



L1[®] Smart3D

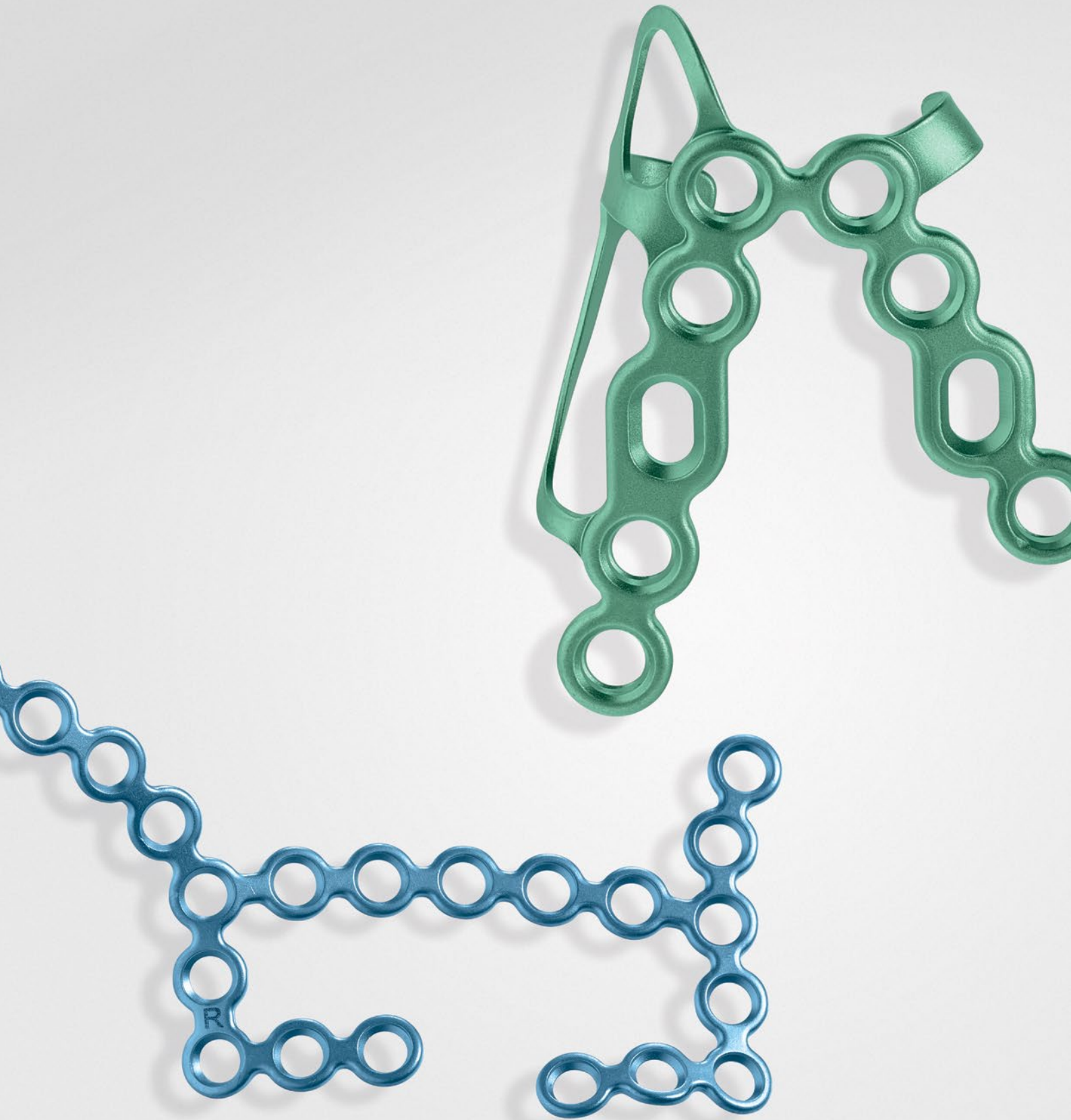
Anatomically pre-shaped
midface and mandibular implants



Oral and maxillo-facial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

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L1® Smart3D

The Concept

The complex structures in the midface consist of strong bony abutments and thin bone lamellae which provide a stable, three-dimensional frame. Nevertheless, fractures repeatedly occur at typical positions following the application of greater force.

Restoration of these structures in both functional and aesthetic terms are demanding tasks for the surgeon. In the fields of traumatology and orthopaedics, anatomically pre-shaped plates have become indispensable and have been the gold standard for the treatment of fractures for many years. To match the complexity of the facial skeleton, we too are committed to offering anatomically pre-shaped plates for oral and maxillofacial surgery.

With the L1® Smart3D osteosynthesis plates, we have succeeded in creating a range of products for the holistic treatment of fractures in the midface and mandible.

Feature, Function and Benefit



The plate range of the L1® Smart3D plates offers a comprehensive selection of pre-shaped plates in different shapes for midface and mandibular osteosynthesis.

The anatomically preformed design of the plates are based on the calculated average surfaces derived from data of more than 125 anonymised patients.

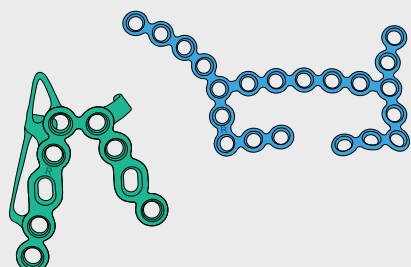
Two independent analyses to determine the necessary plate sizes have shown that a single plate size is sufficient to accommodate adult skeletal structures, regardless of age and sex.

Based on these analyses, the L1®Smart3D osteosynthesis plates demonstrate the best possible accuracy of fit.

L1® Smart3D – Implants

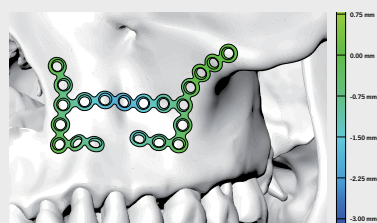
Feature and Function

Benefit



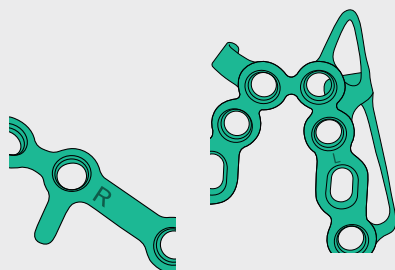
- Holistic portfolio of three-dimensional preformed Smart3D implants.
 - **L1® Midface Smart3D: Profile 0.6 mm**
 - **L1® Mandible Smart3D: Profile 1.0 mm**

- Supplements the standard implants
- Holistic and efficient treatment of midfacial and mandibular fractures



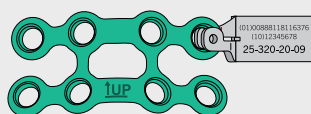
- Based on the average surfaces generated from more than 125 patient datasets of different genders and ethnicities
- Standard size per plate type as a result of several dissertations

- High precision fit
- Clearly structured portfolio
- Unisex plates



- Functional plate design

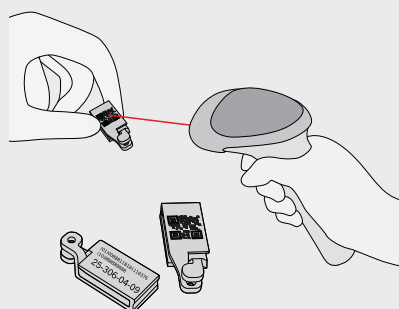
- Option of reduction against the plate
- Guide bracket and hook as positioning and reduction aid



- Detachable ID tag with article number, batch number, GTIN number, and GS1 DataMatrix code

- Enables reading or digital recording of all the relevant data, even in the case of very small implants

- Batch retraceability for every single plate
- Simplified reordering



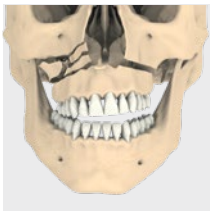
- DataMatrix code for scanning with a 2D code scanner

- Easy recording of all the implant data by scanning the DataMatrix code
- 100% batch retraceability and transparent, patient-related documentation

Step by Step to Optimal Care

Indications

In particular, the L1® Smart3D osteosynthesis implants are used to treat fractures in the midface and mandible. In addition, they can also be used for the fixation of osteotomies and for reconstructive surgery.



