Mandibular Osteosynthesis

X-Fix

Mandible External Fixation System

ref. 90-634-02-04
It’s the head that counts – and the face. There is nothing with which we identify ourselves more than with the face. We are how we see ourselves. And more still: four of our five senses – sight, hearing, smell, and taste – are located in the head and the face.

Congenital facial deformities put individuals at a severe disadvantage not only in terms of outward appearance, but functionally too because severe loss of function is a frequent side-effect of such conditions. Of course, acquired defects can have similar consequences as well. Given the anatomical complexities of the cranial and facial structures, reconstruction and correction require a sort of specialization that fits into the broader context. But that’s not all - because successful treatment wouldn’t be possible without the availability of high-precision and reliable products.

KLS Martin is one of the globally leading suppliers in the field of craniomaxillofacial surgery. Our product portfolio offers you everything you need for advanced osteosynthesis and distraction. This implies that you get more than just standard products. We are always ready to develop patient-specific solutions wherever the need arises.
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Mandible fractures or defect situations associated with compromised bone quality and/or critical soft-tissue impairment are predestinated indications for the Mandible External Fixation System X-Fix.

The system is an external pin fixation system that allows a simple, quick, and atraumatic handling. The X-Fix can be assembled in two unique configurations.
The X-Fix in configuration 1 creates a rigid construct using three basic components: pins, rods and snap-on, adjustable clamps.
## X-Fix: Configuration 1

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7 mm thread and 4 mm shaft diameter</td>
<td>Strong and stable fixation</td>
</tr>
<tr>
<td>Four thread lengths (7, 9, 13, 17 mm)</td>
<td>Accommodation to various soft and bone thicknesses</td>
</tr>
<tr>
<td>Titanium alloy</td>
<td>Secure biocompatibility</td>
</tr>
<tr>
<td>Latex-free PVC protective caps</td>
<td>Prevention of skin injury and clothing damage</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.2 mm thread and 3.2 mm shaft diameter</td>
<td>Extremely stable fixation</td>
</tr>
<tr>
<td>Three thread lengths (7, 11, 13 mm)</td>
<td>Accommodation to various soft and bone thicknesses</td>
</tr>
<tr>
<td>Titanium alloy</td>
<td>Secure biocompatibility</td>
</tr>
<tr>
<td>Latex-free PVC protective caps</td>
<td>Prevention of skin injury and clothing damage</td>
</tr>
</tbody>
</table>

### Symmetric Clamps:
- The design of each clamp is based on two clamping bodies with two clamping openings.
- The clamping bodies can be rotated relative to each other.
- Clamping nuts for locking of clamping bodies.
- Two clamp types: symmetric and asymmetric.

### Asymmetric Clamps:
- Eight different rod designs
- Five rods are anatomically pre-bent
- Further rod contouring is possible

### Connection between a rod and a pin
- Symmetric clamps: With clamping openings only for:
  - pins with 4 mm shaft diameter or
  - rods
- Asymmetric clamps: With clamping openings only for:
  - pins with 4 mm shaft diameter or
  - rods
  and clamping openings only for:
  - pins with 3.2 mm shaft diameter

### Connection between a rod and a pin, irrespective of pin orientation
- Maintenance of rod position during frame assembly and fracture reduction

### Best possible choice for each type of mandible fracture or defect
- Best possible average shapes
- Adjustment to individual patient anatomy
The X-Fix in configuration 2 is an easy-to-use system for mandibular fractures and defects with minimal incisions. The basic components of this configuration are: pins, pin nuts and an acrylic bar.
## X-Fix: Configuration 2

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ 3.2 mm thread and 3.2 mm shaft diameter</td>
<td>■ Extremely stable fixation</td>
</tr>
<tr>
<td>■ Three thread lengths (7, 11, 13 mm)</td>
<td>■ Accommodation to various soft and bone thicknesses</td>
</tr>
<tr>
<td>■ Titanium alloy</td>
<td>■ Secure biocompatibility</td>
</tr>
<tr>
<td>■ Latex-free PVC protective caps</td>
<td>■ Autoclavable</td>
</tr>
<tr>
<td>■ Two methods to make the acrylic splint:</td>
<td>■ Prevention of skin injury and clothing damage</td>
</tr>
<tr>
<td>■ “Molding” technique</td>
<td></td>
</tr>
<tr>
<td>■ “Plastic tube” technique</td>
<td></td>
</tr>
<tr>
<td>■ Acrylic splint is plugged on the X-Fix pins against the flat side of</td>
<td>■ Lower cost fixation option compared to rod fixation (configuration 1)</td>
</tr>
<tr>
<td>the pin nuts and trapped by a second row of pin nuts.</td>
<td>■ Easy to apply</td>
</tr>
</tbody>
</table>

