Instructions for Use
Plate and Screw System Mandible

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

CE
0123

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Instructions for Use

Plate And Screw System Mandible:
– COMPACT 2.0
– COMPACT 2.0 Lock Mandible
– COMPACT 2.4 Trauma
– COMPACT 2.4 Unilock
– Mandible 2.7

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques Compact 2.0 Lock Mandible (036.000.059) and UniLock 2.4 (036.000.051) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The Synthes Plate And Screw System Mandible consist of a 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)

Material(s):	Standard(s):
Titanium	ISO 5832-2
TAN	ISO 5832-11
Stainless steel	ISO 5832-1
Stainless steel for instrument	ISO 7153-1
Aluminum alloy	DIN EN 573

Intended use
The Synthes Plate And Screw System Mandible is intended for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognatic 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 (tumour resections, pseudoarthrosis).
Orthognatic surgery: selective orthognatic surgery of maxilla and chin.
Mandible 2.7 is indicated for fractures in the region from the canine teeth to the mandibular angle where no teeth are available for tension band splin
COMPACT 2.0 Mandible is indicated for fixation of simple stable fractures of the mandible.
COMPACT 2.0 LOCK Mandible is indicated to be used for Mandible trauma, Orthognathic surgery and Reconstructive surgery with microvascular bo grafts.
COMPACT 2.4 UniLOCK is indicated for comminuted fractures, defect fractures, instable and infected mandibular fractures, bridging osteosynthesis without bone graft, both for primary and secondary reconstructions (tumour resections, pseudoarthrosis).
COMPACT 2.4 TRAUMA is indicated to be used for mandibular trauma and reconstruction

Contraindications
COMPACT 2.0 Lock Mandible
Reconstructive surgery without microvascular bone grafts

Side effects
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 impairment of the musculoskeletal 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, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.
– 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.

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
– Do not use screws shorter than 5 mm with 2.4 mm and 3.0 mm diameter screws, as bone purchase might not be sufficient for stable fixation.
– 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 >45 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.
– Drilling speed should never exceed 1800 rpm. Higher speeds can result in thermal necrosis of the bone and increased hole diameter, and may lead to unstable fixation.
– Always irrigate during drilling.
– Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation, or bone stripping.

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
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

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
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 over the fracture or osteotomy site
7. Drill the first hole
8. Measure screw length
9. Insert screw
10. Drill and place the remaining screws Optional steps for bone resection
11. Resect the mandible
12. Replace the implants
13. Apply bone graft
14. Verify intended fixation
15. Close incision

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://www.synthes.com/reprocessing

Additional device-specific information

Reference Number

Lot or batch number


Manufacturing date


Expiration date

Notified body


Caution, see instructions for use

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