Rigid External Distraction

*RED II System*
Most patients showing midfacial hypoplasia are usually preoperated. Often, a large amount of scar tissue formation is limiting the success of any distraction procedure ending up in compromising results. There the RED II is definitely setting new standards. It is extremely efficient in bringing the bone segments in the desired position and simultaneously to keep them there for bone consolidation. As all important components are external, the important vector planning can be corrected at any time. A wide selection of accessories is at your disposition to match any clinical task.
With the introduction of the RED frame back in 1995 KLS Martin was a pioneer company to offer an external halo frame for the correction of severe maxillary hypoplasia mostly associated with Cleft Lip and Palate (CLP) patients.

The incredible successful treatment outcomes led to a complete redesign of the now called RED II frame back in 2000. Since then, the device has been lighter, but simultaneously stronger and more flexible in its application. Over the years the increasing demand of doctors for patient specific solutions led to a bunch of new products. It is the aim of this leaflet to introduce all these modifications to the public.

Product benefits

■ Completely adjustable for any midfacial hypoplasia patient
■ Possibility to perform Le Fort I, II, III and monobloc distraction procedures
■ Force application only on the affected treatment region
■ External distractor – easy definition and correction of all vectors at any time
■ Unlimited distraction distances
■ Very strong distraction force, excellent retention potential
■ Easy and quick assembly in the OR as well as removal in the office or clinical setting
■ Ability to treat patients with severe skeletal deficiencies who are not amenable to, or would receive comprised results with conventional orthognathic surgery
■ No bone grafting required – no uncalculable recidiva involved
OVERVIEW: The system components

Rigid External Distraction
RED II System

For the usual Le Fort I procedure, 51-580-00-04 is already providing most of the items needed. The listing below shows you what it takes.

RED II Distraction system

<table>
<thead>
<tr>
<th>Item No.</th>
<th>RED II Distraction system, complete assembly</th>
</tr>
</thead>
<tbody>
<tr>
<td>51-580-00-04</td>
<td></td>
</tr>
</tbody>
</table>

Consisting of:

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>51-580-01-04</td>
<td>Distraction segment, left</td>
</tr>
<tr>
<td>51-575-15-04</td>
<td>2 Carbon rods, 120 mm, horizontal</td>
</tr>
<tr>
<td>51-580-05-04</td>
<td>1 Center part</td>
</tr>
<tr>
<td>51-575-16-04</td>
<td>1 Carbon rod, 150 mm, vertical</td>
</tr>
<tr>
<td>51-580-45-04</td>
<td>1 Horizontal cross bar assembly, complete with</td>
</tr>
<tr>
<td></td>
<td>horizontal cross bar + holder + 2 spindle units</td>
</tr>
<tr>
<td>51-580-02-04</td>
<td>1 Distraction segment, right</td>
</tr>
<tr>
<td>51-580-85-07</td>
<td>1 Patient screwdriver</td>
</tr>
</tbody>
</table>

To order separately:

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>51-575-90-07</td>
<td>1 Adjustment screwdriver, hexagonal</td>
</tr>
<tr>
<td>51-575-10-09</td>
<td>1 Pack Fixation screws 40 mm, 10/each or</td>
</tr>
<tr>
<td></td>
<td>1 Pack Fixation screws 55 mm, 10/each</td>
</tr>
</tbody>
</table>
### Overview: Adjustment and Set recommendation

**What do you need for which procedure?**

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit</th>
<th>Qty (per pack)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1) Must for Le Fort I and Le Fort II procedures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>51-580-00-04</td>
<td>RED II complete, also containing the patient screwdriver</td>
<td>1</td>
<td>1 piece</td>
</tr>
<tr>
<td>51-575-00-07</td>
<td>Hexagonal screwdriver (for adjustment and pin fixation)</td>
<td>1</td>
<td>1 piece</td>
</tr>
<tr>
<td>51-575-10-09</td>
<td>Fixation screws 40 mm for the adult patient</td>
<td>1</td>
<td>10 pcs.</td>
</tr>
<tr>
<td></td>
<td>or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>51-757-10-09</td>
<td>Fixation screws 55 mm for the pediatric patient</td>
<td>1</td>
<td>10 pcs.</td>
</tr>
</tbody>
</table>

