KLS martin GROUP

Cranial Distraction

www.klsmartin.com

Oral and maxillofacial 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.

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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

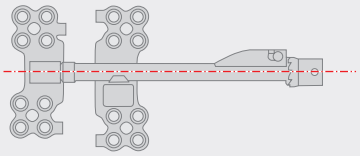
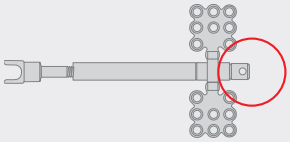
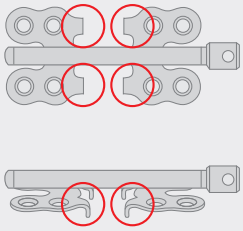
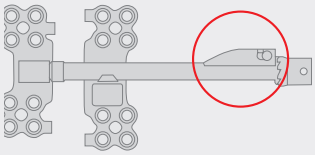
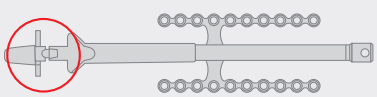
The design of our Cranial Distractors comprises a distractor body and the osteosynthesis plates connected to it. They are available for a distraction path of up to 30 mm.

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
	■ Symmetrical design	■ Possibility to use the same distractor on either side of the skull ■ Reduces stock-keeping
	■ Flexible activator concept due to universal coupling	■ 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
	■ Hooks fitted to the osteosynthesis plates*	■ Distributes distraction force to the bone ■ The load on the screws is as low as possible
	■ Anti relapse ratchet*	■ Prevents backward rotation of the disctractor and consequential relapse of the distracted bone area ■ Can be deactivated intraoperatively for function control
	■ Swivel joint footplate*	■ 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.

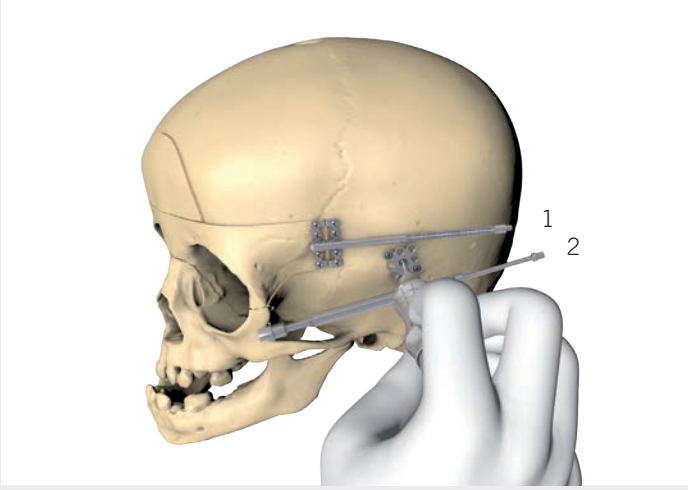
Kawamoto Distractor
The Kawamoto Midface Distractor is intended for internal distraction when treating craniofacial dysplasia, especially craniofacial synostoses. It is used for patients requiring facial advancement (Le Fort III) or frontofacial (monobloc) advancement.
Special indications are:
- Midface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

1. Approach and Osteotomy

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



2. Distractor Fixation

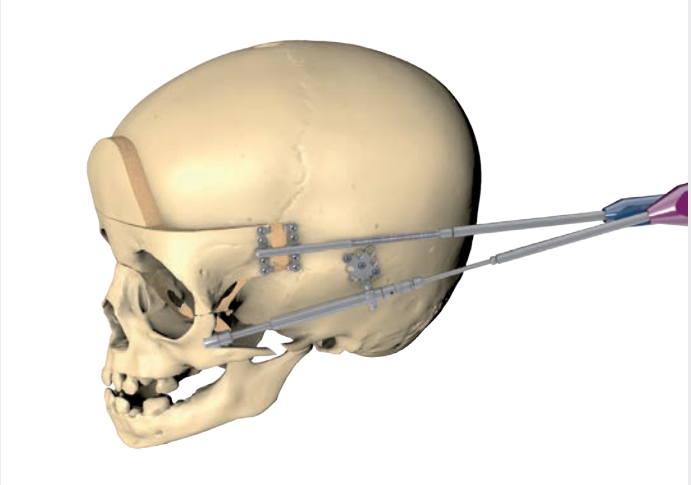
The Marchac Temporal Distractor (2) is placed almost horizontally on both sides of the skull, with the distractor pin anchored behind the zygomatic arch (i.e. the lower part of the lateral zygoma at the transition to the zygomatic arch). Thereafter, the distractor is fixed to the zygoma using 1.5-mm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

