MONDEAL
MEDICAL SYSTEMS GMBH

Technical Guideline

Technical and clinical information

OMF / Oral Maxillo Facial

Structure technical guideline

Implants	 Screws	 Plates
Instruments	• Screw-receiving and fixation • Drilling • Measuring	• Plate-receiving and positioning • Bending, Outlining • Cutting
Containers	 Trays for: • Implants • Instruments	

MONDE | *mandible*

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Overview

MONDE | *mandible*

The modular Mandible System Cluster consisting of three systems, has been especially designed for the reconstruction of the mandible, trauma applications and fractures. Thus, it covers the entire spectrum of all common indications for the lower jaw area:

- Trauma / Polytrauma
- Reconstruction of the mandible
- Tumor surgery
- Fractures of the mandible

MPS (Mandibular Polyvalent System)

The 'Mandibular Polyvalent System' provides a complete selection of plates and screws for both, trauma applications, as well as the reconstruction of the mandible. The modular concept makes it the system of choice for trauma and poly-trauma indications, as well as for the mandibular reconstruction with vascularized bone grafts in the tumor surgery.

BMR (Bendable Mandibular Reconstruction System)

The titanium mandibular reconstruction system is not only suitable for the use of both, primary and secondary bridging indications, but also for the anatomical position fixing or as internal fixation.

FRACTURE System

The fracture implant system ensures a solid fixation in many types of fractures of the mandible. The plates with options of compression allow a safe and easy stabilization of the jaw.

Implants | *Screws*

Features & Advantages

Screw head-design „self-retaining"

- Safe self-retaining mechanism of screw and screwdriver blade
- Easy and simple removal of screw
- Different connection types:
  - CF (CROSS-FIT)
  - MCD (Mondeal Contour Drive)

Screw thread „self-tapping"

- Optimal self-tapping ability thanks to sharp and precise thread
- Stable fixation in the bone

Screw tip „atraumatic"

- Atraumatic screw tip avoids impairments and irritations of the soft tissue
- Gently for patient

Overview Screws

Screw Ø (in mm)	2.0	2.3	2.7	3.0
MPS locking & non locking (Lengths in mm)	✪ ✚ (6/8/10/12/14/16/18)	✪ ✚ (6/8/10/12/14/16/18)	✪ ✚ (8/10/12/14/16/18)	✪ ✚ *EM* (8/12/16)
BMR locking & non locking (Lengths in mm)	✪ ✚ (6/8/10/12/14/16/18)		✪ ✚ (8/10/12/14/16/18)	✪ ✚ *EM* (8/12/16)
FRACTURE non locking (Lengths in mm)		✪ ✚ (6/8/10/12/14/16/18)	✪ ✚ *EM* (8/12/16)	

Length
Ø

Screw head:
✪ MCD
✚ CF

EM Emergency Screw (only non locking)

Implants | *Screws*

Features & Advantages

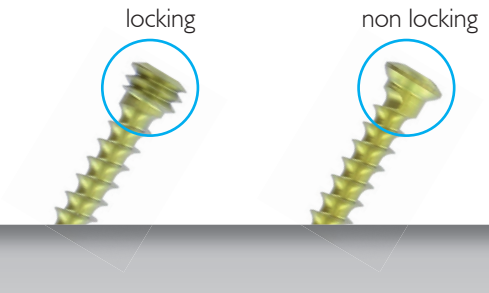
Notes for fixed-angularity

Having a fixed-angle (locking) screw, mind that during pre-drilling there is a drill sleeve screwed into the thread of the plate, which specifies the direction of drilling and also the desired position of the screw in the bone. This position is secured by screwing the external thread of the screw head with the internal thread of the hole of the plate – the basis of an locking system.