Midfacial trauma, osteotomies
and reconstructive surgery



Mandibular trauma, osteotomies
and reconstructive surgery



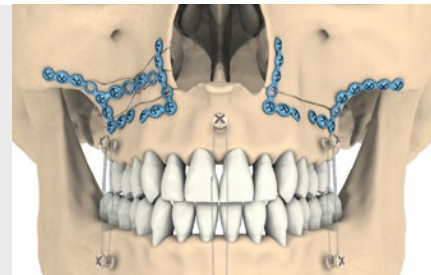
Surgical Techniques

1. Complex Le Fort I midface fracture

Pages 10 - 19

Restoration with three Smart3D-Midface plates:

- Zygomatic plate, profile thickness 0.6 mm
- Paranasal plate, profile thickness 0.6 mm
- Zygomatic paranasal plate, profile thickness 0.6 mm

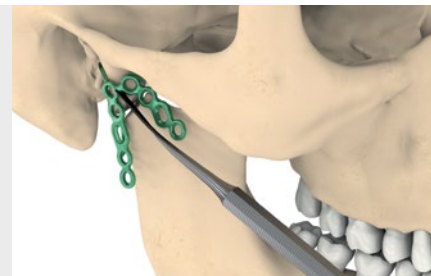


2. Fracture of the mandibular collum

Pages 20 - 29

Restoration with a Smart3D-Mandible plate

- Condylar plate, profile thickness 1.0 mm





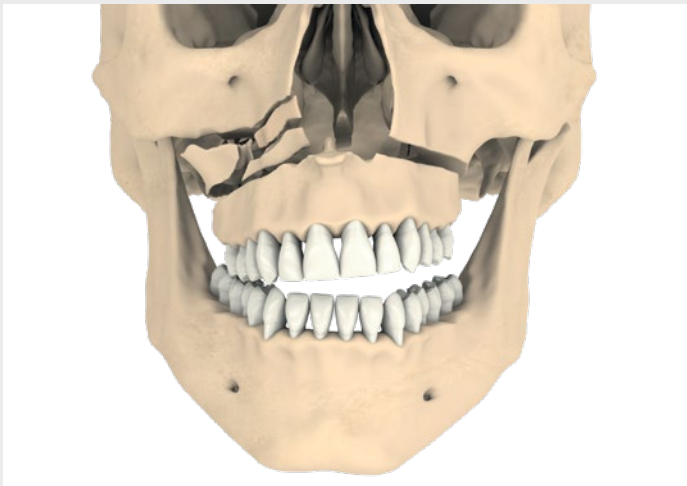
Preoperative planning

The X-ray shows a Le Fort I fracture with a unilateral comminuted fracture (right).



Positioning the patient

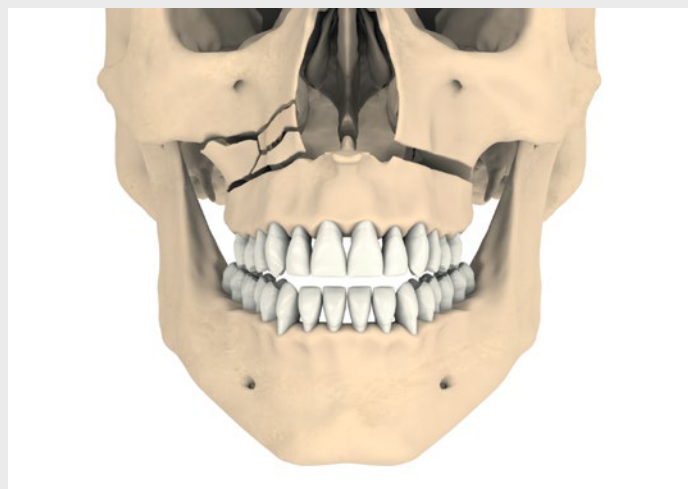
Place the patient in supine position on the operating table. Normally, a nasotracheal intubation is implemented.





1. Access

You can use the known standard approaches (e.g. vestibular) to access the midface. If present, you can utilise existing open lacerations as access point(s) to treat the fracture.



2. Mobilization

After exposing the fracture zone through the vestibular access, you must first mobilize the fragments to enable reduction.



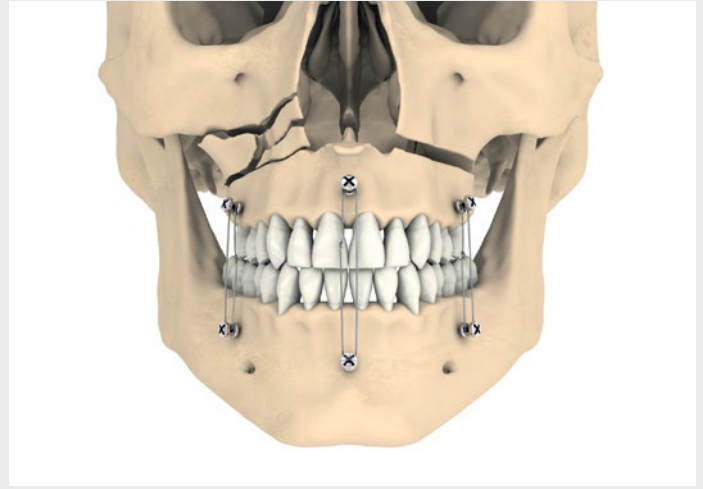
3. Reduction

There are various options to perform reduction of the maxilla.

Reduction with reduction forceps (e.g. 38-700-01-07, 48-360-01-07) lets you reduce the maxilla with great force. Make sure that the reduction forceps are positioned correctly so as not to compromise the row of upper teeth.

Note:

When using these instruments, you must take into account the patient's specific fracture pattern so that this does not lead to shearing at the base of the skull or the orbit and thus remove serious complications.

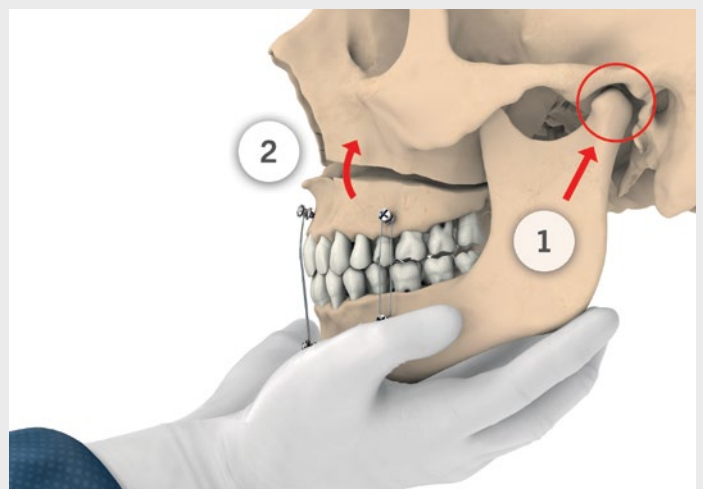


4. Maxillomandibular Fixation (MMF)

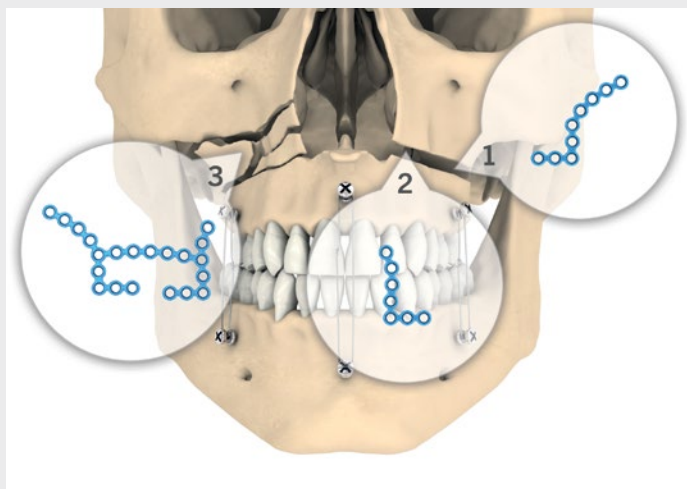
After mobilizing and reducing the fracture fragments, maxillomandibular fixation of the maxilla and mandible should be performed, for example, by using MMF screws.

Note:

If mandibular fractures are also present, these must be treated first.



To ensure that the condylar heads are securely seated in the glenoid fossae (1), push the entire maxillomandibular complex into the fossae and then rotate in the direction of the arrow until it contacts the maxilla (2).



5. Selection of osteosynthesis plates

The fracture fragments are fixated once you have accurately reduced the maxilla. In the present indication case, the following plates are used for the restoration by way of example:

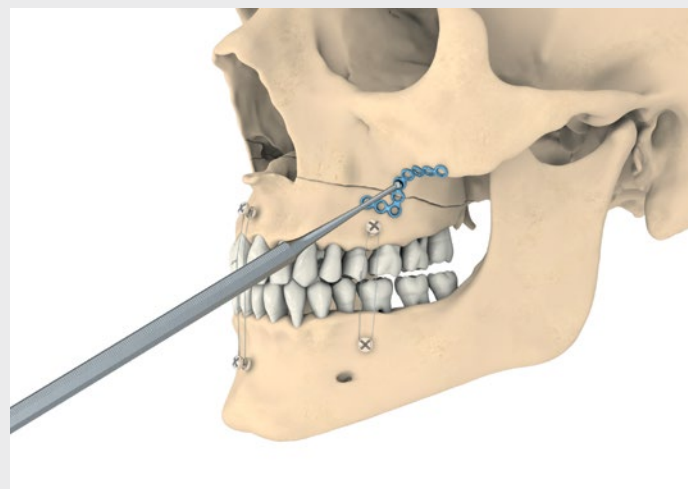
Linear fracture left:

1. Smart3D zygomatic plate
(t = 0.6 mm, 25-320-28-09/-71)

2. Smart3D paranasal plate
(t = 0.6 mm, 25-320-32-09/-71)

Comminuted fracture right:

3. Smart3D zygomatic paranasal plate
(t = 0.6 mm, 25-320-35-09/-71)

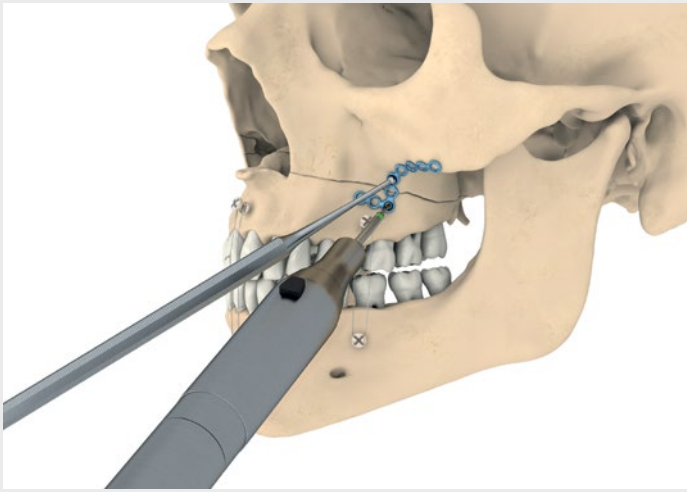


6. Positioning of the zygomatic plate (left, lateral)

As a first step, position the preformed zygomatic plate on the left side of the patient (linear fracture) over the crista zygomatica. The vertical portion of the plate is then placed on the most lateral part of the zygomatic process to allow you to implant the screws securely. The horizontal portion of the plate is placed along the alveolar bone. Exercise special care here not to harm the dental roots. At least two screws must lie below the fracture line.



