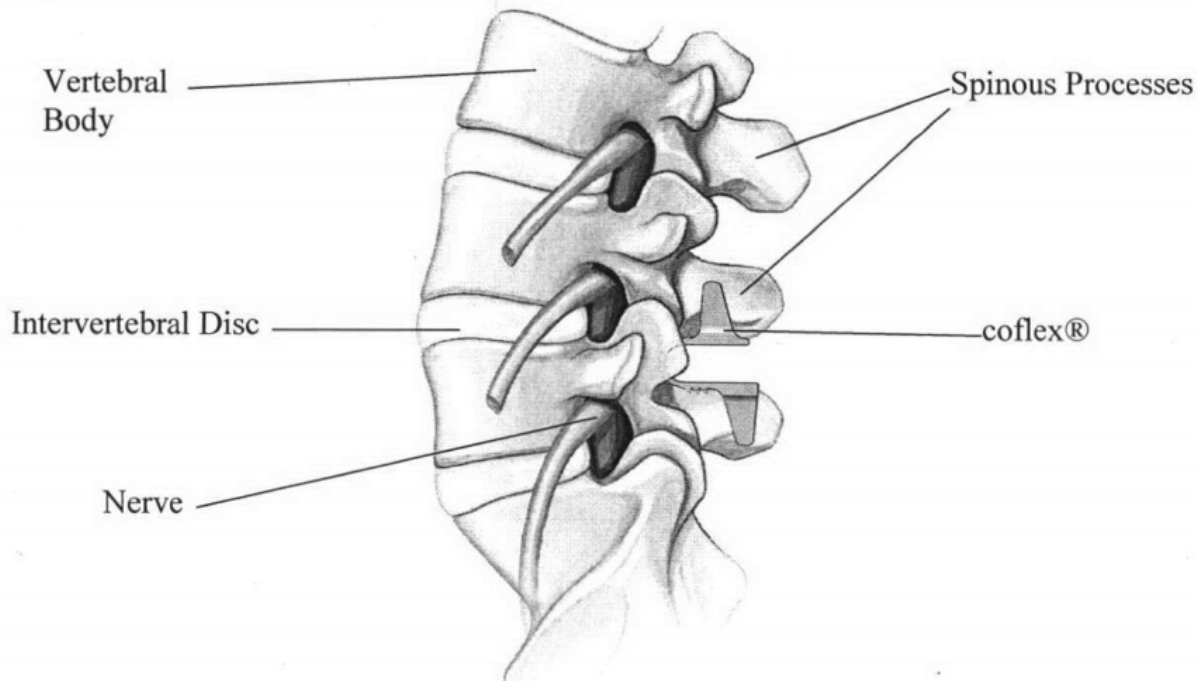
Patient Leaflet

coflex™ Interlaminar Implant

Device Description

The coflex™ is a titanium alloy implant that fits between the spinous processes of the bones in your lower back (please see Figure 2 below). The coflex™ device can help relieve your back pain symptoms by stabilizing the movement of your spine. This may help reduce the pain in your back, groin or legs. The coflex™ can stay in place by clamping onto bones in your spine. Titanium alloy is often used in bone repair in the body.

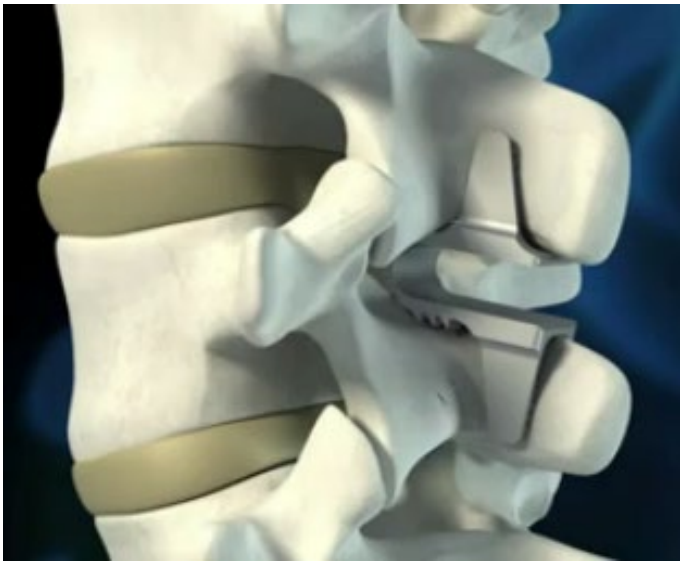


Contact Material Information

These implants are manufactured from a biocompatible titanium alloy (Wrought titanium-6aluminum-4vanadium ELI alloy according to ISO 5832-3 and ASTM F136). This material has been used for decades in implants and shows an excellent biological compatibility.

Intended Purpose

The coflex implant is intended for permanent implantation between the spinous processes of 1 or 2 lumbar motion segments and controls segmental motion in cases of lumbar stenosis or mild degenerative instability. The coflex implant may also be used in up to 2 lumbar motion segments adjacent to fused level(s).



WHAT IS DEGENERATIVE INSTABILITY?

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.

WHAT IS SPINAL STENOSIS?

