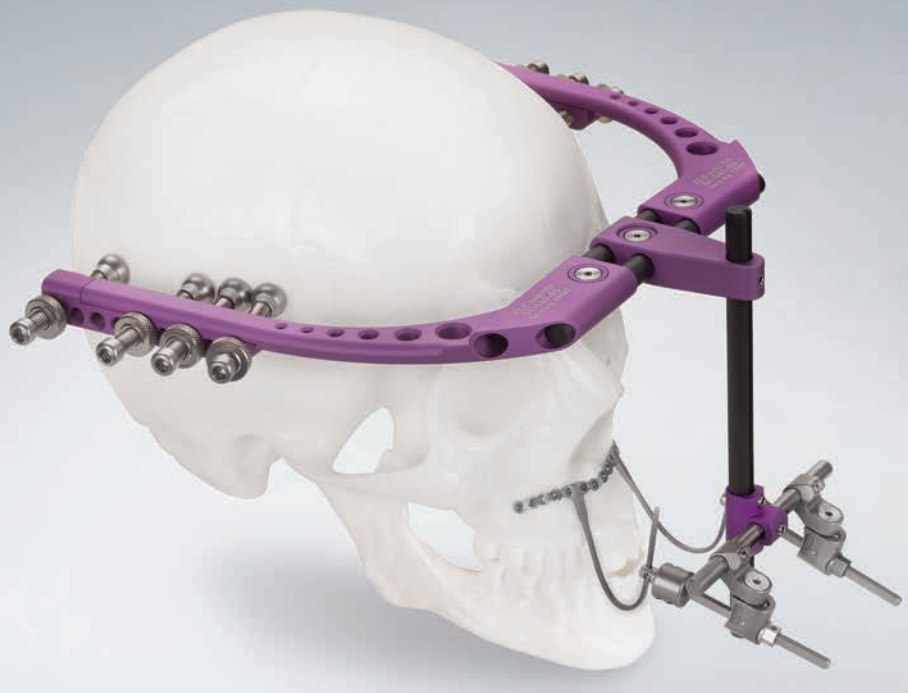
KLS martin GROUP



RED II System

Rigid External Distraction

www.klsmartin.com

Oral and maxillo-facial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

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.

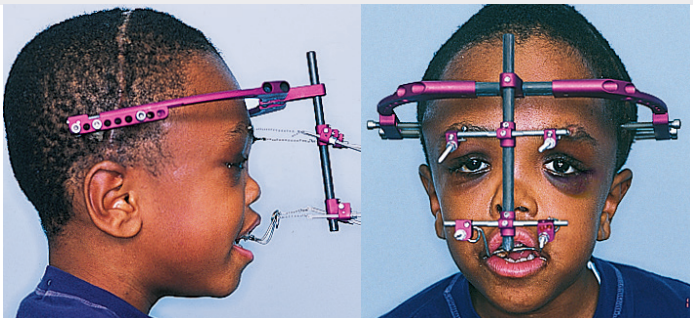
The incredible successful treatment outcomes led to a complete redesign of the now called RED II frame back in 2000. Since then, the device has been lighter, but simultaneously stronger and more flexible in its application.
Over the years the increasing demand of doctors for patient specific solutions 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

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.

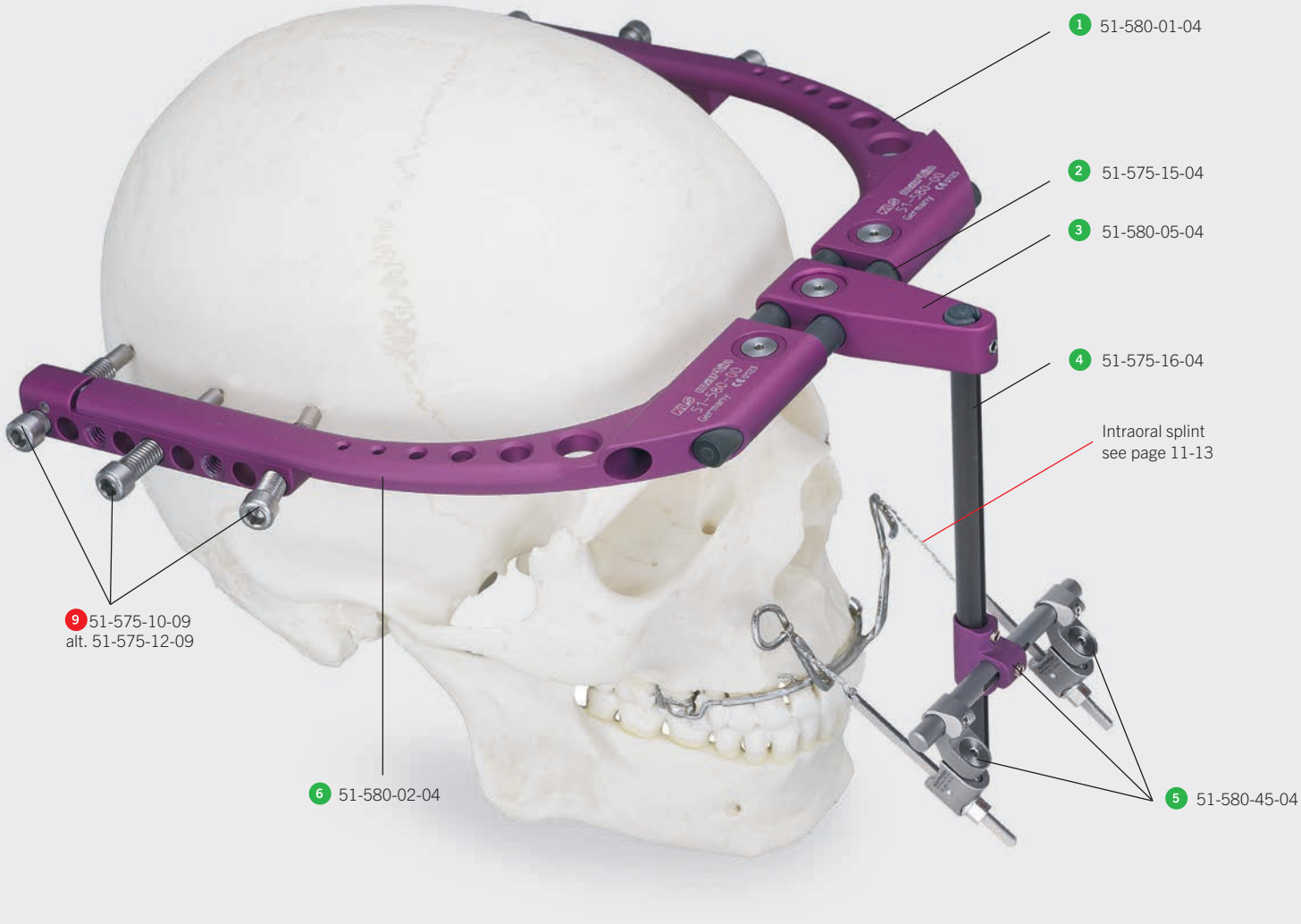


RED II Distraction system

	Item No.		
	51-580-00-04		RED II Distraction system, complete assembly

	Consisting of:		
1	51-580-01-04	1	Distraction segment, left
2	51-575-15-04	2	Carbon rods, 120 mm, horizontal
3	51-580-05-04	1	Center part
4	51-575-16-04	1	Carbon rod, 150 mm, vertical
5	51-580-45-04	1	Horizontal cross bar assembly, complete with horizontal cross bar + holder + 2 spindle units
6	51-580-02-04	1	Distraction segment, right
7	51-580-85-07	1	Patient screwdriver

	To order separately:		
8	51-575-90-07	1	Adjustment screwdriver, hexagonal
9	51-575-10-09	1 Pack	Fixation screws 45 mm, 10/each
	or		
	51-575-12-09	1 Pack	Fixation screws 55 mm, 10/each



