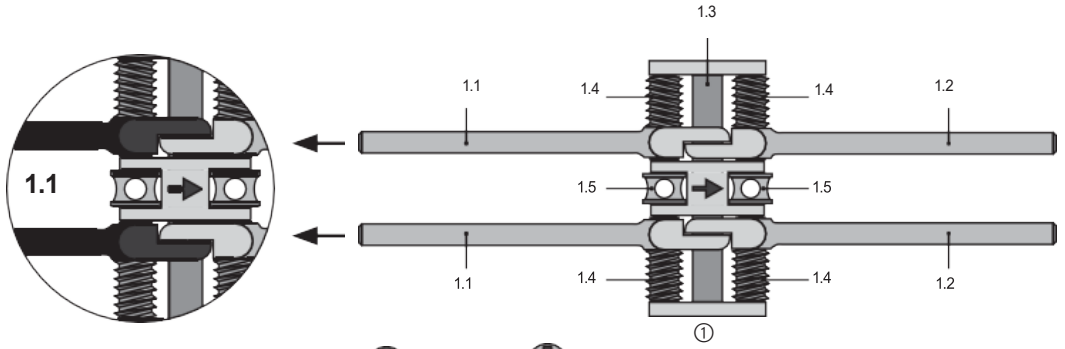
medicon®
MEDICON eG
Gänsäcker15,78532 Tuttlingen
Germany
Tel.: (49) 7462 / 2009-0
Fax: (49) 7462 / 2009-50
E-Mail: sales@medicon.de
Internet: http://www.medicon.de

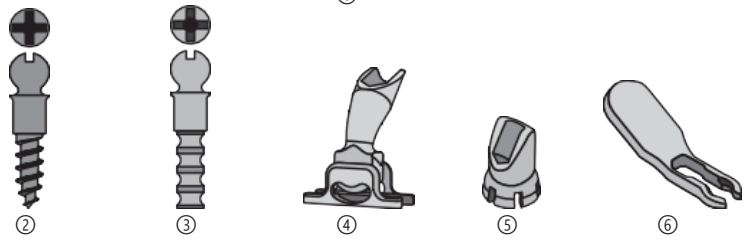
EN

CE 0123 NON STERILE Rx only MD

Rev.: 15-12-2025

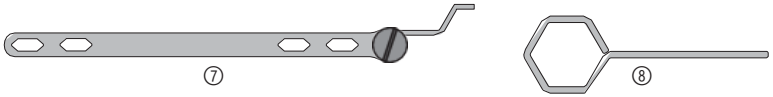
Gebrauchsanweisung



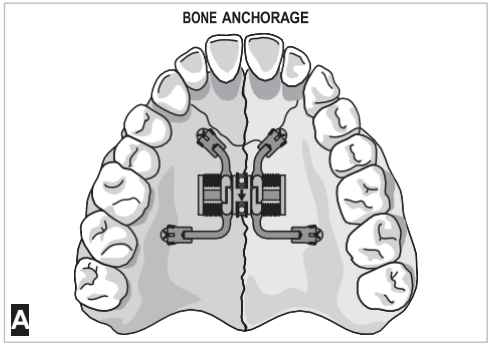



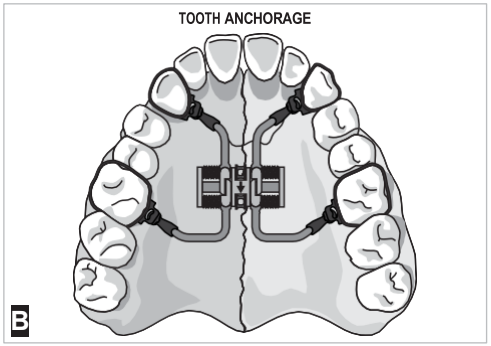

① Maxillary distractor
- 1.1 Outer distraction arms for primary distraction (see enlarged section left)
- 1.2 Inner distraction arms for subsequent distraction
- 1.3 Median sliding axle
- 1.4 Distraction axles (spindles)
- 1.5 Drives to activate the respective distraction axle

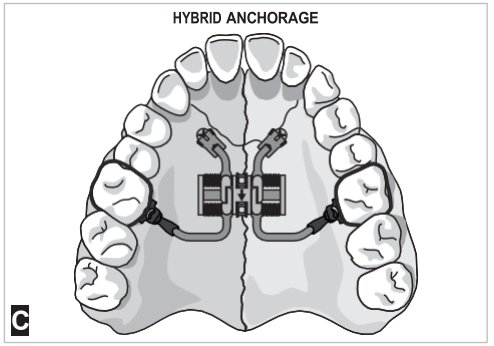
② Anchoring screw
③ Model screw
④ Tooth band fixation module
⑤ Click-on cap
⑥ Positioning aid
⑦ Articulated wrench for activation
⑧ Hexagon key for the dental technician




## ANCHORING METHODS OF THE MAXILLARY DISTRACTOR



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**"MaxPander" maxillary distraction system for individual trans-versal expansion of narrow maxillae. The operating instructions must be read carefully and kept at hand before use in the dental laboratory, practice or clinic. The instructions and notes contained therein must be followed.**

TABLE OF CONTENT



## 1 GENERAL NOTES

The anchor screws② are implants made of titanium. The material is biocompatible, corrosion-resistant and non-toxic in a biological environment. The surface is chemically passive; the material is antimagnetic. It is possible that image artefacts may occur in conventional X-ray imaging, computed tomography and magnetic resonance imaging (MRI).

**The "MaxPander" maxillary distractor①, the tooth band fixation module④, the click-on caps⑤ and the model screws③ are made of stainless steel and supplied non-sterile (as are the screwdriver handle and screwdriver blade). They must therefore be cleaned, disinfected and sterilised before surgical use.**
**Please observe the following notes. These will ensure flawless and reliable functioning of the product.**

## 2 INTENDED USE

The "MaxPander" maxillary distraction system is used for individual transversal expansion of narrow maxillae and may be applied only by surgeons with sufficient experience in oral and maxillofacial surgery or by experienced orthodontists in medical practices and hospitals. It is suitable both in childhood for palatal expansion and in adulthood for maxillary expansion in combination with surgical mobilisation of the maxilla.

