



Patient Leaflet

Streamline[®] TL/MIS Fenestrated Spinal Fixation System

This patient leaflet refers to the Streamline® TL/MIS Fenestrated Spinal Fixation System with the following components as illustrated in the tables below:

Streamline® TL/MIS fenestrated screw	
Streamline® TL/MIS non fenestrated screw	

Device Description

The modular Streamline® TL/MIS Fenestrated Spinal Fixation System is used for the stabilization/fixation of two or more vertebral bodies of the thoracolumbar spine from the back. The fixation can be done with polyaxial fenestrated pedicle screws. Polyaxial screws has a mobile screw head. The screw shank has small openings (holes) at the tip. Through this openings bone cement can flow out of the shank to fix the screw in the vertebral body.

Contact Material Information

The 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. The used material contains no nickel and is not made with natural rubber latex.

Intended Purpose

The Streamline® TL/MIS Fenestrated Spinal Fixation System is intended for long-term implantation. The pedicle screws are placed in the pedicles and connected with a rod, from head-to-toe direction.

The Streamline® TL/MIS Fenestrated Spinal Fixation System for rigid stabilization of the thoracolumbar spine as an adjunct to fusion is intended for spinal stenosis, spondylolisthesis, degenerative disc disease (DDD), trauma (i.e., fractures or dislocation), curvatures (i.e., kyphosis, and/or lordosis), tumor, pseudarthrosis and failed previous fusion.

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.

Spondylolisthesis

Spondylolisthesis is the sliding of vertebrae (vertebral bodies), that means two vertebrae are offset against each other. The degree of displacement is divided into 5 degrees according to Meyerding. Grade 1 is a displacement of the vertebral bodies in relation to each other by less than 25% of the vertebral body depth. Degenerative spondylolisthesis is a spondylolisthesis caused by wear and tear in adults

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.

Trauma

Trauma is external injury or damage to the body, which can result in bone fractures and soft tissue changes.

Curvatures

The spine is not completely straight, it is curved backwards at the rib cage. The sacrum is also bent backward somewhat (kyphosis). The lumbar spine and the cervical spine are curved forward (lordosis). If these curvatures are more pronounced than normal, it is called hyperlordosis or kyphosis, and can cause pain and movement restrictions.

Tumor

A tumor is a tissue growth that can cause narrowing of the spinal canal in the spine. The spinal cord and the nerve fibers that exit the spinal canal (nerve roots) can become narrowed and pinched.

Pseudarthrosis

In pseudarthrosis, a bone does not heal together properly after a fracture. The bone ends can move more in a pseudarthrosis. This is also referred to as a false joint.

Failed Previous Fusion

After spine surgery, a percentage of patients may still experience pain. This is called failed back or failed fusion syndrome, which is characterized by intractable pain and an inability to return to normal activities. Surgery may be able to fix the condition but not eliminate the pain.

Intended patient groups

ARE YOU A CANDIDATE FOR THE PROCEDURE?

- You must be skeletally mature.
- One or more of the reasons listed above under Intended Use, with their implications, should apply to you
- You must have been unsuccessfully treated by a doctor with "non-surgical treatments".
- "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 consider your individual situation.

Before you become a candidate for the Streamline® TL/MIS Fenestrated Spinal Fixation System 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, 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 Streamline® TL/MIS Fenestrated Spinal Fixation System?

- You have a medical condition which precludes the potential benefit of spinal surgery determined by your doctor.
- You are pregnant. Surgery during pregnancy can lead to an increased risk for you and your child.
- 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 dependent on pharmaceuticals, drugs or alcohol. Dependence on the above substances 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 have spinal anatomy or instability that would not allow use of Streamline® TL/MIS Fenestrated Spinal Fixation System. Examples of this are Bone tumors in the proximity of the implant fixation or a severe slipped disc. Streamline® TL/MIS Fenestrated Spinal Fixation System 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, 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 are morbidly obese. This means that you have a body mass index (BMI) above 30, as determined by your doctor. Obesity may lead to more complications during and following surgery.
- 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 the Streamline® TL/MIS Fenestrated Spinal Fixation System implanted. They would need another surgery to remove it.
- You are allergic to titanium or titanium alloy. Patients who are allergic might have to have more surgery to remove the Streamline® TL/MIS Fenestrated System. 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 the Streamline® TL/MIS Fenestrated System.

In combination with use of bone cement:

- You have severe heart and/or lung failure.
- You have sensitiveness to elements of the bone cement.
- You have a thrombophilia. Patients with thrombophilia the blood clots (thromboses) more easily than in people without this clotting disorder. Tell your doctor if you think you have ever had a problem with blood clotting.

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 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.

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 surgeon is responsible for informing you of the potential risks associated with treatment, including complications and adverse reactions.

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

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 replace 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.

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.
- Migration, dislocation, or loss of fixation of the implant
 - The implant may become loose and move.
- Pain and/or abnormal sensations due to the presence of the implant.
- 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.
- 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.
- Neurological injury

- An injury to the brain, spine, or nerves.
- 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.
- Injury to vessels, nerves, the spinal cord, and organs
- Hematoma and/or impaired wound healing
 - 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.
- Change to the spinal curvature
- Impairment of the gastrointestinal, urological and/or reproductive system
 - An impairment of the stomach, intestine, kidney, urethra and or the sexual organs.
- Pain or malaise
- Bursitis
 - The inflammation of a bursa
- Decrease of bone density due to avoiding load
 - Which can lead to vertebral fractures
- Persistence of the symptoms to be treated with the implantation
- Death, sudden death
- Cardiac embolism
 - Cardiac embolism is an obstruction that travels from the heart to lodge in a blood vessel. An embolus can be made up of fatty material, or it can be a blood clot. Many factors can contribute to the formation of blood clots.
- Short term conduction disorder

- A conduction disorder is a problem with the electrical system that makes your heart beat and controls its rate and rhythm. This system is called the cardiac conduction system.
- Fat embolism
 - A piece of fat lodges within a blood vessel and causes a blockage of blood flow.
- Decrease in blood pressure
- Myocardial infarction
 - A type of a heart attack
- Anaphylactic shock
 - An acute potentially life-threatening allergic reaction.
- Tissue damage, nerve damage or circulatory problems by cement leakage

Intended Lifetime

The device is intended for long-term implantation, however adverse events might warrant removal of the implant. The functional lifetime for the rigid stabilization (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 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:

The Streamline® TL/MIS Fenestrated implants 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 the Streamline® TL/MIS Fenestrated implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 to the manufacturer and to the Therapeutic Goods Administration via their webpage

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