

medartis

PRECISION IN FIXATION

SURGICAL TECHNIQUE – STEP BY STEP

# MODUS® 2 Mandible



# MODUS®

# Contents

3	Introduction
3	Product Materials
3	Indications
3	Contraindications
3	Color Coding
4	Possible Combination of Plates and Screws
4	Symbols
5	System Overview
7	Treatment Options
7	Condyle Fractures
8	Body Fractures
9	Ramus and Angle Fractures
10	Atrophic Mandible Fractures
11	HCL Defect Classification
12	Reconstruction
13	Bridging of a Bone Defect
14	Instrument Application
14	General Instrument Application
14	Picking up the Plates
15	Cutting the Plates
18	Bending the Plates
22	Drilling
23	Drilling with Drill Guide
24	Assigning the Screw Length
25	Screw Pick-Up
27	Specific Instrument Application
27	Bending of TriLock Bridging Plates
33	Surgical Techniques
33	General Surgical Techniques
33	Lag Screw Technique
34	Specific Surgical Techniques
34	Temporary Condylar Head Prosthesis
41	Assembly of the C-Adaption for Bridging Plates
43	Use of the Temporary Locking Stopper for TriLock Screws
45	Follow-Up Care and Explantation
45	Follow-Up Care for MODUS 2 Mandible Implants
45	Explantation of MODUS 2 Mandible Implants
46	TriLock Locking Technology
46	Correct Application of the TriLock Locking Technology
47	Correct Locking ( $\pm 15^\circ$ ) of the TriLock Screws in the Plate
48	Appendix
48	Implants and Instruments

For further information regarding the MODUS 2 product line, please visit [www.medartis.com](http://www.medartis.com).

# Introduction

## Product Materials

All MODUS 2 implants are made of pure titanium (ASTM F67, ISO 5832-2) or titanium alloy (ASTM F136, ISO 5832-3). All titanium materials used are biocompatible, corrosion-resistant and non-toxic in a biological environment. The instruments are made of stainless steel, PEEK, aluminum or titanium.

## Indications

MODUS 2 Mandible is indicated for mandibular trauma repair, fixation of mandibular osteotomies, reconstructive procedures and bridging of load-bearing bone segments in the mandible.

## Contraindications

- Pre-existing or suspected infection at or near the implantation site
- Known allergies and/or hypersensitivity to implant materials
- Inferior or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- Blocking of cranial sutures/growth plates with plates and screws
- Not intended for use in direct contact with the dura mater and the central nervous system
- The IMF screws cannot be used in unstable fractures

## Color Coding

### Screw Diameter

2.0  
2.3  
2.5

### Color Code

Blue  
Brown  
Purple

### Plates and Screws

Implant plates gold  
Implant plates blue  
Implant plates silver  
Implant screws gold  
Implant screws silver  
Implant screws green

Rigid fixation plates  
Semi-rigid fixation plates\*  
TriLock plates (locking)  
Cortical screws (fixation)  
TriLock screws (locking)  
SpeedTip screws (self-drilling)  
TriLock SpeedTip screws (locking and self-drilling)

\*Semi-rigid is easier to form than rigid materials with the same plate geometry.

## Possible Combination of Plates and Screws

Screws and plates can be combined as follows:

<b>Plates</b>	<b>Screws</b>
Fixation Plates	2.0 Cortical Screws, HexaDrive 6 2.0 SpeedTip Screws, HexaDrive 6 2.3 Cortical Screws, HexaDrive 6
TriLock Plates	2.0 TriLock Screws, HexaDrive 6 2.0 Cortical Screws, HexaDrive 6 2.0 TriLock SpeedTip Screws, HexaDrive 6 2.0 SpeedTip Screws, HexaDrive 6 2.3 TriLock Screws, HexaDrive 6 2.3 Cortical Screws, HexaDrive 6 2.5 TriLock Screws, HexaDrive 6

### Caution

For bridging of bone defects, 2.5 TriLock screws have to be used in order to provide appropriate stability of the load-bearing screw-plate construct.

## Symbols



HexaDrive

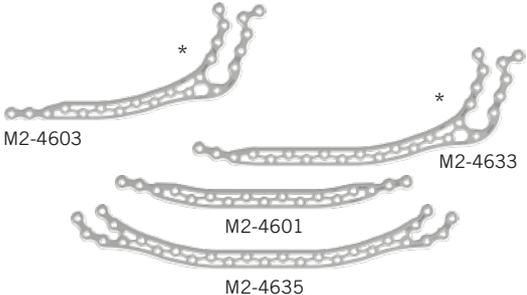
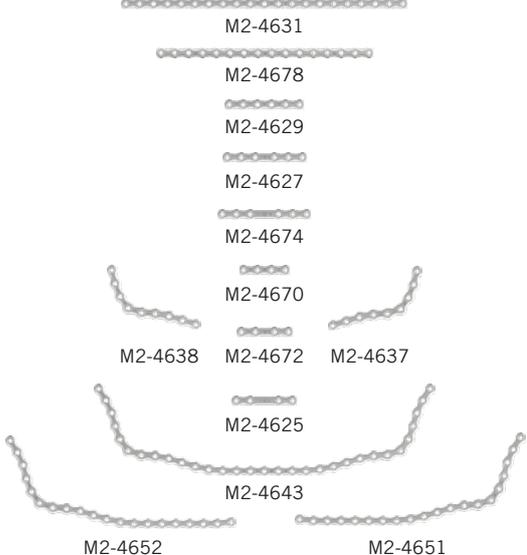
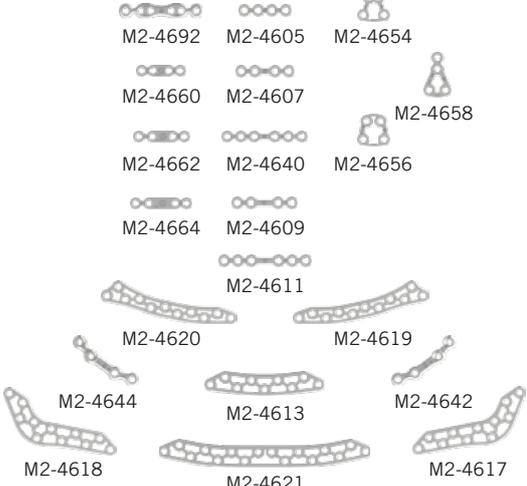


SpeedTip



# System Overview

The implant plates from MODUS 2 Mandible are available in the following designs.

Description	Examples	Plate Thickness	Rigidity
TriLock Bridging Plates*		2.0 mm	
TriLock Plates		1.5 mm	Semi-Rigid
TriLock Plates		1.3 mm	

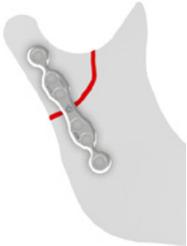
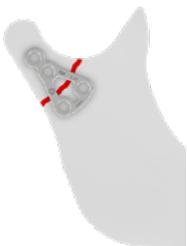
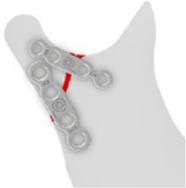
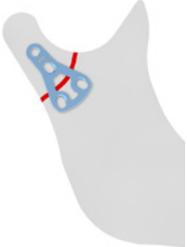
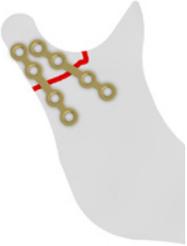
\* TriLock bridging plates M2-4603 and M2-4633 have double-sided TriLock screw holes and can therefore be used for the left and right side.

Description	Examples	Plate Thickness	Rigidity
<p>Fixation Plates</p>		<p>1.0 mm</p>	

# Treatment Options

The following is an overview of typical clinical findings that can be treated with MODUS 2 Mandible implants.

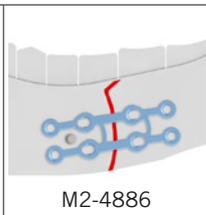
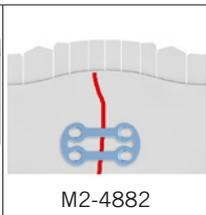
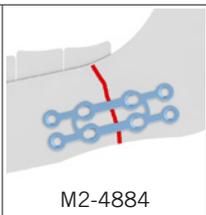
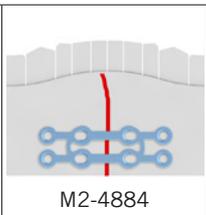
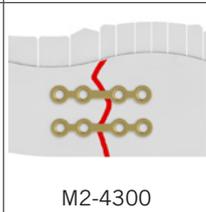
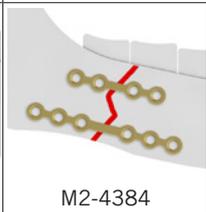
## Condyle Fractures

<p><b>TriLock Condyle Plate</b></p> <p>Plate thickness: 1.5 mm Semi-rigid</p>	 <p>M2-4692</p>				
<p><b>TriLock Condyle Plates</b></p> <p>Plate thickness: 1.3 mm Semi-rigid</p>	 <p>M2-4658</p>	 <p>M2-4654</p>	 <p>M2-4656</p>	 <p>M2-4660 M2-4662 M2-4664</p>	
<p><b>Condyle Plates</b></p> <p>Plate thickness: 1.0 mm Semi-rigid</p>	 <p>M2-4894</p>	 <p>M2-4852</p>	 <p>M2-4854</p>		
<p><b>Mandible Plates, Straight</b></p> <p>Plate thickness: 1.0 mm Rigid</p>	 <p>M2-4300</p>				

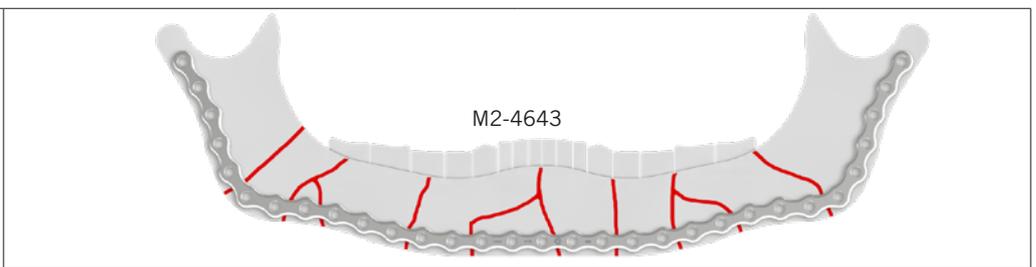
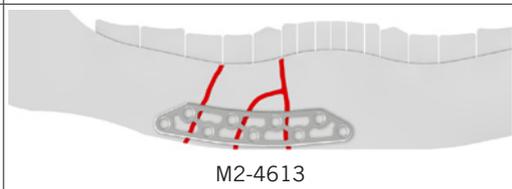
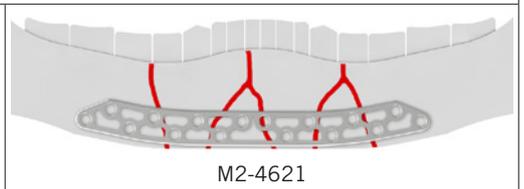
The information provided above is a recommendation only. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case.

