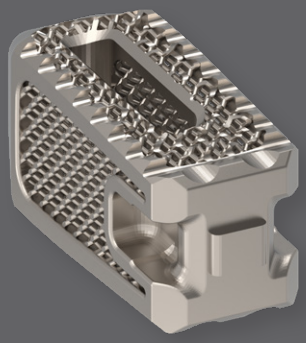
Surgalign™
SPINE TECHNOLOGIES

Fortilink®-TS

IBF Device



with TiPlus Technology

MORE THAN POSSIBLE.™

SURGICAL TECHNIQUE

TABLE OF CONTENTS

Fortilink®-TS

IBF Device

with TiPlus Technology

1.1. DEVICE DESCRIPTION

The Fortilink-TS Ti (Figure 1) is an interbody fusion device intended for the lumbar spine (L2-S1) in patients with degenerative disc disease. The Fortilink-TS Ti interbody fusion devices are manufactured with SLM (selective laser melting) and are built up from implant grade titanium alloy (Ti6Al4V). The Fortilink-TS 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.

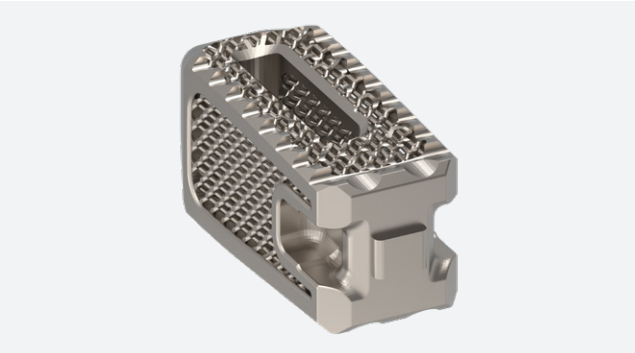


Figure 1
Fortilink®-TS with TiPlus Technology

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

- Dedicated instrument set (see surgical technique for Catalog 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.

1.2. INTENDED PURPOSE

The Fortilink-TS Ti is indicated for transforaminal and posterior 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-TS 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).

2.1 EXPOSURE OF DISC LEVEL

Access the operative site and retract tissues to allow for complete exposure and 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 with unilateral or bilateral near-total facetectomy and foraminotomies, depending on the approach.

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.

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.

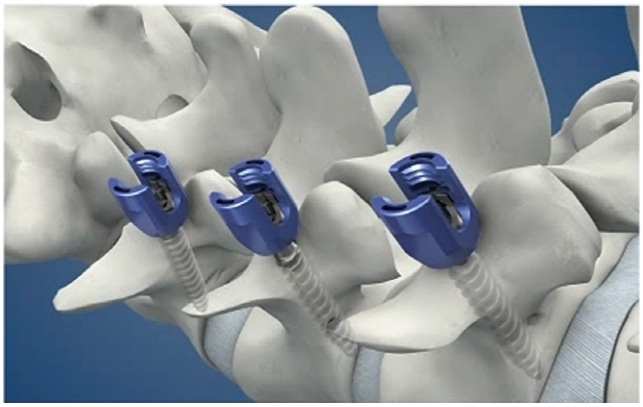


Figure 2

2.4 DISC SPACE PREPARATION

For the bilateral approach, a paddle distractor may be in place. Insert the corresponding shaver on the contralateral side.

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. Rotating cutters 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. Instruments should be moved up and down in a repetitive fashion and angled obliquely toward the midline to prepare as much endplate as possible. For a bilateral approach, repeat on the contralateral side.

⚠ **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. The height of the trial spacer matches the height of the corresponding implant (Figures 3 and 4).

For an overview of the available trial spacers, see 'Catalog 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 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.

The implants are available in different lordotic degrees and sizes, see 'Catalog Implants'.

