

# Fortilink<sup>®</sup>-C

with TiPlus<sup>™</sup> Technology



**SURGICAL** TECHNIQUE



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# INTRODUCTION

## ➤ Device description

The Fortilink-C TiPlus implant (Figure 1) is an interbody fusion device intended for the cervical spine (C2-T1) in patients with degenerative disc diseases. The Fortilink-C TiPlus interbody fusion devices are manufactured with SLM (selective laser melting) and are built up from implant grade titanium alloy (Ti6Al4V). The Fortilink-C 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-C 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®-C with TiPlus™ Technology

## ➤ Intended purpose

The Fortilink-C TiPlus implant is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with cervical disc disease (defined as discogenic back pain with degeneration of the disc and/or myelopathy with herniated disc and/or osteophyte formation on posterior endplates confirmed by patient history and radiographic studies), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

This device is intended to be used with an FDA-cleared supplemental fixation system appropriate for use in the cervical spine. This device is intended to be used in patients who have had six weeks of non-operative treatment.

## ➤ Clinical benefits

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

- Decrease neck pain, as assessed using the Visual Analogue Scale (VAS)
- Clinical improvement, as assessed using the Japanese Orthopaedic Association (JOA) and Odom criteria
- 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

## ➤ 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

## ➤ 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

## ➤ Exposure of disc level

Access the operative site and retract the tissues using appropriate instrumentation. Retract the trachea, esophagus, and coronary artery in order to clearly see the vertebral bodies and discs.

## ➤ Level confirmation

### LEVEL CONFIRMATION

Insert a marker into the disc(s) and confirm the correct operative level(s) utilizing lateral radiograph.

## ➤ Discectomy and endplate preparation

Perform a complete discectomy using appropriate instrumentation. A ring curette and rasp are included in the instrument set for endplate preparation, see 'Ordering guide'. Remove the posterior longitudinal ligament to access and remove any disc material that is pressing on the spinal cord and/or nerve roots. Remove any osteophytes that are contacting the neural elements. Remove the cartilaginous endplates to achieve exposure to the subchondral bone.



### 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

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 with trial spacers

Trial spacers are available to provide guidance prior to implant selection. The height of the trial spacer is line-to-line compared to the height of the corresponding implant (Figure 2). For an overview of the available trial spacers, see 'Ordering guide'.



### 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, see 'Ordering Guide'.



Figure 2

## ➤ Implant insertion

Pack the implant with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Make sure to fill the entire graft cavity.

Select the appropriate Inserters Fork (see 'Ordering Guide') and attach to Inserter, Housing. While threading, ensure the tabs on the fork align with slots in the inserter housing (Figure 3). Slide the fork into the housing base and then thread the housing handle onto the threads of the fork.

Do not tighten completely to allow for implant attachment.

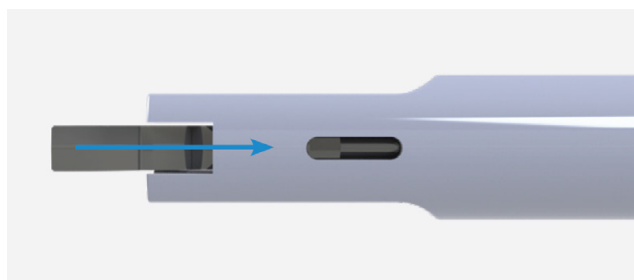


Figure 3

Attach the inserter to the implant by aligning the tabs of the inserter with the slots of the implant (Figure 4A). Tighten the inserter by turning the back of the inserter handle clockwise (Figure 4B).

Align the implant with the prepared disc space and gently tap the inserter until the implant is seated in the desired location. Confirm implant position with A/P and lateral radiographs.

### 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.

A tamp is provided if adjusting the implant position is desired. When using the tamp, ensure the posts on the tamp face align with the inserter slots on the implant.

## ➤ Radiographic verification

### RADIOGRAPHIC VERIFICATION

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

## ➤ Supplemental fixation

Use supplemental internal fixation system appropriate for use in the cervical spine.



### 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.

## ➤ Removal (if necessary)

If removal of the implant is necessary, a Caspar style retractor (or similar device) should be used to distract the disc space.

Once the disc space is distracted, attach the appropriately sized inserter to the implant by placing the forks of the inserter into the slots of the implant. Tighten the inserter by turning the handle clockwise until snug.

Remove the implant from the disc space.



