stryker®

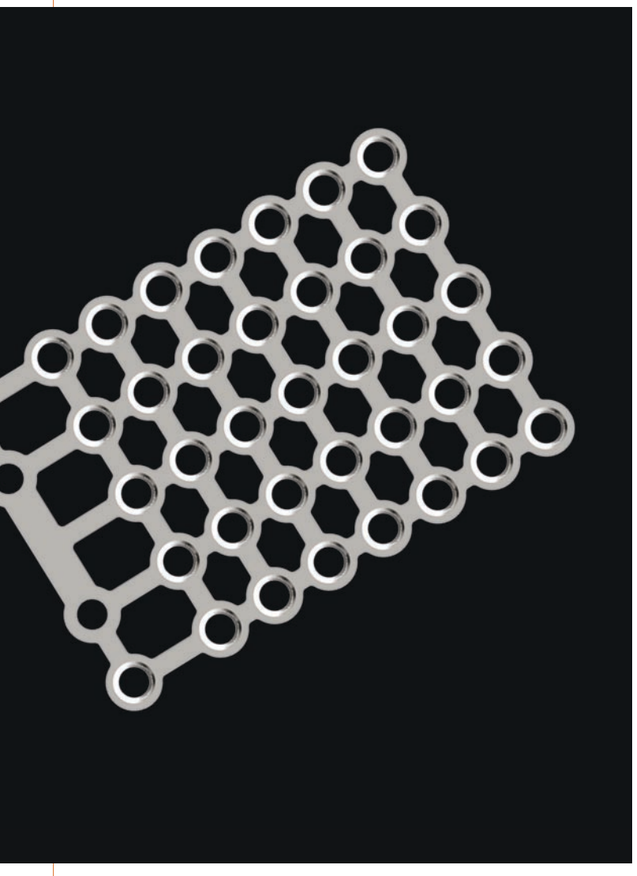
Craniomaxillofacial

Leibinger

Advance
Internal Midface Distraction System
Technical Guide

Product Innovation that Endures

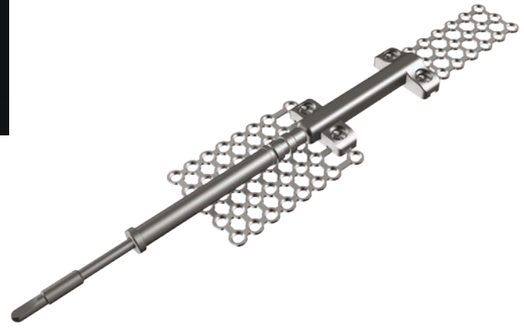
For over half a century, Stryker has been developing products based on the expressed needs of leading practitioners.



Our products are derived from a close working partnership with surgeons, physicians and healthcare experts from the entire spectrum of the healthcare field. That has been the basis of success for nearly eight decades and will continue to foster success into the future. Stryker is one of the preeminent medical products and services companies in the world. Our focus is on the fundamentals and a relentless attention to details of not just design and manufacture, but also of application and outcomes. The output of our work supports the skills and talents of the medical profession. And because of this, we set our standards high and work to surpass our own ambitious goals.

To Make a Difference

We know our efforts make a difference. We also know that everything can be improved and we constantly seek to do just that. We strive to make our customers successful by working on their behalf. We partner with surgeons and medical professionals who are leaders in their field to advance medical care.



Features & Benefits

Device Description

The Internal Midface Distraction System is a distraction system consisting of the following major components: distractor which incorporates connection screws for the plates, a flexible removable activation rod, plates, bone screws and an activation key.

Indications for Use

Treatment of cranial or midfacial conditions for which reconstructive osteotomy and segment advancement are indicated. The indications include conditions such as syndromic craniosynostosis (e.g. Apert, Crouzon, Pfeiffer, Antley Bixler) and midfacial retrusion. The device is intended to provide temporary stabilization and gradual lengthening of facial bones of the cranium and midface. It is not intended to be used in the mandible.