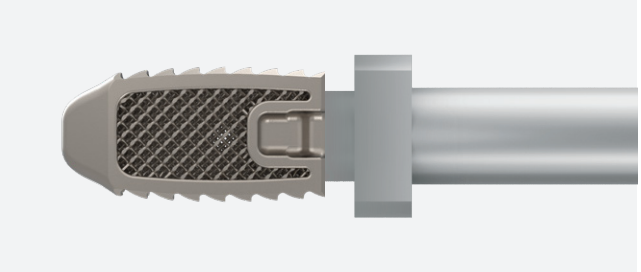


Figure 3
Parallel implant/trial

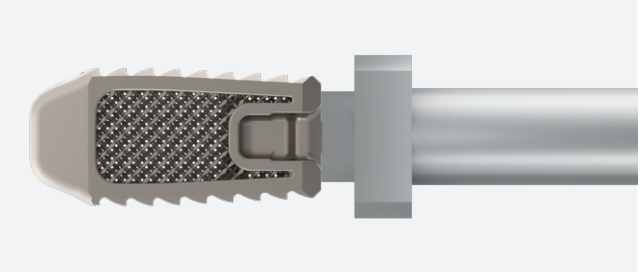


Figure 4
Lordotic implant/trial

2.7 IMPLANT PREPARATION AND INSERTION

Pack the implant with autogenous bone graft and/or allogenic bone graft. If necessary, the thecal sac and inferior nerve root may be gently retracted medially with the nerve root retractor.

⚠ **INSERTION INSTRUMENTS**

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

⚠ **MAXIMIZE GRAFT AREA**

Maximize graft area by packing bone graft lateral and anterior in the interspace prior to the initial implant placement.

⚠ **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.

Attach the inserter to the implant by pulling back on the release collar (Figure 5A), opening the jaws of the inserter. Place the implant in the open jaws of the inserter (Figure 5B) and release the collar. Lock the inserter by twisting the locking knob clockwise (Figure 6).

Figure 5A

Figure 5B

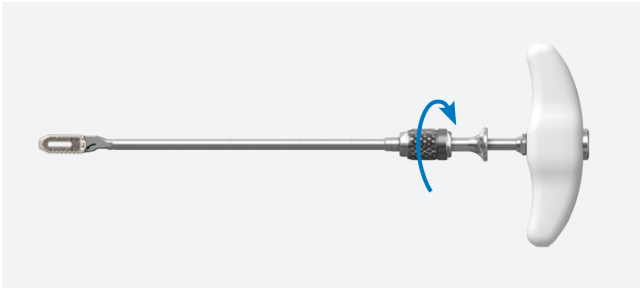


Figure 6

With the implant attached to the inserter, tap the implant to the final desired depth. Figure 7 shows the implant placement for the unilateral approach. The etch markings on the side of the inserter align with the opening arm of the inserter.

⚠ IMPLANT INSERTION

The implants should not be rotated during insertion. Attempting to rotate these implants during insertion may lead to implant failure.

Detach the inserter from the implant by first twisting the locking knob counterclockwise to unlock. Then pull back on the release collar, opening the jaws of the inserter to release the implant.

Once released, remove the inserter from the disc space.

Pack bone graft into the disc space surrounding the implants. If performing a bilateral surgery, leave enough space beneath the annulotomy to allow for placement of the contralateral implant. When the disc space is distracted by an instrument, insert the second implant using the same technique. Figure 8 shows the implant placement for a bilateral approach.

Figure 7

Figure 8

2.8 RADIOGRAPHIC VERIFICATION

⚠ **RADIOGRAPHIC VERIFICATION**

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

2.9 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.

2.10 REMOVAL (IF NECESSARY)

For removal of the implant, slide the jaws into the slots of the implant and fully tighten the locking knob of the inserter. Attach the slap hammer adapter and slap hammer to the end of the inserter.

Using the slap hammer, carefully back slap the implant from the disc space.

