

MATRIXWAVE™ MMF SYSTEM



Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

 Image intensifier control

Warning

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, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyshnthes/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuyshnthes/hcp/reprocessing-care-maintenance>

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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, 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 including swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, 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: intraoperative screw breakage, screw loosening/pull out.

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 individual patient, the broken part should be removed.

Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

MATRIXWAVE™ MMF INTRODUCTION



System Description

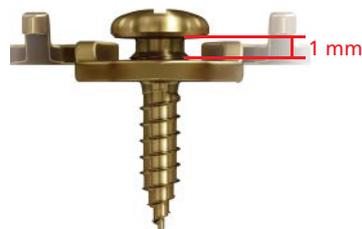
The MatrixWAVE™ MMF System is a bone-borne maxillomandibular fixation system that consists of a wave-shaped plate that is attached to the mandible and maxilla with self-drilling locking screws.

The adaptable plate can be stretched in-plane to optimize screw hole location to avoid tooth roots.



The plate is available in 2 heights to accommodate the use of rigid internal fixation and individual patient anatomy.

The self-drilling locking screws sit above the plate for additional anchor points for optional bridle wires. The dental arches are brought into occlusion by wiring around the plate hooks and/or accessible screw heads.



INTENDED USE, INDICATIONS AND CONTRAINDICATIONS

Intended Use

The system is intended for temporary stabilization of mandibular and maxillary fractures and osteotomies to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (approximately 6-8 weeks). The system affords the ability to compress bone segments across a fracture. The system is not intended to be used as a tension band.

Indications

The MatrixWAVE MMF System is indicated for the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

Contraindications

The contraindications for the use of this device are the following:

- Unstable fractures that cannot be stabilized in occlusion using the system
- Patients in whom damage to un-erupted permanent teeth by screw insertion may be anticipated
- Patients for whom maxillomandibular fixation represents a higher than usual psychological or physical risk
- Patients who are unwilling or unable to adhere to restrictions in eating and mouth opening associated with maxillomandibular fixation
- Patients with poor bone density in whom failure of screw fixation may be anticipated

Material Information

Plates and screws: commercially pure titanium and titanium alloy (Ti-6Al-7Nb)

Wires, instruments: stainless steel

MRI INFORMATION

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 31 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 13.7 °C (1.5 T) and 6.5 °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 aforementioned 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 thermo regulation or temperature sensation should be excluded from MR scanning procedures
- Generally it is recommended to use an MR 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

SURGICAL TECHNIQUE

1

Select the plate with the correct plate height

Implants

04.503.820 MatrixWAVE MMF, Plate 10 holes, small

04.503.821 MatrixWAVE MMF, Plate 10 holes, large

Select the appropriate plate height based on the patient's maxillary/mandibular anatomy, with respect to the desired location of the screws and plate hooks relative to the gum line. Adjustments on plate height can be made by stretching the plate horizontally, by hand. The plate can be stretched up to 10 mm from the neutral position between each screw hole.



2

Fit the plate

Instruments

03.503.039 Plate Cutter for Midface Plates

311.006 Screwdriver Handle, hex coupling, medium

03.500.020 File, Hex Coupling

Contour the plate around the maxilla/mandible.

Precaution: Excessive or significant reverse bends may weaken the plate and lead to plate failure. Do not implant a plate that has been damaged by excessive bending.



Cut excess plate length using the plate cutter. Cut the plate adjacent to the screw hole to avoid compromising the full diameter around the screw hole and locking threads. To ensure adequate stability, the plate must terminate on both sides with a screw hole.



Use the file to deburr and remove sharp edges from all cut surfaces.



3

Insert first self-drilling locking screw

Implants

04.503.824.01 MatrixWAVE MMF, Screw, Ø 1.85 mm self-drilling, L 6 mm

04.503.825.01 MatrixWAVE MMF, Screw, Ø 1.85 mm self-drilling, L 8 mm

Instruments

03.503.072 MatrixMANDIBLE Screwdriver Blade, long, self-retaining, hex coupling

311.023 Ratcheting Screwdriver Handle
or

311.006 Screwdriver Handle, hex coupling, medium



Place the plate on the maxilla/mandible and provisionally insert the appropriate length self-drilling locking screw through the plate at the desired anatomic location. Do not engage the screw locking threads with the plate at this step. This will provide stability to manipulate the plate and insert additional screws, as described in the following steps.