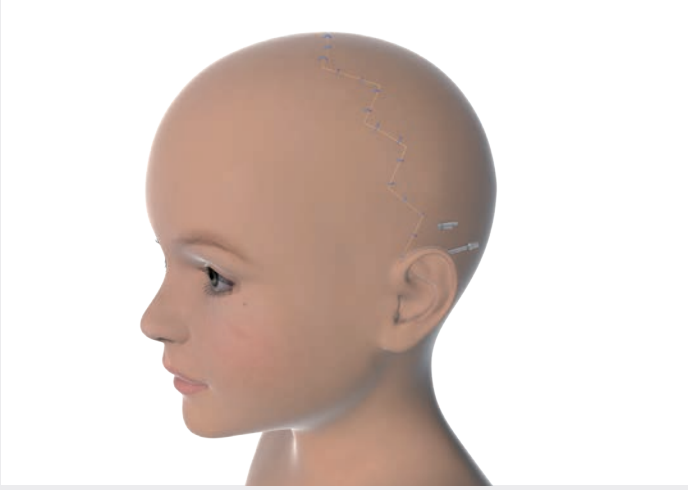
The projecting activator should be rotated a little to achieve a slight advancement as it is important that a resisting force acts upon it right from the start, with the U-type pin positioned securely on the zygomatic arch. If this requirement is not met, there is a risk of failure to activate the distractor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

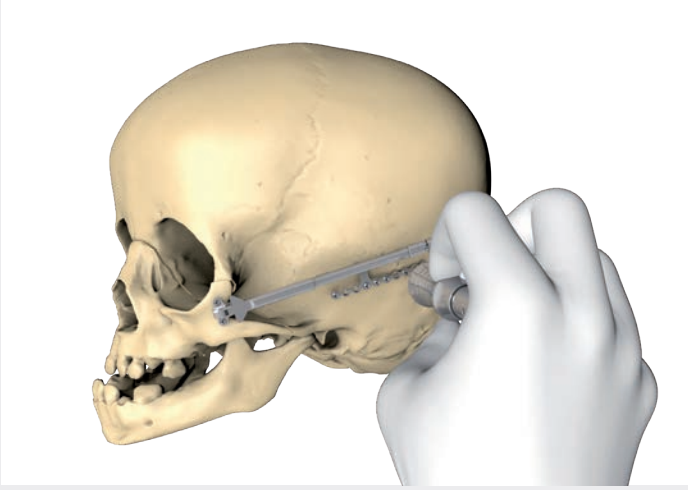
Distraction phase: Distraction of 0.5 or 1.0 mm per day in one or two sessions

Consolidation phase: 3-9 months

Note
A Le Fort 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 ostetomy is performed.



