Instructions for Use
IMF Screw Set

This instruction for use is not intended for distribution in the USA.

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

CE
0123

 EUCMF10004 SE_531335 AC 10/2014

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)

Material(s):	Standard(s):
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

Side effects
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, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage 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 hypersensitivity reactions, 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.

Sterile device

STERILE R terilized 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 ap pro priate 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 if left in postoperatively. The wire 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.

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
- Heating or migration of the device
- Artifacts on MR images

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 Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from: http://www.synthes.com/reprocessing

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
www.synthes.com