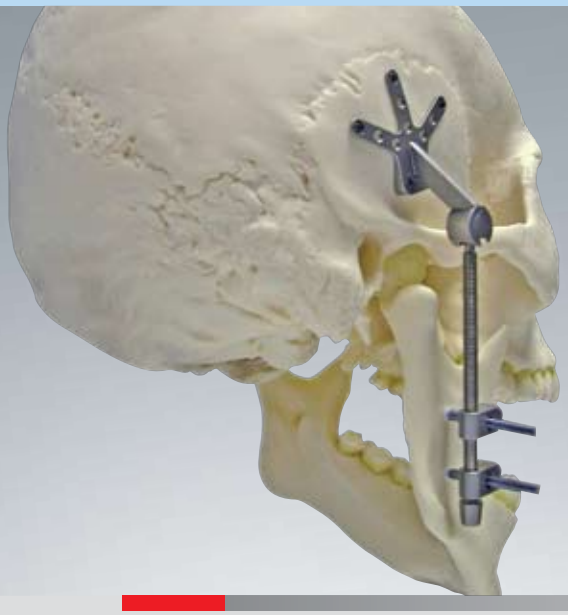
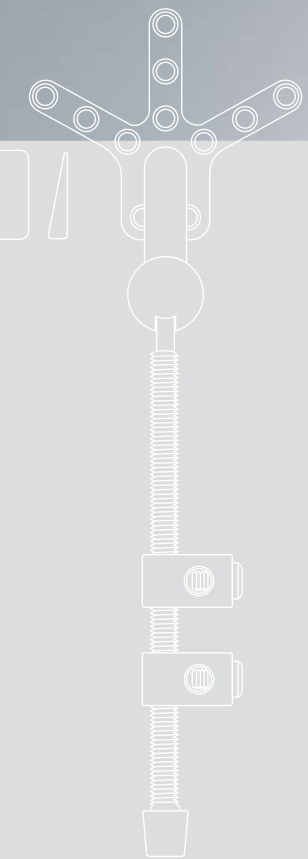


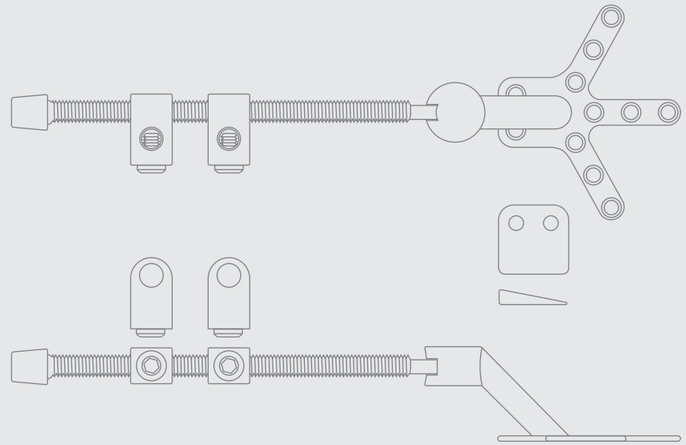


Cranio-Mandibular Fixator

Developed in cooperation with Dr. David Matthews
Charlotte, NC

KLS martin® L.P.

Cranio-Mandibular Fixator -

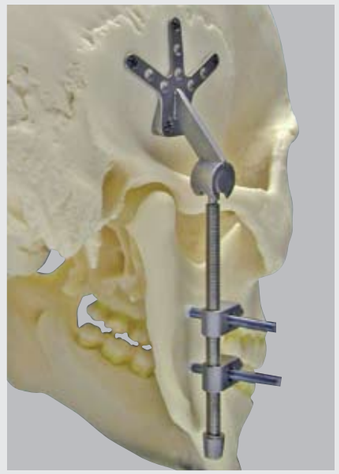


Indications

- Bony Ankylosis, either unilateral or bilateral
- Comminuted intracapsular fractures of the condyle when there is:
  - · absence of the posterior occlusal stop preventing placement of a posterior open bite splint
  - · Severe head trauma when the patient is nonresponsive to therapy or intubated with a prolonged coma or head injury

