Instructions for Use

Custom-made Device, TRUMATCH® CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE™

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

Not all products are currently available in all markets.

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the most current version of each
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Custom-made Device, TRUMATCH® CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE™

Devices in scope:
SD480.100
SD480.101
SD480.102
SD480.110
SD480.111
SD480.112

SD480.100S
SD480.101S
SD480.102S
SD480.110S
SD480.111S
SD480.112S

Associated device systems with these instructions for use are:
MatrixMANDIBLE screws – locking and non-locking

The TRUMATCH CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE is a custom-made patient specific implant that is designed to patient anatomy to fit anatomy of the patient.

The fixation of the implants to the patient's mandible is done with DePuy Synthes MatrixMANDIBLE screw systems. The TRUMATCH CMF Ti 3D Milled Plates for Mandible, MatrixMANDIBLE are available in sterile and non-sterile package configurations.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use before use. Ensure that you are familiar with the appropriate surgical procedure.

Material(s)

Device	Material	Standard
TRUMATCH CMF® Ti 3D Milled Plate for Mandible, MatrixMANDIBLE	Titanium Ti	ISO 5832-2 ASTM F 67

Specific material information for the Screw Implants that are used with the TRUMATCH CMF Ti 3D Milled Plates for Mandible, MatrixMANDIBLE can be found in the respective DePuy Synthes implant instructions for use.

Intended Use
The TRUMATCH CMF Ti 3D Milled Plates for Mandible, MatrixMANDIBLE are intended for use in cranio-maxillofacial surgery, trauma and reconstructive surgery.

Indications
– Trauma
– Reconstructive surgery
Clinical applications may include:
– Comminuted fractures
– Fractures of edentulous and atrophic mandibles
– Unstable and/or infected mandibular fractures
– Primary and secondary mandibular reconstruction (used with vascularized or non-vascularized bone graft)
– Temporary bridging with delayed secondary reconstruction

Contraindications
No contraindications specific for the devices.

For specific contraindications in respect to the MatrixMANDIBLE Screws used for the fixation of the TRUMATCH CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE, please refer to the MatrixMANDIBLE instructions for use.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Patient-related factors:
A series of patient-related factors may have a strong influence on the success of surgery:
a. Occupation or activity. Professional occupations pose a risk when external forces subject the body to substantial physical loads. This can cause the product to fail and even undo the achievements of surgery.
b. Senility, mental illness, or alcoholism. These conditions may cause the patient to ignore certain necessary limitations and precautions, leading to the failure of the product or other complications.
c. Certain degenerative diseases and smoking. In some cases, a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant. In such cases, the products serve only as a means to delay or temporarily relieve the disease.
d. Sensitivity to foreign bodies. Where hypersensitivity to a material is suspected, appropriate tests should be undertaken prior to selecting or implanting the material.

Postoperative care is essential. Patients must follow their physician's postoperative care guidance about the implant's load restrictions and postoperative behavior.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU and the surgical procedures.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of the TRUMATCH CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE when used according to instructions for use and recommended techniques are:
– Protection of underlying anatomical structures
– Restore anatomical shape of patient mandible

Derived from Patient CT Data
– Design fits the planned outcome for faciliating positioning of the grafts at the planned location
– Integration with virtual surgical planning service* for seamless transfer of the surgical plan into the OR, using patient-specific surgical guides* with built-in drill guides that align with the plate holes (optional)

* *Disclaimer: Manufactured by Materialise and distributed by DePuy Synthes*

Custom Design Features
– Screw hole positions and angulations defined individually to avoid screw interference with nerves, tooth roots, osteotomies, existing or future implants
– Screw length prediction and pre-visualization of screw trajectories to ensure a collision free construct
– Compatible with MatrixMANDIBLE Condylar Head Add-on

Strength with Low Profile
– 2.0 mm and 2.5 mm plate thicknesses for improved fatigue strength** with lower profiles compared to standard reconstruction plates

** *Disclaimer: Patient-Specific Plates for Mandible fatigue testing data shows increased fatigue life of both 2.0 and 2.5 mm profiles in comparison with MatrixMANDIBLE 2.5 mm thick plates. Test data does not indicate clinical performance. Test data on file at DePuy Synthes.*