Plate-holding instrument

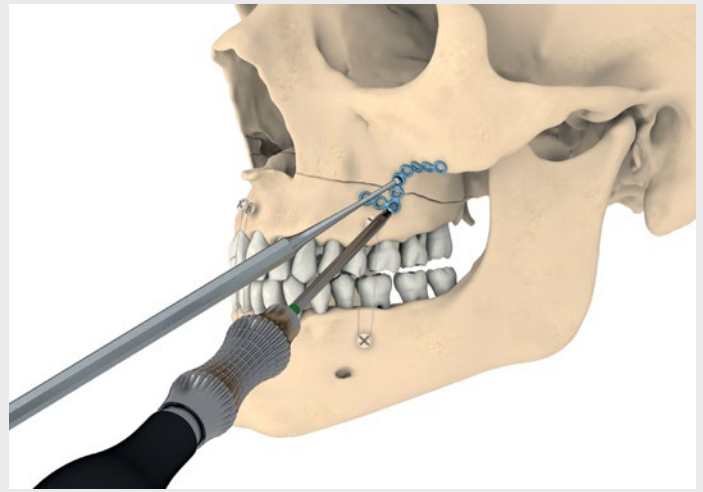


7. Drilling the first core hole

First, pre-drill the core hole with the corresponding drill bit. Drill bits for Ø 1.5-mm screws have a core hole diameter of 1.1 mm and are identified by a green ring. Please ensure that a drill bit with suitable stop length is selected.

Note:

Drill-free screws are also available, which you can screw into the bone without drilling prior.



8. Placement of the first screw

Ensure the correct screw diameter is selected using the measurement clip before inserting into the patient. Insert the first 1.5-mm maxDrive® standard screw (length 5 mm) into the unstable fragment of the maxilla. To do this, the self-retaining maxDrive® screw is picked up with the screwdriver, screwed in, and securely fixed.



Drill bit

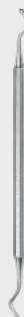


Plate-holding instrument



Plate-holding instrument



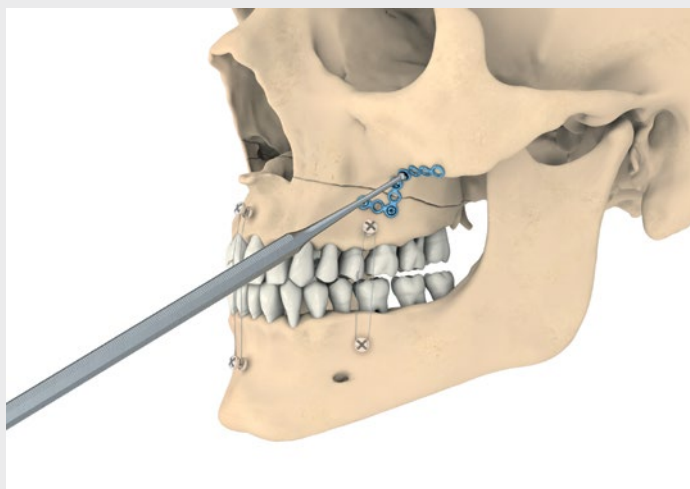
Screw measurement clip



Screwdriver handle

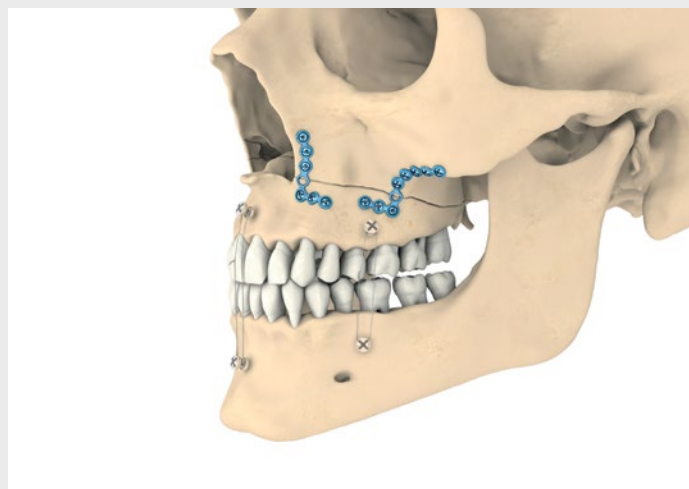


maxDrive® blade



9. Placement of further screws

Implant the second screw (see sequence) in the same way into the unstable fragment of the zygomatic fracture in order to keep the plate in the correct position. Fixate the plate in its position with the holding instrument while inserting further screws (see sequence). In this case, you need to implant at least two screws on either side of the fracture to provide rotational stability. Screw holes through which the fracture line passes or which are too close to the fracture line are not filled.



10. Fixation of the paranasal plate (left, medial)

Fixation of the medially located preformed paranasal plate and implantation of the screws is performed according to the procedure described in steps 6 - 9, whereby the first screws are again inserted in the unstable fragment area.

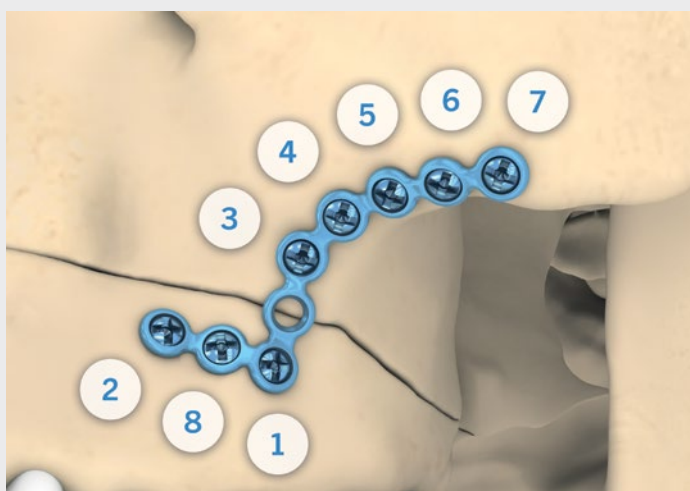


Plate-holding
instrument



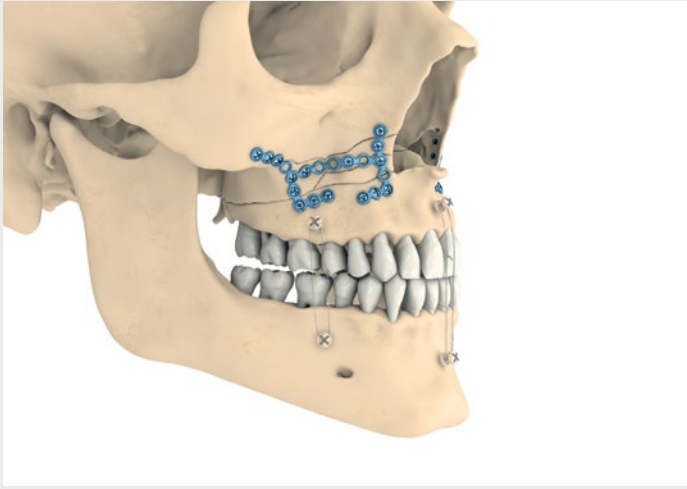
Screw measure-
ment clip



Screwdriver
handle

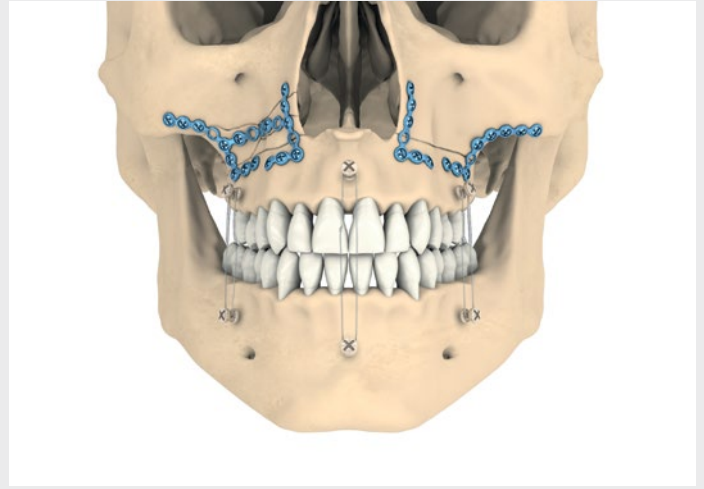


maxDrive®
blade



11. Fixation of the zygomatic paranasal plate (right)

Fixate the preformed zygomatic paranasal plate (see sequence) on the patient's right side (comminuted fracture) in the same manner as the two plates on the patient's left side.