Contraindications

- Patient without adequate bone for fixation
- Accute inflammatory processes
- Patients with insufficient bone volume or quality
- General surgical contraindications
- Additional conditions that would result in poor bone or patient healing
- The final decision on patient candidacy rests with the surgeon

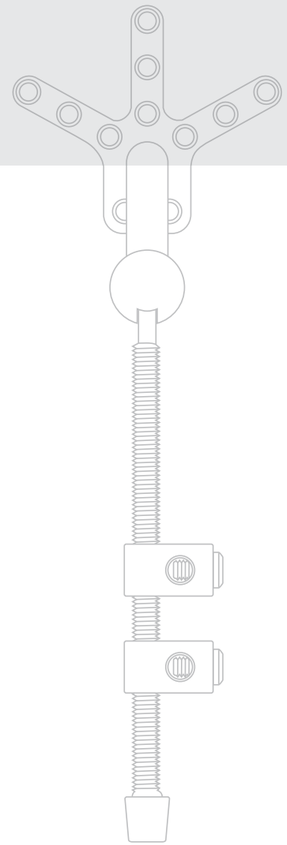


device placed

Placement -

- The cranio-mandibular stabilizing device is divided into two portions; a temporal stabilizing plate and an articulating arm for mandibular placement. They are connected by a limited hinge joint that is constrained in the Z axis. The temporal stabilizing plate is placed in the external temporal fossa so that the hinge joint is over the glenoid fossa. The articulating arm is placed parallel to the mandibular border of the ascending ramus when the mandible is in the closed position.

- It is important that the articulating arm and the central fixation point of the temporal stabilizing plate be parallel and that the hinge axis does not interfere with angulation in the Z axis, which is lateral to the articulating arm. Wedges and bending of the malleable fixation points may be necessary to prevent angulation in the Z plane (medial or lateral angulation) since the angulation can impinge on the hinge functioning.



Intraoperative Approach -

- The ankylosis is approached through a preauricular incision with an extension into the scalp over the external temporal fossa. The dissection is carried down to the temporalis fascia extending down to subperiosteal dissection over the zygomatic arch and then down onto the joint capsule (if it exists) and on the ascending portion of the mandible. After adequate visualization of the zygomatic arch and the joint landmarks, a curved bunion saw blade is then placed to cut the ankylosis. (Note that the blade must be parallel to the glenoid fossa that is slightly inclined inferiorly to prevent penetration into the temporal fossa.) The CT scan is used to approximately judge the thickness of bone to be cut. A curved gouge is used to help spread the osteotomy and a Tessier Joint Spreader is used to further displace the mandible inferiorly, further stretching the soft tissue. This allows access to the condyle to remove any excess bone and to shape the condyle. A hemostatic agent like dry Gelfoam or Surgifoam is used to minimize the bone bleeding. The posterior ½ of the temporalis muscle which is accessed through the scalp incision is then freed from the temporal crest and split in the midportion of the muscle. It is then rotated down underneath the arch to line the depths of the new glenoid fossa. Sutures are placed to secure the muscle after the cranial mandibular stabilizing device is placed.

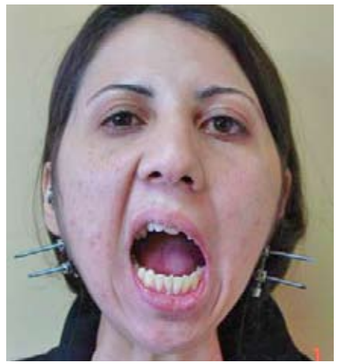
- The temporal stabilizing plate is placed on the temporal bone with the hinge over the glenoid fossa and with the central fixation point parallel to the posterior border of the ascending ramus. The position is adjusted with bending and wedges to keep the hinge plane parallel to the mandibular lateral plane as discussed in the placement section. The pins are then placed in the articulating arm, positioning them parallel to the posterior border when the mandible is in the closed position. The adjusting screw is turned until the pins are over the portion of the ascending ramus chosen for pin placement (the pin holders can be adjusted in their distance apart prior to placement of the pins in their respective holes.) Using the driver, the pins are percutaneously placed. The temporalis muscle is sewn in position and the adjusting screw set for about 10-12mm of displacement between the condyle and the glenoid fossa. The temporalis muscle obviously fills this space. No further adjustments are necessary. The soft tissues are then closed, trying to close the fascia with the drain in the glenoid fossa. This skin is then cut to allow the arm on the temporal fixation plate to be brought through the skin. The skin is then closed in standard fashion. The patient is then started on active range of motion the next day.