**2) Connection to the occlusal level**

| Either | Intraoral splint for connecting the RED to the teeth as shown on pages 11-13 in this brochure | 1 | 1 piece |
| or     | Retention plates as presented on pages 14-21 in this brochure                              | 2 | 1 piece |

**3) Additionally for Le Fort III and monobloc procedures**

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit</th>
<th>Qty (per pack)</th>
</tr>
</thead>
<tbody>
<tr>
<td>51-580-45-04</td>
<td>Second horizontal cross bar</td>
<td>1</td>
<td>1 piece</td>
</tr>
<tr>
<td>51-581-02-09</td>
<td>Threaded fixation plate</td>
<td>2</td>
<td>1 piece</td>
</tr>
<tr>
<td>51-581-15-09</td>
<td>Threaded fixation pin, 15 mm long (see page 25)</td>
<td>2</td>
<td>1 piece</td>
</tr>
<tr>
<td>25-665-05-09</td>
<td>Centre Drive® screws 1.5 x 5 mm</td>
<td>1</td>
<td>5 pcs.</td>
</tr>
<tr>
<td>25-665-07-09</td>
<td>Centre Drive® screws 1.5 x 7 mm</td>
<td>1</td>
<td>5 pcs.</td>
</tr>
</tbody>
</table>

(equivalent Cross Drive or maxDrive® screws would also be correct)

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit</th>
<th>Qty (per pack)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-402-99-07</td>
<td>Screwdriver handle</td>
<td>1</td>
<td>1 piece</td>
</tr>
<tr>
<td>25-430-98-07</td>
<td>Blade for 1.5-mm Centre Drive® screws</td>
<td>1</td>
<td>1 piece</td>
</tr>
</tbody>
</table>

Standard set see pages 4-5
Adjustment of the RED II frame

<table>
<thead>
<tr>
<th>Item No</th>
<th>51-580-85-07</th>
<th>51-575-90-07</th>
<th>51-500-90-07</th>
<th>25-402-99-07</th>
<th>25-430-98-07 Blade for 1.5 mm Centre Drive® screws or 25-483-97-07 Blade for 1.5 mm Cross Drive screws</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td>Patient screwdriver</td>
<td>Adjustment screwdriver</td>
<td>Patient screwdriver</td>
<td>Screwdriver</td>
<td></td>
</tr>
<tr>
<td>hexagonal</td>
<td>hexagonal</td>
<td>straight</td>
<td>hexagonal</td>
<td>1.5 mm Micro</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Activates the distraction movement</td>
<td>For all intraoperative adjustments of the threaded insertion pin</td>
<td>For insertion of the threaded fixation pin</td>
<td>For fixation of the RED II-frame in LeFort III and monobloc procedures</td>
<td></td>
</tr>
</tbody>
</table>

| 2 working ends |

25-483-97-07 Blade for 1.5 mm Cross Drive screws
Spare parts and variations of the RED

Item No. | Description
--- | ---
10 | Fixation ring
11 | Spindle unit with click
12 | Holder for horizontal crossbar
13 | Head cap screw
14 | Hexagonal nut
15 | Hexagonal nut
Coloured REDs
The RED II is now offered in a variety of colors. Patients can select the color of the head frame desired.

- Black: 51-579-00-04
- Silver: 51-579-20-04
- Red: 51-579-40-04
- Gold: 51-579-60-04
- Green: 51-579-80-04
- Purple: 51-580-00-04
Connection on the Le Fort I-Level
Via Retention plates or via Intraoral Splint

In all midfacial distraction procedures it is essential to apply traction to the maxilla. Traditionally this has been achieved by intraoral splints. Recent clinical considerations however show good arguments for using bone-borne retention plates.

Intraoral Splint
= Tooth-borne attachment to the maxilla
(see pages 11-13)

Retention Plates
= Bone-borne attachment to the maxilla
(see pages 14-21)
The Intraoral Splint

In order to apply traction to the maxilla through dentition, a rigid intraoral splint is often the most adequate option.

Orthodontic bands with 0.045 to 0.050 inch head-gear tubes are fitted either on the second primary molars (children under 6 years) or the first permanent molars and an alginate or compound impression is taken of the maxillary arch.

