



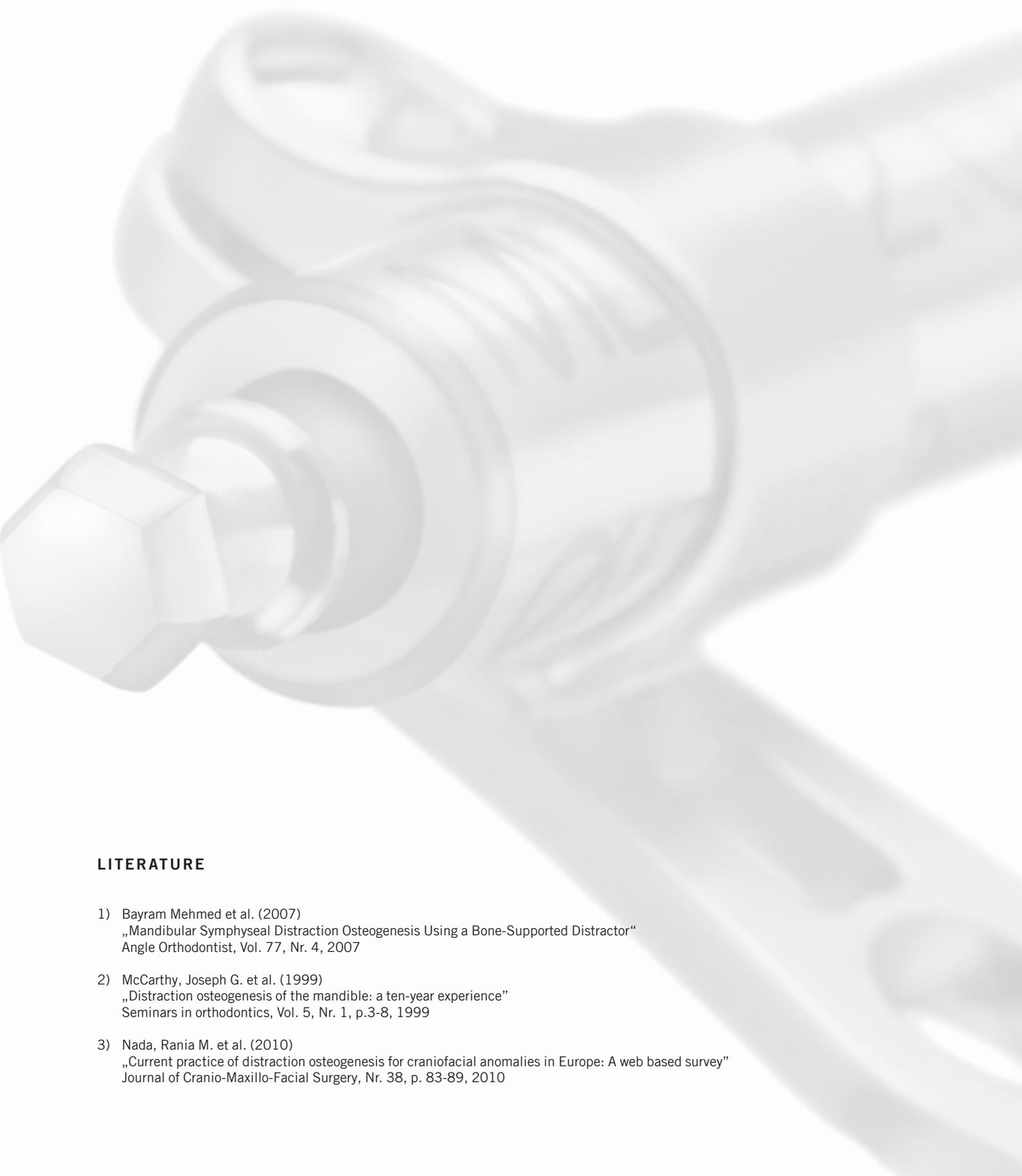
medartis®

PRECISION IN FIXATION

SURGICAL TECHNIQUE – STEP BY STEP

MDO 2.0

MODUS®
Mandible



LITERATURE

- 1) Bayram Mehmed et al. (2007)
„Mandibular Symphyseal Distraction Osteogenesis Using a Bone-Supported Distractor“
Angle Orthodontist, Vol. 77, Nr. 4, 2007
- 2) McCarthy, Joseph G. et al. (1999)
„Distraction osteogenesis of the mandible: a ten-year experience“
Seminars in orthodontics, Vol. 5, Nr. 1, p.3-8, 1999
- 3) Nada, Rania M. et al. (2010)
„Current practice of distraction osteogenesis for craniofacial anomalies in Europe: A web based survey“
Journal of Cranio-Maxillo-Facial Surgery, Nr. 38, p. 83-89, 2010

