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VALUE ANALYSIS BRIEF:

MatrixWAVE™ MMF System

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Maxillomandibular Fixation

Maxillomandibular fixation (MMF) is a crucial step in the management of maxillofacial trauma. Adequate fracture reduction by aligning the maxillary and mandible dentition in occlusion must be obtained to fixate fractures correctly.[1,2] Various methods have been championed by surgeons to achieve MMF including Arch Bars secured with interdental wires and IMF Screws.[1] While these techniques have been used for several years, there are several disadvantages to both treatments.

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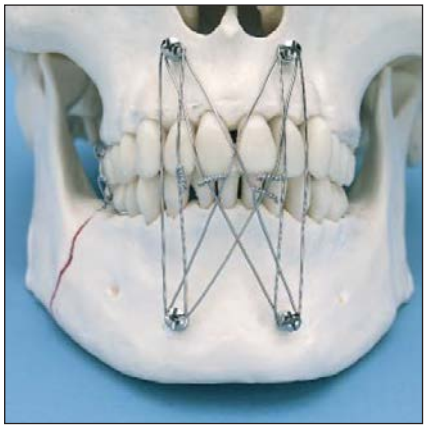
Limitations of Arch Bars

- Prolonged operating room time and expense to apply and remove the system[1,3,4]
- High incidence of needle stick injuries carrying a potential risk of blood-borne pathogens transmission between patient and healthcare provider[1,4,5,6]
- Difficulty in maintaining oral hygiene and gingival health[2,3,6,7]
- Wires tightened during the application of arch bars around the teeth may cause ischemic necrosis of the mucosa and the periodontal membrane and the potential for tooth loss[6,7,8]
- Secondary OR Procedure for removal[2]



Limitations of IMF Screws

- Posterior mandible fractures are more prone to poor reduction and subsequent malocclusion[1]
- Potential risk of screw back-out[2,3]
- Cannot be used alone as definitive treatment for mandible fractures[1,2]

Given these limitations there is a need to develop a versatile MMF system. MatrixWAVE™ MMF is a bone borne MMF system that combines the strength and rigidity of arch bars with the speed and simplicity of IMF screws.[9] MatrixWAVE™ MMF system is a novel system that expands and compresses to achieve maxillomandibular fixation.

Potential Patient and Surgeon Benefits of the MatrixWAVE MMF System

- **Adaptablity:** MatrixWAVE MMF System has an adaptable wave plate that surgeons can stretch or compress with or without the use of an instrument to optimize screw hole location[9] and avoid interference with definitive plating and incision location.
- **Post Application Adjustability:** The novel wave plate pattern enables surgeons to refine bone segment alignment after wiring without repositioning screws.[9]
- **Versatility:** Accessible screw heads are designed to sit proud and offer additional anchor points for occlusional stability and approximation of bone segments[9] and to help minimize soft tissue growth over the screw.[9]

- **Designed to Help Avoid Soft Tissue and Tooth Root Injury:** MatrixWAVE MMF System is designed to protect the gingival soft tissue and enable the surgeon to avoid critical anatomic structures such as tooth roots and nerves.[9]

Potential Patient and Provider Benefits of the MatrixWAVE MMF System

- **Fast Application for Greater OR Efficiency:** MatrixWAVE MMF System combines an adaptable plate with self-drilling locking screws to facilitate faster MMF than arch bars for greater OR efficiency.
- **Designed to Reduce Wire Sticks:** Design eliminates interdental wiring which may reduce the risk of wire sticks for healthcare providers.
- **Removed in Office or Clinic:** MatrixWAVE MMF System can be removed under local anesthesia in the clinic or office setting to reduce the need for OR based removal procedures.

- **MatrixWAVE MMF Provides Opportunity for Better Oral Hygiene:** MatrixWAVE MMF System covers less tooth surface giving patients more access to the teeth for cleaning than Hybrid MMF and arch bars.
- **Designed to Help Avoid Tooth Loosening:** The bone-borne design eliminates the need for interdental wiring potentially reducing the risk of tooth loosening.
- **Designed for Patient Comfort:** The MatrixWAVE MMF plate is designed with rounded, smooth edges. Plate hooks can be bent toward the gingiva after wiring. Screw heads are rounded to help minimize the impact on patient's soft tissue.

References

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2 Cornelius CP and Ehrenfeld M. The Use of MMF Screws: Surgical Technique, Indications, Contraindications, and Common Problems in Review of the Literature. *Craniomaxillofac Trauma Reconstruction 2010;3:55–80.*

3 Rai A, Datarkar A and Borle RM. Are Maxillomandibular Fixation Screws a Better Option Than Erich Arch Bars in Achieving Maxillomandibular Fixation? A Randomized Clinical Study. *J Oral Maxillofac Surg 2011;69:3015-3018.*

4 Vartanian AJ and Alvi A. Bone-screw mandible fixation: An intraoperative alternative to arch bars. *Otolaryngol Head Neck Surg 2000; 123:718-21.*

5 Bali R, Sharma P, Garg A. Incidence and patterns of needlestick injuries during intermaxillary fixation. *British Journal of Oral and Maxillofacial Surgery 2011; 49: 221–224.*

6 Ayoub AF and Rowson J. Comparative assessment of two methods used for interdental immobilization. *Journal of Cranio-Maxillofacial Surgery 2003; 31: 159–161.*

7 Laurentjoye M, Majoufre-Lefebvre C, Siberchicot F, Ricard AS. Result of Maxillomandibular Fixation Using Intraoral Cortical Bone Screws for Condylar Fractures of the Mandible.
J Oral Maxillofac Surg 2009; 67:767-770.

8 Jones DC. The intermaxillary screw: a dedicated bicortical bone screw for temporary intermaxillary fixation. *British Journal of Oral and Maxillofacial Surgery 1999; 37: 115–116.*

9 Mechanical test data on file at DePuy Synthes. Mechanical test results are not necessarily indicative of clinical performance.

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

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.

Contraindications :
- 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

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Limited Warranty and Disclaimer: DePuy Synthes CMF products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please refer to the Instructions for Use for the MatrixWAVE MMF System for complete instructions for use, warnings, and precautions.

Caution: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

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