

MatrixWAVE™ MMF System

Surgical Technique

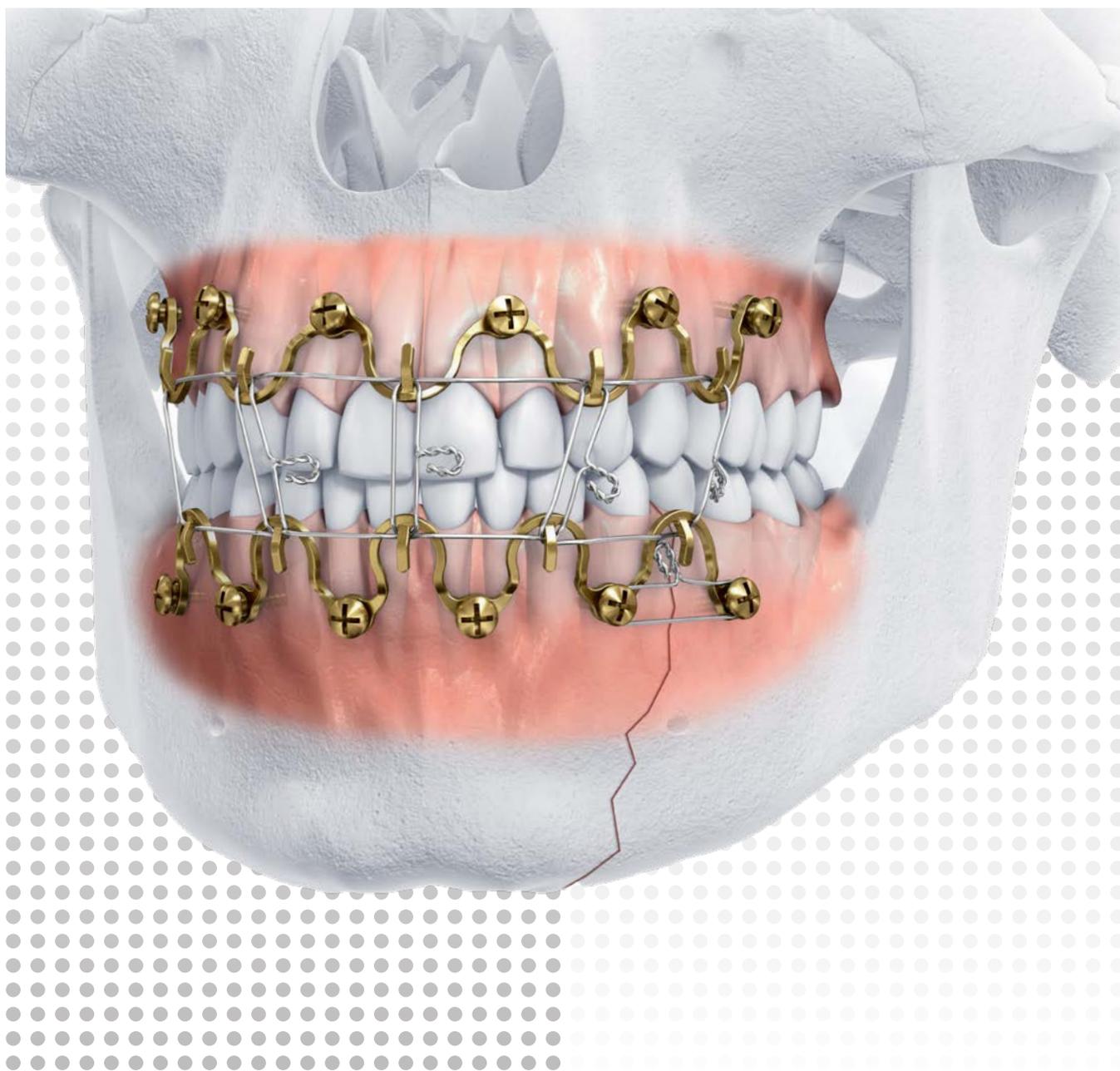


 Image intensifier control

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.depuysynthes.com/hcp/reprocessing-care-maintenance>

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

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

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MatrixWAVE™ MMF Introduction



System Description

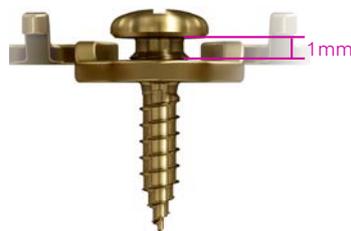
The MatrixWAVE™ MMF System is a maxillomandibular fixation system that consists of a wave-shaped plate that is attached to the mandible and maxilla with self-drilling locking screws.

