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

Clinical Photos: Case A
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.

Clinical Photos: Case B
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

Components

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

<table>
<thead>
<tr>
<th>Part #</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>01-3294</td>
<td>Pediatric, Full Skull ClearView® Model</td>
</tr>
<tr>
<td>01-3292</td>
<td>Pediatric, Full Mandible ClearView® Model</td>
</tr>
</tbody>
</table>

Selective coloration (i.e. teeth, nerves) is available upon request.
**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 @ 30 in-oz = 30 lbf  
1 turn = 0.5 mm

**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

**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

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

**Sterile Drape**  
915-3006

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

*1.5/2.0 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

- **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, Right**
  - SP-1779
  - Designed for infants with non-linear mandibles
  - Template SP-1778-T

- **L-Shaped Thread-Locking Mandibular Infant, Left**
  - SP-1778
  - Designed for infants with non-linear mandibles
  - Template SP-1778-T

**Drive Screws w/ Attached Flex Tube**

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<tr>
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<tbody>
<tr>
<td>SP-1328</td>
<td>15mm Drive Screw w/ 35mm Flex tube</td>
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<tr>
<td>SP-1329</td>
<td>20mm Drive Screw w/ 35mm Flex tube</td>
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<tr>
<td>SP-1330</td>
<td>25mm Drive Screw w/ 35mm Flex tube</td>
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<tr>
<td>SP-1883</td>
<td>15mm Drive Screw w/ 65mm Flex tube</td>
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<tr>
<td>SP-1884</td>
<td>20mm Drive Screw w/ 65mm Flex tube</td>
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<tr>
<td>SP-1885</td>
<td>25mm Drive Screw w/ 65mm Flex tube</td>
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**Recommended Bone Screws**

For all Distractors EXCEPT L-Shape

<table>
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<tr>
<th>Part #</th>
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<tbody>
<tr>
<td>915-2317</td>
<td>1.5 x 6mm Hex Head (2-pack)</td>
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<tr>
<td>915-2318</td>
<td>1.5 x 7mm Hex Head (2-pack)</td>
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<tr>
<td>915-2319</td>
<td>1.5 x 8mm Hex Head (2-pack)</td>
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<tr>
<td>915-2301</td>
<td>Emergency 2.0 x 7mm Hex Head (2-pack)</td>
</tr>
<tr>
<td>915-2302</td>
<td>Emergency 2.0 x 9mm Hex Head (2-pack)</td>
</tr>
</tbody>
</table>

For L-Shape Distractors

<table>
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<tr>
<td>915-2301</td>
<td>2.0 x 7mm Hex Head (2-pack)</td>
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<td>2.0 x 9mm Hex Head (2-pack)</td>
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<td>915-2308</td>
<td>Emergency 2.5 x 7mm Hex Head (2-pack)</td>
</tr>
<tr>
<td>915-2309</td>
<td>Emergency 2.5 x 9mm Hex Head (2-pack)</td>
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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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All surgeries carry risks. For additional information on these risks and warnings, please see package insert or visit our web site at www.biometmicrofixation.com or call 1-800-874-7711.

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