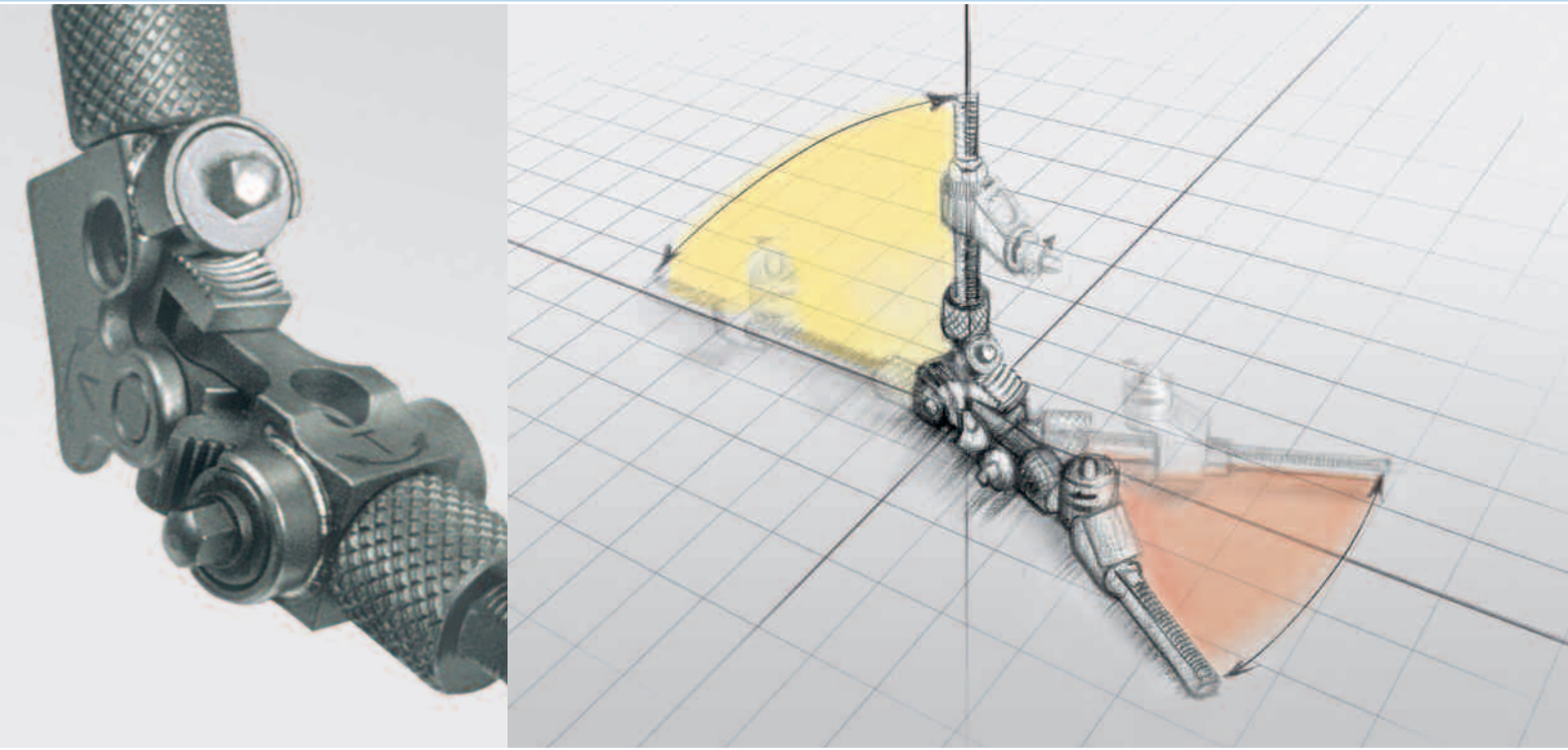


Distraction Osteogenesis



3 DXternal Distraction System

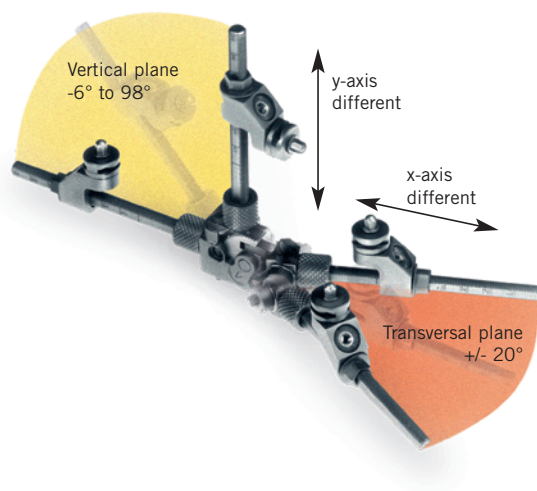
3 DXternal Distraction System

Cases of mandibular micrognathia or asymmetry are usually complex, as the minor growth is affecting both, mandibular body and ascending ramus.