Figure 4A



Figure 4B

## ORDERING GUIDE

### ➤ INSTRUMENT SET - 6 DEGREE (67-LS-CTI-INS-6L)

Product number	Product name	Quantity
65-C-INS-TIPLUS	Insertor Housing	2
65-C-FORK-LG	Insertor Fork Large	1
65-C-FORK-SM	Insertor Fork Small	1
30-C-RASP	Rasp	1
30-C-RCURETTE	Ring Curette	1
65-C-TAMP-LG	Tamp Large	1
65-C-TAMP-SM	Tamp Small	1
30-C-TRL1012-5	Trial Spacer, 10 x 12 x 5mm - 6L	1
30-C-TRL1012-6	Trial Spacer, 10 x 12 x 6mm - 6L	1
30-C-TRL1012-7	Trial Spacer, 10 x 12 x 7mm - 6L	1
30-C-TRL1012-8	Trial Spacer, 10 x 12 x 8mm - 6L	1
30-C-TRL1012-9	Trial Spacer, 10 x 12 x 9mm - 6L	1
30-C-TRL1012-10	Trial Spacer, 10 x 12 x 10mm - 6L	1
30-C-TRL1214-8	Trial Spacer, 12 x 14 x 8mm - 6L	1
30-C-TRL1214-9	Trial Spacer, 12 x 14 x 9mm - 6L	1
30-C-TRL1214-10	Trial Spacer, 12 x 14 x 10mm - 6L	1
30-C-TRL1214-11	Trial Spacer, 12 x 14 x 11mm - 6L	1
30-C-TRL1517-5	14.5 x 17 x 5mm - 6L Trial Spacer, VBR	1
30-C-TRL1517-6	14.5 x 17 x 6mm - 6L Trial Spacer, VBR	1
30-C-TRL1517-7	14.5 x 17 x 7mm - 6L Trial Spacer, VBR	1
30-C-TRL1517-8	14.5 x 17 x 8mm - 6L Trial Spacer, VBR	1
30-C-TRL1517-9	14.5 x 17 x 9mm - 6L Trial Spacer, VBR	1
30-C-TRL1517-10	14.5 x 17 x 10mm - 6L Trial Spacer, VBR	1
30-C-TRL1517-11	14.5 x 17 x 11mm - 6L Trial Spacer, VBR	1



➤ IMPLANT SET - 6 DEGREE (67-LS-CTI-IMP-6L)

Product number	Product name	Width (mm)	Depth (mm)	Height (mm)	Lordosis (°)	Quantity
67-C-1210-05-6L	Fortilink-C Ti 12x10x05-6L	12	10	5	6	2
67-C-1210-06-6L	Fortilink-C Ti 12x10x06-6L	12	10	6	6	2
67-C-1210-07-6L	Fortilink-C Ti 12x10x07-6L	12	10	7	6	2
67-C-1210-08-6L	Fortilink-C Ti 12x10x08-6L	12	10	8	6	2
67-C-1210-09-6L	Fortilink-C Ti 12x10x09-6L	12	10	9	6	2
67-C-1210-10-6L	Fortilink-C Ti 12x10x10-6L	12	10	10	6	2
67-C-1210-11-6L	Fortilink-C Ti 12x10x11-6L	12	10	11	6	2
67-C-1412-05-6L	Fortilink-C Ti 14x12x05-6L	14	12	5	6	2
67-C-1412-06-6L	Fortilink-C Ti 14x12x06-6L	14	12	6	6	2
67-C-1412-07-6L	Fortilink-C Ti 14x12x07-6L	14	12	7	6	2
67-C-1412-08-6L	Fortilink-C Ti 14x12x08-6L	14	12	8	6	2
67-C-1412-09-6L	Fortilink-C Ti 14x12x09-6L	14	12	9	6	2
67-C-1412-10-6L	Fortilink-C Ti 14x12x10-6L	14	12	10	6	2
67-C-1412-11-6L	Fortilink-C Ti 14x12x11-6L	14	12	11	6	2
67-C-1715-05-6L	Fortilink-C Ti 17x15x05-6L	17	15	5	6	2
67-C-1715-06-6L	Fortilink-C Ti 17x15x06-6L	17	15	6	6	2
67-C-1715-07-6L	Fortilink-C Ti 17x15x07-6L	17	15	7	6	2
67-C-1715-08-6L	Fortilink-C Ti 17x15x08-6L	17	15	8	6	2
67-C-1715-09-6L	Fortilink-C Ti 17x15x09-6L	17	15	9	6	2
67-C-1715-10-6L	Fortilink-C Ti 17x15x10-6L	17	15	10	6	2
67-C-1715-11-6L	Fortilink-C Ti 17x15x11-6L	17	15	11	6	2

➤ INSTRUMENT SET - 10 DEGREE (65-LS-CTI-INS-10L)