¼

7 51-580-85-07
18 cm/7 ¼“
Patient screwdriver
hexagonal

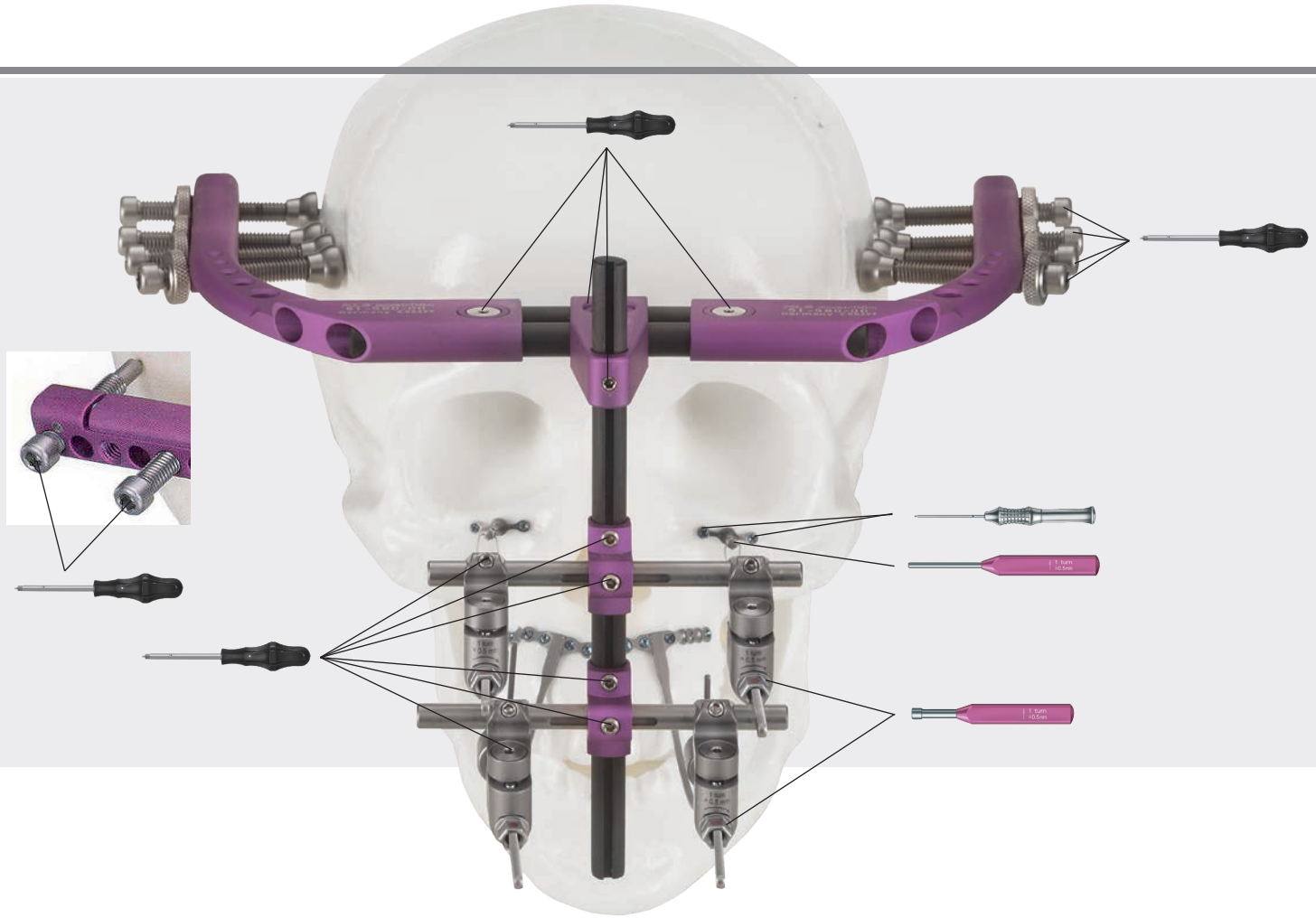
½

8 51-575-90-07
24 cm/9 ½“
Adjustment screwdriver
hexagonal

What do you need for which procedure?

Item No.	Description	Unit	Qty (per pack)
1) Must for Le Fort I and Le Fort II procedures			
51-580-00-04	RED II complete, also containing the patient screwdriver	1	1 piece
51-575-90-07	Hexagonal screwdriver (for adjustment and pin fixation	1	1 piece
51-575-10-09	Fixation screws 45 mm for the adult patient	1	10 pcs.
or 51-575-12-09	Fixation screws 55 mm for the pediatric patient	1	10 pcs.
2) Connection to the occlusal level			
Either	Intraoral splint for connecting the RED to the teeth	1	1 piece
	as shown on pages 11-13 in this brochure		
or	Retention plates as presented on pages 14-21 in this brochure		
	General recommendation: 2 pcs. 51-582-50-04 (1.5-mm system)	2	1 piece
3) Additionally for Le Fort III and monobloc procedures			
	all items as listed under 1) + 2) and additionally		
51-580-45-04	Second horizontal cross bar	1	1 piece
51-581-02-09	Threaded fixation plate	2	1 piece
51-581-15-09	Threaded fixation pin, 15 mm long (see page 25)	2	1 piece
51-500-90-07	Patient screwdriver straight	1	1 piece
25-665-05-09	Centre Drive® screws 1.5 x 5 mm	1	5 pcs.
to 25-665-07-09	Centre Drive® screws 1.5 x 7 mm	1	5 pcs.
	(equivalent maxDrive® screws would also be correct)		
25-402-99-07	Screwdriver handle	1	1 piece
25-430-98-07	Blade for 1.5-mm Centre Drive® screws	1	1 piece

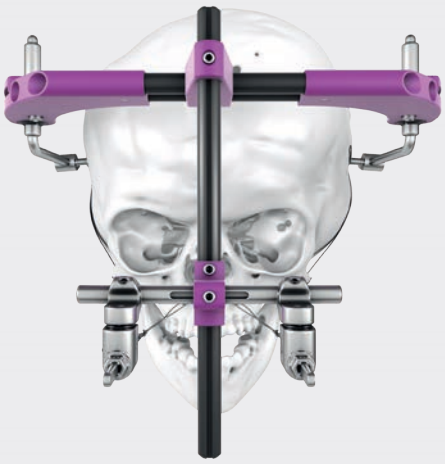
Standard set see pages 4-5



Adjustment of the RED II frame

Item No	**51-580-85-07**	**51-575-90-07**	**51-500-90-07**	**25-402-99-07** Screwdriver handle
				25-489-97-07 Blade for 1.5-mm maxDrive® screws
				25-430-98-07 Blade for 1.5-mm Centre Drive® screws
Application	Patient screwdriver hexagonal	Adjustment screwdriver hexagonal	Patient screwdriver straight	Screwdriver 1.5 mm Micro
Description	Activates the distraction movement	For all intraoperative adjustments of the RED II-frame 2 working ends	For insertion of the threaded insertion pin in LeFort III and monobloc procedures	For fixation of the threaded fixation plate

Patient-specific **RED** II with temporal fixation plates



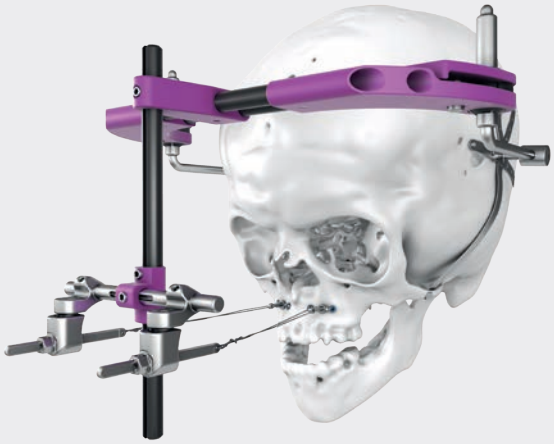
The standard RED II frame is mostly efficient in very young children. The fixation of the conventional titanium pins however remains a challenging task.