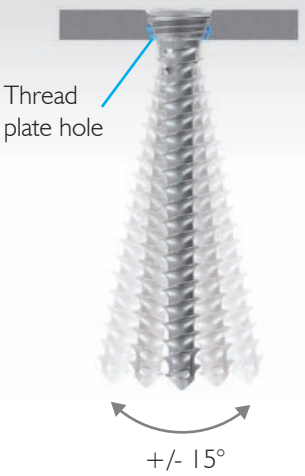
The screw head lines up precisely with the plate and gives a form that cannot be found in conventional non-locking screws- and plating-systems with regard to its stability. Thanks to the reduced contact area between plate and bone, the power transmission also is a positive result of this method because the plate is not pressed on the bone but only in contact with it since the fixation of the screw takes place in the internal thread of the plate. This method in turn is less suitable when the screw shall be used as compression screw to bring up a bone fragment to the plate. In this case, our non-locking system can be used.

Screw head-design "locking"

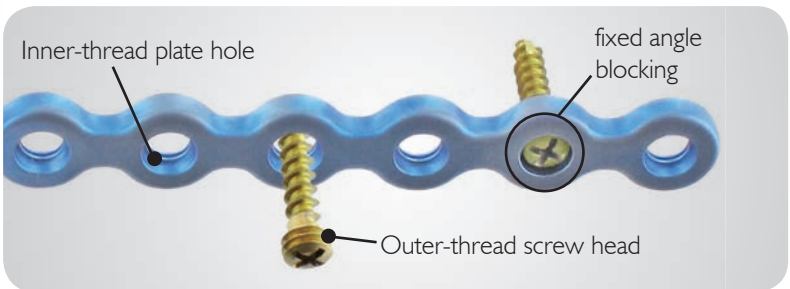
- 2 different screw head types:
  - locking (fixed angle), with external thread on the screw head
  - non locking, without threaded screw head



Polyaxial blocking technology



- Polyaxial (+/- 15°) and locking (fixed angle) blocking
- High stability due to guying of the screw head in the plate area
- The blocking technology promotes an angularly stable junction between the screw with external thread and the internal thread of the plate hole (only with MPS and BMR).

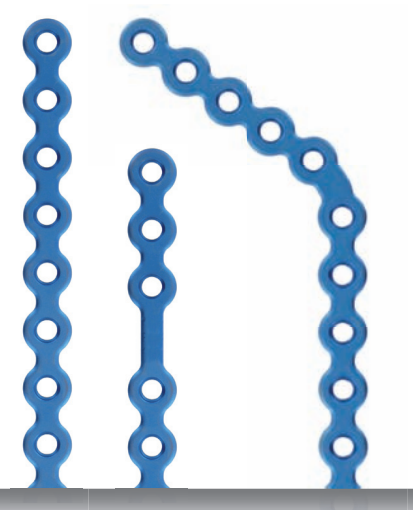


Implants | Plates

MPS

All plates have an internal thread in the plate holes to allow and achieve a poliaxial blocking with a locking screw.

Thickness: 1.5 mm



Plates straight with / without bar

Plates angled right / left

Thickness: 2.0 mm

Plates straight without bar

Plates angled right / left

Thickness: 2.5 mm

Plates straight without bar

Plates angled right / left

Various screw diameters could be used for one plate:

For MPS: Ø 2.0 mm, Ø 2.3 mm, Ø 2.7 mm

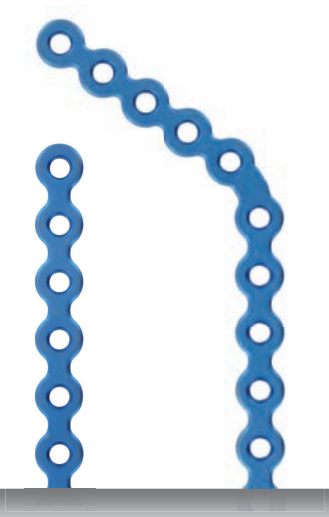
For BMR: Ø 2.0 mm, Ø 2.7 mm

Implants | Plates

BMR

All plates have an internal thread in the plate holes to allow and achieve a poliaxial blocking with a locking screw.