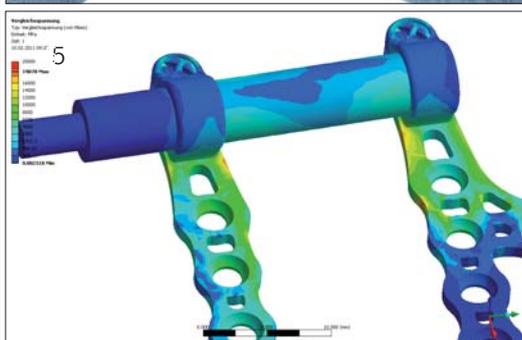
MODUS MDO 2.0

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Features, Technique

Combination is the Solution



- 1 MODUS MDO 2.0 adaption plates in the module
- 2 Detail of adaption plate
- 3 Detail of flexible extension
- 4 Corpus distraction on a bone model
- 5 Finite element analysis of a Medartis distractor

- Easy to handle and assemble
- Unrestricted combination of plates and distraction cylinders
- Integrated capability for extending the distraction distance

SYSTEM BENEFITS

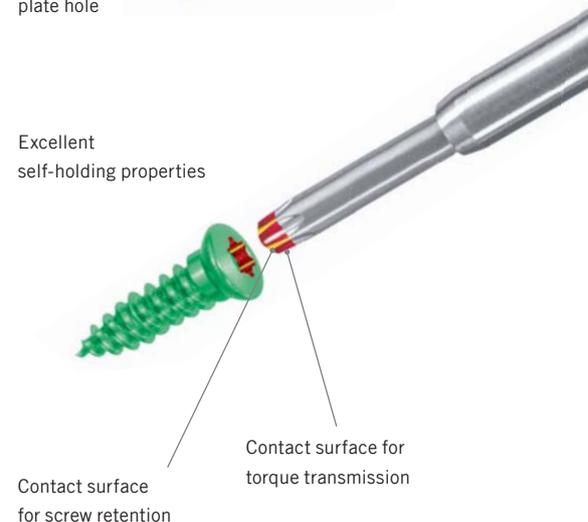
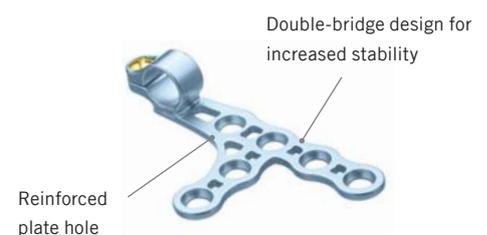
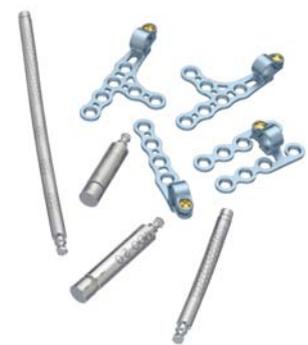
- Both subcutaneous and transmucosal use possible
- Reduced OR time and easy intraoperative handling - only the distraction cylinder (not the fixed plates) has to be removed for the osteotomy
- Large distraction distances possible - once the distraction length for a cylinder has been reached, the cylinder can be reset and distracted once again over its full length
- Easy cylinder activation using rigid or flexible distraction keys

PLATE AND DISTRACTOR CHARACTERISTICS

- Double-bridge design for increased stability
- Optimized bar geometry and plate holes in areas subject to severe stress
- Easy cutting to size using the cutting pliers
- Variety of options to cut to conform to anatomy
- Adaption plates made from semi-rigid pure titanium
- Compact distraction cylinder with coupling for distraction keys
- Flexible and rigid distraction keys available

SCREW FEATURES

- Choice of cross-drive and HexaDrive screws available
- HexaDrive technology– the optimal self-holding mechanism between screw and screwdriver for increased torque transmission
- Outstanding self-tapping characteristics and easy screw insertion thanks to a precise and sharp thread
- Enlarged screw core diameter at the end of the thread for increased shear strength
- Self-drilling SpeedTip screws with cross-drive or HexaDrive screw head design and patented thread for easy insertion with less force required



General Instrument Application

INTRODUCTION

Flexibility and stability for optimal and targeted distraction

Medartis adaption plates and distraction cylinders can be combined and adapted according to the anatomical conditions in order to enable the subcutaneous or transmucosal use of the right elements to achieve the desired distraction.

PRODUCT MATERIALS

All MODUS MDO 2.0 implants are made from pure titanium (ASTM F67, ISO 5832-2) or from titanium alloy (ASTM F136, ISO 5832-3). Distraction cylinders and flexible distraction extensions are made from stainless steel (ASTM F138 and ASTM F139). All of the titanium materials used are biocompatible, corrosion-resistant and non-toxic in a biological environment.

Instruments consist of stainless steel, PEEK or aluminum.

