

THE FOLLOWING INFORMATION IS IMPORTANT FOR THE OPERATING SURGEON

The **FIX8™** Fixation System consists of a variety of titanium components and accessories.

INDICATIONS

The **FIX8™** Fixation System may be used for surgical procedures in which metallic internal fixation is required to align and stabilize bony tissue, including, but not limited to craniofacial skeletal reconstruction and the repair of traumatic fractures of the craniofacial skeleton. A number of surgical techniques may be used for bone fixation and other materials used for the same purpose are also available. The selection of the type of fixation device, its composition, size, and shape is made by the surgeon after evaluating the anatomical and functional demands of the patient.

The following are specific contraindications, adverse effects, and warnings that must be understood by the surgeon and explained to the patient. The general surgical risks that are not included should also be explained to the patient prior to surgery.

CONTRAINDICATIONS

1. Active infections.
2. Patients who are unwilling or unable to follow postoperative instructions due to accompanying conditions (mental or physical).
3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made to rule out this possibility prior to implantation.
4. Inadequate quality or quantity of bone for secure anchoring of the implants.
5. Limitations in blood supply and/or previous infections that may slow healing and increase the possibility of infection and/or rejection of the implants.
6. Any degenerative disease process that would adversely affect proper placement of the implants.
7. Inadequate coverage with healthy tissue.
8. Procedures in which a non-sterile environment exists, i.e., open cavities, such as sinuses.
9. Use in weight bearing and/or load bearing areas.
10. Pedicle screw fixation.

POSSIBLE ADVERSE EFFECTS

1. Decrease in density of bone and/or necrosis of bone due to stress shielding.
2. Vascular changes.
3. Allergic reaction or metal sensitivity to the fixation device.
4. Nerve damage due to surgical trauma.
5. Breakage of the fixation device due to nonunion or delayed union of bony tissue.
6. Bending or fracture of the fixation devices.
7. Migration or loosening of the fixation devices.
8. Pain, discomfort, and/or abnormal sensation due to presence of the fixation devices.
9. Superficial and/or deep infection.
10. Growth restriction.
11. Passive transmigration of the fixation devices.
12. Tissue staining.

WARNINGS

1. Surgical implants must never be re-used and explanted implants should never be re-implanted. Small defects and internal stress patterns may be present, even if the implant appears intact, and may cause failure and breakage of the implant.
2. Adequate patient instruction is a key factor in determining the success of the surgical procedure. Postoperative follow-up and care are very important. The patient must be made aware that a metallic implant is not as strong as normal bone and that excessive physical activity or load bearing may cause loosening, migration, bending, or fracture of the implants.
3. The success of any metallic fixation device is dependent upon careful handling and good surgical technique. Shaping and contouring of metallic implants should be avoided if possible. However, if contouring is required for proper application and the design of the implant allows for it, the surgeon should avoid using sharp bends, reverse bends, and bends at the site of screw holes. The surgeon should also avoid scratching or notching the surface of the implant with sharp instrumentation during contouring. Internal stress patterns can be produced that may cause eventual breakage of the implant. Excessive torque used to insert the screws into bony tissue may also cause screws to fracture during use.

With any implantable device, there is a risk of introducing foreign materials and particulate matter, including glove talc, lint from draping materials, cleaning agents, and other surface contaminants. All efforts should be made to limit handling of the fixation devices. In addition, if any fixation device comes into contact with body fluid, it should not be reused, due to possible transmission of blood borne pathogens.

4. Use of dissimilar metals in close contact with each other (i.e., screws used with a bone plate)

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4. Use of dissimilar metals in close contact with each other (i.e., screws used with a bone plate)

can cause an increase in the corrosion process that may enhance metal fatigue and fracture of these implants. Titanium and titanium alloy plates and screws should be used together, without the addition of any other type of metal implants. Use of instruments not specifically designed for use with titanium fixation devices may cause device failure.

5. Metallic implants may loosen, corrode, migrate, cause pain, or fracture, even after a fracture site has healed. This is especially true in young, active patients. When deciding to remove the implant(s), the operating surgeon must consider the risks and benefits to the patient. If the implant is removed, the patient must receive appropriate postoperative management to avoid refracture of the bony tissue.
6. Proper selection of the implant size, configuration, and location will increase the potential for success of the fracture fixation. The surgeon must be thoroughly familiar with the implants, the method of application, the instrumentation, and the surgical procedure. Emergency screws are provided in the event that the pilot hole is of a diameter too large for adequate gripping of the standard screws. Metallic implants are intended to assist in the healing of bony tissue, not to replace normal tissues. These implants are not designed for use in weight bearing or load bearing applications. The patient must be made aware of the risks of using the devices, including possible adverse effects.
7. Staining of surrounding tissue has been reported with the use of similar titanium fixation devices after these devices have come in contact with human tissue. Fragments and micro particles may become dislodged from the fixation device and may migrate from the implantation site. Once a fixation device is implanted, metallic particles may remain in the body after removal. Long-term effects of these particles are not currently known. It is possible that in the future adverse effects of these particles may become evident.
8. Special considerations are required in the use of this device for pediatric patients. Evidence suggests that growth restriction may occur with these implants. More importantly, intracranial translocation has been described with similar devices. Potential consequences may include intracerebral translocation with associated seizure activity and/or cerebral laceration with permanent disability or death. Use of this device in the pediatric population should be performed only by physicians qualified by specialized education and training. Removal of implants should be strongly considered after adequate healing has occurred.
9. The drill bits are designed to be discarded after each patient use. Always review the instruction manual and warning notices of the instrument manufacture, as improper use may cause serious injury. Eye protection should be worn at all times.
10. The screwdriver blades must be replaced periodically. Each screwdriver blade has a gold colored coating on the tip. Any appearance of silver on the tip of the blade indicates that the blade has worn and must be replaced. Once the blade has worn, correct insertion of the screws may not be possible.
11. Responsibility for completion of adequate training, proper patient selection, choice and placement of implants, and the decision to leave or remove implants postoperatively rests with the physician.

STERILIZATION INSTRUCTIONS

The Titanium Fixation System and accessories are provided NON-STERILE and must be sterilized prior to use. The system is able to withstand multiple sterilizations, but the implantable components and drill bits are for single patient use only. Based on AAMI and current JCAHO standards, the implants and instrumentation should be wrapped and sterilized using moist heat and a vacuum cycle, using the institution's sterilization policy or the following guidelines:

PARAMETERS FOR STEAM STERILIZATION			
Method	Cycle	Temperature	Exposure time
Steam	Vacuum	275° F (135°C)	7 minutes
Steam	Gravity	Not Recommended	

Flash sterilization (gravity cycle) is not recommended for routine sterilization. An appropriate chemical process indicator should be placed in an area of the tray where the greatest chance of air entrapment exists to assure sterility. A biological indicator should also be used to monitor each load containing bone plates and screws. Because the set contains implanted devices, the set should not be used until the results of the biological indicator are known.

WARRANTY

All products are warranted to be free from defects in material and workmanship. No warranty is made for any purpose other than in the product specifications and labeling.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Additional information pertaining to specific devices or issues may be obtained from IOP, Inc.

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