Instructions for Use
MatrixMANDIBLE Plating System

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

MatrixMANDIBLE Plating System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques MatrixMANDIBLE Plating System (036.000.971) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The Synthes MatrixMANDIBLE Plating System consists of a variety of plates that come in multiple shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with the Synthes MatrixMANDIBLE 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	ISO7153-1
Aluminum alloy	DIN EN 573

Intended use
he Synthes MatrixMANDIBLE Plating System is intended for oral, maxillofacial surgery.
The Synthes MatrixMANDIBLE Subcondylar Plates are intended for the trauma of the mandible.

Indications
Trauma
Reconstructive surgery
Orthognathic surgery (surgical correction of dentofacial deformities)
Subcondylar Plates: Fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

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
– 2.0 mm diameter screws should only be used with a blue or gold plate if inserted into a bone graft, or if bone volume does not permit placement of a larger screw.
– Do not use screws shorter than 5 mm with 2.5 mm and 2.8 mm thick plates, 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.

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

See the Synthes MatrixMANDIBLE Plating System Technique Guide for full instructions for use.

Troubleshooting
Bending inserts may remain in the plate if removal may induce any risks.

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

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