INDICATIONS

The MODUS MDO 2.0 modular distraction osteogenesis system is designed for use in unilateral or bilateral underdevelopment (hypoplasia or dysgnathia) or malformations of the ramus, corpus or whole mandible. This includes congenital and acquired deformities such as:

- Congenital malocclusions or malformations:
 - Marked sagittal malformation of the mandible (mandibular retrognathism)
 - Hemifacial microsomia (Pruzansky-Omens classification)
 - Syndromes involving mandibular hypoplasia, microglossia or micrognathia (Hall classification), particularly Pierre Robin Sequence and Hanhart syndrome
 - Transverse mandibular underdevelopment

- Acquired hypoplasia:
Abnormalities affecting the growth of the ascending ramus as a result of TMJ defects due to:
 - Ankylosis
 - Rheumatic lesions
 - Segmental loss of bone substance after treatment of benign or malignant tumors with healing of bone defects

CONTRAINDICATIONS

- Acute or chronic infections or necrosis of the jaw at or near the implant site (dental infections, osteomyelitis, osteoradionecrosis, bisphosphonate-associated osteonecrosis of the jaw)
- Known allergies and/or hypersensitivity to foreign bodies
- Inadequate bone volume or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- The treatment of at-risk groups (particularly with bone metabolism disorders) is inadvisable

COLOR CODING

System	Color code
MODUS 2.0	blue

Plates and Screws

Special implant plates and screws have their own color.

Blue implant plates: Adaption plates, semi-rigid

Gold implant screws: Cortical screws (fixation)

Green implant screws: SpeedTip screws (self-drilling)

Surgical Technique

Distractor Assembly and Distraction

Note:

The MODUS MDO 2.0 modular distraction osteogenesis system is a temporary implant and must be removed again after bones have healed adequately.

It must be ensured prior to surgery that the desired distraction length is achievable with the selected components and that the selected angle setting can be performed.



SELECTING AND ADAPTING THE DISTRACTION CYLINDER AND ADAPTION PLATES

The MODUS MDO 2.0 system distraction cylinders and adaption plates can be combined for each individual case.



M-4932/M-4934/M-4936
Distraction Cylinder

M-4991/M-4992/M-4993/M-4994
Adaption Plates

Cutting the adaption plates

If required, the adaption plates can be cut with plate cutting pliers M-2170.

It is recommended that this step be performed with the distraction cylinder removed rather than with it in situ. Any burrs must be removed after the straight cutting and before the plate is implanted.



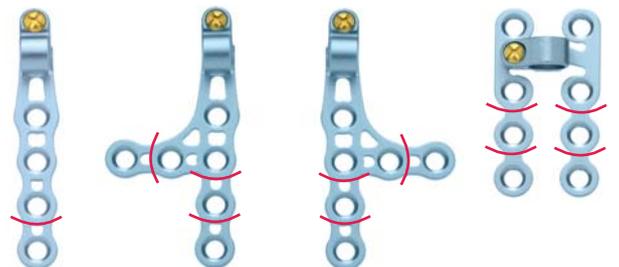
M-2170
0.9-2.0 Plate Cutting Pliers

Note:

The adaption plates may only be cut within the lines marked.

Care must be taken to ensure that at least 3 screws are used for fixation in each case.

Generally the adaption plates must under no circumstances be cut or bent directly at the connection between the bracket and the plate as this will significantly reduce the strength of the bracket-plate connection and may result in intraoperative or postoperative breakage of the connection.



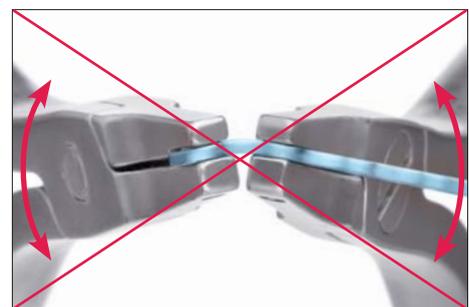
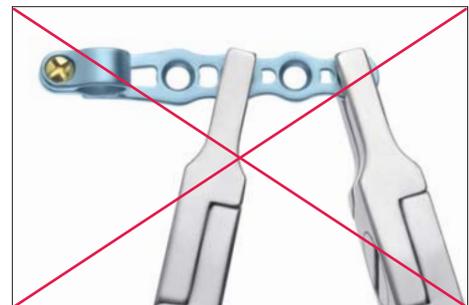
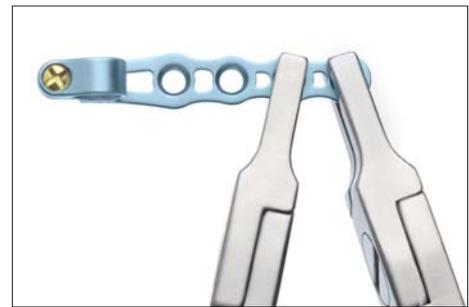
Bending the adaption plates

The adaption plates can be bent using plate bending pliers M-2150. The pin on the pliers fits in the countersink on the adaption plates and protects the plate hole from deformation.