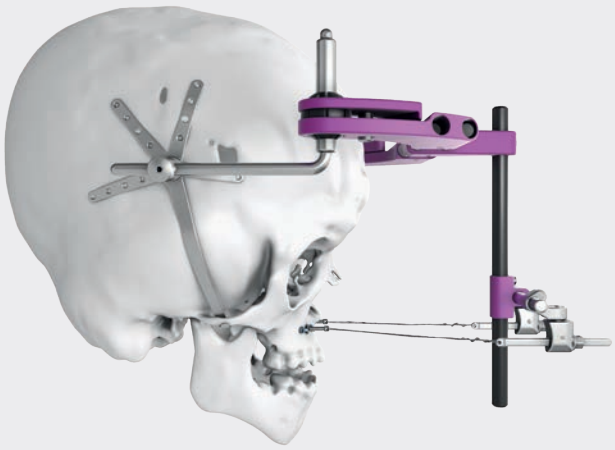
Therefore, as an alternative to our standard RED II a patient-specific design according to the ideas of Prof. J. Obwegeser (Limmatklinik Zurich, Switzerland) is available.

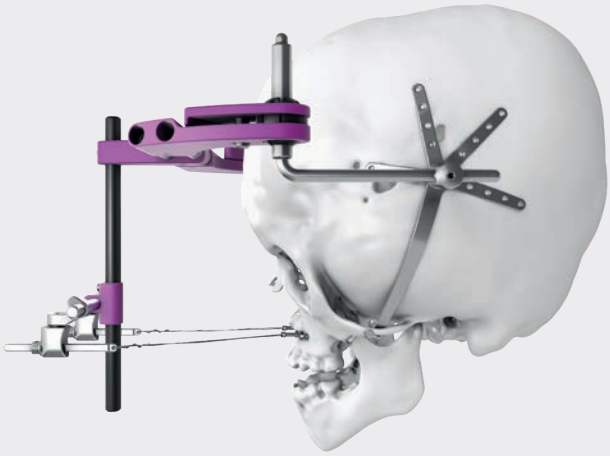
The RED II according to Prof. J. Obwegeser comes with the standard head frame being fixed to temporal fixation plates that are individually manufactured to the anatomics of each patient.

This custom-made device (no CE marking) has to be requested for every single patient via our IPS Gate(R) upload and communication portal.

For further information visit the KLS Martin website.

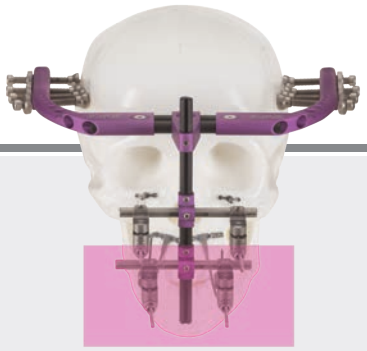






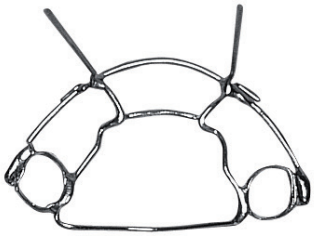
Benefits of the temporal fixation plates and the IPS® Planning Service:

- Stronger anchoring to the skull bone
  ➔ Reduced risk of the RED II distractor becoming detached in the event of the patient falling
- Application in patients with thin-walled skull bone or poor bone quality
- Application in patients with openings in the cranial bone in the region of the temporal bone
- Hook which passes around the zygomatic bone for easier positioning
- If necessary, planning & simulation of the post-operative situation after distraction (IPS® Planning Service)
- If necessary, modified fixation and retention plates in the midface available as IPS® products
- With the help of 3D visualisation a heatmap of the bone thickness in the region of the temporal fixation plates allows for more precise planning

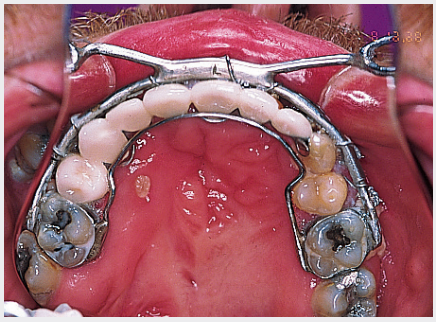


Connection on the Le Fort I-Level
Via Retention plates or via Intraoral Splint

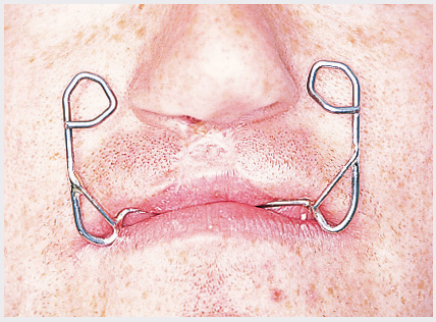
Intraoral Splint
= Tooth-borne attachment to the maxilla
(see pages 11-13)



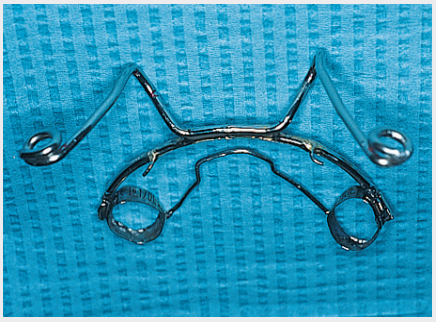
Retention Plates
= Bone-borne attachment to the maxilla
(see pages 14-21)



The completed splint is cemented in the clinical setting and at the time of surgery circumdental wires are passed through most of the maxillary teeth to increase stability.



Reinforced external traction hook in a preoperated patient. A piece of wire is soldered diagonally to decrease the cantilever effect at the free end of the hooks.



Completed intraoral appliance – the outer bow has been bent to form the traction hooks. Note small soldered hooks to be used during the facial mask retention phase after distraction.

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 trans-palatal 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 inter-fering 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 hopital's orthodontic team. Individual differences on patient's dentation may demand a different orthodontic splint.

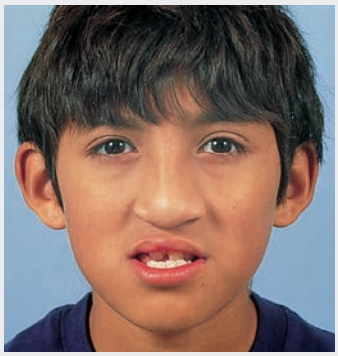


Fig. 1:
9 year 10 month old boy with a repaired left unilateral cleft lip and palate presented with severe maxillary hypoplasia.

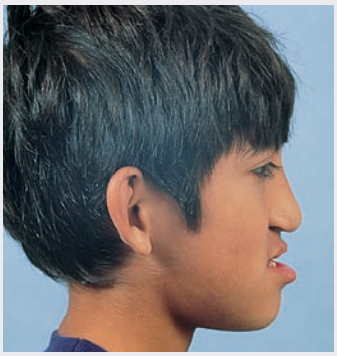


Fig. 2:
The preoperative facial photographs demonstrate the midface deficiency with a concave profile and retrusive upper lip.

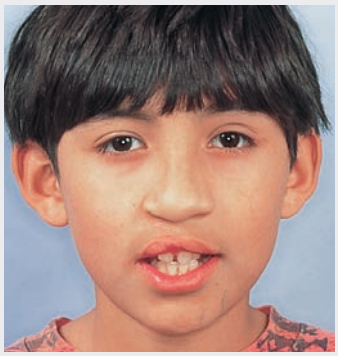


Fig. 3:
After maxillary distraction the facial profile and balance were restored to normal proportions.

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

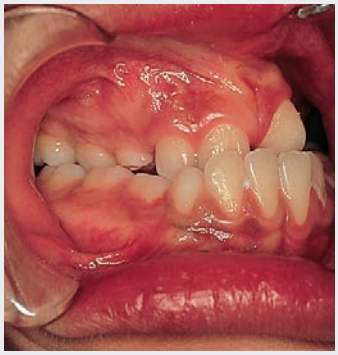


Fig. 5:
Intraorally there were marked anterior and bilateral posterior crossbites.

