IMF SCREW SET
For intermaxillary fixation

SURGICAL TECHNIQUE
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Implant Features
- 2.0 mm screws, available in 8 mm and 12 mm thread lengths
- Made of 316L extra-hard stainless steel for maximum strength
- Self-drilling, self-tapping for easy, one-step insertion
- Groove under screw head secures wires or elastics
- Cruciform head design works with existing DePuy Synthes CMF instrumentation
- Two cross-holes of the screw align with the cruciform head slots, simplifying wire passage

System Features
- Simplified intermaxillary fixation technique when compared to arch bars
- Reduces application time
- Minimizes the potential risk of wire punctures
- Can easily be applied or removed in the operating room (OR), emergency department (ED), or office setting

Patient Comfort Benefits
- Minimal hardware
- Reduced trauma to the soft tissues
- Improved postoperative oral hygiene

These devices are intended for single use only and are offered NONSTERILE only.

MR INFORMATION
This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.
**Indications**
The IMF Screw Set is intended for indirect stabilization of the maxilla and mandible following craniofacial and mandibular trauma or reconstruction.

- Simple, nondisplaced mandibular and maxillary fractures
- Orthognathic procedures
- Edentulous/partially edentulous patients

**Contraindications**
The IMF Screw Set is contraindicated for use in:

- Severely comminuted and/or displaced fractures
- Unstable, segmented maxillary or mandibular arches
- Combined maxillary and mandibular fractures
Note: The following technique assumes that first screw placement is in the maxilla. Screws should be inserted either medial or lateral to the long axis of the canine roots. Screws must be positioned superior to the maxillary tooth roots and inferior to the mandibular tooth roots. Advantages of the lateral approach include increased lateral stability and greater control over posterior open bite. For wiring recommendations, refer to Figures 11a and 11b.

1 Preparation

Determine the number and position of IMF Screws to be inserted, based on fracture type and location (Figure 1).

Figure 1
- Medial to canine roots
- Lateral to canine roots
2

Locate/identify maxillary tooth roots

Locate and identify the maxillary tooth roots, paying particular attention to the canine root which is the longest of the tooth roots. It is important to avoid the existing dentition as well as infraorbital and mental nerves. A helpful guide to estimating the lengths of the dentition from radiographs can be found in Figure 2.

Be aware that supernumerary, unerupted, and developing teeth may be present and should be confirmed or refuted with the appropriate radiograph (panoramic x-ray). Placement of the maxillary screws should be 5 mm superior to the tooth root.

Warning: It is important to identify all anatomic structures of the maxilla and mandible before inserting the screws. Particular attention must be paid to the mental nerve and the tooth roots, in particular, the canine root which is the longest of the tooth roots. Screws need to be inserted superior, and either medial or lateral to the canine root in the maxilla (inferior, and either medial or lateral to the canine root in the mandible).
3

Insert IMF screw into the maxilla

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>313.939</td>
<td>2.4 mm/3.0 mm Cruciform Screwdriver Blade, hex coupling</td>
</tr>
<tr>
<td>313.94</td>
<td>2.4 mm Screwdriver with Holding Sleeve</td>
</tr>
<tr>
<td>313.97</td>
<td>Holding Sleeve</td>
</tr>
</tbody>
</table>

Using the 2.4 mm Screwdriver with Holding Sleeve with 2.4 mm/3.0 mm Cruciform Screwdriver Blade, load an 8 mm or 12 mm IMF Screw. Insert an IMF Screw into the maxilla (Figures 3 and 4). Advance the screw, making sure that the screw shoulder does not compress the mucosa. The screw head’s cruciform slots can be used to orient the cross-holes relative to the occlusal plane.

Warning: Although the screws contain a self-drilling tip, it may be necessary to first pre-drill hole in dense cortical bone.

Technique Tip: Since the IMF Screws are self-drilling, it may not be necessary to incise and elevate the gingiva. If making an initial incision, an electrocautery device, which helps to control bleeding, may be used rather than a scalpel. This may ensure a smoother insertion.

Precautions

- 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 adverse effects 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 drilling over nerve or tooth roots.
- Take care while drilling as to not damage, entrap, or tear a patient’s soft tissue or damage critical structures. Be sure to keep drill clear of loose surgical materials.
- Handle devices with care and dispose worn bone cutting instruments in a sharps container.

*Also available.
4
Insert IMF screw into the mandible

Identify the important anatomic structures before inserting the mandibular screw (See Figure 2 on page 5). Insert the second screw into the mandible 5 mm inferior and medial or lateral to the canine root (Figure 5). If placing these screws inferior and lateral to the canine root in the mandible, greater care must be employed to identify and avoid the mental nerve.

**Warning:** It is important to identify all anatomic structures of the maxilla and mandible before inserting the screws. Particular attention must be paid to the mental nerve and the tooth roots, in particular, the canine root which is the longest of the tooth roots. Screws need to be inserted superior, and either medial or lateral to the canine root in the maxilla (inferior, and either medial or lateral to the canine root in the mandible).

5
Insert additional screws

Repeat this procedure by inserting at least two additional screws on the contralateral side: one in the maxilla and one in the mandible following the previously outlined procedure.
6

Insert wire

Insert either the 0.5 mm (24 gauge) or 0.6 mm (22 gauge) stainless steel wire through the cross-holes of the maxillary and opposing mandibular IMF Screws. The wire may be wrapped around the screw head grooves rather than inserting it through the cross-holes (Figures 6 and 7).