Especially in the growing bone an external distractor is often the method of choice, as its bicortical pins find a better fixation in the soft, not completely ossified bone. The correction of a sagittal discrepancy is a further demand on the device.

The ideal tool should therefore offer:

- Possibility to be adjusted in all 3 dimensions (frontal, sagittal and transversal)
- Flexibility to be adapted individually to the patient's anatomical demands
 - Distraction arms in different lengths
 - Various pin holding clamps
 - Pins in different sizes, materials and diameters
 - Potential for unilateral and bilateral procedures

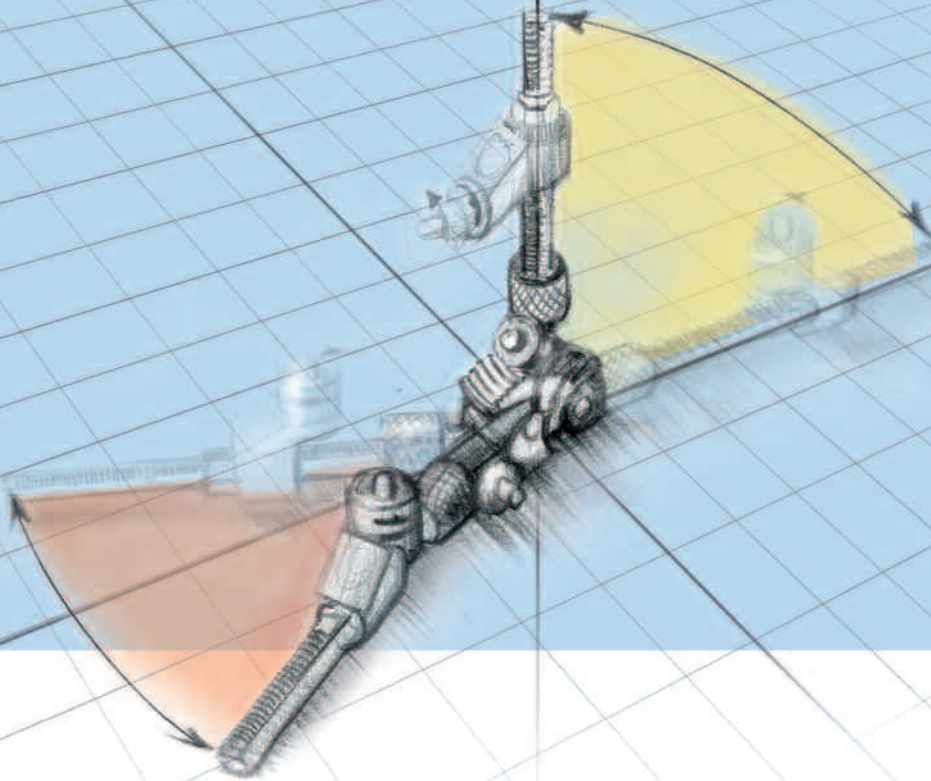


Indications:

- Congenital deficiencies, uni- or bilateral mandibular micrognathia
- Syndromic patients like Pierre Robin or Goldenhar syndrome
- Posttraumatic bone stabilization and bone lengthening
- Pediatric mandibular distraction osteogenesis
- Potential for external multivector transport distraction osteogenesis

Contraindications:

- Patients with insufficient bone volume or quality
- Additional conditions that would result in poor bone or patient healing
- The final decision on patient candidacy rests with the surgeon
- General surgical contraindications or missing patient's compliance