# Body Fractures

## Simple Fractures

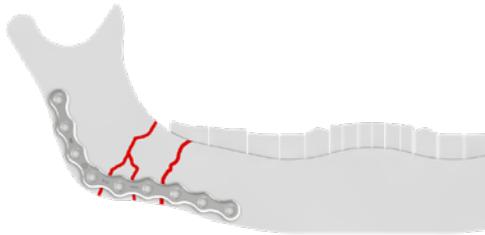
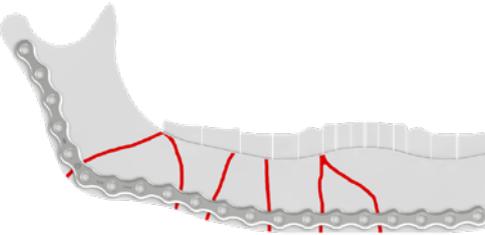
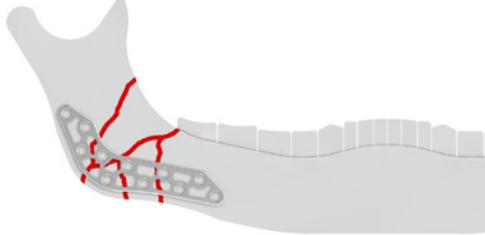
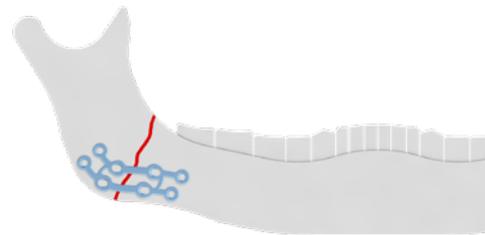
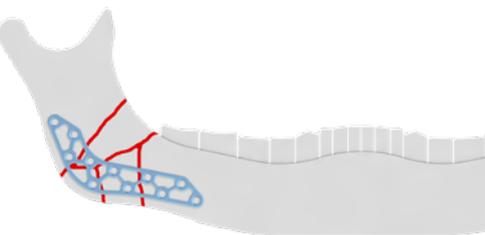
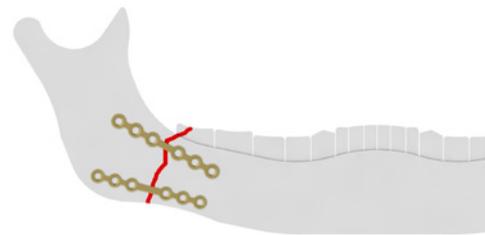
<p><b>Grid Compression Plates</b></p> <p>Plate thickness: 1.0 mm Semi-rigid</p>	 <p>M2-4886</p>	 <p>M2-4882</p>	 <p>M2-4884</p>	 <p>M2-4884</p>	
<p><b>Mandible Plates, Straight</b></p> <p>Plate thickness: 1.0 mm Rigid</p>	 <p>M2-4300</p>	 <p>M2-4384</p>			

## Comminuted Fractures

<p><b>TriLock Plates, Anatomical</b></p> <p>Plate thickness: 1.5 mm Semi-rigid</p>	 <p>M2-4643</p>	
<p><b>TriLock Median Paramedian Plates, Grid</b></p> <p>Plate thickness: 1.3 mm Semi-rigid</p>	 <p>M2-4613</p>	 <p>M2-4621</p>
<p><b>Median Paramedian Plate, Grid</b></p> <p>Plate thickness: 1.0 mm Semi-rigid</p>	 <p>M2-4849</p>	

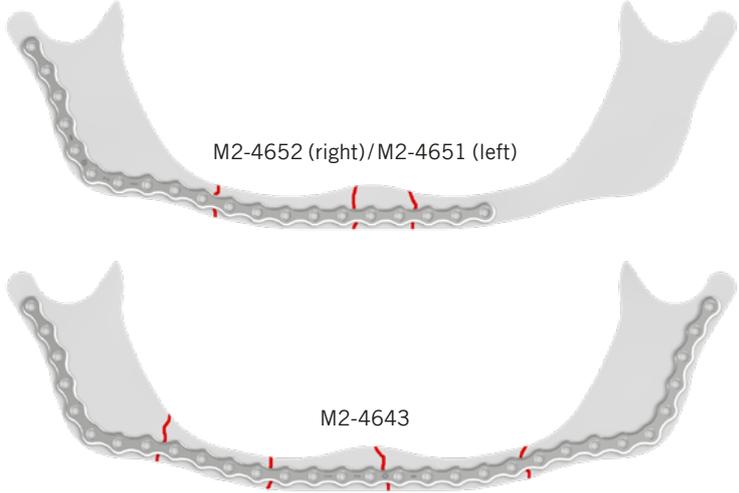
The information provided above is a recommendation only. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case.

# Ramus and Angle Fractures

<p><b>TriLock Plates, Anatomical</b></p> <p>Plate thickness: 1.5 mm Semi-rigid</p>	 <p>M2-4638 (right)/M2-4637 (left)</p>	 <p>M2-4652 (right)/M2-4651 (left)</p>
<p><b>TriLock Mandibular Angle Plate, Grid</b></p> <p>Plate thickness: 1.3 mm Semi-rigid</p>	 <p>M2-4618 (right)/M2-4617 (left)</p>	
<p><b>Mandibular Angle Plates, Grid</b></p> <p>Plate thickness: 1.0 mm Semi-rigid</p>	 <p>M2-4856 (right)/M2-4843 (left)</p>	 <p>M2-4848 (right)/M2-4847 (left)</p>
<p><b>Mandible Plates, Straight</b></p> <p>Plate thickness: 1.0 mm Rigid</p>	 <p>M2-4324/M2-4384</p>	

The information provided above is a recommendation only. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case.

# Atrophic Mandible Fractures

<p><b>TriLock Plates, Anatomical</b></p> <p>Plate thickness: 1.5 mm Semi-rigid</p>	 <p>M2-4652 (right)/M2-4651 (left)</p> <p>M2-4643</p>
<p><b>TriLock Pencilbone Plates, Grid</b></p> <p>Plate thickness: 1.3 mm Semi-rigid</p>	 <p>M2-4620 (right)/M2-4619 (left)</p>

The information provided above is a recommendation only. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case.

## HCL Defect Classification\*

Central defects including both canines are designated "C".

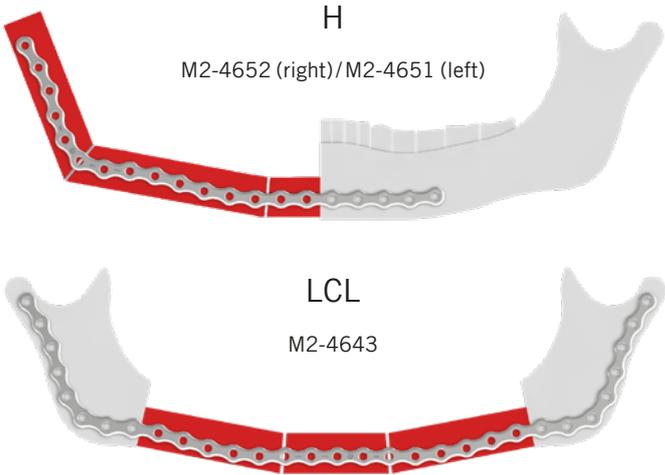
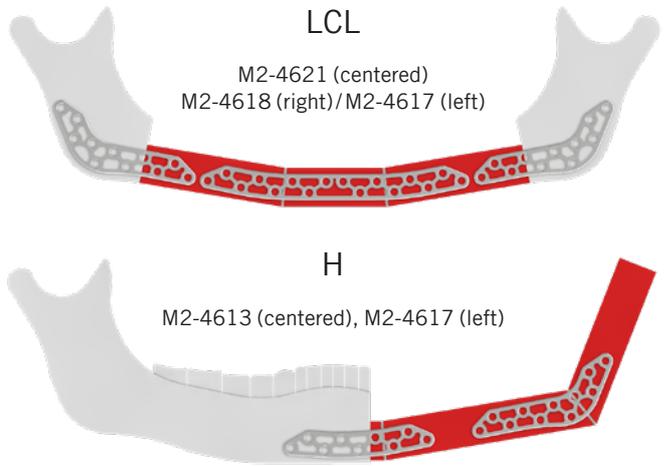
Lateral segments that exclude the condyle are designated "L".

Resecting the condyle along the lateral mandible, the defect is designated "H" (hemimandibular).

Classification	Examples of Defects
C (Central)	
L (Lateral)	
H (Hemi- mandibular)	
HC	
HC	
LCL	
HCL	

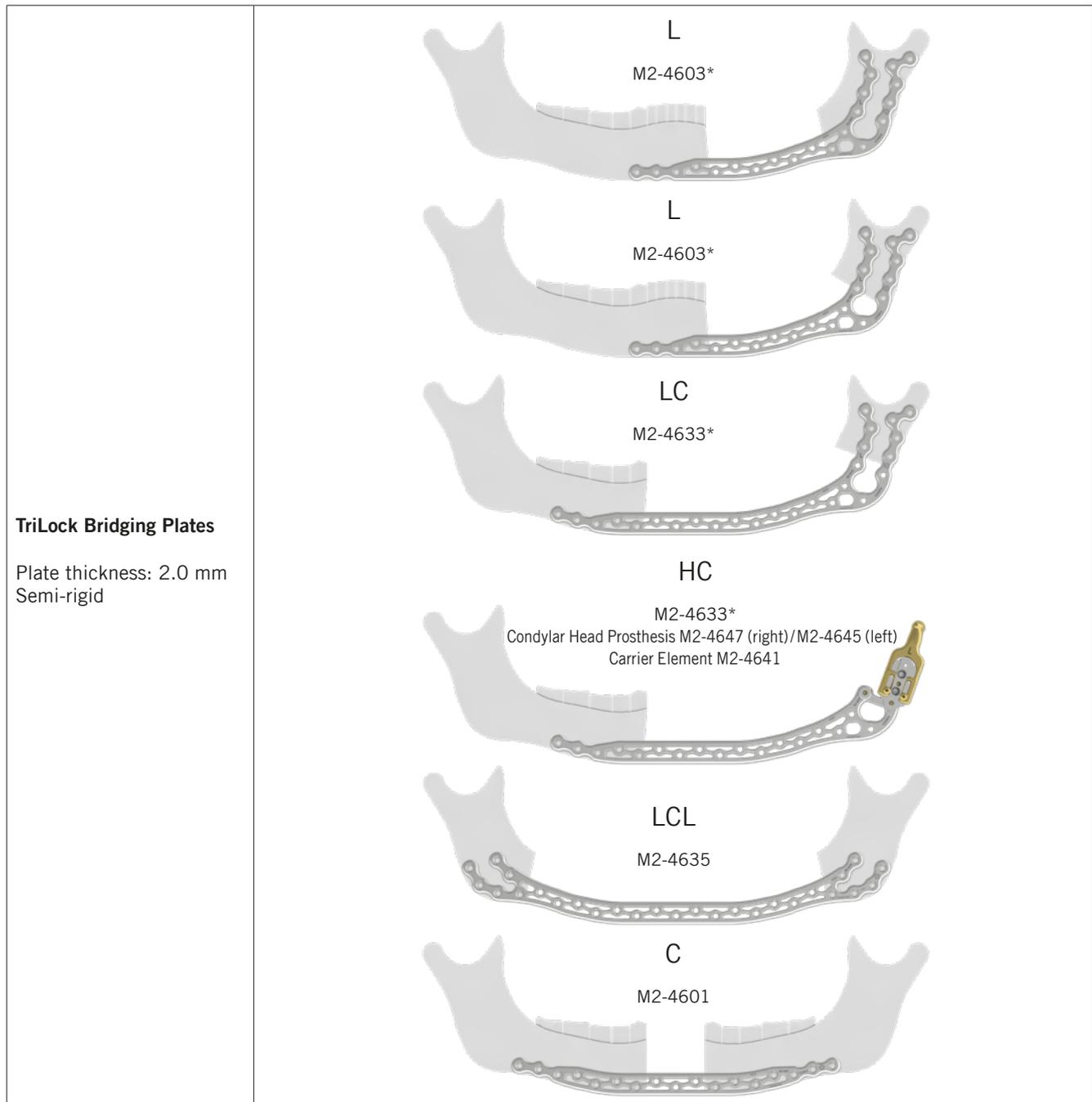
\* according to Jewer et al., 1989

# Reconstruction

<p><b>TriLock Plates, Anatomical</b></p> <p>Plate thickness: 1.5 mm Semi-rigid</p>	 <p>H M2-4652 (right)/M2-4651 (left)</p> <p>LCL M2-4643</p>
<p><b>TriLock Plates, Grid</b></p> <p>Plate thickness: 1.3 mm Semi-rigid</p>	 <p>LCL M2-4621 (centered) M2-4618 (right)/M2-4617 (left)</p> <p>H M2-4613 (centered), M2-4617 (left)</p>
<p><b>Mandible Plates, Straight</b></p> <p>Plate thickness: 1.0 mm Rigid</p>	 <p>LCL M2-4300</p>

The information provided above is a recommendation only. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case.

