CONDYLAR HEAD ADD-ON SYSTEM

Adjustable system for condylar head reconstruction

SURGICAL TECHNIQUE
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Temporary reconstruction of the mandibular condyle
The Condylar Head Add-on System is designed to provide temporary reconstruction of the mandibular condyle in patients undergoing disarticulation resection of the mandible as part of ablative tumor surgery.

Used with reconstruction plates
The Condylar Head Add-on System is used with a reconstruction plate. It can be used with either of the following sets:
- MatrixMANDIBLE Plating System—the condylar head can attach to either the 2.5 mm thick reconstruction plate or the 2.8 mm thick reconstruction plate
- 2.4 mm Locking Reconstruction Plate (LRP) set

Optimal fit in the patient's glenoid fossa
To achieve optimal fit in the patient's glenoid fossa, the system includes 4 fixation plates which allow height adjustment of the condylar head relative to the proximal end of the reconstruction plate (from 0 mm to 6 mm in 2 mm increments).
The Condylar Head Add-on is attached to a reconstruction plate with a fixation plate and 2 titanium screws.

**Condylar head**
- Maintains temporary function of temporomandibular joint
- Oval head for a large contact area
- Offset in a medial direction for anatomically correct positioning of the implant
- Highly polished oval head
- Symmetrical design allows right or left placement

**Fixation plates**
- Fixation plate for height adjustment allows optimal fit of the condylar head in the patient’s glenoid fossa
- 4 different positions: 0 mm to 6 mm, in 2 mm increments
- Labeled to identify position height

**Titanium screws**
- 2 screws are used to attach the condylar head and fixation plate to the reconstruction plate
- The MatrixMANDIBLE Plating System screw is color-coded light blue and has a self-retaining MatrixMANDIBLE Plating System screwdriver blade recess
- The LRP screw is color-coded gray for identification and has a self-retaining cruciform screwdriver blade recess
In 1958, the AO formulated 4 basic principles, which have become the guidelines for internal fixation.1 These principles, as applied to the Condylar Head Add-on System, are:

**Anatomic reduction**
The height adjustment of the condylar implant allows restoration of facial form and anatomic relationships, including the occlusion.

**Stable fixation**
The condylar implant allows stable fixation when used with a 2.5 mm or 2.8 mm thick MatrixMANDIBLE Plating System Reconstruction Plate, or 2.4 mm Locking Reconstruction Plate.

**Preservation of blood supply**
Use of surgical technique preserves the blood supply to soft tissue and bone, minimizes disruption of soft tissue, and preserves vascular blood flow for bone healing.

**Early, active mobilization**
The Condylar Head Add-on System preserves facial form and symmetry; permits jaw movement, chewing function and speech; and improves quality of life.
**INDICATIONS**

**Indications**
The Condylar Head Add-on System is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

**Important:** The Condylar Head Add-on System is not intended for use as a permanent prosthetic device, for patients with temporomandibular joint disorders (TMD), or patients with traumatic injuries to the temporomandibular joint (TMJ).

These devices are intended for single use only and are offered NONSTERILE only.

**MR INFORMATION**
This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

**Warnings**
- The use of the Condylar Head Add-on System is limited to a maximum of 2 years, and 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.
Required sets

<table>
<thead>
<tr>
<th>Set Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.503.150</td>
<td>MatrixMANDIBLE Implant and Instrument Set</td>
</tr>
<tr>
<td>145.401</td>
<td>Locking Reconstruction Plate Module Set with Titanium implants (2.4 mm LRP)</td>
</tr>
</tbody>
</table>

and one of the following sets:

<table>
<thead>
<tr>
<th>Set Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>145.400</td>
<td>Mandibular Modular Fixation Instrument Set, 2-module</td>
</tr>
<tr>
<td>145.402</td>
<td>Mandibular Module Fixation System Set, 4-module, Large</td>
</tr>
<tr>
<td>145.405</td>
<td>Mandibular Module Fixation Instrument Set, 4-module</td>
</tr>
</tbody>
</table>

The following steps are additional to the technique guides for the MatrixMANDIBLE Plating System and 2.4 mm Locking Reconstruction Plate (LRP).

1. **Determine surgical approach**

   If possible, place the patient in Maxillomandibular Fixation (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 Plating System Technique Guide or Locking Reconstruction Plate Technique Guide 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.

**Note:** It is recommended that the plate’s ramus section be cut one hole longer than anticipated to ensure proper fit.

**Warning:** To ensure proper fit of the Condylar Head Add-on System on the reconstruction plate, the last 3 holes in the region of the mandibular ramus should not be bent or restricted.
3

Select and cut and/or contour reconstruction plate
continued

**Technique tip:** Use bending inserts to prevent plate hole deformation while contouring the plate.

Before contouring the plate to the patient’s anatomy, bending inserts may be threaded into the plate holes in regions where more extensive contouring is desired.

