Patient Leaflet

Fortilink®TiPlus IBF

Device Description

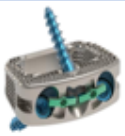
The Fortilink TiPlus cages are interbody fusion devices (or spacers) intended for patients with degenerative disc diseases. The Fortilink® Interbody Fusion (IBF) devices are designed to be inserted between the vertebrae, or bones, of a person's spine and are intended to be used when your doctor wants to fuse, or join, two adjacent vertebra to help reduce your symptoms.
The screws in Fortilink®-SC and Fortilink®-SA provide primary stability to facilitate fusion and supplemental fixation is therefore not required. The retainer locks the screws.

Implant Material

The Fortilink TiPlus interbody fusion devices are manufactured with SLM (selective laser melting) and are built from a titanium alloy (Ti6Al4V ELI (ASTM F3001)). Both the screws and the retainer are made from titanium alloy.

The following tables show the complete list of the Fortilink® with TiPlus Technology interbody fusion devices:

Cervical procedures	
Fortilink®-C with TiPlus Technology	
Fortilink®-SC with TiPlus Technology	

Lumbar procedures	
Fortilink®-TS with TiPlus Technology	
Fortilink®-TC with TiPlus Technology	
Fortilink®-L with TiPlus Technology	
Fortilink®-A with TiPlus Technology	
Fortilink®-SA with TiPlus Technology	

The Fortilink TiPlus cages have an open mesh structure and a bone window both designed to allow bone ingrowth which improves the fusion between the bones in your spine. The box-shaped design is intended to provide primary stability and increase the intervertebral height and lordosis. This facilitates the correct space between your bones and improves the angle of your spine.

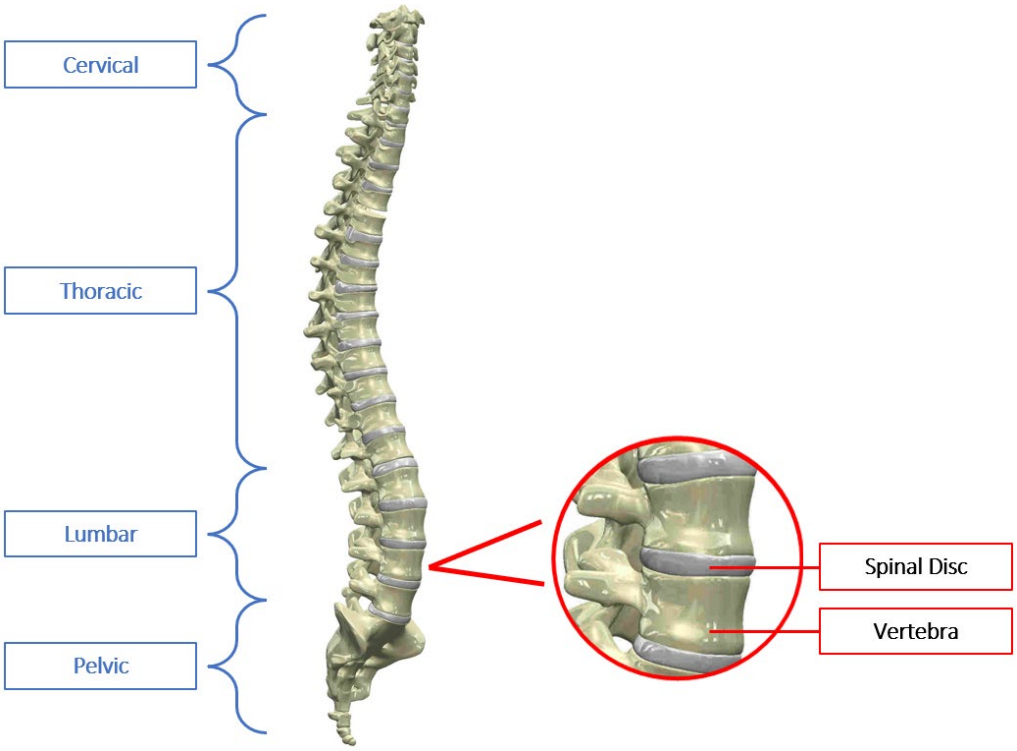
Supplemental Fixation

These devices are designed to withstand the full load of your spine until bone fusion can occur. To make sure this happens correctly, your doctor may need to initially use plate/screws or screws/rods in order to hold the device in place.

Intended Purpose

In a normal spine, intervertebral discs between the bones in your spine act as a cushion between bones. Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and breakdown of these discs. The function of the Fortilink TiPlus cages is to stabilize the segment and to improve overall alignment of your spine. Increasing disc height also provides more room for the nerves. The central chamber and surrounding area are

packed with bone graft material to help promote bone growth (fusion) between adjacent vertebrae.



Degenerative Disc Disease (DDD)

Over time, the discs can lose flexibility, elasticity, and height. When this happens, the discs' shock absorbing characteristics are reduced and can lead to abnormal motion or alignment and instability of the spine.