Intended Use

Treatment of cranial or midfacial conditions for which reconstructive osteotomy and segment advancement are indicated.

Features

- Internal, buried subcutaneous application
- Modular system with a variety of plate options to permit surgeons flexibility in the OR
- Type II anodization of plates and distractor that may reduce the incidence of tissue adhesion
- Activation Rod that may be removed upon completion of distraction
- Utilization of Leibinger Universal 2 1.7 MidFace screws and instruments

Step by Step

Step 1

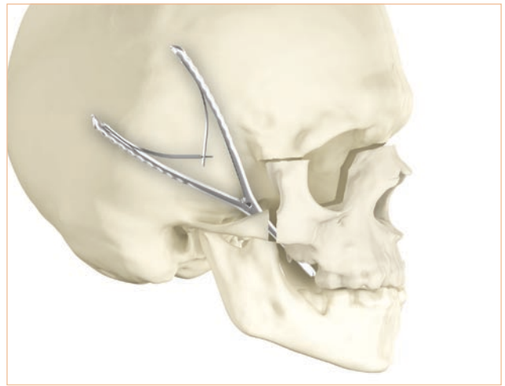
Incision and Exposure:

Perform a coronal incision and carry out a standard Le Fort III dissection.

Performing the Osteotomy:

Perform a standard LeFort III osteotomy and downfracture (figs.1 and 2). It's imperative to fully mobilize the Le Fort III segment.

(fig. 1)



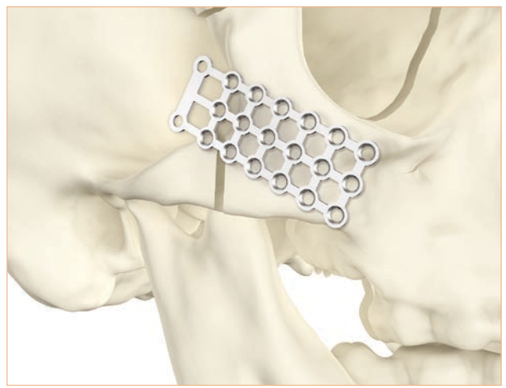
(fig. 2)

Step 2

Determination of the distraction vector:

1. The vector of distraction can be varied from direct horizontal to oblique, depending on the need for both sagittal and vertical LeFort III advancement.

2. Lay out the uncut mesh on the skeleton to obtain optimal mounting position and desired vector (fig. 3).



(fig. 3)

Step 3

Note:

Test the distraction device by running it out to full extension before implantation.

As an alternative the entire distractor may be assembled on a back table and placed as a single device.

Device assembly and placement:

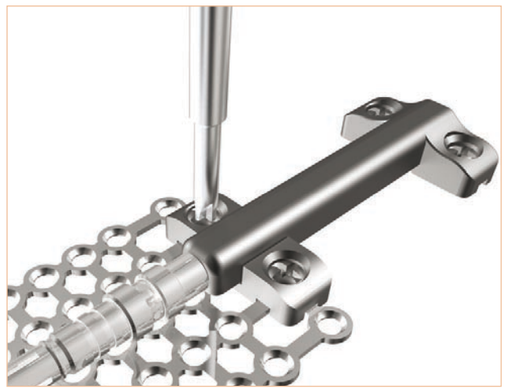
1. Rigidly fixate a properly contoured 3 x 7 Plate to the lateral orbital rim, inferior orbital rim, and body of the zygoma using 1.7 screws.

The Plate can be cut to conform to the inferior and lateral orbital rim, maintaining as broad a surface area as possible along the body of the zygoma. A minimum of 6 screws should be used (figs. 4 and 5).