The model screws③ and positioning aids⑥ are intended for laboratory work only and must not be implanted or used in or on the patient under any circumstances. The positioning aids⑥ on the plaster model can be reused by the dental technician.

With the two distraction axles (1.4) of the "MaxPander" maxillary distractor①, individual transversal maxillary expansion is possible. The narrow maxilla can be extended more extensively in the anterior region than in the posterior region and vice versa.

The "MaxPander" maxillary distraction system is first adapted to the patient by dental technicians and then placed in the maxilla by a surgeon/orthodontist.

The vertebral replacement may only be implanted in hospitals and clinical practices by surgeons with sufficient experience in spinal operations (neurosurgery, orthopaedics, accident surgery, etc.) and who have received an induction into the system. The implants are disposable products and may only be used together with the standard components.

## 3 INDICATIONS

The "MaxPander" maxillary distraction system can be used for individual trans-versal expansion of the maxilla:

- Narrow maxillary dental arch and narrow osseous maxilla
- Uni- or bilateral crossbite
- Anterior crowding in the maxilla (e.g. anterior > expansion)
- Posteriorly narrow, almost parallel maxillary posterior tooth regions with normal maxillary anterior tooth position (for example posterior > expansion)
- Anteriorly narrow and tapering maxillary dental arch with normal-width posterior molar dental arch (for example anterior > expansion)
- All transverse jaw base and dental arch discrepancies including asymmetrical dental arches
- Partially and fully edentulous jaw bases (bone anchoring)
- Impaired nasal breathing in case of narrow maxilla and narrow nasal passages
- Narrow maxilla with periodontally pre-damaged teeth (bone anchoring)

## 4 CONTRAINDICATIONS

The "MaxPander" maxillary distractor① and the MEDICON anchoring system must not be used in:

- Patients who are unable to comply with the physician's instructions, for example due to psychological, mental or neurological problems
- Patients with reduced bone quality, with circulatory disorders, or with acute infections
- Congenital bone diseases, for example with an increased risk of fracture (e.g. brittle bone disease)
- Bleeding tendency, anticoagulant therapy
- Patients in unstable physical and/or mental condition
- Foreign object or hypersensitivity reaction to metals or even titanium intolerance. In this case, appropriate tests are mandatory before treatment (even in case of mere suspicion!)
- Condition after radiotherapy in the head area
- Recurrent disease of the oral mucosa and insufficient oral hygiene
- Patients with previous periodontal diseases, possibly pathological tooth loosening (no tooth and hybrid anchorage possible)

## 5 POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

- Facial swelling, pain, abnormal sensation of the mucous membrane of the mouth or the skin of the face
- Foreign object reaction or allergies
- Tooth root damage with loss of tooth sensitivity and root resorption, for example caused by anchoring screws
- Corrosion damage
- Damage to the mechanics of the distraction system with bending, jamming, twisting, breaking or loosening of the apparatus
- Loosening or migration of the anchoring screws including inflammatory reaction and bone loss
- Failure of the orthodontic therapy
- Decrease in bone density due to stress shielding
- Secondary bleeding due to arterial injury in the palate
- Fracture of the bony palate, asymmetrical expansion of the maxilla
- Receding gums and formation of vestibular bone windows
- Gingival recession/periodontal gum disease
- Breakage of the wrenches due to overloading

In addition to the undesirable effects and complications already mentioned, the procedure can lead to surgery-related problems such as nerve damage, infections, pain etc. that may not necessarily be attributable to the application of the "MaxPander" maxillary distraction system.

**Improper bending of the distraction arms (1.1/1.2) and/or multiple bending at the same location can lead to breakage of the distraction arms.**

## 6 SINGLE USE PRODUCT

**The "MaxPander" maxillary distractor①, the click-on caps ⑤, the anchoring screws②, the tooth band fixation modules④ and the model screws③ are not reusable and have been developed and designed for single use in one patient only.**

These MEDICON products must not be reused. Even if they appear to be intact or fully functional, there may be wear, minor defects and attrition due to overuse that are not visible to the naked eye. As the impact of the forces and conditions inside the body on the stability, function and material quality of the "MaxPander" maxillary distractor① and the "MaxPander" maxillary distraction system cannot be estimated, reuse would entail the risk of premature wear or failure and is therefore unacceptable. The user will be held liable if the operating instructions are not observed.

## 7 MR NOTES

**Instruments**
The use of medical devices poses a risk in the vicinity of an MRI scanner. Individual medical devices must not be located in the immediate vicinity of the equipment during the use of these procedures.

**Implants**
The implants are not MR-safe and have not been tested for MR safety. Use in an MRI environment may therefore pose a risk. It is recommended that patients and medical personnel be advised that the implants are not approved for use in MRI equipment.

## 8 USE AND HANDLING OF THE INSTRUMENTS

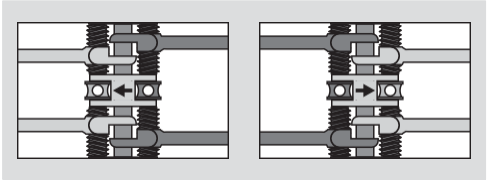
**Selecting the products:**
The treating surgeon/orthodontist is responsible for selecting the appropriate anchoring method. There are three methods of anchoring the distraction system in the maxilla:

- **Bone anchorage (figure A)**
  with four anchoring screws② and for click-on caps⑤
- **Tooth anchorage (figure B)**
  with four tooth band fixation modules④ on four tooth bands
- **Hybrid anchorage (figure C)**
  with two anterior anchoring screws② with click-on caps⑤, and two posterior tooth bands with two tooth band fixation modules④

This requires a treatment plan by the surgeon/orthodontist covering the entire treatment process, the preparation of the treatment documents and, if necessary, consultation with the specialist fields involved.
If the patient is treated in a combination procedure by surgeons who are experienced in oral and maxillofacial surgery, a systematic planning of the operation, possibly with the help of DVT or CT data, is necessary. In the case of planned bone anchorage, care must also be taken to ensure sufficient bone availability in the palate. The instruments intended for application of the "MaxPander" maxillary distractor① and the "MaxPander" maxillary distraction system are subject to wear and mechanical stresses even when used normally, and especially if used too forcefully.
In order to prevent failure or mechanical damage to the instruments during treatment, they must be checked before each use to ensure that they are mechanically intact, that there are no deformations, and that the instruments are fully functioning. Damaged instruments must not be used, and are to be replaced. Use only instruments and accessories specifically approved by MEDICON, in order to avoid risks in connection with the compatibility of the products.