Performance Characteristics of the Device
DePuy Synthes has established the performance and safety of TRUMATCH CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE and that they represent state of the art medical devices when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
- Damage to vital organs or surrounding structures
- Adverse tissue reaction, allergy/hypersensitivity reaction
- Bone damage including intra- and post-operative bone fracture, osteolysis, or bone necrosis
- Symptoms resulting from implant migration, loosening, bending, or breakage
- Soft tissue damage
- Infection
- Injury to user
- Pain or Discomfort
- Poor joint mechanics

Sterile Device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Single-use Device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Contaminated implants must not be reprocessed. Any DePuy 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 and Precautions

Warnings
It is strongly advised that TRUMATCH CMF Ti 3D Milled Plates for Mandible, MatrixMANDIBLE are implanted only by operating surgeons who are familiar with the general problems of cranio maxillofacial surgeries and who can master the product-specific surgical procedures. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

Use the appropriate number of screws to achieve the required stability. Appropriate screw length should be verified. Care should be taken not to exceed the screw insertion torque.

The TRUMATCH CMF Ti 3D Milled Plates are not intended to be bent or contoured. If the plate does not fit the anatomy, then plates from the MatrixMANDIBLE system should be used.

Precautions:
- 2.0 mm diameter screws should only be used with a TRUMATCH CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE 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 thick plates as bone purchase might not be sufficient for stable fixation.
- 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.
- Use caution during TRUMATCH CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE removal to ensure tissue has not adhered to the implant surface or become encapsulated within the implant drainage holes when present, careful dissection may be required.

Combination of Medical Devices
The following screw standard cranio maxillofacial fixation system must only be used with the TRUMATCH CMF Ti 3D Milled Plate for Mandible, MatrixMANDIBLE Implants:
- MatrixMANDIBLE

Please refer to the associated product information for details on its use, precautions, warnings and side effects.

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

Magnetic Resonance Environment
The Custom-made Device, TRUMATCH CMF® Ti 3D Milled Plate for Mandible, MatrixMANDIBLE has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Custom-made Device, TRUMATCH CMF® Ti 3D Milled Plate for Mandible, MatrixMANDIBLE in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Treatment before Device is used

Non-sterile Device:
DePuy 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 in this instructions for use.

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices 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.

Implant Removal
The TRUMATCH CMF® Ti 3D Milled Plate for Mandible, MatrixMANDIBLE is for permanent fixation and not intended for removal once implanted.

However, in clinical situation of temporary bridging with delayed secondary reconstruction or when the treating surgeon decides to remove the implant based on a risk-benefit evaluation in the following situations:
- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

Implant removal should be followed by adequate post-operative management to avoid refracture.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Processing of the Device
These recommendations are for processing non-sterile DePuy Synthes implants. The information provided applies to unused and unsoiled DePuy Synthes implants only. Explanted DePuy Synthes implants must never be reprocessed and should be handled according to hospital protocol upon removal. Any implant that has not been used, but has become soiled, should be handled according to hospital protocol. Do not reprocess soiled implants.

Cautions:
- Any implant that has not been used, but has become soiled with blood, tissue and/or bodily fluids/matter, should be handled according to hospital protocol. DePuy Synthes does not recommend the reprocessing of soiled implants.
- Do not use a DePuy Synthes implant if the surface has been damaged.
- DePuy Synthes implants should not be processed or transported with any type of soiled or contaminated devices.
- All devices must be thoroughly cleaned and inspected prior to sterilization. Long, narrow lumens, blind holes, moving and intricate parts require attention during cleaning and inspection. During cleaning, only use detergents that are labelled for use on medical devices and in accordance with the manufacturer's instructions. Cleaning agents with a used dilution pH of within 7–9.5 are recommended. Highly alkaline conditions (pH >11) can damage components/devices such as aluminum materials. Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-con-

