



## **X**-Fix

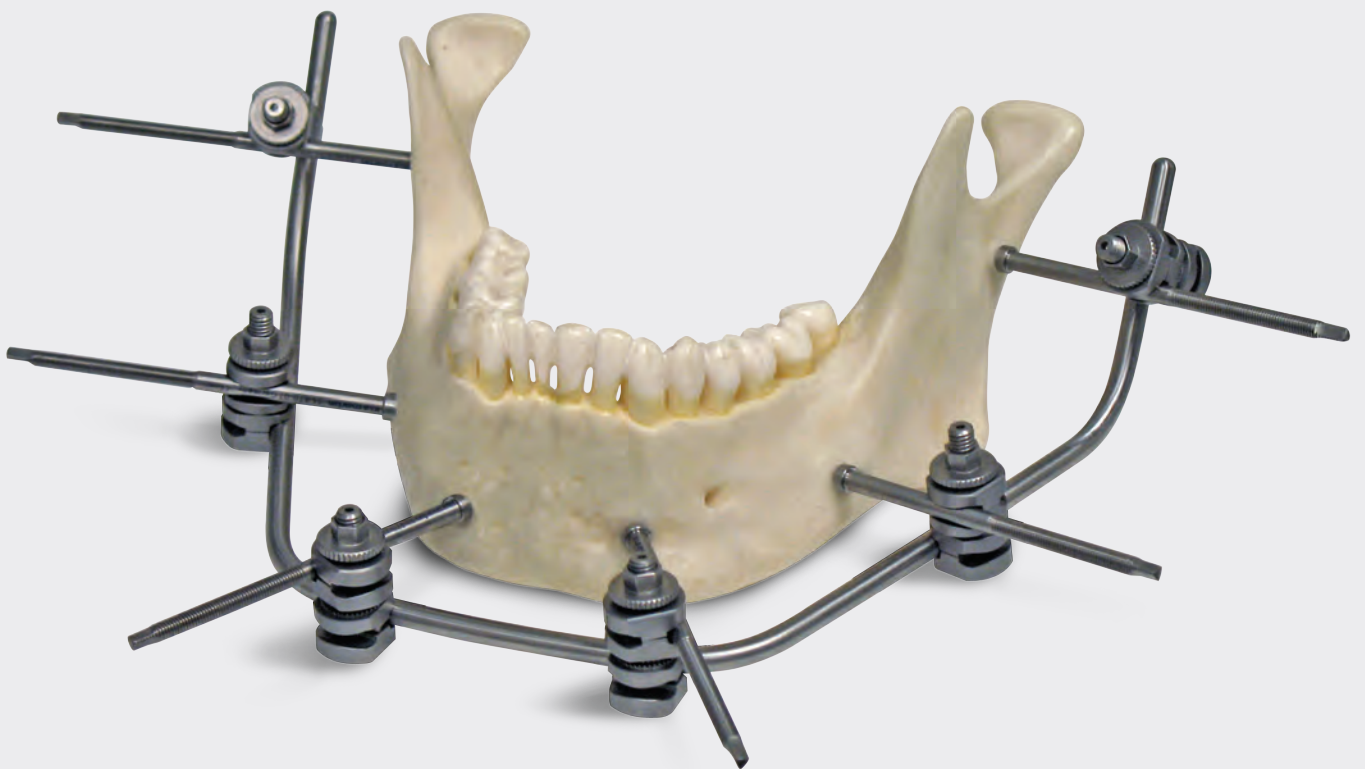
Mandible External Fixation System



Oral and maxillofacial surgery is our passion! We also want to continue our development along with our customers. Day in, day out, we work to develop innovative products and services that satisfy the highest quality demands and contribute to the patient's well-being.

