Instructions for Use
Plate and Screw Fixation System COMPACT MIDFACE

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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Instructions for Use

Plate and Screw Fixation System COMPACT MIDFACE:
Compact Midface System
Compact Orbital Plates
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical technique Compact Midface (DSEM/CMF/0316/0121) carefully before use.
The Compact Midface, Orbital plates, and Orthogmathic Systems offer a wide range of different sizes, lengths, and thickness of plates and screws implants. All implants are offered in a sterile or non-sterile packaging.

Material(s)

Parts:	**Material(s):**	**Standard(s):**
Plates:	Titanium (TiCP)	ISO 5832-2: 1999 ASTM F67-13
Screws:	Titanium (TiCP)	ISO 5832-2: 1999 ASTM F67-13
	TAN (Ti-Al6-Nb7)	ISO 5832-11: 2014 ASTM F1295-11

Intended use
The implants (plates and screws) and their instruments are intended for trauma repair and reconstruction of the craniofacial skeleton.

Indications
The Compact systems are indicated for selective trauma of the midface and craniofacial skeleton, craniofacial surgery, and orthognathic surgery of the midface.

Orbital plates are indicated for trauma repair and reconstruction of the craniofacial skeleton. Specific Indications are:
– orbital floor fractures,
– medial orbital wall fractures, and
– combined orbital floor and medial wall fractures.

Contraindications
The systems are contraindicated for use in areas with active or latent infection or insufficient quantity or quality of bone.

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 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.

Device Specific Adverse Events
Device specific adverse events include but are not limited to:
– Loosening, bending, or breakage of the devices
– Non-union, mal-union, or delayed union that may lead to breakage of the implants
– Pain, discomfort, or abnormal sensation due to the presence of the devices
– Adverse tissue reaction/soft tissue irritation
– Local infection/systemic infection
– Damage to vital organs, surrounding structures, and/or soft tissues
– Peripheral nerve damage
– Bone damage, bone fracture, and/or bone necrosis
– User injury

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.

Warnings
– 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 patient, the broken part should be removed.

Precautions
– Physicians should inform their patients about the implants' load restrictions and develop a plan for postoperative behavior and increasing physical loads.
– Confirm that plate positioning, drill bit, and screw length allow for adequate clearance of nerves, tooth buds and/or tooth roots, the edge of the bone, and any other critical structures.
– Confirm that plate positioning, drill bit, and screw length allow for adequate clearance of nerves, the edge of the bone, and any other critical structures.
– 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 during drilling to ensure removal of debris potentially generated during implantation.
– Always irrigate during drilling to avoid thermal damage to the bone and ensure drill bit is concentric to plate hole, irrigation ensures the removal of debris potentially generate during implantation.
– Confirm that drill bit length and diameter correspond to selected screw length prior to drilling.
– Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures, nerves or tooth roots.
– In order to determine the appropriate amount of screws needed to achieve stable construct fixation, the surgeon should consider the fracture size and shape.
– Avoid contouring of the implant in situ that may lead to implant malposition and/or posterior cantilever effect.
– Instrument tips 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.
– If contouring is necessary, the surgeon should avoid bending the device at a screw hole.
– Avoid sharp bends, repetitive and reverse bending as it increases the risk of implant breakage.
– Confirm screw length prior to implantation.
– Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation or bone stripping. If bone becomes stripped, remove the screw from the bone and replace with an emergency screw.

For Cranial Region Fixation, the following precautions apply:
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy. DePuy Synthes recommends at least three plates when repairing osteotomies. Additional fixation is recommended to ensure stability of large fractures and osteotomies. When using mesh for larger defects, additional screws for fixation are recommended.

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

MRI Information
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 20 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 9.3 °C (1.5 T) and 6 °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

Trauma Repair and Reconstruction:
1. Expose and reduce fracture
2. Select and prepare the implants
3. Contour the plate
4. Position the plate
5. Pre-drilling and screw insertion

Orbital Plates:
1. Select plate design
2. Adapt plate to the bone
3. Drill the hole
4. Fixate plate to the bone

Le Fort I Fixation:
1. Select plate design after complete osteotomy and new maxilla position has been established
2. Adapt plate to the bone
3. Drill the hole
4. Fixate plate to the bone

Please refer to surgical technique (DSEM/CMF/0316/0121) for detailed information on all surgical steps.

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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