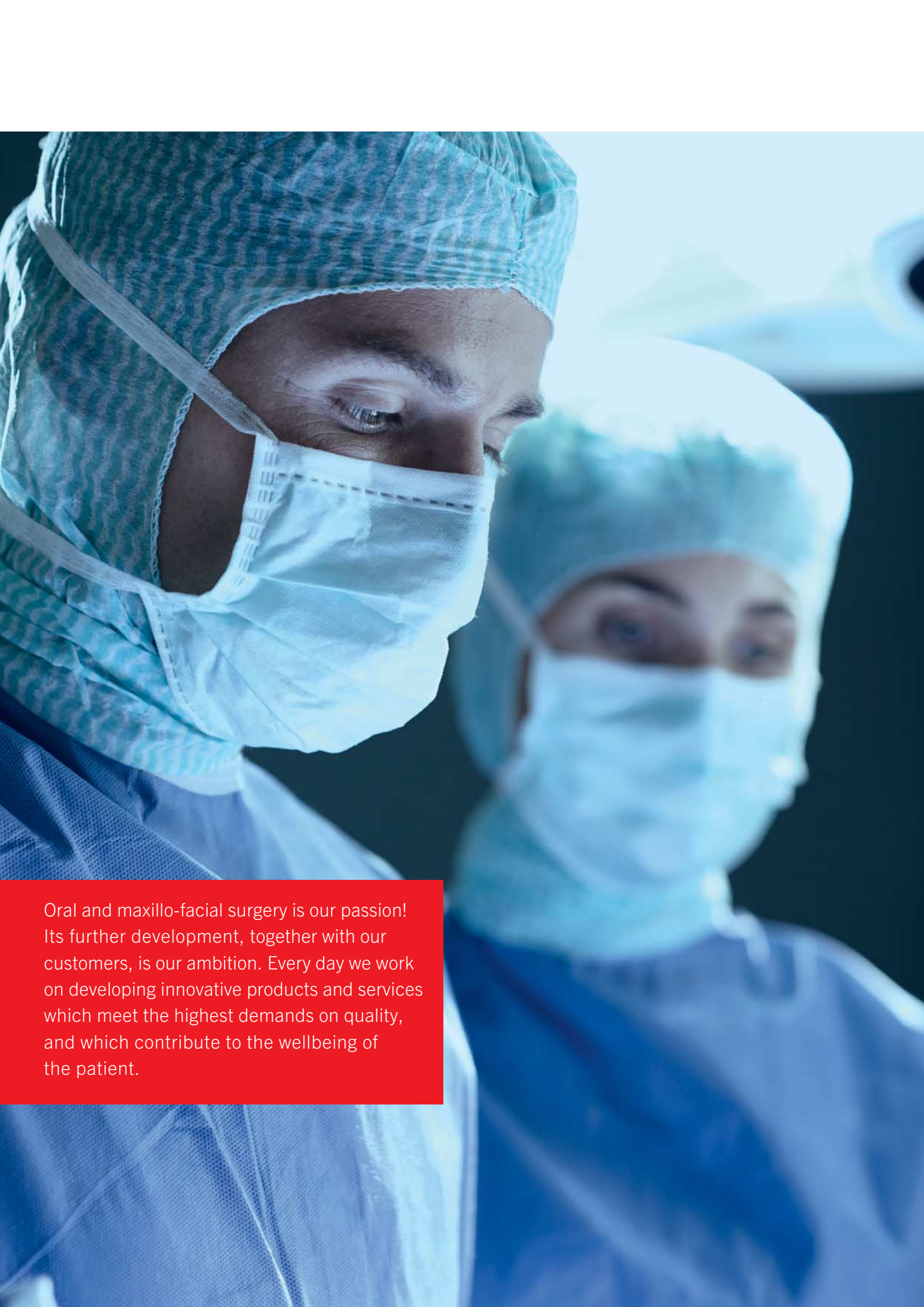




Cranial Distraction



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.

Table of Contents

	Pages
Product Features	6-7
Indications and Surgical Technique	8-9
■ Arnaud/Marchac Distraction System	10-11
■ Kawamoto Distractor	12-13
■ Posterior Cranial Vault Distractor	14-15
Product Range	16-29
■ Distractors	
■ Arnaud/Marchac Distraction System	16-17
■ Kawamoto Distractor	18
■ Posterior Cranial Vault Distractor	19
■ Activators	20-21
■ Screws	22-23
■ Instruments	24-27
■ Storage	28-29



Cranial Distraction

Distraction osteogenesis is a well-established technique used for several decades to repair long bone defects. Over the past 15 - 20 years, distraction osteogenesis has also gained increasing acceptance for correction of various craniofacial deformities.

In traditional craniofacial remodeling, there are creative techniques used to increase the volume and shape of existing bone, but generating bone and tissue through gradual distraction offers a reliable method to achieve treatment goals.

Cranial vault expansion and fronto-facial advancement by distraction osteogenesis has the big advantage of producing new autologous bone of correct shape in their locations, which is alive and vascularized. The technique, although not simple and not risk free, is much less technically challenging and exposes patients to lower risk for the most serious complications compared to single-stage vault expansion or monobloc advancement. Less soft tissue dissection and less devascularization of bone are required thus minimizing bone resorption and epidural dead space seen in traditional cranial remodeling. As the expansion is gradual, wound closure is not under tension resulting in less risk of problems with healing.

The KLS Martin product portfolio offers you everything you need for advanced cranial distraction. Therefore you get more than just standard products from a world technology leader. We are always ready to develop patient-specific solutions wherever the need arises.

Feature, Function and Benefit



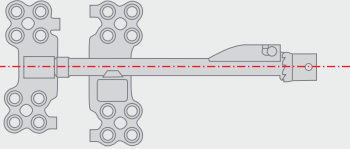
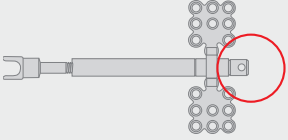
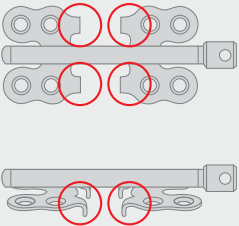
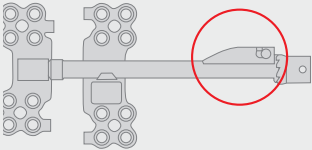
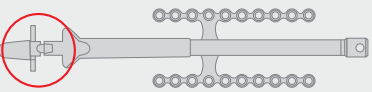
The design of our Cranial Distractors comprises a distractor body and the osteosynthesis plates connected to it. They are available for a distraction path of up to 30 mm.

Our Cranial Distractors are characterized by a symmetric arrangement of the osteosynthesis plates on the distractor body. This ensures that the distractors can be used on either side of the skull.