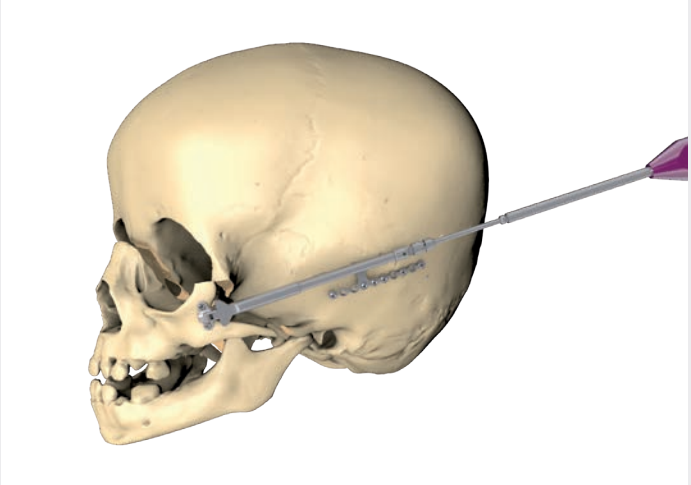
2. Distractor Fixation

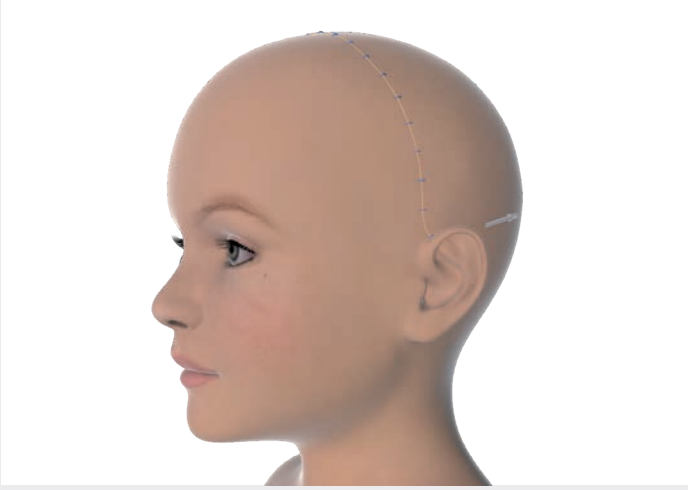
The Kawamoto Distractor is placed on both sides of the skull. For the forward dislocation of the face (Le Fort III) one distractor must be placed on each side of the skull.

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

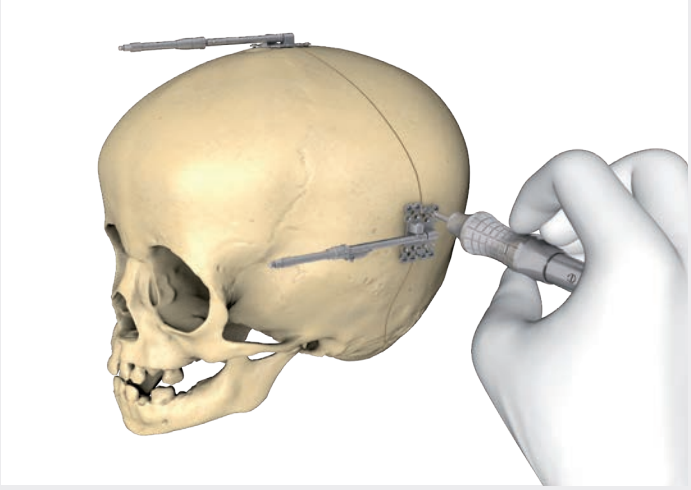
Distraction phase: 2 turns of 360° per day for a total of 1 mm per day

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.

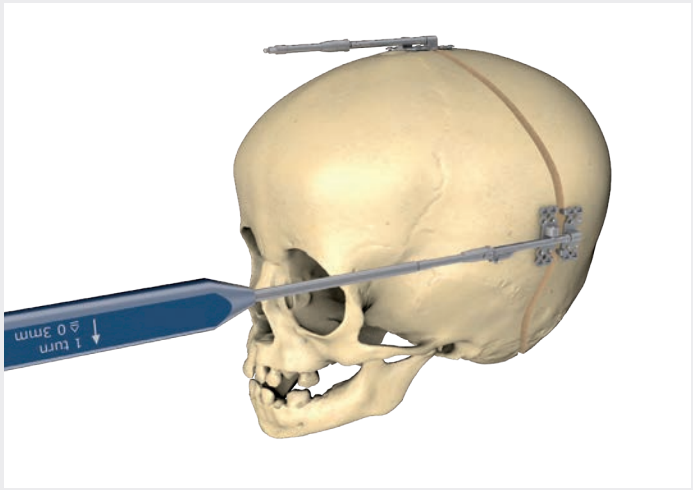


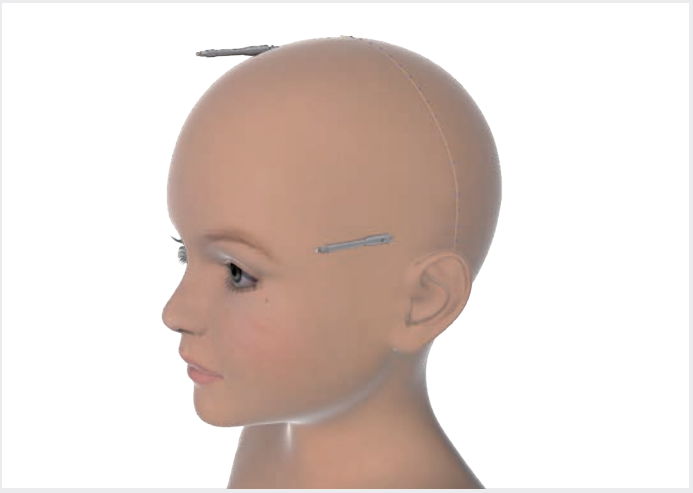
2. Distractor Fixation

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.