## Bridging of a Bone Defect



\* Double-sided

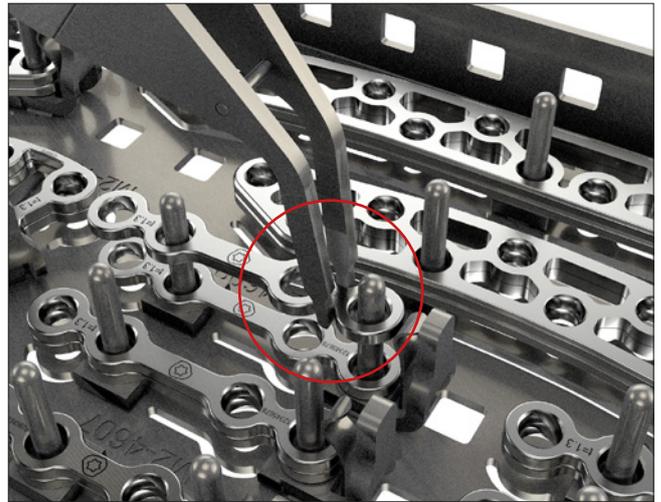
The information provided above is a recommendation only. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case.

# Instrument Application

## General Instrument Application

### Picking up the Plates

The use of the angled plate and screw holding forceps (M-2009 or M-2019) is recommended to remove the plates. Hold the plate with the forceps as close as possible to the plate-holding pin with spring and pull out of the holder from above.



## Cutting the Plates

The “cut before bending” principle applies.

There are two different types of cutting pliers which can be used to cut MODUS 2 Mandible plates:

Type 1: Plate cutting pliers (M2-2116) to  $t \leq 2.0$  mm

Type 2: Plate cutting pliers (A-2045) to  $t \leq 2.0$  mm

### Type 1

All MODUS 2 Mandible plates can be cut with the M2-2116 cutting pliers.

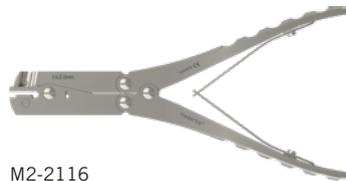
Ensure that there are no remaining plate segments in the cutting pliers (visual check). Hold the implantable plate segment with your hand during and after cutting.

Insert the plate from the left into the open cutting pliers. The hole countersinks must face upward.

### Notice

To facilitate the insertion of the plate, support the cutting pliers gently with your middle finger.

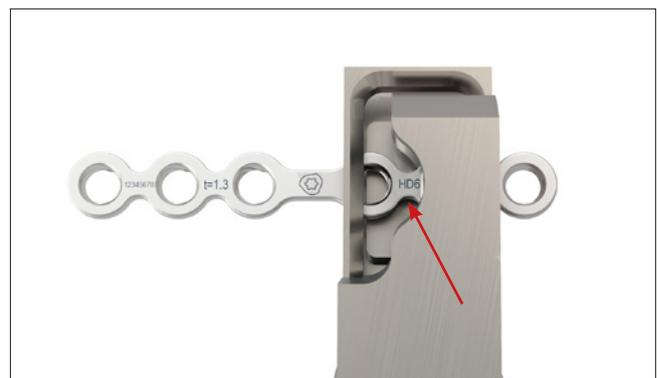
You can visually check the desired cutting line through the cutting window in the head of the pliers (see figure). Always leave enough material on the rest of the plate to keep the adjacent hole intact. The cutting process rounds off the cut edge. The visible part of the plate corresponds to the desired plate length.



M2-2116  
Plate Cutting Pliers  $t \leq 2.0$  mm



A-2045  
2.0–3.5 Plate Cutting Pliers



**Type 2**

All MODUS 2 Mandible plates can be cut with the cutting pliers A-2045. Ensure that there are no remaining plate segments in the cutting pliers (visual check). Insert the plate from the front into the open cutting pliers. The hole countersinks must face upward.

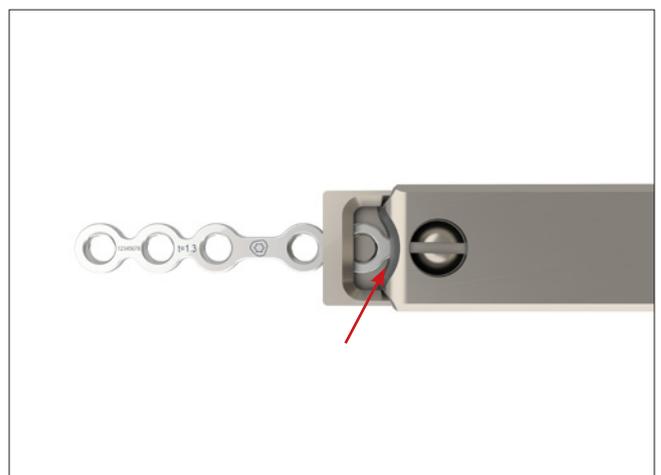


**Notice**

To facilitate the insertion of the plate, support the cutting pliers gently with your middle finger.



You can visually check the desired cutting line through the cutting window in the head of the pliers (see figure). Always leave enough material on the rest of the plate to keep the adjacent hole intact. The cutting process rounds off the cut edge. The visible part of the plate corresponds to the desired plate length.

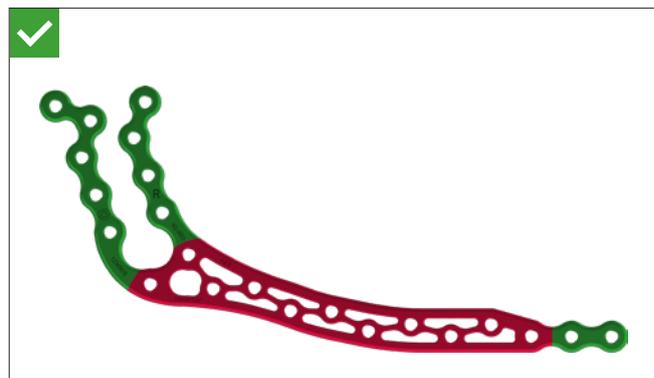


**Notice**

When cutting with both types of pliers, keep your hand loosely around the pliers to ensure that no parts fly off.

**Notice**

Do not cut grid plates in the grid area.



TriLock bridging plates M2-4603/M2-4633 used in combination with the C-adaption M2-4639 are an exception to this rule. In this case the grid structure can be cut as the C-adaption provides stability.



## Bending the Plates

If necessary, the MODUS 2 Mandible plates can be bent. There are various options available for this.

### Plate Bending Pliers with Pin 2.0–2.5 (M2-2158)

Simultaneous bending in multiple planes (3D).

Application: All MODUS 2 Mandible plates

#### Notice

The plate bending pliers with pin are always used in pairs.

#### Notice

To ensure that the TriLock plates lock, they may only be bent with the plate bending pliers with pin (M2-2158).



M2-2158  
2.0-2.5 Plate Bending Pliers with Pin

### Plate Bending Pliers, Flat Nose (M2-2000)

Simultaneous bending in multiple planes (3D).

Application: All non-locking MODUS 2 Mandible fixation plates.



M2-2000  
Plate Bending Pliers, Flat Nose

### Plate Bending Pliers 2.0–2.5 (M2-2006)

Flat plier function, bending outside the plane, bending within the plane.

Application: All non-locking MODUS 2 Mandible fixation plates.



M2-2006  
2.0-2.5 Plate Bending Pliers

### Simultaneous bending in multiple planes – 3D (fixation plates and TriLock plates)

Take the plate and define at the mandible where to start the bending process.



Hold the plate bending pliers with pin (M2-2158) so that the pin enters the plate hole from above (with the “UP” marking on the plate bending pliers pointing upward).

Always insert the TriLock plates into the plate bending pliers with the markings facing upward. The purpose of this process is to protect the plate hole from deformities.



#### Notice

While bending, the plate must always be held at two adjacent holes to prevent contour deformation of the intermediate plate hole.



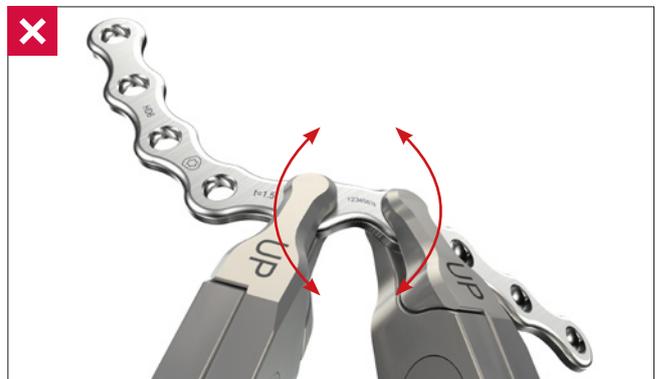
**Notice**

Regularly check the curvature of the plate to prevent overbending and thereby excess strain on the plate.



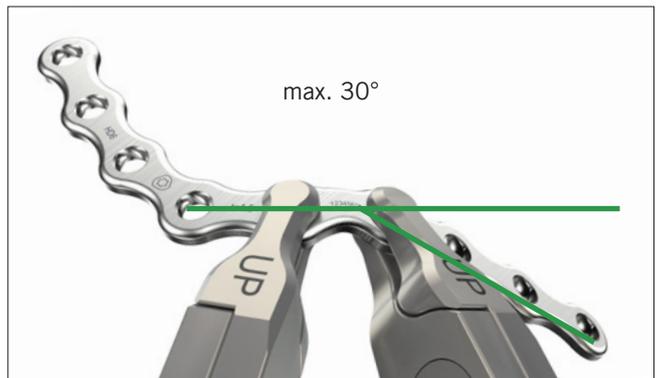
**Caution**

Repeatedly bending 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 correct and secure seating of the screw in the plate and increase the risk of system failure.



**Caution**

Do not bend plates without a bar by more than 30°. Bending the plate further may deform the plate holes and may cause the plate to break postoperatively.



The bending pliers (M2-2158) can also be used to bend all grid plates.

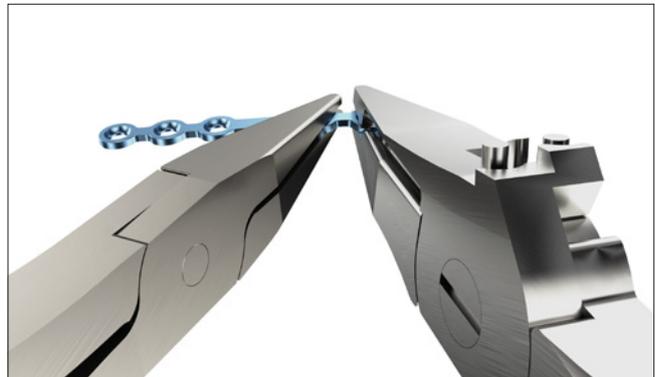


### Flat plier function

2.0–2.5 Plate bending pliers, flat nose (M2-2000)

2.0–2.5 Plate bending pliers (M2-2006)

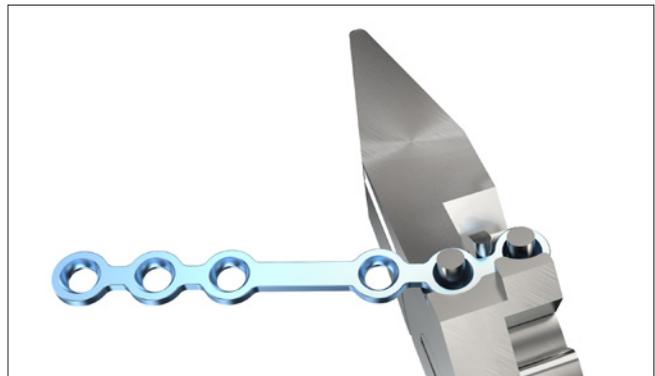
For the non-locking plates, optionally the plate bending pliers with flat nose (M2-2000 and M2-2006) can be used.