Most cranial distractors have a universal coupling that can be connected to different activators from the KLS Martin product range. This flexible activator concept not only allows more flexibility but also leads to an increased patient comfort during the distraction procedure.

Additional features of some cranial distractors as for example the ratchet mechanism or the hooks provided on the osteosynthesis plates enable a secure and easy treatment.

Cranial Distractors

	Feature	Benefit
	<ul style="list-style-type: none"> ▪ Symmetrical design 	<ul style="list-style-type: none"> ▪ Possibility to use the same distractor on either side of the skull ▪ Reduces stock-keeping
	<ul style="list-style-type: none"> ▪ Flexible activator concept due to universal coupling 	<ul style="list-style-type: none"> ▪ Allowing the choice of an individual activator that meets the anatomical requirements of the patient ▪ Different lengths and versions ▪ Increased patient comfort ▪ Activator can be removed during consolidation
	<ul style="list-style-type: none"> ▪ Hooks fitted to the osteosynthesis plates* 	<ul style="list-style-type: none"> ▪ Distributes distraction force to the bone ▪ The load on the screws is as low as possible
	<ul style="list-style-type: none"> ▪ Anti relapse ratchet* 	<ul style="list-style-type: none"> ▪ Prevents backward rotation of the distractor and consequential relapse of the distracted bone area ▪ Can be deactivated intraoperatively for function control
	<ul style="list-style-type: none"> ▪ Swivel joint footplate* 	<ul style="list-style-type: none"> ▪ Optimal adaptation to the cranium ▪ Allows compensation of any occurring forces when the force vector changes

* Not all cranial distractors have this feature

Step by Step to Optimal Fixation

Indications

Arnaud/Marchac Distraction System

The Arnaud/Marchac Distraction System is intended for internal distraction when treating craniofacial dysplasia, especially craniofacial synostoses. It is used for patients requiring facial advancement (Le Fort III) or frontofacial (monobloc) advancement.

Kawamoto Distractor

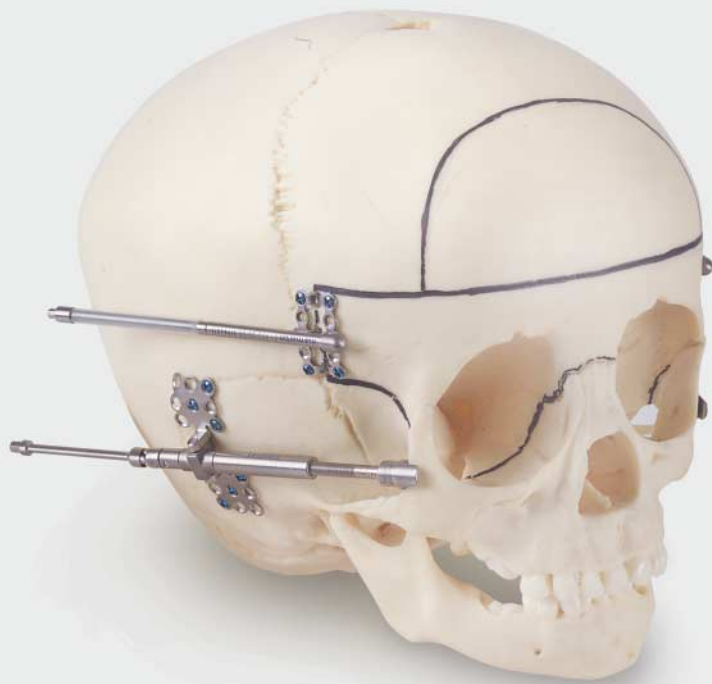
The Kawamoto Midface Distractor is intended for internal distraction when treating craniofacial dysplasia, especially craniofacial synostoses. It is used for patients requiring facial advancement (Le Fort III) or frontofacial (monobloc) advancement.

Special indications are:

- Midface hypoplasia, class III malocclusion in growing patients (age 6 – 12 years)
- Upper airway obstruction associated with midface hypoplasia
- Ocular exposure associated with midface hypoplasia

Posterior Cranial Vault Distractor

The Cranial Vault Distractor is used for treating cranial malformations such as syndromic craniosynostosis and congenital deficiencies.

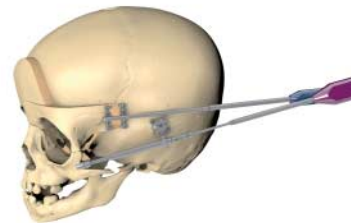


Surgical Techniques

Arnaud/Marchac Distraction System

Monobloc Advancement

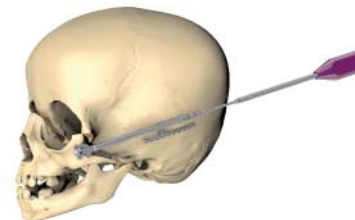
Pages 10-11



Kawamoto Distractor

LeFort III Advancement

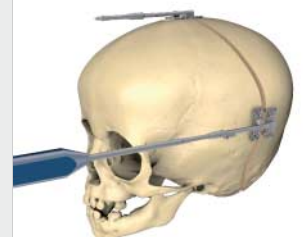
Pages 12-13

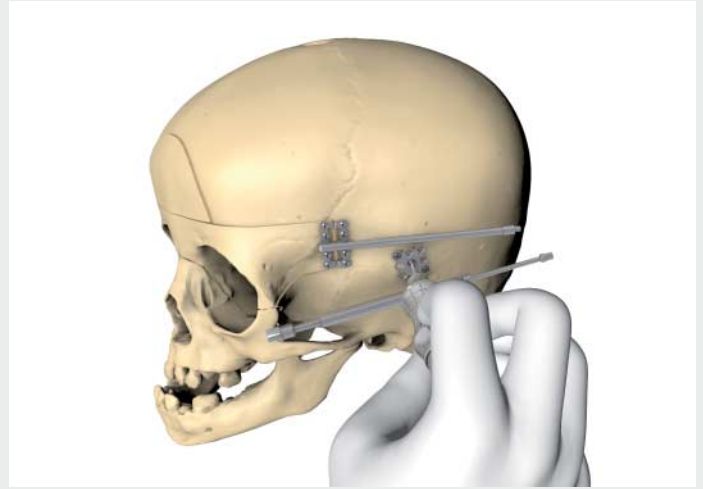
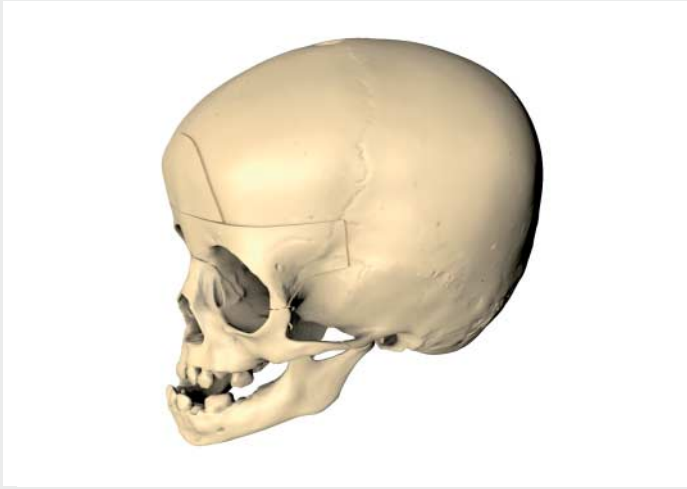


Posterior Cranial Vault Distractor

Cranial Vault Expansion

Pages 14-15





1. Approach and Osteotomy

After coronal incision and exposure of the temporal muscles, a monobloc osteotomy is performed.

