medartis

CASE PLANNING AND INSTRUCTIONS

# CASE C26-0001


CMX Personalized Solutions

# Contents



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



## Symbols

 HexaDrive

 SpeedTip

 TriLock

 Centric

 Direction of compression

# Case Details / Prescription

### Patient Information

| Patient Acronym | Date of Birth (DD.MM.YYYY) |
|---|---|
| Lq65yq<br>See "CMX Portal" for further patient information | 22.07.1925 |

### Qualified Prescriber (Physician)

| First Name | Last Name |
|---|---|
| P | PHYSICIAN |

### Case

| Case ID | Clinical Reference (if available) |
|---|---|
| C26-0001 | HGx61B7ze3s2Tf |

| Indication | Date of Intervention (DD.MM.YYYY) |
|---|---|
| CMX Orthognathics | 19.03.2018<br>The personalized medical devices should be used on the intended date of intervention, at the latest. Any deviation from the date is the sole responsibility of the prescribing physician. |

| Affected Side | Date of Medical Image (DD.MM.YYYY) |
|---|---|
| Not applicable | 21.01.2018<br>The personalized medical devices are based on the provided data. If the patient's anatomy has changed, e.g. due to tumor-growth, the personalized medical devices may no longer fit for the intended purpose. |

# Product Overview

The following products have been validated and are approved by the named physician and are ordered from Medartis. The images shown below do not represent the produced parts, but their digital representation.

**Patient-Matched Medical Devices (PMD)**

| Article No | Image | Description | Specification |
|---|---|---|---|
| 123 | | test1-spec | test1-spec |

**Custom-Made Medical Devices (CMD)**

| Article No | Image | Description | Specification |
|---|---|---|---|
| 456 | | test2-spec | test2-spec |

Custom-made medical devices are supplied with the "Statement Custom-Made Medical Devices". This must always be handed over to the patient.

# Additional Required Products

Alongside the custom-made medical devices, the necessary plates, 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.

| Pieces/Pkg | Article No | Image | Description | Specification |
|---|---|---|---|---|
| 5 | A-4750.102 | | narrow, right, short | ADAPTIVE II Plate |
| 1 | A4242-32.XX | | Screw Example | Compression Screw |

# Detailed Information

## Instruction Card hLUb



### Example instruction subtitle

Example content 1

### Subtitle2

Content 2

# Instruction Card tojJqtvTA3

## Example instruction subtitle

Example content 1

## Subtitle2

Content 2

# Warnings, Cautions and Notices

For application-specific cautions and warnings related to APTUS/MODUS 2 systems, it is mandatory to consult the surgical technique (ifu.medartis.com) of the corresponding product system being used.

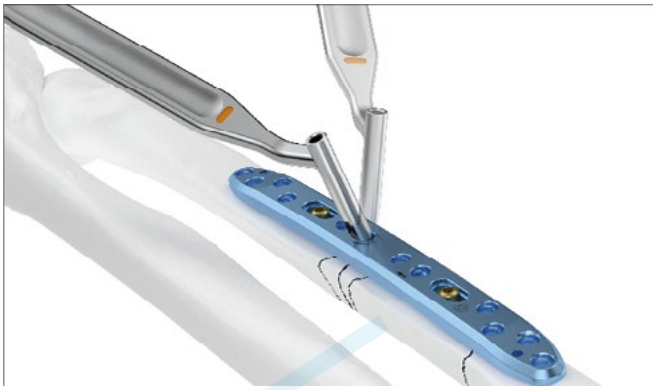
**Warning**
The supplied implants, guides, bone models and positioning aids are personalized medical devices and are intended for SINGLE USE ONLY on a SPECIFIC PATIENT and are not designed to be reused. All components are delivered NON-STERILE and must be cleaned, disinfected and steam sterilized before first use according to the IFU and the Instructions for Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products.

**Warning**
All twist drills must always be guided by a drill guide which is listed in chapter Additional Required Products. Using the drill guide prevents damage to the screw hole and protects the surrounding tissue from direct contact with the drill. The drill guide also serves to limit the pivoting angle.

**Warning**
This symbol marks the end of the drill guide used for centric drilling. This end is used for all fixation and TriLock holes, as well as for lag screws.

**Warning**
The arrow "⟶" indicates the direction of the compression and must always point towards the fracture/osteotomy line.

