

EXTERNAL HALO DISTRACTION DEVICES

ATTENTION OPERATING SURGEON

ALL INSTRUCTIONS MUST BE READ CAREFULLY PRIOR TO CLINICAL USE

DESCRIPTION

Walter Lorenz Surgical, Inc. manufactures and distributes external distraction devices for use in bone stabilization and elongation (lengthening) with correction of oral, cranial, and maxillofacial deficiencies or post traumatic defects require gradual bone distraction. Each device consists of a rigid external frame and distraction mechanism that is attached internally or intraorally to the patient by means of percutaneous screws, internal plates, intraoral splints, and/or stainless steel wire.

Implantable portions for this system are 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

INDICATION

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 or soft tissue, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

POSSIBLE ADVERSE EFFECTS

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 of screws, stripping of threads, or failure of the device.
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 or soft tissue.
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. Scarring.

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

The rigid external frame and distraction mechanism is designed for external use only and is never to be implanted. 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 devices is extremely important. The surgeon is to be thoroughly familiar with the device, the specific method of application, as well as the local biomechanical situation of each patient. The surgeon must also be aware of the mechanical and metallurgical aspects of the device. Incomplete osteotomy or premature osteosynthesis may cause a portion of the device to bend, deflect or break resulting in the device malfunction or failure. The device can loosen, migrate, bend, or break as a result of strenuous activity or traumatic injury. The patient

must be warned by the operating surgeon to limit physical activities accordingly. Limitation of activities may be unique to each patient and the patient must be warned that noncompliance with postoperative instructions could lead to patient injury or complications. The patient must be made aware that deformity or some degree of deformity may be present even after treatment. The surgeon must plan proper placement and orientation of the device for each patient prior to insertion of bone screws, plates, or intraoral appliances. Correct positioning of the device reduces the risk of the 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, which 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 bone or 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. 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. Over insertion or excessive torque of the cranial screws may lead to bone fracture or dural puncture. Care must be taken to assure screws are not excessively inserted.

PATIENT WARNINGS

The patient must be instructed on the postoperative care at the bone screw site. The patient must be warned that this site is a potential source of infection and can easily be contaminated by fingers or other objects which may come into contact with the site. Redness, swelling, and/or drainage may indicate infection and the patient should be instructed to contact their physician. The patient should be warned that the bone screw sites may cause scarring long after healing has occurred.

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 or guardian. The patient is to be warned that failure to follow postoperative instructions can cause failure of the device or the treatment. If loosening or metal fatigue occurs before distraction is complete, revision may be necessary to replace or remove the device. The surgeon should weigh the risks versus benefits when deciding when to remove the device. Adequate postoperative management should follow removal.

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, especially in the presence of delayed union or nonunion. The patient must be warned by the operating surgeon to limit physical activities accordingly. Limitation of activities may be unique to each patient and the patient must be warned that noncompliance with postoperative instructions could lead to patient injury or complications. The patient is to be made aware and warned of general surgical risks, complications, and all possible adverse effects. The patient must be warned not to attempt to adjust or modify the devices without direction from the surgeon.

PRECAUTIONS

Do not reuse these external distraction devices or associated implants. While a device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the distractor. Do not treat patients with devices that have been placed on 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. Walter Lorenz 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:

1. Twist drills are labeled for single use only.
2. When using twist drills, appropriate cooling is necessary to aid in the prevention of injury to bone, skin and tissue. It should be combined with low speed drilling to prevent risks of bone demineralization, possible loosening of the bone screw and injury to the patient.
3. 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.
4. Excessive force may cause unusual stress conditions and result in breakage or fracture of the device.
5. 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 screw length 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.

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.

Authorized Representative in EC:

Biomet UK, Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA, U.K.
Phone: (+44) 1656 655221
Fax: (+44) 1656 645454

European Sales Headquarters:

Biomet Microfixation Europe
Toermalijnring 600
3316 LC Dordrecht
Netherlands
Phone: (+31) 78 629 29 10
Fax: (+31) 78 629 29 12