Thickness: 2.8 mm



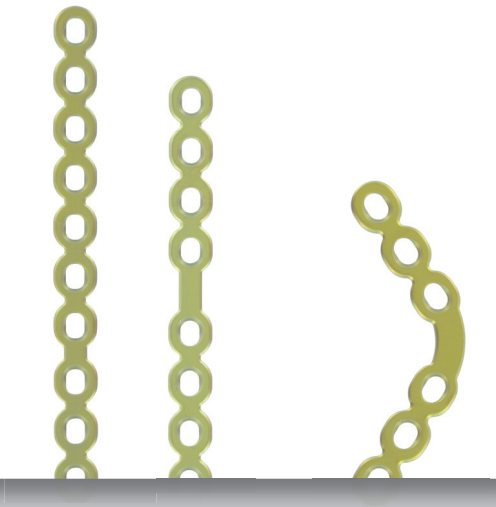
Plates straight without bar

Plates angled right / left

FRACTURE

By screwing and tightening of a non locking screw in an oval compression hole, an active compression of various bone segments within the longitudinal axis of the compression hole is possible.

Thickness: 1.5 mm



Plates straight with / without bar Compression

Plates angled Compression

Benefits of titanium for implants

In general, pure titanium (DIN EN ISO 5832-2/ASTM F67) is used for the manufacturing of bone plates while the titanium alloy (DIN EN ISO 5832-2/ASTM F136) is used for the manufacturing of bone screws.
Worldwide, these materials are used for short and long-term implants in the osteosynthesis for decades.

For the following reasons:

- Completely biocompatible
- Corrosion-resistant
- Non-toxic in the biological environment
- Failure-free imaging with X-rays, computed tomography (CT) and magnetic resonance imaging (MRI)

Clinical Cases | BMR

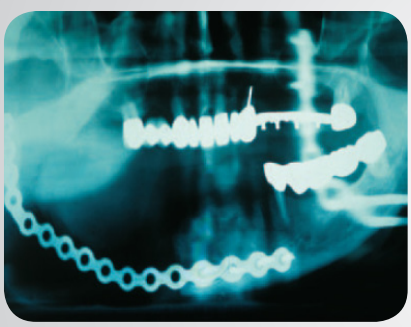
Clinical Case I

Mandibular defect of the right horizontal ramus after tumor resection and reconstruction with a BMR plate.

Same patients detailed view of the proximal mandibular segment with four self-tapping 2.7 mm screws.

Same patients detailed view of the distal mandibular segment with three self-tapping 2.7 mm screws.

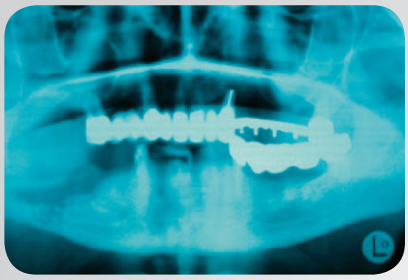
Clinical Case 2



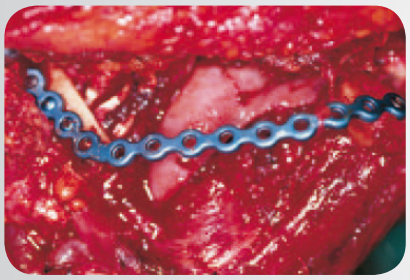
Operation site (x-ray) of a patient primary reconstructed with a BMR plate after tumor resection of the right mandible. An adapted BMR plate was fixed and temporarily removed in order to perform the mandibular resection followed by the final plate fixation for the stable alloplastic reconstruction of the mandible. If possible the BMR plate is then envelopped with pedicled neck muscle. After 2 years without recurrences the mandiblur replacement osteoplasty can be carried out with an autologous bone graft from the illiac crest. If the BMR plate is completely integrated without irritation and all screws are stable inside the bone, the autologous illiac crest graft can be fixed during the approximate four months healing period with the same MONDEAL BMR plate using the 2.0 mm purple color coded transplant screws for bone graft fixation.

Clinical Cases | BMR

Clinical Case 3



Pre-operative x-ray picture of a patient with an extended bone destruction of the right mandible due to a histologicaly secured squamous carcinoma of the right alveolar crest mucosa.