**Using instruments by other manufacturers in conjunction with the MEDICON products is associated with unforeseeable risks, as such products are not designed to be used together. For this reason, only the specially designed MEDICON products should be used together, in order to prevent risks to patients, users and/or third parties.**

The "MaxPander" maxillary distractor① is equipped two distraction axles (1.4), each of which has an activation drive (1.5) located in the centre of the screw. These drives (1.5) can be activated separately from each other. Activation is always carried out with the articulated wrench in the direction of the arrow. The two pairs of distraction arms (1.1/1.2), which are anchored next to each other on the median sliding axle (1.3), can be activated to different degrees and move away from each other upon activation.
The outer distraction arms (1.1) running on the median sliding axle (1.3) can be activated without restriction, the inner distraction arms (1.2) only in depending on the outer ones. Thus, the outer distraction arms (1.1) must always be activated first because they hold the inner distraction arms (1.2) captive on the median sliding axle (1.3). The inner distraction arms (1.2) can be activated only in a second step and only up to the same degree of expansion. The maximum distraction distance is 13 mm on both distraction axles.
The position of the "MaxPander" maxillary distractor ① can be rotated by 180° . The outer distraction arms (1.1) must be positioned at the location of the greater distraction distance. In most cases this is the anterior maxilla, as experience has shown that there a transverse bone deficit is more frequent in this location. (Fig. 01-02)



**The outer distraction arms (1.1) must be activated first, the inner distraction arms (1.2) follow. If the "MaxPander" maxillary distractor① is misaligned, the inner distraction arms (1.2) prevent sufficient expansion, and the distraction target is not achieved.**

## 9 ANCHORING METHODS WITH PRACTICAL INSTRUCTIONS

### 9.1 BONE anchorage (figure A)

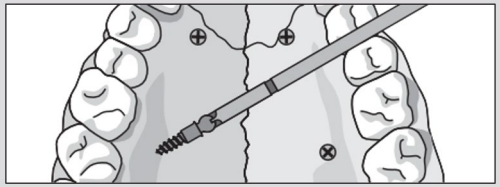
**Diagnosis:**
When using anchoring screws② in the bony palate, the bone availability of the maxilla must be diagnosed beforehand in order to ensure a firm fixation of the anchoring screws②.

Especially in the posterior palate, the bone thickness can be so low that the anchoring screw② cannot be fixed in a permanently stable manner. Increased bone availability is usually found on both sides in the lateral palatal areas posterior to the fifth tooth root and between the palatal roots of the first and second molars, possibly distal to the second molar if the wisdom tooth is still present.

The individual bony thickness of the palate can best be determined by digital volume tomography (DVT) using dental 3D implant software.

**Surgical insertion of the anchoring screws:**
The anchoring screws② are inserted under local anaesthesia using a Phillips screwdriver in the anterior and posterior palate on both sides. The screwdriver blade should be almost in contact with the respectively opposite row of teeth. The anchoring screws② should be screwed in at an angle on both sides of the anterior palate at a minimum distance of 10 mm paramedially. The direction of insertion should allow introduction of force into the bone as axially as possible. However, deviations may occur due to the shape and height of the palate and adjacent tooth roots. Contact with the tooth roots is to be avoided. (Fig. 03)

Fig. 03



**The anchoring screws② should be screwed in until the threadless smooth screw shaft penetrates completely into the palatal mucosa and the upper edge of the screw shaft is flush with the mucosa surface. Firm anchoring of the anchoring screws② in the bone is a prerequisite for the proper function of the "MaxPander" maxillary distraction system.**

**Surgery:**
**During implantation, it is imperative to ensure that not only the tooth roots but also the vessels and nerves remain unharmed. Screws remaining loose (e.g. due to perforation or fracture of an unsuitable thin bone roof) must be removed and screwed in again in an adjacent position.**

**The anchoring screws② may detach from the screwdriver blade and be aspirated, swallowed or transferred to the maxillary sinus.**
**Even in case of primary stability of the anchoring screws ② there is a risk of screw loosening during the distraction procedure.**

**Use of the screwdriver:**
The screwdriver must be inserted into the screw head with axial pressure to ensure that the blade sits tightly on the screw head. This ensures correct longitudinal alignment of screw and screwdriver and prevents slipping of or damage to the screw head or the blade.

**If excessive force is applied when fixing the anchoring screw ②, the anchoring screw② may detach from the screwdriver blade, get lost in the oral cavity and be aspirated. An emergency transfer for diagnosis of the whereabouts of the screw is necessary.**

**Material wear:**
Wear and tear effects to the screwdriver blade impair the firm connection between the blade and screw. In this case, replace the blade with a new one.

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# Gebrauchsanweisung

**Damage to anchoring screws ② can lead to reduction in strength and premature fatigue of the screws.**

Check the screws for damage before inserting them. Damaged anchoring screws ② may not be used and must be replaced. After finishing the implantation, the secure connection between all components must be checked. If necessary, retighten the anchoring screws ②.

**Incorrect implantation of the anchoring screw ② can lead to premature implant loss as well as loosening, bending or implant fractures. The success of the treatment may therefore be at risk!**

**Dental application:**

After implantation of the anchoring screws②, an impression of the maxilla is taken, for example with Impregum® or silicone impression material. Before this, the crossslots in the four screw heads of the anchoring screws② are filled with wax in order to be able to position the heads of the model screws③ exactly in the spherical recesses.

The model screws③ are then inserted into the cured impression and the impression is filled with plaster. After the plaster has cured, the impression tray is removed. Now the four model screws③ in the plaster model are in identical position to the anchoring screws② in the patient's maxilla.