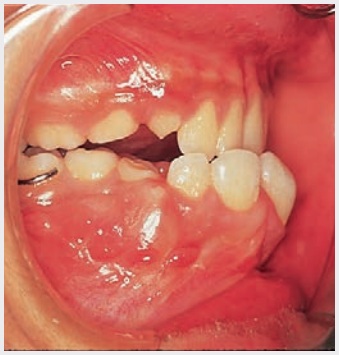


Fig. 6:
The postoperative intraoral photographs demonstrate complete correction of the anterior crossbite. One year after distraction the patient has not shown signs of relapse.

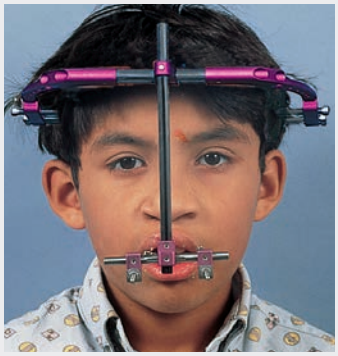
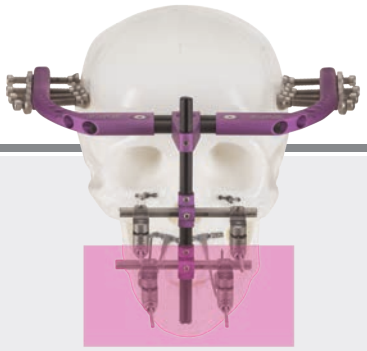


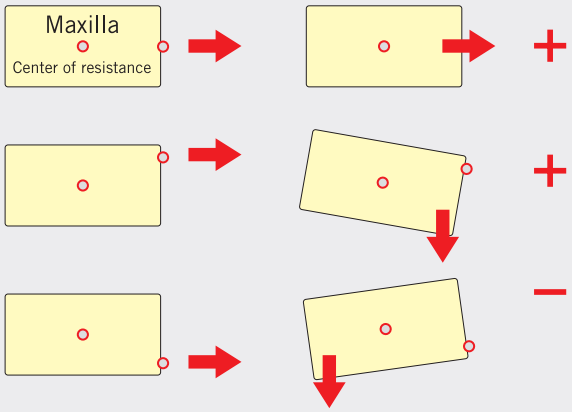
Fig. 7:
The patient underwent a high two piece Le Fort I osteotomy with pterygomaxillary and septal disjunctions. No bone grafting or rigid internal fixation hardware was utilized. There was no repositioning of the maxilla at the time of the surgery.

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



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

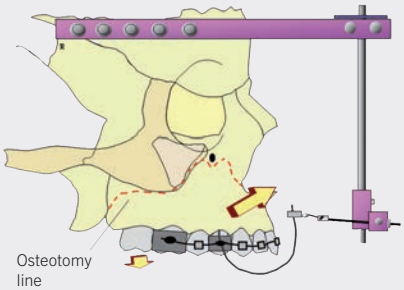
The chart shows the impact of various fixation points on the maxilla. An anchorage on the tooth level will usually lead to a posterior rotation, which is often not desired. An anchorage point higher up, in the center of resistance or above would be better, because this would lead to none or to an anterior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

The advantages are

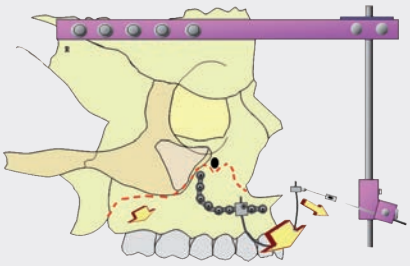
- Solid bone fixation where high distraction forces are involved
- Minor risk of periodontal harm or teeth extractions
- Ready-made – no need for the orthodontist to customize the wire bar
- Easier dental hygiene compared to orthodontic band fixation
- Accurate distraction vector setting, no unwanted 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.

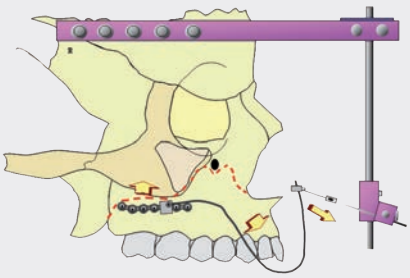


Dental anchorage may cause counter-clockwise rotation of the maxilla.



Retention plate uses bone stock on crista zygomaticoalveolaris for best anchorage

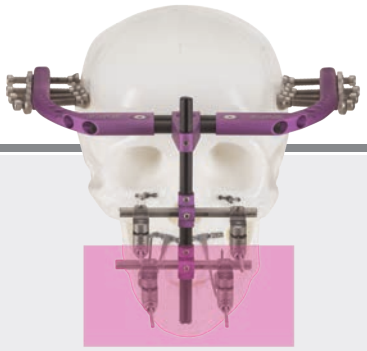
Anterior position of the retention plate will lead to a spring-like action. → Posterior rotation and vertical midfacial elongation.



A posterior placement of the retention plate will counteract the posterior vertical elongation. The surgeon will need long quadrangular rods and a posteriorly-placed rider.

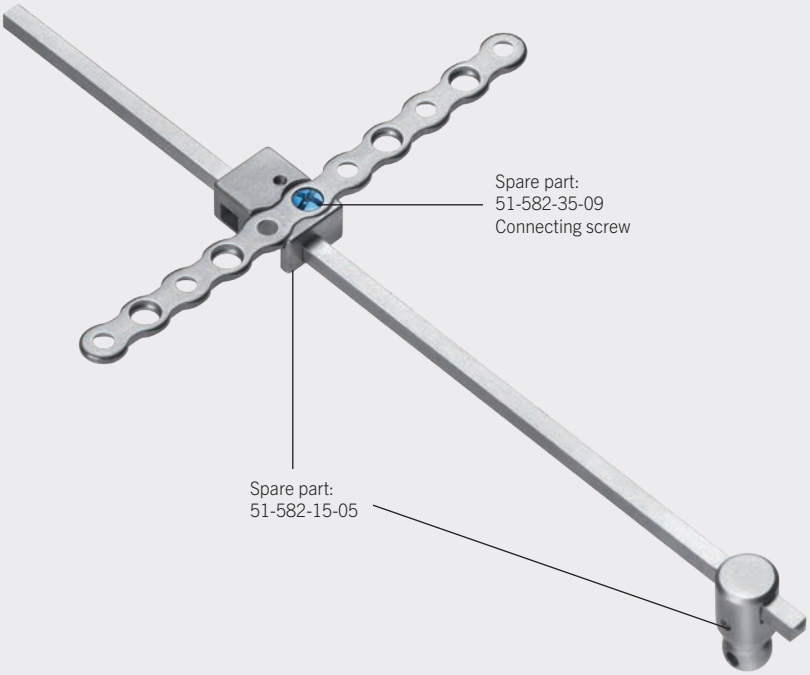
Further indications for retention plates are:

- 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



Retention plates and retention plate connectors

Leipzig Retention Plate*



Retention plates

Item Numbers:	
51-582-50-04	Set 1.5 mm complete (1 each)
51-582-55-04	Set 1.8 mm complete (1 each)

To be fixed with 1.5 mm screws

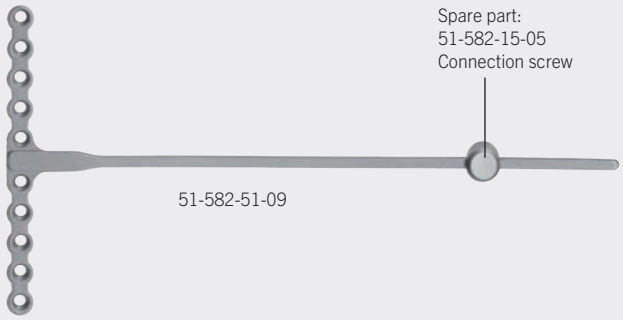
Set includes:
1 bone plate, 11 holes
1 rider incl. screws for rod fixation
1 square rod either 1.8 or 1.5-mm thick
1 fixation eyelet

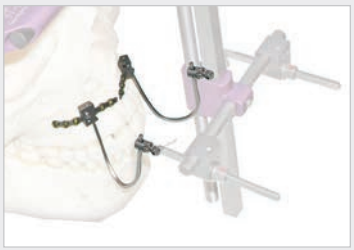
The entire set is designed for single use only !