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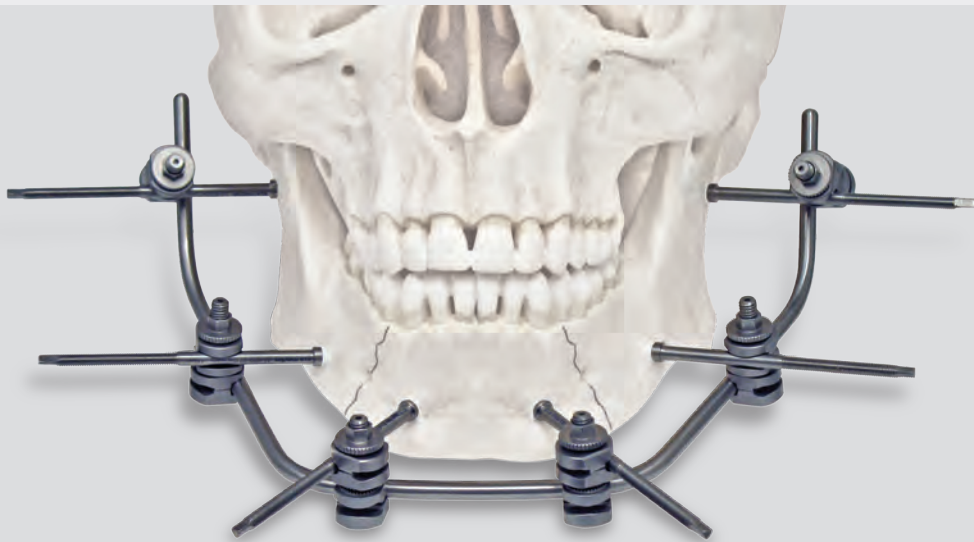


## X-Fix Mandible External Fixation System

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.

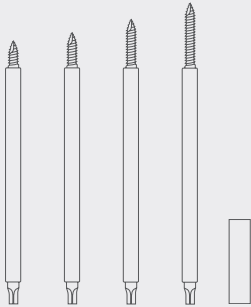
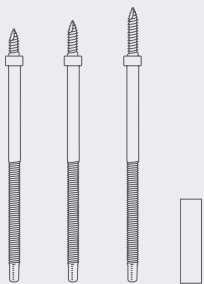
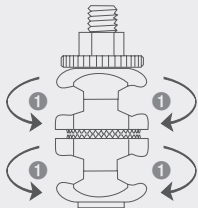
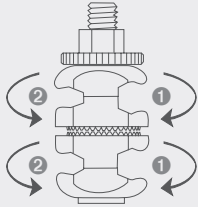
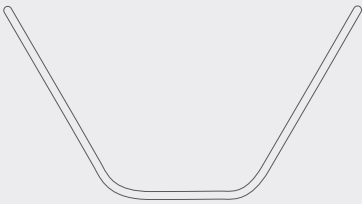
## Feature, Function and Benefit



The X-Fix creates a rigid construct using three basic components: pins, rods and snap-on, adjustable clamps.



## X-Fix – Mandible External Fixation System

	Feature and Function	Benefit
	<ul style="list-style-type: none"> <li>2.7 mm thread and 4 mm shaft diameter</li> <li>Four thread lengths (7, 9, 13, 17 mm)</li> <li>Titanium alloy</li> <li>Latex-free PVC protective caps</li> </ul>	<ul style="list-style-type: none"> <li>Strong and stable fixation</li> <li>Accommodation to various soft and bone thicknesses</li> <li>Secure biocompatibility</li> <li>Prevention of skin injury and clothing damage</li> </ul>
	<ul style="list-style-type: none"> <li>3.2 mm thread and 3.2 mm shaft diameter</li> <li>Three thread lengths (7, 11, 13 mm)</li> <li>Titanium alloy</li> <li>Latex-free PVC protective caps</li> </ul>	<ul style="list-style-type: none"> <li>Extremely stable fixation</li> <li>Accommodation to various soft and bone thicknesses</li> <li>Secure biocompatibility</li> <li>Prevention of skin injury and clothing damage</li> </ul>
 <p>symmetric</p>	<ul style="list-style-type: none"> <li>The design of each clamp is based on two clamping bodies with two clamping openings.</li> <li>The clamping bodies can be rotated relative to each other.</li> <li>Clamping nuts for locking of clamping bodies</li> <li>Two clamp types: symmetric and asymmetric</li> </ul>	<ul style="list-style-type: none"> <li>Connection between a rod and a pin</li> <li>Connection between a rod and a pin, irrespective of pin orientation</li> <li>Maintenance of rod position during frame assembly and fracture reduction</li> <li>Symmetric clamps: With clamping openings ① only for <ul style="list-style-type: none"> <li>pins with 4 mm shaft diameter or rods</li> </ul> </li> <li>Asymmetric clamps: With clamping openings ① only for <ul style="list-style-type: none"> <li>pins with 4 mm shaft diameter or rods</li> </ul> and clamping openings ② only for <ul style="list-style-type: none"> <li>pins with 3.2 mm shaft diameter</li> </ul> </li> </ul>
 <p>asymmetric</p>		
	<ul style="list-style-type: none"> <li>Eight different rod designs</li> <li>Five rods are anatomically pre-bent</li> <li>Further rod contouring is possible</li> </ul>	<ul style="list-style-type: none"> <li>Best possible choice for each type of mandible fracture or defect</li> <li>Best possible average shapes</li> <li>Adjustment to individual patient anatomy</li> </ul>