Bend the plate to the desired geometry. Once the proper bend is achieved (and before affixing the plate to the bone), remove the bending inserts.

**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 2 plate-holding forceps.

**Technique tip:** 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.
Position condylar head

Instruments for MatrixMANDIBLE Plating System

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.503.070</td>
<td>MatrixMANDIBLE Self-retaining Screwdriver Blade, short</td>
</tr>
<tr>
<td>03.503.071</td>
<td>MatrixMANDIBLE Self-retaining Screwdriver Blade, medium</td>
</tr>
<tr>
<td>03.503.072</td>
<td>MatrixMANDIBLE Self-retaining Screwdriver Blade, long</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle</td>
</tr>
<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle</td>
</tr>
<tr>
<td>313.928</td>
<td>2.0 mm/2.4 mm Cruciform Screwdriver Blade, self-retaining, hex coupling</td>
</tr>
</tbody>
</table>

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

Place the neutral fixation plate (0 mm position) onto the condylar head, and fasten to the lateral aspect of the reconstruction plate using the screwdriver blade and 2 titanium screws.

**Technique tip:** Secure titanium screws to the assembly until snug. Verify that no play exists in the assembly. Do not over-tighten.

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

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.

**Warning:** The device should be used with a soft tissue interface, either the natural articular disc or a soft tissue flap, between the condylar head and the bone.
**SECURE MATRIXMANDIBLE SYSTEM PLATE TO DISTAL FRAGMENT**

6a

**Secure 2.5 mm thick (light blue) or 2.8 mm thick (gold) MATRIXMANDIBLE System plate to distal fragment**

**Instruments**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.503.461</td>
<td>MATRIXMANDIBLE 1.8 mm Drill Bit, J-latch, 90 mm</td>
</tr>
<tr>
<td>or</td>
<td>03.503.471</td>
</tr>
<tr>
<td>03.503.044</td>
<td>MATRIXMANDIBLE 1.8 mm Threaded Drill Guide, short</td>
</tr>
<tr>
<td>or</td>
<td>03.503.046</td>
</tr>
<tr>
<td>03.503.072</td>
<td>MATRIXMANDIBLE Self-retaining Screwdriver Blade, long</td>
</tr>
<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle</td>
</tr>
</tbody>
</table>

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

Once the plate and condylar head add-on implant are positioned properly, use at least 4 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 `MATRIXMANDIBLE Plating System Technique Guide` for detailed plate application.

**Technique tip:** In osteoporotic bone, 2.9 mm locking screws are recommended.

**Precautions:**

- Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The adverse effects of an oversized hole include reduced pullout force, increased ease of the screws stripping in bone, and/or suboptimal fixation.
- Always irrigate during drilling.
- 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 a sharps container.
**Secure Reconstruction Plate to Distal Fragment**

### Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>310.520</td>
<td>1.8 mm Drill Bit, quick coupling, 125 mm or 125 mm</td>
</tr>
<tr>
<td>310.540</td>
<td>2.4 mm Drill Bit, quick coupling, 125 mm</td>
</tr>
<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle</td>
</tr>
<tr>
<td>313.928</td>
<td>2.0 mm/2.4 mm Cruciform Screwdriver Blade, self-retaining, hex coupling</td>
</tr>
<tr>
<td>397.441</td>
<td>1.8 mm Threaded Drill Guide, short or 125 mm</td>
</tr>
<tr>
<td>397.442</td>
<td>2.4 mm Threaded Drill Guide, short</td>
</tr>
</tbody>
</table>

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 4 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 3.0 mm screws, use the 2.4 mm drill bit and 2.4 mm threaded drill guide.

Refer to the *Locking Reconstruction Plate Technique Guide* for detailed plate application.

