W.LORENZ BLUEDEVICE Multi-Vector Distraction

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AN ADVANCEMENT IN MULTI-VECTOR DISTRACTION



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MID-FACE ADVANCEMENT

istraction osteogenesis is gaining wider use as a treatment for patients with craniofacial anomalies requiring mid-face advancement. The Blue Device from W. Lorenz Surgical offers a system for achieving superior consistency and accuracy in the correction of craniofacial deficiencies.

A multi-vector distraction system, the Blue Device provides a wide range of adjustments during surgery and throughout the mid-face advancement period.

Features include a vertical rod with anterior/posterior vector control, pre-threaded screw holes for enhanced stability, and a wide variety of plates that can eliminate the need for a dental splint. In addition, the lightweight aluminum halo is designed with non-linear screw-hole options to offer greater latitude in placement.



Indications

Suitable for patients two years old and up, the Blue Device is indicated for the following:

- Craniofacial Anomalies
- LeFort I, II, or III Mid-face Asymmetry
- Maxillary and Mid-face Skeletal Hypoplasia
- Mono-bloc Advancement

The Blue Device is especially useful for patients who are unsuitable for conventional orthognathic surgery. Even acute deformities may be treated, most without the need for bone grafting or internal-fixation hardware.



Easier For The Surgeon—And The Patient.

Providing a rigid force for distraction, the Blue Device is easily applied at the time the osteotomy is performed. It gives the surgeon a wide range of adjustability in distraction force and vector control. Removal is simple and can be performed in a clinical or office setting. using only local anesthesia or light sedation, in most cases.

A Device Of A Different Color.

The Blue Device gives surgeons an invaluable tool in treating craniofacial anomalies. It gives patients hope for a happier future and a better quality of life.

For complete information about the Blue Device, contact W. Lorenz Surgical or visit <u>www.lorenzsurgical.com</u> today.





THE BLUE DEVICE

HALO PLACEMENT GUIDELINES

HALO PLACEMENT



Halo Adjustment:

Align the halo parallel to the Frankfurt plane. Adjust the transverse width of the device to allow the lateral components to be just beyond the scalp skin or hair by 1-2cm on both sides. Hand tighten the cranial screws in a symmetrical fashion on both sides, using a minimum of three screws per side.



Cranial Screw Tightening:

Screw placement should be within the hairline allowing space between the screws to optimize stability. Final tightening of the cranial screws are done with the large hex head driver (01-3558). * An optional torque wrench is available: 01-3660 (wrench), 01-3563 (torque wrench driver)



Note: The device placement guidelines are to be used solely for the purpose of aiding the surgeon in the handling of the product and is not intended to be utilized as a surgical technique.

VECTOR ADJUSTMENT



A/P Control:

The anterior/posterior vector of the carbon rod can be controlled using the large hex head driver (01-3558). An optional solid stem (01-3552) is available for surgeon preference.





Crossbar Adjustment: The small hex head driver (01-3557)

is used to align the crossbars to obtain ideal vector control. Wire is then used to connect the crossbar assembly to the midface plates and can be precisely manipulated throughout the distraction period.

Advancement:

The patient advancement driver (01-3556) is placed directly onto the crossbar assembly for activation. The driver is turned clockwise one full rotation to achieve 0.5mm of advancement. The rate and rhythm of distraction should be determined by the surgeon.







Crossbar Assembly

BLUE Recommendations for LeFort II, III, or MonoBloc Procedures		
Qty Set	Part #	Description
1	01-3550	Lorenz BLUE Device (includes 1 halo, 1 crossbar assembly and 1 carbon rod)
1	01-3551	Crossbar Assembly
8-10	99-3570	45mm Cranial Screw
4	99-3581	2.0 x 15mm Cross-Drive Threaded Fixation Screw
4	99-3582	2.0 x 25mm Cross-Drive Threaded Fixation Screw
2	01-3585	1.5mm 6-Hole Curved Attachment Plate
2	01-3580	1.5mm 5-Hole Straight Attachment Plate
2	01-3584	2.0mm 4-Hole LeFort I Attachment Plate
2	01-3586	2.0mm Right LeFort I Attachment Plate
2	01-3587	2.0mm Left LeFort I Attachment Plate
5/pk.	95-6205	2.0 x 5mm HT Self Drilling Cross-Drive Screw
5/pk.	95-6207	2.0 x 7mm HT Self Drilling Cross-Drive Screw
2	01-3556	Patient Advancement Driver
(2) 5/pk.	95-6105	1.5 x 5mm HT Self Drilling Cross-Drive Screw
(2) 5/pk.	95-6107	1.5 x 5mm HT Self Drilling Cross-Drive Screw
10/pk.	01-5924	Pre-Stretched Wire, 24 Gauge
2	01-3557	Small Hex Head Driver
2	01-3558	Large Hex Head Driver
2	01-7600	2.0/2.4mm Blue Screwdriver Handle
Optional	01-3552	Solid Center Stem
Optional	01-3590	180mm Carbon Rod
Optional	99-3572	65mm Cranial Screw
Optional	99-3575	45mm Positioning Screw

BLUE Recommendations for LeFort I Procedure			
Qty Set	Part #	Description	
1	01-3550	Lorenz BLUE Device (includes 1 halo, 1 crossbar assembly and 1 carbon rod)	
8-10	99-3570	45mm Cranial Screw	
2	01-3584	2.0mm 4-Hole LeFort I Attachment Plate	
2	01-3586	2.0mm Right LeFort I Attachment Plate	
2	01-3587	2.0mm Left LeFort I Attachment Plate	
2	01-3556	Patient Advancement Driver	
5/pk.	95-6205	2.0 x 5mm HT Self Drilling Cross-Drive Screw	
5/pk.	95-6207	2.0 x 7mm HT Self Drilling Cross-Drive Screw	
2	01-3557	Small Hex Head Driver	
2	01-3558	Large Hex Head Driver	
2	01-7600	2.0/2.4mm Blue Screwdriver Handle	
10/pk.	01-5924	Pre-Stretched Wire, 24 Gauge	
Optional	01-3552	Solid Center Stem	
Optional	01-3590	180mm Carbon Rod	
Optional	99-3572	65mm Cranial Screw	
Optional	99-3575	45mm Positioning Screw	

A 1.5/2.0 titanium set is necessary for all procedures.



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ABOUT THE COMPANY

W. Lorenz Surgical is a wholly owned subsidiary of Biomet, Inc. specializing in the design, manufacturing, and marketing of implants and instruments for Oral and Maxillofacial, Plastic, Neuro, and ENT surgical specialties. W. Lorenz currently distributes products in more than 40 countries. The Common Shares of Biomet, Inc. are traded on the Nasdaq Stock market (Trading Symbol: BMET).



Call today to request additional information on Distraction products or visit us on the web at <u>www.lorenzsurgical.com</u>

The following literature is available:



LS Expansion 00-2211ea



Vertical Distraction 00-2208ea



1.5/2.0 CMF Brochure 00-2121ea



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As the manufacturer of this device, Walter Lorenz Surgical does not practice medicine and does not recommend this device for use on any specific individual patient. The surgeon who performs any implant procedure must determine the appropriate device and surgical procedure for each individual patient.