(fig. 4)

(fig. 5)

2. Attach a 5 x 8 hole plate to the distraction device using the screws that are integrated in the distractor (fig. 6).



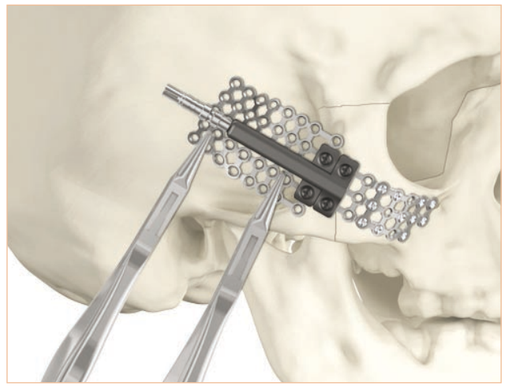
(fig. 6)

Step 3 continued

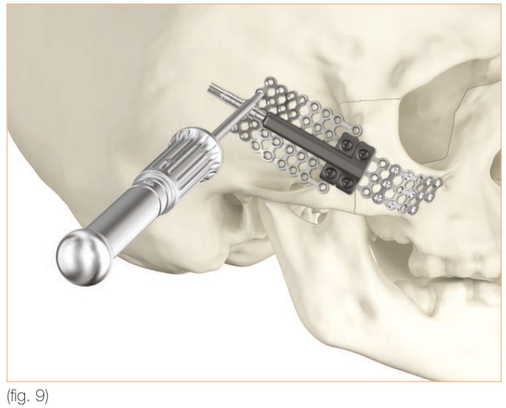
3. Attach the distraction device, already assembled with the posterior mesh, to the anterior 3 x 7 plate (fig. 7).

(fig. 7)

4. Contour the posterior plate and attach it to the temporal bone with at least eight 1.7 mm screws. Ensure that an adequate amount of screws, extended over a broad area, are implanted on the posterior plate to provide a firm base to distract against. The screw length in this region will vary, depending on the age of the patient (figs. 8 and 9).



(fig. 8)

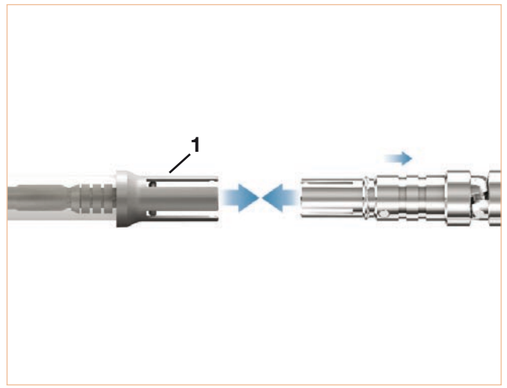


(fig. 9)

5. Repeat the procedure on the opposite side.

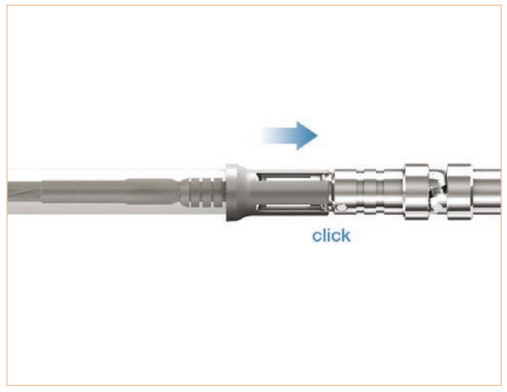
Connect the distractor with the activation rod

6. Retract locking sleeve (1) and insert activation rod to distractor frame coupling (fig. 10) until an audible “click” verifies a first connection.



(fig. 10)

7. Slide the locking sleeve forward until an audible “click” verifies a secure final connection (fig. 11).



(fig. 11)

Step 4

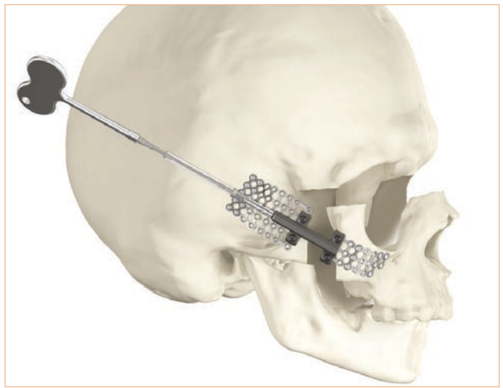
Device inspection

1. Test the distraction devices to ensure that distraction can be effectively carried out and the segment has been effectively mobilized.

