Instructions for Use
External Midface Distractor

Please read these instructions for use, the DePuy Synthes brochure "Important Information" and the corresponding surgical technique External Midface Distractor DSEM/CMF/0115/0053 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Manuals are subject to change;
the most current version of each
manual is always available online.
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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Instructions for Use

Material(s)

Components:	Material(s):	Standard(s):
Footplates:	TiCP	ISO 5832-11 ASTM F67
Cortex/Emergency Screws and Machine Screws:	Ti-6AI-7Nb (TAN)	ISO 5832-11 ASTM F 1295
Maxillary Rods:	Ti-6AI-7Nb (TAN)	ISO 5832-11 ASTM F 1295
Cranial Pins/Wire Fixation Screw:	Ti-6AI-7Nb (TAN)	ISO 5832-11 ASTM F 1295
Head Frame components:	Stainless Steel 17-4PH	ASTM F 899/A 564
	Stainless Steel 304	ISO7153-1 ASTM F 899/A 276
	Ti-6AI-7Nb (TAN)	ISO 5832-11 ASTM F 1295
	Ti6AL4V (TAV	ISO 5832-3 ASTM F 1472
	AL 6061	DIN EN 573 ASTM B 209M, B 211M, B 221M
	PTFE	ISO 16061
	Radel	ISO 16061
	CFRE	

Intended use
The DePuy Synthes External Midface Distractor is intended for use as a bone stabilizer and lengthening device, where gradual bone distraction is required.

Indications
The External Midface Distraction System is indicated for craniofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla. Specifically, it is indicated for distraction where gradual distraction osteosynthesis is required in adult and pediatric populations.

Contraindications
There are no contraindications for the DePuy Synthes External Midface Distractor.

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:
- Neurologic damage or CSF leak, leading to death, due to cranial pins penetration.
- Re-operation:
  - due to relapse.
  - because the distractor system breaks or disengages due to patient excessive activities.
  - because the footplate breaks after implantation surgery, during treatment due to decreased strength as a result of excessive bending of the footplate during implantation.
  - because the footplate breaks postoperatively prior to bone consolidation process is completed due to an excessive strain by the patient.
  - due to the screw migration in thin bone.
  - to correct the regenerate bone due to the distractor being positioned along incorrect vectors as a result of incorrect vector planning or difficulties transferring the treatment plan to surgical placement.
  - to replace the device due to device disturbance by traumatic patient injury not related to procedure or treatment.
  - due to infection at the distractor site.
  - due to device malfunction.
  - due to inadequate device length selected.
  - due to device backup.
  - due to loose distractor footplate.
  - due to bone fracture under load.
  - due to the pin migration into the bone.
  - due to incomplete osteotomies.
  - Non-union or fibrous union leading to re-operation (worst case) because the number of screws used with the footplates is not sufficient.
  - Premature bone consolidation requiring reoperation due to the distractor being activated in the wrong direction after being activated in the proper direction.
  - Restricted/impaired bone growth requiring further surgery because the distractor is not removed after healing is accomplished.
  - Restricted/impaired bone growth requiring further surgery, because the distractor is not removed after healing of the regenerate is accomplished.
- Additional medical treatment for:
  - Soft tissue erosion due to the distractor components pressure on the soft tissue.
  - Patient pain due to end of distractor protruding into soft tissue.
  - Nerve damage requiring subsequent medical treatment.
  - Injury of the patient due to extended OR time, because the screws/distractors cannot be removed.
  - The healing process may be altered for patients with certain metabolic diseases, with active infection or who are immune compromised.
  - Cellulitis.
  - Discomfort of the patient due to long treatment duration.
  - Scar requiring revision.
  - Pain at bony generate site.
  - Cyst caused by pins.
  - Parotid gland injury.
  - Infection at the pins site.
  - Wound dehiscence.
  - Treatment termination due to the patient incompliance.
  - Mild anterior open bite.
  - Dietary problems, weight loss.

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 DePuy 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
- Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
- Take care to avoid nerves, tooth buds,roots or other critical structures when drilling and/or placing screws.
- Consider and verify for adequate bone volume and quantity for screw placement.

