65-A-L14-14L-TRL	Trial Spacer, 40 x 29 x 14mm – 14L	1
65-A-L16-14L-TRL	Trial Spacer, 40 x 29 x 16mm – 14L	1
65-A-L18-14L-TRL	Trial Spacer, 40 x 29 x 18mm – 14L	1

STANDARD IMPLANT SET - 8 & 14 DEGREE (67-LS-ATI-IMP)

Product number	Product name	Width (mm)	Depth (mm)	Height (mm)	Lordosis (°)	Quantity
67-A-3225-08-8L	Fortilink-A Ti 32x25x08-8L	32	25	8	8	2
67-A-3225-10-8L	Fortilink-A Ti 32x25x10-8L	32	25	10	8	2
67-A-3225-12-8L	Fortilink-A Ti 32x25x12-8L	32	25	12	8	2
67-A-3225-14-8L	Fortilink-A Ti 32x25x14-8L	32	25	14	8	2
67-A-3225-16-8L	Fortilink-A Ti 32x25x16-8L	32	25	16	8	2
67-A-3225-18-8L	Fortilink-A Ti 32x25x18-8L	32	25	18	8	1
67-A-3627-08-8L	Fortilink-A Ti 36x27x08-8L	36	27	8	8	2
67-A-3627-10-8L	Fortilink-A Ti 36x27x10-8L	36	27	10	8	2
67-A-3627-12-8L	Fortilink-A Ti 36x27x12-8L	36	27	12	8	2
67-A-3627-14-8L	Fortilink-A Ti 36x27x14-8L	36	27	14	8	2
67-A-3627-16-8L	Fortilink-A Ti 36x27x16-8L	36	27	16	8	2
67-A-3627-18-8L	Fortilink-A Ti 36x27x18-8L	36	27	18	8	1
67-A-4029-08-8L	Fortilink-A Ti 40x29x08-8L	40	29	8	8	2
67-A-4029-10-8L	Fortilink-A Ti 40x29x10-8L	40	29	10	8	2
67-A-4029-12-8L	Fortilink-A Ti 40x29x12-8L	40	29	12	8	2
67-A-4029-14-8L	Fortilink-A Ti 40x29x14-8L	40	29	14	8	2
67-A-4029-16-8L	Fortilink-A Ti 40x29x16-8L	40	29	16	8	2
67-A-4029-18-8L	Fortilink-A Ti 40x29x18-8L	40	29	18	8	1
67-A-3225-10-14L	Fortilink-A Ti 32x25x10-14L	32	25	10	14	2
67-A-3225-12-14L	Fortilink-A Ti 32x25x12-14L	32	25	12	14	2
67-A-3225-14-14L	Fortilink-A Ti 32x25x14-14L	32	25	14	14	2
67-A-3225-16-14L	Fortilink-A Ti 32x25x16-14L	32	25	16	14	2
67-A-3225-18-14L	Fortilink-A Ti 32x25x18-14L	32	25	18	14	1
67-A-3627-10-14L	Fortilink-A Ti 36x27x10-14L	36	27	10	14	2
67-A-3627-12-14L	Fortilink-A Ti 36x27x12-14L	36	27	12	14	2
67-A-3627-14-14L	Fortilink-A Ti 36x27x14-14L	36	27	14	14	2
67-A-3627-16-14L	Fortilink-A Ti 36x27x16-14L	36	27	16	14	2
67-A-3627-18-14L	Fortilink-A Ti 36x27x18-14L	36	27	18	14	1
67-A-4029-12-14L	Fortilink-A Ti 40x29x12-14L	40	29	12	14	2
67-A-4029-14-14L	Fortilink-A Ti 40x29x14-14L	40	29	14	14	2
67-A-4029-16-14L	Fortilink-A Ti 40x29x16-14L	40	29	16	14	2
67-A-4029-18-14L	Fortilink-A Ti 40x29x18-14L	40	29	18	14	1

OPTIONAL TRIAL SET - 20 DEGREE (65-LS-A-TRIAL-20L)