**Note:** In osteoporotic bone, 3.0 mm locking screws are recommended.
7

Check the fit of the condylar head in the fossa

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

<table>
<thead>
<tr>
<th>Implants</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.449.000</td>
<td>Titanium Condylar Head</td>
</tr>
<tr>
<td>04.449.010</td>
<td>0 mm</td>
</tr>
<tr>
<td>04.449.020</td>
<td>2 mm</td>
</tr>
<tr>
<td>04.449.030</td>
<td>4 mm</td>
</tr>
<tr>
<td>04.449.040</td>
<td>6 mm</td>
</tr>
<tr>
<td>04.497.000</td>
<td>Titanium Screw for Condylar Head, for use with LRP</td>
</tr>
<tr>
<td>04.497.001</td>
<td>Slotted Screw for Condylar Head Add-on System, for MatrixMANDIBLE Plating System</td>
</tr>
<tr>
<td>04.497.000</td>
<td>Titanium MatrixMANDIBLE Reconstruction Plates, 2.5 mm thick</td>
</tr>
<tr>
<td>04.503.739</td>
<td>With angle, 7 x 23 holes, left</td>
</tr>
<tr>
<td>04.503.740</td>
<td>With angle, 7 x 23 holes, right</td>
</tr>
<tr>
<td>04.503.741</td>
<td>With double angle, small</td>
</tr>
<tr>
<td>04.503.742</td>
<td>With double angle, medium</td>
</tr>
<tr>
<td>04.503.743</td>
<td>With double angle, large</td>
</tr>
<tr>
<td>04.503.772</td>
<td>Titanium MatrixMANDIBLE Reconstruction Plates, 2.8 mm thick</td>
</tr>
<tr>
<td>04.503.773</td>
<td>With angle, 7 x 23 holes, right</td>
</tr>
<tr>
<td>449.632</td>
<td>2.4 mm Titanium Locking Reconstruction Plates (LRP)</td>
</tr>
<tr>
<td>449.633</td>
<td>With angle, 6 x 23 holes, 44 mm x 214 mm, left</td>
</tr>
<tr>
<td>449.634</td>
<td>With angle, 6 x 23 holes, 44 mm x 214 mm, right</td>
</tr>
<tr>
<td>449.635</td>
<td>With angle, 5 x 8 holes, left</td>
</tr>
<tr>
<td>449.636</td>
<td>With angle, 5 x 8 holes, right</td>
</tr>
<tr>
<td>449.637</td>
<td>With double angle, 4 x 20 x 4 holes</td>
</tr>
<tr>
<td>449.638</td>
<td>With double angle, 5 x 22 x 5 holes</td>
</tr>
<tr>
<td>449.639</td>
<td>With double angle, 6 x 24 x 6 holes</td>
</tr>
</tbody>
</table>
### Graphic Case
- **60.449.005** Module and Lid for Condylar Head Add-on System, MatrixMANDIBLE Plating System

### Implants
- **04.449.000** Titanium Condylar Head, 2 ea.
- **04.449.010** 0 mm
- **04.449.020** 2 mm
- **04.449.030** 4 mm
- **04.449.040** 6 mm
- **04.497.001** Slotted Screw for Condylar Head Add-on System, for MatrixMANDIBLE Plating System, 6 ea.

### Required Set
- **01.503.150** MatrixMANDIBLE Implant and Instrument Set

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For detailed cleaning and sterilization instructions, please refer to:
[www.synthes.com/cleaning-sterilization](http://www.synthes.com/cleaning-sterilization)

In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.

*The module can be wrapped and sterilized separately, or it can be inserted into the MatrixMANDIBLE Instrument Tray auxiliary bin.*
CONDYLAN HEAD ADD-ON SYSTEM SET (01.449.001)

**Graphic Case**
60.449.002* Insert for Condylar Head Add-on System Module (for use with LRP Plates)

**Implants**
04.449.000  Titanium Condylar Head, 2 ea.
04.449.010  0 mm
04.449.020  2 mm
04.449.030  4 mm
04.449.040  6 mm
04.497.000  Titanium Screw for Condylar Head, for use with LRP Plates, 6 ea.

**Required Sets**
145.401  Locking Reconstruction Plate Module Set (with Titanium implants)
and one of the following sets:
145.400  Mandibular Modular Fixation Instrument Set, 2-module
145.402  Mandibular Modular Fixation System Set, 4-module, Large
145.405  Mandibular Modular Fixation Instrument Set, 4-module

**Graphic Case Option**
304.745  Module Case for 2.4 mm/3.0 mm Titanium Locking Reconstruction and Trauma Plates

For detailed cleaning and sterilization instructions, please refer to:
www.synthes.com/cleaning-sterilization

In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.

* The module can be wrapped and sterilized separately, or it can be inserted into the auxiliary bin in the module case for 2.4 mm/3.0 mm titanium locking reconstruction and trauma plates (304.745). The lid must be removed and discarded if the latter option is chosen.
REFERENCES


Note: For additional information regarding the procedure within this Technique Guide, please refer to the following publications.


Some devices listed in this Technique Guide may not have been licensed in accordance with Canadian Law and may not be for sale in Canada. Please contact your Sales Consultant for items approved for sale in Canada.

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