2. Distractor Fixation

The Marchac Temporal Distractor (2) is placed almost horizontally on both sides of the skull, with the distractor pin anchored behind the zygomatic arch (i.e. the lower part of the lateral zygoma at the transition to the zygomatic arch). Thereafter, the distractor is fixed to the zygoma using 1.5-mm screws.

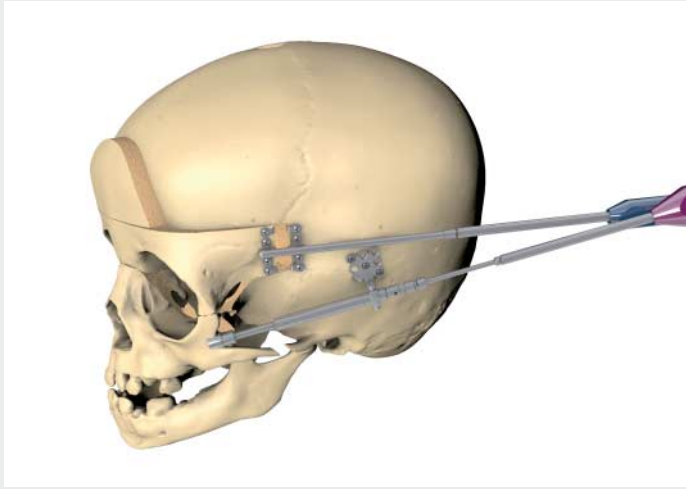
The projecting activator should be rotated a little to achieve a slight advancement as it is important that a resisting force acts upon it right from the start, with the U-type pin positioned securely on the zygomatic arch. If this requirement is not met, there is a risk of failure to activate the distractor later, since the device functions only if pressure is exerted on the distractor pin.

When performing a monobloc advancement the Arnaud Cranio Orbital Distractor (1) is additionally fitted in the cranio-orbital region, using 1.5-mm (for Arnaud 1.5) or 2.0-mm (for Arnaud 2.0) screws.

In this way, it is possible to achieve a slight rotation caudally in addition to the horizontal advancement of the midface to ensure optimal occlusion.

Note

To adapt the osteosynthesis plate to the patient's anatomy, they can be slightly bent using two bending pliers. Care must be taken during the contouring process because the weld may never be bent or subjected to mechanical loads.



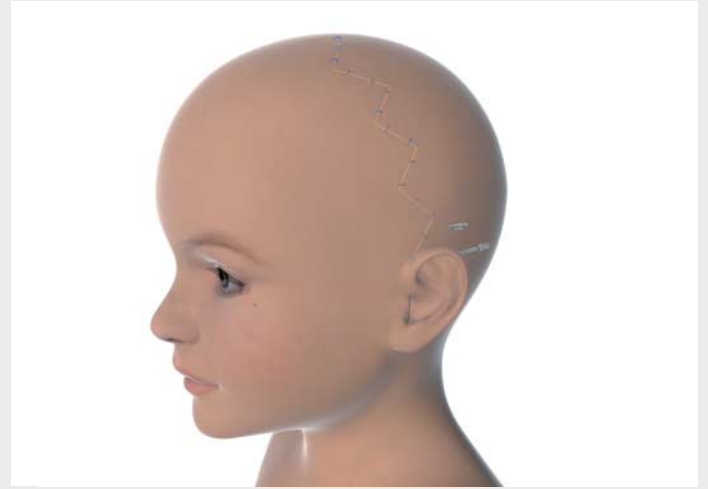
3. Function Control

An intraoperative function control is mandatory to check function of the distractor. Using the patient screwdriver rotate clockwise to advance the distractor.

If there is resistance, stop activation immediately.

Ensure the osteotomy is complete and no damage occurred to the device during contouring.

After testing, return the distractor back to the closed position.



4. Wound Closure

Finally the wound can be closed.

DISTRACTION

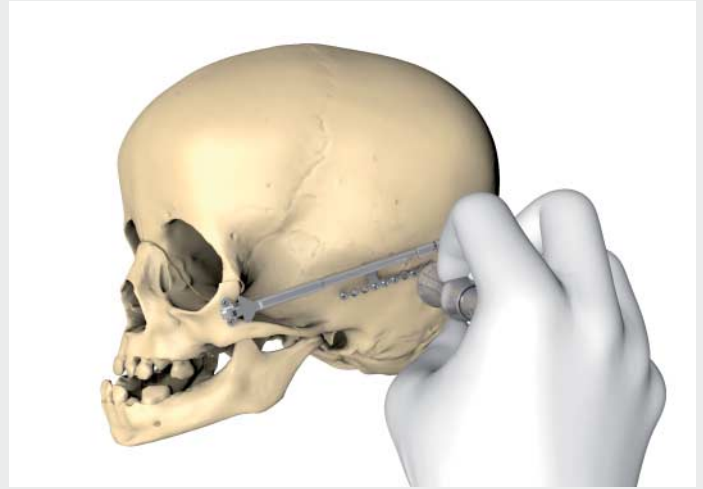
Latency phase: 3-7 days

Distraction phase: Distraction of 0.5 or 1.0 mm per day in one or two sessions

Consolidation phase: 3-9 months

Note

A LeFort III advancement can also be performed with the Arnaud/Marchac Distraction System.



1. Approach and Osteotomy

After coronal incision and exposure of the temporal muscles, a Le Fort III osteotomy is performed.