The heads of the model screws③ are cleared of the surrounding plaster in order to allow positioning of the click-on caps⑤ with the positioning aids⑥ correctly on the model screw heads. They are tilted towards the palate to the screw shoulder in order to stabilise the bony palatal transversely after the distraction. (Fig. 04-06)

Fig. 04

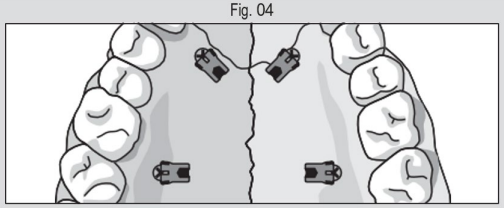


Fig. 05

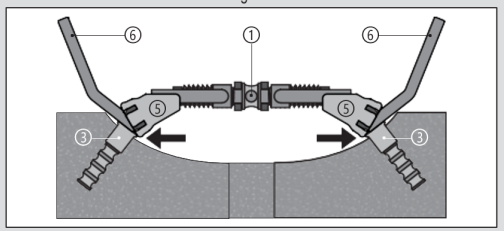
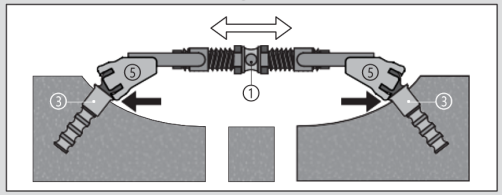



Illustration of the cross-section of a plaster model with model screws③ and inserted positioning aids⑥ for positioning the click-on caps⑤ which touch the upper edge of the screw shaft of the model screws③ (see arrows). In this position, the "MaxPander" maxillary distractor① is fixed to the grooves of click-on caps⑤ by laser welding or soldering.

Fig. 06



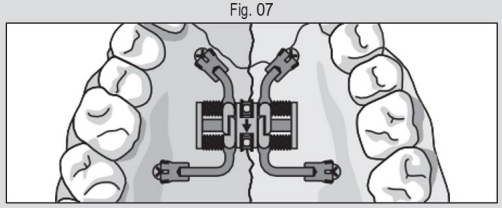

Simulation of the transversal widening of the maxilla on the basis of a plaster model in cross-section with paramedian "maxilla osteotomies" on both sides: The distraction is performed horizontally (white double arrow).
By tilting the click-on caps⑤ onto the respective shoulder edge of the anchoring screws② (black arrows), the transversal bony expansion of the maxilla is stabilised and prevents subsequent scarred shrinkage of the central palatal soft tissue.

Later reduction of the distraction gap (for example by transverse scar formation) can be counteracted. The maxillary distractor① is then positioned on the palate with both distraction axles (1.4) in zero position according to the planning.

However, if the maxillary distractor① is to be used in a patient of prepubertal age without prior surgical mobilisation of the maxilla, the bone-fixed maxillary distractor must be activated by the size of the inverse conical click-on cap, as it is not possible to expand the two halves of the maxilla against each other without prior surgical mobilisation.

The extent of the possible distraction distance is reduced by this length of pre-stretching. The two outer distraction arms (1.1) are positioned at the location where the preferred distraction is planned. In the vast majority of cases this is in the anterior maxillary region. (Fig. 07)

Fig. 07



The distraction arms (1.1/1.2) are then trimmed with cutting and bending pliers from the Medicon range and gently bent towards the click-on⑤ caps and fixed to their grooves by laser welding or soldering.

The plaster model is cut, and the resulting plaster parts with the respective model screws③ are removed from the click-on caps⑤. The "MaxPander" maxillary distraction system is cleaned and prepared, and its function checked.

**Risks:**

**Improper handling of the "MaxPander" maxillary distractor① when bending the distraction arms (1.1/1.2) leads to deformation of individual components of the maxillary distractor① and destruction of the mechanical function.**

Check the components for damage before the laser welding or soldering process. Damaged components may not be used and must be replaced. The dental technician has to ensure that the screw heads are completely free from surrounding plaster material prior to inserting the click-on caps ⑤.

It is the responsibility of the dental technician to ensure that the connection between the distraction arms (1.1/1.2) and the click-on caps⑤ or tooth bands with the tooth band fixation modules ④ is sufficiently stable. In this context, unavoidable influences such as mechanical loads, internal and external stresses and vibrations of the overall construction must be taken into account.

**The firm fixing of the individual components by laser welding or soldering is the sole responsibility of the dental technician and may be carried out only by dental technicians with sufficient knowledge of the composition of the materials available for soldering. The dental technician must have mastered and practised the use of laser welding technology.**

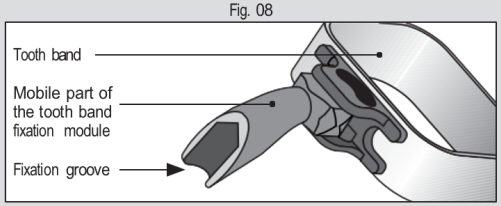
**The model screws③ and positioning aids ⑥ are intended for laboratory work only and must never be implanted or used in or on the patient. The dental technician provides the clinical user with the individual, patient-specific maxillary distractor① with the components required for treatment, if necessary.**

**9.2 Tooth anchorage (figure B)**

After taking of an impression in the maxilla with e.g. Impregum® or silicone im-pression material, a hard plaster model is made. In the case of tooth anchoring of the maxillary distractor①, suitable tooth bands are selected for the anchoring teeth, for example canines and first or second molars.

The base surfaces of the tooth band fixation modules④ are fixed on the outside of the tooth bands by laser welding or soldering in such a way that they lie on the palatal side after being placed on the anchoring teeth of the plaster model. (Fig. 08)

Fig. 08




The maxillary distractor① is then positioned on the palate with both distraction axles (1.4) in zero position according to the planning. The two outer distraction arms (1.1) are located where the greatest distraction is planned, which in most cases is in the area of the anterior maxilla. First, the tooth band fixation module④ is fixed to the palatal side of the tooth band by laser welding or soldering.

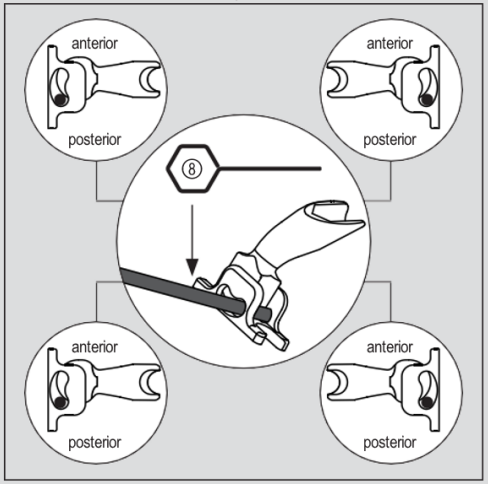
This is followed by pre-bending and adapting each distraction arm (1.1/1.2) to the respective fixation groove of the mobile part of the tooth band fixation module④. The mobile part is then positioned anteriad by inserting the hexagon key⑧ posteriorly through the sliding hole.