12. Fixation of the facial fragments

After you have fixated the plate laterally and medially to the vertical abutments, you can securely fixate the fragments of the facial wall.

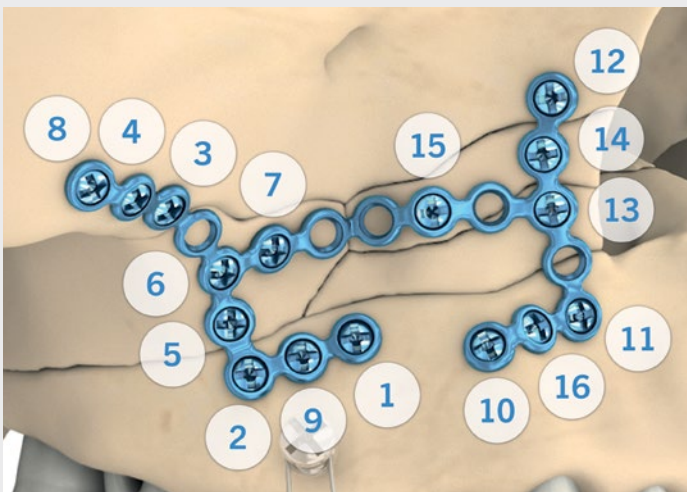


Plate-holding
instrument



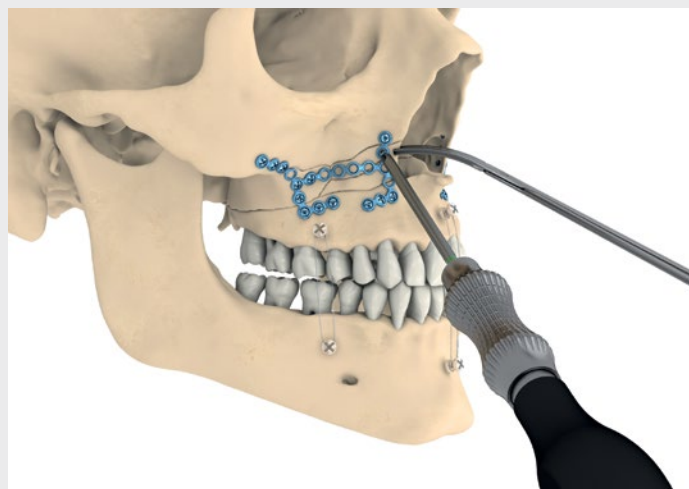
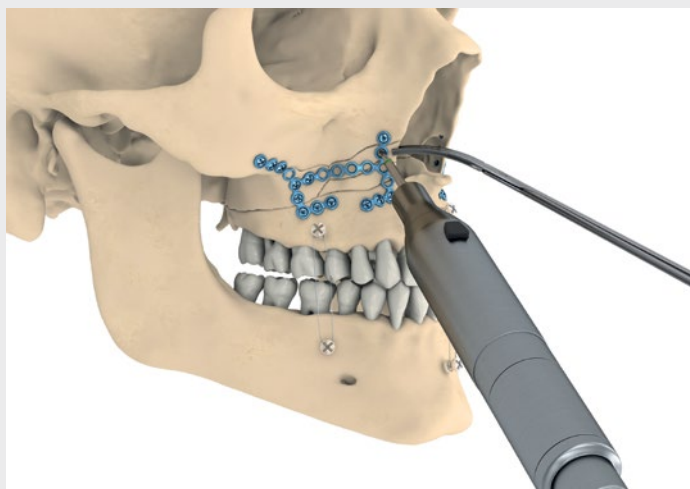
Screw measure-
ment clip



Screwdriver
handle



maxDrive®
blade



Guide to the fixation of the facial fragments

Fixating fragment pieces to the plate is often a major challenge. To do this, hold the fragment pieces in position using a bone clamp or bone hook while you predrill them and then fixate them.



Drill bit



Screw measure-
ment clip



Screwdriver
handle



maxDrive®
blade

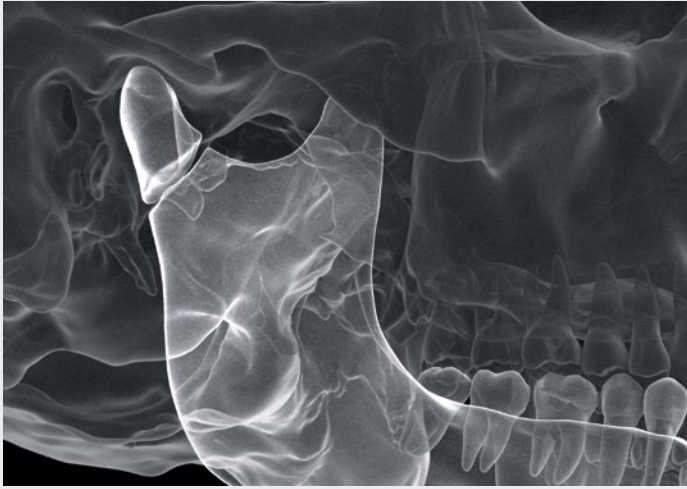


13. Wound closure

Remove the maxillomandibular fixation (MMF) after implanting the plates and check the occlusion before closing the wound. As an option, the maxillomandibular fixation (MMF) can remain temporarily for postoperative follow-up.

Postoperative care

The X-ray shows the postoperative findings.



Preoperative planning

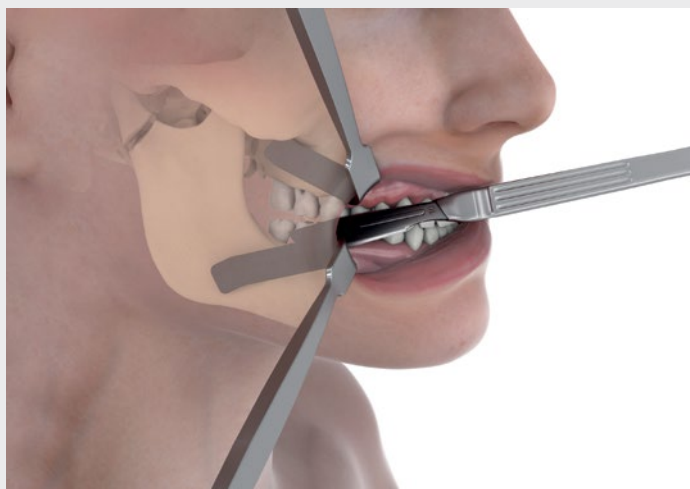
The x-ray shows a right-sided fracture of the mandibular collum.



Positioning the patient

Place the patient in supine position on the operating table. Normally, a nasotracheal intubation is implemented.





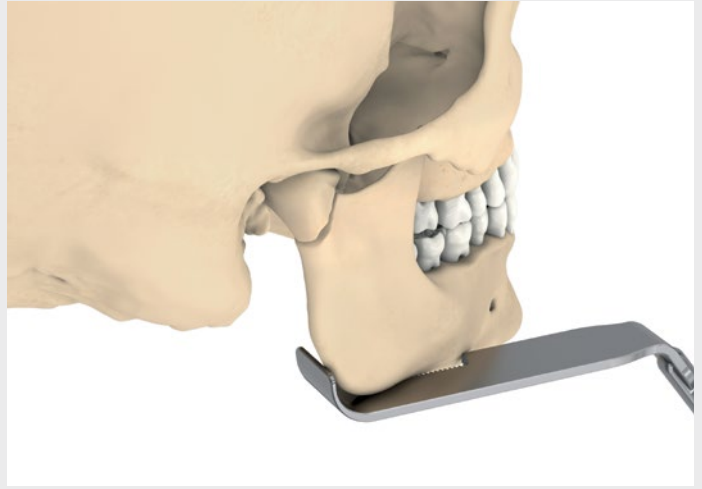
1. Transoral access

The temporomandibular joint process can be accessed via the transoral or extraoral approaches. While the extraoral accesses are technically less complex, transoral access allows you to leave no visible scars as well as reducing the risk of damage to the facial nerve. The transoral access is described as the prime choice in the following text.



Alternative: extraoral access

As an alternative to the transoral access, you can also select an extraoral access (e.g. transparotideal), which makes it unnecessary to use an endoscope.



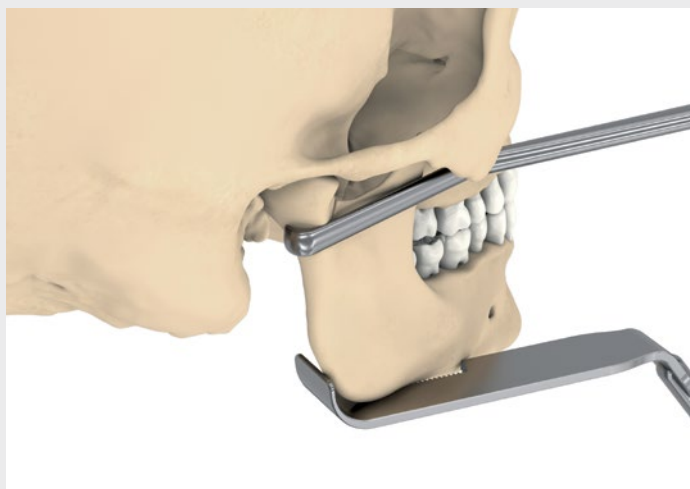
2. Exposure of the fracture

Gain an overview of the nature and location of the fracture. To do this, you can use an endoscope (ideally Ø 4 mm, 30°) with a special soft tissue shaft.