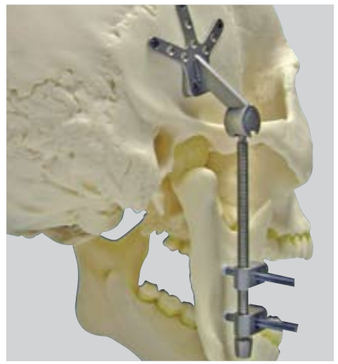
- In cases where the temporalis muscle has been used, temporal parietal fascia soft tissue can be used instead. If this is not available, then shavings of cartilage layered over the exposed joint surface can be used as described by Obwegeser and others.

- When using the cranio-mandibular stabilization device for intracapsular fractures, the temporalis muscle is split along its fibers to insert the temporal stabilizing plate and there is no soft tissue interposition graft. The amount of separation between the glenoid and the condylar fragments is about 8-10mm at least to over-correct the shortened position and maintain until adequate healing is seen, usually a minimum of two months.

- Usual pin care and maintenance, range of motion is started the same day. The range of motion is continued with healing and pin maintenance for approximately two to three months, depending on indications. In radiation cases, a longer period of time and in cases without recurrent ankylosis, a shorter period of time is satisfactory. The device is easily removed in the operating room by opening the superior portion of the incision and taking the screws out and removing the pins with the device. Local care is all that is necessary and range of motion may be started right away.

intercapsular space created and maintained





jaw open

Ordering Details -

	Item No.	*Description*
	51-603-45	small, 1.0 mm plates, 2.0 screws
	51-603-50	regular, 1.0 mm plates, 2.0 screws
	51-604-50	long, 1.0 mm plates, 2.0 screws

Additional product available

Stock No.	Description
51-600-85	Molina pin driver
51-600-90	Molina activator and fixation screwdriver
51-608-60	Distraction pin, 2.7 x 60.0 mm, 7.0 mm cutting shaft
51-610-60	Distraction pin, child/adult, 3.2 x 6.0 mm, 7.0 mm cutting shaft

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

Rev 16

05/03/2010

PRECAUTIONS FOR DISTRACTION DEVICES

This device is provided non-sterile and must be sterilized prior to implantation.

Sterilization by User

The following parameters are recommended:

- For gravity-displacement cycles, a 15 minute exposure time at 270°F.
- For pre-vacuum cycles, a 4 minute exposure time at 270°F.

Caution: Time required for sterilizer to reach temperature is not included in the times given.

This is based on instructions in Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79-2006 and A1:2008, A2:2009.)

KLS Martin®L.P. distributes Distraction Osteogenesis Devices for use in the maxillofacial skeleton. Osteodistraction is a technique of bone lengthening which utilizes the body's natural healing mechanisms to generate new bone. An osteotomy or corticotomy is made in the selected skeletal area in which the distraction device is to be placed. Upon activation, the distraction device slowly elongates the bone to its new dimension while natural ossification produces new bone at the site of distraction.

In using these devices, the surgeon is to be thoroughly familiar with the implant, implant manufacturing source, the method of application, instruments, and the surgical procedure. In all cases, sound surgical practice is to be followed and it is the responsibility of the surgeon to select the appropriate device for treatment. It is the surgeon's responsibility to warn the patient of the risks involved using the device, including the possible adverse effects. It is the surgeon's responsibility to warn the patient that failure to follow the surgeon's postoperative care instructions can cause failure of the device or the treatment.

CONTRAINDICATIONS

1. Active infection
2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or may engage in non-compliant behavior
4. Foreign body sensitivity - where material sensitivity is suspected, tests are to be made prior to implantation
5. General contra-indication is the severely diseased system: Immunodeficiency – irradiated patients - severe diabetes
6. Severe osteoporosis

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but also must be aware of the mechanical and metallurgical aspects of surgical implants. Additionally, the raw materials, manufacturing processes, or quality control procedures of other implant manufacturers cannot be monitored by KLS Martin®L.P. Therefore, we cannot advocate mixing implants manufactured by KLS Martin®L.P. with those of substitute manufacturers. Postoperative care is extremely important. The patient should be warned that noncompliance with postoperative instructions could lead to breakage of the implant and/or possibly loosening, requiring revisional surgery to remove the device.