Then the appropriate pre-bent distraction arms (1.1/1.2) are fixed in the fixation grooves of the mobile part of the tooth band fixation modules④ by laser welding or soldering.

The completed "MaxPander" maxillary distraction system is removed from the plaster model on the tooth bands. Finally, the maxillary distractor① is cleaned, prepared and checked for proper function.

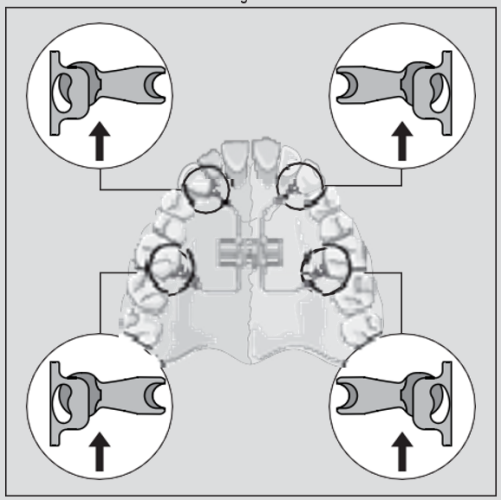
The mobile parts of the tooth band fixation module④ are shifted anteriad (arrows) in order to allow unobstructed transversal expansion of the two halves of the maxilla. This procedure applies to purely dental anchorage and hybrid anchorage alike. (Fig. 09-10)

Fig. 09




The mobile part of all tooth band fixation modules④ is positioned anteriad by inserting the hexagon key⑧ posteriorly through the sliding hole.

Fig. 10



Anteriad positioning of the mobile elements of the tooth band fixation module④ in order to allow unrestricted individual expansion of the maxilla with both distraction axles.

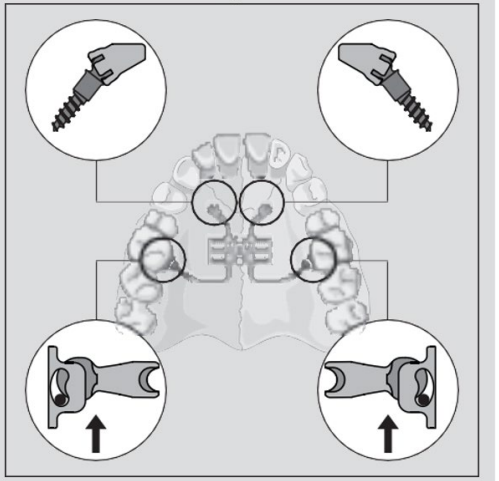
**It must be ensured that the tooth band fixation modules ⑥ are fixed to the tooth bands as parallel to each other as possible, so that the mobile parts enable an unobstructed individual distraction procedure. Only then is the individual, transversal expansion of the maxilla ensured, more extensively in the anterior region than the posterior region and vice versa.**

**9.3 Hybrid anchorage (figure C)**

If hybrid anchorage of the "MaxPander" maxillary distractor ① is planned in case of reduced bone availability in the posterior palatal region or for other reasons, the two anchoring screws ② are first inserted in the anterior palatal region, for example under local anaesthesia.

Then the cross-slots in the ball heads of the two anchoring screws ② are covered with wax, and an impression of the maxilla is taken with Impregum® or silicone impression material. The model screws ③ are positioned in the recesses of the two ball heads, and the impression is poured out.

Fig. 11



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The heads of the model screws ③ are cleared of the surrounding plaster, and the two click-on caps ⑤ are inserted using the positioning aids ⑥. Then the tooth bands are adapted for the molars, and the tooth band fixation modules ④ are fixed to the tooth bands by laser welding or soldering.
The maxillary distractor ① is then positioned on the palate with both distraction axles (1.4) in zero position according to the planning. The outer distraction arms (1.1) must be positioned at the location of the greater distraction distance. The bent and shortened distraction arms (1.1/1.2) are fixed in the grooves of the two click-on caps ⑤, and the two tooth band fixation modules ④ by laser welding or soldering. If the click-on caps ⑤ on the model screws ③ are inverse conical, the plaster model must be cut up to detach the "MaxPander" maxillary distraction system.
Finally, the maxillary distractor ① is cleaned, prepared and checked for proper function. (Fig. 11)

**10 ACTIVATION OF THE MAXILLARY DISTRACTOR**

Activation begins between the fourth and seventh postoperative day. It is performed with the articulated wrench - always in the direction of the arrow - three times a day (morning, noon and evening) with one quarter turn per distraction axle (1.4). Always start with the distraction axle whose distraction arms (1.1) are on the outside, followed by the other distraction axle with the inner distraction arms (1.2).

- **One quarter turn (from hole to hole) corresponds to a distraction of 0.2 mm**
- **Four quarter turns (360° rotation) correspond to a distraction of 0.8 mm**
- **The daily distraction per drive is 3 × 0.2 mm**

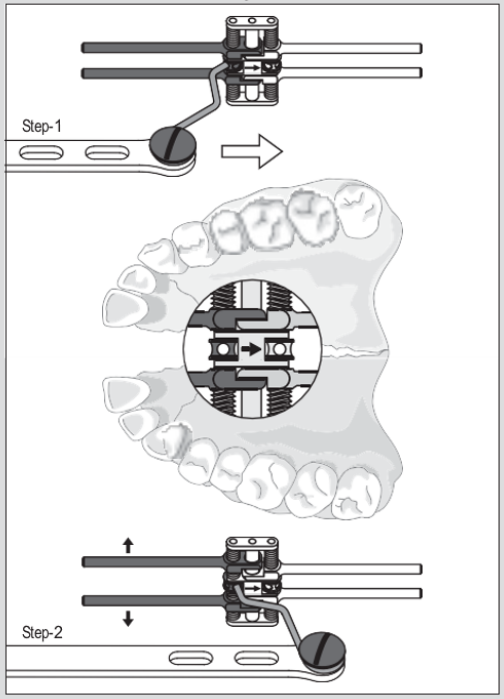
In the individual case, the surgeon/orthodontist determines the drive of the respective distraction axle (1.4), the extent of the daily distraction of both axles and, if the treatment goal is achieved, also the end of the distraction procedure. The distraction axles (1.4) are then inactivated with polyacrylate. Please remember that you must always turn in the direction of the arrow and achieve at least a quarter turn, otherwise the angled wire end of the articulated wrench ⑦ cannot be inserted into the next hole of the drive.

