

medartis

PRECISION IN FIXATION

SURGICAL TECHNIQUE

CMX MODUS 2 Mandible



CMX

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For further information on CMX, please visit www.medartis.com.

Introduction

Product Materials

CMX Custom-Made Devices

All CMX MODUS 2 Mandible plates are made of pure titanium (ASTM F67). The titanium material used is biocompatible, corrosion-resistant and non-toxic in a biological environment.

All CMX MODUS 2 Mandible guides and bone models are made of PA12 (Polyamide/Nylon 12). The polyamide used is biocompatible for the intended type and time of application during surgery (see "Intended Purpose") and non-toxic in a biological environment.

Compatible MODUS 2 Screws and Instruments

All MODUS 2 screws are made of titanium alloy (ASTM F136, ISO 5832-3). The MODUS 2 instruments are made of stainless steel, PEEK, aluminum or titanium.

Notice

Alongside the CMX MODUS 2 Mandible plates and guides, the necessary MODUS 2 screws and the corresponding twist drills as well as the necessary instruments must be available and sterile. These are not included in the CMX delivery.

Intended Purpose

Plates

CMX MODUS 2 Mandible plates are intended for the positionally and functionally stable fixation of fractures and osteotomies and for reconstructive procedures in craniomaxillofacial surgery on a specific patient.

CMX MODUS 2 Mandible plates are indicated for reconstructive procedures and for bridging load-bearing bone segments in the mandible. This does not include the replacement of the condylar head.

Guides

CMX MODUS 2 Mandible guides are intended for use as surgical instruments for guiding purposes when marking, drilling or sawing the bone of a specific patient.

Bone Models

CMX MODUS 2 Mandible bone models are intended to illustrate preoperative and/or postoperative anatomical structures of a specific patient.

Contraindications

- Preexisting or suspected infection at or near the surgical site
- Known allergies and/or hypersensitivity to product materials
- Inferior or insufficient bone quality to securely anchor the implant or the guide
- Patients who are incapacitated and/or uncooperative during the treatment phase
- Blocking of growth plates with plates and screws

Color Coding

CMX MODUS 2 Mandible Plates, Guides and Bone Models

CMX MODUS 2 Mandible plates, guides and bone models are not color coded.

Compatible MODUS 2 Screws and Instruments

Screw Diameter	Color Code
2.0	Blue
2.3	Brown
2.5	Purple
Screws gold	Cortical screws (fixation)
Screws silver	TriLock screws (locking)
Screws green	SpeedTip screws (self-drilling) TriLock SpeedTip screws (locking and self-drilling)

Compatible MODUS 2 Screws

CMX MODUS 2 Mandible plates can be combined with the following **MODUS 2 screws**:

- 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.

CMX MODUS 2 Mandible guides can be combined with the following **MODUS 2 screws**:

- 2.0 Cortical Screws, HexaDrive 6
- 2.0 SpeedTip Screws, HexaDrive 6

Symbols



Use of the MODUS 2 Instruments

Drilling

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

Screw Diameter	Color Code
2.0	Blue
2.3	Brown
2.5	Purple

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

Hole Drilling for Screws Ø 2.0 mm



M2-3119



M2-3139



M2-3159

Core hole drills with Ø 1.5 mm = one colored ring

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

Hole Drilling for Screws Ø 2.3 mm



M2-3176



M2-3196

Core hole drills with Ø 1.9 mm = one colored ring

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

Hole Drilling for Screws Ø 2.5 mm



M2-3236



M2-3256

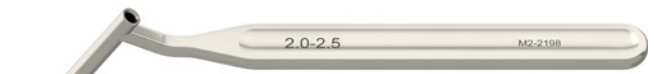
Core hole drills with Ø 2.0 mm = one colored ring

Only twist drills with one colored ring (core hole drills) may be used for CMX MODUS 2 Mandible.

Drilling with Drill Guide

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

After positioning the plate, insert the drill guide and the twist drill into the screw hole. Drilling with a drill guide protects surrounding tissue from direct contact with the drill. The drill guide also serves to limit the pivoting angle.