## Step by Step

## Fields of Use

- 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



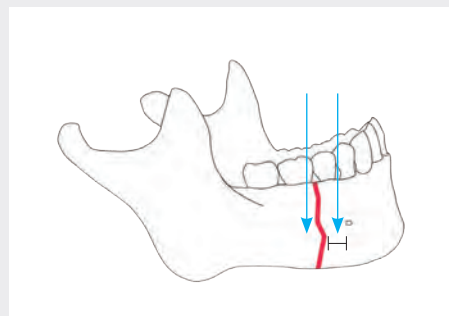
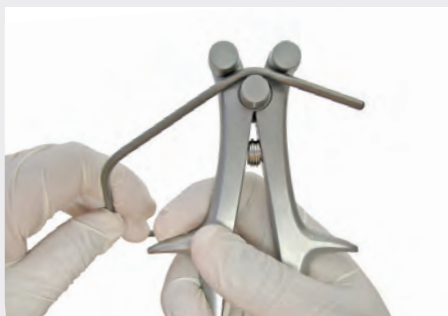


## Surgical Technique

**X-Fix**

Pages 11-15





### 1. Preparatory Work

The surgical procedure 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.

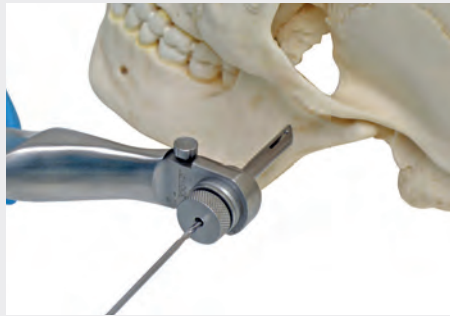
Subsequently, the desired positions for the first and the last X-Fix pin must be determined and marked accordingly. These are the X-Fix pins located farthest away from the defect, proximally and distally.

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.



Bending template for X-Fix rods

Rod bender



## 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.



Trocar handle



Cannula



Trocar



Drill guide



2.2-mm twist drill



Depth gauge



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 with 3.2 mm shaft diameter. 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.



Ratchet screwdriver handle



Triangular X-Fix socket bit



X-Fix clamp, symmetric



X-Fix clamp, asymmetric

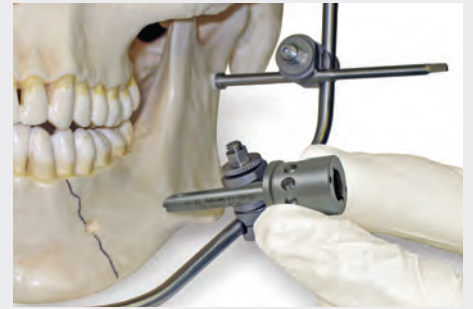


Reduce the fracture in the standard way.

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.



Hex nut driver, size 5 mm



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.