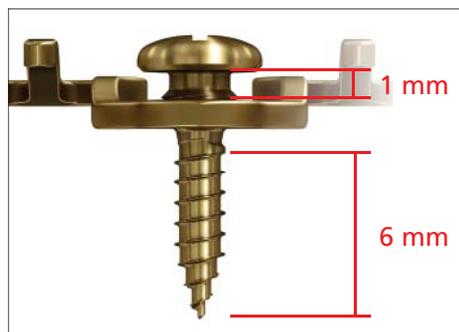
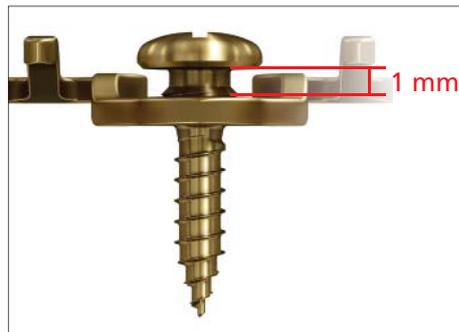
Important: The screw head is designed to sit above the plate to minimize soft tissue over growth and serve as an additional anchor point for wire. When fully locked into the plate the screw will remain 1 mm off the plate.

Technique tip

Screw length is measured from the tip of the screw to the start of the bone thread. Screw length refers to the amount of bone purchase provided by the screw.

Precaution: Placing the device too deep into the vestibule may cause mucosal injury.

Warning: Avoid tooth roots, nerves and the fracture site during screw insertion. Failure to comply may lead to damage of soft tissues/tooth roots.



Technique tips

Locking screws may be placed up to 15° off-axis while maintaining locking capabilities.

To engage the screw on the blade, align the blade over the cruciform recess and slowly rotate it until the blade drops into the recess; firmly press the blade to fully seat it into the screw.

In dense cortical bone, it may be necessary to predrill screw holes. To achieve optimal angular stability with locking screws, the hole must be drilled at a right angle to the plate hole.

Precaution

- **Avoid damaging the plate threads with the drill**
- **Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The disadvantages of an oversized hole include reduced pullout force, increased ease of the screws stripping in bone, and/or suboptimal fixation. Always irrigate during drilling. Avoid placing the drill hole over the nerve or tooth roots**
- **Irrigate and apply suction for removal of debris potentially generated during implantation or removal**

4 Adjust the plate

Instrument

03.503.049 MatrixWAVE MMF Application Instrument

The plate can be expanded up to 10 mm between screw holes to avoid interference with fractures or critical anatomic structures. Stretch or compress the wave pattern of the plate to align the screw holes with the desired location of the remaining screws. The plate can be adjusted by hand or using the application instrument.



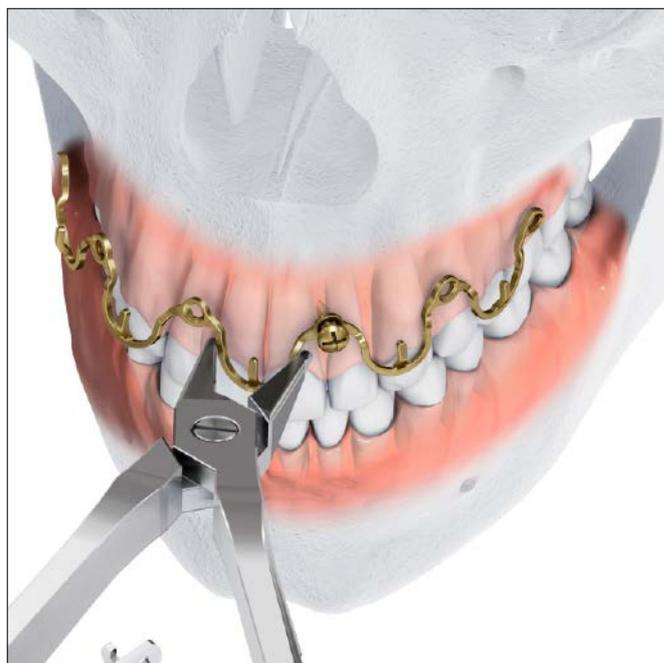
To stretch the plate, place the flats on the tips of the application instruments in between the wave pattern and open the instrument handles.



To compress the plate, grasp the wave pattern with the tips of the instrument and squeeze the instrument handles.