Warning
For TriLock plates ensure that the screw holes are predrilled with a pivoting angle of no more than ±15°. For this purpose, the drill guides feature a limit stop of ±15°. A predrilled pivoting angle of >15° no longer allows the TriLock screws to correctly lock in the plate.



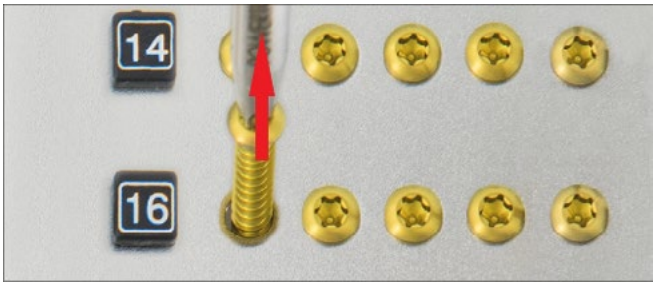
Warning
When using TriLock screws, make sure correct locking has been achieved (see chapter TriLock Locking Technology in Instructions for Use).

Warning
It is important to use the correct depth gauge for the corresponding screw diameter, which is indicated on the slider and handle of the depth gauge.

Warning
Depending on the level of correction, some cases may require bone grafting between the remaining patient bone fragments, autologous bone is recommended. Insufficient bone grafting can increase the risk of breakage of the plate.

Warning
Unless there is a removable tag, the product shall not be modified prior to use, otherwise personalized medical devices cannot be used as intended.

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.



**Caution**
The CMX guide itself features orientation markings. Additionally, there are consecutive numberings in case more than one CMX guide is needed. These must be taken into account when using the guide. To find the correct position of the guide on the bone, place it according to the anatomical fit.

Please refer to the case details.

**Caution**

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


CMX guide with K-wire or cortical screw fixation (1) and irrigation ports (2)

**Caution**
Throughout the application it is important to ensure that no excess force is applied to the personalized medical device as this could cause damage.

**Caution**
Avoid drilling or sawing into the guide or positioning aid. Manipulation of the guide or positioning aid may cause abraded particles which 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.

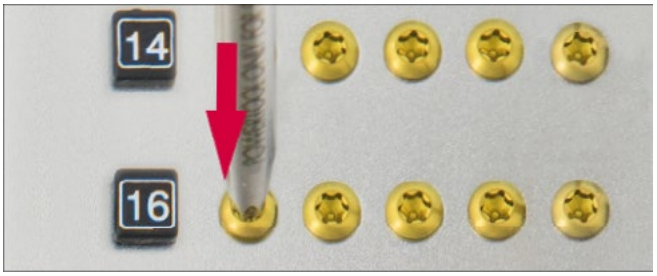
**Caution**
After the operation, ensure that all the K-wire sleeves specified in chapter "Product Overview", are accounted for.

**Caution**
To ensure a precise osteotomy, the saw blade must have the minimum dimensions stated in chapter Additional Required Products.

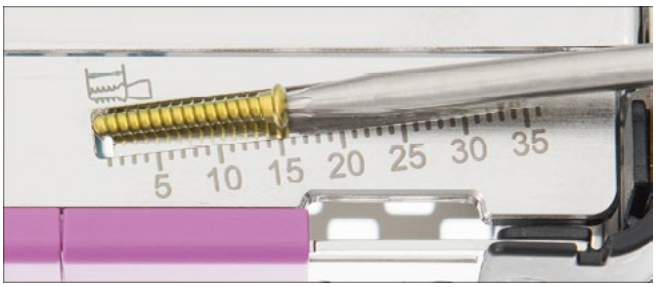
**Caution**
The article name of the personalized medical device may include a reference to the system size. Depending on the product, this may differ from the system size of the additionally required standard products listed in the “Case Planning and Instructions”.

**Notice**
Alongside the personalized medical devices, the necessary plates, 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.

**Notice**
The screw will not hold without axial pressure.




**Notice**
Check the screw length and diameter at the scale of the measuring module. The screw length is determined at the end of the screw head.