### Bending within the plane (Aderer function)

2.0–2.5 Plate bending pliers (M2-2006)

For the cranial plates (plate thickness 1.0 mm), a three-jaw plier function (“Aderer function”) is integrated into the plate bending pliers (M2-2006) so that the plates bend in the plane.

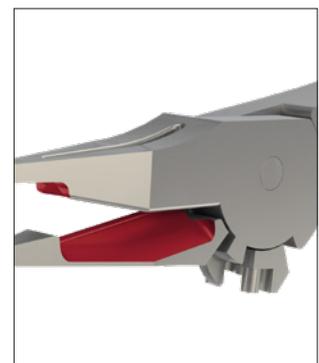


### Bending outside the plane

2.0–2.5 Plate bending pliers (M2-2006)

Bars can be bent with the 90° bending function between the jaws of the plate bending pliers.

Position the plate in the pliers between the jaws. The slot permits the plate to be viewed.



## Drilling

Color-coded twist drills are available for each MODUS 2 screw diameter. All drills are color coded with a ring system.

Screw Diameter	Color Code
2.0	Blue
2.3	Brown
2.5	Purple

There are two different types of twist drill: Core hole drills are marked with one colored ring and gliding hole drills (for lag screw technique) are marked with two colored rings.

### Core Hole Drills

Drills for screws Ø 2.0 (drill Ø 1.5)

Dental	Stryker	
M2-3119	M2-3129	5 mm
M2-3139	M2-3149	7 mm
M2-3159	M2-3169	25 mm



Drills for screws Ø 2.3 (drill Ø 1.9)

Dental	Stryker	
M2-3176	M2-3186	7 mm
M2-3196	M2-3206	25 mm



Drills for screws Ø 2.5 (drill Ø 2.0)

Dental	Stryker	
M2-3236	M2-3246	7 mm
M2-3256	M2-3266	25 mm



### Gliding Hole Drills

Drills for screws Ø 2.0 (drill Ø 2.0)

Dental	Stryker	
M2-3156	M2-3166	25 mm



Drills for screws Ø 2.3 (drill Ø 2.3)

Dental	Stryker	
M2-3336	M2-3346	25 mm



### Caution

It is recommended not to exceed a maximum drilling speed of 1000 revolutions per minute. Higher speeds can cause the bone to overheat.

## Drilling with Drill Guide

The 2.0–2.5 drill guide (M2-2198) can be used for MODUS 2 Mandible TriLock plates and fixation plates.

After positioning the plate, insert the drill guide and the twist drill into the screw hole. The drill is guided by the shaft of the drill and not the drill flute.

Drills for use in combination with the drill guide:

### Core Hole Drills

Drills for screws  $\varnothing$  2.0 (drill  $\varnothing$  1.5)

Dental	Stryker	
M2-3459	M2-3469	25 mm

Drills for screws  $\varnothing$  2.3 (drill  $\varnothing$  1.9)

Dental	Stryker	
M2-3216	M2-3226	25 mm

Drills for screws  $\varnothing$  2.5 (drill  $\varnothing$  2.0)

Dental	Stryker	
M2-3276	M2-3286	25 mm

### Gliding Hole Drills

Drills for screws  $\varnothing$  2.0 (drill  $\varnothing$  2.0)

Dental	Stryker	
M2-3296	M2-3306	25 mm

Drills for screws  $\varnothing$  2.3 (drill  $\varnothing$  2.3)

Dental	Stryker	
M2-3316	M2-3326	25 mm

### Notice

For TriLock plates ensure that the screw holes are pre-drilled with a pivoting angle of no more than  $\pm 15^\circ$ . For this purpose, the drill guides show a limit stop at  $\pm 15^\circ$ . A pre-drilled pivoting angle of  $> 15^\circ$  no longer allows the TriLock screws to correctly lock in the plate.



M2-2198  
2.0–2.5 Drill Guide



M2-3459



M2-3216



M2-3276



M2-3296



M2-3316



### Assigning the Screw Length

The 2.0–2.5 depth gauge (M2-2260) is used to determine the ideal screw length for use in monocortical or bicortical screw fixation.

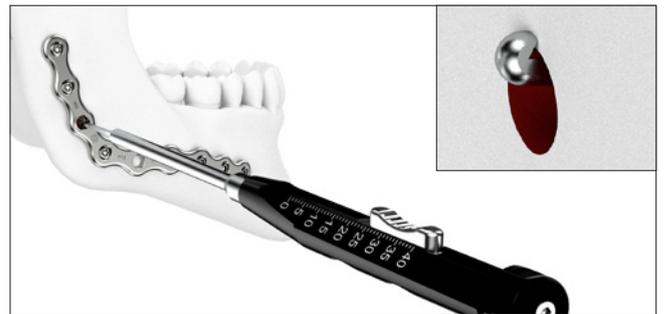


M2-2260  
2.0–2.5 Depth Gauge

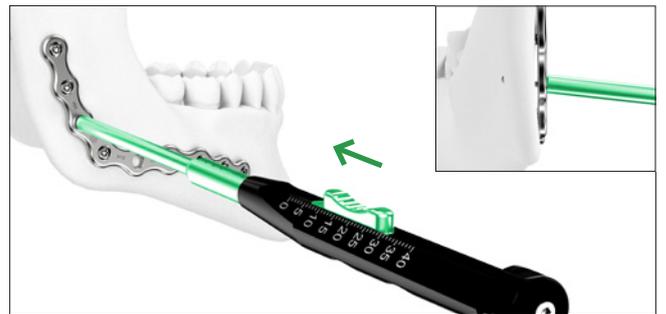
Retract the slider of the depth gauge.



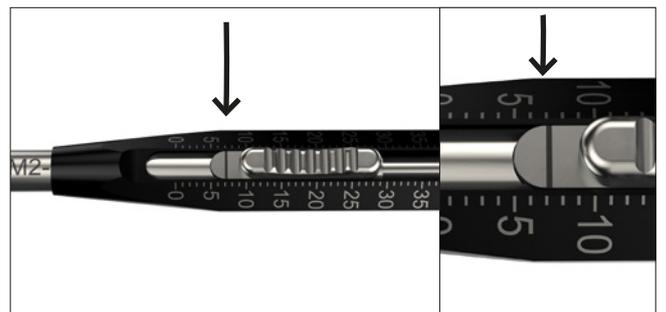
The caliper of the depth gauge has a hooked tip that is either inserted to the bottom of the hole or is used to catch the far cortex of the bone to determine the correct screw length. When using the depth gauge, the caliper stays static and only the slider is adjusted.



To assign the screw length, place the distal end of the slider onto the implant plate.



The ideal screw length for the assigned drill hole can be read on the scale of the depth gauge.



## Screw Pick-Up

The screwdriver handles (M2-2001 and M2-2040) are compatible with the screwdriver blade (M2-2005). The screwdriver blade (M2-2005) features the patented self-holding technology HexaDrive.



M2-2001  
Type 2 Screwdriver Handle



M2-2040  
Type 3 Screwdriver Handle



M2-2005  
Screwdriver Blade, HD6, 95 mm

### Notice

All screws up to 7 mm in length are secured with a securing element. To remove these screws, turn the securing element to the right with the screwdriver. This releases the screws.



To remove the screws from the implant container, insert the appropriately color-coded screwdriver blade perpendicularly into the screw head of the desired screw and pick up the screw with axial pressure.

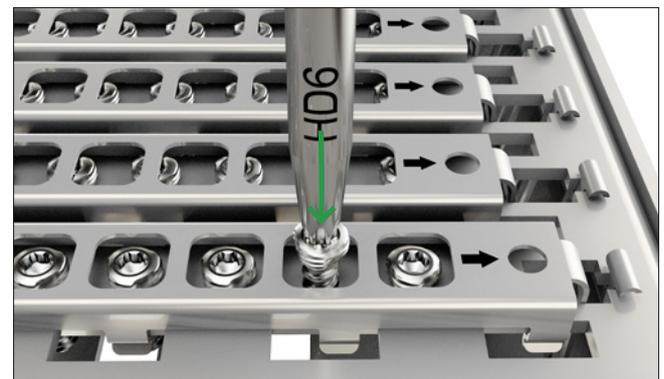
### Notice

The screw will not hold without axial pressure!

Vertically extract the screw from the compartment.

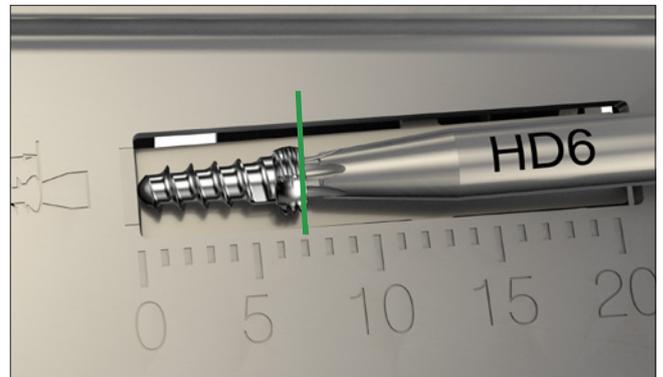
### Notice

Picking up the screw repeatedly may lead to permanent deformation of the self-retaining area of the HexaDrive inside the screw head. Therefore, the screw may no longer be able to be picked up correctly. In this case, a new screw has to be used.



The screw length is checked with the measuring module and read at the end of the screw head.

Check the correct screw diameter: The screw can be inserted into the hole of the appropriate screw diameter. The screw will not fit in the hole for the next screw size down.



**Notice**

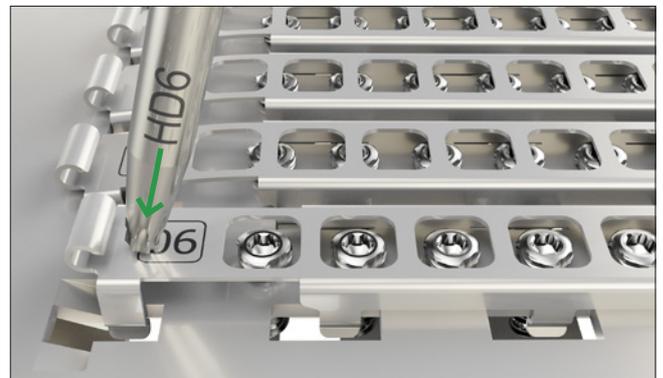
Check 2.0 SpeedTip screws in the hole  $\varnothing$  2.3.



**Notice**

After removing screws up to a length of 7 mm it is important to ensure that the securing elements are closed again to prevent the screws from dropping out.

To do this, lightly press down on the outer left of the securing element and it will close of its own accord.



Screws secured with a securing element cannot be directly removed with the 90° screwdriver.

The screws must be removed with the screwdriver blade and stored temporarily in the screw measuring module. From here the screw can be picked up with the 90° screwdriver.



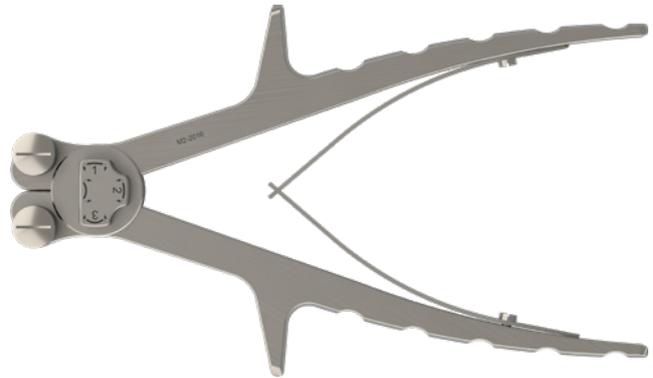
# Specific Instrument Application

## Bending of TriLock Bridging Plates

### Three-point bending pliers (M2-2016)

Bending of grid plates out of the plane.

Application: All MODUS 2 Mandible plates with grid structure (plate thickness 1.0–2.0 mm).



