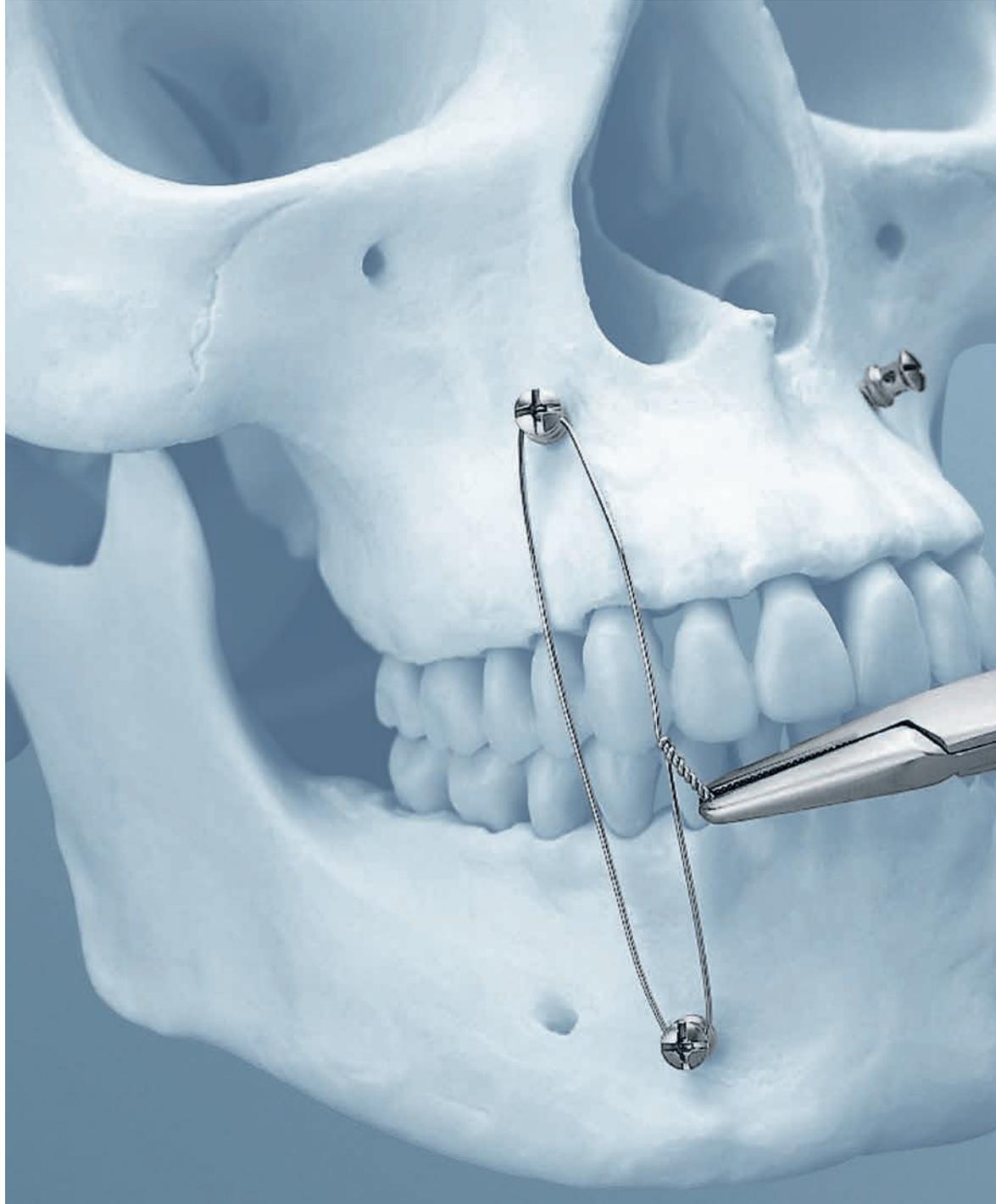


IMF Screw Set. For temporary, perioperative stabilisation of the occlusion in adults.

Surgical Technique



This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.

Table of Contents

Features	2
Intended Use, Indications and Contraindications	3
MRI Information	4
Surgical Technique	5
Instruments and Implants	9

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 or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. 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, Explantation, Pain, Hematoma, Infection.

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.

 Image intensifier control

Warning

This description is not sufficient for immediate application of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Processing/reprocessing of the device

Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the DePuy Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from <http://emea.depuyshsynthes.com/hcp/reprocessing-care-maintenance>

Features

-
- 316L stainless steel for maximum strength
 - Self-drilling screws for one-step insertion
 - Groove under screw head secures wires or elastics
 - Cruciform screw head fits with existing Synthes instrumentation
 - Two cross holes in the screw head align with the cruciform head slots, simplifying wire passage



Intended Use, Indications and Contraindications

Intended use

Temporary, perioperative stabilization of the occlusion in adults.