Spinal stenosis is a narrowing of the spinal canal. Thickening of tissue that connects two bones (ligaments), bulging of discs, or overgrowth of bone can cause it. The spinal cord and nerve fibers that exit the spinal canal (nerve roots) can become crowded and pinched. This may lead to pain, numbness, tingling, and/or weakness in the back and legs. This pain is especially noted when you walk.

Intended Patient Groups

ARE YOU A CANDIDATE FOR THE coflex™ Interlaminar Implant 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 months. "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 the coflex™ Interlaminar Implant 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 treat 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 coflex™ Interlaminar Implant?

- 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 for a deep infection if they have coflex™ implanted. They would need another surgery to remove it.
- You have a systemic and metabolic disease determined by your doctor. Patients with metabolic and systemic disease are at higher risk during and after surgical procedures.
- You are morbidly obese. This means that you have a body mass index (BMI) above 40, as determined by your doctor. Obesity may lead to more complications during and following surgery.
- You are pregnant. Surgery during pregnancy can lead to an increased risk for you and your child.
- You are dependent on pharmaceuticals, drugs or alcohol. Dependence on the above sub-stances can lead to an interference with medications that are necessary as part of the procedure. In addition, this may make it difficult or even impossible to participate in rehabilitation programs.
- You are unwilling to comply with the required pre- and post-operative safety measures that are mandatory with the procedure. This includes the rehabilitation program prescribed by your doctor.
- You are allergic to titanium or titanium alloy. Patients who are allergic might have to have more surgery to remove the coflex™. Tell your doctor if you think you ever had a reaction to a metal or an implant. You may not know if you are allergic to coflex™.
- You have spinal anatomy or instability that would not allow use of coflex™. Examples of this are scoliosis greater than 25 degrees or a severe slipped disc. The coflex™ may not function properly and you may need additional surgery to relieve your pain. Tell your doctor if you have ever had a problem with your back.
- You have bone fractures or reduced bone density (Significant osteopenia). 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.

Precautions

WHAT SHOULD YOU DO BEFORE THE SURGERY?
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.

WHAT SHOULD YOU DO AFTER THE SURGERY?
Follow all of your doctor's instructions after your surgery. This will help you recover better. Each patient is different. Your doctor will know what's best for you. If you don't do what your doctor says after surgery it may delay your recovery and cause you more pain. If a doctor sends you to have an MRI exam, tell him or her you have a coflex™ device. This is important because there are special instructions for use of an MRI on someone with a coflex™ device.

- 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.
- Each patient is different. Ask your doctor what it is OK to do after surgery.
- If appropriate, restrict mobility to allow bony union. Don't do sports until your doctor tells you that you can. Sports include swimming, golf, tennis, racquetball, running, and jogging. 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 surgeon 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 surgeon may revise or remove the system.

WHAT PROBLEMS MAY HAPPEN FROM SPINAL SURGERY? (RISKS)

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture of implant, loss of fixation, dislocation and/or migration
    - Your implant may become loose, change shape permanently (deform), fail, break, wear out, or move.
- Pain and/or abnormal sensations due to the presence of the implant
    - Pain and discomfort resulting from the cutting and healing of tissues, presence of implants, or reaction to the metal used in the implant.
- Primary and/or secondary infections
    - 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.
- Allergic reactions to implant material
    - 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.
- Neurological injury
    - An injury to the brain, spine, or nerves.
- Vertebrae fracture
    - 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.
- Injury to vessels, nerves and organs
- Hematoma and/or impaired wound healing; hemorrhage

    - A hematoma is a collection of blood outside of a blood vessel, depending on their location hematomas can cause e.g., headache or back pain
    - In the case of a wound healing disorder, the healing process of a wound is delayed, and it can become infected.
- Venous thrombosis, lung embolism, and cardiac arrest
    - In thrombosis, a blood clot (thrombus) forms in a blood vessel. If the thrombus forms in a vein, it is called venous thrombosis. A venous thrombus can break loose and travel through the bloodstream to the lungs. If it clogs a blood vessel there, this leads to a lung embolism.
- Death
    - With any surgery, there is the risk of complications. When surgery is done near the spine and spinal cord, these complications (if they occur) can be very serious.

Contact your healthcare professional 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 re-place a consultation with your healthcare professional 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.

Intended Lifetime

The coflex™ Interlaminar Implant provides dynamic stability to a degenerated and destabilized segment. The lifetime of the device is 5 years.

SAFETY INFORMATION

Magnetic Resonance IMAGING (MRI) Safety

If you need an MRI scan, tell the healthcare professional 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.

Magnetic Resonance IMAGING (MRI) instructions for health care professionals:

Non-clinical testing and electromagnetic simulations demonstrated that the devices are MR Conditional.
A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T)
- Spatial gradient field of up to:
    - 11,230 G/cm (112.3 T/m) for 1.5T systems
    - 5,610 G/cm (56.1 T/m) for 3.0T systems.
- Maximum whole body averaged specific absorption rate (SAR) of:
    - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T
    - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

Artifact Information

In testing using a 3.0T system with spin-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 19 mm from the 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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