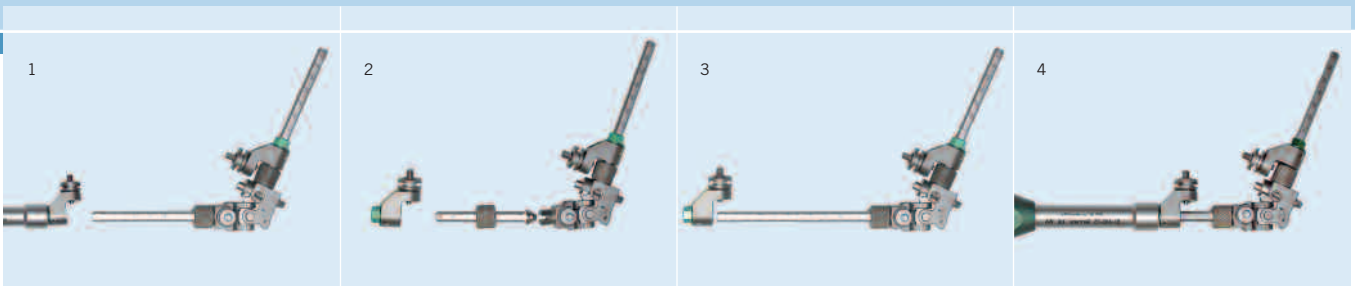


Advantages:

- Flexible and easy-to-adjust on all particular patient needs
- 3-dimensional manipulation of bone segments and multiple vector control at any moment
- Individual bone lengthening of the mandibular body and/or ramus with a single osteotomy
- Closure of open-bite situations during treatment
- Combination of light weight, low profile and highest stability
- Easy vector planning, distractor placement and distractor removal
- Universal device can be used on patient's left or right side
- Possibility to bridge and stabilize the distraction gap with a consolidation bar during consolidation period.

Adapting the 3 DXternal Distraction System to your needs

Cases of mandibular deficiencies are heterogeneous and appear in multiple variations. Depending on patient-specific factors and the individual appearance of the disease, the surgeon needs the freedom to easily adapt the device of his choice. The 3 DXternal distraction device has the potential to interchange all major components. What's more it is designed to be used in both, unilateral or multilateral applications.



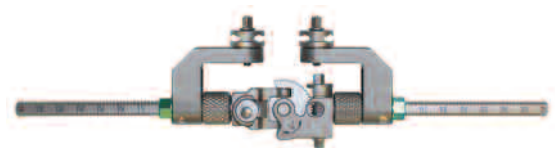
Interchanging the distraction arms (see photos above)

Select the desired distraction arms out of the listing on page 10. The distraction length varies from 15 to 85 mm.

1. Remove the pin holding clamp by inserting the patient screwdriver 51-600-75 over the green nut and turn clockwise.
2. Loosen the knurled nut at the end of the distraction arm.
3. Place the desired distraction arm on the distractor body and tighten.
4. Re-fix the pin holding clamp by turning the screwdriver counterclockwise.

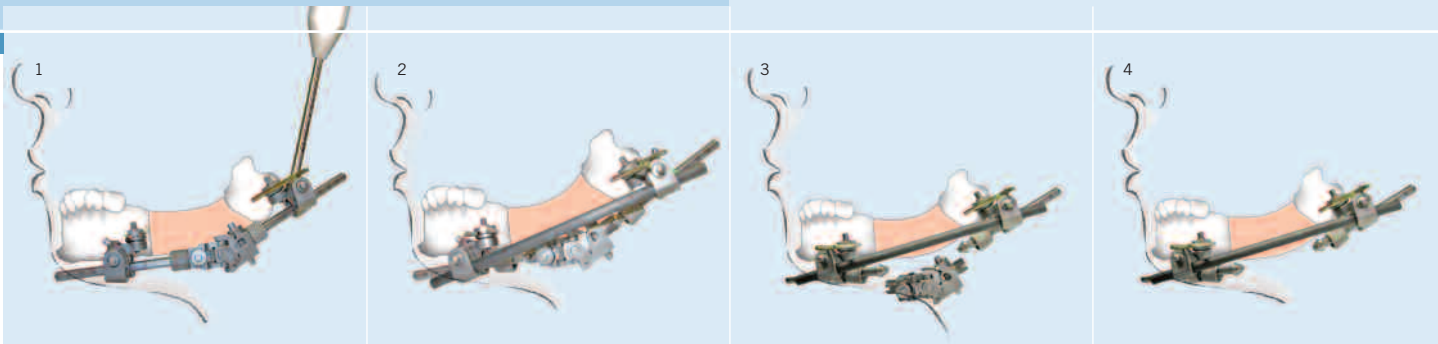
Interchanging the pin holding clamps

- Remove the short standard pin holding clamp 51-601-02 by inserting the patient screwdriver 51-600-75 over the green nut and turn clockwise.
- Select the long pin holding clamp 51-601-08.
- Replace the long pin holding clamp by turning the screwdriver counter-clockwise.