The bands are transferred and the impression is poured with dental stone. The splint is made on the working model. If the patient does not have orthodontic brackets, the labial and palatal wires are bent in close contact with most of the maxillary teeth. If the patient has orthodontic brackets, the labial wire has to be bent outward and gingivally to clear the existing appliances. If needed, a transpalatal bar can be added to increase rigidity. Connecting wires between the labial and palatal arches through the embrasures between the lateral and canine teeth bilaterally or in any other area where the wire can be passed without interfering with the occlusion may also be incorporated.

The device is inserted just prior to OR at the time of surgery. It is preferable to do maxillary arch expansion procedures before or after distraction to avoid moving the maxillary bone simultaneously in several directions where vector control can become more difficult. If the clinician desires to expand simultaneously with anterior distraction, an expansion screw can be incorporated into the splint, which has to be split into two segments. The stability of the device may then be compromised.

The intraoral splint is not a KLS Martin standard product. It will be manufactured by the hospital’s orthodontic team. Individual differences on patient’s dentation may demand a different orthodontic splint.
Fig. 1: 9 year 10 month old boy with a repaired left unilateral cleft lip and palate presented with severe maxillary hypoplasia.

Fig. 2: The preoperative facial photographs demonstrate the mid-face deficiency with a concave profile and retrusive upper lip.

Fig. 3: After maxillary distraction the facial profile and balance were restored to normal proportions.

Fig. 4: Note the improved prominence at the malar level and the improved relationship between the upper and lower lips. Nasal form was also improved as a result of the maxillary advancement through distraction osteogenesis.

Case photos: courtesy of Dr. John Polley, Chicago, USA
Fig. 5: Intraorally there were marked anterior and bilateral posterior crossbites.

Fig. 6: The postoperative intraoral photographs demonstrate complete correction of the anterior crossbite. One year after distraction the patient has not shown signs of relapse.

Fig. 7: The patient underwent a high two piece Le Fort I osteotomy with pterygomaxillary and septal disjunctions. No bone grafting or rigid internal fixation hardware was utilized. There was no repositioning of the maxilla at the time of the surgery.

The RED device was placed immediately after the osteotomy and the patient was discharged the morning after surgery. Distraction was initiated on postoperative day 5 at the rate of 1 mm per day.

The total maxillary advancement was 10 mm. Three weeks of rigid retention were utilized.
Connection on the Le Fort I-Level
Via Retention plates

The advantages are

- Solid bone fixation where high distraction forces are involved
- No risk of periodontal harm or teeth extractions
- Ready-made – no need for the orthodontist to customize the wire bar
- Easier dental hygiene compared to orthodontic band fixation
- Accurate distraction vector setting, no unwanted rotational movements
- Easy fixation and removal (as in standard osteosynthesis plates)

Contraindications

- Cases of inadequate bone volume to fix the osteosynthesis plate.

The general rules and guidelines of Distraction Osteogenesis have to be followed.

Impact of the point of anchorage on the rotational movements of the midface during distraction

The chart shows the impact of various fixation points on the maxilla. An anchorage on the tooth level will usually lead to a posterior rotation, which is often not desired. An anchorage point higher up, in the center of resistance or above would be better, because this would lead to none or to an anterior rotation.
Further indications for retention plates are:

- Distraction to be performed on edentulous patients or patients with severe periodontal disease or the existing risk of periodontal damage

- Especially Cleft Lip and Palate (CLP) patients can often only offer a limited dentition for dental anchorage

- If the maxilla is not only moved horizontally, but also vertically in a downwards direction there is a danger of pulling the wire fixation off the teeth

- Left and right maxillary segments can be manipulated independently which is a major benefit especially in Cleft Lip and Palate (CLP) patients

- Even multipiece distractions (e.g. 3 segments) can be performed

- Simultaneous rapid maxillary expansion is possible (f.e. transversal distraction can be performed during procedure)

- Retention plates are a prerequisite for sutural midfacial distraction
OPERATION TECHNIQUE: Traction via retention plates

Retention plates and retention plate connectors

Leipzig Retention Plate*

51-582-35-09 Connecting screw
51-582-15-05

Retention plates

<table>
<thead>
<tr>
<th>Item Numbers:</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>51-582-50-04</td>
<td>Set 1.5 mm complete (1 each)</td>
</tr>
<tr>
<td>51-582-55-04</td>
<td>Set 1.8 mm complete (1 each)</td>
</tr>
</tbody>
</table>

Set includes:

- 1 bone plate, 11 holes
- 1 rider incl. screws for rod fixation
- 1 square rod either 1.8 or 1.5 mm thick
- 1 fixation eyelet

The entire set is designed for single use only!