**Notice**
Check 1.5 SpeedTip screws in the hole Ø 1.8.
Check 2.0 SpeedTip screws in the hole Ø 2.3.


**Notice**
Do not drill further than the near cortex.

## Indication-specific warnings, cautions and notices:

**Warning for 2.5/2.8 system**
Do not use the orange color-coded 2.5/2.8 screwdriver blade (A-2013) with the large handle (A-2074) or with the T-handle (A-2075), as the high forces generated can damage the locking of the screw head in the plate hole.

A-2075
T-Handle with Quick Connector, AO

**Warning for Wrist**
Insert at least three TriLock screws into the most distal row and two TriLock screws into the second distal row.

**Caution for Forearm**
All APTUS screws are self-tapping. In case of very hard bone, especially in the shaft region of the radius or ulna, it may be necessary to use the 2.8 tap (A-3839) to reduce the insertion torque of the 2.8 mm screws.

A-3839
2.8 Tap

**Caution for 3.5 system**
The T-handle (A-2075) must always be used to lock 3.5 TriLock screws.

### Caution for Ankle

Overdistraction could damage the bone and/or the K-wires. If the forceps are placed at a too high distance from the one, the K-wires may possibly bend.

### Warning for removable tags

The removal must not be carried out near or on the patient. The removal of the marking tag may create sharp edges and/or debris.

### Notice for 2.5 system

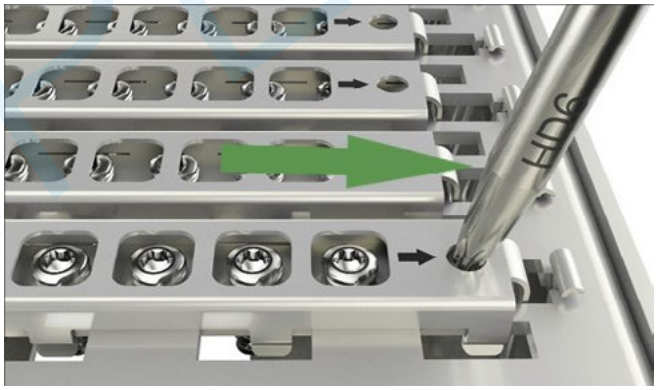
The double-ended drill guide for lag screws (A-2721) is used only to perform the classic lag screw technique according to AO/ASIF.

A-2721

2.5 Drill Guide for Lag Screws

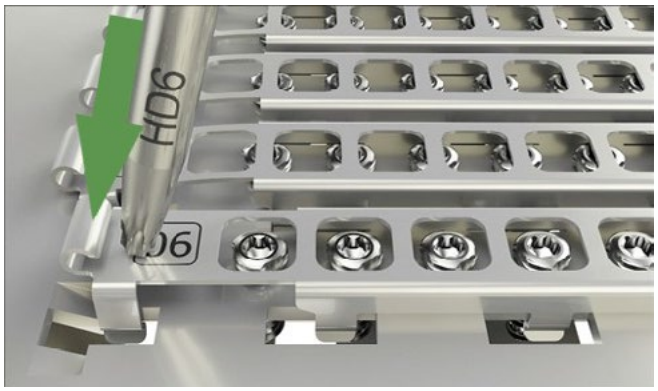
### Notice for MODUS 2

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.



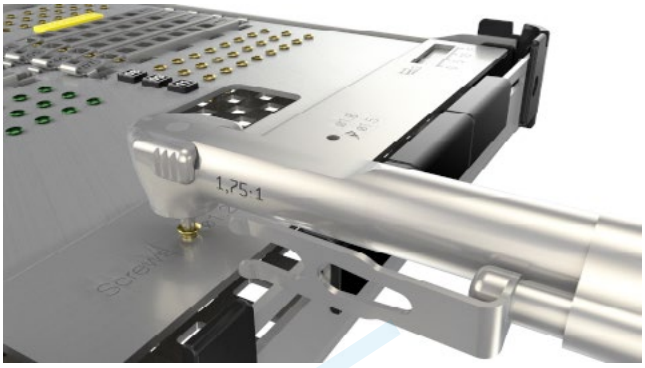

### Notice for MODUS 2

After removing screws up to 7 mm in length, 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 automatically.