Herniated Disc

Degeneration can cause cracks and tears in the outer layer of the intervertebral disc, through which material inside the disc can be forced out, causing the disc to bulge (protrusion), break open (extrusion), or break into pieces (sequestration), putting pressure on a nerve root or the spinal cord.

Spinal Stenosis

This is the narrowing of areas in the spine where nerve roots and the spinal cord must travel. This can be caused by herniated discs, osteophytes (bony projections), or ligaments compressing the spinal cord.
Symptoms of these conditions can include:

- loss of motion
- tingling or numbness in the extremities
- radiating pain, weakness and/or numbness in the extremities

These symptoms may be treated with non-surgical methods for as long as possible.

However, if surgery is required, your doctor may select the Fortilink® Interbody Fusion (IBF) devices. This device was designed to stabilize that segment of spine causing these problems and to improve the alignment of the spine which will increase the disc height between the bones in the spine and provide more room for the nerves.

Intended patient groups

ARE YOU A CANDIDATE FOR THE PROCEDURE?

- You must be skeletally mature.
- You must have moderate to severe spinal stenosis in your lower back. One sign of having moderate to severe spinal stenosis is it is hard to walk a long way. Another sign is having pain in your lower back while standing that goes away when you bend forward.
- You must have been treated by a doctor with "non-surgical treatments" for at least 6 weeks in the cervical area and 6 months if the lumbar region is affected. "Non-surgical treatments" are treatments like those described below.

WHAT ARE YOUR TREATMENT OPTIONS?

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

Before you become a candidate for Fortilink®TiPlus you must have been treated with non-surgical treatments such as:

- Injections from your doctor with a drug (steroids) to lower swelling and treat pain in your hips or down the leg. Pain relief from this may not last long. You should not have more than three injections in a six month time.
- Rest
- Ice or heat
- Weight Control
- Physical therapy and exercise
- Pain management and medication

If these non-surgical treatments do not bring relief after a period of time, surgical treatments may be recommended to take pressure off the nerves that are causing pain by restoring alignment of the spine and/or the space between the vertebrae.

There are a variety of surgical approaches to treating spinal conditions. The choice of which approach to use is dependent on many factors which include patient symptoms, the affected level, patient anatomy, prior surgery, and/or surgeon preference. The surgeon must explain the chosen surgical approach to the patient.

WHO SHOULD NOT RECEIVE Fortilink®TiPlus

- You have a medical condition which precludes the potential benefit of spinal surgery determined by your doctor.
- You have any infection including acute or chronic systemic, spinal or localized infections. Tell your doctor if you have any infection. Patients with infections are at risk of a deep infection. They would need another surgery to remove the implant.
- You are allergic to titanium or titanium alloy. Patients who are allergic might have to have additional surgery to remove the implant. Tell your doctor if you think you ever had a reaction to a metal or an implant in general.
- You have bone fractures, severe deformities or severe instability in the area of surgery, or reduced bone density (severe osteoporosis). These conditions may lead to more bone fractures in your back. Tell your doctor if you have ever had a broken bone or have problems with bone density.
- You have primary or metastatic tumors affecting your spine.
- You have a condition that may place excessive stress on bone and implants, including but not limited to severe obesity, or other degenerative diseases.
- You are unwilling or unable to comply with the required pre- and post-operative safety measures, restrictions, and precautions that are mandatory with the procedure. This includes the rehabilitation program prescribed by your doctor
- You are pregnant. Surgery during pregnancy can lead to an increased risk for you and your child.
- You have Spondylolisthesis. Spondylolisthesis is where one of the bones in your spine, known as a vertebra, slips out of position. It's most

common in the lower back, but it can also happen in the mid to upper back or at the top of the spine at the back of your neck.

Precautions

Preoperative

Ask your doctor or surgeon for detailed information about the procedure. Ask all the questions that are necessary to ensure that you are fully aware of the procedure.

Postoperative

Your surgeon will provide you with clear directions and warnings. He will verify that you are fully familiar with post-operative compliance.

- Do not do any strenuous physical activity after your surgery. Examples of strenuous physical include lifting more than 10 pounds. Partial- or non-weight bearing may be recommended or required to achieve firm bony union.
- If appropriate, restrict mobility to allow bony union. Don't do sports until your doctor tells you that you can. Your implant may move or break part of your spine if you are too active too soon after surgery. This could cause pain. You could need more surgery. Each patient is different. Ask your doctor what it is OK to do after surgery.
- Tell your doctor after surgery if you have fluid leaking from your wound, redness around your wound, or separated edges at the site of the wound. These problems can lead to serious infection and require more surgery if your doctor does not treat them. You may need to ask another person to look at your wound to see if it is leaking.
- Tell your doctor as soon as possible after your surgery if you have pain or swelling in your back or if you feel numbness in your legs or buttocks. These symptoms can be a sign that the implant is not working properly. You may need more surgery. Consult your doctor in the event of malfunction of the device or changes in its performance that may affect safety.
- If you fall, tell your doctor. A fall may hurt you seriously.
- Do not smoke, consume alcohol, and/or take steroids, non-steroidal anti-inflammatory agents and aspirin or other drugs not prescribed by your doctor.

