Instructions for Use
Mandible External Fixator II

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Printed on: Feb 09, 2017

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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EUCMF10013 SE_530880 AG 12/2016

Instructions for Use

Mandible External Fixator II
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques Mandible External Fixator II (DSEM/CMF/1114/0048) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
Fixation of bone fractures by external fixation method using rods, clamps and schanz screws.

Material(s)

Implant(s):	Material(s):	Standard(s):
Schanz Screw	TAN	ISO 5832-11
Connecting rod	TAN	ISO 5832-11
Connecting clamp	TAV	ISO 5832-3
Kirschner wire	Stainless Steel	ISO 5832-1
Bending Template	Silicon Rubber	ASTM F2042
Protective Cap	Polyvinyl Chloride	ASTM D1785-05
Connecting rod	Carbon Fiber Epon	ES0050

Intended use
The Mandible External Fixator II is intended to stabilize and provide treatment for fractures of ther maxillofacial area.

Indications
The Mandible External Fixator II is indicated to stabilize and provide treatment for fractures of the maxillofacial area, including:
- Severe open mandibular fractures
- Highly comminuted closed fractures
- Nonunions and delayed unions (especially associated with infection)
- Fractures associated with infection
- Tumor resections
- Facial deformity corrections
- Gunshot wounds
- Panfacial fractures
- Burn maintenance
- Bone grafting defects

Contraindications
No specific contraindications.

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, malunion, nonunion or delayed union which may lead to breakage of the implant, reoperation.

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
- The rod should be positioned approximately one fingerbreadth away from the patient's skin, evenly throughout the entire length of the rod.
- Do not overtighten the clamp, as this will result in damage to the cannula.
- The reading from the Measuring device represents the depth of the hole and does not represent the bone thickness.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
  - thermal necrosis of the bone,
  - soft tissue burns,
  - an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
- Pin sites should be meticulously cared to avoid pin-tract infection. Schanz Screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. A pin-site care procedure should be reviewed with the patient.
- Select the appropriate Schanz screw for the patient's bony anatomy.

Warning
Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.

Magnetic Resonance Environment

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-14 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 24.10 T/m. The largest image artifact extended approximately 15 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 5.8°C (1.5 T) and 5.5°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 thermoregulation 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.

Special operating instructions
Fixation using Schanz Screws
1. Patient preparation
2. Identify appropriate rods
3. Contour the bending template
4. Contour the rod(s)
5. Verify fit and screw location
6. Make small stab incision
7. Dissect soft tissue
8. Implant Schanz Screw
9. Implant second Schanz Screw
10. Assemble the rigid construct
11. Add third clamp
12. Implant third Schanz Screw
13. Complete the construct
14. Verify reduction and adjust
15. Trim Schanz Screws and Rod (optional)
16. Implant Removal
    For removal of the construct, follow steps 8 through 13 in reverse order to untighten and remove all clamps, then remove the frame and/or connecting rods and subsequently remove the Schanz Screws, using the appropriate instrumentation.

Optional technique to implant Schanz Screws

1. Predrill the bone
2. Use measuring device
3. Select and measure Schanz Screw
4. Load Schanz Screw
5. Implant Schanz Screw
6. Remove adapter from implanted Schanz Screw

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to: http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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