Catalog Number	Description	Width (mm)	Length (mm)	Height (mm)	Lordosis (°)	Quantity
77-TS-1022-08-0L	Fortilink-TS Ti 10x22x08-0L	10	22	8	0	1
77-TS-1022-09-0L	Fortilink-TS Ti 10x22x09-0L	10	22	9	0	1
77-TS-1022-10-0L	Fortilink-TS Ti 10x22x10-0L	10	22	10	0	1
77-TS-1022-11-0L	Fortilink-TS Ti 10x22x11-0L	10	22	11	0	1
77-TS-1022-12-0L	Fortilink-TS Ti 10x22x12-0L	10	22	12	0	1
77-TS-1022-13-0L	Fortilink-TS Ti 10x22x13-0L	10	22	13	0	1
77-TS-1022-14-0L	Fortilink-TS Ti 10x22x14-0L	10	22	14	0	1
77-TS-1022-15-0L	Fortilink-TS Ti 10x22x15-0L	10	22	15	0	1
77-TS-1022-16-0L	Fortilink-TS Ti 10x22x16-0L	10	22	16	0	1
77-TS-1022-08-6L	Fortilink-TS Ti 10x22x08-6L	10	22	8	6	1
77-TS-1022-09-6L	Fortilink-TS Ti 10x22x09-6L	10	22	9	6	1
77-TS-1022-10-6L	Fortilink-TS Ti 10x22x10-6L	10	22	10	6	1
77-TS-1022-11-6L	Fortilink-TS Ti 10x22x11-6L	10	22	11	6	1
77-TS-1022-12-6L	Fortilink-TS Ti 10x22x12-6L	10	22	12	6	1
77-TS-1022-13-6L	Fortilink-TS Ti 10x22x13-6L	10	22	13	6	1
77-TS-1022-14-6L	Fortilink-TS Ti 10x22x14-6L	10	22	14	6	1
77-TS-1022-15-6L	Fortilink-TS Ti 10x22x15-6L	10	22	15	6	1
77-TS-1022-16-6L	Fortilink-TS Ti 10x22x16-6L	10	22	16	6	1
77-TS-1026-08-0L	Fortilink-TS Ti 10x26x08-0L	10	26	8	0	1
77-TS-1026-09-0L	Fortilink-TS Ti 10x26x09-0L	10	26	9	0	1
77-TS-1026-10-0L	Fortilink-TS Ti 10x26x10-0L	10	26	10	0	1
77-TS-1026-11-0L	Fortilink-TS Ti 10x26x11-0L	10	26	11	0	1
77-TS-1026-12-0L	Fortilink-TS Ti 10x26x12-0L	10	26	12	0	1
77-TS-1026-13-0L	Fortilink-TS Ti 10x26x13-0L	10	26	13	0	1
77-TS-1026-14-0L	Fortilink-TS Ti 10x26x14-0L	10	26	14	0	1
77-TS-1026-15-0L	Fortilink-TS Ti 10x26x15-0L	10	26	15	0	1
77-TS-1026-16-0L	Fortilink-TS Ti 10x26x16-0L	10	26	16	0	1
77-TS-1026-08-6L	Fortilink-TS Ti 10x26x08-6L	10	26	8	6	1
77-TS-1026-09-6L	Fortilink-TS Ti 10x26x09-6L	10	26	9	6	1
77-TS-1026-10-6L	Fortilink-TS Ti 10x26x10-6L	10	26	10	6	1
77-TS-1026-11-6L	Fortilink-TS Ti 10x26x11-6L	10	26	11	6	1
77-TS-1026-12-6L	Fortilink-TS Ti 10x26x12-6L	10	26	12	6	1
77-TS-1026-13-6L	Fortilink-TS Ti 10x26x13-6L	10	26	13	6	1
77-TS-1026-14-6L	Fortilink-TS Ti 10x26x14-6L	10	26	14	6	1
77-TS-1026-15-6L	Fortilink-TS Ti 10x26x15-6L	10	26	15	6	1
77-TS-1026-16-6L	Fortilink-TS Ti 10x26x16-6L	10	26	16	6	1
77-TS-1032-10-0L	Fortilink-TS Ti 10x32x10-0L	10	32	10	0	1
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77-TS-1032-13-0L	Fortilink-TS Ti 10x32x13-0L	10	32	13	0	1
77-TS-1032-14-0L	Fortilink-TS Ti 10x32x14-0L	10	32	14	0	1
77-TS-1032-15-0L	Fortilink-TS Ti 10x32x15-0L	10	32	15	0	1
77-TS-1032-16-0L	Fortilink-TS Ti 10x32x16-0L	10	32	16	0	1