M2-2016  
2.0–2.5 Three-Point Bending Pliers

### Ramus plate bending instrument (M2-2026)

Adjustment of the ramus section of the TriLock bridging plates and the TriLock plates.

Application: All MODUS 2 Mandible TriLock bridging plates (plate thickness 2.0 mm) and TriLock plates (plate thickness 1.5 mm)



M2-2026  
Ramus Plate Bending Instrument

### Bending template (example M2-4669)

#### 1. Bending the template

Use the template, which can easily be bent manually, to replicate the shape of the mandible. This design will be transferred to the corresponding TriLock bridging plate.

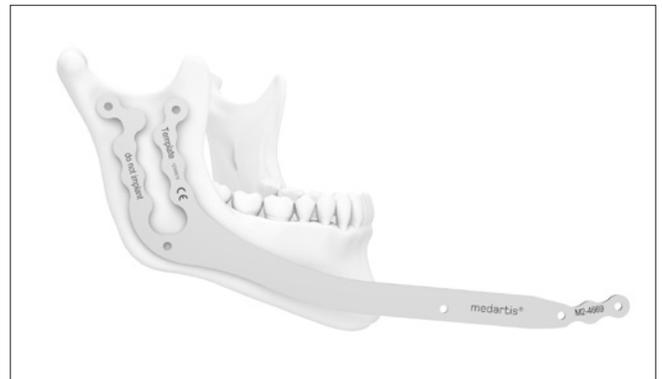
#### Notice

The templates may not be placed on top of each other in the container.

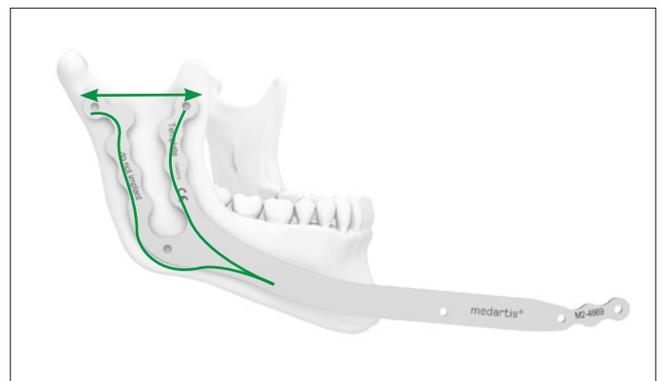


M2-4669  
Template for M2-4633

Place the template in the ramus section.



Adjust the angle of the two arms to the mandibular angle.



Bend the template along the mandible, starting at the ramus section.

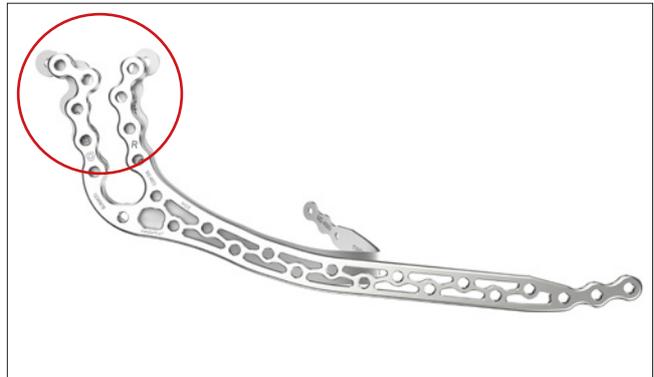


Bent template.



## 2. Bending the plate

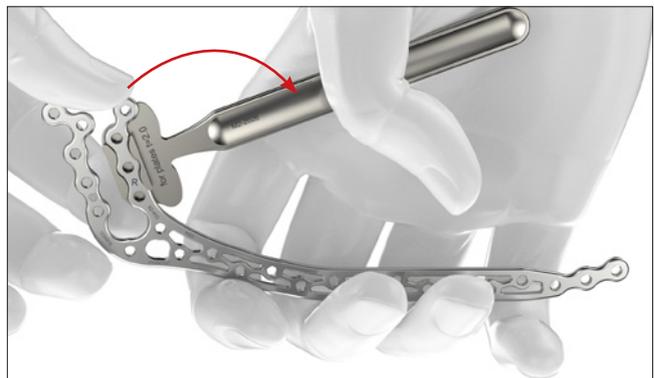
Adjust the ramus section of the plate to the template.



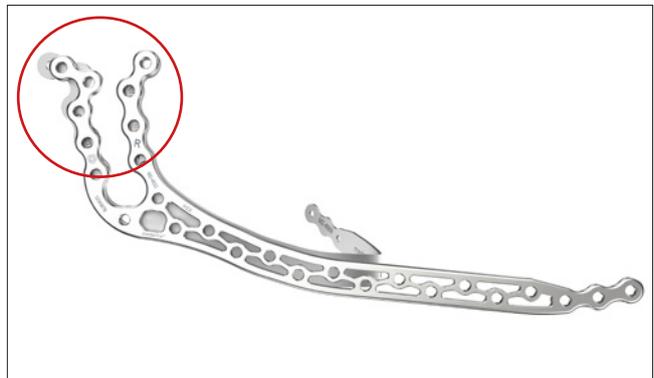
Use the ramus bending instrument (M2-2026) to bend the ramus section.

### Notice

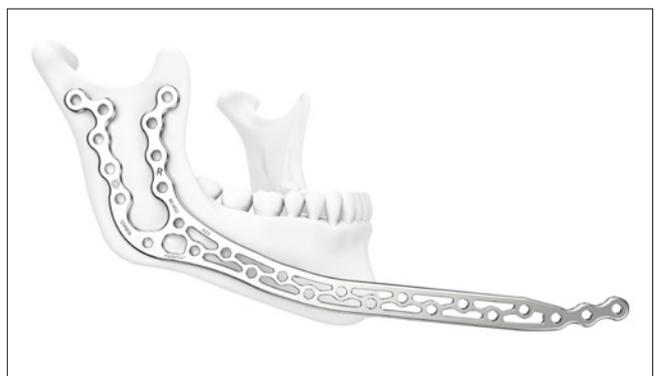
Two ramus bending instruments can be used for simultaneously bending the anterior and posterior arms.



Check the shape of the plate and bend again if necessary.

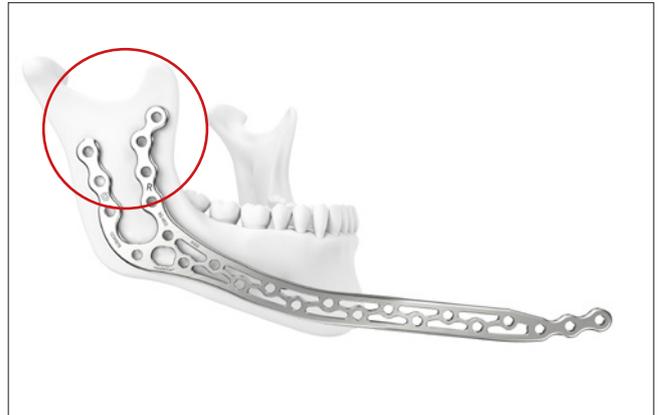


Final fitting of the ramus section of the plate (in situ or on the planning model).

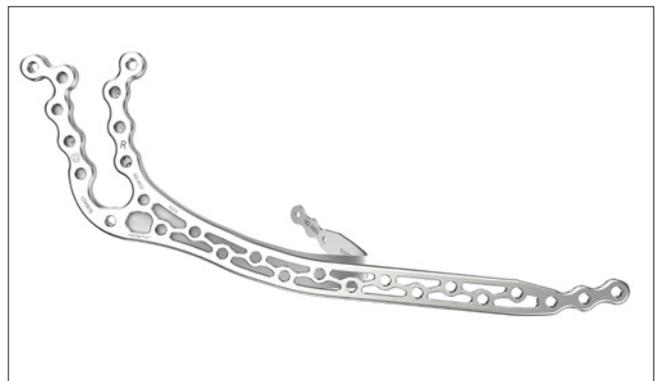


**Notice**

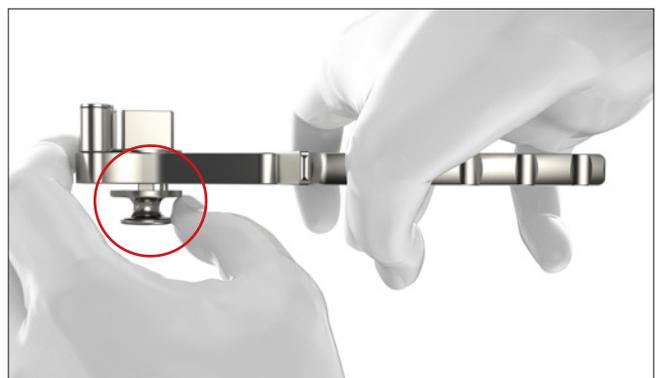
The length of the ramus section of the plate can be cut to fit the patient's anatomy (use of M2-2116, see section "Cutting the Plates").



Final shape of the ramus section.



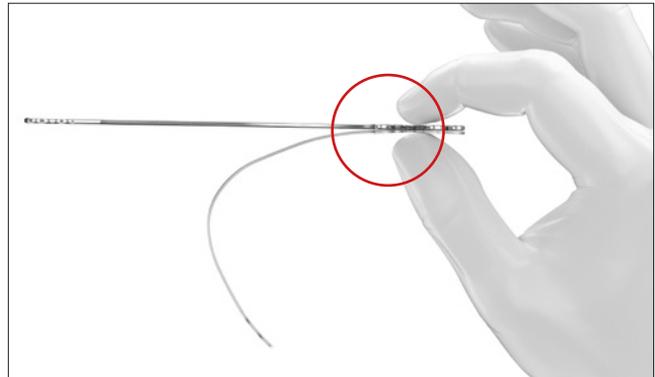
Adjust the three-point bending pliers (M2-2016) to the starting position (1) before starting the bending process.



Hold the plate to the template to define the start of the bending.

**Notice**

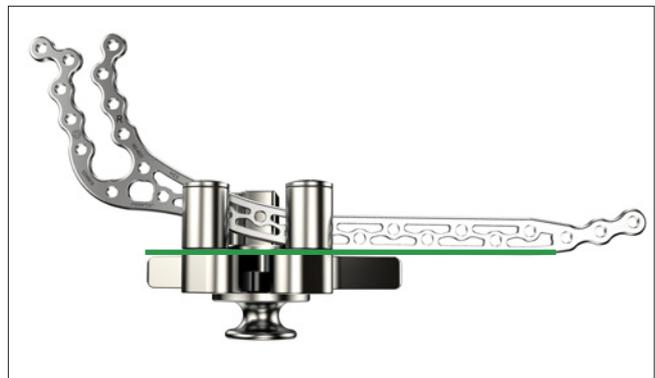
Always start bending at the ramus end of the plate.



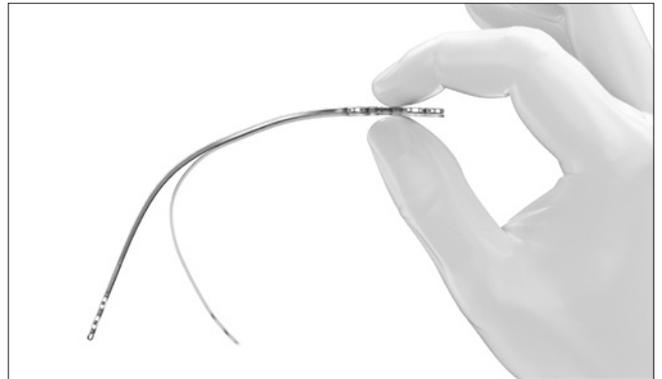
Start bending in position 1 (slight bending).

**Notice**

During the entire bending process, the bridging plate must be placed in the bending pliers so that the anterior grid section is parallel to the contact surface of the bending pliers.



