

DEVICE DESCRIPTION

The iFuse Implant System consists of cannulated triangular, titanium (Ti 6Al4V ELI, ASTM F136) rods coated with commercially pure titanium (C.P. Ti, ASTM F1580) porous plasma spray and a delivery system. Implant coating and shape are designed to prevent rotation and motion of the sacroiliac (SI) joint. The delivery system uses guide pins for accurate placement.

INDICATIONS

The iFuse Implant System® is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life at 12 months post-implantation.

CONTRAINDICATIONS

1. Deformities or anatomic variations that prevent or interfere with iFuse placement.
2. Tumor of sacral or ilial bone.
3. Active infection at treatment site.
4. Unstable fracture of sacrum and or ilium involving the sacroiliac joint.
5. Allergy to metal components.

WARNINGS

1. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.

PRECAUTIONS

1. Carefully read and follow all instructions prior to use.
2. Patient adherence to post-operative physical activity instructions is important to support long-term service life of the implant.
3. Pay careful attention to selection of implant size. Pre-operative X-rays and/or CT scan may be helpful in selecting implant size.
4. Appropriate patient selection is necessary as patient factors such as size and weight may make use of iFuse more difficult or impossible.
5. Inspect iFuse Implants and instruments for damage prior to use. Do not use if damaged or worn. Do not attempt to repair.
6. Do not use any component from an opened or damaged package.
7. Do not use implants after the expiration date.
8. If placing the iFuse Implants in conjunction with an open procedure, the surgeon should take care not to destabilize the joint prior to placing the implants.

MRI SAFETY INFORMATION



MR Conditional for One (1) Implant per SI Joint

It is important to note that a minimum of two (2) iFuse Implants per sacroiliac (SI) joint are recommended for treatment. Treatment typically involves at least three (3) iFuse Implants per SI joint. The iFuse Implant System when a minimum of two (2) implants per SI joint are implanted, has not been evaluated for safety and compatibility in the MR environment for its intended use.

However, the non-clinical testing, conducted for one (1) implant per SI joint, demonstrated that the iFuse Implant is MR conditional when one (1) implant per SI joint is present. For one (1) implant per SI joint, the iFuse Implant is MR conditional for MR Systems that meet the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- When 1 implant is present, maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg
- Normal Operating Mode of operation for the MR system

Under the scan conditions defined above, when only one (1) implant per SI joint is used, the iFuse Implant is expected to produce a maximum temperature rise of less than 3.0 °C after 15 minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by a single iFuse Implant per SI joint extends approximately 20 mm from the device.

As stated above, a minimum of two (2) iFuse implants per SI joint are recommended for treatment. Therefore, *MR Compatibility and Safety* of multiple iFuse Implants have not been evaluated for its intended use.

RISKS

As with other surgical procedures used to treat SI joint conditions, the risks associated with the iFuse surgical procedure include, but are not limited to the following:

1. Adverse reactions to anesthesia
2. Hemorrhage
3. Muscle damage
4. Hematoma or seroma
5. Neurological deficit, nerve root or peripheral nerve injury, irritation or damage
6. Vascular injury or damage that may result in catastrophic or fatal bleeding
7. Neurovascular injury
8. Damage to lymphatic vessels and/or lymphatic fluid exudation
9. Injury to intra-pelvic structures
10. Infection of the wound, deep infection, peritonitis

11. Wound dehiscence
12. Pulmonary or systemic embolism
13. Thrombosis, thrombophlebitis
14. Death
15. Bruising
16. Local swelling
17. Radiation exposure

Potential risks specifically associated with the iFuse Implants and instrumentation include, but are not limited to the following:

1. Infection
2. Pain, discomfort, or abnormal sensations due to presence of the implant
3. Instrument failure resulting in a complication
4. Migration, loosening or fracture of the implant
5. Pain in muscle due to altered biomechanics
6. Nerve root or peripheral nerve root irritation due to local swelling or altered biomechanics
7. Loss of fixation / stabilization
8. Metal sensitivity or allergic reaction
9. Failure to improve symptoms and/or function
10. Increased pain at treated or adjacent levels
11. Need for re-operation or removal of the implant(s)
12. Implant rejection
13. Response to wear debris
14. Decrease in bone density due to stress shielding
15. Failure to achieve SI joint fusion
16. Potential difficulty in delivering fetus vaginally due to device-related restriction of SI joint stretching

HOW SUPPLIED

iFuse Implants are provided sterile; do not resterilize. The iFuse instrumentation is provided separately, non-sterile, and must be sterilized prior to use following the *SI-BONE iFuse Instruments Hospital Cleaning and Sterilization Instructions, U.S.A.*

STORAGE/HANDLING

1. Store packaged implants at room temperature.
2. Handle the iFuse Implant with care to prevent damage to the surface finish.

DIRECTIONS FOR USE

1. For detailed information, refer to the relevant Surgical Technique Manual(s) prior to use of the iFuse Implant System.
2. Place patient in appropriate position for sacroiliac joint surgery. Use C-arm fluoroscopy or other x-ray based imaging throughout the procedure.
3. Make a 3 cm longitudinal incision aligned to a true lateral view of the mid body of the sacrum, starting approximately 1 cm from the alar line progressing distally about 3 cm.
4. Center the guide pin halfway between the anterior cortex of the sacrum and the anterior border of the spinal canal,

at least 1 cm distal to the alar line as visualized on the lateral fluoroscopic image.

5. Insert the soft tissue protector over the pin. Slide tissue protector down to the ilium. Use the gage to determine appropriate implant length. Remove the pin sleeve.
6. Drill over the pin to a point just medial to the SI joint through the lateral sacral cortex, avoiding the sacral foramina and keeping the drill collinear to the pin. Remove the drill sleeve if applicable.
7. Rotate the soft tissue protector handle so that one flat of the triangular profile is parallel to the ala.
8. Insert broach over guide pin to the same depth. Keep pin and broach parallel to the L5-S1 disc on the outlet view, and positioned within the sacral ala on the inlet view.
9. Insert iFuse Implant over the pin, leaving the implant about 2-5 mm proud of lateral ilial cortex.
10. Repeat steps 5-9 above to insert subsequent implants. Avoid orienting the implants such that they are point to point.
11. Use the parallel pin guide to aid in the insertion of subsequent pin(s). Subsequent pin location(s) are localized within the sacral body as viewed on the lateral image, but more caudal than the prior pin.
12. In the event that implant repositioning is needed, a removal adapter may be used to reposition the implant.
13. Close the wound using standard practices.

GRAPHIC SYMBOLS



Caution: Refer to Instructions for Use



Sterilized using Irradiation



Lot Number



Use by



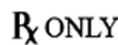
Catalog Number



Single Use Only (implant, pin and drill)



Do not use if package is damaged



Federal Law (USA) restricts this device to sale by or on the order of a physician

Manufactured for:
SI-BONE, Inc.
3055 Olin Avenue
Suite 2200
San Jose, CA 95128

Customer Service:
USA: 408-207-0700 or Toll Free: 855-884-3873

U.S. Patent Nos. 8,202,305; 8,840,623; 8,986,348; and 9,039,743 pending U.S. and foreign patent applications.