To be modified using a 1.5-mm Centre Drive® screwdriver

* Developed in cooperation with PD Dr. Dr. Thomas Hierl / Prof. Dr. Dr. Alexander Hemprich, Leipzig, Germany
Retention plate connector

- Allows a direct attachment of 1.5- and 1.8-mm retention plate eyelets to the quadrangular rods activation spindles of the RED-frame (2 pcs. each).

- To be modified using a 1.5-mm Centre Drive® screwdriver

Solidly connected retention plate:

- Between fixation plate and quadrangular rod.

**Advantages:**
- No connection elements needed
- No risk of losing connection elements
- No risk of harming the patient with exposed metallic elements

**Disadvantage:**
- No lateral attachment is possible.

- To be modified using a 1.5-mm Cross Drive screwdriver
- Unit: 1 piece each
CASE REPORT: Edentulous patient – Traction via retention plate

Fig. 1: 63-year-old patient suffering from CLP. Only one maxillary molar is left. Referral due to insufficiency to facilitate prosthodontic therapy.

Fig. 2: Preoperative CT reconstruction. Severe maxillary retrusion and atrophy.

Fig. 3: Frontal view

Fig. 4: Preoperative lateral cephalogram. Marked midfacial retrusion, no bone stock for implant insertion or prosthodontic therapy.

Fig. 5: Lateral cephalogram after distractor removal. As no dental occlusion will stabilize the new midfacial position, miniplates are temporarily inserted. Simultaneously a bilateral sinus lift procedure and bone augmentation in the cleft area was performed. The bent miniplates represent the amount of forward maxillary displacement. Dental implants will be inserted 3 months later.

Fig. 6: Situation before removal of the RED. See the improvement in midfacial prominence and the uprightening of the nose.

Case photos: courtesy of PD Dr. Dr. Thomas Hierl, D-Leipzig
Fig. 7: Preoperative intraoral situation

Fig. 8: Situation 3 years after distraction, augmentation and implant insertion. Magnetic abutments are used for prosthesis fixation.

Fig. 9: Situation 3 years after distraction. Marked esthetic improvement, good facial balance.

Fig. 10: Lateral cephalogram 3 years after distraction, augmentation and implant insertion.
CASE REPORT: Dentate patient – Traction via retention plate

Fig. 1: 19-year-old man suffering from unilateral Cleft Lip and Palate (CLP). Note the maxillary retrusion and midfacial hypoplasia leading to collapsed and inwardly rotated maxillary segments.

Fig. 2: Preoperative dental situation

Fig. 3: Facial profile view, significant malar deficiency.

Case photos: courtesy of PD Dr. Dr. Thomas Hierl, D-Leipzig
Fig. 4: Post-distraction situation. See the alignment of both maxillary segments using Leipzig retention plates. To correct malar asymmetry, the osteotomy line has been extended on the smaller maxillary segment. Bone grafting in the cleft area and paranasal region was performed during distractor removal.

Fig. 5: Occlusion 4 years after distraction osteogenesis shows stable results. In the meantime, a dental implant has been inserted in the cleft region.

Fig. 6: Facial profile 4 years after two-piece segmental distraction. See improved facial balance.
**Expansion of the RED II**

**additional components**

**Modified central part:**
Allows a lateral shifting in the upper central unit and control on possible asymmetries.

To be modified using 51-575-90-07

*Developed in cooperation with Dr. Jeoffrey Farrow, Dallas, Texas*

**Upper part multidirectional**
Allows a complete adjustment of the central carbon rod in all 3 dimensions.

To be modified using 51-575-90-07 and 51-580-85-07

**Vertical gear bar square rod style**
Designed to allow exact and continuous vertical distraction steering movements during the distraction process.

To be modified using 51-575-90-07 and 51-580-85-07
Adjustable horizontal crossbar:
Allows controlled lateral shifting of 15 mm in each direction during activation process. Lateral adjustment elements are limiting the movement of the distraction elements on the crossbar.

