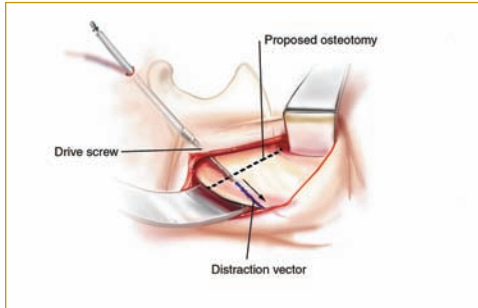


Surgical Guidelines



Plan Vector and Osteotomy Insert Drive Screw

1. Obtain 3D model if possible for planning osteotomy, locating tooth buds and identifying alveolar nerve. If 3D model is not available obtain a standard lateral cephalogram and anterior posterior cephalogram. From the lateral cephalogram, evaluate the position of the base of the tongue relative to the

mandible and oropharyngeal soft tissues and the position of the tooth buds.

2. Determine the optimal distraction vector and osteotomy design. Efforts should be made to minimize the danger of damage to the teeth, tooth buds, and inferior nerve. The osteotomy should be placed behind the molars to allow room for anchorage. Given the limited available bone in infants for screw application, accurate distractor placement and anchorage is essential.

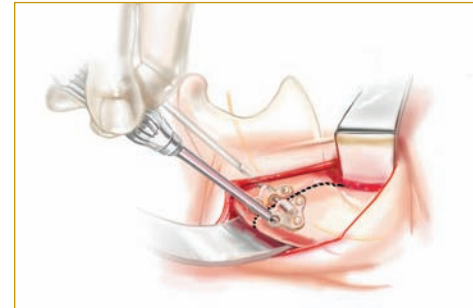
Tips: The 3D model mentioned above may be used for planning the distraction vector and device placement as well as for intra-operative plate contouring. Alternatively, templates of the distraction plates are included in the LactoSorb® Expansion tray and may be used to help with contouring and shaping.

3. Typically, a small incision, approximately 2.0 cm below the angle of the mandible is made to allow for dissection under the platysma and retraction of the marginal mandibular nerve while exposing the ramus angle and body of the mandible in the subperiosteal plane. Scissor dissection below the level of the platysma is performed until the inferior border of the mandible is reached. The marginal mandibular nerve is retracted with the platysma and periosteum.

4. Limited subperiosteal dissection is carried out until enough of the mandible is denuded to place the mandibular infant device.

5. The optimal distraction vector is marked on the mandible.

6. The distraction drive screw is introduced through a separate pre- or postauricular incision, after determining the desired distraction vector. It is placed in the subperiosteal plane and brought through the skin well away from the facial nerve. It should be passed in the same direction as the vector.



Thread Drive Screw into Distractor Fixate Distractor to Bone

7. The drive screw is threaded through the proximal plate into the receiving compartment of the distal plate leaving 4.0 mm between the proximal and distal plates for the osteotomy.

8. LactoSorb® screws and appropriate instrumentation are used to secure the

mandible distractors to the bone. Experience with the LactoSorb® plating system is important.

Tips: The distraction plates are designed for use with the 1.5 mm screws, thus requiring the appropriate drills, taps, or self-drilling taps for the selected screw length, as well as the appropriate screw blade. A complete LactoSorb® SE instrument set should be available.

The Lorenz Power Driver™ is a battery-operated tool that lends itself well to the distraction procedure by providing low speed drilling and tapping (using the self-drilling tap) as well as convenience and timesavings. A high-speed drill is not recommended for this procedure.

If over drilling occurs, 2.0 mm screws may be substituted for 1.5 mm screws to allow for additional anchorage. If this occurs, it is necessary to drill and tap through the existing 1.5 mm hole in the distractor plate for the 2.0 mm screw. Whenever possible, bicortical screws are applied to maximize fixation.

Contouring and shaping the LactoSorb® mandible distractors are possible with an approved LactoSorb® water bath. It is important that the internal threads of the distraction plates are not compromised during heating. Therefore, it is necessary to ensure that either the stainless steel threaded insert or drive screw is threaded into the plates during heating to maintain the shape of the threads and hole diameter. Specific instructions for heating should be followed.