M2-2198
2.0–2.5 Drill Guide

Twist drills for use in combination with the drill guide:

Screw Diameter	Color Code
----------------	------------

2.0	Blue
2.3	Brown
2.5	Purple

Dental	Stryker	
M2-3459	M2-3469	25 mm

Dental	Stryker	
M2-3216	M2-3226	25 mm

Dental	Stryker	
M2-3276	M2-3286	25 mm

Hole Drilling for Screws Ø 2.0 mm



M2-3459

Core hole drills with Ø 1.5 mm = one colored ring

Hole Drilling for Screws Ø 2.3 mm



M2-3216

Core hole drills with Ø 1.9 mm = one colored ring

Hole Drilling for Screws Ø 2.5 mm

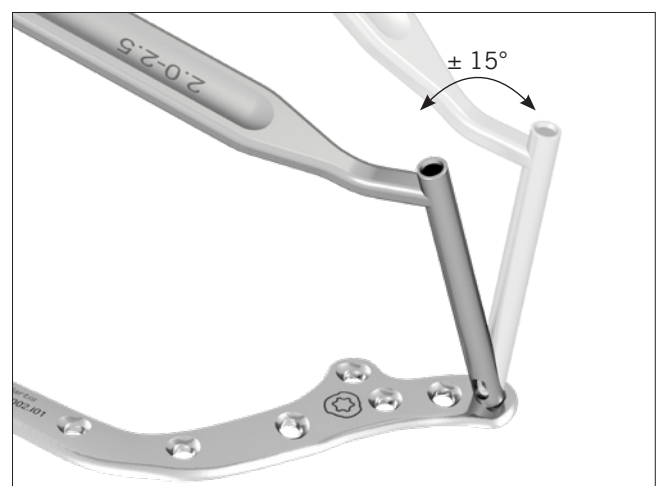


M2-3276

Core hole drills with Ø 2.0 mm = one colored ring

Warning

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



Assigning the Screw Length

The 2.0–2.5 depth gauge (M2-2260) is used to assign 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.

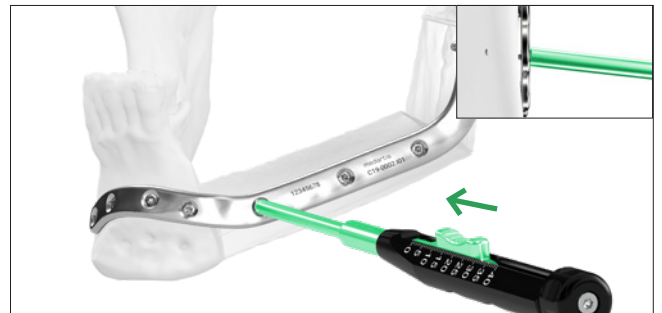


The caliper of the depth gauge has a hooked tip that is either inserted in the bottom of the hole or is used to catch the far cortex of the bone.

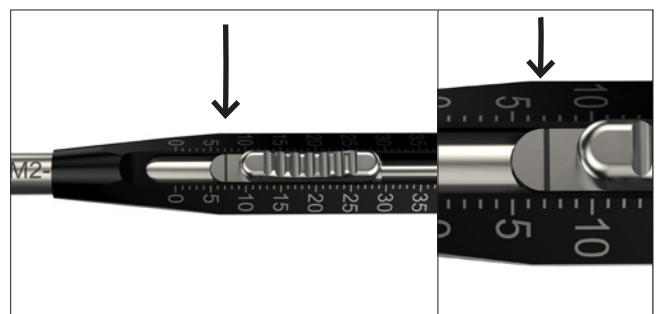
When using the depth gauge, the caliper stays static and only the slider is adjusted.



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 HexaDrive self-holding system.



M2-2001
Screwdriver Handle, Type 2



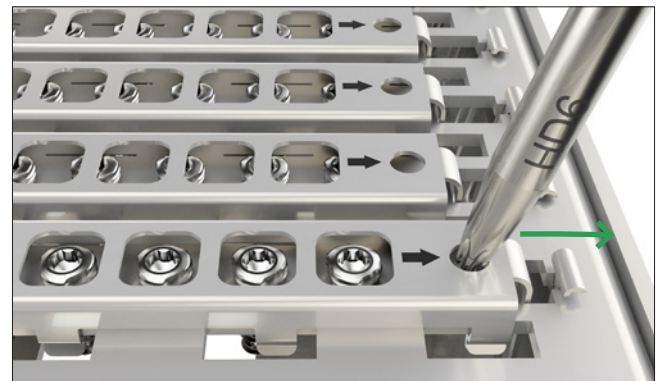
M2-2040
Screwdriver Handle, Type 3



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.