To be modified using a 1.5-mm maxDrive® screwdriver

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

New items:



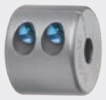


Solidly connected retention plate:
Between fixation plate and quadrangular rod.

Advantages:
- No connection elements needed
- No risk of loosing 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 maxDrive® screwdriver
Unit: 1 piece each



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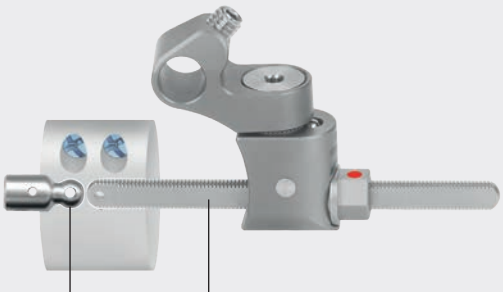
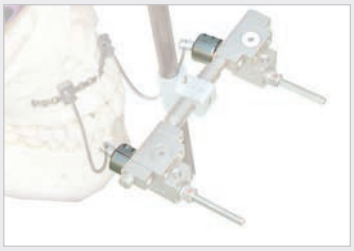




Retention plate connector
Allows a direct attachment of 1.5- and 1.8-mm retention plate eyelets to the quadrangular rods activation spindles of the RED-frame (2 pcs. each).

To be modified using a 1.5-mm maxDrive® screwdriver
Unit: 1 piece each

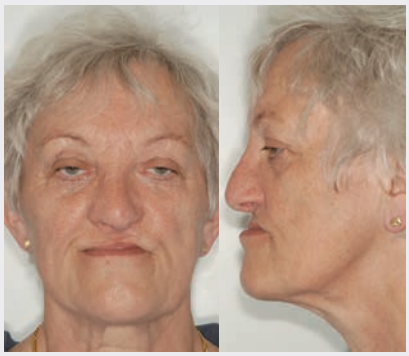


Fig. 1:
63-year-old patient suffering from CLP. Only one maxillary molar is left. Referral due to insufficiency to facilitate prosthodontic therapy.

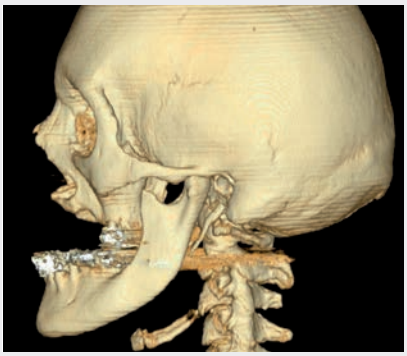


Fig. 2:
Preoperative CT reconstruction. Severe maxillary retrusion and atrophy.

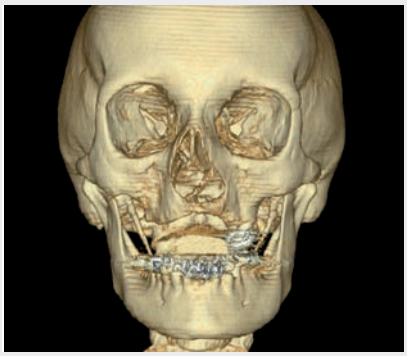


Fig. 3:
Frontal view

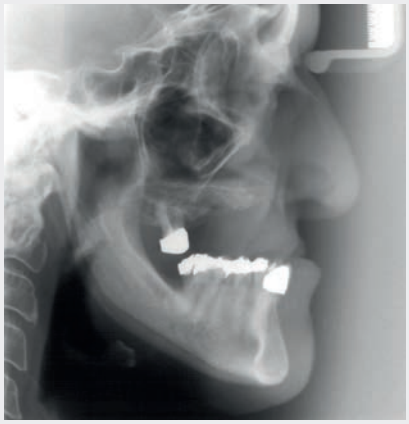


Fig. 4:
Preoperative lateral cephalogram. Marked midfacial retrusion, no bone stock for implant insertion or prosthodontic therapy.

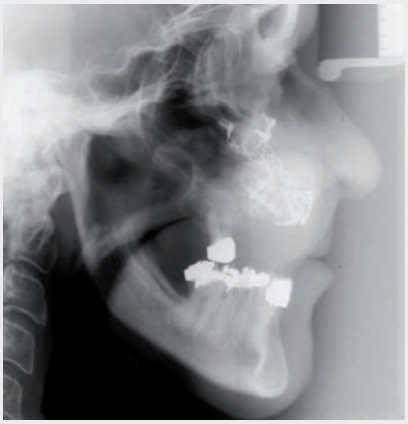


Fig. 5:
Lateral cephalogram after distractor removal. As no dental occlusion will stabilize the new midfacial position, miniplates are temporarily inserted. Simultaneously a bilateral sinus lift procedure and bone augmentation in the cleft area was performed. The bent miniplates represent the amount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

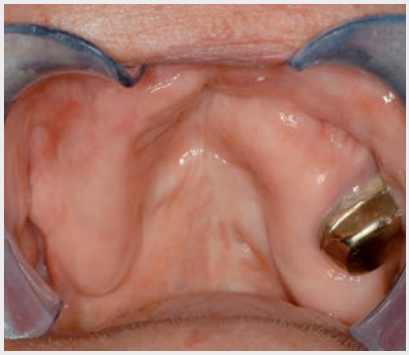


Fig. 7:
Preoperative intraoral situation

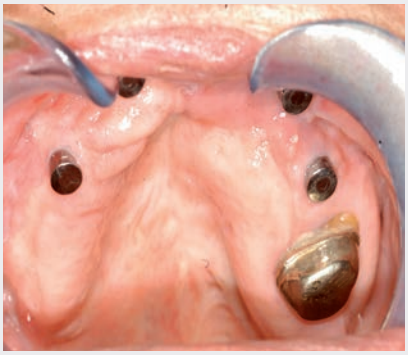


Fig. 8:
Situation 3 years after distraction, augmentation and implant insertion. Magnetic abutments are used for prosthesis fixation.

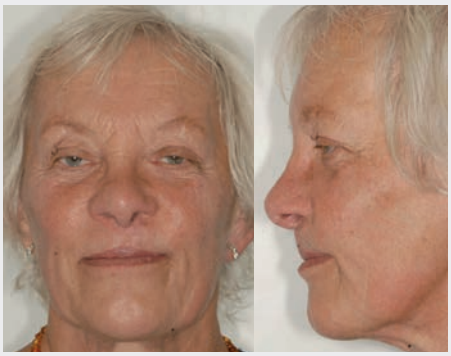


Fig. 9:
Situation 3 years after distraction. Marked esthetic improvement, good facial balance.

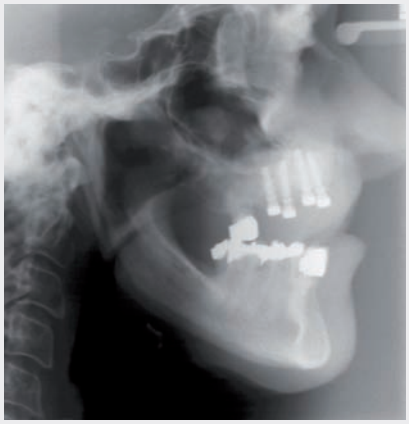


Fig. 10:
Lateral cephalogram 3 years after distraction, augmentation and implant insertion.

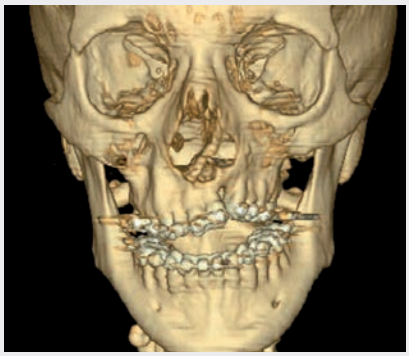


Fig. 1:
19-year-old man suffering from unilateral Cleft Lip and Palate (CLP). Note the maxillary retrusion and midfacial hypoplasia leading to collapsed and inwardly rotated maxillary segments.