2. Distractor Fixation

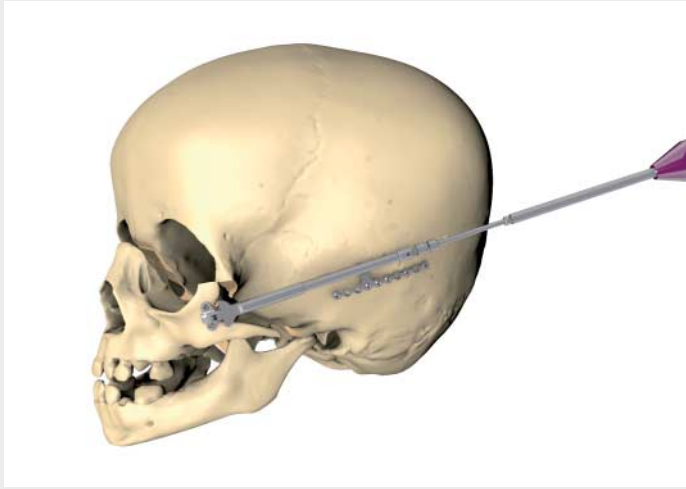
The Kawamoto Distractor is placed on both sides of the skull. For the forward dislocation of the face (Le Fort III) one distractor must be placed on each side of the skull.

The anterior osteosynthesis plates are positioned in such a way that the hooks are in contact with the inner area of the lateral orbital rim, directly where the zygomatic arch begins.

Typically, the superior, posterior osteosynthesis plates are now removed, before the remaining, posterior osteosynthesis plates are placed at the thick bone of the lateral origin of the zygomatic arch. The osteosynthesis plates are fixed using 1.5-mm screws.

Note

To adapt the osteosynthesis plate to the patient's anatomy, they can be slightly bent using two bending pliers. Care must be taken during the contouring process because the weld may never be bent or subjected to mechanical loads.



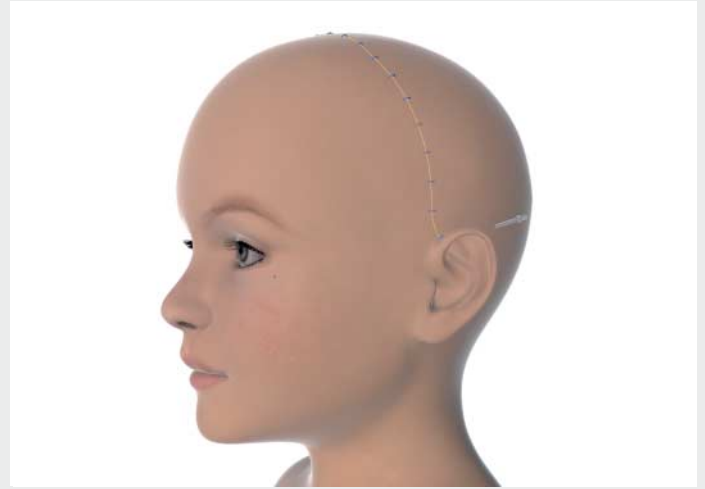
3. Function Control

An intraoperative function control is mandatory to check function of the distractor. Using the patient screwdriver rotate clockwise to advance the distractor.

If there is resistance, stop activation immediately.

Ensure the osteotomy is complete and no damage occurred to the device during contouring.

After testing, return the distractor back to the closed position.



4. Wound Closure

Finally the wound can be closed.

DISTRACTION

Latency phase: 3-7 days

Distraction phase: 2 turns of 360° per day for a total of 1 mm per day

Consolidation phase: 3-9 months

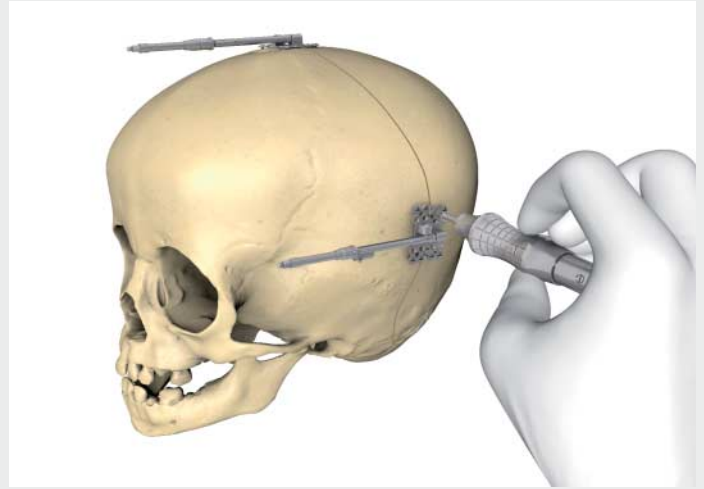
Note

A monobloc advancement can also be performed with the Kawamoto Distractor. In that case two distractors must be used for each side of the skull. This allows for more precise distraction, as the force vector can be adjusted better.



1. Approach and Osteotomy

After coronal incision and exposure of the cranial bone, a bone flap is marked as indicated for the particular case and the osteotomy is performed leaving the bone attached to the dura.



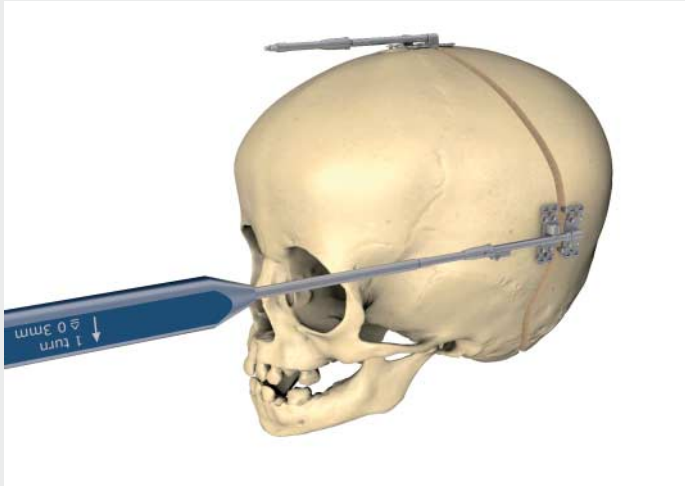
2. Distractor Fixation

Generally three Posterior Cranial Vault Distractors are placed. One on each side of the skull (in the temporal region) and a superior one placed a bit off centre to avoid the sagittal sinus.

The osteosynthesis plates are fixed to the cranial bone using 1.5-mm screws.

Note

To adapt the osteosynthesis plate to the patient's anatomy, they can be slightly bent using two bending pliers. Care must be taken during the contouring process because the weld may never be bent or subjected to mechanical loads.



3. Function Control

An intraoperative function control is mandatory to check function of the distractor. Using the patient screwdriver rotate clockwise to advance the distractor.