taining products). Do not use a cleaning aid that can damage the surface of implants such as steel wool, abrasive cleaners or wire brushes.
– DePuy Synthes implants should not be lubricated.
– DePuy Synthes implants are critical devices and must be terminally sterilized prior to use.
– The sterilization parameters are only valid for devices that are adequately cleaned.
– Only rigid sterilization containers approved for moist heat sterilization may be used with DePuy Synthes devices and loaded cases (a case with all or part of its assigned contents).
– The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with standards such as the ISO 15883 and ISO 17665 series.
– The options in using rigid sterilization containers with DePuy Synthes devices and loaded cases are as follows:
  – No more than one (1) fully loaded case can be placed directly into a rigid sterilization container. Instrument trays from no more than one (1) loaded case can be placed in the rigid sterilization container.
  – Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
  – Rigid sterilization container must have a maximum volume to vent ratio of no greater than 322 cm^3/cm^2.
– Only rigid sterilization containers approved for pre-vacuum steam sterilization can be used with DePuy Synthes devices and loaded cases.
– Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.

Limits on processing:
– Processing cycle as described in these instructions have minimal effects on DePuy Synthes implants.
– DePuy Synthes implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration or residue.
– Any implant with corrosion, scratches, notches, residue or debris should be discarded.

Point of Use Care:
– Implants should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted should be handled.
– Minimal handling of implants is necessary to prevent damage to the surface.

Containment and Transportation:
Implants should not come in contact with soiled devices and/or equipment.

Preparation for Processing:
DePuy Synthes does not recommend the reprocessing of soiled implants.

Cleaning-Manual Method:
1. Rinse device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the device.
2. Soak device in a neutral or mild alkaline detergent solution for a minimum of ten minutes. Follow the detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time.
3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens, channels and other hard to reach areas.
4. Immerse the implants fully in the detergent, ensuring that all lumens or moving parts are flushed to ensure contact. Manually clean devices for a minimum of five minutes in a freshly prepared neutral or mild alkaline detergent solution using a soft-bristled brush. Clean devices under water to prevent aerosolization of contaminants. Note: freshly prepared solution is a newly made, clean solution.
5. Rinse device thoroughly using cold or warm tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumen and channels.
6. Prepare a fresh detergent solution for the ultrasonic bath using a neutral or mild alkaline detergent solution. Follow the detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: a fresh solution is a newly-made, clean solution.
7. Clean DePuy Synthes implant ultrasonically for a minimum of 15 minutes and a bath frequency of minimum 38 kHz.
8. Rinse implant using DI or PURW water for a minimum of two minutes. Actuate joints, handles and other moveable device features to rinse thoroughly, if applicable. Ensure all lumens are flushed. DI or PURW water must be used for final rinse.
9. Dry implant using a clean, soft, lint-free single-use cloth or medical grade compressed air. Ensure that all lumens and articulated areas are dried using compressed air.

Cleaning-Disinfection Automated Method:
1. Rinse devices under running cold tap water for a minimum of one minute. Use a soft-bristled brush or soft lint-free cloth to clean the device.
2. Prepare a fresh detergent solution for the ultrasonic bath using a neutral or mild alkaline detergent. Follow the detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: fresh solution is a newly-made, clean solution.
3. Immerse the implants fully in the detergent, ensuring that all lumens, or moving parts are flushed to ensure contact. Clean DePuy Synthes implants ultrasonically for a minimum of 15 minutes, using a minimum frequency of 38 kHz.
4. Rinse device using DI or PURW water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. DI or PURW water must be used for final rinse. Visually inspect device. Repeat steps 2–5 until devices are visibly clean.
5. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and -2, or to an equivalent standard. Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer's instructions. An example of a validated cycle used for cleaning validation included.

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type of Detergent
Pre-wash	2	Cold tap water (< 40 °C)	N/A
Wash I	2	Cold tap water (< 40 °C)	Cleaning agent*
Wash II	5	Warm tap water (> 40 °C)	Cleaning agent*
Rinse	2	Warm DI or PURW (> 40 °C)	N/A
Thermal disinfection	5	≥ 93 °C	N/A
Dry	40	≥ 90 °C	N/A

*see section Additional Information

Thermal Disinfection:
For automated cleaning-disinfection, thermally disinfect at a minimum of 93 °C for a minimum of 5 minutes (see Cleaning-Disinfection Automated Method, including the water quality requirements). Country specific regulations referring to different thermal disinfection methods (e.g. A0-Concept) can be followed. For devices with cannulations or lumens, orient the parts such that the lumen or cannulation are in a vertical position. If this is not possible due to space limitations within the automated/mechanical washer, use an irrigating rack/load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if necessary.

