Patient Information Leaflet - Australia

THE iFUSE IMPLANT SYSTEM®

The iFuse Implant System® is a surgical system designed to stabilize and fuse the sacroiliac (SI) joint. The surgeon can use either the iFuse Implant or the 3D-printed iFuse-3D Implant™.

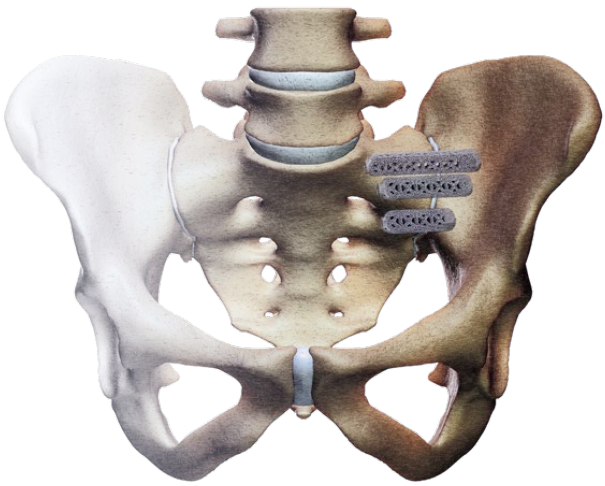
INTENTED PURPOSE OF THE iFUSE IMPLANT SYSTEM®

At least two, and generally three or more, triangular titanium implants are placed through the ilium, or wing bone of the pelvis, across the SI joint, and into the sacrum, the large bone at the base of the spine, to immediately reduce the motion of the joint and facilitate long-term fusion of the ilium to the sacrum. Studies have shown that the iFuse Implant, which has been commercially available since 2009, generally reduces the pain caused by SI joint dysfunction, reduces disability, and improves the quality of life of patients who have undergone the iFuse Procedure™.

WHAT TYPE OF PATIENT IS THE iFUSE IMPLANT SYSTEM INTENDED TO TREAT?

The iFuse Implant System is intended to treat patients with certain types of SI joint dysfunction, which can cause pain in the lower back, buttocks, hip, and down the leg.
The Indication for Use reads:

The iFuse Implant System is intended for sacroiliac joint fusion including use in high and low energy fractures of the pelvic ring.



SI-BONE®

PATIENT OPERATING INSTRUCTIONS FOR USE OF THE iFUSE IMPLANT SYSTEM

Once implanted, there are no post-operative operating instructions for the iFuse Implant System. It is important to develop and follow an appropriate post-operative rehabilitation plan with your surgeon and other healthcare providers, such as your physical therapist.

INTENDED PERFORMANCE OF THE iFUSE IMPLANT SYSTEM

Before deciding on surgery, you will need to undergo a careful diagnosis and evaluation by your physician before undergoing the iFuse Procedure. Lower back pain (LBP) is complex and may be challenging to diagnose. Some patients may have multiple problems causing their lower back pain and the iFuse Procedure alone will not resolve all their pain. It may not be appropriate for all patients and all patients may not benefit.

You should try non-surgical management of your SI joint dysfunction and consult carefully with your surgeon before choosing to have the iFuse Procedure. Women who may in the future want to undergo childbirth should consult with their surgeon prior to undergoing the procedure or prior to delivery if they have had an SI joint fusion procedure.

POTENTIAL RISKS & SIDE EFFECTS

As with all surgeries, the risks associated with the iFuse Procedure include, but are not limited to:

- Adverse reactions to anesthesia
- Hemorrhaging or bleeding which is difficult to control and may become dangerous
- Muscle and/or nerve damage
- Localized bruising or swelling
- Dangerous blood clots
- Wound site infections, wound re-opening and damage to the tissues surrounding the surgical site
- Excessive radiation exposure
- Lung damage
- Death

Risks specific to the iFuse Procedure include, but are not limited to:

- Local injury to the pelvis
- Increased pain in the sacroiliac joint or surrounding tissues and joints
- Allergic reaction to or rejection of the implants
- Migration, loosening, breakage or failure of the implant
- Muscle pain due to the change in function of the SI joint
- Stress to and fracture of the bones in the pelvis surrounding the implants
- Need for additional surgery to remove or adjust the positioning of one or more implants

INTERACTION WITH OTHER EQUIPMENT

Patients who have had the iFuse Procedure can likely still undergo magnetic resonance imaging but should notify their healthcare providers prior to doing so as the imaging procedure needs to be performed in certain ways to adjust for the implants.

iFUSE IMPLANT SYSTEM MAINTENANCE & PERFORMANCE

The iFuse Procedure is designed to last a patient's lifetime and no maintenance is required. Any increased pain in the SI joint or surrounding tissues and joints following surgery should be evaluated with your doctor.

iFUSE IMPLANT SYSTEM MATERIALS & MANUFACTURING

The iFuse-3D implant is constructed using an additive manufacturing process using an implant grade titanium alloy powder known as Ti-6Al-4V ELI. The 3D printing process is intended to create a triangular titanium implant with a porous surface that mimics human cancellous bone.

Patients who are allergic to certain metals, have tumors or active infections in or around the sacroiliac joint should not be treated with iFuse. Patients with certain types of fractures of the pelvis should have those fractures treated first, prior to treatment with iFuse.

SERIOUS ADVERSE INCIDENT REPORTING

If you experience any serious adverse incidents as a direct result of the iFuse Implant System, contact the Therapeutic Goods Administration using the following website address www.tga.gov.au