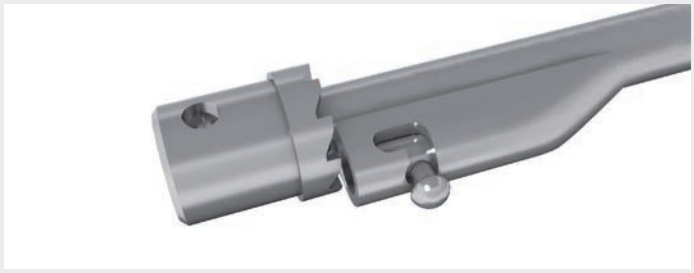
3. Function Control

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

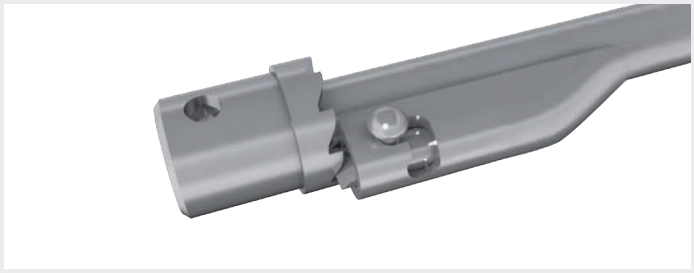
If there is resistance, stop activation immediately.

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

❶ 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	

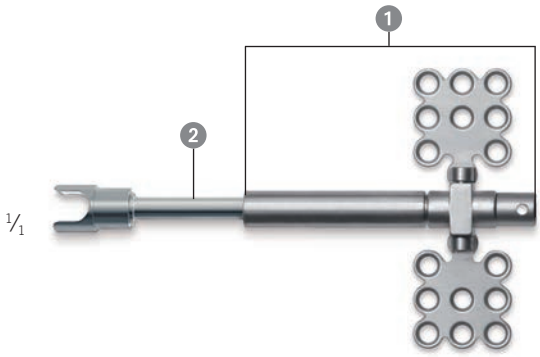
❷ To order separately	
Spindle incl. pin, 40 mm	51-623-40-09
Spindle incl. pin, 50 mm	51-623-50-09
Spindle incl. pin, 60 mm	51-623-60-09
Spindle incl. pin, 70 mm	51-623-70-09

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 0.5 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



1/1

Icon explanations

Ti Titanium

1 Units/pack

Arnaud Cranio-Orbital Distractor

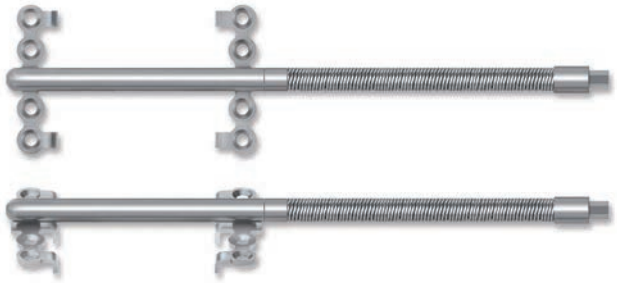
Arnaud 1.5

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

1/1



Arnaud 2.0

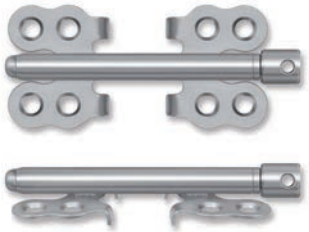
Distractor w/o activator	Item Number
20 mm	51-632-20-09
30 mm	51-632-30-09
Distraction length/turn 0.6 mm	

Ti 1

Recommended screws	
Standard screws:	2.0 x 4 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