Precaution

- The plate can be stretched up to 10 mm from the neutral position between each screw hole. If the plate is stretched too aggressively it can lead to plate failure
- Do not adjust or bend the plate in the areas of the screw holes as doing so may deform the hole and prevent screw locking
- Take care not to injure the soft tissue when using the application instrument to adjust the plate. When adjusting the plate, take care not to compromise the screw purchase of the previously inserted screw
- The overall length of the plate may change during adjustment and require in-situ cutting. Hold the plate during in-situ cutting to avoid creating a loose fragment in the intraoral cavity. When cutting the plate in-situ take care to avoid harming the gingival. Ensure the cut surface of the plate is positioned so as to not irritate the soft tissue
- Use the application instrument to manipulate the plate. If cracks or damage to the plate are observed due to manipulation, the plate should be removed and replaced with a new plate
- MatrixWAVE MMF Plates, Screws and Instruments are designed and validated for use together. The use of plates, screws or instruments from other manufacturers along with DePuy Synthes products can result in incalculable risks to health care providers and/or patients



5

Insert remaining screws

Instruments

03.503.049	MatrixWAVE MMF Application Instrument
03.503.072	MatrixMANDIBLE Screwdriver Blade, long, self-retaining, hex coupling
311.023	Ratcheting Screwdriver Handle or
311.006	Screwdriver Handle, hex coupling, medium

Insert remaining locking screws through the plate; adjusting the position of the screw holes as necessary.

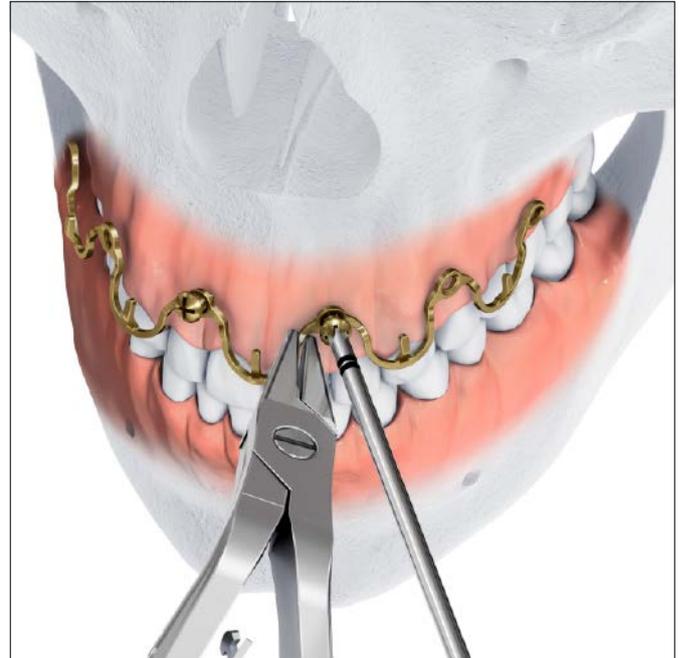
As the screw begins to engage the plate, the application instrument can be used to prevent the plate from prematurely engaging the locking thread. Gently press down on the plate near the screw hole with the application instrument.

Precaution

- **Take care not to damage the plate with the application instrument as this could lead to plate failure**
- **Take care not to injure the soft tissue when using the application instrument**

Use the application instrument to hold the plate adjacent to the screw hole. Grasp the plate in a manner that the prongs of the application instrument provide sufficient off-set if desired, to minimize soft tissue compression while maximizing bony screw purchase. The plate should not be placed more than 1 mm off the attached gingiva to ensure adequate screw purchase.

The application instrument provides counter-torque during screw insertion. Gently tighten all screws until securely locked.



Precaution: Excessive tightening of the screws will cause the plate to rotate. In the final phases of screw tightening, gently tighten each screw to reduce the risk of mechanical damage to the plate, screw, screwdriver, or the bone hole.

No more than one consecutive screw hole should remain empty and the plate must terminate on both sides with a screw.

Warning: Avoid tooth roots, nerves and the fracture site during screw insertion. Failure to comply may lead to damage of soft tissue/tooth roots.

Technique tips

Locking screws may be placed up to 15° off-axis while maintaining locking capabilities.

Screws may be removed and reinserted 1 time without compromising the screw thread. Do not remove and reinsert the same screw more than 1 time as the threads may become damaged and not lock properly.

To engage the screw on the blade, align the blade over the cruciform recess and slowly rotate it until the blade drops into the recess; firmly press the blade to fully seat it into the screw.

In dense cortical bone, it may be necessary to predrill screw holes. To achieve optimal angular stability with locking screws, the hole should be drilled at a right angle to the plate hole.