M-2150
0.9-2.0 Plate Bending Pliers, with Vario pin

While bending, the plate must always be held at 2 adjacent holes preventing deformation of the other adjacent holes.



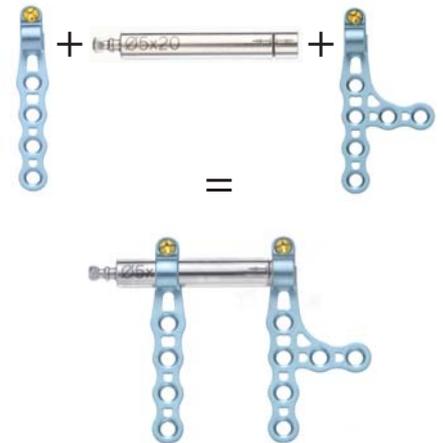
Note:

Repeated bending of the plate in opposite directions may cause the plate to break postoperatively. Always use the provided plate bending pliers to avoid damaging the plate holes.

Damaged plate holes prevent precise seating of the screws in the plate and increase the risk of system failure.

INSTALLING THE DISTRACTION CYLINDERS IN THE ADAPTION PLATES

Place the selected adaption plates (bent and cut to size, if required) on the distraction cylinder prior to fixation on the bone and secure using fixation screwdriver M-2310.

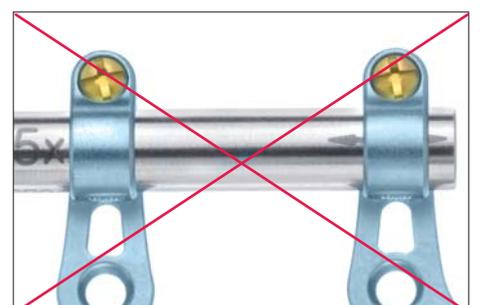


M-2310
MDO fixation screwdriver



Note:

Ensure that the slot on the distraction cylinder is not covered; failure to ensure this will result in the distraction cylinder not opening, making distraction impossible.



FIXATION OF THE PRE-ASSEMBLED SYSTEM

The system can be implanted according to the following procedure:

First, WITHOUT first performing an osteotomy, screw the adaption plates with distraction cylinder installed to the bone using MODUS 2.0 implant screws (self-tapping - M-5240.xx/ M-5140.xx or self-drilling - M-5243.xx / M-5143.xx). During this process, ensure that there are screws in at least three plate holes near to the bracket. The plate hole nearest to the bracket-plate connection should if possible be occupied by a screw.

For submucosal adaption plate placement, the soft tissue pocket must be dissected sufficiently to ensure a tension-free wound closure with the adaption plates completely covered by mucous membrane. A pocket which is too small may make placement of the distraction system more difficult.

Hold the plates/system in place

The assembled plates and cylinder can be positioned on the bone using angled plate holding forceps A-2060.



A-2060

Drilling

If self-tapping cortical screws are used, pre-drilling is necessary. Color coded twist drills are available for every MODUS system size. The twist drills are color-coded blue using a ring system for system size 2.0.



Core hole drills = one/two colored ring(s)

There are two twist drills of different diameters for MODUS MDO 2.0. Medartis recommends the use of a 2.0 drill with one ring (Ø 1.5 mm) up to a maximum screw length of 10 mm, and a 2.0 drill with two rings (Ø 1.6 mm) for screw lengths from 8 - 19 mm.

The adjustable drill guide M-2193 can be used to ensure accurate drilling with long twist drills (M-3203, M-3223, M-3213, M-3243).



M-2193
2.0 drill guide with stop, adjustable

If the anatomical environment is constricted (e.g. intraoral access), 90° screwdriver M-2410 can also be used with twist drill M-3303, Ø 1.5 mm (recommended for drilling behind the bracket).



M-2410
90° screwdriver, without rotation attachment

If intraoral access alone is not sufficient, the MODUS transbuccal set 2.0/2.3/2.5 may be of assistance.



2.0 transbuccal drilling and screwing accessory

Note:

Proper preparation of the screw bed with the twist drill is absolutely essential.

For monocortical fixation, the drilling depth must at least match the screw length. Otherwise, the screw may be overtightened leading the bone thread to strip or causing the screw head to shear off or become damaged.

Depth measuring

The depth gauge M-2250 is used to determine the ideal screw length for use in monocortical or bicortical screw fixation.



M-2250
1.5 - 2.3 Depth Gauge

To measure, place the tip of the depth gauge onto the implant plate or directly onto the bone.



The depth gauge caliper has a hooked tip that is either inserted to the bottom of the hole or is used to catch the far cortex of the bone. When measuring, the caliper stays static, only the slider is adjusted.



A scale on the depth gauge shows the ideal screw length for the measured drill hole.