Indications

- Simple nondisplaced mandibular and maxillary fractures
- Orthognatic procedures
- For temporary use during bone healing

Contraindications

- Severely comminuted and/or displaced fractures
- Unstable, segmented maxillary or mandibular arches
- Combined maxillary and mandibular fractures
- Paediatric

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07

Non-clinical testing of a 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 a 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 above mentioned 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 MRI 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

The following surgical technique assumes that the first screw is placed in the maxilla. However, screw placement, number of screws, and order of insertion are dependent on the fracture type, location and the surgeon's preference.

The screws must be positioned superior to the maxillary tooth roots and inferior to the mandibular tooth roots and be inserted either medial or lateral to the long axis of the canine roots. The advantages of the lateral approach include increased lateral stability and greater control over posterior open bite.

For wiring recommendations, refer to figures 11 and 12, page 7.

1

Determine number and position of screws

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

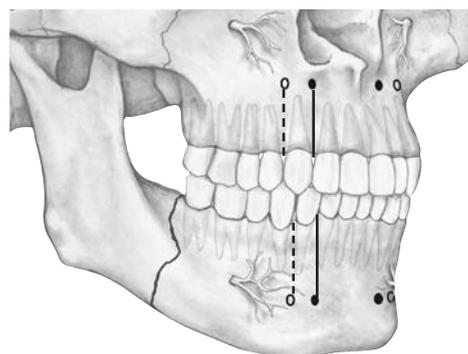


Fig. 1 ● — Medial to canine root
○ - - - Lateral to canine roots

2

Locate maxillary tooth roots

Locate and identify the maxillary tooth roots, paying particular attention to the canine roots which are 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 length of the dentition from radiographs can be found in figure 2.

Precautions:

- Supernumerary, unerupted and developing teeth may be present and should be confirmed or refuted with appropriate x-rays. The maxillary screws should be placed 5 mm superior to the tooth roots.
- Special care must be employed to identify and avoid canine roots and the dental nerve.

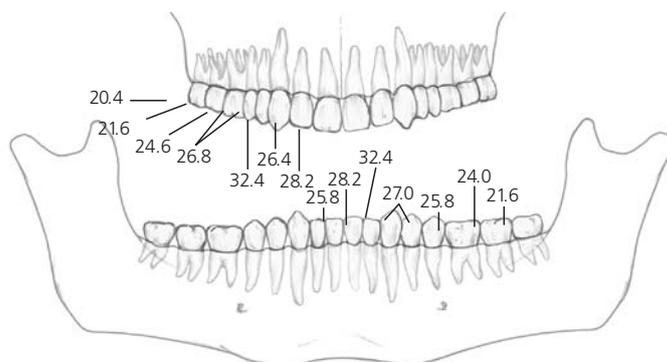


Fig. 2

Average tooth lengths (mm) including a 20 % magnification associated with the radiograph. Actual lengths modified from RC Wheeler (1974) Dental Anatomy, Physiology and Occlusion. WB Saunders Co., 20, Philadelphia.

3

Insert screw into maxilla

Pick up an IMF Screw (8 mm [201.928] or 12 mm [201.932]) using the 2.4 mm cruciform Screwdriver with Holding Sleeve (313.940). Insert the screw into the maxilla (figure 3) and advance it making sure that the screw head does not compress the gingiva. The cruciform slots of the screw head can be used to orient the cross holes relative to the occlusal plane (figure 4).



Fig. 3

Precaution: In dense cortical bone, it may be necessary to predrill with a \varnothing 1.5 mm drill bit.

Since the IMF screws are self-drilling it may not always 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.



Fig. 4

4

Insert screw into mandible

Before inserting the mandibular screw, identify the important anatomic structures. Again, special attention should be paid to the canine roots and the mental nerve (figure 2). 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.

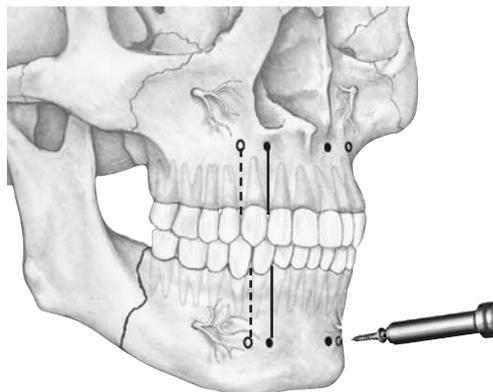


Fig. 5

5

Insert additional screws

Repeat the 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 (figure 6).



