

**INTERNAL DISTRACTION DEVICES
ATTENTION OPERATING SURGEON
ALL INSTRUCTIONS MUST BE READ CAREFULLY PRIOR TO CLINICAL USE**

DESCRIPTION

Biomet Microfixation manufactures and distributes distraction devices for use in bone stabilization and elongation (lengthening) when correction of oral, cranial, and maxillofacial deficiencies or post traumatic defects require gradual bone distraction. Each implantable distraction device has a drive screw mechanism and connection plates which are implanted by fixation with bone screws.

Each device is made from one of the following material(s): Commercially Pure Titanium, ASTM F-67
Titanium 6Al 4V Alloy, ASTM F-136
316L Stainless Steel, ASTM F-138

INDICATIONS

1. Congenital or developed deficiencies of the oral, cranial, and maxillofacial skeleton.
2. Post-traumatic defects of the oral, cranial and maxillofacial skeleton.

CONTRAINDICATIONS

1. Active infection.
2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
3. Patients with limited blood supply, insufficient quantity or quality of bone, insufficient soft tissue quantity or quality, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
5. Use of the pediatric mandible distractor in the mandible on patients over 16 years of age.

POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union may lead to breakage of the implant.
3. Bending, loosening, stripping the threads or fracture of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. If device remains implanted, decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Nerve damage due to surgical trauma.
8. Necrosis of bone.
9. Biomechanical complications after distraction due to positioning of the device.
10. Tension of the soft tissue depending on the speed of distraction and quality of the soft tissues and therefore irritation and / or atrophy.
11. Inadequate healing.
12. Other conditions brought on by the surgical procedure including skin irritation and infection.
13. Bending, loosening, slipping or disconnection of drive attachments.
14. Soft tissue adherence to device during activation.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

WARNINGS

Distraction devices aid the surgeon in the defined step by step elongation of bone in the oral, cranial and maxillofacial skeleton. Correct handling, connection and placement of these implants is extremely important. The surgeon is to be thoroughly familiar with the implant, the specific method of application, use of attachments, as well as the local biomechanical situation of each patient. The surgeon must also be aware of the mechanical and metallurgical aspects of the surgical implant. Incomplete osteotomy, inappropriate osteotomy, or premature osteosynthesis may cause the device to bend or the distraction screw to strip resulting in device malfunction or failure. Compressing a distraction device, activation of a distraction device without proper instrumentation, and excessive angulations may cause a drive attachment to strip, loosen or disconnect. The surgeon must plan proper placement and orientation of the device for each patient prior to implantation. Correct positioning of the device reduces the risk of device loosening from bone or possible biomechanical complications after distraction is complete. In all cases, sound surgical practice is to be followed.

1. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants.
2. Correct handling of the implant is extremely important. Implants should be modified only when necessary. Modifications or excessive contouring of implants may cause damage to the device. Notches, dents, and scratches resulting from the modifications can contribute to breakage.
3. Intraoperative fracture of screws can occur if excessive force is applied while seating bone screws.
4. Implants may be removed after the fracture has healed. Implants can loosen, fracture, corrode or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of refracture.
5. Adequately instruct the patient. The cooperation and willingness of the patient over the course of the complete treatment is extremely important. Postoperative care and the patient's ability and willingness to follow instructions are important aspects of successful distraction and healing. A daily distraction plan should be worked out with the patient and / or guardian. The patient is to be warned that failure to follow postoperative instructions can cause failure of the device or the treatment. Proper instrumentation must be used at all times. If loosening or metal fatigue occurs before distraction is complete, revision surgery may be necessary to replace or remove the device.
6. The patient is to be made fully aware and warned that the device can break, bend or be damaged as a result of stress, activity, and load bearing. The patient is to be made aware and warned of general surgical risks, complications, and all possible adverse effects.
7. The surgeon should weigh the risks versus benefits when deciding to remove the implant. Implant removal should be followed by adequate postoperative management.
8. Correct handling and maintenance of torque limiting drivers are important. Substances entering the driver or physical damage to the driver may affect calibration of the instrument.
9. Torque limiting drivers must not be the only indication of excessive load application to a distraction device. Calibration of the torque limiting drivers is subject to change. The surgeon must be aware of the possible calibration change and utilize tactile feedback as another indication of pending device failure.

