Instructions for Use
Plate and Screw System Compact Mandible

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Plate and Screw System Compact Mandible:
– COMPACT 2.0 Lock Mandible
– COMPACT 2.4 Unilock

Please read these instructions for use, the DePuy Synthes brochure "Important Information" and the corresponding surgical techniques Compact 2.0 LOCK Mandible DSEM/CMF/0115/0051 and Compact 2.4 UniLOCK DSEM/CMF/0216/0115 carefully before use. Ensure that you are familiar with the appropriate surgical technique. The Synthes Plate and Screw System Compact Mandible consist of divers systems offering variety of plates that come in multiple shapes and sizes to meet the anatomical needs of the patient. Each system is designed for use with its corresponding screws that come in multiple diameters and lengths to meet the anatomical needs of the patient.

Material(s)

	Part(s)	Material(s)	Standard(s)
Plates:	TiCP	ISO 5832-2:1999	ASTM F67-13
Screws:	TiCP	ISO 5832-2:1999	ASTM F67-13
	TAN (Ti-6Al-7Nb)	ISO 5832-11:2014	ASTM F1295-11

Intended use
The Synthes Plate and Screw System Compact Mandible is intended for oral, maxillofacial surgery, trauma, reconstructive surgery, and orthognathic surgery (surgical correction of dentofacial deformities).

Indications
Trauma: all fractures, defect fractures, and instable and infected mandibular fractures.
Reconstructive surgery: bridging osteosynthesis with or without bone graft, both for primary and secondary reconstructions (tumor resections, pseudoarthrosis).
Orthognathic surgery: selective orthognathic surgery of maxilla and chin.
COMPACT 2.0 LOCK Mandible is indicated to be used for Mandible trauma, orthognathic surgery, and reconstructive surgery with microvascular bone grafts.
COMPACT 2.4 UniLOCK is indicated for comminuted fractures, defect fractures, instable and infected mandibular fractures, bridging osteosynthesis with or without bone graft, both for primary and secondary reconstructions (tumor resections, pseudoarthrosis).
UniLOCK Reconstruction Plate 2.4 with Condylar Head is indicated for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle.

Contraindications
– COMPACT 2.0 Lock Mandible is contraindicated for Reconstructive surgery without microvascular bone grafts.
– UniLOCK Reconstruction Plate 2.4 with Condylar Head is contraindicated:
  – as a permanent prosthetic device
  – for patients with temporomandibular joint disease (TMD)
  – for 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, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant or reoperation.

Device Specific Adverse Events
Device specific adverse events include but are not limited to:
– 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
– Paresthesia
– Loss of tooth
– Improper placement of condylar head implant may lead to contralateral joint dysfunction and/or potential "open bite" deformity

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.

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 DePuy 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.

Warnings
– These devices can break intraoperatively 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.
– Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail.

UniLOCK Reconstruction Plates 2.4 with Condylar Head warnings:
– The plates are not intended for permanent reconstruction.
– The plates should be used with a soft tissue interface, either the natural articular disc or a soft tissue graft, between the condylar component of the device and the bone. Direct metal-to-bone contact between the condylar component of the device and the natural glenoid fossa should be avoided. If no soft tissue is present, the procedure is contraindicated.
– Improper placement of these implants 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.
– The plates are not intended to be loaded in order to re-establish complete function.
– Normal bite forces may not be tolerated by this prosthesis.

Precautions
- Check instruments for wear or damage before starting surgery.
- Avoid reverse bends as it may weaken the plate and lead to premature implant failure.
- Avoid sharp bends. Sharp bends include a single out-of-plane bend of >30 degrees between two adjacent holes.
- Avoid placing the holes over the nerve or tooth root. If plate requires placement over nerve or tooth root, drill monocortical using the appropriate drill bit with stop.
- Instrument tips and implant edges may be sharp, handle with care and dispose sharp cuttings in an approved sharps container.
- Take care to protect soft tissue from trimmed plate edges.
- 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.
- Avoid damaging the plate threads with the drill.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Always irrigate and apply suction for removal of debris potentially generated during implantation or removal
- Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation, or bone stripping.
- If no vascularized bone graft is applied, a 2.4 mm UniLOCK plate or larger system should be used.

Combination of medical devices
DePuy 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 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
DePuy 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 DePuy Synthes brochure "Important Information".

Special Operating Instructions
1. Expose area to be fixated via standard surgical approach. For trauma, reduce the fracture as required.
2. Select and prepare implants
3. Cut plate (Optional)
4. Select and form the bending template
5. Contour the plate
6. Position the plate and select screws
7. Drill the first hole
8. Measure screw length
9. Insert the first screw
10. Drill and place the remaining screws

Optional Steps for Bone Resection
11. Resect the mandible
12. Reposition the implants
13. Apply bone graft

Special Operating Instructions for Reconstruction Plates 2.4 with Condylar Head
14. Determine surgical approach
15. Measure the ramus height
16. Select and contour plate
17. Position the condylar head
18. Position the plate
19. Place the screws
20. Verify intended fixation
21. Close incision

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 DePuy 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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