Screw Pick-Up

Screwdrivers are available for both HexaDrive 6 (M-2113) and cross-drive interface (M-2143 and M-2103) (see p. 15)



M-2113
2.0 screwdriver, self-holding, HD6



M-2143
2.0 screwdriver, self-holding, cross-drive

HexaDrive:

Screwdriver M-2113 features the patented HexaDrive self-holding system for picking up screws for system size 2.0. To remove the screws from the implant container, vertically insert the screwdriver into the screw head of the desired screw. Use axial pressure and gently move the screwdriver handle in circles to ensure that the screw is securely picked up.



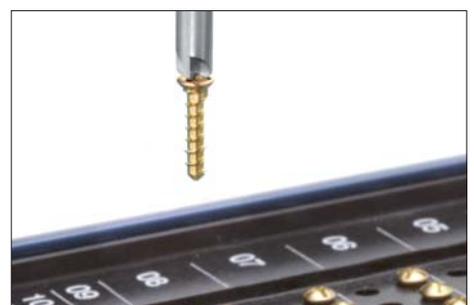
Note:

The screw will not hold without axial pressure!
Vertically extract the screw from the compartment.
The screw is held securely by the blade.
If self-retention between screwdriver and screw cannot be achieved despite being picked up correctly, usually the screw has already been picked up before. This often leads to a permanent deformation of the self-retaining area of the HexaDrive inside the screw head.



Cross-drive with self-holding:

Follow the same procedure as for HexaDrive screws to pick up screws with cross-drive screw head using the self-holding screwdriver M-2143.



Cross-drive with tension sleeve:

To pick up cross-drive screws with screwdriver/tensionsleeve M-2103, proceed as follows:



M-2103
2.0 screwdriver, cross-head with holding device

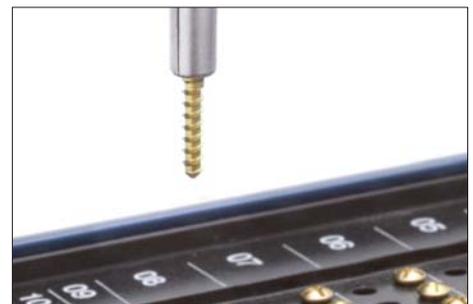
Pull tension sleeve M-2553 towards the grip to expose the tip of the screwdriver blade.



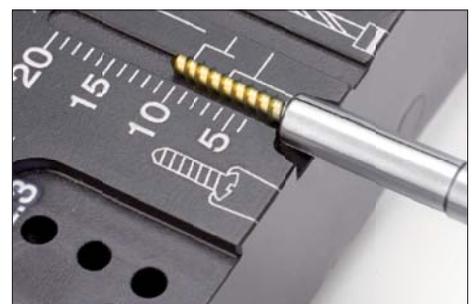
Position the screwdriver blade on the screw and pull the tension sleeve over the screw head.



The screw will be held securely on the blade by the tension sleeve.



The screw length and diameter can be checked on the lower end of the implant container. The screw length is measured to the screw tip.



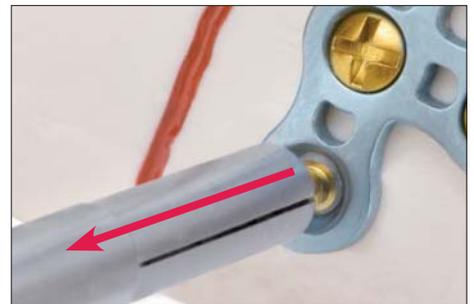
Screw insertion

Screw implant screws in in the direction of the drill hole (coaxially).

At least 3 screws per adaption plate are required for secure fixation.

When inserting cross-drive screws with tension sleeve, proceed as follows:

- Insert screw to about 2 mm before it is completely inserted
- Pull tension sleeve towards the grip to expose the tip of the screwdriver blade
- Insert screw completely

**Note:**

Failure to insert the screws in the same direction as the drill hole, the screw/blade connection may be damaged due to a disproportionate increase of the tightening torque.

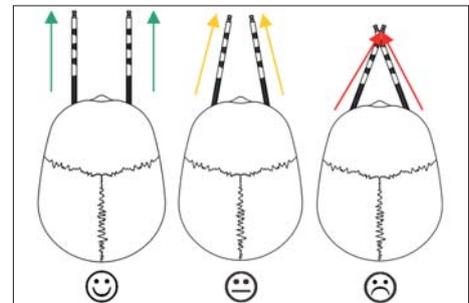
Depending on the clinical situation of the patient, the adaption plates must be fixed to the bone by monocortical or bicortical fixation. Bicortical fixation can be verified by feeling for the point at which the screw tips penetrate through the lingual cortex.

When using self-drilling screws, no predrilling is required. However, if the insertion torque resistance is disproportionately high, appropriate predrilling is always recommended. This makes it easier to screw in the screws, particularly in the case of dense bone.