The adaptable plate can be stretched in-plane to adjust 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.



Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

MRI Information on Torque, Displacement, Image Artifacts and Radio Frequency (RF) – induced heating can be found in the corresponding System Instructions for Use.

Warnings

▲ 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.

Material Information

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

Wires, instruments: stainless steel

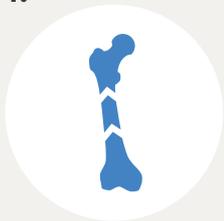
The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles^{1,2}

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

¹ Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991

² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

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 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

04.503.824.05 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

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.

■ Notes:

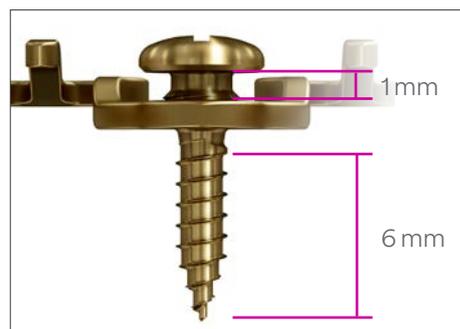
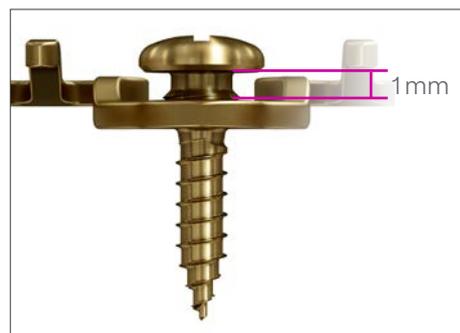
- The screw head sits above the plate to serve as an additional anchor point for wire. When fully locked into the plate the screw will remain 1 mm off the plate.
- Screw length is measured from the tip of the screw to the start of the bone thread. Screw length refers to the amount of bone purchase provided 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 infection and inadequate plate fixation.



Screw placement considerations

Locking screws may be placed up to 15° off-axis.

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 angular stability with locking screws, the hole must be drilled at a right angle to the plate hole.

▲ Precautions:

- 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
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The plate can be expanded up to 10 mm between screw holes. 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.

▲ **Precautions:**

- 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 gingiva. 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 or 311.006	Ratcheting Screwdriver Handle 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.

▲ Precautions:

- 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. The plate should not be placed more than 1 mm off the attached gingiva to ensure 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.

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.

Screw placement considerations

Locking screws may be placed up to 15° off-axis.

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 angular stability with locking screws, the hole should be drilled at a right angle to the plate hole.

▲ Precautions:

- 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

Instruments

03.503.039 Plate Cutter for Midface Plates

03.503.049 MatrixWAVE MMF Application Instrument

398.906 Wire Twister

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.

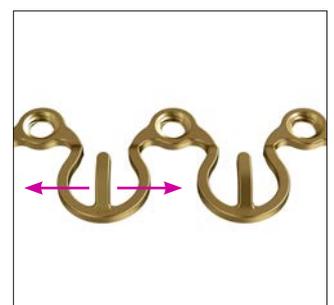
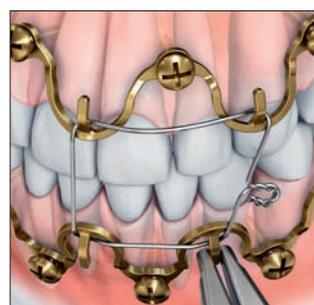
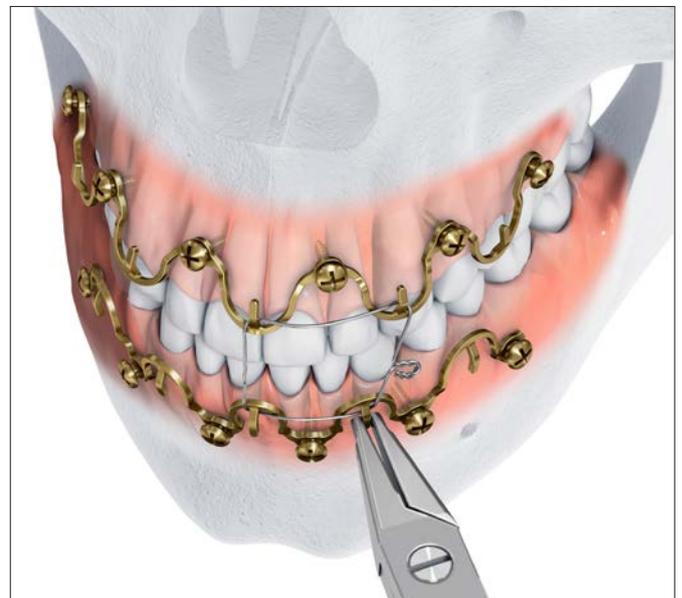
▲ Precaution:

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.



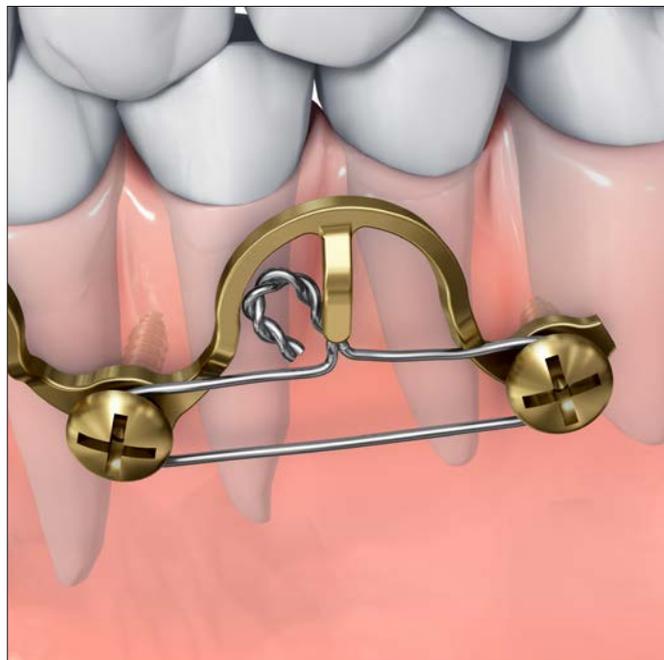
In-plane bending.

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.



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:

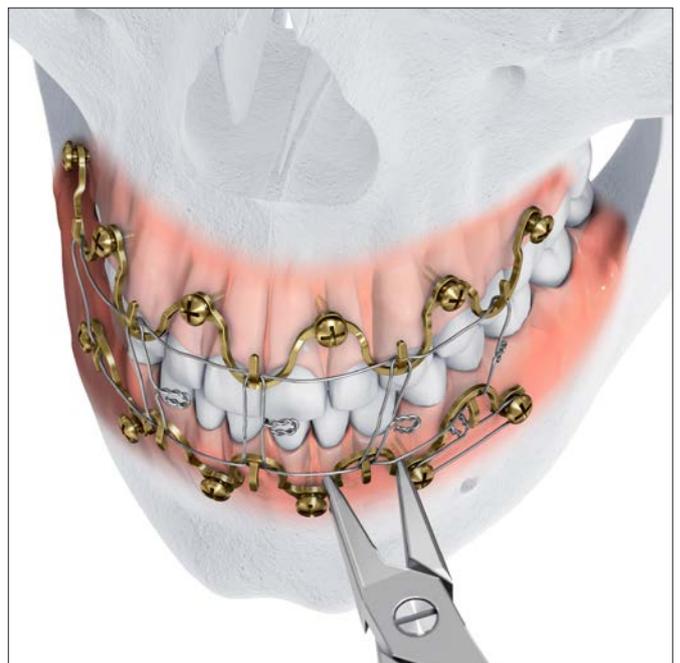
Do not squeeze screw heads with the application instrument as doing so may compromise screw purchase in the bone.

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 or 311.006	Ratcheting Screwdriver Handle 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 to be located during removal.

Screw removal considerations

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
04.503.824.05	MatrixWAVE MMF, Screw, Ø 1.85 mm self-drilling, L 6 mm, pack of 5 units
04.503.825.01	MatrixWAVE MMF, Screw, Ø 1.85 mm, self-drilling, L 8 mm
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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Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.



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