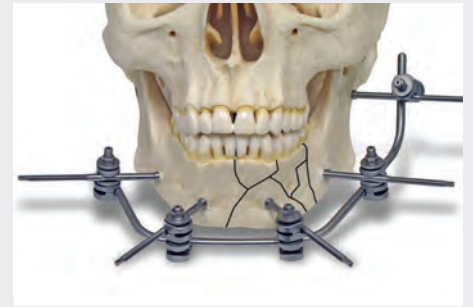
## 6. Final Work

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

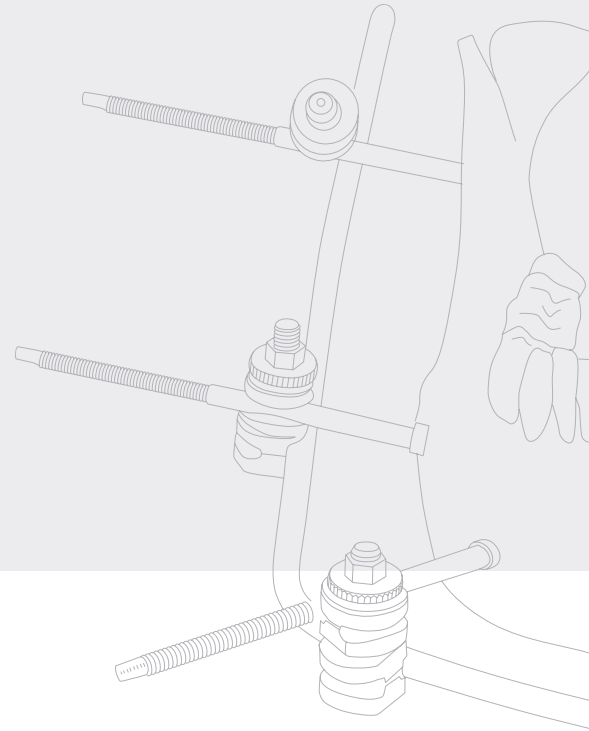
- Used in cases of mandibular angle infection

#### Modular frame

- Used for comminuted fractures
- The modular frame is designed according to the position of the fracture.



## X-Fix Implants and Accessories



### X-Fix pins

Ø 4.0 mm  
Length 80 mm  
Thread Ø 2.7 mm



1/1



Thread length	Item No.
7 mm	51-673-07-09
9 mm	51-673-09-09
13 mm	51-673-13-09
17 mm	51-673-17-09

### X-Fix pins

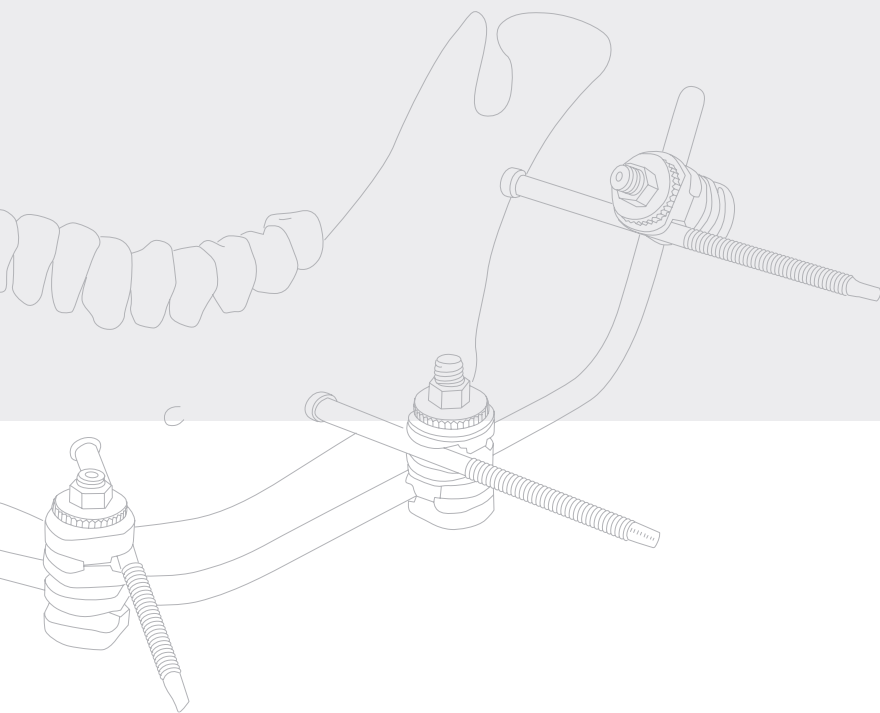
Ø 3.2 mm  
Length 80 mm  
Thread Ø 3.2 mm