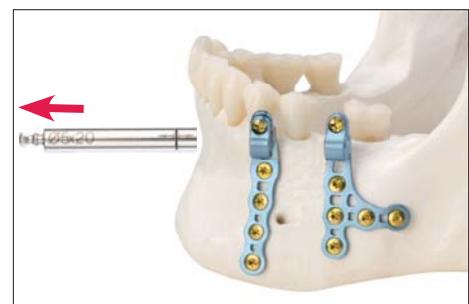
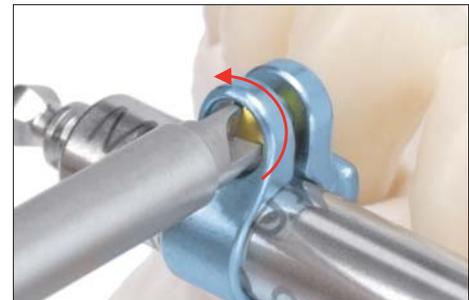
CHECKING THE ASSEMBLY ANGLE

If two distraction cylinders are fixed on both sides of the mandible ensure that the distraction cylinders are aligned parallel to each other. Alignment should ideally be parallel to the sagittal plane. This can be checked visually by placing the flexible extensions (e.g. M-4945) on the distraction cylinders. If the two distraction cylinders are not aligned in parallel in the respective plane, this may result in increased counteracting force between the cylinders and in damage or failure of the system. This will result in failure to achieve the expected distraction outcome.



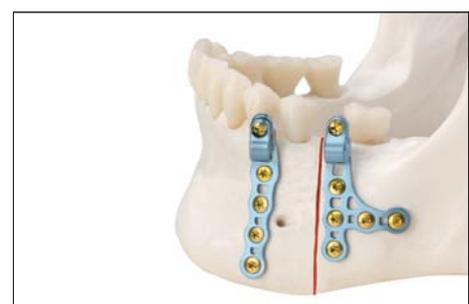
REMOVING THE DISTRACTOR

The distraction cylinder can be removed by loosening the bracket screws using fixation screwdriver M-2310.



PERFORMING AN OSTEOTOMY

Perform the osteotomy between the affixed adaption plates. If desired, the entire system, including distraction cylinders and adaption plates, can be removed from the bone to make it easier to perform the osteotomy. After the osteotomy, re-fix the system in the defined location. After the osteotomy has been performed, the mobility of the bone segments on which the osteotomy was performed must be verified.

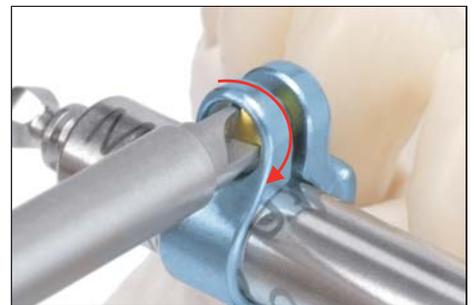
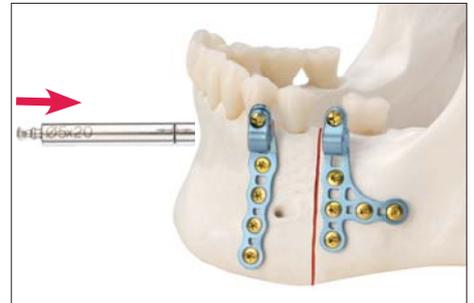


FIXATION OF THE CYLINDER IN POSITION

Reinstall the distraction cylinder in the two brackets on the adaption plates. In doing so, ensure that the slot on the distraction cylinder is not covered. Tighten the locking screws using fixation screwdriver M-2310. Once fixed, the distraction cylinder must not be able to rotate in the brackets.

Note:

In order to ensure the secure fixation of the distraction cylinder in the adaption plates, the bracket screw in the adaption plate must always be tightened using the black fixation screwdriver M-2310.

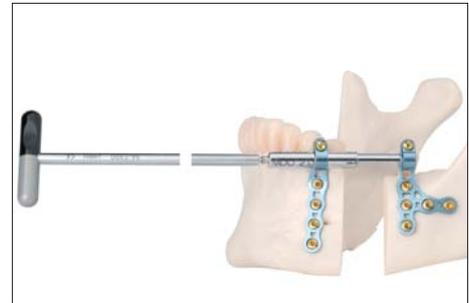


CHECKING DISTRACTOR FUNCTION

Prior to wound closure, an intraoperative check should be performed to verify that the distraction system is functional. If the surrounding soft tissue permits, open the distraction cylinder to the desired distraction length. Once this has been done, close the cylinder again.

Note:

Ensure that no soft tissue or nerves are damaged by extending the cylinder.



The distraction cylinder is activated with distraction key M-2300 or the flexible distraction key M-2330.