1/1



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	

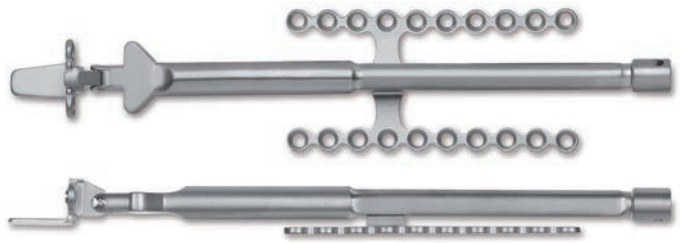
Ti 1

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

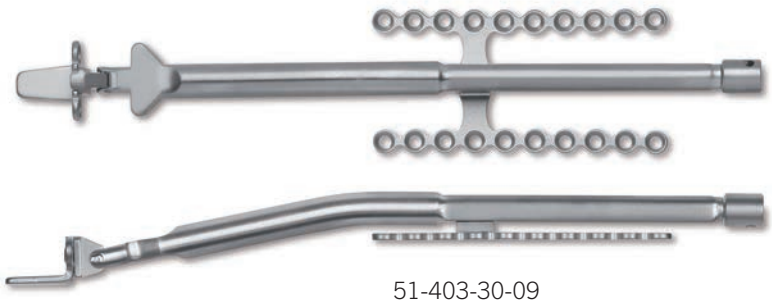
Patient screwdrivers	
Straight 0.5 mm	51-500-90-07
Angled 0.5 mm	51-505-90-07
Combination straight and angled for handle 25-402-99-07	51-505-91-04

Activators
Must be ordered separately – see page 20-21

1/1



51-402-30-09



51-403-30-09

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	
Large spindle, 30 mm, with ratchet	51-563-30-09
Distraction length/turn 0.5 mm	

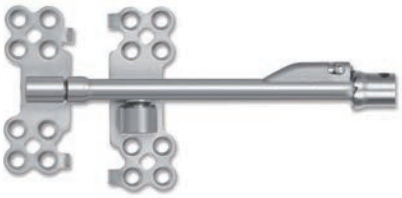
Ti 1

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

1/1



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	Item No.
❶ 	Activation arm, flexible, incl. cardanic element, 30 mm	51-400-30-09
❷ 	Activation arm, flexible, incl. cardanic element, 40 mm	51-400-40-09
❸ 	Activation arm, flexible, incl. cardanic element, 50 mm	51-400-50-09
❹ 	Activation arm, rigid, incl. cardanic element, 25 mm	51-401-25-09
❺ 	Activation arm, rigid, incl. cardanic element, 35 mm	51-401-35-09
❻ 	Activation arm, rigid, incl. cardanic element, 45 mm	51-401-45-09
❼ 	Activation arm, rigid, incl. cardanic element, 50 mm, clipable	51-401-50-09
	Additional	**Item No.**
❽ 	Direct drive activator	51-401-90-09
❾ 	Single cardanic extension for activation arm	51-401-91-09
❿ 	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).

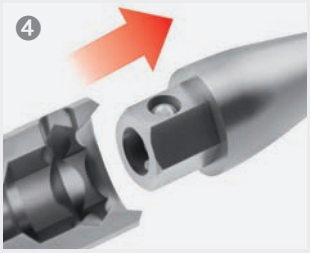
Remote Release Activators

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 these 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.
Remote Release Activators fit to all standard couplings that are designed for removable activators, such as almost all distractors specified in this brochure. They provide an alternative option in addition to the proven, conventional activators. **As standard Remote Release Activators are provided without cardanic element, they must be combined with the cardanic element 51-401-91-09 to reduce the risk of breakage.** If one chooses an additional cardanic element, it will stay with the distractor after removal of the Remote Release Activator.

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

Micro Screws

self-retaining

Ø x Length	Centre Drive®
1.5 x 3.5 mm	25-665-03-09
1.5 x 4 mm	25-665-04-09
1.5 x 5 mm	25-665-05-09
1.5 x 6 mm	25-665-06-09
1.5 x 7 mm	25-665-07-09

Emergency Screws

self-retaining

Ø x Length	Centre Drive®
1.8 x 3.5 mm	25-666-03-09
1.8 x 5 mm	25-666-05-09
1.8 x 7 mm	25-666-07-09

Drill-Free-Screws

self-retaining

Ø x Length	Centre Drive®
1.5 x 4 mm	25-668-04-09
1.5 x 5 mm	25-668-05-09
1.5 x 6 mm	25-668-06-09
1.5 x 7 mm	25-668-07-09