For further information on the plastic material as well as the molding and plastic tube technique, please refer to the instructions for use.
Indications

- Mandibular fractures
- Mandibular fractures associated with infections
- Severe comminuted fractures of the mandible
- Healing problems / non-unions
- Tumor resections
- Bullet injuries
- Fractures with severe soft-tissue impairment
- Fractures in radiation patients
- Panfacial fractures
- Burns
- Bone defects with bone grafts
### Surgical Techniques

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Configuration 1</td>
<td>12-17</td>
</tr>
<tr>
<td>Configuration 2</td>
<td>18-19</td>
</tr>
</tbody>
</table>
1. Preparatory Work

The surgical procedure for configuration 1 starts with maxillomandibular fixation.

After fixing the maxillary and mandibular teeth, the treating physician can proceed with selecting a suitable rod or a combination of rods. In most cases it will not be necessary to modify the contours of the prebent rods.

Should additional bending be indicated, proceed as follows:

To facilitate the bending process, a bending template is available.

The bending template must be shaped so that it reflects the contours of the bone anatomy of the patient.

When bending the template, make sure that a distance of at least one centimeter will be maintained between the rod and the soft tissue once the rod has been finally fixed in place.

Using the rod bender, you can adapt the (prebent) rod to the form of the bending template. Please note that both ends of the rod must be held firmly during the bending process.

If you need to shorten the rod, please use a large cutter and remove the rod from the patient before starting the cutting process.

In the next step, the form of the prebent rod must be checked on the patient for correctness.

Subsequently, the desired positions for the first and the last X-Fix pin must be determined and marked accordingly. These are the X-Fix pins located farthest away from the defect, proximally and distally.

To ensure adequate stability, at least two X-Fix pins are required for each segment. This means that at least two X-Fix pins must be used in the largest as well as in any other segment. Optimally, one X-Fix pin should be inserted at least 10 mm proximally to the defect.
2. Placing the First X-Fix Pin

To be able to insert the first X-Fix pin, a very small incision must be made at the marked spot and the soft tissue dissected as required.

Following this, insert the cannula into the trocar handle and then the trocar into the handle-and-cannula assembly. Thereafter, insert the trocar through the stab incision all the way down to the bone.

Finally, the trocar can be removed.

Now insert the drill guide into the cannula. Then insert the 2.2-mm twist drill through the drill guide to drill the pilot hole.

Once this has been done, remove the drill guide and the twist drill.

Insert the depth gauge through the cannula until it hits the lingual cortex of the mandible, then remove the measuring instrument from the cannula.
Plug the triangular X-Fix socket bit into the ratchet screwdriver handle. Make sure that the ratchet is set to screw-in mode.

Select a X-Fix pin with 4 mm shaft diameter and the appropriate thread length, then plug the X-Fix pin into the ratchet screwdriver fitted with the triangular X-Fix socket bit. The triangular X-Fix socket bit is also compatible with the KLS Martin BOS Driver.

Alternatively, it is also possible to use the X-Fix pins of Configuration 2, but note that these pins may only be used together with the asymmetric clamps. In this case, you need to pre-drill using the 2.5-mm twist drill.

Insert the X-Fix pin through the cannula by clockwise rotation until the tip of the thread hits the buccal cortex. This ensures sufficient implantation depth.

3. Placing the Second X-Fix Pin

The second X-Fix pin is inserted in the same way on the opposite side using the position farthest away from the defect.

4. Attaching the Rod

Attach a clamp to each of the two X-Fix pins, then fix one or more suitable rods to the clamps. The knurled nuts of the clamps can be finger-tightened to position the system.
Reduce the fracture in the standard way.