Inspection:
DePuy Synthes implants should be visually inspected under ambient lighting, after processing, prior to sterilization to verify that the devices do not have visible soil, damage or moisture.
Inspect devices for:
– Lack of moisture, carefully inspect device lumens and moving parts. If moisture is detected, manual drying should be performed.
– Cleanliness, if any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.
– Damage, including but not limited to corrosion (e.g. rust, pitting), discoloration, scratches, flaking, cracks and wear.
– Proper function, including but not limited to missing or removed part numbers.

Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should be discarded.

Packaging:
Put cleaned, dry implants into the proper location in the DePuy Synthes case. Additionally, use an appropriate sterilization wrap or re-usable rigid container system for sterilization, such as a sterile barrier system according to ISO 11607. Care should be taken to protect implants and pointed and sharp instruments from contact with other objects that may damage the surface.
Steam (moist heat) sterilization shall be performed in a locally approved, pre-vacuum (forced air removal) cycle.

Sterilization:
The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8, including compliance to the requirements of ISO 17665. The steam sterilizer should be installed and maintained in compliance to manufacturer's instructions and local requirements. Ensure that a steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance to manufacturer's instructions and does not exceed the maximal sterilizer load.

The following steam sterilization cycles are examples of validated cycles:

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time*
Prevacuum Saturated steamforced air removal (pre-vacuum, minimum three pulses)	4	132 °C	20 minutes
	3	134 °C	20 minutes

* When applying dry times to DePuy Synthes cases and their accessories, dry times outside the standard healthcare prevacuum parameters may be required. This is especially important for polymer-based (plastic) cases/trays used in conjunction with heavy duty nonwoven sterilization wraps. The current recommended

dry times for DePuy Synthes cases can range from a standard 20 minutes to an extended time of 60 minutes. The dry time is most often influenced by the presence of polymer based (plastic) materials; therefore, changes such as elimination of silicone mats and/or change in sterile barrier system (i.e. heavy grade to light grade wrap) can reduce the necessary dry time. Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool-down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.
– Rigid Sterilization Container Use Instructions and Considerations

In order to ensure proper sterilization of DePuy Synthes implants when using a rigid sterilization container, the following must be taken into consideration:
– The rigid sterilization container manufacturer's instructions for use are to be followed. If questions arise regarding the use of the rigid sterilization container, DePuy Synthes recommends contacting the manufacturer of that specific container for guidance.
– The options in using rigid sterilization containers with DePuy Synthes devices and loaded cases are as follows: – No more than one (1) fully loaded case can be placed directly into a rigid sterilization container.– Instrument trays from no more than one (1) loaded case can be placed in the rigid sterilization container. – Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
– When selecting a rigid sterilization container for DePuy Synthes devices and loaded cases, the rigid sterilization container must have a maximum volume to vent ratio of no greater than 322 cm^3/cm^2. For any questions related to the volume to vent ratio, please contact the container manufacturer.
– Only rigid sterilization containers approved for pre-vacuum steam sterilization can be used with DePuy Synthes devices and loaded cases following the parameters provided in the table above.

Storage:
Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

Additional Information:
Further information regarding the use of specific cleaning agents, ultrasonic washers, washer-disinfector, packaging materials or sterilizers during validation studies are available on request. DePuy Synthes used the following during validation of these reprocessing recommendations:
Manual cleaning: Manual Pre-Cleaning with Prolystica® 2 × Concentrate Enzymatic Cleaner 1 mL/L at 14–16 °C and Ultrasonic Cleaning Prolystica® 2 × Concentrate Enzymatic Cleaner 1 mL/L at 12–21 °C.
Automated Cleaning: Manual Pre-Cleaning with Prolystica® 2 × Concentrate Enzymatic Cleaner 1 mL/L at 14–16 °C. Water-disinfector cleaning with (Wash 1) Prolystica® 2 × Concentrate Enzymatic Cleaner 1 mL/L at 23–26 °C and (Wash 2) Prolystica® 2 × Neutral Detergent 1 mL/L at 44–46 °C.
Lint-Free Cloth: Berkshire Durx 670.