**Improper activation can easily destroy the mechanics of the maxillary distractor. Never activate the inner distraction arms (1.2) first. This inevitably leads to destruction of the thread. Multiple loosening and tightening of the spindles during the activation can also cause them to become too loose, twist or slip, and lose their function.**

**Anterior distraction of the maxilla:**

When the arrow on the maxillary distractor ① points towards the palate, the angular, prebent wire, at the end of the articulated wrench handle ⑦, is adjusted about 135° forward and upward for activation, so that the tip of the wire can be inserted into the drill hole of the drive unit with good view of it (step 1).
By pushing the wrench handle in the direction of the palate, the activation is carried out until the tip of the wire slips out of the drill hole again (step 2). The procedure, which has now produced approx. 0.2 mm of distraction, is then repeated, depending on the treatment plan. Subsequently, the 2nd distraction axle is activated in the same way, but to a lesser extent. (Fig. 12)

Fig. 12

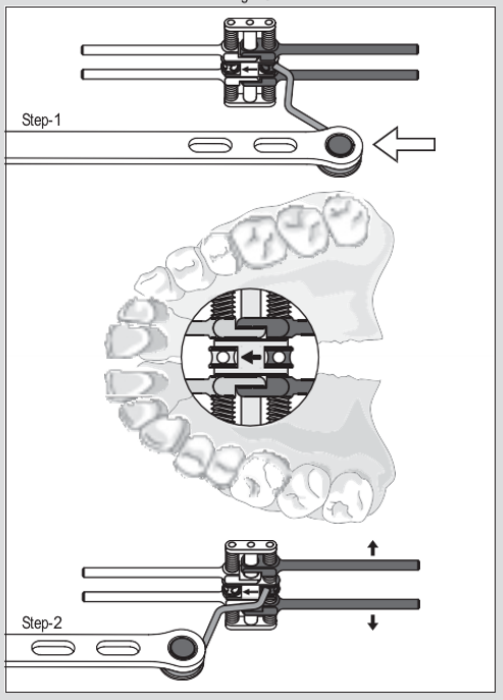



**Posterior distraction of the maxilla:**

When the arrow on the maxillary distractor ① points in the direction of the upper incisors, the articulated wrench is bent backwards and upwards by about 45° and inserted into the hole of the drive unit, which is visible only from the palate, without direct view (step 1). The hole can be visualised using a mirror on the back of the tongue if necessary.
The articulated wrench handle ⑦ is slowly pushed forward towards the upper incisors (step 2). The second distraction axle is then activated in the same way. (Fig. 13)

**Incorrect use of the articulated wrench ⑦ can lead to overloading. We accept no liability for the resulting failure of the wrench.**

Fig. 13




**11 CONDUCT BEFORE, DURING AND AFTER TREATMENT**

**Conduct before and during treatment:**

Before use of the products, the surgeon/orthodontist must discuss the treatment plan, the distraction procedure and the resulting treatment result in detail with the patient and hand over the patient card.
According to the instructions of the treating surgeon/orthodontist, the patient keeps a distraction protocol of the activation process, which is handed out to him before the treatment. This should finally be attached to the medical treatment documents.
In doing so, special attention should be paid to explaining the conduct before and during treatment and to the necessary aftercare.

**The distraction process requires intensive monitoring and regular checks by the treating surgeon/orthodontist.**

**Conduct during and after treatment:**

The treating surgeon/orthodontist must instruct the patient or activating person in intra-oral activation, define the entire treatment procedure, and determine which distraction axle (1.4) is to be activated when and how often. The patient or activating person turns the respective distraction axle (1.4) once a day according to the instructions of the treating surgeon/orthodontist until the desired extension is achieved.
Here one quarter turn corresponds to a distraction of 0.2 mm (from hole to hole). The patient or activating person may use only the articulated wrench ⑦!
The hexagon key⑧ may be used only by the dental technician or orthodontist in order to check the function of the maxillary distractor after the apparatus has been prepared. Under no circumstances may this hexagon key ⑧ be used by the patient or the activating person!
The patient must be instructed to immediately inform the treating surgeon/ orthodontist about any unusual changes at the operation site. The treating surgeon/ orthodontist must consider possible consequences such as the failure of the apparatus and discuss required measures for further healing with the patient. The maxillary distractor ① and the "MaxPander" maxillary distraction system can loosen, shift, bend or break due to overloading.
The treating surgeon/orthodontist decides on the type, duration and intensity of physical activities after the surgery. The patient must be informed that failure to comply with the physician's instructions may lead to non-foreseeable complications. This applies in particular if the patient manipulates the apparatus in a way that deviates from the therapeutic plan. We advise the patient to have regular check-ups with his surgeon/orthodontist and to take good care of his patient care. A "LOT" number (batch number) is indicated on the label of the packaging. To ensure 100% traceability, we recommend noting down the LOT number in patient's distraction protocol.

**Disposal:**

Observe the applicable national laws when disposing of the "MaxPander" maxillary distractor, the "MaxPander" maxillary distraction system and the accessories!

**12 DECONTAMINATION, CLEANING AND STERILISATION**

**The following prion-specific protective measure (vCJD) is indicated when preparing the instrument.**

**In case of diagnosis of definitive or probable (v)CJD:**

- Where use of disposable items is not possible, the instruments used, which are or cannot be excluded to be contaminated, must be disposed of as waste for incineration.

**In suspected cases:**

- If prion contamination is suspected, it is recommended that any medical instruments be incinerated in accordance with the final report by the (v)CJD task force.