Using the modified Metz hook, you can stabilize the ramus during reduction.

Following subperiosteal preparation you can expose the fracture in a completely relaxed patient.

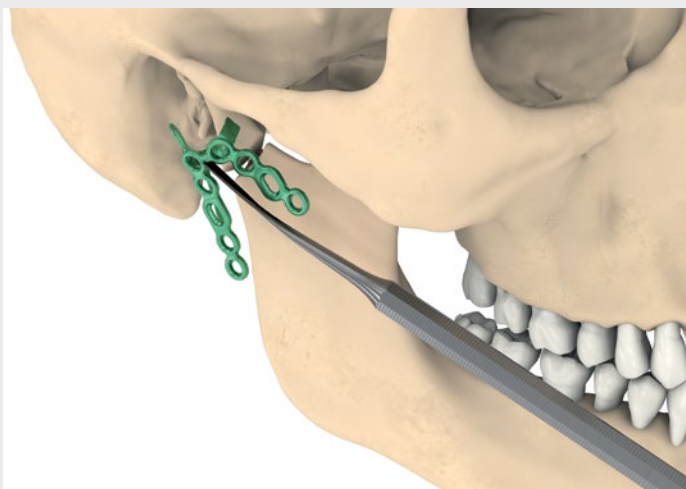




3. Primary reduction of the fracture

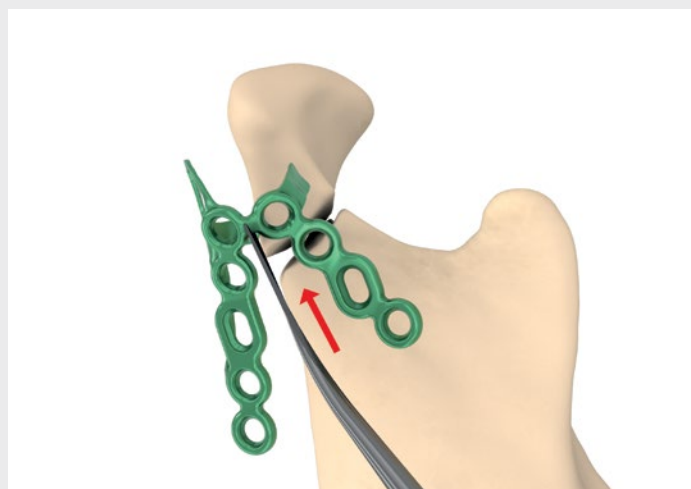
Various instruments can be used for the primary reduction depending on the type and position of the fractured segment:

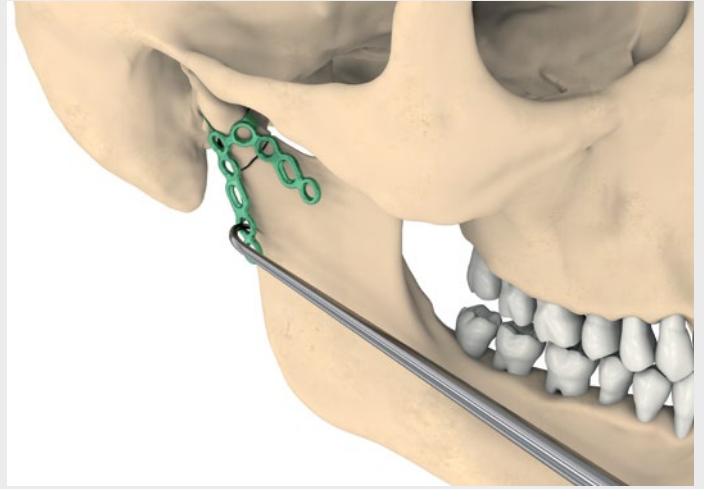
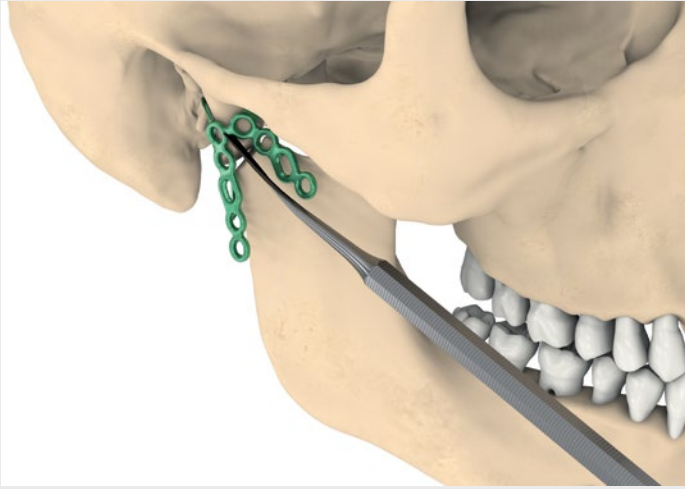
- Reduction clamps
- Ramus retractors
- Elevators



4. Capturing the temporomandibular joint head

Following the primary reduction of the fracture fragments, you can insert the condylar plate laterally to the bone using a grasping instrument (e.g. forceps). The condylar plate is located between the soft tissue (masseter muscle) and jawbone. Using a Luniatschek tampon applicator, grab the condylar plate at the connecting bar of the anterior and posterior arm and slide this dorsally.





Due to the dorsal cranial sliding movement, the upper portion of the condylar plate comes to lie next to the head of the mandibular condyle. With the same movement, and provided the soft tissue has been adequately prepared, you can slide the anterior dorsal arm over the narrowest part of the condylar neck. When doing so, the condylar plate usually first slips anterior (1) over the condylar neck and then posterior (2).

Note:

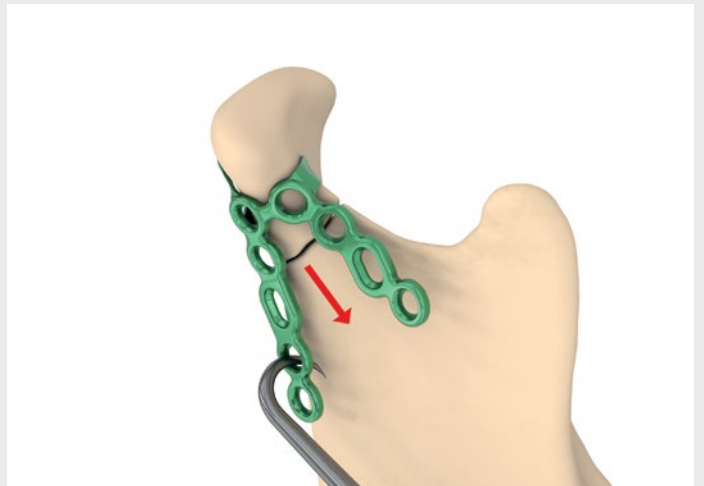
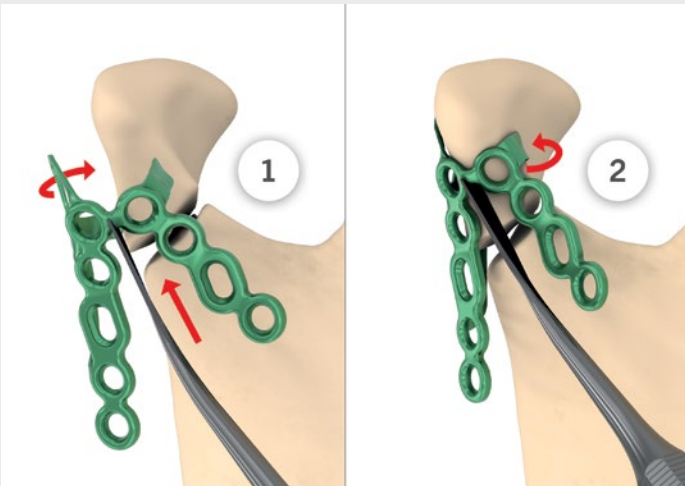
If needed, it may be necessary to bend the two arms slightly open to be able to slide them over the condylar neck.

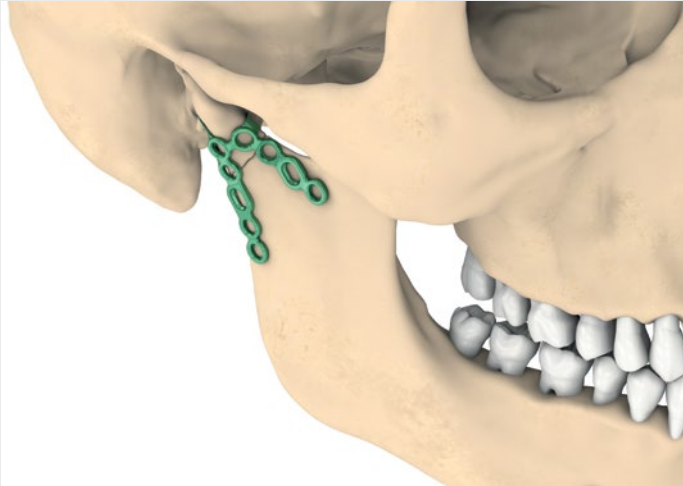
5. Activation of the "capture mechanism"

What is now important is the downward movement of the condylar plate using a hook-shaped instrument (e.g. ramus hook) to activate the anchorage of the condylar plate. It is important to grasp the collum in a controlled manner.