Consolidation bar attachment and removal of the distractor body and arms

The placement of the consolidation bar during consolidation is a treatment option in order to improve patient's comfort during this period. It is not a necessity.



Consolidation bar attachment

1. Attach the fixation clamp for carbon fibre rod 51-601-04 directly to the pin holding clamp 51-601-02 or 51-601-08.
2. Insert the carbon fibre rod 51-601-03 or 51-601-07.
 - Adjust the angle of the pin holding clamp.
 - Tighten the clamp with the angular adjustment driver 51-600-80.
 - Repeat steps on the other pin holding clamp.

Ensure both sides are secure.
The consolidation rod is now in place.
The distractor body and arms can be removed if desired.

3. + 4. Removing the distractor body

Loosen the knurled nut while turning in a counter-clockwise direction. Once both arms are loosened, the distractor body can be removed.

5. Removing the distractor arms

After disconnecting the distractor body, turn the pin holding clamp (green hex nut) with the patient screwdriver 51-600-75 in a clockwise direction until the arm is completely free of the pin holding clamp 51-601-02 or 51-601-08.

Repeat this step for the remaining distraction arm.

Intraoperative approach of a multidirectional procedure

1. An intraoral incision is made parallel to the line of the alveolar crest and the buccal aspect of the mandible is carefully exposed detaching the periosteum. Subperiosteal exposure is recommended.

2. Reevaluate the bony anatomy and confirm that the arm lengths are suitable. If necessary, the distractor arms may be exchanged for other lengths.

3. Mark the approximate site of the osteotomy line and the position of the pins on the bone. Confirm that adequate suitable bone stock is available for placing both sets of pins with the trocar point.

Note: In some patients with inadequate bone stock, adjustment can be made to the pin position or device angulation to accommodate the patient's anatomy.

4. Insert the first pair of pins

It is advisable to retract the skin superiorly so the pins penetrate the skin in the region which usually falls in the submandibular fold, allowing the scar to be in a relatively inconspicuous site. Make a small transbuccal incision superior to the planned osteotomy and bluntly dissect the soft tissue. Insert the self-drilling pin closest to the planned osteotomy by using a pin guide, taking care to avoid the tooth buds. Next, insert the pin farthest from the planned osteotomy always taking care of pin parallelity. If bone conditions are dense and cortical, pre-drilling may be necessary using a 1.5 mm diameter twist drill.

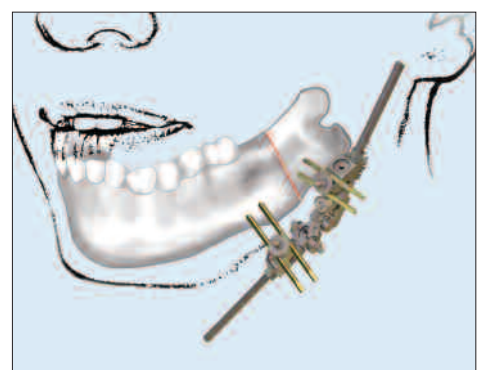
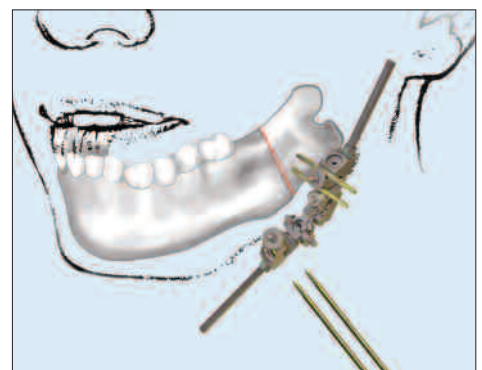
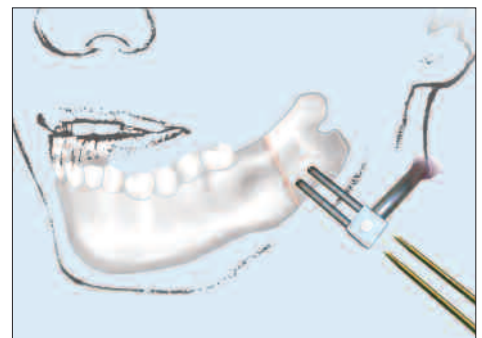
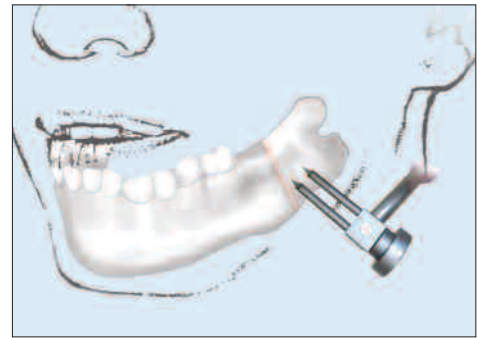
5. Insert the second pair of pins