Same patient, reconstructed mandible using a BMR plate after complete tumor resection including resection of the processus muscularis, horizontal and ascending ramus.

X-ray picture of the same patient after primary alloplastic reconstruction of the mandible with a BMR plate. The picture shows a symmetric reconstruction of the extended mandibular defect.

Mandibular Reconstruction Mesh (acc.to Prof. Dr. Dr. Dumbach)

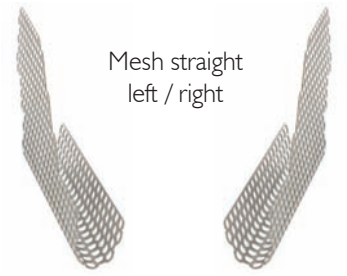
In general, the titanium mesh is suitable for both, primary and secondary osseous reconstruction of any mandibular defect including the temporomandibular joint. It has proven exceptionally good in problem cases with weakened graft sites, after inflammations and radiotherapy, as well as after a failed reconstruction.[I]

Advantages:

- The insertion of enossal implants in the reconstructed mandible is usually possible without any problems due to the particularly favorable quality and quantity of bone.
- The handling of the operational technique is easy. It offers a high certainty of success, hence a smooth and easily follow-up treatment.[II]
- The pre-formed and easily deformable metal mesh allows – regardless to the size and location of the defect – a correct axial, symmetrical and aesthetically impeccable recovery of the mandibular outline; including the problem areas of the chin and jaw angles.[II]
- Despite sufficient stability, a favorable influence of functional stimuli in mandibular movements of the bone grafts is possible. Additionally, the insertion and reconstruction process much faster.[II]
- The duration of the intermaxillary fixation can be substantially reduced; in many cases completely waived.[II]
- A leaving of the mesh in the organism on a permanent basis is possible without compunction in most cases.[II]

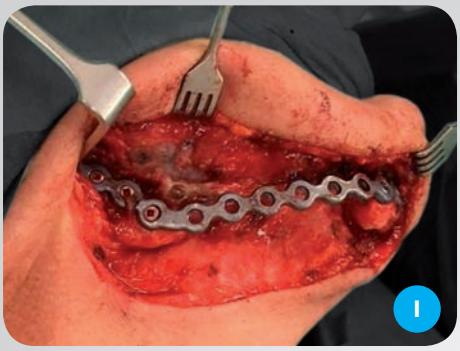
Literature: Dumbach, Josef: Unterkieferrekonstruktion mit Titangitter, autogener Spongiosa und Hydroxylapatit : biomechan., tierexperimentell-histolog. u. klin. Unters. / Josef Dumbach. - München ; Wien : Hanser, 1987. ISBN 3-446-14941-4
I - 6.1: Indikationen zur Verwendung des Titan-Mesh-Systems, S. 66f
II - 6.5: Vor- und Nachteile des Titan-Mesh-Systems, S. 78f

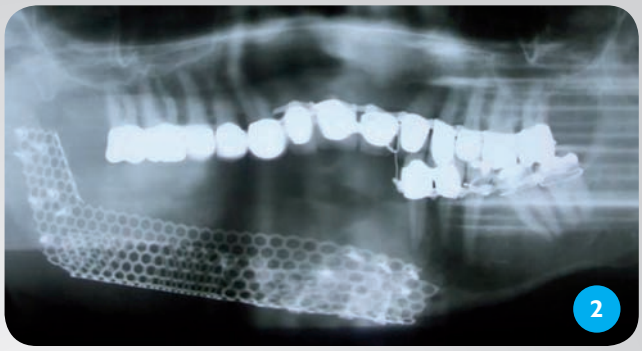
Mandibular Reconstruction Mesh (acc.to Prof. Dr. Dr. Dumbach)



Please use for fixation the screws with 2.0 mm diameter of the BMR System!

