

Condylar Head Add-on System

Adjustable height add-on system for condylar head reconstruction

Surgical Technique

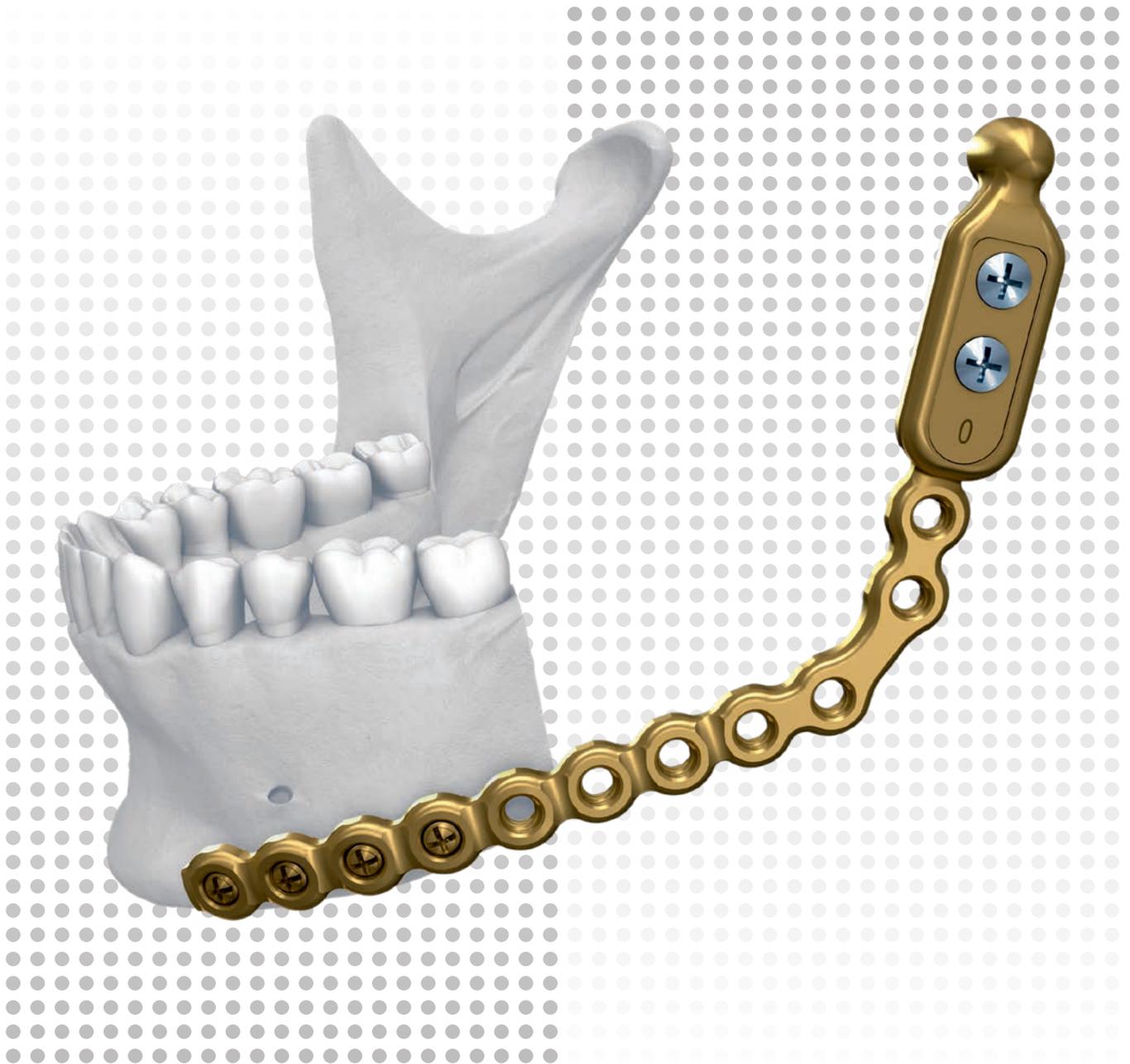


 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

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Condylar Head Add-on System

Adjustable height add-on system for condylar head reconstruction.

System Overview

The Synthes Condylar Head Add-on System provides temporary reconstruction of the mandibular condyle in patients undergoing disarticulation resection of the mandible as part of ablative tumor surgery.

The Synthes Condylar Head Add-on is attached to a Reconstruction Plate with a fixation plate and two set screws.

■ Note:

The Condylar Head Add-on System must only be used with the MatrixMANDIBLE Reconstruction Plates 2.5 mm or 2.8 mm thick.