Place the distractor assembly over the inserted pins and secure loosely. Again apply the pin holding clamp as a guide, on the opposite side of the osteotomy, mark the site for the second set of pins. Remove the distractor assembly and, using the trocar, insert the remaining pins parallel. To minimize the resulting scar caused by the pins, pinch the skin and soft tissue between the area where the two pair of pins will be placed. In case of dense cortical bone, pre-drilling is recommended.

6. Perform the osteotomy

Using a reciprocating saw, perform a complete osteotomy of the mandible extending into the superior and inferior cortices taking care about the position of the inferior alveolar nerve. KLS Martin is recommending complete osteotomies and is not following pure corticotomies sometimes mentioned in literature.

An osteotome may be used to facilitate the fracture. It is advisable to check mobility after osteotomy.



7. Final placement

Place the distractor assembly on the pins and tighten the pin holding clamps.

8. Final adjustments

Adjust the device as necessary to ensure a comfortable fit. The distractor assembly position should allow comfortable activation of both the ramus and body portions of the device. Caps can be applied, if desired. Use the patient screwdriver to activate each distractor arm to confirm mobility of the proximal and distal segments.

9. Latency period

Activation can begin 3 – 7 days after device placement based on the surgeon's treatment plan.

10. Distraction period

Following the desired latency period, distraction usually begins at a rate of 1 mm per day by turning the green activation screwdriver 51-600-75. One full rotation thereby equals 0.5 mm per turn; 2 turns per day.

Vector adjustment

It is recommended to distract at least 10 mm prior to any angular or transverse adjustment. Bone segments must separate prior to adjustments to prevent premature consolidation.

The 3 DXternal Distraction System offers:

Vertical adjustment: -6° to $+98^{\circ}$

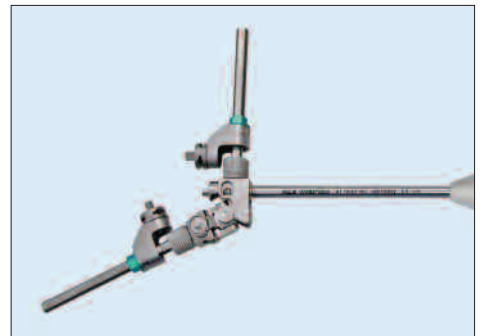
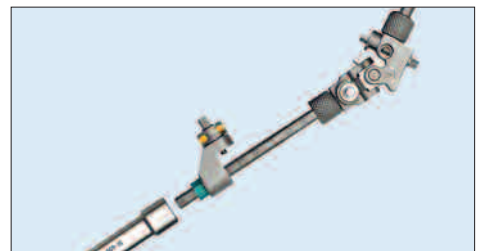
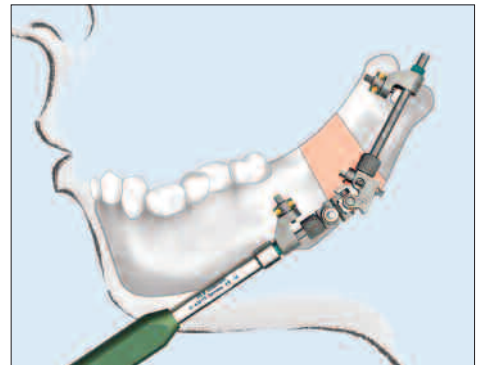
Transverse adjustment: $\pm 20^{\circ}$