Precaution

- **Avoid damaging the plate threads with the drill**
- **Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The disadvantages of an oversized hole include reduced pullout force, increased ease of the screws stripping in bone, and/or suboptimal fixation. Always irrigate during drilling. Avoid placing the drill hole over the nerve or tooth roots. Irrigate and apply suction for removal of debris potentially generated during implantation or removal**

6**Apply wire****Implant**

291.240.10	Cerclage Wire Ø 0.6 mm, L 175 mm
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Instruments

03.503.039	Plate Cutter for Midface Plates
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03.503.049	MatrixWAVE MMF Application Instrument
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398.906	Wire Twister
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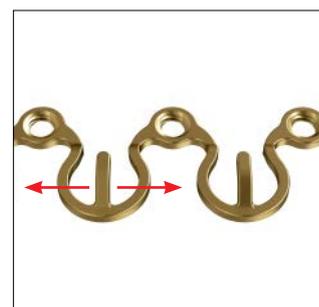
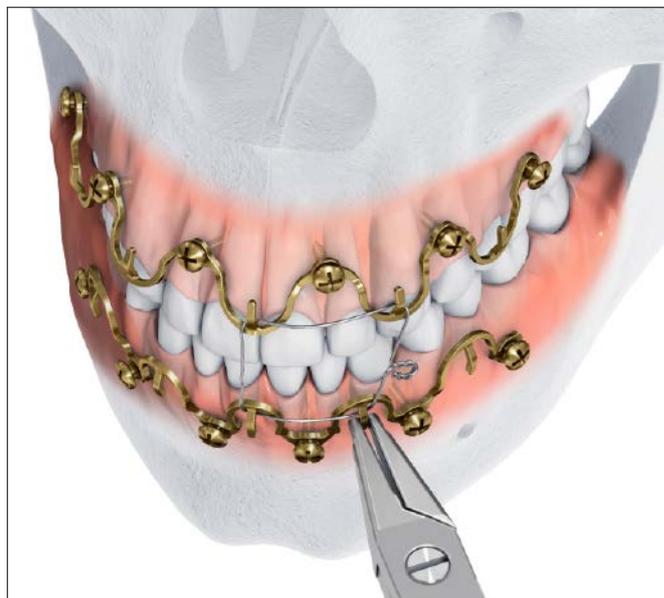
Apply wire loops to the pre-bent plate hooks. Before fully tightening the wires, bring the maxillary and mandibular dentition into occlusion.

Tighten the wires until tight using a wire twister and bend the wire to an atraumatic position. Cut the wire using the cutter. Each hook can accommodate up to 3 loops of wire.

Precaution: Excessively tightening wires may cause wire failure and over the anterior dentition lead to tooth movement/displacement over time.

Plate hooks can be bent in plane or out of plane using the application instrument to accommodate patient anatomy, desired wire pattern and to lessen the impact to the soft tissue.

Precaution: Do not bend the hooks more than 45° in-plane and avoid excessive bending as it may cause the hooks to break. Do not bend hooks out of plane more than required to place the wire. Take care not to bend hooks in a manner that may irritate the soft tissue.

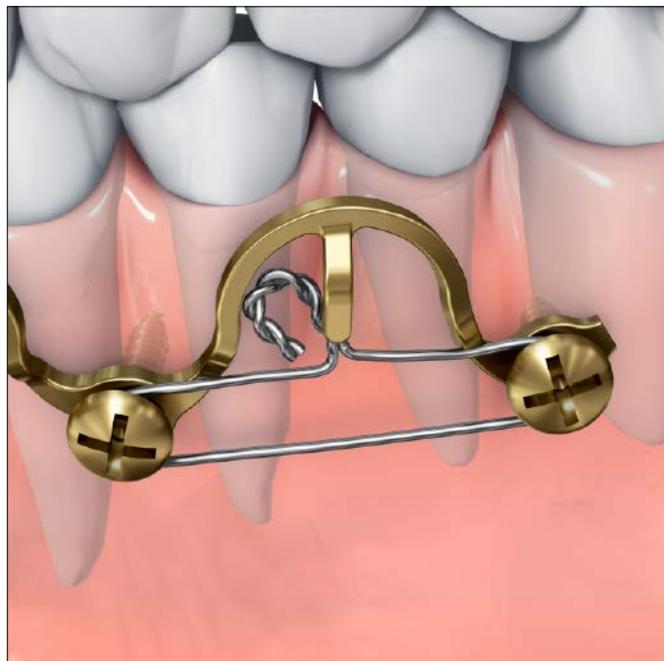


In-plane bending.

Screw heads serve as additional anchor points. A bridle wire can be placed around screw heads and tightened to help approximate bone segments, and for additional stability.

After wiring fully tighten all screws to ensure they are locked into the plate.

Precaution: In the final phases of screw tightening, gently tighten each screw to reduce the risk of mechanical damage to the plate, screw, screwdriver, or the bone hole.



Post application adjustments

Instrument

03.503.049 MatrixWAVE MMF Application Instrument

Verify that the occlusion is properly established and the bone segments are adequately reduced.