Note:

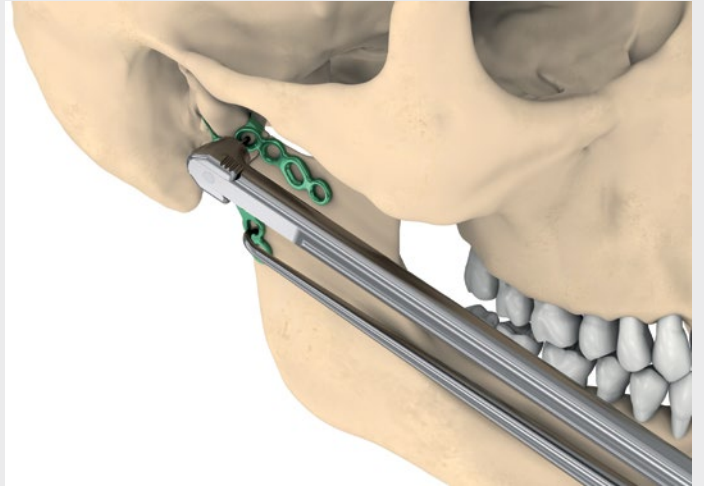
If the condylar plate should slip through, there is the option of activation on the anterior arm of the plate, by bending the latter slightly inward.





6. Reduction

Perform reduction by manual traction against the ascending branch of the mandible. The condylar plate determines the position of the fragment here.

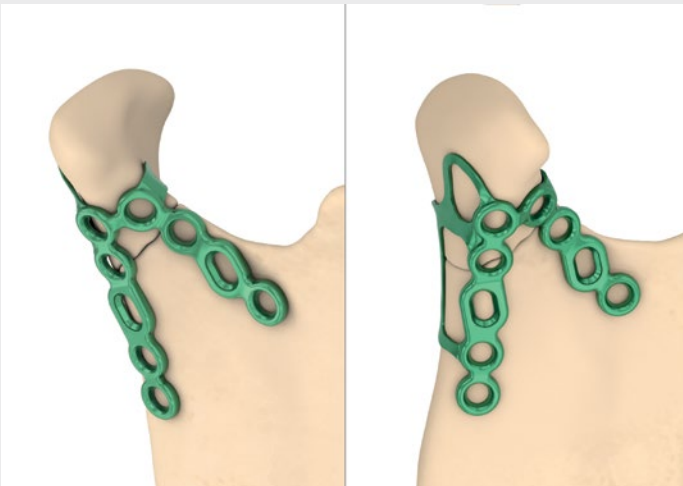


7. Drilling the first core hole for fixation of the plate

First, pre-drill the core hole with the corresponding drill bit:

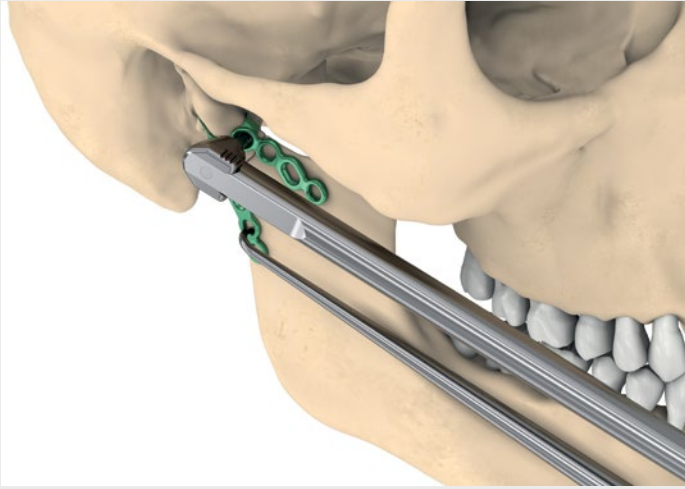
- Drill bit Ø 2.0-mm screws
→ Ø core hole 1.5 mm (red ring)
- Drill bit Ø 2.3-mm screws
→ Ø core hole 1.9 mm (black ring)

Be sure to select a drill bit with suitable stop length.



Angled screwdriver Angulus 2
with motor

Twist drill Angulus 2

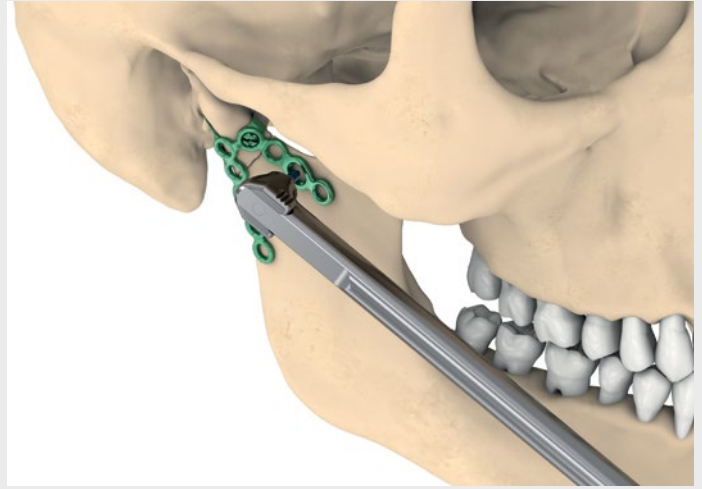


8. Placement of the first screw

Before fixation, check the screw length using the screw measurement clip. Insert the first self-retaining maxDrive® standard screw into the unstable fragment of the mandibular condyle. To do this, the screw is picked up with the angled screwdriver, screwed in, and securely fixated.

Note:

All round holes can be filled with both 2.0-mm and 2.3-mm standard or locking screws. Excluded from this are the oblong holes, which may only be filled with 2.0-mm and 2.3-mm standard screws.



9. Placement of the second screw

First, secure the position of the condyle or the cranial fragment using a second screw (standard screw, blue) in the oblong hole of the caudal, intact jaw region.



Screw measurement clip



Angled screwdriver
Angulus 2 with
manual drive



Bit
Angulus 2



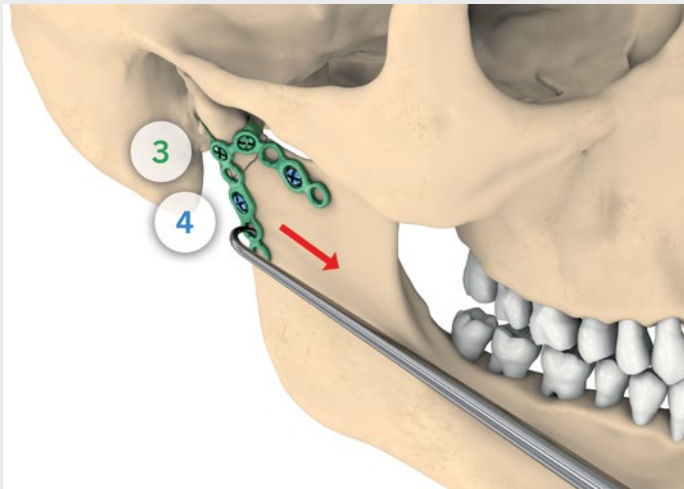
Screw measurement clip



Angled screwdriver
Angulus 2 with
manual drive

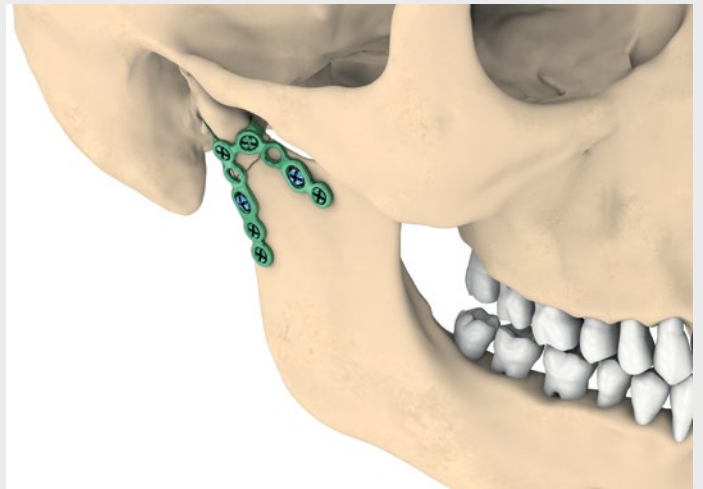


Bit
Angulus 2



10. Final reduction

After you have inserted screw no. 3 (locking screw, green) and 4 (standard screw, blue), the collum can be reduced again by pulling in anterior caudal direction with the holding instrument. To do this, you must not yet fully fixate the two standard screws in the oblong holes in order to allow the plate to slide.