One 360° turn equals 6° of movement

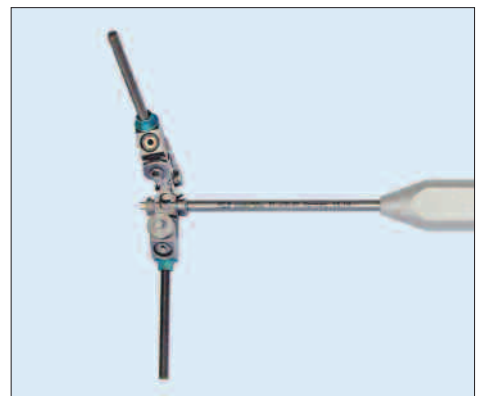
11. Consolidation period

A 6 – 8 week consolidation period is recommended. The distractor or consolidation bar assembly will be removed according to the treatment protocol, taking into account the age of the patient, the actual lengthening and other therapeutic procedures.

If desired, one can have the possibility to attach a consolidation bar for higher stability. **See page 5 for instructions!**



Vertical adjustments

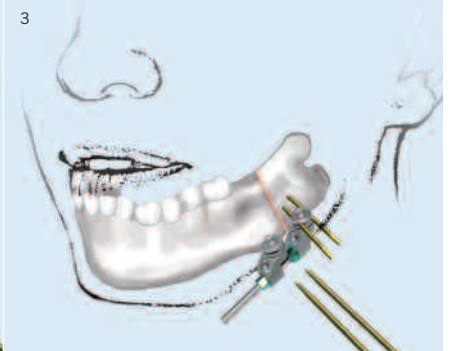
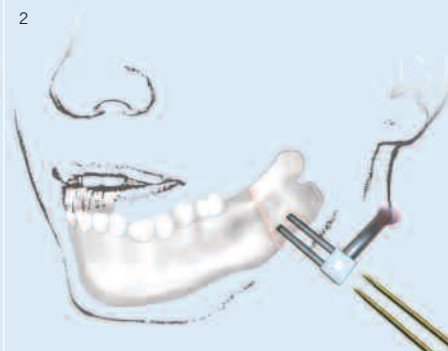
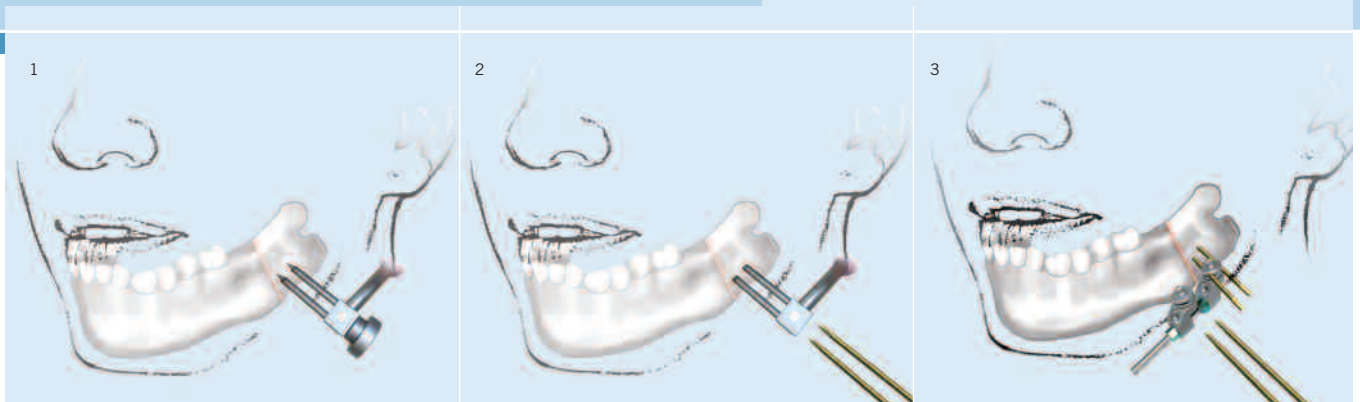
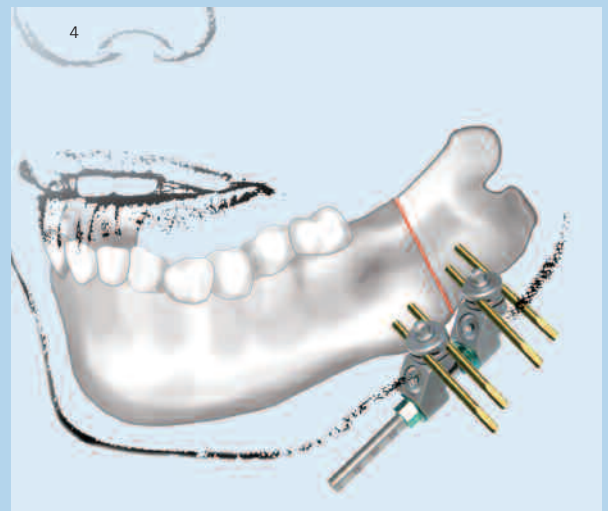