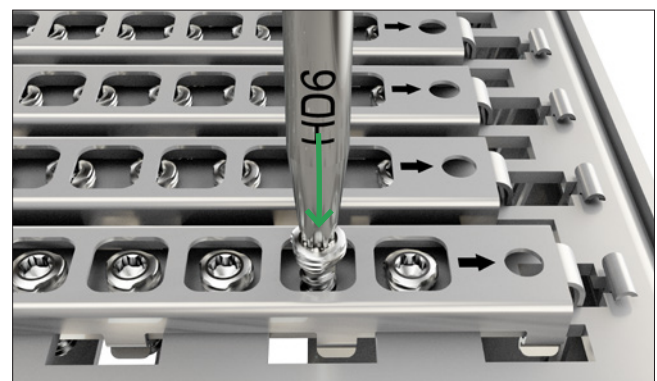
To remove the screws from the implant container, insert the appropriately color-coded screwdriver blade perpendicularly into the screw head of the desired screw and pick up the screw with axial pressure.

Notice

The screw will not hold without axial pressure.

Caution

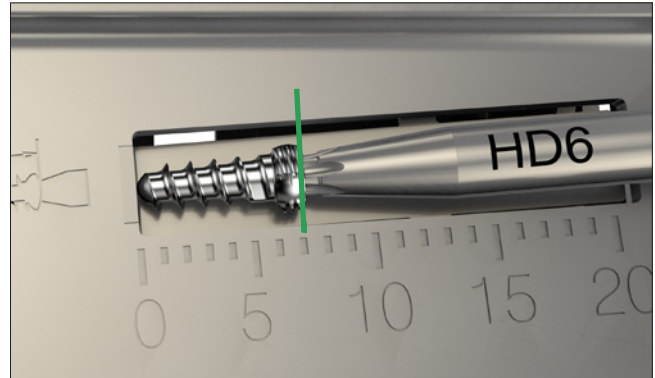
Vertically extract the screw from the compartment. Picking up the screw repeatedly may lead to permanent deformation of the self-retaining area of the HexaDrive inside the screw head. Therefore, the screw may no longer be able to be picked up correctly. In this case, a new screw has to be used.



Notice

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.

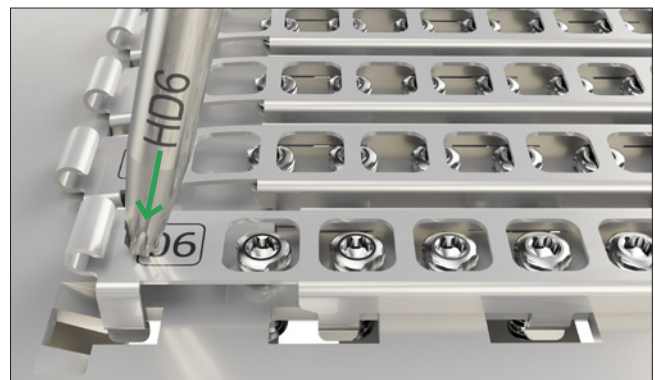
**Notice**

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.



Surgical Technique

Use of the CMX MODUS 2 Mandible Guides

Placing and Fixing the Guide

Before placing the guide on the bone, ensure that the bone is fully exposed to ensure an optimum contact surface.

Caution

The guide itself features orientation markings. These must be taken into account when using the guide. Please refer to the case-specific documents for further details.

To identify the previously defined position of the guide on the bone, it should be placed in various positions. The correct position can be determined based on the fit with the bone. Illustrations are provided in the case-specific documentation as a guide.