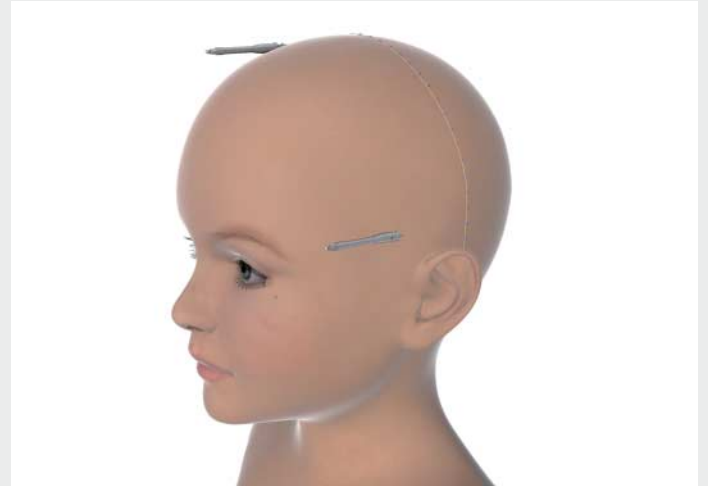
If there is resistance, stop activation immediately.

Ensure the osteotomy is complete and no damage occurred to the device during contouring.

After testing, return the distractor back to the closed position. To allow this, the anti-relapse ratchet needs to be deactivated.



After testing, the ratchet may be activated again.



4. Wound Closure

Finally the wound can be closed.

DISTRACTION

Latency phase: 3-7 days

Distraction phase:

Small spindle: 3 turns of 360° per day for a total of 1 mm per day

Large spindle: 2 turns of 360° per day for a total of 1 mm per day

Consolidation phase: 3-9 months

Distractors

Marchac Temporal Distractor

① Distractors w/o activators	Item Number
25 mm, for babies	51-620-25-09
35 mm, for children and adults	51-620-35-09
Distraction length/turn 0.5 mm	

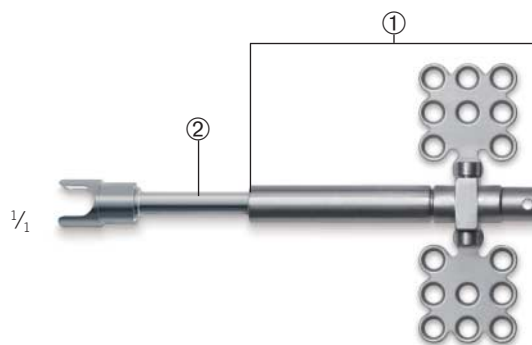
② To order separately	Item Number
Spindle incl. pin, 40 mm	51-623-40-09
Spindle incl. pin, 50 mm	51-623-50-09
Spindle incl. pin, 60 mm	51-623-60-09
Spindle incl. pin, 70 mm	51-623-70-09



Recommended screws	
Standard screws:	1.5 x 3.5 mm to 1.5 x 5 mm
Emergency:	1.8 x 5 mm
Drill-Free:	1.5 x 5 mm

Patient screwdrivers	
Straight 0.5 mm	51-500-90-07
Angled 0.5 mm	51-505-90-07
Combination straight and angled for handle 25-402-99-07	51-505-91-04

Activators	
Must be ordered separately – see page 20-21	





Icon explanations

- Ti Titanium
- 1 Units/pack

Arnaud Cranio-orbital Distractor

Arnaud 1.5

Distractor incl. activator	Item Number
20 mm	51-630-20-09
30 mm	51-630-30-09

Distraction length/turn 0.3 mm

Ti 1

Recommended screws

Standard screws: 1.5 x 3.5 mm to 1.5 x 5 mm

Emergency: 1.8 x 5 mm

Drill-Free: 1.5 x 5 mm

Patient screwdrivers

Straight 0.3 mm 51-525-85-07

Combination straight and angled
for handle 25-402-99-07 51-525-91-04



Arnaud 2.0

Distractor w/o activator	Item Number
20 mm	51-632-20-09
30 mm	51-632-30-09

Distraction length/turn 0.6 mm

Ti 1

Recommended screws

Standard screws: 2.0 x 3.5 mm to 2.0 x 5 mm

Emergency: 2.3 x 5 mm

Drill-Free: 2.0 x 5 mm

Patient screwdrivers

Straight 0.6 mm 51-423-95-07

Combination straight and angled
for handle 25-402-99-07 51-505-91-04



Activators

Must be ordered separately – see page 20-21

Distractors

Kawamoto Distractor

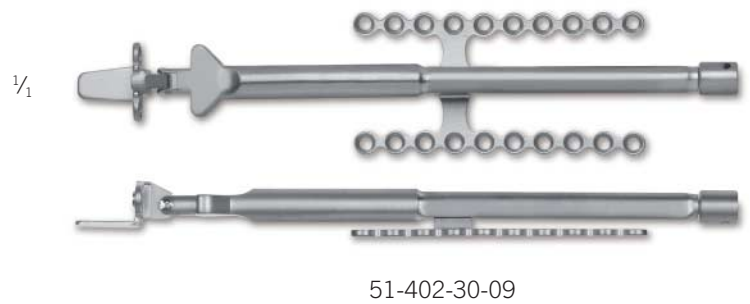
Distractors w/o activators	Item Number
Straight, 30 mm	51-402-30-09
Curved, 30 mm	51-403-30-09
Distraction length/turn 0.5 mm	



Recommended screws	
Standard screws:	1.5 x 3.5 mm to 1.5 x 5 mm
Emergency:	1.8 x 5 mm
Drill-Free:	1.5 x 5 mm

Patient screwdrivers	
Straight 0.5 mm	51-500-90-07
Angled 0.5 mm	51-505-90-07
Combination straight and angled for handle 25-402-99-07	51-505-91-04

Activators	
Must be ordered separately – see page 20-21	





Icon explanations

- Ti Titanium
- 1 Units/pack

Posterior Cranial Vault Distractor

Distractors w/o activators	Item Number
Small spindle, 30 mm, with ratchet	51-405-42-09
Distraction length/turn 0.3 mm	

Ti 1

Distractors w/o activators	Item Number
Large spindle, 30 mm, with ratchet	51-563-30-09
Distraction length/turn 0.5 mm	

Ti 1

Recommended screws	
Standard screws:	1.5 x 3.5 mm to 1.5 x 5 mm
Emergency:	1.8 x 5 mm
Drill-Free:	1.5 x 5 mm

Patient screwdrivers	
Straight 0.3 mm	51-430-95-07
Straight 0.5 mm	51-500-90-07
Angled 0.5 mm	51-505-90-07
Combination straight and angled for handle 25-402-99-07	51-505-91-04

Activators	
Must be ordered separately – see page 20-21	














Distraction Activators Conventional removable Activators

Except the Arnaud Distractor 1.5 all cranial distractors listed in this brochure are delivered without activator allowing the choice of an individual activator that meets the anatomical requirements of the patient instead of using a predefined one.

This not only allows more flexibility but also leads to an increased patient comfort during the distraction procedure.

The whole range of activators includes rigid and flexible activators in different lengths. These activators can additionally be combined with different cardanic extensions to gain more flexibility.

