Instructions for Use
Plate and Screw Fixation System MIDFACE

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

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Instructions for Use

Plate and Screw Fixation System MIDFACE comprising:
Compact Midface System
MatrixMIDFACE System
MatrixORBITAL System
and
Universal Screw Removal Set System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques Compact Midface Technique Guide (036.000.193), MatrixMIDFACE Technique Guide (036.000.938), MatrixORBITAL Technique Guide (036.000.496), and Universal Screw Removal Set Technique Guide (036.000.773) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The systems offer bone screws, plates and their instruments.
All implants are offered either sterile or unsterile and individually packed (plates) or in packs of one or four (screws).
All instruments are offered unsterile. In addition the drill bits are offered also sterile.

All articles are packed with an appropriate package material: clear envelope for unsterile articles, clear envelop with plastic tubes for screwdriver blades and carton with window plus double sterile barriers: double clear blisters (sterile screws and sterile drill bits) or double clear envelopes (sterile plates)

Material(s)

Material(s):	Standard(s):
Plate Material: TiCP	
Standard:	
ISO 5832-2:1999	
ASTM F 67:2006	
Screw Material:	
TAN	
Ti6Al-4V	
Standard	
ISO 5832-11:1994	
ASTM F1295:2005	
Instrument Materials:	
Stainless Steel:	
Standard	
DIN EN 10088-1&3:2005	
Aluminum:	
Standard	
ASTM B209M:2010	
ASTM B221M:2013	
DIN EN 573-3:2007	
DIN 17611:2000	
PTFE:	
FDA-Compliant	

Intended use
The implants (plates and screws) and their instruments are intended for trauma repair and reconstruction of the craniofacial skeleton.
The Universal Screw Removal Set is intended for the removal of intact and damaged screws. It is not intended to be used in combination with a power tool.

Indications
Synthes MatrixMIDFACE System is indicated for use in trauma repair and reconstruction of the craniofacial skeleton.
MatrixORBITAL System is indicated for trauma repair and reconstruction of the craniofacial skeleton. Specific Indications: orbital floor fractures, medial orbital wall fractures and combined orbital floor and medial wall fractures
– Orbital floor fractures
– Medial orbital wall fractures
– Combined orbital floor and medial wall fractures
Compact systems are indicated for selective trauma of the midface and craniofacial skeleton, craniofacial surgery and orthognathic surgery of the midface.
– Compact 2.0 Combi is a combination of 2.0 Midface and 2.0 Mandible and is indicated for selective trauma of the craniofacial skeleton, mandible trauma and orthognathic surgery.
– Compact 2.0 LOCK is indicated for midface: fractures, reconstruction and osteotomies and for mandible trauma: trauma and orthognathic procedures.

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

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.

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
Confirm that plate positioning allows for adequate clearance of nerves, tooth buds and/or tooth roots and any other critical structures.
Use the appropriate amount of screws to achieve a stable fixation.
Confirm that plate positioning allows for adequate clearance of nerves and any other critical structures.
Irrigate thouroughly to prevent overheating of the drill bit and bone.
The slider is used strictly for intraoperative use only; do not leave it in situ.
Avoid contouring of the implant in situ that may lead to implant malposition and/or posterior cantilever effect.
The lateral anterior part of the plate is intentionally prebent higher than the orbital rim anatomy to allow free plate movement during plate positioning. The lateral anterior part can be further contoured to match patient anatomy.
Excessive and repetitive bending of the implant increases the risk of implant breakage.
Instrument tips may be sharp, handle with care.
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.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
Drill bit(s) is (are) combined with power tools.

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

In three-wall fractures involving the lateral wall, in addition to the preformed orbital plate an orbital implant must be used (e.g. Synthes orbital mesh plate).
Preformed orbital plate:
a. Position the lateral edge of the plate along the inferior orbital fissure. Since the implant is anatomic and preformed, it should be positioned in the same location for every patient. The orientation of the implant does not need to change based on the anatomy of the fracture. Place the plate on the stable bony contour.
b. Test for impingement: A forced duction test must be completed to ensure unrestricted lateral and medial movement of the globe.
c. Placement on the posterior ledge should be confirmed intraoperatively.
Orbital retractor: Make an angled bend (red line) to allow the hand position to rest conveniently and away from the surgical view on the patient's forehead. Twisting of the bent end can further improve or facilitate the handling.
MatrixMIDFACE screws: If a pilot hole is desired, use the appropriate 1.1 mm diameter MatrixMIDFACE drill bit for drilling up to 8 mm length and the 1.25 mm diameter MatrixMIDFACE drill bit for drilling 10–12 mm length.
Do not alter the bend in the prebent plates to achieve more than a 1 mm adjustment in either direction.
An exact match is not required when using locking screws, because plate stability is not dependent on plate-to-bone contact when screws are locked.
While manipulating the bone fragment with the Threaded Reduction Tool, avoid excessive bending force on the instrument, as this may cause the tip of the Threaded Reduction Tool to break. If this occurs, the tip must be explanted using a burr to remove the bone surrounding the tip.
Threaded Reduction Tool: If pre-drilling is preferred, drill a hole into bone fragment using a 1.8 mm drill bit.
Threaded Reduction Tool: Drill guides must be used to protect the soft tissue while drilling.

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

REF Reference Number

LOT Lot or batch number

Manufacturing date

Expiration date

0123 Notified body

Caution, see instructions for use

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