

# Instructions for use

## Fortilink®-SA

### with TiPlus Technology

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#### Device description

The Fortilink-SA Ti is a stand-alone interbody fusion device intended for the lumbar spine (L1-S1) in patients with degenerative disc diseases. The Fortilink-SA Ti is composed out of a cage/wedge, three screws and two retainers. The Fortilink-SA Ti interbody fusion devices are manufactured with SLM (selective laser melting) and are built up from implant grade titanium alloy (Ti6Al4V). The Fortilink-SA Ti has an open mesh structure and a bone window both designed to allow bone ingrowth and facilitate fusion. The disc-shaped design is intended to provide primary stability and increase the intervertebral height and lordosis. The screws provide primary stability to facilitate fusion and supplemental fixation is therefore only required for Fortilink-SA Ti with lordotic angles greater than or equal to 20 degrees. The retainer locks the screws. Both the screws and the retainers are made from titanium alloy.

The Fortilink-SA Ti implant 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)

#### Instructions for use

The end-user information consists of the instructions for use and surgical technique. The operating procedure is described step by step in the surgical technique. Further copies of the instructions for use and surgical technique can be requested at the distributor.

#### Indications for use

The Fortilink-SA Ti is indicated for stand-alone anterior lumbar interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and is implanted via an anterior approach. Implants must be used with three of the provided bone screws. This system is to be used in patients who have had six months of non-operative treatment. The Fortilink-SA Ti with lordotic angles greater than or equal to 20 degrees requires the use of FDA-cleared supplemental fixation in addition to the screws intrinsic to the interbody spacer.

#### Clinical benefits

The following benefits to the patient are intended to be achieved with the Fortilink-SA 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

#### 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

### 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.

<p><b>MIXING WITH OTHER DEVICES</b>                  Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.</p>
<p><b>INSTRUMENTS</b>                  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.</p>
<p><b>CLEANING AND STERILIZATION</b>                  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.</p>
<p><b>PACKAGING INTEGRITY</b>                  Inspect the product, including all packaging and labeling materials carefully:</p> <ul style="list-style-type: none"> <li>• Do not use past expiration date specified on the product label.</li> <li>• Do not use if the implant or packaging is damaged or unintentionally opened before use.</li> <li>• Do not use if there are discrepancies in label information.</li> </ul>
<p><b>ENDPLATE PREPARATION</b>                  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.</p>
<p><b>DISTRACTION</b>                  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.</p>
<p><b>SIZE SELECTION</b>                  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.</p>
<p><b>PRODUCT AVAILABILITY</b>                  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.</p>
<p><b>LOAD-BEARING</b>                  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.</p>
<p><b>EXPLANTATION</b>                  After implantation of an interbody fusion device and identification of the presence of fusion, only the supplemental fixation components should be removed.</p>
<p><b>COMORBIDITIES</b>                  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.</p>
<p><b>PREVIOUS SURGERY</b>                  Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.</p>

<p><b>INSTRUMENT WEAR</b> 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.</p>
<p><b>INSTRUMENT FRAGMENTS</b> 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.</p>
<p><b>IMPLANT HANDLING</b> 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.</p>
<p><b>MRI SAFETY INFORMATION</b> Safety in MRI Not Evaluated. This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.</p>
<p><b>DISPOSAL</b> The products must be disposed according to local regulations.</p>

### 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

### Material specification

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

The screws and retainers are made of implant grade titanium alloy Ti6Al4V ELI (ASTM F136).

### Packaging

Packages for each of the components should be intact upon receipt. Damaged or unintentionally opened sterile packages and products should not be used and should be returned to the distributor.

### Recommended storage and handling conditions

The products shall be stored and handled with care. The primary, secondary and eventual tertiary packaging shall remain intact at all times. The products shall be kept dry and stored and handled in an environmentally controlled environment.

### 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.

### Product complaints

If the implant ever "malfunctioned" and/or may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

### Explanation of symbols used in end-user information



Manufacturer



Catalogue Number



Batch Code



Quantity



Sterilized using irradiation



Date of manufacture



Use-by date



Do not re-use



Do not re-sterilize



Do not use if package is damaged



Keep dry



Consult instructions for use



Caution



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.