Conventional removable Activators*

	Activation arms	Item No.
① 	Activation arm, flexible, incl. cardanic element, 30 mm	51-400-30-09
② 	Activation arm, flexible, incl. cardanic element, 40 mm	51-400-40-09
③ 	Activation arm, flexible, incl. cardanic element, 50 mm	51-400-50-09
④ 	Activation arm, rigid, incl. cardanic element, 25 mm	51-401-25-09
⑤ 	Activation arm, rigid, incl. cardanic element, 35 mm	51-401-35-09
⑥ 	Activation arm, rigid, incl. cardanic element, 45 mm	51-401-45-09
⑦ 	Activation arm, rigid, incl. cardanic element, 50 mm, clipable	51-401-50-09
Additional		Item No.
⑧ 	Direct drive activator	51-401-90-09
⑨ 	Single cardanic extension for activation arm	51-401-91-09
⑩ 	Rigid extension 20 mm for activation arm	51-401-92-09
1/1 	Trocar tip for activation arm	51-401-93-09

* Removal of activator

During the consolidation period – once the active distraction process has been completed – activators are basically no longer needed and a source of inconvenience for the patient.

The activators on this page can easily be removed by using special disconnection forceps (item no. 51-400-01-07, see page 25).



Remote Release Activators

Uncoupling procedure



1. Pull out the release lug (some resistance needs to be overcome).



2. The release lug stands in exposed position by turning it clockwise or anti-clockwise by 90°.



3. This lowers the ball and socket of the universal coupling of the activator.



4. The activator can now be easily removed.











Remote Release Activators

	Activators	Item No.
	Remote release activator, flexible, 33 mm	51-411-33-09
	Remote release activator, rigid, 33 mm	51-410-33-09
	Remote release activator, rigid, 43 mm	51-410-43-09
	Remote release activator, rigid, 53 mm	51-410-53-09
	Single cardanic extension for activation arm	51-401-91-09

The special and completely new feature about Remote Release Activators is that the mechanism of coupling and uncoupling is located at the point of activation with the patient screwdriver. Thereby the uncoupling of the activator can be initiated directly from the outside and the dissection of the way to the connection point between distractor and activator is not applicable anymore.







Each Remote Release Activator comes with a dedicated instruction for use providing all important information for handling the device.

Screws, Drill Bits and Screwdriver Blades

Centre Drive® 1.5 mm		maxDrive® 1.5 mm	
	  		  
Micro Screws self-retaining		Micro Screws self-retaining	
	Ø x Length	Centre Drive®	maxDrive®
	1.5 x 3.5 mm	25-665-03-09	25-875-03-09
	1.5 x 4 mm	25-665-04-09	25-875-04-09
	1.5 x 5 mm	25-665-05-09	25-875-05-09
	1.5 x 6 mm	25-665-06-09	25-875-06-09
	1.5 x 7 mm	25-665-07-09	25-875-07-09
Emergency Screws self-retaining		Emergency Screws self-retaining	
	Ø x Length	Centre Drive®	maxDrive®
	1.8 x 3.5 mm	25-666-03-09	25-876-03-09
	1.8 x 5 mm	25-666-05-09	25-876-04-09
	1.8 x 7 mm	25-666-07-09	25-876-05-09
Drill-Free Screws self-retaining		Drill-Free Screws self-retaining	
	Ø x Length	Centre Drive®	maxDrive®
	1.5 x 4 mm	25-668-04-09	25-878-04-09
	1.5 x 5 mm	25-668-05-09	25-878-05-09
	1.5 x 6 mm	25-668-06-09	25-878-06-09
	1.5 x 7 mm	25-668-07-09	25-878-07-09
Screwdriver blades for 1.5-mm Screws for screwdriver handle 25-402-99-07		Drill bits for 1.5-mm Screws with J-notch attachment	
	Centre Drive®	maxDrive®	Item No.
	25-430-98-07	25-489-97-07	1.1 x 50 mm 3.5 mm 25-452-03-91
			1.1 x 50 mm 5 mm 25-452-05-91
			1.1 x 50 mm 7 mm 25-452-07-91




Icon explanations

-  Steel
-  Titanium
-  Units/pack
-  Centre Drive®
-  maxDrive®
-  J-notch attachment


Centre Drive® 2.0 mm   

Mini Screws self-retaining


	Ø x Length	Centre Drive®
	2.0 x 4 mm	25-662-04-09
	2.0 x 5 mm	25-662-05-09
	2.0 x 6 mm	25-662-06-09
	2.0 x 7 mm	25-662-07-09
	2.0 x 9 mm	25-662-09-09
	2.0 x 11 mm	25-662-11-09

maxDrive® 2.0 mm   


Mini Screws self-retaining

	Ø x Length	maxDrive®
	2.0 x 4 mm	25-872-04-09
	2.0 x 5 mm	25-872-05-09
	2.0 x 6 mm	25-872-06-09
	2.0 x 7 mm	25-872-07-09
	2.0 x 9 mm	25-872-09-09
	2.0 x 11 mm	25-872-11-09


Emergency Screws self-retaining

	Ø x Length	Centre Drive®
	2.3 x 5 mm	25-663-45-09
	2.3 x 7 mm	25-663-47-09
	2.3 x 9 mm	25-663-49-09


Emergency Screws self-retaining

	Ø x Length	maxDrive®
	2.3 x 4 mm	25-873-44-09
	2.3 x 5 mm	25-873-45-09
	2.3 x 7 mm	25-873-47-09
	2.3 x 9 mm	25-873-49-09

Drill-Free Screws self-retaining

	Ø x Length	Centre Drive®
	2.0 x 5 mm	25-669-05-09
	2.0 x 7 mm	25-669-07-09


Drill-Free Screws self-retaining

	Ø x Length	maxDrive®
	2.0 x 5 mm	25-879-05-09
	2.0 x 6 mm	25-879-06-09
	2.0 x 7 mm	25-879-07-09
	2.0 x 9 mm	25-879-09-09

Screwdriver blades for 2.0-mm Screws
for screwdriver handle 25-402-99-07

	Centre Drive®	maxDrive®
	25-434-98-07	25-491-97-07

Drill bits for 2.0-mm Screws
with J-notch attachment

	Ø x Length	Stop	Item No.
	1.5 x 50 mm	5 mm	25-449-05-91
	1.5 x 50 mm	7 mm	25-449-07-91
	1.5 x 50 mm	9 mm	25-449-09-91
	1.5 x 50 mm	11 mm	25-449-11-91



