# Patient Leaflet

## DSS™ Stabilization System

This patient leaflet refers to the DSS™ Stabilization System with the following components as illustrated in the tables below:

| | |
|---|---|
| DSS™ Pedicle screws |  |
| DSS™ Pedicle screws, Ti coated |  |
| DSS™ Angle head screws |  |
| DSS™ Dynamic coupler |  |
| DSS™ Fusion coupler |  |
| DSS™ Closure set |  |

## Device Description

The DSS™ Stabilization System is used for the stabilization/fixation of two or more vertebral bodies of the lumbosacral spine from the back. The system allows both dynamic (easily movable; see figure 1) and rigid (fixed; see figure 2) stabilization.

Figure 1

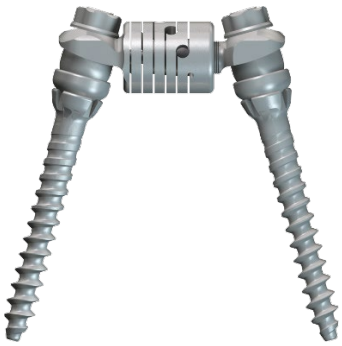

Figure 2

## 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 DSS™ Stabilization System is intended for long-term implantation for 1 to 3 segments from at the lumbar spine to the first sacrum level. The pedicle screws are placed in the pedicles and connected with a dynamic coupler and/or a fusion coupler from head-to-toe direction.

For the implantation as a dynamic system the DSS™ Stabilization System is intended in cases of degenerative spinal stenosis and degenerative spondylolisthesis up to Meyerding grade 1, which were previously unsuccessfully treated.

The DSS™ is a system for rigid stabilization of the thoracolumbar spine as an adjunct to fusion is intended for spinal stenosis, spondylolisthesis, degenerative disc disease (DDD) and trauma (i.e., fractures or dislocation).

## 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.

## 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 DSS™ Stabilization 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 DSS™ Stabilization System?

### For Dynamic Stabilization:

- You have degenerative spondylolisthesis greater than grade 1, or other spondylolistheses that are congenital or acquired in childhood
- You have a curvature greater than 15 degrees
- You have bone fractures
- You have a tumor
- You have any infection including acute or chronic systemic, spinal or localized infections. Tell your doctor if you have any infection.
- You have severe instabilities that would not allow use of dynamic stabilization with the coupler of the DSS™ system, e.g., a spondylolisthesis grade 3 or 4. The coupler may not function properly, and you may need additional surgery to relief you pain. Tell your doctor if you have ever had a problem with your back.

For Rigid and dynamic Stabilization:

- 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 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 have spinal anatomy or instability that would not allow use of DSS™ Stabilization System. Examples of this are Bone tumors in the proximity of the implant fixation or a severe slipped disc. The DSS™ 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 DSS™ 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 DSS™ 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 DSS™ system.

## 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 spinal dynamic or rigid stabilization 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
- Adjacent segment instability

- 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

## 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 DSS™ implant 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 DSS™ implant 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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