To be modified using 51-575-90-07

Adjustable spindle unit assembly:
Designed to allow horizontal adjustment of the spindle unit. Loosen screw, select new position and lock screw.
Unit: 2 pieces each

To be modified using 51-575-90-07

Locking nuts and stops

The locking nut 51-575-94-09 is designed to prevent loosening and over-tightening of the fixation pin.
Unit: 1 piece each

The positive stop 51-575-99-09 securely limits the skull entry of the RED fixation pin.
Unit: 1 piece each
Halo extender
Allows pin fixation on the posterior part of the skull and an extension of the RED-frame. Symmetrical construction – to be used on the right or left side of the patient.
Unit: 1 piece each

Rounded fixation element left
Enables the placement of fixation pins on various levels

Rounded fixation element right
Enables the placement of fixation pins on various levels

RED II with rounded fixation element complete, according to the specifications on page 3

Fixation screws

Fixation screw 45 mm
Unit: 10 pieces each

Fixation screw 55 mm
Unit: 10 pieces each
The longer fixation pin, usually applied for children

Trial fixation pin, 41 mm
Unit: 1 piece each
To be used for intraoperative setting of the RED II. Blunt tips – not for permanent fixation!
To be modified using 51-575-90-07
Central fixation pins and fixation plates

**51-581-15-09**
Threaded central fixation pin, 2.0 x 15 mm:
Unit: 1 piece each
To be inserted using 51-500-90-07

**51-581-21-09**
Threaded central fixation pin, 2.0 x 21 mm:
Unit: 1 piece each
To be inserted using 51-500-90-07

**51-581-08-09**
Habal type 8-mm pin
(5 mm threaded)
Direct anchorage on the affected bone
Unit: 1 piece each
To be inserted using 51-500-90-07

**51-581-10-09**
Habal type 10.5-mm pin
(7.5 mm threaded)
Direct anchorage on the affected bone
To be applied with 51-500-90-07
Unit: 1 piece each
To be inserted using 51-500-90-07

**51-581-02-09**
Straight threaded fixation plate:
For Le Fort III and Monobloc procedures, a second fixation base allows a better control of the distraction vector and the bony structures involved.
Unit: 2 pieces each

**51-581-03-09**
Threaded fixation plate*
is an alternative to the straight threaded fixation plate 51-581-02-09.
Unit: 1 piece each

**51-581-06-09**
Threaded fixation plate*
(0.5 mm threaded)
is an alternative to the straight threaded fixation plate 51-581-02-09.
Especially suitable in round, suborbital bone regions
Unit: 1 piece each

* All to be applied with 1.5-mm micro screws (usually 5 to 7 mm long) on the lateral aspect.
**Latest tendencies**

**Sutural Midface Distraction**

Sutural midfacial distraction (SMD) utilizes the high forces which can be applied with the RED device to a growing organism. Without the need for osteotomies, complex changes of the midfacial architecture may be achieved in short time. It is of paramount importance to check bone thickness of the calvarium prior to SMD to avoid skull punctures or even skull fractures.

Furthermore dental splints must not be used as dental extrusion will result. As SMD is a new procedure, thorough treatment planning and control of the patient during the procedure is mandatory. SMD may not be performed in adult patients.

Retention plates fixed to the midface. Note the bending of the plate to utilize the bone stock of the zygomatic buttress. As anatomy is highly variable, retention plates with moveable riders are suggested.

At least 3 screws anterior to the rider and as many as possible posteriorly should be used. 1.5-mm Drill-Free screws have been inserted. No osteotomy was performed. Standard distraction activation of 1 mm/day is used.

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_Case photos: courtesy of PD Dr. Dr. Thomas Hierl, D-Leipzig_
Sam e patient (6 ys.; syndromal midfacial retrusion) before and after SMD. Midfacial advancement, opening of all sutures (e.g. zygomatic arch), rotation of the midface and rotation of the nasal bones is visible. Due to protraction forces, the maxillary arch will change shape, too.

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Maxillary Distraction Osteogenesis using Le Fort I osteotomy without intraoperative down-fracture
KLS Martin is a pioneering company in distraction osteogenesis and has established in many individual indications its own specific product portfolio. The RED II is a good example for that.

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