11. Final fixation

After you have convinced yourself intraoperatively of the anatomically correct position of the collum or cranial fragment, you can fully fixate the standard screws in holes 3 and 4. The remaining screws are then placed in the sequence as illustrated. After you have successfully inserted the plate, the wound can be closed.



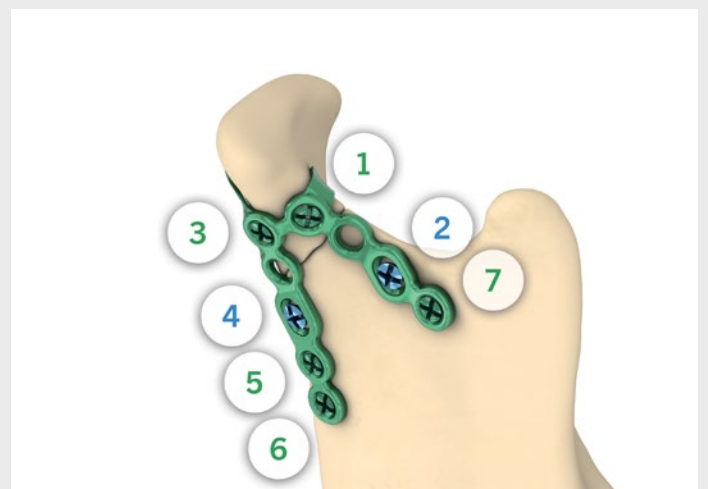
Screw measure-
ment clip

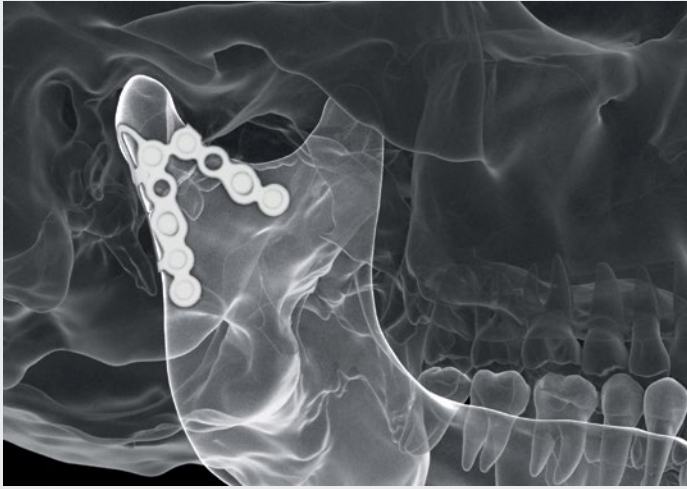


Angled screwdriver
Angulus 2 with
manual drive



Bit
Angulus 2

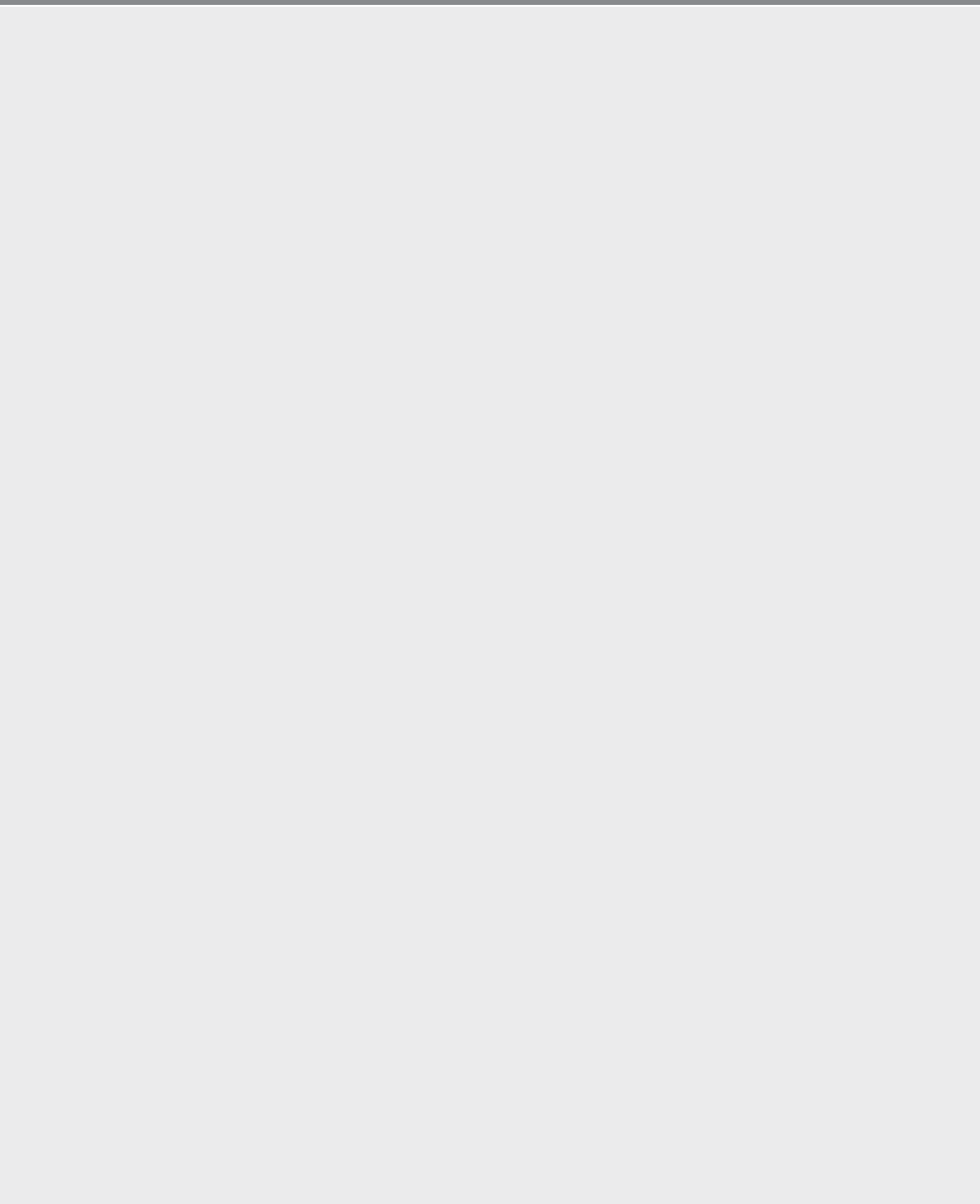




Postoperative check

The postoperative X-ray image shows the reduced condylar process and the correct position of the condylar plates.

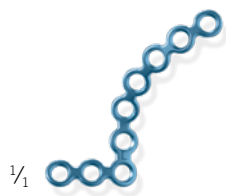
If you use a maxillomandibular fixation (MMF), this should be removed after 1-2 weeks. The patient should only consume soft foods for the first 6-8 weeks.





L1® Midface – 1.5 Smart3D


Plates in profile thickness 0.6 mm

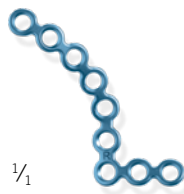
Zygomatic plates





left


25-320-28-09  1
25-320-28-71  1

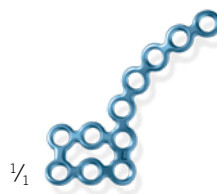
 = 0.6 mm





right


25-320-29-09  1
25-320-29-71  1

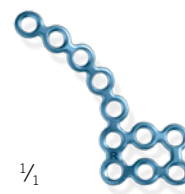
 = 0.6 mm





left


25-320-30-09  1
25-320-30-71  1

 = 0.6 mm



right

25-320-31-09  1
25-320-31-71  1

 = 0.6 mm

1.5 maxDrive®



Standard

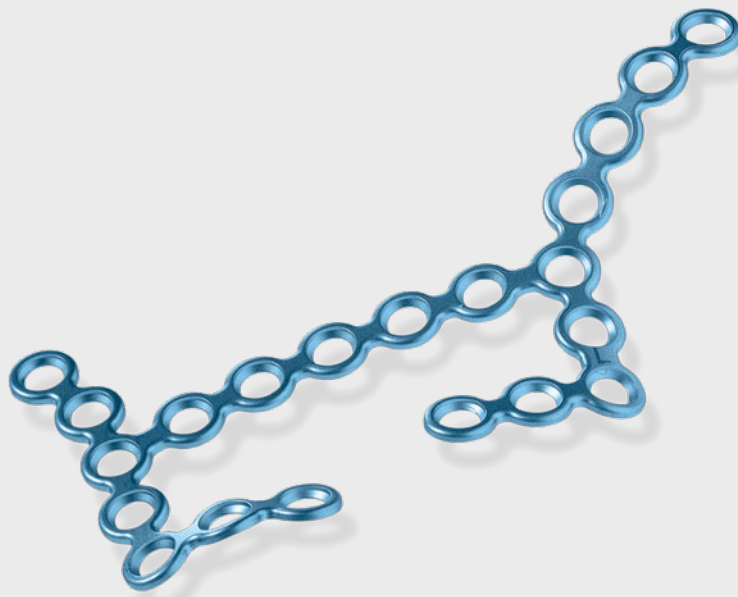


Emergency








Drill-Free

All L1® Midface Smart3D plates can be used with maxDrive® screws Ø 1.5 mm. For detailed information, please refer to the L1® Midface brochure.