- If non-union (no fusion) occurs, the doctor may revise or remove the system.

Warnings

The same medical/surgical conditions or complications that apply to any surgical procedure may also occur during or following implantation of this device system. Your doctor is responsible for informing you of the potential risks associated with treatment, including complications and adverse reactions.

Your doctor may need to perform additional surgery to address any complications or adverse reactions, which may or may not be device related.

Contact your doctor if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your doctor if needed.
Following your doctors' instructions, including any instructions provided by rehabilitation experts, can be immensely important to improving long-term outcomes. Although every patient and surgery is different, patients who fail to follow proven recommendations post-surgery may not experience the same recovery as those who did. This can include improvements in function. By following your doctor's instructions and reporting back during follow ups, you can provide your doctor with insight into what is and is not working. Based on your feedback, doctors can tailor your treatment plans, adjust medications, or explore other options and treatment alternatives.

WHAT PROBLEMS MAY HAPPEN FROM SPINAL SURGERY? (RISKS)

There are risks with spinal implant surgery. A risk is a bad or harmful (adverse) thing together with how often it happens.
Potential risks identified with the use of this intervertebral body fusion device which may require additional surgery include:

- Implant component fracture
    - Implant may become loose, change shape permanently (deform), fail, break, wear out, or move.
- Pulmonary embolism
    - Pulmonary embolism is a blockage in one of the pulmonary arteries in your lungs. In most cases, pulmonary embolism is caused by blood clots that travel to the lungs from deep veins in the legs or, rarely, from veins in other parts of the body

- Migration, dislocation, or subsidence of the implant
    - Cage subsidence was defined as the sum subsidence of the superior and inferior part of the cage into the vertebral body.
    - The implant may become loose and move
- Pneumonia
    - Pneumonia is an infection that inflames the air sacs in one or both lungs.
- Loss of fixation
    - Implant may become loose
- Adjacent segment disease
    - Adjacent segment disease (ASD) is a condition that sometimes occurs after a spinal fusion surgery to join or "lock" two or more bones together, stopping the natural motion at that level. Degenerative changes develop on the discs and joints above or below the level where a previous surgery was performed.
- Pseudoarthrosis (i.e., non-union)
    - Pseudarthrosis is the result of failed attempted spinal fusion. The term suggests the presence of a false joint, although it is commonly used to describe a lack of fusion that occurs after an attempted arthrodesis.
- Dysphagia (difficulty in swallowing)
    - Some people with dysphagia have problems swallowing certain foods or liquids, while others cannot swallow at all. Other signs of dysphagia include coughing or choking when eating or drinking. bringing food back up, sometimes through the nose.
- Fracture of the vertebra
    - Fracture of the vertebra, fracture of the part of your spine that you can feel through the skin on your back (spinous process), or other damage to bony structures during or after surgery.
- Esophageal perforation
    - An esophageal perforation is a hole in the esophagus. The esophagus is the tube that passes through food as it goes from the mouth to the stomach.
- Neurological injury
    - An injury to the brain, spine, or nerves.
- Horner’s syndrome

    - Horner syndrome is a combination of signs and symptoms caused by the disruption of a nerve pathway from the brain to the face and eye on one side of the body.
    - Typically, Horner syndrome results in a decreased pupil size, a drooping eyelid and decreased sweating on the affected side of your face.
- Cardiovascular complications
    - A class of diseases that involve the heart or blood vessels.
- Heterotrophic ossification
    - Heterotopic ossification (HO) is the presence of bone in soft tissue where bone normally does not exist.
- Infection
    - The invasion and growth of germs in the body. The germs may be bacteria, viruses, yeast, fungi, or other microorganisms. Infections can begin anywhere in the body and may spread all through it. An infection can cause fever and other health problems, depending on where it occurs in the body.
- Bone erosion
    - Bone erosions are bony defects developing because of excessive local bone resorption and inadequate bone formation
- Allergic reaction
    - Bad reaction to implant materials (possible allergic reaction) or there may be some wearing of the implant material against bone or another part of the implant that creates very small particles, it is possible that these particles may eventually cause the local tissues such as bone, nerves, and nearby soft tissue to respond badly.
- Epidural scarring
    - The excessive production of scar tissue near the root of a nerve. Most commonly it can occur following spinal surgery. Epidural fibrosis develops as scar tissue adheres to the nerve root during the months after surgery. Epidural fibrosis can occur in successful and failed back surgeries.

Instrument fragments

If instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the doctor'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 doctor advise the patient of

specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.

Intended lifetime

The device is intended for permanent implantation, however adverse events might warrant removal of the implant. The functional lifetime (up to spine fusion) which is normally taken to be one year.

SAFETY INFORMATION

Magnetic Resonance IMAGING (MRI) Safety

If you need an MRI scan, tell your doctor that you have a spinal implant. This is very important to allow your doctor to follow the implant-specific directions given in the Instructions for Use of your implant.

What can you do if your implant causes side effects?

Any serious incident that occurs in relation to the device should be reported to your doctor and also to the manufacturer and to the Therapeutic Goods Administration via their webpage

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