Then tighten the clamping nuts of the clamps using the hex nut driver (size 5 mm). This firmly locks the X-Fix pins and rods in place in the clamps.

Verify correct seat before you proceed with the next steps.

5. Placing the Third X-Fix Pin

Attach a third clamp in the stable bone segment, approximately 10 mm proximally or distally to the defect.
Depending on the thickness of the soft tissue, select the suitable penetration depth for the cannula and fix it in place in the clamp.

Adjust the cannula and the clamp to the angulation required for the desired pin position. Mark the incision site. To facilitate the process, turn the cannula with the clamp upwards to keep them out of the way for the moment.

Make a small incision and dissect the soft tissue as required. Turn the clamp with the cannula back down to its original position. Insert the trocar, then insert the cannula through the incision until it hits the bone. Remove the trocar. Tighten the clamp, making sure that the cannula is securely fixed to the rod.

Insert the X-Fix pin as described above. Loosen the clamp a little and remove the cannula from the X-Fix pin.

Tighten the clamping nut of the clamp that holds the X-Fix pin and the rod in place.

6. Final Work

Insert all the remaining X-Fix pins to complete the frame. Note that at least two X-Fix pins are required on each side of the defect.

Verify proper reduction and alignment. If readjustment is necessary, loosen the clamping nuts of the clamps, adjust the mandible, then retighten the clamps.

If desirable, you can now put the PVC protective caps supplied in place on the projecting triangular ends of the X-Fix pins. This prevents skin injury and clothing damage.
Alternative Frame Configurations

**Half frame**
- Used in cases of mandibular angle infection

**Modular frame**
- Used for comminuted fractures
- The modular frame is designed according to the position of the fracture.
Depending on the size of the fracture or defect, select a suitable number of X-Fix pins on both sides of the still unreduced fracture. At least two X-Fix pins are required on each side.

Use the 2.5-mm twist drill to create pilot holes for the X-Fix pins in a first step. To facilitate correct pin placement, you can use the trocar and the drill guide.

The X-Fix pins can finally be screwed into the bone using the ratchet screwdriver with the triangular X-Fix socket bit.

The triangular X-Fix socket bit is compatible with the KLS Martin BOS Driver.

A connection bar is then attached to one X-Fix pin on each side of the fracture, proceeding as follows:

1. Insert the X-Fix pin into the smaller clamping opening of the connection bar.
2. Tighten the clamping nut of this clamping opening using the hex nut driver (size 2.5 mm).

Subsequently, place a suitable straight rod into the larger clamping opening of the connection bar on one side of the fracture.

Then tighten the corresponding clamping nut using the hex nut driver (size 2.5 mm).

The connection bar is now securely fixed to a X-Fix pin and the straight rod on one side of the fracture.

Reduce the fracture, then connect the straight rod in the same way to the second connection bar on the other side of the fracture. This ensures a stable reduction of the fracture.
2. Molding the Acrylic Splint

You can now fill the mold with the plastic mixture.

In the next step, the pin nuts can be screwed onto the threaded part of the X-Fix pins. The flat side of the nuts should face forward.

As soon as the plastic compound has acquired a putty-like consistency, you can remove it from the mold.

The acrylic splint is then plugged in place on the X-Fix pins against the flat side of the pin nuts. As this process leads to the formation of elongated holes in the splint, the original form of these holes should be restored as far as possible once the acrylic splint has been finally positioned as desired.

Now allow the plastic material to harden completely (see the manufacturer’s specifications).

Be sure to wait with attaching the outer pin nuts until the plastic has cured completely. To tighten these nuts, use the hex nut driver (size 5 mm).

Once the acrylic splint has hardened, the straight rod and the connection bars can be removed. If desirable, you can put the PVC protective caps supplied in place on the projecting triangular ends of the X-Fix pins. This prevents skin injury and clothing damage.