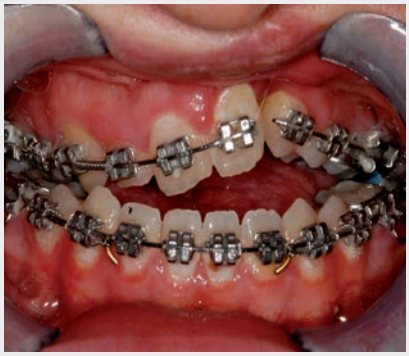


Fig. 2:
Preoperative dental situation

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

Case photos: courtesy of PD Dr. Dr. Thomas Hierl, D-Leipzig

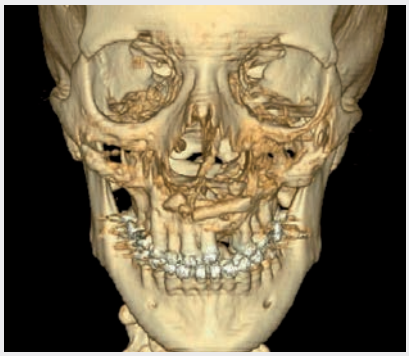


Fig. 4:
Post-distraction situation. See the alignment of both maxillary segments using Leipzig retention plates.
To correct malar asymmetry, the osteotomy line has been extended on the smaller maxillary segment.
Bone grafting in the cleft area and paranasal region was performed during distractor removal.

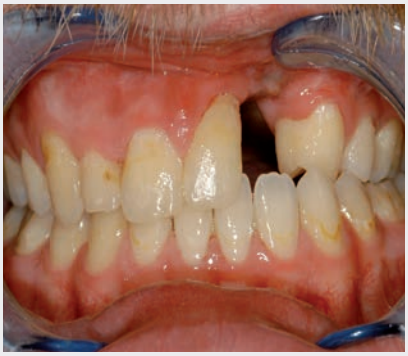
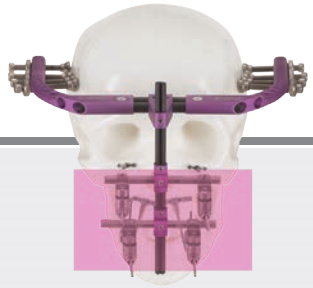
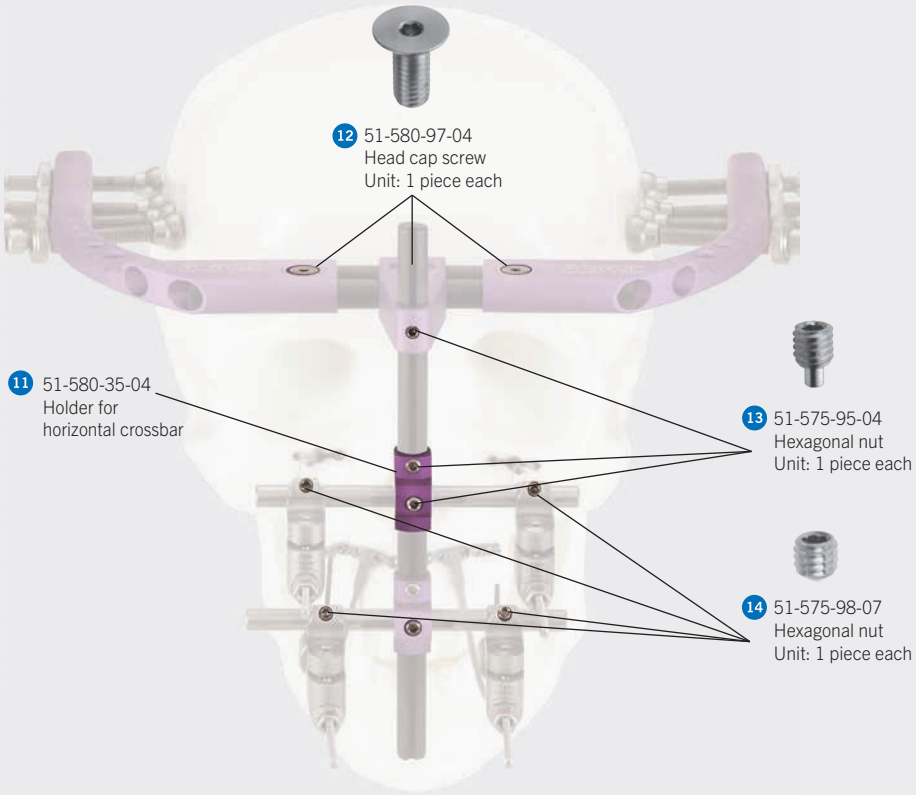


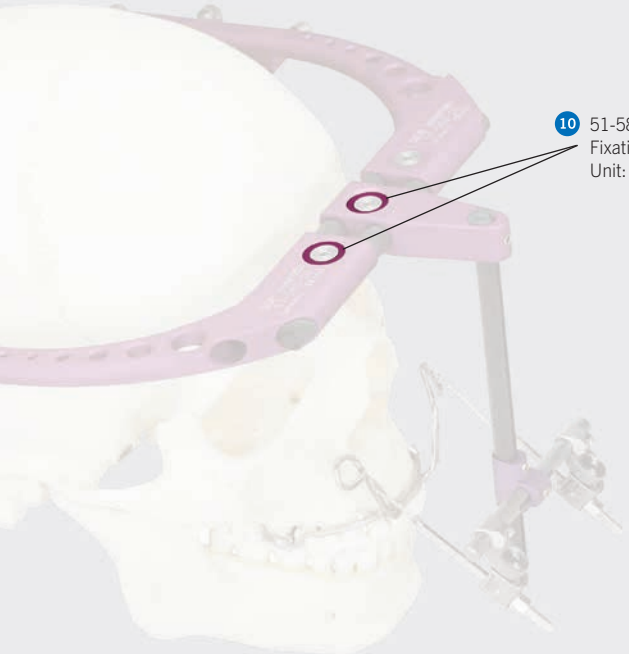
Fig. 5:
Occlusion 4 years after distraction osteogenesis shows stable results.
In the meantime, a dental implant has been inserted in the cleft region.

Fig. 6:
Facial profile 4 years after two-piece segmental distraction. See improved facial balance.

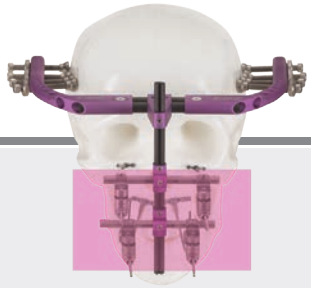


Spare parts
and variations of the **RED** II





	Item No.		
10	51-580-40-07	1	Fixation ring
11	51-580-35-04	1	Holder for horizontal crossbar
12	51-580-97-04	1	Head cap screw
13	51-575-95-04	1	Hexagonal nut
14	51-575-98-07	1	Hexagonal nut



Expansion of the **RED** II additional components

51-580-45-04

Horizontal crossbars:

The redesigned horizontal crossbars and their new spindle units are designed to allow 3D-steering of the distraction movement.

Furthermore, an expansion of the maxilla is now possible as well. Loosen the screw, select new position and lock.

unit: 1 piece

To be modified using 51-575-90-07 

Remarks:

For Le Fort II, Le Fort III and Monobloc procedures a second horizontal cross bar is recommended.

1 distraction unit will always come with the basic RED frame configuration, e.g. 51-580-00-04.