INSTRUMENT LIST FORTILINK-TS TI (PLIF)

Catalog Number	Description
65-TS-INSERTER	Fortilink-TS Inserter
65-TS-TAMP	Fortilink-TS Tamp, w/Tabs
38-SLAPADAPT	SLAP HAMMER, HUDSON, ADAPTER
38-THANDLE	T-HANDLE, HUDSON
38-SLAPHAMMER	SLAP HAMMER, HUDSON
65-TS-TRL22-8	Fortilink-TS Trial Spacer 22x8
65-TS-TRL22-8-6L	Fortilink-TS Trial Spacer 22x8 6L
65-TS-TRL22-9	Fortilink-TS Trial Spacer 22x9
65-TS-TRL22-9-6L	Fortilink-TS Trial Spacer 22x9 6L
65-TS-TRL22-10	Fortilink-TS Trial Spacer 22x10
65-TS-TRL22-10-6L	Fortilink-TS Trial Spacer 22x10 6L
65-TS-TRL22-11	Fortilink-TS Trial Spacer 22x11
65-TS-TRL22-11-6L	Fortilink-TS Trial Spacer 22x11 6L
65-TS-TRL22-12	Fortilink-TS Trial Spacer 22x12
65-TS-TRL22-12-6L	Fortilink-TS Trial Spacer 22x12 6L
65-TS-TRL22-13	Fortilink-TS Trial Spacer 22x13
65-TS-TRL22-13-6L	Fortilink-TS Trial Spacer 22x13 6L
65-TS-TRL22-14	Fortilink-TS Trial Spacer 22x14
65-TS-TRL22-14-6L	Fortilink-TS Trial Spacer 22x14 6L
65-TS-TRL22-15	Fortilink-TS Trial Spacer 22x15
65-TS-TRL22-15-6L	Fortilink-TS Trial Spacer 22x15 6L
65-TS-TRL22-16	Fortilink-TS Trial Spacer 22x16
65-TS-TRL22-16-6L	Fortilink-TS Trial Spacer 22x16 6L
65-TS-TRL26-8	Fortilink-TS Trial Spacer 26x8
65-TS-TRL26-8-6L	Fortilink-TS Trial Spacer 26x8 6L
65-TS-TRL26-9	Fortilink-TS Trial Spacer 26x9
65-TS-TRL26-9-6L	Fortilink-TS Trial Spacer 26x9 6L

Catalog Number	Description
65-TS-TRL26-10	Fortilink-TS Trial Spacer 26x10
65-TS-TRL26-10-6L	Fortilink-TS Trial Spacer 26x10 6L
65-TS-TRL26-11	Fortilink-TS Trial Spacer 26x11
65-TS-TRL26-11-6L	Fortilink-TS Trial Spacer 26x11 6L
65-TS-TRL26-12	Fortilink-TS Trial Spacer 26x12
65-TS-TRL26-12-6L	Fortilink-TS Trial Spacer 26x12 6L
65-TS-TRL26-13	Fortilink-TS Trial Spacer 26x13
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65-TS-TRL32-16	Fortilink-TS Trial Spacer 32x16
65-TS-TRL32-17	Fortilink-TS Trial Spacer 32x17

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

⚠ 5.1. 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 advise 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:

Pioneer Surgical Technology, Inc.
375 River Park Circle
Marquette, MI 49855 USA

Tel: +1 (906) 226-9909
Fax: +1 (906) 226-4455

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.

MAXIMIZE GRAFT AREA
Maximize graft area by packing bone graft lateral and anterior in the interspace prior to the initial implant placement.

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.

IMPLANT INSERTION
The implants should not be rotated during insertion. Attempting to rotate these implants during insertion may lead to implant failure.

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 artifacts should be reported.

DISPOSAL
The products must be disposed according to local regulations.

5.2. 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

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