- Factors to be considered and verified:
  – Occlusal plane
  – Planned length of advancement (consider relapse and overcorrection)
  – Lip closure
  – Soft tissue coverage
  – Patient pain due to distractor interference with soft tissue
  – Access to the screws based on approach
- Footplates should be cut so that the integrity of the screw hole is not compromised.
- Bending beyond anatomic requirements, reverse bending, and repetitive bending may increase the risk of implant breakage.
- 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.
- Avoid damaging the plate threads with the drill.
- Always irrigate during drilling to avoid thermal damage to the bone.
- Firmly press the screwdriver blade into the screw recess to ensure retention of the screw on the screwdriver blade.
- Use the appropriate screw length to avoid distractor loosening or damage of critical/lingual structures.
- Do not fully tighten the screws before making the osteotomy.
- To increase distractor stability in thin bone, insert screws bicortically. In addition, more screws can be used.
- Screws can loosen during the course of treatment if placed in poor quality bone.
- Use a minimum of 3 screws per maxillary footplate.
- Screws must be placed in the holes closest to the maxillary rod for adequate device stability.
- Drill and insert screws closest to the osteotomy first.
- The osteotomy must be complete and the bone must be mobile. The distractor is not designed or intended to break bone and/or complete the osteotomy.
- Trim any excess wire, taking care not to leave any exposed sharp edges.
- The headframe should be placed at a position that is parallel to the Frankfort horizontal plane and at a vertical distance 2 cm above each ear.
- A gap of approximately 2 cm between the scalp and the Headframe Assembly is recommended on all sides for easy access for cleaning. Once this is achieved, the device is appropriately sized for inserting the fixation screws.
- It is important to only turn the activation instrument in the direction of the arrow marked on the handle. Turning the activation instrument in the wrong direction (opposite to the arrow) can interfere with the distraction process.
- The surgeon must instruct the patient/care giver how to activate and protect the distractor during the treatment.
- Patients should also be advised to not tamper with the distractors and to avoid activities that may interfere with treatment. It is important to instruct patients to follow the distraction protocol, keep the wound area clean during treatment and contact their surgeon immediately if they loose the activation instrument.
- To avoid implant migration the distractor should be removed after treatment.
- Loosen each fixation screw individually with a Headframe Adjustment Instrument until the Headframe Assembly disengages from the skull.
- Instrument tips may be sharp, handle with care.

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.
- Tooth movement may affect treatment outcomes and should be carefully considered when using an intraoral splint.
- Fixation screws should be inserted in areas with hard cortical bone at least 4 mm thick.
- Overtightening the fixation screws or placement of pins in thin bone may cause bone fractures or dural penetration.
- At least three fixation screws should be placed in each mounting plate, on both sides of the headframe, before tightening the pins, to ensure equal force distribution.
  – Fixation screws should be placed at least 2 cm above the ear.
- Patients should be advised to avoid high risk activities, as serious injury can occur if the patient falls on the device.
- In instances where emergency intubation is necessary, the device can be removed quickly using wire cutters and a Headframe Adjustment Instrument.

Combination of medical devices
DePuy Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment
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 70.1 T/m. The largest image artifact extended approximately 55 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 19.5°C (1.5 T) and 9.78°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

Application of Internal Hardware for LeFort I and LeFort II Procedures
1. Make an intraoral incision
2. Mark the osteotomy
3. Fit the maxillary footplate assemblies
4. Contour the maxillary rods
5. Mark the positions of the maxillary footplates
6. Perform the osteotomy
7. Reattach the maxillary footplate assemblies
8. Close incisions

Application of Internal Hardware for LeFort III and Monobloc Procedures
1. Make incisions
2. Mark the osteotomy
3. Fit the maxillary footplate assemblies
4. Contour the maxillary rods
5. Mark the positions of the maxillary footplates
6. Remove the maxillary footplate assemblies
7. Fit and attach the zygomatic footplates
8. Perform the osteotomy
9. Reattach the maxillary footplate assemblies
10. Insert the wire fixation screws
11. Close all incisions

Optional Technique for Intraoral Fixation – Intraoral Splint
In order to apply traction to the maxilla through the dentition, a rigid intraoral splint can be created to fit the patient. (Step 1 to 8)

Device Placement
1. Insert positioning pins
2. Unlock the Headframe Assembly for adjustment
3. Place the headframe on the skull
4. Tighten the headframe lock screws
5. Insert the Fixation Screws
6. Attach the Vertical Rod Assembly
7. Adjust the Vertical Rod
   – For angulating Vertical Rod Assembly
   – AP adjustments
   – Transverse adjustments
8. Attach the Horizontal Rod Assembly
9. Position distraction arms
10. Perform final adjustments, if necessary
11. Attach wire

Postoperative Considerations
Suggested Distraction Protocol
Document Progress
Distraction Vector Adjustments
– AP adjustments
– Transverse adjustments

Patient Care
1. Remove wires
2. Detach vertical carbon fiber rod

Device Removal
1. Remove wires
2. Remove Headframe Assembly
3. Remove intraoral/internal fixation

Patient Care
1. Contact your physician, if you have any questions or concerns, or if any redness, drainage or excessive pain occurs during activation.
2. Do not tamper with the distractors and avoid activities that may interfere with treatment.
3. Document progress. A Patient Care Guide is included with the system to help record and monitor device activation.
4. Follow the distraction protocol. Follow the surgeon's instructions regarding the rate and frequency of distraction. Under the physician's instruction, the patient/care giver may need to activate the distractor(s) multiple times each day.
5. Turn the activation instrument in the direction of the arrow marked on the handle. Turning the activation instrument in the wrong direction (opposite to the arrow) can interfere with the distraction process.
6. When turning the distractor with the activation instrument do not pinch the distractor arm with your fingers. It must be able to turn. It is important to only turn the activation instrument in the direction of the arrow marked on the handle. Turning the activation instrument in the wrong direction (opposite to arrow) can interfere with treatment.
7. Contact your surgeon immediately, if you loose the activation instrument.
8. Keep the wound area clean during treatment.
9. Maintain good oral hygiene during all phases of treatment.

Device intended to be used by a trained physician
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

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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