Screwdriver blades for 1.5-mm screws

for screwdriver handle 25-402-99-07

St
1

Centre Drive®	maxDrive®
25-430-98-07	25-489-97-07

maxDrive® 1.5 mm

Micro Screws

self-retaining

Ø x Length	maxDrive®
1.5 x 3.5 mm	25-875-03-09
1.5 x 4 mm	25-875-04-09
1.5 x 5 mm	25-875-05-09
1.5 x 6 mm	25-875-06-09
1.5 x 7 mm	25-875-07-09

Emergency Screws

self-retaining

Ø x Length	maxDrive®
1.8 x 3.5 mm	25-876-03-09
1.8 x 4 mm	25-876-04-09
1.8 x 5 mm	25-876-05-09
1.8 x 7 mm	25-876-07-09

Drill-Free-Screws

self-retaining

Ø x Length	maxDrive®
1.5 x 4 mm	25-878-04-09
1.5 x 5 mm	25-878-05-09
1.5 x 6 mm	25-878-06-09
1.5 x 7 mm	25-878-07-09

Drill bits for 1.5-mm screws

with J-notch attachment

St
1

Ø x Length	Stop	Item No.
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

½

25-402-99-07

Screwdriver handle

Icon explanations

- St Steel
- Ti Titanium
- 1 Units/pack
- Centre Drive®
- maxDrive®
- maxDrive® Hex Head
- J-notch attachment

maxDrive® Hex Head 1.5 mm

Drill-Free Hex Head Screws

Ø x Length	Thread Length	maxDrive®
1.5 x 7 mm	5 mm	50-348-07-09
1.5 x 9 mm	7 mm	50-348-09-09

Screwdriver Blades for 1.5-mm Screws

for screwdriver handle 25-407-03-04

maxDrive®	
25-438-97-07	

Note:

Hex head screws lessen the difficulty of removal if there is bony overgrowth or the screw head is difficult to see during removal. Although hex head screws are drill free, predrilling may be required depending on the specific patient's bone.

The following applies to distractors with ratchet:

The clearance of the distractor must be checked in the extended state. It must be ensured that the hex head screws do not collide with the ratchet device.

½

51-500-90-07

Patient screwdriver
for hex head screws

Screws, Drill Bits and Screwdriver Blades

Centre Drive® 2.0 mm

Micro 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

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

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

Screwdriver Blades for 2.0-mm Screws

for screwdriver handle 25-402-99-07

St
1

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

Icon explanations

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

maxDrive® 2.0 mm

Micro 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	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	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

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

½

25-402-99-07

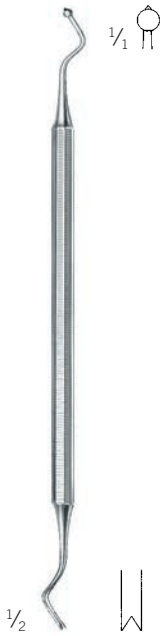
Screwdriver handle

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 ¼"

St 1



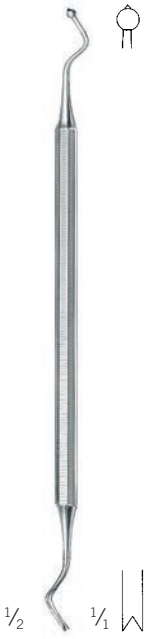
25-435-15-07
Plate-holding
instrument
18 cm/7 ¼"

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 ¼"

St 1



Lindorf
25-435-20-07
Plate-holding
instrument
16 cm/6 ¼"

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 ⅛"

St 1
TC GOLD

51-400-03-07
Body holding forceps
15.5 cm/6 ⅛"

St 1

51-400-02-07
Plate cutter
18 cm/7 ⅛"

St 1

51-400-04-07
Activator
measuring device
10.5 cm/4 ⅛"

St 1

51-400-01-07
Activation arm
disconnection forceps
15.5 cm/6 ⅛"