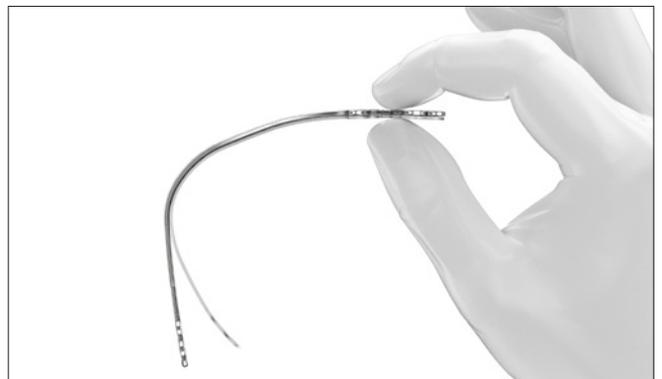
Control the bending and use position 2 (moderate bending) of the bending pliers to continue if necessary.



Check the shape and finalize bending in position 3 (strong bending) if necessary.

**Notice**

It will not always be necessary to use all three bending positions.



Check the final shape of the plate before implantation (in situ or on the planning model).



# Surgical Techniques

## General Surgical Techniques

### Lag Screw Technique

#### 1. Drilling the core hole

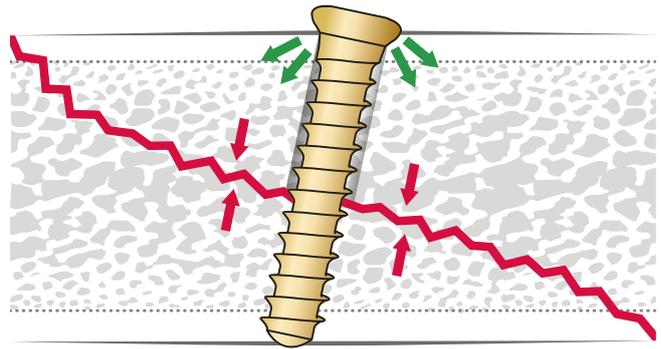
Use the core hole drill (one colored ring) of the same screw diameter to drill to the far cortex.

#### 2. Drilling the gliding hole

Use the gliding hole drill (two colored rings) to drill up to the fracture line.

#### 3. Compressing

Compress with the cortical screw of the corresponding screw diameter.



## Specific Surgical Techniques

### Temporary Condylar Head Prosthesis

The condylar head prosthesis is designed for temporary reconstruction ( $\leq 12$  months) of the mandibular condyle in patients that are not eligible to alternative reconstruction procedures because of their critical clinical condition. These devices are not designed for permanent reconstruction. Temporary condylar head prostheses should therefore be reserved as a last resort in highly morbid patients.

#### **The alloplastic condylar head replacement may be applicable for**

- Patients with increased risk of damage of a potential autograft due to the patient's disease or its recurrence
- Patients with qualitatively and/or quantitatively insufficient donor material
- Patients that require a short surgery time due to their poor general condition

#### **Specific complications that may be associated with the condylar head prosthesis include**

- Postoperative dislocation of the temporomandibular joint
- Resorption of the mandibular fossa and/or penetration of the prosthesis through the temporal bone

Plate breakage and/or plate exposure might be promoted due to patient's underlying pathologies and/or post-surgical treatments (e. g. radiation).

**Potential risk factors contributing to complications include:**

- Radiation
- Tumor stage
- Smoking

**Special considerations for post-operative treatment**

After alloplastic condylar head reconstruction, the patient must be treated carefully. To protect the condylar head replacement and the implants from excess loading, the treating physician has to ensure adequate postoperative treatment, such as immobilization of the temporomandibular joint, taking into account the defect size and shape as well as the patient's clinical condition and his/her compliance. Early load bearing may lead to loosening, migration, or breakage of the implant. Furthermore, the patient's disease state and/or postoperative treatment (e. g. radiation) may increase the risk of implant breakage and/or exposure.

**Assembly of the Temporary Condylar Head Prosthesis**

The condylar head prosthesis is used to compensate for the loss of the bony condyle and allows for vertical adjustment. The head of the prosthesis is offset towards medial and therefore in the anatomically correct position.

**Notice**

For proper prosthesis assembly, two connecting screws are required to fix the condylar head prosthesis to the carrier element. For a detailed description of the procedure, see next page.

**Notice**

Always use the prosthesis assembly in combination with a TriLock bridging plate (M2-4603 or M2-4633).



M2-4647  
Condylar Head  
Prosthesis, Right

M2-4645  
Condylar Head  
Prosthesis, Left

M2-5269.06  
Connecting Screw  
for Condylar Head  
Prosthesis

**Notice**

A total of four connecting screws are required to use the prosthesis assembly in combination with a TriLock bridging plate (M2-4603 or M2-4633):

- Two connecting screws to fix the prosthesis assembly to the bridging plate
- Two connecting screws to fix the stabilizer to the bridging plate

For a detailed description of the procedure, see next page.



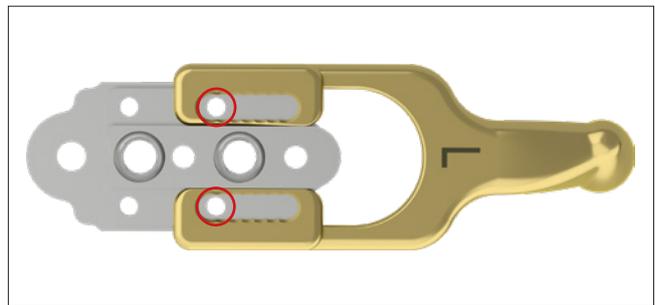
M2-4641  
Carrier Element with Stabilizer for Condylar  
Head Prosthesis

M2-5268.05  
Connecting Screw for M2-  
4639/M2-4641, HD6

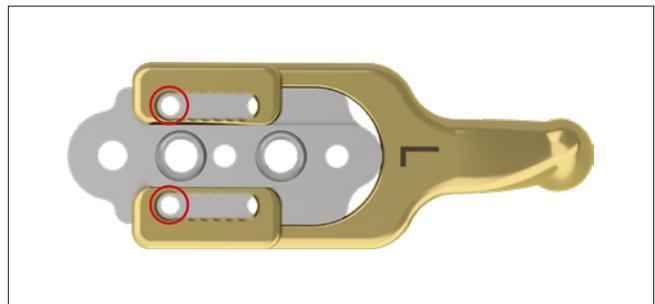
Slide the carrier element into the condylar head prosthesis.



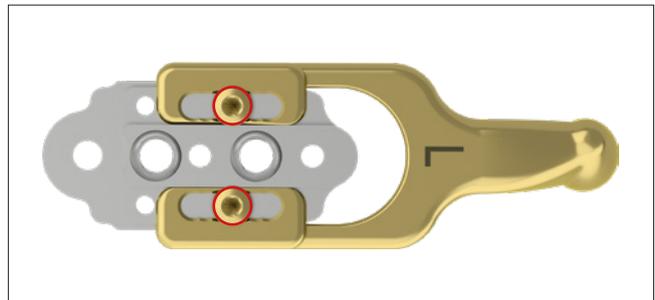
Maximum length.



Minimum length.



Once the required length is achieved, fix the condylar head prosthesis to the carrier element with two connecting screws.



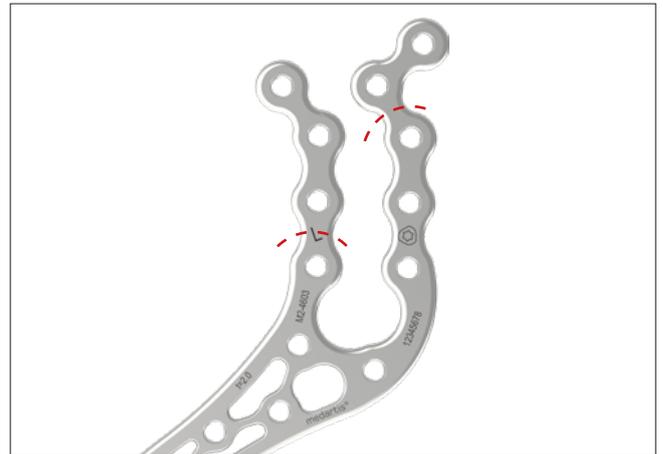
With the TriLock bridging plates (M2-4603 or M2-4633) first adjust the posterior arm with the ramus plate bending instrument to the ramus angle and then follow with the anterior arm.

**Notice**

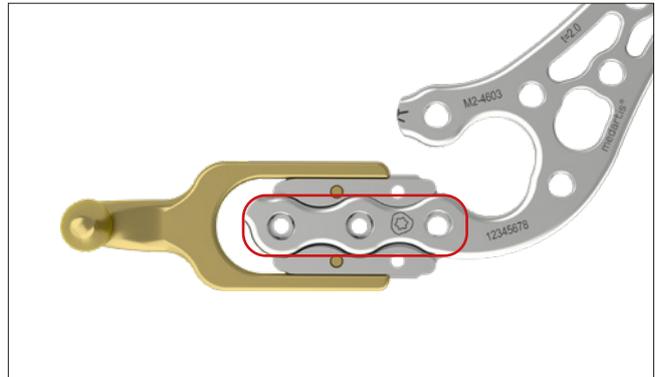
The arms must be parallel to each other.



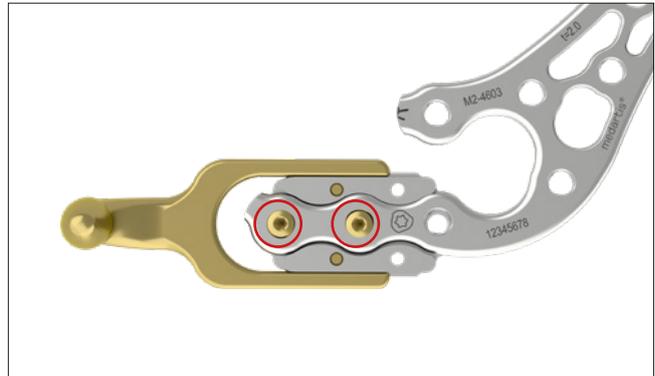
Cut the bridging plate with the plate cutting pliers (M2-2116) (see section "Cutting the Plates"), to prepare the assembly of the condylar head prosthesis.



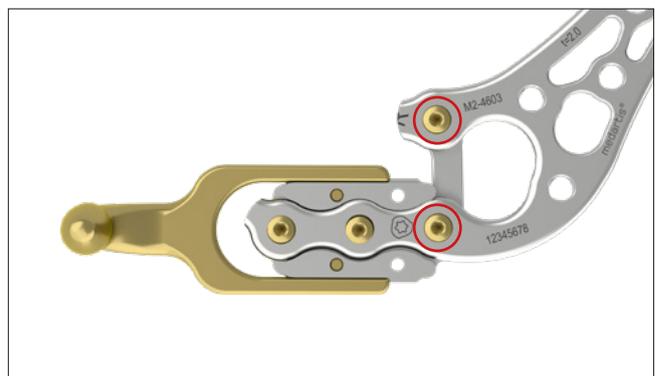
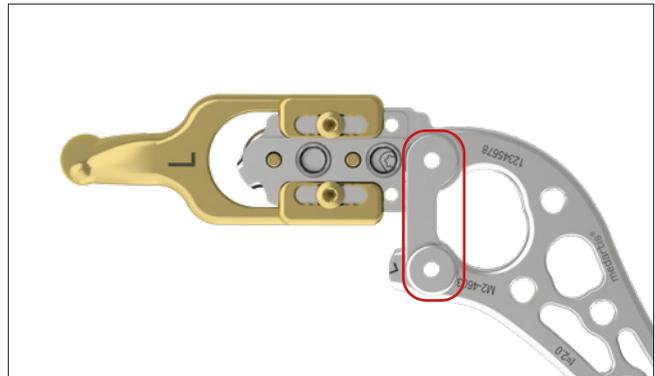
Insert the distal part of the bridging plate into the prosthesis with the assembled carrier element.