Clinical Case





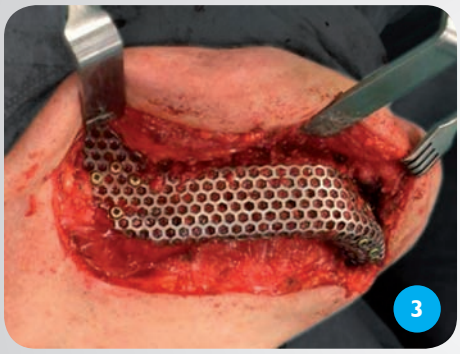


Illustration 1:
Situation after partial resection of the mandible, right side and temporary reconstruction with a bridging plate.

Illustration 2:
Mandibular reconstruction with a MONDEAL titanium mesh and autogenous cancellous bone from the illiac crest.

Illustration 3:
Surgical site after mesh fixation, using mini-screws and filling up with spongiosa.

Illustration 4:
Complete bone regeneration. Situation 2 months after removal of the mesh.

Surgeon:
Dr. Dr. Herbert Rodemer
Leitender Oberarzt der Klinik für Mund-, Kiefer- und Gesichtschirurgie, Klinikum Saarbrücken

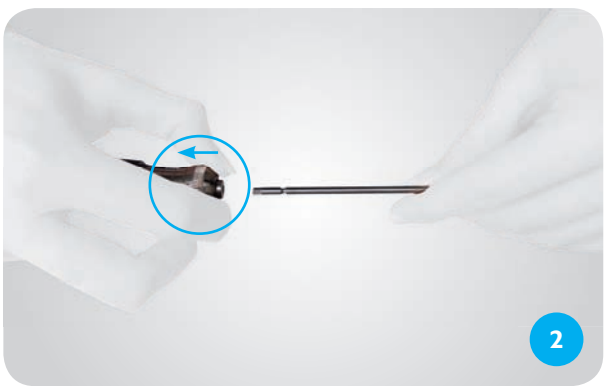
Instruments for screws | **Screw-receiving and fixation**

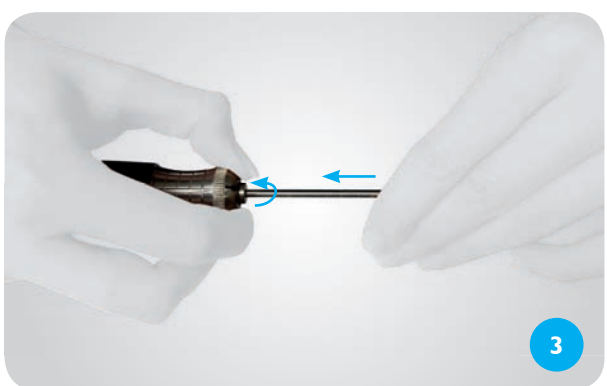
Screwdriver handlle
Length 9.5 cm
(for replaceable blades)

