Instructions for Use
IMF Screw Set

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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Instructions for Use

IMF Screw Set
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques 036.000.325 carefully before use. Ensure that you are familiar with the appropriate surgical technique.
Synthes IMF Screws are designed with cross-axial through holes and a circumferential relief groove to accommodate wire or elastic bands. The IMF Screws are self-drilling, 2.0 mm in diameter, and available in thread lengths of 8 mm to 12 mm. At least four screws are inserted in maxilla and mandible (2+2). The jaws are hold in occlusion by loops of wires connecting pairs of screws from mandible and maxilla.

Material(s)

Implant(s):	Material(s):	Standard(s):
Screws:	316L stainless steel	ISO 5832-1
Cerclage Wire:	316L stainless steel	ISO 5832-1

Intended use
Temporary, perioperative stabilisation 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

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.

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Single-use device
Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and / or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

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.

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

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.

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.

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 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 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.

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Special operating instructions
– Determine number and position of screws.
– Locate maxillary tooth roots.
– Insert screw into maxilla
– Insert the second screw into the mandible 5 mm inferior and medial or lateral to the canine root. If placing these screws inferior and lateral to the canine root in the mandible, greater care must be employed to identify and avoid the dental nerve.
– Insert at least two additional screws on the contralateral side, one in the maxilla and one in the mandible.
– Insert a wire through the cross holes fo the maxillary and opposing mandibular screws.
– Establish occlusion.
– Tighten wires.
– Check stability and ensure that no posterior open bite is produced during tensioning of the wires.

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

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