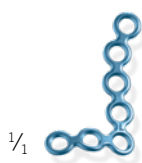
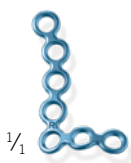





Explanation of icons




-  System diameter 1.5 mm
-  Titanium alloy
-  Pure titanium
-  Units per package
-  Plate profile

STERILE | R Sterile packed implants

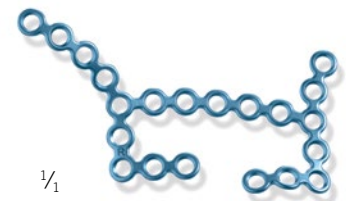
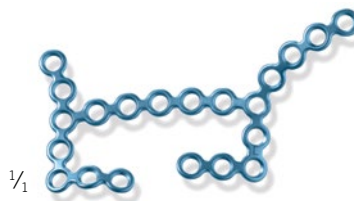
Paranasal plates









left
25-320-32-09  1
25-320-32-71  1
 = 0.6 mm

right
25-320-33-09  1
25-320-33-71  1
 = 0.6 mm

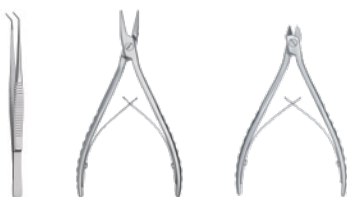
Zygomatic paranasal plates



left
25-320-34-09  1
25-320-34-71  1
 = 0.6 mm

right
25-320-35-09  1
25-320-35-71  1
 = 0.6 mm

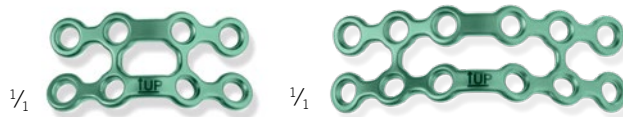
L1® Midface Instruments






All L1® Midface Smart3D plates can be used with the regular L1® Midface instruments. For detailed information, please refer to the L1® Midface brochure.



L1® Midface – 2.0/2.3 Smart3D Plates in profile thickness 1.0 mm


Symphysis plates



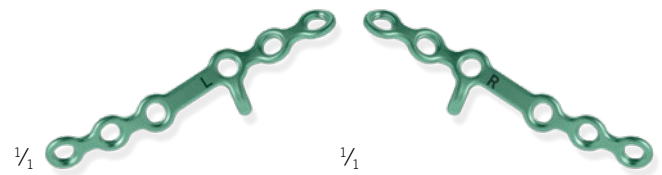
25-320-20-09  1
25-320-20-71  1

 = 1.0 mm



25-320-21-09  1
25-320-21-71  1


 = 1.0 mm

Linea obliqua plates






left

25-320-22-09  1
25-320-22-71  1

 = 1.0 mm

right

25-320-23-09  1
25-320-23-71  1

 = 1.0 mm

2.0 maxDrive®   
2.3 maxDrive®   



Standard



Emergency









Locking

All L1® Mandible Smart3D plates can be used with maxDrive® screws Ø 2.0 mm and 2.3 mm. Please refer to the LevelOne 2.0 Mini and LevelOne 2.0-2.7 Multidirectional Locking Plate System brochures for detailed information.

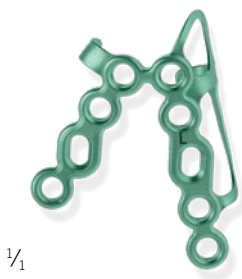


Explanation of icons

-  System diameter 2.0 mm
-  System diameter 2.3 mm
-  Titanium alloy
-  Pure titanium
-  Units per package
-  Plate profile


STERILE IR Sterile packed implants


Condylar plates




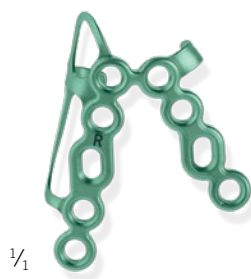
1/1

left

25-320-24-09  1


25-320-24-71  1


 = 1.0 mm




1/1

right

25-320-25-09  1

25-320-25-71  1

 = 1.0 mm

LevelOne 2.0 Mini Instruments



All L1® Mandible Smart3D plates can be used with regular LevelOne 2.0 Mini instruments. For detailed information, please refer to the LevelOne 2.0 Mini brochure.

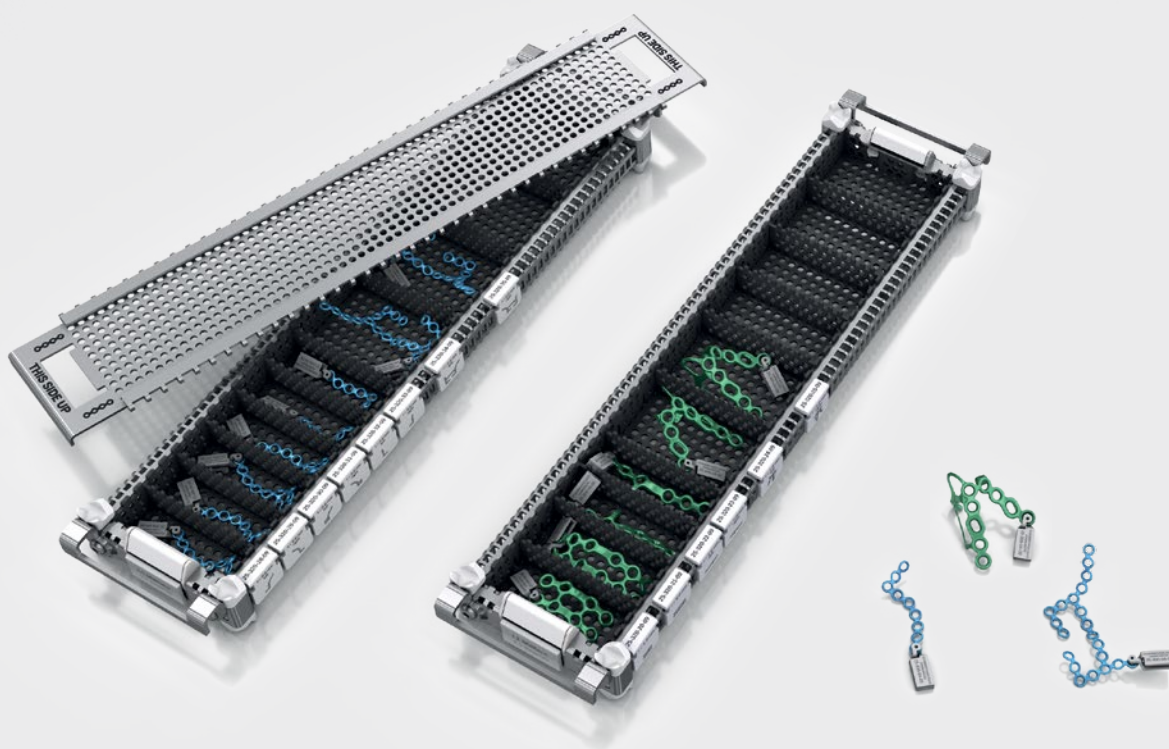
Storage L1® Smart3D

The plates are clearly arranged and kept separate from each other in the two Smart3D plate modules. Each plate compartment is marked on the side with a labeling clip that bears the article number, the profile, and a picture of the plate. As a result, the necessary information is provided for application-oriented access and intuitive refilling.

The matt inner surface of the module increases the contrast and allows comfortable, dazzle-free work under the surgical light.

The plate modules can each be stored and accommodated in the two implant trays of the standard L1® Midface and L1® Mandible systems. Each implant tray has a sliding compartment provided for this purpose.

Both plate modules are cleaning and sterilization validated, and suitable for machine reprocessing, thus meeting the requirements for optimal reprocessing.



Smart3D implant storage

55-990-13-04	Plate module 1/3, L1® Midface 1.5 Smart3D
55-990-14-04	Plate module 1/3, L1® Mandible 2.0/2.3 Smart3D



55-990-13-04
Plate module 1/3
for 1.5 Midface Smart3D plates



55-990-14-04
Plate module 1/3
for 2.0/2.3 Mandible Smart3D plates

Set composition L1® Midface – 1.5 Smart3D

25-320-28-09	Zygomatic plate, 9-hole, left	25-320-32-09	Paranasal plate, 7-hole, left
25-320-29-09	Zygomatic plate, 9-hole, right	25-320-33-09	Paranasal plate, 7-hole, right
25-320-30-09	Zygomatic plate, 11-hole, left	25-320-34-09	Zygomatic paranasal plate, 21-hole, left
25-320-31-09	Zygomatic plate, 11-hole, right	25-320-35-09	Zygomatic paranasal plate, 21-hole, right
55-990-13-04	Plate module 1/3, L1® Midface 1.5 Smart3D		

Set composition L1® Mandible – 2.0/2.3 Smart3D

25-320-20-09	Symphyseal plate, 8-hole	25-320-24-09	Condylar plate, 9-hole, left
25-320-21-09	Symphyseal plate, 12-hole	25-320-25-09	Condylar plate, 9-hole, right
25-320-22-09	Linea obliqua plate, 6-hole, left	25-320-34-09	Zygomatic paranasal plate, 21-hole, left
25-320-23-09	Linea obliqua plate, 6-hole, right	25-320-35-09	Zygomatic paranasal plate, 21-hole, right
55-990-14-04	Plate module 1/3, L1® Mandible 2.0/2.3 Smart3D		

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