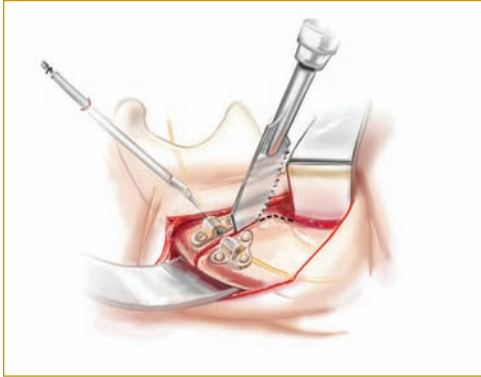
Cutting the plates is possible with the cutting tip on the LactoSorb® heat pen. LactoSorb® material that protrudes beyond the edges of the bone and does not have a screw placed in it is considered superfluous and should be trimmed as it may push against the skin and compromise the healing process.

LactoSorb® Expansion devices are for patients up to 2 years of age

This reference guide is presented to demonstrate the techniques utilized by Fernando D. Burstein, M.D., F.A.C.S., Plastic Surgery, Children's Healthcare of Atlanta

Information contained in this guide is intended to serve as a reference only and is intended for Biomet Microfixation distributors and sales associates for training purposes. It is not intended for distribution to surgeons or patients.

Surgical Guidelines

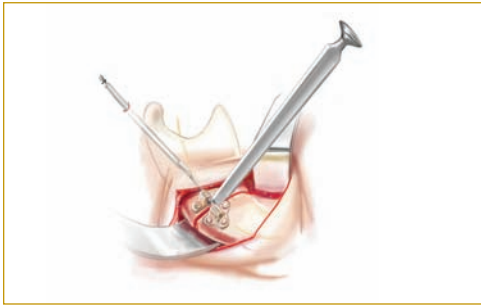


Back out Drive Screw to Proximal Plate Begin Osteotomy

9. Once the distraction plates are secured, the drive screw is then backed out of the distal plate to the proximal plate using the Patient Driver. This should be done carefully to avoid completely unthreading the drive screw from the proximal plate.

Tips: The Patient Driver is required to activate and turn the drive screws. It is important to keep the flexible drive screw extension as straight as possible when using the Patient Driver.

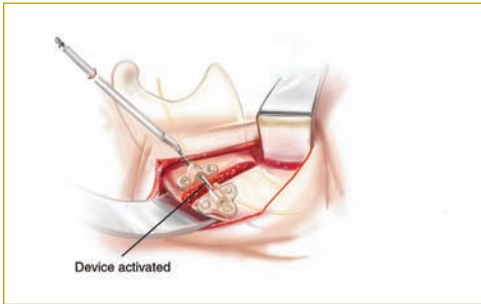
10. A monocortical circumferential osteotomy is performed. The tip of a thin reciprocating saw is used to cut through just the outer cortex of the bone.



Complete Osteotomy

11. The osteotomy is carefully completed with a 4.0 mm osteotome and a bone spreader.

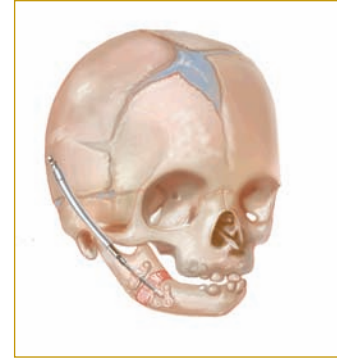
12. With the neurovascular bundle preserved, care is taken to slowly divide the cortices circumferentially, gently spreading the bone edges.



Rethread Drive Screw through Proximal Plate

13. Once the osteotomy has been completed, the drive screw is threaded through the proximal plate into the receiving compartment of the distal plate and the device is activated at least 5.0 mm to ensure a complete osteotomy. Once the distractor is confirmed to have free movement, it is brought back to bone-to-bone contact.

14. Always check the security of the device before closing. In bi-lateral cases, it is necessary to recheck the security of the first device to ensure the drive screw did not disengage while performing the osteotomy on the contra-lateral side.



Distraction Protocol

15. A distraction rate of 2.0 mm per day is recommended after a 48-hour latency period.

16. At the end of consolidation, typically 4 to 6 weeks, the drive screw is removed. This is done in the office and no anesthetic or special instrumentation is required. The proximal and distal plates will resorb within approximately one year from the time of placement.

Device Shapes Available



Small



Medium



Large

Available in standard and threadlocking. Uses 1.5mm screws



L-Shaped Left



L-Shaped Right

Available only in threadlocking. Uses 2.0mm screws

Devices shown actual size