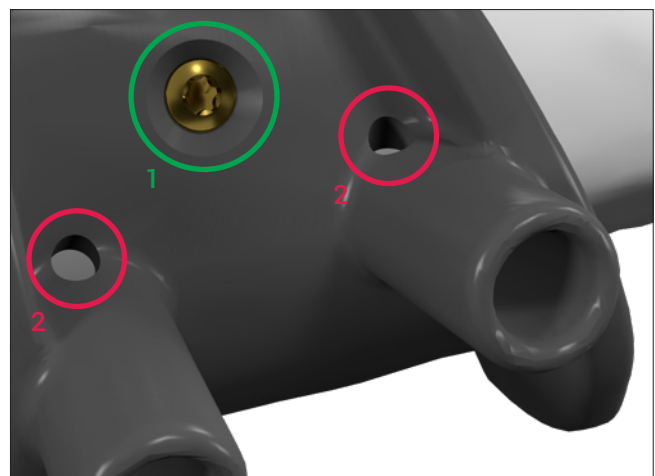
Once the defined position is found, the guide is fixed in the designated drill holes with 2.0 cortical screws (1).

Caution

Irrigation ports (2) may not be used to fix the guide.

Caution

Throughout the application it is important to ensure that no excess force is applied to the product as this could cause damage.



Drilling the Screw Holes for the Plate

After the guide is safely fixed to the bone, all screw holes are drilled. Use the drill guide (M2-2198) and the corresponding twist drill for this purpose. This helps to ensure precise drilling of the holes and to reduce abrasion.

The irrigation ports are used for rinsing and cooling during the drilling process.



Resection of the Mandible and the Donor Region

When all screw holes are predrilled, the bone is resected. The guide can be removed after the resection.

Caution

Avoid drilling or sawing into the guide as this can cause abrasion on the guide. The abrasive material should not enter the tissue. The surgical site must be thoroughly flushed during and after drilling and sawing and any particles must be suctioned away.

The guide may not be adapted either before or during surgery.



Fixing the Plate

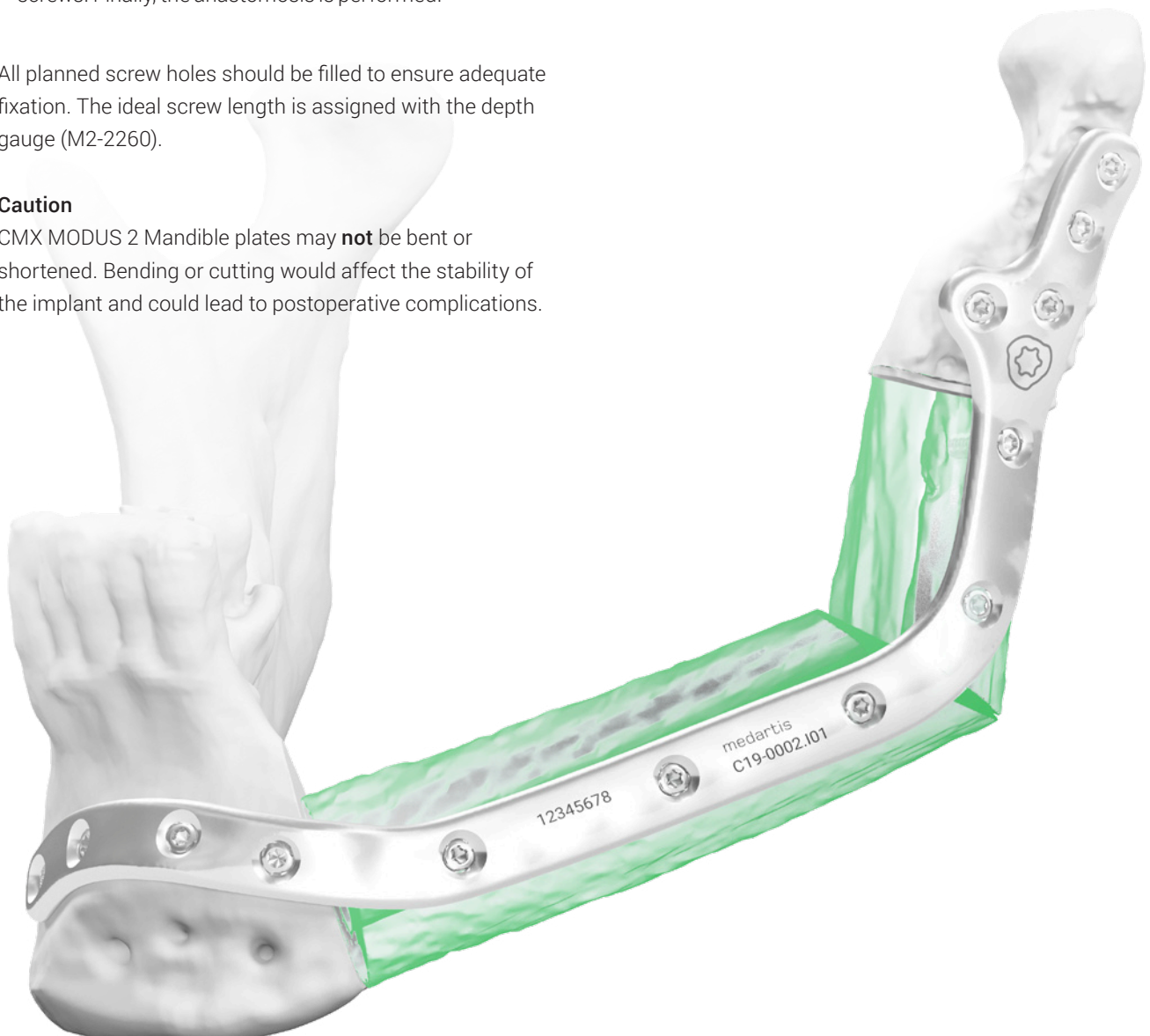
After resection of the mandible and the donor region, there are three possible procedures:

- The bone transplants are fixed to the CMX MODUS 2 Mandible plate. The construct is then fixed to the mandible with the planned screws.
- The CMX MODUS 2 Mandible plate is fixed to the mandible. The transplants are then inserted and the anastomosis is performed. Finally, the transplants are fixed to the plate with the planned screws.
- The CMX MODUS 2 Mandible plate is fixed to the mandible. The transplants are then fixed to the plate with the planned screws. Finally, the anastomosis is performed.

All planned screw holes should be filled to ensure adequate fixation. The ideal screw length is assigned with the depth gauge (M2-2260).

Caution

CMX MODUS 2 Mandible plates may **not** be bent or shortened. Bending or cutting would affect the stability of the implant and could lead to postoperative complications.



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.

Caution

When removing the screws, ensure that any bone ingrowth in the screw head has been removed, that the screwdriver/ screw head connection is aligned in axial direction, and that a sufficient axial force is used between blade and screw.

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

TriLock Locking Technology

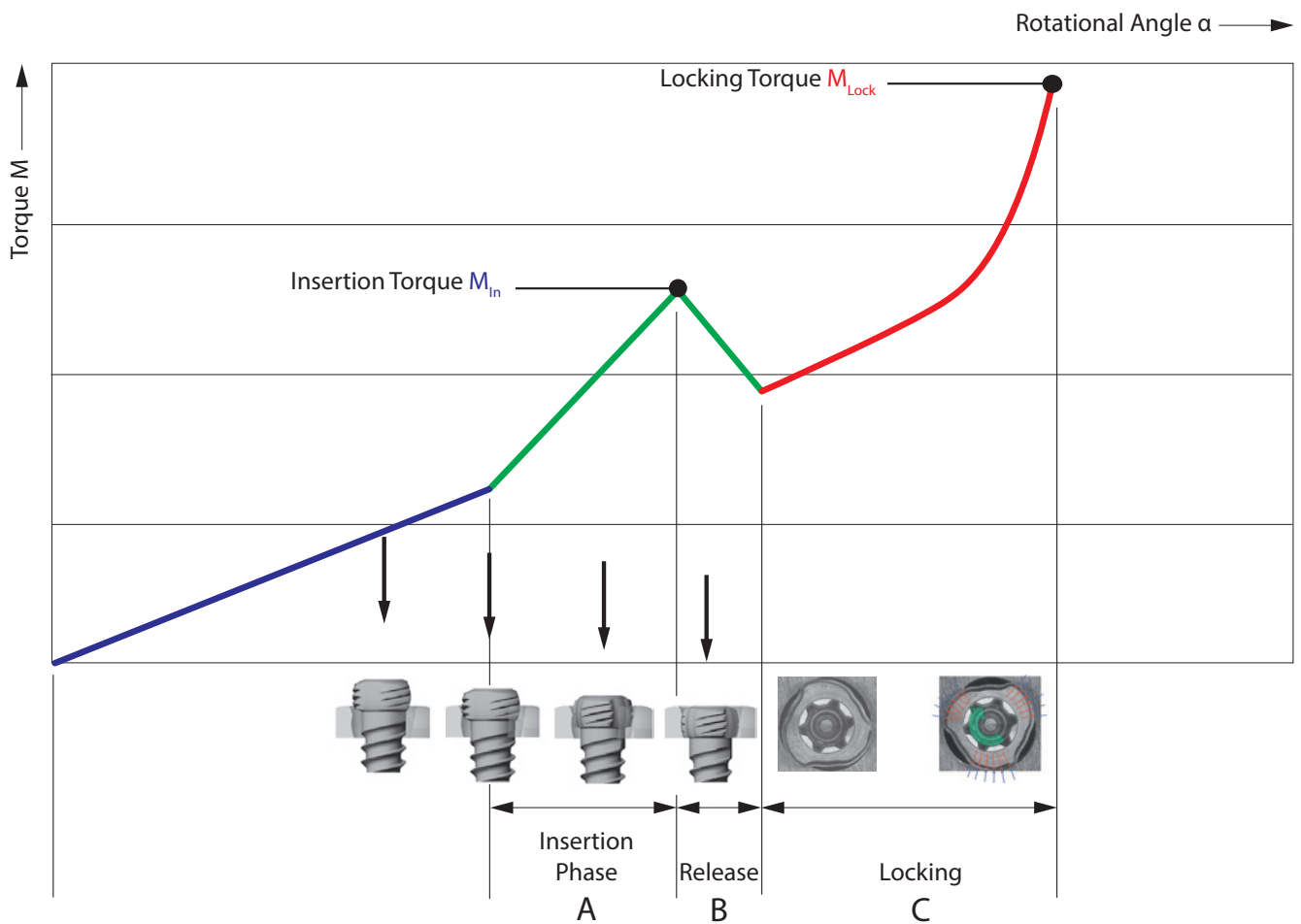
Correct Application of the TriLock Locking Technology

The screw is inserted through the plate hole into a predrilled 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

Correct locking occurs only when the screw head is locked flush with the locking contour (fig. 1 + 3).

After having reached the locking torque (MLock), do not further tighten the screw, otherwise the locking function cannot be guaranteed anymore.

However, if there is still a noticeable protrusion (fig. 2 and 4), the screw head has not completely 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.

Correct: LOCKED

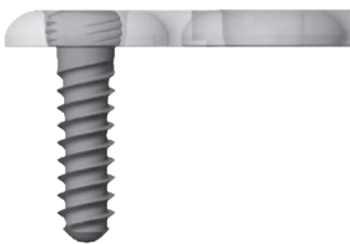


Figure 1

Incorrect: UNLOCKED

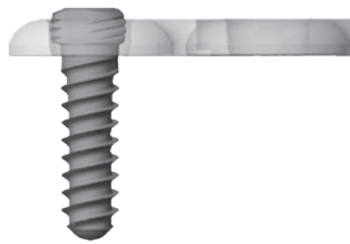


Figure 2

Correct: LOCKED

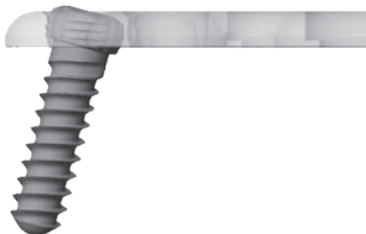


Figure 3

Incorrect: UNLOCKED



Figure 4

Appendix

CMX MODUS 2 Mandible Plates, Guides and Bone Models

For all CMX MODUS 2 Mandible plates, guides and bone models according to the case-specific design freeze document see CMX Portal at cmx.medartis.com.

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