Product number	Product name	Quantity
65-A-INSERTER-TRL	Trial Inserter	2
65-A-S12-20L-TRL	Trial Spacer, 32 x 25 x 12mm – 20L	1
65-A-S14-20L-TRL	Trial Spacer, 32 x 25 x 14mm – 20L	1
65-A-S16-20L-TRL	Trial Spacer, 32 x 25 x 16mm – 20L	1
65-A-S18-20L-TRL	Trial Spacer, 32 x 25 x 18mm – 20L	1
65-A-S20-20L-TRL	Trial Spacer, 32 x 25 x 20mm – 20L	1
65-A-M14-20L-TRL	Trial Spacer, 36 x 27 x 14mm – 20L	1
65-A-M16-20L-TRL	Trial Spacer, 36 x 27 x 16mm – 20L	1
65-A-M18-20L-TRL	Trial Spacer, 36 x 27 x 18mm – 20L	1
65-A-M20-20L-TRL	Trial Spacer, 36 x 27 x 20mm – 20L	1
65-A-L14-20L-TRL	Trial Spacer, 40 x 29 x 14mm – 20L	1
65-A-L16-20L-TRL	Trial Spacer, 40 x 29 x 16mm – 20L	1
65-A-L18-20L-TRL	Trial Spacer, 40 x 29 x 18mm – 20L	1
65-A-L20-20L-TRL	Trial Spacer, 40 x 29 x 20mm – 20L	1

OPTIONAL IMPLANT SET - 20 DEGREE (67-LS-ATI-IMP-20L)

Product number	Product name	Width (mm)	Depth (mm)	Height (mm)	Lordosis (°)	Quantity
67-A-3225-12-20L	Fortilink-A Ti 32x25x12-20L	32	25	12	20	1
67-A-3225-14-20L	Fortilink-A Ti 32x25x14-20L	32	25	14	20	1
67-A-3225-16-20L	Fortilink-A Ti 32x25x16-20L	32	25	16	20	1
67-A-3225-18-20L	Fortilink-A Ti 32x25x18-20L	32	25	18	20	1
67-A-3225-20-20L	Fortilink-A Ti 32x25x20-20L	32	25	20	20	1
67-A-3627-14-20L	Fortilink-A Ti 36x27x14-20L	36	27	14	20	1
67-A-3627-16-20L	Fortilink-A Ti 36x27x16-20L	36	27	16	20	1
67-A-3627-18-20L	Fortilink-A Ti 36x27x18-20L	36	27	18	20	1
67-A-3627-20-20L	Fortilink-A Ti 36x27x20-20L	36	27	20	20	1
67-A-4029-14-20L	Fortilink-A Ti 40x29x14-20L	40	29	14	20	1
67-A-4029-16-20L	Fortilink-A Ti 40x29x16-20L	40	29	16	20	1
67-A-4029-18-20L	Fortilink-A Ti 40x29x18-20L	40	29	18	20	1
67-A-4029-20-20L	Fortilink-A Ti 40x29x20-20L	40	29	20	20	1

Instruments are manufactured by Pioneer Surgical Technology Inc.

WARNINGS

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.

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.

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.

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.

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. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

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.

DISPOSAL

The products must be disposed according to local regulations.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the device is MR Conditional. 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 field gradient of 4,000 G/cm (40.0 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Level Controlled Operating Mode) at 1.5 T and 3 T.

RF Heating
Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than 5.0 °C after 15 minutes of continuous scanning.

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
In non-clinical testing, the image artifact caused by the device extends approximately 3.3 cm from the worst-case device when imaged with a gradient-echo pulse sequence in a 3 T MRI system.

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
- Retrograde ejaculation
- Infection
- Allergic reaction
- Pulmonary embolism
- Pneumonia
- Adjacent segment disease
- Heterotrophic ossification
- Bone erosion
- Epidural scarring
- Ureter damage

NOTES

INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

LIMITED WARRANTY and DISCLAIMER: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

XTANT MEDICAL

Xtant Medical
888-886-9354
cs@xtantmedical.com
xtantmedical.com
664 Cruiser Lane
Belgrade, MT 59714 USA

BAAT Medical Products B.V.
+31 (0)88 5656600
www.baatmedical.com
F. Hazemeijerstraat 800
7555 RJ Hengelo
The Netherlands

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