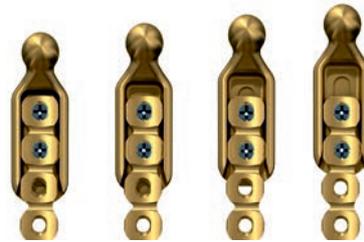
Condylar Head Add-on

- Maintains temporary reconstruction of temporomandibular joint
- Polished oval head with a large contact area
- Offset in a medial direction for positioning of the implant
- Symmetrical design for right or left placement



Fixation plates

- Fixation plate for height-adjustment facilitates the fit of the condylar head in the patient's glenoid fossa
- Four different positions: 0 mm to 6 mm, in 2 mm increments
- Labeled to identify position height



Fit to the patient's glenoid fossa

To fit to the patient's glenoid fossa, the system includes four fixation plates which allow height adjustment of the condylar head add-on relative to the proximal end of the reconstruction plate (from 0 mm to 6 mm in 2 mm increments).



Set screws

- Two screws are used to attach the condylar head add-on and fixation plate to the reconstruction plate
- The MatrixMANDIBLE screw is color-coded light blue and has a self-holding MatrixMANDIBLE screwdriver blade recess



Used with reconstruction plates

The Condylar Head Add-on System is used with a reconstruction plate.

- MatrixMANDIBLE – the condylar head add-on can attach to either the 2.5 mm thick reconstruction plate or the 2.8 mm thick reconstruction plate

The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

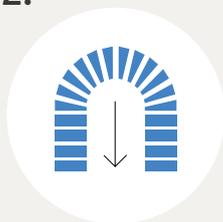
AO Principles^{1,2}

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

¹ Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.

² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Warnings

▲ WARNINGS:

- The use of the Condylar Head Add-on System is not intended for permanent reconstruction.
- When inserting the implant, it is important that the operative surgeon ensures that a soft tissue interface, such as the natural articulating disc or soft tissue graft resides between the implant head (device) and the bone.
- Direct metal-to-bone contact between the condylar component of the device and the natural glenoid fossa should be avoided. The procedure is contraindicated if no soft tissue is present.
- Improper placement of the implant due to surgical technique may lead to contralateral joint dysfunction. Care must be taken to ensure that the plate is positioned vertically in the fossa. A potential “open bite” deformity may result if this vertical position is altered.
- This device is not intended to be loaded in order to reestablish complete function. Normal bite forces may not be tolerated by the implant.
- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user’s glove or skin.



Intended Use, Indications and Contraindications can be found in the corresponding system IFU.

Surgical Technique

The following steps are additional to the surgical technique for the MatrixMANDIBLE System.

1. Determine surgical approach

If possible, place the patient in MMF to maintain the posterior ramus height and the occlusion.

Surgeon preference determines the surgical approach.

■ Note:

Most disarticulation resections and condylar head/reconstruction plate placements will occur with transcutaneous access.

2. Measure ramus height

Prior to the resection, measure the patient's ramus height from the tip of the condyle to the bottom of the ramus (angle).

3. Select and cut and/or contour reconstruction plate

Select the appropriate reconstruction plate to match the planned resection and measured ramus height.

Cut and/or contour the plate to match the patient's anatomy.

Refer to the MatrixMANDIBLE Surgical Technique or for plate contouring and mandible resection.

The Condylar Head Add-on System will add between 11 mm to 17 mm of height to the vertical (ramus) end of the plate.

▲ WARNING:

Ensure the plates are free from burrs/sharp edges after cutting.



■ **Note:**

It is recommended that the plate's ramus section is cut one hole longer than anticipated to ensure proper fit.

▲ **WARNING:**

To ensure proper fit of the Condylar Head Add-on on the reconstruction plate, the last three holes in the region of the mandibular ramus should not be bent or restricted.



▲ **WARNING:**

After resection, the ramus height and the anteroposterior (AP) length must be maintained.



4. Position reconstruction plate

From an anterior approach, clamp the plate to the mandible using two plate holding forceps.

▲ Precaution:

It is essential to hold and stabilize the plate using the plate holding forceps, as its weight can disrupt vertical position, potentially causing an “open bite” deformity.

5. Position condylar head add-on

Instruments for MatrixMANDIBLE Reconstruction Plates

03.503.070	Screwdriver Shaft MatrixMANDIBLE, short, self-holding, for Hexagonal Coupling
or	
03.503.071	Screwdriver Shaft MatrixMANDIBLE, medium, self-holding, for Hexagonal Coupling
or	
03.503.072	Screwdriver Shaft MatrixMANDIBLE, long, self-holding, for Hexagonal Coupling

Before securing the plate, place the patient in temporary MMF to maintain posterior ramus height.