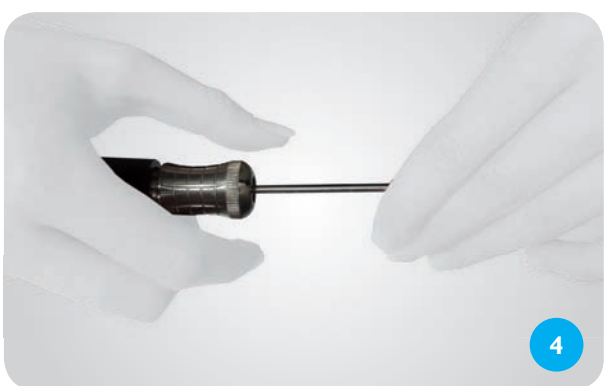
Blade, self-retaining

MCD CF

Assembly of blade (self-retaining) and screwdriver handle

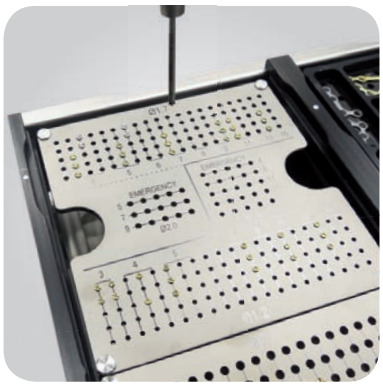


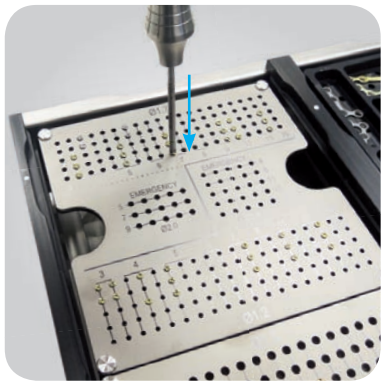


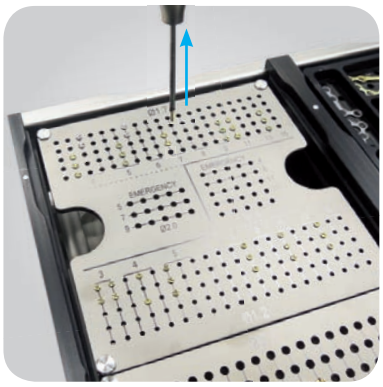


Instruments for screws | **Screw-receiving and fixation**

Screw-receiving out of the tray with self-retaining blade







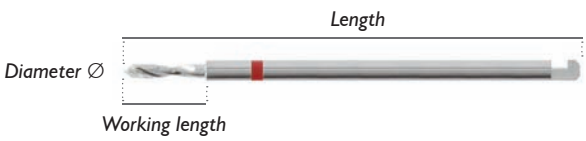
Insert screwdriver blade into the screw head and press firmly. Remove the screw vertically.

Note from General IFU: *Connection screwdriver and screw head*

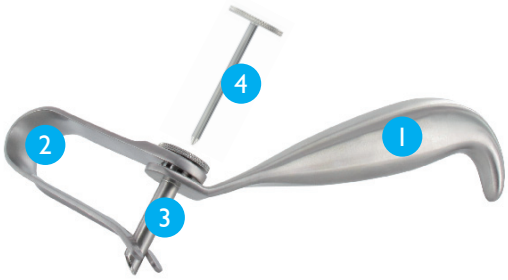
- *It is essential to ensure that the screwdriver/screw head connection is aligned exactly in the vertical direction; otherwise, there is an increased risk of mechanical damage to the implant or the screwdriver.*
- *When engaging the bone screw, axial pressure of the screwdriver into the screw head must be adequately applied to ensure that the blade is fully inserted into the screw head. This results in axial alignment and full contact between screwdriver and screw.*

Instruments for screws | **Drilling**

	Drill for screws	Color code	Diam. x Length	Working length	Connection
MPS BMR	2.0		1.5 x 50 mm	22 mm	Stryker
			1.5 x 105 mm	22 mm	Stryker
MPS FRACTURE	2.3		1.9 x 80 mm	22 mm	Stryker
			1.9 x 105 mm	22 mm	Stryker
MPS BMR	2.7		2.1 x 80 mm	22 mm	Stryker
			2.1 x 105 mm	22 mm	Stryker



Instruments for screws | **Drilling**



Transbuccal trocar and drill guide,
consisting of:

1. Handle
2. Cheek retractor
3. Drill guide
4. Trocar

The transbuccal trocar and drill guide is used for an extraoral access when having tight spaces.

Notes from General IFU: *Drills*

- *Small Drills are recommended for single use only. Damage is difficult to detect due to the small dimensions.*
- *Drills are provided with depth stops to prevent accidental penetration beyond the targeted bone.*
- *A drilling speed of 500-800 rpm must be maintained to avoid overheating and bone necrosis. When using high speed power sources, the user must verify with the manufacturer a setting that corresponds to a maximum speed of 800 rpm.*
- *When using twist drills, it is essential to provide adequate cooling by means of copious normal saline irrigation (NaCl) to minimize thermal damage to the bone tissue. The combination of cooling and low speed (<800 rpm) significantly contribute to the reduction of screw loosening due to bone de-mineralization.*
- *Twist drills are developed and indicated for work at low speeds (<800 rpm). Higher rates of rotations may result in failure of the drill and potential injury to the user, patient or third parties.*
- *Axial guidance of the drill considerably reduces the risk of breakage and wear.*
- *Always use the shortest drill possible given the clinical indication. Longer drills are naturally susceptible to more eccentric rotation, especially when operated in air, free of resistance.*
- *The user must verify the compatibility of the drill with the attachment hand piece. In addition, regular maintenance and inspection of the hand piece are essential to prevent damage to the drill.*