If additional manipulation of the bone segments is required, the plate can be adjusted in-situ using the application instrument.

To stretch the plate, place the flats on the tips of the application instrument in-between the wave pattern and open the instrument handles.

To compress the plate, grasp the wave pattern with the tips of the instrument and squeeze the instrument handles.

Precaution: Do not adjust or bend the plate in the areas of the screw holes as doing so may deform the hole and prevent screw locking.

A bridle wire can be placed around screw heads and tightened to help approximate bone segments, and for additional stability.

Precaution: Do not squeeze screw heads with the application instrument as doing so may compromise screw purchase in the bone.

After final plate manipulation, fully tighten all screws to ensure they are locked into the plate and tension wires.

Precaution: In the final phases of screw tightening, gently tighten each screw to reduce the risk of mechanical damage to the plate, screw, screwdriver, or the bone hole.

If elastics are used instead of wire, they can be placed on the plate hooks or the heads of the locking screws.



Removal

Instruments

03.503.039	Plate Cutter for Midface Plates
03.503.049	MatrixWAVE MMF Application Instrument
03.503.072	MatrixMANDIBLE Screwdriver Blade, long, self-retaining, hex coupling
311.023	Ratcheting Screwdriver Handle or
311.006	Screwdriver Handle, hex coupling, medium

Cut the wires and remove the plates by removing all bone screws using the dedicated screwdriver blade. The screws sit approximately 1 mm off the plate and are designed to be easily located during removal and to minimize soft tissue overgrowth.

Technique tip

If a screw is permanently locked to the plate and cannot be removed with the screwdriver blade; cut the plate on both sides near the screw and rotate it, in order to back the screw out of the bone. While rotating the plate, take care to avoid damaging the soft tissue if sharp edges are present from cutting.

Precaution: Irrigate and apply suction for removal of debris potentially generated during implantation or removal.



ORDERING INFORMATION

Cases

68.590.003	Nano Insert Tray, Single Wide, 1 High
68.590.004	Nano Insert Tray, Single Wide, 2 High
68.590.012	Nano Insert Tray ID Tag - Blank
68.590.031.01	Nano Insert Tray Divider, Single Wide, 1 High
68.590.032.01	Nano Insert Tray Divider, Single Wide, 2 High
68.590.045	Nano IMF Tray
68.590.050	MatrixWAVE MMF System Instrument Module Base
68.590.051	MatrixWAVE MMF System Implant Module Base
68.590.052	MatrixWAVE MMF System Module Lid
68.590.053	MatrixWAVE MMF System Instrument Module ID Tag
68.590.054	MatrixWAVE MMF System Implant Module ID Tag
68.590.055	MatrixWAVE MMF System Insert Tray for 1.85 mm Locking Screws
68.590.056	MatrixWAVE MMF Insert Tray ID Tag for 1.85 mm Locking Screws
68.590.057	MatrixWAVE MMF System Insert Tray ID Tag for Plates
68.590.098	Nano Finger Mat/Full Size
60.590.004	MatrixWAVE MMF System Label Sheet
304.106W	Screw Length Marker for 6 mm Self-Drilling Screws
304.108W	Screw Length Marker for 8 mm Self-Drilling Screws

Instruments

03.500.020	File, Hex Coupling
03.503.039	Plate Cutter for Midface Plates
03.503.049	MatrixWAVE MMF Application Instrument
03.503.072	MatrixMANDIBLE Screwdriver Blade, long, self-retaining, hex coupling
03.511.246	Matrix 1.4 mm Drill Bit, J-latch, 6 mm stop
03.511.248	Matrix 1.4 mm Drill Bit, J-latch, 8 mm stop
311.006	Screwdriver Handle, hex coupling, medium
311.023	Ratcheting Screwdriver Handle
398.906	Wire Twister

Implants

04.503.820	MatrixWAVE MMF, Plate 10 holes, small
04.503.821	MatrixWAVE MMF, Plate 10 holes, large
04.503.824.01	MatrixWAVE MMF, Screw, Ø 1.85 mm self-drilling, L 6 mm
04.503.825.01	MatrixWAVE MMF, Screw, Ø 1.85 mm self-drilling, L 8 mm
04.503.824.05	MatrixWAVE MMF, Screw, Ø 1.85 mm self-drilling, L 6 mm, pack of 5 units
04.503.825.05	MatrixWAVE MMF, Screw, Ø 1.85 mm self-drilling, L 8 mm, pack of 5 units
291.240.10	Cerclage Wire Ø 0.6 mm, L 175 mm, 10 units




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