Place the neutral fixation plate (position 0 mm) onto the condylar head, and fasten to the lateral aspect of the reconstruction plate using the screwdriver blade and two set screws.

Note:

Secure set screws to the assembly until snug. Verify that no play exists in the assembly. Do not over-tighten.

Position the assembled condylar head add-on in the fossa ensuring that there is enough room for the natural articular disc or a soft tissue graft.



0 mm position



2 mm position



4 mm position



6 mm position



If additional ramus height is required to properly seat the condylar head into the fossa, up to 6 mm of height can be added by using different fixation plates (2 mm, 4 mm or 6 mm).

If the ramus height is excessive, one or more holes can be cut from the ramus section of the reconstruction plate and the fixation plates can be used to adjust the height of the condylar head.

For example, cutting one hole section (8 mm long) from the reconstruction plate, then using the 6 mm fixation plate with the condylar head will yield a net reduction of 2 mm in ramus height.

6. Secure Reconstruction Plate to distal fragment

Instruments for MatrixMANDIBLE Reconstruction Plates

03.503.044	Drill Sleeve 1.8, short, with thread, for MatrixMANDIBLE
03.503.046	Drill Sleeve 2.4, short, with thread, for MatrixMANDIBLE
03.503.070	Screwdriver Shaft MatrixMANDIBLE, short, self-holding, for Hexagonal Coupling
or	
03.503.071	Screwdriver Shaft MatrixMANDIBLE, medium, self-holding, for Hexagonal Coupling
or	
03.503.072	Screwdriver Shaft MatrixMANDIBLE, long, self-holding, for Hexagonal Coupling
03.503.461	Drill Bit Ø 1.8 mm, length 90 mm, for J-Latch Coupling*, for 03.503.044
03.503.471	Drill Bit Ø 2.4 mm, length 90 mm, for J-Latch Coupling*, for 03.503.046



* Drill bits with mini quick coupling also available.

▲ Precautions:

- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
 - thermal necrosis of the bone,
 - soft tissue burns,
 - an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Avoid drilling over nerve or tooth roots.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures.
- Be sure to keep drill clear of loose surgical materials.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

Before securing the plate, ensure that the patient is in temporary MMF.

Once the plate and the Condylar Head Add-on implant are positioned properly, use at least four screws to secure the plate to the mandible.

For 2.4 mm screws, use the 1.8 mm drill bit and 1.8 mm threaded drill guide. For 2.9 mm screws use the 2.4 mm drill bit and 2.4 mm threaded drill guide.

Refer to the Surgical Technique of MatrixMANDIBLE for detailed plate application.

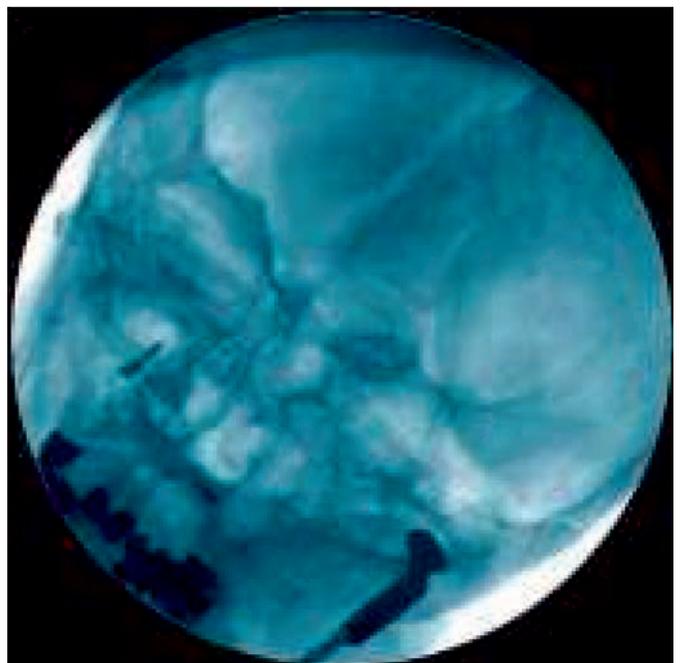
■ **Note:**

In osteoporotic bone, MatrixMANDIBLE 2.9 mm LOCK screws are recommended.



7. Check the fit of the condylar head in the glenoid fossa

Remove the patient from MMF and check to ensure that the condylar head articulates properly in the fossa.