Instruments for screws | **Drilling**

Drilling guide for compression plates in the FRACTURE system, consisting of:

- Handle
- Drill guide eccentric / centric

This symbol identifies the eccentric drilling side for receiving the drilling boring bush.
--> **Only for compression plates of the FRACTURE system.**

The two wavy lines represent the fracture line. If you would like to get an eccentric bore for a compression hole, the arrow on the head of the boring bush has to point in the direction of the fracture line.
However, should you like to get a centric bore for a compression hole, the arrow on the head of the boring brush has to point in the opposite direction away from the fracture line.

This symbol identifies the centric drilling side.
--> This is not relevant for the FRACTURE system.

Notes from General IFU: *Drill guides*

Centric and eccentric drill guides (in conjunction with compression plates) ensure a low-strain seat of the bone screw in the bone plate and thus, make maximum axial compression possible (for compression techniques).

Instruments for screws | **Measuring**

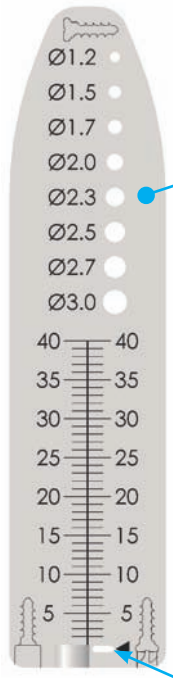
Depth measuring gauge (Measuring range 0 - 50 mm)

Notes from General IFU: *Depth measuring gauges*

- *A depth gauge can be used to measure the depth of the hole drilled to determine the length of the bone screw to be inserted.*
- *If not otherwise expressly specified, the screw length is measured by the plate hole (i.e. applied plate).*
- *The value displayed on the scale of the depth gauge corresponds to the entire length of the bone screw.*
- *The length specified on the packaging label is the entire length of the bone screw. The screw measuring scale of the implant tray is laid out on the entire length.*
- *If the depth gauge has an angled probe on the end of the sensor, the surface facing the body of the instrument is the measuring point and not the surface facing away from the body.*
- *Factors such as profile height, screw seat in the hole of the bone plate, etc. have been taken into account in the depth gauges according to the product system.*

Instruments for screws | **Measuring**

Screws measuring plate

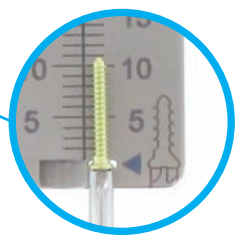


Screw diameter

The scale on the left side is not relevant for the MONDE|***mandible***.

The scale on the right side measures the **length of the screw** if the screw is fixed on a self-retaining blade.

Blade, self-retaining



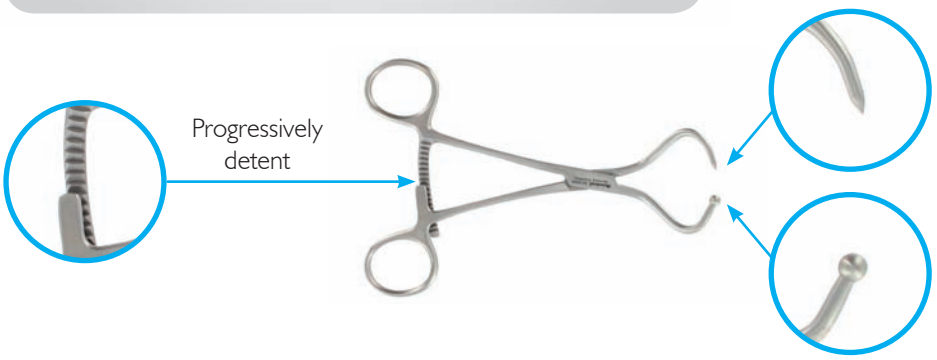
For exact measurement, the screw has to be positioned with the screw head laterally aligned in the fitting slot.

