Instructions for Use
Mandible External Fixator II

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

CE
0123

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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 (036.000.928) 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)

Material(s):	Standard(s):
TAN	ISO 5832-11
TAV	ISO 5832-3
Stainless steel Instr.	ISO7153-1
Silicon Rubber	ASTM F2042
PVC	
Carbon Fiber	

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 intended 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

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.
Implant failure from selecting the wrong implant and/or overloading the osteosynthesis
Allergic reactions from material incompatibility
Delayed healing from vascular disturbances
Pain triggered by the implant

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.
A minimum of two Schanz screws per segment (two
screws in greatest segment and two in other segments) isrecommended to ensure adequate stability. Optimal location of Schanz screws will place one screw 10 mm distal and another screw 10 mm proximal to the defect.
Synthes recommends using the Compact Air Drive II or an equivalent drill with an operating speed of approximately 900 RPM.
Do not overtighten the clamp, as this will result in damage to the cannula.
The reading from the device (03.305.005) does not represent the bone thickness.

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
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. Pre-drill the bone (optional)
10. Use measuring device (optional)
11. Select Schanz Screw (optional)
12. Measure Schanz Screw (optional).
13. Load Schanz Screw (optional).
14. Implant Schanz Screw (optional)
15. Remove adapter from implanted Schanz Screw (optional)
16. Implant second Schanz Screw
17. Assemble the rigid construct
18. Build the construct
19. Prepare to implant third Schanz Screw
20. Implant third Schanz Screw
21. Complete the construct.
22. Verify reduction and adjust
23. Trim Schanz Screws and Rod (optional)

Fixation Using Kirschner Wires
1. Identify location of first Kirschner wire
2. Prepare to implant first Kirschner wire
3. Implant first Kirschner wire
4. Prepare to implant second Kirschner wire
5. Implant second Kirschner wire
6. Build the construct
7. Tighten the rigid construct
8. Trim wires and apply protective caps

See the respective Technique Guide of the Synthes Mandible External Fixator II System for full instructions for use

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

Reference Number

Lot or batch number


Manufacturer


Manufacturing date


Do not use when packaging is damaged

Notified body


Caution, see instructions for use

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