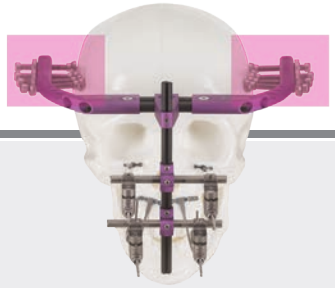
51-580-45-04: Horizontal cross bar in **purple color**

51-580-26-04

In order to possibly update existing RED II distraction devices with the new spindle, one can order the spindle as a spare part.

unit: 1 piece

To be modified using 51-575-90-07 



Expansion of the **RED** II additional components

Fixation screws

51-575-10-09

Fixation screw 45 mm
Unit: 10 pieces each

51-575-12-09

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

51-575-14-09

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 

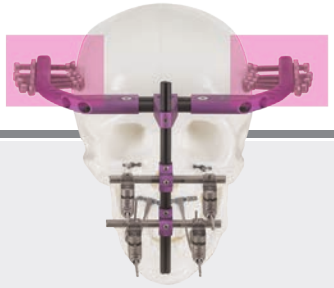
Locking nuts and stops

51-575-94-09

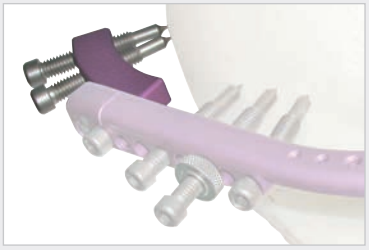
The **locking nut** 51-575-94-09 is designed to prevent loosening and over-tightening of the fixation pin.
Unit: 1 piece each

51-575-99-09

The **positive stop** 51-575-99-09 securely limits the skull entry of the RED fixation pin.
Unit: 1 piece each



51-580-08-04



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

51-583-01-04

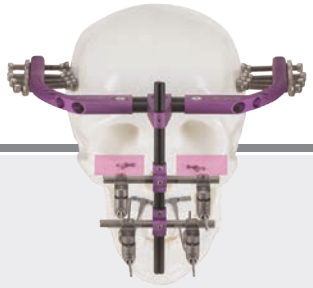
Rounded fixation element left
Enables the placement of fixation pins on various levels

51-583-02-04

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

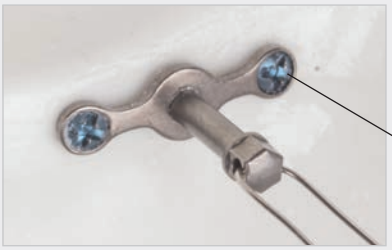
51-583-00-04

RED II with rounded fixation element complete,
according to the specifications on page 4-5



Expansion of the **RED** II additional components

Central fixation pins and fixation plates



Micro screws usually
1.5 x 5 mm to 1.5 x 7 mm

51-581-15-09

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

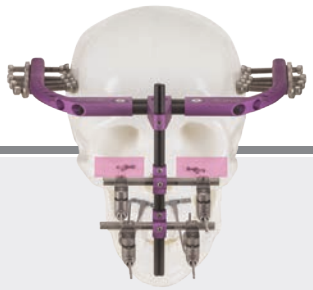
51-581-21-09
Threaded central fixation pin, 2.0 x 21 mm:
Unit: 1 piece each

To be inserted using 51-500-90-07 

51-581-30-09

51-581-30-09
Threaded central fixation pin, 2.0 x 30 mm:
Unit: 1 piece each

To be inserted using 51-500-90-07 



51-581-08-09

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

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

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: 1 piece each

To be fixed with 1.5 mm screws

51-581-03-09

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

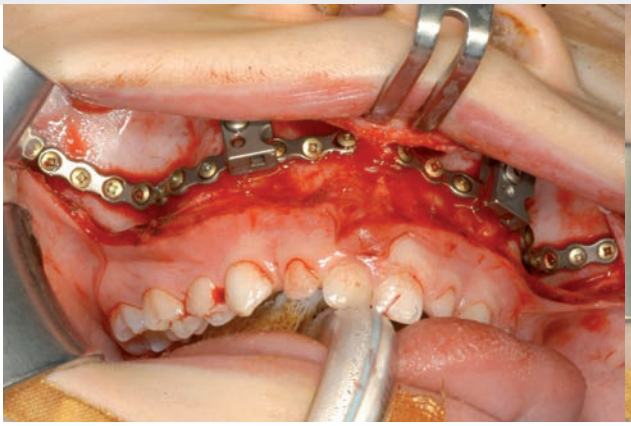
51-581-06-09
Threaded fixation plate*
(0.5 mm threaded)
is an alternative to the straight threaded fixation plate 51-581-02-09.
Especially suitable in round, suborbital bone regions
Unit: 1 piece each

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

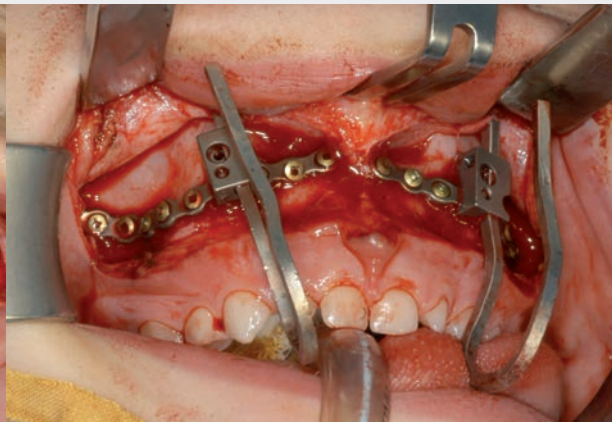
Sutural Midface Distraction

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.

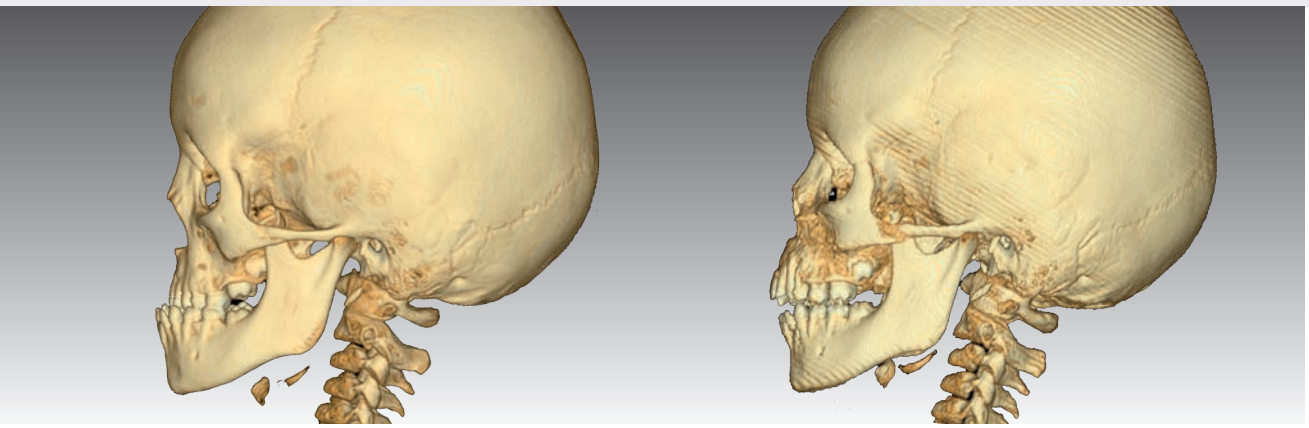


Retention plates fixed to the midface. Note the bending of the plate to utilize the bone stock of the zygomatic buttress. As anatomy is highly variable, retention plates with moveable riders are suggested.



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.

