Instructions for Use
Condylar Head Add-on System

This instruction for use is not intended for distribution in the USA.

EC REP

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Instructions for Use

Condylar Head Add-on System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical technique Condylar Head Add-on System (DSEM/CMF/0316/0120) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

The Synthes Condylar Head Add-on System is an adjustable height add-on system for use with the 2.5 mm or 2.8 mm thick MatrixMANDIBLE Plate System or 2.4 UniLOCK Reconstruction Plates.

The system consists of an elliptical shaped condylar head, two (2) set screws, and four (4) different fixation plates which allow the surgeon to adjust the height of the condylar head add-on relative to the proximal end of the reconstruction plate.

Material(s)

	Material(s):	Standard(s):
Implants:	Commercially Pure Titanium	ISO 5832-2
Screws:	Commercially Pure Titanium	ISO 5832-2
	Titanium Aluminium Niobium (TiAl6Nb7)	ISO 5832-11
Bending Templates:	Aluminium 1050A	DIN EN 573

Intended use
The Condylar Head Add-on System is intended for temporary reconstruction of the mandibular condyle.

Indications
The Condylar Head Add-on System is indicated for temporary reconstruction of the mandibular condyle in patients undergoing ablative surgery requiring the removal of the mandibular condyle.

Contraindications
The Condylar Head Add-on System is contraindicated for use as a permanent prosthetic device, for patients with temporomandibular joint disorders (TMD), or patients with traumatic injuries to the temporomandibular joint (TMJ).

General Adverse Events
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairement of the muskuloskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hypersensitivity reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, malunion, non-union or delayed union which may lead to breakage of the implant, reoperation.

Device-specific adverse events
- Loosening, bending, or breakage of the device
- Non-union, mal-union or delayed union which may lead to breakage of the implant
- Pain, discomfort or abnormal sensation due to the presence of the device
- Infection, nerve and/or tooth root damage and pain
- Soft tissue irritation, laceration or migration of the device through the skin
- Allergic reactions from material incompatibility
- Glove tear or user puncture
- Graft failure
- Restricted or impaired bone growth
- Possible transmission of bloodborne pathogens to the user
- Injury of patient
- Soft tissue thermal damage
- Bone necrosis
- Parasthesia
- Loss of tooth

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

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

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and /or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
- 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.
- 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.

Warnings
- The use of 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.
- 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.
- After resection, the ramus height and the anteroposterior (AP) length must be maintained.
- Ensure the plates are free from burrs/sharp edges after cutting.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment
Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07
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 F2182-11a
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.

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure “Important Information”.

Special Operating Instructions
– Determine surgical approach (e.g., percutaneous incision, etc.)
– Measure ramus height
– Select and cut and/or contour reconstruction plate
– It is recommended that the plate’s ramus is cut one hole longer than anticipated to ensure proper fit
– Position reconstruction plate
– Position Condylar Head Add-on
– Secure reconstruction plate to distal fragment
– Check the fit of the condylar head in the glenoid fossa ensuring that there is enough room for the natural articular disc or a soft tissue graft

See the respective Surgical Technique of the Synthes Condylar Head Add-on for full instructions for use.

Device intended to be used by a trained physician
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 of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure “Important Information”. Assembly and disassembly instructions of instruments “Dismantling multipart instruments” can be downloaded from
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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