**Technique Tip:** Use smaller wire (0.5 mm) medial to the canines and the larger wire (0.6 mm) posterior to the canines.

**Warning:** 0.5 mm or 0.6 mm wire may be used with the IMF Screws to achieve intermaxillary fixation. These wires are inserted through the cross-holes or wrapped around the screw head groove.

7

Establish occlusion

Before tightening the wires, the occlusion should be established. Bring the maxillary and mandibular dentition into occlusion, making sure that each condyle is in its proper position within the glenoid fossa.

**Warning:** The occlusion should be established before tightening the wires. This is to ensure that the condyle is in the proper place within the glenoid fossa. In addition, during tensioning of the wires, check to ensure that no posterior open bite is produced. Ernst ligatures or Ivy loops on the posterior dentition may be used to prevent or correct this condition.
TIGHTEN WIRES

8
Tighten wires

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Item Description</th>
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<tbody>
<tr>
<td>398.906</td>
<td>Wire Twister</td>
</tr>
<tr>
<td>398.909</td>
<td>Wire-Cutting Scissors, straight, pointed</td>
</tr>
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</table>

Tighten the wire by first clamping the free ends in the Wire Twister. Pull the wire taut to hold the jaws in occlusion and then twist the wires to tension (Figure 8). Cut the wires with the Wire-Cutting Scissors and bend the cut wire ends under to prevent soft tissue irritation.

In order to consolidate rather than splay segments, it is important to secure the wire in an X-pattern in addition to the vertical pattern that provides maxillomandibular stabilization and reduces lateral excursion (see Figures 9, 10 and 11).

Notes

- Due to the tension placed on the wires and screws in this application, there is a potential for loosening if left in post-operatively. The wire should be carefully monitored for this condition during postsurgical evaluations and tightened as necessary.
9

Verify fracture reduction

Check to ensure that no posterior open bite is produced during tensioning of the wires. The placement of additional IMF Screws, Ernst ligatures or Ivy loops on the posterior dentition may be used to prevent or correct this condition (Figure 12).

**Note:** Overtightening of the wires could lead to rotation of the segments and interference with the reduction. Verify that the fracture is adequately reduced at the inferior border.

Figure 12
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Image</th>
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<tbody>
<tr>
<td>313.939</td>
<td>2.4 mm/3.0 mm Cruciform Screwdriver Blade, hex coupling</td>
<td><img src="image1.png" alt="Image" /></td>
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<tr>
<td>313.94</td>
<td>2.4 mm Screwdriver with Holding Sleeve</td>
<td><img src="image2.png" alt="Image" /></td>
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<tr>
<td>317.72</td>
<td>1.5 mm Drill Bit, Stryker J-latch, with 12 mm stop, 44.5 mm</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>398.906</td>
<td>Wire Twister</td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>398.909</td>
<td>Wire-Cutting Scissors, straight, pointed</td>
<td><img src="image5.png" alt="Image" /></td>
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IMF SCREW SET (115.630)

<table>
<thead>
<tr>
<th>Module</th>
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<tbody>
<tr>
<td>304.708</td>
<td>IMF Screw Module</td>
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<th>Implants</th>
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<tbody>
<tr>
<td>201.928</td>
<td>2.0 mm IMF Screw, self-drilling, 8 mm, 6 pkg of 5</td>
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<tr>
<td>201.932</td>
<td>2.0 mm IMF Screw, self-drilling, 12 mm, 6 pkgs of 5</td>
</tr>
<tr>
<td>291.230.98</td>
<td>0.5 mm Precut Cerclage Wire, 175 mm, 2 pkgs of 10</td>
</tr>
<tr>
<td>291.240.98</td>
<td>0.6 mm Precut Cerclage Wire, 175 mm, 2 pkgs of 10</td>
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</tr>
<tr>
<td>317.72</td>
<td>1.5 mm Drill Bit, Stryker J-latch, with 12 mm stop, 44.5 mm, 2 ea</td>
</tr>
<tr>
<td>398.906</td>
<td>Wire Twister</td>
</tr>
<tr>
<td>398.909</td>
<td>Wire-Cutting Scissors, straight, pointed</td>
</tr>
</tbody>
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<tr>
<th>Also Available</th>
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<tbody>
<tr>
<td>306.757</td>
<td>IMF Screw Module, Compact for MatrixMANDIBLE Plating System™</td>
</tr>
<tr>
<td>306.760</td>
<td>IMF Screw Module, Full Size for MatrixMANDIBLE Plating System</td>
</tr>
<tr>
<td>313.97</td>
<td>Holding Sleeve</td>
</tr>
<tr>
<td>316.652</td>
<td>1.5 mm Drill Bit with 12 mm stop, 52 mm, hex coupling</td>
</tr>
<tr>
<td>317.82</td>
<td>1.5 mm Drill Bit with 12 mm stop, 44.5 mm, mini quick coupling</td>
</tr>
<tr>
<td>398.905</td>
<td>Auto Wire Twister</td>
</tr>
<tr>
<td>398.907</td>
<td>Wire-Cutting Scissors, Universal</td>
</tr>
<tr>
<td>398.908</td>
<td>Wire Manipulator</td>
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</table>

For detailed cleaning and sterilization instructions, please refer to: [www.synthes.com/cleaning-sterilization](http://www.synthes.com/cleaning-sterilization)

In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.
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Rx Only

Not all products are currently available in all markets.