PRECAUTIONS

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.

Surgical instruments must be used only for the device systems for which they are designed. Use of other manufacturer instruments can involve incalculable risks for the implant and instrument, thereby potentially

endangering the patient, user, or third party. Intra-operative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Biomet Microfixation recommends that all instruments be regularly inspected for wear and disfigurement.

Bone Plates:

Distraction devices have bone plates for implanting the device. These plates may require contouring to the surface of the bone by bending the plates with a bending instrument.

- Care must be taken to achieve the appropriate contour with as few bends as possible. Repeated bending of titanium increases the risk of fracture.
- Sharp angles and small bending radii must be avoided to reduce the risk of the device breaking.
- The bending instruments must be used with care because they can cause damage to the implant. The operating surgeon should always inspect the implant after bending for damage which may include notches, dents, or deformed screw holes. These defects can lead to breakage of the implant. Deformed screw recesses due to bending may impair the proper fit of the screw head.
- Cutting bone plates may increase the risk of failure of the implant. If the operating surgeon elects to cut a plate, care must be taken to cut in such a way to maintain adequate strength, support, and fixation for the intended use. Cutting a plate between the screw holes is the preferred method to maintain strength characteristics. Sharp edges should be smoothed to avoid soft tissue damage or irritation. When cutting a plate, extra care must be taken to prevent the portion being cut from projecting towards the patient, user, or third party.

Bone Screws:

- The screwdriver which has been designed for a particular system of screws must always be used to be sure that proper screwdriver/screw head connection is achieved.
- Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver.
- Excessive torque can cause the screw to fracture.

Drive Shaft Extensions and Connections

- Flexible shafts may be weakened or break as a result of excessive force.
- The connection sleeve must be locked down and remain locked during the entire distraction period.

Twist Drills:

- Twist drills are labeled for single use only.
- When using twist drills, appropriate cooling is necessary to minimize thermal damage to bone tissue. It should be combined with low speed drilling to prevent the risk of bone demineralization and possible loosening of the bone screw.
- The manufacturer's instructions for the hand piece used with the twist drill must be followed. The manufacturer of the handpiece may recommend proper speeds to avoid failures such as breakage of the twist drill.
- Excessive force may cause unusual stress conditions and result in breakage or fracture of the device.
- Breakage of twist drills may result in injury to the patient, the user, or third party.

Drill Guides and Cannulas

Drill guides and cannulas are provided to assist the operating surgeon in guiding the twist drill and to aid in the protection of the patient, user and third parties. Drill guides and cannulas should be properly irrigated to prevent risks of injury to the patient.

Depth Gauges:

Depth gauges are used to measure the hole drilled into the bone and assist in proper selection of the length of screw to be used. It is recommended to use a depth gauge designed for the system of screws being used since screw head thickness varies between the systems. The depth gauges indicate the entire length of the screw, which corresponds to the labeling. Plate thickness and screw seating in the plate is already taken into account.

Torque Limiting Drivers:

Torque limiting drivers are used as indicators of excessive load being applied to a device. It is recommended to use a torque limiting driver when activating distraction devices. Torque limiting drivers are calibrated to indicate when applied loads are approaching device damage. Fluid or debris entering the driver or damage to the driver may affect the calibration. Correct care, handling and maintenance must be maintained to assure proper function. While the torque driver is expected to aid the physician in avoiding device damage, surgeons must also rely on tactile feedback as an indication of load limitations.

STERILITY

Distraction devices are supplied non-sterile and must be sterilized prior to surgical use. Unused implants can be re-sterilized. Following is a recommended minimum cycle for steam sterilization that has been validated by Biomet Microfixation under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of recommended minimum cycle parameters described below.

Pre-vacuumed Steam Sterilization (Hi-VAC) Wrapped:

Temperature: 270 ° Fahrenheit (132 ° Celsius)

Time: Four (4) minutes

Drying Time: Thirty (30) minutes MINIMUM

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Since Biomet Microfixation is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet Microfixation cannot assume responsibility for sterility even though the guideline is followed.

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

Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.

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