1/2

25-402-99-07
Screwdriver handle

Instruments for Distractor Placement

1.5 mm Micro

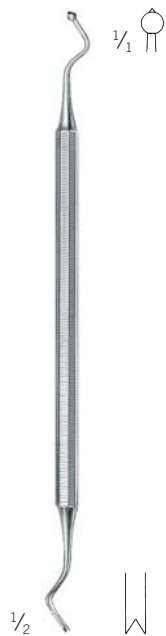
(For all distractors fixed with 1.5-mm screws)



25-441-16-07

Plate-holding
forceps, curved
18 cm/7 $\frac{1}{4}$ "

St 1



25-435-15-07

Plate-holding
instrument
18 cm/7 $\frac{1}{4}$ "

St 1

2.0 mm Mini

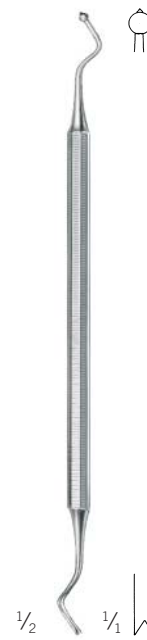
(For all distractors fixed with 2.0-mm screws)



25-441-18-07

Plate-holding
forceps, curved
18 cm/7 $\frac{1}{4}$ "

St 1



Lindorf
25-435-20-07

Plate-holding
instrument
16 cm/6 $\frac{1}{4}$ "

St 1



Icon explanations

St Steel

1 Units/pack

TC GOLD Instruments with tungsten carbide inserts

For both sizes



25-486-13-07
Modeling pliers
2 items recommended
13 cm/5 1/8"

St 1

TC GOLD



51-400-03-07
Body holding forceps
15.5 cm/6 1/8"

St 1



51-400-02-07
Plate cutter
18 cm/7 1/8"

St 1



51-400-04-07
Activator
measuring device
10.5 cm/4 1/8"

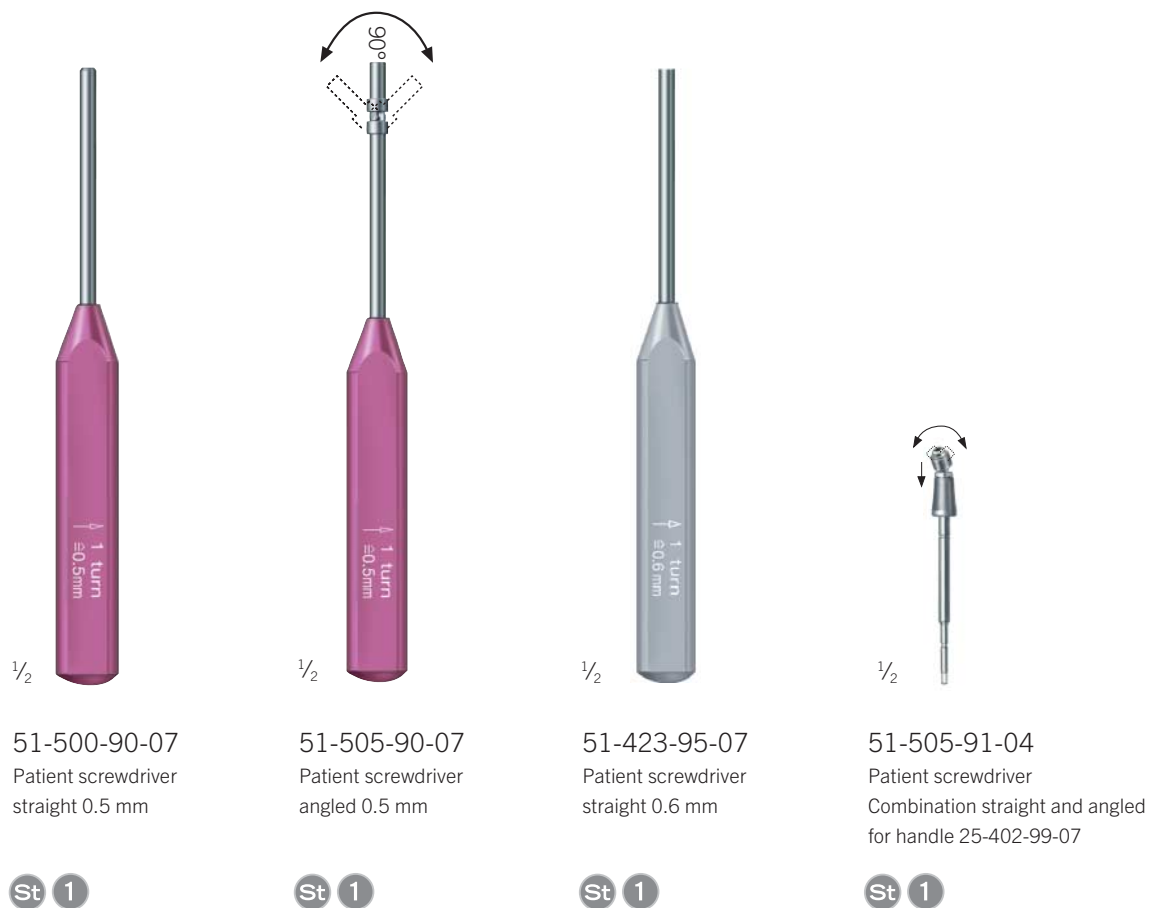
St 1



51-400-01-07
Activation arm
disconnection forceps
15.5 cm/6 1/8"

St 1

Patient Screwdrivers





Icon explanations

St Steel

1 Units/pack



1/2

51-430-95-07
Patient screwdriver
straight 0.3 mm

St 1



1/2

51-525-85-07
Patient screwdriver
straight 0.3 mm

St 1



1/2

51-525-91-04
Patient screwdriver
Combination straight and angled
for handle 25-402-99-07