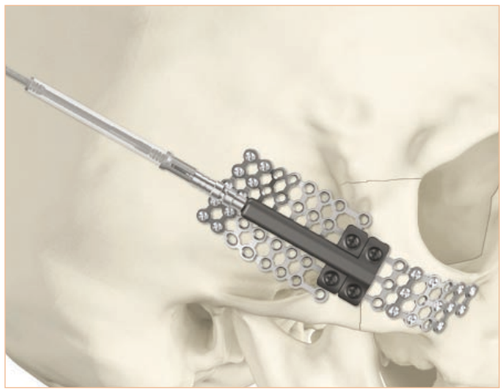
Full activation of the device is required to assure the intended goal will be reached, turning the activation rods either simultaneously to activate the distraction device, or 1 mm at a time to prevent undue torque on the contralateral side.

If bending or malfunction occurs, identify the site and correct before closing.

2. If distraction proceeds well, return the device to the starting position (figs. 12 and 13).



(fig. 12)



(fig. 13)

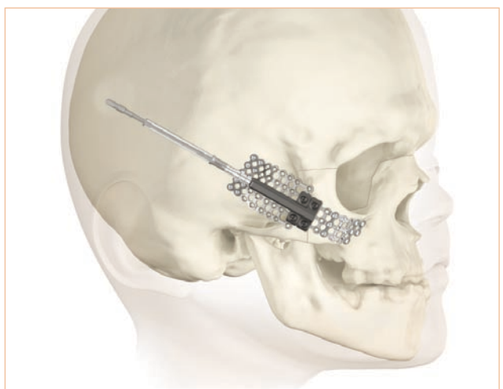
Step 5

Closure

Close the coronal incision in a standard fashion and apply antibiotic ointment around the wound (fig 14).

Note:

If removal of the activation rod at the end of the distraction phase is desired, ensure that the activation rod incision is positioned so that an adequate amount of the outer sleeve is exposed. This is due to the activation rod becoming shorter equal to the amount of distraction during the activation process.



(fig. 14)

Step 6

Distraction Phase

One full turn (360°) of the activation rod in the clockwise direction results in 0.5 mm of advancement. Definite statements about the rate and rhythm of distraction distance are not possible. Distractors that have been used successfully were manipulated at a rate of 1 mm of distraction per day with two daily manipulations of 0.5 mm. Publications and lectures indicate that rate and rhythm of distraction can vary under certain conditions.

Disassembly of the activation Rod

Upon completion of distraction, the activation rod may be disassembled. This has to be performed by a surgeon. For disassembly, secure the end of the activation rod (where the activation key attaches) and hold in place. While still holding the inner rod in place, grasp the outer tube (plastic) and pull back. An audible click signifies disconnection. Activation rod may now be removed.

Step 7

Removal of the distractor

The distractor is a temporary implant. The distractor should be removed when the surgeon determines sufficient bone consolidation.

Important Notice:

The materials contained in this booklet have been provided for general education information purposes only. The information contained in this booklet cannot and should not replace the independent medical judgement of the treating physician.

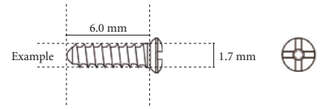
As a manufacturer, Stryker does not provide medical advice or services and does not recommend specific technique or instruction. It is always the responsibility of the treating physician to determine the appropriate treatment and technique, based on the physician's medical knowledge and the individual circumstances of the particular case. It is also the treating physician's sole responsibility to inform the patient about potential risks, complications, and benefits of certain products and procedures. In addition, the information contained herein is not intended to and should not replace the instructions-for-use provided with the Leibinger Advance Internal Midface Distraction System. The treating physician should review the instructions-for-use in their entirety before using any Stryker product because the materials contained herein may not include all relevant potential risks and complications.

