

LactoSorb® Distraction

Resorbable Distraction



BIOMET[®]
MICROFIXATION
Anticipate. Innovate.™

A New Application for a Proven Technology

Anticipation and Innovation. These two qualities have made Biomet Microfixation an industry leader. Founded by Walter Lorenz more than thirty years ago, Biomet Microfixation offers instrumentation, plating systems and related products for a wide range of surgical procedures. Among our most widely known and used products is LactoSorb SE. First introduced in 1996, The LactoSorb plating system represented a major step forward in craniomaxillofacial fixation. Over ten years and 50,000 cases later with no change to the original formulation, the LactoSorb plating system remains the most thoroughly proven product of its kind.

Now, the benefits of this proven resorbable plating system have been incorporated into the design of a new device for infant mandibular distraction. The new LactoSorb Distraction device provides a more efficient alternative to titanium distraction for patients up to 2 years of age. Featuring resorbable plates and a flexible drive screw extension, the LactoSorb Distraction devices offer a wide range of advantages to both surgeons and patients

Advantages

- **Requires only a single surgical procedure** - resorbable plates and screws eliminate the need for a device removal surgery and are completely resorbed within 12 months.
- **Precise plate adaption** - plates can be thermally contoured to fit any shape mandible.
- **High patient acceptance** - flexible drive screw extension allows for increased patient comfort during the distraction process.
- **Convenient drive screw removal** - removal of the drive screw after consolidation is a convenient in-office procedure.
- **No long-term hardware problems** - LactoSorb plates and screws are completely resorbed within 12 months.
- **Lower overall costs** - elimination of device removal surgery reduces overall procedure cost.

Indications*

- Pierre Robin Sequence
- Sticklers Syndrome
- Craniofacial Microsomia
- Isolated Mandibular Hypoplasia

*For patients up to 2 years of age.



Clinical Photos

Components

Clinical Photos: Case A



Before expansion

Clinical Photos: Case B



Before expansion, device in place



2 years after expansion



After expansion, at time of device removal

3-week old female with Pierre Robin Sequence. Patient underwent bilateral mandibular osteotomies with placement of the medium mandibular infant devices. Approximately 20mm of expansion was achieved.

6-week old female with Sticklers Syndrome. Patient underwent bilateral mandibular osteotomies with placement of the medium mandibular infant devices. Approximately 20mm of expansion was achieved.

Photos are courtesy of Dr. Fernando Burstein, Children's Healthcare of Atlanta

Anatomical Models

An anatomical model of the patient's mandible can be made to facilitate surgical planning. This model can be sterilized and used in the OR to shape the distractor prior to placing it on the patient.* Contact Biomet Microfixation for a CT scanning protocol.

*The threaded insert (packaged with the distractor) or the drive screw must be threaded into the distractor when heating.

ClearView® Anatomical Models

Part #	Description
01-3294	Pediatric, Full Skull ClearView® Model
01-3292	Pediatric, Full Mandible ClearView® Model

Selective coloration (i.e. teeth, nerves) is available upon request.



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Patient Distraction Drivers*



Ratcheting Patient Driver
SP-1918

Ratcheting feature designed to prevent patients/parents from activating the drive screw in the wrong direction



Patient Driver
01-3205 OC

Surgeon Distraction Driver*



Surgeon Distraction Driver
SP-1919

Activates drive screws in either direction. Intended for use in the OR to be able to return the proximal plate to bony contact after checking for a complete osteotomy

Tip of Ratcheting Patient Driver (SP-1918) and Surgeon Distraction Driver (SP-1919) holds onto the end of the drive-screw.

Torque Limited drivers shear off @30in-oz \approx 30lbf
1 turn = 0.5mm

Additional Items**



Power Driver
50-1000

Using the Power Driver with the self-drilling tap ensures bone preservation and maximum screw purchase

Battery (Sterile)
50-1010



Water Bath
120v 915-4005
240v 915-4010

Sterile Drape
915-3006



Air Activated Heat Source
Single 915-2055
5-Pack 915-2057



1.5 Self-Drilling Tap
for Power Driver™
915-2185

2.0 Self-Drilling Tap
for Power Driver™
915-2175



LS SE Heat Contouring Pen
915-3100



LactoSorb Distraction Tray*
915-3350

*1.5/2.0 LactoSorb® Instrument Set is necessary for all procedures as it contains the appropriate drills, taps, and drivers needed to implant the LactoSorb® screws. Please refer to the LactoSorb® brochure for a complete listing of all LactoSorb® screws and instrumentation.

**All items not to scale.

Distractors



Small Thread-Locking
Mandibular Infant
SP-1688

*Designed for smallest neonates
and emergent distraction.*
Template 914-3320



Small 5/4 Hole Thread-Locking
Mandibular Infant
SP-1944

*Designed for infants with slightly larger mandibles.
Provides more hole options*
Template SP-1944-T



L-Shaped Thread-Locking
Mandibular Infant, Right
SP-1779

*Designed for infants with non-linear mandibles
(uses 2.0mm screws)*
Template SP-1778-T



Medium Thread-Locking
Mandibular infant
SP-1689

Designed for irregularly shaped mandibles
Template 914-3330



Large Thread-Locking
Mandibular-infant
SP-1690

*Designed for large infants
up to 2 years of age*
Template 914-3110



L-Shaped Thread-Locking
Mandibular Infant, Left
SP-1778

*Designed for infants with non-linear mandibles
(uses 2.0mm screws)*
Template SP -1778-T



Drive Screws w/ Attached Flex Tube

Part #	Description
SP-1328	15mm Drive Screw w/ 35mm Flex tube
SP-1329	20mm Drive Screw w/ 35mm Flex tube
SP-1330	25mm Drive Screw w/ 35mm Flex tube
SP-1883	15mm Drive Screw w/ 65mm Flex tube
SP-1884	20mm Drive Screw w/ 65mm Flex tube
SP-1885	25mm Drive Screw w/ 65mm Flex tube

Recommended Bone Screws

For all Distractors EXCEPT L-Shape



Part #	Description
915-2317	1.5 x 6mm Hex Head (2-pack)
915-2318	1.5 x 7mm Hex Head (2-pack)
915-2319	1.5 x 8mm Hex Head (2-pack)
915-2301	Emergency 2.0 x 7mm Hex Head (2-pack)
915-2302	Emergency 2.0 x 9mm Hex Head (2-pack)

For L-Shape Distractors

Part #	Description
915-2301	2.0 x 7mm Hex Head (2-pack)
915-2302	2.0 x 9mm Hex Head (2-pack)
915-2308	Emergency 2.5 x 7mm Hex Head (2-pack)
915-2309	Emergency 2.5 x 9mm Hex Head (2-pack)

What fascinates you about the body is also what drives us. That's why we're always pushing the boundaries of engineering to make products that help you keep the human form as glorious as it was intended. To learn more about our breadth of products, call 800-874-7711 or visit us online at biometmicrofixation.com. We'd love to join you in a conversation about the future.



For more information on LactoSorb® Expansion, please contact us at:

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