For further information on the plastic material as well as the molding and plastic tube technique, please refer to the instructions for use.
Implants and Accessories  X-Fix

Configuration 1

<table>
<thead>
<tr>
<th>X-Fix pins</th>
<th>Ø 4.0 mm</th>
<th>Length 80 mm</th>
<th>Thread Ø 2.7 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thread length</td>
<td>Item No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 mm</td>
<td>51-673-07-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 mm</td>
<td>51-673-09-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 mm</td>
<td>51-673-13-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 mm</td>
<td>51-673-17-09</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>X-Fix pins</th>
<th>Ø 3.2 mm</th>
<th>Length 80 mm</th>
<th>Thread Ø 3.2 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thread length</td>
<td>Item No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 mm</td>
<td>51-670-07-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 mm</td>
<td>51-670-11-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 mm</td>
<td>51-670-13-09</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Icon explanations**

- **Ti**: Titanium
- **St**: Steel
- **■**: Packing unit

**X-Fix Rods**

<table>
<thead>
<tr>
<th>Ø 4.0 mm</th>
<th>Item No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>prebent, entire mandible</td>
<td>51-672-01-09</td>
</tr>
<tr>
<td>prebent, entire mandible, large</td>
<td>51-672-02-09</td>
</tr>
<tr>
<td>prebent, from mandibular angle to mandibular angle</td>
<td>51-672-03-09</td>
</tr>
<tr>
<td>prebent, 3/4</td>
<td>51-672-04-09</td>
</tr>
<tr>
<td>prebent, 1/2</td>
<td>51-672-05-09</td>
</tr>
<tr>
<td>straight, 102 mm</td>
<td>51-672-08-09</td>
</tr>
<tr>
<td>straight, 160 mm</td>
<td>51-672-06-09</td>
</tr>
<tr>
<td>straight, 325 mm</td>
<td>51-672-07-09</td>
</tr>
</tbody>
</table>

**X-Fix clamp**

- **51-670-04-09**: Symmetric, with hexagon clamping nut, wrench size 5 mm
  - Large openings  for X-Fix pins Ø 4 mm or X-Fix rods Ø 4 mm

- **51-670-05-09**: Asymmetric, with hexagon clamping nut, wrench size 5 mm
  - Large openings  for X-Fix pins Ø 4 mm or X-Fix rods Ø 4 mm
  - Small openings  for X-Fix pins Ø 3.2 mm

**X-Fix clamp**

- **51-672-01-09**: Prebent, entire mandible
- **51-672-02-09**: Prebent, entire mandible, large
- **51-672-03-09**: Prebent, from mandibular angle to mandibular angle
- **51-672-04-09**: Prebent, 3/4
- **51-672-05-09**: Prebent, 1/2
- **51-672-06-09**: Straight, 102 mm
- **51-672-07-09**: Straight, 160 mm
- **51-672-08-09**: Straight, 325 mm
Implants and Accessories X-Fix

Configuration 2

**X-Fix pins**
- Ø 3.2 mm
- Length 80 mm
- Thread Ø 3.2 mm

<table>
<thead>
<tr>
<th>Thread length</th>
<th>Item No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 mm</td>
<td>51-670-07-09</td>
</tr>
<tr>
<td>11 mm</td>
<td>51-670-11-09</td>
</tr>
<tr>
<td>13 mm</td>
<td>51-670-13-09</td>
</tr>
</tbody>
</table>

**Straight rods**
- Ø 4 mm
- Carbon-fiber-reinforced plastic

<table>
<thead>
<tr>
<th>Length</th>
<th>Item No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mm</td>
<td>51-601-03-04</td>
</tr>
<tr>
<td>150 mm</td>
<td>51-601-07-04</td>
</tr>
</tbody>
</table>
Icon explanations:

- **TI**: Titanium
- **St**: Steel
- **CF**: Carbon-fiber-reinforced plastic
- **P**: Packing unit

51-670-02-07
Connection bar

51-670-01-09
Pin nut

51-671-27-07
X-Fix mold
for acrylic splint

---

51-670-02-07
Connection bar

51-670-01-09
Pin nut

51-671-27-07
X-Fix mold
for acrylic splint
PRODUCT RANGE: X-Fix Instruments

Instruments X-Fix

for Configuration 1 and 2

50-125-16-07
Rod bender

51-671-28-09
Bending template for X-Fix rods

50-501-01-07
Trocar handle
50-501-10-07  
Cheek retractor

50-501-19-07  
Cannula

50-501-09-07  
Trocar

50-501-40-07  
Depth gauge

50-501-29-07  
Drill guide

Icon explanations:
- Blue: Titanium
- Steel
- Packing unit
**PRODUCT RANGE: X-Fix Instruments**