St 1

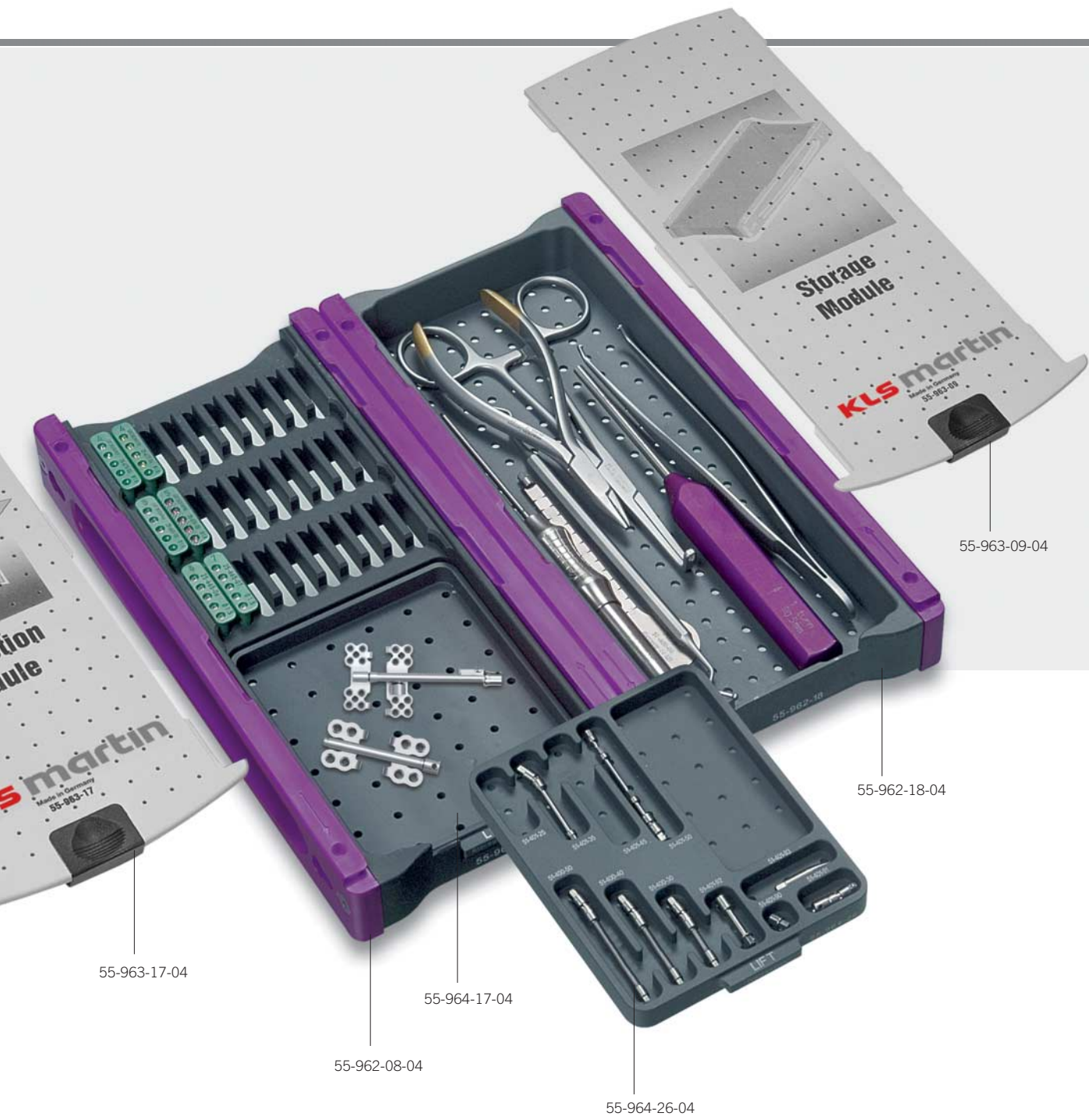
Storage Module



Storage Module

This storage proposal offers you enough room to integrate the most important application tools.

	Item No.	
	Basic module, purple	55-962-08-04
	Insert, universal	55-964-17-04
	Insert for activation arms	55-964-26-04
	Lid for distraction module	55-963-17-04
	Storage module, purple	55-962-18-04
Lid for storage module	55-963-09-04	



55-963-17-04

55-964-17-04

55-962-08-04

55-964-26-04

55-962-18-04

55-963-09-04

CMF Surgery

SonicWeld Rx®

Resorbable implants for use in craniomaxillofacial osteosynthesis

- Resorb x®
- Resorb xG

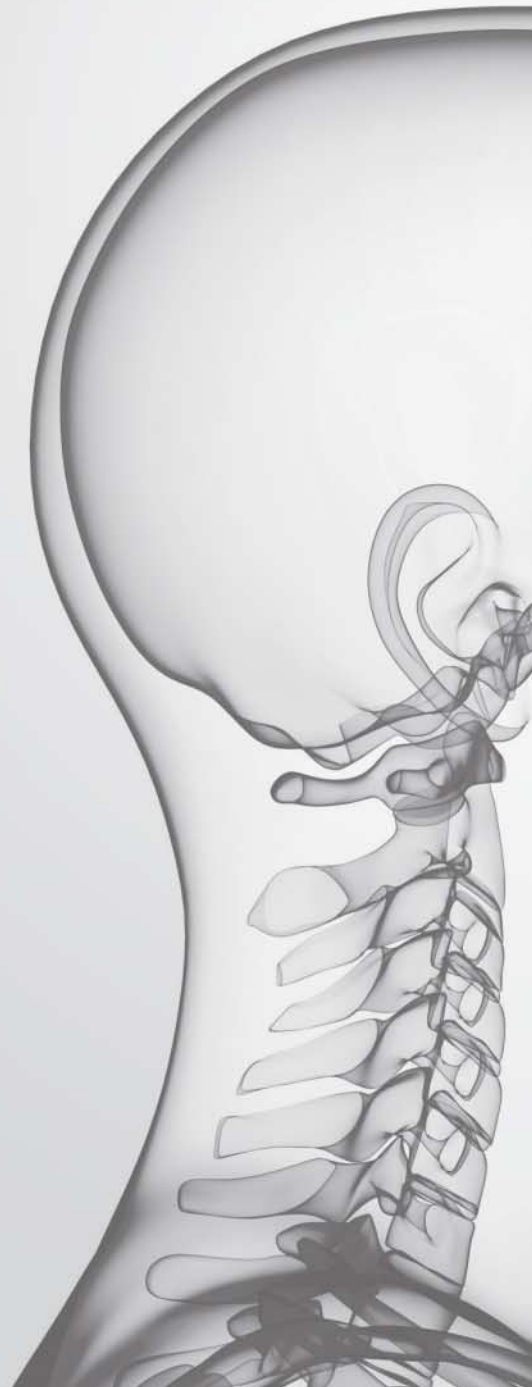


It is the face that makes humans unique and unmistakable – “There is nothing that more closely reflects the life of an individual than the human face*.”

Our objective is to simplify craniofacial surgery with specially designed implant systems that ensure optimum satisfaction for both surgeon and patient. Together with renowned users we translate new ideas into innovative products and are constantly enhancing them.

Our range of products includes everything necessary for modern craniofacial surgery. We not only set standards but we also go beyond to take advantage of modern technology in the development of solutions customized for the individual patient.

KLS Martin – your competent and reliable partner for both everyday challenges and special challenges.



* © Kurt Haberstich (*1948)

Distractors

Devices for use in correction of malformations

- Cranial distraction
- Midface distraction
- Mandibular distraction



Individual Patient Solutions

Patient-specific solutions for use in craniomaxillofacial surgery

- IPS Implants®
- IPS CaseDesigner®
- IPS Gate®



LevelOne Fixation

Titanium implants and instruments for use in craniomaxillofacial osteosynthesis

- Traumatology
- Reconstruction
- Orthognatic surgery



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