The following are specific warnings, precautions and adverse effects, which should be understood by the surgeon and explained to the patient. Warnings do not include all adverse effects, which could occur with surgery in general, but are important considerations particular to metallic distraction devices. General surgical risks should be explained to the patient prior to surgery.

CONTRAINDICATIONS

1. Pre-Op planning. Distraction Osteogenesis often requires complex movements of the mandible and/or the maxilla. Extreme care should be taken when applying devices bi-laterally to avoid opposing vectors. When using bi-lateral devices, they should be placed as close as possible to parallel the mid-sagittal plane. Anticipated complex movement should be planned preoperatively with the use of stereo lithographic models.

2. Correct selection of the distractor is extremely important. The potential for a successful outcome is increased by the selection of the proper size, shape and design of the distractor. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of distractors. Metallic internal distraction devices cannot withstand activity levels and/or loads equal to those placed on normal, healthy bone.

3. Distraction devices can fracture if excessive force is applied to the activation mechanism. The surgeon should advise the patient of the proper rate, rhythm, and direction for distraction activation to avoid distractor fracture.

4. Corrosion. Implanting metals and alloys in the human body subjects them to a constant changing environment of salts, acids and alkalis, which can cause corrosion. Putting dissimilar metals in contact with each other can accelerate the corrosion process, which in turn may enhance fatigue fracture of implants. Thus, every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws in the distractor. Additionally, the raw materials, manufacturing processes, or quality control procedures of other implant manufacturers cannot be monitored by KLS Martin®L.P. Therefore, we cannot advocate mixing implants manufactured by KLS Martin® L.P. with those of substitute manufacturers.

5. Pin Placement. Fixation pins utilized to secure the Rigid External Distractor (R.E.D., R.E.D. II) can penetrate the cranial bone if excessive force is applied. Surgeons should consult neurosurgery for assistance in placing the head frame to prevent cranial penetration of fixation pins. Surgeons should limit patient's activity to appropriate levels to prevent injury due to contact while wearing the R.E.D. or if the activator is turned in the wrong direction.

PRECAUTIONS

1. **Surgical implants must never be reused.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage. The label on the packing shows an ID number. It is advisable to attach the ID number to the patient's record so that manufacturing lot codes can be traced from a particular implant.

2. **Correct handling of this implant is extremely important.** Contouring or bending any part of the device is not recommended and should be avoided. If the operating surgeon elects to contour the osteosynthesis plate, care must be taken to avoid sharp bends, reverse bends, bending in the area of a screw hole, or any notching or scratching of the device. The surgeon must protect the weld area of the distractor during the bending process preventing plate breakage. The body of the device should never be bent. These factors can produce internal stresses that may lead to implant breakage. Care must also be used when seating mini or micro bone screws. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws into position.

3. **Removal of distractor after consolidation phase.** Metallic implants can loosen, fracture, corrode, and migrate, cause pain or stress shield bone even after healing particularly in young active patients. It is not possible to state with certainty that an otherwise asymptomatic (titanium) device left in-situ in the long term is harmless. The removal of a non-functioning (titanium) device is desirable provided that the procedure to remove the device does not cause any undue risk to the patient. (Adequate postoperative management to avoid complications should follow implant removal).

4. **Adequately instruct the patient.** Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the distractor, and that physical activity and full weight bearing or load bearing has been implicated in premature loosening, migration, bending or fracture of internal distraction devices. The patient should understand that a metallic distractor is not as strong as normal, healthy bone and will fracture under normal weight bearing or load bearing, in the absence of complete bone healing.

POSSIBLE ADVERSE EFFECTS

1. Nonunion or delayed union which may lead to breakage of the distractor
2. Bending or fracture of the distractor
3. Metal sensitivity or allergic reaction to a foreign body
4. Decrease in bone density due to stress shielding
5. Pain, discomfort or abnormal sensations due to the presence of the device
6. Nerve damage due to surgical trauma
7. Necrosis of the bone
8. Implant loosening

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