**In case of exclusion of (v)CJD:**

- Reuse after final processing. Otherwise all the instruments where contamination has taken place or cannot be excluded must be disposed of as waste for incineration.

**If (v)CJD cannot be detected:**

- Even if there is nothing to suggest presence of a prion disease, two procedures with at least partial effectiveness against prion contamination should be used for processing, e.g. alkaline mechanical cleaning combined with steam sterilisation

If an alkaline mechanical cleaning process is not used, or another cleaning process with proven effectiveness against prion contamination is deployed, and medical devices that come into contact with risk tissue (CNS, eyes, lymphatic tissue) are used, the Robert Koch Institute (IRK) recommends an extended sterilisation time of 18 minutes at 134°C (273°F).

**Cleaning solutions to which hydrogen peroxide has been added and/or very alkaline washing solutions can cause colour changes. This may cause the coding function to be lost. Instruments made of stainless steels must not be stored in physiological saline (NaCl) solution because prolonged exposure will lead to corrosion problems such as pitting and stress corrosion. Only cleaned and disinfected implants and instruments may be sterilised.**

**Limitations on recprocessing**

Frequent reprocessing has a slight impact on implants

**Place of use**

**Implants contaminated with blood and/or secretions must not be placed back into the implant storage tray. They must be disposed of.**

- Immediately after use, remove any gross contamination from the instruments using a disposable cloth or paper.
- Do not use any fixing agents or hot water (>40 °C (104 °F)), as this would result in fixation of residues and may affect the success of the cleaning.
- Feed the instruments into reprocessing immediately.
- Dry disposal is to be preferred.

**Preparation for decontamination**

Jointed instruments must be opened for processing. The instruments and the implant storage tray must be placed on washer-proof instrument carriers such that they can be rinsed thoroughly.
The instrument carriers (for example wire mesh trays) must be such that sub-sequent cleaning in the washer-disinfector (WD) is not impaired by "rinsing shadows" or "sound shadows" that may render any areas inaccessible to ultra-sound or rinsing.

medicon®
MEDICON eG
Gänsäcker15,78532 Tuttlingen
Germany
Tel.: (49) 7462 / 2009-0
Fax: (49) 7462 / 2009-50
E-Mail: sales@medicon.de
Internet: http://www.medicon.de

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# Gebrauchsanweisung

**Precleaning**
Always use a fresh and previously unused cleaning solution for manual pre-cleaning in the ultrasonic bath to prevent cross-contamination.
- Place the implant storage tray in the ultrasonic bath and treat it with ultrasound for 15 minutes at 40 ° C (104 ° F) using 0.5% alkaline cleaner (neodisher® MediClean forte)
- Remove the implant storage tray and thoroughly rinse it with cold water

**Machine cleaning of implants:**
To prevent cross-contamination during machine processing, always clean and disinfect the implant cassette containing the implants to be reprocessed in the WD in a separate batch from instruments contaminated with blood or secretion. The washer-disinfector (WD) must meet the requirement of DIN EN ISO 15883-1.
- Pre-rinse: 3 minutes with softened cold water, without additives
- Emptying
- Cleaning: with softened water, heating to 55 ° C (131 ° F) and 5 minutes washing and cleaning
- metering of the cleaning agent at 45 ° C (113 ° F), alkaline cleaning agent (neodisher® MediClean forte), dosage 0.5%
- Emptying
- Neutralisation: 3 minutes with warm water (>40 ° C (104 ° F)) with addition of neutraliser, dosage 1 ml/l
- Emptying
- Final rinsing: 2 minutes with warm, fully demineralised water (>40 ° C (104 ° F)) (with no other additives)
- Emptying

**Machine cleaning of instruments:**
The washer-disinfector (WD) must meet the requirement of DIN EN ISO 15883-1.
- 1. Pre-rinse: 1 minute with softened cold water, without additives
- Emptying
- 2. Pre-rinse: 3 minutes with softened cold water, without additives
- Emptying
- Cleaning: with softened water, heating to 55 ° C and 10 minutes washing and cleaning, adding of the cleaning agent at 45 ° C (113 ° F), alkaline cleaning agent, dosage 0.5 %
- Emptying
- Neutralisation: 3 minutes with warm water (>40 ° C (104 ° F)) with addition of neutraliser, dosage 1 ml/l
- Emptying
- Final rinsing: 2 minutes with warm, fully demineralised water (>40 ° C (104 ° F)) (without any other additives)
- Emptying

**Disinfection**
Thermal disinfection A0 value 3000:
- Fully demineralised water, thermal disinfection is carried out at temperatures >80 ° C (176 ° F) with a corresponding application time according to the A0 concept of standard DIN EN ISO 15883 and DGKH, DGSV and AKI guidelines (for example A0 3000 = 90 ° C (194 ° F) and 5 minutes application time)
- The healthcare facility is responsible for the A0 value to be implemented

**Drying**
Ensure sufficient drying in the WD, e.g. 60 ° C (140 ° F), 30 minutes. The instruments must be removed from the WD immediately after completion of the cleaning and disinfection programme.
If necessary, use of compressed air for drying is recommended due to its good and rapid effect (RKI recommendation).

**Manual cleaning and disinfection:**
As a matter of principle, the detergents and disinfectants to be used must be suitable for the manual cleaning and disinfection of instruments, and they must also be mutually compatible.
The effectiveness of the disinfectant must be verified. When choosing the disinfectant and procedure, refer to the relevant lists and recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (DGHM).

**Pre-cleaning**
- Immerse the instruments into cold water for 5 minutes
- Brush the instruments (using plastic brushes) under running cold water until all visible dirt has been removed
- Rinse the interior cavities, threads and drilled holes with the water gun for 10 seconds each, and then brush them again
- Remove the instruments and rinse them with cold, fully desalinated water

**Cleaning and disinfection:**
- Place the instruments into a bath with an approved detergent and disinfectant
- The instruments must be completely immersed into the solution
- The contact times, temperatures and concentrations specified by the manufacturer of the cleaning or disinfectant agent must be absolutely complied with
- Remove the instruments and rinse them with cold demineralised water for two minutes
- Repeat the cleaning process if any residual contamination can still be seen on the instrument
- If necessary, perform cleaning and disinfection in an ultrasonic bath with sonication

Working solutions freshly prepared each day must be used. In cases of heavy contamination, the working solution must be changed more frequently. A high level of contamination in the ultrasonic bath will impair the cleaning effect and promote corrosion. The cleaning solution must be regularly replaced, depending on the conditions of use. The criterion is visually recognisable contamination. In any case, the bath must be changed frequently, at least once a day. Observe the applicable national guidelines.