To open the distraction cylinder, turn the distraction key in the direction of the arrow, i.e. counterclockwise. One complete turn (360°) corresponds to a distraction length of 0.25 mm. This information can be found on the handle of the distractor key.

Note:

Placing the flexible extension on the patient's lip may result in pressure points. This can be prevented by selecting a shorter distraction extension, the end of which remains in the oral cavity.



General notes:

Medartis does not practice medicine and is therefore unable to make definitive statements regarding the distraction rate and time interval. Various distraction systems currently in use are operated with a distraction rate of 1 mm per day.

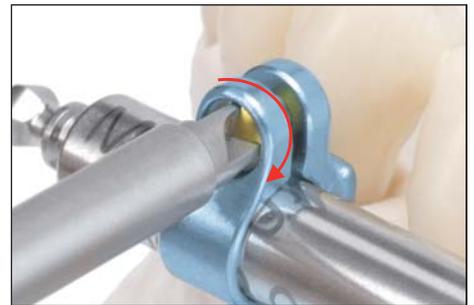
Experience has shown that the distraction rate can vary depending on the specific use between 0.3 mm and 2 mm per day. Only the attending physician can assess the frequency and schedule x-ray checkups.

DISTRACTION PHASE

The images below show one possible distraction process. The distraction phase usually starts 4 - 5 days after implantation of the distractor. (latency phase)

Phase 1

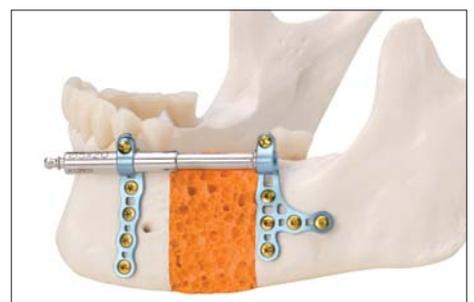
After the distractor has been correctly fixed, the bracket screws are once again tightened using black fixation screwdriver M-2310.



Following activation with a distraction key, the osteotomy gap opens.



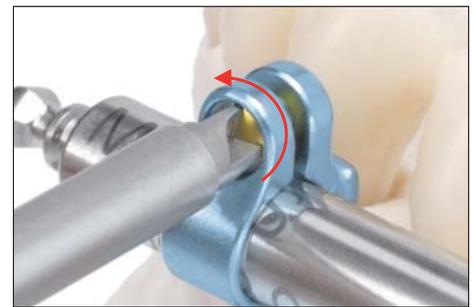
The distraction phase has ended. At most, it corresponds to the length of the fully extended distraction cylinder.



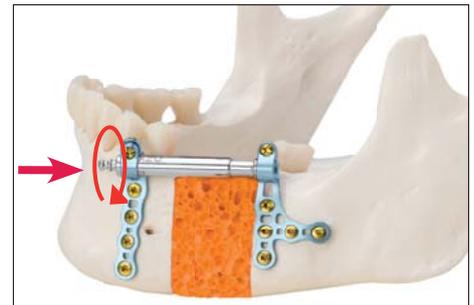
Phase 2

If the distraction length of the selected distraction cylinder is not sufficient, the existing distraction cylinder can be used further as follows without being removed:

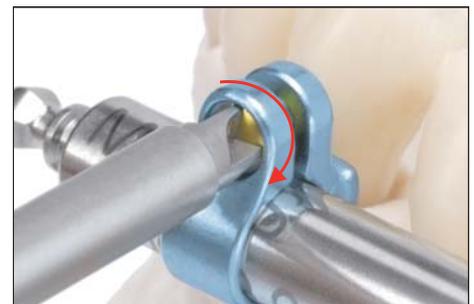
Open the bracket screw on the activation side of the distractor.



Rotate clockwise to turn the distraction cylinder back without changing the osteotomy gap.

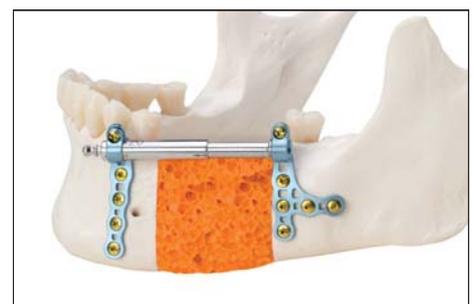


Once the new desired position (e.g. end of the cylinder) has been reached, retighten the bracket screw using the black fixation screwdriver M-2310.

**Note:**

In order to prevent a shift in the gap due to the callus still being soft, it is recommended that intermaxillary fixation (IMF) be performed.

The distraction can be continued by reactivating the distractor with a distractor key.



ATTACHING THE FLEXIBLE EXTENSIONS

Optionally, flexible extensions (M-4942, M-4943, M-4944, M-4945) of various lengths (30 mm, 40 mm, 60 mm and 80 mm) can be attached to the distraction cylinders before or during surgery. This is done by placing the flexible extension axially on the distraction cylinder. As soon as the sleeve on the cylinder clicks into the extension, the rod will remain secure on the cylinder.