The cleaning and sterilization information is provided in accordance with ISO 17664. The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile DePuy Synthes medical device. It remains the responsibility of the processor to ensure that the processing is performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.
The chemical quality of the water used during reprocessing can impact device safety. Facilities should use the recommended water quality requirements for device reprocessing in accordance with local guidance (such as AAMI TIR 34, Water for the reprocessing).

Material Compatibility of DePuy Synthes Implants in Clinical Processing:
Knowledge of the material and its properties is essential for ensuring that implants are proficiently processed and maintained.

Detergents, disinfectants, rinsing aids and other additives:
Excessive concentrations of these products or strongly acidic or alkaline detergents can attack the protective oxide layer of stainless steel, titanium and aluminum and lead to corrosion, discoloration or other changes of the materials, properties and surface conditions. When using such products, always follow the manufacturer's recommendations in respect of concentrations, contact times, temperatures and material compatibility. Products with pH levels between 7 and 9.5 are recommended. During repeated and prolonged use some rinsing aids can attack certain plastics and lead to discoloration or embrittlement. If the instruments are cleaned in an automated washer-disinfector, follow the directions of the manufacturers of the washer-disinfector, detergents, rinsing aids and other additives.

Steel wool, steel brushes, files and other abrasive cleaning tools:
Never use extra fine or normal steel wool, steel brushes, files or other cleaning tools with abrasive effect on metals to clean surgical instruments as this will result in mechanical damage to the passive layer, leading to corrosion and malfunction.

Detergent residues in packing cloths:
Cloths used to pack the devices for sterilization must be free of detergent or other residues. Such residues can be transferred to the device surface via steam and can interact with the surface.

Device-related Storage and Handling Information

Correct handling
Correct handling of the implants and instruments is extremely important. If the shape of the implant must be altered, the device should not be bent sharply, bent backwards, notched, or scratched. Such manipulations, in addition to all other improper handling or use, can produce surface defects and/or concentrate stress in the core of the implant. This in turn may eventually cause the product to fail.

Special Operating Instructions
1. Expose area to be fixated via standard surgical approach
2. Cut plate (optional)*
3. Select proper MatrixMANDIBLE screw diameter for implantation
4. Position the PROPLAN CMF® Surgical Guides (optional)
5. Drill holes using the built-in drill guides from PROPLAN CMF® Surgical Guides (optional)
6. Resect bone (optional)
7. Position plate
8. Drill hole for screw with appropriately sized drill using drill guides; if non-threaded drill guides are used, ensure that screw-to-plate angulation does not exceed 15°
9. Measure screw length using depth gauge (optional)
10. Load screw onto blade and insert into surgical site at desired location
11. Repeat screw insertion with the desired number screws; allow for 3–4 screws per bone segment (minimum 2 screws per graft segment)
12. Apply graft and repeat steps 3 through 11 (optional)
13. Verify intended fixation

Note: Alternatively, the graft can be attached to the plate after step 6, then the construct can be transferred to the reconstruction site.

Removal (if required)
Incision and access to the implantation location should be exposed.
Ensure soft tissue has not adhered to the surface or connected through the fixation holes of the implant. If so, carefully separate the soft tissue from the surface without the creation of debris from the implant.
Remove any fixation devices from the bone.
Close the surgical site using standard methods.

* Patient Specific Plates are designed and manufactured to be the appropriate length per patient anatomy. However, if there is a change in patient anatomy, or preoperative plan, the plate may be cut to the desired length. The plate may be cut using the Bolt Cutter (388.720). A significant amount of force is required to cut the plate. To avoid soft tissue damage, deburr the cut plate when appropriate, using a manual deburring instrument. The deburring feature of the Shortcut Plate Cutter (03.503.057) may be used. Due to the lack of cutting features in the plate, the Short Cut Plate Cutter MUST NOT be used to cut the plate.

Additional Device-specific Information

REF Reference number

LOT Lot or batch number

Legal manufacturer

EC REP DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

Expiration date

Do not re-use

Double sterile barrier system

NON STERILE Non-sterile

MD Medical device

MATERIAL Material

Packaging content

Consult instructions for use

Caution, see instructions for use

2008 –12 Manufacturing date

Disposal
Any DePuy 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.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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