1/1



Thread length	Item No.
7 mm	51-670-07-09
11 mm	51-670-11-09
13 mm	51-670-13-09



Explanation of icons

- Ti** Titanium
- St** Stainless steel
- 1** Units per package



51-672-01-09



51-672-02-09



51-672-03-09



51-672-04-09



51-672-05-09



51-672-08-09

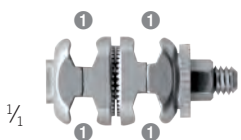


51-672-06-09



1/4

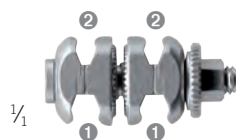
51-672-07-09



51-670-04-09 **Ti** **St** **1**

X-Fix clamp symmetric,  
with hexagon clamping nut,  
wrench size 5 mm

Large openings **1** only for X-Fix pins Ø 4 mm  
or X-Fix rods Ø 4 mm



51-670-05-09 **Ti** **St** **1**

X-Fix clamp asymmetric,  
with hexagon clamping nut,  
wrench size 5 mm

Large openings **1** only for X-Fix pins Ø 4 mm  
or X-Fix rods Ø 4 mm

Small openings **2** for X-Fix pins Ø 3.2 mm

**X-Fix Rods**

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

## X-Fix Instruments



1/2

50-125-16-07 St 1

Rod bender



1/2

51-671-28-09 Ti 1

Bending template for X-Fix rods



1/2

50-501-01-07 St 1

Trocar handle

Explanation of icons

- Ti** Titanium
- St** Stainless steel
- 1** Units per package



1/2

50-501-10-07 **St 1**  
Cheek retractor



1/2

50-501-19-07 **St 1**  
Cannula



1/2

50-501-09-07 **St 1**  
Trocar



1/2

50-501-40-07 **St 1**  
Depth gauge



1/2

50-501-29-07 **St 1**  
Drill guide

## X-Fix Instruments



½

50-022-15-07 St 1

Twist drill  
2.2 x 115 mm  
J-notch attachment



½

50-126-06-07 St 1

Twist drill  
2.5 x 105 mm  
J-notch attachment



½

51-600-85-07 St 1

Triangular  
nut driver



½

51-600-65-07 St 1

Hex nut driver  
size 2.5 mm  
for connection bar

Explanation of icons

**St** Stainless steel

**1** Units per package



1/2

51-600-70-07 **St** **1**

Hex nut driver  
size 5 mm

- for clamping nuts of symmetric and asymmetric clamps
- for pin nuts



1/2

25-410-00-07 **St** **1**

Ratchet screwdriver handle



1/2

51-600-86-07 **St** **1**

Triangular X-Fix socket bit

## X-Fix Storage

### X-Fix Rods

55-969-45-04	Storage tray for X-Fix system, complete
55-969-39-04	Storage tray for X-Fix system, 30 x 45 cm, with fixation strips
55-963-39-04	Lid for X-Fix storage tray



55-962-37-04\*

Twin insert module, gray

\* 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).



55-963-36-04

X-Fix lid for twin insert module



55-964-61-04

X-Fix insert for twin insert module, 14 mm high for symmetric and asymmetric clamps





Storage tray for X-Fix system, complete



55-964-62-04

X-Fix insert for twin insert module,  
free storage, 6 mm high  
for twist drills



55-964-65-04

X-Fix insert for twin insert module, 20 mm high  
- for X-Fix pins  $\varnothing$  4 mm  
- for X-Fix pins  $\varnothing$  3.2 mm  
- for symmetric and asymmetric clamps



55-964-99-04

X-Fix insert for twin insert module,  
without contents, 20 mm high  
for X-Fix pins  $\varnothing$  4 mm

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