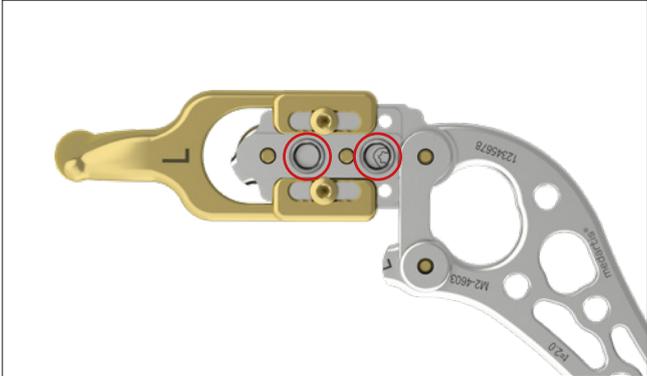
Fix the prosthesis assembly to the plate with two connecting screws from the lingual side of the plate.



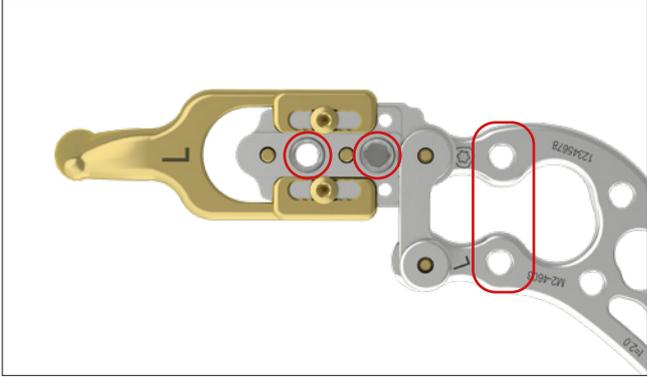
Place the stabilizer transversely onto the remaining distal part of the plate and fix it with two connecting screws from the lingual side of the plate.



Assembled temporary condylar head prosthesis.



The condylar head prosthesis can be positioned higher on the bridging plate for a very high ramus. For this assembly option, two holes have to be left on the anterior arm.



## Assembly of the C-Adaption for Bridging Plates

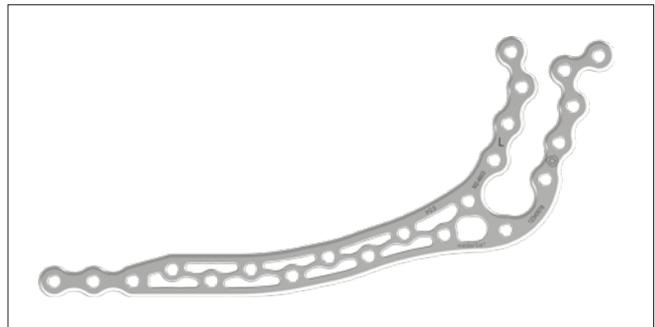
The TriLock bridging plates (M2-4603, M2-4633) can be used in combination with the C-adaption (M2-4639). Pre-operatively the plates have to be cut (see section "Cutting the Plates") and bent (see section "Bending the Plates") to fit the patient's anatomy.



M2-5268.05  
Connecting Screw for  
M2-4639/M2-4641, 2/Pkg



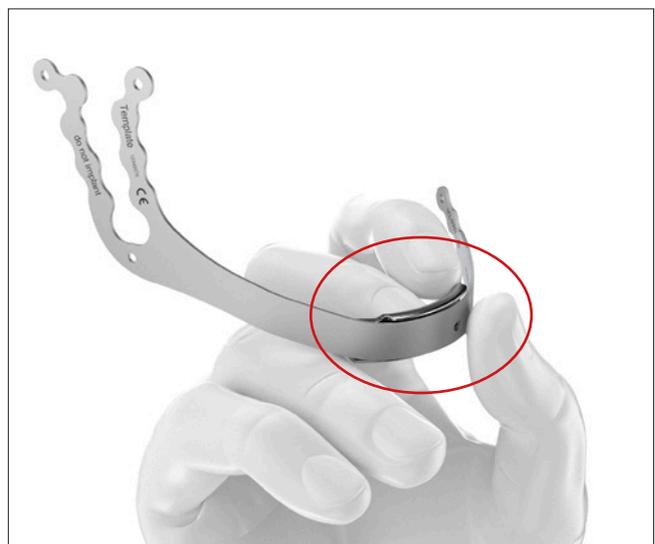
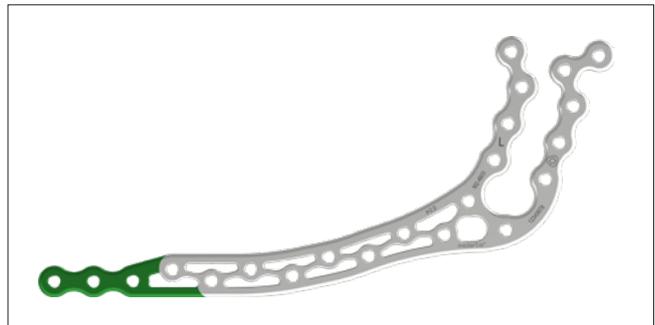
M2-4639  
C-Adaption for Bridging Plates



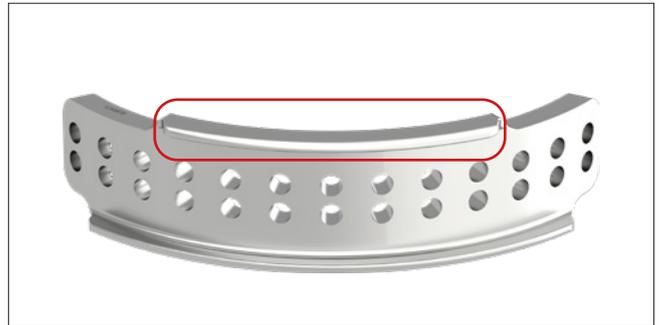
Use the preformed template (see section "Bending of TriLock Bridging Plates") to determine the cutting line on the plate. Use the plate cutting pliers (M2-2116) to obtain a cut without sharp edges.

### Notice

Always cut before bending.



The short “lip” of the C-adaption has to point upward ↑, to avoid collision with the shaped plates during the assembly.



**Notice**

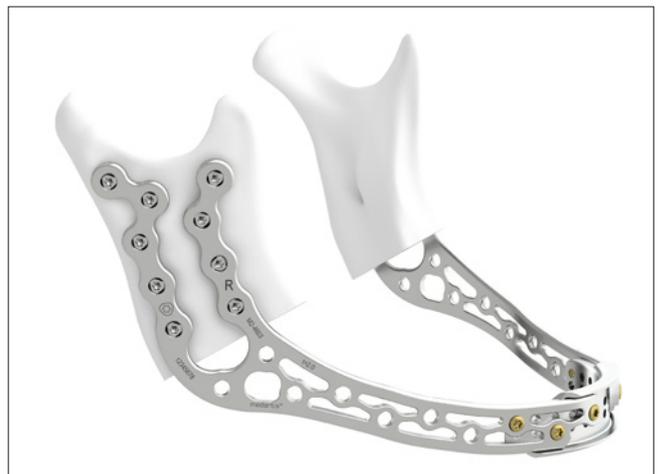
Make sure to insert at least 3 screws per side.



Assembled C-adaption.

**Notice**

2.5 TriLock screws have to be used for bridging of bone defects.



## Use of the Temporary Locking Stopper for TriLock Screws

When using locking plates, it is not possible to pull the plate onto the bone with TriLock screws as these are locked in the plate when they come into contact with the locking mechanism and therefore cannot build up any traction. The locking stopper for TriLock screws can be used with all 2.0/2.3/2.5 TriLock screws.



M2-2007  
Temporary Locking Stopper TriLock Screws

Position the prepared plate in situ. Drill the first hole close to the fracture and insert the TriLock screw with a distance to the plate.

### Notice

The use of TriLock screws with a minimum length of 7 mm is recommended to ensure that the locking stopper can be inserted correctly.



Position the locking stopper over the screw head.



Tighten the screw. The locking stopper prevents locking and the plate is drawn towards the bone.



Drill the remaining holes and insert TriLock screws.



Loosen the screw in the locking stopper and remove the locking stopper. Then lock the last screw.



# Follow-Up Care and Explantation

## Follow-Up Care for MODUS 2 Mandible Implants

Taking into account the individual fracture conditions and patient compliance, it is important to ensure adequate postoperative relief of the osteosynthesis in terms of adaptation or mobilization stability (e.g. splinting and/or immobilization). Postoperatively, the fixation achieved with the implants must be treated with care until the bone has fully healed. Patients must strictly observe follow-up instructions given by their physicians to avoid detrimental strain on the implants. Early load bearing can increase the risk of loosening, migration or breakage of the implants.

## Explantation of MODUS 2 Mandible Implants

Use the appropriate screwdrivers to remove the screws to explant MODUS 2 implants.

### **Notice**

Only original MODUS 2 instruments are recommended for the explantation of MODUS 2 implants.

# TriLock<sup>®</sup> Locking Technology

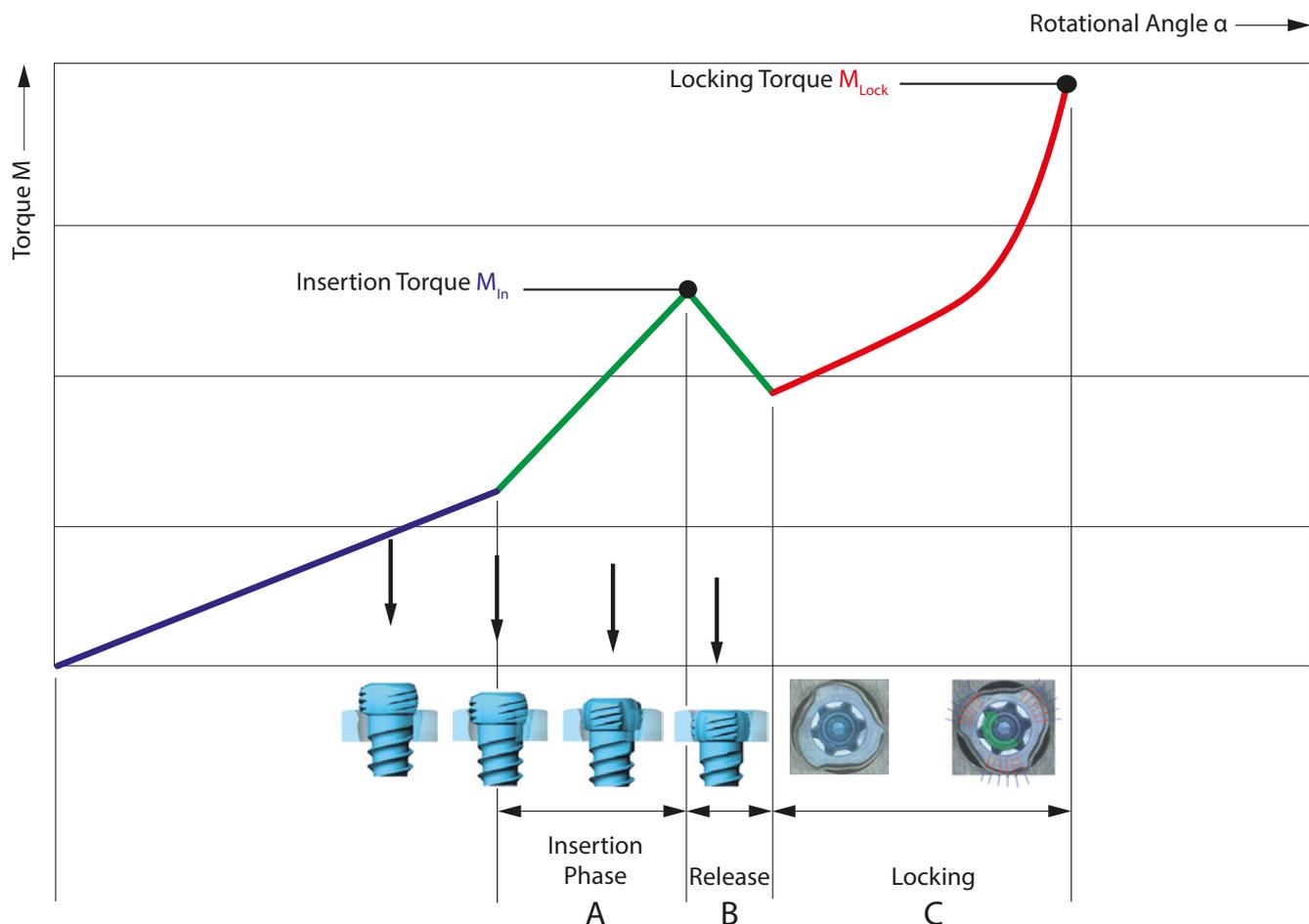
## Correct Application of the TriLock Locking Technology

The screw is inserted through the plate hole into a pre-drilled canal in the bone. An increase of the tightening torque will be felt as soon as the screw head makes contact with the plate surface.