Product number	Product name	Quantity
65-C-INS-TIPLUS	Insertor Housing	2
65-C-FORK-LG	Insertor Fork Large	1
65-C-FORK-SM	Insertor Fork Small	1
65-C-TAMP-LG	Tamp Large	1
65-C-TAMP-SM	Tamp Small	1
30-C-RASP	Rasp	1
30-C-RCURETTE	Ring Curette	1
65-C-TRL-S-6-10L	Trial Spacer, 10 x 12 x 6mm - 10L	1
65-C-TRL-S-7-10L	Trial Spacer, 10 x 12 x 7mm - 10L	1
65-C-TRL-S-8-10L	Trial Spacer, 10 x 12 x 8mm - 10L	1
65-C-TRL-S-9-10L	Trial Spacer, 10 x 12 x 9mm - 10L	1
65-C-TRL-S-10-10L	Trial Spacer, 10 x 12 x 10mm - 10L	1
65-C-TRL-S-11-10L	Trial Spacer, 10 x 12 x 11mm - 10L	1
65-C-TRL-M-6-10L	Trial Spacer, 12 x 14 x 6mm - 10L	1
65-C-TRL-M-7-10L	Trial Spacer, 12 x 14 x 7mm - 10L	1
65-C-TRL-M-8-10L	Trial Spacer, 12 x 14 x 8mm - 10L	1
65-C-TRL-M-9-10L	Trial Spacer, 12 x 14 x 9mm - 10L	1
65-C-TRL-M-10-10L	Trial Spacer, 12 x 14 x 10mm - 10L	1
65-C-TRL-M-11-10L	Trial Spacer, 12 x 14 x 11mm - 10L	1
65-C-TRL-L-6-10L	Trial Spacer, 14.5 x 17 x 6mm - 10L	1
65-C-TRL-L-7-10L	Trial Spacer, 14.5 x 17 x 7mm - 10L	1
65-C-TRL-L-8-10L	Trial Spacer, 14.5 x 17 x 8mm - 10L	1
65-C-TRL-L-9-10L	Trial Spacer, 14.5 x 17 x 9mm - 10L	1
65-C-TRL-L-10-10L	Trial Spacer, 14.5 x 17 x 10mm - 10L	1
65-C-TRL-L-11-10L	Trial Spacer, 14.5 x 17 x 11mm - 10L	1

➤ IMPLANT SET - 10 DEGREE (67-LS-CTI-IMP-10L)

Product number	Product name	Width (mm)	Depth (mm)	Height (mm)	Lordosis (°)	Quantity
67-C-1210-06-10L	Fortilink-C Ti 12x10x06-10L	12	10	6	10	2
67-C-1210-07-10L	Fortilink-C Ti 12x10x07-10L	12	10	7	10	2
67-C-1210-08-10L	Fortilink-C Ti 12x10x08-10L	12	10	8	10	2
67-C-1210-09-10L	Fortilink-C Ti 12x10x09-10L	12	10	9	10	2
67-C-1210-10-10L	Fortilink-C Ti 12x10x10-10L	12	10	5	10	2
67-C-1210-11-10L	Fortilink-C Ti 12x10x11-10L	12	10	11	10	2
67-C-1412-06-10L	Fortilink-C Ti 14x12x06-10L	14	12	6	10	2
67-C-1412-07-10L	Fortilink-C Ti 14x12x07-10L	14	12	7	10	2
67-C-1412-08-10L	Fortilink-C Ti 14x12x08-10L	14	12	8	10	2
67-C-1412-09-10L	Fortilink-C Ti 14x12x09-10L	14	12	9	10	2
67-C-1412-10-10L	Fortilink-C Ti 14x12x10-10L	14	12	10	10	2
67-C-1412-11-10L	Fortilink-C Ti 14x12x11-10L	14	12	11	10	2
67-C-1715-06-10L	Fortilink-C Ti 17x15x06-10L	17	15	6	10	2
67-C-1715-07-10L	Fortilink-C Ti 17x15x07-10L	17	15	7	10	2
67-C-1715-08-10L	Fortilink-C Ti 17x15x08-10L	17	15	8	10	2
67-C-1715-09-10L	Fortilink-C Ti 17x15x09-10L	17	15	9	10	2
67-C-1715-10-10L	Fortilink-C Ti 17x15x10-10L	17	15	10	10	2
67-C-1715-11-10L	Fortilink-C Ti 17x15x11-10L	17	15	11	10	2

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.

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### 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.

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### 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.

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### 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.

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### 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.

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### EXPLANTATION

After implantation of an interbody fusion device and identification of the presence of fusion, only the supplemental fixation components should be removed.

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### 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.

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### 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.

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### 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.

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### 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.

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### 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.

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### 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
- Infection
- Allergic reaction
- Pulmonary embolism
- Pneumonia
- Adjacent segment disease
- Dysphagia
- Esophageal perforation
- Horner's syndrome
- Heterotrophic ossification
- Bone erosion
- Epidural scarring

## NOTES





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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.

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STG-000030 Rev A