Case photos: courtesy of PD Dr. Dr. Thomas Hierl, D-Leipzig



Same 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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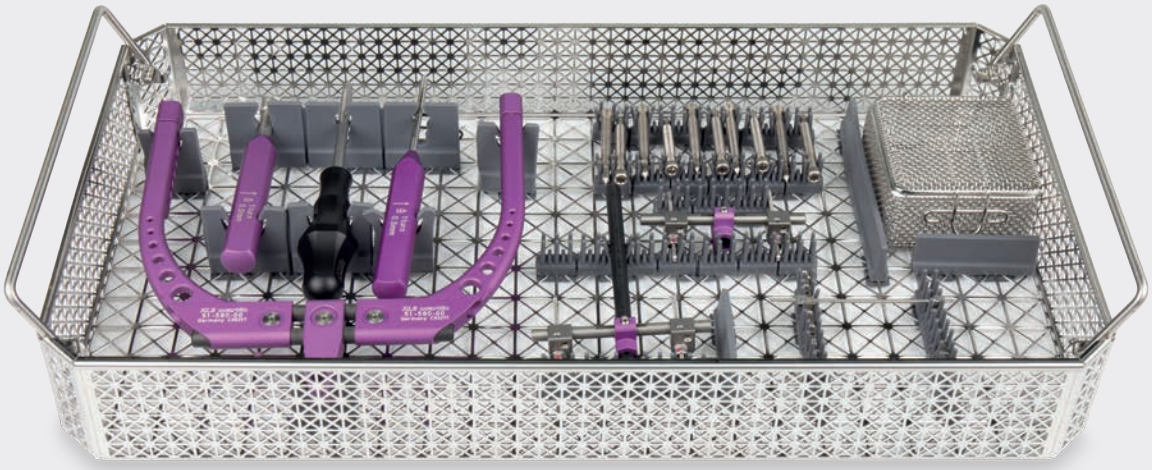
Storage Recommendation



Storage Recommendation

Qty	Item No	Specification
1x	55-804-50-01	Mesh Tray 477 x 251 x 64 mm
1x	55-805-52-01	Lid
1x	55-234-13-04	Marsafe Container 553 x 272 x 133 mm
1x	55-891-40-01	Small-parts basket, fine mesh 80 x 80 x 40 mm
1x	55-806-11-04	3x Instrument holder, Ø 15 mm high
1x	55-806-12-04	3x Instrument holder, Ø 20 mm high
1x	55-806-20-04	3x Fixation element universal H = 40 mm
1x	55-806-10-04	6x Instrument holder Ø 8-10mm high
2x	55-806-50-04	Separator 123 x 9 x 22mm, with clips
7x	55-806-25-04	6x Studded strip, 22 mm

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Source: Dr. Camilo Roldán, Hamburg

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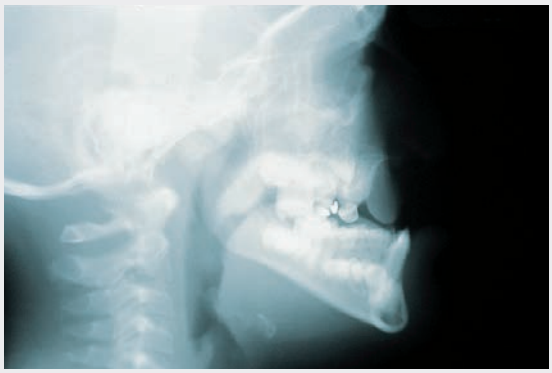

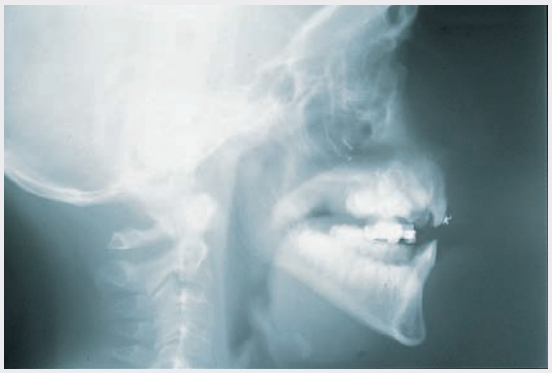

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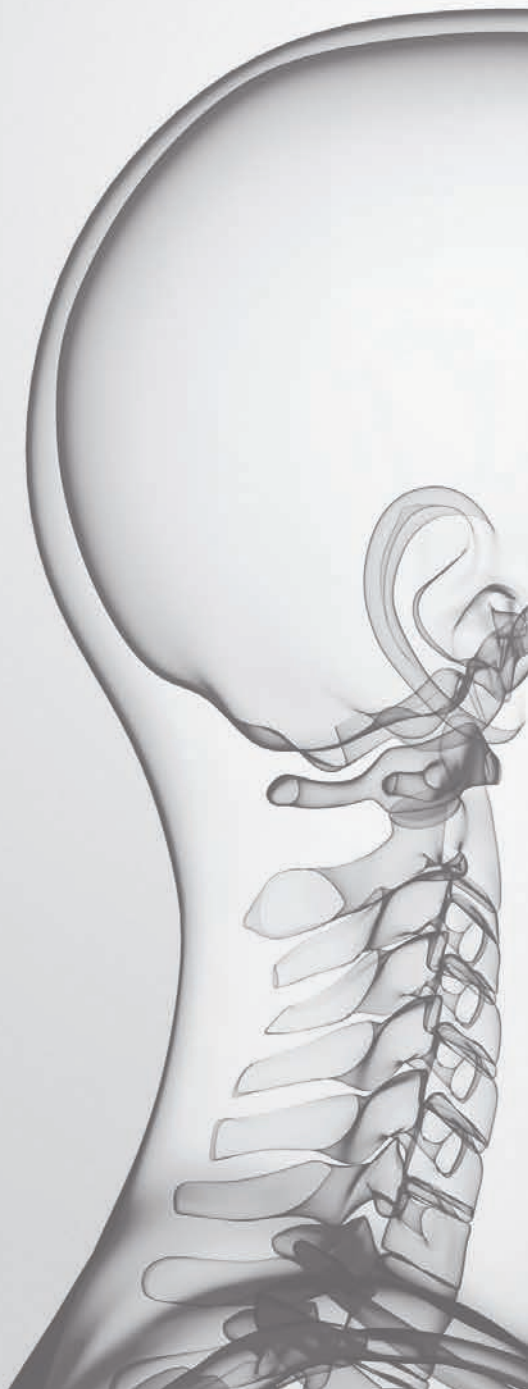

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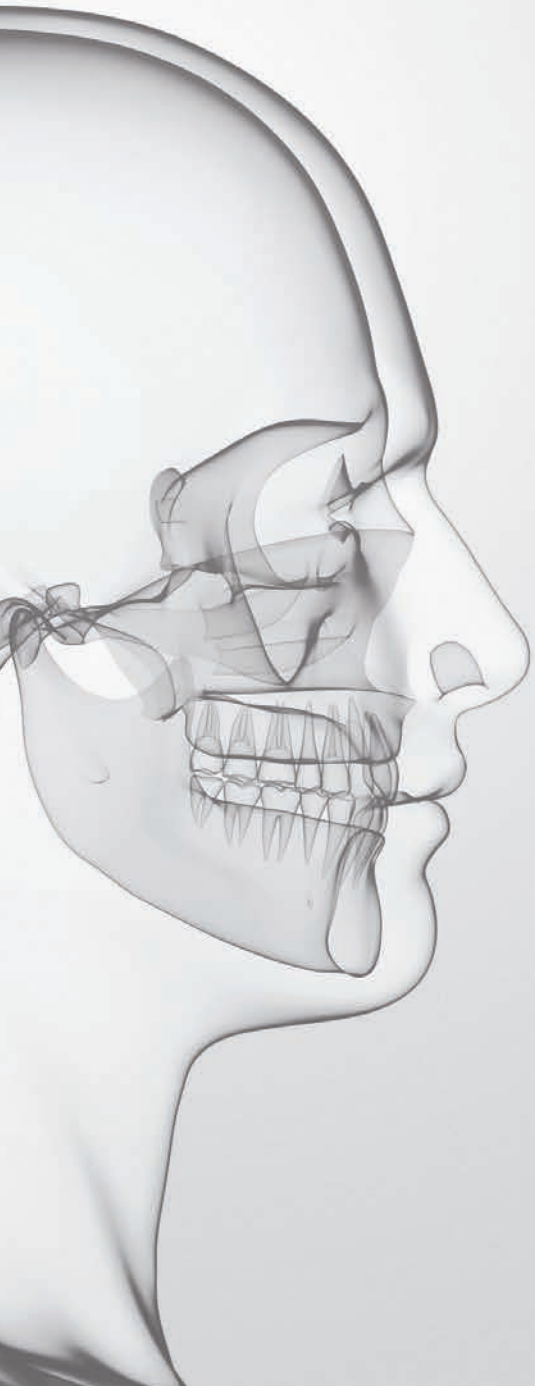

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