St 1

Patient Screwdrivers

½

51-500-90-07
Patient screwdriver
straight 0.5 mm

St 1

½

51-505-90-07
Patient screwdriver
angled 0.5 mm

St 1

½

51-423-95-07
Patient screwdriver
straight 0.6 mm

St 1

½

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

St 1

Icon explanations

St Steel

1 Units/pack

½

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

St 1

½

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

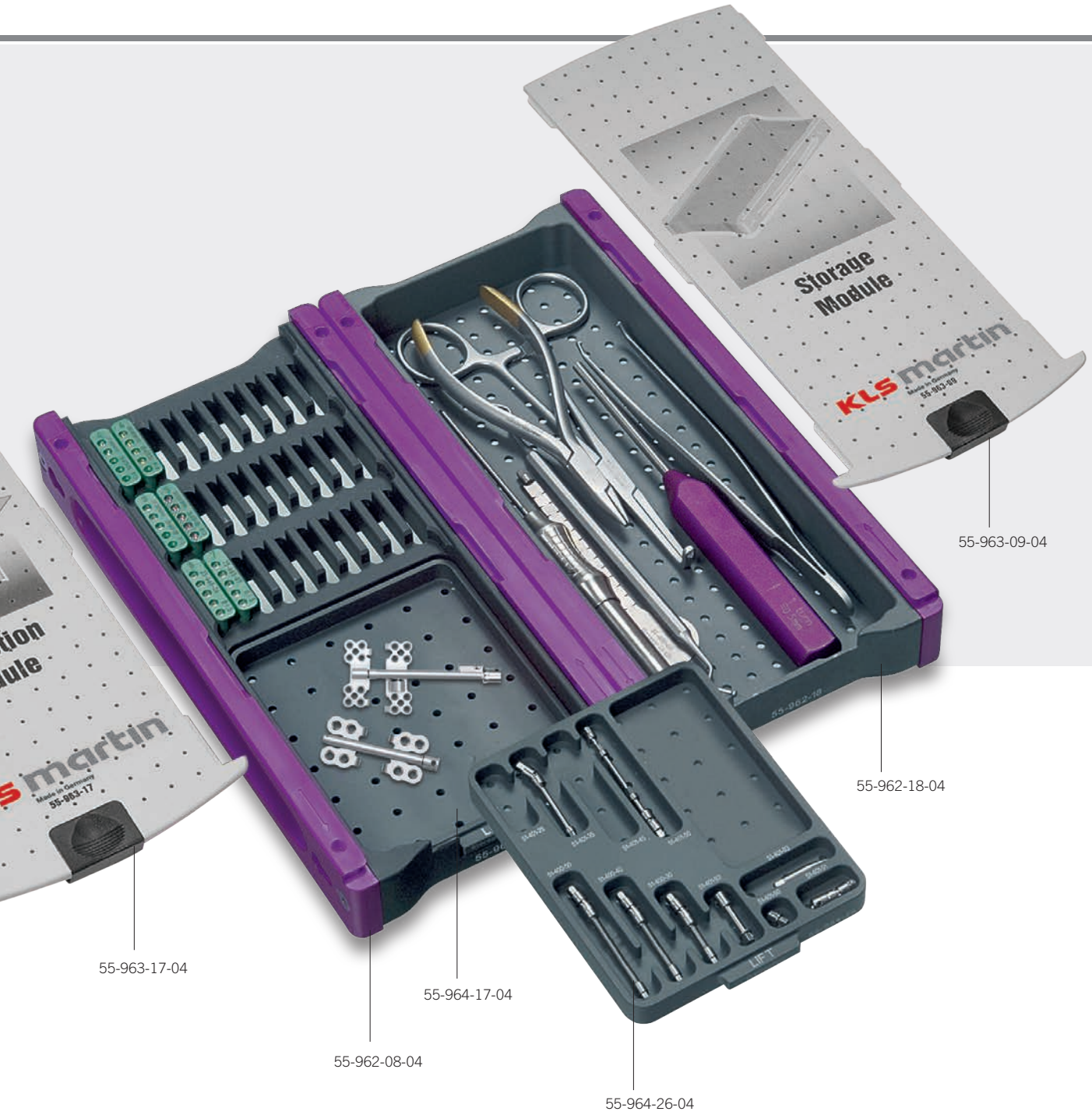
St 1

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


Storage Module
KLS martin
55-963-09
55-963-17
55-963-09-04
55-962-18-04
55-963-17-04
55-964-17-04
55-962-08-04
55-964-26-04

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