Ordering Information

Distractor Frame and Components

	REF	Description
	**62-00420**	Midface Distractor, 20 mm
	**62-00435**	Midface Distractor, 35 mm
	**62-00060**	Activation Key
	**62-00080**	Activation Rod Rigid, Short
	**62-00082**	Activation Rod Flexible
	**62-00081**	Activation Rod Flexible, Short

Bone Screws, Cross Pin



1.7 mm Self Tapping

1.7 x 8 mm screw / illustrated scale 2:1

REF Non-Sterile 5/ea. Pack	Length
50-17003	1.7 x 3 mm
50-17004	1.7 x 4 mm
50-17005	1.7 x 5 mm
50-17006	1.7 x 6 mm
50-17007	1.7 x 7 mm
50-17008	1.7 x 8 mm

1.7 mm Self Drilling

1.7 x 3 mm screw / illustrated scale 2:1

REF Non-Sterile 5/ea. Pack	Length
50-17903	1.7 x 3 mm
50-17904	1.7 x 4 mm
50-17905	1.7 x 5 mm
50-17906	1.7 x 6 mm

1.9 mm Self Tapping (Emergency)

1.9 x 7 mm screw / illustrated scale 2:1

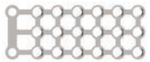
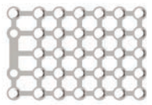
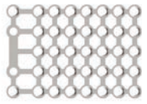
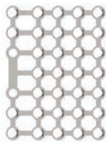
REF Non-Sterile 5/ea. Pack	Length
50-19003	1.9 x 3 mm
50-19005	1.9 x 5 mm

Twist Drills

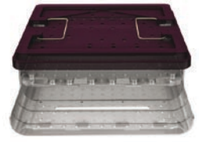
	REF	Description
	**60-13505**	1.35x50mm, 5mm WL
	**60-14008**	1.4x54mm, 8mm WL

Ordering Information

Distraction Plates

	REF	Description
	**54-00134**	Distraction Plate 3x4, Regular
	**54-00034**	Distraction Plate 3x4, Narrow
	**54-00137**	Distraction Plate 3x7, Regular
	**54-00038**	Distraction Plate 3x8, Narrow
	**54-00157**	Distraction Plate 5x7, Regular
	**54-00058**	Distraction Plate 5x8, Narrow
	**54-00175**	Distraction Plate 7x5, Regular
	**54-00075**	Distraction Plate 7x5, Narrow

Container / Module / Tray

	REF	Description
	**29-17150**	Midface Distraction Implant Module
	**50-00306**	Description Shield “MidfaceDistractor”
	29-13071	Midface Distraction Instrument Tray
	**29-15012** **29-13017**	Half Size Sterilization Container Half Size Lid Distraction

Instruments

	REF	Description
	**62-20285**	Screwdriver Handle, Metal
	62-12170	Screwdriver Blade
	**62-20295**	**Optional Screwdriver Handle:** Screwdriver Handle, Revolving/Rigid

Ordering Information

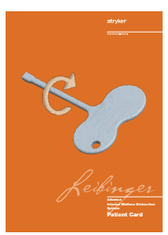
Instruments

REF	Description
01-08110	Plate Holding Forceps, Angled, Standard
	Optional Forceps:
01-08115	Plate Holding Forceps, Angled, Locking
62-18110	Plate Holding Forceps, Straight, Standard
01-08105	Plate Holding Forceps, Straight, Locking
01-08100	Plate Holding Forceps, Straight, Standard

REF	Description
36-00726	Plate Bending Pliers

REF	Description
62-18330	In-Situ Cutter

Patient Card



REF	Description
90-20107	Patient Card Distraction

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Literature Number 9410-400-133 Rev. None

Stryker Craniomaxillofacial
Kalamazoo, MI 49002 USA
t: 269 324 5346
toll free: 800 962 6558
f: 877 648 7114

www.stryker.com