Transverse adjustments

Single vector / uni-directional procedures

According to the multidirectional procedure mentioned before, the distractor is also suitable for unilateral bone lengthening on both, the ascending ramus or the mandibular body.

Also an oblique vector direction, affecting mandibular body and the ascending ramus can be realized.

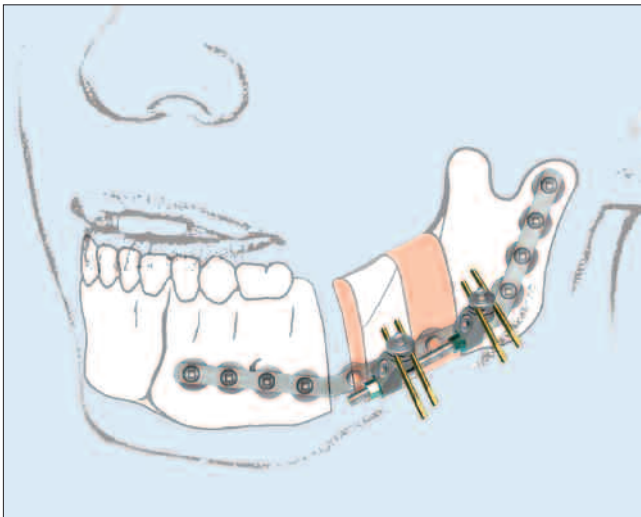


- No need for a distractor body.
- Select one suitable distraction arm out of the product range on page 10.
- The placement instructions are similar for the multi-directional intra-operative approach.

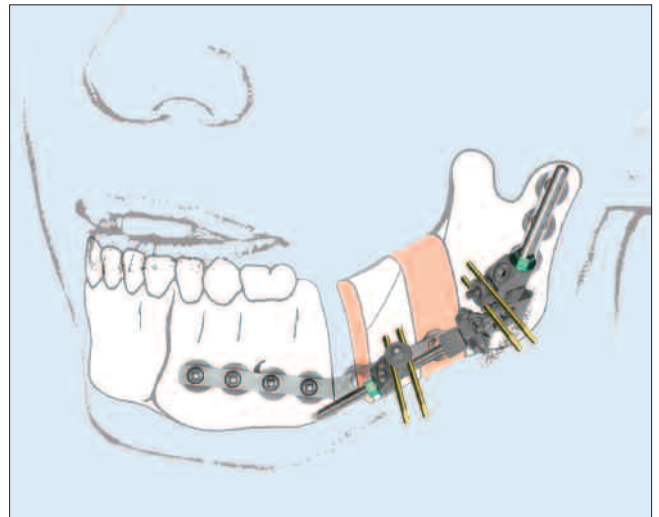


Bony defect transport distraction osteogenesis

Because of its great flexibility, the 3 DX distraction system has the potential to be used as an external transport distraction solution. The possibility to influence the transport disc in a 3-dimensional way enables the surgeon to also follow curved movements to a large extent when reconstructing mandibular defects.



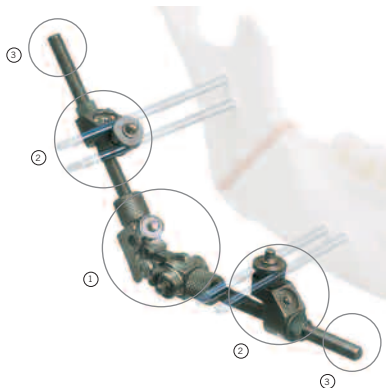
3-dimensional



Uni-directional

The system components

The basic set 51-601-00 already provides you an almost ready-to-use solution which only needs to be completed with the right selection of pins. However, the user has the possibility to exchange all major system components, as distraction arms or pin holding clamps. The selection of a suitable consolidation bar is another option to increase patient's comfort during consolidation period.