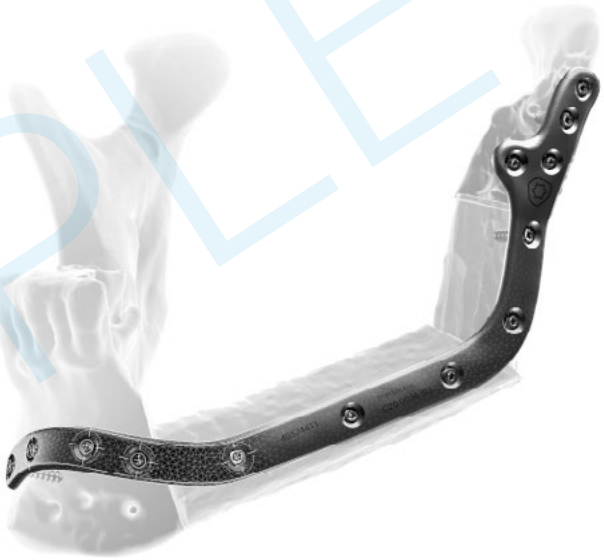


Screws secured with a securing element cannot be directly removed with the 90° screwdriver.

These 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.



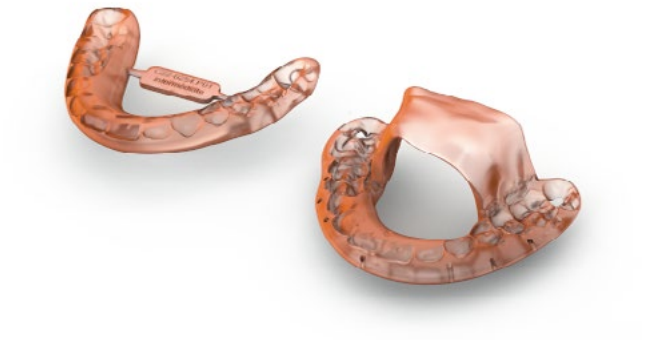

Caution for MODUS 2
CMX MODUS 2 Mandible plates may not be bent or cut. Bending or cutting would affect the stability of the implant and could lead to postoperative complications.



Notices for positioning aid
Due to sterilization, the color of the positioning aid might slightly change. The color change is expected for the used material and does not affect the product performance.

The wiring and positioning aid are removed according to the treatment plan. The positioning aid should not remain in the patient's mouth for more than 30 days.

A ligature wire with a maximum diameter of 0.7 mm may be used to secure the positioning aid between the upper and lower dentition of the patient.



Warnings for positioning aid
Some superficial cracking on the positioning aids is expected. However, if such cracks compromise structural integrity or pose a risk of fragment detachment, the device should no longer be used.

Please refer to the positioning aid or the marking tag to determine whether it is intended for intermediate or final positioning.

Remove the marking tag from the positioning aid prior to use.

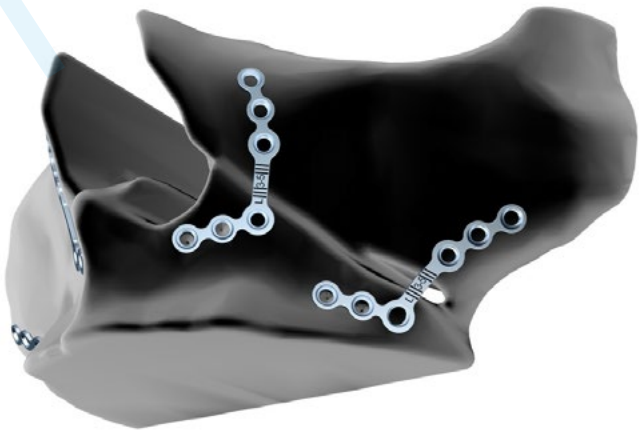
The removal must not be performed near the patient. Avoid sharp edges. Any sharp edges must be removed or rounded off.

Unless there is a removable tag, the positioning aid must not be modified prior to use.

Do not damage the positioning aid while cutting the ligature wires.

The patient shall be instructed to stop use the positioning aid if there is any visible damage. An immediate consultation with the treating surgeon is required.

Notice for CMX MODUS 2 Orthognathics Bone Model
When using the CMX bone model to prebend MODUS 2 orthognathic plates, fix the plate to the model using 1.5 SpeedTip screws in the reference holes for the final bending check. Do not reuse the SpeedTip screws which have been used on the bone model intraoperatively.





Explantation

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 an axial direction, and that a sufficient axial force is used between the blade and the screw.

Only original Medartis instruments are recommended for the explantation of Medartis implants.

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