This indicates the start of the “Insertion Phase” as the screw head starts entering the locking zone of the plate (section “A” in the diagram). Afterwards, a drop of the tightening

torque occurs (Section “B” in the diagram). Finally, the actual locking is initiated (section “C” in the diagram) as a friction connection is established between screw and plate when tightening firmly.

The torque applied during fastening of the screw is decisive for the quality of the locking as described in section “C” of the diagram.



## Correct Locking ( $\pm 15^\circ$ ) of the TriLock Screws in the Plate

Visual inspection of the screw head projection provides an additional indicator of correct locking. Correct locking has occurred only when the screw head has locked flush with the locking contour (figures 1 + 3).

However, if there is still a noticeable protrusion (Fig. 2 and 4), the screw head has not completely entered the plate and reached the locking position. In this case the screw has to

be retightened to obtain full penetration and proper locking. In case of poor bone quality, slight axial pressure may be necessary to achieve proper locking. Due to the system characteristics, a screw head protrusion of around 0.2 mm exists when using plates with 1.0 mm thickness.

**Do not overtighten the screw, otherwise the locking function cannot be guaranteed anymore.**

Correct: LOCKED

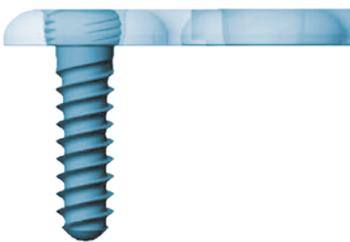


Figure 1

Incorrect: UNLOCKED

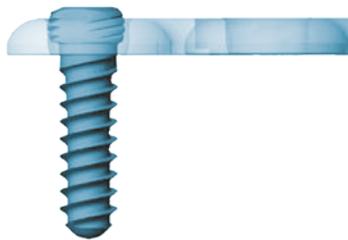


Figure 2

Correct: LOCKED

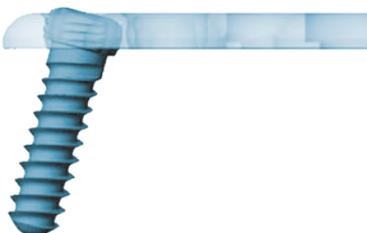


Figure 3

Incorrect: UNLOCKED

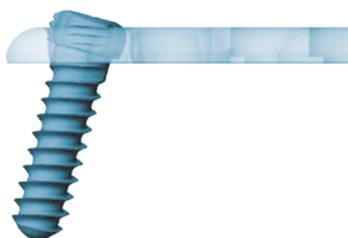


Figure 4

# Appendix

## Implants and Instruments

For detailed ordering information, please refer to the MODUS 2 Mandible Product Information at [www.medartis.com](http://www.medartis.com).

### Plates

Art. No.	Art. No.	Art. No.	Art. No.
M2-4300	M2-4619	M2-4654S	M2-4852S
M2-4300S	M2-4619S	M2-4656	M2-4854
M2-4303	M2-4620	M2-4656S	M2-4854S
M2-4303S	M2-4620S	M2-4658	M2-4856
M2-4318	M2-4621	M2-4658S	M2-4856S
M2-4318S	M2-4621S	M2-4660	M2-4860
M2-4322	M2-4625	M2-4660S	M2-4860S
M2-4322S	M2-4625S	M2-4662	M2-4864
M2-4324	M2-4627	M2-4662S	M2-4864S
M2-4324S	M2-4627S	M2-4664	M2-4882
M2-4378	M2-4629	M2-4664S	M2-4882S
M2-4378S	M2-4629S	M2-4670	M2-4884
M2-4380	M2-4631	M2-4670S	M2-4884S
M2-4380S	M2-4631S	M2-4672	M2-4886
M2-4384	M2-4633	M2-4672S	M2-4886S
M2-4384S	M2-4633S	M2-4674	M2-4894
M2-4390	M2-4635	M2-4674S	M2-4894S
M2-4390S	M2-4635S	M2-4678	
M2-4392	M2-4637	M2-4678S	
M2-4392S	M2-4637S	M2-4692	
M2-4394	M2-4638	M2-4692S	
M2-4394S	M2-4638S	M2-4800	
M2-4601	M2-4639	M2-4800S	
M2-4601S	M2-4639S	M2-4826	
M2-4603	M2-4640	M2-4826S	
M2-4603S	M2-4640S	M2-4837	
M2-4605	M2-4641	M2-4837S	
M2-4605S	M2-4642	M2-4839	
M2-4607	M2-4642S	M2-4839S	
M2-4607S	M2-4643	M2-4843	
M2-4609	M2-4643S	M2-4843S	
M2-4609S	M2-4644	M2-4845	
M2-4611	M2-4644S	M2-4845S	
M2-4611S	M2-4645	M2-4847	
M2-4613	M2-4647	M2-4847S	
M2-4613S	M2-4651	M2-4848	
M2-4617	M2-4651S	M2-4848S	
M2-4617S	M2-4652	M2-4849	
M2-4618	M2-4652S	M2-4849S	
M2-4618S	M2-4654	M2-4852	

### Screws

Art. No.	Art. No.	Art. No.
M2-5240.04	M2-5243.07/1	M2-5247.07/1S
M2-5240.04/1	M2-5243.07/1S	M2-5247.08
M2-5240.04/1S	M2-5243.08	M2-5247.08/1
M2-5240.05	M2-5243.08/1	M2-5247.08/1S
M2-5240.05/1	M2-5243.08/1S	M2-5250.05
M2-5240.05/1S	M2-5243.09	M2-5250.05/1
M2-5240.06	M2-5243.09/1	M2-5250.05/1S
M2-5240.06/1	M2-5243.09/1S	M2-5250.06
M2-5240.06/1S	M2-5243.11	M2-5250.06/1
M2-5240.07	M2-5243.11/1	M2-5250.06/1S
M2-5240.07/1	M2-5243.11/1S	M2-5250.07
M2-5240.07/1S	M2-5245.05	M2-5250.07/1
M2-5240.08	M2-5245.05/1	M2-5250.07/1S
M2-5240.08/1	M2-5245.05/1S	M2-5250.08
M2-5240.08/1S	M2-5245.06	M2-5250.08/1
M2-5240.09	M2-5245.06/1	M2-5250.08/1S
M2-5240.09/1	M2-5245.06/1S	M2-5250.09
M2-5240.09/1S	M2-5245.07	M2-5250.09/1
M2-5240.11	M2-5245.07/1	M2-5250.09/1S
M2-5240.11/1	M2-5245.07/1S	M2-5250.11
M2-5240.11/1S	M2-5245.08	M2-5250.11/1
M2-5240.13	M2-5245.08/1	M2-5250.11/1S
M2-5240.13/1	M2-5245.08/1S	M2-5250.13
M2-5240.13/1S	M2-5245.09	M2-5250.13/1
M2-5240.15	M2-5245.09/1	M2-5250.13/1S
M2-5240.15/1	M2-5245.09/1S	M2-5250.15
M2-5240.15/1S	M2-5245.11	M2-5250.15/1
M2-5240.17	M2-5245.11/1	M2-5250.15/1S
M2-5240.17/1	M2-5245.11/1S	M2-5250.17
M2-5240.17/1S	M2-5245.13	M2-5250.17/1
M2-5240.19	M2-5245.13/1	M2-5250.17/1S
M2-5240.19/1	M2-5245.13/1S	M2-5250.19
M2-5240.19/1S	M2-5245.15	M2-5250.19/1
M2-5243.05	M2-5245.15/1	M2-5250.19/1S
M2-5243.05/1	M2-5245.15/1S	M2-5255.07
M2-5243.05/1S	M2-5247.06	M2-5255.07/1
M2-5243.06	M2-5247.06/1	M2-5255.07/1S
M2-5243.06/1	M2-5247.06/1S	M2-5255.08
M2-5243.06/1S	M2-5247.07	M2-5255.08/1
M2-5243.07	M2-5247.07/1	M2-5255.08/1S

Art. No.
M2-5255.09
M2-5255.09/1
M2-5255.09/1S
M2-5255.11
M2-5255.11/1
M2-5255.11/1S
M2-5255.13
M2-5255.13/1
M2-5255.13/1S
M2-5255.15
M2-5255.15/1
M2-5255.15/1S
M2-5255.17
M2-5255.17/1
M2-5255.17/1S
M2-5255.19
M2-5255.19/1
M2-5255.19/1S
M2-5265.07
M2-5265.07/1
M2-5265.07/1S
M2-5265.08
M2-5265.08/1
M2-5265.08/1S
M2-5265.09
M2-5265.09/1
M2-5265.09/1S
M2-5265.11
M2-5265.11/1
M2-5265.11/1S
M2-5265.13
M2-5265.13/1
M2-5265.13/1S
M2-5265.15
M2-5265.15/1
M2-5265.15/1S
M2-5265.17
M2-5265.17/1
M2-5265.17/1S
M2-5265.19

Art. No.
M2-5265.19/1
M2-5265.19/1S
M2-5268.05
M2-5268.05S
M2-5269.06

## RCI

Art. No.	Art. No.
M2-3119	M2-3296
M2-3119S	M2-3296S
M2-3129	M2-3306
M2-3129S	M2-3306S
M2-3139	M2-3316
M2-3139S	M2-3316S
M2-3149	M2-3326
M2-3149S	M2-3326S
M2-3156	M2-3336
M2-3156S	M2-3336S
M2-3159	M2-3346
M2-3159S	M2-3346S
M2-3166	M2-3459
M2-3166S	M2-3459S
M2-3169	M2-3469
M2-3169S	M2-3469S
M2-3176	
M2-3176S	
M2-3186	
M2-3186S	
M2-3196	
M2-3196S	
M2-3206	
M2-3206S	
M2-3216	
M2-3216S	
M2-3226	
M2-3226S	
M2-3236	
M2-3236S	
M2-3246	
M2-3246S	
M2-3256	
M2-3256S	
M2-3266	
M2-3266S	
M2-3276	
M2-3276S	
M2-3286	
M2-3286S	

## Instruments

Art. No.
A-2045
M-2009
M-2019
M2-2000
M2-2001
M2-2005
M2-2006
M2-2007
M2-2016
M2-2026
M2-2040
M2-2116
M2-2158
M2-2198
M2-2260
M2-2260.1
M2-4667
M2-4668
M2-4669
M2-4671

MANDIBLE2-01010001\_v1/© 2021-01, Medartis AG, Switzerland. All technical data subject to alteration.

#### **MANUFACTURER & HEADQUARTERS**

Medartis AG | Hochbergerstrasse 60E | 4057 Basel/Switzerland  
P +41 61 633 34 34 | F +41 61 633 34 00 | [www.medartis.com](http://www.medartis.com)

#### **SUBSIDIARIES**

Australia | Austria | Brazil | China | France | Germany | Japan | Mexico | New Zealand | Poland | Spain | UK | USA

For detailed information regarding our subsidiaries and distributors, please visit [www.medartis.com](http://www.medartis.com)



Disclaimer: This information is intended to demonstrate the Medartis portfolio of medical devices. A surgeon must always rely on her or his own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. Medartis is not giving any medical advice. The devices may not be available in all countries due to registration and/or medical practices. For further questions, please contact your Medartis representative ([www.medartis.com](http://www.medartis.com)). This information contains CE-marked products.  
For US only: Federal law restricts this device to sale by or on the order of a physician.