**Drying:**
Manual drying must be carried out using compressed air and a lint-free cloth. Use of compressed air for drying is recommended due to its good and quick effect (RKI recommendation).

**Maintenance, control and inspection:**
Following cleaning and disinfection, the implants and instruments must be macroscopically clean, i.e. free from visible dirt and residues. The inspection is performed visually. Insufficiently cleaned implants and instruments must be cleaned again and then rinsed and dried sufficiently.
Deformed or damaged implants must be sorted out and disposed of, as safe use cannot be guaranteed. Instruments with moving parts must be cooled and oiled with an instrument care oil, for example:

REF 46.00.40 MEDICON instrument care oil

prior to functional testing. Instruments that are fitted with a latch, such as clamps and needle holders, may be closed only to the first notch (danger of stress corrosion cracking). Defective instruments (with hairline cracks, deformation or wear) must be replaced, as they cannot fulfil their function, or cannot fulfil it safely enough. Similarly, any rusty instruments must be removed, as they can cause corrosion through the spread of rust.

**Packaging:**
The instruments/instrument storage tray are to be placed in an appropriate sterile barrier system. The sterile barrier system must meet the following requirements:
- DIN EN 868
- DIN EN ISO 11607
- Suitable for steam sterilisation (steam permeability)
- Sufficient temperature resistance up to 138 °C (281 °F)

Sterilisation accessories and sterilisation packaging must be adapted to the package content as well as to the sterilisation procedure to be applied.

**Sterilisation:**
For sterilisation, the following sterilisation method must be used, taking into account all applicable national requirements:
- Fractionated vacuum procedure, triply fractionated and with sufficient product drying
- Steam steriliser validated according to DIN EN 13060 or DIN EN 285, respectively, and according to DIN EN ISO 17665-1

Sterilisation time and temperature:
- At least 5 minutes holding time at 134 °C (273 °F)

**Reaching an SAL (Sterility Assurance Level) of $10^{-6}$ is indispensable.**

**Storage:**
Reprocessed sterile implants are to be stored in dry, dust-protected, low-germ, dark and cool rooms, free of vermin, in an appropriate reusable sterilisation container. To prevent condensation, extreme temperature fluctuations should be avoided during storage. No chemicals may be stored together with implants.
Walls, floors and ceilings of the storage room should be smooth and easy to clean and disinfect. Shelves must have a ground clearance of at least 30 cm. The permissible onsite storage period depends on the type of sterile barrier system used and on the storage conditions. The permissible storage period is to be specified by the operator.

**Additional information on reprocessing:**
A validated automated cleaning and disinfection method is always preferable to manual cleaning because of the greater reliability of the method. Thorough cleaning also helps to maintain value and is a prerequisite for successful sterilisation.

Please take note of the following points regarding automated processing:
- For effective automated processing, load the wire mesh baskets in such a way that they can easily be mechanically rinsed; mesh baskets must not be overloaded
- Avoid "rinsing shadows" cast by large instruments
- To avoid any damage, the mechanical sensitivity of the instruments must be taken into account when they are placed down or stored

The times and temperatures stated in these reprocessing instructions are minimum requirements that must not be undercut. Should any reduction be needed for procedural reasons, this must be validated by the operator.
Exceeding the specified times and temperatures is generally possible. However, this will lead to increased stress on the material, which can cause premature wear. We accept no responsibility if other sterilisation methods are used.

**Information on validation of the processing method**
The validation was carried out with the following devices, materials and chemicals:

| | |
|---|---|
| Washer-disinfector (WD): | Type Miele Disinfector G 7735 CD and 7836 CD<br>Trolley for surgical instruments |
| Alkaline detergent: | neodisher® FA<br>Dr. Weigert GmbH & Co. KG |
| Neutral detergent: | Endozime<br>Ruhof (enzymatic) Decondex 23<br>Neutrazym Borer Switzerland |
| Neutraliser: | neodisher® Z<br>Dr. Weigert GmbH & Co. KG |
| Water gun: | Selecta |
| Cleaning brushes: | With plastic or nylon bristles |
| Ultrasonic bath: | Sonorex |
| Sterilisers: | MMM Vakulab 969 S 3000 MMM Selectomat S 3000 Stiefenhofer KS 666-2ED H+P Varioklav 400E |

**Note:**
The person processing the products is responsible for ensuring that the processing actually performed with the equipment, materials and staff at the reprocessing facility achieves the desired results. Validation and routine monitoring of the process are normally required for this.
If the devices, materials and chemicals described above are not available, it is up to the persons processing the instruments to have their procedures appropriately validated. Please observe the notes and regulations of the relevant national laws and standards. MEDICON eG reserves the right to make changes to these instructions due to new findings.

**11 LIABILITY**
In the event of any discrepancies between the non-German and the German version of these operating instructions, only the German version shall be authoritative. Only the latest revision of the operating instructions applies. Due to constant technical development, the content of these MEDICON operating instructions is updated regularly. MEDICON eG assumes no liability for damage caused by improper use, incorrect postoperative conduct, care or maintenance, or non-compliance with the restrictions on use and other guidelines in the operating instructions. MEDICON eG will accept liability neither for changes or repairs made to the product without the prior written authorisation of MEDICON eG, nor for repairs that were not carried out by workshops authorised by MEDICON eG or the MEDICON Repair Service (MRS).

**12 DESCRIPTION OF SIGNS AND SYMBOLS**

| | |
|---|---|
| | Manufacturer |
| | Manufacturing date |
| LOT | LOT number |
| REF | Item number |
| NON STERILE | Non steril |
| MR | Do not reuse |
| | Warning |
| | Follow Instruction |
| MR | MR unsafe |
| CE 0123 | CE-label |
| Rx only | Prescription only |
| STERILIZE | Do not re-sterilize |

**CAUTION: According to US federal law, in the USA this product may be bought only by a physician or hospital or upon prescription.**