Instructions For Use – iFuse Implant System®

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 joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruptions and degenerative sacroiliitis.

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 delivery 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.

MRI SAFETY AND COMPATIBILITY

MR Conditional

The iFuse Implant is MR conditional. Non-clinical testing demonstrated that the iFuse Implant is MR conditional. A patient with this device can be scanned safely, immediately after placement under 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
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
- Normal Operating Mode of operation for the MR system

Under the scan conditions defined above, the iFuse Implant is expected to produce a maximum temperature rise of less than 3.0 ºC after 15 minutes of continuous scanning.

The image artifact extends approximately 20 mm from the device, when scanned in nonclinical testing using a gradient echo (GRE) pulse sequence in a 3-Tesla (Excite, Software 14X.m5, General Electric Healthcare) MR system with a send-receive RF coil.

Surgeons should advise patients that the iFuse Implant is MR conditional with details available at:
www.si-bone.com

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 or Delivery System 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 Instrument Set is provided separately, non-sterile, and must be sterilized prior to use following the *Hospital iFuse Instruments Sterilization Instructions.*

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. Place patient in appropriate position for sacroiliac joint surgery. Use C-arm fluoroscopy or other x-ray based imaging throughout the procedure.
2. Make a 3 cm longitudinal incision aligned to a true lateral view of the posterior cortex of the sacrum, starting approximately 1 cm from the alar line progressing inferiorly about 3 cm.
3. 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.
4. 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.
5. 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.
6. Rotate the soft tissue protector handle so that one flat of the triangular profile is parallel to the ala.
7. Insert broach over guide pin to the same depth. Keep pin, drill bit and broach parallel to the L5-S1 disc on the outlet view, and positioned within the sacral ala on the inlet view.
8. Insert iFuse Implant over the pin, leaving the implant about 2-5 mm proud of lateral ilial cortex.
9. Repeat steps 4-8 above to insert subsequent implants. Avoid orienting the implants such that they are point to point.
10. Use the parallel pin guide to aid in the insertion of subsequent pin locations localized within the sacral body as viewed on the lateral image, but more caudal than the prior pin.
11. Close the wound using standard practices.

For more information, please see the *iFuse Implant System Surgical Technique Manual.*

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 and 8,840,623; pending U.S. and foreign patent applications.