Instructions for Use
MatrixMANDIBLE Preformed Plates

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

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CMF
COMPANIES OF Johnson&Johnson

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EUCMF08009 SE_530350 AC 10/2014

Instructions for Use

MatrixMANDIBLE Preformed Plates
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques MatrixMANDIBLE Preformed Plates (036.000.020) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The plates' shapes are anatomical approximations of mandible models obtained from CT scans.
The plates are:
– anatomically shaped
– right / left
– 3 sizes: small, medium and large
– 2/3 plate covering the vertical ramus and going up to the opposite mental foramen covering all main tumor resections
– Plate thickness 2.5mm
– Reduced number of undercuts due to reduced need for plate bending and higher fatigue strength
– MatrixMANDIBLE LOCK Screws.

Material(s)

Material(s):	Standard(s):
Titanium	ISO 5832-2
TAN	ISO 5832-11
Stainless steel Instr.	ISO7153-1
Aluminum alloy	DIN EN 573

Intended use
Mandibular plates specifically preformed intended for mandibular reconstruction with bone graft (vascularized or not), temporary bridging until secondary reconstruction, the treatment of the comminuted fractures of the mandible and the treatment of fractures in edentulous and atrophic mandibles, and unstable and/or infected mandibular fractures.

Indications
Primary mandibular reconstruction (used with vascularized bone graft)
Primary mandibular reconstruction (used with bone graft)
Temporary bridging with delayed secondary reconstruction
Comminuted fractures
Fractures of edentulous and atrophic mandibles
Unstable and infected mandibular fractures

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
Stable fixation requires a minimum of 3–4 screws inboth proximal (posterior) and distal (anterior) segments,depending on indication.

When using the MatrixMANDIBLE Preformed Reconstruction Plates as a temporary bridging device with 2.4 or 2.9 mm locking screws, allow for four screws per segment. If limited bone length or poor bone quality exists, a minimum of three 2.9 mm locking screws should be used.

If the Condylar Head Add-On System will be used,
the last three holes in the region of the ramus should not be bent or restricted.

For extensive bending, bending screws may be used. Extensive bending includes bends that exceed 20 degrees in torsion and "in-plane" bending, and 45 degrees for "out-of-plane" bending.

When bending out-of-plane in a single point (using
the "LAST HOLE BEND" feature of the bending pliers with nose or the bending irons) bend in a controlled manner. Do the bend in small increments. Do not excessively bend outwards
in a single point, or plate breakage may occur. Distribute sharp bending over several holes whenever possible

Drilling speed should never exceed 1800 rpm.
Higher speeds can result in thermal necrosis of the bone. Always irrigate during drilling.

To achieve optimal angular stability with locking screws, the hole must be drilled coaxially with the plate hole, or at a right angle to the plate. However, a certain amount of variation can be tolerated.

For maximum stability, locking screws are recommended. Use nonlocking screws if a bone fragment has to be repositioned by pulling it against the plate, or if a high screw angulation is needed.

If using the cannula 2.0 (as described in step 8, option 3), remove the drill sleeve, then insert the self-holding screwdriver with the screw engaged on the blade.

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
– Expose area to be fixated via standard surgical approach (e.g. submandibular incision, etc.)
– Determine the proper plate and bending template size using the sizers
– Form bending template to the bony anatomy
– Adapt the plate if needed and cut to desired length
– Drill hole for screw with appropriate drill size
– Select the screw length for implantation
– Load screw onto blade and insert into surgical site at desired location
– Repeat drilling, hole measuring and screw insertion with the desired number of screws
– Verify the intended fixation
– Closure

See the respective Technique Guide of the Synthes MatrixMANDIBLE Preformed Plates 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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