**Instruments X-Fix**

For Configuration 1 and 2

- **50-022-15-07**
  - Twist drill
  - 2.2 x 115 mm
  - J-notch attachment

- **50-126-06-07**
  - Twist drill
  - 2.5 x 105 mm
  - J-notch attachment

- **51-600-65-07**
  - Triangular nut driver
  - 2.5 mm

- **51-600-85-07**
  - Hex nut driver
  - 2.5 mm
  - For connection bar
51-600-70-07
**Hex nut driver**
size 5 mm
- for clamping nuts of symmetric and asymmetric clamps
- for pin nuts

25-410-00-07
**Ratchet screwdriver handle**

51-600-86-07
**Triangular X-Fix socket bit**

Icon explanations
- Steel
- Packing unit
Storage System X-Fix

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>55-969-45-04</td>
<td>Storage tray for X-Fix system, complete</td>
</tr>
<tr>
<td>55-969-39-04</td>
<td>Storage tray for X-Fix system, 30 x 45 cm, with fixation strips</td>
</tr>
<tr>
<td>55-963-39-04</td>
<td>Lid for X-Fix storage tray</td>
</tr>
<tr>
<td>55-962-37-04*</td>
<td>Twin insert module, gray</td>
</tr>
<tr>
<td>55-964-36-04</td>
<td>X-Fix lid for twin insert module</td>
</tr>
<tr>
<td>55-964-61-04</td>
<td>X-Fix insert for twin insert module, 14 mm high</td>
</tr>
<tr>
<td></td>
<td>- for symmetric and asymmetric clamps</td>
</tr>
<tr>
<td>55-964-62-04</td>
<td>X-Fix insert for twin insert module, free storage, 6 mm high</td>
</tr>
<tr>
<td></td>
<td>- for twist drills</td>
</tr>
<tr>
<td>55-964-65-04</td>
<td>X-Fix insert for twin insert module, 20 mm high</td>
</tr>
<tr>
<td></td>
<td>- for X-Fix pins Ø 4 mm</td>
</tr>
<tr>
<td></td>
<td>- for X-Fix pins Ø 3.2 mm</td>
</tr>
<tr>
<td></td>
<td>- for symmetric and asymmetric clamps</td>
</tr>
</tbody>
</table>

* The twin insert module with X-Fix lid can be stored in the storage tray for X-Fix system (art. no. 55-969-39-04).
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>55-964-99-04</td>
<td>X-Fix insert for twin insert module, without contents, 20 mm high</td>
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<td></td>
<td>- for X-Fix pins Ø 4 mm</td>
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<tr>
<td>55-964-55-04</td>
<td>X-Fix insert for twin insert module, without content</td>
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<tr>
<td></td>
<td>- for accessories of configuration 2</td>
</tr>
<tr>
<td></td>
<td>- double height, 20 mm</td>
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<tr>
<td></td>
<td>- for X-Fix pins, pin nuts, connection bars and PVC protective caps</td>
</tr>
<tr>
<td>55-964-56-04</td>
<td>X-Fix insert for twin insert module, without content</td>
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<tr>
<td></td>
<td>- for accessories of configuration 2</td>
</tr>
<tr>
<td></td>
<td>- standard height, 10 mm</td>
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</table>
Additional Brochures

Distraction Product Overview

ThreadLockTS

ThreadLockTS Smart

Mandible Mesh Tray

Patient Specific Implants

BOS Driver and BOS Drill
KLS Martin is a pioneering company in distraction osteogenesis and has established in many individual indications its own specific product portfolio. The RED II is a good example for that.

Besides these specific disciplines the KLS Martin product range also includes the complete spectrum of systems for traumatology, orthognathic surgery and reconstruction in today’s oral maxillofacial surgery. The Level One brochures are the standard work to all osteosynthesis products.

You should also get to know SonicWeld Rx®: It is worldwide patented the only resorbable osteosynthesis program, which is entirely based on ultrasound technology to weld in resorbable pins.

Resorbable osteosynthesis can just be so easy!
Distribuidor de:

KLS Martin Group