Implants

04.449.000/
04.449.000S Condylar Head Add-on



04.449.010/
04.449.010S Fixation Plate for Condylar Head
Add-on,
Position 0 mm



04.449.020/
04.449.020S Fixation Plate for Condylar Head
Add-on,
Position 2 mm



04.449.030/
04.449.030S Fixation Plate for Condylar Head
Add-on,
Position 4 mm



04.449.040/
04.449.040S Fixation Plate for Condylar Head
Add-on,
Position 6 mm



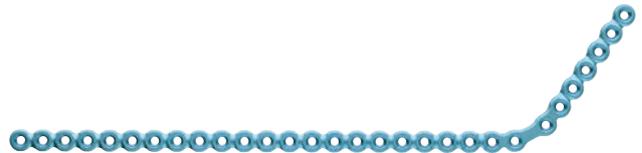
04.497.001/
04.497.001S MatrixMANDIBLE Set Screw
for Condylar
Head Add-on (for use with
MatrixMANDIBLE Reconstruction
Plates)



The following plates can be used with the Condylar Head Add-on System

MatrixMANDIBLE Reconstruction Plates

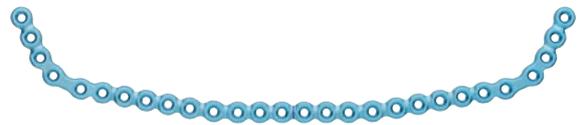
04.503.739/
04.503.739S MatrixMANDIBLE Reconstruction Plate,
angled, left, 7+23 holes, thickness
2.5 mm, Pure Titanium



04.503.740/
04.503.740S MatrixMANDIBLE Reconstruction Plate,
angled, right, 7+23 holes, thickness
2.5 mm, Pure Titanium



04.503.741/
04.503.741S MatrixMANDIBLE Reconstruction Plate,
double-angled, small, thickness 2.5 mm,
Pure Titanium, sterile



04.503.742/
04.503.742S MatrixMANDIBLE Reconstruction Plate,
double-angled, medium, thickness
2.5 mm, Pure Titanium, sterile



04.503.743/
04.503.743S MatrixMANDIBLE Reconstruction Plate,
double-angled, large, thickness 2.5 mm,
Pure Titanium, sterile



04.503.772/
04.503.772S MatrixMANDIBLE Reconstruction Plate,
angled, left, 7+23 holes,
thickness 2.8 mm, Pure Titanium



04.503.773/
04.503.773S MatrixMANDIBLE Reconstruction Plate,
angled, right, 7+23 holes,
thickness 2.8 mm, Pure Titanium



**2.4 mm cortex, 2.4 mm and/or 2.9 mm
MatrixMANDIBLE LOCK screws used to secure
the MatrixMANDIBLE Reconstruction Plates
to the mandible**

04.503.435.01C– MatrixMANDIBLE Screws Ø 2.4 mm,
04.503.448.01C self-tapping, Titanium Alloy (TAN),
04.503.435.04C– length 5 to 18 mm
04.503.448.04C



04.503.638.01C– MatrixMANDIBLE LOCK Screws
04.503.648.01C Ø 2.4 mm, self-tapping,
04.503.638.04C– Titanium Alloy (TAN),
04.503.648.04C length 8 to 18 mm



04.503.465.01C– MatrixMANDIBLE Emergency Screws
04.503.478.01C Ø 2.7 mm, self-tapping, Titanium Alloy
(TAN), length 5 to 18 mm



04.503.668.01C– MatrixMANDIBLE LOCK Screws
04.503.678.01C Ø 2.9 mm, self-tapping,
04.503.668.04C– Titanium Alloy (TAN),
04.503.678.04C length 8 to 18 mm



Sets

Insert for Implants for Condylar Head Add-on System, for use with MatrixMANDIBLE Reconstruction Plates

Fits in the auxiliary bin of the MatrixMANDIBLE Compact Recon (Art. No. 61.503.840).

Required sets

For 2.5 mm thick (blue) or 2.8 mm thick (gold) MatrixMANDIBLE Reconstruction Plates

01.503.831	Instrument Set for MatrixMANDIBLE Recon
01.503.834	MatrixMANDIBLE Recon Plates
01.503.836	MatrixMANDIBLE Recon Screws
or	
01.503.831	Instrument Set for MatrixMANDIBLE Recon
01.503.840	MatrixMANDIBLE Compact Recon



MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213, ASTM F2052-06e1 and ASTM F2119

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 5.4 T/m. The largest image artifact extended approximately 31 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182

Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 13.7 °C (1.5 T) and 6.5 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes).

▲ Precautions:

The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.
Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.
All Surgical Techniques are available as PDF files at www.depuysynthes.com/ifu



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