Fig. 6

6

Insert wire

Insert a wire through the cross holes of the maxillary and opposing mandibular screws (figure 7). The wire may also be wrapped around the screw head grooves rather than inserting it through the cross holes.



Fig. 7

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.

8

Tighten wires

Clamp the free ends of the wires into the Wire Twister (398.906). Pull the wires taut to hold the jaws in occlusion and then twist the wires to tension (figure 8). Cut the wires with the Wire-Cutting Scissors (398.909) and bend the cut wire end under to prevent soft tissue irritation (figures 9 and 10).

In order to consolidate the segments it is important to secure the wire in an X-pattern in addition to the vertical pattern that provides maxillomandibular stabilisation and reduces lateral excursion (figures 11 and 12).

Precaution: Due to the tension placed on the wires, there is a potential for loosening of the wire or the screw if left in postoperatively. The wire and screw should be carefully monitored for this condition during postsurgical evaluations and tightened as necessary.

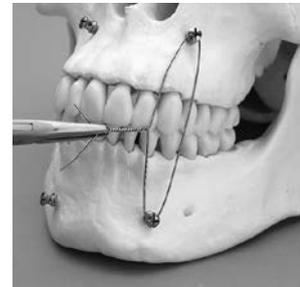


Fig. 8

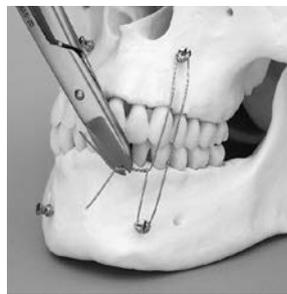


Fig. 9

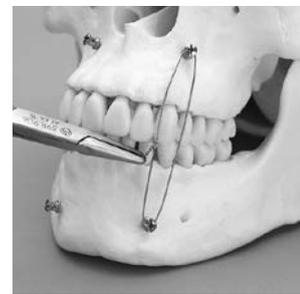


Fig. 10

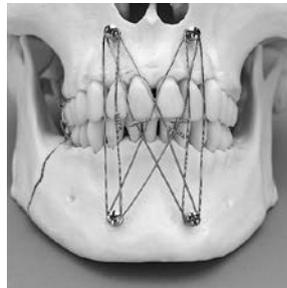


Fig. 11

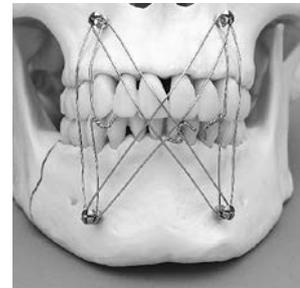


Fig. 12

9

Check stability

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 13).

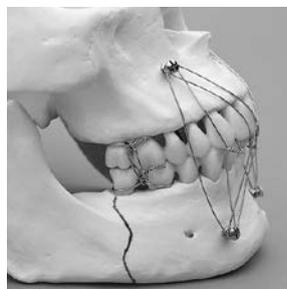


Fig. 13

Precaution: 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.

Instruments and Implants

Instrument Set for IMF Screws (174.736)
Module IMF Screws (674.736)



IMF Screws, Stainless Steel (201.928/932)

Diameter 2.0 mm
Length 8 and 12 mm



Cerclage Wire, Stainless Steel (291.240)

Diameter 0.6 mm
Length 175 mm



Handle, medium, with Quick Coupling (311.421)



Screwdriver Shaft 2.4, cruciform, not self-holding (313.448)



Holding Sleeve (313.970)



Drill Bit \varnothing 1.5 mm with Stop (317.680)

Length 44.5/8 mm, 2-flute, for J-Latch Coupling



Drill Bit \varnothing 1.5 mm with Stop (317.720)

Length 44.5/12 mm, 2-flute, for J-Latch Coupling

Wire Twister (398.906)



Wire-Cutting Scissors, Straight (398.909)



Additionally available:

- Module, small, for IMF Screws \varnothing 2.0 mm (304.728)
- Screwdriver Shaft 2.4, cruciform, self-holding, for Quick Coupling (314.447)
- Drill Bit \varnothing 1.5 mm with Stop, length 44.5/8 mm, 2-flute, for Mini Quick Coupling (317.780)
- Drill Bit \varnothing 1.5 mm with Stop, length 44.5/12 mm, 2-flute, for Mini Quick Coupling (317.820)