3D Xternal Distraction System

Designation/Unit	Quantity	Item Number
3D X basic set	1 unit	51-601-00
consisting of:		
① Distractor body	1 unit	51-601-01
② Pin holding clamp, short	2 units	51-601-02
③ Distraction arm, 35 mm distraction length	2 units	51-601-35



Pins

Material	Dimensions (mm)	Sales Unit	Item Number
Titanium	2.0 x 40	2/pack	51-606-40
Titanium	2.7 x 60	2/pack	51-608-60
Steel	2.0 x 50	4/pack	51-620-50
Steel	2.7 x 60	4/pack	51-627-60



Distraction arm

Distraction length	Total length	Item Number
15 mm	31 mm	51-601-15
25 mm	41 mm	51-601-25
35 mm	51 mm	51-601-35
50 mm	66 mm	51-601-50
65 mm	81 mm	51-601-65
85 mm	101 mm	51-601-85



Additional components

Designation/Unit	Item Number
Distractor body	51-601-01
Pin holding clamp, short	51-601-02
Pin holding clamp, long	51-601-08
Pin holding clamp, for consolidation (locking slider)	51-601-09



51-601-01



51-601-09

 $\frac{1}{2}$

51-601-02



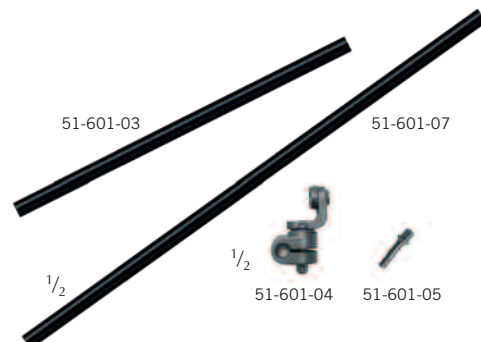
51-601-08

Consolidation bar attachment

Designation/Unit	Item Number
Carbon fibre rod for consolidation, 98 mm	51-601-03
Carbon fibre rod for consolidation, 150 mm	51-601-07
Fixation clamp for carbon fibre rod	51-601-04
Hexagonal screw for pin holding clamp	51-601-05

51-601-03

51-601-07

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51-601-04

51-601-05



Complete & flexible

Instruments and storage



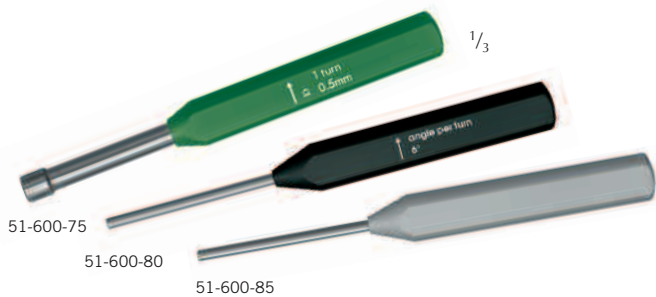
Instruments

Designation/Unit	Item Number
Patient screwdriver	51-600-75
Angle adjustment driver	51-600-80
Screwdriver for pins	51-600-85
for 2.0 mm pins	
Pin guide	51-601-06
Twin soft tissue protector, only	50-501-18*
Twin trocar	50-501-06
for 2.7 mm pins	
Pin guide	51-601-16
Twin soft tissue protector, only	50-501-28*
Twin trocar	50-501-36

* to be used in connection with transbuccal handle 50-501-01! The handle is a part of the Transbuccal System 50-502-00

Storage

Designation/Unit	Item Number
Twin insert module, purple	55-962-08
Storage module, purple	55-962-18
Lid for 3 DX system	51-963-20
Lid storage module	51-963-09
Insert for complete 3 DX devices	51-964-33
Insert for 3 DX single components	51-964-34



If you still have any questions ...

... we will be glad to answer them anytime.

You can reach us personally, either by e-mail or through our customer hotline.

Additional product brochures and information materials

- Distraction Devices overview Item number 90-173-02-04
- Level One catalog Item number 90-896-49-04

Customer hotline: +49-74 61-706-216

E-mail: kerstin.braun@klsmartin.com

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