Note:

Perform an intraoperative check to verify whether the flexible extension can be rotated without friction after being fixed to the cylinder.

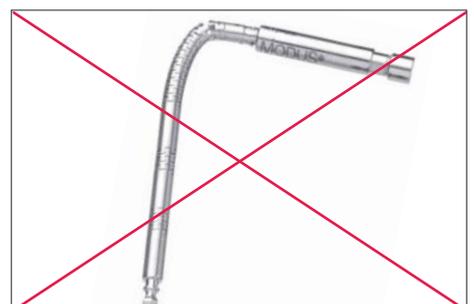
The flexible extension must be positioned in a radius appropriate for the anatomical environment.



Kinks in the flexible extension must be avoided under all circumstances.

Note:

The flexible extensions are intended for single use only.



USING THE DISTRACTION KEY

Once the latency phase is complete, the distraction cylinder can be activated using distraction key M-2300, flexible distraction key M-2330 or distraction key for patients M-2340.

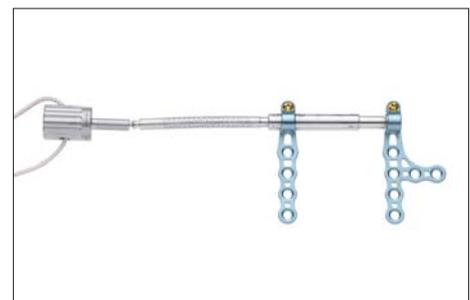
To open the distraction cylinder, turn the distraction key in the direction of the arrow, i.e. counterclockwise. One complete turn (360°) corresponds to a distraction length of 0.25 mm. This information can be found on the handle of the distractor key.

When the distraction cylinder is activated by the patient, the patient is provided with distraction key M-2340 (for patient use). Rigid distraction key M-2300 and flexible distraction key M-2330 are not suitable for patient use.

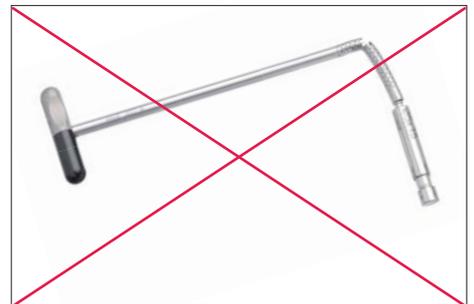
Only the attending physician can decide whether the distraction process can be activated by the patient. However, as the manufacturer, Medartis recommends that activation be performed on an outpatient basis in the presence of the attending physician. The attending physician is also responsible for deciding on the distraction rate and time interval.

Note:

A lanyard should be passed through the hole in patient distraction key M-2340. In this way, the distraction key can be worn around the neck during activation and any risk of choking can be avoided.



The flexible part of flexible distraction key M-2330 must be set up by bending in an appropriate radius. Kinks in the flexible part are not permitted.



REMOVING THE FLEXIBLE EXTENSIONS

Once the distraction phase has been completed, the flexible extension can be removed using pulling-off device M-2320.



M-2320
MDO Pulling-off Device

Pull back the sleeve on the pulling-off device M-2320 and advance it over the ball hexagon on the flexible extension.

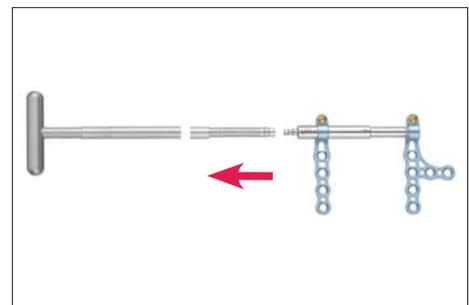


Push the sleeve on the pulling-off device M-2320 axially toward the distractor to prevent the flexible extension from being lost.



The flexible extension can be extracted from the distractor by pulling on pulling-off device M-2320.

It is recommended that the distractor be supported during the pulling-off process to prevent excessive axial pulling force on the distractor and adaption plates.



INSTRUCTIONS FOR REMOVING THE DISTRACTOR AFTER DISTRACTION IS COMPLETE

Before the distractor is removed, there must be a stabilization period (consolidation phase) in order to ensure adequate ossification of the newly formed bone.

As soon as adequate osseous consolidation has occurred in the distraction area, the distractor can be removed.

If the adaption plates and implant screws were placed submucosally, the distractor must be exposed from the intraoral side, after which the bracket screws between the distraction cylinder and adaption plate must be loosened and the cylinder removed. After this, the plates and screws must be removed.

If the adaption plates were affixed transmucosally, the bracket screws between the distraction cylinder and adaption plates must be loosened from the intraoral side and the cylinder then removed. After this has been done, the plates and screws must be exposed from the intraoral side and removed.

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