Notes from General IFU: *Measuring plates*

- *Measuring plates and screw measuring scales in trays are only intended for rough determination of screws in length and diameter. For diameter drilling jigs on the measuring plates, the screw must be carefully positioned and pulled out again to avoid jamming or stripping of the screw. When used improperly, particles of material could be transferred from the gauge to the screw.*

Instruments for plates | **Plate-receiving and positioning**

The **plate holding forceps** is available in two varieties for the right and the left side. It supports in placing and positioning of the mandible plates to fix the screws.



Instruments for plates | **Cutting**

Plate cutters

Instruments for plates | **Bending and outlining**

Plate bending pliers with rolls

For precise **horizontal bending** of the plate and exact adaption to the individual jaw shape.
(for BMR and MPS)

Plate bending tool with lock

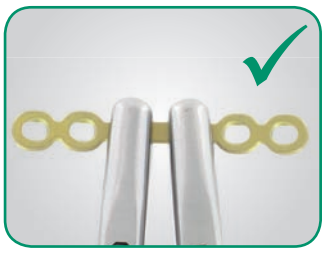
Plate bending tool without lock

Plate bending tool

For **vertical bending** and twisting of the plate. In general, the plate bending tool is used by pairs. The lock serves as fixation of the blade in the device when bending.
(for BMR)

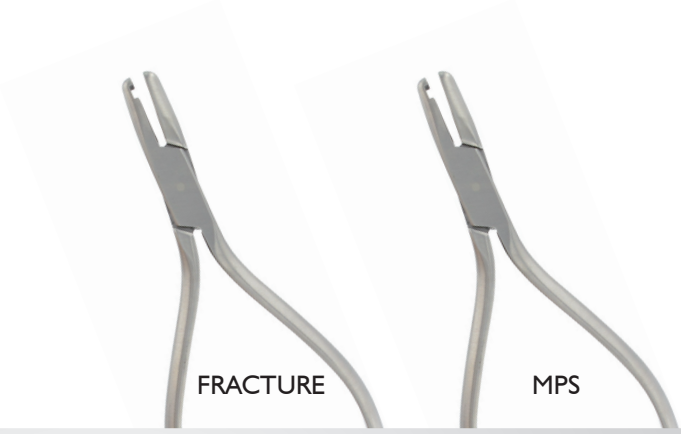
Instruments for plates | **Bending and outlining**

During bending, the plate should be hold on two consecutive plate holes so that the shape of the intermediate plate hole does not get damaged.



It should be avoided to bend the plate by alternating movements. The plate should be bend to the maximum extent of both jaw parts of the bending pliers contact each other.

Plate bending pliers



Notes from General IFU: *Bending instruments*

- *Bone plates can be easily, quickly and precisely adjusted to any possible surface using bending instruments.*
- *The cold process during the bending procedure increases the hardness of the titanium and decreases its flexibility. Therefore, it is essential that the required form of the implant be achieved with as few bending maneuvers as possible. Excessive bending can cause the plate to break postoperatively. The convergence of extreme angles and small bending radii must be avoided due to the risk of damage to the implant (cracks, deformed screw holes, etc.) detectable postoperatively on a microscopic level. In these cases, the implant must be replaced by a new implant bent with greater care.*
- *Deformed screw holes mean not only an increased risk of breakage of the implant in this area, but also mean complications in the precision placement of the screw head.*

Containers

Das MONDE|*mandible* modular design principle provides the user a variety of configuration options for an individual combination of screws, plates and instruments. This advantage is also reflected in the modular container system. The container components are arranged and combined depending on the user's preferences and the selection of the individual elements.

Containers


Trays with inlays for implants (screws and plates) and for small instruments (drills, blades etc.)
Basket for instruments
Sterilisation container

MONDE | *mandible*

High Quality Implants

Made by MONDEAL

MONDEAL
MEDICAL SYSTEMS GMBH

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